Comparative Effectiveness Review
Number 151

Management of Postpartum Hemorrhage



Number 151

Management of Postpartum Hemorrhage

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

We welcome comments on this systematic review. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Management of Postpartum Hemorrhage

Structured Abstract

Objectives. To systematically review evidence addressing the management of postpartum hemorrhage (PPH)), including evidence for the benefits and harms of nonsurgical and surgical treatments, interventions for anemia after PPH is resolved, and effects of systems-level interventions.

Data sources. We searched the MEDLINE[®], Embase, and Cumulative Index to Nursing and Allied Health Literature (CINAHL[®]) databases for articles published in English since 1990.

Review methods. We included comparative studies of nonsurgical and surgical interventions to manage PPH published in English from 1990 to November 2014 and conducted in high-resource countries. We also included case series addressing harms of interventions and benefits and harms of procedures and surgeries for PPH, as these interventions are unlikely to be addressed in randomized studies. Two investigators independently screened studies against predetermined inclusion criteria (including study design, country of conduct, and outcomes addressed) and independently rated the quality of included studies. We extracted data into evidence and summary tables and summarized them qualitatively.

Results. We identified a total of 68 unique studies. Sixty-one studies addressed effectiveness outcomes: none of good quality, 23 fair, and 38 poor. Fifty studies reported harms of interventions for PPH management: 11 good quality and 39 poor. Few studies addressed pharmacologic or medical management, including transfusion for supportive management of ongoing PPH, and evidence is insufficient to comment on effects of such interventions. The success of uterine-sparing techniques, such as uterine balloon tamponade, embolization, uterine compression sutures, and uterine and other pelvic artery ligation, in controlling bleeding without the need for additional procedures or surgeries ranged from 36 to 98 percent. However, these data come from a limited number of studies with a small number of participants. Harms of interventions were diverse and not well understood. Studies suggested an association between recombinant activated factor VIIa and thromboembolic events, but sample sizes were small. Some studies with longer term followup reported adverse effects on future fertility and menstrual changes in women undergoing embolization. Studies also reported need for reoperation after hysterectomy. No study (out of two addressing such interventions) demonstrated benefits associated with transfusion or iron supplementation for anemia after PPH is stabilized. Systemslevel interventions had little effect on reducing the incidence or severity of PPH or the need for transfusion or hysterectomy.

Conclusions. The literature addressing management of PPH comprises predominantly studies of poor quality. Diagnosis of PPH is subjective and management is urgent, often involving rapid and simultaneous initiation of interventions. Therefore, comparing the severity of PPH and trajectory of care across studies is challenging. Further research is needed across all interventions for PPH management.

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Executive Summary

Introduction

Postpartum hemorrhage (PPH) is commonly defined as blood loss exceeding 500 mL following vaginal birth and 1,000 mL following cesarean. Definitions vary, however, and diagnosis of PPH is subjective and often based on inaccurate estimates of blood loss. Moreover, average blood loss at birth frequently exceeds 500 or 1,000 mL, and symptoms of hemorrhage or shock from blood loss may be hidden by the normal plasma volume increases that occur during pregnancy. PPH is often classified as primary/immediate/early, occurring within 24 hours of birth, or secondary/delayed/late, occurring from more than 24 hours postbirth to up to 12 weeks postpartum. In addition, PPH may be described as third or fourth stage depending on whether it occurs before or after delivery of the placenta, respectively. Multiple studies have noted an increase in PPH in high-resource countries, including the United States, Canada, Australia, Ireland, and Norway, since the 1990s. 5-9

PPH is a leading cause of maternal mortality and morbidity worldwide, and accounts for nearly one-quarter of all maternal pregnancy-related deaths. ¹⁰ Multiple studies have suggested that many deaths associated with PPH could be prevented with prompt recognition and more timely and aggressive treatment. ¹¹⁻¹³ Morbidity from PPH can be severe, with sequelae including organ failure, shock, edema, compartment syndrome, transfusion complications, thrombosis, acute respiratory distress syndrome, sepsis, anemia, intensive care, and prolonged hospitalization. ¹⁴⁻¹⁶

The most common etiology of PPH is uterine atony (impaired uterine contraction after birth), which occurs in about 80 percent of cases. Atony may be related to overdistention of the uterus, infection, placental abnormalities, or bladder distention. Although the majority of women who develop PPH have no identifiable risk factors, clinical factors associated with uterine atony, such as multiple gestation, polyhydramnios, high parity, and prolonged labor, may lead to a higher index of suspicion. Other causes of PPH include retained placenta or clots, lacerations, uterine rupture or inversion, and inherited or acquired coagulation abnormalities. 17,18

Interventions To Manage PPH

Organizations and associations including the World Health Organization, International Confederation of Midwives, International Federation of Gynecologists and Obstetricians, American College of Obstetricians and Gynecologists, California Maternal Quality Care Collaborative, and Royal College of Obstetricians and Gynaecologists have released guidelines for PPH prevention and management. ^{10,15,17-21} Initial management includes identifying PPH, determining the cause, and implementing appropriate interventions based on the etiology.

Interventions to treat PPH generally proceed from less to more invasive and include compression techniques, medications, procedures, and surgeries. PPH management may also involve adjunctive therapies, such as blood and fluid replacement and/or an antishock garment, ^{22,23} to treat the blood loss and other sequelae that result from PPH. PPH management varies significantly according to available resources.

Conservative management techniques, such as uterotonic medications, external uterine massage, and bimanual compression, are generally used as "first-line" treatments. Procedures used in PPH management include manual removal of the placenta, manual removal of clots,

uterine balloon tamponade, and uterine artery embolization. ^{10,15,17,18} Laceration repair is indicated when PPH is a result of genital tract trauma.

Surgical options when other measures fail to control bleeding include curettage, uterine and other pelvic artery ligation, uterine compression sutures, and hysterectomy. ^{10,15,17,18} More invasive procedures (e.g., uterine balloon tamponade and uterine artery embolization) and surgical techniques are generally used after first-line conservative management has failed to control bleeding and can be considered second-line interventions. ²⁴ Table 1 in the full report includes brief descriptions of interventions used in PPH management.

After PPH has been controlled, followup management varies. It may include laboratory testing (e.g., hemoglobin and hematocrit), iron replacement therapy, and other interventions to assess and treat sequelae of PPH.

At a systems level, PPH has been the focus of perinatal care safety initiatives that attempt to improve patient outcomes by incorporating a variety of strategies, such as practice guidelines or protocols, simulation drills, and teamwork training. ²⁵⁻²⁹ These systems-level interventions may influence management of PPH.

Scope and Key Questions

This systematic review provides a comprehensive review of potential benefits of PPH management (medical and surgical), as well as harms associated with treatments in women with PPH. We assess intermediate outcomes, such as blood loss, hospital and intensive care unit (ICU) stay, and anemia, and longer term outcomes, including uterine preservation, fertility, breastfeeding, psychological impact and harms of treatment, and mortality related to treatment.

Key Questions

We synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ1. What is the evidence for the effectiveness of interventions for management of postpartum hemorrhage?

- a. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to atony?
- b. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to retained placenta?
- c. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to genital tract trauma?
- d. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to uncommon causes (e.g., coagulopathies, uterine inversion, subinvolution, abnormal placentation)?

KQ2. What is the evidence for choosing one intervention over another and when to proceed to subsequent interventions for management of postpartum hemorrhage?

KQ3. What are the harms, including adverse events, associated with interventions for management of postpartum hemorrhage?

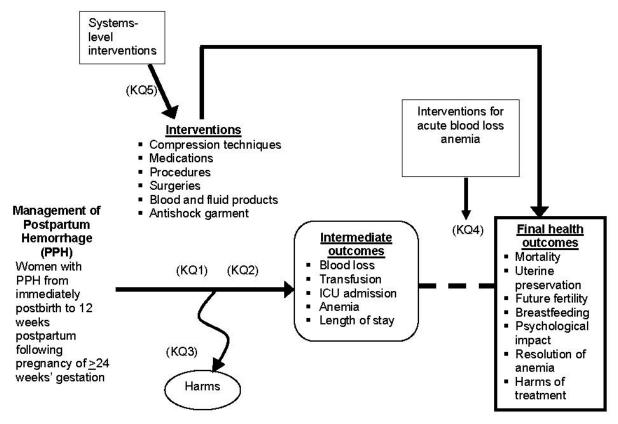
KQ4. What is the effectiveness of interventions to treat acute blood loss anemia after stabilization of postpartum hemorrhage?

KQ5. What systems-level interventions are effective in improving management of postpartum hemorrhage?

Analytic Framework

The analytic framework illustrates the population, interventions, and outcomes that guided the literature search and synthesis (Figure A). The framework for management of PPH includes women with PPH from immediately postbirth to 12 weeks postpartum following pregnancy of at least 24 weeks' gestation. The figure depicts the KQs within the context of the population, intervention, comparator, outcomes, timing, and setting (PICOTS) parameters described in the review. In general, the figure illustrates how interventions such as compression techniques, medications, procedures, surgeries, blood and fluid products, antishock garments, or systems-level interventions may result in intermediate outcomes such as blood loss, transfusion, ICU admission, anemia, or length of stay and/or in final health outcomes such as mortality, uterine preservation, future fertility, breastfeeding, or psychological impact. Also, adverse events may occur at any point after the intervention is received.

Figure A. Analytic framework



ICU = intensive care unit; KQ = Key Question.

Methods

Literature Search Strategy

A librarian employed search strategies, provided in Appendix A of the full report, to retrieve research on interventions for PPH. We searched MEDLINE® via the PubMed® interface, the Cumulative Index of Nursing and Allied Health Literature (CINAHL®), and Embase (Excerpta Medica Database). We limited searches to the English language and to studies published from 1990 to the present in order to reflect current standards of care for PPH. Our last search was conducted in November 2014. We manually searched reference lists of included studies and of recent narrative and systematic reviews and meta-analyses.

Inclusion and Exclusion Criteria

We developed criteria for inclusion and exclusion (Table A) in consultation with a Technical Expert Panel. We limited studies to those published in English and conducted in Very High Human Development countries as ranked by the United Nations Development Programme Human Development Index (Table A). In the opinion of our clinical experts, processes of care and interventions available in these countries best reflect the system of health care in the United States. A considerable body of evidence addresses PPH management in developing countries. However, the limited availability of skilled clinicians and treatment options in many of these countries results in different standards of care and clinical approaches from those in the United

States.

PPH is a complex condition. Treatments are selected not only by PPH etiology and severity, but also by factors related to the setting of care, the availability of medications or other therapeutic options, the availability of personnel, and the standards of care in a given treatment center. Treatment availability and the feasibility of providing certain treatments differ across developed and developing nations, and even within any given nation. Because the context of care in most developing nations differs significantly from care in the United States, we instituted language and country limitations in order to identify studies that are most applicable to guiding care by clinicians in the United States, who are the intended audience for this report.

In order to provide contextual information about effectiveness and harms reported in studies conducted in developing nations, we provide summaries of recent reviews of interventions for PPH, which include studies conducted in any country, in the Discussion section (Findings in Relation to What Is Already Known) of the full report.

Table A. Inclusion criteria

KQs 1–3, 5: Women with PPH from immediately postbirth to 12 weeks postpartum following pregnancy >24 weeks' gestation KQ4: Women with stabilized PPH and acute blood loss anemia All modes of birth in any setting Time period 1990 to present	Category	Criteria			
Publication languages	Study population	following pregnancy >24 weeks' gestation • KQ4: Women with stabilized PPH and acute blood loss anemia			
Very High Human Development countries as indicated by the United Nations Development Programme Human Development Index. Countries as of April 2014 include Norway, Australia, United States, Netherlands, Germany, New Zealand, Ireland, Sweden, Switzerland, Japan, Canada, Republic of Korea, Hong Kong, Iceland, Denmark, Israel, Belgium, Austria, Singapore, France, Finland, Slovenia, Spain, Lieothenstein, Italy, Luxembourg, United Kingdom, Czech Republic, Greece, Brunei Darussalam, Cyprus, Malta, Andorra, Estonia, Slovakia, Qatar, Hungary, Barbados, Poland, Chile, Lithuania, United Arab Emirates, Portugal, Latvia, Argentina, Seychelles, and Croatia Admissible evidence (study design and other criteria) • KQ3 1–2, 4: RCTs or prospective/retrospective cohort studies, population-based case series or registry studies with ≥50 cases of PPH treatment, case series of procedures (uterine balloon tamponade, uterine artery embolization) or surgical approaches with ≥50 women • KQ3: RCTs or prospective retrospective cohort studies, case series with ≥50 cases addressing interventions for PPH • KQ5: Pre-post studies related to large-scale health systems changes, RCTs, prospective/retrospective cohort studies Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results • Studies targeting women with PPH who meet the population criteria described above • Studies that address: • Treatment modality aimed at treatment/management of PPH in a relevant population or treatment for acute blood loss anemia following stabilization of PPH • Outcomes related to interventions; primary outcomes of interest include blood loss, transfusion, ICU admission, anemia, length of stay, mortality, uterine preservation, future fertility, breastfeeding, and psychological impact, as well as harms • Studies must include extractable data presented in text or tables (vs. solely in figures) or relevant outcomes • For KQ5, studies must explicitly assess effe	Time period	1990 to present			
Programme Human Development Index. Countries as of April 2014 include Norway, Australia, United States, Netherlands, Germany, New Zealand, Ireland, Sweden, Switzerland, Japan, Canada, Republic of Korea, Hong Kong, Iceland, Denmark, Israel, Belgium, Austria, Singapore, France, Finland, Slovenia, Spain, Liechtenstein, Italy, Luxembourg, United Kingdom, Czech Republic, Greece, Brunei Darussalam, Cyprus, Malta, Andorra, Estonia, Slovakia, Qatar, Hungary, Barbados, Poland, Chile, Lithuania, United Arab Emirates, Portugal, Latvia, Argentina, Seychelles, and Croatia Admissible evidence (study design and other criteria) KQS 1−2, 4: RCTs or prospective/retrospective cohort studies, population-based case series or registry studies with ≥50 cases of PPH treatment, case series of procedures (uterine balloon tamponade, uterine artery embolization) or surgical approaches with ≥50 women KQ3: RCTs or prospective retrospective cohort studies, case series with ≥50 cases addressing interventions for PPH KQ5: Pre-post studies related to large-scale health systems changes, RCTs, prospective/retrospective cohort studies Other criteria Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results Studies targeting women with PPH who meet the population criteria described above Studies that address: Treatment modality aimed at treatment/management of PPH in a relevant population or treatment for acute blood loss anemia following stabilization of PPH Outcomes related to interventions; primary outcomes of interest include blood loss, transfusion, ICU admission, anemia, length of stay, mortality, uterine preservation, future fertility, breastfeeding, and psychological impact, as well as harms Studies must include extractable data presented in text or tables (vs. solely in figures) or relevant outcomes For KQ5, studies must explicitly assess effects of a systems-level intervention on PPH management as a primary or secondary aim; analytic models must	Publication languages	English only			
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information about effects of strategy on management of PPH; discussion interprets the	(study design and	 Emirates, Portugal, Latvia, Argentina, Seychelles, and Croatia Admissible designs KQs 1–2, 4: RCTs or prospective/retrospective cohort studies, population-based case series or registry studies with ≥50 cases of PPH treatment, case series of procedures (uterine balloon tamponade, uterine artery embolization) or surgical approaches with ≥50 women KQ3: RCTs or prospective retrospective cohort studies, case series with ≥50 cases addressing interventions for PPH KQ5: Pre-post studies related to large-scale health systems changes, RCTs, prospective/retrospective cohort studies Other criteria Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results Studies targeting women with PPH who meet the population criteria described above Studies that address: Treatment modality aimed at treatment/management of PPH in a relevant population or treatment for acute blood loss anemia following stabilization of PPH Outcomes related to interventions; primary outcomes of interest include blood loss, transfusion, ICU admission, anemia, length of stay, mortality, uterine preservation, future fertility, breastfeeding, and psychological impact, as well a harms Studies must include extractable data presented in text or tables (vs. solely in figures) relevant outcomes For KQ5, studies must explicitly assess effects of a systems-level intervention on PPH management as a primary or secondary aim; analytic models must indicate data 			

ICU = intensive care unit; KQ = Key Question; PPH = postpartum hemorrhage; RCT = randomized controlled trial.

Study Selection

Two reviewers independently assessed each abstract. If one reviewer concluded that the article could be eligible based on the abstract, we retained it for review of the full text. Two reviewers independently assessed the full text of each included study, with any disagreements adjudicated by a senior reviewer.

Data Extraction and Synthesis

We extracted data from included studies into evidence tables that report study design, descriptions of the study population (for applicability), description of the interventions, and baseline and outcome data on constructs of interest. Data were initially extracted by one team member and reviewed for accuracy by a second. The final evidence tables are presented in Appendix D of the full report.

We completed evidence tables for all included studies, and data are presented in summary tables and analyzed qualitatively in the text. We did not conduct meta-analyses, given significant heterogeneity in the study populations, interventions, and outcomes.

Quality (Risk-of-Bias) Assessment of Individual Studies

We used tools appropriate for specific study designs to assess quality/risk of bias of individual studies: the Cochrane Risk of Bias tool for randomized trials;³⁰ the Newcastle-Ottawa Scale for Non-Randomized Studies;³¹ the National Heart, Lung, and Blood Institute scale for pre-post studies;³² a tool for case series adapted from RTI Item Bank questions;³³ and a four-item harms assessment instrument for cohort studies derived from the McMaster Quality Assessment Scale of Harms (McHarm) for Harms Outcomes³⁴ and the RTI Item Bank.³³ Appendix B of the full report includes questions used in each tool.

Two team members independently assessed each included study, with discrepancies resolved through discussion to reach consensus and/or adjudication by a senior reviewer. The results of these assessments were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality designations, as described in the full report. Quality ratings for each study are in Appendix E of the full report.

Strength of the Body of Evidence

Two senior investigators graded the body of evidence for key intervention/outcome pairs using methods based on the "Methods Guide for Effectiveness and Comparative Effectiveness Reviews." The team reviewed the final strength-of-evidence designation. The possible grades were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

Applicability

We assessed applicability by identifying potential PICOTS factors likely to affect the generalizability of results (i.e., applicability to the general population of women being treated for PPH). We considered factors related to the availability of interventions; severity of PPH; characteristics of the population, such as mode of birth, that may be associated with PPH; and setting of the intervention as particularly likely to affect applicability.

Results

Article Selection and Overview

We identified 3,266 nonduplicative titles or abstracts with potential relevance, with 920 proceeding to full-text review. We excluded 844 studies at full-text review and included 68 unique studies (76 publications) in the review. We present findings by intervention and outcome area where possible under each KQ. For KQ1, we integrated discussion of subquestions because there was not adequate distinction in the literature to address different etiologies separately.

While a number of studies were classified as prospective or retrospective studies using our study classification algorithm (Appendix G of the full report), few cohort studies provided comparative analyses between the groups, and many were confounded by indication in that women who received interventions such as massive transfusion or hysterectomy likely had more severe cases of PPH. Additionally, initial management of PPH using first-line interventions such as uterotonics and uterine massage differed across studies and across women, as each study generally included a number of patients transferred from other hospitals. Thus, populations were heterogeneous in terms of severity and level of stabilization prior to second-line interventions. Given the lack of data from randomized or controlled studies of PPH management, we present data from cohort studies and case series, and note potential confounding.

The following sections summarize findings within the literature meeting our criteria. Overall, the evidence to answer questions about PPH management did not reach standards for high strength of evidence (Tables B–E). We briefly summarize strength-of-evidence findings in each section below and provide a full discussion of strength-of-evidence assessment in the Discussion section of this Executive Summary and in the full report.

KQ1. Effectiveness of Interventions for Management of PPH

Fifty-one unique studies examined the effectiveness of interventions for management of PPH. Some studies addressed multiple interventions. We classified these studies broadly as medical interventions, procedures, and surgical interventions, and more specifically by the type of intervention, including pharmacologic interventions (12 studies), transfusion as an intervention for management of acute PPH (4 studies), intrauterine balloon tamponade (5 studies), embolization (19 studies), uterine compression sutures (3 studies), uterine and other pelvic artery ligation (5 studies), embolization and hysterectomy (1 study), hysterectomy (8 studies), and combined approaches (4 studies). Studies that address transfusion as an intervention for anemia once PPH is stabilized are summarized under KQ4.

Pharmacologic Interventions

We identified few studies of pharmacologic interventions for PPH that met our review criteria (n = 12). Six small studies of fair and poor quality each addressed different drugs. One retrospective cohort study reported successful control of bleeding following oxytocin and other uterotonics in 49 percent of women. One randomized controlled trial (RCT) of tranexamic acid versus no tranexamic acid reported significantly less blood loss, duration of bleeding, and need for transfusion in the tranexamic acid arm compared with control. A cohort study comparing misoprostol and methylergonovine reported no group differences in transfusion or need for other treatments or surgeries. Case series of sulprostone and carboprost tromethamine reported control of bleeding without additional procedures or surgeries in 83 and 88 percent of participants,

respectively, and a cohort study assessing recombinant human soluble thrombomodulin reported greater D-dimer decreases in women with PPH and disseminated intravascular coagulopathy treated with thrombomodulin than in matched controls.

Six small studies of recombinant activated factor VIIa (rFVIIa) had mixed results. In one retrospective cohort study, women in the rFVIIa group required more blood products and had greater blood loss than women not receiving the treatment. In a case-control study, differences in change in prothrombin time were not significant between women treated with rFVIIa and those who were not. Used as a second-line intervention, rFVIIa controlled bleeding without the need for further procedures or surgeries in 27 to 31 percent of women in one cohort study, a rate that was similar to the rate for treatment with other second-line interventions in that study. In registry studies, bleeding was considered improved after one or multiple doses of rFVIIa in 64 to 80 percent of women after the final dose. No study included more than 177 women receiving rFVIIa.

Strength of evidence is insufficient for all outcomes of each of the agents studied (oxytocin and other uterotonics, misoprostol, tranexamic acid, carboprost tromethamine, thrombomodulin, and rFVIIa) for PPH management due to the study sizes and lack of studies addressing each agent.

Transfusion for Supportive Management of Ongoing PPH

Three studies of fair quality and one of poor quality addressed transfusion for supportive management of PPH. Two of the studies found that ICU admissions and death were higher with combined blood products versus single (whole blood or packed red blood cells) and massive transfusion versus nonmassive transfusion. These differences may reflect that women in the groups with poorer outcomes had more severe PPH. A third study found that estimated blood loss, blood products transfused, and mean length of stay did not differ between cryoprecipitate and fibrinogen concentrate groups, and a fourth reported reduced use of blood products after the introduction of fibrinogen. Strength of evidence for outcomes related to transfusion is insufficient. While there were three fair-quality studies of transfusion, two of them were so confounded that we could not confidently ascertain their outcomes.

Procedures

Both of the procedures assessed in the studies we reviewed (uterine balloon tamponade, embolization) showed positive results for PPH management. The median success rate (defined as control of bleeding without additional procedures or surgeries) of intrauterine balloon tamponade as the initial second-line procedure (i.e., first procedure following conservative management) was 75 percent in three studies reporting data on success. In one study of a protocol change to add balloon tamponade as the initial procedure after medication failure, rates of some invasive procedures (beyond tamponade) decreased in women who had vaginal births. The median success rate for embolization as the initial second-line procedure among 15 studies providing such data was 89 percent (range, 58% to 98%). However, there was wide variation in the materials used for embolization, the arteries that were embolized, and the interventions that were used before and in conjunction with embolization. The availability of embolization, which is performed by an interventional radiologist, varies by hospital; therefore, this treatment modality is not available to all women with PPH. Strength of evidence for outcomes related to uterine balloon tamponade is insufficient, given the small number of studies and small sample sizes.

Strength of evidence is low for embolization controlling bleeding without additional procedures or surgeries.

Surgical Interventions

The effectiveness of surgical interventions varied. The success rate of uterine compression sutures was 60 and 70 percent in the two studies from which this could be ascertained. Ligation had a median success rate of 92 percent in three studies (range, 36% to 96%). Hysterectomy used as the first procedure after conservative management controlled bleeding without further surgeries or procedures in a median of 57 percent of women (range, 20% to 93%) in two studies. One study compared embolization and hysterectomy, and reported significantly more ICU admissions and a greater median length of stay in the hysterectomy group than the embolization group. Strength of evidence is insufficient for the success of uterine compression sutures and hysterectomy in controlling bleeding, given the few studies available. Strength of evidence is low for ligation controlling bleeding without further procedures or surgeries.

Combined Approaches

Three studies examined a combination of medical and surgical interventions for secondary PPH. Interventions included conservative management (including uterotonics), transfusion, surgical evacuation, curettage, and hysterectomy. In the two studies that compared medical and surgical approaches, hospital readmission and repeat surgical evacuation occurred more frequently in women who initially received medical management versus surgical. One cohort study of women with primary PPH reported greater need for transfusion, ICU admission, and greater hospital length of stay in women undergoing procedures and/or surgery compared with women who were medically managed. Strength of evidence for studies of combination interventions and length of stay was insufficient, given the small sample sizes and inconsistency in interventions.

KQ2. Evidence for Choosing Interventions and Proceeding to Subsequent Interventions

We did not identify any studies addressing this question.

KQ3. Harms of Interventions for PPH

Harms varied considerably across the 50 studies reporting harms data. Harms were generally mild in the few studies of medications that met our review criteria. Four studies of rFVIIa reported on thrombotic events, but sample sizes were small and studies were of fair to poor quality. Few studies of uterine balloon tamponade reported adverse events, and studies of embolization reported on subsequent menstrual changes, infertility, and pregnancy complications, including spontaneous abortion. Few women, however, were followed long term, and rates of such complications ranged from 0 to 43 percent across studies. Two small studies assessing uterine compression sutures and preterm birth reported no differences in preterm births between cases and controls, and studies of ligation and hysterectomy reported primarily on operative injuries and reoperation.

Strength of evidence for harms of interventions was typically insufficient, given the diversity of harms reported in single studies. Strength of evidence was low for hematoma, infertility, and menstrual changes associated with embolization and low for a lack of association between

embolization and spontaneous abortion. Strength of evidence was also low for the association between hysterectomy and operative organ damage and reoperation due to the greater number of studies and more consistent reporting of adverse events.

KQ4. Effectiveness of Interventions for Acute Blood-Loss Anemia After Stabilization of PPH

Two small poor-quality RCTs addressed interventions for acute blood loss after PPH is stabilized. In a study comparing women treated with intravenous versus oral iron supplementation after PPH, there was no significant difference in hemoglobin level between groups at any time point. In a study that assessed differences in fatigue and quality of life between women treated with blood transfusion versus no transfusion, the difference in these outcomes between groups was minimal and possibly clinically equivalent. Strength of evidence is insufficient for all outcomes and harms in studies of interventions for anemia after PPH, given the few studies, small number of participants, and differences in intervention approaches.

KQ5. Effectiveness of Systems-Level Interventions

Across a range of systems-level interventions that range from a complex multiphase project with 11 distinct components to simple 3-component models for audit and feedback, findings are inconsistent about benefit. All sites, including those participating in the active sites of a null cluster randomized trial, were aware of a programmatic emphasis on improving response to and outcomes of PPH. Despite this built-in bias toward finding an effect—since estimated blood loss was rarely quantitatively measured and self-report of performance would be expected to be optimistic—results of a large trial and the higher quality studies do not demonstrate ability to reduce incidence or severity of PPH, or key maternal outcomes such as transfusion, hysterectomy, and ICU admission. Strength of evidence is moderate for a lack of benefit for systems-level interventions in reducing PPH incidence or severity, preventing hysterectomy, or affecting ICU admissions. Strength of evidence is moderate for no effect on the need for transfusion and insufficient for effects on mortality.

Discussion

Key Findings

We included 68 unique studies (76 publications) in this review, including 4 RCTs, 2 prospective and 14 retrospective cohort studies, 10 pre-post studies (studies that compare PPH management and/or outcomes before and after an intervention, such as introduction of a new protocol), 4 case-control studies, and 34 case series. Most studies were conducted in Europe (n = 33), and 18 were conducted in the United States or Canada, 13 in Asia, 3 in Australia or New Zealand, and 1 in Argentina. No studies were of good quality for effectiveness outcomes. We considered 23 studies as fair quality for effectiveness outcomes and 38 as poor (including case series, which we considered poor quality by default). Seven studies provided only harms data. Among the 50 studies reporting harms, we considered 11 as good quality for harms reporting and the remainder as poor quality.

Six small studies of fair and poor quality addressed different pharmacologic agents. Three studies, each of different agents (oxytocin and other uterotonics, tranexamic acid, sulprostone, carboprost tromethamine), reported reduced bleeding or control of bleeding. One study

comparing misoprostol and methylergonovine reported no group differences in outcomes, and one of recombinant human soluble thrombomodulin to treat disseminated intravascular coagulation reported greater decrease in D-dimer in the thrombomodulin arm. Six small studies of rFVIIa had mixed results related to need for transfusion and control of bleeding.

Medications commonly used for PPH in the United States are oxytocin, methylergonovine maleate, carboprost tromethamine, and misoprostol. One study that met our inclusion criteria addressed oxytocin; one study included methylergonovine maleate and misoprostol. Because evidence regarding first-line management, particularly pharmacologic management, is critical for decisionmaking by clinicians and guidelines developers, we summarize findings from other recent studies of agents and interventions conducted in any country in the Discussion section of the full report.

The success of uterine-sparing techniques, such as uterine balloon tamponade, embolization, uterine compression sutures, and uterine and other pelvic artery ligation, in controlling bleeding without the need for additional procedures or surgeries ranged from 36 to 98 percent. However, these data come from a limited number of studies with a small number of participants. Harms reporting was limited to 50 studies and was difficult to synthesize because diverse adverse events were reported inconsistently across studies. Only two studies addressed interventions for anemia after PPH is stabilized. Systems-level interventions (n = 9 studies) showed little benefit in reducing the incidence or severity of PPH or the need for transfusion or hysterectomy.

Strength of Evidence

We included case series in our assessment of strength of evidence for harms and success rates of procedures and surgeries, and we rated strength of evidence for outcomes we considered to be clinically significant, consistently defined, and plausibly linked to the intervention. Overall, the evidence to answer questions about PPH management did not reach standards for high strength of evidence (Tables B–E). Strength of evidence was insufficient for all interventions/outcomes except for the success of embolization and ligation in controlling bleeding without further procedures or surgeries, which had low strength of evidence.

Strength of Evidence for Interventions To Manage PPH

The strength of evidence for interventions is summarized below:

Pharmacologic interventions. Strength of evidence is insufficient for all outcomes of each agent studied (oxytocin and other uterotonics, misoprostol, tranexamic acid, carboprost tromethamine, thrombomodulin, and rFVIIa) for PPH management because of the study sizes and lack of studies addressing each agent.

Transfusion for supportive management of PPH. While three fair-quality studies addressed transfusion, two of them were so confounded that we could not confidently ascertain their outcomes; thus, strength of evidence for all outcomes in insufficient.

Uterine balloon tamponade. Strength of evidence for the success of uterine balloon tamponade in controlling bleeding is insufficient.

Uterine artery embolization. Strength of evidence for embolization controlling bleeding without additional procedures or surgeries is low because of a lack of comparative studies and small sample sizes in studies providing data to assess success of the intervention.

Uterine compression sutures. Strength of evidence is insufficient for the success of uterine compression sutures.

Uterine and other pelvic vessel ligation. Strength of evidence is low for ligation controlling bleeding without further surgeries or procedures.

Hysterectomy. Strength of evidence is insufficient for all outcomes of hysterectomy.

Combined interventions. Strength of evidence is insufficient for all outcomes.

As noted, we identified few studies of medications meeting our review criteria. However, a number of studies of misoprostol and oxytocin have been conducted in developing countries. Four recent systematic reviews of interventions for PPH, including two Cochrane reviews, assessed uterotonics, including misoprostol. We summarize these reviews fully in the Findings in Relation to What Is Already Known section in the full report and provide a brief summary here.

In one Cochrane review, oxytocin infusion was more effective and caused fewer side effects than misoprostol when used as first-line therapy for the treatment of primary PPH. When used *after* prophylactic uterotonics, misoprostol and oxytocin infusion had similar effects. The review concluded that adding misoprostol for women receiving treatment with oxytocin did not appear to be beneficial. In another Cochrane review, differences in maternal mortality and morbidity, except for fever, did not differ significantly between misoprostol and control groups. The investigators concluded that misoprostol did not increase or decrease morbidity or mortality, with the exception of fever, and the lowest effective dose should be used. In another review of misoprostol versus placebo, misoprostol did not reduce PPH risk significantly compared with placebo. In the fourth review and meta-analysis, higher doses of misoprostol (600 vs. 400 micrograms) were no more effective at preventing blood loss.

Table B. Summary of evidence in studies addressing effectiveness of interventions (KQ1)

Category	Intervention	Key Outcome(s)	Strength of Evidence Grade	Findings
	Oxytocin and other uterotonics	Control of bleeding	Insufficient	Control of bleeding in 45/91 women (49%) receiving oxytocin and other uterotonics in a single short-term study with high study limitations.
	Tranexamic acid vs. no tranexamic acid	Anemia, transfusion, blood loss, ICU stay	Insufficient	Less blood loss, need for transfusion, and progression to severe PPH in TXA group vs. control (p <.05) reported in a single small short-term cohort study with high study limitations.
	Misoprostol vs. methylergonovine maleate	Transfusion, uterine preservation	Insufficient for superiority of 1 agent over another in affecting any outcome	No group differences in need for transfusion or additional medical or surgical treatments in a single small short-term cohort study with high study limitations.
Pharmacologic Interventions	Sulprostone	Success in controlling bleeding	Insufficient	In a single short-term study with high study limitations, bleeding was controlled in 83% of 1,370 women.
	Carboprost tromethamine	Success in controlling bleeding	Insufficient	In a single short-term study with high study limitations, bleeding was controlled by carboprost in 81% of 237 cases of PPH.
	Thrombomodulin vs. no thrombomodulin	Uterine preservation, bleeding, transfusion	Insufficient	Greater D-dimer decrease from baseline in intervention arm vs. control in a single small short-term cohort study with high study limitations.
	RFVIIa	Transfusion, anemia, uterine preservation, LOS	Insufficient	Need for transfusion was greater with rFVIIa in 1 small study with high study limitations and not different in another. Rates of hysterectomy, LOS were similar.

Table B. Summary of evidence in studies addressing effectiveness of interventions (KQ1) (continued)

Category	Intervention	Key Outcome(s)	Strength of	Findings
Calegory	intervention	ney outcome(s)	Evidence Grade	Fillulligs
Other Medical Interventions	Transfusion for supportive management of ongoing PPH	ICU admission, LOS	Insufficient	Inconsistency in direction of effect (greater LOS and ICU admission in transfusion or whole blood groups in 2 studies; no group differences in another study); high study limitations.
	Uterine tamponade	Success in controlling bleeding	Insufficient	Tamponade without further procedure or surgery controlled bleeding in 75-86% of women in 3 studies, and tamponade plus additional intervention controlled bleeding in 86-98% in another, but studies were small with high study limitations.
Procedures	Embolization	Success in controlling bleeding	Low for positive effect in controlling bleeding	Median success rate of 89% as initial second-line intervention in 15 studies with high limitations; conservative management and severity of PPH varied across studies. A higher SOE is not possible due to the lack of comparisons in this literature and small sample sizes.

Table B. Summary of evidence in studies addressing effectiveness of interventions (KQ1) (continued)

Category	Intervention	Key Outcome(s)	Strength of Evidence Grade	Findings
	Uterine compression sutures	Success in controlling bleeding	Insufficient	In 2 small studies with medium limitations, bleeding controlled by suture following conservative management in 60-70% of women.
Surgeries	Ligation	Success in controlling bleeding	Low for positive effect in controlling bleeding	92% success rate for controlling bleeding without further procedure or surgeries in 3 small studies of ligation alone with medium study limitations. Ligation with or without suture controlled bleeding in 91% in 1 case series.
	Hysterectomy	LOS, ICU admission	Insufficient	Insufficient SOE due to few comparative studies, high limitations.
Other Interventions	Combined interventions	LOS in women with primary and secondary PPH	Insufficient	Greater LOS in women with primary PPH undergoing procedures/surgeries vs. medical management in 1 small study with high limitations. No differences in LOS between surgical and medical management groups in 2 small studies with high limitations addressing secondary PPH.

ICU = intensive care unit; KQ = Key Question; LOS = length of stay; PPH = postpartum hemorrhage; rFVIIa = recombinant activated factor VIIa; SOE = strength of evidence; TXA = tranexamic acid.

Strength of Evidence for Harms of Interventions

Generally strength of evidence was insufficient, given the diversity of harms reported in single studies. However, strength of evidence rose above insufficient for selected harms related to uterine compression sutures, embolization, and hysterectomy because of the greater number of studies and more consistent reporting of adverse events (Table C).

As noted, few studies of uterotonics met our inclusion criteria. However, harms reported in recent systematic reviews of uterotonics for PPH treatment included shivering and fever. (See Findings in Relation to What Is Already Known section in the full report for more information.) In one review, oral misoprostol was associated with a significant increase in vomiting and shivering compared with either oxytocin or rectal misoprostol. In another review, differences in maternal mortality and morbidity, except for fever, did not differ significantly between misoprostol and control groups. Risk of fever was increased in misoprostol groups and was highest in studies with a misoprostol dose of 600 micrograms or more. In another review of misoprostol versus placebo, shivering and fever were significantly more common in misoprostol arms. A fourth review noted more adverse effects related to misoprostol than placebo.

While evidence in the current review was insufficient to comment on the association between rFVIIa and thrombolic events, studies in other populations have suggested increased risk of arterial events. In one review of RCTs in nonhemophilia patients, the pooled relative risk of thrombolic events across studies of prophylactic and therapeutic uses of rFVIIa was 1.45 (95%)

confidence interval, 1.02 to 2.05). Another review of fertility outcomes following embolization, ligation, and sutures concluded that the techniques reviewed did not appear to compromise fertility, but the number and quality of studies were limited.

Table C. Summary of evidence in studies addressing harms of interventions (KQ3)

		studies addressing h		, ,
Intervention	Intervention	Key Outcome(s)	Strength of	Findings
Category		1	Evidence Grade	1. 4
	Tranexamic acid	All harms	Insufficient	In 1 small RCT with low study limitations, serious harms did not differ between groups and mild transient harms occurred more often in TXA group.
	Sulprostone	All harms	Insufficient	Insufficient SOE, as there was only 1 study considered poor quality for harms reporting.
Pharmacologic Interventions	Methylergonovine maleate	Acute coronary syndrome and myocardial infarction	Low SOE for lack of association of methylergonovine maleate with acute coronary syndrome and myocardial infarction	No significant difference in the incidence of these conditions in the exposed and nonexposed groups in 1 large cohort study with low study limitations.
	Carboprost tromethamine	All harms	Insufficient	Insufficient SOE, as there was only 1 study considered poor quality for harms reporting.
	RFVIIa	Thromboembolic events	Insufficient	4 of 5 studies (unclear overlap in 2 studies) reported thromboembolic events (pulmonary embolus, deep vein thrombosis, myocardial infarction), but sample sizes were small and study limitations high.
Other Medical Interventions	Transfusion for supportive management of ongoing PPH	All harms	Insufficient	Inconsistency in harms reported in 7 studies with high study limitations.

Table C. Summary of evidence in studies addressing harms of interventions (KQ3) (continued)

Intervention Category	Intervention	Key Outcome(s)	Strength of Evidence Grade	Findings
	Uterine tamponade	All harms	Insufficient	Small studies with high limitations and few harms reported.
Embol	Embolization	Infertility	Low SOE for negative effect of embolization on future fertility	Infertility rate among women who had embolization in these studies was greater than that of the overall population (range, 0 to 43%), but few women (n = 300) available for long-term followup; high study limitations and inconsistency in 5 studies.
Procedures		Spontaneous abortion in subsequent pregnancy	Low SOE for lack of association between embolization and spontaneous abortion in subsequent pregnancy	Small number of women followed up; rates of miscarriage ranged from 5% to 21.4% in 7 studies with high study limitations. Rates were comparable to estimates in the general population.
		Menstrual changes	Low SOE for an association between embolization and subsequent menstrual changes	Rates of menstrual change, including heavier, lighter, or irregular menses and amenorrhea, ranged from 2% to 22% in 8 studies with high limitations.
		Hematoma	Low SOE for association between embolization and hematoma	Rates ranged from 1.7% to 6% in 7 studies with high limitations.

Table C. Summary of evidence in studies addressing harms of interventions (KQ3) (continued)

Intervention Category	Intervention	Key Outcome(s)	Strength of Evidence Grade	Findings
	Uterine compression sutures	Preterm birth	Low SOE for no effect on subsequent preterm birth	In 2 studies with medium limitations, preterm births did not differ between women in case and control arms in subsequent pregnancies.
Surgeries	Ligation	Surgical injury	Insufficient	High study limitations and imprecision in 2 studies. Injuries (inadvertent ligation of the ureters and secondary hysterectomy disunion with sepsis) related to ligation reported in both studies.
	Hysterectomy	Bladder and ureter lesions	Low SOE for association of hysterectomy and operative organ damage	Rates of bladder and ureter lesions ranged from 6% to 12% and 0.4% to 41%, respectively, in 6 small studies with high study limitations.
		Reoperation	Low SOE for association between hysterectomy and reoperation	Rates of reoperation ranged from 1.8% to 29% in 5 small studies with high study limitations.

KQ = Key Question; PPH = postpartum hemorrhage; RCT = randomized controlled trial; rFVIIa = recombinant activated factor VIIa; SOE = strength of evidence; TXA = tranexamic acid.

Strength of Evidence for Interventions for Anemia

There is insufficient strength of evidence for all outcomes and harms in studies of interventions for anemia after PPH is stabilized, given the few studies, small number of participants, and differences in intervention approaches (Table D).

Table D. Summary of evidence in studies addressing interventions for anemia after PPH (KQ4)

Intervention	Key Outcome(s)	Strength of	Findings
		Evidence Grade	
Iron supplementatio n	Anemia	Insufficient	No differences in groups receiving oral vs. intravenous iron in 1 small RCT with high study limitations and indirect outcomes.
Transfusion for anemia	Fatigue	Insufficient	No significant group differences in 1 small RCT with high study limitations.
	Quality of life	Insufficient	No significant group differences in 1 small RCT with high study limitations.
Iron supplementatio n and transfusion for anemia	All harms (transfusion reactions, infections, endometritis, thromboembolic events)	Insufficient	Of 2 small RCTs, harms were not prespecified in 1 study. No serious adverse reactions were attributed to the study drugs in either RCT but reporting in 1 RCT is not clear.

KQ = Key Question; PPH = postpartum hemorrhage; RCT = randomized controlled trial.

Strength of Evidence for Systems-Level Interventions

Overall the strength of evidence for any systems-level intervention on any outcome is insufficient or moderate, as the observational data are biased and a single very large trial suggests that at least one clearly described and implemented program did not change risk of

severe hemorrhage or meaningfully modify processes of care or overall maternal outcomes. Strength of evidence is moderate that these multicomponent interventions did not change specific outcomes, such as severity of PPH, transfusion, hysterectomy, and ICU admission (Table E).

Table E. Summary of evidence in studies addressing systems-level interventions for PPH (KQ5)

Intervention	Key Outcome(s)	Strength of Evidence Grade	Findings
Systems-Level Approaches	Incidence of PPH	Moderate SOE for lack of benefit in reducing PPH incidence	Sites were aware of objectives with regard to reducing PPH, and assessors of a somewhat subjective outcome were not masked in 1 large cluster RCT with medium study limitations.
	Severity of PPH	Moderate SOE for lack of benefit in reducing severity of PPH	Sites were aware of objectives with regard to reducing severity of PPH, and assessors of a somewhat subjective outcome were not masked. Severity was unchanged in 1 RCT, reduced in 2 pre-post studies, and had no difference in 3. Mean estimated blood loss >1,000mL declined in 1 study and increased in another.
	Transfusion	Moderate SOE for no effect on transfusion	Transfusion was unchanged in 1 RCT, increased in 1 pre-post study, and was unchanged in 2; 1 study found decreased use of total blood products related to decrease in risk of disseminated intravascular coagulation; another found decreased overall use of transfusion and blood products.
	Hysterectomy	Moderate SOE for lack of benefit in preventing hysterectomy	Hysterectomy was unchanged in 1 RCT with low study limitations. There was no significant change in 3 pre-post studies, in which hysterectomies increased in 2 and declined in the third. Risk significantly increased in 1 study and was similar between time periods in a third.
	ICU admission	Moderate SOE for lack of benefit	No change in 1 RCT and no change in 2 pre-post studies, all with low study limitations.
	Mortality	Insufficient SOE for benefit	Only 1 small pre-post study with medium study limitations reported on changes in mortality.

ICU = intensive care unit; KQ = Key Question; PPH = postpartum hemorrhage; RCT = randomized controlled trial; SOE = strength of evidence.

Applicability

Studies differed in terms of study population and outcome measures. Most studies did not make direct comparisons between treatments or characterize populations well in terms of severity of PPH and prior management strategies. This lack of direct comparison of treatment options hinders our ability to understand what treatments are most effective and in what order they should be used, both of which are paramount questions for clinicians. Overall, findings of studies in the review are generally applicable to the population of women who would be experiencing PPH in hospitals in high-resource nations. Most studies were conducted in Europe or the United States in tertiary care centers. Studies frequently included a number of women with PPH who were transferred from smaller or community hospitals, which can occur when women with PPH requiring additional treatment are stable enough to be moved to facilities with interventional radiology or other services. More women had PPH after cesarean birth than vaginal birth in the 50 studies reporting mode of birth (estimated 6,304 vaginal and 7,924 cesarean births among the 14,228 births for which mode was clearly reported). The most common cause of PPH was atony, which aligns with the most frequent cause of PPH in the larger

community and literature. Studies of pharmacologic agents typically included women with mild to moderate PPH, while studies of procedures or surgical approaches generally included women with more severe PPH that had not been controlled with first-line therapies such as uterotonics.

The uterotonics, blood products, and iron supplements studied are generally widely available; however, the accessibility of procedures such as embolization may be limited in smaller community hospitals. Similarly, community hospitals may lack personnel with experience with arterial ligation and compression sutures. Comparators across studies with more than one group were typically either no specific treatment (e.g., rFVIIa or no rFVIIa) or another treatment (e.g., embolization or ligation) and are likely confounded by patient and provider characteristics that may have affected the choice of intervention. For example, patients with more severe hemorrhage likely received more aggressive treatment, and providers could offer only the options available in their facilities. Outcomes addressed across studies were appropriate and clinically relevant; however, few studies reported longer term outcomes such as future fertility or patient-centered outcomes such as quality of life.

The populations included in the systems-level interventions, both in the United States and Europe, are similar in size and type (rural, academic, etc.) to current labor and delivery environments in the United States. Likewise the interventions designed and implemented in these studies were informed by processes of identifying evidence and crafting guidance that conform to typical quality improvement and outcomes-based research. The content of the interventions is feasible to implement across a full range of settings, and the approaches to measuring outcomes are applicable to practice. Overall the systems-level interventions assessed have good applicability to current practice in the United States.

Research Gaps

Future research needs around management of PPH are both clinical and methodologic. Priorities for future research include the following:

- Reaching consensus on definitions and criteria for PPH and first-line management strategies to promote consistency within the literature.
- Standardizing a definition of PPH, potentially with gradations of severity, to allow for meaningful comparison of outcomes.
- Conducting more rigorously controlled studies of all interventions for PPH management, especially medication studies, in light of the fact that these are considered first-line management and few studies in developed/high-resource nations addressed agents commonly in use. While studies in the PPH population are likely to be retrospective, studies should clearly describe first-line management and timing of management to clarify the course of care. Studies must report a priori study size calculation to ensure that the number of subjects will be adequate to show a difference (if the study is designed for superiority). In addition, comparative studies must declare within the design and methods section whether the study is a superiority trial or a noninferiority trial.
- Conducting cluster RCTs of intervention bundles that address order of medications, order and timing of manual interventions such as uterine massage and bimanual compression, number of times to repeat medications prior to moving on to second-line interventions, hemodynamic monitoring, and supportive care such as transfusion.
- Clearly identifying the trajectory of care, including which interventions were used and the order and timing of interventions.
- Identifying markers that can inform the decision to move to an alternative intervention.

- Investigating the effectiveness of agents used to control bleeding in other clinical areas and of new medications to address PPH. It is likely that new agents would be compared with or added to existing agents and not compared with placebo.
- Conducting additional RCTs or controlled studies of treating anemia after PPH is stabilized.
- Conducting additional prospectively designed and reported studies that report data from large national databases. These studies can describe effects in larger population samples and may be valuable for identifying longer term harms—for example, effects on breastfeeding, psychological trauma, and future fertility.
- Replicating the intrauterine balloon tamponade study that found it was effective in reducing invasive interventions.
- Using and clearly reporting objective methods to diagnose PPH and evaluate management, including accurate measurement of blood loss. Visual estimation of blood loss is too imprecise to be used in research.
- Dedication to prospective objective measures, such as estimated blood loss, time course of intervention, and use of intervention components.
- Greater capture and multivariable adjustment, including metaregression, for known risk factors and confounders to allow better understanding of the attributable impact, if any, of the intervention.
- Attention to the possibility that effect modifiers hide efficacy in some groups, which means
 that studies will need to be powered and specify a priori stratified analyses by candidate
 effect modifiers, such as grand multiparity, route of birth, induction, prolonged oxytocin
 infusion, or infection in labor.
- Prespecifying harms, differentiating harms of interventions from sequelae of PPH wherever possible, and studying longer term effects of procedures and surgical interventions.
- Using multivariate modeling. The size of the study populations in systems-level interventions can clearly support multivariate modeling and could serve to drive better understanding of the general lack of effectiveness. In particular, such data are well-suited to use of risk-adjustment models, and adjusting for these underlying differences in study population characteristics would allow comparison not only across time periods but across studies.
- Attention to the possibility that systems-level interventions are working against a biologically determined risk of PPH, meaning that within a specific population with particular characteristics, there is an irreducible level of risk, and event rates cannot be driven below that "floor." If this floor were demonstrated with risk-adjustment methods, this finding would fundamentally change the focus of study design and care. A floor would suggest that we need very large pragmatic trials aimed not at reducing the occurrence of PPH but at diminishing associated morbidity, mortality, personal harm and distress, and costs. The systems-level intervention studies available now cannot fully inform this goal, but primary meta-analyses of the highest quality cohorts with risk adjustment could determine if the evidence seen in some of the included studies that suggest benefits are worth pursing on a larger scale, including a scale large enough to separate the influence of candidate components to determine their individual contributions to improvements in care.

Limitations of the Evidence Base

Studies included in this review are methodologically and clinically limited. There is not a universally agreed management strategy for PPH. Medications were typically used as the initial

treatment; however, the specific drugs, dosages, and order varied. The selection of interventions, including which interventions were performed and in which order, was also inconsistent. Management was not well described in many studies, especially for women who transferred from other hospitals. Methods for estimating blood loss, when reported, varied and were limited. Overall, it was difficult to ascertain confidently the complete trajectory of care of women in many of the studies we reviewed, which compromises our ability to draw meaningful comparisons. As noted, few studies that met our criteria addressed commonly used uterotonics such as oxytocin; however, prior systematic reviews that have included studies in developing countries have reported similar effects on bleeding for misoprostol and oxytocin and benefits for misoprostol in reducing blood loss with side effects, including fever.

Procedures and surgical interventions also differed across studies. For example, materials used for embolization varied, as did the sites of embolization and ligation. There is no clear trigger for starting subsequent interventions, so success rates have limited reliability. It may be that women would have recovered after the first-line treatment if time allowed. In addition, there is the potential for cumulative effects of multiple interventions that cannot be measured. Outcomes other than control of bleeding can be difficult to assess. For example, transfusion could be an adverse outcome if treatment was not sufficient and timely to halt bleeding rapidly. Alternatively, early transfusion can be the appropriate intervention. Therefore, it is sometimes hard to know whether to classify transfusion as an adverse outcome. Measuring harms is similarly challenging. In some cases, it can be difficult to assess if harms are due to PPH or management interventions and how much each contributed, especially to deaths. There is a significant lack of truly comparative studies. Randomized studies would be ideal, yet are complex to conduct with a life-threatening condition such as PPH. Studies were typically conducted or data collected over long timeframes (median study duration, 5 years; range, 6 months to 29 years), and it is likely that interventions and patient characteristics would have changed over time, but few studies account for secular changes such as the introduction of new interventions.

In systems-level interventions, a natural tension exists between the desire to implement robust interventions and the challenges of understanding which components may have value. In the case of these interventions, it is particularly challenging because lower quality studies with looser measures of outcomes were more likely to report intervention effects. The literature about systems-level interventions is limited by lack of analyses that seek to adjust for secular trends and changes in confounders, such as proportion of births by cesarean and trends in rising bodymass index. Likewise, lack of multivariable modeling may obscure the influence of elements of care, such as induction of labor, and comorbidities, such as chorioamnionitis, that could identify which predictors may be exerting substantial influence and inform new approaches to diminishing risk of PPH.

Implications for Clinical and Policy Decisionmaking

A limited body of evidence addresses interventions for managing PPH. Few studies addressed medications commonly used to treat PPH, precluding our ability to draw conclusions about their effectiveness. Success rates for uterine balloon tamponade or surgeries are typically above 60 percent (e.g., success of uterine balloon tamponade as the initial second-line therapy in one study was 86%; success rates for ligation as the first second-line intervention to control bleeding ranged from 36% to 96%). Studies of embolization suggested that it may be associated with a median rate of successful control of bleeding without the need for additional procedures

or surgeries of 89 percent, with a wide range of success (58% to 98%) across studies. However, few studies clearly provided data on the success of these procedures and surgeries as the initial second-line approach, so rates are based on a small number of cases. Adverse events and longer term outcomes associated with procedures and surgical interventions are also not well understood. At this point, the evidence is insufficient to comment on the effectiveness and harms of most interventions for most outcomes.

Given the mixed and insufficient evidence, clinicians will likely need to continue to make individual decisions about the care of women with PPH based on each woman's clinical situation and the management options available in the setting. This body of evidence does not provide clear answers to the key clinical questions of what interventions to use and in what order.

Conclusions

A limited body of evidence addresses interventions for managing PPH. The most effective treatments and the order in which to use treatments remain unclear. Diagnosis of PPH is subjective, which makes it difficult to compare the severity of PPH and determine the comparability of participants within and across studies. The trajectory of care, rationale for choice of intervention, and component of care ultimately responsible for controlling bleeding are also frequently unclear because of the need for rapid intervention in an emergency situation. Few studies included in this review addressed pharmacologic or medical management, including transfusion for supportive management of ongoing PPH, and the evidence reviewed is insufficient to comment on effects of such interventions. The success of uterine-sparing techniques, such as uterine balloon tamponade, embolization, uterine compression sutures, and uterine and other pelvic artery ligation, in controlling bleeding without the need for additional procedures or surgeries ranged from 36 to 98 percent. However, these data come from a limited number of studies with a small number of participants. Harms of interventions are diverse and not well understood. Some studies reported an association between rFVIIa and thromboembolic events, but sample sizes were small. Some studies with longer term followup reported adverse effects on future fertility and menstrual changes in women undergoing embolization. Need for reoperation was reported after hysterectomy. Evidence is insufficient to assess the effects of interventions for anemia after PPH is stabilized, and systems-level interventions showed little benefit in reducing the incidence or severity of PPH or the need for transfusion or hysterectomy. Further research is needed across all interventions for PPH management, especially pharmacologic interventions, which are the most frequently used first-line therapies.

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Introduction

Definition and Prevalence

Postpartum hemorrhage (PPH) is commonly defined as blood loss exceeding 500 milliliters (mL) following vaginal birth and 1000 mL following cesarean. Definitions vary, however, and diagnosis of PPH is subjective and often based on inaccurate estimates of blood loss. Moreover, average blood loss at birth frequently exceeds 500 or 1000 mL, and symptoms of hemorrhage or shock from blood loss may be hidden by the normal plasma volume increases that occur during pregnancy. Proposed alternate metrics for defining and diagnosing PPH include change in hematocrit, need for transfusion, rapidity of blood loss, and changes in vital signs, all of which are complicated by the urgent nature of the condition. PPH is often classified as primary/immediate/early, occurring within 24 hours of birth, or secondary/delayed/late, occurring more than 24 hours post-birth to up to 12 weeks postpartum. In addition, PPH may be described as third or fourth stage depending on whether it occurs before or after delivery of the placenta, respectively.

The overall prevalence of PPH worldwide is estimated to be 6 to 11 percent of births with substantial variation across regions. Prevalence differs by assessment method and ranges from 10.6 percent when measured by objective appraisal of blood loss to 7.2 percent when assessed with subjective techniques to 5.4 percent when assessment is unspecified. Multiple studies have noted an increase in PPH in high-resource countries, including the United States, Canada, Australia, Ireland, and Norway, since the 1990s. 11 In the United States, one study found that the incidence of PPH increased 26% from 1994 to 2006 (2.3% vs. 2.9%, respectively, p < 0.001). Another U.S. study reported the incidence of severe PPH doubled from 1.9 percent in 1999 to 4.2 percent in 2008 (p < 0.0001). Factors underlying the increase remain unclear, and both recent U.S. studies found rising PPH rates were not explained by changes in risk factors (e.g., maternal age, cesarean birth, multiple gestation).

Adverse Outcomes Associated With Postpartum Hemorrhage

PPH is a leading cause of maternal mortality and morbidity worldwide and accounts for nearly one-quarter of all maternal pregnancy-related deaths. ¹⁴ Multiple studies have suggested that many deaths associated with PPH could be prevented with prompt recognition and more timely and aggressive treatment. ¹⁵⁻¹⁷ Morbidity from PPH can be severe with sequelae including organ failure, shock, edema, compartment syndrome, transfusion complications, thrombosis, acute respiratory distress syndrome, sepsis, anemia, intensive care, and prolonged hospitalization. ¹⁸⁻²⁰

The most common etiology of PPH is uterine atony (impaired uterine contraction after birth), which occurs in about 80 percent of cases. Atony may be related to overdistention of the uterus, infection, placental abnormalities, or bladder distention. Though the majority of women who develop PPH have no identifiable risk factors, clinical factors associated with uterine atony, such as multiple gestation, polyhydramnios, high parity, and prolonged labor, may lead to a higher index of suspicion. Other causes of PPH include retained placenta or clots, lacerations, uterine rupture or inversion, and inherited or acquired coagulation abnormalities.

Interventions

Organizations and associations including the World Health Organization, International Confederation of Midwives, International Federation of Gynecologists and Obstetricians, American College of Obstetricians and Gynecologists, Royal College of Obstetricians and Gynaecologists, and the California Maternity Quality Care Collaborative have released guidelines for PPH prevention and management. Initial management includes identifying PPH, determining the cause, and implementing appropriate interventions based on the etiology. A variety of medical, procedure, and surgical interventions are available (see Table 1).

Interventions to treat PPH generally proceed from less to more invasive and include compression techniques, medications, procedures, and surgeries. PPH management may also involve adjunctive therapies, such as blood and fluid replacement and/or an anti-shock garment, ^{26, 27} to treat the blood loss and other sequelae that result from PPH. Conservative management techniques such as uterotonic medications, which cause the uterus to contract, external uterine massage, and bimanual compression are generally used as "first-line" treatments. ²⁸ These compression techniques encourage uterine contractions that counteract atony and assist with expulsion of retained placenta or clots. Aortic compression is another compression technique that has been used for severe PPH. ^{29, 30}

The medications most commonly used in PPH management are uterotonic agents. These medications include oxytocin (Pitocin®), misoprostol (Cytotec®), methylergonovine maleate (Methergine®,), carboprost tromethamine (Hemabate®), and dinoprostone (Prostin E2®). 14, 19, 21, 22, 31 All of these medications are available in the United States. Only oxytocin, methylergonovine maleate, and carboprost tromethamine are approved by the U.S. Food and Drug Administration (FDA) specifically for PPH management; use of these other medications is off label. Typically, oxytocin is used as the initial medication for PPH management then other uterotonics are administered if oxytocin fails to stop bleeding. A recent U.S. study found wide variation in the use of these other uterotonics, which was not attributable to patient or hospital characteristics. In cases of severe blood loss from PPH, the hemostatic recombinant activated factor VIIa (NovoSeven®) and the antifibrinolytic tranexamic acid (Cyklokapron®) have been used. 33

Procedures used in PPH management include manual removal of the placenta, manual removal of clots, uterine balloon tamponade, and uterine artery embolization. ^{14, 19, 21, 22} Laceration repair is indicated when PPH is a result of genital tract trauma. Surgical options when other measures fail to control bleeding include curettage, uterine and other pelvic artery ligation, uterine compression sutures, and hysterectomy. ^{14, 19, 21, 22} More invasive procedures (e.g., uterine balloon tamponade and uterine artery embolization) and surgical techniques are generally used after "first-line" conservative management (e.g., uterotonics, uterine massage, bimanual compression, manual placenta and clot removal, and laceration repair) has failed to control bleeding and can be considered "second-line" interventions. ²⁸ Procedures and surgeries can increase the risk of infection and other complications, and they may eliminate or adversely affect future fertility and pregnancy.

After PPH has been controlled, followup management varies and may include laboratory testing (e.g., hemoglobin and hematocrit), iron replacement therapy, and other interventions to assess and treat sequelae of PPH. The immediate postpartum period is a unique physiologic state with relative intravascular volume expansion with a reduction in cardiovascular demand compared to pregnancy. The physiologic anemia of pregnancy may be exacerbated by acute

blood loss anemia from PPH. These physiologic realities may allow women with low hematocrits to be asymptomatic. Interventions for acute blood loss anemia include red blood cell transfusion and iron supplementation. Erythropoietin-stimulating agents (Aranesp[®], Epogen[®], Procrit[®]) have also been used for anemia following stabilization of PPH, but they are not approved by the FDA for this use.¹⁹

At a systems level, PPH has been the focus of perinatal care safety initiatives that attempt to improve patient outcomes by incorporating a variety of strategies, such as practice guidelines or protocols, simulation drills, and teamwork training. These systems-level interventions may influence management of PPH.

A variety of outcomes related to PPH management are reported.³⁹⁻⁴⁴ Blood loss itself is measured, although often inaccurately as previously noted. Transfusion and anemia are sometimes used as markers for the amount of blood loss. The outcomes of intensive care unit (ICU) admission and extended hospitalization are used as indicators of maternal morbidity. Severe hemorrhage can lead to hysterectomy and death.

PPH can occur in any birth setting: hospital, birth center, or home. In home birth and birth center settings, severe or recalcitrant PPH can necessitate transfer for inpatient care. In considering setting, it is important to note that PPH management varies significantly according to available resources. All U.S. hospitals do not have immediate access to all interventions for PPH, and hospital volume appears to influence maternal morbidity and mortality from PPH. In addition, many studies conducted in low-resource countries have limited to no applicability for higher-resource countries such as the United States.

Table 1. Brief descriptions of interventions used in PPH management

Intervention	Description
Anti-shock garment	Garment with segments that are wrapped around the woman's legs, pelvis, and abdomen then tightened with Velcro straps. The garment places pressure that forces blood to the heart, lungs, and brain to prevent or treat shock.
Aortic compression	Compressing the aorta, by applying firm pressure with a closed fist just above the umbilicus, slows bleeding.
Curettage	Insertion of a curette into the uterus to remove any retained fragments of the placenta or clots. This is most commonly performed for secondary PPH.
External uterine massage and bimanual compression	External uterine massage is performed by placing a hand on the lower abdomen. For bimanual compression, the clinician places one hand on the abdomen and the other hand inside the vagina then compresses the uterus between the two hands. These techniques cause the uterus to contract, which treats atony and assists with expulsion of retained placenta or clots.
Hysterectomy	Surgical removal of the uterus is usually performed as a last resort when other treatments fail. Hysterectomy can be total (includes removal of the cervix) or subtotal (cervix is left intact). Hysterectomy stops bleeding in most cases of PPH.
Manual removal of the placenta and/or clots	Insertion of the clinician's hand into the uterus to remove the placenta and/or clots when they are not being expelled by contractions alone.
Recombinant activated factor VIIa (rFVIIa)	This hemostatic medication helps bleeding stop by activating the extrinsic pathway of the coagulation cascade, which is a process that causes blood to clot.
Tranexamic acid	This antifibrinolytic medication reduces blood loss by preventing clot breakdown.
Transfusion	Transfusion is the intravenous administration of blood products, including red blood cells, fresh frozen plasma, platelet concentrates, and cryoprecipitate. Red blood cells help maintain blood volume and improve the blood's capacity to carry oxygen. Fresh frozen plasma and cryoprecipitate contain coagulation factors, which are proteins that are needed to help the blood clot so that bleeding will stop. Platelet concentrates replace functioning platelets necessary for thrombus formation in patients with low platelet levels (due to low baseline levels or consumption from ongoing bleeding or disseminated intravascular coagulation) or dysfunctional platelets (due to hereditary platelet disorders or pharmacologic effects).

Table 1. Brief descriptions of interventions used in PPH management (continued)

Intervention	Description
Uterine and other pelvic artery ligation	Tying a suture around an artery to occlude blood flow. Uterine artery ligation is most commonly performed for PPH; utero-ovarian and internal iliac arteries can also be ligated.
Uterine artery embolization	Injection of one or more embolizing agents (e.g., absorbable gel particles, gelatin sponge pledgets, foam, metal coils) into the uterine arteries to reduce blood flow. This procedure is performed by an interventional radiologist.
Uterine compression sutures	Placing sutures around the uterus to compress it and stop bleeding. This surgery is performed for uterine atony that does not respond to other treatments. The most common technique for uterine compression is the B-lynch suture.
Uterine tamponade	Uterine tamponade can be performed with a balloon or packing. Intrauterine balloon tamponade is performed by inserting an inflatable balloon device through the vagina or abdomen (if a cesarean was performed) into the uterine cavity and then filling it with sterile saline. For packing, gauze, which may be coated with material to enhance clotting, is used to firmly fill the uterine cavity. The balloon or packing exerts pressure on the uterine wall, which stops bleeding, and is later removed.
Uterotonic medications (oxytocin, misoprostol, methylergonovine, carboprost tromethamine)	These uterotonic medications cause contractions and increase uterine tone. These effects counter uterine atony, which is the most common cause of PPH.

Abbreviations: PPH = postpartum hemorrhage

Scope and Key Questions

Scope of Review

This systematic review provides a comprehensive review of potential benefits of PPH management (medical and surgical) as well as harms associated with treatments in women with PPH. We assess intermediate outcomes such as blood loss, hospital and ICU stay, and anemia, and longer term outcomes including uterine preservation, fertility, breastfeeding, psychological impact and harms of treatment, and mortality related to treatment.

Key Questions

We have synthesized evidence in the published literature to address the following Key Questions (KQs):

KQ1.What is the evidence for the comparative effectiveness of interventions for management of postpartum hemorrhage?

- e. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to atony?
- f. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to retained placenta?
- g. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to genital tract trauma?
- h. What is the effectiveness of interventions intended to treat postpartum hemorrhage likely due to uncommon causes (e.g., coagulopathies, uterine inversion, subinvolution, abnormal placentation)?

KQ2. What is the evidence for choosing one intervention over another and when to proceed to subsequent interventions for management of postpartum hemorrhage?

KQ3. What are the harms, including adverse events, associated with interventions for management of postpartum hemorrhage?

KQ4. What is the effectiveness of interventions to treat acute blood loss anemia after stabilization of postpartum hemorrhage?

KQ5.What systems-level interventions are effective in improving management of postpartum hemorrhage?

Table 2 outlines the population, intervention, comparator, outcomes, timing, and setting (PICOTS) characteristics for the KQs.

Table 2. PICOTS

PICOTS	Criteria		
Population	 KQ 1-3: Women with postpartum hemorrhage immediately post-birth to 12 weeks postpartum following pregnancy > 24 weeks' gestation KQ4: Women with stabilized PPH and acute blood loss anemia KQ 1-5: All modes of birth 		
Intervention(s)	 KQ 1-3 Compression techniques (external uterine massage, bimanual compression, aortic compression) Medications (oxytocin [Pitocin], misoprostol [Cytotec], methylergonovine maleate [Methergine], carboprost tromethamine [Hemabate], dinoprostone [Prostin E2], recombinant activated factor VIIa [NovoSeven], and tranexamic acid [Cyklokapron]) Devices (Bakri postpartum balloon, Foley catheter, Sengstaken-Blakemore tube, Rusch balloon) Procedures (manual removal of placenta, manual evacuation of clot, uterine balloon tamponade, uterine artery embolization, laceration repair) Surgeries (curettage, uterine and other pelvic artery ligation, uterine compression sutures, hysterectomy) Blood and fluid products Antishock garment KQ4 Interventions for acute blood loss anemia (e.g., iron replacement, erythropoietin) KQ5 Systems-level interventions (e.g., implementation of protocols, training) 		
Comparator	Different intervention (any intervention compared with any other intervention) Placebo		
Outcomes	Intermediate outcomes Blood loss Transfusion ICU admission Anemia Length of stay	Final outcomes • Mortality • Uterine preservation • Future fertility • Breastfeeding • Psychological impact • Harms	
Timing	 Immediately post-birth to 12 weeks postpartum Primary (< 24 hours postpartum) or secondary (≥ 24 hours postpartum) 		

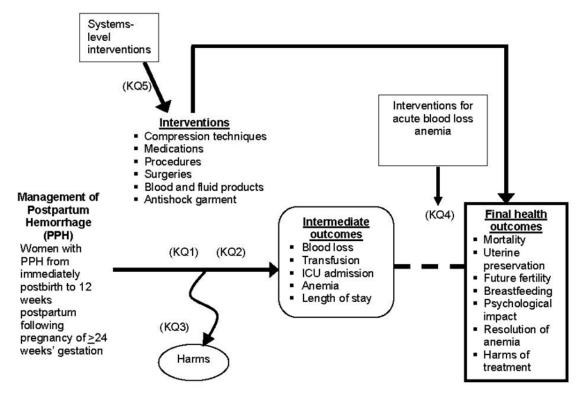
PICOTS	Criteria
Setting	All birth settings (hospital, birth center, home)

Abbreviations: ICU = intensive care unit; KQ = Key Question; PICOTS = population, intervention, comparator, outcome, timing, setting

Analytic Framework

The analytic framework illustrates the population, interventions, and outcomes that guided the literature search and synthesis (Figure 1). The framework for management of PPH includes women with PPH immediately post-birth to 12 weeks postpartum following pregnancy of > 24 weeks' gestation. The figure depicts the KQs within the context of the PICOTS described in the document. In general, the figure illustrates how interventions such as compression techniques, medications, procedures, surgeries, blood and fluid products, anti-shock garments or systems-level interventions may result in intermediate outcomes such as blood loss, transfusion, ICU admission, anemia, or length of stay and/or in final health outcomes such as mortality, uterine preservation, future fertility, breastfeeding, or psychological impact. Also, adverse events may occur at any point after the intervention is received.

Figure 1. Analytic framework



Abbreviations: ICU = intensive care unit; KQ = Key Question.

Organization of This Report

The Methods section describes the review processes including search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, methods for extraction of data into evidence tables, and compiling evidence. We also describe our approach to grading the quality of the literature and to describing the strength of the body of evidence.

The Results section presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies. We present findings by intervention and outcome area where possible under each KQ and focus on comparative studies of higher quality. Cohort and case-control studies, pre-post studies, case series of procedural or surgical approaches, and randomized trials are also described in more detail in summary tables for each KQ. We integrate discussion of sub-questions within that for each KQ because there was not adequate distinction in the literature to address them separately. We also report harms data from case series and note that harms reported in all studies of interventions for PPH are described under KQ3.

The Discussion section of the report discusses the results and expands on methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in the field.

The report includes a number of appendixes to provide further detail on our methods and the studies assessed. The appendices are as follows:

- Appendix A. Search Strategies
- Appendix B. Screening and Quality Assessment Forms
- Appendix C. Excluded Studies
- Appendix D. Evidence Tables
- Appendix E. Quality/Risk of Bias Ratings
- Appendix F. Applicability Tables
- Appendix G. Study Design Classification Algorithm

We also provide a list of abbreviations and acronyms at the end of the report.

Uses of This Evidence Report

We anticipate this report will be of primary value to organizations that develop guidelines for managing PPH and to clinicians who provide intrapartum and postpartum care for women. Interested organizations would include the American Congress of Obstetricians and Gynecologists, the Society for Maternal-Fetal Medicine, the American College of Nurse-Midwives, the American Academy of Family Physicians, the Association of Women's Health, Obstetric, and Neonatal Nurses, the Society of Interventional Radiology, and the Society for Obstetric Anesthesia and Perinatology.

PPH is diagnosed and treated by clinicians including obstetricians, maternal-fetal medicine physicians, midwives, family physicians, nurses, interventional radiologists, and anesthesiologists. This report supplies practitioners and researchers up-to-date information about the current state of evidence, and assesses the quality of studies that aim to determine the outcomes of treatments for PPH.

Researchers, including perinatal safety researchers, can obtain a concise analysis of the current state of knowledge of interventions in this field. They will be poised to pursue further investigations that are needed to advance research methods, develop new treatment strategies, and optimize the effectiveness and safety of clinical care for women with this potentially lifethreatening condition.

This report is unlikely to be used by women and their families given that PPH is often unanticipated and requires rapid intervention.

Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center (EPC) used to produce a comparative effectiveness review (CER) on approaches to treatment of postpartum hemorrhage (PPH). These procedures follow the methods outlined in the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program "Methods Guide for Effectiveness and Comparative Effectiveness Reviews."

Topic Refinement and Review Protocol

The topic for this report was nominated by the American College of Obstetricians and Gynecologists in a public process using the Effective Health Care Web site. Working from the nomination, we drafted the initial KQs and analytic framework and refined them with input from key informants representing the fields of obstetrics and gynecology, nursing, midwifery, obstetric anesthesiology, quality improvement, and perinatal safety. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team had any conflicts.

After review from the AHRQ, the questions and framework were posted online for public comment. No changes to the questions or framework were recommended. We also developed population, interventions, outcomes, timing, and settings (PICOTS) criteria for intervention KQs.

We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of obstetrics and gynecology, midwifery, nursing, patient and perinatal safety, quality improvement, and maternal-fetal medicine, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included seven members serving as technical or clinical experts. To ensure robust, scientifically relevant work, we called on the TEP to review and provide comments as our work progressed. TEP members participated in conference calls and discussions through e-mail to:

- Help to refine the analytic framework and KQs at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria; and
- Provide input on the set of studies identified for inclusion.

The final protocol was posted to the AHRQ Effective Health Care web site and registered in the PROSPERO international register of systematic reviews (ID#: CRD42014010123).

Literature Search Strategy

Search Strategy

To ensure comprehensive retrieval of relevant studies of therapies for women with PPH, we used three key databases: the MEDLINE[®] medical literature database via the PubMed[®] interface, the Cumulative Index of Nursing and Allied Health Literature (CINAHL[®]), and EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid[®] interface. Search strategies applied a combination of controlled vocabulary (Medical Subject Headings [MeSH], CINAHL medical headings, and Emtree headings) to focus specifically on management of PPH and harms of interventions. We restricted literature searches

to studies published from 1990 to the present to reflect current standards of care for PPH. Interventions such as the B-Lynch suture were introduced in the late 1990s, ⁴⁷ and embolization techniques were not widely used until the mid- to late-1990s. ^{48, 49} Misoprostol was initially used as a treatment for gastric ulcer and not broadly used for PPH prevention or treatment until the 2000s. The World Health Organization recommended its use for prevention of PPH in 2007. ^{50, 51} Given that currently used interventions were not in widespread use prior to 1990, we set 1990 as a conservative lower bound for the search.

We only included studies published in English as a review of non-English citations retrieved by our MEDLINE search identified few studies of relevance. Appendix A lists our search terms and strategies and the yield from each database. Searches were last executed in November 2014.

We carried out hand searches of the reference lists of recent systematic reviews or metaanalyses of therapies for PPH. The investigative team also scanned the reference lists of studies included after the full-text review phase for additional studies that potentially could meet our inclusion criteria.

Gray Literature

AHRQ's Scientific Resource Center requested Scientific Information Packets (SIPs) from companies that produce medications or devices with U.S. Food and Drug Administration (FDA) approval for management of uterine bleeding (oxytocin [Pitocin®], misoprostol [Cytotec®], methylergonovine maleate [Methergine®], carboprost tromethamine [Hemabate®], dinoprostone[Prostin E2®], recombinant coagulation factor VIIa [NovoSeven®], and tranexamic acid [Cyklokapron®]; and devices for PPH including BakriTM postpartum balloon, non-pneumatic anti-shock garment [NASG], Foley catheter, Sengstaken-Blakemore tube, and the Rusch balloon) and searched for regulatory data for approved products. We also searched ClinicalTrials.gov to assess publication bias and to identify any study results that may not have been identified in our other database searches.

Inclusion and Exclusion Criteria

Table 3 lists the inclusion/exclusion criteria we used based on our understanding of the literature, key informant and public comment during the topic-refinement phase, input from the TEP, and established principles of systematic review methods.

Table 3. Inclusion criteria

Category	Criteria
Study population	 KQ1-3, 5: Women with postpartum hemorrhage (PPH) immediately post-birth to 12 weeks postpartum following pregnancy > 24 weeks' gestation KQ4: Women with stabilized PPH and acute blood loss anemia All modes of birth in any setting
Time period	1990 to present
Publication languages	English only
Country	Very High Human Development countries as indicated by the United Nations Development Programme Human Development Index. Countries as of April 2014 include: Norway, Australia, US, Netherlands, Germany, New Zealand, Ireland, Sweden, Switzerland, Japan, Canada, Republic of Korea, Hong Kong, Iceland, Denmark, Israel, Belgium, Austria, Singapore, France, Finland, Slovenia, Spain, Liechtenstein, Italy, Luxembourg, U.K., Czech Republic, Greece, Brunei Darussalam, Cyprus, Malta, Andorra, Estonia, Slovakia, Qatar, Hungary, Barbados, Poland, Chile, Lithuania, United Arab Emirates, Portugal, Latvia, Argentina, Seychelles, and Croatia

Table 3. Inclusion criteria (continued)

Category	Criteria		
Admissible evidence (study design and other criteria)	 Admissible designs KQ 1-2, 4: RCT or prospective/ retrospective cohort studies, population-based case series or registry studies with ≥ 50 cases of PPH treatment, case series of procedures (uterine balloon tamponade, uterine artery embolization) or surgical approaches with ≥ 50 women KQ3: RCT or prospective/ retrospective cohort studies, case series with ≥ 50 cases addressing interventions for PPH KQ5: Pre- and post-studies related to large-scale health systems changes, RCTs, prospective/retrospective cohort studies 		
	Other criteria Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results Studies targeting women with PPH and meet the population criteria as described above Studies that address: Treatment modality aimed at treatment/management of PPH in a relevant population or treatment for acute blood loss anemia following stabilization of PPH Outcomes related to interventions; primary outcomes of interest include blood loss, transfusion, ICU admission, anemia, length of stay, mortality, uterine preservation, future fertility, breastfeeding, and psychological impact, and harms. Studies must include extractable data presented in text or tables (vs. solely in figures) on relevant outcomes For KQ5, studies must explicitly assess effects of an systems-level intervention on PPH management as a primary or secondary aim; analytic models must indicate data analysis of the effect of the strategy as it relates to PPH treatment; results data include information about effects of strategy on management of PPH; discussion interprets the strategy as potentially having value/not having value for PPH management		

Abbreviations: ICU = intensive care unit; KQ = Key Question; PPH = postpartum hemorrhage; RCT = randomized controlled trial

Case series comprise much of the literature addressing treatments for PPH. We limited inclusion of case series to those with at least 50 cases of PPH in order to balance the need to identify rigorously conducted studies with identifying studies large enough to suggest effects of the interventions. We include effectiveness and harms data from case series of procedural (uterine balloon tamponade, uterine artery embolization) and surgical (arterial ligation, uterine compression sutures, hysterectomy) approaches because they report pertinent evidence for the effects of such interventions that are unlikely to be found in randomized controlled trials (RCTs). These procedural and surgical approaches are rarely addressed in RCTs, and patients who would be receiving these second-line interventions have an unstable and quickly changing health status and typically are not eligible for RCTs.

We also limited studies to those published in English and conducted in Very High Human Development countries as ranked by the United Nations Development Programme Human Development Index (Table 3). In the opinion of our clinical experts, processes of care and interventions available in these countries best reflect the system of health care in the United States. A considerable body of evidence addresses PPH management in developing countries; however, the limited availability of skilled clinicians and treatment options in many of these countries results in different standards of care and clinical approaches than those in the United States. PPH is a complex condition. Treatments are selected not only by PPH etiology and

severity but also by factors related to the setting of care, the availability of medications or other therapeutic options, the availability of personnel, and the standards of care in a given treatment center. Treatment availability and feasibility of providing certain treatments differ across developed and developing nations, and even within any given nation. Because the context of care in most developing nations differs significantly from care in the United States, ^{52, 53} we instituted language and country limitations in order to identify studies that are most applicable to guiding care by clinicians in the United States, who are the intended audience for this report.

In order to provide contextual information about effectiveness and harms reported in studies conducted in developing nations, we provide summaries of recent reviews of interventions for PPH, which include studies conducted in any country in the Discussion section (Findings in Relation to What's Known).

Study Selection

Once we identified articles through the electronic database searches and hand-searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion/exclusion criteria. Disagreements between reviewers were resolved by a senior reviewer. All abstract and full text reviews were conducted using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Appendix C includes a list of excluded studies and the reasons for exclusion.

Data Extraction

The staff members and clinical experts (including two nurse-midwives, three obstetrician/gynecologists, one hematologist, and two epidemiologists) who conducted this review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our Key Questions. Two evidence table templates were employed to facilitate the extraction of data based on study type; one form was designed for case series that reported harms data and one to accommodate all types of comparative studies and population-based case series. We based the format of our evidence tables on successful designs used for prior systematic reviews.

The team was trained to extract data by extracting several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. All team members shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. A senior reviewer reconciled disagreements concerning the information reported in the evidence tables.

The full research team met regularly during the article extraction period and discussed global issues related to the data extraction process (e.g., determining harms of treatment vs. harms of PPH itself). In addition to outcomes related to intervention effectiveness, we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the

narrower definition of adverse events. The final evidence tables are presented in their entirety in Appendix D.

Data Synthesis

We considered conducting a meta-analysis, but the small number of comparative studies of any given intervention and the heterogeneity of interventions and outcomes made a meta-analysis inappropriate. We completed evidence tables for all included studies (Appendix D), and data are presented in summary tables and analyzed qualitatively in the text.

We also tabulated success rates reported in studies of procedures and surgical approaches in which we could extract data on the effectiveness of the first intervention following conservative management. We refer to these as "initial second-line interventions." Some studies reported success rates for procedures and/or surgeries only in combination or after multiple interventions; therefore, not all studies addressing a given intervention are represented in these tables. When multiple second-line interventions are combined in analysis, it is impossible to determine which of these stopped the bleeding and thus would be reasonable to use initially. We defined success for a specific intervention as control of bleeding without need for subsequent medical or surgical interventions (not including transfusion or iron supplementation). In some cases, bleeding may have ceased, but a participant ultimately died. If death was not considered to be related to the intervention but was thought to be caused by the PPH and its sequelae, we include the case in the estimate of successful control of bleeding.

Quality (Risk of Bias) Assessment of Individual Studies

We used separate tools appropriate for specific study designs to assess quality of individual studies: the Cochrane Risk of Bias tool for RCTs,⁵⁴ the Newcastle-Ottawa Quality Assessment Scale for cohort and case-control studies,⁵⁵ the National Heart, Lung, and Blood Institute's (NHLBI) Quality Assessment Tool for Before-After (Pre-Post) Studies,⁵⁶ and a tool adapted from questions outlined in the RTI item bank to assess case series.⁵⁷ We used questions adapted from the RTI item bank and from the McMaster McHarms⁵⁸ tools to assess reporting of harms.

The Cochrane Risk of Bias tool is designed for the assessment of studies with experimental designs and randomized participants. Fundamental domains include sequence generation, allocation concealment, blinding, completeness of outcome data, and selective reporting bias. The Newcastle-Ottawa Quality Assessment Scale was used to assess the quality of nonrandomized studies and assesses three broad perspectives: the selection of study groups, the comparability of study groups, and the ascertainment of either the exposure or outcome of interest for case-control or cohort studies, respectively. The NHLBI tool considers questions related to study objectives, description of participants and intervention, outcome assessment, length of followup, and statistical analysis and is designed for studies without a control group. Similarly, the case series and harms tools address questions related to participant and outcome assessment and pre-specification of harms.

Quality assessment of each study was conducted independently by two team members using the forms presented in Appendix B. Any discrepancies were adjudicated by the two team members or a senior investigator. Investigators did not rely on the study design as described by authors of individual papers; rather, the methods section of each paper was reviewed to determine which rating tool to employ. The results of these tools were then translated to the Agency for Healthcare Research and Quality standard of "good," "fair," and "poor" quality as described below. Appendix E reports quality scoring for each study.

Determining Quality Ratings

- We required that RCTs receive a positive score (i.e., low risk of bias for RCTs) on all of the questions used to assess quality to receive a rating of good/low risk of bias. RCTs had to receive at least five positive scores to receive a rating of fair/moderate risk of bias, and studies with ≤ four positive ratings were considered poor quality/high risk of bias. We considered a score of "unclear" for a question as a positive score as long as the consensus of the investigators assessing quality was that study outcomes were not likely to be biased by the factor.
- We required that case-control or cohort studies receive positive scores (stars) on all elements to receive a rating of good, ≤ 2 negative ratings for fair, and > 2 negative scores for a rating of poor quality.
- For pre-post studies we required that studies receive positive scores on all questions to receive a rating of good. We considered studies with ≤ four negative ratings as fair quality and those with more than four as poor quality.
- We required that studies assessed for harms reporting receive a positive rating (i.e., affirmative response) on all four questions to receive a rating of good. Studies with at least three positive responses were considered fair quality and those with less than three positive responses as poor quality.
- Case series have inherently high risk of bias and presumptive low quality. Nonetheless, prospective case series that enroll participants consecutively and control for potentially confounding factors may provide evidence to support comparative studies. We assessed case series using questions identified in the AHRQ Effective Health Care program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews." The elements on which they were scored and the results are presented in Appendix E.

Strength of the Body of Evidence

We applied explicit criteria for rating the overall strength of the evidence for each key intervention-outcome pair for which the overall risk of bias is not overwhelmingly high. We established concepts of the quantity of evidence (e.g., numbers of studies, aggregate ending-sample sizes), the quality of evidence (from the quality ratings on individual articles), and the coherence or consistency of findings across similar and dissimilar studies and in comparison to known or theoretically sound ideas of clinical or behavioral knowledge.

The strength of evidence evaluation is that stipulated in the Effective Health Care Program's "Methods Guide for Effectiveness and Comparative Effectiveness Reviews". and in the updated strength of evidence guide which emphasizes five major domains: study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown or not applicable), directness (direct, indirect), precision (precise, imprecise), and reporting bias. Study limitations are derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome for each comparison of interest is given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence was graded as outlined in Table 4. Two senior staff members independently graded the body of evidence; disagreements were resolved as needed through discussion or third-party adjudication. We recorded strength of evidence assessments in tables, summarizing results for each outcome. We considered case series in the assessment of

strength of the evidence for harms and for success of procedural and surgical interventions as such interventions are not likely to be represented in RCTs given the urgent nature of PPH treatment. We presumed the quality of case series providing data to assess the success of interventions to be low.

Table 4. Strength of evidence grades and definitions^a

Grade	Definition
High	We are very confident that the estimate of effect lies close to the true effect for this
	outcome . The body of evidence has few or no deficiencies. We believe that the findings are
	stable, i.e., another study would not change the conclusions.
Moderate	We are moderately confident that the estimate of effect lies close to the true effect for
	this outcome. The body of evidence has some deficiencies. We believe that the findings are
	likely to be stable, but some doubt remains.
Low	We have limited confidence that the estimate of effect lies close to the true effect for
	this outcome. The body of evidence has major or numerous deficiencies (or both). We
	believe that additional evidence is needed before concluding either that the findings are stable
	or that the estimate of effect is close to the true effect.
Insufficient	We have no evidence, we are unable to estimate an effect, or we have no confidence in
	the estimate of effect for this outcome. No evidence is available or the body of evidence
	has unacceptable deficiencies, precluding reaching a conclusion.

^aExcerpted from Berkman et al. 2013⁵⁹

Applicability

We assessed the applicability of findings reported in the included literature to the general population of women who experience PPH by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include the definition and severity of PPH, the age range and parity of the participants, and the setting in which the intervention took place. Applicability tables for each intervention are in Appendix F.

Peer Review and Public Commentary

Researchers and clinicians with expertise in managing PPH and individuals representing stakeholder and user communities provided external peer review of this report; AHRQ and an associate editor also provided comments. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment. We addressed all reviewer comments, revised the text as appropriate, and documented changes and revisions to the report in a disposition of comments report that will be made available 3 months after AHRQ posts the final review on the AHRQ Web site.

Results

Results of Literature Searches

We identified 3266 nonduplicative titles or abstracts with potential relevance, with 920 proceeding to full text review (Figure 2). We excluded 844 studies at full text review and included 68 unique studies (76 publications) in the review. We present findings by intervention and outcome area where possible under each Key Question (KQ). Comparative studies and case series that provided harms or data on successful controlling of bleeding are also described in more detail in summary tables in each KQ. We tabulated success rates reported in studies of procedures and surgical approaches in which we could extract data on the effectiveness of the intervention as the initial second-line intervention (i.e., first intervention following routine conservative management) and defined success as controlling of bleeding without need for additional procedures or surgeries.

We integrate discussion of subquestions within that for each KQ because there was not adequate distinction in the literature to address them separately. Harms of interventions for postpartum hemorrhage (PPH) are described under KQ3. Transfusion as an intervention for anemia following stabilization of PPH is addressed under KQ4, and transfusion as an intervention to manage ongoing PPH is described under KQ1. We also briefly summarize the strength of the evidence (SOE) for interventions and key outcomes in each Key Points section and describe SOE more fully in the Discussion section.

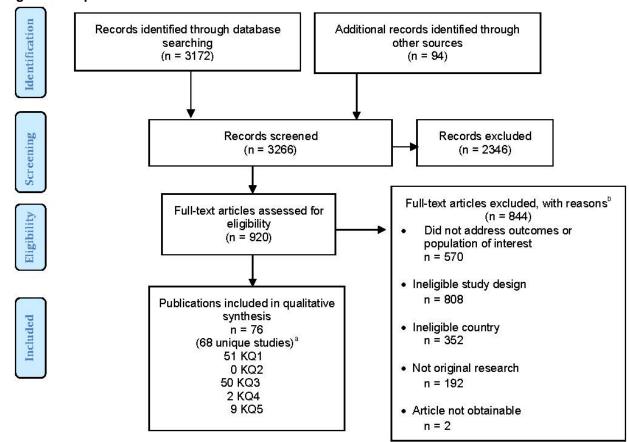


Figure 2. Disposition of studies identified for this review

Abbreviations: KQ = Key Question; n = number.

^bNumbers do not tally as studies could be excluded for multiple reasons.

Description of Included Studies

The 68 unique studies included in the review comprise four randomized controlled trials (RCTs), two prospective and 14 retrospective cohort studies, 10 pre-post studies (defined as studies that compare PPH management and/or outcomes before and after an intervention, such as introduction of a new protocol), four case-control studies, and 34 case series. Most studies were conducted in Europe (n = 33), and 18 were conducted in the United States or Canada, 13 in Asia, and three in Australia or New Zealand and one in Argentina (Table 5). No studies were of good quality for effectiveness outcomes. We considered 23 studies as fair quality for effectiveness outcomes and 38 as poor quality (including case series, which we considered poor quality by default). Seven studies (one retrospective cohort, two case-control, four case series) provided only harms data. 60-66 Among the 50 studies reporting harms of interventions for management of PPH, we considered 11 as good quality for harms reporting and the remainder as poor quality.

While a number of studies were classified as prospective or retrospective studies using our study classification algorithm (Appendix G), few cohort studies provided comparative analyses, and many were confounded by indication in that women who received interventions such as massive transfusion or hysterectomy likely had more severe cases of PPH. Additionally, initial management of PPH using first-line interventions such as uterotonics and uterine massage

^aNumbers next to each KQ indicate number of unique studies addressing the question. Studies could address more than one KQ.

differed across studies and across women as each study generally included a number of patients transferred from other hospitals. Thus, populations were heterogeneous in terms of severity and level of stabilization prior to second-line interventions. Given the lack of data from randomized or controlled studies of PPH management, we present data from cohort studies and case series and note potential confounding.

Table 5. Characteristics of included studies addressing effectiveness and harms

Table 5. Characteristics of I	iiciuu c u	Studies	auui c aaii	ig eneci	iveness (anu nam	13	
Characteristic	RCTs ^a	Prospective Cohort Studies	Retrospective Cohort Studies	Pre-Post Studies	Case-Control Studies	Population- Based Case Series	Retrospective Case Series	Total Literature ^b
Intervention								
Pharmacologic	1	1	5	0	1	5	0	13
Transfusion for supportive management of ongoing PPH	0	0	3	1	0	1	2	7
Uterine balloon tamponade	0	0	1	1	0	1	2	5
Uterine artery embolization	0	2	5	0	1	0	12	20
Uterine and other pelvic artery ligation	0	1	1	0	0	0	3	5
Uterine compression sutures	0	1	1	0	2	0	1	5
Hysterectomy	0	1	2	0	0	4	3	10
Combined interventions	0	0	2	0	0	0	2	4
Interventions for anemia once PPH is stabilized	2	0	0	0	0	0	0	2
Systems-level interventions	1	0	0	8	0	0	0	9
Population Characteristics								
Study population								-
U.S./Canada	0	0	3	4	1	4	6	18
Europe	3	2	6	6	2	4	10	33
Asia	0	0	5	0	1	0	7	13
Other	1	0	0	0	0	2	1	4
Total N participants (where reported)	737	477	142309 ^c	5726 ^d	359	3757	3049	156414

Abbreviations: PPH = postpartum hemorrhage; RCT= randomized controlled trial; rFVIIa = recombinant activated factor VIIa aDoes not include N participants in one systems-level RCT.³⁷

bTotal across interventions exceeds 68 as some interventions were addressed in multiple studies.

One cohort study using data from a utilization database includes 139,617 women exposed to methylergonovine during hospitalization for birth.

^dDoes not include N participants in 2 pre-post studies.^{67, 68}

KQ1. Effectiveness of Interventions for Management of PPH

Studies of Medical Interventions

Pharmacologic Interventions

Key Points

- Six small, single studies of fair and poor quality addressed various pharmacologic interventions not including recombinant activated factor VIIa (rFVIIa) with mixed results.
- In one fair quality retrospective cohort study assessing oxytocin and other uterotonics, bleeding was controlled with uterotonic medications without need for further procedures/surgeries in 45 of 91 women (49% success rate).
- In one RCT of tranexamic acid (TXA), blood loss, progression to severe PPH, and need for transfusion were reduced in the TXA arm compared with the non-TXA control arm, but need for further interventions did not differ.
- Need for transfusion or further interventions did not differ in a retrospective cohort study comparing misoprostol and methylergonovine maleate.
- In a small, population-based case series, sulprostone stopped bleeding in 83 percent of participants without need for further intervention.
- Carboprost tromethamine controlled bleeding in 88 percent of women in a small, population-based case series.
- Blood loss and transfusion in women with PPH and disseminated intravascular coagulation (DIC) did not differ in a retrospective study comparing women who received recombinant thrombomodulin with matched controls who did not receive the drug.
- Six small studies of rFVIIa also had mixed results. In one retrospective cohort study, women in the rFVIIa group required more blood products and had greater blood loss than women not receiving the treatment. Differences in change in prothrombin time were not significant between women treated with rFVIIa and those who were not in a case-control study. rFVIIa used as a second-line intervention controlled bleeding without need for further procedures or surgeries in 27 to 31 percent of women in one cohort study, a rate that was similar to treatment with other second-line interventions in that study. In registry studies bleeding was considered improved after one or multiple doses of rFVIIa in 64 to 80 percent of women after the final dose. No study included more than 177 women receiving rFVIIa.
- Strength of the evidence is insufficient for all outcomes of oxytocin and other uterotonics, misoprostol, tranexamic acid, carboprost tromethamine, thrombomodulin, and rFVIIa for PPH management due to the study sizes and lack of studies addressing each agent.

Overview of the Literature

Twelve studies addressed pharmacologic agents for the treatment of PPH:⁶⁹⁻⁸⁰ one RCT,⁶⁹ five cohort studies,^{72, 73, 77-79} one case-control study,⁷⁴ and five population-based case series or registry studies.^{70, 71, 75, 76, 80} Studies were conducted in France,^{69, 70} the United States,^{71, 78} Finland,⁷³ Ireland,⁷⁴ Japan,⁷² the United Kingdom,⁷⁷ Hong Kong,⁷⁹ and Australia and New Zealand.^{76, 80} These studies from Australia and New Zealand report on data collected from one registry over differing time periods, but because the overlap in data is not clear, we have

presented results from both studies but note that the populations likely overlap to some extent. Another registry study reported data from various northern European countries.⁷⁵

Six of these studies (two cohort studies, ^{73, 77} one case-control, ⁷⁴ and three registry studies ^{75, 76, 80}) addressed rFVIIa. Atony accounted for many of the cases of PPH in studies reporting etiology (range = 18 to 56% of cases).

Other agents were each addressed in one study: tranexamic acid (one RCT, n = 144), ⁶⁹ oxytocin and other (unspecified) uterotonics (one retrospective cohort, n=49), ⁷⁹ misoprostol compared with methylergonovine maleate (one retrospective cohort, n = 58), ⁷⁸ sulprostone (one population-based case series, n = 1,370), ⁷⁰ carboprost tromethamine (one registry study, n = 236), ⁷¹ and recombinant human soluble thrombomodulin (rTM; one cohort study, n = 36). ⁷² Two studies included only women with atonic PPH, ^{70,71} and, where reported, atony accounted for 27 to 65 percent of cases. We rated the RCT as poor quality for all effectiveness outcomes and the five cohort and case-control studies as fair quality. The case series were considered poor quality by default. Table 6 provides an overview of key outcomes in studies with comparison groups. We note that one additional cohort study reported only harms of methylergonovine maleate and is discussed in KQ3. ⁶⁰

Detailed Analysis

Oxytocin and Other Uterotonics

One fair quality retrospective cohort study reported on 91 women (mean age=33.3±4.6, median parity=0, range 0-3) undergoing treatment for massive PPH (defined as estimated blood loss of \ge 1500ml within 24 hours after birth). 79 PPH was due to atony in 41.8 percent of cases. Women were initially treated with intravenous oxytocin (n=33 receiving oxytocin only) and other uterotonic agents (n=16 receiving oxytocin plus other agents). Other uterotonics used could have included carboprost, rectal misoprostol, and sulprostone, though the study does not specify which agents were actually administered. Among the 49 women who received oxytocin and other uterotonics only (i.e., PPH resolved without need for additional procedures or surgeries), atony accounted for 26.5 percent of cases, and "other causes" (uterine rupture, coagulopathy, retained placenta) accounted for 42.9 percent. Causes of PPH differed significantly among women receiving uterotonics only and those requiring second-line therapies (n=42) to control bleeding (p<.001), in whom atony and placenta previa or accreta accounted for most cases. Among the 33 women treated with oxytocin only, bleeding was controlled in 32, and one required subsequent hysterectomy (97% success rate). Among those 16 treated with oxytocin plus other uterotonics, bleeding was controlled in 13, and three required hysterectomy (81%) success). Thus, bleeding was controlled without need for further procedures/surgeries in 45 of 91 women receiving oxytocin alone or with other uterotonics (49% success rate). Women receiving only conservative management had a median length of stay of 6 days (range 3-29), and 12 (24.5%) were admitted to the ICU. Length of stay and ICU admissions appear to be similar among the 42 women who received second-line therapies (length of stay ranging from 4 to 54 days, number admitted to ICU ranging from 3 to 8 women), but the study does not report analytic comparisons.

Tranexamic Acid

A single RCT (rated poor quality for all efficacy outcomes) with 144 participants reported reduction of blood loss in women with PPH treated with high-dose TXA (n = 72). The RCT was an open-label trial at multiple centers in France and included women with PPH > 800 mL

following vaginal birth. All women received packed red blood cells (PRBCs) and colloids as ordered by clinicians. The use of additional procoagulant treatments was permitted only in cases involving intractable bleeding. The treatment group received TXA in a loading dose of 4 g over 1 hour, then infusion of 1 g/hour over 6 hours. Women in the control group did not receive TXA, and groups did not differ on maternal or obstetric characteristics at baseline. The primary outcome was efficacy of TXA in the reduction of blood loss as measured using collection pouches. The volume of blood loss between enrollment and 6 hours later was significantly lower in the TXA group (median = 173 mL; first to third quartiles, 59 to 377) than in the control group (median = 221 mL; first to third quartiles 105 to 564, p = 0.041).

Secondary outcomes included PPH duration, anemia, transfusion, and the need for invasive interventions. In the TXA group, bleeding duration was shorter and progression to severe PPH and PRBC transfusion was less frequent than in the control group (p < 0.03). PPH stopped after only uterotonics and PRBC transfusion in 93 percent of the women who received TXA versus 79 percent of the women in the control group (p = 0.016). There was no significant difference between the groups in the ratio of invasive interventions performed.

Misoprostol Versus Methylergonovine Maleate

A fair quality retrospective cohort study compared intramuscular methylergonovine maleate versus rectal misoprostol for patients who had a clinical diagnosis of PPH and were treated between 2000 and 2005. Inclusion criteria were gestational age at birth of 37 to 42 weeks, singleton pregnancy, a "clinical diagnosis of PPH" in the medical record, and the patient "required something more than standard oxytocin." Fifty-eight records were included for review. Forty patients received misoprostol, and 18 received methylergonovine maleate. The study reported no differences between the groups in age, gestational age, or type of birth. There were no differences in the need for blood transfusion, "third-level" medical treatment, or surgical interventions. However, the number of participants was small; therefore, the apparent lack of difference in outcomes could be due to Type II error. Furthermore, the assignment to intervention was by provider choice, which introduced selection bias.

Sulprostone

One retrospective population-based case series reports outcomes following sulprostone administration in women with PPH (defined as blood loss of $\geq 500 \text{mL}$ of blood loss necessitating manual placenta removal and/or uterine examination) who were treated at one of 106 French maternity hospitals. Outcomes related to a multifaceted educational intervention conducted in these hospitals with the aim of lowering PPH rates are described under KQ5. Among the 9,365 cases of PPH occurring in the study period (2004-2006), 4,038 women had clinically assessed atonic PPH, of whom 1370 received sulprostone (995 after vaginal birth, 375 after cesarean birth). Women received additional treatments including uterine cavity or genital tract examination (n = 1634), oxytocin (n = 1297), and vascular volume expansion (n = 653). Among women who received sulprostone, bleeding stopped without the need for additional procedures or surgeries in 83.4 percent. Need for embolization, surgery, or hysterectomy was more common after cesarean birth compared with vaginal birth (26.1% vs. 13%, p < .01).

Carboprost Tromethamine

A retrospective population-based case series reviewed carboprost tromethamine for PPH in 236 women (237cases of PPH) at 12 U.S. obstetrics units. The women (mean age 25.3 ± 5.7 years) were given either 125 micrograms or 250 micrograms of carboprost tromethamine (range

one to five doses), preceded in 96 percent of cases by oxytocics. The decision to administer carboprost tromethamine was made at the discretion of independent practitioners. Hemorrhage was controlled in 208 of 237 cases (87.8%). In 17 cases, PPH was controlled with additional oxytocics. Second-line treatments in the 12 women in which carboprost tromethamine failed included nine arterial ligations (followed by hysterectomy in four cases) and immediate hysterectomy in three women. Twenty-seven percent of women received transfusions, but the timing of transfusion (pre- or post-carboprost tromethamine) is not clear.

Recombinant Human Soluble ThromboModulin (rTM)

A fair quality retrospective cohort of the use of rTM in 10 consecutive patients with severe PPH complicated by DIC reported no significant difference in total blood loss or transfusion requirements between those treated with rTM and matched controls. All 36 patients were admitted to a single tertiary center. The primary outcome was the efficacy of recombinant human soluble thrombomodulin (rTM) in disseminated intravascular coagulation (DIC) associated with severe PPH. Ten consecutive patients with DIC associated with severe PPH were treated with rTM. Twenty-six patients with DIC associated with severe PPH were chosen for comparison. The baseline characteristics of the control group were described as "similar" to the treated group. On day 2 following treatment, D-dimer decrease from baseline was significantly greater in the rTM group compared with the control group (p<.05). The intervention is targeted for DIC, and is not a treatment for PPH without the presence of DIC.

Table 6. Key outcomes in comparative studies of pharmacologic agents

Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
Chan et al. 2013 ⁷⁹ Hong Kong G1: Oxytocin only (33) G1a: Oxytocin ± other uterotonics (16) G2: Uterine compression sutures (21) G3: Embolization alone (4) G4: Uterine balloon tamponade (11) G5: Two second-line therapies (6) Quality: Fair	Age, mean ± SD G1-G5: 33.3±4.6 Parity, median G1-G5: 0 (range: 0-3)	 1/33 women receiving oxytocin alone required subsequent hysterectomy 3/16 receiving oxytocin plus other uterotonics required subsequent hysterectomy Estimated blood loss among all 49 women=1.8 liters (range 1.5-15); median 3 units (range 0-39) red blood cells transfused Median LOS=6 days (range: 3-29); 24.5% required ICU admission
Ducloy-Bouthers et al. 2011 ⁶⁹ France G1: Tranexamic acid (78) G2: Control (74) Quality: Poor/High risk of bias for all outcomes	Age, mean ± SD G1: 29 ± 4 G2: 28.5 ± 5 Primipara, n (%) G1: 46 (64) G2: 50 (69)	 Blood loss for G1 was significantly lower vs. G2 (G1: median 170 mL vs. G2: median 221 mL) Bleeding duration was shorter for G1: n = 28 (36%) with persistent bleeding after 6 hours vs. G2: n = 37 (50%), p = 0.03

Table 6. Key outcomes in comparative studies of pharmacologic agents (continued)

Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
Baruah et al., 2008 ⁷⁸ US G1: Misoprostol (40) G2: Methylergonovine maleate (18) Quality: Fair	Age, n (%) Under 20 G1: 6 (15) G2:1(5.5) 20-29 G1: 14 (35) G2: 9 (50) 30-39 G1: 19 (47.5) G2: 8 (44.4) ≥ 40 G1:1(2.5) G2: 0 Primipara, n (%) G1: 14 (35) G2: 6 (33)	 5 women in G1 needed transfusion and none in G2, p = 0.11 Need for third line medical or surgical therapy was comparable G1: 27 (67.5%) vs, G2: 14 (77.8%) One woman in each group had hysterectomy
Sugawara et al. 2013 ⁷² Japan G1: Recombinant thrombomodulin (10) G2: No thrombomodulin (26) Quality: Fair	Age, Mean ± SEM G1: 33.2 ± 1.7 G2: 31.7 ± 1.1 Parity NR	 Participants did not differ at baseline on blood loss, transfusions, obstetrical complications; shock index (PPH severity) significantly greater in G1 vs. G2 (p < .05) G1 received 380 U/kg/day thrombomodulin for 3.0 ± 0.6 days + blood products as needed; incidence of undefined bleeding symptoms was not significantly less in G1 vs. G2 (22.2% vs. 42.3% at day 1 and 11.1% vs. 19.2% at day 2, p = .28) No adverse events associated with either group were reported

Abbreviations: G = group; ICU = intensive care unit; LOS = length of stay; n = number; NR = not reported; SD = standard deviation; SEM = standard error of the mean

Recombinant Activated Factor VIIa (rFVIIa)

A fair quality retrospective cohort study in Finland compared the effectiveness of rFVIIa versus standard management (no rFVIIa) among women with PPH (defined as loss of 1.5 times patient's blood volume). Eligible participants were identified using medical records at a single tertiary referral hospital. Of the 48 women identified, 26 were treated with rFVIIa and 22 were not. There were no statistically significant differences in age, body mass index (BMI), obstetrical course (cause of PPH, mode of birth, length of hospital stay after birth), lowest hemoglobin, or lowest platelet count between the two groups. Activated partial thromboplastin time, liters of total bleeding (11.3 vs. 8.0, p = 0.005), units of RBC (20 vs. 13, p = 0.003), units of platelets (23 vs. 14, p = 0.014), and number with fibrinogen concentrate transfused (15 vs. 5, p = 0.014) were significantly greater among women treated with rFVIIa than among untreated women. There was no statistical comparison of maternal or fetal outcomes between the groups.

A retrospective case-control study in Ireland compared the effectiveness of rFVIIa in reversing coagulopathy associated with massive PPH versus standard management (no rFVIIa) between 2003 and 2006.⁷⁴ Twenty-eight women with massive PPH (defined as transfusion of > 5 units of PRBC in 24 hours) were identified using medical records at a single Irish hospital. Of these, six women who were treated with rFVIIa and had a prolonged prothrombin time (PT) were matched with six women with the largest number of PRBC units transfused and prolonged PTs

who were not treated with rFVIIa. There were no statistically significant differences in age, obstetrical factors (gestation, parity, cause of massive PPH, or number of hysterectomies), or coagulopathy factors (PRBC, platelets, fresh frozen plasma [FFP], or cryoprecipitate transfused, or worst PT or fibrinogen levels) between the two groups. The PT improved with management in both groups, and there was no significant difference in the magnitude or absolute value of improvement (p = 0.9). There was no statistical comparison of maternal or fetal outcomes between the groups.

One fair quality cohort study used data from the U.K. Obstetric Surveillance System (UKOSS). The UKOSS includes all hospitals with a consultant-led maternity unit in the United Kingdome. Clinicians in these hospitals reported data on PPH cases and treatment to the UKOSS using case notification cards completed monthly. UKOSS personnel also followed up with hospitals to identify potential missed cases. In this study, 31 women received rFVIIa as the initial second-line therapy after failure of conservative PPH management approaches. Sixteen received rFVIIa after uterotonic failure, and 15 received it after failure of uterotonics plus intrauterine balloon tamponade (either with balloon or packing). Among the 16 who had received only uterotonics plus rFVIIa, 11 had successful cessation of bleeding. One required compression sutures, two had ligations, one had interventional radiology, and seven required hysterectomy to control bleeding. Thus, the success rate (control of bleeding without further procedures or surgeries) for rFVIIa was 31 percent. Among the 15 who had rFVIIa after intrauterine tamponade with balloon or packing plus uterotonics, seven required hysterectomy while interventional radiology controlled bleeding after rFVIIa in four (27% success rate for rFVIIa plus uterine tamponade).

Three registry studies also assessed use of rFVIIa. A voluntary registry study described outcomes of treatment of PPH with rFVIIa in nine Northern European countries.⁷⁵ Eligible women (128 total identified, 108 included in the analysis) were identified differently in each country, with most identified by physicians or pharmacists who responded to requests for information about use of rFVIIa for treatment of PPH. In Finland and the Netherlands, information was collected for national surveys prior to initiation of this study, and those data were provided to the study group. Information on study endpoints was gathered retrospectively via standardized surveys completed by local practitioners in some instances and via national survey data in others. The registry gathered information on hematologic parameters after the use of rFVIIa as the primary treatment for PPH and as secondary prophylaxis if other interventions were used prior to rFVIIa. Clinicians noted improvements in bleeding after a single dose in 80 percent of the 92 women receiving rFVIIa to treat PPH and in 75 percent of the 16 women receiving it as secondary prophylaxis. Clinicians judged rFVIIa as failing to control bleeding in 15 cases overall (13.8%) Hemoglobin increased in 51 percent of cases in which bleeding was reduced after rFVIIa and showed no significant change in 32 percent of cases. Hemoglobin levels dropped post-administration in 17 percent of cases.

Two comprehensive registry studies were performed to describe outcomes of off-label use of rFVIIa for treatment of PPH in Australia and New Zealand. Registry Cases were identified between 2002 and 2008 from the Australian and New Zealand Haemostasis Registry (developed using unrestricted educational grant funds from Novo Nordisk Pharmaceuticals, the maker of rFVIIa), representing 38 hospitals in those countries. Data were collected via standardized data forms from 105 case medical records and treating clinicians of women with acute obstetric hemorrhage who received rFVIIa. Overall, bleeding stopped or decreased in 76 percent of women. Most (78%) women received a single dose of rFVIIa, and 64 percent of these women had decrease or

cessation of bleeding. Median dose of rFVIIa was 92 micrograms/kg (range 9 to 139). Most women (76%) required < 6 units PRBC transfusion after receiving rFVIIa, and 13 women (21%) required hysterectomy after rFVIIa failed to control bleeding.

In the second registry study, which includes some of the same women in study summarized above, cases with off-label use of rFVIIa (non-hemophilia indications) were identified at 96 hospitals between 2000 and 2009 in the Australian and New Zealand Haemostasis Registry. The registry included 95 percent of off-license use of rFVIIa during that time frame. Of 3,446 cases of off-label rFVIIa use identified, 177 were obstetric cases from 175 women with PPH. Data were collected both retrospectively (2000-2005) and prospectively (2005-2009) by trained data collectors, and were validated by central registry staff. A single dose of rFVIIa was used in 134 (76%) of women, and bleeding stopped or decreased in 99 (56%) of women after a single dose, and 114 (64%) of women after the final dose was given. Table 7 outlines key outcomes in comparative studies.

Table 7. Key outcomes in comparative studies of rFVIIa

Author, Year Country Groups (n) Quality	Age Parity	Key Outcomes
Ahonen et al., 2007 ⁷³ Finland G1: rFVIIa (26) G2: control (22) Quality: Fair	Age, mean ± SD G1: 33 ± 4 G2: 35 ± 4 Nulliparous, n (%): G1:.12 (46) G1: 12 (54.5)	 Response to rFVIIa was considered good (n = 17, 65%), moderate (n = 3, 12%), and poor (n = 6, 23%) Blood loss (liters) was significantly greater in G1 (mean 11.3 ± 4.5) vs. G2 (mean 8.0 ± 3.1)
McMorrow et al., 2008 ⁷⁴ Ireland G1: rFVIIa (6) G2: control (6) Quality: Fair	Age, mean ± SD G1: 34 ± 2.8 G2: 31 ± 4.6 Parity, mean ± SD: G1: 2 ± 0.5 G1: 1 ± 0.75	 Prothrombin time improved in both groups with no significant differences between the groups (p = 0.09) Women in both groups received uterotonics (oxytocin, ergometrine, misoprostol, carboprost tromethamine), and uterine massage The number of hysterectomies performed was comparable in G1: 50% and G2: 67%
Kayem et al. 2011 ^{77.} 82 UK G1: Uterine compression sutures (199) G2: Pelvic vessel ligation (20) G3: Interventional radiology (embolization, arterial balloon) (22) G4: rFVIIa (31) Quality: Fair	Age < 35, n (%) G1: 128 (64) G2: 12 (60) G3: 12 (55) G4: 21 (68) > 35, n (%) G1: 71 (36) G2: 8 (40) G3: 10 (45) G4: 10 (32) Nulliparous, n (%) G1: 92 (46) G2: 3 (15) G3: 6 (27) G4: 9 (29)	 Among all women receiving these second-line therapies, 205 had prior uterotonic therapy (oxytocin, ergometrine, carboprost tromethamine, misoprostol) alone, 67 had prior uterotonics and intrauterine tamponade rFVIIa was successful in controlling bleeding in 5/16 women who received only uterotonics and in 4/15 who had uterotonics and tamponade as a first-line therapy 14 women who received rFVIIa ultimately required hysterectomy

 $Abbreviations: G = group; \ n = number; \ rFVIIa = recombinant \ activated \ factor \ VIIa; \ SD = standard \ deviation$

Studies of Other Medical Interventions

Transfusion for Supportive Management of Ongoing PPH

Key Points

- No good quality studies addressed transfusion for supportive management of PPH.
- In one retrospective cohort study, women receiving combination blood products compared
 with whole blood or PRBC only for supportive management of PPH had a greater level of
 transfusion, greater likelihood of intensive care unit (ICU) stay, and greater risk of adverse
 outcomes.
- Estimated blood loss, blood products transfused, and mean length of stay did not differ between groups in a retrospective cohort study comparing outcomes following cryoprecipitate or fibrinogen transfusion for supportive management of PPH. In a pre-post study, use of blood products was reduced after the introduction of fibrinogen.
- Strength of the evidence for outcomes related to transfusion for supportive management of PPH is insufficient. While there were three fair quality studies of transfusion for this purpose, two of these were so confounded that we could not confidently ascertain their outcomes.

Overview of the Literature

Three fair quality retrospective cohort studies and one poor quality pre-post study addressed transfusion as a therapy for management of PPH. Studies that address transfusion as an intervention for anemia once PPH is stabilized are summarized under KQ4. Transfusion in these studies was evaluated as a method of supportive management of the complications of PPH (e.g. coagulopathy, anemia, hypovolemia), rather than to reverse the underlying cause of PPH. Cohort studies were conducted in the United States, ⁸³ Ireland, ⁸⁴ and Korea ⁸⁵ and included a total of 1,700 women. The pre-post study was conducted in the UK and included 93 women. Causes of PPH, where reported, included atony (range = 2.5 to 38%), placental abruption or placenta previa (8-17%), chorioamnionitis (21%), and placenta accreta (14%). Studies assessed different aspects of transfusion for supportive management of PPH: whole blood vs. PRBC vs. a combination of products, ⁸³ massive transfusion vs. no massive transfusion, ⁸⁵ cryoprecipitate vs. fibrinogen concentrate, ⁸⁴ and use of fresh frozen plasma vs. fibrinogen concentrate. ⁸⁶ One additional Canadian case series, ⁶³ one French case series, ⁶¹ and one case series from Italy ⁶⁵ reported only on harms of transfusion and are described in KQ3.

Detailed Analysis

A fair quality, single-center, retrospective cohort study conducted in the United States compared complication rates between whole blood transfusion, PRBC transfusion alone, and combination blood product transfusion for supportive management of PPH. ⁸³ Eligible participants with PPH (defined as hypovolemia sufficient to provoke hemodynamic instability) were identified using a database of obstetric and neonatal outcomes. Of 1,540 women identified, 659 received whole blood transfusion, 593 received PRBC only, and 288 received a combination of blood products. There were no statistically significant differences between groups in age, race, or parity, but women in the combination blood product group were more likely to have perineal trauma, placenta previa or abruption, and hysterectomy than the other groups. Mean units of blood product transfused was significantly greater among women getting a combination of blood products when compared with women receiving whole blood or PRBC only (5.5, 2.2, and. 2.3

units in the combination blood products, whole blood, and PRBC groups, respectively, p < 0.001). Women in the combination transfusion group were also significantly more likely to be transferred to the ICU (23%, 4%, and 7% in the combination blood products, whole blood, and PRBC alone groups, respectively, p < 0.05) and to die (2%, 0%, and 1% in the combination blood products, whole blood, and PRBC alone groups, respectively, p = 0.03) than women in the other two groups.

Another fair quality, single-center, retrospective cohort study used electronic medical records at a Korean academic hospital to determine whether patients with an elevated shock index at the time of presentation with PPH would be more likely to require massive transfusion. 85 Women with PPH (defined as blood loss \geq 500 mL) were identified as part of the massive transfusion group (defined as receiving transfusion of > 10 units PRBC within 24 hours of birth, n=26) or the non-massive transfusion group (n=100). Groups did not differ in terms of age, parity, mode of birth, bleeding time. Significantly fewer women in the massive transfusion group had an alert mental status (18 vs. 95, p < 0.01) and underwent embolization (22 vs. 36, p < 0.01), and significantly more women in this group required ICU stay (11 vs. 5, p < 0.01) and died (3 vs. 0, p < 0.01). Additionally the median systolic and diastolic blood pressures and hemoglobin levels were significantly lower (5.9 vs. 9.5, p < 0.01), and the median shock index (1.3 vs. 0.8, p <0.01) and length of hospital stay (4.0 vs. 2.0, p < 0.01) were significantly higher in the massive transfusion group than in the non-massive transfusion group. Transfusion requirements were significantly higher in the first 24 hours and during the hospitalization among the massive transfusion group than the non-massive transfusion group (18.0 units and 3.0 units in the first 24 hours, respectively, and 20.0 units and 4.0 units during the hospitalization, respectively). These finding are confounded by indication as the massive transfusion group was presumably experiencing more severe PPH given their lower median hemoglobin and lower median systolic and diastolic blood pressures than the non-massive transfusion group.

A fair quality, single-center, retrospective cohort study from Ireland compared the effectiveness of transfusion with cryoprecipitate (n = 14) versus fibrinogen concentrate (n = 20) for supportive management of PPH. States Women were identified for inclusion in a major obstetric hemorrhage database if they experienced PPH (defined as blood loss of \geq 2.5 L, transfusion of \geq 5 units PRBC, or treatment of a coagulopathy in the acute event). Eligible participants from the database were women treated with either cryoprecipitate or fibrinogen concentrate between 2009 and 2011. There were no statistically significant differences between groups in age, race, BMI, parity, gestation at birth, birth weight, or cause of PPH, but women in the cryoprecipitate group were more likely have previous cesarean birth. There was no statistically significant difference between groups in mean estimated blood loss; number of units of PRBC, Octaplas/fresh frozen plasma, or platelets transfused; medical and surgical treatments administered; and mean length of hospital stay.

Finally, one poor quality pre-post study from the United Kingdom compared the effectiveness of fibrinogen concentrate (n=51) versus fresh frozen plasma (n=42) for management of PPH-associated coagulopathy. ⁸⁶ Eligible participants were identified within a single hospital if they had major obstetric blood loss (defined as > 1500 mL) associated with coagulopathy between April 2011 and June 2013, with participants treated between April 2011 and March 2012 receiving treatment with a major obstetric hemorrhage algorithm that included fresh frozen plasma, and participants included from July 2012 through June 2013 receiving treatment with fibrinogen concentrate. Women treated with fibrinogen concentrate received significantly fewer total blood components (3.0 vs 8.0, for the fibrinogen concentrate group vs.

the plasma group, p=0.0004), pooled bags of cryoprecipitate (numbers not reported), total quantity of fibrinogen (0 vs. 3.2, for the fibrinogen concentrate group vs. the fresh frozen plasma group, p=0.0005), and doses of platelets (numbers not reported). Units of red blood cells given to the two groups did not differ significantly, nor did ICU admission, transfusion-related acute lung injury (n=0 in both periods), or hysterectomy. There was a significantly higher rate of transfusion-associated circulatory overload in the fresh frozen plasma group (p=.04). Table 8 outlines key outcomes.

Table 8. Key outcomes in comparative studies of transfusion for supportive management of PPH

Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
Alexander et al., 2009 ⁸³ US Groups: G1: Whole blood only (659) G2: PRBC only (593) G3: Combinations of	Age, year, n (%): 17 or less G1: 54 (8) G2: 39 (7) G3: 28 (10) 35 or older G1: 66 (10) G2: 54 (9) G3: 34 (12)	 Mean units of blood transfused was 2.2 units for G1, 2.3 units for G2, and 5.5 units for G3 (p < 0.001) G3 more likely than G1 and G2 to be transferred to the ICU (23%, 4%, and 7%, respectively, p < 0.05) and to die (2%, 0%, and 1%, respectively, p = 0.03)
blood products (208) Quality: Fair	Nulliparous, n (%) G1: 333 (51) G2: 306 (52) G3: 135 (47)	
Sohn et al. 2013 ⁸⁵ Korea G1: Massive transfusion requiring 10 or more units of PRBCs (26) G2: Received < 10 units PRBCs (100) Quality: Fair	Age, median (IQR range) G1: 31 (29.8-34.5) G2: 31 (29-34) Primiparous, n (%) G1: 17 (65.4) G2: 56 (56) Multiparous, n (%) G1: 9 (34.6) G2: 44 (44)	 Women in G1 had greater length of stay and need for ICU care compared with G2 (p < 0.01) Findings confounded by indication
Ahmed et al., 2012 ⁸⁴ Ireland G1: Cryoprecipitate (14) G2: Fibrinogen (20) Quality: Fair	Age, mean G1: 32.8 G2: 31.0 Nulliparous, n (%) G1: 6 (43) G2: 6 (30)	 Cryoprecipitate was used prior to July 2009 and then replaced with fibrinogen Hypofibrinogenemia was resolved with both treatments The two groups had comparable hemoglobin, hematocrit, and platelet counts
Mallaiah et al., 2014 ⁸⁶ United Kingdom G1: Fresh frozen plasma (42) G2: Fibrinogen concentrate (51) Quality: Poor	Age NR Parity NR	 FFP used in massive PPH algorithm prior to June 2012, and was then replaced with fibrinogen concentrate. Use of fibrinogen concentrate resulted in transfusion of significantly fewer total blood components and units of FFP and cryoprecipitate vs. use of FFP. The groups had similar outcomes, with similar rates of ICU admission and hysterectomy, and there were no deaths.

Abbreviations: FFP = fresh frozen plasma; G = group; ICU = intensive care unit; IQR = interquartile range; n = number; NR = not reported; PPH = postpartum hemorrhage; PRBC = packed red blood cells

Studies of Procedures

Uterine Balloon Tamponade

Key Points

- No good quality studies addressed uterine balloon tamponade.
- In one fair quality pre-post study, 86% of women who had balloon tamponade did not require further procedures or surgeries.
- Case series reported a decrease or cessation of bleeding in 75 to 98 percent of patients treated with a balloon tamponade device, with and without prior or subsequent surgeries or procedures.
- Strength of the evidence for outcomes related to uterine balloon tamponade is insufficient given the small number of studies and small sample sizes.

Overview of the Literature

Five studies, one pre-post study, one retrospective cohort study, two retrospective case series, and one population-based case series, addressed the use of intrauterine balloon tamponade for the management of PPH. The pre-post study was conducted in France, cohort study in Hong Kong, and case series in the United States, Finland, and Italy. Many of the women in these studies had atony (100% in pre-post study, 57.2% in the cohort study, and 16%-72.7% in case series). A total of 208 women had intrauterine tamponade using Bakri, ^{87,90}Sengstaken-Blakemore, Rusch, ⁸⁹ or Belfort-Dildy Obstetrical Tamponade System ⁸⁸ balloons.

Detailed Analysis

One fair quality pre-post study examined the rate of invasive procedures (embolization and surgery) after adding balloon tamponade to the protocol for PPH management in a maternity unit at a tertiary care university hospital in France. 87 The new protocol required that intrauterine balloon tamponade be performed prior to any invasive intervention in cases of PPH due to uterine atony that were nonresponsive to sulprostone. Data were collected prospectively for 30 months after implementation of the new protocol. The patients in the control group (n = 290, none of whom had balloon tamponade) were identified from electronic medical records as women admitted to the hospital with PPH due to atony requiring sulprostone therapy in the 30 months prior to the new protocol implementation. During the study period, 395 women with PPH required sulprostone therapy, which was unsuccessful in 72 women. Of these women who needed additional procedures or surgeries, 43 had intrauterine balloon tamponade as the initial second-line therapy. No additional procedures or surgeries were required after balloon tamponade in 92% (11/12) of the women who had cesarean births and 84% (26/31) of the women who had vaginal births. Among the six women for whom balloon tamponade was unsuccessful, three had embolization, two had conservative surgical interventions (defined as artery ligations and/or uterine compression sutures), and one had hysterectomy. The overall success rate of balloon tamponade was 86% (37/43 women). Adding balloon tamponade to the protocol decreased the rates of arterial embolization (8.2% pre vs. 2.3% post, p = 0.006, OR 0.26, 95 percent CI: 0.09-0.72) and conservative surgical procedures (5.1% pre vs. 1.4% post, p = 0.029, OR 0.26, 95% CI: 0.07-0.95) among women with vaginal births. Hysterectomy and transfusion rates were unchanged. Rates of invasive interventions and transfusion were unchanged among women with cesarean births (Table 9).

In a fair quality cohort study (see full description in Oxytocin and Other Uterotonics section above), 42 of 91 women with massive PPH required second-line procedures or surgeries to control bleeding.⁷⁹ Procedures included balloon tamponade (n=12), embolization (n=5), and sutures (n=26), and women receiving second-line therapies did not differ in terms of age, BMI, parity, mode of birth, or causes of PPH. Twelve women received uterine balloon tamponade with a Sengstaken-Blakemore tube, with successful control of bleeding in 9 (75%). One woman required subsequent embolization, and two required hysterectomy to control bleeding.

One population-based case series examined the outcomes of women with PPH treated with a dual-balloon catheter tamponade device, the Belfort-Dildy Obstetrical Tamponade System, using postmarketing surveillance data from medical records and clinician interviews at 11 hospitals in the United States. During the study period (September 2010 – October 2012), 51 women with PPH were treated with the balloon tamponade device. Of these, 28 women had vaginal births and 23 had cesarean births. The median time interval between birth and insertion of the balloon was 2.2 hours (range 0.3-210 hours). Estimated median blood loss was 2000mL (range 855-8700). Thirty-nine (77%) patients required PRBC transfusion, and 12 (24%) were admitted to the ICU. Bleeding was considered to be decreased in 22 (43%) women and stopped in 28 (55%). Eight patients (16%) required additional procedures or surgeries after the balloon placement including hysterectomy (n = 4), uterine artery embolization (n = 4), and surgical repair (n = 3); some required more than one intervention. The overall success rate of balloon tamponade in controlling or decreasing bleeding was 98% (50/51 women, who also had prior medical or surgical interventions). Table 9 outlines key outcomes in studies of uterine balloon tamponade.

A retrospective case series evaluated uterine tamponade conducted with a Rusch balloon between 2002 and 2012 at one Italian center. ⁸⁹ All 52 women who had balloon tamponade (mean age=34.4±4.4, 39% multiparous, 60% with atony) received initial uterotonics and other conservative management. Oxytocin was continuously infused in conjunction with tamponade (20 IU for 24 hours). Tamponade balloons were filled with 200 mL in cases of abnormal placentation and 400mL in cases of atony. Women also received antibiotics for 24 hours, and those receiving balloon tamponade after vaginal birth had vaginal packing. Balloons were left in place for a mean of 23.1±9.0 hours (range: 3.5-40 hours). Sixty-three percent of women also received red blood cell transfusion. Balloon tamponade as the initial second-line procedure successfully controlled bleeding in 39 of 52 women (75%, success in 11 of 14 cases of PPH following vaginal birth and 28 of 38 cesarean births). Two women had subsequent uterine artery ligation, one had compression sutures, and 10 had hysterectomies. More failures of balloon tamponade requiring hysterectomy occurred in cases of PPH due to placenta previa and accreta (success in 2 of 5 cases) and in cases due to atony accompanied by placenta previa and/or accreta (success in 3 of 7 cases).

A final retrospective case series reported on 50 women with PPH (n=44) or at risk of PPH (n=6) receiving a Bakri uterine balloon after conservative management including uterotonics, laceration repair, and curettage as needed. Overall, 29 women had vaginal births and 21 had cesarean births (N primigravid=30). PPH was most often due to placental retention (30% of cases) or vaginal rupture/paravaginal hematoma (22%). Uterine balloons were inserted in the vagina or lower uterine segment and left in situ for a mean of 12.7 hours (range 1-28 hours). Four women had compression sutures or ligation concomitantly with uterine balloon tamponade, and the study reports data on successful control for all women (i.e., not separately for those women who received tamponade alone). In all, uterine balloon tamponade successful controlled bleeding in 43 of 50 women (86%). Three women required subsequent embolization, two

required supravaginal uterine amputation, one required compression sutures plus supravaginal uterine amputation, and one had embolization followed by hysterectomy. Because success data are not extractable for women who received uterine balloon tamponade alone, this study is not included in Table 10, which reports rates of successful control of bleeding following uterine tamponade.

Table 9. Key outcomes in studies of uterine balloon tamponade

Author, Year, Country Study Design Groups (N)	Age, Years Parity	Key Outcomes
Study Quality		
Laas et al. 2012 ⁸⁷ France Pre-post G1: Women with PPH due to atony and nonresponsive to sulprostone admitted to the maternity service after implementation of new protocol using intrauterine balloon tamponade as first-line therapy after medication failure (395) G2: Control group, had PPH requiring sulprostone during the 30 months before implementation of new protocol (290)	Age, median (range) G1: 30 (27-34) G2: 31 (26-34) Nulliparous, n (%) G1: 212 (53.7) G2: 160 (55.2)	 In G1, 72 women required interventions beyond medication and 43 of these had intrauterine balloon tamponade No additional procedures or surgeries were required after balloon tamponade in 92% (11/12) of women who had cesareans and 84% (26/31) of women who had vaginal births The rates of invasive interventions among women who had vaginal births were significantly lower after introduction of new protocol
Quality: Fair		
Chan et al. 2013 ⁷⁹ Hong Kong Cohort study G1: Oxytocin only (33) G1a: Oxytocin ± other uterotonics (16) G2: Uterine compression sutures (21) G3: Embolization alone (4) G4: Uterine balloon tamponade (11) G5: Two second-line therapies (6) Quality: Fair	Age, mean ± SD G1-G5: 33.3±4.6 Parity, mean ± SD G1-G5: 21.6±3.2	 2/12 women receiving uterine balloon tamponade required hysterectomy. 1/12 required embolization. Estimated blood loss among 11/12 women=12.3 liters (range 1.5-8.7); median 10 units (range 3-34) RBC transfused Median LOS=8 days (range: 4-12); 72.7% required ICU admission

Table 9. Key outcomes in studies of uterine balloon tamponade (continued)

Author, Year, Country Study Design Groups (N) Study Quality	Age, Years Parity	Key Outcomes
Dildy et al. 2013 ⁸⁸ US Case series G1: Dual-balloon tamponade (51)	Age, median (range) G1: 33 (19-47) Parity NR	 77% required red blood cell transfusion 24% were admitted to the ICU Bleeding was considered to be decreased or stopped in 98% of cases 16% required surgical interventions after balloon tamponade
Ferrazzani et al. 2014 ⁸⁹ Italy Case series G1: Rusch uterine balloon tamponade (52)	Age, mean ± SD G1: 34.4±4.4 Multiparous, n (%) G1: 20 (38.5)	 Total, mean ± SD estimated blood loss=1759,± 1011 mL; mean ± SD days of hospital admission=6.2±3.0 Uterine tamponade successful in controlling bleed in 20/24 cases of PPH due to atony, 3/7 cases due to atony+ placenta previa or accreta, 9/11 cases due to placenta previa, 5/5 cases of placenta accreta, 2/5 cases due to placenta previa-accreta (39/52 cases overall)
Gronvall et al. 2012 ⁹⁰ Finland Case series G1: Bakri uterine balloon tamponade (50)	Age, mean (range) G1: 31.3 (19-47) Parity, n 0: 30 1-2: 16 ≥3: 4	 Uterine balloon tamponade successfully controlled bleeding in 43/50 cases, in 4 cases women had concomitant ligation or sutures Mean blood loss after balloon insertion=525 mL (range=0-3250 mL). Mean inflation volume of balloon=367 mL (range 30-500mL)

Abbreviations:; G = group; ICU = intensive care unit; LOS = length of stay; mL = milliliter; n = number; NR = not reported; PPH = postpartum hemorrhage; RBC = red blood cells; SD = standard deviation

Table 10 reports rates of successful control of bleeding after uterine tamponade.

Table 10. Success rates after uterine balloon tamponade as the initial second-line procedure

Study Design	Study Country	Quality	Total N Treated	Total N Successful	% Success
Pre-Post Studies	Laas 2012 ⁸⁷ France	Fair	43	37	86.1
Cohort Studies	Chan 2013 ⁷⁹ Hong Kong	Fair	12	9	75
Case Series	Ferrazzani 2014 ⁸⁹ Italy	Poor	52	39	75
	Total	NA	107	85	Range: 75-86% Median Success Rate: 75%

Abbreviations: n = number; NA = not applicable

Note: Success = control of bleeding without further procedure or surgery

Embolization

Key Points

• No good quality studies addressed embolization.

- Embolization materials, arteries embolized, and interventions used prior to and concomitantly with embolization varied across studies.
- Success (control of bleeding without further procedures or surgeries) rates for embolization as the initial procedure after conservative management ranged from 58 to 98 percent (success in 1251/1435 women), with a median rate of 89 percent.
- Strength of the evidence is low for embolization controlling bleeding without additional procedures or surgeries.

Overview of the Literature

Nineteen studies addressed embolization to treat PPH. 49, 77, 79, 91-108 Seven studies had explicit comparison groups: one poor quality case-control study⁹¹ and six fair quality cohort studies (reported in multiple publications), five of which were retrospective 49, 79, 92-96 and one prospective.⁷⁷ Four studies were conducted in France in tertiary care hospitals, ^{91, 92, 95, 96} one in Korea, ⁴⁹ in a hospital that serves Jehovah's Witnesses, one in the United Kingdom, ⁷⁷ which reported data collected via the UKOSS (described in the section on rFVIIa), and one in Hong Kong. ⁷⁹ Ten women in one cohort study also had concomitant vessel ligation and/or uterine compression sutures, 92-94 one woman in each of two studies had prior or concomitant artery ligation, ^{49, 95} and three in another study ⁷⁷ also had intra-arterial balloon placement along with embolization. Eighty-one percent of the cases of PPH reported in the case-control study were due to atony. 91 Rates of atony in the cohort studies ranged from 9 to 69.5 percent. Other causes in all populations included placenta accreta, percreta, and/or previa (range: 9.4 to 22%); thrombus, vascular anomaly, or coagulopathy (range: 2 to 10%); and genital tract lacerations or uterine tears (range: 1 to 14%). The case-control study and two retrospective cohort studies reported primarily on longer-term fertility with followup of participants at ≥ 12 months post-embolization (fertility data reported in KQ3). 91, 92, 95 The prospective cohort study reported primarily success of embolization and the need for additional second-line interventions 77 as did one retrospective cohort study. 96 Remaining studies also reported primarily on the rate of success (i.e., controlling bleeding without further procedures or surgical interventions) of embolization.

Twelve retrospective case series also addressed embolization. Studies were conducted in France (n = 4), Asia (n = 7), the United States (n = 1). Most cases of PPH were due to atony (range = 43 to 100%), and most studies reported primarily on rates of success. One study reported on embolization to control secondary PPH, and one case series included 50 women in who embolization was performed because of high risk for PPH. 108

Detailed Analysis

One fair quality retrospective cohort study reported in three publications $^{92-94}$ included all 101 women who had pelvic artery embolization for PPH from 1994 to 2007 at a tertiary care facility in France. Embolization failed to control bleeding in 11 of 101 women, seven of whom required a postpartum hysterectomy. Failure was associated with increased blood loss as 100 percent of failed cases had blood loss greater than 1500 ml (p < .001). Failure was also associated with increased rate of transfusion with 90 percent of women in whom embolization failed receiving more than 5 units PRBC compared with 43 percent of the successful embolizations (p < .004). Cases of failed embolization were more likely to be complicated by wound infection (27% vs. 6% in the success group, p < .04).

A second fair quality retrospective cohort study conducted in France assessed outcomes in 52 women undergoing selective embolization using gelfoam (n = 41, mean age = 29.2 ± 4.65 years,

9 primiparous, 11 vaginal births), hysterectomy (n = 6, mean age = 30.1 ± 4.11 , 2 primiparous, 2 vaginal births), or both embolization and hysterectomy (n = 5, mean age = 36.6 ± 4.56 , 0 primiparous, 0 vaginal births). All women were treated between 1996 and 2005, and atony was the most frequent cause of PPH across groups (69.5%). All women had medical management (oxytocin, manual placenta removal, uterine massage, prostaglandins, transfusion) prior to embolization or hysterectomy. Embolization successfully stopped bleeding in 41 of 46 cases (89.1%). Five women required additional embolization procedures (insertion of coil to correct injury sustained in cesarean birth, ovarian artery embolization, embolization beyond gluteal artery, embolization of internal iliac artery, embolization of ligated hypogastric arteries). Among five women proceeding to hysterectomy following failed embolization, two women had placenta accreta, one had percreta, and one had sustained arterial injury during embolization. The study also assessed fertility in women who had had embolization (n = 37 available for followup) 2 to 11 years earlier: of the 16 women who desired a future pregnancy, all became pregnant 1 to 11 months following the decision to try to conceive (total of 19 pregnancies in the followup period).

In one fair quality retrospective cohort study reporting outcomes after embolization, ligation, or hysterectomy (see full study description in Ligation section), eight of 61 women with PPH underwent embolization using gelatin sponge or coils as the first secondary procedure. Embolization failed in three cases: one woman undergoing embolization also required methotrexate, one required subsequent ligation, and one required hysterectomy (63% success rate for embolization alone). This study also reported intervention by cause of PPH: among eight cases treated with primary embolization, three women had PPH due to atony (one cesarean birth). Embolization failed in one case, which resulted in hysterectomy and subsequent death. Embolization was successful in two cases of PPH due to accreta (one cesarean birth) and in one case due to placental abruption (vaginal birth). The procedure failed in one case of PPH due to genital tract laceration (instrumented vaginal birth), leading to subsequent ligation, and successfully controlled bleeding in another case following lacerations. ⁹⁶

Another fair quality retrospective cohort study reported outcomes after second-line procedures (see full description in the Oxytocin and Other Uterotonics section) in 42 women with PPH. Procedures included balloon tamponade (n=12), embolization (n=5), and sutures (n=26), and women receiving second-line therapies did not differ in terms of age, BMI, parity, mode of birth, or causes of PPH. Although five women underwent embolization after the failure of conservative management including oxytocin and other uterotonics, the paper reports etiology only for the four women who had embolization alone (i.e., not followed by another second-line approach). Two women had atony, one had placenta previa, and one had placenta accreta. Embolization successfully controlled bleeding without need for further procedure or surgery in three of the five women receiving embolization (60%). One woman required subsequent compression sutures and one required hysterectomy to control bleeding.

One poor quality case-control study conducted in France assessed the effects of embolization on fertility in 53 women exposed to embolization following PPH and 106 women who had not undergone embolization and were matched on date of birth, age, gravidity and parity, fertility assistance, and mode of birth. Women (mean age = 34.3, range 19-44) had undergone embolization (78.5% using absorbable gelatin, 1.8% using coils, 7.1% using microparticles, 12.6% using gelatin+other) between 2000 and 2006, and the primary cause of PPH was atony (81.1%). Embolization successfully controlled bleeding in 100 percent of women, but three required more than one embolization procedure.

One fair quality prospective cohort study reported UKOSS data collected between 2007 and 2009.⁷⁷ The study reported an analysis of outcomes of second-line therapies (i.e., interventions received after uterotonics alone or with intrauterine tamponade via balloon or packing). Secondline interventions included interventional radiology (defined as embolization or occlusion with an intra-arterial balloon), ligation (of any of the internal iliac, uterine, hypogastric, or ovarian arteries), compression sutures (including B-lynch, modified B-lynch, multiple vertical or horizontal sutures, squared compression sutures, and others), or rFVIIa. Among an estimated 1,237,385 births in the study period, 272 women had PPH treated with the interventions of interest as a second-line intervention. More than 50 percent of PPH cases (53%) were primarily due to atony. Other causes included placenta previa (9%), placenta accreta (10%), uterine tears (13%), and other (15%, includes placental abruption, genital bleeding, amniotic fluid embolism, infection, clotting abnormalities, undetermined causes). Women who had a cesarean birth (n = 230) were treated with a surgical method in 199 (87%) of the cases, and those who gave birth vaginally (n = 42) were more likely to be treated by interventional radiology or rFVIIa (52%, p < 0.001). Among the 272 cases of PPH, 205 women received uterotonics alone, and 67 had uterotonics plus intrauterine tamponade as first-line procedures. Data for each of the second-line therapies addressed in the study are reported under the appropriate intervention type (suture, etc.). Among the 22 women treated with interventional radiology, 19 had embolization alone, two had embolization plus balloon, and one had balloon only. Fourteen of the 22 women received uterotonics prior to interventional radiology. The interventional radiology procedures failed to control bleeding in two women (14%; 95% CI: 0 to 43), who required hysterectomy. Among the eight of 22 women who received uterotonics and intrauterine tamponade prior to interventional radiology, bleeding was controlled in seven cases, and one woman (12%, 95% CI: 0 to 53) required an additional (unstated) intervention. The study does not report the success of embolization alone but only the success of both interventional radiology procedures together.

One fair quality retrospective cohort conducted at a hospital that treated Jehovah's Witnesses in Korea reported results from women treated with embolization or hysterectomy between 2002 and 2009 (see Hysterectomy section for results from that arm). All women were initially treated with uterotonics (oxytocin, ergots, prostaglandins), uterine massage, transfusion (in patients who were not Jehovah's Witnesses), and fluid replacement. Among the 124 women (eight Jehovah's Witnesses) experiencing primary PPH, 60 (mean age 31.0 ± 4.8 years, 17 primiparous, 23 vaginal births) underwent selective embolization using gelfoam. PPH was most frequently due to atony (92.4%), and mean blood loss prior to embolization was 676.7 ml. Embolizations were performed by the same two interventionists across the study period. Mean ICU stay in the embolization group was 5 days (mean overall LOS = 8.6 days). Two women in the embolization group required hysterectomy due to continued bleeding from the cesarean uterine wound and from vaginal and cervical lacerations after vaginal birth.

In case series, rates of success (control of bleeding after embolization without further procedures or surgeries) ranged from 58 to 98 percent. In some cases, women had a procedure such as ligation or balloon tamponade prior to embolization. Five studies also reported on resumption of menses and/or pregnancies achieved (see discussion in KQ3).

One population-based case series reported on 211 women undergoing embolization either to control ongoing PPH (n=161, mean age=32.4 \pm 4.8 years, primipara=47.2%) or prophylactically (n=50, mean age=30.1 \pm 6.1 years, primipara=50%). Of note, this study included 56 women (37 in the emergency embolization group and 19 in the prophylactic group) who were <22 weeks gestation at the time of treatment. Most cases of prophylactic embolization were performed for

retained placenta (n=37), while most cases of emergency embolization were for atony (n=73). Embolic materials included gelatin sponge in most cases (n=193 cases), but metal coils (n=11) and other materials including N-butyl-2-cyanoacrylate (n=7) were also used. Embolization successfully controlled bleeding in 181 of 211 women (86%); 12 women required a second embolization procedure, and 18 required hysterectomies. Because the study does not clearly report how women who had second embolizations also had hysterectomies, we do not include this study in the success rates in Table 12. One retrospective case series reported on 117 cases of embolization (mean age=32.0±5.0, 69 vaginal births, 56 primiparous) for PPH performed between 2006 and 2013 at a Korean hospital. 106 More than half of the cases of PPH in the embolization group (54.7%) were due to atony, and women were treated initially with fluids, uterotonics, uterine massage, suture of lacerations, and uterine evacuation as needed. Embolization was performed with gelatin particles, coils, glue, or polyvinyl alcohol particles and was successful overall at controlling bleeding without further procedural or surgical intervention in 103 of 117 women (88%). Ten women required additional embolization, and four had hysterectomies. Embolization failure was associated with DIC (OR 3.364, 95% CI: 0.838 to 13.503, p=.08), greater than 10 RBC units transfused (OR 8.011, (95% CI: 1.531 to 41.912, p=.014), and embolization of uterine and ovarian arteries (OR 20.472, (95% CI: 2.715 to 154.365, p=.003). Nineteen of the 117 cases of PPH were secondary (12 cesarean births, p=.03 compared with primary PPH group), and embolization successfully controlled bleeding in 18 of these cases. This study includes data on 20 women who underwent hysterectomy but no outcomes of interest for the current review were reported; thus we did not include the hysterectomy data.

One retrospective case series included 56 women (median age = 33 years, median gravida = 2, median para = 2) with severe PPH (defined as ≥ 1000mL blood loss via clinical estimation or weighing of blood collecting bag; ≥ 500mL blood loss with poor clinical signs; continued bleeding; need for transfusion; or DIC) undergoing embolization at a French tertiary care hospital between 1995 and 2005. All women received initial medical treatment including suturing of vaginal or cervical lesions, oxytocin, uterine massage, and sulprostone. Thirty births were vaginal without instrumentation (54.5%), nine were instrumented vaginal (16.5%), and 16 were cesarean (29%). All women had atony, and 36 required transfusion (64.3%). Embolization was performed with gelfoam or sponge. Embolization successfully stopped bleeding in 55 cases (98% success rate). One woman required a second embolization session to control bleeding, and none needed further surgical interventions for bleeding.

Another French retrospective case series including 113 women (mean age = 31 years, 67 cesarean births) reported on menses and fertility outcomes and success of the embolization procedure. PPH was most frequently due to atony (75% of cases), and all women received medical management prior to embolization. Embolization materials included gelatin sponge, powder, and microparticles. Eighteen women required surgery prior to embolization (sutures, n = 11; ligation, n = 7). Embolization successfully controlled bleeding in 111 cases (results not reported for women who had embolization without a prior surgical procedure). Two women required hysterectomy post-embolization.

In a Korean retrospective case series reporting on 251 women with primary PPH (mean age 32 ± 4 years, 139 nulliparous, 141 vaginal births), most cases of PPH were due to atony (78.9%). The study reviewed data from women treated between 2000 and 2011. All women had medical management prior to embolization, and 22 had surgical interventions prior to embolization (hysterectomy, n = 15; uterine artery ligation, n = 2; laparotomy, n = 2; suture or

uterine wall repair, n=2; dilatation and curettage, n=1). Embolization was performed with gelatin sponge or multiple particles. Embolization successfully controlled bleeding in 201 of the 229 women for whom embolization was the first second-line procedure (88%). Among all 251 women, embolization successfully controlled bleeding in 217 (87%). Twelve women required a repeat embolization (success in nine cases, one hysterectomy, one laparotomy, one death), nine required hysterectomy, six required laparotomy (one death), three required additional conservative management, one required uterine artery ligation, and three died after the first embolization session. Successful embolization was associated with vaginal birth, absence of DIC, and absence of need for transfusion of > 10 PRBC units (p values < .05).

A retrospective review of embolization for PPH conducted at two Korean hospitals between 2006 and 2011 included data from 176 women (mean age = 33.9 years, 105 vaginal births, 73 primiparous) undergoing 189 embolization procedures. Women who had cesarean births were significantly older than those with vaginal births (p = 0.035). Twenty-five cases of PPH were secondary, and overall, PPH was most frequently due to atony (57.6% of cases). Embolizations were done with gelatin sponge, particles, coils, or a combination. Bleeding successfully stopped after embolization in 158 cases (89.7%). Twelve women needed a repeat embolization, 11 needed a surgical procedure (five hysterectomies), and one needed vascular ligation.

One retrospective case series reporting data from a U.S. tertiary care hospital included 76 women (mean age = 33 years, 18 cesarean births) who had PPH. ⁹⁹ Ten women were excluded from analysis because they had interventions prior to or concomitant with embolization or had an ectopic pregnancy. Embolization (performed with gelfoam and/or coils) successfully controlled bleeding without further procedures or surgeries in 63 of 66 women (95%). Three women required a subsequent hysterectomy. Embolization was successful in 98% (49/50) of the women with primary PPH and 88% (14/16) of the women who had secondary PPH (presentation 4 to 72 days post-birth, mean = 25 days). Women required a mean 0.4 units PRBC after embolization, and the mean hospital stay overall was 3.5 days (range 1-12 days). Among those with primary PPH, mean hospital stay was 3.9 days and was 2 days in the secondary PPH group.

One Japanese retrospective case series included data from 55 women (median age 33 years, 34 vaginal births, median parity = 1, range 0-3) with PPH treated with embolization between 2003 and 2013. Most cases of PPH were due to atony (n = 41), and all women had initial conservative management including uterine massage, packing, and uterotonics. The embolization material was gelatin sponge, and embolization successfully stopped bleeding without an additional intervention in 46 women (84%). Bleeding stopped in two women who went on to hysterectomy after embolization due to uterine necrosis. The study does not report the interventions performed for the other seven women who required another procedure after embolization. Advanced maternal age and retained placenta were independent risk factors for failure of embolization (OR 1.46, 95% CI: 1.12 to 2.18 and OR 15.48, 95% CI: 2.04 to 198.12, respectively).

One French retrospective case series reported outcomes among 102 women (mean age 31.8 \pm 5.9 years, 82 vaginal births, mean parity 2.01 \pm 1.11) undergoing embolization at an academic medical center between 1998 and 2002. Women may have had medical management including uterine massage and oxytocin prior to embolization. PPH was due to atony in 43 percent of women. Mean ICU stay was 2.07 \pm 1.2 days, and units of whole blood, platelets, and fresh frozen plasma transfused ranged from 0 to 31. Embolization was successful without further surgical procedure in 59 women. Fourteen women required a second embolization to control bleeding, and 29 required surgery (nine laparotomies, two uterine artery ligations, seven

hysterectomies, 11 genital tear repairs plus subsequent embolization). Embolization was more successful in women with vaginal births (success in 63/81 vaginal births) compared with cesarean (success in 11/21 cesarean births, p = 0.017; OR for poor outcome associated with cesarean birth: 0.16, 95% CI: 0.04 to 0.5). Atony as the cause of PPH was also associated with greater success (success in 39/44 women; OR 4.13, 95% CI: 1.35 to 12.6).

Another retrospective case series conducted in a French tertiary care hospital reported on success rates for embolization in 98 women with PPH (33 considered "major" PPH, defined as change in peripartum hemoglobin level of ≥ 4 g/dL and/or hemodynamic instability and/or hypovolemic shock). All women had treatment (resuscitation, uterotonics, manual placenta removal, surgical repair of tears as indicated) prior to embolization, and most cases of PPH were due to atony. Forty-five women had vaginal births, 14 had instrumented vaginal births, and 28 had cesarean births. Embolization was performed with gelatin sponge pledgets and coils as needed. Twenty-six women had a surgical procedure prior to embolization (vaginal or cervical suture, n = 17; uterine suture, n = 1; artery ligation, n = 3; hysterectomy, n = 9; packing, n = 2). Embolization successfully controlled bleeding in 90 of the 98 cases of PPH. Women in whom PPH failed to control bleeding required subsequent uterine suture (n = 4), laparotomy for vessel ligation (n = 2), and repair of genital tears (n = 2). Embolization plus uterine sutures failed in three cases, leading to hysterectomy.

In another large retrospective case series from Korea, 257 women (mean age = 32 years, 162 primiparas, 112 cesarean births) underwent embolization for PPH between 2004 and 2011. PPH was most often caused by atony (n = 156 cases), and embolization materials included gelatin sponge, N-butyl-cyanoacrylate, or both. Nineteen cases of PPH were secondary. Nine women had a surgical procedure prior to embolization (eight hysterectomies, one artery ligation). Embolization successfully stopped bleeding in 233 women overall (91%). In the 248 women for whom embolization was the first second-line procedure, embolization was successful in 226 (91%). Women for whom embolization failed to control bleeding were more likely to have DIC (OR 6.57, 95% CI: 1.60 to 26.9, p = .009), and the rate of major complications was significantly greater among failed embolizations vs. successful (9.4% vs. 37.5%, p < .01).

Finally, one retrospective case series conducted in Korea included 52 women (mean age 31.6 years, range=25-40) with secondary PPH. Bleeding began a median 10 days post-birth (range 1-39 days) and was most frequently related to retained placental tissue (44.2% of cases). All women had initial conservative management prior to embolization, which was conducted with gelatin particles, N-butyl cyanoacrylate, and/or microcoils. Embolization successfully controlled bleeding without further procedure or surgery in 47 of 52 women (90.4%). In univariate analyses, successful control of bleeding was not associated with obstetric characteristics, mode of birth, onset of bleeding post-birth, length of stay, amount of transfusion, or cause of bleeding (all p values=ns). One woman needed repeat embolization, one had further conservative management, and three women had subsequent hysterectomy. In the 44 women available for followup at a mean of 12.6 months post-procedure (range 1-62 months), all women had regular menstruation and five had pregnancies, although the number desiring pregnancy was not reported. The investigators note that no complications occurred. Table 11 outlines key outcomes in all studies of embolization.

Table 11. Key outcomes in studies of embolization

Study Design	Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
	Sentilhes et al. 2010 ⁹²⁻⁹⁴ France G1: Embolization alone (58 at followup) G2: Embolization + vessel ligation and/or suture (10 at followup) Quality: Fair	Age NR Parity NR	 Bleeding not controlled by embolization in 11/101 women 7 women required hysterectomy 100% percent of failed cases had blood loss greater than 1500 ml (p < .001) 90% of women in whom embolization failed received more than 5 units PRBC compared with 43% of successful embolizations (p < .004). Cases of failed embolization were more likely to be complicated by wound infection (27% vs. 6 % in the success group, p < .04)
	Chaleur et al. 2008 ⁹⁵ France G1: Embolization (41) G2: Hysterectomy (6) G3: Embolization and hysterectomy (5) Quality: Fair	Age, mean ± SD G1: 29.2 ± 4.65 G2: 30.1 ± 4.11 G3: 36.6 ± 4.56 Primiparous, n (%) G1: 9 (21.9) G2: 2 (33) G3: 0	 All patients had had medical management prior to procedure 5 second-line hysterectomies (G3) were performed due to embolization failure Among 16 women in G1 desiring future pregnancy, all were able to conceive 1-11 months after beginning to try to conceive
Cohort Studies	Ledee et al. 2001 ⁹⁶ France G1: Hysterectomy (10) G2: Bilateral hypogastric artery ligation (48) G3: Embolization (9) Quality: Fair	Age NR Parity NR	All women underwent bimanual compression, oxytocin and prostaglandin IV administration, and resuscitation before further intervention Embolization was primary procedure in 8 cases and secondary in 1. In 3 cases, an additional intervention was needed to control bleeding
	Chan et al. 2013 ⁷⁹ Hong Kong G1: Oxytocin only (33) G1a: Oxytocin ± other uterotonics (16) G2: Uterine compression sutures (21) G3: Embolization alone (4) G4: Uterine balloon tamponade (11) G5: Two second-line therapies (6)	Age, mean ± SD G1-G5: 33.3±4.6 Parity, mean ± SD G1-G5: 21.6±3.2	Mean estimated blood loss in 4 women undergoing only embolization=5.1 liters (range 1.5-15 liters); mean PRBC transfused=20 packs (range 2-32) women (75%) admitted to ICU Embolization successful in 3/5 women; 1 woman required subsequent hysterectomy to control bleeding
	Quality: Fair		

Table 11. Key outcomes in studies of embolization (continued)

Study Design	Author, Year Country Groups (n) Quality	Age, years Parity	Key Outcomes
Cohort Studies	Kayem et al. 2011 ^{77, 82} UK G1: Uterine compression sutures (199) G2: Pelvic vessel ligation (20) G3: Interventional radiology (embolization, arterial balloon) (22) G4: RFVIIa (31) Quality: Fair Kim et al. 2013 ⁴⁹ Korea G1: Embolization (60) G2: Hysterectomy (61) Quality: Fair	Age < 35, n (%) G1: 128 (64) G2: 12 (60) G3: 12 (55) G4: 21 (68) > 35, n (%) G1: 71 (36) G2: 8 (40) G3: 10 (45) G4: 10 (32) Nulliparous, n (%) G1: 92 (46) G2: 3 (15) G3: 6 (27) G4: 9 (29) Age, mean ± SD G1: 31.0 ± 4.8 G2: 31.8 ± 4.0 Primiparous, n G1: 17 G2: 22	 Among all women receiving these second-line therapies, 205 had had prior uterotonic therapy (oxytocin, ergometrine, carboprost tromethamine, misoprostol) alone, 67 had had uterotonics and intrauterine tamponade 19 women had embolization only, 2 had occlusion with intra-arterial balloon and embolization, and 1 had balloon only Interventional radiology after uterotonics alone was successful as first second-line therapy in 12/14 women; 2 went on to hysterectomy. Interventional radiology was successful as first second-line therapy after uterotonics+ tamponade in 7/8 cases. 1 women required an additional (unstated) intervention Overall, 71 women had hysterectomy(47 after failure of second-line therapy, 24 after failure of uterotonics/ tamponade and subsequent treatments) Primary cause of hemorrhage in both groups = atony 8 women in study were Jehovah's Witnesses-4 in each group All women in G1 and G2 received uterotonics (G1: oxytocin = 100%, sulprostone = 68%, Ervin = 36%; G2: oxytocin = 100%, sulprostone = 60.6%; Ervin = 19.6%). 25 women in G1 and 36 in G2 required transfusion prior to procedure Embolization was successful in 96% of G1; 2 women required hysterectomy due to continued bleeding from cesarean uterine wound and vaginal and cervical lacerations Mean days in ICU in G1 = 5 days (5 women). ICU days not reported in G2 but 39 women required ICU care; LOS in hospital was 8.60 days in G1 and 11.5 in G2
Case- Control	Hardeman et al. 2010 ⁹¹ France G1: Embolization (53) G2: No embolization (106) Quality: Poor	Age, mean (range) G1: 34 (19-44) G2: NR Parity, mean (range) G1: 2.02 (1-5)	43 cases of PPH due to atony Embolization successful in controlling bleeding without additional procedure or surgery in 50/53 cases Three women required a second embolization, which was successful in all cases

Table 11. Key outcomes in studies of embolization (continued)

Study Design	Author, Year Country Groups (n) Quality	Age, years Parity		Key Outcomes
Case Series	Inoue et al. 2014 ¹⁰⁸ Japan G1a: Emergency embolization (161) G1b: Prophylactic embolization (50)	Age, mean ± SD G1a: 32.4 ± 4.8 G1b: 30.1 ± 6.1 Primiparous, n (%) G1a: 76 (47.2) G1b: 25 (50)		 One of more embolization procedures successfully controlled bleeding in 91.9% of G1a and 96% of G1b 12 women required more than on embolization procedure, and 18 had hysterectomy Among 113 women followed for 3 months to 3 years post-procedure, 106 resumed menses
	Cheong et al. 2014 ¹⁰⁶ Korea G1: Embolization (117)	Age, mean G1: 32 Primiparous, n (%) G1: 56 (47.9)		Among 117 women undergoing embolization, 19 (16.2%) had secondary PPH 36.8% of women required >10 red blood cell units 14 women required another embolization and/or hysterectomy to control bleeding
	Fiori et al. 2009 ⁹⁷ France G1: Embolization (56) Gaia et al. 2009 ⁹⁸ France G1: Embolization (412)	Age, median G1: 33 Parity, median (range) G1: 2 (1-4) Age, mean G1: 33	 Embolization successful in 55/56 cases (98%) Regular menses in 30/34 available for followup Embolization successfully controlled bleeding in 111 cases; 2 women required hysterectomy post-emboliza 99/107 with available fertility data had resumed mense 	
Casa Sarios	(113)	NR = 2		normal menses in 66 (menorrhagia = 10, oligomenorrhea = 23, amenorrhea = 6) 29 women desired future pregnancy, 18 conceptions mean conception delay 11 months from decision to try to conceive)
Case Series	Lee et al. 2012 ¹⁰¹ Korea G1: Embolization (251)	Age, mean ± SD G1: 32 ± 4 Nulliparous, n (%) G1: 139 (55)	 22 women had surgical procedure before embolization embolization successful in controlling bleeding as the f second-line procedure in 201/229 women (88%) Success rate among all 251 women = 86.5% Success associated with vaginal birth, absence of DIC absence of massive transfusion (all p values < .05) Among 113 women with ≥ 6 months followup, 110 had regular menses 	
	Lee et al. 2009 ¹⁰⁵ Korea G1: Embolization (176)	Age, mean G1: 33.9 Primiparous, n		Bleeding successfully stopped after embolization in 158 cases (89.7%) 2 women had repeat embolization, 11 had surgical procedure (5 hysterectomies), and 1 had vascular ligation some women had more than 1 procedure)

Table 11. Key outcomes in studies of embolization (continued)

Study Design	Author, Year Country Groups (n) Quality	Age, years Parity	Key Outcomes
	Ganguli et al. 2011 ⁹⁹ US G1: Embolization (66)	Age, mean G1: 33 Parity, mean (range) G1: 1.8 (0-9)	 Embolization successfully controlled bleeding without further procedures or surgeries in 63 of 66 women overall (95%). Embolization successful in 14/16 women with secondary PPH (88%) Embolization successful in 49/50 cases of primary PPH (98%) Women required a mean 0.4 units PRBC after embolization Mean hospital stay overall was 3.5 days (range 1-12 days)
	Yamasaki et al. 2013 ¹⁰⁴ Japan G1: Embolization (55)	Age, mean G1: 33 Parity, median (range) G1: 1 (0-3)	 Successful controlling of bleeding without further procedures or surgeries in 46/55 Bleeding stopped in two women who went on to hysterectomy after embolization due to uterine necrosis Advanced maternal age (OR 1.46 95% CI: 1.12 to 2.18) and retained placenta were independent risk factors for failure of embolization (15.48 95% CI: 2.04 to 198.12)
	Touboul et al. 2008 ¹⁰³ France G1: Embolization (102)	Age, mean ± SD G1: 31.8 ± 5.9 Parity, mean ± SD G1: 2.01 ± 1.11	 Embolization successful without further surgical procedure in 59/102 cases Embolization more successful in women with vaginal births (success in 63/81) compared with cesarean (success in 11/21, p = 0.017; OR for poor outcome associated with cesarean birth: 0.16, 95% CI: 0.04 to 0.5) Atony associated with greater success (success in 39/44 women; OR 4.13, 95% CI: 1.35 to 12.6) Mean ICU stay 2.07 ± 1.2 days Units of whole blood, platelets, and fresh frozen plasma transfused ranged from 0 to 31
Case Series	Poujade et al. 2012 ¹⁰² France G1: Embolization (98)	Age, mean ± SD Successful embolization: 32.3 ± 5.7 Failed embolization: 31.2 ± 6.4 Parity, mean ± SD Successful embolization: 2.1 ± 1.3 Failed embolization: 2.1 ± 1.7	 Embolization successfully controlled bleeding in 90 of the 98 women, 26 of whom also had surgical procedure prior to embolization Women in whom PPH failed to control bleeding required subsequent uterine suture (n = 4), laparotomy for vessel ligation (n = 2), and repair of genital tears (n = 2). Embolization plus uterine sutures failed in three cases, leading to hysterectomy
	Kim et al. 2013 ¹⁰⁰ Korea G1: Embolization (257)	Age, mean G1: 32 Primiparous, n G1: 162	 Embolization successful in 233/257 women overall Success rate in the 248 women for whom embolization was the first second-line procedure = 91% Overall, women for whom embolization failed to control bleeding were more likely to have DIC (OR 6.57, 95% CI: 1.60 to 26.9, p = .009)

Table 11. Key outcomes in studies of embolization (continued)

Study Design	Author, Year Country Groups (n) Quality	Age, years Parity		Key Outcomes
	Park et al. 2014 ¹⁰⁷ Korea G1: Embolization for secondary PPH (52)	Age, mean (range) G1: 31.6 (25-40) Parity, primiparous, n (%) G1: 35 (67.3)	• M • Bl • W • In m • St m	ean time to onset of PPH post-birth=13.3 days (range 1-9 days) ost cases due to retained placenta (n=23) eeding successfully controlled in 47/52 women. One oman required repeat embolization, 3 had hysterectomy, had conservative management women followed up for 1-62 months, normal eenstruation returned in 100%; 5 subsequent pregnancies uccess of embolization not significantly associated with aternal characteristics, mode of birth, bleeding onset ost-birth, length of stay, cause of bleeding or transfusion equirements

Abbreviations: CI = confidence interval; DIC = disseminated intravascular coagulation; G = group; ICU = intensive care unit; LOS = length of stay; n = number; NR = not reported; OR = odds ratio; PRBC = packed red blood cells; PPH = postpartum hemorrhage; SD = standard deviation

Embolization Success Rates

As noted earlier, we tabulated success rates reported in studies of embolization in which we could extract data on the effectiveness of the procedure as the initial second-line procedure (i.e., women routinely had first-line conservative management prior to the procedure). Some studies only reported rates in combination with other procedures/interventions or after an initial procedure or intervention, thus not all studies addressing embolization are represented. Success rates for embolization, which was performed using different materials and on different arteries across studies, ranged from 58 to 98 percent (success in 1251/1435 women), with a median rate of 89 percent (Table 12).

Table 12. Success rates after embolization as the initial second-line procedure

	Study Country	Quality	Total N Treated	Total N Successful	% Success
	Kim 2013 ⁴⁹ Korea	Fair	60	58	96.67
	Chan 2013 ⁷⁹ Hong Kong	Fair	5	3	60
Cohort Studies	Zwart 2010 ¹⁰⁹ Netherlands ^a	Fair	114	94	82.46
	Chaleur 2008 ⁹⁵ France	Fair	46	41	89.13
	Ledee 2001 ⁹⁶ France	Fair	8	5	62.50
Case- Control	Hardeman 2010 ⁹¹ France	Poor	53	50	94.34
	Cheong 2014 ¹⁰⁶ Korea	Poor	117	103	88.03
	Yamasaki 2013 ¹⁰⁴ Japan	Poor	55	46	83.64
	Lee 2013 ¹⁰⁵ Korea	Poor	176	158	89.77
	Kim 2013 ¹⁰⁰ Korea	Poor	248	226	91.13
Case Series	Sentilhes 2011 ⁹⁴ France	Poor	100	89	89.00
Series	Ganguli 2011 ⁹⁷ US	Poor	66	63	95.45
	Lone 2010 ¹¹⁰ U.K.	Poor	229	201	87.77
	Fiori 2009 ⁹⁷ France	Poor	56	55	98.21
	Touboul 2008 ¹⁰³ France	Poor	102	59	57.84
	Total	NA	1435	1251	Range: 58-98% Median Success Rate: 89.00%

Note: Success = control of bleeding without further procedure or surgery

Abbreviations: N = number; NA = not applicable

Studies of Surgical Interventions

Uterine Compression Sutures

Key Points

• No good quality studies addressed uterine compression sutures.

^aOutcomes of this study described in section on embolization and hysterectomy

- In one fair-quality prospective cohort study, sutures were effective in controlling bleeding without further procedures or surgeries in 140 of 199 women, all of whom received uterotonics and/or intrauterine balloon tamponade prior to sutures (70% success rate). Sutures were successful in 15 of 21 women in another study (71%).
- Strength of the evidence is insufficient for the success of uterine compression sutures in controlling bleeding given the few studies available.

Overview of the Literature

Three studies addressed uterine compression sutures, one prospective cohort study (reported in two publications), one retrospective cohort study, and two retrospective case series. ^{77, 79, 82, 111} The prospective cohort study, rated as fair quality, reported data collected via the UKOSS. ^{77, 82} Two-hundred and eleven cases of PPH were treated with sutures in the study period. One retrospective cohort study reported on 26 women with massive PPH in Hong Kong. ⁷⁹ The case series reported data from interventions performed by a single surgeon in Argentina ¹¹¹ The study reports on 539 cases of PPH treated with ligation or suture and does not clarify how many women received each technique. Two additional studies of compression sutures reported harms outcomes only and are described under KQ3. ^{62, 66}

Detailed Analysis

One fair quality prospective cohort study reported UKOSS data collected between 2007 and 2009. The study reported an analysis of outcomes of second-line therapies (i.e., interventions received after uterotonics alone or with intrauterine tamponade via balloon or packing. Among women who were initially treated with uterotonics alone, 161 went on to require compression sutures, which were successful in controlling bleeding in 120 cases (74.53% success rate). Twenty-five women required hysterectomy (without another intervening procedure) after sutures. Three women had ligation after suture; seven had either embolization or balloon placement (three of these went on to require hysterectomy); and six had rFVIIa (four ultimately required hysterectomy). Thus, compression sutures with or without subsequent procedures failed to control bleeding in 32 women, leading to hysterectomy. Among 38 women who required sutures after failure of uterotonics plus intrauterine tamponade, 14 went on to require hysterectomy (eight immediately, two after ligation and/or rFVIIa, two after interventional radiology and/or rFVIIa, and two after rFVIIa alone). Overall (among women who received uterotonics and intrauterine tamponade), sutures successfully controlled bleeding in 70 percent of cases (n = 140/199 cases)⁷⁷

Another publication from this study, ⁸²which includes data from the majority (n = 199/211) of the participants who received sutures described above, ⁷⁷ reported on 211 women receiving compression sutures (B-lynch, n = 79; modified B-lynch, n = 48; other, including square sutures or combination sutures, n = 32; unspecified, n = 52) to treat PPH in the study period. The most common reason for the hemorrhage was uterine atony (n = 129, 61%). As in the first study, all women had prior uterotonic treatment either for prophylaxis or treatment of PPH. Ten women had embolization or ligation, 41 had uterine balloon or packing, and two had rFVIIa prior to sutures. Embolization or ligation following sutures was required in 18 cases, rFVIIa in nine, and uterine packing or balloon in 25. Overall, sutures as the initial second-line therapy failed to control bleeding, leading to subsequent hysterectomy, in 46 cases and successfully controlled hemorrhage in 153 cases (sutures were not the initial second-line therapy in 12 cases). Fifty-two women (25%) of all women (those who received sutures as the initial second-line therapy and

those who received sutures in combination with or after another second-line procedure) required hysterectomy to control bleeding. More women who required an additional second-line intervention went on to require hysterectomy (OR 3.09, 95% CI: 1.46 to 6.56).

In a fair quality retrospective cohort study (see full description in Oxytocin and Other Uterotonics section), 42 of 91 women with massive PPH required second-line procedures or surgeries to control bleeding.⁷⁹ A total of 26 women received sutures (including B-Lynch, Hwu, Cho square, and Hayman), 21 of whom received sutures alone, and five of whom also had sequential embolization. In the 21 women receiving sutures alone, bleeding was successfully controlled in 15 (71.4%). Six women required subsequent hysterectomy. None of the women who had both sutures and embolization required hysterectomy. One retrospective case series reported data on 539 cases of PPH treated with either uterine sutures or arterial ligation in hospitals in Argentina between 1989 and 2009. 111 Sutures were placed by a single surgeon, and suture types included B-lynch, Cho, Hayman, and Pereira. The number of sutures compared with ligations, and potential overlap between interventions, is not clear. Overall, the study reports cessation of bleeding in 499 cases. Forty women required hysterectomy, but whether this occurred after suture or ligation or a combination is not clear. B-lynch sutures were reported as successful in 81 of 86 cases, Hayman sutures in 34 of 37, Cho sutures in 281 of 313 cases, and Pereira in 11 of 11 cases, but again, prior or subsequent interventions are not clear. Because the number of women who received sutures as the initial second-line intervention is clearly reported in only two studies, ^{77, 79, 82} we do not include a success rate table for uterine compression sutures. Table 13 outlines data from studies with comparison groups.

Table 13. Key outcomes in studies of uterine compression sutures

Author, Year Country Study Design Groups (n) Quality	Age, Years Parity	Key Outcomes
Kayem et al. 2011 ^{77,} 82 UK Cohort study G1: Uterine compression sutures (199) G2: Pelvic vessel ligation (20) G3: Interventional radiology (embolization, arterial balloon) (22) G4: RFVIIa (31) Quality: Fair	Age < 35, n (%) G1: 128 (64) G2: 12 (60) G3: 12 (55) G4: 21 (68) > 35, n (%) G1: 71 (36) G2: 8 (40) G3: 10 (45) G4: 10 (32) Nulliparous, n (%) G1: 92 (46) G2: 3 (15) G3: 6 (27) G4: 9 (29)	 Among all women receiving these second-line therapies, 205 had had prior uterotonic therapy (oxytocin, ergometrine, carboprost tromethamine, misoprostol) alone, 67 had had uterotonics and uterine tamponade Compression sutures used more often in PPH caused by atony (63%, interventional radiology used more often for cases related to genital or ligament bleeding or clotting abnormalities) Sutures as the first second-line therapy were successful in 120/161 women who received prior uterotonics only; 25 required immediate hysterectomy, 3 required ligation (no subsequent hysterectomy), 7 interventional radiology (3 subsequent hysterectomies), 6 rFVIIa (4 subsequent hysterectomies). In total 32 went on to hysterectomy Among women who received uterotonics plus intrauterine tamponade, sutures were successful in 20/38 cases Overall (across all groups) 71 women had hysterectomy(47 after failure of second-line therapy, 24 after failure of tamponade and subsequent treatments)

Table 13. Key outcomes in studies of uterine compression sutures (continued)

Author, Year Country Groups (n) Quality	Age, years Parity	Key Outcomes
Chan et al. 2013 ⁷⁹ Hong Kong Cohort study G1: Oxytocin only (33) G1a: Oxytocin ± other uterotonics (16) G2: Uterine compression sutures alone (21) G3: Embolization alone (4) G4: Uterine balloon tamponade (11) G5: Two second-line therapies (6) Quality: Fair	Age, mean ± SD G1-G5: 33.3±4.6 Parity, mean ± SD G1-G5: 21.6±3.2	11/26 women receiving sutures required subsequent hysterectomy or embolization (58% success rate) Estimated blood loss among 21 women who received sutures not followed by hysterectomy=2.0 liters (range 1.5-20.0); median 4 units (range 0-77) RBC transfused. Median LOS=7 days (range: 4-31); 38.1% required ICU admission
Palacios- Jaraquemada 2011 ¹¹¹ Argentina Case series G1: Arterial ligation or uterine suture (539)	Age NR Parity NR	 Review of 539 cases of ligation or suture for PPH conducted by single surgeon Techniques successful in controlling bleeding in 499 cases; 40 women required subsequent hysterectomy Suture (B-lynch, Hayman, Cho, Pereira) appears to have been successful in 431 cases but denominator not clearly presented, nor are procedures received prior to or in conjunction with sutures clearly reported

Abbreviations: G = group; ICU = intensive care unit; LOS = length of stay; n= number; NR = not reported; PPH = postpartum hemorrhage; RBC = red blood cells; rFVIIa = recombinant activated factor VIIa; SD = standard deviation

Uterine and Other Pelvic Artery Ligation

Key Points

- No good quality studies addressed uterine and other pelvic artery ligation (hereafter, ligation).
- Rates of successful control of bleeding without further procedures or surgeries ranged from 36 to 96 percent with a median of 92 percent in three studies.
- Strength of the evidence is low for ligation controlling bleeding without further procedures or surgeries.

Overview of the Literature

Five studies reported data on ligation. ^{77, 96, 111-113} Studies include two fair quality cohort studies, one conducted in the U.K., ⁷⁷ and one in France. ⁹⁶ In the prospective study of ligation of pelvic vessels (unspecified), 25 percent of cases of PPH were due to atony, 30 percent due to uterine tears, 20 percent due to accreta, and 25 percent due to other causes, and most women were under age 35 (60%). ⁷⁷ Nearly 40 percent of cases of PPH in the retrospective cohort study, which included cases of bilateral hypogastric artery ligation, were due to atony, and participant age was not reported. ⁹⁶ Studies primarily reported rates of success for ligation. Three

retrospective case series also reported data on ligation: one reported cases of bilateral uterine artery ligation or selective pelvic pedicle ligation, performed by a single surgeon in Argentina, one reported on outcomes after uterine artery ligations over 30 years in a U.S. center, and the final study reported on triple uterine artery ligation conducted over 9 years in France Case series primarily reported success rates and provide little data on participant characteristics.

Detailed Analysis

Outcomes of ligation were reported in a fair quality UKOSS cohort study described fully above. To required vessel ligation as second-line procedure following uterotonics alone. Ligation successfully controlled bleeding in five women, and five required sutures (followed by hysterectomy in three), two required rFVIIa (followed by hysterectomy in one), and two required hysterectomy immediately after ligation. Six women had ligation after uterotonics and intrauterine tamponade failure, and three went on to hysterectomy to control bleeding (two after sutures plus rFVIIa, one after sutures alone).

Another fair quality retrospective cohort study reported data from women with PPH admitted to a French ICU between 1983 and 1998 and included some data on future fertility. 96 Sixty-one cases of PPH occurred in the time period, 48 of which were treated with bilateral ligation of the hypogastric arteries, eight with embolization using gelatin sponge or coils, and five with hysterectomy as the primary procedure. Across groups, 39 women required transfusion of four or more blood units. Most of the 56 women requiring either ligation or embolization as a primary procedure had cesarean births (n = 41). The women requiring primary hysterectomy all had hemorrhagic shock. The primary procedure failed in eight cases (described under each intervention). Among the 48 women undergoing primary ligation, four required hysterectomy to correct bleeding (92% success rate for primary ligation). This study also reported intervention by cause of PPH: 20 women had PPH due to atony and received ligation as the primary intervention. Nineteen of these 20 had cesarean births (elective or emergency). Ligation was successful in controlling bleeding in 18 of 20 cases, with two women requiring subsequent hysterectomy (one vaginal birth and one cesarean birth). Eleven women (10 cesarean births) had PPH due to accreta. Ten ligations were successful in this group; one woman who had a cesarean birth required hysterectomy and subsequently died. Seven women had PPH due to genital tract laceration (seven vaginal births, 4 instrumented), and ligation was successful in all cases. Six women had placental abruption (six cesarean births), and ligation was successful in all cases. Two women had uterine rupture or pre-rupture (two cesarean births) with bleeding controlled successfully by ligation in both cases. Two women had PPH due to uterine artery injury, presumably incurred during cesarean birth. Ligation successfully controlled bleeding in one case, and the other women died. Finally, one woman with a cesarean birth had PPH related to placenta previa. Ligation failed to control bleeding, leading to subsequent hysterectomy. ⁹⁶

One French retrospective case series included 56 women with PPH (median age=31.5, median parity=0.5) who underwent triple uterine artery ligation with (n=43) or without (n=13) concomitant uterine compression sutures. The PPH treatment protocol in the hospital studied included oxytocin followed by sulprostone followed by ligation as needed, sutures as needed, and other procedures including hysterectomy or embolization if bleeding remained uncontrolled. Most cases (80.4%) of PPH were due to atony. All women received initial oxytocin, and 83.9 percent also received sulprostone. Overall, ligation alone and ligation with suture controlled bleeding in 51 of 56 women (91.1%). Four women had a subsequent hysterectomy and one required embolization. Failure of ligation with or without suture occurred more often in cases of

PPH due to accreta (4 cases) compared with atony (1 case, p=.0004, [OR for failure of ligation ± suture=15.07, 95% CI: 1.12 to 201.9, p=.041]). Ligation with or without suture was also significantly less likely to fail when women had first received sulprostone (p=.025).

One retrospective case series reported data on 539 cases of PPH treated with either uterine sutures or arterial ligation in hospitals in Argentina between 1989 and 2009. Interventions were conducted by a single surgeon. The number of sutures compared with ligations, and potential overlap between interventions, is not clear. Overall, the study reports cessation of bleeding in 499 cases. Forty women required hysterectomy, but whether this occurred after suture or ligation or a combination is not clear. Ligation was reported as successful in 68 of 105 cases, but again, prior or subsequent interventions are not clear.

Another retrospective case series reviewed data from 29 years (1963-1992) of ligations performed in a U.S. hospital. Women received initial medical therapy including uterotonics, and 265 underwent bilateral uterine artery ligation after cesarean birth. Atony accounted for most cases of PPH across the study period (n = 135), and the rate of PPH treated with ligation declined across decades (n = 124, 60, 81 per each decade from 1963-1992). Overall, ligation failed to control bleeding in 10 women, eight of whom had abnormal placentation. Six of these 10 women had total hysterectomies, three had sutures, and one had ovarian artery ligation. Most treatment failures (n = 7) occurred in the first decade reviewed. The study reports that menstrual flow was not affected, but method and timing of followup is not clear. Table 14 outlines key outcomes of studies.

Table 14. Key outcomes in studies of uterine and other pelvic artery ligation

Study Design	Author, Year Country Groups (n) Quality	Age, Years Parity	nd other pelvic artery ligation Key Outcomes
Cohort Studies	Kayem et al. 2011 ^{77.} UK G1: Uterine compression sutures (199) G2: Pelvic vessel ligation (20) G3: Interventional radiology (embolization, arterial balloon) (22) G4: rFVIIa (31) Quality: Fair Ledee et al. 2001 ⁹⁶ France G1: Hysterectomy (10)	Age <35, n (%) G1: 128 (64) G2: 12 (60) G3: 12 (55) G4: 21 (68) >35, n (%) G1: 71 (36) G2: 8 (40) G3: 10 (45) G4: 10 (32) Nulliparous, n (%) G1: 92 (46) G2: 3 (15) G3: 6 (27) G4: 9 (29) Age NR Parity NR	 Among all women receiving these second-line therapies, 205 had had prior uterotonic therapy (oxytocin, ergometrine, carboprost tromethamine, misoprostol) alone, 67 had had uterotonics and intrauterine tamponade Ligation as the initial second-line therapy was successful in 5/14 women, 2 went on to immediate hysterectomy, 5 required sutures (3 subsequent hysterectomies), 2 required rFVIIa (1 subsequent hysterectomy). In total, 6 women had hysterectomies. Overall, 71 women had hysterectomy(47 after failure of second-line therapy, 24 after failure of uterotonics/ tamponade and subsequent treatments) All women underwent bimanual compression, oxytocin and prostaglandin IV administration, and resuscitation before further intervention Ligation was primary procedure in 48 women and secondary in 1; ligation failed to control bleeding in 4 cases, which all required hysterectomy
	G2: Bilateral hypogastric artery ligation (48) G3: Embolization (9) Quality: Fair		cases, which all required hysterectomy
	Blanc et al. 2012 ¹¹³ France G1: Triple uterine artery ligation (56)	Age, median (range) G1: 31.5 (17-44) Parity, median (range) G1: 0.5 (0-8)	 Mean red blood cells =4.1 units, mean 2.25 units of fresh frozen plasma. 7 women required ICU admission Ligation with or without concomitant Cho sutures controlled bleeding in 91.1% of women (51/56)
Case Series	Palacios- Jaraquemada 2011 ¹¹¹ Argentina G1: Arterial ligation or uterine suture (539)	Age NR Parity NR	Review of 539 cases of ligation or suture for PPH conducted by single surgeon Techniques successful in controlling bleeding in 499 cases; 40 women required subsequent hysterectomy Ligation appears to have been successful in 68 cases but denominator not clearly reported, nor are procedures received prior to or in conjunction with ligation
	O'Leary 1995 ¹¹² US G1: Uterine artery ligation (265)	Age NR Parity NR	265 cases of PPH treated over 30 years; ligation failed in 10 cases leading to hysterectomy (6 cases), placental site ligation (3 cases), ovarian artery ligation (1 case) Menstrual flow reportedly not affected but followup not clearly described PPH = postpartum hemography rEVIIa = postpartum hemography rEVIIa = postpartum hemography results.

Abbreviations: G = group; ICU = intensive care unit; n = number; NR = not reported; PPH = postpartum hemorrhage; rFVIIa = recombinant activated factor VIIa

Ligation Success Rates

Ligation was performed on multiple sites (e.g., internal iliac, uterine arteries) within and across studies, and rates of successful control of bleeding ranged from 36 to 96 percent with a median of 92 percent (Table 15).

Table 15. Success rates after uterine and other pelvic artery ligation as the initial second-line procedure

Study Design	Study Country	Quality	Total N Treated	Total N Successful*	% Success ^a
Cohort	Kayem 2011 ⁷⁷ UK	Fair	14	5	35.71
Studies	Ledee 2001 ⁹⁶ France	Fair	48	44	91.67
Case	O'Leary 1995 ¹¹² US	Poor	265	255	96.23
Series	Total	NA	422	372	Range: 36-96% Median success rate: 91.67%

^aSuccess = control of bleeding without further procedure or surgery

Abbreviations: NA = not applicable

Embolization and Hysterectomy

Key Points

- One study compared embolization and hysterectomy.
- Embolization failed to control bleeding in 20 cases (18%), leading to 17 hysterectomies.
- Women in the hysterectomy group had significantly more ICU admissions compared with the embolization group (RR 1.6, 95% CI: 1.1 to 2.4) and had a greater median length of stay (LOS, 10 days vs. 7 days).
- Strength of the evidence was low for embolization controlling bleeding without additional procedures or surgeries and insufficient for the effects of hysterectomy.

Overview of the Literature

One fair quality prospective cohort study conducted in the Netherlands¹⁰⁹ compared outcomes following embolization or hysterectomy. The 205 women in the study most frequently had PPH related to atony (33%), and 43.4 percent were age 40 or older.

Detailed Analysis

One fair quality cohort study (Table 16) conducted in the Netherlands (LEMMoN: Nationwide Study into Ethnical Determinants of Maternal Morbidity in the Netherlands) prospectively collected data on severe maternal morbidity from all 98 Dutch maternity hospitals between 2004 and 2006 using a standardized collection form. Two hundred and five women required either embolization (n = 114) or hysterectomy (n = 108) or both (n=17) during the study period. More than 40 percent (43.4%) of women in both groups were age 35 or older, 39.5 percent were nulliparous, and 49.8 percent had cesarean births. The most frequent cause of PPH in the embolization arm was atony (33%) and disorders of placentation (placenta previa, morbidly adherent placenta) in the hysterectomy group (35%). Women in both arms had other interventions prior to either embolization or hysterectomy including oxytocin (> 80% of both

groups); sulprostone (> 50% of both groups); plasma replacement, frozen plasma, or red blood cell transfusion (> 78% of both groups); and other surgical interventions including arterial ligation, B-lynch suture, inspection (6 women in embolization and 11 in hysterectomy groups).

Embolization failed to control bleeding in 20 cases (18%): 17 women in the embolization group also ultimately required hysterectomy to control PPH (two of these were due to uterine necrosis) and one case was resolved with balloon tamponade. In sub-analyses of these failed cases, embolization had a failure rate of 25 percent following cesarean birth. Women in the hysterectomy group required more transfusions (median 14 vs. 10, p = 0.002) and more massive transfusions (\geq eight units of red blood cells) compared with women undergoing embolization (RR 1.5, 95% CI: 1.1 to 2.1); however, timing of transfusion (i.e., pre- or post-embolization or hysterectomy) is not clear. Women in the hysterectomy group also had significantly more ICU admissions compared with the embolization group (RR 1.6, 95% CI: 1.1 to 2.4) and had a greater median LOS (10 days vs. 7 days). ¹⁰⁹

Table 16. Key outcomes in studies of embolization and hysterectomy

Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
Zwart et al. 2010 ¹⁰⁹	Age, greater than 35, %	Women in both groups had additional interventions including misoprostol (13% in both groups), sulprostone (G1: 67%, G2:
G1: Embolization (114)	G1+G2 : 43.4	86%), transfusion (98% of both groups), balloon therapy G1: 21%, G2: 30%), ligation or suture (G1: 10%, G2: 6%)
G2: Hysterectomy (108)	Nulliparity, % G1+G2: 39.5	17 women in G1 went on to have hysterectomy, 1 went on to balloon tamponade after embolization
Quality: Fair	Parity ≥ 3: G1+G2: 7.3	 Women in G2 required more massive transfusions (≥ 8 units red blood cells) than G1 (RR:1.5, 95% CI: 1.1 to 2.1) but the timing of transfusion (pre- or post-procedure) is not clear Women in G2 more often admitted to ICU than women in G1 (RR: 1.6, 95% CI: 1.1 to 2.4); 67 women in G1 admitted to ICU (number NR for G2)
		 Median length of hospitalization for G1 = 7 days (range 1-38) vs. 10 days (range 2-65) for G2

Abbreviations: CI = confidence interval; G = group; ICU = intensive care unit; n = number; NR = not reported; RR = relative risk

Hysterectomy

Key Points

- Two of eight studies reported data to calculate control of bleeding without additional procedures or surgeries. In these two studies bleeding was controlled after hysterectomy as the initial second-line intervention in a median of 57 percent of cases.
- In one case series analyzing data by hospital volume, there was no difference in transfusion, intraoperative injury, length of stay, or medical complications based on hospital volume after adjusting for age, race, hospital size, year of diagnosis, and hospital type.
- Strength of the evidence is insufficient for all hysterectomy outcomes given the few studies available.

Overview of the Literature

Eight studies reported outcomes of hysterectomy. 45, 49, 96, 110, 114-117 Studies included two retrospective cohort studies of fair quality, one conducted in France (n=10)⁹⁶ and the other in

Korea (total n = 61). ⁴⁹ Atony accounted for 75 percent of the 61 cases in one study, ⁴⁹ while PPH in the 10 women undergoing hysterectomy in the second was due to genital tract lacerations in three cases, atony in three cases, placenta accreta or previa or placenta abruption in three cases, and uterine rupture in the final case. Four population-based case series also reported on outcomes following hysterectomy. Case series were conducted in Canada, ¹¹⁴ Denmark, ¹¹⁵ the U.K., ¹¹⁶ and the United States. ⁴⁵. One retrospective case series reported on 55 peripartum hysterectomies conducted at one U.S. hospital. ¹¹⁷ Finally, another retrospective case series conducted at a university hospital in the U.K. and including data from 52 cases of PPH also reported risk factors for hysterectomy. ¹¹⁰Participant ages ranged from 14 to 54 years in the studies reporting age, ^{45, 110, 114} and PPH was typically due to atony (range 30 to 56% of cases) or placenta previa or accreta (range: 20 to 38% of cases). One additional case series assessing hysterectomy reported only harms data and is addressed in KQ3. ⁶⁴

Detailed Analysis

In one fair quality cohort study including women undergoing embolization (results described in embolization section) or hysterectomy, all women were initially treated with uterotonics (oxytocin, ergots, prostaglandins), uterine massage, transfusion (in patients who were not Jehovah's Witnesses) and fluid replacement. Among the 124 women (eight Jehovah's Witnesses) experiencing primary PPH, 61 (mean age 31.8 ± 4.0 years, 22 primiparous, 33 vaginal deliveries) underwent hysterectomy. PPH was most frequently due to atony (75.4%), and mean blood loss prior to procedure was 1288.3 ml. Significantly more women in the hysterectomy group had DIC, hypotension, elevated heart rate, greater blood loss before intervention, and greater total transfusion requirements than in the comparison arm of women undergoing embolization (all p values < 0.001). Mean total LOS was 11.5 days. Thirty-nine women in the hysterectomy group required ICU care; however, the study does not report mean ICU stay. Fifty-seven women in the hysterectomy group required transfusion after surgery, and four also required embolization post-hysterectomy.

In another fair quality retrospective cohort study reporting outcomes after embolization, ligation, or hysterectomy (see full study description in Ligation section above), five of 61 women received hysterectomy as the primary procedure. The women requiring primary hysterectomy all had hemorrhagic shock, and the procedure was not successful at controlling bleeding in four cases. One woman also required subsequent embolization. This study also reported intervention by cause of PPH: hysterectomy was the primary procedure in three cases of PPH due to genital tract laceration (three vaginal births). As noted, one woman required subsequent embolization, and the other two died. Similarly, one woman who had a cesarean birth died after hysterectomy for PPH due to uterine rupture. Hysterectomy successfully controlled bleeding in one case of PPH due to placental abruption. ⁹⁶

One population-based case series reported on outcomes following peripartum hysterectomy due to PPH. In this study there were 315 cases of PPH that resulted in hysterectomy identified via UKOSS between 2005 and 2006. The median ICU stay was 2 days. Sixty-two women had a return to the operating room for a second surgery after hysterectomy. Fourteen percent of these women had a second surgery due to continued bleeding and 6 percent had return due to damage to other organs during hysterectomy. The median number of blood units transfused ranged from nine to 12 depending on etiology of transfusion.

Another population-based case series from the United States was conducted with data from a nationwide validated database that collected quality and resource utilization data (Perspective)

data from 500 facilities in the United States. The main hypothesis of this study was that hospital volume affects outcomes of postpartum hysterectomy. Among the 2,209 patients identified, overall maternal mortality was 1.2 percent among low, intermediate, and high volume facilities, reoperation rates were 3.2 to 6.4 percent (p = 0.02). Intensive care use rates were 45 percent, 39.6 percent and 27.4 percent for low, medium and high-volume institutions, respectively (p < 0.001). The mean length of stay was 3.5 to 4.1 days. After adjusting for age, race, hospital size, year of diagnosis and hospital type, there was no difference in transfusion or length of stay based on hospital volume. Perioperative death was higher at low volume facilities (1.8% compared with 0.9 and 0.8% at medium and high volume hospitals, p = 0.02). Adjusted OR for perioperative death was 0.22 at high volume facilities.

A population-based case series in Denmark collected peripartum hysterectomy data from 1995 to 2004 using the Danish Medical Birth Register, which records information on all births in the country since 1973. 115 Peripartum hysterectomy was defined in this study as a hysterectomy taking place immediately after and up to one month after birth. Out of 653,482 births, there were 152 peripartum hysterectomies to control hemorrhage; thirty percent of cases of PPH were due to atony. Prior to hysterectomy, 80 percent of women received oxytocin, 73 percent prostaglandins, 43 percent misoprostol, and 43 percent ergot alkaloid. Ligation was performed in 21 percent of patients and B-lynch suture was also done in 21 percent prior to hysterectomy. Hysterectomy was more often performed after cesarean birth (n = 101, RR for hysterectomy after cesarean compared with vaginal birth = 11.1, 95% CI: 7.9 to 15.6, p < .0001). Sixteen women (11%) needed reoperation.

An additional population-based case series reported on all cases of postpartum hysterectomy done between 1999 and 2006 in a Canadian hospital.¹¹⁴ All obstetric care in the region is linked to a regional database. Investigators identified all hysterectomies that occurred within 24 hours of birth. A total of 87 peripartum hysterectomies were performed in the study period, a rate of 0.8 per 1,000 births. Thirty-four percent of women in the series had placenta previa or accreta. All women received uterotonics prior to hysterectomy, and 86 percent received blood transfusion. Pelvic vessels were ligated in 33 percent of cases. B-lynch suture was done 3 times. Forty-six women (53%) were admitted to the ICU, and mean length of stay after birth was 6 days (range 2 to 16). Eighty-one percent of hysterectomies took place after cesarean birth (n = 70).

Two retrospective case series reported on emergency hysterectomy outcomes and were conducted in the U.K. 110 and the U.S. 117 In the U.K. series, most (n=50/52) women had primary PPH and all had numerous interventions, including uterotonics, packing, balloon tamponade, and sutures, prior to hysterectomy to control bleeding. 110 In multivariate analyses, multiparity, placenta previa, primary PPH, and failed induction were significant risk factors for hysterectomy (all p values <.02). The U.S. series reported on 55 peripartum hysterectomies (17 vaginal births, 38 cesarean; mean age=29 \pm 6.8), typically for PPH due to atony (56.4% of cases). 117 Mean overall length of stay was 11 ± 7.9 days, mean number units transfused was 6.9 ± 5.3 , and mean estimated blood loss was 3325.6 ± 1839.2 mL. Table 17 outlines outcomes.

Table 17. Key outcomes in studies of hysterectomy

Table 17. I	17. Key outcomes in studies of hysterectomy				
	Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes		
Cohort Studies	Kim et al. 2013 ⁴⁹ Korea G1: Embolization (60) G2: Hysterectomy (61) Quality: Fair	Age, mean ± SD G1: 31.0 ± 4.8 G2: 31.8 ± 4.0 Primiparous, n G1: 17 G2: 22	 Primary cause of hemorrhage in both groups was atony 8 women in study were Jehovah's Witnesses-4 in each group All women in G1 and G2 received uterotonics (G1: oxytocin = 100%, sulprostone = 68%, Ervin = 36%; G2: oxytocin = 100%, sulprostone = 60.6%; Ervin = 19.6%). 25 women in G1 and 36 in G2 required transfusion prior to procedure Embolization was successful in 96% of G1; 2 women required hysterectomy due to continued bleeding from cesarean uterine wound and vaginal and cervical lacerations Hysterectomy was successful in 93% of G2. 4 women required embolization following hysterectomy for extrauterine vaginal bleeding or continued bleeding of ligated vessels 57 women required transfusion post-hysterectomy in G2 Mean days in ICU in G1 = 5 days (5 women). ICU days not reported in G2 but 39 women required ICU care; LOS in hospital was 8.60 days in G1 and 11.5 in G2 		
	Ledee et al. 2001 ⁹⁶ France G1: Hysterectomy (10) G2: Bilateral hypogastric artery ligation (48) G3: Embolization (9) Quality: Fair	Age NR Parity NR	 All women underwent bimanual compression, oxytocin and prostaglandin IV administration, and resuscitation before further intervention Hysterectomy was the primary procedure in 5 women (all with hemorrhagic shock) and secondary in 5 Hysterectomy as a primary procedure failed to control bleeding in 4 cases—3 deaths, 1 subsequent embolization 		

17. Key outcomes in studies of hysterectomy (continued)

17. Key	outcomes in studies of hysterectomy (continued)				
	Author, Year Country Groups (n) Quality	Age, years Parity	Key Outcomes		
Case Series	Knight et al. 2008 ¹¹⁶ UK G1: Hysterectomy (315)	Age NR Parity NR	 Median ICU stay = 2 days Need for further procedure or surgery in 62 cases; 14% due to continued bleeding, 6% due to organ damage incurred during hysterectomy Median number of blood units transfused ranged from 9 to 12 depending on etiology 		
	Wright et al. 2010 ⁴⁵ US G1: Hysterectomy (2209)	Age, n (%) < 30 years: 673 (30.5) ≥ 30 years: 1536 (69.5) (overall median = 33, range = 14 to 50) Parity NR	 35% of cases of PPH due to atony, 35% due to placenta accreta Reoperation rates were 3.2% to 6.4% (p = 0.02 among low, intermediate, high volume hospitals) Intensive care use was 45%, 39.6%, and 27.4% for low, medium and high-volume institutions, respectively (p < 0.001), mean length of stay was 3.5 to 4.1 days No difference in transfusion, intraoperative injury, length of stay, or medical complications based on hospital volume in adjusted analyses Perioperative death was higher at low volume facilities (1.8% compared with 0.9% and 0.8% at medium and high volume hospitals, p = 0.02). Adjusted OR for perioperative death was 0.22 at high volume facilities 		
	Sakse et al. 2007 ¹¹⁵ Denmark G1: Hysterectomy (152)	Age G1: NR Nulliparous, n G1: 36	 Most hysterectomies performed after cesarean birth (n = 101); RR for hysterectomy after cesarean birth compared with vaginal = 11.1, 95% CI: 7.9 to 15.6, p < .0001 Women generally received initial medical management Ligation was performed in 21% and B-lynch suture in 21% prior to hysterectomy 16 women (11%) needed reoperation 		
	Glaze et al. 2008 ¹¹⁴ Canada G1: Hysterectomy (87)	Age, mean ± SD G1: 34 ± 5 Primiparous, n (%) G1: 37 (43)	 All women received uterotonics prior to hysterectomy; 86% had blood transfusion; 33% had pelvic vessel ligation 53% admitted to ICU Mean LOS 6 days (SD = 3, range = 2-16) 		
	Lone et al. 2010 ¹¹⁰ UK G1: Hysterectomy (52)	Age, mean (range) G1: 29.4 (14-54) Parity, mean G1: 1.35	 Most women had multiple interventions prior to hysterectomy: bimanual compression, n = 46; oxytocin, n = 52; arterial ligation, n = 28; uterine packing, n = 18; intrauterine balloon, n = 17; Blynch suture, n = 15; rfVIIa, n = 2 Primary PPH, induction, placenta previa were significant risk factors for hysterectomy in multivariate analyses 		
	Forna et al. 2004 ¹¹⁷ US G1: Hysterectomy (55)	Age, mean ± SD G1: 29.0±6.8 Parity, mean G1: 3.3±2.8	 Mean LOS=11±7.9 days 15 women had uterine artery ligation prior to hysterectomy, 1 had hypogastric artery ligation Women had a mean 2.1±1.2 postoperative complications 		

Abbreviations: CI = confidence interval; G = group; ICU = intensive care unit; LOS = length of stay; n = number; NR = not reported; OR = odds ratio; PPH = postpartum hemorrhage; rFVIIa = recombinant activated factor VIIa; SD = standard deviation

Studies of Combined Approaches

Key Points

- One cohort study of women with primary PPH reported greater need for transfusion, ICU admission, and hospital length of stay in women undergoing procedures and/or surgery compared with women who were medically managed.
- In three studies of women with secondary PPH, interventions included medical and surgical interventions. In one study, curettage resolved bleeding in 92 percent of women.
- Strength of the evidence for studies of combination interventions and length of stay was insufficient given the small sample sizes and inconsistency in interventions.

Overview of the Literature

Four studies addressed combination approaches and reported data in such a way that findings for individual interventions could not be isolated. Studies included two fair quality retrospective cohort studies 118, 119 and two case series 120, 121 that were conducted in France, 118 Israel, 119 the United States, 121 and the United Kingdom. Three studies included women with secondary PPH, typically defined as bleeding occurring \geq 24 hours after birth and up to 12 weeks later. Studies of secondary PPH included a total of 413 women, and all studies typically reported on success of interventions to control bleeding.

Detailed Analysis

One fair quality French retrospective cohort study compared outcomes in women initially treated for PPH medically (n = 147) or using "advanced interventional procedures" (n = 110), which included uterine artery embolization (n = 85), embolization plus surgery (n = 11), or surgery alone (n = 14; surgery included peritoneal packing, arterial ligation, hysterectomy, or combination of all three). 118 Women (median age = 31 years) were treated between 2004 and 2005. Twelve women required hysterectomy: four in the medically managed group and eight in the advanced procedures group (p = NS). Both groups required transfusion, with the procedures group requiring significantly more units of RBC (2.8 vs. 1.2, p = 0.0004) and fresh frozen plasma (1.6 vs. 0.6, p = 0.003). Six women in the medical group and 31 in the advanced group were admitted to the ICU (p < 0.0001), and the median length of stay in the hospital was significantly greater in the procedures group (3.2 days vs. 1.0, p < .0001). However, the procedures group was likely experiencing more severe PPH given their lower median hemoglobin and systolic and diastolic blood pressures than the medically managed group. The study identified five factors that predicted the need for an advanced procedure: abnormalities of placental implantation, prothrombin time < 50 percent, fibringen < 2 g/l, troponin detectable, and heart rate > 115 beats per minute.

Three studies, one fair quality retrospective cohort study and two case series, focused on secondary PPH. $^{119-121}$ The cohort study, conducted in Israel and including data from 1990 to 2002, compared initial surgical evacuation of the uterus (n = 50, mean age = 29.9, 4 cesarean births) or primary medical treatment (n = 118, mean age = 28.5, 16 cesarean births) with regard to immediate complications and future reproduction. 119 The study defined secondary PPH as occurring 24 hours after the end of the third stage of labor and up to 12 weeks later. More women in the medical group also had primary PPH compared with the surgical group (15 vs. 14, p = .03), and more women in the surgical group had manual separation of the placenta than did women in the medical group (8 vs.5, p = .02). Need for blood transfusion, antibiotics,

hysterectomy, uterine perforation, readmission, hospitalization > 2 days, and hemoglobin drop of > 20g/L did not differ significantly between groups. One woman in the surgical group required a hysterectomy (0 in the medical group, p = NS). More women in the medical group required a secondary surgical evacuation than in the surgical group (31 vs. 4, p = .01).

A case series conducted in the U.K. reported on 132 women with secondary PPH (excessive vaginal blood loss or lochial discharge occurring \geq 24 hours after the end of third stage of labor and up to 6 weeks following), 33 of whom had had primary PPH. More than half of the women presented with secondary PPH in the first two weeks postpartum (19% at \leq 7 days after birth, 41% at 8-14 days, 23% at 15-21 days, 12% at 22-28 days, and 5% at > 28 days). Initially, 57 women had conservative management and 75 women had uterine evacuation. Most women (97%) received antibiotics as an initial treatment, 17 percent had blood transfusion, and overall 63 percent had uterine evacuation. The majority of the women were hospitalized (84%), and the mean length of stay was 3.5 ± 2.3 days. Women who were initially managed conservatively were more likely to be readmitted to the hospital than women who had surgical evacuation (OR 7.8, 95 per CI: 1.2-28.8) One woman required a hysterectomy after uterine perforation.

The second case series reports on cases of secondary PPH (defined as vaginal bleeding post-discharge severe enough to require readmission or surgery) over a 10-year period (1981-1991) at two tertiary hospitals in the United States. ¹²¹ One-hundred and thirteen women had secondary PPH (mean age = 26, range = 16-39, 10 cesarean births, 22 cases of prior PPH) occurring at a mean of 18 days postpartum. Eleven percent of bleeding occurred > 6 weeks after birth. Two-thirds of the women required hospitalization (67%, mean LOS = 4 days) and one-third had transfusion (35%, mean PRBC = 3 units). Bleeding resolved in 12% of women with conservative management. The majority of women (88%) had curettage, which was successful for 92%. Of the nine women who required additional surgical intervention to control bleeding, six had hysterectomy, one had ligation, and one had laparotomy. Table 18 outlines outcomes.

Table 18. Key outcomes in studies of combined interventions

Author, Year Country Groups (n) Quality Gayat et al. 2011 ¹¹⁸	Age, Years Parity Age, median (first to	Key Outcomes
France G1: Advanced interventions (embolization, ligation, surgery, packing, hysterectomy) (110) G2: Medical management (147) Quality: Fair	Age, filedian (first to third quartile) G1: 32 (30-36) G2: 31 (27-35) Primiparous, n (%) G1: 32 (29) G2: 57 (39)	 Women in both groups received transfusion, sulprostone (> 80% in each group) prior to procedure Women in G1 received embolization (n = 85), surgery only (n = 14), or embolization + surgery (n = 11). Surgery included one or combination of peritoneal packing, ligation of arteries, hysterectomy. 12 women had a hysterectomy and 11 women had ligation before transfer to study hospital. 14 of these women were still actively bleeding on arrival to study hospital ICU and LOS in obstetric unit significantly longer in G1 vs. G2 (ICU: median 31 days vs. 6 days, p < .0001, LOS in unit: median 3.2 vs. 1.0 days, p < .0001)
Feigenberg et al. 2009 ¹¹⁹ Israel G1: Initial medical treatment for secondary PPH(118) G2: Surgical evacuation of uterus for secondary PPH (50) Quality: Fair	Age, mean G1: 28.5 G2: 29.9 Mean pregnancies prior to PPH G1: 3 G2: 2.7	 All women had secondary PPH—mean time to admission post-birth was 16.8 days in G1 and 27.9 days in G2 (p = .0003) 48 women in G1 and 22 in G2 required > 2 days hospitalization, p = ns 1 woman in G2 required hysterectomy (0 in G1), p = ns
Hoveyda et al. 2001 120 UK G1: Medical and surgical management for secondary PPH (132)	Age NR Nulliparous, n (%) G1: 56 (42.4)	 Initial management of women with secondary PPH was conservative (n = 57) or surgical evacuation (n = 75); 84% were hospitalized More women initially treated conservatively required readmission compared with women initially treated with evacuation (OR 7.8, 95% CI: 2.1 to 28.8) Mean LOS = 3.5 ± 2.3 days
Boyd et al. 1995 ¹²¹ US G1: Medical and surgical management for secondary PPH (113)	Age, mean (range) G1: 26 (16-39) Nulliparous, % G1: 39	 Bleeding resolved in 91/99 women treated with curettage; 6 had hysterectomy, 1 had ligation, 1 had laparotomy Bleeding resolved in 12/99 treated conservatively Mean LOS = 4 days, range 1-19 days

Abbreviations: CI = confidence interval; G = group; ICU = intensive care unit; LOS = length of stay; n = number; NR = not reported; $OR = odds \ ratio$; $PPH = postpartum \ hemorrhage$; $rFVIIa = recombinant \ activated \ factor \ VIIa$

KQ2. Evidence for Choosing One Intervention Over Another and Proceeding to Subsequent Interventions

We did not identify any studies addressing this question.

KQ3. Harms of Interventions for Management of PPH

Key Points

- Fifty studies reported harms of interventions for management of PPH. Eleven of these were assessed as good quality for harms reporting and the remainder as poor quality.
- In four of the five studies that reported harms related to rFVIIa, 2 to 9 percent of women who received rFVIIa had thrombotic complications. None of the women in the two of these studies that had comparator groups had thromboembolic events; however, this may be due to the small sample sizes rather than evidence of an adverse effect of the medication.
- Sixteen studies reported harms in women who underwent embolization; however, the harms reported in these studies are diverse and few studies report the same harms. The most frequently reported adverse events were infertility (0-43%), PPH in subsequent pregnancy (5%-23%), spontaneous abortion in subsequent pregnancy (5%-21%), and hematoma at puncture site (1%-6%).
- Nine studies reported diverse harms among women who had hysterectomy. The most frequently reported adverse events were ureter lesion (0.4%-41%), reoperation (1.8%-29%), infection (7%-54.6%), and bladder lesion (6%-12%).
- Multiple studies reported harms of transfusion (seven studies), intrauterine balloon tamponade (three studies), uterine and other pelvic artery ligation (two studies), curettage (two studies), and combined approaches (two studies); however, they did not report comparable adverse events.
- Two case-control studies reported on adverse pregnancy outcomes following uterine compression sutures to control PPH in the index pregnancy and noted no significantly greater incidence of preterm birth among women who had sutures compared with women in the control group.
- Harms for tranexamic acid, sulprostone, methylergonovine maleate, and carboprost tromethamine were only reported in one study per intervention. Most side effects were mild.
- Strength of the evidence for harms of interventions was typically insufficient given the diversity of harms reported in single studies. Strength of the evidence was low for hematoma, infertility, and menstrual changes associated with embolization and low for a lack of association between embolization and spontaneous abortion. Strength of the evidence was also low for the association of hysterectomy and operative organ damage and reoperation due to the greater number of studies and more consistent reporting of adverse events.

Overview of the Literature

Fifty unique studies (reported in 55 publications) reported harms of interventions for management of PPH. $^{37, 45, 49, 60-66, 69-71, 73-77, 80, 81, 82, 83, 84, 86, 87, 89-95, 97-106, 108-117, 119-121}$ These include two RCTs, $^{37, 69, 70, 81}$ with harms data from one RCT reported in subsequent case series publications; two prospective cohort studies; $^{77, 109}$ nine retrospective cohort studies; $^{92-96, 119}$ four case-control studies; $^{62, 66, 74, 91}$ two pre-post studies; $^{86, 87}$ nine population-based case series; $^{45, 61, 71, 75, 76, 80, 114-116}$ and 23 retrospective case series. $^{63-65, 89, 90, 97-106, 108, 110-113, 117, 120, 121}$ Eleven studies were assessed as good quality for harms reporting; $^{45, 60, 62, 65, 66, 69, 76, 100, 105, 117, 119}$ the remaining were of poor quality. Thirteen studies were conducted in France, $^{37, 61, 69, 70, 81, 87, 91-98, 102, 103, 113}$ nine in the United States, $^{45, 60, 66, 71, 83, 99, 112, 117, 121}$ six in Korea, $^{49, 62, 100, 101, 105, 106}$ five in the United Kingdom, $^{77, 86, 110, 116, 120}$ three in Canada, $^{63, 64, 114}$ two in Ireland, $^{74, 84}$ two in

Japan, ^{108, 122} two (with unclear overlap of participants) in Australia and New Zealand, ^{76, 80} two in Italy, ^{65, 89} two in Finland, ^{73, 90} and one each in Argentina, ¹¹¹ Israel, ¹¹⁹ the Netherlands, ¹⁰⁹ Denmark, ¹¹⁵ and multiple European countries. ⁷⁵

In most studies, authors differentiated harms that seemed to be related to the intervention from those that were thought to be due to complications of PPH. When that is the case, we report only those harms attributed to the intervention. When that distinction was not made, we report all harms listed in the study. In almost all cases of maternal mortality, the authors provided detailed explanations that made it clear that the deaths were due to the PPH and its sequelae rather than the intervention. In this section, we have only reported deaths for which there was no detail about the cause and thus we could not distinguish if it was attributable to the intervention, the hemorrhage, or some other etiology.

Detailed Analysis

Medical Interventions

Pharmacologic Interventions

Tranexamic acid. In an RCT that compared women who received tranexamic acid with women who did not (n = 72 per group), serious side effects did not differ between the two groups. Two women in the tranexamic acid group and one in the control group had deep vein thrombosis (p = 0.37). None of the women experienced renal failure, seizures, or death. Mild, transient adverse effects occurred more often in the tranexamic acid group than in the control group (24% vs. 6%, p = 0.03). These side effects included nausea and vomiting (15% vs. 2%, p = 0.002), phosphenes (11% vs. 3%, p = 0.02), and dizziness (6% vs. 4%, p = 0.28). The trial was not adequately powered to report safety but was good quality for harms reporting.

Sulprostone. In one population-based case series of 1,370 women treated with sulprostone, 51 women (3.7%) experienced at least one side effect. These side effects included digestive effects (n = 34), hyperthermia and chills (n = 7), cardiac effects (n = 5), high blood pressure (n = 2), respiratory effects (n = 2), and dizziness (n = 2). The cardiac side effects (tachycardia, n = 1; atypical chest pain, n = 1; ischemia, n = 3) were considered severe by the investigators and resolved with cessation of sulprostone. Other severe harms included acute hypertension in one woman and acute cyanosis in a woman with asthma, both of which also resolved with cessation of sulprostone. This study, which is part of family of studies reporting on a systems-level intervention for PPH, 37,70,81 was rated as poor quality for harms reporting.

Methylergonovine maleate. One cohort study (rated good quality for harms reporting) used data from U.S. hospital admissions collected over 4 years to identify women who had been given methylergonovine maleate during hospitalization for birth (n = 139,617) and those who had not (n = 2,094,013). The study compared rates of myocardial ischemia and infarction in the exposed and unexposed women. Six women in the methylergonovine maleate group and 52 in the non-methylergonovine maleate group had an acute coronary syndrome (composite of acute myocardial infarction and unstable angina). The adjusted relative risk of developing an acute coronary syndrome associated with methylergonovine maleate exposure was 1.67 (95% CI: 0.40 to 6.97), and the risk difference was 1.44 per 100,000 patients (95% CI: -2.56 to 5.45). Four

women in the methylergonovine maleate group and 44 in the non-exposed group had an acute myocardial infarction (RR for infarction associated with methylergonovine maleate = 1.00m 95% CI: 0.20 to 4.95, risk difference per 100,000 patients = 0, 95% CI: -3.47 to 3.47).

Carboprost tromethamine. One-fifth (n = 48/237) of the participants in a population-based case series experienced a side effect attributed to the drug. Harms reported included diarrhea (11.4%), elevated blood pressure (6.8%), vomiting (6.8%), elevated temperature (2.1%), flushing (1.7%), and tachycardia (1.7%). Quality for the reporting of harms was assessed as poor.⁷¹

Recombinant activated factor VIIa (**rFVIIa**). Five studies (one good⁷⁶ and four poor quality for harms reporting^{73-75, 80}) with rFVIIa as an intervention reported harms. Two women who received rFVIIa in a retrospective cohort study⁷³ (n = 26) experienced adverse events that may be related to the medication. These included pulmonary edema (n = 1) and PE (n = 1). Neither of these events occurred in women who did not receive rFVIIa (n = 22), but this may be due to the small sample size rather than evidence of an effect of the medication.⁷³ One case-control study reported one case of acute respiratory distress syndrome (ARDS) among the six women who received rFVIIa. There were no long term sequelae, though exact long term complications of interest were not described.⁷⁴ In a population-based case series, adverse events potentially related to rFVIIa in the 92 women to whom it was administered included thromboembolism (n = 4; 2 had PE, one had bilateral ovarian vein thrombosis, and one had a thrombus involving the jugular and subclavian vein, upper arm, and axilla that was not thought to be related to rFVIIa), myocardial infarction (n = 1), and allergic reaction (n = 1). None of these events occurred in women who did not receive rFVIIa (n = 16), but this may be due to the small sample size.⁷⁵

Two studies reported data from the same rFVIIa registry for differing time periods; however, because the overlap between studies is not clear, we report these studies separately. In one study, rated as good quality for harms reporting, and including 105 women with PPH, adverse events potentially related to rFVIIa included cerebrovascular accident (n=1), deep venous thrombosis (n=1), and pulmonary embolism (n=1). The other study reporting data from this registry included 175 cases of rFVIIa use for PPH and reported that 15 women (8.6%) had thromboembolic adverse events, the most common of which were venous thrombosis among five women (2.9%), disseminated intravascular coagulation in nine (5.1%), and other thrombosis in three (1.7%). There were two arterial thrombotic events including one (0.6%) myocardial infarction.

Transfusion for Supportive Management of PPH

Seven studies reported harms of transfusion for PPH management. ^{37, 61, 63, 65, 70, 81, 83, 84, 86} One retrospective cohort study included 659 women who received whole blood transfusion, 593 who received packed red blood cells (PRBC) only, and 288 who received a combination of blood products. There was a significant difference in the number of women who experienced acute tubular necrosis (0.3% whole blood only vs. 2% PRBC only vs. 4% combinations), acute respiratory distress (0.5% vs. .3% vs. 2%), pulmonary edema (7% vs. 4% vs. 14%), and hypofibrinogenemia (0.2% vs. 0.3% vs. 16%). ⁸³ In another retrospective cohort study, there were no thrombotic complications or adverse reactions to cryoprecipitate or fibrinogen concentrate among 34 women receiving either treatment. ⁸⁴ In a population-based case series addressing the thromboembolic risk associated with severe PPH and blood replacement therapies in 317 women with severe PPH (defined as uterine bleeding in the first 24 hours after birth, persisting after

manual exploration of the uterine cavity and requiring IV uterotonics with a decrease of hemoglobin > 40g/l⁻¹, or > 4 U RBCs, hemostatic intervention or death), none of the women developed symptomatic deep vein thrombosis (DVT) or PE.⁶¹ Three women developed superficial venous thrombosis (SVT). Severe PPH or packed RBC unit transfusions were found to be a risk factor for SVT. Other variables, such as cesarean birth, absence of low molecular weight heparin use, pre-eclampsia, severe pre-eclampsia, HELLP syndrome, placenta abruption, pregnancy loss, unexplained pregnancy loss, or F12C46T polymorphism were found to be significant risk factors for SVT. In one report from a larger, systems-level RCT ^{37, 70, 81} that included 660 women who received a transfusion, five transfusion-related adverse events (not described) occurred. The investigators considered one case of pulmonary edema to be a severe harm.⁸¹ A pre-post study comparing transfusion with a combination of red blood cells, fresh frozen plasma, and platelets vs. a combination of red blood cells, platelets, and fibrinogen concentrate in 93 women with PPH reported the development of transfusion-associated circulatory overload in four women in the non-fibrogen period and none in the fibrinogen period (p=.04).⁸⁶

Another retrospective case series including 104 women requiring transfusion for PPH reported pulmonary complications in 2.8 percent of women and cardiac complications in 1 percent but did not describe complications further. A final series included 71 women with PPH and assessed the risk of developing transfusion-related acute lung injury (TRALI) associated with transfusion. Of these 71 women, 13 met criteria for a diagnosis of TRALI as they developed new-onset hypoxemia within 6 hours of transfusion without cardiogenic or other cause, and one woman met criteria for possible TRALI with the same symptoms but an alternative risk factor as a possible cause of symptoms. Women with pregnancy-related hypertensive disorders were more likely to develop TRALI (36% vs. 5% in the TRALI vs. no TRALI groups, p=0.006). Age, smoking status, pre-existing morbidities, non-pregnancy related hypertensive disorders, parity, caesarean section, and the need for surgical intervention were not associated with the development of TRALI.

We rated one study as good quality for harms reporting,⁶⁵ and six as poor quality for harms reporting.

Procedures

Uterine balloon tamponade. Only one adverse event was reported among 43 women who had intrauterine balloon tamponade (Bakri balloon) in a pre-post study with poor quality for harms reporting. One woman was diagnosed with endometritis, which was successfully treated with antibiotics. Harms associated with Rusch balloon tamponade in one retrospective case series (poor quality for harms) included one case of inadvertent discharge of the balloon and two cases of postpartum sepsis. Among the 31 of 42 women who did not have hysterectomy and were available for followup 4 to 108 months after the tamponade procedure, seven had had subsequent pregnancies, with four term births, two early abortions, and one ectopic pregnancy. The study did not report the number of women desiring pregnancy; however, 9 of 31 did not desire pregnancy because of psychological trauma associated with the previous pregnancy, and one had difficulty conceiving. Another poor quality case series including 50 women reported two cases of spontaneous expulsion of a Bakri balloon for uterine tamponade and no other complications due to the balloon.

Embolization. Sixteen studies (in multiple publications) reported harms in women who underwent embolization (Table 19); ^{49, 91-95, 97-106, 108, 109} however, the harms reported in these studies are diverse and few studies report the same harms. Table 20 summarizes adverse events of embolization that were comparably reported in two or more studies. The most frequently reported adverse events were infertility (0-43%), PPH in subsequent pregnancy (5%-23%), spontaneous abortion in subsequent pregnancy (5%-21%), and hematoma at a puncture site (1-6%). Although authors report PPH in subsequent pregnancy, it is likely related to history of PPH, which increases risk of recurrence, rather than the intervention. ^{123, 124}

Table 19. Harms reported in embolization studies

Author Year Country Study Design	Quality	n	Followup n Duration	Reported Harms
Kim et al., 2013 ¹⁰⁰ Korea Retrospective case series	Good	257	257 NR	 Paresthesia in the posterior thigh (n = 10, 4%) Uterine abscess (n = 3, 1%) Postembolization syndrome (n = 2, 1%)
Lee et al., 2013 ¹⁰⁵ Korea Retrospective case series	Good	176	Mean: 22.4 months (range: 2-58)	 Postembolization syndrome (n = 13, 9%) Hematoma at the arterial puncture site (n = 3, 2%) Heavier menses (n = 5, 3%) Lighter menses (n = 17, 11%) Dysmenorrhea (n = 1, 0.7%) Uterine infarctions (n = 0) Ischemic injuries (n = 0) Neurologic complications (n = 0) Major complications, not specified (n = 0) Complications in subsequent pregnancies: preterm birth (n = 2/13, 15%)
Lee et al., 2012 ¹⁰¹ Korea Retrospective case series	Poor	251	113 Mean: 30 ± 23 months (range 6-99)	 Dissection of the uterine arteries (n = 2, 0.8%) Transient numbness of the lower extremities (n = 2, 1%) Edema of the lower legs (n = 1, 0.4%) Hematoma at the puncture site (n = 3, 1%) Irregular menses (n = 2, 2%)
Inoue et al. 2014 ¹⁰⁸ Japan Retrospective case series	Poor	211	113 (76 for pregnancy outcomes) 3 months-3 years	 Amenorrhea (n = 7, 6%) Intrauterine infection (n = 6, 5.3%) Asherman syndrome (n = 4, 3.5%) Uterine necrosis (n = 3, 2.7%) Abnormal menses (n = 2, 1.8%) "Overall complication rate"=13.3% Complications in subsequent pregnancies (n=42 pregnancies in 40 of 76 women followed postembolization): preterm births (n=4/42, 9.5%), miscarriages (n=9/42, 21.4%), pregnancy terminations (indication not specified, n=3, 7.1%), recurrent PPH (n=7/42, 23.3%), placenta accreta (n=5, 16.7%)
Cheong et al. 106 Korea Retrospective case series	Poor	117	117 NR	 Uterine necrosis requiring hysterectomy (n = 3, 2.6%) Fever >38.5°C without focus of infection (n = 1, 1.7%) Puncture site hematoma (n = 1, 1.7%)

Table 19. Harms reported in embolization studies (continued)

Author Year Country Study Design	Quality	n	Follow-up n Duration	Reported Harms
Zwart et al., 2010 ¹⁰⁹ Netherlands Prospective cohort	Poor	114	114 NR	 Infection (n = 9, 8%) Acute respiratory distress syndrome (n = 1, 1%) Laparotomy (n = 3, 3%) Ischemic complaints (n = 2, 2%) Maternal death (n = 3, 3%), no details provided
Gaia et al., 2008 ⁹⁸ France Retrospective case series	Poor	113	107 Mean ± SD: 46.4 ± 21.8 months (range: 12-84)	 Pulmonary embolism (n = 2, 2%) Acute pulmonary edema (n = 1, 1%) Myocardial infarction (n = 1, 1%) Femoral vein thrombosis (n = 5, 4%) Urinary disorders (n = 8, 7%) Vaginal dryness (n = 11, 10%) Hot flushes (n = 13, 12%) Dyspareunia (n = 14, 13%) Menorrhagia (n = 10, 10%) Oligomenorrhea (n = 23, 21%) Amenorrhea and diffuse uterine synechiae (n = 6, 6%) Infertility (n = 11/29 desiring pregnancy, 38%) Complications in subsequent pregnancies: spontaneous abortion (n = 1/19, 5%), PPH (n = 3/18, 17%)
Touboul et al., 2008 ¹⁰³ France Retrospective case series	Poor	102	102 NR	 Ischemia of the lumbar plexus (n = 1, 1%) Gluteal pain (n = 1, 1%)

Table 19. Harms reported in embolization studies (continued)

Table 19. Harms reported in embolization studies (continued)				
Author			Follow-up	Reported Harms
Year	Quality	n	n	
			Duration	
Sentilbes et al. 2011 ⁹²⁻⁹⁴	Poor	101	68 (fortility and	- Puttock poorogic requiring debridgment (p = 1
Country Study Design Sentilhes et al., 2011 ⁹²⁻⁹⁴ France Retrospective cohort	Poor	101		 Buttock necrosis requiring debridement (n = 1, 1%) Pulmonary embolism (n = 1, 1%) Postpartum myocarditis (n = 1, 1%) Poncture site hematoma (n = 1, 1%) Postpartum fever (n = 22, 22%) Endometritis (n = 14, 14%) Wound infection (n = 8, 8%) Increased menstruation (n = 11, 16%) Amenorrhea or decreased menstrual flow (n = 15, 22%) Synechia (n = 8, 12%) Ovarian insufficiency (n = 7, 10%) Infertility (13/30 desiring pregnancy, 43%) although the authors state there was no secondary infertility Complications in subsequent pregnancies: miscarriage (n = 4/26, 15%), ectopic pregnancy (n = 1/26, 4%), uteroplacental insufficiency (1/19, 5%), recurrent PPH (n = 6/19, 32%) Psychological outcomes (may be due to PPH or PPH+treatment) Symptoms requiring psychological care post-PPH (n = 2, 3%) Fear of death post-PPH (n = 24, 35%) Negative memory of pain post-PPH (n = 13, 19%) Negative memory of separation from baby post-PPH (n = 6, 9%) Complete amnesia about the birth (n = 3, 4%) Think about event at least once/month (n = 16, 24%) De novo phobia post-PPH (n = 5, 7%)
				 Persistent fear of death (n = 5, 7%) Impossible to have sexual intercourse for ≥ 12 months (n = 4, 6%) Marital problems considered related to event (n = 3, 4%)
				 Fear of PPH recurrence that lead to decision to avoid further pregnancy (n = 14, 21%) Partners' negative feelings about PPH lead to decision to avoid further pregnancy (n = 13, 19%) Anxiety or depression in subsequent pregnancy related to prior PPH (n = 16, 24%)
Poujade et al.,	Poor	98	98	• Pulmonary edema (n = 1, 1%)
2012 ¹⁰² France Retrospective case series			NR	 Uterine necrosis (n = 1, 1%) Hysterectomy due to UAE-associated uterine necrosis (n = 1, 1%) Endometritis (n = 11, 11%) Wound infection (n = 1, 1%)

Table 19. Harms reported in embolization studies (continued)

Table 19. Harms reported in embolization studies (continued)				
Author Year Country Study Design	Quality	n	Follow-up n Duration	Reported Harms
Ganguli et al., 2011 ⁹⁹ US Retrospective case series	Poor	66	66 NR	 Lower extremity DVT (n = 1, 2%) Pancreatitis (n = 1, 2%) Endometritis (n = 1, 2%) Minor complications, not specified (n = 0)
Kim et al., 2013 ⁴⁹ Korea Retrospective cohort	Poor	60	60 2 years	 Transient fever > 38.5°C (n = 11, 18%) Infection per blood culture findings (n = 0) Ovarian failure (n = 1, 2%)
Fiori et al., 2009 ⁹⁷ France Retrospective case series	Poor	56	34 Median 44.4 months (range: 8.3-118.2)	 Hypomenorrhea due to partial corporeal uterine synechiae: (n = 1, 3%) Irregular menstrual bleeding (n = 1, 3%) Infertility (n = 2/15 desiring pregnancy, 13%) Complications in subsequent pregnancies: spontaneous abortion (n = 3/20, 15%) and ectopic pregnancy (n = 1/20, 5%), preterm birth (n = 1/12, 8%), PPH (n = 1/12, 8%)
Yamasaki et al., 2013 ¹⁰⁴ Japan Retrospective case series	Poor	55	55 NR	 Fever (n = 6, 11%) Lower limb neuropathy (n = 1, 2%) Uterine necrosis (n = 2, 4%) Hysterectomy due to UAE-associated uterine necrosis and infection (n = 2, 4%)
Hardeman et al., 2010 ⁹¹ France Case-control	Poor	53	53 Range:12-70 months	 Pain and fever (n = 19, 36%) Hematoma/inguinal pain (n = 3, 6%) Metrorrhagia (n = 2, 4%) Amenorrhea (n = 3, 6%) Infertility (2/14 desiring pregnancy, 14%) Complications in subsequent pregnancies: late miscarriage (n = 1/14, 7%), recurrent PPH (n = 2/12, 17%)
Chauleur et al., 2008 ⁹⁵ France Retrospective cohort	Poor	46	46 Range: 2-11 years	 Allergy to iodine (n = 1, 2%) Acute pulmonary edema related to massive volume expansion (n = 1, 2%) Hematoma from the puncture site resulting in cardiovascular instability (n = 1, 2%) Major hemoperitoneum related to dissection of the epigastric artery (n = 1, 2%) Infertility (n = 0/16 desiring pregnancy) Death from methotrexate-related nephrotoxicity in one woman with placenta percreta given methotrexate in conjunction with embolization; death appears to be related to treatment but not to embolization Complications in subsequent pregnancies: spontaneous abortion (n = 1/19, 5%), twin pregnancy with preterm birth and fetal growth restriction (n = 1/19, 5%), PPH (n = 1/19, 5%)

Abbreviations: DVT = deep vein thrombosis; n = number; NR = not reported; PPH = postpartum hemorrhage; SD = standard deviation; UAE = uterine artery embolization

Table 20. Adverse events reported in multiple embolization studies

Adverse Event	Number of Studies	Incidence
Spontaneous abortion in subsequent	6 ^{91, 92, 95, 97, 98, 108}	5%-21.4%
pregnancy		
Hematoma at puncture site	691, 94, 95, 101, 105, 106	1%-6%
PPH in subsequent pregnancy	5 ^{91, 95, 97, 98, 108}	5%-23.3%
Infertility	5 ^{91, 92, 95, 97, 98}	0-43%
Amenorrhea	4 ^{91, 92, 98, 108}	6%-22%
Preterm birth in subsequent pregnancy	4 ^{95, 97, 105, 108}	5%-15%
Fever	4 ^{49, 94, 104, 106}	1.7%-22%
Uterine necrosis	4 ^{102, 104, 106, 108}	1%-4%
Endometritis or intrauterine infection	4 ^{94, 99, 102, 108}	2%-14%
Lighter menses	3 ^{97, 98, 105}	3%-21%
Heavier menses	392, 98, 105	3%-20%
Irregular menses	391, 97, 101	2%-4%
Infection, not defined or wound infection	3 ^{94, 102, 109}	1%-8%
Thromboembolic event (DVT or PE)	3 ^{94, 98, 99}	1%-4%
Lower extremity neuropathy, including	3 ^{100, 101, 104}	1%-4%
numbness or paresthesia		
Pulmonary edema	3 ^{95, 98, 102}	1%-2%
Ischemia	3 ^{103, 105, 109}	0-2%
Ectopic pregnancy in subsequent	2 ^{97, 115}	4%-5%
pregnancy		
Postembolization syndrome	2 ^{100, 105}	1%-9%

Abbreviations: DVT = deep vein thrombosis; PE = pulmonary embolism; PPH = postpartum hemorrhage

Surgical Interventions

Uterine compression sutures. One case-control study of good quality for harms compared outcomes in the subsequent pregnancy in women who had PPH treated with multiple square or Hayman sutures in the index pregnancy (n=42, mean age=34.8±3.0 years, nulliparous=39) and age- and parity-matched women who had a cesarean birth (n=139, mean age=33.8±3.2, nulliparous=136). Women did not differ significantly in terms of parity, cesarean births, age, interval to next pregnancy, method of conception, or singleton pregnancy. Adverse outcomes did not differ between groups (preterm birth= 2 in suture group vs. 7 in control group; miscarriage=4 in suture group vs. 14 in control group; ectopic pregnancy=1 in suture group vs. 2 in control group; fetal or perinatal loss=1 in suture group vs.1 in control group; chromosomal abnormality=0 in suture group vs. 1 in control group). More women in the suture group had pelvic adhesions in the subsequent pregnancy compared with the control group (34.3% vs. 17.5%, p=.03). Three women in the suture group and two in the control group had PPH in the subsequent pregnancy (p=ns).

Another retrospective case-control study of good quality for harms reporting compared adverse pregnancy outcomes (after 24 weeks gestation) in the subsequent pregnancy in women who had PPH and a B-Lynch suture (n=63) and women who had PPH managed without B-Lynch sutures (n=189). ⁶⁶Women in the non-B-Lynch group were treated with transfusion (n=25), artery ligation (n=7), and uterine artery embolization (n=2). Other treatment modalities were not specified. Groups did not differ at baseline on age, BMI, or adverse outcomes in the index pregnancy, but women in the suture group were less likely to be nulliparous, have greater estimated blood loss, and greater likelihood of blood loss than those who did not receive sutures (all p values<.05). Adverse pregnancy outcomes (abnormal placentation, preeclampsia, preterm birth, impaired fetal growth) did not differ significantly between groups. In analyses adjusted for use of suture in the index pregnancy, blood loss, parity, and prior adverse outcomes, there was no

association between use of B-Lynch sutures and risk for any adverse outcome in the next pregnancy.

Uterine and other pelvic artery ligation. One retrospective cohort (poor quality for harms) reported a case of "secondary hysterectomy disunion with sepsis" (not clearly described) following ligation. ⁹⁶ This study also reports fertility outcomes for an unstated number of women who had ligation: among the number followed, 10 planned another pregnancy and seven were able to conceive 1 to 4 years post-ligation. A retrospective case series described 265 women who underwent uterine artery ligation to treat PPH after a cesarean. ¹¹² Two of the women who had uterine artery ligation had small broad ligament hematomas. None of the women experienced a major complication or long-term adverse effects. This study was rated poor quality for harms reporting.

Uterine compression sutures and uterine and other pelvic artery ligation. In one poor quality retrospective case series including 56 women with PPH who underwent triple uterine artery ligation with (n=43) or without (n=13) concomitant uterine compression sutures, ¹¹³ two women developed endometritis requiring antibiotics (3.6%).

In another retrospective case series of poor quality for harms reporting, 539 women underwent a variety of surgeries involving uterine compression sutures and arterial ligation. Five women had inadvertent ligation of the ureters, and one woman developed uterine necrosis. At 6 to 12 months after surgery, 404 women had a hysteroscopy (n = 100) or MRI (n = 304). Endometrial adhesions were present in three of the women who had hysteroscopy. None of the women who had MRI had endometrial adhesions or uterine morphological alterations. The study also notes 116 successful, spontaneous pregnancies in the study period, but the number desiring pregnancy and the method and timing of followup is not clear.

Hysterectomy. Nine studies reported harms of hysterectomy. $^{45, 49, 64, 109, 110, 114-117}$ In a prospective cohort study, complications among 108 women who underwent hysterectomy included urinary tract lesions (n = 11, including 8 bladder and 3 ureter lesions), ovarian removal (n = 8), infection/abscess (n = 8), relaparotomy (n = 15, including one case of burst abdomen), Sheehan syndrome (n = 4), paralytic ileus (n = 3), DVT/PE (n = 3), and other (n = 2, exact harm not reported).

Harms reported in a retrospective cohort study of 61 women who had a hysterectomy included 14 cases of transient fever and two skin wounds. Blood cultures did not identify any infections.⁴⁹

Reported harms in a retrospective case series of 52 women who had an emergency hysterectomy included ureteric injury (n = 4 women), bladder injury (n = 3), small bowel injury (n = 2), urinary tract infection (n = 4), septicemia (n = 3), wound infection (n = 4), ARDS (n = 9), renal failure (n = 2), DIC (n = 11), repeat surgery (n = 15), and cardiac arrest (n = 2). This authors did not distinguish which harms were specific to hysterectomy, but some of the adverse events (e.g., ARDS and renal failure) are likely unrelated to the surgical intervention.

In one population-based case series reporting data from the UKOSS, 18 of 315 women (6%) undergoing hysterectomy had a return to the operating room for a second surgery due to damage to other organs during hysterectomy. Damage to organs such as ovaries (n = 28), bladder (n = 38) or ureters (n = 14) was reported in 67 women (21%).

In one U.S. population-based case series reporting on 2,209 peripartum hysterectomies, 715 hysterectomies were performed at low volume, 867 at intermediate volume, and 627 at high volume hospitals. 45 Harms included intraoperative injury and surgical and medical complications. Rates of bladder injury ranged from 7 to 9 percent across hospital types; ureteral injury ranged from 2 to 3 percent; intestinal injury from 3 to 4 percent; and vascular and "other" (not defined) injures from 0 to 10.7 percent. Rates of intraoperative injuries did not vary significantly across hospital types. Wound complications were higher in low volume hospitals (9.9%, 6.8%, 6.7% in low, intermediate, and high volume hospitals, respectively). Postoperative hemorrhage rates were 4.3 percent at intermediate volume, 5.9 percent at high volume, and 6.9 percent at low volume hospitals (p = ns). Rates of venous thromboembolism ranged from 0.8 to 2.2 percent (p = ns). Pulmonary complications were lowest in high volume hospitals (9.7%) compared with intermediate (12.6%) and low volume hospitals (14.1%), p = .05. Cardiovascular, gastrointestinal, and infectious complications ranged from 4.3 to 6.4 percent, 7.3 to 8.8 percent, and 11.6 to 12.4 percent, respectively and did not differ significantly across hospital types. Volume was not associated with rates of intraoperative injuries or medical complications in analyses adjusted for age, race, year of diagnosis, insurance status, hospital type, and hospital size. The incidence of perioperative surgical complications, however, was lower in high volume hospitals compared with low volume (OR 0.66, 95% CI: 0.47 to 0.93).

A population-based case series from Denmark with 152 women reported the following complications after hysterectomy: reoperation (n = 16), infection (n = 13), bladder lesion (n = 10), oophorectomy (n = 8), ureter lesion (n = 3), abscess (n = 3), death (n = 2), and pulmonary embolism (n = 1). No details are provided about the women who died.

In one Canadian retrospective review (rated poor quality for harms) of hysterectomies conducted at one institution over 28 years, 56 women (out of 30290 births) had emergency obstetric hysterectomies. ⁶⁴ Harms reported included febrile morbidity (n=31), ureteric injury (n=23), renal failure (n=19), pulmonary atelectasis (n=18), wound infection (n=17), septicemia (n=13), psychological disturbance (n=13), hypovolemia (n=12), and pelvic abscess (n=9)

In another U.S. case series (good quality for harms) including 55 peripartum hysterectomies, investigators classified complications into hematologic (anemia, coagulopathy), infectious (fever, bacteremia), gastrointestinal (ileus), pulmonary (edema, effusion, emboli), genitourinary (urinary retention, hydronephrosis, tubular necrosis), cardiovascular (cardiomyopathy, pericardial effusion), psychiatric (depression), neurologic (encephalopathy), and other (reoperation, readmission, death, wound dehiscence, hematoma, hypokalemia, thrombosis). Women had an average of 2.1±1.2 complications, with most having hematologic (98%) or infectious (54.6%) complications. Eighteen percent of women had other complications, 16 percent of women had pulmonary complications, 10.9 percent had genitourinary, and gastrointestinal, cardiovascular, and psychiatric complications were each experienced by 3.6 percent of women. Less than 2 percent (1.8%) had neurologic complications.

Finally, one Canadian population-based case series reports postoperative complications in 87 women undergoing peripartum hysterectomy: anemia (n = 32), DIC (n = 17), ileus (n = 8), fever (n = 7), depression (n = 1), hematoma (n = 1), and pneumonia (n = 1). This study also did not distinguish which adverse events were thought to be related to hysterectomy versus other causes.

Eight of these studies were assessed as poor quality for reporting harms and one was of good quality. Table 21 outlines harms reported in more than one study. Reoperation is included in the harms for hysterectomy (and not for other procedures or surgical interventions) because it is

typically considered the final surgical intervention and no further procedural or surgical intervention should be expected.

Table 21. Harms reported in multiple hysterectomy studies

Harm	N Studies Reporting	Incidence
Ureter lesion	6 ^{45, 64, 109, 110, 115, 116}	0.4%-41%
Any Infection	5 ^{45, 64, 109, 110, 115, 117}	7%-54.6%
Reoperation ^a	5 ^{109, 110, 115-117}	1.8%-29%
Bladder lesion	5 ^{45, 109, 110, 115, 116}	6%-12%
Fever	3 ^{49, 64, 114}	8%-55%
DVT/PE	3 ^{45, 109, 115}	1%-3%
Psychological effects	2 ^{64, 117}	3.6%-23%
Ileus	2 ^{109, 114, 117}	3%-10.9%
DIC	2 ^{110, 114}	20%-21%

^aNote: reoperation rates in one study¹¹⁷ could have included readmission, death, hematoma, wound dehiscence, hypokalemia, ovarian vein thrombosis.

Curettage. Two retrospective case series, both of poor quality for harms reporting, described women who were treated with curettage for secondary PPH. ^{120, 121} In a series of 99 women, two had documented cases of Asherman syndrome on follow-up and one had uterine perforation from curettage that required repair via laparotomy. ¹²¹ In a series of 85 women, three had uterine perforation, one of whom underwent hysterectomy. ¹²⁰ These were the only harms reported in these studies.

Combined interventions. One prospective cohort study of 272 women addressing multiple second-line therapies (embolization, uterine compression sutures, ligation, and rFVIIa) reported ARDS (five cases), pulmonary edema (11 cases), and cardiac arrest (six cases). The study also reports six instances of the following harms but does not clarify the number of cases of each: hypoxic brain injury, renal failure, pulmonary embolism, and bladder damage after hysterectomy. The study also does not clarify if any of the reported harms were due to intervention or the PPH itself. This study was assessed as poor quality for harms reporting.⁷⁷

In a retrospective cohort study including 168 women with secondary PPH treated initially with either medical approaches or surgical evacuation, two women in the surgical group had uterine perforation. At followup, 12.1 percent of the medical group (n = 90, mean 88.3 months after PPH) and 30.8 percent of the surgical group (n = 41, mean 81.6 months after PPH) had secondary infertility. (p = .06). The majority of the women (74% of medical group and 65% of surgical group) desired a subsequent pregnancy. More women in the surgical group (28%) than medical group (11%) required infertility treatments, but this difference was not significant. The mean number of births among those who conceived was 1.5 in the medical arm and 2.8 in the surgical arm (p = .004) Miscarriages did not differ between groups, and 3 percent of women in the medical group and 16 percent in the surgical arm required adhesiolysis (p = .003) in the followup period. We rated this study as good quality for harms reporting.

Abbreviations: DIC = disseminated intravascular coagulation; DVT = deep vein thrombosis; N = number; PE = pulmonary embolism

KQ4. Effectiveness of Interventions To Treat Acute Blood Loss Anemia in Women With Stabilized PPH

Key Points

- One small RCT reported elevations in hemoglobin in women with anemia after PPH receiving either oral or intravenous iron with no significant between group differences.
- One small RCT reported a decrease in fatigue and improvements in quality of life among women with asymptomatic anemia after PPH treated with transfusion, but differences between groups were not significant.
- Strength of the evidence is insufficient for all outcomes and harms in studies of interventions
 for anemia after PPH given the few studies, small number of participants, and differences in
 intervention approaches.

Overview of the Literature

We identified few studies addressing anemia after PPH is stabilized. Two studies (reported in multiple publications) addressed iron supplementation and transfusion. We did not identify studies of erythropoietin stimulating agents or other interventions. The two RCTs addressing interventions for post-PPH anemia were both rated as poor quality for all effectiveness outcomes and good and poor quality for harms. Studies were conducted in Australia and the Netherlands and assessed transfusion and iron supplementation in women with stabilized hemorrhage. The RCTs included a total of 593 women followed for 6 weeks post-birth.

Detailed Analysis

A randomized non-inferiority trial, rated as poor quality for all effectiveness outcomes and good quality for reporting of harms, conducted in the Netherlands compared the effect of PRBC transfusion versus no intervention on quality of life among women with anemia due to PPH at 37 Dutch university and general hospitals. 125, 126 Eligible women were enrolled between 12 and 24 hours after birth, and had a hemoglobin concentration between 4.8 and 7.9 g/dl after experiencing PPH (defined as blood loss of ≥ 1000 mL and/or decrease hemoglobin concentration of ≥ 1.9 g/dl). Women with severe symptoms of anemia were excluded from the study. In total, 521 women were randomized to receive transfusion with PRBC (259 women) or no intervention (262 women). There were no significant differences in baseline characteristics between groups (no p-value reported), and there was no significant difference between baseline hemoglobin concentration (7.3 vs. 7.4 in the transfusion vs. non-intervention groups, p = 0.56). The hemoglobin at discharge was significantly higher among women receiving transfusions than those that did not (9.0 g/dL vs. 7.4 g/dL in the transfusion vs. non-intervention groups, p < 0.001), but there was not a statistically significant difference in hemoglobin concentration between groups at 6 weeks (12.1 g/dL vs. 11.9 g/dL in the transfusion vs. non-intervention groups, p = 0.18). The non-intervention group had greater mean fatigue, but the difference in mean physical fatigue between groups did not meet pre-specified non-inferiority parameters and was negligible overall. There was no significant difference in health-related quality of life between groups after removing questions not answered within the study timeframe. There was also no significant difference between groups in rate of postpartum depression, which was only

reported in one woman in the entire study. 126 There was no difference between the groups in rates of breastfeeding at 6 weeks (64% vs. 71% in the transfusion vs. non-intervention groups, p = 0.30). There was no difference between the transfusion and no transfusion groups in length of stay or in complications (transfusion reactions, thromboembolic events, urinary tract infections, infected surgical wound, infected episiotomy/rupture, endometritis, and total infectious complications [10.5% vs. 11.4% in the transfusion vs. non-transfusion groups, p = 0.90]).

An Australian RCT (rated as poor quality for all outcomes) compared the effectiveness of intravenous versus oral iron supplementation among anemic women with PPH. 127 Eligible participants were women with iron-deficiency anemia (hemoglobin < 110 g/L and ferritin < 12 µg/L) after PPH. Women were identified within 72 hours of cesarean or vaginal birth with blood loss > 500mL. Women (74 total) were enrolled over a 2-year period, and were randomized to either two intravenous infusions of 200 mg of iron sucrose (31 women) or daily oral ferrous iron sulfate tablets (43 women, total 160 mg iron daily) for a six-week period following enrollment. Hemoglobin and ferritin levels were measured at baseline and on days 1, 14, and 42, and transfusion of PRBC and drug reactions were documented. There was no statistically significant difference in mean hemoglobin levels at any time point between the intravenous and oral iron supplementation groups (baseline hemoglobin 96 vs. 95, p = 0.5; hemoglobin on day fourteen 115 vs. 118, p = 0.2, and hemoglobin on day forty-two 124 vs. 127, p = 0.7 in the IV intravenous iron vs. oral iron groups, respectively). Ferritin was significantly higher on days 14 and 42 among women in the intravenous iron repletion group than the oral iron repletion group (ferritin on day fourteen 101 vs. 37, p < 0.001; ferritin on day forty-two 46 and 19 and p = 0.01). There was no statistically significant difference in rate of red blood cell transfusion between the treatment groups. The study reports arrhythmia in one participant and notes that no other adverse reactions occurred. Table 22 summarizes key outcomes in these studies.

Table 22. Key outcomes in studies in women with stabilized PPH and anemia

Author, Year Country Groups (n) Quality	Age, Years Parity	Key Outcomes
Prick et al. 2014 ^{125, 126} Netherlands G1: Red blood cell transfusion following resolved PPH (258) G2: No transfusion (261) Quality: Poor for all outcomes	Age, mean ± SD G1: 30.7 ± 5.0 G2: 30.9 ± 5.3 Nulliparous, n (%) G1: 152 (59) G2: 143 (55)	 13% of G2 also received transfusion for anemic symptoms, blood loss, endometritis, inability to tolerate parenteral iron G1 received a median of 2 red blood cell units and at discharge had a median Hb concentration of 9.0 g/dl (range: 8.5-9.5) vs. 7.4 (range: 6.8-7.7) in G2, p < .001 Hb concentration at 6 weeks was not significantly different between groups (12.1 vs. 11.9 g/dl) LOS did not differ between groups (median 2 days) Physical fatigue scores were statistically significantly higher in G2 vs. G1 at all time points though the differences were not clinically significant Harms in both groups included transfusion reactions, infections, endometritis, thromboembolic events; group differences were not significant
Froessler et al. 2013 ¹²⁷ Australia G1: IV iron sucrose (31) G2: Oral iron sulfate (43) Quality: Poor for all outcomes	Age, median (range) G1: 28 (26-32) G2: 30 (26-34) Parity NR	 Hb increased significantly in both groups by Day 14 and remained elevated at Day 42; G1: mean at baseline 96 g/dL (range: 87-102) and at Day 42 124 g/dL (118-132); G2: mean at baseline 95 g/dL (range: 89-106) increased to 127 g/dL (range:120-132) No differences in Hb levels between the groups at any time point Increased levels of ferritin in both groups, however time course of changes differed by treatment; levels were significantly increased for G1 from baseline 18 mg/L (range: 11-32), at Day 14 mean 101 (range:82-114) and Day 42 mean = 46 (range: 24-64) while levels for G2 baseline mean = 21 (range:24-52) were increased only at Day 14 = 37 (range: 24-52), and had dropped to by day 42 = 19 (range: 13-33) Ferritin levels were significantly higher for G1 vs. G2 at Day 14 and Day 42 Blood loss at birth was comparable for both groups (mean 775 mL for G1 and 800 mL for G2) No serious drug reactions observed (one patient excluded due to arrhythmia during first iron transfusion but since she had prior occurrence it was deemed not related)

Abbreviations: G = group; Hb = hemoglobin; LOS = length of stay; n = number; NR = not reported; PPH = postpartum hemorrhage; rFVIIa = recombinant activated factor VIIa; SD = standard deviation

KQ5. Effectiveness of Systems-Level Interventions for Management of PPH

Key Points

- No clinical trials demonstrate effectiveness of a systems-level intervention for reducing severity of PPH or improving maternal outcomes.
- The sole cluster randomized trial in 106 French maternity units, with more than 146,000 births, used a multicomponent intervention of academic detailing of protocols, local champions, protocol reminders, and peer review compared to passive dissemination. Prevalence of severe PPH did not differ between arms.
- In general, multicomponent systems-level interventions do not reliably reduce severity of PPH.

- Three European pre-post publications used audit of PPH cases with feedback to teams and individual providers. Two reported significantly reduced incidence of severe PPH, in each case by more than 1 percent absolute risk among total births, and in an extended follow-up of one intervention, sustained at 0.6% among vaginal births.
- No U.S. studies relied primarily on audit and feedback.
- One large and diverse hospital system with 32,059 births across the study period used a
 detailed clinical staging and care algorithm to manage PPH and reduced blood product use by
 26 percent.
- A large urban teaching hospital in U.S., that dramatically revised clinical responsibilities of residents and attending physicians, had no maternal mortality from PPH in a 36-month intervention period that followed a 24-month window with two maternal deaths. Overall PPH severity did not change.
- In a subsequent report, this teaching hospital found an increase in PPH diagnosis (p=0.002), increase in mean estimated blood loss (p = 0.014), and increase in the proportion of PPH with estimated blood loss greater than 1500 mL (p=0.010), though use of uterotonics, balloon tamponade, B-Lynch sutures and embolization increased (p ≤ 0.05). Transfusion, postpartum hysterectomy, and ICU admission did not decline (p > 0.05) though length of stay in ICU was shorter.
- Strength of the evidence is moderate for a lack of benefit for systems-level interventions in reducing PPH incidence or severity; preventing hysterectomy; and affecting ICU admissions. Strength of the evidence is moderate for no effect on the need for transfusion and insufficient for effects on mortality.

Overview of the Literature

We classified research as system-level interventions when an entire administrative unit within a health system was responsible for implementing policies or protocols that were intended to improve management of PPH. The level from which interventions were launched ranged from an entire region of a national health system, to multihospital collaborations, to individual department decisions about labor and delivery routines that encompassed all care providers. Interventions were varied and included broad multicomponent interventions, implementation of emergency response teams, and audit and feedback of outcomes data about severe PPH to groups and individual providers.

We identified a total of nine studies (reported in 11 publications) that were designed to investigate the effectiveness of one or more system-level interventions for reducing severity of PPH or improving specific maternal outcomes. ^{34-37, 67, 68, 128-132} Six were of fair quality, ^{36, 37, 67, 68, 128, 129, 132} and three were of poor quality. ^{34, 35, 130, 131}

Because system-level randomized trials are rare, we decided during design of this review that we would include studies that were not randomized but examined the influence of multicomponent systems-level interventions over time. Eight studies compared a baseline period with subsequent trends after implementation of the interventions intended to improve management of PPH and to reduce severity of adverse maternal consequences. 34-36, 67, 128-130 Within this group one conducted formal trend analyses across a seven-year window beginning with launch 130, 131

For brevity in tables and text we have called these pre-post assessments. One publication provided outcomes from a randomized trial.³⁷ The trial was conducted in 106 maternity units in

defined maternity regions of France.³⁷ Of the remaining pre-post studies, four were conducted in Europe, ^{35, 36, 129-131} and four in the United States.^{34, 67, 68, 128, 132}

When an entire system undertakes a change all the components are working in concert and are typically designed to do so. Given this intentional interaction between parts, the intervention that is being tested is the "bundle" of components that are being conducted together. For example the influence of audit and feedback in the context of an intervention that includes measuring blood loss, mock emergencies practice, and flow charts to track delivery of key treatments at specific intervals is being conducted in a different environment than audit and feedback in an intervention that does not measure blood loss, or use flow charts, but that did incorporate mock emergency practice.

At times in reviews of systems-level approaches the components are similar enough and the trials large enough that we can conduct meta-analyses of trials with well-operationalized outcomes to attempt (while noting the strong influence of context) to partially isolate the influence of a single component on outcomes. In this literature, the lack of a group of strong trials, the variation in implementation of even similar types of components, duplication of populations over time in publications, and wide range of operational definitions of outcomes, made such analysis implausible. We thus considered all components of an intervention as one systems-level intervention in our analyses below.

Detailed Analysis

The outcomes of systems-levels interventions are summarized in Table 23 in reverse chronological order. We summarize outcomes by study design below.

Table 23. Systems-level interventions to improve management of PPH

Author, Year; Country	Study Type & Time Period	Setting & Population Pre: PPH cases/births Post: PPH cases/births	Management Strategies Addressed by Intervention	Outcomes
Dupont et al. 2014 ¹³⁰ , France	Trend Analysis 2005 - 2012 Pre-Post 2005, 2008	Level III maternity unit: 2005: 27/2,919 (1.2%) 2006: 25/3,113 (1.0%) 2007: 9/3,213 (0.7%) 2008: 9/3,213 (0.4%) 2009: 16/3,539 (0.6%) 2010: 13/3,966 (0.4%) 2011: 16/4,019 (0.5%) 2012: 18/4,085 (0.6%) 2 maternity units (level III and level II) Pre: 77/4500 (1.71% Post: 42/5112 (0.82)	Quarterly clinical audit meetings for review of all severe PPH after vaginal birth with trend feedback using process control tools Goal: reduce the incidence of severe PPH; with secondary goals of increasing use of four key management components	Severe PPH (defined by EBL>1500 cc or need for specified interventions including transfusion and surgical interventions) decreased by half (p < 0.001) System reached and maintained reduced PPH target in the first quarter of 2009. Trends for use of all four key management components document statistically significant increase in consistency of use. Pre-Post: Severe PPH declined from 1.52% to 0.96% of births at level III hospital (p = 0.048) and from 2.08% to 0.57% at level II hospital (p < 0.001)
Einerson et al. 2014 ¹²⁸ , 132 United States	Pre-Post 2007 - 2011	Urban tertiary care hospital Pre: 5.3% Post: 6.0% Total cases n = 3105 Total n = 52,819	Multicomponent evidence-based patient safety program to assist in management of PPH: education of all nursing and physician staff, introduction of a management checklist, universal use of active management of third stage Goal: sustained reduction in maternal morbidity from severe PPH	Increase in PPH diagnosis (p=0.002), increase in mean EBL (p = 0.014), and increase in the proportion of PPH with estimated blood loss greater than 1500 mL (p=0.010) Use of uterotonics, balloon tamponade, B-Lynch sutures and embolization increased (p \leq 0.05) Transfusion, postpartum hysterectomy, and ICU admission did not decline (p > 0.05) though length of stay in ICU was shorter.
^a Shields et al. 2014 ⁶⁸ United States	Pre-Post 2010, 2011 (2 mos prior, 5 and 10 mos after)	29 hospital health system including range from small rural to large urban facilities	Labor and delivery nursing and physician education, with three progressive stages of intervention implementation via algorithm. Goal: reduce blood transfusion and peri-partum hysterectomy	Blood product use declined 25.9% (p < 0.01) and hysterectomy declined 14.8% but change was not significant (p = 0.2)

Table 23. S	Table 23. Systems-level interventions to improve management of PPH (continued)										
Author, Year; Country	Study Type & Time Period	Setting & Population Pre: PPH cases/births Post: PPH cases/births	Management Strategies Addressed by Intervention	Outcomes							
Markova et al. 2012 ¹²⁹ Denmark	Pre-Post 2003, 2005, 2007		Multi-professional skills training for management of a range of obstetric emergencies including PPH Goal: reduce need for transfusion and shorten interval to PPH interventions	No effect of the intervention on transfusion for PPH and an unchanged delay in management of retained placenta with trend towards longer duration							
^a Shields et al. 2011 ⁶⁷ United States	Pre- Post 2009, 2011	Rural hospital Pre: 62/2,939 (2.11%) Post: 148/5,813 (2.55%)	Labor and delivery nursing and physician education, with three progressive stages of intervention implementation via algorithm. Goal: promote early intervention, reduce stage of severity of hemorrhage, promote early use of blood products, and reduce DIC	Severity of PPH declined. After implementation 82% of women with PPH were treated successfully with Stage 1 intervention (supportive measures and uterine massage only or with a single dose of tocolytic) compared to 35% at baseline (p = 0.02)							
Deneux- Tharaux et al. 2010 ³⁷ France	Cluster RCT 2004 - 2006	106 maternity units Control: 6.37% of 70,707 Intervention: 6.37% of 76,074	Passive vs. active dissemination of protocol with academic detailing, nurse and physician champions, reminders, and peer review of severe PPH cases Goal: reduce severity of PPH through multi-faceted early intervention	Proportion of women with severe PPH did not differ by intervention group (1.65% control sites and 1.64% intervention sites)							
Audureau et al. 2009 ³⁶ France	Pre-Post 2002, 2005	19 maternity units Pre: 164/17,664 (0.93%) Post: 166/ 17,722 (0.94%)	Multifaceted intervention including dissemination of clinical guidelines, local opinion leaders, reminders, and blood collection bags Goal: Primary goals were use of intervention components, reducing prevalence of severe PPH analyzed as secondary outcome	Prevalence of severe PPH remained constant across time periods. Use of transfusion (p = 0.01) and hemostatic surgery increased significantly (p = 0.03)							
Skupski et al. 2006 ³⁴ United States	Pre-Post 2000- 2001, 2002- 2005	Urban university hospital Major PPH Pre: 12/5811 (0.21%) Post: 49/12,912 (0.38%)	Multicomponent approach including rapid response team, clinical pathways, guidelines, and protocols, dedicated obstetric inpatient service, change in duties, didactic sessions Goal: reduce severity of PPH and improve maternal outcomes	Maternal deaths declined from two deaths in the baseline period to none in the follow-up period (p = 0 .04). Severity of hemorrhage remained unchanged							

Table 23. Systems-level interventions to improve management of PPH (continued)

Author, Year;	Study Type &	Setting & Population	Management Strategies Addressed by Intervention	Outcomes		
Country	Time Period	Pre: PPH cases/births Post: PPH cases/births				
Rizvi et al., 2004 ³⁵	Pre-Post	Single hospital	Audit of PPH > 1,000ml and near- miss maternal mortality for	PPH > 1,000ml declined from 1.7% to 0.45% (p < 0.001) with		
Ireland	6 months in 1999	Pre: 54/3,176 (1.7%) Post: 15/3,300 (0.45%)	departures from guidelines; intervention included review of guidelines, staff training and practice drills	100% adherence to guidelines in the follow-up period		
	months in 2002		Goal: reduce incidence of PPH > 1,000ml			

^aStudies used the same intervention tools in a "comprehensive patient safety initiative "but report on different time periods and different numbers of hospitals; thus, we have analyzed as two separate studies.

Randomized Controlled Trial

In 1998, the French government introduced perinatal networks organized within geographical regions. The networks encompass all public and private hospitals and include at least one tertiary care unit per network. The mandate for networks includes care coordination and quality improvement research. The single clinical trial of multicomponent interventions was a large cluster randomized trial conducted in two large maternity care regions of France representing six networks; 106 of a potential 109 maternity units in these networks participated.³⁷ Sites were stratified within network and by size, then centrally randomized to implement the full intervention or to have the related protocol passively disseminated without programmatic support.

At intervention sites outreach visits were held to plan for implementation and anticipate challenges. A protocol intended to reduce the rate of severe PPH was introduced by usual channels and reinforced through academic detailing by local opinion leaders and by reminders in the maternity units. The intervention proceeded in two phases that allowed sites to consider how to best optimize the quality of implementation at their site, to prepare staff, and to make changes to facilities or resources on hand. All types of care providers were engaged and had roles in the protocol. The second phase included implementation tools such as emergency response kit to hold key drugs, crisis response phone numbers, transfusion and lab order forms, and other items as desired by the units and provision of a "PPH chronological checklist" to track implementation of the protocol, estimate total estimated blood loss, and encourage minimal loss of time in crucial decisions. The intervention also included peer review of all births with severe PPH and critical analysis of the care provided in reference to the protocol guidance.

With a total of more 146,000 births in the two study arms, severe PPH did not differ across sites with an incidence of 1.64 percent at the intervention sites and 1.65 percent at the control comparison sites. Some components of the intervention suggested improvements in practice, such as involving senior staff sooner (p = 0.005), using second-line pharmaceutical options sooner (p = 0.06), and more prompt checks of hematocrit (p = 0.09). However, taken together these differences and the global intervention package did not significantly influence overall

Abbreviations: DIC = disseminated intravascular coagulation; EBL = estimated blood loss; ICU = intensive care unit; PPH = postpartum hemorrhage

maternal outcomes. In a followup case series (n = 9365) from this RCT⁸¹ that assessed transfusion practices, only half (n = 423/858, 49%) of women with PPH and a hemoglobin level below 7.0 g/dL received RBC transfusion. These results suggest poor compliance with transfusion recommendations in the national French guidelines.

Observational Studies

Eight nonrandomized studies used prospective observational designs in which baseline data about processes of care and patient outcomes were collected for an extended period of time prior to implementation of a policy, protocol, or procedure change, ^{34-36, 67, 68, 128-131} then followup data were collected over time after implementation. One study (published in two papers) used the first quarter of the year of implementation as an anchor for trend analysis. ^{130, 131} Across these studies numerous types of components were implemented and evaluated (Table 24).

Table 24. Components of interventions in systems-level studies

Problem solving/quality improvement stage

Specific protocols in place

Phased roll out

Educational components including training sessions or didactic materials

Clinical champions who assisted locally in engrafting implementation

Multi-professional target group meaning nurses and physicians from obstetrics, anesthesia, and potentially pediatrics were included

Mock events or simulations to allow role play of response to PPH

Documented risk assessments such as risk scores recorded on admission to the labor and delivery unit

Use of tracking tools, checklists, or timelines to support protocol implementation and/or ensure timely response

Emergency response kits such as crash carts with key medications and drapes for measuring estimated blood loss

Tools like fluid collection drapes, approaches to weighing linens for fluid, and/or mandates for tracking estimated blood loss

New staffing response plans to provide additional or more senior staffing in the event of PPH

Audit and feedback in which individuals or groups regularly reviewed data from PPH events to examine trends and responsiveness to protocols

Abbreviations: PPH = postpartum hemorrhage

All systems-level studies evaluated the influence of combinations of these approaches (see Table 25). ^{34-37, 67, 128-132} Two of the observational studies documented statistically meaningful changes in use of selected intervention components. ^{36, 128, 132} Increases in use of management strategies included use of uterotonics, ^{128, 132} hemostatic sutures at cesarean, ^{128, 132} hemostatic interventions including embolization and hysterectomy ³⁶ and transfusion ³⁶ in the period after new protocols were introduced. In neither of these studies were the primary maternal outcomes such as incidence of severe PPH, DIC, hysterectomy, or ICU admission decreased.

Four studies reported reduced severity of PPH after implementation of new multicomponent programs. $^{35, 67, 68, 130, 131}$ In the most recent of these, reported in the United States, the investigators established a staging system to define severity. $^{67, 68}$ The staging was linked to the level of intervention ultimately required to control the hemorrhage with higher stages indicating greater morbidity. Use of the comprehensive maternal hemorrhage protocols was described first in a single hospital. In the baseline data collection in this hospital before implementation, 35 percent of women giving birth by cesarean or vaginally were successfully treated with only Stage 1 (basic) interventions such as a single dose of uterotonic and uterine massage. This improved to 82 percent after the systems-level intervention program was in place (p = 0.02). The program emphasized vigilant observation, tracking of time course, and formal measurement of estimated blood loss and also allowed for shifting of staff to better match acuity. They then implemented

this protocol in a 29-hospital system to test influence on reducing transfusion and peri-partum hysterectomy as the clinical outcomes. Blood product use declined 25.9 percent (p < 0.01), but the decline in hysterectomy (14.8%) was not significant (p = 0.2). Unlike in the initial single site study, in the multisite intervention across the 10 months of follow-up there was an increase in the percentage of Stage 2 and 3 interventions. 68

A French study in two maternity units reported in an initial paper 130 that the incidence of severe PPH declined in both a level II and level III hospital with the greater reduction in the lower acuity hospital. Incidence in that hospital fell from 2.09 percent to 0.57 percent of all births (p < 0.001) with a significant but less than one percent drop in the level III unit. In an extended follow-up of the program maintained across the level III sites for seven years, they documented achievement and persistence of a meaningfully reduced incidence of severe PPH to less than 0.6% (p < 0.001). This program and that of the final study that reports reduced incidence was driven predominantly by a process of systematic audit of the charts of severe PPH cases with feedback to suggest improvements. The earliest group to examine audit and feedback reported similar scope of reductions in severe PPH (defined as > 1,000ml estimated blood loss) from 1.7 percent to 0.45 percent (p = < 0.001) while noting that compliance with guidelines for intervention improved to 100 percent in the follow-up period. They attribute a portion of this success to training and use of practice drills.

Table 25. Summary of components of systems-level interventions

Components of interventions Author, Year	Problem Solving/Quality Improvement Stage	Specific Protocols in Place	Phased Roll Out	Educational Component	Clinical Champions	Multi-Professional Target Group	Mock Events/Simulations	Documented Risk Assessments	Tracking Tools/Checklists to Support Protocols	Emergency Response Kits	Tools/Mandate for Tracking EBL	Staffing Response Plan for PPH	Audit and Feedback
Dupont et. al. 2014 130, 131		Х											Х
Einerson et al 2014 128, 132	Х	Х		Х					Х				
Shields et al. 2014 ⁶⁸	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	
Markova et al. 2012 ¹²⁹				Х		Х	Х						
Shields et al., 2011 ⁶⁷	Х	Х	Х	Х		Х	Х	Х	Х	Х	Х	Х	
Deneux-Tharaux et al., 2010 ³⁷	Х	Х	Х		Х				Х	Х	Х		Х
Audureau et al., 2009 ³⁶	Х	Х		Х	Х	Х			Х		Х		
Skupski et al., 2006 ³⁴	Х	Х		Х		Х		Х		Х		Х	
Rizvi et al., 2004 ³⁵		Х		Х			Х						Х
Total Studies (n)	6	8	3	7	2	5	4	3	5	4	4	3	3

Abbreviations: EBL = estimated blood loss; PPH = postpartum hemorrhage

One study in a large urban teaching hospital in the United States examined maternal mortality over a 24-month baseline and a 36-month post-implementation phase. They had two deaths in the period that prompted the systems-level intervention and none during the post-phase (p = 0.036). While this intervention included many similar components to others, the authors also report major adjustments to how operations were changed across the entire department to enhance the ability to have dedicated teams focused on laboring and postpartum women. These included separating coverage responsibilities for gynecologic and obstetric inpatients and redefining the oversight role of the covering obstetrician for both public and private patients. Such staffing and organizational changes exceed that in other studies. Subsequent reports from this teaching hospital implementing additional components of intervention found an increase in PPH diagnosis (p=0.002), increase in mean estimated blood loss (p = 0.014), and increase in the proportion of PPH with estimated blood loss greater than 1500 mL (p=0.010) alongside increased use of interventions like uterotonics, balloon tamponade, B-Lynch sutures and embolization (p \leq 0.05) $^{128,\,132}$

Four of the eight studies, along with the only systems-level RCT, did not document benefits of the tested intervention packages for reducing PPH severity or complications; this includes the study that reported reduced maternal mortality. ^{34, 36, 128, 129, 132} These studies shared common features among those without evidence of effectiveness as well as among those that reported

reduced incidence and/or severity. No clear pattern emerges to suggest an "active ingredient" to these multicomponent interventions.

Audit and feedback was used in two of the three studies that reported reduced severity. In evaluating this evidence it is crucial to underscore that there was no masking of the definitions of severity, of those who assessed severity, or of the overall intent of the research. Because obstetric care providers may use charted estimated blood loss as a proxy for level of concern and desire for vigilance in follow-up assessments, it could be that a shift occurred from labelling someone as high risk by indicating high estimated blood loss at the time of the birth to a lower estimate of estimated blood loss with concerns captured elsewhere in the protocols.

Only the randomized trial conducted any multivariate analysis to take into account secular trends in factors such as proportions of birth by cesarean and vaginal route or scheduled versus emergent cesarean. They detected a statistical trend of falling overall risk of PPH at both control and intervention sites. The reduction was similar over time and did not confound the trial analysis. The authors also used multilevel models to account for clustering within site.

One team reported analyses stratified by potential confounders.³⁶ Two teams used forms of trends analysis including graphical control charts but without adjustment for patient characteristics or route of birth trends.^{131, 132} Others noted changes in trends that could modify risk, such as proportion of births by cesarean, but did not conduct adjusted analyses. Such factors alongside any changes in the risk profile of women receiving care can both obscure potential effects or introduce the appearance of an effect when there is none.

Gray Literature

In response to 10 requests for Scientific Information Packets, we received only one document, an unpublished systematic review conducted by a company that markets the Bakri Postpartum Balloon. The document yielded no studies of relevance for this review; all 23 identified studies were case series, typically with less than 20 participants, and a number were conducted in developing nations. Our search of ClinicalTrials.gov did not yield any results not identified in our other searches.

Discussion

State of the Literature

We included 68 unique studies (76 publications) in this review, including four randomized controlled trials (RCTs), two prospective and 14 retrospective cohort studies, 10 pre-post studies (defined as studies that compare PPH management and/or outcomes before and after an intervention, such as introduction of a new protocol), four case-control studies, and 34 case series. Most studies were conducted in Europe (n = 33), and 18 were conducted in the United States or Canada, 13 in Asia, and three in Australia or New Zealand and one in Argentina (Table 5). No studies were of good quality for effectiveness outcomes. We considered 23 studies as fair quality for effectiveness outcomes and 38 as poor (including case series, which we considered poor quality by default). Seven studies provided only harms data. Among the 50 studies reporting harms, we considered 11 as good quality for harms reporting and the remainder as poor quality.

While a number of studies were classified as prospective or retrospective studies using our study classification algorithm (Appendix G), few cohort studies provided comparative analyses between the groups, and many were confounded by indication in that women who received interventions such as massive transfusion or hysterectomy likely had more severe cases of postpartum hemorrhage (PPH). Given the lack of data from randomized or controlled studies of PPH management, we present data from cohort studies and case series and note potential confounding as appropriate.

Overall, it appears that 50 deaths occurred in the included studies addressing non-systems level interventions out of roughly 152,264 participants (note that 139617 of these participants were included in a large database study reporting harms following methylergonovine maleate given in the peripartum hospitalization⁶⁰). Only one death was potentially linked to PPH management: a woman who was given methotrexate in conjunction with embolization died from methotrexate-related nephrotoxicity. ⁹⁵ The remaining deaths appear to be the result of PPH and its sequelae rather than interventions used for management.

Summary of Key Findings

Findings are summarized below by Key Question (KQ).

KQ1. Effectiveness of Interventions for Management of PPH

Sixty-one unique studies examined the effectiveness of interventions for management of PPH. Some studies addressed multiple interventions. We classified these studies broadly as medical interventions, procedures, and surgical interventions and more specifically by the type of intervention including pharmacologic interventions (12 studies), transfusion (four studies), intrauterine balloon tamponade (five studies), embolization (19 studies), uterine compression sutures (three studies), uterine and other pelvic artery ligation (five studies), embolization and hysterectomy (one study), hysterectomy (eight studies), and combined approaches (four studies).

Medical Interventions

Pharmacologic Interventions

Six of the pharmacologic intervention studies were small, single studies of fair and poor quality with mixed results. The other six pharmacologic intervention studies assessed the effectiveness of recombinant activated factor VIIa (rFVIIa). These small studies (largest n = 175) also had mixed results. Overall, additional research is needed for pharmacologic interventions, particularly in light of the fact that these are typically considered the first line in management of PPH.

Transfusion for Supportive Management of Ongoing PPH

Four studies of fair and poor quality addressed transfusion for PPH management. Two of the studies found ICU admissions and death were higher with combined blood products versus single (whole blood or packed red blood cells [PRBC]) and massive transfusion versus non-massive transfusion. These differences may reflect that women in the groups with poorer outcomes had more severe PPH. A third study found cryoprecipitate and fibrinogen concentrate were equally efficacious. A final pre-post study reported a significant reduction in the usage blood products for PPH after the introduction of fibrinogen.

Procedures

Both of the procedures (uterine balloon tamponade, embolization) we reviewed showed positive results for PPH management. The median success rate (defined as control of bleeding without additional procedures or surgeries) of intrauterine balloon tamponade as the initial second-line procedure (i.e., the first procedure used after first-line conservative management had failed to control bleeding) in one study was 86 percent and 75 percent in two other studies. In a study of a protocol change to add balloon tamponade as the initial procedure after medication failure, rates of some invasive interventions (beyond tamponade) decreased in women who had vaginal births. Uterine balloon tamponade is a relatively simple, fast, and inexpensive procedure that warrants further study.

The median success rate for embolization as the initial second-line procedure among 14 studies was 89 percent (range = 58% to 98%). However, there was wide variation in the materials used for embolization, the arteries that were embolized, and the interventions that were used before and in conjunction with embolization. The availability of embolization, which is performed by an interventional radiologist, varies by hospital; therefore, this treatment modality is not available to all women with PPH.

Surgical Interventions

The effectiveness of surgical interventions varied. The success rate of uterine compression sutures was 70 percent in the one study from which this could be ascertained. In three studies of ligation, the median success rate was 92 percent in (range = 36%-96%). Hysterectomy used as the first procedure after conservative management controlled bleeding without further surgeries or procedures in a median of 57 percent of women (range = 20%-93%) in two studies. One study compared embolization and hysterectomy and reported significantly more ICU admissions and a greater median length of stay in the hysterectomy group than the embolization group.

Combined Approaches

Three studies examined a combination of medical and surgical interventions for secondary PPH. In the two studies that compared medical and surgical approaches, hospital readmission and repeat surgical evacuation occurred more frequently in women who initially received medical management versus surgical.

KQ2. Evidence for Choosing Interventions and Proceeding to Subsequent Interventions

We did not identify any studies addressing this question.

KQ3. Harms of Interventions for PPH

Fifty studies reported harms of interventions for management of PPH; eleven of these were good quality for harms reporting and the remainder were poor. In four of the five studies that reported harms related to rFVIIa, 2 to 9 percent of women who received rFVIIa had thrombotic complications. None of the women in the two of these studies that had comparator groups had thromboembolic events; however, this may be due to the small sample sizes rather than evidence of an adverse effect of the medication. The harms reported in embolization studies are diverse and few studies report the same harms. The most frequently reported adverse events were infertility (0-43%), PPH in subsequent pregnancy (5%-23%), spontaneous abortion in subsequent pregnancy (5%-21%), and hematoma at a puncture site (1%-6%). Two studies of uterine compression sutures reported cases of preterm birth following sutures but noted no significant differences with control groups. The most frequently reported adverse events in nine hysterectomy studies were ureter lesions (0.4%-41%), reoperation (1.8%-29%), infection (7%-54.6%), and bladder lesion (6%-12%). Harms for other procedural or surgical interventions were either incomparable across studies or were only reported in a single study per intervention.

KQ4. Effectiveness of Interventions for Acute Blood Loss Anemia After Stabilization of PPH

Two small, poor quality RCTs addressed interventions for acute blood loss after PPH is stabilized. In a study comparing women treated with intravenous versus oral iron supplementation after PPH, there was no significant difference in hemoglobin level at any time point between groups. In a study that assessed differences in fatigue and quality of life between women treated with blood transfusion versus no transfusion, the difference in these outcomes between groups was minimal and possibly clinically equivalent.

KQ5. Effectiveness of Systems-Level Interventions

Across a range of systems-level interventions that range from complex multiphase project with 11 distinctive components to simple three component models for audit and feedback, findings are inconsistent about benefit. All sites, including those participating in the active sites of the null cluster randomized trial were aware of a programmatic emphasis on improving response to and outcomes of PPH. Despite this built-in bias towards finding an effect – since estimated blood loss was rarely quantitatively measured and self-report of performance would be expected to be optimistic – results of a large trial and the higher quality studies do not

demonstrate ability to reduce incidence or severity of PPH, or key maternal outcomes like transfusion, hysterectomy, and ICU admission.

Strength of the Evidence

Overall the evidence to answer questions about PPH management did not reach standards for high strength of evidence. The strength of evidence (SOE) tables summarize the total number of studies and the number of participants within those studies noting the study designs and quality (Tables 26-32). The tables also provide the assessment of the study limitations, consistency of findings across studies, directness of the evidence, precision of the estimate, and presence of reporting bias. We included case series in our assessment of SOE for harms and success rates of interventions, and we rated SOE for outcomes we considered to be clinically significant, consistently defined, and plausibly linked to the intervention.

SOE is insufficient for all outcomes of oxytocin and other uterotonics, misoprostol, tranexamic acid, carboprost tromethamine, thrombomodulin, and rFVIIa for PPH management due to the study sizes and lack of studies addressing each agent (Table 26). As noted, we identified few studies of medications meeting our review criteria; however, a number of studies of misoprostol and oxytocin have been conducted in developing countries. Four recent systematic reviews of interventions for PPH, including two Cochrane reviews, assessed uterotonics including misoprostol. We summarize these reviews fully in the Findings in Relation to What is Known section below and provide a brief summary here. In one Cochrane review, oxytocin infusion was more effective and caused fewer side effects when used as first-line therapy for the treatment of primary PPH compared with misoprostol. 133 When used after prophylactic uterotonics, misoprostol and oxytocin infusion had similar effects. The review concluded that adding misoprostol for women receiving treatment with oxytocin did not appear beneficial. In another Cochrane review differences in maternal mortality and morbidity, except for fever, did not differ significantly between misoprostol and control groups. 134 The investigators concluded that misoprostol did not increase or decrease morbidity or mortality, with the exception of fever, and the lowest effective dose should be used. In another review of misoprostol vs. placebo, misoprostol did not reduce PPH risk significantly compared with placebo. 135 In the fourth review and meta-analysis, higher doses of misoprostol (600 vs. 400) micrograms) were no more effective at preventing blood loss.⁵⁰

Table 26. Strength of the evidence for studies addressing medications

			or studies addre			D	Fig. dis.
Intervention /Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Oxytocin and Other Uterotonics							
Intervention success	Retrospective cohort-1 fair (91) ⁷⁹	High	Unknown	Direct	Imprecise	NA	Control of bleeding in 45/91 (49%) women receiving oxytocin and other uterotonics. Insufficient SOE for success in controlling bleeding due to single, short-term study with high study limitations
TXA Vs. No TXA							
All outcomes (anemia, transfusion, ICU, blood loss)	RCT-1 poor (144) ⁶⁹	High	Unknown	Direct	Imprecise	Undetected	Less blood loss, need for transfusion, progression to severe PPH in TXA group vs. control, p<.05, but insufficient SOE for all outcomes due to single small, short-term cohort study with high study limitations

Table 26. Strength of the evidence for studies addressing medications (continued)

Table 26. Strength of the evidence for studies addressing medications (continued)										
Intervention / Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade			
Misoprostol Vs. Methyler- gonovine Maleate										
All outcomes (transfusion, uterine preservation)	Retrospective cohort -1 fair (58) ⁷⁸	High	Unknown	Direct	Imprecise	NA	No group differences in need for transfusion, additional medical or surgical treatments. Insufficient SOE for superiority of one agent over another in affecting any outcome due to single small, short-term cohort study with high study limitations			
Sulprostone										
Intervention success	Case series-1 poor (1370) ⁷⁰	High	Unknown	Direct	Precise	NA	Bleeding controlled in 83% of 1370 women receiving sulprostone. Insufficient SOE for success in controlling bleeding due to single, short-term study with high study limitations			

Table 26. Strength of the evidence for studies addressing medications (continued)

	rength of the e	<u>(continuea)</u>	1				
Intervention /Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Carboprost Trometh- amine							
Intervention success	Case series-1 poor (237) ⁷¹	High	Unknown	Direct	Imprecise	NA	Bleeding controlled by carboprost in 81% of 237 cases of PPH. Insufficient SOE for success in controlling bleeding due to single small, short-term cohort study with high study limitations
Thrombo- modulin Vs. No Thrombo- modulin							
All outcomes (uterine preservation, bleeding, transfusion)	Retrospective cohort-1 Fair quality (36) ⁷²	High	Unknown	Direct	Imprecise	NA	Greater D- dimer decrease from baseline in intervention arm vs. control, p<.05. Insufficient SOE for all outcomes due to single small, short- term cohort study with high study limitations

Table 26. Strength of the evidence for studies addressing medications (continued)

			or studies addre			i i	
Intervention / Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
rFVIIa							
Transfusion	Case-control- 1 fair (12) ⁷⁴ Retrospective cohort-1 fair (48) ⁷³	High	Inconsistent	Direct	Imprecise	NA	Greater need for transfusion in rFVIIa group in one study and no difference in the second.
							SOE due to inconsistency in effects on transfusion, high study limitations
Anemia	Retrospective cohort-1 fair (48) ⁷³	High	Unknown	Direct	Imprecise	NA	Insufficient SOE due to one small study with high study limitations;; need for transfusion greater in rFVIIa arm vs. control
Uterine preservation	Case-control- 1 fair (12) ⁷⁴	High	Inconsistent	Direct	Imprecise	NA	Insufficient SOE. No difference in hysterectomy rates in one small, imprecise study with high study limitations
LOS	Retrospective cohort-1 fair (48) ⁷³	High	Unknown	Direct	Imprecise	NA	Insufficient SOE. Similar LOS for treated and untreated groups in one small, imprecise study with high study limitations

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

Abbreviations: ICU = intensive care unit; LOS = length of stay; NA = not applicable; PPH = postpartum hemorrhage; RCT = randomized controlled trial; rFVIIa = recombinant activated factor VIIa; SOE = strength of the evidence; TXA = tranexamic aid

The SOE for outcomes related to transfusion and uterine balloon tamponade is insufficient (Table 27). While there were three fair quality studies of transfusion, two of these were so confounded that we could not confidently ascertain their outcomes. There is low SOE for embolization controlling bleeding without additional procedures or surgeries.

Table 27. Strength of the evidence for studies addressing other medical interventions and

procedures

Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Transfusion for Supportive Management of PPH							
ICU admission and overall LOS	Retrospective cohort-3 fair (1700) ⁸³⁻⁸⁵	High	Inconsistent	Direct	Precise	NA	Insufficient SOE due to inconsistency in direction of effect (greater LOS and ICU admission in transfusion or whole blood groups in 2 studies; no group differences in another study), high study limitations

Table 27. Strength of the evidence for studies addressing other medical interventions and procedures (continued)

Uterine Balloon Tamponade							
Intervention success ^b	Pre-post-1 fair (43) ⁸⁷ Retrospective cohort-1 fair (12) ⁷⁹ Case series-3 poor (153) ⁸⁸⁻⁹⁰	High	Consistent	Direct	Imprecise	NA	Balloon tamponade without further procedure/surg ery controlled bleeding in 75%-86% of women in 3 studies, and tamponade plus additional intervention controlled bleeding in 86- 98% in another 2. Insufficient SOE due to small sample sizes, high study limitations
Embolization							
Intervention success ^b	Prospective cohort-1 fair (114) 109 Retrospective cohort-4 fair (114) 49, 79, 95, 96 Case-control-1 poor (53) 1 Case series-9 poor (1232) 94, 97, 99, 100, 103-106, 110	High	Consistent	Direct	Precise	NA	Low SOE for success of embolization in controlling bleeding without additional procedures or surgeries (median success rate of 89% as initial second-line intervention; conservative management and severity of PPH varied across studies). A higher SOE is not possible due to the lack of comparisons in this literature and small sample sizes

Abbreviations: ICU = intensive care unit; LOS = length of stay; NA = not applicable; PPH = postpartum hemorrhage; SOE = strength of the evidence

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

bSuccess defined as control of bleeding without additional procedures or surgeries when used as the initial second-line procedure (i.e., the first procedure used after first-line conservative management failed to control bleeding)

There is insufficient SOE for the success of uterine compression sutures (Table 28). There is low SOE for ligation controlling bleeding without further procedures or surgeries and insufficient SOE for all hysterectomy outcomes.

Table 28. Strength of the evidence for studies of surgical interventions

Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Report- ing Bias	Finding Strength of Evidence Grade
Compression Sutures							
Intervention success ^b	Prospective cohort-1 fair (211) ^{77, 82} Retrospective cohort-1 fair (26) ⁷⁹	Medium	Consistent	Direct	Imprecise	NA	Insufficient SOE due to small studies; bleeding controlled by suture following conservative management in 60%-70% of women
Ligation							
Intervention success ⁵	Prospective cohort-1 fair (20) ⁷⁷ Retrospective cohort-1 fair (48) ⁹⁶ Case series-2 poor (321) ¹¹²	Medium	Consistent	Direct	Precise	NA	Low SOE due to small sample size. 92% success rate for controlling bleeding without further procedure or surgery in 3 small studies of ligation alone. Ligation with or without suture controlled bleeding in 91% in one case series
Hysterectomy							
LOS, ICU admission	Prospective cohort-1 fair (108) 109	High	Unknown	Direct	Imprecise	NA	Insufficient SOE due to few comparative studies, high limitations

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

^bSuccess defined as control of bleeding without additional procedures or surgeries when used as the initial second-line procedure (i.e., the first procedure used after first-line conservative management failed to control bleeding)

Abbreviations: ICU = intensive care unit; LOS = length of stay; NA-not applicable; PPH = postpartum hemorrhage; SOE-strength of the evidence

Table 29 outlines the SOE for studies of combination interventions. Two studies assessed length of stay; however, we considered the SOE for the effect of intervention to be insufficient given the small sample sizes and inconsistency in interventions.

Table 29. Strength of the evidence for studies of combination interventions

Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
LOS in women with primary PPH	Retrospective cohort-1 fair (257) ¹¹⁸	High	Unknown	Direct	Imprecise	NA	Greater LOS in women undergoing procedures/ surgeries vs. medical management, p<.001. Insufficient SOE due to small, single study
LOS in women with scondary PPH	Retrospective cohort-2 fair (168) ¹¹⁹	High	Unknown	Direct	Imprecise	NA	No differences in LOS between surgical and medical management groups. Insufficient SOE due to small, single study

Abbreviations: LOS = length of stay; NA = not applicable; PPH = postpartum hemorrhage; SOE = strength of the evidence

The SOE for harms of interventions for management of PPH can be found in Table 30. Generally SOE was insufficient given diversity of harms reported in single studies. However, SOE rose above insufficient for selected harms related to embolization and hysterectomy due to the greater number of studies and more consistent reporting of adverse events. As noted, few studies of uterotonics met our inclusion criteria; however, harms reported in recent systematic reviews of uterotonics for PPH treatment included shivering and fever (see Findings in Relation to What's Known section for full summary). In one review, oral misoprostol was associated with a significant increase in vomiting and shivering compared with either oxytocin or rectal misoprostol. In another review, differences in maternal mortality and morbidity, except for fever, did not differ significantly between misoprostol and control groups. A Risk of fever was increased in misoprostol groups and was highest in studies with a misoprostol dose of 600 μ g or more. In another review of misoprostol vs. placebo, shivering and fever were significantly more common in misoprostol arms. A fourth review noted more adverse effects related to misoprostol vs. placebo.

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

While evidence in the current review was insufficient to comment on the association between rFVIIa and thrombolic events, studies in other populations have suggested increased risk of arterial events. In one review of RCTs in non-hemophilia patients, the pooled relative risk of thrombolic events across studies of prophylactic and therapeutic uses of rFVIIa was 1.45 (95% CI: 1.02 to 2.05). Another review of fertility outcomes following embolization, ligation, and sutures concluded that the techniques reviewed did not appear to compromise fertility, but the number and quality of studies was limited. ¹³⁷

Table 30. Strength of the evidence for harms of interventions for management of PPH

Intervention Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Pharmacologic							
Tranexamic acid All harms	RCT-1 good (114) ⁶⁹	Low	Unknown	Direct	Imprecise	Undetected	Insufficient SOE due to small sample size, but serious harms did not differ between groups and mild, transient harms occurred more often in TXA group
Sulprostone All harms	Case series-1 poor (1370) ⁷⁰	High	Unknown	Direct	Precise	NA	Insufficient SOE as only one study considered poor quality for harms reporting

Table 30. Strength of the evidence for harms of interventions for management of PPH (continued)

Intervention Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Pharmacologic							
Methyler- gonovine maleate Acute coronary syndrome and myocardial infarction	Retrospective cohort study-1 good (139,617) ⁶⁰	Low	Unknown	Direct	Precise	NA	Low SOE for lack of association of methyler-gonovine maleate with acute coronary syndrome and myocardial infarction; no significant difference in the incidence of these conditions in the exposed and non-exposed groups
Carboprost tromethamine All harms	Case series-1 poor (237) 71	High	Unknown	Direct	Imprecise	NA	Insufficient SOE as only one study considered poor quality for harms reporting
rFVIIa Thrombo- embolic events	Case-control- 1 fair (12) ⁷⁴ Retrospective cohort-1 fair (48) ⁷³ Retrospective case series- 1 good, 2 poor (unclear due to overlap of 2 studies) ^{75, 76, 80}	High	Consistent	Direct	Imprecise	NA	Insufficient SOE; 4 of 5 studies (unclear overlap in 2 studies) reported thromboembol ic events (pulmonary embolus, deep vein thrombosis, myocardial infarction) but sample sizes were small and study limitations are high

Table 30. Strength of the evidence for harms of interventions for management of PPH (continued)

Intervention Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations a	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Other Medical Interventions							
Transfusion for supportive management of PPH All harms	Retrospective cohort-2 poor (1574) ^{83, 84} Pre-post-1 poor (93) ⁸⁶ Case series-1 good, 3poor (1152) ^{61, 63, 65, 81}	High	Inconsistent	Direct	Precise	NA	Insufficient SOE due to inconsistency, study limitations
Procedures							
Uterine balloon tamponade All harms	Pre-post-1 poor (43) ⁸⁷ Case series-2 poor (102) ⁸⁰ ,	High	Consistent	Direct	Imprecise	NA	Insufficient SOE due to small studies with high limitations
Embolization Infertility	Retrospective cohort-2 poor (152) ⁹²⁻⁹⁵ Case-control-1 poor (53) ⁹¹ Case series-2 poor (169) ^{97,} ₉₈	High	Inconsistent	Direct	Imprecise	NA	Low SOE for negative effect of embolization on future fertility. Infertility rate among women who had embolization in these studies was greater than that of the overall population rate (range 0-43%), but few women (n = 300) available for long-term followup; high study limitations and inconsistency among studies

Table 30. Strength of the evidence for harms of interventions for management of PPH (continued)

Intervention	Study	Study	Consistency	Direct-	Precision	Reporting	Finding
	Design	Limit-		ness		Bias	Strength of
Outcome		ations					Evidence
	Quality and	а					Grade
	Number of						
	Studies (N Total with						
	PPH)						
Embolization	-						
Spontaneous	Retrospective	High	Consistent	Direct	Imprecise	NA	Low SOE for
abortion in	cohort-2 poor (152) ⁹²⁻⁹⁵						lack of
subsequent pregnancy	(152)**						association between
programoy	Case-control-						embolization
	1 poor (53) ⁹¹						and
	Case series-1						spontaneous abortion in
	good 3 poor						subsequent
	(421) 97, 98, 105,						pregnancy in the small
							number of
							women
							followed-up; rates ranged
							from 5-21.4%,
							which is comparable to
							estimates in
							the general
Menstrual	Detroppostive	Lliab	Consistent	Direct	Improsico	NA	population Low SOE for
changes	Retrospective cohort-2 poor	High	Consistent	Direct	Imprecise	INA	an association
	(152) ⁹²⁻⁹⁵						between
	Case-control-						embolization and menstrual
	1 poor (53) ⁹¹						changes.
	Coop parion 1						Rates of
	Case series-1						menstrual change
	good, 4 poor (709) 97, 98, 101,						(heavier,
	105, 108						lighter, or irregular
							menses and
							amenorrhea)
							ranged from 2 to 22%
Hematoma	Retrospective	High	Consistent	Direct	Precise	NA	Low SOE for
	cohort-2 poor (152) ⁹²⁻⁹⁵						association
	(132)						between embolization
	Case-control-						and
	1 poor (53) ⁹¹						hematoma; rates ranged
	Case series-1						from 1.7-6%
	good, 2 poor (544) ^{101, 105, 106}						
	(544)						

Table 30. Strength of the evidence for harms of interventions for management of PPH (continued)

Intervention	Study	Study	Consistency	Direct-	Precision	Reporting	Finding
Outcome	Design Quality and Number of Studies (N Total with PPH)	Limit- ations	Consistency	ness	recision	Bias	Strength of Evidence Grade
Surgical Interventions							
Uterine compression sutures							
Preterm birth	Case-control- 2 good (105 with PPH and sutures) ^{62, 66}	Mediu m	Consistent	Direct	Imprecise	NA	Low SOE for no effect of sutures on preterm birth; in 2 studies; preterm births did not differ between women in case and control groups
Ligation Surgical injury	Retrospective cohort study- 1 poor (48) ⁹⁶ Case series-1 poor (539-not clear how many had ligation) ¹¹¹	High	Consistent	Direct	Imprecise	NA	Insufficient due to high study limitations and imprecision; injuries (inadvertent ligation of the ureters and secondary hysterectomy disunion with sepsis) related to ligation reported in both studies
Hysterectomy Bladder and ureter lesions	Prospective cohort-1 poor (108) ¹⁰⁹ Case series-5 poor (2784) ⁴⁵ , 64, 110, 115, 116	High	Consistent	Direct	Precise	NA	Low SOE for association of hysterectomy and operative organ damage; rates of bladder and ureter lesions ranged from 6%-12% and 0.4%-41%, respectively

Table 30. Strength of the evidence for harms of interventions for management of PPH (continued)

Intervention Outcome	Study Design Quality and Number of Studies (N Total with PPH)	Study Limit- ations	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Surgical Interventions							
Hysterectomy							
Reoperation	Prospective cohort-1 poor (108) ¹⁰⁹ Case series-3 poor, 1 good (574) ^{110, 115-117}	High	Consistent	Direct	Precise	NA	Low SOE for association between hysterectomy and reoperation. Rates of reoperation ranged from 1.8-29%

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

Abbreviations: LOS = length of stay; NA = not applicable; PPH = postpartum hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence; TXA = tranexamic acid

SOE is insufficient for all outcomes and harms in studies of interventions for anemia after PPH given the few studies, small number of participants, and differences in intervention approaches (Table 31).

Table 31. Strength of the evidence for interventions for anemia after PPH

Outcome	Study Design Quality and Number of Studies (N Total With PPH)	Study Limit- ations	Consistency	Direct- ness	Precision	Reporting Bias	Finding Strength of Evidence Grade
Iron Supple- mentation							
Anemia	RCT-1 poor (74) ¹²⁷	High	Unknown	Indirect	Imprecise	Undetected	No differences in groups receiving oral or IV iron. Insufficient SOE for effects on anemia due to small sample size, indirect measures.

Table 31. Strength of the evidence for interventions for anemia after PPH (continued)

Outcome	ength of the evi	Study	Consistency	Direct-	Precision	Reporting	Finding
	Quality and Number of Studies (N Total with PPH)	Limit- ations	-	ness		Bias	Strength of Evidence Grade
Transfusion for Anemia Post-PPH							
Fatigue	RCT-1 poor (519) ¹²⁵	High	Unknown	Direct	Imprecise	Undetected	No significant group differences. Insufficient SOE for effects on fatigue related to anemia due to single, small study with high study limitations
Quality of life	RCT-1 poor (519) ¹²⁵	High	Unknown	Direct	Imprecise	Undetected	No significant group differences. Insufficient SOE for effects on quality of life due to single study with high limitations
Iron Supplement ation and Transfusion for Anemia							
All harms (transfusion reactions, infections, endo- metritis, thrombo- embolic events)	RCT-1 good, 1 poor (593) ^{125, 127}	High	Inconsistent	Direct	Imprecise	Undetected	Insufficient SOE; harms were not pre- specified in 1 study. No serious reactions attributed to the study drugs but reporting in one RCT is not clear

Abbreviations: LOS = length of stay; PPH = postpartum hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence. ^aStudy limitations are rated on a low to high scale. Low limitations=more rigorously designed study.

Overall the SOE for any systems-level intervention on any outcome is insufficient or moderate as the observational data are biased and a single, very large trial suggest that at least one clearly described and implemented program did not change risk of severe hemorrhage or meaningfully modify processes of care or overall maternal outcomes (Table 32). SOE is moderate that these multicomponent interventions did not change specific outcomes such as severity of PPH, transfusion, hysterectomy, and ICU admission.

Table 32. Strength of the evidence for studies addressing multicomponent, systems-level interventions

interventi	ons			11		1	
Outcome	Study Design Quality and Number of Studies (Participants With PPH/Total N)	Study Limit- ations ^a	Consistency	Direct- ness	Precisio n	Reporting Bias	Findings and Strength of Evidence Grade
Incidence of PPH	Cluster RCT: 1 Fair (9350/146781) ³⁷	Medium	Unknown	Direct	Precise	Undetecte d	Moderate SOE for lack of benefit in reducing PPH incidence. Sites aware of objectives with regard to reducing PPH and assessors of a somewhat subjective outcome not masked
Severity of PPH	Cluster RCT: 1 Fair (9350/146781) ³⁷ Pre/Post: 3 fair, 2 poor (4241/152194) ^{35, 36, 67, 128, 130-} 132	Medium	Unknown	Direct	Precise	Undetecte d	Moderate SOE for lack of benefit in reducing severity of PPH. Sites aware of the objectives with regard to reducing severity of PPH and assessors of a somewhat subjective outcome not masked. Severity unchanged in RCT; reduced in 2 pre-post studies, no difference in 3, and mean EBL >1000mL declined in 1 study and increased in another.

Table 32. Strength of the evidence for studies addressing multicomponent, systems-level interventions (continued)

(continued)	Study Design	Study	Consistency	Direct-	Precision	Reporting	Findings and
Outcome	Quality and Number of Studies (Participants with PPH/Total N)	Limit- ations ^a	Consistency	ness	recision	Bias	Strength of Evidence Grade
Transfusion	Cluster RCT: 1 Fair (9350/146781) ³⁷ Pre/Post: 5 Fair	Low	Unknown Inconsistent	Direct Direct	Precise Precise	Undetected	Moderate SOE for no effect on transfusion. Transfusion unchanged in
	(4108/129164) ³⁶ , 67, 68, 128, 129, 132						unchanged in RCT, increased in one pre-post study and unchanged in two; one with decreased use of total blood products related to decrease in risk of disseminated intravascular coagulation; another decreased overall use of transfusion and blood products
Hyster- ectomy	Cluster RCT: 1 Fair (9350/146,781) ³	Low	Unknown	Direct	Precise	Undetected	Moderate SOE for lack of benefit in preventing hysterectomy. Hysterectomy
	Pre/Post: 3Fair, 1 Poor, (3504/66969) ³⁵ , 36, 68, 128, 132	Low	Inconsistent	Direct	Precise	NA	unchanged in RCT. No significant change in three pre-post studies in which hysterectomies increased in two and declined in third; risk significantly increased in one study and was similar between time periods in a third

Table 32. Strength of the evidence for studies addressing multicomponent, systems-level interventions (continued)

Outcome	Study Design Quality and Number of Studies (Participants with PPH/Total N)	Study Limit- ations ^a	Consistency	Direct- ness	Precision	Reporting Bias	Findings and Strength of Evidence Grade
ICU admission	Cluster RCT 1 Fair (9350/146781) ³⁷	Low	Unknown	Direct	Precise	Undetected	Moderate SOE for lack of benefit. No
	Pre/Post: 1 Fair, 1 Poor (3174/59295) ^{35,} 128, 132	Low	Consistent	Direct	Precise	NA	change in RCT and no change in two pre-post studies
Mortality	Pre/Post:1 Poor; (61/18723) ³⁴	Medium	Unknown	Direct	Imprecise	NA	Insufficient SOE for benefit—one smaller study

^aNote: Study limitations are rated on a low to high scale. Low limitations=more rigorously designed study. Abbreviations: EBL = estimated blood loss; ICU = intensive care unit: LOS = length of stay; NA = not applicable; PPH = postpartum hemorrhage; RCT = randomized controlled trial; SOE = strength of the evidence

Findings in Relation to What Is Already Known

Findings in recent (2009-present) systematic reviews and meta-analyses of interventions to manage PPH are largely in line with findings reported here in that while reviews reported some positive effects, studies included in the reviews typically had significant limitations that precluded firm conclusions. Reviewers noted a lack of high quality literature, small sample sizes, limited followup, and a preponderance of observational studies of procedures or surgical approaches given the urgent nature of PPH. We summarize findings of reviews of pharmacologic studies conducted in developing nations as the current review contains few comparable studies of pharmacologic agents. We also summarize recent reviews of procedures and surgical approaches.

Few drug studies met our inclusion criteria, which specified studies must be conducted in the high-resource countries where care would be applicable to that in the United States. Four recent reviews, however, have addressed uterotonics, primarily in lower resource settings. Overall, these reviews had conflicting findings about the effectiveness of misoprostol; however, this medication was consistently associated with adverse effects, particularly fever and shivering.

One 2014 Cochrane review assessed the effectiveness and safety of any intervention used for the treatment of primary PPH. The uterotonic interventions included in the search strategy (search dates: up to August 2013) were ergonovine, oxytocin, and prostaglandin medications. Seven RCTs evaluated misoprostol. Four RCTs (1,881 participants) compared misoprostol with placebo given in addition to other conventional uterotonics. Adjunctive use of misoprostol (600-1000 micrograms) with simultaneous administration of other uterotonics did not provide additional benefit for maternal mortality, serious maternal morbidity, admission to intensive care, or hysterectomy. Three RCTs (1,851 participants) compared oral misoprostol with oxytocin infusion (n=2 RCTs) or rectal misoprostol (n=1 RCT) as primary PPH treatment. Primary outcomes including maternal mortality, hysterectomy, ICU admission, and serious maternal morbidity did not differ between the groups. Oral misoprostol, however, was associated with a significant increase in vomiting and shivering compared with either oxytocin or rectal

misoprostol. No RCTs of ergonovine or carboprost tromethamine met the inclusion criteria. The investigators concluded that, overall, the clinical trials included in the review were not adequately powered to assess impact on the primary outcome measures. Compared with misoprostol, oxytocin infusion was more effective and caused fewer side effects when used as first-line therapy for the treatment of primary PPH. When used *after* prophylactic uterotonics, misoprostol and oxytocin infusion had similar effects. Adding misoprostol for women receiving treatment with oxytocin does not appear beneficial.

A 2013 Cochrane review (search dates: up to January 2013) assessed maternal deaths in studies of misoprostol for prevention and treatment of PPH and included 78 RCTs reporting on 59,216 women; only seven of these studies focused on treatment vs. prevention, and most studies were conducted in low-resource countries. Overall, differences in maternal mortality and morbidity, except for fever, did not differ significantly between misoprostol and control groups. Risk of fever was increased in misoprostol groups and was highest in studies with a misoprostol dose of 600 μ g or more. The investigators concluded that misoprostol does not increase or decrease morbidity or mortality, with the exception of fever, and the lowest effective dose should be used.

In another review (search dates: not specified) including three RCTs (2,346 participants) of misoprostol vs. placebo, misoprostol did not reduce PPH risk significantly compared with placebo, and shivering and fever were significantly more common in misoprostol arms. ¹³⁵A review of maternal deaths and dose-related effects of misoprostol included 46 trials with more than 40,000 participants. The investigators found more adverse effects related to misoprostol than placebo and no evidence, in a meta-analysis, that higher doses of misoprostol (600 vs. 400 micrograms) were more effective at preventing blood loss. Fever was higher among women given misoprostol and occurred more frequently with higher doses (600 vs. 400-500 micrograms)⁵⁰

One review (search dates: not specified) evaluating uterine tamponade in resource-poor settings included 13 observational studies and reported successful treatment of PPH in 234 of 241 women. Almost women had oxytocin and ergometrine or other medications prior to tamponade, and the tamponade device varied among studies. Another systematic review (search dates: 1950-2012) assessed menstrual and fertility outcomes after uterine-sparing interventions for PPH. Studies included in the review addressed embolization (n = 17), ligation (n = 5), and compression sutures (n = 6). Overall, 183 of 235 women who desired another pregnancy were able to conceive, and 553 of 606 resumed normal menstruation within 6 months of birth. Within each intervention type, most women who wanted to conceive were able to do so: 86 percent (24/28) of women who had sutures (21 total term live births, 0 preterm births, pregnancy losses, or cases of recurrent PPH), 85 percent (33/39) of women who had ligation (68 total term live births, 1 preterm birth, 23 pregnancy losses, 8 cases of recurrent PPH), and 75 percent (126/168) of women who had embolization (136 total term live births, 4 preterm births, 30 pregnancy losses, 18 cases of recurrent PPH). The investigators conclude that the techniques reviewed do not appear to compromise fertility, but the number and quality of studies was limited.

One review (search dates: up to August 2009) evaluated emergency postpartum hysterectomy for PPH performed within 48 hours of birth and included 24 studies reporting on 981 cases of hysterectomy (73% cesarean births, 78% multiparous) in women in developed nations. ⁴² More than half (55.8%) of women received uterotonics or other surgical interventions prior to hysterectomy, and 43.6 percent had blood transfusion. Ten percent of women required another surgery after hysterectomy to control bleeding (ligation, adnexectomy, laparotomy). Harms were

reported in four studies in the review and included fever (n = 135 cases), DIC (116 cases), infection (83 cases), genitourinary morbidity (68 cases), pulmonary morbidity (60 cases), gastrointestinal morbidity (25 cases), neurologic morbidity (16 cases), renal morbidity (8 cases), and cardiovascular morbidity (8 cases). Overall, morbidity did not differ between women undergoing total vs. subtotal hysterectomy.

Finally, one recent review (search dates: not specified) examined effects of PPH guideline implementation and included seven studies (6 cohort studies and one RCT). Studies were conducted in the United States, Europe, South America, and Pakistan. The incidence of PPH (diagnosed using variable criteria across studies) after guideline implementation declined in four studies and increased in three. The investigators concluded that guidelines can have positive effects on decreasing PPH incidence but note significant flaws among the studies.

Applicability

We set inclusion criteria intended to identify studies with applicability to women being treated for primary or secondary PPH. Studies differed in terms of study population and outcome measures. Most studies did not make direct comparisons between treatments or characterize populations well in terms of severity of PPH and prior management strategies. This lack of direct comparison of treatment options hinders our ability to understand what treatments are most effective and in what order they should be used, both of which are paramount questions for clinicians. We summarize overall applicability below, and Appendix F contains applicability tables for individual interventions.

Overall, findings of studies in the review are generally applicable to the population of women who would be experiencing PPH in hospitals in high-resource nations. Most studies were conducted in Europe or the United States in tertiary care centers. Studies frequently included a number of women with PPH who were transferred from smaller or community hospitals, which can occur when women with PPH requiring additional treatment are stable enough to be moved to facilities with interventional radiology or other services. More women had PPH after cesarean birth than vaginal birth in the 50 studies reporting mode of birth (estimated 6,304 vaginal and 7,924 cesarean births among the 14,228 births for which mode was clearly reported). The most common cause of PPH was atony, which aligns with the most frequent cause of PPH in the larger community and literature. Studies of pharmacologic agents typically included women with mild to moderate to PPH while studies of procedures or surgical approaches generally included women with more severe PPH that had not been controlled with first-line therapies such as uterotonics.

Uterotonics, blood products, and iron supplements studied are generally widely available; however, the accessibility to procedures such as embolization may be limited in smaller community hospitals. Similarly, community hospitals may lack personnel with experience with arterial ligation and compression sutures. Comparators across studies with more than one group were typically either no specific treatment (e.g., rFVIIa or no rFVIIa) or another treatment (e.g., embolization or ligation) and are likely confounded by patient and provider characteristics that may have affected the choice of intervention. For example, patients with more severe hemorrhage likely received more aggressive treatment, and providers could only offer the options available in their facilities. Outcomes addressed across studies were appropriate and clinically relevant; however, few studies reported on longer term outcomes such as future fertility or on patient-centered outcomes such as quality of life.

The populations included in the systems-level interventions both in the United States and Europe reflect those typical of similar size and type (rural, academic, etc.) obstetric units in current labor and delivery environments in the United States. Likewise the interventions designed and implemented in these studies were informed by processes of identifying evidence and crafting guidance that conforms to typical quality improvement and outcomes based research. The content of the interventions is feasible to implement across a full range of settings and the approaches to measuring outcomes are applicable to practice. Overall the systems-level interventions assessed have good applicability to current practice in the United States.

Implications for Clinical and Policy Decisionmaking

A limited body of evidence addresses interventions for managing PPH. Few studies addressed medications commonly used to treat PPH, precluding our ability to draw conclusions about their effectiveness. Success rates for uterine balloon tamponade or surgeries are typically above 60 percent (e.g., success of uterine balloon tamponade as the initial second-line therapy in one study was 86%; success rates for ligation as the first second-line intervention to control bleeding ranged from 36 to 96%). Studies of embolization suggested that it may be associated with a median rate of successful control of bleeding without the need for additional procedures or surgeries of 89 percent, with a wide range of success (58% to 98%) across studies; however, few studies clearly provided data on the success of these procedures and surgeries as the initial second-line approach, so rates are based on a small number of cases. Adverse events and longer term outcomes associated with procedures and surgical interventions are also not well-understood. Some studies reported menstrual changes and infertility rates higher than the general population rates after embolization. Studies of other procedures and surgical interventions did not consistently report fertility data. At this point, the evidence is insufficient to comment on the effectiveness and harms of most interventions for most outcomes.

Thus, given the mixed and insufficient evidence, clinicians will likely need to continue to make individual decisions about the care of women with PPH based on each woman's clinical situation and the management options available in the setting. Embolization, for example, requires an interventional radiologist and may not be widely available. Transportation to a radiology suite may also lead to treatment delays. Choice of some interventions may be guided by the availability of skilled clinicians or may naturally follow cesarean birth (when the abdomen is already open) vs. vaginal birth. This body of evidence does not provide clear answers to the key clinical questions of what interventions to use and in what order.

Limitations of the Comparative Effectiveness Review Process

We included studies published in English only. In our scan of the non-English language literature published since 1990 and located via our MEDLINE search, we determined that the majority would not meet our review criteria. Given the high percentage of non-eligible items in this scan (90%), we feel that excluding non-English studies did not introduce significant bias into the review. We also included only studies conducted very high human development countries as determined by the World Health Organization as these studies have systems of care most relevant to the United States. We recognize that this criterion eliminated many studies of first-line uterotonics such as misoprostol that have been conducted in developing or low resource

nations. We provide a summary of recent systematic review of those studies to supplement our analysis (See Findings in Relation to What's Known section above).

Limitations of the Evidence Base

There are a number of limitations in the studies that we reviewed. There is not a universally agreed management strategy for PPH. Medications were typically used as the initial treatment; however, the specific drugs, dosages, and order varied. The selection of interventions, including which interventions were performed and in which order, was also inconsistent. Management was not well described in many studies, especially for women who transferred from other hospitals. Methods for estimating blood loss, when reported, varied and were limited. Overall, it was difficult to ascertain confidently the complete trajectory of care of women in many of the studies we reviewed, which compromises our ability to draw meaningful comparisons. As noted, few studies that met our criteria addressed commonly used uterotonics such as oxytocin; however, prior systematic reviews that have included studies in developing countries have reported similar effects on bleeding for misoprostol and oxytocin and benefits for misoprostol in reducing blood loss with side effects including fever.

Procedures and surgical interventions also differed across studies. For example, materials used for embolization varied, as did the sites of embolization and ligation. There is no clear trigger for starting subsequent interventions, so success rates have limited reliability. It may be that women would have recovered after the first line treatment if time allowed. In addition, there is the potential for cumulative effects of multiple interventions that cannot be measured. Outcomes other than controlling bleeding can be difficult to assess. For example, transfusion could be an adverse outcome if treatment was not sufficient and timely to halt bleeding rapidly. Alternately early transfusion can be the appropriate intervention; therefore, it is sometimes hard to know whether to classify transfusion as an adverse outcome. There are also challenges for measuring harms. In some cases, it can be difficult to assess if harms are due to PPH or management interventions and how much each contributed, especially to deaths. There is a significant lack of truly comparative studies and randomized studies, which would be ideal yet are complex to conduct with a life-threatening condition such as PPH. Studies were typically conducted or data collected over long time frames (median study duration = 5 years, range 6 months to 29 years), and it is likely that interventions and patient characteristics would have changed over time, but few studies account for secular changes such as the introduction of new interventions.

In the systems-level interventions, a natural tension exists between the desire to implement robust interventions and the challenges of understanding which components may have value. In the case of these interventions, it is particularly challenging because lower quality studies with looser measures of outcomes were more likely to see intervention effects. The literature about systems-level intervention is limited by lack of analyses that seek to adjust for secular trends and changes in confounders, such as proportion of births by cesarean and trends in rising body-mass index. Likewise lack of multivariable modeling may obscure the influence of elements of care, such as induction of labor, and comorbidities, such as chorioamnionitis, that could identify which predictors may be exerting substantial influence and inform new approaches to diminishing risk of PPH.

Research Gaps

Future research needs around management of PPH are both clinical and methodologic. Priorities for future research include the following:

- Reaching consensus on definitions and criteria for PPH and first-line management strategies to promote consistency within the literature.
- Standardizing a definition of PPH, potentially with gradations of severity, to allow for meaningful comparison of outcomes.
- Conducting more rigorously controlled studies of all interventions for PPH management, especially medication studies in light of the fact that these are considered first-line management, and few studies in developed/high resource nations addressed agents commonly in use. While studies in the PPH population are likely to be retrospective, studies should clearly describe first-line management and timing of management to clarify the course of care. Studies must report a priori study size calculation to ensure that the number of subjects will be adequate to show a difference (if the study is designed for superiority). In addition, comparative studies must declare within the design and methods section whether the study is a superiority trial or a non-inferiority trial.
- Conducting cluster randomized control trials of intervention bundles that address order of medications, order and timing of manual interventions such as uterine massage and bimanual compression, number of times to repeat medications prior to moving on to second-line interventions, hemodynamic monitoring, and supportive care such as transfusion.
- Clearly identifying the trajectory of care, including which interventions were used and the order and timing of interventions.
- Identifying markers that can inform the decision to move to an alternate intervention.
- Investigating the effectiveness of agents used to control bleeding in other clinical areas and of new medications to address PPH. It is likely that new agents would be compared with or added to existing agents and not compared with placebo.
- Conducting additional RCTs or controlled studies of treating anemia after PPH is stabilized.
- Conducting additional prospectively designed and reported studies that report data from large national databases. These studies can describe effects in larger population samples and may be valuable for identifying longer term harms--for example, effects on breastfeeding, psychological trauma, and future fertility.
- Replicating the intrauterine balloon tamponade study that found it was effective in reducing invasive interventions.
- Using and clearly reporting objective methods to diagnose PPH and evaluate management including accurate measurement of blood loss. Visual estimation of blood loss is too imprecise to be used in research.
- Dedication to prospective objective measures such as estimated blood loss, time course of intervention, and use of intervention components.
- Greater capture and multivariable adjustment, including meta-regression, for known risk factors and confounders to allow better understanding of the attributable impact, if any, of the intervention.
- Attention to the possibility that effect modifiers hide efficacy in some groups, which means
 that studies will need to be powered and specify a priori stratified analyses by candidate
 effect modifiers, such as grand multiparity, route of birth, induction, prolonged oxytocin
 infusion, or infection in labor.

- Prespecifying harms, differentiating harms of interventions from sequelae of PPH wherever possible, and studying longer term effects of procedures and surgical interventions.
- Using multivariate modeling. The size of the study populations in systems-level interventions
 can clearly support multivariate modeling and could serve to drive better understanding of
 the general lack of effectiveness. In particular, such data are well-suited to use of riskadjustment models, and adjusting for these underlying differences in study population
 characteristics would allow comparison not only across time periods but across studies.
- Attention to the possibility that systems-level interventions are working against a biologically determined risk of PPH, meaning that within a specific population with particular characteristics there is an irreducible level of risk and event rates cannot be driven below that "floor." If this floor were demonstrated with risk adjustment methods, this finding would fundamentally change the focus of study design and care. A floor would suggest that we need very large pragmatic trials aimed not at reducing the occurrence of PPH but at diminishing associated morbidity, mortality, personal harm and distress, and costs. The systems-level intervention studies available now cannot fully inform this goal, but primary meta-analyses of the highest quality cohorts with risk adjustment could determine if the evidence seen in some of the included studies that suggest benefits are worth pursing on a larger scale, including a scale large enough to separate the influence of candidate components to determine their individual contributions to improvements in care.

Conclusions

A limited body of evidence addresses interventions for managing PPH. The most effective treatments and the order in which to use treatments remain unclear. Diagnosis of PPH is subjective, which makes it difficult to compare the severity of PPH and determine the comparability of participants within and across studies. The trajectory of care, rationale for choice of intervention, and component of care ultimately responsible for controlling bleeding are also frequently unclear because of the need for rapid intervention in an emergency situation. Few studies included in this review addressed pharmacologic or medical management, including transfusion for supportive management of ongoing PPH, and the evidence reviewed is insufficient to comment on effects of such interventions. The success of uterine-sparing techniques, such as uterine balloon tamponade, embolization, uterine compression sutures, and uterine and other pelvic artery ligation, in controlling bleeding without the need for additional procedures or surgeries ranged from 36 to 98 percent; however, these data come from a limited number of studies with a small number of participants. Harms of interventions are diverse and not well-understood. Some studies reported an association between rFVIIa and thromboembolic events, but sample sizes were small. Some studies with longer term followup reported adverse effects on future fertility and menstrual changes in women undergoing embolization. Need for re-operation was reported after hysterectomy. Evidence is insufficient to assess the effects of interventions for anemia after PPH is stabilized, and systems-level interventions showed little benefit in reducing the incidence or severity of PPH or the need for transfusion or hysterectomy. Further research is needed across all interventions for PPH management, especially pharmacologic interventions, which are frequently used as first-line therapies.

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Abbreviations and Acronyms

AHRQ Agency for Healthcare Research and Quality
ANZHR Australian and New Zealand Haemostasis Registry

ARDS Acute respiratory distress syndrome

BMI Body Mass Index

CER Comparative Effectiveness Review

CI Confidence Interval

DIC Disseminated Intravascular Coagulation

DVT Deep Vein Thrombosis
EBL Estimated blood loss

EPC Evidence-Based Practice Center

FFP Fresh Frozen Plasma ICU Intensive Care Unit

Hb Hemoglobin

HELLP Hemolysis, Elevated Liver enzymes, Low Platelet counts syndrome

KQ Key Question

L Liter

LOS Length of Stay Milliliter

MRI Magnetic Resonance Imaging

NHLBI National Heart, Lung, and Blood Institute

NR Not Reported OR Odds ratio

PE Pulmonary Embolism

PICOTS Population, Intervention, Comparator, Outcomes, Timing, and Setting

PPH Post-Partum Hemorrhage
PRBCs Packed Red Blood Cells
PT Prothrombin Time
RBC Red Blood Cells

RCT Randomized Controlled Trial rFVIIa Recombinant activated factor VII

RR Relative risk

rTM Recombinant Human Soluble Thrombomodulin

SD Standard Deviation

SVT Superficial Venous Thrombosis TEP Technical Expert Panel

TRALI Transfusion-related acute lung injury

TXA Tranexamic Acid

UKOSS U.K. Obstetric Surveillance System

Appendix A. Search Strategies

Table A-1. MEDLINE search strategies (PubMed interface)

Searc	ch terms	Search results
#1	"postpartum hemorrhage"[MeSH Terms] OR "postpartum hemorrhage"[tiab] OR "postpartum haemorrhage"[tiab] OR (PPH[tiab] AND postpartum[tiab]) OR "obstetric hemorrhage"[tiab] OR (("postpartum period"[MeSH Terms] OR post-partum[tiab]) AND ("hemorrhage"[MeSH Terms] OR hemorrhage[tiab] OR haemorrhage[tiab]))	7128
#2	management[tiab] OR therapy[tiab] OR "Therapeutics" [Mesh:NoExp] OR treatment[tiab] OR "fundal massage" [tiab] OR "uterine massage" [tiab] OR "(fundus[tiab] OR fundal[tiab] OR uterus[tiab] OR "uterus [Mesh Terms] OR uterine [tiab] AND (massage[tiab] OR "massage] [Mesh Terms]) OR compression[tiab] OR "antishock garments" [tiab] OR "antishock garments" [tiab] OR "oxytocin" [Mesh Terms] OR "Fluid Therapy" [mh] OR uterotonic[tiab] OR oxytocin [tiab] OR "oxytocin" [Mesh Terms] OR Pitocin[tiab] OR oxytoxic[tiab] OR Oxytocics[mesh] OR misoprostol[tiab] OR "misoprostol[tiab] OR methylergonovine[tiab] OR "methylergonovine" [Mesh Terms] OR methergine[tiab] OR ergonovine[tiab] OR "ergonovine[tiab] OR "ergonovine[tiab] OR "ergonovine[tiab] OR "ergonovine[tiab] OR "ergonovine[tiab] OR "ergonovine[tiab] OR "carboprost" [Mesh Terms] OR ergonovine[tiab] OR "ergonovine[tiab] OR "carboprost" [Mesh Terms] OR carboprost tromethamine" [Supplementary Concept] OR "Fige1" [tiab] OR membate[tiab] OR "isotonic carboprost tromethamine" [Supplementary Concept] OR "Fige1" [tiab] OR membate[tiab] OR "isotonic carboprost tromethamine" [supplementary Concept] OR "fitab] OR "ergonovine[tiab] OR "sotonic crystalloids olutions" [Supplementary Concept] OR "Fige1" [tiab] OR "isotonic saline" [tiab] OR "sotonic carboprost" [tiab] OR "isotonic carboprost" [tiab] OR "isotonic saline" [tiab] OR "lactated "ingers" [tiab] OR "langers" [tiab] OR	8820233
#3	#1 AND #2 AND English[lang]	4379
#4	newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice	5019085

	guideline[pt] OR guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt]	
#5	#3 NOT #4	2729
#6	#5 AND ("1990/01/01"[PDAT] : "3000/12/31"[PDAT])	2124*

Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading; [PDAT] publication date *Note: numbers do not tally as some articles are excluded in more than one category

Table A-2. CINAHL (via Ebsco) search results

Search terms		Search results	
#1	(MH "Postpartum Hemorrhage") OR "postpartum hemorrhage" OR "postpartum haemorrhage" OR "obstetric hemorrhage" OR "obstetric haemorrhage" OR ("PPH" AND "postpartum") OR (((MH "Postnatal Period") OR "post-partum") AND ((MH "Hemorrhage") OR (MH "Uterine Hemorrhage") OR hemorrhage OR "haemorrhage" OR "excessive bleeding" OR "excessive blood loss"))	1258 R	
#2	"management" OR "therapy" OR (MH "Therapeutics") OR treatment OR "fundal massage" OR "uterine massage" OR (((MH "Uterine Fundus") OR fundus OR fundal OR (MH "Uterus") OR uterus OR uterine) AND (((MH "Massage") OR massage)) OR compression OR (MH "Compression Garments") OR (MH "Compression Therapy") OR "antishock garment" OR "antishock garments" OR (MH "Fluid Therapy") OR "fluid therapy" OR "uterotonic" OR (MH "Oxytocin") OR "oxytocin" OR "oxytoxic" OR "oxytoxics" OR (MH "Misoprostol") OR "misoprostol" OR "cytotec" OR "methylergonovine" OR "methergine" OR (MH "Ergonovine") OR "ergonovine" OR "ergotrate" OR (MH "Ergot Alkaloids") OR "ergot" OR "ergometrine" OR "carboprost" OR "PGE1" OR "hemabate" OR (MH "Blood Transfusion") OR "transfusion" OR (MH "Fluid Resuscitation") OR "fluid resuscitation" OR (MH "Isotonic Solutions") OR (MH "Crystalloid Solutions") OR "isotonic crystalloids" OR "isotonic crystalloids" OR "isotonic crystalloids" OR "isotonic saline" OR (MH "Normal Saline") OR "blood products" OR "volume replacement" OR (MH "Fibrinogen") OR "fibrinogen" OR "fresh frozen plasma" OR (MH "Plasma") OR "cryoprecipitate" OR "uterine tamponade" OR (MH "Balloon Dilatation") OR "balloon tamponade" OR "intrauterine balloon" OR "uterine balloon" OR (((MH "Uterus") OR "arterial embolization" OR "arterial embolization") OR "arterial ligation" OR (MH "Embolization, Therapeutic") OR "artery ligation" OR (MH "Ligation") OR "arterial ligation" OR (MH "Embolization, Therapeutic") OR "artery ligation" OR (MH "Hysterectomy") OR "hysterectomy" OR "B-lynch" OR (MH "Laparotomy") OR (MH "Sutures") OR (MH "Blood Coagulation Factors") OR (MH "Laparotomy") OR (MH "Sutures") OR (MH "Butures") OR "suturing" OR (MH "Uterine Inertia/TH/PC") OR (MH "Uterine Inversion/TH") OR (MH "Uterine Rupture/TH") OR (MH "Dilatation and Curettage") OR "curettage"	842318	
#3	#1 AND #2	872	
#4	#3 AND limiters: English language, Exclude MEDLINE records	196*	

Table A-3. Embase search strategy (OvidSP interface, MEDLINE results)

Search terms		Search results
#1	postpartum hemorrhage/ OR "postpartum hemorrhage" OR "postpartum haemorrhage" OR (PPH AND postpartum) OR "obstetric hemorrhage" OR "obstetric haemorrhage" OR ((puerperium/ OR post-partum) AND (hemorrhage OR haemorrhage))	10554
#2	management OR therapy OR therapy/ OR treatment OR fundal massage OR ((fundus OR uterine fundus/ OR fundal OR uterus OR uterus/ OR uterine) AND (massage OR massage/)) OR compression OR compression instrument/ OR artery compression/ OR compression stocking/ or compression bandage/ or compression sleeve/ or compression/ or compression therapy/ or compression garment/ OR mast suit/ OR "antishock garment" OR "antishock garments" OR "fluid therapy" OR fluid therapy/ OR uterotonic OR oxytocin OR oxytocin/ OR pitocin or uterotonic agent/ OR oxytocic agent/ OR misoprostol/ OR misoprostol OR cytotecOR methylergometrine/ OR methylergonovine OR methergine OR methylergometrine maleate/ OR ergometrine/ OR ergonovine OR ergotrate OR ergot alkaloid/ OR carboprost/ OR carboprost	8527763

Key: [mh] Medical Subject Heading
*Note: numbers do not tally as some articles are excluded in more than one category

trometamol/ OR "carboprost tromethamine" OR prostaglandin E1/ OR PGE1 OR hemabate OR transfusion OR blood transfusion/ OR fluid resuscitation/ OR "isotonic crystalloids" OR "isotonic crystalloid" OR "crystalloid solutions" OR "crystalloid solution" OR crystalloid/ OR Ringer lactate solution/ OR "ringer's lactate" OR "lactated ringer's" OR isotonic solution/ OR "isotonic saline" OR whole blood/ OR blood product/ OR "blood products" OR "volume replacement" OR fibrinogen/ OR fibrinogen OR fresh frozen plasma/ OR "fresh frozen plasma" OR plasma/ OR erythrocyte concentrate/ OR "packed cells" OR cryoprecipitate/ OR cryoprecipitate OR uterine tamponade/ OR "uterine tamponade" OR "balloon tamponade" OR intrauterine balloon/ OR "intrauterine balloon" OR "uterine balloon tamponade" OR "Bakri balloon" OR ((uterus OR uterus/ OR uterine OR intrauterine) AND (pack?)) OR artificial embolism/ OR "arterial embolization" OR "artery embolization" OR "therapeutic embolization" OR artery ligation/ OR "artery ligation" OR "arterial ligation" OR "laceration repair" OR laceration/su OR recombinant blood clotting factor 7a/ OR "recombinant activated factor VII" OR "rFVIIa" OR blood clotting factor 7a/ AND laparotomy/ OR laparotomy OR hysterectomy/ OR hysterectomy OR "B-lynch" OR suturing method/ OR suture? OR suturing OR uterine atony/dm, dt, su, th OR uterus rupture/dm, su, th, dt OR curettage OR curettage/ OR "uterine exploration" OR bladder catheterization/ OR "urinary catheterization" OR "catheter balloon" OR balloon catheter/ OR Foley balloon catheter/ OR "foley catheter" OR condom catheter/ OR "condom catheter" OR "condom tamponade" OR (condom/ AND balloon) OR "Rusch balloon" OR "Sengstaken-Blakemore" OR ("manual removal" AND placenta) OR retained placenta/dt, su, th OR resource allocation/ OR "resource allocation" OR health care delivery/ OR program development/ OR "program development" OR clinical pathway/ OR "critical pathways" OR "guideline adherence" OR clinical protocol/ OR "clinical protocol" OR "clinical protocols" OR algorithm/ OR algorithm? OR protocol? OR system OR systems OR systemic OR patient care/ OR "guideline implementation" OR checklist/ OR checklist? OR ae.fs OR unsafe OR safety OR harm OR harms OR harmful OR complication/ OR complication OR complications OR side effect/ OR adverse drug reaction/ OR "side effect" OR "side effects" OR ((undesirable OR adverse) AND (effect OR effects OR reaction OR reactions OR event OR events OR outcome OR outcomes)) OR sequelae OR sequela OR postoperative complication/ OR "postoperative complications" OR ((postoperative OR surgical OR postsurgical OR "post operative" OR "post surgical") AND (complication OR complications)) OR drug contraindication/ OR treatment contraindication/ OR co.fs #1 AND #2 7916 Limit #3 to (human and english language and yr="1990 -Current") 5624

Key: ?=truncation; fs=floating subheading; / s all subheadings; ae=adverse drug reaction subheading; co=complication subheading; dm=disease management subheading; dt=drug therapy subheading; su=surgery subheading; th=therapy subheading;

#3

Table A-4. MEDLINE search strategies (PubMed interface) for Key Question 4

Search terms		Search results	
#1	"postpartum hemorrhage"[MeSH Terms] OR "postpartum hemorrhage"[tiab] OR "postpartum haemorrhage"[tiab] OR (PPH[tiab] AND postpartum[tiab]) OR "obstetric hemorrhage"[tiab] OR (("postpartum period"[MeSH Terms] OR post-partum[tiab]) AND ("hemorrhage"[MeSH Terms] OR hemorrhage[tiab] OR haemorrhage[tiab]))	7348	
#2	"Anemia, Iron-Deficiency/therapy"[mesh] OR ((Erythropoietin[mesh] OR erythropoietin*[tiab] OR epoetin*[tiab] OR ferric*[tiab] OR ferrous*[tiab] OR "Iron Compounds"[mesh] OR Iron[mesh] OR iron*[tiab]) AND ("Anemia, Iron-Deficiency" [mesh] OR anemia[tiab] OR anaemia[tiab] OR anemic[tiab]))	25489	
#3	#1 AND #2 AND English[lang]	36	
#4	newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice guideline[pt] OR guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt]	5118038	
#5	#3 NOT #4	21	

^{*}Note: numbers do not tally as some articles are excluded in more than one category

#6 #5 AND ("1990/01/01"[PDAT] : "3000/12/31"[PDAT]) 18*	
---	--

Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading; [PDAT] publication date *Note: numbers do not tally as some articles are excluded in more than one category

Table A-5. CINAHL search strategies (EbscoHost interface) for Key Question 4

Search terms		Search results
#1	((MH "Postpartum Hemorrhage") OR "postpartum hemorrhage" OR "postpartum haemorrhage" OR (PPH AND postpartum) OR "obstetric hemorrhage" OR "obstetric haemorrhage") OR ((MH "Postnatal Period+") OR postpartum OR post-partum) AND ((MH "Hemorrhage") OR (MH "Uterine Hemorrhage+") OR hemorrhage OR haemorrhage))	1450
#2	(MH "Anemia, Iron Deficiency/TH") OR (((MH "Erythropoietin") OR erythropoietin* OR epoetin* OR ferric* OR ferrous* OR iron* OR (MH "Iron Compounds+") OR (MH "Iron")) AND ((MH "Anemia, Iron Deficiency") OR anemia OR anaemia OR anemic))	3724
#3	#1 AND #2	10
#4	#3 AND limiters: English language, Human, Exclude MEDLINE records	1
#5	#5 AND limiter: Published Date: 19900101-20140731	1*

Key: [mh] Medical Subject Heading;

^{*}Note: numbers do not tally as some articles are excluded in more than one category

Table A-6. Embase search strategy (OvidSP interface) for Key Question 4

Search terms		Search results
#1	exp postpartum hemorrhage/ OR "postpartum hemorrhage" OR "postpartum haemorrhage" OR (PPH AND postpartum) OR "obstetric hemorrhage" OR "obstetric haemorrhage" OR obstetric hemorrhage/ OR ((puerperium/ OR postpartum OR post-partum) AND (bleeding/ OR hemorrhage OR haemorrhage))	11971
#2	iron deficiency anemia/th OR ((erythropoietin/ OR recombinant erythropoietin/ OR erythropoietin* OR epoetin* OR ferric* OR ferrous* OR iron derivative/ OR iron/ OR iron therapy/ OR iron*) AND (iron deficiency anemia/ OR anemia OR anaemia OR anaemic* OR anaemic*))	6883
#3	#1 AND #2	19
#4	Limit #3 to (human and english language and yr="1990 -Current")	15

Key: exp=explode, s terms narrower than the search term;
*Note: numbers do not tally as some articles are excluded in more than one category

Appendix B. Screening and Quality Assessment Forms

Screening Forms

Abstract Review Form

1. Is the paper original read and reviews of the literat ☐ Yes ☐ No ☐ Cannot D	•	ntaries, letters to the editor,		
2. What country(s) is the	study population located? (check as	many as applicable)		
 □ Andorra □ Argentina □ Australia □ Barbados □ Belgium □ Brunei Darussalam □ Canada □ Chile □ Croatia □ Cyprus □ Czech Republic □ Denmark □ Estonia □ Frinland □ France □ Germany 	□ Greece □ Hong Kong, China (SAR) □ Hungary □ Iceland □ Ireland □ Israel □ Italy □ Japan □ Korea, Republic of □ Latvia □ Liechtenstein □ Lithuania □ Luxembourg □ Malta □ Netherlands □ Norway	□ Poland □ Portugal □ Qatar □ Seychelles □ Singapore □ Slovakia □ Slovenia □ Spain □ Sweden □ Switzerland □ United Arab Emirates □ United Kingdom □ United States □ Multi-site □ Other: □ Cannot Determine		
3. Does the study MORE THAN ONE woman with postpartum hemorrhage (PPH)—any age and severity? Yes No Cannot Determine 4. Does the study address one or more of the following: Outcomes of treatment/management of PPH Systems-level studies of approaches for treatment/management of PPH Followup treatment/management for women with anemia following PPH Harms of treatment/management for PPH				
	dress (check all that apply):			

 □ Prevention of PPH only (d □ Active management of 3rd □ Basic science or anatomy s □ Imaging or diagnostic stud □ Other 	study	nent)
6. Retain for: □ Background/Discussion 7. Comments:	□ Review of References	□ Other

Full-Text Review Form

 1. Is the paper original research (excludes editorials, commentaries, letters to the editor, and reviews/systematic reviews of the literature)? Yes No 2. In what country(s) is the study population located? (check as many as applicable) 				
•	□ Multi-site			
	□ Other:			
	□ Cannot Determine			
□ Barbados				
□ Belgium				
□ Brunei Darussalam				
□ Canada				
□ Chile				
□ Croatia				
Cyprus				
□ Czech Republic □ Denmark				
□ Estonia				
□ Finland				
□ France				
□ Germany				
□ Greece				
□ Hong Kong, China (SAR)				
□ Hungary				
□ Iceland				
□ Ireland				
□ Israel				
□ Italy				
□ Japan				
□ Korea, Republic of				
□ Latvia				
□ Liechtenstein				
□ Lithuania				
□ Luxembourg				
□ Malta				
□ Netherlands				
□ New Zealand				
□ Norway				
□ Poland				
□ Portugal				
□ Qatar				
□ Seychelles				
□ Singapore □ Slovakia				
□ Slovakia □ Slovenia				
□ Spain				
□ Sweden				
□ Switzerland				
□ United Arab Emirates				
□ United Kingdom				

3. Does the study address of		
☐ Outcomes of treatment/man	•	
admission, anemia, length of	• • •	rvation, future fertifity,
psychological impact, breastf	_	oturout/monogonout of DDII:
•	studies of approaches for the	atment/management of PPH in
women		C II . DDII
□ Outcomes or harms of treat		
☐ Timing OR order of interve	` '	nt in women
☐ Harms of treatment/manage	ement for PPH in women	
□ None of the above		
4. Is the study one of the fol	lowing (check all that apply)	:
□ RCT or prospective or retro		
outcomes of interventions to		
	_	ssing harms/adverse effects of
interventions to manage PPH		8
•		ssing outcomes of treatment for
		nent of anemia in women with
stabilized PPH		
□ RCT or prospective or retro	ospective cohort study addres	ssing timing/selection of
interventions for PPH		
□ Population-based (state or i	region) case series/registry st	udy with at least 50 women
with PPH and addressing out		
-		ssing harms/adverse effects of
treatment for PPH	Wollies With 1111 and addict	osing narms, au voise erreers er
□ Comparative (s intervention	n and comparison or pre/post	group) study addressing
systems-level interventions for		group) study uddressing
•		omes/harms of intervention for
PPH (will not be d—data coll	•	of files, figures of files vention for
□ None of these	ection question)	
1 None of these		
5. Please record total N par	ticipants with PPH:	
6. If excluded, retain for:		
□ Background/Discussion	□ Review of References	□ Other
- Duengiouna Discussion	- Review of References	
7 Comments:		

Quality Assessment Forms

Cochrane Collaboration Modified Tool for Assessing Risk of Bias in RCTs

REF ID:	REF ID: Reviewer:							
Domain	Description	High risk of bias	Low risk of bias	Unclear risk of bias	Reviewer Assessment			
Selection bias Random sequence generation	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. Reviewer Comments:	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.	Random sequence generation method should produce comparable groups	Not described in sufficient detail	Judgment: Random Sequence generation High Low Unclear			
Allocation	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment. Reviewer Comments:		Intervention allocations likely could not have been foreseen in advance of, or during, enrollment	Not described in sufficient detail	Judgment: Allocation concealment High Low Unclear			
Reporting Bias Selective reporting	State how the possibility of selective outcome reporting was examined by the authors and what was found. Reviewer Comments:	Reporting bias due to selective outcome reporting.	Selective outcome reporting bias not detected	Insufficient information to permit judgment of 'Low risk' or 'High risk'. (It is likely that the majority of studies will fall into this category.)	Judgment: Selective reporting High Low Unclear			
Other bias Other sources of bias	Any important concerns about bias not addressed above. If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry.	Bias due to problems not covered elsewhere in the table.	No other bias detected	There may be a risk of bias, but there is either: Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.	Judgment: Other sources of bias High Low Unclear			

	Comments:				
Outcome(s):					
Domain	Description	High risk of bias	Low risk of bias	Unclear risk of bias	Reviewer Assessment
Performance bias Blinding (participants and personnel)	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective. Reviewer Comments:	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	Judgment: Blinding (participants and personnel) High Low Unclear
Detection bias Blinding (outcome assessment)	measures used, if	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	Judgment: Blinding (outcome assessment) High Low Unclear
Attrition bias Incomplete outcome data	Described the completeness of outcome data for each main outcome,	to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusions to permit judgment of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided)	Judgment: Incomplete outcome data High Low Unclear

Comme	ents:		

Newcastle-Ottawa Quality Assessment Form for Case-Control Studies

Note: A study can be given a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Re	viewer:	Ref ID:
Se	election	
	Is the case definition adequate?: a) Yes, with independent valida b) Yes, e.g., record linkage or b c) No description	tion (one star)
2)	Representativeness of the cases a) Consecutive or obviously rep b) Potential for selection biases	presentative series of cases (one star)
3)	Selection of controls: a) Community controls (one st b) Hospital controls c) No description	ar)
4)	Definition of controls: a) No history of disease (endpose) b) No description of source	int) (one star)
	omparability Comparability of cases and contr	ols on the basis of the design or analysis controlled for confounders:
		one star) ors (list) (one star) on the basis of the design or analysis controlled for confounders
Ex	posure	
1)	Ascertainment of exposure: a) Secure record (e.g., surgical b) Structured interview where b c) Interview not blinded to case d) Written self report or medical e) No description	record) (one star) lind to case/control status (one star) /control status
2)	Same method of ascertainment f Yes (one star) No	or cases and controls:
3)	Non-response rate: a) Same rate for both groups (c) b) Non-respondents described c) Rate different between case	one star) s and controls with no description

Newcastle-Ottawa Quality Assessment Form for Cohort Studies

Note: A study can be given a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability.

Rev	view	er: Ref ID:
Se 1)	Repa) a) b) c)	bresentativeness of the exposed cohort: Truly representative (one star) Somewhat representative (one star) Selected group No description of the derivation of the cohort
2)	a) b)	ection of the non-exposed cohort Drawn from the same community as the exposed cohort (one star) Drawn from a different source No description of the derivation of the non exposed cohort
3)	a) b) c) d)	sertainment of exposure: Secure record (e.g., surgical record) (one star) Structured interview (one star) Written self report No description Other
4)	Der a) b)	nonstration that outcome of interest was not present at start of study: Yes <i>(one star)</i> No
Co	mr	parability
1)	Cor a)	mparability of cohorts on the basis of the design or analysis controlled for confounders: The study controls for age (one star) Study controls for other factors (list)(one star)
O١	itco	ome
	Ass a) b) c)	Independent blind assessment (one star) Record linkage (one star) Self report No description
2)	Wa a) b)	s follow-up long enough for outcomes to occur: Yes <i>(one star)</i> No
Indi abo	cate	the median duration of follow-up and a brief rationale for the assessment
3)	Ade a) b) c) d)	equacy of follow-up of cohorts: Complete follow up- all subject accounted for <i>(one star)</i> Subjects lost to follow up unlikely to introduce bias- number lost less than or equal to 20% or description of those lost suggested no different from those followed. <i>(one star)</i> Follow up rate greater than 80% and no description of those lost No statement

Case Series Quality/Risk of Bias Form

Reviewer	Initials:	Ref ID:	

Risk of Bias	Criterion	YES	NO	NA	NR	COMMENTS
Selection bias and confounding	Were the important confounding and modifying variables taken into account in the design and analysis?					
Performance bias	2. Was any impact from a concurrent intervention or an unintended exposure that might bias results ruled out by the researchers?					
	3. Was the study free from variations from the study protocol that could compromise the conclusions of the study?					
Attrition bias	4. Was there a low rate of differential or overall attrition? (note: low≤20%)					
	5. Attrition did not result in a difference in group characteristics between baseline and follow-up					
Detection bias	6. Were the outcome assessors blinded to the intervention or exposure status of participants?					
	7a. Are the inclusion/exclusion criteria clearly stated? (note: consider whether level of detail would allow for replication)					
	7b. Were the measures implemented consistently across all study participants?					
	8a. Are interventions/exposures assessed using appropriate measures?					
	8b. Were the interventions implemented consistently across all study participants?					
	9a. Are primary outcome measurement approaches clearly described? List outcome. Outcome1:					
	Outcome 2:					
	Outcome 3:					
	Outcome 4:					
	Outcome 5:					
	Outcome 6:					
	9b. Are primary outcomes assessed using appropriate measures? List outcome. Outcome 1:					
	Outcome 2:					

	Outcome 3:			
	Outcome 4:			
	Outcome 5:			
	Outcome 6:			
	9b. Was outcome assessment implemented consistently across all study participants?			
	10a. Are confounding variables assessed using appropriate measures?			
	10b. Was assessment of confounding variables implemented consistently across all study participants?			
	11. Did the study account for secular trends and regression to the mean?			
Reporting bias	12a. Are the potential outcomes pre-specified by the researchers?			
	12b. Are harms pre-specified by the researchers?			
	13. Are all pre-specified outcomes reported?			
	13a. Are all pre-specified harms reported?			

Harms Risk of Bias Assessment Form

Reviewer: _____ **Ref ID:** _____

Question	Yes	No	Comments
Were the harms predefined using standardized or precise definitions? (mcharms)			
Are all pre-specified harms reported? (RTI case series)			
Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection? (mcharms)			
Are the statistical methods used to assess the main harm or adverse event outcomes adequate? (RTI cohort)			

Appendix C. Excluded Studies

Reasons for Exclusion

- X-1 Not original research
- X-2 Ineligible country
- X-3 Ineligible population
- X-4 Does not address outcomes or population of interest
- X-5 Ineligible study design
- X-6 Article not obtainable
- 1. Aggregate analysis of oxytocin incidents. X-1
- 2. Abdel-Aleem H, Aboelnasr MF, Jayousi TM, et al. Indwelling bladder catheterisation as part of intraoperative and postoperative care for caesarean section. PMID: X-3, X-4
- 3. Abdel-Aleem H, Alhusaini TK, Abdel-Aleem MA, et al. Effectiveness of tranexamic acid on blood loss in patients undergoing elective cesarean section: randomized clinical trial. PMID: X-2, X-4
- 4. Abdul Sultan A, Grainge MJ, West J, et al. Impact of risk factors on the timing of first postpartum venous thromboembolism: a population-based cohort study from England. PMID: X-4
- Abdul Sultan A, Tata LJ, Fleming KM, et al. Pregnancy Complications and Adverse Birth Outcomes Among Women With Celiac Disease: A Population-Based Study From England. PMID: X-3, X-4
- Abramovici A, Szychowski JM, Biggio JR, et al. Epidural Use and Clinical Chorioamnionitis among Women Who Delivered Vaginally. PMID: X-4
- 7. Adeniran AS, Fawole AA, Fakeye OO, et al. Grandmultiparity: evaluating obstetric and neonatal outcomes after eliminating confounders. PMID: X-4
- 8. Aditya V. LMN Facial Palsy in Pregnancy: An Opportunity to Predict Preeclampsia-Report and Review. PMID: X-3, X-4
- 9. Aggarwal RS, Mishra VV, Jasani AF, et al. Acute renal failure in pregnancy: our experience. PMID: X-2, X-4
- 10. Ahmadzia HK, Thomas SM, Heine RP, et al. Survey of peripartum hysterectomy experiences: anticipated, unplanned, or averted. X-4, X-5

- 11. Alfirevic Z, Aflaifel N, Weeks A. Oral misoprostol for induction of labour. PMID: X-1, X-4
- 12. Allam IS, Gomaa IA, Fathi HM, et al. Incidence of emergency peripartum hysterectomy in Ain-shams University Maternity Hospital, Egypt: aretrospective study. PMID: X-2, X-4
- 13. Almansa C, Camano I, Villar O, et al. Puerperal curettage after cesarean section delivery. X-4, X-5
- 14. Almeida LM, Santos CC, Caldas JP, et al. Obstetric care in a migrant population with free access to health care. PMID: X-4
- 15. Amsalem H, Aldrich CJ, Oskamp M, et al. Postpartum uterine response to oxytocin and carbetocin. PMID: X-4, X-5
- 16. Arrowsmith S, Wray S. Oxytocin: its mechanism of action and receptor signalling in the myometrium. PMID: X-1, X-4
- 17. Fareh OI, Rizk DE, Thomas L, et al. PMM.21 Antenatal Haemoglobin Levels and Blood Transfusion. PMID: X-3, X-4
- 18. Zimmermann R, Breymann C, Richter C, et al. PMM.74 Are We Forgetting The Folates? PMID: X-1
- 19. Recent ACOG bulletin covers management of postpartum hemorrhage. Am Fam Physician. 1990 Oct;42:1117-9. PMID: 2220516; X-1, X-2, X-4, X-5
- Alabi EM. Cultural practices in Nigeria. Newsl Inter Afr Comm Tradit Pract Affect Health Women Child. 1990 May:6-7. PMID: 12157983; X-2

- Andres RL, Piacquadio KM, Resnik R. A reappraisal of the need for autologous blood donation in the obstetric patient. Am J Obstet Gynecol. 1990 Nov;163:1551-3. PMID: 2240105; X-4
- Begley CM. The effect of ergometrine on breast feeding. Midwifery. 1990 Jun;6:60-72. PMID: 2195299; X-3
- 23. Begley CM. A comparison of 'active' and 'physiological' management of the third stage of labour. Midwifery. 1990 Mar;6:3-17. PMID: 2182978; X-4
- Chattopadhyay SK, Deb Roy B, Edrees YB. Surgical control of obstetric hemorrhage: hypogastric artery ligation or hysterectomy? Int J Gynaecol Obstet. 1990 Aug;32:345-51. PMID: 1977629; X-2, X-4, X-5
- Evaldson GR. The grand multipara in modern obstetrics. Gynecol Obstet Invest. 1990;30:217-23. PMID: 2289702; X-2, X-4
- 26. Healey JM. The Jehovah's Witness parent's right to refuse treatment. Conn Med. 1990 Jun;54:357. PMID: 2373012; X-1, X-5
- Hood DD, Holubec DM. Elective repeat cesarean section. Effect of anesthesia type on blood loss. J Reprod Med. 1990 Apr;35:368-72. PMID: 2352227; X-4, X-5
- 28. Imberti R, Preseglio I, Trotta V, et al. Blood transfusion during cesarean section. A 12 years' retrospective analysis. Acta Anaesthesiol Belg. 1990;41:139-44. PMID: 2371803; X-1, X-4
- Lao TT, Huengsburg M. Labour and delivery in mothers with asthma. Eur J Obstet Gynecol Reprod Biol. 1990 May-Jun;35:183-90. PMID: 2335253; X-4
- 30. Levy DB, Peppers MP, Miller K. A last resort for postpartum hemorrhage. Emergency. 1990;22:16-7. PMID: X-1
- 31. P OP, Suthutvoravut S, Chaturachinda K. Hydrops fetalis due to Bart hemoglobinopathy at Ramathibodi Hospital (1978-1987): a 10-year review. J Med Assoc Thai. 1990 Feb;73 Suppl 1:65-8. PMID: 2351917; X-1, X-3, X-4
- 32. Peyser MR, Kupferminc MJ. Management of severe postpartum hemorrhage by intrauterine irrigation with prostaglandin E2. Am J Obstet Gynecol. 1990 Mar;162:694-6. PMID: 2316571; X-2, X-4, X-5

- 33. Sofat R. Post-partum Copper-T insertion -- a trial. Indian J Matern Child Health. 1990 Jan-Mar;1:23-4. PMID: 12319239; X-1, X-4
- 34. Sonneveld SW, Correy JF. Outcome of pregnancies complicated by epilepsy in Tasmania 1981-1988. Aust N Z J Obstet Gynaecol. 1990 Nov;30:286-9. PMID: 2082881; X-2, X-3, X-4
- 35. St George L, Crandon AJ. Immediate postpartum complications. Aust N Z J Obstet Gynaecol. 1990 Feb;30:52-6. PMID: 2346452: X-4
- 36. Sweeney G, Holbrook AM, Levine M, et al. Pharmacokinetics of carbetocin, a longacting oxytocin analogue, in nonpregnant women. Current Therapeutic Research Clinical and Experimental. 1990;47:528-40. PMID: X-1, X-3, X-4
- 37. Thomas IL, Jeffers TM, Brazier JM, et al. Does cord drainage of placental blood facilitate delivery of the placenta? Aust N Z J Obstet Gynaecol. 1990 Nov;30:314-8. PMID: 2082886; X-4
- 38. Thorp JM, Jr., Fowler WC, Donehoo R, et al. Antepartum and intrapartum events in women exposed in utero to diethylstilbestrol. Obstet Gynecol. 1990 Nov;76:828-32. PMID: 2216234; X-4
- 39. Woodcock HC, Read AW, Moore DJ, et al. Planned homebirths in Western Australia 1981-1987: a descriptive study. Med J Aust. 1990 Dec 3-17;153:672-8. PMID: 2246990; X-4
- 40. Recently introduced products. Drug Ther Bull. 1991 Mar 4;29:17-9. PMID: 1935601; X-1, X-4
- 41. When is manual placental extraction necessary? Emergency Medicine (00136654). 1991;23:90-1. PMID: X-1, X-4, X-5
- 42. Abdel-razik MS. Postpartum haemorrhage as a public health problem. J Egypt Soc Obstet Gynecol. 1991 Jan;17:51-61. PMID: 12317331; X-1, X-4
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Appendix D. Evidence Tables

Table D-1. Evidence table for studies addressing management of PPH (Cheong 2014)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author: Cheong et al., 2014¹ Country: Korea Enrollment period: January 2006 to June 2013 Birth setting: Hospital Facility characteristics:	Intervention: Pelvic arterial embolization (PAE) Groups: G1: Embolization G1a: following vaginal delivery G1b: following cesarean delivery G1c: PAE success G1d: PAE failure N at enrollment: G1: 117 G1a: 69 (59%) G1b: 48 (41%) G1c: 103 G1d: 14 Duration of treatment: NR Timing of treatment: NR Order of treatment: NR Length of follow-up: NR	Operational definition of PPH: Primary PPH occurring within first 24 hours Secondary PPH occurring from 24 hours to 6 weeks after delivery Definition of success of treatment: Cessation of bleeding after PAE without need for repeat procedure or additional surgery during the hospital stay Method of blood loss measurement: NR Severity: NR Inclusion criteria: All patient who underwent pelvic arterial embolization for primary or secondary PPH Exclusion criteria: Patients who underwent Cesarean hysterectomy prior to PAE Maternal age, yrs, mean ± SD: G1a: 32.0 ± 5.0 G1b: 33.0 ± 5.0 p= 0.29 G1c: 32.0 ± 5.0 G1d: 32.0 ± 4.0 p= 0.16 Parity, n (%): Primiparity G1a: 41 (59.4) G1b: 15 (31.3) p=0.003	Blood loss: NR Transfusion: G1c: 32 (31.1) G1d: 11 (78.6) p= 0.002 ICU admission: NR Anemia – Initial hgb <8 g/dL G1c: 48 (46.6) G1d: 7 (50.0) Length of stay: NR Mortality: NR Uterine preservation: NR Future fertility: NR Breastfeeding: NR Psychological impact: NR Harms of intervention: Clinical Success: 103/117 (88) Clinical Failure: 14/117 Hemostatic hyst 4/14 Repeat PAE 10/14 G1a: 9 (13) G1b: 5 (10.4 p= 0.66
			One PAE success

Study	Intervention	Inclusion/Exclusion	Outcomos
Description	intervention	Criteria & Population	Outcomes
•		G1c: 51 (49.5)	G1c : 103/103 (100)
		G1d: 5 (35.7)	G1d : 4/14 (28)
		p= 0.33	. ,
			Two or more PAE
		Weeks gestation, n (%):	G1c : 0 (0)
		< 34	G1d : 10/14 (71.4)
		G1a: 0	Harms pre-specified: No
		G1b : 1 (2.1)	namis pre-specified. No
		G1c: 1 (1.0)	Harms, n (%):
		G1d: 0 (0)	PPH-related complications: 12 (10.3)
		314. 0 (0)	Acute renal failure
		34-36 week 6 days	G1: 5 (4.3)
		G1a: 4 (5.8)	3.1.5 (,
			Hepatic failure
		G1b : 8 (16.7)	G1 : 1 (0.9)
		G1c: 11 (10.7)	31. 1 (0.0)
		G1d: 1 (7.1)	Pulmonary edema
			G1: 3 (2.6)
		≥ 37 weeks	G1. 3 (2.0)
		G1a: 65 (94.2)	Dootportum cardiomyonathy
		G1b : 39 (81.3)	Postpartum cardiomyopathy
		G1c: 91 (88.3)	G1: 3 (2.6)
		G1d: 1 (7.1)	DAE 1 (1
			PAE-related complications: 7 (6.0)
		Single pregnancy, n (%): NR	
			Uterine necrosis requiring hysterectomy
		Twin pregnancy, n (%):	G1: 3 (2.6)
		G1a : 0	
		G1b: 3 (6.3)	Buttock necrosis requiring surgical debridment
			G1 : 0
		Race/ethnicity: NR	
		riaco, caminons, rink	Fever > 38.5° C without a focus of infection
		BMI: NR	G1: 2 (1.7)
		Baseline hemoglobin: NR	Puncture site hematoma
		Buseline nemoglobin: 1414	G1: 2 (1.7)
		SES: NR	
		JEG. IVIX	
		Mode of birth, n:	
		Vaginal	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1a: 69	
		G1c: 60 (58.3)	
		G1d: 9 (64.3)	
		Cesarean	
		G1b: 48	
		G1c : 43 (41.7)	
		G1d : 5 (35.7)	
		Type of PPH, n (%)	
		Primary	
		G1a : 62 (89.9)	
		G1b : 36 (75)	
		G1c: 85 (82.5)	
		G1d: 13 (92.9)	
		Secondary	
		G1a: 7 (10.1)	
		G1b : 12 (25)	
		p=0.032 (type of PPH by type of delivery)	
		G1c : 18 (17.5)	
		G1d : 1 (7.1)	
		p= 0.3 (Type of PPH by PAE success or failure)	
		Risk factors, n (%):	
		Preeclampsia	
		G1a: 1 (1.4)	
		G1b : 6 (12.5) p=0.038	
		p=0.036	
		Primary etiology of PPH, n (%):	
		Atony	
		G1a: 39 (56.5)	
		G1b: 25 (52.1)	
		G1c : 57 (55.3)	
		G1d: 7 (50)	
		Abnormal placentation	
		G1a: 2 (2.9)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1b : 15 (31.3)	
		G1c: 14 (13.6)	
		G1d: 3 (21.4)	
		Low genital tract trauma	
		G1a: 25 (36.2)	
		G1b: 0	
		G1c: 22 (21.4)	
		G1d: 3 (21.4)	
		Retained placental fragments G1a: 2 (2.9) G1b: 1 (2.1) G1c: 2 (1.9) G1d: 1 (7.1)	
		Others	
		G1a: 1 (1.4)	
		G1b : 7 (14.6)	
		G1c: 8 (7.8)	
		G1d : 0 (0)	
			!

Table D-2. Evidence table for studies addressing management of PPH (Cowan 2014)

Study Description	Intervention	nanagement of PPH (Cowan 2014) Inclusion/Exclusion Criteria & Population	Outcomes
Author: Cowan et al., 2014 ²	Intervention: B-lynch suture Groups:	Operational definition of PPH: Estimated blood loss > 500 mL for vaginal delivery or > 1000 mL for cesarean	Blood loss, index pregnancy, mean (range): G1: 1,800 (1,400-2,200) G2: 1,200 (1,000-1,500) p= <0.001
Country: US	G1: B-lynch suture G2: controls (no suture)	Definition of success of treatment: NR	Transfusion, n (%):
Enrollment period:	N at enrollment: G1: 63	Method of blood loss measurement: NR	G1 : 14 (29.2) G2 : 25 (13.3)
January 2000 to June 2010	G2 : 189	Severity: NR	p=0.01
Birth setting:	N at follow-up: G1: 63	Inclusion criteria: Women with PPH between Jan 2000 and June 2010	ICU admission: NR
Hospital	G2 : 189	who had subsequent pregnancy that achieved 24 weeks gestation	Anemia: NR
Facility	Duration of treatment: NR	Cases: had B-lynch suture Controls: subsequent three cases per each case with	Length of stay: NR
characteristics: Tertiary care	Timing of treatment: NR Order of treatment: NR	index pregnancy complicated by PH but did not receive suture	Mortality: NR
Funding: NR	Length of follow-up: NR	Exclusion criteria: NR	Uterine preservation: NR
Design: Retrospective cohort		Maternal age at index pregnancy, yrs, mean ± SD: G1: 31.0 ± 3.9 G2: 30.5 ± 4.8 p=0.48 Maternal age at subsequent pregnancy, yrs, mean ± SD: G1: 33.5 ± 5.0 G2: 33.7 ± 3.7 p=0.81 Parity, n: Nulliparous G1: 40 (63.5) G2: 149 (78.8) p=0.02	Future fertility, n (%): Pregnancy outcomes in subsequent pregnancy Composite G1: 9 (14.3) G2: 26 (13.8) p=0.92 Previa G1: 5 (7.9) G2: 7 (3.7) p=0.17 Accreta G1: 1 (1.6) G2: 1 (0.5) p=0.41
		Weeks gestation, n (%): NR Single pregnancy, n (%): NR	Preeclamsia

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
_			G1 : 0
		Multiple pregnancy, n (%)	G2: 7 (3.7)
		G1: 5 (2.6)	p= 0.13
		G2: 1 (1.6)	
		p=1.0	Preterm birth
		Race/ethnicity, n (%):	G1: 5 (7.9)
		White	G2: 19 (10.1)
		G1 : 46 (73)	p= 0.62
		G2 : 124 (65.6)	·
			SGA (small for gestational age)
		Black	G1 : 0
		G1: 1 (1.6)	G2: 8 (4.2)
		G2 : 20 (10.6)	p=0.1
		` '	j'
		Latina	Breastfeeding: NR
		G1: 10 (15.9)	
		G2 : 25 (13.2)	Psychological impact: NR
			Herma of intervention, ND
		Asian	Harms of intervention: NR
		G1 : 1 (1.6)	Confounders: NR
		G2 : 8 (4.2)	
			Effect modifiers: NR
		Other or unknown	
		G1: 5 (7.9)	
		G2 : 12 (6.3)	
		BMI, mean ± SD	
		G1: 29.9 ± 4.2	
		G2: 33.7 ± 4.8	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, n (%):	
		Vaginal	
		G1: 1 (1.6)	
		G2: 3 (1.6)	
		Cesarean	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description		G1: 62 (98.4) G2: 186 (98.4)	
		Risk factors/pregnancy complications in index pregnancy, n (%): Placenta previa G1: 2 (3.2) G2: 9 (4.8)	
		Preeclampsia G1: 4 (6.3) G2: 11 (5.8)	
		Preterm birth G1: 5 (7.9) G2: 16 (8.5)	
		Small for gestational age birth index G1: 6 (9.8) G2: 10 (5.3)	
		Primary etiology of PPH, n (%): NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Incidence of severe PPH by year, n (%):
Dupont et al.,	First stage started in 2005:	Severe PPH was defined as one of more of following	2005 : 27 (1.2)
2014 ³	Combining a clinical audit with	criteria: blood loss > 1500 mL or transfusion with	2006: 25 (1.0)
	quarterly audits of morbidity and	concentrated red cells, treatment by radiologic	2007 : 16 (0.7)
See also	mortality from severe PPH	embolization, or conservative surgical treatment, or	2008 : 9 (0.4)
Dupont et al.,		hysterectomy, or transfer to critical care department or	2009: 16 (0.6)
2011 ⁴		intrapartum hemoglobin loss of 4 g/dl or more, or	2010 : 13 (0.4)
`a	summary forms completed by	maternal death	2011: 16 (0.5)
Country:	obstetric staff during daily staff		2012 : 18 (0.6)
rance	meetings. Quality of care defined as	Definition of success of treatment: NR	· ·
Enrollment	optimal if four key steps were taken:		p for trend < 0.001
period:	1) call to senior physician < 10	Method of blood loss measurement: blood collector	Care provided, n (%):
2005 to 2012	minutes, 2) performance of manual	bags	Optimal
	uterine exam or manual removal of		2005 : 7 (25.9)
Birth setting:	placenta < 15 minutes, 3)	Severity: see definition above	2006: 4 (16)
Hospital	administration of oxytocin as first line		2007 : 7 (43.8)
	treatment and 4) sulprostome in 30	Inclusion criteria:	2008: 6 (66.7)
Facility	minutes after diagnosis if atony	All women with vaginal delivery between 2005 and 2012	2009: 8 (50)
characteristics:	persisted.	(21,822) d 140 cases of severe PPH	2010 : 9 (69.2)
evel 3 University	Third stage began in 2010 added	Exclusion criteria: NR	2011: 11 (68.8)
nospital	quarterly monitoring of severe PPH	Exclusion criteria: NR	2012: 12 (66.7)
•	rate	Maternal age, yrs, mean ± SD: NR	2012. 12 (00.1)
Funding: NR	late		Suboptimal
Design:	N severe PPH by year:	Parity, n: NR	2005 : 10 (37)
Pre-post systems	2005 : 27		2006: 17 (68)
evel	2006: 25	Weeks gestation, n (%): NR	2007: 8 (50)
evei	2007 : 16		2008: 2 (22.2)
	2008: 9	Single pregnancy, n (%): NR	2009: 4 (25)
	2009: 16		2010: 3 (23.1)
	2010: 13	Multiple pregnancy, n (%): NR	2011: 4 (25)
	2011: 16		2012: 3 (16.7)
	2012 : 18	Race/ethnicity: NR	2012. 0 (10.17)
	2012: 10	•	Non-optimal
	Duration of treatment: NR	BMI: NR	2005: 10 (37)
	Timing of treatment, ND		2006: 4 (16)
	Timing of treatment: NR	Baseline hemoglobin: NR	2007: 1 (6.3)
	Order of treatment: NR		2008 : 1 (11.1)
	o. a.c. o. a.camionia ini	SES: NR	2009 : 4 (25)
	Length of follow-up: NR		

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
•		Mode of birth, n:	2010 : 1 (7.7)
		Vaginal delivery (100%)	2011: 1 (6.25)
			2012: 3 (16.7)
		Risk factors, n (%): NR	p for trend < 0.001
		Primary etiology of PPH, n (%):	Prophylactic administration of oxytocin
		Atony	2005 : 5 (18.5)
		2005 : 24 (88.9)	2006 : 18 (72)
		2006 : 19 (769)	2007 : 10 (63)
		2007: 8 (50)	2008 : 9 (100)
		2008 : 7 (77.8)	2009: 14 (87.5)
		2009: 10 (62.5)	2010: 13 (100)
		2010 : 8 (61.5)	2011: 16 (100)
		2011: 9 (56.3)	2012: 16 (88.8)
		2012: 10 (100)	p for trend < 0.001
			Examination of the uterine cavity
			2005 : 19 (70.4)
			2006: 23 (92)
			2007 : 16 (100)
			2008 : 8 (89)
			2009: 15 (93.8)
			2010 : 12 (92.3)
			2011: 16 (100)
			2012: 18 (100)
			p for trend =0.03
			Examination of the uterine cavity within 15
			minutes of PPH diagnosis
			2005 : 7 (25.9)
			2006: 22 (88)
			2007: 10 (63)
			2008 : 8 (89)
			2009 : 15 (93.8)
			2010: 12 (92.3)
			2011: 16 (100)
			2012: 17 (94.4)
			p for trend <0.001
			Instrumental examination of vagina/cervix
			2005 : 11 (40.7)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			2006: 18 (72)
			2007 : 9 (56)
			2008: 8 (89)
			2009: 15 (93.8)
			2010 : 13 (100)
			2011: 15 (95.8)
			2012: 18 (100)
			p for trend < 0.001
			Intravenous administration of sulprostone for
			subset with severe PPH due to uterine atony
			2005: 11 (45.8)
			2006: 15 (78.9)
			2007: 7 (87.5)
			2008: 6 (85.7)
			2009: 8 (80)
			2010 : 8 (100)
			2011 : 8 (88.9)
			2012 : 8 (80)
			p for trend =0.1
			Intravenous administration of sulprostone within
			30 minutes of PPH diagnosis for subset with
			severe PPH due to uterine atony
			2005 : 0
			2006: 8 (42.1)
			2007 : 2 (25)
			2008: 6 (85.7)
			2009: 5 (50)
			2010: 5 (62.5)
			2011: 8 (88.9)
			2012 : 8 (80)
			p for trend < 0.001
			Harms of intervention: NR
			Confounders: NR
			Effect modifiers: NR

Table D-4. Evidence table for studies addressing management of PPH (Einerson 2014)

Study	ce table for studies addressing man	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
	Intervention:	Operational definition of PPH:	Blood loss, estimated mL G1: 1,168 ± 688
Einerson et al.,	Training program for perinatal	Estimated blood loss greater than 500 mL for vaginal	G2: 1,265 ± 905
	nursing, residents, fellows, midwives	delivery and > 1,000 mL for cesarean delivery or if	p= 0.014
	and physicians in OB and anesthesia departments in early diagnosis and	received a blood transfusion or uterotonic medications for obstetric hemorrhage	EBL > 1,500 mL, n (%)
	management of PPH.		G1: 127 (21.5)
Enrollment		Definition of success of treatment : changes in patient	G2: 669 (26.6)
period:	sessions to improve EBL	care and outcomes	p= 0.01
	assessment, 2) multidisciplinary		
		Method of blood loss measurement: NR	Transfusion, n (%):
	institution if universal active		Packed red cells
Birth setting:	management of 3 rd stage of labor.	Severity: NR	G1: 63 (10.6)
Hospital	Crounce	Inclusion exiterio:	G2: 134 (12.5)
	Groups:	Inclusion criteria:	p= 0.21
. aomity	G1: pre protocol	Query electronic records to identify women with PPH	P= 0.21
	G2: post protocol	defined as EBL of > 500 mL for vaginal delivery or >	Fresh frezen plaama
Tertiary care	N:	1000 mL for cesarean or if received a blood	Fresh frozen plasma G1: 18 (3.0)
	G1: 592	transfusion or uterotonic medications for obstetric	
i anang.	C2. 2512	hemorrhage	G2 : 64 (2.6)
Kenneth and Anne		Records identified electronically were individually	p= 0.50
	Duration of treatment: NR	reviewed to confirm diagnosis of PPH	
Griffin Foundation	Duration of treatment. 1410	Exclusion criteria: NR	Cyroprecipitate
Design:	Timing of treatment: NR	Exclusion cinteria. NIX	G1: 11 (1.9)
Pre-post (Systems	Order of treatment: NR	Maternal age, yrs, mean ± SD:	G2: 94 (3.8)
level)	Order of treatment: NR	G1: 31.5 ± 6.1	p= 0.02
10101)	Length of follow-up: NR	G2: 32.0 ± 5.6	
		p=0.038	Platelets
			G1 : 7 (1.2)
		Parity, n (%):	G2: 39 (1.6)
		Nulliparous	p= 0.50
		G1: 378 (63.9)	
		G2: 1543 (61.4)	More than 2 units pRBCs
		p= 0.265	G1: 27 (4.6)
			G2: 113 (4.5)
		Gestational age, mean weeks ± SD:	p= 0.94
		G1: 38.6 ± 2.8	·
		G2: 38.6 ± 2.7	More than 2 units FFP
		p=0.879	G1: 9 (1.5)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Single pregnancy, n (%): NR	G2 : 36 (1.4)
			p= 0.87
		Multiple pregnancy, n (%):	ľ
		G1 : 75 (12.7)	More than 2 units cryoprecipitate
		G2: 309 (12.3)	G1 : 1 (0.2)
		p=0.802	G2 : 22 (0.9)
		p=0.002	p= 0.07
		Race/ethnicity:	β= 0.07
		Caucasian	More than 2 units platelets
		G1: 307 (51.9)	G1: 1 (0.2)
		G2: 1379 (54.9)	G2: 11 (0.4)
		G2. 1379 (34.9)	
		African American	p= 0.34
		African-American	4 an magne unite tatal black muskuste
		G1 : 72 (12.2)	4 or more units total blood products
		G2 : 282 (11.2)	G1: 22 (3.7)
			G2 : 106 (4.2)
		Hispanic	p= 0.58
		G1 : 107 (18.1)	
		G2 : 444 (17.7)	ICU admission
			G1: 14 (2.4)
		Asian	G2: 57 (2.3)
		G1 : 19 (3.2)	p= 0.93
		G2: 185 (7.4)	
			Anemia: NR
		Other	
		G1: 87 (14.7)	Length of stay: NR
		G2: 220 (8.8)	
		p< 0.001	Mortality: None
		ВМІ	Uterine preservation, n (%):
		G1: 30.4 ± 5.9	Embolization via interventional radiology
		G2: 31.4 ± 6.5	G1 : 4 (0.7)
		p< 0.001	G2 : 45 (1.8)
		F	p= 0.05
		Baseline hemoglobin: NR	
			Hysterectomy
		SES: NR	G1: 7 (1.2)
		320.111	G2: 43 (1.7)
		Mode of birth, n:	p= 0.36
		Mode of biffit, it.	ρ= υ.ου

Study Description	Intervention	Inclusion/Exclusion	Outcomes
		Criteria & Population	
		Spontaneous vaginal	Future fertility: NR
		G1: 271 (45.8)	
		G2: 1084 (43.1)	Breastfeeding: NR
		Operative vaginal	Psychological impact: NR
		G1: 63 (10.6)	Harms of intervention: NR
		G2: 215 (8.6)	O and a sound a mark NID
		Cesarean	Confounders: NR
		G1: 258 (43.6)	Effect modifiers: NR
		G2: 1215 (48.3)	116 6 1 (00)
		p= 0.067	Uterotonic used, n (%):
			G1: 278 (47.0)
		Risk factors, n (%):	G2: 1628 (64.8)
		History of cesarean	p<0.001
		G1 : 71 (12)	Intrauterine balloon tamponade, n (%):
		G2 : 362 (14.4)	G1: 17 (2.9)
		p=0.13	G2: 155 (6.2)
		Labaria du atia a	p=0.002
		Labor induction	B-Lynch, n (%):
		G1: 158 (26.7) G2: 793 (31.6)	G1: 23 (3.9)
		p=0.021	G2 : 151 (6.0)
		p=0.021	p = 0.042
		Preeclampsia	·
		G1 : 54 (9.1)	Curettage, n (%):
		G2 : 269 (10.7)	G1 : 29 (4.9)
		p=0.26	G2 : 127 (5.1)
		ľ	p = .875
		Placenta previa	Use of >2 uterotonics, n (%):
		G1 : 20 (3.4)	G1: 125 (21.1)
		G2 : 73 (2.9)	G2: 1064 (42.3)
		p=0.54	p<.001
		Use of oxytocin	
		G1: 378 (64.2)	
		G2 : 1659 (66.3)	
		p=0.32	
		0	
		Chorioamnionitis	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 : 65 (11) G2 : 300 (11.9) p=0.52	
		Primary etiology of PPH, n (%): NR	

Comments: See also Lappen et al., 2013 for earlier report on same intervention

Table D-5. Evidence table for studies addressing management of PPH (Ferrazzani 2014)

Study	ce table for studies addressing man	Inclusion/Exclusion Criteria & Population	Outcomes
Ferrazzani et al., 2014 ⁶ Country: Italy	Intervention: Intrauterine inflated catheter balloon (Rusch balloon) inserted after failure of medical treatment to control PPH Groups: G1: intrauterine balloon	Operational definition of PPH: According to ACOG definition and/or any blood loss that had the potential to produce hemodynamic instability Definition of success of treatment: Bleeding stopped – "positive tamponade test"	Blood loss, mean ± SD: G1: 1759 ± 1011 Transfusion, meadian (range): RBC Units G1: 2 (0-15)
December 2002 to July 2012 Birth setting: Hospital Facility	Duration of treatment: NR Timing of treatment: after medical treatment failed Order of treatment: Initial treatment	Method of blood loss measurement: clinical estimation, collection bag after vaginal delivery; both suction and collection of blood loss by drape measurement during cesarean Severity: NR Inclusion criteria:	ICU admission: NR Anemia: NR Length of stay (days of postpartum admission) G1: 6.2 ± 3.0
Two hospitals Funding: NR Design:	or i.v.v methylergometrine, and finally iv. Sulprostone (0.5 mg in 250 mL saline)	PPH Exclusion criteria: traumatic cases of PPH, such as vaginal or cervical lacerations Maternal age, yrs, mean ± SD:	Mortality: G1: 0 Uterine preservation: n (%) G1: 42/52 (80)
Prospective case series		G1: 34.4 ± 4.4 Parity, n (%): G1: 39 (75) Weeks gestation, mean ± SD: G1: 36.2 ± 4.2	Future fertility n=31 Follow-up in 4-108 months G1: 7/31 (had subsequent pregnancies) 4 carried to term without complications 1 still pregnant at follow up 2 early abortions
		Single pregnancy, n (%): NR Multiple pregnancy, n (%): G1: 5 (9.6) Race/ethnicity: NR BMI: NR	1 ectopic pregnancy Breastfeeding: NR Psychological impact G1: 9/31 psychological trauma Harms of intervention Harms pre-specified: No
			Harms, n (%):

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
		Baseline hemoglobin, mean ± SD:	Inadvertant discharge of balloon
		Prepartum	G1: 1 (1.9)
		G1: 11.0 ± 1.6	Doct continue consis
		Deathartum	Post-partum sepsis G1: 2 (3.8)
		Postpartum G1: 7.5 ± 1.7	G1. 2 (3.6)
		O1. 7.5 ± 1.7	Successful treatment: 39/52 (75)
		SES: NR	, ,
			Successful treatment by cause of PPH: NR
		Mode of birth, n (%):	Atony alone: 20/24 (83)
		Vaginal	
		G1 : 12 (23)	Atony & previa &/or accrete: 3/7 (42)
			Previa alone: 9/11 (81)
		Instrumental G1: 2 (3.8)	Previa-accreta: 2/5 (40)
		G1. 2 (3.6)	1 1evia-accieta. 2/3 (40)
		Emergency cesarean	
		G1: 19 (36.5)	
		,	
		Elective cesarean	
		G1 : 19 (36.5)	
		Risk factors, n (%): NR	
		(70). Tit	
		Primary etiology of PPH, n (%):	
		Atony	
		G1 : 31 (59.6)	
		Placenta accrete	
		G1: 5 (9.6)	
		Placenta previa	
		G1: 11 (21.2)	
		31. 11 (21.2)	
		Placenta previa and accrete	
		G1 : 5 (9.6)	

Table D-6. Evidence table for studies addressing management of PPH (Inoue 2014)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author: Inoue et al., 2014 ⁷ Country: Japan Enrollment period: Jan 2002 to Dec 2011 Birth setting: Hospitals (n=23) Facility characteristics: Tertiary care, Funding: Agency/NR Design: Case series, retrospective	Intervention: Transarterial embolization (TAE) Groups: G1: intervention G1a: emergency TAE G1b: preventive TAE N at enrollment: G1: 211 G1a: 161 G1b: 60 Duration of treatment: NR Timing of treatment: NR Order of treatment: NR Length of follow-up: 3 months to 3 years (n=113)	Operational definition of PPH: Over 500 mL of bleeding Definition of success of treatment: In emergency situation: no other surgical procedure necessary for hemostasis Preventive procedure: when hemorrhage could be controlled with no additional procedures Method of blood loss measurement: NR Severity: NR Inclusion criteria: Women who underwent TAE for PPH in time period, including as preventative treatment Exclusion criteria: None Maternal age, yrs, mean ± SD: G1a: 32.4 ± 4.8 G1b: 30.1 ± 6.1 Parity, n: Primipara G1a: 76 (47.2) G1b: 25 (50) Multipara G1a: 85 (52.8) G1b: 25 (50) Weeks gestation, n (%): < 22 weeks G1a: 37 (23) G1b: 19 (38) ≥ 22 weeks	Blood loss, n (%): 0-500 mL G1a: 8 (5.0) G1b: 30 (60) 500-1999 mL G1a: 34 (24.2) G1b: 4 (8.0) 2000-4999 mL G1a: 54 (33.5) G1b: 2 (4.0) > 5000 mL G1a: 25 (15.5) G1b: 0 Not reported G1a: 40 (24.8) G1b: 14 (28.0) Transfusion, n (%): Red blood cell G1a: 113 (70.2) G1b: 2 (2.0) Fresh frozen plasma G1a: 85 (62.8) G1b: 0 Platelets G1a: 47 (29.2) G1b: 0 ICU admission: NR
		G1a: 124 (77)	Anemia: NR

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
•		G1b : 31 (62)	
			Length of stay: NR
		Single pregnancy, n (%): NR	
			Mortality: None reported
		Multiple pregnancy, n (%): NR	'
			Uterine preservation:
		Race/ethnicity: NR	Success of TAE procedure
			G1a : 91.9%
		BMI: NR	G1b : 96%
		Baseline hemoglobin: NR	Hysterectomy
			G1 : 18
		SES: NR	
			Future fertility:
		Mode of birth, n: NR	Pregnancies conceived after TAE
		· · · · · · · · · · · · · · · · · · ·	G1: 42 pregnancies in 40 women
		Risk factors, n (%): NR	
			Pregnancy rate among spontaneous conceived
		Primary etiology of PPH, n (%):	or visited fertility clinic (n=76)
		Subset > 22 weeks gestation n=155	G1 : 52.6%
		Atony	
		G1 : 73/155	Breastfeeding: NR
		Placental polyp/retained placenta	Pough alouis alimona de NID
		G1 : 53/155	Psychological impact: NR
			Harms of intervention:
		Amniotic embolism	Amenorrhea
		G1: 8	G1 : 7/113
		Placenta accreta	Abnormal menstruation
		G1: 8	G1 : 2/113
		Placenta previa	Asherman syndrome
		G1: 5	G1 : 4/113
		Low lying placenta	Intrauterine infection
		G1: 4	G1: 6/113
		Vaginal and vulva hematoma	Uterine necrosis
		G1 : 10	G1 : 3/113

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Uterine rupture G1: 4	Acute complications G1: 5.3%
		Vaginal and perinlea tears G1: 3	Overall complication rate G1 : 13.3%
		Uterine arteriovenous malformation	Confounders: NR
		G1: 2	Effect modifiers: NR
		Others G1: 8	

Table D-7. Evidence table for studies addressing management of PPH (Mallaiah 2014)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	
Mallaiah et al.,	Phase 1- shock pack major	Estimated blood loss > 1500 mL	Blood loss, n:
2014 ⁸	hemorrhage packs of 4 units RBS, 4	Estimated blood loss > 1500 file	< 1499 mL
2014	units FFP, and one adult dose of	Definition of success of treatment: NR	G1 : 10
Country:	platelets	Definition of success of treatment. Nix	G2: 12
UK	Phase 2- fibrinogen- protocol	Method of blood loss measurement: NR	
Enrollment	updated to remove blind	metriod of blood loss measurement. Wit	1500-2999 mL
period:	administration of FFP from start of	Severity: NR	G1: 12
•	pathway	Severity. NIX	G2: 19
April 2011 to	,	Inclusion criteria:	
June 2013	Groups:	Major obstetric hemorrhage, EBL > 1500 mL) associated	3000-4999 mL
Birth setting:	G1: shock pack April 2011-Mar 2012	with coagulopathy (FIBTEM A5 < 12 mm, indicative of	G1 : 8
Hospital	G2: fibrinogen July 2012 to June	plasma fibrinogen level of 2 g.l ⁻¹	G2: 7
	2013	Exclusion criteria:	
Facility	N at enrollment:		> 5000 mL
characteristics:		patients receiving anticoagulant therapy	G1: 3
Tertiary care,	G1 : 42 G2 : 51	Maternal age, yrs, mean ± SD: NR	G2 : 3
Funding: NR	N at follow-up:	Parity, n: NR	Not recorded
Design:	G1 : 42		G1: 9
	G2 : 51	Weeks gestation, n (%): NR	G2 : 10
Pre-post			
	Duration of treatment: NR	Single pregnancy, n (%): NR	Transfusion, median (range):
	Timing of treatment: NR		Blood components
	Timing of treatment. NIX	Multiple pregnancy, n (%): NR	G1: 8.0 (0-32)
	Order of treatment: NR		G2: 3.0 (0-26
	Length of follow-up: NR	Race/ethnicity: NR	p= 0.0004
		BMI: NR	Fibrinogen
			G1: 3.2 (0-20.4)
		Baseline hemoglobin: NR	G2: 0 (0-12.4)
			p= 0.0005
		SES: NR	
			ICU admission, n (%)
		Mode of birth, n: NR	G1 : 4 (9%)
		Risk factors, n (%): NR	G2 : 1 (2%)
		Primary etiology of PPH, n:	Anemia: NR

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
		Abruption	Length of stay: NR
		G1: 3	
		G2 : 7	Mortality: None
		Placenta previa	Uterine preservation, n (%):
		G1: 5	Postpartum hysterectomy
		G2 : 1	G1 : 6 (14)
			G2 : 3 (6)
		Trauma	p=ns
		G1: 11	P=113
		G2: 19	Balloon tamponade
		G2. 19	G1: 9
		A4	G2 : 6
		Atony	G2: 0
		G1: 7	
		G2 : 5	Brace suture
			G1: 8
		Uterine inversion	G2 : 7
		G1 : 0	
		G2 : 2	Future fertility: NR
		Other	Breastfeeding: NR
		G1 : 6	3
		G2 : 17	Psychological impact: NR
			Harms of intervention, n (%):
			TACO
			G1 : 4 (9)
			G2 : 0
			p= 0.0367
			TRALI
			G1: 0
			G2 : 0
			Confounders: NR
			Effect modifiers: NR

Table D-8. Evidence table for studies addressing management of PPH (Park 2014)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author: Park et al., 20149 Country: S. Korea Enrollment period: January 2000 to December 2012 Birth setting: NR Facility characteristics: Tertiary care	Intervention: Transcatheter arterial embolization performed by interventional radiologists to treat secondary PPH Groups: G1: Embolization G1a: Successful G1b: Failed N: G1: 52 G1a: 47 G1b: 5 Duration of treatment: NR Timing of treatment: NR	·	Successful control of bleeding n, (%): G1: 47/52 (90.4) Harms pre-specified: Classified as major vs. minor using Society of Interventional Radiology guidelines Harms, n: Procedure related complications G1: 0
Funding: NR Design: Retrospective case series	exploration of uterine cavity, uterine	Exclusion criteria: NR Maternal age, yrs, mean (range): G1: 31.6 (25-40) Parity, n (%): Primiparous G1: 35 (67.3) Multiparous G1: 17 (32.7) Weeks gestation, n (%): NR Single pregnancy, n (%): NR Multiple pregnancy, n (%): NR Race/ethnicity: NR	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, n (%): Vaginal G1: 34 (65.4)	
		Cesarean G1: 18 (34.6)	
		Risk factors, n: History of cesarean G1: 8	
		Primary etiology of PPH, n: Retained placenta G1: 23	
		Placental anomaly G1: 3	
		Placental accreta/increta G1: 2	
		Placenta previa G1: 1	
		Uterine AVM G1: 6	
		Rupture or injury of uterine artery G1: 9	
		Uterine subinvolution/atony G1: 5	
		Trauma (cervical laceration) G1: 1 Coagulopathy (maternal ITP)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 : 2	
		Unknown	
		G1: 3	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Intervention:	Operational definition of PPH:	Fatigue, measured by Multidimensional
Prick et al., 2014 ^{10,}	Red blood cell (RBC) transfusion of	blood loss of ≥1000 ml and/or a decrease in Hb	Fatigue Inventory, mean adjusted for
1	at least one unit of RBCs aiming to	concentration of ≥1.9 g/dl (1.2 mmol/l) and had an Hb	baseline and mode of delivery:
	reach Hb concentration of at least 8.9	concentration between 4.8 and 7.9 g/dl (3.0-4.9 mmol/l)	At three days:
Country:	g/dl (5.5 mmol.l).	12-24 hours after delivery	G1: 15.68
Netherlands	,	, and the second	G2: 16.45
	Non-intervention group were allowed	Definition of success of treatment: in transfused	G1 vs G2 : p=0.024
Enrollment	RBC transfusion if severe symptoms	subjects, aim was to reach Hb concentration of at least	·
period:	of anemia developed or at physicians		At one week:
May 2004 to	discretion.	3.1 (3.1)	G1 : 14.02
ebruary 2011		Method of blood loss measurement: NR	G2: 15.08
	Additional use of iron and/or folic acid		G1 vs G2: p=0.007
Birth setting:	supplementation according to local	Severity: NR	0.10 0 <u>1.</u> p 0.00.
delivered at	protocol was allowed		At three weeks:
nospital or were	protoco: was anowed	Inclusion criteria:	G1: 10.88
	Groups:	 postpartum hemorrhage (defined above) 	G2: 11.54
	G1: RBC transfusion	 good knowledge of the Dutch language 	G1 vs G2 : p=0.14
ionic birti	G2: Control	good knowledge of the Dutch language	01 10 02. p=0.11
Facility	Additional use of iron and/or folic acid	Exclusion criteria:	At six weeks:
characteristics:	supplementation according to local	severe symptoms of anemia (defined as dyspnea,	G1: 8.69
	protocol was allowed	syncope, tachycardia >100 beats/minute, angina	G2: 8.95
•	•	pectoris and/or transient ischemic attacks	G1 vs G2: p=0.56
Funding:	N at enrollment:	RBC transfusion administered during or within 12	Blood loss ml, during delivery, median
Grants from	G1 : 259	hours after delivery	(IQR):
andsteiner	G2 : 262	severe pre-eclampsia	G1 : 1485 (1000-1950)
Foundation for			G2 : 1500 (1000-1975)
Blood Transfusion	N at follow-up:	severe infectious disease	
	G1: 258	congenital hemolytic disease	Transfusion:
Stichting Vrienden		compromised immunological status	Received transfusion n (%)
an de		malignancy	G1: 251/258 (97)
	Duration of treatment: NA	severe comorbidity (ASA II/III)	G2 : 33/261 (13)
Jioediiaiisiusie	Datation of treatment. NA	death or critical condition of the neonate	52. 55/251 (15)
Design:	Timing of treatment: NR		Total units (including units transfused during
RTC, stratified for		Maternal age, yrs, mean ± SD:	follow up)
	Order of treatment: NR	G1: 30.7 ± 5.0	G1: 517
	Length of follow-up:	G2: 30.9 ± 5.3	G2: 88
	6 weeks postpartum		G1 vs G2 : p <0.001
ioopitai	Wooko postpartam	Parity, n:	01 10 02. p <0.001

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Nulliparous	Units per woman, median (IQR)
		G1 : 152 (59)	G1: 2 (2-2)
		G2: 143 (55)	G2 : 0 (0-0)
			G1 vs G2: p <0.001
		Weeks gestation, median (IQR):	ICU admission: NR
		G1 : 40 ⁺¹ (38 ⁺⁵ -41 ⁺¹)	
		G2: 40 ⁺⁰ (38 ⁺³ -41 ⁺⁰)	Anemia: NR
		62. 40 (00 41)	Alloma. WY
		Single pregnancy: See below	Hb concentration after transfusion (q/dl),
		onigio prognancy. Goo bolow	median (IQR):
		Multiple pregnancy, n (%):	G1 : 9.0 (8.5-9.6)
		Twin pregnancy	G2 : 8.9 (8.2-9.7)
		G1 : 13 (5%)	G1 vs G2: p =0.56
		G2 : 16 (6%)	G1 VS G2. ρ =0.56
		G2. 10 (0%)	Lib concentration at discharge (g/di)
		Dana /athariaita	Hb concentration at discharge (g/dl):
		Race/ethnicity	G1 : 9.0 (8.5-9.5)
		"Western" ethnic origin (not defined)	G2 : 7.4 (6.8-7.7)
		G1 : 186 (78%)	G1 vs G2: p<0.001
		G2 : 177 (76%)	
			Hb concentration at 6 weeks (g/dl):
		BMI (preconception, kg/m²)	G1 : 12.1 (11.3-12.6)
		G1: 23.3 (21.1-26.6)	G2: 11.9 (10.9-12.6)
		G2 : 22.9 (20.8-26.5)	P=0.18
		Baseline hemoglobin (g/dl), median (IQ range)	Length of stay (median days):
		G1: 7.3 (6.8-7.7)	G1: 2
		G2 : 7.4 (6.8-7.7)	G2 : 2
		, ,	G1 vs G2 : p=0.37
		SES, n (%)	Mortality: NR
		Highest education:	
		None/Primary school	Uterine preservation: NR
		G1: 4 (3%)	Otorino prosorvation: Tit
		G2 : 5 (3%)	Future fertility: NR
		52. 5 (576)	i atalo lorunty. MX
		Lower/Senior secondary vocational education	Breastfeeding, continued until 6 weeks:
		G1: 88 (56%)	G1 : 99/154 (64%)
		G2: 77 (51%)	G2 : 101/143 (71%)
		32. 77 (3170)	52. 101/1 13 (/ 1/0)
		Higher professional education and university	Psychological impact:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1 : 64 (41%)	Health-related quality of life
		G2 : 70 (46%)	Harms of intervention
		, ,	Transfusion reactions:
		Mode of birth, n (%):	G1 : 3 (1%)
		Vaginal	G2 : 0 `
		G1 : 213 (83)	
		G2 : 206 (79)	Physical complications during follow-up
		, ,	Thromboembolic event:
		Operative vaginal (subset of total vaginal)	G1 : 2 (0.9%)
		G1 : 62 (30)	G2 : 2 (0.9%)
		G2 : 48 (24)	
			Urinary tract infection:
		Elective cesarean	G1: 10 (4.4%)
		G1 : 8 (3)	G2 : 14 (6.2%)
		G2 : 15 (6)	
			Infected surgery wound:
		Emergency cesarean	G1: 0
		G1 : 37 (14)	G2: 1 (2.2%)
		G2 : 40 (15)	(===,0)
			Infected episiotomy/rupture:
		Risk factors: NR	G1 : 6 (4.1%)
			2: 6 (4.4%)
		Primary etiology of PPH: NR	Endometritis:
			G1: 5 (2.2%)
			G2: 3 (1.3%)
			Confounders: NR
			Effect modifiers: NR

Table D-10. Evidence table for studies addressing management of PPH (Shields 2014)

Author: Shields et al., 2014 12 Country: US Enrollment period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Birth setting: Brith setting: Browprehensive protocol for treatments: Comprehensive protocol for treatment: Comprehensive protocol for treatment operation: Brate and postpartum to peration: Comprehensive protocol for treatment of maternal hemorrhage. Estimated blood loss > 500 mL for vaginal delivery or > 1000 mL for cesarean Brith setting: Definition of success of treatment: Compliance with treatment: readment: compliance with 5 monitored parameter G1: 54% G3: 80% Transfusion, n: Packed red blood cells G1: 232 G2: 180 G3: 197 Compliance vith 5 monitored parameter delivery or > 1000 mL for cesarean louding with reatment: readment: recompleted, correct lab results obtained for stage 2 uterotonics given without doctor present, blood products administered according to pr	
Shields et al., 2014 12	
Shields et al., 2014 ¹² Comprehensive protocol for treatment of maternal hemorrhage. Initial risk assessment at time of admission. Stage 0: normal intra and postpartum period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Groups: Comprehensive protocol for treatment of maternal hemorrhage. Initial risk assessment at time of admission. Stage 0: normal intra and postpartum treatment protocols assessed by checklist Admission hemorrhage risk assessment completed, correct blood bank request based on risk, blood and clots weighed per protocol, correct lab results obtained for stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Stage 3: continuous bleeding with actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR	
Country: US Initial risk assessment at time of admission. Stage 0: normal intra and postpartum course Enrollment period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Initial risk assessment at time of admission. Stage 0: normal intra and postpartum course Definition of success of treatment: Compliance with streatment protocols assessed by checklist Admission hemorrhage risk assessment completed, correct blood bank request based on risk, blood and clots weighed per protocol, correct lab results obtained for stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR	
Country: US Initial risk assessment at time of admission. Stage 0: normal intra and postpartum course Period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Initial risk assessment at time of admission. Stage 0: normal intra and postpartum treatment of admission. Stage 0: normal intra and postpartum treatment occurse Stage 0: normal intra and postpartum treatment protocols assessed by checklist Admission hemorrhage risk assessment completed, correct blood bank request based on risk, blood and clots weighed per protocol, correct lab results obtained for stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR G1: 54% G3: 80% Transfusion, n: Packed red blood cells G1: 232 G2: 180 G3: 197 Change from G1 to G3: -15% p =0.02 Platelets, n G1: 65 G2: 37 G3: 26	rs
Enrollment period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Birth setting: Hospital Stage 0: normal intra and postpartum course Stage 1: bleeding > 500 mL for correct blood bank request based on risk, blood and clots weighed per protocol, correct lab results obtained for stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR G3: 80% Transfusion, n: Packed red blood cells G1: 232 G2: 180 G3: 197 Change from G1 to G3: -15% p =0.02 Platelets, n G1: 65 G2: 37 G3: 26	
Enrollment period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Course Stage 1: bleeding > 500 mL for vaginal or > 1000 mL Cesarean Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 3: continuous bleeding with actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR Admission hemorrhage risk assessment completed, correct blood bank request based on risk, blood and clots weighed per protocol, correct lab results obtained for stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: 65 G2: 37 G3: 26	
period: Baseline: Nov 2011 to Dec 2011 Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Stage 1: bleeding > 500 mL for vaginal or > 1000 mL Cesarean Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 3: bleeding > 500 mL for vaginal or > 1000 mL Cesarean Stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR Stage 1: bleeding > 500 mL for vaginal or > 1000 mL Cesarean Stage 2 and 3 hemorrhage, were > 2 uterotonics given without doctor present, blood products administered according to protocol Change from G1 to G3: -15% p =0.02 Platelets, n G1: 65 G2: 37 G3: 26	
Baseline: Nov 2011 to Dec 2011 Post	
2011 to Dec 2011 Post respond to conservative treatment outlined in stage 1 Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 3: continuous bleeding with actual or expected blood loss > 1500 Sept. 2012 to Oct 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Stage 2: bleeding that did not respond to conservative treatment outlined in stage 1 Stage 3: continuous bleeding with administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: 232 G2: 180 G3: 197 Change from G1 to G3: -15% p =0.02 Platelets, n G1: 65 G2: 37 G3: 26	
Post implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Post implementation respond to conservative treatment outlined in stage 1 Stage 3: continuous bleeding with actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR G2: 180 G3: 197 Change from G1 to G3: -15% p =0.02 Platelets, n G1: 65 G2: 37 G3: 26	
implementation: April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital outlined in stage 1 Stage 3: continuous bleeding with actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: baseline G2: post implementation time 1 administered according to protocol Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: baseline G2: post implementation time 1	
April 2012 to June 2012 Sept. 2012 to Oct 2012 Birth setting: Hospital Stage 3: continuous bleeding with actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: baseline G2: post implementation time 1 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: 65 G2: 37 G3: 26	
2012 actual or expected blood loss > 1500 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Birth setting: Hospital Birth setting: G1: baseline G2: post implementation time 1 Method of blood loss measurement: recommended: weighing all lap sponges, bed linens if needed, and fluid in collection systems Severity: NR Method of blood loss measurement: recommended: Weighing all lap sponges, bed linens if needed, and fluid in collection systems G1: 65 G3: 26	
Sept. 2012 to Oct 2012 ML	
2012 Groups: in collection systems Birth setting: Hospital G2: post implementation time 1 in collection systems G2: 37 G3: 26	
Birth setting: Hospital G1: baseline G2: post implementation time 1 G3: 26 G3: 26	
Hospital G2: post implementation time 1	
G3: post implementation time 2 Inclusion criteria: NR Change from G1 to G3: -60% p < 0.01	
Cryoprecipitate, n	
N deliveries: Exclusion criteria: NR G1: 43	
[G2: 18]	
lin size from small G2. 10,457 G3: 18	
rural to large G3: 11,109 Parity, n: NR	
Stage 2, n (% per 1000 deliveries): Change from G1 to G3: -58% p < 0.01	
G1: 73 (7.01) Weeks gestation, n (%): NR Fresh frozen plasma, n	
Funding: G2: 99 (9.47) Single programmy n (%) NIP	
Agency/NR G3: 107 (9.58) Single pregnancy, n (%): NR G2: 24	
Design: Stage 3, n (% per 1000 deliveries(: Multiple pregnancy, n (%): NR	
Pre-post (systems G1 · 28 (2 68)	
level) G2: 32 (3.06) Race/ethnicity: NR Total blood products, n (% per 1000 deli	
G3: 48 (4 29)	1100)
Note: See related	
study Shields et al. 13 Duration of treatment: NR G3: 297 (26.6)	
Timing of treatment: NR Baseline hemoglobin: NR	
Change from G1 to G3: -25.9% p < 0.0)1

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Order of treatment: NR	SES: NR	ICU admission: NR
	Length of follow-up: NR	Mode of birth, n: NR	Anemia: NR
		Risk factors, n (%): NR	Length of stay: NR
		Primary etiology of PPH, n (%): NR	Mortality: NR
			Uterine preservation: Hemorrhage with peripartum hysterectomy, n (per 1000 births) (by calendar year) 2011: 82 (1.22) 2012: 67 (1.04) Difference -14.8% (p=0.2)
			Future fertility: NR
			Breastfeeding: NR
			Psychological impact: NR
			Harms of intervention: NR
			Confounders: NR
			Effect modifiers: NR

Comments: Authors note 6 items in protocol compliance checklist but report on compliance with 5 items (not specified).

Table D-11. Evidence table for studies addressing management of PPH (Teofili 2014)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention: Transfusion	Operational definition of PPH: NR	Harms pre-specified: No
Teofili et al., 2014 ¹⁴	Groups: G1: intervention	Definition of success of treatment: NR	Harms, n (%): Transfusion-related acute lung injury (TRALI),
Country: Italy	N at enrollment: G1: 71	Method of blood loss measurement: NR	including possible TRALI (defined as new onset hypoxemia within 6 hours after transfusion, with
Enrollment period:	N at follow-up:	Severity: NR Inclusion criteria:	bilateral pulmonary changes, in absence of cardiogenic pulmonary edema) n: G1: 14
Jan 2005 to Dec 2011	G1: 71 Duration of treatment: NR	patients receiving at least 3 units of blood within in 24 hours after delivery	Transfusion-associated circulatory overload
Birth setting: Hospital	Timing of treatment: NR	Exclusion criteria: NR	(TACO) (d in above count) G1: 1
Facility	Order of treatment: NR Length of follow-up: NR	Maternal age, yrs, mean \pm SD: G1: 34 ± 5.5	
characteristics: Tertiary care,		Parity, n: NR	
Funding: NR (Authors state		Weeks gestation, n (%): NR	
no competing interests exist)		Single pregnancy, n (%): NR	
Design: Case series,		Multiple pregnancy, n (%): NR	
retrospective		Race/ethnicity: NR BMI: NR	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, %: Vaginal G1: 21	
		Cesarean G1: 79	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Risk factors, n (%): Pregnancy associated hypertensive disorders G1: 8 (11.3) Preexisting morbidities G1: 21 (29.6) Primary etiology of PPH, n (%): NR	

Table D-12. Evidence table for studies addressing management of PPH (Zatta 2014)

Intervention Intervention: Criteria & Population Outcomes		nce table for studies addressing ma	Inclusion/Exclusion	L .
Zatta et al., 2014 ¹⁵ Received ir Villa for off-label indication-subset of registry cases who received it for obstetric hemorrhage Australia and New Zealand Enrollment period: 2000 to 2009 Birth setting: NR Facility characteristics: 96 hospitals d, 75 reported off-label use of rFVIIa patients (177 cases) Use of rFVIIa Unrestricted educational grant from Novo Nordisk Pharmaceuticals (makers of rFVIIa) Design: Registry case series Received ir Villa for off-label use of resistry cases who received it for obstetric hemorrhage Received ir Villa for off-label use of resistry name of the period: Severity: NR Method of blood loss measurement: NR Severity: NR Method of blood loss measurement: NR Severity: NR Received ir Villa it for obstetric hemorrhage Method of blood loss measurement: NR Severity: NR Received if Villa it for obstetric hemorrhage Method of blood loss measurement: NR Severity: NR Received if Villa it for obstetric hemorrhage Method of blood loss measurement: NR Severity: NR Receiverity: NR Receiverity: NR Registry patients receiving rFVIIa to preempt or treat clinical bleeding episodes outside the approved indications oriteria: Patients with acquired hemophilia Maternal age, yrs, mean ± SD: NR Parity, n: NR Weeks gestation, n (%): NR Multiple pregnancy, n (%): NR Multiple pregnancy, n (%): NR Patients with DIC G1: 1 (0.6) Patients with DIC G1: 2 (0.6) Patients with DIC G1: 2 (0.6) Patients with DIC G1: 3 (1.7) Patients with DIC G1: 9 (61:) Method of blood loss measurement: NR Method of blood loss measurement: NR Method of blood loss measurement: NR Bellusin criteria: Registry patients receiving rFVIIa to preempt or treat clinical bleeding episodes outside the approved indications G1: 1 (0.6) Acute myocardial infarction G1: 1 (0.6) Venous thrombosis G1: 1 (0.6) Pulmonary embolism G1: 1 (0.6) Patients with DIC G1: 9 (61:) Method of birth, n: NR Severity: NR Baseline hemoglobin: NR Severity: NR Method of birth, n: NR		Intervention		Outcomes
Risk factors, n (%): NR	Study Description Author: Zatta et al., 2014 ¹⁵ Country: Australia and New Zealand Enrollment period: 2000 to 2009 Birth setting: NR Facility characteristics: 96 hospitals d, 75 reported off-label use of rFVIIa Funding: Unrestricted educational grant from Novo Nordisk Pharmaceuticals (makers of rFVIIa) Design: Registry- case	Intervention: Received rFVIIa for off-label indication- subset of registry cases who received it for obstetric hemorrhage Groups: G1: intervention N: 3446 cases of off-label use of rFVIIa, 177 obstetric cases G1: 175 patients (177 cases) Duration of treatment: NR Timing of treatment: NR Order of treatment: NR Length of follow-up: up to 28 days following rFVIIa administration	Inclusion/Exclusion Criteria & Population Operational definition of PPH: NR Definition of success of treatment: NR Method of blood loss measurement: NR Severity: NR Inclusion criteria: Registry patients receiving rFVIIa to preempt or treat clinical bleeding episodes outside the approved indications criterion 2 Exclusion criteria: patients with acquired hemophilia Maternal age, yrs, mean ± SD: NR Parity, n: NR Weeks gestation, n (%): NR Single pregnancy, n (%): NR Multiple pregnancy, n (%): NR Race/ethnicity: NR BMI: NR Baseline hemoglobin: NR SES: NR Mode of birth, n: NR	Harms, n (%): 28-day mortality G1: 11 (6) Total with thromboembolic adverse events G1: 15 (8.6) Arterial thrombosis G1: 2 (1.1) Cerebrovascular accident G1: 1 (0.6) Acute myocardial infarction G1: 1 (0.6) Venous thrombosis G1: 5 (2.9) Deep vein thrombosis G1: 1 (0.6) Pulmonary embolism G1: 1 (0.6) Other thrombosis G1: 3 (1.7) Patients with DIC G1: 9 (5.1) Stroke
Primary etiology of PPH, n (%):				

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Atony G1 : 39	
		Placenta previa G1: 46	
		Placenta accreta/percreta G1: 30	
		Intrauterine fetal death G1: 23	
		Preeclampsia/Eclampsia G1: 20	
		Placental abruption G1: 17	
		Other G1 : 2	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description Author: An et al., 2013 ¹⁶ Country: Korea Enrollment period: 2006-2011 Birth setting: Hospital Facility characteristics: Tertiary care Funding: NR (No conflicts of interest) Design: Case-control	Intervention: Modified B-Lynch suture and square	Criteria & Population Operational definition of PPH: NR Definition of success of treatment: NR Method of blood loss measurement: NR Severity: NR Inclusion criteria: Women who received uterine compression sutures including modified B-Lynch or multiple square sutures Conceived again and received antenatal care at hospital Controls matched for age and parity who did not require uterine compression sutures during prior cesarean Exclusion criteria: women whose subsequent pregnancy outcomes were unknown Maternal age at subsequent pregnancy, yrs, mean ± SD: G1: 34.8 ± 3.0 G2: 33.8 ± 3.2 Parity, n: Nulliparity G1: 39 (92.9) G2: 136 (97.8) Previous delivery, n (%): Emergent cesarean, n (%): G1: 34 (81) G2: 108 (77.7) Weeks gestation, mean: G1: 38.4 ± 0.87	Estimated blood loss (mL): G1: 654 ± 152 G2: 621 ± 144 Transfusion, n (%) G1: 0 G2: 2 (1.7) Preoperative hemoglobin (g/dL): G1: 11.7 ± 1.2 G2: 12.0 ± 1.1 p= 0.19 Postoperative hemoglobin (g/dL): G1: 10.4 ± 1.0 G2: 10.8 ± 1.1 p= 0.05 Pelvic adhesions, n (%): G1: 12 (34.3) G2: 21 (17.5) p= 0.03 Uterine compression sutures, n (%): G1: 1 (2.9) G2: 0 p= 0.06 ICU admission: NR Anemia: NR Length of stay Post op hospital stay over 5 days, n (%): G1: 4 (11.4)
		G2 : 38.4 ± 0.81 Single pregnancy, n (%):	G2: 6 (5.0) 'p= 0.23

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G2: 137 (98.6)	Subsequent pregnancy outcomes, n (%)
			Term delivery
		Race/ethnicity: NR	G1 : 34 (81)
			G2 : 114 (82)
		BMI: NR	p=0.88
			p=0.00
		Baseline hemoglobin: NR	Preterm delivery
		Daddinio nomogiosim. Att	G1: 2 (4.7)
		SES: NR	G2 : 7 (5)
		SES. NIX	
		Made of birth in	p=0.60
		Mode of birth, n:	Microsyliana
		Cesarean	Miscarriage
		Risk factors, n (%):	G1 : 4 (9.5)
		Prior PPH (100%)	G2 : 14 (10.1)
		1 1101 1 1 1 (10070)	p=0.92
		History of emergent cesarean	
		G1: 34 (81)	Ectopic pregnancy
		G2 : 108 (77.7)	G1: 1 (2.4)
		G2. 106 (77.7)	G2: 2 (1.5)
		Deimony of along of DDII in (0/), ND	p=0.68
		Primary etiology of PPH, n (%): NR	
			Fetal death
			G1 : 0
			G2: 1 (0.7)
			p=0.58
			P 5.55
			Perinatal loss
			G1 : 1 (2.4)
			G2: 0
			p=0.07
			p=0.07
			Chromosomol ohromasiiti
			Chromosomal abnormality
			G1 : 0
			G2: 1 (0.7)
			p=0.58
			Breastfeeding: NR
			Psychological impact: NR

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
			Harms of intervention: NR
			Confounders: NR
			Effect modifiers: NR

Table D-14. Evidence table for studies addressing management of PPH (Bateman 2013)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Odicomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Bateman et al.,	Injectable or Oral Methylergonovine		Transfusion:
2013 ¹⁷	administered during delivery	Definition of success of treatment: NR	Packed red blood cells (units), n (%)
Country: US	Groups:	Method of blood loss measurement: NR	G1: 133,312 (95.48)
-	G1: Methylergonovine		G2: 2,078,170 (99.24)
Enrollment	G2: Control (no exposure)	Severity: Measured by charge codes for the number	
period:		of units of packed red blood cells that	1-5
2007-2011	N at enrollment:	were transfused	G1 : 5580 (4.00)
2007 2011	G1: 139,617		G2: 14,893 (0.71)
Birth setting:	G2: 2,094,013	Inclusion criteria:	
Hospitals	32. 2,00 1,010	All inpatient admissions of	6-9
i iospitais	N at follow-up: NR		G1: 469 (0.34)
Facility	at follow-up. NIX		G2 : 670 (0.03)
characteristics:	Duration of treatment: NR	use of a validated algorithm	G2. 070 (0.03)
Varied	Duration of freatment. NR	months down a series of the se	≥ 10
vaned	Timing of treatment, ND	methylergonovine exposure defined by presence of	
F	Timing of treatment: NR	charge code for injectable or oral methylergonovine	G1 : 256 (0.18)
Funding:	Colored ND	during delivery hospitalization	G2 : 280 (0.01)
Supported by the	Order of treatment: NR		
T32 Training		Exclusion criteria:	Fresh frozen plasma (units)
Grant	Length of follow-up: NR	Hospitalizations with diagnoses that indicate	0
		ectopic pregnancy, hydatiform mole,	G1: 138,386 (99.12)
Design:		or other abnormal products of conception	G2: 2,092,159 (99.91)
Retrospective		or procedure codes that indicate abortion	
cohort			1-5
		Maternal age, yrs, mean:	G1: 967 (0.69)
		G1 + G2: 27.7	G2 : 1520 (0.07)
		Parity, n: NR	6-9
			G1 : 157 (0.11)
		Weeks gestation: NR	G2: 214 (0.01)
			≥ 10
		Single pregnancy: NR	G1: 107 (0.08)
			G2: 120 (0.01)
		Multiple pregnancy, n (%):	·
		G1: 4422 (3.17)	ICU admission: NR
		G2: 38,218 (1.83)	

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
		Race/ethnicity, n (%):	Anemia: NR
		White	
		G1 : 68,880 (49.33)	Length of stay: NR
		G2: 1,078,758 (51.52)	
			Mortality: NR
		Black	
		G1 : 16,378 (11.73)	Uterine preservation:
		G2 : 288,592 (13.78)	Peripartum hysterectomy
			G1 : 636 (0.46)
		Hispanic	G2: 1398 (0.07)
		G1: 19,254 (13.79)	,
		G2: 226,627 (10.82)	Future fertility: NR
			_
		Other/Unknown	Breastfeeding: NR
		G1: 35,105 (25.14)	· ·
		G2: 500,036 (23.88)	Psychological impact: NR
			Harms of intervention:
		BMI: NR	Acute Coronary Syndrome (ACS) n, (%):
			Unadjusted
		Baseline hemoglobin: NR	G1: 6 (0.004)
			G2: 52 (0.002)
		SES: NR	Risk ratio (95% CI), Risk difference (95% CI):
			1.73 (0.74-4.03), 1.81 (-1.69 to 5.32)
		Mode of birth, %:	
		Cesarean	Propensity score matched
		G1 + G2: 34.0	G1: 5(0.003)
			G2: 3(0.002)
		Risk factors, n (%):	,
		History of cesarean delivery, n (%):	Risk ratio (95% CI), Risk difference (95% CI):
		G1: 18,131 (12.99)	1.67 (0.40-6.97) 1.44 (-2.56 to 5.45)
		G2: 345,487 (16.50)	(
			Acute Myocardial Infarction (AMI) n, (%):
		Mild Preeclampsia, n (%):	Unadjusted
		G1: 1863 (1.33)	G1: 4 (0.003)
		G2 : 50,322 (2.40)	G2 : 44 (0.002)
			Risk ratio (95% CI), Risk difference (95% CI):
		Eclampsia, n (%):	1.36 (0.49-3.79), 0.76 (-2.11 to 3.64)
		G1: 876 (0.63)	
		G2 : 31,033 (1.48)	Propensity score matched

Study	latementia.	Inclusion/Exclusion	Outcome
Description	Intervention	Criteria & Population	Outcomes
•		Pregnancy-induced hypertension, n (%):	G1 : 4(0.003)
		G1 : 3294 (2.36)	G2 : 3(0.002)
		G2 : 75,697 (3.61)	Risk ratio (95% CI), Risk difference (95% CI):
		(0.0.1)	1.00 (0.20-4.95), 0.00 (-3.47 to 3.47)
		Pre-existing hypertension, n (%):	1.00 (0.20 4.30), 0.00 (0.47 to 0.47)
		G1: 1491 (1.07)	Confounders:
		G2: 45,246 (2.16)	Patient demographics (age, race/ethnicity, and calendar year of delivery)
		Preexisting hypertension with superimposed	Obstetric/medical conditions: hypertensive
		preeclampsia, n (%):	disorders (including preexisting a/o gestational
		G1 : 278 (0.20)	disorder or preeclampsia), diabetes mellitus
		G2 : 11,946 (0.57)	(preexisting or gestational), chronic ischemic
		(0.0.7)	heart disease, chronic renal disease, obesity,
		Obesity n, (%):	dyslipidemia, drug or alcohol abuse, tobacco
		G1: 4980 (3.57)	use, asthma, hypercoagulable conditions,
		G2 : 80,503 (3.84)	migraine headache, chronic anemia, cesarean
		G2. 60,503 (3.64)	
		Description disherence (0/)	delivery, previous cesarean, still
		Preexisting diabetes, n, (%):	birth/intrauterine fetal death, multiple
		G1 : 1041 (0.75)	gestations, chorioamnionitis, and major
		G2: 19,022 (0.91)	puerperal infection
			Markers of the presence, cause and severity of
		Gestational diabetes mellitus, n (%)	obstetric hemorrhage
		G1 : 7902 (5.66)	Characteristics of the hospital at which the
		G2: 116,709 (5.57)	delivery occurred.
		Multiple gestation n, (%):	Effect modifiers: NR
		G1: 4422 (3.17)	
		G2: 38,218 (1.83)	
		Chorioamnionitis n, (%):	
		G1: 4273 (3.06)	
		G2 : 31,224 (1.49)	
		, ,	
		Primary etiology of PPH, n (%):	
		Abnormal Placentation:	
		G1: 4717 (3.38)	
		G2 : 22,640 (1.08)	
		, ()	
		Atony:	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		G1 : 19,410 (13.90)	
		G2: 22,915 (1.09)	
		Coordinathuu	
		Coagulopathy:	
		G1: 795 (0.57)	
		G2 : 3648 (0.17)	
		Trauma:	
		G1 : 10,808 (7.74)	
		G2 : 140,088 (6.69)	
		GE : 140,000 (0.00)	
		Amniotic fluid embolism:	
		G1 : 31 (0.02)	
		G2: 74 (0.00)	
		Uterine rupture:	
		G1: 144 (0.10)	
		G2 : 984 (0.05)	
		, ,	
		Placental abruption:	
		G1: 2016 (1.44)	
		G2: 21,504 (1.03)	
		Antepartum hemorrhage from other sources:	
		G1: 653 (0.47)	
		G2: 6030 (0.29)	
		Delayed hemorrhage:	
		G1: 2050 (1.47)	
		G2: 3128 (0.15)	

Table D-15. Evidence table for studies addressing management of PPH (Bonnet 2013)

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Description		Criteria & Population	Blood loss: NR
A 4 la a	late a continue	Operational definition of BBU	BIOOD IOSS: NR
Author:	Intervention:	Operational definition of PPH:	-
Bonnet et al.,		PPH defined as > decline2.0 g/dL decline in hemoglobin	
201318		level.	RBC only, n (%):
Country:	or cesarean delivery)		G1 (overall): 168/426 (39.4)
France		Clinical definition of PPH: > 500 mL blood loss and/or	G1a : 65 (38.2)
Tance	RBC, fresh frozen plasma (FFP),	excessive blood loss prompting manual removal of	G1b : 17 (27.9)
Enrollment	platelets, blood-derived product	placenta or examination of the uterine cavity.	G1c: 46 (42.2)
period:	(fibrogen concentrates), use of		G1d: 40 (46.5)
December 2004 to	RBC+FFP+PLT+fibrinogen, or	Definition of success of treatment: NR	p=NS
November 2006	massive transfusion > 10 RBC Units		
	Crawna	Method of blood loss measurement: NR	FFP, n (%):
Birth setting:	Groups:	Inclusion aritaria.	G1 (overall): 248/426 (58.1)
Hospital (all	(Inclusion criteria:	G1a: 102 (60.0)
levels)	(within 12 hrs of PPH diagnosis)	Clinical dx of PPH that required RBC transfusion	G1b: 44 (72.1)
	Data for G1 is further broken down	within 12 hrs of diagnosis	G1c: 59 (54.1)
Facility	spontaneous vaginal delivery	Exclusion criteria:	G1d: 43 (50.0)
characteristics:	(170/426); operative vaginal delivery	PPH defined by hemoglobin decline, but not clinical	p = 0.04
Maternity units at	(61/426); cesarean delivery before	diagnosis of PPH	
public, private and	labor (109/246) and cesarean	diagnosis of FFF	Fibrogen, n (%):
university-based	delivery during labor (86/246)	Maternal age, yrs (%):	G1 (overall): 83/426 (19.5)
institutions that	G1a: spontaneous vaginal	<25 yrs:	G1a: 31 (18.2)
belong to regional	G1b: operative vaginal	G1 (overall): 65/426 (15.3)	G1b: 12 (19.7)
perinatal networks	G1c: cesarean before labor	G2 970/6170 (15.7)	G1c: 23 (21.1)
	G1d: cesarean during labor		G1d: 17 (19.8)
Funding:		25-35 yrs:	p=NS
	G2 (overall): not transfused or	G1: 257/426 (60.3)	
Pithagore6 project	transfused later than 12 hrs of PPH	G2: 4061/6170 (65.8)	Platelets, n (%):
funded by the	DX		G1 (overall): 52/426 (12.2)
French Ministry of	N at enrollment: n (%)	>35 yrs:	G1a : 18 (10.6)
	G1 (overall): 426 (65.8% of all	G1: 104/426 (24.4)	G1b : 13 (21.3)
Research Hospital	transfused)	G2: 1137/6170 (18.4)	G1c: 15 (13.8)
Program (contract	G1a: 170 (40)		G1d: 6 (7.0)
no. 27-35)	G1b : 61 (14.3)	Maternal BMI (kg/m ²),n (%)	p=ns
This study was	G1c: 109 (25.5)	Note: data not clearly reported in both groups: G1 totals	
5 mp p 5 . 10 m 2 y m	G1d: 86 (20.1)	357 (83.9%) here and G2 totals 5384 (87.3%)	RBC + FFP + Platelets + Fibrogen, n (%):
doctoral grant	G 14. 00 (20.1)		G1 (overall): 32/426 (7.5)
from AXA	G2 : 6170	≤ 18 (kg/m²):	G1a : 14 (8.2)
Research Funds.	G2. 0170	, ,	- · · · · · · · · · · · · · · · · · · ·

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
		G1 (overall): 22/426 (5.2)	G1b: 8 (13.1)
Design:	N at follow-up: NR	G2 284/6170 (4.6)	G1c: 7 (6.4)
Population-based	Duration of treatment: NR		G1d: 3 (3.5)
retrospective case	Timing of treatment:	19-25 (kg/m ²):	p=ns
series	G1: within 12 hrs of PHH Dx	G1 : 255/426 (59.9)	F 110
	G2: later than 12 hrs post PPH Dx or	G2 : 3837/6170 (62.2)	Median transfused quantity
Note: See related	not transfused	()	RBC, units, (IQR):
studies Deneux-	The translated	26-30 (kg/m ²):	G1 (overall): 3(2-6)
Tharaux 2010 ¹⁹ ,	Order of treatment:	G1 : 55/426 (12.9)	G1a: 3 (2-5)
Schmitz 2011 ²⁰	Step 1: transfusion	G2: 848/6170 (13.8)	G1b : 4 (3-9)
	Step 2: surgical intervention		G1c : 3 (2-6)
	(embolization, conservative surgery,	>30 (kg/m ²):	G1d : 4 (2-5)
	hysterectomy)	G1 : 25/426 (5.9)	p=0.01
	lifysterectority)	G2: 415/6170 (6.7)	p-0.01
	Length of follow-up: NR	<u> </u>	FFP, units (IQR):
		Race/ethnicity: NR	G1 (overall): 4 (2-6)
			G1a: 3 (2-4)
		Prenatal HB level (g/dL), mean ± SD:	G1b : 4 (2-6)
		G1: 11.5 ± 1.4	G1c : 4 (3-6)
		G2: 12.0 ± 1.2	G1d: 3 (2-4)
		p<0.001	p=0.0004
			P 5.555
		Labor and Delivery:	Fibrogen, g (IQR):
		Mode of birth, n (%):	G1 (overall): 3 (3-4.5)
		Vaginal (spontaneous or operative delivery)	G1a :3 (1.5-4.5)
		G1 : 231/246 (54.2)	G1b: 4 (3 – 7.5)
		G2 : 53456170 (86.6)	G1c: 4 (3-5.5)
		p<0.001	G1d: 3 (2 – 4.5)
			p=ns
		Spontaneous vaginal delivery	
		G1 , 170/426 (73.6)	Platelets units (IQR):
		G2 : 4147/6170(77.6)	G1 (overall): 1 (1-2)
			G1a : 1 (1-2)
		Operative vaginal delivery	G1b : 1 (1-2)
		G1 : 61/426 (26.4)	G1c: 1 (1-2)
		G2: 1198/6170 (22.4)	G1d: 2 (1-2)
			p=ns
		Caesarean delivery (before or during labor)	
		G1: , 195/426 (21.3)	≥10 RBC units, n (%):

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G2 : 824/6170 (13.4)	G1 (overall): 46 (10.8)
			G1a : 10 (5.9)
		Caesarean delivery before labor	G1b : 15 (24.6)
		G1: , 109/426 (55.9)	G1c : 16 (14.7)
		G2 : 439/6170 (53.3)	G1d: 5 (5.8)
		(00.0)	p=<0.001
		Caesarean delivery during labor	p= 10.00 i
		G1: , 86/426 (44.1)	FFP/RBC:
		G2: 385/6170 (46.7)	Median (IQR):
		32. 303/01/0 (40.7)	G1 (overall): 0.9=8 (0.5-1)
		Time from delivery to PPH dx, median (IQR)	G1a: 0.7 (0.6-1)
		G1: 12 min (2-45)	G1b: 0.8 (0.5-1)
		G2 : 15 min (9-30)	G1c : 0.8 (0.6-1)
		Risk factors, n (%):	G1d : 0.6 (0.5-1)
		Prior PPH, n (%)	p=ns
		G1 : 29/426 (6.8)	
		G2 : 2876170 (4.7)	FFP/RBC ≥ 0.5, n (%):
		p=<0.04	G1 (overall): 209 (84.3)
		p=<0.0 1	G1a: 85 (83.3)
		Prior Cesarean, n (%)	G1b : 39 (88.6)
		G1: 70/426 (16.4)	G1c: 52 (88.1)
		G2 : 554/6170 (9.0)	G1d: 33 (76.7)
		(p<0.001)	p=ns
		Primiparous, n (%)	Median time from PPH dx to RBC admin (IQR):
		G1: 173/426 (40.6)	G1 (overall): 2 h 18 min (1 hr 18 min to 3 hr 54
		G2: 3130/6170 (50.7)	min)
		p<0.001	G1a: 2 h 30 min (1hr 24 min to 4 h 18 min)
			G1b: 2 hr 12 min (1 hr 18 min to 3 hr 48 min)
		Multiple pregnancies n (%)	G1c: 2 hr 0 min (48 min to 3 hr 36 min)
		G1 : 33/426 (7.8)	G1d: 2 hr 12 min (1 hr 06 min to 3 hr 48 min
		G2 : 216/6170 (3.5)	,
		p<0.001	p=ns
		Drive any etials my of DDII.	Use of pro-hemostatic agents, n (%):
		Primary etiology of PPH:	G1 (overall): 17 (4.0)
		Atony	G1a: 6(3.5)
		Coagulopathy	G1b: 7 (11.5)
		Trauma	G1c: 2 (1.8)
		Abnormal placenta	G1d: 2 (2.3)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	into vention	Criteria & Population	
		Unidentified	p= NA
			ICU Admission, n (%):
			G1 (overall): 180/426 (42.3)
			G1a: 64/170 (37.7)
			G1b: 33/61 (54.1)
			G1c: 45/109 (41.3)
			G1d: 38/86 (44.2)
			p=ns
			P-110
			Anemia: NR
			Length of stay: NR
			Mortality: NR
			Uterine preservation: see Harms
			Future fertility: NR
			Breastfeeding: NR
			Psychological impact: NR
			Harms of intervention: see below
			Confounders: NR
			Effect modifiers: NR
			Harms pre-specified: No
			Harms, n (%), p across all 4 groups: 5 transfusion-related adverse effects were
			recorded; one was severe (pulmonary edema requiring ICU admission)
			Secondary disseminated intravascular
			coagulation (DIC), n (%):
			G1 (overall): 110/426 (25.8) G1a: 42/170 (24.7)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
•			G1b : 19/61 (31.2)
			G1c: 22/109 (20.2)
			G1d: 27/86 (31.4)
			p=ns
			Embolization, n (%):
			G1 (overall): 106/426 (24.9)
			G1a: 49/170 (28.8)
			G1b : 19/61 (31.2)
			G1c: 22/109 (20.2)
			G1d: 16/86 (18.6)
			p=ns
			Conservative treatment, n (%):
			G1 (overall): 58/426 (13.6)
			G1a : 12/170 (7.1)
			G1b: 12/61 (19.7)
			G1c: 23/109 (21.1)
			G1d: 11 (12.8)
			p=0.004
			Hysterectomy, n (%):
			G1 (overall): 64/426 (15.0)
			G1a : 23/170 (13.5)
			G1b : 13/61 (21.3)
			G1c: 23/109 (21.1)
			G1d: 5/86 (15.0)
			p=0.01

Table D-16. Evidence table for studies addressing management of PPH (Chan 2013)

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes

Author:	Intervention:	Operational definition of PPH:	
Chan et al.,	Use and success of second line	Estimated blood loss of at least 4500 msl within 24 become	Blood loss, L mean (range):
2013 ²¹	therapies including uterine	lafter birth	G1: 2 (1.5-20)
2013	compression sutures, uterine artery	aller birtir	G3a: 2.0 (1.5-20)
Country:	compression sutures, uterine aftery	Definition of success of treatment: NR	G3b: 5.1 (1.5-15.0)
Hong Kong		Definition of Success of treatment. NR	G3c: 2.3 (1.5-8.7)
	after failure of uterine massage and	Mathed of blood lose measurement. Duelest collection	G3d: 3.3 (1.6-4.5)
Enrollment	uterotonic agents to stop bleeding.	Method of blood loss measurement: Bucket collection	G3e 1.8 (1.5-15)
period:	Groups:	for vaginal deliveries. Volume estimated with measuring	
Jan 2006 to Dec	G1: intervention	jar. Blood on sheets or pads estimated subjectively by	Transfusion, n (%):
2011	G1a: second line therapies	midwives or doctors. Blood loss in operating theatre	Received packed cell transfusion
Birth setting:	G1b: oxytocin only	usually sucked into measuring bottle and objectively	G1: 79 (86.8)
Hospital	G1c: oxytocin and other uterotonic	measured.	G3a: 4 (0-77)
i iospitai	agents	Once with the NID	G3b: 20 (2-32)
Facility	G2: second line therapies subgroup	Severity: NR	G3c: 10 (3-34)
characteristics:	G2a: sutures	Inclusion criteria:	G3d: 10.5 (10-24)
Consultant led	G2b: balloon tamponade	Gestational age at least 24 weeks	G3e: 3 (0-39)
maternity center	G2c: uae	Massive PPH- EBL at least 1500 mL	
maternity center	0201 000		Volume transfused, pints of packed red cells
Funding:	Alternate groupings	Exclusion criteria: NR	G1 : 4 (0-77)
NR (authors report	G3a: sutures	Maternal age, yrs, mean ± SD:	
no conflicts of	G3b: embolization	G1: 33.3 ± 4.6	Admitted to ICU, n (%):
interest)	G3c: balloon tamponade	G1. 55.5 ± 4.0	G3a: 8/21 (38.1)
Decima	G3d: 2 second line therapies	Parity, n:	G3b: 3/4 (75)
Design:	G3e: no second line therapy	G1: 0 (0-3)	G3c : 8/11 (72.7)1
Cohort	and the decentarine uncrupy		G3d: 6/6 (100)
		Weeks gestation, n (range):	G3e : 12/49 (24.5)
	N:	G1: 38.3 (26.6 - 41.4)	
	G1 : 91		Length of hospital stay, days (range):
	G1a: 42	Single pregnancy, n (%): NR	G3a : 7 (4-31)
	G1b : 33		G3b: 10.5 (5-94)
	G1c : 16	Multiple pregnancy, n (%):	G3c : 8 (4-12)
	G2 : 42	G1: 8 (8.8)	G3d : 7.5 (7-9)
	G2a: 25 (followed by UAE n=4)		G3e : 6 (3-29)
	G2b: 12 (followed by UAE n=1	Race/ethnicity: NR	
	G2c: 5 (followed by sutures n=1)	-	Mortality, n:
	G3a : 21	BMI:	G1 : 1
	G3b : 4	G1: 21.6 ± 3.2	G3a: 0
	G3c : 11		G3b : 0
	G3d : 6	Baseline hemoglobin: NR	G3c: 1/11 (9.1)
	G3e 49		G3d: 0

Duration of treatment: NR	SES: NR	G3e : 0
Timing of treatment: NR	Mode of birth, n:	Uterine preservation, n (%):
	Spontaneous vaginal	Hysterectomy
Order of treatment: NR	G1 : 21 (23.1)	G1: 13 (14.3)
	G3a: 0/21	G1a: 9/42
Length of follow-up: NR	G3b: 0/4	G1b : 1/33
Length of follow-up. NR	G3c: 4/11 (36.3)	G1c : 3/16
	G3d: 1/6 (16.7)	
	G3e 16/49 (32.7)	For G2: subset who received second line
	000 10/10 (02:17)	therapy
	Instrumental (vacuum or low forceps)	N, Success % (95% CI)
	` '	
	G1: 4 (4.4)	G2a : 6 71.4% (51.2%-88.5%)
	G3a: 1/21 (4.8)	G2b : 2 81.6% (59.1%-100%)
	G3b : 0/4	G2c : 1 75% (39.6%-100%)
	G3c: 2/11 (18.2)	
	G3d : 0/6 (G3a: 6 (28.6)
	G3e 1/49 (2.0)	G3b: 1 (25)
		G3c: 2 (18.2)
	Elective cesarean	G3d: 0
	G1: 38 (41.7)	G3e: 4 (8.2)
	G3a: 11/21 (52.4)	
	G3b: 4/4 (100)	Disseminated intravascular coagulopathy
	G3c: 2/11 (18.2)	G1: 16 (17.6)
	G3d: 4/6 (66.6)	G3a : 5 (23.8)
	G3e 18/49 (36.7)	G3b: 2 (50)
	(33.1)	G3c : 5 (45.5)
	Emergency cesarean	G3d: 1 (16.7)
	G1: 28 (30.8)	G3e: 2 (4.1)
	G3a : 9/21 (42.8)	300. 2 (4.1)
	G3b: 0/4	Harms of intervention, n:
	G3c : 3/11 (27.3)	Hysterectomy
	, ,	G1a: 9/42
	G3d : 1/6 (16.7)	G1b+ G1c: 4/49
	G3e 14/49 (28.6)	DIC
		G1a: 13 / 42
	Risk factors, n (%): NR	G1b+ G1c: 2/49
	Primary etiology of PPH, n (%):	Maternal death
	Atony	G1a: 1/42
	G3a: 12/21 (57.2)	G1b+ G1c: 0/49
	G3b : 1/4 (25)	J. 10. 0/40

G3c: 8/11 (72.7) G3d: 1/6 (16.7) G3e 13/49 (26.5)	Confounders: NR Effect modifiers: NR
Placenta previa G3a: 7/21 (33.3) G3b: 2/4 (50) G3c: 0/11 G3d: 2/6 (33.30) G3e 4/49 (8.2)	
Placenta accreta G3a: 2/21 (9.5) G3b: 1/4 (25) G3c: 0/11 G3d: 3/6 (50) G3e 3/49 (6.1)	
Lower genital tract bleeding G3a: 0/21 G3b: 0/4 G3c: 1/11 (9.1) G3d: 0/6 G3e 8/49 (16.3)	
Others G3a: 0/21 G3b: 0/4 G3c: 2/11 (18.2) G3d: 0/6 G3e 21/49 (42.9)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	lataman dia a		Disadisas ad
Author:	Intervention:	Operational definition of PPH: NR	Blood loss, mL:
Dildy et al.,	Dual-balloon catheter tamponade	D (1) (1)	G1 : 2000 (855-8700)
2013 ²²	device (Belfort-Didly Obstetrical	Definition of success of treatment: NR	
Country: US	Tamponade System- ebb)		Transfusion:
-	Groups:	Method of blood loss measurement: NR	Recevied transfusion, n (%)
Enrollment period:	G1: BD-OTS	Severity: NR	G1: 39 (77)
September 2010	N at enrollment:	Inclusion criteria:	Units transfused, n median (range)
to October 2012	G1: 57 (55 had PPH)		G1 : 3 (1-17)
5 1.41.441	, ,	Diagnosis of PPH	
Birth setting:	N at follow-up:	Uterine device placed according to product labeling	ICU admission:
Hospital	G1: 51 with diagnosis of PPH who	Exclusion criteria:	G1 : 12 (24)
	had BD-OTS placed according to	• NR	Parakala da da al imparato
Facility	product labeling	• IVIX	Psychological impact:
characteristics:	Duration of treatment: NR	Maternal age, yrs, median (range)	Harms of intervention
Multi-site study	Duration of treatment. NIX	G1 : 33 (19-47)	Uterine rupture
Funding:	Timing of treatment: NR		G1 : 1
	C. I (A A. I.D.	Parity, n:	
Post marketing	Order of treatment: NR	Primigravid	Hysterectomy after balloon insertion
surveillance study	Length of follow-up: NR	G1: 15 (29)	G1 : 4 (8)
Design:			
Case series		Weeks gestation, median range):	Serious adverse events attributable to device
		G1: 38.4 (22.0-42.0)	G1: 0
Funding:			Confounders: NR
Supported by		Single pregnancy: NR	Comounders. NA
Glenveigh			Effect we edificate. ND
Medical,		Multiple pregnancy, n (%):	Effect modifiers: NR
manufacturer of		G1 : 12 (24)	
the medical			
device, and the		Race/ethnicity: NR	
two lead authors			
		BMI: NR	
are the inventors			
and patent holders		Baseline hemoglobin: NR	
of the device			
		SES: NR	
		Mode of birth, n:	
		Cesarean	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 : 23 (45) Risk factors: NR	
		Primary etiology of PPH, (%): Atony G1: (73)	
		Abnormal placentation G1: (33)	
		Multiple causes G1: NR	

Table D-18. Evidence table for studies addressing management of PPH (Froessler 2013)

Study Description	nce table for studies addressing ma Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss at delivery (mL), median (IQR):
Froessler et al.,	Intravenous Iron sucrose: 400 mg		G1b: 775 (500-1175)
2013 ²³	of Intravenous iron sucrose divided	Definition of success of treatment: NR	G2b: 800 (637-1100)
Carratur	into two 200 mg infusions of 30		G1b Vs G2b: p = 0.6
Country:	minutes duration, given a minimum of	Method of blood loss measurement: NR	
Australia	24 hours apart, plus folate tablets		Received transfusion, n (%):
Enrollment	(folic acid 600 µg) until delivery.	Severity: NR	RBC
period:		Inclusion criteria:	G1b: 0
2009-2010	FGF tablets: Two FGF tablets		G2b: 1 (2.2)
Diath author ND	(containing ferrous iron sulfate 250	Women who met the criteria for iron deficiency anemia When the criteria for iron deficiency anemia Women who met the criteria for iron deficiency anemia	
Birth setting: NR	mg, equiv. elemental iron 80 mg, folic	(Hb <110 g/L and ferritin <12 μg/L) and were	Hemoglobin (g/L),median (IQR):
Cocility	acid 600 µg) totaling 160 mg of	hemodynamically stable	Post delivery
Facility	elemental iron daily until delivery or	Women identified during either the antenatal period (at routing elinic appointments between 38 and 36)	Day 14:
characteristics:	for six weeks following delivery,	(at routine clinic appointments between 28 and 36 weeks gestation) or within 72 hours of birth following	G1b : 115 (107-123)
INK	depending on the timing of		G2b : 118 (110-127)
Funding: NR	recruitment (either antenatal or postnatal).	either a caesarean section or vaginal delivery with blood loss > 500 ml	G1b Vs G2b: p =0.2
Design: RCT	,	Exclusion criteria:	Day 42:
	Groups:	Women who did not consent to the study	G1b : 124 (118-132)
	G1: Iron sucrose	Women who presented with other causes of anemia,	G2b: 127 (120-132)
	G1a: Antenatal cohort	acute systemic infection, vitamin B12 or folate	G1b Vs G2b: p =0.7
	G1b: Postnatal cohort	deficiency, hepatitis, HIV, severe asthma	p Value (across time within group) for all groups
	G2: FGF tablets	Allergy to iron	<0.001
	G2a: Antenatal cohort	Pre-treatment ferritin levels >300 ng/mL	
	G2b: Postnatal cohort	Multiple pregnancy or high risk of premature birth.	Ferritin (µg/L) median (IQR):
	N at enrollment:	• Multiple pregnancy of high risk of premature birth.	Day 14:
	G1: 137	Maternal age, yrs, median (IQR):	G1b : 101 (82-141)
	G2: 134	G1 : 27 (23-32)	G2b : 37 (24-52)
	G2. 104	G1b : 28 (26-32)	G1b Vs G2b: p < 0.001
	N at follow-up:	G2: 29 (25-33)	
	G1 : 100	G2b : 30 (26-34)	Day 42:
	G1a : 69	Parity n. NP	G1b : 46 (24-64)
	G1b : 31	Parity, n: NR	G2b : 19 (13-33)
	G2: 94	Weeks gestation, median (IQR): NR	G1b Vs G2b: p 0.01
	G2a : 51	weeks gestation, median (IQK). NK	p Value (across time within group) for all groups
	G2b : 43	Single pregnancy: NR	<0.005
	Duration of treatment: NR	Single pregnancy. NIX	
			ICU admission: NR

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention Timing of treatment: NR Order of treatment: NR Length of follow-up: NR	Criteria & Population Multiple pregnancy: NR Race/ethnicity: NR BMI, (kg/m²), mean ± SD: G1b: 29 ± 6 G2b: 30 ± 7 Baseline hemoglobin (g/L), median (IQR): G1b: 96 (87-102) G2b: 95 (89 -106) Ferritin (µg/L) G1b: 18 (11-32) G2b: 21 (12-36) SES: NR Mode of birth, n: NR Risk factors: NR Primary etiology of PPH: NR	Length of stay: NR Mortality: NR Uterine preservation: NR Future fertility: NR Breastfeeding: NR Psychological impact: NR Harms of intervention: G1b: n=1 excluded due to arrhythmia during first transfusion (authors stated it appeared unrelated as it had occurred previously) No other serious adverse effects observed. Confounders: NR Effect modifiers: NR

Table D-19. Evidence table for studies addressing management of PPH (Lee 2013)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: Classified as major vs.
Lee et al.,	Transcatheter arterial embolization	Early-onset PPH occurred within the first 24 hours after	minor using Society of Interventional Radiology
2013 ²⁴	performed by interventional	delivery and late-onset occurred > 24 hours after	quidelines
	radiologists	delivery	
Country:		,	Harms, n (%):
Korea	Groups:	Definition of success of treatment:	Needed repeat embolization or surgical
Enrollment	G1: Embolization	Technical success: cessation of bleeding on	intervention
period:	N at enrollment:	angiography or successful embolization of bleeding	G1 : 18 (10.2)
January 2006 to	G1 : 176	artery	
August 2011	61. 176	Clinical success: obviation of repeated embolization or	Hysterectomy
August 2011	N at follow-up:	surgical intervention	G1: 5 (2.8)
Birth setting:	G1 : 148	ourgiour intervention	
Hospital	Demotion of the street ND	Method of blood loss measurement: NR	Mortality
•	Duration of treatment: NR	motified of blood loop modedicinent. (1)	G1 : 2 (1.1)
Facility	Timing of treatment: NR	Severity: NR	
characteristics:		ocverity: Nix	Immediate Complications, including transient
Tertiary care	Order of treatment: Patients	Inclusion criteria:	fever, mild leukocytosis, and abdominal pain
(academic medical	received primary treatment in	Patients with PPH treated with transcatheter arterial	(Postembolization syndrome):
center)	obstetric wards, including i.v.	embolization at two medical centers between Jan.	G1: 13
,	uterotonic drug administration, blood	2006 to Aug. 2011	
Funding: NR	transfusions, fluid resuscitation,		Hematoma formation
Design:	vaginal packing, uterine massage,	Exclusion criteria:	G1 : 3
•	vaginal, cervical, and perineal	• NR	
Retrospective	inspection, and tear suturing when	Maternal age was mean (range):	Altered menstrual quality
case series	needed. If bleeding continued,	Maternal age, yrs, mean (range):	G1: 23
	patient referred for angiography and	G1 : 33.9 (24-46)	Heavier n=5
	transcatheter arterial embolization.	Parity, n (%):	Lighter n=17
		Primiparous	Dysmenorrhea n=1
	Six patients had surgical procedure	G1: 73 (41.5)	
	prior to embolization: 5		No major complications related to embolization
	hysterectomies, 1 vascular ligation	Multiparous	No uterine infarctions, ischemic injuries or
	Length of follow-up: NR	G1 : 103 (58.5)	neurological complications
	Length of follow-up. NK		nieurological complications
		Weeks gestation: NR	Minor complications:
		Trocke goodkien in the	
		Single pregnancy: NR	Axillary sweating G1: 1
		onigic programoy. With	GI. I
		Multiple pregnancy, n (%):	
		Twin pregnancy	
	i	Li wiii bioglialicy	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1 : 16 (9.1)	
		Race/ethnicity: NR	
		BMI: NR	
		Hemoglobin, mean ± SD: G1: 8.4 ± 2.0	
		SES: NR	
		Mode of birth, n: Cesarean G1: 71 (40.3)	
		Vaginal G1 : 105 (59.7)	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Atony G1: 102 (57.6)	
		Cervical or vaginal laceration G1 : 21 (11.9)	
		Abnormal placentation (including placenta accrete and percreta) G1: 52 (29.5)	
		Placental abruption G1: 1 (0.6)	

Table D-20. Evidence table for studies addressing management of PPH (Kim 2013a)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	into vontion	Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss (ml), mean:
Kim et al.,	Uterine artery embolization	Blood loss of 500ml or more as measured by the pad	G1 : 676.7
2013 ²⁵	performed by two interventional	count in the first 24 hours following delivery	G2: 1769.1
O =	radiologists; preferred for patients		
Country:	with stable systolic and diastolic BP	Definition of success of treatment:	Transfusion, n (%):
Korea	or heart rate. Performed using	Cessation of bleeding and stable vital signs	G1: 25 (41.6)
Enrollment	gelfoam pieces approximately 4 mm		G2: 57 (93.4)
period:	in diameter.	Method of blood loss measurement: Pad count	
Feb 2002 to Dec			ICU admission, n:
2009	Other medications received, n (%):	Severity: NR	G1 : 5 (8.3)
	Oxytocin		G2: 39 (63.9)
Birth setting:	G1 : 60 (100)	Inclusion criteria:	
Hospital	G2 : 60 (100)	Diagnosed with PPH or referred from primary care	Duration (days), mean:
	,	facility with diagnosis	G1 : 5
Facility	Sulprostone	l aam, maagaa	
characteristics:	G1 : 41 (68)	Exclusion criteria:	DIC, n (%):
Tertiary care	G2: 37 (60.6)	Three patients who did not undergo Uterine artery	G1 : 4 (6.6)
hospital.	- (,	embolization or	G2 : 34 (55.7)
Funding: NR	Ervin	CH within 24 hours after delivery	p<0.001 ′
ruliulig. NK	G1 : 22 (36)		
Design:	G2 : 12 (19.6)	Maternal age, yrs, mean ± SD:	Anemia: NR
Retrospective		G1: 31.0 ± 4.8	
cohort study	Groups:	G2: 31.8 ± 4.0	Length of stay in days, mean:
•	G1: Uterine artery embolization	p = 0.358	G1 : 8.60
	G2: Complete hysterectomy (CH)		G2: 11.5
	N at enrollment:	Parity, mean ± SD:	
	G1: 60	G1 + G2: 2.5 ± 0.2	Length of time in ICU, mean:
	G2: 61		G1: 5
	32. 01	Primaparous, n:	
	N at follow-up: NR	G1 : 17	Mortality, n (%):
	Boonetten of treatments ND	G2: 22	G1 + G2: 5 (4)
	Duration of treatment: NR		J. 1 J. 1 (1)
	Timing of treatment: NR	Weeks gestation, mean ± SD:	Uterine preservation:
		G1 + G2 : 36.6 ± 2.5	Subsequent complete hysterectomy:
	Order of treatment: NR		G1: 2
	Length of follow-up: NR	Preterm deliveries, n:	J 2
	Length of follow-up. NIX	G1 :14	Future fertility:
		G2: 15	Ovarian failure after Uterine artery embolization

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Single pregnancy: NR	, n
			G1: 1
		Multiple pregnancy, n (%):	
		Twins	Breastfeeding: NR
		G1 : 5 (8.3)	ŭ
		G2 : 4 (6.5)	Psychological impact: NR
			Harms of intervention, n:
		Race/ethnicity: NR	Surgical complications
		Tasy Till	Transient fever (> 38.5 C)
		BMI: NR	G1: 11
		Dini. WY	G2: 14
		Baseline hemoglobin (g/dL), mean ± SD:	92. 17
		G1: 10.5 ± 2.3	Skin wounds in CH revision
		G2 : 9.0 ± 2.8	G2: 2
			92. 2
		p = 0.004	
		OEO ND	Continued bleeding after CH, n
		SES: NR	G2 : 4
		M. I. (11 11 1 10/)	Confounders: NR
		Mode of birth, n (%):	
		Vaginal	Effect modifiers: NR
		G1: 23 (38)	
		G2: 33 (54)	
		p = 0.081	
		Risk factors: NR	
		Primary etiology of PPH, n (%):	
		Atony	
		G1 + G2 : 101(83.4)	
		G1: 55 (92.4)	
		G2: 46 (75.4)	
		()	
		Placenta previa with Placenta accrete:	
		G1 + G2: 4 (3.3)	
		G2 : 4 (6.5)	
		52. 7 (0.0)	
		Placenta previa without Placenta accrete:	
		G1 + G2: 4 (3.3)	
		G1 : 4 (7.5)	
		Vaginal wall laceration:	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 + G2 : 12 (9.8) G1 : 1 (1.6) G2 : 11 (18.0)	

Comments: The patient with ovarian failure had a previous history of pelvic arterial embolization as a result of adenomyosis and uterine multiple myomas and a history of infertility. She had conceived the present pregnancy through in vitro fertilization.
Study hospital is a bloodless medical center serving Jehovah's Witnesses

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Harms pre-specified: Yes
Kim et al., 2013 ²⁶	Pelvic arterial embolization (PAE)		
O =	C	Definition of success of treatment: Technical success	Harms, n (%):
Country:	Groups:	was defined as the cessation of bleeding on	Total
Korea	G1a: successful PAE (intervention)	angiography and/or angiographically successful emboli-	G1a : 22 (9.4)
Enrollment	G1b: failed PAE (intervention)	zation of the uterine or anterior division of the	G1b: 9 (37.5)
period:	N at enrollment:	hypogastric artery (12). Clinical success was defined as	p < 0.01
March 2004 -	G1 : 257	the cessation of bleeding after one PAE session. Clinical	
January 2011	G1a: 233	failure was defined as the need for subsequent	Embolization related total:
	G1b: 24	intervention, including repeat embolization or additional	G1a: 11
Birth setting:		surgery during the hospital stay.	G1b: 4
hospital	Duration of treatment: NR		p = 0.01
	Timing of treatment: NR	Method of blood loss measurement: NR	
Facility	Tilling of treatment. NA		Paresthesia: 10
characteristics:	Order of treatment:	Severity: NR	G1a: 7
Tertiary care	PAE was performed due to continued		G1b: 3
Francisco ND	bleeding despite appropriate medical	Inclusion criteria:	
Funding: NR	and/or surgical treatments	 Patients undergoing PAE at hospital within study 	Uterine abscess: 3
Design:		period	G1a: 2
Retrospective	Length of follow-up: NR	Exclusion criteria: NR	G1b: 1
case series		LACIUSION CINENA. NIX	
		Maternal age, yrs, median (range):	Postembolization syndrome: 2
		G1: 32 (20-40)	G1a: 2
		, ,	G1b: 0
		Maternal age >32 y, n (%):	
		G1a: 102 (87.2)	Transfusion related:
		G1b : 15 (12.8)	Pulmonary edema: 5
		p = 0.08	G1a: 4
		D	G1b: 1
		Primiparity, n:	p = 0.41
		G1a: 150 (92.6)	- 0.11
		G1b : 12 (7.4)	Hypovolemia-related total: 11
		p = 0.19	G1a: 7
			G1b: 4
		Weeks gestation: NR	p < 0.01
			P <0.01
		Single pregnancy: NR	Cerebral infarction: 5
			G1a: 2
		Multiple pregnancy: NR	Gia. 2

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
			G1b: 3
		Race/ethnicity: NR	
		·	Optic nerve ischemia: 2
		BMI: NR	G1a: 2
			G1b : 0
		Baseline hemoglobin (<8 g/dl):	
		G1a : 103 (85.1)	Acute renal failure: 2
		G1b : 18 (14.9)	G1a : 2
		p < 0.01	G1b: 0
		p < 0.01	G1b. 0
		SES: NR	Multiorgan failure:
		JES. NK	G1a: 1
		Made of hirth n.	G1a: 1 G1b: 1
		Mode of birth, n:	GID: 1
		Cesarean, n (%):	
		G1a : 103 (92.0)	
		G1b : 9 (8.0)	
		Risk factors, n (%):	
		PAE after failed surgical procedure, n (%): 9	
		G1a: 7	
		G1b: 2	
		p = .20	
		ρ = .20	
		Primary etiology of PBH n (%)	
		Primary etiology of PPH, n (%):	
		Atony: 154	
		G1a : 140 (89.7)	
		G1b : 16 (10.3)	
		p = 0.53	
		Lower genital tract laceration: 44	
		G1a: 38 (86.4)	
		G1b: 6 (13.6)	
		p = 0.39	
		Placenta accrete: 22	
		G1a : 20 (90.9)	
		G1b: 2 (9.1)	
		p = 0.66	
		Retained placental fragments: 19	
		G1a: 19 (100)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1b : 0	
		Placenta previa: 16	
		G1a : 16 G1b : 0	

Table D-22. Evidence table for studies addressing management of PPH (Lappen 2013)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:		Blood loss:
Lappen et al.,	Safety program that d 1) educational	Estimated blood loss greater than 500 mL for vaginal	EBL (mL)
2013 ²⁷		delivery and > 1,000 mL for cesarean delivery)	G1: 1,211 ± 681
Country: US	loss estimation, 2) training regarding		G2 : 1,274 ± 932
Country. 03	and institution of a checklist for	Definition of success of treatment : Changes in patient	p= 0.33
Enrollment	management of PPH, and 3)	care and outcomes	EBL > 1,500 mL
period:	institution of routine use of active		G1 : 45 (16.2)
Pre: 6 month prior	management of 3 rd stage of labor.	Method of blood loss measurement: NR	G2: 62 (18.2)
to systems	Groups:		p= 0.51
intervention	G1: period A- pre intervention	Severity: NR	
	G2: period B: post	Inclusion criteria:	Transfusion:
Intervention:	GZ. period B. post		Any packed red cells
Feb 2008 to Jan	N:	of PPH	G1: 34 (44.7)
2009	G1 : 278	011111	G2: 42 (55.3)
	G2: 341	Exclusion criteria:	4 or more Units pRBCs
Post: 6 months	Duration of treatment: NR	All patients presenting with PPH during time period d	G1: 9 (3.2)
after intervention	Duration of treatment. 1410	Motornal aga vra maan + SD:	G2: 11 (3.2)
Birth setting:	Timing of treatment: NR	Maternal age, yrs, mean ± SD: G1: 31.6 ± 6.0	
Hospital	Order of treatment: NR	G2: 31.6 ± 6.2	Fresh frozen plasma
i iospitai	Order of treatment. NR	G2. 31.0 ± 0.2	G1 : 9 (3.2)
Facility	Length of follow-up: NR	Parity, n:	G2 : 8 (2.4)
characteristics:		Nulliparous	Cyroprosinitate
Tertiary care		G1: 183 (66)	Cyroprecipitate
hospital		G2: 235 (69)	G1 : 4 (1.4) G2 : 4 (1.2)
			G2. 4 (1.2)
Funding:		Gestational age, weeks mean:	ICU admission
Ken and Anne		G1: 38.6 ± 2.87	G1: 7 (2.5)
Griffin Foundation		G2 : 38.9 ± 244	G2 : 12 (3.5)
Design:			p= 0.47
Pre-post		Single pregnancy, n (%):	P- 0.71
1 10 post		G1 : 243 (87)	Anemia:
		G2 : 296 (88)	Nadir Hemoglobin g/dL
			G1: 8.8 ± 1.6
		Multiple pregnancy, n (%):	G2: 8.9 ± 1.6
		G1 : 35 (13)	p= 0.55
		G2 : 41 (12)	p= 0.00
		Race/ethnicity:	Length of stay: NR
		Caucasian	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1 : 139 (52)	
		G2 : 176 (55)	Mortality: NR
		AC: A :	His day was a day AID
		African-American	Uterine preservation: NR
		G1 : 41 (16)	Headan and an amballanthan
		G2 : 32 (10)	Uterine artery embolization:
		Hieraria	G1: 1 (0.4)
		Hispanic G1 : 53 (20)	G2: 5 (1.5) Hysterectomy:
		G2 : 60 (19)	G1: 3 (1.1)
		G2. 00 (19)	G2: 6 (1.8)
		Asian	92. 0 (1.0)
		G1 : 9 (3)	Composite morbidity (transfusion,
		G2 : 15 (5)	embolization, hysterectomy, ICU
		52. 10 (0)	admission):
		Other	G1: 36 (13.0)
		G1 : 36 (9)	G2 : 42 (12.3)
		G2 : 58 (11)	p= 0.81
		()	F STS
		ВМІ	Future fertility: NR
		G1: 29.9 ± 5.7	
		G2: 31.3 ± 6.6	Breastfeeding: NR
		Baseline hemoglobin: NR	Psychological impact: NR
		SES: NR	Harms of intervention: NR – "There were no
		3E3: NK	adverse events related to interventions for
		Made of birth no	PPH, including the use of uterotonics or B-lynch
		Mode of birth, n: Spontaneous vaginal	sutures, in either time period of the stuy.
		G1: 135 (49)	Confounders: NR
		G2 : 140 (41)	Confounders: NR
		62. 140 (41)	Effect modifiers: NR
		Operative vaginal	
		G1 : 29 (10)	
		G2 : 34 (10)	
		Cesarean	
		G1: 114 (41)	
		G2 : 167 (49)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	- Cutoomico
		Risk factors, n (%): Race/ethnicity: NR	
		History of cesarean G1: 35 (13) G2: 41 (12)	
		Labor induction/augmentation G1: 81 (29) G2: 120 (35)	
		Preeclampsia G1: 32 (12) G2: 35 (10) Placenta previa G1: 9 (3) G2: 7 (2)	
		Birth weight (g) G1: 3310 +/- 701 G2: 3384 +/- 698	
		Multiple gestation G1: 35 (13) G2: 45 (13)	
		Chorioamnionitis G1: 38 (14) G2: 54 (16)	
		Retained placenta: NR	
		Antepartum hemorrhage: NR	
		Magnesium sulfate use G1: 32 (12) G2: 33 (10)	
		Any oxytocin	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1 : 185 (67)	
		G2: 249 (73)	
		Primary etiology of PPH, n (%):	
		Uterine Atony	
		G1: 169 (160.8)	
		G2 : 214 (62.8)	
		Surgical laceration	
		G1 : 47 (16.9)	
		G2 : 76 (22.3)	
		Vaginal laceration	
		G1 : 17 (6.1)	
		G2: 27 (7.9)	
		Retained products	
		G1: 19 (6.8)	
		G2: 16 (4.7)	
		Placenta accreta	
		G1: 4 (1.4)	
		G2: 2 (0.6)	
		Uterine inversion	
		G1: 2 (0.7)	
		G2: 1 (0.3)	
		Other	
		G1 : 20 (7.2)	
		G2: 5 (1.4)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Blood loss:
Sohn et al., 2013 ²⁸	Massive transfusion- patients who	Blood loss of 500 mL or more that occurs within 24	Transfusion amount, median (IQR) units
Country: Korea	required transfusion of 10 or more units pRBCs	hours after birth.	Packed RBCs during initial 24 hours G1 : 18 (11.8-24)
Enrollment period:	Groups: G1: required Massive transfusion G2: did not require Massive	Method of blood loss measurement: NR Severity: NR	G2: 3 (2-5) p< 0.01 pRBCs during hospitalization
January 2004 to May 2012	transfusion	Inclusion criteria: • Primary PPH patients who presented to Emergency	G1: 20 (15.8-28.8) G2: 4 (2-6)
Birth setting:	N at enrollment: G1: 26	Department	p< 0.01
Hospital	G2 : 100	Exclusion criteria: • Transfusion of > 1 U packed RBCs before Emergency	FFP during hospitalization G1 : 11.5 (7.8-15.8)
Facility characteristics:	N at follow-up: G1: 26	Dept arrival	G2 : 0 (0-3)
Tertiary care hospital	G2: 100	 Missing data for initial vital sign Maternal age, yrs, median (IQR): 	PCs during hospitalization G1 : 14 (10-25.5)
Funding:	Duration of treatment: NR Timing of treatment: NR	G1: 31 (29.8-34.5)	G2: 0 (0-0)
NR (No conflicts)	Order of treatment: NR	G2: 31 (29-34) p = 0.67	p< 0.01
Design: Retrospective cohort	Length of follow-up: NR	Parity, n: Primipara G1: 17 (65.4) G2: 56 (56)	ICU admission: G1: 11 (42.3) G2: 5 (5) p < 0.01
		Multipara G1: 9 (34.6) G2: 44 (44) p = 0.39	Anemia: Hemoglobin, g/dL, median (IQR) G1: 5.9 (4.7-9.6) G2: 9.5 (8.3-10.5) p< 0.01
		Weeks gestation: NR	Hematocrit G1: 18.4 (15.2-29)
		Single pregnancy: NR	G2: 28.5 (25.8-31.8) p< 0.01
		Multiple pregnancy: NR	Platelets
		Race/ethnicity: NR BMI: NR	G1: 129.5 (93.8-161.5) G2: 174.5 (142.3-201

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		•	p< 0.01
		Baseline hemoglobin: NR	
			Length of stay, days median (IQR):
		SES: NR	G1: 4 (3-6.5)
		020. Titl	G2: 2 (1-3)
		Mode of birth, n:	p < 0.01
		Vaginal	p < 0.01
			Martality in boonital
		G1 : 20 (76.9)	Mortality in hospital:
		G2 : 77 (77)	G1 : 3 (11.5)
			G2 : 0
		Cesarean	p< 0.01
		G1: 6 (23.1)	
		G2: 23 (23)	Uterine preservation:
		p = 0.99	Hysterectomy
		Disadian time minutus median (IOD)	G1: 2 (3.8)
		Bleeding time, minutues median (IQR):	G2 : 1 (1)
		G1 : 122 (76.3-162.3)	p = 0.37
		G2: 138 (81-219)	Embolization
		p = 0.15	G1 : 22 (84.6)
		Risk factors, n (%):	G2 : 36 (36)
		Initial Mental Status	p < 0.01
			p < 0.01
		(alert, verbal, unresponsive	Future fertility: NR
		p < 0.01	dure lettinty. MX
		Initial vital signs, median (IQR)	Breastfeeding: NR
		SBP, mmHg	
			Psychological impact: NR
		G1: 101.5 (80.0 – 118.8)	1 Sychological Impact: NIX
		G2: 118.5 (105.0 – 129.0)	Harms of intervention: NR
		p < 0.01	
			Confounders:
		SBP < 90mmHg, n (%)	Initial mental status
		G1: 8 (30.8)	SBP
		G2 : 11 (11.0)	Hypotensive state
		p = 0.03	DBP
			HR
		DBP, mmHg	SI
		G1: 59.0 (52.0 – 66.5)	
		G2: 71.0 (63.3 – 81.0)	Effect modifiers: NR
		p < 0.01	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes	
		HR, beats/min G1: 129.0 (119.3 – 144.3) G2: 97.5 (82.3 – 109.0) p < 0.01		
		Body temperature, °C G1 : 36.7 (36.2 – 37.4) G2 : 37.0 (36.5 – 37.5) p = 0.28		
		Shock Index (SI), median (IQR) G1: 1.3 (1.0 – 1.7) G2: 0.8 (0.7 – 1.0) p < 0.01		
		Primary etiology of PPH: NR		

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	-	Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss, ml mean ± SE:
Sugawara et al.,	Recombinant human soluable	Blood loss > 500 mL after vaginal delivery and > 1000	G1: 4665.1 ± 625.4
2013 ²⁹	thrombomodulin (rTM), 380 U/kg per	mL after cesarean	G2: 3927.3 ± 424.9
Carratera	day drip infused for 30 minutes once		Bleeding symptoms, day 1(%):
Country:	daily	Definition of success of treatment : Posttreatment	G1: 22.2
Japan	Patients were also treated with fresh	improvement in disseminated intravascular coagulation	G2: 42.3
Enrollment	frozen plasma (FFP), platelet	(DIC) assessed by Japanese Ministry of health and	G1 vs G2: p=0.14
period:	concentrate (PC), red cell	Wellness (JMHW) DIC criteria	·
April 2006 to May	concentrate (RCC), or antithrombin-		Bleeding symptoms, day 2 (%):
2011	III concentrate	Method of blood loss measurement: NR	G1: 11.1
_			G2: 19.2
Birth setting:	Control group received gabexate	Severity: Shock index, mean ± SE:	G1 vs G2: p=0.28
Hospital	mesilate (GAB)	(defined as systolic blood pressure divided by heart rate	0. 10 02. p 0.20
·	mediate (e/tz)	and corresponded to the severity of PPH)	Transfusion, units, mean ± SE:
Facility	Groups:	G1: 1.5 ± 0.2	RCC
characteristics:	G1: rTM	G2: 1.1 ± 0.1	G1: 16.3 ± 3.0
Tertiary care	G2: control	G1 vs G2: p< 0.05	G2: 15.9 ± 1.7
•	N. at annually and	G1 V3 G2. ρ< 0.00	FFP
Funding:	N at enrollment:	Inclusion criteria:	G1: 16.3 ± 3.1
No financial	G1 : 10	PPH, complicated by DIC (all patients fulfilled criteria	G2: 14.6 ± 1.9
support; no	G2 : 26	of International Society on Thrombosis and	G2: 14.0 ± 1.9
conflicts of interest	N at follow-up:	Hemostasis classification for overt DIC)	DO.
Decian:	G1 : 10	, and the second	PC
Design:	G2 : 26	Exclusion criteria:	G1 : 20
Retrospective	62 . 20	• NR	G2: 18.4 ± 2.5
cohort	Duration of treatment: NR	Meternal are two mach : CF:	
	Tining of Alpha	Maternal age, yrs, mean ± SE:	Use of PC, n (%)
	Timing of treatment: NR	G1: 33.2 ± 1.7	G1 : 4 (40)
	Order of treatment: NR	G2 : 31.7 ± 1.1	G2 : 13 (50)
		Parity, mean ± SE:	
	Length of follow-up: 3 days	G1: 1.0 ± 0.4	ICU admission: NR
		G2: 1.2 ± 0.2	
		VE. 1.2 ± 0.2	Anemia: NR
		Weeks gestation, mean ± SE:	
		G1: 34.6 ± 2.1	Length of stay: NR
			Mortality: NR
		G2 : 35.4 ± 0.9	-
		Cinale programme MD	Uterine preservation: NR
		Single pregnancy: NR	
		Multiple pregnancy: NR	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
			Future fertility: NR
		Race/ethnicity: NR	B and the NB
		DMI- ND	Breastfeeding: NR
		BMI: NR	Psychological impact: NR
		Baseline hemoglobin, mean ± SE	Psychological impact: NR
		G1 : 6.7 ± 0.4	Harms of intervention:
		G2: 7.4 ± 0.4	No treatment related adverse events observed
		52. 7.4 ± 0.4	in either group
		SES: NR	Confounders: NR
		Mode of birth, n (%):	Effect modifiers: NR
		Cesarean	
		G1: 2 (20)	
		G2 : 11 (42.3)	
		Cesarean, hysterectomy	
		G1 : 4 (40)	
		G2 : 5 (19.2)	
		Risk factors: NR	
		Primary etiology of PPH, n (%):	
		Atony	
		G1 : 3 (30)	
		G2 : 10 (38.4)	
		Placenta accrete	
		G1: 2 (20)	
		G2 : 22 (7.7)	
		Placenta previa	
		G1: 2 (20)	
		G2: 3 (11.5)	
		Discontal objuntion	
		Placental abruption	
		G1 : 3 (30)	
		G2: 10 (38.4)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Uterine rupture	
		G1: 0	
		G2: 1 (3.8)	

Table D-25. Evidence table for studies addressing management of PPH (Yamasaki 2013)

Study	nce table for studies addressing mai	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Harms pre-specified: No
	transcatheter pelvic arterial		Harras in (0/):
2013 ³⁰	embolization (TAE) performed by	Definition of success of treatment:	Harms, n (%): Fever:
Country: Japan	expert radiologists. Catheterization occurred from the right femoral artery	Sufficient hemostasis achieved by a series of embolization without surgical treatments.	G1: 6 (10.9)
Enrollment	with subsequent embolization of uni-		
period:	or bilateral uterine arteries with use of	Method of blood loss measurement: NR	Lower limb neuropathy
January 2003 to	absorbable gelatin sponge.		G1: 1 (1.8)
January 2013	Performed under pelvic angiogram at	Severity: NR	Uterine necrosis
1	interventional radiology unit. In case	Inclusion criteria:	G1: 2 (3.6)
Birth setting:	of insufficient nemostasis,		G1. 2 (3.0)
hospitals	embolization of different vessels	intractable PPH within 24 hours after delivery	
Facility	including iliac, ovarian, inferior gluteal	Exclusion criteria:	
characteristics:	and round ligament arteries done	• NR	
university hospital	subsequently.	Motornal ago vra moon (rango):	
1 .	Groups:	Maternal age, yrs, mean (range):	
Funding: NR	G1: embolization	G1 : 33 (21-46)	
Design:	N	Parity, n:	
Case series	N at enrollment:	Number of previous deliveries, median (range):	
Odde defied	G1: 55	G1 : 1 (0-3)	
	N at follow-up:		
	G1: 55	Weeks gestation, median (range):	
	Duration of treatment: N/A	G1 : 39 (23-41)	
	Duration of treatment: N/A	Cin als and an an AlD	
	Timing of treatment	Single pregnancy: NR	
	TAE occurred after assessment for	Multiple pregnancy: NR	
	cause and conservative management		
	, J	Race/ethnicity: NR	
	uterin packing, uterotonic medication		
	including oxytocin, methyl-ergonovine	BMI: NR	
	and prostaglandin analogue.	B P I I I I . NB	
	Order of treatment	Baseline hemoglobin: NR	
	TAE occurred after conservative	SES: NR	
	management.		
	9	Mode of birth, n:	
	Length of follow-up: NR	Vaginal delivery	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 : 34	
		Cesarean section G1: 21	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Atony G1: 41 (74.5)	
		Retained placenta G1: 11 (20)	
		Cervical laceration G1: 3 (5.5)	

Table D-26. Evidence table for studies addressing management of PPH (Blanc 2012)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
Author: Blanc et al., 2012 ³¹	Intervention: Uterine-sparing procedures including triple uterine artery ligation (TUAL)	Operational definition of PPH: NR Definition of success of treatment: NR	Successful control of bleeding, n (%): G1: 51/56 (91) Harms pre-specified: No
Country: France	possibly complimented with hemostatic multiple square suturing (HMSS)	Method of blood loss measurement: NR	Transfusion G1 : 20 (35.7)
Enrollment period: 2000 to 2009 Birth setting:	Groups: G1: intervention N:	Severity: NR Inclusion criteria: Delivered by cesarean Diagnosed with PPH	ICU admission G1: 7 (12.5)
Hospital	G1: 59 Duration of treatment: NR	Managed by uterine sparing surgical management using TUAL, possibly complimented with HMSS criterion 2	Harms, n (%): Hemorrhagic shock G1: 4 (7.1)
Facility characteristics:	Timing of treatment: NR	Exclusion criteria:	Heater initial
Tertiary care	Order of treatment:	three patients not managed according to institution	Ureter injury G1: 0
Funding: Agency/NR	Oxytocin administration and uterine revision (n=59)	guidelines Maternal age, yrs, median (range):	Endometritis requiring antibiotic therapy rupture
Design:	Sulrostone administration (n=50)	G1 : 31.5 (17-44)	G1 : 2 (3.6)
Case series	One step TUAL (n=56)	Parity, median (range):	
	HMSS of uterus (n=43)	G1: 0.5 (0-8) Weeks gestation, median (range):	
	Selective embolization (n=1)		
	Hemostatic hysterectomy (n=4)	G1 : 37 (25-41)	
	Length of follow-up: NR	Single pregnancy, n (%): G1: 52 (92.9)	
		Multiple pregnancy, n (%): G1: 4 (7.1)	
		Race/ethnicity: NR	
		BMI, median (range) G1: 28 (19-45)	

Baseline hemoglobin: NR	
SES: NR	
Mode of birth: NR	
Risk factors, n (%): Previous cesarean G1: 16 (28.6) Primary etiology of PPH, n (%): Atony G1: 45 (80.4)	
Placenta accrete G1: 11 (19.6)	
Uterine rupture during labor (associated with atony) G1: 3 (5.4)	
Placental abruption G1: 3 (5.4)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss (Peripartum hemoglobin loss ≥
Laas, et al.	Intrauterine balloon tamponade/24		2g/dl) n (%):
2012 ³²	hours/ once	Definition of success of treatment:	G1v: 117/218 (53.7)
	Groups	No need for surgical procedures including hysterectomy	G2v : 129/194 (66.5)
Country:	Groups:	and embolization	G1c: 77/177 (43.5)
France	G1: post balloon G2: pre ballon		G2c: 54/96 (56.3)
Enrollment	G2. pre ballon	Method of blood loss measurement: NR	
period:	N at enrollment:		Embolization:
Pre: July 2005 to	All PPH	Severity: NR	G1v: 5/218 (2.3)
March 2008	G1T : 663	Inclusion criteria:	G2v: 16/194 (8.2)
Post:April 2008 to	G2T : 820		G1c : 2/177 (1.1)
December 2010		All patients with PPH due to uterine atony that is Unresponding to authorstone from 7/2005. March 2008.	G2c : 0/96
December 2010	Received sulposterone	unresponsive to sulprostone from 7/2005-March 2008 and April 2008-December 2010	
Birth setting:	G1: 395	and April 2006-December 2010	Conservative surgical procedures:
hospital	G2 : 290	Exclusion criteria:	G1v: 3/218 (1.4)
•		Placenta accrete, lacerations, retained placenta	G2v: 10/194 (5.1)
Facility	Stratified by delivery type		G1c: 23/177 (13.0)
characteristics:	G1v: 218/395 (vaginal)	Maternal age, yrs, median (IQR):	G2c: 12/96 (12.5)
Tertiary care	G2v: 194290 (vaginal)	G1av: 31 (27-36)	
Funding, ND	G1c: 177/395 (cesarean)	G2av: 30 (26-33)	Transfusion:
Funding: NR	G2c: 96/290 (cesarean)	G1av: 31 (27-35)	G1v : 23/218 (10.6)
Design:		G2av: 32 (29-35)	G2v: 16/194 (8.3)
Pre-post	Did not respond to sulposterone	G1b : 31 (27-34)	G1c : 20/177 (11.3)
•	G1: 72/395	N. III (0/)	G2c : 9/96 (9.4)
	G1av: 35 vaginal	Nulliparous, n (%):	
	G1ac: 37 cesarean	G1av: 15 (42.9)	ICU admission: NR
	G2: 38/290	G2av: 12 (46.2)	
	G2ac: 12 cesarean	G1ac: 13 (35.1)	Anemia: NR
	G2av: 26 vaginal	G2ac: 4 (33.3)	
		G1b: 15 (34.9)	Length of stay: NR
	Received tamponade test	Weeks gestation median (IOR):	
	G1b : 43	Weeks gestation, median (IQR):	Mortality: 0
	G2b: NA	G1av: 39 (38-41)	
	Duration of treatment: 24 hours	G2av: 40 (38-41)	Uterine preservation:
			Hysterectomy
	Timing of treatment After failure of	G2ac: 39 (35-41)	G1v: 1/ 218 (0.46)
	protocol which d oxytocin, circulatory	G1b : 39 (38-41)	G2v : 2/194 (1.0)
	support, sulprostone infusion		G1c: 3/177 (1.7)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
	0	Single pregnancy: NR	G2c: 1/96 (1.0)
	Order of treatment:		
	Intrauterine tamponade was after	Multiple pregnancy, n (%):	Future fertility: NR
	failure of sulprostone infusion	G1av: 5 (14.3)	
	Length of follow-up: NR	G2av: 4 (15.4	Breastfeeding: NR
	3	G1ac: 12 (32.4)	
		G2ac: 1 (8.3)	Psychological impact: NR
		G1b : 7 (16.3)	Harms of intervention:
		, ,	Endometritis
		Race/ethnicity: NR	G1b : 1/43 (2.3%)
		PMI modian (IOP)	Confounders: NR
		BMI, median (IQR)	
		G1av : 21.9 (19.9-23.7)	Effect modifiers: NR
		G2av : 20.5 (19.2-23.4)	
		G1ac: 23.0 (21.5-26.4)	
		G2ac: 27.7 (26.2-28.6)	
		G1b: 22.7 (20.7-25.7)	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, n:	
		Vaginal	
		G1 : 218/395	
		G2 : 194/290	
		32. 10 1/200	
		Cesarean	
		G1 : 177/395	
		G2 : 96/290	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Atony	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Lee et al.,	Pelvic arterial embolization (PAE)	Primary PPH occurring within the first 24 hours after	Harms, n (%):
2012 ³³	performed with local anesthesia by	delivery and secondary PPH was bleeding occurring	Failure to achieve success after first session of
Country:	interventional radiologists in	later than this and until 6 th week of puerperium	lembolization
Korea	conventional angiographic suite		G1: 34 (13.5)
Norea	Groups:	Definition of success of treatment: Technical success	G1. 54 (15.5)
Enrollment	G1: intervention	defined as cessation of bleeding on postembolization	Popost ambalization failure
period:	G1. Intervention	angiogram and cessation of vaginal bleeding at	Repeat embolization failure G1: 3/12
Jan 2000 to	N at enrollment:	speculum inspection performed immediately after PAE	G1. 3/12
Feb 2011	G1: 251	Clinical success defined as cessation of bleeding after	Hyptoroptomy
		PAE without need for repeat PAE or additional surgery	Hysterectomy G1: 10/251
Birth setting:	N at follow-up (more than 6	during hospital stay.	G1. 10/251
Hospital	months):		Montality in (0/)
	G1 : 113	Method of blood loss measurement: NR	Mortality, n (%)
Facility	Duration of treatment: NR		G1: 5 (2) (three after first session, one after
characteristics:		Severity: NR	repeat embolization, and one after additional
Tertiary care	Timing of treatment: NR	Inclusion outcoin.	laparotomy)
(academic medical	Order of treatment: NR	Inclusion criteria:	Total Camplications
center).	Order of treatment. NIX	Primary PPH and underwent PAE during time period	Total Complications G1: 8
Funding:	Length of follow-up, months mean	Exclusion criteria:	G1: 0
NR No authors	(range):	Women with secondary PPH	Diagostian of utaring artarias
reported any	G1: 30 ± 23 (6-99)	,	Dissection of uterine arteries G1: 2
potential conflicts		Maternal age, yrs, mean ± SD:	G1. 2
of interest		G1: 32 ± 4 (range: 19-45)	Other miner complications
		Parity, n:	Other minor complications G1: 6
Design:		Nulliparous	G1: 0
Retrospective		G1: 139	Transient numbness of lower extremities
case series		61. 109	
		Weeks gestation: NR	G1 : 2
		Weeks gestation. TVIC	Edomo of lower lowe
		Single pregnancy: NR	Edema of lower legs G1: 1
		Single pregnancy. Nix	G1: 1
		Twin pregnancy, n:	I la manta mana at mumatuma aita
		G1: 14	Hematoma at puncture site
		O1. 17	G1 : 3
		Race/ethnicity: NR	
I			
Ì		BMI: NR	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, n: Vaginal G1: 141	
		Cesarean G1: 110	
		Risk factors, n: History of cesarean G1: 13	
		Primary etiology of PPH, n: Atony G1: 198	
		Coagulopathy G1: 6	
		Retained placenta G1: 24	
		Vaginal or cervical laceration G1: 20	
		Uterine rupture G1: 3	

Table D-29. Evidence table for studies addressing management of PPH (Ahmed 2012)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss, estimated L, mean ± SE:
Ahmed et al.,	Cryoprecipitate supplied by IBTS in	Estimated blood loss of 2.5 L or more, transfusion of five	G1: 5.19 ± 1.07
2012 ³⁴	pools of five donor units with	or more units RCC, or treatment of a coagulopathy in	G2: 3.34 ± 0.51
Ca	minimum fibrinogen content of > 700	acute event. 77 cases of MOH identified during the	p = 0.10
Country:	mg pool and mean of 1470 ± 263	period and 34 received treatment for	
Ireland	(range 727-2182). It was withdrawn	hypofibrinogenaemia.	Hematocrit, min, mean ± SE:
Enrollment	in July 2009 but patients received it		G1: 0.21 ± 0.02
period:	until stocks were depleted.	Treatment of MOH used d: (shown in figure) oxytocin	G2: 0.19 ± 0.01
Jan 2009 to June		bolus, oxytocin infusion, ergometrine, misoprotol,	p = 0.25
2011	in Nov. 2009	haemabate, and:	
_		,	Platelets minimum (x 10 ⁹ g/L), mean ± SE:
Birth setting:	Mean dose of cryoprecipitate 2.2 ±	Intra uterine hydrostatic balloon	G1 : 92.9 ± 12.98
Hospital		G1: 7	G2: 100.6 ± 10.07
	g	G2: 7	p = 0.49
Facility			
characteristics:	Groups:	Internal iliac ligation	Fibrinogen level, minimum (g/L), mean ± SE:
Tertiary care/	G1: cryoprecipitate	G1: 2	G1 : 1.04 ± 0.13
Academic medical	G2: fibrinogen	G2: 0	G2: 1.23 ± 0.18
center	N at enrollment:		p = 0.42
C din a	G1 : 14	Recombinant Factor VII	
Funding:	G2 : 20	G1: 1	Transfusion:
NR; Authors	62 . 20	G2: 0	RCC units, mean ± SE
reported no	N at follow-up:		G1 : 7.21 ± 1.23
conflicts of interest	G1 : 14	Hysterectomy	G2: 5.90 ± 0.96
Design:	G2 : 20	G1: 3	p = 0.40
Retrospective	Describes of transfer out ND	G2: 2	p = 0.10
cohort	Duration of treatment: NR	52. 2	Octaplas units, mean ± SE
	Timing of treatment: NR	Definition of success of treatment: NR	G1: 4.07 ± 0.74
		Definition of Success of treatment. TWO	G2: 3.15 ± 0.65
	Order of treatment: NR	Method of blood loss measurement: NR	p = 0.36
	Length of follow-up:	modica of blood 1035 medadi ement. 1410	F = 0.00
	Medical record review (up to	Severity: NR	
	discharge)	October 1410	
	uiscriarge)	Inclusion criteria:	Platelets, pools, mean ± SE
		Patients who required treatment with cryoprecipitate	G1: 1.00 ± 0.36
		or fibrinogen (identified retrospectively)	G2: 1.00 ± 0.30
		• Fibrinogen level < 2 g/L	p = 0.99
			μ = 0.33
		Exclusion criteria:	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Patient who received both products	Fibrinogen post treatment (g/L), mean ± SE
		·	G1: 3.05 ± 0.19
		Maternal age, yrs, mean:	G2: 3.34 ± 0.22
		G1 : 32.8	p = 0.35
		G2: 31.0	ICU admission:
		Parity, n:	G1 : 0
		0	G2 : 1
		G1: 6	
		G2 : 6	Anemia: Hgb 1-3d post event
		G2: 0	G1: 8.55 ± 0.49
			G2: 8.79 ± 0.20
		≥ 1	p = 0.46
		G1: 8	p = 0.40
		G2 : 14	Length of stay:
		Days gestation, mean:	Duration of obstetric high-dependency unit
		G1 : 247	(HDU) stay, hours, mean ± SE
		G2 : 252	G1: 34.1 ± 4.32
			G2: 33.6 ± 5.44
		Single pregnancy: NR	p = 0.95
		Multiple pregnancy: NR	Duration of hospital stay, days, mean ± SE G1: 5.21 ± 0.33
		Dogg/othnicity;	G2: 6.55 ± 0.81
		Race/ethnicity:	p = 0.19
		Caucasian	p = 0.13
		G1 : 9	Mortality:
		G2 : 14	No maternal deaths
		OII	i vo matemai deaths
		Other	Uterine preservation:
		G1: 5	
		G2: 6	Hysterectomy
		2	G1 : 3 G2 : 2
		BMI, mean kg/m ² :	62. ∠
		G1: 25.8	Fortuna familita a NID
		G2: 24.5	Future fertility: NR
		Baseline hemoglobin, mean g/dL:	Breastfeeding: NR
		G1: 12.4	
		G2 : 11.9	Psychological impact: NR
			Harms of intervention:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
		SES: NR	None (no adverse reaction to RCC,
			cryoprecipitate or fibrinogen and no thrombotic
		Mode of birth, n:	complications record up to hospital discharge)
		Previous cesarean	O C C ND
		G1 : 6	Confounders: NR
		G2 : 2	
		p = 0.04	Effect modifiers: NR
		Risk (causative) factors, n (%):	
		Uterine atony	
		G1: 7 (50)	
		G2: 11 (55)	
		62. 11 (66)	
		Placenta previa	
		G1: 4 (28.6)	
		G2 : 3 (15)	
		Placental abruption	
		G1 : 1 (7.1)	
		G2: 5 (25)	
		Placenta accreta	
		G1 : 4 (28.6)	
		G2 : 3 (15)	
		Retained products of conception	
		G1: 1 (7.1)	
		G2 : 3 (15)	
		32. 3 (13)	
		Uterine rupture	
		G1 : 1 (7.1)	
		G2 : 0	
		3 0	
		Uterine/broad lig tear	
		G1: 0	
		G2 : 1 (5)	
		Coming I / vaging I to ar	
		Cervical/vaginal tear G1: 0	
	1	G2 : 1 (5)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
- Control		Coagulopathy G1: 4 (28.6) G2: 10 (50)	
		Primary etiology of PPH, n (%): Atony G1: 6 (42.9) G2: 7 (35)	
		Coagulopathy G1: 1 (7.1) G2: 3 (15)	
		Trauma G1: 1 (7.1) G2: 2 (10)	
		Placenta accreta G1: 3 (21.4) G2: 2 (10) Placenta previa G1: 0 G2: 1 (5)	
		Placental abruption G1: 0 G2: 2 (10)	
		Retained products of conception G1: 0 G2: 2 (10)	
		Vascular malformation G1: 1 (7.1) G2: 0	
		Mixed etiology G1: 1 (7.1)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G2: 1 (5) First trimester (miscarriage with MOH at surgical evacuation of uterus) G1: 1 (7.1) G2: 0	

Comments: The authors also provide definitions of uterine atony, placenta accrete, and retained placental tissue. Note: many cases of MOH have multiple causative factors.

Table D-30. Evidence table for studies addressing management of PPH (Gronvall 2012)

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author: Gronvall et al., 2012 ³⁵	Intervention: Bakri balloon tamponade (BBT) Groups:	Operational definition of PPH: Massive PPH (blood loss > 1000 mL) Expected high risk of PPH (blood loss < 1000 mL)	Blood loss, before insertion of balloon, n < 1000 mL G1: 6
Country: Finland Enrollment	G1: intervention N at enrollment: G1: 50	Definition of success of treatment: Hemostasis achieved after balloon placement Method of blood loss measurement: NR	1000-2500 mL G1 : 18 2500-5000 mL
period: Oct 2008 to June 2011	N at follow-up: G1: 50	Severity: NR	G1: 16 5000-10,000 mL
Birth setting: Hospital	Duration of treatment: NR Timing of treatment: NR	Inclusion criteria: Women who delivered at Helsinki University hospital during study period and who had tamponade after	G1: 6 > 10,000 mL
Facility characteristics: Tertiary care	Order of treatment: NR Length of follow-up: NR	delivery Exclusion criteria: NR	G1: 4 Transfusion: NR
Funding: Helsinki University Hospital research		Maternal age, yrs, mean: G1: 31.3 (range 19-47) Parity, n:	ICU admission: NR Anemia: NR
grants Design:		0 G1 : 30	Length of stay: NR
Case series, retrospective		1-2 G1 : 16	Mortality: NR Uterine preservation, n:
		≥ 3 G1 : 4	Bilateral uterine artery embolization G1 : 3
		Weeks gestation, mean (range): G1: 38 ⁺⁶ range (31 ⁺⁶ to 42 ⁺²)	Hysterectomy after AE G1: 1
		Single pregnancy, n (%): NR Multiple pregnancy, n (%): NR	Hysterectomy after tamponade failure G1: 2
		Race/ethnicity: NR	Supravaginal uterine amputation G1: 3

Future fertility: NR BMI: NR Baseline hemoglobin: NR Breastfeeding: NR SES: NR Psychological impact: NR Harms of intervention (complications), n: Mode of birth, n: Groin hematoma after embolization Vaginal **G1**: 1 G1: 29 (11 spontaneous, 10 induced, 8 vacuum extraction) Wound infection after cesarean, mild **G1**: 2 Cesarean, elective **G1**: 9 Wound infection after episiotomy, mild **G1**: 1 Cesarean, emergency **G1**: 9 Readmission for placental retention **G1**: 2 Cesarean, crash **G1:** 3 Confounders: NR Risk factors, n: Effect modifiers: NR History of cesarean **G1**: 30 Primary etiology of PPH, n: Atony **G1**: 8 Cervical rupture **G1:** 7 Vaginal rupture a/o paravaginal hematoma **G1**: 11 Placenta previa **G1:** 9 Placeta retention **G1:** 15 (5 had placenta accrete)

Comments: Authors state complications not due to tamponade

Table D-31. Evidence table for studies addressing management of PPH (Markova 2012)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	District ND
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Markova et al.,	Obstetric skills training for all staff	5 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	
2012 ³⁶	including midwives, nurses, auxiliary	Definition of success of treatment: NR	Transfusion rates:
Country:	nurses and doctors. Training d a		G1 : 1.5%
Denmark	variety of emergency obstetric	Method of blood loss measurement: NR	G2 : 1.6
Bornnark	situations associated with vaginal		G3 : 1.2
Enrollment	birth including PPH.	Severity: NR	
period:	Groups:	Inclusion criteria:	Number of units, n (%):
2003, 2005, and	G1: "Before" (2003) hardly anyone	Received RBC transfusion w/in 7 days of birth	1 unit
2007	had training	Able to obtain medical record	G1 : 3 (6)
Dirth cotting, ND	G2: "During" (2005) almost all had	Able to obtain medical record	G2: 2 (3.8)
Birth setting: NR	recent training		G3 : 5 (10.9)
Facility	G3: "After" (2007) the training was	Exclusion criteria:	
characteristics:	routine & had been repeated	Unable to obtain medical record	2 units
		Transfusion not associated with PPH	G1 : 32 (64)
University nospital	N=number of deliveries	Bleeding due to medical conditions or anticoagulant	G2 : 27 (51.9)
Funding: None	G1T: 3284	treatment	G3 : 26 (56.5)
Da alima	G2T : 3272		3 units
Design:	G3T: 3905	Maternal age, yrs, mean ± SD: NR	G1 : 3 (6)
Pre-post	N =number of patients who had RBC	Parity: NR	G2 : 7 (13.5)
(retrospective	transfusion for PPH	anty. Wit	G3 : 8 (17.4)
database audit)	G1: 50	Weeks gestation: NR	
	G2: 52	Trocke goodalon. The	4 units
	G3 : 46	Single pregnancy: NR	G1: 4 (8)
	63. 40	omgio prognancy. Tit	G2 : 9 (17.3)
	Duration of treatment: NR	Multiple pregnancy: NR	G3 : 5 (10.9)
	Timing of treatments Appl		
	Timing of treatment: Any	Race/ethnicity: NR	5 + units
	transfusion within 7 days of birth		G1 : 8 (16)
	Order of treatment: NR	BMI: NR	G2 : 7 (13.5)
			G3 : 2 (4.3)
	Length of follow-up: NR	Baseline hemoglobin: NR	T-4-1
			Total G1: 162
		SES: NR	- · · · · -
			G2: 172
		Mode of birth, n:	G3 : 135
		Vaginal,	Immediate transfusions (within 24 become)
		,	Immediate transfusions (within 24 hours), n:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
•		G1+ G2+G3: 98	G1 : 26
			G2 : 29
		Cesarean	G3 : 21
		G1+ G2+G3: 50	00.21
		01+ 02+03. 50	Delayed transfusions (24 hours to 7 days),
		Risk factors: NR	,
			n:
		Primary etiology of PPH vaginal birth, n (%):	G1: 22
		Atony	G2 : 17
		G1 : 7 (14)	G3 : 19
		G2 : 9 (17.3)	Immediate/delayed-ratio
		G3 : 12 (26.1)	G1: 1.2
			G2: 1.7
		Trauma/laceration	G3: 1.1
		G1 : 4 (8)	30. 1.1
		G2 : 9 (17.3)	ICU admission: NR
		G3 : 12 (26.1)	ICO admission. NK
			Anemia:
		Retained placenta	Pre-transfusion Hgb mmol/L mean,(median;
		G1 : 16 (23)	•
		G2 : 15 (28.8)	range)
		G3: 14 (30.4)	G1: 4.3 (4.4; 3.5-5.3)
		30. 14 (30.4)	G2: 4.4 (4.5; 3.7-5.0)
		Primary etiology of PPH cesarean birth, n (%):	G3: 4.3 (4.3; 3.5-5.3)
		Atony	Post-transfusion Hgb mean mmol/L
		G1 : 12 (24)	G1 : 5.7
		G2: 7 (13.5)	G2 : 6.1
		G3: 4 (8.7)	G3: 5.6
		Operative complication incl uterine rupture	Median time from delivery to manual
		G1 : 2 (4)	removal of the placenta (excluding cases
		G2: 5 (9.6)	where placental tissue was retained for more
		G3: 1 (2.2)	
			than 8 hours): min (n, range):
		Placenta accreta	G1: 64 (11, 33-131)
		G1 : 4 (8)	G2 : 70 (13, 23-497)
		G2 : 2 (3.8)	G3 : 75 (13, 35-397)
		G3: 2 (4.3)	Need for anesthetic support, n
			G1 : 18
		Placenta previa	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		G1 : 2 (4)	G2 : 28
Í		G2: 3 (5.8)	G3 : 24
		G3 : 1 (2.2)	
			Time from decision to perform surgery to
		Placental abruption	commencement of the intervention (for
		G1: 3 (6)	manual removal, exploration of the uterus, &
		G2: 2 (3.8)	uterine massage or compression, minutes (n,
		G3: 0	range):
			G1: 30 (15, 0-60)
			G2: 30 (17, 0-80)
			G3: 30 (14, 15-53.5)
			Delay for laceration or paravaginal
			hematomas, min (n, range):
			G1: 53.5 (2, 42-65)
			G2: 60 (6, 15-185)
			G3: 22.5 (6, 15-405)
			Length of stay: NR
			Mortality: NR
			Uterine preservation: NR
			Future fertility: NR
			Breastfeeding: NR
			Psychological impact: NR
			Harms of intervention: NR
			Confounders: NR
			Effect modifiers: NR

Table D-32. Evidence table for studies addressing management of PPH (Poujade 2012)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: 1 or more of the	Harms pre-specified: No
Poujade et al.,	Emergency pelvic angiography and	following: peripartum Hgb ? of 4g/dL or more,	nams pre-specified. No
2012 ³⁷	pelvic embolization for intractable	hemodynamic instability, or hypovolemic shock	Harms, n (%): Pulmonary edema with transfusion-associated
Country: France Enrollment period: Jan 2007 to Nov 2009 Birth setting: Hospital Facility characteristics: Tertiary care? Funding: NR (Authors report no conflicts of interest)	PPH Prior to embolization women were treated with standard protocol including: Exam of uterine cavity and/or manual removal of placenta, manual compression, uterine massage. Ultrasound exam performed. IV oxytocin (10 IU during delivery and 10 IU diluted in 50 ml of 0,.9% sodium chloride solution infused up to 120 ml/min) If persistent atony, IV sulprostome (500 µg diluted in 50 ml 0.9% sodium chloride infused at rate 500 µg /hour and subsequently 500 µg at rate of 100 µg/hour In case of persistent PPH, pelvic	Definition of success of treatment: cessation of hemorrhage with hemodynamic stability and absence of subsequent surgical procedure Method of blood loss measurement: NR Severity: NR Inclusion criteria: • Women with PPH referred for emergency pelvic angiography and Uterine artery embolization Exclusion criteria: • NR Maternal age, yrs, mean ± SD: G1a: 32.3 ± 5.7 G1b: 31.2 ± 6.4 Parity, n:	Pulmonary edema with transfusion-associated circulatory overload G1: 1 (1) Uterine necrosis (diagnosed 21 days after embolization and requiring hysterectomy) G1: 1 (1) Endometritis G1: 11 (11.2) Wound infection G1: 1 (1)
Design: Case series	angiography and pelvic arterial embolization In case of major PPH, uterine	G1a : 2.1 ± 1.3 G1b : 2.1 ± 1.7	
	compression sutures and/or uterine or hypogastric artery ligation or stepwise uterine devascularization and ultimately hysterectomy	Weeks gestation, mean ± SD: G1a: 38.6 ± 3.1 G1b: 39.5 ± 1.1	
	Groups: G1: intervention	Twin pregnancy, n (%): G1a: 6 (6.6) G1b: 0	
	N at enrollment: G1: 98 G1a: 90 success G1b: 8 failure	Race/ethnicity: NR	
	Duration of treatment: NR	BMI: NR Baseline hemoglobin: NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description	Timing of treatment: NR		
	_	SES: NR	
	Order of treatment: NR	Mode of birth, n:	
	Length of follow-up: As reported/NR	Vaginal G1 : 45 (45.9)	
		Instrumental extraction G1: 14 (14.2)	
		Cesarean before labor G1 : 28 (28.5)	
		Emergency cesarean G1: 11 (11.2)	
		Risk factors, n (%):	
		History of ceasarean G1a: 12 (13.3)	
		G1b : 1 (12.5) p = 0.93	
		Gestational diabetes mellitus	
		G1a: 8 (8.8)	
		G1b: 2 (25) p=0.14	
		Gestational hypertension	
		G1a: 6 (6.6)	
		G1b : 2(25) p=0.06	
		Preeclampsia	
		G1a: 13 (14.4) G1b: 0	
		p=0.24	
		Labor induction	
		G1a: 25 (27.7) G1b: 3 (37.5)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Cutomes
		p= 0.64	
		Cervical or vaginal tear	
		G1a: 25 (27.7)	
		G1b: 3 (37.5)	
		p = 0.80	
		Third or fourth degree perineal tear	
		G1a: 3 (3.3)	
		G1b: 0	
		p=0.56	
		Prolonged labor (second stage)	
		G1a: 10 (11.1)	
		G1b: 1 (12.5)	
		p=0.75 \	
		Primary etiology of PPH, n (%):	
		Atony	
		G1a: 80 (88.8)	
		G1b: 8 (100)	
		p=0.65	
		F 5.55	
		Retained placenta	
		G1a : 11 (12.2)	
		G1b: 2 (25)	
		p=0.71	
		r ····	
		Placenta accreta	
		G1a: 4 (4.4)	
		G1b: 3 (37.5)	
		p = <.0005	
		· · · · · · · · · · · · · · · · · · ·	
		Placenta previa	
		G1a: 4 (4.4)	
		G1b : 1 (12.5)	
		p = .35	
		Lower genital tract lacerations	
		G1a : 10 (11.1)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
•		G1b: 3 (37.5) p = 0.11	

Table D-33. Evidence table for studies addressing management of PPH (Ducloy-Borthers 2011)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss
	Tranexamic acid, 4 g mixed with 50	All patients with PPH > 500 mL managed according to	Persistent bleeding at T2, n (%):
al, 2011 ³⁸	mL normal saline IV over an hour.	French practice guidelines.	G1: 28 (36)
	After load dose infusion,	Study eligible: Vaginal delivery with PPH > 800 MI within	G2: 40 (54)
Country:	maintenance infusion administered	in 2 hours	p=0.03
France	for 6 hours.		
	Groups:	Definition of success of treatment : Reduction in blood	Hemoglobin drop > 4 g/dl, n (%):
Enrollment	G1: tranexamic acid	loss	G1: 19 (25)
period:	G2: control		G2 : 32 (43)
2005 to 2008		Method of blood loss measurement: Under buttocks	p=0.02
	N at enrollment:	drape with a graduated collection pouch measured at 4	
Birth setting:	G1 : 78	time points. Gauze was kept for weighing.	Transfusion:
8 obstetric centers	G2 : 74		PRBC transfusion before T4, n (%):
		Severity: NR	G1: 10 (13)
Facility	N at follow-up (ITT):	Inclusion criteria:	G2 : 13 (18)
characteristics:	G1 : 77	• PPH > 800 mL	p=0.17
Tertiary care (n=5)	G2 : 74	Exclusion criteria:	
and secondary		age < 18 years	PRBC units administered before T4, n:
care obstetric	Duration of treatment: 6 hours	absence of informed consent	G1: 32
units (n=3)	Timing of treatment	caesarean section	G2 : 62
, ,	Order of treatment: bladder	presence of known hemostatic abnormalities before	p=0.26
Funding:	catheter, manual removal of retained	pregnancy	
French Ministry of	placenta, genital tract exam, uterine	 history of thrombosis or epilepsy 	PRBC transfusion total through day 42, n (%):
Health	exploration, oxytocin 30 U/30	Instity of thornbosis of epilepsy	G1 : 13 (17)
	minutes. If these procedures	Maternal age, yrs, mean ± SD:	G2 : 20 (27)
Design: RCT	inefficacious, sulprostone (500 µg in	G1: 29 ± 4	p=0.33
· ·	1 hour) without any precoagulant	G2: 28 ± 5	
	treatment	G2. 20 ± 5	PRBC units administered through day 42, n
		Parity priminarea p (9/).	(%):
	Length of follow-up:	Parity, primiparae n (%): G1: 46 (64)	G1 : 28
	T1: inclusion	\ ,	G2 : 62
	T2: T1 + 30 minutes	G2 : 50 (69)	P< 0.0001
	T3: T1 + 2 hours	Wooks gostation, mann + SD:	
	T4: T1 + 6 hours	Weeks gestation, mean ± SD: G1: 39.5 ± 2	ICU admission, n (%)
		1 - 11	G1: 3 (3.9)
		G2: 39.5 ± 1.8	G2: 5 (6.7)
		Twin prognancy n (9/).	D=1
		Twin pregnancy, n (%):	Arterial embolization, n (%)
		G1 : 4 (6)	

Intervention	Inclusion/Exclusion	Outcomes
intervention	Criteria & Population	Outcomes
		G1: 5 (6.8)
		G2 : 5.1 (6.1)
	Race/ethnicity	p=1
		ľ
		Uterine preservation
	ВМІ	Surgical arterial ligature or hysterectomy, n (%)
		G1: 0
	G1 : 67 + 16	G2: 2 (2.7)
		p=0.24
	62. 66 ± 12	p=0.24
	Height cm. mean ± SD:	Late postpartum curettage, n (%)
	G1: 164 ± 5	G1 : 1 (1.3)
	G2 : 165 ± 6	G2 : 2 (2.7)
	021 100 20	p=1
	Baseline hemoglobin: NR	P
		Any vasopressor, n (%)
	SES: NR	G1 : 4 (5.2)
		G2 : 4 (5.4)
	Mode of birth no	p=1
		ρ-1
	vaginai (10070)	Mild dyspnea, n (%)
	Risk factors in (%):	G1: 0
		G2 : 1 (1.3)
		p=1
		ρ= ι
	G2. 3 (4)	Multiple organ failure, n (%)
	Instrumental delivery	G1: 0
		G2 : 0
	G2: 10 (14)	p=1
	Oxytocin for labor induction	Anemia: NR
		Aliginia. Wi
		Length of stay: NR
	32. 12 (11)	Length of Stay. INIX
	Mean labor duration, hours	Mortality: NR
		Future fertility: NR
	32. 0 ± 0	i didio fortinty. 1410
	Enidural analgesia	Breastfeeding: NR
	Intervention	Criteria & Population G2: 3 (4) Race/ethnicity NR BMI Weight kg, mean ± SD: G1: 67 ± 16 G2: 65 ± 12 Height cm, mean ± SD:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Odicomes
		G1 : 59 (82)	
		G2 : 61 (84)	Psychological impact: NR
		Abnormal placental insertion	Harms of intervention
		G1 : 2 (3)	Severe side effects:
		G2 : 3 (4)	Deep vein thrombosis, n (%)
		. ,	G1: 2 (3)
		Primary etiology of PPH, n (%):	G2: 1 (1)
		Atony	p=0.4
		G1 : 54 (75)	·
		G2 : 50 (69)	Renal failure, n (%)
			G1: 0
			G2 : 0
			Mean T4 urea, g/l ± SD
			G1 : 0.17 ± 0.06
			G2: 0.2 ± 0.1
			p=0.9
			Mean T4 creatininemia, mg/l ± SD
			G1: 6.3 ± 1.8
			G2: 6.4 ± 1.7
			p= 0.79
			Mean T4 diuresis, ml ± SD
			G1: 1,058 ± 1,010
			G2: 882 ± 480
			p=0.25
			Seizures, n (%)
			G1: 0
			G2: 0
			Maternal death, n (%)
			G1 : 0
			G2: 0
			Non severe side effects
			Nausea/vomiting, n (%)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
_			G1 : 12 (15)
			G2: 1 (2)
			p=0.002
			Phosphenes, n (%)
			G1 : 9 (12)
			G2 : 2 (3)
			p=0.02
			Dizziness, n (%)
			G1 : 4 (5)
			G2 : 3 (4)
			P=0.28
			Total non severe adverse events, n (%)
			G1 : 18 (23)
			G2 : 4 (6)
			P=0.03
			Confounders: NR
			Effect modifiers: NR

Table D-34. Evidence table for studies addressing management of PPH (Dupont 2011)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Rates of Severe PPH (2005 vs. 2008), n (%):
Dupont et al.,	Quarterly clinical audit meetings; team	Severe PPH was defined as a PPH associated with	Level II Unit:
2011 ⁴	of reviewers analyzed all cases of	one or more of the following: blood transfusion, arterial	
Country: France		embolization, arterial ligation, other conservative	G2a: 11 (.6)
Country. I fance	quality of care and where all staff	uterine surgery, hysterectomy, transfer to an intensive	G1a vs G2a: p <0.01
Enrollment	actively participated	care unit, peripartum haemoglobin drop of 4 g/dl or	
period:	Groups:	more, or maternal death.	Level III Unit:
2005 to 2008	G1: Severe PPH, year 2005		G1b : 45 (1.5)
Dinth acttion.	G1a: Level II Unit; 2005	Definition of success of treatment: NR	G2b: 31 (1.0)
Birth setting:	G1b: Level III Unit; 2005		G1b vs G2b: p= 0.05
Hospital	GIB. Level III Offit, 2005	Method of blood loss measurement: NR	
-	G2. Sovere BBH year 2009		Confounders: NR
Facility	G2: Severe PPH, year 2008 G2a: Level II Unit; 2008	Severity: see definition above	
characteristics:	G2b: Level III Unit; 2008	Inclusion criteria:	Effect modifiers: NR
One level 3			
University hospital	N at enrollment:	Severe PPH	
and one level 2	G1a: 32	Exclusion criteria:	
hospital	G1b : 45	Women with transfusion during the postpartum	
Funding:	G2b : 11	period but not clinically diagnosed with PPH	
French Ministry of	G2b : 31		
Health under its		Maternal age: NR	
Clinical Research	N at follow-up: NA	Parity: NR	
Hospital Program	Duration of treatment: NA	l unity. This	
		Weeks gestation, n (%): NR	
Design:	Timing of treatment: NA	Treeks gestation, if (70). Tel	
Pre-post systems	Order of treatment:	Single pregnancy, n (%): NR	
level	1 Examination of the uterine cavity	chilgle pregnancy, if (70). NIX	
		Multiple pregnancy, n (%): NR	
	within 15 minutes of the PPH diagnosis	manapic prognancy, ir (70). Text	
		Race/ethnicity: NR	
	2 Call for additional staff and	Trace/enfincity. TVIX	
	instrumental examination of the vagina	BMI: NR	
	and cervix	DIVII. IVIX	
	3 Intravenous administration of oxytocin	Baseline hemoglobin: NR	
		3	
	4 If PPH persisted and was due to	Mode of birth, n:	
	uterine atony, intravenous	Vaginal delivery	
	administration of sulprostone within 30	G1a : 21	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description	min of the initial diagnosis	G2a: 8	
	Length of follow-up: NR	G1b: 27 G2b: 9	
		Cesarean delivery G1a:11 G2a: 3	
		G1b: 18 G2b: 22	
		Risk factors: Previous cesarean delivery Multiple pregnancy Placenta praevia or accreta Mode of delivery: Cesarean Mode of delivery: Instrumental vaginal delivery Foetal macrosomia (baby's weight >4000 g) Postpartum hemorrhage	
		Primary etiology of PPH, n (%): Uterine Atony G1: 56/77 (72.7) G2: 25/42 97 (59.5)	

Comments: Risk factors presented for all births in the time period (not the subset with severe PPH)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Phase 1 Outcomes (identifying factors
Gayat et al.,	Phase 1		predictive of severe postpartum hemorrhage
2011 ³⁹		Definition of success of treatment: NR	requiring an advanced interventional
Country:	procedure (AIP) defined as uterine		procedure)
France	,	Method of blood loss measurement: NR	
riance	packing, arterial ligation or	Inclusion criteria:	Blood loss: NR
Enrollment	hysterectomy for suspected		
period:	persistent active bleeding	any parturient patient admitted and registered with a	Transfusion: NR
Phase 1: January	0	main diagnosis. PPH was coded as "postpartum	
1. 2004 –	Groups:	complication" and "haemorrhagic shock" or "acute	ICU admission:
December 31,	Phase 1:	anaemia" or "shock"	G1 : 31 (28)
2005	G1: AIP	 Same inclusion criteria for Phase 1 and Phase 2, just 	G2 : 6 (4)
Phase 2 - 2007	G2: medical management (after initial	different enrollment time periods	G1 vs G2 : p < 0.0001
1 11d36 Z - 2001	evaluation, bleeding was considered	Exclusion criteria: NR	
Birth setting:	non-active)	Exclusion criteria: NR	Anemia: NR (only reported on admission not
Phase 1 – referral		Maternal age, yrs, median (1st to 3rd quartile):	post intervention)
hospital	Phase 2:	G1 : 32 (30-36)	post intervention)
Phase 2 – 7	G1: AIP	G2 : 31 (27-35)	Length of stay in ICU, days, mean (IQR):
referral centers	G2: medical management	G1 vs G2 : p= 0.02	G1: 3.2 (2.3 – 6.2)
(including center	N	0.10 021 p= 0.02	G2: 1 (0.7 – 2.1)
from Phase 1)	N at enrollment:	Parity, n (%):	G1 vs G2: P < 0.0001
	Phase 1	First delivery	G1 VS G2. P < 0.0001
Facility	G1 : 110	G1: 45 (41)	Montolity in (0/).
characteristics:	G2: 147	G2: 72 (49)	Mortality, n (%):
Tertiary care		G1 vs G2: p = ns	G1 : 2 (2)
Terliary Care	Phase 2 (n = 237):	'	One death from amniotic fluid embolism and
Funding: NR	G1 : NR	First pregnancy	one from refractory hemorrhagic shock
_	G2: NR	G1: 32 (29)	G2 : 0 (0)
Design:	N of follows and ND	G2 : 57 (39)	G1 vs G2 : p=ns
Phase 1 –	N at follow-up: NR	G1 vs G2: p = ns	
retrospective	Duration of treatment: NR	01 43 02. p = 113	Uterine preservation: NR
cohort (using		Weeks gestation, median (1 st – 3 rd quartile):	
algorithm	Timing of treatment: NR	G1 : 39 (37-40)	Future fertility: NR
Phase 2 – Severe	Treetment detail =	G2 : 39 (38-40)	_
PPH (SPPH)	Treatment detail, n	, ,	Breastfeeding: NR
score validation	Embolization only	G1 vs G2: p= 0.04	
	G1 : 85	Cinale programme MD	Psychological impact: NR
		Single pregnancy: NR	
I	Open surgery only	Multiple was an englished (0/)	Harms of intervention: NR
	G1 : 14	Multiple pregnancy (twins), n (%):	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	0.00000
I		G1: 8 (7)	Independent factors predicting the need for
	Combined embolization and surgery	G2: 7(6)	advanced interventional procedure:
	G1 : 11	G1 vs G2 : p = ns	Abnormalities of placental implantation
	Length of follow-up: NR	Race/ethnicity: NR	Prothrombin time < 50%
		BMI: NR	HR > 115 bpm
		Baseline hemoglobin, median (1 st – 3 rd quartile):	Fibrinogen < 2 g/l
		G1 : 8.7 (7.0 – 9.9)	Troponin I detectable
		G2: 9.5 (8.2 – 10.6)	·
		G1 vs G2: p= 0.001	Phase 2 Outcomes
			The SPPH score was established and d each
		Mode of birth, n (%):	of the five predictive factors with a value of 0 or
		Cesarean	1 when absent or present on admission,
		G1: 45 (35)	respectively, with the total ranging from 0 to 5.
		G2 : 37 (25)	Area wader the arms (ALIC).
		G1 vs G2: p=ns	Area under the curve (AUC): Global validation cohort: 0.83
			Primary center: 0.83
		Risk factors, n (%):	Referral centers: 0.82
		Prior PPH	Referral certiers. 0.02
		G1 : 2 (2)	Sensitivity, specificity, and
		G2 : 6 (4)	positive and negative predictive values were
		G1 vs G2: p=ns	0.91, 0.58, 0.62 and 0.90 for SPPH scores C1,
			and 0.62, 0.85, 0.76 and 0.76 for SPPH scores
		Labor induction/augmentation	C2 in the multicentre validation cohort.
		G1: 12 (13)	
		G2 : 37 (25)	
		G1 vs G2: p= 0.03	
		Fibroids	
		G1: 3 (3)	
		G2 : 9 (6)	
		G1 vs G2 : p=ns	
		Preeclampsia	
		G1 : 12 (12)	
		G2 : 18 (12)	
		G1 vs G2: p=ns	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
·		Prolonged labor; labor duration, hours (mean, 1 st – 3 rd quartiles) G1: 4 (2-6) G2: 6 (4-8) G1 vs G2: p= 0.02	
		Primary etiology of PPH, n (%): Atony G1: 69 (61) G2: 109 (74)	
		Genital Tract Laceration G1: 22 (20) G2: 34 (23) Abnormalities of placentation G1: 16 (14) G2: 4 (3)	
		Uterine rupture G1: 3 (3) G2: 0 (0)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Kayem et al.,	Uterine compression sutures		
2011 ⁴⁰	Pelvic vessel ligation	Definition of success of treatment:	Transfusion, n (%):
Country of LUZ	Interventional radiological techniques	No requirement for either a further therapy to	Red cells
Country: UK	Recombinant factor VIIa (rFVIIa)	treat PPH or hysterectomy	G1: 168 (87) G2: 19 (95)
Enrollment			G3 : 21 (95)
period:	Groups:	Method of blood loss measurement: NR	G4 : 30 (100)
September 2007	G1: Uterine compression sutures		
to March 2009	G2: Pelvic vessel ligation	Severity: NR	Fresh frozen plasma
	G3: Interventional radiological		G1 : 124 (66)
Birth setting:	techniques	Inclusion criteria:	G2 : 17 (85)
Consultant-led	G4: Recombinant factor VIIa (rFVIIa)	Woman giving birth and undergoing treatment	G3 : 16 (73)
maternity units		for PPH with the following procedures: uterine	G4: 30 (100)
	N at enrollment:	compression sutures, rFVIIa, interventional	Platelets
Facility	G1 : 199	radiology including intra-arterial balloon occlusion	G1 : 65 (35)
characteristics:	G2: 20	and arterial embolization or pelvic vessel ligation	G2 : 13 (65)
NR	G3 : 22	during the study period.	G3 : 9 (41)
	G4: 31	Exclusion criteria:	G4: 24 (80)
Funding:		Women who had a PPH treated successfully by	Cryoprecipitate
Wellbeing of	N at follow-up: NR	intra-uterine balloon tamponade, and who were not	G1: 47 (26)
Women.	Duration of treatment: NR	managed with any of the other therapies	G2 : 11 (55)
AXA Research		managed with any of the other therapies	G3 : 6 (29)
Fund.	Timing of treatment : NR	Maternal age, yrs, n (%):	G4 : 24 (80)
National	Order of treatment: NR	<35	
Coordinating	Order of treatment. WK	G1 : 128 (64)	Success rates, n (%), 95% CI:
Centre for	Length of follow-up: NR	G2: 12 (60)	After Uterotonic only, n=205
Research		G3 : 12 (55)	G1 : 120 (75), 67-81
Capacity	Primary treatment of women	G4: 21 (68)	G2: 5 (36), 13-65 G3: 12 (86), 57-98
Development of	managed with different second-		G3 : 12 (66), 57-96 G4 : 5 (31), 11-59
the National	line therapies, n (%):	≥35	After failure of intrauterine tamponade, n=67
Institute for Health	Uterotonic prophylaxis	G1 : 71 (36)	G1: 20 (53), 36–69
Research.	G1 : 195 (98)	G2 : 8 (40)	G2 : 1 (17), 0–64
Policy Research	G2: 20 (100)	G3 : 10 (45)	G3: 7 (87), 47–100
,	,,		G4: 4 (27), 8–55

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Programme	G3 : 22 (100)	G4 : 10 (32)	
in the Department	G4: 30 (97)	D-vite - (0/)	Additional treatment, n (%), 95% CI:
of Health part		Parity, n (%):	After Uterotonic only
funded UKOSS	Primary uterotonic treatments:	Nulliparous	G1 : 16 (10), 6–16
(Independent	Oxytocin	G1 : 92 (46)	G2 : 7 (50), 23–77
study from which	G1 : 195 (98)	G2 : 3 (15)	G3 : 0 (0), 0–23 G4 : 4 (25), 7–52
this paper reports)	` ,	G3 : 6 (27)	34. 4 (23), 7–32
	G3 : 18 (82)	G4 : 9 (29)	After failure of intrauterine tamponade
Design:	C4: 28 (00)		G1: 10 (26), 13–43
Prospective cohort	64. 20 (90)	Multiparous	G2 : 5 (83), 36–100
study	Franchine	G1 : 107 (54)	G3: 1 (12), 0–53
	Ergometrine	G2 : 17 (85)	G4: 4 (27), 8–55
Note: See related	G1: 106 (53)	G3 : 16 (73)	
study, Kayem	G2 : 6 (30)	G4: 22 (71)	Uterine preservation, total n (%), 95% CI:
2011 ⁴¹	G3 : 6 (27)		Hysterectomy after Uterotonic only
	G4 : 11 (35)	Weeks gestation: NR	G1 : 32 (20), 14-27
		3	G2 : 6 (43), 18-71 G3 : 2 (14), 0-43
	Misoprostol	Single pregnancy: NR	G4: 7(44), 20-70
	G1 : 127 (64)	omgio prognamo): tax	0117(11), 2010
	G2 : 8 (40)	Multiple pregnancy, n (%):	Hysterectomy after failure of intrauterine
	G3 : 9 (41)	G1 : 19 (10)	tamponade
	G4: 18 (58)	G2 : 1 (5)	G1 : 14 (37), 22–54
		G3 : 1 (5)	G2 : 3 (50), 12–88
	Carboprost	Y 7	G3 : 0 (0), 0–37
	G1 : 142 (71)	G4: 0	G4 : 7 (47), 21–73
	G2 : 12 (60)		ICU admission: NR
	G3 : 11 (50)	Race/ethnicity: NR	ICO admission: NR
	G4 : 17 (55)		Anemia: NR
		BMI (kg/m2), n (%):	Taloma. Tal
	Uterine balloon or packing	<30	Length of stay: NR
	before second-line therapy	G1: 149 (80)	
	procedure	G2 : 15 (79)	Mortality, total n: 0
	G1: 38 (19)	G3 : 12 (71)	
	G2 : 6 (30)	G4: 25 (89)	Future fertility: NR
	1 ' '		Donasto dia mando
	G3 : 8 (36)		Breastfeeding: NR

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
	G4 : 15 (48)	≥30	Psychological impact: NR
		G1 : 37 (20)	Harms of intervention, total n:
		G2 : 4 (21)	Acute Respiratory Syndrome
		G3 : 5 (29)	5
		G4 : 3 (11)	
		, ,	Pulmonary oedema
		Baseline hemoglobin: NR	11
		SES: NR	Cardiac arrest
			5
		Mode of birth, n (%):	
		Vaginal birth	Other
		G1 : 17 (9)	6
		G2 : 3 (15)	O of the ND
		G3 : 7 (32)	Confounders: NR
		G4: 15 (48)	Effect modifiers: NR
		Caesarean section during labour	
		G1: 96 (48)	
		G2 : 5 (25)	
		G3 : 4 (18)	
		G4: 5 (16)	
		Caesarean section before labour	
		G1 : 86 (43)	
		G2 : 12 (60)	
		G3 : 11 (50)	
		G4: 11 (35)	
		Risk factors, n (%):	
		History of cesarean:	
		G1: 57 (29)	
		G2 : 9 (45)	
		G3 : 11 (50)	

Study	Intervention	Inclusion/Exclusion	Quita a mana
Description	Intervention	Criteria & Population	Outcomes
		G4: 11 (35)	
		Previous uterine surgery:	
		G1: 33 (17)	
		G2 : 4 (20)	
		G3 : 1 (5)	
		G4: 5 (17)	
		Placenta praevia diagnosed	
		before labour:	
		G1: 19 (10)	
		G2 : 4 (20)	
		G3 : 8 (36)	
		G4 : 6 (19)	
		Placenta accreta suspected	
		before labour:	
		G1: 3 (2)	
		G2: 1 (5)	
		G3 : 4 (18)	
		G4 : 2 (6)	
		Multiple gestation	
		G1: 19 (10)	
		G2 : 1 (5)	
		G3: 1 (5)	
		G4: 0	
		Induction of labour:	
		Yes	
		G1 : 53 (27)	
		G2 : 1 (5)	
		G3: 3 (14)	
		G4 : 13 (42)	

Study	Intomontion	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		No	
		G1 : 146 (73)	
		G2 : 19 (95)	
		G3: 19 (83)	
		G4: 18 (58)	
		Use of oxytocin during labour:	
		Yes	
		G1: 57 (51)	
		G2: 2 (25)	
		G3 : 3 (27)	
		G4 : 8 (40)	
		No	
		G1 : 54 (48)	
		G2 : 6 (75)	
		G3 : 8 (73)	
		G4 : 12 (60)	
		Primary etiology of PPH, n (%):	
		Atony	
		G1 : 126 (63)	
		G2 : 5 (25)	
		G3 : 2 (9)	
		G4 : 13 (42)	
		Placenta accreta	
		G1 : 17 (9)	
		G2 : 1 (5)	
		G3 : 4 (18)	
		G4 : 4 (13)	
		Placenta previa without accreta	
		G1: 13 (7)	
		31. 13 (1)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		G2 : 4 (20)	
		G3 : 4 (18)	
		G4: 3 (10)	
		Uterine tear	
		G1 : 22 (11)	
		G2: 6 (30)	
		G3 : 3 (14)	
		G4 : 3 (10)	
		Other	
		G1 : 21 (11)	
		G2 : 4 (20)	
		G3 : 9 (41)	
		G4 : 8 (26)	
		Disseminated intravascular coagulation	
		G1 : 24 (12)	
		G2 : 3 (15)	
		G3 : 3 (14)	
		G4: 12 (39)	

Table D-37. Evidence table for studies addressing management of PPH (Kayem 2011b)

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
		Operational definition of PPH: NR	BIOOG IOSS: NR
Kayem et al.,	Uterine compression suture		
2011 ⁴¹	Uterine compression suture followed	Definition of success of treatment: NR	Transfusion: NR
Country: UK	by hysterectomy		
Country. Or		Method of blood loss measurement: NR	ICU admission: NR
Enrollment	Groups:		
period:	G1: Uterine compression suture	Severity: NR	Anemia: NR
September 2007	G1a: Uterine compression suture	Inclusion criteria:	
to March 2009	only		Length of stay: NR
	G1b: Uterine compression suture	All women in whom uterine compression sutures	
Birth setting:	followed by hysterectomy	were used to treat a postpartum hemorrhage from the	Mortality: NR
Consultant-led		entire cohort of U.K. births during the study period	,
maternity units	N at enrollment:	Exclusion criteria: NR	Uterine preservation:
-	G1 : 211	Exclusion Chiena. NA	Hysterectomies after specific uterine
Facility	G1a: 159	M-(compression sutures, n (% [95% confidence
characteristics:	G1b : 52	Maternal age, yrs, n (%), OR (95% CI):	interval]):
NR	N of fallow one NID	<35	B-Lynch
	N at follow-up: NR	G1a : 106(80),	G1b : 19 (24 [15–35])
Funding:	Duration of treatment: NR	G1b : 26 (20)	G 10. 19 (24 [15–35])
Wellbeing of	Burdion of troutment: Att	P=1	M EG I D I
Women.	Timing of treatment: NR		Modified B-Lynch
AXA Research	Onder of the store and ND	≥35	G1b : 17 (35 [22–51])
Fund.	Order of treatment: NR	G1a: 53 (67)	
National		G1b: 26(33)	Other
Coordinating	Length of follow-up: NR	2.00 (1.06–3.78)	G1b : 4 (13 [4–29])
Centre for			
Research	Number of Women Treated With	Parity, n (%), OR (95% CI):	Unspecified
Capacity	Specific Uterine Compression	Nulliparous	G1b : 12 (23 [12–37])
Development of	Sutures, n (%):	G1a: 81 (86)	
the National	B-Lynch	G1b: 13 (14)	Any suture
Institute for Health	G1 : 79 (37)	P=1	G1b : 52 (25 [19–31])
	, ,		1/
Research.	Modified B-Lynch	Multiparous	Rate of failure leading to hysterectomy,%:
Policy Research	G1: 48 (23)	•	≥ 35yrs, 33
Programme	(30)	G1a : 78 (67)	<35 yrs, 20
in the Department	Other	G1b : 39 (33)	100 y13, 20
of Health part	G1: 32 (15)	3.12 (1.55–6.28)	Multiparous, 33
funded UKOSS	J.1.02 (10)		
(Independent	Unspecified	Weeks gestation: NR	Nulliparous, 14
study from which	Onspecialed		

Study	I	Inclusion/Exclusion	Outcome
Description	Intervention	Criteria & Population	Outcomes
this paper reports)	G1 : 52 (25)	Single pregnancy: NR	Unemployed and routine or manual
			occupational groups, 28
Da alama	Any suture	Multiple pregnancy, n (%),	
Design:	G1 : 211 (100)	OR (95% CI):	Managerial or professional
Population-based	Other treatment, n (%):	Yes	Groups, 17
case series	Uterine balloon or packing before	G1a: 15 (75)	
	uterine compression suture:	G1b : 5 (25)	Vaginal delivery, 47
Note: See related	Yes	1.02 (0.35–2.96)	Cesarean delivery group, 22
	G1a : 45 (68)		Delay from delivery to uterine suture
study, Kayem	G1b : 21 (32)	No	compression:
2011 ⁴⁰		G1a: 144 (74)	2-6hrs, 42
	No	G1b: 47 (26)	<1hr, 16
	G1a: 114 (80)	1	
	G1b: 28 (20)		Future fertility: NR
		Race/ethnicity, n (%), OR (95% CI):	5
	Uterine balloon or packing after	White	Breastfeeding: NR
	uterine compression suture:	G1a : 122 (75)	-
	G1 : 25 (38)	G1b : 40 (25)	Psychological impact: NR
	Artarial ambalization or ligation	1	Harms of intervention: NR
	Arterial embolization or ligation before Uterine compression suture :	Digal, or other other minerity	0 ())
	G1: 10 (5)	Black or other ethnic minority Groups	Confounders: NR
	G1. 10 (3)	G1a: 37 (76)	Effect modifiers: NR
	Recombinant factor VIIa before	G1b: 12 (24)	
	Uterine compression suture:	0.99 (0.47–2.08)	
	G1: 2 (1)	0.55 (0.47-2.00)	
	G1. 2 (1)	Socioeconomic group, n (%), OR (95% CI):	
	Arterial embolization or ligation after	Managerial	
	Uterine compression suture :	G1a: 48 (83)	
	G1 : 18 (9)	G1b : 10 (17)	
		1	
	Recombinant factor VIIa Uterine after		
	compression suture:	Unemployed or nonmanagerial	
	G1 : 9 (4)	G1a : 81 (72)	
	, ,	G1b: 32 (28)	
		1.90 (0.86–4.20)	
		BMI (kg/m²), n (%), OR (95% CI):	
		<30	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1a : 124 (75)	
		G1b: 41 (25)	
		1	
		≥30	
		G1a : 28 (85)	
		G1b: 5 (15)	
		0.54 (0.20–1.49)	
		Smoking status, n (%), OR (95% CI):	
		Never or exsmoker	
		G1a : 131 (75)	
		G1b : 44 (25)	
		1	
		Smoked during pregnancy	
		G1a: 27 (87)	
		G1b: 4 (13)	
		0.44 (0.15–1.33)	
		Baseline hemoglobin: NR	
		Mode of birth, n,	
		OR (95% CI):	
		Vaginal	
		G1a : 10 (53)	
		G1b : 9 (47)	
		3.12 (1.04–9.10)	
		0	
		Cesarean	
		G1a : 149 (78)	
		G1b : 43 (22)	
		1	
		Risk factors, n (%), OR (95% CI):	
		Multiparity:	
		G1a : 78 (67)	
		G1b : 39 (33)	
		Popolathniaitus	
		Race/ethnicity:	1

Study	It	Inclusion/Exclusion	0(
Description	Intervention	Criteria & Population	Outcomes
		White	
		G1a: 122 (75)	
		G1b : 40 (25)	
		1	
		Black or other ethnic minority	
		Groups	
		G1a: 37 (76)	
		G1b : 12 (24)	
		0.99 (0.47–2.08)	
		History of cesarean:	
		Yes	
		G1a: 23 (64)	
		G1b : 13 (36)	
		2.09 (1.07–4.07)	
		No	
		G1a: 136 (78)	
		G1b: 38 (22)	
		1	
		Primary etiology of PPH, n (%) or n(% [95% CI]):	
		Atony:	
		G1 : 129 (61)	
		G1a: 96 (74)	
		G1b: 33 (26 [18–34])	
		Uterine tear	
		G1: 27 (13)	
		G1a: 18 (67)	
		G1b : 9 (33 [17–54])	
		□ 10. 3 (00 [17 - 0+])	
		Placenta accreta:	
		G1 : 18 (9)	
		G1a : 11 (61)	
		G1b : 7 (39 [17–64])	
		, L 2/	
		Placenta previa without accreta:	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1 : 15 (7) G1a : 13 (87) G1b : 2 (13 [2–40])	
		Others (Placental abruption, Amniotic fluid embolism, infection, bleeding in left broad ligament and unspecified): G1: 22 (10) G1a: 21 (95) G1b: 1 (5 [0–23])	

Comments: G1b = number of women who had a uterine compression suture who subsequently had a hysterectomy (G1b is a subset of G1)

Table D-38. Evidence table for studies addressing management of PPH (Palacios-Jaraquemada 2011)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss:
Palacios-	Surgical interventions including		Accurate hemostasis
Jaraquemada,	selective arterial ligation and	Definition of success of treatment: Control of uterine	G1: 499 (93%)
2011 ⁴²	compression procedures:	bleeding; accurate hemostasis was defined as complete	
Country:	(a) Bilateral uterine artery ligation; (b)	cessagtion of bleeding after the use of a specific surgical	Transfusion: NR
Argentina	selective ligation of pelvic	hemostatic technique	
Argentina	subperitoneal pedicles; (c) B-Lynch		ICU admission: NR
Enrollment	procedure; (d) Hayman's procedure;	Method of blood loss measurement: NR	
period:	(e) Cho's procedure; (f) Pereira's		Anemia: NR
August 1989 to	procedure	Severity: NR	
Dec 2009	Groups:	Inclusion criteria: NR	Length of stay: NR
Birth setting:	G1: intervention		
Hospital		Exclusion criteria: NR	Mortality:
поѕрна	N at enrollment: G1: 539 (541 were initially presented,	Maternal age, yrs, mean ± SD: NR	Multi-organ failue after massive transfusion G1: 2
Facility	but 2 died prior to intervention)	Parity: NR	
characteristics:	,	Failty. NK	Uterine preservation:
12 sites (single	Duration of treatment: NR	Weeks gestation: NR	Hysterectomy
practitioner)	Timing of treatment: NR	Weeks gestation. Nix	G1 : 40
Funding:	Thining of treatment. WY	Single pregnancy: NR	
None (No conflict	Order of treatment: NR	olingio prognancy. All	Future fertility:
of interest)	Length of follow-up:	Multiple pregnancy: NR	Spontaneous successful pregnancy
·	6-12 months for 404/501 women who	indiciple programby. The	G1 : 116
Design: Case	retained their uterus)	Race/ethnicity: NR	
series	l letained their dierus)	Traco, our monty. The	Breastfeeding: NR
		BMI: NR	
			Psychological impact: NR
		Baseline hemoglobin: NR	Harms of intervention: NR
		OFO: ND	Confounders: NR
		SES: NR	Comounders: NR
		Mada of history	Effect modifiers: NR
		Mode of birth: NR	Herma nra anacifiad. No
		Risk factors: NR	Harms pre-specified: No
			Harms, n:
		Primary etiology of PPH, n (%):	G1: 541
		Atony	
		G1: 114 (21.1)	Postsurgical bleeding

Placenta accrete	G1 : 9
G1: 361 (67.0)	
	Inadvertent ligation of uterus
Cervical scar pregnancy	G1 : 5
G1: 19 (3.5)	
	Postpartum hypophysiary necrosis (Sheehan's
Placenta previa	syndrome)
G1 : 21 (3.9)	G1: 2
Litarina convical vaginal toors	Uterine necrosis
Uterine-cervical-vaginal tears G1: 24 (4.5)	G1: 1
G1. 24 (4.0)	91. 1
	Endometrial adhesions
	G1: 3/100 followed up by hysteroscopy

Table D-39. Evidence table for studies addressing management of PPH (Schmitz 2011)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Severity of blood loss:
Schmitz et al.,	Sulprostone administration after Dx	Biologically defined: peripartum hemoglobin decline of >	
2011 ²⁰	of PPH	2 g/dL (equivalent of blood loss of >500 mL)	– 3 rd quartile):
Country	Groups		G1a: 3.4 (2.1 – 4.7)
Country: France	Groups: G1: atonic PPH post-delivery treated	Clinically defined: blood loss of > 500 mL or excessive	G1b: 3.5 (2.3 – 4.5)
riance		blood loss that motivated manual removal of placenta	p=0.41
Enrollment	with sulprostone G1a: atonic PPH after vaginal	and/or examination of uterine cavity.	
period: NR	delivery treated with sulprostone		Hemoglobin decrease ≥ 4 g/dL, n (%):
period. NA	G1b: atonic PPH after cesarean	Severe PPH defined as PPH with blood transfusion,	G1a: 360/995 (36.2)
Birth setting:	delivery treated with sulprostone	arterial embolization, arterial ligation, other conservative	G1b: 140/375 (37.3)
As reported/NR		uterine surgery, hysterectomy, transfer to ICU,	p=0.97
· ·	N at enrollment: (4038 women with	peripartum Hb decline ≥ 4 g/dL (blood loss ≥ 1000 mL)	
Facility	clinically assessed atonic PPH) (%)		Red cell transfusion, n (%), mean # units (min,
characteristics:	G1 (total of a +b): 1370/4038 (33.9)	Definition of success of treatment: NR	max):
Hospitals (public,	G1a : 995/3570 (27.9)		G1a: 202/995 (20.3), 4.8 (1, 31)
private and	G1b: 375/468 (80.1)	Method of blood loss measurement: NR	G1b: 124/375 (33.1), 4.4 (1, 17)
university-based)	N - (fall		p<0.01, p=0.43
within 6 perinatal	N at follow-up:	Severity: NR	
networks	G1 (total of a +b): 1370 G1a: 995	Inclusion criteria:	Hysterectomy, n (%):
From allian are	1	Women with PH selected from the Pithagore6 trial	G1a : 29/995 (2.9)
Funding:	G1b : 375	population (see Driessen, 2011, PMID: 21173641	G1b: 14/375 (3.7)
French Ministry of	Duration of treatment: NR	' '	p=0.61
Health's Clinical		for details)	rd
research Hospital	Timing of treatment:	Exclusion criteria:	Any of the 3 rd line treatments (embolization,
Program (contract	Per the French guidelines,	Pts with PPH with no excessive bleeding and who did	conservative surgery or hysterectomy), mean
27-35)	continuous intravenous infusion of	not receive specific care for PPH	(%):
Design:	sulprostone not later than 30 min	•	G1a : 129/995 (13.0)
Population-based	after PPH Dx. (see Driessen article	Maternal age: NR	G1b : 98/375 (26.1)
case series	for details)	Parity: NR	p<0.01
case selles	·		
Note: See related	Order of treatment:	Weeks gestation: NR	Women not requiring additional treatment
studies Bonnett	Step 1: administration of oxytocin	3	beyond sulprostone to control bleeding, n (%):
2013 ¹⁸ , Deneux-	and/or ergometrine	Single pregnancy: NR	G1a : 866/995 (87)
Tharaux 2010 ¹⁹	Step 2: administration of		G2b : 277/375 (73)
THAIRMA ZOTO	prostaglandins (sulprostone)	Multiple pregnancy: NR	Overall, 83.4% of the 1370 sulprostone
	Step 3: embolization, conservative		recipients did not require additional treatment.
	surgery, hysterectomy	Race/ethnicity: NR	ICH admission, ND
	Total dose of sulprostone,	BMI: NR	ICU admission: NR

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	micrograms, (mean ± SD): G1a: 964 (837±343) G1b: 370 (943 ± 359)	Baseline hemoglobin: NR	Anemia: NR
	p<0.01	SES: NR	Length of stay: NR
	Initial Care, n (%):	Mode of birth, n:	Mortality: NR
	Examination of uterine cavity: G1a: 947/995 (69.1)	G1a: vaginal delivery (995) G1b: cesarean delivery (468)	Uterine preservation: NR
	G1b: NA	Risk factors: NR	Future fertility: NR
	Instrumental examination of genital tract: G1a: 681/995 (68.4)	Primary etiology of PPH, n (%): Atony (100)	Breastfeeding: NR
	G1b : NA		Psychological impact: NR
	Prophylactic oxytocin:		Confounders: NR
	G1a : 696/995 (69.9) G1b : 357/375 (95.2)		Effect modifiers: NR
	p<0.01		Harms prespecified: No
	Oxytocin: G1a: 942/995 (94.7) G1b: 355/375 (94.7) p=0.78		Harms, n (%): ≥ side effects of sulprostone: G1: 51/1370 (3.7) (95% CI: 2.7 to 4.7)
	Vascular volume expansion: G1a: 475/995 (47.7)		Digestive side effects: G1: 34/1370 (2.5) (95% CI: 1.7 to 3.5)
	G1b : 178/375 (47.5) p=0.46		Hyperthermia, chills: G1: 7/1370 (0.5) (95% CI: 0.2 to 1.0)
	Length of follow-up: As reported/NR		Cardiac side effects : G1: 5/1370 (0.4) (95% CI: 0.1 to 0.8)
			High blood pressure: G1: 2/1370 (0.1) (95% CI: 0.02 to 0.5)
			Respiratory side effects: G1: 2/1370 (0.1) (95% CI: 0.02 to 0.5)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
			Dizziness: G1: 2/1370 (0.1) (95% CI: 0.02 to 0.5)
			Severe cardiovascular or respiratory symptoms (including acute high blood pressure and acute cyanosis): G1: 7/1370 (0.5) (95% CI: 0.2 to 1.0)

Table D-40. Evidence table for studies addressing management of PPH (Shields 2011)

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Blood loss:
Shields et al.,	Maternal Hemorrhage Protocol	Bleeding greater than expected for normal delivery	Overall hemorrhage rate was 3.6% (Stages 1-
2011 ¹³	Algorithms for Stages 0-3	(>500mL vaginal, >1000mL cesarean)	3)
	r agentamic for chages of s	(* 555= taga., * 1555= 555aa)	Hemorrhage rate for Stages 2-3 combined was
Country: US	Stage 0 – normal intrapartum and	Definition of success of treatment:	1.5%
Enrollment	postpartum course	Patients requiring less intervention for treatment of PPH	
period:	Stage 1 – Bleeding greater than	(1) facilitate early intervention	Transfusion, n
Protocol		(2) Reduction in number of blood product units used	Average number of blood products used per
Development:	vaginal, > 1000mL cesarean)	(3) decrease DIC	month:
November 2008-	Stage 2 – Bleeding not responsive to		G1: (12 mo post protocol): 6.3
January 2009	conservative management	Method of blood loss measurement:	G2: (12 mo pre protocol): 16.7
	Stage 3 - Continued bleeding with	Weighing all lap sponges, bedware if needed, and	p < 0.01
Educational	actual or expected blood loss	fluid in collection systems	
Phase: February –	>1500mL	Subtraction of non-blood fluid in collection systems	ICU admission: NR
April 2009	Crounce	Changed bedding after delivery to reduce risk of	
'	Groups: G1: post-protocol	amniotic fluid contamination	Anemia: NR
Protocol	G2: control/pre-protocol		
Implementation:	G2. control/pre-protocor	Severity:	Length of stay: NR
May 2009	N at enrollment:	Stage 0 - normal	
	N = 5813 deliveries during study	Stage 1: Bleeding greater than expected for normal	Mortality: NR
	period (doesn't specify which study	delivery	
varied for different	period or give dates)	Stage 2: bleeding not responsive to conservative	Uterine preservation: NR
aspects of		management (uterine massage, uterotonics)	
maternal	(1) Reduction in severity of		Future fertility: NR
hemorrhage	hemorrhage, N:	(tamponade, D&C, laceration repair, compression	
protocol:	G1: 2874 deliveries	sutures)	Breastfeeding: NR
	G2: 985 deliveries	Inclusion criteria:	
(1) Reduction in	(2) More aggressive mgmt. and	• NR	Psychological impact: NR
severity of	use of blood products:	ASSUMED to be: admitted to L&D unit at the hospital	Harms of intervention: NR
hemorrhage:	G1: 2874 deliveries	("protocol was initiated at the time of admission")	
 4 mo prior to 	G2: 2939 deliveries	,	Confounders: NR
protocol		Exclusion criteria: NR	
(control)	Duration of treatment: NR	Maternal age: NR	Effect modifiers: NR
• 12 mo after	Timing of treatment: NR		OTHER OUTCOMES:
protocol		Parity: NR	
(intervention)	Order of treatment:		DIC:
divided into 3 4-	Algorithms for Stages 0-3 for order of		Rate of DIC was reduced 64% in the 12 mo
month periods	treatment	Single pregnancy: NR	post protocol period (doesn't report how long

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
(post-period 1, 2, 3)	Length of follow-up: NR	Multiple pregnancy: NR	the pre-protocol period was for this comparison or give raw data, or the definition of DIC). p = 0.06
(2) Aggressive mgmt. and liberal		Race/ethnicity: NR	Staff and physician survey:
use of blood products		BMI: NR	"Significant shift in low levels of comfort to being most comfortable/confident in
Preprotocol (12 months prior to		Baseline hemoglobin: NR	hemorrhage situations and team communications"
protocol and training)		SES: NR	Physicians p < 0.01
 Postprotocol (12 		Mode of birth, n: NR	Nursing staff p < 0.01
months after			(No raw data given)
protocol)		Risk factors: NR	Systems level outcomes:
(3) Staff and physician survey on perceptions Pre and post protocol		Primary etiology of PPH: NR	 Number of patients treated at either stage 1 or 2: no difference pre vs post protocol (raw data and P value not given) Number of patients successfully treated at each stage
Birth setting: hospital			Stage 1
			G2: (pre-protocol): 22 (35%)
Facility characteristics:			G1a: (post protocol 1): 25 (51%)
Tertiary care			G1b: (post protocol 2): 27 (69%)
Funding: NR			G1c: (post protocol 3): 49 (82%)
Design: Systems level intervention			p = 0.02 (more patients treated at Stage 1 after institution of protocol, which translates into less blood loss)
See related study			• <u>Stage 2</u>
Shields 2014 ¹²			G2: (pre protocol): 33 (53%)
			G1a: (post protocol 1): 22 (45%)
			G1b: (post protocol 2): 7 (18%)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
			G1c : (post protocol 3): 5 (8%)
			p = 0.02 (fewer patients treated at stage 2 after institution of protocol)
			• <u>Stage 3</u>
			G2: (pre-protocol): 7 (11%)
			G1a: (post protocol 1): 2 (4%)
			G1b: (post protocol 2): 5 (13%)
			G1c: (post protocol 3): 6 (10%)
			p = non-significant but actual P value NR

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention: Pelvic arterial embolization	Operational definition of PPH: NR	Harms pre-specified: No
2011 ⁴³ Country:	Groups: G1: Pelvic arterial embolization	Definition of success of treatment: NR Method of blood loss measurement: NR	Harms, n (%):* Psychological impact: Negative memories of the event
rance	N at enrollment:	Severity: NR	No G1: 22 (32.4)
eriod:	N at follow-up: G1: 68	Inclusion criteria: All consecutive women with postpartum hemorrhage who underwent embolization at the tertiary obstetric	Yes G1 : 46 (67.6)
Birth setting: NR	Duration of treatment: NR	center (Rouen University Hospital) and whose uterus was preserved	Main negative memories of the event:
acility	Timing of treatment: NR		Fear of death G1 : 24 (35.3)
characteristics: University- affiliated tertiary	Order of treatment: NR Length of follow-up, mean months	Women with PPH undergoing peripartum hysterectomy	Pain G1 : 13 (19.1)
	(range): G1: 71.4 (12-152)	Maternal age, yrs, n (%): <25 G1 : 10 (14.7)	Separation from the baby G1: 6 (8.8)
Design: Retrospective ase series		25-35 G1 : 48 (70.6)	Complete amnesia about the birth G1: 3 (4.4)
tee related tudies, Sentilhes 009 ^{44, 45}		>35 G1 : 10 (14.7)	Long-term repercussion of PPH: No G1: 40 (58.8)
		Parity, n (%): Primiparous G1: 24 (35.3)	Yes G1 : 28 (41.2)
		Weeks gestation: NR	Type of long-term repercussion: Thought about the event at least
		Single pregnancy: NR	once a month
		Multiple pregnancy, n (%): G1: 7 (10.3)	G1 : 16 (23.5) De novo phobia G1 : 5 (7.3)

White **G1**: 61 (89.7) Persistent fear of death **G1**: 5 (7.3) Sub-Saharan Africa Impossible to have sexual **G1:** 4 (5.9) intercourse with their partner for North Africa at least a year **G1**: 3 (4.4) **G1**: 4 (5.9) BMI: NR Problems in marital relationships that women considered to be Baseline hemoglobin: NR related to this event **G1**: 3 (4.4) SES, n (%): Never married Fear of a recurrence of PPH caused **G1**: 20 (29.4) women to decide against another pregnancy Mode of birth, n, (%): **G1**: 14 (20.6) Cesarean before labor Harms of intervention, n (%): **G1:** 18 (26.5) Major maternal complication **G1:** 2 (2.9) Cesarean during labor **G1:** 18 (26.5) Pulmonary embolism **G1:** 1 (1.5) Spontaneous vaginal delivery **G1**: 20 (29.4) Postpartum myocarditis **G1:** 1 (1.5) Operative vaginal delivery **G1:** 12 (17.6) Other, n (%): History of psychiatric disorder, including depression **G1:** 1(1.5) Risk factors, n (%): Prior PPH **G1:** 7 (10.3) Advanced maternal age Multiparity **G1**: 7 (10.3)

	Primary etiology of PPH, n (%): Uterine atony G1: 37 (54.4) Placenta accreta/percreta G1: 10 (14.7) Placenta previa G1: 6 (8.8)	
	Vascular abnormality G1: 9 (13.2)	
	Lower genital tract lacerations G1: 4 (5.9)	
	Coagulopathies G1: 2 (3.0)	

Comment: *women completing the survey may have considered both the actual PPH and the treatment process in their responses

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Sentilhes et al.,	Pelvic arterial embolizations	Primary PPH - postpartum hemorrhage occurring	
201144		within the first 24 hours after delivery	Harms of intervention, n (%):
•	Groups:	Secondary PPH - postpartum hemorrhage occurring 24	Major complications
Country:	G1: Total Pelvic arterial	hours to 6 weeks after delivery	G1a: 2 (2)
France	embolizations	·	G1b : 1 (9)
Enrollment	G1a: Successful Pelvic arterial	Definition of success of treatment : An arrest of the	G1a vs. G1b: $p = 0.30$
period:	embolizations	hemorrhage after pelvic arterial embolization, whatever	·
May 1994 to	G1b: Failed Pelvic arterial	the number of pelvic arterial embolization procedures,	Buttock necrosis requiring surgical debridement
July 2007	embolizations	with no subsequent surgical procedure.	G1 : 1 (1)
•			G2: 0 ′
Birth setting: NR	N at enrollment: G1: 100	Method of blood loss measurement: NR	G1a vs. G1b: p > 0 .99
Facility	G1a: 89	Severity: NR	Pulmonary embolism
characteristics:	G1b : 11	ocverity. Nix	G1: 0
University-		Inclusion criteria:	G2 : 1 (9)
affiliated tertiary	N at follow-up:	All consecutive women with postpartum hemorrhage	G1a vs. G1b: p = 0.11
referral center	G1 : 100	who underwent embolization at the tertiary obstetric	014 10. 015. p = 0.11
	G1a: 89	center (Rouen University Hospital)	Postpartum myocarditis
E . P . ND	G1b : 11	 Patients who were referred to the institution from 	G1 : 1 (1)
Funding: NR	Duration of treatment: NR	other centers where pelvic arterial embolization was	G2: 0
Design:	Duration of treatment. NK	not available or who had undergone a surgical	G1a vs. G1b: p > .99
Retrospective	Timing of treatment: NR	procedure before or after the pelvic arterial	Grave: Grave: p > .00
case series		embolization	Minor complications (see comments)
	Order of treatment:	Evolucion cuitorio.	G1: 19 (21)
Note: See related	Step 1: blood transfusion	Exclusion criteria:	G2 : 4 (36)
studies Sentilhes	Step 2: Digital subtraction	Subsequent pregnancies with postpartum	G1a vs. G1b: p = 0.27
2009 ^{43, 45}	angiography	hemorrhage requiring pelvic arterial embolization in	0.21
	Step 3: Aortography	patients with a previous history of pelvic arterial	Puncture site hematoma
	Step 4: selective catheterization of	embolization for postpartum hemorrhage	G1 : 1 (1)
	uterine artery or anterior trunk of the	Maternal age, yrs, n (%):	G2: 0
	hypogastric artery	<25	G1a vs. G1b: p > 0.99
	Step 5: Same procedure or	G1a : 16 (18)	- 10 10 10 10 10 10 10 10 10 10 10 10 10
	contralateral artery	G1b : 1 (9)	Postpartum fever higher
			than 38.5°C
	Length of follow-up: NR	25-35	G1: 18 (20)
		G1a : 59 (66)	G2 : 4 (36)
		G1b : 8 (73)	G1a vs. G1b: p = 0.25

Intervention	Inclusion/Exclusion	Outcomes
intervention	Criteria & Population	
		Endometritis
		G1 : 13 (15)
	G1b : 2 (18)	G2 : 1 (9)
		G1a vs. G1b: p > 0.99
	Parity, n (%):	
		Wound infection
		G1: 5 (6)
	G2: 3 (27)	G2: 3 (27)
		G1a vs. G1b: $p = 0.04$
	Weeks gestation: NR	
	Single pregnancy: NR	
	Multiple pregnancy, n (%):	
	G1: 9 (10)	
	Race/ethnicity: NR	
	BMI: NR	
	Baseline hemoglobin: NR	
	SES: NR	
	Mode of birth n (%):	
	32. 0 (21)	
	Cesarean during labor	
	G2: 1 (9)	
	G2 : 3 (27)	
		Criteria & Population >35 G1a: 14 (16) G1b: 2 (18) Parity, n (%): Nulliparity G1: 38 (42) G2: 3 (27) Weeks gestation: NR Single pregnancy: NR Multiple pregnancy, n (%): Twin pregnancy G1: 9 (10) G2: 3 (27) Race/ethnicity: NR BMI: NR Baseline hemoglobin: NR SES: NR Mode of birth, n (%): Cesarean before labor G1: 25 (28) G2: 3 (27) Cesarean during labor G1: 20 (23)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		Operative vaginal delivery G1: 17 (19)	
		G2 : 4 (37)	
		Risk factors, n (%): Prior PPH:	
		G1: 8 (9)	
		G2: 0	
		History of cesarean:	
		G1 : 23 (26)	
		G2: 4 (36)	
		Labor induction/augmentation:	
		G1: 24 (27)	
		G2 : 3 (27)	
		Chorioamnionitis:	
		G1 : 9 (10) G2 : 3 (27)	
		32. 3 (21)	
		Primary etiology of PPH, n (%):	
		Uterine atony	
		G1 : 49 (55)	
		G2: 4 (36)	
		Placenta accreta/percreta	
		G1 : 13 (14)	
		G2 : 4 (36)	
		Retained placental tissue	
		G1 : 5 (38)	
		G2: 0	
		Uterine cavity empty	
		G1 : 8 (62) G2 : 4 (100)	
		G2. 4 (100)	
		Placenta Previa	
		G1: 6 (7)	
		G2: 0	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Vascular abnormality G1: 7 (8) G2: 3 (28) Lower genital tract lacerations G1: 12 (13) G2: 0 Coagulopathies G1: 2 (2) G2: 0	

Comments: minor complications = postpartum fever > 38.5°C with endometriosis or wound infection

Table D-43. Evidence table for studies addressing management of PPH (Sentilhes 2011c)

Study	nce table for studies addressing ma Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Menstruation:
Sentilhes et al.,	Embolization as the sole procedure	Primary PPH - PPH occurring within the first 24 hours	Resumed
2011 ⁴⁵	Embolization in combination with	Secondary PPH - PPH occurring 24 hours to 6 weeks	G1 + G2 : 63 (92.6)
Country:	uterine-sparing surgery	following delivery	G1: 53 (91.4)
France		Definition of success of treatment: NR	G2: 10 (100) p >0.99
Enrollment	Groups: G1: Embolization as the sole	Method of blood loss measurement: NR	p > 0.33
period:	procedure		Unchanged
May 1994 to		Severity: NR	G1 + G2 : 42 (61.8)
July 2007	G2: Embolization in combination with	Inclusion criteria:	G1: 38 (65.5)
Dinth a attin on ND	uterine-sparing surgery	All consecutive women with PPH who underwent	G2: 4 (40)
Birth setting: NR	N at enrollment:	embolization as either the sole procedure or in	p = 0.16
Facility	G1 + G2 : 85	combination with uterine-sparing surgery	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
characteristics:	01 + 02. 00	at the tertiary obstetric center (Rouen University	Increased flow of menstruation 11 (16.2)
University-	N at follow-up:	Hospital) during the study period	G1 : 9 (15.5) G2 : 2 (20)
	G1+ G2: 68	Exclusion criteria:	p = 0.66
referral center	G1: 58	Women with peripartum hysterectomy or vaginal	p = 0.00
Funding: NR	G2 : 10	artery-only embolization	Amenorrhoea or decreased flow of
1	Duration of treatment: NR	Matarnal aga, NP	menstruation:
Design:		Maternal age: NR	G1 + G2: 15 (22.0)
Retrospective	Timing of treatment: NR	Parity: NR	G1 : 11 (19)
cohort study	Order of treatment: NR	Weeks gestation: NR	G2 : 4 (40)
Note: See related	Length of follow-up: 13 months		p = 0.21
studies: Sentilhes	Length of follow-up: 13 months	Single pregnancy: NR	Menstrual change secondary to synechia
2009 ⁴⁴ and		Multiple pregnancy: NR	G1 + G2 : 8 (11.8)
Sentilhes 2011 ⁴³		Race/ethnicity: NR	G1 : 6 (10.3)
		BMI: NR	G2 : 2 20) p = 0.33
		DIVII: NK	p = 0.33
		Baseline hemoglobin: NR	Cause of menstrual change not investigated
		SES: NR	G1 + G2 : 7 (26.5)
		Mode of birth, n: NR	G1: 5 (8.6)
		,	G2 : 2 (40) p = 0.27
		Risk factors: NR	P = 0.21
		Primary etiology of PPH: NR	Clinical ovarian insufficiency:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			G1 + G2 : 7 (10.3)
			G1: 6 (10.3)
			G2 : 0
			p >0.99
			Normal hormonal profiles
			G1 + G2: 3 (4.4)
			G1: 3 (5.2)
			G2 : 0
			p >0.99
			Not investigated
			G1 + G2 : 4 (5.9)
			G1: 4 (6.9)
			G2 : 0
			p >0.99
			Future fertility (n=68 with data available):
			Biological ovarian insufficiency
			G1 + G2: 0
			G1 : 0
			G2: 0
			p = 1
			Preserved fertility (n = 66)
			G1 + G2 : 66 (97.1)
			G1: 56 (96.6)
			G2 : 10 (100)
			p = 1
			Desire for pregnancy (n = 30)
			G1 + G2 : 30 (45.5)
			G1: 25 (44.6)
			G2 : 5 (50)
			p = 1
			·
			Previous history of infertility
			G1 + G2 : 2 (6.7)
			G1: 0

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
			G2 : 2 (40)
			p = 0.02
			Secondary infertility
			G1 + G2 : 0
			G1 : 0
			G2 : 0
			p = 1
			Participants attempting to become pregnant
			G1 + G2 : 13 (43.3)
			G1: 13 (52)
			G2: 0
			p = 0.053
			Conception delay >24 months
			G1 + G2 : 0
			G1 : 0
			G2 : 0
			p = 1
			P = 1
			Participants succeeding in becoming pregnant
			G1 + G2: 17 (56.7)
			G1 : 12 (48)
			G2 : 5 (100)
			p = 0.053
			p = 0.033
			Pregnancies obtained (n = 26):
			G1 + G2: 26
			G1: 18
			G2 : 8
			p = NR
			Maan concention delay maan : CD (72775)
			Mean conception delay, mean ± SD (range)
			G1 + G2 : 11.5 ± 11.9 (1–48)
			G1 : 11.6 ± 12.5 (1–48)
			G2: 12.3 ± 11.1 (3–36)
			p = 0.82

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			Conception delay >24 months
			G1 + G2 : 1 (3.8)
			G1: 1 (5.6)
			G2: 1 (12.5)
			p = 0.53
			p = 0.00
1			With assisted reproductive techniques
			G1 + G2 : 0
			G1: 0
			G2 : 0
			p = 1
			Pregnancy with birth of live child (n = 19):
			G1 + G2 : 19 (73.1)
			G1 : 13 (72.2)
			G2 : 6 (75)
			p = 1
			Full tarms must make a committee to a
			Full-term pregnancy with no complications
			G1 + G2 : 19 (100)
			G1: 13 (100)
			G2 : 6 (100)
			p = 1
			Concerned delivery
			Caesarean delivery
			G1 : 6 (31.6)
			4 (30.8)
			2 (33.3)
			p = 1
			Decrement mosttime because (v. 0)
			Recurrent postpartum hemorrhage (n = 6):
			G1 + G2 : 6 (31.6)
			G1: 3 (23.1)
			G2: 3 (50)
			p = 0.32
			Uterine atony in followup pregnancy
			G1 + G2: 4 (66.7)
			G1: 3 (100)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	G2 : 1 (33.3) p = 0.40
			Placenta accrete in followup pregnancy G1 + G2 : 2 (33.3) G1 : 0 G2 : 2 (66.7) p = 0.40
			Confounders: NR
			Effect modifiers: NR
			Harms: Harms prespecified: No
			Synechia, n (%): G1 + G2: 8 (11.8) G1: 6 (10.3) G2: 2 (20) p = 0.33
			Postpartum fever, n: G1+G2: 13
			Endometritis, n: G1+G2: 6
			See also fertility data above

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Incidence of severe PPH mean ± SD (min,
Deneux-Tharaux	Multifaceted intervention for	PPH was defined by a peripartum hemoglobin decrease	max):
et al.,	maternity unit including educational	of 2 g/dl or more (equivalent to loss of more than 500 ml	G1: 1.64 ± 0.80 (0.00, 3.84)
2010 ¹⁹	sessions, instruction on PPH	of blood).	G2: 1.65 ± 0.96 (0.29, 4.29)
Cauntry France	protocol, local implementation of the		OR=1.02 (95% CI: 0.83 to 1.24)
Country: France		Severe PPH - a PPH associated with one or more: blood	
Enrollment		transfusion, arterial embolization, arterial ligation, other	Severe PPH blood transfusion (% of
period:	"PPH box" (emergency kit w/drugs,	conservative uterine surgery, hysterectomy, transfer to	deliveries) mean rate (SD) (min, max)
September 2004 –		intensive care unit, peripartum hemoglobin decrease of 4	G1: 0.44 ± 0.30 (0.00, 1.00)
November 2006	severe PPH. (intervention: more than	g/dl or more (equivalent to loss of 1000 ml or more of	G2: 0.41 ± 031 (000, 1.47)
5 1.41.44	3 mo. in duration)	blood), maternal death.	OR=1.13 (95% CI: 0.88 to 1.44)
Birth setting:	Groups:		
NR	G1: educational intervention	Definition of success of treatment: effect of the	Severe PPH postpartum haemoglobin change
E 1114	G2: passive dissemination of PPH	multifaceted intervention on mean rate of severe PPH.	≥ 4 g/dl) (% of deliveries) mean rate ± SD
Facility	protocol	(#deliveries with severe PPH / total number of deliveries)	(min, max):
	•		G1: 1.49 ± 0.75 (0.00, 3.83)
106 maternity	N (maternity units) at enrollment:	Method of blood loss measurement:	G2: 1.44 ± 0.88 (0.15, 3.95)
units (university,	G1 : 54	Prepartum hemoglobin measured as part of routine	OR=1.05 (95% CI: 0.86 to 1.29)
public and private)	G2 : 52	prenatal care during last weeks of pregnancy.	
within six perinatal	N (matemate, unite) et falleur un		All PPH (% of deliveries) mean ± SD (min,
networks	N (maternity units) at follow-up:	Severity: defined above	max):
Funding:	G1 : 54	Inclusion criteria:	G1: 6.37 ± 3.63 (1.95, 22.05)
French Ministry of	G2 : 52	Maternity units belonging to one of six health networks	G2 : 6.37 ± 4.16 (1.52, 17.63)
Health's Clinical	Duration of treatment:	watering units belonging to one of six health hetworks	OR=1.01 (95% CI: 0.8 to 1.3)
Research Hospital	Phase 1 of intervention = ≥ 3 mo	Exclusion criteria:	
Program (contract	Phase 2 of intervention (data	Maternity units involved in concomitant clinical study	Embolization for PPH, mean rates ± SD:
no. 27-35)		Maternal area ND	G1 : 0.09 ± 0.15
•	collection) = 1 year.	Maternal age: NR	G2 : 0.10 ± 0.21
Design:	Timing of treatment: NR	Parity: NR	
Cluster-	I mining of treatment. NR		Conservative uterine surgery, mean rates ±
randomized	Order of treatment: NA	Weeks gestation: NR	SD:
controlled trial	order of freatment. NA		G1 : 0.04 ± 0.05
Nata Caa nalata d	Length of follow-up: NR	Single pregnancy: NR	G2: 0.04 ± 0.07
Note: See related			Hysterectomy, mean rates ± SD:
studies Bonnett		Multiple pregnancy, mean ± SD (min, max):	G1 : 0.05 ± 0.07
2013 ¹⁸ , Schmitz 2011 ²⁰		Rate of multiple pregnancy:	G2: 0.04 ± 0.06
2011-		G1 : 1.1 ± 0.7 (0.1; 2.9)	T () 1011 1 0D
		G2 : $1.3 \pm 0.9 (0.0; 4.6)$	Transfer to ICU, mean rates ± SD:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	inter vention	Criteria & Population	
			G1 : 0.16 ± 0.15
		Race/ethnicity: NR	G2: 0.16 ± 0.22
			ot ot
		BMI: NR	Mean ± SD rate of severe PPH between 1 st
			three month period to 3 rd three month period:
		Baseline hemoglobin: NR	G1 : 1.79 ± 1.21 to 1.52 ± 0.87 (p =0.07)
		CEC. ND	G2: 1.91 \pm 1.44 to 1.60 \pm 1.05 (p <0.05)
		SES: NR	Mean ± SD rate of ALL PPH between 1st
		Mode of birth mean ± SD (min, max):	three month period to 3 rd three month period:
		Rate of caesarean delivery	G1: 7.02 ± 4.48 to 6.2 ±3.82 (<i>p</i> <0.05)
		G1: 20.2 ± 4.2 (11.1; 28.8)	G2: 7.33 \pm 5.49 to 6.61 \pm 4.75 (<i>p</i> <0.05)
		G2: 20.0 ± 4.7 (11.8; 34.0)	62. 7.33 ± 3.49 to 6.61 ± 4.73 (p<0.65)
		, , ,	Procedures for PPH Management:
		Risk factors: NR	Examination of uterine cavity and/or manual
			removal of placenta (PPH after vaginal
		Primary etiology of PPH: NR	delivery) mean rate ± SD (min, max):
			G1 : 75.9 ± 15 (30.8, 97.6)
			G2 : 76.3 ± 13.4 (42.9, 100)
			OR=0.97 (95% CI: 0.71 to 1.32)
			Examination of uterine cavity and/or manual
			removal of placenta within 15 min of PPH DX*
			after vaginal delivery (incomplete data) mean
			rate ± SD (min, max):
			G1: 53.2 ± 16.9 (15.4, 96)
			G2 : 49.5 ± 19.5 (0, 81.6)
			OR=1.05 (95% CI: 0.79 to 1.4)
			Instrumental examination of vaging and coming
			Instrumental examination of vagina and cervix (PPH after vaginal delivery) mean rate ± SD
			(min, max):
			G1: 28.8 ± 17.2 (0, 69.8)
			G2: 24.0 ± 18.1 (0, 66.7)
			OR= 1.26 (95% CI: 0.87 to 1.81)
			Call for help from senior staff mean rate ± SD
			(min, max):
			G1: 79.9 ± 14.7 (42.7, 100)
			G2: 71.2 ± 19.1 (27.8,100)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			OR=1.65 (95% CI: 1.17 to 2.33)
			Call for help from senior staff within 15 min of
			PPH Dx* (data incomplete) mean rate ± SD
			(min, max)
			G1: 67.0 ± 17,3 (27.6, 100)
			G2: 58.4 ± 19.4 (17.6, 100)
			OR=1.48 (95% CI: 1.05 to 2.09)
			Administration of oxytocin, mean rate ± SD
			(min, max):
			G1 : 92.2 ± 6.6 (76.5, 100)
			G2 : 91.9 ± .6 (52.9, 100)
			OR=0.92 (95% CI: 0.63 to 1.33)
			01.0.92 (33 % 01. 0.03 to 1.33)
			Procedures for Severe PPH Management:
			Administration of sulprostone (uterine atony or
			retained placenta) (severe PPH), mean ± SD
			(min, max):
			G1 : 48.7 ± 25.3 (0, 100)
			G2 : 39.9 ± 26.0 (0, 100)
			OR=1.45 (95% CI: 0.99 to 2.13)
			01.4-1.10 (00/0 01. 0.00 to 2.10)
			Administration of sulprostone within 30 min of
			PPH Dx (uterine atony or retained placenta)
			(severe PPH) mean ± SD (min, max):
			G1: 24.2 ± 17.5 (0, 75.0)
			G2: 16.9 ± 15.9 (0, 51.9)
			OR=1.39 (95% CI: 0.96 to 2.00)
			Blood test for hemoglobin and hemostasis
			within 60 min of PPH Dx* (incomplete data)
			Mean ± SD (min, max):
			G1 : 37.5 ± 20.5 (0, 87.5)
			G2 : 28.4 ± 22.1 (0, 80.0)
			OR=1.36 (95% CI: 0.95 to 1.94)

Comments: *data on time of procedure missing in 19.1% of cases for exam of uterine cavity; 2.4% for call for extra help; 2.6% for admin of sulprostone and 10% for blood test

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Ganguli et al.,	Uterine artery embolization (Uterine	Primary PPH was defined as hemorrhage that occurred	Inamis pre-specified. No
2008 ⁴⁶	artery embolization (oterme	within the first 24 hours after delivery.	Transfusion of PRBCs (units), mean (range):
	artery embolization j	Secondary PPH was defined as hemorrhage occurring	Primary PPH: 0.4(0-4)
Country: US	Groups:	more than 24 hours after delivery.	
Enrollment	G1: Uterine artery embolization	Thore than 24 hours after delivery.	Harms, n (%):
period:	G1a: Uterine artery embolization for	Definition of success of treatment:	Hysyerectomy, total
52 months ending	primary PPH	Technical success was defined as successful	G1: 3 (4.5)
in April 2009	G1b: Uterine artery embolization for	catheterization of both uterine arteries with embolization	G1a: 1
III April 2009	secondary PPH	to stasis, embolization of a nonuterine pelvic vessel	G1b: 2
Birth setting:	N at enrollment:	giving rise to active contrast agent extravasation, or	
Hospital	G1 : 76		Hysterectomy due to persistent PPH
		(ie, pseudoaneurysm).	G1 : 2 (3)
Facility	N at follow-up, n (%):	Clinical success of Uterine artery embolization was	
characteristics:	G1 : 66	defined as obviation of subsequent hysterectomy.	Hysterectomy due to endometritis
Tertiary care	G1a : 50 (76)	,	G1: 1 (1.5)
hospital	G1b : 16 (24)	Method of blood loss measurement: NR	
Funding: NR	Duration of treatment: NR		Overall complication
r unung. M		Severity: NR	G1: 3 (4.5)
Design:	Timing of treatment: After usual	Inclusion criteria:	
Cases series	obstetric maneuvers performed	All and the second of the seco	Lower extremity deep vein thrombosis
	Order of treatment:	All women who underwent Uterine artery embolization for	G1 : 1
	Intravenous uterotonic agents,	obstetric reasons at a single institution during a	
	Aggressive uterine massage,	52-month period culminating in April	Post procedural pancreatitis
	Manual extraction of	2009	G1 : 1
	the placenta,	2003	
	Examination and repair of genital	Exclusion criteria:	Presumed endometritis after Uterine artery
	lacerations,	Those with leiomyoma- or tumor-	embolization as well as dilation and curettage
	Balloon tamponade	related uterine hemorrhage	G1: 1
	Uterine artery embolization	Maternal ago vrs. mean (range):	Deat Heading automorphistical in the State
	·	Maternal age, yrs, mean (range): G1: 33 (17-47)	Post-Uterine artery embolization hospital
	Length of follow-up: NR	G1: 33 (17-47) G1a: 32.7 (17-44)	stay in days, mean (range):
		G1b: 32.4 (21-42)	Total
		OID. 02.7 (21-42)	G1 : 3.5 (1-12)
		Parity, mean (range):	G1a: 3.9 (1-12)
		G1: 1.8 (0-9)	G1b : 2 (1-5)
		G1a: 1.9 (1-9)	

	G1b : 1.8 (1-4)	Mortality, n:
		G1 : 0
	Weeks gestation: NR	
	Single pregnancy: NR	
	Multiple pregnancy: NR	
	Race/ethnicity: NR	
	BMI: NR	
	Baseline hemoglobin: NR	
	SES: NR	
	Mode of birth, n: Vaginal delivery, n (%) G1: 48 (73)	
	Cesarean section, n (%) G1: 18 (27) G1a 12/50 (24) G1b: 6/16 (38)	
	Risk factors: NR	
	Primary etiology of PPH, n:	
	Retained products of conception:	
	G1b : 13/16 (81)	
	Uterine artery pseudoaneurysm:	
	G1b: 3/16 (19)	

Comment: Authors note one woman experienced a peripartum seizure that did not appear related to Uterine artery embolization procedure.

Table D-46. Evidence table for studies addressing management of PPH (Lone 2010)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Harms pre-specified: No
Lone et al., 2010 ⁴⁷	Emergency obstetric hysterectomy		Hormo n (9/):
Country: UK	performed after 24 completed weeks	Definition of success of treatment: NR	Harms, n (%):
Country. On	of pregnancy and up to 6 weeks post-		Operative: Ureteric injury
Enrollment	partum.	Method of blood loss measurement: NR	G1: 4 (7.7)
period:	Groups:		G1. 4 (7.7)
Jan 1989 to	G1: Emergency obstetric	Severity: NR	Bladder injury
Jan 2009	hysterectomy	Inclusion criteria:	G1: 3 (5.8)
Birth setting:	, ,	Women who underwent hysterectomy at Mayday	
Hospital	N:	University Hospital, Croydon, UK, between January	Small bowel injury
	G1 : 52	1989 and January 2009	G1 : 2 (3.8)
Facility	N at follow-up: NR		
characteristics:	Tractione aprilia	Exclusion criteria: NR	Infective:
Tertiary care	Interventions to control prior to		Urinary tract infection
(university)	emergency hysterectomy:	Maternal age, yrs, mean (range):	G1: 4 (7.7)
` ,	G1a: n=25 (1989-1998)	G1 : 29.4 (14-54)	
Funding: NR	G1b: n=27 (1999-2009)	Parity, mean:	Septicemia
Design:	,	G1: 1.35	G1: 3 (5.8)
Retrospective	Bimanual compression, n (%):		
case series	G1a: 23 (92)	Weeks gestation, n (%):	Wound infection
	G1b: 23 (85.2)	Less than 28	G1: 4 (7.7)
		G1: 3 (5.8)	
	Intravenous oxytocin, n (%):		Adult respiratory distress syndrome
I	G1a: 25 (100)	29-32	G1: 9 (17.3)
	G1b : 27 (100)	G1: 7 (13.5)	
			Renal failure
	Ergometrine, n (%):	33-37	G1 : 2 (3.8)
	G1a : 20 (80)	G1: 13 (25)	Discominated introversales association
	G1b : 22 (81.5)		Disseminated intravascular coagulation
		38-42	G1 : 11 (21.1)
	Internal iliac artery ligation, n (%):	G1 : 26 (50)	Popost surgery
	G1a: 21 (84)	M 11 10	Repeat surgery G1: 15 (28.8)
	G1b : 7 (25.9)	More than 42	G1. 13 (20.0)
	Litarina naskina na (0/):	G1 : 3 (5.8)	Cardiac arrest
	Uterine packing, n (%):	Cin ale magneness ND	G1: 2 (3.8)
	G1a: 16 (64)	Single pregnancy: NR	31. 2 (3.0)
	G1b : 2 (7.4)		

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
	Intrauterine balloon, n (%):	Multiple pregnancy: NR	Maternal mortality
	G1a: 1 (4)		G1: 1 (1.9)
	G1b : 16 (59.3)	Race/ethnicity, n (%):	
		African-Caribbean	
	B-Lynch suture, n (%): G1a: 2 (8)	G1 : 26 (50)	
	G1b: 13 (48.1)	White	
		G1 : 13 (25)	
	Factor V11, n (%):		
	G1a: 0	Asian	
	G1b: 2 (7.4)	G1: 10 (19.2)	
	Duration of treatment:	Other	
	Operating time, hrs, mean (range) G1: 2.5 (1.5-4.5)	G1: 3 (5.8)	
	Timing of treatment: NR	BMI: NR	
	Order of treatment: NR	Baseline hemoglobin: NR	
	Length of follow-up: NR	SES: NR	
		Mode of birth, n (%):	
		Cesarean	
		G1 : 38 (73.1)	
		Instrumental vaginal	
		G1 : 10 (19.2)	
		Normal Vaginal	
		G1 : 4 (7.7)	
		Risk factors, n (%):	
		Primary PPH:	
		G1 : 50 (96.2)	
		Placenta previa	
		G1 : 20 (40)	
		Uterine atony	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population G1: 14 (28)	
		G1. 14 (20)	
		Uterine rupture	
		G1 :10 (20)	
		Extension of the uterine incision	
		G1 : 6 (12)	
		Secondary PPH:	
		Severe sepsis	!
		G1 : 2 (3.8)	
		Risk factors, unadjusted OR (95% CI):	
		Univariate analysis:	
		Primary PPH G1: 18.83 (7.06-50.19)	
		p=0.022	
		Maternal age	
		G1: 1.13 (1.05-1.20)	
		p=0.001	
		Multiparity	
		G1: 1.32 (1.04-1.67)	
		P<0.001	
		Duration of gestation	
		G1: 0.925 (0.84-1.02)	
		p=0.110	
		Race/ethnicity:	
		Bangladeshi	
		G1 : 8.76 (1.05-73.18)	
		p=0.045	
		African-Caribbean	
		G1 : 3.10 (1.04-9.25)	
		p<0.001	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		History of cesarean G1: 6.88 (2.49-19.0) p<0.001	
		Placenta previa G1: 20.9 (6.22-70.4) p<0.001	
		Failed induction G1: 12.44 (4.65-33.3) p<0.001	
		Multivariate analysis: Primary PPH G1: 10.69 (3.33-34.3) p<0.001	
		Multiparity G1: 1.35 (1.06-1.73) p=0.017	
		Placenta previa G1: 14.4 (3.72-55.4) p<0.001	
		Failed induction G1: 9.29 (2.81-30.9) p<0.001	

nce table for studies addressing ma	nagement of PPH (Wright 2010)	
Intervention	Inclusion/Exclusion	Outcomes
intervention		
Intervention:	Operational definition of PPH: NR	Blood loss: NR
Peripartum hysterectomy within 2		
days of cesarean delivery	Definition of success of treatment: NR	Received transfusion n, %, unadjusted:
Groups		G1a : 409 (57.2%)
	Method of blood loss measurement: NR	G1b: 405 (46.7%)
		G1c : 283 (45.1%)
· ·	Severity: NR	p<.001
•	Inclusion criteria:	
		ICU admission, n (%), unadjusted:
		G1a: 322 (45.0)
		G1b: 343 (39.6)
•		G1c: 172 (27.4)
` '		p<.001
		A to AID
		Anemia: NR
	detected by ICD 9 codes	Langth of story
,	Exclusion criteria:	Length of stay:
G1c: 627 (28.4)	concomitant diagnosis of invasive malignancy	Unadjusted mean ± SD G1a: 3.5 ± 2.5
N at follow-up:	Motornal ago at surgery yes, madian (range)	G1b: 4.0 ± 4.6
		G1c: 4.1 ± 11.0
		G1C. 4.1 ± 11.0
Duration of treatment: NA		Mortality, n (%) unadjusted
Timing of treatment: hysterectomy	2 30. 1330 (03.370)	G1a: 13 (1.8)
	Parity, n: NR	G1b: 8 (0.9)
•		G1c: 5 (0.8)
Order of treatment NA	Weeks gestation: NR	p=.02
Length of follow-up: NR	a	ľ
	Single pregnancy: NR	Uterine preservation: NA
	Multiple and an entropy ND	
	Multiple pregnancy: NR	Future fertility: NA
	Pacolothnicity n (%)	
		Breastfeeding: NR
		Psychological impact: NR
	31. 1100 (30.2)	Harms of intervention
	African American	Intraoperative injury, n, (%), unadjusted:
		Bladder injury
	J. 55 (17.5)	G1a: 52 (7.2)
	Intervention Intervention: Peripartum hysterectomy within 2 days of cesarean delivery Groups: Subgroups (tertiles based on hospital volume), n of facilities: G1a: low-volume hospitals 221 facilities (69%) G1b: intermediate-volume 73 facilities (23 G1c: high-volume hospitals 26 facilities (8%) N at enrollment n (%): G1: 2209 G1a: 715 (33.4) G1b: 867 (39.3) G1c: 627 (28.4) N at follow-up: G1: 2209 Duration of treatment: NA Timing of treatment: hysterectomy within 2 days of cesarean delivery Order of treatment NA	Intervention Intervention: Peripartum hysterectomy within 2 days of cesarean delivery Groups: Subgroups (tertiles based on hospital volume), n of facilities: G1a: low-volume hospitals 221 facilities (69%) G1b: intermediate-volume 73 facilities (23 G1c: high-volume hospitals 26 facilities (8%) N at enrollment n (%): G1: 2209 G1a: 715 (33.4) G1b: 867 (39.3) G1c: 627 (28.4) N at follow-up: G1: 2209 Duration of treatment: NA Timing of treatment: hysterectomy within 2 days of cesarean delivery within 2 days of cesarean delivery Weeks gestation: NR Method of blood loss measurement: NR Severity: NR Inclusion criteria: • data d in the Perspective database of acute care US hospitals • women aged 50 years or less • treated between 2002 and 2007 • underwent peripartum hysterectomy defined as hysterectomy within 2 days of cesarean delivery detected by ICD 9 codes Exclusion criteria: • concomitant diagnosis of invasive malignancy Maternal age at surgery, yrs, median (range) G1: 33 (14-50) > 30: 673 (30.5%) ≥ 30: 1536 (69.5%) Parity, n: NR Weeks gestation: NR

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		Other	G1b : 69 (8.0)
		G1: 707 (32.0)	G1c : 56 (8.9)
		, ,	
		BMI: NR	Ureteral injury
			G1a 2 (0.3)
		Baseline hemoglobin: NR	G1b: 3 (0.4)
			G1c: 3 (0.5)
		SES, type of insurance, %:	
		Commercial insurance	Intestinal injury
		G1 : 61	G1a : 3 (0.4)
			G1b: 3 (0.4)
		Medicaid	G1c: 4 (0.6)
		G1: 32	(0.0)
		0.1.02	Vascular injury
		No insurance	G1a: 1 (0.1)
		G1: 3	G1b : 0
			G1c : 0
		Mode of birth: NR	310.0
			Other injury
		Risk factors: NR	G1a: 69 (9.7)
			G1b: 89 (10.3)
		Primary etiology of PPH: NR	G1c: 61 (9.7)
			010.01 (0.1)
		Indication for hysterectomy, n (%)	Perioperative surgical complications, n (%),
		Placenta accrete	unadjusted:
		G1: 775 (35.1%)	Reoperation
			G1a: 46 (6.4)
		Uterine atony	G1b : 38 (4.4)
		G1: 770 (34.9%)	G1c: 20 (3.2)
			916. 20 (3.2)
		Extension of hysterotomy	Postoperative hemorrhage
		G1 : 72 (3.3%)	G1a: 49 (6.9)
			G1b : 37 (4.3)
		Uterine rupture	G1c3: 37 (4.3)
		G1: 18 (0.8%)	0103. 37 (3.3)
			Wound complication
		Delayed hemorrhage	G1a: 71 (9.9)
		G1: 49 (2.2%)	G1a: 71 (9.9) G1b: 59 (6.8)
		Leiomyoma	G1c : 42 (6.7)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		G1: 230 (10.4%)	
			Venous thromboembolism
			G1a : 6 (0.8)
			G1b: 14 (1.6)
			G1c: 14 (2.2)
			Medical Complications, n (%), unadjusted:
			Cardiovascular
			G1a: 46 (6.4)
			G1b : 40 (4.6)
			G1c: 27 (4.3)
			Pulmonary
			G1a : 101 (14.1)
			G1b :109 (12.6)
			G1c : 61 (9.7)
			010.01(0.7)
			Gastrointestinal
			G1a: 58 (8.1)
			G1b : 63 (7.3)
			G1c: 55 (8.8)
			0.01 00 (0.0)
			Renal
			G1a: 24 (3.4)
			G1b: 19 (2.2)
			G1c: 10 (1.6)
			Infectious
			G1a : 83 (11.6)
			G1b : 106 (12.2)
			G1c: 78 (12.4)
			(== 1)
			Adjusted OR (95% CI), provided for G1b and
			G1c only (age, race, year diagnosis,
			insurance status, hospital type and size):
			Intraoperative injury
			G1b : 0.97 (0.68-1.38)
			G1c : 0.95 (0.61-1.48)
			0.00 (0.00)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
			Perioperative surgical complication
			G1b : 0.66 (0.51-0.86)
			G1c: 0.66 (0.47-0.93)
			Medical complication
			G1b: 0.97 (0.74-1.28)
			G1c: 0.98 (0.71-1.34)
			Transfusion
			G1b: 0.83 (0.54-1.27)
			G1c: 0.79 (0.42-1.47)
			Length of stay
			G1b : 0.44 (-0.27-1.14)
			G1c: 0.63 (-0.20-1.45)
			Intensive care use
			G1b : 0.81 (0.60-1.09)
			G1c : 0.53 (0.34-0.83)
			Perioperative death '
			G1b: 0.41 (0.16-1.03)
			G1c: 0.29 (0.10-0.88)
			Confounders: NR
			Effect modifiers: NR

Comments: Women could have multiple or unknown indications for hysterectomy.

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Zwart et al.,	Hysterectomy/ Arterial embolization		
2010 ⁴⁹	Groups:	Definition of success of treatment: NR	Transfusion, n (%): Plasma replacement therapy
Country: Netherlands	G1a: Hysterectomy G1b: Arterial embolization	Method of blood loss measurement: NR	G1a : 86 (80)
Enrollment period:	G2: Total number of births in the Netherlands during the study period	Severity: NR	G1b: 75 (77) Recombinant factor VII
August, 2004 –	N at enrollment:	Inclusion criteria:	G1a :19 (18)
August, 2006	G1 : 205 G2 : 358, 874	All women with hysterectomy or arterial embolization because of obstetric hemorrhage	G1b:14 (14)
Birth setting: Hospital or home	G1a: 108 (17 women had hysterectomy after embolization)	during pregnancy, delivery, and puerperium (limited to 6 weeks after delivery)	Prothrombin complex G1a : 1 (1)
	G1b : 114	Exclusion criteria: NR	G1b : 2 (2)
Facility characteristics:	N at follow-up: NR	Maternal age ≥ 35yrs, %:	Fibrinogen
	Duration of treatment: NR	G1 : 43.4 G2 : 24.7	G1a : 3 (3) G1b : 1 (1)
Funding: Netherlands	Timing of treatment for G1a, n (%): Hysterectomy after vaginal	Parity, %: Nulliparity	Red blood cells
Organization for	Delivery: 41(38)	G1: 39.5	G1a : 105 (98) G1b : 89 (98)
Health Research	Cesarean hysterectomy: 29(27) Relaparotomy after caesarean	G2: 45.2	3.2. 66 (66)
and the Matty Brand Foundation	Delivery: 38(35)	≥ 3	≥ 8 red blood cells
brand Foundation	Order of treatment: NR	G1 : 7.3	G1a : 86 (80)
Design:		G2: 5.0	G1b: 59 (65)
Prospective cohort	Length of follow-up: NR	62. 5.0	Fresh frezen pleame
study		Weeks gestation: NR	Fresh frozen plasma G1a: 90 (89)
		Trocke good with the	G1b: 86 (95)
		Single pregnancy: NR	G1b. 86 (93)
			Platelets
		Multiple pregnancy, %:	G1a : 61 (62)
		G1 : 10.2	G1b : 49 (53)
		G2: 1.7	()
			Red Blood Cells, median
		Race/ethnicity, %:	G1a : 14
		Non-Western Immigrant	G1b: 10

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
-		G1 : 24.4	p = 0.002
		G2: 16.8	ľ
			≥ 8 units of red blood cells, RR (95% CI)
		BMI (kg/m²), %	G1a: 1.5 (1.1-2.1)
		≥ 25 (overweight)	G1b < G1a
		G1 : 28.2	
		G2 : 31.7	ICU admission, RR (95% CI):
		≥ 30 (obese)	G1a : 1.6 (1.1-2.4)
		G1: 10.9	G1b < G1a
		G2: 9.8	GID C GIA
		G2. 9.0	Anemia: NR
		> 05 (Anemia: NK
		≥ 35 (morbidly obese)	I anoth of stay, days madian/ray
		G1: 4.7	Length of stay, days, median(range):
		G2 : N/A	G1a : 10 (2-65)
			G1b : 7 (1-38)
		Baseline hemoglobin: NR	
			Mortality, n:
		SES:	Total: 4/205 (2%)
		Low income, %	G1a : 1
		G1 : 26.7	G1b : 2
		G2: N/A	G1a & G1b: 1
		Mode of birth, %:	Uterine preservation, %:
		Induction of labor:	G1b: 46
		G1 : 29.8	
		G2: 12.3	Future fertility,n (%):
			G1b : 95 (46)
		Cesarean delivery:	
		G1 : 49.8	Breastfeeding: NR
		G2: 13.0	Psychological impact: NR
		32. 10.0	Harms of intervention, n (%):
		Prelabor cesarean delivery:	Hysterectomy (n=108):
		G1: 23.9	Urinary tract lesions
		G2: 5.9	G1a: 11 (10)
		G2. 5.9	G1a. 11 (10)
		Ventouse/forceps:	Removal of ovary
		G1 : 11.7	G1a : 8 (7)
		G2: 8.6	
			Infection

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		Home delivery:	G1a : 8 (7)
		G1 : 3.4	
		G2: 31.6	Relaparotomy
			G1a: 15 (14)
		Breech delivery:	
		G1: 9.3	Sheehan syndrome
		G2 : 4.9	G1a: 4 (4)
		02. 4.0	G14. 4 (4)
I		Risk factors,%, RR (95%CI):	Paralytic ileus
		Patient:	G1a : 3 (3)
		Advanced maternal age ≥ 35yrs:	
		G1: 43.4	Deep venous
		G2 : 24.7	thrombosis/pulmonary
		2.3 (1.8-3.1)	embolism
			G1a : 3 (3)
		Low income, %	J 121 6 (6)
		G1: 26.7	Others
		G2: N/A	G1a : 2 (2)
		52. 14/7 (G14. 2 (2)
		BMI (kg/m ²):	Embolization (n=114):
		≥ 25 (overweight)	Hysterectomy
		G1 : 28.2	G1b : 17 (15)
		G2 : 31.7,	
		0.9(0.6-1.2)	Infection (9 after cesarean delivery)
		0.0(0.0 1.2)	G1b: 9 (8)
		≥ 30 (obese)	
		G1 : 10.9	Acute respiratory distress syndrome
		G2: 9.8,	G1b : 1 (1)
		1.1 (0.6–1.9)	Laparotomy
		1.1 (0.0–1.9)	G1b: 3 (3)
		> 25 (marhidly above)	G ID. 3 (3)
		≥ 35 (morbidly obese) G1: 4.7	la chamia complaints
			Ischemic complaints
		G2 : N/A	G1b : 2 (2)
		Race/ethnicity:	Confounders:NR
		Non-Western Immigrant	Effect medificate AID
		G1: 24.4	Effect modifiers: NR
		G2: 16.8	
i		1.6 (1.2–2.2)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		Pregnancy:	
		History of cesarean: G1: 26.8	
		G2 : 10.1	
		3.3 (2.4–4.5)	
		3.3 (2.4–4.3)	
		Placenta previa:	
		G1 : 10.7	
		G2: N/A	
		Nulliparity:	
		G1: 39.5	
		G2 : 45.2	
		0.8 (0.6–1.1)	
		Multiparity: ≥ 3	
		G1: 7.3	
		G2: 5.0	
		1.5 (0.9–2.5)	
		- (
		Multiple gestation:	
		G1: 10.2	
		G2: 1.7	
		6.6 (4.2–10.4)	
		A wtificial warmed cation	
		Artificial reproduction techniques: in vitro	
		fertilization/intracytoplasmic	
		sperm injection:	
		G1: 9.5	
		G2: 1.9	
		5.4 (3.2–9.0)	
		Delivery:	
		Labor induction/augmentation:	
		G1 : 29.8	
		G2: 12.3	
		3.1 (2.3–4.2)	
		3.1 (2.3–4.2)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Cesarean delivery:	
		G1 : 49.8	
		G2: 13.0	
		6.6 (5.0–8.7)	
		Prelabor cesarean delivery:	
		G1: 23.9	
		G2: 5.9	
		5.0 (3.6–6.9)	
		Ventouse/forceps:	
		G1 : 11.7	
		G2 : 8.6	
		1.4 (0.9–2.2)	
		Home delivery:	
		G1: 3.4	
		G2: 31.6	
		0.1 (0.04–0.2)	
		Breech Delivery:	
		G1 : 9.3	
		G2: 4.9	
		2.1 (1.3–3.4)	
		Primary etiology of PPH, n (%):	
		Disorders of placentation:	
		G1a: 37 (35)	
		G1b : 5 (5)	
		Uterine atony:	
		G1a: 29 (28)	
		G1b: 32 (33)	
		318.02 (00)	
		Uterine rupture:	
		G1a: 11 (10)	
		G1b : 0	
		Retained placenta or placental remnants:	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description		G1a: 10 (10) G1b: 30 (31)	
		latrogenic during surgery: G1a: 8 (8) G1b: 13 (14)	
		Genital tract laceration: G1a: 4 (4) G1b: 11 (11)	
		Blood coagulation disorders: G1a: 1 (1) G1b: 0	
		Miscellaneous: G1a: 4 (4) G1b: 4 (4)	
		Placenta previa as single diagnosis: G1a: 1 (1) G1b: 1 (1)	
		Total placenta previa: G1a: 15 (14) G1b: 7 (7)	

Comment: There were 4 deaths; one women who received both hysterectomy and embolization.

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Hardeman et al., 2010 ⁵⁰	Embolization of uterine arteries	Definition of success of treatment: NR	Transfusion: NR
	Groups:		IOU - during in the ND
Country:	G1: Embolization	Method of blood loss measurement: NR	ICU admission: NR
France	G2: control		Anemia: NR
		Severity: NR	
Enrollment	N at enrollment:		Length of stay: NR
period:	G1: 53	Inclusion criteria:	
October 2000 to	G2 : 106	Cases: women who underwent embolization and	Mortality: NR
August 2006		responded to follow-up questionnaire	Uterine preservation: NR
	N at follow-up:	Controls: women who had never undergone	oterme preservation. NR
Birth setting:	G1: 53	embolization, matched by date of delivery, age, parity,	Future fertility:
Hospital	G2: 106	total number of pregnancies, spontaneous vs fertility-	Desire to become pregnant
		assisted pregnancy, and mode of delivery	G1: 14 (26.4) (text reports n=17 but three were
Facility	Duration of treatment: NR		still using o.c. due to fear of another
characteristics:		Exclusion criteria: NR	hemorrhage)
Tertiary care	Timing of treatment: NR		G2 : NR
		Maternal age, yrs, (range):	
Funding:	Order of treatment: NR	G1 : 34.3 (19-44)	Occurrence of pregnancy
NR (Authors		G2: NR	G1 : 12/14
report nothing to	Length of follow-up:		G2: 37/denominator not clear
disclose)	Maximal months, n	Parity, mean (range):	G1 vs G2: p=0.17
	G1 : 82	G1 : 2.02 (1-8)	
Design:	G2 : 83	G2: NR	Breastfeeding: NR
Case-control			
		Weeks gestation, n (%):	Psychological impact: NR
		≥ 37 weeks	Harms of intervention:
		G1: 43 (81.1)	Total complications (n=53)
		G2: NR	G1 : 19 (35.9)
		32-37 weeks	Pain and fever
		G1 : 7 (13.2)	G1: 16 (30.2)

Internantian	Inclusion/Exclusion	Outcomes
intervention	Criteria & Population	Outcomes
	G2: NR	
		Hematoma/inguinal pain
	28-32 weeks	G1 : 3 (5.7)
	G1: 2 (3.8)	Menstrual cycles (n=53)
	G2: NR	Normal/unchanged
	≤ 28 weeks	G1 : 40 (75.5)
	G1: 1 (1.9)	
	G2: NR	Metrorrhagia
		G1 : 2 (3.8)
	Single pregnancy, n (%):	, ,
	G1 : 48 (91)	Secondary amenorrhea
	G2: NR	G1 : 11 (20.7)
	Multiple pregnancy, n (%):	Absence due to contraception
		G1 : 8/11 (15.1)
		,
		Absence due to embolization
	Race/ethnicity: NR	G1 : 3/11 (5.6%)
	,	(3.3.3)
	BMI: NR	Confounders: NR
	Baseline hemoglobin: NR	Effect modifiers: NR
	SES: NR	
	Mode of birth, n:	
	Cesarean	
	Risk factors: NR	
	Intervention	Criteria & Population

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Primary etiology of PPH, n (%):	
		Atony G1: 43 (81.1)	
		Placenta accreta G1: 5 (9.4)	
		Thrombus G1 : 2 (3.8)	
		Vascular damage G1: 3 (5.7)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
		Operational definition of PPH: NR	BIOOU IOSS: NR
Alexander et al., 2009 51	Blood transfusion (any type) to treat	Definition of success of treatment: NR	Transferient ND
2009	hypovolemia caused by obstetric	Definition of success of treatment: NR	Transfusion: NR
Country: US	hemorrhage	Method of blood loss measurement: NR	Unite transferred (mass).
	Groups:	Method of blood loss measurement: NR	Units transfused (mean): G1: 2.2
Enrollment	G1: whole blood transfusion	Inclusion criteria:	G2: 2.3
period:	G2: packed RBCs	Admitted to hospital for delivery	G3: 5.5
March 2002 to	G3: combination of blood products	Hypovolemia from obstetric hemorrhage as defined	G3: 5.5
June 2006	·	by one or more of the following: 1) systolic blood	ICII admission n (9/).
Birth setting:	N at enrollment:	pressure less than 100 mm Hg not due to regional	ICU admission, n (%):
hospital	G1 : 659 (43%)	analgesia or anesthesia; 2) pulse 100 beats per	G1: 4 (1)
noophan	G2 : 593 (39%)	minute or more; 3) a positive "tilt" test (20 beats per	G2 : 7 (1) G3 : 23 (8)
Facility	G3 : 288 (19%)	minute increase in pulse or decrease in systolic	
characteristics:	N at follow-up: NR	blood pressure of 20 mm Hg) or of the static	p < 0.05
Tertiary care	•	symptoms (to dizziness, fainting, nausea, or	Anemia :
_	Duration of treatment: NR	vomiting upon sitting up); and 4) urine flow less than	
Funding:	Timing of treatment: NR	30 mL/h.	HCT at time of transfusion, mean (IQR)
Authors report no	Timing of treatment. WK	hematocrit less than 20% secondary to hemorrhage	G1 : 24.1 (21.3-27.2) G2 : 24.2 (21.6-27.5)
financial conflicts	Order of treatment: NR	or who had a hematocrit between 20% and 30% in	
Design:	l angth of follow up. ND	the face of ongoing hemorrhage and evidence of	G3 : 24.3 (20.9-27.2) p = NR
Population-based	Length of follow-up: NR	hemodynamic instability per the above criteria	p = NK
observation study		received blood.	Length of stay: NR
observation study			Length of Stay. NIX
		Exclusion criteria: NR	Mortality:
		Maternal age, yrs (%):	G1: 0
		G1: 17 or less – 54 (8)	G2: 1
		35 or more – 66 (10)	Maternal death in a woman with diabetes and
		G2: 17 or less – 39 (7)	chronic congestive heart failure after
		35 or more – 54 (9)	cesarean for prolonged labor and
		G3: 17 or less – 28 (10)	nonreassuring fetal heart rate pattern
		35 or more – 34 (12)	G3: 2
			One maternal death thought to be due to
		Parity (Nulliparity), n (%):	pulmonary embolism and multiorgan failure
		G1 : 333 (51)	following primary cesarean for a failed
		G2 : 306 (52)	induction of labor for severe preeclampsia
		G3 : 135 (47)	induction of labor for severe preediampsia
			One maternal death in a woman with severe
		Weeks gestation: NR	one material death in a wornair with severe

Study	Internantic	Inclusion/Exclusion	0
Description	Intervention	Criteria & Population	Outcomes
			preeclampsia who experienced placental
		Single pregnancy: NR	abruption and liver failure leading to
		onigio programoji i i i	multisystem organ failure and respiratory
		Multiple pregnancy: NR	failure
		Multiple pregnancy. NA	lalidie
		Race/ethnicity, n (%):	Uterine preservation:
		Hispanic	Hysterectomy, n (%)
		G1 : 573 (83%)	G1: 18(3)
		G2 : 493 (83%)	G2 : 16 (3)
		G3 : 236 (82%)	G3 : 48 (17)
			p < 0.001
		African American	F
		G1: 61 (9%)	Future fertility: NR
		G2: 75 (13%)	ratare fortility. NIX
			Procettoeding, ND
		G3: 30 (10%)	Breastfeeding: NR
		White	Psychological impact: NR
		G1: 17 (3%)	
		G2 : 14 (2%)	Other outcomes reported, n, (%):
		G3 : 12 (4%)	Acute tubular necrosis
			G1: 2 (0.3)
		Other	G2 : 12 (2)
		G1: 8 (1%)	G3 : 11 (4)
		G2: 11 (2%)	p <0.001
		G3: 10 (3.5%)	Adult respiratory distress
		D111 001 1 2 1010	G1: 3 (0.5)
		BMI, 30 kg/m ² or more, n/N (%):	G2 : 2 (0.3)
		G1: 328/582 (56%)	G3 : 6 (2)
		G2 : 328/548 (59%)	p < 0.01
		G3 : 139/257 (54%)	p < 0.01
		Baseline hemoglobin: NR	Pulmonary edema
		baseline nemoglobin. Nr.	G1 : 47 (7)
		CEC. ND	G2 : 24 (4)
		SES: NR	G3 : 39 (14)
		Mode of birth: NR	p < 0.001
		ASA Class, n (%):	Hypofibrinogenemia
		MOM Class, II (/0).	G1: 1 (0.2)
		l l	G2: 2 (0.3)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
		G1 : 8(1) G2 : 0(0)	G3: 47 (16) p <0.01
		G3 : 2 (0)	
		G3. 2 (0)	Harms of intervention: NR
		II	Confounders: NR/list
		G1: 517 (78)	
		G2 : 470 (79)	Effect modifiers: NR/list
		G3 : 219 (76)	
		 G1 : 45 (7)	
		G1. 45 (7) G2: 50 (8)	
		G3 : 41(14)	
		IV IV	
		G1 : 2 (0)	
		G2 : 5 (1)	
		G3 : 4 (1)	
		N	
		Not available	
		G1 : 87 (13) G2 : 68 (11)	
		G3 : 22 (8)	
		Risk factors, n (%):	
		Advanced maternal age	
		(see above)	
		Cesarean delivery n (%):	
		G1 : 337 (51)	
		G2: 305 (51)	
		G3 : 164 (57)	
		p = 0.22	
		Labor induction/augmentation, n (%):	
		Total	
		G1: 359 (55) G2: 322 (54)	
		G2 : 322 (34) G3 : 55 (19)	
		p = 0.24	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Induction	
		G1 : 151 (23)	
		G2 : 143 (24)	
		G3: 82 (28)	
		p = 0.63	
		Augmentation	
		G1 : 208 (32)	
		G2 : 179 (30)	
		G3 : 0	
		Dragon and related by residen	
		Pregnancy-related hypertension G1 : 176 (27)	
		G2 : 179 (30)	
		G3 : 84 (29)	
		p = 0.38	
		p = 0.00	
		Placenta previa or abruption	
		G1 : 31 (5)	
		G2: 47 (8)	
		G3 : 46 (16)	
		p < 0.001	
		Chorioamnionitis	
		G1 : 141 (21)	
		G2 : 127 (21)	
		G3 : 56 (19)	
		p = 0.76	
		Perineal trauma	
		G1: 4 (1)	
		G2: 7 (1)	
		G3 : 23 (8)	
		p < 0.001	
		P 10.001	
		Primary etiology of PPH, n (%):	
		Uterine atony	
		G1 : 22 (3)	
		G2: 11 (2)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G3 : 6 (2) p = 0.22	

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
•	Intervention:	Operational definition of PPH:	Prevalence of prophylactic oxytocin
Audureau et al.,	Multifaceted intervention conducted	The definition of PPH was based on its clinical diagnosis	administration after birth at all units Sample
2009 ⁵²	in a French regional perinatal	by attending staff, or by reports of abnormal bleeding	l, n (%):
	network including all maternity unites	leading to examination of the uterine cavity or manual	G1a : 137 (58.8)
Country:	of a defined geographic region and	removal of the placenta.	G2a : 195 (75.9)
France	aimed at increasing the translation	'	G1a vs G2a: p < 0.0001
Enrollment	into practice of clinical guidelines	Major PPH was defined by the presence of one or more	Dravelance of use of blood collection bene
period:	related to PPH. The primary objective	of the following criteria: blood transfusion of one unit or	Prevalence of use of blood collecting bags
2002 to 2005	of the study was to assess the impact	more, arterial embolization, arterial ligation, or other	after vaginal delivery at all units, n (%):
(Pre: Sep to Dec	of the intervention on practices for	conservative uterine surgery, hysterectomy, peripartum	G1a: 9 (3.9)
	prevention, diagnosis, and	hemoglobin delta of 4 g/dl or more or maternal death.	G2a : 196 (76.3)
Sep to Dec 2005)	management of PPH. The secondary		G1a vs G2a: p < 0.0001
	objective was to evaluate the impact	Definition of success of treatment: NR	Management of PPH practices from Sample
	of the intervention on the prevalence		Il Examination of the uterine cavity and/or
Maternity Units	of major PPH.	Method of blood loss measurement: blood collecting	manual removal of placenta, n (%):
		bags	G1b : 129 (84.9)
Facility	Sample I: random selection of all		G2b: 118 (78.7)
characteristics:	women delivering in the time period	Severity: PPH; Major PPH	G1b vs G2b: p=0.18
Level 1 (no non-		Inclusion criteria:	·
routine neonatal	Sample II: representative sample of		Instrumental examination of the genital
care facilities),	women with PPH deliveries	Deliveries in the study area during 2002 and 2005	tract, n (%):
Level 2 (neonatal		Exclusion criteria: NR	G1b: 29 (17.7)
care unit), and	Sample III: all cases of major PPH	M-((OD)-	G2b: 40 (24.1)
Level 3 (onsite	Groups:	Maternal age, yrs, mean (SD):	G1b vs G2b: p=0.32
	G1: All deliveries 2002	G1a : 29.2 (5.1)	
care unit) units	G1a: Sample I 2002	G1b : 29.8 (5.4)	Intravenous administration of oxytocin, n
	G1b: Sample II 2002	G1c: 29.2 (9.1)	(%):
Funding:	G1c: Sample III 2002	G2a : 29.6 (5.6)	G1b: 127 (77.4)
Grant from the	OTC. Gample in 2002	G2b: 28.7 (5.3)	G2b: 125 (75.3)
Hospital Program	G2: All deliveries 2005	G2c : 29.4 (5.0)	G1b vs G2b: p=0.70
for Clinical	G2a: Sample I 2005	Parity: NR	
Research from the	G2b: Sample II 2005		Intravenous administration of sulprostone
French Ministry of	G2c: Sample III 2005	Weeks gestation: NR	in case of persistent uterine atony, n (%):
Health			G1b: 19 (50.0)
Daniere.	N:	Single pregnancy: NR	G2b: 18 (56.3)
	G1 : 17,664		G1b vs G2b: p=0.64
	G1a : 294	Multiple pregnancy: NR	
level	G1b : 164	Race/ethnicity: NR	Blood transfusion of one unit or more if

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
•	G1c : 143	•	hematocrit was below 28%, n (%):
	G2 : 17,772	BMI, mean (SD):	G1b : 6 (28.6)
	G2a: 300	G1a: 23.7 (5.2)	G2b : 12 (37.5)
	G2b : 166	G1b: 23.4 (4.8)	G1b vs G2b: p=0.56
	G2c : 152	G1c: 23 (3.9)	'
		G2a : 23.4 (5.0)	Major PPH, n (prevalence):
	Duration of treatment: NR	G2b : 23.1 (4.3)	G1 : 142 (0.80)
		G2c: 22.9 (4.5)	G2 : 153 (0.86)
	Timing of treatment: NR		G1 vs G2: p=0.54
		Baseline hemoglobin: NR	
	Order of treatment:		PPH with peripartum hemoglobin delta ≥4
	Main steps of the protocol for	Mode of birth, n:	g/dl, n (prevalence):
	prevention and management of PPH	Cesarean	G1:124 (0.70)
	4 Drawantian Customatic introvenses		G2 : 125 (0.71)
	1 Prevention: Systematic intravenous	G1b: 7.3	G1 vs G2: p=0.97
	prophylactic injection of 10 IU	G1c: 12.6	01 v3 02. p=0.97
	oxytocin during the third stage of	G2a: 14.3	PPH requiring major treatment, n
	labor	G2b: 9.6	(prevalence):
	2 Diagnosis: Systematic use of a	G2c: 17.8	G1: 36 (0.20)
	blood collecting bag after vaginal	G2C. 17.0	, ,
	delivery	Risk factors, %:	G2 : 63 (0.36)
		Prior PPH	G1 vs G2 : p=0.01
	3 Management: For PPH after	G1a: 2.4	Autorial ambalization in (musualamas).
	vaginal delivery	G1b: 4.3	Arterial embolization, n (prevalence):
	Immediate manual removal of	G1c : 6.3	G1 : 11 (0.06)
		G2a: 2.0	G2 : 16 (0.09)
	placenta and/or examination of the	G2b: 4.2	G1 vs G2 : p=0.34
	uterine cavity; instrumental	00 7.0	
	examination of the vagina and cervix	0_01 / 10	Hemostatic Surgery, n (prevalence):
	Immediate intravenous administration	Parity: NR	G1 : 10 (0.06)
	of oxytocin	Turky. Till	G2 : 22 (0.12)
		Maternal Age: NR	G1 vs G2: p=0.03
	Intravenous administration of		
	sulprostone in case of persistent PPF	Obesity: NR	Emergency Hysterectomy, n (%):
	because of uterine atony 30 minutes	Obesity. Nix	G1b: 4 (.02)
	after oxytocin administration	Multiple gestation: NP	G2b: 10 (.06)
	Dod blood call transfersion if	Multiple gestation: NR	G1 vs G2: p=0.11
	Red blood cell transfusion if	Macrosomia: NR	
	hematocrit below 28%		
	Length of follow-up: NR	Primary etiology of PPH, (%):	
		Uterine Atony	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
-		G1b: 50.0 G2b: 42.8	
		Retained Placenta G1b: 32.9 G2b: 35.5	
		Genital Tract Lesion G1b: 5.5 G2b: 6.6	
		Abnormal Placental Implantation G1b: 1.2 G2b: 3.0	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Study			Blood loss: NR Transfusion, n (%): G1: 11 (9.3) G2: 10 (20) p= 0.07 ICU admission: NR Anemia: Hemoglobin drop > 20 g/L G1: 16 (13.6) G2: 5 (10) p= 0.62 Readmission G1: 18 (15.5) G2: 4 (8.2) p= 0.32 Length of stay (hospitalization > 2 days) G1: 48 (41) G2: 22 (44) p= 0.73 Mortality: None Uterine preservation: Hysterectomy G1: 0 G2: 1 (2) p= 0.30
		Parity, mean: G1: 3 G2: 2.7 p=NS	Secondary surgical evacuation G1 : 31 (26.3) G2 : 4 (8) p= 0.01
		Weeks gestation: NR	Future fertility:

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
•		Single pregnancy: NR	Secondary infertility, (%) G1: 8 (12.1) G2: 8 (30.8)
		Multiple pregnancy: NR	p= 0.06
		Race/ethnicity: NR	Breastfeeding: NR
		BMI: NR	Psychological impact: NR
		Baseline hemoglobin: NR	Harms of intervention: Broad spectrum antibiotics
		SES: NR	G1: 10 (8.5) G2: 9 (18.4)
		Mode of birth, n: NR	p= 0.11 Perforation
		Risk factors: NR	G1 : 0 G2 : 2 (4.1)
		Primary etiology of PPH: NR	p= 0.09 Any negative primary outcome: G1: 19 (16.5) G2: 18 (37.5) p= 0.01
			Any negative secondary outcome: G1: 68 (59.1) G2: 26 (53.1) p= 0.49
			Confounders: NR
			Effect modifiers: NR
			Need for adhesiolysis, n (%): G1: 3 (2.5) G2: 8 (16.0) p=0.03

Table D-53. Evidence table for studies addressing management of PPH (Fiori 2009)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Fiori et al.,	Emergency pelvic angiographic	Severe PPH as PPH with more than 1000 mL blood loss	Harms, n (%):
2009 ⁵⁴	selective artery embolization for	after clinical estimation or after weighing blood bag or	Menstrual disorders
Country:	severe PPH	more than 500 mL with poor clinical tolerance of blood	G1: 3/33 (9%)
France	Groups:	loss (hypotension, etc) but also if PPH was persistent	Hypomenorrhea related to partial corporeal
	G1: pelvic arterial embolization	despite medical treatment or if a persistent PPH induced	uterine synechiae n=1, metrorrhagia related to
Enrollment	N of any all monts	disseminated intravascular coagulopathy (DIC) or required transfusion.	diffuse uterine adenomyosis n=1, irregular
period:	N at enrollment:		menstrual bleeding, n=1
April 1995 to July 2005	G1: 56	Definition of success of treatment: NR	
2005	N at follow-up:	Dominion of Success of treatment.	Failure to conceive
Birth setting:	G1: 34	Method of blood loss measurement: clinical	G1: 2/15 (13)
Hospital	Duration of treatment: NR	estimation; weighing blood bag	19 (56%) women reported no desire for future pregnancy
Facility	Timing of treatment: NR	Severity: >1000 mL or >500 mL with poor clinical	
characteristics:	Order of treatment:	tolerance of blood loss	
NR		Inclusion criteria:	
Funding: NR	checked for local lesions that are	Severe PPH (see above)	
	sutures if necessary	 Severe FFH (see above) PAE performed after failure of initial medical treatment 	
Design:	1	FAL performed after failure of initial medical freatment	
Retrospective case series		Exclusion criteria:	
case series	the bladder inserting a Foley	 Women underwent hysterectomy on post embolization 	
	catheter, uterus is explored manually, and an intravenous bolus of 5-10 IU	day 25 for secondary endometriosis	
		Maternal age, median (range):	
	exceeding 50 IU since delivery	G1 : 33 (20-43)	
		, ,	
	o ii biocaii g poi cioto, tiio atorao io	Parity, median (range):	
	orprored again, and personn enternal	G1 : 1 (1-4)	
	uterus massage and administer 1 vial	Weeks gestation, median (range):	
	of sulprostone (500 ug) by slow		
	intravenous injection over 30 minutes to 1 hour; 1 st vial can be followed by	G1: 39 (20-41)	
	2 nd over 5 hours	Single pregnancy: NR	
	4 Arterial embolization procedure	Multiple pregnancy: NR	
	could take place during or after the		
	second vile of sulprostone	Mode of birth, n:	
		Spontaneous vaginal delivery	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
•	Length of follow-up:	G1: 30 (54.5)	
	Median followup 44.4 months (range,		
	8.3-118.2)	Cesarean delivery	
		G1 : 16 (29)	
		Instrumental vaginal delivery G1: 9 (16.5)	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Uterine atony G1: 56 (100)	
		Lower genital tract lacerations G1: 4 (7)	
		Placenta accreta G1: 4 (7)	

Table D-54. Evidence table for studies addressing management of PPH (Gaia 2009)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Gaia et al.,	Embolotherapy for PPH	500 mL within 24 hours after delivery or delayed PPH	Horme n (9/)
2009 ⁵⁵	Groups	500 mL greater than 24 hours after delivery.	Harms, n (%):
Country:	Groups: G1: intervention		Any major perioperative complication, total: G1 : 9/113 (8)
France	G1. Intervention	Definition of success of treatment : control of bleeding	G1. 9/113 (6)
riance	N at enrollment:		Dulmananyamhaliam
Enrollment	G1: 113	Method of blood loss measurement: NR	Pulmonary embolism G1: 2 (1.7)
period:	N. of College		G1. 2 (1.7)
Dec 1999 to	N at follow-up:	Severity: NR	A quita nulmanany adama
August 2006	G1: 107 (6 women were unreachable	Inclusion criteria:	Acute pulmonary edema
•	by telephone)		G1: 1 (1)
Birth setting: NR	Duration of treatment: NR	• PPH	Myocardial infarction
		Unresolved bleeding w medical & surgical procedures	G1 : 1 (1)
Facility	Timing of treatment:	Exclusion criteria:	Fare and train through a sig
characteristics:	Mean duration of PPH before	Severe PPH requiring total hysterectomy (n=6)	Femoral vein thrombosis
Tertiary care.	embolization was 220 min, ranging	l Severe 1 1 11 requiring total riyotorootomy (n=o)	G1: 5 (4)
Funding: NR		Maternal age, yrs, mean ± SD:	Language side offerto y 407.
	delayed & diagnosed at 2,2,5,7, & 10	G1: 31 (range 18-47)	Long term side effects, n=107:
Design:	days.	Parity: NR	Urinary disorders
Case series	Order of treatment: Initial medical	Failty. NK	G1 : 8 (7)
	treatment consisting of oxytocic	Weeks gestation, mean (range):	Variable drawage
	agents. 18 had pre-embolization	G1: 30 (32-42)	Vaginal dryness
	surgery (16%). Primary management	G1. 30 (32-42)	G1 : 11 (10)
	d use of oxytocin (& prostaglandin	Single pregnancy: NR	Llot fluck on
	analogues, manual exploration of the	Single pregnancy. Nix	Hot flushes
		Multiple pregnancy: NR	G1 : 13 (12)
	lacerations. Blood transfusions were	Multiple pregnancy. NR	Dyonouronia
	performed. Once medical & surgical	Race/ethnicity: NR	Dyspaurenia
	measures were found to not control	nace/enfincity. MA	G1 : 14 (13)
	the bleeding, pts transferred for	BMI: NR	Amenorrhea after embolization and diffuse
	embolization.	DIVII. IVIX	
	GITIDOTIZATIOIT.	Baseline hemoglobin: NR	uterine synechiae
	Length of follow-up:	Daseille Hemoglobili. 1415	G1 : 6/107 (5.6)
	Average follow-up time was 46.4 ±	SES: NR	Moncoo n (9/)
	21.8 months (range 12-84 months).	JCG. IVIX	Menses, n (%):
	, ,	Mode of birth, n (%):	Recovery 99 (92.5)
		Vaginal	Normal 66/407
		•	Normal 66/107
		G1: 46 (40.7)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		•	Subjective changes 33/107
		Cesarean G1: 67 (59.3)	Menorrhagia 10/33
		Risk factors: NR	Oligomenorrhea 23/33
		Primary etiology of PPH, n (%): Atony G1 :85 (75)	
		Coagulopathy G1: 5 (4)	
		Trauma (vaginal or cervical laceration) G1: 11 (10)	
		Placental pathology G1 : 11 (10)	
		Vascular accident G1: 1 (1)	

Table D-55. Evidence table for studies addressing management of PPH (Phillips 2009)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Intervention: Administration of recombinant	Operational definition of PPH: NR	Blood loss: NR
2009 ⁵⁶	activated factor VII (rFVIIa) (off-label	Definition of success of treatment:	Transfusion
Country:	use)	Reduction or cessation of bleeding	PRBCs, n (%):
Acceptable and Name	Median dose 92 μg/kg (IQR range 9- 139)	Method of blood loss measurement: NR	None G1a before: 6 (6)
Enrollment	Received single dose: 82 (78%)	Severity: NR	G1a after: 29 (28) 1-5 units
period:	Groups:	Inclusion criteria:	G1a before: 12 (11)
Jan 2002 to July	G1: intervention	Women who received rFVIIa as treatment for PPH	G1a after: 51 (49)
2008	N:	Registry report	6-10 units
Birth setting:	G1: 110 (5 received as prophylaxis	Exclusion criteria:	G1a before: 28 (27) G1a after: 16 (15)
38 hospitals	before delivery)	rFVIIa used for prophylaxis	11-15 units
Facility	G1a: 105		G1a before: 28 (27)
characteristics:		Maternal age, yrs, mean ± SD (range):	G1a after: 4 (4)
	Duration of treatment: NR	G1: 32 ± 6 (17 to 48)	16-20 units
		Parity, n:	G1a before: 19 (18)
Funding:	Timing of treatment: NR	G1: NR	G1a after: 0
Novo Nordisk	Order of treatment:		21-25 units
		Weeks gestation: NR	G1a before: 4 (4)
	Step 1: hysterectomy (53% of pts) Step 2: administration of packed red	Single pregnancy ND	G1a after: 3 (3) Over 25 units
Design:	blood cells (PRBCs) (83% of pts)	Single pregnancy: NR	G1a before: 8 (8)
Case series-		Multiple pregnancy: NR	G1a after: 2 (2)
registry	Step 4: administration of <6 units	multiple pregnancy. With	p< 0.001
	PRBCs (76% of pts)	Race/ethnicity: NR	
	Length of follow up. 20 days		Fresh Frozen Plasma (FFP):
	Length of follow-up: 28 days	BMI: NR	None
			G1a before: 7 (7)
		Baseline hemoglobin: NR	G1a after: 59 (56)
			1-5 units
		SES: NR	G1a before: 29 (28)
			G1a after: 30 (29)
		Mode of birth: NR	6-10 units
		Risk factors: NR	G1a before: 49 (47) G1a after: 9 (9)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Primary etiology of PPH, n (%):	11-15 units
		Atony	G1a before: 12 (11)
		G1a : 19 (18)	G1a after: 5 (5)
			16-20 units
		Uterine rupture	G1a before: 6 (6)
		G1a: 3 (3)	G1a after: 1 (1)
			21-25 units
		Placenta accrete/percreta	G1a before: 1 (1)
		G1a: 17 (16)	G1a after: 0
		G14: 17 (10)	Over 25 units
		Placenta previa	G1a before: 1 (1)
		G1a : 13 (12)	G1a after: 1 (1)
		G1a. 13 (12)	p< 0.001
		Dia contal abountion	p< 0.001
		Placental abruption	0
		G1a: 9 (9)	Cryoprecipitate, n (%)
			None
		Retained placenta	G1a before: 37 (35)
		G1a: 4 (4)	G1a after: 70 (67)
			1-5 units
		Preeclampsia/eclampsia	G1a before: 18 (17)
		G1a : 6 (6)	G1a after: 15 (14)
			6-10 units
		Acute fatty liver of pregnancy	G1a before: 32 (31)
		G1a: 3 (3)	G1a after: 13 (12)
			11-15 units
		Intrauterine fetal death	G1a before: 7 (7)
		G1a : 9 (9)	G1a after: 1 (1)
			16-20 units
		Obstetric injury	G1a before: 6 (6)
		G1a: 4 (4)	G1a after: 5 (5)
			21-25 units
		Amniotic fluid embolism	G1a before: 4 (4)
		G1a: 3 (3)	G1a after: 0
		J. a. o (o)	Over 25 units
		Other (see comment)	G1a before: 1 (1)
		G1a: 10 (10)	G1a after: 1 (1)
		G1a. 10 (10)	
		No identificable access	p< 0.001
		No identifiable cause	D 1 + 1 + + + + + + + + + + + + + + + + +
		G1a : 5 (5)	Platelet concentrate, n (%)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			None
			G1a before: 26 (25)
			G1a after: 49 (47)
			1-5 units
			G1a before: 65 (62)
			G1a after : 45 (43)
			6-10 units
			G1a before: 9 (9)
			G1a after: 8 (8)
			11-15 units
			G1a before: 1 (1)
			G1a after: 3 (3)
			16-20 units
			G1a before: 3 (3)
			G1a after: 0
			21-25 units
			G1a before: 0
			G1a after: 0
			Over 25 units
			G1a before: 1 (1)
			G1a after: 0
			p< 0.003
			ICU admission: NR
			Anemia: NR
			Length of stay: NR
			Mortality within 28 days of receiving rFVIIa:
			G1 : 9
			Five within 8 hr of rFVII admin of underlying
			conditions or exsanguination and 4 within the
			first 17 days of rFVII from multi-system failure
			after embolectomy, neurological injury
			following severe disseminated intravascular
			coagulation, hypoxic cerebral event and
			secondary to eclampsia and thrombotic
			thrombocytopenic purpura.

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
			Uterine preservation: NR
			Future fertility: NR
			Breastfeeding: NR
			Psychological impact: NR
			Harms of intervention (Total n=39) within 28 days of receiving rFVIIa
			Cerebrovascular accident G1: 1
			Deep vein thrombosis G1: 1
			Pulmonary embolism G1: 1
			Disseminated intravascular coagulopathy G1: 8
			Multiorgan failure G1: 7
			Acute respiratory distress syndrome G1: 3
			Other G1: 18, s reactive thrombocytosis (n=1), ileus (n=1), hypodensities of liver and spleen (n=1), pelvic hematoma (n=1), hyperbilirubinemia (n=1), hypertension (n=2), superficial thrombophlebitis (n=1), mild peripheral edema (n=1), rebleeding (n=1), pleural effusion (n=1), abdominal pain (n=1), small troponin rise (n=1), cecal perforation (n=1), peripartum
			(n=1), rebleeding (n=1), pleural ef abdominal pain (n=1), small tropo

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
			syndrome (n=1), left lung collapse (n=1)
			Confounders: NR
			Effect modifiers: NR

Table D-56. Evidence table for studies addressing management of PPH (Balki 2008)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Intervention: Blood transfusion within 24 hours of delivery Groups: G1: intervention N at enrollment: G1: 104 N at follow-up: G1: 104 Duration of treatment: NR Timing of treatment: NR Order of treatment: NR	Criteria & Population Operational definition of PPH: Blood loss > 500 mL after vaginal delivery, > 1000 Ml after Cesarean, or a 10% change in hematocrit. Other factors d need for blood transfusion, or any amount of blood loss that affected woman's hemodynamic stability. Definition of success of treatment: NR Method of blood loss measurement: NR Severity: NR Inclusion criteria: At least 24 weeks gestation and received blood transfusion within 24 hours of delivery	Harms pre-specified: No Harms: Pulmonary complications: 2.8% Cardiac complications: 1% Coagulopathy, including DIC: 20% Required ICU admission: 24%
Tertiary care Funding: NR Design: Case series, retrospective	Length of follow-up: NR	Exclusion criteria: NR Maternal age, yrs, mean ± SD: G1: 33.6 ± 4.8 Parity, n: Primipara G1: 56 (53.8) Multipara G2: 48 (46.2) Weeks gestation, mean ± SD: G1: 35.8 ± 6.1 Single pregnancy, n (%): NR Multiple pregnancy, n (%): NR	
		Race/ethnicity: NR BMI: Weight, kg , mean ± SD	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	IIITEI VEIITIOII	Criteria & Population	Outcomes
		G1: 75.9 ± 13.3	
		Baseline hemoglobin: NR	
		SES: NR	
		3E3: NR	
		Mode of birth, n:	
		Vaginal	
		G1 : 67	
		Elective Cesarean	
		G1 : 12	
		Occasion design to be an	
		Cesarean during labor G1: 25	
		G1. 23	
		Risk factors, n (%):	
		Prior PPH	
		G1 : 5 (4.8)	
		Multiple gestation	
		G1: 18 (17.3)	
		Macrosomia	
		G1 : 17 (16.3)	
		Abnormal placentation	
		G1 : 17 (16.3)	
		Pregnancy induced hypertension	
		G1: 14 (13.5)	
		Chorioamnionitis	
		G1: 9 (8.7)	
		Blood disorders/anticoagulation	
		G1 : 8 (7.7)	
		Antepartum hemorrhage	
		G1: 21 (20.1)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description		Criteria & Population	
		Previous uterine surgery	
		G1 : 22 (21.1)	
		Prolonged labor first stage G1: 12/92 (13)	
		Prolonged second stage G1: 6/92 (6.5)	
		Prolonged third stage G1: 1/92 (1.1)	
		Primary etiology of PPH, n (%): Atony	
		G1: 40 (38.5)	
		Coagulopathy G1: 7 (6.7)	
		Trauma genital tract G1: 13 (12.5)	
		Retained placenta G1: 35 (33.7)	
		Undetermined G1: 9 (8.7)	
		Placenta previa G1: 7 (6.7)	
		Placenta accreta G1: 7 (6.7)	
		Placenta percreta G1: 3 (2.9)	
		Placenta abruption G1: 1 (0.9)	

Table D-57. Evidence table for studies addressing management of PPH (Knight 2007)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Knight,	Peripartum hysterectomy		
2007 ⁵⁸		Definition of success of treatment: NR	Transfusion, median units transfused
	Groups:		(range):
Country: UK	G1: Peripartum hysterectomy	Method of blood loss measurement: NR	G1a: 10 (0-116)
	G1a: total hysterectomy		G1b: 10 (0-80)
Enrollment	G1b: subtotal hysterectomy	Severity: NR	
period:			ICU admission:
Feb 2005 to Feb	N:	Inclusion criteria:	G1: 265 (84)
2006	G1: 315	Women undergoing peripartum hysterectomy for PPH at a	
	G1a: 149	UKOSS-participating hospital	Anemia: NR
Birth setting:	G1b : 162	1 11 11 3 11 11	
Hospital	Type unknown for n=4	Exclusion criteria:	Length of ICU stay days, median
•	71	Hysterectomy for malignancy	(range):
Facility	G1 : 315	injetereotemy for mangriamoy	G1 : 2 (1-26)
characteristics:		Maternal age, yrs, mean ± SD: NR	, ,
Consultant-led	Duration of treatment: NR		Mortality:
maternity units		Parity: NR	G1: 2 (0.6%) (95%CI: 0-1.5%)
, , , , ,	Timing of treatment:	· uniyi · · · ·	
Funding:	Within 24 hours of birth: 89%	Weeks gestation: NR	Uterine preservation: None
Oxford Deanery	1-38 days post-birth: 11%	Trooks goodanom tik	
public health		Single pregnancy: NR	Future fertility: NA
training program	Order of treatment:	omgio prognamoji i i i	,
and the National	Other treatments prior to	Multiple pregnancy: NR	Breastfeeding: NR
Coordinating	hysterectomy, n:	pro programoji i m	
Centre for	Syntocinon: 259	Race/ethnicity: NR	Psychological impact: NR
Research	Ergometrine: 141		Harms of intervention, n (%):
Capacity	Prostaglandin: 171	BMI: NR	Bladder damage
Development of	Misoprostol: 31		G1 : 38 (12.1)
the Department of		Baseline hemoglobin: NR	,
Health	Intrauterine balloon: 83		Ureter damage
	N-lynch or brace suture: 50	SES: NR	G1: 18 (5.8)
Design:	Arterial ligation: 34		- (5.5)
Population-based	rFVIIa: 28	Mode of birth, %:	Ovary removal
case series	Embolization: 9	Cesarean	G1: 28 (8.9)
	Uterine packing: 40	G1: 80	()
	Other: 34	01. 00	Any further surgery
		Spontaneous vaginal	G1: 62 (19.8)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
	Length of follow-up: NR	G1: 16 Assisted vaginal	ORs for surgical damage between women with subtotal and total
		G1: 4 Risk factors, n (%): NR	hysterectomy, not significant Other morbidity
		Primary etiology of PPH, n (%): Uterine Atony	G1: 53 (17) Need for ventilation
		G1: 167 (53) Placenta accreta/increta/percreta	G1: 23 Cardiac arrest
		G1: 121 (38) Uterine rupture	G1: 6 Renal failure
		G1: 26 (8) Extension of uterine incision at delivery	G1: 4 Thromboembolic events
		G1: 20 (6) Uterine infection	G1: 4 ARDS acute respiratory distress
		G1 : 16 (5)	syndrome G1: 2
		Fibroids G1: 11 (3)	Multiple organ failure G1: 2
		Genital tract laceration G1: 11 (3)	Confounders: NR
		Extension of previous uterine scar at delivery G1 : 43 (14)	Effect modifiers: NR
		Other including placenta praevia, clotting abnormally and placental abruption G1: 43 (14)	

Table D-58. Evidence table for studies addressing management of PPH (Baruah 2008)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
Author:	Intervention:		Need for third line (medical/surgical)
Baruah et al.,	Rectal misoprostol as second line	Primary PPH: Bleeding within first 24 hours after delivery	therapy, n (%):
2008 ⁵⁹	therapy, dose varied from 800 to	and blood loss > 500 mL	G1 : 27 (67.5)
Ca	1,000 µg		G2 : 14 (77.77)
Country: US		Definition of success of treatment: NR	p=0.91
Enrollment	Control group received		
period:	methylergonovine maleate 0.2 mg IM	Method of blood loss measurement: NR	Medical treatment as third line therapy, n
July 2000 to Feb			(%):
2005	Groups:	Severity: NR	G1 : 22 (55)
	G1: Misoprostol	In alcohom and tanks	G2 : 10 (55.5)
Birth setting:	G2: Methyergonovine Maleate	Inclusion criteria:	p=0.96
Hospital	N	 who were between 37 and 42 weeks gestational age, 	ľ
	N at enrollment:	 who received a clinical diagnosis of PPH following 	Surgical intervention as third or fourth line
Facility	G1 : 40	delivery of singleton pregnancy and	therapy, n (%):
characteristics:	G2 : 18	 Required uterotonics as second-line treatment after 	G1 : 5 (12.5)
Academic,	N at follow-up:	failed initial oxytocin therapy	G2 : 4 (22.2)
Research and	L =	Maternal age, yrs, n:	p=0.51
Teaching Hospital	G2 : 18	Under 20	
Funding: NR		G1: 6	Dilation and curettage:
i unung. Nix	Duration of treatment: NR	G2 : 1	G1 : 8 (30)
Design:	Timing of treatment: NR	G2. 1	G2 : 4 (22)
Retrospective	•	20-29	p=0.84
cohort		IG1: 14	
	therapy	G2: 9	Uterine packing:
	Langth of fallows and ND	G2. 9	G1 : 2 (5)
	Length of follow-up: NR	30-39	G2 : 0 '
		G1 : 19	p=0.92
		G2: 8	
		G2. 0	Uterine artery embolization:
		≥ 40	G1 : 1 (3)
		2 40 G1 : 1	G2 : 0
		G2: 0	p=0.49
		G2. 0	
		Parity, n:	Uterine artery ligation:
		Primparous	G1 : 1 (3)
		G1 : 14	G2 : 1 (6)
		G2 : 6	p=0.55
			[

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
		Multiparous	Blood loss: NR
		G1 : 26	
		G2 : 12	Transfusion, needed, n (%):
			G1 : 5 (12.5)
		Weeks gestation: NR	G2 : 0 `
			p=0.11
		Single pregnancy, %: 100	·
			ICU admission: NR
		Multiple pregnancy, n (%): 0	
			Anemia: NR
		Race/ethnicity, n:	
		White	Length of stay: NR
		G1: 26	
		G2 : 7	Mortality: NR
			mortaniyi i ii c
		Hispanic	Uterine preservation, n (%):
		G1 : 5	Hysterectomy
		G2 : 3	G1 : 1 (3)
		32. 3	G2 : 1 (6)
		Black	p=0.55
		G1 : 5	p=0.55
		G2: 4	Future fertility: NR
		62. 4	r didie fertility. Nix
		Native American	Breastfeeding: NR
		G1: 4	Dieastieeding. WY
		G2: 4	Psychological impact: NR
		G2. 4	rsychological impact. NA
		BMI: NR	Harms of intervention: NR (Side effects listed
		DIVII. INIX	in discussion)
		Baseline hemoglobin: NR	O C NO NO
		baseline nemoglobin. NR	Confounders: NR
		SES: NR	Effect modifiers: NR
		SES. NR	
		Mode of birth: NR	
		Wode of biltii. NK	
		Risk factors: NR	
		Primary etiology of PPH: NR	
<u> </u>			t micenreatel methylergensyine malesta) and / or surgical

Comments: Third-line treatments d a medical intervention (e.g., the administration of either carboprost, misoprostol, methylergonovine maleate) and / or surgical intervention (e.g., dilation and curettage, uterine packing, uterine artery ligation, uterine artery embolization and hysterectomy) and/ or blood transfusion.

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Transfusion, n (%):
Chauleur et al.,	Analyze the relationship between	PPH was defines as uterine bleeding occurring in the	Red blood cells
2008 ⁶⁰	severe PPH, its related blood-derived	first 24 hours after delivery, persisting after manual	G1a : 317 (100)
Country	substitutive treatments and the	exploration of the uterine cavity and requiring I.V.	
Country: France	occurrence of venous	prostaglandin administration.	Platelets
Tance	thromboembolism (VTE) in the		G1a: 29 (9.1)
Enrollment	following first six weeks post birth	Severe PPH was defined as peripartum decrease of	
period:	Groups:	hemoglobin >40 g/l ⁻¹ -the reference value taken into	Fresh frozen plasma
January 1999 to	G1: Women during their first	consideration was the last hemoglobin concentration	G1a: 51 (16.1)
ebruary 2004	pregnancy	before delivery-; or in case of transfusion of at least four	
Diath a still an	G1a: Subgroup of women who	packed red blood cell (RBC) units, of hemostatic	Fibrinogen concentrates
Birth setting:	developed severe PPH	intervention (surgical uterine sutures, artery litigation,	G1a: 29 (9.1)
Hospital	developed severe FFR	artery embolization, hysterectomy) or of death.	
F==!!!(N at enrollment:		Harms, n:
Facility	G1: 32,463	Definition of success of treatment: NR	Lower limb DVT
characteristics:	G1a: 317 (0.98%)		G1 : 11
Jniversity	N of follows and NID	Method of blood loss measurement: NR	
Funding: NR	N at follow-up: NR		Superficial vein thrombosis
•	Duration of treatment: NR	Severity: See above	G1 : 60
Design:		Inclusion criteria:	G1a: 3
Population-based	Timing of treatment: NR		
case series	Order of treatment:	Women during their first intended pregnancy	Venous thromboembolism
	1 As soon as excessive bleeding was	Exclusion criteria:	G1a : 0
	observed, manual explorations of the	Previous occurrence of superficial or deep vein	
	uterus and oxytocin injection were	thrombosis (DVT) in the patient or in any first degree	Mortality, n:
	performed	relative	G1a : 0
		Chronic treatment during pregnancy interfering with	Confounders: NR
	2 Sulprostone was injected IV in the	the hemostatic system, including low- or high- dose	Comounacis. WY
	case of persistent hemorrhage: initial	aspirin	Effect modifiers: NR
	500 ug dose was given over a one	Any missing data on pregnancy loss	
	hour duration, then a second dose		
	over three to five hours	Maternal age, yrs, mean (range):	
	3 Fluid therapy was used to obtain	G1 : 29.2 (21-36)	
	hemodynamic stability and	G1a : 29 (22-36)	
		Parity: NR	
	4 Transfusion of packed RBC units	Weeks gestation, mean (range):	
	was performed to maintain the	G1a: 39 (22-41)	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	Outoonies
	hemoglobin level above 70 g/l ⁻¹ 5 The practitioner in charge of the	Single pregnancy: NR	
	patient decided to inject 20 ml/kg ⁻¹ of fresh frozen plasma (FFP) in case of	Multiple pregnancy, n (%):	
	plasma factor V lower than 30% normal values and one unit of platelet	G1 : 340 (1) G1a : 6 (1.9)	
	(PLT) per 10 kg body weight in case of thrombocytopenia lower than 50 g/l ⁻¹	Race/ethnicity, n (%): European Caucasians G1: 26,323 (81.1)	
	Length of follow-up: NR	Northern Africa Caucasians G1: 4,447 (13.7)	
		Africans G1 : 1,006 (3.1)	
		Asians G1: 683 (2.1)	
		BMI, Mean (range), kg/m ⁻² G1: 24.3 (16.1-33.7) G1a: 23.9 (19.1-30.3)	
		Baseline hemoglobin: NR	
		Mode of birth, n, (%): Cesarean G1: 6,957 (21.4) G1a: 76 (24)	
		Vaginal delivery G1: NR G1a: 241 (76)	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Uterine atony G1a: 199 (62.8)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		Birth canal trauma G1a: 29 (9.1)	
		Placenta accreta G1a: 2 (0.6)	
		Placenta praevia, uterine inversion G1a: 1 (0.3)	
		Placenta abruption, uterine atony G1a: 23 (7.3)	
		Retained secondines G1a: 20 (6.3)	
		Retained secondines, disseminated intravascular coagulation G1a: 5 (1.6)	
		Retained secondines, uterine atony G1a: 30 (9.5)	
		Retained secondines, uterine inversion 8 G1a: 8 (2.5)	

uterine artery embolization or Definition of success of treatmer	Mortality: G1a: 1 (treated with in situ methotrexate and died 4 months after embolization due to methotrexate-related nephrotoxicity
2008 ⁶¹ to medical treatment who underwent uterine artery embolization or Definition of success of treatmen	died 4 months after embolization due to
2008 ⁶¹ to medical treatment who underwent uterine artery embolization or Definition of success of treatmen	died 4 months after embolization due to
Country	nt: cessation of methotrexate-related nephrotoxicity
	· · · · · ·
France	Uterine preservation:
Enrollment Groups: Method of blood loss measureme	
neriod: G1a: embolization	G1a: 41/46 (89.1)
1006 to 2005 G1b: nysterectomy Severity: NR	Five patients underwent additional procedures
G1c: embolization & hysterectomy	
Birth setting: N: Inclusion criteria:	1. parametrical dissecting hematoma,
Hospital G13: 41 • Women with a primary PPH resis	stant to medical embolization completed by the insertion of a
c1b: 6 treatment who underwent uterine	coil into the R uterine artery (G1c)
Facility or hysterectomy	2. Ovarian artery embolization
characteristics:	3. Hypogastric artery catheterized &
Tertiary care Duration of treatment: NR	embolization performed beyond the gluteal
Maternal age vrs median (range	artery.
Funding: NR Timing of treatment: NR	4. Superselective embolization of the internal
Design: Order of treatment: NR Overall: 27.3 (19-41)	illiac artery branch
Case series G1a: 29.2 ± 4.65	5. Embolization performed after ligation of
Length of follow-up: G1b: 30.1 ± 4.11	hypogastric arteries (embolization of the
NR, follow-up interview in 2007 G1c: 36.6 ± 4.56	residual stump of hypogastric artery &
	anastomatic pelvic trats).
Parity, n (%):	anasiomatic pervic trais).
Primiparous	
G1a : 9 (21.9)	Future featility (date for 07/44)
G1b: 2 (33)	Future fertility (data for 37/41)
G1c: 0	No wish for further children: 16
	No present wish for another child: 5
Multiparous	Wanted another child: 16 (39%)
G1a : 32 (78)	Became pregnant within 1-11 months: 16/16
G1b : 4 (66)	(100%)
G1c : 5 (100)	Return of normal menses
	G1a: 41 (100%)
Weeks gestation: NR	More than 1 pregnancy after embolization: 6 Repeat PPH - 1
Single pregnancy, n:	Harms of intervention:
G1a: 36	Allergy to iodine, n
Multiple pregnancy, n:	G1a: 1

G1a: 10 Acute pulmonary edema, n Race/ethnicity: NR G1a: 1 BMI: NR Cardiovascular instability G1a: 1 Baseline hemoglobin: NR Major hemoperitoneum related to dissection of SES: NR epigastric artery (re-operated 4 times), n **G1a**: 1 Mode of birth, n (%): Confounders: NR Unassisted vaginal delivery **G1a:** 9 (21.9) Effect modifiers: NR **G1b**: 2 (33) G1c: 0 Instrumental vaginal **G1a:** 2(4.8) **G1b:** 0 **G1c**: 0 Cesarean **G1a:** 30 (73.1) **G1b**: 4 (66) **G1c:** 5 (100) Risk factors, n (%): NR Primary etiology of PPH, n (%): Atony **G1a:** 32 (69.5) Placenta accreta or percreta **G1a:** 8 (17.3) Placenta previa **G1a:** 3 (6.5) Placental abruption **G1a**: 1 (2) Myoma and atony **G1a**: 1 (2)

	Parametrical dissecting hematoma G1a: 1 (2)	
	Time between delivery & procedure, min (range) G1a : 263 (90-750)	

Table D-61. Evidence table for studies addressing management of PPH (Glaze 2008)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Glaze et al.,	Peripartum hysterectomy		
2008 ⁶²	Groups:	Definition of success of treatment: NR	Transfusion, n (%):
Country:	G1: Peripartum hysterectomy		PRBCs
Canada	G1. Felipartum hysterectomy	Method of blood loss measurement: NR	G1: 65 (75)
Cariaua	N:		
Enrollment	G1 : 87	Severity: NR	ICU admission
period:	Duration of treatment, ND	Inclusion criteria:	G1: 46 (53)
Jan. 1999 to Dec.	Duration of treatment: NR		
2006 (2 study	Timing of treatment: NR	 Peripartum hysterectomy- any hysterectomy performed within 24 hours of a birth 	Anemia
periods:1999-		performed within 24 hours of a birth	G1: 32 (37)
2004 and 1999-	Order of treatment: NR	Exclusion criteria: NR	
2006)	Length of follow-up: NR	20 ()	Length of stay in days, mean ± SD (range)
Dinth a attimus	Length of follow up: WK	Maternal age, yrs, mean ± SD (range):	G1: 6 ± 3 (2-16)
Birth setting:		G1 : 34 ± 5 (18-44)	
Calgary Health		Parity, median, IQR (range):	Mortality, n (%)
region hospitals		G1 : 1, 0 to 2 (1-10)	G1: 0
Faailia.		,	
Facility		Weeks gestation: NR	Uterine preservation: NA
characteristics:		3 3 3 3 3 3 3 3 3 3	
NR		Single pregnancy, n (%):	Future fertility: NA
Funding: NR		G1 : 82 (94)	
			Breastfeeding: NR
Design:		Multiple pregnancy, n (%):	
Case series		G1 : 5 (6)	Psychological impact:
			Harms of intervention, n (%)
		Race/ethnicity: NR	G1 : 17 (20)
		BMI: NR	DIC
			G1 : 17 (17)
		Baseline hemoglobin: NR	
			lleus
		SES: NR	G1 : 8 (9)
			_
		Mode of birth, n (%):	Fever
		Emergency cesarean	G1: 7 (8)
		G1 : 51 (59)	
		Planned cesarean	Depression

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	
		G1: 19 (22)	G1 : 1 (1)
		SVD	Hematoma
		G1 : 11 (13)	G1 : 1 (1)
		Operative delivery	Pneumonia
		G1 : 6 (7)	G1: 1 (1)
			No complications
		Risk factors, n (%):	G1: 31 (36)
		No recorded complications	
		G1: 35 (40)	Confounders: NR
			Effect modifiers: NR
		Labor induction/augmentation	
		G1: 24 (28)	
		Fibroids	
		G1: 6 (7)	
		Pregnancy-induced hypertension	
		G1 : 15 (17)	
		Diabetes, gestational	
		G1 : 10 (11)	
		Placenta previa	
		G1 : 19 (22)	
		Placenta abruption	
		G1 : 2 (2)	
		G1. 2 (2)	
		HELLP	
		G1 : 2 (2)	
		Thrombocytopenia	
		G1 : 1 (1)	
		Other (20)	
		G1 : 17 (20)	
		Previous cesarean	
		G1 : 27 (31)	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
·		Primary etiology of PPH, n (%): Indications for hysterectomy Atony G1: 32 (37)	
		Placenta accrete G1: 29 (33)	
		Bleeding NOS G1: 22 (25)	
		Extension of incision G1: 3 (3)	
		Fibroids G1: 2 (2)	
		Sepsis G1: 2 (2)	
		Uterine rupture G1: 1 (1)	

Table D-62. Evidence table for studies addressing management of PPH (McMorrow 2008)

Study		Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Blood loss: NR
McMorrow et al.,	Recombinant factor VII a	Massive PPH requires treatment of greater than 5 units	
2008 ⁶³	Both groups received: uterotonics	red cell concentrate (RCC) within 24 hours	Transfusion:
Country	oxytocin i.v., ergometrine i.m.,		RCC units
Country: Ireland	misoprotol (intrauterine and/or PR),	Definition of success of treatment: NR	G1 : 18 ± 11.2
litelatiu	haemobate (i.m or intramyometrial)		G2 : 16 ± 6.1
Enrollment	and uterine massage.	Method of blood loss measurement: NR	FFP units
period:	Groups:		G1: 9 ± 4.5
Three year period	G1: recombinant factor VII a	Severity: NR	G2 : 10 ± 6.9
starting in 2003	G2: control (no rFVIIa)	Inclusion criteria:	
Birth setting:	,	Massive PPH	Pooled platelets
Hospital	N at enrollment:	Cases received rFVIIa (all had prolonged PTs)	G1 : 4 ± 2.4 G2 : 2 ± 1.6
i loopital	G1 : 6	Controls transfused with largest number of RCC and	G2. 2 ± 1.0
Facility	G2 : 6	had prolonged PT	Pooled cyroprecipitate
characteristics:	N at follow-up:		G1: 4 ± 3
NR	G1 : 6	Exclusion criteria:	G2: 1 ± 1.6
Formalian and NID	G2 : 6	See above	52. 1 ± 1.0
Funding: NR	Duration of treatment: NR	Maternal age, yrs, mean ± SD:	ICU admission: NR
Design:	Duration of treatment. NR	G1 : 34 ± 2.8	
Case-control	Timing of treatment: NR	G2 : 31 ± 4.6	Anemia: NR
(retrospective)	Order of treatment: NR	Devites no	
	Order of treatment. NK	Parity, n: G1: 2 ± 0.5	Other:
	Length of follow-up: NR	G2: 1 ± 0.75	Prothrombin time (PT), worst
		G2. 1 ± 0.75	G1: 27 ± 5.7
		Gestation, days, mean ± SD:	G2: 25 ± 5.9
		G1: 263 ± 45.7	PT time, best
		G2 : 279 ± 8.7	G1: 14 ± 3.1
		51 27 5 2 5.7	G2: 18 ± 3.4
		Single pregnancy: NR	Ethain and James And
			Fibrinogen, lowest g/L
		Multiple pregnancy: NR	G1 : 1.2 ± 0.8 G2 : 1.2 ± 0.7
			G2. 1.2 ± U.1
		Race/ethnicity: NR	Length of stay: NR
			Longin or stay. 1410
		BMI: NR	Mortality: No deaths
		Baseline hemoglobin: NR	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
			Uterine preservation:
		SES: NR	Hysterectomy
			G1 : 3/6 (50)
		Mode of birth, n (%):	G2: 4/6 (67)
		Cesarean	
		G1: 5 (83)	Future fertility: NR
		G2: 5 (83)	
			Breastfeeding: NR
		Risk factors: NR	
			Psychological impact: NR
		Primary etiology of PPH: NR	Harms of intervention:
			ARDS
			G1: 1/6
			G2: 0
			G2. 0
			Confounders: NR
			Effect modifiers: NR

Comments: "There were few short-term complications in both groups. All mothers in both groups survived with no long-term sequelae

Table D-63. Evidence table for studies addressing management of PPH (Touboul 2008)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Touboul et al.,	Selective arterial embolization (SAE)	Severe PPH: blod loss > 1500 cc and either	ICU admission: 100% post procedure
2008 ⁶⁴		hemodynamic shock (defined by need for continuous	Post procedure
Country:	Prior to SAE:	perfusion of vasopressors) or disseminated intravascular	Mortality:
France	Management for vaginal delivery:	coagaiation (platelet count < 50,000 per min , elevated	G1: 2
Tarioc	bimanual uterine exam, removal of	prothrombin time defined as greater than twice the	01. 2
Enrollment	retained placental parts, inspection	control values, hypofibrinogenemia, defined as less than	Harms, n (%):
period:	for laceration or tears; surgical tears	150 mg/dl and a prothrombin rate < 50%) or both.	Cardiogenic pulmonary edemas related to
Jan 1998 to Jan	repaired prior to SAE.		hemorrhage
2002	For cesarean delivery: abdominal	Definition of success of treatment: Uterine	G1 : 5
Dieth a attima.	ultrasound to verify absence of	preservation	
Birth setting:		SAE effective: 73 (71.5%) 14 required second	Transient renal failure
Hospital	hemoperitoneum. Medical	embolization during 1 st 24 hours	G1: 7 (1 patient developed cortical necrosis
Facility		Surgery required: 29	and end stage renal failure)
Facility	oxytocicin up to 55IU, and		,
characteristics:		Method of blood loss measurement: Collection bag	Myocardial ischemia
University	over an hour and second injection	placed at end of delivery. For transfer patients added	G1 : 3
teaching hospital	500 µg over 4 hours).	estimated blood loss evaluated by medical team of	
Funding:		hospital of origin.	Ischemia of lumbar plexus
None to report	12 (11.7%) at their hospital and 90		G1 : 1
•	(88.3) transferred from other obstetric	Severity: NR	
Design:	units	Inclusion criteria:	Gluteal pain (4 months)
Case series	Groups:	 Women with life threatening PPH who underwent SAE 	G1 : 1
	G1: SAE		
	GI. SAL	Either gave birth at hospital or were transferred from their institutions that did not have ICLL or vegetaler.	
	N:	other institutions that did not have ICU or vascular	
	G1 : 102	imaging unit	
	Direction of transferents ND	Exclusion criteria: NR	
	Duration of treatment: NR		
	Timing of treatment: Following	Maternal age, yrs, mean ± SD:	
	procedures as listed above.	G1 : 31.8 ± 5.9 (21-45)	
		Parity, n:	
	Order of treatment: NR	G1 : 2.01 ± 1.11 (1-6)	
	Length of follow-up: NR		
		Weeks gestation, n (%):	
		G1 : 38.3 ± 2.9 (28-42)	
		Single pregnancy: NR	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		Multiple pregnancy, n (%): G1: 4 (3.9)	
		Race/ethnicity: NR	
		BMI: NR	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, n:	
		Vaginal G1: 82 (79.4)	
		Forceps: 28/81 (34.5)	
		Cesarean G1: 22 (20.6)	
		Risk factors: NR	
		Primary etiology of PPH, n (%): Atony G1: 44 (43.1)	
		Cervical or vaginal tears G1 : 20 (19.6)	
		Abnormal placentation including placenta accrete and percreta) G1: 14 (13.6)	
		Vaginal thrombosis G1: 11 (10.7)	
		Intrauterine retention G1: 7 (6.8)	
		Placental abruption	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G1: 4 (3.9) Repaired uterine rupture G1: 2 (1.9)	

Table D-64. Evidence table for studies addressing management of PPH (Sakse 2007)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH: NR	Blood loss: NR
Sakse et al.,	Peripartum hysterectomy		Harms, n (%):
2007 ⁶⁵		Definition of success of treatment: NR	Complications following peripartum
	Groups:		hysterectomy
Country:	G1a: Cesarean hysterectomy	Method of blood loss measurement: NR	Infection: 13 (9)
Denmark	G1b: Postpartum hysterectomy		
	Total: 152 hysterectomies due to	Severity: NR	Bladder lesion: 10 (7)
Enrollment	bleeding		
period:		Inclusion criteria:	Ureter lesion: 3 (2)
1995-2004	Duration of treatment: NA	Peripartum hysterectomy	
			Ooforectomy: 8 (5)
Birth setting:	Timing of treatment: NA	Parity, n:	
Hospital		Nulliparous	Abscess: 3 (2)
	Order of treatment:	G1a: 23	
Facility	Women received the following	G1b: 13	Lung embolus: 1 (1)
characteristics:	treatments, n:		
Multiple Danish	Oxytocin: 128	Multiparous	Death: 2 (1)
hospitals	Ergot alkaloid:59	G1a: 78	
	Prostaglandin: 93	G1b : 38	Re-operation: 16 (11)
Funding:	Misoprostol: 56		
Novo Nordisk,	Uterine/vaginal packing: 23	Weeks gestation: NR	
Hvidovre Hospital	Ligation: 32		
	b-Lynch: 26	Single pregnancy: NR	
Design:	rFVIIa: 3		
Population-based		Multiple pregnancy: NR	
Case Series	Length of follow-up: NR		
(Registry)		Mode of birth, n:	
		Cesarean: 101	
		Vaginal: 51	
		Risk factors: NR	
		Primary etiology of PPH, n (%):	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
		Atony	
		G1a: Nulliparous: 14 (61)	
		G1a: Multiparous: 14 (18)	
		G1b: Nulliparous parae: 6 (46)	
		G1b: Multiparous: 12 (32)	
		Placenta previa	
		G1a: Nulliparous: 1 (4)	
		G1b: Multiparous: 14 (18)	
		Placenta accreta	
		G1a: Nulliparous: 2 (9)	
		G1a: Multiparous: 36 (46)	
		G1b: Multiparous: 3 (8)	
		DIC	
		G1a: Nulliparous: 4 (17)	
		G1a: Multiparous: 4 (5)	
		G1b: Nulliparous parae: 3 (23)	
		G1b: Multiparous: 5 (13)	
		Laceration	
		G1a: Nulliparous: 1 (4)	
		G1a: Multiparous: 9 (12)	
		G1b: Nulliparous parae 3 (23)	
		G1b: Multiparous 17 (44)	
		Unclassified	
		G1a: Nulliparous: 1 (4)	
		G1a: Multiparous: 1 (1)	
		G1b: Nulliparous parae: 1 (8)	
		G1b: Multiparous: 1 (3)	

Table D-65. Evidence table for studies addressing management of PPH (Ahonen 2007)

Study	nce table for studies addressing ma	Inclusion/Exclusion	2
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Blood loss, mean ± SD (range):
Ahonen et al.,	Recombinant activated factor VIII	Consider use of rFVIIa when patient has lost about 1.5	Total bleeding, liters
2007 ⁶⁶	Dose	times her blood volume	G1: 11.3 ± 4.5 (4.4-20.0)
Country	G1: 100 ± 14 (73-122) ug/kg		G2: 8.0 ± 3.1 (5.0-19.0)
Country:		Definition of success of treatment : Good response if	p=0.005
Finland	Groups: G1: rFVIIa	bleeding after administration was 1000 ml or less and no	
Enrollment	G2: control	additional interventions needed or only vaginal	Transfusion:
period:	G2. Control	lacerations sutured. Moderate response if bleeding more	RBC (units)
NR to Nov. 2006	N at enrollment:	than 1000 ml but no additional surgical or radiological	G1 : 20 ± 8 (7-39)
Diath acttions	G1 : 26	procedures required. Poor response if cessation of	G2 : 13 ± 6 (6-26)
Birth setting:	G2 : 22	bleeding necessitated a subsequent selective arterial	p=0.003
Hospital	N of follow was	embolization or surgical interventions (laparotomy for	
Facility	N at follow-up:	hemostasis and/or arterial ligation)	Platelets (units)
Facility	G1: 26 G2: 22		G1 : 23 ± 12 (8-54)
characteristics:	G2: 22	Method of blood loss measurement: NR	G2 : 14 ± 10 (8-48)
Tertiary referral	Duration of treatment: NR		p=0.014
Funding: NR		Severity: Entire cohort defined as "massive PPH"	
	Timing of treatment: NR	Inclusion criteria:	FFP units
Design:	Order of treatment: NR	Cases were women treated with rFVIIa during	G1 : 12 ± 6 (4-22)
Retrospective		existence of guidelines	G2 : 10 ± 5 (4-18)
cohort	Length of follow-up: NR	 Controls treated for a major PPH during same period 	
		without rFVIIa	Response to rFVIIA, n:
		Without IF viia	Good
		Exclusion criteria: NR	G1 : 17
		Maternal age, yrs, mean ± SD:	Moderate
		G1: 33 ± 4	G1: 3
		G2: 35 ± 4	01. 5
			Poor
		Parity, n:	G1 : 6
		1 st pregnancy	
		G1 : 12	ICU admission
		G2 : 12	G1: 1
		and	G2: 0
		2 nd pregnancy	
		G1: 5	Anemia:
		G2 : 6	Hemoglobin (g/l)
		3 rd pregnancy	G1: 56 ±16 (30-95)
		G1: 6	31. 00 ±10 (00 00)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	intervention	Criteria & Population	Outcomes
•		G2: 1	G2 : 64 ± 17 (27-92)
			p=0.126
		4 th or more	i constant
		G1: 3	Length of stay, mean ± SD (range)
		G2 : 3	G1 : 8 ± 3 (3-18)
		02. 0	G2 : 8 ± 4 (4-16)
		Weeks gestation, n (%):	32. 0 ± 4 (4-10)
		G1 : 38 ± 3	Mortality: None
			wortailty. None
		G2 : 38 ± 4	the decrease of a
			Uterine preservation:
		Single pregnancy: NR	Hysterectomy
			G1: 8
		Multiple pregnancy, n (%):	G2: 6
		Twin	
		G1: 4 (15.4)	Future fertility: NR
		G2: 6 (27.3)	
		, ,	Breastfeeding: NR
		Race/ethnicity: NR	
		,	Psychological impact: NR
		ВМІ	
		Height, cm	Harms of intervention:
		G1: 167 ± 6	Pulmonary edema
		G2: 165 ± 8	G1: 1
		G2. 105 ± 0	G2: 0
		NA	
		Weight, kg	Pulmonary embolism
		G1 : 78 ±11	G1: 1
		G2 : 89 ±21	G2: 0
			32. 0
		Baseline hemoglobin: NR	Plasmapheresis due to pre-eclampsia and
			HELLP
		SES: NR	G1: 0
			G2 : 1
		Mode of birth, n:	G2: 1
		Vaginal	Confounders: NR
		G1 : 15	
		G2: 10	Effect modifiers: NR
		Instrumental	
		G1: 1	

Description Criteria & Population	Outcomes
00.4	
G2 : 1	
Cesarean	
G1 : 10	
G2: 11	
Risk factors, n:	
Pre-eclampsia Pre-eclampsia	
G1: 2	
G2 : 3	
UELLD	
HELLP	
G1 : 0	
G2 : 1	
Previous endometriosis	
G1: 4	
G2 : 2	
Primary etiology of PPH, n (%):	
Atony	
Atony	
G1 : 9 (34.6)	
G2 : 8 (36.4)	
Abnormal placentation	
G1: 3 (11.5)	
G2 : 3 (13.6)	
G2. 3 (13.0)	
Retained placenta	
G1 : 5 (19.2)	
G2 : 4 (18.2)	
OZ. 7 (10.2)	
Uterine or birth canal tear	
G1: 9 (34.6)	
G2 : 7 (31.8)	

Table D-66. Evidence table for studies addressing management of PPH (Alfirevic 2007)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Blood loss, estimated L mean (range):
Alfirevic et al.,	Recombinant activated factor VIIa		G1a: 5.8 (4.5-9.4)
2007 ⁶⁷	Groups:	Definition of success of treatment: NR	G1b: 2.5 (0.6-9)
Country:	G1a: troated with rE\/IIa as primary		
JK, Denmark,	therapy for PPH	Method of blood loss measurement: NR	Transfusion, n (%):
Finland, France,	G1b: treated with rFVII as secondary		Packed RBCs (range)
celand, Ireland,	prophylaxis after or as support for	Severity: NR	G1a : 13 (8-21)
Vetherlands,		Inclusion criteria:	G1b: NR
Norway, Sweden	considered successful on its own	Cases of obstetric hemorrhage in which rFVIIa was	None
Norway, Sweden	Considered successful off its own	used	G1a : 3 (3)
Enrollment	N:	useu	G1b : 3
period:	G1a: 92	Exclusion criteria: NR	
2000 to 2004	G1b : 16	Metawal are two many CD: ND	Less than 10
Dirth cotting.		Maternal age, yrs, mean ± SD: NR	G1a : 24 (27)
Birth setting:	Medical management of PPH:	Parity, primipara n (%):	G1b : 6
Hospitals	None	G1a: 38 (45)	
Engility	G1a: 5 (5)	G1b: 7	10-14.9
Facility characteristics:	G1b: 0		G1a: 24 (27)
		Weeks gestation: NR	G1b : 3
Tertiary care,	One medical treatment		
community	G1a: 16 (17)	Single pregnancy: NR	15-19.9
nospital, etc. – all	G1b: 3		G1a : 15 (17)
maternity hospitals		Multiple pregnancy: NR	G1b: 1
in participating countries	More than 1 medical treatment		
Countiles	G1a: 71 (77)	Race/ethnicity: NR	20 or more
Funding:	G1b: 13		G1a: 24 (27), 2 missing
Novo Nordisk,		BMI: NR	G1b: 2, 1 missing
Bagsvaerd,	Hemostatic interventions:		
Denmark.	None reported	Baseline hemoglobin: NR	Platelets
Docien.	G1a : 12 (13)		G1a: 2 (1-4)
Design:	G1b : 2	SES: NR	G1b: NR
Case series			
(voluntary registry	Manual exploration	Mode of birth, n:	None
- 54.4% of	G1a: 44	Spontaneous vaginal	G1a: 16 (20)
hospitals did not	G1b : 12	G1a: 33 (36)	G1b : 9
respond)		G1b: 7	
	Uterine packing		Less than 3
	G1a: 25	Instrumental	G1a: 35 (43)

	G1b : 2	G1a : 13 (14)	G1b : 2
		G1b: 1	
	Embolization		3-4.9
	G1a : 8	Cesarean	G1a: 12 (15)
	G1b: 2	G1a : 46 (50)	G1b: 3
		G1b: 8	
	Hysterectomy	0.0.0	5-6.9
	G1a: 33	Risk factors: NR	G1a : 10 (12)
	G1b : 1	Mak ractors. MK	G1b: 1
	GIB. 1	Primary etiology of PPH, n:	GIB. I
	Vessel ligation	Atony	7 or more
	G1a: 16	G1a: 52	G1a: 9 (11), 10 missing
	G1b: 2	G1b: 8	G1b: 0, 1 missing
	010. 2	018.0	Orb. 0, 1 missing
	Hemostatic sutures	Trauma/birth canal tears	Fresh frozen plasma
	G1a : 15	G1a: 27	G1a: 2 (1.1-3.7)
	G1b: 2	G1b: 4	G1b: NR
	018.2	015. 4	O I D. TVIC
	Other surgery	Placenta previa	None
	G1a: 16	G1a : 15	G1a : 4 (5)
	G1b: 2	G1b: 3	G1b: 6
	D and a section of AID	Placental abruption	Less than 1
	Duration of treatment: NR	G1a: 6	G1a : 12 (14)
	Timing of treatment: NR	G1b : 0	G1b: 4
	Order of treatment: NR, but all of	Retained placenta	1-2.9
	G1b received rFVIIa after primary	G1a: 17	G1a : 41 (47)
	treatment for PPH (as prophylaxis	G1b: 3	G1b : 1
	after successful initial therapy)		
	Length of follow-up: NR	Infection	3-4.9
	Length of follow-up. NR	G1a : 5	G1a : 17 (19)
		G1b: 1	G1b: 1
			3.2.
		Other	5 or more
1		G1a: 7	G1a: 14 (16), 4 missing
		G1b: 2	G1b: 3, 1 missing
			ICU admission:
			G1a : 71 (78)
			G1b: 10 (1 missing)

,
Days on ICU: G1a: 2 (1-4), 65 G1b: 2 (1-14), 10 Anemia: NR
Length of stay: NR
Mortality: G1a: 5 (5) G1b: 0
Uterine preservation: Total # with hysterectomy prior to rFVIIa G1a: 33 G1b: 0 Total # with hysterectomy after rFVIIa G1a: 13 G1b: 1
Future fertility: NR
Breastfeeding: NR
Psychological impact: NR
Harms of intervention, n (%): DVT or pulmonary embolism, G1a: 4 (4) 3 missing G1b: 0
Sepsis G1a: 6 (7) 3 missing G1b: 1
Clinical DIC G1a: 21 (26), 10 missing G1b: 4, 6 missing
HELLP G1a: 1 (1), 3 missing

	G1b : 2
	Suspected amniotic fluid embolism G1a: 0, 3 missing G1b: 0
	Renal failure requiring dialysis G1a: 5 (5), 1 missing G1b: 0
	Respiratory failure requiring ventilation G1a: 23 (25), 1 missing G1b: 0
	Other organ failure G1a: 4 (5), 4 missing G1b: 0
	Cardiac arrest G1a: 7 (8), 3 missing G1b: 0 Myocardial infarction: NR
	Suspected allergic reaction: NR
	No reported complications G1a: 17 (18) G1b: 6
	Confounders: NR
	Effect modifiers: NR

PPH and 1 woman developed thrombosis involving jugular and subclavian vein right upper arm and axilla not thought to be related to rFVIIa use).

BOTH groups were exposed to FVIIa, so one could potentially attribute any complication in G1a or G1b to exposure to the intervention.

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss (mL):
Skupski et al.,	Safety/early intervention program	1 or more of the following: estimated blood loss of ≥	G1 : 2725 ± 1289
2006 ⁶⁸	that d 1)formation of obstetric rapid	1500 mL, need for blood transfusion, need for uterine	G2 : 2429 ± 1214
Country:US	response team, modeled after the	packing, performance of uterine artery ligation, and	p=0.46
Country.03	cardiac arrest team, including	performance of cesarean hysterectomy. => Called this	
Enrollment	quarterly mock drills on all shifts for	"major obstetric hemorrhage" and differentiated it from	Transfusion (mL):
period:	various emergency clinical	regular PPH	G1 : 1313 ± 1029
Pre: 2000-2001	scenarios. 2)development of clinical		G2 : 1194 ± 1547
	pathways, guidelines, and protocols	Definition of success of treatment : Changes in patient	p= 0.8
Intervention: late	designed to provde for early	care and outcomes (maternal mortality, lowest pH, and	
2001	diagnosis of patients at risk for	lowest temperature, occurrence of coagulopathy)	ICU admission: NR
	major obstetric hemorrhage and for		
Post: 2002-2005	streamline care in emergency	Method of blood loss measurement: NR	Anemia: NR
	situations. 3) separation of in-house		
Birth setting:	obstetric and gynecologic	Severity: per definition, all d cases more severe than	Length of stay: NR
Hospital	responsibilities to allow the in-house		
	obstetrician to focus on obstetric		Mortality:
Facility	emergencies without fear of possibly	Inclusion criteria:	G1 : 2 (16.7)
characteristics:	neglecting gynecologic	Identified prospectively through an ongoing Quality	G2 : 0 (0.0)
Tertiary care	emergencies. 4) formally revised the	Assurance program for the entire patient cohort (2000-	
academic hospital	duties of the in-house obstetrician to	2005), and meeting criteria of major obstetric	Uterine preservation: NR
Eundina, ND	continuous and frequent monitoring	hemorrhage	
Funding: NR	of all patients on the Labor and	Exclusion criteria:	Future fertility: NR
Design:	Delivery unit, including those	all patients presenting with major obstetric	
Pre-post	patients who had other private		Breastfeeding: NR
•	obstetricians. 5)Empowered care	hemorrhage during time period d	
		Maternal age was mean + SD:	Psychological impact: NR
	1 1 1 1 1 1	Maternal age, yrs, mean ± SD:	, , , ,
	# P 1 :: \ \	G1 : 36.5 ± 6.0	Harms of intervention: NR
	involve senior members of the	G2 : 34.2 ± 5.9	Confounders: NR
		Parity, n:	Comounacis. IVIX
		G1 : 1 (0-3)	Effect modifiers: NR
		G2 : 1 (0-5)	
	(particularly in cases of hemorrhage		II ND
		Weeks gestation: NR	Harms: NR
	the severity of hemorrhage). A		
	senior member of the department	Single pregnancy: NR	
	then discussed the issue	angle prognancy int	

Study	Intervention	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
-	immediately with the attending	Multiple pregnancy: NR	
	physician to avoid delay and		
	address problems earlier. 6)	Race/ethnicity: NR	
	Through weekly didactic sessions,		
	staff were educated to recognize the	BMI: NR	
	stages of hemorrhage described in		
	the Advanced Trauma Life Support	Baseline hemoglobin NR	
	Manual and disseminated		
	information regarding the new	SES: NR	
	protocols for patient care.		
	7) Established the role of the	Mode of birth: NR	
	Trauma Team that responds to	Risk factors, n (%):	
	assist in cases of severe obstetric	Prior PPH: NR	
	hemorrhage.	FIIOLFFII. INC	
		Advanced maternal age: NR	
	Additionally, they 1) prepared for	Advanced maternal age. 1417	
	major hemorrhage in patients with	Multinarity: NR	
	known placenta previa. 2) Prepared	inditiparity. 1410	
	for major nemorrnage in patients	Race/ethnicity: NR	
	with suspected placenta accrete. 3)	Trado, our mony. The	
	Obtained peripartum or	History of cesarean:	
	intraoperative consultation with the	G1: 6 (50.0)	
	Trauma Team as necessary. 4)	G2 : 32 (65.3)	
	Counseled patients with suspected		
	placenta accrete about the likely	Labor induction/augmentation: NR	
	decreased maternal mortality of	ŭ	
	planned cesarean hysterectomy. 5) Schedule cesarean delivery and	Fibroids: NR	
	cesarean hysterectomy in the main		
	operating room under the direction	Preeclampsia: NR	
	of senior gynecologic surgeons.		
	or serilor gyriecologic surgeons.	Eclampsia: NR	
	Groups:		
	G1: 2000-2001, pre intervention	Pregnancy-induced hypertension: NR	
	G2: 2002-2005, post intervention		
	N:	Pre-existing hypertension: NR	
	G1 : 12		
	G2: 49	Obesity: NR	
	52. 40		
		Diabetes: NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Duration of treatment: NR	Placenta previa: NR	
	Timing of treatment: NR	Multiple gestation: NR	
	Order of treatment: NR	Polyhydramnios: NR	
	Length of follow-up: NR	Prolonged labor: NR	
		Chorioamnionitis: NR	
		Retained placenta: NR	
		Antepartum hemorrhage: NR	
		Primary etiology of PPH, n (%): Atony: NR	
		Coagulopathy: NR	
		Trauma: NR	
		Placenta accrete G1: 4 (33.3) G2: 11 (22.4)	
		Placenta previa: NR	
		Placental abruption: NR	
		Retained placenta: NR	
		Uterine inversion: NR	
		Subinvolution: NR	

Table D-68. Evidence table for studies addressing management of PPH (Akinbiyi 2004)

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
-	intervention	·	Catoonico
Author:	Intervention:	Operational definition of PPH: NR	Harms of intervention, n (%):
Akinbiyi et al.,	Emergency hysterectomy		Febrile morbidity
2004 ⁶⁹	Total hysterectomy n=50	Definition of success of treatment: NR	G1: 31 (55.4)
	Subtotal hysterectomy n=6		, ,
Country:		Method of blood loss measurement: NR	Ureteric injury
Canada	Groups:		G1: 23 (41.1)
Enrollment	G1: intervention	Severity: NR	
period:	N at enrollment:	ooverny. The	Blood transfusion
		Inclusion criteria:	G1: 20 (35.7)
Jan 1965 to	G1 : 56	Underwent emergency hysterectomy within 24 hours of	G1. 20 (33.7)
Dec 1993	N at follow-up:	delivery	Daniel fallens
Birth setting:	G1 : 56	Residents of province of Saskatchewan	Renal failure
•	G1. 30	Retrievable case record	G1 : 19 (33.9)
Hospital	Duration of treatment: NR	Tetrievable dase record	
F:!!!		Exclusion criteria: NR	Pulmonary atelectasis
Facility	Timing of treatment: NR		G1: 18 (32.1)
characteristics:	Order of treatment: NR	Maternal age, yrs, mean (range):	
Tertiary care	Order of treatment. NA	G1 : 29.5 (14-44)	Wound infection
Funding: NR	Length of follow-up: NR	Parity, mean (range):	G1 : 17 (30.4)
runuing. NK			
Design:		G1 : 4.2 (1-10)	Septicemia
Case series,		West and the second	G1: 13 (23.2)
retrospective		Weeks gestation, n (range):	31. 10 (20.2)
Tottoopootivo		G1 : 36.6 (28-42)	Psychological disturbance
		Single pregnancy, n (%): NR	G1 : 13 (23.2)
		Multiple pregnancy, n (%): NR	Hypovolemia
			G1: 12 (21.4)
		Race/ethnicity: NR	
			Pelvic abcess
		BMI, mean (range):	G1: 9 (16.1)
		Height	O - uf - v - d ND
		G1 : 164.2 (145-187)	Confounders: NR
		G1. 104.2 (140-101)	Effect modifiers: NR
		NA	Littot modifiers. Mix
		Weight, kg	
		G1 : 67.5 (42-130)	
		Baseline hemoglobin: NR	

SES: NR Mode of birth, n: NR Risk factors associated with hysterectomy, n: Prior PPH **G1**: 14 Chorioamnionitis **G1**: 8 Previous cesarean **G1**: 27 Grande multiparity **G1**: 21 Oxytocin augmentaiton **G1**: 25 Tocolytic administration **G1**: 5 Indication for Hysterectomy, n (%): Atony **G1:** 27 (48.2) Placenta accrete **G1**: 15 (26.8) Uterine rupture **G1:** 6 (10.7) Chorioamnionitis **G1:** 6 (10.7) Extension of uterine incision (cervical) **G1:** 2 (3.6)

Table D-69. Evidence table for studies addressing management of PPH (Forna 2004)

mergency peripartum hysterectomy	Criteria & Population Operational definition of PPH: NR	Outcomes Blood loss, estimated (mL), mean ± SD
mergency peripartum hysterectomy	Operational definition of PPH: NR	
		G1: 3325.6 ± 1839.2
	Definition of success of treatment: NR	Transfusion, units transfused, mean ± SD
	Method of blood loss measurement: NR	G1 : 6.9 ± 5.3
at enrollment: 1: 55	Severity: NR	ICU admission: NR
at lollow-up.	Inclusion criteria:	Anemia: NR
uration of treatment: NR	delivery	Length of stay, days, n ± SD G1: 11.0 ± 7.9
to the section of Alba	Exclusion criteria: Peripartum hysterectomies performed for gynecologic	Mortality, n (%)
rder of treatment: NR	reasons (2 for cervical cancer and 1 for leiomyomata)	G1 : 2 (3.6)
	Maternal age, yrs, mean ± SD: G1: 29.0 ± 6.8	Uterine preservation: NA
		Future fertility: NA
		Breastfeeding: NR
	G1: 38.2 ± 4.0	Psychological impact: NR
	Single pregnancy, n (%): NR	Harms of intervention, n (%) Hematologic
	Multiple pregnancy, n (%): NR	G1 : 54 (98.2)
	Race/ethnicity: NR	Infectious G1: 30 (54.6)
	BMI: NR	Pulmonary
	Baseline hemoglobin: NR	G1 : 9 (16.4)
	SES: NR	Genitourinary G1 : 6 (10.9)
	Mode of birth, n: Vaginal	Gastrointestinal G1: 2 (3.6)
u ir	ration of treatment: NR ming of treatment: NR der of treatment: NR mgth of follow-up: NR	Had hysterectomy during same hospitalization as delivery Exclusion criteria: Peripartum hysterectomies performed for gynecologic reasons (2 for cervical cancer and 1 for leiomyomata) Maternal age, yrs, mean ± SD: G1: 29.0 ± 6.8 Parity, n: G1: 3.3 ± 2.8 Weeks gestation, mean ± SD: G1: 38.2 ± 4.0 Single pregnancy, n (%): NR Multiple pregnancy, n (%): NR Race/ethnicity: NR BMI: NR Baseline hemoglobin: NR SES: NR

Ta	T
G1 : 17	
	Cardiovascular
Cesarean	G1: 2 (3.6)
G1 : 38	
	Psychiatric
Risk factors, n (%):	G1: 2 (3.6)
History of cesarean	G1. 2 (3.0)
G1: 24 (43.6)	N
	Neurologic
≥ 2 previous cesarean deliveries	G1 : 1 (1.8)
G1: 11 (20.0)	
G1. 11 (20.0)	Other
	G1: 10 (18.2)
Placenta previa	
G1 : 4 (7.3)	Confounders: NR
Chorioamnionitis	Effect modifiers: NR
G1: 12 (21.8)	
G1: 12 (21.0)	
Primary indication for hysterectomy, n (%):	
Atony	
G1: 31 (56.4)	
G1. 31 (30.4)	
Placenta accreta	
G1 : 11 (20.0)	
Infection	
G1 : 6 (10.9)	
Bleeding	
G1 : 3 (5.4)	
Dehiscence/rupture	
G1: 3 (5.4)	
31. 3 (3.7)	
Other	
G1: 1 (1.8)	
10.1. (1.0)	

Table D-70. Evidence table for studies addressing management of PPH (Rizvi 2004)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH:	Blood loss:
Rizvi et al., 2004	Revised management guidelines	Primary PPH > 1000 ml	Total > 1500 mL
71	distributed to all staff involved with		G1: 28 (52)
	labor and delivery care. Regular	Definition of success of treatment: NA	G2: 5 (33)
Country:	training and use of practice drills.		
Ireland		Method of blood loss measurement: Not routine to	Total > 2000 mL
	Hospital had active management	measure blood loss postpartum for all deliveries. When	G1: 15 (28)
Baseline period:	policy for 3 rd stage including 1 mL	blood loss considered substantial ascertained by	G2 : 0
Jan 1999 to June	syntometrine im following all vaginal	measuring blood from suction containers and weighing of	
1999	deliveries unless evidence of	swabs	Total > 2500 mL
1	hypertension (then 5 IU i.v.)		G1 : 10 (19)
Evaluation		Severity: near miss mortality defined as PPH ≥2500 ml	G2: 0
period:	i.v.	blood loss, transfusion ≥ 8 units, development of DIC and	
Jan 2002-June		admission to ICU	Total > 3000 mL
2002	Groups:	damission to 100	G1: 7 (13)
2002	G1: pre	Inclusion criteria:	G2: 1 (6.7)
Birth setting:	G2: post	Treatment for PPH in hospital under study	32. 1 (0.7)
Hospital	62. post	Treatment for FFTT in nospital under study	Transfusion, n (%):
Ποσριίαι	Total N deliveries:	Exclusion criteria:	Any blood transfusion
Facility	G1 : 3,176		G1: 26 (48)
characteristics:	G2 : 3,300	See inclusion	G2 : 5 (33)
Unclear	G2. 3,300	Metamalaga yan maan y CD:	G2. 3 (33)
Unclear	N with massive PPH:	Maternal age, yrs, mean ± SD:	Blood transfusion > 6 units
Eundina: ND	G1 : 54	G1 : 28.5 ± 6.1	
Funding: NR		G2 : 27.6 ± 4.8	G1 : 9 (17)
D!	G2 : 15		G2 : 0
Design:	p< 0.001	Parity, n (%):	1011 - 1 - 1 - 1 (0/)
pre-post	-	Primiparous	ICU admission, n (%):
	Duration of treatment: NA	G1: 27 (50)	G1 : 25 (46)
		G2: 7 (47)	G2 : 2 (13)
	Timing of treatment: NA		
		Weeks gestation: NR	Required examination under general
	Order of treatment, % receiving		anesthesia
	component:	Single pregnancy: NR	G1 : 6 (11)
	Oxytotic agent		G2: 5 (33)
	G1 : 100	Multiple pregnancy: NR	
			Uterine preservation, n (%):
I	Repeat oxytotic	Race/ethnicity: NR	Peripartum hysterectomy
	G1 : 18		G1: 3 (5.6)

Study	Intervention	Inclusion/Exclusion	Outcomes
escription	intervention	Criteria & Population	Outcomes
-		BMI: NR	G2 : 0
	Ergot derivative		
	G1 : 15	Baseline hemoglobin: NR	Deviation from hospital guidelines, n (%)
		,	Spontaneous vaginal delivery
	Oxytocin infusion	SES: NR	G1 : 10 (77)
	G1: 85	02011111	G2: 0
	3 1. 33	Mode of birth, n:	52. 0
	Misoprostol	Spontaneous vaginal	Elective lower segment cesarean
	G1: 47	G1: 13 (24)	G1: 3 (21)
	91. 47	G2 : 4 (27)	G2: 0
	Coult on root	G2. 4 (21)	G2. 0
	Carboprost		
	G1 : 7	Lower segment c/s elective	Emergency lower section cesarean
		G1 : 14 (26)	G1: 2 (11)
	Length of follow-up: NR	G2 : 2 (13)	G2 : 0
		Lower segment c/s emergency	Instrumental delivery
		G1: 19 (35)	G1 : 5 (63)
		G2 : 4 (27)	G2 : 0
		Instrumental delivery	Total
		G1: 8 (15)	G1: 20 (37)
		G2 : 5 (33)	G2: 0
		Risk factors, n (%):	Significant deviation from guidelines
		Prior PPH	G1: 7 (13)
		G1 : 2 (3.7)	G2: 0
		G2 : 1 (6.7)	52. 0
		(0.1)	Less need for transfusion, lower ICU
		History of cesarean	admission rate in the post vs. pre period.
		C4. 7 (42)	admission rate in the post vs. pre penod.
		G1 : 7 (13)	Amanaia ND
		G2 : 0	Anemia: NR
		Antepartum hemorrhage	Length of stay: NR
		G1: 9 (17)	Longin or stay. Wit
		G2: 1 (6.7)	Mortality: NR
		52. 1 (0.1)	Mortality. 1913
		Primary etiology of PPH, n (%):	Future fertility: NR
		Atony	,
		G1 : 41 (76)	Breastfeeding: NR

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		G2: 10 (67) Genital tract trauma G1: 5 (9.3) G2: 2 (13)	Psychological impact: NR Harms of intervention: NR Confounders: NR
		Others G1: 8 (15) G2: 5 (33)	Effect modifiers: NR

Table D-71. Evidence table for studies addressing management of PPH (Hoveyda 2001)

Study	nce table for studies addressing ma	Inclusion/Exclusion	
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Hoveyda and	Treatment of secondary PPH	Secondary PPH was defined as excessive vaginal blood	
McKenzie, 2001 ⁷²	including uterine evacuation,	loss or heavy lochial discharge occurring at least 24	Harms, n (%):
Country (111/	antibiotic treatment, conservative	hours after the end of the third stage of labour and	Uterine perforation during surgical evacuation
Country: UK	management (without uterine	during the following six weeks, and in sufficient quantity	G1a: 3/85 (3%)
Enrollment	evacuation)	to prompt a review by an obstetrician.	Hysterectomy
period:	Groups:		One woman underwent hysterectomy after
January 1996 to	G1: women with secondary PPH	Definition of success of treatment : NR (case series)	uterine perforation with metal curette 14 days
December 1998	G1a: utoring ovacuation	N. d. a L. d. L. a L. a L. a L. a L. a L.	after delivery
Birth setting:	G1b: conservative management	Method of blood loss measurement: NR	
Obototrio unit		Inclusion criteria:	
Obototno unit	N at enrollment:	Women with secondary PPH identified from a	
Facility	G1: 132	computerized maternity data set for an OB unit that	
characteristics:	G1a: 87 total (75 had uterine	served a specific health district	
Tertiary hospital	evacuation at initial admission, 12 were treated conservatively at initial	Admitted within 3 year study period	
Funding: NR	•	Exclusion criteria: NR	
runding. NK	evacuation at a later time)	Exclusion criteria. Nix	
Design:	G1b: 45	Maternal age: NR	
Retrospective	N. A. C. H.	Parity, (Nulliparae) n (%):	
case series	N at follow-up:	G1 : 56 (42.4)	
	G1 : 132	3 (12.1)	
	Duration of treatment: NR	Weeks gestation: NR	
	Timing of treatment: NR		
	0-1	Single pregnancy: NR	
	Order of treatment:	Multiple programme (0/)	
		Multiple pregnancy, n (%): G1: 3 (2.3)	
	therapy	G1. 3 (2.3)	
	57 were treated with conservative	Race/ethnicity: NR	
	management as first therapy; 21	indo,onimony. Mix	
	(16%) were reviewed in hospital and	BMI: NR	
	discharged home with antibiotics. 16		
	(28%) re-attended unit with	Baseline hemoglobin: NR	
	continuing symptoms and 12 had		
	uterine evacuation between 1 and 21	SES: NR	
	days after initial admission for		
	continuing symptoms)	Mode of birth, n:	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	Ultrasound of uterus for n=51; 47 (92%) had retained placental tissue;	Induced labour n (%): G1: 40 (30.3)	
	46 underwent uterine curettage; 39 had evacuation without previous ultrasound scanning.	Spontaneous vaginal delivery, n (%): G1: 90 (68.2)	
	Length of follow-up: NR	Assisted vaginal delivery, n (%): G1: 27 (20.4)	
		Cesarean, total, n (%): G1: 15 (11.4)	
		Cesarean, prelabour, n, (%): G1: 5 (3.8)	
		Risk factors, n (%): Primary PPH, n (%) G1: 33 (28.2)	
		Retained placenta, n (%) G1 : 7 (6.0)	
		Primary etiology of PPH: NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Blood loss: NR
_edee et al.,	Hospitalization in ICU for intractable	Intractable PPH: cases that did not respond to usual	
2001 ⁷³	PPH .	treatment within 60 minutes or worsening of maternal	Transfusion, n:
_	Initial treatment: simple bimanual	condition	Received < 4 units RBCs
Country:	compression, oxytocin followed by		G1 : 21
rance	prostaglandin (PGE2) IV and	Definition of success of treatment: NR	G2: 1
Enrollment	maternal resuscitation.		G3 : 0
eriod:		Method of blood loss measurement: Estimated by	
983 to 1998	Follow-up treatments: embolizing the	volume of blood transfused	Received 4-7 units
903 10 1990	selective pelvic vessels or ligating the		G1: 10
Birth setting:	hypogastric arteries	Severity: Intractable PPH	G2: 5
Hospital			G3 : 1
•	Groups (based on primary second-		03. 1
acility	line attempt to arrest hemorrhage):	Patients hospitalized for intractable PPH between	Received 8-20 units
haracteristics:	G1: Bilateral hypogastric artery	1983 and 1998	G1: 11
Tertiary care	ligation		G2: 1
university hospital	G2: Embolization	Exclusion criteria: NR	
	G3: Hysterectomy	Maternal age: NR	G3 : 1
Funding:		imaternal age. Nix	D : 1 00 %
Agency/NR	N at enrollment:	Parity: NR	Received > 20 units
	G1 : 48		G1 : 6
Design:	G2: 8	Weeks gestation: NR	G2 : 1
Retrospective	G3 : 5	•	G3: 3
cohort study	Describes of transfer ND	Single pregnancy: NR	
	Duration of treatment: NR	omgio programoji rak	ICU admission: NR
	Timing of treatment:	Multiple pregnancy: NR	
	Initial treatment: simple bimanual	indupio prognancy. The	Anemia: NR
		Race/ethnicity: NR	
	prostaglandin (PGE2) IV and	Nace/enfincity: Nix	Length of stay: NR
	maternal resuscitation.	BMI: NR	
	Inaternal resuscitation.	DIVII. IVIX	Mortality:
	Follow up treatments, ambalizing the	Baseline hamanlahin, ND	Maternal deaths, total
	Follow-up treatments: embolizing the		G1+G2+G3: 7
	selective pelvic vessels or ligating the		
	hypogastric arteries	SES: NR	Maternal deaths post hysterectomy
	Order of treatment:		G3: 5
	G1: 4 women required hysterectomy	Mode of birth, n (%):	
	post-ligation	Cesarean	Uterine preservation
	G2: 1 women required methotrexate,	G1+ G2: 41/56 (73)	G1+G2+G3: 10 total hysterectomies

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
	1 required ligation, 1 required hysterectomy post-embolization G3: 1 required embolization Length of follow-up: NR	Vaginal G1+G2: 15/56 (27) Risk factors: NR Primary etiology of PPH, n (%): Group 1 Received < 4 units RBCs n=22 Atony: 8/22 Group 2 Received 4-7 units RBCs n=16 Atony: 8/16 Group 3 Received 8-20 units RBCs n=13 Atony: 5/13 Group 4 Received > 20 units RBCs n=10 Atony: 8/22	Future fertility: G1: 7 pregnancies among 10 women desiring pregnancy 1-4 years post-ligation G2: 1 pregnancy 1 year post-embolization (number desiring pregnancy NR) Breastfeeding: NR Psychological impact: NR Harms of intervention: NR Confounders: NR Effect modifiers: NR

Comments: Details for each maternal death (n=7) reported separately in the text.

Table D-73. Evidence table for studies addressing management of PPH (Boyd 1995)

Study	nce table for studies addressing ma	Inclusion/Exclusion	Outcomes
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
Boyd et al., 1995	Interventions for severe delayed	severe delayed postpartum hemorrhage defined as	Harms, n:
/4	postpartum hemorrhage, including	vaginal bleeding occurring after hospital discharge and	Perforation sustained during curettage:
Country: US	curettage, hysterectomy, hypogastic	severe enough to require readmission and/or severe	G1: 1
	artery ligation, laparotomy, oxytocin	enough to require surgery in the operating room (not	
Enrollment	and/or antibiotics,	including patients evaluated in the emergency room not	Asherman's syndrome, n
period:	Groups:	requiring readmission). Hospital policy required admission for any patients needing blood transfusion or	G1a: 2
January 1981 to	G1: patients readmitted with delayed	curettage.	
December 1991	hemorrhage		
Birth setting:	G1a: patients who received curettage	Definition of success of treatment: NR	
hospital			
	N: G1: 113	Method of blood loss measurement: NR	
Facility	G1a : 99 (88%)		
characteristics:	, ,	Severity: severe	
Two tertiary university	Duration of treatment: NA	Inclusion criteria:	
hospitals	Timing of treatment: NR	Medical records reviewed using codes for PPH,	
· .		postpartum complications, delayed PPH, retained	
Funding: NR	Order of treatment:	products of conception, postpartum complications	
Design:	For patients whose bleeding did not	undefined, and post-partum readmission	
case series	resolve with curettage, 6 were ultimately treated by hysterectomy,	Exclusion criteria:	
	one had successful hypogastric	Patients evaluated in emergency room without	
	artery ligation, one had laparotomy	readmission	
	for repair of perforation sustained		
	during curettage	Maternal age, yrs, mean (range):	
	Langth of follow up. ND	G1 : 26 (16-39)	
	Length of follow-up: NR	Parity, %:	
		Multiparous	
		G1 : 61	
		Mark and the second second	
		Weeks gestation, man (range):	
		G1 : 38 (22-42)	
		Single pregnancy: NR	
		onigic pregnancy. Mix	
		Multiple pregnancy: NR	
		Race/ethnicity: NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
		BMI: NR	
		Baseline hemoglobin: NR	
		SES: NR	
		Mode of birth, %: Spontaneous vaginal G1: 69	
		Vacuum extraction G1: 12	
		Forceps G1: 8	
		Cesarean G1: 9	
		Unknown delivery status G1: 2	
		Risk factors, %: History of cesarean G1: 4	
		Previous uterine curettage related to pregnancy loss G1: 27	
		Primary etiology of PPH, n (%): Retained products of conception G1a: 55	

Table D-74. Evidence table for studies addressing management of PPH (O'Leary 1995)

Study	Ince table for studies addressing ma	Inclusion/Exclusion	01
Description	Intervention	Criteria & Population	Outcomes
Author:	Intervention:	Operational definition of PPH:	Harms pre-specified: No
O'Leary,	Bilateral ligation of uterine vessels	Estimated blood loss > than 1,000 mL	Harms, n:
1995 ⁷⁵	Groups:		Broad ligament hematomas
Country: US	G1: intervention	Definition of success of treatment: Bleeding controlled	G1: 2
Enrollment	N at enrollment:		Treatment failures
period:	G1: 265	Method of blood loss measurement: NR	G1a : 7
1963-1992	N by time period:	Constitut ND	G1b: 1
Birth setting:	G1a : 124 (1963-1972)	Severity: NR	G1c: 3
Hospital	G1b : 60 (1973-1982)	Inclusion criteria:	Management of the street fallows and
	G1c : 81 (1983-1992)	Women who experienced PPH at time of cesarean.	Management of treatment failures, n:
Facility	Duration of treatment: NR	Patients selected for ligation after usual mechanical	Hysterectomy G1a: 3
characteristics:	Duration of treatment: NR	techniques and pharmacologic preparations (including	G1b: 1
NR	Timing of treatment: NR	oxytocin i.v., methylergonovine maleate and 15-methyl prostaglandin $F_{2\alpha \text{ IM}}$) failed.	G1c: 2
Funding: NR	Order of treatment: Patients		
Daolani	selected for ligation after usual	Exclusion criteria: NR	Placental site ligation
Design: Case series	mechanical techniques and	Maternal age: NR	G1a : 3
Case selles	pharmacologic preparations		G1b: 0
	(including oxytocin i.v.,	Parity: NR	G1c : 0
	methylergonovine maleate and 15-	Waste matetian ND	Ovarian artery ligation
	methyl prostaglandin F2α IM) failed	Weeks gestation: NR	G1a: 1
	Length of follow-up: NR	Single pregnancy: NR	G1b : 0
		omgie pregnancy. WK	G1c: 1
		Multiple pregnancy: NR	
		Race/ethnicity: NR	
		BMI: NR	
		Baseline hemoglobin: NR	
		Dassins nonlogiosin. 1410	
		SES: NR	
		Mode of birth, %:	
		Cesarean section: 100	
		Risk factors: NR	

Study Description	Intervention	Inclusion/Exclusion Criteria & Population	Outcomes
Description		Primary etiology of PPH, n: Atony G1a: 45 G1b: 38 G1c: 52	
		Placenta previa G1a: 16 G1b: 11 G1c: 9	
		Placental abruption G1a: 14 G1b: 3 G1c: 10	
		Lacerations G1a: 18 G1b: 6 G1c: 7	
		Other G1a: 31 (24 elective) G1b: 2 G1c: 3	

Table D-75. Evidence table for studies addressing management of PPH (Oleen 1990)

Study	Intervention	Inclusion/Exclusion	Outcomes
Description		Criteria & Population	
Author:	Intervention:	Operational definition of PPH: NR	Cessation of hemorrhage, immediate, n (%):
Oleen et al.,	Carboprost tromethamine sterile		G1: 208/237 (87.8)
1990 ⁷⁶	solution (125 or 250 ug)	Definition of success of treatment : Control of	
Countrial	intramuscular, intramyometrial,	hemorrhage	Cessation of hemorrhage, with further
Country:US	intravenous, intrauterine, or		oxytocins:
Enrollment	intracervical	Method of blood loss measurement: NR	G1 : 17/237
period:	Crounce		
Jan 1986 to March	Groups: G1: intervention	Severity: NR	Therapy failed:
1987	G1: Intervention	Inclusion criteria:	G1 : 12/237 (5.1)
	N at enrollment:		
Birth setting:	G1: 237 (blood loss could not be	Receipt of carboprost tromethamine at a study	Blood loss, ml mean (range):
Hospitals	estimated for 10 cases)	hospital	G1: 970 ± 955 (100-9500)
	G1a: 215 success	Data accessible in medical record	G1a: 900 ± 748 (100-9500)
Facility	G1b: 12 failure	Exclusion criteria:	G1b: 2229 ± 2454 (500-9500)
characteristics:		See inclusion	
Multisite- 12 sites	Duration of treatment: NR		Transfusion:
Funding:	Timing of treatment: NR	Maternal age, yrs, mean ± SD:	RBC, n (%)
Upjohn Company		G1: 25.3 ± 5.7	G1 : 64 (27)
'	Order of treatment: NR	Pority n.	
Design:	Length of follow-up: NR	Parity, n:	FFP, cryoprecipitate, or albumen, n (%)
Case series	Length of follow-up. NR	Primiparous	G1: 9 (4)
		G1 : 108	, ,
		Multiparaua	ICU admission: NR
		Multiparous	
		G1 : 113	Anemia: NR
		Name debte effection	
		Non-viable offspring	Length of stay: NR
		G1 : 15	
		Waste wastation ND	Mortality: NR
		Weeks gestation: NR	
		Cin ale magneton ND	Uterine preservation:
		Single pregnancy: NR	Hysterectomy
		M M I	G1: 7
		Multiple pregnancy: NR	Future fertility: NR
		December 114 ND	
		Race/ethnicity: NR	Breastfeeding: NR
		DMI-ND	
		BMI: NR	

Description Criteria & Population Baseline hemoglobin: NR SES: NR Mode of birth, n: Cesarean G1: 72 (30.4) Risk factors, n (%): Labor induction/augmentation G1: 92 (38.8) Fibroids	Psychological impact: NR Confounders: NR Effect modifiers: NR Harms pre-specified: No Harms, n (%): Diarrhea G1: 27 (11.4) Elevated blood pressure G1: 16 (6.8)
Mode of birth, n: Cesarean G1: 72 (30.4) Risk factors, n (%): Labor induction/augmentation G1: 92 (38.8)	Effect modifiers: NR Harms pre-specified: No Harms, n (%): Diarrhea G1: 27 (11.4) Elevated blood pressure
Mode of birth, n: Cesarean G1: 72 (30.4) Risk factors, n (%): Labor induction/augmentation G1: 92 (38.8)	Harms pre-specified: No Harms, n (%): Diarrhea G1: 27 (11.4) Elevated blood pressure
Cesarean G1: 72 (30.4) Risk factors, n (%): Labor induction/augmentation G1: 92 (38.8)	Harms, n (%): Diarrhea G1: 27 (11.4) Elevated blood pressure
Preeclampsia (magnesium treated) G1: 43 (18.1) Primary etiology of PPH, n (%): Chorioamnionitis G1: 3 (1.3) Retained products of conception G1: 27 (11.4) Lacerations G1: 35 (14.8) Peripheral coagulopathy G1: 4 (1.7)	Vomiting G1: 16 (6.8) Elevated temperature G1: 5 (2.1) Flushing G1: 4 (1.7) Tachycardia G1: 4 (1.7)

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Evidence Table Abbreviations

μg Micrograms

μg/kg Micrograms per Kilogram μg/L Micrograms per Liter

ACS Acute Coronary Syndrome

AIP Advanced Interventional Procedure

AMI Acute Myocardial Infarction

ARDS Acute Respiratory Distress Syndrome

AUC Area Under Curve
BMI Body Mass Index
BP Blood Pressure

CH Complete Hysterectomy
CI Confidence Interval
DBP Diastolic Blood Pressure

DIC Disseminated Intravascular Coagulation

DVT Deep Vein Thrombosis

DX Diagnosis

EBL Estimated Blood Loss
FFP Fresh Frozen Plasma
FGF Fibroblast Growth Factor
g/dl Grams per Deciliter
GAB Gabexate mesilate

Hb Hemoglobin

HDU High-Dependency Unit

HELLP Hemolysis, Elevated Liver enzymes, Low Platelet count

HR Heart Rate

ICU Intensive Care Unit IQR Interquartile Range IU International Units

kg/m² Kilograms per Square Liter

L Liters
mg Milligrams
mL Milliliters

mmHg Millimeters of Mercury mmol/L Millimoles per Liter

mo Months

NA Not Applicable NR Not Reported

PAE Pelvic arterial embolization
PC Post cibum (after a meal)
PPH Post-Partum Hemorrhage
pRBC Packed Red Blood Cells

RBC Red Blood Cells

RCC Red Cell Concentrate

rTM Recombinant human soluable Thrombomodulin

SAE Selective Arterial Embolization

SBP Systolic Blood Pressure
SD Standard Deviation
SE Standard Error

SES Socioeconomic Status

SI Shock Index

TAE Transcatheter pelvic Arterial Embolization

UKOSS UK Obstetric Surveillance System

VTE Venous Thromboembolism

Appendix E. Quality/Risk of Bias Ratings

Table E-1. Quality assessment of randomized controlled trials

Outcome Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Anemia								
Ducloy-Bouthors 2011 ¹	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB
Duration of bleeding								
Ducloy-Bouthors 2011 ¹	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB
Ferritin level								
Froessler 2012 ²	High	High	Low	Low	High	High	High	Poor/High RoB
Hemoglobin level								
Froessler 2012 ²	High	High	Low	Low	High	High	High	Poor/High RoB
Need to call for additional help								
Ducloy-Bouthors 2011 ¹	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB
Need for Transfusion/ Transfusion practice								
Ducloy-Bouthors 2011 ¹	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB

Outcome Author, Year	Sequence Generation	Allocation Concealment	Selective Reporting	Other Bias	Blinding of Participants/ Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data	Risk of Bias Rating for Outcome
Deneux-Tharaux 2010 ³	Low	Low	Low	Low	High	High	Low	Fair/Moderate RoB
Physical fatigue								
Prick 2014 ⁴	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB
Quality of life								
Prick 2014 ⁴	Low	Low	Low	Unclear	High	High	Low	Poor/High RoB
Rate of PPH (Overall)								
Deneux-Tharaux 2010 ³	Low	Low	Low	Low	Unclear	Unclear	Low	Fair/Moderate RoB
Rate of severe PPH								
Deneux-Tharaux 2010 ³	Low	Low	Low	Low	Unclear	Unclear	Low	Fair/Moderate RoB
Rate of sulprostone use, use of recommended interventions								
Deneux-Tharaux 2010 ³	Low	Low	Low	Low	High	High	Low	Fair/Moderate RoB

Table E-2. Quality assessment of pre-post studies

Author, Year	Objective clearly stated	Selection criteria prespecified and clearly described	Participants representative of those who would be eligible for the intervention	All eligible participants enrolled	Sample size sufficient	Intervention clearly described and delivered consistently	Outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently	Outcomes assessors blinded	Loss to follow-up after baseline 20% or less and accounted for in analysis	Statistical methods examined changes in outcome measures from pre to post	Outcome measures of interest taken multiple times pre and post	For group level interventions, statistical analysis accounted for use of individual-level data	Rating
Mallaiah, 2014 ⁵	+	+	+	CD	-	+	+	-	+	+	-	-	Poor
Shields, 2014 ⁶	+	+	+	+	+	-	+	-	+	+	+	-	Fair
Lappen, 2013 ^{7, 8}	+	+	+	+	+	+	-	-	+	+	+	-	Fair
Laas, 2012 ⁹	+	+	+	+	-	+	+	-	+	+	-	-	Fair
Markova, 2012 ¹⁰	+	+	+	+	-	+	+	-	+	+	-	-	Fair
Shields, 2011 ¹¹	+	+	+	+	-	+	+	-	+	+	-	-	Fair
Dupont, 2011 ^{12, 13}	+	+	+	+	-	-	+	-	+	+	-	-	Poor
Auduraeu, 2009 ¹⁴	+	+	+	+	+	+	+	-	+	+	-	-	Fair
Skupski, 2006 ¹⁵	+	+	+	-	-	+	+	-	+	+	-	-	Poor
Rizvi, 2004 ¹⁶	-	+	+	CD	-	-	-	-	+	-	-	-	Poor
CD-cannot d	determin	e											

Table E-3. Quality assessment of cohort studies

Author, Year	Represent ative- ness of exposed cohort	Selection of non-exposed cohort	Ascertain- ment of exposure	Outcome of interest not present at start of study	Comparability of cohorts	Assessment of outcome	Duration of follow-up	Adequacy of follow- up of cohorts	Quality Rating
Kim 2014 ¹⁷	-	+	+	+	-	+	+	+	Fair
Chan 2013 ¹⁸	+	+	+	+	-	+	+	+	Fair
Sohn 2013 ¹⁹	-	+	+	+	+	+	-	+	Fair
Bateman 2013 ²⁰	+	+	+	+	+	+	+	+	Good
Ahmed 2012 ²¹	+	+	+	+	-	+	+	+	Fair
Sugawara 2012 ²²	+	+	+	+	+	+	-	+	Fair
Gayat 2011 ²³	+	+	+	+	-	+	+	+	Fair
Markova 2011 ¹⁰	+	+	+	+	-	+	+	+	Fair
Dupont 2011 ¹²	+	+	+	+	-	+	+	+	Fair
Kayem 2011 ^{24, 25}	+	+	-	+	-	-	+	+	Fair
Alexander 2009 ²⁶	+	+	+	+	-	+	+	+	Fair
Feigenber g 2009 ²⁷	+	+	+	+	-	+	+	+	Fair
Sentilhes 2009 ²⁸	+	+	+	+	-	+	+	+	Fair
Zwart 2009 ²⁹	+	+	+	+	-	+	+	+	Fair
Baruah	+	+	+	+	-	+	+	+	Fair

Author, Year	Represent ative- ness of exposed cohort	Selection of non-exposed cohort	Ascertain- ment of exposure	Outcome of interest not present at start of study	Compar- ability of cohorts	Assessment of outcome	Duration of follow-up	Adequacy of follow- up of cohorts	Quality Rating
2008 ³⁰									
Chauleur 2008 ³¹	+	+	+	+	-	+	+	+	Fair
Ahonen 2007 ³²	-	+	+	+	+	+	+	+	Fair
Rizvi 2004 ¹⁶	+	+	+	+	-	+	+	+	Fair
Ledee 2001 ³³	+	+	+	+	-	+	+	+	Fair

Table E-4. Quality assessment of case-control studies

Author, Year	Case definition adequate	Represent- ativeness of cases	Selection of controls	Definition of controls	Comparability of cases and controls	Ascertainment of exposure	Same method of ascertainment for cases and controls	Non- response rate	Quality Rating
Hardeman 2010 ³⁴	+	+	-	+	-	+	+	-	Poor
McMorrow 2008 ³⁵	+	+	-	+	-	+	+	N/A	Fair

Table E-5. Quality assessment of studies reporting harms

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm adequate?	Rating
Cheong 2014 ³⁶	-	unsure	+	+	Poor
Cowan 2014 ³⁷	+	+	+	+	Good
Ferrazzani 2014 ³⁸	-	unsure	+	+	Poor
Inoue 2014 ³⁹	-	unclear	+	+	Poor
Kim 2014 ¹⁷	-	unsure	+	+	Poor
Mallaiah 2014 ⁵	-	unclear	+	+	Poor
Prick 2014 ⁴	+	+	+	+	Good
Teofili 2014 ⁴⁰	+	+	+	+	Good
Zatta 2014 ⁴¹	-	unsure	+	+	Poor
An 2013 ⁴²	+	+	+	+	Good
Gronvall 2013 ⁴³	-	unsure	+	+	Poor
Kim 2013 ⁴⁴	+	+	+	+	Good

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm adequate?	Rating
Lee 2013 ⁴⁵	+	+	+	+	Good
Yamasaki 2013 ⁴⁶	-	unsure	-	+	Poor
Bateman 2013 ²⁰	+	+	+	+	Good
Blanc 2012 ⁴⁷	-	unclear	+	+	Poor
Laas 2012 ⁹	-	unsure	+	+	Poor
Lee 2012 ⁴⁸	-	unsure	+	+	Poor
Poujade 2012 ⁴⁹	-	unsure	+	+	Poor
Froessler 2012 ²	-	unsure	unsure	unsure	Good
Bonnet 2012 ^{50, 51}	-	unsure	+	+	Poor
Ahmed 2012 ²¹	-	unsure	+	+	Poor
Ducloy-Bouthors 2011 ¹	+	+	+	+	Good
Palacios- Jaraquemada 2011 ⁵²	-	unsure	+	+	Poor

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm adequate?	Rating
Sentilhes 2011 ^{53,} 54:#1378	-	unsure	+	+	Poor
Kayem 2011 ^{24, 25}	-	unsure	-	-	Poor
Ganguli 2010 ⁵⁵	-	unsure	+	+	Poor
Wright 2010 ⁵⁶	+	+	+	+	Good
Hardeman 2010 ³⁴	-	unsure	unsure	+	Poor
Feigenberg 2009 ²⁷	+	+	+	+	Good
Fiori 2009 ⁵⁷	-	unsure	+	+	Poor
Lone 2009 ⁵⁸	-	unsure	+	+	Poor
Phillips 2009 ⁵⁹	+	+	+	+	Good
Zwart 2009 ²⁹	-	unsure	+	+	Poor
Alexander 2009 ²⁶	-	unsure	+	+	Poor
Balki 2008, ⁶⁰	-	unclear	+	+	Poor

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm adequate?	Rating
Chauleur 2008 ³¹	-	unsure	+	+	Poor
Gaia 2008 ⁶¹	-	unsure	+	+	Poor
Glaze 2008 ⁶²	-	unsure	unsure	+	Poor
McMorrow 2008 ³⁵	-	-	unsure	-	Poor
Touboul 2008 ⁶³	-	unsure	-	+	Poor
Chauleur 2008 ⁶⁴	-	unsure	+	+	Poor
Alfirevic 2007 ⁶⁵	-	unsure	+	+	Poor
Sakse 2007 ⁶⁶	Unsure	unsure	+	+	Poor
Knight 2007 ⁶⁷	-	unsure	+	+	Poor
Ahonen 2007 ³²	-	unsure	+	+	Poor
Akinbiyi 2004 ⁶⁸	-	unclear	+	+	Poor
Forna 2004 ⁶⁹	+	+	+	+	Good

Author, Year	Were the harms predefined using standardized or precise definitions?	Were all pre-specified harms reported?	Did the author(s) use STANDARD scale(s) or checklist(s) for harms collection?	Were the statistical methods used to assess the main harm adequate?	Rating
Hoveyda 2001 ⁷⁰	-	unsure	+	+	Poor
O'Leary 1995 ⁷¹	-	unsure	+	+	Poor
Boyd 1995 ⁷²	-	unsure	+	+	Poor
Oleen 1990 ⁷³	-	unsure	+	+	Poor

Table E-6. Quality assessment of case series

Table E-6. Qua	iity asse	ssmer	it or c	Jas	5 26	HE	<u> </u>	- 1	- 1					, ,	-	1	1	1			,		1		1		, ,	1	-	1	-			1
Author, Year Cheong, 2014 ³⁶	Confounding and modifying variables accounted for +	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	+ Low rate (≤20/5) attrition	Z Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	+ Clearly stated inclusion/exclusion criteria	+ Measures implemented consistently	+ Appropriate measures for assessing interventions/exposures	Z Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)		Clearly described measures for outcome assessment (Outcome: ICU)	Clearly described measures for outcome assessment (Outcome: Cessation)	+ Clearly described measures for outcome assessment (Outcome: Success)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	+ Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	+ Consistent implementation of outcome assessment	+ Appropriate measures for confounding variables assessment	+ Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	+ Pre-specified potential outcomes	+ Reporting of all pre-specified outcomes
5.1351ig, 2014		INA	1411		A					A						<u>'</u>	,	<i>'</i>	,		,	′	,	•	′		′	, 						
Ferrazzani, 2014 ³⁸	+	-	NR	+	N A	-	+	+	+	N A	/	/	/	/	+	/	/	/	/	/	/	/	/	+	/	/	/	/	+	+	+	-	+	+

Author, Year Inoue, 2014 ³⁹	Confounding and modifying variables accounted for	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	+ Low rate (≤20/5) attrition	Attrition did not result in difference in groups baseline & followup	_	+ Clearly stated inclusion/exclusion criteria	_	Appropriate measures for assessing interventions exposures Z Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described intersures for outcome assessment (Outcome: Ifailstusion)	Clearly described measures for outcome assessment (Outcome: ICU)	Clearly described measures for outcome assessment (Outcome: Cessation)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	+ Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	+ Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	+ Pre-specified potential outcomes	+ Reporting of all pre-specified outcomes
111006, 2014	-	-	INK	+	A		_ †	*	A				*	'	'	'	1	/	1	′	'	+	1	1		/	+	-	-	-	+	+
Park, 2014 ⁷⁴	+	-	NR	+	N A	-	+ +	+	N A	′ /	/	' /	+	/	/	/	/	/	/	/	/	+	/	/	/	/	+	+	+	-	+	+

Author, Year	Confounding and modifying variables accounted for	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20/5) attrition			Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described measures for outcome assessment (Outcome: Transfusion)	Clearly described measures for outcome assessment (Outcome: ICU)	Clearly described measures for outcome assessment (Outcome: Cessation)	Clearly described measures for outcome assessment (Outcome: Success)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	_		Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Reporting of all pre-specified outcomes
Zatta, 2014 ⁴¹	NA	-	NR	N A	N A	N A	+	N R	+	N A	/	/	/	-	/	/	/	/	/	/	/	/	+	1	/	/	/	/	+	-	-	-	+	+
Dildy, 2013 ⁷⁵	+	-	NR	N A	N A	-	+	+	+	-	-	-	+	+	/	/	/	/	/	-	+	+	+	/	/	/	/	/	+	-	N R	NA	+	+

Author, Year	Confounding and modifying variables accounted for	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20/5) attrition	Attrition did not result in difference in groups baseline & followup	Outcome assessors blinded	Clearly stated inclusion/exclusion criteria	Measures implemented consistently	Appropriate measures for assessing interventions/exposures	Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described measures for outcome assessment (Outcome: Transfusion)	Clearly described measures for outcome assessment (Outcome: ICU)	Clearly described measures for outcome assessment (Outcome: Cessation)	Clearly described measures for outcome assessment (Outcome: Success)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Reporting of all pre-specified outcomes
Gronvall, 2013 ⁴³	-	-	NR	+	N A	- .	+ +	- +		N A	/	/	/	/	+	/	/	/	/	/	/	/	/	+	/	/	/	/	+	-	-	-	+	+
Lee, 2013 ⁴⁵	+	-	NR	+	N A	-	+ +	+		V A	/	/	/	/	+	/	/	/	/	/	/	/	/	+	/	/	/	/	+	+	+	-	+	+

Author, Year Blanc, 2012 ⁴⁷	Confounding and modifying variables accounted for +	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	+ Low rate (≤20/5) attrition		_	+ Clearly stated inclusion/exclusion criteria		_	Z Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described measures for outcome assessment (Outcome: Transfusion)	Clearly described measures for outcome assessment (Outcome: ICU)	Clearly described measures for outcome assessment (Outcome: Cessation)	+ Clearly described measures for outcome assessment (Outcome: Success)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	+ Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	+ Consistent implementation of outcome assessment	+ Appropriate measures for confounding variables assessment	+ Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	+ Pre-specified potential outcomes	+ Reporting of all pre-specified outcomes
Dialic, 2012	+	-	INK	+	+	-	† †			A	/	1	/	/	+	/	1	′	′	/	1	/	'	+	/	/	/	/	+	+	+	-	+	+
Lee, 2012 ⁴⁸	+	-	NR	-	N R	-	+ +	- +		N A	/	+	/	/	+	-	/	/	/	/	+	/	/	+	+	/	/	/	-	+	+	-	+	+

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Author, Year	Confounding and modifying variables accounted for	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	Low rate (≤20/5) attrition		Outcome assessors blinded		Appropriate measures for assessing interventions/exposures	_	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described measures for outcome assessment (Outcome: Transfusion)	Clearly described measures for outcome assessment (Outcome: ICII)	Clearly described measures for outcome assessment (Outcome: Cessation)	Clearly described measures for outcome assessment (Outcome: Success)	Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	Consistent implementation of outcome assessment	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Reporting of all pre-specified outcomes
Palacios- Jaraquemada, 2011 ⁵²	-	-	NR	+	N A	-	- N		N A			/	/	+	/	/	/	/	/	/	/	/	+	/	/	/	/	+	-	-	-	+	+
Wright, 2010 ⁵⁶	+	-	NR	+	+		+	+	N A	/	+	+	/	/	/	/	+	/	/	+	+	/	/	/	/	+	/	+	+	+	-	+	+

Lone, 2010 ⁵⁸ + - NR + N - + + + N / / / / / / / / / / / / / / / /

Author, Year Gaia, 2009 ⁶¹	Confounding and modifying variables accounted for	Concurrent intervention/unintended exposure ruled out	Study free from variations from protocol	- Low rate (≤20/5) attrition		_		_	_	Interventions implemented consistently	Clearly described measures for outcome assessment (Outcome: Blood Loss)	Clearly described measures for outcome assessment (Outcome: Transfusion)	Clearly described measures for outcome assessment (Outcome: ICU)			Clearly described measures for outcome assessment (Outcome: Fertility)	Clearly described measures for outcome assessment (Outcome: Hemostasis)	Clearly described measures for outcome assessment (Outcome: LOS)	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)	Appropriate measures for outcome assessment (Outcome: Blood Loss)	Appropriate measure for outcome assessment (Outcome: Transfusion)	Appropriate measure for outcome assessment (Outcome: ICU)	Appropriate measure for outcome assessment (Outcome: Cessation)	- Appropriate measure for outcome assessment (Outcome: Success)	Appropriate measure for outcome assessment (Outcome: Fertility)	Appropriate measure for outcome assessment (Outcome: Hemostasis)	Appropriate measure for outcome assessment (Outcome: LOS)	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)	_	Appropriate measures for confounding variables assessment	Consistent assessment of confounding variables	Secular trends and regression to the mean accounted for	Pre-specified potential outcomes	Reporting of all pre-specified outcomes
Gala, 2009	-	-	INK	+	N A	-	+ +	+ +		N A	'	'	/	/	+	+	'	/	1	′	/	1	/	+	+	/		/	+	-	-	-	+	+
Fiori, 2009 ⁵⁷	-	-	NR	-	N R	-	+ +	+ +		N A	/	/	/	/	+	+	/	/	/	/	/	/	/	+	+	/	/	/	+	+	+	-	+	+

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Oleen, 1990 ⁷³	Author, Year
+	Confounding and modifying variables accounted for
-	Concurrent intervention/unintended exposure ruled out
NR	Study free from variations from protocol
+	Low rate (≤20/5) attrition
N A	Attrition did not result in difference in groups baseline & followup
- +	Outcome assessors blinded
+	Clearly stated inclusion/exclusion criteria
+	Appropriate measures for assessing interventions/exposures
N A	Interventions implemented consistently
-	Clearly described measures for outcome assessment (Outcome: Blood Loss)
+	Clearly described measures for outcome assessment (Outcome: Transfusion)
/	Clearly described measures for outcome assessment (Outcome: ICU)
/	Clearly described measures for outcome assessment (Outcome: Cessation)
/	Clearly described measures for outcome assessment (Outcome: Success)
/	Clearly described measures for outcome assessment (Outcome: Fertility)
/	Clearly described measures for outcome assessment (Outcome: Hemostasis)
/	Clearly described measures for outcome assessment (Outcome: LOS)
/	Clearly described measures for outcome assessment (Outcome: Uterine Preservation)
+	Appropriate measures for outcome assessment (Outcome: Blood Loss)
+	Appropriate measure for outcome assessment (Outcome: Transfusion)
/	Appropriate measure for outcome assessment (Outcome: ICU)
/	Appropriate measure for outcome assessment (Outcome: Cessation)
/	Appropriate measure for outcome assessment (Outcome: Success)
/	Appropriate measure for outcome assessment (Outcome: Fertility)
/	Appropriate measure for outcome assessment (Outcome: Hemostasis)
/	Appropriate measure for outcome assessment (Outcome: LOS)
/	Appropriate measure for outcome assessment (Outcome: Uterine Preservation)
+	
+	Appropriate measures for confounding variables assessment
+	Consistent assessment of confounding variables
NA	Secular trends and regression to the mean accounted for
+	Pre-specified potential outcomes
+	Reporting of all pre-specified outcomes

NA=not applicable, NR=not reported, / =outcome not rated for this study

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Appendix F. Applicability Tables

Pharmacologic Interventions

Table F-1. Applicability for tranexamic acid studies

Domain	Description of applicability of evidence compared to question
Population	Study population similar to women with mild-moderate PPH
Intervention	Drug is available, but use for PPH is off-label in the U.S.A. and therefore should be part of a clinical trial with IRB approval
Comparators	Comparisons were standard
Outcomes	Outcomes assessed were those of clinical importance
Setting	Study conducted in a tertiary care hospitals in France

Table F-2. Applicability for oxytocin and misoprostol studies

Domain	Description of applicability of evidence compared to question
Population	Study population similar to women with mild-moderate PPH
Intervention	Drugs are widely available in the USA and approved for use in the treatment of PPH
Comparators	Comparisons were standard
Outcomes	Outcomes assessed were those of clinical importance
Setting	Study conducted in large medical centers in the USA and Hong Kong

Table F-3. Applicability for recombinant human soluble thrombomodulin (rTM) studies

Domain	Description of applicability of evidence compared to question
Population	Study population similar only to women with DIC as a complication of severe PPH
Intervention	Intervention may not be available at many sites in the USA, exact intervention in this study was created in Japan
Comparators	Comparisons were standard
Outcomes	Outcomes assessed were those of clinical importance
Setting	Study conducted in Japan

Table F-4. Applicability for carboprost tromethamine studies

Domain	Description of applicability of evidence compared to question
Population	Study population similar to women with mild-moderate PPH
Intervention	Drug is available in the USA and approved for use in the treatment of PPH
Comparators	Comparisons were standard
Outcomes	Outcomes assessed were those of clinical importance
Setting	Study conducted in a medical center in the USA

Table F-5. Applicability for recombinant activated FVII (rFVIIa) studies

	Table F-5. Applicability for recombinant activated FVII (FFVIIa) studies	
Domain	Description of applicability of evidence compared to question	
Population	Registry study populations included women from any obstetric population within nine	
	European countries or Australia and New Zealand, and two other retrospective studies	
	included women from academic centers in Finland and Ireland. Women included in the	
	studies had post-partum hemorrhage treated with rFVIIa and were identified retrospectively	
	through medical charts or through physician and pharmacist response to mailed surveys.	
	There were no specific inclusion/exclusion criteria other than use of rFVIIa in the post-	
	partum period in women without a history of hemophilia.	
Intervention	Use of rFVIIa for post-partum hemorrhage.	
Comparators	Comparators included placebo and other methods to control PPH (prophylactic rFVIIa,	
	procedures, surgeries)	
Outcomes	Outcomes included transfusion and uterine preservation rates, rates of anemia and length of	
	stay. All studies reported harms associated with treatment with rFVIIa (thromboembolic	
	events and adult respiratory distress syndrome (ARDS) were most common) and rates of	
	maternal death. Harms outcomes were not pre-defined in the methods section. There are	
	no reported long term outcomes.	
Setting	Studies were conducted in Australia, New Zealand, Finland, Ireland, Denmark, France,	

Iceland, the Netherlands, Norway, Sweden, and the United Kingdom and included women from any hospital setting (academic and community). The registry studies attempted to be inclusive of all populations, but ultimately included a sample of hospitals in the regions. Generalization of these study findings to general clinical practice may be limited as many
hospitals in the regions assessed did not participate in data collection.

Table F-6. Applicability for transfusion studies

Population	The populations from studies examining the efficacy and harms of transfusion of various blood products after post-partum hemorrhage included women with PPH. PPH was defined differently in each study. In one retrospective cohort study women included in the study had PPH (volume not defined) with clinical symptoms of hypovolemia (hypotension, tachycardia, positive "tilt" test, or oliguria)
Intervention	The transfusion studies studied different interventions. Transfusion with whole blood versus packed red blood cells only versus combinations of blood products or transfusion of cryoprecipitate versus fibrinogen concentrates, or massive transfusion (≥ 10 units of blood) versus standard transfusion (< 10 units of blood), transfusion versus no transfusion, and transfusion with fibrinogen
Comparators	Comparators are as above
Outcomes	Outcomes assessed included ICU admission, length of stay, uterine preservation, and volume of transfusion
Setting	All studies were performed at academic hospitals in Korea, Ireland, the Netherlands and the US. Generalization of these study findings to community settings may be limited as they were single center studies at large institutions.

Table F-7. Applicability for studies of uterine tamponade

Domain	Description of applicability of evidence
Population	The study population was women with PPH
Intervention	Uterine balloon tamponade, including Bakri, Belfort-Dildy, Sengstaken-Blakemore, and Rusch balloons. In one pre-post study all comparisons were done between women who reached the 4 th step in the protocol (treated with sulprostone) before and after the implementation of a new protocol. Therefore changes in these outcomes do not reflect the impact of the intervention itself (uterine balloon tamponade) but the influence of a new protocol implementation in the overall management of PPH
Comparators	In one pre-post study, controls (before) were identified by searching electronic medical records while data for the study period (after) were collected prospectively.
Outcomes	Outcomes measured were successful control of bleeding, blood loss, transfusion, and hysterectomy. One study also reported rates of invasive surgical procedures before and after protocol implementation.
Setting	Studies were conducted in France, Finland, Italy, the US, and Hong Kong. Studies were conducted in a tertiary care centers or large hospitals and may not be applicable to other birth settings.

Table F-8. Applicability for studies of uterine artery embolization

Domain	Description of applicability of evidence
Population	Women at larger or tertiary care hospitals receiving embolization for PPH treatment, typically after failure of first-line interventions. More cesarean births when reported
Intervention	Arterial embolization using agents such as gelfoam, microparticles, coils, or a combination. The number of arteries and areteries embolized varied across studies. Embolization may not be widely available in smaller community hospitals, thus applicability is somewhat limited.
Comparators	Comparators were no embolization or use of another intervention. Most studies were case series.
Outcomes	Outcomes measured were typically success of intervention, fertility, resumption of menses, and harms. Loss to followup for fertility outcomes was high.
Setting	Studies were conducted in Europe, Korea, United States, Japan, UK, Hong Kong. Eight of 19 studies were conducted in France and 6 in Korea. Hospital settings applicable to tertiary care centers or centers with interventional radiology available in the U.S.

Table F-9. Applicability for studies of uterine and other pelvic artery ligation

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Domain	Description of applicability of evidence
Domain	Description of applicability of evidence

Population	Women receiving arterial ligation for PPH treatment, typically after failure of first-line interventions.
Intervention	Ligation sites varied across studies and included uterine, ovarian, and hypogastric arteries. Ligation availability may depend on availability of skilled providers and may not be widely available
	in smaller community hospitals, thus applicability is somewhat limited.
Comparators	Comparators were no ligation or use of another intervention.
Outcomes	Outcomes measured were typically success of intervention, fertility, resumption of menses, and
	harms. Loss to followup for fertility outcomes was high.
Setting	Studies were conducted in Europe, United States, and Argentina.

Table F-10. Applicability for studies of uterine compression sutures

Domain	Description of applicability of evidence
Population	The study population was 811 women receiving sutures for PPH treatment, typically after failure of
	first-line interventions. 230 cesarean and 42 vaginal births in the one study reporting mode.
Intervention	Typres of sutures varied across studies. Skilled personnel may not be widely available in smaller
	community hospitals, thus applicability is somewhat limited.
Comparators	Comparators were no suture or use of another intervention. Most studies were case series.
Outcomes	Outcomes measured were typically success of intervention, fertility, resumption of menses, and
	harms. Loss to followup for fertility outcomes was high.
Setting	Studies were conducted in France, the UK and Argentina.

Table F-11. Applicability for studies of hysterectomy

Domain	Description of applicability of evidence
Population	Over 3000 women receiving hysterectomy, preceded by a combination of interventions including uterotonics, ligation, embolization, and sutures
Intervention	Total and subtotal hysterectomy; prior interventions differed across studies, which aligns with typical care as hysterectomy generally the intervention of last resort when possible
Comparators	Most studies were case series
Outcomes	Outcomes measured were typically success of intervention, transfusion rates, ICU stay, and harms
Setting	Studies were conducted Europe, Canada, US, Denmark, Korea, in a variety of hospitals. Some case series/registry studies reported data from across a country or region.

Table F-12. Applicability for studies of combined interventions

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Domain	Description of applicability of evidence	
Population	Women with primary and secondary PPH (3 studies) receiving interventions including medical, procedural, and surgical approaches.	
Intervention	Medical and surgical approaches including curettage, embolization, hysterectomy, surgical evacuation.	
Comparators	Comparator was medical/conservative vs. surgical. procedural treatment. Two studies were case series.	
Outcomes	Clinically appropriate outcomes including cessation of bleeding, transfusion rates, complications/harms.	
Setting	Studies were conducted Europe, Canada, US, Korea, typically in tertiary care hospitals. Some case series/registry studies reported data from varied hospitals across a country or region	

Table F-13. Applicability of studies addressing interventions for anemia

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Domain	Description of applicability of evidence compared to question
Population	One RCT included women with iron deficiency anemia (Hb <110 g/L and ferritin < 12 µg/L) who were hemodynamically stable after PPH of ≥ 500 mL blood loss. Another RCT included women with PPH and hemoglobin between 4.8-7.9 g/dl post-birth
Intervention	400 mg of intravenous iron sucrose divided into two 200 mg infusions given a minimum of 24 hours apart or two iron tablets totaling 160 mg elemental iron daily for six weeks following delivery in one study and transfusion vs. no transfusion
Comparators	Intravenous iron supplementation was compared with oral iron supplementation; no transfusion
Outcomes	Outcomes included blood hemoglobin and ferritin levels performed on days 1, 14, and 42 post-partum, quality of life, fatigue

Setting	Studies were conducted in Australia and the Netherlands in a single hospital and in multiple Dutch hospitals. One RCT was conducted at a single hospital outside of a city in Australia. The catchment area of the hospital predominantly included the local neighborhood composed predominantly of women of low educational attainment and socio-economic
	composed predominantly of women of low educational attainment and socio-economic
	status, with high levels of unemployment and teen pregnancy.

Table F-14. Applicability of systems-level interventions

Domain	Description of applicability of evidence compared to question
Population	Populations both in the United States and Europe reflect those typical of similar size and type (rural, academic, etc.) obstetric units in current labor and delivery environments in the United States. Overall the systems-level interventions assessed have good applicability to current practice in the United States.
Intervention	Interventions were informed by processes of identifying evidence and crafting guidance that conforms to typical quality improvement and outcomes based research. The content of the interventions is feasible to implement across a full range of settings and the approaches to measuring outcomes are applicable to practice
Comparators	Most studies used pre-post designs.
Outcomes	Outcomes were clinically relevant and included change in PPH incidence, changes in procedures and interventions.
Setting	Studies were conducted in Europe and the United States and reflect settings typical of similar size and type (rural, academic, etc.) obstetric units in current labor and delivery environments in the United States.

Appendix G. Study Design Classification Algorithm

