Comparative Effectiveness Review
Number 195

Management of Uterine Fibroids

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Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 290-2015-00003-I

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AHRQ Publication No. 17(18)-EHC028-EF
December 2017

Key Messages

Purpose of Review
To review treatment effectiveness and the risk of leiomyosarcoma (LMS) in women with fibroids.

Key Messages

- Gonadotropin-releasing hormone (GnRH) agonists, mifepristone, ulipristal, and uterine artery embolism (UAE) reduce fibroid size, and improve symptoms and quality of life. High intensity focused ultrasound reduces fibroid size, but impact on quality of life was not measured. Myomectomy and hysterectomy also improve quality of life. Direct comparisons of interventions provide little evidence.
- For women in their 30s, the chance of needing retreatment for fibroids within the next 2 years was 6–7 percent after medical treatment or myomectomy and 44 percent after UAE. For older women, the chance was 9–19 percent after medical treatment or UAE and 0 percent after myomectomy.
- Using data from160 studies, risk of unexpected LMS ranged from less than 1 to 13 of 10,000 surgeries.
- Survival time appears shorter with power morcellation; however, confidence intervals are wide and overlap with other surgical approaches.

This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00003-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the report.

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Suggested citation: Hartmann KE, Fonnesbeck C, Surawicz T, Krishnaswami S, Andrews JC, Wilson JE, Velez-Edwards D, Kugley S, Sathe NA. Management of Uterine Fibroids. Comparative Effectiveness Review No. 195. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2015-00003-I.) AHRQ Publication No. 17(18)-EHC028-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2017. www.effectivehealthcare.ahrq.gov/reports/final.cfm. doi: https://doi.org/10.23970/AHRQEPCCER195.

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.

If you have 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, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Ms. Sanura Latham and Ms. Jessica Kimber were invaluable resources for assisting with data extraction and validation, helping to locate studies, and tracking and distributing project materials. Dr. Mamata Raj assisted with screening studies. Dr. Jill Huppert and Dr. Christine Chang (AHRQ) assisted with subject matter perspective and readability. We sincerely appreciate their dedicated work, as well as the input of our Task Order Officer; Associate Editor, Timothy Carey, M.D., M.P.H.; and Key Informants and Technical Experts.

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 Task Order Officer 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 conflicting 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 Uterine Fibroids

Structured Abstract

Objectives. We assessed the evidence about management of uterine fibroids. Specifically, we sought to determine effectiveness of interventions, risks of harm, and whether individual or fibroid characteristics influence outcomes.

Data sources. We searched MEDLINE® via PubMed® and Embase® to identify publications, as well as reviewed the reference lists of included studies.

Methods. We included studies published in English from January 1985 to September 2016. We identified randomized clinical trials to assess outcomes and harms of interventions. We used data from trials in a meta-analysis to estimate probability and timing of subsequent interventions for fibroids based on initial type of intervention. To describe risk of unrecognized leiomyosarcoma, we included studies that allowed calculation of prevalence of leiomyosarcoma discovered at the time of surgery for masses believed to be fibroids. We also identified publications that indicated operative approaches to removal of leiomyosarcoma tissue and built models to estimate survival. We extracted data, assessed risk of bias, and rated the strength of evidence for informing care.

Results. Of 97 included randomized trials, 43 studies assessed medications, 28 assessed procedures, and 37 assessed surgeries. Gonadotropin-releasing hormone (GnRH) agonists, mifepristone, and ulipristal reduced fibroid size and improved fibroid-related symptoms, including bleeding and quality of life (moderate strength of evidence [SOE] except quality of life for GnRH agonist [low SOE]). Several other medications have promise but are not supported by sufficient evidence. Uterine artery embolization (UAE) (high SOE) as well as high intensity focused ultrasound (low SOE) are effective for decreasing fibroid size/volume. Few other outcomes are well investigated for high intensity focused ultrasound. UAE studies reported improved outcomes for bleeding (moderate SOE), and quality of life (moderate SOE). Myomectomy and hysterectomy improved quality of life (both low SOE). Few well-conducted trials directly compared different treatment options. No studies were designed to evaluate expectant management, and evidence is insufficient to guide clinical care. Subsequent intervention ranged from 0 to 44 percent in studies that followed women after initial fibroid treatment. At 2-year followup, subsequent intervention rates were lowest for initial medical management and higher for UAE and myomectomy, especially among younger women. No individual characteristics of women or their fibroids were definitely associated with likelihood of intervention benefits or patient satisfaction. These findings were limited by the number and size of available studies. Using data from 160 studies, we estimated that among 10,000 women having surgery for presumed fibroids, between 0 and 13 will have a leiomyosarcoma detected. Of the surgical approaches, the 5-year survival after leiomyosarcoma diagnosis was 30 percent with power morcellation (95% Bayesian credible interval [BCI]: 13% to 61%), 59 percent with scalpel morcellation (BCI: 33% to 84%), and 60 percent with intact removal (BCI: 24% to 98%).

Conclusion. A range of interventions are effective for reducing fibroid size and improving symptoms. Some medications and procedures also improve quality of life. Few studies directly compare interventions. The risk of encountering a leiomyosarcoma at the time of fibroid surgery is low, and the method of fibroid removal may influence survival. Evidence to guide choice of

intervention is likely best when applied in the context of individual patient needs and preferences.

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Evidence Summary

Introduction

Uterine fibroids (i.e., leiomyomata) are common benign smooth muscle tumors of the uterus. Most women will develop one or more uterine fibroids during their reproductive lifespan.[1] In the United States, an estimated 26 million women between the ages of 15 and 50 have uterine fibroids.[1-4] More than 15 million of them will experience associated symptoms or health concerns.[5,6] On average, African American women are younger at onset of fibroids, and have larger and more numerous tumors.[1,3] They are also more likely to have surgical interventions for fibroids.[7] Over the reproductive lifetime prevalence becomes more similar so that by age 49, more than 70 percent of white women and 84 percent of African American women have fibroids documented by imaging or surgical records.[1]

The personal and societal costs of diminished quality of life, disruption of usual activities and roles, lost work time, and healthcare expenditures are substantial. Including all types of interventions, direct annual healthcare costs in the United States are projected to exceed $9.4 billion.[8] Lost wages, productivity, and short-term disability are estimated to total more than $5 billion, perhaps as much as $17 billion, with roughly $4,624 in costs per woman in the first year of diagnosis.[8,9]

Treatment options differ in fundamental aspects such as cost, invasiveness, recovery time, risks, likelihood of long-term resolution of symptoms, need for future care for fibroids, and influence on future childbearing. Thus synthesis of available evidence is crucial to assist women and their care providers in making well-informed and personalized decisions.

One concern affecting surgical treatment is the risk of discovering a leiomyosarcoma, a cancer of the uterine muscle, rather than a fibroid at surgery. These are rare but ominous: an average of 1,600 new cases occur in the United States each year. They have poor outcomes with an average 5-year survival of 36 percent if cancer is not isolated to the uterus.

Scope

To inform clinical decisions about care we focused on evidence from randomized controlled trials (RCTs) that assess currently available interventions for women of any age with fibroids. We also sought to identify factors that might influence likelihood of favorable results or harms from treatments. We included studies evaluating medications (including intrauterine devices [IUDs] as they deliver medication), procedures, and surgeries for the management of uterine fibroids. We considered more invasive interventions that are typically performed in an operating room or require at least a brief hospital stay as surgical and interventions that can typically be conducted in an office or as same-day surgery as procedures.

We also summarized data from women who were followed within trials without active intervention. In light of recent uncertainty about the risk of cancer dissemination following morcellation of fibroids, this review also includes literature to estimate the prevalence of leiomyosarcoma and influence of morcellation on survival in women with leiomyosarcoma.

Key Questions

Key Question 1. What is the comparative effectiveness (benefits and harms) of treatments for uterine fibroids, including comparisons among these interventions?

Key Question 2. Does treatment effectiveness differ by patient or fibroid characteristics (e.g., age; race/ethnicity; symptoms; menopausal status; imaging characteristics; vascular supply to fibroids; or number, size, type, location, or total volume of fibroids)?

Key Question 3. What is the risk of encountering a leiomyosarcoma for masses believed to be uterine fibroids at the time of myomectomy or hysterectomy?

Key Question 4. Does survival after leiomyosarcoma differ by patient or fibroid characteristics (e.g., age; race/ethnicity; symptoms; menopausal status; imaging characteristics; vascular supply to fibroids; or number, size, type, location, or total volume of fibroids) or by surgical approach to morcellation?

Methods

We searched MEDLINE® via PubMed® and Embase® to identify publications in English from January 1985 to September 2016. We also checked the reference lists of included studies. We dually reviewed each publication against *a priori* inclusion/exclusion criteria. For Key Question (KQ) 1 and KQ2, we identified RCTs to assess benefits or harms of medical, procedural, or surgical interventions compared with an alternative intervention or inactive control, including expectant management, placebos, or sham procedures. Eligible studies for KQ1 or KQ2 had to report one or more patient-centered outcomes or fibroid characteristics at baseline and in followup (e.g., symptom improvement, bleeding pattern, pain, quality of life). We did not present studies reporting only intermediate outcomes such as technical success, conversion to alternate procedure, estimated blood loss during procedure, wound healing status, length of stay, and readmission or reoperation, except in the discussion of specific harms (see analytic framework in full report).

We extracted data, assessed risk of bias, and rated the strength of the evidence for informing care using standard Agency for Healthcare Research and Quality (AHRQ) systematic review methods. We used followup data across all trials of medical management, UAE, or myomectomy that included subsequent treatment to estimate probabilities of selecting subsequent treatment. The probability of the occurrence of subsequent treatment events was estimated using a Poisson model, where the rate of occurrence was assumed to be a function of patient age and study followup time, on a logarithmic scale.

To understand risk of leiomyosarcoma and the influence of morcellation on survival (KQ3 and KQ4) we conducted dual review and data extraction from observational studies, and trials with relevant data. Our models included the effect of the mean age of women in each study and the year in which it was published as candidate covariates and we stratify by prospective versus

retrospective study design. For KQ3, we structured a search to encompass the papers included in a 2015 review and meta-analysis[10] that estimated the prevalence of leiomyosarcoma among tumors presumed to be fibroids. We updated the search, used comparable eligibility criteria, and calculated new estimates for the prevalence of leiomyosarcoma identified at the time of surgery for presumed fibroids including both the prior studies and newly identified papers. To be included, papers were required to provide data to calculate the proportion of surgeries for fibroids that revealed leiomyosarcoma. We calculated meta-estimates of the probability of leiomyosarcoma for all relevant studies and by study characteristics.

For KQ4 we conducted a broad search and reviewed potentially eligible papers for those that included data about leiomyosarcoma diagnosis and survival as well as the proportion of women exposed to morcellation who were subsequently diagnosed with leiomyosarcoma or disseminated leiomyosarcoma (meaning presence or recurrence of leiomyosarcoma beyond the initial operative tissue specimen). We extracted data to allow comparison of survival for three groups: those with power morcellation, those with sharp (scalpel) morcellation, and those with no morcellation (the uterus was removed intact). We generated Kaplan-Meier survival curves using event times when they were available in order to compare survival time by method of surgical removal of the specimen.

Results

The first AHRQ systematic review on the management of uterine fibroids was published in 2001 and included 30 randomized trials of interventions to treat fibroids.[11] A more recent AHRQ review in 2007 identified 29 additional trials.[12] Across reviews, most studies had poor quality and typically reported only on technical success of the intervention with abbreviated followup of outcomes. Longer-term outcomes such as quality of life, fertility, sexual function, improvement in symptoms and satisfaction with care were rarely reported. These reviews served to answer key questions about epidemiologic correlates of fibroids, to demonstrate lack of evidence about natural history of disease, provided models of lifetime incidence and need for treatment and included cohort studies as a surrogate for trials to examine preliminary evidence of effectiveness and predictors of outcomes.

In the intervening years, the literature has grown to include 121 publications from 97 unique trials (see main report for full reference list). Newer studies have been of somewhat higher quality—18 in this report were judged good quality trials, 27 fair, and 52 poor quality. More interventions have been assessed for longer followup periods, up to 5 years. Patient-reported outcomes are more common, reported in 63 percent of studies, as are data to determine what sequences of interventions are most likely to be chosen subsequently by women with reference to their prior treatment allocation in trials (48 studies). More trials also provide more data to examine whether particular desired outcomes are more likely to be achieved among women with specific characteristics. Six studies provided information about factors such as age, menopausal status, and fibroid characteristics that may modify outcomes or risk of adverse events.

Clinical trials are not powered to detect harms. To address the current pressing concerns of potential for cancer dissemination at the time of surgery for fibroids, we identified a separate literature of 160 publications to examine risk that a mass believed to be a fibroid was found to be a leiomyosarcoma. We also sought data within 28 papers that allowed estimation of the risk of progression of leiomyosarcoma by type of morcellation used, estimating aggregate mortality by surgical methods used. Lastly, we combed these papers for data about whether characteristics of women or the masses believed to be fibroids were associated with leiomyosarcoma presence or

modified the likelihood that morcellation during a surgery for fibroids would be associated with harm.

KQ1: Effectiveness of Treatments for Fibroids

The included RCTs reported effectiveness more often than harms. We summarize our results below by category of intervention, providing data about adverse events when available and statistically informative. We categorized interventions using the publication authors' description. Interventions include expectant management or placebo; medications to improve or resolve symptoms or reduce size of fibroids (including those delivered via IUDs); procedures (uterine artery occlusion via embolization, ligation, or coagulation; and fibroid ablation (e.g., high intensity focused ultrasound, radiofrequency); and surgery (including endometrial ablation; hysterectomy via abdominal, vaginal, and laparoscopic approaches and those with robotic assistance; and myomectomy via laparotomy, laparoscopy, hysteroscopy, or with robotic assistance).

Evidence Map for KQ1

We summarize the number of studies reporting final health outcomes, number of participants and duration of followup for medications (Table A), procedures (Table B), and surgeries (Table C). Complete outcomes data are available in the Systematic Review Data Repository.

Table A. Final health outcomes reported in medication studies

Intervention	Outcome Category	Studies Reporting N	Baseline Participants N	Duration of Followup, Range in Months[a]
GnRH Agonists[b]	Symptom status	13	785	<1 to 36
	Sexual function	1	60	0
	Fibroid characteristics	18	912	<1 to 36
	Subsequent treatment for fibroids	1	51	6
Progesterone Receptor Agents[c] (mifepristone, ulipristal, levonorgestrel IUD)	Symptom status	18	1,916	0 to 18
	Pregnancy outcomes	1	220	9
	Sexual function	1	220	9
	Fibroid characteristics	18	1,916	0 to 18
	Subsequent treatment for fibroids	8	1,224	3 to12
Estrogen Receptor Agents[d] (raloxifene, tamoxifen, HRT)	Symptom status	6	201	2 to 60
	Fibroid characteristics	6	201	2 to 60
	Subsequent treatment for fibroids	1	10	60
Other Medications (cabergoline, tranexamic acid, tibolone)	Symptom status	3	178	0.23 to 3
	Fibroid characteristics	2	55	0.23
	Subsequent treatment for fibroids	1	30	0.23

GnRH = gonadotropin-releasing hormone; HRT = hormone replacement therapy; IUD = intrauterine device; N = number

[a]Duration of followup is defined as months elapsed from end of active treatment to evaluation of outcome(s)
[b]Includes only those GnRH studies discussed in the GnRH report section
[c]Anti-progestins, selective receptor modulators, and levonor-gestrel IUD
[d]Selective receptor modulators, antagonists, and HRT (transdermal estradiol plus cyclic oral medroxyprogesterone acetate)

Table B. Final health outcomes reported in studies of procedures

Intervention	Outcome Category	Studies Reporting N	Baseline Participants N	Duration of Followup, Range in Months[a]
Uterine Artery Embolization	Symptom status	14	963	3 to 60
	Fibroid characteristics	21	1204	3 to 60
	Subsequent treatment for fibroids	11	784	6 to 60
	Satisfaction with outcomes	8	584	6 to 60
Radiofrequency Fibroid Ablation	Symptom status	2	76	0 to 24
	Fibroid characteristics	2	76	0 to 24
High Intensity Focused Ultrasound for Fibroid Ablation[b]	Symptom status	2	53	1 to 24
	Sexual function	1	50	<1
	Fibroid characteristics	5	216	1 to 24

N = number
[a]Duration of followup is defined as months elapsed from procedure to evaluation of outcome(s); [b]High intensity focused ultrasound includes procedures guided by magnetic resonance imaging

Table C. Final health outcomes reported in surgical studies

Intervention	Outcome Category	Studies Reporting N	Baseline Participants N	Duration of Followup, Range in Months[a]
Endometrial Ablation	Symptom status	1	96	12
	Subsequent treatment for fibroids	1	96	12
Myomectomy	Symptom status	4	285	3 to 24
	Pregnancy outcomes	5	447	12 to 36
	Sexual function	1	52	6
	Fibroid recurrence	5	494	6 to 40
	Subsequent treatment for fibroids	3	219	24 to 36
	Satisfaction with outcomes	4	339	3 to 24
Hysterectomy	Symptom status	1	30	24
	Satisfaction with outcomes	5	317	1 to 24
Hysterectomy or Myomectomy	Symptom status	2	71	12 to 60
	Pregnancy outcomes	1	20	12
	Fibroid characteristics	1	51	60
	Subsequent treatment for fibroids	2	115	12 to 60
	Satisfaction with outcomes	2	115	12 to 60

N = number
[a]Duration of followup is defined as months elapsed from surgery to evaluation of outcome(s)

To synthesize anticipated effects of interventions based on this literature, we group trial arms in text and tables to be able to describe outcomes of those interventions together. Throughout this report, we refer to whether or not a study assessed ***change*** in specific measures including fibroid characteristics like size or volume, symptoms (bleeding or pain), and quality of life. Indicating the study assessed change means it evaluated the characteristic or symptom at baseline and again

at one or more times after treatment. Noting that a study or studies assessed change is not equivalent to noting a beneficial effect or statistical significance in changes. Rather, noting measurement of change in a parameter establishes the total count of studies that addressed this outcome.

Expectant Management

We did not identify any studies intentionally designed to determine outcomes of no intervention, also called expectant management or watchful waiting. However, 16 small RCTs compared a treatment to no intervention, typically trials that compared a medication with placebo. Of these trials two were of good quality, six were fair, and eight were poor quality. The evidence, based on an average followup time of five months (range: 3 to 12 months), suggests the size of fibroids does not meaningfully change over these short timespans. One study reported a four percent reduction in size and those that reported volume measures documented an average increase in size of about 9 cm^3, which is about one-fifth the size of a golf ball. The two studies that followed postmenopausal women for a full year did not detect an increase in total volume of fibroids.

Likewise, bleeding characteristics, such as days of bleeding and severity of bleeding as measured by hemoglobin, heaviness of periods, and severity of heavy bleeding episodes, did not change meaningfully during followup for those without active management. The proportion of the 514 women enrolled in these trials who presented specifically with problem bleeding, as opposed to other fibroid-related symptoms, is not known. However, the data suggests that women with fibroids should not expect that bleeding patterns will worsen over the near term.

Summary/Strength of Evidence (SOE): None of these studies were designed to evaluate expectant management. The number of women in the literature followed without intervention is small, and these participants may be fundamentally different from other women with fibroids since they were willing to risk randomization to no intervention. For these reasons, the evidence is insufficient to inform choice of expectant management over other options.

Medical Management

We identified 43 studies assessing effectiveness of medical treatment (including progesterone delivered by IUD) for uterine fibroids. Ten studies had placebo or no treatment comparison groups. Approximately one third were industry sponsored. The longest duration of followup after the end of treatment was 60 months in one study. Women included in the studies were predominately premenopausal (39 studies). Four studies evaluated therapies in postmenopausal women. We assessed four as good quality, 12 as fair quality, and 27 as poor quality for effectiveness outcomes.

GnRH (Gonadotropin-Releasing Hormone)Agonists

Eighteen studies (reported in twenty publications) addressed GnRH agonists, which included seven studies of “add-back” therapy (addition of a second agent to a GnRH agonist). The studies included 912 participants, and followup was typically limited to the immediate end of treatment. Only six studies followed women post-treatment, for 3 to 6 months. GnRH agonists reduce the size of fibroids, with reductions in volume of fibroids documented between 64 and 175 cm^3 and reductions in the total volume of the uterus between 131 and 610 cm^3.

Six studies reported complete absence of bleeding during treatment, three noting statistical significance for clinically important reduction from baseline. No study reported an increase in

bleeding or worsening in hemoglobin or hematocrit. Individual women in several studies discontinued treatment because bleeding became more irregular or did not decrease.

Pain symptoms improved by GnRH treatment in four studies included pelvic pressure, pelvic and abdominal pain, and dysmenorrhea. Two studies reported similar improvements but without statistical comparisons of baseline to followup. Studies consistently reported significant improvement in measures of quality of life symptoms (days of bleeding, heavy menstrual bleeding, pelvic pressure, pelvic pain, urinary frequency, and constipation). Harms associated with GnRH included onset of menopausal symptoms, unfavorable changes in lipid profile, declines in cognitive function and memory, and bone loss, although some of these can be ameliorated with hormonal add-back therapy. Extended followup of women after they discontinue GnRH agonists is limited.

Summary/SOE: Moderate strength of evidence supports that GnRH agonists (with and without add-back therapy) reduce the size of fibroids, the overall size of the uterus, and bleeding symptoms. Low strength of evidence suggests that fibroid-related quality of life improves with and without add-back therapy.

Progesterone Receptor Agents: Anti-Progestins, Selective Receptor Modulators, and Levonorgestrel IUD

Seven studies provided data about outcomes of the anti-progestin mifepristone treatment. Average length of time for off-medication followup was 11 months with the longest untreated followup being 18 months. All studies observed a decrease in the size of fibroids at the completion of the period of active treatment. The magnitude of change in size of the largest fibroid ranged from a decrease of 37 cm^3 to 95 cm^3, with an average decrease of 71 cm^3 among the 575 women receiving mifepristone. Total uterine volume also decreased across women receiving mifepristone.

All studies of mifepristone that assessed bleeding reported reduced heaviness of bleeding. Two comparisons found mifepristone superior to placebo. Women were more or equally likely to have decreased bleeding or absent menses on the lower doses compared with the higher doses. Each of six studies that evaluated pelvic pain before and at conclusion of treatment noted substantial improvements (present in 68% to100% at baseline compared with 9% to 28% after 3 months of treatment); findings were similar at the conclusion of 6 to 9 months of treatment and maintained post-treatment in roughly 60 percent to 90 percent of women in three RCTs with longer term followup. Four studies reporting the outcome consistently noted significant improvements in quality of life measures. Some studies suggested fibroids do resume growth after treatment. Few participants in these trials pursued other treatment during or after active treatment. Harms included spotting, elevations in liver function enzymes, and endometrial hyperplasia.

Six studies investigated treatment with ulipristal, a selective progesterone receptor modulator. All studies found ulipristal effective for reducing the size of individual fibroids and the overall fibroid burden as measured by total fibroid or uterine volume. Ulipristal, as intended, resulted in absent menses for the majority of women during treatment (range: 62% to 100%) and improved or stabilized hematocrit or hemoglobin. The exception was among women who had submucous fibroids who, in one study, had less improvement in bleeding. Compared with placebo, all ulipristal doses improved fibroid-related quality of life, and two of the six trials also documented improvement in pain. Durability of effect at 6 months was assessed in two studies:

one found minimal resumption of fibroid growth (8.1%) after completion of treatment regardless of ulipristal dose. A second found that the 10 mg dose sustained fibroid size reduction while there was increase in size on the 5 mg dose that was similar to placebo. Ulipristal was associated with hot flashes, hyperplasia, and increases in liver function enzymes, although it is not clear if these effects persist after treatment ends.

Levonorgestrel (LNG) IUD improved bleeding (the only outcome of interest reported); however, the single available trial was of poor quality including lack of participant masking.

Summary/SOE: There is moderate strength of evidence that both mifepristone and ulipristal effectively reduce the size of fibroids and bleeding symptoms, while improving quality of life. Duration of effects is uncertain. Evidence is insufficient to choose between higher and lower doses. Evidence was insufficient to assess the effectiveness of the LNG-IUD on any outcomes

Estrogen Receptor Agents

Six studies included agents that act at the estrogen receptor. Three studies, two of fair quality and one of poor quality, investigated raloxifene (which acts as an anti-estrogen in breast and endometrial tissue) in comparison with placebo. Fibroid size decreased by 4.4 cm^3 to 34.2 cm^3 in two studies of raloxifene and did not change size in another raloxifene study (To put this in perspective, 40 cm^3 is the volume of a golf ball). In raloxifene studies with premenopausal women, neither bleeding pattern (in 3 studies) nor hemoglobin levels (in one study) were improved compared with placebo. Among postmenopausal women, the percent of treatment cycles without bleeding was similar and the number of episodes of spotting and severity of bleeding were similar among women in the treated and control group.

A single poor quality study evaluated tamoxifen, which acts as an anti-estrogen within breast tissue and as an estrogen ligand in the endometrium. Tamoxifen use in premenopausal women did not influence length or severity of bleeding compared with placebo. Change in fibroid characteristics was not reported. Women receiving tamoxifen had less pain after four months of treatment compared with placebo.

Two poor quality RCTs had a total of 42 women receiving hormone replacement therapy (HRT) (transdermal estrogen replacement plus cyclic oral medroxyprogesterone acetate) after menopause. They compared hormone therapy to tibolone (not available in United States) for menopausal symptom management with attention to whether treatment increased size of fibroids. Growth was approximately 10 cm^3, which is a quarter the size of a golf ball. In the longer study there was no further growth between 6 and 12 months.

No studies reported any serious adverse effects.

Summary/SOE: Studies provide low strength of evidence that, if prescribed to women with fibroids for other conditions such as breast cancer prophylaxis, raloxifene will not cause significant growth of existing fibroids or exacerbate bleeding. Evidence is insufficient to assess if tamoxifen or HRT does or does not promote fibroid growth.

Procedures for Uterine Fibroids

We identified 28 studies assessing procedures for uterine fibroids. Most studies compared similar procedures, two compared different procedures, and nine compared procedures against surgery or medications. The longest duration of followup after the end of treatment was 5 years in two studies. Participants were predominately premenopausal. We assessed 6 studies as good quality, 8 as fair quality, and 14 as poor quality for effectiveness outcomes.

Uterine Artery Embolization (UAE) and Occlusion

We identified 21 studies that randomized women to UAE or uterine artery occlusion. We assessed five studies as good quality, eight as fair quality, and eight as poor quality for effectiveness outcomes. Fibroid and uterine volume decreased significantly and consistently following UAE (up to 12 months postprocedure) regardless of the embolization agent or size of particles used to occlude the fibroid arteries. Longer-term followup reports from the Embolization for the Treatment of Symptomatic Uterine Fibroid Tumors Study, called the EMMY Trial, confirmed that fibroid and uterine volume reductions persist up to 5 years after UAE; however, 28 percent (23/81) of women underwent subsequent hysterectomy. Subsequent treatment was reported in 11 trials with length of followup ranging from 6 to 60 months (Table 23 in the full report). Hysterectomy was the most frequent intervention (8.9%) followed by repeat embolization (4.2%), myomectomy (3.6%), medication or IUD (1.1%) and endometrial ablation (0.1%).[13-23]

For UAE, bleeding effects were consistent, with declines in bleeding or bleeding-related measures reported in seven studies. Pain improved in up to 84 percent of women in two studies reporting this outcome. Only eight studies of UAE measured quality of life, which consistently improved postprocedure with durability in the two studies with longer-term followup. Treatment satisfaction was high in seven studies reporting this outcome.

No women receiving UAE required transfusion. Risk of major complications during and following UAE ranged from 1.2 to 6.9 percent around the time of the procedure up to about 5 percent by 2 years. The probability of "major complications" as defined by authors was high in two studies that reported long-term followup (21% at 5 years in the Randomised comparison of uterine artery embolisation with surgical treatment in patients with symptomatic uterine fibroids Study, termed the REST Trial, and 16.8% at 32 months in a second study) in large part because they considered any subsequent procedure a complication, while other authors did not. Fertility outcomes were not evaluated in the UAE-only trials. When available, pregnancy outcomes after UAE are presented in the sections that compare UAE to other procedures or surgeries.

Trials of uterine artery occlusion were small, and a variety of intervention methods were described, which prohibits conclusions.

Summary/SOE: There was high strength of evidence that UAE is effective for reducing the size of fibroids and total uterine volume. Moderate strength of evidence finds that bleeding and quality of life is improved following embolization. The effect of UAE on reproductive outcomes is not well studied and evidence is insufficient to guide care or determine safety.

High Intensity Focused Ultrasound for Fibroid Ablation

Six studies (reported in 7 publications) assessed high intensity focused ultrasound (HIFU) for fibroid ablation, but only one fair quality pilot study (n=20) used magnetic resonance imaging (MRI) guidance, which is used in the United States. The other studies were rated as poor quality primarily due to lack of masking participants and outcome assessors to the intervention received. In four studies reporting effects on fibroid size, the magnitude of fibroid volume reduction was greater at 12 months after ultrasound destruction than at 1 month post-treatment. One year after treatment fibroid volume decreased by averages of 90 and 170 cm^3 in two studies. Studies did not report on bleeding, pain, or pregnancy outcomes. One study addressed quality of life but did not report baseline data, and one reported improvements in sexual function. One study reported no transfusions among 48 participants. No study reported major complications.

Summary/SOE: HIFU reduced fibroid and uterine size, but strength of evidence is low because of short followup and poor quality of overall study design. Evidence related to patient reported outcomes is insufficient.

Radiofrequency Fibroid Ablation

Two RCTs, both assessed as poor quality, addressed radiofrequency ablation of fibroids. Both studies reported the technique was successful in delivering treatment to 5 percent or more of the targeted fibroid volume. Studies provided limited data on effects of ablation on bleeding, quality of life, and subsequent pregnancies, but did not report pain outcomes and noted no major complications.

Summary/SOE: The strength of evidence for radiofrequency ablation is insufficient to inform care.

Surgical Management

We identified 37 randomized trials with at least one arm that assessed surgical intervention (endometrial ablation, myomectomy, or hysterectomy) for uterine fibroids. One compared myomectomy to hysterectomy, the remainder evaluated outcomes in women treated by UAE, uterine artery occlusion, HIFU, or medication. The longest duration of followup after the end of treatment was 60 months in two studies. Women included in the studies were predominately premenopausal. We assessed nine as good quality, 11 as fair quality, and 17 as poor quality for effectiveness outcomes.

Endometrial Ablation

One fair quality study addressed endometrial ablation and reported significant decreases in bleeding after both rollerball and thermal balloon ablation, with similar rates of reintervention (9%) in both groups. More women in the rollerball group had complications. More than a third of women receiving each intervention noted dissatisfaction with ablation results on a single item with three levels of satisfaction. Dissatisfaction was associated with failure to achieve amenorrhea.

Myomectomy

Fifteen RCTs reported health outcomes after myomectomy and five additional studies provided information about harms. We assessed four studies as good quality, six as fair quality, and 10 as poor quality. Studies did not report changes in fibroid characteristics (e.g., proportion of fibroids removed at myomectomy, decrease in uterine volume). One small study reported improved bleeding patterns one year after surgery in 12 of 15 women. Another described change in undefined symptoms with relief reported by 51 of 88 women. Fibroid recurrence, reported in five studies, ranged from 2.5 percent to 25 percent with duration of followup ranging from 6 to 60 months. Two additional studies reported no recurrences at 6 month followup. Laparoscopic myomectomy was associated with faster return to usual activity than comparator surgeries in three studies and with improved quality of life compared with hysterectomy in one study. Laparoscopic myomectomy was also associated with better fertility and pregnancy outcomes over other myomectomy techniques in one study (n=136), but outcomes were comparable in another RCT (n=131). Transfusion rates were most often zero (1,040 participants in 10 studies). Six studies reported 25 transfusions among 502 participants treated by myomectomy, and seven did not report transfusion. Intraoperative conversion from myomectomy to another procedure

ranged from 0 to 17 percent in eight studies (n=658). Harms associated with myomectomy included transfusion and pelvic organ injury. Harms did not differ among techniques.

Summary/SOE: Myomectomy is associated with improved quality of life (low strength of evidence). Since myomectomy removes fibroids, the effect on fibroid size is not measured, and strength of evidence is not graded. Evidence is insufficient to determine if myomectomy meaningfully improves bleeding patterns or anemia. Myomectomy is an option for women desiring future fertility, though evidence is insufficient to define potential benefit.

Hysterectomy

We identified 14 RCTs assessing hysterectomy (via abdominal, vaginal or laparoscopic-assisted approaches) in women with uterine fibroids. Seven reported harms only (i.e., did not report final health outcomes for effectiveness). Assessment duration (where clearly reported) in comparative studies ranged from 15 days to 24 months. We assessed five as good quality, three as fair quality, and six as poor quality for effectiveness outcomes. Among seven studies reporting health outcomes, one noted a decrease in hemoglobin postoperatively, and two reported increases in hemoglobin levels 24 months after surgery. Pain symptoms improved in three RCTs reporting outcomes of fibroid-related pain. Time to return to usual activity after hysterectomy averaged 30 to 40 days in three studies. One study reported faster recovery (mean 22 days) after laparoscopic hysterectomy. Women reported good or very good satisfaction postoperatively, though one study reported worsened physical health compared with baseline measures at 5-year followup.

The percent of women needing transfusion following hysterectomy ranged from 0 to 20 percent in 890 women from 11 studies. An event of organ perforation occurred in one study, but overall risk across studies cannot be calculated since bowel and bladder injury were not uniformly reported across studies.

Summary/SOE: Hysterectomy de facto reduces uterine size and bleeding; the strength of this evidence cannot be graded. There is low strength of evidence that hysterectomy improves quality of life.

Direct Comparisons of Interventions

In total, 17 studies compared the effectiveness of two or more interventions. We identified four studies designed to compare outcomes across two or more of drugs (e.g., GnRH vs. ulipristal acetate). Overall these studies were small and inadequately powered for providing definitive evidence of greater effectiveness.

Two studies compared HIFU to other interventions, with greater tumor destruction after radiofrequency ablation compared with HIFU, and comparable sexual function after HIFU or myomectomy, but faster recovery in the HIFU groups.

Other direct comparisons of procedures included comparisons of UAE to myomectomy or hysterectomy. Technical success and quality of life were similar between UAE and myomectomy but reintervention rates were higher with UAE. Because of low power to detect differences, the evidence is insufficient to determine if pregnancy outcomes are better after myomectomy compared to UAE. Likewise ovarian reserve was assessed in only one study comparing UAE to hysterectomy. Symptom relief and quality of life outcomes were generally similar between UAE and hysterectomy (regardless of surgical approach), with faster recovery associated with UAE. Subsequent treatment rates were higher in the UAE group than in the hysterectomy group at each time point in followup; however, the majority of women randomly assigned to have UAE avoided hysterectomy for the duration of followup, which included 5

years of surveillance in the largest study. Fewer than one in three women with UAE required additional treatment.

Summary/SOE: Because of low power to detect differences, the evidence is insufficient to determine if outcomes differ in direct comparisons of procedure or medications

Analysis of Subsequent Treatment Following Initial Treatment for Uterine Fibroids

From data reported in 38 studies, we estimated the probabilities of receiving additional treatment for fibroids after randomization to initial treatment with medical management, UAE, or myomectomy. For women in their 30s, the model predicted that the probability of subsequent intervention for fibroids over 2 years varied from 6 to7 percent after medical treatment or myomectomy, to 44 percent after UAE. For women in their 40s and 50s, modelled 2-year reintervention rates were 9 to19 percent following medical treatment or UAE, and 0 percent after myomectomy.

Overall, fewer than half of women had another intervention within 24 months. UAE was most often followed by myomectomy among those in their 30s, and by hysterectomy among those in their 50s. Younger women who initially had myomectomy were most likely to have repeat myomectomies over the 2 years of followup. After medical treatment, very few women in any age group had subsequent treatment within 2 years.

KQ2: Influence of Patient/Fibroid Characteristics on Effectiveness

Among 97 randomized clinical trials of interventions, none were explicitly designed to address whether intervention effectiveness varied by patient or fibroid characteristics. Six studies provided some information about influence of characteristics on outcomes within or across arms (two of medications, two comparing UAE and surgery, one of myomectomy vs. no treatment, and one assessing the effects of baseline characteristics on outcomes among women who received high intensity focused ultrasound or radiofrequency ablation). None were statistically powered to examine effect modification by characteristics to answer questions such as: do those with fewer or smaller fibroids do better that those with more or larger fibroids? do women using hormonal contraceptive have different outcomes over time after this treatment compared to those who don't? and does baseline BMI determine results? As a result there is little data that can be used to guide care based on individual or fibroid characteristics.

KQ3: Risk of Leiomyosarcoma When Mass Thought to Be a Fibroid

We replicated and updated the search from a recently published meta-analysis of prevalence of leiomyosarcoma among women treated for benign uterine fibroids.[10] We added 27 studies (26 cohort studies and 1 RCT) published since the conduct of the prior meta-analysis. We fit a Bayesian binomial random effects model to update the estimate of prevalence of identifying a leiomyosarcoma at the time of surgery for presumed fibroids. The most inclusive estimated prevalence, from 68 prospective studies where conflicting data were clarified, is 0.02 percent (95% credible interval, 0.00 to 0.09%). When we limit the analysis to retrospective studies, the estimate is 0.09 percent (95% credible interval, 0.05 to 0.13%). Lack of precision means these estimates are not credibly different. In other words, using data from 160 studies, an unexpected leiomyosarcoma will be identified in fewer than one and up to 13 of every 10,000 surgeries performed for symptomatic fibroids.

KQ4: Factors Affecting Leiomyosarcoma Survival

Survival time for women with leiomyosarcoma for whom power morcellation was used was reduced compared with women for whom sharp morcellation (with a scalpel) was used and with those for whom the uterus was removed intact. From our meta-analysis, power morcellation has expected 5-year survival of 30 percent (95% Bayesian credible interval [BCI] 13% to 61%); scalpel morcellation, 59 percent (BCI: 33% to 84%); and intact removal, 60 percent (BCI: 24% to 98%).Though confidence bounds overlap, this analysis suggests method of morcellation may contribute to overall lethality of this aggressive form of cancer among those diagnosed with leiomyosarcoma after hysterectomy or myomectomy for fibroids. Evidence was insufficient to conclude whether patient and fibroid characteristics affected survival in women with leiomyosarcoma.

Discussion

Evidence about effectiveness of treatment is synthesized across arms of studies that used the intervention in order to describe outcomes by intervention. If a study included different types of interventions, each is included in the related synthesis and discussion.

KQ1. Effectiveness of Treatments for Fibroids

Insufficient evidence suggests that expectant management results in minimal change over followup periods of a year or less. Our findings are compatible with a prior review that included observational cohorts. [12] Outcomes are likely to differ by menopausal status, and longer term studies are needed.

Among medical therapies, GnRH agonists, mifepristone, and ulipristal reduced fibroid size and improved fibroid-related symptoms including bleeding and quality of life (moderate SOE, except for quality of life for GnRH agonist (low SOE)). Several other medications have promise but are not supported by sufficient evidence. Evidence is insufficient to detect differences by medication dose, duration of treatment, long term effectiveness and harms. Evidence is lacking for common clinical approaches such as non-steroidal anti-inflammatory drugs, oral contraceptives and is insufficient for the LNG-IUD.

With notable exceptions, the majority of surgical studies did not follow patients beyond the postoperative period. Therefore, many studies did not report patient-specific, or symptom related outcomes such as change in fibroid-related pain or bleeding. Many of the studies with surgical or procedural interventions reported intermediate outcomes only, such as technical success, hospital length of stay, or estimates of blood loss related to the surgery (e.g., postoperative hemoglobin, intra- or postoperative transfusion). Despite these limitations, we found that uterine artery embolization (UAE) (high SOE) as well as HIFU (low SOE) are effective for decreasing fibroid size/volume. Few other outcomes are well investigated for HIFU. UAE studies reported improved bleeding outcomes (moderate SOE), pain, and quality of life (moderate SOE). Myomectomy improves quality of life (low SOE). Hysterectomy improves quality of life (low SOE) and de facto resolves bleeding and bulk symptoms.

Table D summarizes the strength of evidence for the effectiveness of interventions on fibroid/uterine volume, fibroid-related bleeding, and quality of life because these were most frequently reported outcomes in the eligible studies for KQ1. For the complete assessment of strength of evidence, including risk of bias, study limitations, reporting bias, precision, consistency and directness of results, see the summaries presented in the full report.

Table D. Strength of evidence and summary of findings for intervention effects on fibroid volume, fibroid-related bleeding, and quality of life

Intervention Category Total N Participants	Key Outcome(s)	Strength of Evidence	Key Findings
Expectant management N=514	Change in fibroid size or uterine volume	Insufficient	Few women followed in 16 study arms; findings inconsistent; data inadequate to project course of watchful waiting (followup from 3-12 months)
	Change in bleeding	Insufficient	As above
	Quality of life	Insufficient	As above
GnRH agonist N=912	Change in fibroid size and uterine volume	Moderate	Consistent reductions in size or volume
	Change in bleeding	Moderate	Bleeding outcomes (e.g., menorrhagia, perceived blood loss, days of bleeding) consistently improved
	Quality of life	Low	Consistent improvements in arms reporting varied measures of quality of life
Mifepristone N=690	Change in fibroid size or uterine volume	Moderate	Consistent reductions in size or volume in study arms reporting these outcomes
	Change in bleeding	Moderate	Consistent improvements in bleeding outcomes (e.g., hemoglobin, amenorrhea, hypermenorrhea) in arms reporting these outcomes
	Quality of life	Moderate	Quality of life improved in study arms reporting varied measures of quality of life
Ulipristal N=1,095	Change in fibroid size and uterine volume	Moderate	Improvements in arms reporting these outcomes, with reductions generally maintained over 6 month followup
	Change in bleeding	Moderate	Bleeding outcomes (e.g., amenorrhea, hemoglobin) consistently improved in study arms reporting these outcomes
	Quality of life	Moderate	Improvement in fibroid-related quality of life in study arms reporting varied measures of quality of life
LNG-IUD N=30	Change in bleeding	Insufficient	Limited data in one small study with high risk of bias
Estrogen receptor agents (raloxifene, tamoxifen) N=117	Change in fibroid size and uterine volume	Low	Lack of effect on fibroid size with raloxifene
	Change in bleeding	Low	No changes in bleeding patterns or hemoglobin with raloxifene
Uterine artery embolization and occlusion N=1,376	Change in fibroid size and uterine volume with UAE	High	Consistent reduction in size in study arms reporting these outcomes, with two studies reporting continued effects for 5 years
	Change in bleeding with UAE	Moderate	Improvements in bleeding outcomes (e.g., days of bleeding, hemoglobin, patient-rated bleeding) in study arms reporting these outcomes
	Quality of life with UAE	Moderate	Improvements in study arms reporting varied

Intervention Category Total N Participants	Key Outcome(s)	Strength of Evidence	Key Findings
			measures of quality of life
	Change in bleeding, fibroid size with uterine artery occlusion	Insufficient	Heterogeneity of intervention methods prohibits conclusions
HIFU for fibroid ablation N=264	Change in fibroid size and uterine volume	Low	Reduction in study arms reporting these outcomes
Radiofrequency fibroid ablation N =75	Change in bleeding	Insufficient	Limited data available to assess outcome
Endometrial ablation N=96	Change in bleeding	Insufficient	Limited data available to assess outcome
Myomectomy N=2,257	Change in fibroid size and uterine volume	N/A	N/A
	Change in bleeding	Insufficient	Few studies reported outcome; improvement in heavy bleeding noted in one study
	Quality of life	Low	Improvements in study arms reporting varied measures of quality of life
Hysterectomy N=1,116	Change in fibroid size and uterine volume	N/A	N/A
	Change in bleeding	N/A	N/A
	Quality of life	Low	Improvements in study arms reporting varied measures of quality of life

GnRH = gonadotropin-releasing hormone; HIFU = high intensity focused ultrasound; LNG-IUD = levonorgestrel intrauterine device; NA = not applicable, not measured; SOE = strength of evidence

Comparative Effectiveness

Studies comparing different categories of intervention were rare. Most were single studies of the specific comparison investigated. Two studies compared UAE to myomectomy; 3 studies compared UAE to hysterectomy; and four studies compared different drugs, but because of quality and size of these single comparison studies, evidence is insufficient to guide choices between medications and procedures.

Subsequent Intervention

For each of these interventions (uterine artery embolization, myomectomy, and medical management) and the subsequent treatment possibilities, the meta-analysis estimates 44 percent of women in their 30s received subsequent intervention after UAE. The findings are intriguing but inadequate to guide care about the sequence of treatments that may have the best outcomes

because the overall quality of trials is limited and few women were followed long enough to identify treatment patterns. It is likely that much fewer than half of women will choose subsequent treatment in the near-term after an initial intervention. However, we can also speculate that the priorities which led women to participate in the initial trials reflected the intensity of treatments they were most interested in pursuing so it is not surprising surgeries were most followed by other procedures promptly (within 6 months) by those were not satisfied with initial results while those who enrolled in medication trials were less likely to pursue more aggressive options. Because of the limited roster of studies that followed women for 6, 12, or 24 months, this analysis does not substitute for study of treatment trajectories in which all initial treatments can be followed by all possible combinations of next treatments.

KQ2. Influence of Patient/Fibroid Characteristics on Effectiveness

Overall, data are inadequate to assist women in choosing one intervention over another based on her individual characteristics or the characteristics of her fibroids. Too few studies were adequately powered to determine within arms if one subgroup or another has superior outcomes within a treatment. Such information is required as a first step towards using individual characteristics to inform treatment choice.

KQ3. Risk of Leiomyosarcoma When Mass Thought To Be a Fibroid

Overall, from 160 studies, we conclude that in every 10,000 who have surgery for fibroids, between 0 to 13 women, may be found to have a leiomyosarcoma. This is within the range of the point estimates that others have produced. [10,24,25] Our analysis includes a larger sample size, more prospective studies, and more recently published data. One advantage to prospective studies is that they employ standardized approaches for inclusion and data collection and apply quality controls for histopathology. Participants in prospective studies were somewhat younger than those in retrospective studies (mean age 38.5 versus 43.4 years, respectively). Among prospective studies 57 percent focused on myomectomy findings; 36 percent on hysterectomy, and 6 percent included both types of surgery. Among retrospective studies 32 percent focused on myomectomy; 49 percent hysterectomy, and 19 percent both. Because leiomyosarcoma risk increases with age [25,26], differences in age distribution and potentially in surgery type would be expected to result in a lower prevalence estimated by our models.

The literature investing the prevalence of leiomyosarcoma in presumed fibroids has grown rapidly and this continues to inform risk estimates. Unfortunately, the published literature does not contain enough detail to stratify risks by age, menopausal status, or surgical approach. Similarly, the literature lacks information on individual or fibroid characteristics that could discriminate those at high risk from those with lower risk. Thus the available data produces wide confidence intervals for broad groups of women when estimating rare outcomes. See "Limitations of the Evidence Base" in the full report for further discussion.

KQ4. Factors Affecting Leiomyosarcoma Survival

At this time, definitive data that power morcellation is associated with poor long-term outcomes in the presence of unsuspected leiomyosarcoma is limited. In our meta-analysis of 24 studies that provide data about use of morcellation in three categories: none, scalpel, or power; we find that power morcellation may be a determinant of death from leiomyosarcoma. Some

recent estimates in the literature find otherwise. As noted above, we cannot discern from the available literature any patient or fibroid characteristics that predict survival.

Uncertainty in estimates of prevalence and evolving data about methods for tissue extraction and their consequences call for explorations of ethical and shared decision making topics to offer coherent care recommendations that support patients' and surgeons' autonomy.

Applicability

Overall, our findings are widely applicable to the general population of women seeking treatment for uterine fibroids. For KQs 1 and 2 we set inclusion criteria for this review to women of any age with uterine fibroids with patient outcome data beyond intermediate outcomes only. We excluded studies in pregnant women, and restricted our synthesis to treatments currently available in the United States. Over 40 percent of the studies were conducted in European countries and another 27 percent were conducted in the United States or Canada. Although the outcomes collected may differ by country and by healthcare setting, the interventions were selected to be comparable so that the results reported in this review are expected to apply to women with fibroids in the United States.

Evaluation of expectant management was not an explicit aim of any trial. Sixteen studies with placebo arms or no treatment arms that included 514 women served as a surrogate. This population is not an ideal substitute as participants in the trials presumably hoped to receive active treatment and may report their status differently than women willing to be randomized to watchful waiting. This could restrict applicability but since the majority of studies included a plausible level of participant masking, they would be unlikely to know if they were on an active agent.

Medical management of fibroids was assessed in over 2,800 predominately premenopausal women from 43 studies (15 industry-sponsored and 11 conducted in the United States). Procedures, including UAE, HIFU, and radiofrequency fibroid ablation were evaluated in 28 studies including almost 2,000 women. Surgical studies evaluated hysterectomy, myomectomy, and endometrial ablation in over 3,000 women. Although none of the surgical studies were conducted in the United States, the surgical procedures are comparable to those widely available to women in the United States.

Data in these studies were inadequate to assess applicability based on patient characteristics (age, race/ethnicity, pregnancy intention, or menopausal status) or fibroid characteristics (size, position, and number) that could influence effectiveness outcomes.

While there are limitations in the literature as discussed below, the information that is available from these trials is relevant to contemporary practice. In summary, this review is generally applicable to women in the United States seeking one of the many treatment choices currently available for fibroids.

For KQ3 and 4: Data can only be systematically obtained from published research or publically available research. Those represented in the literature may differ from the universe of women having surgery for fibroids in the US. The literature about risk and outcomes of leiomyosarcoma does not separate cases well by type or surgery or menopausal status. Prospective studies which include a greater representation of myomectomy patients may be more applicable for discussing risk among younger women.

Limitations of the Systematic Review Process

Methodologic choices constrain the findings of this report. We chose to focus on publications in the English-language literature, to restrict to randomized clinical trials for the comparative effectiveness synthesis (KQs 1 and 2), and to review only those studies that included at least one intervention that is available in the United States. Similar reviews have documented in the past that language restrictions do not increase risk of omitting high quality trials. This is especially true for the topic of fibroids because the fibroid research community is small. Our technical expert panel and authors are familiar with prior and ongoing work and helped assure relevant studies have not been overlooked. Restricting to trials allowed us to sharply focus on proof of effectiveness. Because all individuals whose outcomes were assessed in these studies were randomly assigned to the intervention received, provider and patient biases in intervention choice are reduced and risk of confounding, difficult to fully assess or adjust for in cohort studies, is minimized. Random assignment to intervention arm in trials reduces bias and allows aggregation and summary of the findings by study arm, as presented in this report.

Restricting the review to randomized controlled trials limited ability to detect the full range of harms since studies were generally not designed or powered to evaluate harms, and many had a short duration of follow up.

Our analysis of subsequent intervention after a first intervention could be biased by the types of studies that reported this data and by differences in the willingness of women to be randomized to different types of intervention.

For meta-estimates related to leiomyosarcoma risk, available evidence based on pathology specimens for estimating presence of leiomyosarcoma in a mass believed to be a fibroid is accruing rapidly and will likely continue after the production of this report. Our estimates and that of Pritts and colleagues[10] find that the estimates are lower in data from more contemporary prospective cohorts of women having surgery compared to retrospectively collected data. This may be explained by inaccuracies in retrospectively collected data even when pathology specimen banks are used to index a full population of surgical patients. On the other hand, it is important to note that prospectively collected data may enroll younger patients and a larger proportion undergoing myomectomies. As a rule, data for estimating rare events is volatile, which is demonstrated by the changes in prevalence estimates when we exclude studies that included hysteroscopy.

The risk of inaccuracy is especially true in understanding and estimating the degree to which morcellation method influences survival when a woman is found to have a leiomyosarcoma that was believed to be a fibroid. More nuanced data is needed to be able to include exact ages and uniform staging data at an individual level and to account for secular trends in aggressiveness of treatment and range of modalities used in treating leiomyosarcomas.

Focusing on interventions available in the United States, and excluding those that cannot be obtained here could neglect a promising intervention but does restrict the report to data that is of immediate value to women and their care providers who must make decisions among available options. We have included some interventions that are not widely available in the United States such as HIFU without MRI guidance. For any woman, her geographic location, local provider training or insurance coverage may restrict the availability of some options.

Limitations of the Evidence Base

While the literature about the effectiveness of uterine fibroids treatment has grown since the last evidence report in 2007, significant gaps in knowledge persist. The 97 studies unique intervention arms enrolled 9,179 women, an average of 98 women per study with a range of 16 to 451. Individual studies were often small and powered to address a single continuous outcome such as hematocrit or score on a quality of life scale.

Our analytic framework was created by expert consensus to reflect the outcomes that matter to women when making decisions. The available literature has substantial gaps in collecting this information as indicated by the number of studies that addressed each of our eight primary outcomes. Fibroid characteristics and symptom status were the most frequently reported outcomes, addressed in 65 percent and 59 percent of the studies respectively, though assessment techniques and measures varied. Other key outcomes including quality of life and satisfaction with outcomes (39%), sexual function (12%), and future reproductive outcomes (8%) were addressed in only a handful of studies. Detailed descriptions of subsequent treatment were reported in 29 percent of the included trials.

Little continuity exists in approaches to measuring outcomes and use of unvalidated measures is common. When data are combined across studies for a particular intervention, risk of serious rare harms cannot be fully assessed. In many instances ability to synthesize evidence across studies is absent, weak because of biased collection methods (e.g., assessors not blind to intervention), or difficult to aggregate across studies because of use of different metrics.

Paucity of "similar" articles (populations, settings, patient characteristics, and outcomes measured) also precludes efforts to pool data about characteristics of the study populations as they contribute to predicting outcomes. No studies were appropriately powered to understand whether specific groups of patients, such as those closer to menopause or with a specific symptom pattern have outcomes that are modified by those characteristics. Lastly, the lack of direct comparisons limits the information this can provide to help a woman or her care provider make an evidence-driven selection among choices in the context of the patient's priorities.

Limitations about leiomyosarcoma data: Because cases are rare and detailed age data for non-cases is lacking, only rough models of risk by age can be produced. [25] We need more prospective studies that include nuanced data such as patient and fibroid characteristics, patient age, menopausal status and surgical approach, hormonal exposures and genetic factors so that we can give more accurate estimates to patients.

Future Research

Key components of study design, analysis, and reporting remain the leading weaknesses of the literature for each topic addressed in this review. Overall, the literature identified is limited by the following gaps and problems discussed in detail in the full report. Future research should aim to remediate these concerns:

- Ability to assess internal and external validity
- Study populations of adequate size for assessing key outcomes
- Use of standard nomenclature and validated measures
- Analysis methods matched to the outcomes of interest
- Direct comparisons of treatment options
- Formal development of patient centered outcome measures for fibroid care

A range of content priorities also need to be addressed. These include the burden of disease and societal costs from loss of ability to function well in the usual family or occupational roles. Transitions associated with appearance of uterine fibroids, growth patterns, and influences on growth (e.g., concurrent medical conditions like diabetes, use of medications like hormonal contraception, influence of lactation and duration) are high-priority topics, as are predictors of symptom development and resolution. Variation in care-seeking behaviors, differences in severity at presentation, and health and quality of life outcomes are other matters that investigators should attempt to address. Likewise reproductive outcomes such as fertility and risk of future pregnancy complications are very important to women as they make decisions about fibroid treatment and the current literature is insufficient to guide choices. In addition, the current literature cannot address from trials whether disparities between white and black women in the age at appearance of fibroids and in the number and size of fibroids also foreshadows different treatment outcomes and durability of results.

In current practice, women without symptoms may forego intervention because of the general belief that care should be aimed at improving symptoms or addressing a specific clinical concern such as difficulty conceiving or recurrent pregnancy loss. Although foregoing intervention can be wise in the absence of data that the intervention will prevent future difficulties, research on the natural history of fibroids and likelihood of developing symptoms or other health effects is limited. No data is available to indicate whether use of therapeutics short of surgery might forestall or prevent future changes in fibroids or appearance of symptoms. The concept of preventive strategies is appealing. However, as long as the etiology of fibroids remains unclear, preliminary trials are not assessing lifestyle interventions, and the prospect for dietary management, nutritional supplementation, exercise, hormonal management, or other prevention trials is slim.

The clinical research agenda will likely depend on new translational research and large-scale epidemiology studies. Much remains to be learned that will require large-scale prospective observational studies of sufficient size and rigor to support time-to-event analysis of outcomes, such as that being conducted in the COMPARE Uterine Fibroids 10,000 woman registry supported by AHRQ and PCORI. These studies may afford greater power to examine effect modification and to determine trajectories of care over a reproductive lifespan for women with fibroids. Additionally, such studies will be better able to estimate both common and rare harms, including the risk of occult leiomyosarcoma. Research effort must be focused on documenting first the course and consequences of uterine fibroids using optimal imaging strategies. We must then deploy more robust statistical techniques across aggregated data in order to understand the modifiers of that course and of the effectiveness of treatment, so that we can offer women an accurate account of the likely outcome of intervention choices based on their individual status.

Conclusions

A range of interventions are effective for reducing fibroid size and improving symptoms. Some medications and procedures also improve quality of life. Direct comparisons among treatment options remain sparse. No studies have explicitly evaluated expectant management, which is a crucial missing piece of the evidence about whether symptoms relapse and remit. The literature must come to include uniformly longer followup to determine whether women's objectives for treatment were met by the intervention received. Few women have only one concern driving their desire for intervention, yet remarkably many trials are directed at evaluating a single outcome. Likewise concerns about harms, such as drug side effects, serious

surgical complications, and risk of undetected leiomyosarcoma, need to exploit larger and more nuanced data to be able to better determine what individual and fibroid characteristics best predict adverse events to better inform personalized care.

Across management options, we must note that lack of evidence is not equivalent to evidence of no benefit or of harm. Evidence to inform probability of risk or benefit based on patient characteristics is lacking. Uncontrolled studies are not a substitute since they are notably biased for overestimating the degree of benefit subsequently reported in randomized trials. Indeed, not uncommonly, trials negate the findings of what in this case is largely retrospective and case series research. The current state of the literature does not permit definitive conclusions about comparative benefit, harm, or relative costs to achieve similar results across the range of available options and lacks strength of evidence for interventions such as use of continuous birth control pill regimens, progesterone containing IUDs, and endometrial ablation that are often used in routine clinical practice.

Given how common and concerning fibroids can be to women and their care providers, a redoubled emphasis on promoting high-quality fibroid research in the United States is imperative. Women need better information to guide their choices.

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Introduction

Condition

Uterine fibroids (i.e., leiomyomata) are common benign smooth muscle tumors of the uterus. The etiology is not well understood, and a variety of factors including race/ethnicity, parity, and age at menarche have been examined. By age 49, more than 70 percent of white women and 84 percent of African American women have fibroids documented by imaging or surgical records.[1] In the United States, an estimated 26 million women between the ages of 15 and 50 have uterine fibroids. [1-3,1-3,5,6,27,28] Fibroids may be asymptomatic, or can produce health effects that include profound bleeding and anemia, pelvic pressure or pain, urinary frequency, abnormal bowel function, pain with intercourse, as well as effects on fertility and pregnancy outcomes.[29] More than 15 million US women will experience associated symptoms or health concerns.[5,6] A disproportionate number of black women have symptoms in part due to earlier age at onset of fibroids with larger and more numerous tumors.[1-3,27,28,29] Black women are also more likely to have surgical interventions for fibroids.[7]

Symptoms from fibroids can result in considerable personal and societal costs including diminished quality of life, disruption of usual activities and roles, lost work time, and substantial healthcare expenditures. Across types of interventions, direct annual healthcare costs in the United States are projected to exceed $9.1 billion. Lost wages, productivity, and short-term disability are estimated to total another $5 to $17 billion annually, with roughly $4,624 in costs per woman in the first year of diagnosis.[8,9]

Management of Uterine Fibroids

Asymptomatic fibroids do not require intervention. Discussion of management options for *symptomatic* fibroids is among the most frequent conversations in gynecology and primary care and is the most common reason for gynecologic surgery.[30,31] These discussions are shaped by future reproductive goals.[32,33] Treatment options differ in fundamental aspects such as cost, invasiveness, recovery time, risks, likelihood of long-term resolution of symptoms, need for future care for fibroids, and influence on future childbearing. Thus synthesis of available evidence is crucial to assist women and their care providers in making well-informed and personalized decisions.

This report is organized from least invasive to more invasive treatment options: expectant management, then medical treatment, and then outpatient procedures and major surgeries.

Medications

In any given year, a greater proportion of women with symptomatic fibroids receive medical therapy than surgery.[9] Though no medications have been specifically cleared by the U.S. Food and Drug Administration (FDA) for fibroid treatment, several medications are used off-label for fibroid symptoms. Those commonly used in clinical practice include birth control pills, stool softeners, and nonsteroidal anti-inflammatory agents. Others are characterized as gonadotropin-releasing hormone releasing hormone (GnRH) agonists, progesterone receptor agents, estrogen receptor agents, and antifibrinolytics. Because the mechanism of action is the progesterone it

contains, we include the levonorgestrel (LNG) intrauterine device (IUD) as a progesterone medication in this review.

GnRH agonists down-regulate ovarian production of estrogen and progesterone and decrease stimulation of hormone receptors. This "medical menopause" decreases fibroid growth, promotes uterine involution, and reliably produces amenorrhea. This improves bulk symptoms, bleeding and the anemia associated with fibroids. Estrogenic add-back therapy may be used with a GnRH agonist to offset unwanted side effects such as hot flashes, vaginal dryness, and decrease in bone density. GnRH agonists include the injectable leuprolide , goserelin (an implant) and triptorelin.

Progesterone receptor agents modulate progesterone activity. *Mifepristone* competitively binds to the intracellular progesterone receptor, blocking the effects of progesterone and reducing fibroid size. Two things may limit its use: Mifepristone exhibits antiglucocorticoid activity, and only physicians with a prescriber's agreement with the manufacturer can obtain the drug in the United States.[34] *Ulipristal acetate* is a selective progesterone receptor modulator that is structurally similar to mifepristone, but has less antiglucocorticoid activity. [35-37] It has been FDA cleared since 2010 for emergency contraception. Ulipristal is cleared in Europe for long term medical management and preoperative therapy for fibroids. *Levonorgestrel-IUD* releases 20 µgr of levonorgestrel daily. It reduces bleeding by inhibiting endometrial proliferation.

Estrogen receptor agents: Selective estrogen receptor modulators bind to estrogen receptors to mimic or block estrogen activity, and have differential effects across tissue types (e.g., bone, brain, liver). *Tamoxifen* was introduced to block estrogen action in the treatment of breast cancer, but has estrogen –like effects on the uterus. *Raloxifene* has estrogen-like effects on bone, but anti-estrogen effects in the breast and uterus. It is used to treat osteoporosis and prevent breast cancer, and reduce fibroid size.

Combined hormonal replacement treatment (HRT): The transdermal estradiol patch plus a progestin can be used to reduce menopausal symptoms in women with fibroids. Combined birth control pills can be used to reduce bleeding and pain in pre-menopausal women.

Antifibrinolytics: *Tranexamic acid* improves blood clotting and is used to reduce heavy menstrual bleeding and to minimize postoperative blood loss.

Procedures

We considered those interventions that can typically be conducted in an office or as same-day surgery as procedures. These include uterine artery embolization or occlusion, high intensity focused ultrasound (HIFU) and radiofrequency fibroid ablation.

Uterine artery occlusion and embolization are techniques to interrupt the blood supply to uterine fibroids, which causes infarction and cell death within the fibroid, thus reducing fibroid size and symptoms. **Uterine artery embolization (UAE)** involves placement of a catheter through a blood vessel in the groin, using techniques similar to cardiac catheterization. Selected arteries are then blocked by introducing an embolization agent to close off the blood flow to the fibroid(s). UAE is an interventional radiology procedure, usually performed as an outpatient in an imaging suite. This procedure is an option for women who wish to avoid surgery, are poor candidates for surgery, or who wish to retain their uterus. It is not currently recommended for women who wish to have future pregnancies

Uterine artery occlusion is an older, less selective technique to directly occlude the main uterine vessels with sutures or coagulation at the time of open or laparoscopic surgery. Generally, occlusion is more invasive (requiring general anesthesia and an operating suite) and

less selective than embolization. In one study, the authors describe "occlusion" as the use of vascular coils placed via uterine artery catheterization, which does not require surgery.[38]

High intensity focused ultrasound (HIFU), guided by ultrasound or MRI, directs a focused ultrasound beam to the fibroid. This induces thermal destruction of the target tissue. When MRI is used, the procedure is conducted in an MRI suite using a system that integrates real-time MRI and thermometry with an ultrasound unit specially designed to focus ultrasound waves. In 2004, the FDA approved one system (Magnetic Resonance Guided Focused Ultrasound (MRgFUS) for ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids with a uterine size of less than 24 weeks.

Radiofrequency ablation uses a laparoscopic approach to map fibroids with ultrasound, which are then ablated with an instrument that delivers the radiofrequency energy into the fibroid. One system is FDA cleared for use in the United States.

Surgery

We classify more invasive interventions that are typically performed in an operating room or require at least a brief hospital stay as surgical approaches. These include endometrial ablation, myomectomy, and hysterectomy.

Endometrial ablation is a procedure that destroys (ablates) the uterine lining (endometrium) using one of these techniques: laser, radiofrequency, thermal balloon, electricity (cautery, roller-ball), freezing, or microwave. The goal of endometrial ablation is to reduce or eliminate uterine bleeding. Pregnancy is not recommended after endometrial ablation, and tubal occlusion may be performed in conjunction with the procedure.

A **myomectomy** excises the fibroid(s) and repairs any defect in the uterine wall, while preserving the uterus. For this reason, myomectomy is an option for women who desire future pregnancies or who wish to retain their uterus. After myomectomy, fibroids could recur, which could lead to subsequent intervention(s).[39] The surgical approach may be through an open abdominal incision (laparotomy) or a smaller open incision (minilaparotomy). A laparoscope can be used to remove the fibroid(s) through small incisions in the abdominal wall (laparoscopic) or a hysteroscope can be used to reach the fibroid(s) through the cervix (hysteroscopic). Myomectomy can be completed with or without a morcellator. Myomectomy can also be combined with endometrial ablation or uterine artery embolization.

Hysterectomy- the complete surgical removal of the uterus- is a definitive treatment for symptomatic fibroids in women who have completed childbearing. Hysterectomy does not require removal of the fallopian tubes and ovaries. Surgery that removes the entire uterus plus fallopian tubes and ovaries is properly called "total hysterectomy with bilateral salpingo-oophorectomy." Surgery that leaves the uterine cervix intact is called supracervical hysterectomy. The surgical approach may be through an open abdominal incision (laparotomy), though the vagina (vaginal) or with the use of a laparoscope (laparoscopic). The open incision may be reduced in size (minilaparotomy). The laparoscopic procedure may be exclusive (total laparoscopic hysterectomy), or may include a vaginal procedure (laparoscopic assisted vaginal hysterectomy). Hysterectomy procedures can be completed with or without a morcellator.

Additional Management Concerns

Although it is not a separate procedure, it is important to discuss **morcellator** use for fibroid removal. Morcellation reduces the fibroid tissue to smaller fragments that can then be removed through smaller incisions. For several decades, power morcellators have been used to

facilitate hysterectomy and myomectomy via less invasive laparoscopic approaches. Fragments can be removed directly through a port or using a flexible bag system that can then be removed through a port. One technique creates the fragments inside the bag system before removal. Several morcellation devices have FDA approval; all currently are included in a 2014 FDA safety communication that advises **against** using power morcellators "in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids" due to the risk of disseminating cancer in women with occult leiomyosarcoma. The FDA estimated the risk of occult leiomyosarcoma to be 20 (range: 11 to 38) per 10,000 women undergoing surgery for presumed fibroids.[40,24] As a result of this advisory, women and surgeons are choosing more invasive treatments for fibroid removal, with the attendant increases in costs, risk of harm, and recovery time.[41,42]

Leiomyosarcomas are rare: an average of 1,600 new cases occur in the United States each year.[43] However, they have poor outcomes with an average 5-year survival of 36 percent if cancer has spread to the pelvis and not isolated to the uterus. The primary means of dissemination of leiomyosarcoma is believed to be hematogenous. More than half of women with leiomyosarcomas develop distant metastasis before local recurrence in the pelvis, and most progress to higher stage disease regardless of order of spread.[44,45]

If the leiomyosarcoma is disrupted during removal, both visible and microscopic particles may be spilled. If spillage worsens stage and survival, then removing a leiomyosarcoma by power morcellation would have a poorer outcome than using scalpel morcellation, and both of these would be inferior to removing the uterus and tumor intact.

Scope and Key Questions

Scope

To best inform clinical decisions about care we focused on evidence from randomized trials that assessed effectiveness of currently used interventions for women of any age with fibroids. We also sought to identify factors that might modify likelihood of favorable results or harms from treatments. We included studies evaluating medications, procedures, and surgeries for the management of uterine fibroids. For expectant management, we summarize data from women who were followed within trials without active intervention. In order to inform women and providers, accurate estimates are needed regarding the prevalence of leiomyosarcoma and risks of dissemination after morcellation.

This review does not cover preoperative adjunctive treatments such as GnRH agonists or intraoperative techniques, like use of cell savers that have established effectiveness as preoperative or adjunctive interventions to minimize blood loss or otherwise improve short-term operative outcomes. We also do not review trials comparing operative devices (such laparoscopic instruments for ligation versus cautery of the uterine vessels) if the trial included only intermediate outcomes. Except in the context of factors assessed at the time of imaging that may help identify risk of dissemination of leiomyosarcoma, we do not address diagnostic accuracy of imaging. We did however seek to examine conventional fibroid characteristics as assessed by imaging and how they relate to achieving desired outcomes.

Key Questions

Key Question 1. What is the comparative effectiveness (benefits and harms) of treatments for uterine fibroids, including comparisons among these interventions?

Key Question 2. Does treatment effectiveness differ by patient or fibroid characteristics (e.g., age; race/ethnicity; symptoms; menopausal status; imaging characteristics; vascular supply to fibroids; or number, size, type, location, or total volume of fibroids)?

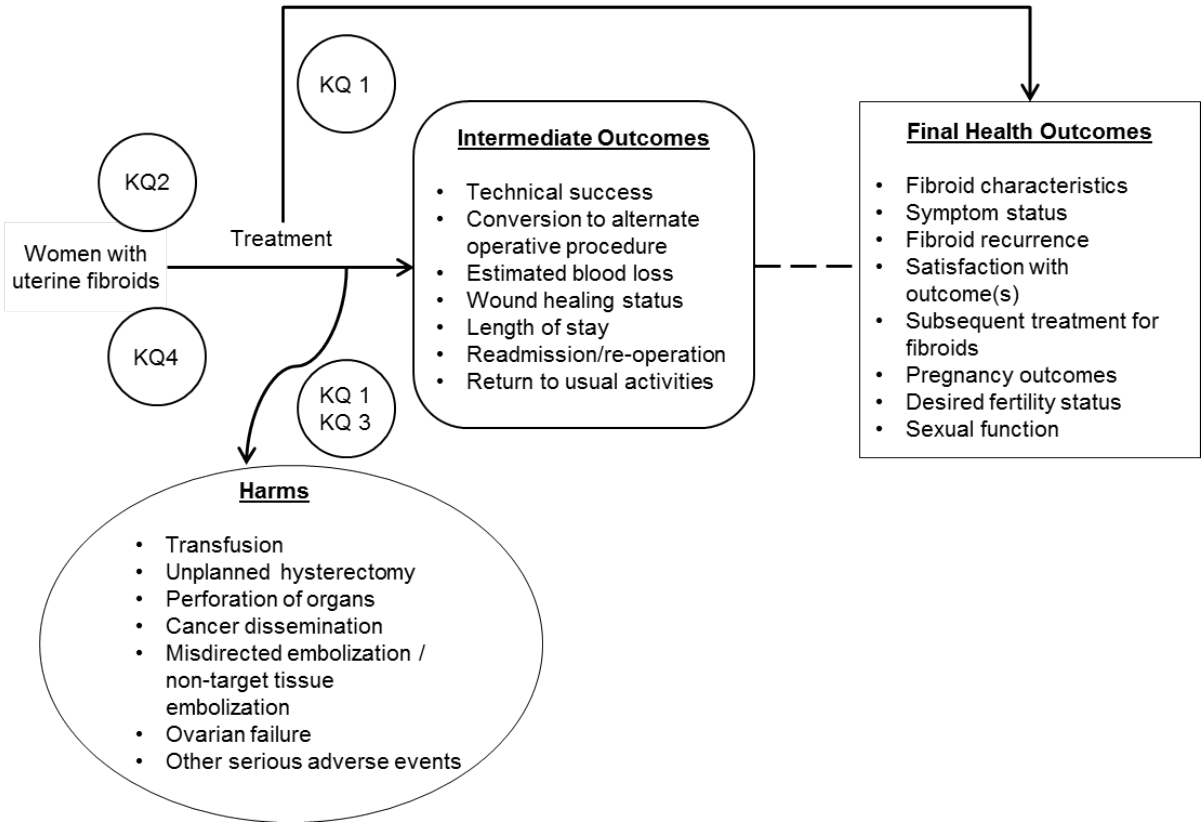
Key Question 3. What is the risk of encountering a leiomyosarcoma for masses believed to be uterine fibroids at the time of myomectomy or hysterectomy?

Key Question 4. Does survival after leiomyosarcoma differ by patient or fibroid characteristics (e.g., age; race/ethnicity; symptoms; menopausal status; imaging characteristics; vascular supply to fibroids; or number, size, type, location, or total volume of fibroids) or by surgical approach to fibroid morcellation?

Analytic Framework

The analytic framework provides context for our Key Questions (KQs) and illustrates the population, intermediate outcomes, final health outcomes, and interest in a specific set of harms that guided the literature search and synthesis of evidence (Figure 1).

Figure 1. Analytic framework



KQ = Key Question

Organization of This Report

The overall structure of the report arranges findings in order to address the most common questions of women and care providers, as follows.

1. What are the options for managing fibroids and what are typical outcomes? Meaning, if a woman chooses a type of intervention, how is that choice likely to turn out? Will fibroids change, will symptoms improve, will quality of life improve, and will she be satisfied with this choice? These questions are answered by arranging all the outcome data about a particular drug, procedure, or surgery together and showing the aggregate expectations for available outcomes such as change in fibroids or change in bleeding. When multiple studies included an outcome we used tables to summarize this data. When few studies addressed the outcome (such as future pregnancy outcomes, or harms), we address these outcomes in text. (KQ1a)

2. If a woman chooses an option, how likely is it that she will need additional intervention in the near future? We modeled subsequent intervention by category of initial intervention to address this question. We note that women choosing to participate in randomized controlled trials of different types of interventions may differ in key ways that cannot be defined from the literature (KQ1b).

3. What information is available that directly compares one type of intervention compared to other types of interventions? This question is best answered by review of truly comparative studies, for instance those that examine medication versus procedure, or procedure versus a particular surgery. If study data speak only to the question of choosing a dose, choosing a drug within a category, or choosing a surgical approach (e.g., laparoscopic vs. open) we included those studies in our summary of results for each category of intervention (KQ1c), as it primarily informs the first question above (i.e., effects from a given type of drug or surgery). In this section at the end of KQ1 we address genuine comparisons of different management approaches (Comparative Effectiveness Studies) because this is what women and care providers are considering. They are weighing whether one type of intervention is better on average than another choice, or if equivalent, do patient values and priorities make it easier to choose knowing they are equivalent.

4. Is there anything about a woman or her fibroids that can help determine what is likely to work well? We attempted to identify characteristics in the literature that may address this question (KQ2).

5. If a woman has a mass thought to be a fibroid, what is the likelihood that she has a leiomyosarcoma? Are there factors which would influence survival of a woman with leiomyosarcoma? We then address the risk of leiomyosarcoma (KQ3) and then present information about individual and fibroid characteristics and surgical approach that may modify leiomyosarcoma survival (KQ4).

Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center (EPC) used to develop this comparative effectiveness report. We first describe the development of the topic and scope of review, including formulation of Key Questions (KQs). We present our strategy for identifying relevant literature, our inclusion and exclusion criteria, and the process we used to abstract relevant information and synthesize evidence. We also discuss our criteria for summarizing the risk of bias for individual studies and the overall strength of the evidence for each intervention category with respect to selected high-priority outcomes. Detailed records about EPC methods are available at the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program Web site (http://www.effectivehealthcare.ahrq.gov) and key documents related to conduct of this report are included in the appendices.

Topic Refinement and Review Protocol

The EPC engaged in a public process to refine the original topic submission, draft the KQs, and develop a systematic review protocol. A panel of 10 Key Informants provided input via teleconferences and individual communication. Key Informants represented the fields of gynecology, patient advocacy, and regulatory and industry stakeholders. The draft KQs were posted on the Agency for Healthcare Research and Quality Effective Health Care Web site for public review and critique for three weeks. Comments did not necessitate any significant changes to the KQs, review scope, or inclusion criteria. The EPC then recruited a panel of nine technical experts to provide high-level content and methodologic expertise throughout the review. The technical expert panel members represented the fields of gynecology, interventional radiology, reproductive endocrinology, and epidemiology. The final protocol was registered with PROSPERO (registration CRD42015025929) and posted on the Effective Health Care Web site (http://www.effectivehealthcare.ahrq.gov).

Finding and Selecting Studies

Published Literature

We searched MEDLINE® via PubMed® to identify publications (Table 1 and Table 2). The full search strategy is presented in Appendix A. We limited the search to literature published after January 1985 in order to encompass modern surgical methods including the widespread introduction of laparoscopy as well as current nonsurgical interventions and medications. We conducted a literature search update during the time of peer review of the draft report and include relevant studies identified through September 2016. We also checked the reference lists of included studies, and incorporated relevant, eligible studies identified by peer reviewers or public commenters. A portal was available 3/14/2016 to 4/11/2016 on the Effective Health Care Web site to receive scientific information and regulatory information on medications, procedures, and devices used to treat uterine fibroids.

Table 1. Literature search strategy: interventions for uterine fibroids

Search	Query	Results
#1	((leiomyoma[mh]) OR (fibroma[mh] AND (uterine diseases[mh] OR uterus[mh]))	17,656
#2	(Uterine[tiab] AND (fibroma*[tiab] OR fibroid*[tiab] OR leiomyoma*[tiab] OR myoma*[tiab] OR fibromyoma*[ti-ab]) OR (submucous fibroid*[tiab] OR submucosal fibroid*[tiab] OR Intramural fibroids [tiab]) NOT medline[sb]	985
#3	#1 OR #2	18,621
#4	("Mifepristone"[Mesh] OR "ulipristal"[Supplementary Concept] OR "Anti-Inflammatory Agents, Non-Steroidal"[Mesh] OR "Antifibrinolytic Agents"[Mesh] OR "Goserelin"[Mesh] OR "cetrorelix"[Supplementary Concept] OR "Selective Estrogen Receptor Modulators"[Mesh] OR "Levonorgestrel"[Mesh] OR "Nafarelin"[Mesh] OR "Triptorelin Pamoate"[Mesh] OR "Leuprolide"[Mesh])	90,459
#5	(Mifepristone[tiab] OR Ulipristal acetate[tiab] OR NSAID[tiab] OR antifibrinolytic[tiab] OR Goserelin[tiab] OR cetrorelix acetate[tiab] OR Selective estrogen receptor modulators[tiab] OR SERM[tiab] OR mirena[tiab] OR lng-ius[tiab] OR levonorgestrel-releasing intrauterine system[tiab] OR management[tiab] OR leuprolide[tiab] OR triptorelin[tiab] OR nafarelin[tiab]) NOT medline[sb]	92,082
#6	#4 OR #5	182,541
#7	therapy[sh:noexp] OR drug therapy[mh] OR drug therapy[sh] OR complementary therapies[mh] OR cam[sb] OR Treatment outcome[mh]	4,576,056
#8	surgery[sh] OR surgical procedures, operative[mh] OR embolization, therapeutic[mh]	3,058,662
#9	(Hysterectomy[tiab] OR myomectomy[tiab] OR hysteroscopy[tiab] OR emboliz*[tiab] OR ablation[tiab] OR magnetic resonance guided[tiab] OR focused ultrasound[tiab] OR artery occlusion[tiab] OR UAE[tiab] OR morcellat*[tiab] OR electrosurg*[tiab] OR cryoablation[tiab] OR myolysis[tiab]) NOT medline[sb]	16,834
#10	#8 OR #9	3,075,456
#11	#6 OR #7 OR #10-	6,846,698
#12	#3 AND #11	10,260

Notes: "Drug therapy"[mh] includes hormone therapy; "Surgical procedures, operative"[mh] includes ultrasound ablation, embolization, and hysterectomy; **Search lines:** #3=uterine fibroid concept; #6 drug treatment concept; #7=therapy or treatment general concept; #10=surgical and procedural interventions concept; #11=any intervention; #12=any intervention or treatment and fibroid

Table 2. Literature search strategy: morcellation and risk of cancer dissemination

	PubMed (3/13/15) Query	Results
#1	morcellation	445
#2	morcellat* AND uterine	256
#3	morcellat*	562
#4	("Electrosurgery/adverse effects"[Mesh]) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	1,251
#5	("Electrosurgery/adverse effects"[Mesh] AND uterine) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	742

Gray Literature

We searched Web sites of organizations likely to conduct research, issue guidance, or generate policies relevant to management of uterine fibroids and government and regulatory agency Web sites for information on morcellation. We searched ClinicalTrials.gov for information about relevant ongoing trials and to confirm that we obtained any available publications of results from completed trials.

Inclusion and Exclusion Criteria

We included studies evaluating expectant management, medications, procedures, and surgeries to treat fibroids in women of any age (Table 3). An assessment of the literature suggested that limiting the search to studies published in or after 1985 did not omit critical literature and eliminated a number of treatments that are not used in contemporary care. We detail the acceptable criteria for patients/participants, interventions, comparators, outcomes, timing, and setting (PICOTS) in Appendix B.

For KQ1 and KQ2 we restricted the literature to randomized controlled trial (RCTs) evaluating the benefits or harms of a medical, procedural, or surgical intervention compared with an inactive control, including expectant management, placebos, or alternate intervention. We limited inclusion to RCTs because they are (1) superior to cohorts for providing direct evidence about effectiveness and comparative effectiveness of interventions; (2) clearly define the patient population; (3) standardize the intervention(s) provided; and (4) uniformly, prospectively assess the intended outcomes. During topic scoping and refinement of the KQs, we documented a substantial increase in the quality and volume of publications from RCTs since the prior review.[12]

Eligible studies for KQ1 or KQ2 had to report one or more patient-centered outcomes (e.g., symptom improvement, blood loss, pain, quality of life or harms) or fibroid characteristics (e.g., size) at both baseline and followup. We did not include studies reporting intermediate outcomes only. Studies reporting only outcomes related to healthcare delivery (e.g., costs, access) were not included. Cost data are linked with operative time and clinician skill sets, which may be affected by a number of factors. Older cost data also have limited utility. We excluded studies in pregnant women. We excluded studies that compared surgical technique or device only (e.g., one type of morcellator vs. a different type). We excluded studies that evaluated a drug not approved for use in the United States except when the study also included a relevant comparator (e.g., studies with a placebo (expectant management) comparison arm or an alternate medication approved for use in the United States).

For KQ3 and KQ4, we included nonrandomized cohort studies and observational studies that provided data to calculate the proportion of fibroid or uterine specimens found to include leiomyosarcoma (KQ3) or the proportion of women exposed to use of power, scalpel, or no morcellation who were followed for survival (also described as dissemination and disease progression) after an identified leiomyosarcoma (KQ4).

A 2015 systematic review conducted by Pritts and colleagues[10] estimated the risk of encountering a leiomyosarcoma at the time of fibroid surgery (KQ3). We updated the search and used similar eligibility criteria to identify papers published from six months prior to the end of their search in 2014. We prioritized an unbiased denominator of women at risk; therefore, we excluded studies with incomplete documentation of pathology.

To address the characteristics that influence survival after leiomyosarcoma, including surgical approach to morcellation, (KQ4) we created a broad search for literature with data about leiomyosarcoma diagnosis and survival. To be included, papers had to provide method of removal of the fibroid (intact/no morcellation, sharp morcellation, power morcellation) and followup time with disease and survival status. We excluded studies with incomplete documentation of pathology and those studies in which morcellation method was not described.

Table 3. Inclusion criteria

Category	Criteria
Population	Women with uterine fibroids (KQs 1-4)
Design	• Randomized controlled trial (KQs 1, 2) • Randomized controlled trials or cohort studies (KQs 3, 4)
Other	• Original research (KQs 1-4) • Publication language: English (KQs 1-4) • Publication year: 1985-2016 (KQs 1-4) • Reports one or more— o Patient-centered uterine fibroid treatment/intervention outcome (KQs 1, 2) o Harm or adverse event from uterine fibroid treatment/intervention (KQs 1, 2) o Data to estimate occult leiomyosarcoma prevalence (KQ3) o Data to estimate risk of leiomyosarcoma dissemination or cancer progression following uterine fibroid treatment (KQ4) • Sufficient detail of methods and results to enable data extraction (KQs 1-4) • Reports outcome data by target population or intervention (KQs 1-4)

KQ = Key Question

Study Selection

We conducted two levels of screening using dual review and explicit inclusion and exclusion criteria (Table 3). We- documented study selection using an abstract screening form and full text screening form (Appendix C). The abstract screening form contained questions about the primary exclusion and inclusion criteria for initial screening. Exclusion of abstract required two team members to classify, independently, the publication as ineligible. We retrieved and reviewed all articles that were not excluded based on the title and abstract screening. We used a more detailed form (full-text screening form) to examine the full-text of references that met criteria for inclusion in abstract review. Two team members independently reviewed eligibility, and we resolved conflicting assessments in team discussions.

Data Extraction and Management

We created data extraction forms to collect detailed information about study characteristics, participant characteristics, intervention(s), comparator(s), reported outcomes (benefits and harms), tools used for outcome measures, length of followup, study results, and elements required for risk of bias assessment. We extracted additional information, when reported, to assess whether the effectiveness of interventions differed by patient or fibroid characteristics.

We assigned codes to document reasons for exclusion and recorded these in an EndNote® (Thomson Reuters, New York, NY) bibliographic database. We used Microsoft Excel to record information about each included publication. We prepared the study outcomes that were used in the meta-analysis for submission to the Systematic Review Data Repository (SRDR).

Outcomes

We extracted the- value at baseline, end of treatment, and last followup by arm for each eligible outcome and each measure reported in the paper. For medication treatment, the end of treatment was typically defined by the treatment duration. Surgical and procedural trials often reported estimated intermediate outcomes such as blood loss, operative time, length of stay, pain, and transfusions. Trials of procedures and medications frequently evaluated need for further intervention and quality of life. Medication studies typically assessed patient symptoms (e.g.,

pain, uterine bleeding) and fibroid characteristics (e.g., fibroid volume, fibroid size, uterine volume). We sought to collect outcomes uniformly within the predefined groupings of "Final Health Outcomes" illustrated in the Analytic Framework (Figure 1). However if data were not provided for a final outcome (e.g., satisfaction with outcomes, desired fertility status) in any of the publications for the category of intervention, there is not a header for that outcome in the related text.

We tabulated the incidence of harms and serious adverse events reported in the studies included in KQ1. We limited extraction of harms to a pre-specified list (Figure 1) and recorded the frequency, including "0", during or after the intervention and at last followup. We extracted these data by arm and did not include comparative rates of harms within studies as studies were not powered to detect differences in harms and did not include sufficient duration of followup. For this same reason, we did not assess the quality of harms reporting within these studies. We categorized the following as serious or major adverse events: death, life-threatening complication, deep vein thrombosis, pulmonary embolism, cardiovascular complication, pulmonary complication, and uterine artery dissection.

Outcome Measures

Fibroid Characteristics

Fibroid characteristics may include the number, size, volume, and blood flow at baseline and followup, and at followup may include those left in situ or identified by authors as appearance of a new fibroid. Some literature relates imaging findings and symptom profiles, but the correlation between fibroid size, number, total volume and symptom status is inconsistent. Women with large fibroids can have minimal symptoms, and those with small fibroids may have significant symptoms.

Fibroid-Related Bleeding

Measurements of fibroid-related bleeding in this literature vary. Some studies measured self-reported bleeding characteristics, such as days of bleeding and severity of bleeding. Other measures included hemoglobin, presence of amenorrhea, change in bleeding scores, or an operational definition of menorrhagia.

Fibroid-Related Pain

Fibroid-related symptoms including dysmenorrhea, pelvic pain, pelvic pressure, urinary frequency, and constipation were measured with varied approaches including 100-point Visual Analog Scales (VAS). Lower scores indicate improved symptoms. Some studies assessed pain from daily diaries, symptom logs, or by asking patients to grade their pain on a 0 to 5 point scale during followup clinical exams.

Quality of Life

Quality of life was measured with several tools: The Uterine Fibroid Symptom and Quality of Life Questionnaire (UFS-QOL) is a validated measurement tool that includes 37 patient-reported items in two scales, the Symptom Severity Scale (eight items) and the Health Related Quality of Life Scale (HRQoL) (29 items).[46] The Symptom Severity Scale assesses severity of fibroid-related symptoms (including items that reflect bleeding characteristics, pressure, urinary frequency, and fatigue). The scale is reported as 0 to 100, with a higher score representing

greater severity of symptoms. The HRQoL scale includes subscales to assess concern, activities, energy/mood, control, self-consciousness, and sexual function. The HRQoL scale is also reported as scores from 0 to 100, with higher scores reflecting better quality of life. The UFS-QOL is responsive to treatment for uterine fibroids and is a useful outcome measure for uterine-sparing fibroid treatments.[47] Approximately half of the studies that reported quality of life (9/19) used the UFS-QOL.

The Short Form 36 (SF-36) is a validated, patient-reported survey that assesses general physical and mental health status. It addresses eight concepts: vitality, physical functioning, bodily pain, general health perceptions, physical role function, social role function, and mental health. Scores are reported from 0 to 100 with higher scores indicating greater functioning. .[48] The European Quality of Life 5D (EQ-5D™) is a general measure of five domains of health-related quality of life (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression); a single weighted index score is calculated with a score of 1 representing full health and less than 1 indicating reduced health status.[49]

Sexual Function

Sexual function was measured using the following validated instruments: the UFS-QOL, the Brief Index of Sexual Functioning for Women (BISF-W), and the Sexual Activity Questionnaire (SAQ). The USF-QOL includes a sexual function subscale. Scores higher than baseline indicate improved outcome. The BISF-W consists of 22 questions that measure the following seven aspects of sexual life: desire, arousal, frequency of activity, receptiveness, pleasure/orgasm, relational satisfaction, and problems affecting sexuality. The total scores range from −16 to +75; higher scores indicate higher quality of sexual function with the exception of the problem dimension. The SAQ is a nine-item measure of three dimensions: pleasure from sexual intercourse (desire, enjoyment, and satisfaction), discomfort during intercourse, and habit (frequency). Higher scores for pleasure and habit and lower scores for discomfort are considered good. Total scores range from 0 to 27.

Pregnancy and Fertility

We considered the following as measures of pregnancy and fertility: number and outcome of pregnancies (e.g., live birth, miscarriage), ovarian failure or ovarian reserve, documented adhesive disease (scarring) reducing fertility, and time to pregnancy. To ascertain a pregnancy success rate, publications must include the number of participants who wished to become pregnant (denominator) as well as the number of pregnancies achieved. We considered loss of fertility as an outcome, which includes conversion from myomectomy to hysterectomy in reproductive-age women.

Reintervention and Recurrence

We defined reintervention as the sum of all repeat procedures or surgeries (e.g., uterine artery embolization [UAE], myomectomy, hysterectomy) due to any cause, including complications or technical failure. We reported recurrence as subsequent treatment for fibroids for persistent or recurrent symptoms and not for complications of the initial intervention.

Quality (Risk of Bias) Assessment of Individual Studies

We evaluated the methodologic quality of studies using guidance from the Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[50] We used prespecified items from

"Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions"[51] to evaluate the methodologic quality of RCTs. Two senior investigators evaluated each included study independently in six specific domains of assignment of bias (Appendix E). Discordance at the level of any domain was resolved through discussion to reach a final adjudicated assignment. We established thresholds to assign an overall rating of "low", "moderate", or "high" risk of bias (Appendix E).[52] Studies with all six domains rated as low risk of bias as well as those with only a single fault for not masking those doing MRI imaging, were classified as low risk of bias. For semantic clarity, we refer to these as good quality studies. Studies with moderate risk of bias for one or two domains were deemed fair quality and studies with moderate risk of bias in three or more domains or high risk in any domain are referred to as poor quality studies.

Data Synthesis

We provided a qualitative synthesis and summarize data from studies meeting our review criteria for KQ 1 and 2.

For the outcome of having subsequent treatment for fibroids, we estimated the probabilities after randomization to initial treatment with medical management, including intrauterine devices (IUDs); UAE; or myomectomy. Subsequent treatments were grouped into six categories: 1) no intervention; 2) IUD; 3) UAE; 4) high intensity focused ultrasound [HIFU] for fibroid ablation; 5) myomectomy; and 6) hysterectomy. We extracted sufficient data to fit models for three initial interventions: UAE, myomectomy, and medical management across mean age in the treatment arm (centered at age 40) and followup time in months (6, 12 or 24 months). The probability of a subsequent intervention was assumed to be a function of both age and followup time. As some studies did not report the average age in constituent study arms, we imputed the missing values jointly with the model, using a Student-t distribution to characterize the distribution of ages across studies. Note that this assumes reported ages are missing completely at random and are not omitted for any reason related to the underlying event probabilities.

Specifically, we were interested in estimating:

$$\phi_{ijk} = \Pr(I_F = j | I_0 = i, T_F = t_k, A = a_k)$$

where I_0 is an initial intervention, which takes a specific value i for each candidate intervention type. I_F is the followup intervention that may take any of the six values of *j* listed above, a_k is the mean age for the treatment arm of study *k* (centered at age 40), and t_k is corresponding followup time in months, which generally will be 6, 12 or 24 months. Hence, the probability of a subsequent intervention was assumed to be a function of both age A and followup time T_F.

The rates of subsequent intervention for each intervention category were estimated using a Poisson model:

$$y_{ijk} \sim Poisson(\phi_{ijk} n_{ik})$$

where y_{ijk} is the number of individuals is study with initial intervention *i* that underwent subsequent intervention *j*, and n_{ik} the corresponding number of women in study *k* that received initial intervention *i*.

The quantities of interest are the transition probabilities π_{ij} corresponding to each of the initial candidate interventions *i*. These probabilities were modeled on the logarithmic scale as a function of age and followup length covariates as:

$$log(\phi_{ijk}) = \theta_{ij} + X_k\beta_{ij} + \epsilon_k$$

where θ_{ij} is a baseline transition probability (on the logit scale), X_k a matrix of study-arm-specific covariates, β_{ij} the corresponding coefficients, and ϵ_k a mean-zero random effect for study *k*, which accounts for the correlation among arms within the same study.

An attractive benefit to using Bayesian inference for this model is that it is easy to generate predictions from the model, via the posterior predictive distribution. We present estimates of the distribution of the expected rate of women requiring a particular followup intervention; this factors in both residual uncertainty in the rate estimates, as well as the sampling uncertainty of the intervention.

For KQ 3, we fit a Bayesian binomial random effects model to update the estimate of prevalence of leiomyosarcoma, consistent with the inclusion methods of the Pritts and colleagues systematic review.[10]

For KQ 4, to estimate survival for each surgical intervention, we fit parametric survival models using a Bayesian hierarchical approach, using the data extracted from publications that made it available. To account for heterogeneity among studies, we included a study-level random effect in the hierarchical baseline survival parameter. A simple exponential survival function was found to be a poor fit to the data, therefore we fit a Weibull survival function that resulted in an adequate fit.

Grading the Strength of Evidence

Strength of Evidence Assessments

We followed *AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews* and updated guidance for grading the strength of a body of evidence.[52] We assessed and graded "domains" using established concepts of the quantity and quality of evidence, and coherence or consistency of findings. We focused on evidence that addressed final outcomes in which there was sufficient literature and did not grade all possible outcomes. We did not assess the strength of evidence for harms.

Two senior staff independently graded the body of evidence; discordance was resolved in meetings of the full team. We assessed strength of evidence for the effect of medical, procedural, and surgical interventions on fibroid volume, bleeding, and quality of life. We assigned an overall evidence grade based on the ratings for the following domains: study limitations, directness, consistency, precision, and reporting bias.

Overall Strength of Evidence

We summarize the four grades (high, moderate, low, and insufficient) used for the overall assessment of the body of evidence in Table 4 (adapted from the AHRQ Methods Guide updated guidance for grading the strength of a body of evidence[52]). Typically, when only one study was available for an outcome or comparison of interest, we graded the evidence as insufficient.

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 and/or numerous deficiencies. 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.

[a] Excerpted from Berkman et al. (2013)[52]

Peer Review and Public Commentary

Researchers and clinicians with expertise in treating uterine fibroids and individuals representing stakeholder and user communities provided external peer review of this report. The draft report was posted on the AHRQ Web site for four 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 three months after AHRQ posts the final review on the AHRQ Web site.

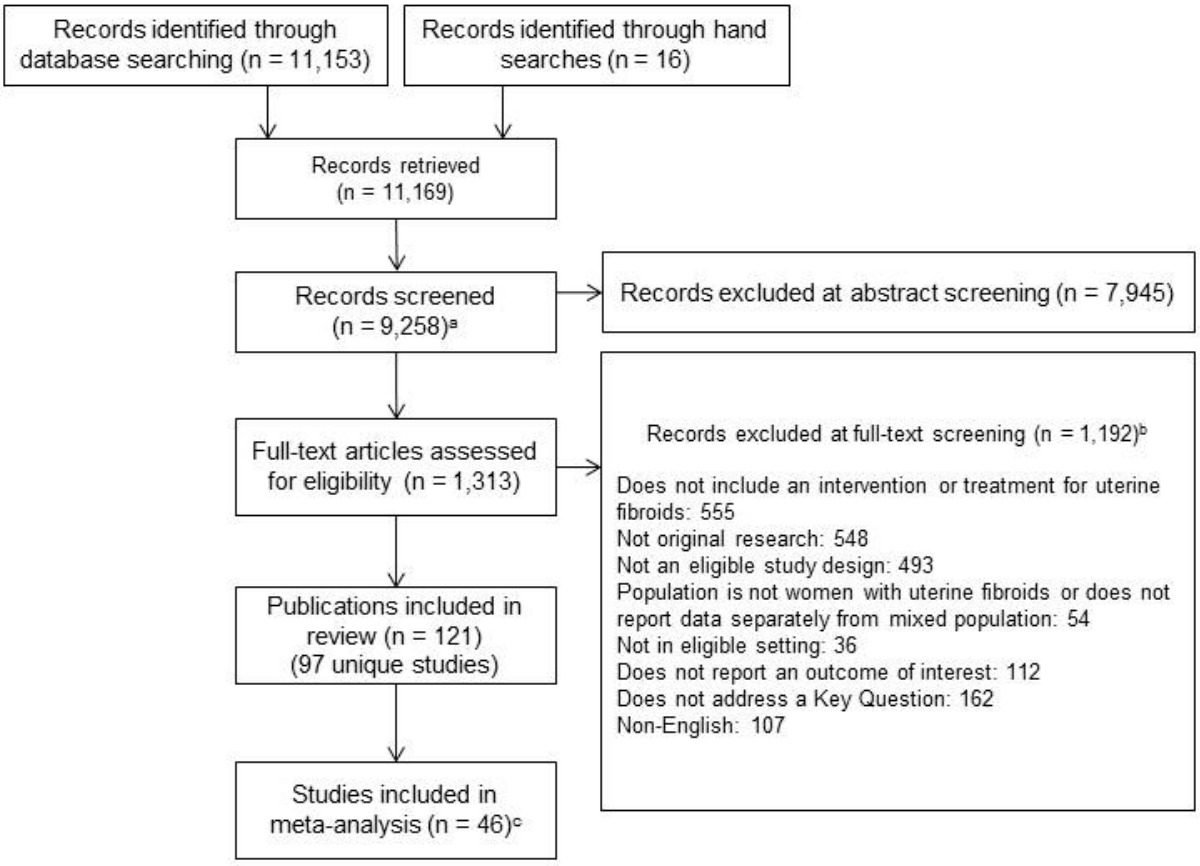
Results

This chapter presents the evidence to address our four Key Questions (KQs): KQ1, effectiveness of interventions; KQ2, factors that modify effectiveness; KQ3, risk of leiomyosarcoma at the time of fibroid surgery; and KQ4, influence of patient or fibroid characteristics or morcellation approach on survival after leiomyosarcoma. When a final outcome is not discussed it means that the literature did not provide evidence to help understand whether the intervention had any effect on that outcome.

For KQ1 and KQ2, we screened 11,169 records and excluded 7,945 at the time of abstract review. We retrieved the full text of 1,313 publications; 1,192 were excluded for one or more reasons. We identified 121 publications representing 97 unique studies (Figure 2). We included 160 studies for KQ3 (Figure 3) and 28 unique studies (24 of which contributed data to the survival analysis) for KQ4 (Figure 4). In all, we retained 311 publications, representing 285 unique studies, to address one or more KQs in this review. We did not receive any scientific information submissions through the portal on the Effective Health Care Web site.

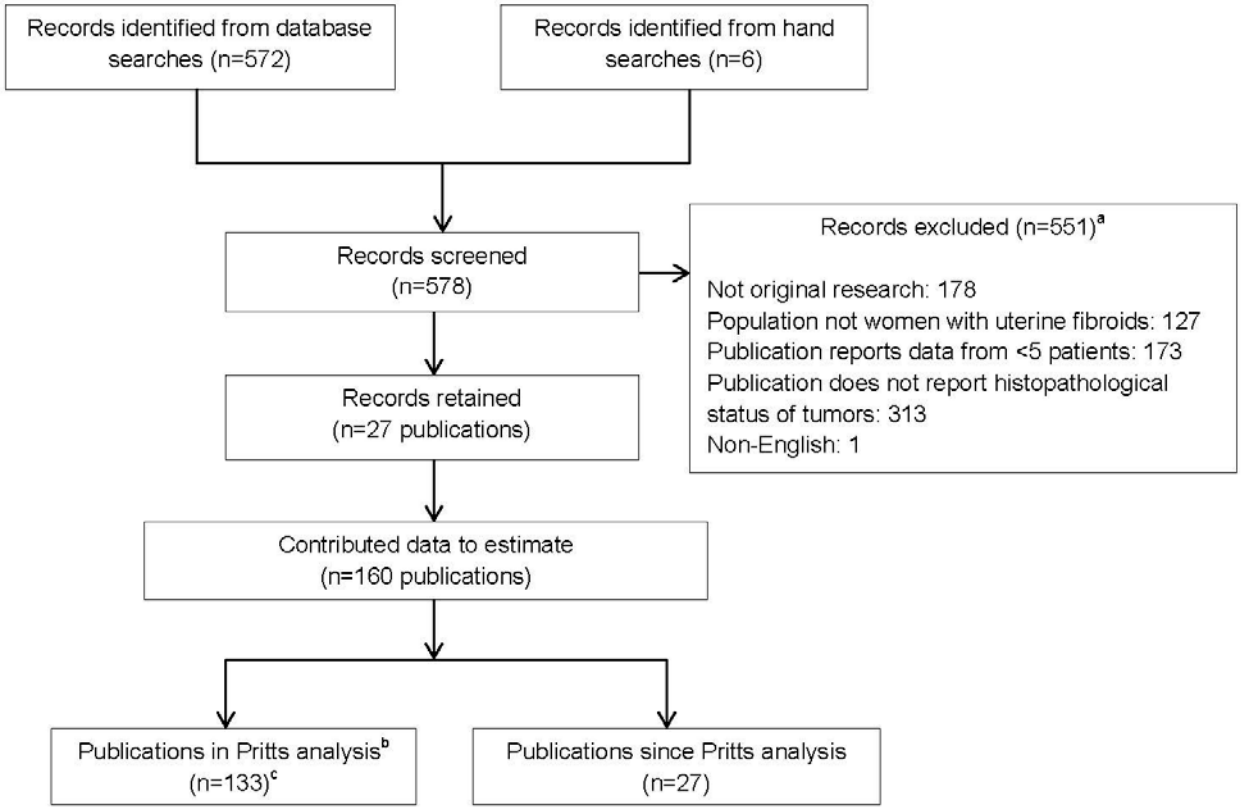
Appendix D includes a list of excluded publications and reason for exclusion.

Figure 2. Literature flow diagram for Key Question 1 and Key Question 2



[a] Excluding publications older than 1985 (n = 1911).
[b] Records could be excluded for more than one reason.
[c] Subset of studies that met additional criteria for inclusion in quantitative analysis of estimated probability of subsequent treatment

Figure 3. Literature flow diagram for Key Question 3

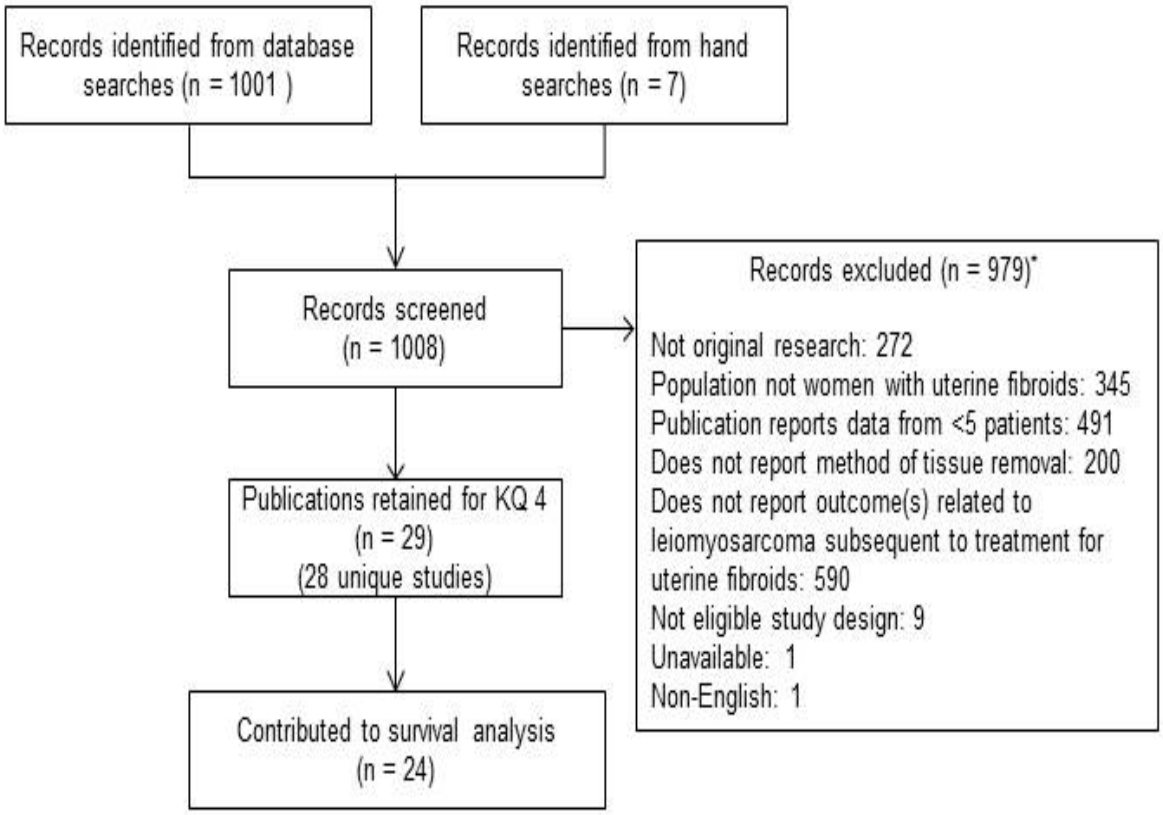


[a]Records could be excluded for more than one reason.

[b]Pritts EHA, Parker WH, Brown J, et al. Outcome of occult urine leiomyosarcoma after surgery for presumed uterine fibroids: a systematic review. J Minim Invasive Gynecol. 2015 Jan;22(1):26-33.

[c]One publication (Silva et al. 2000) contributed data from a retrospective and prospective component. The Pritts analysis counted the publication as two studies; the publication is counted as one study in our updated analysis.

Figure 4. Literature flow diagram for Key Question 4



*Records could be excluded for more than one reason.

Content of the Literature About Effectiveness

We included 97 unique randomized controlled trials (reported in 121 publications).[13-23,36,38,53-160] These studies included 9,179 women with the majority of studies conducted in Europe (Table 5). Forty three studies included a medical intervention (including intrauterine devices [IUDs]);[54,59,64-67,75,79,84,87,88,94,98,102,103,106,108,115,116,118,119,122-124,128,129,136-140,142-153] 28 assessed a procedural intervention;[13-16,18,20,22,23,38,53,57,58,60,62,68,78,81,92,104,105,108,113,114,117,127,155,156,158] and 37 assessed surgical treatments.[14,16,20,22,56,57,63,68,72,76,77,80,85,86,89,90,95,100,101,107,110,112-114,120,121,125,126,130-132,134,135,137,141,148,160] We included two studies for their expectant management arms only, because the intervention arms used tibolone [139] or asoprisnil [103], neither of which are approved for use in the United States). Eleven studies compared interventions from more than one category (e.g., procedure vs. surgery).[14,16,20,22,57,68,104,113,114,137,148]

Table 5. Characteristics of studies included for Key Question 1

Characteristic		Med vs. Exp	Med vs. Med	Med vs. Surg	Proc vs. Exp	Proc vs. Proc	Proc vs. Surg	Surg vs. Exp	Surg vs. Surg	All
Studies (N)		**14**	**27**	**2**	**1**	**18**	**9**	**1**	**25**	**97**
Location	North America[a]	8	9	0	1	7	0	0	0	25
	Europe	5	11	2	0	4	7	1	15	45
	Asia	0	3	0	0	7	2	0	8	20
	Middle East	1	4	0	0	0	0	0	1	6
	South America	0	0	0	0	0	0	0	1	1
Decade of Publication	1985 to1995	2	6	1	0	0	0	0	0	9
	1996 to 2005	5	8	1	0	3	2	0	10	29
	2006 to 2016	7	13	0	1	15	7	1	15	59
Study Quality	Good	2	2	0	0	4	2	0	8	18
	Fair	5	7	0	1	4	3	0	7	27
	Poor	7	18	2	0	10	4	1	10	52
Participants	Randomized	1,159	2,570	114	20	1,171	962	181	3,002	9,179

Note: None of the included studies compared medication with procedure or procedure with expectant management
Exp = expectant management; Med = medical; N = number; Proc = procedural; Surg = surgical

[a]Includes studies conducted in the United States, Canada, and Cuba.

We assessed risk of bias for all studies included for KQ1. We considered 18 (18.6%) of these studies to have low risk of bias (good quality), 27 (27.8%) to have moderate risk of bias (fair quality), and 52 (53.6%) to have high risk of bias (poor quality). The most common shortcoming was failure to blind assessors or participants to treatment status. For most studies we assessed risk of bias from the published report only; we also identified the study protocol for 19 of the included studies (Appendix F).We enumerate the risk of bias assessments and source of bias for all studies in Appendix E.

Key Question 1. Effectiveness of Treatment for Uterine Fibroids

Key Points

This summary reflects synthesis of outcomes across arms of studies that used the intervention. If a study included different types of interventions, each arm is included in the related synthesis and discussion. Assessment of harms was limited to those reported by randomized trials and these are reported in the text.

<u>Expectant Management</u>

- The number of women followed without intervention is small (n=514) and data is insufficient to project the outcomes of expectant management (insufficient strength of evidence).

<u>Medications</u>

- Gonadotropin-releasing hormone (GnRH) agonists reduced the size of fibroids and the overall size of the uterus (moderate strength of evidence).

- GnRH agonists, with or without add-back therapy, improved bleeding symptoms, (moderate strength of evidence) and improved quality of life (low strength of evidence)
- Mifepristone reduced fibroid size and improved bleeding outcomes and improved quality of life (moderate strength of evidence).
- Ulipristal reduced fibroid size, improved bleeding outcomes and improved quality of life measures (moderate strength of evidence).
- Raloxifene did not change fibroid size and did not cause changes in hemoglobin in postmenopausal women (low strength of evidence).

Uterine Artery Embolization (UAE) or Occlusion

- UAE reduces the size of fibroids (high strength of evidence) with data from two long term studies demonstrating effectiveness up to 5 years.
- Bleeding outcomes and fibroid-related quality of life measures also improved following UAE (moderate and moderate strength of evidence, respectively).
- Data are inadequate to comment on other methods of occlusion (insufficient strength of evidence).

High Intensity Focused Ultrasound (HIFU) for Fibroid Ablation

- HIFU reduces fibroid and uterine size (low strength of evidence).
- The effects on bleeding, quality of life outcomes, or other patient reported outcomes are unknown (insufficient strength of evidence).

Myomectomy

- Fibroid-related quality of life improved following myomectomy (low strength of evidence).

Hysterectomy

- Fibroid-related quality of life improved following hysterectomy (low strength of evidence).

Direct comparative effectiveness:

- Because of the small number of women studied there was insufficient strength of evidence for outcomes of ulipristal versus GnRH, and UAE versus Myomectomy

Estimation of Subsequent Treatment for Uterine Fibroids

- Modelling estimates that for women in their 30s, the probability of subsequent intervention for fibroids over 2 years varied from 6-7 percent after medical treatment or myomectomy to 44 percent after UAE. For women in their 40s and 50s, modelled 2-year reintervention rates were 9-12 percent following medical treatment or UAE, and 0 percent after myomectomy.

Expectant Management: Overview

We did not identify any studies intentionally designed to determine outcomes of no intervention, also called expectant management or watchful waiting. However, 16 randomized controlled trials (RCTs)(reported in 17 publications) included 514 women in expectant management arms (defined as no treatment, placebo or sham treatment, or minimal intervention such as multivitamin use) compared to active treatment.[36,59,61,65,67,74,79,103,106,107,118,123,128,129,139,147,150,156] Two of these trials were of good quality, six fair, and eight poor. Expectant management arms assessed changes in fibroid or uterine size (13 studies),[36,65,74,79,103,106,118,123,128,139,147,150,156] bleeding patterns (4 studies),[65,74,79,147]

pain, pressure, or symptom severity (8 studies),[36,65,74,103,106,129,147,156] sexual function (3 studies),[65,103,147] and pregnancy outcome (1 study).[107]

Expectant Management: Results

The majority of women evaluated for expectant management came from 14 drug trials.[36,65,67,74,79,103,106,118,123,128,129,139,147,150] Other no-intervention groups include one study arm from a myomectomy trial to evaluate pregnancy outcomes[107] and one from a placebo-controlled pilot study of MRI-guided focused ultrasound (MRgFUS).[156] The studies were small and almost half (7 of 16) did not report masking those conducting or interpreting the imaging measurements to group status. The placebo-controlled trials did describe credible placebos, which diminishes concern that imaging measures would be modified by participant report of their intervention status. Unless knowledge of study arm was directly available to those interpreting measures from imaging, the effect of bias may not be substantial.

Expectant Management and Fibroid Characteristics

The overall evidence suggests the size of fibroids does not meaningfully change over short timespans, based on an average followup time of 5 months (range, 3 to 12 months) (Table 6). Neither of the two studies[128,139] with women who were postmenopausal and followed for a full year detected an increase in total volume of fibroids.

Table 6. Change in fibroid and uterine size with expectant management by study arm[a]

Author (Year)	Intervention	N	Treatment months (Imaging)	Followup Months	Fibroid Size Baseline; Followup, cm^3 mean ± SD or median [IQR]/(range)	Change, cm^3	Uterine Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change, cm^3
Jacoby V et al. (2016)[156]	Sham procedure	7	3 (MRI)	3	313.0 ± 157.0 NR	0 p=NS	692.0 ± 254.0 671.0 ± NR	↓21.0 (3%) p=NR
Esteve J et al. (2013)[65]	Placebo	47	3 (US)	3	119.0 ± 95.0 123.0 ± 84.0	↑4.0 p=NR	428.0 ± 211.0 439.0 ± 210.0	↑11.0 p=NR
Donnez J et al. (2012)[74]	Placebo + iron	48	3 (US)	3	62.0 [25 to 159] NR	NR*	319.0 [216.0 to 496.0] NR	median ↑5.9% p=NR
Nieman L et al. (2011)[161]	Placebo	14	3 (MRI)	3	149.0 ± 121.0 159.0 ± NR	↑10.4 p=NR	NR NR	NR
Levens E et al. (2008)[36]	Placebo	6	3 (MRI)	3	290.0 (12 to 4,112) NR	↑6.0% p=NR	NR NR	NR
Chwalisz K et al. (2007)[103]	Placebo	31	3 (US)	3	NR NR	↓4.0% p=NR	NR NR	↑1.0% p=NR
Fiscella K et al. (2006)[106]	Placebo	20	6 (US)	6	NR NR	NR	449.0 ± 236.0 NR	↑73.0 p=NS
Jirecek S et al. (2004)[118]	No treatment	12	3 (US)	3	68.0 ± 48.0 78.0 ± 62.0	↑10.3 p=0.09	NR NR	NR
Palomba S et al. (2002)[123]	Multivitamin	29	6 (US)	6	49.0 ± 15.0 55.0 ± 18.0	↑6.3 p<0.05	196.0 ± 57.0 202.0 ± 53.0	↑6.1 p<0.05
Palomba S et al. (2001)[128]	Placebo	31	12 (US)	12	139.0 ± 56.0 NR	No change p=NS	317.0 ± 114.0 NR	No change p=NS
Sadan O et al. (2001)[129]	Placebo	10	6 (US)	6	NR NR	NR	486.0 ± NR NR	NR p=NS

Author (Year)	Intervention	N	Treatment months (Imaging)	Followup Months	Fibroid Size Baseline; Followup, cm^3 mean ± SD or median [IQR]/(range)	Change, cm^3	Uterine Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change, cm^3
Gregoriou O et al. (1997)[139]	No treatment	20	12 (US)	12	118.4 ± NR 117.5 ± NR	↓0.9 p=NS	NR NR	NR
Friedman A et al. (1991)[147]	Placebo	64	5.5 (US/MRI)	5.5	206.0 ± 42.0 NR	No significant change	492.0 ± 51.0 517.0 ± NR	↑25.0 (5%) p=NS
Friedman A et al. (1989)[150]	Placebo	20	6 (US)	6	NR NR	NR	426.0 ± 43.0 429.0 ± 52.0	↑3.0 p=NS

cm^3 = cubic centimeters; IQR = interquartile range; MRI = magnetic resonance imaging; N = number; NR = not reported; NS = not significant; SD = standard deviation; US = ultrasound

[a]Single study may contribute more than one entry if more than one arm received the intervention. Table does not include Eder S et al. (2013)[67] or Casini ML et al. (2006)[107] as these studies do not report uterine or fibroid size/volume.

Expectant Management and Bleeding

Bleeding characteristics, measured by bleeding (days and severity) or hemoglobin, did not change meaningfully during followup for those with expectant management (Table 7). Some studies reported no statistically significant change in other bleeding outcomes such as heaviness of periods,[139] monthly hemoglobin measures within normal range,[162] and number and severity of heavy bleeding episodes over 12 months.[128]

Some groups with expectant management experienced modest improvements; 6.3 percent of one placebo group had resolution of intermenstrual bleeding over three months.[65] Symptom severity score improved slightly in the placebo group after 12 weeks (4.2 ± 6.5).[79] In a double-blind study of women who presented with heavy menstrual bleeding, 26 of 37 (70%) in the expectant management group reported resolution or improvement at final visit (24 weeks after enrollment).[147]

The proportion of the 514 women enrolled in these trials who presented specifically with problem bleeding, as opposed to other fibroid-related symptoms, is not known. However, the data suggest that women with fibroids should not expect that bleeding patterns will worsen over the near term.

Table 7. Change in bleeding characteristics with expectant management by study arm*

Author (Year)	Intervention	N	Treatment Months	Followup Months	Bleeding Baseline; Followup mean ± SD or median [IQR]	Change	Hemoglobin Baseline; Followup, g/dL mean ± SD	Change
Jacoby V et al. (2016)[156]	Sham procedure	7	3	3	NR NR	NR	12.0 ± 2.0 NR	NR p=NS
Eder S et al. (2013)[67]	Placebo	139	6	6	MBL, ml 177.3 173.0	↓4.3 p=NR	NR NR	NR p=NR
Esteve J et al. (2013)[65]	Placebo	47	3	3	NR NR	NR	11.8 ± 1.6 11.8 ± NR	0 p=NS
Donnez J et	Placebo +	48	3	3	PBAC	↓59	9.6 ± 1.2	↑3.1 ± 1.7

Author (Year)	Intervention	N	Treatment Months	Followup Months	Bleeding Baseline; Followup mean ± SD or median [IQR]	Change	Hemoglobin Baseline; Followup, g/dL mean ± SD	Change
al. (2012)[74]	iron				376 [241 to 608] 336 [115 to 543] p=NR	IQR [-216 to -58]	12.6 ± 1.3	p=NR
Nieman L et al. (2011)[79]	Placebo	14	3	3	NR NR	NR	12.3 ± 1.4 12.2 ± 1.1	↓0.1 p=0.82
Levens E et al. (2008)[36]	Placebo	6	3	3	NR NR	NR	NR NR	↓0.9 p=NS
Chwalisz K et al. (2007)[103]	Placebo	31	3	3	NR NR	NR	>12.0 NR	↓0.34 p=NR
Fiscella K et al. (2006)[106]	Placebo	20	6	6	NR NR	NR	12.2 11.6	↓0.6 p=0.11
Palomba S et al. (2002)[123]	Multivitamin	29	6	6	Bleeding, days 3.9 ± 1.3 4.0 ± 1.3	↓0.1 p=NS	13.9 ± 1.7 13.8 ± 1.6	↓0.1 p=NS
Palomba S et al. (2002)[123]	Multivitamin	29	6	6	Severity (VAS) 6.1 ± 2.1 6.0 ± 2.1	↓0.1 p=NS	NR NR	NR
Sadan O et al. (2001)[129]	Placebo	10	6	6	NR NR	NR	NR NR	↑1.0% p=NS
Friedman A et al. (1991)[147]	Placebo	64	5.5	5.5	NR NR	NR	12.6 ± 0.3 12.3 ± 0.2	↓0.3 p=NR
Friedman A et al. (1989)[150]	Placebo	20	6	6	NR NR	NR	12.3 ± 0.3 11.3 ± 0.6	↓1.0 p=NS

g/dL = grams per deciliter; IQR = interquartile range; ml = milliliters; MBL = menstrual blood loss; NR = not reported; NS = not significant; PBAC = pictorial blood loss assessment chart; SD = standard deviation; VAS = visual analog scale

*a single study may contribute more than one entry if more than one arm received the intervention.

These findings of minimal change over followup periods of a year or less are compatible with a prior review that included observational cohorts.[12] The number of women in the literature followed without intervention is small (n=514) and these participants may be fundamentally different from other women with fibroids since they were willing to risk randomization to no intervention. Because none of these studies were designed to evaluate expectant management, the overall quality of the research is poor to inform choice of expectant management over other options and strength of the evidence is insufficient.

Medical Management: Overview

We sought studies that addressed whether medications can reduce symptoms or delay the need for other management. Our intended scope was wide, including common clinical interventions such as continuous oral contraceptives to avoid menstrual periods, nonsteroidal anti-inflammatory agents to improve bleeding or dysmenorrhea, and agents such as stool softeners to prevent constipation from bulky fibroids. However, we identified RCTs for five types of clinically less common medications: GnRH agonists**,** progesterone receptor agents,

estrogen receptor agents**,** hormone replacement therapy**,** and antifibrinolytic treatment. We did not review trials in which medications were used as adjuncts and in which all participants were scheduled for surgery**.**[163] We excluded medications that cannot be prescribed in the United States.

Medical Management: Results

We identified 43 studies (48 publications) assessing effectiveness of medical treatment for uterine fibroids[54,55,59,61,64-67,75,79,84,87,88,94,98,102,103,106,108,115,116,118,119,122-124,128,129,136-140,142-153,157,164] We rated four studies as good quality (low risk of bias), 12 as fair (moderate risk of bias), and 27 as poor quality (high risk of bias). Common reasons for classification as poor quality included: no description or unclear description of randomization method (4 studies),[98,118,138,145] no report of assessment of medication adherence,[128] and failure to blind outcome assessors.[94,98]

Eleven studies included a placebo or no treatment comparison group[36,65,67,74,106,118,123,128,129,147,150]. Eight studies compared two or more medications[73,84,87,102,124,133,136,149,153] and 10 compared doses of the same drug.[54,64,66,75,79,88,119,123,140,146] Several studies evaluated dose schedules or regimens that change over time. Another eight studies[94,98,122,138,142,144,145,151] examined the role of an additional drug (i.e., add-back) given to decrease the side effects of the primary GnRH treatment. Six studies of medical interventions are discussed in other sections of this report: the placebo arm of two studies are discussed in the section on expectant management, because the active agents (tibolone, asoprisnil) are not approved for use in the United States; [139] [103]; two studies are discussed in the section on comparison of effectiveness across intervention categories[84,102]; and two studies that compared a GnRH agonist to surgery[137,148] are summarized in the surgical intervention section.

Approximately 35 percent of the medication studies (15/43) were industry sponsored.[54,59,64-67,73-75,98,103,137,140,142,147] [137] The duration of followup ranged from no additional followup after the end of treatment with the medication to 5 years after conclusion of the medication. Women included in the studies were predominantly premenopausal (39 studies). Four studies[124,128,136,139] enrolled postmenopausal women.

We have organized this section to first present the evidence about effectiveness for each category of drug when an important outcome has been measured by multiple studies. We also note if several specific doses or routes of delivery of the drug (e.g., injection vs. oral) have been investigated. We reserve discussion of direct comparisons between categories of medications to the end of the section.

To summarize outcomes we move from changes in the fibroids, to changes in symptoms, including bleeding characteristics, pain, and sexual function. When reported we also summarize fertility status and pregnancy outcomes as well as satisfaction with treatment and subsequent treatments over time. Only hemoglobin/hematocrit laboratory values, severity of uterine bleeding, and standardized quality of life and functional status measures were reported using validated approaches.

GnRH Agonists

Eighteen studies reported in 20 publications evaluated GnRH agonists.[73,87,94,98,116,122,133,138,140,142-147,149-151,153] Thirteen studies (2 good [101, 108,]2 fair [124, 136,] and 9 poor quality [73,87,94,98,116,122,133,138,140,142-147,149-151,153]) evaluated leuprolide (seven with an add-back

agent), three poor quality studies[98,137,149] included goserelin, and two poor quality studies used triptorelin as the GnRH agonist. [68,126,]

A total of 912 participants were randomized to GnRH treatment; study size ranged from 16 to 101 women. This small study size limits power for discerning differences across treatment groups and virtually prohibits meaningful evaluation of factors that may influence outcomes within groups. In general, study size was selected to detect differences in fibroid size and bleeding characteristics that are measured as continuous variables. The clinical significance of small to modest changes in fibroid size is unknown. Few studies were specifically designed to assess if treatment improved patient reported outcomes such as quality of life, sexual function, or satisfaction with treatment.

As in much of the fibroid literature, lack of followup over time is a limitation. Most studies completed their followup of participants when treatment ended. Only seven studies[98,143,146,147,149,150,153] followed women from 3 to 9 months after end of treatment, limiting the information about how durable the effects may be. Only one study re-contacted participants 3 years after treatment and found 23/59 (39%) had undergone hysterectomy.[137]

Effects of GnRH Agonist Treatment on Fibroid Characteristics

GnRH agonists reduce the size of fibroids, with reductions in volume of fibroids documented between 64 and 175 cm^3 and reductions in the total volume of the uterus between 131 and 610 cm^3 (Table 8). As a point of reference, the volume of a golf ball is 40 cm^3. It may be that change in size is related to initial size, in other words bigger fibroids have more capacity to shrink, but these studies are not able to assess that hypothesis. The duration of treatment was not directly related to reduction in volume in this literature. Two studies that measured fibroids more than once across the course of treatment found the change in the first round of imaging to be the greatest,[146,147] but another small study reported the largest volume reduction two months after treatment ended.[153]

Table 8. Change in fibroid and uterine size with GnRH agonists by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months (Imaging)	Last Followup Months	Fibroid Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change, cm^3 mean ± SD or median [IQR]	Uterine Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change cm^3 mean ± SD or median [IQR]
Goserelin								
Morris E et al. (2008)[98]	3.6 SQ/month	23	6 (US)	12	NR NR	Mean % change ± SEM ↓61 ± 3.3 p<0.05	NR NR	Mean % change ± SEM ↓58 ± 2.1 p<0.05
Costantini S et al. (1990)[149]	3.6 SQ/month	21	6 (US)	12	192 ± 126 98 ± 86	↓94.0 p=NR	253 ± 52 122 ± 50	↓131 p=NR
Leuprolide								
Donnez J et al. (2012)[73]	3.75 SQ/month	101	3 (US)	3	3 largest fibroids 59 [28 to 156] NR	↓53%, [-69% to -36%] p=NR	200 [138 to 272] NR	↓47% [-57% to -37%] p=NR

Author (Year)	Dose, mg	N	Treatment Months (Imaging)	Last Followup Months	Fibroid Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change, cm^3 mean ± SD or median [IQR]	Uterine Size Baseline; Followup, cm^3 mean ± SD or median [IQR]	Change cm^3 mean ± SD or median [IQR]
Donnez J et al. (2012)[73]	3.75 SQ/month	44[b]	3 (US)	8.7	3 largest fibroids 41 [24 to 73] 33 [17 to 65]	↓17%, [-41% to +19%] p=NR	172 [128 to 239] 131 [105 to 182]	↓11% [-22% to -1%] p=NR
Palomba S et al. (2008)[94]	11.25 IM each 3 months	55	6 (US)	6	NR NR	NR	565 ± 89 NR	↓NR p<0.05
Hazlina N et al. (2005)[153]	3.75 IM or SQ/ month	17	3 (US)	12	NR NR	↓43.0% p<0.01	NR NR	NR
Palomba S et al. (2002)[122]	3.75 SQ/month	50	6 (US)	6	189 ± 54 NR	↓NR p<0.05	446 ± 105 NR	↓NR p<0.05
Takeuchi H et al. (2000)[133]	1.88 SQ/month	33	5.2 (US)	5.2	Largest fibroid 172 ± 166 108 ± 139	↓64 p<0.01	NR NR	NR
Palomba S et al. (1998)[138]	3.75 SQ/ month	25	6 (US)	6	308 ± 65 133 ± 34	↓175 p<0.01	996 ± 170 386 ± 95	↓610 p<0.01
Scialli A et al. (1995)[142]	3.75 SQ/month	32[c]	6 (US)	6	NR NR	NR	454 ± 102 195 ± 36	↓259 p<0.05
Carr B et al. (1993)[145]	1.0 SQ/day	9	3 (MRI)	3	345 ± 177 301 ± 161	↓44 p=NS	1278 ± 205 937 ± 188	↓341 p<0.04
Watanabe Y et al. (1992)[146]	1.88 SQ/ month	20	5.5 (US)	12	NR NR	↓54.0% (n=9) p<0.01	553 ± 499 295 ± 351	↓258 p<0.01
Watanabe Y et al. (1992)[146]	3.75 SQ/month	21	5.5 (US)	12	NR NR	↓43.0% (n=7) p<0.01	452 ± 224 271 ± 314	↓181 p<0.01
Friedman A et al. (1991)[147]	3.75 SQ/month	60	5.5 (US/MRI)	12	Largest fibroid 143 ± 43 86 ± NR	↓57 p<0.001	522 ± 52 289 ± NR	↓233 p<0.001
Friedman A et al. (1989)[150]	3.75 SQ/ month	18	6 (US)	9	NR NR	NR	505 ± 93 305 ± 57	↓200 p<0.05
Friedman A et al. (1993)[144]	3.75 SQ/month	51	3 (US)	12	NR NR	NR	820 ± 127 NR	↓36.0% p<0.05
Friedman A et al. (1988)[151]	0.5 SQ/day	7	6 (US)	6	NR NR	NR	601 ± 62 294 ± 46	↓307 p<0.01
Triptorelin								
Parsanezhad M et al. (2010)[87]	3.6 SQ/ month[c]	27	3 (US)	3	95 ± NR 64 ± NR	−33.2% p=0.02	NR NR	NR
Broekmans F et al. (1996)[140]	500 x 1 wk, 100 x 7 wks, variable dose (5, 20, or 100) x 18 wks	24	2 (MRI)	2	NR	↓31.1% p≤0.001	931 ± NR 692 ± NR	↓239 p≤0.001
		24	6 (MRI)	6	NR	↓36.1% p≤0.001	931 ± NR 525 ± NR	↓406 p≤0.001

Abbreviations: cm^3 = cubic centimeters; IM = intramuscular; IQR = interquartile range; mg = milligrams; MRI = magnetic resonance imaging; N = number; NR = not reported; SD = standard deviation; SEM = standard error of mean; SQ = subcutaneous; Rx = treatment; US = ultrasound; wk = week

[a]Single study may contribute more than one entry if more than one arm received the intervention. Parazzini F et al. ((1999)[137] only reports baseline number/size of fibroids for goserelin (n=59)
[b]Subset from the PEARL II trial who did not have surgery following 3 months of treatment
[c]Uterine volume [a]t baseline and after 6 month of leuprolide treatment among 32 individuals from both arms

Seven studies provided information on durability of treatment effects on fibroid size from 3 to 9 months after the end of treatment.[73,143,146,147,149,150,153] All of these reported increases or regrowth often back to pre-treatment levels.[73,143,146,147,149,150,153] A single study reported that two doses (1.88 mg and 3.75 mg) of GnRH were equally effective in reducing uterine volume.[146] Use of add-back raloxifene to GnRH agonists -resulted in greater reduction in fibroid size but no change in fibroid related symptoms.[122] Add-back therapy of tibolone was protective for bone mineral density without interfering with fibroid size reduction.[98] Only one trial found that effects can be maintained over 2 years.[143] Two thirds of 51 women continued GnRH treatment while 17 (33%) discontinued treatment, three for other medication options, five had myomectomies, and nine had hysterectomy.

Effects of GnRH Agonist Treatment on Bleeding

GnRH agonists produce hypogonadism and many women completely stop bleeding (Table 9). Of the 20 published reports, five reported absence of bleeding, three noting statistical significance for clinically important reduction from baseline. One study reported reduction in days of bleeding[98] without a statistical test, and four reported improvement in hemoglobin levels with three of the four reporting significance. No study reported an increase in bleeding or worsening in measures such as hemoglobin or hematocrit within a treatment group. In several studies, some women discontinued treatment because bleeding became more irregular or did not decrease.

The symptoms and side effects of hypogonadism caused by GnRH are often treated with add-back hormonal therapy. GnRH plus add-back therapy was evaluated in eight studies and the effects on bleeding were mixed. Women who received medroxyprogesterone (MPA) as add-back therapy had improved hemoglobin levels reported in two small trials.[142,151] A single trial that evaluated raloxifene as add-back therapy in conjunction with leuprolide acetate noted no difference in the proportion of women who continued to bleed after six cycles of raloxifene (6.3%) vs. placebo (8.3%).[122]Another small study that compared estrogen-progestin to progestin only add-back with leuprolide acetate depot reported improved hemoglobin levels in both groups.[144].Women receiving goserelin plus tibolone had significantly higher mean number of days of bleeding (6.3 days) compared with the goserelin and placebo group (2.9 days).[98] In another 6-month study of leuprolide acetate with or without tibolone, both groups had reductions in the number of women reporting bleeding, but a small number of women continued to bleed with the add-back of tibolone compared with none in the placebo arm.[138] Bleeding outcomes were not assessed in the third study.[94]

Table 9. Change in bleeding characteristics with GnRH agonists by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Baseline; Followup mean ± SD or median [IQR]	Change, mean or median [IQR]	Hemoglobin Baseline; Followup (g/dL) mean ± SD or median (IQR)	Mean Change
Goserelin								
Morris E et al. (2008)[98]	3.6 implant/ month	23	6	12	4.3 days 2.9 days	NR	NR NR	NR
Costantini S et al. (1990)[149]	3.6 SQ/month	21	6	12	NR 0 days by 8 weeks	NR	NR NR	NR
Leuprolide								
Donnez J et al. (2012)[73]	3.75 IM/month	93 82	3	3	PBAC score 297 [189 to 443] 0 [0 to 1]	↓274 [-430 to -161]	12.1 ± 1.8 12.7 ± 1.6	↑0.6 p=NR
Donnez J et al. (2012)[73]	3.75 IM/month	43[b]	3	8.7	PBAC score 273 [186 to 474] 239 [103 to 458]	↓115 [-161 to -19]	NR NR	NR
Palomba S et al. (2008)[94]	11.25 IM each 3 months	55	6	6	Menorrhagia[b] 7.7 ± 1.6 0.0 ± 0.0	↓7.7 p=0.001	NR NR	NR
Hazlina N et al. (2005)[153]	3.75 IM or SQ/ month	18	3	9	NR NR	NR	11.59 ± 2.19 11.69 ± 1.81	↑0.1 p=NR
Palomba S et al. (2002)[122]	3.75 SQ/month	46	6	6	Menorrhagia[c] 7.8 ± 1.9 0.0 ± 0.0	↓7.8 p<0.05	NR NR	NR
Palomba S et al. (1998)[138]	3.75 SQ/month	25	6	6	Menorrhagia[c] 8.2 ± 0.9 0.0 ± 0.0	p<0.01	NR NR	NR
Scialli A et al. (1995)[142]	3.75 SQ/month	14 13	12	12	NR NR	NR	10.3 ± 0.8 11.2 ± 0.6	↑0.9 p<0.05
Watanabe Y et al. (1992)[146]	3.75 SQ/month	21	5.5	12	NR 0 days by 4 weeks	NR	NR NR	NR
Friedman A et al. (1991)[147]	3.75 SQ/month	60	5.5	12	NR NR	NR	12.6 ± 0.2 13.1 ± 0.2	↑0.5 p<0.05
Friedman A et al. (1989)[150]	3.75 SQ/month	18	6	9	NR NR	NR	12.3 ± 0.4 13.0 ± 0.3	↑0.7 p=NS
Friedman A et al. (1988)[151]	0.5 SC/day	7	6	6	NR NR	NR	12.7 ± 0.3 14.1 ± 0.2	↑1.4 p<0.001

g/dL = grams per deciliter; IM = intramuscular; IQR = interquartile range; mg = milligrams; NR = not reported; NS = not significant; PBAC = pictorial blood loss assessment chart; SD = standard deviation; SQ = subcutaneous

[a]Single study may contribute more than one entry if more than one arm received the intervention. Multiple values for N indicate the number of patients at baseline and followup;
[b]Subset from the PEARL II trial who did not have surgery following 3 months of treatment.
[c]Menorrhagia score, values from 0 to 10 where 0 indicates no bleeding.

Effect of GnRH Agonist Treatment on Fibroid-Related Pain

Compared to baseline, GnRH treatment significantly improved pain symptoms including pelvic pressure,[94,98,122,143] pelvic and abdominal pain,[94,98,122,143] and dysmenorrhea.[98] Other studies reported similar improvements but without statistical comparisons of baseline to followup.[144,147]

Effects of GnRH Agonist Treatment on Grouped Symptoms

Palomba and colleagues have conducted multiple studies treating women for 6 months with leuprolide and placebo or a comparator arm not available in the United States.[94,122,138] Within the leuprolide arms of these studies, women experienced a significant improvement in fibroid-related symptoms that were scored on a 1 to 10 point validated scale that includes menorrhagia, pelvic pressure, pelvic pain, urinary frequency, and constipation. Total scores and each individual scale item were improved, in each study bleeding and constipation completely resolved and other scores improved by 3 to 5 points, a substantial and likely clinically significant change. Mood and quality of life were also improved by treatment.[94] In studies with raloxifene add-back, similar improvements were documented in both the raloxifene and placebo add-back groups.[122]

Using a similar, but not identical, five-item scale, Friedman and colleagues also demonstrated improvements in menorrhagia, bulk symptoms, pelvic pressure, urinary frequency, and pelvic pain that were sustained over 1 and 2 years of treatment with leuprolide and either estrogen and progestin add-back or just progestin add-back; with an overall advantage for the combined estrogen and progestin add-back group.[143,144]

Harms Reported in Studies of GnRH Agonist Treatment

Because of estrogen suppression, GnRH is associated with onset of menopausal symptoms,[94,98,138,147] unfavorable changes in lipid profile,[138,144] and bone loss (ranging from 2.6% to 5.5%).[98,138,143] These effects increase motivation for investigating add-back therapy. Estrogen and progesterone together normalized adverse lipid effects, while progesterone only did not.[144] Addition of raloxifene protects bone[138] and estrogen-progestin or progestin add-back stabilized bone loss when initiated after a 12-week period of GnRH only.[144]

Six months of treatment with leuprolide was associated with declines in cognitive function and memory as measured by the Mini-Mental Status Exam and the Wechsler Memory Scale..[94]

GnRH Agonists Summary

GnRH agonists reduce the size of fibroids and the overall size of the uterus. Both with and without add-back therapy, bleeding symptoms, hemoglobin, fibroid-related pain and other symptoms improve over baseline. Add-back medication relieves associated menopausal symptoms and can ameliorate bone loss and lipid changes. Only one trial examined outcomes of treatment after more than 24 months. Extended followup of women after they discontinue GnRH agonists is not available, thus information about potential harms to guide care is limited.

Progesterone Receptor Agents: Anti-Progestins, Selective Receptor Modulators, and Levonorgestrel IUD

This section includes 14 studies designed to test the effectiveness of medications that work through progesterone pathways.[36,54,55,59,61,64-66,73-75,79,88,106,115,119,157,165] They include seven studies

of mifepristone,[64-66,75,88,106,119] ; six of ulipristal,[36,54,59,73,74,79,157]; and a single study of a progesterone-containing IUD.[152]

Mifepristone

Seven studies (eight publications) provide data about outcomes of mifepristone treatment.[64-66,75,88,106,119] This literature is dominated by two teams: a group led by Carbonell and colleagues who conducted five of the included studies in Cuba; and by Eisinger and Fiscella at University of Rochester School of Medicine who conducted two included studies.[106,115,119] Overall, 5 good quality and 2 poor quality trials provided information on 690 women. Two studies compared a 5 mg dose to placebo,[65,106] one study compared 2.5 mg and 5 mg doses,[64] the remainder compared 5 mg and 10 mg doses. Four groups included followup after treatment with mifepristone had ended. Average length of time for off-medication followup was 11 months with the longest untreated followup being 18 months.[66,166]

Effects of Mifepristone on Fibroid Characteristics

All studies observed a decrease in the size of fibroids at the completion of active treatment. The decrease in size of the largest fibroid ranged from 37 cm^3 to 95 cm^3, with an average of 71 cm^3 among the 575 women studied (Table 10).[64-66,75,88] Likewise, total uterine volume decreased in all groups receiving mifepristone.[64-66,75,88,106,115,119] This was consistent across doses from 2.5 mg to 10 mg each day, with statistically significant reductions at 5 mg and 10 mg doses documented in three trials.[88,106,119] Because most trials were designed to compare doses, authors often did not provide statistical comparisons within groups from baseline to followup.

In the studies designed to determine if changes in fibroid size were durable, all four trials reported no statistically significant change in the size of the largest fibroid or uterine volume after completion of treatment.[64,66,75,115] However , while volume of the largest fibroid remained smaller than baseline at nine months of followup off medication, the total uterine volume was slightly increased over baseline. With 12 and 18 months of followup, fibroid and uterine volume tended to increase, often above baseline,[66,75] suggesting that treatment suspends fibroid growth but does not have lasting effects to forestall future growth of fibroids.

It is also important to note in these studies that the number of women available at followup was often fewer than at enrollment. This loss to followup includes those who did not continue medication or who did not improve and had subsequent treatments including surgery. Since intention-to-treat analyses with last uterine volume carried forward were not done, this means as the women are lost to follow up, the measures may under-represent changes in fibroids if we speculate that those who were lost could be more likely to have increase in size over time.

Table 10. Change in fibroid and uterine size with mifepristone by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months (Imaging)	Last Followup, months	Largest Fibroid Size Baseline; Followup(s), cm^3 mean ± SD	Mean Change, cm^3	Uterine Size Baseline; Followup, cm^3 mean ± SD	Mean Change, cm^3
Carbonell J et al. (2013)[64]	2.5 5 10 5 10 5 10 5	110 102 90 110 106 100 35 31 9 35 34 9 74 74 74 70 70 70 50 50 50 49 22	3 (US) 3 (US) 9 (US) 9 (US) 6 (US) 6 (US) 3 (US) 3 (US) 6	- 3 12 - 3 12 - 9 27 - 9 27 - 6 18 - 6 18 3 3 6	136 ± 129 98 ± 107 129 ± 157 112 ± 118 60 ± 67 99 ± 91 125 ± 95 88 ± 79 115 ± 100 55 ± 41 169 ± 86 263 ± 471 90 ± 77 255 ± 156 133 ± 176 81 ± 102 138 ± 117 108 ± 103 56 ± 61 128 ± 108 172 ± 161 77 ± 125 187 ± 184 103 ± 124 NR	↓38 p=NR ↓7 p=NS ↓62 p=NR ↓13 p=NS ↓37 p=NR ↓60 p=NR ↑54 p=NS ↓38 p=NR ↓8 p=NS ↓52 p=NR ↑5 p=NS ↓52 p=NR ↑20 p=NS ↓95 p<0.001 ↓84 p<0.001 NR	455 ± 314 372 ± 272 495 ± 321 426 ± 305 332 ± 243 489 ± 265 458 ± 236 354 ± 202 542 ± 362 361 ± 175 715 ± 433 866 ± 578 533 ± 570 892 ± 412 573 ± 480 417 ± 271 666 ± 219 544 ± 353 379 ± 259 596 ± 299 481 ± 257 305 ± 192 552 ± 499 332 ± 200 719 ±	↓83 p=NS ↑40 p=NS ↓94 p=NS ↑40 p=NS ↓104 p=NR ↓181 p=NR ↑173 p=NS ↓333 p=NR ↑26 p=NS ↓156 p=NR ↑93 p=NS ↓165 p=NR ↑52 p=NS ↓176 p<0.001 ↓220 p=0.002 ↓200

Author (Year)	Dose, mg	N	Treatment Months (Imaging)	Last Followup, months	Largest Fibroid Size Baseline; Followup(s), cm^3 mean ± SD	Mean Change, cm^3	Uterine Size Baseline; Followup, cm^3 mean ± SD	Mean Change, cm^3
et al. (2006)[106]			(US)		NR		663 519 ± NR	p=0.02
Eisinger S et al. (2003)[119]	5	19	6 (US)	6	NR NR	NR	832 ± 443 435 ± NR	↓397 p<0.001
Eisinger S et al. (2003)[119]	10	20	6 (US)	6	NR NR	NR	850 ± 380 438 ± NR	↓412 p<0.001

cm^3 = cubic centimeters; mg = milligrams; N = number NR = not reported; NS = not significant; SD = standard deviation; US = ultrasound

[a]Single study may contribute more than one entry if more than one arm received the intervention. Multiple values for N indicate the number of patients at baseline and followup(s); Eisinger SH et al. ((2005)[115] reports similar results (52-53% reduction in uterine volume) for 12 months of treatment, but combines 5 mg and 10 mg groups.

Effects of Mifepristone on Bleeding

All studies that assessed bleeding reported heaviness of bleeding was reduced by treatment (Table 11). Those that made comparison found the active drug superior to placebo.[65,106] Women were as likely to have decreased bleeding or absent menses on the lower doses compared with the higher doses.[66,88,115] When bleeding occurred it was often described as spotting or staining.[64,65,75]

Table 11. Change in bleeding characteristics and hemoglobin with mifepristone by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Measure	Baseline; Followup(s) percent or mean ± SD	Change
Carbonell J et al. (2013)[64]	2.5	102	3	12	Percent with hemoglobin <10 g/dL	37.3% 14.7%	p=0.02
Carbonell J et al. (2013)[64]	5	106	3	12	Percent with hemoglobin <10 g/dL	40.9% 6.6%	p=0.02
Esteve J et al. (2013)[65]	5	58	3	3	Hemoglobin (g/dL)	11.0 ± 2.0 11.7 ± 2.1	↑0.7 p=0.023
Carbonell J et al. (2013)[66]	5	31	9	9	Percent with amenorrhea	NR 100.0%	NR
Carbonell J et al. (2013)[66]	10	34	9	9	Percent with amenorrhea	NR 80.0%	NR
Esteve J et al. (2012)[75]	5	74 74 74	6	- 6 18	Hypermenorrhea score[a]	8.3 ± 2.2 0.1 ± 0.5 6.6 ± 2.2	p<0.01
Esteve J et al. (2012)[75]	10	70 70 70	6	- 6 18	Hypermenorrhea score[a]	8.9 ± 1.8 0.1 ± 0.3 6.2 ± 2.6	p<0.01

Author (Year)	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Measure	Baseline; Followup(s) percent or mean ± SD	Change
Carbonell J et al. (2008)[88]	5	50	3	3	Hypermenorrhea percent	78.0% 4.0%	NR
Carbonell J et al. (2008)[88]	10	49	3	3	Hypermenorrhea percent	66.0% 6.1%	NR
Carbonell J et al. (2008)[88]	5	50	3	3	Percent with amenorrhea	NR 90.0%	NR
Carbonell J et al. (2008)[88]	10	49	3	3	Percent with amenorrhea	NR 89.8%	NR
Fiscella K et al. (2006)[106]	5	22	6	6	Hemoglobin (g/dL)	12.0 ± NR 13.5 ± NR	↑1.5 p<0.001
Eisinger S et al. (2003)[115]	5	19	12	- 6 12	Percent with amenorrhea	0% 63.0% 75.0%	NR
Eisinger S et al. (2003)[115]	10	20	12	- 6 12	Percent with amenorrhea	0% 60.0% 40.0%	NR

g/dL = grams per deciliter; mg = milligrams; N = number; NR = not reported; SD = standard deviation

[a]Single study may contribute more than one entry if more than one arm received the intervention.
[b] Hypermenorrhea evaluated by a self-reported visual analog scale from 0 to 10 where 0 represented an absence of symptoms and 10 indicated the maximum value

Effects of Mifepristone on Fibroid-Related Pain

Each of six publications that evaluated pelvic pain before treatment and at conclusion of treatment noted substantial improvements.[64-66,75,88,106] At baseline, 68 to 100 percent of women in these trials reported pelvic pain. By three months of treatment, this was reduced to a range of 9 to 28 percent with those in the lower dose groups having lower or equivalent prevalence of pelvic pain.[64,65,88] Similar findings persisted at conclusion of 6 and 9 months of treatment. Once off treatment, prevalence of pelvic pain remained meaningfully lower, with 6.3- 37.0 percent of women affected at 9 months,[64,66] 16.2 to 18.6 percent at 12 months,[75] and 10 to 11 percent at 18 months.[66] The Rochester group reported change in pain using the McGill Pain Questionnaire and documented a steady decline from a high score of approximately 20 to about 6 points during the 6 months of treatment.[106] Strength of evidence was not graded for pain.

Effects of Mifepristone Treatment on Quality of life

Four studies (374 women) reported quality of life metrics: for the three that used the UFS-QOL, composite scores improved,[64-66] as much as 50 of a possible 100 points (with placebo controls improving by 17 points). Dose was not convincingly related to quality of life scores.[64,66] The study that used the Short Form 36 subscales documented improvements in energy and fatigue, health status, and pain domains.[106] Statistically significant improvements from baseline were noted in these aspects across studies at one or more doses:

- Symptoms[64,65,106]
- Concern[64,65,106]
- Activity[64,65]
- Inhibition/Self-consciousness[64,106]
- Control[64,65]

- Sexual function[64,106]
- Energy and mood[64,65]

Other Effects of Mifepristone Treatment

In the Cuban studies, improvements were observed for other symptoms including pelvic pressure, urinary symptoms, lumbar pain, rectal pain, and dyspareunia. In each case, the proportion with the symptom dropped by one to two-thirds or more. Improvement was sustained with less than 6 percent increase in prevalence over the additional 9 to 18 months of followup. [64-66,75,88] The Rochester group also reported that improvements in pelvic pressure, urinary frequency, low back pain, rectal pain, and pain with intercourse improved across treatment with active drug compared with placebo, with significant benefits for reducing pain with intercourse.[106]

Harms Reported in Studies of Mifepristone Treatment

No unanticipated adverse drug effects were identified in these trials. All trials conducted surveillance for the most serious known risk of harm, which is development of endometrial hyperplasia. All seven trials (eight publications) conducted an endometrial biopsy at an interim point or at the completion of treatment, unless the subject declined. [64-66,75,88,106,115,119] In four of these studies, biopsies were conducted at more than one followup time point.[64,66,75,115,119] The proportion of participants with at least one post-treatment biopsy result ranged from 73 percent to 99 percent. The total number of biopsies subsequent to treatment in all studies combined was 782.

Two placebo controlled studies with 5 mg mifepristone as the active intervention reported no hyperplasia in either group after 3 or 6 months of treatment.[65, 106] One study compared 5 mg to 2.5 mg mifepristone and reported no hyperplasia in either group after 3 months of treatment.[64] Four studies (reported in five publications) compared 10 mg to 5 mg mifepristone with treatment durations of 3 months,[88] 6 months,[75,119] 9 months,[66] and 12 months.[115] One study[119] reported an additional 6-month continuation, with a revised report of pathology at the 6-month timepoint.[115] Table 12 summarizes the number of women across the four studies who had biopsies with the indicated findings at specific timepoints.[66,75,88,115,119] There were no reported cases of atypical hyperplasia. The counts of simple hyperplasia at 3 months of treatment were 2/92 (2%) for 5 mg dosage and 2/118 (2%) for 10 mg dosage. The counts of simple hyperplasia at 6 months of treatment were 2/85 (2%) for 5 mg dosage and 6/100 (6%) for 10 mg dosage. Data for 9 months and 12 months are sparse. In aggregate, there were 13 cases of simple hyperplasia detected among 446 biopsies.

Table 12. Number of mifepristone-treated women with indicated endometrial status upon biopsy

Pathology Report	3 months[66,75,88]		6 months[66,75,115,119]		9 months[66]		12 months[115]	
	5 mg (3 studies)	10 mg (3 studies)	5 mg (3 studies[a])	10 mg (3 studies[a])	5 mg (1 study)	10 mg (1 study)	5 mg (1 study)	10 mg (1 study)
PAEC	14	32	22	39	5	11	0	0
Simple hyperplasia	2	2	2	6	0	0	0	1
Atypical hyperplasia[b]	0	0	0	0	0	0	0	0
Normal[c]	76	84	61	55	8	6	11	9
Total N women	92	118	85	100	13	17	11	10

mg = milligrams; PAEC = benign progesterone modulator associated endometrial changes

[a] Three studies reported in four publications;
[b] Endometrial intraepithelial neoplasia has replaced atypical hyperplasia as the preferred term;
[c] Normal secretory or proliferative endometrium, other benign descriptor, or insufficient sample.

All seven trials also monitored liver function enzymes as elevations have been reported but not overt or sustained liver damage. .The percentages of women with elevated transaminases following mifepristone treatment ranged from 5.0 to 12.7 percent in the Cuban studies. [64-66,75,88]. The maximum values when reported did not exceed 100 IU. Increases in liver enzymes were also noted in zero and 8 percent of the women in two U.S. studies [119].[106] Abnormal liver enzymes were similar between the group treated with mifepristone (49/652, 7.5%) and the group who received placebo (5/67, 7.5%). There were no reports of any liver damage.

Mifepristone Summary

Moderate evidence from 5 fair and 2 poor quality studies supports that mifepristone reduces size of fibroids and overall uterine volume and improves quality of life. Heaviness of bleeding is reduced during treatment and measures of anemia improve. Information is unavailable to contribute to dose selection between higher and lower doses.

Some evidence suggests fibroids do resume growth after treatment; however, the majority of women achieve symptomatic relief for a year or more after cessation of active treatment. Few participants in these trials pursued subsequent treatment during medical management or in the time after concluding active treatment suggesting that treatment with mifepristone can provide sufficient management of fibroid-related symptoms.

Ulipristal Acetate

Six trials, reported in nine publications, investigated use of ulipristal acetate as a treatment for fibroids, enrolling 691 women in the ulipristal arms. Two small, poor quality trials were conducted at National Institutes of Health[36,79] and four in research networks in Europe (the PEARL trials), of which two were good and two fair quality.[54,55,59,61,73,74,157] The two earliest studies[36,79] followed participants to the end of 12 weeks of treatment with active drug. Two trials reported on drug efficacy in women seeking surgery for management of heavy bleeding and fibroids.[73,74] PEARL I randomized women to 5 or 10 mg doses or placebo for three months[74] and PEARL II randomized women to 5 or 10 mg doses or leuprolide acetate.[73] The PEARL III study assessed up to four courses of 10 mg dose for 12 weeks[59] followed with a daily progestin (norethisterone acetate) or placebo. PEARL IV compared 5 and 10 mg doses in women for four repeated 12 week cycles.[157] There was a drug-free interval following each treatment cycle, with the next treatment round resuming at the start of the second menstrual cycle. Final followup was conducted three months after the completion of medication.[54,157]

Effects of Ulipristal on Fibroid Characteristics

All six studies found ulipristal effective for reducing the size of individual fibroids and the overall fibroid burden as measured by total fibroid and uterine volume (Table 13). A single course of 5 or 10 mg reduced fibroids size by 17 to 38 percent;[36,54,59,79] a repeated course of treatment reduced volume of the three largest fibroids by 54 to 58 percent from baseline to completion of both cycles.[59]

A study that monitored women in ulipristal trial arms who did not go on to have surgery found minimal resumption of fibroid growth (8.1%) that was not statistically significant at six

months after completion of treatment regardless of ulipristal dose.[73] A related trial with similar design found that the 10 mg dose sustained lack of fibroid growth beyond six months while there was increase in size on the 5 mg dose that was similar to placebo.[74] Durability of effects remains unknown. Extended followup after treatment cessation is needed because fibroid growth patterns may differ for women in these trials who did proceed to surgery.

Table 13. Change in fibroid and uterine size with ulipristal acetate by study arm[a]

Author (Year)	Dose, mg	N (Imaging)	Treatment Months	Last Followup Months	Fibroid Size Baseline; Followup(s), cm^3 median [IQR] or (range)	Change, cm^3 percent or median [IQR]	Uterine Size Baseline; Followup, cm^3 Median [IQR]	Change, cm^3 median [IQR]
Donnez J et al. (2015)[54,157] PEARL IV	5	228 (US)	11	14	3 largest fibroids 43 [24 to 94] NR	↓72% [-88% to -33%]	177 [113 to 270] NR	NR
Donnez J et al. (2015)[54,157] PEARL IV	10	223 (US)	11	14	3 largest fibroids 44 [27 to 117] NR	↓73% [-88% to -47%]	175.22 [116.6 to 267.6] NR	NR
Donnez J et al. (2015)[54,157] PEARL IV	5	228 (US)	11	14	N with ≥ 25% fibroid volume reduction	135/166 (81%)	NR NR	NR
Donnez J et al. (2015)[54,157] PEARL IV	10	223 (US)	11	14	N with ≥ 25% fibroid volume reduction	150/170 (88%)	NR NR	NR
Donnez J et al. (2014)[59] PEARL III	10	209 (US)	2.5	5.5	3 largest fibroids* 54 [24 to 129] NR	NR	200 [125 to 291] NR	NR
Donnez J et al. (2012)[74] PEARL I	5	95 (US)	3	3	101 [40 to 205] NR	↓21.2% [-41% to -1%]	338 [236 to 503] NR	↓12% [-28% to +3%]
Donnez J et al. (2012)[74] PEARL I	5	49[b] (US)	3	8.7	81 [33 to 167] 65 [24 to 164]	↑7% [-23% to +31%]	NR NR	NR
Donnez J et al. (2012)[74] PEARL I	10	94 (US)	3	3	97 [32 to 181] NR	↓12.3% [-39% to +4%]	326 [213 to 453] NR	↓12% [-28% to +6%]
Donnez J et al. (2012)[74] PEARL I	10	41[b] (US)	3	8.7	62 [36 to 156] 56 [27 to 121]	↓13% [-44% to +15%]	NR NR	NR
Donnez J et al. (2012)[73] PEARL II	5	93 (US)	3	3	3 largest fibroids 80 [30 to 151] NR	↓36% [-58% to -11%]	199 [150 to 315] NR	↓20% [-40% to -3%]
Donnez J et al. (2012)[73] PEARL II	5	45[c] (US)	3	8.7	3 largest fibroids 52 [27 to 89] 29 [10 to 55]	↓45% [-75% to -12%]	168 [133 to 259] 162 [108 to 203]	↓22% [-38% to -6%]

Author (Year)	Dose, mg	N (Imaging)	Treatment Months	Last Followup Months	Fibroid Size Baseline; Followup(s), cm^3 median [IQR] or (range)	Change, cm^3 percent or median [IQR]	Uterine Size Baseline; Followup, cm^3 Median [IQR]	Change, cm^3 median [IQR]
Donnez J et al. (2012)[73] PEARL II	10	95 (US)	3	3	3 largest fibroids 48 [24 to 111] NR	↓42% [-69% to -14%]	198 [121 to 298] NR	↓22% [-45% to 0%]
Donnez J et al. (2012)[73] PEARL II	10	46[b] (US)	3	8.7	3 largest fibroids 32 [18 to 71] 18 [7 to 48]	↓55% [-75% to +2%]	172 [111, 260] 136 [109, 193]	↓15% [-25% to +5%]
Nieman LK et al. (2011)[79]	10	14 (MRI)	2.8	5.8	NR Decreased in 10/13 women	↓17%	NR NR	NR
Nieman LK et al. (2011)[79]	20	14 (MRI)	2.8	5.8	NR Decreased in 11/13 women	↓24%	NR NR	NR
Levens ED et al. (2008)[36]	10	6 (NR)	3	3	116 (20 to 963) NR	↓36%	NR NR	NR
Levens ED et al. (2008)[36]	20	6 (NR)	3	3	411 (102 to 1343) NR	↓21%	NR NR	NR

cm^3 = cubic centimeters; IM = intramuscular; IQR = interquartile range; mg = milligrams; MRI = magnetic resonance imaging; N = number; NR = not reported; US = ultrasound

[a] Single study may contribute more than one entry if more than one arm received the intervention;
[b] Subset from PEARL I study who did not have surgery following initial 3 months of treatment;
[c] Subset from PEARL II study who did not have surgery following initial 3 months of treatment.

Effects of Ulipristal on Bleeding

Ulipristal, as intended, resulted in absent menses for the majority of women during treatment (range 62 to 100%) and the large majority reported improved bleeding (Table 14).[36,54,73,74,79] This was also documented by improved or stable hematocrit or hemoglobin levels.[36,54,79] Cessation of bleeding at onset of treatment was prompt, ranging from a mean of 4 to 7 days.[54,59,73] Absence of bleeding was achieved more consistently with higher doses.[54,73,79]

Other Effects of Ulipristal

Compared with placebo, all ulipristal doses resulted in improved overall fibroid-related quality of life or subscale scores as measured by the UFS-QOL scale[36,79] though some time points lack statistical testing. Similar improvements were seen in fibroid-related quality of life as measured by the Short Form 36 (SF-36),[74]and two trials also documented improvement in pain.[54,74]

Harms Reported in Studies of Ulipristal Treatment

Among 978 biopsies at completion of treatment, six cases of confirmed hyperplasia (one with atypia) were reported (0.6%). The two smallest studies reported modest elevations of liver function enzymes during treatment; one larger trial documented change in liver function

enzymes was comparable to those taking placebo. About 2 to 10 percent of women taking ulipristal experienced hot flashes.

Ulipristal Summary

Moderate evidence supports the effectiveness of ulipristal for reducing the size of fibroids and improving bleeding and quality of life. Bleeding is reduced with most women reporting absence of menses and measures of anemia stabilized or improved during treatment. Evidence is insufficient to contribute to dose selection between higher and lower doses. Data on extended followup are lacking to gauge whether fibroids resume growth after treatment. Use of a progestin for 10 days to prompt onset of menses shortened the time between treatment cycles in a single study.

Table 14. Change in median PBAC score with ulipristal acetate by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months	Last Followup Months	Baseline Followup, median [IQR]	Change, median [IQR]
Donnez J et al. (2015) [54,157] PEARL IV	5	218	11	14	224 [148 to 357] After cycle 1 123 [45 to 313] After cycle 2 92 [44 to 253] After cycle 4 77.5 [NR]	After cycle 1 ↓87 [-167 to +13] After cycle 2 ↓95 [-216 to +9]
Donnez J et al. (2015) [54,157] PEARL IV	10	214	11	14	215 [151 to 373] After cycle 1 129 [56 to 285] After cycle 2 99 [37 to 202] After cycle 4 76 [NR]	After cycle 1 ↓85 [-209 to -12] After cycle 2 ↓110 [-236 to -50]
Donnez J et al. (2014) [59] PEARL III	10	201	2.5	5.5	216 [126 to 376] 31 [11 to 100]	↓120 [-255 to -45]
Donnez J et al. (2012) [74]	5 + iron supplementation	95	3	3	386 [235 to 627] 0 [0 to 5]	↓329 [-571 to -205]
Donnez J et al. (2012) [74]	5 + iron supplementation	50[b]	3	8.7	321 [219 to 536] 234 [102 to 450]	↓81 [-195 to +27]
Donnez J et al. (2012) [74]	10 + iron supplementation	94	3	3	330 [235 to 537] 0 [0 to 0]	↓326 [-527 to -226]
Donnez J et al. (2012) [74]	10 + iron supplementation	41[b]	3	8.7	272 [212 to 433] 174 [46 to 321]	↓161 [-256 to +13]
Donnez J et al. (2012) [73]	5	93	3	3	286 [190 to 457] 0 [0 to 2]	↓268 [-412 to -172]
Donnez J et al. (2012) [73]	5	43[b]	3	8.7	299 [213 to 391] 236 [143 to 387]	↓73 [-242 to +65]
Donnez J et al. (2012) [73]	10	95	3	3	271 [183 to 392] 0 [0 to 0]	↓268 [-387 to -179]
Donnez J et al. (2012) [73]	10	45[c]	3	8.7	244 [173 to 351] 141 [103 to 311]	↓96 [-155 to -62]

IQR = interquartile range; mg = milligrams; N = number; NR = not reported; PBAC = pictorial blood loss assessment chart

[a] Single study may contribute more than one entry if more than one arm received the intervention.

[b] Subset from PEARL I study who did not have surgery following initial 3 months of treatment
[c] Subset from PEARL II study who did not have surgery following initial 3 months of treatment

Levonorgestrel (LNG) Intrauterine Device

One small, poor quality study compared a daily oral progestin (norethindrone acetate) with LNG-IUD for improving bleeding patterns among 60 premenopausal women with uterine fibroids. [152] No placebo was used and women were not blind to intervention group.

Effects of LNG-IUD on Fibroid Characteristics

The study did not report changes in fibroid volume.

Effects of LNG-IUD on Bleeding

Participants used the Visual Blood Scoring system,[167] a standardized pictorial method for reporting blood loss in a diary over the course of treatment. Visual blood loss scores improved by 6 months in both groups, with greater improvement in the LNG-IUD group (p=0.03). Improvement in hemoglobin likewise occurred in both groups with a statistically greater improvement among those with an IUD.

Other Effects of LNG-IUD

Women with the LNG-IUD were more satisfied and more likely to continue treatment than women taking norethindrone acetate. This study did not report harms of LNG-IUD.

LNG-IUD Summary

This trial suggests the LNG- IUD can improve bleeding even among women whose fibroid symptoms were considered appropriate for surgical intervention. However, the quality of the study was poor and thus evidence to guide care is inadequate. Based on the criteria for this review, evidence is insufficient for effects of LNG-IUD on bleeding, fibroid size, and quality of life.

Estrogen Receptor Agents and Combined Hormonal Therapy

Six studies included agents that act at the estrogen receptor.[118,123,124,128,129,136] Three studies (two fair and one poor quality) investigated raloxifene in 73 women compared to placebo.[118,123,128] Two were conducted in Italy by Palomba and colleagues with a total of 160 participants,[123,128] and the third, a smaller study with 25 women in Austria.[118] Two of these studies focused on premenopausal women; one enrolled only post-menopausal women.[128] A single poor quality pilot study (n=20) evaluated tamoxifen. [129] Two small poor quality trials conducted in Italy (n=38) and Turkey (n=46) had arms that provided estrogen plus progestin replacement to postmenopausal women with fibroids.[124,136]

Effects of Estrogen Receptor Agents on Fibroid Characteristics

Fibroid size decreased by 4.4 cm^3 to 34.2 cm^3 in two studies of raloxifene and did not change size in another raloxifene study (to put this in perspective, 40 cm^3 is the volume of a golf ball). Change in fibroid characteristics was not reported in the trial of tamoxifen (Table 15).

Table 15. Change in fibroid and uterine size with estrogen receptor agents by study arm[a]

Author (Year)	Dose, mg	N	Treatment Months (Imaging)	Followup Months	Fibroid Size Baseline; Followup(s), cm^3 mean ± SD	Change, cm^3	Uterine Size Baseline; Followup, cm^3 mean ± SD or (range)	Change, cm^3
Raloxifene								
Jirecek S et al. (2004)[118]	180	13	3 (US)	3	59.0 ± 48.1 54.4 ± 47.9	↓4.4 p=0.03	NR NR	NR
Palomba S et al. (2002)[123]	60	29	6 (US)	6	51.7 ± 18.9 57.4 ± 23.7	↑5.7 p<0.05	203.9 ± 58.4 209.5 ± 59.3	↑5.6 p<0.05
Palomba S et al. (2002)[123]	180	30	6 (US)	6	47.4 ± 16.3 47.7 ± 21.8	↑0.3 p=NS	206.7 ± 61.0 207.5 ± 64.4	↑0.8 p=NS
Palomba S et al. (2001)[128]	60	31	12 (US)	12	127.1 ± 38.2 NR	↓27.0% p<0.05	295.5 ± 81.0 NR	↓40.0% p<0.05
Tamoxifen								
Sadan O et al. (2001)[129]	20	10	6 (US)	7	NR NR	NR	334 (130 to 712) NR	NR p=NS

cm^3 = cubic centimeters; mg = milligrams; N = number; NR = not reported; NS = not significant; SD = standard deviation

[a] Single study may contribute more than one entry if more than one arm received the intervention.

Effects of Estrogen Receptor Agents on Bleeding

In studies of raloxifene with premenopausal women, neither bleeding pattern[118,123,128] nor hemoglobin levels[123] improved compared with placebo, and a lower versus higher dose had similar results for days and severity of bleeding.[123] Among postmenopausal women, most women remained amenorrheic (83% in the raloxifene group and 86% in the placebo group at 9 months); the number of episodes of spotting and severity of bleeding were similar among women in the treated and control group. In the pilot study, tamoxifen use in premenopausal women also did not influence length or severity of bleeding compared with placebo.[129]

Effects of Estrogen Receptor Agents on Other Symptoms

Only the small pilot tamoxifen comparison to placebo assessed pain; 70 percent of participants had pain at enrollment. The treatment group reported significantly less pain after four months of treatment but not earlier.[129] The study did not report on improvement in other symptoms or quality of life.

Risk of Harms With Estrogen Receptor Agents

These studies reported no drug-related adverse events, and withdrawal from treatment for perceived side effects or adherence was rare and equal to placebo groups.[118,123,128] Simple ovarian cysts occurred in raloxifene treated women which resolved once off medication.[118] Endometrial thickening occurred with tamoxifen, and biopsies in this very small study were normal.[129] However, these randomized controlled trails were not designed or powered to detect all harms related to this therapy.

Combined Hormone Replacement Therapy

Two poor quality RCTs had a total of 42 women receiving transdermal estrogen plus cyclic oral medroxyprogesterone acetate after menopause. [124,136]They compared hormone therapy to tibolone (not available in United States) for menopausal symptom management with attention to whether treatment increased size of fibroids. Combined estrogen plus progestin therapy resulted in timed cyclic bleeding as intended among postmenopausal women.[136] In the HRT arm fibroid size increased by approximately 10 cm^3 after 6 months.[124] In the longer study there was no further growth between 6 and 12 months.[136]

Summary of Estrogen Receptor Agents

These agents were related to no or small decreases in fibroid size without improvement in bleeding among those who were premenopausal.

These studies provide a low strength of evidence that raloxifene is unlikely to prompt significant fibroid growth or to exacerbate bleeding if they are needed to treat women with fibroids for other conditions such as breast cancer prophylaxis. Two small studies of combined hormone replacement therapy did not find any changes in fibroid size after 6 or 12 months of therapy. This is insufficient to gauge if estrogen plus progestin therapy for menopausal symptoms does or does not promote fibroid growth.

Tranexamic Acid

We include one study, a pooled analysis of data from two independent trials of tranexamic acid treatment versus placebo for heavy uterine bleeding.[67] We did not include the primary studies that contributed data to the pooled analysis because those studies did not meet our review inclusion criteria (outcomes were not reported by fibroid status). The pooled analysis included a subset of women with uterine fibroids from each study. Women with fibroids who received tranexamic acid reported statistically significant ($p<0.001$) reductions in menstrual blood loss at treatment cycle three compared with placebo. We did not rate the quality or risk of bias for the pooled analysis or the primary studies from which the data was drawn.

Procedures for Fibroid Intervention: Overview

In this section we include studies of procedures to treat uterine fibroids including uterine artery embolization (UAE) and occlusion, high intensity focused ultrasound (HIFU) for fibroid ablation, and radiofrequency fibroid ablation. The literature discussed in this section includes studies focusing on UAE only, with the exception of UAE compared with laparoscopic occlusion of the uterine arteries. Studies comparing UAE to surgery are discussed in the section about direct comparisons.

Procedures: Results

We include 28 studies addressing UAE, HIFU including MRgFUS, and radiofrequency fibroid ablation.[13-23,38,53,57,58,60,62,68,70,71,78,81,82,91-93,96,97,99,104,105,108,109,111,113,114,117,127,155,156,158] Studies included 2,149 women and were conducted in 15 different countries, most frequently in the United States (7 studies) or China (6 studies).) Many (15) of these [14,15,18,22,23,53,58,62,81,92,105,108,117,127,155] did not report source of funding. Three studies, two comparing embolic agents[13,78] and one that evaluated radiofrequency fibroid ablation,[57] were industry supported. Nine studies compared a procedural intervention to hysterectomy or

myomectomy.[14,16,20,22,57,68,104,113,114] The longest duration of followup after the end of treatment was 5 years in two studies.

Uterine Artery Embolization or Occlusion

We identified 21 studies (reported in 34 publications) that randomized women to UAE or uterine artery occlusion.[13-23,38,62,70,71,78,82,91-93,96,97,99,104,105,108,109,111,113,114,117,127,155,158]. Of 18 studies of UAE (30 publications), ten studies compared an embolization agent to a different agent or different size,[13,15,18,23,62,78,92,117,155,158] seven studies compared UAE to surgery,[14,16,20,22,104,113,114] and one compared UAE to a GnRH agonist (goserelin).[108] We assessed six studies to be good quality, six were of fair quality and six were poor quality.

We identified three studies (one fair quality and 2 poor quality) reported in four publications that assessed uterine artery occlusion. Two studies (reported in three publications) compared transcatheter[38] or laparoscopic[83,105] uterine artery occlusion to UAE; one compared laparoscopic bipolar coagulation alone to laparoscopic bipolar coagulation plus laparoscopic ligation of uterine nerves to determine if the addition of laparoscopic uterine nerve ablation would improve postoperative pain and dysmenorrhea .[127]

Much of the information on safety and long-term outcomes of UAE is from two large trials (EMMY[114] and REST[104]). The duration of followup ranged from 2 months to 60 months after treatment, with an average of 15 months.

Effects of UAE on Fibroid Characteristics

Fibroid and uterine volume decreased consistently and significantly following UAE (up to 12 months postprocedure) regardless of the embolization agent or size of particles used to occlude the fibroid arteries (Table 16). Additional longer-term followup reports from the EMMY trial confirm that fibroid and uterine volume reductions persist up to 5 years after UAE; however in four studies with two to five years of followup, the proportion of women seeking subsequent treatment following UAE ranged from 19 percent to 38 percent Appendix G includes additional tables with data on changes in uterine volume.

Table 16. Change in fibroid volume with uterine artery embolization by study arm[a]

Author (Year)	Embolic Agent	N (Imaging)	Followup, months	Baseline; Followup cm^3 mean ± SD or (range)	Change, cm^3 mean or percent ± SD
Wang X et al. (2015)[155]	PVA particles (200 µm)	65 (US)	6	114.9 ± 13.0 23.9 ± 9.4	↓91 p<0.05
Wang X et al. (2015)[155]	PVA particles (500 µm)	65 (US)	6	116.4 ± 12.6 44.7 ± 10.7	↓71.7 p<0.05
Shlansky-Goldberg R et al. (2014)[13]	PVA particles	28 (MRI)	3	NR 104.2 ± 116.1	↓76.9 ± 135.8 p=NR
Shlansky-Goldberg R et al. (2014)[13]	TAG microspheres	28 (MRI)	3	NR 117.1 ± 179.5	↓27.4 ± 42.3 p=NR
Song Y et al. (2013)[62]	Gelatin sponge particles	30 (MRI)	3	265.3 ± 339.0 112.1 ± 167.4	↓153.2 p=NR
Song Y et al. (2013)[62]	PVA particles	30 (MRI)	3	184.1 ± 141.3 97.2 ± 88.7	↓86.9 p=NR
Yu S et al. (2011)[15]	PVA particles	30 (US)	9	197.7 ± 179 NR	NR ↓44.3% ± 52.4%

Author (Year)	Embolic Agent	N (Imaging)	Followup, months	Baseline; Followup cm^3 mean ± SD or (range)	Change, cm^3 mean or percent ± SD
Yu S et al. (2011)[15]	TAG microspheres	30 (US)	9	181.3 ± 140.0 NR	NR ↓55.0% ± 30.0%
Worthington-Kirsch R et al. (2011)[78]	PVA particles	22 (MRI)	6	130 ± 69 NR	NR[b] NR
Worthington-Kirsch R et al. (2011)[78]	TAG microspheres	24 (MRI)	6	96 ± 50 NR	NR[b] NR
Bilhim T et al. (2011)[18]	PVA particles, large	76 (MRI)	6	193.0 ± NR 98.0 ± NR	↓95.0 ↓49.2%
Bilhim T et al. (2011)[18]	PVA particles, small	77 (MRI)	6	210.0 ± NR 91.0 ± NR	↓119.0 ↓56.7%
Siskin G et al. (2008)[92]	PVA microspheres	27 (MRI)	1	190.6 (0.4 to 670.7) 140.8 (NR)	↓49.8 ↓26.2%
Siskin G et al. (2008)[92]	TAG microspheres	26 (MRI)	1	196.9 (14.1 to 536.6) 161.4 (NR)	↓35.5 ↓18.0%
Mara M et al. (2008)[21]	TAG microspheres	38 (MRI)	6	166.0 ± NR 69.0 ± NR	↓97.0 ↓58.7%
Vilos G et al. (2006)[108]	PVA particles	10 (US)	12	257.3 ± 302.9 34.9 ± 42.4	↓222.4 ↓86.0%
Vilos G et al. (2006)[108]	PVA; goserelin 24 hours post UAE	12 (US)	12	225.7 ± 182.9 94.7 ± 88.9	↓131.0 ↓58.0%
Spies J et al. (2005)[23]	PVA particles	17 (MRI)	3	142.4 ± 126.6 NR	↓29.6 ± 19.1 NR
Spies J et al. (2005)[23]	TAG microspheres	19 (MRI)	3	150.1 ± 178.9 NR	↓39 ± 27 NR
Spies J et al. (2004)[117]	TAG microspheres	54 (MRI)	3	138.4 ± 139.5 NR	NR ↓56.5% ± 22.2%
Spies J et al. (2004)[117]	PVA particles	46 (MRI)	3	162.4 ± 169.3 NR	NR ↓42.5% ± 25.8%
Pinto I et al. (2003)[22]	PVA particles	38 (MRI and US)	6	84.4 (1.8 to 408) 45.5 (0.5 to 408)	↓38.9 ↓46.0%
Volkers N et al.(2007)[99,114]	PVA particles	87 72 73 66 62 (US)	- 1.5 6 12 24	121.5 ± 150 70.5 ± 105 54.4 ± 95 41.6 ± 78 40.1 ± 87	NA ↓14.8% ↓42.1% ↓54.5% ↓60.5%

cm^3 = cubic centimeters; MRI = magnetic resonance imaging; µm = micrometers; NA = not applicable; PVA = polyvinyl alcohol; SD = standard deviation; TAG = trisacryl gelatin; UAE = uterine artery embolization; US = ultrasound

[a] Single study may contribute more than one entry if more than one arm received the intervention. Multiple values for N indicate the number of patients at baseline and followup(s);
[b] Data reported in figure only

Effects of UAE on Bleeding

Changes in bleeding were reported as incidence of amenorrhea, change in bleeding score using a scale from −5 to +5, and self-reported dysmenorrhea or menorrhagia (Table 17).

Table 17. Change in bleeding outcomes with uterine artery embolization by study arm[a]

Author (Year)	Embolic Agent	N	Outcome	Followup, months	Baseline; Followup(s), mean ± SD or median (range)	Change, mean ± SD
Song Y et al. (2013)[62]	Gelatin sponge particles	30	Bleeding Questionnaire[b]	3	8.1 ± NR 2.0 ± NR	NR
Song Y et al. (2013)[62]	PVA particles	30	Bleeding Questionnaire[b]	3	7.9 ± NR 2.5 ± NR	NR
Spies J et al. (2004)[117]	PVA particles	46	Bleeding Questionnaire[c]	3	NR NR	↑3.3 ± 1.5 p=NR
Spies J et al. (2004)[117]	TAG microspheres	54	Bleeding Questionnaire[c]	3	NR NR	↑3.2 ± 1.9 p=NR
Spies J et al. (2005)[23]	PVA particles	17	Bleeding Questionnaire[c]	3	NR 3.1 ± 1.7	NR
Spies J et al. (2005)[23]	TAG microspheres	19	Bleeding Questionnaire[c]	3	NR 4.0 ± 1.4	NR
Ruuskanen A et al. (2010)[20]	Microspheres		Days of menstrual flow	24	4.9 ± 2.4 3.3 ± 4.4	↓1.6 p=NR
Rashid S et al. (2010)[82,104]	NR	75 69	Days of menstrual flow	6 12	NR NR NR	↓1.4 ± 3.7 p<0.05 ↓1.7 ± 3.8 p<0.05
Cunningham E et al. (2008)[38]	Microspheres	8	Bleeding, mean change in AMSS	3	NR NR	↓58.0% p=NR
Cunningham E et al. (2008)[38]	Vascular coils	6	Bleeding, mean change in AMSS	3	NR NR	↓63.0% p=NR
Ruuskanen A et al. (2010)[20]	Microspheres	27	Hemoglobin, g/L	24	131.4 ±13.9 NR	↑9.5 ±13.9 p=NR
Volkers N et al. (2007)[99,114]	PVA particles	81	Hemoglobin, g/dL	24	NR NR	↑1.37 p=NR
Volkers N et al. (2007)[99]	PVA particles	88 81 80 81 81	Days of heavy menstruation	- 1.5 6 12 24	3 (1 to 28) 2 (0 to 14) 2 (0 to 7) 1 (0 to 10) 0 (0 to 6)	NA NR NR NR NR

AMSS = Aberdeen Menorrhagia Severity Scale; g/dL = grams per deciliter; g/L = grams per liter; NA = not applicable; NR = not reported; PVA = polyvinyl alcohol; SD = standard deviation; TAG = trisacryl gelatin; UAE = uterine artery embolization

[a] Single study may contribute more than one entry if more than one arm received the intervention. Multiple values for N indicate the number of patients at baseline and followup(s);
[b] Questionnaire range from 0 (no impact) to 10 (severe impact);
[c] 11-point questionnaire range from -5 (markedly worse) to +5 (markedly improved)

Effects of Uterine Artery Embolization or Occlusion on Fibroid-Related Pain

Most women who underwent uterine artery occlusion via laparoscopic bipolar coagulation reported improvement in dysmenorrhea symptoms at 6 months after procedure (76.2% of women who were treated by coagulation of uterine vessels alone). [127] At baseline, 73 women (90.1%) in the UAE arm of the EMMY trial complained of lower abdominal pain. At 24 months of followup, 84.9 % of women reported moderate improvement of pain.[99] In another study, nine of

the 27 women (33%) in the UAE arm reported dysmenorrhea at baseline while only four (15%) complained of dysmenorrhea at the 2 year followup, thus showing a reduction of 56 % from baseline.[20]

Other Treatment Effects of Uterine Artery Embolization or Occlusion

Quality of Life

Overall improvement in symptoms and physical well-being following UAE were reported using UFS-QOL, SF-36, and European Quality of Life 5D (EQ-5D™) scores. Quality of life was not reported following laparoscopic bipolar coagulation or transcatheter uterine artery occlusion[38,83,105 127]

Quality of Life: UFS-QOL

After UAE, significant improvement in symptoms was reported by the UFS-QOL in a small study (n=36) [23] The 2014 study by Shlansky-Goldberg and colleagues[13] reported changes in total quality of life or symptom and subscores on the UFS-QOL in figures only. Changes in the total quality of life score were reported in figures only in another small study (n=44) comparing UAE with trisacryl gelatin microspheres to UAE with polyvinyl alcohol particles.[78] Total quality of life scores improved at 3 months after uterine artery embolism in both groups (UAE with trisacryl gelatin microspheres: 36.0 ± 25.5 and UAE with polyvinyl alcohol particles: 23.1 ± 23.4, p-values not reported).[117] A 2012 study was powered to detect a 10-point difference in quality of life outcomes among premenopausal women with symptomatic fibroids following abdominal myomectomy or UAE.[16] Authors reported significant improvements from baseline in overall quality of life and severity scores after UAE (p=NR).[16]

Quality of Life: SF-36

Four trials reported SF-36 quality of life outcome measures following UAE. Two assessed at 6 months,[14,155] and two, the REST[104] and EMMY[93] trials, up to 60 months (Table 18). At 6 months, both trials identified significant improvements in quality of life scores from baseline (p=NR and p<0.05).[14,155] The REST trial[17] reported a gain in quality of life after UAE with five year measures of SF-36 scores being comparable to normative data. The EMMY trial[93] also found those in the UAE group had improved general health-related quality of life at 6 months and later when compared with baseline values (p<0.05). Using the Body Image Scale, the EMMY trial[96] reported that body image also improved significantly from baseline (p<0.05) in the UAE group at 6 (−1.34), 18 (−1.24) and 24 (−1.06) months with lower scores representing favorable body image and negative numbers indicating improvement.

Table 18. Change in quality of life (SF-36) with uterine artery embolization by study arm[a]

Author (Year)	N	Domains	Followup(s) Months	Baseline, Mean ± SD	Followup(s), mean ± SD or mean change
Wang X et al. (2015)[155] UAE 200 µm PVA particles	65	Physical function Physical role Bodily pain General health	6	55.4 ± 5.3 49.0 ± 6.4 56.9 ± 5.1 57.1 ± 6.0	83.5 ± 6.4 84.8 ± 7.0 84.3 ± 6.0 85.9 ± 5.1 p=NR

Author (Year)	N	Domains	Followup(s) Months	Baseline, Mean ± SD	Followup(s), mean ± SD or mean change
Wang X et al. (2015)[155] UAE 500 µm PVA particles	65	Physical function Physical role Bodily pain General health	6	55.4 ± 4.0 48.8 ± 6.2 57.0 ± 5.2 57.3 ± 6.2	74.9 ± 5.1 78.5 ± 6.0 76.0 ± 5.3 71.6 ± 6.3 p=NR
Jun F et al. (2012)[14]	62	Physical function Social function Mental health Emotional role Vitality	6	57.7 ± 17.0 44.6 ± 7.0 43.3 ± 22.1 50.0 ± 24.9 54.0 ± 11.5	68.4 ± 6.1 63.0 ± 10.2 71.9 ± 6.2 69.6 ± 6.7 66.2 ± 6.0 p=NR
Moss J et al. (2011)[17,82,104]	94	Physical function Social function Mental health Emotional role Vitality Physical role Bodily pain General health	60	82 ± 19 63 ± 27 63 ± 18 60 ± 43 41 ± 22 51 ± 41 52 ± 22 61 ± 19	90 ± 18 86 ± 23 76 ± 17 82 ± 35 63 ± 22 84 ± 32 79 ± 22 78 ± 19 p=NR
van der Kooij S et al. (2010)[19]	78 81 70	Mental Component Summary	12 24 60	NR NR NR	6.3 (p<0.05) 5.8 (p<0.05) 6.3 (p<0.05)
van der Kooij S et al. (2010)[19]	78 81 70	Physical Component Summary	12 24 60	NR NR NR	7.3 (p<0.05) 9.4 (p<0.05) 8.5 (p<0.05)

N = number; NR = not reported; PVA = polyvinyl alcohol; SD = standard deviation; SF-36 = Medical Outcomes Study 36-Item Short Form General Health Survey; UAE = uterine artery embolization

[a] Single study may contribute more than one entry if more than one arm received the intervention. Multiple values for N indicate the number of patients at baseline and followup(s)

Quality of Life: EQ-5D

The REST trial did not report the change in EQ-5D or symptom status score from baseline at 12 months or at 5 years, though the absolute scores showed improvement.[17,104] Significant improvements ($p<0.05$) from baseline in EQ-5D scores were observed at 6 months and afterwards in the EMMY trial.[93]

Satisfaction

Out of the seven studies comparing UAE with surgeries, satisfaction rates were reported in all but one study (FUME trial[16]). Satisfaction with outcome was measured by asking women if they would undergo the same treatment again,[22] if they obtained symptom relief,[21,113] if they were satisfied with the treatment,[19,20] and if they would recommend treatment to a friend.[14,19,104] One trial also reported satisfaction without providing details of the criteria.[14] Satisfaction rates (Table 19) ranged from 78 to 89 percent at 6 months[21,22] to 82 to 88 percent at 1 year[14,104] to about 90 percent at 2 years.[19,20] Satisfaction rates remained high (84% to 90%) at 5-year followup.[17,19]

Table 19. Patient satisfaction with uterine artery embolization

Author (Year)	N	Outcome	Followup(s) Months	Percent
Pinto I et al. (2003)[22]	36	Would choose treatment again	6	78.0
Mara M et al. (2008)[21]	58	Symptoms relieved	6	88.5
Edwards R et al. (2007)[104]	95	Would recommend to a friend	12	88.0
Jun F et al. (2012)[14]	62	Would recommend to a friend	12	82.0
	62	Satisfactory rating	12	84.0
van der Kooij S et al. (2010)[19]	81	Satisfaction with outcome	12	84.0
	81		24	91.4
	81		60	84.0
	81	Would recommend to a friend	60	77.2
Ruuskanen A et al. (2010)[20]	26	Would choose treatment again	24	89.0
Moss J et al. (2011)[17]	93	Would recommend to a friend	60	90.0

N = number

Recurrence and Subsequent Treatment

Two studies[21,71] reported fibroid recurrence. In one trial, women were followed for a mean period of 26 months after UAE.[21] By 2 years, there were six women (10.3%) with regrowth or recurrence of fibroids.[21] The REST trial reported fibroid recurrence in five out of 68 women (7%) 5 years after UAE treatment.[71]

Subsequent treatment was reported in 11 trials with length of followup ranging from 6 to 60 months (Table 20). Hysterectomy was the most frequent intervention (8.9%) followed by repeat embolization (4.2%), myomectomy (3.6%), medication or IUD (1.1%) and endometrial ablation (0.1%).

Table 20. Subsequent fibroid treatment following uterine artery embolization by study arm[a]

Author (Year)	Baseline N	Followup Months	Followup N	HYS	MYO	UAE	ABL	MED/ IUD	No Tx	Percent receiving subsequent treatment
Mara M et al. (2008)[21]	58	24	58	0	19	0	0	0	39	32.8
Manyonda I et al. (2012)[16]	82	12-24	63	6	2	1	0	0	54	14.3
Moss J et al. (2011)[17]	106	60	96	18	0	8	0	0	69	28.1
Jun F et al. (2012)[14]	63	6-12	62	0	1	5	0	0	56	9.7
van der Kooij S et al. (2010)[19]	88	60	75	23	2	0	1	7	37	37.5
Pinto I et al. (2003)[22]	38	6	37	2	0	0	0	0	35	5.4

Author (Year)	Baseline N	Followup Months	Followup N	HYS	MYO	UAE	ABL	MED/ IUD	No Tx	Percent receiving subsequent treatment
Ruuskanen A et al. (2010)[20]	27	24	26	3	1	0	0	1	21	19.2
Shlansky-Goldberg R et al. (2014)[13]	60	12	56	1	0	0	0	0	55	1.8
Yu S et al. (2011)[15]	60	24	56	9	1	0	0	0	46	17.9
Bilhim T et al. (2011)[18]	160	6	153	2	0	14	0	0	137	11.5
Spies J et al. (2005)[23]	36	12	36	0	0	2	0	0	34	5.6
Hald K et al. (2007)[83,105]	29	6	29	1	0	0	0	1	27	6.9

HYS = hysterectomy; MED/IUD = medication or intrauterine device; MYO = myomectomy; N = number; No Tx = no treatment; UAE = uterine artery embolization

[a] Single study may contribute more than one entry if more than one arm received the intervention.

Effects of UAE on Ovarian Reserve and Pregnancy Outcomes

Ovarian reserve and pregnancy outcomes were not uniformly evaluated following UAE.[83,105,127] (Table 21) Ovarian failure, measured by follicle stimulating hormone (FSH) >40 IU/L and anti-Mullerian hormone (AMH), was reported in two trials.[82,97] In the EMMY trial 88 women were assigned to UAE. Their average age at baseline was 45. In this group FSH increased significantly by 12.1 IU/L compared with baseline (p=0.001) by 24 months after treatment with UAE. Ovarian failure (FSH >40 IU/L) was reported in 12 percent and 18 percent at 12 and 24 months, respectively.[97] Levels of AMH were significantly lower, indicating ovarian aging at each followup up to 24 months after UAE (p<0.05).[97] These changes in FSH and AMH were comparable to those randomized to hysterectomy (p=0.37). The only predictor of becoming menopausal in each group was being older than 45 at randomization. A similar proportion of 73 women (11%) were observed to have menopausal levels of FSH at 12 months after UAE in the REST study. This was also comparable to levels in the surgical arm of their trial (p=0.47). Participants in REST also had an average age in their mid-forties at the time of randomization.[82]

The trial by Mara and colleagues included 58 women randomized to UAE. The average age of participants in their study was more than a decade younger than the other trials.[21] In this younger study population the risk of elevated FSH >10 IU/L after intervention was higher among those with UAE (13.8%) than myomectomy (3.2%; p<0.05), though no participants became frankly menopausal. This study, though under-powered, was the only study that prespecified pregnancy and live birth as outcomes of interest. By two years, there were 13 pregnancies (50%) and five live births (19.2%) reported out of 26 women wanting to conceive. The REST trial[104] did not prespecify pregnancy outcomes, but did report seven pregnancies after UAE at 12 months which included four miscarriages, two livebirths, and one intrauterine fetal death at 33

weeks with no known cause. The EMMY trial[99] reported one unplanned pregnancy after UAE at 24 months in a 39-year-old multipara, who delivered a healthy child after secondary cesarean section for fetal distress.

Table 21. Pregnancy and fertility status following uterine artery embolization

Author (Year)	N (Imaging)	Followup, months	Number (%) or µg/L mean change
FSH >40 IU/L			
Hehenkamp W et al. (2007)[97]	79	1.4	10/79 (13.0)
	78	6	7/78 (9.0)
	74	12	9/74 (12.0)
	80 (US)	24	14/80 (18.0)
Rashid S et al. (2010)[82]	62 (US)	12	7/62 (11.0)
Mara M et al. (2008)[21]	58 (US)	6	8/58 (13.8)
Anti-Mullerian hormone			
Hehenkamp W et al. (2007)[97]	79	1.4	−0.62[a]
	78	6	−0.23[a]
	74	12	−0.31[a]
	80 (US)	24	−0.42[a]
Pregnancy			
Edwards R et al. (2007)[104]	95 (MRI)	12	7/95 (7.4)
Volkers N et al. (2007)[99]	81 (US)	24	1/81 (1.2)
Mara M et al. (2008)[21]	26 (US/MRI)	24	13/26 (50.0)

FSH = follicle stimulating hormone; IU/L = international units per liter; µg/L=micrograms per liter; MRI = magnetic resonance imaging; US = ultrasound

[a] Compared to expected AMH decrease due to ageing from baseline values.

Harms in Studies of UAE

Transfusion

Three studies of UAE compared with myomectomy or hysterectomy reported incidence of transfusion.[21,22,114] None of the 186 patients required transfusion after UAE.

Other Major Complications

The proportion of major complications, including unplanned hysterectomy, rehospitalization, ovarian failure, and pulmonary embolism during and following UAE ranged from 1.2 to 6.9 percent within a month of the procedure, up to 3 percent by 1 year,[16] and about 5 percent at 2 years.[91] The rates of major complications were highest in two studies that reported long-term followup (21% at 5 years in the REST trial[17] and 16.8% at 32 months in a second study[104].

Complication rates were generally low in the studies comparing embolic agents[15,18,62,92,117] (Appendix G), however the duration of followup among these studies was 9 months or less.

Summary of Uterine Artery Embolization or Occlusion

There was high strength of evidence that UAE is effective for reducing fibroid volume. The strength of evidence supporting improvements in bleeding and quality of life is moderate for UAE. Five-year followup data were available from two large good quality trials in which well over half the women who received an embolization did not need a subsequent intervention (including hysterectomy). The effect of UAE on reproductive outcomes is not well studied and evidence is insufficient to guide care or determine safety.

Because of small numbers and heterogeneity of methods, there is insufficient evidence to make any conclusions about uterine artery occlusion.

High Intensity Focused Ultrasound for Fibroid Ablation

The prior review[12] included findings from a prospective case series that was conducted to support an application for FDA approval of the MRgFUS.[168,169] Since then, we identified six studies reported in seven publications,[53,58,60,68,69,81,156] assessing HIFU as treatment for uterine fibroids. Interventions included MRgFUS in one study,[156] HIFU in two studies with three publications,[68,69,81] HIFU plus contrast enhanced ultrasound in two studies,[53,60] and HIFU plus ethanol injection into the fibroid in one study.[58] These trials were published between 2010 and 2016. Four studies were conducted in China and one each in Italy and the United States. Study size ranged from 20 to 100 women and included a total of 316 participants. The MRgFUS pilot study was fair quality and the other studies were poor quality.

Effects of HIFU for Fibroid Ablation on Fibroid Characteristics

Four studies reported fibroid volume following HIFU (Table 22).[53,58,60,156] The magnitude of fibroid volume reduction was greater at 12 months[53] after HIFU than at 1 month post-treatment.[58]

Table 22. Change in uterine fibroid volume following HIFU by study arm[a]

Author (Year)	Intervention	N	Followup, months	Baseline; Followup, cm^3 mean ± SD	Change, cm^3
Jacoby V et al. (2016)[156]	HIFU plus MRguidance	13	3	217 ± 139 176 ± NR	↓41 -18% p=NR
Jiang N et al. (2014)[60]	HIFU	40	0	NR 82.6 ± 102.0	NR
Jiang N et al. (2014)[60]	HIFU plus CEUS	40	0	NR 58.6 ± 69.3	NR
Orsi F et al. (2015)[53]	HIFU	17	12	189.6 ± 190.0 100.0 ± 144.0	↓89.9 −47.2% p=NR
Orsi F et al. (2015)[53]	HIFU plus CEUS	20	12	419.2 ± 409.0 249.3 ± 257.0	↓169.9 −40.5% p=NR
Yang Z et al. (2014)[58]	HIFU	20	1	156.2 ± 130.1 108.3 ± 926.1	↓47.9 p=NR
Yang Z et al. (2014)[58]	HIFU plus USg intramural ethanol injection	20	1	157.7 ± 198.5 112.8 ± 145.2	↓44.9 p=NR

CEUS = contrast enhanced ultrasound; cm3 = cubic centimeters; HIFU = high intensity focused ultrasound; NR = not reported; USg = ultrasound-guided

[a] Single study may contribute more than one entry if more than one arm received the intervention.

Effects of HIFU for Fibroid Ablation on Bleeding and Fibroid-Related Pain

There was no change in hemoglobin levels after twelve weeks in one small study.[156] Patient-reported bleeding symptoms were not reported in these trials.

Other Treatment Effects of HIFU for Fibroid Ablation

One month after HIFU, the mean change in UFS-QOL score was increased by 16 or more points among 37 patients (baseline not reported); however, four patients experienced persistent symptoms and underwent a second HIFU procedure.[53] A study that compared myomectomy to HIFU reported treatment effects on sexual function at 6 months postprocedure among 100 women. The total sexual function score using the brief index of sexual function for women (BISF-W) improved from 24.6 ± 6.6 at baseline to 26.7 ± 5.2 at 6 months in the HIFU group (n=48; $p<0.05$).[68]

Harms Reported in Studies of HIFU for Fibroid Ablation

No major harms were observed postprocedure in the 316 patients who received HIFU for fibroid treatment.[53,58,60,68,81,156] One study reported on transfusion; none of the 48 women who received HIFU required a transfusion (Appendix G).[68]

HIFU for Fibroid Ablation Summary

HIFU reduced fibroid and uterine size, but strength of evidence is low because of short followup and poor quality of overall study design. Studies of HIFU for fibroid ablation reported intra- and postprocedural outcomes, specifically technical success and safety of the technique.. Publications did not assess symptoms or long-term outcomes, including pregnancy. Limited data suggests that QOL and sexual function do not worsen post-procedure. Evidence related to patient reported outcomes is insufficient.

Radiofrequency Fibroid Ablation

We included two studies (4 publications) that assessed outcomes of radiofrequency fibroid ablation. These studies were conducted in China and Germany and included 75 patients. Both were assessed as poor quality. The Chinese study published in 2010 randomized women to radiofrequency ablation (n=50) or HIFU (n=50).[81] The smaller German study compared a different radiofrequency ablation device (n=25) with myomectomy (n=25).[57,154,159] One and two year followup data included quality of life, bleeding outcomes, reinterventions, and pregnancy outcomes.

Effects of Radiofrequency Fibroid Ablation on Fibroid Characteristics

The effect of the procedure on fibroid volume was only reported as technical success during the procedure. In the German study, authors reported that radiofrequency ablation successfully excised 71 of 72 fibroids (98.6 percent) in 25 patients.[57] The Chinese study reported ablation success of 86 percent (by volume) and 90 percent (by diameter) following radiofrequency ablation among 50 women.[81]

Effects of Radiofrequency Fibroid Ablation on Bleeding and Pain

At one year post-ablation, 94.4 percent of women (n=21) reported improved or no change in menstrual blood loss as measured by the Menstrual Impact Questionnaire.[159] The German study assessed pain and quality of life outcomes at 2 years. Uterine pain did not improve: 3 of 25 women (12%) reported uterine pain at baseline and 5/21 (24%) reported pain at 2 years after ablation.[154] The authors did not take into account recurrent fibroids. Mean health-related quality of life scores improved from 77.1 at baseline to 89.4 at 2 years (p=0.08).

Effects of Radiofrequency Fibroid Ablation on Pregnancy Outcomes

Three pregnancies, culminating in three live births were noted fin the German study after two years of followup for 21 women.[154]

Harms Reported in Studies of Radiofrequency Fibroid Ablation

With the exception of one case of rehospitalization for unexplained vertigo after treatment,[57] authors reported no complications following radiofrequency ablation treatment.[81]

Radiofrequency Fibroid Ablation Summary

We identified two small studies, both poor quality, that evaluated radiofrequency ablation techniques for fibroid symptoms. Two-year followup noted improvements in symptoms and quality of life. This study plans for a total of five years of followup to obtain long-term pregnancy and satisfaction outcomes.[57,156,159]

Surgical Intervention: Overview

Surgical Interventions: Results

We identified 37 studies[14,16,20,22,56,57,63,68,72,76,77,80,85,86,89,90,95,100,104,107,110,112-114,120,121,125,126,130-132,134,135,137,141,148,160] evaluating a surgical intervention to treat women with uterine fibroids. Studies were conducted in seven countries (Brazil, China, France, Germany, Italy, Korea, and Taiwan) and randomized 3,172 women with uterine fibroids to endometrial ablation, hysterectomy, or myomectomy. We assessed study quality as good in ten studies,[56,76,86,89,90,95,114,120,121] fair in ten studies,[16,22,100,104,113,130-132,134,135,141] and poor in 17 studies.[14,20,57,63,68,72,77,80,85,107,110,112,125,126,137,148,160]

Endometrial Ablation

We identified one study of endometrial ablation.[132] This fair quality study reported amenorrhea, bleeding, hemoglobin, patient satisfaction and the incidence of harms in patients treated by roller-ball (n=54) vs. thermal balloon endometrial ablation (n=42).

Effects of Endometrial Ablation on Bleeding

Menorrhagia, reported by pictorial blood loss chart, decreased significantly ($p<0.0001$) in both groups from baseline to 12 month after procedure. This patient-reported outcome was confirmed by a clinically significant increase in mean hemoglobin in both groups ($p<0.001$).[132] Table 23 reports changes in hemoglobin.

Table 23. Change in hemoglobin with endometrial ablation by method

Author (Year)	Intervention	N	Followup, months	Baseline; Followup, g/dL mean ± SD	Change, g/dL mean ± SD
Soysal ME et al. (2001)[132]	Rollerball	54	12	9.8 ± 1.2 12.9 ± 0.9	↑3.0 ± 1.6 p<0.0001
Soysal ME et al. (2001)[132]	Thermal balloon	42	12	10.0 ± 1.5 12.8 ± 0.9	↑2.7 ± 1.9 p<0.0001

g/dL = grams per deciliter; N = number; SD = standard deviation

Other Treatment Effects of Endometrial Ablation

The rate of reintervention was similar following rollerball (8.3%) and thermal balloon ablation (8.9%). Rates of dissatisfaction were high in both the rollerball (33%) and thermal balloon (39%) groups.[132]

Harms Reported in Studies of Endometrial Ablation

The endometrial ablation procedure using rollerball necessitates general anesthesia whereas the thermal balloon ablation procedure can be conducted under local anesthesia. The number of intraoperative complications was correspondingly higher in the group who underwent the more invasive procedure (five complications including one case of cervical injury). There were no complications reported during procedures in the thermal ablation group (Appendix G). Overall rates of patient satisfaction were equally poor as noted above.[132]

Endometrial Ablation Summary

Evidence is insufficient to assess the effectiveness of endometrial abalation to improve fibroid symptoms. Limited data suggest that bleeding outcomes remained improved one year following ablation.

Myomectomy

We included 20 studies (reported in 24 publications) that assessed myomectomy for treatment of uterine fibroids.[16,57,63,68,72,76,77,80,85,86,90,95,100,107,110,113,130,134,141,160] Of these, 15 studies reported final health outcomes following myomectomy for fibroids. Five studies reported harms only.[72,76,86,90,95] We considered four RCTs to be good quality, six to be fair quality and ten to be poor quality. Myomectomy techniques include laparoscopic, laparotomy, minilaparotomy, laparoscopically-assisted minilaparotomy, and hysteroscopic approaches.

Effects of Myomectomy on Fibroid Characteristics

Because fibroids are removed at the time of myomectomy, reduction in fibroid and uterine volume are not often reported as an outcome. Fibroid recurrence was reported in seven studies with duration of followup ranging from 6 to 40 months.[77,85,110,113,130,134,141] No recurrences were reported in two studies that evaluated 114 women by ultrasonography 6 months following myomectomy.[85,110] In five studies, recurrence rates ranged from 2.5 to 24.7 percent (56 recurrences reported in 456 women). Recurrence rates did not differ by type of incision in four studies that compared different surgical approaches.[110,113,130,134,141]

Effects of Myomectomy on Bleeding

One trial reported absence of heavy menstrual bleeding at 12 months after the procedure for 12 of 15 (87%) women who had reported it as a problem at baseline.[159] Another noted persistent abnormal menstruation in three (1.9%) women who had myomectomy plus uterine artery occlusion at 2-year followup.[77] No other studies reported changes in symptomatic fibroid-related bleeding, such as heaviness of menses or total days of bleeding. Lack of this outcome means evidence is insufficient for determining if myomectomy improves an extremely common concern among women who seek intervention for fibroids.

Other Treatment Effects of Myomectomy

Return to Usual Activity

Recovery time ranged from 15 days up an average of 30 days as reported in three studies.[110,113,141] Type of incision was a major determinant in recovery time in two studies with more women reporting feeling fully recovered by day 15 following laparoscopy compared with minilaparotomy[110] or abdominal myomectomy.[141] Recovery time from myomectomy averaged 30 days in another small study.[113]

Quality of Life and Symptom Status

Improvement in quality of life or symptom status was reported in five studies (7 publications).[16,21,57,77,80,154,159] Quality of life significantly improved in three studies that assessed it. The FUME trial comparing myomectomy to UAE reported improved quality of life for both groups after one year as measured by the UFS-QOL.[16] A large Chinese study reported improvements in all four domains (physical, psychological, environment, and social relationship) after two years following laparoscopic uterine artery occlusion plus myomectomy using the abbreviated World Health Organization Quality of Life (WHOQOL-BREF) measure. A small study of 25 women documented significant improvements in health related quality of life scores after two years as measured by UFS-QOL (p=0.04) and EQ-5D (p=NR).[154]

Measures of symptom status were reported in two studies. Symptom relief from six symptoms including heavy menstrual bleeding, dysmenorrhea, dyspareunia, pelvic pain, dysuria, and pressure improved for 88 percent (51/58) of women after six months assessed by a questionnaire Symptom improvement including constipation, urinary frequency and menorrhagia improved for 85 percent of women postoperatively in a study evaluating loop ligation for women with larger fibroids.[80] Patient satisfaction with scarring measured using a visual analog scale was comparable in a single study that compared single-port laparoscopically- assisted transumbilical ultraminilaparotomic with single-port laparoscopic myomectomy. [160]

Effects of Myomectomy on Pregnancy Outcomes

Fertility and Pregnancy

Reproductive outcomes were reported in five studies.[21,100,107,134,154] One study described no significant difference in pregnancy outcomes following laparoscopic myomectomy (54%) compared with myomectomy by laparotomy (56%).[134] An RCT (n=136) compared myomectomy approaches (laparoscopic vs. minilaparotomic) and assessed 12-month reproductive outcomes for a total of 556 and 669 cycles, respectively.[100] There was no significant difference in the cumulative pregnancy rate, or the cumulative live-birth rate. However, the time to first pregnancy (5 months

vs. 6 months) and live birth (14 months vs.15 months) was lower after laparoscopic than minilaparotomic myomectomy($p<0.01$). A post-hoc subgroup analysis stratified fibroid patients according to indication: symptoms vs. unexplained infertility. In patients without infertility, the cumulative pregnancy rate, pregnancy rate per cycle (11.1% vs. 5.4%) and live-birth rate per cycle (9.9% vs. 4.8%; $p<0.05$) were significantly higher following laparoscopic than minilaparotomy myomectomy. In patients without infertility, the times to first pregnancy and live birth were significantly lower after laparoscopic than minilaparotomic approach. In patients with unexplained infertility, no difference in any reproductive outcomes assessed was observed between the two myomectomy approaches.[100]

One RCT enrolled 181 women with fibroids and infertility (trying to conceive for at least 1 year without success) then subdivided the women according to the location of the fibroid (submucous, intramural, subserosal) and randomized them to myomectomy or no surgery.[107] For women with subserosal or intramural fibroids, there was no significant difference in the pregnancy rate, comparing myomectomy with no treatment. For women with submucous fibroids, the group who underwent myomectomy had a greater pregnancy rate (40.4%) than those who did not undergo surgery (21.4 percent).[104] A subset of women from a RCT comparing myomectomy to UAE among women with reproductive plans noted that among women who attempted to conceive following myomectomy, 31 of 40 were pregnant at 13 months after fibroid removal and the delivery rate was 47.5 percent (19/40).[21] In a small study comparing ablation (n=26) to myomectomy (n=25), there were six pregnancies culminating in four live births, one induced abortion, and one ongoing pregnancy among twenty-two women after 2 years of followup after myomectomy.[154]

Harms Reported in Studies of Myomectomy

Transfusion

Following treatment for fibroids with myomectomy, transfusion rates were most often zero (1,040 participants in 10 studies).[63,72,76,80,85,95,100,101,110,130,134] Six studies[68,76,80,113,134,160] reported 25 transfusions among 502 participants treated by myomectomy (Appendix G). Seven studies did not report transfusion following myomectomy.[16,57,77,86,90,107,141] One study reported no significant difference in transfusion outcomes following laparoscopic myomectomy compared with laparotomic myomectomy.[134] One study (n=166) reported no significant difference in transfusion outcomes following laparoscopic myomectomy plus uterine artery occlusion compared with laparoscopic myomectomy alone.[72] One study (n=384) reported fewer transfusions following gasless laparoscopic myomectomy compared with conventional laparoscopic myomectomy.[76] Postoperative transfusion risk was found to be comparable in one study comparing a single-port laparoscopically-assisted transumbilical minilaparotomy approach (n=3, 6.5%) with single-port laparoscopic myomectomy (n=4, 8.7%).[160]

Other Surgical Complications

One study (n=80) comparing isobaric laparoscopically-assisted myomectomy with myomectomy via minilaparotomy reported no organ perforations in either group, but was underpowered to assert comparability.[86] Another study (n=148) reported one small bowel injury and one conversion to laparotomy due to hemostasis difficulties in the laparoscopic myomectomy group while no complications were noted in the minilaparotomy group.[110]

Readmission

One study (n=80) comparing isobaric laparoscopically-assisted myomectomy with myomectomy via minilaparotomy reported no readmissions or reoperations, but was underpowered to assert comparability.[86] Another study (n=148) reported that one woman had acute peritonitis and underwent abdominal surgery 10 days after laparoscopic myomectomy, with no complications following minilaparotomic myomectomy.[110] The Mara trial[21] (n=121) reported just one readmission (1.6%) within 30 days after myomectomy.

Reintervention and Recurrence

One study (n=136) reported technical failure (conversion to laparotomy) was more common after myomectomy by minilaparotomy (9%) compared with laparoscopic myomectomy (0%) (p=NR).[100] The reintervention rate was 3.2 % due to fibroid recurrence in another study including 121 women. [21] One woman required hysterectomy 7 months after myomectomy in a second study including 163 women.[16]

Total Complications

In one study (n=136) that reported total complications, these were higher among mini-laparotomy (16%) compared to those who had laparoscopic myomectomy (3%).[100] The FUME trial[16] (n=163) reported six major complications (8%), all occurring during the hospital stay after myomectomy while another trial (n=121) reported "unexpected intrauterine penetration" (not defined) after myomectomy in three cases (5%).[21]

Myomectomy Summary

There is low strength of evidence that women had improved quality of life following myomectomy. Evidence is insufficient to determine if myomectomy improves bleeding. This procedure is an option for women desiring future fertility, but evidence is insufficient to define the potential benefit. There is some risk of fibroid recurrence (reported ranges from 0 to 25%) that does not vary by type of surgical technique.

Hysterectomy

We identified 14 studies reported in 23 publications [19,20,22,56,70,77,89,91,93,96,97,99,109,111,112,114,120,121,125,126,131,135,137] assessing hysterectomy in women with uterine fibroids. Seven reported harms only (i.e., did not report final health outcomes for effectiveness).[56,89,120,125,126,131,135] One study[137] did not report results for the women who were randomized to immediate hysterectomy; the results from the comparator arm (women treated with a GnRH) is reported in the medication section above and in the comparative effectiveness section below.

Studies addressed the following interventions: intrafascial supracervical hysterectomy,[77] laparoscopic assisted vaginal hysterectomy,[56,89,120,126,131,135] total laparoscopic hysterectomy,[56,125], vaginal hysterectomy,[56,89,112,120,121,131,135] and total abdominal hysterectomy.[22,112,120,121,125] Three studies used more than one hysterectomy approach (i.e., type and route not standardized) or did not describe the type of hysterectomy.[20,114,137] Assessment duration (where clearly reported) ranged from 15 days to 24 months. We assessed five studies as good quality,[56,89,114,120,121] three as fair quality,[22,131,135] and six as poor quality for effectiveness outcomes.[20,77,112,125,126,137]

Effects of Hysterectomy on Bleeding

Two studies reported increases in hemoglobin levels at 24 months after surgery.[20,114] The mean increase reported in the EMMY trial was statistically significant (2.03 g/dL; 95% CI, 1.44 to 2.61, p<0.0001).

Effects of Hysterectomy on Pain

Two studies reported pain or pressure outcomes. At 24 months after hysterectomy, 28 women (93%) reported total or substantial improvements in pressure symptoms. Lower abdominal pain decreased from 16 participants (53%) at baseline to three (10%) after 2 years.[20] A majority (78%) of the women who had lower abdominal pain at baseline reported improvement at 24 months after hysterectomy.[99] Of those without pain at baseline (n=14), one woman reported worsening of symptoms after hysterectomy.[99]

Other Treatment Effects of Hysterectomy

Return to Usual Activity

Mean time to return to work or usual activity ranged from 22 to 41 days as reported in four studies.[20,22,120,125] Women who received a vaginal or laparoscopic vaginal hysterectomy had a significantly faster recovery (mean 22 to 30 days) compared with total abdominal hysterectomy (mean 36 to 41 days) as reported in two studies[120,125] Mean recovery time for abdominal hysterectomy averaged 37 days in one study[22] and 35 days in another study that used a variety of surgical procedures.[20] We did not assess the strength of evidence for return to usual activities

Quality of Life and Symptom Status

Improvements in quality of life or symptom status were reported in four trials. Two studies reported short terms results (1-month after surgery) [112,121] and two studies reported results after 24 months.[77,93] Short-term results compared vaginal to abdominal hysterectomy in 179 women. Quality of life assessed by the SF-36 was better after vaginal hysterectomy than abdominal hysterectomy.[112] Patient satisfaction with treatment assessed using an unvalidated questionnaire was higher for women after vaginal than abdominal hysterectomy.[121] After two years, quality of life was significantly improved after hysterectomy in the EMMY trial[93] assessed by HRQOL and SF-36. A Chinese study reported improved quality of life two years after hysterectomy as measured by the WHOQOL-BREF questionnaire.[77]

Harms Reported in Studies of Hysterectomy

Transfusion

The proportion of women requiring transfusion following hysterectomy ranged from zero to 20 percent in 890 women from 11 studies (Appendix G, Table G-9). Six studies reported no significant difference in transfusion outcomes following different hysterectomy approaches for fibroids: laparoscopic-assisted vaginal versus total abdominal,[135] laparoscopic-assisted vaginal versus vaginal [56,131] laparoscopic-assisted vaginal versus total laparoscopic,[56]vaginal versus total abdominal, [112] vaginal versus total laparoscopic, [56] and total laparoscopic versus total abdominal,[125] Authors reported 5 percent (3/61) of patients randomized to laparoscopic hysterectomy with bipolar coagulation of uterine vessels or laparoscopic hysterectomy alone required transfusion.[126]

Thromboembolism

Two thromboembolic events (one pulmonary embolism and one deep vein thrombosis) were reported following hysterectomy in 227 patients from four studies that reported thromboembolism after hysterectomy (Appendix G, Table G-7).[22,114,121]

Perforation of Organs

Two studies (n=179) reported no organ perforation following different hysterectomy interventions for fibroids.[112,121] One RCT (n=122) reported that one woman randomized to total laparoscopic hysterectomy was converted to total abdominal hysterectomy because of intraoperative bowel injury.[125]

Hysterectomy Summary

There is low strength of evidence that women had improved quality of life following hysterectomy, regardless of surgical approach. Overall, patient satisfaction and recovery time following hysterectomy was better for women who received a vaginal hysterectomy compared with total abdominal hysterectomy, but the strength of this evidence was not graded. Harms, including the need for blood transfusion and organ perforation, were similar for all types of hysterectomy.

Hysterectomy or Myomectomy

We found three studies reported in six publications (one good quality[104] and two poor quality[14,148]) that randomized women to an arm that allowed either myomectomy or hysterectomy.

Quality of life was the primary outcome for two studies comparing UAE to surgery (myomectomy or hysterectomy). [14,104] In the REST trial, scores on the SF-36 and the EQ-5D for the surgery groups were significantly improved after 12 months.[17,71,82,104] In the trial by Jun and colleagues, there was limited improvement for the surgery group after 6 months as assessed by the SF-36 questionnaire. Scores were improved for the mental health and vitality measures only, while physical health, social function and emotional role were almost unchanged.[14]

One study compared a GnRH agonist to myomectomy or hysterectomy.[148] Symptom improvement and fertility outcomes were reported.[148] Three of five women who underwent myomectomy for infertility had term pregnancies.

Surgical Intervention Summary

The strength of evidence was low for improvement in quality of life after myomectomy and hysterectomy. We found insufficient evidence that myomectomy improves bleeding .Evidence is insufficient to assess the effectiveness of endometrial abalation in improving fibroid symptoms. With notable exceptions,[16,82,97] the majority of these studies did not follow patients beyond the postoperative period. Therefore, many studies did not report important patient outcomes such as change in fibroid-related pain or bleeding. Many of the studies with surgical or procedural interventions reported intermediate outcomes such as technical success, hospital length of stay, or estimates of blood loss related to the invasive procedure (e.g., postoperative hemoglobin, intra- or postoperative transfusion rate). While these are important measures, they do not provide evidence about patient-centered outcomes of surgery for fibroids such as relief from symptoms, improvement in quality of life, and sexual function.

Comparative Effectiveness Studies

Content of Literature for Comparing Effectiveness of Interventions

Direct comparisons of alternative treatment strategies are crucial to support informed decisions by women and their care providers. Direct comparative effectiveness studies provide unbiased comparisons by randomly assigning similar groups of women to different interventions and assessing the same outcomes with the same yardstick. When different approaches within the same category of intervention were compared (e.g., uterine artery occlusion vs. UAE, or myomectomy via laparoscopy vs. minilaparotomy) those findings are reviewed in the previous sections for each category.

In this section, we review comparisons across categories of interventions. In total we found 17 studies which compared the effectiveness of different categories of interventions.[14,16,20,22,57,68,73,77,81,84,102,104,113,114,127,137,165] Available comparisons are summarized in Table 24.

Table 24. Randomized trial comparisons across categories of interventions

Method	Medical	High Intensity Focused Ultrasound Ablation	UAE or Occlusion	Radiofrequency Ablation	Myomectomy	Hysterectomy	Count
	4[73,84,102,165]	0	0	0	0	1[137]	
			0	1[81]	1[68]	0	
			1[127a]	0	2[16,113]	5[14,20,22,104,114]	
					1[57]	0	
						1[77]	

UAE = uterine artery embolization

[a] Reviewed with surgical comparisons as vascular occlusion was done via laparoscope.

Comparisons of Medical Management

We identified four studies designed to compare outcomes across different categories of drugs.[73,84,102,152] One good quality study compared ulipristal acetate to leuprolide.[73] Two compared a GnRH agonist to cabergoline, which is a dopamine receptor agonist.[84,102] The fourth compared the levonorgestrel IUD to daily oral progesterone.[152] A single study randomized women interested in hysterectomy to immediate hysterectomy or goserelin to determine if medical management allowed some women to avoid surgery.[137] Overall, these studies were small and inadequately powered to provide definitive evidence; they are briefly described below.

Comparison of GnRH Agonist to Ulipristal Acetate

A single good quality, multisite European trial compared two doses of daily oral ulipristal to monthly injection of 3.75 mg leuprolide.[73] They recruited 307 women whose bleeding was severe enough that they were considering surgery. The three groups had similar outcomes for change in size of the three largest fibroids and improvements in pain and quality of life measures. The overall reduction in uterine size was superior for leuprolide. Across three arms, 5 mg and 10 mg of ulipristal achieved results at least as good, or better, than leuprolide for control of bleeding. In 90 percent, 98 percent, and 89 percent, respectively bleeding improved to normal as assessed by the standardized and validated pictorial blood loss assessment chart. The average time to absence of bleeding in women with complete cessation was shorter for ulipristal than leuprolide (5-7 days vs. 21 days) ($p<0.001$). Hot flashes were substantially more common among those receiving leuprolide (40% vs. 10%-11% in ulipristal arms). At 13 weeks the proportion of adverse events and individuals discontinuing medication were equivalent, though women in the leuprolide group had evidence of greater bone resorption as measured by biomarkers. Endometrial samples were benign in both groups. Forty-nine percent of these participants who had initially sought evaluation for surgery had not had surgery by the end of 6 months of followup. In a subgroup of these women, growth of fibroids at one month had resumed in some women who received leuprolide while at 6 months fibroid size remained reduced in the majority of women who received ulipristal. In summary, evidence was insufficient to choose between ulipristal and leuprolide, based on a single study with small numbers.

Comparison of GnRH Agonist to Cabergoline

The GnRH agonist used in these two small, poor quality studies (Diphereline) is not available in the United States, however similar drugs are. [84,102] Cabergoline is available in the United States for off-label use. In both trials, GnRH was given for one month and cabergoline for 6 weeks of treatment. Fibroid volume decreased in both groups and was not statistically different. [84,102] [84,102] [84,102] 84,102 83,10179,97 Those on GnRH agonists were more likely to stop bleeding and to have hot flashes. In both arms bleeding days decreased compared with baseline, with the fewest days in the GnRH agonist arm.[84,102] Pain was similarly reduced in both groups.[84,102] Side effects of GnRH matched those reviewed above; cabergoline was associated with headaches and nausea in the first week of use.[84,102] Carbergoline side effects caused one woman to discontinue treatment, compared with none in the GnRH group.[84,102]

In summary, evidence was insufficient to choose between the GnRH agonist and cabergoline but them.

Comparison of Oral Versus IUD Delivered Progesterone

One poor quality Turkish study randomly assigned 30 women in each arm to daily norethindrone acetate or levonorgestrel IUD (LNG-IUD) among premenopausal women with fibroids who had declined surgery.[152]Visual blood loss scores improved by 6 months in both groups, with significantly greater improvement in the LNG-IUD group ($p=0.028$). Improvement in hemoglobin likewise occurred in both groups with a significantly greater improvement among those with an LNG-IUD ($p<0.01$). Women with the LNG-IUD were more satisfied and more likely to continue treatment than the oral treatment group.

This trial suggests that both norithindrone acetate and the LNG-IUD might improve bleeding even among women whose fibroid symptoms were considered appropriate for surgical intervention. However, evidence to choose between them is insufficient.

Comparison of Goserelin With Immediate Hysterectomy

Seventy-two premenopausal women older than 45, with at least one fibroid larger than 10 cm in diameter, heavy menses for three months or longer, and who were eligible for hysterectomy were randomized to immediate surgery (n=13) or treatment with a GnRH agonist (n=59) (goserelin 3.6 mg depo injection each month for three months) [137] Participants were followed for 3 years and allowed up to two more rounds of treatment if their bone mineral density was not at risk. Those on medication could opt for hysterectomy at any time. Twenty three of the 59 women assigned to medication, 39 percent (95% CI, 26 to 62), had continued to hysterectomy by the end of the third year.

In summary, some women may be able to use GnRH agonist therapy to delay hysterectomy. The quality of this study was judged to be poor in part because of lack of researcher and participant masking to assigned intervention; if participants were inclined to want surgery this bias would tend to increase the proportion who opted for hysterectomy rather than forestall that choice. The evidence is intriguing but insufficient to encourage selection of medication if hysterectomy is planned.

Comparisons of Procedures

Two studies compared HIFU to alternate interventions: one to radiofrequency ablation[81] and another to myomectomy.[68] The MRI guided HIFU system that is approved in the United States was not used in any direct comparison studies. Other direct comparisons of procedures included two comparisons of UAE to myomectomy,[16,113] three comparisons of UAE to hysterectomy,[20,22,114] and two comparisons of UAE to surgery (myomectomy or hysterectomy).[14,104]

Comparisons of HIFU for Fibroid Ablation to Radiofrequency Ablation

One RCT (n=100) of premenopausal women compared HIFU to radiofrequency ablation. However, the study reported only technical success (58% for HIFU vs 90% with radiofrequency ablation) Followup of fibroids and symptom resolution were not studied so evidence is insufficient to guide choice among these options.[81]

Comparisons of HIFU for Fibroid Ablation to Myomectomy

One RCT randomized women to HIFU vs. myomectomy. Fifty-five women were randomized to each arm; only results for women who completed followup (n=48 HIFU and n=52 myomectomy) are reported. Sexual function was comparable in both groups after 6 months of followup. Women having HIFU had shorter hospitalizations, earlier ambulation, and faster recovery; they had no blood loss and no surgery-related symptoms.[68,69] Fibroid outcomes and symptom resolution were not studied, therefore, evidence is insufficient to help women choose between options.

Comparisons of UAE to Myomectomy

Two European RCTs reported in three publications[16,21,113] compared UAE to myomectomy. The studies included 284 women ages 31 to 50 years; 96 percent of participants had symptoms, some had only fertility concerns. In total there were 121 embolizations and 122 myomectomies with followup. Technical success was similar.[21] as were improvements in quality of life (measured by UFS-QOL) one year after treatment, [16] and symptom relief (88% at an average of 17 months after intervention.)[113]

Length of stay is significantly shorter for UAE (averaging 2 days) compared with myomectomy (4 to 6 days).Blood loss was associated only with myomectomy.[16,21] Time away from work was at least 10 days shorter for those who had UAE compared with myomectomy.[21]

Around 2 years of followup, women in the UAE group had experienced more subsequent interventions (re-embolizations and myomectomies) compared with the myomectomy group (32.8% vs. 3.2%; p<0.0001).[21] However, subsequent intervention in the UAE group could have been driven by a protocol to recommend myomectomy if there was not reduction in fibroid size by 6 months or if or if a fibroid greater than 5 cm in size persisted. Risk of fibroid recurrence, satisfaction and quality of life are similar across groups. Thus, the likely cause of additional interventions among those with UAE was linked to the clinical protocol in this trial.

Reproductive outcomes were reported for 66 women (26 after UAE and 40 after myomectomy) in one study.[21,113] After 2 years pregnancy was significantly more common after myomectomy (78% vs. 50%; p<0.05) while miscarriage risk was higher after UAE (64% vs. 23%; p<0.05). Nineteen percent of women who had UAE had live births compared with 48 percent after myomectomy (p<0.05).[21] All participants in this study received care in a fertility clinic, for other underlying causes of infertility and treatment options included in vitro fertilization. As a result findings may not represent the general population of women with fibroids who plan to conceive.

In summary, two small studies of fair quality suggest UAE achieved similar results to myomectomy with a shorter recovery time. Because of low power to detect differences in outcomes, the evidence is insufficient to determine if outcomes are better after myomectomy compared to UAE. Women who have UAE may be more likely to have future interventions though this may have been driven by clinical protocol in these trials. Evidence is insufficient to guide choice between these options.

Comparisons of UAE to Hysterectomy

Three RCTs comparing UAE with hysterectomy are published in 12 reports. Study participants were all from Europe. The EMMY trial[19,70,91,93,96,97,99,109,111,114] is a multicenter trial (28 hospitals) conducted in the Netherlands. A Spanish trial by Pinto and colleagues[22] and a trial from Finland by Ruuskanen and colleagues[20] were single-center trials. Combined, these studies included 291 women aged 33 to 57 years with symptomatic uterine fibroids, who were candidates for hysterectomy. The EMMY trial excluded women with submucosal leiomyoma while the Spanish trial excluded women with leiomyomas larger than 10 cm in diameter. The third trial [62]did not exclude women based on the size or location of fibroids. Across studies, 153 women were allocated to UAE and 138 to hysterectomy. Followup duration of these three trials varied from 6 months[22] to 2 years[20,22] and 5 years.[19]

Early Procedure Outcomes and Recovery

Blood loss from the procedure was negligible for UAE and higher for hysterectomy.[114] In the surgical group of the Finnish trial,[20] 19 percent of the vaginal or laparoscopic hysterectomies were converted to abdominal hysterectomy due to technical difficulties; and the EMMY trial reported four conversions of laparoscopic or vaginal hysterectomy to laparotomy (5.3%)[114] Length of hospital stay was shorter (p<0.001) for UAE (1.3 to 1.7 days) compared with hysterectomy (3.5 to 5.9 days).[20,22,114] Re-admission rates were the same (5%) in both arms of the Spanish study[22] while the EMMY trial reported significantly higher near term re-admission rates after UAE (11% vs. 0%, p<0.003) compared with hysterectomy.[109,114] Despite this, time to return

to usual activities was significantly (p<0.001) shorter in the UAE group (fewer than 20 days) compared with hysterectomy group (more than 30 days).[20,22,114]

Fibroid Characteristics

By definition, women who have hysterectomy have 100% reduction in fibroids. For the UAE groups, effects on fibroid characteristics are included in Table 16.

Bleeding

By definition, women who have hysterectomy stop bleeding. Improvement in bleeding in the UAE arms is included in Table 17. Increase in hemoglobin levels from baseline at two years was significantly higher for the hysterectomy group compared with the UAE group (+2.03 vs. +1.37 g/dL; p=0.037) in EMMY[99] but not in the Finnish trial (p=0.16),[20] which may reflect inadequate power to detect modest differences.

Symptoms

Overall relief of symptoms was good across groups (82% UAE vs. 93% hysterectomy; p=0.173) in the Finnish study at 2 years.[20] For both groups, there was a significant decrease in pain from baseline at all time points (p≤0.03) and by 24 months women reported similar improvement of pain (84.9% after UAE vs. 78% after hysterectomy; p=0.30).[99] Greater improvement in pressure symptoms was reported after UAE compared with hysterectomy (95% vs. 69%; p=0.03).[20] More urinary bladder symptoms were reported after hysterectomy than after UAE (30% vs. 7%; p=0.03).

Quality of Life

In the EMMY trial, overall health related quality of life improved in both trial arms and was comparable across groups by completion of 5 years of followup.[19] One secondary outcome (change in bowel movements) was worse in the hysterectomy group than UAE at 5 years from baseline (p=0.01) while the UAE group had improvement from 6 month onwards.[19] At 6 months, body image scores improved significantly more in UAE group than in hysterectomy group (p=0.02), but there was no group difference in body image or sexual function scores at 24 months or later.[19]

Subsequent Treatment

Three studies assessed subsequent treatment at 6 months to 5 years. Subsequent treatment was higher in the UAE group than in the hysterectomy group at each time point in followup.[16,20,114] At 6 months, 1-year, 2-year, and 5-year followup, the EMMY trial reported significantly higher rates of any subsequent gynecologic intervention (9.8%, 17.3%, 28.3%, and 34.6%) after UAE versus 1.3 percent, 5.3 percent, 8.0 percent, and 10.7 percent after hysterectomy.[19] The risk of additional intervention was reported at 2-year followup in another study (19.2% with UAE and 10.3% after hysterectomy; p=0.24).[20] Some early reinterventions are repeat UAE, myomectomy, or hysterectomy among the small percentage of women (1.0% to 4.9%) for whom effective occlusion of the uterine vessels could not be achieved at the time of the initial procedure.[16,114] These data are included in the meta-analysis of subsequent intervention section.

Compared to women with UAE, women who received hysterectomy reported higher satisfaction rates after 1 (p=0.001) and 2 years (p=0.02) but satisfaction levels for both groups were comparable by 5 years (p=0.13) (Table 25). Forty six percent of women after UAE and 56

percent of women after hysterectomy were very satisfied with the outcome by 5 years (overall satisfaction, 84% vs. 88%; p=0.37).

Table 25. Satisfaction in studies of uterine artery embolization versus hysterectomy

Measure Author (Year)	Time Point, Month	UAE, Percent	Hysterectomy, Percent	Significance
Satisfied[a]				
Hehenkamp WJ et al. (2008)[19,93,114]	12	84.0	86.7	p=0.001[b]
	24	91.4	88.0	p=0.02[b]
	60	85.3	88.6	p=0.13[b]
Would undergo same treatment				
Pinto I et al. (2003)[22]	6	77.7	88.2	NR
Ruuskanen A et al. (2010)[20]	24	88.9	96.7	p=0.34

NR = not reported; NS = not significant; UAE = uterine artery embolization

[a] Satisfied from the EMMY trial includes very satisfied, satisfied, and moderately satisfied.
[b] P-values reported for comparison across seven possible levels of satisfaction that include very satisfied and satisfied.

Reproductive Status

Ovarian reserve, pregnancy, and sexual function related outcomes were reported only in the EMMY trial.[97] Reduction in ovarian reserve was based on FSH and AMH hormone levels. Levels of FSH, suggesting diminished reserves, increased from baseline (p=0.001) in both groups at 24 months followup but there was no group difference (p=0.32). The number of women with FSH >40 IU/L, confirming menopause, at 24 months was 14/80 (18%) in the UAE group compared with 17 women (21%) in the hysterectomy group, with no differences over continued followup (p=0.37). The change scores of AMH levels from baseline were significantly different between the groups only at 6 weeks of treatment (p=0.005) and the AMH levels remained decreased only in the UAE group during the followup.

Harms

Harms are reviewed for each category of intervention within the sections for UAE and specific surgeries above and in Appendix G.

Summary

Compared to hysterectomy, UAE provides similar relief of pressure and pain symptoms, similar improvements in quality of life, and fewer side effects. Though subsequent intervention is more common after UAE than hysterectomy, the majority (66%) of women randomly assigned to have UAE avoided hysterectomy for the duration of followup, which included up to 5 years of surveillance in the largest study. However, at present evidence is insufficient to shape clinical decisions.

Comparisons of UAE to Patient Choice of Myomectomy or Hysterectomy

A larger trial of good quality conducted in the United Kingdom[104] and a poor quality study conducted in China[14] made this comparison. Combined, these studies randomly assigned 169 women to UAE and 115 women to conventional surgeries for uterine fibroids.[14,104] Both found UAE to have shorter hospital stay and recovery time. UAE was associated with fewer

complications at the time of the procedure but a greater proportion of women had a subsequent intervention in followup. Similar to the studies detailed above, the study that included 1-year followup reported that among women assigned to UAE, 12.6 percent had subsequent interventions for inadequate control of symptoms. In the UK trial, quality of life (measured by the SF-36) at 1 month the UAE group had significant improvements in multiple areas of function, however by one year improved similarly in both groups.

In summary, these studies contribute to a growing body of evidence that UAE has a shorter recovery and is as effective as surgery in major domains of patient outcomes. The primary caveat is that this comes with risk of subsequent intervention, which is also addressed in our meta-analysis.

Comparisons of Surgeries

The majority of surgical studies that made comparisons did so within a category of intervention, for instance comparing myomectomy conducted by laparoscopy to myomectomy through a laparotomy incision. These are reviewed within categories of interventions above and when clinically and statistically significant advantages have been demonstrated they are noted. Comparisons across types of surgical interventions were meager, and the three related studies are noted below.

Comparison of Laparoscopic Bipolar Coagulation With and Without Uterine Nerve Ablation

In this small (n=85), poor quality study of women with fibroids and menstrual pain, 41 women were randomly assigned to also have laparoscopic uterine nerve ablation at the time of laparoscopic occlusion (bipolar coagulation) of the uterine vessels.[127] Both groups had equal reduction in size of fibroids and in reduction of bulk symptoms. Women in the nerve ablation group had less postoperative pain at 1 month as measured by a non-standardized five-point scale ($p<0.05$) and by 6 months painful menses were improved in 92.1 percent of the nerve ablation group compared with 73.8 percent of the occlusion only group ($p<0.05$).[127] The results are insufficient to inform a decision to include uterine nerve ablation at the time of coagulation of the uterine vessels.

Comparisons of Radiofrequency Ablation With Laparoscopic Myomectomy

A small study, reported in three publications, compared laparoscopic use of radiofrequency (n=26) to laparoscopic myomectomy (n=25).[57,154,159] Ultrasound was performed during the procedures to definitively identify fibroids and document immediate intervention outcomes. Intermediate outcomes (technical success, blood loss and length of stay) were better in the radiofrequency group compared with the myomectomy group [57]At 1 and 2 years, both groups experienced improvements in health related quality of life and symptom severity as assessed by UFS-QOL and EQ-5D scores. The majority of women were moderately or very satisfied with their treatment at 12 months (86% in both groups).[159] Three pregnancies, culminating in three live births were noted for the radiofrequency ablation group and six pregnancies (four live births, one induced abortion, and one ongoing) were reported for the myomectomy group.[154]

Radiofrequency appears to offer some advantages to myomectomy, but there is insufficient evidence to determine clinical decisions.

Comparisons of Myomectomy Plus Uterine Artery Occlusion with Hysterectomy

A single moderate size study of poor quality conducted in China compared laparoscopic uterine artery occlusion (n=158) plus myomectomy to supracervical hysterectomy (n=174).[77] Supracervical hysterectomy is rarely performed in the United States. This RCT assessed quality of life using the WHOQOL-BREF. At two months after surgery, physical and social domains were superior in the myomectomy plus occlusion compared with the hysterectomy groups; no other areas were meaningfully different. By two years, myomectomy plus occlusion was superior to hysterectomy in all domains except environment ($p<0.01$) and both study groups had meaningful improvements compared with their baseline. Women treated with myomectomy plus uterine artery occlusion had a 2.5 percent fibroid recurrence rate.

In summary this single study provides insufficient strength of evidence that myomectomy plus uterine artery occlusion differs from supracervical hysterectomy for improving quality of life in physical, psychological, and relationship domains.

Comparison of Transfusion Requirements

Transfusion was reported in 40 arms across 23 studies. Transfusions by intervention category are summarized in Table 26.

Table 26. Transfusion by intervention category

Intervention Category (Number of Arms)	Women Transfused	Total N	Percent
Hysterectomy (18)	36	785	4.6
Hysterectomy or Myomectomy (1)	4	20	20.0
Myomectomy (18)	18	1,286	1.4
Uterine artery embolization (3)	0	158	0
All (40)	58	2,297	2.5

Analysis of Subsequent Treatment Following Initial Treatment for Uterine Fibroids

We estimated the probabilities of subsequently receiving additional treatment for fibroids after randomization to a given initial treatment of medication, UAE, or myomectomy for uterine fibroids from data reported in in 46 studies (Table 27).[13-16,20,22,23,54,57,64,66,79,80,84,85,87,92,98,100,102,104,105,107,110,113,114,118,122,123,127-129,134,136,140,148,150,151]

Subsequent treatments were grouped into these categories: 1) no intervention; 2) LNG-IUD; 3) UAE; 4) HIFU for fibroid ablation; 5) myomectomy, and 6) hysterectomy (Appendix H). Rates of subsequent intervention ranged from zero up to 44 percent. For women in their 30s, the model predicted that the probability of subsequent intervention for fibroids over 2 years varied from 6 to 7 percent after medical treatment or myomectomy to 44 percent after UAE. For women in their 40s and 50s, modelled 2-year reintervention rates were 9 to 19 percent following medical treatment or UAE, and 0 percent after myomectomy. Overall, fewer than half of women had another intervention within 24 months. Rates of subsequent intervention were lowest for initial medical management and higher following myomectomy or UAE. UAE was most often followed by myomectomy among those in their 30s and by hysterectomy among those in their 50s. Younger women who initially had myomectomy were most likely to have repeat myomectomies over the 2 years of followup. After medical treatment, few (6-11 percent) women in any age

group had subsequent treatment within 2 years. Appendix G includes data for subsequent treatment at up to 6 and 12 months of followup.

Table 27. Estimated probability of subsequent treatment by age at up to 24 months of followup

Initial Intervention	Next Intervention Age	None	LNG IUD	UAE	HIFU for Fibroid Ablation	Myomectomy	Hysterectomy
Medical	**30**	0.94 (0.89 to 0.97)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.06 (0.03 to 0.11)
	40	0.91 (0.89 to 0.94)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.09 (0.06 to 0.11)
	50	0.89 (0.85 to 0.92)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.12 (0.08 to 0.15)
UAE	**30**	0.56 (0.43 to 0.69)	0.00 (0.00 to 0.00)	0.05 (0.01 to 0.11)	0.00 (0.00 to 0.00)	0.37 (0.23 to 0.51)	0.01 (0.00 to 0.04)
	40	0.88 (0.84 to 0.92)	0.00 (0.00 to 0.00)	0.02 (0.01 to 0.03)	0.00 (0.00 to 0.00)	0.03 (0.01 to 0.06)	0.06 (0.04 to 0.10)
	50	0.81 (0.70 to 0.90)	0.00 (0.00 to 0.02)	0.00 (0.00 to 0.01)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.01)	0.18 (0.09 to 0.29)
Myomectomy	**30**	0.93 (0.77 to 1.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.07 (0.01 to 0.22)	0.00 (0.00 to 0.01)
	40	1.00 (0.99 to 1.00)	0.00 (0.00 to 0.00)	0.00 (0.00, 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.01)	0.00 (0.00 to 0.01)
	50	1.00 (0.89 to 1.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.00)	0.00 (0.00 to 0.010)	0.00 (0.00 to 0.06)

Notes: Table reports estimated probability (95% credible interval)
HIFU = high intensity focused ultrasound; LNG IUD = levonorgestrel intrauterine device; UAE = uterine artery embolization

Key Question 2. Influence of Patient/Fibroid Characteristics on Effectiveness

Key Points

- Among 97 RCTs of interventions, none were explicitly designed to address whether intervention effectiveness varied by patient or fibroid characteristics.
- Six studies provided some information about influence of characteristics on outcomes within or across arms.

Description of Studies

For this KQ we systematically reviewed all included trials (n=97) for each category of intervention. We sought: (1) indication that the study aimed to determine the influence of patient or fibroid characteristics on effectiveness and/or (2) described statistical analyses that allowed determination of whether patient of fibroid characteristics modified outcomes.

At its core, this question is about effect modification, also called interaction, which can be used to inform clinical decisions. For instance if women with five or more fibroids are found to have less improvement of their hematocrit 6 months after an intervention than those with fewer than five initial fibroids, and the p-value for that comparison is significant, we would say there is modification of the effectiveness of the intervention by fibroid number, such that women with fewer fibroids may experience superior improvement in hematocrit. No studies were explicitly powered to investigate effect modification.

We identified only six trials that contributed related analyses: two trials of medications (in three publications),[115,119,123] two studies that compared UAE to surgery, each with multiple publications (REST[71,82,104] and EMMY[19,109,114]), and one surgical trial.[107] One additional study addressed whether baseline characteristics influenced likelihood of success across procedure arms.[81] We assessed two studies as good quality,[19,71,82,104,109,114] two as fair quality,[115,119,123] and two as poor quality.[81,107]

Detailed Synthesis of Effect Modifiers

Medical Intervention

In a dose comparisons trial of oral mifepristone (5 mg vs. 10 mg), the authors reported no difference in uterine fibroid volume size when analyses were adjusted for baseline volume, dose, and treatment duration (6 or 12 months). There was no significant difference in uterine volume reduction between the two dose groups (p=0.94). However in pooled analyses, for every 10 cm^3 larger increment in baseline fibroid volume, fibroid volume reduction increased, on average, by 3.8 cm^3 after adjusting for dose and time (95% CI, 2.7 to 4.9; p<0.001).[115]

Within a raloxifene arm (60 mg for six cycles) authors found the drug demonstrated selective action on leiomyoma by menopausal status, such that postmenopausal women were more likely to achieve decreased uterine and fibroid size. Thirteen of 31 postmenopausal women had decreased size of fibroids[128] compared with one of 29 premenopausal women.[123]

Procedures

Uterine Artery Embolization

In one followup publication from the REST trial comparing UAE to surgery (hysterectomy or myomectomy), the authors found that 5-year reintervention rate after UAE did not differ (p=0.123) by the degree of infarction achieved during the initial procedure, as measured by MRI.[71] Study authors reported no effect of age (p=0.77), uterine volume (p=0.50) or fibroid diameter (p=0.57) on the degree of infarction as measured by MRI at 6 months. Similarly, age (p=0.13), uterine volume (p=0.81) and fibroid diameter (p=0.81) did not modify the need for reintervention.[71] The presence of a single fibroid (OR=6.21; 95% CI, 1.65 to 23.41) and small uterine volume (less than 500 cm^3) (OR=10.8; 95% CI, 1.25 to 93.36) were associated with higher risk of procedural failure.

The finding of no significant group difference in the rate of ovarian failure as measured by FSH >40 IU/L at 1 year after treatment (UAE vs. any surgery) was not modified by age less than 45 years or age of 45 years and older.[82] The risk for major complications (OR=5.68; 95% CI, 2.05 to 15.75) and high pain scores (higher than score of 5) (OR=1.97; 95% CI, 1.08 to 3.58) increased with each extra vial of polyvinyl alcohol used, though there was no significant association (p=NS) between high pain scores and uterine size, fibroid size, or total number of fibroids at 6 weeks after the procedure.[109]

A multivariate analysis indicated that compared with baseline, after 24 months of treatment, higher number of fibroids was associated with lower risk of poor sexual function (OR=0.69; 95% CI, 0.51 to 0.94); while the presence of a comorbid condition was associated with an increased risk of a worse sexual function (OR=3.2; 95% CI, 1.38 to 7.41).[96]

HIFU for Fibroid Ablation

A study comparing radiofrequency fibroid ablation to HIFU for fibroid ablation examined intermediate outcomes across groups by fibroid characteristic (fibroid blood supply and size).[81] The rate of complete ablation was significantly different between groups with different grades of blood supply. The radiofrequency ablation technical success rate was 89.3 % versus 54.2 % among individuals with Grade II blood supply (direct vessels to fibroid readily visualized). No difference was seen within groups with no clear blood supply or widespread "halo" like blood supply; however the size of this trial was too small for meaningful assessment of true effect modification (total n =100). Completeness of ablation was similar among the subgroups of patients with fibroid diameter between 2 cm and 4 cm, whereas the technical success for radiofrequency ablation was superior to HIFU in patients with fibroid diameters between 4 and 6 cm and between 6 and 8 cm ($p<0.05$).[81]

Surgical Interventions

An RCT with 181 women with fibroids who had been trying to conceive for at least 1 year without success, subdivided the women according to the location of the fibroid (i.e., submucous, intramural, subserosal) and randomized to myomectomy (laparoscopic myomectomy or hysteroscopic myomectomy) or no surgery.[107] For women with subserosal or intramural fibroids, there was no significant difference in the pregnancy rate, comparing myomectomy with no treatment. For women with submucous fibroids, the group who underwent myomectomy had a greater pregnancy rate (40.4%) than those who did not undergo surgery (21.4%) ($p<0.05$).[107]

Summary of Effect Modification

Overall, there is insufficient evidence for women to choose one intervention over another based on individual characteristics or the characteristics of their fibroids. Too few studies have been adequately powered to determine within arms if one subgroup or another has superior outcomes within a treatment. Such information is required as a first step towards using individual characteristics to inform treatment choice.

Key Question 3. Risk of Leiomyosarcoma When Mass Thought To Be a Fibroid

Key Points

- The overall risk of discovering a leiomyosarcoma during surgery for presumed fibroids is 0.02 percent (range: 0% to 0.09%) in prospective studies and 0.08 percent (range: 0.05% to 0.13%) in retrospective studies. In other words, using data from 160 studies, an unexpected leiomyosarcoma will be identified in fewer than one and up to 13 of every 10,000 surgeries performed for symptomatic fibroids.

Overview

The risk of fragmenting and disseminating a leiomyosarcoma into the pelvic cavity is at the heart of the FDA and professional organizations concerns about the safety of power morcellation. The defining component of this risk is determining how likely it is that a surgeon who is operating for a fibroid encounters a leiomyosarcoma. To address KQ3 we pursued evidence in the literature to

estimate the prevalence of uterine leiomyosarcoma among women having surgery for uterine fibroids.

Description of Studies

We sought literature from studies of myomectomy or hysterectomy for presumed benign disease that included histopathologic analysis of all excised fibroid specimens. In the course of our work, Elizabeth Pritts and her colleagues published such an estimate using a similar approach, with a stated aim to estimate the prevalence of occult leiomyosarcoma at time of treatment for presumed benign tumors (fibroids).[10] We confirmed our search method included their articles and then updated their search using similar eligibility criteria to identify papers published since the end of their inclusion period in 2014. In addition to the 133 unique studies included in the prior analysis, we identified 27 additional studies, including twenty-four retrospective cohorts,[170, 172-194] two prospective cohorts,[195,196] and one RCT.[197] The RCT was included with the prospective studies in the analysis.

Detailed Synthesis

The 2015 Pritts analysis extracted data from 133 publications including 30,193 women.[10] The 27 new studies included an additional 106,002 women bringing the total to 160 studies and 136,195 women. Among prospective studies 56.7% focused on myomectomy findings; 35.8% hysterectomy, and 6.0% both types of surgery. Among retrospective studies 31.9% focused on myomectomy; 48.9% hysterectomy, and 19.2% both. Over 40,000 (29%) of the included women are from prospective studies. In prospective studies, subjects had an age range of 20 to 83 with a mean age of 38.5±6.0 years, while retrospective studies included women from age 18 to 96 with a mean age 43.4±5.6.

Following methods described in Pritts and colleagues[18] we fit a Bayesian binomial random effects models to update the estimate of prevalence of leiomyosarcoma and achieved good model fit. The point estimates and credible intervals for prevalence are summarized below for the original Pritts study and for our five new models. (Table 28)

We identified some errors in counts from the data extraction in the Pritts analysis. [10] We ran analyses with the original (model 1) and corrected data (model 2). We added data from 27 new studies (model 3, most inclusive, largest data set). Then, we excluded prospective studies that included hysteroscopic fibroid resection because of concerns that hysteroscopy might yield incomplete tissue for pathology (model 4). Because we had noticed some discrepancies, we reviewed all publications and reclassified them based on our confidence that complete histopathologic evaluation was performed for all subjects. We attempted to contact authors to confirm when necessary. For model 5, we restricted our analysis to those publications for which we had high confidence of complete histopathologic evaluation for every subject, as the most refined estimate (model 5).

We present estimates for prospective and retrospective studies separately since statistical models suggest meaningful heterogeneity is introduced by study design. Regardless of model assumptions, all estimates from retrospective data produced higher estimates (5.1 to 8.5 cases per 10,000 surgeries) than prospective studies (0.5 to 2.9 cases per 10,000 surgeries). An aggregate estimate combining both retrospective and prospective studies is 8.3 per 10,000 surgeries (95% CI: 1.17, 9.39) but this model is difficult to interpret because assessment of statistical heterogeneity suggests the estimates are distinctively different, thus a combined estimate is not appropriate. We have greater confidence in the ability of prospective studies using standardized

protocols to evaluate histology to detect incident cases than retrospective studies that rely on clinical pathology reports and retrospective determination of inclusion. Although we planned to estimate the effect of age on leiomyosarcoma risk, the lack of granular data (especially for non-cases) prevented us from doing so.

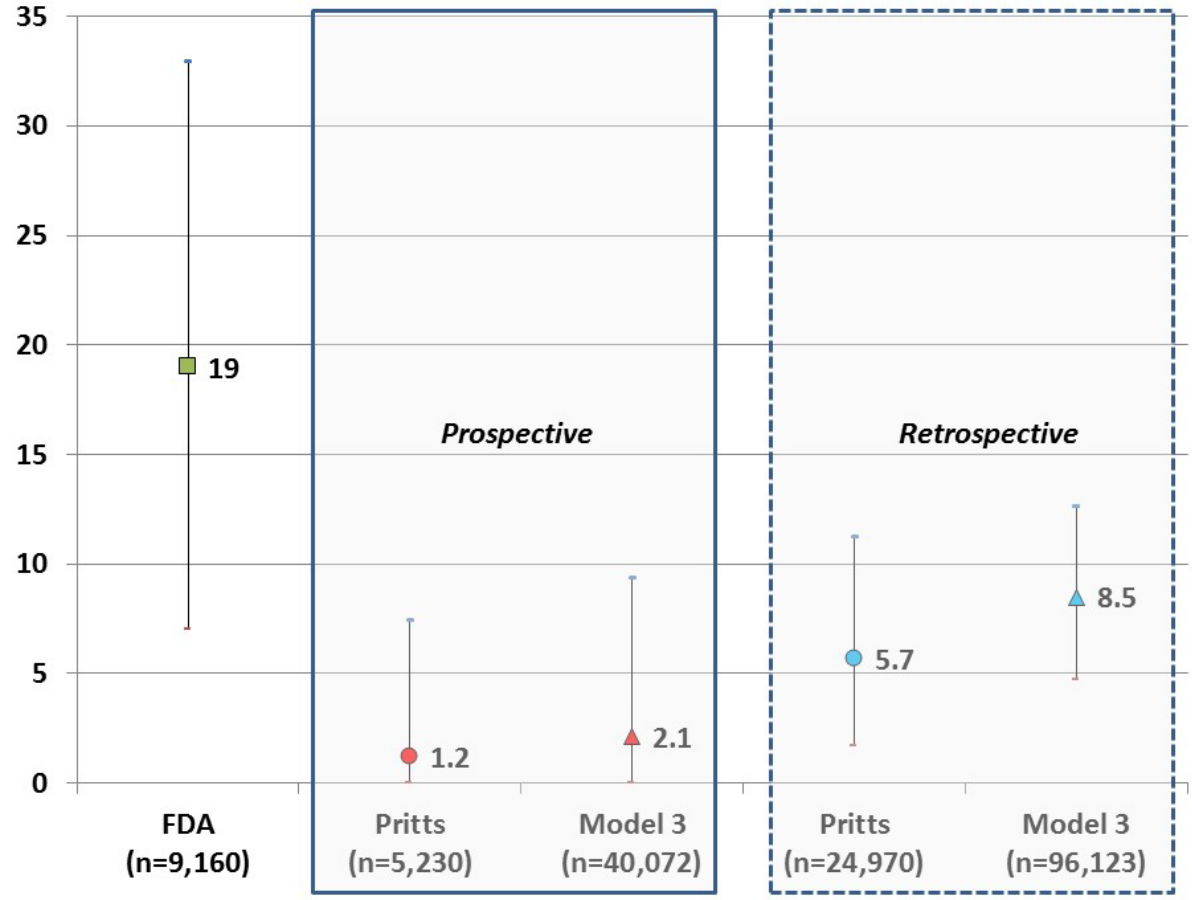
In her report, Pritts repeated the FDA analysis using a Bayesian binomial model. [10,24] To keep comparisons on the same scale, we plot these two published estimates on the same Bayesian binomial scale as our conservative model 3 (Figure 5.) While the point estimates differ, confidence intervals overlap.

Table 28. Leiomyosarcoma prevalence estimates

Model	Data Source Included in Analysis	Prevalence Estimate per 10,000 Surgeries (95% Credible Interval)	
Original		**Prospective**	**Retrospective**
	Pritts analysis[18]	1.2 (0 to 7.5)	5.7 (1.7 to 11.3)
Updated models:			
1.	Replication of Pritts analysis with raw data	2.9 (0 to 10.6)	5.1 (1.3 to 9.6)
2.	Pritts analysis using corrected data[a]	2.1 (0 to 9.3)	5.1 (0.9 to 9.4)
3.	Studies in Pritts analysis (corrected data) plus new studies[b]	2.1 (0 to 9.4)	8.5 (4.7 to 12.7)
4.	Studies in Pritts analysis (corrected data) plus new studies, excluding hysteroscopy	0 (0 to 0)[c]	7.2 (3.1 to 11.5)
5.	Studies in Pritts analysis (corrected data) plus new studies; restricted to studies with high confidence of histopathologic evaluation for all subjects	0.5 (0 to 2.9)	7.4 (3.4 to 12.2)

[a] We identified some errors in counts from the data extraction in the Pritts analysis.[10] We ran analyses with and without these corrections as indicated.
[b] Studies meeting inclusion criteria and published since the publication of the Pritts analysis.
[c] Estimate and credible interval below 1 in 10,000.

Figure 5. Risk of leiomyosarcoma at surgery for presumed fibroids



Notes: Point estimates (cases per 10,000 surgeries) and 95% credible interval for published estimates[10] and current model. Grouped by prospective (solid box) vs. retrospective (dashed box) study design. N= number of women included in each analysis. FDA indicates estimates from earlier Food and Drug Administration summary document.[24,40]

Summary

The literature investigating the prevalence of leiomyosarcoma in presumed fibroids has grown rapidly and has added more data but not greater precision to estimates of this rare event. From 160 prospective and retrospective studies, the estimate of leiomyosarcoma ranges from 0 to 13 cases out of 10,000 surgeries. Our estimate based on 68 prospective studies biased in favor of detection (model 3), estimates that two (range: fewer than one and up to 9) women in every 10,000 who have surgery for fibroids may be found to have a leiomyosarcoma.

Key Question 4. Influence of Morcellation and Patient/Fibroid Characteristics on Leiomyosarcoma Survival

Key Points

- Uterine leiomyosarcoma has high mortality regardless of surgical approach.
- For women with uterine leiomyosarcoma, survival time appears shorter for those where power morcellation was used compared to those where sharp morcellation with a scalpel was

used or to those who had intact removal of the uterus (no morcellation), however, confidence intervals are wide and overlap.

- We found insufficient data on the influence of patient or fibroid characteristics on leiomyosarcoma survival.

Description of Studies

Twenty-eight studies (29 publications) provided data about disease progression and vital status for women who had a leiomyosarcoma identified at the time of an initial surgery and for whom the method of removal of the surgical specimens was known and survival time data could be extracted.[170-172,177,184-192,194,198-212] The research was conducted in 14 different countries, including nine from the United States. The largest studies were from Norway and the United States. The majority identified baseline surgical data and outcomes after the events had occurred or relied on prospective registries and were able to provide followup for participants present at baseline. These studies included 715 women with leiomyosarcoma and the time of their initial surgeries ranges from the 1980s through 2015. This overlaps well with the period of growth in minimally invasive surgery for fibroids and with the use of power morcellation.

We reviewed studies for information about whether individual characteristics of the women or presumed fibroid status helped to identify those most at risk of harm. Similar to KQ2, we sought evidence that investigated effect modification by factors such as age, menopausal status, and imaging characteristics which can be known before surgery and have potential to inform decisions about surgical approach. Twenty-four studies (384 women) contributed data to models to compare survival time based on use of power morcellation, scalpel morcellation, or no morcellation. For studies that did not explicitly provide individual survival data[186,194,199,207] we were able to manually extract data from published survival curves using an online digitizing tool.[213] Another four studies (reported in five publications) provided information about survival, but we could not confidently extract data to include in the analysis because we either could not determine event times with confidence[170,171,198,204] or because the data in the tables and text did not align with those shown in the survival curves.[208]

Detailed Synthesis

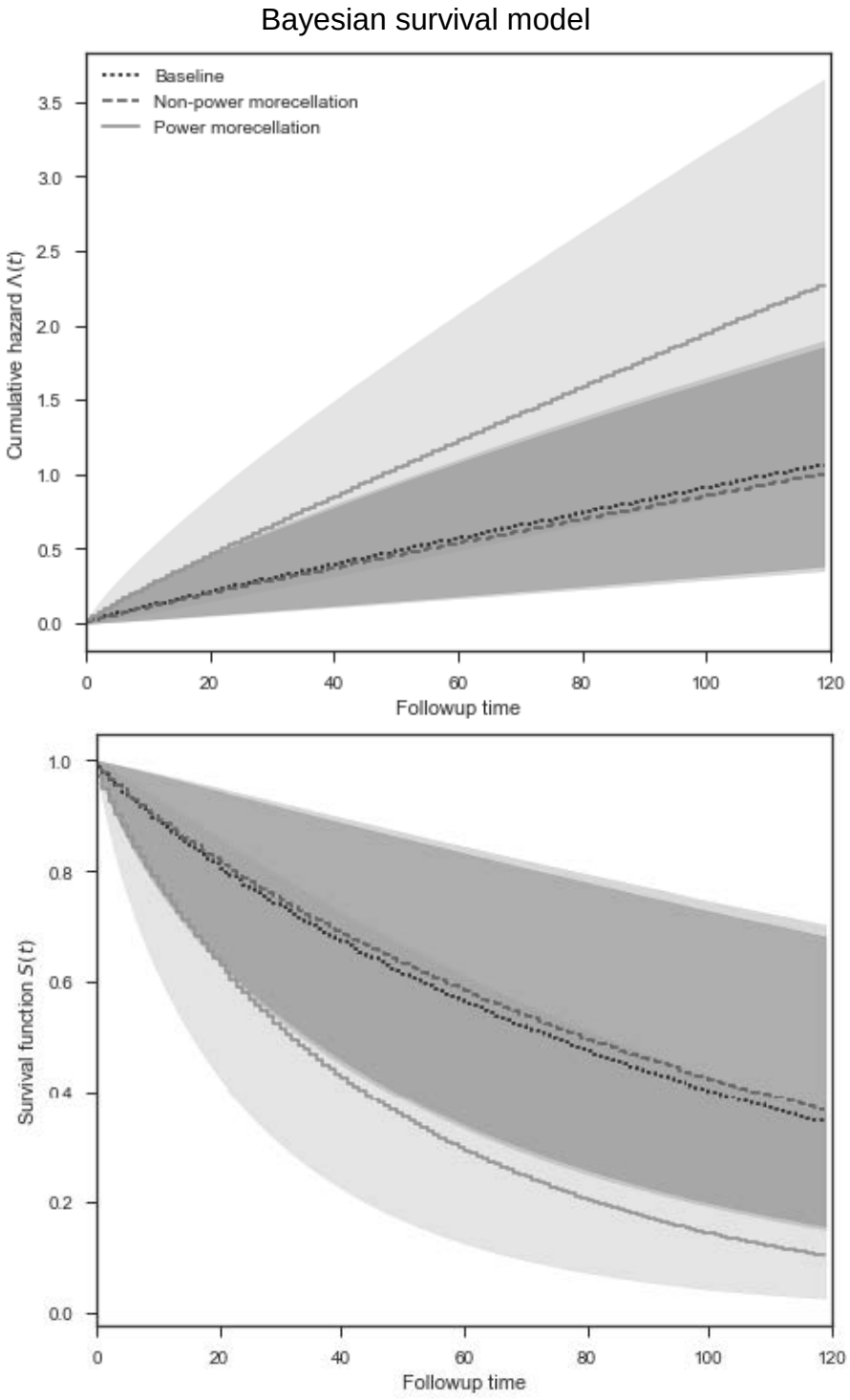
Our purpose for this aim was to determine if leiomyosarcoma dissemination was influenced by method of morcellation and to compare this with no use of morcellation while also assessing characteristics of patients and fibroids that might be associated with risk of dissemination.

There is no clinical way to detect dissemination of leiomyosarcoma at the time of surgery. If the tumor is disrupted, both visible and microscopic particles may be spilled. However, even without visible tumor disruption, microscopic or hematogenous dissemination may occur. As a result, stage of disease, progression or recurrence of disease, and survival become surrogates for recognizing dissemination. Thus we hypothesize that stage and survival would be worse for those in whom leiomyosarcomas were removed by power morcellation compared with scalpel morcellation and that both of these would be inferior to no breach of the integrity of the tumor by removing the tumor intact.

To estimate survival for each surgical intervention, we fit parametric survival models using a Bayesian hierarchical approach, using the data extracted from publications that made it available. To account for heterogeneity among studies, we included a study-level random effect in the hierarchical baseline survival parameter. A simple exponential survival function was found to be a poor fit to the data, therefore we fit a Weibull survival function that resulted in an adequate fit.

Figure 6 captures cumulative hazard estimated by these models, with the shaded areas indicating the 95% Bayesian credible intervals (BCI) for each intervention group: no morcellation, scalpel morcellation and power morcellation.

Figure 6. Estimated survival after surgical intervention for leiomyosarcoma by morcellation approach



Notes: Survival curves plot x-axis as follow up time in months with hazard ratio indicated by y-axis. Dotted line indicates baseline comparison which is no use of morcellation. The darkest grey shading shows the 95% credible interval. Non-power morcellation is indicated with dashed line and medium grey shading for credible interval. Power morcellation is solid line with pale grey credible interval shaded.

By 5 years of followup (60 months), a typical interval considered in cancer outcomes, 30% (95% BCI, 13% to 61%) of women for whom power morcellation was used were alive. This is compared to 59% (95% BCI, 33% to 84%) of women for whom scalpel morcellation was used and 60% (95% BCI, 24% to 98%) with no use of morcellation. While the point estimate of power morcellation survival was much lower than for either non-morcellated or scalpel morcellation patients, the uncertainty in these estimates was very large, particularly at longer followup times. However this literature is evolving rapidly and more than half of the cases and papers that contribute to our estimates have appeared in the literature in 2015 or 2016.

Five papers, as described below, did not contribute to our estimates. Two small studies, one with 18 cases of leiomyosarcoma,[198] the other with 56 cases spread over 21 years,[208] suggested increase in disease recurrence and worse survival after morcellation. In contrast, a final paper that did not report individual level data that could be extracted identified 53 patients with leiomyosarcoma and found rates of pelvic recurrence did not differ by use of morcellation at three or six months of followup with comparable disease-free survival rates in both groups.[204] Three studies did not present data in a way to allow inclusion in our aggregate survival estimates. They include the findings of a recent review and lifetable analysis by Pritts and colleagues[214] and an analysis of data from Norway.[170,171] These studies do not find a statistically meaningful disadvantage to morcellation when aggregate data are used to calculate survival.

Individually, few authors had sufficient number of cases to address differences in risk of dissemination or survival by other characteristics of the women found to have leiomyosarcoma at the time of surgery for presumed fibroids. If we consider only those studies with more than 10 cases with scalpel or power morcellation, only five publications with total size of 15 to 56 participants have potential to contribute information.[199,204,207,208,215] Two do not provide adjusted multivariable models or stratification by characteristics other than operative approach.[215,216] None report assessment of effect modification by any trait other than surgical approach to removal of the uterus or fibroids.

Characteristics reported not to confound the association between risk of dissemination and outcome in multivariable time-to-event models included: age,[207,208] menopausal status,[207,208] adjuvant treatment including radiotherapy,[207,208] and BMI.[208] In the publications authored by Perri and Park, only surgical approach (grouped as total abdominal hysterectomy or other approaches with any morcellation or breech of the tumor capsule) compared to removal intact significantly influenced outcomes.[207,208] Lin and colleagues adjusted for age, tumor size, and mitotic count, but including these covariates in the model did not meaningfully change estimates.[199] Thus, this literature lacks information to identify those most likely to have a more aggressive course of disease beyond pathology features of tumor differentiation and stage. This is not unexpected since leiomyosarcoma is rare and power is limited. It is helpful, however, that larger studies do not find other characteristics act as confounders. This implies that our aggregate estimate and those of others are not likely to be seriously confounded by commonly measured clinical factors.

In summary, this literature provides data to indicate that method of morcellation is a potential determinant of outcomes, with power morcellation being associated with decreased 5 year survival. However, confidence intervals overlap, and even those who have leiomyosarcoma with removal of the uterus intact have substantial mortality risk.

Discussion

Key Findings

Strength of Evidence

We assessed the strength of evidence for medical, procedural, and surgical intervention effects on fibroid volume, uterine bleeding, and quality of life. The summaries below are organized by category of intervention and reflect findings for all arms of the included trials that examined the intervention. We report strength of evidence for those studies that report on these outcomes. Not all outcomes are considered by all publications. Tables 29-36 outline strength of evidence findings.

Expectant Management

Table 29. Strength of evidence for expectant management

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Fibroid Volume							
11 studies, 331 participants	Low: 2 Moderate: 3 High: 6	High	Direct	Inconsistent	Precise	Not detected	Insufficient
Bleeding							
13 studies, 400 participants	Low: 2 Moderate: 6 High: 5	High	Direct	Inconsistent	Precise	Not detected	Insufficient

Medications

Table 30. Strength of evidence for GnRH treatment

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Fibroid Volume							
12 studies, 534 participants	Low: 2 Moderate: 1 High: 9	High	Direct	Consistent	Precise	Not detected	Moderate for reduction in fibroid volume
Bleeding							
14 studies, 666 participants	Low: 1 Moderate: 3 High: 10	High	Direct	Consistent	Precise	Not detected	Moderate for improved bleeding, including cessation of menses
Quality of Life							
3 studies, 285 participants	Low: 1 Moderate: 1 High: 1	Medium	Direct	Consistent	Precise	Not detected	Low for improved fibroid-related quality of

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
							life

GnRH = gonadotropin-releasing hormone

Table 31. Strength of evidence for progesterone antagonist and selective receptor modulators

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Fibroid Volume							
Mifepristone (7 studies, 690 participants)	Moderate: 5 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for reduction in fibroid volume
Ulipristal (6 studies, 1,095 participants)	Low: 2 Moderate: 2 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for reduction in fibroid volume
Bleeding							
Mifepristone (7 studies, 690 participants)	Moderate: 5 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for improved bleeding
Ulipristal (6 studies, 1,095 participants)	Low: 2 Moderate: 2 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for improved bleeding
LNG-IUD (1 study, 30 participants)	High: 1	High	Direct	Unknown	Imprecise	Not detected	Insufficient
Quality of Life							
Mifepristone (4 studies, 374 participants)	Moderate: 2 High: 2	High	Direct	Consistent	Precise	Not detected	Moderate for improved fibroid-related quality of life
Ulipristal (6 studies, 1,095 participants)	Low: 2 Moderate: 2 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for improved fibroid-related quality of life

LNG-IUD = levonorgestrel intrauterine device

Table 32. Strength of evidence for estrogen receptor agents

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Fibroid Volume							
3 studies, 107 participants	Moderate: 2 High: 1	Medium	Direct	Inconsistent	Imprecise	Not detected	Low for lack of effect on fibroid size

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
							with raloxifene, insufficient for tamoxifen or HRT
Bleeding							
4 studies, 117 participants	Moderate: 2 High: 2	Medium	Indirect	Consistent	Imprecise	Not detected	Low for lack of effect on bleeding with raloxifene, insufficient for tamoxifen or HRT

Procedures

Table 33. Strength of evidence for uterine artery embolization or occlusion

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
UAE							
Fibroid Volume							
12 studies, 838 participants	Low: 4 Moderate: 4 High: 4	Low	Direct	Consistent	Precise	Not detected	High for reduction in fibroid volume
Bleeding							
9 studies, 438 participants	Low: 1 Moderate: 4 High: 4	Medium	Direct	Consistent	Precise	Not detected	Moderate for improved bleeding
Quality of Life							
8 studies, 623 participants	Low: 2 Moderate: 4 High: 2	Medium	Direct	Consistent	Precise	Not detected	Moderate for improved fibroid-related quality of life
Fibroid Size and Bleeding							
2 studies, 82 participants	Medium: 1 High: 1	High	Direct	Consistent	Imprecise	Not detected	Insufficient
Uterine Artery Occlusion by Any Other Method							
Bleeding, Fibroid Size							
3 studies, 225	Medium: 1	Medium	Direct	Inconsistent	Imprecise	Not	Insufficient

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
participants	High: 2					detected	due to heterogeneity of intervention methods

Table 34. Strength of evidence for HIFU for fibroid ablation

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Fibroid Volume							
HIFU (3 studies, 153 participants)	High: 3	High	Direct	Consistent	Imprecise	Not detected	Low for reduction in fibroid volume

HIFU = high intensity focused ultrasound

Surgery

Table 35. Strength of evidence for surgery

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Bleeding							
Endometrial ablation (1 study, 96 participants	Moderate: 1	Medium	Direct	Unknown	Imprecise	Not detected	Insufficient
Myomectomy (2 studies, 183 randomized)	High: 2	High	Direct	Inconsistent	Imprecise	Not detected	Insufficient
Quality of Life							
Myomectomy (3 studies, 264 participants)	Moderate: 1 High: 2	High	Direct	Consistent	Precise	Not detected	Low for improved fibroid-related quality of life
Hysterectomy (2 studies, 204 participants)	High: 2	High	Direct	Consistent	Precise	Not detected	Low for improved fibroid-related quality of life

Direct Comparisons of Interventions

Table 36. Strength of evidence for direct comparisons of interventions

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
Ulipristal vs. GnRH							
Bleeding, Fibroid Size							

Studies, Total N	Risk of Bias	Study Limitations	Directness	Consistency	Precision	Reporting Bias	Strength of Evidence
1 study, 307 participants	Low: 1	Low	Direct	Unknown	Precise	Not detected	Insufficient
UAE vs. Myomectomy							
Quality of Life							
1 study, 163 participants	Medium: 1	Medium	Direct	Unknown	Imprecise	Not detected	Insufficient
UAE vs. Hysterectomy							
Quality of Life							
1 study, 177 participants	Low: 1	Low	Direct	Unknown	Imprecise	Not detected	Insufficient

GnRH = gonadotropin-releasing hormone agonist; UAE = uterine artery embolization

Findings in Relation to What Is Known

Existing Systematic Reviews

We searched for systematic reviews published between 2002 and 2015. We evaluated each for relevance to our Key Questions using the review patients/participants, interventions, comparators, outcomes, timing, and setting (PICOTS). We identified 24 systematic reviews of interventions to treat uterine fibroids (Appendix I).[12,163,217-238] The reviews addressed the following categories of interventions: medical (12 reviews), uterine artery embolization (UAE) (5 reviews), procedural (2 reviews), uterine sparing (1 review), surgical (3 reviews), and multiple interventions (1 review). The reviews overall were characterized by small numbers of included studies and limited data on long-term outcomes including future fertility. Harms were addressed in only a few reviews.

Existing Reviews of Medical Interventions

The medical interventions evaluated in the 12 medical systematic reviews included gonadotropin-releasing hormone (GnRH) analogues in four reviews,[163,217,224,233] , progesterone-containing intrauterine devices (IUDs) in 4 reviews, [222,228,235,236], and single reviews of progesterone antagonists including mifepristone,[237] selective estrogen receptor modulators (SERMs),[231] aromatase inhibitors[226] and tranexamic acid.[219]

GnRH analogues were evaluated in four reviews.[163,217,224,233] A Cochrane review of GnRH with add-back therapy assessed quality of life in 14 randomized clinical trials (RCTs).[217] Add-back therapies included medroxyprogesterone, tibolone, raloxifene, estriol, ipriflavone, and conjugated estrogens. Tibolone was associated with an improved quality of life and add-back therapies of tibolone, estriol, and ipriflavone helped preserve bone mass, but the quality of evidence for these findings was considered low.

Three reviews examined use of GnRH analogues as pre-medication prior to surgical procedures. Lethaby and colleagues summarized 20 RCTs that demonstrated preoperative GnRH agonist treatment reduced uterine volume and fibroid size and improved surgical bleeding outcomes.[163] Chen and colleagues analyzed data from three RCTs that compared GnRH versus no treatment or placebo prior to laparoscopic myomectomy.[233] GnRH significantly reduced intraoperative blood loss but did not shorten the operation time. Kamath and colleagues only found two studies that compared GnRH with placebo or no treatment in women with submucosal

fibroids prior to hysteroscopic resection.[224] The primary outcome of symptom relief was inconclusive.

Progestogen-releasing IUDs were evaluated in four systematic reviews.[222,228,235,236] A small Cochrane report of progestogens included only a single small study that compared levonorgestrel (LNG) IUD to oral contraceptives and found significant reduction in blood loss for IUD users.[228] LNG-IUD was associated with reduced menstrual blood loss reported in three other reviews that included few to no RCTs.[222,235,236] Women with fibroids may have higher device expulsion rates.[235]

A Cochrane review of SERMs used to treat leiomyoma only included three small RCTs.[231] All of the studies evaluated raloxifene but the evidence for the effectiveness in reducing fibroid size and improving clinical outcomes was inconclusive. An older systematic review of mifepristone included six pre-post studies.[237] Mifepristone was associated with a reduction in fibroid size and improvement in symptoms but there were no comparative studies in this review.

Another Cochrane review of aromatase inhibitors found only a single RCT comparing letrozole to GnRH agonist.[226] There were no statistically significant differences in fibroid volume after 12 weeks of treatment. A single review of tranexamic acid for management of menorrhagia due to fibroids noted that it may reduce perioperative blood loss during myomectomy.[219]

Our review documents effectiveness of GnRH agonists for reducing fibroid volume and improving bleeding outcomes and improved symptom status when combined with add-back therapy and provides comparative trial evidence for the effectiveness of mifepristone in fibroid size reduction and resolving bleeding problems.

Existing Reviews of Procedural Interventions

Two reviews evaluated MRI-guided focused ultrasound (MRgFUS) treatment of uterine fibroids.[223,227] The reviews did not include any RCTs; conclusions were from analysis of retrospective studies and case series. Outcomes assessed included symptom severity from UFS-QOL, subsequent pregnancy, and harms. MRgFUS treated women had an improved quality of life as assessed 6 months following treatment, future fertility was preserved, and the procedure was well tolerated with only one serious adverse event of deep vein thrombosis reported.

In contrast, the studies of high frequency ultrasound (HIFU) and MRgFUS included in our review (all RCTs) did not report pregnancy or other patient- centered outcomes, but focused on technical success.

Existing Reviews of UAE

Uterine artery embolization (UAE) was evaluated in five systematic reviews.[218,225,229,230,232] Four of these reviews reported on comparative studies of UAE versus surgical treatments for uterine fibroids.[218,229,230,232] More favorable short-term outcomes, including reduced blood loss[232] and a quicker return to usual activities,[232] were noted for UAE compared with surgery. The risk of major complications was reduced with UAE,[229,230] but the procedure is associated with higher rates for reintervention reported in three systematic reviews.[229,230,232] There were no differences in patient satisfaction after 2 and 5 years[218] and long-term quality of life was comparable.[218,232] Data for live birth outcomes following UAE were limited.[218] One review that examined comparative studies of UAE using different embolic agents did not find any evidence of superiority of any particular agent.[225]

Our findings on patient satisfaction and quality of life outcomes following embolization in comparison with surgical treatments were comparable to what has been previously reported.

Existing Reviews of Uterine-Sparing Interventions

A single systematic review of five RCTs in premenopausal women who wanted to preserve their uterus reported comparisons between UAE with myomectomy and laparoscopic uterine artery occlusion.[221] Patient satisfaction was better for UAE and myomectomy compared with laparoscopic uterine artery occlusion. Limited evidence was available for fertility and pregnancy outcomes. Our review also had limited evidence for reproductive outcomes following uterine-sparing procedures.

Existing Reviews of Surgical Interventions

Three systematic reviews evaluated surgical treatments for uterine fibroids.[220,234,238] A large review of 34 RCTs compared vaginal, abdominal, and/or laparoscopic-assisted hysterectomies in women with benign disease, although only six of these trials specifically addressed surgical treatment for uterine fibroids. Vaginal hysterectomy was associated with a quicker return to usual activities and fewer infections compared with abdominal hysterectomy.[238] A review of nine RCTs comparing laparoscopic or hysteroscopic versus open myomectomy found improved short-term outcomes (less postoperative pain and shorter hospitalization) for laparoscopic procedures.[220] Another small review of four RCTs noted a significantly shorter operation time for hysteroscopic myomectomy compared with laparoscopic. Data was not available for long-term outcomes in these reviews. Our review also reports higher patient satisfaction and shorter recovery time for vaginal hysterectomy compared with abdominal hysterectomy.

Existing Reviews of Multiple Interventions

One review, an update of 2001 review of multiple therapies, addressed medical and surgical approaches or procedures to treat uterine fibroids.[12] Preoperative medical management reduced fibroid volume but did not provide sufficient evidence of improvement in operative outcomes. In studies of GnRH agonists, treatment reduced fibroid size, and add-back therapy did not affect the extent of reduction. Studies typically reported improved hemoglobin and mixed effects on symptoms including menorrhagia and pelvic pain. Harms associated with GnRH treatment included increases in low density lipoprotein levels with leuprolide and bone mineral density loss with leuprolide and leuprolide plus tibolone, and GnRH plus raloxifene. Mifepristone reduced menstrual blood loss and uterine volume and was associated with endometrial hyperplasia in 8 percent of participants receiving higher doses. Raloxifene decreased fibroid size in postmenopausal women and increased it in premenopausal. Studies of UAE reported high levels of symptom improvement and satisfaction with treatment and reductions in uterine volume of 27 to 47 percent over time. The incidence of UAE complications, including procedure-associated pain, hospitalization, unplanned increases in care, and minor complications requiring no treatment, ranged from 0.6 percent to 92 percent (for pain) across studies.

Quality of life, bulk symptoms, and bleeding improved with HIFU, and harms of treatment included pain and nerve palsy. Data on the effects of myomectomy on long-term outcomes were limited, and complications, including hematoma, infection, ileus, organ injury, conversion to hysterectomy, transfusion, and fever, typically increased with the number of fibroids removed. Hysterectomy studies primarily reported complications including a rate of severe operative and postoperative complications of less than 5% in one case series. Other complications included

readmission or conversion to laparotomy (for laparoscopic approaches), febrile morbidity, transfusion, ileus, and postoperative pain. The review notes that no well-conducted trials in U.S. populations directly compared treatment options or followed women to determine whether the intervention met their treatment objectives.

Existing Estimations of Occult Leiomyosarcoma Prevalence

In 2014, the FDA estimated the risk of occult leiomyosarcoma to be 1 in 498 women undergoing surgery for presumed fibroids.[24,40] This corresponds to 20 cases per 10,000 (95% binomial exact confidence interval 11-38). They identified 18 publications, and only included data from nine, one of which is only an abstract. They identified a total of 9,160 women, of which only 505(6%) were identified in prospective studies. Most of the studies included only hysterectomy patients.

In contrast, we identified 160 studies that included 136,195 women, of whom 29% were from prospective studies. Our estimates and that of Pritts[10] find that the prevalence of leiomyosarcoma are lower in data from more contemporary prospective cohorts of women having surgery compared to retrospectively collected data. This may be explained by challenges in applying uniform definitions and quality controls in retrospectively collected data even when pathology specimen banks are used to index a full population of surgical patients. Prospectively collected data also includes more women who are having myomectomies who are on average somewhat younger than those having hysterectomies. It is known that the incidence of sarcoma has been shown to increase with age through the sixth decade of life.[26,187]

Applicability

Overall, our findings are widely applicable to the general population of women seeking treatment for uterine fibroids. For KQs 1 and 2 we set inclusion criteria for this review to women of any age with uterine fibroids with patient outcome data beyond intermediate outcomes only. We excluded studies in pregnant women, and restricted our synthesis to include only treatments currently available in the United States. Over 40 percent of the studies were conducted in European countries and another 27 percent were conducted in the United States or Canada. This could have implications because the available options and attitudes and expectations about outcomes of fibroid care may differ by country and by healthcare setting. The interventions themselves were selected to be comparable so that the results reported in this review are expected to apply to women with fibroids in the United States.

Evaluation of expectant management was not an explicit aim of any trial. Sixteen studies with placebo arms or no treatment arms that included 514 women served as a surrogate. This population is not an ideal substitute as participants in the trials presumably hoped to receive active treatment and may report their status differently than women willing to be randomized to watchful waiting. This could restrict applicability but since the majority of studies included a plausible level of participant masking, they would be unlikely to know if they were on an active agent.

Medical management of fibroids was assessed in over 2,800 predominately premenopausal women from 43 studies (15 industry-sponsored and 11 conducted in the United States). Procedures, including UAE HIFU, and radiofrequency fibroid ablation were evaluated in 28 studies including almost 2,000 women, although data was lacking for some interventions (radiofrequency ablation was evaluated in only two small studies, IUDs in one). Surgical studies

evaluated hysterectomy, myomectomy, and endometrial ablation in over 3,000 women. Although none of these studies were conducted in the United States, the surgical techniques described are comparable and the comparators are procedures widely available to women in the United States.

Data in these studies were inadequate to assess applicability based on patient characteristics, such as age, race/ethnicity, pregnancy intention, or menopausal status, or fibroid characteristics, such as size, position, and number, that could influence effectiveness outcomes.

While there are limitations in the literature as discussed below, the information that is available from these trials is relevant to contemporary practice. For key questions 1 and 2, this review is generally applicable to women in the United States seeking one of the many treatment choices currently available for fibroids.

For key questions 3 and 4 (leiomyosarcoma risk), data can only be systematically obtained from publically available research. Those represented in the literature may differ from the universe of women having surgery for fibroids in the US. The group of interest to surgeons trying to determine appropriate use of morcellation is premenopausal women. Nearly all women having myomectomies are premenopausal. This is the group with potential future pregnancy desires and indications such as anemia, menorrhagia, and bulk symptoms who make up the majority of women seeking care for fibroids. The literature about risk and outcomes of leiomyosarcoma does not separate cases well by type or surgery or menopausal status. Prospective studies which include a greater representation of myomectomy patients may be more applicable for discussing risk among younger women.

Implications for Clinical and Policy Decisionmaking

Available evidence in this literature is predominantly restricted to understanding outcomes of specific interventions and not comparisons among them. Therefore, this review reports evidence that an intervention delivers certain desired outcomes but not how those outcomes vary across types of intervention. While it is helpful to know that confidence in particular medications, procedures, or surgeries is not misplaced, it is not sufficient to fully inform choice among the options or to drive decisions about coverage by health plans.

Some implications for clinical care and other decisionmaking can be highlighted. Women with fibroids and symptoms typically have time to make decisions and the process need not feel emergent or rushed. This presumes that a patient's medical condition is not acutely emergent which is an exceptionally small minority of those seeking care. More typically symptoms are persistent and troubling but not life threatening. In these instances, RCT data from placebo groups show that fibroids do not grow substantially over a period of time that averaged 7 months, neither did bleeding pattern substantially worsen.

Several medications show benefit for reducing the size of fibroids, improving bleeding, and reducing symptoms. These include GnRH agonists and ulipristal. Mifepristone provided stabilizing effects on the size of fibroids (no growth) with similar improvement in symptoms. In a single study, among women randomized to have an immediate hysterectomy or to defer hysterectomy and be treated with a GnRH agonist, 61 percent did not have surgery over three years of followup, suggesting a meaningful proportion of symptomatic women who wish to pursue medical intervention may avoid surgical intervention.[137] Harms of medical therapies vary and include menopausal symptoms, unfavorable lipid profile, cognitive decline, bone loss, endometrial hyperplasia, and liver toxicity. Some are reversible, however, it is not clear if other effects persist after treatment ends. These medical management options are likely underutilized in clinical practice and care guidelines might more directly address instances that merit

consideration. Certainly all women with fibroids should at minimum be aware that medications for management of fibroids exist. We also note that these interventions are not compatible with and in some cases prevent pregnancy, while in others contraception is required.

Procedures also deliver the expected results. Uterine artery embolization reduces the size of fibroids, reduces bleeding, improves pressure and bulk symptoms, and improves quality of life. High intensity focused ultrasound and radiofrequency ablation each have fewer trials but they provide evidence of effectiveness for reducing fibroid size, but uncertain effects on bleeding, symptoms, and quality of life and durability of improvements. This poses challenges for determining if procedures should be covered or if healthcare systems should invest in professional expertise and equipment to perform new procedures. Other interventions are more rarely used or not included in the literature but are important. These are discussed in future research needs.

Surgeries are most studied. Hysterectomy remains the definitive treatment. Less invasive hysterectomy options (vaginal or laparoscopic compared with an abdominal approaches) have superior patient satisfaction and shorter recovery. Overall harms did not differ in ways that would warrant consideration of harms driving a clinical choice. Myomectomy follows the same pattern, less invasive approaches had less impact on women's lives and harms were equivalent. Women are at times advised to have myomectomy to improve reproductive outcomes and this review, as well as a related recent Cochrane review of randomized trials of myomectomy,[239] suggests this is not the case. It is notable that evidence suggests only intervention for submucous fibroids (those in the uterine cavity), as opposed to other more common locations, improve subsequent pregnancy outcomes.

Few direct comparisons across categories of intervention are available to inform care. Two small studies of fair quality compared UAE to hysterectomy or myomectomy[16,21] as did three larger studies, including the 28-site EMMY trial.[20,22,114] As a group these studies provide a good case for why more trials making direct comparisons are needed. The studies find UAE provided similar symptom relief, quality of life, and risk of fibroid recurrence (the latter compared with myomectomy). UAE had shorter recovery and lower transfusion risk than both myomectomy and hysterectomy. In the high quality study with longest followup at 5 years, fewer than one third of women assigned to UAE required additional intervention, emphasizing that over two-thirds avoided surgery.[114] Our modelling data supports the low risk of subsequent intervention for most women after UAE. However, the major complication rate was three percent at one year and up to 21 percent at five years after UAE, and the impact of UAE on fertility remains unclear.

Likely no topic in gynecologic surgery, other than abortion ethics, has stirred as much public controversy as recent concerns about use of power morcellators in the care of women with fibroids. The concern pivots on an essential question about risk that we have updated from the last estimate in the published literature. The bedrock question on which all other considerations rest is: What is the expected risk of planning a surgery for uterine fibroids and unintentionally encountering a leiomyosarcoma? While women and their physicians alike would like this number to be zero, it is not, but it is a small risk. The point estimate of prevalence from 68 prospective studies is 0.02 percent (95% credible interval, 0.00 to 0.09) Using both prospective and retrospective studies, we estimate fewer than one to 13 women in 10,000 who have surgery for a fibroid may have a leiomyosarcoma.

Leiomyosarcomas have poor outcomes.[240] In our meta-analysis of 24 studies that provide data about use of morcellation in three categories: none, scalpel, or power; we find that power morcellation may be a determinant of dissemination and death from leiomyosarcoma. Some

recent estimates in the literature find otherwise,[170] and it is important to note that primary means of dissemination of this cancer is believed to be hematogenous,. More than half of women with leiomyosarcomas present with distant metastasis before recurrent cancer in the pelvis, and most progress to higher stage disease regardless of order of spread.[44,45] Unfortunately, the literature does not speak to characteristics of the individual or characteristics revealed by imaging of her fibroids that can discriminate those at high risk from those with lower risk. While we know risk increases with age through the sixth decade of life, age is neither sensitive nor specific given such a rare condition.

Taken together these findings suggest that the current ban on power morcellation requires continued investigation with expanded data. Some have cautiously argued such a ban in all age groups could result in an increase in harms to women.[42,241] Is it prudent with a known leiomyosarcoma to avoid breaching the mass and to aim for intact removal? Of course. Might containment systems in which morcellation occurs within a closed bag-like system help? Potentially. Is it wise to perhaps advise older women that they are at increased risk of leiomyosarcoma and if childbearing is completed may wish to consider intact removal by hysterectomy? Perhaps, but the magnitude of risk averted is unknown. In each of these instances we have outstripped the evidence and guidance reverts to expert opinion. In discussion of future research we consider what data may better inform clinical and policy guidance.

Taken in total, women and care providers now have more and higher quality evidence of effectiveness than a decade ago, and the literature addresses multiple types of intervention in each of the categories of medication, procedural, and surgical management. Individual women should have access to this information to inform their decisions and factual estimates of outcomes should be used to guide the consenting process. Nonetheless, we need to continue to pursue questions about care trajectories, comparisons across categories of intervention and longer-term followup to best guide care and policy.

Limitations of the Systematic Review Process

Methodologic choices constrain the findings of this report. We chose to focus on publications in the English-language literature, to restrict to randomized clinical trials (for KQ 1 and KQ2 comparative effectiveness), and to review only those studies that included at least one intervention that is available in the United States. Similar reviews have documented in the past that language restrictions have a negligible effect on estimates of effectiveness.[242-244] This is especially true for the topic of fibroids because the fibroid research community is small. Our Technical Expert Panel and investigators are familiar with prior and ongoing work and helped assure relevant studies have not been overlooked. Restricting to trials allowed us to focus sharply on proof of effectiveness. Because all individuals whose outcomes were assessed in these studies were randomly assigned to the intervention received, provider and patient biases in intervention choice are reduced and risk of confounding, that is difficult to fully assess or adjust for in cohort studies, is minimized. Reduced risk of bias in assignment in trials allows aggregation and summary of the findings by study arm, as we have done in summaries and tables in this report. This approach provides a clearer picture of the expected outcomes and gaps in knowledge about specific interventions. Considering each possible combination of intervention arms and reporting per combinations of interventions fractionates this literature into very small groupings in which concordant and discordant findings about outcomes are more easily obscured.

Restricting our review to randomized controlled trials may have limited our ability to detect the full range of harms associated with medications or therapies for fibroids. Studies were

generally not designed or powered to evaluate harms, and many had a short duration of follow up.

Our analysis of subsequent intervention after a first intervention could be biased by the types of studies that reported this data; however, in general they were higher quality trials with longer followup. Nonetheless, subsequent care, even in longer followup, often represented a small number of women and our analysis can only broadly address probability of a next intervention by type.

For meta-estimates related to leiomyosarcoma prevalence and morcellation risk, available evidence, based on pathology specimens for estimating presence of leiomyosarcoma in a mass believed to be a fibroid, is accruing and will likely continue to do so through and past the production of this report. Our estimates and those of Pritts and colleagues[10] find that the estimates are lower in data from more contemporary prospective cohorts of women having surgery. This suggests some inaccuracies in retrospectively collected data even when pathology specimen banks are used to index a full population of surgical patients. On the other hand, it is important to note that prospectively collected data often includes younger patients and a larger proportion undergoing myomectomies. This risk of inaccuracy is especially true in understanding and estimating the potential that morcellation method influences survival when a woman is found to have a leiomyosarcoma that was believed to be a fibroid. All sources of information, including women with fibroids removed intact at hysterectomy must be included in order to accurately capture risk of this rare outcome. Focusing only on disease progression rate and risk of death among those with use of power morcellation fundamentally misrepresents the true comparisons. We have taken this approach for this review; however, such comparisons will only be complete and more robust for informing care when the literature contains more longitudinal data with common metrics.

Focusing on interventions available in the United States, and excluding those that cannot be obtained here could neglect a promising intervention but does restrict the report to data that is of immediate value to women and their care providers who must make decisions among available options. We have included interventions that are not widely available in the United States such as high frequency ultrasound ablation and operative thermal ablation, so in the strictest sense of applicability, some women live in locations, or have access to a limited group of providers or face limitations of insurance coverage that may restrict the availability of some options.

Limitations of the Evidence Base

While the literature about the effectiveness of uterine fibroids treatment has grown from 35 randomized clinical trials available in 2007 to 97 unique trials included in this report, significant gaps in knowledge persist. Across all studies, the 97 included RCTs with 36 unique interventions, enrolled a total of 9,179 women. Individual studies were often small and powered to address only a single continuous outcome such as hematocrit or score on a quality of life scale.

Our analytic framework was created to reflect the outcomes that matter to women when making decisions. The available literature has substantial gaps in collecting this information as indicated by the number of studies that addressed each of our eight primary outcomes:

- Fibroid characteristics (e.g., change in size, number, volume): 63
- Symptoms status (e.g., bleeding, pain, bulk symptoms): 57
- Sexual function: 12
- Quality of life and satisfaction with outcomes: 38
- Desired fertility status: 1

- Pregnancy outcomes: 8
- Fibroid recurrence: 8
- Subsequent treatment for fibroids: 48

Little continuity exists in approaches to measuring outcomes and use of unvalidated measures is common. Most postprocedural studies focused on perioperative outcomes, although a small minority recorded long-term outcomes, with one study reporting on 5-year outcomes. The literature is further restricted in its ability to answer questions of immediate relevance to the management of uterine fibroids because only a small number of studies compared different types of fibroid management. Although several studies compared different types of hysterectomy, myomectomy, or medical management, only 17 studies compared treatment from substantively different categories of intervention.

Even when data is combined across studies for a particular intervention, risk of serious rare harms cannot be fully assessed. This is not a comparable shortcoming for all the categories of intervention because the larger literature on surgical and medical interventions captures many of the "general risks," for instance the risk of postoperative hemorrhage after hysterectomy or adverse drug reactions to a specific drug formulation. Relative lack of harms data is more concerning for fibroid-specific interventions such as UAE, methods to ablate fibroids, and myomectomy because there is no broader literature to turn to outside this review that originates within clinical trials though cohort and surveillance data can provide insight.

In many instances ability to synthesize evidence across studies is absent, weak because of biased collection methods (e.g., assessors not blind to intervention), difficult to aggregate across studies because different metrics are used, or the studies did not have adequate power or followup time to assess a key outcome that would ideally be measured.

Paucity of "similar" articles (populations, settings, patient characteristics, and outcomes measured) also precludes efforts to pool data about characteristics of the study populations as they contribute to predicting outcomes and no studies were appropriately powered to understand whether specific groups of patients, such as those closer to menopause or with a specific symptom pattern, have outcomes that are modified by those characteristics.

Overall quality of the literature is improving over time but remains limited. Among 97 trials, 18 were good quality, 27 were fair quality, and 52 were poor quality. Secular trends for improvement in trial methods do not explain poor quality. Some studies of good quality are older, and some studies of poor quality are very recent. Lastly, a disappointing lack of direct comparisons means this review is hindered in providing summaries with data to help a woman or her care provider make an evidence-driven selection among choices in the context of the patients' priorities.

Limitations about leiomyosarcoma data: Because cases are rare and detailed age data for non-cases is lacking, only rough models of risk by age can be produced. [25]We need more prospective studies that include nuanced data such as patient and fibroid characteristics, patient age, menopausal status and surgical approach, hormonal exposures and genetic factors so that we can give more accurate estimates to patients.

Research Recommendations

Key components of study design, analysis, and reporting remain the leading weaknesses of the literature for each topic addressed in this review. Overall, the literature identified is limited by the following gaps and problems. Future research should aim to remediate these concerns:

Ability To Assess Internal and External Validity. Key characteristics of populations studied (e.g., race/ethnicity, reproductive history) and detailed operational definitions of inclusion and exclusion criteria are not reported consistently. Furthermore, the dominance of European literature means that we cannot assume that processes of care and outcomes will be similar to those in the United States. Moreover, practice and outcomes have been shown in other areas of research (such as cardiac care) to have substantial variability within the United States and even within individual states and facilities. We see no reason to believe that such variation is not also at work in the care of fibroids; more and better information from U.S. studies is required to advance our understanding about this important women's health issue.

Study Populations of Adequate Size for Assessing Key Outcomes and Modifiers. The small size of most of the included trials, which averaged fewer than 100 participants, stymies ability to understand modifiers of outcomes that could be extremely relevant to clinical decisionmaking. Though most trials reported power calculations, calculations were often linked to intermediate outcomes such as blood loss at surgery, length of hospital stay, or bleeding pattern at conclusion of 3 months of medical therapy. Even with power calculations, the sizes of the samples precluded having adequate numbers of participants for the types of answers that are needed to inform women and their care providers about the critical questions raised for this report. Future research would be better able to provide such answers if funding agencies supported studies of adequate size to answer questions about priorities for patient centered outcomes, minimal important differences on standard measures, resolution of symptoms, satisfaction with outcomes, recurrence or growth of fibroids, and further care needs at time horizons of a year and longer.

Standard Nomenclature and Validated Measures. To advance knowledge, investigators need to adopt common classifications across the whole spectrum of operational definitions required for research. Several deficiencies handicap our ability to compare interventions and populations or aggregate data to estimate effect size and outcome probabilities. Three shortcomings are especially problematic: (1) failure to define operationally details such as fibroid type or position in the uterus; (2) reliance on clinical measures such as estimated blood loss from operative reports or febrile morbidity from nursing notes as endpoints; and (3) use of ad hoc measures of outcome that lack validity and reliability data (e.g., intuitively derived approaches to collecting data about success in controlling bleeding or altering bleeding patterns).

Analysis Methods Matched to the Outcomes of Interest. Followup data that investigate topics such as time to return to work, maintenance of symptom control, recurrence of fibroids, subsequent surgery, and fertility and pregnancy outcomes should be addressed with analysis methods that explicitly incorporate time-to-event analyses. Few studies used life table or hazard model approaches to reporting outcomes. Likewise determinants of outcomes may be examined by use of tools such as classification and regression tree analysis to partition extant dates in ways that better reveal the contribution of fibroid and patient characteristics to outcomes.

Direct Comparisons of Treatment Options. Randomized trials with common endpoints that reflect the treatment goals of women with fibroids must become a priority. Promising efficacy studies should be rapidly followed by larger effectiveness and comparison studies. Although changing entrenched treatment patterns is often difficult, especially for surgical

procedures that have been clinically available in varied forms for decades, trials must be done that compare surgery to medication and to procedures. When possible, such as for women without or with mild symptoms, trials should include a delayed treatment arm or expectant management group in order to better understand the natural history of fibroids and to examine the degree to which symptoms may wax and wane.

Content Priorities. With the goal of achieving care tailored to the individual woman's fibroid status and characteristics, we need sophisticated information about a considerable array of issues. These include the burden of disease for both her and, possibly, her family; along with societal costs from loss of ability to function well in the usual family or occupational roles. Transitions associated with appearance of uterine fibroids, growth patterns, and influences on growth (e.g., concurrent medical conditions like diabetes, use of medications like hormonal contraception, influence of lactation and duration) are also high-priority topics, as are predictors of symptom development and resolution. Variation in care-seeking behaviors, differences in severity at presentation, and health and quality-of-life outcomes with and without treatment are yet other matters that investigators should attempt to address. Indeed this literature cannot currently address from trials whether disparities between white and black women in the age at appearance of fibroids and in the number and size of fibroids also foreshadows different treatment outcomes and durability of results.

In current practice, women without symptoms may forego intervention because of the general belief that care should be aimed at improving symptoms or addressing a specific clinical concern such as difficulty conceiving or recurrent pregnancy loss. A patient's preferences, age and menopausal status also play into these decisions. Although foregoing intervention can be wise in the absence of data that the intervention will prevent future difficulties, no data indicates whether harms from expectant management are any less than use of other therapeutics. Likewise data is lacking on whether therapeutics, short of surgery, might forestall or prevent future changes in fibroids or appearance of symptoms which would be a desirable reason to intervene early. The concept of preventive strategies is appealing. However, as long as the etiology of fibroids remains unclear, preliminary trials are not assessing lifestyle interventions, and the prospect for dietary management, exercise, hormonal management, or other prevention trials is slim.

The clinical research agenda will likely depend on new translational research and large-scale epidemiology studies that are yet to be done. Much remains to be learned that will require large-scale prospective observational studies of sufficient size and rigor to support time-to-event analysis of outcomes, such as that being conducted in the COMPARE Uterine Fibroids 10,000 woman cohort study supported by AHRQ and PCORI. These studies may afford greater power to examine effect modification and to determine trajectories of care over a reproductive lifespan for women with fibroids. Additionally, such studies will be better able to estimate both common and rare harms.

While we did not review these topics, many of the trials raise the question of what underpins the presence of symptoms and what modifies risk of growth. We must also continue to invest in basic and translational research to understand the pathogenesis and pathophysiology of uterine fibroids. Such research is required to best guide selection of pathways for exploration of genetic determinants of the timing and severity of disease, gene-environment interactions that may influence onset and symptoms, proteomic and treatment targeting research, as well as to discover potential prevention strategies. Research effort must be focused on documenting first the course and consequences of uterine fibroids using optimal imaging strategies, then the modifiers of that

course, so that we can offer women an accurate account of the likely outcome of expectant management based on their individual status.

Conclusions

A range of interventions are effective for reducing fibroid size and improving symptoms. Some medications and procedures also improve quality of life. In accord with the prior AHRQ systematic evidence review on management of uterine fibroids, we find a lack of high-quality evidence in several areas. Specifically notable is the lack of well-conducted trials in U.S. populations. Fewer than a quarter of the trials were conducted in the United States. Direct comparisons among different treatment options remain sparse. No studies have explicitly evaluated expectant management, which is a crucial missing piece of the evidence about the natural history of disease that would provide information about whether symptoms relapse and remit even after a woman presents seeking resolution of symptoms. The literature must include longer followup to determine whether women's objectives for treatment were met by the intervention received. Few women have only one concern driving their desire for intervention, yet remarkably many trials are directed at evaluating a single outcome. Likewise concerns about harms, such as drug side effects, serious surgical complications, and risk of undetected leiomyosarcoma, need to exploit larger and more nuanced data to be able to better determine what individual and fibroid characteristics best predict adverse events to better inform personalized care.

The range of options for medical management is expanding. However, no new agent has appeared that overcomes limitations of existing options (such as reducing hormonal side effects or allowing shorter duration of treatment). Appearance of new fibroids and growth of existing fibroids is poorly studied among the management options that leave the uterus in situ. Data to help women with fibroids who desire a pregnancy make treatment decisions are problematic because they originate primarily in populations dominated by participants with known fertility impairments or adverse pregnancy outcomes and often the proportion of women who wished to conceive is not known.

Across management options, we must note that lack of evidence is not equivalent to evidence of no benefit or of harm. Some of these interventions are effective in some patients but ability to estimate based on patient characteristics who would benefit most, or risk most, is lacking. Uncontrolled studies are not a substitute since they are notably biased for overestimating the degree of benefit subsequently reported in randomized trials. Indeed, not uncommonly, trials negate the findings of what in this case is largely retrospective and case series research. The current state of the literature does not permit definitive conclusions about comparative benefit, harm, or relative costs to achieve similar results across the range of available options and lacks strength of evidence for interventions such as use of continuous birth control pill regimens, progesterone containing IUDs, and endometrial ablation that are often used in routine clinical practice.

Finally, the uncertainty in estimates of leiomyosarcoma prevalence and evolving data about methods for tissue extraction will require explorations of ethical and shared decision making topics to offer coherent care recommendations and to support patients' and surgeons' autonomy. Given how common and concerning fibroids can be to women and their care providers, a redoubled emphasis on promoting high-quality fibroid research in the United States is imperative. Women need better information to guide their choices.

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Abbreviations

Abbreviation	Definition
AMSS	Aberdeen menorrhagia severity scale
BISF-W	Brief Index of Sexual Functioning for Women
BMI	body mass index
CEUS	contrast enhanced ultrasound
CI	confidence interval
cm	Centimeter
cm^3	cubic centimeters
E2	Estradiol
EQ-5D™	EuroQol Group standardized quality of life instrument, EQ-5D
FSH	follicle-stimulating hormone
g	Gram
g/dL	grams per deciliter
GnRH	gonadotropin-releasing hormone
GSP	gelatin sponge particle
HRQoL	health-related quality of life
HIFU	high intensity focused ultrasound
IQR	interquartile range
IM	Intramuscular
IU	international units
IUD	intrauterine device
IU/L	international units per liter
mg	Milligram
ml	Milliliter
MPA	Medroxyprogesterone Acetate
MR	magnetic resonance
MRgFUS	magnetic resonance guided focused ultrasound
MRI	magnetic resonance imaging
N	Number
NA	not applicable
NR	not reported
NS	not significant
NSAID	nonsteroidal anti-inflammatory drug
OR	odds ratio
PBAC	pictorial blood loss assessment chart
PVA	polyvinyl alcohol microspheres
RCT	randomized controlled trial
SAQ	Sexual Activity Questionnaire
SD	standard deviation
SEM	standard error of mean
UAE	uterine artery embolization
UFS-QOL	Uterine Fibroid Symptom and Health-Related Quality of Life Questionnaire
UK	United Kingdom
U.S.	United States
VAS	Visual Analog Scale

Abbreviation	Definition
vs.	Versus

Appendix A. Search Strategy

Key Question 1 and Key Question 2 Search Strategies

Table A-1. PubMed (3/24/15)

Search	Query	Records
1	((leiomyoma[mh]) OR (fibroma[mh] AND (uterine diseases[mh] OR uterus[mh])))	17656
2	(Uterine[tiab] AND (fibroma*[tiab] OR fibroid*[tiab] OR leiomyoma*[tiab] OR myoma*[tiab] OR fibromyoma*[tiab])) OR (submucous fibroid*[tiab] OR submucosal fibroid*[tiab] OR Intramural fibroids [tiab]) NOT medline[sb]	985
3	#1 OR #2	18621
4	("Mifepristone"[Mesh] OR "ulipristal"[Supplementary Concept] OR "Anti-Inflammatory Agents, Non-Steroidal"[Mesh] OR "Antifibrinolytic Agents"[Mesh] OR "Goserelin"[Mesh] OR "cetrorelix"[Supplementary Concept] OR "Selective Estrogen Receptor Modulators"[Mesh] OR "Levonorgestrel"[Mesh] OR "Nafarelin"[Mesh] OR "Triptorelin Pamoate"[Mesh] OR "Leuprolide"[Mesh])	90459
5	(Mifepristone[tiab] OR Ulipristal acetate[tiab] OR NSAID[tiab] OR antifibrinolytic[tiab] OR Goserelin[tiab] OR cetrorelix acetate[tiab] OR Selective estrogen receptor modulators[tiab] OR SERM[tiab] OR mirena[tiab] OR lng-ius[tiab] OR levonorgestrel-releasing intrauterine system[tiab] OR management[tiab] OR leuprolide[tiab] OR triptorelin[tiab] OR nafarelin[tiab]) NOT medline[sb]	92082
6	#4 OR #5	182541
7	therapy[sh:noexp] OR drug therapy[mh] OR drug therapy[sh] OR complementary therapies[mh] OR cam[sb] OR Treatment outcome[mh]	4576056
8	surgery[sh] OR surgical procedures, operative[mh] OR embolization, therapeutic[mh]	3058662
9	(Hysterectomy[tiab] OR myomectomy[tiab] OR hysteroscopy[tiab] OR emboliz*[tiab] OR ablation[tiab] OR magnetic resonance guided[tiab] OR focused ultrasound[tiab] OR artery occlusion[tiab] OR UAE[tiab] OR morcellat*[tiab] OR electrosurg*[tiab] OR cryoablation[tiab] OR myolysis[tiab]) NOT medline[sb]	16834
10	#8 OR #9	3075456
11	#6 OR #7 OR #10	6846698
12	#3 AND #11	10260

Notes: “Drug therapy”[mh] includes hormone therapy; “Surgical procedures, operative”[mh] includes ultrasound ablation, embolization, and hysterectomy; Search lines: #3=uterine fibroid concept; #6 drug treatment concept; #7=therapy or treatment general concept; #10=surgical and procedural interventions concept; #11=any intervention; #12=any intervention or treatment and fibroid

Table A-2. PubMed (4/26/16)

Search	Query	Records
1	((leiomyoma[mh]) OR (fibroma[mh] AND (uterine diseases[mh] OR uterus[mh])))	18618
2	(Uterine[tiab] AND (fibroma*[tiab] OR fibroid*[tiab] OR leiomyoma*[tiab] OR myoma*[tiab] OR fibromyoma*[tiab])) OR (submucous fibroid*[tiab] OR submucosal fibroid*[tiab] OR Intramural fibroids [tiab]) NOT medline[sb]	1206
3	#1 OR #2	19824
4	("Mifepristone"[Mesh] OR "ulipristal"[Supplementary Concept] OR "Anti-Inflammatory Agents, Non-Steroidal"[Mesh] OR "Antifibrinolytic Agents"[Mesh] OR "Goserelin"[Mesh] OR "cetrorelix"[Supplementary Concept] OR "Selective Estrogen Receptor Modulators"[Mesh] OR "Levonorgestrel"[Mesh] OR "Nafarelin"[Mesh] OR “Leuprolide"[Mesh])	95001
5	(Mifepristone[tiab] OR Ulipristal acetate[tiab] OR NSAID[tiab] OR antifibrinolytic[tiab] OR Goserelin[tiab] OR cetrorelix acetate[tiab] OR Selective estrogen receptor modulators[tiab] OR SERM[tiab] OR mirena[tiab] OR lng-ius[tiab] OR levonorgestrel-releasing intrauterine system[tiab] OR management[tiab] OR leuprolide[tiab] OR	109218

Search	Query	Records
	triptorelin[tiab] OR nafarelin[tiab]) NOT medline[sb]	
6	#4 OR #5	204219
7	therapy[sh:noexp] OR drug therapy[mh] OR drug therapy[sh] OR complementary therapies[mh] OR cam[sb] OR Treatment outcome[mh]	4840736
8	surgery[sh] OR surgical procedures, operative[mh] OR embolization, therapeutic[mh]	3228356
9	(Hysterectomy[tiab] OR myomectomy[tiab] OR hysteroscopy[tiab] OR emboliz*[tiab] OR ablation[tiab] OR magnetic resonance guided[tiab] OR focused ultrasound[tiab] OR artery occlusion[tiab] OR UAE[tiab] OR morcellat*[tiab] OR electrosurg*[tiab] OR cryoablation[tiab] OR myolysis[tiab]) NOT medline[sb]	19444
10	#7 OR #8 OR #9	7106684
11	#6 OR #10	7245249
12	#3 AND #11	10940
13	#12: Publication date from 2015/01/01	650

Notes: Imported 573 after 77 duplicates discarded by Endnote

Table A-3. Ovid® Embase (Excerpta Medica)

Date	Search strategy and limits	Retrieval
3/1/2015	*uterus myoma/dt, su [Drug Therapy, Surgery] (limited to English language; exclude medline journals; year="1985 -Current")	331*
4/26/2016	*uterus myoma/dt, su [Drug Therapy, Surgery] (limited to English language; exclude medline journals; year="2015 -Current")	56ǂ

Notes: *Retrieval: 331, imported 303 after duplicates were discarded; ǂ Retrieval: 56; imported 16 after 40 duplicates were discarded.

Key Question 3 Search Strategy

Table A-4. PubMed (2/2/2016)

Search	Query	Records
1	25016181 OR 24347933 OR 24012921 OR 23962573 OR 23189178 OR 23053310 OR 22905461 OR 22732808 OR 22626269 OR 22472335 OR 22142874 OR 22095838	12
2	Similar articles for PubMed (Select 12 documents) Filters: Publication date from 2014/03/01 to 2016/12/31	443

Notes: After duplicates removed, this literature strategy contributed 410 unique records.

Table A-5. PubMed (9/13/2016)

Search	Query	Results
#1	25016181 OR 24347933 OR 24012921 OR 23962573 OR 23189178 OR 23053310 OR 22905461 OR 22732808 OR 22626269 OR 22472335 OR 22142874 OR 22095838	12
#2	Similar articles for PubMed (Select 12 documents)	1844
#3	Filters: Publication date from 2014/03/01 to 2016/12/31	521

Notes: This literature search updated contributed 198 records, after 323 duplicates were removed.

Table A-6. Hand search

Search	Query	Results
#1	Records in Pritts Review	110
#2	Records identified in the UF CER literature library	14
#3	Records identified through other methods	9

Key Question 4 Search Strategy

Table A-7. PubMed (3/13/15)

Search	Query	Records
1	morcellation	445
2	morcellat* AND uterine	256
3	morcellat*	562
4	("Electrosurgery/adverse effects"[Mesh]) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	1251
5	("Electrosurgery/adverse effects"[Mesh] AND uterine) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	742

Notes: This literature search added 742 records.

Table A-8. PubMed (10/21/15)

Search	Query	Records
1	morcellation	520
2	morcellat* AND uterine	325
3	morcellat*	648
4	("Electrosurgery/adverse effects"[Mesh]) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	1374
5	("Electrosurgery/adverse effects"[Mesh] AND uterine) OR "Uterine Myomectomy/adverse effects"[MeSH] OR morcellat*	850

Notes: This literature search update added 102 records, after 748 duplicates were discarded.

Appendix B. Population, Intervention, Comparator, Outcomes, Timing, and Setting

Table B-1. Population, intervention, comparator, outcomes, timing, and setting

PICOTS	Criteria and Key Question(s)	
Population	Women who are being treated for uterine fibroids (KQs 1-4)	
Intervention(s)	Surgical (KQs 1-4) Procedural (KQs 1, 2) Medical / Pharmacologic (KQs 1, 2) Morcellation (KQs 1-4)	
Comparator	Inactive treatment including wait list control, expectant management, or placebo Active treatment	
Outcomes	<u>Intermediate outcomes (KQ 1)</u> Technical success Conversion to alternate operative procedure Estimated blood loss Wound healing status Length of stay Readmission/reoperation Return to usual activities <u>Final health outcomes (KQ 1)</u> Symptom status Desired fertility status Pregnancy outcomes Sexual function Fibroid characteristics Fibroid recurrence Subsequent treatment for fibroids Satisfaction with outcomes	<u>Adverse effects / Harms (KQs 1, 3)</u> Transfusion Unplanned hysterectomy Perforation of organs Cancer dissemination Misdirected embolization / non-target tissue embolization Ovarian failure Other serious adverse events
Timing	Any length of followup (KQs 1-4)	
Setting	Clinical setting in countries with health care systems similar to the U.S. (defined as inclusion as a Very High Human Development country on the United Nations Development Programme Human Development Index (KQs1-4) *Countries include: Albania, Algeria, Andorra, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Barbados, Belarus, Belgium, Belize, Bosnia and Herzegovina, Brazil, Brunei Darussalam, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominica, Dominican Republic, Ecuador, Estonia, Fiji, Finland, France, Georgia, Germany, Greece, Grenada, Hong Kong, China (SAR), Hungary, Iceland, Iran (Islamic Republic of), Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Montenegro, Netherlands, New Zealand, Norway, Oman, Palau, Panama, Peru, Poland, Portugal, Qatar, Romania, Russian Federation, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sri Lanka, Suriname, Sweden, Switzerland, Thailand, The former Yugoslav Republic of Macedonia, Tonga, Trinidad and Tobago, Tunisia, Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Uruguay, Venezuela*	

Abbreviations: KQ=key question, PICOTS= Population, Intervention, Comparator, Outcomes, Timing, and Setting

Appendix C. Screening Forms

Key Question 1. Literature Screening Forms

Table C-1. Screening Form: Level 1

Question Text	Choice(s)	Code
1. Study evaluates a surgical or procedural or medical intervention(s) for women with uterine fibroids (If "NO," answer question 1a, submit this form, and move to next. If paper addresses morcellation harms, check Retain below before submitting.)	Yes	Yes
	No	X-1
	Cannot Determine	Unclear
1a. If no, the study evaluates (check all that apply)	Basic science	X-1a
	Genetics/etiology	X-1b
	Imaging/diagnosis	X-1c
	Pathophysiology/physiology	X-1d
	Pre-operative adjuncts to shrink fibroids or improve anemia	X-1e
	Risk factors	X-1f
	Case report	X-1g
	Other	X-1h
	Not uterine fibroid	X-1i
2. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.)	Yes	Yes
	No	X-2
	Cannot Determine	Unclear
3. Eligible study design: randomized controlled trial	Yes	Yes
	No	X-3
	Cannot Determine	Unclear
3a. If no, please select study design	Prospective or retrospective cohort study	X-3a
	Non-randomized trial	X-3b
	Case series	X-3c
	Case report	X-3d
	Case-control	X-3e
	Other	X-3f
Screener Comments:		
Retain for:	Background/Discussion	Bkg
	Review of references	Refs
	Harms/AE data	Harms
	Other	Oth

Table C-2. Screening Form: Level 2

Question Text	Choice(s)	Code
1. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.) NOTE: If the publication appears relevant to the topic, consider whether it should be retained for “review for references” (see check boxes below the form). These publications will be flagged for review, but not promoted for full text screening.	Yes	Yes
	No	X-2

Table C-2. Screening Form: Level 2, continued

Question Text	Choice(s)	Code
2. Study evaluates an intervention/treatment for uterine fibroids	Yes	Yes
	No	X-1
2a. If no, the study evaluates (check all that apply)	Basic science	X-1a
Reason	Genetics/etiology	X-1b
	Imaging/diagnosis	X-1c
	Pathophysiology/physiology	X-1d
	Pre-operative adjuncts to shrink fibroids or improve anemia	X-1e
	Risk factors	X-1f
	Case report	X-1g
	Other	X-1h
	Not uterine fibroid	X-1i
3. Eligible study design: randomized controlled trial	Yes	Yes
	No	X-3
3a. If no, please select study design	Prospective or retrospective cohort study	X-3a
	Non-randomized trial	X-3b
	Case series	X-3c
	Case report	X-3d
	Case-control	X-3e
	Other	X-3f
4. The study population is women with uterine fibroids or, for studies of mixed conditions, data is reported separately for women with uterine fibroids.	Yes	Yes
	No	X-5
5. Eligible setting: Any setting (clinic, hospital) in countries with health care systems similar to the U.S.	Yes	Yes
	No	X-4
6. Reports outcome(s) of interest	Yes	Yes
	No	X-6
Intermediate Outcomes	Technical success	IO01
	Conversion to alternate operative procedure	IO02
	Estimated blood loss	IO03
	Wound healing status	IO04
	Length of stay	IO05
	Readmission or reoperation	IO06
	Return to usual activities	IO07
Final Health Outcomes	Symptom status	FH01
	Desired fertility status	FH02
	Pregnancy outcome	FH03
	Sexual function	FH04
	Fibroid characteristic	FH05
	Fibroid recurrence	FH06
	Subsequent treatment for uterine fibroids	FH07
	Satisfaction with outcomes	FH08
Adverse effects / Harms	Transfusion	AE01
	Unplanned hysterectomy	AE02

Question Text	Choice(s)	Code
	Perforation of organs	AE03

Table C-2. Screening Form: Level 2, continued

Question Text	Choice(s)	Code
	Misdirected embolization	AE04
	Cancer dissemination	AE05
	Other	AE06
7. Addresses Key Question(s) If the aim of the study is to assess adhesion status, evaluate the preoperative or adjunctive medical treatment to minimize intraoperative blood loss or postoperative pain, or to report operative technique, time, or cost, check "no" and provide a brief explanation.	Yes	Yes
	No	X-7
Reason	Text	
Check one or more Key Question	(KQ1) What is the comparative effectiveness of treatments for uterine fibroids?	KQ1
	(KQ2) Does treatment effectiveness differ by patient or fibroid characteristics?	KQ2
	(KQ3) What is the risk of harm from morcellation of uterine fibroids at the time of myomectomy or hysterectomy?	KQ3
	(KQ4) Does risk of harm from morcellation differ by patient or fibroid characteristics?	KQ4
Check one or more intervention or treatment category	Hysterectomy	HYS
	Myomectomy	MYO
	Uterine artery embolization	UAE
	Ablative procedures (e.g., magnetic resonance-guided focused ultrasound [MRgFUS], cryoablation)	ABL
	Progestin-containing intrauterine devices	IUD
	Medication to resolve symptoms or reduce size of fibroids	MED
Type of comparator(s) in the study	Inactive control (e.g., expectant management, placebo)	IAC
	Other	OTH
	Alternate intervention/treatment	ALT
Comparator category	Hysterectomy	HYS
	Myomectomy	MYO
	Uterine artery embolization	UAE
	Ablative procedure (e.g., magnetic resonance-guided focused ultrasound [MRgFUS], cryoablation)	ABL
	Progestin-containing intrauterine devices	IUD
	Medication to resolve symptoms or reduce size of fibroids	MED
Retain	Background	Bkg
	Review of references	Refs
	Harms data	Harms
	Other	Oth

Question Text	Choice(s)	Code
Comments	Text	
Part of a family	Yes	Yes
	No	No

Table C-2. Screening Form: Level 2, continued

Question Text	Choice(s)	Code
	Unclear	Unclear
Related Ref ID(s):	Text	
Administrative	Unavailable	X-10
	Non-English	X-11
	Duplicate	X-12

Key Question 3. Literature Screening Forms

Table C-3. Screening Form: Level 1

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
	Unclear	UC
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2
3. Publication includes (or reports data from) 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
	Unclear	UC
4. Publication reports the histopathological status of tumors from all women treated for uterine fibroids.	Yes	Yes
	No	X-3
	Unclear	UC
Number of women with uterine fibroids:	*text*	-
Number with confirmed leiomyosarcoma:	*text*	-
Leiomyosarcoma rate:	*text*	-
Retain for: Review of references	*checkbox*	REFS
Retain for: Team Review	*checkbox*	TEAM
Retain for: Other	*checkbox*	OTH

Table C-4. Screening Form: Level 2

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2

Question Text	Choice(s)	Code
3. Publication includes (or reports data from) 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
4. Publication reports the histopathological status of tumors from all women treated for uterine fibroids.	Yes	Yes
	No	X-3

Table C-4. Screening Form: Level 2, continued

Question Text	Choice(s)	Code
Number of women with uterine fibroids:	*Text*	-
Number with confirmed leiomyosarcoma:	*Text*	-
Leiomyosarcoma rate:	*Text*	-
Retain for: Review of references	*Checkbox*	REFS
Retain for: Team Review	*Checkbox*	TEAM
Retain for: Other	*Checkbox*	OTH
Comments:	*Text*	-
Admin: Duplicate	*Checkbox*	X-11
Admin: Unavailable	*Checkbox*	X-12
Admin: Non-English	*Checkbox*	X-13
Admin: Published before 2014	*Checkbox*	X-14

Key Question 4. Literature Screening Forms

Table C-5. Screening Form: Level 1

Question Text	Choice(s)	Code
1. Reports original research (includes analysis of clinical or administrative data).	Yes	Yes
	No	X-1
	Unclear	Unclear
2. Population is women with uterine fibroids.	Yes	Yes
	No	X-2
3. Publication includes 5 or more patients (or data from patients) treated for uterine fibroids.	Yes	Yes
	No	X-3
	Unclear	Unclear
Number of patients included /number of clinical or administrative records analyzed:	*Text*	
4. The publication reports morcellator use.	Yes	Yes
	No	X-4
	Unclear	Unclear
5. The publication reports outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids. Check "yes" when the publication describes patients treated for uterine fibroids and follows those individuals forward in time. A publication that reports tumor pathology at time of treatment only (i.e., postoperative histopathologic information) should not be included unless it	Yes	Yes
	No	X-5
	Unclear	Unclear

Question Text	Choice(s)	Code
also reports subsequent outcomes such as residual disease, recurrence, survival, etc. Do not include papers that identify cases of leiomyosarcoma or uterine malignancy and look back to ascertain the time, type, and indication for initial treatment.		
Brief description of relevance of findings to KQ 4	*Text*	-
Brief description of reason for exclusion:	*Text*	-
Retain for: Background	*Checkbox*	BKG

Table C-5. Screening Form: Level 1, continued

Question Text	Choice(s)	Code
Retain for: Review of references	*Checkbox*	REFS
Retain for: Team Review	*Checkbox*	TEAM
Retain for: LMS prevalence	*Checkbox*	LMS
Retain for: Other	*Checkbox*	OTH

Table C-6. Screening Form: Level 2

Question Text	Choice(s)	Code
1. Paper reports original research (i.e., paper is not a review, editorial, commentary, letter to editor, etc.)	Yes	Yes
	No	X-1
2. Study reports use of morcellation or en bloc removal of the uterus or uterine fibroid.	Yes	Yes
	No	X-2
3. Eligible study design: case series, cohort, or trial Do not include studies that identify cases of leiomyosarcoma or uterine malignancy and look back at treatment/ exposure status	Yes	Yes
	No	X-3
3a. If no, please select study design / article type:		
Article type: Case report	*Checkbox*	X-3a
Article type: Literature review	*Checkbox*	X-3b
Article type: Surgical technique	*Checkbox*	X-3c
Article type: Retrospective cohort	*Checkbox*	X-3e
Article type: Other	*Checkbox*	X-3d
4. The paper includes 5 or more patients treated for uterine fibroids.	Yes	Yes
	No	X-4
5. The publication reports outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids. Check "yes" when the publication describes patients treated for uterine fibroids and follows those individuals forward in time. A publication that reports tumor pathology at time of treatment only (i.e., postoperative histopathologic information) should not be included unless it also reports subsequent outcomes such as residual disease, recurrence, survival, etc. Do not include papers that identify cases of leiomyosarcoma or uterine malignancy and look back to ascertain the time, type, and indication for initial treatment.	Yes	Yes
	No	X-5
Retain for: Background	*Checkbox*	BKG
Retain for: Review of references	*Checkbox*	REFS
Retain for: LMS prevalence (KQ3)	*Checkbox*	LMS

Question Text	Choice(s)	Code
Other	*Checkbox*	OTH
Comments	*Text*	
Related Ref ID(s):	*Text*	
Admin: Unavailable	*Checkbox*	X-10
Admin: Non-English	*Checkbox*	X-11
Admin: Duplicate	*Checkbox*	X-12

Appendix D. Reasons for Exclusion

Table D-1. Reasons for exclusion: Key Question 1 (n = 1,192*)

Exclusion Code	Exclusion Reason	Count
X-1	Does not include an intervention or treatment for uterine fibroids	555
	Basic science (X-1a)	
	Genetics/etiology (X-1b)	
	Imaging/diagnosis (X-1c)	
	Pathophysiology/physiology (X-1d)	
	Pre-operative adjuncts to shrink fibroids or improve anemia (X-1e)	
	Risk factors (X-1f)	
	Case report (X-1g)	
	Other (X-1h)	
	Not uterine fibroid (X-1i)	
X-2	Not original research	548
X-3	Not an eligible study design	493
	Prospective or retrospective cohort study (X-3a)	
	Non-randomized trial (X-3b)	
	Case series (X-3c)	
	Case report (X-3d)	
	Case-control (X-3e)	
	Other (X-3f)	
X-4	Not conducted in an eligible country	36
X-5	Population is not women with uterine fibroids or does not report data separately from mixed population	54
X-6	Does not report an outcome of interest	112
X-7	Does not address a Key Question	162
X-10	Unavailable	1
X-11	Non-English	107
X-12	Duplicate	6

*Total count exceeds number of records as records can be excluded for more than one reason

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3. Darney PD. Sonographically guided extraction of a submucous myoma. Obstet Gynecol. 1985 Nov;66(5):731-2. PMID: 3903586. X-1, X-1g, X-3, X-3d
4. Driessen F. Myomectomy in treatment of uterine fibroids. Trop Doct. 1985 Apr;15(2):68. PMID: 4002330. X-2
5. Gilardenghi F. [Fibromas in pregnancy. Clinico-therapeutic considerations]. Minerva Ginecol. 1985 Oct;37(10):571-80. PMID: 3908982. X-2, X-11
6. Kanshin NN, Umarov AU, Maksimov Iu M. [A method of mechanical compression opening of hollow organs]. Khirurgiia (Mosk). 1985 Dec(12):105-7. PMID: 3910930. X-1, X-1h, X-1i, X-2
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8. Krasnopol'skii VI. [Conservative myomectomy]. Akush Ginekol (Mosk). 1985 Mar(3):72-5. PMID: 3161378. X-11

9. Kuznetsova LV. [Computer-assisted prognosis of the reproductive function of patients following conservative myomectomy]. Akush Ginekol (Mosk). 1985 Mar(3):50-3. PMID: 3161369. X-11

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Table D-2. Reasons for exclusion: Key Question 3 (n = 539*)

Exclusion Code	Exclusion Reason	Count*
X-1	Not original research	178
X-2	Not women with fibroids	127
X-3	Does not report the histopathological status of tumors from all women treated for uterine fibroids	313
X-4	Does not include at least 5 patients	173
X-13	Non-english	1
X-14	Published before 2014	4

*Total count exceeds number of records as records can be excluded for more than one reason

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Table D-3. Reasons for exclusion: Key Question 4 (n = 979*)

Exclusion Code	Exclusion Reason	Count*
L1: X-1; L2: X-1	Not original research	272
L1: X-2	Not women with fibroids	345
L1: X-3; L2: X-4	Does not include at least patients treated for uterine fibroids	491
L1: X-4; L2: X-2	Does not report method for tissue removal	200
L1: X-5; L2: X-5	Does not report outcome(s) related to leiomyosarcoma subsequent to treatment for uterine fibroids	584
L2: X-3	Ineligible study design or article type	9
L2: X-10	Unavailable	1
L2: X-11	Non-English	1

*Total count exceeds number of records as records can be excluded for more than one reason

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Appendix E. Risk of Bias Form and Summary

Table E-1. Risk of bias assessment form: KQ1 studies

Domain-Specific Question	Response
Selection Bias (SB)	
SB1. Was the allocation sequence generated adequately (e.g., random number table, computer generated randomization)? Inadequate methods of allocation include non-random assignment (e.g., by participant last name, day of the week).	Yes. The authors report an acceptable method of assigning participants to an intervention or control group.
	No. The authors report an inadequate method of assignment to intervention or control group.
	Not reported. The authors do not describe how participants were allocated to the intervention and control groups.
SB2. Was allocation adequately concealed (e.g., pharmacy-controlled, sealed envelopes)?	Yes. The authors used an adequate method of allocation was concealed.
	No. The authors did not use a method to conceal the allocation of participants to study arms or the allocation concealment was inadequate.
	Not reported. Concealment is not described in the methods or mentioned by the publication authors.
SB3. Were the intervention and comparison groups comparable at baseline? Note: If randomization and allocation concealment approaches were successful, the groups should be similar.	Yes. Baseline characteristics such as age, severity, and fibroid characteristics were similar between groups or differences between groups at baseline were minimal and likely due to chance.
	No. There were differences between groups that may be a potential source of bias.
Overall assessment of selection bias:	High
	Medium
	Low
Comments on sources of selection bias:	
Performance Bias (PB)	
PB1. Did authors describe allowable concurrent interventions or assess participants for use of concomitant interventions?	Yes
	No
	Not reported
PB2. Did authors assess adherence (i.e., fidelity) to the intended treatment (e.g., collected pill counts, supplied and reviewed a medication diary), surgical, or procedural protocol?	Yes
	No
	Not applicable
Overall assessment of performance bias:	High
	Medium
	Low
Comments on sources of performance bias:	
Reporting Bias	
RB1. Were the outcomes specified a priori?	Yes. Authors describe the outcomes and harms that would be assessed and reported.
	No. Authors do not describe prespecified outcomes.
RB2. Were all prespecified outcomes reported in the findings/results?	Yes. All prespecified outcomes were reported in the study publication.

Table E-1. Risk of bias assessment form: KQ1 studies, continued

Domain-Specific Question	Response
	No. One or more of the prespecified outcomes were not reported in the publication.
Overall assessment of reporting bias:	High
	Medium
	Low
Comments on sources of reporting bias:	
Attrition Bias (AB)	
AB1. Did authors adequately report the disposition of all randomized participants? Mark "yes" if there was no attrition (i.e., the number randomized equals the number reported in followup).	Yes. The authors described the number of participants who were analyzed and accounted for participants who were lost to follow-up and/or dropped out.
	No. The authors did not account for participants who did not complete the study.
Intervention LTF rate:	
Control LTF rate:	
Study LTF rate:	
AB2. Were characteristics of the lost-to-followup / drop-out group evaluated for differences with the study group?	Yes. Authors compare the loss-to-followup / drop-outs group to the whole group.
	No. Authors do not comment on the characteristics of the group lost to followup compared with the overall study population.
	Not applicable. Attrition was minimal or none.
AB3. Did authors use an intention-to-treat approach in analysis of outcomes?	Yes
	No
	Not reported
AB4. Were incomplete outcome data adequately addressed?	Yes. Authors used an appropriate method for missing data (e.g., imputation), the missing data was minimal and reasons were similar between groups, or there was no missing data.
	No. Authors did not address missing data, a substantial proportion of patients withdrew, or missing outcome data could have biased observed effect size.
	Not sure.
How did authors handle missing data?	
Overall assessment of attrition bias:	High
	Medium
	Low
Comments on sources of attrition bias:	
Detection Bias (DB)	
DB1. Was the intervention fully described?	Yes. The authors reported sufficient detail to allow replication of the intervention or the authors reference a treatment manual.
	No. The authors did not report sufficient detail to replicate the intervention.
DB2. Was the length of followup similar for all study groups for primary outcomes?	Yes
	No
	Not reported

Table E-1. Risk of bias assessment form: KQ1 studies, continued

Domain-Specific Question	Response
DB3. Were the primary outcomes coded by individuals blinded to the intervention status of the participants?	Yes. The outcome assessors were unaware of an individual participant's group assignment.
	No. The outcome assessors knew which group participants were assigned to.
	Not reported
DB4. Did authors use reliable and valid measures/tools to assess primary outcomes?	Yes. Outcomes were assesses using previously validated measure(s) or the authors establish the validity in the current publication.
	No. The outcomes were assessed using measures of uncertain validity and reliability.
	Not sure. There is not enough information to rate this criterion.
Overall assessment of detection bias:	High
	Medium
	Low
Comments on sources of detection bias:	
Other Bias (OB)	
OB1. Was a priori sample size calculation provided for the primary outcome? See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3409926/ for more information on estimating sample size for clinical studies.	Yes
	No
Overall assessment of other bias:	High
	Medium
	Low
Comments on sources of other bias:	
Risk of Bias for Individual Outcomes	
Risk of bias associated with specific outcome(s) of interest differs from the risk of bias assessments above?	Yes (or likely yes)
	No
	Unsure
Assess risk of bias for harm(s) reported in this study?	Yes
	No
	Unsure

Assessment of Overall Risk of Bias for Individual Studies

The team preselected individual questions to assess the risk of bias in randomized controlled trials from a list of design-specific criteria.[1] The team developed an appraisal form that included 16 questions across six domains:

- Selection Bias *(3 items)*
- Performance bias *(2 items)*
- Reporting bias *(2 items)*
- Attrition bias *(4 items)*
- Detection bias *(4 item)*
- Other bias *(1 item)*

Two team members independently assessed the risk of bias for each domain. Conflicts were reconciled through discussion. We used the cumulative assessments from the six domains to categorize studies as high risk of bias, medium risk of bias, or low risk of bias based on the following:

- Low risk of bias: low risk of bias for all domains OR low risk of bias in all domains except for masking of those conducting imaging when placebo was used or the individual conducting the original intervention was not involved in the imaging.
- Medium risk of bias: medium risk of bias for one or two domains OR unclear risk of bias for one or more domains, together with no known important limitation that could invalidate its results.
- High risk of bias: medium risk of bias for 3 or more domains OR high risk of in any domain

The overall risk of bias for the study was calculated from individual domain assessments:

- Low risk of bias = **Good** quality
- Medium risk of bias = **Fair** quality
- High risk of bias = **Poor** quality

Table E-2. Risk of bias assessment summary: KQ1 RCTs

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Alessandri F et al. (2006)[2]	148	L	L	L	H	M	M	3	2	1			●
Ardovino M et al. (2013)[3]	170	M	H	L	M	M	M	1	4	1			●
Benassi L et al. (2002)[4]	119	L	L	L	L	M	L	5	1	0	●		
Bilhim T et al. (2011)[5]	160	M	M	M	M	M	H	0	5	1			●
Broekmans FJ et al. (1996)[6]	27	H	H	L	H	M	H	1	1	4			●
Brucker SY et al. (2014)[7]	51	M	L	H	M	M	M	1	4	1			●
Carbonell Esteve JL et al. (2008)[8]	100	M	M	L	L	L	L	4	2	0		●	
Carbonell JL et al. (2013)[9]	220	M	L	L	H	M	L	3	2	1			●
Carbonell JL et al. (2013)[10]	70	L	L	L	M	L	L	5	1	0		●	
Carr BR et al. (1993)[11]	16	H	H	L	L	L	H	3	0	3			●
Casini ML et al. (2006)[12]	181	H	H	L	M	M	H	1	2	3			●
Chwalisz K et al. (2007)[13]	129	L	L	L	L	M	L	5	1	0	●		
Cicinelli E et al. (2009)[14]	80	M	M	L	L	M	H	2	3	1			●
Costantini S et al. (1990)[15]	42	H	H	L	L	L	H	3	0	3			●
Cunningham E et al. (2008)[16]	16	L	L	L	H	L	M	4	1	1			●
Donnez J et al. (2012)[17]	307	L	L	L	L	L	L	6	0	0	●		

Table E-2. Risk of bias assessment summary: KQ1 RCTs, continued

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Donnez J et al. (2012)[18]	242	L	L	L	L	L	L	6	0	0	●		
Donnez J et al. (2015)[19]	451	L	M	L	L	L	L	5	1	0		●	
Edwards RD et al. (2007)[20]	157	L	L	L	L	L	L	6	0	0	●		
Eisinger SH et al. (2003)[21]	40	L	M	L	L	M	L	4	2	0		●	
Esteve JL et al. (2012)[22]	176	L	L	L	M	L	L	5	1	0		●	
Esteve JL et al. (2013)[23]	124	M	M	L	H	L	L	3	2	1			●
Fedele L et al. (1991)[24]	42	M	M	L	M	M	M	1	5	0			●
Fedele L et al. (2000)[25]	38	M	M	L	L	M	M	2	4	0			●
Ferrari MM et al. (2000)[26]	62	L	L	L	L	L	M	5	1	0		●	
Fiscella K et al. (2006)[27]	42	M	L	L	L	L	L	5	1	0		●	
Friedman AJ et al. (1988)[28]	16	H	M	L	L	M	M	2	3	1			●
Friedman AJ et al. (1989)[29]	38	M	L	L	L	L	M	4	2	0		●	
Friedman AJ et al. (1991)[30]	128	M	L	L	H	M	M	2	3	1			●
Friedman AJ et al. (1993)[31]	51	H	H	L	H	M	H	1	1	4			●
Gregoriou O et al. (1997)[32]	40	H	H	L	L	M	H	2	1	3			●
Hald K et al. (2007)[33]	66	L	L	L	M	L	L	5	1	0		●	
Hazlina N et al. (2005)[34]	35	M	M	L	M	L	L	3	3	0			●
Hehenkamp WJ et al. (2005)[35]	177	L	L	L	L	L	L	6	0	0	●		
Hwang JL et al. (2002)[36]	90	L	L	L	L	M	L	5	1	0	●		
Jacoby VL et al. (2016)	20	L	L	L	L	L	M	5	1	0		●	
Jiang N et al. (2014)[37]	80	H	M	L	L	M	H	2	2	2			●
Jirecek S et al. (2004)[38]	25	M	M	L	M	M	M	1	5	0			●
Jun F et al. (2012)[39]	127	M	L	L	L	M	M	3	3	0			●
Levens E et al. (2008)[40]	22	L	M	L	M	L	H	3	2	1			●
Liu M et al. (2011)[41]	359	M	M	L	M	L	L	3	3	0			●
Macnaught G et al. (2016)	20	H	L	L	L	L	M	4	1	1			●
Mais V et al. (1996)[42]	40	L	L	L	L	M	M	4	2	0		●	
Manyonda IT et al. (2012)[43]	163	L	L	L	M	L	L	5	1	0		●	
Mara M et al. (2006)[44]	63	L	L	L	L	M	M	4	2	0		●	
Melli MS et al. (2007)[45]	50	M	M	L	M	H	M	1	4	1			●
Meng X et al. (2010)[46]	100	H	M	L	M	M	H	1	3	2			●
Morris EP et al. (2008)[47]	75	M	M	L	M	L	L	3	3	0			●

Table E-2. Risk of bias assessment summary: KQ1 RCTs, continued

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Nieman LK et al. (2011)[48]	42	L	M	L	L	L	H	4	1	1			●
Orsi F et al. (2015)[49]	33	M	M	L	M	M	H	1	4	1			●
Palomba S et al. (1998)[50]	50	M	M	L	L	L	L	4	2	0		●	
Palomba S et al. (2001)[51]	70	L	M	L	M	L	L	4	2	0		●	
Palomba S et al. (2002)[52]	100	L	L	L	L	M	L	5	1	0	●		
Palomba S et al. (2002)[53]	90	L	L	L	M	L	L	5	1	0		●	
Palomba S et al. (2007)[54]	136	L	L	L	L	L	M	5	1	0		●	
Palomba S et al. (2008)[55]	110	L	M	L	L	M	H	3	2	1			●
Parazzini F et al. (1999)[56]	72	H	M	L	H	M	M	1	3	2			●
Parsanezhad ME et al. (2010)[57]	70	M	M	L	M	L	H	2	3	1			●
Pinto I et al. (2003)[58]	57	M	L	L	M	L	L	4	2	0		●	
Rossetti A et al. (2001)[59]	81	L	L	L	L	L	M	5	1	0		●	
Ruuskanen A et al. (2010)[60]	57	M	L	L	L	M	H	3	2	1			●
Sadan O et al. (2001)[61]	20	M	M	L	L	M	M	2	4	0			●
Sayyah-Melli M et al. (2009)[62]	60	M	M	L	H	M	H	1	3	2			●
Scialli AR et al. (1995)[63]	41	M	M	L	M	H	M	1	4	1			●
Seracchioli R et al. (2000)[64]	131	L	L	L	M	M	L	4	2	0		●	
Seracchioli R et al. (2002)[65]	122	L	L	L	L	M	H	4	1	1			●
Sesti F et al. (2008)[66]	80	L	L	L	L	L	L	6	0	0	●		
Sesti F et al. (2008)[67]	100	L	L	L	L	L	L	6	0	0	●		
Sesti F et al. (2014)[68]	108	L	L	L	L	L	L	6	0	0	●		
Shlansky-Goldberg RD et al. (2014)[69]	60	L	L	L	L	L	L	6	0	0	●		
Silva-Filho AL et al. (2006)[70]	60	M	M	L	L	L	H	3	2	1			●
Simsek T et al. (2002)[71]	46	H	M	H	H	M	H	0	2	4			●
Siskin GP et al. (2008)[72]	53	L	L	L	L	L	L	6	0	0	●		
Song YG et al. (2013)[73]	60	M	L	L	L	M	L	4	2	0		●	
Soriano D et al. (2001)[74]	80	M	L	L	L	L	M	4	2	0		●	
Soysal ME et al. (2001)[75]	96	L	L	L	L	L	M	5	1	0		●	
Spies JB et al. (2004)[76]	100	L	L	L	M	M	L	4	2	0		●	
Spies JB et al. (2005)[77]	36	L	L	L	L	L	L	6	0	0	●		
Takeuchi H, Kobori H, Kikuchi I, et al. (2000)[78]	67	H	L	L	H	M	H	2	1	3			●

Table E-2. Risk of bias assessment summary: KQ1 RCTs, continued

Citation	Participants	Selection	Performance	Reporting	Attrition	Detection	Other	Low Count	Medium Count	High Count	Overall Low	Overall Medium	Overall High
Tan J et al. (2008)[79]	52	L	L	L	L	M	L	5	1	0	●		
Tan J et al. (2009)[80]	80	L	L	L	L	L	L	6	0	0	●		
Tosun AK et al. (2014)[81]	60	H	H	M	H	M	H	0	2	4			●
Vercellino G et al. (2012)[82]	166	L	H	L	M	M	L	3	2	1			●
Vilos GA et al. (2006)[83]	26	L	L	L	H	L	H	4	0	2			●
Wang JJ et al. (2011)[84]	384	L	L	L	L	L	L	6	0	0	●		
Wang X et al. (2013)[85]	110	M	L	L	M	L	M	3	3	0			●
Wang X et al. (2015)	130	M	H	L	L	M	M	2	3	1			●
Watanabe Y et al. (1992)[86]	41	M	M	L	M	M	H	1	4	1			●
Worthington-Kirsch RL et al. (2011)[87]	46	M	L	L	M	L	L	4	2	0		●	
Yang Z et al. (2014)[88]	40	M	M	L	M	M	L	2	4	0			●
Yen YK et al. (2001)[89]	81	H	L	L	M	M	M	2	3	1			●
Yen YK et al. (2002)[90]	61	H	L	L	M	M	M	2	3	1			●
Yu SC et al. (2011)[91]	60	L	L	L	L	L	L	6	0	0	●		
Yuk JS et al. (2015)	92	M	M	L	M	M	L	2	6	0			●
Zhao F et al. (2011)[92]	105	H	M	L	M	M	M	1	4	1			●

Notes: Does not include related publications. Does not include: Eder S et al. (2013)[93] (pooled analysis). Abbreviations: L=low; M=medium; H=high; N=number of participants.

Table E-3. Overall risk of bias

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
Low (18 Studies; 2,334)	Benassi L et al. (2002)[4]	L	L	L	L	M	L	119
	Chwalisz K et al. (2007)[13]	L	L	L	L	M	L	129
	Donnez J et al. (2012)[17]	L	L	L	L	L	L	307
	Donnez J et al. (2012)[18]	L	L	L	L	L	L	242
	Edwards RD et al. (2007)[20]	L	L	L	M	L	L	157
	Hehenkamp WJ et al. (2005)[35]	L	L	L	L	L	L	177
	Hwang JL et al. (2002)[36]	L	L	L	L	M	L	90
	Palomba S et al. (2002)[52]	L	L	L	L	M	L	100
	Sesti F et al. (2008)[66]	L	L	L	L	L	L	80
	Sesti F et al. (2008)[67]	L	L	L	L	L	L	100

Table E-3. Overall risk of bias, continued

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Sesti F et al. (2014)[68]	L	L	L	L	L	L	108
	Shlansky-Goldberg RD et al. (2014)[69]	L	L	L	L	L	L	60
	Siskin GP et al. (2008)[72]	L	L	L	L	L	L	53
	Spies JB et al. (2005)[77]	L	L	L	L	L	L	36
	Tan J et al. (2008)[79]	L	L	L	L	M	L	52
	Tan J et al. (2009)[80]	L	L	L	L	L	L	80
	Wang JJ et al. (2011)[84]	L	L	L	L	L	L	384
	Yu SC et al. (2011)[91]	L	L	L	L	L	L	60
Medium (25 Studies; 2,328)	Carbonell Esteve JL et al. (2008)[8]	M	M	L	L	L	L	100
	Carbonell JL et al. (2013)[10]	L	L	L	M	L	L	70
	Donnez J et al. (2015)[19]	L	M	L	L	L	L	451
	Eisinger SH et al. (2003)[21]	L	M	L	L	M	L	40
	Esteve JL et al. (2012)[22]	L	L	L	M	L	L	176
	Ferrari MM et al. (2000)[26]	L	L	L	L	L	M	62
	Fiscella K et al. (2006)[27]	M	L	L	L	L	L	42
	Friedman AJ et al. (1989)[29]	M	L	L	L	L	M	38
	Hald K et al. (2007)[33]	L	L	L	M	L	L	66
	Jacoby VL et al. (2016)	L	L	L	L	L	M	20
	Mais V et al. (1996)[42]	L	L	L	L	M	M	40
	Manyonda IT et al. (2012)[43]	L	L	L	M	L	L	163
	Mara M et al. (2006)[44]	L	L	L	L	M	M	63
	Palomba S et al. (1998)[50]	M	M	L	L	L	L	50
	Palomba S et al. (2001)[51]	L	M	L	M	L	L	70
	Palomba S et al. (2002)[53]	L	L	L	M	L	L	90
	Palomba S et al. (2007)[54]	L	L	L	L	L	M	136
	Pinto I et al. (2003)[58]	M	L	L	M	L	L	57
	Rossetti A et al. (2001)[59]	L	L	L	L	L	M	81
	Seracchioli R et al. (2000)[64]	L	L	L	M	M	L	131
	Song YG et al. (2013)[73]	M	L	L	L	M	L	60
	Soriano D et al. (2001)[74]	M	L	L	L	L	M	80
	Soysal ME et al. (2001)[75]	L	L	L	L	L	M	96
	Spies JB et al. (2004)[76]	L	L	L	M	M	L	100
	Worthington-Kirsch RL et al. (2011)[87]	M	L	L	M	L	L	46
High (52 Studies, 4,155)	Alessandri F et al. (2006)[2]	L	L	L	H	M	M	148
	Ardovino M et al. (2013)[3]	M	H	L	M	M	M	170
	Bilhim T et al. (2011)[5]	M	M	M	M	M	H	160
	Broekmans FJ et al. (1996)[6]	H	H	L	H	M	H	27
	Brucker SY et al. (2014)[7]	M	L	H	M	M	M	51
	Carbonell JL et al. (2013)[9]	M	L	L	H	M	L	220

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Carr BR et al. (1993)[11]	H	H	L	L	L	H	16

Table E-3. Overall risk of bias, continued

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Casini ML et al. (2006)[12]	H	H	L	M	M	H	181
	Cicinelli E et al. (2009)[14]	M	M	L	L	M	H	80
	Costantini S et al. (1990)[15]	H	H	L	L	L	H	42
	Cunningham E et al. (2008)[16]	L	L	L	H	L	M	16
	Esteve JL et al. (2013)[23]	M	M	L	H	L	L	124
	Fedele L et al. (1991)[24]	M	M	L	M	M	M	42
	Fedele L et al. (2000)[25]	M	M	L	L	M	M	38
	Friedman AJ et al. (1988)[28]	H	M	L	L	M	M	16
	Friedman AJ et al. (1991)[30]	M	L	L	H	M	M	128
	Friedman AJ et al. (1993)[31]	H	H	L	H	M	H	51
	Gregoriou O et al. (1997)[32]	H	H	L	L	M	H	40
	Hazlina N et al. (2005)[34]	M	M	L	M	L	L	35
	Jiang N et al. (2014)[37]	H	M	L	L	M	H	80
	Jirecek S et al. (2004)[38]	M	M	L	M	M	M	25
	Jun F et al. (2012)[39]	M	L	L	L	M	M	127
	Levens E et al. (2008)[40]	L	M	L	M	L	H	22
	Liu M et al. (2011)[41]	M	M	L	M	L	L	359
	Macnaught G et al. (2016)	H	L	L	L	L	M	20
	Melli MS et al. (2007)[45]	M	M	L	M	H	M	50
	Meng X et al. (2010)[46]	H	M	L	M	M	H	100
	Morris EP et al. (2008)[47]	M	M	L	M	L	L	75
	Nieman LK et al. (2011)[48]	L	M	L	L	L	H	42
	Orsi F et al. (2015)[49]	M	M	L	M	M	H	33
	Palomba S et al. (2008)[55]	L	M	L	L	M	H	110
	Parazzini F et al. (1999)[56]	H	M	L	H	M	M	72
	Parsanezhad ME et al. (2010)[57]	M	M	L	M	L	H	70
	Ruuskanen A et al. (2010)[60]	M	L	L	L	M	H	57
	Sadan O et al. (2001)[61]	M	M	L	L	M	M	20
	Sayyah-Melli M et al. (2009)[62]	M	M	L	H	M	H	60
	Scialli AR et al. (1995)[63]	M	M	L	M	H	M	41
	Seracchioli R et al. (2002)[65]	L	L	L	L	M	H	122
	Silva-Filho AL et al. (2006)[70]	M	M	L	L	L	H	60

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Simsek T et al. (2002)[71]	H	M	H	H	M	H	46
	Takeuchi H, Kobori H, Kikuchi I, et al. (2000)[78]	H	L	L	H	M	H	67
	Tosun AK et al. (2014)[81]	H	H	M	H	M	H	60
	Vercellino G et al. (2012)[82]	L	H	L	M	M	L	166
	Vilos GA et al. (2006)[83]	L	L	L	H	L	H	26
	Wang X et al. (2013)[85]	M	L	L	M	L	M	110
	Wang X et al. (2015)	M	H	L	L	M	M	130
	Watanabe Y et al. (1992)[86]	M	M	L	M	M	H	41

Table E-3. Overall risk of bias, continued

Overall Risk of Bias	Citation	Selection	Performance	Reporting	Attrition	Detection	Other	Participants
	Yang Z et al. (2014)[88]	M	M	L	M	M	L	40
	Yen YK et al. (2001)[89]	H	L	L	M	M	M	81
	Yen YK et al. (2002)[90]	H	L	L	M	M	M	61
	Yuk JS et al. (2015)	M	M	L	M	M	L	92
	Zhao F et al. (2011)[92]	H	M	L	M	M	M	105

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Appendix F. Registered Study Protocols

Table F-1. Registered protocols from studies included in Key Question 1

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01629563 (See Ref ID: 95)	**Drug**: PGL4001 5 mg **Drug**: PGL4001 10 mg	PregLem SA Industry	6/1/2012; 1/1/2015 Completed, No Results Available	551
A Study to Evaluate the Safety and Effectiveness of Asoprisnil in the Treatment of Uterine Fibroids NCT00160459 (See Ref ID: 3324)	**Drug**: Asoprisnil	Abbott Industry	5/1/2000; 7/1/2001 Completed, No Results Available	129
Mifepristone to Treat Uterine Fibroids NCT01786226 (See Ref ID: 629)	**Drug**: Oral administration of mifepristone 2.5 mg daily for three months **Drug**: Oral administration of mifepristone 5 mg daily for three months	Mediterranea Medica S. L. Other	3/1/2010; 3/1/2012 Terminated, No Results Available	220
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01156857 (See Ref ID: 414)	**Drug**: PGL4001, placebo **Drug**: PGL4001, progestin	PregLem SA Industry	7/1/2010; 2/1/2012 Completed, No Results Available	209
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata (PEARLIII-extension Study) NCT01252069 (See Ref ID: 414)	**Drug**: PGL4001, placebo, **Drug** free period **Drug**: PGL4001, progestin, **Drug** free period	PregLem SA Industry	1/1/2011; 1/1/2014 Completed, No Results Available	200
Mifepristone 10 or 5 mg for 6 Months to Treat Uterine Fibroids NCT00886873 (See Ref ID: 2635)	**Drug**: Mifepristone	Mediterranea Medica S. L. Other	5/1/2008; 5/1/2009 Completed, No Results Available	100
Treatment of Uterine Fibroids With the Selective Progesterone Receptor Modulator CDB-2914 NCT00290251 (See Ref ID: 1849)	**Drug**: Ulipristal acetate **Drug**: Ulipristal acetate **Drug**: Placebo	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) HRA Pharma National Institutes of Health Clinical Center (CC) NIH, Industry	2/1/2006; 8/1/2010 Completed, Has Results	72

Table F-1. Registered protocols from studies included in Key Question 1, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Trial of Mifepristone for Fibroids NCT00133705 (See Ref ID: 3407)	**Drug**: Mifepristone	University of Rochester Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Other, NIH	7/1/2003; 6/1/2010 Completed, Has Results	70
High Intensity Focused Ultrasound Ablation Virus Myomectomy to Treat Uterine Fibroids NCT01239641 (See Ref ID: 793; 804)	**Procedure**: High intensity focused ultrasound	Chongqing Medical University Other	9/1/2010; 7/1/2013 Recruiting, No Results Available	220
Emmy Trial: Uterine Artery Embolization (UAE) Versus Hysterectomy for Uterine Fibroids NCT00100191 (See Ref ID: 815; 1986; 2759; 2971; 3120; 3175; 3192; 3678; 3721; 3819)	**Procedure**: Embolization **Procedure**: Hysterectomy	The Netherlands Organisation for Health Research and Development Boston Scientific Corporation Other, Industry	2/1/2002; 4/1/2006 Completed, No Results Available	120
A Prospective Study Comparing Contour SE™ Microspheres to Embosphere® Microspheres for Treating Symptomatic Uterine Fibroids With Uterine Fibroid Embolization (UFE) NCT00628901 (See Ref ID: 347)	**Procedure**: Embolization **Device**: Contour SE™ Microspheres **Device**: Embosphere® Microspheres	Boston Scientific Corporation Industry	1/1/2006; 1/1/2011 Completed, Has Results	60
Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions NCT01750008 (See Ref ID: 392)	**Procedure**: Global Fibroid Ablation **Procedure**: Myomectomy	Halt Medical, Inc. Industry	11/1/2012; 9/1/2018 Active, Not Recruiting, No Results Available	50
Comparison Study in the Treatment of Uterine Fibroids Uterine Fibroid Embolization Using BeadBlock™ Embolic Agent NCT00361036 (See Ref ID: 1806)	**Device**: Uterine fibroid embolization BeadBlock™ **Device**: Uterine fibroid embolization Embosphere®	Worthington-Kirsch, Robert L., M.D. Terumo Medical Corporation Biocompatibles UK Ltd Other, Industry	8/1/2006; 3/1/2010 Completed, No Results Available	44

Table F-1. Registered protocols from studies included in Key Question 1, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Laparoscopic Occlusion of Uterine Vessels Compared to Uterine Fibroid Embolization for Treatment of Uterine Fibroids NCT00277680 (See Ref ID: 2303; 3382)	**Procedure**: Laparoscopic bilateral occlusion of uterine artery **Procedure**: Radiological embolization (UFE)	Ullevaal University Hospital Oslo University Hospital Other	12/1/2000; 4/1/2010 Active, Not Recruiting, No Results Available	60
Temporary Clipping of the Uterine Arteries During Laparoscopic Myomectomy NCT01530802 (See Ref ID: 1108)	**Procedure**: Clipping of uterine arteries during laparoscopic myomectomy	Charite University, Berlin, Germany Other	1/1/2007; 12/1/2009 Completed, No Results Available	166
Multicentre randomised controlled trial comparing uterine artery embolisation with surgical treatment for uterine fibroids ISRCTN23023665 (See Ref ID: 3365)	**Procedure**: Embolisation **Procedure**: Surgery	Greater Glasgow Health Board (North Glasgow University Hospitals Division) (UK) Government	1/11/2000; 1/09/2010 Completed, No Results Available	200
Magnetic Resonance-Guided Focused Ultrasound to Treat Uterine Fibroids: A Pilot Randomized, Placebo-Controlled Trial NCT01377519 (See Ref ID: 11180)	**Procedure**: MR Guided Focused Ultrasound **Procedure**: Placebo MR Guided Focused Ultrasound	University of California, San Francisco Other	6/1/2011; 12/1/2012 Completed, No Results Available	20
A Phase III, Randomized, Parallel Group, Double-blind, Double-dummy, Active Comparator-controlled, Multicenter Study to Assess the Efficacy and Safety of PGL4001 vs GnRH-agonist for Pre-operative Ttt of Symptomatic Uterine Myomas NCT00740831 (See Ref ID: 1278)	**Drug**: Ulipristal acetate (PGL4001) **Drug**: Leuprorelin	PregLem SA Industry	8/1/2008; 6/1/2010 Completed, Has Results	301
A Phase III, Randomized, Parallel Group, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy and Safety of PGL4001 (Ulipristal) Versus Placebo for Pre-Operative Treatment of Symptomatic Uterine Myomas NCT00755755 (See Ref ID: 1279)	**Drug**: Ulipristal acetate (PGL4001) **Drug**: Placebo	PregLem SA Industry	10/1/2008; 8/1/2010 Completed, Has Results	241

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Evaluation of a Hysteroscopic Morcellator in Hysteroscopic Treatment of Submucosal Fibroids NCT02406898	**Device**: Morcellator uterine system (MH) Karl Storz, Tuttligen-Germany	Assistance Publique Hopitaux De Marseille Other	4/1/2015; 3/1/2018 Not Yet Recruiting, No Results Available	60
Safety and Efficacy in Premenopausal Women With Heavy Menstrual Bleeding (HMB) Associated With Uterine Fibroids (UF) NCT01817530	**Drug**: Elagolix, elagolix sodium	AbbVie Industry	1/1/2013; 12/1/2015 Active, Not Recruiting, No Results Available	520
A Study of the Safety and Efficacy of Intermittent Ulipristal Treatment of Abnormal Uterine Bleeding Associated With Leiomyomas NCT02147158	**Drug**: Ulipristal acetate (UPA) 5 mg **Drug**: Ulipristal acetate (UPA) 10 mg **Drug**: Placebo	Watson Pharmaceuticals Industry	1/1/2014; 12/1/2015 Recruiting, No Results Available	400
Bay1002670, Fibroids, Safety and Efficacy NCT02131662	**Drug**: BAY1002670	Bayer Industry	5/1/2014; 3/1/2016 Recruiting, No Results Available	300
Ulipristal Acetate 10 mg and Assisted Reproduction NCT02425878	**Drug**: Ulipristal Acetate **Drug**: Placebo	Instituto Valenciano de Infertilidad, IVI VALENCIA Other	5/1/2015; Null Not Yet Recruiting, No Results Available	282
Safety and Efficacy Pre-Menopausal Women With Heavy Uterine Bleeding and Uterine Fibroids NCT01441635	**Drug**: Elagolix, elagolix sodium	AbbVie Industry	9/1/2011; 2/1/2014 Completed, No Results Available	271
A Study of the Efficacy and Safety of a Single Ulipristal Treatment Course for the Treatment of Abnormal Uterine Bleeding Associated With Leiomyomas NCT02147197	**Drug**: Ulipristal acetate 5 mg **Drug**: Ulipristal acetate 10 mg **Drug**: Placebo	Watson Pharmaceuticals Industry	4/1/2014; 3/1/2015 Recruiting, No Results Available	150
Ulipristal Acetate Versus GnRH Analogue Treatment Before Hysteroscopic Resection of Uterine Leiomyoma NCT02361879	**Drug**: Ulipristal acetate **Drug**: Leuprolide acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	146
Ulipristal Acetate Versus GnRH Analogue and Myometrial Preservation	**Drug**: Ulipristal acetate **Drug**: Leuprolide acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	110

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
NCT02357563				

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Ulipristal vs. GnRHa Prior to Laparoscopic Myomectomy NCT02288130	**Drug**: GnRHa **Drug**: Ulipristal	VU University Medical Center Other	12/1/2014; 9/1/2016 Recruiting, No Results Available	100
PGL4001 Efficacy Assessment in Reduction of Symptoms Due to Uterine Leiomyomata NCT01642472	**Drug**: Ulipristal acetate - open label	PregLem SA Industry	7/1/2012; 11/1/2014 Active, Not Recruiting, No Results Available	90
Study of Tumor-shrinking Decoction (TSD) to Treat Symptomatic Uterine Fibroids NCT02189083	**Drug**: TSD	The University of Hong Kong Other	5/1/2014; 2/1/2016 Recruiting, No Results Available	78
The Effect of Ulipristal Acetate (UPA) on Women Ovarian Reserve NCT02361892	**Drug**: Ulipristal acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	73
Study of the Efficacy of Dienogest in the Treatment of Uterine Leiomyomas When Compared to Desogestrel and Goserelin NCT01738724	**Drug**: Dienogest **Drug**: Goserelin **Drug**: Desogestrel	University of Sao Paulo Other	1/1/2013; 12/1/2013 Not Yet Recruiting, No Results Available	63
GnRH Agonist Pretreatment in Hysteroscopic Myomectomy NCT01873378	**Drug**: Triptorelin 3.75 mg	Azienda Ospedaliera S. Maria della Misericordia Other	1/1/2013; Null Recruiting, No Results Available	60
Intra-arterial Lidocaine for Pain Control Post Uterine Fibroid Embolization NCT02293447	**Drug**: Lidocaine per-embolization **Drug**: Lidocaine post-embolization	University Health Network, Toronto Other	11/1/2014; 4/1/2016 Recruiting, No Results Available	60
Vasopressin Versus Epinephrine in Myomectomy NCT01861015	**Drug**: Epinephrine **Drug**: Vasopressin	CHA University Other	5/1/2013; 4/1/2016 Recruiting, No Results Available	60
Misoprostol for Reduction of Blood Loss During Fibroid Surgery NCT02209545	**Drug**: Misoprostol **Drug**: Placebo	Northwestern University Other	10/1/2014; 5/1/2018 Recruiting, No Results Available	50

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
A Multi-Center, Parallel Design, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of 6 and 12 mg ProellexÂ® (Telapristone Acetate) Administered Orally in the Treatment of Premenopausal Women With Confirmed Symptomatic Uterine Fibroids NCT02301897	**Drug**: Telapristone Acetate **Drug**: Placebo	Repros Therapeutics Inc. Industry	12/1/2014; 12/1/2016 Recruiting, No Results Available	45
A Phase 2, Study to Evaluate the Safety and Efficacy ProellexÂ® (Telapristone Acetate) Administered Vaginally in the Treatment of Uterine Fibroids NCT02323646	**Drug**: Telapristone Acetate (ProellexÂ®)	Repros Therapeutics Inc. Industry	12/1/2014; 12/1/2016 Recruiting, No Results Available	45
Ulipristal Acetate for the Preoperative Management of Hypoechoic Cellular Leiomyomas NCT02361905	**Drug**: Ulipristal acetate **Drug**: Leuprolide acetate	University Magna Graecia Other	2/1/2015; 9/1/2017 Recruiting, No Results Available	42
Clinical Trial of Uterine Artery Embolization for Uterine Leiomyoma NCT00821275	**Procedure**: Interventional radiological or surgical management	Sun Yat-sen University Other	1/1/2008; 12/1/2018 Enrolling By Invitation, No Results Available	900
Post Market TRUST - U.S.A. Study NCT02163525	**Procedure**: Global Fibroid Ablation (GFA) **Procedure**: Abdominal or Laparoscopic Myomectomy **Procedure**: Uterine Artery Embolization (UAE)	Halt Medical, Inc. Industry	6/1/2014; 12/1/2021 Recruiting, No Results Available	300
Post Market TRUST Study NCT01563783	**Procedure**: Global Fibroid Ablation (GFA) **Procedure**: Abdominal or Laparoscopic Myomectomy **Procedure**: Uterine Artery Embolization	Halt Medical, Inc. Industry	12/1/2012; 12/1/2019 Recruiting, No Results Available	260

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
	(UAE)			

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Sonalleve Fibroid Ablation Pivotal Clinical Trial for MR-HIFU of Uterine Fibroids NCT01504308	**Device**: MRgHIFU system	Philips Healthcare Industry	5/1/2012; 4/1/2019 Active, Not Recruiting, No Results Available	224
High Intensity Focused Ultrasound Ablation Virus Myomectomy to Treat Uterine Fibroids NCT01239641 (See Ref ID: 793; 804)	**Procedure**: High intensity focused ultrasound	Chongqing Medical University Other	9/1/2010; 7/1/2013 Recruiting, No Results Available	220
Uterine Artery Embolization (UAE) Versus High-Intensity-Focused-Ultrasound (HIFU) for Treatment of Uterine Fibroids NCT01834703	**Procedure**: Embolization **Procedure**: HIFU	Chinese University of Hong Kong Prince of Wales Hospital, Shatin, Hong Kong Other	5/1/2009; Null Recruiting, No Results Available	200
The FIRSTT: Comparing MRgFUS (MR-guided Focused Ultrasound) Versus UAE (Uterine Artery Embolization) for Uterine Fibroids NCT00995878	**Procedure**: Focused ultrasound (MRgFUS) **Procedure**: Uterine artery embolization (UAE)	Mayo Clinic Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Other, NIH	10/1/2009; 12/1/2015 Active, Not Recruiting, No Results Available	180
Sonography Guided Transcervical Ablation of Uterine Fibroids NCT02228174	**Device**: Intrauterine Ultrasound-Guided Radiofrequency Ablation System	Gynesonics Industry	10/1/2014; 4/1/2019 Recruiting, No Results Available	147
Laparoscopic Radiofrequency Ablation (RFA) of Symptomatic Uterine Fibroids NCT00874029	**Device**: Halt **Procedure**	Halt Medical, Inc Industry	3/1/2009; 3/1/2014 Completed, Has Results	137
China Clinical Trial for Therapeutic MR-HIFU Ablation of Uterine Fibroids NCT01588899	**Device**: MRgHIFU system	Philips Healthcare Industry	5/1/2012; 6/1/2015 Active, Not Recruiting, No Results Available	110
ExAblate UF V2 System for the Treatment of Symptomatic Uterine Fibroids	**Device**: ExAblate Treatment UF V2	InSightec Industry	5/1/2012; 4/1/2015 Recruiting, No	106

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
NCT01285960			Results Available	

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Diffusion -and Perfusion Weighted MRI for Response Prediction of Symptomatic Leiomyomas Following Uterine Artery Embolization NCT01514617	**Procedure**: Diffusion - and perfusion weighted MRI including IV contrast agent injection	Universitaire Ziekenhuizen Leuven Other	1/1/2012; 12/1/2016 Recruiting, No Results Available	100
Uterine Leiomyoma Treatment With Radiofrequency Ablation NCT01840124	**Procedure**: Radiofrequency ablation	University of California Other	7/1/2013; Null Recruiting, No Results Available	100
Clinical Study of the Mirabilis High-Intensity Focused Ultrasound System for Non-Invasive Treatment of Uterine Fibroids NCT01946178	**Device**: Mirabilis High-Intensity Focused Ultrasound Treatment System	Mirabilis Medica, Inc. Industry	1/1/2011; Null Active, Not Recruiting, No Results Available	80
Uterine Fibroid Embolization-Long Term Follow up and Technical Perspectives NCT01852734	**Procedure**: Embolization	Odense University Hospital Other	11/1/2013; 11/1/2015 Recruiting, No Results Available	60
Laparoscopic Uterine Sparing Techniques Outcomes and Reinterventions NCT01750008 (See Ref ID: 392)	**Procedure**: Global Fibroid Ablation **Procedure**: Myomectomy	Halt Medical, Inc. Industry	11/1/2012; 9/1/2018 Active, Not Recruiting, No Results Available	50
Post Market Evaluation of Acessa With TAG NCT01842789	**Device**: Acessa **Procedure**	Halt Medical, Inc. Industry	4/1/2013; 12/1/2015 Recruiting, No Results Available	50
Factors Influencing Volumetric MR-HIFU Ablation of Uterine Fibroids NCT02386137	**Device**: Contrast-enhancement ultrasound with Sonovue	University Hospital, Bordeaux Other	3/1/2015; 3/1/2017 Not Yet Recruiting, No Results Available	40
Laparoscopic Cryoablation of Uterine Fibroids NCT01735812	**Device**: IceSense3 system	IceCure Medical Ltd. Industry	12/1/2012; Null Recruiting, No Results Available	30
Clinical Test of the MRgHIFU System on Uterine Fibroids NCT02283502	**Device**: MRgHIFU system	Chin-Jung Wang National Health Research	9/1/2014; 5/1/2015 Recruiting, No Results Available	20

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
		Institutes, Taiwan Chang Gung Memorial Hospital Other		

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Safety and Effectiveness of OCL 503 in the Treatment of Women With Leiomyomata NCT02410018	**Device**: OCL 503 (uterine artery embolization)	IMBiotechnologies Ltd. Industry	4/1/2015; 9/1/2015 Recruiting, No Results Available	10
Far Infrared Radiation Treatment for Uterine Fibroids NCT00574418	**Procedure**: Far Infrared Radiation (5Î¼m to 20Î¼m wavelength)	GAAD Medical Research Institute Inc. Other	1/1/2006; 9/1/2008 Active, Not Recruiting, No Results Available	2
Hysteroscopic Monopolar and Bipolar Resection NCT00323999	**Procedure**: Hysteroscopic resection of fibroids, polyps and endometrium	Ullevaal University Hospital Other	12/1/2004; 12/1/2007 Recruiting, No Results Available	Null
MyoSure Hysteroscopic Tissue Removal System Registry Study NCT01369758	**Device**: MyoSure Tissue Removal System	Hologic, Inc. Industry	11/1/2010; 11/1/2013 Active, not recruiting	600
Study of Conventional Laparoscopic Hysterectomy Versus Robot-Assisted Laparoscopic Hysterectomy at a Teaching Institution NCT01581905	**Procedure**: Conventional Laparoscopic Hysterectomy (LH) **Procedure**: Robot Assisted Hysterectomy	Milton S. Hershey Medical Center Other	3/1/2012; 6/1/2013 Recruiting, No Results Available	400
Single Incision Laparoscopic Surgery (SILS) Versus Conventional Laparoscopic Hysterectomy NCT01483417	**Procedure**: Single incision Laparoscopic hysterectomy **Procedure**: Conventional laparoscopic hysterectomy	Samsung Medical Center Other	12/1/2011; 3/1/2013 Recruiting, No Results Available	240
Minimally Invasive Benign Hysterectomy NCT01865929	**Procedure**: Vaginal or laparoscopic hysterectomy	Region Skane Other	1/1/2010; 12/1/2015 Recruiting, No Results Available	200
Single-port Access Laparoscopic-assisted Vaginal Hysterectomy	**Procedure**: Single-port LAVH	Taipei Veterans General Hospital, Taiwan	10/1/2009; 10/1/2010 Recruiting, No	100

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
NCT01048931		National Yang Ming University Other	Results Available	

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Vaginal vs. Laparoscopic Hysterectomy NCT02059954	**Procedure**: Hysterectomy	Medical University of Graz Austrian Urogynecology Working Group (AUWG) Other	1/1/2014; 7/1/2015 Recruiting, No Results Available	100
HOME Study: Hysteroscopic Office Myomectomy Evaluation NCT01152112	**Device**: Myomectomy	Hologic, Inc. Industry	6/1/2010; 3/1/2013 Active, Not Recruiting, No Results Available	86
Barbed Suture in Single-port Laparoscopic Myomectomy NCT01984632	**Procedure**: Single-port laparoscopic myomectomy **Procedure**: Multi-port laparoscopic myomectomy	CHA University Other	11/1/2013; 11/1/2015 Recruiting, No Results Available	80
Barbed Suture Versus Traditional Suture Material for Laparoscopic Myomectomy NCT01347385	**Procedure**: Laparoscopic myomectomy with unidirectional barbed suture **Procedure**: Traditional suture material	Sunnybrook Health Sciences Centre Other	1/1/2012; Null Not Yet Recruiting, No Results Available	80
Surgical Success After Laparoscopic vs Abdominal Hysterectomy NCT01793584	**Procedure**: Laparoscopic hysterectomy **Procedure**: Abdominal hysterectomy	University of Texas Southwestern Medical Center Other	2/1/2013; 6/1/2016 Recruiting, No Results Available	75
Laparoscopic Occlusion of Uterine Vessels Compared to Uterine Fibroid Embolization for Treatment of Uterine Fibroids NCT00277680 (See Ref ID: 2303; 3382)	**Procedure**: Laparoscopic bilateral occlusion of uterine artery **Procedure**: Radiological embolization (UFE)	Ullevaal University Hospital Oslo University Hospital Other	12/1/2000; 4/1/2010 Active, Not Recruiting, No Results Available	60
Single or Triple Uterine	**Procedure**: Single	RagÄ±p Atakan Al	3/1/2015; 5/1/2017	60

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Tourniquet at Myomectomy NCT02392585	tourniquet **Procedure**: Triple tourniquet	Ataturk University Other	Recruiting, No Results Available	
Use of v Care in Abdominal Hysterectomy NCT02371811	**Device**: Uterine manipulator (v care)	Ain Shams Maternity Hospital Other	2/1/2015; 8/1/2015 Recruiting, No Results Available	60

Table F-2. Registered protocols for ongoing studies of interventions for uterine fibroids, continued

Study Name NCT (Related Publication)	Intervention(s)	Sponsor Funding Type	Start Date; Completion Date Study Status	Estimated Enrollment
Laparoscopic Myomectomy Using Barbed or Conventional Sutures NCT02166411	**Procedure**: Myomectomy using barbed sutures **Procedure**: Myomectomy using conventional sutures	Cairo University Other	12/1/2013; 12/1/2015 Recruiting, No Results Available	54
Influence of Aromatase Inhibitors and GnRH Analogs to Treat Uterine Leiomyoma by Vaginal Hysterectomy NCT01280045	**Procedure**: Vaginal hysterectomy	University of Sao Paulo Other	1/1/2011; 1/1/2015 Recruiting, No Results Available	50
Assessment of the Manageability and Safety of ADBLOCK Adhesion Barrier System in Laparoscopic Gynaecological Surgery NCT01745432	**Device**: ADBLOCK	Terumo Europe N.V. Industry	8/1/2012; 11/1/2014 Active, Not Recruiting, No Results Available	30

Appendix G. Study Outcome Data

Outcome Data for Key Question 1 and Key Question 2

We extracted intermediate and final health outcomes from all studies included for KQ 1. We recorded data on 414 discreet outcome measures representing 19 prespecified outcome categories: symptom status; desired fertility status; pregnancy outcomes; sexual function; fibroid characteristics; fibroid recurrence; subsequent treatment for fibroids; satisfaction with outcomes; transfusion; unplanned hysterectomy; perforation of organs; cancer dissemination; other serious adverse events; technical success; conversion to another procedure; estimated intraoperative blood loss; length of stay; readmission / reoperation; return to usual activities. We report additional data on effectiveness outcomes and harms not represented in the main report

All data are publicly available in the Systematic Review Data Repository (SRDR).

Effectiveness Outcomes Data

Table G-1. Change in uterine volume following uterine artery embolization

Author, Year	Embolic Agent	N (Imaging)	Followup, months	Baseline; Followup cm^3	Change cm^3 mean ± SD or Percent
Macnaught G et al. (2015)[1]	Embospheres	10 (MRI)	6	NR NR	↓396.5 p=<0.01
Macnaught G et al. (2015)[1]	Gelfoam	10 (MRI)	6	NR NR	↓117.1 p=NS
Wang X et al. (2015)[2]	200 µm PVA particles	65 (US)	6	290.78 ± 14.88 168.24 ± 12.87	↓122.54 p<0.05
Wang X et al. (2015)[2]	500 µm PVA particles	65 (US)	6	291.73 ± 16.44 123.76 ± 13.99	↓167.97 p<0.05
Shlansky-Goldberg R et al. (2014)[3]	TAG microspheres	28 (MRI)	3	NR 909.1 ± 610.8	↓557.8 ± 1101.1 p=NR
Shlansky-Goldberg R et al. (2014)[3]	PVA particles	28 (MRI)	3	NR 1058.0 ± 613.4	↓436.4 ± 352.1 p=NR
Song Y et al. (2013)[4]	Gelatin sponge particles	30 (MRI)	3	960.27 ± 548.1 498.61 ± 301.74	NR
Song Y et al. (2013)[4]	PVA particles	30 (MRI)	3	934.47 ± 320.78 534.12 ± 193.67	NR
Yu S et al. (2011)[5]	PVA	30 (NA)	NA	NR NR	NR
Yu S et al. (2011)[5]	TAG microspheres	30 (NA)	NA	NR NR	NR
Worthington-Kirsch R et al. (2011)[6]	TAG microspheres	24 (MRI)	6	650.0 ± 180.0 NR	NR[a]
Worthington-Kirsch R et al. (2011)[6]	PVA	22 (MRI)	6	540.0 ± 90.0 NR	NR[a]
Bilhim T et al. (2011)[7]	PVA particles, large	76 (MRI)	6	482.0 ± NR 266.0 ± NR	↓44.8% p=NR
Bilhim T et al. (2011)[7]	PVA particles, small	77 (MRI)	6	515.0 ± NR 314.0 ± NR	↓39.0% p=NR
Siskin G et al. (2008)[8]	PVA microspheres	27 (MRI)	1	564.0 ± NR 470.7 ± NR	↓16.5% p=NR
Siskin G et al.	TAG	26	1	611.6 ± NR	↓12.6%

Author, Year	Embolic Agent	N (Imaging)	Followup, months	Baseline; Followup cm^3	Change cm^3 mean ± SD or Percent
(2008)[8]	microspheres	(MRI)		534.3 ± NR	p=NR
Vilos G et al. (2006)[9]	PVA particles	10 (US)	12	476.6 ± 279.3 200.6 ± 74.1	↓58.0% p=NR
Vilos G et al. (2006)[9]	PVA plus goserelin	12 (US)	12	556.4 ± 271.8 305.1 ± 141.3	↓45.0% p=NR
Spies J et al. (2005)[10]	PVA particles	17 (MRI)	3	510.5 ± 314.8 NR	↓16.4 ± 23.5% p=NR
Spies J et al. (2005)[10]	TAG microspheres	19 (MRI)	3	618.9 ± 305.1 NR	↓27.4 ± 22.4% p=NR
Spies J et al. (2004)[11]	PVA particles	46 (MRI)	3	603.9 ± 343.3 NR	↓30.2 ± 17.3% p=NR
Spies J et al. (2004)[11]	TAG microspheres	54 (MRI)	3	648.7 ± 326.7 NR	↓35.1 ± 16.7% p=NR
Pinto I et al. (2003)[12]	PVA particles	38 (NA)	NA	NR NR	NR
Volkers N et al. (2007)[13]	PVA particles	87 (US)	1.5	471.9 ± 450 268.0 ± 209.0†	↓20.9% p<0.001
Volkers N et al. (2007)[13]	PVA particles	66 (US)	6	NR 235.3 ± 204.0	↓30.9% p<0.001
Volkers N et al. (2007)[13]	PVA particles	62 (US)	12	NR 201.2 ±198.0	↓44.3% p<0.001
Volkers N et al. (2007)[13]	PVA particles	62 (US)	24	NR 170.2 ± 135.0	↓48.2% p<0.001
Ananthakrishnan G et al. (2013)[14]	NR	85 (MRI)	6	670.0 ± 503.0 422.0 ± 353.0*	↓34.0% p=NR
Ananthakrishnan G et al. (2013)[14]	NR	68 (MRI)	60	NR 292.0 ± 287.0	↓53.0% p=NR

Notes: Uterine volume not reported in the following: Yu SC et al. (2011);5 Mara M et al. (2008);15 Pinto I et al. (2003);12
*n=84; †n=69; Abbreviations: MRI= magnetic resonance imaging; nPVA= non spherical polyvinyl alcohol; NR= not reported; PVA= polyvinyl alcohol; SPVA= spherical polyvinyl alcohol; TAG= tris-acryl gelatin; TAGM= tris-acryl gelatin microspheres; UAE= uterine artery embolization; US= ultrasound

Table G-2. Change in bleeding characteristics and hemoglobin with ulipristal acetate

Author, Year	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Measure	Baseline Followup	Change
Donnez J et al. (2015)[16, 17] PEARL IV	5	228	5.5	14	Amenorrhea at end of both treatment cycles	NR 122/197 (62%)	NR
Donnez J et al. (2015)[16, 17] PEARL IV	5	228	11	14	Amenorrhea at end of four treatment cycles	NR 94/150 (63%)	NR
Donnez J et al. (2015)[16, 17] PEARL IV	10	223	5.5	14	Amenorrhea at end of both treatment cycles	NR 136/187 (73%)	NR
Donnez J et al. (2015)[16, 17] PEARL IV	10	223	11	14	Amenorrhea at end of four treatment cycles	NR 106/147 (72%)	NR
Donnez J et al. (2015)[16, 17] PEARL IV	5	218	11	14	PBAC score Median (IQR)	224 (148, 357) After	After cycle 1 ↓87 (↓167, ↑13)

Author, Year	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Measure	Baseline Followup	Change
						cycle 1 123 (45, 313) After cycle 2 92 (44, 253) After cycle 4 77.5 (NR)	After cycle 2 ↓95 (↓216, ↑9)
Donnez J et al. (2015)[16, 17] PEARL IV	10	214	11	14	PBAC score Median (IQR)	215 (151, 373) After cycle 1 129 (56, 285) After cycle 2 99 (37, 202) After cycle 4 76 (NR)	After cycle 1 ↓85 (↓209, ↓12) After cycle 2 ↓110 (↓236, ↓50)
Donnez J et al. (2014)[18] PEARL III	10	199	2.5	5.5	Hemoglobin (g/dl)	12.5 ± 1.8 NR	NR
Donnez J et al. (2014)[18] PEARL III	10	201	2.5	5.5	PBAC score Median (IQR)	216 (126, 376) 31 (11,100)	↓120 (↓255,↓45)
Donnez J et al. (2012)[19] PEARL I	5 + iron supplementation	95	3	3	Hemoglobin (g/dl)	9.3 ± 1.5 13.5 ± 1.3	↑4.25 ± 1.9 p<0.001
Donnez J et al. (2012)[19]	5 + iron supplementation	95	3	3	PBAC score Median (IQR)	386 (235, 627) 0 (0, 5)	↓329 (↓571,↓205)
Donnez J et al. (2012)[19]	5 + iron supplementation	50[a]	8.7	8.7	PBAC score Median (IQR)	321 (219, 536) 234 (102, 450)	↓81 (↓195, ↑27)
Donnez J et al. (2012)[19]	5 + iron supplementation	95	3	3	PBAC score <75	NR 86/94 (91%)	NR
Donnez J et al. (2012)[19]	5 + iron supplementation	95	3	3	PBAC score ≤ 2 (amenorrhea)	NR 69/94 (73%)	NR
Donnez J et al. (2012)[19]	10 + iron supplementation	94	3	3	Hemoglobin (g/dl)	9.5 ± 1.6 13.6 ± 1.2	↑4.2 ± 1.8 p<0.001
Donnez J et al. (2012)[19]	10 + iron supplementation	94	3	3	PBAC score Median (IQR)	330 (235, 537) 0 (0, 0)	↓326 (↓527,↓226)
Donnez J et al. (2012)[19]	10 + iron supplementation	41[a]	8.7	8.7	PBAC score Median (IQR)	272 (212, 433) 174 (46, 321)	↓161 (↓256,↓ ↑13)

Author, Year	Dose, mg	N	Treatment Months	Last Followup Months	Bleeding Measure	Baseline Followup	Change
Donnez J et al. (2012)[19]	10 + iron supplementation	94	3	3	PBAC score <75	NR 86/93 (92%)	NR
Donnez J et al. (2012)[19]	10 + iron supplementation	94	3	3	PBAC score ≤ 2 (amenorrhea)	NR 76/93 (82%)	NR
Donnez J et al. (2012)[20] PEARL II	5	93	3	3	Hemoglobin (g/dl)	12.4 ± 1.6 12.8 ± 1.4	↑0.4 p=NR
Donnez J et al. (2012)[20]	5	93	3	3	PBAC score Median (IQR)	286 (190, 457) 0 (0, 2)	↓268 (↓412,↓172)
Donnez J et al. (2012)[20]	5	43[b]	8.7	8.7	PBAC score Median (IQR)	299 (213, 391) 236 (143, 387)	↓73 (↓242, ↑65)
Donnez J et al. (2012)[20]	5	93	3	3	PBAC score < 75	NR 84/93 (90%)	NR
Donnez J et al. (2012)[20]	5	93	3	3	PBAC score ≤ 2 (amenorrhea)	NR 70/93 (75%)	NR
Donnez J et al. (2012)[20]	10	95	3	3	Hemoglobin (g/dl)	12.4 ± 1.6 12.9 ± 1.2	↑0.5 p=NR
Donnez J et al. (2012)[20]	10	95	3	3	PBAC score Median (IQR)	271 (183, 392) 0 (0, 0)	↓268 (↓387,↓179)
Donnez J et al. (2012)[20]	10	45[b]	8.7	8.7	PBAC score Median (IQR)	244 (173, 351) 141 (103, 311)	↓96 (↓155,↓62)
Donnez J et al. (2012)[20]	10	95	3	3	PBAC score < 75	NR 93/95 (98%)	NR
Donnez J et al. (2012)[20]	10	95	3	3	PBAC score ≤ 2 (amenorrhea	NR 85/95 (89%)	NR
Levens ED et al. (2008)[21]	10 or 20	12	3	3	Hemoglobin (g/dl)	NR NR	↓0.3 p=NS

Notes: A Subset from PEARL I study who did not have surgery following initial 3 months of treatment b Subset from PEARL II study who did not have surgery following initial 3 months of treatment; Abbreviations: g/dl= Grams per deciliter; IQR= interquartile; mg= milligrams; n= number; NR= not reported; NS= not significant; PBAC= pictorial blood loss assessment chart

Harms and Serious Adverse Event Data

We extracted the incidence of harms and serious adverse events reported in the studies included in KQ 1. We limited presentation of harms in the tables below to a prespecified list (transfusion; unplanned hysterectomy; organ perforation; cancer dissemination; ovarian failure; misdirected embolization; and other serious AE including death, life-threatening complication, deep vein thrombosis, pulmonary embolism, cardiovascular complication, pulmonary complication, uterine artery dissection) and recorded the frequency, including "0", during or after the intervention and at last followup. We recorded the rate as the count of patients with the

event per the number of patients available for analysis and treated per protocol unless study authors indicated that intention to treat was used to calculate the incidence of harms. If the count of harms was reported during or after treatment and at last followup and was cumulative, we recorded the count only in the interval in which the event occurred. We organized the tables by intervention category (i.e., medical interventions, procedural interventions, and surgical interventions). We report these data by arm and do not include comparative rates of harms within studies as studies were not designed to capture harms adequately (i.e., studies were not powered to detect differences in harms or did not include sufficient duration of followup). For this same reason, we did not assess the quality of harms reporting within these studies. We report the incidence of transfusion separately from other harms, as transfusion is a common risk of surgical or procedural removal of fibroids (or the uterus) and is of clinical significance in a population at increased risk of anemia due to excessive uterine bleeding caused by leiomyoma. See SRDR for all harms extracted.

Medical Interventions

Table G-3. Harms reported at the end of medical treatment for uterine fibroids

Author, Year	Intervention	Harm	EOT Incidence	%
Donnez J et al. (2012)[22]	ulipristal acetate, 5 mg	uterine hemorrhage	0/95	0
	ulipristal acetate, 10 mg	uterine hemorrhage	1/98	1
	ulipristal acetate, 5 mg	ovarian hemorrhage	1/95	1
	ulipristal acetate, 10 mg	ovarian hemorrhage	0/98	0
Donnez J et al. (2015)[16]	ulipristal, 10mg	fibroid expulsion, partial[a]	1/205	0.5
		arteriospasm, coronary	1/205	0.5
		obstruction, small intestine	1/205	0.5
	ulipristal, 5mg	fibroid expulsion, partial	0/215	0
		arteriospasm, coronary	0/215	0
		obstruction, small intestine	0/215	0
Eder S et al. (2013)[23]	tranexamic acid, 3.9mg	adverse event, treatment emergent	4/232	1.7
Fedele L et al. (1991)[24]	buserelin, intranasal	transfusion	0/15	0
Jirecek S et al. (2004)[25]	raloxifene, 180mg	adverse event, serious (not defined)	0/13	0
Palomba S et al. (2002)[22]	leuprolide plus placebo	adverse event, serious[b]	0/50	0
	leuprolide plus raloxifene	adverse event, serious[b]	0/50	0

Notes: [a] assessed as possibly related to intervention by study investigators; [b] death, overdose, diagnosis of cancer, or any life-threatening, permanently disabling or requiring hospitalization.

Procedural Interventions

Table G-4. Harms reported during or after procedural intervention for uterine fibroids

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
Bilhim T et al. (2011)[7]	UAE with PVA particles, large	complication, major	1/80	ND	ND	ND
	UAE with PVA particles, small	complication, major	2/80	ND	ND	ND
	uterine artery occlusion, laparoscopic	claudication, buttock	1/29	3.5	ND	ND
		embolism, pulmonary	1/29	3.5	ND	ND
	UAE	fibroid expulsion	5/29	17.2	ND	ND

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
		claudication, buttock	0/29	0	ND	ND
		embolism, pulmonary	0/29	0	ND	ND
Hehenkamp WJ et al. (2005)[26]	UAE	sepsis	0/81	0	1/81	1.2
		embolism, pulmonary	1/81	1.2	0/81	0
Jacoby VL et al. (2016)	MrgFUS	adverse event, serious	0/13	0	ND	ND
Jiang N et al. (2014)[27]	HIFU plus CEUS	complication, major	0/40	0	ND	ND
Jun F et al. (2012)[28]	UAE	complication, major	ND	ND	0/62	0
Manyonda IT et al. (2012)[29]	UAE	sepsis, pelvic requiring IV antibiotics	ND	ND	1/67	1.5
Mara M et al. (2006)[30]	UAE	complication, life threatening	ND	ND	0/30	0
		complication, serious	ND	ND	3/30	10
		dissection, uterine artery	1/30	3.3	ND	ND
Meng X et al. (2010)[31]	HIFU	complication, major	0/50	0	0/50	0
Orsi F et al. (2015)[32]	HIFU	complication, major	0/16	0	ND	ND
	HIFU plus CEUS	complication, major	0/17	0	ND	ND
Pinto I et al. (2003)[12]	UAE	abscess, intraabdominal	ND	ND	0/40	0
		abscess, surgical wound	ND	ND	0/40	0
		dissection, uterine artery	2/40	5.0	ND	ND
		perforation, gluteal artery	2/40	5.0	ND	ND
		thrombosis, deep vein	ND	ND	1/40	2.0
Song YG et al. (2013)[4]	UAE with gelatin sponge particles	complication, major	ND	ND	0/30	0
	UAE with PVA	complication, major	ND	ND	0/30	0
Spies JB et al. (2004)[11]	UAE with PVA	embolism, pulmonary	0/46	ND	0/46	0
	UAE with TAG microspheres	embolism, pulmonary	1/54	ND	1/54	1.9
Wang X et al. (2013)[33]	HIFU	death	0/48	0	ND	ND
		complication, severe	0/48	0	ND	ND
Wang X et al. (2015)	PVA	bleeding	1/65	1.5	ND	ND
Yang Z et al. (2014)[34]	HIFU	complication, major SIR Class C-F	0/20	0	ND	ND
	HIFU plus ultrasound guided intramural ethanol injection	complication, major SIR Class C-F	0/20	0	ND	ND
Yu SC et al. (2011)[5]	UAE with PVA	complication, major SIR Class D	ND	ND	2/30	6.6
		ovarian failure, premature	ND	ND	3/29	11.0
	UAE with TAG microspheres	complication, major SIR Class D	ND	ND	0/30	0
		ovarian failure, premature	ND	ND	2/27	7.0

Abbreviations: CEUS=contrast enhanced ultrasound; EOT=end of treatment; LFU=last followup; UAE=uterine artery embolization; PVA=polyvinyl alcohol particles; TAG=tris-acryl gelatin particles; nPVA= ; HIFU=high intensity focused ultrasound; SIR=Society of Interventional Radiology

Surgical Interventions

Table G-5. Organ injury or perforation rates of surgical interventions for uterine fibroids

Author, Year	Intervention	Harm	Incidence*	%
Brucker SY et al. (2014)[35]	ablation, radiofrequency volumetric thermal	injury, bladder, ureter, bowel or vessels	0/25	0
	myomectomy	injury, bladder, ureter, bowel or vessels	0/25	0
Hahn M et al. (2015)	radiofrequency volumetric thermal ablation	uterine perforation, unplanned hysterectomy	1/26	3.8
Hwang JL et al. (2002)[36]	hysterectomy, abdominal	injury, major organ or vessel	0/30	0
	hysterectomy, laparoscopic assisted vaginal	injury, major organ or vessel	0/30	0
	hysterectomy, vaginal	injury, major organ or vessel	0/30	0
Kramer B et al. (2016)	radiofrequency volumetric thermal ablation	uterine perforation, unplanned pregnancy	ND	ND
Mara M et al. (2006)[30]	myomectomy	dissection, uterine artery	0/33	0
Pinto I et al. (2003)[12]	hysterectomy, abdominal	dissection, uterine artery	0/30	0
		perforation, gluteal artery	0/20	0
Seracchioli R et al. (2002)[37]	hysterectomy, abdominal	injury, bowel	0/62	0
	hysterectomy, total laparoscopic	injury, bowel	1/60	1.7
Silva-Filho AL et al. (2006)[38]	hysterectomy, total abdominal + hysterectomy, vaginal	laceration, bladder	1/60	1.7
Soysal ME et al. (2001)[39]	ablation, endometrial roller ball	injury, cervical	1/28	2.1
	ablation, endometrial thermal balloon	injury, cervical	0/45	0
Yen YK et al. (2002)[40]	hysterectomy, laparoscopic assisted vaginal	injury, urinary tract	0/32	0
	hysterectomy, laparoscopic assisted vaginal with bipolar coagulation of uterine vessels	injury, urinary tract	0/29	0

Notes: *Intraoperative or postoperative

Other Interventions

Table G-6. Harms reported at the end of other treatment for uterine fibroids

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
Nik Hazlina N et al. (2005)[7]	Herbal treatment	adverse event, serious	0/18	0	ND	ND
	GnRH agonist	adverse event, serious	0/17	0	ND	ND

Table G-7. Incidence of other serious harms reported during or after surgical intervention for uterine fibroids

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
Alessandri F et al. (2006)[41]	myomectomy, laparoscopic	peritonitis, acute diffuse	1/74	ND	ND	ND
Benassi L et al.	hysterectomy,					

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
(2002)[42]	abdominal	embolism, pulmonary	0/60	0	ND	ND
	hysterectomy, vaginal	embolism, pulmonary	0/60	0	ND	ND
Ferrari MM et al. (2000)[43]	hysterectomy, laparoscopic assisted vaginal	complication, major	0/31	0	ND	ND
	hysterectomy, vaginal	complication, major	0/31	0	ND	ND
Hehenkamp WJ et al. (2005)[26]	hysterectomy	sepsis	0/75	0	0/75	0
		embolism, pulmonary	1/75	1.3	0/75	0
Jun F et al. (2012)[28]	hysterectomy or myomectomy	complication, major	ND	ND	4/62	6.0
Manyonda IT et al. (2012)[29]	myomectomy	embolism, pulmonary	ND	ND	1/73	1.4
		sepsis, e. coli	ND	ND	1/73	1.4
Mara M et al. (2006)[30]	myomectomy	complication, life threatening	ND	ND	0/33	0
		complication, serious	ND	ND	1/33	3.0
Meng X et al. (2010)[31]	ablation, radiofrequency	complication, major	0/50	0	0/50	0
Pinto I et al. (2003)[12]	hysterectomy, abdominal	abscess, intraabdominal	ND	ND	1/20	5.0
		abscess, surgical wound	ND	ND	3/20	15.0
		thrombosis, deep vein	ND	ND	1/20	5.0
Rossetti A et al. (2001)[44]	myomectomy, abdominal	complication, major or late	0/40	0	ND	ND
	myomectomy, laparoscopic	complication, major or late	0/41	0	ND	ND
Seracchioli R et al. (2002)[37]	hysterectomy, abdominal	wound infection	6/62	9.7	ND	ND
	hysterectomy, total laparoscopic	wound infection	0/60	0	ND	ND
Sesti F et al. (2008)[45]	myomectomy, isobaric gasless laparoscopy	complication, major	0/50	0	ND	ND
	myomectomy, minilaparotomy	complication, major	0/50	0	ND	ND
Tan J et al. (2008)[46]	myomectomy, isobaric gasless laparoscopic assisted minilaparotomy	complication, intraoperative	0/26	0	ND	ND
	myomectomy, isobaric gasless laparoscopy	complication, intraoperative	0/26	0	ND	ND
Tan J et al. (2009)[47]	myomectomy, laparoscopic assisted minilaparotomy	complication, intraoperative	0/40	0	ND	ND
	myomectomy, minilaparotomy	complication, intraoperative	0/40	0	ND	ND
Vercellino G et al. (2012)[48]	myomectomy	hydronephrosis	1/86	1.2	ND	ND
		cardiac arrhythmia	1/86	1.2	ND	ND
		embolism, pulmonary	1/86	1.2	ND	ND
	myomectomy plus uterine artery clipping	hydronephrosis	1/80	1.3	ND	ND
		sepsis due to pyelonephritis	1/80	1.3	ND	ND
		hernia, trocar site	1/80	1.3	ND	ND

Author, Year	Intervention	Harm	EOT Incidence	%	LFU Incidence	%
		thrombosis, sinus venous	1/80	1.3	ND	ND
Wang X et al. (2013)[33]	myomectomy	death	0/52	0	ND	ND
		complication, severe	0/52	0	ND	ND

Abbreviations: EOT=end of treatment; LFU=last followup; ND=no data

Transfusion Rates

Table G-8. Transfusion rates during or following myomectomy

Author, Year	Myomectomy Approach	Incidence	%
Alessandri F et al. (2006)[41]	minilaparotomy	0/74	0
Alessandri F et al. (2006)[41]	laparoscopic	0/74	0
Ardovino M et al. (2013)[49]	laparoscopic standard	0/72	0
Ardovino M et al. (2013)[49]	laparoscopic mini-invasive	0/98	0
Table Cicinelli E et al. (2009)[50]	minilaparotomy	0/40	0
Cicinelli E et al. (2009)[50]	laparoscopic assisted minilaparotomy	0/40	0
Mara M et al. (2006)[30]	open or laparoscopic	2/33	6.1
Rossetti A et al. (2001)[44]	laparoscopic	0/41	0
Rossetti A et al. (2001)[44]	abdominal	0/40	0
Seracchioli R et al. (2000)[51]	laparoscopic	0/66	0
Seracchioli R et al. (2000)[51]	abdominal	3/65	4.6
Sesti F et al. (2008)[45]	minilaparotomy	0/50	0
Sesti F et al. (2008)[45]	isobaric gasless laparoscopy	0/50	0
Vercellino G et al. (2012)[48]	myomectomy plus uterine artery clipping	0/80	0
Vercellino G et al. (2012)[48]	laparoscopic	0/86	0
Wang JJ et al. (2011)[52]	gasless laparoscopic	0/194	0
Wang JJ et al. (2011)[52]	conventional laparoscopic	6/190	3.2
Wang X et al. (2013)[33]	myomectomy	1/52	1.9
Zhao F et al. (2011)[53]	loop ligation with vasopressin	0/35	0
Zhao F et al. (2011)[53]	myomectomy with vasopressin	1/35	2.8
Zhao F et al. (2011)[53]	myomectomy	5/35	14.3

N is the number analyzed. The number analyzed was equal to the number randomized in all arms. Transfusion counts are intraoperative or postoperative. Eight studies did not report whether transfusion was required[29, 35, 46, 47, 54-57]

Table G-9. Transfusion rates during or following hysterectomy

Author, Year	Hysterectomy Approach	Incidence	%
Benassi L et al. (2002)[42]	abdominal	4/59	6.8
Benassi L et al. (2002)[42]	vaginal	2/60	3.3
Ferrari MM et al. (2000)[43]	laparoscopic assisted vaginal	0/31	0
Ferrari MM et al. (2000)[43]	vaginal	1/31	3
Hehenkamp WJ et al. (2005)[26]	hysterectomy	10/89	13.3
Hwang JL et al. (2002)[36]	abdominal	1/30	3.3
Hwang JL et al. (2002)[36]	laparoscopic assisted vaginal	5/30	16.7
Hwang JL et al. (2002)[36]	vaginal	1/30	3.3
Pinto I et al. (2003)[12]	abdominal	4/20	20
Seracchioli R et al. (2002)[37]	abdominal	1/62	1.6
Seracchioli R et al. (2002)[37]	total laparoscopic	0/60	0
Sesti F et al. (2008)[58]	laparoscopic assisted vaginal	0/40	0
Sesti F et al. (2008)[58]	vaginal	0/40	0
Sesti F et al. (2014)[59]	laparoscopic assisted vaginal	2/36	5.6
Sesti F et al. (2014)[59]	total laparoscopic	0/36	0

Author, Year	Hysterectomy Approach	Incidence	%
Sesti F et al. (2014)[59]	vaginal	0/36	0
Silva-Filho AL et al. (2006)[38]	total abdominal + hysterectomy, vaginal*	1/60	1.7
Soriano D et al. (2001)[60]	laparoscopic assisted vaginal	1/40	2.7
Soriano D et al. (2001)[60]	vaginal	1/40	2.5
Yen YK et al. (2002)[40]	laparoscopic assisted vaginal	2/32	6.3

Table G-9. Transfusion rates during or following hysterectomy, continued

Author, Year	Hysterectomy Approach	Incidence	%
Yen YK et al. (2002)[40]	laparoscopic assisted vaginal with bipolar coagulation of uterine vessels	1/29	3.4

N is the number analyzed. The number analyzed was equal to the number randomized in all arms. *One study reported transfusion counts for both groups. Transfusion counts are intraoperative or postoperative. Three studies did not report if transfusion was required[55, 61,, 62]

Table G-10. Transfusion rates during or following uterine artery embolism, occlusion, or HIFU (5 studies)

Author, Year	UAE/ UAO	Incidence	%
Hehenkamp WJ et al. (2005)[26]	UAE	0/81	0
Mara M et al. (2006)[30]	UAE	0/30	0
Mara M et al. (2008)[15]	UAE	0/58	0
Pinto I et al. (2003)[12]	UAE	0/40	0
Wang X et al. (2013)[33]	HIFU	0/48	0

Abbreviations: UAE=uterine artery embolization; HIFU=high intensity focused ultrasound

Data for Key Questions 3 and 4

Table G-11. Data extracted for Key Question 3

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Adelusola KA, Ogunniyi SO (2001)[63]	Retrospective	177	NR	NR	0	0/177
Ahmed AA, Stachurski J, Aziz EA, et al. (2002)[64]	Prospective	10	NR	NR	0	0/10
Angle HS, Cohen SM, Hidlebaugh D (1995)[65]	Retrospective	41	41	NR	0	0/41
Balgobin S, Maldonado PA, Chin K, et al. (2016)[66]	Retrospective	1629	46	11.3	0	0/435
Banaczek Z, Sikora K, Lewandowska-Andruszuk I (2004)[67]	Retrospective	309	44.5	NR	0	0/309
Barbieri RL, Dilena M, Chumas J, et al. (1993)[68]	RCT	20	33.7	NR	0	0/15
Begum S, Khan S (2004)[69]	Prospective	91	NR	NR	0	0/91
Bernard JP, Rizk E, Camatte S, et al. (2001)[70]	Prospective	75	NR	NR	0	0/75
Betjes HE, Hanstede MM, Emanuel MH, et al. (2009)[71]	Retrospective	539	44.3	NR	0	0/539
Birsan A, Deval B, Detchev R, et al. (2003)[72]	Prospective	24	NR	NR	0	0/24
Bojahr B, De Wilde RL, Tchartchian G (2015)[73]	Retrospective	10731	NR	NR	2	2/8720
Brohl AS, Li L, Andikyan V, et al. (2015)[74]	Retrospective	2075	38.3	6.1	2	2/2075
Bronz L, Suter T, Rusca T (1997)[75]	Prospective	25	NR	NR	0	0/25
Brown J, Taylor K, Ramirez PT, et al. (2015)[76]	Retrospective	808	NR	NR	1	1/400
Butt JL, Jeffery ST, Van der Spuy ZM (2012)[77]	Retrospective	106	NR	NR	0	0/106

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Campo S, Campo V, Gambadauro P (2005)[78]	Prospective	80	NR	NR	0	0/80
Chen SY, Chang DY, Sheu BC, et al. (2008)[79]	Prospective	136	NR	NR	0	0/136
Cicinelli E, Romano F, Anastasio PS, et al. (1995)[80]	Prospective	11	NR	NR	0	0/11
Clark Donat L, Clark M, Tower AM, et al. (2015)[81]	Retrospective	64	48.5	7.87	0	0/64
Colgan TJ, Pendergast S, LeBlanc M (1993)[82]	Retrospective	77	36.9	NR	0	0/77
Cormio G, Loizzi V, Ceci O, et al. (2015)[83]	Retrospective	588	NR	NR	3	3/588
Corson SL, Brooks PG (1991)[84]	Retrospective	92	40.1	NR	2	2/92
Crescini C (1993)[85]	Prospective	25	NR	NR	0	0/25
Cusidó M, Fargas F, Baulies S,et al. (2015)[86]	Retrospective	4014	46	NR	12	12/4014
Bushaqer NJ (2014)[87]	Retrospective	137	36	NR	0	0/137
De Falco M, Staibano S, Mascolo M, et al. (2009)[88]	RCT	62	37.3	NR	0	0/62
Deligdisch L, Hirschmann S, Altchek A (1997)[89]	Retrospective	60	NR	NR	0	0/60
Di Lieto A, De Falco M, Mansueto G, et al. (2005)[90]	RCT	70	36.8	NR	0	0/70
Dijkhuizen FP, De Vries LD, Mol BW, et al. (2000)[91]	Prospective	9	NR	NR	0	0/9
Dundr P, Mara M, Maskova J, et al. (2006)[92]	Retrospective	20	NR	NR	0	0/20
El-Mowafi D, Madkour W, Lall C, et al. (2004)[93]	Retrospective	165	45.8	NR	0	0/165
Emanuel MH, Wamsteker K (2005)[94]	Retrospective	28	NR	NR	0	0/28
Emanuel MH, Wamsteker K, Hart AA, et al. (1999)[95]	Retrospective	285	NR	NR	1	1/285
Fanfani F, Fagotti A, Bifulco G, et al. (2005)[96]	Prospective	213	NR	NR	0	0/213
Fedele L, Bianchi S, Dorta M, et al. (1991)[97]	Prospective	71	NR	NR	0	0/71
Ferrari MM, Berlanda N, Mezzopane R, et al. (2000)[98]	RCT	62	NR	NR	0	0/62
Fukuda M, Shimizu T, Fukuda K, et al. (1993)[99]	Retrospective	20	NR	NR	0	0/20
Gao Z, Li L, Meng Y. A .(2016)[100]	Retrospective	3986	47.9	NR	17	17/3986
Garcia CR, Tureck RW (1984)[101]	Prospective	17	NR	NR	0	0/17
Gavai M, Hupuczi P, Papp Z (2006)[102]	Retrospective	504	33	NR	0	0/504
Gaym A (2004)[103]	Retrospective	588	38.5	NR	0	0/588
Geethamala K, Murthy VS, Vani BR, Rao S (2016)[104]	Retrospective	820	NR	NR	1	1/820
Goldrath MH (1990)[105]	Retrospective	151	NR	NR	1	1/151
Gowri M, Mala G, Murthy S, et al. (2013)[106]	Retrospective	259	NR	NR	0	0/259
Grigoriadis C, Papaconstantinou E, Mellou A, et al. (2012)[107]	Retrospective	10	38.2	NR	0	0/10
Gurung G, Pradhan N, Rana SRA (2015)[108]	Retrospective	40	NR	NR	0	0/40
Hallez JP (1995)[109]	Retrospective	284	NR	NR	0	0/284
Hanafi M (2005)[110]	Retrospective	145	NR	NR	0	0/145
Hanafi M (2013)[111]	Retrospective	134	43.7	NR	0	0/134

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Harmanli OH, Bevilacqua SA, Dandolu V, et al. (2005)[112]	Retrospective	333	44.2	NR	0	0/333
Hasson HM, Rotman C, Rana N, et al. (1992)[113]	Retrospective	56	37.2	NR	0	0/56
Hasson HM, Rotman C, Rana N, et al. (1993)[114]	Retrospective	22	40.4	NR	0	0/22
Hoffman MS, DeCesare S, Kalter C (1994)[115]	Prospective	47	41.9	NR	0	0/47
Huang JQ, Lathi RB, Lemyre M, et al. (2010)[116]	Retrospective	131	41	NR	0	0/131
Huang PS, Sheu BC, Huang SC, Chang WC (2016)[117]	Retrospective	83	41.1	7.5	0	0/83
Jansen FW, de Kroon CD, van Dongen H, et al. (2006)[118]	Prospective	89	43.8	NR	0	0/89
Jha R, Pant AD, Jha A, et al. (2006)[119]	Retrospective	55	37.6	NR	0	0/55
Johns DA, Diamond MP (1994)[120]	Retrospective	11	39.2	NR	0	0/11
Kafy S, Huang JY, Al-Sunaidi M, et al. (2006)[121]	Retrospective	934	59.6	NR	0	0/934
Kalogiannidis I, Prapas N, Xiromeritis P, et al. (2010)[122]	Prospective	75	34.8	4.5	0	0/75
Kamikabeya TS, Etchebehere RM, Nomelini RS, et al. (2010)[123]	Retrospective	1364	NR	NR	1	1/1364
Kiltz RJ, Rutgers J, Phillips J, et al. (1994)[124]	Prospective	28	31	1.8	0	0/28
Kinay T, Basarir ZO, Tuncer SF et al. (2016)[125]	Retrospective	947	47.1	NR	2	2/947
Klimentova DV, Braila AD, Simionescu C, et al. (2012)[126]	Retrospective	959	NR	NR	0	0/959
Kohama T, Hashimoto S, Ueno H, et al. (1997)[127]	Prospective	25	NR	NR	0	0/25
Kuzel D, Toth D, Fucikova Z, et al. (1999)[128]	Prospective	45	NR	NR	0	0/45
Landi S, Zaccoletti R, Ferrari L, et al. (2001)[129]	Prospective	368	NR	NR	0	0/368
Laughead MK, Stones LM (1997)[130]	Prospective	8	NR	NR	0	0/8
Leibsohn S, d'Ablaing G, Mishell DR, Jr., et al. (1990)[131]	Retrospective	1429	NR	NR	7	7/1429
Leung F, Terzibachian JJ, Gay C, et al. (2009)[132]	Retrospective	1297	48	NR	3	3/1297
Levens ED, Wesley R, Premkumar A, et al. (2009)[133]	RCT	18	NR	NR	0	0/18
Lieng M, Berner E, Busund B (2015)[134,]	Retrospective	4771	61.2	12.3	6	6/4771
Lim SS, Sockalingam JK, Tan PC (2008)[136]	RCT	66	46.5	NR	0	0/64
Litta P, Fantinato S, Calonaci F, et al. (2010)[137]	RCT	160	37.34	NR	0	0/160
Liu L, Li Y, Xu H, et al. (2011)[138]	Prospective	167	NR	NR	0	0/167
Liu WM, Tzeng CR, Yi-Jen C, et al. (2004)[139]	Prospective	486	NR	NR	0	0/486
Lyons TL, Adolph AJ, Winer WK (2004)[140]	Retrospective	54	47.3	NR	0	0/54
MacKenzie IZ, Naish C, Rees M, et al. (2004)[141]	Retrospective	118	47.5	NR	0	0/118
Mais V, Ajossa S, Guerriero S, et al. (1996)[142]	RCT	40	NR	NR	0	0/40
Mansour FW, Kives S, Urbach DR, et al. (2012)[143]	Retrospective	59	34.7	NR	0	0/59

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Mara M, Fucikova Z, Kuzel D, et al. (2006)[144]	Prospective	80	33.5	NR	0	0/80
Marana R, Busacca M, Zupi E, et al. (1999)[145]	RCT	55	NR	NR	0	0/55
Mecke H, Wallas F, Brocker A, et al. (1995)[146]	Retrospective	215	36	NR	0	0/215
Mettler L, Alvarez-Rodas E, Semm K (1995)[147]	Retrospective	500	43.2	NR	1	1/500
Milad MP, Morrison K, Sokol A, et al. (2001)[148]	Prospective	69	43.9	NR	0	0/69
Miskry T, Magos A (2003)[149]	RCT	36	NR	NR	0	0/9
Moghadam R, Lathi RB, Shahmohamady B, et al. (2006)[150]	Retrospective	144	41	NR	0	0/144
Muhammad Z, Ibrahaim S, Agu O (2009)[151]	Retrospective	78	46.6	NR	0	0/75
Munoz JL, Jimenez JS, Hernandez C, et al. (2003)[152]	Retrospective	120	44.8	NR	0	0/120
Nemec W, Inwald EC, Buchholz S, et al. (2016)[153]	Retrospective	984	53.8	NR	5	5/984
Nezhat F, Nezhat CH, Admon D, et al. (1995)[154]	Retrospective	28	NR	NR	0	0/28
Obed JY, Bako B, Usman JD, et al. (2011)[155]	Prospective	331	30.1	NR	0	0/331
O'Hanlan KA, Dibble SL, Garnier AC, et al. (2007)[156]	Retrospective	258	50	NR	0	0/258
Okezie O, Ezegwui HU (2006)[157]	Retrospective	190	NR	NR	0	0/190
Ouldamer L, Rossard L, Arbion F, et al. (2014)[158]	Retrospective	709	49.5	NR	0	0/709
Palomba S, Orio F, Jr., Russo T, et al. (2005)[159]	RCT	40	53.4	NR	0	0/40
Palomba S, Zupi E, Falbo A, et al. (2010)[160]	Prospective	30	30.2	NR	0	0/30
Palomba S, Zupi E, Russo T, et al. (2007)[161]	RCT	136	NR	NR	0	0/136
Parker WH, Fu YS, Berek JS (1994)[162]	Retrospective	1332	NR	NR	1	1/1332
Paul GP, Naik SA, Madhu KN, et al. (2010)[163]	Retrospective	1001	32.6	NR	1	1/1001
Perveen S, Tayyab S (2008)[164]	Retrospective	20	NR	NR	0	0/20
Phillips DR, Nathanson HG, Milim SJ, et al. (1995)[165]	Prospective	38	NR	NR	0	0/38
Picerno TM, Wasson MN, Gonzalez Rios AR, et al. (2016)[166]	Retrospective	1004	45.7	NR	0	0/258
Polena V, Mergui JL, Perrot N, et al. (2007)[167]	Retrospective	235	47.9	NR	0	0/235
Pron G, Mocarski E, Cohen M, et al. (2003)[168]	Prospective	8	NR	NR	0	0/8
Radosa MP, Owsianowski Z, Mothes A, et al. (2014)[169]	Retrospective	224	37.9	NR	0	0/224
Raine-Bennett T, Tucker LY, Zaritsky E, et al. (2016)[170]	Pop based cohort	34728	NR	NR	172	81/34728
Raspagliesi , F. (2016)[171]	Retrospective	4000	47.2	NR	91	91/4000
Rechberger, T .(2016)[172]	Retrospective	334	NR	NR	0	0/334
Rein MS, Friedman AJ, Stuart JM, et al. (1990)[55]	RCT	20	NR	NR	0	0/20
Reiter RC, Wagner PL, Gambone JC	Retrospective	104	41.5	NR	0	0/104

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
(1992)[173]						
Rodriguez AM, Asoglu MR, Sak ME, et al. (2015)[174]	Retrospective	13964	40.9	7	19	19/13964
Rosenblatt P, Makai G, DiSciullo A (2010)[175]	Retrospective	24	50.2	NR	0	0/24
Rovio PH, Helin R, Heinonen PK (2009)[176]	Retrospective	53	44.7	NR	0	0/53
Rutgers JL, Spong CY, Sinow R, et al. (1995)[177]	RCT	46	38	NR	0	0/46
Sahagun Quevedo JA, Perez Ruiz JC, Cherem B, et al. (1994)[178]	Retrospective	594	NR	NR	0	0/594
Samaila M, Adesiyun AG, Agunbiade OS, et al. (2009)[179]	Retrospective	196	44.6	NR	0	0/196
Sandberg EM, van den Haak L, Bosse T, et al. (2016)[180]	Prospective	5	34.6	NR	0	0/5
Sayyah-Melli M, Tehrani-Gadim S, Dastranj-Tabrizi A, et al. (2009)[181]	RCT	23	39.67	NR	0	0/23
Schutz K, Possover M, Merker A, et al. (2002)[182]	RCT	48	NR	NR	0	0/48
Seidman MA, Oduyebo T, Muto MG, et al. (2012)[183]	Retrospective	1091	NR	NR	1	1/1091
Seki K, Hoshihara T, Nagata I (1992)[184]	Retrospective	1886	45.5	NR	7	7/1886
Seracchioli R, Venturoli S, Vianello F, et al. (2002)[185]	RCT	122	46.3	NR	0	0/122
Serur E, Zambrano N, Brown K, et al. (2016)[186]	Retrospective	117	NR	NR	1	1/88
Shen CC, Wu MP, Kung FT, et al. (2003)[187]	Retrospective	1521	45.5	NR	0	0/1521
Shergill SK, Shergill HK, Gupta M, et al. (2002)[188]	RCT	34	NR	NR	0	0/34
Sikora-Szczęśniak DL, Sikora W, Szczęśniak G (2013) [189]	Retrospective	294	45.6	NR	0	0/39
Silva BA, Falcone T, Bradley L, et al. (2000)[190]	Prospective	39	37	NR	0	0/37
Silva BA, Falcone T, Bradley L, et al. (2000)[190]	Retrospective	37	37	NR	0	0/37
Sinha R, Hegde A, Mahajan C, et al. (2008)[191]	Prospective	505	34.44	NR	2	2/505
Smits R, De Kruif J, Van Heteren C (2016)[192]	Retrospective	358	44.5	NR	0	0/171
Song T, Kim TJ, Lee SH, et al. (2015)[193]	RCT	100	39.3	5.7	0	0/100
Takamizawa S, Minakami H, Usui R, et al. (1999)[194]	Retrospective	923	44.5	NR	1	1/923
Tan J, Sun Y, Dai H, et al. (2008)[195]	RCT	52	NR	NR	0	0/52
Tan J, Sun Y, Zhong B, et al. (2009)[196]	RCT	80	36.3	NR	0	0/80
Theben JU, Schellong AR, Altgassen C, et al. (2013)[197]	Retrospective	1132	45.9	NR	2	2/1132
Tinelli A, Hurst BS, Hudelist G, et al. (2012)[198]	Prospective	235	NR	NR	0	0/235
Toubia T, Moulder JK, Schiff LD, et al. (2016)[199]	Prospective	20	NR	NR	0	0/20
Uccella S, Cromi A, Serati M, et al. (2014)[200]	Retrospective	71	48	NR	0	0/71
Ueki M, Okamoto Y, Tsurunaga T, et al. (1995)[201]	Retrospective	230	42.5	NR	0	0/230
van Dongen H, Emanuel MH, Wolterbeek R, et al. (2008)[202]	RCT	22	48.2	NR	0	0/22

Citation	Design	N	Age, Mean	Age, SD	LMS	LMS Rate
Varma R, Soneja H, Clark TJ, et al. (2009)[203]	Prospective	92	NR	NR	1	1/92
Venkatesan AM, Partanen A, Pulanic TK, et al. (2012)[204]	Prospective	9	NR	NR	0	0/9
Vercellini P, Cribiù FM, Bosari S, et al. (2016)[205]	Retrospective	2356	39	6	1	1/2356
Walid MS, Heaton RL (2010)[206]	Retrospective	41	NR	NR	0	0/41
Wamsteker K, Emanuel MH, de Kruif JH (1993)[207]	Prospective	51	NR	NR	0	0/51
Wang CJ, Soong YK, Lee CL (2007)[208]	Prospective	18	NR	NR	0	0/18
West S, Ruiz R, Parker WH (2006)[209]	Retrospective	91	40	NR	0	0/91
Widrich T, Bradley LD, Mitchinson AR, et al. (1996)[210]	Prospective	13	NR	NR	0	0/13
Williams AR, Critchley HO, Osei J, et al. (2007)[211]	RCT	33	NR	NR	0	0/33
Williams CD, Marshburn PB (1998)[212]	Prospective	5	38.5	NR	0	0/5
Wortman M, Dagget A (1995)[213]	Retrospective	75	43.2	NR	0	0/75
Yen YK, Liu WM, Yuan CC, et al. (2002)[214]	RCT	64	NR	NR	0	0/61
Ylikorkala O, Tiitinen A, Hulkko S, et al. (1995)[215]	RCT	101	43	NR	0	0/101
Yoo EH, Lee PI, Huh CY, et al. (2007)[216]	Retrospective	512	33	NR	0	0/512
Yoon HJ, Kyung MS, Jung US, et al. (2007)[217]	Retrospective	51	34.9	NR	0	0/51
Zhang J, Li T, Zhang J, et al. (2016)[218]	Retrospective	3021	47.88	6.2	5	5/3021
Zhang J, Zhang J, Dai Y, et al. (2015)[219]	Retrospective	4248	NR	NR	1	1/4248
Zhao WC, Bi FF, Li D, et al. (2015)[220]	Retrospective	10248	48.2	7.64	13	13/10248
Zhu L, Lang JH, Liu CY, et al. (2009)[221]	RCT	101	NR	NR	0	0/101
Zullo F, Palomba S, Corea D, et al. (2004)[222]	RCT	60	28.2	NR	0	0/60

Table G-12. Patient data extracted from studies for Key Question 4

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
Einstein MH et al., 2008[223] (5)	Benign	LSC SCH	Yes	Yes	I	No	30	NED	NR	NR	
	Benign	LMYO M	Yes	Yes	I	Yes	61	NED	NR	NR	
	Benign	SCH	Yes	No	I	Yes	31	AWD	NR	NR	
	Benign	SCH BSO	No	No	I	No	37	NED	NR	NR	
	Benign	SCH BSO	No	No	I	Yes	6	AWD	NR	NR	
Kamikabeya TS et al., 2010[123] (1)	Benign	TAH BSO	No	No	NR	No	2	Dead	58	Post	
Takamiza	Benign	TAH	No	No	NR	NR	132	NED	44	NR	Received

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
wa S et al., 1999[224] (1)											chemo as treatment
Oduyebo T et al., 2014[225] (14)	Benign	LSC SCH	Yes	Yes	I	No	27	NED	NR	NR	
	Benign	LSC SCH	Yes	Yes	I	No	38	NED	NR	NR	
	Benign	LMYOM	Yes	Yes	I	No	48.7	NED	NR	NR	
	Benign	LSC SCH	Yes	Yes	IV	NA	3	Dead	NR	NR	
	Benign	LAVH	Yes	No	NR	NA	72	AWD	NR	NR	
	Benign	LMYOM	Yes	Yes	I	Yes	37.5	Dead	NR	NR	
	Benign	LSC SCH	Yes	Yes	III	Yes	5.1	Dead	NR	NR	
	Benign	LSC SCH	Yes	Yes	NR	NA	48	Dead	NR	NR	
	Benign	LSC SCH	Yes	Yes	I	No	20.2	NED	NR	NR	
	Benign	TVH	Yes	No	I	NA	26	NED	NR	NR	
	Benign	TVH	Yes	No	I	NA	1.8	NED	NR	NR	
	Benign	Robotic TLH	Yes	Yes	I	NA	15.3	NED	NR	NR	
	Benign	LSC HYST	Yes	No	NR	NA	30.4	Dead	NR	NR	
	Benign	LAVH	Yes	No	I	No	4.5	NED	NR	NR	
Graebe K et al., 2015[226] (2)	Benign	MIS HYST	Yes	Yes	I	Yes	8	AWD	NR	Pre	Mass staging years later
	Benign	MIS HYST	Yes	Yes	I	Yes	13	AWD	NR	Pre	
Tan-Kim J et al., 2014[227] (5)	Benign	LSC HYST	Yes	Yes	NR	no	31	NED	51	Post	
	Benign	LSC HYST	Yes	Yes	NR	Yes	51	NED	41	Pre	
	Benign	LSC HYST	Yes	Yes	NR	Yes	36	Dead	48	Pre	
	Benign	TAH+BSO	no	no	NR	no	37	Alive	66	post	
	Benign	TAH+BSO	no	no	NR	yes	23	Dead	54	post	
Sinha R et al., 2008[228] (2)	Benign	LSC MYOM	Yes	Yes	NR	NR	42	Alive	NR	Pre	
	Benign	LSC MYOM	Yes	Yes	NR	NR	42	Alive	NR	Pre	
Tan A et al., 2015[229] (2)	Benign	LSC MYOM	Yes	Yes	NR	NR	34	Dead	48	Pre	
	Benign	VAG HYST	Yes	No	NR	NR	21	AWD	38	Pre	
Seidman MA et al., 2012[230] (7)	Benign	Varied	Yes	Yes	I	No	38	NED	43	NR	
	Benign	Varied	Yes	Yes	I	No	9	NED	48	NR	
	Benign	Varied	Yes	Yes	I	No	42	Alive	42	NR	
	Benign	Varied	Yes	Yes	I	Yes (late)	27	Dead	58	Post	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	Varied	Yes	Yes	I	Yes	17	Dead	47	NR	
	Benign	Varied	Yes	Yes	I	Yes	39	Alive	49	NR	
	Benign	Varied	Yes	Yes	I	Yes	29	Dead	68	Post	
Zhang J et al., 2015[231] (1)	Benign	ABD MYOM	Yes	No	NR	No	58	NED	35	Pre	
Bojah B et al., 2015[232] (2)	Benign	LSC SCH	Yes	Yes	I	No	137	NED	49	NR	
	Benign	LSC SCH	Yes	Yes	I	Yes (late)	13	Dead	49	NR	
Theben JU et al., 2013[233] (2)	Benign	LSC SCH	Yes	No	pT1b, pNx, cM0	No	52	NED	43	NR	
	Benign	LSC SCH	Yes	Yes	pT1c, pNx,cM0	No	36	NED	49	NR	
Serur E et al., 2016[186] (1)	Benign	LSC HYST	Yes	No	NR	NR	28	NED	56	post	
Vercellini P et al., 2016[205] (1)	Benign	LSC MYOM	Yes	Yes	NR	NR	4	Dead	39	NR	
Cusido M et al., 2015[86] (8)	Benign	HYST	Yes	Yes	NR	NR	36	AWD	50	NR	
	Benign	HYST	Yes	No	NR	NR	33	Dead	48	NR	
	Benign	MYOM	Yes	Yes	NR	NR	27	Dead	56	NR	
	Benign	HYST	Yes	No	NR	NR	22	AWD	46	NR	
	Benign	HYST	No	No	NR	NR	14	AWD	47	NR	
	Benign	HYST	No	No	NR	NR	90	AWD	52	NR	
	Benign	HYST	No	No	NR	NR	16	AWD	51	NR	
	Benign	HYST	No	No	NR	NR	12	AWD	63	NR	
Nemec W et al., 2016[153] (64)	Benign	HYST	Yes	No	I	NR	28	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	31	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	39	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	41	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	52	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	66	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	67	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	93	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	104	Alive	53.8	NR	
	Benign	HYST	Yes	No	I	NR	113	Alive	53.8	NR	
	Benign	HYST	Yes	No	II to IV	NR	127	Alive	53.8	NR	
	Benign	HYST	Yes	No	II to IV	NR	23	Dead	53.8	NR	
	Benign	HYST	Yes	No	II to IV	NR	34	Dead	53.8	NR	
	Benign	HYST	Yes	No	NR	NR	41	Dead	53.8	NR	
	Benign	HYST	Yes	No	NR	NR	127	Dead	53.8	NR	
	Benign	HYST	No	No	I	NR	17	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	18	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	20	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	26	Alive	53.8	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	HYST	No	No	I	NR	31	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	34	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	36	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	40	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	42	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	43	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	43	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	44	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	45	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	53	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	55	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	64	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	68	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	72	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	92	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	94	Alive	53.8	NR	
	Benign	HYST	No	No	I	NR	95	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	96	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	101	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	101	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	116	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	125	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	128	Alive	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	1	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	2	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	4	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	4	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	5	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	9	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	12	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	13	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	15	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	15	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	16	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	18	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	19	Dead	53.8	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	HYST	No	No	II to IV	NR	21	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	25	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	29	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	33	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	34	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	43	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	53	Dead	53.8	NR	
	Benign	HYST	No	No	II to IV	NR	77	Dead	53.8	NR	
	Benign	HYST	No	No	NR	NR	78	Dead	53.8	NR	
Raspagliesi F et al., 2016[171] (91)	Benign	varied	No	No	I	No	5	Alive	NR	NR	
	Benign	varied	No	No	I	No	7	Alive	NR	NR	
	Benign	varied	No	No	I	No	8	Alive	NR	NR	
	Benign	varied	No	No	I	No	11	Alive	NR	NR	
	Benign	varied	No	No	I	No	12	Alive	NR	NR	
	Benign	varied	No	No	I	No	15	Alive	NR	NR	
	Benign	varied	No	No	I	No	16	Alive	NR	NR	
	Benign	varied	No	No	I	No	22	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	8	Dead	NR	NR	
	Benign	varied	No	No	I	No	11	Dead	NR	NR	
	Benign	varied	No	No	I	No	13	Dead	NR	NR	
	Benign	varied	No	No	I	No	13	Dead	NR	NR	
	Benign	varied	No	No	I	No	13	Dead	NR	NR	
	Benign	varied	No	No	I	No	15	Dead	NR	NR	
	Benign	varied	No	No	I	No	15	Dead	NR	NR	
	Benign	varied	No	No	I	No	18	Dead	NR	NR	
	Benign	varied	No	No	I	No	19	Dead	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	No	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	10	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	10	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	10	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	10	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	10	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	11	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	15	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	18	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	20	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	23	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	23	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	23	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	24	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	24	Dead	NR	NR	
	Benign	varied	yes	yes	I	No	6	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	10	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	12	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	14	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	15	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	19	Alive	NR	NR	
	Benign	varied	yes	yes	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	
	Benign	varied	yes	No	I	No	24	Alive	NR	NR	

Author (LMS Total)	**Preoperative**	**Initial Surgery**	**Morcellation**	**Power**	**Cancer Stage (First)**	**Upstaged**	**Months followup**	**Outcome**	**Age**	**Menopausal Status**	**Notes**
Brown J et al., 2015[234] (1)	Benign	LSC SCH (converted to TAH)	no	no	NR	no	54.3	Dead	60	post	
Brohl A et al., 2015[235] (1)	Benign	H'SCOPE MYO	no	no	NR	yes	14	NED	49	pre	
Zhang J et al., 2016[236] (2)	Benign	TLH + BSO	yes	no	NR	NR	54	NED	56	post	
	Benign	TAH	no	no	NR	no	17	NED	43	post	
Cormio G et al.[237] (3)	Benign	LAP MYOM	yes	no	NR	no	24	NED	NR	NR	
	Benign	LAP MYOM	yes	no	NR	no	22	NED	NR	NR	
	Benign	LAP MYOM	yes	no	NR	NR	64	Dead	NR	NR	
Lin KH et al., 2015[238] (20)	Benign	TAH	No	No	I	No	20	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	25	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	26	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	43	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	43	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	43	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	43	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	57	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	57	Dead	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
	Benign	TAH	No	No	I	NR	248	Alive	52.7	NR	
Perri T et al., 2009[239] (37)	NR	TAH	No	No	I	NR	6	Dead	48	Post	
	NR	TAH	No	No	I	NR	10	Dead	48	Post	
	NR	TAH	No	No	I	NR	14	Dead	48	Post	
	NR	TAH	No	No	I	NR	14	Dead	48	Post	
	NR	TAH	No	No	I	NR	15	Dead	48	Post	
	NR	TAH	No	No	I	NR	17	Dead	48	Post	
	NR	TAH	No	No	I	NR	49	Dead	48	Post	
	NR	TAH	No	No	I	NR	56	Dead	48	Pre	
	NR	TAH	No	No	I	NR	78	Dead	48	Pre	
	NR	TAH	No	No	I	NR	11	Alive	48	Pre	
	NR	TAH	No	No	I	NR	43	Alive	48	Pre	
	NR	TAH	No	No	I	NR	62	Alive	48	Pre	
	NR	TAH	No	No	I	NR	72	Alive	48	Pre	
	NR	TAH	No	No	I	NR	140	Alive	48	Pre	
	NR	TAH	No	No	I	NR	149	Alive	48	Pre	
	NR	TAH	No	No	I	NR	180	Alive	48	Pre	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	NR	TAH	No	No	I	NR	203	Alive	48	Pre	
	NR	TAH	No	No	I	NR	211	Alive	48	Pre	
	NR	TAH	No	No	I	NR	265	Alive	48	Pre	
	NR	TAH	No	No	I	NR	265	Alive	48	Pre	
	NR	TAH	No	No	I	NR	265	Alive	48	Pre	
	NR	ABD MYOM	Yes	No	I	NR	3	Dead	52	Post	
	NR	ABD MYOM	Yes	No	I	NR	4	Dead	52	Pre	
	NR	ABD MYOM	Yes	No	I	NR	7	Dead	52	Pre	
	NR	ABD MYOM	Yes	No	I	NR	7	Dead	52	Pre	
	NR	H'SCO PE MYO	Yes	No	I	NR	11	Dead	52	Post	
	NR	H'SCO PE MYO	Yes	No	I	NR	16	Dead	52	Pre	
	NR	H'SCO PE MYO	Yes	No	I	NR	16	Dead	52	Pre	
	NR	H'SCO PE MYO	Yes	No	I	NR	16	Dead	52	Pre	
	NR	LSC HYST	Yes	No	I	NR	23	Dead	52	Post	
	NR	LSC HYST	Yes	No	I	NR	24	Dead	52	Pre	
	NR	SCH	Yes	No	I	NR	24	Dead	52	Pre	
	NR	SCH	Yes	No	I	NR	35	Dead	52	Pre	
	NR	SCH	Yes	No	I	NR	18	Alive	52	Post	
	NR	SCH	Yes	No	I	NR	308	Alive	52	Post	
	NR	TAH UT INJ	Yes	No	I	NR	387	Alive	52	Post	
	NR	TAH UT INJ	Yes	No	I	NR	387	Alive	52	Pre	
Raine-Bennett T et al., 2016[240] (111)	Benign	varied	Yes	No	I	NR	6	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	6	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	12	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	12	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	18	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	18	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	24	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	30	Dead	NR	NR	
	Benign	varied	Yes	No	I	NR	6	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	12	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	30	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	No	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	12	Dead	NR	NR	
	Benign	varied	Yes	Yes	I	NR	12	Dead	NR	NR	
	Benign	varied	Yes	Yes	I	NR	30	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	36	Alive	NR	NR	
	Benign	varied	Yes	Yes	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	12	Dead	NR	NR	
	Benign	varied	No	No	I	NR	12	Dead	NR	NR	
	Benign	varied	No	No	I	NR	12	Dead	NR	NR	
	Benign	varied	No	No	I	NR	12	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Dead	NR	NR	
	Benign	varied	No	No	I	NR	24	Dead	NR	NR	
	Benign	varied	No	No	I	NR	24	Dead	NR	NR	
	Benign	varied	No	No	I	NR	24	Dead	NR	NR	
	Benign	varied	No	No	I	NR	24	Dead	NR	NR	
	Benign	varied	No	No	I	NR	24	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	30	Dead	NR	NR	
	Benign	varied	No	No	I	NR	36	Dead	NR	NR	
	Benign	varied	No	No	I	NR	36	Dead	NR	NR	
	Benign	varied	No	No	I	NR	36	Dead	NR	NR	
	Benign	varied	No	No	I	NR	18	Alive	NR	NR	
	Benign	varied	No	No	I	NR	24	Alive	NR	NR	
	Benign	varied	No	No	I	NR	24	Alive	NR	NR	
	Benign	varied	No	No	I	NR	24	Alive	NR	NR	
	Benign	varied	No	No	I	NR	30	Alive	NR	NR	
	Benign	varied	No	No	I	NR	30	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	

Author (LMS Total)	Preoperative	Initial Surgery	Morcellation	Power	Cancer Stage (First)	Upstaged	Months followup	Outcome	Age	Menopausal Status	Notes
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	
	Benign	varied	No	No	I	NR	36	Alive	NR	NR	

Notes: Unable to extract data from Morice P., et al. 2003[241] ; authors did not report patient level data; Abbreviations: ABD MYOM = abdominal myomectomy; AWD = alive with disease; BSO = bilateral salpingo-oophorectomy; H'SCOPE MYO = hysteroscopic myomectomy; LAVH = laparoscopic-assisted vaginal hysterectomy; LMYOM = laparoscopic myomectomy with morcellation; LMS = leiomyosarcoma; LSC ASST VH = laparoscopic assisted vaginal hysterectomy; LSC HYST = laparoscopic hysterectomy; LSC MYOM = laparoscopic myomectomy; LSC SCH = Laparoscopic supracervical hysterectomy; malign = malignant; MIS HYST = minimally invasive hysterectomy; MRI = magnetic resonance imaging; NA = not applicable; NED = no evidence of disease; ND = no data; NR = not reported; Onc = oncology; Post = postmenopausal; Poss Malig = possibly malignant; Pre = premenopausal; SAH = supracervical abdominal hysterectomy; SCH = supracervical hysterectomy; TAH = total abdominal hysterectomy; TAH BSO= total abdominal hysterectomy with bilateral salpingo-oophorectomy; TAH UT INJ = total abdominal hysterectomy uterus injured; TLH = total laparoscopic hysterectomy; TVH = total vaginal hysterectomy; VAG HYST = vaginal hysterectomy

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Appendix H. Estimates of Subsequent Treatment for Uterine Fibroids

Table H-1. Estimated probability of subsequent treatment for fibroids following medical management

Next Intervention		None	IUD	UAE	MRgFUS	Myomectomy	Hysterectomy
Age	Followup						
30	6	0.99 (0.98, 0.99)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.01 (0.01, 0.02)
	12	0.98 (0.96, 0.99	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.02 (0.01, 0.04)
	24	0.94 (0.89, 0.97)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.06 (0.03, 0.11)
40	6	0.98 (0.98, 0.99)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.02 (0.01, 0.02)
	12	0.97 (0.96, 0.98)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.03 (0.02, 0.04)
	24	0.91 (0.89, 0.94)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.09 (0.06, 0.11)
50	6	0.98 (0.96, 0.99)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.02 (0.01, 0.04)
	12	0.96 (0.94, 0.98)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.04 (0.02, 0.06)
	24	0.89 (0.85, 0.92)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.12 (0.08, 0.15)

Table H-2. Estimated probability of subsequent treatment for fibroids following uterine artery embolization

Next Intervention		None	IUD	UAE	MRgFUS	Myomectomy	Hysterectomy
Age	Followup						
30	6	0.66 (0.46, 0.81)	0.00 (0.00, 0.01)	0.13 (0.03, 0.32)	0.00 (0.00, 0.00)	0.18 (0.05, 0.38)	0.00 (0.00, 0.00)
	12	0.64 (0.48, 0.78)	0.00 (0.00, 0.00)	0.10 (0.02, 0.22)	0.00 (0.00, 0.00)	0.24 (0.10, 0.41)	0.01 (0.00, 0.02)
	24	0.56 (0.43, 0.69)	0.00 (0.00, 0.00)	0.05 (0.01, 0.11)	0.00 (0.00, 0.00)	0.37 (0.23, 0.51)	0.01 (0.00, 0.04)
40	6	0.93 (0.90, 0.94)	0.00 (0.00, 0.01)	0.04 (0.03, 0.06)	0.00 (0.00, 0.00)	0.01 (0.01, 0.02)	0.02 (0.01, 0.03)
	12	0.92 (0.90, 0.94)	0.00 (0.00, 0.00)	0.03 (0.02, 0.04)	0.00 (0.00, 0.00)	0.02 (0.01, 0.03)	0.03 (0.02, 0.04)
	24	0.88 (0.84, 0.92)	0.00 (0.00, 0.00)	0.02 (0.01, 0.03)	0.00 (0.00, 0.00)	0.03 (0.01 to 0.06)	0.06 (0.04, 0.10)
50	6	0.90 (0.58, 0.97)	0.03 (0.00, 0.38)	0.01 (0.00, 0.02)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.05 (0.02, 0.10)
	12	0.89 (0.77, 0.96)	0.01 (0.00, 0.14)	0.01 (0.00, 0.01)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.08 (0.04, 0.14)
	24	0.81 (0.70, 0.90)	0.00 (0.00, 0.02)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.18 (0.09, 0.29)

Table H-3. Estimated probability of subsequent treatment for fibroids following myomectomy

Next Intervention		None	IUD	UAE	MRgFUS	Myomectomy	Hysterectomy
Age	**Followup**						
30	6	0.97 (0.84, 1.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.02 (0.00, 0.14)	0.00 (0.00, 0.02)
	12	0.97 (0.85, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.03 (0.00, 0.14)	0.00 (0.00, 0.01)
	24	0.93 (0.77, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.07 (0.01, 0.22)	0.00 (0.00, 0.01)
40	6	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)
	12	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)
	24	1.00 (0.99, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)
50	6	0.60 (0.00, 1.00)	0.00 (0.00, 0.13)	0.00 (0.00, 0.05)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)	0.00 (0.00, 0.14)
	12	1.00 (0.84, 1.00)	0.00 (0.00, 0.01)	0.00 (0.00, 0.01)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.09)
	24	1.00 (0.89, 1.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.00)	0.00 (0.00, 0.06)

Appendix I. Summary of Existing Systematic Reviews

Medical Interventions

Table I-1. Existing reviews of medical interventions for uterine fibroids (8 reviews)

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
Peitsidis et al. 2014[1]	Medical -Tranexamic acid	Women of reproductive age with symptomatic fibroids Administration of tranexamic acid Literature from 1950 to 2014	Menorrhagia Periprocedural blood loss	5 studies 349 women; of these 206 patients treated with tranexamic acid and 101 patients allocated to placebo groups	Only 5 included studies Presence of bias related to size and location of fibroids Tranexamic acid may reduce blood loss perioperatively in myomectomies
Kamath et al. 2014[2]	Medical -GnRH analogues	Women undergoing hysteroscopic resection of submucous fibroids RCTs Literature from 1980 to July 2012	Menstrual symptoms	2 studies Study 1: 47 patients (24 intervention; 23 control) Study 2: 39 patients (20 intervention; 19 control)	Only 2 included studies No significant difference in symptom relief Inadequate evidence to show support for routine use
Chen et al. 2011[3]	Medical -GnRH agonists	Comparison of GnRH agonist pretreatment with placebo or no pretreatment RCTs Literature from January 1950 to June 2010	Intraoperative blood loss Transfusion Duration of surgery	3 RCTs encompassing 7 reports Included 168 women, 85 received GnRH and 83 who did not	GnRH pretreatment had no effect on operative time Intraoperative blood loss was statistically lowered
Steinauer et al. 2004[4]	Medical -Mifepristone	Mifepristone Literature from 1985 to 2002	Leiomyoma or uterine size	6 studies All before and after clinical trials comparing pretreatment and posttreatment leiomyoma or uterine volume	Small sample sizes in studies Mifepristone helped to reduce leiomyoma size Improvement in symptoms
Lethaby et al. 2002[5]	Medical -GnRH analogues (GnRHa)	GnRHa administered prior to surgery Literature from 1980 to 2000 RCTs	Uterine and fibroid volume Duration of operation Complications	GnRHa vs no therapy (14 studies) GnRHa vs placebo (6 studies) GnRHa vs lynestrenol (1 study)	Pre- and post-operative hemoglobin and hematocrit significantly improved Reduction in uterine and fibroid volume Pelvic symptoms were reduced but with adverse events GnRHa beneficial in correction of preoperative iron deficiency anemia

Table I-1. Existing Reviews of Medical Interventions for Uterine Fibroids (8 reviews), continued

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
Deng et al. 2012[6]	Medical -Selective estrogen receptor modulators (SERMs)	Women with confirmed uterine fibroids Women of reproductive age RCTs	Fibroid size Quality of life Symptoms Adverse events	3 studies, number of participants ranged from 25 to 100	Raloxifene used in all included studies Included studies were of poor quality Use of SERMs show reduction of fibroid size No included studies reported quality of life
Song et al. 2013[7]	Medical -Aromatase inhibitors	Use of aromatase inhibitors for uterine fibroids RCTs	Fibroid size Symptoms Adverse events	1 study with 70 participants	Only 1 included study No evidence of relief of symptoms Study failed to report important clinical outcomes
Moroni et al. 2015[8]	Medical -Add back therapy for GnRH analogue treatment	Women with symptomatic uterine fibroids RCTs	Quality of life Bone density Vasomotor symptoms Uterine volume and bleeding	14 studies Data extracted from 12 studies with 622 participants	Most (9/12) assessed as high risk of bias Maximum followup was 6 months Some evidence that add back with tibolone improves quality of life

Procedural Interventions

Table I-2. Existing reviews of procedural interventions for uterine fibroids (2 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Clark, N et al 2014[9]	MRI-guided focused ultrasound	MRgFUS for treatment of uterine fibroids	Symptoms Subsequent reproductive outcomes Pregnancy	39 (subset of 10 included in meta-analysis) Case reports, case series, reviews and retrospective evaluations	Symptom severity scores improved from baseline 56.3 to 31.0 after 6 months (95% CI: 23.9-38.2) 35 pregnancies reported Average time to conception was 8 months after procedure
Gizzo et al, 2014[10]	MRI-guided focused ultrasound myomectomy	Studies reporting data of myomectomy by MRgFUS	Number of fibroids treated Fibroid volume UFS-QOL Fertility Harms	38 studies including case reports, retrospective and prospective case series (included approximately 2500 women)	Most frequently reported complications skin burns, abdominal pain, sciatic nerve paresthesia or leg pain. UFS-QOL scores improved at 3, 6 and 12 months following treatment

Levonorgestrel Intrauterine Device (IUD)/Levonorgestrel Intrauterine System (LNG-IUS)

Table I-3. Systematic reviews of LNG-IUS (4 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Jiang W, Shen Q, Chen M, et al. 2014[11]	LNG-IUS	Premenopausal women with symptomatic uterine leiomyoma Search dates: database inception through July 2013	Fibroid and bleeding outcomes Adverse effects	11 studies; sample sizes ranging from 10 to 104	Fibroid and bleeding outcomes uterine volume: decreased menstrual blood loss: reduced hemoglobin: increased ferritin: increased hematocrit: increased leiomyoma volume: no change Adverse effects Device expulsion increased with leiomyoma size (larger than 3cm) not associated with leiomyoma location Irregular bleeding/ spotting Observed at the beginning of the follow-up period and then decreased
Varma R, Sinha D, Gupta JK. 2006[12]	LNG-IUS	Observational and experimental studies of LNG-IUS Search dates: 1996 to 2005	Fibroid and bleeding outcomes	3 RCTs; 7 observational studies for fibroids or fibroid related menorrhagia	Fibroid and bleeding outcomes menstrual blood loss: decreased 84–90% hemoglobin: increased 2–3 g/dl fibroid size: inconsistent (decreased and no change)
Zapata LB, Whiteman MK, Tepper NK, et al. 2010[13]	LNG-IUS	Women with uterine fibroids IUD (copper or levonorgestrel-releasing) use and uterine fibroids Search dates: database inception through June 2009	Fibroid and bleeding outcomes Expulsion rates	11 studies	Fibroid and bleeding outcomes menstrual blood loss: decreased (11 studies) among women using IUD hemoglobin, hematocrit and ferritin levels increased LNG-IUD expulsion rates women with uterine fibroids: 0-20% (2 cohort studies, fair to poor quality; 6 noncomparative studies) women without uterine fibroids: 0 - 3% (2 cohort studies, fair to poor quality)

Table I-3.Systematic Reviews of LNG-IUS (4 reviews), continued

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Sangkomkamhang US, Lumbiganon P, Laopaiboon M, et al. 2013[14]	LNG-IUS	Premenopausal women with uterine fibroids	Fibroid symptoms and characteristics Quality of life Recurrence Adverse events Cost effectiveness	3 RCTs with 187 women	No evidence of effectiveness of progestogens Limited evidence of effectiveness of LNG-IUS Small sample sizes and few studies

Uterine Artery Embolization (UAE)

Table I-4. Existing reviews of UAE interventions for uterine fibroids (5 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Das et al, 2014[15]	UAE, comparison of embolic agents	Reproductive age women Uterine artery embolization for uterine fibroids.	UFS-QOL Imaging outcomes Fibroid infarction rate Fibroid volume	5 RCTs (295 women) 5 non-RCTs (617 women)	No evidence for superiority of any embolic agent
Martin et al, 2013[16]	UAE	Uterine artery embolization	Complication Reintervention	8 RCTs with 350 participants 76 non-RCTs with 11,195 participants 41 case studies with 83 participants	Significantly lower rates of major complications with UAE compared to surgery (2 RCTs) Increased risk (ORs ranging from 2.7-10.4) of reintervention for UAE ((3 RCTs) UAE failure (4%), fever (4%), and postembolization syndrome (2.9%)
Toor et al, 2012[17]	UAE	Women treated with UAE for uterine fibroids Minimum followup of 1 month	Complication Reintervention	54 studies with 8159 participants including 7 RCTs, 37 prospective cohorts and 10 retrospective	Rate of major complications was 2.9% (95% CI 2.2-3.8%) The rate of follow up hysterectomy to resolve complication was 0.7% (95% CI 0.5-0.9%) Reintervention rates were 5.3%
Van der Kooji et al, 2011[18]	UAE vs surgery	Premenopausal women with heavy bleeding due to symptomatic fibroids Controlled trials comparing UAE vs surgery	Procedure results Return to activities Symptom status Quality of life Complication Reintervention	4 RCTs with 515 participants	UAE associated with less blood loss, and quicker return to normal activities. Long-term quality of life results were comparable for UAE and surgical groups Higher reintervention rate following UAE

Table I-4. Existing reviews of UAE interventions for uterine fibroids (5 reviews), continued

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Gupta et al, 2014[19]	UAE vs medical or surgical comparator	Women with symptomatic uterine fibroids RCTs comparing UAE to any medical or surgical therapy	Patient satisfaction Live birth	7 RCTs with 793 participants	No differences in patient satisfaction up to 2 or 5 years Higher rate of reintervention for UAE within 2 years No differences in risk of major complications Higher rate of minor complications associated with UAE Limited data on live births

Uterine Sparing Interventions

Table I-5. Existing reviews uterine sparing interventions for uterine fibroids (1 review)

Author, Year	Intervention	Inclusion Criteria	Outcome(s)	# Studies Included	Key Findings
Panagiotopoulou et al. 2014[20]	Uterine sparing	Premenopausal women with fibroids who wished to preserve their uterus RCTs Literature from 1948 to 2013	Patient satisfaction Re-intervention rate Reproductive outcomes Recovery time Complications Length of hospital stay	5 studies 436 women were included 3 studies comparing UAE with LUAO 2 studies comparing UAE with myomectomy	UAE better patient satisfaction Evidence of fertility/pregnancy outcomes poor Myomectomy requires longer hospital stay and recovery time

Surgical Interventions

Table I-6. Existing reviews of surgical interventions for uterine fibroids (3 reviews)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Nieboer, et al 2009[21]	Hysterectomy (vaginal, abdominal, laparoscopic assisted	Women undergoing hysterectomy for benign disease including uterine fibroids RCTs comparing abdominal, vaginal, and laparoscopic assisted hysterectomy	Return to normal activities Satisfaction and quality of life Intraoperative visceral injury Major complications Operation time Intraoperative complications Costs	34 RCTs (4495 women) 6 studies specifically included women with symptomatic UF	Vaginal hysterectomy associated with faster return to normal activities, fewer infections, and shorter hospital stay compared to abdominal hysterectomy. Laparoscopic assisted vaginal hysterectomy associated with faster return to normal activities, less blood loss, and shorter hospital stay More urinary or bladder injuries in LAVH compared to abdominal hysterectomy Data were not available for many long-term outcomes
Yi et al, 2011[22]	Myomectomy (vaginal and laparoscopic)	RCTs comparing laparoscopic and vaginal myomectomy	Operative outcomes including time, blood loss, length of stay, gas recovery time Major and minor complications	4 RCTs (466 women)	Vaginal myomectomy associated with significantly shorter operation time Other differences in outcomes were not statistically significant Data were limited and unavailable for major complications and long-term outcomes
Bhave Chittawar et al. 2014[23]	Myomectomy (laparoscopic or hysteroscopic vs open)	RCTs comparing myomectomy types in premenopausal women with UF	Primary outcomes: postoperative pain, in-hospital adverse events Secondary outcomes: Length of stay, operating time and recurrence	9 RCTs (808 women)	Laparoscopic myomectomy associated with less postoperative pain and shorter hospital stay No differences noted for recurrence rates between laparoscopic vs open procedures

Multiple Interventions

Table I-7. Existing reviews of medical and surgical interventions and procedures for uterine fibroids (1 review)

Author, Year	Intervention Category	Inclusion Criteria	Outcome(s)	Included Studies	Key Findings
Viswanathan, et al 2007[24]	Multiple	Women undergoing treatment (medical, surgical, procedures) for uterine fibroids Controlled trials, prospective trials with historical controls, prospective or retrospective cohort studies, and medium-to-large case series (n > 100) Studies conducted in developed nations	Symptom status, Harms, Treatment complications, Pregnancy and fertility, Sexual function, Quality of life, Fibroid recurrence, Need for subsequent treatment	107 studies addressing prevalence and treatment outcomes	Medical treatment reduced fibroids; weak evidence supported treating submucous fibroids with hyseteroscopy to preserve fertility. Evidence was not sufficient to comment on UAE vs surgical options. No well-conducted trials directly compared treatment options, including expectant management or had longer term followup. Evidence was limited overall

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