



## Comparative Effectiveness Review Number 226

# Labor Dystocia



# *Comparative Effectiveness Review*

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Number 226

## **Labor Dystocia**

### **Prepared for:**

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## **Key Messages**

### **Purpose of Review**

To review the evidence on the definition of “normal” labor progression and the comparative effectiveness of different strategies for treating labor dystocia in women with otherwise uncomplicated pregnancies. Strategies assessed include amniotomy, supportive care measures, epidural analgesia, frequency of cervical examination, intrauterine pressure catheters, high-versus low-dose oxytocin protocols, electronic fetal monitoring or intermittent auscultation during augmentation with oxytocin, and delayed or Valsalva pushing.

### **Key Messages**

- Use of partograms did not impact important maternal or neonatal outcomes.
- Amniotomy plus oxytocin decreases duration of labor without increasing cesarean delivery rates.
- Emotional support interventions may reduce cesarean deliveries and instrumental deliveries.
- Much of the evidence on different interventions came from studies performed outside the United States. Differences in patient, provider, health system, and other characteristics may affect the applicability of these results to a U.S. setting.

This report is based on research conducted by the Duke Evidence-based Practice Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00004-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 healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare 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.

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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 website at [www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov). Search on the title of the report.

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## Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new healthcare 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](http://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 healthcare system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the website ([www.effectivehealthcare.ahrq.gov](http://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](mailto:epc@ahrq.hhs.gov).

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## Key Informants

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

Key Informants must disclose any financial conflicts of interest greater than \$5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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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.

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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 \$5,000 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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# Labor Dystocia

## Structured Abstract

**Objectives.** This review evaluates the comparative effectiveness of different strategies for treating labor dystocia in women with otherwise uncomplicated pregnancies.

**Data sources.** We searched PubMed®, Embase®, CINAHL®, and the Cochrane Database of Systematic Reviews (CDSR), limiting the searches to studies in the English language and comparative studies published from January 1, 2005, to February 15, 2019.

**Review methods.** Two investigators screened each abstract and full-text article for inclusion, abstracted data, rated quality and applicability, and graded evidence. When possible, random-effects models were used to compute summary estimates of effects.

**Results.** Our review included 167 articles (158 unique studies). Studies included 25 relevant to defining abnormal labor, 12 relevant to amniotomy, 75 relevant to supportive care measures, 25 relevant to epidural analgesia, 1 relevant to cervical examination, 1 relevant to intrauterine pressure catheters, 17 relevant to high-dose versus low-dose oxytocin protocols, 1 relevant to fetal monitoring strategies, and 7 relevant to timing of pushing in the second stage. Evidence suggests that the duration and pattern of “normal” labor progress based on modern management are quite different from historical data, and that labor progress differs between nulliparous and parous women. Use of partograms did not change important maternal or neonatal outcomes, although the applicability of this evidence to modern U.S. settings is limited. Routine amniotomy decreased the total duration of labor in nulliparous women without affecting other outcomes (moderate strength of evidence [SOE]); routine amniotomy with oxytocin augmentation decreased labor duration without increasing cesarean delivery (high SOE). Although supportive care is considered to improve parental satisfaction with the birthing process, satisfaction outcomes were rarely assessed in the included clinical trials. An existing systematic review of 11 studies found that women receiving continuous emotional support were less likely to rate their birth experience negatively. Of the different types of supportive therapies, only emotional support interventions showed reductions in cesarean (low SOE for doula support, moderate SOE for continuous emotional support) and instrumental deliveries (moderate SOE). For women choosing analgesia (epidural vs. combined spinal epidural, or epidural vs. patient-controlled intravenous analgesia), neither type nor timing affected cesarean delivery rates (moderate SOE).

**Conclusions.** The normal progress of labor given current practice is quite different from that originally described, although there is still uncertainty about the duration of “normal” labor in the absence of augmentation. Further work is needed to identify (1) the cesarean delivery rate that optimally balances maternal and neonatal outcomes and patient preferences, and (2) the best strategies to achieve this rate.

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# Evidence Summary

## Background

### Condition and Treatment Strategies

Approximately 80 percent of American women will eventually have at least one child,<sup>1</sup> and the majority of these women will undergo labor. “Labor dystocia”—difficult or obstructed labor<sup>2</sup>—encompasses a variety of concepts, ranging from “abnormally” slow dilation of the cervix or descent of the fetus during active labor<sup>3</sup> to entrapment of the fetal shoulders after delivery of the head (“shoulder dystocia,” an obstetric emergency). For the purposes of this systematic review, we assume that “labor dystocia” refers to “abnormal” labor progression during the latent (up to 4–6 cm dilation) or active phases (from 4–6 cm until full dilation) of the first stage of labor, or during the second stage (from complete cervical dilation until delivery of the baby, although, as discussed below, there have been substantial changes in practice since these “traditional” definitions were developed which raise questions about their generalizability to modern populations. We also limit our review to women in spontaneous labor, with definitions varying somewhat between studies but generally including the onset of spontaneous uterine contractions, and explicitly exclude studies of women undergoing induction, or women with premature rupture of membranes at term in the absence of contractions.

Prolonged labor may increase the risk for maternal and neonatal infection, fetal distress, neonatal hypoxia, uterine rupture, and postpartum hemorrhage; it may also be a marker for increased risk of maternal pelvic floor and genital trauma during delivery (with a subsequent increased risk for future incontinence and pelvic organ prolapse).<sup>4</sup> Reducing the likelihood of these adverse maternal and neonatal outcomes is the underlying rationale for performing a cesarean delivery for the primary indication of labor dystocia.<sup>3</sup>

However, there is a tradeoff, since cesarean delivery itself increases the risk of maternal hemorrhage, venous thromboembolism, and injury to the bladder and other internal organs, and can affect post-delivery mother–baby interactions.<sup>3,5</sup> Further, having one cesarean delivery increases the likelihood of having subsequent cesarean deliveries.<sup>3</sup> A woman’s risk for abnormal placentation (placenta previa or accreta, each of which is associated with significant maternal and neonatal morbidity and mortality) is directly related to the number of prior cesarean deliveries she has had.<sup>6</sup>

Although there is no consensus on the “optimal” cesarean delivery rate (conceptually, the rate that strikes a balance between benefits and harms for both mother and baby that is considered acceptable to most patients), there is general consensus that current rates in the United States are too high,<sup>3,7</sup> although whether the factors driving this rate are amenable to evidence-based solutions has been questioned.<sup>8</sup> There is also growing concern about increases in rates internationally, as reflected by a World Health Organization consensus statement.<sup>9</sup> Strategies to prevent a woman’s first, or primary, caesarean delivery may therefore lead to significant improvements in maternal and neonatal outcomes by reducing both the number of primary and repeat cesareans.<sup>3</sup> For this reason, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) have issued a joint consensus statement aimed at “preventing the first cesarean delivery.”<sup>3</sup> with similar efforts instituted by the American College of Nurse-Midwives.<sup>10</sup> Since abnormalities of labor progression are the single most common cause of primary cesarean delivery in the United

States,<sup>3,11</sup> strategies aimed at reducing cesarean delivery for dystocia may have the largest potential impact on overall cesarean rates.

The effective management of labor dystocia is first dependent on the tool used to diagnose the disorder. In the 1950s, Friedman published his observations on the rate of cervical change among a cohort of women in spontaneous labor<sup>12</sup> and from this constructed labor curves representing the expected rate of cervical change in a population. Deviations from these curves, particularly rates of cervical change slower than expected from the Friedman curve are referred to as protracted or arrest disorders and represent labor dystocia. The Friedman curve has been the primary tool used to diagnose abnormal labor since then, though more recent data from the Consortium on Safe Labor have demonstrated that rates and characteristics of cervical change seen in modern obstetrics are quite different from that represented by the Friedman curve.<sup>13</sup> Identifying what constitutes normal labor is an important initial step in the management of labor dystocia as it first dictates when various treatment options are initiated. Variation between providers about definitions or perceptions of “abnormal” labor length may contribute to variations in rates of diagnosis.

There are a number of strategies that may either facilitate earlier diagnosis of labor, directly or indirectly (e.g., choice of pain management strategies) prevent a diagnosis of labor dystocia, or accelerate labor progress after a diagnosis of dystocia. Strategies addressed in this report include:

- Use of graphs of cervical dilation over time (“partograms”) to identify patients with slow labor progress, often with an indicator of when intervention is appropriate.
- Timing of the artificial rupture of the amniotic membranes (amniotomy) during labor.
- Various options for maternal positioning, ambulation, and feeding during labor.
- Use of epidural analgesia, or, alternatively, variations in technique (timing, choice of analgesic agents).
- Variations in monitoring labor progress (such as frequency of cervical examination or use of intrauterine pressure catheters) and fetal well-being (fetal heart rate monitoring).
- Variations in strategies for how oxytocin is used during labor augmentation including timing of augmentation relative to labor progress and variation in dosing regimens.
- Variations in strategies for reducing the length of the second stage of labor (after cervical dilation is complete but before the baby has delivered), including different approaches to maternal pushing.

The overall goal of treating labor dystocia is to optimize delivery outcomes for mother and child, while reducing excess cesarean delivery.

## Scope and Key Questions

This systematic review evaluates the comparative effectiveness of different strategies for treating labor dystocia in women with otherwise uncomplicated pregnancies. We also limit our review to women in spontaneous labor and exclude those who are undergoing induced labor. In addition, one potential source of uncertainty in the available evidence may be variability in the definitions for different phases of labor, and what constitutes “normal” labor across studies and likely in practice as well. In order to better understand the impact of this variability on the evidence on specific interventions, we also review the evidence on the definition of “normal” labor progression.

We explicitly excluded studies which included women with other potential indications for cesarean section (e.g., multiple pregnancies, prior cesarean) or other conditions which might affect either the likelihood of diagnosis of dystocia (e.g., use of magnesium sulfate in preeclampsia) or lead to contraindications to some interventions (e.g., HIV and amniotomy). We also did not include interventions such as estimation of fetal size or clinical pelvimetry which might affect physician perception of the risk of labor dystocia.

The specific Key Questions (KQs) addressed in this review are listed below, and Figure A displays the analytic framework that guided our work.

**KQ 1: Do delivery outcomes for management of abnormal labor differ based on the criteria used to define protracted or arrested labor at different stages of the labor process?**

**KQ 2: What are the benefits and harms of amniotomy in women in spontaneous labor?**

**KQ 3: What are the benefits and harms of supportive care measures, including emotional support, ambulation, nutrition, and hydration, during spontaneous labor?**

**KQ 4: What are the benefits and harms of epidural analgesia in labor, particularly in terms of the risk of a diagnosis of prolonged labor?**

**KQ 5: How does the frequency of cervical examination affect the probability of specific benefits and harms?**

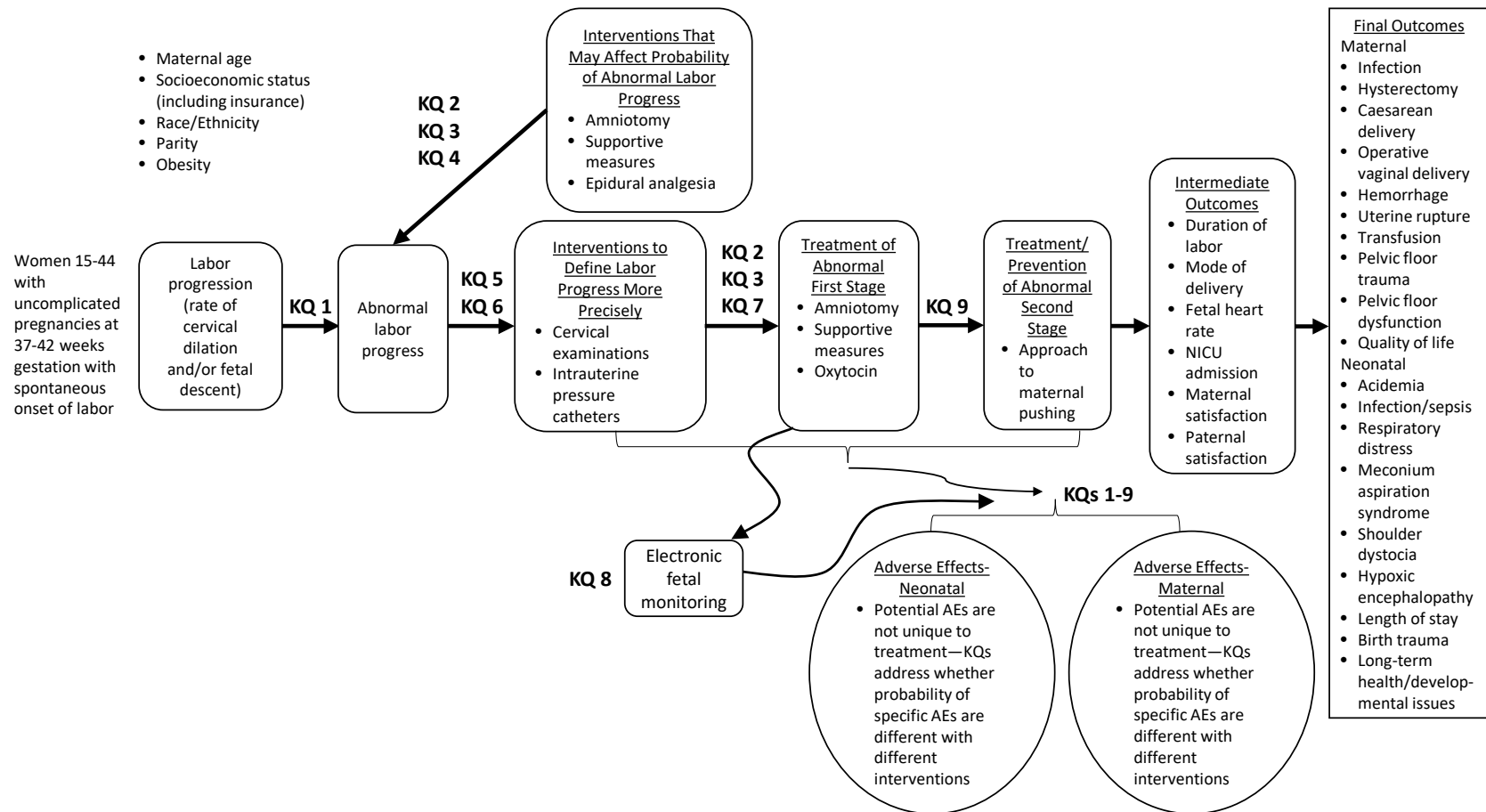
**KQ 6: What are the benefits and harms of intrauterine pressure catheters in the diagnosis and management of labor dystocia?**

**KQ 7: For women with abnormal labor, what are the relative benefits and harms of high- versus low-dose oxytocin protocols (including nipple stimulation)?**

KQ 8: For women in spontaneous labor undergoing augmentation with oxytocin, what are the relative benefits and harms (in terms of both maternal and neonatal outcomes) of electronic fetal monitoring versus intermittent auscultation?

KQ 9: For women in the second stage of labor, is there a benefit from delayed or Valsalva pushing for time to delivery or mode of delivery?

**Figure A. Analytic framework**



Abbreviations: AEs=adverse effects; KQ=Key Question; NICU=neonatal intensive care unit

## Methods

Detailed methods are available in the full report and the posted protocol (<https://effectivehealthcare.ahrq.gov/products/labor-dystocia/research-protocol>). Our literature search was limited to studies published in English from January 1, 2005, to February 15, 2019, depending on the database. We also completed manual searches of citations from a set of key primary and review articles. Additionally, we attempted to identify relevant grey literature. We graded the strength of evidence for each outcome assessed using the approach described in the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>14-16</sup> A more detailed description of our search and our risk of bias and strength of evidence calculations can be found in the full report.

## Literature Search Strategy

To identify relevant published literature, we searched PubMed®, Embase®, CINAHL®, and the Cochrane Database of Systematic Reviews (CDSR), limiting the searches to studies published in English from January 1, 2005, to February 15, 2019. These databases were selected based on internal expert opinion that they would identify most of the relevant literature on this topic and that they reflect the databases used in related systematic reviews (SRs), particularly reviews conducted by the Cochrane Pregnancy and Childbirth Group. An experienced search librarian guided all searches. The exact search strings used are given in Appendix A.

We supplemented the electronic searches with a manual search of citations from a set of key primary and review articles. The reference lists for identified key articles were manually searched and cross-referenced against our database, and additional relevant articles not already under consideration were retrieved for screening. All citations were imported into an electronic bibliographical database (EndNote® Version X7; Thomson Reuters, Philadelphia, PA).

To identify relevant gray literature, the EPC Scientific Resource Center notified stakeholders that the EPC was interested in receiving information relevant to the KQs. We also searched ClinicalTrials.gov for two purposes: (1) to identify relevant articles from completed studies that may not have appeared through other search strategies and (2) as one mechanism to ascertain publication bias in recent studies. For the latter goal, we sought to identify completed but unpublished studies that could impact the findings of the review. We also explored the possibility of publication bias specifically in our quantitative synthesis of the included literature through meta-analysis (MA) techniques such as funnel plots when appropriate. Further gray literature assessment included searching the World Health Organization International Clinical Trials Registry Platform search portal and the National Guidelines Clearinghouse to identify potentially relevant study records; we subsequently searched for relevant articles from among the completed studies.

We specified our inclusion and exclusion criteria based on the PICOTS (populations, interventions, comparators, outcomes, timing, and settings) identified for each question. For citations retrieved from PubMed, Embase, and the Cochrane Database of Systematic Reviews, two reviewers independently screened each title and abstract for potential relevance to the research questions using prespecified inclusion/exclusion criteria. Articles included by either reviewer underwent full-text screening. Articles meeting eligibility criteria at the full-text stage were included for data abstraction. Based on their clinical and methodological expertise, a pair of researchers were assigned to abstract data from each of the eligible articles. One researcher abstracted the data, and the second over-read the article and the accompanying abstraction to

check for accuracy and completeness. Disagreements were resolved by consensus or by obtaining a third reviewer's opinion if consensus could not be reached.

## **Risk of Bias Assessment of Individual Studies**

We assessed methodological quality, or risk of bias, for randomized and nonrandomized individual study designs using a components approach, assessing each study for specific aspects of design or conduct (such as allocation concealment for randomized controlled trials (RCTs), or use of methods to address potential confounding), as detailed in AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>14</sup> Briefly, we rated each study as being of good, fair, or poor quality based on its adherence to well-accepted standard methodologies. For each study, one investigator assigned a summary quality rating, which was then reviewed by a second investigator; disagreements were resolved by consensus or by a third investigator if agreement could not be reached.

## **Data Synthesis**

We began by summarizing key features of the included studies for each KQ. To the degree that data were available, we abstracted information on study design; patient characteristics; clinical settings; interventions; and intermediate, final, and adverse event outcomes.

We then determined the feasibility of completing a quantitative synthesis (i.e., meta-analysis, decision analysis, or simulation model). For a meta-analysis, feasibility depends on the volume of relevant literature (requiring at least three relevant studies), conceptual homogeneity of the studies (similar intervention comparisons and outcome definitions), completeness of the reporting of results, and the adequacy and completeness of any existing meta-analyses (MAs).

## **Strength of the Body of Evidence**

We graded the strength of evidence for each outcome assessed using the approach described in AHRQ's *Methods Guide*.<sup>14-16</sup> We also discussed the consistency of our findings with recent SRs, along with possible causes for disagreement and impact on strength of evidence ratings, in the results. Newly identified studies are presented separately from the results of existing reviews. Overall strength of evidence findings are based on the primary evidence. Existing SRs were incorporated into the summary strength of evidence (SOE) when available. Only good- and fair-quality SRs were considered, with heavier weighting to findings from good-quality SRs. A summary rating of high, moderate, or low strength of evidence was assigned for each outcome after discussion by two reviewers. When no evidence was available, or when evidence on the outcome was too weak, sparse, or inconsistent to permit any conclusion to be drawn, a grade of "insufficient" was assigned.

## Results

We briefly summarize the results of our literature searches, description of included studies, key points, and strength of evidence for each KQ.

### Summary of Studies

The literature search yielded 11,746 unique citations. In total, 1,082 full-text articles were retrieved and screened. Of these, 915 were excluded at the full-text screening stage, leaving 167 articles for data abstraction. These 167 articles described 158 unique studies. The relationship of studies to the review questions is as follows: 25 studies relevant to KQ 1, 12 studies relevant to KQ 2, 75 studies relevant to KQ 3, 25 studies relevant to KQ 4, 1 study relevant to KQ 5, 1 study relevant to KQ 6, 17 studies relevant to KQ 7, 1 study relevant to KQ 8, and 7 studies relevant to KQ 9 (some studies were relevant to more than one KQ).

In all tables, criteria for downgrading SOE are described as “Rationale;” when these criteria are insufficient for understanding the final SOE, additional explanation is provided. Abbreviations common to all tables include RCT for randomized controlled trial, SOE for strength of evidence, and SR for systematic review.

### Key Question 1. Criteria Used To Define Abnormal Labor

We identified 19 individual studies that examined whether labor outcomes among women in spontaneous labor differed based on the criteria used to define abnormal labor.<sup>17-33</sup> Key findings include:

- No differences were seen in postpartum hemorrhage rates (moderate SOE), neonatal acidemia rates (low SOE), or vaginal delivery rates (moderate SOE) between women managed with varying partogram strategies.
- Maternal satisfaction was also no different between partogram strategies (low SOE).
- Modern labor curves constructed from the Consortium on Safe Labor (CSL) demonstrate significantly different rates of cervical change, duration of labor, and appearance of the curve (absence or presence of an inflection point) between nulliparous and parous women.
- Modern labor curves constructed from the CSL cohort vary significantly from curves constructed from historical cohorts (Friedman or National Collaborative Perinatal Project [NCPP]), with modern curves suggesting a longer duration of the first stage of labor.
- Maternal age influences the duration of the first and second stage of labor among nulliparous women (older women having longer labors).

Table A summarizes the SOE for the use of partograms. In general, the SOE was reduced for outcomes because the evidence was based on findings from non-U.S. settings (and several studies focused on low-resource settings).



**Table A. Partogram use: Evidence summary for major outcomes and adverse events**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Operative Vaginal Delivery	1 RCT <sup>24</sup> (1,929)  1 SR <sup>34</sup> (1,813 patients, 3 studies)	<b>No difference:</b> No difference in operative vaginal delivery rates between women managed with varying partogram strategies.	Moderate (non-U.S. setting)  Findings consistent with SR
	Process Related Outcomes – Parental Preferences	1 RCT <sup>24</sup> (1,929)	<b>No difference:</b> An RCT in the UK demonstrated no difference in maternal satisfaction scores between women managed with a two-hour action line partogram compared to women managed with a four-hour action line partogram.	Low (non-U.S. setting, 1 study)
Adverse Events	Maternal Outcomes – Hemorrhage	3 RCTs <sup>24,25,29</sup> (3,700)	<b>No difference:</b> No difference in postpartum hemorrhage rates among women managed with varying partogram strategies.	Moderate (non-U.S. setting)
	Neonatal Outcomes – Acidemia	1 RCT <sup>24</sup> (1,929)	<b>No difference:</b> No difference in neonatal acidemia rates between women managed with varying partogram strategies.	Low (non-U.S. setting, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 2. Amniotomy

We identified nine RCTs that examined the benefits and harms of amniotomy ( $\pm$  oxytocin) in women in spontaneous labor.<sup>35-43</sup> Key findings include:

- Amniotomy decreases the total duration of labor in nulliparous women (moderate SOE) and those with unspecified parity (low SOE).
- There was no difference in the rate of cesarean delivery for early amniotomy versus control in women with unspecified parity (moderate SOE)
- There were no differences in rates of maternal infection, hemorrhage, or trauma to the pelvic floor (moderate SOE) for early amniotomy versus control.
- Routine amniotomy plus oxytocin decreases the duration of labor and has a similar effect in both nulliparous and parous women (high SOE).
- Routine amniotomy plus oxytocin does not differ compared with control treatment in cesarean delivery rates in both nulliparous and parous women (high SOE).

Tables B–F summarize the SOE for amniotomy ( $\pm$  oxytocin) versus control treatment.

**Table B. Early amniotomy versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	5 RCTs <sup>35-37,40,42</sup> (1,593)  1 SR (379 patients, 4 studies) <sup>44</sup>	<b>Improvement with early amniotomy:</b> All trials demonstrated a decrease in the duration of labor in women randomized to early amniotomy.	Moderate (Medium risk of bias, Inconsistent, Indirect)  SOE was reduced given inconsistency with existing SR which found no difference in less contemporary RCTs
Adverse Events	Maternal Outcomes - Infection	3 RCTs <sup>36,37,42</sup> (1,593)	<b>No difference:</b> Two good quality RCTs and one fair-quality RCT support no increased risk of infection	Moderate (imprecise)
	Maternal Outcomes – Trauma to pelvic floor	3 RCTs <sup>36,37,40</sup> (437)	<b>No difference:</b> Three good quality RCTs support no evidence of increased risk of pelvic floor trauma	Moderate (imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table C. Early amniotomy versus control: Evidence summary in women with unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	4 RCTs <sup>36,38,41,43</sup> (912)	<b>Improvement with early amniotomy:</b> Three studies suggest shorter duration of total labor with early amniotomy. One study from the middle east did not find a difference.	Low (Indirect, inconsistent)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>36,38,41,43</sup> (912)  1 SR (874 patients, 3 studies) <sup>44</sup>	<b>No difference:</b> There was no difference in the rate of cesarean delivery between women randomized to early amniotomy versus control.	Moderate (Indirect, consistent)  Existing SR was consistent with RCT findings
Adverse Events	Maternal Outcomes – Infection	2 RCTs <sup>36,37</sup> (973)	<b>No difference:</b> There was no evidence of increased risk of infection associated with early amniotomy versus control.	Moderate (Imprecise)
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>36,37</sup> (973)	<b>No difference:</b> There was no evidence of increased risk of maternal hemorrhage associated with early amniotomy.	Moderate (Imprecise)
	Maternal Outcomes – Trauma to Pelvic Floor	3 RCTs <sup>36,37,40</sup> (683)	<b>No difference:</b> There was no evidence of increased risk of trauma to the pelvic floor associated with early amniotomy.	Moderate (Medium risk of bias)
	Neonatal Outcomes – Infection	1 RCT <sup>37</sup> (690)	<b>No difference:</b> There was no evidence of increased risk of neonatal infection associated with early amniotomy.	Low (1 study)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	3 RCTs <sup>36,38,40</sup> (611)	<b>No difference:</b> There was no evidence of increased risk of operative vaginal delivery associated with early amniotomy.	Low (Indirect, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table D. Amniotomy plus oxytocin versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>45,46</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the duration of the first stage of labor.	High
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>45</sup> (2,737 patients, 5 studies)	<b>No difference:</b> There was no difference in the duration of second stage of labor between groups.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>45,46</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> The duration of labor was shortened in women randomized to amniotomy plus oxytocin as compared to routine care.	High
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>45,46</sup> (7,653 patients, 11 studies)	<b>No difference:</b> There was no difference in cesarean delivery rates between amniotomy plus oxytocin compared with control.	High

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table E. Amniotomy plus oxytocin versus control: Evidence summary in women with unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>45,46</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the duration of the first stage of labor.	High
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>45</sup> (2,737 patients, 5 studies)	<b>No difference:</b> There was no difference in the duration of the second stage of labor in the amniotomy plus oxytocin group as compared with control.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>45,46</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the total duration of labor.	High
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>45,46</sup> (7,653 patients, 11 studies)	<b>No difference:</b> There was no difference in cesarean delivery rates between amniotomy plus oxytocin compared with control.	High

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Maternal Outcomes – Infection	3 RCTs <sup>37</sup> (1,933)  2 SRs <sup>44-46</sup> (3,475 patients, 6 studies)	<b>No difference:</b> There was no difference in risk of infection between groups.	High  Findings from existing SR consistent with RCT evidence
	Maternal Outcomes – Hemorrhage	2 SRs <sup>44-46</sup> (2,674 patients, 4 studies)	<b>No difference:</b> No difference in risk of hemorrhage between groups.	High
	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>36</sup> (283)	<b>No difference:</b> One RCT examined active management of labor with early amniotomy and oxytocin as compared with routine care, there was no difference in risk of trauma to the pelvic floor between groups.	Low (1 study)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	1 SR <sup>44,46</sup> (5,738 patients, 9 studies)	<b>No difference:</b> There was no difference in risk of operative vaginal delivery between groups.	High
	Process Related Outcomes – Parental Preferences	2 SRs <sup>44-46</sup> (2,436 patients, 2 studies)	<b>No difference:</b> No difference between the two groups in scores of maternal/parental satisfaction.	Moderate (Imprecise, varying metrics)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table F. Amniotomy plus oxytocin versus control: Evidence summary in parous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>45,46</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy:</b> Amniotomy decreased the duration of the first stage of labor compared with control	Moderate (Imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>45</sup> (2,737 patients, 5 studies)	<b>No difference:</b> No difference in the duration of second stage of labor between groups.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>45,46</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Modest decrease in duration of labor in the intervention group as compared with controls.	Moderate (Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>45,46</sup> (7,653 patients, 11 studies)	<b>No difference:</b> No difference in the rate of cesarean delivery between groups.	Moderate (Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

### Key Question 3. Supportive Care

We identified 64 articles<sup>47-110</sup> representing 61 individual RCTs that examined the benefits and harms of supportive care measures in women during spontaneous labor. Supportive care measures included interventions such as continuous emotional support, perineal massage, water birth, acupuncture, ambulation and positioning strategies.

Key findings include:

- Supportive care measures during labor encompass a wide variety of interventions and within individual categories of interventions, there is considerable heterogeneity in the nature and timing of the interventions.
- Although supportive care therapies are often seen as increasing parental satisfaction with the birthing process, these outcomes were only assessed in five of the included RCTs with sparse evidence. An earlier SR of 11 studies however did find that women receiving continuous emotional support were less likely to rate their birth experience negatively (moderate SOE).
- Two studies addressing continuous emotional support included in the present review did not show a benefit in reducing 1<sup>st</sup> or 2<sup>nd</sup> stage labor duration, although prior SR/MAs of 12 studies (including these two studies) indicated a benefit for total labor duration (moderate SOE).
- Emotional support interventions reduced cesarean deliveries (low SOE for doula support, moderate SOE for continuous emotional support) and instrumental deliveries (moderate SOE).
- There was no difference in rates of cesarean deliveries for women receiving perineal compresses or massage (low SOE), but severe perineal trauma was reduced in nulliparous women (low SOE).
- There was no difference in duration of labor in women using water birth (low SOE).
- Women undergoing acupuncture/acupoint nerve stimulator did not experience differences in labor duration or rates of maternal hemorrhage (low SOE for both outcomes).
- Ambulation was associated with shorter duration of labor (low SOE).
- No differences were found in duration of labor (low SOE) or cesarean delivery rates (moderate SOE) for women using differing positioning interventions. Women in kneeling position were more likely than women in sitting position to have reduced trauma to the pelvic floor (low SOE).
- Administration of intravenous fluids compared with oral intake alone demonstrated a reduction in the duration of labor (low SOE), while not increasing cesarean delivery rates (moderate SOE), maternal hemorrhage (low SOE), or operative vaginal delivery rates (moderate SOE).

Table G summarizes the SOE for continuous emotional support versus control in nulliparous women. Strength of evidence for continuous emotional support versus control in women of mixed parity was rated as insufficient for all outcomes.

**Table G. Continuous emotional support versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>79,90</sup> (326)	<b>No difference:</b> Good-quality studies of nulliparous women found that continuous emotional support did not reduce duration of 1 <sup>st</sup> stage labor.	Moderate (Indirect)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	2 RCTs <sup>79,90</sup> (326)	<b>No difference:</b> Good-quality studies of nulliparous women found that continuous emotional support did not reduce duration of 2 <sup>nd</sup> stage labor.	Moderate (Indirect)
	Process Related Outcomes – Duration of Total Labor	1 SR <sup>111</sup> (5,366 patients, 12 studies)	<b>Improvement with continuous emotional support:</b> Systematic review of 12 studies found shorter total duration of labor	Moderate (Indirect)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>70,79</sup> (599)  Doula support: 1 SR <sup>111,112</sup> (2,008 patients, 5 studies)  Continuous emotional support: 1 SR <sup>111</sup> (5,366 patients, 12 studies)	<b>Improvement with Doula support:</b> Doula support reduced cesarean deliveries as compared to control therapy.  <b>Improvement with continuous emotional support:</b> Continuous emotional support lowered risk of cesarean delivery (RR 0.78, 95% CI 0.67 to 0.91) based on SR of 22 studies.	Low – Doula (Indirect)  Inconsistency between SRs and included RCTs  Moderate – Continuous Emotional Support (Indirect)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	Doula support: 1 SR <sup>111,112</sup> (1,587 patients, 4 studies)  Continuous emotional support: 1 SR <sup>111</sup> (14,118 patients, 19 studies)	<b>Improvement with Doula support:</b> Doula support reduced risk of instrumental vaginal delivery  <b>Improvement with continuous emotional support:</b> Continuous emotional support lowered risk of instrumental vaginal delivery based on SR of 19 studies.	Moderate (Indirect)
Adverse Events	Process Related Outcomes – Abnormal Fetal Heart Tracing	1 RCTs <sup>79</sup> (212)	<b>No difference:</b> Supportive care was not associated with significant differences in fetal heart tracings.	Low (Indirect, imprecise, 1 study)
	Process Related Outcomes – Parental Preferences	1 SR <sup>111</sup> (11,133 patients, 11 studies)	<b>Improvement with continuous emotional support:</b> SR of 11 studies found women receiving continuous emotional support less likely to rate their birth experience negatively	Moderate

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; hr=hours; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

Tables H–K summarize the SOE for perineal compresses or massage versus control in nulliparous women and women of mixed parity. In general the SOE was rated as low given evidence from only one study.

**Table H. Perineal compresses or massage versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>87</sup> (717)	<b>No difference:</b> No significant differences in the proportion of cesarean deliveries was reported for the massage/compress group.	Low (Indirect, 1 study)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>87</sup> (717)	<b>Improvement with massage/compress:</b> Severe perineal trauma (third- and fourth-degree perineal laceration) was lower incidence for the massage/compress group.	Low (1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table I. Perineal compresses or massage versus control: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>76</sup> (1,211)	<b>No difference:</b> Duration of 2nd stage labor was not statistically significantly different between the intervention and usual care groups.	Low (Indirect, 1 study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>76</sup> (1,211)	<b>No difference:</b> No significant differences in the proportion of cesarean deliveries was reported for the massage/compress group.	Low (Indirect, 1 study)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>76</sup> (1,211)	<b>No difference:</b> No significant differences in perineal trauma were reported between the intervention and control groups.	Low (1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table J. Massage during labor versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>56,57</sup> (123)	<b>No difference:</b> Total duration of labor was not significantly different in the massage group compared to usual care.	Low (Indirect, Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>56,57</sup> (123)	<b>No difference:</b> The proportion of cesarean deliveries was not significantly different between the massage group and control group.	Low (Indirect, Imprecise)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table K. Water birth versus control: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>68</sup> (106)  1 SR <sup>113</sup> (291 patients, 2 studies)	<b>No difference:</b> No difference in duration of 2 <sup>nd</sup> stage labor was reported.	Low (Medium risk of bias, indirect, imprecise)  SOE was increased to low given findings from SR which also demonstrated no difference between water birth versus control

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

For the studies which compared acupressure versus control, although findings were consistent between studies, the SOE was rated as insufficient for all outcomes given the small number of patients, the potential risk of bias, and the imprecision of the findings.

Tables L and M summarize the SOE for acupuncture/acupoint nerve stimulator versus control therapy. Other than the outcomes listed below, the SOE was rated as insufficient for all other outcomes given inconsistent findings from studies with variability in interventions.

**Table L. Acupuncture/acupoint nerve stimulator versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	4 RCTs <sup>47,66,104,110</sup> (601)	<b>No difference:</b> in 2 <sup>nd</sup> stage labor between the acupuncture and control groups was reported.	Low (Medium risk of bias, indirect, Imprecise)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table M. Acupuncture/acupoint nerve stimulator versus control: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	2 RCTs <sup>47,66</sup> (350)	<b>No difference:</b> No significant difference in 2 <sup>nd</sup> stage labor between the acupuncture and control groups was reported.	Low (Medium risk of bias, indirect, imprecise)
Adverse Events	Maternal Outcomes – Hemorrhage	1 RCT <sup>53</sup> (253)	<b>No difference:</b> No significant difference in hemorrhage was reported for the intervention group compared to the control.	Low (High risk of bias, imprecise)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence



The SOE findings for all outcomes comparing aromatherapy and control treatment was rated as insufficient given the potential risk of bias, small study size, and inconsistent findings. The SOE findings for outcomes comparing *Anethum graveolens* seeds (dill) and control treatment was rated as insufficient.

Tables N–P summarize the SOE for ambulation or positioning versus control therapy. Overall the SOE was reduced given the potential risk of bias in the included studies.

**Table N. Ambulation versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>77,80</sup> (271)	<b>Improvement with ambulation:</b> 1 good-quality <sup>80</sup> and 1 poor-quality study <sup>77</sup> found that ambulation was associated with significantly reduced duration of the first stage and total duration of labor.	Low (Medium risk of bias, indirect, imprecise, inconsistent with SR)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table O. Positioning versus control: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	5 RCTs <sup>65,71,74,86,91</sup> (798)	<b>No difference:</b> None of the studies examining use of a birth ball, kneeling, sitting, or semi-sitting laboring positions found statistically significant differences in duration of active labor.	Low (High risk of bias, indirect, imprecise, inconsistent with SR)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	5 RCTs <sup>59,74,96,100,101</sup> (4,546)  1 SR <sup>114</sup> (2,079 patients, 8 studies)	<b>No difference:</b> No significant differences were found between the intervention and control groups in mode of delivery.	Moderate (Medium risk of bias, indirect, imprecise, consistent)  The SOE was increased given the support of a SR of 11 studies.
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>74</sup> (271)	<b>Improvement with kneeling:</b> Women in kneeling position were more likely than women in sitting position to have an intact perineum (51 vs. 37%) and fewer 3rd or 4th degree tears (3 vs. 6%).	Low (Imprecise, one study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table P. Positioning versus control: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	3 RCTs <sup>72,81,98</sup> (1,287)	<b>Improvement with positioning:</b> Second stage of labor was significantly shorter in women using either a peanut ball or a squatting position.	Low (Medium risk of bias, indirect, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

Table Q summarizes the SOE for nutritional intervention and oral or parenteral hydration intervention in nulliparous women. The SOE was insufficient for outcomes in women of mixed parity.

**Table Q. Specific nutritional intervention and oral or parenteral hydration intervention recommendations or limitations: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	3 RCTs <sup>55,60,73</sup> (861)  1 SR <sup>115</sup> (1,781 patients, 9 studies)	<b>Improvement with intravenous fluids:</b> Administration of intravenous fluids compared with oral intake alone demonstrated a reduction in the duration of labor.	Low (Indirect, inconsistent, imprecise)  The SOE was reduced given the inconsistency in the findings of individual trials and with the SR and the variability in hydration strategies.
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	6 RCTs <sup>55,61,64,67,69,73</sup> (1,373)	<b>No difference:</b> No significant differences were found between groups of women receiving oral hydration versus high-level intravenous hydration (OR 1.26, 95% CI 0.08 to 18.84).	Moderate (Indirect, Imprecise)
Adverse Events	Maternal Outcomes – Hemorrhage or Infection	2 RCTs <sup>60,69</sup> (539)	<b>No difference:</b> No significant differences in rates of maternal hemorrhage or infection were found between groups of women receiving infusions of 5% or 10% dextrose and normal saline.	Low (Imprecise)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	5 RCTs <sup>55,60,67,73</sup> (1,234)	<b>No difference:</b> No difference in operative vaginal delivery rates amongst 5 studies using varying methods of hydration.	Moderate (Indirect, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; OR=odds ratio; RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 4. Epidural Analgesia

We identified 26 articles<sup>47,104,110,116-138</sup> representing 22 individual RCTs that examined the benefits and harms of epidural analgesia (EA) in labor. Key findings included:

- For nulliparous women, a meta-analysis showed no significant differences between EA and combined spinal epidural (CSE) in duration of the first stage of labor (low SOE) or duration of the second stage of labor (low SOE). However, total duration of labor (from time of intervention to delivery) was significantly longer for EA relative to CSE (moderate SOE). There were no differences between EA and CSE in rates of cesarean delivery (moderate SOE).
- For women of mixed parity, there was no difference between EA and CSE for total duration of labor (low SOE), or rates of cesarean delivery (moderate SOE).
- For women of mixed parity, there were no differences between EA and patient-controlled intravenous analgesia (PCIA) in duration of labor or rates of cesarean delivery (low SOE for both outcomes).
- For nulliparous women, there was no difference in duration of first or second stage labor or rates of cesarean delivery for early versus late EA (moderate SOE for all outcomes).
- For women of mixed parity, there was no evidence of a difference between EA and no EA for the duration of the first stage of labor or rates of cesarean delivery. There was a slight increase in the duration of the second stage for women with EA (moderate SOE for all outcomes).

Tables R and S summarize the SOE for EA versus CSE. In general, meta-analysis of the included studies resulted in low and moderate SOE for major outcomes of interest.

**Table R. Epidural analgesia versus combined spinal epidural: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	5 RCTs <sup>119,123,125,131,136</sup> (1,424)	<b>No difference:</b> Meta-analysis showed no significant differences between EA and CSE in duration of the first stage of labor (mean difference [MD] 32.7 minutes; 95% CI -19.3 to 84.7).	Low (Medium risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	5 RCTs <sup>119,123,125,131,136</sup> (1,424)	<b>No difference:</b> Meta-analysis showed no significant differences between EA and CSE in duration of the second stage of labor (MD -0.2 minutes; 95% CI -21.9 to 21.6).	Low (Medium risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Total Duration of Labor	5 RCTs <sup>119,123,125,131,136</sup> (1,424)	<b>Worsening with EA:</b> Meta-analysis showed total duration of labor (from time of intervention to delivery) was significantly longer for EA relative to CSE, with an MD of 62.0 minutes (95% CI 7.2 to 116.7).	Moderate (Medium risk of bias, imprecise)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	5 RCTs <sup>119,123,129,131,136</sup> (1,604)	<b>No difference:</b> Meta-analysis of the data from 1604 patients in these 5 RCTs showed no statistically significant difference in cesarean delivery rates between EA and CSE (OR 1.1; 95% CI 0.9 to 1.2).	Moderate (Indirect)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; MD=mean difference; OR=odds ratio; RCT=randomized controlled trial; SOE=strength of evidence

**Table S. Epidural analgesia versus combined spinal epidural: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Total Duration of Labor	2 RCTs <sup>118,125</sup> (258)	<b>No difference:</b> No significant difference between EA and CSE for total duration of labor.	Low (Medium risk of bias, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>118,125,128,130</sup> (374)	<b>No difference:</b> Meta-analysis generated an estimate of the odds ratio of cesarean delivery associated with CSE relative to EA of 0.8 (95% CI: 0.5 to 1.3).	Moderate (Medium risk of bias)
Adverse Events	Process Related Outcomes – Abnormal Fetal Heart Tracing	2 RCTs <sup>118,130</sup> (190)	<b>Improvement with EA:</b> CSE was associated with a higher proportion of patients with abnormal fetal heart rate tracings than EA in one study and a risk ratio of 2.28 (95% CI: 0.64 to 8.16) for an abnormal fetal heart tracing in another study.	Low (Medium risk of bias, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; RCT=randomized controlled trial; SOE=strength of evidence

Table T summarizes the SOE for EA versus patient-controlled intravenous analgesia. In general, the SOE was judged insufficient for outcomes given the imprecision of the findings, findings for specific outcomes from just one study, and the non-U.S. settings. Low SOE was reported for duration of labor and cesarean delivery in women with mixed or unspecified parity.

**Table T. Epidural analgesia versus patient-controlled intravenous analgesia: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Total Duration of Labor	3 RCTs <sup>47,122,127</sup> (177)	<b>No difference:</b> Meta-analysis did not identify differences in duration of labor, with the estimated mean after EA administration minus duration after PCIA being -10.1 minutes (95% CI -134.3 to 114.1).	Low (Medium risk of bias, imprecise, non-U.S. settings)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>47,122,127</sup> (17)	<b>No difference:</b> Meta-analysis generated an estimate of the odds ratio for cesarean delivery of EA relative to PCIA of 1.3 (95% CI 0.3 to 5.6).	Low (Medium risk of bias, imprecise, non-U.S. settings)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; EA=epidural analgesia; PCIA=patient-controlled intravenous analgesia; RCT=randomized controlled trial; SOE=strength of evidence

The SOE findings for EA versus intravenous tramadol in women of mixed parity was rated as insufficient for all outcomes. Table U summarizes the SOE for early versus late epidural analgesia. The SOE was rated as moderate for all outcomes based on evidence from the SR. The SOE was lowered given that the included studies from the SR spanned 1994 to 2006.

**Table U. Early versus late epidural analgesia: Evidence summary in nulliparous women<sup>a</sup>**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 SR <sup>139</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA with an odds ratio of 0.95 (95% CI 0.81 to 1.10).	Moderate
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>139</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA with a weighted mean difference of 0.52 minutes (95% CI -5.03 to 6.06 minutes)	Moderate
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 SR <sup>139</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA (odds ratio=1.00, 95% CI 0.83 to 1.21)	Moderate

<sup>a</sup> Early epidural was defined as immediate initiation of EA at first request (< 4 cm), and late initiation consisted of delay of EA until the cervix was dilated to at least 4 cm.

<sup>b</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

Strength of evidence was rated as insufficient for all outcomes of these comparisons:

- Routine EA versus analgesia on request
- CSE versus nonpharmacologic pain relief
- EA versus intravenous meperidine
- EA versus low-dose infusion EA
- EA acupuncture point nerve stimulation
- EA versus no EA in nulliparous women

Table V summarizes the SOE for outcomes comparing EA versus no EA in women of mixed parity. The SOE was rated as moderate for major outcomes of labor duration and cesarean delivery based on the findings from a large SR.

**Table V. Epidural analgesia versus no epidural analgesia: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>47</sup> (120)  1 SR <sup>140</sup> (2,981 patients, 11 studies)	<b>No difference:</b> No evidence of a significant difference between EA and no EA (MD 18.51 minutes, 95% CI -12.91 to 49.42).	Moderate  Consistent with SR findings.
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>47</sup> (120)  1 SR <sup>140</sup> (4,233 patients, 13 studies)	<b>Worsening with EA:</b> Women with epidural analgesia had a statistically significant longer second stage of labor (average MD 13.66 minutes, 95% CI 6.67 to 20.66).	Moderate  Consistent with SR findings.
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>47</sup> (120)  1 SR <sup>140</sup> (8,417 patients, 27 studies)	<b>No difference:</b> No evidence of a significant difference in the risk of caesarean section overall (RR 1.10, 95% CI 0.97 to 1.25).	Moderate  Consistent with SR findings.

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; EA=epidural analgesia; MD=mean difference; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

## Key Question 5. Frequency of Cervical Examination

We identified no RCTs and only one good-quality SR<sup>141</sup> that met the inclusion criteria for this KQ. The focus of the SR was to compare different methods of assessing labor progression through the use of vaginal examinations. The objective was to compare digital vaginal examinations for assessing progress of labor to other strategies or different timings. There was insufficient SOE for all outcomes regarding the frequency of cervical examination.

## Key Question 6. Intrauterine Pressure Catheters

We did not identify any RCTs that met the inclusion criteria for this KQ. One good-quality SR addressed the benefits and harms of intrauterine pressure catheters in the diagnosis and management of labor dystocia.<sup>142</sup> There were no statistically significant differences between intrauterine pressure catheters and external uterine monitoring for the outcomes of mode of delivery, mean time to delivery, neonatal acidemia, or admission to the neonatal intensive care unit (moderate SOE for all outcomes).

Table W summarizes the SOE for intrauterine pressure catheters versus external monitoring. The SOE was rated as moderate for all outcomes assessed given consistent findings from good-quality RCTs included in the SR.

**Table W. Intrauterine pressure catheters versus external monitoring: Evidence summary in women of unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	1 SR <sup>142</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in mean time to delivery with intrauterine pressure catheters compared to external monitoring	Moderate (Indirect)
	Process Related Outcomes – Mode of Delivery	1 SR <sup>142</sup> (750 patients, 2 studies)	<b>No difference:</b> Comparing intrauterine pressure catheters to external monitoring, there was no difference in delivery by operative vaginal delivery (RR 1.25, 95% CI 0.91 to 1.73) or by cesarean deliver (RR 1.25, 95% CI 0.91 to 1.71).	Moderate (Indirect)
Adverse Events	Maternal Outcomes – Infection	1 SR <sup>142</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in signs of infection in labor in women with intrauterine pressure catheters compared to external monitoring (RR 0.69, 95% CI 0.44 to 1.08).	Moderate (Indirect)
	Neonatal Outcomes – Acidemia	1 SR <sup>142</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in neonatal acidemia (pH<7.15) in infants of women with intrauterine pressure catheters compared to external monitoring (RR 1.31, 95% CI 0.95 to 1.79).	Moderate (Indirect)
	Neonatal Outcomes – Admission to NICU	1 SR <sup>142</sup> (489 patients, 2 studies)	<b>No difference:</b> No differences in admission to NICU in infants of women with intrauterine pressure catheters compared to external monitoring (RR 0.34, 95% CI 0.07 to 1.67).	Moderate (Indirect)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; NICU=neonatal intensive care unit; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

## Key Question 7. High-Dose Versus Low-Dose Oxytocin Protocols

We identified 12 articles<sup>36,39,143-152</sup> representing 11 individual RCTs that examined the benefits and harms of high-dose versus low-dose oxytocin protocols for women with abnormal labor. Key findings include:

- In nulliparous women, high-dose oxytocin is associated with a lower cesarean delivery rate (moderate SOE) compared with low-dose oxytocin protocols with no difference in maternal hemorrhage (low SOE).
- Early administration of oxytocin is associated with a shorter duration of labor (moderate SOE) but does not affect the overall cesarean delivery rate compared with delayed administration (moderate SOE). There is no difference in adverse events of maternal outcomes of hemorrhage or transfusion (low SOE) or in mode of delivery (low SOE).
- Pulsatile administration of oxytocin is associated with a longer duration of labor compared with continuous administration (low SOE).

- There is no difference in cesarean delivery rate between women managed with oxytocin and those with expectant management (moderate SOE).

Tables X–AA summarize the SOE for varying oxytocin protocols strategies. For many outcomes the SOE was rated as insufficient or low except where existing SRs were able to add to the evidence base.

**Table X. High-dose versus low-dose oxytocin protocols: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>39,143,152</sup> (1,052)  2 SRs <sup>153,154</sup> (945 patients, 9 studies)	<b>Improvement with high-dose oxytocin:</b> High-dose oxytocin augmentation was associated with a reduction in the risk of cesarean section.	Moderate (inconsistent, imprecise)  Findings supported by 2 RCTs and 2 SRs increasing SOE. Inconsistency with a third study not showing a difference and substantial heterogeneity.
Adverse Events	Maternal Outcomes – Infection	2 RCTs <sup>39,143</sup> (1,052)	<b>No difference:</b> No difference in the rate of maternal infection between high-and low-dose oxytocin as part of an active management of labor protocol compared to a conventional management of labor protocol.	Low (Imprecise)
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>143,152</sup> (1,387)	<b>No difference:</b> SOE was low given imprecise findings from 2 non-U.S. setting studies.	Low (imprecise, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table Y. Early versus delayed oxytocin protocols: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor	2 RCTs <sup>145,147</sup> (1,042)  2 SRs <sup>155,156</sup> (2,583 patients, 10 studies)	<b>Improvement with early administration of oxytocin:</b> shorter duration of labor in early oxytocin group.	Moderate (non-U.S. setting, potential risk of bias)  Consistent with SR findings
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>145,147</sup> (1,042)  2 SRs <sup>155,156</sup> (2,583 patients, 10 studies)	<b>No difference:</b> no difference in mode of delivery given early oxytocin group.	Moderate (non-U.S. setting, potential risk of bias)  Consistent with SR findings
Adverse Events	Maternal Outcomes – Transfusion	2 RCTs <sup>145,147</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)



Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>145,147</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	2 RCTs <sup>145,147</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)
	Process Related Outcomes – Mode of Delivery (Spontaneous)	2 RCTs <sup>145,147</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

**Table Z. Pulsatile versus continuous oxytocin protocols: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2nd Stage Labor	1 RCT <sup>144</sup> (487)	<b>No difference:</b> No difference in the duration of the second stage of labor among women managed with pulsatile compared to continuous oxytocin for augmentation of labor.	Low (Indirect, imprecise)
	Process Related Outcomes – Duration of Labor	3 RCTs <sup>144,148,150</sup> (1,488)	<b>Improvement with continuous oxytocin:</b> Women managed with pulsatile compared to continuous oxytocin for augmentation of labor had a longer duration of labor.	Low (Indirect, imprecise, non-U.S. setting, high risk of bias)
Adverse Events	Process Related Outcomes – Mode of Delivery (Operative delivery)	1 RCT <sup>144</sup> (500)	<b>No difference:</b> No difference in operative delivery rate between women managed with pulsatile compared to continuous oxytocin for augmentation of labor. The cesarean delivery rate was not reported.	Low (Indirect, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table AA. Oxytocin versus expectant management: Evidence summary in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>36</sup> (99) 2 SRs <sup>156,157</sup> (457 patients, 5 studies)	<b>No difference:</b> No difference in cesarean delivery rate between women managed with oxytocin compared to expectant management.	Moderate (Imprecise, consistency with SR)  SOE was increased to moderate given findings from SRs which also found no difference in cesarean delivery rates.

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>36</sup> (99)  1 SR <sup>156</sup> (138 patients, 3 studies)	<b>No difference:</b> No difference in operative vaginal delivery rate between women managed with oxytocin compared to expectant management.	Low (Imprecise)  Consistent with SR findings

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 8. Electronic Fetal Monitoring Versus Intermittent Auscultation

We were unable to identify any relevant RCTs that met our inclusion criteria for this KQ. We identified 4 potential SRs that compared electronic fetal monitoring with intermittent auscultation,<sup>158-161</sup> but these were ultimately excluded because the studies included in the SRs utilized interventions that are not currently used in the United States.

## Key Question 9. Timing of Pushing in the Second Stage

We identified six articles<sup>162-167</sup> representing five RCTs that examined pushing techniques. Key findings include:

- Valsalva/coached and spontaneous/uncoached pushing have similar risks of trauma to the pelvic floor (low SOE).
- There is limited evidence that immediate pushing has a shorter labor duration when compared to delayed pushing in nulliparous women (low SOE).
- There was limited evidence of no difference in neonatal outcomes for immediate versus delayed pushing (low SOE).

Table BB summarizes the SOE for spontaneous pushing versus Valsalva pushing. In general, SOE was judged insufficient for all outcomes, with the exception of the process related outcome of Cesarean delivery.

**Table BB. Spontaneous pushing versus Valsalva pushing: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCT <sup>163,165,166</sup> (508)	<b>No difference:</b> Three RCTs reported no difference in the rate of cesarean deliveries between coached pushing and uncoached pushing.	Low (Medium risk of bias, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

Table CC summarizes the SOE for immediate versus delayed pushing. In general, SOE was judged low for all outcomes, given findings from just one study.

**Table CC. Immediate versus delayed pushing: Evidence summary in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor (from intervention to delivery)	1 RCT <sup>167</sup> (2,404)	<b>Improvement with immediate pushing:</b> shorter mean duration of the second stage of labor in women randomized to immediate pushing compared to delayed pushing.	Low (one study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>167</sup> (2,404)	<b>No difference:</b> No difference in cesarean delivery rate between women randomized to immediate pushing compared to delayed pushing.	Low (one study)
Adverse Events	Maternal Outcomes – Postpartum Hemorrhage	1 RCT <sup>167</sup> (2,404)	<b>Improvement with immediate pushing:</b> Postpartum hemorrhage was significantly greater in the delayed vs the immediate pushing group.	Low (one study)
	Maternal Outcomes – Chorioamnionitis	1 RCT <sup>167</sup> (2,404)	<b>Improvement with immediate pushing:</b> Chorioamnionitis was significantly greater in the delayed vs the immediate pushing group.	Low (one study)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>167</sup> (2,404)	<b>No difference:</b> No different in mode of delivery with delayed vs immediate pushing.	Low (one study)
	Neonatal Outcomes – Neonatal Death, major birth injury, respiratory distress transient tachypnea	1 RCT <sup>167</sup> (2,404)	<b>No difference:</b> No different in neonatal death with delayed vs immediate pushing.	Low (one study)
	Neonatal Outcomes – Neonatal Acidemia	1 RCT <sup>167</sup> (2,404)	<b>Improvement with immediate pushing:</b> In prespecified exploratory analyses, a lower rate of acidemia with immediate and delayed pushing groups	Low (one study)
	Neonatal Outcomes – Neonatal Infection/Sepsis	1 RCT <sup>167</sup> (2,404)	<b>Improvement with immediate pushing:</b> The proportion of suspected sepsis was higher in the delayed versus immediate pushing group	Low (one study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Discussion

In general, the findings of the review were consistent with current understanding of the overall strength of evidence for different strategies for management of labor. Estimates of the rate of progress of “normal” labor derived from contemporary data in the United States are quite different from the classic curves described by Friedman.<sup>13</sup> These differences may be attributable to a number of factors, including secular trends in patient characteristics (e.g., increasing age at first birth and increasing rates of obesity) and increasing use of interventions such as induction of labor or the use of oxytocin to augment labor. More recent data suggest that the transition to

active labor occurs later in the course of labor than originally described, which is reflected in more recent guidelines suggesting a higher threshold for observing labor duration before intervention with cesarean delivery.

The definition of “normal” labor is fundamental in evaluating the evidence related to managing “abnormal” labor progression, analogous to the threshold value used to define “normal” for a continuous laboratory value. Ideally, the definition would be derived based on data from a large group of women who were followed without intervention and had optimal maternal and neonatal outcomes, but there are obvious practical and ethical barriers to this. , The sensitivity and specificity of the test will vary depending on the choice of threshold, but so will the estimates of the effectiveness of interventions based on that threshold. Comparing results across studies requires a common definition for such “normal” labor and permeates our review.

There is evidence that partograms are useful in low-resource settings, but they have not been shown to improve labor outcomes in high-resource settings. This may be due in part to differences in the data sources for generating labor curves and thresholds. Feasibility and ethical challenges with obtaining a large, contemporary sample of women laboring with minimal to no intervention limits our fundamental scientific understanding of normal labor, normal labor progress, and when durations of labor lead to worse maternal/child outcomes.

In general, our findings that “normal” labor in modern settings is generally longer than earlier guidance are consistent with current guidelines <sup>3</sup>, which are largely informed by the CSL data and encourage allowing longer durations for both first and second stages of labor before intervening with cesarean delivery. However, as noted, over half of women in the “normal” group received augmentation in the Consortium on Safe Labor (CSL) data, and the data are not informative about optimal timing of augmentation. Routine amniotomy is not specifically recommended, although the recommendations note that amniotomy may be helpful in the transition from latent to active labor. Based on the same Cochrane review finding, improved satisfaction and lower cesarean and operative vaginal delivery rates, emotional support is recommended. The potential effect of epidural analgesia on duration of labor is noted as a potential consideration in allowing longer durations before intervention, but there are no recommendations about specific techniques. Cervical exam frequency, intrauterine pressure monitoring, oxytocin dosing protocols, methods for routine fetal monitoring, or timing of pushing in the second labor are not discussed, consistent with the relative paucity of evidence.

The impact of regional anesthesia on the length of the first stage of labor is uncertain, leading to conflicting recommendations from different professional societies. Our findings do not provide greater clarity.

## **Applicability**

Two broad issues relate to the overall applicability of the available evidence to clinical practice in the United States—one geographic and one temporal. Many of the RCTs meeting our criteria were performed outside of the United States. Aside from issues related to differences in study oversight or reporting, the populations of these studies may differ from U.S. women in labor in terms of health systems, patient preferences and expectations, provider perceptions of risk, availability of resources, and so on. This is particularly relevant to studies that directly compared management strategies based on explicit criteria for defining abnormal labor and studies that attempted to define a “normal” duration of labor (KQ 1). Particularly for studies where the primary outcome is cesarean delivery, factors that affect the threshold for performing cesarean—both the explicit “cutpoint” for duration of labor used and broader factors ranging

from the relative safety of surgery versus vaginal delivery in low resource settings to cultural expectations to legal concerns—may affect the estimates of effectiveness of an intervention.

A number of studies included the use of a partogram—a graphical comparison of a woman’s labor progress compared to a standard—with thresholds for intervention clearly identified. Strength of evidence was judged to be low, with one major factor being a lack of U.S.-based studies. In low-resource settings, the use of a partogram was associated with lower overall cesarean delivery rates compared with labor managed without a partogram, and earlier interventions were associated with lower cesarean delivery rates. In high-resource settings, the use of a partogram that included an assessment of latent phase duration, and which had a threshold for action at 3 hours compared to 4 hours, had higher cesarean delivery rates; but otherwise the use of a partogram compared with no partogram, or other time intervals for action lines, did not affect mode of delivery, duration of labor, indication for cesarean delivery, or complications including postpartum hemorrhage, maternal infection, or neonatal acidemia. Outside of U.S.-based settings, populations, health systems, and management of both prenatal and intrapartum care are quite different—and the impact of these differences on both the relative effectiveness and the absolute difference in outcomes is likely substantial.

Even more fundamentally, use of a tool such as a partogram, or specific interventions such as amniotomy, requires evidence on “normal” labor in order to define requires evidence on “normal” labor in order to define appropriate thresholds for action. The studies we reviewed that attempted to define “normal” labor differed based on parity, the time period in which the studies were conducted, and, among nulliparous women, maternal age. Evidence from the CSL, representing the most recent available large-scale population data<sup>19</sup> suggest a longer duration of first stage of labor compared to earlier studies, including the National Collaborative Perinatal Project (NCPP).<sup>22</sup> However, the most striking difference between these two studies was the proportion of women who received oxytocin augmentation (14.6% in the NCPP cohort from 1959 to 1966 compared with 45.9% in the CSL cohort from 2002 to 2008).

The CSL population that was used to generate new labor curves consists of women who had spontaneous onset of labor and a vaginal delivery, and thus the labor curves presented provide an estimate of “normal” labor that does not end in a cesarean delivery. Since such a large proportion of women received augmentation, these data do not provide insight into the range of rates of labor progression among women who do not receive augmentation, and cannot provide insight into the relative harms and benefits of augmentation, or the most appropriate thresholds for the timing or dosing of augmentation. The association between a longer duration of the first stage of labor and the greater use of oxytocin among women with a vaginal delivery is consistent with the possibility that greater use of oxytocin may avoid cesarean delivery, but not with observed secular trends in cesarean delivery rates. One would expect that any changes in the threshold for cesarean delivery caused by greater “patience” (allowing a longer duration) and/or “medical management” (greater use of oxytocin) would lead to decreases in cesarean delivery rates.

In summary, evidence suggests that the specific criteria used to define “normal” labor, or a specific threshold for intervention, may affect cesarean delivery rates but not other maternal or neonatal outcomes in some settings. Yet there is no available evidence for the United States. Among women in the United States with spontaneous onset of labor and vaginal delivery, labor progression is slower for women having their first baby compared to women with prior deliveries, but the high proportion of women receiving oxytocin augmentation prevents drawing any inferences about the “normal” labor curve in women with spontaneous onset of labor, no interventions to augment labor, and no adverse maternal or neonatal outcomes.

## Research Recommendations

We identified several areas of needed future research:

- It would be extremely useful to have separate labor curves derived from contemporary U.S. data for women with spontaneous onset of labor, no augmentation with oxytocin or other pharmacologic agents, and vaginal delivery of healthy baby, stratified by parity, as well as for women with augmented labor. Such labor curves would provide a better understanding of the modern natural course of labor and may provide better information on when to initiate agents to augment labor and when to proceed with cesarean delivery. Such studies could also potentially include laboring women with cesareans for non-labor diagnoses, although the threshold for intervention might be influenced by perceptions of the effect of labor duration on the condition leading to the intervention (e.g., women with pre-eclampsia).
- Evaluation of specific labor management strategies (including the use of partograms) derived from contemporary data sources such as the CSL should be a priority. This evaluation should include comparison of different methods for integrating decision support into existing technologies, such as methods and timing of augmenting labor (oxytocin administration, artificial rupture of the membranes), fetal monitoring, tools to monitor uterine contraction strength and frequency, and the impact of supportive therapies (massage, fluids, nutrition, positioning) on mode of delivery. This evaluation would help generate best practice recommendations for safe reduction of the primary cesarean delivery rate while balancing maternal and neonatal outcomes. Given the potential difficulties in recruiting patients into randomized trials, consideration should be given to both high-quality observational studies as well as research designs that combine randomization with allowance for patient preferences.<sup>168,169</sup>
- Given the importance of the labor process to patient preferences and their birthing experience and the lack of evidence about the impact of available interventions on these preferences, the development of tools for estimating patient preferences for both the process and maternal and neonatal outcomes of labor should be a priority. Discrete choice experiments would be one method appropriate for estimating preferences for these complex tradeoffs.
- Comparison of patient preferences of nulliparous to parous women are of great interest as preferences may vary based on prior labor experiences and expectations.
- Studies of these tools/methods should also explore the complexity of decision making that needs to incorporate both maternal and paternal preferences, as well as preferences where parents are acting as surrogates for infants. For example, in a study which elicited preferences for an adverse neonatal outcome with long-term health implications for the purposes of economic analysis, each parent would have preferences that reflect the impact of the condition on their roles as parents, and could provide a preference acting as a surrogate for the child, but the child might have quite different preferences.<sup>170-172</sup> Validated measures should be incorporated into clinical trials and prospective studies as specific outcomes.
- Encouragement of use of core outcome sets, such as those developed as part of the CROWN (Core Outcomes in Women's Health) initiative.<sup>173</sup>

## Conclusions

Dystocia is a common indication for cesarean delivery. Recent data demonstrate that the normal progress of labor with current practice is quite different from curves originally described, although there is still uncertainty about the duration of “normal” labor in the absence of augmentation. Amniotomy and oxytocin decrease duration of labor without increasing cesarean delivery. Emotional support reduces operative delivery rates and patient satisfaction. Further work is needed to identify strategies for management of labor that optimize maternal and neonatal outcomes and patient preferences while minimizing cesarean delivery rates.

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# Introduction

## Background

### Condition

Approximately 80 percent of American women will eventually have at least one child,<sup>1</sup> and the majority of these women will undergo labor. “Labor dystocia” (difficult or obstructed labor)<sup>2</sup> encompasses a variety of concepts, ranging from “abnormally” slow dilation of the cervix or descent of the fetus during active labor<sup>3</sup> to entrapment of the fetal shoulders after delivery of the head (“shoulder dystocia,” an obstetric emergency). For the purposes of this systematic review, we assume that “labor dystocia” refers to “abnormal” labor progression during the latent (up to 4-6 cm dilation) or active phases (from 4-6 cm until full dilation) of the first stage of labor, or during the second stage (from complete cervical dilation until delivery of the baby), although, as discussed below, there have been substantial changes in practice since these “traditional” definitions were developed which raise questions about their generalizability to modern populations. We also limit our review to women in spontaneous labor, with definitions varying somewhat between studies but generally including the onset of spontaneous uterine contractions, and explicitly exclude studies of women undergoing induction, or women with premature rupture of membranes at term in the absence of contractions.

Prolonged labor may increase the risk for maternal and neonatal infection, fetal distress, neonatal hypoxia, uterine rupture, and postpartum hemorrhage; it may also be a marker for increased risk of maternal pelvic floor and genital trauma during delivery (with a subsequent increased risk for future incontinence and pelvic organ prolapse).<sup>4</sup> Reducing the likelihood of these adverse maternal and neonatal outcomes is the underlying rationale for performing a cesarean delivery for the primary indication of labor dystocia.<sup>3</sup>

However, there is a tradeoff, since cesarean delivery itself increases the risk of maternal hemorrhage, venous thromboembolism, and injury to the bladder and other internal organs, and can affect post-delivery mother–baby interactions.<sup>3,5</sup> Further, having one cesarean delivery increases the likelihood of having subsequent cesarean deliveries.<sup>3</sup> A woman’s risk for abnormal placentation (placenta previa or accreta, each of which is associated with significant maternal and neonatal morbidity and mortality) is directly related to the number of prior cesarean deliveries she has had.<sup>6</sup>

Although there is no consensus on the “optimal” cesarean delivery rate (conceptually, the rate that strikes a balance between benefits and harms for both mother and baby that is considered acceptable to most patients), there is general consensus that current rates in the United States are too high,<sup>3,7</sup> although whether the factors driving this rate are amenable to evidence-based solutions has been questioned.<sup>8</sup> There is also growing concern about increases in rates internationally, as reflected by a World Health Organization consensus statement.<sup>9</sup> Strategies to prevent a woman’s first, or primary, caesarean delivery may therefore lead to significant improvements in maternal and neonatal outcomes by reducing both the number of primary and repeat cesareans.<sup>3</sup> For this reason, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) have issued a joint consensus statement aimed at “preventing the first cesarean delivery,”<sup>3</sup> with similar efforts instituted by the American College of Nurse-Midwives.<sup>10</sup> Since abnormalities of labor progression are the single most common cause of primary cesarean delivery in the United

States,<sup>3,11</sup> strategies aimed at reducing cesarean delivery for dystocia may have the largest potential impact on overall cesarean rates.

Uncertainty about optimal management of dystocia may play a major role in the well-documented variation in cesarean delivery rates between hospitals that does not appear to be completely attributable to patient characteristics<sup>12</sup> (although other factors not directly related to evidence on comparative effectiveness, such as patient and provider preferences, real or perceived malpractice concerns, and local practice norms may also be important factors). Another source of uncertainty is that there are complex tradeoffs between patient preferences for the labor and delivery process, on the one hand, and outcomes on the other. These considerations involve issues related to setting (home, birthing center, hospital), provider (lay midwife, nurse-midwife, family physician, obstetrician), and available technology (including analgesia, fetal heart rate monitoring, and measurement of intrauterine pressure).<sup>13-15</sup> There is also wide variety in the maternal and neonatal outcomes that are reported, and the degree to which patient preferences for both process and outcomes is considered.<sup>15-17</sup>

## **Diagnosis**

The effective management of labor dystocia is first dependent on the tool used to diagnose the disorder. In the 1950s, Friedman published his observations on the rate of cervical change among a cohort of women in spontaneous labor<sup>18</sup> and from this constructed labor curves representing the expected rate of cervical change in a population. Deviations from these curves, particularly rates of cervical change slower than expected from the Friedman curve are referred to as protracted or arrest disorders and represent labor dystocia. The Friedman curve has been the primary tool used to diagnose abnormal labor since then, though more recent data from the Consortium on Safe Labor have demonstrated that rates and characteristics of cervical change seen in modern obstetrics are quite different from that represented by the Friedman curve.<sup>19</sup> Identifying what constitutes normal labor is an important initial step in the management of labor dystocia as it first dictates when various treatment options are initiated. Variation between providers about definitions or perceptions of “abnormal” labor length may contribute to variations in rates of diagnosis.

## **Prevention and Treatment Strategies**

There are a number of strategies that may either facilitate earlier diagnosis of labor, directly or indirectly (e.g., choice of pain management strategies) prevent a diagnosis of labor dystocia, or accelerate labor progress after a diagnosis of dystocia. Strategies addressed in this report include:

- Use of graphs of cervical dilation versus time (“partograms”) to identify patients with slow labor progress, often with an indicator of when intervention is appropriate.
- Timing of the artificial rupture of the amniotic membranes (amniotomy) during labor.
- Various options for maternal positioning, ambulation, and feeding during labor.
- Use of epidural analgesia, or, alternatively, variations in technique (timing, choice of analgesic agents).
- Variations in monitoring labor progress (such as frequency of cervical examination or use of intrauterine pressure catheters) and fetal well-being (fetal heart rate monitoring).
- Variations in strategies for how oxytocin is used during labor augmentation including timing of augmentation relative to labor progress and variation in dosing regimens used.

- Variations in strategies for reducing the length of the second stage of labor (after cervical dilation is complete but before the baby has delivered), including different approaches to maternal pushing.

The overall goal of treating labor dystocia is to optimize delivery outcomes for mother and child, while attempting to achieve an optimal cesarean delivery rate. As discussed above, the optimal cesarean delivery rate is not known but is the lowest rate that balances benefits and harms to mother and child.

## Scope and Key Questions

### Scope of the Review

The present review evaluates the comparative effectiveness of different strategies for treating labor dystocia in women with otherwise uncomplicated pregnancies. We also limit our review to women in spontaneous labor and exclude those who are undergoing induced labor. In addition, one potential source of uncertainty in the available evidence may be variability in the definitions for different phases of labor, and what constitutes “normal” labor across studies and likely in practice as well. The definition of “normal” may vary across different populations and may depend on whether “normality” is based on a specified quantile of the distribution of rates of cervical change in the first stage of labor or rate of fetal descent in the second stage of labor, or on maternal and neonatal outcomes.<sup>20-22</sup> The statistical approach used to define “normality,” primarily in reference to rates of cervical change, has also been the source of controversy.<sup>23-25</sup> In order to better understand the impact of this variability on the evidence on specific interventions, we also review the evidence on the definition of “normal” labor progression.

We explicitly excluded studies which included women with other potential indications for cesarean section (e.g., multiple pregnancies, prior cesarean) or other conditions which might affect either the likelihood of diagnosis of dystocia (e.g., use of magnesium sulfate in preeclampsia) or lead to contraindications to some interventions (e.g., HIV and amniotomy). We also did not include interventions such as estimation of fetal size or clinical pelvimetry which might affect physician perception of the risk of labor dystocia.

Note that many studies evaluated interventions in nulliparous (women who have not previously given birth) and parous women (women who have previously borne one or more children) separately. Other studies did not indicate the women’s parity and were considered to be mixed parity or unspecified parity defined as potentially including both nulliparous and parous women.

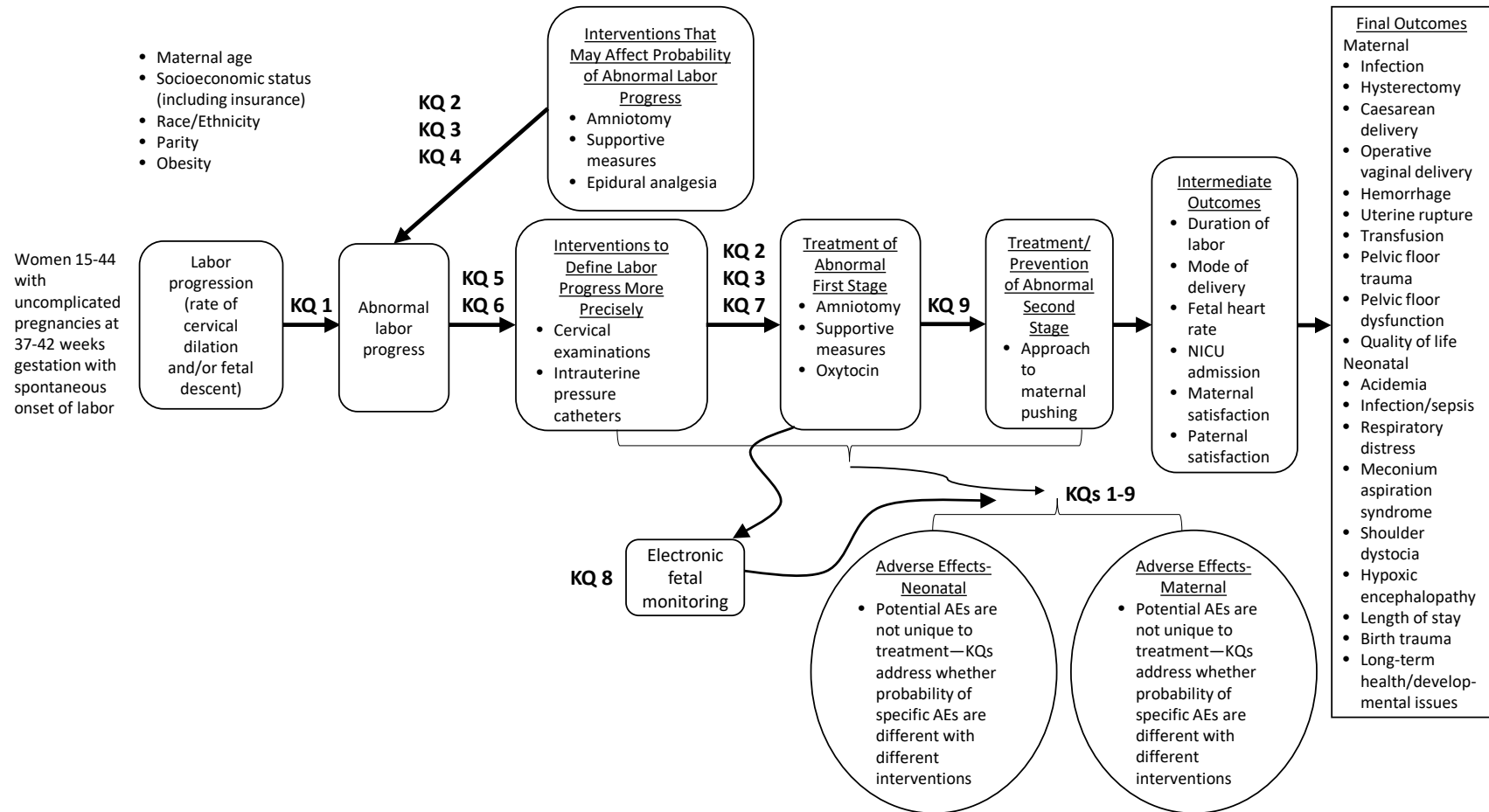
## Key Questions

The specific Key Questions (KQs) addressed in this review are listed below, and Figure 1 displays the analytic framework that guided our work.

- KQ 1: Do delivery outcomes for management of abnormal labor differ based on the criteria used to define protracted or arrested labor at different stages of the labor process?
- KQ 2: What are the benefits and harms of amniotomy in women in spontaneous labor?
- KQ 3: What are the benefits and harms of supportive care measures, including emotional support, ambulation, nutrition, and hydration, during spontaneous labor?
- KQ 4: What are the benefits and harms of epidural analgesia in labor, particularly in terms of the risk of a diagnosis of prolonged labor?
- KQ 5: How does the frequency of cervical examination affect the probability of specific benefits and harms?
- KQ 6: What are the benefits and harms of intrauterine pressure catheters in the diagnosis and management of labor dystocia?
- KQ 7: For women with abnormal labor, what are the relative benefits and harms of high- versus low-dose oxytocin protocols (including nipple stimulation)?
- KQ 8: For women in spontaneous labor undergoing augmentation with oxytocin, what are the relative benefits and harms (in terms of both maternal and neonatal outcomes) of electronic fetal monitoring versus intermittent auscultation?
- KQ 9: For women in the second stage of labor, is there a benefit from delayed or Valsalva pushing for time to delivery or mode of delivery?

Figure 1 depicts the KQs within the context of the populations, interventions, comparators, outcomes, timings, and settings (PICOTS) considered in this review. It illustrates the progression of spontaneous labor, which may be affected by interventions or management strategies performed prior to the diagnosis of abnormal progression; the criteria used to diagnose abnormal progression; and interventions performed after the diagnosis of abnormal progression.

**Figure 1. Analytic framework**



Abbreviations: AEs=adverse effects; KQ=Key Question; NICU=neonatal intensive care unit

## Organization of This Report

The remainder of the report details our methodology and presents the results of our literature synthesis, with summary tables and strength of evidence grading for major comparisons and outcomes. In the discussion section, we offer our conclusions, summarized findings, and other information that may be relevant to translating this work for clinical practice and future research.

Appendixes provide further details on our methods and the studies we assessed, as follows:

- Appendix A. Exact Search Strings
- Appendix B. Data Abstraction Elements
- Appendix C. List of Included Studies
- Appendix D. List of Excluded Studies
- Appendix E. Characteristics of Included Studies
- Appendix F. A Measurement Tool to Assess Systematic Review (AMSTAR) Quality Assessment for Systematic Reviews
- Appendix G. Risk of Bias Assessment for Included Studies

A list of abbreviations and acronyms is provided at the end of the report.



## Methods

The methods for this systematic review (SR) follow the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (hereafter referred to as the *Methods Guide*) for the Evidence-based Practice Center (EPC) program<sup>26</sup> and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.<sup>27</sup> See the review protocol<sup>28</sup> for full details.

### Topic Refinement and Review Protocol

The topic of this report and preliminary Key Questions (KQs) arose through nomination from a professional society and initial development by the Scientific Resource Center for AHRQ's Effective Health Care (EHC) program. During the subsequent topic refinement phase, a panel of Key Informants gave input to the EPC on the KQs to be examined; these KQs were posted on AHRQ's EHC website for public comment in September 2015 for 3 weeks and revised in response to comments. We then drafted a protocol for the SR and recruited a technical expert panel to provide high-level content and methodological expertise throughout the development of the review. The Key Informants and Technical Expert Panel represented members of medical professional societies and clinician/researchers in the areas of obstetrics and gynecology, midwifery, and pediatrics; scientific experts; payers; and patients/consumers. The finalized protocol is posted on the EHC website.<sup>28</sup> The PROSPERO registration is CRD42016035567.

### Literature Search Strategy

#### Search Strategy

To identify relevant published literature, we searched PubMed®, Embase®, CINAHL®, and the Cochrane Database of Systematic Reviews (CDSR), limiting the searches to studies published in English from January 1, 2005, to February 15, 2019. These databases were selected based on internal expert opinion that they would identify most of the relevant literature on this topic and that they reflect the databases used in related SRs, particularly reviews conducted by the Cochrane Pregnancy and Childbirth Group. An experienced search librarian guided all searches. The exact search strings used are given in Appendix A.

We supplemented the electronic searches with a manual search of citations from a set of key primary and review articles.<sup>29-57</sup> The reference lists for identified key articles were manually searched and cross-referenced against our database, and additional relevant articles not already under consideration were retrieved for screening. All citations were imported into an electronic bibliographical database (EndNote® Version X7; Thomson Reuters, Philadelphia, PA). While the draft report is under peer review, we will update the search and include any eligible studies identified either during that search or through peer or public reviews in the final report.

To identify relevant gray literature, the EPC Scientific Resource Center notified stakeholders that the EPC was interested in receiving information relevant to the KQs. We also searched ClinicalTrials.gov for two purposes: (1) to identify relevant articles from completed studies that may not have appeared through other search strategies and (2) as one mechanism to ascertain publication bias in recent studies. For the latter goal, we sought to identify completed but unpublished studies that could impact the findings of the review. Search terms used for ClinicalTrials.gov are provided in Appendix A. We also explored the possibility of publication bias specifically in our quantitative synthesis of the included literature through meta-analysis

(MA) techniques such as funnel plots when appropriate. Further gray literature assessment included searching the World Health Organization International Clinical Trials Registry Platform search portal and the National Guidelines Clearinghouse to identify potentially relevant study records; we subsequently searched for relevant articles from among the completed studies.

## Inclusion and Exclusion Criteria

We specified our inclusion and exclusion criteria based on the PICOTS (populations, interventions, comparators, outcomes, timing, and settings) identified for each question. Table 1 lists inclusion and exclusion criteria. For the purpose of the review, “uncomplicated pregnancies” excluded populations with either maternal (e.g., hypertension or diabetes) or fetal (e.g., congenital anomalies, growth restriction) conditions which could affect thresholds for intervention.

**Table 1. Inclusion and exclusion criteria**

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Populations	<ul style="list-style-type: none"> <li>KQs 1-5: Women aged 15-44 with uncomplicated pregnancy at 37-42 weeks gestation with a singleton pregnancy with vertex presentation. For the purposes of this review, women who are undergoing induction of labor for any indication are excluded, because the probability of specific outcomes is necessarily different for them.</li> <li>KQ 6: Women aged 15-44 with uncomplicated pregnancy at 37-42 weeks with suspected abnormalities of the first stage of labor</li> <li>KQ 7: Women aged 15-44 with uncomplicated pregnancy at 37-42 weeks with a diagnosed abnormality of the first stage of labor</li> <li>KQ 8: Women aged 15-44 with uncomplicated pregnancy at 37-42 weeks gestation with a diagnosed abnormality of the first stage of labor undergoing augmentation with oxytocin</li> <li>KQ 9: Women aged 15-44 with uncomplicated pregnancies at 37-42 weeks who have reached complete cervical dilation (with or without augmentation); relevant subgroups include women with and without epidural analgesia</li> <li>KQs 1-9: Relevant subgroups for all KQs include: (a) maternal age (particularly adolescents and women 35-44 years old); (b) parity; (c) maternal race/ethnicity; (d) maternal socioeconomic status, including insurance status; and (e) maternal obesity.</li> </ul>	<ul style="list-style-type: none"> <li>Women &lt;15 or &gt;44 years of age</li> <li>Women in preterm labor</li> <li>Women undergoing labor induction for any indication</li> <li>Women with prior history of cesarean delivery</li> <li>Women with spontaneous rupture of membranes without contractions</li> <li>KQs 6-8: Studies which do not provide either a definition of “dystocia,” “prolonged labor,” “arrest of labor,” “arrest of descent,” or other relevant diagnosis within the Methods section, or which do not provide a citation with such a definition</li> </ul>

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Interventions	<ul style="list-style-type: none"> <li>• KQ 1: Definitions of abnormalities of the latent and active phases of the first stage of labor (up until complete dilation of the cervix) and of the second stage of labor (from complete dilation until delivery of the infant), developed based on data from the Safe Labor Consortium.<sup>3</sup></li> <li>• KQ 2: Routine amniotomy (artificial rupture of membranes)</li> <li>• KQ 3: Emotional support, ambulation, routine maternal oxygen supplementation, specific nutritional recommendations or limitations, specific oral or parenteral hydration recommendations or limitations, peanut ball, Lamaze, hypnobirthing, positioning, acupuncture, hydrotherapy, other nonpharmacologic interventions identified through the search</li> <li>• KQ 4: Epidural analgesia</li> <li>• KQ 5: Regular cervical examinations (timing may vary)</li> <li>• KQ 6: Use of internal pressure catheters for measuring timing and strength of uterine contractions</li> <li>• KQ 7: Infusion of low-dose oxytocin</li> <li>• KQ 8: Electronic fetal monitoring (external or internal)</li> <li>• KQ 9: Immediate pushing upon complete dilatation</li> </ul>	
Comparators	<ul style="list-style-type: none"> <li>• KQ 1: Definitions of labor abnormalities based on older data (Friedman Curve)<sup>23,24</sup></li> <li>• KQ 2: No amniotomy, amniotomy for specific indications (e.g., placement of fetal scalp monitor or intrauterine pressure catheter)</li> <li>• KQ 3: Usual care; interventions above compared to each other</li> <li>• KQ 4: No analgesia, other methods of analgesia (e.g., parenteral narcotics such as morphine or nitrous oxide), nonpharmacologic methods of pain management</li> <li>• KQ 5: Cervical examination only in the setting of clinical concern about labor progress; regular cervical examinations at differing frequencies</li> <li>• KQ 6: External tocodynamometry, no monitoring</li> <li>• KQ 7: High-dose oxytocin; nipple stimulation; maternal oxygen supplementation as an adjunct to oxytocin; different formulations of oxytocin</li> <li>• KQ 8: Intermittent auscultation of fetal heart rate</li> <li>• KQ 9: Other specified maternal techniques/approaches to pushing</li> </ul>	

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Outcomes	<ul style="list-style-type: none"> <li>• KQs 1, 3-9:               <ul style="list-style-type: none"> <li>○ Maternal                   <ul style="list-style-type: none"> <li>• Cesarean delivery</li> <li>• Operative vaginal delivery</li> <li>• Infection (chorioamnionitis, endometritis, wound infection)</li> <li>• Hemorrhage</li> <li>• Uterine rupture</li> <li>• Hysterectomy</li> <li>• Transfusion</li> <li>• Trauma to the pelvic floor (vaginal/perineal/cervical/bladder/rectal injury at the time of delivery)</li> <li>• Pelvic floor dysfunction (long-term urinary or fecal incontinence, fistulae, pelvic organ prolapse)</li> <li>• Maternal/paternal experience/satisfaction</li> </ul> </li> <li>○ Neonatal                   <ul style="list-style-type: none"> <li>• Neonatal acidemia (pH&lt;7.1)</li> <li>• Hypoxic encephalopathy</li> <li>• Respiratory distress (need for oxygen supplementation, CPAP, intubation/ventilatory support)</li> <li>• Meconium aspiration syndrome</li> <li>• Neonatal infection/sepsis</li> <li>• Shoulder dystocia</li> <li>• Birth trauma (including brachial plexus injury)</li> <li>• Long-term neonatal health and developmental abnormalities (including cerebral palsy)</li> <li>• Admission to NICU &gt; 24 hours</li> <li>• Neonatal length of stay</li> </ul> </li> <li>○ Process-related outcomes                   <ul style="list-style-type: none"> <li>• Abnormal fetal heart rate tracing</li> <li>• Duration of labor</li> <li>• Mode of delivery (vaginal delivery, assisted vaginal delivery, cesarean delivery)</li> <li>• Parental preferences/satisfaction</li> </ul> </li> </ul> </li> <li>• KQ 2:               <ul style="list-style-type: none"> <li>○ Same as above plus umbilical cord prolapse</li> </ul> </li> </ul>	For admission to NICU, studies which did not report length of stay if indication distribution was not reported
Timing	<ul style="list-style-type: none"> <li>• KQs 1-9:               <ul style="list-style-type: none"> <li>○ Short-term: from beginning of spontaneous labor until discharge home (or equivalent for home delivery) for mother and infant</li> <li>○ Long-term: from discharge onwards</li> </ul> </li> </ul>	

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Settings	<ul style="list-style-type: none"> <li>KQs 1-9: <ul style="list-style-type: none"> <li>Location: hospital, birthing center, home</li> <li>Providers: obstetrician, family physician, nurse midwife, lay midwife, doula</li> </ul> </li> </ul>	
Study design	<ul style="list-style-type: none"> <li>KQ 1: <ul style="list-style-type: none"> <li>Original data, including SRs and MAs</li> <li>RCTs, prospective and retrospective observational studies with comparator</li> <li>Observational studies: sample size <math>\geq 100</math> subjects</li> </ul> </li> <li>KQs 2-9: <ul style="list-style-type: none"> <li>Original data, including SRs and MAs</li> <li>RCTs</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Editorials, non-SRs, letters, case series, case reports, abstracts only, retracted/withdrawn articles</li> <li>Because observational studies with <math>&lt;100</math> subjects are often underpowered, they were excluded.</li> <li>SR/MAs were excluded if they did not provide a quantitative summary of results for an outcome of interest</li> </ul>
Publications	<ul style="list-style-type: none"> <li>KQs 1-9: <ul style="list-style-type: none"> <li>English-language only</li> <li>Published on or after January 1, 2005<sup>b</sup></li> <li>Relevant methods articles (used for background only)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Non-English-language publications<sup>a</sup></li> </ul>

<sup>a</sup> Non-English language articles were excluded due to (1) the high volume of literature available in English language publications, (2) the focus of our review on applicability to populations in the United States, and (3) the scope of our KQs.

<sup>b</sup> Through discussion with our Technical Expert Panel, we determined the start date of our search. Given changes in many aspects of practice, there was concern that earlier studies may not be appropriate, and therefore it was limited to 2005 onward.

Abbreviations: CPAP=continuous positive airway pressure; KQ=Key Question; MA=meta-analyses; NICU=neonatal intensive care unit; PICOTS=populations, interventions, comparators, outcomes, timing, settings; RCT=randomized controlled trial; SR=systematic review

## Study Selection

For citations retrieved from PubMed, Embase, CINAHL, and the Cochrane Database of Systematic Reviews, two reviewers independently screened each title and abstract for potential relevance to the KQs using the prespecified inclusion/exclusion criteria described in Table 1. Articles included by either reviewer underwent full-text screening.

At the full-text screening stage, two reviewers independently reviewed the full text of each article and indicated a decision to include or exclude the article for data abstraction. When paired reviewers arrived at different decisions about whether to include or exclude an article, or about the reason for exclusion, we reconciled the difference through review and discussion among investigators. Articles meeting eligibility criteria were included for data abstraction. At random intervals, quality checks were conducted by senior team members to ensure that screening and abstraction were consistent with inclusion/exclusion criteria and abstraction guidelines. We made screening decisions and abstracted data based on the published literature and available online appendices. We did not contact study authors for additional data. All results were tracked using the DistillerSR data synthesis software program (Evidence Partners Inc., Manotick, ON, Canada).

Appendix C provides a list of all articles included for data abstraction. Appendix D provides a list of articles excluded at the full-text screening stage, with reasons for exclusion.

## Data Extraction

The research team created data abstraction forms for the KQs that were programmed into DistillerSR software. The abstraction forms were pilot-tested with a sample of included articles to ensure that all relevant data elements were captured and that there was consistency and reproducibility between abstractors. Based on their clinical and methodological expertise, a pair of researchers were assigned to abstract data from each of the eligible articles. One researcher abstracted the data, and the second over-read the article and the accompanying abstraction to check for accuracy and completeness. Disagreements were resolved by consensus or by obtaining a third reviewer's opinion if consensus could not be reached. We linked related publications to avoid duplication of patient cohorts.

We designed the data abstraction forms to collect the data required to evaluate the specified eligibility criteria for inclusion in this review, as well as demographic and other data needed for determining outcomes (intermediate, final, and adverse events outcomes). We paid particular attention to describing the details of the treatment (e.g., frequency of cervical examination, criteria used to diagnose dystocia), patient characteristics (e.g., age, body mass index, parity), and study design (e.g., randomized controlled trial [RCT] versus observational) that may be related to outcomes. In addition, we described comparators carefully, as treatment standards may have changed during the period covered by the review. The safety outcomes were framed to help identify adverse events, including those from drug therapies. Data necessary for assessing quality and applicability, as described in the *Methods Guide*,<sup>26</sup> were also abstracted. A complete list of data abstraction elements is provided in Appendix B.

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

We assessed methodological quality, or risk of bias, for randomized and nonrandomized individual study designs using a components approach, assessing each study for specific aspects of design or conduct (such as allocation concealment for RCTs, or use of methods to address potential confounding), as detailed in AHRQ's *Methods Guide*.<sup>26</sup> Briefly, we rated each study as being of good, fair, or poor quality based on its adherence to well-accepted standard methodologies. For each study, one investigator assigned a summary quality rating, which was then reviewed by a second investigator; disagreements were resolved by consensus or by a third investigator if agreement could not be reached. Table 2 describes the overall study quality assessment ratings. Appendix G presents the risk of bias assessment components for the individual included studies.

**Table 2. Definitions of overall quality ratings**

Quality Rating	Description
Good (low risk of bias)	These studies had the least bias, and the results were considered valid. These studies adhered to the commonly held concepts of high quality, including the following: a clear description of the population, setting, approaches, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytical methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.

Quality Rating	Description
Fair (moderate risk of bias)	These studies were susceptible to some bias, but not enough to invalidate the results. They did not meet all the criteria required for a rating of good quality because they had some deficiencies, but no flaw was likely to cause major bias. The study may have been missing information, making it difficult to assess limitations and potential problems.
Poor (high risk of bias)	These studies had significant flaws that might have invalidated the results. They had serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.

The grading was outcome-specific such that a given study that analyzed its primary outcome well but did an incomplete analysis of a secondary outcome could be assigned a different quality grade for each of the two outcomes. Studies of different designs were graded within the context of their respective designs. Thus, RCTs were graded good, fair, or poor, and observational studies were separately graded good, fair, or poor (Appendix G). We acknowledge that one limitation to these standard criteria in settings where patients have strong *a priori* preferences for certain outcomes or aspects of the process (like labor) may affect willingness to be randomized, and may lead to issues related to generalizability or other biases, although available evidence suggests that there is little impact on internal validity.<sup>58</sup>

We also rated quality for included SRs. Rating was performed using A Measurement Tool to Assess Systematic Review (AMSTAR) for assessing the methodological quality of SRs.<sup>59</sup> For each study, one investigator assigned a summary quality rating, a second investigator reviewed the rating; disagreements were resolved by consensus or by a third investigator. Reviews were then assigned overall quality scores according to the following categories:<sup>60</sup>

- Good (low risk of bias)—Systematic reviews that have few or no methodological shortcomings and a low risk of bias.
- Fair (moderate risk of bias)—Systematic reviews that have some methodological flaws but the investigators conclude that the flaws will not seriously bias or invalidate the results.
- Poor (high risk of bias)—Systematic reviews that contain a serious flaw or flaws that, in the judgment of the investigators, are highly likely to bias or invalidate the results.

The AMSTAR quality assessment components for the individual SRs are detailed in Appendix F.

## Data Synthesis

We began by summarizing key features of the included studies for each KQ. To the degree that data were available, we abstracted information on study design; patient characteristics; clinical settings; interventions; and intermediate, final, and adverse event outcomes.

We then determined the feasibility of completing a quantitative synthesis (i.e., meta-analysis, decision analysis, or simulation model). For a meta-analysis, feasibility depends on the volume of relevant literature (requiring at least three relevant studies), conceptual homogeneity of the studies (similar intervention comparisons and outcome definitions), completeness of the reporting of results, and the adequacy and completeness of any existing meta-analyses (MAs). Because there are a large number of existing SRs for this topic, particularly from the Cochrane Collaboration, we considered these results using suggested guidance from the *Methods Guide* chapter on integrated bodies of evidence,<sup>61</sup> as outlined in more detail below. As recommended

there, we based judgments about the benefit of performing a new quantitative synthesis on an assessment of the existing strength of evidence (using the domains of study limitations, consistency, precision, directness, and reporting bias), and on a judgment about the degree to which a new quantitative synthesis would change conclusions about benefit harm/trade-offs, assessment of strength of evidence, substantially improve the precision of the estimate, or provide a more up-to-date estimate reflecting current practice.

When a meta-analysis was appropriate, we used random-effects models to synthesize the available evidence quantitatively. We tested for heterogeneity using graphical displays and test statistics ( $Q$  and  $I^2$  statistics), while recognizing that the ability of statistical methods to detect heterogeneity may be limited. For comparison, we also performed fixed-effect MAs. We present summary estimates, standard errors, and confidence intervals in the Results chapter. We anticipated that intervention effects might be heterogeneous. We hypothesized that the methodological quality of individual studies, study type, characteristics of the comparator, and patients' underlying clinical presentation would be associated with the intervention effects. When there were sufficient studies, we performed subgroup analyses and/or meta-regression analyses to examine these hypotheses. We performed quantitative and qualitative syntheses separately by study type and discuss their consistency qualitatively.

## Strength of the Body of Evidence

We graded the strength of evidence for each outcome assessed; thus, the strength of evidence for two separate outcomes in a given study may be graded differently. The strength of evidence was assessed using the approach described in AHRQ's *Methods Guide*.<sup>26,62,63</sup> In brief, the approach requires assessment of five domains: study limitations (previously named risk of bias), consistency, directness, precision, and reporting bias, which includes publication bias, outcome reporting, and analysis reporting bias, as described above. Additional domains used when appropriate (most relevant to observational studies) were dose-response association, impact of plausible residual confounders, and strength of association (magnitude of effect). When the body of evidence for a particular outcome included both RCTs and observational studies, we graded each study type separately using design-specific criteria. In considering the overall strength of the entire body of evidence, we considered the extent to which the observational evidence is consistent with RCT data, particularly with regard to direction and magnitude of effect. We also explored the consistency of our findings with recent SRs. Because of the risk of unmeasured confounding, observational studies generally do not contribute to estimates of the magnitude of effect, and judgments about the precision of the effect, when RCT data are available. If there are other issues (such as differences in when and where RCTs were performed compared to observational studies, and how these differences might affect applicability), this would generally lead to increased uncertainty about the magnitude and precision of any treatment effect.<sup>64</sup> These domains were considered qualitatively, and a summary rating of high, moderate, or low strength of evidence was assigned for each outcome after discussion by two reviewers. In some cases, high, moderate, or low ratings were impossible or imprudent to make, for example, when no evidence was available or when evidence on the outcome was too weak, sparse, or inconsistent to permit any conclusion to be drawn. In these situations, a grade of "insufficient" was assigned. This four-level rating scale consisted of the following definitions:



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

As noted above, there is already a large body of SRs, some with MAs, in this area. We used the recommendations outlined in the *Methods Guide* chapter on integrating existing SRs in incorporating this body of evidence into our review.<sup>61</sup> Briefly, we confirmed that a given paper was an SR by requiring that the review include an explicit and adequate search, application of predefined eligibility criteria to select studies, risk of bias assessment for included studies, and qualitative or quantitative synthesis of results. Relevance of published reviews meeting these criteria was assessed based on comparability of PICOTS and the extent to which included studies reflect current practice. The quality of relevant existing reviews was graded to determine if the SR was of sufficient quality to inform our evidence base. Key components of this determination included search of multiple sources, use of a generally accepted tool for risk of bias assessment, and sufficient information to assess the strength of the body of evidence that includes the major domains of risk of bias, directness, consistency, precision, and reporting bias (Appendix G). Key aspects of previous reviews described include number and types of studies included, strength of evidence assessment, and overall qualitative or quantitative findings. Newly identified studies are presented separately from the results of existing reviews. Overall strength of evidence findings are based on the primary evidence. Existing SRs were incorporated into the summary SOE when available. Only good- and fair-quality SRs were considered, with heavier weighting to findings from good-quality SRs

## Applicability

We assessed applicability across our KQs using the method described in AHRQ's *Methods Guide*.<sup>26,65</sup> In brief, this method uses the PICOTS format as a way to organize information relevant to applicability. The most important issue with respect to applicability is whether the outcomes were different across studies that recruited different populations (e.g., age groups, exclusions for comorbidities) or used different methods to implement the interventions of interest; that is, important characteristics are those that affect baseline (control group) rates of events, intervention group rates of events, or both. We used a checklist applied to each abstracted study to guide the assessment of applicability (Appendix B). For each study, one investigator assigned a summary quality rating, which was then reviewed by a second investigator; disagreements were resolved by consensus or by a third investigator if agreement could not be

reached. We then used these data across KQs to evaluate the applicability to clinical practice, paying special attention to study eligibility criteria, demographic features of the enrolled population in comparison to the target population, characteristics of the intervention used in comparison with care models currently in use, the possibility of diagnostic tool or treatment intervention learning curves, and clinical relevance and timing of the outcome measures. We summarized issues of applicability qualitatively.

## **Peer Review and Public Commentary**

Experts in the fields of obstetrics and gynecology, midwifery, pediatrics and neonatology, and methodology, and individuals representing stakeholder and user communities were invited to provide external peer review of the draft report; AHRQ and an associate editor, and members of the TEP were also invited to provide comments. In addition, the draft report was posted on the AHRQ website for public comment from September 5, 2018, through October 10, 2018. We have addressed all reviewer comments, revising the text as appropriate, and documented everything in a disposition of comments report that will be made available 3 months after the Agency posts the final report on the EHC website. A list of peer reviewers submitting comments on the draft report is provided in the front matter of this report.

# Results

## Introduction

In what follows, we begin by describing the results of our literature searches. We then provide an overall description of the included studies. The remainder of the chapter is organized by Key Question (KQ). Under each of the nine KQs, we begin with a brief description of the included studies, followed by a bulleted list of the key points of the findings and a detailed synthesis of the evidence. The detailed syntheses are organized first by treatment comparison and then by outcome. We conducted quantitative syntheses where possible, as described in the Methods chapter. Each KQ results section concludes with a summary of the strength of evidence for the main findings.

## Results of Literature Searches

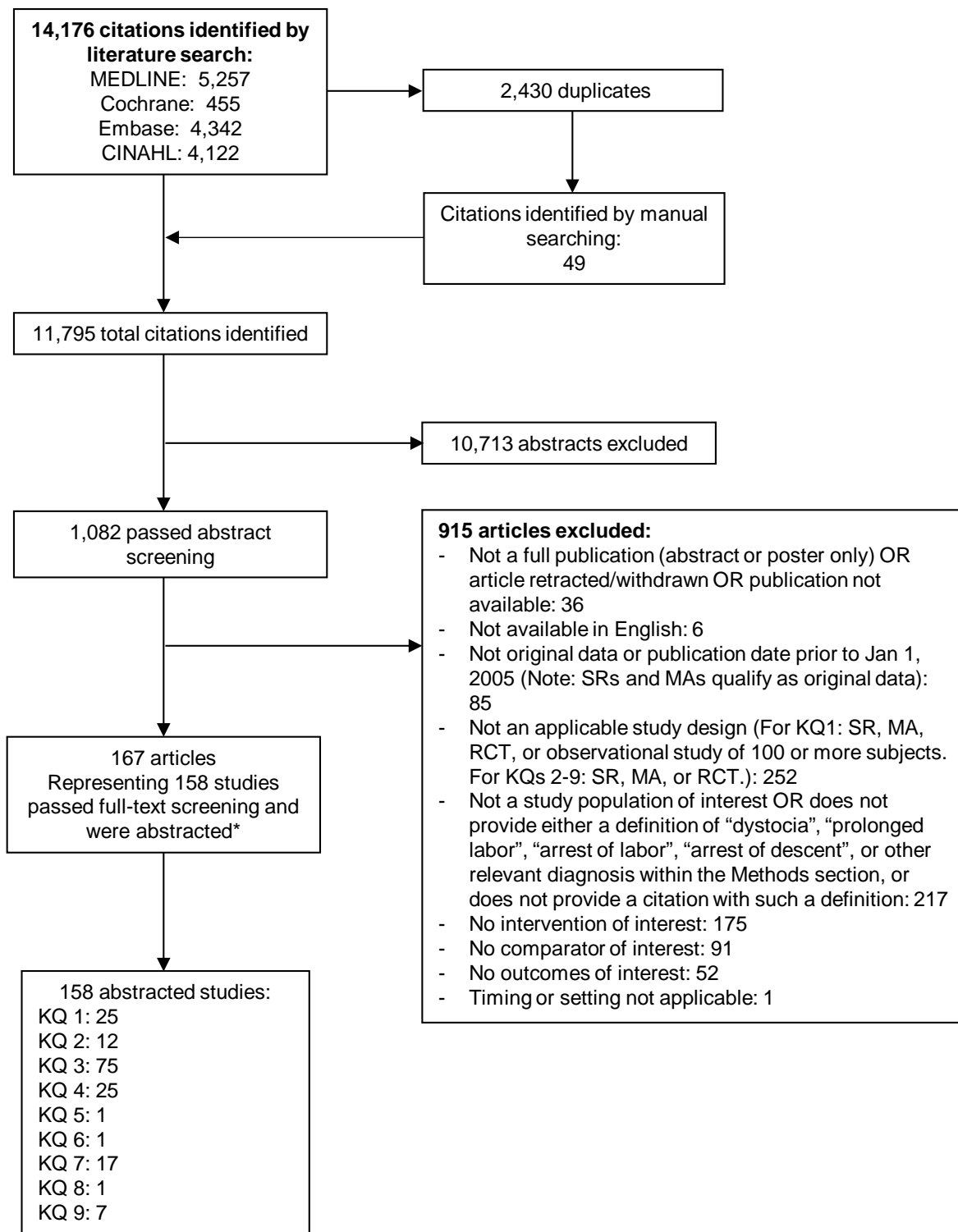
Figure 2 depicts the flow of articles through the literature search and screening process. Searches of PubMed, Embase, CINAHL, and the Cochrane Database of Systematic Reviews yielded 14,176 citations, 11,746 of which were unique. Manual searching of gray literature databases and bibliographies of key articles or referral by investigators identified 49 additional citations, for a total of 11,795 citations. No responses were received through public notification to manufacturers of requests for scientific information packets. After applying inclusion/exclusion criteria at the title-and-abstract level, 1,082 full-text articles were retrieved and screened. Of these, 915 were excluded at the full-text screening stage, leaving 167 articles for data abstraction. These 167 articles described 158 unique studies. The relationship of studies to the review questions is as follows: 25 studies relevant to KQ 1, 12 studies relevant to KQ 2, 75 studies relevant to KQ 3, 25 studies relevant to KQ 4, 1 study relevant to KQ 5, 1 study relevant to KQ 6, 17 studies relevant to KQ 7, 1 study relevant to KQ 8, and 7 studies relevant to KQ 9 (some studies were relevant to more than one KQ).

Studies with more than one article are listed in Table 3.

**Table 3. Key to primary and companion articles**

Study Designation	Primary Abstracted Article	Companion Articles
COMET (Comparative Obstetric Mobile Epidural Trial)	Wilson, 2009 <sup>66</sup>	Wilson, 2011 <sup>67</sup>
TREAT Trial	Wassen, 2015 <sup>68</sup>	van den Bosch, 2018 <sup>69</sup>
None	Akbarzadeh, 2015 <sup>70</sup>	Akbarzadeh, 2015 <sup>71</sup>
None	Bloom, 2006 <sup>72</sup>	Schaffer, 2005 <sup>73</sup>
None	Dencker, 2009 <sup>74</sup>	Bergqvist, 2012 <sup>75</sup>
None	de Orange, 2011 <sup>76</sup>	Orange, 2012 <sup>77</sup>
None	Pascual-Ramirez, 2011 <sup>78</sup>	Pascual-Ramirez, 2012 <sup>79</sup>
None	Ragnar, 2006 <sup>80</sup>	Altman, 2007 <sup>81</sup>
None	Shafaie, 2017 <sup>82</sup>	Ahadi Yulghunlu, 2018 <sup>83</sup>

**Figure 2. Literature flow diagram**



\* Some studies were relevant to more than one KQ.

Abbreviations: KQ=Key Question; RCT=randomized controlled trial; SR/MA=systematic review/meta-analysis

## Description of Included Studies

Overall, we included 158 studies described in 167 publications: 25 studies relevant to KQ 1, 12 studies relevant to KQ 2, 75 studies relevant to KQ 3, 25 studies relevant to KQ 4, 1 study relevant to KQ 5, 1 study relevant to KQ 6, 17 studies relevant to KQ 7, 1 studies relevant to KQ 8, and 7 studies relevant to KQ 9. Of the 158 studies, 122 were RCTs or observational in study design and 36 were SRs. The 122 RCTs/observational studies were conducted wholly or partly in continental Europe or the United Kingdom (26 studies, 21%), the United States or Canada (24 studies, 19%), the Middle East (34 studies, 28%), Asia (26 studies, 21%), Latin America (7 studies, 6%), and other locations (Africa [3 studies] and Australia/New Zealand [2 studies], total 4%). Appendix C provides a detailed listing of included articles. Appendix D provides a complete list of articles excluded at the full-text screening stage, with reasons for exclusion. Further details on the studies included for each KQ are provided in the relevant results sections, below, and in Appendix E. Detailed risk of bias information for each included study is reported in Appendices F and G.

We searched the ClinicalTrials.gov registry of clinical studies as a mechanism for ascertaining publication bias by identifying studies that have been completed but are as yet unpublished. Among available registries with varying geographic ranges, it is the opinion of the investigators that this widely used, U.S.-based source provided the most relevant information to the populations and interventions of interest in this review. Our search yielded 33 records of completed trials for screening. Manual review identified three of these records as potentially relevant to the KQs. We identified publications (six in total) for all three of these studies, thus finding no indication of publication bias that would impact the results of this review. Five of these publications had been previously identified in our PubMed, Embase, and Cochrane Database of Systematic Reviews searches. The remaining study was a novel publication and was entered into our screening process. Note that we did not compare ClinicalTrials.gov records or protocols listing intended/pre-specified outcomes against published findings.

## Key Question 1. Criteria Used To Define Abnormal Labor

KQ 1 was: Do delivery outcomes for management of abnormal labor differ based on the criteria used to define protracted or arrested labor at different stages of the labor process?

This KQ examined whether labor outcomes among women in spontaneous labor differed based on the criteria used to define abnormal labor. In addition, we sought to determine what constitutes normal labor related to the rate of cervical change and overall duration of labor.

## Description of Included Studies

We identified 19 individual studies that examined whether labor outcomes among women in spontaneous labor differed based on the criteria used to define abnormal labor.<sup>21,22,84-98</sup> Of the 17 included studies, four were RCTs,<sup>89,90,94,98</sup> while 15 were observational.<sup>21,22,84-88,91-93,95-97,99,100</sup> Twelve studies were conducted in the United States,<sup>21,22,84,86,88,91,93,95-97,99,100</sup> three were conducted in Asia,<sup>87,90,92</sup> two were conducted in UK/Europe,<sup>85,89</sup> one study was conducted in Australia/NZ,<sup>94</sup> and one study was conducted in the Middle East.<sup>98</sup> All but one study<sup>90</sup> was conducted in a hospital setting. This lone study was conducted in a maternity home. Seven studies reported government funding,<sup>21,22,84,86-88,96</sup> two studies reported non-government/non-industry funding,<sup>99,100</sup> one study reported a combination of funding from government and non-government, non-industry funding,<sup>91</sup> and nine studies were unclear or did not report the funding

source.<sup>85,89,90,92-95,97,98</sup> Fourteen studies were rated as good quality,<sup>22,86,88-99</sup> three as fair quality,<sup>21,85,100</sup> and two as poor quality.<sup>84,87</sup>

In addition to the above studies, six systematic reviews (4 good quality,<sup>35,101-103</sup> 1 fair quality,<sup>47</sup> and 1 poor quality<sup>104</sup>) addressed management of abnormal labor based on certain criteria are also discussed below.

## **Key Points for Criteria Used To Define Abnormal Labor**

### ***Comparisons of pregnancy outcomes based on the criteria used to define abnormal labor***

- Evidence was insufficient regarding rates of cesarean delivery and total duration of labor for different action line partograms.
- No differences were seen in postpartum hemorrhage rates (moderate strength of evidence [SOE]), neonatal acidemia rates (low SOE), or vaginal delivery rates (moderate SOE) between women managed with varying partogram strategies.
- Maternal satisfaction also was not different between partogram strategies (low SOE).

### ***What constitutes normal labor?***

- Modern labor curves constructed from the Consortium on Safe Labor (CSL) demonstrate significantly different rates of cervical change, duration of labor, and appearance of the curve (absence or presence of an inflection point) between nulliparous and parous women.
- Modern labor curves constructed from the CSL cohort vary significantly from curves constructed from historical cohorts (Friedman or National Collaborative Perinatal Project [NCPPI]), with modern curves suggesting a longer duration of the first stage of labor.
- Maternal age influences the duration of the first and second stage of labor among nulliparous women (older women having longer labors).

## **Detailed Synthesis for Criteria Used To Define Abnormal Labor**

### **Pregnancy Outcomes Based on Criteria Used To Define Abnormal Labor**

Four RCTs,<sup>89,90,94,98</sup> five observational studies,<sup>87,91,93,95,96</sup> and two good-quality SRs<sup>35,102</sup> compared outcomes among women in spontaneous labor based on the criteria used to define abnormal labor. None of these directly compared outcomes in women whose labor was managed by the Friedman curve versus the CSL curve, but four studies<sup>91,93,95,96</sup> compared delivery outcomes based on cervical dilation at time of admission.

### **Partograms**

In the 1950s, Friedman published his observations of normal labor through graphical representations of changes in cervical dilation.<sup>18</sup> This work resulted in the use of the Friedman curve as the basis for determining normal labor and the development of partograms.<sup>18,105</sup> A partogram is a graphical representation of a woman's progress in labor. Partograms typically consist of three sections, the first addressing maternal status, the second addressing fetal condition, and the third addressing the progress of labor. The section of the partogram addressing the progress of labor typically contains an alert line which, when crossed, signifies that a

woman's rate of cervical change is slower than expected. The initial partograms by Philpott and Castle<sup>105</sup> were constructed with an alert line representing a mean rate of cervical change slower than 10 percent of the population in the active phase of the first stage of labor.<sup>102</sup> In addition, partograms also include an action line, which initially was positioned 4 hours to the right of the alert line.<sup>102</sup> The action line serves to help diagnose protracted or arrested labor so that appropriate interventions (e.g., assisted rupture of the membranes, oxytocin augmentation, and/or transfer to a higher level of care) can be administered. The World Health Organization (WHO) developed a partogram that is similar to the Philpott and Castle partogram, with an action line 4 hours to the right of the alert line.<sup>106</sup> In addition, other groups utilize partograms with action lines 2 or 3 hours to the right of the alert line. We identified four good-quality RCTs,<sup>89,90,94,98</sup> and one good-quality Cochrane review<sup>102</sup> addressing labor outcomes among women managed by partograms. Findings from these studies are summarized in Table 4.

Lavender et al.<sup>89</sup> conducted an RCT at a single site in England comparing outcomes in 2,975 nulliparous women managed with a 2-hour action line partogram versus a 4-hour action line partogram. There were no differences in the overall cesarean delivery rate, indication for cesarean delivery, operative vaginal delivery rate, or rates of neonatal acidemia, postpartum hemorrhage, or maternal satisfaction between the two groups. Women managed on the 2-hour action line partogram demonstrated a significantly shorter duration of labor, reported as the time from randomization to delivery.

Fahdhy et al.<sup>90</sup> conducted a randomized trial in Indonesia of births managed in a maternity home with a partogram compared to no partogram; randomization was at the level of the midwife, rather than the patient. The trial included both nulliparous and parous women and results were not stratified by parity. Women managed with the partogram had significantly lower cesarean delivery rates, though no differences were seen in postpartum hemorrhage rates or neonatal resuscitation.

Lee et al.<sup>94</sup> conducted a randomized trial in Brisbane of 99 nulliparous women in spontaneous labor managed with a partogram containing an action line to women managed with a stepped line (dystocia line) partogram. There were no differences in mode of delivery or rates of postpartum hemorrhage, or a composite neonatal outcome between the two interventions. Women managed with the partogram containing the action line had significantly longer duration of labor compared to women managed with the partogram containing the dystocia line (503 vs 291 min,  $p=0.018$ ).

Tolba et al.<sup>98</sup> conducted a randomized controlled trial in Egypt of 110 nulliparous women in spontaneous labor managed with the WHO partogram compared to women managed with the "Labour Scale." The Labour Scale is a tool described in 2014<sup>107</sup> that represents a modification to the WHO partogram. The Labour Scale modification included guidelines for labor management as outlined by the National Institute of Clinical Evidence (NICE). Women managed with the Labour Scale had a significantly lower overall cesarean delivery rate compared with women managed with the WHO partogram (3.6% vs. 18.2%,  $p=0.03$ ), but there was no difference in the mean duration of the active phase of labor between the two groups (4.84 vs. 4.40 hours,  $p=0.16$ ).

Neal et al.<sup>91</sup> also used data from the CSL to determine if the rate of cervical change among women admitted in active labor was associated with mode of delivery. Active labor was defined as an admission cervical dilation of 4 or 5 cm followed by cervical change of greater than or equal to 1 cm within 2 hours or an admission cervical examination of greater than or equal to 6 cm. Women admitted in active labor were then divided into those with "physiologic labor progress" or those with "labor dystocia." Physiologic labor progress was defined as falling to the

left of the dystocia line on the physiologic partograph,<sup>108</sup> while women with cervical change falling to the right of the dystocia line were defined as having labor dystocia. Women with labor dystocia, as defined by the physiologic partograph, had a higher rate of cesarean delivery compared to women with physiologic labor progress (20.3% vs 5.9%,  $p < 0.001$ ).

The inconsistency between the findings for these studies for cesarean delivery rates and the duration of labor, and the non-U.S. settings among four of the five, resulted in insufficient SOE.

The Cochrane review by Lavender et al.<sup>102</sup> addresses the use of partograms in labor outcomes. This review included 11 studies with 9,475 participants and made the following comparisons:

- Partogram versus no partogram
- Partograms with 2-hour versus 4-hour action lines
- Partograms with 2-hour versus 3-hour action lines
- Partograms with 3-hour versus 4-hour action lines
- Partograms with an alert line only versus with both an alert and action line
- Early interventions using a partogram versus late interventions using a partogram

The review planned subgroup analyses by low- and high-resource setting and did not analyze data by parity. In high-resource settings (not explicitly defined in the review), using the partogram compared with not using the partogram, or use of partograms with different action line durations, did not affect overall cesarean delivery rates or indication for cesarean delivery, except that women being managed using a partogram with a 3-hour action line had higher cesarean delivery rates than women managed using a partogram with a 4-hour action line.<sup>102</sup> In low-resource settings (not explicitly defined in the review), the use of a partogram compared with no partogram did not affect overall cesarean delivery rates.<sup>102</sup>

Women in low-resource settings managed by a partogram with only an alert line had significantly lower cesarean delivery rates compared with women managed by a partogram with both an alert and action line. Similarly, in women in low-resource settings managed by a partogram, those managed with early intervention versus late interventions had lower cesarean delivery rates. In addition, women in high-resource settings managed with a partogram that contained an assessment of latent phase duration had higher overall cesarean delivery rates compared to women managed with a partogram that did not include an assessment of latent phase duration. This relationship was primarily driven by an increased cesarean delivery rate for the indication of non-reassuring fetal status in women managed by the partogram with a latent phase (Table 4).

Women in a high-resource setting managed using a partogram with a 2-hour action line compared to women managed using a partogram with stepped dystocia line had similar rates of cesarean delivery. Similarly, women in a high-resource setting managed with a partogram had similar rates of cesarean delivery compared to women managed using a “labour scale.”<sup>102</sup>

The Cochrane review also found that rates of operative vaginal delivery, duration of the first stage of labor, duration of the second stage of labor, rates of neonatal acidemia, maternal infection, or postpartum hemorrhage did not differ based on whether a partogram was used or not, whether the partogram included a 2-hour versus 4-hour action line, a 2-hour versus 3-hour action line, or a 3-hour versus 4-hour action line.<sup>102</sup> Combined with the RCT evidence, these findings resulted in moderate SOE for these outcomes other than acidemia, which had low SOE based on the findings of one RCT.



**Table 4. Summary of labor outcomes using partograms**

Study Quality Design	Int	Com	Duration of Labor: Int (SD)	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: Difference (95% CI)	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Lavender, 2006 <sup>89</sup>  Good RCT	Partogram 2 hour action line	Partogram 4 hour action line	539.6 (260.3) min	566.4 (289.7) min	0.008	136/1490 (9.1%)	135/1485 (9.1%)	RR 1.0 (0.80 to 1.26)	No	High-resource setting
Fahdhy, 2005 <sup>90</sup>  Good RCT	Partogram	No partogram	—	—	—	24/322 (4.9%)	15/304 (7.4%)	P=0.011, OR 0.64 (0.45 to 0.90)	—	Low-resource setting
Lee, 2017 <sup>94</sup>  Good RCT	Partogram with dystocia line	Partogram with action line	291 (135 to 539) min Median (IQR)	503 (297 to 665) min Median (IQR)	0.018	9/50 (18%)	8/49 (16.3%)	RR 1.10 (0.46 to 2.64)	No	High-resource setting
Tolba, 2017 <sup>98</sup>  Good RCT	Labour Scale	WHO partogram	4.84 (2.51) hr	4.40 (1.96) hr	0.16	2/55 (3.6%)	10/55 (18.2%)	P=0.03	No	Low-resource setting
Neal, 2018 <sup>91</sup>  Good Obs	Labor dystocia as defined on the physiologic partograph	Physiologic labor progress as defined on the physiologic partograph	—	—	—	164/806 (20.3%)	462/7866 (5.9%)	P<0.001	—	High-resource setting
Lavender, 2018 <sup>102</sup>  Good SR	Partogram	No partogram	—	—	—	42/334 (12.6%)	71/323 (22.0%)	RR 0.65 (0.22 to 1.91)	—	Low-resource setting
Lavender, 2018 <sup>102</sup>  Good SR	Partogram	No partogram	First stage: 16.8 (7.3) hr Second stage: 2.4 (1.8) hr	First stage: 16.0 (7.6) hr Second stage: 2.4 (1.9) hr	First stage Mean diff: 0.80 (-0.06, 1.66) Second stage mean diff: 0.0 (-0.21, 0.21)	125/580 (21.5%)	121/576 (21.0%)	RR 1.03 (0.82 to 1.28)	No	High-resource setting

Study Quality Design	Int	Com	Duration of Labor: Int (SD)	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: Difference (95% CI)	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Lavender, 2018 <sup>102</sup>  Good SR	Partogram	No partogram	—	—	—	167/914 (18.3%)	192/899 (21.4%)	RR 0.77 (0.40 to 1.46)	—	All subjects (both low- and high-resource settings)
Lavender, 2018 <sup>102</sup>  Good SR	Partogram with Two-hour action line	Partogram with Four-hour action line	--	--	--	40/570 (7.0%)	37/578 (6.4%)	RR 1.09 (0.71 to 1.68)	--	Low-resource setting
Lavender, 2018 <sup>102</sup>  Good SR	Partogram with Two-hour action line	Partogram with Four-hour action line	—	—	—	Overall: 171/1805 (9.5%) NRFHT: 51/1805 (2.8%) Delay: 120/1805 (6.6%)	Overall: 161/1796 (9.0%) NRFHT: 39/1796 (2.2%) Delay: 122/1796 (6.8%)	Overall: RR 1.06 (0.85 to 1.32) NRFHT: RR 1.30 (0.86 to 1.96) Delay: RR 0.98 (0.77 to 1.25)	—	High-resource setting
Lavender, 2018 <sup>102</sup>  Good SR	Partogram with Two-hour action line	Partogram with Four-hour action line	--	--	--	Overall: 211/2375 (8.9%)	Overall: 198/2374 (8.3%)	Overall: RR 1.06 (0.88 to 1.28)	--	All subjects (both low- and high-resource settings)
Lavender, 2018 <sup>102</sup>  Good SR	Partogram with 2-hour action line	Partogram with Three-hour action line	—	—	—	Overall: 35/315 (11.1%) NRFHT: 12/315 (3.8%) Delay: 23/315 (7.3%)	Overall: 43/302 (14.2%) NRFHT: 12/302 (4.0%) Delay: 31/302 (10.3%)	Overall: RR 0.78 (0.51 to 1.18) NRFHT: RR 0.96 (0.44 to 2.10) Delay: RR 0.71 (0.42 to 1.19)	—	High-resource setting
Lavender, 2018 <sup>102</sup>  Good SR	Partogram with 3-hour action line	Partogram with 4-hour action line	—	—	—	Overall: 43/302 (14.2%) NRFHT: 12/302 (4.0%) Delay: 31/302 (10.3%)	Overall: 26/311 (8.4%) NRFHT: 7/311 (2.2%) Delay: 19/311 (6.1%)	Overall: RR 1.70 (1.07 to 2.70) NRFHT: RR 1.77 (0.70 to 4.42) Delay: RR 1.68 (0.97 to 2.91)	—	High-resource setting

Study Quality Design	Int	Com	Duration of Labor: Int (SD)	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: Difference (95% CI)	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Lavender, 2018 <sup>102</sup> Good SR	Partogram with Alert line only	Partogram with Alert and Action line	—	—	—	Overall: 55/344 (16.0%)	Overall: 82/350 (23.4%)	Overall: RR 0.68 (0.50 to 0.93)	—	Low-resource setting
Lavender, 2018 <sup>102</sup> Good SR	Partogram and Early Intervention	Partogram and Late Intervention	—	—	—	Overall: 55/344 (16.0%)	Overall: 82/350 (23.4%)	Overall: RR 0.68 (0.50 to 0.93)	—	Low-resource setting
Lavender, 2018 <sup>102</sup> Good SR	Partogram and Early Intervention	Partogram and Late Intervention	—	—	—	Overall: 171/1490 (11.5%)	Overall: 161/1485 (10.8%)	Overall: RR 1.06 (0.85 to 1.32)	—	High-resource setting
Lavender, 2018 <sup>102</sup> Good SR	Partogram and Early Intervention	Partogram and Late Intervention	—	—	—	Overall: 226/2149 (10.5%)	Overall: 243/2146 (11.3%)	Overall: RR 0.94 (0.67 to 1.31)	—	All subjects (both low- and high-resource settings)
Lavender, 2018 <sup>102</sup> Good SR	Partogram with latent phase	Partogram without latent phase	—	—	—	Overall: 83/350 (23.7%) NRFHT: 65/350 (18.6%) Delay: 12/350 (3.4%)	Overall: 38/393 (9.7%) NRFHT: 15/393 (3.8%) Delay: 10/393 (2.5%)	Overall: RR 2.45 (1.72 to 3.50) NRFHT: RR 4.87 (2.83 to 8.37) Delay: RR 1.35 (0.59 to 3.08)	—	High-resource setting
Lavender, 2018 <sup>102</sup> Good SR	Partogram with 2-hour action line	Partogram with stepped dystocia line	—	—	—	9/50 (18%)	8/49 (16.3%)	RR 1.10 (0.46 to 2.62)	—	High-resource setting (includes only a single study)
Lavender, 2018 <sup>102</sup> Good SR	Partogram	Labour scale	—	—	—	5/61 (8.2%)	12/61 (19.7%)	RR 0.42 (0.16 to 1.11)	—	High-resource setting (includes only a single study)

Abbreviations: —=not reported; CI=confidence interval; Com=comparator; hr=hour; Int=intervention; IQR=interquartile range; NRFHT=Nonreassuring Fetal Heart Rate Tracing; RCT=randomized controlled trial; RR=relative risk; SD=standard deviation; SR=systematic review

## **Hoppe-University of Washington Cohort**

Hoppe et al. conducted a retrospective cohort study of women in spontaneous labor at the University of Washington to determine if women with long duration of active labor as defined by the Consortium on Safe Labor (CSL) labor curves would exhibit higher rates of delivery outcomes compared to women with shorter duration of active labor.<sup>100</sup> Women with active labors lasting longer than the CSL 95<sup>th</sup> percentile and women whose active labor progressed longer than the median and up to the 95<sup>th</sup> percentile were compared to women with active labor shorter than the CSL median. Women with duration of active labor lasting longer than both the 95<sup>th</sup> percentile and longer than the median and up to the 95<sup>th</sup> percentile had higher odds of cesarean delivery compared to women whose labor lasted shorter than the CSL median labor duration (odds ratio[OR] 6.8 [95% confidence interval (CI) 3.9, 11.7] and OR 3.1 [95% CI 1.8, 5.5] for >95<sup>th</sup> percentile and between the median and 95<sup>th</sup> percentile, respectively). Women with active phase of labor greater than the 95<sup>th</sup> percentile of women in the CSL cohort were also more likely to have postpartum hemorrhage (OR 1.6 [95% CI 1.0, 2.7]) and women with an active phase greater than the median and up to the 95<sup>th</sup> percentile were more likely to develop chorioamnionitis (OR 2.5 [95% CI 1.1, 5.9]) compared to women with active labor lasting shorter than the CSL median. There were no differences in the proportion of neonates with an Apgar score less than 7 or risk for being admitted to the intensive care nursery based on duration of labor as defined by the CSL labor curves.

## **Cervical Dilation at Admission and Delivery Outcomes**

Following publication of the CSL demonstrating that modern labor curves may differ from those originally described by Friedman, a number of studies have looked at delivery outcomes based on the definition used for active labor and whether cervical dilation at time of admission is associated with mode of delivery and other labor outcomes.

Wood et al.<sup>96</sup> conducted a secondary analysis of data collected as part of a prospective cohort study of women presenting in spontaneous labor at the Barnes-Jewish Hospital in St. Louis. Women admitted at less than 6 cm dilated were compared to women admitted with cervical dilation of greater than or equal to 6 cm. Outcomes were stratified by parity and the study included 2,033 women. Among nulliparous women, there was no significant difference in the overall cesarean delivery rate among women admitted with a cervical dilation less than 6 cm compared to those admitted with a cervical dilation greater than or equal to 6 cm (16.8% vs. 7.1%, relative risk [RR] 2.35, 0.90 to 6.13). In contrast, among parous women, women admitted with cervical dilation less than 6 cm had a significantly overall increased rate of cesarean delivery compared to women admitted at greater than 6 cm (11.0% vs. 2.5%, RR 4.36, 1.80 to 10.52). There were no differences in the cesarean delivery rate for arrest of dilation between the two groups in either nulliparous or parous women.

Kauffman et al.<sup>93</sup> performed a retrospective cohort study of women in spontaneous labor delivering in 14 Washington State hospitals to determine if cervical dilation at time of admission was associated with labor outcomes. Women with cervical dilation less than 4 cm were compared to women with cervical dilation greater than or equal to 4 cm. Data were stratified by parity. Among nulliparous women, women admitted with cervical dilation less than 4 cm had an increased overall cesarean delivery rate compared to women admitted in spontaneous labor at 4 cm or greater (21.8% vs. 14.5%, RR 1.50, 1.32 to 1.70). There were no differences in rates of operative vaginal delivery or transfusion between the two groups. Among parous women admitted with cervical dilation less than 4 cm a higher overall cesarean delivery rate was

demonstrated compared to parous women admitted with cervical dilation greater than or equal to 4 cm (3.7% vs. 1.9%, RR 1.95, 1.47 to 2.57). Parous women admitted at less than 4 cm cervical dilation had higher operative vaginal delivery rates (4.4% vs. 2.8%, RR 1.62, 1.11 to 2.37) but no differences in rate of transfusion compared to parous women admitted at greater than or equal to 4 cm.

Neal et al.<sup>95</sup> conducted a good-quality retrospective cohort of women in spontaneous labor managed at the Ohio State University Wexner Medical Center to determine if the definition used for active labor affected labor outcomes among nulliparous women in spontaneous labor. The definitions for active labor were based on those of (1) Friedman,<sup>18</sup> (2) the NICE guidelines,<sup>109</sup> and (3) the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine.<sup>110</sup> Women admitted prior to active labor had higher overall cesarean delivery rates compared to women admitted in active labor regardless by which definition was used to diagnose active labor (Friedman 13.8% vs 7.0%,  $p<0.001$ ; NICE guidelines 16.9% vs 6.7%,  $p<0.001$ ; ACOG/SMFM 13.4% vs. 9.7%,  $p<0.05$ ). There were also significant differences in the rate of a composite adverse maternal outcome that included fever during labor and postpartum hemorrhage among women admitted prior to active labor compared to those admitted in active labor (Friedman 8.9% vs 3.7 %,  $p<0.01$ ; NICE guidelines 10.7% vs 5.5%,  $p<0.001$ ; and ACOG/SMFM 8.6% vs 3.9%,  $p<0.01$ ).

## Suzuki Cohort

An observational study conducted in Japan by Suzuki et al.<sup>87</sup> compared duration of the first stage of labor among 2,369 nulliparous women having a vaginal delivery following spontaneous labor from 4 sites with published data from the Friedman and CSL cohorts. Women in the Suzuki study had a mean (standard deviation [SD]) duration of first stage of labor of 12.3 (7.7) hours compared with 13.3 (7.6) hours in the Friedman data. The CSL data for the duration of the first stage of labor was 7.3 (95% CI 3.3 to 13.7) hours in the CSL datasets. The operative vaginal delivery rates varied significantly between the 3 cohorts (3.5% vs. 51.2% vs. 13.0% in the Suzuki, Friedman, and CSL cohorts, respectively). In addition, the Suzuki study compared the time it took to change from one centimeter dilation to the next centimeter dilation during the first stage of labor to similar data obtained from the CSL study in nulliparous women. In both studies, the rate of cervical change increased with advancing cervical dilation, though the rate of change in the Japanese cohort was slower than in the CSL cohort, resulting in a longer duration of the first stage of labor (Table 5).

**Table 5. Median time intervals (hours) by cervical dilation in nulliparous women, Japanese cohort (Suzuki study) versus CSL (Zhang study)**

Cervical Dilation, cm	Suzuki Study <sup>87</sup> (95% CI)	CSL Zhang Study <sup>21</sup> (95% CI)
2 to 3	7.5 (2.7 to 21.0)	3.2 (0.6 to 15.0)
3 to 4	6.2 (2.2 to 17.7)	2.7 (0.6 to 10.1)
4 to 5	4.8 (1.5 to 15.7)	1.7 (0.4 to 6.6)
5 to 6	3.3 (1.0 to 10.7)	0.8 (0.2 to 3.1)
6 to 7	2.6 (0.7 to 9.3)	0.6 (0.2 to 2.2)
7 to 8	1.8 (0.5 to 6.8)	0.5 (0.1 to 1.5)
8 to 9	1.0 (0.2 to 4.4)	0.4 (0.1 to 1.3)
9 to 10	0.9 (0.3 to 2.6)	0.4 (0.1 to 1.4)

Abbreviations: CI=confidence interval; cm=centimeter; CSL=Consortium on Safe Labor

## **Active Management of Labor**

The active management of labor was first described by O'Driscoll and colleagues<sup>111</sup> based on their experience in the National Maternity Hospital in Dublin and was originally designed to allow for a shorter duration of labor and reduce the number of prolonged labors, but more recently it has also been applied to help lower cesarean delivery rates. The originally described active management of labor includes the following interventions: one-to-one nursing support during labor, routine use of amniotomy, intravenous oxytocin, strict diagnosis of labor, strict monitoring of the progress of labor (typically with use of a partogram), strict criteria for the diagnosis of protracted or arrested labor, and peer review of assisted deliveries.<sup>35</sup> We identified one Cochrane Review that addressed the use of a package of care for the active management of labor.<sup>35</sup> The review included 7 studies with 5,390 subjects. The authors planned to stratify results by parity, but all of the included studies only included nulliparous women. The overall cesarean delivery rate did not differ between women receiving active management of labor and women receiving usual care when all studies were included. In 1 of the 7 studies, approximately one-third of the subjects were excluded post-randomization, as randomization occurred at 30 weeks and many women developed reasons for exclusion following this.<sup>112</sup> In sensitivity analysis that excluded this study, active management of labor resulted in significantly lower cesarean delivery rates and shorter duration of labor when compared with usual care (Table 6).<sup>35</sup> Active management of labor was also associated with shorter duration of time from admission to delivery and the first stage of labor compared to usual care. The second stage of labor was not different between the two groups (Table 6). Active management of labor did not affect rates of operative vaginal delivery, postpartum hemorrhage, maternal satisfaction, or maternal infection.

**Table 6. Labor outcomes by active management of labor**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value (95% CI)	Cesarean: Int	Cesarean: Com	Cesarean: Difference (95% CI)	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Brown, 2013 <sup>35</sup> Good	Active management of labor	Routine care	—	—	—	Overall: 343/2573 (13.3%)	Overall: 416/2817 (14.8%)	Overall: RR 0.88 (0.77 to 1.01)	—	All studies including 1 with high number of post-randomization exclusions
Brown, 2013 <sup>35</sup> Good	Active management of labor	Routine care	Admission to delivery: 7.7 (1.9) hr First stage: 6.8 (2.3) hr Second stage: 0.86 (0.43) hr	Admission to delivery: 9.4 (1.7) hr First stage: 8.3 (1.9) hr Second stage: 0.89 (0.44) hr	Difference in admission to delivery: -1.69 (-2.08 to -1.31) hr Difference in first stage: -1.56 (-2.17 to -0.96) hr Difference in second stage: -0.02 (-0.06 to 0.02) hr	Overall: 146/1564 (9.3%)	Overall: 240/1911 (12.5%)	Overall: RR 0.77 (0.63 to 0.94)	Yes	Sensitivity analysis with 1 study excluded (high-post randomization exclusion rate)

Abbreviations: —=not reported; CI=confidence interval; Com=comparator; hr=hour; Int=intervention; RR=relative risk

## What Constitutes Normal Duration of Labor?

Eight observational studies<sup>21,22,84,86,88,92,97,99</sup> and three fair-quality systematic reviews/meta-analyses (SR/MAs)<sup>47,101,103</sup> addressed the question of what constitutes normal duration of labor. The populations studied varied based on parity and whether labor was augmented, both of which may affect the duration of labor. Furthermore, the CSL investigators performed a subgroup analysis to determine the progression of labor among women receiving oxytocin augmentation.<sup>99</sup>

## National Collaborative Perinatal Project, the Consortium on Safe Labor, and the Inde Cohort

The NCPP and the CSL were two large observational studies that both addressed duration of labor. The NCPP was a large observational study conducted at 12 sites between 1959 and 1966 and included 54,304 singleton pregnancies that delivered at 20 weeks or later.<sup>22</sup> Of these, labor outcomes were reported for 26,838 parturients with singleton gestation, spontaneous onset of labor, and who completed the first stage of labor.<sup>22</sup> In contrast, the CSL was a large observational study conducted at 19 sites between 2002 and 2008, with 87 percent of the births occurring between 2005 and 2007.<sup>21</sup> The CSL included 62,415 subjects who had spontaneous onset of labor and a vaginal delivery. The rate of labor augmentation differed significantly between the two cohorts. Within the NCPP cohort, 14.6 percent of women received oxytocin augmentation (20% of nulliparous, 12% of parous 1, and 12% of parous 2+),<sup>22</sup> while 45.9 percent of women in the CSL cohort received oxytocin augmentation (47% of nulliparous, 45% of parous 1, and 45% of parous 2+).<sup>21</sup>

Unlike the nulliparous labor curve of Friedman, which demonstrates a clear inflection point at which the rate of cervical dilation changes dramatically (transition from latent to active phase of labor) during the course of the first stage of labor, neither the NCPP or CSL nulliparous labor curves demonstrate a clear inflection point at which the rate of cervical dilation changes.<sup>18,19,21,22</sup> In contrast, the labor curves for parous women in both the NCPP and CSL cohorts demonstrate an inflection point at which the rate of cervical dilation changes. In the NCPP cohort, the inflection point for Parous 1 women occurred at 5.5 cm, while for Parous 2+ women, the inflection point occurred at 5 cm dilation.<sup>22</sup> In the CSL cohort, the inflection point occurred at 6 cm cervical dilation for both Parous 1 and Parous 2+ women.<sup>21</sup>

Inde et al.<sup>92</sup> conducted an observational retrospective cohort study of women admitted in spontaneous labor who progressed to have a spontaneous vaginal delivery at six hospitals in Japan with the goal of creating normal labor curves for their population. Within their population, the study found that the labor curve for nulliparous women had an inflection point occurring at six centimeters, above which the rate of cervical change increased. Parous women, both with one prior or more than one prior delivery, demonstrated an inflection point at 5 cm, above which the rate of cervical change increased. The mean (95<sup>th</sup> percentile) duration of labor differed significantly ( $p < 0.001$ ) for women in the cohort by parity; 8.48 (20.0), 4.4 (10.4), and 4.0 (10.1) hours for nulliparous, parous 1 and parous 2+ women, respectively.

There were significant differences in maternal characteristics between the three cohorts, including maternal age, race/ethnicity, body mass index, cervical dilation at admission, and/or rate of oxytocin augmentation. The extent to which differences in these patient characteristics contributed to the observed differences in labor curves is unclear.

Oladapo et al.<sup>101</sup> conducted an SR that included seven observational studies and 99,971 women to determine the expected rate of cervical change among women in spontaneous labor.



Results were stratified by parity. They found that the rate of cervical changes at approximately 5 to 6 cm dilation among nulliparous and parous women. The NCPP, CSL, Inde, and Oladapo datasets all reported the time it took to change from one centimeter dilation to the next centimeter dilation during the first stage of labor (Table 7).

**Table 7. Median time intervals (hours) by cervical dilation and parity from one cervical dilation score to the next, all cohorts**

Cervical Dilation, cm	NCP Cohort <sup>22</sup> Parity 0	NCP Cohort Parity 1	NCP Cohort Parity 2+	CSL Cohort <sup>21</sup> Parity 0	CSL Cohort Parity 1	CSL Cohort Parity 2+	Inde et Cohort <sup>92</sup> Parity 0	Inde Cohort Parity 1	Inde Cohort Parity 2+	Olada SR <sup>101</sup> Parity 0	Olada SR Parity 1+
3-4	1.2 (6.6)	–	–	1.8 (8.1)	–	–	2.2 (8.0)	0.9 (4.0)	0.8 (4.5)	2.0	2.4
4-5	0.9 (4.5)	0.7 (3.3)	0.7 (3.5)	1.3 (6.4)	1.4 (7.3)	1.4 (7.0)	1.8 (5.8)	0.5 (2.2)	0.5 (2.4)	1.5	1.2
5-6	0.6 (2.6)	0.4 (1.6)	0.4 (1.6)	0.8 (3.2)	0.8 (3.4)	0.8 (3.4)	1.3 (4.7)	0.4 (2.2)	0.3 (2.1)	0.9	0.7
6-7	0.5 (1.8)	0.4 (1.2)	0.3 (1.2)	0.6 (2.2)	0.5 (1.9)	0.5 (1.8)	1.1 (3.1)	0.3 (1.7)	0.3 (1.7)	0.7	0.4
7-8	0.4 (1.4)	0.3 (0.8)	0.3 (0.7)	0.5 (1.6)	0.4 (1.3)	0.4 (1.2)	1.0 (3.3)	0.3 (1.7)	0.3 (1.5)	0.6	0.4
8-9	0.4 (1.3)	0.3 (0.7)	0.2 (0.6)	0.5 (1.4)	0.3 (1.0)	0.3 (0.9)	0.8 (2.2)	0.3 (1.3)	0.2 (1.0)	0.5	0.3
9-10	0.4 (1.2)	0.2 (0.5)	0.2 (0.5)	0.5 (1.8)	0.3 (0.9)	0.3 (0.8)	0.5 (2.2)	0.2 (1.2)	0.2 (1.2)	0.5	0.3

Abbreviations: cm=centimeter; CSL=Consortium on Safe Labor; NCP=National Collaborative Perinatal Project

The time from admission to 10 cm cervical dilation based on the cervical dilation at the time of admission among nulliparous women was reported for each of the three cohorts. The median (95<sup>th</sup> percentile) time from admission to delivery within the NCPP cohort was 6.3 (20.7), 4.5 (16.2), 3.2 (14.2), and 2.1 (9.3) hours for women admitted at 2-2.5 cm, 3-3.5 cm, 4-4.5 cm, and 5-5.5 cm cervical dilation, respectively.<sup>22</sup> For nulliparous women in the CSL cohort, the median (95<sup>th</sup> percentile) time from admission to delivery was 8.4 (20.0), 6.9 (17.4), 5.3 (16.4), and 3.8 (12.7) hours for women admitted at 2-2.5 cm, 3-3.5 cm, 4-4.5 cm, and 5-5.5 cm cervical dilation, respectively.<sup>21</sup> For nulliparous women in the Inde cohort, the median (95<sup>th</sup> percentile) time from admission to delivery was 6.7 (16.8), 5.1 (13.5), 3.7 (10.2), and 3.0 (8.9) hours for women admitted at 2 cm, 3cm, 4cm, and 5 cm cervical dilation, respectively. Among nulliparous women included in the Oladapo SR, the median (95<sup>th</sup> percentile) time from admission to delivery was 7.8, 6.4, 4.9, and 3.4 hours for women admitted at 2 cm, 3cm, 4cm, and 5cm cervical dilation, respectively.

### **Consortium on Safe Labor Subgroup Analysis; Oxytocin Augmentation**

Zhang et al conducted a subgroup analysis of the CSL dataset to determine the progress of labor among women requiring oxytocin augmentation during labor.<sup>99</sup> For this analysis, they included women within the CSL cohort with a non-anomalous singleton gestation in the vertex presentation at 37 weeks or greater who had a vaginal delivery and for whom oxytocin data was available. The group conducted two analyses: (1) duration of labor for progressing from one centimeter to the next centimeter dilation when oxytocin was started at the beginning of the interval (Table 8) and (2) duration of labor for progressing from one centimeter to the next when the oxytocin infusion rate reached the highest dose prior to the start of the cervical dilation interval studies (Table 9). The authors found that as labor progressed, the time required to change from one centimeter to the next became shorter when oxytocin was started later in labor. In addition, once the maximal required infusion rate was achieved, the rate of cervical dilation progressed more quickly the later in labor that the maximal rate was achieved.

**Table 8. Duration of labor in hours for cervical dilation to the next centimeter with oxytocin starting at the beginning of the interval<sup>a</sup>**

<b>Starting Oxytocin at the Interval</b>	<b>N Nulliparous</b>	<b>Nulliparous 50<sup>th</sup> Percentile (95<sup>th</sup>)</b>	<b>N Parous</b>	<b>Parous 50<sup>th</sup> Percentile (95<sup>th</sup>)</b>
4-5 cm	740	2.9 (8.8)	850	3.1 (10.1)
5-6 cm	460	1.7 (5.8)	646	1.9 (8.0)
6-7 cm	319	1.4 (5.2)	445	1.3 (6.1)
7-8 cm	221	1.1 (5.0)	316	1.0 (4.6)
8-9 cm	139	1.5 (6.4)	219	0.9 (3.8)
9-10 cm	105	1.8 (5.5)	150	0.7 (2.9)
6-10 cm	319	2.1 (6.0)	445	1.7 (6.20)

<sup>a</sup> Interval-censored regression

**Table 9. Duration of labor in hours for cervical dilation to the next centimeter with oxytocin reaching the highest dose before the start of the interval<sup>a</sup>**

Starting Oxytocin at the Interval	N Nulliparous	Nulliparous 50 <sup>th</sup> Percentile (95 <sup>th</sup> )	N Parous	Parous 50 <sup>th</sup> Percentile (95 <sup>th</sup> )
4-5 cm	967	0.7 (2.4)	551	0.6 (1.9)
5-6 cm	1596	0.5 (1.5)	1188	0.4 (1.1)
6-7 cm	2126	0.4 (1.0)	1848	0.3 (0.8)
7-8 cm	2533	0.4 (1.0)	2434	0.3 (0.6)
8-9 cm	2917	0.4 (0.9)	2958	0.2 (0.5)
9-10 cm	3200	0.5 (1.6)	3362	0.2 (0.6)
6-10 cm	2127	0.5 (1.5)	1855	0.4 (0.9)
2 <sup>nd</sup> stage without epidural analgesia	89	0.5 (2.2)	212	0.1 (0.4)
2 <sup>nd</sup> stage with epidural analgesia	3340	1.2 (3.1)	3452	0.4 (1.1)

<sup>a</sup> Interval-censored regression

## Interbirth Interval and Labor Curve

In a fair-quality observational study,<sup>97</sup> labor curves were constructed for parous women presenting to the Prentice Women's Hospital to determine if the interbirth interval, the time between the prior and current birth affected the shape of the labor curve. Women were divided into one of three groups, by duration of the interbirth interval; less than 59 months, 60 to 119 months, and greater than or equal to 120 months. The mean duration of labor for each of the three groups was not reported. Summary labor curves for each of the three groups were constructed and equations fitting the curves were reported where cervical dilation is expressed by; 1)  $\text{cm} = 4.67 * e^{(0.079 * \text{time})}$  for the interbirth interval group of less than 59 months, 2)  $\text{cm} = 4.94 * e^{(0.079 * \text{time})}$  for the interbirth interval group of 60 to 119 months, and 3)  $\text{cm} = 4.87 * e^{(0.090 * \text{time})}$  for the interbirth interval group of greater than or equal to 120 months. The mean rate of cervical dilation for each of the three groups was 0.57, 0.52, and 0.78 cm per hour, respectively, with women in the longer interbirth interval demonstrating significantly slower rates of cervical change.

## Frigo Italian Cohort and the Abalos SR

Frigo et al.<sup>85</sup> conducted a fair-quality observational cohort of nulliparous women in spontaneous labor who delivered vaginally to determine the duration of the first stage and second stage of labor, with the ultimate goal of constructing labor curves for their population and then comparing those curves to the curves published by Friedman and the CSL. All women in the Frigo cohort received regional analgesia and were assigned in an alternating fashion to combined spinal plus epidural analgesia or to epidural analgesia alone. The mean duration of the first stage of labor in their population was 4 hours and 30 minutes (SD 1.52 hours), and the mean duration of the second stage of labor was 1 hour and 10 minutes (SD 0.43 hours). Oxytocin augmentation was received in 55.9 percent of the study population. Within this cohort, women with combined spinal plus epidural analgesia had significantly shorter mean (SD) duration of the first (4.01 [1.43] vs. 4.60 [1.39] hours,  $p=0.043$ ) and second (1.05 [0.38] vs. 1.15 [0.35] hours,  $p=0.036$ ) stages of labor compared to women receiving epidural analgesia alone (Table 10).

Finally, Abalos et al.<sup>103</sup> conducted an SR of 37 studies including 208,000 women to determine the median duration of the first and second stages of labor. Among nulliparous women, the median (95<sup>th</sup> percentile) duration of the first stage of labor ranged from 3.7 to 5.9

hours (14.5 to 16.7 hours) when active labor was considered to begin at 4 cm cervical dilation and ranged from 3.8 to 4.3 hours (11.3 to 12.7 hours) when active labor was considered to begin at 5 cm cervical dilation.

**Table 10. Duration of labor and oxytocin augmentation in the Frigo, Friedman, and CSL cohorts**

Outcome	Frigo Cohort <sup>85</sup>	Friedman Cohort <sup>19</sup>	CSL Cohort <sup>21</sup>
Mean (SD) Duration of first stage, hours	4.50 (1.5)	4.35	5.50
Mean (SD) Duration of second stage, hours	1.10 (0.4)	0.39	0.53
Oxytocin augmentation, % of study population	55.9	50	45.9

Abbreviation: CSL=Consortium on Safe Labor; SD=standard deviation

## Labor Outcomes by Duration of Labor and Maternal Age

A large, single-center observational study<sup>86</sup> of 10,661 nulliparous women in spontaneous labor assessed delivery outcomes based on the duration of labor. The duration of the first stage of labor was divided into 3 categories: <5<sup>th</sup> percentile, 5<sup>th</sup> to 95<sup>th</sup> percentile, and >95<sup>th</sup> percentile. Mode of delivery and rates of postpartum hemorrhage, chorioamnionitis, and endometritis varied by duration of the first stage of labor (Table 11). The incidence of third or fourth degree perineal laceration, neonatal acidemia, neonatal sepsis, shoulder dystocia, or birth trauma was not influenced by duration of the first stage of labor. In variable analysis, mode of delivery (overall adjusted odds ratio [aOR] 0.62 [95% CI, 0.45 to 0.84] for cesarean delivery and aOR 2.28 [95% CI, 1.92 to 2.72] for first stage duration for the <5<sup>th</sup> percentile and >95<sup>th</sup> percentile compared to the 5<sup>th</sup> to 95<sup>th</sup> percentile, respectively) and chorioamnionitis (aOR 0.31 [95% CI, 0.17 to 0.56] and aOR 1.58 [95% CI, 1.25 to 1.98] for first stage duration for the <5<sup>th</sup> percentile and >95<sup>th</sup> percentile compared to the 5<sup>th</sup> to 95<sup>th</sup> percentile, respectively) remained significantly different based on duration of the first stage of labor.

**Table 11. Maternal outcomes by duration of the first stage of labor**

Outcome	<5 <sup>th</sup> Percentile (0-2.8 Hours) n=525	5 <sup>th</sup> to 95 <sup>th</sup> Percentile (2.8-30 Hours) n=9,611	>95 <sup>th</sup> Percentile (>30 Hours) n=525	P Value
Mode of delivery, % spontaneous vaginal	80.6	72.9	63.8	<0.001
Mode of delivery, % operative vaginal	17.4	21.0	22.6	<0.001
Mode of delivery, % cesarean	2.0	6.1	13.5	<0.001
Postpartum hemorrhage, %	8.6	9.8	14.0	0.004
Chorioamnionitis, %	2.9	12.5	23.5	<0.001
Endometritis, %	1.0	2.4	3.2	0.04

The duration of labor is affected by maternal age. A single-center observational study of 31,976 women demonstrated that the duration of the first and second stage of labor is associated with maternal age.<sup>88</sup> In multivariable analysis including only those women in spontaneous labor (excludes women who were induced), older nulliparous women demonstrated significantly

longer first stage of labor compared to younger women, though this relationship was not seen among parous women. Older nulliparous and parous women had longer adjusted duration of the second stage of labor compared to younger women (Table 12).

**Table 12. Duration of labor (minutes) by maternal age<sup>a</sup>**

Parity and Stage of Labor	<20 Yrs	20-24 Yrs	25-29 Yrs	30-34 Yrs	35-39 Yrs	≥40 Yrs
Nulliparous first stage	550 (170 to 1400)	555 (170 to 1423)	595 (180 to 1445)	630 (180 to 1590)	660 (180 to 1734)	585 (200 to 1740)
Nulliparous second stage	51 (10 to 232)	65 (12 to 245)	89 (15 to 282)	118 (19 to 317)	127 (21 to 336)	148 (21 to 381)
Parous first stage	368 (117 to 1080)	365 (103 to 1080)	355 (95 to 1075)	345 (90 to 1080)	345 (90 to 1110)	343 (80 to 1098)
Parous second stage	16 (3 to 120)	15 (3 to 128)	18 (3 to 160)	20 (3 to 191)	24 (4 to 221)	26 (3 to 197)

<sup>a</sup> Data are median duration of labor (95% confidence interval) in minutes. Includes women who were induced (range 12.7 to 19.7%).

Abbreviations: yrs=years

## Labor Duration by Initial Rate of Cervical Change at Admission

An observational study of 216 nulliparous women compared the duration of labor and mode of delivery based on the initial rate of cervical change at the time of admission.<sup>84</sup> Women with an initial rate of cervical change of <0.5 cm per hour in the first 4 hours were defined as being in pre-labor, and women with an initial rate of cervical change of >0.5 cm per hour were defined as being in active labor. Women in active labor were less likely to be delivered by cesarean deliver and had shorter duration of labor from admission to 10 cm compared to women in admitted in pre-labor.

A fair-quality SR of 18 studies including 7009 nulliparous women by the same lead author<sup>47</sup> demonstrated that the mean (SD) duration of the active phase of labor in nulliparous women was 6.0 (2.0) hours, with an associated mean (SD) rate of cervical change of 1.2 (0.5) cm per hour.

## Strength of Evidence for Criteria Used To Define Abnormal Labor

Table 13 summarizes the SOE for the use of partograms described above. In general, the SOE was reduced for outcomes because of inconsistencies between studies (which may be related to variation in the definitions used to build the partograms), and because the evidence was largely based on studies from non-U.S. settings (and several focused on low-resource settings). This is largely because of questions related to whether differences in the characteristics of patients, providers, or settings between U.S. and non-U.S. settings affect the generalizability of the results to the US.

**Table 13. Partogram use: Strength of evidence for major outcomes and adverse events**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>89,90,94,98</sup> (3,810)  1 Obs <sup>91</sup> (8,672)  1 SR <sup>102</sup> (1,813 patients, 3 studies)	<b>Inconclusive:</b> Inconsistent findings from 4 studies combined with non-U.S. settings resulted in insufficient SOE.	Insufficient (Indirect [non-U.S. setting], Inconsistent)  SR evidence also was inconsistent between low and high-resource settings.
	Process Related Outcomes – Operative Vaginal Delivery	1 RCT <sup>89</sup> (1,929)  1 SR <sup>102</sup> (1,813 patients, 3 studies)	<b>No difference:</b> No difference in operative vaginal delivery rates between women managed with varying partogram strategies.	Moderate (non-U.S. setting)  Findings consistent with SR
	Process Related Outcomes – Parental Preferences	1 RCT <sup>89</sup> (1,929)	<b>No difference:</b> An RCT in the UK demonstrated no difference in maternal satisfaction scores between women managed with a two-hour action line partogram compared to women managed with a four-hour action line partogram.	Low (non-U.S. setting, 1 study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>89,90,94,98</sup> (3,810)  1 Obs <sup>91</sup> (8,672)  1 SR <sup>102</sup> (1,813 patients, 3 studies)	<b>Inconclusive:</b> Inconsistent findings from 4 studies combined with non-U.S. settings resulted in insufficient SOE.	Insufficient (Indirect [non-U.S. setting], Inconsistent)  SR evidence also was inconsistent between low and high-resource settings.
Adverse Events	Maternal Outcomes – Hemorrhage	3 RCTs <sup>89,90,94</sup> (3,700)	<b>No difference:</b> No difference in postpartum hemorrhage rates among women managed with varying partogram strategies.	Moderate (non-U.S. setting)
	Neonatal Outcomes – Respiratory Distress	1 RCT <sup>90</sup> (626)	<b>Inconclusive:</b> SOE was rated as insufficient given findings from 1 study in non-U.S. low resource setting.	Insufficient (non-U.S. setting, 1 small study)
	Neonatal Outcomes – Acidemia	1 RCT <sup>89</sup> (1,929)	<b>No difference:</b> No difference in neonatal acidemia rates between women managed with varying partogram strategies.	Low (non-U.S. setting, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: Obs=observational; RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 2. Amniotomy

KQ 2 was: What are the benefits and harms of amniotomy in women in spontaneous labor?

## Description of Included Studies

We identified nine RCTs that examined the benefits and harms of amniotomy ( $\pm$  oxytocin) in women in spontaneous labor.<sup>113-121</sup> Of these, four studies were conducted in the Middle East,<sup>113-115,118</sup> three were conducted in Asia,<sup>117,120,121</sup> and two were conducted in Africa.<sup>116,119</sup> All but one study<sup>118</sup> were conducted in a hospital setting. The lone exception was a study conducted in an obstetrics and gynecology unit. All nine studies were unclear about or did not report their funding source. Six studies were rated as good quality,<sup>114-117,119,121</sup> and three studies were rated as fair quality.<sup>113,118,120</sup>

Comparisons of interest were amniotomy versus an alternative control treatment without amniotomy (eight studies<sup>113-116,118-121</sup>) and amniotomy plus oxytocin versus control treatment (two studies<sup>114,117</sup>). Several studies evaluated timing of amniotomy and varied in their definitions though most assumed early amniotomy was defined as receiving amniotomy at 4-5 cm cervical dilation.

In terms of parity, four studies reported results for nulliparous women only;<sup>113,117,118,120</sup> one reported results for nulliparous and parous women separately (with no analysis of combined results);<sup>115</sup> one reported results for nulliparous and parous women combined and for each of the parity subgroups;<sup>114</sup> and three reported results for women of unspecified parity.<sup>116,119,121</sup> We were able to combine results across parity subgroups for some dichotomous outcomes of interest; we report those below.

In addition to the above studies, three good-quality SRs addressed the benefits and harms of amniotomy.<sup>35,122,123</sup> All three SR/MAs examined the role of amniotomy, with or without oxytocin, to prevent labor dystocia,<sup>122</sup> shorten spontaneous labor,<sup>123</sup> or prevent cesarean delivery<sup>35</sup> in spontaneous labor. Wei et al. performed a meta-analysis to estimate the effects of amniotomy plus oxytocin for prevention of, or therapy for, delay in labor progress on the cesarean delivery rate and on indicators of maternal and neonatal morbidity. Smyth et al.<sup>123</sup> compared amniotomy alone to intention to preserve the membranes to shorten the duration of labor. The primary objective of the analysis performed by Brown et al.<sup>35</sup> was to determine whether a predefined package of interventions during childbirth such as “active management of labor” reduces the cesarean delivery rate in low-risk women and improves women’s satisfaction. Several of the studies included in our review overlapped with studies included in these three reviews.

## Key Points for Amniotomy

### *Amniotomy versus control treatment*

- Amniotomy decreases the total duration of labor in nulliparous women (moderate SOE) and those with unspecified parity (low SOE).
- There was no difference in the rate of cesarean delivery for early amniotomy versus control in women with unspecified parity (moderate SOE)
- There were no differences in rates of maternal infection, hemorrhage, or trauma to the pelvic floor (moderate SOE) for early amniotomy versus control.

### *Amniotomy plus oxytocin versus control treatment*

- Routine amniotomy plus oxytocin decrease the duration of labor and has a similar effect in both nulliparous and parous women (high SOE).



- Routine amniotomy plus oxytocin do not differ compared to control treatment in cesarean delivery rates in both nulliparous and parous women (high SOE).

## **Detailed Synthesis for Amniotomy**

### **Amniotomy Versus Control Treatment**

Amniotomy is the practice of rupturing the amniotic sac during the course of labor and may be performed for a variety of indications. For the purpose of preventing labor dystocia, amniotomy is performed early in the labor process although the optimal timing is an area of active debate. Across included studies, amniotomy has been compared to various control treatments. The specific control treatment was described across all studies as care according to the obstetric providers' discretion without intentional amniotomy in the absence of other indications (such as direct monitoring of fetal heart rate or intrauterine pressure).

### **Results in Nulliparous Women for Amniotomy**

Five RCTs examined amniotomy versus control treatment in nulliparous women.<sup>113-115,118,120</sup>

### **Duration of Labor and Cesarean Delivery Rates for Amniotomy**

Four studies<sup>113-115,118</sup> demonstrated a statistically significant decrease in the total duration of labor in women randomized to amniotomy (moderate SOE) and one fair-quality trial found that the duration of labor was not statistically different amongst the two groups (Table 14).<sup>120</sup> One fair-quality trial<sup>113</sup> also demonstrated a significantly decreased cesarean delivery rate in women randomized to amniotomy. Another fair-quality trial<sup>120</sup> demonstrated an increase in the number of cesarean deliveries in women randomized to amniotomy. The remaining three studies, showed no significant differences in cesarean delivery rates between groups. The SOE was rated as insufficient given inconsistent and imprecise findings.

**Table 14. Amniotomy versus control in nulliparous women—total duration of labor and cesarean delivery rates**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int (%)	Cesarean: Com (%)	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Abdullah, 2010 <sup>118</sup> Fair	Routine amniotomy N=100	Amniotomy for specific indications N=100	399.6 min ±84.6	456 min ±104.4	<0.001	8 (8%)	10 (10%)	0.62	No	Duration of labor defined as time from enrollment to delivery
Ghafarzadeh, 2015 <sup>113</sup> Fair	Routine amniotomy at <4 cm N=150	Amniotomy for specific indications N=150	450 min ±42	504 min ±60	<0.001	17 (11.3%)	59 (39.3%)	<0.0001 aOR 0.183 (95% CI, 0.099 to 0.338) – adjusted for BMI, age, gestational age, neonatal weight, cervical dilation, cervical effacement	Yes	Duration of labor defined as onset of uterine contractions until 1 hr after expulsion of placenta
Mikki, 2007 <sup>115</sup> Good	Amniotomy shortly after admission N=74	Routine care/ amniotomy if indicated N=83	231 min ±110	291 min ±138	<0.001	–	–	Unadjusted OR 0.52 (95% CI 0.12 to 2.2); p=0.48	No	Duration of labor defined as time from randomization to full dilation
Nachum, 2010 <sup>114</sup> Good	Amniotomy N=21	No intervention N=23	629 min ±338	740 min ±294	0.25	2 (9.5%)	0 (0%)	0.22	–	Duration of labor defined as time from enrollment until delivery
Ruamsap, 2017 <sup>120</sup> Fair	Early amniotomy N=60	Late/ Selective amniotomy N=60	241.5 min (125 to 454)	244.50 min (55 to 768)	0.763	26 (43.3%)	12 (20%)	0.006	No	Duration of labor defined as time from enrollment to delivery

Abbreviations: aOR=adjusted odds ratio; BMI=body mass index; Com=comparator; CI=confidence interval; cm=centimeter; hr=hour; Int=intervention; min=minute; N=number; OR=odds ratio

## Maternal Outcomes After Amniotomy

In two good quality RCTs<sup>114,115</sup> and one fair quality RCT<sup>120</sup>, there was no evidence of increased risk of infection or maternal hemorrhage associated with amniotomy (moderate SOE). In one good quality RCT comparing amniotomy shortly after admission (N=74) to control treatment (N=83), there were no cases of maternal fever in the intervention group, and 1 case (1.2%) of maternal fever in the control group. There was 1 case of postpartum hemorrhage in the intervention group (1.4%) compared to 2 cases in the comparator group (2.4%).<sup>115</sup>

In another good quality RCT, comparing amniotomy (N=21) to unrandomized women whose labor progressed spontaneously without intervention (N=23), there were 3 cases (14%) of intrapartum fever/antibiotic use in the intervention group, as compared with 0 cases (0%) in the control group (p=0.10). There were no cases of postpartum hemorrhage in either group.<sup>114</sup>

One fair quality RCT comparing early amniotomy (N=60) to late amniotomy (N=60), there were no cases of postpartum infection among the two groups.<sup>120</sup>

Three good-quality studies described trauma to the pelvic floor, as outlined in Table 15. There was no evidence of increased risk of pelvic floor trauma in either group (moderate SOE).

**Table 15. Amniotomy versus control in nulliparous women—trauma to the pelvic floor**

Study Quality	Intervention	Comparator	Specific Outcome	Results Intervention (%)	Results Comparator (%)	P Value
Abdullah, 2010 <sup>118</sup> Fair	Amniotomy N=100	Amniotomy for specific indications N=100	Episiotomy	53 (53%)	61 (61%)	0.25
Mikki, 2007 <sup>115</sup> Good	Amniotomy shortly after admission N=74	Routine care/ amniotomy if indicated N=83	Episiotomy	54 (74.0%)	59 (72.0%)	0.78
Mikki, 2007 <sup>115</sup> Good	Amniotomy shortly after admission N=74	Routine care/ amniotomy if indicated N=83	Tears (not further specified)	11 (15.1%)	19 (22.9%)	0.21
Nachum, 2010 <sup>114</sup> Good	Amniotomy N=21	No intervention N=23	Anal sphincter tear	0 (0%)	0 (0%)	NS

Abbreviations: NS=not significant

## Neonatal Outcomes After Amniotomy

In one good quality RCT comparing amniotomy shortly after admission (N=74) to control treatment (N=83),<sup>115</sup> there were no cases of neonatal fever in either group (insufficient SOE). In a fair quality RCT comparing early amniotomy (N=60) to late amniotomy (N=60), there were 2 (3.33%) admission to the ICU for the early amniotomy group and 0 for the late amniotomy group, which was not statistically significant. There were 8 (13.33%) cases of meconium-stained amniotic fluid in the early amniotomy group as compared to 10 (16.67%) in the late amniotomy group, also reported to not be statistically significant.<sup>120</sup>

## Process-Related Outcomes After Amniotomy

In a small good quality RCT, comparing amniotomy (N=21) to control treatment (N=23) maternal satisfaction was reported by patients on a scale of 1-5. Women randomized to

amniotomy reported a lower average maternal satisfaction score ( $4.4 \pm 0.9$ ), compared to control treatment ( $5.0 \pm 0.2$ ) (insufficient SOE).<sup>114</sup>

## **Results in Parous Women for Amniotomy**

Two good-quality RCTs compared amniotomy to control treatment in parous women.<sup>114,115</sup>

### **Duration of Labor and Cesarean Delivery Rates for Amniotomy**

One study demonstrated a decreased total duration of labor in parous women randomized to amniotomy versus control treatment. A second good quality study did not demonstrate this difference (insufficient SOE). There was no difference in cesarean delivery rates between groups in the second study (insufficient SOE).

The first study was a good quality RCT, comparing amniotomy (N=266) to control treatment (N=267) in parous women, there was a significantly decreased total duration of labor in the intervention group ( $133 \pm 71$  minutes) as compared with the comparison group ( $172 \pm 106$  minutes) ( $p < 0.001$ ).<sup>115</sup> Rates of cesarean delivery were not reported for this study.

The second good quality RCT, compared amniotomy (N=49) to unrandomized women whose labor progressed spontaneously without intervention (N=47) in parous women, there was no difference in the total duration of labor in the intervention group ( $352 \pm 320$  minutes) as compared with the comparison group ( $376 \pm 232$  minutes;  $p=0.67$ ). The rate of cesarean was similar in both groups in this study. There were no cesarean deliveries in the intervention group, and 1 cesarean delivery in the intervention group (2%).<sup>114</sup>

### **Maternal Outcomes After Amniotomy**

In two good quality RCTs, there was no evidence of increased risk of infection, maternal hemorrhage or pelvic floor trauma associated with amniotomy as compared with control treatment in parous women (moderate SOE).<sup>114,115</sup>

In one good quality RCT comparing amniotomy shortly after admission (N=266) to control treatment (N=267) in parous women, there was 1 case (0.4%) of maternal fever in the intervention group, and 0 cases (0%) in the control group. There were 2 cases (0.7%) of postpartum hemorrhage in the intervention group and 2 cases (0.7%) in the comparison group. In regards to pelvic floor trauma, there were 8 cases of episiotomy (3.0%) in the intervention group and 14 cases of comparison group (5.3%). Lacerations were reported in 29.0% of women in the intervention group and in 33.7% of women in the comparison group.<sup>115</sup>

In another good quality RCT, comparing amniotomy (N=49) to unrandomized women whose labor progressed spontaneously without intervention (N=47) in parous women, there was 1 case (2%) of maternal fever/antibiotic use in the intervention group, as compared with 0 cases (0%) in the control group. There were no cases of postpartum hemorrhage in either group. Pelvic floor trauma was reported as rates of anal sphincter tear. There were no cases of anal sphincter tear reported in either group.<sup>114</sup>

### **Neonatal Outcomes After Amniotomy**

In one good quality RCT comparing amniotomy shortly after admission (N=266) to control treatment (N=267) in parous women, there were no cases of neonatal fever in the intervention group (0%) and 1 case (0.4%) in the comparison group.<sup>115</sup>

## Process-Related Outcomes After Amniotomy

In a good quality RCT, comparing amniotomy (N=49) to control treatment (N=47) maternal satisfaction was reported by parous women on a scale of 1-5. Parous women randomized to amniotomy reported a similar average score ( $4.9 \pm 0.4$ ) as compared to control treatment ( $5.0 \pm 0.0$ ;  $p=0.087$ ).<sup>114</sup>

## Results in Women of Mixed or Unspecified Parity for Amniotomy

Four good-quality RCTs compared amniotomy to control treatment in women of unspecified<sup>116</sup> or mixed<sup>114,119,121</sup> parity. In addition, we combined nulliparous and parous results (reported separately, without a combined analysis), where possible, for dichotomous outcomes from a third good-quality trial.<sup>115</sup>

## Duration of Labor and Cesarean Delivery Rates for Amniotomy

One RCT reported outcomes for a group of women of unspecified parity.<sup>116</sup> Low-risk women who presented in labor were randomized to amniotomy (n=58) versus control treatment (n=59). In this study, control treatment was defined as monitoring with a partogram until delivery, with labor augmentation if progress was not considered satisfactory. Augmentation consisted of the use of intravenous oxytocin infusion in the control group, and amniotomy was considered after 1 hour or more. Mean total duration of labor ( $\pm$  SD) was significantly shorter in women randomized to amniotomy ( $208.27 \pm 22.52$  minutes) versus control treatment ( $292.07 \pm 23.41$  minutes;  $p<0.05$ ). There was also a statistically significant ( $p<0.05$ ) decrease in the duration of the first stage of labor (randomization to full cervical dilation) in the intervention group (mean  $182.17 \pm$  SD  $19.70$  minutes) versus controls (mean  $265.02 \pm$  SD  $20.40$  minutes). There was no significant difference in the duration of the second stage of labor. There was no significant difference in cesarean delivery rates between the two groups (1.5% in both).

A second RCT<sup>114</sup> examined delivery outcomes in women who were randomized to amniotomy (n=70) as compared to a control group (n=70). In this case, the control group was composed of unrandomized women whose labor progressed spontaneously without intervention. Results were reported for nulliparous and parous women combined and for each of the parity subgroups. For the combined population, there were no significant differences between treatment groups in total duration of labor. Mean total duration of labor ( $\pm$  SD) was  $431 \pm 346$  minutes in women randomized to amniotomy. Mean total duration of labor ( $\pm$  SD) was  $498 \pm 306$  minutes in women randomized to control ( $p=0.23$ ). There was no significant difference in cesarean rate between treatment groups (intervention 2.8%, control 1.4%) (low SOE).

Another RCT<sup>119</sup> compared delivery outcomes of 214 women randomly assigned to receive early amniotomy (n=107) versus a control group whose membranes were conserved (n=107). Women randomized to receive amniotomy received amniotomy at 4-5 cm cervical dilation. The total duration of labor was statistically lower for women randomly assigned to receive early amniotomy ( $279.4 \pm 53.7$  minutes) as compared to the control group ( $354.4 \pm 67.5$  minutes). The duration of labor for nulliparous women was also statistically lower for those women assigned to receive early amniotomy was  $287.1 \pm 66.54$  minutes compared to  $358.6 \pm 60.64$  minutes for women in the control group. The rate of emergency cesarean delivery was not statistically significant among the two group.

The last RCT in this group,<sup>121</sup> reported the outcomes for women randomly assigned to receive amniotomy (N=143) compared to conservative management (N=144), in which patients did not receive amniotomy unless medically indicated. The median duration of labor was reported to be statistically shorter for women who were randomized to receive amniotomy (235

with interquartile range 117-355) compared to conservative management (364 with interquartile range 201-580). The cesarean delivery rate among the two group was not statistically significant.

### **Maternal Outcomes After Amniotomy**

In two good quality RCTs, there was no significant increased risk of infection, maternal hemorrhage, or pelvic floor trauma associated with amniotomy as compared with control treatment in a mixed group (parous and nulliparous) of women.<sup>114,115</sup> SOE was moderate for all three outcomes.

In one good quality RCT comparing amniotomy shortly after admission (N=340) to control treatment (N=350) in nulliparous and parous women, there was 1 case (0.3%) of maternal fever in the intervention group, and 1 case (0.3%) in the control group. There were 3 cases (0.9%) of postpartum hemorrhage in the intervention group and 4 cases (1.1%) in the comparison group. In regards to pelvic floor trauma, there were 62 cases of episiotomy (18.2%) in the intervention group and 72 cases (20.9%) in the comparison group. Lacerations were reported in 25.9% of women in the intervention group and in 31.1% of women in the comparison group.<sup>115</sup>

In another good quality RCT, comparing amniotomy (N=70) to unrandomized women whose labor progressed spontaneously without intervention (N=70) in nulliparous and parous women, there were 3 cases (4%) of intrapartum fever and 1 case (1%) of postpartum fever in the intervention group, as compared with 0 cases of intrapartum or postpartum fever in the control group. There were no cases of postpartum hemorrhage in either group. Pelvic floor trauma was reported as rates of anal sphincter tear. There were no cases of anal sphincter tear reported in either group.<sup>114</sup>

One good quality RCT that compared amniotomy to conservative management recorded one case of cord prolapse (0.7%) in the amniotomy group and zero in the conservative management group. Although not statistically significant, the trial showed an increase number of postpartum hemorrhage, 8 (5.6%), for women in the conservative management group opposed to women who received amniotomy, 4 (2.8%). The occurrence of postpartum fever for women in the conservative management, reported as 7 (4.9%), group was statistically higher than that of women who received amniotomy, which was 1 (0.7%).<sup>121</sup>

### **Neonatal Outcomes After Amniotomy**

In one good quality RCT comparing amniotomy shortly after admission (N=340) to control treatment (N=350) in the composite results of nulliparous and parous women, there were no cases of neonatal fever in the intervention group (0%) and 1 case (0.3%) in the comparison group (low SOE).<sup>115</sup> One study that compared receiving early amniotomy (N=107) to allowing membranes to remain intact (N=107) found no statistical difference for Newborn Special Care Unit admission across the two groups. In addition, the trial found no statistically significant difference between birth weight for the amniotomy group ( $3.2 \pm 0.493$  kg) and the control group ( $3.1 \pm 0.418$  kg).<sup>119</sup>

### **Process-Related Outcomes After Amniotomy**

In a good quality RCT, comparing amniotomy (N=70) to control treatment (N=70), maternal satisfaction was reported by a mixed population (parous and nulliparous) women on a scale of 1-5. Women randomized to amniotomy reported a similar average maternal satisfaction score ( $4.7 \pm 0.6$ ) as compared to control treatment ( $5.0 \pm 0.1$ ).<sup>114</sup>

## Relevant Systematic Reviews/Meta-Analyses for Amniotomy

A single Cochrane good-quality review<sup>123</sup> compared amniotomy alone to control treatment to shorten the duration of labor. The objective of this review was to determine the effectiveness and safety of amniotomy alone for routinely shortening all spontaneous labor. The study included singleton pregnancies regardless of parity or gestation at trial entry in spontaneous labor. This meta-analysis included RCTs comparing amniotomy alone versus intention to preserve the membranes. This review included 15 studies, randomizing a total of 5583 women. One of these 15 studies was also included in our review.<sup>116</sup> The remaining 14 included studies were excluded because of date of publication (prior to January 1, 2005). There was no evidence that amniotomy shortened the duration of labor. There was no reduction in the duration of the first stage of labor (MD -20.43 minutes; 95% CI, -95.93 to 55.06) or increased the risk of cesarean delivery (RR 1.27; 95% CI, 0.99 to 1.63). These findings were also seen in subgroups of nulliparous women only or parous women only. There were no statistically significant differences in risk for other maternal or neonatal adverse outcomes.

## Strength of Evidence for Amniotomy

Tables 16-18 summarize the SOE for the comparison of amniotomy versus control treatment.

**Table 16. Early amniotomy versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	5 RCTs <sup>113-115,118,120</sup> (1,593)  1 SR (379 patients, 4 studies) <sup>123</sup>	<b>Improvement with early amniotomy:</b> All trials demonstrated a decrease in the duration of labor in women randomized to early amniotomy.	Moderate (Medium risk of bias, Inconsistent, Indirect)  SOE was reduced given inconsistency with existing SR which found no difference in less contemporary RCTs
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	5 RCTs <sup>113-115,118,120</sup> (1,593)  1 SR (2,674 patients, 6 studies) <sup>123</sup>	<b>Inconclusive:</b> SOE was insufficient given inconsistent and imprecise findings from studies of varying quality.	Insufficient (Medium risk of bias, Indirect, inconsistent, imprecise)  Existing SR did not resolve inconsistency in findings
Adverse Events	Maternal Outcomes - Infection	3 RCTs <sup>114,115,120</sup> (1,593)	<b>No difference:</b> Two good quality RCTs and one fair-quality RCT support no increased risk of infection	Moderate (imprecise)
	Maternal Outcomes – Trauma to pelvic floor	3 RCTs <sup>114,115,118</sup> (437)	<b>No difference:</b> Three good quality RCTs support no evidence of increased risk of pelvic floor trauma	Moderate (imprecise)
	Neonatal Outcomes - Infection	1 RCT <sup>115</sup> (157)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)
	Neonatal Outcomes – NICU admissions	1 RCT <sup>120</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Neonatal Outcomes – Meconium-stained fluid	1 RCT <sup>120</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)
	Process Related Outcomes – Parental Satisfaction	1 RCT <sup>114</sup> (44)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table 17. Early amniotomy versus control: Evidence profile in women with unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	4 RCTs <sup>114,116,119,121</sup> (912)	<b>Improvement with early amniotomy:</b> Three studies suggest shorter duration of total labor with early amniotomy. One study from the middle east did not find a difference.	Low (Indirect, inconsistent)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>114,116,119,121</sup> (912) 1 SR (874 patients, 3 studies) <sup>123</sup>	<b>No difference:</b> There was no difference in the rate of cesarean delivery between women randomized to early amniotomy versus control.	Moderate (Indirect, consistent)  Existing SR was consistent with RCT findings
Adverse Events	Maternal Outcomes – Infection	2 RCTs <sup>114,115</sup> (973)	<b>No difference:</b> There was no evidence of increased risk of infection associated with early amniotomy versus control.	Moderate (Imprecise)
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>114,115</sup> (973)	<b>No difference:</b> There was no evidence of increased risk of maternal hemorrhage associated with early amniotomy.	Moderate (Imprecise)
	Maternal Outcomes – Trauma to Pelvic Floor	3 RCTs <sup>114,115,118</sup> (683)	<b>No difference:</b> There was no evidence of increased risk of trauma to the pelvic floor associated with early amniotomy.	Moderate (Medium risk of bias)
	Neonatal Outcomes – Infection	1 RCT <sup>115</sup> (690)	<b>No difference:</b> There was no evidence of increased risk of neonatal infection associated with early amniotomy.	Low (1 study)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	3 RCTs <sup>114,116,118</sup> (611)	<b>No difference:</b> There was no evidence of increased risk of operative vaginal delivery associated with early amniotomy.	Low (Indirect, imprecise)
	Process Related Outcomes – Parental Satisfaction	1 RCT <sup>114</sup> (273)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review



**Table 18. Early amniotomy versus control: Evidence profile in parous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>114,115</sup> (973)  1 SR (386 patients, 3 studies) <sup>123</sup>	<b>Inconclusive:</b> SOE was insufficient given conflicting evidence from available studies.	Insufficient (Indirect, inconsistent, imprecise)  Existing SR did not resolve inconsistency
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>114</sup> (533)  1 SR (1,473 patients, 2 studies) <sup>123</sup>	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Indirect, imprecise)  Existing SR did not resolve inconsistency
	Process Related Outcomes – Parental Satisfaction	1 RCT <sup>114</sup> (273)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study	Insufficient (Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Amniotomy Plus Oxytocin Versus Control Treatment

Labor management with amniotomy is often combined with latent use of oxytocin in labor protocols. Two RCTs examined amniotomy plus oxytocin in this context. One of the two studies reported results for nulliparous and parous women combined and for each of the parity subgroups.<sup>114</sup> The other reported results only for nulliparous women.<sup>117</sup>

A good quality RCT<sup>114</sup> examined delivery outcomes in women who were randomized to amniotomy (n=16) as compared to a control group (n=20). In this case, the control group was composed of (unrandomized) women whose labor progressed spontaneously without intervention.

A second RCT<sup>117</sup> compared an active management of labor protocol to control treatment for nulliparous women in spontaneous labor in a low resource setting. Active management was defined as amniotomy within 1 hour of admission, frequent vaginal exams, and routine administration of high dose oxytocin if cervical dilation fell below a rate of 1cm/hour. Control treatment was conventional care at the discretion of the provider. Of note, while patients in the intervention group received oxytocin more frequently than those in the comparison group (p<0.05), 47% of patients in the comparison group received oxytocin.

Two relevant good-quality SRs were identified.<sup>35,122</sup> Wei et al.<sup>122</sup> performed a meta-analysis to estimate the effects of amniotomy plus oxytocin for prevention of, or therapy for, delay in labor progress on the cesarean delivery rate and on indicators of maternal and neonatal morbidity. The SR/MA included 14 trials, randomizing a total of 8033 women. Two of these 14 studies are also included in our review.<sup>114,117</sup> The remaining 12 studies were excluded from our included studies because of date of publication (prior to January 1, 2005). Given the overlap of our two included studies with the SR, and given the high-quality of SR/MA from a trusted source (Cochrane) we considered the findings of this entire SR/MA in the rating of the SOE. The results of SR/MA by Brown et al is summarized in detail in KQ 1.<sup>35</sup>

## **Results in Nulliparous Women for Amniotomy Plus Oxytocin**

### **Duration of Labor and Cesarean Delivery Rates for Amniotomy Plus Oxytocin**

In two good-quality RCTs of nulliparous women, the first stage and total duration of labor was shortened in women randomized to amniotomy plus oxytocin as compared to control treatment.<sup>114,117</sup> These findings were also supported by a good-quality SR discussed below and the combined evidence resulted in a high SOE.

### **Maternal Outcomes After Amniotomy Plus Oxytocin**

Two good quality RCTs reported maternal outcomes including infection, hemorrhage and pelvic floor trauma and identified no increased risk of maternal adverse outcomes in nulliparous women randomized to amniotomy with oxytocin as compared to control treatment. In nulliparous women, amniotomy and oxytocin does not significantly increase the risk of adverse maternal outcomes as compared with control treatment.

In a good quality RCT, comparing amniotomy (N=16) to unrandomized women whose labor progressed spontaneously without intervention (N=23) in nulliparous women, there were no cases of intrapartum, postpartum fever, antibiotic use, postpartum hemorrhage or anal sphincter tear in either group.<sup>114</sup>

Another good quality RCT compared amniotomy and oxytocin protocol (n=320) to control treatment (n=640) for nulliparous women in spontaneous labor in a low resource setting. There were 26 cases (8.1%) of maternal fever in the intervention group, and 53 cases (8.3%) in the comparison group. There were no cases of postpartum hemorrhage in either group.<sup>117</sup>

### **Neonatal Outcomes After Amniotomy Plus Oxytocin**

There was very little information on neonatal adverse outcomes in this subgroup. A good quality RCT, comparing amniotomy and oxytocin protocol (n=320) to control treatment (n=640) for nulliparous women in spontaneous labor in a low resource setting, reported no cases of chorioamnionitis in the intervention group, and 6 cases (0.9%) in the comparison group. The difference was not statistically significant.<sup>117</sup>

### **Process-Related Outcomes After Amniotomy Plus Oxytocin**

In a good quality RCT, comparing amniotomy (N=16) to control treatment (N=23), maternal satisfaction was reported by parous women on a scale of 1-5. Parous women randomized to amniotomy reported a similar average score ( $4.8 \pm 0.5$ ) as compared to control treatment ( $5.0 \pm 0.2$ ;  $p=0.15$ ).<sup>114</sup>

## **Results in Parous Women for Amniotomy Plus Oxytocin**

### **Duration of Labor and Cesarean Delivery Rates for Amniotomy Plus Oxytocin**

One good-quality RCT<sup>114</sup> examined amniotomy and oxytocin (n= 55) versus control treatment (N=47) in parous women. There was a statistically significant decrease in the total duration of labor in the intervention group ( $279 \pm 201$  minutes) compared with the control group ( $376 \pm 232$  minutes;  $p=0.03$ ). There was no significant difference in cesarean delivery rates. The cesarean rate in the intervention group was 0.02% and 0.04% in the comparison group.

### **Maternal Outcomes After Amniotomy Plus Oxytocin**

One good-quality RCT<sup>114</sup> examined amniotomy and oxytocin (n= 55) versus control treatment (N=47) in parous women. There were no cases of intrapartum fever, postpartum fever or antibiotic use in either group. There were 3 cases (6%) of postpartum hemorrhage in the intervention group, there were no cases in the comparison group (p=0.25). There were no cases of anal sphincter tear in either group.

### **Neonatal Outcomes After Amniotomy Plus Oxytocin**

No data was available on neonatal adverse outcomes for parous women in spontaneous labor randomized to amniotomy and oxytocin as compared with control treatment.

### **Process-Related Outcomes After Amniotomy Plus Oxytocin**

In a good quality RCT, comparing amniotomy (N=55) to control treatment (N=47), maternal satisfaction was reported by parous women on a scale of 1-5. Parous women randomized to amniotomy reported a similar average score ( $4.9 \pm 0.5$ ) as compared to control treatment ( $5.0 \pm 0.0$ ; p=0.14).<sup>114</sup>

### **Results in Women of Mixed or Unspecified Parity for Amniotomy Plus Oxytocin**

A single study reported results for amniotomy plus oxytocin versus control treatment in women of mixed parity.<sup>114</sup>

### **Duration of Labor and Cesarean Delivery Rates for Amniotomy Plus Oxytocin**

In one good-quality RCT examining women of mixed parity,<sup>114</sup> there was a statistically significant difference in the total duration of labor for women randomized to amniotomy plus oxytocin (n= 71; 312 +/- 245 minute) as compared with control treatment (n= 70; 498 +/- 306 minutes; p<0.001). There was no difference in cesarean delivery rates between the two treatment groups (1% in both groups).<sup>114</sup>

### **Maternal Outcomes After Amniotomy Plus Oxytocin**

One good-quality RCT examined the risks of adverse maternal outcomes in women of mixed parity randomized to amniotomy plus oxytocin (N=71) compared to control (N=70). There was no increased risk of adverse maternal outcomes in either group. There were no cases of intrapartum fever, postpartum fever, or antibiotic use in this subgroup. There were 3 cases of postpartum hemorrhage (4%) in the intervention group as compared to 0 cases in the comparison group. This difference was not statistically significant. There were no cases of anal sphincter injury in either group.<sup>114</sup>

### **Neonatal Outcomes After Amniotomy Plus Oxytocin**

No data were available on neonatal adverse outcomes for women of mixed parity in spontaneous labor randomized to amniotomy and oxytocin as compared with control treatment.

### **Process-Related Outcomes After Amniotomy Plus Oxytocin**

In a good quality RCT, comparing amniotomy (N=71) to control treatment (N=70), maternal satisfaction was reported by parous women on a scale of 1-5. Parous women randomized to amniotomy reported a similar average score ( $4.9 \pm 0.5$ ) as compared to control treatment ( $5.0 \pm 0.1$ ; p=.10)<sup>114</sup>

## Relevant Systematic Reviews/Meta-Analyses for Amniotomy Plus Oxytocin

Wei et al.<sup>122</sup> performed a meta-analysis to estimate the effects of amniotomy plus oxytocin for prevention of, or therapy for, delay in labor progress on the cesarean delivery rate and on indicators of maternal and neonatal morbidity. The SR/MA included 14 trials, randomizing a total of 8033 women. Two of these 14 studies represent the two included studies in our review.<sup>114,117</sup> The remaining 12 included studies were excluded from our report because of date of publication (prior to January 1, 2005). Again, given the quality of the SR/MA and alignment with our interventions of interest, we incorporated the findings in to our SOE ratings. Studies included unselected pregnant women in spontaneous labor and pregnant women in spontaneous labor with a delay in the first stage of labor. The length of first stage of labor was shortened in the amniotomy plus oxytocin group compared with the expectant management group (mean difference [MD] -1.57 hours; 95% CI, -2.14 to -1.01). Amniotomy plus oxytocin was also associated with a reduction in the total duration of labor (MD -1.28 hours; 95% CI, -1.97 to -0.59). The cesarean delivery rate was reduced in 11 trials looking at prevention of dystocia (11 trials, 7653 women, average RR 0.87; 95% CI, 0.77 to 0.99). In women who were randomized to amniotomy plus oxytocin, the time from admission to giving birth was reduced (MD 1.3 hours; 95% CI, -1.97 to -0.59).

## Strength of Evidence for Amniotomy Plus Oxytocin

Tables 19-21 summarize the SOE for the comparison of amniotomy plus oxytocin versus control treatment. In general, the SOE was judged as moderate or high based on existing SR/MAs.

**Table 19. Amniotomy plus oxytocin versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>35,122</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the duration of the first stage of labor.	High
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>35</sup> (2,737 patients, 5 studies)	<b>No difference:</b> There was no difference in the duration of second stage of labor between groups.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>35,122</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> The duration of labor was shortened in women randomized to amniotomy plus oxytocin as compared to routine care.	High
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>35,122</sup> (7,653 patients, 11 studies)	<b>No difference:</b> There was no difference in cesarean delivery rates between amniotomy plus oxytocin compared with control.	High

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: SOE=strength of evidence; SR=systematic review

**Table 20. Amniotomy plus oxytocin versus control: Evidence profile in women with unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>35,122</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the duration of the first stage of labor.	High
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>35</sup> (2,737 patients, 5 studies)	<b>No difference:</b> There was no difference in the duration of the second stage of labor in the amniotomy plus oxytocin group as compared with control.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>35,122</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Amniotomy plus oxytocin decreased the total duration of labor.	High
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>35,122</sup> (7,653 patients, 11 studies)	<b>No difference:</b> There was no difference in cesarean delivery rates between amniotomy plus oxytocin compared with control.	High
Adverse Events	Maternal Outcomes – Infection	3 RCTs <sup>115</sup> (1,933) 2 SRs <sup>35,122,123</sup> (3,475 patients, 6 studies)	<b>No difference:</b> There was no difference in risk of infection between groups.	High  Findings from existing SR consistent with RCT evidence
	Maternal Outcomes – Hemorrhage	2 SRs <sup>35,122,123</sup> (2,674 patients, 4 studies)	<b>No difference:</b> No difference in risk of hemorrhage between groups.	High
	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>114</sup> (283)	<b>No difference:</b> One RCT examined active management of labor with early amniotomy and oxytocin as compared with routine care, there was no difference in risk of trauma to the pelvic floor between groups.	Low (1 study)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	1 SR <sup>122,123</sup> (5,738 patients, 9 studies)	<b>No difference:</b> There was no difference in risk of operative vaginal delivery between groups.	High
	Process Related Outcomes – Parental Preferences	2 SRs <sup>35,122,123</sup> (2,436 patients, 2 studies)	<b>No difference:</b> No difference between the two groups in scores of maternal/parental satisfaction.	Moderate (Imprecise, varying metrics)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table 21. Amniotomy plus oxytocin versus control: Evidence profile in parous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 SRs <sup>35,122</sup> (2,431 patients, 4 studies)	<b>Improvement with amniotomy:</b> Amniotomy decreased the duration of the first stage of labor compared with control	Moderate (Imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>35</sup> (2,737 patients, 5 studies)	<b>No difference:</b> No difference in the duration of second stage of labor between groups.	Moderate (Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 SRs <sup>35,122</sup> (4,675 patients, 7 studies)	<b>Improvement with amniotomy plus oxytocin:</b> Modest decrease in duration of labor in the intervention group as compared with controls.	Moderate (Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 SRs <sup>35,122</sup> (7,653 patients, 11 studies)	<b>No difference:</b> No difference in the rate of cesarean delivery between groups.	Moderate (Imprecise)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: SOE=strength of evidence; SR=systematic review

## Key Question 3. Supportive Care

KQ 3 was: What are the benefits and harms of supportive care measures, including emotional support, ambulation, nutrition, and hydration, during spontaneous labor?

## Description of Included Studies

We identified 64 articles<sup>70,71,80-83,124-181</sup> representing 61 individual RCTs that examined the benefits and harms of supportive care measures in women during spontaneous labor. Supportive care measures included interventions such as continuous emotional support, perineal massage, water birth, acupuncture, ambulation and positioning strategies.

Of the 61 included studies, 25 were conducted in the Middle East,<sup>70,82,125-127,133,136-138,140,143,147,148,151,155-157,162,164-166,174,175,178,179</sup> 15 were conducted in Asia,<sup>124,129,135,139,141,150,153,158,159,161,163,167,170,176,181</sup> 7 were conducted in the United States,<sup>130,142,144,145,149,154,171</sup> 4 were conducted in Latin America,<sup>131,146,152,172</sup> 8 were conducted in UK/Europe,<sup>80,128,134,168,169,173,177,180</sup> one was conducted in Australia/NZ,<sup>160</sup> and one was conducted in Canada.<sup>132</sup> All but three studies<sup>129,131,172</sup> were conducted in a hospital setting. These three studies were conducted in birthing centers. Eleven studies reported government funding,<sup>82,124,130,141,145,149,152,172,173,176,181</sup> 21 reported nongovernment, nonindustry funding,<sup>70,126,127,132,133,136,138,140,142,151,153,155-158,161,163,164,167,171,172</sup> and two reported a mixture of funding from government and non-government sources.<sup>128,177</sup> Twenty seven studies were unclear or did not report the funding source.<sup>80,125,129,131,134,135,137,139,143,144,146-148,150,154,159,160,162,165,166,168-170,174,175,178,180</sup> Finally, of the 60 included studies, 23 were rated as good quality,<sup>80,131,132,135,139,141,142,144-146,148,149,151-153,160,163,165-167,171-173</sup> 31 as fair quality,<sup>82,124,125,128-130,133,134,136,137,140,143,147,154-158,162,164,168-170,174-181</sup> and 7 as poor quality.<sup>70,126,127,138,150,159,161</sup>

In addition to the above studies, 14 SRs that addressed the benefits and harms of supportive care measures are also discussed below. Four were rated as fair quality,<sup>182-185</sup> while 10 reviews were rated as good quality.<sup>34,36,38,45,48,50,52,54,186,187</sup>

## Key Points for Supportive Care

- Supportive care measures during labor encompass a wide variety of interventions and within individual categories of interventions, there is considerable heterogeneity in the nature and timing of the interventions.
- Although supportive care therapies are often seen as increasing parental satisfaction with the birthing process, these outcomes were only assessed in five of the included RCTs with sparse evidence. An earlier SR of 11 studies however did find that women receiving continuous emotional support were less likely to rate their birth experience negatively (moderate SOE).
- Two studies addressing continuous emotional support included in the present review did not show a benefit in reducing 1<sup>st</sup> or 2<sup>nd</sup> stage labor duration, although prior SR/MAs of 12 studies (including these two studies) indicated a benefit for total labor duration (moderate SOE).
- Emotional support interventions reduced cesarean deliveries (low SOE for doula support, moderate SOE for continuous emotional support) and instrumental deliveries (moderate SOE).
- There was no difference in rates of cesarean deliveries for women receiving perineal compresses or massage (low SOE), but severe perineal trauma was reduced in nulliparous women (low SOE).
- There was no difference in duration of labor in women using water birth (low SOE)
- Women undergoing acupuncture/acupoint nerve stimulator did not experience differences in labor duration or rates of maternal hemorrhage (low SOE for both outcomes).
- Ambulation was associated with shorter duration of labor (low SOE).
- No differences were found in duration of labor (low SOE) or cesarean delivery rates (moderate SOE) for women using differing positioning interventions. Women in kneeling position were more likely than women in sitting position to have reduced trauma to the pelvic floor (low SOE).
- Administration of intravenous fluids compared with oral intake alone demonstrated a reduction in the duration of labor (low SOE), while not increasing cesarean delivery rates (moderate SOE), maternal hemorrhage (low SOE), or operative vaginal delivery rates (moderate SOE).

## Detailed Synthesis for Supportive Care

The supportive care interventions as compared with control treatment were:

- Continuous emotional support
- Perineal compresses or massage
- Massage during labor
- Water birth
- Acupressure
- Acupuncture
- Aromatherapy
- *Anethum graveolens* seeds
- Ambulation and positioning strategies
- Specific nutritional intervention and oral or parenteral hydration intervention recommendations or limitations
- Transcutaneous electrical nerve stimulation (TENS)
- Oral bicarbonate
- Hyoscine or hot shower
- Assessment and support during early labor

Below we detail each of these comparisons in terms of the included studies, outcomes assessed, and strength of evidence. Within each comparison we discuss findings in nulliparous women, in parous women, and then in women of mixed or unspecified parity.

### Continuous Emotional Support Versus Control Treatment

Results for this intervention were reported for nulliparous women in three studies<sup>145,152,163</sup> and for a mixed population of women in two studies (three articles).<sup>70,71,180</sup> Three relevant good-quality SR/MAs were identified.<sup>52,54,187</sup>

### Results in Nulliparous Women

Three studies<sup>145,152,163</sup> examined the effects of continuous emotional support during labor provided by either a doula<sup>145</sup> or a relative or companion of the patient's choosing.<sup>152,163</sup> All three studies were good quality.<sup>145,152,163</sup>

### Duration of Labor and Cesarean Delivery Rates for Continuous Emotional Support

No significant difference in duration of labor was reported in the two primary studies reporting on this outcome.<sup>152,163</sup> The duration of first-stage labor was nonsignificantly shorter in the companion arm [(3.4 vs. 3.8 hours,  $p=0.123$ )<sup>152</sup> and (4.48 vs. 5.02 hours,  $p=0.09$ )<sup>163</sup>] The duration of second-stage labor was non-significantly longer in the companion arm in both studies [(18 vs. 16.2 minutes,  $p=0.368$ );<sup>152</sup> (58 vs. 50.1 minutes,  $p=0.26$ )<sup>163</sup>]. These findings were also included in the SR discussed below and based on that larger set of studies we found a moderate strength of evidence that there was an overall reduction in duration of labor for women receiving emotional support.

Cesarean deliveries were reported significantly less often in the doula arm in one study (13.4% vs. 25.0%,  $p=0.002$ ),<sup>145</sup> whereas a similar proportion of cesarean deliveries was reported in both treatment arms in another study (10.5% in the continuous support arm vs. 11.2% in the



control arm, RR 0.93, 95% CI 0.43 to 2.02).<sup>152</sup> Based on these findings in combination with the SR evidence discussed below we rated the SOE as low for a reduction in cesarean deliveries with doula support.

### **Neonatal Outcomes for Continuous Emotional Support**

No significant difference was reported for altered fetal heart rate in one study (RR 1.18, 95% CI 0.84 to 1.66) (low SOE).<sup>152</sup>

## **Results in Women of Mixed or Unspecified Parity**

### **Duration of Labor and Cesarean Delivery Rates for Continuous Emotional Support**

One poor-quality study reported in two separate articles,<sup>70,71</sup> and one fair-quality study<sup>180</sup> evaluated duration of labor. One study evaluated the duration of labor in a mixed population of 150 nulliparous and parous women receiving continuous emotional support from a doula or receiving usual care. The duration of labor in the doula group was significantly shorter than the control group for first-stage labor (157 vs. 281 minutes,  $p < 0.001$ ) and second-stage labor (58.9 vs. 128.4 minutes,  $p < 0.001$ ).<sup>70</sup> The second study of 63 primiparous or parous women reported shorter duration of labor in the group of women receiving continuous support from a midwifery student than the women receiving usual care (8.0 hours vs 12.7 hours,  $p < 0.001$ ).<sup>180</sup> Given the small sizes and the poor/fair quality of the studies, the evidence was rated as insufficient for all outcomes assessed.

### **Relevant Systematic Reviews/Meta-Analyses for Continuous Emotional Support**

We identified two good-quality SR/MAs that addressed either doula support<sup>52</sup> or continuous emotional support<sup>54</sup> during labor. Doula support compared with standard care was associated with a significantly reduced risk of cesarean delivery (OR 0.68, 95% CI 0.47 to 0.99) based on 2008 women across 5 studies (low SOE) and reduced risk of instrumental vaginal delivery (OR 0.54, 95% CI 0.35 to 0.92) based on 1587 women across 4 studies (moderate SOE).<sup>52</sup> One study included in the present review was included in this SR.<sup>145</sup>

Continuous emotional support was associated with a shorter total duration of labor (mean difference -0.58 hours, 95% CI -0.85 to -0.31) based on 5366 women across 12 studies (moderate SOE).<sup>54</sup> It also was associated with a lower risk of cesarean delivery (RR 0.78, 95% CI 0.67 to 0.91) based on 15,175 women across 22 studies (moderate SOE), a lower risk on instrumental vaginal delivery (RR 0.90, 95% CI 0.85 to 0.96) based on 14,118 women across 19 studies (moderate SOE), and a higher risk of spontaneous vaginal delivery (RR 1.08 95% CI 1.04 to 1.12) based on 14,119 women across 19 studies.<sup>54</sup> Women receiving continuous emotional support were also less likely to rate their birth experience negatively (RR 0.69, 95% CI 0.59 to 0.79), based on 11,133 women across 11 studies (moderate SOE).<sup>54</sup> No significant differences were observed for trauma to the pelvic floor or neonatal admission to special care nursery.<sup>54</sup>

An update of the 2013 systematic review of continuous emotional support<sup>54</sup> was published in 2017.<sup>187</sup> Continuous emotional support was associated with a shorter duration of labor (mean difference -0.69 hour, 95% CI -1.04 to -0.34) based on 5,429 women across 13 studies. It also was associated with a lower risk of cesarean delivery (RR 0.75, 95% CI 0.64 to 0.88) based on 15347 women across 24 studies, a lower risk of instrumental vaginal birth (RR 0.90, 95% CI

0.85 to 0.96) based on 14,118 women across 19 studies, and a higher likelihood of spontaneous vaginal birth (RR 1.08, 95% CI 1.04 to 1.12) based on 14,369 women across 21 studies.

Five of the studies included in the present review were included in the SR/MAs of continuous emotional support.<sup>70,145,152,163,180</sup>

## Strength of Evidence for Continuous Emotional Support

Tables 22 and 23 summarize the SOE for the above outcomes in nulliparous and mixed parity women.

**Table 22. Continuous emotional support versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>152,163</sup> (326)	<b>No difference:</b> Good-quality studies of nulliparous women found that continuous emotional support did not reduce duration of 1 <sup>st</sup> stage labor.	Moderate (Indirect)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	2 RCTs <sup>152,163</sup> (326)	<b>No difference:</b> Good-quality studies of nulliparous women found that continuous emotional support did not reduce duration of 2 <sup>nd</sup> stage labor.	Moderate (Indirect)
	Process Related Outcomes – Duration of Total Labor	1 SR <sup>54</sup> (5,366 patients, 12 studies)	<b>Improvement with continuous emotional support:</b> Systematic review of 12 studies found shorter total duration of labor	Moderate (Indirect)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>145,152</sup> (599)  Doula support: 1 SR <sup>52,54</sup> (2,008 patients, 5 studies)  Continuous emotional support: 1 SR <sup>54</sup> (5,366 patients, 12 studies)	<b>Improvement with Doula support:</b> Doula support reduced cesarean deliveries as compared to control therapy.  <b>Improvement with continuous emotional support:</b> Continuous emotional support lowered risk of cesarean delivery (RR 0.78, 95% CI 0.67 to 0.91) based on SR of 22 studies.	Low – Doula (Indirect)  Inconsistency between SRs and included RCTs  Moderate – Continuous Emotional Support (Indirect)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	Doula support: 1 SR <sup>52,54</sup> (1,587 patients, 4 studies)  Continuous emotional support: 1 SR <sup>54</sup> (14,118 patients, 19 studies)	<b>Improvement with Doula support:</b> Doula support reduced risk of instrumental vaginal delivery  <b>Improvement with continuous emotional support:</b> Continuous emotional support lowered risk of instrumental vaginal delivery based on SR of 19 studies.	Moderate (Indirect)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Process Related Outcomes – Abnormal Fetal Heart Tracing	1 RCTs <sup>152</sup> (212)	<b>No difference:</b> Supportive care was not associated with significant differences in fetal heart tracings.	Low (Indirect, imprecise, 1 study)
	Process Related Outcomes – Parental Preferences	1 SR <sup>54</sup> (11,133 patients, 11 studies)	<b>Improvement with continuous emotional support:</b> SR of 11 studies found women receiving continuous emotional support less likely to rate their birth experience negatively	Moderate

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; hr=hours; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

**Table 23. Continuous emotional support versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>70</sup> (150)	<b>Inconclusive:</b> SOE was insufficient given 1 small study with high risk of bias.	Insufficient (High risk of bias, Indirect, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>70</sup> (150)	<b>Inconclusive:</b> SOE was insufficient given 1 small study with high risk of bias.	Insufficient (High risk of bias, Indirect, imprecise)
	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>70,180</sup> (213)	<b>Inconclusive:</b> SOE was insufficient given two small studies with high risk of bias	Insufficient (High risk of bias, Indirect, imprecise)
	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>70</sup> (150)	<b>Inconclusive:</b> SOE was insufficient given 1 small study with high risk of bias.	Insufficient (High risk of bias, Indirect, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence

## Perineal Compresses or Massage Versus Control Treatment

Results for this intervention were reported for nulliparous women in two studies (one good quality)<sup>160</sup> and one fair quality<sup>156</sup>) and for a mixed population of women in one good-quality study.<sup>149</sup> No relevant SR/MAs were identified.

## Results in Nulliparous Women

Two studies, assessed the effects of perineal compresses or massage on labor outcomes, including duration of labor, cesarean delivery rate, and incidence of perineal trauma. The interventions were warm compresses applied to the perineum during second-stage labor<sup>160</sup> or cold compresses applied to the body during first-stage labor and to the perineum during second-stage labor.<sup>156</sup>

## **Duration of Labor and Cesarean Delivery Rates for Perineal Compresses or Massage**

Warm compresses or perineal massage showed no statistically significant difference in duration of second-stage labor (82.09 vs. 86.64 minutes,  $p=0.35$ ),<sup>160</sup> whereas a statistically significant shortening of both first-stage (190.44 vs. 273.91 minutes,  $p<0.001$ ) and second-stage (32.12 vs. 41.15 minutes) labor was reported with cold compresses.<sup>156</sup> Given the inconsistent findings for second-stage labor and to small number of patients in the fair-quality study for first-stage labor, both these outcomes were rated as insufficient SOE. The proportion of cesarean deliveries was not significantly different for women who had warm compresses applied to the perineum (12/360 in the intervention group vs. 8/357 in the control group,  $p=0.64$ ) (low SOE).

## **Maternal Outcomes for Perineal Compresses or Massage**

Severe perineal trauma (third- and fourth-degree perineal laceration) was reported in one study, with a significantly lower incidence in the intervention group (4.2% vs. 8.7%, OR 2.16, 95% CI 1.15 to 4.10).<sup>160</sup> A significantly lower rate of urinary incontinence at 3 months in the intervention care group was also reported (9.7% vs. 22.4,  $p=0.0001$ ).<sup>160</sup> Strength of evidence was rated as low for both outcomes.

## **Results in Women of Mixed or Unspecified Parity**

One good-quality study compared compresses applied to the perineum versus perineal massage versus control treatment in a population comprised of nulliparous and parous women.<sup>149</sup>

## **Duration of Labor and Cesarean Delivery Rates for Perineal Compresses or Massage**

The duration of second-stage labor was not statistically significantly different between the intervention groups (41 minutes for warm compresses, 33 minutes for perineal massage, and 36 minutes for control treatment).<sup>149</sup> Spontaneous vaginal delivery occurred in 96.0% of the warm compress group, 99.3% of the perineal massage group, and 98.5% of the control group.<sup>149</sup> The SOE was rated as low for both outcomes.

## **Maternal Outcomes for Perineal Compresses or Massage**

Third- or fourth-degree perineal trauma was reported for 0.7% of the warm compress group, 1.3% of the perineal massage group, and 1.5% of the control group ( $p$  value not reported) (low SOE).<sup>149</sup>

## **Relevant Systematic Reviews/Meta-Analyses for Perineal Massage**

We identified one fair-quality systematic review that examined perineal trauma and mode of delivery comparing women who had perineal massage to usual care.<sup>184</sup> One study described above<sup>149</sup> was included in the meta-analysis. Severe perineal trauma (third or fourth degree lacerations) was reported for nulliparous women in three studies with a total of 340 women and for parous women in two studies with a total of 2,147 women. The relative risk for nulliparous women was 0.09 (95% CI 0.01-1.62) based on no events in the perineal massage group (0/170) vs. 5 events among 170 women in the control group. The reported relative risk for the parous women was 1.06 (95% CI 0.59-1.92), however this appears to be an error. The reported number of controls in the total column ( $N=2036$ ) does not equal the total of the individual studies ( $N=1036$ ). Based on data from the two individual studies, the event rate for the controls should

be 30/1036 (2.9%) not 30/2036 (1.5%) as reported in the meta-analysis. The event rate in the women receiving perineal massage was 17/1111 (1.5%). Conclusions about parous women cannot be made due to the apparent erroneous data. Mode of delivery was not significantly different between women who had perineal massage versus usual care.

## Strength of Evidence for Perineal Compresses or Massage

Tables 24 and 25 summarize the SOE for the above studies. In general the SOE was rated as low given evidence from only one study.

**Table 24. Perineal compresses or massage versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>156</sup> (64)	<b>Inconclusive:</b> SOE was rated as insufficient given findings from 1 small study with medium risk of bias.	Insufficient (Medium risk of bias, indirect, 1 small study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>156,160</sup> (781)	<b>Inconclusive:</b> SOE was rated as insufficient given inconsistent findings from 2 studies with medium risk of bias.	Insufficient (Medium risk of bias, Inconsistent, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>160</sup> (717)	<b>No difference:</b> No significant differences in the proportion of cesarean deliveries was reported for the massage/compress group.	Low (Indirect, 1 study)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>160</sup> (717)	<b>Improvement with massage/compress:</b> Severe perineal trauma (third- and fourth-degree perineal laceration) was lower incidence for the massage/compress group.	Low (1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; OR=odds ratio; RCT=randomized controlled trial; SOE=strength of evidence

**Table 25. Perineal compresses or massage versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>149</sup> (1,211)	<b>No difference:</b> Duration of 2nd stage labor was not statistically significantly different between the intervention and usual care groups.	Low (Indirect, 1 study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>149</sup> (1,211)	<b>No difference:</b> No significant differences in the proportion of cesarean deliveries was reported for the massage/compress group.	Low (Indirect, 1 study)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>149</sup> (1,211)	<b>No difference:</b> No significant differences in perineal trauma were reported between the intervention and control groups.	Low (1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Massage During Labor Versus Control Treatment

Results for massage during labor versus control treatment were reported for nulliparous women in three studies.<sup>131,132,138</sup> and in women of mixed parity in one study.<sup>166</sup> No relevant SR/MAs were identified.

### Results in Nulliparous Women

Three studies, two good quality<sup>131,132</sup> and one poor quality,<sup>138</sup> evaluated the effects of massage during labor. The duration and timing of the intervention varied between studies ranging from 30 minutes of massage<sup>131</sup> up to 5 hours of massage.<sup>132</sup>

### Duration of Labor and Cesarean Delivery Rates for Massage During Labor

Duration of labor (first- or second-stage or total duration) was not significantly different between the massage and control groups in the two good-quality studies (Table 26).<sup>131,132</sup> The poor-quality study reported that the active phase of labor was 3.1 hours shorter in the massage group ( $p<0.001$ ).<sup>138</sup> Based on these findings the SOE was rated as insufficient for the duration of 1<sup>st</sup> stage labor and for 2<sup>nd</sup> stage but low for the total duration of labor.

Additionally, the proportion of cesarean deliveries was not significantly different between the massage groups and control groups in the two studies reporting this outcome (low SOE).

**Table 26. Effects of massage during labor versus control treatment**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value
Silva Gallo, 2013 <sup>131</sup> Good	Massage (30 min) adjunct to usual care N=23	Usual care N=23	Total duration 6.8 hr (1.6)	Total duration 5.7 hr (1.5)	Mean difference (95% CI) 1.1 (0.2 to 2.0)	6/23	4/23	RR 1.5, 95% CI 0.5 to 4.6
Janssen, 2012 <sup>132</sup> Good	Massage (up to 5 hr) adjunct to usual care N=37	Usual care N=40	1 <sup>st</sup> stage 897.4 min (507.4) 2 <sup>nd</sup> stage 136.0 min (89.6)	1 <sup>st</sup> stage 788.6 min (336.8) 2 <sup>nd</sup> stage 125.0 min (81.7)	0.28  0.36	9/37	7/40	0.71
Mortazavi, 2012 <sup>138</sup> Poor	Massage (30 min x 3) adjunct to usual care N=40	Usual care N=40	Active phase 2.6 hr (0.95)	Active phase 5.7 hr (1.89)	<0.001	–	–	–

Abbreviations: CI=confidence interval; Com=comparator; hr=hours; Int=intervention; min=minutes; RR=relative risk

### Results in Women of Mixed Parity

One good quality study<sup>166</sup> of 100 women of mixed parity evaluated the effect of at least 30 minutes of massage on duration of labor and type of delivery. Women receiving massage had statistically significantly shorter first stage labor (8.96 vs. 11.46 hours,  $p<0.0001$ ) and second stage labor (49.29 vs 64.14 minutes,  $p=0.0003$ ). There were fewer cesarean deliveries in the massage group than the control group (1/50 vs. 3/50) but the differences were not statistically significant.

## Strength of Evidence for Massage During Labor

Tables 27 and 28 summarize the SOE for the effects of massage during labor.

**Table 27. Massage during labor versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>132,138</sup> (197)	<b>Inconclusive:</b> SOE was insufficient given inconsistent and imprecise findings from 2 studies.	Insufficient (Medium risk of bias, indirect, Inconsistent, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>132</sup> (77)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)
	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>131,132</sup> (123)	<b>No difference:</b> Total duration of labor was not significantly different in the massage group compared to usual care.	Low (Indirect, Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>131,132</sup> (123)	<b>No difference:</b> The proportion of cesarean deliveries was not significantly different between the massage group and control group.	Low (Indirect, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table 28. Massage during labor versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>166</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>166</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>166</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Water Immersion Versus Control Treatment

Two studies reported outcomes for women laboring in a warm bath.<sup>143,179</sup> In one study, the women were immersed in water during active labor until cervical dilation reached (4cm to 10cm) and then had usual care for delivery,<sup>179</sup> and in the other, the women were immersed in water during both labor and delivery.<sup>143</sup> Results for this intervention were reported for nulliparous women in one study<sup>179</sup> and in women of mixed parity in the other study.<sup>143</sup> One relevant good-quality SR/meta-analysis was also identified.<sup>48</sup>

## Results in Nulliparous Women

One RCT of fair quality assessed labor outcomes among 90 women who were immersed in water during active labor (4 cm to 10 cm dilation) and then received usual care for delivery compared to 90 women who received usual care throughout labor and delivery.<sup>179</sup> First-stage active labor was significantly longer in the intervention group than the usual care group (232.95 vs. 165.81 minutes,  $p<.001$ ). There was no difference in the duration of second stage labor (48.40 vs. 48.00 minutes,  $p=0.631$ ). There also was no difference in mode of delivery, with cesarean sections in 2.2% of the intervention group and 3.3% of the usual care group ( $p=.902$ ). Satisfaction with birth was significantly higher in the intervention group than the control group (8.85 vs. 5.08 on a 10-point scale,  $p<0.001$ ).

## Results in Women of Mixed or Unspecified Parity

One RCT of fair quality assessed labor outcomes among 106 women giving birth in a warm water bath compared with conventional deliveries.<sup>143</sup> First-stage active labor was significantly shorter in the water birth group (114.4 vs. 186 minutes,  $p=0.004$ ), whereas no difference was observed in duration of second-stage labor (20.9 vs. 20.6 minutes,  $p=0.9$ ). All water births were vaginal deliveries compared with 79.2% in the conventional group.

## Relevant Systematic Reviews/Meta-Analyses for Water Birth

We identified one good-quality SR/meta-analysis that addressed the effects of immersion in water on labor outcomes.<sup>48</sup> Analyses that were restricted to women in spontaneous labor included 1 to 3 studies, with 60 to 291 women included in different analyses. No statistically significant differences were observed in length of first- or second-stage labor, cesarean deliveries, hemorrhage, perineal trauma, neonatal ICU admission, or neonatal sepsis. Based on one study within that meta analysis, women who gave birth in water immersion were less likely to report being dissatisfied with their birth experience (RR 0.24, 95% CI 0.07 to 0.80). One study included in the present review was also included in the SR/meta-analysis.<sup>143</sup> A 2018 update of this systematic review stated that they were not able to perform planned sub-group analyses of spontaneous versus induced labor due to lack of data relating to sub-groups.<sup>188</sup>

Given the findings of this sole fair-quality RCT and the combined evidence from the SR we rated the SOE for total duration of labor as low for no difference between water birth and control and insufficient for the outcome of cesarean delivery for women of mixed parity.

## Strength of Evidence for Water Birth

Tables 29 and 30 summarize the SOE for water birth compared to control therapy.

**Table 29. Water birth versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Total Duration of Labor	1 RCT <sup>179</sup> (90)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>179</sup> (90)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Indirect, Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review



**Table 30. Water birth versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>143</sup> (106)  1 SR <sup>48</sup> (291 patients, 2 studies)	<b>No difference:</b> No difference in duration of 2 <sup>nd</sup> stage labor was reported.	Low (Medium risk of bias, indirect, imprecise)  SOE was increased to low given findings from SR which also demonstrated no difference between water birth versus control
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>143</sup> (106)	<b>Inconclusive:</b> SOE was rated as insufficient given imprecise findings in 1 study with potential risk of bias.	Insufficient (Medium risk of bias, Indirect, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Acupressure Versus Control Treatment

Results for this intervention were reported for nulliparous women in two studies<sup>151,162</sup> and for women of unspecified parity in two studies.<sup>70,137</sup> One study was judged to be good quality,<sup>151</sup> two fair quality,<sup>137,162</sup> and one poor quality.<sup>70</sup> No relevant SR/MAs were identified.

## Results in Nulliparous Women

### Duration of Labor and Cesarean Delivery Rates for Acupressure

One good-quality<sup>151</sup> and one fair-quality<sup>162</sup> study assessed duration of labor in nulliparous women. Each measure of duration of labor was significantly shorter for the acupressure group compared with the control group: active phase (4.2 vs. 7.4 hours,  $p=0.0001$ ),<sup>151</sup> total first-stage (6.02 vs. 9.45 hours,  $p=0.002$ ),<sup>162</sup> and second-stage (23.42 vs. 34.89 minutes,  $p=0.04$ ).<sup>162</sup> Given the small size of the studies, the imprecision in the findings, and the potential risk of bias the strength of evidence for all duration of labor outcomes was rated as insufficient. One good-quality study reported a smaller proportion of cesarean deliveries in the acupressure group compared with the control group (6/60 vs. 25/60,  $p=0.0001$ ) (insufficient SOE).<sup>151</sup>

## Results in Women of Mixed or Unspecified Parity

### Duration of Labor and Cesarean Delivery Rates for Acupressure

One fair-quality<sup>137</sup> and one poor-quality<sup>70</sup> study assessed duration of labor in mixed populations of nulliparous and parous women. Each study reported a statistically significantly shorter duration of first-stage labor (161.7 vs. 281.0 minutes,  $p<0.0001$ )<sup>70</sup> and 146.4 vs. 185.4 minutes,  $p<0.001$ <sup>137</sup> and second-stage labor (56.1 vs. 128.4 minutes,  $p<0.0001$ )<sup>70</sup> and 20.51 vs. 28.5 min,  $p=0.038$ .<sup>137</sup> The lower quality of these included studies and the imprecision of the findings resulted in a insufficient strength of evidence rating for these outcomes.

In the fair-quality study, women in the acupressure group were significantly more satisfied with the birth process than those in the control group (5.76 [0.63] vs. 5.36 [1.08], respectively) (insufficient SOE).<sup>137</sup>

## Strength of Evidence for Acupressure

Tables 31 and 32 summarize the SOE for available outcomes within this comparison. Although findings were consistent between studies, the SOE was rated as insufficient for all outcomes given the small number of patients, the potential risk of bias, and the imprecision of the findings.

**Table 31. Acupressure versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>162</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and only one study	Insufficient (Medium risk of bias, indirect, imprecise, 1 study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>162</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and only one study.	Insufficient (Medium risk of bias, indirect, Imprecise, 1 study)
	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>151,162</sup> (220)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and small study size	Insufficient (Medium risk of bias, indirect, Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>151</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from only one study	Insufficient (Indirect, Imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table 32. Acupressure versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>70,137</sup> (250)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and small studies	Insufficient (High risk of bias, indirect, Imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	2 RCTs <sup>70,137</sup> (250)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and small studies	Insufficient (High risk of bias, indirect, Imprecise)
	Process Related Outcomes – Duration of Total Labor	2 RCTs <sup>70,137</sup> (250)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias, imprecise findings, and small studies	Insufficient (High risk of bias, indirect, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Acupuncture Versus Control Treatment

Seven studies reported on the effects of acupuncture<sup>125,126,128,141,176,181</sup> or acupoint nerve stimulator<sup>124</sup> on labor outcomes. Results were reported for nulliparous women in four studies<sup>125,128,176,181</sup> and for women of mixed parity in three studies.<sup>124,126,141</sup> One study was good quality,<sup>141</sup> four were fair quality,<sup>124,125,128,176,181</sup> and one was poor quality.<sup>126</sup> Comparisons included sham acupuncture<sup>125,141</sup>, no analgesia or available standard of care.<sup>124,126,128,141</sup> and no

analgesia or combined spinal-epidural anesthesia.<sup>176</sup> One study compared both acupuncture and electroacupuncture with control treatment.<sup>128</sup> another compared electroacupuncture to sham acupuncture and control treatment<sup>141</sup> and another compared combined spinal epidural anesthesia with patient-controlled epidural anesthesia with and without electroacupuncture.<sup>181</sup> One relevant good-quality SR/meta-analysis was identified.<sup>45</sup>

## **Results in Nulliparous Women**

### **Duration of Labor and Cesarean Delivery Rates for Acupuncture**

Results were not consistent across studies or within one study in regard to the duration of labor. The acupuncture group had a significantly shorter duration of first-stage labor when compared with sham acupuncture (130 vs. 250 minutes,  $p=0.001$ ) but no difference in second-stage labor (36 vs. 35 minutes,  $p=0.739$ ) in one study.<sup>125</sup> A second study found no significant difference in total duration of labor between the acupuncture and control group (619 vs. 615 minutes, hazard ratio 1.03, 95% 0.75 to 1.41), but a significantly shorter duration of labor in the electroacupuncture group (500 vs. 615 minutes, HR 1.44, 95% 1.06 to 1.97).<sup>128</sup> The third study found no significant difference in duration of active stage labor between the acupuncture and control groups (3.0 vs. 3.3 hours,  $p>0.05$ ), both of which were significantly shorter than the combined spinal-epidural anesthesia group (4.5 hours,  $p<0.05$ ).<sup>176</sup> There were no significant differences between the acupuncture, control and combined spinal-epidural analgesia in the duration of 2<sup>nd</sup> stage (0.9 hour, 0.8 hour, 0.9 hour, respectively,  $p>0.05$ ) or 3<sup>rd</sup> stage (0.2 hour, 0.2 hour, 0.2 hour,  $p>0.05$ ) labor. The fourth study found a statistically significantly shorter duration of first stage labor and third stage labor in the epidural anesthesia plus electroacupuncture group compared to the epidural alone group (260.00 vs 362.50 minutes,  $p=0.00$  for first stage, 6.00 vs 8.00 minutes,  $p=0.02$  for third stage), but no difference in second stage labor (81.50 vs. 92.50 minutes,  $p=0.90$ ).<sup>181</sup> Given the inconsistency of findings and variability in interventions, the SOE was rated as insufficient for the duration of first stage and total duration of labor. The consistency of findings for second stage resulted in a low SOE rating for no difference.

The proportion of cesarean deliveries was smaller, but not significantly different for the acupuncture (8.4%, OR 0.64, 95% CI 0.23 to 1.79) or electroacupuncture (5.7%, OR 0.41, 95% CI 0.14 to 1.26) groups compared with the control group (13.3%).<sup>128</sup> Cesarean deliveries were also lower but not significantly different in the epidural anesthesia plus electroacupuncture group versus epidural anesthesia alone (1.64% versus 9.1%,  $p=0.07$ ).<sup>181</sup> In the other study, the cesarean delivery rates were lowered in the intervention groups as compared to control therapy.<sup>124</sup> Given the inconsistency in findings the SOE was rated as insufficient.

### **Maternal Outcomes for Acupuncture**

Perineal trauma (third or fourth degree laceration) was not significantly different in the acupuncture group (5.3%, OR 1.19, 95% CI 0.28 to 5.16) or electroacupuncture group (4.9%, OR 0.92, 95% CI 0.21 to 3.92) compared with the control group (5.6%) (insufficient SOE).<sup>128</sup>

## **Results in Women of Mixed or Unspecified Parity**

### **Duration of Labor and Cesarean Delivery Rates for Acupuncture**

One study reported a significantly shorter duration of active-phase labor<sup>126</sup> in the acupuncture group, whereas the other two studies found no significant differences in duration of the first-stage, the second-stage, or total duration of labor when comparing the acupuncture group with the control group or with a sham acupuncture group (insufficient SOE for first stage labor, low SOE for no difference in second stage labor duration).<sup>124,141</sup> In one fair-quality study, acupuncture was associated with a significant reduction in cesarean deliveries (1/30 vs. 8/30,  $p<0.05$ ) (insufficient SOE).<sup>124</sup> Table 33 shows results for these studies.

### **Maternal Outcomes for Acupuncture**

Postpartum hemorrhage was not significantly different between the acupuncture and control groups, with one study reporting severe hemorrhage in 8.0% of the control group and 4.0% of the acupuncture group ( $p=0.537$ ),<sup>126</sup> and another study stating no significant differences in postpartum hemorrhage without reporting specific data.<sup>141</sup>

**Table 33. Effects of acupuncture versus control treatment**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value
Allameh, 2015 <sup>126</sup> Poor	Acupuncture adjunct to usual care N=27	Usual care N=28	Active phase 175.8 min	Active phase 243.77 min	Mean difference <0.001	2/27	3/28	0.67
Liu, 2015 <sup>124</sup> Fair	Acupuncture N=30	No analgesic intervention/expectant management N=30	1 <sup>st</sup> stage 430.1 min (119.8)	1 <sup>st</sup> stage 439.6 min (200.3)	0.82	1/30	8/30	0.011
	Acupuncture N=30	No analgesic intervention/expectant management N=30	2 <sup>nd</sup> stage 43.3 min (17.5)	2 <sup>nd</sup> stage 46.3 min (20.6)	0.54	–	–	–
Ma, 2011 <sup>141</sup> Good	Electro-acupuncture adjunct to usual care N=92	Usual care N=100	1 <sup>st</sup> stage latent 219.60 min (130.19)	1 <sup>st</sup> stage latent 244.20 min (164.76)	0.25	–	–	–
	Sham acupuncture adjunct to usual care N=94	Usual care N=100	1 <sup>st</sup> stage latent 246.60 min (161.54)	1 <sup>st</sup> stage latent 244.20 min (164.76)	0.92	–	–	–
	Electro-acupuncture adjunct to usual care N=92	Usual care N=100	1 <sup>st</sup> stage active 186.05 min (99.66)	1 <sup>st</sup> stage active 161.03 min (87.23)	0.06	–	–	–
	Sham acupuncture adjunct to usual care N=94	Usual care N=100	1 <sup>st</sup> stage active 196.76 min (100.91)	1 <sup>st</sup> stage active 161.03 min (87.23)	0.009	–	–	–

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value
	Electro-acupuncture adjunct to usual care N=92	Usual care N=100	2 <sup>nd</sup> stage 30.65 min (19.40)	2 <sup>nd</sup> stage 31.92 min (19.99)	0.66	–	–	–
	Sham acupuncture adjunct to usual care N=94	Usual care N=100	2 <sup>nd</sup> stage 30.02 min (19.39)	2 <sup>nd</sup> stage 31.92 min (19.99)	0.50	–	–	–
	Electro-acupuncture adjunct to usual care N=116	Usual care N=100	Total duration 443.44 min (176.88)	Total duration 444.21 min (193.34)	0.97	–	–	–
	Sham acupuncture adjunct to usual care N=117	Usual care N=100	Total duration 480.85 min (206.80)	Total duration 444.21 min (193.34)	0.16	–	–	–
Xiao, 2019 <sup>181</sup>  Fair	CSEA plus patient-controlled epidural anesthesia plus electro-acupuncture N=60	CSEA plus patient-controlled epidural anesthesia N=60	1 <sup>st</sup> stage (3-10 cm) 260.00 min (236.25)	1 <sup>st</sup> stage (3-10 cm) 362.50 min (355.00)	0.00	1/60	6/60	0.07
	CSEA plus patient-controlled epidural anesthesia plus electro-acupuncture N=60	CSEA plus patient-controlled epidural anesthesia N=60	2 <sup>nd</sup> stage 81.50 min (127.50)	2 <sup>nd</sup> stage 92.50 min (81.00)	0.90	–	–	–

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value
	CSEA plus patient-controlled epidural anesthesia plus electro-acupuncture N=60	CSEA plus patient-controlled epidural anesthesia N=60	3rd stage 6.00 min (3.75)	2 <sup>nd</sup> stage 8.00 min (4.75)	0.02	—	—	—

Abbreviations: —=not reported; Com=comparator; CSEA= combined spinal-epidural anesthesia; Int=intervention; min=minute

## Relevant Systematic Reviews/Meta-Analyses for Acupuncture

We identified one good-quality SR/MA that examined the effects of acupuncture on labor outcomes.<sup>45</sup> Analyses that were restricted to women in spontaneous labor included 1 to 3 studies, with 128 to 448 women in the various analyses of mode of delivery. No statistically significant differences were observed in the proportion of cesarean deliveries, assisted vaginal births, or spontaneous vaginal births. None of these studies were included in our review given their publication date. They also did not analyze findings by parity.

## Strength of Evidence for Acupuncture

Tables 34 and 35 summarize the SOE for acupuncture/acupoint nerve stimulator versus control therapy. In general, the SOE was rated as insufficient given inconsistent findings from studies with variability in interventions.

**Table 34. Acupuncture/acupoint nerve stimulator versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	6 RCTs <sup>124-126,141,176,181</sup> (775)	<b>Inconclusive:</b> given inconsistency in findings, variability in interventions, and potential risk of bias within the studies.	Insufficient (High risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	4 RCTs <sup>124,141,176,181</sup> (601)	<b>No difference:</b> in 2 <sup>nd</sup> stage labor between the acupuncture and control groups was reported.	Low (Medium risk of bias, indirect, imprecise)
	Process Related Outcomes – Duration of Total Labor	3 RCTs <sup>125,128,141</sup> (602)	<b>Inconclusive:</b> SOE was insufficient given inconsistency in findings, variability in interventions, and potential risk of bias within the studies.	Insufficient (Medium risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>124,128,181</sup> (493)	<b>Inconclusive:</b> SOE was insufficient given inconsistency in findings, variability in interventions, and potential risk of bias within the studies.	Insufficient (Medium risk of bias, indirect, inconsistent, imprecise)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>128</sup> (253)	<b>Inconclusive:</b> SOE was rated as insufficient given findings from 1 study with medium risk of bias.	Insufficient (Medium risk of bias, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table 35. Acupuncture/acupoint nerve stimulator versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	4 RCTs <sup>124-126,141</sup> (524)	<b>Inconclusive:</b> Results were inconsistent as to the effects of manual or electroacupuncture with a shorter duration reported in some but not all studies	Insufficient (Medium risk of bias, indirect, inconsistent, imprecise)



Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	2 RCTs <sup>124,141</sup> (350)	<b>No difference:</b> No significant difference in 2 <sup>nd</sup> stage labor between the acupuncture and control groups was reported.	Low (Medium risk of bias, indirect, imprecise)
	Process Related Outcomes – Duration of Total Labor	3 RCTs <sup>125,128,141</sup> (602)	<b>Inconclusive:</b> Results were inconsistent as to the effects of manual or electroacupuncture on total duration labor, with a shorter duration reported in only 1 study. SOE was rated as insufficient.	Insufficient (Medium risk of bias, indirect, Inconsistent, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>124,128</sup> (373)	<b>Inconclusive:</b> SOE was rated as insufficient given findings from 1 study with medium risk of bias.	Insufficient (Medium risk of bias, indirect, imprecise)
Adverse Events	Maternal Outcomes – Hemorrhage	1 RCT <sup>128</sup> (253)	<b>No difference:</b> No significant difference in hemorrhage was reported for the intervention group compared to the control.	Low (High risk of bias, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Aromatherapy Versus Control Treatment

Aromatherapy was compared to control therapy for nulliparous women in four studies, two good quality,<sup>165,167</sup> one fair quality<sup>157</sup> and one poor quality.<sup>127</sup> No relevant SR/MAs were identified.

## Results in Nulliparous Women

### Duration of Labor and Cesarean Delivery Rates for Aromatherapy

Four studies addressed duration of first stage labor<sup>127,157,165,167</sup> and three addressed duration of second stage labor.<sup>157,165,167</sup> Aromatherapy was not associated with a significantly shorter first-stage labor in three of the studies (Table 36).<sup>157,165,167</sup> In the fourth study, salvia aromatherapy was associated with a significantly shorter duration of first-stage labor ( $p=0.001$ ) whereas there was no significant difference between jasmine aromatherapy and placebo. No significant differences in second stage labor were reported in two studies,<sup>165,167</sup> whereas the third study reported a significantly shorter second stage labor with salvia aromatherapy than either jasmine aromatherapy or placebo.<sup>157</sup>

No significant difference in the proportion of cesarean deliveries was reported in two studies.<sup>127,167</sup>

In the fair-quality study, women were more “content” (51.2%) compared with those in the control group (23.8%) ( $p<0.001$ ) (insufficient SOE).<sup>157</sup>

**Table 36. Effects of aromatherapy versus control treatment**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value
Kaviani, 2014 <sup>127</sup> Poor	Aromatherapy (Salvia) N=46	Aromatherapy (Jasmine) N=48	1st stage labor 460.3 min (65.5)	1st stage labor 493.6 min (59.8)	0.001 (salvia vs other groups)	6/52 (11.5%)	4/52 (7.7%)	0.6
	Aromatherapy (Salvia) N=46	Placebo (distilled water) N=45	1st stage labor 460.3 min (65.5)	1st stage labor 509.3 min (60.1)	0.4 (jasmine vs placebo)	6/52 (11.5%)	7/52 (13.5%)	0.6
	Aromatherapy (Salvia) N=46	Aromatherapy (Jasmine) N=48	2nd stage labor 44.3 min (7.6)	2nd stage labor 46 min (7.2)	0.003 (salvia vs other groups)	–	–	–
	Aromatherapy (Salvia) N=46	Placebo (distilled water) N=45	2nd stage labor 44.3 min (7.6)	2nd stage labor 49.83 min (8.6)	–	–	–	–
Kaviani, 2014 <sup>157</sup> Fair	Aromatherapy (lavender) N=80	Placebo (distilled water) N=80	1 <sup>st</sup> stage labor 3.6 hrs (1.39)	1 <sup>st</sup> stage labor 3.9 hrs (0.5)	NS	–	–	–
Tanvisut, 2018 <sup>167</sup> Good	Aromatherapy (Jasmine, geranium rose, citrus or lavender) N=52	Usual care N=52	1 <sup>st</sup> stage labor 775.6 min (334.9)	1 <sup>st</sup> stage labor 669.7min (463.7)	0.205	–	–	–
	Aromatherapy (Jasmine, geranium rose, citrus or lavender) N=52	Usual care N=52	2 <sup>nd</sup> stage labor 30.2 min (28.1)	2 <sup>nd</sup> stage labor 23.6 min (20.4)	0.201	4/52 (7.7%)	6/52 (11.5%)	0.506
Yazdkhasti, 2016 <sup>165</sup> Good	Lavender essence N=60	Placebo (distilled water) N=59	1 <sup>st</sup> stage active 170.2 min (91.08)	1 <sup>st</sup> stage active 181.5 min (93.6)	0.5	–	–	–
	Lavender essence N=60	Placebo (distilled water) N=59	2 <sup>nd</sup> stage 59.4 min (34.4)	2 <sup>nd</sup> stage 48.66 min (23.5)	0.6	–	–	–

Abbreviations: –=not reported; Int=intervention; Com=comparator; NS=not significant

## Strength of Evidence for Aromatherapy

Table 37 summarizes the SOE for outcomes comparing aromatherapy and control treatment. Given the potential risk of bias, small study size, and inconsistent findings, the SOE was rated as insufficient for all outcomes.

**Table 37. Aromatherapy versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	4 RCTs <sup>127,157,165,167</sup> (522)	<b>Inconclusive:</b> SOE was rated as insufficient given inconsistent findings among studies with potential risk of bias.	Insufficient (High risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	3 RCTs <sup>127,165,167</sup> (362)	<b>Inconclusive:</b> SOE was rated as insufficient given inconsistent findings among types of aromatherapy from 1 study with high potential risk of bias.	Insufficient (High risk of bias, indirect, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>127,167</sup> (260)	<b>Inconclusive:</b> SOE was rated as insufficient findings from 1 study with high potential risk of bias.	Insufficient (High risk of bias, indirect, imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## *Anethum Graveolens* (Dill) Seeds Versus Control Treatment

Results for this intervention were reported for nulliparous and parous women in one study.<sup>155</sup> No relevant SR/MAs were identified.

### Results in Nulliparous Women

One fair-quality RCT evaluated the effect of consumption of a boiled extract of *Anethum graveolens* L. (dill) seeds at the start of active-phase labor on duration of labor.<sup>155</sup> Statistically significantly shorter durations of labor were reported for the intervention group for both first-stage (192.01 vs. 397.71 minutes,  $p=0.001$ ) and second-stage labor (23.10 vs. 39 minutes,  $p=0.001$ ). Given that the findings are from one small fair-quality study the SOE was rated as insufficient.

### Results in Parous Women

The same fair-quality study<sup>155</sup> reported outcomes for parous women. Duration of first-stage labor was statistically significantly shorter in the intervention group (145 vs. 279.69 minutes,  $p=0.001$ ), whereas differences for second-stage labor were not significant (12.50 vs. 16.56 minutes,  $p=0.12$ ). Again given that the findings are from one small fair-quality study the SOE was rated as insufficient.

## Strength of Evidence for *Anethum Graveolens* (Dill) Seeds

Tables 38 and 39 summarize the SOE for dill seeds versus control treatment.

**Table 38. *Anethum graveolens* seeds versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>155</sup> (103)	<b>Inconclusive:</b> SOE was rated as insufficient given imprecise findings from 1 small study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, imprecise, 1 study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>155</sup> (103)	<b>Inconclusive:</b> SOE was rated as insufficient given imprecise findings from 1 small study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

**Table 39. *Anethum graveolens* seeds versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>155</sup> (103)	<b>Inconclusive:</b> SOE was rated as insufficient given imprecise findings from 1 small study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, imprecise, 1 study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>155</sup> (103)	<b>Inconclusive:</b> SOE was rated as insufficient given imprecise findings from 1 small study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Ambulation and Positioning Strategies Versus Control Treatment

Sixteen studies examined the effects of ambulation and positioning strategies during labor on labor outcomes.<sup>80,129,134,140,146,147,150,153,154,158,159,161,164,169,170,172</sup> Four of these studies were rated as good-quality<sup>80,146,153,172</sup> and nine studies were rated as fair quality.<sup>129,134,140,147,154,158,164,169,170</sup>

Three studies were judged to be of poor quality<sup>150,159,161</sup> due to unclear and inconsistent reporting, discrepant participant numbers, and poor control group/usual care definitions.

Results were reported for nulliparous women in 12 studies.<sup>80,129,134,140,146,150,153,158,159,161,164,172</sup> Table 40 shows results for these studies.

Results were reported for a mixed population of women in four studies.<sup>147,154,169,170</sup> Two relevant good-quality SR/MAs were identified.<sup>34,50</sup>

## Results in Nulliparous Women

One good-quality study<sup>153</sup> and one poor-quality study<sup>150</sup> examined the effects of ambulation (moving, swaying, rocking, etc.) compared with being confined to bed. Ten studies examined positioning using various methods: angle of the head of the birthing bed,<sup>129</sup> birth seat,<sup>134</sup> birth ball,<sup>140,164</sup> peanut ball,<sup>159</sup> upright position,<sup>146,173</sup> kneeling position,<sup>80</sup> squatting position<sup>168</sup> and the Prince of Songkla University (PSU) birthing bed.<sup>158,161</sup> One study compared a combination of strategies used in sequence – birth ball, lumbosacral massage and warm shower- to usual care.<sup>172</sup>

## Duration of Labor and Cesarean Delivery Rates for Ambulation and Positioning Strategies

Ambulation during first-stage labor was associated with significant reduction in labor duration compared with confinement to bed in two studies ( $p<.05$ <sup>153</sup>;  $p<.001$ <sup>150</sup>) (low SOE).

Studies investigating upright laboring positions demonstrated heterogeneity in both interventions and comparators, and reported outcomes were mixed. Statistically significantly shorter second stage labor in the intervention group was reported in two studies,<sup>159,168</sup> statistically significantly longer duration in two studies<sup>80,173</sup> and no significant difference in one study.<sup>146</sup> One study comparing a semi-sitting (head of bed at 45 degrees) position to a supine position found significant differences in duration of second-stage labor ( $p<.05$ ).<sup>129</sup> Using a birth seat, which may help maintain an upright position, was found to significantly reduce duration of second-stage labor ( $p<.001$ ) compared with all other positions in one study.<sup>134</sup> By comparison, two studies compared use of a birth ball, which may also help maintain an upright position, with reclining in bed and/or heat therapy and did not find significant differences in duration of active-phase labor.<sup>140,164</sup> A study that evaluated a combination of interventions (birth ball, massage and warm shower) reported a significantly shorter second stage labor in the intervention group than the control group, but no significant difference in total duration of labor.<sup>172</sup> The strength of evidence was rated as low for duration of the first stage of labor given the potential risk of bias in two studies and the heterogeneity in interventions. Given the inconsistency in findings the SOE was rated as insufficient for the duration of second stage labor.

Two studies investigated lying positions using a bed with several optional adjustments (PSU bed; head and foot of bed angles, lumbar support, leg placement, etc.).<sup>158,161</sup> One study found statistically significant lower duration of second-stage labor in the intervention group compared with lying with the head of the bed at 45, 60, and 15 degrees,<sup>158</sup> and the other found significant differences between groups using the PSU bed and those in traditional beds.<sup>161</sup> SOE was rated as insufficient for all interventions other than ambulation during the first stage of labor.

Of the twelve studies with nulliparous participants, six reported cesarean delivery outcomes.<sup>80,134,150,168,172,173</sup> Four studies found lower numbers of cesarean deliveries in intervention groups,<sup>80,134,150,172</sup> though only one poor quality study showed a statistically significant difference ( $p<0.01$ ).<sup>150</sup> One study reported the same number of cesarean deliveries in the intervention and control groups<sup>168</sup> and one reported non-significantly higher rates of cesarean deliveries in the control group.<sup>173</sup> Given the potential high risk of bias, the SOE was rated as insufficient for ambulation. The SOE was rated as moderate for positioning given the consistent findings of the included studies and the support of the meta analysis discussed below.

### **Maternal Outcomes for Ambulation and Positioning Strategies**

Two good-quality studies reported maternal outcomes.<sup>80,173</sup> In one study a kneeling position was associated with non-significant reductions in pelvic floor trauma (vaginal laceration, sphincter rupture, third- and fourth-degree perineal tears).<sup>80</sup> In a second study, no significant difference in perineal tear severity or postpartum hemorrhage was found between upright vs. lying down position during second stage labor.<sup>173</sup> (low SOE).

### **Neonatal Outcomes for Ambulation and Positioning Strategies**

Two good quality<sup>172,173</sup> and two poor-quality studies<sup>150,159</sup> reported neonatal outcomes. In one good-quality study, metabolic acidosis (cord artery pH<7.05) in the upright position group was less frequent but not significantly different than the control group (6/1556 vs. 17/1537, RR 0.35, 95% CI 0.10 to 1.18). The other good quality study reported non-significant differences in shoulder dystocia (0/40 in the intervention group and 1/40 in the usual care group).<sup>172</sup> Abnormal fetal heart rate tracing data were reported without significance values in two studies.<sup>150,159</sup> The study using a movement intervention found 0.9 percent of the experimental group and 1.9 percent of the control group experienced abnormal fetal heart rate (FHR) tracing,<sup>150</sup> and a study

investigating a supported sitting versus supine position showed 7 of 100 individuals in the experimental group with abnormal FHR tracing compared to 13 of 100 individuals in the control group.<sup>159</sup> Given the potential risk of bias in these studies, the SOE was rated as insufficient.

### **Process-Related Outcomes for Ambulation and Positioning Strategies**

One good quality<sup>172</sup> and two poor-quality studies<sup>150,159</sup> reported on parental preferences.<sup>150,159</sup> In the good quality study, satisfaction with the overall labor experience was higher in the combination intervention group than the usual care group (3.6 vs. 2.0 on a 4-point scale, difference 1.6, 95% CI 1.2 to 2.0), as was satisfaction with duration of labor and pain severity during labor, while satisfaction with the quality of care received was not significantly different between the groups. In one of the poor-quality studies,<sup>150</sup> in the intervention group, 23.6 percent of mothers rated their satisfaction level as “moderate” while 76.4 percent rated it as “high.” In the control group, 11.4 percent rated satisfaction as “low,” 26.7 percent as “moderate,” and 61.9 percent as “high” ( $p < 0.01$ ). In comparing a supported sitting position with a supine position, 93 percent of those women in the sitting (experimental) group expressed a higher preference for assigned position for next childbirth, compared with 61 percent of women in the supine position.<sup>150</sup> 92 percent of women in the supported sitting position agreed that the assigned position was more comfortable for giving birth, compared with 54 percent in the supine group. In the second poor-quality study,<sup>159</sup> 93 percent of women stated a higher preference of the supporting sitting position for their next childbirth, compared with 61 percent in the supine position. Given the high risk of bias in these two studies the SOE was rated as insufficient.

**Table 40. Effects of ambulation versus control treatment**

Study Quality	Int	Com	Duration of Labor: Int	Duran of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Epidural and Position Trial Collaborative Group, 2017 <sup>173</sup> Good	Any upright position during 2 <sup>nd</sup> stage labor N=1556	Lying down position during 2 <sup>nd</sup> stage labor N=1537	Median duration of 2 <sup>nd</sup> stage labor 149 minutes (IQR 100 to 197)	Median duration of 2 <sup>nd</sup> stage labor 141 minutes (IQR 95 to 188)	0.01	158/1556 (10.2%)	127/1537 (8.3%)	RR 1.23 (95% CI 0.92-1.64)	Shorter 2 <sup>nd</sup> stage labor and lower cesarean rate in control group	–
Gallo, 2018 <sup>172</sup> Fair	Birth ball for 40 min, then massage for 40 min, then warm shower for 40 min N=40	Usual care N=40	Total duration of labor 373 min (154)  2 <sup>nd</sup> stage labor 19 min (12)	Total duration of labor 445 min (189)  2 <sup>nd</sup> stage labor 37 min (35)	-72 (-148 to 5)  -18 (-30 to -5)	5/40 (13%)	10/40 (25%)	RR 0.50 (95% CI 0.19-1.33)	–	–
Ganapathy, 2012 <sup>159</sup> Poor	HOB elevated to 60° in 2 <sup>nd</sup> stage of labor (N=100)	Flat supine (N=100)	2 <sup>nd</sup> stage: 56 min	67 min	<0.05	Only “instrumental deliveries” reported	–	–	–	–
Miquelutti, 2007 <sup>146</sup> Good	Information and encouragement for upright position during 1 <sup>st</sup> stage	Free to move as desired (usual care) N=53	1 <sup>st</sup> stage: Median=390 min (NR) n=35  2 <sup>nd</sup> stage: 29.5 min	Median=325 min (NR) n=42  36 min	0.59  0.76	NR: only “normal delivery” reported	–	–	–	“Normal” delivery RR: Intervention 0.85 (0.63 to 1.14)

Study Quality	Int	Com	Duration of Labor: Int	Duran of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Moraloglu, 2017 <sup>168</sup> Fair	Squatting position during 2 <sup>nd</sup> stage labor (N=50)	Supine at 45 degree during 2 <sup>nd</sup> stage labor (N=50)	2 <sup>nd</sup> stage labor 21.02 min (5.60)  3 <sup>rd</sup> stage labor 6.18 min (1.77)	2 <sup>nd</sup> stage labor 55.40 min (6.91)  3 <sup>rd</sup> stage labor 5.92 min (1.60)	<0.001  NS	1/51 (2%)	1/51 (2%)	NS	–	–
Phumdoung, 2007 <sup>161</sup> Poor	PSU Cat position (alternate with high head) (N=40)	PSU Cat (alternate with supine) (N=40)	Time in active phase: 212.38 min (114.54)	289.88 min (106.68)	<0.001 (between-group differences)	–	–	–	–	Music therapy group removed for N; 1 cesarean delivery in entire group (arm NR)
	PSU Cat position (alternate with high head) (N=40)	High head position (N=41)	Time in active phase: 212.38 min (114.54)	208.29 min (82.10)	<0.001 (between-group differences)	–	–	–	–	–
	PSU Cat position (alternate with high head) (N=40)	Supine position (N=43)	Time in active phase: 212.38 min (114.54)	379.74 min (126.59)	<0.001 (between-group differences)	–	–	–	–	Supine group had longer labor duration than all other groups (significance NR)
Prabhakar, 2015 <sup>153</sup> Good	Ambulation for 1-1.5 hr with rest periods (N=30)	Confined to bed most of the time (N=30)	Duration: 575.27 min (79.33)	617.20 min (62.3)	0.027	Only “normal” vs. “abnormal” reported	–	–	–	–



Study Quality	Int	Com	Duration of Labor: Int	Duran of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Ragnar, 2006 <sup>80</sup> Good	Kneeling position, leaning toward HOB (N=138)	Sitting position, HOB at 60° (N=133)	2 <sup>nd</sup> stage= 48.5 min (27.6)  Total labor duration= 9.4 hr (5.8)	41 min (23.4)  9.1 hr (4.6)	0.017  0.64	0	2	0.15	Yes; significance NR	–
Santhi, 2012 <sup>129</sup> Fair	Semi-sitting position: HOB at 45° during 2 <sup>nd</sup> stage labor  N= 25	Supine position  N=25	Mean duration of 2 <sup>nd</sup> stage: 33 min (SD NR)	59 min (SD NR)	<.05	–	–	–	–	–
Sasitorn, 2013 <sup>158</sup> Fair	PSU birthing bed without the holding bar (N=60)	PSU birthing bed with the holding bar (N=60) Usual birthing bed with HOB at 45-60° (N=60) Usual birthing bed with HOB at 15° (N=60)	2 <sup>nd</sup> stage: 17.63 min (9.70)	16.58 min (8.47)  24.18 min (14.20)  31.63 min (14.22)	<0.001	–	–	–	–	Both PSU groups had significantly lower duration of 2 <sup>nd</sup> stage
Taavoni, 2011 <sup>140</sup> Fair	Birth ball/Peanut ball  N=NR (Total N enrolled= 62)	Reclining on bed	Active phase: 1.78 hr (0.58) (N=NR)	1.67 hr (0.98) (N=NR)	0.605	–	–	–	Unknown	–
Taavoni, 2016 <sup>164</sup> Fair	Birth ball for 30 min during active labor (N=30)	Heat applied to sacral and perineal area for 30 min during active labor (N=30)	1 <sup>st</sup> stage active labor 1.78 hr (0.58)	1 <sup>st</sup> stage active labor 1.95 hr (0.01)	0.562	–	–	–	–	–

Study Quality	Int	Com	Duration of Labor: Int	Duran of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
	Birth ball for 30 min during active labor (N=30)	Usual care (N=30)	1 <sup>st</sup> stage active labor 1.78 hr (0.58)	1 <sup>st</sup> stage active labor 1.67 hr (0.98)	0.562	–	–	–	–	–
Thies-Lagergren, 2013 <sup>134</sup>  Fair	Birth seat (N=500)	Mother's choice of birth position (including birth seat) (N=502)	1 <sup>st</sup> stage=444 min (236)  2 <sup>nd</sup> stage=38 min (25)  3 <sup>rd</sup> stage=14 min (15)	455 min (228)  44 min (27)  13 min (15)	0.494  0.001  0.620	n=23 4.6%	n=29 5.8%	0.39	Shorter 2 <sup>nd</sup> stage in intervention group consistent with lower cesarean delivery rate	–
Vaijayanthimala, 2014 <sup>150</sup>  Poor	Movement during labor (walking, rocking, swaying on a birthball, etc.) discussed/ encouraged (N=106)	Control (movement during labor not discussed) (N=105)	< 12hr: 53 (50%)  12-14hr: 21 (19.8%)  >14hr: 32(30.2%)	24 (22.9%)  29 (27.6%)  52 (49.5%)	0.001	14 (13.3%)	21 (21.1%)	<0.01	Yes	–

Abbreviations: Com=comparator; HOB=head of bed; Int=intervention; min=minutes; NR=not reported; NS=not significant; RR=relative risk; SD=standard deviation

## **Results in Women of Mixed or Unspecified Parity**

Three fair-quality studies examined the effects of ambulation and positioning in populations of unclear parity.<sup>147,154,170</sup> One compared a squatting position with a supine position in second-stage labor<sup>147</sup>, another compared a hands-and-knees position with a supine position in second-stage labor<sup>170</sup> and the third compared use of a peanut ball after an epidural to a control group.<sup>154</sup>

## **Duration of Labor and Cesarean Delivery Rates for Ambulation and Positioning Strategies**

Two studies found statistically significant reductions in duration of labor. Women using a squatting position experienced shorter second-stage labor ( $p < 0.05$ ),<sup>147</sup> while women using a peanut ball had reductions in duration of first and second stages of labor ( $p = 0.006$  and  $p < 0.001$ , respectively).<sup>154</sup> The third study reported significantly longer second stage labor in the women in the hands-and-knees position than the control group (45.3 minutes vs. 32.1 minutes,  $p < 0.001$ ) but significantly shorter third stage labor (9.2 minutes vs. 11.0 minutes,  $p = 0.0080$ ).<sup>170</sup> Given findings from just one study regarding the first stage labor duration, the SOE was rated as insufficient. The consistent findings across the two studies resulted in a low SOE rating for the second stage labor duration outcome.

In all three studies, intervention groups had lower rates of cesarean delivery, with statistically significant differences in the peanut ball study ( $p = 0.011$ )<sup>154</sup> and the hands-and-knees delivery study ( $p = 0.015$ )<sup>170</sup> (insufficient SOE).

## **Maternal Outcomes for Ambulation and Positioning Strategies**

One study reported data on pelvic floor trauma and hemorrhage, showing non-significant differences in periurethral tears, second- and third-degree perineal tears, and postpartum hemorrhage between groups laboring in a squatting position versus a seated position.<sup>147</sup> A second study also reported non-significant differences in second degree perineal tears comparing hands-and-knees delivery to supine delivery<sup>170</sup> (insufficient SOE).

## **Neonatal Outcomes for Ambulation and Positioning Strategies**

Two studies reported on shoulder dystocia by delivery position.<sup>147,170</sup> Shoulder dystocia was reported for two neonates in the control group using a seated position for labor, versus no reports of shoulder dystocia in the squatting position group.<sup>147</sup> There also were no instances of shoulder dystocia in the hands-and-knees delivery group versus 4 in the supine delivery group ( $p = 0.60$ ).<sup>170</sup>

## **Process-Related Outcomes for Ambulation and Positioning Strategies**

Nonsignificant differences were reported between groups of women using a peanut ball and the control group in numbers of forceps and vacuum deliveries.<sup>154</sup> Eleven percent of the group using a squatting position had forceps delivery compared with 24 percent in the supine group ( $p < 0.05$ ) (insufficient SOE).

## **Relevant Systematic Reviews/Meta-Analyses for Ambulation and Positioning Strategies**

We identified two good-quality SR/MAs that examined the effects of ambulation and positioning during labor on labor outcomes, with mixed parity groupings. One assessed the effects of various upright positions (including ambulation, sitting, kneeling, and standing) compared to recumbent positions (including supine).<sup>34</sup> Analyses of up to 11 studies indicated

reduced duration of first-stage labor for women in upright positions (MD -1.43, 95% CI -2.35 to -0.50). These findings were inconsistent with our primary studies which demonstrated no difference (low SOE).

Consistent with our included studies, this meta-analysis also supported no difference in cesarean delivery rates (RR 0.70, 95% CI 0.49 to 1.01) (moderate SOE). There were no significant differences for other outcomes for mothers or babies. In spite of methodological and quality heterogeneity, sensitivity analyses of higher quality studies supported the main findings.

A second review examined whether encouraging women to adopt an upright position or ambulate during first-stage labor reduced the duration of this stage.<sup>50</sup> Analyses of 5 studies with between 68 and 1024 participants found non-statistically significant reductions in favor of upright position/ambulation in duration of first-stage labor in nulliparous women (WMD -0.52 hours, 95% CI -2.13 to 1.09) and parous women (WMD -0.54 hours, 95% CI -1.75 to 0.671). Other outcomes, including mode of delivery, maternal, and neonatal outcomes, were not affected.

## Strength of Evidence for Ambulation and Positioning Strategies

Tables 41-43 summarize the SOE for ambulation or positioning versus control therapy. Overall the SOE was reduced given the potential risk of bias in the included studies.

**Table 41. Ambulation versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>150,153</sup> (271)	<b>Improvement with ambulation:</b> 1 good-quality <sup>153</sup> and 1 poor-quality study <sup>150</sup> found that ambulation was associated with significantly reduced duration of the first stage and total duration of labor.	Low (Medium risk of bias, indirect, imprecise, inconsistent with SR)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>150</sup> (211)	<b>Inconclusive:</b> The SOE was rated as insufficient given findings from 1 study with high risk of bias.	Insufficient (High risk of bias, indirect, imprecise, 1 study)
Adverse Events	Neonatal Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>150</sup> (211)	<b>Inconclusive:</b> The SOE was rated as insufficient given findings from one study with high risk of bias.	Insufficient (High risk of bias, indirect, imprecise, 1 study)
	Process Related Outcomes – Parental Preferences	1 RCT <sup>150</sup> (211)	<b>Inconclusive:</b> The SOE was rated as insufficient given findings from 1 study with high risk of bias.	Insufficient (High risk of bias, indirect, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table 42. Positioning versus control: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	5 RCTs <sup>80,140,146,159,164</sup> (798)	<b>No difference:</b> None of the studies examining use of a birth ball, kneeling, sitting, or semi-sitting laboring positions found statistically significant differences in duration of active labor.	Low (High risk of bias, indirect, imprecise, inconsistency with SR)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	10 RCTs <sup>80,129,134,146,158,159,161,168,172,173</sup> (5,307)	<b>Inconclusive:</b> Given the inconsistency, imprecision, and potential risk of bias, the SOE was rated as insufficient.	Insufficient (High risk of bias, indirect, Inconsistent, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	5 RCTs <sup>80,134,168,172,173</sup> (4,546)  1 SR <sup>34</sup> (2,079 patients, 8 studies)	<b>No difference:</b> No significant differences were found between the intervention and control groups in mode of delivery.	Moderate (Medium risk of bias, indirect, imprecise, consistent)  The SOE was increased given the support of a SR of 11 studies.
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>80</sup> (271)	<b>Improvement with kneeling:</b> Women in kneeling position were more likely than women in sitting position to have an intact perineum (51 vs. 37%) and fewer 3rd or 4th degree tears (3 vs. 6%).	Low (Imprecise, one study)
	Neonatal Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>159</sup> (200)	<b>Inconclusive:</b> The SOE was rated as insufficient given findings from one study with high risk of bias.	Insufficient (High risk of bias, indirect, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

**Table 43. Ambulation/positioning versus control: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>154</sup> (201)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias and findings from 1 study.	Insufficient (Medium risk of bias, indirect, Imprecise, one study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	3 RCTs <sup>147,154,170</sup> (1,287)	<b>Improvement with positioning:</b> Second stage of labor was significantly shorter in women using either a peanut ball or a squatting position.	Low (Medium risk of bias, indirect, Imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>147,154,170</sup> (1,287)	<b>Inconclusive:</b> SOE was rated as insufficient given potential risk of bias and 2 studies where only 1 demonstrated statistical significance.	Insufficient (Medium risk of bias, indirect, Inconsistent, imprecise)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	2 RCTs <sup>147,170</sup> (1,086)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias and findings with heterogeneous interventions.	Insufficient (Medium risk of bias, Imprecise)
	Maternal Outcomes – Hemorrhage	1 RCT <sup>147</sup> (200)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias and findings from 1 study.	Insufficient (Medium risk of bias, Imprecise, 1 study)
	Neonatal Outcomes – Shoulder Dystocia	2 RCTs <sup>147,170</sup> (1,086)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias and findings with heterogeneous interventions.	Insufficient (Medium risk of bias, Imprecise)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	1 RCT <sup>154</sup> (142)	<b>Inconclusive:</b> SOE was insufficient given potential risk of bias and findings from 1 study.	Insufficient (Medium risk of bias, indirect, Imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations Versus Control Treatment

Ten studies, described in 11 papers, examined the effects of specific nutritional intervention<sup>133</sup> and oral or parenteral hydration intervention recommendations or limitations on labor outcomes.<sup>82,83,130,135,136,139,142,144,148,171</sup> One good-quality study compared oral with parenteral hydration,<sup>139</sup> another good-quality study compared combined oral and parenteral hydration to discretionary parenteral and oral hydration,<sup>142</sup> and one fair quality study compared oral and parenteral hydration combined to oral hydration alone.<sup>82,83</sup> Three good-quality studies compared parenteral hydration of normal saline and dextrose to normal saline alone.<sup>135,144,171</sup> Three good-quality<sup>139,142,148</sup> and one fair-quality study<sup>136</sup> examined the effects of varying hydration volumes using Lactated Ringer's solution. One fair-quality study examined the effects of parenteral hydration using D5LR, a Lactated Ringer's solution containing a 5 percent dextrose injection.<sup>130</sup>

Six good-quality<sup>135,139,142,144,148,171</sup> and two fair-quality<sup>82,130,136</sup> studies examined the effects of oral and parenteral hydration recommendations and limitations on labor outcomes in nulliparous women. Table 44 shows results for these studies.

One fair-quality study examined the effects of oral carbohydrate intake on women of mixed parity.<sup>133</sup> Two relevant good-quality SR/MAs were identified.<sup>36,38</sup>

## Results in Nulliparous Women

### Duration of Labor and Cesarean Delivery Rates for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations

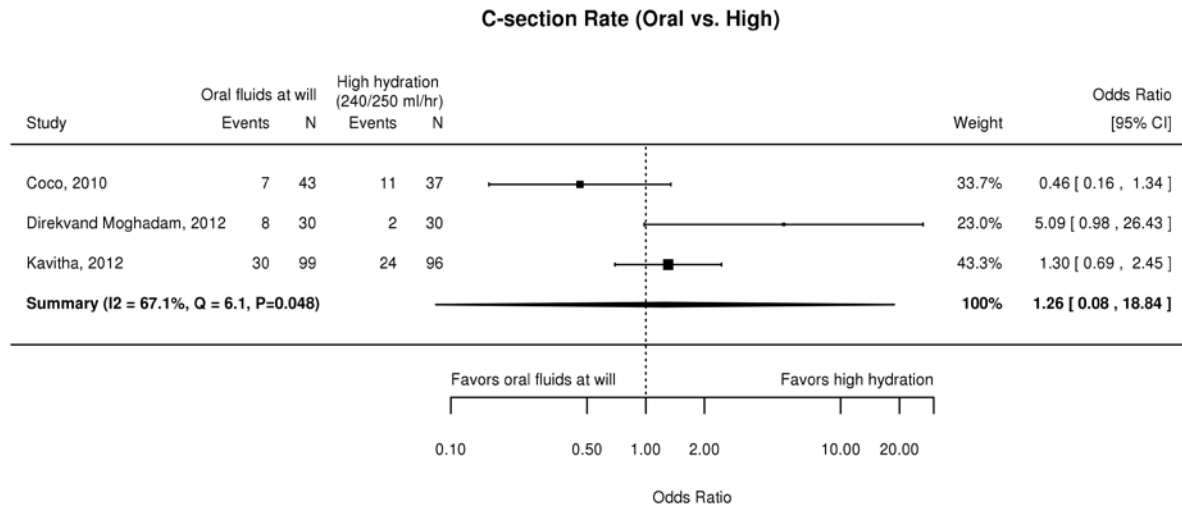
The five studies examining the effects of intravenous hydration with a Lactated Ringer's (LR) solution were divided in significant findings.<sup>82,83,136,139,142,148</sup> Different rates of intravenous hydration with LR was found to significantly decrease ( $p<.001$ ) duration of active labor compared to oral hydration only in one fair-quality study,<sup>136</sup> yet had no significant effects when oral hydration was unrestricted in two good-quality studies.<sup>139,142</sup> When compared with a lower volume of LR solution (125 ml/hr) in one study, a higher volume (250 ml/hr) resulted in a shorter mean duration of labor ( $p=.001$ ).<sup>148</sup>

One study described in two articles<sup>82,83</sup> comparing intravenous LR, intravenous 5 percent dextrose and oral intake reported significantly shorter total duration of labor in the LR and 5 percent dextrose groups as compared to the oral groups and significantly shorter duration in the 5 percent dextrose group than the LR group. Second stage labor was longer in the LR group than the dextrose or oral group.<sup>83</sup> D5LR at 125 ml/hr and 250 ml/hr with limited oral intake was not found to significantly reduce labor duration compared to a rate of 25 ml/hr and ad libitum oral hydration.<sup>130</sup> However, a 5 percent intravenous dextrose (D5) solution was associated with reductions in second-stage labor ( $p=0.01$ ) and time from fluid initiation to delivery ( $p=0.02$ ).<sup>144</sup> Infusion of a dextrose and saline solution was associated with significantly decreased overall labor duration ( $p=0.0$ ).<sup>135</sup> When combined with the SR evidence discussed below we rated the SOE as low for a reduction in total duration of labor. The SOE was reduced given the inconsistency in the findings from the individual trials and the variability in interventions assessed.

Eight studies reported cesarean delivery rates.<sup>82,83,130,136,139,142,144,148,171</sup> While infusions of LR at both 125 and 250 ml/hr did not result in significantly fewer cesarean deliveries, there was a trend in that direction with increased hydration ( $p=0.1$ ).<sup>148</sup> Parenteral D5LR,<sup>130</sup> intravenous solutions of 5 percent and 10 percent dextrose,<sup>144</sup> or dextrose 5 percent or 2.5 percent<sup>171</sup> resulted in significant differences in rate of cesarean delivery compared to normal saline ( $p=0.309$ ,<sup>130</sup>  $p=0.21$ <sup>144</sup> and  $p=0.46$ <sup>171</sup>). No significant differences were noted when comparing 250 ml/hr LR to unrestricted oral hydration ( $p=0.30$ <sup>142</sup>), LR at 125ml/hr, 250ml/hr, and oral hydration ( $p=0.824$ <sup>139</sup>), LR at 60, 120, and 240 ml/hr with oral hydration ( $p=0.58$ <sup>136</sup>); LR with 5 percent dextrose or oral intake ( $p$  not reported).<sup>82,83</sup>

Meta-analysis of the data from three RCTs<sup>136,139,142</sup> with moderate heterogeneity ( $I^2=67.1\%$ ,  $Q=6.1$ ,  $p=0.048$ ) showed no significant difference in cesarean delivery rates (OR 1.26, 95% CI 0.08 to 18.84) for women receiving high levels of intravenous hydration (either 240 or 250 ml/hr) compared to those with ad libitum oral hydration only (Figure 3) (moderate SOE). These findings were supported by the two SRs discussed below.

**Figure 3. Forest plot of cesarean delivery rate for oral hydration versus high-level intravenous hydration (number of events)**



Abbreviations: CI=confidence interval



### **Maternal Outcomes for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

Three good-quality studies reported maternal outcomes.<sup>135,144,171</sup> All found that intravenous dextrose solution was not significantly associated with lower rates of chorioamnionitis (infection) or postpartum hemorrhage compared to normal saline alone (low SOE).

### **Neonatal Outcomes for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

One good-quality study reported neonatal outcomes. Statistical significance was not found for participants experiencing abnormal fetal heart rate tracing in one study comparing 5 percent and 10 percent dextrose solutions to normal saline (5% arm, 2/94 individuals; 10% arm, 8/98 individuals; control/normal saline arm: 2/97 individuals).<sup>144</sup>

### **Process-Related Outcomes for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

Five studies reported other process-related outcomes. Intravenous dextrose and normal saline solution was associated with a significantly lower number of participants experiencing prolonged labor ( $p=0.009$ ) compared to normal saline alone, but not with number of operative vaginal deliveries, though intervention groups experienced fewer ( $p=0.1$ ).<sup>135</sup> Number of operative vaginal deliveries were not significantly different between arms receiving infusions of LR at 125 or 250 ml/hr compared with unrestricted oral fluids and LR at 25 ml/hr.<sup>130</sup> Differences in incidence of prolonged labor were not noted when comparing intravenous LR at rates of 125 and 250 ml/hr with oral hydration.<sup>139</sup> No significant differences in vacuum extractions were noted with increased intravenous hydration (moderate SOE).<sup>142,148</sup>

**Table 44. Effects of specific nutritional intervention and oral or parenteral hydration intervention**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Coco, 2010 <sup>142</sup>  Good	LR 250 @ 250 ml/hr plus unrestricted oral fluids (N=37)	LR at provider's discretion plus unrestricted oral fluids (usual care) (N=43)	1 <sup>st</sup> stage (mean hr; vaginal deliveries only): 7.9	1 <sup>st</sup> stage (mean hr; vaginal deliveries only): 8.0	0.90	11	7	0.30	–	–
			2 <sup>nd</sup> stage (mean hr; vaginal deliveries only): 1.6	2 <sup>nd</sup> stage (mean hr; vaginal deliveries only): 1.4	0.49	11	7	0.30	–	–
			Total (mean hr; vaginal deliveries only): 9.5	Total (mean hr; vaginal deliveries only): 9.4	0.92	11	7	0.30	–	–
Direkvand-Moghadam, 2012 <sup>136</sup>  Fair	LR 60 ml/hr (N=24)	LR 120 ml/hr (N=26)	Active phase of 1 <sup>st</sup> phase: 237.8 min (36.4) 2 <sup>nd</sup> phase: 54.8 min (16.2) 3 <sup>rd</sup> phase: 6.2 min (2.9)	Active phase of 1 <sup>st</sup> phase: 231.7 min (43.5) 2 <sup>nd</sup> phase: 51.3 min (11.9) 3 <sup>rd</sup> phase: 6.1 min (4.0)	0.5949  0.3857  0.9204	20	13.3	0.0167	–	NR significant between LR arms
	LR 60 ml/hr (N=24)	LR 240 ml/hr (N=28)	Active phase of 1 <sup>st</sup> phase: 237.8 min (36.4) 2 <sup>nd</sup> phase: 54.8 min (16.2) 3 <sup>rd</sup> phase: 6.2 min (2.9)	Active phase of 1 <sup>st</sup> phase: 206.2 min (38.3) 2 <sup>nd</sup> phase: 49.8 min (11.4) 3 <sup>rd</sup> phase: 5.7 min (2.7)	<0.001	–	6.7	–	–	NR significant between LR arms

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
	LR 60 ml/hr (N=24)	Oral fluids at will (N=22)	Active phase of 1 <sup>st</sup> phase: 237.8 min (36.4) 2 <sup>nd</sup> phase: 54.8 min (16.2) 3 <sup>rd</sup> phase: 6.2 min (2.9)	Active phase of 1 <sup>st</sup> phase: 252.3 min (40.9) 2 <sup>nd</sup> phase: 64.3 min (13.9) 3 <sup>rd</sup> phase: 6.9 min (3.6)	0.01	26.6	–	0.58	–	NR significant between LR arms
Edwards, 2014 <sup>130</sup> Fair	125 ml/hr D5LR (N=105)	250 ml/hr D5LR (N=105)	Total duration: 11.6 hr (5.9) 1 <sup>st</sup> stage: 10.2 hr (5.6)	Total duration: 11.4 hr (5.5) 1 <sup>st</sup> stage: 10.3 hr (5.2)	0.998	23	18	0.309	–	–
	125 ml/hr D5LR (N=105)	25 ml/hr D5LR (N=105)	Total duration: 11.6 hr (5.9) 1 <sup>st</sup> stage: 10.2 hr (5.6)	Total duration (hr): 11.5 (5.9) 1 <sup>st</sup> stage (hr): 9.9 (5.7)	0.671	23	17	0.3605	–	–
Eslamian, 2006 <sup>148</sup> Good	LR 125ml/hr (N=153)	LR 250 ml/hr (N=147)	1 <sup>st</sup> stage: 367 min (105) 2 <sup>nd</sup> stage: 18.52 min (10) Total: 386 min (110)	1 <sup>st</sup> stage: 236 min (86) 2 <sup>nd</sup> stage: 16.55 min (7) Total: 253 min (97)	0.0001 0.08 0.001	10	1	0.1	Yes. But cesarean delivery difference is NS (“trend toward a lower frequency of cesarean deliveries”)	–
Fong, 2017 <sup>171</sup> Good	5% Dextrose in normal saline 125ml/hr (N=66)	2.5% Dextrose in normal saline 250ml/hr (N=66)	1 <sup>st</sup> stage 471.7 min (324.3) 2 <sup>nd</sup> stage 107.6 min (92.9) Total: 609.8 min (401.1)	1 <sup>st</sup> stage 501.6 min (368.7) 2 <sup>nd</sup> stage 106.2 (96.2) Total: 577.9 min (336.1)	0.83 0.93 0.92	– – 26/92 (28.3%)	– – 24/90 (26.7%)	– – 0.46	–	–
	5% Dextrose in normal saline 125ml/hr	Normal saline 250ml/hr (N=73)	1 <sup>st</sup> stage 471.7 min (324.3) 2 <sup>nd</sup> stage 107.6 min	1 <sup>st</sup> stage 509.6 min (345.1) 2 <sup>nd</sup> stage 98.0 min	–	–	–	–	–	–

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
	(N=66)		(92.9) Total: 609.8 min (401.1)	(67.3) Total: 607.6 min (358.6)			19/92 (20.7%)			
Kavitha, 2012 <sup>139</sup>  Good	Oral hydration (N=99)	LR 125 ml/hr (N=98)	Active labor: 391.3 min (211)	Active labor: 363.1 min (172)	0.203	30.6%	31%	0.824	—	—
	Oral hydration (N=99)	LR 250 ml/hr (N=96)	Active labor: 391.3 min (211)	Active labor (min): 343 min (171)	0.203	30.6%	25%	0.824	—	—
Sharma, 2012 <sup>135</sup>  Good	Normal saline with dextrose alternating with normal saline at 175 ml/hr (N=122)	Normal saline at 175 ml/hr (N=121)	Total duration: 297.8 min (154.4)	473.8 min (220.5)	0.000	—	—	—	—	—
Shrivastava, 2009 <sup>144</sup>  Good	5% dextrose in normal saline (N=76)	10% dextrose in normal saline (N=72)	Median Min from fluid initiation to complete cervical dilation: 299 (82-1091)	Median Min from fluid initiation to complete cervical dilation: 328 (61-672)	0.1	18	24	0.21	—	—
			2 <sup>nd</sup> stage: 69 (17-227)	2 <sup>nd</sup> stage: 62 (14-191)	0.01					
			Min from fluid initiation to delivery: 392 (100-1157)	Min from fluid initiation to delivery: 393 (97-827)	0.02					

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
	5% dextrose in normal saline (N=76)	normal saline (control) (N=84)	Median Min from fluid initiation to complete cervical dilation: 299 (82-1091)  2 <sup>nd</sup> stage: 69 (17-227)  Min from fluid initiation to delivery: 392 (100-1157)	Median Min from fluid initiation to complete cervical dilation: 360 (95-1203)  2 <sup>nd</sup> stage: 106 (24-266)  Min from fluid initiation to delivery: 464 (185-1336)	0.1  0.01  0.02	18	14	0.21	—	—
Ahadi Yulghunlu, 2018 <sup>83</sup> and Shafaie, 2017 <sup>82</sup>  Fair	LR 125ml/hr (N=63)	5% Dextrose (N=65)	1 <sup>st</sup> stage active 276.7 min (91.3)	1 <sup>st</sup> stage active 150.6 min (78.5)	LR vs.Dex <0.001 Dex vs oral <0.001 LR vs oral 0.965	4/67	2/67	0.002	—	—

Abbreviations: —=not reported; Com=comparator; D5LR=lactated Ringer's 5% dextrose; hr=hours; Int=intervention; IQR=interquartile range; LR=lactated ringer's solution; min=minutes; NR=not reported; NS=not significant

## **Results in Women of Mixed or Unspecified Parity**

### **Duration of Labor and Cesarean Delivery Rates for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

Oral carbohydrate intake was associated with a significant decrease in duration of second-stage labor compared to water only ( $p=0.04$ ).<sup>133</sup> Differences in third-stage and overall duration were not statistically significant ( $p=0.1$  and  $0.3$ , respectively). Oral carbohydrate intake was not associated with significant differences in rates of cesarean delivery ( $p=0.9$ ). These findings were all rated as insufficient SOE given imprecise findings from one fair-quality study.

### **Process-Related Outcomes for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

Oral carbohydrate intake was not associated with significant differences between rates of spontaneous, instrumental vaginal, or caesarian delivery ( $p=0.9$ ) (insufficient SOE).<sup>133</sup>

### **Relevant Systematic Reviews/Meta-Analyses for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations**

We identified SR/MAs (three good-quality and two fair-quality) that examined the effects of specific nutritional intervention and oral or parenteral hydration intervention recommendations or limitations on labor outcomes.<sup>36,38,182,183,185</sup> Three of the reviews examined the impact of food or carbohydrate consumption during labor,<sup>36,182,185</sup> while the other two examined the impact of intravenous fluids.<sup>38,183</sup>

One systematic review investigated the harms and benefits of oral food and fluid restriction with and without intravenous hydration.<sup>36</sup> Analyses included 4 pertinent studies (one excluded due to including labor induction) with between 60 and 328 patients, all women with low risk of complications. No statistically significant differences were observed in cesarean delivery rates, duration of labor, or any outcomes, indicating insufficient evidence for oral fluid restrictions.

A second review (fair quality) compared food or oral carbohydrate solution intake to ice chips or water.<sup>185</sup> Less restrictive food intake was associated with a significantly shorter duration of labor (-16.01 minutes, 95% CI -24.91 to -7.12) based on 9 studies with 3,675 participants. Other outcomes of interest including cesarean delivery and admission to NICU did not differ significantly between the intervention and control group. This review included one of the individual studies described above.<sup>133</sup>

The third review (fair quality) focused only on carbohydrate supplementation during labor.<sup>182</sup> Four of the six studies (698 women total) included in this systematic review were also included in the review described above.<sup>185</sup> There was no difference in the total duration of active labor (3.15 minutes, 95% CI -35.64 to 41.95). There also was no significant difference in cesarean births (RR 1.15, 95% CI 0.83 to 1.61).

The first of the reviews focused on intravenous fluids during labor examined whether routine administration of intravenous fluids reduced the duration of labor or affected maternal or neonatal health.<sup>38</sup> Analyses of nine studies revealed some decrease in labor duration in some studies. This meta analysis included three of our primary RCTs.<sup>136,139,142</sup> No differences in rate of cesarean delivery or neonatal outcomes (when reported) were noted.

Another fair-quality review assessed intravenous fluid infusion rate, regardless of the fluid used, on labor outcomes in nulliparous women.<sup>183</sup> Higher infusion rate (250ml/hr vs 125ml/h) was associated with reduced risk for cesarean delivery, 12.5% vs 18.1%, RR 0.70, 95% CI 0.53-0.92 based on 7 studies with a total of 1215 women. Total duration of labor was significantly shorter in the high infusion groups (-64.38 minutes, 95% CI -121.88 to -6.88) based on six studies with 1155 women. Second stage labor was also significantly shorter (-2.80 minutes, 95% CI -4.49 to -1.10) based on four studies with 899 women. Chorioamnionitis, postpartum hemorrhage and NICU admission did not differ significantly between the intervention groups. This review included four of the individual studies described above.<sup>130,136,139,148</sup>

Heterogeneity in quality and methodology across studies precludes recommendation of routine parenteral hydration in laboring women.

## Strength of Evidence for Specific Nutritional Intervention and Oral or Parenteral Hydration Intervention Recommendations or Limitations

Tables 45 and 46 summarize the SOE for nutritional, oral, or parenteral hydration interventions in nulliparous or mixed parity women.

**Table 45. Specific nutritional intervention and oral or parenteral hydration intervention recommendations or limitations: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	3 RCTs <sup>130,135,148</sup> (861)  1 SR <sup>38</sup> (1,781 patients, 9 studies)	<b>Improvement with intravenous fluids:</b> Administration of intravenous fluids compared with oral intake alone demonstrated a reduction in the duration of labor.	Low (Indirect, inconsistent, imprecise)  The SOE was reduced given the inconsistency in the findings of individual trials and with the SR and the variability in hydration strategies.
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	6 RCTs <sup>130,136,139,142,144,148</sup> (1,373)	<b>No difference:</b> No significant differences were found between groups of women receiving oral hydration versus high-level intravenous hydration (OR 1.26, 95% CI 0.08 to 18.84)	Moderate (Indirect, Imprecise)
Adverse Events	Maternal Outcomes – Hemorrhage or Infection	2 RCTs <sup>135,144</sup> (539)	<b>No difference:</b> No significant differences in rates of maternal hemorrhage or infection were found between groups of women receiving infusions of 5% or 10% dextrose and normal saline.	Low (Imprecise)
	Neonatal Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>144</sup> (289)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Indirect, Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	5 RCTs <sup>130,135,142,148</sup> (1,234)	<b>No difference:</b> No difference in operative vaginal delivery rates amongst 5 studies using varying methods of hydration.	Moderate (Indirect, Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; OR=odds ratio; RCT=randomized controlled trial; SOE=strength of evidence

**Table 46. Specific nutritional intervention and oral or parenteral hydration intervention recommendations or limitations: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>133</sup> (177)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, Imprecise, 1 study)
	Process Related Outcomes – Duration of Total Labor	1 RCT <sup>133</sup> (177)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>133</sup> (177)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study with potential risk of bias.	Insufficient (Medium risk of bias, indirect, Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Operative Vaginal Delivery)	1 RCT <sup>133</sup> (177)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study with potential risk of bias.	Insufficient (Imprecise)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## TENS Versus Control Treatment

Two studies reported on the effects of transcutaneous electrical nerve stimulation (TENS) on labor outcomes.<sup>175,178</sup> Results were reported for nulliparous women in one study<sup>178</sup> and for women of mixed parity in the other study.<sup>175</sup> Both studies were fair quality.<sup>175,178</sup> One study compared TENS to an inactive TENS unit or usual care<sup>178</sup> and the other compared TENS, Entonox (nitrous oxide) or the combination of the two.<sup>175</sup>

## Results in Nulliparous Women

### Duration of Labor for TENS

The duration of first-stage labor was significantly shorter in the women using the TENS unit than those with the inactive unit or usual care (Table 47).<sup>178</sup> The duration of second or third-stage labor was not significantly different between the groups.

### Maternal Outcomes for TENS

Maternal hemorrhage (500-1000ml blood loss) was not significantly different across the treatment groups, occurring in 10% of the TENS group, 10% of the inactive TENS group and 16.7% of the usual care group,  $p=0.66$ .<sup>178</sup>

## Results in Women of Mixed or Unspecified Parity

### Duration of Labor

The duration of first-stage labor was not significantly different between the Entonox group and the TENS plus Entonox group, but was significantly longer in the TENS group (Table 47).<sup>175</sup>



**Table 47. Effects of TENS versus control treatment**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value
Shahoei, 2017 <sup>178</sup>  Fair	TENS N=30	Inactive TENS N=30	1 <sup>st</sup> Stage 158.42 min (136.64)	1 <sup>st</sup> Stage 262.5 min (125.23)	<0.0002
		Usual care N=30		1 <sup>st</sup> Stage 257.16 min (114.10)	
	TENS N=30	Inactive TENS N=30	2 <sup>nd</sup> Stage 43 min (29.37)	2 <sup>nd</sup> Stage 57.5 (41.39)	0.12
		Usual care N=30		2 <sup>nd</sup> Stage 44.03 (29.17)	
	TENS N=30	Inactive TENS N=30	3 <sup>rd</sup> Stage 11.6 min (4.2)	3 <sup>rd</sup> Stage 13.27 min (8.7)	0.29
		Usual care N=30		3 <sup>rd</sup> Stage 13.00 min (10.87)	
Samadzadeh, 2017 <sup>175</sup>  Fair	TENS N=40	Entonox N=40	1 <sup>st</sup> stage 300.1 min (224.8)	1 <sup>st</sup> stage 228.5 min (92.4)	Not reported
		TENS & Entonox N=40		1 <sup>st</sup> stage 214.6 min (151.4)	

Abbreviations: Com=comparator; Int=intervention; min=minute; TENS=transcutaneous electrical nerve stimulation

## Oral Bicarbonate Versus Control Treatment

One fair-quality RCT examined the effect of oral bicarbonate on labor outcomes in women with labor dystocia.<sup>177</sup> Two hundred nulliparous women who had labor dystocia, defined as crossing the action line on a partogram or labor arrest for  $\geq 2$  hours, were randomized to receive an oral bicarbonate solution followed by oxytocin administration in 1 hour or immediate oxytocin administration.

### Results in Nulliparous Women

Duration of labor, as defined by the proportion of women with active time of delivery >12 hours, was not significantly different between the women receiving bicarbonate in advance of oxytocin administration and those receiving immediate oxytocin (49% vs. 40%,  $p=0.2$ ). There also was no difference in the proportion of women with cesarean delivery (8.9% vs. 8.1%,  $p=0.8$ ). Post-partum hemorrhage was reported in none of the women receiving bicarbonate and oxytocin and in 16.2 percent of the women receiving oxytocin only ( $p$ -value not reported).

## Hyoscine or Hot Shower Versus Control Treatment

One fair-quality RCT examined the effect of intravenous injections of hyoscine or a hot shower versus usual care on labor outcomes.<sup>174</sup> A total of 162 nulliparous women were randomized, with women in the intervention groups either receiving the hyoscine injection or taking a 20-minute hot shower at 4 cm and 7 cm cervical dilation.

### Results in Nulliparous Women

Duration of active labor, as defined by the time from 4 cm dilation to full dilation, was significantly longer in the usual care group (312.6 minutes) than either the hyoscine group (221.2

minutes) or the hot shower group (201.9 minutes) ( $p < 0.001$  for hot shower vs. usual care;  $p = 0.003$  for hyoscine vs. usual care;  $p = 0.522$  for hyoscine vs. hot shower). The number of cesarean deliveries was the same in each group (5/53 in the hyoscine group, 5/55 in the hot shower group, and 5/54 in the usual care group).

## **Assessment and Support During Early Labor Versus Control Treatment**

We identified one systematic review that compared assessment and support interventions during early labor versus control treatments.<sup>186</sup> The interventions evaluated in the review were assessment versus direct admission in early labor (1 study), home support versus telephone triage (3 studies) and one-to-one structured care versus usual care (1 study).

Assessment during early labor as compared to direct admission was associated with shorter duration of labor in hospital (-5.20 hours, 95% CI -7.06 to -3.34) and higher maternal satisfaction score (16.0, 95% CI 7.53 to 24.47), but no significant difference in rate of cesarean section (RR 0.72, 95% CI 0.30 to 1.72).

Home support versus telephone triage was associated with no significant difference in rate of cesarean section (RR 1.05, 95% CI 0.95 to 1.17) or neonatal admission to special care unit (RR 0.84, 95% CI 0.50 to 1.42). A higher maternal satisfaction score (3.47, 95% CI 1.00 to 5.94) for the intervention was reported in one study.

One-on-one structured care versus usual care showed no significant differences in rate of cesarean section (RR 0.93, 95% CI 0.84 to 1.02) or neonatal admission to special care unit (RR 0.98, 95% CI 0.80 to 1.21).

## **Key Question 4. Epidural Analgesia**

KQ 4 was: What are the benefits and harms of epidural analgesia in labor, particularly in terms of the risk of a diagnosis of prolonged labor?

In this Key Question, we focus on the evidence on the effect of specific methods for analgesia during labor, particularly various approaches to regional analgesia using epidural or other methods, on the duration of labor and the risk of cesarean delivery. If certain characteristics of labor analgesia (e.g., type of analgesia, timing, dosage) increase the duration of labor, then it is plausible that this increased duration would be associated with an increased risk of cesarean delivery for dystocia.

## **Description of Included Studies**

We identified 26 articles<sup>66-69,76-79,124,176,181,189-203</sup> representing 22 individual RCTs that examined the benefits and harms of epidural analgesia in labor. Four studies were each described in two publications, as follows:

- de Orange, 2011: Primary report<sup>76</sup> and a companion paper<sup>77</sup>
- Pascual-Ramirez, 2011: Primary report<sup>78</sup> and a companion paper<sup>79</sup>
- Wilson, 2009: Primary report<sup>66</sup> and a companion paper<sup>67</sup>
- Wassen, 2015: Primary report<sup>68</sup> and a companion paper<sup>69</sup>

However, while the companion papers for Pascual-Ramirez, 2011, and Wilson, 2009, individually met inclusion criteria, they did not provide additional unique information on

outcomes of interest to this review beyond the information provided in the primary report. The companion paper for de Orange, 2011 is cited where relevant under “Detailed Synthesis” below.

Of the 22 included studies, 8 were conducted in UK/Europe,<sup>66,68,78,189,190,192,194,197</sup> 6 were conducted in Asia,<sup>124,176,181,201-203</sup> 3 were conducted in the Middle East,<sup>191,198,199</sup> 3 were conducted in Latin America,<sup>76,195,196</sup> 1 was conducted in Africa,<sup>193</sup> and 1 was conducted in the United States.<sup>200</sup> Fifteen studies were conducted in a hospital,<sup>68,78,124,176,181,189,191-193,196,198-200,202,203</sup> while 7 studies were unclear or reported other settings.<sup>66,76,190,194,195,197,201</sup> Five studies reported government funding,<sup>66,124,176,181,199</sup> two reported nongovernment, nonindustry funding,<sup>198,200</sup> and 1 reported a mixture of funding from government and nongovernment sources.<sup>190</sup> Fourteen studies were unclear or did not report the funding source.<sup>68,76,78,189,191-197,201-203</sup> Finally, of the 22 included studies, 8 studies were rated as good quality,<sup>68,76,78,191,199,200,202,203</sup> 11 as fair quality,<sup>66,124,176,181,189,190,192,195-198</sup> and 3 as poor quality.<sup>193,194,201</sup>

## Key Points for Epidural Analgesia

- For nulliparous women, a meta-analysis showed no significant differences between epidural analgesia (EA) and combined spinal epidural (CSE) in duration of the first stage of labor (low SOE) or duration of the second stage of labor (low SOE). However, total duration of labor (from time of intervention to delivery) was significantly longer for EA relative to CSE (moderate SOE). There were no differences between EA and CSE in rates of cesarean delivery (moderate SOE).
- For women of mixed parity, there was no difference between EA and CSE for total duration of labor (low SOE), or rates of cesarean delivery (moderate SOE).
- For women of mixed parity, there were no differences between EA and patient-controlled intravenous analgesia (PCIA) in duration of labor or rates of cesarean delivery (low SOE for both outcomes).
- For nulliparous women, there was no difference in duration of first or second stage labor or rates of cesarean delivery for early versus late EA (moderate SOE for all outcomes)
- For women of mixed parity, there was no evidence of a difference between EA and no EA for the duration of the first stage of labor or rates of cesarean delivery. There was a slight increase in the duration of the second stage for women with EA (moderate SOE for all outcomes).

## Detailed Synthesis for Epidural Analgesia

Comparisons of interest were:

- Epidural analgesia versus combined spinal epidural analgesia
- Epidural analgesia versus patient-controlled intravenous analgesia
- Epidural analgesia versus intravascular tramadol
- Early versus late epidural analgesia
- Routine epidural analgesia versus analgesia on request
- Combined spinal epidural analgesia versus nonpharmacologic pain relief
- Epidural analgesia versus intravenous meperidine
- Epidural analgesia versus low-dose infusion epidural analgesia
- Epidural analgesia versus acupuncture point nerve stimulation
- Epidural analgesia versus no epidural analgesia

## **Epidural Analgesia Versus Combined Spinal Epidural Analgesia**

Of the 22 included studies, 9 RCTs representing 1,251 patients compared EA with CSE, which involves both epidural and spinal analgesia.<sup>66,78,190,191,193,195-197,202</sup> Of these nine RCTs, four were conducted in UK/Europe,<sup>66,78,190,197</sup> two were conducted in Asia or the Middle East,<sup>191,202</sup> and three were conducted in Latin America or Africa.<sup>193,195,196</sup> One RCT reported funding from a government agency,<sup>66</sup> one reported a mixture of funding from government and nongovernment sources,<sup>190</sup> and the remaining seven were unclear or did not report the funding source. Three RCTs were rated as good quality,<sup>78,191,202</sup> five were rated as fair,<sup>66,190,195-197</sup> and one was rated as poor quality.<sup>193</sup>

Of the nine RCTs that compared EA with CSE, five included only nulliparous women.<sup>66,191,193,197,202</sup> and one included both nulliparous and parous women but reported duration of labor results separately for the 52.8% of the patient population who were nulliparous.<sup>78</sup> The remaining three RCTs included mixed parity populations, with the following proportion of nulliparous women in each study: 68.7%,<sup>190</sup> 82.5%,<sup>195</sup> and 68.8%.<sup>196</sup> None of the studies reported findings specifically for parous women.

No SR/MAs were identified that were relevant to this comparison.

## **Results in Nulliparous Women**

### **Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Combined Spinal Epidural Analgesia**

Six of the nine RCTs that compared EA with CSE reported duration of labor,<sup>78</sup> cesarean delivery rates,<sup>66</sup> or both<sup>191,193,197,202</sup> in nulliparous women. Table 48 shows results for these studies; outcomes are described following the table.

**Table 48. Effects of epidural analgesia versus combined spinal epidural in nulliparous women**

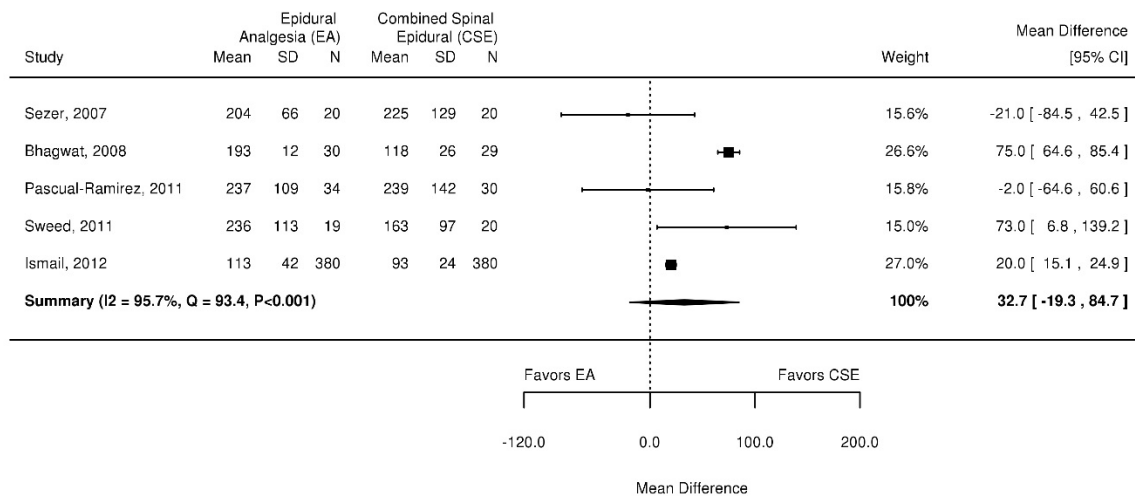
Study Quality	Int N	Com N	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?
Bhagwat, 2008 <sup>202</sup> Good	EA 30	CSE 30	Stage 1: 193 min ± 12 Stage 2: 30 min ± 7	Stage 1: 118 min ± 26 Stage 2: 19 min ± 21	Stage 1: <0.001 Stage 2: 0.409	2 (6.7%)	2 (6.7%)	1	No
Ismail, 2012 <sup>191</sup> Good	EA 380	CSE 380	Stage 1, latent phase: 468 min ± 54 Stage 1, active phase: 113 min ± 42 Stage 2: 60 min ± 30 Total: 648 min ± 234	Stage 1, latent phase: 396 min ± 42 Stage 1, active phase: 93 min ± 24 Stage 2: 48 min ± 18 Total: 582 min ± 180	Stage 1, latent phase: <0.0001 Stage 1, active phase: <0.0001 Stage 2: <0.0001 Total: <0.0001	95 (25.0%)	87 (22.9%)	0.50	No
Pascual-Ramirez, 2011 <sup>78</sup> Good	EA 34 33 33	CSE 30 29 29	Stage 1: 237 min ± 109 Stage 2: 48 min ± 32 Total: 282 min ± 113	Stage 1: 239 min ± 142 Stage 2: 51 min ± 34 Total: 185 min ± 145	Stage 1: 0.94 Stage 2: 0.76 Total: 0.91	—	—	—	No
Sezer, 2007 <sup>197</sup> Fair	EA 20	CSE 20	Stage 1: 204 min ± 66 Stage 2: 66 min ± 48 Total: 270 min ± 73	Stage 1: 225 min ± 129 Stage 2: 56 min ± 27 Total: 299 min ± 138	Stage 1: 0.52 Stage 2: 0.42 Total: 0.41	4 (20.0%)	4 (20.0%)	1	No
Sweed, 2011 <sup>193</sup> Poor	EA 20	CSE 20	Stage 1: 236 min ± 113 Stage 2: 41 min ± 33	Stage 1: 163 min ± 97 Stage 2: 66 min ± 40	Stage 1: 0.03 Stage 2: 0.049	1 (5.0%)	0 (0%)	0.31	No
Wilson, 2009 <sup>66</sup> Fair	EA 353	CSE 351	—	—	—	98 (27.8%)	99 (28.2%)	0.91	—

Abbreviations: —=not reported; CI=confidence interval; Com=comparator; CSE=combined spinal epidural; EA=epidural analgesia; Int=intervention; Min=minutes; N=number of patients/participants; SD=standard deviation

Five of the nine RCTs that compared EA with CSE reported either mean time from randomization or initiation of the analgesia intervention to delivery, or duration of both the first and second stages of labor<sup>78,191,193,197,202</sup> in nulliparous women (Table 48). Three of these RCTs were rated as good quality,<sup>78,191,202</sup> one as fair,<sup>197</sup> and one as poor.<sup>193</sup> These 5 RCTs represented 962 patients. Four studies included only nulliparous patients,<sup>191,193,197,202</sup> and one<sup>78</sup> reported findings for duration of labor separately for the subset of patients who were nulliparous.

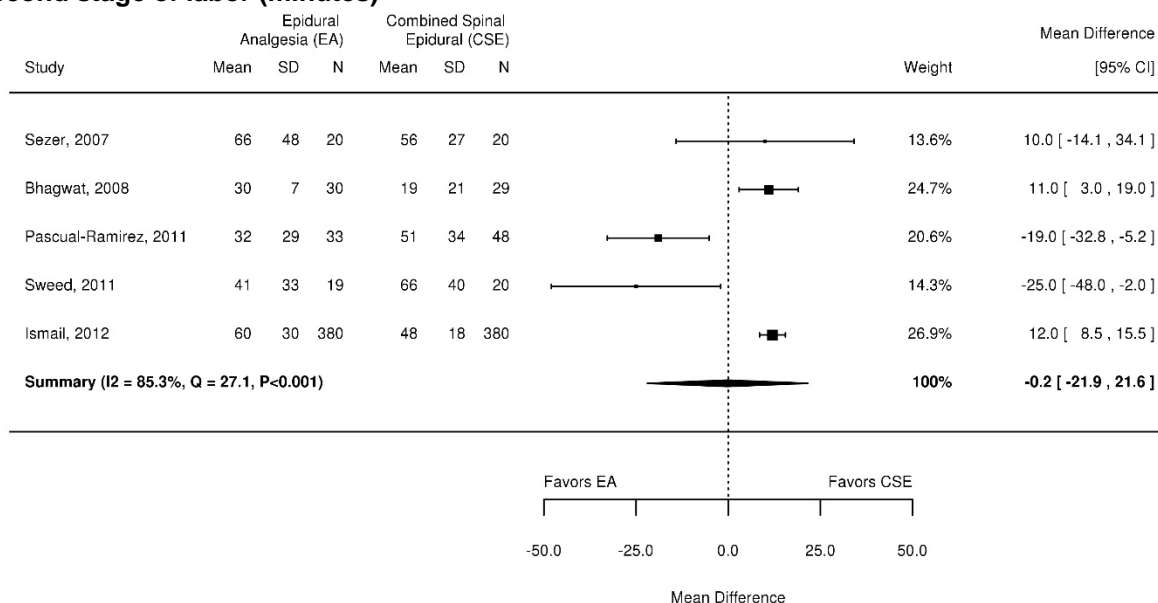
Meta-analysis of the data from these RCTs showed no significant differences between EA and CSE in duration of the first stage of labor (MD 32.7 minutes; 95% CI -19.3 to 84.7) (Figure 4, low SOE) or duration of the second stage of labor (MD -0.2 minutes; 95% CI -21.9 to 21.6) (Figure 5, low SOE). However, total duration of labor (from time of intervention to delivery) was significantly longer for EA relative to CSE, with an MD of 62.0 minutes (95% CI 7.2 to 116.7) (Figure 6, moderate SOE).

**Figure 4. Epidural analgesia versus combined spinal epidural in nulliparous women—duration of first stage of labor (minutes)**



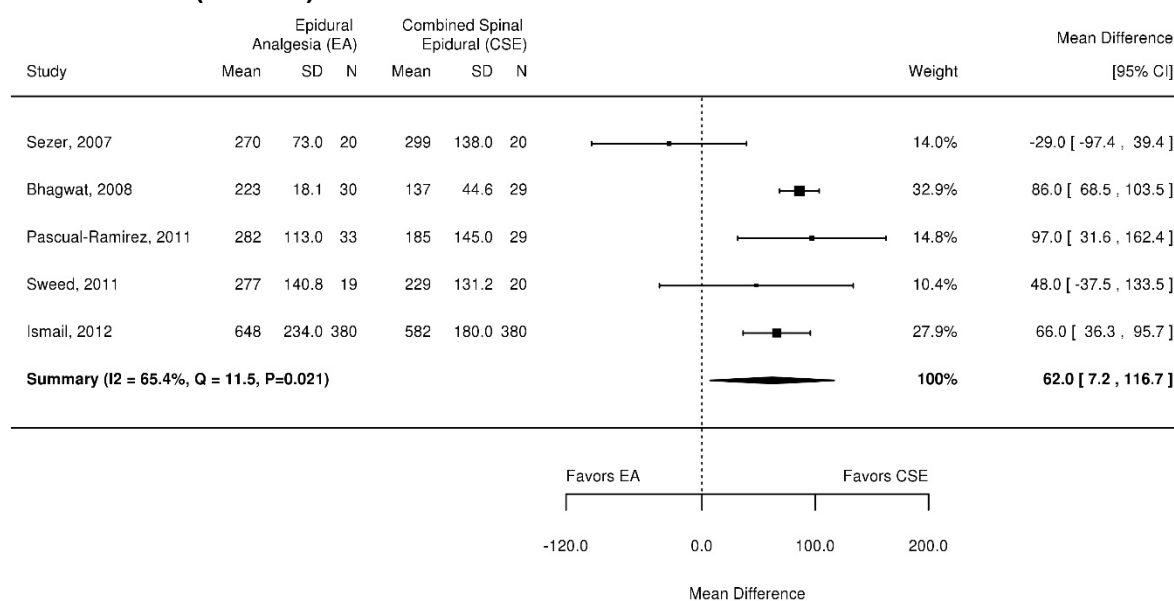
Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; N=number of participants; SD=standard deviation

**Figure 5. Epidural analgesia versus combined spinal epidural in nulliparous women—duration of second stage of labor (minutes)**



Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; N=number of participants; SD=standard deviation

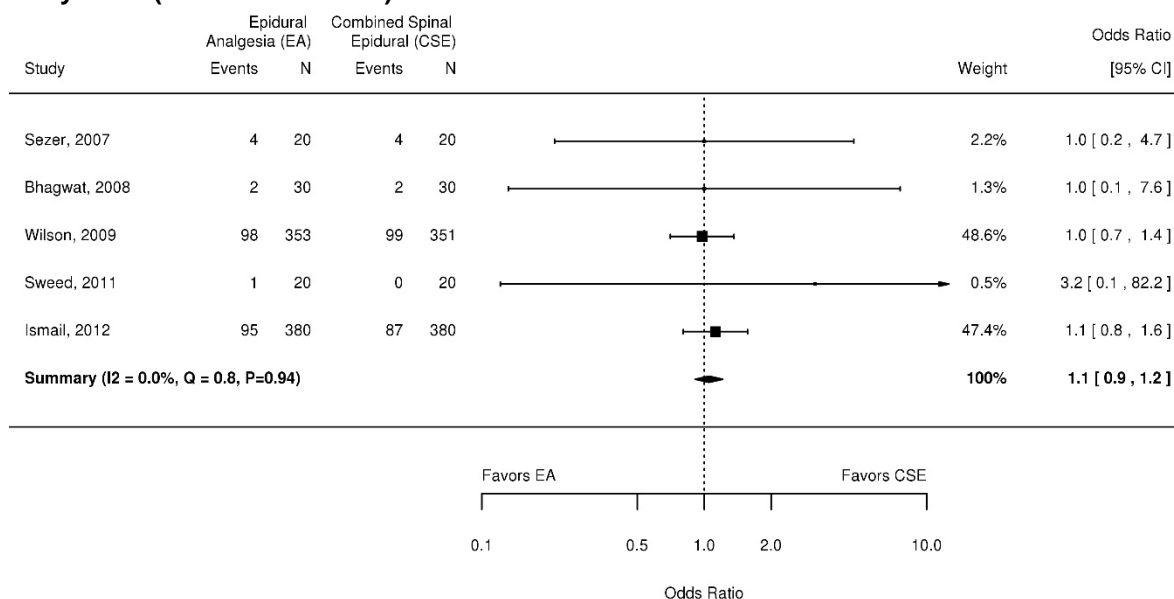
**Figure 6. Epidural analgesia versus combined spinal epidural in nulliparous women—total duration of labor (minutes)**



Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; N=number of participants; SD=standard deviation

Five RCTs compared cesarean delivery rates associated with EA versus CSE among nulliparous women.<sup>66,191,193,197,202</sup> (Table 48). Two of these RCTs were rated as good quality,<sup>191,202</sup> two as fair,<sup>66,197</sup> and one as poor.<sup>193</sup> Meta-analysis of the data from 1604 patients in these 5 RCTs showed no statistically significant difference in cesarean delivery rates between EA and CSE (odds ratio [OR] 1.1; 95% CI 0.9 to 1.2) (Figure 7, moderate SOE).

**Figure 7. Epidural analgesia versus combined spinal epidural in nulliparous women—cesarean delivery rates (number of events)**



Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; N=number of participants; SD=standard deviation

## Process-Related Outcomes for Epidural Analgesia Versus Combined Spinal Epidural Analgesia

A good-quality RCT involving 1,140 patients assessed maternal overall satisfaction with analgesia 24 hours after delivery using a 4-point verbal scale ranging from very satisfied to very dissatisfied (1=very dissatisfied, 2=dissatisfied, 3=satisfied, 4=very satisfied).<sup>191</sup> Mean maternal satisfaction scores (SD) associated with each of the 3 study interventions were 2.8 (0.8) for EA, 3.9 (0.6) for CSE, and 3.0 (0.7) for patient-controlled intravenous analgesia ( $p<0.001$  for the 3-way comparison).

## Results in Women of Mixed or Unspecified Parity

### Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Combined Spinal Epidural Analgesia

Four RCTs compared EA with CSE in women with mixed parity. The proportion of nulliparous women in each of these studies was as follows: 68.8 percent,<sup>196</sup> 82.5 percent,<sup>195</sup> 52.8 percent,<sup>78</sup> and 68.7 percent.<sup>190</sup> Table 49 shows results for these studies; the two outcomes are described following the table.



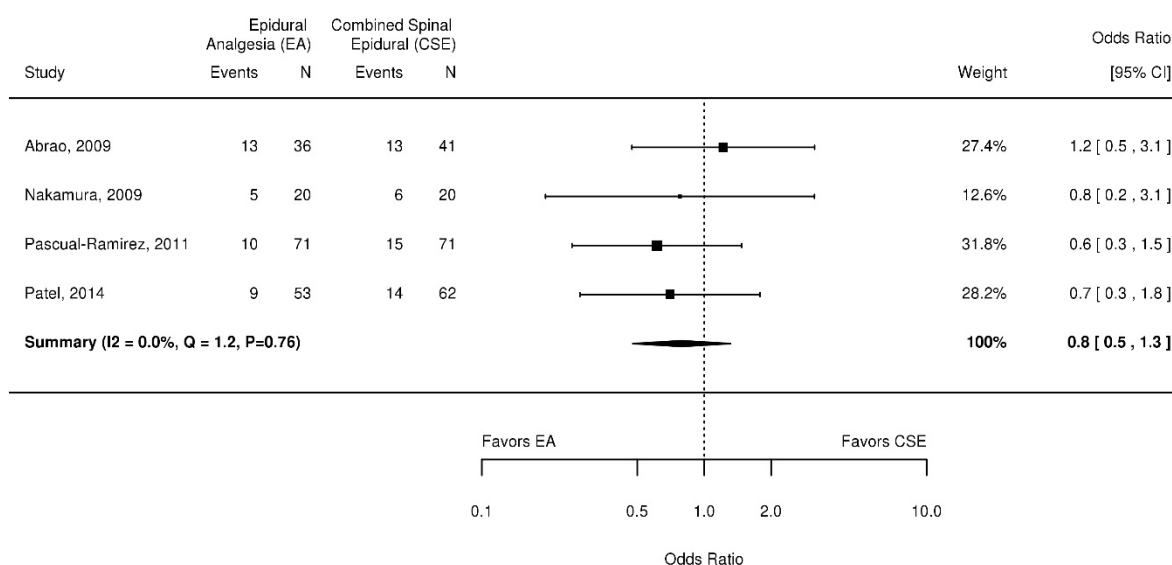
**Table 49. Effects of epidural analgesia versus combined spinal epidural in women of mixed or unspecified parity**

Study Quality	Int N	Com N	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?
Abrao, 2009 <sup>196</sup> Fair	EA 36	CSE 41	—	—	—	13 (36%)	13 (32%)	0.68	No
Nakamura, 2009 <sup>195</sup> Fair	EA 20	CSE 20	—	—	—	5 (25%)	6 (30%)	0.72	No
Pascual-Ramirez, 2011 <sup>78</sup> Good	EA 63 62 62	CSE 58 57 57	Stage 1: 204 min ±109 Stage 2: 42 min ±32 Total: 246 min ±112	Stage 1: 212 min ±133 Stage 2: 43 min ±34 Total: 255 min ±144	Stage 1: 0.85 Stage 2: 0.60 Total: 0.77	10 (14.1%)	15 (21.1%)	0.27	No
Patel, 2014 <sup>190</sup> Fair	EA 53	CSE 62	Total: Median 431 min (IQR 283 to 589)	Total: Median 462 min (IQR 291 to 611)	NS	9 (17.0%)	14 (22.6%)	0.45	No

Abbreviations: —=not reported; CI=confidence interval; Com=comparator; CSE=combined spinal epidural; EA=epidural analgesia; Int=intervention; IQR=interquartile range; Min=minutes; N=number of patients/participants; NS=not significant

A single, good-quality study involving 144 patients of mixed parity reported duration of labor in the comparison of EA versus CSE.<sup>78</sup> In this study, mean duration of the first stage of labor was 204 minutes (SD=109) for EA compared with 212 minutes (SD=133) for CSE ( $p=0.85$ ), and mean duration of the second stage of labor was 42 minutes (SD=32) for EA compared with 43 minutes (SD=34) for CSE ( $p=0.60$ ). SOE was rated as insufficient for both outcomes. Mean time for total duration of labor was 246 minutes (SD=112) for EA, versus 255 minutes (SE=144) for CSE ( $p=0.77$ ). A fair-quality study involving 115 patients also found no difference in median duration of total labor between EA and CSE (low SOE).<sup>190</sup> All four RCTs that compared EA with CSE in a mixed parity population reported cesarean delivery rates.<sup>78,190,195,196</sup> Meta-analysis of these data involving 374 patients of mixed parity generated an estimate of the odds ratio of cesarean delivery associated with CSE relative to EA of 0.8 (95% CI: 0.5 to 1.3) (Figure 8, moderate SOE).

**Figure 8. Epidural analgesia versus combined spinal epidural in women of mixed or unspecified parity—cesarean delivery rates (number of events)**



Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; N=number of participants; SD=standard deviation

## Neonatal Outcomes for Epidural Analgesia Versus Combined Spinal Epidural Analgesia

Neither EA nor CSE was associated with neonatal intensive care admissions in the single, fair-quality RCT involving 115 patients that compared EA with CSE and reported this outcome (insufficient SOE).<sup>190</sup>

## Process-Related Outcomes for Epidural Analgesia Versus Combined Spinal Epidural Analgesia

CSE was found to be associated with a higher proportion of patients with abnormal fetal heart rate tracings than EA in a fair-quality RCT involving 77 patients (31.7% vs. 5.6%, respectively;  $p<0.01$ ).<sup>196</sup> In another fair-quality RCT involving 115 patients,<sup>190</sup> an abnormal fetal heart tracing pattern was noted in 13% of patients in the CSE arm, compared with 6% in the EA

group. This corresponds to a risk ratio of 2.28 (95% CI 0.64 to 8.16) of CSE relative to EA (low SOE).

Another good-quality RCT involving 144 patients assessed maternal satisfaction with analgesia at three different time points: initially; during stage 1 of labor; and during stage 2 of labor.<sup>78</sup> The median maternal satisfaction score of 1 for initial satisfaction was statistically lower (indicating a higher level of satisfaction) for EA compared with CSE with the median score of 2 (p=0.005). There were no statistically significant between-group differences in satisfaction with analgesia during either the first or second stages of labor (insufficient SOE).

## Strength of Evidence for Epidural Analgesia Versus Combined Spinal Epidural Analgesia

Tables 50 and 51 summarize the SOE for the comparison of EA versus CSE. In general, meta analysis of the included studies allowed low and moderate SOE for major outcomes of interest.

**Table 50. Epidural analgesia versus combined spinal epidural: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	5 RCTs <sup>78,191,193,197,202</sup> (1,424)	<b>No difference:</b> Meta-analysis showed no significant differences between EA and CSE in duration of the first stage of labor (mean difference [MD] 32.7 minutes; 95% CI -19.3 to 84.7).	Low (Medium risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	5 RCTs <sup>78,191,193,197,202</sup> (1,424)	<b>No difference:</b> Meta-analysis showed no significant differences between EA and CSE in duration of the second stage of labor (MD -0.2 minutes; 95% CI -21.9 to 21.6).	Low (Medium risk of bias, indirect, inconsistent, imprecise)
	Process Related Outcomes – Total Duration of Labor	5 RCTs <sup>78,191,193,197,202</sup> (1,424)	<b>Worsening with EA:</b> Meta-analysis showed total duration of labor (from time of intervention to delivery) was significantly longer for EA relative to CSE, with an MD of 62.0 minutes (95% CI 7.2 to 116.7).	Moderate (Medium risk of bias, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	5 RCTs <sup>66,191,193,197,202</sup> (1,604)	<b>No difference:</b> Meta-analysis of the data from 1604 patients in these 5 RCTs showed no statistically significant difference in cesarean delivery rates between EA and CSE (OR 1.1; 95% CI 0.9 to 1.2).	Moderate (Indirect)
Adverse Events	Process Related Outcomes – Parental Preferences	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study	Insufficient (imprecise, one study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; MD=mean difference; OR=odds ratio; RCT=randomized controlled trial; SOE=strength of evidence

**Table 51. Epidural analgesia versus combined spinal epidural: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>78</sup> (144)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study	Insufficient (Indirect, imprecise, one study)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>78</sup> (144)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study	Insufficient (Indirect, imprecise, one study)
	Process Related Outcomes – Total Duration of Labor	2 RCTs <sup>78,190</sup> (258)	<b>No difference:</b> No significant difference between EA and CSE for total duration of labor.	Low (Medium risk of bias, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	4 RCTs <sup>78,190,195,196</sup> (374)	<b>No difference:</b> Meta-analysis generated an estimate of the odds ratio of cesarean delivery associated with CSE relative to EA of 0.8 (95% CI: 0.5 to 1.3).	Moderate (Medium risk of bias)
Adverse Events	Neonatal Outcomes – Admission to NICU	1 RCT <sup>190</sup> (115)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study	Insufficient (Medium risk of bias, imprecise, one small study)
	Process Related Outcomes – Abnormal Fetal Heart Tracing	2 RCTs <sup>190,196</sup> (190)	<b>Improvement with EA:</b> CSE was associated with a higher proportion of patients with abnormal fetal heart rate tracings than EA in one study and a risk ratio of 2.28 (95% CI: 0.64 to 8.16) for an abnormal fetal heart tracing in another study.	Low (Medium risk of bias, imprecise)
	Process Related Outcomes – Parental Preferences	1 RCT <sup>78</sup> (142)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study	Insufficient (Imprecise, one small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; CSE=combined spinal epidural; EA=epidural analgesia; RCT=randomized controlled trial; SOE=strength of evidence

## Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia

Results for the comparison of EA and combined PCIA were reported for nulliparous women in one study<sup>191</sup> and for a mixed population of women in three studies.<sup>124,192,194</sup> We also identified one good-quality SR/meta-analysis relevant to this comparison.<sup>33</sup>

### Results in Nulliparous Women

#### Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia

A single, good-quality RCT conducted in Egypt compared duration of labor and cesarean delivery rates associated with EA in comparison with both PCIA with remifentanyl and CSE in 1140 nulliparous women.<sup>191</sup> Duration of labor did not appear to be different between these two groups. Mean duration of labor in hours for EA compared with PCIA were, respectively, 10.8 (SD=3.9) versus 10.3 (SD=3.5) for total labor duration; 7.8 (SD=0.9) versus 7.7 (SD=0.8) for

duration of the latent phase of the first stage; 1.88 (SD=0.7) versus 1.80 (SD=0.6) for duration of the active phase of the first stage; and 1.0 (SD=0.5) versus 0.95 (SD=0.4) for duration of the second stage. The cesarean delivery rate was 25.0% in both groups. Given findings from one RCT in a non-U.S. setting the SOE was rated as insufficient for all outcomes.

### **Process-Related Outcomes for Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia**

The RCT by Ismail et al.<sup>191</sup> assessed maternal overall satisfaction with analgesia 24 hours after delivery was assessed using a 4-point verbal scale ranging from very satisfied to very dissatisfied (1: very dissatisfied, 2: dissatisfied, 3: satisfied, 4: very satisfied).<sup>191</sup> Statistical significance testing for the EA versus PCIA comparison was not reported, but the mean maternal satisfaction score of 2.8 (SD=0.8) for EA was similar to the satisfaction score of 3.0 (SD=0.7) for PCIA (insufficient SOE).

### **Results in Women of Mixed or Unspecified Parity**

Three RCTs compared EA with PCIA among women with mixed or unspecified parity. One was a fair-quality study conducted in Norway involving 23 nulliparous and 16 parous women,<sup>192</sup> one was a fair-quality study conducted in China involving 120 patients of unclear parity,<sup>124</sup> and one was a poor-quality RCT conducted in The Netherlands involving 12 nulliparous and 14 parous patients.<sup>194</sup> Results were not reported separately by parity. Table 52 shows results for these studies.

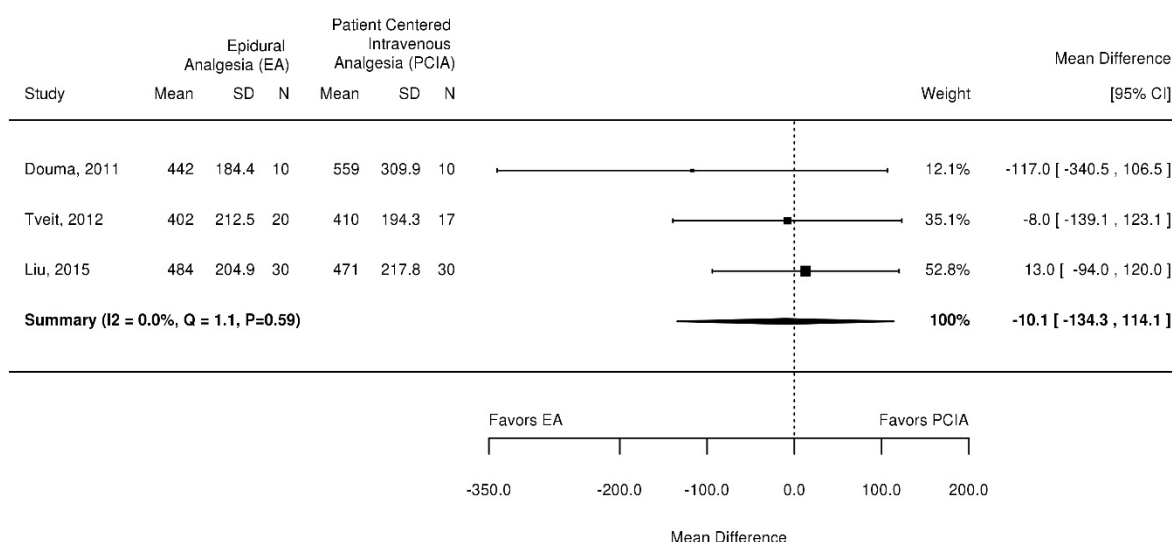
**Table 52. Effects of epidural analgesia versus patient-controlled intravenous analgesia in women of mixed or unspecified parity**

Study Quality	Int N	Com N	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?
Douma, 2011 <sup>194</sup> Poor	EA 10	PCIA 10	Stage 1: 410 min ±173 Stage 2: 32 min ±14	Stage 1: 488 min ±277 Stage 2: 71 min ±40	Stage 1: 0.42 Stage 2: 0.009	2 (20%)	1 (10%)	0.53	No
Liu, 2015 <sup>124</sup> Fair	EA N=30	PCIA 30	Stage 1: 423 min ±181 Stage 2: 61 min ±29	Stage 1: 425 min ±199 Stage 2: 46 min ±9	Stage 1: 0.97 Stage 2: 0.03	2 (6.7%)	2 (6.7%)	1	No
Tveit, 2012 <sup>192</sup> Fair	EA 20	PCIA 17	Stage 1: 360 min ±186 Stage 2: 42 min ±32	Stage 1: 359 min ±188 Stage 2: 51 min ±34	Stage 1: 0.98 Stage 2: 0.41	3 (15.0%)	1 (5.9%)	0.37	No

Abbreviations: Com=comparator; EA=epidural analgesia; Int=intervention; min=minutes; N=number of patients/participants; PCIA=patient-controlled intravenous analgesia

Meta-analysis of these 3 RCTs did not identify differences in duration of labor between these two strategies for analgesia, with the estimated mean difference in total duration of labor after EA administration minus duration after PCIA being -10.1 minutes (95% CI -134.3 to 114.1) (Figure 9). Given the potential risk of bias in all of the included studies and their non-U.S. settings, the SOE was rated as low.

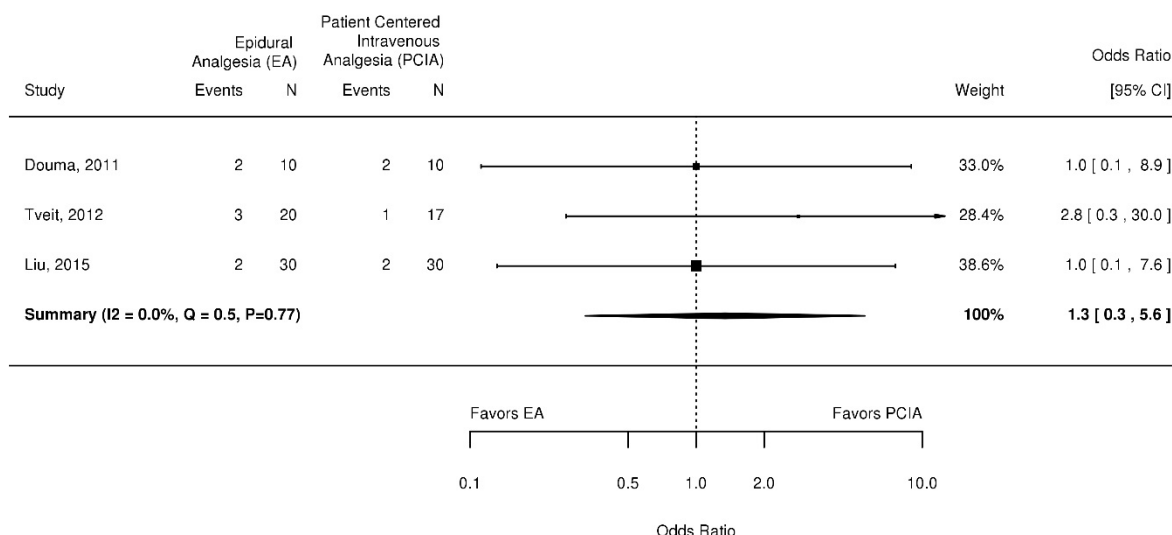
**Figure 9. Epidural analgesia versus patient-controlled intravenous analgesia in women of mixed or unspecified parity—total duration of labor (minutes)**



Abbreviations: CI=confidence interval; EA=epidural analgesia; N=number of participants; PCIA=patient-controlled intravenous analgesia; SD=standard deviation

Meta-analysis of the three RCTs that compared EA with PCIA<sup>124,192,194</sup> generated an estimate of the odds ratio for cesarean delivery of EA relative to PCIA of 1.3 (95% CI 0.3 to 5.6) (Figure 10). This suggests that there is no statistically significant difference in cesarean delivery rates between these two interventions. Again given potential risk of bias, non-U.S. setting, and the imprecision of the findings the SOE was rated as low.

**Figure 10. Epidural analgesia versus patient-controlled intravenous analgesia in women of mixed or unspecified parity—cesarean delivery rates (number of events)**



Abbreviations: CI=confidence interval; EA=epidural analgesia; N=number of participants; PCIA=patient-controlled intravenous analgesia; SD=standard deviation

## Process-Related Outcomes for Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia

In the RCT by Tveit et al.,<sup>192</sup> abnormal fetal heart rate tracings were present in one of 20 patients in the EA group and 2 of 17 patients in the PCIA group. In the same RCT, one of 20 patients in the EA group and none of the 17 patients in the PCIA group delivered a baby with congenital hip displacement. Maternal self-reports of satisfaction with analgesia were similar between the two intervention groups. The SOE was rated as insufficient given imprecise findings in this single small study.

## Relevant Systematic Reviews/Meta-Analyses for Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia

A good-quality SR and meta-analysis published in 2014, with a final search date of November 29, 2012, reviewed and synthesized the findings from published RCTs that compared EA with PCIA with the analgesic medication remifentanyl.<sup>33</sup> Parity of the women included in the studies was not reported. Of the five RCTs included in that SR, three are also included in our review.<sup>191,192,194</sup> We excluded the remaining two studies that were included in the SR by Liu et al. because they did not report outcomes of interest and therefore the findings of the SR do not add to our included evidence and findings.

Two other good-quality reviews, one a Cochrane review<sup>204</sup> and the other an independent review,<sup>205</sup> included 9 trials, but the 6 not included in this review included women who were undergoing induction of labor, and results were not reported separately and therefore did not impact our strength of evidence ratings.



## Strength of Evidence for Epidural Analgesia Versus Patient-Controlled Intravenous Analgesia

Tables 53 and 54 summarize the SOE for the comparison of EA versus CSE. In general, the strength of evidence was judged insufficient for outcomes given the imprecision of the findings, findings for specific outcomes from just one study, and the non-U.S. settings. Low SOE was reported for duration of labor and cesarean delivery in women with mixed or unspecified parity.

**Table 53. Epidural analgesia versus patient-controlled intravenous analgesia: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)
	Process Related Outcomes – Total Duration of Labor	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)
Adverse Events	Process Related Outcomes – Parental Preferences	1 RCT <sup>191</sup> (1,140)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table 54. Epidural analgesia versus patient-controlled intravenous analgesia: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Total Duration of Labor	3 RCTs <sup>124,192,194</sup> (177)	<b>No difference:</b> Meta-analysis did not identify differences in duration of labor, with the estimated mean after EA administration minus duration after PCIA being -10.1 minutes (95% CI -134.3 to 114.1).	Low (Medium risk of bias, imprecise, non-U.S. settings)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>124,192,194</sup> (17)	<b>No difference:</b> Meta-analysis generated an estimate of the odds ratio for cesarean delivery of EA relative to PCIA of 1.3 (95% CI 0.3 to 5.6).	Low (Medium risk of bias, imprecise, non-U.S. settings)
Adverse Events	Process Related Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>192</sup> (37)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Parental Preferences	1 RCT <sup>192</sup> (37)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecise, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; EA=epidural analgesia; PCIA=patient-controlled intravenous analgesia; RCT=randomized controlled trial; SOE=strength of evidence

## Epidural Analgesia Versus Intravascular Tramadol

Results for this comparison were reported for women of mixed parity in one study.<sup>201</sup> No relevant SR/MAs were identified.

### Results in Women of Mixed or Unspecified Parity

A poor-quality RCT (N=90) conducted in India compared epidural tramadol plus bupivacaine versus intravenous tramadol in a mixed parity population.<sup>201</sup> The only outcome of interest reported concerned parental preferences.

### Process-Related Outcomes for Epidural Analgesia Versus Intravascular Tramadol

The distribution of responses for parturient satisfaction (“poor,” “average,” “good,” “excellent”) favored the epidural group ( $p<0.05$ ). Given the high risk of bias, small size, and non-U.S. setting the SOE was rated as insufficient.

## Strength of Evidence for Epidural Analgesia Versus Intravascular Tramadol

Table 55 summarizes the SOE for the comparison of EA versus intravascular tramadol.

**Table 55. Epidural analgesia versus intravascular tramadol: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Parental Preferences	1 RCT <sup>201</sup> (90)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (High risk of bias, Imprecise, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Early Versus Late Epidural Analgesia

Results for this comparison were reported in two good-quality RCTs.<sup>199,200</sup> One relevant good-quality SR/meta-analysis was also identified.<sup>49</sup> All three of these studies focused exclusively on nulliparous women. Although the specifics of the EA protocols differed, in all studies early initiation was defined as EA initiated before the cervix was dilated to 4-5 cm.

### Results in Nulliparous Women

#### Duration of Labor and Cesarean Delivery Rates for Early Versus Late Epidural Analgesia

A good-quality RCT conducted in Israel compared early with late initiation of EA in 449 nulliparous women.<sup>199</sup> Early initiation of EA consisted of immediate initiation of EA at first

request (< 4 cm), and late initiation consisted of delay of EA until the cervix was dilated to at least 4 cm. Mean duration (SD) of the first stage of labor from time of randomization was significantly shorter for early (5.9 hours [2.9]) vs. late (6.6 hours [3.5];  $p=0.04$ ) initiation of EA. Mean duration (SD) of the second stage of labor did not differ between early (95 minutes [59]) vs. late (105 minutes [64];  $p=0.12$ ) initiation of EA. Cesarean delivery rates did not differ between the two groups. Early initiation of EA was associated with a 13% cesarean delivery rate, compared with 11% for late initiation ( $p=0.77$ ).<sup>199</sup>

Another good-quality RCT conducted in the United States randomly allocated 750 nulliparous women to intrathecal fentanyl (using a spinal-epidural technique) at the first request for analgesia and epidural analgesia at the second request for analgesia (early EA) versus systemic hydromorphone at the first request for analgesia and epidural analgesia at either cervical dilatation of 4.0 cm or greater or at the third request for analgesia (late EA).<sup>200</sup> Relative to late EA, early EA was associated with a shorter median time to vaginal delivery with a mean difference of 81 minutes (95% CI 28 to 123) and a shorter duration of the first stage of labor with a mean difference of 81 minutes (95% CI 35 to 123). Mean duration of the second stage of labor, however, did not differ between the two groups, with a mean difference of 11 minutes (95% CI -6 to 21). The cesarean delivery rate of 17.8% associated with early EA was not statistically different from the rate of 20.7% associated with late EA ( $p=0.31$ ).

## Relevant Systematic Reviews/Meta-Analyses for Early Versus Late Epidural Analgesia

A good-quality SR published in 2007 evaluated the effects that different timing of initiation of regional analgesia has on labor outcomes in nulliparous women.<sup>49</sup> The review identified and included 9 eligible RCTs involving a total of 3320 patients. Meta-analysis of 8 of these RCTs involving a total of 2980 patients generated an estimated pooled OR of 1.0 (95% CI 0.82 to 1.23) for cesarean delivery for early neuraxial analgesia relative to control interventions. The duration of labor was no different between interventions. The two RCTs included in our review and summarized above were included in this SR. The remaining 7 RCTs were published prior to the earliest eligible publication date for our review. Given the overlap of this SR with our included studies and the high quality of this SR, our SOE ratings emphasize the findings of the SR. The SOE was lowered, however, given that the included studies from the SR spanned 1994-2006 and may not reflect contemporary clinical practice strategies. Note though that the findings from the later studies included in our review as individual RCTs aligned with the findings of the SR.

## Strength of Evidence for Early Versus Late Epidural Analgesia

Table 56 summarizes the SOE for early versus late epidural analgesia. The SOE was rated as moderate for all outcomes based on evidence from the good-quality SR.

**Table 56. Early versus late epidural analgesia: Evidence profile in nulliparous women<sup>a</sup>**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	1 SR <sup>49</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA with an odds ratio of 0.95 (95% CI 0.81 to 1.10).	Moderate

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	1 SR <sup>49</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA with a weighted mean difference of 0.52 minutes (95% CI -5.03 to 6.06 minutes)	Moderate
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 SR <sup>49</sup> (1,739 patients, 6 studies)	<b>No difference:</b> No differences between early and late EA (odds ratio=1.00, 95% CI 0.83 to 1.21)	Moderate

<sup>a</sup> Early epidural was defined as immediate initiation of EA at first request (< 4 cm), and late initiation consisted of delay of EA until the cervix was dilated to at least 4 cm.

<sup>b</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; EA=early epidural; RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Routine Epidural Analgesia Versus Analgesia on Request

Results for this comparison were reported for women of mixed parity in one study.<sup>68</sup> Results for changes in quality-of-life between antepartum and 6 weeks postpartum from this same study were reported in a subsequent publication.<sup>69</sup> No relevant SR/MAs were identified.

## Results in Women of Mixed or Unspecified Parity

A good-quality RCT conducted in The Netherlands compared routine EA with analgesia on request in the form of intramuscular opiates or EA at the first or second request for pain relief after opiates.<sup>68</sup> Of the 233 patients randomized to routine EA and the 255 women randomized to analgesia on request, 115 (49%) and 122 (48%), respectively, were nulliparous.

## Duration of Labor and Cesarean Delivery Rates for Routine Epidural Analgesia Versus Analgesia on Request

Median duration of the second stage of labor did not differ between EA (20 minutes; IQR, 10 to 50) compared with analgesia on request (19 minutes; IQR, 8.0 to 45). This corresponds to a difference in means of 2.0 (95% CI -3.2 to 7.1).<sup>68</sup> In the EA group, 44 patients (19% of all patients randomized to EA) underwent cesarean delivery versus 39 patients in the analgesia on request group (15% of all patients randomized to analgesia on request). This corresponds to a between-group difference in percentage of 3.6 (95% CI -3.1 to 10.3).<sup>68</sup> Given the imprecision in findings from one study the SOE was rated as insufficient.

## Maternal Outcomes for Early Versus Late Epidural Analgesia

The maternal outcomes reported in this study were postpartum hemorrhage and trauma to the pelvic floor (perineal laceration). There was no difference in the percentage of patients who experienced postpartum hemorrhage of greater than 1000 mL of blood loss between women in the EA group (6.0%) versus women in the analgesia-on-request group (4.3%). This corresponds to a difference in percentage of -0.6 (95% CI -3.5 to 2.4).<sup>68</sup>

There was no difference in the percentage of patients who experienced third- or fourth-degree perineal laceration between women in the EA group (0.9%) versus women in the analgesia-on-request group (1.6%). This corresponds to a difference in percentage of -0.7 (95% CI -2.6 to 1.2).<sup>68</sup> Again the SOE was rated as insufficient given the findings from this one study.

A later publication from this study reported on change in generic quality-of-life between antepartum and 6 weeks postpartum, as measured by the Short Form 36 (SF-36) and found no difference in either overall score or scores on individual subscales (n=488). Again the SOE was rated as insufficient given the findings from this one study.<sup>69</sup>

### Neonatal Outcomes for Early Versus Late Epidural Analgesia

Delivery was complicated by shoulder dystocia in 5 patients (2.1%) in the EA group versus 8 patients (3.1%) in the analgesia-on-request group. This corresponds to a difference in percentage of -1.0 (95% CI: -3.8 to 1.8) (insufficient SOE).<sup>68</sup>

### Strength of Evidence for Early Versus Late Epidural Analgesia

Table 57 summarizes the SOE for early versus late epidural analgesia. The SOE was rated as insufficient for all outcomes.

**Table 57. Routine epidural analgesia versus analgesia on request: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>68</sup> (603)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>68</sup> (603)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>68</sup> (603)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Maternal Outcomes – Hemorrhage	1 RCT <sup>68</sup> (603)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Maternal Outcomes-Quality of life	1 RCT <sup>69</sup> (488)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (imprecision, one study, non-U.S. setting)
	Neonatal Outcomes – Shoulder Dystocia	1 RCT <sup>68</sup> (603)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

### Combined Spinal Epidural Analgesia Versus Nonpharmacologic Pain Relief

Results for this comparison were reported for women of mixed parity in one study, which was described in two papers.<sup>76,77</sup> No relevant SR/MAs were identified.

## Results in Women of Mixed or Unspecified Parity

A good-quality RCT conducted in Brazil randomized 35 patients of mixed parity to CSE and 35 patients to only nonpharmacologic methods of pain relief during delivery. Patients in both groups received continuous support throughout labor, including assistance provided by a doula, the use of exercise balls, massage, and music therapy.<sup>76</sup>

### Duration of Labor and Cesarean Delivery Rates for Combined Spinal Epidural Analgesia Versus Nonpharmacologic Pain Relief

Median duration of the first stage of labor was significantly shorter among patients who received CSE (180 minutes; IQR, 90 to 240) versus patients who received nonpharmacologic care only (265 minutes; IQR, 160 to 365;  $p=0.01$ ). Median duration of the second stage of labor was not different between CSE and nonpharmacologic care (30 minutes; IQR, 20 to 47.5 vs. 30 minutes; IQR, 20 to 50, respectively;  $p=0.97$ ).<sup>76</sup> Of the 35 patients randomized to CSE, 4 (11%) delivered via cesarean delivery compared with 7 of 35 patients (21%) randomized to nonpharmacologic care only ( $p=0.23$ ).<sup>76</sup> SOE was rated as insufficient for all outcomes given findings from one small study.

### Process-Related Outcomes for Combined Spinal Epidural Analgesia Versus Nonpharmacologic Pain Relief

This study reported two process-related outcomes, abnormal fetal heart rate tracings and maternal satisfaction. There was no between-group difference in the rate of abnormal fetal heart rate tracings (6% for CSE vs. 9% for nonpharmacologic care only;  $p=0.5$ ) (insufficient SOE).

Maternal satisfaction was significantly greater for CSE than for nonpharmacologic care only, with 97% of the patients in the CSE group reporting satisfaction with the method of pain control versus 69% in the nonpharmacologic care group ( $p=0.001$ ), and 94% versus 71% ( $p=0.01$ ), respectively, reporting satisfaction with delivery (insufficient SOE).<sup>77</sup>

### Strength of Evidence for Combined Spinal Epidural Analgesia Versus Nonpharmacologic Pain Relief

Table 58 summarizes the SOE for combined spinal epidural analgesia versus nonpharmacologic pain relief. The SOE was rated as insufficient for all outcomes.

**Table 58. Strength of evidence for combined spinal epidural analgesia versus nonpharmacologic pain relief in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>76</sup> (70)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>76</sup> (70)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>76</sup> (70)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Process Related Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>76</sup> (70)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – Parental Preferences	1 RCT <sup>76</sup> (70)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one small study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Epidural Analgesia Versus Intravenous Meperidine

Results for this comparison were reported for nulliparous women in one study.<sup>198</sup> No relevant SR/MAs were identified.

### Results in Nulliparous Women

A fair-quality RCT conducted in Iran randomized 395 nulliparous women to EA (n=197) or a single dose of intravenous meperidine (n=198).<sup>198</sup> Given findings from one study in a non-U.S. setting with medium risk of bias the SOE was rated as insufficient for all outcomes.

### Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Intravenous Meperidine

There were no significant between-group differences (p values reported as not significant) in either the mean duration of the active phase of the first stage of labor (2.5 hours [SD 1.4] for EA versus 2.4 hours [SD 1.6] for meperidine) or the second stage of labor (1.0 hours [SD 0.7] for EA versus 0.9 hours [SD 0.7] for meperidine).<sup>198</sup> There were no significant between-group differences (p values reported as not significant) in rates of cesarean delivery for dystocia (4% for EA vs. 4% for meperidine) or for bradycardia (8% for EA vs. 5% for meperidine).<sup>198</sup>

### Neonatal Outcomes for Epidural Analgesia Versus Intravenous Meperidine

There were no admissions to the neonatal intensive care unit associated with either EA or meperidine.<sup>198</sup>

### Strength of Evidence for Epidural Analgesia Versus Intravenous Meperidine

Table 59 summarizes the SOE for epidural analgesia versus intravenous meperidine. The SOE was rated as insufficient for all outcomes.

**Table 59. Epidural analgesia versus intravenous meperidine: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>198</sup> (395)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>198</sup> (395)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>198</sup> (395)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
Adverse Events	Neonatal Outcomes – NICU Admissions	1 RCT <sup>198</sup> (395)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: NICU=neonatal intensive care unit; RCT=randomized controlled trial; SOE=strength of evidence



## Epidural Analgesia Versus Low-Dose Infusion Epidural Analgesia

Results for this comparison were reported for nulliparous women in one study.<sup>66</sup> No relevant SR/MAs were identified.

### Results in Nulliparous Women

A fair-quality RCT conducted in the UK randomized 1052 nulliparous women to EA (n=253), CSE (n=351), or low dose infusion EA (n=350) to allow for ambulation during labor.<sup>66</sup> Results for the comparison of EA versus low-dose infusion EA are reported below. Cesarean delivery rate was the only outcome of interest reported. Given the imprecise findings from only one study performed in a non-U.S. setting the SOE was rated as insufficient.

### Cesarean Delivery Rates for Epidural Analgesia Versus Low-Dose Infusion Epidural Analgesia

Rates of cesarean delivery did not appear to differ between EA (27%) and low-dose infusion EA (29%) (p value not reported).<sup>66</sup>

### Strength of Evidence for Epidural Analgesia Versus Low-Dose Infusion Epidural Analgesia

Table 60 summarizes the SOE for epidural analgesia versus low-dose infusion epidural analgesia. The SOE was rated as insufficient for all outcomes.

**Table 60. Epidural analgesia versus low-dose infusion epidural analgesia: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>66</sup> (1,052)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Epidural Analgesia Versus Acupuncture

Results for this comparison were reported for nulliparous women in two studies<sup>176,181</sup> and women of unspecified parity in one study.<sup>124</sup> No relevant SR/MAs were identified.

### Results in Nulliparous Women

In one fair-quality RCT conducted in China, 131 nulliparous women were randomized to continuous spinal EA (n=45), acupuncture (n=43), or no analgesia (n=43); formal comparisons were only made between acupuncture and epidural, and acupuncture and control.<sup>176</sup> The second fair quality RCT randomized 127 nulliparous women to continuous spinal EA with patient-controlled EA alone (n=66) or continuous spinal EA and patient-controlled EA plus electroacupuncture (n=61). Given findings from two small studies in a non-U.S. setting, and differences in the comparisons, the SOE was rated as insufficient for all outcomes.

## Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Acupuncture

In the study of Wu et al, mean duration (SD) of the active first stage of labor in women randomized to EA was 4.5 hours (2.3) compared to 3.0 hours (1.0) in women randomized to acupuncture ( $p<0.05$ ). There were no significant differences reported for duration of second stage of labor. Mode of delivery was not reported.<sup>176</sup>

In the study of Xiao et al, which evaluated electroacupuncture as an adjunct to epidural alone, median duration (interquartile range) of the first stage was 260 minutes (236 minutes) in the electroacupuncture group and 362 minutes (355 minutes) for the epidural only group ( $p<0.05$ ). Second stage of labor was not significantly different between groups (median 81 minutes with electroacupuncture, 92 minutes without). Cesarean section rates were also lower with electroacupuncture, but low overall numbers limited power (1.6% vs 9.1%,  $p=0.07$ ). Use of oxytocin was significantly lower with electroacupuncture (16.7% vs 50%,  $p<0.05$ )<sup>181</sup>

## Maternal Outcomes for Epidural Analgesia Versus Acupuncture

In the Wu et al study, the mean (SD) volume of estimated blood loss was significantly higher with EA—320.0 (85.6) ml—compared to acupuncture--273.7 (53.6) ml—but the clinical significance of this difference was not reported.<sup>176</sup>

## Neonatal Outcomes for Epidural Analgesia Versus Acupuncture

In the Wu study, although the authors reported “neonatal asphyxia” (defined as Apgar less than 7), they did not specify whether these were 1 or 5 minute Apgar scores. There was no difference in incidence (11.1% in the epidural group vs 9.3% in the acupuncture group).<sup>176</sup> Xiao et al. did not report an incidence for neonatal asphyxia; median cord blood pH and 1 and 5 minute Apgar scores were identical between the two groups.

## Strength of Evidence for Epidural Analgesia Versus Acupuncture

Table 61 summarizes the SOE for epidural analgesia versus acupuncture. The SOE was rated as insufficient for all outcomes.

**Table 61. Epidural analgesia versus acupuncture point nerve stimulation: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	2 RCTs <sup>176, 181</sup> (258)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from two studies performed in a non-U.S. setting.	Insufficient (Imprecision, two studies, non-U.S. setting)
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	2 RCTs <sup>176, 181</sup> (258)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from two studies performed in a non-U.S. setting.	Insufficient (Imprecision, two studies, non-U.S. setting)
Adverse Events	Maternal Outcomes – Hemorrhage	1 RCT <sup>176</sup> (131)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Neonatal Outcomes – Hypoxia	2 RCTs <sup>176, 181</sup> (258)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from two studies performed in a non-U.S. setting.	Insufficient (Imprecision, two studies, non-U.S. setting)

<sup>a</sup>Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Results in Women of Mixed or Unspecified Parity

In a fair-quality RCT conducted in China, 120 patients of unspecified parity were randomized to EA (n=30), PCIA (n=30), acupuncture point nerve stimulation (n=30), or no analgesia (n=30).<sup>124</sup> Results for the comparison of EA versus acupuncture point nerve stimulation are reported below. Given findings from one small study in non-U.S. setting, the SOE was rated as insufficient for all outcomes.

### Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus Acupuncture Point Nerve Stimulation

Mean duration (SD) of the first stage of labor associated with EA was 423 minutes (181) compared with 430 minutes (120) for acupuncture point nerve stimulation. Mean duration (SD) of the second stage of labor was 61 minutes (29) for EA versus 43 minutes (18) for acupuncture point nerve stimulation. Statistical significance testing for these two comparisons was not reported.<sup>124</sup> Two of the 30 patients (6.7%) randomized to receive EA delivered via cesarean delivery, compared with 1 of the 30 patients (3.3%) in the acupuncture point nerve stimulation group (p value not reported).<sup>124</sup>

### Maternal Outcomes for Epidural Analgesia Versus Acupuncture Point Nerve Stimulation

The only maternal outcome reported in this study was postpartum hemorrhage. The mean volume of postpartum blood loss (SD) was estimated to be 125 mL (24) for the patients in the EA group, compared with 127 mL (23) in the acupuncture point nerve stimulation group (p value not reported).<sup>124</sup>

### Neonatal Outcomes for Epidural Analgesia Versus Acupuncture Point Nerve Stimulation

Neonatal hypoxia (not described further in the original report) occurred in 1 of 30 patients (3.3%) in the EA group and 2 of 30 (6.7%) in the acupuncture point nerve stimulation group (p value not reported).<sup>124</sup>

### Strength of Evidence for Epidural Analgesia Versus Acupuncture Point Nerve Stimulation

Table 62 summarizes the SOE for epidural analgesia acupuncture point nerve stimulation. The SOE was rated as insufficient for all outcomes.

**Table 62. Epidural analgesia versus acupuncture point nerve stimulation: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
Adverse Events	Maternal Outcomes – Hemorrhage	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)
	Neonatal Outcomes – Hypoxia	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting.	Insufficient (Imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Epidural Analgesia Versus No Epidural Analgesia

Results for this comparison were reported for nulliparous women in two studies<sup>189,203</sup> and for women of unspecified parity in another.<sup>124</sup> One relevant good-quality SR/meta-analysis that included studies of both nulliparous and parous women was identified.<sup>43</sup>

### Results in Nulliparous Women

A fair-quality RCT conducted in Turkey randomly allocated 50 nulliparous patients each to vaginal delivery with EA (bupivacaine and fentanyl) or with no EA (1% lidocaine).<sup>189</sup> Three patients in the EA group and 2 in the no-EA group underwent cesarean delivery and were thus excluded from the study. Duration of labor was the only outcome of interest reported.

A good-quality RCT conducted in China randomly allocated 400 nulliparous women in spontaneous labor with an epidural in place to either continued epidural analgesia (ropivacaine and sufentanil) or placebo during the second stage of labor. Duration of second stage, mode of delivery, and neonatal Apgar scores were reported.<sup>203</sup>

### Duration of Labor and Mode of Delivery for Epidural Analgesia Versus No Epidural Analgesia

Mean duration (SD) of the active phase of the first stage of labor was significantly shorter in the EA group (218 minutes [166]) than in the no-EA group (259 minutes [158];  $p=0.048$ ). However, mean duration of the second stage of labor was significantly longer in the EA group (29.6 minutes [43.0]) than in the no-EA group (24.8 minutes [35.3];  $p=0.043$ ).<sup>189</sup> Given findings from one study in a non-U.S. setting with medium risk of bias, the SOE was rated as insufficient.

Mean duration (SD) of the second stage did not differ between women allocated to epidural (52 minutes [25]) or placebo (51 minutes [27]). Mode of delivery also did not differ significantly, but the number of non-vaginal deliveries was quite low (2 cesarean sections in the epidural group vs 0 in the placebo group, 5 forceps deliveries in the epidural group vs 2 in the

placebo group). Given findings from one study in a non-U.S. setting with substantial imprecision, the SOE was rated as insufficient.<sup>203</sup>

### **Neonatal Outcomes for Epidural Analgesia Versus No Epidural Analgesia**

Apgar scores less than 9 at 5 minutes did not differ, but the number of events was, again, quite low (0 in the placebo group, 3 in the epidural group). Given findings from one study in a non-U.S. setting with substantial imprecision, the SOE was rated as insufficient.

### **Results in Women of Mixed or Unspecified Parity**

In a fair-quality RCT conducted in China, 120 patients of unspecified parity were randomized to EA (n=30), PCIA (n=30), acupuncture point nerve stimulation (n=30), or no analgesia (n=30).<sup>124</sup> In this section we focus only on the EA versus no EA groups.

### **Duration of Labor and Cesarean Delivery Rates for Epidural Analgesia Versus No Epidural Analgesia**

Mean duration (SD) of the first stage of labor associated with EA was 423 minutes (181), compared with 440 minutes (200) for no analgesia ( $p=0.73$ ). Mean duration (SD) of the second stage of labor was 61 minutes (29) for EA versus 46 minutes (21) for no analgesia ( $p=0.02$ ).<sup>124</sup> Two of the 30 patients (6.7%) randomized to receive EA delivered via cesarean delivery, compared with 8 of the 30 patients (27%) in the no-analgesia group ( $p=0.036$ ).<sup>124</sup>

### **Maternal Outcomes for Epidural Analgesia Versus No Epidural Analgesia**

The only maternal outcome reported in this study was postpartum hemorrhage. The mean volume of postpartum blood loss (SD) was estimated to be 125 mL (24) for the patients in the EA group, compared with 140 mL (29) in the no-analgesia group ( $p=0.03$ ).<sup>124</sup>

### **Neonatal Outcomes for Epidural Analgesia Versus No Epidural Analgesia**

Neonatal hypoxia (not described further in the original report) occurred in 1 of 30 patients (3.3%) in the EA group and 2 of 30 (6.7%) in the no analgesia group ( $p=0.55$ ).<sup>124</sup>

### **Relevant Systematic Reviews/Meta-Analyses for Epidural Analgesia Versus No Epidural Analgesia**

A good-quality SR published in 2011 summarized and synthesized data from eligible RCTs that compared EA with non-epidural analgesia or no analgesia in labor.<sup>43</sup> The authors of that review identified and included 38 studies involving 9,658 patients of mixed parity. Neither of the two RCTs that compared EA with no analgesia that met our eligibility criteria were included in this SR because of publication date eligibility criteria. Similar to our included study, results of MAs reported in this SR suggest that relative to non-epidural analgesia or no analgesia in labor, the duration of the first stage of labor associated with EA is not significantly longer (MD 18.51 minutes, 95% CI -12.91 to 49.42), but that the duration of the second stage of labor is slightly longer with EA (MD 13.66 minutes, 95% CI 6.67 to 20.66). Different from our included study, the pooled RR for cesarean deliveries associated with EA relative to nonepidural or no analgesia was estimated to be 1.10 (95% CI 0.97 to 1.25) demonstrating no difference. These findings are from studies with mixed parity.

## Strength of Evidence for Epidural Analgesia Versus No Epidural Analgesia

Tables 63 and 64 summarize the SOE for outcomes comparing epidural analgesia versus no epidural analgesia. The SOE was rated as moderate for major outcomes of labor duration and cesarean delivery based on the findings from a large SR.

**Table 63. Epidural analgesia versus no epidural analgesia: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>189</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting with medium risk of bias.	Insufficient (Medium risk of bias, imprecision, one study, non-U.S. setting)
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	2 RCTs <sup>189,203</sup> (500)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from two studies performed in a non-U.S. setting with medium risk of bias.	Insufficient (Medium risk of bias, imprecision, two studies, non-U.S. setting)
Adverse Events	Neonatal outcomes – Apgar score <9 at 5 minutes	1 RCT <sup>203</sup>	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one study performed in a non-U.S. setting	Insufficient (Medium risk of bias, imprecision, one study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

**Table 64. Epidural analgesia versus no epidural analgesia: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – 1 <sup>st</sup> Stage of Labor	1 RCT <sup>124</sup> (120)  1 SR <sup>43</sup> (2,981 patients, 11 studies)	<b>No difference:</b> No evidence of a significant difference between EA and no EA (MD 18.51 minutes, 95% CI -12.91 to 49.42).	Moderate  Consistent with SR findings.
	Process Related Outcomes – 2 <sup>nd</sup> Stage of Labor	1 RCT <sup>124</sup> (120)  1 SR <sup>43</sup> (4,233 patients, 13 studies)	<b>Worsening with EA:</b> Women with epidural analgesia had a statistically significant longer second stage of labor (average MD 13.66 minutes, 95% CI 6.67 to 20.66).	Moderate  Consistent with SR findings.
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>124</sup> (120)  1 SR <sup>43</sup> (8,417 patients, 27 studies)	<b>No difference:</b> No evidence of a significant difference in the risk of caesarean section overall (RR 1.10, 95% CI 0.97 to 1.25).	Moderate  Consistent with SR findings.
Adverse Events	Maternal Outcomes – Hemorrhage	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study performed in a non-U.S. setting with medium risk of bias.	Insufficient (Medium risk of bias, imprecision, 1 study, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Neonatal Outcomes – Hypoxia	1 RCT <sup>124</sup> (120)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study performed in a non-U.S. setting with medium risk of bias.	Insufficient (Medium risk of bias, imprecision, 1 study, non-U.S. setting)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; EA=epidural analgesia; MD=mean difference; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

## Key Question 5. Frequency of Cervical Examination

KQ 5 was: How does the frequency of cervical examination affect the probability of specific benefits and harms?

### Description of Included Studies

We identified no RCTs and only one good-quality SR<sup>206</sup> that met the inclusion criteria for this KQ. The focus of the SR was to compare different methods of assessing labor progression through the use of vaginal examinations. The objective was to compare digital vaginal examinations for assessing progress of labor to other strategies or different timings.

### Key Point for Frequency of Cervical Examination

- There was insufficient SOE for all outcomes regarding the frequency of cervical examination.

### Detailed Synthesis for Frequency of Cervical Examination

We identified one good-quality SR<sup>206</sup> which included two studies comparing the effects of vaginal examinations versus other strategies or different timings on the progression of labor and maternal and neonatal health outcomes. Only one of the studies included was relevant to this KQ: an RCT of 150 women undergoing routine vaginal examinations every 2 hours compared to every 4 hours.<sup>207</sup> The authors of the SR considered this study to be of poor quality due to the lack of description regarding allocation concealment in the randomization process and participants being excluded from the study after randomization who developed exclusion criteria prior to labor. The included study did not meet our inclusion criteria due to date of publication (1996).

The main outcomes were mode of birth, length of labor, incidence of maternal or neonatal infection requiring antibiotics, maternal satisfaction with intrapartum care, and hemorrhage. There was no difference between every-2-hour and every-4-hour examinations for cesarean deliver (RR 0.77; 95% CI, 0.36 to 1.64), spontaneous vaginal birth (RR 0.98; 95% CI, 0.80 to 1.21), and operative vaginal birth (RR 1.44; 95% CI, 0.66 to 3.17). The mean difference in length of labor was -6.00 minutes (95% CI, -88.70 to 76.70). There were no data on the incidence of maternal or infant infection requiring antibiotics or maternal satisfaction in labor (SOE insufficient for all outcomes).

## Strength of Evidence for Frequency of Cervical Examination

Table 65 summarizes the SOE for the findings described above. All outcomes had insufficient SOE.

**Table 65. Cervical examination versus other strategies: Evidence profile in women of unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	1 RCT <sup>206</sup> (150)	<b>Inconclusive:</b> SOE was insufficient given evidence from 1 older poor-quality study with imprecise findings.	Insufficient (High risk of bias, Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>206</sup> (150)	<b>Inconclusive:</b> SOE was insufficient given evidence from 1 older poor-quality study with imprecise findings.	Insufficient (High risk of bias, Imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 6. Intrauterine Pressure Catheters

KQ 6 was: What are the benefits and harms of intrauterine pressure catheters in the diagnosis and management of labor dystocia?

### Description of Included Studies

We did not identify any RCTs that met the inclusion criteria for this KQ. Below we describe results from one good-quality SR that addressed the benefits and harms of intrauterine pressure catheters in the diagnosis and management of labor dystocia.<sup>37</sup>

### Key Point for Intrauterine Pressure Catheters

- There were no statistically significant differences between intrauterine pressure catheters and external uterine monitoring for the outcomes of mode of delivery, mean time to delivery, neonatal acidemia, or admission to the NICU (moderate SOE for all outcomes).

### Detailed Synthesis for Intrauterine Pressure Catheters

A good-quality SR included 3 good-quality RCTs comparing the use of intrauterine pressure catheters versus external monitoring in women being induced or augmented in labor. One study (n=150) was restricted to women in spontaneous labor with a diagnosis of dystocia while the other two included both augmented and induced labors; one of these reported results by indication for oxytocin (500 women were augmented). We summarize here the pooled subgroup analyses for this population. The primary studies were not included in our review because of date of publication.

Maternal outcomes included the process outcomes of mode of delivery and duration of labor in addition to risk of infection. In the pooled analyses, internal monitoring increased the proportion of operative vaginal deliveries (OR 1.25, 95% CI 1.02 to 1.53); cesarean delivery rates were also higher with internal monitoring, but not significantly (OR 1.25, 95% CI 0.91 to 1.21). Of note, there was statistically significant evidence of heterogeneity in results comparing



the augmented to the induced subgroups. There was no significant difference in the mean time to delivery in women with augmented labor who had an intrauterine pressure catheter (296.84 minutes) versus external fetal monitoring (297.19 minutes) in the one study that reported this outcome ( $p=0.99$ ); median times to delivery in both studies were also similar. There were no differences for signs of infection in labor for women with internal versus external tocodynamometry (RR 0.69; 95% CI, 0.44 to 1.08).

Neonatal outcomes were not reported for the relevant subgroups.

## Strength of Evidence for Intrauterine Pressure Catheters

Table 66 summarizes the SOE for the findings described above. The SOE was rated as moderate for all outcomes assessed given consistent findings from good-quality RCTs.

**Table 66. Intrauterine pressure catheters versus external monitoring: Evidence profile in women of unspecified parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Total Labor	1 SR <sup>37</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in mean time to delivery with intrauterine pressure catheters compared to external monitoring	Moderate (Indirect)
	Process Related Outcomes – Mode of Delivery	1 SR <sup>37</sup> (750 patients, 2 studies)	<b>No difference:</b> Comparing intrauterine pressure catheters to external monitoring, there was no difference in delivery by operative vaginal delivery (RR 1.25, 95% CI 0.91 to 1.73) or by cesarean deliver (RR 1.25, 95% CI 0.91 to 1.71).	Moderate (Indirect)
Adverse Events	Maternal Outcomes – Infection	1 SR <sup>37</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in signs of infection in labor in women with intrauterine pressure catheters compared to external monitoring (RR 0.69, 95% CI 0.44 to 1.08).	Moderate (Indirect)
	Neonatal Outcomes – Acidemia	1 SR <sup>37</sup> (1,456 patients, 2 studies)	<b>No difference:</b> No differences in neonatal acidemia ( $pH < 7.15$ ) in infants of women with intrauterine pressure catheters compared to external monitoring (RR 1.31, 95% CI 0.95 to 1.79).	Moderate (Indirect)
	Neonatal Outcomes – Admission to NICU	1 SR <sup>37</sup> (489 patients, 2 studies)	<b>No difference:</b> No differences in admission to NICU in infants of women with intrauterine pressure catheters compared to external monitoring (RR 0.34, 95% CI 0.07 to 1.67).	Moderate (Indirect)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: CI=confidence interval; NICU=neonatal intensive care unit; RCT=randomized controlled trial; RR=relative risk; SOE=strength of evidence; SR=systematic review

## Key Question 7. High-Dose Versus Low-Dose Oxytocin Protocols

KQ 7 was: For women with abnormal labor, what are the relative benefits and harms of high-versus low-dose oxytocin protocols (including nipple stimulation)?

In this Key Question, we review the evidence on the effect on specific approaches to oxytocin augmentation, including dose, method of administration (pulsatile vs. continuous), and timing of administration relative to phase of labor. Note that how high and low dose oxytocin is defined varies between studies and so we have listed each study's specific protocol within the text.

### Description of Included Studies

We identified 12 articles<sup>74,75,114,117,208-215</sup> representing 11 individual RCTs that examined the benefits and harms of high-dose versus low-dose oxytocin protocols for women with abnormal labor. Of the 11 included studies, 6 were conducted in UK/Europe,<sup>74,208-211,215</sup> 3 were conducted in Asia,<sup>117,213,214</sup> one was conducted in Canada,<sup>212</sup> and one was conducted in the Middle East.<sup>114</sup> All eleven studies were conducted in a hospital setting. Four studies reported government funding,<sup>74,208-210</sup> two reported non-government, non-industry funding,<sup>211,213</sup> one reported a combination of government and non-government, non-industry funding,<sup>212</sup> and four were unclear or did not report the funding source.<sup>114,117,214,215</sup> Finally, of the eleven included studies, seven were rated as good quality,<sup>114,117,208-211,215</sup> three were rated as fair quality,<sup>74,212,214</sup> and one was rated as poor quality.<sup>213</sup>

Of the 11 studies, 6 RCTs<sup>117,208,212-215</sup> and 3 SR/MAs<sup>216-218</sup> addressed high-dose versus low-dose oxytocin protocols for women with abnormal labor. Two RCTs<sup>74,210</sup> and two SR/MAs<sup>219,220</sup> addressed the timing of oxytocin augmentation following a diagnosis of abnormal labor. Two RCTs<sup>209,213</sup> studied the effect of pulsatile oxytocin infusions and another<sup>211</sup> the use of adjuvant beta-blockade with oxytocin. One SR/MA studied the effect of oxytocin augmentation with regional analgesia,<sup>221</sup> and one SR/MA<sup>220</sup> and two RCTs<sup>114,218</sup> compared oxytocin with no oxytocin in women with abnormal labor.

In addition to the above studies, five good-quality systematic reviews<sup>216,217,219-221</sup> and one fair-quality systematic review<sup>218</sup> addressed the benefits and harms of oxytocin protocols are also discussed below.

### Key Points for High-Dose Versus Low-Dose Oxytocin Protocols

- In nulliparous women, high-dose oxytocin is associated with a lower cesarean delivery rate (moderate SOE) compared with low-dose oxytocin protocols with no difference in maternal hemorrhage (low SOE).
- Early administration of oxytocin is associated with a shorter duration of labor (moderate SOE) but does not affect the overall cesarean delivery rate compared with delayed administration (moderate SOE). There is no difference in adverse events of maternal outcomes of hemorrhage or transfusion (low SOE) or in mode of delivery (low SOE).
- Pulsatile administration of oxytocin is associated with a longer duration of labor compared with continuous administration (low SOE).
- There is no difference in cesarean delivery rate between women managed with oxytocin compared to expectant management (moderate SOE).

## Detailed Synthesis for High-Dose Versus Low-Dose Oxytocin Protocol

Oxytocin is a peptide and powerful uterotonic agent that is synthesized in the hypothalamus and secreted in a pulsatile fashion from the posterior pituitary. The synthetic version of oxytocin, Pitocin, is identical to the naturally-occurring hormone and is commonly used in obstetrics for induction and augmentation of labor. Due to its short serum half-life and narrow therapeutic range, oxytocin is given as a continuous intravenous infusion and begun at a low rate and then incrementally increased until a regular contraction pattern is achieved. Intravenous oxytocin dosing protocols are typically classified as either low-dose or high-dose based on the initial starting dose and by the interval of dose increase (Table 67).<sup>222</sup>

**Table 67. Low-dose and high-dose oxytocin infusion protocols**

Regimen	Starting Dose (mU/min)	Incremental Increase (mU/min)	Dosage Interval (min)
Low-dose	0.5-2	1-2	15-40
High-dose	4 or higher	3-6	15-40

Abbreviations: mU/min=milliunits per minute; min=minutes

## High-Dose Versus Low-Dose Oxytocin for Abnormal Labor

### Results in Nulliparous Women

#### Duration of Labor and Cesarean Delivery Rates for High-Dose Versus Low-Dose Oxytocin

We identified four RCTs<sup>117,208,212,215</sup> and three SR/MAs<sup>216-218</sup> that compared high-dose versus low-dose oxytocin protocols for nulliparous women with abnormal labor. One good-quality RCT<sup>117</sup> consisted of 960 nulliparous women in spontaneous labor in Thailand and compared active management versus conventional management of labor. The active management included early rupture of the membranes and a high-dose oxytocin infusion protocol (starting at 6 mU/min, increasing by 2 mU/min every 30 minutes to a maximal rate of 40 mU/min or to five contractions in 10 minutes). The specifics of the low-dose oxytocin protocol were not provided.

Women receiving the high-dose oxytocin protocol had a shorter duration of the first stage of labor but no difference in the duration of the second stage of labor compared with women receiving the conventional protocol, but there was no difference in mode of delivery or indication for cesarean or rates of maternal fever or chorioamnionitis between the two groups.<sup>117</sup> (Table 68).

In a second good-quality RCT<sup>215</sup>, high-dose (6.6mU/min with incremental increases of 6.6mU/min) oxytocin was compared to low-dose (3.3mU/min with incremental increases of 3.3mU/min) oxytocin in 1295 nulliparous women in Sweden with delayed labor. This study found no difference in cesarean delivery rate between groups, but the high-dose group had shorter labors and more instances of tachysystole.

In a third good-quality RCT,<sup>208</sup> high-dose oxytocin was compared to a standard protocol among nulliparous women in the UK with spontaneous onset of labor and labor complicated by dystocia. This study was a feasibility pilot RCT. Duration of labor was not reported, but there were no differences in mode of delivery or indication for cesarean.<sup>208</sup> (Table 68).

In another feasibility pilot RCT (fair-quality) conducted in Canada,<sup>212</sup> 79 nulliparous women with labor dystocia were randomized to low-dose (2mU/min with dosage increases of 2mU/min)

and high-dose (4mU/min with dosage increases of 4mU/min) oxytocin infusion regimens. The high-dose group received a greater maximum oxytocin infusion than the low-dose group, but there were no significant differences in duration of labor or mode of delivery<sup>212</sup> (Table 68).

**Table 68. Labor outcomes by high- and low-dose oxytocin protocols in nulliparous women**

Study Design Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Dy, 2018 <sup>212</sup> RCT Fair	High-dose oxytocin (4mU/min with 4mU/min increments)	Low-dose oxytocin (2mU/min with 2mU/min increments)	Second stage: 1.4 hr (SD: 4.3 hr)	Second stage: 2.1 hr (SD: 1.6 hr)	RR -0.72 (-2.3 to 0.90) p=0.38	6/40 (15%)	10/39 (25.6%)	0.59 (0.24, 1.45) p=0.25	Unknown	—
Kenyon, 2013 <sup>217</sup> SR Good	High-dose oxytocin	Low-dose oxytocin	Oxytocin to delivery: 7.8 hr (2.7)	Oxytocin to delivery: 11.3 hr (6.1)	Mean difference: -3.50 hr (-6.38 to -0.62)	Overall (all subjects): 43/320 (13.4%) Overall (nulliparous): 30/138 (21.7%) Overall (parous): 8/82 (9.7%)	Overall (all subjects): 71/324 (21.9%) Overall (nulliparous): 48/162 (29.6%) Overall (parous): 14/62 (22.6%)	Overall (all subjects): RR 0.62 (0.44 to 0.86) Overall (nulliparous): RR 0.71 (0.47 to 1.06) Overall (parous): RR 0.43 (0.19 to 0.97)	Yes	—
Kenyon, 2013 <sup>208</sup> RCT Good	High-dose oxytocin	Low-dose oxytocin	—	—	—	17/47 (36.2%)	15/47 (31.9%)	0.66	—	—
Selin, 2018 <sup>215</sup> RCT Good	High-dose oxytocin (6.6mU/min with 6.6mU/min increments)	Low-dose oxytocin (3.3mU/min with 3.3mU/min increments)	Active phase to birth: 744 min (209)	Active phase to birth: 768 min (196)	Mean difference: -23.4 min (95% CI: -45.3; -1.5) p=0.021	80/647 (12.4%)	80/648 (12.3%)	Mean difference: 0.0 (95% CI: -3.7; 3.8) p=1.00	No	—

Study Design Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Somprasit, 2005 <sup>117</sup>  RCT  Good	Early AROM, 2-hour vaginal exams with high-dose oxytocin given if dilated <1 cm	No protocol for initiating/stopping oxytocin, vaginal exams as indicated	First stage: 538.0 min (242.9)	First stage: 589.4 min (263.8)	0.0036	38/320 (11.9%)	94/640 (14.7%)	0.23	Trend toward lower cesarean delivery rate with shorter labor	Low-resource setting
Wei, 2010 (SR) <sup>216</sup>  RCT  Good	High-dose oxytocin	Low-dose oxytocin	Labor duration >12 hr: 75/741 (10.1%)	Labor duration > 12 hr: 156/763 (20.4%)	RR 0.46 (0.30 to 0.70)	361/2748 (13.1%)	405/2675 (15.1%)	RR 0.85 (0.75-0.97)	Yes	—

Abbreviations: —=not reported; AROM=artificial rupture of membranes; CI=confidence interval; Com=comparator; hr=hours; Int=intervention; min=minutes; RCT=randomized controlled trial; RR=relative risk; SR=systematic review

## Maternal Outcomes

There was no significant difference in maternal pelvic floor trauma or hemorrhage<sup>208</sup> or fever/infection<sup>117,208,215</sup> between high- and low-dose protocols in the studies that reported it, although the Kenyon study was not powered to detect differences.

## Neonatal Outcomes

There was no significant difference in the incidence of neonatal respiratory distress, or neonatal length of stay, in the one study which reported this outcome, but it was not powered to detect differences.<sup>208</sup>

## Strength of Evidence for High-Dose Versus Low-Dose Oxytocin in Nulliparous Women

Table 69 summarizes the SOE for the high-dose versus low-dose oxytocin protocols described above. In general, the SOE was inconclusive given imprecise findings other than for mode of delivery.

**Table 69. High-dose versus low-dose oxytocin protocols: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 1 <sup>st</sup> Stage Labor	2 RCTs <sup>117,208</sup> (1,052)	<b>Inconclusive:</b> SOE was insufficient given imprecise and inconsistent findings from 2 studies.	Insufficient (Inconsistent, imprecise, non-U.S. setting)
	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	3 RCTs <sup>117,208,215</sup> (2,315)	<b>Inconclusive:</b> SOE was insufficient given imprecise and inconsistent findings from 3 studies.	Insufficient (Inconsistent, imprecise, non-U.S. setting)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCTs <sup>117,208,215</sup> (1,052) 2 SRs <sup>216,217</sup> (945 patients, 9 studies)	<b>Improvement with high-dose oxytocin:</b> High-dose oxytocin augmentation was associated with a reduction in the risk of cesarean section.	Moderate (inconsistent, imprecise)  Findings supported by 2 RCTs and 2 SRs increasing SOE. Inconsistency with a third study not showing a difference and substantial heterogeneity.
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>208</sup> (92)	<b>Inconclusive:</b> SOE was insufficient given imprecise and finding from 1 small pilot study	Insufficient (imprecise, non-U.S. setting, 1 small study)
	Maternal Outcomes – Infection	2 RCTs <sup>117,208</sup> (1,052)	<b>No difference:</b> No difference in the rate of maternal infection between high-and low-dose oxytocin as part of an active management of labor protocol compared to a conventional management of labor protocol.	Low (Imprecise)
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>208,215</sup> (1,387)	<b>No difference:</b> SOE was low given imprecise findings from 2 non-U.S. setting studies.	Low (imprecise, non-U.S. setting)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Neonatal Outcomes – Respiratory Distress	1 RCT <sup>208</sup> (92)	<b>Inconclusive:</b> SOE was insufficient given imprecise and finding from 1 small pilot study.	Insufficient (imprecise, non-U.S. setting, 1 small study)
	Neonatal Outcomes – Neonatal Length of Stay	1 RCT <sup>208</sup> (92)	<b>Inconclusive:</b> SOE was insufficient given imprecise and finding from 1 small pilot study.	Insufficient (imprecise, non-U.S. setting, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Results in Parous Women

### Duration of Labor and Cesarean Delivery Rates for High-Dose Versus Low-Dose Oxytocin

We identified two RCTs (one fair quality,<sup>214</sup> one poor quality<sup>213</sup>) that compared high-dose and low-dose oxytocin in parous women.

The fair-quality study,<sup>214</sup> compared low-dose (1mU/min, increased by 1mU/min every 20 minutes) and high-dose (5mU/min increased by 5mU/min every 20 minutes) oxytocin infusions in a total of 211 parous women in India with slow-progressing spontaneous labor. The duration of labor was significantly reduced in the high-dose group, but there was no difference in cesarean section rates between the groups (Table 70).<sup>214</sup>

In the second study, rated as poor-quality,<sup>213</sup> 900 parous women with arrested labor progress in China were randomized into five groups: oxytocin regimens of 1mU/min (initial dose 2mU/min), 4mU/min (initial dose 8mU/min), 16mU/min (continuous infusion), 5mU/min quarter-hourly, and pulsatile administration with a syringe pump. Outcomes of the pulsatile administration regimen compared to the continuous infusion regimen are in the pulsatile oxytocin section, below. The continuous infusion and 1mU/min groups had similar rates of instrument-facilitated delivery, which were higher than the rates of instrument-facilitated delivery for the 4mU/min and 5mU/min quarter-hourly regimens. The continuous infusion had the highest rate of uterine hyperstimulation. Maternal and child deaths and Apgar scores under 7 were also measured, but differences were not statistically significant (Table 70).



**Table 70. Labor outcomes by high- and low-dose oxytocin protocols in parous women**

Study Design Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Geeta, 2015 <sup>214</sup> RCT Fair	High-dose oxytocin (starting at 5mU/min)	Low-dose oxytocin (starting at 1mU/min)	4.88 hr (SD: 1.00 hr)	6.86 hr (SD: 0.99 hr)	p<0.05	29/110 (26.36%)	28/101 (27.72%)	p=0.95	Unknown/ No	—
Liu, 2018 <sup>213</sup> RCT Poor	High-dose oxytocin: 4mU/min (initial 8mU/min dose), 5mU/min quarter-hourly.	low-dose: 1mU/min (initial 2mU/min dose)	Infusion to delivery: 4mU/min: ~10 hours; 5mU/min quarter-hourly: ~10.5 hours  First stage of labor to delivery: 4mU/min: ~8.4 hours; 5mU/min quarter-hourly: ~8.2 hours	Infusion to delivery: ~10.4 hours  First stage of labor to delivery: ~8.2 hours	Infusion to delivery: 5mU/min quarter-hourly compared to 4mU/min: p<0.0001  1mU/min compared to 4mU/min: p=0.0103  First stage of labor to delivery: all of these groups: p≥0.05	5mU/min quarter-hourly: 5/162 (3%) 4mU/min: 6/162 (4%)	1mU/min: 13/162 (8%)	4mU/min compared to 1mU/min: p=0.0078  5mU/min quarter-hourly compared to 4mU/min: p=0.3188	Unknown	—

Abbreviations: —=not reported; Com=comparator; hr=hours; Int=intervention; min=minutes; RCT=randomized controlled trial; SD=standard deviation

## Maternal Outcomes

In the poor-quality study there was no significant difference in maternal deaths (insufficient SOE).<sup>213</sup>

## Neonatal Outcomes

In the poor-quality study there was no significant difference in neonatal deaths or Apgar scores less than 7 (insufficient SOE).<sup>213</sup>

## Relevant Systematic Reviews/Meta-Analyses for Dosage of Oxytocin

Two SR/MAs analyzed the effect of high-dose oxytocin protocols on labor outcomes among women with dystocia. Wei et al.<sup>216</sup> conducted an SR/MA of 10 studies including 5,423 women with labor dystocia. The studies included both nulliparous and parous women, though results were not stratified by parity. High-dose oxytocin was associated with an overall lower risk for cesarean delivery and associated higher rate of spontaneous vaginal delivery. High-dose oxytocin was associated with lower rates of labor duration greater than 12 hours but higher rates of uterine tachysystole. There were no differences in the rate of postpartum hemorrhage, need for maternal transfusion, uterine atony, uterine rupture, shoulder dystocia, chorioamnionitis, nonreassuring fetal heart rate tracings, fetal distress, meconium aspiration, neonatal acidemia, or maternal satisfaction were seen between the two groups (Table 68).

In the second SR/MA, Kenyon et al. conducted a Cochrane review<sup>217</sup> addressing high-dose versus low-dose oxytocin protocols for augmentation of abnormal labor. Their review included 4 studies with 644 subjects. High-dose oxytocin was associated with a lower overall cesarean delivery rate and with a higher rate of spontaneous vaginal delivery and shorter duration of labor. Subgroup analysis based on parity demonstrated that lower cesarean delivery rates were seen only in parous women, while nulliparous women had lower but nonsignificant cesarean delivery rates. One of the four studies was judged to be at high risk of bias. When that study was removed from the analysis, the overall cesarean delivery rate among all subjects was no longer significantly different between the two oxytocin-dosing protocols. There were no differences in maternal satisfaction, chorioamnionitis, postpartum hemorrhage, emergent delivery for nonreassuring fetal status, or neonatal acidemia between the two oxytocin-dosing protocols.

## Strength of Evidence for High-Dose Versus Low-Dose Oxytocin in Parous Women

Table 71 summarizes the SOE for the high-dose versus low-dose oxytocin protocols described above. The SOE was insufficient for all outcomes given findings from studies with high risk of bias performed in non-U.S. settings.

**Table 71. High-dose versus low-dose oxytocin protocols: Evidence profile in parous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor	2 RCTs <sup>213,214</sup> (1,111)	<b>Inconclusive:</b> SOE was insufficient given imprecise and inconsistent findings from 2 studies in non-U.S. settings with potential risk of bias.	Insufficient (imprecise, inconsistent, non-U.S. setting, high risk of bias)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>213,214</sup> (1,111)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 2 studies in non-U.S. settings with potential risk of bias.	Insufficient (imprecise, non-U.S. setting, high risk of bias)
Adverse Events	Maternal Outcomes – Death	1 RCT <sup>213</sup> (900)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study in non-U.S. settings with high risk of bias.	Insufficient (imprecise, non-U.S. setting, high risk of bias)
	Neonatal Outcomes – Death	1 RCT <sup>213</sup> (900)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study in non-U.S. settings with high risk of bias.	Insufficient (imprecise, non-U.S. setting, high risk of bias)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Timing of Oxytocin Administration

### Results in Nulliparous Women

#### Duration of Labor and Cesarean Delivery Rates for High-Dose Versus Low-Dose Oxytocin

Two RCTs<sup>74,210</sup> (one good quality and one fair quality) addressed the timing of oxytocin augmentation following a diagnosis of abnormal labor in nulliparous women. Dencker et al.<sup>74</sup> conducted a fair-quality RCT of early (following no progress 1 hour after amniotomy, oxytocin infusion was administered within 20 minutes) versus delayed (postponement of oxytocin augmentation for 3 hours) oxytocin administration for augmentation of labor in nulliparous women. The study was conducted at 2 sites in Sweden and included 630 women. There were no significant differences in mode of delivery between the two groups, but early administration of oxytocin was associated with a shorter duration of labor from randomization to delivery. There were no differences in duration of the second stage of labor or rates of postpartum hemorrhage, need for transfusion, anal sphincter laceration, or neonatal acidosis between the two groups (Table 72).

Hinshaw et al.<sup>210</sup> conducted a good-quality RCT of early (within 20 minutes of randomization) versus delayed (withheld for a period of 8 hours unless intervention became clinically indicated) oxytocin administration for labor augmentation in nulliparous women. The study was conducted at 12 sites in the UK and included 412 women. There were no differences in rates of cesarean delivery between the two groups, but again duration of labor from randomization to delivery was shorter in the early oxytocin group. There were no differences in the rates of postpartum hemorrhage, need for transfusion, neonatal death or infection, or maternal satisfaction between the two groups (Table 72).

**Table 72. Labor outcomes by timing of oxytocin administration in nulliparous women**

Study Design Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Dencker, 2009 <sup>74</sup> RCT Fair	Early administration of oxytocin	Delayed administration of oxytocin	Randomization to delivery: 5.2 hr (2.8) Second stage: 1.7 hr (1.2)	Randomization to delivery: 6.7 hr (3.2) Second stage: 1.8 hr (1.3)	Randomization to delivery: p<0.001 Second stage: p=0.68	Overall: 29/314 (9.2%)	Overall: 34/316 (10.8%)	Overall: RR 0.8 (0.5 to 1.4)	No	—
Hinshaw, 2008 <sup>210</sup> RCT Good	Early administration of oxytocin	Delayed administration of oxytocin	Randomization to delivery: 5 hr 52 min (IQR 3:52 to 8:02)	Randomization to delivery: 9 hr 8 min (IQR 5:06 to 13:16)	P<0.001	Overall: 28/208 (13.5%) NRFHT: 4/208 (1.9%) Delay: 21/208 (10.1%)	Overall: 28/204 (13.7%) NRFHT: 6/204 (2.9%) Delay: 17/204 (8.3%)	Overall: RR 0.98 (0.6 to 1.7) NRFHT: Not provided but NS Delay: RR 1.23 (0.6 to 2.4)	No	—
Wei, 2009 <sup>219</sup> SR/MA Good	Early administration of oxytocin	Delayed administration of oxytocin	—	—	Admission to delivery: Mean difference -1.36 hr (-2.82 to 0.09)	Overall: 153/1010 (15.1%)	Overall: 167/973 (17.2%)	Overall: RR 0.87 (0.71 to 1.06)	No	—
Bugg, 2013 <sup>220</sup> SR/MA Good	Early administration of oxytocin	Delayed administration of oxytocin	Randomization to delivery: 5.26 hr (0.89)	Randomization to delivery: 7.50 hr (1.39)	Randomization to delivery: Mean difference -2.20 hr (-3.29 to -1.10)	Overall: 74/610 (12.1%)	Overall: 76/590 (12.9%)	Overall: RR 0.88 (0.66 to 1.19)	No	—

Abbreviations: —=not reported; Com=comparator; hr=hours; Int=intervention; IQR=interquartile range; NRFHT=nonreassuring fetal heart rate tracing; NS=not significant; RCT=randomized controlled trial; RR=relative risk; SR/MA=systematic review/meta analysis

## Maternal Outcomes

In the two studies described above, there were no significant differences in postpartum hemorrhage or need for transfusion.<sup>74,210</sup> In the Dencker study, there were no differences in anal sphincter laceration,<sup>74</sup> and in the Hinshaw et al study no difference in maternal satisfaction.<sup>210</sup> Hinshaw et al.<sup>210</sup> conducted an RCT of early (within 20 minutes of randomization) versus delayed (withheld for a period of 8 hours unless intervention became clinically indicated) oxytocin administration for labor augmentation in nulliparous women. The study was conducted at 12 sites in the UK and included 412 women. There were no differences in rates of cesarean delivery between the two groups, but again duration of labor from randomization to delivery was shorter in the early oxytocin group. There were no differences in the rates of postpartum hemorrhage, need for transfusion, neonatal death or infection, or maternal satisfaction between the two groups (Table 72).

## Neonatal Outcomes

There were no significant differences in neonatal death or infection<sup>210</sup> or acidosis<sup>74</sup> in the included studies.

## Relevant Systematic Reviews/Meta-Analyses for Timing of Oxytocin

Wei et al.<sup>219</sup> conducted a meta-analysis on early oxytocin administration for augmentation of labor that included 9 studies and 1,983 women. Early oxytocin augmentation was defined as immediate oxytocin administration when dystocia was identified. The studies included both nulliparous and parous women, though results were not stratified by parity. Early administration of oxytocin was associated with a higher rate of spontaneous vaginal delivery but similar to our included RCTs no differences in rate of cesarean delivery or operative vaginal delivery. Early administration was associated with uterine tachysystole, but there were no differences in the duration of labor (admission to delivery) or rates of postpartum hemorrhage, need for transfusion, maternal fever or chorioamnionitis, or fetal distress (Table 72).

Bugg et al. conducted a Cochrane review<sup>220</sup> addressing early versus delayed (delayed use by one hour or more) administration of oxytocin for labor augmentation. They identified 8 studies including 1388 women. The studies included both nulliparous and parous women, though results were not stratified by parity. Both our included RCTs were also included in this SR. Early administration of oxytocin was associated with a shorter duration of labor from randomization to delivery, but there were no differences in mode of delivery or rates of uterine tachysystole, postpartum hemorrhage, or maternal satisfaction between the two groups (Table 72).

Gaucher et al.<sup>218</sup> completed a fair-quality SR of studies evaluating oxytocin regimens for women with dystocia, but many descriptive studies were included, and they were not evaluated separately. Several included studies addressed immediate v. delayed oxytocin (delayed by 2+, 3, or 8 hours), and the authors concluded that early administration of oxytocin can reduce duration of labor as compared to delayed administration in dystocia during the active phase of labor.

## Strength of Evidence for Timing of Oxytocin

Table 73 summarizes the SOE for the timing of oxytocin described above. The SOE was moderate for outcomes informed both by individual RCTs and existing SRs.

**Table 73. Early versus delayed oxytocin protocols: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor	2 RCTs <sup>74,210</sup> (1,042) 2 SRs <sup>219,220</sup> (2,583 patients, 10 studies)	<b>Improvement with early administration of oxytocin:</b> shorter duration of labor in early oxytocin group.	Moderate (non-U.S. setting, potential risk of bias)  Consistent with SR findings
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	2 RCTs <sup>74,210</sup> (1,042) 2 SRs <sup>219,220</sup> (2,583 patients, 10 studies)	<b>No difference:</b> no difference in mode of delivery given early oxytocin group.	Moderate (non-U.S. setting, potential risk of bias)  Consistent with SR findings
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor	1 RCT <sup>74</sup> (630)	<b>Inconclusive:</b> SOE was insufficient given findings from one non-U.S. study with potential risk of bias	Insufficient (Imprecise, non-U.S. setting, risk of bias, one study)
	Maternal Outcomes – Transfusion	2 RCTs <sup>74,210</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)
	Maternal Outcomes – Hemorrhage	2 RCTs <sup>74,210</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)
	Neonatal Outcomes – Neonatal Infection/Sepsis	1 RCT <sup>210</sup> (412)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from one non-U.S. study	Insufficient (Imprecise, non-U.S. setting, one study)
	Neonatal Outcomes – Neonatal Acidemia	1 RCT <sup>74</sup> (630)	<b>Inconclusive:</b> SOE was insufficient given findings from one non-U.S. study with potential risk of bias	Insufficient (Imprecise, non-U.S. setting, risk of bias, one study)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	2 RCTs <sup>74,210</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)
	Process Related Outcomes – Mode of Delivery (Spontaneous)	2 RCTs <sup>74,210</sup> (1,042)	<b>No difference:</b> No difference between women managed with early versus delayed oxytocin administration.	Low (non-U.S. setting, potential risk of bias)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## **Pulsatile Oxytocin Administration and Adjuvants to Oxytocin**

Endogenous oxytocin is released in a pulsatile fashion from the pituitary gland. In contrast, oxytocin is most commonly given as a continuous intravenous infusion for both induction and augmentation of labor.

### **Results in Women of Mixed Parity**

#### **Duration of Labor and Cesarean Delivery Rates for Oxytocin Administration and Adjuvants to Oxytocin**

Tribe et al.<sup>209</sup> conducted an RCT of pulsatile versus continuous oxytocin for augmentation of labor. The trial was conducted at two sites in the UK and included 500 women. The trial included both nulliparous and parous women and results were not stratified by parity. Pulsatile oxytocin was associated with longer duration of labor compared with continuous infusion. Fewer women delivered vaginally within 24 hours in the pulsatile group, but overall cesarean delivery rates were not reported. There was no difference in the rate of neonatal infection, hypoxic ischemic encephalopathy or neonatal seizures between the two groups (Table 74).

Labor is a high catecholamine state and endogenous catecholamines may interfere with uterine contractility as beta2-adrenergic receptor agonists are known tocolytic agents. Palomaki et al.<sup>211</sup> conducted an RCT of combined propanol (beta adrenergic receptor antagonist) plus oxytocin compared with oxytocin alone for augmentation of labor. The trial was conducted at a single site in Finland and included 107 women. Both nulliparous and parous women were included and the results were not stratified by parity. There were no differences in mode of delivery or duration of labor between the two groups (Table 74).

Liu et al.<sup>213</sup> compared several oxytocin regimens in their RCT, as described in the high-dose vs. low-dose section, above. One group was assigned a pulsatile regimen, which was primarily compared to the group receiving the 16mU/min continuous infusion. The duration of labor was longest with pulsatile administration, though that regimen also had the lowest rate of uterine hyperstimulation. The pulsatile administration group had the lowest rate of failed vaginal birth within 24 hours of instrument-facilitated delivery (Table 74).

**Table 74. Labor outcomes with pulsatile oxytocin or with adjuvants in women of mixed parity**

Study Design Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Tribe, 2012 <sup>209</sup>  RCT  Good	Pulsatile oxytocin	Continuous oxytocin	Infusion to delivery: 9.61 hr (95% CI 8.95 to 10.27) First and second stage of labor: 15.79 hr (95% CI 14.93 to 16.65)	Infusion to delivery: 7.17 hr (95% CI 6.58 to 7.77) First stage and second stage of labor: 14.06 hr (95% CI 13.20 to 14.92)	Infusion to delivery: RR 2.4 (1.6 to 3.3) First and second stage of labor: RR 1.7 (0.5 to 2.9)	Failed vaginal delivery in 24 hours: 119/251 (47.4%)	Failed vaginal delivery in 24 hours: 93/249 (37.3%)	Failed vaginal delivery in 24 hours: 1.27 (1.03 to 1.56)	Unknown	Overall cesarean delivery rates were not reported in the study.
Palomki, 2006 <sup>211</sup>  RCT  Good	Oxytocin plus propranolol	Oxytocin alone	Duration of augmented labor: 185 min Total duration of labor (first, second and third stage): 810 min	Duration of augmented labor: 223 min Total duration of labor (first, second, third stage): 768 min	Duration of augmented labor: p=0.217 Total duration of labor (first, second, third stage): p=0.486	Overall: 6/55 (10.9%)	Overall: 2/52 (3.8%)	Overall: p=0.154	No	—
Liu, 2018 <sup>213</sup>  RCT  Poor	Pulsatile oxytocin (pulses of 1/8 the continuous infusion)	Continuous oxytocin (16mU/min)	Infusion to delivery: ~16 hours. first stage of labor to delivery: ~9 hours	Infusion to delivery: ~10 hours. first stage of labor to delivery: ~8.2 hours	Infusion to delivery: p<0.0001. first stage of labor to delivery: p<0.0001	Cesarean: 1/162 (1%)  Failed vaginal delivery in 24 hours: 12/162 (7%)	Cesarean: 15/162 (9%)  Failed vaginal delivery in 24 hours: 40/162 (25%)	Cesarean: p=0.0001  Failed vaginal delivery in 24 hours: p<0.0001	Unknown	—

Abbreviations: —=not reported; CI=confidence interval; Com=comparator; hr=hours; Int=intervention; min=minutes; RCT=randomized controlled trial; RR=relative risk



## Maternal Outcomes

In the study Liu et al.,<sup>213</sup> the pulsatile regimen had the lowest rate of postpartum hemorrhage.

## Neonatal Outcomes

In the study of Tribe et al.,<sup>209</sup> there was no difference in the rate of neonatal infection, hypoxic ischemic encephalopathy or neonatal seizures between the two groups (Table 74).

## Strength of Evidence for Pulsatile Oxytocin Protocols in Women of Mixed Parity

Table 75 summarizes the SOE for pulsatile oxytocin protocols described above. In general, the SOE was rated as low or insufficient given imprecise findings from non-U.S. settings.

**Table 75. Pulsatile versus continuous oxytocin protocols: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2nd Stage Labor	1 RCT <sup>209</sup> (487)	<b>No difference:</b> No difference in the duration of the second stage of labor among women managed with pulsatile compared to continuous oxytocin for augmentation of labor.	Low (Indirect, Imprecise)
	Process Related Outcomes – Duration of Labor	3 RCTs <sup>209,211,213</sup> (1,488)	<b>Improvement with continuous oxytocin:</b> Women managed with pulsatile compared to continuous oxytocin for augmentation of labor had a longer duration of labor.	Low (Indirect, imprecise, non-U.S. setting, high risk of bias)
Adverse Events	Maternal Outcomes – Postpartum hemorrhage	1 RCT <sup>213</sup> (900)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study in non-U.S. settings with high risk of bias	Insufficient (imprecise, non-U.S. setting, high risk of bias)
	Process Related Outcomes – Mode of Delivery (Operative delivery)	1 RCT <sup>209</sup> (500)	<b>No difference:</b> No difference in operative delivery rate between women managed with pulsatile compared to continuous oxytocin for augmentation of labor. The cesarean delivery rate was not reported.	Low (Indirect, imprecise)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>211</sup> (107)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Imprecise, 1 small study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## **Oxytocin Versus Expectant Management**

### **Results in Women of Mixed Parity**

#### **Duration of Labor and Cesarean Delivery Rates for Oxytocin Versus Expectant Management**

We identified one good quality RCT<sup>114</sup> and two good quality systematic reviews<sup>220,221</sup> comparing various methods for labor augmentation. In Nachum et al.<sup>114</sup> there were three intervention arms: amniotomy alone, amniotomy with oxytocin, and oxytocin alone. The control arm included expectant management. The results of the amniotomy and amniotomy plus oxytocin augmentation compared with expectant management are presented in KQ 2. There was no difference in mode of delivery, duration of the first stage of labor, or duration of the second stage of labor. There were no differences or rates of postpartum hemorrhage, anal sphincter laceration or postpartum fever between women receiving oxytocin alone compared to women in the expectant management group. Women managed with oxytocin had greater mean satisfaction scores compared with the expectantly managed group (4.7 [0.6] vs. 5.0 [0.1],  $p < 0.05$  after post-hoc testing) on a five-point scale from absolutely not satisfied (1) to absolutely satisfied (5). The study included both nulliparous and parous women and results were not stratified by parity.

#### **Maternal Outcomes**

Nachum et al.<sup>114</sup> found that there were no significant differences in rates of postpartum hemorrhage, anal sphincter laceration or postpartum fever between women receiving oxytocin alone compared to women in the expectant management group. Women managed with oxytocin had greater mean satisfaction scores compared with the expectantly managed group (4.7 [0.6] vs. 5.0 [0.1],  $p < 0.05$  after post-hoc testing) on a five-point scale from absolutely not satisfied (1) to absolutely satisfied (5).

#### **Relevant Systematic Reviews for Oxytocin Versus Expectant Management**

There were two good-quality SRs that addressed oxytocin expectant for augmentation of labor.<sup>220,221</sup> One review was in the setting of concomitant regional analgesia<sup>221</sup> and the other was a Cochrane review on the effect of oxytocin augmentation versus expectant management for labor dystocia.<sup>220</sup> Costley et al. performed an SR/MA of oxytocin augmentation versus expectant management in women with epidural analgesia.<sup>221</sup> The review included two studies involving 319 nulliparous women. There were no differences in mode of delivery or rates of postpartum hemorrhage between the two groups. Bugg et al. conducted a Cochrane review that included 8 studies with 1388 subjects on the use of oxytocin versus expectant management for labor dystocia as well as the use of early or delayed oxytocin administration.<sup>220</sup> The studies included both nulliparous and parous women and results were not stratified by parity. Of the eight studies, three (138 subjects) compared oxytocin administration with expectant management. There was no difference in cesarean delivery or operative vaginal delivery between the two groups (Table 76).

**Table 76. Labor outcomes with oxytocin compared to expectant management in women of mixed parity**

Study Quality	Int	Com	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Costley, 2012 <sup>221</sup> SR/MA Good	Oxytocin augmentation	No intervention/ Expectant management	—	—	—	—	—	Overall: RR 0.95 (0.42 to 2.12)	—	Women with epidural analgesia
Bugg, 2013 <sup>220</sup> SR/MA Good	Oxytocin augmentation	No intervention/ Expectant management	—	—	—	Overall: 8/65 (12.3%)	Overall: 10/73 (13.7%)	Overall: RR 0.84 (0.36 to 1.96)	—	—
Nachum, 2010 <sup>114</sup> RCT Good	Oxytocin augmentation	No intervention/ Expectant management	Random-ization to delivery: 494 min (327) First stage: 463 min (313) Active phase: 103 min (89) Second stage: 31 min (46)	Random-ization to delivery: 498 min (306) First stage: 460 min (285) Active phase: 127 min (96) Second stage: 38 min (54)	Random-ization to delivery: p=0.94 First stage: p=0.95 Active phase: p=0.12 Second stage: p=0.41	Overall: 2/72 (2.8%)	Overall: 1/70 (1.4%)	Overall: p=0.9	No	—

Abbreviations: —=not reported; Com=comparator; hr=hours; Int=intervention; RCT=randomized controlled trial; RR=relative risk; SR/MA=systematic review/meta analysis

## Strength of Evidence for Oxytocin Versus Expectant Management

Table 77 summarizes the SOE for oxytocin versus expectant management.

**Table 77. Oxytocin versus expectant management: Evidence profile in women of mixed parity**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor (from intervention to delivery)	1 RCT <sup>114</sup> (99)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 small study.	Insufficient (Imprecise, 1 small study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>114</sup> (99) 2 SRs <sup>220,221</sup> (457 patients, 5 studies)	<b>No difference:</b> No difference in cesarean delivery rate between women managed with oxytocin compared to expectant management.	Moderate (Imprecise, consistency with SR)  SOE was increased to moderate given findings from SRs which also found no difference in cesarean delivery rates.
Adverse Events	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>114</sup> (99) 1 SR <sup>220</sup> (138 patients, 3 studies)	<b>No difference:</b> No difference in operative vaginal delivery rate between women managed with oxytocin compared to expectant management.	Low (Imprecise)  Consistent with SR findings

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence; SR=systematic review

## Key Question 8. Electronic Fetal Monitoring Versus Intermittent Auscultation

KQ 8 was: For women in spontaneous labor undergoing augmentation with oxytocin, what are the relative benefits and harms (in terms of both maternal and neonatal outcomes) of electronic fetal monitoring versus intermittent auscultation?

### Description of Included Studies

We were unable to identify any relevant RCTs that met our inclusion criteria at this time. We identified 4 potential SRs that had comparisons of electronic fetal monitoring to intermittent auscultation,<sup>31,51,55,56</sup> but these were ultimately excluded because the studies included in the reviews evaluated interventions that are not currently used in the United States. We did identify one SR<sup>223</sup> that had included studies on the comparisons of electronic fetal monitoring to intermittent auscultation.

### Key Point for Electronic Fetal Monitoring Versus Intermittent Auscultation

- There was insufficient SOE for all outcomes regarding electronic fetal monitoring versus intermittent auscultation

## Detailed Synthesis for Electronic Fetal Monitoring Versus Intermittent Auscultation

We identified one SR by Martis et al.<sup>223</sup> that examined electronic fetal monitoring versus intermittent auscultation. This SR included three studies comparing the effect of electronic fetal monitoring versus intermittent auscultation on maternal and neonatal health outcomes. All three studies were conducted in Africa and included a total of 6,241 women and 6,241 babies. Two of the three studies (3,242 women and 3,242 babies) were included in the quantitative synthesis (meta-analysis) since the other study was found to have questionable data reporting. The authors of the review considered both of the studies in the meta-analysis to be of high risk for performance bias due to inability to blind. One of the included studies in the meta-analysis did not meet our inclusion criteria because of the 1994 publication date. Two comparisons were made in this review, intermittent electronic fetal monitoring with Pinard and Doppler ultrasonography with routine Pinard.

There were no differences in intermittent electronic fetal monitoring versus routine Pinard for the outcomes of low Apgar scores at 5 minutes or perinatal mortality. Neonatal seizures were reduced in the electronic fetal monitoring group (RR 0.05, 95% CI 0.00 to 0.89). This outcome include 633 infants and was considered to have very low quality evidence. No outcomes on mortality, morbidity, cerebral palsy, or neurosensory disability. Of the maternal outcomes, higher rates of cesarean section were found among the electronic fetal monitoring group (RR 2.92, 95% CI 1.78 to 4.80). This outcome included 633 women and was judged to have moderate quality evidence compared to routine Pinard. No differences were found with instrumental vaginal births. No outcomes related to maternal mortality, instrumental vaginal birth for fetal distress and or acidosis, analgesia in labor, mobility or restriction during labor, and postnatal depression.

When comparing Doppler ultrasound versus routine Pinard, no differences were found between groups for Apgar scores, perinatal mortality, or neonatal seizures. Outcomes related to cord blood acidosis, composite of mortality and serious morbidity, cerebral palsy, neurosensory disability were not reported. Of the maternal outcomes, women allocated to the Doppler ultrasonography had higher rates of cesarean section for fetal distress compared to routine Pinard (RR 2.71, 95% CI 1.64 to 4.48). This outcome included 627 women and was judged to be moderate quality evidence. There was no difference in instrumental vaginal births between groups. No other maternal outcomes were reported.

## Key Question 9. Timing of Pushing in the Second Stage

KQ 9 was: For women in the second stage of labor, is there a benefit from delayed or Valsalva pushing for time to delivery or mode of delivery?

### Description of Included Studies

We identified six articles<sup>72,73,224-227</sup> representing five RCTs that examined pushing techniques among 605 nulliparous women. Two fair-quality RCTs were conducted in the UK/Europe,<sup>224,226</sup> one fair-quality RCT was conducted in the Middle East,<sup>225</sup> and two good-quality RCTs were conducted in the United States.<sup>72,227</sup> Two studies reported government funding,<sup>72,224</sup> one reported university internal funding,<sup>225</sup> one reported a combination of government and non-government funding,<sup>227</sup> and one did not report a funding source or it was unclear.<sup>226</sup>

In addition, we identified two SRs that met our inclusion criteria.<sup>228,229</sup> Of the above RCTs, three<sup>72,73,224</sup> were identified in the 2016 SR by Barasinski et al.,<sup>229</sup> and four were identified in the

2017 SR by Lemos et al.<sup>228</sup> The original RCT by Koyucu et al.<sup>226</sup> was not included in the Lemos et al. SR, most likely because of its later publication date.

## **Key Points for Timing of Pushing**

- Valsalva/coached and spontaneous/uncoached pushing have similar rates of cesarean delivery (low SOE).
- There is limited evidence that immediate pushing has a shorter labor duration when compared to delayed pushing in nulliparous women (low SOE).
- There was limited evidence of no difference in neonatal outcomes for immediate versus delayed pushing (low SOE).

## **Detailed Synthesis for Timing of Pushing**

### **Coached Pushing Versus Uncoached Pushing**

Results for this intervention were reported for nulliparous women in four studies.<sup>72,224-226</sup> No relevant SR/MAs were identified.

### **Results in Nulliparous Women**

Four RCTs compared pushing techniques (coached/Valsalva pushing versus spontaneous or uncoached pushing) among nulliparous women without epidural analgesia.

### **Duration of Labor and Cesarean Delivery Rates for Coached Pushing Versus Uncoached Pushing**

One study<sup>224</sup> demonstrated a statistically significant increase in the length of the second stage of labor in women randomized to Valsalva pushing (40.8 vs. 50.1 minutes,  $p=0.045$ ) (Table 78). The cesarean delivery rate for women after randomization was not reported for this study. In contrast, the other three studies<sup>72,225,226</sup> demonstrated that coached/Valsalva technique was associated with a shorter duration of the second stage compared with uncoached pushing (spontaneous or Valsalva). SOE was rated as insufficient for duration of labor given inconsistent and imprecise findings. There was no difference in rate of cesarean deliveries among these studies (low SOE).

**Table 78. Duration of labor and cesarean delivery rates for spontaneous pushing versus Valsalva pushing**

Study Quality	Int	Comp	Duration of Labor: Int	Duration of Labor: Com	Duration of Labor: P Value	Cesarean: Int	Cesarean: Com	Cesarean: P Value	Shorter Labor Associated With Lower Cesarean Delivery Rate?	Comments
Bloom, 2006 <sup>72</sup> Good	Coached Pushing N=163	Un-coached Pushing N=157	Duration 46.3 min ±41.5	Duration 59.1 min ±49.1	0.014	1 (<1%)	5 (3%)	0.109	No	—
Koyucu, 2017 <sup>226</sup> Fair	Spontaneous Pushing Group N=40	Valsalva Pushing with Instruction N=40	Duration 63.2 min (SD=21.3)	Duration 46.6 min (SD=23.4)	0.001	--	--	--	--	All patients had vaginal delivery in cephalic position
Yildirim, 2008 <sup>224</sup> Fair	Valsalva Pushing N=50	Spontaneous Pushing N=50	Duration 50.1 min ±26.3	Duration 40.8 min ±19.1	0.045	—	—	—	Unknown	—
Vaziri, 2016 <sup>225</sup> Fair	Spontaneous Pushing in Lateral Position N=35	Valsalva Pushing in Supine Position N=34	Duration 76.32 min (SD=8.26)	Duration 64.56 (SD=15.24)	<0.001	1 (<1%)	2 (1%)	—	NA	—

Abbreviations: —=not reported; Com=comparator; Int=intervention; min=minutes; NA=not applicable; RR=relative risk; SD=standard deviation

## Maternal Outcomes for Coached Pushing Versus Uncoached Pushing

While evidence is limited, there was no statistically significant increase in the incidence of maternal adverse outcomes including forceps delivery or perineal lacerations (Table 79).<sup>72,224</sup> The companion study also showed no difference in the incidence of urodynamic stress incontinence (low SOE).<sup>73</sup> One study demonstrated a statistically significant increase in postpartum hemoglobin among the intervention group of spontaneous pushing.<sup>226</sup> There were no data on maternal infection or maternal satisfaction.

**Table 79. Maternal adverse outcomes for spontaneous pushing versus Valsalva pushing**

Study Quality	Intervention	Comparator	Outcome	Results: Intervention	Results: Comparator	P Value
Yildirim, 2008 <sup>224</sup> Fair	Valsalva pushing N=50	Spontaneous pushing N=50	2 <sup>nd</sup> Degree	6 (12%)	4 (8%)	0.167
			Cervical tear	2 (4%)	0 (0%)	0.495
Bloom, 2006 <sup>72</sup> Good	Coached pushing N=163	Uncoached pushing N=157	Forceps	6 (4%)	7 (5%)	0.725
			3 <sup>rd</sup> Degree	12 (7%)	13 (8%)	0.73
			4 <sup>th</sup> Degree	6 (4%)	2 (1%)	0.087
Koyucu, 2017 <sup>226</sup> Fair	Spontaneous pushing N=40	Valsalva pushing N=40	Episiotomy	34 (85%)	35 (87.5%)	0.745
			1 <sup>st</sup> degree	3 (7.5%)	2 (5%)	0.236
			2 <sup>nd</sup> degree	3 (7.5%)	3 (7.5%)	—
			2 <sup>nd</sup> degree with episiotomy	24 (60.0%)	16 (40.0%)	—
			Extended episiotomy	10 (25.0%)	18 (45.0%)	—
			3 <sup>rd</sup> degree	--	1 (2.5%)	—
			Cervical lacerations	1 (2.5%)	4 (10.0%)	—
			Postpartum haemoglobin	9.87 (SD=1.05)	9.10 (SD=1.0)	0.001
			Rate of decline in Hb levels	0.60 (SD=0.86)	1.06 (SD=1.18)	0.05

Abbreviation: --not reported; Hb=hemoglobin

## Neonatal Outcomes for Coached Pushing Versus Uncoached Pushing

While evidence is limited, there was no statistically significant difference between groups in the risk of fetal heart rate abnormalities, assisted respiration, acidemia, respiratory distress, sepsis evaluation, or stillbirth.<sup>72,224</sup> One study showed a statistically significant difference in the level of cord blood pO<sub>2</sub> (28.29 [SD 11.76]) in the spontaneous pushing group vs 18.83 (SD 9.86) in the Valsalva group; p<0.001). Given the imprecise findings and the small numbers of events, the SOE was rated as insufficient.

## Strength of Evidence for Coached Pushing Versus Uncoached Pushing

Table 80 summarizes the SOE for the findings described above. In general, SOE was judged insufficient for all outcomes, with the exception of the mode of delivery outcome.



**Table 80. Spontaneous pushing versus Valsalva pushing: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of 2 <sup>nd</sup> Stage Labor	4 RCTs <sup>72,224-226</sup> (605)	<b>Inconclusive:</b> SOE was insufficient given inconsistent and imprecise findings from 4 studies.	Insufficient (Medium risk of bias, inconsistent, imprecise)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	3 RCT <sup>72,225,226</sup> (508)	<b>No difference:</b> Three RCTs reported no difference in the rate of cesarean deliveries between coached pushing and uncoached pushing.	Low (Medium risk of bias, Imprecise)
Adverse Events	Maternal Outcomes – Trauma to the Pelvic Floor; postpartum hemoglobin	3 RCTs <sup>72,224,226</sup> (1,041)	<b>Inconclusive:</b> SOE was insufficient given inconsistent and imprecise findings from 3 available studies about heterogeneous outcomes.	Insufficient (Medium risk of bias, inconsistent, imprecise)
	Neonatal Outcomes – Neonatal Acidemia	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Neonatal Outcomes – Respiratory Distress	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Neonatal Outcomes – Neonatal Infection/Sepsis	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Neonatal Outcomes – Long Term Health	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Process Related Outcomes – Mode of Delivery (Spontaneous)	1 RCT <sup>72</sup> (320)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Imprecise, 1 study)
	Process Related Outcomes – Abnormal Fetal Heart Tracing	1 RCT <sup>224</sup> (100)	<b>Inconclusive:</b> SOE was insufficient given imprecise findings from 1 study.	Insufficient (Medium risk of bias, imprecise, 1 study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Immediate Versus Delayed Pushing Among Nulliparous Women

Results for this intervention were reported for nulliparous women in one good-quality study.<sup>227</sup> No relevant SR/MAs were identified.

## Results in Nulliparous Women

One good-quality RCT compared pushing techniques (immediate versus delayed) among nulliparous women receiving neuraxial analgesia.

## Duration of Labor and Cesarean Delivery Rates for Immediate Versus Delayed Pushing

One large good-quality RCT<sup>227</sup> demonstrated a statistically significant shorter mean duration of the second stage of labor in women randomized to immediate pushing compared to delayed pushing (102.4 vs 134.2 minutes, respectively; mean difference, -31.8 minutes [95%CI, -36.7 to -26.9],  $P < .001$ ). The cesarean delivery rate for women after randomization were not statistically ( $p=0.55$ ) different between immediate (7.8%) and delayed (7.6%) pushing groups. SOE was rated as low for both outcomes given findings from one study.

## Maternal Outcomes for Immediate Versus Delayed Pushing

A statistically significant increase was found in the incidence of maternal adverse outcomes including postpartum hemorrhage, chorioamnionitis and third degree perineal laceration (low SOE).<sup>227</sup> Postpartum hemorrhage was significantly greater in the delayed vs the immediate pushing group (4.0% versus 2.3%, respectively;  $p=0.03$ ). Chorioamnionitis was significantly greater in the delayed vs the immediate pushing group (6.7% versus 9.1%, respectively;  $p=0.005$ ). In a prespecified exploratory analysis third degree perineal laceration was also significantly greater in the immediate versus delayed pushing group (6.7% versus 9.1%, respectively;  $p=0.005$ ). Vacuum assisted, forceps assisted delivery, endometritis, and perineal laceration of  $\geq$  second degree were not significantly different between groups.

## Neonatal Outcomes for Immediate Versus Delayed Pushing

While evidence is limited to one study,<sup>227</sup> there was no statistically significant difference between groups in the risk of neonatal death, major birth injury, respiratory distress, transient tachypnea, hypoxic-ischemic encephalopathy, hypoglycemia, hypothermic treatment, shoulder dystocia, fetal sex, fetal weight or NICU admission. In prespecified exploratory analyses, a statistically significant difference in acidemia (umbilical cord arterial pH  $<7.1$ ) between immediate and delayed pushing groups (0.8% versus 1.2%, respectively;  $p=0.01$ ). The proportion of suspected sepsis was significantly ( $p=0.003$ ) higher in the delayed (4.4%) versus immediate pushing group (3.2%). SOE was rated as low for these neonatal outcomes.

## Strength of Evidence for Immediate Versus Delayed Pushing

Table 81 summarizes the SOE for the findings described above for immediate versus delayed pushing. In general, SOE was judged low for all outcomes, given findings from just one study.

**Table 81. Immediate versus delayed pushing: Evidence profile in nulliparous women**

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Intermediate or Final Outcomes	Process Related Outcomes – Duration of Labor (from intervention to delivery)	1 RCT <sup>227</sup> (2,404)	<b>Improvement with immediate pushing:</b> shorter mean duration of the second stage of labor in women randomized to immediate pushing compared to delayed pushing	Low (one study)
	Process Related Outcomes – Mode of Delivery (Cesarean Delivery)	1 RCT <sup>227</sup> (2,404)	<b>No difference:</b> No difference in cesarean delivery rate between women randomized to immediate pushing compared to delayed pushing.	Low (one study)

Category	Outcome	Study Design (Sample Size)	Conclusion	SOE (Rationale) <sup>a</sup>
Adverse Events	Maternal Outcomes – Postpartum Hemorrhage	1 RCT <sup>227</sup> (2,404)	<b>Improvement with immediate pushing:</b> Postpartum hemorrhage was significantly greater in the delayed vs the immediate pushing group	Low (one study)
	Maternal Outcomes – Chorioamnionitis	1 RCT <sup>227</sup> (2,404)	<b>Improvement with immediate pushing:</b> Chorioamnionitis was significantly greater in the delayed vs the immediate pushing group	Low (one study)
	Process Related Outcomes – Mode of Delivery (Instrumental Delivery)	1 RCT <sup>227</sup> (2,404)	<b>No difference:</b> No different in mode of delivery with delayed vs immediate pushing	Low (one study)
	Neonatal Outcomes – Neonatal Death, major birth injury, respiratory distress transient tachypnea	1 RCT <sup>227</sup> (2,404)	<b>No difference:</b> No different in neonatal death with delayed vs immediate pushing	Low (one study)
	Neonatal Outcomes – Neonatal Acidemia	1 RCT <sup>227</sup> (2,404)	<b>Improvement with immediate pushing:</b> In prespecified exploratory analyses, a lower rate of acidemia with immediate and delayed pushing groups	Low (one study)
	Neonatal Outcomes – Neonatal Infection/Sepsis	1 RCT <sup>227</sup> (2,404)	<b>Improvement with immediate pushing:</b> The proportion of suspected sepsis was higher in the delayed versus immediate pushing group	Low (one study)

<sup>a</sup> Criteria for downgrading SOE are described as Rationale; when these criteria are insufficient for understanding the final SOE, additional explanation is provided.

Abbreviations: RCT=randomized controlled trial; SOE=strength of evidence

## Discussion

In this comparative effectiveness review, we reviewed 158 studies described in 1167 publications relevant to criteria used to define protracted or arrested labor (Key Question [KQ 1]); the benefits and harms of amniotomy (KQ 2), supportive care measures (KQ 3), and epidural analgesia (KQ 4) in spontaneous labor, particularly in regards to increasing or decreasing the risk of a diagnosis of prolonged labor; the benefits and harms of cervical examination frequency (KQ 5) and intrauterine pressure catheters (KQ 6) in diagnosis and management of abnormal labor; the benefits and harms of high- and low-dose (including nipple stimulation) oxytocin augmentation in women diagnosed with abnormal labor progression (KQ 7); the benefits and harms of electronic fetal monitoring versus intermittent auscultation in women undergoing oxytocin augmentation for prolonged labor (KQ 8); and the benefit of delayed or Valsalva pushing during the second stage of labor (KQ 9).

### Key Findings and Strength of Evidence

Our review included 167 articles (158 unique studies). This included 25 studies relevant to defining abnormal labor, 12 studies relevant to amniotomy, 75 studies relevant to supportive care measures, 25 studies relevant to epidural analgesia, 1 study relevant to cervical examination, 1 study relevant to intrauterine pressure catheters, 17 studies relevant to high-dose versus low-dose oxytocin protocols, 1 studies relevant to fetal monitoring strategies, and 7 studies relevant to timing of pushing in the second stage. Evidence suggests that the duration and pattern of “normal” labor progress based on modern management is quite different than historical data, and that labor progress is different in nulliparous compared to parous women. Use of partograms did not impact important maternal or neonatal outcomes, although the applicability of this evidence to modern U.S. settings is limited. Routine amniotomy decreases the total duration of labor in nulliparous women without affecting other outcomes (moderate strength of evidence [SOE]), while routine amniotomy with oxytocin augmentation as needed decreased duration of labor without increasing cesarean delivery (high SOE). Although supportive care therapies are often seen as benefiting parental satisfaction with the birthing process, these outcomes were rarely assessed in clinical trials meeting our inclusion criteria, although an existing systematic review of 11 studies did find that women receiving continuous emotional support were less likely to rate their birth experience negatively. Of the different types of supportive therapies, only emotional support interventions showed reductions in cesarean (low SOE for doula support, moderate SOE for continuous emotional support) and instrumental deliveries (moderate SOE). For women choosing analgesia, type (epidural vs. combined spinal epidural, or epidural vs. patient-controlled intravenous analgesia) or timing during labor did not affect cesarean delivery rates (moderate SOE).

### Findings in Relationship to What Is Already Known

In general, the findings of the review were consistent with current understanding of the overall strength of evidence for different strategies for management of labor. Estimates of the rate of progress of “normal” labor derived from contemporary data in the United States are quite different from the classic curves described by Friedman.<sup>19</sup> These differences may be attributable to a number of factors, including secular trends in patient characteristics (e.g., increasing age at first birth and increasing rates of obesity) and increasing use of interventions such as induction of labor or the use of oxytocin to augment labor. More recent data suggest that the transition to

active labor occurs later in the course of labor than originally described, which is reflected in more recent guidelines suggesting a higher threshold for observing labor duration before intervention with cesarean delivery.

The definition of “normal” labor is fundamental in evaluating the evidence related to managing “abnormal” labor progression, analogous to the threshold value used to define “normal” for a continuous laboratory value. Ideally, the definition would be derived based on data from a large group of women who were followed without intervention and had optimal maternal and neonatal outcomes, but there are obvious practical and ethical barriers to this. , The sensitivity and specificity of the test will vary depending on the choice of threshold, but so will the estimates of the effectiveness of interventions based on that threshold. Comparing results across studies requires a common definition for such “normal” labor and permeates our review.

There is evidence that partograms are useful in low-resource settings, but they have not been shown to improve labor outcomes in high-resource settings. This may be due in part to differences in the data sources for generating labor curves and thresholds. Feasibility and ethical challenges with obtaining a large, contemporary sample of women laboring with minimal to no intervention limits our fundamental scientific understanding of normal labor, normal labor progress, and when durations of labor lead to worse maternal/child outcomes.

In general, our findings that “normal” labor in modern settings is generally longer than earlier guidance are consistent with current guidelines <sup>3</sup>, which are largely informed by the Consortium on Safe Labor (CSL) data and encourage allowing longer durations for both first and second stages of labor before intervening with cesarean delivery. However, as noted, over half of women in the “normal” group received augmentation in the CSL data, and the data are not informative about optimal timing of augmentation. Routine amniotomy is not specifically recommended, although the recommendations note that amniotomy may be helpful in the transition from latent to active labor. Based on the same Cochrane review finding, improved satisfaction and lower cesarean and operative vaginal delivery rates, emotional support is recommended. The potential effect of epidural analgesia on duration of labor is noted as a potential consideration in allowing longer durations before intervention, but there are no recommendations about specific techniques. Cervical exam frequency, intrauterine pressure monitoring, oxytocin dosing protocols, methods for routine fetal monitoring, or timing of pushing in the second labor are not discussed, consistent with the relative paucity of evidence.

The impact of regional anesthesia on the length of the first stage of labor is uncertain, leading to conflicting recommendations from different professional societies. Our findings do not provide greater clarity.

## **Applicability**

Table 82 summarizes the applicability scores across KQs. Applicability ratings provide information as to whether the population, interventions, comparators, outcomes, or settings evaluated in the included studies are applicable to clinical practice and specific KQs of interest. Note that applicability ratings were performed for the 124 primary included studies and not for the included systematic reviews.

**Table 82. Potential issues with applicability of included studies<sup>a</sup>**

	Issues	KQ 1 N=19	KQ 2 N=9	KQ 3 N=61	KQ 4 N=22	KQ 5 N=0	KQ 6 N=0	KQ 7 N=11	KQ 8 N=0	KQ 9 N=5	Total N=122
<b>Population</b>	Study population demographics not representative of intended population	3	2	17	3	0	0	1	0	0	23
	Narrow or unrepresentative severity/ stage/ comorbidity	1	0	0	0	0	0	3	0	0	4
<b>Intervention</b>	Intervention details not representative of current practice	0	1	4	1	0	0	3	0	0	9
	Change in standard of care	0	0	1	0	0	0	0	0	0	0
<b>Comparator</b>	Comparator not representative of current practice	0	0	12	3	0	0	0	0	0	13
<b>Outcomes</b>	Timing of outcome assessment	0	0	0	0	0	0	0	0	0	0
<b>Setting</b>	Standards or access to care vary from US setting	3	1	46	5	0	0	6	0	1	59
	Specialty population or level of care	3	0	0	0	0	0	0	0	0	3

<sup>a</sup> Numbers in cells represent the number of included studies that were identified as having potential issues related to the specific item. Columns represent numbers for each Key Question and then for all included studies.

Two broad issues relate to the overall applicability of the available evidence to clinical practice in the United States—one geographic and one temporal. Many of the randomized controlled trials (RCTs) meeting our criteria were performed outside of the United States. Aside from issues related to differences in study oversight or reporting, the populations of these studies may differ from U.S. women in labor in terms of health systems, patient preferences and expectations, provider perceptions of risk, availability of resources, and so on. This is particularly relevant to studies that directly compared management strategies based on explicit criteria for defining abnormal labor and studies that attempted to define a “normal” duration of labor (KQ 1). Particularly for studies where the primary outcome is cesarean delivery, factors that affect the threshold for performing cesarean—both the explicit “cutpoint” for duration of labor used and broader factors ranging from the relative safety of surgery versus vaginal delivery in low resource settings to cultural expectations to legal concerns—may affect the estimates of effectiveness of an intervention.

A number of studies included the use of a partogram—a graphical comparison of a woman’s labor progress compared to a standard—with thresholds for intervention clearly identified. Strength of evidence was judged to be low, with one major factor being a lack of U.S.-based studies. In low-resource settings, the use of a partogram was associated with lower overall cesarean delivery rates compared with labor managed without a partogram, and earlier

interventions were associated with lower cesarean delivery rates. In high-resource settings, the use of a partogram that included an assessment of latent phase duration, and which had a threshold for action at 3 hours compared to 4 hours, had higher cesarean delivery rates; but otherwise the use of a partogram compared with no partogram, or other time intervals for action lines, did not affect mode of delivery, duration of labor, indication for cesarean delivery, or complications including postpartum hemorrhage, maternal infection, or neonatal acidemia. Outside of U.S.-based settings, populations, health systems, and management of both prenatal and intrapartum care are quite different—and the impact of these differences on both the relative effectiveness and the absolute difference in outcomes is likely substantial.

Even more fundamentally, use of a tool such as a partogram, or specific interventions such as amniotomy, requires evidence on “normal” labor in order to define requires evidence on “normal” labor in order to define appropriate thresholds for action. The studies we reviewed that attempted to define “normal” labor differed based on parity, the time period in which the studies were conducted, and, among nulliparous women, maternal age. Evidence from the CSL, representing the most recent available large-scale population data<sup>21</sup> suggest a longer duration of first stage of labor compared to earlier studies, including the National Collaborative Perinatal Project (NCPP).<sup>22</sup> However, the most striking difference between these two studies was the proportion of women who received oxytocin augmentation (14.6% in the NCPP cohort from 1959 to 1966 compared with 45.9% in the CSL cohort from 2002 to 2008).

The CSL population that was used to generate new labor curves consists of women who had spontaneous onset of labor and a vaginal delivery, and thus the labor curves presented provide an estimate of “normal” labor that does not end in a cesarean delivery. Since such a large proportion of women received augmentation, these data do not provide insight into the range of rates of labor progression among women who do not receive augmentation, and cannot provide insight into the relative harms and benefits of augmentation, or the most appropriate thresholds for the timing or dosing of augmentation. The association between a longer duration of the first stage of labor and the greater use of oxytocin among women with a vaginal delivery is consistent with the possibility that greater use of oxytocin may avoid cesarean delivery, but not with observed secular trends in cesarean delivery rates. One would expect that any changes in the threshold for cesarean delivery caused by greater “patience” (allowing a longer duration) and/or “medical management” (greater use of oxytocin) would lead to decreases in cesarean delivery rates.

In summary, evidence suggests that the specific criteria used to define “normal” labor, or a specific threshold for intervention, may affect cesarean delivery rates but not other maternal or neonatal outcomes in some settings. Yet there is no available evidence for the United States. Among women in the United States with spontaneous onset of labor and vaginal delivery, labor progression is slower for women having their first baby compared to women with prior deliveries, but the high proportion of women receiving oxytocin augmentation prevents drawing any inferences about the “normal” labor curve in women with spontaneous onset of labor, no interventions to augment labor, and no adverse maternal or neonatal outcomes.

Many of these issues may also contribute to heterogeneity when trying to combine studies for the purposes of meta-analysis.

## **Implications for Clinical and Policy Decision Making**

There is widespread consensus that the current cesarean delivery rate in the United States is too high, and national organizations suggest implementation of strategies to safely decrease the cesarean delivery rate. Cesarean delivery is performed for a range of indications, and any

strategy to reduce the overall rate needs to be multifaceted and based on achieving an optimal rate (balancing both maternal and neonatal outcomes) for each indication—although the optimal cesarean delivery rate that balances maternal and neonatal outcomes is not known. Because abnormal labor is a common indication for cesarean delivery (particularly for first cesareans), strategies for reducing the rate of cesarean for prolonged labor have the potential to reduce the overall rate by decreasing both primary and repeat cesareans.

Data on the “normal” range of labor duration from the CSL are useful for developing guidance for when (or whether) to consider intervention with cesarean section. However, because (a) a very high proportion of women received oxytocin augmentation and (b) separate curves are not reported for those with and without augmentation, this evidence is not helpful in developing strategies for when to initially intervene with oxytocin or other labor stimulus.

Given the evidence that partograms have been useful in other settings, and the potential benefit of formal decision tools seen in other conditions, there may be potential for incorporating more direct decision aids to help guide when, or when not, to intervene in otherwise uncomplicated labor based on the temporal progress of labor. Such tools need to incorporate both clinical evidence and patient preferences for choices about the process of labor.

## **Limitations of the Systematic Review Process**

Several aspects of the review process may have affected the results. First, there were constraints in our search strategy, developed in consultation with the Key Informants and Technical Expert Panel. We limited the search to papers published after January 2005. This meant that studies completed prior to the cutoff date, which otherwise might have met inclusion criteria, were excluded. While we believe that the majority of these studies were included in the systematic reviews we used to supplement each KQ, it is possible that potentially relevant articles were missed. Given broad changes in clinical practice over the past decade, the impact of missing earlier studies on conclusions about comparative effectiveness of currently used treatment alternatives is unclear.

We also did not include studies published in languages other than English, primarily due to resource limitations. Given the high volume of literature available in English-language publications, the focus of our review on applicability to populations in the United States, and the scope of our current KQs, non-English articles were excluded.

## **Research Recommendations**

We identified several areas of needed future research:

- It would be extremely useful to have separate labor curves derived from contemporary U.S. data for women with spontaneous onset of labor, no augmentation with oxytocin or other pharmacologic agents, and vaginal delivery of healthy baby, stratified by parity, as well as for women with augmented labor. Such labor curves would provide a better understanding of the modern natural course of labor and may provide better information on when to initiate agents to augment labor and when to proceed with cesarean delivery. Such studies could also potentially include laboring women with cesareans for non-labor diagnoses, although the threshold for intervention might be influenced by perceptions of the effect of labor duration on the condition leading to the intervention (e.g., women with pre-eclampsia).



- Evaluation of specific labor management strategies (including the use of partograms) derived from contemporary data sources such as the CSL should be a priority. This evaluation should include comparison of different methods for integrating decision support into existing technologies, such as methods and timing of augmenting labor (oxytocin administration, artificial rupture of the membranes), fetal monitoring, tools to monitor uterine contraction strength and frequency, and the impact of supportive therapies (massage, fluids, nutrition, positioning) on mode of delivery. This evaluation would help generate best practice recommendations for safe reduction of the primary cesarean delivery rate while balancing maternal and neonatal outcomes. Given the potential difficulties in recruiting patients into randomized trials, consideration should be given to both high-quality observational studies as well as research designs that combine randomization with allowance for patient preferences.<sup>230,231</sup>
- Given the importance of the labor process to patient preferences and their birthing experience and the lack of evidence about the impact of available interventions on these preferences, the development of tools for estimating patient preferences for both the process and maternal and neonatal outcomes of labor should be a priority. Discrete choice experiments would be one method appropriate for estimating preferences for these complex tradeoffs.
- Comparison of patient preferences of nulliparous to parous women are of great interest as preferences may vary based on prior labor experiences and expectations.
- Studies of these tools/methods should also explore the complexity of decision making that needs to incorporate both maternal and paternal preferences, as well as preferences where parents are acting as surrogates for infants. For example, in a study which elicited preferences for an adverse neonatal outcome with long-term health implications for the purposes of economic analysis, each parent would have preferences that reflect the impact of the condition on their roles as parents, and could provide a preference acting as a surrogate for the child, but the child might have quite different preferences.<sup>232-234</sup> Validated measures should be incorporated into clinical trials and prospective studies as specific outcomes.
- Encouragement of use of core outcome sets, such as those developed as part of the CROWN (Core Outcomes in Women's Health) initiative.<sup>235</sup>

## Conclusions

Dystocia is a common indication for cesarean delivery. Recent data demonstrate that the normal progress of labor with current practice is quite different from curves originally described, although there is still uncertainty about the duration of “normal” labor in the absence of augmentation. Amniotomy and oxytocin decrease duration of labor without increasing cesarean delivery. Emotional support reduces operative delivery rates and patient satisfaction. Further work is needed to identify strategies for management of labor that optimize maternal and neonatal outcomes and patient preferences while minimizing cesarean delivery rates.

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## Acronyms and Abbreviations

AE	Adverse events
AHRQ	Agency for Healthcare Research and Quality
AMSTAR	A Measurement Tool to Assess Systematic Reviews
aOR	Adjusted odds ratio
AROM	Artificial rupture of membranes
BMI	Body mass index
CDSR	Cochrane Database of Systematic Reviews
CI	Confidence interval
CPAP	Continuous positive airway pressure;
CSE	Combined spinal epidural
CSL	Consortium on Safe Labor
EA	Epidural analgesia
EHC	Effective Health Care
FHR	Fetal heart rate
HOB	Head of bed
IQR	Interquartile range
KQ	Key Question
MA	Meta-analysis
MD	Mean difference
NA	Not applicable
NCPP	National Collaborative Perinatal Project
NICU	Neonatal intensive care unit
NR	Not reported
NS	Not significant
NRFHT	Nonreassuring Fetal Heart Rate Tracing
OR	Odds ratio
PCIA	Patient-controlled intravenous analgesia
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting
PSU	Prince of Songkla University
RCT	Randomized controlled trial
RR	Relative risk
SD	Standard deviation
SOE	Strength of evidence
SR	Systematic review
WMD	Weighted mean difference

# Appendix A. Exact Search Strings

## PubMed® Search Strategy (February 15, 2019)

Search Number	Search String
#1	"Dystocia"[Mesh] OR "Dystocia"[tiab] OR "Dystocias"[tiab] OR "hypotonic contractions"[tiab] OR "slow progress"[tiab] OR "lack of progress"[tiab] OR "unsatisfactory progress"[tiab] OR "failure to progress"[tiab] OR "abnormal labor"[tiab] OR "labor arrest"[tiab] OR "labour arrest"[tiab] OR "arrested labor"[tiab] OR "arrest of labor"[tiab] OR "prolonged labor"[tiab] OR "dysfunctional labor"[tiab] OR "obstructed labor"[tiab] OR "labor obstruction"[tiab] OR "abnormal labour"[tiab] OR "labour arrest"[tiab] OR "arrested labour"[tiab] OR "arrest of labour"[tiab] OR "prolonged labour"[tiab] OR "dysfunctional labour"[tiab] OR "obstructed labour"[tiab] OR "labour obstruction"[tiab] OR "inefficient uterine contractions"[tiab] OR "protracted"[tiab] OR "arrested descent"[tiab] OR "arrest of descent"[tiab] OR "inertia uteri"[tiab] OR "uterine inertia"[tiab] OR "uterus inertia"[tiab] OR "Uterine Atony"[tiab] OR "inefficient uterine action"[tiab] OR "prolonged deceleration phase"[tiab] OR "abnormal progress"[tiab] OR "transverse arrest"[tiab] OR "prolonged second stage"[tiab] OR "delayed second stage"[tiab] OR "non-progressive labor"[tiab] OR "non-progressive labour"[tiab] OR "protraction disorder"[tiab] OR "protraction disorders"[tiab] OR "arrest disorder"[tiab] OR "arrest disorders"[tiab] OR "hypocontractile labour"[tiab] OR "hypocontractile labor"[tiab]
#2	"Labor, Obstetric"[Mesh] OR "Delivery, Obstetric"[Mesh] OR "Labor Onset"[Mesh] OR "Obstetric Delivery"[tiab] OR "Obstetric Deliveries"[tiab] OR "obstetric labor"[tiab] OR "obstetric labour"[tiab] OR "normal labor"[tiab] OR "normal labour" OR "term labor" OR "term labour" OR "labor onset"[tiab] OR "labour onset"[tiab] OR "Second Labor Stages"[tiab] OR "Second Labour Stages"[tiab] OR "Second Stage of Labor"[tiab] OR "Second Stage of Labour"[tiab] OR "Second Stage Labor"[tiab] OR "Second Stage Labour"[tiab] OR "First Stage of Labor"[tiab] OR "First Stage of Labour"[tiab] OR "First Stage Labor"[tiab] OR "First Stage Labour"[tiab] OR ((labour[tiab] OR labor[tiab]) AND ("Pregnancy"[Mesh:NoExp] OR "Pregnant Women"[Mesh] OR "pregnancy"[tiab] OR "pregnant"[tiab] OR "pregnancies"[tiab] OR "gestation"[tiab] OR "Prenatal Care"[Mesh] OR "childbirth"[tiab] OR "Parity"[Mesh] OR "nulliparous"[tiab] OR "multiparous"[tiab] OR "Cervical Dilatation"[tiab] OR "Cervical Dilatations"[tiab]))
#3	#1 AND #2
#4	("Labor Onset"[Mesh] OR "labor onset"[tiab] OR "labour onset"[tiab] OR "Second Labor Stages"[tiab] OR "Second Labour Stages"[tiab] OR "Second Stage of Labor"[tiab] OR "Second Stage of Labour"[tiab] OR "Second Stage Labor"[tiab] OR "Second Stage Labour"[tiab] OR "First Stage of Labor"[tiab] OR "First Stage of Labour"[tiab] OR "First Stage Labor"[tiab] OR "First Stage Labour"[tiab]) AND ("Time Factors"[Mesh] OR "Pregnancy Outcome"[Mesh])
#5	#3 OR #4
#6	#5 NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (animals[mh] NOT humans[mh])
#7	Limits: English; Date-2005 - Present
#8	"Amnion/surgery"[Mesh] OR "Amniotomy"[tiab]

Search Number	Search String
#9	"Exercise"[Mesh] OR "walking"[tiab] OR "ambulation"[tiab] OR "Nutrition Processes"[Mesh] OR "Eating"[tiab] OR "drinking"[tiab] OR "Diet"[Mesh:NoExp] OR "Fasting"[Mesh] OR "fasting"[tiab] OR "nutrition"[tiab] OR "intravenous dextrose"[tiab] OR "normal saline"[tiab] OR "Infusions, Intravenous"[Mesh] OR "Intravenous Drip"[tiab] OR "Infusion Drip"[tiab] OR "IV hydration"[tiab] OR "intravenous hydration"[tiab] OR "Ringer solution"[tiab] OR "Ringer-locke solution"[tiab] OR "hydration fluids"[tiab] OR "oral fluids"[tiab] OR "Bradley Method"[tiab] OR "Pain/prevention and control"[Mesh] OR "Doulas"[Mesh] OR "Doulas"[tiab] OR "Doula"[tiab] OR "labor coach"[tiab] OR "labor coaches"[tiab] OR "Natural Childbirth"[Mesh] OR "emotional support"[tiab] OR "Coaching"[tiab] OR "Peanut ball"[tiab] OR "birthing ball"[tiab] OR "childbirth education"[tiab] OR "Lamaze"[tiab] OR "hypnobirthing"[tiab] OR "hypnosis"[tiab] OR "HypnoBabies"[tiab] OR "Complementary Therapies"[Mesh] OR "Healthy Birth"[tiab] OR "Patient Care Planning"[Mesh:NoExp] OR "supplemental oxygen"[tiab] OR "oxygen supplementation"[tiab] OR "Fetal Distress/therapy"[Mesh] OR "Oxygen Inhalation Therapy"[Mesh:NoExp] OR "Hydrotherapy"[Mesh] OR "hydrotherapy"[tiab] OR "hydrotherapies"[tiab] OR "Whirlpool Baths"[tiab] OR "Whirlpool Bath"[tiab] OR "birthing tub"[tiab] OR "Warm Baths"[tiab] OR "warm bath"[tiab] OR "Patient Positioning"[Mesh] OR "supine"[tiab] OR "Posture"[Mesh] OR "Psychoprophylaxis"[tiab] OR "Acupuncture"[tiab] OR "Acupressure"[tiab] OR "Aromatherapy"[tiab] OR "music therapy"[tiab] OR "massage"[tiab])
#10	"analgesia, epidural"[MeSH] OR "Anesthesia, Epidural"[Mesh] OR "epidural"[tiab]
#11	"Gynecological Examination"[Mesh] OR "Gynecological Examination"[tiab] OR "Gynecological Examinations"[tiab] OR "Gynecological Exam"[tiab] OR "Gynecological Exams"[tiab] OR "Gynaecological Examination"[tiab] OR "Gynaecological Examinations"[tiab] OR "Gynaecological Exam"[tiab] OR "Gynaecological Exams"[tiab] OR "Vaginal Examination"[tiab] OR "Vaginal Examinations"[tiab] OR "Vaginal Exam"[tiab] OR "Vaginal Exams"[tiab] OR "Cervical Examination"[tiab] OR "Cervical Examinations"[tiab] OR "Cervical Exam"[tiab] OR "Cervical Exams"[tiab] OR ("Cervix Uteri"[Mesh] AND ("Examination"[tiab] OR "Examinations"[tiab] OR "Exam"[tiab] OR "Exams"[tiab])) OR "Pelvic Examination"[tiab] OR "Pelvic Examinations"[tiab] OR "Pelvic Exam"[tiab] OR "Pelvic Exams"[tiab]
#12	"Uterine Monitoring"[Mesh] OR "Uterine Monitoring"[tiab] OR "intrauterine pressure catheter"[tiab] OR "intrauterine pressure catheters"[tiab] OR "IUPC"[tiab] OR Tocodynamometry[tiab] OR Tocography[tiab] OR Tocograms[tiab] OR Tocogram[tiab]
#13	"Oxytocin"[Mesh] OR "Oxytocics"[Mesh] OR "Oxytocin"[tiab] OR "Syntocinon"[tiab] OR "Pitocin"[tiab] OR "nipple stimulation"[tiab]
#14	"Valsalva Maneuver"[Mesh] OR "Valsalva Maneuvers"[tiab] OR "Valsalva Maneuver"[tiab] OR "Valsalva pushing"[tiab] OR "passive descent"[tiab] OR "delayed pushing"[tiab] OR "open glottis pushing"[tiab]
#15	(randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized[tiab] OR randomised[tiab] OR randomization[tiab] OR randomisation[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab] OR systematic[sb] OR "meta-analysis"[Publication Type] OR "meta-analysis as topic"[MeSH Terms] OR "meta-analysis"[tiab] OR "meta-analyses"[tiab]) NOT (Editorial[ptyp] OR Letter[ptyp] OR Case Reports[ptyp] OR Comment[ptyp]) NOT (animals[mh] NOT humans[mh])
#16	(#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)
#17	#2 AND #15 AND #16
#18	Limits: English; Date-2005 - Present
#19	#7 OR #18

# Embase® Search Strategy (February 15, 2019)

Platform: Embase.com

Search Number	Search String
#1	'dystocia'/exp OR 'dystocia':ab,ti OR 'dystocias':ab,ti OR 'hypotonic contractions':ab,ti OR 'slow progress':ab,ti OR 'lack of progress':ab,ti OR 'unsatisfactory progress':ab,ti OR 'failure to progress':ab,ti OR 'abnormal labor':ab,ti OR 'labor arrest':ab,ti OR 'arrested labor':ab,ti OR 'arrest of labor':ab,ti OR 'prolonged labor':ab,ti OR 'dysfunctional labor':ab,ti OR 'obstructed labor':ab,ti OR 'labor obstruction':ab,ti OR 'abnormal labour':ab,ti OR 'labour arrest':ab,ti OR 'arrested labour':ab,ti OR 'arrest of labour':ab,ti OR 'prolonged labour':ab,ti OR 'dysfunctional labour':ab,ti OR 'obstructed labour':ab,ti OR 'labour obstruction':ab,ti OR 'inefficient uterine contractions':ab,ti OR 'protracted':ab,ti OR 'arrested descent':ab,ti OR 'arrest of descent':ab,ti OR 'inertia uteri':ab,ti OR 'uterine inertia':ab,ti OR 'uterus inertia':ab,ti OR 'uterine atony':ab,ti OR 'inefficient uterine action':ab,ti OR 'prolonged deceleration phase':ab,ti OR 'abnormal progress':ab,ti OR 'transverse arrest':ab,ti OR 'prolonged second stage':ab,ti OR 'delayed second stage':ab,ti OR 'non-progressive labor':ab,ti OR 'non-progressive labour':ab,ti OR 'protraction disorder':ab,ti OR 'protraction disorders':ab,ti OR 'arrest disorder':ab,ti OR 'arrest disorders':ab,ti OR 'hypocontractile labour':ab,ti OR 'hypocontractile labor':ab,ti
#2	'delivery'/exp OR 'childbirth'/exp OR 'obstetric delivery':ab,ti OR 'obstetric deliveries':ab,ti OR 'obstetric labor':ab,ti OR 'obstetric labour':ab,ti OR 'normal labor':ab,ti OR 'normal labour' OR 'term labor' OR 'term labour' OR 'labor onset':ab,ti OR 'labour onset':ab,ti OR 'second labor stages':ab,ti OR 'second labour stages':ab,ti OR 'second stage of labor':ab,ti OR 'second stage of labour':ab,ti OR 'second stage labor':ab,ti OR 'second stage labour':ab,ti OR 'first stage of labor':ab,ti OR 'first stage of labour':ab,ti OR 'first stage labor':ab,ti OR (labour:ab,ti OR labor:ab,ti AND 'pregnancy'/de) OR 'pregnant woman'/exp OR 'pregnancy':ab,ti OR 'pregnant':ab,ti OR 'pregnancies':ab,ti OR 'gestation':ab,ti OR 'prenatal care'/exp OR 'childbirth':ab,ti OR 'parity'/exp OR 'nulliparous':ab,ti OR 'multiparous':ab,ti OR 'cervical dilatation':ab,ti OR 'cervical dilatations':ab,ti
#3	#1 AND #2
#4	'labor stage'/exp OR 'labor onset':ab,ti OR 'labour onset':ab,ti OR 'second labor stages':ab,ti OR 'second labour stages':ab,ti OR 'second stage of labor':ab,ti OR 'second stage of labour':ab,ti OR 'second stage labor':ab,ti OR 'second stage labour':ab,ti OR 'first stage of labor':ab,ti OR 'first stage of labour':ab,ti OR 'first stage labor':ab,ti AND 'parameters concerning the fetus, newborn and pregnancy'/exp
#5	#3 OR #4
#6	#5 NOT ('case report'/exp OR 'case study'/exp OR 'editorial'/exp OR 'letter'/exp OR 'note'/exp OR 'conference paper'/exp OR [conference abstract]/lim OR [conference paper]/lim OR [editorial]/lim OR [letter]/lim OR [note]/lim)
#7	#6 AND [humans]/lim AND [english]/lim AND [2005-2016]/py
#8	'amniotomy'/exp OR 'amniotomy':ab,ti
#9	'exercise'/exp OR 'walking':ab,ti OR 'ambulation':ab,ti OR 'nutrition'/exp OR 'eating':ab,ti OR 'drinking':ab,ti OR 'diet'/de OR 'diet restriction'/exp OR 'fasting':ab,ti OR 'nutrition':ab,ti OR 'intravenous dextrose':ab,ti OR 'normal saline':ab,ti OR 'intravenous drug administration'/exp OR 'intravenous drip':ab,ti OR 'infusion drip':ab,ti OR 'iv hydration':ab,ti OR 'intravenous hydration':ab,ti OR 'ringer solution':ab,ti OR 'ringer locke solution':ab,ti OR 'hydration fluids':ab,ti OR 'oral fluids':ab,ti OR 'bradley method':ab,ti OR ('prevention and control'/exp AND 'pain'/exp) OR 'doula'/exp OR 'doulas':ab,ti OR 'doula':ab,ti OR 'labor coach':ab,ti OR 'labor coaches':ab,ti OR 'natural childbirth'/exp OR 'emotional support':ab,ti OR 'coaching':ab,ti OR 'peanut ball':ab,ti OR 'birthing ball':ab,ti OR 'childbirth education':ab,ti OR 'lamaze':ab,ti OR 'hypnobirthing':ab,ti OR 'hypnosis':ab,ti OR 'hypnobabies':ab,ti OR 'alternative medicine'/exp OR 'healthy birth':ab,ti OR 'patient care planning'/exp OR 'supplemental oxygen':ab,ti OR 'oxygen supplementation':ab,ti OR ('fetus distress'/exp AND 'therapy'/de) OR 'oxygen therapy'/exp OR 'hydrotherapy'/exp OR 'hydrotherapy':ab,ti OR 'hydrotherapies':ab,ti OR 'whirlpool baths':ab,ti OR 'whirlpool bath':ab,ti OR 'birthing tub':ab,ti OR 'warm baths':ab,ti OR 'warm bath':ab,ti OR 'patient positioning'/exp OR 'birthing position'/exp OR 'supine':ab,ti OR 'psychoprophylaxis':ab,ti OR 'acupuncture':ab,ti OR 'acupressure':ab,ti OR 'aromatherapy':ab,ti OR 'music therapy':ab,ti OR 'massage':ab,ti
#10	'analgesia'/exp OR 'epidural anesthesia'/exp OR 'epidural':ab,ti
#11	'gynecological examination'/exp OR 'gynecological examination':ab,ti OR 'gynecological examinations':ab,ti OR 'gynecological exam':ab,ti OR 'gynecological exams':ab,ti OR 'gynaecological

Search Number	Search String
	examination':ab,ti OR 'gynaecological examinations':ab,ti OR 'gynaecological exam':ab,ti OR 'gynaecological exams':ab,ti OR 'vaginal examination':ab,ti OR 'vaginal examinations':ab,ti OR 'vaginal exam':ab,ti OR 'vaginal exams':ab,ti OR 'cervical examination':ab,ti OR 'cervical examinations':ab,ti OR 'cervical exam':ab,ti OR 'cervical exams':ab,ti OR ('uterine cervix'/exp AND ('examination':ab,ti OR 'examinations':ab,ti OR 'exam':ab,ti OR 'exams':ab,ti)) OR 'pelvic examination':ab,ti OR 'pelvic examinations':ab,ti OR 'pelvic exam':ab,ti OR 'pelvic exams':ab,ti
#12	'fetus monitoring'/exp OR 'uterine monitoring':ab,ti OR 'intrauterine pressure catheter'/exp OR 'intrauterine pressure catheter':ab,ti OR 'intrauterine pressure catheters':ab,ti OR 'iupc':ab,ti OR 'tocodynamometry':ab,ti OR 'tocography':ab,ti OR 'tocograms':ab,ti OR 'tocogram':ab,ti
#13	'oxytocin'/exp OR 'oxytocic agent'/exp OR 'ocytocin':ab,ti OR 'syntocinon':ab,ti OR 'pitocin':ab,ti OR 'nipple stimulation':ab,ti
#14	'Valsalva maneuver'/exp OR 'Valsalva maneuvers':ab,ti OR 'Valsalva maneuver':ab,ti OR 'Valsalva pushing':ab,ti OR 'passive descent':ab,ti OR 'delayed pushing':ab,ti OR 'open glottis pushing':ab,ti
#15	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14
#16	'randomized controlled trial'/exp OR 'crossover procedure'/exp OR 'double blind procedure'/exp OR 'single blind procedure'/exp OR random* OR factorial* OR crossover* OR cross NEAR/1 over* OR placebo* OR doubl* NEAR/1 blind* OR singl* NEAR/1 blind* OR assign* OR allocat* OR volunteer*
#17	#2 AND #15 AND #16
#18	#17 NOT ('case report'/exp OR 'case study'/exp OR 'editorial'/exp OR 'letter'/exp OR 'note'/exp OR 'conference paper'/exp OR [conference abstract]/lim)
#19	#18 AND [humans]/lim AND [english]/lim AND [2005-2016]/py
#20	#7 OR #19
#21	#20 AND [embase]/lim NOT [medline]/lim

# CINAHL (Cumulative Index to Nursing & Allied Health Literature) Search Strategy (February 15, 2019)

Search Number	Search String
S1	TI ("dystocia" OR "dystocias" OR "hypotonic contractions" OR "slow progress" OR "lack of progress" OR "unsatisfactory progress" OR "failure to progress" OR "abnormal labor" OR "labor arrest" OR "arrested labor" OR "arrest of labor" OR "prolonged labor" OR "dysfunctional labor" OR "obstructed labor" OR "labor obstruction" OR "abnormal labour" OR "labour arrest" OR "arrested labour" OR "arrest of labour" OR "prolonged labour" OR "dysfunctional labour" OR "obstructed labour" OR "labour obstruction" OR "inefficient uterine contractions" OR "protracted" OR "arrested descent" OR "arrest of descent" OR "inertia uteri" OR "uterine inertia" OR "uterus inertia" OR "uterine atony" OR "inefficient uterine action" OR "prolonged deceleration phase" OR "abnormal progress" OR "transverse arrest" OR "prolonged second stage" OR "delayed second stage" OR "non-progressive labor" OR "non-progressive labour" OR "protraction disorder" OR "protraction disorders" OR "arrest disorder" OR "arrest disorders" OR "hypocontractile labour" OR "hypocontractile labor") OR AB ("dystocia" OR "dystocias" OR "hypotonic contractions" OR "slow progress" OR "lack of progress" OR "unsatisfactory progress" OR "failure to progress" OR "abnormal labor" OR "labor arrest" OR "arrested labor" OR "arrest of labor" OR "prolonged labor" OR "dysfunctional labor" OR "obstructed labor" OR "labor obstruction" OR "abnormal labour" OR "labour arrest" OR "arrested labour" OR "arrest of labour" OR "prolonged labour" OR "dysfunctional labour" OR "obstructed labour" OR "labour obstruction" OR "inefficient uterine contractions" OR "protracted" OR "arrested descent" OR "arrest of descent" OR "inertia uteri" OR "uterine inertia" OR "uterus inertia" OR "uterine atony" OR "inefficient uterine action" OR "prolonged deceleration phase" OR "abnormal progress" OR "transverse arrest" OR "prolonged second stage" OR "delayed second stage" OR "non-progressive labor" OR "non-progressive labour" OR "protraction disorder" OR "protraction disorders" OR "arrest disorder" OR "arrest disorders" OR "hypocontractile labour" OR "hypocontractile labor") OR (MH "Dystocia+")
S2	TI ("childbirth" OR "obstetric delivery" OR "obstetric deliveries" OR "obstetric labor" OR "obstetric labour" OR "normal labor" OR "normal labour" OR "term labor" OR "term labour" OR "labor onset" OR "labour onset" OR "second labor stages" OR "second labour stages" OR "second stage of labor" OR "second stage of labour" OR "second stage labor" OR "second stage labour" OR "first stage of labor" OR "first stage of labour" OR "first stage labor" OR (labour OR labor AND pregnancy) OR "pregnant woman" OR "pregnancy" OR "pregnant" OR "pregnancies" OR "gestation" OR "prenatal care" OR "childbirth" OR "parity" OR "nulliparous" OR "multiparous" OR "cervical dilatation" OR "cervical dilations") OR AB ("childbirth" OR "obstetric delivery" OR "obstetric deliveries" OR "obstetric labor" OR "obstetric labour" OR "normal labor" OR "normal labour" OR "term labor" OR "term labour" OR "labor onset" OR "labour onset" OR "second labor stages" OR "second labour stages" OR "second stage of labor" OR "second stage of labour" OR "second stage labor" OR "second stage labour" OR "first stage of labor" OR "first stage of labour" OR "first stage labor" OR (labour OR labor AND pregnancy) OR "pregnant woman" OR "pregnancy" OR "pregnant" OR "pregnancies" OR "gestation" OR "prenatal care" OR "childbirth" OR "parity" OR "nulliparous" OR "multiparous" OR "cervical dilatation" OR "cervical dilations") OR ((MH "Labor Stages+") AND (MH "Time Factors" OR MH "Pregnancy Outcomes"))
S3	S1 AND S2
S4	TI ("labor stage" OR "labor onset" OR "labour onset" OR "second labor stages" OR "second labour stages" OR "second stage of labor" OR "second stage of labour" OR "second stage labor" OR "second stage labour" OR "first stage of labor" OR "first stage of labour" OR "first stage labor" AND ("Time Factors" OR "Pregnancy Outcome")) OR AB ("labor stage" OR "labor onset" OR "labour onset" OR "second labor stages" OR "second labour stages" OR "second stage of labor" OR "second stage of labour" OR "second stage labor" OR "second stage labour" OR "first stage of labor" OR "first stage of labour" OR "first stage labor" AND ("Time Factors" OR "Pregnancy Outcome")) OR (MH "Labor Stages+") AND (MH "Time Factors" OR MH "Pregnancy Outcomes")
S5	S3 OR S4
S6	S5 NOT PT (Abstract OR Book OR Book Chapter OR Book Review OR Case Study OR Commentary OR Doctoral Dissertation OR Editorial OR Letter OR Masters Thesis OR Pamphlet OR Pamphlet Chapter OR Poetry )
S7	S6 Limiters - English Language; Published Date: 20050101-20161231



Search Number	Search String
S8	TI ("Amnion surgery" or Amniotomy ) OR AB ( "Amnion surgery" or Amniotomy ) OR (MH "Fetal Membranes, Artificial Rupture")
S9	TI ("walking" OR "ambulation" OR "fasting" OR "intravenous dextrose" OR "normal saline" OR "intravenous drug administration" OR "intravenous drip" OR "infusion drip" OR "iv hydration" OR "intravenous hydration" OR "ringer solution" OR "ringer locke solution" OR "hydration fluids" OR "oral fluids" OR "bradley method" OR "doulas" OR "doula" OR "labor coach" OR "labor coaches" OR "natural childbirth" OR "emotional support" OR "coaching" OR "peanut ball" OR "birthing ball" OR "childbirth education" OR "lamaze" OR "hypnobirthing" OR "hypnosis" OR "hypnobabies" OR "alternative medicine" OR "healthy birth" OR "patient care planning" OR "supplemental oxygen" OR "oxygen supplementation" OR "oxygen therapy" OR "hydrotherapy" OR "hydrotherapies" OR "whirlpool baths" OR "whirlpool bath" OR "birthing tub" OR "warm baths" OR "warm bath" OR "patient positioning" OR "birthing position" OR "supine" OR "psychoprophylaxis" OR "acupuncture" OR "acupressure" OR "aromatherapy" OR "music therapy" OR "massage") OR AB ("walking" OR "ambulation" OR "fasting" OR "intravenous dextrose" OR "normal saline" OR "intravenous drug administration" OR "intravenous drip" OR "infusion drip" OR "iv hydration" OR "intravenous hydration" OR "ringer solution" OR "ringer locke solution" OR "hydration fluids" OR "oral fluids" OR "bradley method" OR "doulas" OR "doula" OR "labor coach" OR "labor coaches" OR "natural childbirth" OR "emotional support" OR "coaching" OR "peanut ball" OR "birthing ball" OR "childbirth education" OR "lamaze" OR "hypnobirthing" OR "hypnosis" OR "hypnobabies" OR "alternative medicine" OR "healthy birth" OR "patient care planning" OR "supplemental oxygen" OR "oxygen supplementation" OR "oxygen therapy" OR "hydrotherapy" OR "hydrotherapies" OR "whirlpool baths" OR "whirlpool bath" OR "birthing tub" OR "warm baths" OR "warm bath" OR "patient positioning" OR "birthing position" OR "supine" OR "psychoprophylaxis" OR "acupuncture" OR "acupressure" OR "aromatherapy" OR "music therapy" OR "massage") OR (MH "Exercise+" OR MH "Hydrotherapy+" OR MH "Alternative Birth Methods+" OR MH "Alternative Therapies+" OR MH "Prepared Childbirth")
S10	TI ("analgesia" OR "epidural") OR AB ("analgesia" OR "epidural") OR (MH "Analgesia, Epidural" OR MH "Anesthesia, Epidural")
S11	TI ("gynecological examination" OR "gynecological examinations" OR "gynecological exam" OR "gynecological exams" OR "gynaecological examination" OR "gynaecological examinations" OR "gynaecological exam" OR "gynaecological exams" OR "vaginal examination" OR "vaginal examinations" OR "vaginal exam" OR "vaginal exams" OR "cervical examination" OR "cervical examinations" OR "cervical exam" OR "cervical exams" OR ("cervix" AND ("examination" OR "examinations" OR "exam" OR "exams")) OR "pelvic examination" OR "pelvic examinations" OR "pelvic exam" OR "pelvic exams") OR AB ("gynecological examination" OR "gynecological examinations" OR "gynecological exam" OR "gynecological exams" OR "gynaecological examination" OR "gynaecological examinations" OR "gynaecological exam" OR "gynaecological exams" OR "vaginal examination" OR "vaginal examinations" OR "vaginal exam" OR "vaginal exams" OR "cervical examination" OR "cervical examinations" OR "cervical exam" OR "cervical exams" OR ("cervix" AND ("examination" OR "examinations" OR "exam" OR "exams")) OR "pelvic examination" OR "pelvic examinations" OR "pelvic exam" OR "pelvic exams") OR (MH "Gynecologic Examination")
S12	TI ("fetus monitoring" OR "uterine monitoring" OR "intrauterine pressure catheter" OR "intrauterine pressure catheters" OR "iupc" OR tocodynamometry OR tocography OR tocograms OR tocogram) OR AB ("fetus monitoring" OR "uterine monitoring" OR "intrauterine pressure catheter" OR "intrauterine pressure catheters" OR "iupc" OR tocodynamometry OR tocography OR tocograms OR tocogram) OR (MH "Uterine Monitoring" OR MH "Fetal Monitoring+" OR MH "Fetal Monitoring, Electronic+")
S13	TI ("oxytocin" OR "oxytocic agent" OR "ocytocin" OR "syntocinon" OR "pitocin" OR "nipple stimulation") OR AB ("oxytocin" OR "oxytocic agent" OR "ocytocin" OR "syntocinon" OR "pitocin" OR "nipple stimulation") OR (MH "Oxytocin" OR MH "Oxytocics+")
S14	TI ("Valsalva maneuvers" OR "Valsalva maneuver" OR "Valsalva pushing" OR "passive descent" OR "delayed pushing" OR "open glottis pushing") OR AB ("Valsalva maneuvers" OR "Valsalva maneuver" OR "Valsalva pushing" OR "passive descent" OR "delayed pushing" OR "open glottis pushing") OR (MH "Valsalva's Maneuver")
S15	S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S16	TI ("randomized controlled trial" OR "controlled clinical trial" OR "randomized" OR "randomized" OR "randomization" OR "randomization" OR "placebo" OR "randomly" OR "trial" OR "groups" OR "systematic review" OR "meta-analysis" OR "meta-analyses" OR AB ("randomized controlled trial" OR "controlled clinical trial" OR "randomized" OR "randomized" OR "randomization" OR "randomization"

Search Number	Search String
	OR "placebo" OR "randomly" OR "trial" OR "groups" OR "systematic review" OR "meta-analysis" OR "meta-analyses") OR (MH "Randomized Controlled Trials" OR MH "Systematic Review" OR MH "Meta Analysis")
S17	S2 AND S15 AND S16
S18	S17 NOT PT ( Abstract OR Book OR Book Chapter OR Book Review OR Case Study OR Commentary OR Doctoral Dissertation OR Editorial OR Letter OR Masters Thesis OR Pamphlet OR Pamphlet Chapter OR Poetry )
S19	S18 Limiters - English Language; Published Date: 20050101-20161231
S20	S7 OR S19

## Cochane Search Strategy (February 15, 2019)

Platform: Wiley

Database searched: Cochrane Database of Systematic Reviews

Search Number	Search String
#1	Dystocia or Dystocias or hypotonic contractions or slow progress or lack of progress or unsatisfactory progress or failure to progress or abnormal labor or labor arrest or labour arrest or arrested labor or arrest of labor or prolonged labor or dysfunctional labor or obstructed labor or labor obstruction or abnormal labour or labour arrest or arrested labour or arrest of labour or prolonged labour or dysfunctional labour or obstructed labour or labour obstruction or inefficient uterine contractions or protracted or arrested descent or arrest of descent or inertia uteri or uterine inertia or uterus inertia or Uterine Atony or inefficient uterine action or prolonged deceleration phase or abnormal progress or transverse arrest or prolonged second stage or delayed second stage or non-progressive labor or non-progressive labour or protraction disorder or protraction disorders or arrest disorder or arrest disorders or hypocontractile labour or hypocontractile labor
#2	Obstetric Delivery or Obstetric Deliveries or obstetric labor or obstetric labour or normal labor or normal labour or term labor or term labour or labor onset or labour onset or Second Labor Stages or Second Labour Stages or Second Stage of Labor or Second Stage of Labour or Second Stage Labor or Second Stage Labour or First Stage of Labor or First Stage of Labour or First Stage Labor or First Stage Labour or ((labour or labor) and (Pregnant Women or pregnancy or pregnant or pregnancies or gestation or Prenatal Care or childbirth or Parity or nulliparous or multiparous or Cervical Dilatation or Cervical Dilatations))
#3	#1 and #2
#4	(labor onset or labour onset or Second Labor Stages or Second Labour Stages or Second Stage of Labor or Second Stage of Labour or Second Stage Labor or Second Stage Labour or First Stage of Labor or First Stage of Labour or First Stage Labor or First Stage Labour) and (Time Factors or Pregnancy Outcome)
#5	#3 or #4
#6	#5 Publication Year from 2005 to 2016, in Cochrane Reviews (Reviews and Protocols)
#7	Amnion surgery or Amniotomy
#8	Exercise or walking or ambulation or Nutrition Processes or Eating or drinking or Diet or fasting or nutrition or intravenous dextrose or normal saline or Intravenous Drip or Infusion Drip or IV hydration or intravenous hydration or Ringer solution or Ringer-locke solution or hydration fluids or oral fluids or Bradley Method or Doulas or Doula or labor coach or labor coaches or Natural Childbirth or emotional support or Coaching or Peanut ball or birthing ball or childbirth education or Lamaze or hypnobirthing or hypnosis or HypnoBabies or Complementary Therapies or Healthy Birth or Patient Care Planning or supplemental oxygen or oxygen supplementation or Fetal Distress or Oxygen Inhalation Therapy or Hydrotherapy or hydrotherapy or hydrotherapies or Whirlpool Baths or Whirlpool Bath or birthing tub or Warm Baths or warm bath or Patient Positioning or supine or Posture or Psychoprophylaxis or Acupuncture or Acupressure or Aromatherapy or music therapy or massage
#9	epidural
#10	Gynecological Examination or Gynecological Examinations or Gynecological Exam or Gynecological Exams or Gynaecological Examination or Gynaecological Examinations or Gynaecological Exam or

Search Number	Search String
	Gynaecological Exams or Vaginal Examination or Vaginal Examinations or Vaginal Exam or Vaginal Exams or Cervical Examination or Cervical Examinations or Cervical Exam or Cervical Exams or (Cervix and (Examination or Examinations or Exam or Exams)) or Pelvic Examination or Pelvic Examinations or Pelvic Exam or Pelvic Exams
#11	Uterine Monitoring or intrauterine pressure catheter or intrauterine pressure catheters or IUPC or Tocodynamometry or Tocography or Tocograms or Tocogram
#12	Oxytocics or Oxytocin or Syntocinon or Pitocin or nipple stimulation
#13	Valsalva Maneuvers or Valsalva Maneuver or Valsalva pushing or passive descent or delayed pushing or open glottis pushing
#14	{or #7-#13}
#15	#2 and #14
#16	#15 Publication Year from 2005 to 2016, in Cochrane Reviews (Reviews and Protocols)
#17	#6 or #16

## Grey Literature Searches

### ClinicalTrials.gov (September 26, 2018)

Search Terms	Recruitment	Study Results	Study Type
labor dystocia OR partogram OR (labor progress AND Obstetric)	Completed studies	All studies	All studies

Total number of results: 33

### WHO: International Clinical Trials Registry Platform Search Portal (September 26, 2018)

Search Terms	labor dystocia OR partogram OR labor progress
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Total number of results: 44

### National Guidelines Clearinghouse (March 23, 2016)

Platform: [www.guideline.gov](http://www.guideline.gov)

Keyword	Clinical Specialty
Labor	Obstetrics and Gynecology

Total number of results: 49

## Appendix B. Data Abstraction Elements

### Study Characteristics

- Study Identifiers
  - Study Name or Acronym
  - NCT number
  - Last name of first author
- Additional Articles Used in This Abstraction
- Study Sites
  - Single Center, Multicenter, Unclear/Not reported
  - Number of sites
- Geographic Location (Select all that apply)
  - US, Canada, UK/Europe, Latin America, Middle East (includes Israel), Asia, Africa, Australia/NZ, Unclear/Not reported
- Study Design
  - RCT
  - Observational
- Funding Source
  - Government, Industry, Non-government/non-industry, Unclear/Not reported
- Setting
  - Hospital, Birthing Center, Home Birth, Other (specify), Unclear/Not reported
- Provider
  - Obstetrician, Family Physician, Nurse Midwife, Lay Midwife, Doula, Other (specify), Unclear/Not reported
- Study Definition of Dystocia as reported
- Study Enrollment/Study Completion
  - N enrolled/included
  - N completed
- Key Question Applicability
  - KQ1, KQ2, KQ3, KQ4, KQ5, KQ6, KQ7, KQ8, KQ9
- Comments

**Baseline Characteristics** – Record the following elements for Total Population, Arm 1, Arm 2, Arm 3, Arm 4, Arm 5, and Arm 6 (as applicable)

- Number of Patients (N and %)
- Age in years
  - Mean
  - Median
  - Standard Deviation
  - Minimum
  - Maximum
  - 25% inter-quartile range
  - 75% inter-quartile range
  - Categorical
  - Other (specify)
- Gender (N and %)

- Women
  - Men (Unclear/Not Reported)
- Race/Ethnicity (N and %) (indicate if Reported or Unclear/Not Reported)
  - Hispanic or Latino
  - Black/African American
  - American Indian or Alaska Native
  - Asian
  - Native Hawaiian or Pacific Islander
  - White
  - Multiracial
  - Other (specify)
- Body Weight (indicate if Reported or Unclear/Not Reported)
- Parity (indicate if Unclear/Not Reported)
- Socioeconomic Factors
  - Insurance Status
  - Income Level
  - Social Class
  - Level of Education
  - Other (specify)
  - Unclear/Not Reported
- Stage of Labor at Entry into Study
  - 1st stage latent (<4 cm dilation)
  - 1st stage active (4 - 10 cm dilation)
  - 2nd stage (full dilation - delivery)
  - Not reported/Unclear
  - Other, specify
  - Additional comments
- Study Definition of Labor
- Were there potentially relevant ( $p < 0.1$ ) differences noted between groups in any baseline characteristics? (Yes/No)
  - If yes, please explain the differences
- Is this study entirely composed of a population that would be considered a subgroup of interest? (Yes/No)
  - If yes, which subgroup?
    - Maternal age (particularly adolescents and women 35-44 years old)
    - Parity
    - Maternal race/ethnicity
    - Maternal socioeconomic status, including insurance status
    - Maternal obesity
- Comments

### **Intervention Characteristics**

- If applicable, describe the usual care intervention applied across all arms.
- Intervention Descriptors
  - Describe the intervention received by patients in each arm (Arms 1, 2, 3, 4, 5, and 6 as applicable).

- Intervention Components (for each Arm)
  - Amniotomy
    - Routine amniotomy
    - Amniotomy for specific indications (e.g., placement of fetal scalp monitor or intrauterine pressure catheter)
  - Supportive care measures
    - Ambulation
    - Routine maternal oxygen supplementation
    - Specific nutritional recommendations or limitations
    - Specific oral or parenteral hydration recommendations or limitations
    - Continuous emotional support
    - Peanut ball or birthing ball
    - Lamaze
    - Hypnobirthing
    - Positioning
    - Acupuncture
    - Hydrotherapy
    - Acupressure
    - Aromatherapy
    - Massage/warm compresses
    - Cold packs
    - TENS
    - Anethum Graveolens (dill) supplement
    - Other (specify)
  - Analgesia/Pain management
    - Epidural
    - Other methods of analgesia (parenteral narcotics, morphine, nitrous oxide)
    - Nonpharmacological methods of pain management
  - Cervical examination
    - Routine (indicate frequency)
    - As indicated (describe indication)
    - Unclear/Not reported
  - Contraction monitoring
    - Internal pressure catheter
    - External tocodynamometry
  - Oxytocin
    - Low dose oxytocin
    - High dose oxytocin
    - Nipple stimulation
    - Maternal oxygen supplementation as an adjunct to oxytocin
    - Different formulations of oxytocin (specify)
  - Fetal monitoring
    - Internal electronic fetal monitoring
    - External electronic fetal monitoring
    - Intermittent auscultation of fetal heart rate
  - Pushing strategy.

- Immediate pushing
  - Delayed/Valsalva pushing
  - Other
- No intervention/expectant management
- Other “usual care” as defined in study
- Placebo
- Comments

## Outcomes

- Select the outcome category reported on this form:
  - Maternal outcomes
    - Infection (chorioamnionitis, endometritis, wound infection)
    - Hemorrhage
    - Uterine rupture
    - Hysterectomy
    - Transfusion
    - Trauma to the pelvic floor (vaginal/perineal/cervical/bladder/rectal injury at the time of delivery)
    - Pelvic floor dysfunction (long-term urinary or fecal incontinence, fistulae, pelvic organ prolapse)
  - Neonatal outcomes
    - Neonatal acidemia (pH<7.1)
    - Hypoxic encephalopathy
    - Respiratory distress (need for oxygen supplementation, CPAP, intubation/ventilatory support)
    - Meconium aspiration syndrome
    - Neonatal infection/sepsis
    - Shoulder dystocia
    - Birth trauma (including brachial plexus injury)
    - Long-term neonatal health and developmental abnormalities (including cerebral palsy)
    - Admission to NICU > 24 hours
    - Neonatal length of stay
  - Process-related outcomes
    - Abnormal fetal heart rate tracing
    - Duration of labor
    - Mode of delivery (vaginal delivery, assisted vaginal delivery, cesarean delivery)
    - Parental preferences/satisfaction
- Any additional description / clarification of the outcome reported on this form
- Is this outcome form for a subgroup of interest? (Yes/No)
  - What subpopulation is this outcome reported for on this form?
    - Maternal age
    - Maternal race/ethnicity
    - Maternal obesity/BMI
    - Parity

- Socioeconomic status, including insurance status
  - Any additional description / clarification of subgroup reported on this form
- Total N Analyzed for this outcome
- What timepoint is reported on this form
  - Short-term: from beginning of spontaneous labor until discharge home (or equivalent for home delivery) for mother and infant
  - Long-term: from discharge onwards
  - Unclear
- Specify the timepoint for this outcome (with units: minutes, hours, days, weeks, months, years, NA)
- For each arm:
  - N Analyzed (UNK if unknown)
  - Unadjusted Result
    - Mean
    - Median
    - Mean within group change
    - Mean between group change
    - Number of patients with outcome
    - % of patients with outcome
    - Events/denominator
    - Odds ratio
    - Hazard ratio
    - Relative risk
    - Other (specify)
  - Unadjusted Result Variability
    - Standard Error (SE)
    - Standard Deviation (SD)
    - IQR
    - 95% CI
    - Other % CI (specify)
    - Other (specify)
  - Unadjusted Result, p-value between groups
  - Unadjusted Result, Reference group (for comparison between groups)
  - Adjusted Result
    - Mean
    - Median
    - Mean within group change
    - Mean between group change
    - Number of patients with outcome
    - % of patients with outcome
    - Events/denominator
    - Odds ratio
    - Hazard ratio
    - Relative risk
    - Other (specify)
  - Adjusted Result Variability



- Standard Error (SE)
  - Standard Deviation (SD)
  - IQR
  - 95% CI
  - Other % CI (specify)
  - Other (specify)
- Adjusted Result, p-value between groups
- Adjusted Result, Reference group (for comparison between groups)
- If adjusted data is recorded, indicate the adjustments applied
- Comments

## Quality

- Study Type (select one): RCT, Observational (Case-Control or Cohort)
- If RCT, select Yes/No/Unclear for each of the following questions:
  - Random sequence generation
    - Was the allocation sequence generated adequately (e.g., random number table, computer-generated randomization)?
  - Allocation concealment
    - Was the allocation of treatment adequately concealed (e.g., pharmacy-controlled randomization or use of sequentially numbered sealed envelopes)?
  - Blinding of participants, personnel and outcome assessors
    - Was knowledge of the allocated intervention adequately prevented during the study?
    - Were participants analyzed within the groups they were originally assigned to?
    - Does the design or analysis control account for important confounding and modifying variables through matching, stratification, multivariable analysis, or other approaches?
  - Incomplete outcome data
    - Were incomplete outcome data adequately addressed?
  - Selective outcome reporting
    - Are reports of the study free of suggestion of selective outcome reporting?
  - Other sources of bias
    - Was the study apparently free of other problems that could put it at a high risk of bias?
- If Case-Control, answer each of the following questions:
  - Selection
    - Is the case definition adequate?
      - Yes, with independent validation
      - Yes, e.g., record linkage or base on self reports
      - No description
    - Representativeness of the cases
      - Consecutive or obviously representative series of cases
      - Potential for selection biases or not stated
    - Selection of controls

- Community controls
    - Hospital controls
    - No description
  - Definition of controls
    - No history of disease (endpoint)
    - No description of source
- Comparability
  - Comparability of cases and controls on the basis of the design or analysis
    - Study controls
    - Study controls for any additional factor
- Exposure
  - Ascertainment of exposure
    - Secure record (e.g., surgical records)
    - Structured interview where blind to case/control status
    - Interview not blinded to case/control status
    - Written self report or medical record only
    - No description
  - Same method of ascertainment for cases and controls
    - Yes
    - No
  - Non-response rate
    - Same rate for both groups
    - Non-respondent described
    - Rate different and no designation
- If Cohort, answer each of the following questions:
  - Selection
    - Representativeness of the exposed cohort
      - Truly representative of the average \_ in the community
      - Somewhat representative of the average \_ in the community
      - Selected group of users (e.g., nurses, volunteers)
      - No description of the derivation of the cohort
    - Selection of the non-exposed cohort
      - Drawn from the same community as the exposed cohort
      - Drawn from a different source
      - No description of the derivation of the non-exposed cohort
    - Ascertainment of exposure
      - Secure record (e.g., surgical records)
      - Structured interview
      - Written self report
      - No description
    - Demonstration that outcome of interest was not present at start of study
      - Yes
      - No
  - Comparability
    - Comparability of cohorts on the basis of the design or analysis

- Study controls
    - Study controls for any additional factor
  - Outcome
    - Assessment of outcome
      - Independent blind assessment
      - Record linkage
      - Self report
      - No description
    - Was follow-up long enough for outcome to occur
      - Yes
      - No
    - Adequacy of follow up of cohorts
      - Complete follow up—all subjects accounted for
      - Subjects lost to follow up unlikely to introduce bias – small number lost - >95% follow up, or description provided of those lost
      - Follow up rate <95% and no description of those lost
      - No statement
- Overall Study Rating (Good/Fair/Poor)
  - **Good** (low risk of bias). These studies have the least bias, and the results are considered valid. These studies adhere to the commonly held concepts of high quality, including the following: a clear description of the population, setting, approaches, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytical methods and reporting; no reporting errors; a low dropout rate; and clear reporting of dropouts.
  - **Fair**. These studies are susceptible to some bias, but not enough to invalidate the results. They do not meet all the criteria required for a rating of good quality because they have some deficiencies, but no flaw is likely to cause major bias. The study may be missing information, making it difficult to assess limitations and potential problems.
  - **Poor** (high risk of bias). These studies have significant flaws that may have invalidated the results. They have serious errors in design, analysis, or reporting; large amounts of missing information; or discrepancies in reporting.
  - If the study is rated as “Fair” or “Poor,” provide rationale.
- Outcome-specific quality rating
  - Do you think that any of the outcomes abstracted for this study should be assigned a quality rating DIFFERENT from the overall study rating? (No/Yes)
    - If you think any of the abstracted outcomes should have a quality rating different from the overall study, please provide the outcome(s), rating(s) and rationale(s).

**Applicability** – Use the PICOS format to identify specific issues, if any, that may limit the applicability of the study.

- Population (P)
  - Study population demographics not representative of intended population
  - Narrow or unrepresentative severity/stage/comorbidity
- Intervention (I)
  - Treatment protocol not representative of current practice
  - Change in standard of care
- Comparator (C)
  - Comparator not representative of current practice
- Outcomes (O)
  - Timing of outcome assessment
- Setting (S)
  - Standards or access to care vary from US setting
  - Specialty population or level of care
- Do you have any other concerns regarding applicability of this study? (Yes/No)
- Comments

## Appendix C. List of Included Studies

- Abdullah A, Saboohi S and Hashami U. Effects of amniotomy versus spontaneous rupture of membrane on progress of labour and foetal outcome in primigravidae. *Journal of the Liaquat University of Medical and Health Sciences* 2010;9(1):33-36.
- Abrao KC, Francisco RP, Miyadahira S, et al. Elevation of uterine basal tone and fetal heart rate abnormalities after labor analgesia: a randomized controlled trial. *Obstet Gynecol* 2009;113(1):41-7. DOI: 10.1097/AOG.0b013e31818f5eb6. PMID: 19104358.
- Ajadi MA, Kuti O, Orji EO, et al. The effect of amniotomy on the outcome of spontaneous labour in uncomplicated pregnancy. *J Obstet Gynaecol* 2006;26(7):631-4. DOI: 10.1080/01443610600903420. PMID: 17071428.
- Akbarzadeh M, Masoudi Z, Zare N, et al. Comparison of the effects of doula supportive care and acupressure at the BL32 point on the mother's anxiety level and delivery outcome. *Iran J Nurs Midwifery Res* 2015;20(2):239-46. PMID: 25878703.
- Akbarzadeh M, Masoudi Z, Zare N, et al. Comparison of the Effects of Maternal Supportive Care and Acupressure (at BL32 Acupoint) on Labor Length and Infant's Apgar Score. *Glob J Health Sci* 2015;8(3):48239. DOI: 10.5539/gjhs.v8n3p236. PMID: 26493430.
- Albers LL, Sedler KD, Bedrick EJ, et al. Midwifery care measures in the second stage of labor and reduction of genital tract trauma at birth: a randomized trial. *J Midwifery Womens Health* 2005;50(5):365-72. DOI: 10.1016/j.jmwh.2005.05.012. PMID: 16154062.
- Allameh Z, Tehrani HG and Ghasemi M. Comparing the impact of acupuncture and pethidine on reducing labor pain. *Adv Biomed Res* 2015;4:46. DOI: 10.4103/2277-9175.151302. PMID: 25789272.
- Altman D, Ragnar I, Ekstrom A, et al. Anal sphincter lacerations and upright delivery postures--a risk analysis from a randomized controlled trial. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;18(2):141-6. DOI: 10.1007/s00192-006-0123-9. PMID: 16636770.
- Anim-Somuah M, Smyth RM and Jones L. Epidural versus non-epidural or no analgesia in labour. *Cochrane Database Syst Rev* 2011;(12):Cd000331. DOI: 10.1002/14651858.CD000331.pub3. PMID: 22161362.
- Asadi N, Maharlouei N, Khalili A, et al. Effects of LI-4 and SP-6 Acupuncture on Labor Pain, Cortisol Level and Duration of Labor. *J Acupunct Meridian Stud* 2015;8(5):249-54. DOI: 10.1016/j.jams.2015.08.003. PMID: 26433802.
- Bakker JJ, Janssen PF, van Halem K, et al. Internal versus external tocodynamometry during induced or augmented labour. *Cochrane Database Syst Rev* 2013;8:Cd006947. DOI: 10.1002/14651858.CD006947.pub3. PMID: 23913521.
- Bergqvist L, Dencker A, Taft C, et al. Women's experiences after early versus postponed oxytocin treatment of slow progress in first childbirth--a randomized controlled trial. *Sex Reprod Healthc* 2012;3(2):61-5. DOI: 10.1016/j.srhc.2012.03.003. PMID: 22578752.
- Bhagwat A, Dua C, Saxena K, et al. Comparison of combined spinal epidural technique and low dose epidural technique in progress of labour. *Indian J Anaesth* 2008;52(3):282-7.
- Bloom SL, Casey BM, Schaffer JJ, et al. A randomized trial of coached versus uncoached maternal pushing during the second stage of labor. *Am J Obstet Gynecol* 2006;194(1):10-3. DOI: 10.1016/j.ajog.2005.06.022. PMID: 16389004.
- Brown HC, Paranjothy S, Dowswell T, et al. Package of care for active management in labour for reducing caesarean section rates in low-risk women. *Cochrane Database Syst Rev* 2013;9:Cd004907. DOI: 10.1002/14651858.CD004907.pub3. PMID: 24043476.
- Bruggemann OM, Parpinelli MA, Osis MJD, et al. Support to woman by a companion of her choice during childbirth: A randomized controlled trial. *Reproductive Health* 2007;4.

Bugg GJ, Siddiqui F and Thornton JG. Oxytocin versus no treatment or delayed treatment for slow progress in the first stage of spontaneous labour. *Cochrane Database Syst Rev* 2013;6:Cd007123. DOI: 10.1002/14651858.CD007123.pub3. PMID: 23794255.

Cahill AG, Srinivas SK, Tita ATN, et al. Effect of Immediate vs Delayed Pushing on Rates of Spontaneous Vaginal Delivery Among Nulliparous Women Receiving Neuraxial Analgesia: A Randomized Clinical Trial. *Jama* 2018;320(14):1444-1454. DOI: 10.1001/jama.2018.13986. PMID: 30304425.

Chaichian S, Akhlaghi A, Rousta F, et al. Experience of water birth delivery in Iran. *Arch Iran Med* 2009;12(5):468-71. PMID: 19722768.

Cheng YW, Shaffer BL, Bryant AS, et al. Length of the first stage of labor and associated perinatal outcomes in nulliparous women. *Obstet Gynecol* 2010;116(5):1127-35. DOI: 10.1097/AOG.0b013e3181f5eaf0. PMID: 20966698.

Cluett ER and Burns E. Immersion in water in labour and birth. *Cochrane Database Syst Rev* 2009;(2):Cd000111. DOI: 10.1002/14651858.CD000111.pub3. PMID: 19370552.

Coco A, Derksen-Schrock A, Coco K, et al. A randomized trial of increased intravenous hydration in labor when oral fluid is unrestricted. *Fam Med* 2010;42(1):52-6. PMID: 20063224.

Costley PL and East CE. Oxytocin augmentation of labour in women with epidural analgesia for reducing operative deliveries. *Cochrane Database Syst Rev* 2012;5:Cd009241. DOI: 10.1002/14651858.CD009241.pub2. PMID: 22592738.

Dahlen HG, Homer CS, Cooke M, et al. Perineal outcomes and maternal comfort related to the application of perineal warm packs in the second stage of labor: a randomized controlled trial. *Birth: Issues in Perinatal Care* 2007;34(4):282-290 9p.

Dawood F, Dowswell T and Quenby S. Intravenous fluids for reducing the duration of labour in low risk nulliparous women. *Cochrane Database Syst Rev* 2013;6:Cd007715. DOI: 10.1002/14651858.CD007715.pub2. PMID: 23780639.

de Orange FA, Passini R, Jr., Amorim MM, et al. Combined spinal and epidural anaesthesia and maternal intrapartum temperature during vaginal delivery: a randomized clinical trial. *Br J Anaesth* 2011;107(5):762-8. DOI: 10.1093/bja/aer218. PMID: 21743067.

Dencker A, Berg M, Bergqvist L, et al. Early versus delayed oxytocin augmentation in nulliparous women with prolonged labour--a randomised controlled trial. *Bjog* 2009;116(4):530-6. DOI: 10.1111/j.1471-0528.2008.01962.x. PMID: 19250364.

Direkvand-Moghadam A and Rezaeian M. Increased intravenous hydration of nulliparas in labor. *Int J Gynaecol Obstet* 2012;118(3):213-5. DOI: 10.1016/j.ijgo.2012.03.041. PMID: 22717414.

Douma MR, Middeldorp JM, Verwey RA, et al. A randomised comparison of intravenous remifentanyl patient-controlled analgesia with epidural ropivacaine/sufentanil during labour. *Int J Obstet Anesth* 2011;20(2):118-23. DOI: 10.1016/j.ijoa.2010.11.009. PMID: 21376564.

Downe S, Gyte GM, Dahlen HG, et al. Routine vaginal examinations for assessing progress of labour to improve outcomes for women and babies at term. *Cochrane Database Syst Rev* 2013;7:Cd010088. DOI: 10.1002/14651858.CD010088.pub2. PMID: 23857468.

Edwards RK, Reed CA, Villano KS, et al. Effect of hydration on spontaneous labor outcomes in nulliparous pregnant women: a multicenter randomized controlled trial comparing three methods. *Am J Perinatol* 2014;31(6):455-62. DOI: 10.1055/s-0033-1351661. PMID: 23884718.

El Hamid, Obaya HE and Gaafar HM. Effect of Acupressure on Labor Pain and Duration of Delivery among Laboring Women Attending Cairo University Hospital. *Indian Journal of Physiotherapy & Occupational Therapy* 2013;7(2):71-76.

Eslamian L, Marsoosi V and Pakneeyat Y. Increased intravenous fluid intake and the course of labor in nulliparous women. *Int J Gynaecol Obstet* 2006;93(2):102-5. DOI: 10.1016/j.ijgo.2006.01.023. PMID: 16542657.

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Fortier JH and Godwin M. Doula support compared with standard care: Meta-analysis of the effects on the rate of medical interventions during labour for low-risk women delivering at term. *Canadian Family Physician* 2015;61(6):e284-e292.

Frigo MG, Larciprete G, Rossi F, et al. Rebuilding the labor curve during neuraxial analgesia. *J Obstet Gynaecol Res* 2011;37(11):1532-9. DOI: 10.1111/j.1447-0756.2011.01568.x. PMID: 21676079.

Ganapathy T. Childbirth in Supported Sitting Maternal Position. *International Journal of Nursing Education* 2012;4(2):87-91 5p.

Genc M, Sahin N, Maral J, et al. Does bupivacaine and fentanyl combination for epidural analgesia shorten the duration of labour?. *J Obstet Gynaecol* 2015;35(7):672-5. DOI: 10.3109/01443615.2014.991299. PMID: 25546524.

Ghafarzadeh M, Moeininasab S and Namdari M. Effect of early amniotomy on dystocia risk and cesarean delivery in nulliparous women: a randomized clinical trial. *Arch Gynecol Obstet* 2015;292(2):321-5. DOI: 10.1007/s00404-015-3645-x. PMID: 25666481.

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## Appendix D. List of Excluded Studies

All studies listed below were reviewed in their full-text version and excluded for the reasons cited. Reasons for exclusion signify only the usefulness of the articles for this study and are not intended as criticisms of the articles.

### **Not a full publication (abstract or poster only) OR article retracted/withdrawn OR publication not available:**

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## Appendix E. Characteristics of Included Studies

Table E-1 shows the study characteristics for the included studies. For full study citations, please refer to the report's main reference list.

**Table E-1. Characteristics of included RCTs and observational studies, KQs 1-9**

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Abdullah, 2010 <sup>118</sup>  KQ 2	RCT Middle East  N enrolled: 200 patients N completed: 200 patients	Total Mean: 24.69 SD: 3.03	Stage of Labor at Entry: First stage active, Second stage  Study's Definition of Labor: First stage active (4-10 cm), Second stage (10 cm- delivery)  Parity: Nulliparous	Artificial rupture of membranes and prophylactic antibiotic vs. Spontaneous rupture of membranes	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor (Parity)	Fair
Abrao, 2009 <sup>196</sup>  KQ 4	RCT Latin America  N enrolled: 91 patients N completed: 77 patients	Arm 1 Mean: 23.95 SD: 5.99  Arm 2 Mean: 23.61 SD: 6.84	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: First stage latent (<4 cm dilation), first stage active (4- 10 cm dilation)  Parity: Nulliparous, Mixed Parity	Epidural vs. Combined Spinal Epidural (CSE)	Mode of delivery; Abnormal fetal heart rate tracing	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Ajadi, 2006 <sup>116</sup>  KQ 2	RCT Africa  N enrolled: 128 patients N completed: 128 patients	Arm 1 Mean: 29.4 SD: 5.7  Arm 2 Mean: 28.6 SD: 6.9	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active (4-10 cm dilation)  Parity: Parous	Amniotomy - Follow labor with partogram, and augment with oxytocin if needed vs. Control - follow with a partogram and augment if needed with oxytocin. If this did not result in progress, then amniotomy was performed after 1 h more	Mode of delivery; Duration of Labor	Good
Akbarzadeh, 2015 <sup>70</sup>  KQ 3  Companion: Akbarzadeh, 2015 <sup>71</sup>	RCT Middle East  N enrolled: 150 patients N completed: 150 patients	Total Min. age: 18 Max. age: 35	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4 cm dilation and at least 2-3 contractions in 10 min  Parity: First or Second Pregnancy	Supportive care - Doula provided emotional support, information, massage and help in changing position vs. Acupressure - Pressure applied at BL32 acupoint during contractions. vs. Usual care - routine care, not further described	Duration of Labor	Poor
Albers, 2005 <sup>149</sup>  KQ 3	RCT U.S.  N enrolled: 1,211 patients N completed: 1,211 patients	Arm 1 Mean: 24.9 SD: 5.3  Arm 2 Mean: 24.5 SD: 5.2  Arm 3 Mean: 24.5 SD: 5.1	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Active fetal descent or fetal head visible with a uterine contraction.  Parity: Nulliparous, Parous	Warm compresses applied to perineum continuously vs. Perineal massage with lubricant was gentle, slow massage, with 2 fingers of the midwife's gloved hand moving from side to side just inside the patient's vagina. vs. No touch meant no touching of the woman's perineum during the second stage until crowning of the infant's head	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor; Abnormal fetal heart rate tracing	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Allameh, 2015 <sup>126</sup>  KQ 3	RCT Middle East  N enrolled: 85 patients N completed: Unclear	Total Min. age: 18 Max. age: 35	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4-5 cm dilatation  Parity: First or Second Pregnancy	Acupuncture -- 2 needles in LI4 point in two hands and in ST-36 points in two legs, left in for 20- 30 min vs. Usual care - oral communication and no painkiller.	Duration of Labor; Maternal Hemorrhage; Mode of delivery	Poor
Asadi, 2015 <sup>125</sup>  KQ 3	RCT Middle East  N enrolled: 71 patients N completed: 63 patients	Total Mean: 26.1 SD: 4	Stage of Labor at Entry: First stage active  Study's Definition of Labor: ≥4cm dilation and 3+ contractions lasting >40 s within 10 min  Parity: Nulliparous	Acupuncture - Needles at LI-4 and SP-6 for 20 min Manipulated until DeQi sensation, manipulated every 5 min vs. Sham acupuncture - Superficial contact of needles at sites other than correct points for acupuncture. Shaken every 5 min	Duration of Labor	Fair
Bhagwat, 2008 <sup>202</sup>  KQ 4	RCT Asia  N enrolled: 60 patients N completed: 59 patients	Arm 1 Mean: 24.15 SD: 1.872  Arm 2 Mean: 23.30 SD: 2.130	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4-5 cm dilatation  Parity: Nulliparous	Epidural vs. Combined Spinal Epidural (CSE)	Duration of Labor; Mode of delivery; Neonatal Birth Trauma (Parity)	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Bloom, 2006 <sup>72</sup>  KQ 9  Companion: Schaffer, 2005 <sup>73</sup>	RCT U.S.  N enrolled: 325 patients N completed: 320 patients	Arm 1 Mean: 21.1 SD: 3.7  Arm 2 Mean: 21.1 SD: 3.7	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second stage (full dilation - delivery)  Parity: Nulliparous	Coach patient to pull back on both knees and tuck her chin while the provider or partner supports the legs vs. "Do what comes natural"	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor; Neonatal acidemia; Neonatal Respiratory distress; Neonatal infection/sepsis; Long-term neonatal health (Parity)	Good
Bolbol-Haghighi, 2016 <sup>166</sup>  KQ 3	RCT Middle East  N enrolled: 100 patients N completed: 100 patients	Total Mean: 24.63 SD: 5.02	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Mixed Parity	Massage Therapy vs. Control group	Duration of Labor; Mode of delivery	Good
Bruggemann, 2007 <sup>152</sup>  KQ 3	RCT Latin America  N enrolled: 212 patients N completed: 212 patients	Arm 1 Mean: 20.6  Arm 2 Mean: 20.1	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-6 cm cervical dilation  Parity: Nulliparous	Presence of a chosen companion during labor and delivery vs. No companion support	Duration of Labor; Mode of delivery; Abnormal fetal heart rate tracing (Parity)	Good
Cahill, 2018 <sup>227</sup>  KQ 9	RCT U.S.  N enrolled: 2,414 patients N completed: 2,404 patients	Arm 1 Mean: 26.5 SD: 5.9  Arm 2 Mean: 26.6 SD: 6.2	Stage of Labor at Entry: Full cervical dilation (10cm)  Study's Definition of Labor: Full cervical dilation (10cm)  Parity: Nulliparous	Immediate pushing vs. Delayed pushing	Duration of Labor; Mode of delivery	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Chaichian, 2009 <sup>143</sup>  KQ 3	RCT Middle East  N enrolled: 106 patients N completed: 106 patients	Arm 1 Mean: 26.4 SD: 5.9  Arm 2 Mean: 27.1 SD: 5.9	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	Water birth – Labor and delivery in standardized warm water pools vs. Control - Conventional delivery method at the hospital	Mode of delivery; Duration of Labor	Fair
Cheng, 2010 <sup>86</sup>  KQ 1	Observational U.S.  N enrolled: 10,661 patients N completed: 10,661 patients	Total < 35 yrs (9,006) ≥35 yrs (1,640)	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: Onset of labor defined as regular, painful contractions occurring at least every 5 min or three contractions in 10 min and cervical change.  Parity: Nulliparous, Mixed Parity	Duration of First stage of labor <5% vs. Duration of the First stage of labor 5-95% vs. Duration of the First stage of labor >95%	Maternal Trauma to the Pelvic Floor; Maternal Infection; Maternal Hemorrhage; Mode of delivery; Neonatal acidemia; Meconium aspiration syndrome; Neonatal infection/sepsis; Neonatal Shoulder dystocia; Neonatal Birth trauma (Parity)	Good
Coco, 2010 <sup>142</sup>  KQ 3	RCT U.S.  N enrolled: 80 patients N completed: 80 patients	Arm 1 Mean: 22.7 SD: 4.3  Arm 2 Mean: 20.5 SD: 4.3	Stage of Labor at Entry: active  Study's Definition of Labor: Spontaneous active labor (2- 5 cm)  Parity: Nulliparous	IV fluid of lactated Ringer's solution at 250 mL/hr plus unrestricted access to oral fluids vs. Usual care - lactated Ringer's solution for medical indications at the discretion of the provider plus unrestricted access to oral fluids	Mode of delivery; Duration of Labor	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Dahlen, 2007 <sup>160</sup>  KQ 3	RCT Australia/NZ  N enrolled: 717 patients N completed: 599 patients	Arm 1 Mean: 27 SD: 5.5  Arm 2 Mean: 27.2 SD: 4.9	Stage of Labor at Entry: Late second stage  Study's Definition of Labor: Baby's head began to distend the perineum.  Parity: Nulliparous	Warm pack applied to perineum at second stage of labor vs. Standard Care	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor; Maternal Pelvic floor dysfunction (Parity)	Good
Darsareh, 2018 <sup>179</sup>  KQ 3	RCT Middle East  N enrolled: 180 patients N completed: 180 patients	Arm 1 Mean: 23 SD: 2.08  Arm 2 Mean: 22 SD: 2.87	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active (4 cm dilation)  Parity: Nulliparous	Water immersion during First stage of active labor vs. Routine care	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal Trauma to the Pelvic Floor; Neonatal Respiratory distress; Neonatal NICU admissions; Maternal satisfaction	Fair
de Orange, 2011 <sup>76</sup>  KQ 4  Companion: Orange, 2012 <sup>77</sup>	RCT Latin America  N enrolled: 70 patients N completed: 70 patients	Arm 1 Mean: 22.57  Arm 2 Mean: 21.65	Stage of Labor at Entry: Entered in study at dilation 3-6 cm  Study's Definition of Labor: First stage latent (<4 cm dilation), first stage active (4- 10 cm dilation)  Parity: Nulliparous, Mixed Parity	Epidural plus Combined Spinal Epidural (CSE) vs. Usual care	Abnormal fetal heart rate tracing; Mode of delivery; Duration of Labor; Parental preferences	Good



<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Dencker, 2009 <sup>74</sup>  KQ 7  Companion: Bergqvist, 2012 <sup>75</sup>	RCT UK/Europe  N enrolled: 630 patients N completed: 630 patients	Arm 1 Mean: 28.4 SD: 4.4  Arm 2 Mean: 28 SD: 4.5	Stage of Labor at Entry: stage active  Study's Definition of Labor: First stage active (4-10 cm dilation)  Parity: Nulliparous	Labor augmentation by oxytocin within 20 min of diagnosis of arrest of cervical dilation vs. Labor augmentation by oxytocin was delayed until 3 h after diagnosis of arrest of cervical dilation	Maternal Trauma to the Pelvic Floor; Maternal Hemorrhage; Mode of delivery; Duration of Labor; Neonatal acidemia	Fair
Direkvand-Moghadam, 2012 <sup>136</sup>  KQ 3	RCT Middle East  N enrolled: 120 patients N completed: 120 patients	Arm 1 Mean: 25.9 SD: 4.6  Arm 2 Mean: 25.5 SD: 4.6  Arm 3 Mean: 25.5 SD: 4.7  Arm 4 Mean: 25.7 SD: 4.8	Stage of Labor at Entry: Spontaneous active  Study's Definition of Labor: active 4 - 5 cm  Parity: Nulliparous, Mixed Parity	60 mL/h IV Ringer lactate solution and oral fluids at will vs. 120 mL/h IV Ringer lactate solution and oral fluids at will vs. 240 mL/h IV Ringer lactate solution and oral fluids at will vs. Usual care - oral fluids at will	Duration of Labor; Mode of delivery	Fair
Douma, 2011 <sup>194</sup>  KQ 4	RCT UK/Europe  N enrolled: 26 patients N completed: 20 patients	Arm 1 Mean: 32.7 SD: 5.9  Arm 2 Mean: 31.0 SD: 5.2	Stage of Labor at Entry: Excluded if >5 cm dilation  Study's Definition of Labor: First stage latent (<4 cm dilation), first stage active (4-5 cm dilation)  Parity: Nulliparous	Epidural vs. Patient Controlled IV Analgesia	Mode of delivery; Duration of Labor; Neonatal acidemia	Poor

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Dy, 2018 <sup>212</sup>  KQ 7	RCT Canada  N enrolled: 137 patients N completed: 79 patients	Arm 1 Mean: 29.6 SD: 5.2  Arm 2 Mean: 29.7 SD: 5.1	Stage of Labor at Entry: Active Stage  Study's Definition of Labor: Active labour, cervical dilatation <10 cm  Parity: Nulliparous	Gradual Oxytocin Titration (GOT) vs. Accelerated Oxytocin Titration (AOT)	Duration of Labor; Mode of delivery; Hemorrhage; Neonatal respiratory distress; Neonatal NICU admissions; Maternal satisfaction	Fair
Edwards, 2014 <sup>130</sup>  KQ 3	RCT U.S.  N enrolled: 324 patients N completed: 311 patients	Arm 1 Mean: 21.9 SD: 5.1  Arm 2 Mean: 21.3 SD: 4.6  Arm 3 Mean: 21.7 SD: 5.6	Stage of Labor at Entry: Active  Study's Definition of Labor: Active (at least 2 cm)  Parity: Nulliparous	125 mL/hr IV of lactated ringers with 5% dextrose-ice chips, popsicles, hard candy vs. 250 mL/h IV of lactated ringers with 5% dextrose-ice chips, popsicles, hard candy vs. 25 mL/hr IV of lactated ringers with 5% dextrose-oral hydration ad libitum with water, Gatorade, ice chips, popsicles, hard candy	Duration of Labor; Mode of delivery	Fair
El Hamid, 2013 <sup>162</sup>  KQ 3	RCT Middle East  N enrolled: 100 patients N completed: 100 patients	Total Min. age: 20 Max. age: 30	Stage of Labor at Entry: Early First stage active  Study's Definition of Labor: 3-4cm dilation  Parity: Nulliparous	Acupressure applied at sp6 acupoint of both sides during each uterine contraction vs. Routine hospital procedures - Insertion of IV fluids, enema, providing hygienic care, and routine medical methods for pain relief.	Duration of Labor (Parity)	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Eslamian, 2006 <sup>148</sup>  KQ 3	RCT Middle East  N enrolled: 300 patients N completed: 300 patients	Arm 1 Mean: 21.6 SD: 4.1  Arm 2 Mean: 21.79 SD: 4.2	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: 3-5 cm, First stage latent (<4 cm), First stage active (4-10 cm)  Parity: Nulliparous	125 mL/h Ringer solution IV vs. 250 mL/h Ringer solution IV	Mode of delivery; Duration of Labor (Parity)	Good
The Epidural and Position Trial Collaborative Group, 2017 <sup>173</sup>  KQ 3	RCT UK/Europe  N enrolled: 3,236 patients N completed: 3,093 patients	Arm 1 Mean: 28.4 SD: 5.7  Arm 2 Mean: 28.4 SD: 5.6	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Cervical fully dilated of the presenting part was visible  Parity: Nulliparous	Upright position during second stage of labor vs. Lying down position	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal Trauma to the Pelvic Floor; Pelvic floor dysfunction; Hemorrhage; Transfusion; Neonatal acidemia; Neonatal Respiratory distress; Neonatal infection/sepsis; Long-term neonatal health; Maternal satisfaction	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Fahdhy, 2005 <sup>90</sup>  KQ 1	RCT Asia  N enrolled: 721 patients N completed: 626 patients	Arm 1 Mean: 26.8 SD: 5.4  Arm 2 Mean: 26.4 SD: 4.9	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Women presenting with cervical dilatation of more than 8 cm were excluded from the study but cared for according to standard procedure of the Ministry of Health  Parity: Unclear/NR	A 2-day training program was held on the use of the WHO partograph for the 10 midwives in the intervention group vs. Provide usual care to patients. No partograph training was provided	Mode of delivery; Maternal Hemorrhage; Neonatal Respiratory distress	Good
Fong, 2017 <sup>171</sup>  KQ 3	RCT U.S.  N enrolled: 285 patients N completed: 274 patients	Arm 1 Mean: 25.0 SD: 5.6  Arm 2 Mean: 25.1 SD: 5.5  Arm 3 Mean: 25.3 SD: 5.4	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active (3-5 cm dilation)  Parity: Nulliparous	Control - Normal saline at 250 mL/h vs. High dose intravenous fluids at: 5% dextrose in normal saline at 125 mL/h vs. 2.5% dextrose in normal saline at 250 mL/h	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal Infection (chorioamnionitis); Neonatal NICU admissions; Neonatal Respiratory distress	Good
Frigo, 2011 <sup>85</sup>  KQ 1	Observational UK/Europe  N enrolled: 600 patients N completed: 545 patients	Arm 1 Mean: 31.26 SD: 4.92  Arm 2 Mean: 30.85 SD: 4.23	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: All were in labor at less than 4 cm  Parity: Nulliparous	Combined Spinal Epidural (CSE) vs. Usual care - Epidural	Duration of Labor	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Gallo, 2018 <sup>172</sup>  KQ 3	RCT Latin America  N enrolled: 286 patients N completed: 80 patients	Total Min. age: 18 Max. age: 35	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4-5 cm dilation  Parity: Primagravida	Pelvic motion exercises using Swiss ball at beginning of active labor; 40 min massage along path that corresponds with the hypogastric plexus and pudendal nerve path by physiotherapist; warm shower for 40 min vs. Usual care - routine care, not further described	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Hemorrhage; Trauma to the pelvic floor; Maternal experience; Maternal satisfaction; Neonatal respiratory distress; Shoulder dystocia	Good
Ganapathy, 2012 <sup>159</sup>  KQ 3	RCT Asia  N enrolled: 200 patients N completed: 200 patients	Arm 1 Mean: 21.4 SD: 2.02  Arm 2 Mean: 21.3 SD: 1.94	Stage of Labor at Entry: Active labor  Study's Definition of Labor: First stage active (-4-10 cm)  Parity: Nulliparous	Patient's upper back was elevated to 60° angle to assume upright supported sitting birthing position by the simple backrest attached adjustable standard delivery cot as felt most comfortable and desirable by the participants vs. Supine position - lying flat on back	Duration of Labor; Mode of delivery; Abnormal fetal heart rate tracing; Parental preferences (Parity)	Poor
Geeta, 2015 <sup>214</sup>  KQ 7	RCT Asia  N enrolled: 211 patients N completed: 211 patients	Arm 1 Mean: 26.4 SD: 3.64  Arm 2 Mean: 25.38 SD: 3.95	Stage of Labor at Entry: First stage  Study's Definition of Labor: >4 cm dilation and 50% effacement  Parity: Nulliparous, Parous	Low dose oxytocin – 1 IU to 500 mL of ringer lactate, infused at the rate of 1 mIU/min; increased by 1 mIU/min until 3 contractions per 10 min vs. High dose oxytocin – 5 IU to 500 mL of ringer lactate, infused at the rate of 5 mIU/min every 20 min until three contractions per 10 min	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Genc, 2015 <sup>189</sup>  KQ 4	RCT UK/Europe  N enrolled: 100 patients N completed: 95 patients	Arm 1 Mean: 22.1 SD: 2.1  Arm 2 Mean: 21.8 SD: 4.2	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Cervical dilation of 3-5 cm and 3-5 uterine contractions per 10 min with a mean intensity of 60 (range, 40-80) mmHg and a mean duration of 60 (range, 30-90) s in NST  Parity: Nulliparous	Epidural anesthesia vs. No epidural anesthesia	Duration of Labor	Fair
Ghafarzadeh, 2015 <sup>113</sup>  KQ 2	RCT Middle East  N enrolled: 300 patients N completed: 300 patients	Arm 1 Mean: 25.7 SD: 3.3  Arm 2 Mean: 25.6 SD: 2.6	Stage of Labor at Entry: Spontaneous labor  Study's Definition of Labor: Spontaneous labor(<4 cm dilation)  Parity: Unclear	Amniotomy at less than or equal to 4 cm dilation vs. Usual care (which included fetal heart rate monitoring, contraction monitoring, analgesia or supportive measures)	Duration of Labor; Mode of delivery; Neonatal Umbilical cord prolapse	Fair
Greenberg, 2007 <sup>88</sup>  KQ 1	Observational U.S.  N enrolled: 31,976 patients N completed: 31,976 patients	Arm 1 <20 Arm 2 20-24 Arm 3 25-29 Arm 4 30-34 Arm 5 35-39 Arm 6 ≥40	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active (4-10 cm dilation)  Parity: Nulliparous, Parous	Age category <20 vs. Age category 20-24 vs. Age category 25-29 vs. Age category 30-34 vs. Age category 35-39 vs. Age category ≥40	Duration of Labor (Parity)	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Hamidzadeh, 2012 <sup>137</sup>  KQ 3	RCT Middle East  N enrolled: 100 patients N completed: 100 patients	Total Min. age: 20 Max. age: 40	Stage of Labor at Entry: First active stage  Study's Definition of Labor: 3-5 cm dilation  Parity: Nulliparous, Parous,	Acupressure at L14 point (between thumb and index finger) on both hands. Ten s of pressure and 2 s of rest repeated 5 times with each contraction, starting at the onset of active labor (3-4cm dilation) and done for 20 min vs. Control - touched at the L14 point but pressure was not applied	Duration of Labor; Parental preferences	Fair
Hekmatzadeh, 2014 <sup>155</sup>  KQ 3	RCT Middle East  N enrolled: 105 patients N completed: 103 patients	Arm 1 Mean: 22.82 SD: 2.36  Arm 2 Mean: 24.49 SD: 2.83	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-4 cm dilation with regular uterine contractions.  Parity: Unclear	Consumption of 100 cc of water in which 10 g (two tablespoon) of Anethum Graveolens seeds were boiled for 10 min. Once after beginning active phase of labor vs. Routine care	Duration of Labor (Parity)	Fair
Hinshaw, 2008 <sup>210</sup>  KQ 7	RCT UK/Europe  N enrolled: 412 patients N completed: 412 patients	Arm 1 Median: 22 (20, 28)  Arm 2 Median: 23 (19, 29)	Stage of Labor at Entry: Early active phase of labor.  Study's Definition of Labor: Dilation of at least 3cm with at least 2 contractions in 10 min.  Parity: Nulliparous	Active management - Oxytocin 2mu/min started within 20 min of randomization. Dose was doubled every 30 min until contraction rate of 4-5 contractions in 10 min was achieved or max dose of 32 mu/min vs. Conservative management - Oxytocin was withheld for 8 h unless intervention became clinically indicated. If women did not progress to delivery within 8 h, oxytocin was started if clinically indicated	Mode of delivery; Maternal Hemorrhage; Maternal Transfusion; Duration of Labor; Neonatal infection/sepsis; Neonatal Respiratory distress	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Hoppe, 2018 <sup>100</sup>  KQ 1	Observational U.S.  N enrolled: 642 patients N completed: 642 patients	Arm 1: 18-24: 49 (22.6%) 25-34: 130 (59.9%) 35+: 38 (17.5%)  Arm 2: 18-24: 56 (18.8%) 25-34: 196 (65.8%) 35+: 46 (15.4%)  Arm 3: 18-24: 26 (20.5%) 25-34: 79 (62.2%) 35+: 22 (17.3%)	Stage of Labor at Entry: Active Stage  Study's Definition of Labor: 6 cm dilatation  Parity: Nulliparous	Women progressing at or below the median labor duration vs. Women progressing between the median and the 95 <sup>th</sup> percentile Vs. Women exceeding the 95th percentile	Duration of Labor; Mode of delivery; Maternal hemorrhage; NICU admissions	Fair
Inde, 2018 <sup>92</sup>  KQ 1	Observational Asia  N enrolled: 3,172 patients N completed: 3,172 patients	Arm 1 Median: 30 (23, 37)  Arm 2 Median: 32 (25, 38)  Arm 3 Median: 34 (27, 39)	Stage of Labor at Entry: Admission to hospital  Study's Definition of Labor: Onset of labor was defined as onset of labor pains, which continued to delivery, with ≤ 10 min interval between contractions, or ≥ 6 times the number of contractions per hr  Parity: Primiparous, Parous	Cervical dilation curve in women with different parities. Primiparous vs. Parous (parity=1) vs. Parous (parity≥2)	Duration of Labor; Mode of delivery	Good
İsbir, 2017 <sup>180</sup>  KQ 3	RCT UK/Europe  N enrolled: 72 patients N completed: 63 patients	Arm 1 Mean: 24.9 SD: 5.9  Arm 2 Mean: 25.0 SD: 4.7	Stage of Labor at Entry: First stage  Study's Definition of Labor: ≤3 cm dilatation  Parity: Nulliparous, Parous	Continuous intrapartum supportive care during labor and delivery (physical, emotional, instructional, informational, and advocacy support) vs. Routine care	Duration of Labor; Maternal experience and satisfaction	Fair



<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Ismail, 2012 <sup>191</sup>  KQ 4	RCT Middle East  N enrolled: 1,140 patients N completed: 1,140 patients	Arm 1 Mean: 28.6 SD: 5.49  Arm 2 Mean: 28.35 SD: 5.54  Arm 3 Mean: 28.8 SD: 5.50	Stage of Labor at Entry: Excluded if dilation >4 cm at time of first analgesic event  Study's Definition of Labor: First stage latent (<4 cm dilation)  Parity: Nulliparous	Epidural vs. Combined Spinal Epidural (CSE) vs. Patient Controlled IV Analgesia	Duration of Labor; Mode of delivery; Parental preferences (Parity)	Good
Jaitley, 2011 <sup>201</sup>  KQ 4	RCT Asia  N enrolled: 90 patients N completed: 90 patients	Arm 1 Mean: 24.67  Arm 2 Mean: 25  Arm 3 Mean: 24.76	Stage of Labor at Entry: Established active stage of labor (uterine contraction 2 per 10 s, lasting for 30 to 40 s and cervical dilation more than 3 cm.)  Study's Definition of Labor: First stage active (4-10 cm dilation)  Parity: Nulliparous, Parous	IV tramadol vs. Epidural tramadol and bupivacaine vs. Control	Parental preferences; Mode of delivery	Poor
Janssen, 2012 <sup>132</sup>  KQ 3	RCT Canada  N enrolled: 77 patients N completed: 77 patients	Arm 1 18-24 yrs 16.7% 25-29 yrs 30.6% 30-34 yrs 38.9% 35+ yrs 13.9%  Arm 2 18-24 yrs 8.8% 25-29 yrs 20.6% 30-34 yrs 55.9% 35+ yrs 14.7%	Stage of Labor at Entry: First stage  Study's Definition of Labor: Spontaneous labor defined as painful contractions with cervix ≥1 cm dilated and ≥25% effacement  Parity: Nulliparous	Massage - up to 5 h of Swedish massage during labor as woman wished, ending if she decided to have epidural analgesia vs. Control - massage during the first 24 h postpartum	Duration of Labor; Mode of delivery	Good

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Kashanian, 2010 <sup>151</sup>  KQ 3	RCT Middle East  N enrolled: 120 patients N completed: 120 patients	Arm 1 Mean: 23.17 SD: 4.54  Arm 2 Mean: 23.16 SD: 4.6	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-4 cm dilation with at least 3 contractions of 45-60 second duration in 10 min  Parity: Nulliparous	Acupressure at the Sanyinjiao point was performed by the investigator during the contractions for a total duration of acupressure of 30 min vs. Just the touch of this point by the same investigator was performed	Duration of Labor; Mode of delivery (Parity)	Good
Kauffman, 2016 <sup>93</sup>  KQ 1	Observational U.S.  N enrolled: 11,368 patients N completed: 11,368 patients	Total: <20: 5.8% 21-34: 78.1% >35: 16.2%	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Cervical dilation  Parity: Mixed Parity	Cervical dilation on admission:  <4 cm vs. ≥4 cm	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Hemorrhage; Trauma to the pelvic floor; Admission to NICU	Good
Kaviani, 2014 <sup>127</sup>  KQ 3	RCT Middle East  N enrolled: 156 patients N completed: 139 patients	Total Min. age: 18 Max. age: 30	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-4 cm dilation  Parity: Nulliparous	Aromatherapy jasmine - Used in incense device with water tank and mask, used for 15 min vs. Aromatherapy salvia - Used in incense device with water tank and mask, used for 15 min vs. Control	Duration of Labor; Mode of delivery	Poor
Kaviani, 2014 <sup>157</sup>  KQ 3	RCT Middle East  N enrolled: 160 patients N completed: 160 patients	Arm 1 Mean: 23 SD: 3.9  Arm 2 Mean: 22 SD: 3.86	Stage of Labor at Entry: First stage  Study's Definition of Labor: 3-4 cm dilation  Parity: Nulliparous	In the aroma group, 15x15cm tissues containing 0.1 mL of lavender essence mixed with 1 mL of distilled water were used vs. The control group inhaled 2 mL of distilled water	Duration of Labor; Parental preferences (Parity)	Fair

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Kavitha, 2012 <sup>139</sup>  KQ 3	RCT Asia  N enrolled: 293 patients N completed: 293 patients	Arm 1 Mean: 23.8  Arm 2 Mean: 23.9  Arm 3 Mean: 24.1	Stage of Labor at Entry: Spontaneous active  Study's Definition of Labor: 3-6 cm dilation  Parity: Nulliparous	Oral hydration vs. 125 mL/hr Lactated Ringer's solution with oral fluids on request vs. 250 mL/hr Lactated Ringer's solution with oral fluids on request	Mode of delivery; Duration of Labor	Good
Kenyon, 2013 <sup>208</sup>  KQ 7	RCT UK/Europe  N enrolled: 94 patients N completed: 92 patients	Arm 1 Mean: 28 SD: 5.2  Arm 2 Mean: 26 SD: 5.0	Stage of Labor at Entry: First stage active  Study's Definition of Labor: ≥4 cm dilation and regular painful contractions.  Parity: Nulliparous	High Dose Oxytocin: Start at 4 mU/min and increase every 30 min by 4 mU/min to a maximal rate of 64 mU/min vs. Standard Dose Oxytocin: Start at 2 mU/min and increase every 30 min by 2 mU/min to a maximal rate of 32 mU/min	Duration of Labor; Mode of delivery; Neonatal length of stay; Maternal Trauma to the Pelvic Floor; Maternal Infection; Maternal Hemorrhage; Neonatal Respiratory distress	Good
Koyucu, 2017 <sup>226</sup>  KQ 9	RCT UK/Europe  N enrolled: 116 patients N completed: 116 patients	Arm 1 Mean: 22.4 SD: 3.5  Arm 2 Mean: 22.6 SD: 3.6	Stage of Labor at Entry: First Stage  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Spontaneous pushing vs. Valsalva pushing	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Hemorrhage; Trauma to the pelvic floor; Meconium aspiration	Fair
Lavender, 2006 <sup>89</sup>  KQ 1	RCT UK/Europe  N enrolled: 3,000. N completed: 2,975 patients	Arm 1 Mean: 25.4 SD: 5.5  Arm 2 Mean: 25.3 SD: 5.5	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: ≥3 cm dilation, cervix was effaced, and regular contractions at least every 5 min and lasting ≥20 sec  Parity: Nulliparous	Women were assigned to have their labors recorded on a partogram with an action line 2 h to the right of the alert line vs. Women were assigned to have their labors recorded on a partogram with an action line 4 h to the right of the alert line	Mode of delivery; Duration of Labor; Maternal Hemorrhage; Parental preferences (Parity)	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Lee, 2018 <sup>94</sup>  KQ 1	RCT Australia/NZ  N enrolled: 116 patients N completed: 99 patients	Arm 1 Mean: 28 SD: 5  Arm 2 Mean: 29.6 SD: 4.7	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Dystocia line partograph vs. Action line partograph	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal experience and satisfaction; Admission to NICU	Good
Liu, 2015 <sup>124</sup>  KQ 3, KQ 4	RCT Asia  N enrolled: 120 patients N completed: 120 patients	Total Min. age: 20 Max. age: 29	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3 cm dilation  Parity: Unclear	Han's Acupoint Nerve Stimulator vs. Epidural vs. Patient-controlled IV analgesia vs. Control	Duration of Labor; Mode of delivery; Maternal Hemorrhage; Neonatal Respiratory distress	Fair
Liu, 2018 <sup>213</sup>  KQ 7	RCT Asia  N enrolled: 810 patients N completed: 810 patients	Arm 1 Mean: 25.75 SD: 1.84  Arm 2 Mean: 25.46 SD: 1.95  Arm 3 Mean: 25.53 SD: 2.46  Arm 4 Mean: 26.84 SD: 1.62  Arm 5 Mean: 28.44 SD: 3.07	Stage of Labor at Entry: Arrested progress of labor as defined by the partogram  Study's Definition of Labor: Unclear/NR  Parity: Primiparous	Oxytocin Administration: 16 mU/min continuous administration vs. 2 mU/min following 1 mU/min normal frequency vs. 8 mU/min following 4 mU/min normal frequency vs. 5 mU/min quarter-hourly vs. Pulsatile preparations	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Hemorrhage; Trauma to the pelvic floor; Admission to NICU; Mortality	Poor

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Ma, 2011 <sup>141</sup>  KQ 3	RCT Asia  N enrolled: 350 patients N completed: 350 patients	Arm 1 Mean: 26.15 SD: 2.83  Arm 2 Mean: 26.39 SD: 2.96  Arm 3 Mean: 25.55 SD: 3.00	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: 2-3 dilation and regular uterine contractions.  Parity: Nulliparous, Parous	Acupuncture - Electroacupuncture at SP6 vs. Sham acupuncture - Needle did not penetrate skin and no electricity applied vs. Control - usual care	Duration of Labor	Good
Maddady, 2018 <sup>174</sup>  KQ 3	RCT Middle East  N enrolled: 162 patients N completed: 147 patients	Arm 1 Mean: 23.6 SD: 3.8  Arm 2 Mean: 22.6 SD: 3.8  Arm 3 Mean: 24.5 SD: 4.14	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4 cm dilatation  Parity: Nulliparous	Hot shower vs. IV injection of hyoscine vs. Routine care	Duration of Labor; Maternal experience; Admission to NICU	Fair
Mason, 2018 <sup>97</sup>  KQ 1	Observational U.S.  N enrolled: 250 patients N completed: 245 patients	Arm 1 Mean: 33.1 SD: 13.3  Arm 2 Mean: 31.3 SD: 5.2  Arm 3 Mean: 33.7 SD: 4.1	Stage of Labor at Entry: Spontaneous labor  Study's Definition of Labor: Unclear/NR  Parity: Parous	Interbirth interval between studied pregnancy and most recent birth:  0-59 months vs. 60-119 months vs. ≥120 months	Duration of Labor; Birthweight	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
McGrath, 2008 <sup>145</sup>  KQ 3	RCT U.S.  N enrolled: 387 patients N completed: 387 patients	Arm 1 Mean: 28.97 SD: 4.83  Arm 2 Mean: 28.60 SD: 4.49	Stage of Labor at Entry: First stage active (early)  Study's Definition of Labor: Not specified  Parity: Nulliparous	Doula care – Close physical proximity, touch, eye contact and verbal encouragement vs. Control	Mode of delivery (Parity)	Good
Mikki, 2007 <sup>115</sup>  KQ 2	RCT Middle East  N enrolled: 690 patients N completed: 690 patients	Arm 1 Mean: 27.3 SD: 5.3  Arm 2 Mean: 26.9 SD: 5.1  Arm 3 Mean: 21.7 SD: 3.7  Arm 4 Mean: 21.4 SD: 4.2	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: Active labor  Parity: Nulliparous, Parous	Parous Intervention- membranes ruptured shortly after randomization vs. Parous Control - amniotomy if indicated (2 h arrest of cervical dilation, dystocia, fetal monitor insertion) vs. Nulliparous Intervention- membranes ruptured shortly after randomization vs. Nulliparous Control - amniotomy if indicated (2 h arrest of cervical dilation, dystocia, fetal monitor insertion)	Duration of Labor; Maternal Hemorrhage; Maternal Infection; Maternal Trauma to the Pelvic Floor; Neonatal Respiratory distress; Neonatal infection/sepsis; Mode of delivery (Parity)	Good
Miquelutti, 2007 <sup>146</sup>  KQ 3	RCT Latin America  N enrolled: 107 patients N completed: 107 patients	Total Median: 21	Stage of Labor at Entry: First stage active  Study's Definition of Labor: $\geq 3$ cm and $\leq 5$ cm dilation.  Parity: Nulliparous	Information that provided possible benefits of upright position and encouraged to assume this position during labor. Encouraged to return to upright position whenever they had been in the supine position for >30 min vs. Usual care. No orientation concerning upright position. Free to move around during labor.	Mode of delivery; Duration of Labor	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Moraloglu, 2017 <sup>168</sup>  KQ 3	RCT UK/Europe  N enrolled: 102 patients N completed: 100 patients	Arm 1 Mean: 23.96 SD: 3.75  Arm 2 Mean: 22.04 SD: 3.46	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second the interval between the complete opening of the cervix until delivery  Parity: Nulliparous	Influence of position on birth outcomes: Squatting using a bar vs. Supine position modified to 45 degree of semi-fowler	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Hemorrhage; Maternal experience and satisfaction; Neonatal respiratory distress	Fair
Mortazavi, 2012 <sup>138</sup>  KQ 3	RCT Middle East  N enrolled: 120 patients N completed: 120 patients	Arm 1 Mean: 23.12 SD: 3.17  Arm 2 Mean: 22.45 SD: 3.45  Arm 3 Mean: 23.50 SD: 4.24	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: ≤4 cm  Parity: Nulliparous	Massage - Massage of shoulder or back, abdominal effleurage and sacral pressure for 30 min in all labor phases vs. Attendant - Attendant accompanied women during entire labor vs. Control - Usual care	Duration of Labor	Poor
Nachum, 2010 <sup>114</sup>  KQ 2,KQ 7	RCT Middle East  N enrolled: 283 patients N completed: 283 patients	Arm 1 Mean: 28.1 SD: 4.9  Arm 2 Mean: 28.5 SD: 5.3  Arm 3 Mean: 28.2 SD: 5.0  Arm 4 Mean: 28.7 SD: 4.7	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: 2-4 cm dilation, prolonged latent phase  Parity: Nulliparous, Parous	Amniotomy vs. Oxytocin vs. Both Amniotomy and Oxytocin performed and started simultaneously after admission to the delivery ward. vs. Control	Maternal Trauma to the Pelvic Floor; Maternal Infection; Maternal Hemorrhage; Mode of delivery; Duration of Labor; Parental preferences (Parity)	Good

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Nafisi, 2006 <sup>198</sup>  KQ 4	RCT Middle East  N enrolled: 395 patients N completed: 395 patients	Arm 1 Mean: 23.2 SD: 2  Arm 2 Mean: 22.03 SD: 3	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Active labor, <+4 cm dilation)  Parity: Nulliparous	Epidural vs. Intravenous meperidine plus single dose meperidine.	Mode of delivery; Duration of Labor; Neonatal admission to NICU	Fair
Nakamura, 2009 <sup>195</sup>  KQ 4	RCT Latin America  N enrolled: 40 patients N completed: 40 patients	Arm 1 Mean: 21.4 SD: 4.4  Arm 2 Mean: 19.9 SD: 3.6	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	Epidural vs. Combined Spinal Epidural (CSE)	Mode of delivery	Fair
Nasir, 2007 <sup>147</sup>  KQ 3	RCT Middle East  N enrolled: 200 patients N completed: 200 patients	Unclear/NR	Stage of Labor at Entry: Active  Study's Definition of Labor: Active labor with cephalic presentation and longitudinal lie  Parity: Unclear	Squatting position during Second stage of labor vs. Supine in lithotomy position during Second stage of labor	Maternal Trauma to the Pelvic Floor Neonatal Shoulder dystocia Maternal Hemorrhage; Mode of delivery	Fair
Neal, 2014 <sup>84</sup>  KQ 1	Observational U.S.  N enrolled: 223 patients N completed: 216 patients	Arm 1 Median: 26  Arm 2 Median: 26.5	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: Spontaneous labor onset, dilated at least 1 cm but no more than 6 cm  Parity: Nulliparous	Admission of women in active labor vs. Admission of women in pre-active/early labor	Duration of Labor; Mode of delivery; Maternal Infection	Poor



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Neal, 2017 <sup>95</sup>  KQ 1	Observational U.S.  N enrolled: 2,537 patients N completed: 2,537 patients	Arm 1 Mean: 26.4 SD: 5.9  Arm 2 Mean: 27.1 SD: 5.9	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	Compare risk for caesarean delivery for women admitted in active labor by diagnostic guidelines: Friedman curve vs. NICE guidelines vs. ACOG/SMFM Guidelines	Mode of delivery; Duration of Labor	Good
Neal, 2018 <sup>91</sup>  KQ 1	Observational U.S.  N enrolled: 27,077 patients N completed: 27,077 patients	Total: Median: 24 (17, 35)	Stage of Labor at Entry: Cervical examination performed within 1 h of hospital admissions  Study's Definition of Labor: Preactive labor was diagnosed when cervical dilation was: 1) <4 cm at admission regardless of subsequent cervical change 2) 4 or 5 cm at admission but subsequent cervical change was <1 cm in 2 h  Parity: Nulliparous	Women admitted during active labor vs. Women admitted before active labor onset	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Hemorrhage; Neonatal respiratory distress; Admission to NICU; Birthweight	Good
Ohel, 2006 <sup>199</sup>  KQ 4	RCT Middle East  N enrolled: 449 patients N completed: 449 patients	Unclear/NR	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: Established labor, spontaneous or induced with at least 2 painful contractions in 10 min, up to 3cm dilation, and at least 80% effaced  Parity: Nulliparous	Early Epidural vs. Late Epidural	Mode of delivery; Duration of Labor (Parity)	Good

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Onah, 2015 <sup>119</sup>  KQ 2	RCT Africa  N enrolled: 214 patients N completed: 214 patients	Arm 1 20-24: 8.4% 25-29:16.8% 30-34: 8.4% 35-39:45.8% 40-44:20.6%  Arm 2 20-24:11.2% 25-29:20.6% 30-34:10.3% 35-39:42.1% 40-44:15.9%	Stage of Labor at Entry: Active labor  Study's Definition of Labor: Active labor (dilation < 5 cm.  Parity: Mixed parity	Amniotomy vs. Control	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor	Good
Palomaki, 2006 <sup>211</sup>  KQ 7	RCT UK/Europe  N enrolled: 107 patients N completed: 107 patients	Arm 1 Median: 27 (20, 43)  Arm 2 Median: 27 (18, 39)	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Enrolled with failure to progress in the active phase of the first stage of labor.  Parity: Nulliparous, Parous	Propranolol and Oxytocin - 2mg Propranol with Oxytocin 2.5 mIU/min IV over 10 min, raised by 2.5 mIU/min every 30 min until contractions reached 150 Montevideo units vs. Placebo and Oxytocin - Oxytocin 2.5 mIU/min IV over 10 min, raised by 2.5 mIU/min every 30 min until contractions reached 150 Montevideo units	Mode of delivery; Duration of Labor	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Pascual-Ramirez, 2011 <sup>78</sup>  KQ 4  Companion: Pascual-Ramirez, 2012 <sup>79</sup>	RCT UK/Europe  N enrolled: 144 patients N completed: 144 patients	Arm 1 Mean: 31 SD: 5  Arm 2 Mean: 29 SD: 6	Stage of Labor at Entry: First stage latent (<4 cm dilation), first stage active (4-10 cm dilation)  Study's Definition of Labor: Eligible individuals had to meet at least 2 out of 3 criteria (in addition to analgesia request): regular contractions every 2–3 min, cervical effacement, and cervix dilation of 2 cm.  Parity: Nulliparous, Parous	Low-dose epidural vs. Combined Spinal Epidural (CSE)	Mode of delivery; Duration of Labor; Parental preferences (Parity)	Good
Patel, 2014 <sup>190</sup>  KQ 4	RCT UK/Europe  N enrolled: 115 patients N completed: 115 patients	Arm 1 Mean: 30.3 SD: 5.2  Arm 2 Mean: 31.0 SD: 5.3	Stage of Labor at Entry: First stage active, 2-6 cm dilation  Study's Definition of Labor: Active labor between 2 and 6 cm dilation.  Parity: Nulliparous, Mixed Parity	Epidural vs. Combined Spinal Epidural (CSE)	Duration of Labor; Mode of delivery; Neonatal admission to NICU; Abnormal fetal heart rate tracing	Fair
Phumdoung, 2007 <sup>161</sup>  KQ 3	RCT Asia  N enrolled: 210 patients N completed: 164 patients	Total Mean: 21.51 SD: 3.62	Stage of Labor at Entry: Unclear/NR Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Prince of Songkla University (PSU) bed and cat position (alternate with high head) vs. PSU bed and cat position (alternate with supine) vs. High head position group - Women in the high head group were assigned to lie in the bed with a 45deg lift vs. Supine position	Duration of Labor (Parity)	Poor

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Phumdoung, 2013 <sup>158</sup>  KQ 3	RCT Asia  N enrolled: 332 patients N completed: 264 patients	Total Mean: 23.38 SD: 4.31	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Prince of Songkla University (PSU) birthing bed without the holding bar vs. PSU birthing bed with the holding bar vs. Usual birthing bed with the head of the bed elevated 45 to 60 degrees vs. Usual birthing bed with the head of the bed elevated 15 degrees	Duration of Labor (Parity)	Fair
Prabhakar, 2015 <sup>153</sup>  KQ 3	RCT Asia  N enrolled: 60 patients N completed: 60 patients	Arm 1 16-20:53.3% 21-25: 40 % 26-30: 6.7%  Arm 2 16-20: 30% 21-25:53.3% 26-30:16.7%	Stage of Labor at Entry: First stage labor  Study's Definition of Labor: Unclear/NR  Parity: Unclear/NR	Each woman in the experimental group was ambulated for an average of 1-1.5 h according to their tolerance and giving rest periods in between. vs. The control group women were confined to bed most of the time	Duration of Labor; Mode of delivery; Neonatal Birth trauma (Parity)	Good
Ragnar, 2006 <sup>80</sup>  KQ 3  Companion: Altman, 2007 <sup>81</sup>	RCT UK/Europe  N enrolled: 271 patients N completed: 218 patients	Arm 1 Mean: 26.4 SD: 4.0  Arm 2 Mean: 26.5 SD: 4.3	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second stage (fully dilated and retracted cervix)  Parity: Nulliparous	Kneeling position, leaning towards the head of the delivery bed or a cushion, vs. Sitting position on the delivery bed, with the head of the bed raised at least 60 degrees from the horizontal plane	Mode of delivery; Duration of Labor; Maternal Trauma to the Pelvic Floor (Parity)	Good
Rahmani, 2012 <sup>133</sup>  KQ 3	RCT Middle East  N enrolled: 180 patients N completed: 180 patients	Arm 1 Mean: 25.4 SD: 4.1  Arm 2 Mean: 26.8 SD: 3.6	Stage of Labor at Entry: Unclear, 3-4cm dilation  Study's Definition of Labor: 3-4 cm dilation  Parity: Mixed parity	Carbohydrates - 3 medium dates with 110 mL water OR 3 dates with light tea without sugar OR 110 mL orange juice drink vs. Control - water only	Duration of Labor; Mode of delivery	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Ruamsap, 2017 <sup>120</sup>  KQ 2	RCT Asia  N enrolled: 120 patients N completed: 120 patients	Arm 1 Median: 25 (15, 35)  Arm 2 Median: 23 (15, 34)	Stage of Labor at Entry: Active labor  Study's Definition of Labor: Active labor (dilation < 5 cm.  Parity: Mixed parity	Early amniotomy vs. Late amniotomy	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Hemorrhage; Fetal heart rate	Fair
Samadzadeh, 2017 <sup>175</sup>  KQ 3	RCT Middle East  N enrolled: 120 patients N completed: 120 patients	Arm 1 Mean: 25.9 SD: 5.84  Arm 2 Mean: 26.68 SD: 6.49  Arm 3 Mean: 29.31 SD: 6.41	Stage of Labor at Entry: First stage  Study's Definition of Labor: First stage with dilation <4 cm  Parity: Unclear	TENS unit plus oxygen vs. Entonox plus TENS unit applied to participant but not turned on vs. TENS unit plus Entonox	Duration of Labor; Maternal experience and satisfaction (Parity)	Fair
Santhi, 2012 <sup>129</sup>  KQ 3	RCT Asia  N enrolled: 50 patients N completed: 50 patients	Unclear/NR	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second stage complete cervical dilation: 10 cm  Parity: Nulliparous	Semi-sitting position - Head of labor table propped up to 45 degrees during stage 2 labor vs. Supine position	Duration of Labor	Fair
Selin, 2018 <sup>215</sup>  KQ 7	RCT UK/Europe  N enrolled: 1,351 patients N completed: 1,295 patients	Arm 1 Mean: 29 SD: 4.5  Arm 2 Mean: 29 SD: 4.6	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Active labor with <6cm dilation  Parity: Nulliparous	High-dose Oxytocin vs. Low-dose Oxytocin	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Hemorrhage; Fetal heart rate; NICU admissions; Maternal experience and satisfaction	xxx

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Sezer, 2007 <sup>197</sup>  KQ 4	RCT UK/Europe  N enrolled: 40 patients N completed: 40 patients	Arm 1 Mean: 24.2 SD: 3.3  Arm 2 Mean: 24.2 SD: 3.4	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Active labor with <6cm dilation  Parity: Nulliparous	Epidural vs. Combined Spinal Epidural (CSE)	Mode of delivery; Duration of Labor	Fair
Shafaie, 2017 <sup>82</sup>  KQ 3  Companion: Yulghunlu, 2018 <sup>83</sup>	RCT Middle East  N enrolled: 201 patients N completed: 201 patients	Arm 1 Mean: 23.0 SD: 3.4  Arm 2 Mean: 22.8 SD: 3.2  Arm 3 Mean: 24.0 SD: 4.4	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Spontaneous active labor (4 cm)  Parity: Nulliparous	IV fluid - Ringer's solution at 125 mL/h plus access to oral fluids per dietitians guidance vs. IV fluid – dextrose 5% at 125 mL/h plus access to oral fluids per dietitians guidance vs. Usual care - access to oral fluids per dietitians guidance	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Shahoei, 2017 <sup>178</sup>  KQ 3	RCT Middle East  N enrolled: 90 patients N completed: 90 patients	Arm 1: 16-20:13.4% 21-25: 40% 26-30: 40% 31-35: 3.3% >36: 3.3%  Arm 2: 16-20:26.7% 21-25:56.7% 26-30: 10% 31-35: 3.3% >36: 3.3%  Arm 3: 16-20: 20% 21-25: 40% 26-30: 30% 31-35: 6.7% >36: 3.3%	Stage of Labor at Entry: Active phase of labor  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Switched-on TENS device vs. Switched-off TENS device vs. No TENS device	Mode of delivery; Operative vaginal delivery; Maternal Trauma to the Pelvic Floor; Hemorrhage	Fair
Sharma, 2012 <sup>135</sup>  KQ 3	RCT Asia  N enrolled: 250 patients N completed: 243 patients	Arm 1 Mean: 25.1  Arm 2 Mean: 25.1	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-5 cm dilation, active spontaneous labor with or without ruptured membranes Parity: Nulliparous	Normal saline with dextrose (500 mL) alternating with normal saline (500mL) at rate of 175 mL/hr vs. Normal saline at rate of 175 mL/hr	Duration of Labor; Mode of delivery; Maternal Infection	Good
Shen, 2017 <sup>203</sup>  KQ 4	RCT Asia  N enrolled: 400 patients N completed: 400 patients	Arm 1 Mean: 28.0 SD: 3.1  Arm 2 Mean: 28.1 SD: 3	Stage of Labor at Entry: Second stage  Study's Definition of Labor: <6 cm dilation  Parity: Nulliparous	Motor sparing epidural analgesia infusion vs. Placebo	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Maternal preferences and satisfaction	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Shirvani, 2014 <sup>156</sup>  KQ 3	RCT Middle East  N enrolled: 64 patients N completed: 64 patients	Total Min. age: 18 Max. age: 35	Stage of Labor at Entry: Beginning of First stage active  Study's Definition of Labor: 3-4 cm dilation  Parity: Nulliparous	Ice pack, applied by doula/midwife to back, abdomen and lower parts of the abdomen for 10 min since initiation of active phase, applied to perineum during Second phase vs. No additional interventions beyond routine care	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor (Parity)	Fair
Shrivastava, 2009 <sup>144</sup>  KQ 3	RCT U.S.  N enrolled: 300 patients N completed: 289 patients	Arm 1 Mean: 23.9 SD: 5.8  Arm 2 Mean: 24.2 SD: 5.7  Arm 3 Mean: 23.7 SD: 5.7	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 3-5 cm dilation, spontaneous active labor with or without ruptured membranes.  Parity: Nulliparous	5% dextrose solution in normal saline vs. 10% dextrose solution in normal saline vs. normal saline	Maternal Infection; Maternal Hemorrhage; Mode of delivery; Duration of Labor Abnormal fetal heart rate tracing	Good
Silva Gallo, 2013 <sup>131</sup>  KQ 3	RCT Latin America  N enrolled: 46 patients N completed: 46 patients	Arm 1 Mean: 19 SD: 3  Arm 2 Mean: 19 SD: 4	Stage of Labor at Entry: First stage active  Study's Definition of Labor: 4-5 cm dilation  Parity: Nulliparous	Massage - 30 min of massage delivered during contractions by physiotherapist beginning when 4-5cm dilated. vs. Control - Physiotherapist accompanied patient for 30 min at 4-5cm dilation. Observed and answered questions only.	Duration of Labor; Mode of delivery	Good



<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Simarro, 2017 <sup>169</sup>  KQ 3	RCT UK/Europe  N enrolled: 150 patients N completed: 150 patients	Arm 1 Mean: 33.4 SD: 3  Arm 2 Mean: 33.9 SD: 3	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second stage after full cervical dilation  Parity: Mixed Parity	Postural changes during Second stage of parturients with epidural analgesia vs. Supine position only	Mode of delivery; Duration of Labor; Cesarean delivery; Operative vaginal delivery	Fair
Somprasit, 2005 <sup>117</sup>  KQ 2,KQ 7	RCT Asia  N enrolled: 975 patients N completed: 960 patients	Arm 1 Mean: 24.4 SD: 4.5  Arm 2 Mean: 24.2 SD: 4.5	Stage of Labor at Entry: First stage active, Second stage  Study's Definition of Labor: Regular painful contractions occurring at least once every 5 min; contraction duration of at least 40 sec/min; either spontaneous rupture of membranes or bloody show with cervical dilatation and full effacement  Parity: Nulliparous	Active management: AROM within 1 h of admission, 2-hourly vaginal assessments; high dose oxytocin augmentation if cervical dilatation was less than 1 cm/h in the first stage of labor. vs. Conventional management	Mode of delivery; Duration of Labor; Maternal Infection (Parity)	Good
Suzuki, 2010 <sup>87</sup>  KQ 1	Observational Asia  N enrolled: 2,369 patients N completed: 2,369 patients	Arm 1 Unclear/NR  Arm 2 Mean: 23  Arm 3 Mean: 28.4	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: <7 cm dilation at admission, spontaneous onset of labor  Parity: Nulliparous	Friedman Curve vs. Zhang curve vs. Suzuki curve (current cohort)	Duration of Labor	Poor

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Sweed, 2011 <sup>193</sup>  KQ 4	RCT Africa  N enrolled: 60 patients N completed: 59 patients	Arm 1 Mean: 22  Arm 2 Mean: 22  Arm 3 Mean: 23.05	Stage of Labor at Entry: First stage active (4-10 cm dilation)  Study's Definition of Labor: Nulliparous women in active labor with cervical dilatation of 5 cm and cephalic presenting fetus  Parity: Nulliparous	Epidural vs. Combined Spinal Epidural (CSE) vs. IV Analgesia	Mode of delivery; Duration of Labor	Poor
Taavoni, 2011 <sup>140</sup>  KQ 3	RCT Middle East  N enrolled: 62 patients N completed: 60 patients	Arm 1 Mean: 31.26 SD: 4.92  Arm 2 Mean: 30.85 SD: 4.23	Stage of Labor at Entry: First stage  Study's Definition of Labor: First stage active (4-8 cm dilation)  Parity: Nulliparous	Birth ball – 30 min of sitting on ball, rocking hips in back and forth or circular motion vs. Usual care - Reclining on bed without ambulation	Duration of Labor	Fair
Taavoni, 2016 <sup>164</sup>  KQ 3	RCT Middle East  N enrolled: 90 patients N completed: 87 patients	Arm 1 Mean: 24.80 SD: 3.30  Arm 2 Mean: 24.43 SD: 3.67  Arm 3 Mean: 23.73 SD: 4.07	Stage of Labor at Entry: First stage  Study's Definition of Labor: Cervical dilation between 4-8 cm  Parity: Primiparous	Control vs. Heat Therapy vs. Birthing Ball	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Maternal preferences and satisfaction; Neonatal Respiratory distress	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Tanvisut, 2018 <sup>167</sup>  KQ 3	RCT Asia  N enrolled: 106 patients N completed: 104 patients	Arm 1 Mean: 26.54 SD: 4.692  Arm 2 Mean: 24.92 SD: 4.315	Stage of Labor at Entry: First stage  Study's Definition of Labor: Regular contractions more than 3 times in 10 min with cervical progression  Parity: Primagravidae	Aromatherapy vs. Routine care	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Duration of Labor; Fetal heart rate	Good
Thies-Lagergren, 2013 <sup>134</sup>  KQ 3	RCT UK/Europe  N enrolled: 1,020 patients N completed: 1,002 patients	Total <25: 17.5% 25-34: 71.8% >35: 10.6%	Stage of Labor at Entry: Active  Study's Definition of Labor: Spontaneous onset of labor and women induced after spontaneous rupture of membranes without spontaneous contractions for >24 hrs  Parity: Mixed parity	Birth seat vs. Usual care - position of mother's choice, most were supine or supine with stirrups	Duration of Labor; Mode of delivery	Fair
Tolba, 2018 <sup>98</sup>  KQ 1	RCT Middle East  N enrolled: 122 patients N completed: 110 patients	Arm 1 Mean: 20 (19-21)  Arm 2 Mean: 21 (19-22.5)	Stage of Labor at Entry: First stage  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	Novel labor scale vs. WHO partograph	Cesarean delivery; Duration of Labor; Hemorrhage	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Tribe, 2012 <sup>209</sup>  PULSE  KQ 7	RCT UK/Europe  N enrolled: 502 patients N completed: 500 patients	Arm 1 Mean: 30.1 SD: 5.9  Arm 2 Mean: 29.7 SD: 5.3	Stage of Labor at Entry: Unclear  Study's Definition of Labor: Requiring oxytocin augmentation because of failure to maintain adequate contractility.  Parity: Nulliparous, Parous	Continuous oxytocin infusion: Start at 2 mU/min then follow protocol vs. Pulsatile oxytocin infusion: Start at 2 mU/pulse and then follow protocol	Mode of delivery; Duration of Labor	Good
Tussey, 2015 <sup>154</sup>  KQ 3	RCT U.S.  N enrolled: 142 patients N completed: 142 patients	Arm 1 Mean: 27.5 SD: 6.7  Arm 2 Mean: 27.3 SD: 6.2	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	The peanut ball vs. Control	Mode of delivery; Duration of Labor (Parity)	Fair
Tveit, 2012 <sup>192</sup>  KQ 4	RCT UK/Europe  N enrolled: 39 patients N completed: 37 patients	Arm 1 Mean: 26  Arm 2 Mean: 27	Stage of Labor at Entry: First stage latent, First stage active  Study's Definition of Labor: >2 cm dilation, regular uterine contractions  Parity: Mixed parity	Epidural vs. Patient Controlled IV Analgesia	Abnormal fetal heart rate tracing; Mode of delivery; Duration of Labor; Neonatal acidemia; Long-term neonatal health; Parental preferences	Fair
Vadivelu, 2017 <sup>121</sup>  KQ 2	RCT Asia  N enrolled: 288 patients N completed: 287 patients	Arm 1 Mean: 24.9 SD: 3.9  Arm 2 Mean: 25.4 SD: 4.1	Stage of Labor at Entry: First stage active  Study's Definition of Labor: Regular and strong contraction and 3-5 cm dilation  Parity: Mixed Parity	Amniotomy vs. Conservative management	Duration of Labor; Mode of delivery; Umbilical cord prolapse; Maternal hemorrhage; Maternal infection; Neonatal Respiratory distress; Admission to NICU; Maternal and parental satisfaction	Good

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Vaijayanthimala, 2014 <sup>150</sup>  KQ 3	RCT Asia  N enrolled: 240 patients N completed: 211 patients	Unclear/NR	Stage of Labor at Entry: Active  Study's Definition of Labor: Active stage of labor (3-6 cm dilation)  Parity: Nulliparous,	Movement throughout labor vs. Control	Duration of Labor; Mode of delivery; Abnormal fetal heart rate tracing; Parental preferences (Parity)	Poor
Vaziri, 2016 <sup>225</sup>  KQ 9	RCT Middle East  N enrolled: 102 patients N completed: 72 patients	Arm 1 Mean: 22.23 SD: 4.32  Arm 2 Mean: 22.18 SD: 4.60	Stage of Labor at Entry: Entering Second stage  Study's Definition of Labor: Second stage  Parity: Nulliparous	Valsalva method while in supine position vs. Spontaneous pushing while in lateral position	Mode of delivery; Duration of Labor; Maternal experience; Abnormal fetal heart rate tracing	Fair
Vixner, 2014 <sup>128</sup>  KQ 3	RCT UK/Europe  N enrolled: 303 patients N completed: 253 patients	Arm 1 Mean: 28.1 SD: 5.1  Arm 2 Mean: 26.5 SD: 4.7  Arm 3 Mean: 27.7 SD: 4.6	Stage of Labor at Entry: First stage latent, first stage active  Study's Definition of Labor: Not specified  Parity: Nulliparous	Manual acupuncture vs. Electro-acupuncture - Acupuncture location chosen with regard to pain location vs. Usual care--had access to analgesia	Duration of Labor; Mode of delivery; Maternal Trauma to the Pelvic Floor	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Wassen, 2015 <sup>68</sup>  KQ 4	RCT UK/Europe  N enrolled: 493 patients N completed: 463 patients	Arm 1 Median: 30 (27, 34)  Arm 2 Median: 30 (26, 33)	Stage of Labor at Entry: Randomized prior to start of labor. Intervention started when they presented in First stage of labor.  Study's Definition of Labor: 2 cm dilation with effaced cervix and regular contractions.  Parity: Nulliparous, Mixed Parity	Epidural vs. Analgesia on request	Duration of Labor; Mode of delivery; Neonatal Shoulder dystocia; Maternal Hemorrhage; Maternal Trauma to the Pelvic Floor; Neonatal acidemia	Good
Wiberg-Itzel, 2018 <sup>177</sup>  KQ 3	RCT UK/Europe  N enrolled: 200 patients N completed: 200 patients	Arm 1 Mean: 32.2 SD: 5.2  Arm 2 Mean: 31.9 SD: 4.8	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Primiparous	Bicarbonate vs. No bicarbonate	Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal Hemorrhage; Maternal infection; Neonatal Respiratory distress; Admission to NICU	Fair
Wilson, 2009 <sup>66</sup>  COMET  KQ 4  Companion: Wilson, 2011 <sup>67</sup>	RCT UK/Europe  N enrolled: 1,054 patients N completed: 1,054 patients	Arm 1 <19: 14.7% 25-29:30.9% 30-34:23.2% 35+: 9.1%  Arm 2 <19: 14% 25-29:30.5% 30-34:23.6% 35+: 9.1%  Arm 3 <19: 14.9% 25-29:30.9% 30-34:22.6% 35+: 9.4%	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous	High-dose Epidural (control) vs. Combined Spinal Epidural (CSE) vs. Low-dose Infusion Epidural	Mode of delivery	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Wong, 2005 <sup>200</sup>  KQ 4	RCT U.S.  N enrolled: 750 patients N completed: 720 patients	Arm 1 Mean: 31.3 SD: 5.2  Arm 2 Mean: 31.3 SD: 5.4	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: Spontaneous labor or spontaneous rupture of the membranes and <4 cm dilation  Parity: Nulliparous	Combined Spinal Epidural (CSE) vs. IV and IM Analgesia	Duration of Labor; Mode of delivery; Abnormal fetal heart rate tracing	Good
Wood, 2016 <sup>96</sup>  KQ 1	Observational U.S.  N enrolled: 2033 patients N completed: 2033 patients	Arm 1 Mean: 31.26 SD: 4.92  Arm 2 Mean: 30.85 SD: 4.23	Stage of Labor at Entry: First stage latent  Study's Definition of Labor: All were in labor at less than 4 cm  Parity: Nulliparous	Combined Spinal Epidural (CSE) vs. Usual care - Epidural	Duration of Labor	Good
Wu, 2017 <sup>176</sup>  KQ 3, 4	RCT Asia  N enrolled: 150 patients N completed: 131 patients	Arm 1 Mean: 25.0 SD: 3.2  Arm 2 Mean: 25.8 SD: 3.3  Arm 3 Mean: 25.8 SD: 3.1	Stage of Labor at Entry: Active labor  Study's Definition of Labor: First stage active (–4-10 cm)  Parity: Nulliparous	Respiratory guidance plus: Acupuncture analgesia vs. Spinal-epidural anesthesia vs. No additional treatment	Duration of Labor; Maternal Hemorrhage; Pelvic floor dysfunction; Maternal experience; Neonatal Respiratory distress	Fair
Xiao, 2019 <sup>181</sup>  KQ 3, 4	RCT Asia  N enrolled: 127 patients N completed: 120 patients	Arm 1 Mean: 27.62 SD: 2.86  Arm 2 Mean: 27.72 SD: 2.6	Stage of Labor at Entry: First stage  Study's Definition of Labor: First stage – 2-3 cm  Parity: Primiparous	CSEA with PCEA + Epidural Analgesia vs. CSEA with PCEA	Duration of Labor; Mode of delivery; Maternal Hemorrhage; Umbilical cord pH	Fair

<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Yazdkhasti, 2016 <sup>165</sup>  KQ 3	RCT Middle East  N enrolled: 121 patients N completed: 120 patients	Arm 1 Mean: 18.26 SD: 2.83  Arm 2 Mean: 19.13 SD: 2.56	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active >3-4cm  Parity: Nulliparous	Control vs. Aromatherapy (lavender essence)	Duration of Labor; Mode of delivery	Good
Yildirim, 2008 <sup>224</sup>  KQ 9	RCT UK/Europe  N enrolled: 100 patients N completed: 100 patients	Total Mean: 22.9 SD: 3	Stage of Labor at Entry: Second stage  Study's Definition of Labor: Second stage, full dilation (10 cm to delivery)  Parity: Nulliparous	Spontaneous pushing - encouraged and supported to push spontaneously in the second stage of labor, bearing down in response to contractions. vs. Valsalva pushing - Valsalva type pushing in the second stage of labor	Abnormal fetal heart rate tracing; Duration of Labor; Maternal Trauma to the pelvic floor (Parity)	Fair
Yuenyong, 2012 <sup>163</sup>  KQ 3	RCT Asia  N enrolled: 120 patients N completed: 114 patients	Total Mean: 22.8 SD: 3.6	Stage of Labor at Entry: Unclear/NR  Study's Definition of Labor: Whenever women arrived at hospital believing they were in labor.  Parity: Nulliparous	Support of close female relative vs. Control	Duration of Labor (Parity)	Good



<b>Study Acronym Key Question Companion Article</b>	<b>Study Design Geographic Location N enrolled N completed</b>	<b>Age Data (Years Unless Specified)</b>	<b>Stage of Labor at Entry Study Definition of Labor Parity in Population</b>	<b>Comparisons</b>	<b>Outcomes (Subgroup Analyzed)</b>	<b>Quality</b>
Zhang, 2010 <sup>21</sup>  CSL  KQ 1	Observational U.S.  N enrolled: 62,415 patients N completed: 62,415 patients	Arm 1 Mean: 24.6 SD: 5.8  Arm 2 Mean: 27.7 SD: 5.7  Arm 3 Mean: 30.0 SD: 5.4	Stage of Labor at Entry: Median (10th, 90th percentiles at admission) Parity 0: 4 (1,7) Parity 1: 4.5 (2,8) Parity 2+: 5 (2, 8)  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	Nulliparous vs. Parity 1 vs. Parity 2 or more	Duration of Labor	Fair
Zhang, 2010 <sup>22</sup>  KQ 1	Observational U.S.  N enrolled: 40,973 patients N completed: 26,838 patients	Arm 1 Mean: 20.3 SD: 3.9  Arm 2 Mean: 22.7 SD: 4.4  Arm 3 Mean: 27.4 SD: 5.5	Stage of Labor at Entry: Cervical dilation at admission (cm) - Parity 0: median (10th percentile, 90th percentile) = 3 (1, 6) Parity 1: median (10th percentile, 90th percentile) = 3.5 (2, 7) Parity 2+: median (10th percentile, 90th percentile) = 3.5 (1.5, 6.5)  Study's Definition of Labor: Unclear/NR  Parity: Nulliparous, Parous	Nulliparous vs. Parity 1 vs. Parity 2 or more	Mode of delivery; Duration of Labor (Parity)	Good

Study Acronym Key Question Companion Article	Study Design Geographic Location N enrolled N completed	Age Data (Years Unless Specified)	Stage of Labor at Entry Study Definition of Labor Parity in Population	Comparisons	Outcomes (Subgroup Analyzed)	Quality
Zhang, 2017 <sup>170</sup>  KQ 3	RCT Asia  N enrolled: 1400 patients N completed: 886 patients	Arm 1 Mean: 25.9 SD: 3.9  Arm 2 Mean: 26.5 SD: 4.2	Stage of Labor at Entry: First stage active  Study's Definition of Labor: First stage active (not defined)  Parity: Nulliparous	Hands-and-knees position vs. Supine position	Duration of Labor; Mode of delivery; Cesarean delivery; Operative vaginal delivery; Maternal Hemorrhage; Neonatal Respiratory distress; Shoulder dystocia; Abnormal fetal heart rate tracing	Fair
Zhang, 2018 <sup>99</sup>  KQ 1	Observational U.S.  N enrolled: 8,988 patients N completed: 8,988 patients	Arm 1 (Nulliparous women) Mean: 24.1 SD: 4.4  Arm 2 (Parous women) Mean: 28.6 SD: 4.8	Stage of Labor at Entry: When high-dose Oxytocin was administered  Study's Definition of Labor: High-dose Oxytocin was administered on average at 2-3 cm dilation.  Parity: Nulliparous, Parous	Progress of labor among women requiring oxytocin augmentation during labor stratified by parity  4–5 cm vs. 5–6 cm vs. 6–7 cm vs. 7–8 cm vs. 8–9 cm vs. 9–10 cm vs. 6–10 cm	Duration of Labor; Mode of delivery; (Parity)	Good

Abbreviations: ACOG=American College of Obstetricians and Gynecologists; CSE=combined spinal epidural; cm=centimeter; h=hour/hours; IV=intravenous; mL=milliliter; mmHG=millimeter of mercury; LI4=acupuncture location; min=minute/minutes; N=number; NICU=neonatal intensive care unit; NR=not reported; RCT=randomized controlled trial; s=second/seconds; SD=standard deviation; SMFM=Society for Material-Fetal Medicine; WHO=World Health Organization

## Appendix F. AMSTAR Quality Assessment for Systematic Reviews

Table F-1 shows the AMSTAR (A Measurement Tool to Assess Systematic Reviews) quality assessment for the included systematic reviews. For full study citations, please refer to the report's main reference list.

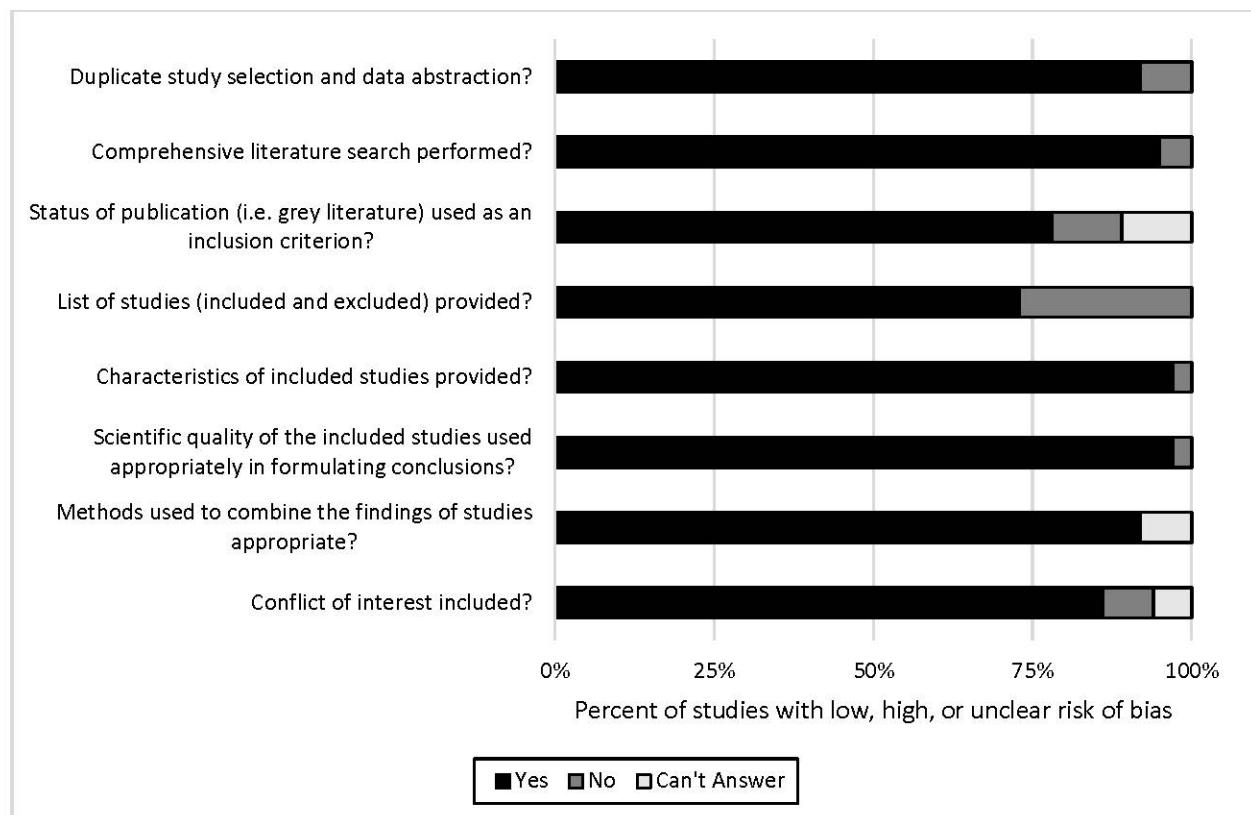
**Table F-1. AMSTAR assessment for included systematic reviews**

Study	Duplicate study selection and data abstraction?	Comprehensive literature search performed?	Status of publication (i.e. grey literature) used as an inclusion criterion?	List of studies (included and excluded) provided?	Characteristics of included studies provided?	Scientific quality of the included studies used appropriately in formulating conclusions?	Methods used to combine the findings of studies appropriate?	Conflict of interest included?
Abalos, 2018 <sup>103</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Anim-Somuah, 2011 <sup>43</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Aquino, 2018 <sup>184</sup>	Y	Y	C	N	Y	Y	C	C
Bakker, 2013 <sup>37</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Barasinski, 2016 <sup>229</sup>	N	Y	Y	N	Y	Y	Y	Y
Béranger, 2017 <sup>104</sup>	Y	N	N	N	N	N	Y	Y
Bohren, 2017 <sup>187</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Brown, 2013 <sup>35</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Bugg, 2013 <sup>220</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Ciardulli, 2017 <sup>185</sup>	Y	Y	N	N	Y	Y	C	C
Cluett, 2009 <sup>48</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Costlet, 2012 <sup>221</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Dawood, 2013 <sup>38</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Downe, 2013 <sup>206</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Ehsanipoor, 2017 <sup>183</sup>	Y	Y	C	N	Y	Y	Y	N
Fortier, 2015 <sup>52</sup>	Y	Y	N	N	Y	Y	Y	Y
Gaucher, 2017 <sup>218</sup>	Y	Y	C	Y	Y	Y	Y	N

<b>Study</b>	<b>Duplicate study selection and data abstraction?</b>	<b>Comprehensive literature search performed?</b>	<b>Status of publication (i.e. grey literature) used as an inclusion criterion?</b>	<b>List of studies (included and excluded) provided?</b>	<b>Characteristics of included studies provided?</b>	<b>Scientific quality of the included studies used appropriately in formulating conclusions?</b>	<b>Methods used to combine the findings of studies appropriate?</b>	<b>Conflict of interest included?</b>
Hodnett, 2013 <sup>54</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Kenyon, 2013 <sup>217</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Kobayashi, 2017 <sup>186</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Lavender, 2018 <sup>102</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Lawrence, 2013 <sup>34</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Liu, 2014 <sup>33</sup>	Y	Y	Y	N	Y	Y	Y	Y
Malin, 2016 <sup>182</sup>	N	Y	Y	N	Y	Y	Y	N
Martis, 2017 <sup>223</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Marucci, 2007 <sup>49</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Neal, 2010 <sup>47</sup>	N	N	N	N	Y	Y	C	Y
Oladapo, 2018 <sup>101</sup>	Y	Y	Y	N	Y	Y	Y	Y
Singata, 2013 <sup>36</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Smith, 2011 <sup>45</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Smyth, 2013 <sup>123</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Souza, 2006 <sup>50</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Wei, 2013 <sup>122</sup>	Y	Y	Y	Y	Y	Y	Y	Y
Wei, 2010 <sup>216</sup>	Y	Y	C	Y	Y	Y	Y	Y
Wei, 2009 <sup>219</sup>	Y	Y	Y	Y	Y	Y	Y	Y

Abbreviations: C=Can't answer; N=No; Y=Yes

**Figure F-1. Summary of AMSTAR quality assessment for included systematic reviews**



## Appendix G. Risk of Bias Assessment for Included Studies

Table G-1 shows the risk of bias quality assessment for the included cohort studies. For full study citations, please refer to the report's main reference list.

**Table G-1. Risk of bias assessment for included cohort studies**

Study	Potential Issues with Selection	Potential Issues with Comparability	Potential Issues with Outcomes
Cheng, 2010 <sup>86</sup>	N	N	N
Frigo, 2011 <sup>85</sup>	N	N	N
Greenberg, 2007 <sup>88</sup>	N	N	Y
Hoppe, 2018 <sup>100</sup>	Y	N	N
Inde, 2018 <sup>92</sup>	Y	N	N
Kauffman, 2016 <sup>93</sup>	N	N	N
Mason, 2018 <sup>97</sup>	Y	Y	N
Neal, 2018 <sup>91</sup>	Y	N	N
Neal, 2017 <sup>95</sup>	Y	N	N
Neal, 2014 <sup>84</sup>	N	Y	N
Suzuki, 2010 <sup>87</sup>	N	N	N
Wood, 2016 <sup>96</sup>	Y	N	N
Zhang, 2010 <sup>21</sup>	N	Y	N
Zhang, 2010 <sup>22</sup>	N	N	Y
Zhang, 2018 <sup>99</sup>	N	N	N

Abbreviations: N=No; Y=Yes

**Figure G-1. Summary of risk of bias assessment for included cohort studies**

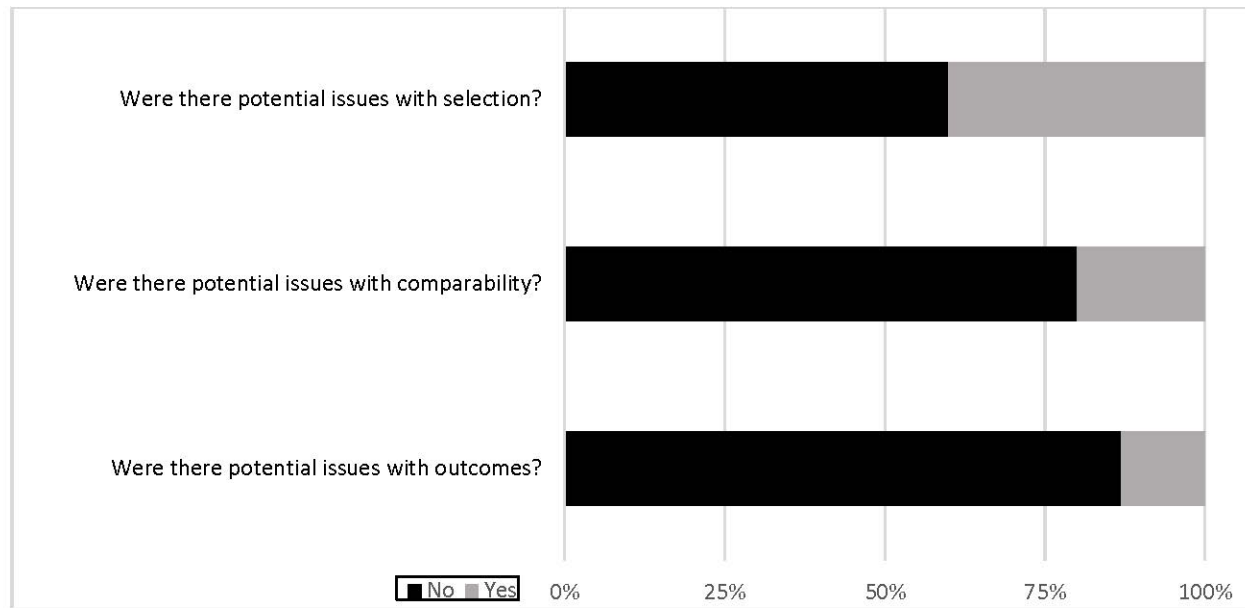


Table G-2 shows the risk of bias quality assessment for the included RCTs. For full study citations, please refer to the report's main reference list.

**Table G-2. Risk of bias assessment for included RCTs**

Study	Allocation sequence generated adequately?	Allocation of Treatment adequately concealed?	Was knowledge of the allocated intervention adequately prevented during the study?	Were incomplete outcome data adequately addressed?	Are reports of the study free of suggestion of selective outcome reporting?	Was the study apparently free of other problems that could put it at a high risk of bias?
Abdullah, 2010 <sup>118</sup>	N	U	U	N	U	Y
Abrao, 2009 <sup>196</sup>	Y	Y	Y	N	Y	N
Ajadi, 2006 <sup>116</sup>	Y	Y	Y	Y	Y	Y
Akbarzadeh, 2015 <sup>70</sup>	U	N	N	Y	Y	N
Albers, 2005 <sup>149</sup>	Y	Y	N	Y	Y	Y
Allameh, 2015 <sup>126</sup>	N	U	N	U	Y	N
Asadi, 2015 <sup>125</sup>	N	N	U	N	Y	N
Bhagwat, 2008 <sup>202</sup>	Y	Y	Y	Y	Y	Y
Bloom, 2006 <sup>72</sup>	Y	Y	Y	Y	Y	Y
Bolbol-Haghighi, 2016 <sup>166</sup>	Y	Y	N	Y	Y	Y
Bruggemann, 2007 <sup>152</sup>	Y	Y	N	Y	Y	Y
Cahill, 2018 <sup>227</sup>	Y	Y	N	Y	Y	Y
Chaichian, 2009 <sup>143</sup>	U	U	N	Y	U	Y
Coco, 2010 <sup>142</sup>	Y	Y	U	Y	Y	Y
Dahlen, 2007 <sup>160</sup>	Y	N	N	Y	Y	U
Darsareh, 2018 <sup>179</sup>	U	Y	N	Y	Y	Y
de Orange, 2011 <sup>76</sup>	Y	Y	N	Y	Y	Y
Dencker, 2009 <sup>74</sup>	Y	Y	U	Y	Y	U
Direkvand-Moghadam, 2012 <sup>136</sup>	Y	Y	U	N	Y	Y
Douma, 2011 <sup>194</sup>	U	U	N	N	Y	N
Dy, 2018 <sup>212</sup>	Y	Y	Y	Y	U	U
Edwards, 2014 <sup>130</sup>	Y	Y	N	N	Y	N
Epidural and Position Trial Collaborative Group, 2017 <sup>173</sup>	Y	Y	N	Y	Y	Y
El Hamid, 2013 <sup>162</sup>	U	U	U	U	U	U
Eslamian, 2006 <sup>148</sup>	Y	Y	Y	Y	Y	Y
Fahdhy, 2005 <sup>90</sup>	N	U	U	Y	Y	Y
Fong, 2017 <sup>171</sup>	Y	Y	Y	U	Y	Y
Gallo, 2018 <sup>172</sup>	Y	Y	N	Y	Y	Y
Ganapthy, 2012 <sup>159</sup>	Y	U	N	Y	Y	Y



<b>Study</b>	<b>Allocation sequence generated adequately?</b>	<b>Allocation of Treatment adequately concealed?</b>	<b>Was knowledge of the allocated intervention adequately prevented during the study?</b>	<b>Were incomplete outcome data adequately addressed?</b>	<b>Are reports of the study free of suggestion of selective outcome reporting?</b>	<b>Was the study apparently free of other problems that could put it at a high risk of bias?</b>
Geeta, 2015 <sup>214</sup>	U	U	U	N	U	U
Genc, 2015 <sup>189</sup>	U	U	U	Y	Y	Y
Ghafarzadeh, 2015 <sup>113</sup>	Y	U	U	Y	U	U
Hamidzadeh, 2012 <sup>137</sup>	U	U	N	Y	Y	Y
Hekmatzadeh, 2014 <sup>155</sup>	Y	U	U	Y	Y	Y
Hinshaw, 2008 <sup>210</sup>	Y	Y	N	Y	Y	Y
Isbir, 2017 <sup>180</sup>	Y	U	N	N	Y	Y
Ismail, 2012 <sup>191</sup>	Y	Y	N	Y	Y	Y
Jaitley, 2011 <sup>201</sup>	U	U	N	N	N	N
Janssen, 2012 <sup>132</sup>	Y	Y	N	Y	Y	Y
Kashanian, 2010 <sup>151</sup>	Y	Y	N	Y	Y	Y
Kaviani, 2014 <sup>157</sup>	N	N	N	Y	Y	Y
Kaviani, 2014 <sup>127</sup>	N	U	N	Y	Y	Y
Kavitha, 2012 <sup>139</sup>	Y	Y	U	Y	Y	Y
Kenyon, 2013 <sup>208</sup>	Y	Y	Y	Y	U	U
Koyucu, 2017 <sup>226</sup>	N	U	N	Y	Y	Y
Lavender, 2006 <sup>89</sup>	Y	Y	N	Y	Y	Y
Lee, 2018 <sup>94</sup>	Y	Y	N	Y	Y	Y
Liu, 2018 <sup>213</sup>	U	U	U	Y	U	U
Liu, 2015 <sup>124</sup>	Y	N	N	Y	U	Y
Ma, 2011 <sup>141</sup>	Y	U	Y	Y	Y	Y
Maddady, 2018 <sup>174</sup>	U	Y	N	Y	Y	Y
McGrath, 2008 <sup>145</sup>	Y	Y	N	Y	Y	Y
Mikki, 2007 <sup>115</sup>	Y	Y	Y	Y	Y	Y
Miquelutti, 2007 <sup>146</sup>	Y	Y	N	Y	Y	Y
Moraloglu, 2017 <sup>168</sup>	N	U	N	Y	Y	Y
Mortazavi, 2012 <sup>138</sup>	N	N	U	Y	N	U
Nachum, 2010 <sup>114</sup>	Y	Y	Y	Y	Y	Y
Nafisi, 2006 <sup>198</sup>	N	N	N	Y	Y	Y
Nakamura, 2009 <sup>195</sup>	U	U	U	U	N	Y
Nasir, 2007 <sup>147</sup>	N	N	U	U	U	U
Ohel, 2006 <sup>199</sup>	U	Y	N	Y	Y	Y
Onah, 2015 <sup>119</sup>	Y	Y	U	Y	Y	Y
Palomaki, 2006 <sup>211</sup>	Y	U	Y	Y	Y	Y
Pascual-Ramirez, 2011 <sup>78</sup>	Y	Y	Y	Y	Y	Y
Patel, 2014 <sup>190</sup>	U	Y	Y	Y	Y	U

Study	Allocation sequence generated adequately?	Allocation of Treatment adequately concealed?	Was knowledge of the allocated intervention adequately prevented during the study?	Were incomplete outcome data adequately addressed?	Are reports of the study free of suggestion of selective outcome reporting?	Was the study apparently free of other problems that could put it at a high risk of bias?
Phumdoung, 2007 <sup>161</sup>	U	U	U	N	N	U
Prabhakar, 2015 <sup>153</sup>	Y	U	N	U	Y	Y
Ragnar, 2006 <sup>80</sup>	Y	Y	N	Y	Y	Y
Rahmani, 2012 <sup>133</sup>	Y	N	N	N	Y	Y
Ruamsap, 2017 <sup>120</sup>	Y	U	U	Y	Y	Y
Samadzadeh, 2017 <sup>175</sup>	N	N	Y	Y	Y	Y
Santhi, 2012 <sup>129</sup>	U	U	N	Y	Y	Y
Sasitorn, 2013 <sup>158</sup>	U	U	U	Y	Y	Y
Schaffer, 2005 <sup>73</sup>	Y	Y	Y	Y	Y	Y
Selin, 2018 <sup>215</sup>	Y	Y	Y	Y	Y	Y
Sezer, 2007 <sup>197</sup>	U	Y	U	Y	Y	Y
Shafaie, 2017 <sup>82</sup>	U	U	U	Y	Y	Y
Shahoei, 2017 <sup>178</sup>	N	N	U	Y	Y	Y
Sharma, 2012 <sup>135</sup>	Y	U	N	Y	Y	Y
Shen, 2017 <sup>203</sup>	Y	Y	Y	Y	Y	Y
Shirvani, 2014 <sup>156</sup>	Y	U	N	Y	Y	Y
Shrivastava, 2009 <sup>144</sup>	Y	Y	Y	Y	Y	Y
Silva Gallo, 2013 <sup>131</sup>	Y	U	Y	Y	Y	Y
Simarro, 2017 <sup>169</sup>	N	N	N	N	Y	Y
Somprasit, 2005 <sup>117</sup>	Y	Y	Y	Y	Y	Y
Sweed, 2011 <sup>193</sup>	U	U	N	Y	N	N
Taavoni, 2016 <sup>164</sup>	U	U	N	Y	Y	N
Taavoni, 2011 <sup>140</sup>	Y	N	N	U	Y	Y
Tanvisut, 2018 <sup>167</sup>	Y	Y	N	N	Y	Y
Thies-Lagergren, 2013 <sup>134</sup>	N	Y	N	Y	Y	Y
Tolba, 2018 <sup>98</sup>	Y	Y	Y	Y	Y	Y
Tribe, 2012 <sup>209</sup>	Y	Y	N	Y	Y	Y
Tussey, 2015 <sup>154</sup>	Y	Y	N	U	Y	N
Tveit, 1501 <sup>192</sup>	Y	Y	N	Y	Y	Y
Vadivelu, 2017 <sup>121</sup>	Y	Y	Y	Y	Y	Y
Vaijayanthimala, 2014 <sup>150</sup>	U	U	U	Y	U	N
van den Bosch, 2018 <sup>69</sup>	Y	N	N	Y	Y	Y
Vaziri, 2016 <sup>225</sup>	Y	U	U	Y	Y	Y
Vixner, 2014 <sup>128</sup>	Y	Y	N	U	Y	Y

<b>Study</b>	<b>Allocation sequence generated adequately?</b>	<b>Allocation of Treatment adequately concealed?</b>	<b>Was knowledge of the allocated intervention adequately prevented during the study?</b>	<b>Were incomplete outcome data adequately addressed?</b>	<b>Are reports of the study free of suggestion of selective outcome reporting?</b>	<b>Was the study apparently free of other problems that could put it at a high risk of bias?</b>
Wassen, 2015 <sup>68</sup>	Y	Y	N	Y	Y	Y
Wiberg-Itzel, 2018 <sup>177</sup>	U	U	N	N	Y	Y
Wilson, 2009 <sup>66</sup>	U	U	U	Y	Y	Y
Wong, 2005 <sup>200</sup>	Y	Y	U	Y	Y	Y
Wu, 2017 <sup>176</sup>	U	N	N	U	Y	U
Xiao, 2019 <sup>181</sup>	U	Y	N	N	Y	Y
Yazdkhasti, 2016 <sup>165</sup>	Y	Y	N	Y	Y	Y
Yildirim, 2008 <sup>224</sup>	U	U	U	Y	Y	Y
Yuenyong, 2012 <sup>163</sup>	Y	Y	N	Y	Y	Y
Zhang, 2017 <sup>170</sup>	Y	Y	N	N	Y	Y

Abbreviations: N=No; U=Unclear; Y=Yes

**Figure G-2. Summary of risk of bias assessment for included RCTs**

