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Labor Induction Methods and Their Impact on Duration of Labor and Rate of Cesarean Section

Ashley M. Golinghorst
Bethel University

LABOR INDUCTION METHODS AND THEIR IMPACT ON THE DURATION OF LABOR AND RATE OF CESEREAN SECTION

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Ashley M Golinghorst

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Approvals:

Project Advisor Name: Bernita Missal, PhD, RN

Project Advisor Signature: _____

Second Reader Name: Jane Wrede, PhD, APRN, CNM

Second Reader Signature: _____

Director of Nurse-Midwifery Program Name: Jane Wrede. PhD, APRN

Director of Nurse-Midwifery Program Signature: _____

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Abstract

Background/Purpose: The purpose of this paper is to critically review current literature regarding current methods for labor induction and their impact on the duration of labor and rate of cesarean section.

Theoretical Framework: Imogene King's Theory of Goal Attainment is the framework used for this literature appraisal. King's theory focuses on the dynamic interacting systems for goal attainment (Gonzalo, 2011).

Methods: Twenty-one original research articles involving labor induction methods were critically reviewed. Additionally, six systematic reviews involving labor induction methods were also included.

Results/Findings: Labor induction is associated with an overall increased risk of cesarean section. Intravenous oxytocin use alone was associated with the highest risk of cesarean section when used in nulliparous women. The risk of cesarean section was not as high when a combination of labor induction methods was utilized. The use of mechanical cervical ripening agents, such as Foley-bulb or Cook catheters were associated with a lower rate of cesarean section when compared with pharmacological cervical ripening agents. Mechanical cervical ripening is also associated with a shorter duration of labor when used simultaneously with intravenous oxytocin.

Implications for Research and Practice: Nurse-midwives need to be knowledgeable about the various methods for labor induction. It is crucial that they discuss the risks and benefits of labor induction with their patients and that labor inductions are not performed without medical indication. When a labor induction is performed nurse-midwives should utilize a combination of methods to shorten the duration of labor and minimize the risk of cesarean section.

Conclusion: The findings of this critical review of the literature support the use of a combination of labor induction methods and avoiding non-medically indicated inductions due to the increased rate of cesarean section associated with labor induction.

Keywords: labor induction, cesarean section, duration of labor, mechanical cervical ripening, Cook catheter, Foley-bulb catheter, transcervical ripening balloon, pharmacological cervical ripening, misoprostol, dinoprostone, Mifepristone, oxytocin, amniotomy, King's Theory of Goal Attainment, nurse-midwifery, hallmarks of midwifery

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Chapter I: Introduction

In obstetrics, the induction of labor is one of the most commonly performed procedures during pregnancy (Ruhl & Bingham, 2014). The rate of labor induction continues to rise in the United States. In 2010, the National Center for Health Statistics reported that 23.4 percent of labors in the United States were induced (Ruhl & Bingham, 2014). The rate of labor induction has more than doubled in the past two decades (Ruhl & Bingham, 2014). Women who have their labor induced have been shown to have a higher rate of cesarean section; this is especially true for nulliparous women (Ruhl & Bingham, 2014). The increased rate of labor inductions has been attributed to an increased rate of cesarean section in the United States, as one of the most common indications for cesarean section is failed induction (Ruhl & Bingham, 2014). The rate of cesarean section has dramatically increased over the past two decades in correlation with the rising rate of labor inductions. According to the Centers for Disease Control and Prevention (CDC), the rate of cesarean section was 31.9 percent for 2016, which was an improvement from the peak rate in 2009 of 32.9 percent (Centers for Disease Control and Prevention, 2017). For many years, the World Health Organization (WHO) recommended a cesarean section rate between 10-15 percent, however a recent review of current research has found that there is no improvement in maternal or newborn mortality rates when the cesarean section rate of a population level exceeds 10 percent (World Health Organization, 2015). Considering the correlation between labor induction and cesarean section rate, there is the question of how to use induction methods in a way that optimizes labor outcomes. This paper will provide a critical review of research regarding various induction methods and their impact on the rate of cesarean section and the duration of labor.

Statement of Purpose

The purpose of this paper is to examine current research on methods commonly used for labor induction and their impact on the duration of labor and rate of cesarean section. This paper will discuss how the combination of these methods may be beneficial in reducing the duration of labor and the rate of cesarean section in women undergoing induction of labor. The methods addressed in this paper will include mechanical cervical dilation, pharmacological agents used for cervical ripening, intravenous oxytocin, and amniotomy. Mechanical methods discussed in this paper will include commonly used transcervical balloons such as Foley-bulbs and Cook catheters. Pharmacological agents for cervical ripening and labor induction, as reviewed in this paper include misoprostol, dinoprostone, and mifepristone. Also addressed will be the timing of the amniotomy, also referred to as artificial rupture of membranes (AROM) and how adjusting the timing of AROM may impact the duration of labor and the rate of cesarean section. This paper will also discuss how King's Theory for Goal Attainment can be applied to inductions to lead to improved labor outcomes.

Evidence Demonstrating Need

Considering the increasing rate of labor inductions and the correlation with an increased rate of cesarean delivery, it is imperative that healthcare providers are only performing labor inductions when medically indicated and with evidence-based methods. The American College of Obstetricians and Gynecologists (ACOG) released an updated practice bulletin addressing the induction of labor in 2009. ACOG (2009) discussed the importance of cervical ripening before labor induction and addressed various methods. For cervical ripening, mechanical and pharmacological methods were addressed. The goal of cervical ripening is to create a favorable cervix, as defined by a Bishop score of greater than six. Research has found that a Bishop score

greater than eight results in similar rates of vaginal delivery after labor induction that are comparable with the rate of vaginal delivery after spontaneous labor. ACOG addressed the different methods of cervical ripening for labor induction and made recommendations on their usage. However, even within those recommendations, there is no clear single method that is associated with decreased duration of labor and decreased rate of cesarean deliveries (ACOG, 2009). The recommendations focused on the use of single methods but did not have recommendations on how to utilize combination methods for cervical ripening. This practice bulletin is also now ten years old and, as such, has not taken into account research in recent years.

ACOG (2009) also discussed the use of oxytocin and amniotomy for labor inductions. Oxytocin is the most commonly used agent for labor inductions but there is still a lack of consensus on optimal dosing and maximum dosage. ACOG does recommend that cervical ripening is done prior to the start of oxytocin to improve the rates of successful inductions. Amniotomy, when used alone for labor inductions, was associated with an unpredictable duration of labor. There was also not enough evidence at the time to support using amniotomy alone for labor inductions; however, some providers still use this as a primary method for labor inductions (ACOG, 2009). Although ACOG has recommendations for individual methods used for cervical ripening and labor induction, various combinations of methods are not specifically addressed. There is also a lack of consensus on which methods are best practice. More research on how these methods can be used in combination with one and another to decrease the duration of labor and the rate of cesarean section needs to be reviewed for conclusions and recommendations to be made.

There is agreement from both the American College of Nurse-Midwives (ACNM) and ACOG that inductions should be performed when medically indicated and not for elective reasons (ACNM, 2010). However, there continues to be a lack of consensus on the optimal method or combination of methods for labor induction that would be associated with decreased duration of labor and decreased rate of cesarean section. This paper will review current research on the various methods of cervical ripening and labor induction and focus on how those may be used in combination to promote improved delivery outcomes.

Significance to Nurse-Midwifery

Nurse-midwives are on the frontlines providing care for women during pregnancy, labor, and delivery. The scope of midwifery practice includes applying knowledge, skills, and abilities in the intrapartum period (ACNM, 2012). Nurse-midwives are also expected to follow the *Hallmarks of Midwifery* including recognition of birth as a normal physiologic and developmental process, advocacy of non-intervention in normal processes in the absence of complications, incorporation of scientific evidence into clinical practice, empowerment of women as partners in health care, advocacy for informed choice, shared decision making, and the right to self-determination and skillful communication, guidance, and counseling (ACNM. 2012). Regarding labor inductions, nurse-midwives need to apply these specific hallmarks. It is crucial that nurse-midwives incorporate scientific evidence into clinical practice; this includes utilizing the most recent research available on induction methods and applying those to how they are performing labor inductions.

It is the position of ACNM that induction of labor should be offered to women only for medical indications that are supported by scientific evidence when the benefits outweigh the risks (ACNM, 2010). Essentially, nurse-midwives should avoid performing labor inductions

when there are not clear medical indications. Also, nurse-midwives need to uphold the hallmark of midwifery that empowers women as partners in their health care. In order to be able to do this, nurse-midwives need to be well-informed on various induction methods and be able to provide their patients with information that is supported by current research. Empowering women by providing accurate information also enables women to make informed decisions regarding their health care.

The ACNM also recommends careful consideration should be given to the need for cervical ripening when labor induction is deemed medically necessary (ACNM, 2010). The research reviewed in this paper will address those various methods for cervical ripening and their association with the duration of labor and rate of cesarean section. Reviewing the current recommendations from both the ACNM and ACOG, there is support for performing labor inductions when medically necessary and ensuring that cervical ripening is performed to help improve induction outcomes and reduce the risk of cesarean delivery. Nurse-midwives should be well informed on how to utilize a combination of cervical ripening methods and labor induction methods to optimize the labor induction process and reduce complications.

Theoretical Framework

King's Theory for Goal Attainment is a conceptual framework that focuses on the dynamic interacting systems for goal attainment (Gonzalo, 2011). According to this theory, humans are rational and sentient; they can perceive, think, feel, choose, set goals, and decide how to achieve those goals by the decisions they make (Nursing Theory, 2015). King's Theory of Goal Attainment focuses on the three fundamental needs of humans. These needs are the need for when health information can be used, the need for care to prevent illness, and the need for care when they are unable to care for themselves (Nursing Theory, 2015).

With King's theory, the focus is also placed on the importance of the nurse-patient relationship and how that relationship will help patients to reach their health goals. In this case, the focus would be placed on the relationship between the patient and the nurse-midwife and the trust that is present in that relationship. Basically, King's theory operates with the patient and the nurse-midwife communicating information, using that information to set a mutual goal, and then acting in a way that helps to attain that goal (Gonzalo, 2011).

King's theory can be applied to the labor process because there is a shared goal of labor that must be carried out through the dynamic interactions between the expectant mother and the nurse-midwife. If a woman is informed about her choices for induction methods and her provider is informed as well, together they can decide on which induction method to use or if they should wait for labor to occur naturally. So, the first step is the sharing of information between the nurse-midwife and the patient. Ideally, the nurse-midwife discusses with the patient the benefits for waiting for labor to occur naturally; however, if there is a medical indication or if the patient decides to proceed with an elective induction, the nurse-midwife needs to share information regarding the different induction methods that are available and their impact on the duration of labor and rate of cesarean section when compared with waiting for labor to occur naturally.

Next, after the sharing of that information, the nurse-midwife and the patient set the goal. The goal ultimately is that the patient has a vaginal delivery of a healthy infant, but the specifics of the goal would include which methods of labor induction the patient would use. The overall goal is that the birth results in a healthy mother and a healthy baby by whichever path is chosen.

Then, to achieve the goal, the nurse-midwife would implement the chosen intervention for labor and adjust the actions based on the plan that was created following the setting of the goal. During this process of labor, depending on how things are progressing, the cycle continues.

The overall goal stays the same. Additionally, the sharing of information between the nurse-midwife and the patient continues. Information is shared regarding how the labor is progressing and what the results of the different induction methods are for the patient. For example, if the initial decision was to perform cervical ripening with a pharmacological agent such as misoprostol, after the implementation of this intervention, the provider would share information with the patient about how this intervention has been working. Perhaps, after two doses of misoprostol, a cervical check would be performed, and the patient is found to be at three centimeters and 30 percent effaced but having no consistent contractions. At that point in time, the provider might discuss with the patient the additional use of other interventions for the induction of labor, such as the use of a transcervical catheter for further ripening and dilation or starting intravenous oxytocin. The goal is still the delivery of a healthy infant, but the plan to achieve the goal would need to be adapted based on the continual sharing of information between the nurse-midwife and the patient. This is an overview of how King's Theory of Goal Attainment could be applied to labor induction methods.

Summary

With the association between increased rates of labor induction and increased rates of cesarean section, there is a need to determine induction methods that, when used in combination with one and another, optimize birth outcomes. Nurse-midwives are uniquely equipped as partners in health care with women to be able to empower them and enable them to make informed decisions regarding labor inductions. In order for nurse-midwives to be able to best serve these women, they need to be up-to-date on current research and apply that research to clinical practice. Applying King's Theory of Goal Attainment to the labor induction process can further help to empower women and hopefully increase the rate of vaginal deliveries following

labor inductions. Chapter Two of this paper will address the specific methods used to gather and appraise current research on the topic of labor induction methods. Chapter Three will be a synthesis of current research. This will include important findings, strengths, limitations, and recommendations for nurse-midwifery practice regarding labor induction methods. Finally, Chapter Four will be a discussion on the implications for nurse-midwifery practice and labor induction methods, focusing on how to combine these methods and optimize birth outcomes by shortening the duration of labor and reducing the rate of cesarean section.

Chapter II: Methods

This chapter will discuss the procedures utilized to identify current research and literature related to cervical ripening and labor induction methods and their impact on the duration of labor and rate of cesarean section. Specific labor induction methods included are mechanical cervical ripening, pharmacological agents, intravenous oxytocin, and amniotomy. A comprehensive search was performed utilizing multiple search engines. Also included in this chapter will be the keywords utilized and the criteria for inclusion and exclusion. A brief summary of the studies selected for the literature review will also be discussed. Finally, the method used for appraising the level and quality of the evidence will be thoroughly explained.

Search Strategies

An initial search was conducted using the Cumulative Index to Nursing and Allied Health Literature (CINAHL) utilizing the search terms labor, induced-methods, balloon dilatation-utilization, amniotomy: fetal membranes, artificial rupture, timing of amniotomy, and oxytocin and labor induction. A total of 59 articles were reviewed from CINAHL. A search of PubMed was conducted, using the search terms labor induction, duration, and cesarean. A total of 47 articles were reviewed. Another search was conducted utilizing the Cochrane Library: Cochrane Central Register of Controlled Trials. This search used the terms labor induction and cesarean; which resulted in 53 results. Additionally, a search of the Cochrane Library: Database of Systematic Reviews was conducted. The search term used was labor induction methods; which yielded 86 systematic reviews.

Criteria for Inclusion and Exclusion

The articles selected for this review of the literature were included based on interventions used for labor induction. The interventions that were focused on were misoprostol, mifepristone,

dinoprostone, Foley-bulb, Cook catheter, intravenous oxytocin, and amniotomy. The articles included used either one of these methods or a combination of methods. Articles of original research were the primary focus, with consideration given to systematic reviews as well. The main focus of the literature review was randomized controlled trials. Additionally, research articles chosen specifically included data on the duration of labor, the rate of cesarean section and indications for cesarean section. Articles within the past five years were the primary focus, but that was increased to the past ten years to gather adequate literature for this review.

Exclusion criteria included studies that focused on women with previous cesareans and studies that did not clearly state which methods were being used for induction. Studies were also excluded if they were in a language other than English or if the full-text article could not be located. Duplicate studies, those that appeared in the search results of the multiple databases were excluded and were only included once in the literature review.

Summary of Selected Studies

After applying the inclusion and exclusion criteria, a total of nine articles were chosen from the CINAHL search. For the inquiry from PubMed, after applying the inclusion and exclusion criteria, five articles were chosen to be included in the literature review. Regarding the search of the Cochrane Library, Cochrane Central Register of Controlled Trials, after applying inclusion and exclusion criteria, a total of seven of these research articles were included in this literature review. A complete total of 21 original research articles were included in the literature review. After reviewing the search results of the Cochrane Library, Database of Systematic Reviews, six systematic reviews were chosen to be included in the literature review of this paper. Of the 21 original research articles, 13 were randomized controlled trials, seven were observational studies, and one was a prospective quasi-randomized controlled trial.

Evaluation Criteria

All the research articles selected were evaluated utilizing the Johns Hopkins Research Evidence Appraisal Tool (Dearholt & Dang, 2012). The level of evidence was evaluated on a scale of I-IV. Randomized controlled trials (RCTs), experimental studies, and systematic reviews of RCTs are considered to be Level I evidence. Level II evidence includes quasi-experimental studies, systematic reviews of a combination of RCTs and quasi-experimental, or systematic reviews of quasi-experimental studies only. Level III evidence includes non-experimental studies, systematic reviews of a combination of RCTs, quasi-experimental and non-experimental studies, or systematic reviews of non-experimental studies only. Level IV evidence includes the opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence; specifically, clinical practice guidelines and consensus panels (Dearholt & Dang, 2012).

After evaluating articles and identifying the level of evidence, articles were assessed for quality. Evidence of all levels, I-IV, are classified as either high, good, or low quality. Levels I-III have the same criteria for determining quality; however, Level IV has different criteria. The criteria for Levels I-III, high quality includes the following: consistent, generalizable results, sufficient sample size for the study design, adequate control, definitive conclusions, and consistent recommendations based on a comprehensive literature review that includes thorough reference to scientific evidence (Dearholt & Dang, 2012). Good quality for Levels I-III evidence has the following criteria: reasonably consistent results, sufficient sample size for the study design, some control, fairly definitive conclusions, and reasonably consistent recommendations based on a fairly comprehensive literature review that includes some reference to scientific

evidence (Dearholt & Dang, 2012). No evidence of low quality was used for this literature review.

All of the 21 research articles used for this literature review were either high or good quality. A total of 13 of the research articles were Level I. One article was Level II. The remaining seven research articles were Level III.

Summary

Multiple database searches were performed with the results being screened for inclusion and exclusion criteria; this resulted in a total of 21 original research articles and six systematic reviews. Databases searched included CINAHL, PubMed, and the Cochrane Library, all of which utilized Bethel University's library system. All of the original research articles that were chosen were evaluated using the Johns Hopkins Research Evidence Appraisal Tool to determine the level of evidence and quality of results.

Chapter III: Literature Review and Analysis

Synthesis of Matrix

Research was gathered on the topic of different labor induction methods. Specifically, it addresses the impact of different methods on the duration of labor and the rate of cesarean section. A matrix format was used to organize scholarly research articles. This matrix includes thirteen randomized controlled trials, three retrospective cohort studies, one prospective cohort study, one non-experimental longitudinal prospective observational study, one cross-sectional observational study, one prospective quasi-randomized controlled trial, and one non-experimental cohort observational study. The quality and level of evidence for each research study were appraised using the Johns Hopkins Research Evidence Appraisal Tool (Dearholt & Dang, 2012). Included in the matrix are the purpose of the study, description of the sample, evidence level and quality, study design, methods, instruments, study results, conclusions, strengths and limitations of the studies, author recommendations, and implications for practice. The matrix is organized alphabetically by author. Systematic reviews were not included in the matrix, only original research studies were included. Purpose, study design, and important findings of the studies were evaluated, and the synthesis of this data is discussed in chapter three.

Synthesis of Major Findings

The 21 original research articles evaluated in the matrix discussed various methods of labor induction. The methods discussed include pharmacological cervical ripening, mechanical cervical ripening, intravenous oxytocin, and amniotomy. Pharmacological agents used for cervical ripening in these research articles include misoprostol, mifepristone, and dinoprostone. Mechanical methods for cervical ripening include Foley-bulb and Cook catheter. These labor

induction methods were either used individually or in combination with each other; most often they were used in combination. The results of the research studies included the impact on the duration of labor, the success of labor induction, specifically the achievement of vaginal delivery, fetal distress, and correlation with the rate of cesarean section. This synthesis of major findings will include the duration of labor and the rate of cesarean section for each labor induction method, as well as the methods when used in combination.

Duration of labor. Of the research articles, nineteen addressed the duration of labor in their findings (Baev et al., 2017, Bala et al., 2017, Battarbee et al.,2016, Beckmann et al., 2015, Bricker & Luckas, 2012, Connolly et al., 2016, Cromi et al., 2012, Du et al., 2015, Gagnon-Gervais et al., 2012, Garba et al., 2016, Gross et al., 2012, Mackeen et al.,2018, Makarem et al., 2013, Macones et al., 2012, Schoen et al., 2017, Tam et al., 2012, Wollmann et al., 2017, and Wu et al., 2018). Some of the studies referred to induction to delivery interval (IDI) or time to delivery instead of a total duration of labor. In a retrospective cohort observational study, Tam, Conte, Schuler, Malang, and Roque (2012), evaluated the labor outcomes of women undergoing elective inductions (n=848). This study looked at all labor induction methods being used during the time frame of the study. The study found that of all the methods used, there was a statistically significant shorter duration of labor in the group that had amniotomy along with oxytocin. Of all the methods used, the use of oxytocin was the only method that was found to have a statistically significant difference on the duration of labor. The average length of induction time for the use of oxytocin was 11.9 hours, with a p-value of 0.05. The other methods in this study include Foley bulb with amniotomy, Foley bulb with Cervidil, Foley bulb with Cytotec (misoprostol),

oxytocin with Foley bulb, amniotomy, dinoprostone, misoprostol, Foley bulb, and oxytocin (Tam et al., 2012).

Mechanical and pharmacological cervical ripening. In one randomized controlled trial (RCT), mifepristone usage (n=74) had a duration of labor of 505.97 ± 205.07 minutes versus 507.80 ± 193.83 minutes for the expectant management (n=75) group; the difference in duration of labor was not statistically significant with a p-value of 0.338 (Baev, Rumyantseva, Tysyachnyu, Kozlova, & Sukhikh, 2017). Wollmann, Ahlberg, Petersson Saktvedt and Stephansson (2017) performed a non-experimental retrospective chart review that compared dinoprostone (n=3297), vaginal misoprostol (n=1424), and balloon catheter (n=2830) induction methods. The study found that mean time to delivery was shortest with the balloon catheter group (15.04 hours) when compared with the dinoprostone (25.20 hours) and the misoprostol (24.59 hours) groups. This difference was statistically significant according to the others, but no p-value was provided for that statistic (Wollmann et al., 2017). There is not enough research available to conclude which mechanical or pharmacological method for cervical ripening is superior for reducing the duration of labor. However, current research does indicate that mechanical cervical ripening may result in a shorter duration of labor than when pharmacological agents are used by themselves.

Amniotomy. An RCT done by Macones, Cahill, Stamilio, and Obido (2012) looked at whether an early amniotomy reduced the duration of labor during an induction. This study included amniotomy being used with oxytocin, misoprostol, Cervidil, Foley Bulb, and more than one agent but focused on the timing of the amniotomy. The study found that early amniotomy shortens the duration of labor by about two hours (19.0 hours vs. 21.3 hours) with a p-value of

0.04 making this finding to be statistically significant (Macones et al., 2012). However, a systematic review by Bricker and Luckas (2012), found that there was not enough evidence to support the use of amniotomy alone for labor induction.

Amniotomy and intravenous oxytocin. A prospective RCT (Bala, Bagga, Kalra, & Dutta, 2017), found that an early amniotomy (n=75) led to a significantly reduced induction to delivery interval (by four hours) when compared with delayed amniotomy (n=75) with a p-value of 0.000. Gagnon-Gervais et al. (2012), in a randomized controlled trial, compared early (n=71) versus delayed (n=72) amniotomy with the use of oxytocin. The study found that the duration of labor was shorter in the early amniotomy group in nulliparous women (12.1 ± 6.7 hours vs. 15.4 ± 5.6 hours); this difference was statistically significant with a p-value of 0.03 (Gagnon-Gervais et al., 2012). Gross, Fromke, and Hecker (2012) compared the timing of amniotomy and oxytocin in nulliparous (n=2090) and multiparous (n=1873) women in a non-experimental longitudinal prospective observational study. This study found that median time from oxytocin to birth was shorter in multiparous women (1.4 hours) than in nulliparous women (3.2 hours). The study also found that the first stage of labor was accelerated when an amniotomy was performed when compared to the spontaneous rupture of membranes or the membranes remaining intact; which was true for both nulliparous and multiparous women (Gross et al., 2012). Overall, research does indicate that early amniotomy may be effective at shortening the duration of labor, but this benefit should be weighed against potential risks.

Amniotomy and mechanical cervical ripening. Battarbee, Palatnik, Peress, and Grobman (2016) in a retrospective matched cohort study, compared early amniotomy after Foley balloon catheter ripening (n=273) and no early amniotomy (n=273) following Foley balloon catheter ripening;

early amniotomy was defined as less than one hour after Foley balloon removal. This study found that the early amniotomy group had a statistically significant shorter duration of labor when compared with no early amniotomy with a p-value of 0.02 (Battarbee et al., 2016).

Amniotomy and pharmacological cervical ripening. Beckmann, Kumar, and Flenady (2015) compared prostaglandin vaginal gel followed by amniotomy (n=121) to repeat prostaglandin vaginal gel doses (n=124) in a randomized controlled trial. The study found that the duration of labor was significantly shorter in the amniotomy group (24.8 hours) than the repeat dose group (30.0 hours) (Beckmann et al., 2015). A randomized controlled trial done by Makarem, Zahran, Abdellah, and Karen (2013) compared early amniotomy after misoprostol(n=160) and no amniotomy after misoprostol (n=160) for labor induction. Women in the amniotomy group were found to have a shorter duration of labor by about four hours than those of the control group (9.72±4.61 hours vs 13.61±5.61 hours). The difference between the two groups was statistically significant with a p-value of 0.002 (Makarem et al., 2013). Overall, the research demonstrated that the use of amniotomy with pharmacological agents may result in a shorter duration of labor.

Mechanical cervical ripening and intravenous oxytocin. Connolly et al. (2016) was a randomized controlled trial that compared the use of Foley balloon induction with either sequential use of oxytocin (n=84) or simultaneous use of oxytocin (n=82). The study found that the simultaneous group (15.92 hours) delivered significantly early by about three hours when compared with the sequential group (18.87 hours), a p-value of 0.004 (Connolly et al., 2016). An RCT done by Mackeen et al. (2018) compared Foley catheter use plus oxytocin (n=93) with oxytocin use alone (n=108). The average induction time was shorter in the Foley group when

compared with the oxytocin alone group, but the difference was not statistically significant (mean of 6.9 hours versus 7.9 hours). In a different randomized controlled trial, Schoen, Grant, Berghella, Hoffman, and Sciscione (2017) performed a randomized controlled trial comparing the use of Foley catheter with oxytocin in nulliparous (n=90) and multiparous women (n=71) and Foley catheter followed by oxytocin in nulliparous(n=94) and multiparous women (n=67). In nulliparous women with Foley with oxytocin use the mean total time to delivery was 20.9 hours and with the Foley followed by oxytocin was 26.1 hours. This difference was statistically significant with a p-value of 0.003. In multiparous women with Foley and oxytocin, the mean time to delivery was 14.9 hours and Foley followed by oxytocin was 18.6 hours; the difference being statistically significant with a p-value of 0.01. In both nulliparous and multiparous women, the duration of labor was shorter in the group using a Foley catheter at the same time as oxytocin (Schoen et al., 2017). In an RCT done by Wu et al. (2017), a comparison was made between the use of a double-balloon catheter and oxytocin (n=60) versus oxytocin alone (n=60). The study found that the duration of labor for the double-balloon catheter was shorter (8.12 ± 2.65 hours) than the oxytocin alone group (15.01 ± 6.06 hours), which was a statistically significant difference (Wu et al., 2017). Overall, research reviewed demonstrated that the concurrent use of mechanical methods of cervical ripening and intravenous oxytocin may significantly reduce the duration of labor.

Mechanical cervical ripening, pharmacological cervical ripening, and intravenous oxytocin. Cromi et al. (2012) compared the use of a double-balloon catheter, Cook catheter (n=105), with the use of a dinoprostone vaginal insert (n=103) in a randomized controlled trial. The study found that the double-balloon catheter had time to delivery of 19.7 ± 5.9 hours

compared to the dinoprostone group with a time of 20.4 ± 10.3 hours. The time to delivery was significantly less in the double-balloon group (Cromi et al., 2012). Du et al. (2014), in a prospective cohort study, found that the duration of labor was shorter in the group for the double-balloon catheter (n=79) than the dinoprostone group (n=79). In the double-balloon catheter group, the mean duration of labor was 4.79 hours and in the dinoprostone group the mean duration of labor was 6.41 hours; this was a statistically significant difference with a p-value of 0.023 (Du et al., 2014). A prospective RCT done by Garba et al. (2016) compared Foley-balloon plus oxytocin (n=70) and vaginal misoprostol plus oxytocin (n=66). This study found that the induction to delivery time was statistically shorter in the misoprostol group (5.54±1.8 hours) than in the Foley balloon plus oxytocin group (6.65 ±1.7 hours) with a p-value of 0.035. Kandil, Emarh, Sayyed, and Masood (2012) performed a prospective quasi-randomized controlled trial comparing Foley catheter and misoprostol use both followed by oxytocin if labor had not occurred. The study found that the induction to delivery interval was significantly shorter in the Foley group compared to the misoprostol group (897.36±116.0 vs. 960.98 ± 94.18 minutes). Levine et al. (2016) did a stratified RCT comparing misoprostol (n=120), misoprostol and Foley catheter (n=123), Foley only (n=123), and Foley plus oxytocin (n=125). This study found that a combination of methods produced a shorter duration of labor. Women in the misoprostol and Foley catheter group were twice as likely to deliver sooner than the other groups (Levine et al., 2016). Overall, research appears to indicate that the use of mechanical methods of labor induction may reduce the duration of labor when compared to the use of pharmacological agents used alone.

Rate of cesarean section. All 21 research articles used addressed the wide range of the rate of cesarean section in the findings of their studies; the rate of cesarean varied greatly depending on the labor induction methods utilized (Alfirevic et al., 2009, Alfirevic et al., 2018, Battarbee et al., 2016, Bala et al., 2017, Baev et al., 2017, Beckmann et al., 2015, Connolly et al., 2016, Cromi et al., 2012, Du et al., 2015, Gagnon-Gervais et al., 2012, Garba at al., 2016, Gross et al., 2012, Guerra et al., 2011, Howarth & Botha, 2013, Jozwiak et al., 2012, Kandil et al., 2012, Levine et al., 2016, Mackeen et al., 2018, Macones et al., 2012, Makarem et al., 2013, Schoen et al., 2017, Seyb et al., 1999, Thomas et al., 2014, Wollmann et al., 2017, and Wu et al., 2018). Also, the indication or reason for the cesarean section will be discussed in this section, if available in the study. A cross-sectional observational study done in Latin America compared elective induction (n=1847) and spontaneous labor (n=35597) (Guerra et al., 2011). This study looked at all the methods used for labor induction and included oxytocin, misoprostol, other prostaglandins, amniotomy, and a combination of methods. The study found that the rate of cesarean section was 11.8 percent in women undergoing elective induction compared to a rate of 8.6 percent in women who went into labor spontaneously. Also, when looking at all inductions, medical and elective the cesarean section rate was 29.5 percent. This study concluded that there was a statistically significantly higher rate of cesarean sections in women undergoing induction of labor with a relative risk of 1.16 and a confidence interval of 95 percent (Guerra et al., 2011). A non-experimental cohort observational study done by Seyb, Berka, Socol, and Dooley (1999) focused on the risk of cesarean section in nulliparous women receiving an elective induction of labor at term. The study included women in spontaneous labor (n=1124), elective inductions (n=143), and medical inductions (n=294). Cesarean section rates for the groups were 7.8 percent for the spontaneous labor, 17.5 percent for an elective induction, and 17.7 percent for medication

induction. The most common indication for cesarean section was labor dystocia (Seyb et al., 1999).

Mechanical and pharmacological cervical ripening. Baev et al. (2017), found that mifepristone usage had a cesarean section rate of 33.8 percent versus 25.3 percent for the expectant management group with a p-value of 0.097 and a p-value of less than 0.05 being considered significant. Guerra et al (2011) found that misoprostol inductions had a cesarean section rate of 21.8 percent and other prostaglandin inductions had a cesarean section rate of 18.2 percent. The study done by Wollmann et al. (2017) that compared dinoprostone, misoprostol, and balloon catheter inductions found that there was no significant difference in the risk for a cesarean section between the groups. A systematic review of oral misoprostol for induction of labor reviewed seventy-five randomized controlled trials (Alfirevic, Aflaifel, &Weeks, 2018). This systematic review concluded that misoprostol use was effective as a labor induction method and resulted in statistically significant fewer cesarean sections (Alfirevic et al., 2018). A systematic review conducted by Jozwiak et al. (2012), included seventy-one randomized controlled trials utilizing mechanical methods for labor induction. This systematic review concluded that mechanical methods resulted in similar rates of a cesarean section when compared with pharmacological methods; however mechanical methods reduced the risk of cesarean section when compared with intravenous oxytocin use (Jozwiak et al., 2012). A systematic review done by Thomas, Fairclough, Kavanagh, and Kelly (2014) found that pharmacological agents for cervical ripening did not influence the rate of cesarean section. Overall, research supports the use of pharmacological and mechanical methods of cervical

ripening for labor induction as a way to reduce the rate of cesarean section and the duration of labor.

Intravenous oxytocin. Tam et al. (2012) found that the use of oxytocin as a labor induction method in nulliparous women with an unfavorable cervix resulted in a statistically significant higher rate of cesarean section when compared with women with a favorable cervix. A systematic review done by Alfirevic, Kelly, and Dowswell (2009), found an increased rate of cesarean section when oxytocin alone was used for cervical ripening and induction of labor (19.1 percent versus 13.7 percent) with a relative risk of 0.16 with a 95 percent confidence interval.

Amniotomy. In the study done by Macones et al. (2012), researchers found no statistically significant difference in the rate of cesarean section between early amniotomy group (41 percent) and standard management group (40 percent). However, the early amniotomy group did have two cases of cord prolapse that required emergency cesarean sections, whereas the standard group did not have any cases of cord prolapse (Macones et al., 2012).

Amniotomy and intravenous oxytocin. Bala et al. (2017), found a cesarean section rate of 10.7 percent for early amniotomy compared with a rate of 2.7 percent for delayed amniotomy with a p-value of 0.0495; with a value of <0.05 being considered statistically significant. In Gagnon-Gervais et al. (2012) the rate of cesarean section in nulliparous women in the early amniotomy group was 18 percent and 17 percent in the late amniotomy group; no statistically significant difference. However, the same study also compared multiparous women and found a rate of three percent for cesarean section in the early amniotomy group and no cesarean sections in the late amniotomy group. This study found that the difference in the rate of cesarean section between nulliparous and multiparous women to be statistically significant. The most common

indication for cesarean section in this study was arrest of labor (Gagnon-Gervais et al., 2012). Gross et al. (2012) found that oxytocin administration in the second stage of labor increased the risk for cesarean section in nulliparous women. This study also found that performing amniotomy in the first stage of labor increased the risk of cesarean section for nulliparous women. Overall, the study found that oxytocin administration at any time during labor did increase the risk of cesarean section for both nulliparous and multiparous women with a hazard ratio of 2.2 (Gross et al., 2012). A systematic review done by Howarth and Botha (2013) looked at seventeen trials involving 2566 women. This review did not find any statistically significant differences overall in the rate of cesarean section with amniotomy and intravenous oxytocin use; however, the authors concluded that more research should be done due to lack of sufficient data (Howarth & Botha, 2013). Research appears to indicate that early amniotomy and the use of intravenous oxytocin increases the rate of cesarean section.

Amniotomy and mechanical cervical ripening. The study done by Battarbee et al. (2016) found a cesarean section rate of 48 percent in the early amniotomy group compared to 52.4 percent in the no early amniotomy group; a total of 274 of the 546 study participants receiving cesarean sections. The most common indication for a cesarean section in both groups was the arrest of dilation (Battarbee et al., 2016). This research contradicts other research found in this review regarding the timing of amniotomy. However, this study also did have an overall high rate of cesarean section.

Amniotomy and pharmacological cervical ripening. The RCT performed by Beckmann et al. (2015) had a 36.4 percent cesarean section rate for the amniotomy group compared to a 37.1 percent cesarean section rate for the repeat doses group. The most common reason given for

cesarean section in both groups was for slow progress, as defined by once in active labor (cervix >four centimeters) a lack of progressive cervical dilatation of less than 0.5 cm per hour over a four-hour period (Beckmann et al., 2015). In the study done by Makarem et al. (2013), there was no statistically significant difference in the rate of cesarean between the amniotomy (26.88 percent) and the control group (34.37 percent). The most common indications for cesarean section for both groups were failure to progress and fetal distress. This research does not show a statistically significant difference in any of the groups for the rate of cesarean section.

Mechanical cervical ripening and intravenous oxytocin. In the Connolly et al. (2016) study, there was not a statistically significant difference in the rate of cesarean section between the two groups; simultaneous had a cesarean section rate of 46 percent and sequential had a rate of 38 percent. The two most common indications for cesarean section were arrest of dilation and failed induction of labor; however, failed induction of labor was not clearly defined in this study (Connolly et al., 2016). Mackeen et al. (2018), found that the cesarean section rate was slightly higher in the oxytocin alone group (19 percent) than the Foley plus oxytocin group (27 percent), but the difference was not considered statistically significant. The most common indications for cesarean section were category II or III fetal heart rate tracing, active phase arrest, and second stage arrest of labor with no statistically significant difference between the two groups (Mackeen et al., 2018). In the Schoen et al. (2017) study, the rate of cesarean section for nulliparous women was 42 percent in the Foley plus oxytocin group and 32 percent in the Foley followed by oxytocin group. In multiparous women, the rate of cesarean section was 13 percent in the Foley plus oxytocin group and 16 percent in the Foley followed by oxytocin group. The difference in the rate of cesarean section in all groups was not of statistical significance. In the nulliparous

group, indications for cesarean section included failed induction, arrest of dilation, arrest of descent, and nonreassuring fetal heart rate tracings. In the multiparous women group, the indications for cesarean section were arrest of dilation and nonreassuring fetal heart rate tracings. No statistically significant differences were found in the indications for cesarean section among the groups (Schoen et al., 2017). Wu et al. (2017) found that the oxytocin alone group had a cesarean section rate of 36.67 percent compared to a 6.67 percent rate in the double-balloon catheter group; the difference was statistically significant with a reported p-value of less than 0.05. Overall, the research in this section shows a higher rate of cesarean section with oxytocin use, however not a statistically significant difference in any of the studies.

Mechanical cervical ripening, pharmacological cervical ripening, and intravenous oxytocin. Cromi et al. (2012) found no significant difference in cesarean section rate between the two groups: double-balloon catheter (23.8 percent) and dinoprostone (26.2 percent). The most common indication for cesarean section for both groups was nonreassuring fetal heart rate tracings (Cromi et al., 2012). Du et al. (2014) found a cesarean section rate of 39.5 percent for the double-balloon catheter group and 31.6 percent for the dinoprostone group; the difference was not statistically significant. The most common indications for cesarean section were failure to progress and non-reassuring fetal heart tracing. The double-balloon catheter group (17.1 percent) was statistically significantly higher for failure to progress than the dinoprostone group (2.5 percent). There was no statistically significant difference between the two groups for non-reassuring fetal heart rate tracings (Du et al., 2014). Garba et al. (2016) found that the misoprostol group had a cesarean section rate of 20 percent compared to the Foley balloon group with a rate of 9.1 percent. The most common indication for cesarean section in this study was no

progress in the second stage of labor (Garba et al., 2016). Kandil et al. (2012) found a cesarean section rate of 18 percent in the Foley catheter group and 16 percent in the misoprostol group; with no statistically significant difference. The most common indication for cesarean section in this study was ominous fetal heart tracings for both groups, with the misoprostol group having this occur slightly more often. The other reason listed for a cesarean section was labor dystocia, which was slightly more common in the Foley catheter group (Kandil et al., 2012). Levine et al. (2016) did not find any statistically significant difference in the rate of cesarean section between the groups. The rate of cesarean section ranged from 24.2 percent to 30.4 percent with the highest rate being the Foley and oxytocin group and the lowest rate being in the misoprostol-only group (Levine et al., 2016). Overall, the research demonstrated no significant difference in the rate of cesarean section among any of the labor induction methods.

Critique of Strengths and Weaknesses

This review of the literature has both strengths and weaknesses. One of the strengths of this review is that it looks at multiple labor induction methods. This review addressed the use of a combination of methods, which more accurately reflects what is being done in clinical practice, as it is rare for only one method of labor induction to be utilized. This review also contained original research studies that were of high and good quality, most of which were randomized controlled trials. Another strength was that some of the studies had large sample sizes which translate to the results being more generalizable to other populations.

A major weakness of this review is also one of the strengths; while the review focuses on many different induction methods and their combination, there was not adequate good quality research on single induction methods available. That makes it difficult to draw specific

conclusions as to what individual induction methods might have for an impact on the duration of labor and the rate of cesarean section. There are some studies that have smaller sample sizes that were unable to show statistically significant results in differences between labor inductions methods and their impact on the rate of cesarean. Therefore, the results might be different if studies were done with larger sample sizes that are adequately powered to show statistical significance. Another potential weakness to this review is that some of the studies are from countries other than the United States; this may result in the conclusions from the studies not being able to transferable to the United States. However, since the physiology of labor and delivery is the same regardless of country, this impact should be minimal. Even though this review has weaknesses, the strength of the review outweighs the weaknesses.

Summary

There are multiple labor induction methods and many different combinations of these induction methods. In general, the duration of labor was found to be shorter when a combination of labor induction methods was used versus when only one labor induction method was utilized. Overall, labor induction increased the rate of cesarean section when compared to spontaneous labor. However, the rate of cesarean section was found to be less overall when the cervix was ripened prior to the start of other induction methods. Cervical ripening can be performed by either pharmacological methods or mechanical methods or a combination of both. In clinical practice, most of the time multiple methods need to be used in order to achieve successful delivery and so research and review of the literature should focus on the use of combinations of methods and their impact on the rate of cesarean section.

Chapter IV: Discussion, Implications, and Conclusions

The purpose of this review was to compare different methods of labor induction and their impact on the duration of labor and rate of cesarean section. Twenty-one original research articles were selected for critical analysis using the Johns Hopkins Research Evidence Appraisal Tool. After completion of the research appraisal, implications for nurse-midwifery practice as well as deficiencies in current research were identified. Chapter four will discuss these implications for nurse-midwifery practice and the areas that future research should be focused on. This chapter will also include the integration of Imogene King's nursing theory and how the application of this theory can improve labor induction outcomes.

Literature Synthesis

The research question for this critical literature review was "what is the impact of various labor induction methods on the duration of labor and the rate of cesarean section." The labor induction methods addressed in this review included pharmacological cervical ripening, mechanical cervical ripening, amniotomy, and intravenous oxytocin. Mechanical methods of cervical ripening reviewed include commonly used transcervical balloons such as Foley-bulbs and double-balloon (Cook) catheters. Pharmacological agents used for cervical ripening and labor induction include misoprostol, dinoprostone, and mifepristone.

Trend and Gaps in the Literature

Overall, the research reviewed demonstrated that utilizing a combination of methods had the greatest impact on shortening the duration of labor. Methods that were associated with a shorter duration of labor were early amniotomy (Bala et al., 2017, Battarbee et al., 2016, Gagnon-Gervais et al., 2012, Gross et al., 2012, & Macones et al., 2012) and the use of mechanical methods for cervical ripening (Connolly et al., 2016, Cromi et al., 2012, Du et al.,

2014, Kandil et al., 2012, & Levine et al., 2016). Research did not show a particular method that resulted in a lower rate of cesarean section; however, amniotomy and intravenous oxytocin were overall associated with an increased rate of cesarean section in nulliparous women (Bala et al., 2017, Battarbee et al., 2016, & Gagnon-Gervais et al., 2012). Based on current research, the induction of labor in nulliparous women is associated with an increased rate of cesarean section regardless of the methods utilized (Guerra et al., 2011, Seyb et al., 1999, & Tam et al., 2012).

More research does need to be done to fill in the gaps such as what methods are best to use and the timing of such methods. This will be further discussed in the following section.

Implications for Midwifery Practice

Nurse-midwives should avoid the use of non-medically indicated labor inductions due to the increased rate of cesarean section. In circumstances when labor induction is medically indicated, nurse-midwives should consider utilizing a combination of methods to shorten the duration of labor and reduce the rate of cesarean section. Ultimately, nurse-midwives should focus on practicing in a way that decreases the rate of cesarean section and allows the body time to respond to the induction methods that are being used.

Research does support the use of mechanical cervical ripening when able to do so as a method that reduces the duration of labor. Mechanical cervical ripening is associated with a shorter duration of labor and fewer issues with nonreassuring fetal heart rate tracings when compared to pharmacological agents (Connolly et al., 2016, Cromi et al., 2012, Du et al., 2014, Kandil et al., 2012, & Levine et al., 2016). Nurse-midwives should also utilize the Bishop score to determine cervical ripening needs prior to starting oxytocin (ACOG, 2009). If possible, pharmacological and mechanical cervical ripening should be done until a Bishop score of eight is

achieved. Intravenous oxytocin should be started, if possible after a score of eight has been achieved.

Recommendations for Future Research

There is a need for additional research in the future. Future research should focus on comparing labor induction methods when used individually and when used in combination with one and other. Research should also address the optimal method for mechanical cervical ripening, specifically addressing whether a single or double-balloon catheter is more effective and what volume of fluid is most effective. The timing of interventions used for labor induction should also be addressed in further research; for example, should there be a delay in starting the next intervention to allow the body time to start the physiological process of labor. Another recommendation for future research would be to have a study address the amount of time a woman is allowed to have for labor induction before it is considered a failed induction and a cesarean section is performed. More research should be done on the time allowed for mechanical cervical ripening, current guidelines are for removal of the balloon after twelve hours if not spontaneous expulsion has not occurred. Additional research could also focus on the option of performing mechanical cervical ripening on an outpatient basis, as a way to reduce the length of hospital stay. There are definitely multiple areas of focus for future research in regard to labor induction methods and their impact on the duration of labor and rate of cesarean section.

Integration of King's Theory for Goal Attainment

Imogene King's Theory for Goal Attainment is a conceptual framework that focuses on the dynamic interacting systems for goal attainment (Gonzalo, 2011). Specifically, focusing on three fundamental needs: the need for when health information can be used, the need for care to prevent illness, and the need for care when they are unable to care for themselves (Nursing

Theory, 2015). Based on this theory, humans are rational and sentient, meaning they can perceive, think, feel, choose, set goals, and then decide how to achieve those goals with the decisions they make (Nursing Theory, 2015). Additionally, King's theory focuses on the relationship between the patient and the provider.

In the case of labor induction, the relationship would be between the nurse-midwife and the patient. The goal would be a successful vaginal delivery utilizing various labor induction methods. King's theory can be applied with the sharing of knowledge between the nurse-midwife and the patient. The nurse-midwife needs to be knowledgeable on the various inductions methods and the benefits of using those in combination to shorten labor duration and reduce the rate of cesarean section. Together, the patient and the nurse-midwife set the goal of successful vaginal delivery and discuss the options for labor induction, focusing on doing so only when medically indicated. The nurse-midwife shares information about what current research says about labor induction methods, specifically that pharmacological and mechanical methods of cervical ripening should be used prior to starting intravenous oxytocin. The first goal would be to obtain a Bishop score of at least eight utilizing those methods following current practice guidelines. Ideally, those methods would trigger labor to start, however, in the event that they do not, the nurse-midwife and the patient would need to decide if intravenous oxytocin should also be used. As the labor progresses, decisions regarding which methods to be utilized need to be made and the information that the nurse-midwife shared with the patient prior to starting the induction process would need to be reiterated, allowing the patient to make informed decisions regarding her care with the end goal being the delivery of her infant.

Conclusion

The pertinent findings of this review include the importance of utilizing a combination of labor induction methods and avoiding non-medically indicated inductions due to the increased rate of cesarean section with labor inductions. The findings of this review indicate a potential benefit to utilizing mechanical methods of cervical ripening prior to starting intravenous oxytocin as a possible method for reducing the rate of cesarean section. The twenty-one original research articles reviewed using the Johns Hopkins Research Evidence Appraisal Tool showed mixed results as to which labor induction method has the greatest impact on reducing the duration of labor and the rate of cesarean section. It is important for nurse-midwives to consider current research in addition to recommendations from ACNM and ACOG when performing labor inductions. Utilizing a combination of labor induction methods and refraining from using inductions for non-medically indicated reasons has the potential to lower the rate of cesarean sections. Nurse-midwives also need to focus on the Hallmarks of Midwifery that support women as partners in their healthcare and informed decision makers. Additionally, nurse-midwives need to remember that one of the hallmarks of midwifery is viewing labor as a physiological process and not a pathological one requiring intervention.

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Appendix 1 – Literature Review Matrix

Source: Baev, O. R., Rumyantseva, V. P., Tysyachnyu, O. V., Kozlova, O. A., & Sukhikh, G. T. (2017). Outcomes of mifepristone usage for cervical ripening and induction of labour in full-term pregnancy. randomized controlled trial. *European Journal of Obstetrics, Gynecology, and Reproductive Biology, 217*, 144-149. doi:10.1016/j.ejogrb.2017.08.038			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: Evaluate the efficacy and safety of mifepristone use for cervical ripening and induction of labor versus expectant management in full-term pregnancy. **Sample/Setting:** Department of Obstetrics of Research Centre for Obstetrics, Gynecology and Perinatology, Moscow from January 2014 to January 2015. Size: 74 for study group and 75 for control group. Inclusion Criteria: Age 18-45 years, singleton live pregnancies, cephalic presentation, at least 40 +4 weeks, unripe cervix (Bishop score<8), intact membranes, no contraindication for vaginal delivery, no contraindication for induction, informed written consent was obtained. Exclusion Criteria: Uterine anomaly, parity greater than 3, severe hypertension/preeclampsia, prior cesarean,	**Study Design**: Randomized controlled trial **Instruments**: • One-to-one randomization schedule followed a computer-generated list of random numbers organized into permuted block of four and then concealed in sequentially numbered, opaque, sealed envelopes by independent staff members. **Methods:** • One tablet of mifepristone 200 mg by mouth at the moment of enrollment, assessed after 24 hours, if Bishop score <8, second dose was given, and another Bishop score obtained in 24 more hours. If after 72 hours from first dose, Bishop score was unchanged,	**Results:** • No significant differences among groups in age, BMI, gestational age, number of nulliparous, or initial Bishop score. • After 48h of mifepristone, Bishop score was twice as much as the expectant management group. • Significantly more of the study group were in labor within 24, 48, and 72 hours than the expectant management group. • Significant improvement in mean Bishop score after mifepristone treatment. **Conclusion:** • Mifepristone was efficient on inducing cervical ripening and labor	**Strengths:** • High comparability of the group. • Accurate exclusion of the cofounders, such as different pregnancy complications and indications for induction. • Comparison of low risk population group allows to focus research attention on the direct effect of induction. **Limitations:** • The study is not blinded and placebo-controlled. • Only short period of gestation was evaluated. • The sample size was small but was adequate based off a completed power analysis.

diabetes, impaired renal, adrenal, or hepatic function, fetal malformations, breech, estimated fetal weight (>4500 g or <2500g), any fetal concerns, or any indication for cesarean. **Johns Hopkins Evidence Appraisal Level of Evidence: Level I** **Quality: Good**	induction was considered failed. • If after 2nd dose of mifepristone, score was 6-7- dose of 0.5 mg dinoprostone, then another 0.5 mg after 6h and if needed a third dose given after 12h. • Once the Bishop score was >8, transferred to L&D for AROM and continued monitoring. • The control group had routine appointments and monitoring up to 42 weeks. They were induced if spontaneous labor did not occur prior to 42 weeks.	in full term pregnancy. • No significant differences in maternal and neonatal outcome between mifepristone use and expectant management. • No serious adverse effects of mifepristone. However, uterine contractions were more painful.	
Author Recommendations: • Mifepristone has the ability to induce cervical ripening in term pregnancy. • More comparative studies are needed to find out in which situations, gestational age, indications and combinations to other methods of induction to see which is most effective.			
Implications: • Mifepristone use for induction of labor (cervical ripening) is effective for producing labor within 72 hours from first dose. • Mifepristone use may be appropriate for inducing labor after 40 weeks gestation but before 42 weeks.			

Source: Bala, A., Bagga, R., Kalra, J., & Dutta, S. (2017). Early versus delayed amniotomy during labor induction with oxytocin in women with bishop's score of >=6: A randomized trial. *Journal of Maternal-Fetal & Neonatal Medicine,* , 20171-20178. Retrieved from http://ezproxy.bethel.edu/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=cgh&AN=CN-01403387&site=ehost-live&scope=site			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To study the effect of "early amniotomy" initiating induction of labor with amniotomy followed by oxytocin versus "late amniotomy" initiating IOL with oxytocin followed by amniotomy 4-8 hours later in induced labor. **Sample/Setting:** Sample size of 150 women with Bishop's score of >6 undergoing IOL. Study done at Post Graduate Institute of Medical Education & Research (PGIMER) in Chandigarh, India from July 2013 to December 2014. 150 women were included in study. Inclusion criteria: single live fetus at least 37 weeks with cephalic presentation, fetal	**Study Design**: Prospective Randomized Controlled Trial **Instruments**: Women admitted for IOL were screened to meet inclusion criteria. Sample was randomized into two groups using a computer-generated randomization table. **Methods:** • Group 1 was the early amniotomy group. IOL initiated with amniotomy and oxytocin started 30-60 minutes after amniotomy. • Group 2 was delayed amniotomy. IOL initiated with oxytocin and amniotomy was performed 4-8 h later unless deemed necessary earlier (for nonreassuring fetal heart status). • Primary outcome was induction to delivery interval (IDI). Secondary outcomes were CS rate, maternal outcomes, and fetal outcome.	**Results:** • Nearly two-thirds of women in study were nulliparous. • The overall CS rate was 6.67% and was higher in the early amniotomy group (10.7%) versus delayed (2.7%). • Early amniotomy the mean IDI was reduced significantly by about 4 h and more women delivered within 12 h. • The mean maximum oxytocin concentration was significantly lower for the early amniotomy. • Neonatal outcomes were comparable for both groups. **Conclusion:** Significant reduction in the IDI	**Strengths:** • The sample size was determined to be adequate based on a power analysis. • The results of this study do correlate with other research study results. **Limitations:** • There was a higher Bishop score in the early amniotomy group; which may have contributed to the shorten IDI.

head fixed at pelvic brim, intact amniotic membranes, reactive nonstress test and Bishop's score at least 6. Exclusion criteria: maternal infection, fever, heart disease, severe anemia, uncontrolled diabetes, major medical illness, previous uterine scar, severe preeclampsia, severe fetal growth restriction and fetal malformations. **Johns Hopkins Evidence Appraisal Level of Evidence: Level I Quality: Good**		for early amniotomy group. Other benefits of early amniotomy were lower maximum oxytocin concentrations and reduced requirement of labor analgesia. There was a statistically significant higher rate of CS in the early amniotomy group. Higher CS rate seemed to be related to arrest of labor and fetal distress.	
Author Recommendations: • Low-risk women with a favorable cervix and fetal head fixed at pelvic brim, initiating IOL with amniotomy followed by oxytocin (early amniotomy) has advantages and should be considered effective.			
Implications: • IOL with early amniotomy followed by oxytocin does reduced duration of labor when compared with oxytocin followed by amniotomy. • Early amniotomy is associated with a higher CS rate when compared with delayed amniotomy.			

Source: Battarbee, A. N., Palatnik, A., Peress, D. A., & Grobman, W. A. (2016). Association of early amniotomy after Foley balloon catheter ripening and duration of nulliparous labor induction. *Obstetrics and Gynecology, 128*(3), 592-597. doi:10.1097/AOG.0000000000001563 [doi]			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To evaluate the association between early amniotomy after ripening with a Foley balloon catheter and duration of labor induction. **Sample/Setting:** Northwestern Memorial Hospital between January 2010 and October 2013. 546 nulliparous women with singleton viable gestation undergoing cervical ripening with a Foley balloon catheter. 273 in each group. Inclusion criteria: nulliparous with singleton viable gestation undergoing labor induction with Foley bulb for cervical ripening. **Johns Hopkins Evidence Appraisal**	**Study Design**: Retrospective matched cohort study **Instruments**: Electronic medical records were used to identify all women who underwent cervical ripening with a single-balloon Foley Catheter inflated to 80 cc and taped on tension. **Methods:** The initial cervical examination after Foley placement was performed based on symptoms or after 6 h. If spontaneous expulsion did not occur, it was retaped for tension and reassessed at 12 h. At that time, it was removed and another agent for cervical ripening was considered. After expulsion standard protocol for oxytocin was followed; starting at 2 milliunits/min and increased by 2 every 15-20 minutes until	**Results:** • Older women were more likely to undergo early amniotomy. • Early amniotomy was significantly associated with shorter duration from catheter removal to complete dilation and to delivery. • No significant differences in maternal or neonatal outcomes. • Early amniotomy associated with higher odds of vaginal delivery within 24 hours; although the difference was not statistically significant. **Conclusion:** Early amniotomy after Foley balloon catheter removal is associated with shorter duration of labor induction in nulliparous women.	**Strengths:** • Large sample size studying specifically the timing of amniotomy after mechanical ripening of with a Foley balloon catheter. • Standard protocols for labor induction and Foley balloon management were followed. • Women in control group and intervention group were matched according to healthcare provider type, favorability of cervical exam, indication for induction- reducing bias that is common in retrospective studies. **Limitations:** • Cannot exclude the possibility of unmeasured confounding variables. • Due to this being an observational study, causality cannot be assured.

Level of Evidence: Level III **Quality: Good**	labor pattern was established. Early amniotomy was defined as AROM less than 1 hour after bulb removal.		
Author Recommendations: • Implementing a more proactive approach to management of labor induction my decrease the duration of labor and resource utilization.			
Implications: • Early amniotomy following removal of cervical ripening catheter may be effective in reducing duration of labor. • Early amniotomy in this study was associated with a lower CS rate; however, that was not statistically significant.			

Source: Beckmann, M., Kumar, S., Flenady, V., & Harker, E. (2015). *Prostaglandin vaginal gel induction of labor comparing amniotomy with repeat prostaglandin gel* doi://doi-org.ezproxy.bethel.edu/10.1016/j.ajog.2015.07.043			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: Compare 2 inductions of labor protocol. Investigating women who underwent IOL who had already received an initial dose of PGE2 vaginal gel. To determine whether there is advantage or disadvantage in continuing to administer more PGE2 rather than perform AROM. **Sample/Setting:** At Mater Health Services Brisbane between March 2010 and August 2013. All women with live singleton pregnancies at or beyond 37 weeks gestation who were booked for IOL with the use of PGE2 vaginal gel and with a modified Bishop's score < 7. Total sample size of 245 women; randomly assigned to either the repeat PGE2	**Study Design**: Randomized controlled trial **Instruments**: Women were approached by the medical officer on the evening of their IOL and asked to participate in the study; informed consent was obtained. Study approval was obtained from the ethics committee. Randomization into the 2 study groups was done according to a random allocation list. Sealed sequentially numbered opaque envelopes were prepared. After patients consented to participate, the envelope was opened by the midwife caring for the patient and the intervention in the envelope was followed. **Methods:** After an initial dose of PGE2 vaginal gel in the evening (2mg for nulliparous and 1 mg for multiparous women), women were checked at 0600 the	**Results:** • 245 women participated in the study. 124 in repeat PGE2 group and 121 in amniotomy group. • Baseline characteristics of women in each group did not differ with respect to age, BMI, gestational age, ethnicity, or indication for IOL. • Most common indication for IOL was post-dates. • More than 80% of the indications were performed for an identifiable clinical indication. • Overall the IOL to birth was more than 5 hours shorter in women in the amniotomy group than the repeat PGE2 group. • There was a cesarean rate of 36.4% in the amniotomy group and 37.1% in the repeat PGE2 group; no statistically significant difference in the two groups. • Most common indication for cesarean	**Strengths:** • Low risk for bias with this study design. • Randomization resulted in similar characteristics for each group; these were found to be representative of the characteristics of all women undergoing IOL during the time period of this study. **Limitations:** • There was a high number of protocol violations (such as delay in starting oxytocin. • The sample size was smaller than ideal but was what able to be done with the grant funding that was received.

gel (124) group or amniotomy (121) group. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	next morning. Immediately before cervical examination, the envelope assigning the women to the different groups was opened. Women in the amniotomy group underwent AROM regardless of Bishop score and received further doses of PGE2 gel only if AROM was not physically possible. The repeat PGE2 received further doses of 1 mg every 6 hours to a maximum of 3 doses until Bishop score was at least 7- at which time AROM was performed. In both group oxytocin was started once ROM occurred. Rate started at 1mU/min and increased by 4mU/min every 30 minutes to a maximum rate of 32mU/min until 3-4 contractions every 10 minutes was achieved. Primary outcome was length of time from IOL until birth. The start of IOL was the time the first dose of PGE2. Secondary outcomes were mode of birth, use of epidural, need for antibiotics, postpartum hemorrhage, uterine hyperstimulation, and duration of hospital	for both groups was fetal distress and slow progress. **Conclusion:** AROM after the initial dose did lead to shorter duration of labor than repeating doses. No statistically significant differences in the two group for secondary outcomes.	

	stay.		

Author Recommendations:

- AROM after an initial dose of PGE2 vaginal gel is statistically significant at reducing IOL to birth time and should be considered once technically possible.
- Future research should focus on health care costs of different induction methods.

Implications:

- There does not appear to be any advantage to repeating doses of PGE2 vaginal gel prior to AROM in regard to mode of delivery (vaginal versus cesarean).
- AROM after initial dose of PGE2 does significantly reduce IOL to birth time.

Source: Connolly, K. A., Kohari, K. S., Rekawek, P., Smilen, B. S., Miller, M. R., Moshier, E., . . . Bianco, A. T. (2016). A randomized trial of Foley balloon induction of labor trial in nulliparas (FIAT-N). *American Journal of Obstetrics and Gynecology, 215; 3*(3) doi:10.1016/j.ajog.2016.03.034			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To determine whether simultaneous use of Foley balloon inflated to 60 mL and oxytocin decreases time to delivery in nulliparous women compared to the sequential use of Foley balloon followed by oxytocin. **Sample/Setting:** Nulliparous women presenting for induction of labor at Mount Sinai Hospital, New York from December 2013 to March 2015. Nulliparous women at least 24 weeks gestation with live, non-anomalous singleton fetus in vertex presentation with initial cervical dilation <3 cm admitted for induction of labor with cervical	**Study Design**: Randomized controlled trial **Instruments**: Patients who were eligible were approached by study personnel and informed of risks and benefits. Informed consent obtained. A random number generator from OpenEpi, Version 3 allocated participants into either simultaneous or sequential group. Study approved by IRB. **Methods:** Eligible patients were approached and those that choose to participate were then randomized into either the simultaneous or sequential group. After enrollment each patient had a transcervical Foley balloon placed and inflated with 60 mL saline. For those in the simultaneous group oxytocin was started within 1 hour of insertion. Started at a rate of 2 mU/min	**Results:** • Total of 166 women enrolled; 82 in the simultaneous and 84 in the sequential group. • Baseline demographic data did not diff much between the two groups. • Time to delivery for simultaneous group on average was 15.92 hours; for sequential group was 18.87 hours. • Simultaneous group difference time to deliver was statistically significant. • No significant difference in cesarean rate between the two groups. • However, the simultaneous group had a higher rate of cesarean for nonreassuring fetal heart tones. • No major differences in maternal or neonatal outcomes. • Cesarean rate for simultaneous group was 46%; sequential rate was 38%.	**Strengths:** • Power analysis performed prior to study; sample size was more than adequate to detect statistically significant differences. • Randomization helps with eliminating bias. **Limitations:** • Patients and providers were not blinded. • Decision to perform a cesarean delivery in the context of nonreassuring fetal heart rate tracing or failed in duction may have been influenced by the provider's knowledge of the length of oxytocin exposure. • Generalizability of results may be difficult due to differences in oxytocin protocol between this facility and other facilities.

ripening with Foley balloon was planned were eligible for enrollment. Sample size of 166, 82 in simultaneous group and 84 in sequential group. Exclusion criteria: prior uterine surgery, unexplained vaginal bleeding, latex allergy, or any contraindication to vaginal delivery. **Johns Hopkins Evidence Appraisal Level of Evidence: Level I Quality: Good**	which was doubled every 30 minutes until 16 mU/min and then increased by 2mU/min every 30 minutes to a maximum dose of 30 mU/min. Patients in the sequential group, oxytocin was started within 1 hour of spontaneous expulsion of the balloon following the same protocol for increasing doses. If spontaneous expulsion did not occur within 12 hours, the balloon was removed, and oxytocin was started.	**Conclusion:** Simultaneous use of Foley balloon and oxytocin statistically reduces time to delivery when compared with sequential use. No statistical significance in difference between cesarean rate for these groups.	
Author Recommendations: • Simultaneous use of Foley balloon and oxytocin results in shorter time to delivery without increased risk of maternal or neonatal complications and should be considered for induction protocol. • Future studies should focus on other populations (i.e. multiparous, previous cesarean, or multiple gestation) with these two induction protocols.			
Implications: • Simultaneous use of Foley balloon and oxytocin results in shorter time to deliver but also increased incidence of cesarean due to nonreassuring fetal heart tones. • Both induction protocols followed for this study had a high rate of cesarean delivery.			

Source: Cromi, A., Ghezzi, F., Uccella, S., Agosti, M., Serati, M., Marchitelli, G., & Bolis, P. (2012). *A randomized trial of preinduction cervical ripening: Dinoprostone vaginal insert versus double-balloon catheter* doi://doi-org.ezproxy.bethel.edu/10.1016/j.ajog.2012.05.020			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To compare the efficacy of a double-balloon transcervical catheter to that of a prostaglandin (PG) vaginal insert among women undergoing labor induction. **Sample/Setting:** Sample size of 210 (105 in each group) women with Bishop score <6 were assigned randomly to cervical ripening with either a double-balloon catheter or a PGE2. Patients from Obstetrics Department of University of Insubria, Varese, Italy from August 2010 to October 2011. Inclusion criteria: singleton gestation, vertex presentation, Bishop <6, intact membranes, gestational age >34 weeks, and	**Study Design**: Randomized controlled trial **Instruments**: Patients with unfavorable cervixes scheduled to undergo labor induction were screened for study inclusion. Women who wanted to participate were recruited by a staff physician and then randomly allocated to either preinduction cervical ripening with a double-balloon catheter or 10mg controlled release dinoprostone vaginal insert. The randomization was created with a computer-generated randomization scheme with a 1:1 allocation. **Methods:** The group assigned to mechanical ripening with a double-balloon catheter, which was inserted into the cervical canal under direct visualization during a sterile speculum examination. Once both balloons	**Results:** • More women in the double-balloon group achieved vaginal delivery in 24 hours than the PGE2 group (6.8% versus 49.5%). • No difference in cesarean rate between the two groups (23.8% versus 26.2%). • Oxytocin and epidural analgesic were administered more frequently when a double-balloon device was used. • Uterine tachysystole or hypertonus occurred more frequently in the PGE2 group. • Nonreassuring fetal heart tones leading to cesarean section were more common in the group with the PGE2 vaginal insert. **Conclusion:** The use of a double-balloon catheter for cervical ripening is associated with a higher rate of vaginal birth within 24 hours compared with a PGE2	**Strengths:** • A power analysis was performed prior to the study to ensure that sample size was adequate. This applies only to the primary outcome of vaginal delivery within 24 h. • The randomization process prevented bias. **Limitations:** • Patient satisfaction was no addressed. • The nature of balloon catheter treatment means that it would not have been possible to conceal treatment allocation, therefore managing obstetrician could have inadvertently influenced factors related to time to delivery or decision to perform cesarean. • The study lacks sufficient power to show significance to secondary outcomes.

reassuring fetal heart tracing on admission. **Johns Hopkins Evidence Appraisal Level of Evidence: Level I Quality: Good**	entered the cervical canal, the first balloon was filled with 50 mL saline above the level of the internal os and then pulled snugly back against the os. The second (vaginal) balloon was then inflated with 50 mL of saline. The external end of the device was taped without traction to the medial aspect of the patient's thigh. Then patients were monitored for 30 minutes for fetal heart rate. The device was left in place for 12 hours per manufacturer's recommendation. The catheter was removed either because maximal time was reached, SROM occurred, the balloon was expelled spontaneously, or patient entered labor. In the group for pharmacological ripening, the insert was placed, and fetal heart rate was monitored for at least 1 hour. The insert was removed for the following reasons: maximum time (24h), onset of labor, or uterine hyperstimulation or nonreassuring fetal heart rate patterns. After removal of either	vaginal insert.	

	the catheter or the vaginal insert, oxytocin was administered if the women were not in labor. Oxytocin was started at 5mU/min and increased by 5mU/min every 15 minutes to achieve 7 contractions in 15 minutes or up to a maximum dose of 30mU/min. If slow progress occurred (<1cm of cervical change in 2 h) then an amniotomy was performed if membranes were intact.		
Author Recommendations: • Further research should be conducted to clarify the usefulness of targeting subgroups of patients that would most likely benefit from mechanical methods; those that are at an increased risk for fetal distress.			
Implications: • Mechanical dilation had improved rates of vaginal delivery within 24 h than pharmacological ripening. • Pharmacological ripening had higher rates of fetal distress (nonreassuring heart tones) that lead to cesarean. • Double-balloon catheter may be a more efficient method for cervical ripening and result in fewer incidences of fetal distress.			

Source: Du, C., Liu, Y., Liu, Y., Ding, H., Zhang, R., & Tan, J. (2015). Double-balloon catheter vs. dinoprostone vaginal insert for induction of labor with an unfavorable cervix. *Archives of Gynecology & Obstetrics, 291*(6), 1221-1227. doi:10.1007/s00404-014-3547-3			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To compare the efficacy of a double-balloon catheter with the dinoprostone vaginal insert for induction of labor in women with an unfavorable cervix. **Sample/Setting:** Study was conducted at the Obstetrics Department of Sun Yat-sen Memorial Hospital of Sun Yat-sen University, China, from May 2010 to January 2013. A total of 155 women participated in the study: 76 women in double-balloon catheter group and 79 in dinoprostone vaginal insert group. Inclusion criteria were singleton gestation, vertex presentation, intact membranes, Bishop score <6, gestational age of	**Study Design**: Prospective cohort study **Instruments**: Women undergoing induction with unfavorable cervix were informed of the study and the risks and benefits of the two methods, the women then chose which method they wanted to use. Information was gathered during patient's stay and from additional chart review. **Methods:** Labor induction was performed with either a 10 mg-controlled release dinoprostone vaginal insert or a double-balloon catheter. After agreeing to the study, patients were allowed to choose the induction method they wanted to use. The vaginal insert was inserted and left in for 24h unless labor or uterine hyperstimulation occurred. If labor did not occur, amniotomy was performed, if 1 h	**Results:** • No significant differences between the two groups in baseline characteristics. • No significant differences between the groups in change of Bishop score, vaginal delivery within 24 h or 48. • No significant difference between the groups on the rate of cesarean section. • Time in active labor was less for the double-balloon catheter group. • The length of the first stage of labor was significantly longer in the vaginal insert group. • More patients in the double-balloon group received oxytocin. • Uterine hyperstimulation was also less in the double-balloon group. (no cases vs 10%). • No significant differences in neonatal outcomes. **Conclusion:** Double-balloon	**Strengths:** • Allowing patients to choose their method might more accurately reflect what is happening in clinical practice than a random controlled trial. **Limitations:** • Patients were allowed to choose the preferred induction method, which has potential to produce bias. • Chinese patients have a mistrust of clinical trials and many declined participating. • There is the potential for an error in the study groups for up to 23%; there was not very high power with this study.

at least 37 weeks, and normal preinduction fetal heart rate tracing. Exclusion criteria: any contraindication for vaginal delivery, previous uterine or cervical surgery, intrauterine death, antepartum bleeding, active infection, eclampsia. **Johns Hopkins Evidence Appraisal Level of Evidence: Level III Quality: Good**	after amniotomy labor had still not occurred, then oxytocin was started per facility protocol as outlined below. For the balloon catheter induction, both balloons were filled with 80 mL and left in place for 12h. If a patient did not go into labor within 12 h after balloon insertion, an amniotomy was performed, if labor did not begin 1 h after amniotomy, then oxytocin was started. Oxytocin rate was started at 2.5 mU/min and increased every 15 minutes up to a maximum of 20 mU/min or until 3 contractions within 10 min, lasting 30-60 seconds. Primary outcome was vaginal delivery within 24 h. Secondary outcome was cesarean rate section. Other outcomes measured included: interval from the start of induction to active labor to delivery, the length of first stage of labor and total length of labor, the need for oxytocin, occurrence of hyperstimulation, meconium staining, and neonatal outcomes.	catheter and dinoprostone vaginal insert are associated with similar vaginal delivery and cesarean section rates and neonatal outcomes. No major differences between the two methods were found in this study.	

Author Recommendations: • Additional studies should be done with adequate statistical power to detect differences. • Further research should be done with larger sample size to determine more accurate results.
Implications: • This study did not show any significant differences in vaginal delivery within 24h between the two methods. • The authors admitted that their study lacked adequate statistical power and may have a high error rate; so, the results of this study should be interpreted cautiously.

Source: Gagnon-Gervais, K., Bujold, E., Iglesias, M., Duperron, L., Masse, A., Mayrand, M., … Audibert, F. (2012). Early versus late amniotomy for labour induction: a randomized controlled trial. *The Journal of Maternal-Fetal & Neonatal Medicine*, *25*(11), 2326-2329. doi:10.3109/14767058.2012.695819			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To compare early vs. late amniotomy in a population of women undergoing labor induction at term. **Sample/Setting:** Study conducted at two academic perinatal centers in Montreal, Canada from October 2006 to May 2010. A total of 143 women enrolled in the study; 71 for early amniotomy with oxytocin and 72 for late amniotomy. Inclusion criteria: admission to hospital for labor induction, >18 years, term singleton fetus in cephalic presentation, intact membranes, and normal fetal heart rate tracing. Exclusion: maternal infection, maternal fever, fetal growth restriction, severe	**Study Design**: Randomized controlled trial **Instruments**: Randomization was done using numbered opaque sealed envelopes (which was done with a computer program) from October 2006 to June 2009. From July 2009 to May 2010, randomization was done using a web-based system due to a second center joining the study. Outcomes were collected after delivery by a research assistant that was blinded for allocation group. **Methods:** After informed consent was obtained, a digital examination was performed to confirm feasibility of amniotomy. If a woman was still eligible, then she was randomized into a treatment group. In early amniotomy, oxytocin infusion and amniotomy was started	**Results:** • The trial was stopped after 3 years due to low recruitment rate. • Both groups were comparable for baseline characteristics. • Indications for induction were similar between the groups; postdates was most common. • Cesarean rates were similar in both groups (18% vs 17%). Most common reason for cesarean was arrest of labor. No cord prolapses occurred. • Duration of labor was significantly shorter in the early amniotomy group. **Conclusion:** There was no statistically significant difference in the rate of cesarean between the two groups. There was significant difference in duration of labor; early amniotomy was much shorter.	**Strengths:** • The randomization • Stratification by parity • A strict oxytocin administration protocol • Strict definitions of early and late amniotomy • Very high compliance of the allocated treatment. **Limitations:** • A power analysis determined that each group needed to have 180 participants (360 total) to detect significant differences; however due to low recruitment and the study being stopped the sample size was inadequate. • Selection bias in the recruitment process toward a very low-risk group of women. The study was underpowered to show differences in rate of cesarean. • The number of eligible women was

preeclampsia, prior cesarean, SROM, unfavorable cervix (Bishop <6), or women who had received prostaglandins for cervical ripening. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	within the first hour of randomization. In the late amniotomy group, oxytocin infusion was started with amniotomy performed after 4h or unless deemed necessary by physician. Oxytocin was started at 1mU/min, increased to 2, 4, 8, and then by 2mU/min every 30 minutes- decreased or stopped if hyperstimulation occurred. Primary outcome was cesarean delivery. Secondary outcomes included the mean duration of labor, the mean amniotomy to delivery interval and rate of fever.		not recorded because several women were not offered to participate by the attending physicians.
Author Recommendations: • Further research should be done with adequate power to show statistically significant differences. • Early amniotomy should be considered to help shorten the duration of labor.			
Implications: • This study was well designed but due to inadequate sample size, it is difficult to draw conclusions. • This study does suggest that early amniotomy with oxytocin for induction leads to shorter duration of labor without an increase in cesarean rate.			

Source: Garba, I., Muhammed, A. S., Muhammad, Z., Galadanci, H. S., Ayyuba, R., & Abubakar, I. S. (2016). Induction to delivery interval using transcervical Foley catheter plus oxytocin and vaginal misoprostol: A comparative study at aminu kano teaching hospital, kano, nigeria. *Annals of African Medicine, 15; 3*(3), 114-119. doi:10.4103/1596-3519.188890			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To compare the induction delivery intervals using transcervical Foley catheter plus oxytocin and vaginal misoprostol, and to identify the factors associated with successful induction among postdate singleton multiparous. **Sample/Setting:** All consenting postdates singleton multiparous pregnant women at Aminu Kano Teaching Hospital in Africa from February to May 2015. Gestational age of 41 weeks and 3 days. Sample size of 136; 70 in misoprostol group and 66 in Foley Catheter oxytocin group. **Johns Hopkins Evidence Appraisal Level of**	**Study Design**: Prospective randomized controlled trial **Instruments**: Data analyzed using SPSS version 17 computer software; comparisons of categorical variables were done using Chi-squared test. Computer-generated random numbers were used to allocate the study groups. Questionnaire was administered before and completed after delivery for baseline characteristics. **Methods:** Informed consent was obtained. Patients were randomly assigned to either the Foley catheter or vaginal misoprostol group. Induction to delivery interval was calculated from cervical dilatation of 4 cm to the delivery of the fetus. The APGAR scores, maternal vital signs, estimated blood loss, and induction to delivery interval were	**Results:** • Both groups were comparable in baseline and demographic characteristics. • Higher rate of cesarean in misoprostol group (20% versus 9%). • Induction to delivery interval was shorter in the misoprostol group than in the Foley plus oxytocin group. • Failed IOL was more common in the misoprostol group. • There were no cases of fetal distress in the Foley plus oxytocin group. **Conclusion:** Use of vaginal misoprostol for cervical ripening and IOL was found to result in shorter labor duration. There were no statistically significant differences in maternal and neonatal outcomes.	**Strengths:** • Results of this study are comparable to similar past studies. **Limitations:** • Study only focused on IOL for postdates and not on any other indications. • Power analysis was not performed so it is not known if sample size would be adequate. • Study does not detail the oxytocin protocol that was followed for dosing.

Evidence: **Level I** **Quality: Good**	recorded on the questionnaire.		
Author Recommendations: The use of vaginal misoprostol for cervical ripening and IOL, among postdate multiparous singleton pregnant women, is recommended and preferred over Foley catheter plus oxytocin infusion.			
Implications: • This study showed that cesarean rate was higher with the misoprostol group than the Foley plus oxytocin group. • Duration of labor was shorter for the misoprostol group. • Due to the small sample size, lack of power analysis and short time frame for the study; the results of this need to be taken cautiously.			

Source: Gross, M. M., Fromke, C., & Hecker, H. (2014). The timing of amniotomy, oxytocin and neuraxial analgesia and its association with labour duration and mode of birth. *Archives of Gynecology & Obstetrics, 289*(1), 41-48. doi:10.1007/s00404-013-2916-7			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To study the association of different timings of intrapartum interventions with labour duration and mode of birth. These interventions include the timing of augmentation with oxytocin, amniotomy, and neuraxial analgesia. **Sample/Setting:** Data collected from 47 maternity units in Germany during and after births between April and October 2005. Pregnant women with a single fetus in cephalic presentation and planning a vaginal birth. Pregnancy of at least 34 weeks. Nulliparous (n=2,090) and multiparous (n=1,873). **Johns Hopkins**	**Study Design:** Non-experimental Longitudinal Prospective observational study. **Instruments:** Data was collected in the German state of Lower Saxony in 47 maternity units during and after births between April-October 2005. Institutional approval for the anonymous gathering of information was granted by the Ethics Committee of Hannover Medical School and by the Ethics Committee for public hospitals. **Methods:** Data collected from 47 maternity units in Germany. Pregnant women with singleton gestation in cephalic presentation and planning a vaginal birth were included. Pregnancies of at least 34 weeks were included. The onset of labor was defined as regular or irregular contractions in	**Results:** Nulliparous (n=2090) and multiparous (n=1873) were included in the study. • Intrapartum amniotomy was performed in 34.4% of nulliparous and 41.8% of multiparous. • Oxytocin augmentation was 52.4% in nulliparous and 27% in multiparous. Median initiation was 6 hours after the onset of labor in nulli. and 4 hours in multi. • Median time from oxytocin to birth was shorter in multiparous (1.4hr) than nulliparous (3.2hrs). • For nulliparous women oxytocin was associated with a higher risk of C-section. • First stage of labor was accelerated when an amniotomy was performed when compared to SROM or membranes remaining intact. However, for nulliparous women this increased the need for an emergency C-section	**Strengths:** • Combination of a longitudinal methodological approach with a dynamic environment. • Time to event analysis is a promising technique to analyze the timed sequence of interventions during labor. **Limitations:** • Lack of cervical dilation data • Lack of information on uterine contractions • Lack of data on fetal head staging • Imprecision in defining the onset of labor • Lack of data regarding oxytocin dose and titration • Lack of information regarding type and drug concentration of neuraxial analgesia • Inclusion of VBAC patients • Lack of data regarding indication for interventions • Non-inclusion

Evidence Appraisal **Level of Evidence: Level III** **Quality: Good**	association with increasing cervical dilatation as assessed by a midwife. Additional variables that may have confounded labor were grouped and included: demographics, risk-associated, induction and infant variables. Woman with previous cesarean section with no vaginal birth were classified as nulliparous. After power analysis target number of n=1,888 for each nulliparous and multiparous. This study looked at hazard ratios for different outcomes.	in the first stage. • Oxytocin augmentation in the second stage of labor increased risk C-section rate in nulliparous and operative vaginal birth in both groups. **Conclusion:** The administration of amniotomy, oxytocin initiation or neuraxial analgesia is associated with when a woman will give birth as compared to women who do not receive these interventions. However, the birth mode is altered as well. Oxytocin administrations is associated with an increased risk of adverse outcomes such as cesarean section and fetal distress which often requires additional interventions and may lead to a cesarean. Applying amniotomy, oxytocin and neuraxial analgesia at their optimal timing may improve the progress and outcome of labor such as vaginal delivery, assisted delivery (vacuum or forceps) or cesarean section.	of all eligible patient. • Not all variable with significantly altered hazard ratios may be clinically significant.

Author Recommendations:

- Observations need to be interpreted cautiously. Results were reporting evidence of time-related associations and not definitive causal relationships.
- Results regarding amniotomy timing demonstrate a need for an RCT for the timing of amniotomies.
- The effects of these interventions should be studied further regarding time-related effects.

Implications:

- Oxytocin administration does increase the risk of adverse outcomes such as C-section or operative vaginal birth in nulliparous women.
- More research needs to be found on cause/effect relationships between these interventions and C-section/duration of labor.
- This study shows that these methods may speed up the labor process but does not take into effect why these interventions are being done and what those factors might have on the timing of labor.

Source: Guerra, G. V., Cecity, J. G., Souza, J. P., Founds, A., Morais, S. S., Gülmezoglu, A. M., . . . Carroli, G. (2011). Elective induction versus spontaneous labour in Latin America. *Bulletin of the World Health Organization, 89*(9), 657-665. doi:10.2471/BLT.08.061226			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To evaluate the frequency of elective induction of labor in Latin America, the procedure's rate of success in achieving vaginal delivery, the factors determining its application and any associated unfavorable maternal and perinatal outcomes. **Sample/Setting:** All women who had elected inductions from 120 randomly selected facilities in 8 randomly selected countries in Latin America. Sample size was 97,095 total births with 1,847 elective induction of low-risk women which were included in the study. These were compared with 35,597 low-risk women who went in labor	**Study Design**: Cross-sectional observational study **Instruments**: A secondary analysis was performed on data obtained from the World Health Organization Global Survey on Maternal and Perinatal Health (WHOGS). Database was from WHOGS 2004-2005. **Methods:** Data was collected from medical records in 120 randomly selected health facilities from eight randomly selected countries in Latin America. In each country data was collected on every single woman who gave birth in every selected facility. Primary outcome measured was vaginal delivery.	**Results:** • Of elective inductions 88.2% resulted in vaginal delivery with little variation of induction method used. • Oxytocin administration was the most common induction method used. • Cesarean was performed in 11.8% of the elective inductions; compared with 8.6% of women in spontaneous labor. This difference is statistically significant. • No increased occurrence of neonatal complications in the elective induction group. • Women that underwent elective induction, did have an	**Strengths:** • Very large sample size. **Limitations:** • Study was done in Latin America and was done by reviewing medical records. • The specific protocols used for induction was not addressed (although the method used was), it is not known how the protocol used might have varied from different facilities and how that would compare with what other facilities in other countries are doing.

spontaneously. Exclusion criteria: previous uterine scarring, clinical or obstetrical pathological condition, induction for medical reasons, pre-term, post-term and non-cephalic presentation. **Johns Hopkins Evidence Appraisal** **Level of Evidence: Level III** **Quality: Good**		increased risk of adverse maternal outcomes. • The cesarean rate for all inductions (including those that were done for medical reasons) was 29.5%. • Cesarean rate for misoprostol was 21.8%. **Conclusion:** Women with inductions had increased rates of cesarean section.	
Author Recommendations: Caution should be exercised when inducing labor electively (without medical indication), since no clear benefits outweigh the associated risks.			
Implications: • Elective induction is associated with a higher rate (11.8%) of cesarean than spontaneous labor (8.6%). Overall, induction (including those done for medical indications) has a higher rate of cesarean (29.5%). • There are no clear benefits outweighing the risk of elective inductions.			

Source: Kandil, M., Emarh, M., Sayyed, T., & Masood, A. (2012). Foley catheter versus intra-vaginal misoprostol for induction of labor in post-term gestations. *Archives of Gynecology & Obstetrics, 286*(2), 303-307. doi:10.1007/s00404-012-2292-8			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To investigate whether a fluid-filled intra-uterine extra-amniotic Foley catheter is an effective alternative to vaginal misoprostol in inducing labor in primigravid women with post-term gestation. **Sample/Setting:** At total of 100 primigravid women with post-term gestation (more than 41 weeks) were enrolled and randomly assigned to two groups (50 in each group). Study was done at the Department of Obstetrics and Gynecology, Menofyia University Hospital, Egypt between January and October 2010. **Johns Hopkins Evidence Appraisal Level of Evidence:**	**Study Design**: Prospective quasi-randomized controlled trial. **Instruments**: Women were selected from clinic that were post-term and scheduled for labor induction. Women with odd dates were allocated to group one, women with even dates were allocated to group two. **Methods:** In group 1 (Foley group) Foley catheter was inserted sterile fashion into cervix with speculum exam and inflated to 30mL, then taped to thigh with tension. Left in place until expelled spontaneously or removed in 12h. In group 2 (misoprostol), women were given 25 micrograms vaginally every 4 hours. For both groups once 3-4 cm dilation occurred, amniotomy was performed. Oxytocin was used if labor did not progress for 2h. Induction was	**Results:** • All patients were primigravida at 41 weeks or more. • No major differences in baseline characteristics between the 2 groups. • Induction to delivery time in the Foley group was significantly shorter than the misoprostol group. This was statistically significant. • Cesarean rates were similar in the two groups; however, the misoprostol group did have cesarean done for nonreassuring fetal heart more than the Foley group. The other reason for cesarean was labor dystocia. **Conclusion:** Fluid filled Foley catheter seems to be superior to 25	**Strengths:** • The study was well designed; however, it was a small sample size. **Limitations:** • The number of women enrolled was too low to relate to intra-partum complications.

Level II **Quality: Good**	considered successful if women delivered within 12h of amniotomy and start of oxytocin. Cesarean was performed for failed induction or for nonreassuring fetal heart tone. Outcomes measured were induction to delivery interval, need for oxytocin, route of delivery, occurrence of chorioamnionitis, APGAR at 1 and 5 min, and admission to NICU. Results were analyzed on an IBM computer using Epi Info, word-processing, and statistics program.	micrograms of vaginal misoprostol regimen when used to induce labor in primigravida women with post-term gestation with have a shorter induction to delivery interval but more need oxytocin administration.	
Author Recommendations: • Foley catheter use is an effective method for inducing labor. • Additional studies with larger sample sizes should be performed to confirm these findings. • Also, studies should be done to find the ideal volume to inflate the balloon to.			
Implications: • Mechanical dilation with Foley catheter is effective at inducing labor and has a shorter time to delivery. • Misoprostol use is associated with more cases of uterine hyperstimulation and fetal distress than Foley use; this should be considered when deciding which method to use.			

Source: Levine, L. D., Downes, K. L., Elovitz, M. A., Parry, S., Sammel, M. D., & Srinivas, S. K. (2016). Mechanical and pharmacologic methods of labor induction: A randomized controlled trial. *Obstetrics and Gynecology, 128; 6*(6), 1357-1364. doi:10.1097/AOG.0000000000001778			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To compare the time to delivery among four different routinely used cervical-ripening methods for induction of labor including two different combination methods. **Sample/Setting:** Study done at the Hospital of the University of Pennsylvania from May 2013 to June 2015. Total sample size was 491: Misoprostol only (n=120), misoprostol and cervical Foley (n=123), cervical Foley only (n=123), cervical Foley and oxytocin (n=125). Inclusion criteria: at least 18 years old, full term (37 weeks), singleton gestation, cephalic presentation, both nulliparous and multiparous, intact membranes,	**Study Design**: Stratified Randomized controlled trial **Instruments**: Patients approached by healthcare providers; informed consent obtained. Patients randomized into one of the 4 groups using an internet-based clinical trial management system, Research Electronic Data Capture. Computer-generated randomization scheme that used balanced treatment allocation in blocks of 20; randomization was stratified by parity. **Methods:** Approval was obtained from IRB at University of Pennsylvania. Eligible patients were identified and approached for study inclusion by healthcare providers. After consent was obtained, they were randomized into one of the four treatment groups. Each group had a standard protocol for induction. No blinding to providers or patients	**Results:** • Baseline characteristics similar among the groups. • Overall, combination methods achieved a faster time to delivery than single methods. This occurred in both nulliparous and multiparous. • Misoprostol-Foley was superior, and those women were twice as likely to deliver sooner. • No statistically significant difference in cesarean rate among the 4 groups; Rate of cesarean ranged from 24.2% to 30.4%; highest rate was with the Foley-oxytocin group and lowest rate was with misoprostol only group. **Conclusion:** Combination induction methods do significantly reduce the time to delivery when compared with single methods.	**Strengths:** • Large sample size, appropriately powered. • Randomized trial that compared head to head four common methods of induction. • Management was standardized to limit confounding factors. • Very few induction indications were excluded, increasing the generalizability of the findings. **Limitations:** • Neither patients nor provider were blinded to intervention. • The study was powered to detect statistically significant differences for the primary outcome but was not powered adequately to detect differences for the secondary outcomes such as cesarean rate.

Bishop <6, cervical dilation <2cm. Exclusion criteria: Contraindication for vaginal delivery, previous cesarean, maternal infection, known fetal anomaly, nonreassuring fetal heart rate tracings, fetal growth restriction, prior attempt at induction. **Johns Hopkins Evidence Appraisal** **Level of Evidence: Level I** **Quality: Good**	but research personnel was blinded to study group during data abstraction. Misoprostol group received 25 micrograms vaginally every 3 hours up to 5 additional doses up to 24 h. Oxytocin was initiated if there was a contraindication to another misoprostol dose or if additional cervical ripening was not indicated and labor had not started on its own. Cervical-Foley only group, had an 18F Foley placed and inflated to 60 mL and then taped to thigh with gentle traction. Removed after 12 h if not expelled spontaneously. Oxytocin was started if labor did not begin on its own once Foley was no longer in place. Misoprostol-Foley group had both placed using the procedures outlined above. Foley-oxytocin group had Foley placed as described above and oxytocin was started concurrently. Oxytocin was given per the following protocol: 2mU/min, increasing by 2 mU/min every 15		

	minutes until regular contractions occur. Maximum dose for 40 mU/min; no limit to the amount of time. Providers were able to perform amniotomy at any point during the labor course. Cesarean done at their discretion with guidelines if not in active labor after 36 hours or if undelivered after 12h of active labor. Primary outcome was time to delivery. Secondary outcomes were cesarean delivery rate, time to vaginal delivery, time to cesarean delivery, time to active labor, delivery within 12h, within 24h and maternal length of stay.		
Author Recommendations: Future studies should focus on validating these results in different patient populations and be large enough to evaluate secondary outcomes such as cesarean rate.			
Implications: • Combining induction methods has potential to significantly reduce the duration of labor. • This study lacks power to show differences in cesarean rate of the different methods.			

Source: Mackeen, A. D., Durie, D. E., Lin, M., Huls, C. K., Qureshey, E., Paglia, M. J., . . . Sciscione, A. (2018). Foley plus oxytocin compared with oxytocin for induction after membrane rupture: A randomized controlled trial. *Obstetrics and Gynecology, 131; 1*(1), 4-11. doi:10.1097/AOG.0000000000002374			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To assess whether cervical ripening with Foley catheter plus oxytocin decrease interval to delivery and associated complications compared with oxytocin alone in women at 34 weeks gestation or greater with PROM. **Sample/Setting:** Conducted at 4 institutions: Geisinger (PA), Lehigh Valley Health Network (PA), Banner University Medical Center (AZ), and Christiana Care Health System (DE) from March 2014 to July 2016. Women with a live, singleton gestation at least 34 weeks with PROM, an unfavorable cervix (less than 2cm or 80% effaced), no contraindication	**Study Design**: Multicenter stratified Randomized controlled Trial **Instruments**: Randomization based on a one-to-one computer-generated schema in random-sized blocks stratified by multiparty or primiparity; maintained through a Microsoft Access database at each site. Data collected from charts. **Methods:** Women with live, singleton gestation at least 34 weeks with PROM and unfavorable cervix were approached for study participation. Informed consent was obtained, and women were enrolled then randomized into one of two groups. Either oxytocin alone or Foley with oxytocin. Oxytocin started at 2mU/min, increased by 2 mU/min every 30 minutes up to 30 mU/min until adequate contraction pattern was achieved. For women	**Results:** • Baseline characteristics were similar between the two groups. • In 84% of patients, Foley was removed due to spontaneous expulsion within the 12 h time period. • Epidural use similar between both groups. • Average induction time was shorter in the Foley group when compared with the oxytocin alone group; but the difference was not considered statistically significant. (mean of 6.9 hours to 7.9h) • No significant differences in rate of cesarean section between the groups; slightly higher rate in oxytocin alone group but this was not statistically significant. • No major differences in maternal or neonatal complications between the two groups.	**Strengths:** • Multicenter randomized controlled trial with a diverse patient population. • Computerized randomization with stratification for hospital site, parity, and preterm status. • All patients had an initial cervical exam prior to being considered for inclusion. • All four sites used the same oxytocin protocol. • Data entry was double-checked for accuracy **Limitations:** • Initial calculations were for a sample size of 194 women to detect statistical significance. After the study was done, a power analysis showed only a 70% power to detect the difference. • The results of the study were neither statistically significant or clinically significant.

for labor. Sample size total was 201 women; 93 in Foley plus oxytocin group and 108 to oxytocin alone group. Exclusion criteria: active labor, infection, abruption, latex allergy, prior cesarean, fetal anomalies, category II or III fetal heart rate tracings. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	in Foley group, 16F Foley placed and inflated to 30 mL and taped to thigh with gentle traction. If not expelled in 12h, Foley was removed. Primary outcome was interval from induction to delivery. Secondary outcomes of note: cesarean delivery, vaginal delivery in 24h, 48h, infection, complications, and neonatal complications. Planned sample size was determined after a power analysis was performed and minimum sample size needed to detect statistical significance was 194.	• No statistically significant differences in indication for cesarean between the two groups. **Conclusion:** In patients with PROM, there was not a statistically significant difference between using oxytocin alone or Foley with oxytocin in shortening the duration of labor.	
Author Recommendations: Further studies should be done to confirm these results; preferably with higher power.			
Implications: • This study did not show any significant difference in duration of labor between the two methods even though there was a slightly shorter duration in the Foley group. • This study also did not show any statistically significant difference in rate of cesarean, even though the oxytocin alone group did have a slightly higher rate. • A study with a larger sample size should be done to detect any statistically significant differences.			

Source: Macones, G. A., Cahill, A., Stamilio, D. M., & Odibo, A. O. (2012). *The efficacy of early amniotomy in nulliparous labor induction: A randomized controlled trial* doi://doi-org.ezproxy.bethel.edu/10.1016/j.ajog.2012.08.032			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To assess whether early amniotomy reduces the duration of labor or increases the proportion of subjects who are delivered within 24 hours in nulliparous patients with undergo labor induction. **Sample/Setting:** Study performed at Washington University in St Louis and the University of Pennsylvania. A total of 585 patients were randomized into two groups; 292 to early amniotomy and 293 to standard management. Inclusion criteria: nulliparity, singleton, term gestation, need for labor induction. **Johns Hopkins Evidence Appraisal Level of Evidence:** Level I	**Study Design**: Randomized controlled trial. **Instruments**: A permuted block randomization procedure was used to formulate assignment lists to assure close to equal numbers of subjects in each group; a uniform block size of 4 was used. Information was gathered during the induction/delivery with additional information gathered from chart review. **Methods:** Eligible subjects were approached by trained research nurses and were offered enrollment into the trial. After informed consent was received, subjects were randomized into one of two groups. Early amniotomy was performed prior to 4cm. Standard management was amniotomy done after 4 cm. The decision for amniotomy in the standard treatment	**Results:** • Early amniotomy shortens the time to delivery by at least 2 hours. • Early amniotomy increases the proportion of induced nulliparous women who deliver within 24 hours. • 2 most common indications for induction were >40 weeks and gestational hypertension. • The improved labor outcomes did not come at the expense of increased complications. • Most women received misoprostol for induction, 30% received Foley bulb; most women received multiple methods. • No difference in cesarean rate between the 2 groups (rates of 41% and 40%). • Increased rates of chorioamnionitis in the early amniotomy group. • Cord prolapse occurred 2 times in	**Strengths:** • Randomization strategy effectively balanced the study groups with respect to potentially confounding effects and maximally balanced them on unmeasured confounders. • The study is relatively large in size. • Diverse group of patients with various indications and methods; leading to generalization of results. • Broad inclusion criteria and leaving decision making up to physician may lead to results translating better into clinical practice. **Limitations:** • The study was unblinded which could have potential for unequal distribution of cointerventions. • There is potential for bias. • Different induction methods were used and not

Quality: Good	group was left to the treating physicians. The primary method of induction was also at the discretion of the physicians. Statistical analyses were performed. Primary outcome was time from induction to delivery and number of women delivered within 24 h. Secondary outcomes included cesarean delivery rates, indications for cesarean, maternal complications, and neonatal complications.	early group and none in standard. **Conclusion:** Early amniotomy is a safe and efficacious adjunct in nulliparous labor inductions.	addressed by the study; there was not a standard induction method or induction protocol followed- this was left completely up to the physicians
Author Recommendations: Early amniotomy does shorter the duration of labor in nulliparous inductions and should be considered for use in adjunct with inductions.			
Implications: • Early amniotomy should be considered for use to shorter labor in inductions, but more research on how that plays a role with different induction methods/protocols should be done to determine other confounding factors.			

Source: Makarem, M. H., Zahran, K. M., Abdellah, M. S., & Karen, M. A. (2013). Early amniotomy after vaginal misoprostol for induction of labor: A randomized clinical trial. *Archives of Gynecology and Obstetrics, 288; 2*(2), 261-265. doi:10.1007/s00404-013-2747-6			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To test the effectiveness and safety of early amniotomy after vaginal misoprostol for the induction of labor at term. **Sample/Setting:** Women's Health Center, Assiut University, from September 2008 to December 2010. A total of 320 patients; 160 to each group. Patients with medical or obstetric indication for labor induction were approached for inclusion. Inclusion criteria: at least 36 weeks, singleton living fetus, cephalic presentation, AFI more than 5cm, reactive non-stress test. Exclusion criteria: macrosomia, fetal anomalies, growth restriction, uterine scars, PPROM, head not applied	**Study Design**: Randomized controlled trial **Instruments**: Randomly assigned to a group by a computer-generated randomization table and allocation kept in consecutively numbered sealed opaque envelopes; data collected during induction process and obtained from chart review. **Methods:** After random assignment to intervention or control group. Patients received Misoprostol 50 micrograms vaginally every 6 h until labor achieved or maximum of 200 micrograms. Early amniotomy was done for group A when cervix was at 3 cm, provided head well applied to cervix. Group B did not have amniotomy done and either had SROM or AROM as judged by senior resident. Primary outcome was successful induction by	**Results:** • Groups were similar in baseline characteristics including indication for induction. • More subjects in amniotomy group achieved vaginal delivery within 24h, than in control group. • Shorter duration of labor in amniotomy group by about 4 h. This was statistically significant. • No difference in neonatal outcomes or maternal complications. • Early amniotomy group had fewer cesarean deliveries than control group but that difference was not statistically significant. **Conclusion:** In well-selected cases, early intervention with amniotomy after vaginal misoprostol for labor induction has a higher rate of vaginal delivery within 24 h and a shorter induction interval.	**Strengths:** • Randomized study • Adequate sample size. • Diversity of patient population increases ability to generalize results. **Limitations:** • Study was not blinded to either participants or providers. • Performing amniotomy in control group was left up to the discretion of the provider.

on cervix at time of amniotomy. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	vaginal delivery within 24 h. Secondary outcomes were induction to delivery interval, amniotomy delivery interval, duration of labor, number of misoprostol doses, need for oxytocin, and neonatal outcomes.		
Author Recommendations: Early amniotomy should be considered for patients undergoing misoprostol induction when feasible to help with increased rate of vaginal delivery.			
Implications: • This study shows that early amniotomy may be associated with a shorter duration of labor without increasing the rate of cesarean.			

Source: Schoen, C. N., Grant, G., Berghella, V., Hoffman, M. K., & Sciscione, A. (2017). Intracervical Foley catheter with and without oxytocin for labor induction: A randomized controlled trial. *Obstetrics and Gynecology, 129; 6*(6), 1046-1053. doi:10.1097/AOG.0000000000002032			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To evaluate whether adding oxytocin to preinduction cervical ripening with a Foley catheter increases the rate of delivery within 24 h. **Sample/Setting:** From January 2015 to July 2016, at Thomas Jefferson University Hospital in Philadelphia and Christiana Care Hospital in Newark, Delaware, 323 patients were enrolled in the study; 184 nulliparous and 139 multiparous. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	**Study Design**: Randomized controlled trial **Instruments**: Information was recorded during labor induction and obtained from chart reviews. Research Electronic Data Capture used to support data collection. Randomization completed by computer software; done separately for nulliparous and multiparous **Methods:** Women scheduled for labor induction meeting the criteria were approached and offered participation in the study. Written consent was obtained. Patients were randomly assigned to either concurrent use of oxytocin with Foley catheter or sequential use of oxytocin. Depending on the site and provider, either a 16 F 30 mL balloon (inflated to 60 mL), 75 mL Foley balloon (inflated to 60mL), or a Cook double-balloon catheter was placed.	**Results:** • Baseline characteristics were similar among the groups. • A total of 90 nulliparous and 71 multiparous were assigned to Foley with concurrent oxytocin. • A total of 94 nulliparous and 67 multiparous were assigned to Foley followed by oxytocin. • In nulliparous, the rate of delivery within 24 h with Foley and oxytocin was 64% compared to 43% in women with Foley followed by oxytocin. • In multiparous, rate of delivery in 24 h was higher in concurrent group (87% vs 72%) • Nulliparous, Foley and oxytocin had a Cesarean rate of 42%. Foley then oxytocin had a rate of 32% • Multiparous Foley and oxytocin had a 13% cesarean compared to Foley followed by oxytocin which was 16%.	**Strengths:** • The study was powered for parity; which allowed it to detect differences in the primary outcome. • Population is generalizable given it was multicentered and diverse. • Management after Foley expulsion was left to the discretion of the provider; so, it holds more similarities to clinical practice. **Limitations:** • Study was not blinded. • Different catheters were in use, but all were inflated to 60 mL. • Primary outcome and safety were not powered for all the subgroups. • Differences in secondary outcomes (such as mode of delivery) might lack statistical power/significance.

	For Cook catheter, only the internal os balloon was inflated to 60 mL (both were not inflated). Oxytocin was administered either at the time of placement of balloon or after removal (either spontaneous or after 12h). Oxytocin started at 2mU/min and increased by 2mU/min every 30 minutes with a maximum of 40mU/min as tolerated by mother and fetus. If active labor started during Foley placement oxytocin was not used. Primary outcome was vaginal delivery in 24h or less. Secondary outcomes were time to Foley expulsion, change in Bishop score, the need for additional ripening, analgesia, time in second stage, delivery within 12 h, total time to delivery, duration of oxytocin use, mode of delivery, and maternal and neonatal complications.	**Conclusion:** Induction with concurrent oxytocin infusion added to Foley significantly increased the rate of delivery within 24 hours in both nulliparous and multiparous when compared with Foley followed by oxytocin.	
Author Recommendations: Combination methods such as Foley catheter with concurrent oxytocin use should be considered to help shorter the duration of labor. Further research should look at combination methods with larger sample sizes to confirm these results.			

Implications:

- Combining Foley catheter use with oxytocin does show shorter duration of labor.
- Concurrent use of Foley and oxytocin in nulliparous does have a higher rate of cesarean but this study lacked power to show if this is a statistically significant difference.

Source: Seyb, S. T., Berka, R. J., Socol, M. L., & Dooley, S. L. (1999). *Risk of cesarean delivery with elective induction of labor at term in nulliparous women* doi://doi-org.ezproxy.bethel.edu/10.1016/S0029-7844(99)00377-4			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To quantify the risk of cesarean delivery associated with elective induction of labor in nulliparous women at term. **Sample/Setting:** All term nulliparous women admitted to the labor and delivery unit at Prentice Women's Hospital of Northwestern Memorial Hospital from November 1996 to June 1997 were considered. Inclusion criteria was women laboring with a singleton fetus in vertex presentation at 37 weeks or later. Women undergoing cesarean delivery without labor were excluded. 1561 women met the inclusion	**Study Design:** Non-experimental Cohort observational study **Instruments:** Data collected from Prentice Women's Hospital of Northwestern Memorial Hospital during an 8-month period. **Methods:** All term (at least 37 weeks) nulliparous women during the 8-month period with vertex, singleton gestation were divided into three groups: Spontaneous labor, elective induction, and medical induction. The risk of cesarean delivery was determined using stepwise logistic regression to control for potential confounding factors. Indications for medical induction: gestational age over 41 weeks, premature rupture of membranes, fetal growth restriction, preeclampsia, chronic hypertension, nonreassuring fetal	• **Results:** • Women undergoing elective induction tended to be older, white, and to have a private obstetrician. The mean BMI was higher in the medical induction group than in the other two groups; which was found to be statistically significant. • Women in the elective induction group tended to have an epidural analgesia more frequently than the other 2 groups. • Cervical ripening was used for 55 women in the medical induction group and for 21 women in the elective induction group. • Cesarean delivery rate for spontaneous labor group was 7.8%. • Medical induction cesarean rate was 17.7%. • Elective induction cesarean rate was 17.5%. • Factors	**Strengths:** • This study had a large sample size (n=1561). • Those conducting the study did do a power calculation to estimate a minimum number for the sample size for each group. • This study considered multiple factors that might impact mode of delivery. • This study clearly explained the inclusion and exclusion criteria for the study. • The study was able to show statistically significance for the findings. **Limitations:** • The data was collected from one hospital; so, although many different providers practice (deliver) at this facility, the results may not be the same at another facility. • This study did not look at the

criteria for the study. Spontaneous labor (n=1124) Elective induction (n=143) Medical induction (n=294) **Johns Hopkins Evidence Appraisal** **Level of Evidence:** Level III **Quality:** Good Quality	surveillance (nonreactive nonstress test or amniotic fluid index <5), macrosomia, diabetes mellitus, and other (cholestasis of pregnancy, maternal thrombocytopenia, recurrent nephrolithiasis). Indications for elective induction group: elective (term, favorable cervix or "impending" postdates), "suspect" preeclampsia, "suspect" fetal growth restriction, "suspect" macrosomia, decreased amniotic fluid (but > 5), and other (history of multiple pregnancy losses, idiopathic polyhydramnios, remote history of genital herpes, paraplegia, gastroenteritis, family history of preeclampsia, successful external cephalic version, history of cholelithiasis, infertility with donor oocyte). Criteria for spontaneous labor were regular, painful uterine contractions together with either complete cervical effacement or	associated with higher cesarean delivery risk: elective or medical induction, maternal BMI greater than 26, gestational age of 40 weeks or greater, birth weight greater than 4000g, PROM, epidural use, magnesium sulfate use in labor, and chorioamnionitis. • Most common indication for cesarean delivery was labor dystocia. • Induction of labor required significantly more time on labor and delivery than spontaneous labor and was associated with a longer postpartum stay. No increase in postpartum complications. • Neonatal outcomes were not statistically significantly different among the three groups. • Cost analysis was lowest for spontaneous labor. Increased for elective induction by 17.4% and by 29.1% for the medical induction group. • Risk of cesarean was twice as high if there was	different interventions used for induction.

	rupture of membranes.	epidural placement before 4 cm dilation than if epidural was placed later. • **Conclusion:** Both elective and medically indicated labor inductions are significant risk factor for cesarean delivery. • There is an increased cost burden for both elective and medically indicated labor inductions.	
Author Recommendations: • That it is prudent to consider other pain management techniques prior to 4 cm dilatation; holding off on epidural placement until after that 4 cm. • To not perform inductions for liberal indications; rather to perform them for appropriate medical indications.			
Implications: • That induction increases the risk of cesarean delivery, more than twice as likely to occur for an induction than when compared with spontaneous labor. • That there is an increased cost occurred with inductions than with spontaneous labor. • Hospital stays are longer with inductions than with spontaneous labor.			

Source: Tam, T., Conte, M., Schuler, H., Malang, S., & Roque, M. (2013). Delivery outcomes in women undergoing elective labor induction at term. *Archives of Gynecology & Obstetrics, 287*(3), 407-411. doi:10.1007/s00404-012-2582-1			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To determine elective induction of labor outcomes in term, low-risk women who delivered in a community teaching hospital. **Sample/Setting:** Women admitted from January 2006 to January 2010 for elective induction of labor at a community teaching hospital (resurrection Healthcare/Saint Joseph hospital). Low risk patients between 39 and 41 weeks with singleton pregnancies in vertex presentation. 1,159 women identified and of those 848 were included in the sample size for the study. **Johns Hopkins Evidence Appraisal Level of**	**Study Design**: Retrospective cohort observational study **Instruments**: Manual chart review. Descriptive statistics, frequencies and percentages were reported using multiple regression analysis, analysis of variance, and effect tests with respective values. Data analyzed using JMP software by SAS Institute Inc. **Methods:** Data abstracted from manual chart review. Data was de-identified in accordance with HIPPA regulations. The office of the Institutional Review Board at Resurrection Health Care/Saint Joseph Hospital approved the study. Data included patient demographics, admission cervical examination and induction method. Outcome measures were delivery method and cesarean indications.	**Results:** • Ages ranged from 16-43 years old. Mean age 28.2 • Mean gestational age was 39.9 weeks. • The majority of patients had oxytocin as the primary induction agent. • There is a statistically significant shorter length of induction for patients induced with AROM and oxytocin. • Having a parity of >1 held statistical significance for a vaginal delivery. • The majority of patients who had cesarean delivery were nulliparous. **Conclusion:** • The use of oxytocin on women with unfavorable cervical exams resulted in a higher rate of cesarean. • Oxytocin was the only induction method that showed to have significantly less time to delivery.	**Strengths:** • Large sample size. • Study did look at induction agents that were used together. **Limitations:** • Study included both nulliparous and multiparous women. • The study was done at only one facility which may make the results not as applicable to other facilities.

Evidence: Level III **Quality:** Good Quality	Time categories were length of induction-which was determined from initiation of induction method until delivery. Exclusion criteria: prepregnancy medical conditions (include but not limited to pre-gestational diabetes, chronic hypertension, cardiac disorders, and neurological disorders), gestational diabetes, gestational hypertension, preeclampsia, polyhydramnios, oligohydramnios, prior hysterotomy, and multiple gestations. Fetal exclusion criteria: intrauterine growth restriction, intrauterine fetal demise, known fetal anomaly, nonreassuring fetal heart tracing, fetal malpresentation on admission, and gestational age > 41 weeks. Induction methods include oxytocin, prostaglandin cervical ripening agents (dinoprostone or misoprostol), mechanical dilator with cervical ripening balloon or amniotomy. For the purpose of the study only the initial induction method was	• Cervical ripening catheter had the longest time to delivery. • A favorable initial cervical exam for elective induction results in a higher rate of vaginal delivery.	

	analyzed even though multiple methods in combination were often used.		
Author Recommendations: • Initial cervical exam is an important factor in deciding which of the several induction methods to choose for induction of labor. Women with unfavorable exams should have steps that make the cervix more favorable before oxytocin is started. • Other hospitals can use the same methodology as this study to determine criteria for elective inductions.			
Implications: • Inductions are more successful if the cervix is favorable; bishop score should be taken into consideration with which induction method is being used. • Oxytocin use with unfavorable cervix resulted in a higher rate of cesarean section. Should perform interventions to make the cervix favorable prior to starting oxytocin. • Oxytocin resulted in shorter time to delivery than cervical ripening catheter or prostaglandin agents for cervical ripening.			

Source: Wollmann, C. L., Ahlberg, M., Petersson, G., Saltvedt, S., & Stephansson, O. (2017). Time-to-delivery and delivery outcomes comparing three methods of labor induction in 7551 nulliparous women: a population-based cohort study. *Journal of Perinatology*, *37*(11), 1197-1203. doi:10.1038/jp.2017.122			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: Determine time to delivery and mode of delivery in labor induction among women with unripe cervix. **Sample/Setting:** 7551 nulliparous women with singleton deliveries at 37 weeks or greater gestation with induced labor from January 2008 to October 2014 at seven hospitals. Only live-birth in cephalic presentation and Bishop scores less than or equal to 6. **Johns Hopkins Evidence Appraisal** **Level of Evidence: Level III** **Quality: Good Quality**	**Study Design**: Non-experimental, retrospective chart review. Descriptive design. **Instruments**: Data was collected from the population-based Stockholm-Gotland Obstetric Cohort. This database contains daily automatically forwarded data from electronic medical records systems. **Method**: Participant information was obtained from the database. all nulliparous women with a singleton, live-born infant in cephalic presentation at 37 completed gestational weeks or later with induced labor from 21 January 2008 and until 22 October 2014 were included. Women registered with more than one first induction method or Bishop Score 7 or more were excluded.18 Incomplete Bishop Score (five components	• In vaginal deliveries and cesarean deliveries due to labor dystocia and induction, mean time-to-delivery was 2.1 h and 9.8 h shorter in women induced with misoprostol and balloon catheter respectively, compared with women induced with dinoprostone. • 95% of women induced with the balloon catheter delivered within 24 h, whereas only 55% and 54% where delivered within 24 h for the misoprostol and dinoprostone group respectively. **Conclusion:** the balloon catheter compared with prostaglandins had a significantly shorter length of labor, with no difference in mode-of-delivery or adverse maternal and neonatal outcomes	**Strengths:** the population-based design with access to prospectively collected data in standardized electronic medical records and templates including maternal characteristics, pregnancy and delivery information, such as Bishop Score at induction start, data on labor progress, interventions during delivery and neonatal outcome. Because data on exposure was recorded before outcome there was no possibility for recall bias. The large sample size of more than 7500 induced primiparous women enabled them to study time-to-delivery and adverse maternal and neonatal outcomes with high statistical power. **Limitations:** collected data was not specially designed to answer the study questions and there is always a risk of

	ordinarily evaluated) were considered as missing. The primary outcome was time-to-delivery from the start of the induction. Women with c-section due to fetal distress were excluded.		residual confounding. Further, some women with induced labor might not have been recorded as inductions and therefore not included in the study population. Oxytocin augmentation was more often used in the balloon catheter group; however, they considered oxytocin as a mediator rather than a confounder and consequently did not adjust for it in the multivariable analysis. Since induction methods were not blinded in the study, this may have influenced other aspects of the labor management, for example, it is possible that the increased use of oxytocin may be an explanation for the shorter duration-of delivery in the balloon catheter group. A separate study would have to investigate the different usage of oxytocin in balloon catheter versus prostaglandin inductions. Higher usage of epidural anesthesia is rather a signal of pain than different

			administration by induction method. On the contrary epidural has been associated with longer deliveries and would therefore have a negative influence on time-to-delivery. Due to limitations in the data they had no possibility to report on the magnitude of additional interventions during labor such as number of misoprostol doses, cumulative dose of oxytocin, occurrence of tachysystole with fetal heart rate tracing abnormalities, and need for tocolysis.
Author Recommendations: Performing randomized controlled trials with the different interventions and having more control in future studies.			
Implications: Trans-cervical balloon catheter inductions did show a decrease in length of labor when compared with medication methods for cervical ripening. This study answers part of the PICO question on how trans-cervical balloon catheter inductions and medications impact labor duration.			

Source: Wu, X., Wang, C., Li, Y., Ouyang, C., Liao, J., Cai, W., . . . Chen, H. (2018). Cervical dilation balloon combined with intravenous drip of oxytocin for induction of term labor: A multicenter clinical trial. *Archives of Gynecology & Obstetrics, 297*(1), 77-83. doi:10.1007/s00404-017-4564-9			
Purpose/Sample	**Design (Method/Instruments)**	**Results**	**Strengths/Limitations**
Purpose: To investigate the effectiveness and safety of a method combining double-balloon catheter for cervical ripening and intravenous drip of oxytocin on the induction of term labor, providing reference for clinical safety. **Sample/Setting:** Total of 120 term pregnant women hospitalized between January 2015 and June 2015 at Longgang District Center Hospital of Shenzhen, China. Each group had 60 patients. Inclusion criteria: 18-40 years, 37-41 weeks gestation, Bishop score <6, single live fetus with cephalic presentation, without premature rupture of membranes, reactive NST. Exclusion criteria:	**Study Design**: Randomized controlled trial. **Instruments**: Data collected during induction process and additional data retrieved from reviewing patients' chart. **Methods:** Patients randomly divided into research group (double-balloon with oxytocin) or control group (oxytocin). Informed consent obtained. Study approval from IRB. Oxytocin was increased every 15 minutes until regular contraction pattern was achieved. Double-balloon catheter was placed, and each balloon filled with 80 mL saline. Remained in place for 12h unless spontaneous expulsion occurred. After removal AROM was performed, if not in labor after 1 h, oxytocin was started with the same dosing as the control group. If patients were not in	**Results:** • No major difference in baseline characteristics of the two groups. • The group that used double-balloon catheter and oxytocin had statistically significant higher rates of successful induction, vaginal delivery rate, and decreased duration of labor. • No significant differences in maternal or neonatal complications. • The oxytocin only group had a 36.67% rate of cesarean compared to a 6.67% rate in the double-balloon and oxytocin group. **Conclusion:** Compared to labor induction of oxytocin, the method of combining double-balloon catheter for cervical ripening and oxytocin for induction of labor has a higher vaginal delivery rate, shorter total duration of labor and does not	**Strengths:** • Patients randomly assigned • Results were statistically significant. **Limitations:** • Small sample size; may make generalization of results difficult.

severe maternal complications, contraindications for vaginal delivery, or fetal anomalies. **Johns Hopkins Evidence Appraisal** **Level of Evidence:** **Level I** **Quality: Good**	active labor after 48h; induction was considered a failure.	increase the incidence of postpartum hemorrhage and neonatal infection. It is a safe and effective method for induction of term labor.	
Author Recommendations: Double-balloon catheter use with oxytocin decreases the duration of labor and the rate of cesarean when compared with oxytocin use alone for induction.			
Implications: • Double balloon catheter use with oxytocin is safe and effect for labor induction. • It results in shorter duration of labor and lower rate of cesarean.			