Southern California CSU DNP Consortium

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CERVICAL RIPENING BALLOON: EVIDENCE FOR SAFETY IN VAGINAL BIRTH AFTER CESAREAN

A DOCTORAL PROJECT
Submitted in Partial Fulfillment of the Requirements
For the degree of
DOCTOR OF NURSING PRACTICE

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ABSTRACT

In the United States, cesarean birth rates are among the highest in the world. A significant contributor to this is that many women who have had a cesarean birth are not offered a trial of labor after a cesarean (TOLAC) in the subsequent pregnancy. Although research and current recommendations of obstetrics organizations support the benefits and safety of vaginal birth after cesarean (VBAC), rates remain low. Of women with prior cesarean, the subset least likely to be offered TOLAC is women who require induction of labor. Methods to induce labor are available for the woman desirous of a TOLAC, but are often not offered due to provider hesitancy related to multiple factors: fear of litigation; perceived or real lack of emergency resources in the case of a traumatic uterine rupture; and lack of knowledge regarding the efficacy and safety of certain induction approaches. The cervical ripening balloon is an approach with demonstrated safety and efficaciousness in women without prior cesarean; however, it has been studied less in women with prior cesarean.

For this doctor of nursing practice project, a literature review was conducted to determine the available evidence on the use of a mechanical, non-pharmacologic approach, the cervical ripening balloon (CRB), for women with prior cesarean who desire a TOLAC and require induction of labor. In order to ensure the preservation of rigor in this integrative review the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) framework was employed.
Key MeSH terms, VBAC, vaginal birth after cesarean section, knowledge, induction, and balloon across four databases yielded 402 abstracts, which were reviewed. A total of 11 English language studies with 1,118 patients are included in the table of evidence. The primary outcome, average uterine rupture rate was 0.6% and the secondary outcome, VBAC success rate averaged 62%. Preliminary evidence points to safety in the use of CRB in TOLAC patients; however, further studies are needed.
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ACKNOWLEDGMENTS

From the day that I decided to apply for the doctoral program, the difficult decision to delay my admission date, to the night before the first class when I almost withdrew, the countless reviews and edits of my papers, the constant encouragement, support, and love, my husband and best friend Bill has been by my side. I would have never completed this journey without him and for that I will be forever grateful. I’m the lucky one.

To my children, Rob, Elizabeth, son in law, Jimmy, and granddaughter Nina, thank you for trusting in me. It is my hope that my example of what can be accomplished at any age will give you the strength and courage to live your dreams. I am so very proud of all of you. Thank you to my parents, Ken and Phyllis Anderson; your constant examples of love and guidance built the foundation that allowed me to pursue my dream of obtaining a doctoral degree.

Words cannot express my sincere gratitude to my chair, Dr. Ruth Mielke. Her persistent yet gentle expert guidance along this journey made it possible for me to have the courage to visualize and bring this project to a reality. To Dr. Penny Weismuller, my committee member, your never-ending faith in me, and your words of wisdom gave me the strength to continue when I didn’t believe in myself. To Dr. Dana Rutledge for her insights and countless generous comments from spring of 2015 and beyond. And to Sarah Douville, MBA for her utmost patience with my never ending questions, emails, and venting sessions.
BACKGROUND

Problem Statement

In the United States, cesarean birth rates are among the highest in the world. A significant contributor to this is that in subsequent pregnancies, women with prior cesarean births are not always offered the option of a trial of labor after a cesarean (TOLAC). As excellent maternal and fetal outcomes support the safety of vaginal birth after cesarean (VBAC) (Guise et al., 2010), one would expect TOLAC rates to increase. However, the numbers of women attempting a TOLAC have remained constant. Often, women desiring a TOLAC are not offered this option due to provider hesitancy particularly when induction of labor is indicated. In addition, when TOLAC is an option, women may wish to avoid the use of medications such as oxytocin and prostaglandin E2, but may be open to a non-pharmacological method such as a cervical ripening balloon (CRB) to initiate induction of labor (IOL). This doctoral project included an integrated literature review and the findings were written in a manuscript. The focus, the efficacy and use of cervical ripening balloons for women with a prior cesarean was written for submission to the Journal of Midwifery. The manuscript, a systematic review, used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher, Liberati, Tetzlaff, & Altman, 2009) in order to demonstrate the safety of CRB in IOL with TOLAC.

Trends in Cesarean Deliveries

Cesarean birth rates are at an all-time high and are continuing to rise in all developed nations (OECD, 2013). In 1996, in the United States, 21 babies out of 100 were delivered by cesarean and by 2009, 33 out of 100 were delivered by cesarean.
et al., 2011; Menacker & Hamilton, 2010; Osterman & Martin, 2014). The number of cesareans increased 71% from 1996 to 2007 making cesarean delivery the most common surgical procedure in the United States (Main et al., 2011; Menacker & Hamilton, 2010).

There is wide variability in cesarean rates across the United States. In California hospitals with more than 100 deliveries a year, overall rates range from 18-51% and in low risk women, from 9-51% (Main et al., 2011). In 1995, the World Health Organization (WHO) recommended 15% as the target rate for cesarean deliveries in all countries (Gibbons et al., 2010; Main et al., 2011). Similarly, the American College of Obstetricians and Gynecologists (ACOG, 2010) proposed a target rate of 15.5% in low risk women pregnant with their first baby (nulliparous and singleton) in the head down (vertex) position. These recommended thresholds have not been met; as a result, in the recent Healthy People (HP) 2020 objectives, the readjusted goal is a cesarean rate of 23.9% or a 10% reduction from 2007 to 2020. Even so, the data does not demonstrate an appreciable decrease in this rate since the 2007 rate of 26.5% (Healthy People 2020, 2015a).

Another approach to reduce overall cesarean rates is to decrease recurrent cesarean deliveries. Therefore, HP 2020 also recommended doubling the percentage of women experiencing VBAC (Healthy People 2020, 2015; Main et al., 2011). But in fact, the rate of women attempting a TOLAC decreased from 28.3% of all live births in 1996 to 8.7% in 2010 (Guise et al., 2010). Currently, 90% of women will deliver by repeat cesarean rather than attempting a VBAC (Guise, 2010, Healthy People 2020, 2015). The most recent ACOG practice bulletin on VBAC states, “the current VBAC rate of 8.5% is not acceptable.” (ACOG, 2010)
The high rate of cesareans in the U.S. increases the overall cost of giving birth, thereby depleting resources that could be directed to improve maternal/infant outcomes. In 2009, the cost of a cesarean delivery in California was $6,200 more than that of a vaginal delivery (Main et al., 2011). Preventing cesareans and lowering hospital cesarean rates to the WHO recommended 15% would result in an overall cost savings of $441.5 million annually (Main et al., 2011). Therefore, the overuse of cesarean delivery in the United States is a critical public health issue that must be addressed at various levels in order to better utilize health resources and improve the health of mothers and newborns.

**Prevention of Cesarean Deliveries**

Despite the near doubling of cesarean deliveries over the past decade, minimal documented health benefit for newborns and mothers exists (Main et al., 2011). Both ACOG and the Society for Maternal Fetal Medicine have noted that the increase in cesarean deliveries has not been justified as no improved maternal or fetal outcomes have resulted (ACOG, 2014). In a 2011 population study, the most common reasons for primary cesarean delivery were (a) mothers not progressing through labor fast enough as determined by providers, (b) mothers not delivering in an arbitrarily prescribed time period, or (c) abnormal or difficult to interpret fetal heart rate tracings in labor causing provider concern for fetal safety (Barber et al., 2011). Such reasons highlight the influence of provider personal beliefs and interpretations on the decision for a cesarean.

The Joint Commission is also paying attention to the alarming rise in cesarean rates and recommends hospitals with more than 1,100 deliveries per year to work toward reducing these rates in first-time mothers (Dekker, 2013). Beginning January 2014, the Joint Commission advised that hospitals publicly report perinatal core measures, one of
which is the cesarean delivery rate in low risk women. Although not consistently defined, “low risk” involves pregnancies in nulliparous women with singleton vertex babies (Dekker, 2013; Milton, 2014).

Cesarean delivery in general increases the risk of severe maternal morbidities three fold as compared to vaginal delivery ("Obstetric Care Consensus: Safe Prevention of the Primary Cesarean Delivery," 2014; Signore, 2012). Such morbidities include transfusion, hysterectomy, ruptured uterus, surgical injury, cardiac arrest, renal failure, anesthesia complications, infection, deep vein thrombosis, wound disruption or hematoma, and the need for assisted ventilation. The risk for these morbidities with vaginal delivery is 0.9% while for cesarean is 2.7% (Liu et al., 2007).

Prevention of the primary cesarean is but one aspect of reducing the overall cesarean rate and thereby improving maternal outcomes. Concurrently, there must also be efforts to decrease recurrent cesarean delivery. Women experiencing recurrent cesarean delivery incur not only the immediate risks associated with cesarean delivery but also lifelong risks in subsequent pregnancies that include painful adhesions, infertility, abnormal placentation, amniotic fluid embolism, unplanned hysterectomy, and respiratory morbidity. By the third cesarean delivery, the risk for placenta accreta (invasive placental implantation) is 40%, which increases risk of maternal death and has neonatal consequences; Neonatal Intensive Care Unit (NICU) admission and even neonatal death (Silver et al., 2006). Overall, maternal mortality is more than tripled when women have elective repeat cesarean delivery (ERCD) (13/100,000), compared to VBAC (4/100,000) (Signore, 2012). Primarily these risks are avoided by preventing the first
cesarean. Secondarily they are reduced when maternal choice for a TOLAC is supported, thereby minimizing risk for recurrent cesareans.

**Statement of the Problem**

Coupled with the rise in primary cesarean delivery is the decline in women who experience VBAC. Rates of women attempting a TOLAC have decreased from 28.3% of all live births in 1996 to 8.7% in 2010 (Guise et al., 2010). Fear of litigation is the primary reason for these reduced rates (Schifrin & Cohen, 2013). The decline is also related to other factors: smaller hospitals not having resources for in-house emergency providers; increase in reimbursement rates for repeat cesarean delivery; provider impatience or failure to allow for physiologic labor; and providers not discussing VBAC as an option (Guise et al., 2010).

Education and accurate informed consent are keys to prevention of second cesarean deliveries. Findings from two studies, one each from the U.S. and Scotland, indicate that women were more likely to have an ERCD when TOLAC options were not discussed with them, or by clinicians not educating patients of the risks and benefits of such options (Cleary-Goldman, Cornelisse, Simpson, & Robinson, 2005b; Renner, Eden, Osterweil, Chan, & Guise, 2007). Further, women value provider opinions over those of partners, family members, or the Internet (Guise et al., 2010).

Moreover, while the numbers of women who are offered TOLAC has dropped, the success rate for those attempting VBAC has remained constant. In the U.S., 74% of women who attempted VBAC were successful (Guise et al., 2010). Therefore, educating women about risks and benefits of ERCD could help increase numbers of women who attempt a TOLAC (Scaffidi, Posmontier, Bloch, & Wittmann-Price, 2014).
Local Problem

As a certified nurse-midwife (CNM) who works in a facility that meets ACOG criteria to offer women VBAC, I have observed an increase in women who are unhappy with previous birth experiences, and who seek less intervention with subsequent deliveries along with safety. I struggle to undo the distrust created by these earlier experiences. In some instances, the trust issues cross the lines of safety. While women’s concerns may cause internal conflict, I strive to find a safe compromise that makes everyone comfortable. In our large group practice with providers having different experience levels and education, I seek to defend patient rights to be adequately informed in order to ensure they understand risks and benefits with the choice of TOLAC over ERCD.

Significance of the Problem

The safety of VBAC for women in spontaneous labor is generally well-accepted. Recent evidence also supports induction of labor in women desirous of a VBAC (Ouzounian, Miller, Hiebert, Battista, & Lee, 2011; Shatz et al., 2013). This is in contrast to prior assertions that VBAC was unsafe when induction agents were necessary ACOG, 2002, 2004). Concerns related to induction of labor in women with prior cesarean have largely been associated with the use of prostaglandins. Specifically, misoprostol is one such prostaglandin, which has been associated with uterine rupture rate of 6% (Ophir, Odeh, Hirsch, & Bornstein, 2012). Despite studies suggesting lower complication rates with prostaglandin cervical ripening agents, in 2006 ACOG continued to discourage their use in women with prior cesarean needing cervical ripening (ACOG, 2006; Ouzounian et al., 2011). As a result, many hospitals prohibited labor induction for women who want a
TOLAC, and only women with signs of spontaneous labor (e.g., with contractions or ruptured membranes prior to labor onset) are allowed TOLAC.

However, the most recent ACOG practice bulletin supports induction of labor with oxytocin for maternal or fetal indications as an option for women undergoing a TOLAC, even allowing that women with two previous cesarean deliveries may be considered candidates (ACOG, 2010). Use of misoprostol was still not recommended for cervical ripening and given limited data; no conclusions were drawn as to whether another prostaglandin (E2) should be avoided. The bulletin deems mechanical dilation methods such as cervical ripening balloon as possibly useful for TOLAC candidates with an unfavorable cervix (ACOG, 2010). In spite of these recommendations, many providers do not offer the option of induction of labor in women desirous of a TOLAC (Schifrin & Cohen, 2013).

For many women, cervical ripening is critical prior to induction. A woman with a cervix that is ready or “ripe” as determined by a pre-labor Bishop score (Figure 4) has a much better chance for a successful induction. In women with an unripe cervix, cervical ripening agents can be used to prepare the cervix for labor. Choices of such agents include two pharmacological approaches (prostaglandins, oxytocin) and two mechanical methods (amniotomy, cervical ripening balloon).

Provider reluctance to offer cervical ripening is in part related to conflicting evidence as to which options are reasonably safe and will best optimize VBAC success. To date, more studies have suggested that selected prostaglandins and/or oxytocin may be safe for labor induction due to fetal or maternal indications. (Ouzounian et al., 2011). However, fewer studies have reported outcomes of mechanical methods – specifically the
cervical ripening balloon. As a non-pharmacologic agent, the cervical ripening balloon is less likely to cause uterine hyper stimulation (Jozwiak et al., 2012) and is a safe and efficacious method for induction of labor in women with a prior cesarean delivery (Shatz et al., 2013). Therefore, focused attention to the outcomes of the less-studied, but promising use of the cervical ripening balloon in women desirous of VBAC may promote provider acceptance of this modality and in so doing increase rates of VBAC in the United States.

**Supporting Framework**

Figure 1 demonstrates the framework for the project. The population of interest was women who desire a TOLAC to achieve a VBAC. For women with a favorable cervix as measured by Bishop score, amniotomy (the intentional rupture of amniotic membranes) is a reasonable approach to initiate labor. An option for women with an unfavorable Bishop score or an unripe cervix includes cervical ripening (i.e., cervical balloon ripening).

Two types of women with a history of prior cesarean delivery desiring a TOLAC were identified: those who wish to undergo induction with only non-pharmacological/mechanical methods (artificial rupture of membranes (AROM) or cervical ripening balloon); and those who agree to any acceptable method possible. Possible pathways for TOLAC are as follows:

- For women with a favorable Bishop score, AROM with or without oxytocin.
- For those with unfavorable scores, a cervical ripening balloon, or cervical ripening balloon with oxytocin.
The empirical evidence identified will be useful for making decisions for women with unfavorable Bishop scores who desire a non-pharmacologic approach to induction of labor. The research studies identified will be scrutinized for the primary outcome of interest; uterine rupture rate in women undergoing cervical ripening with a prior cesarean. The secondary outcome of interest is the VBAC success rate in this population.

**Project Goal**

For this project, the goal was to conduct a literature review using PRISMA guidelines (Moher et al., 2009) to appraise the highest level of evidence on the use of the cervical ripening balloon for women with prior cesarean who desire a TOLAC and require induction of labor. A manuscript based on the literature review was developed and will be submitted to the *Journal of Midwifery & Women’s Health.*
Figure 1. Conceptual Framework.
REVIEW OF LITERATURE

Primary Outcome: Uterine Rupture Rates

It is important for clinicians to understand uterine rupture rates in order to appropriately counsel women who wish to consider a trial of labor and if necessary, induction of labor after a prior CD. Ouzounian et al. (Ouzounian et al., 2011) assessed rates of uterine rupture in 16,218 women with one prior low transverse cesarean delivery between 1998 and 2001. For comparison purposes, the uterine rupture rate was 0.02% in women without a prior cesarean delivery \((n = 105,140)\) during that period (Ouzounian et al., 2011). Of the women with prior cesarean delivery, 6833 women underwent a trial of labor and had a uterine rupture rate of 1.1% \((p < 0.0001)\), which is consistent with similar studies of women attempting VBAC (Ophir et al., 2012; Rossi & Prefumo, 2015; Shatz et al., 2013).

Of specific interest was that the uterine rupture rates in the group attempting VBAC were not significantly different between the induction of labor \((1.2\% \text{ or } 22/1806)\) and the spontaneous labor groups \((1.0\% \text{ or } 52/5026)\) (Ouzounian et al., 2011). This finding suggests that induction of labor, which in this study was done using either oxytocin or PGE2, is a reasonable approach for women with prior cesarean. A limitation of the study was that the uterine rupture rate for women undergoing an ERCD was not reported. However, the study was strengthened by the large sample size of women who were being cared for in a single health care system with in-house providers (Ouzounian et al., 2011).

Similar uterine rupture rates to those reported by Ouzounian et al. (2011) are evident in a meta-analysis of eight studies, in which Rossi and Prefumo report uterine
rupture rates of 1.1% in the induced labor group \((n = 46/4038)\) as compared to 0.6% in the spontaneous labor group \((n = 90/13,374)\) (Rossi & Prefumo, 2015). In a systematic review of method of labor induction in women with prior cesarean, Ophir et al. similarly reported uterine rupture rates in women attempting TOLAC as being: oxytocin 1.1%; and prostaglandin (E2) 2%. Their finding that the uterine rupture rate for misoprostol (E1) was notably higher (6%) supports the contemporary reluctance to use this specific prostaglandin (Ophir et al., 2012) in women with prior CD. However, the similarity of uterine rupture rates in women who are induced by either oxytocin or prostaglandin (E2) implies that some methods of induction are associated with fewer uterine ruptures and therefore discussion of such methods is a critical component of patient counseling.

Another aspect of counseling for the women with prior CD is that even one cesarean scar increases the risk for uterine rupture in subsequent pregnancies irrespective of mode of delivery. The 2010 ACOG practice bulletin compares risk of uterine rupture in women with one CD as being 0.4-0.5% for ERCD and to the undergoing a TOLAC as 0.7-0.9% (ACOG, 2010). This is an important comparison to note as it does not support provider/ client perception that uterine rupture only occurs when VBAC is attempted.

**Secondary Outcome: VBAC Success Rates**

The likelihood for VBAC is also an important area of counseling that should be provided to women with prior CD. Spontaneous labor is associated with the highest success rates (Ouzounian et al., 2011; Rossi & Prefumo, 2015; Shatz et al., 2013). with VBAC success of 73% to 86% compared to 66%, to 67% in women requiring either oxytocin or prostaglandin (E2) induction (Ouzounian et al., 2011; Rossi & Prefumo, 2015; Shatz et al., 2013).
When the woman will likely not have spontaneous labor and induction of labor is necessary, it is important for providers to understand that VBAC success varies based on method of induction. It is also essential for providers to be cognizant of less studied but possible approaches that will minimize risk for uterine rupture while maximizing likelihood of achieving VBAC. To that end, this project focuses on the safety and efficacy for a non-pharmacologic approach—the use of a cervical ripening balloon—in women desiring at TOLAC who have a medical indication compelling consideration for delivery before the onset of labor.

**Influence of Provider Advice on Patient Decision for a TOLAC**

Appropriate provider advice plays a key role in women’s decisions for a TOLAC while inadequate or incorrect information decreases the number of women who will attempt a VBAC (Appendix B, Table 1). This is evident in that Cleary-Goldman et al. (2005) reported that 63% of women who attended a VBAC counseling program chose VBAC, compared to 38% of women not given the opportunity to attend the program. Similarly, Scaffidi et al. (2013) found that women with better knowledge of VBAC demonstrated a significant higher likelihood of choosing to attempt a TOLAC over women with less knowledge. Women valued the opinion of their providers over that of their families; only 6% discussed their decision for mode of delivery with their families (Cleary-Goldman et al., 2005b). These studies support the responsibility of the provider to provide counseling that is not only timely but also accurate.

**Bishop Score for Induction Approach**

As pregnancy approaches term, cervical collagen fibers start to soften and breakdown allowing the cervix to thin out or efface and then dilate with the onset of labor.
contractions. The Bishop Score is the sum of the assessed aspects on a cervical examination (Figure 2). Initially intended for women who previously had a vaginal delivery, it is currently also used to assess women who would benefit from cervical ripening prior to induction of labor. A Bishop score of nine can indicate a high likelihood of successful induction (Cunningham et al., 2014). What is less clear is the variation in what is believed to be an unripe or unfavorable cervix requiring pre-induction cervical ripening. In patients with an unfavorable Bishop score, the collagen fibers remain firm and the cervix is deemed unfavorable for induction of labor (Blackburn & Loper, 1992). The literature is conflicting as to which Bishop score should be used as the measurement to initiate cervical ripening prior to induction of labor (Teixeira, Lunet, Rodrigues, & Barros, 2012). In my facility, women with Bishop scores less than six can receive outpatient cervical ripening if they have not had a prior cesarean birth or uterine surgery.

Appendix B, Table 2 demonstrates the importance of determining the readiness of the cervix for induction of labor by use of the Bishop scoring system.

<table>
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<th>Bishop Score</th>
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<td><strong>SCORE</strong></td>
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<td>Station</td>
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<td>Consistency</td>
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<td>Position</td>
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*Figure 2.* Bishop score grid. Adapted from “Pelvic Scoring for Elective Induction” by E. Bishop, 1964, Obstetrics and Gynecology, 24(2), 266-268.
Cervical Ripening Balloon in Women without Prior Cesarean Birth

The cervical ripening balloon is thought to prepare the cervix for labor through mechanical dilatation of the cervix and the release of endogenous prostaglandins (Trofatter, 1992). Figures 4 and 5 show two commonly used types: the Foley cervical ripening balloon (FCRB) and the Cooks’ double balloon device (CDBD).

Appendix B, Table 3 presents evidence for the use of a CRB in women with an unfavorable Bishop score who have not experienced cesarean in prior deliveries. Cromi et al. (2006) conducted a retrospective chart review of 602 Italian women with unfavorable cervix who had FCRB (Foley-type, Figure 3) placed from January 2000 to May 2006 (Cromi, Ghezzi, Tomera, Ucella, et al., 2006). Of the 602 women, 453 were nulliparous; and all were over 37 weeks, had a Bishop score of less than 4, and a medical indication for induction of labor. The outcomes for nulliparous and multiparous women were the same:

- 26.6% achieved active labor after the balloon was placed and did not require any additional pharmacological intervention.
- 31.2% achieved a Bishop score greater than 7, but required oxytocin to continue labor.
- 42.2% had additional prostaglandin gel application for ripening.

The cesarean birth rate for women with the balloon was 25.6% The authors concluded that placement of the FCRB above the cervical os is a safe pre-induction method for cervical ripening and the concomitant risk to the mother or the baby is insignificant (Cromi, Ghezzi, Tomera, Ucella, et al., 2006).
In a randomized controlled trial of 368 Israeli women admitted with an indication for labor induction with intact membranes and a Bishop score of less than six, Salim et al. (2011) compared two balloons used for the purpose of cervical ripening among 293 women with complete data (Salim et al., 2011). Blinding was impossible due to the ability to see and feel the type of balloon placed during pelvic exams. There were 145 women in the FCRB (Figure 3) and 148 in the CDBD groups (Figure 4). Both balloons were effective in producing cervical ripening and reducing length of time from onset of induction to delivery. There were no differences in effect among multiparous vs. nulliparous women. The cesarean birth rate was not significantly different between the two groups, and was 17.6% in the CDBD and 10.3% in the FCRB (Salim et al., 2011).

Both studies (Cromi et al., 2006, Salim et al., 2011) support that the use of the cervical ripening balloon is effective among women with no prior cesarean deliveries. Cromi et al. (2006) demonstrated that despite the effectiveness of the balloon for cervical ripening, a high number of women will need oxytocin or prostaglandin in addition to the balloon cervical ripening to effect a vaginal delivery.

*Figure 3. Foley Cervical Ripening Balloon (FCRB).  Figure 4. Cook’s Double Ripening Device (CDBD).*
METHODS

Focus of the Project

Many issues relate to what should be for most women a normal, physiological event: overuse of cesarean delivery; approaches to preventing the first cesarean; and for women with a prior cesarean, promotion of accurate provider advice regarding TOLAC. However, this project addressed a single question: can women with a prior cesarean birth be safely induced using a cervical ripening balloon?

For this project, a systematic literature review was conducted to find empirical evidence on the use of this cervical ripening option in women with prior cesarean. In order to ensure the preservation of rigor in this integrative review the PRISMA guidelines were employed. PRISMA guidelines represent a standardized system for reporting findings in a integrative review and aid in a systematic search to identify studies which have potential for use in addressing a pre determined research question (Moher et al., 2009). The PRISMA flow diagrams enhance the thoroughness of the project through the inclusion of a flow chart by documenting the search process with identifying, screening, sampling decisions, and inclusion of studies into the systematic review (Moher et al., 2009; Polit & Beck, 2012). Further, the stages of an integrative review process; developing the problem statement, search strategy, data collection, evaluation of the quality of the studies, analyzing and interpreting the data, in order to present results (Polit & Beck, 2012), are preserved through adherence to the PRISMA checklist. The advantage of such a review is the objectivity the results carry. Another researcher following the PRISMA checklist and using the same data should reach the same conclusions (Polit & Beck, 2012).
Search Terms

In this literature review, databases searched were Cochrane, CINAHL, PubMed, and Google Scholar. The reference lists of the accepted articles were reviewed for appropriate further references. Initially, the search was limited to publications from 2009 to 2015. Subsequently, the search was expanded with no time limit in order to capture earlier studies that might include the cervical ripening balloon (CRB) method in the VBAC population. The key search words are listed in the table below:

Table 1

Search Terms by Data Base

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<thead>
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Search Strategy

A systematic literature review was conducted to answer the question: Does the evidence support the safety for the use of a cervical ripening balloon in a woman who desires to undergo a trial of labor after a cesarean delivery? A search was conducted using Cochrane, CINAHL, PubMed, and Google Scholar databases. The key search terms are listed in Table 1, and the search strategy diagram is presented in Figure 5. Of the 402 abstracts reviewed, 346 non-empirical studies were eliminated, and 56 studies were reviewed. All requested studies had their reference lists scrutinized for potential
further sources of evidence. Of those, 39 were eliminated due to the wrong population, intervention, or outcome being measured. Seventeen studies were reviewed and added to the TOE. A second reviewer then evaluated those identified and an additional six studies were eliminated, as the results were not clear or combined with multiple outcomes rather than the primary outcome desired in this project. The final 11 studies are included in the TOE in Appendix B, Table 4. The primary outcome of interest is the uterine rupture rate in women with a history of a prior CD undergoing cervical ripening with a CRB. The secondary outcome is the VBAC success rate in this population.

Ethics

This Doctor of Nursing Practice project does not involve any activities that would require Institutional Review Board approval.
Figure 5. Search strategy.

Search using key MeSH terms conducted across four identified databases

Potential Studies Identified

402 Abstracts reviewed

346 Non-empirical studies eliminated

56 Identified studies reviewed

36 Studies rejected for wrong intervention, population, or outcome measured

17 Studies added to be considered for the table of evidence

6 Eliminated by second reviewer

11 Studies included in final table of evidence
RESULTS

Cervical Ripening Balloon in Women with Prior Cesarean

The search strategy resulted 11 research studies representing 1,118 patients (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold, Blackwell, & Gauthier, 2004; Cheuk, Lo, Lee, & Yeung, 2015; Ebeid & Nassif, 2013; Jozwiak, Van de Lest, Burger, Dijksterhuis, & De Leeuw, 2014; Khotaba et al., 2001; Ravasia, Wood, & Pollard, 2000; Sananes et al., 2014; Voon, Wong, Ting, & Suharjono, 2015; Ziyauddin, Hakim, & Beriwal, 2013). Of note is that none of the studies were conducted in the United States. Appendix B, Table 4 displays the evidence for use of a CRB in women desiring VBAC.

The primary goal of this literature review was to describe the uterine rupture rates associated with the use of the CRB in women attempting a TOLAC and to determine if the evidence supports the safe use of this mechanical device specific to these women. In the 11 studies (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013), 1,118 women undergoing induction with a history of a prior cesarean birth underwent cervical ripening with either a Foley catheter or double balloon device. The uterine rupture rate ranged from 0% to 1.7% with the average of 0.6% across all studies (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013). These rates compare to the expected uterine rupture rates reported by ACOG, and others as stated above (ACOG, 2010; Ophir et al., 2012; Ouzounian et al., 2011; Rossi & Prefumo, 2015).
The secondary outcome, VBAC success rates, was of interest as well. Of the 1,118 patients, VBAC success rates varied between 43.7% and 83% with the average of 62%. The higher rates (Jozwiak et al., 2014; Shatz et al., 2013) are consistent with the 74.5% success rate quoted by Guise et al (Guise et al., 2010). Lower VBAC success rates were reported in three older studies (Ben-Aroya et al., 2002; Bujold et al., 2004; Ravasia et al., 2000). The lower rates may be related to the definitions of active labor and failure to progress, which have been evolving in the past five years. In a small observational study with 25 women using CDBD, Ebied and Nassif reported a 53% VBAC success rate among 17 women (Ebeid & Nassif, 2013). Moreover, in this small sample, if the membranes ruptured, the balloon device was removed and as such, the benefit of cervical ripening was lost (Ebeid & Nassif, 2013). Sananes et al. and Voon et al. also reported similarly low VBAC success rates of 44%-45% (Sananes et al., 2014; Voon et al., 2015). In both of these studies, the method for induction was the CRB alone without any pharmacological intervention, which would account for the limited success rate.

**Project Manuscript**

The results of the search were the basis for a manuscript (Appendix A) that will be submitted to the peer-reviewed journal of the American College of Nurse-Midwives: *The Journal of Midwifery and Women’s Health* (JMWH). The aim and scope of the JMWH is to “present new research and current knowledge across a broad range of clinical and interdisciplinary topics including maternity care, gynecology, primary care for women and newborns, public health, health care policy, and global health. With a focus on evidence-based practice, JMWH is dedicated to improving the health care of women throughout their lifespan and promoting excellence in midwifery. JMWH readers
include midwives, physicians, and nurses. This integrative review project was selected for and will be presented at the round table discussion sessions at the 61st American College of Nurse-Midwives’ convention, May 2016. This project has also been selected for display and discussion at a poster presentation at the Western Institute of Nursing conference April 2016. Tables of Evidence used in the development of this project are in Appendix B.
DISCUSSION

This integrative review demonstrated how a critical appraisal of research on a topic pertinent to my practice will not only enhance my practice as a certified nurse-midwife but may also foster practice change in my facility. An integrative review of the literature allows for a better understanding of the best available evidence regarding a clinical question or problem (Polit & Beck, 2012). Incorporation of such evidence into a daily practice is paramount to providing evidence based care or developing evidence based clinical practice guidelines (Polit & Beck, 2012). The challenge in this review was the heterogeneity of the studies: different methodologies, criteria for inclusion, and variable definitions employed by the authors. In order to control for researcher bias and to increase the value of this review, inclusion of the studies into this review required acceptance by both the primary researcher and the project chair.

In this review, the studies were either observational, retrospective, and one small prospective case controlled study. A weakness of this review was that available studies were not consistent in criteria for selection of control groups. Several studies did not control for parity (Ashwal et al., 2015; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Ravasia et al., 2000; Voon et al., 2015), a factor, which affects VBAC success rate (Salim et al., 2011). Additionally, researchers for studies more than ten years old used different definitions for the active phase of labor, which would alter VBAC success rates (Ben-Aroya et al., 2002; Bujold et al., 2004; Khotaba et al., 2001; Ravasia et al., 2000). None of the 11 studies were conducted in the U. S. Historically, providers in some countries have much more tolerance for slow labor progress and even allow for the CRB to remain in place for more than four days with or
without ruptured membranes (Jozwiak et al., 2014). The lack of available U.S. studies demonstrates the gap that exists in the literature for this population, and may reflect lack of use of CRB among U.S. providers. Among the included studies, women in the intervention group could have received combined CRB and oxytocin or prostaglandin E2, or just CRB alone. Despite these issues, these studies report a uterine rupture rate consistent with that in the general literature of women with prior cesarean (0%-1.7%) and an overall average of 0.6% (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziauddin et al., 2013).
CONCLUSION AND RECOMMENDATIONS

Conclusion

The resistance of providers to support TOLAC and induction of labor in women eligible for VBAC is well recognized (Guise et al., 2010; Schifrin & Cohen, 2013). The results of the literature review suggested that the cervical ripening balloon might be a reasonable option for induction and cervical ripening in women with a history of a prior cesarean birth.

In response to the primary outcome, uterine rupture; this review presents evidence that the use of CRB in women undergoing induction of labor after a prior cesarean delivery is not associated with a higher risk of uterine rupture. With regards to the secondary outcome, VBAC success ranged from 44% to 83% depending on how the induction was managed prior to CRB insertion, during ripening, and after the balloon was removed or expelled. Irrespective of the variable use of the CRB amongst the studies, VBAC success using the CRB was markedly higher than the 8.5% reported overall in the United States.

Therefore, despite the small numbers of women in the identified studies, the results of this project suggest that CRB use in women with prior CD who have a medical indication for induction: (a) is associated with uterine rupture rates that are similar to those associated with pharmacologic ripening agents, and therefore (b) may afford another option for cervical ripening, but more globally (c) will assist providers in counseling women based on evidence rather than personal belief and therefore, (d) has the potential to decrease cesarean deliveries overall in the United States.
**Recommendation for Research**

To empirically demonstrate the safety and efficacy of CRB, direction for future study with a prospective randomized, multiple centers, clinical trials are needed to compare CRB alone, CRB with oxytocin, and spontaneous labor without cervical ripening. Criteria for such studies should include controls for induction methods as well as parity, type of balloon, maximum time allowed for balloon ripening, use of balloon with or without ruptured membranes, amount of balloon fill, definition of active phase of labor, failed induction, and arrest of dilatation. Clear operational definitions of terms need to be clarified (e.g., the definition of uterine rupture as compared to uterine dehiscence). A future large study encompassing multiple centers with standardized inclusion criteria is encouraged yet may also be difficult to accomplish.

A preliminary power analysis was calculated in order to detect a statistically significant difference of 0.2% with a 95% confidence. Each group: 1) women who had an ERCD compared to 2) women with a prior CD who underwent cervical ripening and 3) induction with a balloon and oxytocin would need about 42,940 women. Not only is this number impossible to achieve, randomization within these groups is unethical. While it is impossible to achieve the number of patients a power analysis would dictate, a large-scale study could provide further information in order answer to the question of evidence for safety in the use of a CRB in women who are faced with a medical indication for IOL and with a history of a prior CD. The risk of the use of a CRB in this population should be weighed against the risk of continuing a pregnancy with a confounding indication for delivery or repeat cesarean deliveries (Rossi & Prefumo, 2015).
**Recommendation for Practice**

The power of provider counseling and advice with regards to decision-making in the choice of VBAC is evident (Cleary-Goldman, Cornelisse, Simpson, & Robinson, 2005a; Scaffidi et al., 2014). Midwives and physicians are ethically obligated to present factual, unbiased evidence based information to women with prior cesarean delivery so that they can make an informed choice. Based on the findings of this project, appendix B presents counseling topics that should be included for women who are considering VBAC and in particular, may need an induction of labor to do so.

Nurse-midwives and midwives are well positioned to lead in efforts to reduce cesarean deliveries whether it is by preventing the first cesarean or promoting the first VBAC. As providers who influence women from prenatal through postpartum periods midwives; (a) encourage women who are good candidates to consider VBAC, (b) seek means of providing women with accurate counseling on the risks and benefits of VBAC and ERCD, (c) offer non-pharmacologic options e.g., cervical ripening balloon when cervical ripening is necessary for TOLAC, (d) support and guide women during pre-labor/labor and delivery when they are attempting a VBAC, and ultimately (e) listen to their birth stories afterwards that reflect self-determination in their choice of delivery options.

Despite the differences in the studies noted above, the evidence points to a low uterine rupture rate which is comparable to the uterine rupture rate in women who are attempting a VBAC and enter labor spontaneously. Ongoing critical analysis of the literature can help midwives and obstetricians guide patient teaching with regard to the
evidence for safety in the use of mechanical methods for cervical ripening in the woman who is considering a VBAC.
REFERENCES


APPENDIX A

MANUSCRIPT TO BE SUBMITTED TO THE
JOURNAL OF MIDWIFERY & WOMEN'S HEALTH

INTRODUCTION

The cesarean delivery rate in the United States has been a significant concern for decades. Yet, attention to the issue from professional organizations, media, consumer groups, and payers has had little impact with the current rate of 32.2% (Hamilton, 2015), which is not much different than the high of 32.9% in 2009 (Osterman & Martin, 2013). Current reduction efforts focus on prevention of primary cesarean (ACOG, 2014; Dekker, 2013; Milton, 2014; Smith, Peterson, Lagrew, & Main, 2016) but less so on prevention of repeat cesarean delivery (CD).

The lowest recent CD rate of 20.7% was in 1996 when substantial numbers of women with prior cesarean had a vaginal birth after cesarean (VBAC). However when the number of women seeking VBAC increased so did uterine rupture and other complications. Coupled with organizational constraints and increased litigation, fewer women were offered a trial of labor after cesarean (TOLAC) (Guise et al., 2010). Subsequently, the rate of women attempting a TOLAC decreased from 28.3% of all live births in 1996 to 8.7% in 2010 (Guise et al., 2010). Currently, 90% of women will deliver by repeat cesarean rather than attempting a VBAC (Guise et al., 2010, Healthy People 2020, 2015). The most recent ACOG practice bulletin on VBAC states that “the current VBAC rate of 8.5% is not acceptable” (ACOG, 2010). Organizational moratoria and concern for litigation related to VBAC have certainly been significant forces that have diminished VBAC on a larger scale, but local factors such as provider advice and patient education also influence the low VBAC rate.
Accurate provider advice and counseling are critical to a woman’s decision to attempt a VBAC. Women with better knowledge of VBAC are more likely to attempt a TOLAC over women with less knowledge (Scaffidi, Posmontier, Bloch, & Wittmann-Price, 2014). Decision-making for VBAC appears to be less dependent on family opinion and more related to focused VBAC educational programs and direct provider counseling (Cleary-Goldman, Cornelisse, Simpson, & Robinson, 2005). Therefore, individual providers as well as others in health systems must provide counseling that is timely, accurate and consistent.

Women desirous of a VBAC face challenges in identifying providers who will genuinely support their wish for a TOLAC. A woman with prior cesarean may select the practice because of its stated support for a TOLAC. However, when she presents to the obstetric unit with signs of labor but is remote from delivery, it is not unusual for the combination of labor discomfort and provider recommendation for “a “controlled, safe repeat cesarean” to dissuade her from TOLAC.

The greatest deterrent for the opportunity of a TOLAC however is when there is a medical indication for induction of labor and cervical ripening is necessary. In many practice settings, concern over the use of pharmacologic ripening agents, e.g., prostaglandins in women with prior cesarean, has effectively eliminated TOLAC as an option. Non-pharmacologic approaches such as the cervical ripening balloon that have gained widespread favor in women without prior cesarean would appear to be a reasonable approach.

The primary focus of this review was to examine the available evidence, the efficacy, and outcomes related to the use of the cervical ripening balloon (CRB) for
women with a prior cesarean. This systematic review used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher, Liberati, Tetzlaff, & Altman, 2009) to examine two outcomes; risk of uterine rupture (UR) and VBAC success rate. The secondary focus of the review was to develop a counseling tool for clinicians to guide an evidence based discussion with women who desire VBAC.

**BACKGROUND**

Prevention of the primary cesarean is but one aspect of reducing the overall cesarean rate and thereby improving maternal outcomes. Concurrently, there must also be efforts to decrease recurrent CD. Cesarean delivery in general increases the risk of severe maternal morbidities three fold as compared to vaginal delivery (ACOG, 2014; Signore, 2012). Such morbidities include transfusion, hysterectomy, ruptured uterus, surgical injury, cardiac arrest, renal failure, anesthesia complications, infection, deep vein thrombosis, wound disruption or hematoma, and the need for assisted ventilation. The risk for these morbidities with vaginal delivery is 0.9% while for cesarean is 2.7% (Liu et al., 2007).

Women experiencing recurrent CD incur not only the immediate risks associated with CD but also lifelong risks in subsequent pregnancies that include painful adhesions, infertility, abnormal placentation, amniotic fluid embolism, unplanned hysterectomy, and respiratory morbidity. By the third CD, the risk for placenta accreta (invasive placental implantation) is 40%, which increases risk of maternal death and has neonatal consequences: Neonatal Intensive Care Unit admission and even neonatal death (Silver et al., 2006).
More profoundly, maternal mortality is at a minimum tripled when women have elective repeat cesarean delivery (ERCD) (13/100,000), compared to VBAC (4/100,000) (Signore, 2012). Klar & Michels (2014) conducted a meta-analysis of six cohort and nine case-control studies of women with prior cesarean delivery. Increased likelihood for placental abnormalities in subsequent pregnancies was observed for all sub-groups: 47% for placenta previa (95% CI: 1.44-1.51); 96% for placenta accreta (95% CI: 1.41-2.74) and 38% for placenta abruption (95% CI 1.35-1.41) Therefore, even one prior cesarean resulted in 40-96% higher risk of developing one or more of the above-mentioned placental disorders in subsequent pregnancies Klar & Michels, 2014). Primarily these risks are avoided by preventing the first cesarean. Secondarily they are reduced when maternal choice for a TOLAC is supported, thereby minimizing risk for recurrent cesareans.

On a positive note, if offered TOLAC, most women with prior cesarean delivery will have a VBAC. Most reports of VBAC success rates range from 60% to 86% (ACOG, 2010; Bujold, Blackwell, Gauthier, 2004; Landon et al., 2004; Ouzounian, Miller, Hiebert, Battista, & Lee, 2011; Rossi & Prefumo, 2015). Compared to repeat cesarean delivery, vaginal birth after cesarean is associated with fewer post-delivery complications, decreased recovery time, enhanced successful breastfeeding, and increased maternal satisfaction with the birth experience (ACOG, 2014; Klar & Michels, 2014; Liu et al., 2007; Signore, 2012; Silver et al., 2006).

However, many women desiring TOLAC are not offered this option due to provider hesitancy when induction of labor is indicated. In contrast to prior assumptions that VBAC was unsafe and that use of induction agents was contraindicated, recent
evidence supports VBAC safety when induction of labor is indicated (Ouzanian, 2011; Shatz et al., 2013). Further, ACOG has supported the induction of labor for maternal or fetal indications as an option for women undergoing a TOLAC (2010).

A key issue related to hesitancy to offer induction of labor (IOL) is that women may require cervical ripening prior to the use of more accepted induction approaches such as oxytocin. ACOG (2010) supports the use of oxytocin for IOL in women with prior cesarean, but certain prostaglandins such as misoprostol are absolutely contraindicated in women with prior cesarean based on higher uterine rupture rates (Ophir, Odeh, Hirsch, & Bornstein, 2012) The evidence for the use of other prostaglandins for cervical ripening is less definitive. (ACOG, 2010).

Concern related to the use of prostaglandins limits the provider’s choice of agents when cervical ripening is necessary. However, non-pharmacologic dilation methods such as the cervical ripening balloon (CRB) were deemed as possibly useful for TOLAC candidates with an unfavorable cervix (ACOG, 2010).

**Primary Outcome: Uterine Rupture**

It is important for clinicians to understand uterine rupture rates in order to appropriately counsel women who wish to consider a trial of labor, and if necessary, induction of labor after a prior CD. Ouzounian et al. (2011) assessed rates of uterine rupture in 16,218 women with one prior low transverse CD between 1998 and 2001. For comparison purposes, the uterine rupture rate was 0.02% in women without a prior CD ($n = 105,140$) during that period (Ouzounian et al., 2011). Of the women with prior CD, 6,833 women underwent a trial of labor and had a uterine rupture rate of 1.1% ($p <$
0.0001), which is consistent with similar studies of women attempting VBAC (Landon, 2004; Ophir et al., 2012; Rossi & Prefumo, 2015; Shatz et al., 2013).

Of specific interest was that the uterine rupture rates in the group attempting VBAC were not significantly different between the induction of labor (1.2% or 22/1806) and the spontaneous labor groups (1.0% or 52/5026) (Ouzounian et al., 2011). This finding suggests that induction of labor, which in this study was done either oxytocin or PGE2, is a reasonable approach for women with prior cesarean. A limitation of the study was that the uterine rupture rate for women undergoing an ERCD was not reported. However, the study was strengthened by the large sample size of women who were being cared for in a single health care system with in-house providers (Ouzounian et al., 2011).

Similar uterine rupture rates to those reported by Ouzounian et al. (2011) are evident in a meta-analysis of eight studies, in which Rossi and Prefumo report uterine rupture rates of 1.1% in the induced labor group (n = 46/4038) as compared to 0.6% in the spontaneous labor group (n = 90/13,374) (Rossi & Prefumo, 2015). Landon et al. (2004) reported a symptomatic 0.7% UR rate in 17,898 women undergoing a TOLAC (Landon et al., 2004). In a systematic review of method of labor induction in women with prior cesarean, Ophir et al. similarly reported uterine rupture rates in women attempting TOLAC as being: oxytocin 1.1%; and prostaglandin (E2) 2%. Their finding that the uterine rupture rate for misoprostol (E1) was notably higher (6%) supports the contemporary reluctance to use this specific prostaglandin (Ophir et al., 2012) in women with prior CD. Barger et al., (2011) conducted a case-controlled study of 348 uterine ruptures in Massachusetts. The study represents the largest number of patients who experienced uterine rupture to date (Barger et al., 2011). Induction of labor was
associated with a small increase risk from a baseline of 0.5% to 1.0-1.5% (Barger et al., 2011). Barger et al., (2011), found that the use of prostaglandin alone was not associated with UR, however, with the combination of prostaglandin and oxytocin, the odds for UR were increased (Barger et al., 2011). The similarity of uterine rupture rates in women who are induced by either oxytocin or prostaglandin (E2) implies that some methods of induction are associated with fewer uterine ruptures and as noted by Barger et al., (2011), the combination of agents may increase the risk of UR and therefore discussion of such methods is a critical component of patient counseling.

Another aspect of counseling for women with prior CD is that even one cesarean scar increases the risk for uterine rupture in subsequent pregnancies irrespective of mode of delivery. The 2010 ACOG practice bulletin compares risk of uterine rupture in women with one CD as being 0.4-0.5% for ERCD and to undergoing a TOLAC as 0.7-0.9% (ACOG, 2010). This is an important comparison to note; as it does not support provider/ client perception that uterine rupture only occurs when VBAC is attempted.

**Secondary Outcome: VBAC Success**

The likelihood for VBAC is also an important area of counseling that should be provided to women with prior CD. Spontaneous labor is associated with the highest success rates (Ouzounian et al., 2011; Rossi & Prefumo, 2015; Shatz et al., 2013) with VBAC success of 73% to 86% compared to 66%, to 67% in women requiring either oxytocin or prostaglandin (E2) induction (Ouzounian et al., 2011; Rossi & Prefumo, 2015; Shatz et al., 2013).

**METHODS**

PubMed, Google Scholar, CINAHL, and Cochrane databases searches were
performed with each search limited to English language health science journals between 2014 and 2015. MeSH search terms used were “vaginal birth after cesarean” AND “cervical ripening” OR “induction” OR “balloon.” These search terms yielded 402 abstracts, of which 346 non-empirical studies were eliminated, and 56 studies were reviewed. Manual searches of selected studies were also scrutinized for further sources of evidence. Thirty-nine studies were eliminated based on wrong population, intervention, or outcome being measured, and a second reviewer analyzed a total of 16 articles. The final table of evidence includes 11 English language studies from 2002-2015.

In order to ensure the preservation of rigor in this integrative review the PRISMA guidelines were employed. PRISMA guidelines represent a standardized system for reporting findings in an integrative review and aid in a systematic search to identify studies which have potential for use in addressing a pre-determined research question (Moher et al., 2009). The PRISMA flow diagrams enhance the thoroughness of the project through the inclusion of a flow chart by documenting the search process with identifying, screening, sampling decisions, and inclusion of studies into the systematic review (Moher et al., 2009; Polit & Beck, 2012). Further, the stages of an integrative review process; developing the problem statement, search strategy, data collection, evaluation of the quality of the studies, analyzing and interpreting the data, in order to present results (Polit & Beck, 2012), are preserved through adherence to the PRISMA checklist. The advantage of such a review is the objectivity the results carry. Another researcher following the PRISMA checklist and using the same data should reach the same conclusions (Polit & Beck, 2012).
Search Strategy

Figure 1: Search Strategy.
Talking Points for Women Considering VBAC

- Elective repeat cesarean delivery is not without risk.\textsuperscript{1, 2, 3}
- Increasing cesarean deliveries increases the risk in future pregnancies for uterine scar separation, placental implantation abnormalities including placenta previa or placenta accreta.\textsuperscript{1}
  - With multiple cesareans, some women require an emergency, unplanned hysterectomy at the time of delivery.\textsuperscript{1}
- Compared to cesarean, vaginal delivery is safer for both mother and baby with less risk for hemorrhage, infection, venous thromboembolism, neonatal NICU admissions, and neonatal seizures.\textsuperscript{1, 2}
  - Less pain, lower need for narcotic pain medication, faster recovery
  - Immediate skin to skin bonding & Immediate breast feeding
- Between 66-86\% of all women who attempt a TOLAC are successful at achieving a VBAC.\textsuperscript{3}
- Spontaneous labor is associated with the highest rate of success of 86\%.\textsuperscript{3}
  - Induced labor is associated with a 66\% success rate.\textsuperscript{3}
    - The active labor definition and provider expectation of active labor has changed which may positively affect this.\textsuperscript{4}
  - Factors that decrease the likelihood of success include reason for prior cesarean delivery such as; the position of the baby’s head prevented descent through the bones of the pelvis, or active labor did not dilate the cervix to 10 centimeters in an expected time frame.\textsuperscript{3}
- If spontaneous labor is not imminent or likely, women with prior cesarean delivery who are candidates for TOLAC should be offered IOL.\textsuperscript{5}
- Methods of induction are:
  - Pharmacologic
    - Oxytocin\textsuperscript{5}
    - Prostaglandin E2 (controversial)\textsuperscript{3, 4, 6}
  - Non-pharmacologic (mechanical)
    - Membrane stripping\textsuperscript{5}
    - Cervical ripening balloon\textsuperscript{5, 6, 7}
  - Combination of above\textsuperscript{7}
- CRB appears to for a reasonable option for cervical preparation as it does not cause excessive uterine activity.\textsuperscript{8}
  - However, many women who start with CRB will still require a subsequent method of IOL
- Cytotec or Misoprostol is an absolute contraindication in a TOLAC.\textsuperscript{2, 5}
- The major risk for TOLAC is the approximate 0.8\% risk for uterine rupture in labor although women with ERCD are at increased risk of uterine rupture also.\textsuperscript{4}
  - Uterine rupture risk in women without a uterine scar is: 0.02\%\textsuperscript{3}
  - Preliminary evidence demonstrates uterine rupture risk in women using CRB ranges from 0\%-1.7\% but that includes combined methods for induction including PGE2 and Oxytocin or both.\textsuperscript{5}

\textit{Figure 2.} Talking Points for Women with Prior Cesarean Considering VBAC.
RESULTS

The search strategy resulted in 11 research studies representing 1,118 patients.

Five of these compared use of CRB to women with a prior CD in spontaneous labor (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013). The other six reported the outcomes when CRB was used in women with prior CD (Cheuk, Lo, Lee, & Yeung, 2015; Ebeid & Nassif, 2013; Jozwiak, Van de Lest, Burger, Dijksterhuis & De Leeuw, 2014; Khotaba et al., 2001; Voon, Wong, Ting, & Suharjono, 2015; Ziyauddin, Hakim, & Beriwal, 2013). Of note is that none of the studies were conducted in the United States.

Table 1 displays the outcomes when CRB was used in women desiring VBAC.

The primary goal of this literature review was to describe the uterine rupture rates associated with the use of the CRB in women attempting a TOLAC and to determine if the evidence supports the safe use of this mechanical device specific to these women. In the 11 studies (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013), 1,118 women
undergoing induction with a history of a prior cesarean delivery underwent cervical ripening with either a Foley catheter or double balloon device. The uterine rupture rate ranged from 0% (Ashwal et al., 2015; Cheuk et al., 2015; Ben-Aroya et al., 2002; Ebeid & Nassif, 2013; Khotaba et al., 2001; Sananes et al., 2014; Ziyauddin et al., 2013) to 1.7% (Bujold et al., 2004; Voon et al., 2015) with the average of 0.6% across all studies (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013). These rates compare to the expected uterine rupture rates reported by ACOG, and others as stated above (ACOG, 2010; Landon et al., 2004; Ophir, et al., 2012; Ouzounian, et al., 2011; Rossi & Prefumo, 2015).

The secondary outcome, VBAC success rates, was of interest as well. Of the 1,118 patients, VBAC success rates varied between 43.7% and 83% with the average of 62%. The higher rates (Jozwiak et al., 2014; Shatz et al., 2013) are consistent with the 74.5% success rate quoted by Guise et al (Guise et al., 2010). Lower VBAC success rates were reported in three older studies (Ben-Aroya et al., 2002; Bujold et al., 2004; Ravasia et al., 2000). The lower rates may be related to the definitions of active labor and failure to progress, which have been evolving in the past five years. In three studies from 2013-2015, the VBAC success ranged from 44-53%. One speculation of their low success rate was that if the membranes ruptured, the balloon device was removed and as such, the benefit of cervical ripening was lost (Ebeid & Nassif, 2013; Sananes et al., 2014; Voon et al., 2015). In the Sananes (2014) study, a repeat cesarean delivery was performed if the Bishop score remained 6 or less after the FC balloon was removed (Sananes et al., 2014).
If there was an attempt to augment the labor despite an unfavorable Bishop score with oxytocin, the VBAC success rate may possibly have improved. Voon et al., (2015) filled the Cook’s balloons up to 80 ml and removed the balloons if there was maternal discomfort thus minimizing the benefit of cervical ripening. If the fill of the balloon was reduced or the patient was given an option for pain relief, there is a possibility the VBAC success rate could have improved with better cervical ripening. Moreover, in this small study, there were two unstable presentations that occurred after confirmation of vertex and balloon placement as well as two cesareans performed for suspected UR, which were not confirmed at the time of surgery (Voon et al., 2015).
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
<th>VBAC Success</th>
</tr>
</thead>
</table>
| Ashwal et al., 2015   | 59 | Retrospective Cohort | Inclusion: Prior single LTCS, IOL  
Exclusion: EFW >4,000 g, non-cephalic, known uterine malformation, less than 18 months from previous CD, US suspicious for uterine scar dehiscence during current pregnancy | Comparison: Prior single previous LTCS & SL  
Comments: BS < 7  
Ripening followed by oxytocin if indicated  
Balloon fill 60-80 ml  
Ripening failure if no change in BS after 24 hours  
Induced women had higher rate of co morbidities (pre-GDM, CHTN)  
Rate of previous VB similar in both groups  
Mixed parity  
SL group had higher VBAC success | 0%  
83% |
| Ben-Aroya et al., 2002 | 161 | Retrospective Cohort | Inclusion: Second pregnancy and prior LTCS; no prior VB  
Exclusion: Non-cephalic; GA < 36 weeks or >42 weeks, indicated CD, more | Comparison: second pregnancy, SL and previous LTCS | 0%  
59% |
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
</tr>
</thead>
</table>
| Bujold, Blackwell, & Gauthier, 2004, Canada | 255  | Observational cohort | *Inclusion:* TOL after previous LTCS after 24 weeks gestation  
*Exclusion:* Multiple gestation, lethal congenital anomalies, IUFD Prostaglandin IOL | *Comparison:* SL and previous LTCS  
*Comments:*  
BS < 6  
Lower modified BS (4 or less) statistically significant lower rate of successful VBAC  
Ripening followed by amniotomy or oxytocin if indicated |
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
<th>VBAC Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheuk, Lo, Lee, &amp; Yeung, 2015 Hong Kong</td>
<td>24</td>
<td>Retrospective</td>
<td><em>Inclusion:</em> One previous LTCS requiring IOL at term, and unfavorable cervix <em>Exclusion:</em> 2 or more previous CD; Classical, inverted T or J, low vertical, or previous uterine scar for gynecologic conditions, congenital uterine malformation, multiple gestation, IUFD, non-cephalic, fibroids which could obstruct labor, SROM, chorioamnionitis, suspected macrosomia, polyhydramnios, congenital fetal abnormalities, maternal condition which would contraindicate VB</td>
<td>FC balloon fill 50 ml prior VD higher likelihood of favorable BS FC group lower likelihood of prior VD Mixed parity but 49% primiparous success rate SL group had higher VBAC success</td>
<td>0% 75%</td>
</tr>
<tr>
<td>Study, Location, Date</td>
<td>N</td>
<td>Study Type</td>
<td>Inclusion/Exclusion Criteria</td>
<td>Comparison group(s)/Comments</td>
<td>VBAC Success</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----</td>
<td>----------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
</tbody>
</table>
| Ebeid & Nassif, 2013  | 17  | Observational  | **Inclusion:** One LTCS desiring VBAC between 41 3/7-42 weeks, singleton, vertex, NIAL, Intact membranes, BS < 6  
| United Kingdom        |     |                | **Exclusion:** Previous uterine surgery apart from LTCS, classical, abnormal placentation, non-cephalic, SROM, abnormal FHRT, active genital HSV | **Comparison:** No comparison  
|                       |     |                | **Comments:** BS < 6  
|                       |     |                | Cook’s Balloons filled 80 uterine/80 vaginal  
|                       |     |                | Balloons removed if SROM or 12 hours without expulsion  
|                       |     |                | oxytocin following expulsion if indicated  
|                       |     |                | Mixed parity  
|                       |     |                | **VBAC Success:** 0%                                                                 |              |
| Joswiak et al., 2014  | 208 | Retrospective  | **Inclusion:** Prior CD with or without ROM; one prior LTCS; BS < 6  
| Netherlands           |     |                | **Exclusion:** Multiple gestation; IUFD, lethal anomalies, non-cephalic  
|                       |     |                | **Comparison:** No comparison  
|                       |     |                | **Comments:** BS < 6  
|                       |     |                | FC balloon fill to 30 ml  
|                       |     |                | AROM after BS 6 or greater oxytocin augmentation as indicated  
|                       |     |                | FC balloon up to 48 hours, dc x 24  
<p>|                       |     |                | <strong>VBAC Success:</strong> 0.5%                                                                 | 71.2%        |</p>
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
<th>VBAC Success</th>
</tr>
</thead>
</table>
| Khotaba et al., 2001,  
Israel                               | 37 | Observational  
Short report | *Inclusion:* Previous CD; BS <4  
*Exclusion:* Not reported                                                                 | Mixed parity  
Previous VB ($n = 71$) associated with higher VBAC success rate | 0% 64.9% |
| Ravasia et al., 2000,  
Canada                              | 129 | Retrospective  
Inclusion: Previous CD requiring IOL  
Exclusion: Not reported | *Comparison:* SL and previous CD  
*Comments:* IOL by a) PGE2; b) FC balloon 30-40 ml with or without traction; c) oxytocin and/or AROM | PGE2 associated with UR risk of 2.9%  
Mixed parity  
SL had higher VBAC success | 0.76% 60.8% |
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
<th>Uterine Rupture</th>
</tr>
</thead>
</table>
| Sananes et al., 2014  | 135| Observational Cohort | **Inclusion:** Singleton with one prior CD with or without SROM  
**Exclusion:** Low lying placenta, suspected chorioamnionitis, hydramnios  | **Comparison:** SL and previous CD  
**Comments:** Bishop score < 6  
Balloon removed after 24 hours  
oxytocin or AROM augmentation after balloon expelled or removed  
Repeat CD if BS < 6 after balloon removed  
Mixed parity; FC group had significantly fewer prior VB  
And significantly lower BS which would account for lower VBAC success  
SL and favorable BS at start of IOL had higher VBAC success  | VBAC Success |
|                       |    |                |                                                                                             |                                                                                               | 0% 43.7%        |
| Voon et al., 2015     | 58 | Retrospective  | **Inclusion:** Previous CD and/or grandmultiparity requiring IOL, beyond 36 weeks, singleton, BS < 7, vertex  
**Exclusion:** Multiple gestation, favorable BS, more than one prior CD, previous large loop excision of the transformation zone, maternal fever, and any  | **Comparison:** Grandmultiparity to previous CD with or without grandmultiparity  
**Comments:** BS < 7  
CDBD: Balloons filled equally 40-80 ml  |                |
<p>|                       |    |                |                                                                                             |                                                                                               | 1.7% 44.8%      |</p>
<table>
<thead>
<tr>
<th>Study, Location, Date</th>
<th>N</th>
<th>Study Type</th>
<th>Inclusion/Exclusion Criteria</th>
<th>Comparison group(s)/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>contraindication for vaginal birth</td>
<td>Study focused on risk of hyper stimulation in two high risk groups; Previous CD and grandmultiparity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Balloons removed 12-24 hours after insertion or if SROM, significant discomfort, or maternal fever.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>AROM followed by oxytocin after balloons removed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Prior VB associated with greater VBAC success</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.7% UR may be related to small numbers in study (1/58) and was diagnosed 24 hours after delivery</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 CD for suspected UR were not confirmed operatively</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mixed parity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>VBAC success rate affected by two suspected dehiscence and two unstable lie</td>
</tr>
<tr>
<td>Study, Location, Date</td>
<td>N</td>
<td>Study Type</td>
<td>Inclusion/Exclusion Criteria</td>
<td>Comparison group(s)/Comments</td>
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<tr>
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<td>---------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
</tbody>
</table>
| Ziyauddin et al, 2013 | 35   | Prospective       | **Inclusion:** one prior LTCS; GA 37 weeks or greater; cephalic, singleton, reassuring FHRT; BS 6 or less  
**Exclusion:** ruptured membranes, IUFD, multiple gestation, polyhydramnios, placenta previa, or any contraindication to IOL | **Comparison:** Case matched to PGE2 IOL and previous CD  
**Comments:**  
BS 6 or less  
FC balloon fill to 30 ml  
Balloon removed after 12 hours then AROM and oxytocin  
Did not state parity  
FC VBAC success better than PGE2 VBAC success (60%) | 0%  
71.4% |

**Note:** BS = Bishop score; CD = cesarean delivery; CDBD = Cook’s double balloon device; CHTN = chronic hypertension; EFW = estimated fetal weight; FC = Foley catheter; FD = fetal distress; FHRT = fetal heart rate tracing; GA = gestational age; GDM = gestational diabetes; HSV = herpes simplex virus; IOL = induction of labor; IUFD = intrauterine fetal demise; LTCS = low transverse cesarean section; NIAL = not in active labor; NR = not reported; TOL = trial of labor; SL = spontaneous labor; SROM = spontaneous rupture of membranes; ROM = rupture of membranes; UC = uterine contractions; US = ultrasound; VB = vaginal birth; VBAC = vaginal birth after cesarean.
DISCUSSION

We found overall that women with a prior cesarean delivery who required medically indicated IOL had similar rupture rates to those in spontaneous labor. Specifically, with regards to our primary outcome, uterine rupture in women using CRB was similar to the UR rates as previously reported (Barger et al., 2011; Landon, 2004; Ophir et al., 2012; Ouzounian et al., 2011; Rossi & Prefumo, 2015; Shatz et al., 2013). When studies in which CRB with or without oxytocin were compared to IOL with PGE2 (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotab et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013), the UR rates of 0-1.7% were statistically lower than 2.9% as reported by Ravasia et al. (2000). Barger, et al., (2011) did not find a difference in the UR rate with the use of prostaglandin alone, but noted an increase when prostaglandin was combined with oxytocin, which was similar to the risk use of oxytocin alone.

Grobman et al. (2007) studied 11,778 women who underwent a TOLAC to identify factors associated with successful VBAC. They reported that irrespective of prior vaginal delivery, IOL was statistically associated with a higher likelihood of repeat CD and that spontaneous labor more likely resulted in a successful VBAC. In the current review, all of the five studies that compared spontaneous labor to an IOL method were consistent with this finding (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Ravasia et al., 2000; Sananes et al., 2014). Several studies did not control for parity (Ashwal et al., 2015; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Ravasia et al., 2000; Voon et al., 2015), a factor which affects
VBAC success rate (Salim et al., 2011). Additionally, studies more than ten years old used different definitions for the active phase of labor, which would alter VBAC success rates (Ben-Aroya et al., 2002; Bujold et al., 2004; Khotaba et al., 2001; Ravasia et al., 2000). For more than 50 years, the definitions of the active phase of labor and arrest of dilation have been grounded on the research by Friedman. His observations were based on 500 primigravid women at term. Friedman noted a mean duration of the active phase of labor of 4.6 hours (Friedman, 1955). More recently, Zhang, Troendle, and Yancey (2002), found that the time from 4cm to 10 cm took approximately 5.5 hours compared to Friedman’s labor curve of 2.5 hours. Their conclusion was that the labor progression is significantly slower than what Friedman described and that the criterion to diagnose protracted labor is too strict in nulliparous women (Zhang et al., 2002). Similarly, Neal et al. (2010) performed a systematic review examining the active labor phase in nulliparous women. The review included 18 studies with 7009 women. Nulliparous women in spontaneous labor had a mean active labor time of 6.0 hours and the statistical limits of 13.4 hours (defined as the mean + 2 standard deviations) and concluded that the Friedman definition of active labor is too stringent (Neal et al., 2010). Thus, comparing studies prior to 2002 to studies after 2002 may account for a difference in the VBAC success rates. Moreover, expectant management and active management of labor vary widely from institutions, providers, and locations. These variances can account for the difference in the VBAC success rates in the studies, specifically the research after 2002 (Neal et al., 2010).

None of the 11 studies were conducted in the U. S. Historically, providers in some countries have much more tolerance for slow labor progress and even allow for the
CRB to remain in place for more than four days with or without ruptured membranes (Jozwiak et al., 2014). The lack of available U.S. studies demonstrates the gap that exists in the literature for this population, and may reflect lack of use of CRB among U. S. providers. Among the included studies, women in the intervention group could have received combined CRB and oxytocin or prostaglandin E2, or just CRB alone. Despite these issues, these studies report a uterine rupture rate consistent with that in the general literature of women with prior cesarean (0%-1.7%) and an overall average of 0.6% (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013).

CONCLUSION AND RECOMMENDATIONS

Conclusion

The resistance of providers to support TOLAC when induction of labor is necessary is well recognized (Guise et al., 2010; Schifrin & Cohen, 2013). The results of this literature review suggest that the cervical ripening balloon is a reasonable option for induction and cervical ripening in women with a history of a prior cesarean delivery.

In response to the primary outcome, uterine rupture, this review presents evidence that the use of CRB in women undergoing induction of labor after a prior cesarean delivery is not associated with a higher risk of uterine rupture. With regards to the secondary outcome, VBAC success ranged from 44% to 83% depending on how the induction was managed prior to CRB insertion, during ripening, and after the balloon was removed or expelled. Irrespective of the variable use of the CRB amongst the studies,
VBAC success using the CRB was markedly higher than the 8.5% reported overall in the United States.

Therefore, despite the small numbers of women in the identified studies, the results of this project suggest that CRB use in women with prior CD who have a medical indication for induction: (a) is associated with uterine rupture rates that are similar to those associated with pharmacologic ripening agents, and therefore (b) may afford another option for cervical ripening, but more globally (c) will assist providers in counseling women based on evidence rather than personal belief and therefore, (d) has the potential to decrease cesarean deliveries overall in the United States. The risk of the use of a CRB in this population should be weighed against the risk of continuing a pregnancy with a confounding indication for delivery or repeat cesarean deliveries (Rossi & Prefumo, 2015).

**Recommendations**

The power of provider counseling and advice with regards to decision-making in the choice of VBAC is evident (Cleary-Goldman et al., 2005; Scaffidi et al., 2014). Clinicians are ethically obligated to present factual, unbiased evidence based information to women with prior cesarean delivery so that they can make an informed choice. Based on the findings of this project, Figure 1 presents counseling topics that should be included for women who are considering VBAC and in particular, may need an induction of labor to do so.

In particular, nurse-midwives and midwives are well positioned to lead in efforts to reduce cesarean deliveries whether it is by preventing the first cesarean or promoting the first VBAC. As providers who influence women from prenatal through postpartum
period, midwives: (a) encourage women who are good candidates to consider VBAC, (b) seek means of providing women with accurate counseling on the risks and benefits of VBAC and ERCD, (c) offer non-pharmacologic options e.g., cervical ripening balloon when cervical ripening is necessary for TOLAC, (d) support and guide women during pre-labor/labor and delivery when they are attempting a VBAC, and ultimately (e) listen to their birth stories afterwards that reflect self-determination in their choice of delivery options.

**CONFLICT OF INTEREST**

The authors have no conflicts of interest to disclose.
REFERENCES


http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_12.pdf


APPENDIX B

TALKING POINTS FOR WOMEN CESAREAN CONSIDERING VBAC
Elective repeat cesarean birth is not without risk\(^1\),\(^2\),\(^3\), increasing cesarean births increases the risk in future pregnancies for uterine scar separation, placental implantation abnormalities including placenta previa or placenta accreta\(^1\).

- With multiple cesareans, some women require an emergency, unplanned hysterectomy at the time of delivery\(^1\).

Compared to cesarean, vaginal birth is safer for both mother and baby with less risk for hemorrhage, infection, venous thromboembolism, neonatal NICU admissions, and neonatal seizures\(^1\),\(^2\).

- Less pain, lower need for narcotic pain medication, faster recovery
- Immediate skin to skin bonding & Immediate breast feeding

Between 66-86% of all women who attempt a TOLAC are successful at achieving a VBAC\(^3\).

Spontaneous labor is associated with the highest rate of success of 86%\(^3\).

- Induced labor is associated with a 66% success rate\(^3\).
  - The active labor definition and provider expectation of active labor has changed which may positively affect this\(^4\).

Factors that decrease the likelihood of success include reason for prior cesarean birth such as; the position of the baby’s head prevented descent through the bones of the pelvis, or active labor did not dilate the cervix to 10 centimeters in an expected time frame\(^3\).

If spontaneous labor is not imminent or likely, women with prior CD who are candidates for TOLAC should be offered IOL\(^5\).

Methods of induction are:

- Pharmacologic
  - Oxytocin\(^5\)
  - Prostaglandin E2 (controversial)\(^3\),\(^4\),\(^6\)
- Non-pharmacologic (mechanical)
  - Membrane stripping\(^5\)
  - Cervical ripening balloon\(^5\),\(^6\),\(^7\)
- Combination of above\(^7\)

CRB appears to for a reasonable option for cervical preparation as it does not cause excessive uterine activity\(^8\).

- However, many women who start with CRB will still require a subsequent method of IOL

Cytotec or Misoprostol is an absolute contraindication in a TOLAC\(^2\),\(^5\).

The major risk for TOLAC is the approximate 0.8% risk for uterine rupture in labor although women with ERCD are at increased risk of uterine rupture also\(^4\).

- Uterine rupture risk in women without a uterine scar is: 0.02%\(^3\)
- Preliminary evidence demonstrates uterine rupture risk in women using CRB ranges from 0%-1.7% but that includes combined methods for induction including PGE2 and Oxytocin or both\(^5\).
1 (Guise et al., 2010; Liu et al., 2007)
2 (Shatz et al., 2013)
3 (Ouzounian et al., 2011)
4 (Zhang, Troendle, & Yancey, 2002)
5 (ACOG, 2010)
6 (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Cheuk et al., 2015; Ebeid & Nassif, 2013; Jozwiak et al., 2014; Khotaba et al., 2001; Ravasia et al., 2000; Sananes et al., 2014; Voon et al., 2015; Ziyauddin et al., 2013)
7 (Ashwal et al., 2015; Ben-Aroya et al., 2002; Bujold et al., 2004; Ravasia et al., 2000; Sananes et al., 2014)
8 (Cromi, Ghezzi, Tomera, Ucella, et al., 2006; Salim et al., 2011)
## APPENDIX C

### TABLES OF EVIDENCE

Evidence Table 1. *Influence of Provider Advice on Patient Decision for Trial of Labor after Cesarean*

<table>
<thead>
<tr>
<th>Study/Purpose</th>
<th>Sample/Location</th>
<th>Inclusion Criteria</th>
<th>Methods/Main Outcome</th>
<th>Findings/Results</th>
<th>Limitations/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleary-Goldman et al. (2005)</td>
<td>95 patients attended the training</td>
<td>Prior CD</td>
<td>Prospective</td>
<td>60/95 participants (63%) chose TOLAC</td>
<td>Small study</td>
</tr>
<tr>
<td>Determine if formal teaching about VBAC during pregnancy after C/S increases satisfaction with mode of delivery</td>
<td>221 eligible were not offered VBAC training by their providers</td>
<td>Attended formal counseling program for R/B/A for TOLAC or ERCD</td>
<td>Providers notified of available VBAC counseling program for patients eligible for TOLAC</td>
<td>All women who attended teaching had significantly better satisfaction scores comparing first delivery to studied delivery</td>
<td>Only 6% discussed their delivery choice with their family.</td>
</tr>
<tr>
<td></td>
<td>Vermont, United States</td>
<td>Surveyed during pregnancy and after delivery</td>
<td>Women with prior cesarean invited by providers to attend formal counseling program.</td>
<td>Highest satisfaction was successful VBAC group</td>
<td>100% of patients who were offered the counseling program enrolled.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measured patient satisfaction</td>
<td>Lowest satisfaction in failed TOLAC group but despite failing TOLAC, majority pleased with decision for TOLAC</td>
<td>100% of successful VBAC patients would make the same decision again</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30% of eligible patients were offered the study by their providers</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Validity threat, limitation and bias: provider bias regarding mode of delivery may have precluded the offer for VBAC counseling to their patients.</td>
</tr>
<tr>
<td>Scaffidi et al. (2014)</td>
<td>45 patients</td>
<td>United States</td>
<td>One prior CD and no prior VD</td>
<td>Cross-sectional, descriptive study</td>
<td>Higher knowledge significantly increased decision for TOLAC</td>
</tr>
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<td>-----------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Does knowledge of R/B/A for ERCD and TOLAC influence decision by women about mode of delivery?</td>
<td>Singleton pregnancy 10-22 weeks</td>
<td>English literate only</td>
<td>Excluded: Women with history of preexisting chronic medical conditions, psychological, or OB problems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does level of decision self-efficacy influence the decision for ERCD or TOLAC?</td>
<td></td>
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</tbody>
</table>

*Notes:* CD = cesarean delivery; C/S = cesarean section; ERCD = elective repeat cesarean delivery; R/B/A = risks, benefits, and alternatives; TOLAC = trial of labor after cesarean; VBAC = vaginal birth after cesarean; VD = vaginal delivery.
Evidence Table 2. Bishop Score for Induction Approach

<table>
<thead>
<tr>
<th>Study Objective/Purpose</th>
<th>Sample Location</th>
<th>Inclusion Criteria</th>
<th>Methods/Main Outcome</th>
<th>Findings/Results</th>
<th>Limitations/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. BS as relates to possible prematurity and poor dates.</td>
<td>Opinion paper based on experience</td>
<td>Candidates for pelvic scoring for possible IOL</td>
<td>Selected acceptable patients for induction over a period of several years based on scoring</td>
<td>Elective IOL successful with BS 9 or &gt; Scoring helped with best timing for IOL (convenience; score predicts relevance to actual onset of spontaneous labor)</td>
<td>Opinion paper Published 1964 but BS widely accepted today for IOL candidacy</td>
</tr>
<tr>
<td>2. BS as relates to timing to VD for MD and Patient warning</td>
<td>500 pelvic exams and NSVD charted on scatter plot to demonstrate prediction to timing of delivery</td>
<td>Multiparity 36 wk GA SVP</td>
<td>Unremarkable Obstetric history</td>
<td>Scoring helps confirm dating or warns of prematurity or post maturity Scoring helps predict best ERCD timing</td>
<td>Included only multiparous women Elective IOL 37 wk-39 wk no longer accepted practice Used to help confirm dating as menses dating considered unreliable</td>
</tr>
<tr>
<td>3. BS as indicator for timing for ERCD</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4. BS as warning for post term or poor dates</td>
<td></td>
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</tr>
<tr>
<td>Teixeira et al. (2012) Purpose to evaluate the Bishop score as it relates to successful IOL</td>
<td>59 studies</td>
<td>Meta-analysis</td>
<td>Higher BS = likelihood of VD and less time to delivery BS cheapest and most accurate method to predict IOL &amp; VD</td>
<td>Large variability across studies Could not control for factors known to increase CD BS = subjective</td>
<td></td>
</tr>
</tbody>
</table>

Notes: BS = Bishop score; CD = cesarean delivery; ERCD = elective repeat cesarean delivery; GA = gestational age; IOL = induction of labor; hx = history; n/a = not applicable; MD = obstetrician or medical doctor; Nl = normal; OB = obstetrical; SVP = singleton vertex presentation; VD = vaginal delivery; VE = vaginal examinations; wk = week; vtx = vertex presentation.
## Evidence Table 3. Cervical Ripening Balloon in Women without Prior Cesarean Birth

<table>
<thead>
<tr>
<th>Study Objective/Purpose</th>
<th>Number (n)/Location</th>
<th>Inclusion Criteria</th>
<th>Methods/Main Outcome</th>
<th>Findings/Results</th>
<th>Limitations/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examine maternal and neonatal consequences in patients undergoing pre induction cervical ripening with FCRB</td>
<td>Cromi et al. (2006) 602 patients Italy University teaching hospital</td>
<td>SVP BS &lt; 4 435 nulliparity 167 multiparity Excluded: Uterine scar, GBS; Chorioamnionitis</td>
<td>Prospective chart review Main outcome measurements: chorioamnionitis, uterine infection (endometritis) and neonatal sepsis either proven by culture or suspected</td>
<td>FCRB placed for pre induction ripening: 26.6% FCRB started active labor 31.1% Required oxytocin after expulsion 42.2% additional PE2 C/S rate 25.6% FCRB – Del time; 94 to 3350 minutes. (Median 1469m)</td>
<td>FC is efficacious for pre induction ripening Safe method for ripening Could not place device (6): 2 did not tolerate 3 SROM 1 CC</td>
</tr>
<tr>
<td>Compare IOL success between FCRB and CDBD</td>
<td>Salim et al. (2011) 293 patients Israel</td>
<td>IOL with intact membranes and Bishop score 6 or less SVP Primip and Multip included</td>
<td>Prospective randomized Demographics same both device groups. Primary outcome: time from insertion to delivery Secondary: mode of delivery</td>
<td>Equal insertion to delivery time between devices regardless of parity Multip w previous SVD higher vag delivery rate CDBD = higher OP rate No difference in C/S rate or intrapartum fever rate</td>
<td>CDBD-one face presentation (mentum posterior) - C/S One transverse lie at removal; version successful-SVD. One cord prolapse FCRB: no cord prolapse or abnormal presentation FCRB low cost $.60; CDBD $37.00</td>
</tr>
</tbody>
</table>
Notes: BS = Bishop score; CC = closed cervix; Chorio = chorioamnionitis; CDBD = Cook’s double balloon device; C/S = cesarean section; Del = delivery; FCRB = Foley catheter ripening balloon; GBS = group b streptococcus carrier; Hx = history; IOL = induction of labor; m = minutes; multip = multiparous; NS = not significant; OP = operative delivery includes Vacuum and Cesarean; PE2 = prostaglandin E2 vaginal gel; primip = primiparous; S = significant; SVP = singleton vertex presentation; SROM = spontaneous rupture of membranes; vag = vaginal; w = with.
<table>
<thead>
<tr>
<th>Authors. Year, Location</th>
<th>Number (n)</th>
<th>Study Method &amp; Level of Evidence a (Scott et al., 2015)</th>
<th>Inclusion Criteria</th>
<th>UR</th>
<th>VBAC Success</th>
<th>Limitations</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ashwal et al., (2015) Tel Aviv</td>
<td>59 CRB 193 PGE2 7</td>
<td>Retrospective Level II-2</td>
<td>Prior single CD attempting VBAC</td>
<td>0%</td>
<td>83% b</td>
<td>83% includes PGE2 IOL Mixed parity Mixed group reporting VBAC success</td>
<td>Compared VBAC IOL success rate to VBAC SL Balloon fill 60-80 ml VBAC success rate includes all IOL methods</td>
</tr>
<tr>
<td>Ben-Aroya et al., (2002) Israel</td>
<td>161 CRB 55 PGE2 1432 SL control</td>
<td>Retrospective Level II-2</td>
<td>Prior CD, second pregnancy Required cervical ripening</td>
<td>0%</td>
<td>59%</td>
<td>Bishop score not defined Unclear definition of active labor</td>
<td>Compared VBAC IOL success rates in FCRB and PGE2 groups Parity controlled Excluded multiple methods used together</td>
</tr>
<tr>
<td>Cheuk et al., (2015) Hong Kong</td>
<td>24 IOL CDB</td>
<td>Retrospective Level II-3</td>
<td>CDB IOL One prior CD Bishop score &lt; 6</td>
<td>0%</td>
<td>75%</td>
<td>Small study Mixed parity Removed balloons if SROM reducing effectiveness of cervical ripening</td>
<td>Explored efficacy and safety of CDB IOL with one prior CD U Balloon fill phased in increments of 40, 50, 60cc</td>
</tr>
<tr>
<td>Study (Year)</td>
<td>Country</td>
<td>Sample Size</td>
<td>Study Design</td>
<td>IOL</td>
<td>Bishop Score</td>
<td>Success Rate</td>
<td>Parity</td>
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<tr>
<td>Ebeid &amp; Nassif, (2013)</td>
<td>United Kingdom</td>
<td>17 IOL</td>
<td>Observational Level II-2</td>
<td>IOL Prior CD 41 3/7 and 42 weeks Bishop score &lt; 6</td>
<td>0%</td>
<td>53%</td>
<td>Small study</td>
</tr>
<tr>
<td>Jozwiak et al., (2014)</td>
<td>Netherlands</td>
<td>208 FB</td>
<td>Retrospective Level II-2</td>
<td>IOL with FB Prior CD Bishop score &lt; 6</td>
<td>0.5%</td>
<td>71.2%</td>
<td>Explored complication rates in IOL with CRB in TOLAC FB fill 30 ml FB in place up to 48 hours Included ruptured membranes with or without GBS</td>
</tr>
<tr>
<td>Khotaba et al., (2001)</td>
<td>Israel</td>
<td>37 ATAD DB</td>
<td>Observational Level II-3</td>
<td>IOL DBD Prior CD Burnett’s modified Bishop score 4 or less</td>
<td>0%</td>
<td>60.8%</td>
<td>Small study Short report</td>
</tr>
<tr>
<td>Ravasia et al., (2000)</td>
<td>Canada</td>
<td>129 FB 172 PGE2 1544 SL</td>
<td>Retrospective Level II-2</td>
<td>All Prior CD between 1992-1998 TOLAC</td>
<td>0.76%</td>
<td>60.8%</td>
<td>Mixed parity Bishop score not reported Unclear definition of active labor</td>
</tr>
<tr>
<td>Sananes et al., (2014)</td>
<td>France</td>
<td>135 FB; 89 AROM +/-oxytocin; 1045 SL; 806 ERCD = 0.3% UR (2/806)</td>
<td>Observational Level II-2</td>
<td>Single prior CD 2007-2012 FB Bishop score &lt; 6</td>
<td>0%</td>
<td>43.7%</td>
<td>Mixed parity</td>
</tr>
<tr>
<td>Authors</td>
<td>Study Design</td>
<td>Study Site</td>
<td>Study Details</td>
<td>Bishop Score(s)</td>
<td>VBAC Success Rate</td>
<td>Study Type</td>
<td>Findings</td>
</tr>
<tr>
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<tr>
<td>Voon et al., (2015)</td>
<td>Retrospective Level II-2</td>
<td>Sarawak</td>
<td>Prior CD or/and grand multiparity Bishop score &lt; 7</td>
<td>1.7% 44.8%</td>
<td>Mixed parity</td>
<td>Compared CRB in grand multipara to CRB in VBAC FTP if 6-8 hours adequate contractions and no active phase of labor accounts for low VBAC success</td>
<td>Authors interested in CDBD use in women who are high risk for UR including prior CD and/or grandmultiparity</td>
</tr>
<tr>
<td>Ziyauddin et al., (2013)</td>
<td>Prospective Case matched Level II-1</td>
<td>India</td>
<td>One prior CD Bishop score &lt; 6</td>
<td>0% 71.4%</td>
<td>Mixed parity</td>
<td>Compared PGE2 to FB in VBAC</td>
<td></td>
</tr>
</tbody>
</table>

**Notes:** AROM = artificial rupture of membranes; CD = Cesarean delivery; CRB = cervical ripening balloon; CDBD = Cook’s double balloon device; DB = double balloon; DBD = double balloon device; ERCD = elective repeat cesarean delivery; FB = Foley catheter ripening balloon; FTP = failure to progress; IOL = induction of labor; NS = not statistically significant; PGE2 = Prostaglandin E2; PP = postpartum; RCS = repeat cesarean section; SL = spontaneous labor; SVD = spontaneous vaginal delivery; TOLAC = trial of labor after cesarean; U = uterine; UR = uterine rupture; VBAC = vaginal birth after cesarean.

*a* Levels of evidence assigned based on ACOG’s department publication; Reading the Medical Literature (Scott et al., 2015).

*b* VBAC success rate reported included all methods of induction: CRB, PGE2, and CRB + PGE2 e.g., was not stratified.