2023

Outpatient Cervical Ripening Balloon - Healthcare Costs and Patient Satisfaction: An Integrative Review

Krystal A. Hall
Bethel University

Danielle Pfister
Bethel University

OUTPATIENT CERVICAL RIPENING BALLOON- HEALTHCARE COSTS AND PATIENT SATISFACTION: AN INTEGRATIVE REVIEW

A CAPSTONE PROJECT

SUBMITTED TO THE GRADUATE FACULTY

OF THE GRADUATE SCHOOL

BETHEL UNIVERSITY

BY

KRYSTAL HALL AND DANIELLE PFISTER

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MASTER OF SCIENCE IN NURSING

MAY 2023

BETHEL UNIVERSITY

Outpatient Cervical Ripening Balloon- Healthcare Costs and Patient Satisfaction: An Integrative Review

Krystal Hall and Danielle Pfister

May 2023

Approvals:

Project Advisor Name: Rebecca M. Smith, MSN, CNM

Project Advisor Signature: _____

Second Reader Name: Julie Ann Vingers, PhD, APRN, CNM, FACNM

Second Reader Signature: _____

Director of Nurse-Midwifery Program Name: Katrina Wu, PhD, APRN, CNM

Director of Nurse-Midwifery Program Signature: _____

Acknowledgments

The authors would like to thank their research librarian Lyndi Fabbrini for her advice on the discovery of the research. They are also immensely grateful to their adviser, Rebecca Smith, MSN, CNM for providing her guidance throughout this project. They would also like to thank the second reader Dr. Julie Ann Vingers, DNP, CNM, and their editor, Anne Marie Gruber for their expertise. Lastly, the authors would like to thank their families; this work would not have been possible without their love and support.

-Danielle Pfister and Krystal Hall

I would like to thank God, first and foremost, for making this journey possible, for opening and shutting doors, and for guiding me step by step, even when I couldn't always see it. I want to thank my husband, David, for selflessly encouraging me to pursue my dream, even though it made his life more complicated. Thank you for loving me, and our children so well. I want to thank my mother, Mary, for leaving her own home, to help care for my children, while I was away. You have given of yourself in so many ways throughout my life…thank you for everything.

To Jeremiah, Emily, Klara, and Josiah, it is such a blessing to be your mom, and I am thankful for you every single day. Over the past three years, you have shared me with this midwifery program, and I deeply regret how much time it has required me to be away from you. When I began the program, I had no idea it would demand so much of me, but never once did any of you give me anything less than support and love. Thank you. My prayer for each of you is that you follow Jesus, pursue your dreams, and live with love.

I want to thank all of my preceptors, especially Kayla and Nicole. Thank you for giving me so much of your time. Thank you for teaching me, and for being patient with me. Lastly,

thank you to Marcia in Indiana, and the Pfister family in Massachusetts. You shared your home and yourselves with me, and I am forever grateful.

-Krystal Hall

I would like to take this opportunity to thank my amazingly supportive husband Zach. This journey has been trying, but you have handled it with inspiring grace. Without your unwavering support and encouragement, this would have not been possible. My two sons George and Elliot, thank you for being my rocks and motivation. To my in-laws Lyn and Scott, thank you for taking such great care of our boys when I had to be at clinical. And to my parents for always encouraging me to chase my dreams no matter how big. I would also like to thank all my educators and preceptors, especially my two primary preceptors Nicole and Shelly. I am forever grateful to you all for teaching me what it takes to be a midwife.

-Danielle Pfister

Abstract

Introduction: Induction of labor (IOL) is common practice in the United States, with a rate of 25.7% in 2018. IOL can be a lengthy process, placing undue strain on the healthcare system, increasing healthcare costs, and decreasing patient satisfaction. The purpose of this integrative review is to determine how outpatient mechanical cervical ripening with a cervical ripening balloon (CRB) correlates with a change in hospital length of stay, patient satisfaction, and cost.

Methods: A keyword search strategy was utilized in PubMed, CINAHL, and Scopus databases. The inclusion criteria included original research published in the last 10 years, available in the English language, focusing on women undergoing outpatient cervical ripening with a CRB. A journal hand search was performed for articles published in the last 5 years in three publications. Finally, a citation search of the selected articles was completed. This search process yielded 24 articles for analysis. The social-ecological model was used to organize the findings according to areas of impact: individual, interpersonal, organizational, community, and public policy.

Results: Among these 24 articles, the total number of participants was 14,376. Findings revealed that overall patient satisfaction was high with CRB use. Most studies demonstrated a shorter hospital stay in outpatient CRB groups and indicated that CRB was not associated with adverse maternal or neonatal outcomes. Moderate cost savings were noted in three studies.

Discussion: This review reaffirms the evidence that outpatient use of CRB demonstrated safety and effectiveness. Patients have reported satisfaction with CRB, especially in the outpatient setting. Outpatient CRB demonstrated a reduction in inpatient hospital time which could result in reducing strain on healthcare systems and associated costs of hospitalization. Future research opportunities exist for a large randomized controlled trial (RCT) measuring time admitted to the hospital, costs, and patient satisfaction of CRB in the inpatient versus outpatient setting.

Keywords: Catheter balloon, labor induction, outpatient cervical ripening, balloon catheter

Outpatient Cervical Ripening Balloon- Healthcare Costs and Patient Satisfaction: An Integrative Review

Introduction

Labor induction is the attempt to artificially prompt the onset of labor through mechanical and/or pharmacological methods. Labor induction may be indicated due to medical complications, or be offered electively once a patient reaches 39 weeks' gestation (ACOG, 2018). The U.S. labor induction rate increased from 9.6% in 1990 to 25.7% in 2018 (Declercq et al., 2020). Induction of labor (IOL) can result in lengthy hospital stays, particularly in nulliparous women or women with an unfavorable cervix, where the patient will first require cervical ripening. The resultant long hospital stays place increased strain on patients, their families, and the healthcare system.

Cervical ripening is performed when a patient's cervix is considered unfavorable for labor, which is determined by applying the Bishop scoring system. The Bishop score measures cervical position, consistency, length, and dilation, in addition to fetal station. The assigned score can range from 0 to 13, with lower numbers indicating less cervical readiness for labor. In patients with a score less than 6, cervical ripening is often performed via mechanical or pharmacological methods (ACOG, 2018). Research investigating cervical ripening via mechanical means, specifically using a Foley or Cooks balloon catheter, will be the focus of this review.

Mechanical cervical ripening methods are safely performed in the outpatient setting. In fact, the American College of Obstetricians and Gynecologists (ACOG) states:

> Mechanical methods may be particularly appropriate in the outpatient setting. A randomized trial comparing the Foley catheter in an outpatient versus inpatient setting for

pre-induction cervical ripening demonstrated similar efficacy and safety with a reduction of hospital stay of 9.6 hours (2016).

In addition to safety benefits, outpatient cervical ripening could decrease healthcare costs and length of hospital stay, and potentially improve patient satisfaction by allowing the patient more time at home. The average inpatient cost per day in U.S. hospitals is $2883 (Kaiser Family Foundation, 2023), so if this procedure were to be done as an outpatient, it could potentially result in cost savings equal to one day of an inpatient stay. Women undergoing labor induction in the inpatient setting, even with mechanical methods, require nursing care and some form of fetal monitoring, both of which add to the burden on the healthcare system.

Despite ACOG's supportive position on outpatient cervical ripening with mechanical methods, the practice has not been widely accepted in the United States. The purpose of this integrative review is to determine how outpatient mechanical cervical ripening with a cervical ripening balloon (CRB) correlates with a change in hospital length of stay, patient satisfaction, and cost.

Using the social-ecological (McLeroy et al., 1988) model as the theoretical framework, this review will compare inpatient and outpatient cervical ripening and impacts at the individual, interpersonal, community, organizational, and policy levels. At the individual level, we will examine factors related to patient satisfaction, perception of safety, the importance of place, provider views, and any individual cost savings. The interpersonal level will focus on the impact of the patient-provider relationship, education, and communication. The community level will explore practice change among healthcare providers and the effect of expanded standards of care for labor induction. The organizational level will review the impact on hospital bed availability

and staff burden, as well as liability risk. Lastly, at the policy level, this review will look at insurance coverage, hospital policy, and professional guidelines.

Methods

This integrative review was conducted using Whittemore and Knafl's (2005) integrated review methodology. This approach involves identifying a problem, searching the current literature, evaluation, and data analysis. The literature search includes retrieval of experimental and non-experimental research studies from computerized databases, journal hand searching, and cited reference searching.

Search Strategy

A Bethel University librarian was consulted in creating a search strategy and determining search terms, inclusion, and exclusion criteria. The search terms used included, "outpatient cervical ripening balloon", "outpatient cooks balloon", "outpatient cervical ripening foley", "outpatient foley bulb induction", "outpatient cooks catheter", "inpatient cervical ripening balloon", "inpatient cooks balloon", "inpatient cervical ripening foley", "inpatient foley bulb induction", "inpatient cooks catheter", "inpatient mechanical cervical ripening", and "outpatient mechanical cervical ripening". The inclusion criteria included original research published within the last 10 years (between 2013 and 2023), and articles focusing on women who underwent inpatient or outpatient cervical ripening with a balloon catheter. Studies must have been available in the English language. The exclusion criteria included, research published in or before 2012 (older than 10 years), research studies unavailable in English, dissertations, case studies, reviews of literature, or theoretical cohorts.

A database search was conducted using the above criteria in January 2023 using the following databases: CINHAL (n= 34), PubMed (n=14), and Scopus (n= 62). The search results

were then added to Covidence Systematic Review Software. A total of 39 duplicates were automatically removed by the software. Title and abstract screening were then conducted individually by the authors and an additional 46 studies were screened out. Twenty-five articles underwent full-text review, with each article reviewed by the authors together. Four publications were excluded by mutual agreement for inapplicable study design (n=3) and the use of a mechanical dilation device other than a balloon catheter (n=1). The remaining 21 studies were found to be acceptable for this integrative review.

A journal hand search was performed in February 2023 for articles published in the last 5 years in the *American Journal of Obstetrics and Gynecology* (AJOG), *Midwifery: An International Journal*, and *The Journal of Midwifery and Women's Health*. This hand search resulted in one additional publication that met the inclusion criteria.

A citation search was completed by the authors by reviewing the reference lists of the selected articles to find relevant articles published within the past 5 years. This search yielded two results that met the criteria for this integrative review. This brought the total number of articles to 24. The selected publications were then sorted and organized into a literature matrix (see Appendix). Each primary study was analyzed using the *Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines* (Dang & Dearholt, 2017) which ranks research evidence on a scale of I-III for the type of research and high, good, or low-quality research to ensure that the evidence is valid and credible. Finally, the *Social-Ecological* model (McLeroy et al., 1988) was applied to the selected articles, which were then organized into the following categories: 1) individual, 2) interpersonal, 3) community, 4) organizational, and 5) policy.

Results

This integrative review includes 24 original research publications published between 2013 and 2022. A variety of methodologies were included: randomized controlled trials, cost-effectiveness analyses, retrospective and prospective cohort studies, qualitative exploratory design studies, and survey research. These studies were conducted in several countries including the United States, Singapore, Australia, Malaysia, Finland, and the Netherlands. The total number of participants throughout all studies was n=14,376. These studies included both nulliparous (n=9,356) and multiparous women (n=863) of diverse ethnic backgrounds and childbearing age (at least 18 years). Common themes noted throughout participant selection criteria included: Singleton term pregnancies (37-41 weeks 6 days gestation) in the cephalic position, Bishop score <6, and reassuring fetal heart tracing.

Twelve of the publications were considered level I evidence, seven were considered level II evidence, and five were level III evidence based on the *Johns Hopkins Nursing Evidence-Based Practice* (Dang & Dearholt, 2017) rating hierarchy for research evidence. The publications were also categorized into high, good, or low-quality evidence. One study was found to be high quality, 21 were good quality, and two were low quality.

Ten studies measured inpatient versus outpatient CRB use. Five studies measured inpatient cervical ripening with prostaglandins versus outpatient cervical ripening balloons. Two studies measured outpatient balloons versus outpatient prostaglandins. One study measured the pain/discomfort with the insertion of the Foley catheter insertion. Three measured inpatient CRB versus inpatient prostaglandins. One measured the timing of adverse events associated with the Foley catheter. One study measured patient attitudes toward outpatient cervical ripening. One study evaluated patient and clinician perceptions of a double balloon catheter for induction.

Length of Hospital Stay/Time to Delivery

The length of hospital stay was addressed in eleven studies. When comparing inpatient to outpatient CRB, most of the findings demonstrated a reduction of time spent in the hospital, with outpatients' stay between 4.3 and 10 hours less than inpatient groups. When comparing inpatient prostaglandin to inpatient CRB, a large, randomized controlled trial including 7551 nulliparous participants demonstrated that the time-to-delivery interval was on average 6.9 hours shorter in patients who received a CRB versus dinoprostone (Wollmann et al., 2017). In the studies comparing inpatient prostaglandin cervical ripening versus outpatient CRB, one study demonstrated a reduction in hours admitted to the hospital before birth 9.7 hours in the inpatient dinoprostone group versus 13.9 hours in the outpatient group (Austin et al., 2015).

Outpatient dinoprostone was shown in a retrospective comparison of 153 women to have comparable outcomes to outpatient CRB. However, there was an increased risk of uterine tachysystole and the need for another cervical ripening method when dinoprostone was utilized compared to the CRB.

Patient Satisfaction

Patient satisfaction scores were assessed in 14 studies. The majority of participants were satisfied with the CRB in both the inpatient and outpatient settings and most patients felt this was a satisfactory and safe method of cervical ripening. The outpatient group of one study reported feeling less isolated or emotionally alone (Wilkinson et al., 2015). The majority of the patients in one study would choose this cervical ripening method again in a subsequent pregnancy and recommend it to a friend or family member (Waldron et al., 2022). One study reported that the outpatient balloon group experienced less pain "significant discomfort" rated by patients at 26% versus 58%) and had more sleep (5.8 hours versus 3.4 hours) compared to the inpatient prostaglandin group (Henry et al., 2013). Gidazewski et al., (2018) found that digital cervical

examination and speculum insertion was more uncomfortable than the insertion of a Foley catheter. However, in a study by Waldron et al., (2021) all of the participants (n=20) found the placement procedure of the balloon to be uncomfortable. A significant majority, (87%) of those patients, were given medications that were effective in reducing their discomfort

Sutton et al. (2016) assessed satisfaction with the use of a CRB in a high-risk cohort. Only 33% of high-risk participants reported that they would feel happy to undergo cervical ripening at home. This could be in part due to their self-perceived risk and therefore may not be generalizable to a lower-risk population (Sutton et al., 2016).

Safety, Efficacy, and Adverse Outcomes

Safety, efficacy, and adverse outcomes were addressed in 17 of the studies. Overall, the cervical ripening balloon was found to be safe and effective. There were no adverse outcomes or increase in maternal or neonatal harm from the use of a CRB. However, Beckmann et al. (2019) found an increased likelihood of cesarean (C/S) delivery in multiparous women (n=187) undergoing induction with a CRB (17.2% vs 5.1%) compared to the prostaglandin group. The reason for this increased risk was undetermined. The indications for cesarean section included slow progress, failed induction, fetal distress, failed instrument, cord prolapse, undiagnosed breech in labor, and "other". There is no differentiation between the reasons listed for nulliparous and multiparous women (Beckmann et al., 2019). Several other studies reported no increased risk of cesarean delivery (Ausbeck, et al., 2020; Austin et al., 2015; Henry et al., 2013; Kruit et al., 2016; Kuper et al., 2018; Washburn et al., 2021), while one study (Policiano et al, 2016) reported a lower rate of C/S for failed induction of labor. Blair et al., (2020) demonstrated that patients in the prostaglandin group were more likely to experience uterine tachysystole and require another

method of cervical ripening. The same study cited no differences in maternal and neonatal outcomes.

Wollmann et al. (2017) published a large RCT including 7,551 participants, and the balloon catheter was found to be the most effective cervical ripening method in term nulliparous women when compared to misoprostol and dinoprostone. Adjusted mean time to delivery interval was 6.9 and 1.5 hours shorter respectively when inducing with a balloon catheter or misoprostol compared with dinoprostone. This study also did not find any significant differences between the different induction methods in maternal or infant adverse outcomes including cesarean delivery, or maternal/neonatal complications (Wollmann et al., 2017).

Cost Comparison

The potential for cost savings is addressed in 4 studies (Austin et al., 2015; Merollini & Beckmann, 2021; Ten Eikelder et al., 2017; Washburn et al., 2021). Moderate cost savings were noted in 3 studies, and 1 reported no cost savings. Merollini and Beckmann (2021) reported a cost of $7294 in the outpatient balloon group compared with $7585 in the inpatient prostaglandin group, a savings of $291. An additional study noted savings of $408 per delivery from admission to discharge (Washburn et al., 2021).

Ten Eikelder et al. (2017) compared the cost of inpatient misoprostol and inpatient balloon, finding an average cost difference of €312 (approximately $340) in favor of the balloon. The authors suggested that if the balloon was moved to the outpatient setting there could be a potential cost savings of €1000 (approximately $1090) per induction (Ten Eikelder et al., 2017).

Socio-ecological Theoretical Framework: Individual

Individual factors were addressed as either primary or secondary outcome measures in several of the reviewed studies. These studies examined patient satisfaction with various aspects

of the outpatient induction process: comfort level and degree of perceived safety in staying home during cervical ripening, level of preparedness and knowledge about the induction process, and pain during catheter or vaginal prostaglandin insertion. Individual cost savings to the patient was not addressed by any of the studies. Some of the individual factors were intrinsically related to interdependent factors, such as counseling or education they received from their provider before beginning the cervical ripening process.

The theme of the importance of place was explored, with mixed results; some participants expressed the desire to be in the comfort of one's home, while still experiencing the perception of safety that is offered by the hospital (Coates et al., 2020). In the same qualitative study (which was performed alongside a randomized controlled trial that compared outpatient vaginal prostaglandin pessary to outpatient balloon catheter), the patient's desire to maintain some level of control over the process was explored. The majority of participants expressed a desire for an induction process that was less medicalized, and the ability to stay home for cervical ripening was seen as a way to help fulfill this. Additionally, many women felt the balloon catheter to be more natural than a vaginal prostaglandin, with all but two participants expressing they would want to have the option of a balloon catheter in the future, should they require cervical ripening in a subsequent pregnancy (Coates et al., 2020). In contrast, in 3 studies comparing patient satisfaction related to the method and/or place of cervical ripening, participants stated they were pleased with whichever method they experienced, with no significant differences in patient satisfaction scores (Ausbeck et al., 2020; Lim et al., 2018; Wang et al., 2021).

Finally, Waldron et al. (2022) and Wilkinson et al. (2015) explored provider views concerning outpatient cervical ripening, with most midwives and doctors expressing that outpatient cervical ripening should be offered to eligible patients. The majority also reported a

greater comfort level in the use of a balloon catheter for outpatient cervical ripening, rather than a vaginal prostaglandin. However, approximately half of the midwives and physicians surveyed by Wilkinson et al. (2015) considered the balloon catheter to be more invasive than prostaglandin gels.

Interpersonal

None of the reviewed studies focused primarily on interpersonal factors, though 2 studies (Coates et al., 2020; Crosland et al., 2022) mentioned the importance of provider-patient communication. Crosland et al. (2022) noted that patient education and counseling, performed before induction, were closely related to patient satisfaction. In a qualitative study (Coates et al., 2020) performed alongside a randomized controlled trial, there was a common theme that women felt underprepared for the induction process, despite verbal and written communication being provided. This illustrates the importance of effective communication and shared decision-making between patient and provider. One benefit of being in the hospital was the nearby presence of midwifery staff, which most women felt was comforting and provided a sense of safety (Coates et al., 2020).

Community

Community impacts include the provision of additional cervical ripening options for eligible women. Henry et al. (2013) noted that because outpatient induction of labor was not available in the community, it may have influenced patient perception; many trial participants were eager to have outpatient induction available to them. Increased bed availability and reduced staff burden are potential benefits, as Ausbeck et al. (2020) and Hamdan et al. (2021) cited a decreased time in labor and delivery or a reduction in overall hospital length of stay. However, this was not demonstrated in all studies. Austin et al., (2015) concluded that outpatient CRB

demonstrated fewer inpatient hours and lower costs before delivery. There was no reduction in overall inpatient hours or time to delivery from admission to the birthing unit.

Organizational

Kuper et al., (2018) raised concern that implementation of outpatient cervical ripening created an increased demand on the healthcare provider's time, to ensure fetal well-being, initiate cervical ripening, and potentially field increased patient phone calls. Potential organizational benefits included decreased hospital length of stay (Hamdan et al., 2021), decreased catheter placement to delivery time (Wollmann et al., 2017), reduction in cesarean deliveries for failed induction in the outpatient group (Policiano et al., 2017), and decreased organizational cost (Ten Eikelder et al., 2017; Washburn et al., 2021). In contrast, 1 study demonstrated no organizational cost savings due to no reduction in total inpatient hours (Austin et al., 2015).

Policy

Among all of the socio-economic model components, policy was discussed the least in the reviewed studies. As mentioned above, the American College of Obstetricians and Gynecologists states that "mechanical methods may be particularly appropriate in the outpatient setting" (ACOG, 2016). Good clinical maternal/neonatal outcomes, while obviously of extreme importance, should not be the only consideration in providing excellent obstetric care (Beckmann, et al., 2020). This point is emphasized by the World Health Organization (2018), which noted that a positive childbirth experience should be considered a "significant endpoint for all women undergoing labor" (p. 1). They go on to further define a positive experience as fulfilling a woman's expectations, in a safe environment that includes clinical and emotional support, with the presence of clinically competent staff.

Discussion regarding financial remuneration related to insurance policies for obstetric care was mentioned in 1 study (Kuper et al., 2018). They noted that the required clinic visit for outpatient catheter placement is unlikely to be paid for separately by insurance providers due to global fee billing, which is common in obstetric practice. This conflicts with studies that observed potential organizational cost savings, as discussed above.

Discussion

This integrative review utilized the socio-ecological model (McElroy et al., 1988) which explores the interrelated nature of individual, interpersonal, organizational, community, and policy factors. Application of this framework allowed us to examine how each level impacts and influences the other, related to the use of a balloon catheter for cervical ripening in the outpatient setting. Whittemore and Knafl's (2005) integrated review methodology was utilized in the literature search, evaluation, and analysis of data. This information was then organized according to the socio-ecological framework to better understand its impact at the various levels.

Application of the Socio-ecological Model

Patient satisfaction, perception of safety, the importance of place, and provider views were components reviewed at the individual level. The importance of place was identified, with inconsistent results, as some women found comfort in remaining at home for a longer period, while others preferred the hospital setting as a perceived place of safety. The idea that the cervical balloon catheter was a more natural way to begin labor was expressed, as was the perception of having increased control over the induction process (Coates, et al, 2020). Interestingly, in 3 studies that compared patient satisfaction according to method and place of cervical ripening, participants largely favored whichever cervical ripening method they received, with similar patient satisfaction scores among the various interventions (Ausbeck et al., 2020;

Lim et al., 2018; Wang et al., 2021). This lack of significant difference in patient satisfaction scores may reflect interpersonal factors that influence a person's overall experience. Indeed, the interpersonal factors of patient education and access to healthcare providers were cited as influencing patient satisfaction (Coates et al., 2020; Crosland et al., 2022).

Two studies explored provider perception of outpatient cervical ripening with a balloon catheter, with most providers agreeing that outpatient cervical ripening should be an option for eligible patients. Half of the midwives and physicians surveyed by Wilkinson et al. (2015) considered the balloon catheter to be more invasive than prostaglandin gels. Reasons for this were not stated, but one may speculate that it could be due to patient discomfort at the time of insertion.

Increased inpatient bed availability, decreased organizational cost, and reduced nursing staff burden are intriguing potential community and organizational benefits to the expanded use of outpatient cervical ripening. However, this review demonstrated conflicting results. One study (Henry et al., 2013) summarized that the desire to participate in a trial for outpatient cervical ripening, which was not a standard option in the community, may have influenced patient perception of the procedure. This indicates that increased options for cervical ripening may be appealing to pregnant women.

Findings were inconsistent regarding organizational benefits. Three studies cited actual or potential cost savings (Merollini et al., 2021; Ten Eikelder et al., 2017, and Washburn et al., 2018). Decreased time in labor and delivery or a reduction in overall hospital length of stay was cited in three studies (Ausbeck et al., 2020; Hamdan et al., 2021; Policiano et al., 2017); however, this finding was not demonstrated in all studies as evidenced by conflicting results in Austin et al. (2015). Kuper et al. (2018) raised the concern of increased time burden for the

healthcare provider to ascertain fetal well-being prior to initiating cervical ripening, and the potential for increased phone calls once the patient went home to continue cervical ripening. The same study also raised concern that insurance policies may decline to reimburse outpatient cervical catheter balloon placement due to the common practice of obstetric global fee billing. Global billing in the United States covers care from pregnancy through birth and the postpartum period. If there can be cost savings for induction of labor, it could result in an increase in profit for the hospital or provider.

Length of Hospital Stay/Time to Delivery

The use of a cervical ripening balloon has been found to decrease the total cervical ripening time whether in the inpatient or outpatient setting. In the inpatient setting, the total time to delivery interval was found to be less in the balloon group when compared to prostaglandins. When comparing outpatient cervical ripening balloons to inpatient cervical ripening the time spent admitted to the hospital was found to be significantly less. This reduction in hospital stay length has the potential to lead to a significant reduction of strain on the healthcare system and nursing costs. In a meta-analysis, Pierce-Williams et al. (2022) analyzed 8 randomized controlled trials, finding a significant reduction in time patients who received an outpatient cervical ripening balloon were admitted to labor and delivery units, with a mean difference of 7.24 hours.

Patient Satisfaction

Although the procedure to place the balloon was found to be uncomfortable by most patients, this pain was slightly less when placed by digital exam compared to speculum placement. In most cases, the discomfort decreased the longer the balloon catheter was in place, and the pain medication was effective in reducing discomfort associated with the insertion procedure. Greater satisfaction, hours of sleep, feeling more emotionally supported, and less

perceived pain and feelings of isolation were found in the outpatient cervical ripening groups. The majority of patients who underwent outpatient cervical ripening with balloons were more likely to choose this method in future pregnancies and recommend it to their family or friends. The meta-analysis by Pierce-Williams e. al., (2022) also found that patients were equally or more satisfied with outpatient cervical ripening compared to the inpatient setting.

High-risk patients were the exception. They were not comfortable with starting their cervical ripening at home (AUTHOR, YEAR). This could be due to their self-perceived high risk; therefore, these results are not generalizable to the low-risk population.

Safety, Efficacy, and Adverse Outcomes

This review found that in the majority of studies, outpatient cervical ripening was not associated with an increased risk of maternal or neonatal morbidity or mortality. One study found an increased risk of cesarean section in multiparous women, but further research is needed to determine if that is a generalizable finding (Beckmann et al., 2020). The meta-analysis published by Pierce-Williams, et al. (2022) found that the outpatient cervical ripening groups were less likely to undergo a cesarean section (26% versus 21%). The researchers also found infrequent maternal or neonatal adverse outcomes, and no reported stillbirths or neonatal deaths. These findings are consistent with our findings.

Cost Comparison

There were findings of cost savings in the outpatient balloon catheter group. This cost savings is likely the direct result of the reduction in time spent inpatient in the hospital setting, thereby reducing inpatient hospital and nursing care costs. In a theoretical cohort of 760,000 low-risk nulliparous women at term, a cost savings of $2159 is estimated in favor of the outpatient

cervical ripening balloon group (Christensen et. al., 2021). As mentioned above, this cost savings could result in increased profit for hospitals and obstetric care providers.

Implications for Advanced Practice Nurses

Though this review found some conflicting results regarding organizational benefits, overall patient satisfaction was high for those who participated in outpatient cervical ripening. Additionally, there were no associated significant adverse outcomes demonstrated. The American College of Obstetricians and Gynecologists states that mechanical cervical ripening may be a particularly appropriate outpatient option (ACOG, 2016), and the World Health Organization (2018) advocates that healthcare providers strive to provide a positive childbirth experience for women. This review demonstrates that the ability to remain at home for cervical ripening is an appealing option for some. With these factors in mind, certified nurse-midwives (CNM) have the opportunity to offer outpatient cervical ripening as a viable, safe option for eligible women.

Implications for Future Research

There were several smaller randomized controlled trials currently published and available for this review, some comparing prostaglandins to cervical ripening balloons in various settings. To attain the most accurate information, a large multiregional RCT directly comparing inpatient to outpatient would be necessary, measuring patient satisfaction, pain scores, inpatient time savings, cost savings, and adverse outcomes.

Limitations

The authors acknowledge this review is not without limitations. Though we made every effort to be thorough with our search terms, there may be some studies that were missed due to search term selection; to minimize this, we conducted a journal hand search. The reviewed

studies were conducted in several countries including the United States, Singapore, Australia, Malaysia, Finland, and the Netherlands, but may not be generalizable to countries without similar healthcare and economic infrastructure.

Conclusion

The current evidence supports cervical ripening in the outpatient setting with the use of a cervical ripening balloon for low-risk pregnant women. This review reaffirms the evidence that outpatient use of CRBs has demonstrated safety and effectiveness. Patient satisfaction scores with the CRB were equivalent to prostaglandin cervical ripening methods and were greater in the outpatient setting. Outpatient ripening with a balloon catheter has demonstrated a reduction in inpatient hospital time which could result in reducing strain on healthcare systems and associated costs of hospitalization.

References

American College of Obstetricians and Gynecologists. (2016). *IOL with Foley*. https://www.acog.org/education-and-events/creog/curriculum-resources/cases-in-high-value-care/iol-with-foley

American College of Obstetricians and Gynecologists. (2018). *Induction of labor at 39 weeks*. https://www.acog.org/womens-health/faqs/induction-of-labor-at-39-weeks

Ausbeck, E. B., Jauk, V. C., Xue, Y., Files, P., Kuper, S. G., Subramaniam, A., Casey, B. M., Szychowski, J. M., Harper, L. M., & Tita, A. T. (2020). Outpatient Foley catheter for induction of labor in nulliparous women. *Obstetrics & Gynecology*, *136*(3), 597–606. https://doi.org/10.1097/aog.0000000000004041

Austin, K., Chambers, G. M., de Abreu Lourenco, R., Madan, A., Susic, D., & Henry, A. (2015). Cost-effectiveness of term induction of labor using inpatient prostaglandin gel versus outpatient Foley catheter. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, *55*(5), 440–445. https://doi.org/10.1111/ajo.12348

Beckmann, M., Acreman, M., Schmidt, E., Merollini, K. M. D., & Miller, Y. (2020). Women's experience of induction of labor using PGE2 as an inpatient versus balloon catheter as an outpatient. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *249*, 1–6. https://doi.org/10.1016/j.ejogrb.2020.03.031

Beckmann, M., Gibbons, K., Flenady, V., & Kumar, S. (2019). Induction of labour using prostaglandin E 2 as an inpatient versus balloon catheter as an outpatient: A multicentre randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, *127*(5), 571–579. https://doi.org/10.1111/1471-0528.16030

Blair, R., Harvey, M.-A., Pudwell, J., & Bougie, O. (2020). Retrospective comparison of PGE2 vaginal insert and Foley catheter for outpatient cervical ripening. *Journal of Obstetrics and Gynaecology Canada*, *42*(9), 1103–1110. https://doi.org/10.1016/j.jogc.2020.02.112

Christensen, A., Hersh, A. R., Hermesch, A., Sciscione, A., & Caughey, A. B. (2021). 1075 Outpatient cervical ripening with foley catheter in low-risk women: A cost-effectiveness analysis. *American Journal of Obstetrics and Gynecology*, *224*(2), S664–S665. https://doi.org/10.1016/j.ajog.2020.12.1100

Coates, R., Cupples, G., Scamell, A., McCourt, C., & Bhide, A. (2020). Women's experiences of outpatient induction of labour with double balloon catheter or prostaglandin pessary: A qualitative study. *Women and Birth*, *34*(4), e406-415. https://doi.org/10.1016/j.wombi.2020.07.006

Crosland, A., Shrivastava, V., & Naidoo, D. (2022). 1072 Patient satisfaction during outpatient versus inpatient Foley catheter induction of labor. *American Journal of Obstetrics and Gynecology*, *226*(1), S680. https://doi.org/10.1016/j.ajog.2021.11.1122

Dang, D., & Dearholt, S. (2017). *Johns Hopkins Nursing Evidence-Based Practice Model and Guidelines* (3rd ed.). Sigma Theta Tau International Honor Society of Nursing.

Declercq, E., Belanoff, C., & Iverson, R. (2020). Maternal perceptions of the experience of attempted labor induction and medically elective inductions: Analysis of survey results from listening to mothers in California. *BMC Pregnancy and Childbirth*, *20*(1). https://doi.org/10.1186/s12884-020-03137-x

Gidaszewski, B., Khajehei, M., & McGee, T. (2018). Outpatient cervical ripening: Discomfort/pain during speculum and Foley catheter insertion. *Midwifery*, *67*, 57–63. https://doi.org/10.1016/j.midw.2018.09.012

Hamdan, M., Shuhaina, S., Hong, J. G., Vallikkannu, N., Zaidi, S. N., Tan, Y. P., & Tan, P. C. (2021). Outpatient vs inpatient Foley catheter induction of labor in multiparas with unripe Cervixes: A randomized trial. *Acta Obstetricia Et Gynecologica Scandinavica*, *100*(11), 1977–1985. https://doi.org/10.1111/aogs.14247

Henry, A., Madan, A., Reid, R., Tracy, S. K., Austin, K., Welsh, A., & Challis, D. (2013). Outpatient Foley catheter versus inpatient prostaglandin E2 gel for induction of labour: A randomised trial. *BMC Pregnancy and Childbirth*, *13*(1), Article 25. https://doi.org/10.1186/1471-2393-13-25

Kaiser Family Foundation. (2023, January 17). *Hospital adjusted expenses per inpatient day*. https://www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day/

Kruit, H., Heikinheimo, O., Ulander, V.-M., Aitokallio-Tallberg, A., Nupponen, I., Paavonen, J., & Rahkonen, L. (2016). Foley catheter induction of labor as an outpatient procedure. *Journal of Perinatology*, *36*(8), 618–622. https://doi.org/10.1038/jp.2016.62

Kuper, S. G., Jauk, V. C., George, D. M., Edwards, R. K., Szychowski, J. M., Mazzoni, S. E., Wang, M. J., Files, P., Tita, A. T., Subramaniam, A., & Harper, L. M. (2018). Outpatient Foley catheter for induction of labor in Parous Women. *Obstetrics & Gynecology*, *132*(1), 94–101. https://doi.org/10.1097/aog.0000000000002678

Lim, S. E., Tan, T. L., Ng, G. Y. H., Tagore, S., Kyaw, E. E. P., & Yeo, G. S. H. (2018). Patient satisfaction with the cervical ripening balloon as a method for induction of labour: A

randomised controlled trial. *Singapore Medical Journal*, *59*(8), 419–424. https://doi.org/10.11622/smedj.2018097

McLeroy, K. R., Bibeau, D., Steckler, A., & Glanz, K. (1988). An ecological perspective on health promotion programs. *Health Education Quarterly*, *15*(4), 351–377. https://doi.org/10.1177/109019818801500401

Merollini, K. M. D., & Beckmann, M. (2021). Induction of labor using balloon catheter as an outpatient versus prostaglandin as an inpatient: A cost-effectiveness analysis. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *260*, 124–130. https://doi.org/10.1016/j.ejogrb.2021.03.020

Pierce-Williams, R., Lesser, H., Cohen, I., Bauer, M., Berghella, V., D'Adamo, C., & Ehsanipoor, R. (2022). Inpatient versus outpatient transcervical Foley catheter use for cervical ripening: A randomized controlled trial. *American Journal of Obstetrics and Gynecology*, *226*(1), S772-773. https://doi.org/10.1016/j.ajog.2021.11.1268

Pierce-Williams, R. , Lesser, H. , Saccone, G. , Harper, L. , Chen, V. , Sciscione, A. , Kuper, S. , Subramaniam, A. , Ehsanipoor, R. & Berghella, V. (2022). Outpatient cervical ripening with balloon catheters. *Obstetrics & Gynecology, 139* (2), 255-268. doi: 10.1097/AOG.0000000000004644.

Policiano, C., Pimenta, M., Martins, D., & Clode, N. (2017). Outpatient versus inpatient cervix priming with Foley catheter: A randomized trial. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *210*, 1–6. https://doi.org/10.1016/j.ejogrb.2016.11.026

Sutton, C., Harding, J., & Griffin, C. (2016). Patient attitudes towards outpatient cervical ripening prior to induction of labour at an Australian tertiary hospital. *Journal of*

Obstetrics and Gynaecology, *36*(7), 921–928. https://doi.org/10.1080/01443615.2016.1174826

Ten Eikelder, M. L. G., van Baaren, G.-J., Oude Rengerink, K., Jozwiak, M., de Leeuw, J. W., Kleiverda, G., Evers, I., de Boer, K., Brons, J., Bloemenkamp, K. W. M., & Mol, B. W. (2017). Comparing induction of labour with oral misoprostol or Foley catheter at term: Cost-effectiveness analysis of a randomised controlled multi-centre non-inferiority trial. *BJOG: An International Journal of Obstetrics & Gynaecology*, *125*(3), 375–383. https://doi.org/10.1111/1471-0528.14706

Waldron, S., Contziu, H., Aleshin, O., & Phipps, H. (2022). A snapshot of women's and clinicians' perceptions of the double balloon catheter for induction of Labor. *European Journal of Midwifery*, *6*(May), 1–6. https://doi.org/10.18332/ejm/146689

Wang, M. J., Jauk, V. C., George, D. M., Kuper, S. G., Edwards, R. K., Szychowski, J. M., Mazzoni, S. E., Files, P., Tita, A. T., Subramaniam, A., & Harper, L. M. (2021). Patient satisfaction with outpatient cervical ripening in parous women. *American Journal of Perinatology*, *38*(S 01), e71-e76. https://doi.org/10.1055/s-0040-1705170

Washburn, M. C., Washburn, M., Hong, C., Roth, P., & Richter, P. (2021). Outpatient Foley catheter induction protocol provides clinical and cost benefits. *Birth*, *48*(4), 574–582. https://doi.org/10.1111/birt.12568

Whittemore, R., & Knafl, K. (2005). The integrative review: updated methodology. Journal of advanced nursing, 52(5), 546–553. https://doi.org/10.1111/j.1365-2648.2005.03621.x

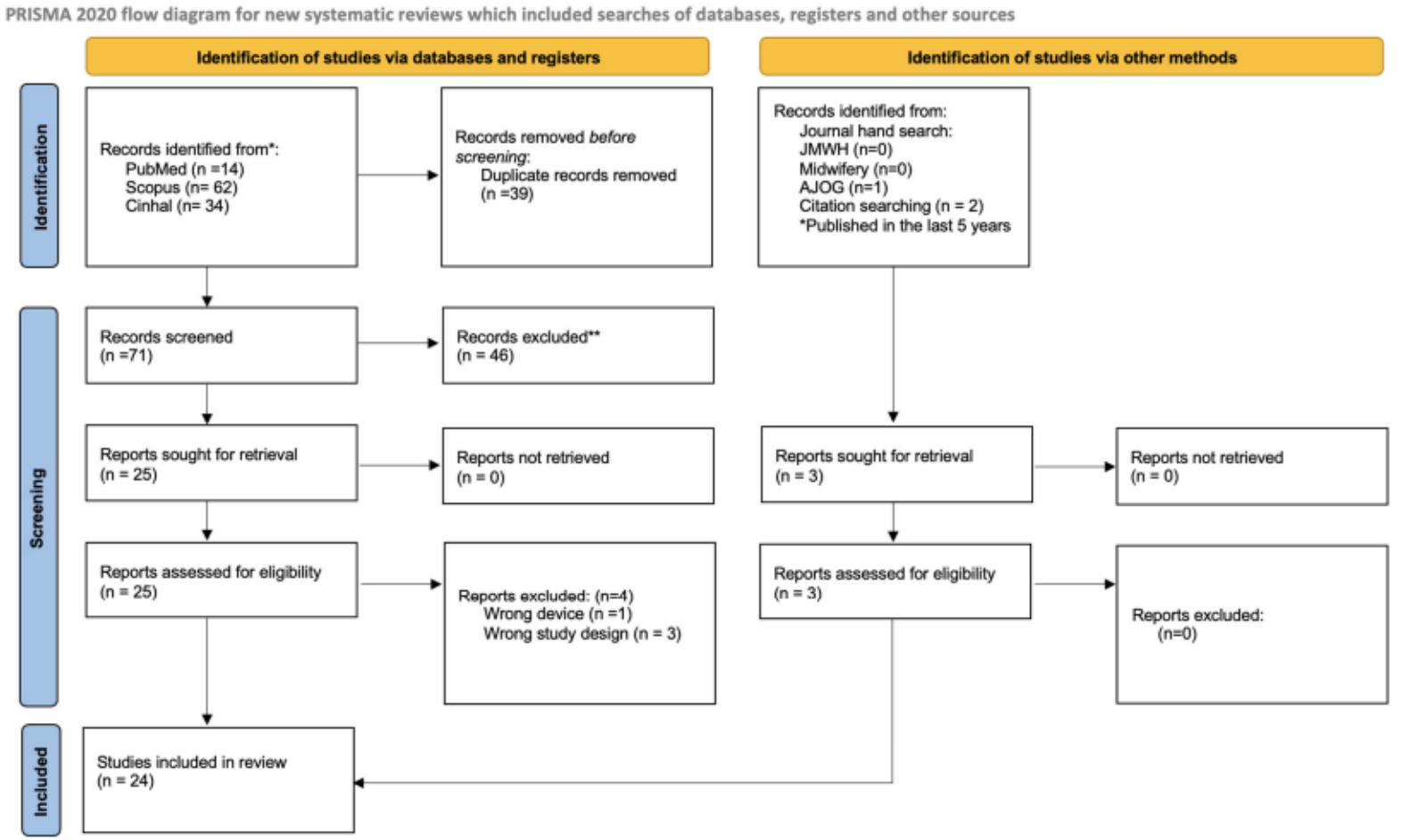
Wilkinson, C., Adelson, P., & Turnbull, D. (2015). A comparison of inpatient with outpatient balloon catheter cervical ripening: A pilot randomized controlled trial. *BMC Pregnancy and Childbirth*, *15*(1), Article 126. https://doi.org/10.1186/s12884-015-0550-z

Wollmann, C. L., Ahlberg, M., Petersson, G., Saltvedt, S., & Stephansson, O. (2017). Time-to-delivery and delivery outcomes comparing three methods of labor induction in 7551 nulliparous women: A population-based cohort study. *Journal of Perinatology*, *37*(11), 1197–1203. https://doi.org/10.1038/jp.2017.122

World Health Organization. (2018). *WHO recommendations: Intrapartum care for a positive childbirth experience*. https://apps.who.int/iris/bitstream/handle/10665/260178/9789241550215-eng.pdf

Figure 1

PRISMA Flow Chart



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.

Table 1

Literature Review Matrix

Authors	Year	Title	Purpose	Design	Sample	Outcomes Evaluated	Level/Quality
Ausbeck et al.	2020	Outpatient Foley Catheter for Induction of Labor in Nulliparous Women: A Randomized Controlled Trial	Assess if outpatient cervical ripening with a transcervical Foley catheter in nulliparous women undergoing elective labor induction shortens the time from admission to delivery.	RCT	N=126; Outpatient (n=63), Inpatient (n=63) Eligibility Criteria: Nulliparous, were undergoing induction of labor, ≥18 y/o with a singleton fetus in the cephalic presentation, and a gestational age between 39 0/7 and 41 6/7	Decreased time from admission to delivery in the outpatient group by 4.3 hours in the outpatient group when compared to inpatient with concurrent Pitocin administration. Compared hospital admission to delivery time among nulliparous low-risk women undergoing elective induction. Both outpatient and inpatient groups received a transcervical Foley catheter. The inpatient group received concurrent Pitocin administration, as per hospital protocol.	Level 1, Quality B

Austin et al.	2015	Cost-effectiveness of term induction of labour using inpatient prostaglandin gel versus outpatient Foley catheter	Evaluating the cost-effectiveness of induction of labor (IOL) using outpatient mechanical cervical ripening using a Foley catheter (OFC) compared to inpatient chemical ripening using prostin gel (IPG).	Cost-effectiveness analysis from a hospital perspective alongside an RCT.	N=101; IPG (n=51), OFC (n=50) (Nullip vs. Parous-Unspecified) Eligibility Criteria: Term, pregnant women with unfavorable cervix requiring IOL	Primary economic measures were mean patient costs, the incremental cost per predelivery inpatient hour prevented, and incremental cost per vaginal delivery within 12 h of admission to the birthing unit.	Level 2, Quality B

Beckman et al.	2020	Women's experience of induction of labor using PGE2 (Dinoprostone) as an inpatient versus balloon catheter as an outpatient.	Compare women's healthcare experiences following IOL using a balloon catheter (DBC) and going home, versus prostaglandin (PG) and remaining an inpatient.	RCT	366 questionnaires collected	This study compared prostaglandin IOL in an inpatient setting, with balloon catheter insertion for IOL in the outpatient setting. A questionnaire was used to measure women's satisfaction, perception of pain, and the likelihood of choosing this method of IOL again. Outpatient cervical ripening was found to be more acceptable to these participants, however, a qualitative approach was not undertaken to determine why this was so. A variety of factors could be considered: autonomy, the comfort of own home, and family/social support, among others.	Level 1, Quality B

Beckman et al.	2020	Induction of labour using prostaglandin E2 (dinoprostone) as an inpatient versus balloon catheter as an outpatient: a multicentre randomised controlled trial	To compare clinical outcomes following induction of labor (IOL) using a balloon catheter as an outpatient, versus prostaglandin (PG) as an inpatient	RCT	N=448; Outpatient DBC (n=215) Inpatient PG (n=233) Nullip (n=261), Parous (n=187) Eligibility Criteria: live singleton pregnancy, cephalic presentation, ≥37 weeks gestation, and undergoing IOL for low-risk indications including post-term (41 + 0 weeks), 'social' or 'elective' reasons, advanced maternal age (40 years or more), presumed macrosomia, and well-controlled gestational diabetes.	The primary outcome was a composite neonatal measure comprising nursery admission, intubation/ cardiac compressions, acidemia, hypoxic-ischemic encephalopathy, seizure, infection, pulmonary hypertension, stillbirth, or death. Clinical and process outcomes are reported	Level 1, Quality B
Blair et al	2020	Retrospective Comparison of PGE2 (dinoprostone) Vaginal Insert and Foley Catheter for Outpatient Cervical Ripening	Compare the efficacy of two methods of outpatient cervical ripening (CR): an intracervical Foley catheter and a prostaglandin E2 (PGE)2 slow-release vaginal insert	Retrospective cohort study	N= 153; Foley (n=82), PGE2 (n=71), Nullip (n=99), Parous (n=54) Eligibility Criteria: Must have undergone cervical ripening as an outpatient, ≥18 y/o, singleton pregnancy, no prior c/s, and no contraindications for either ripening method	The primary outcome (time from initial cervical ripening insertion to delivery) was measured from the time the PGE2 insert or Foley catheter was first placed until the time of delivery. Other measured outcomes: tachysystole rates, maternal safety, and neonatal complications.	Level 3, Quality B

Coates et al.	2020	Women's experiences of outpatient induction of labour with double balloon catheter or prostaglandin pessary: A qualitative study	Examining in-depth women's views on an outpatient induction of labor and understanding women's experiences and preferences regarding the methods of induction of labor.	Qualitative exploratory design	N= 21; Nullip (n=17), Parous (n=4) Eligibility Criteria: ≥37 weeks pregnant with singleton pregnancy, ≥18 y/o, uncomplicated pregnancy, booked for IOL	Ownership and understanding of the IOL process, the importance of place, and perception of control over the IOL process	Level 3, Quality B
Crosland et al.	2022	Patient satisfaction during outpatient versus inpatient Foley catheter induction of labor	Compare patient satisfaction between outpatient versus inpatient induction of labor with Foley catheter	Prospective unblinded RCT	N=81; Outpatient (n=44), Inpatient (n=37) (Nullip vs. Parous-Unspecified) Eligibility criteria: women ≥18 y/o undergoing IOL with a singleton pregnancy ≥37 weeks gestations	13 questions about expectations and satisfaction were asked, responses are Likert scale.	Level 1, Quality B

Gidazewski et al.	2018	Outpatient cervical ripening: discomfort/ pain during speculum and foley catheter insertion	To examine discomfort/pain associated with the Foley catheter insertion process and explore factors affecting discomfort/pain.	A prospective cohort study was conducted in the context of a larger randomized clinical trial comparing silicone and latex Foley catheters.	N= 534; Nullip (n=371), Parous (n=163) Eligibility Criteria: ≥16 y/o, intact membranes, no placenta previa, no undiagnosed vaginal bleeding, bishop score <7, reassuring fetal tracing, gestational age >36 weeks	Digital vaginal examination and speculum insertion were moderately uncomfortable while insertion of a Foley catheter and having the catheter in situ for several hours were less uncomfortable procedures.	Level 3, Quality B
Hamdan et al.	2021	Outpatient vs inpatient Foley catheter induction of labor in multiparas with unripe cervixes: A randomized trial.	Primary outcomes were delivery during "working hours" 08:00–18:00 h and maternal satisfaction on allocated care (assessed by an 11-point visual numerical rating score 0–10, with a higher score indicating more satisfaction).	RCT	N= 163; Outpatient (n= 82), Inpatient (n=81). Eligibility Criteria: Multiparas, ≥18 years, singleton pregnancy, term gestation (≥37 weeks) at enrollment, cephalic presentation with an unfavorable cervix (Bishop score ≤5), intact membranes, reassuring pre-induction fetal heart rate tracing, access to a vehicle and telephone, and staying within a 30-minute ride from the hospital.	Primary outcomes were delivery during "working hours" 08:00–18:00 h and maternal satisfaction on allocated care (assessed by an 11-point visual numerical rating score 0–10, with a higher score indicating more satisfaction).	Level 1, Quality B

Henry et al.	2013	Outpatient Foley catheter vs. inpatient prostaglandin E2 (dinoprostone) gel for induction of labour: a randomised control trial	The purpose of this study was to assess the feasibility, clinical effectiveness, and patient acceptability of outpatient Foley catheter (OPC) vs. inpatient vaginal PGE2 (IP) for induction of labor (IOL) at term.	Non blinded RCT	N= 101; Outpatient Foley (n=50), Inpatient PG gel (n= 51), Nullip (n=91), Parous (n=10) Eligibility criteria: Women ≥18 y/o, ≥37 weeks gestation, requiring cervical ripening	The main outcome measures were inpatient stay (before birth, in the Birthing Unit, total), mode of birth, induction to delivery interval, adverse reactions, and patient satisfaction. OPC was feasible and acceptable for IOL of women with an unfavorable cervix at term compared to IP, however, did not show a statistically significant reduction in total inpatient stay and was associated with increased oxytocin IOL.	Level 1, Quality B
Kruit et al.	2016	Foley catheter induction of labor as an outpatient procedure	The study aimed to introduce outpatient induction of labor by Foley catheter and to compare outcomes and preferences between in-patients and outpatients.	Clinical cohort study	N=485; Outpatient (n=204), Inpatient (n=281), Nullip (n=312), Parous (n=173) Eligibility Criteria: Uncomplicated singleton pregnancy ≥ 37 weeks, intact membranes, cephalic presentation, Bishop score <6	Induction of labor by Foley catheter appears suitable for outpatient and resulted in no differences in cesarean delivery or infection rates compared with in-patients. Most women were satisfied with the outpatient induction.	Level 2, Quality B

Kuper et al.	2018	Outpatient Foley Catheter for Induction of Labor in Parous Women: A Randomized Controlled Trial	Determine if outpatient cervical ripening with a transcervical Foley catheter, in parous women undergoing elective labor induction, shortens the length of time from hospital admission to delivery.	RCT	N=129; Outpatient (n=65) Inpatient (n= 64). Eligibility Criteria: Parous women ≥39 weeks gestation or with a cervix 3 cm or less dilated, or, if 2–3 cm dilated, less than 80% effaced and reassuring fetal heart rate	Compared hospital admission to delivery time among parous low-risk women undergoing elective induction. Both outpatient and inpatient groups received a transcervical Foley catheter. The inpatient group received concurrent Pitocin administration, as per hospital protocol. Secondary factors such as the number of patient phone calls to staff, SROM, and admissions before the scheduled time, were also documented.	Level 1, Quality B

Lim et al.	2018	Patient satisfaction with the cervical ripening balloon as a method for induction of labour: a randomised controlled trial.	Design a prospective randomized controlled study to evaluate patient acceptance of the cervical ripening balloon (CRB) for IOL.	RCT	N=83; CRB (n=31), PGE (n=52), Nullip (n=42), Parous (n= 41) Eligibility Criteria: Pregnant women aged 21–40 years old at term (37+0 weeks to 41+6 weeks) with a singleton pregnancy who were suitable for a vaginal delivery	The main outcome measures were participant characteristics, labor and birth outcomes, pain score, satisfaction scores, and whether the participant would recommend the mode of IOL.	Level 1, Quality B
Merollini et. al.	2021	Induction of labor using balloon catheter as an outpatient versus prostaglandin as an inpatient: a cost-effective analysis	This work aimed to assess the cost-effectiveness of induction of labor with outpatient balloon catheter cervical priming versus inpatient prostaglandin vaginal gel or tape.	Cost-effective analysis alongside a multi-center RCT	N=448; Outpatient (n=205), Inpatient (n=243) (Nullip vs. Parous-Unspecified) Eligibility Criteria: women pregnant with a live singleton pregnancy, cephalic presentation, ≥ 37 weeks, and were undergoing IOL for low-risk indications.	Outpatient-balloon induction of labor may be cost-saving compared to inpatient induction of labor with prostaglandin and is most likely to be cost-effective for nulliparous women, but more research is warranted in other settings to explore the generalizability of results.	Level 2 Quality B

Pierce-Williams et al.	2022	Inpatient versus outpatient transcervical Foley catheter use for cervical ripening: a randomized controlled trial	Evaluate the difference in time from hospital admission to delivery when undergoing inpatient versus outpatient cervical ripening with a transcervical Foley catheter.	RCT	N=30; Outpatient (n=15), Inpatient (n=15) (Nullip vs. Parous-Unspecified) Eligibility Criteria: Singleton pregnancy ≥ 37 weeks gestation, bishop score ≤6	The primary outcome was the difference in time from admission to delivery.	Level 1 Quality B
Policiano et al.	2017	Outpatient vs. Inpatient cervical priming with Foley catheter: an RCT	Compare clinical efficacy between outpatient and inpatient cervix priming with Foley catheter	RCT	N=130; Outpatient (n=65), Inpatient (n=65), Nullip (n=97), Parous (n=33) Eligibility Criteria: Term pregnancies with a single fetus in cephalic presentation, Bishop score < 6, gestational age ≥ 41 weeks, or a medical indication for induction of labor.	The primary outcome was Bishop score change between outpatient and inpatient groups. Secondary comparisons included: delivery route and catheter application-to-delivery time. Outpatient priming with a Foley catheter is as safe and effective as in the inpatient setting with shorter hospital stays and fewer cesarean deliveries for failed induction.	Level 1, Quality B

Sciscione et al.	2014	The timing of adverse events with foley catheter pre-induction cervical ripening; implications for outpatient use	Determining the rate and timing of adverse events that occur during pre-induction cervical ripening using the Foley catheter before extrusion of the balloon and institution of oxytocin.	Retrospective cohort study	N=1905; (Nullip vs. Parous-Unspecified) Eligibility Criteria: Requiring cervical ripening using a Foley catheter, singleton pregnancy ≥ 37 weeks, vertex presentation	Outcomes were cesarean delivery for non-reassuring fetal tracing, vaginal bleeding, placental abruption, or intrapartum stillbirth occurring between 2 hours after Foley catheter placement and 6 am.	Level 2, Quality B
Sutton et al.	2016	Patient attitudes towards outpatient cervical ripening before induction of labour at an Australian tertiary care hospital	Assess attitudes and opinions toward outpatient cervical ripening in women attending an Australian tertiary hospital's labor and birth suite for a booked induction of labor.	Prospective patient questionnaire	N=57; Foley catheter balloon only (n=41), Foley catheter balloon and vaginal prostaglandin (n=8), vaginal prostaglandin only (n=2) (Nullip vs. Parous-Unspecified)	33% of patients stated, both before the commencement of cervical ripening and after delivery, that they would feel happy to undergo outpatient cervical ripening.	Level 3, Quality C

Ten Eikelder et al.	2017	Comparing IOL with oral misoprostol or foley catheter at term: cost-effective analysis of an RCT multi-center non-inferiority trial	Assess the costs of labor induction with oral misoprostol vs. Foley catheter.	Cost analysis alongside an RCT	N= 1845; Misoprostol (n = 924), Foley catheter (n = 921). (Nullip vs Parous-Unspecified) Eligibility Criteria: Women with a viable term singleton pregnancy in cephalic presentation, intact membranes, an unfavorable cervix (Bishop score <6) without a previous cesarean section	Mean costs and differences were calculated per woman induced with oral misoprostol or Foley	Level 1, Quality A

Waldron et al.	2022	A snapshot of women's and clinicians' perceptions of the double balloon catheter for induction of labor	Explore the views regarding double balloon catheter insertion and effectiveness from women being induced with the catheter and the clinicians involved in the catheter insertion and care.	A prospective descriptive survey of two deidentified, self-reported questionnaires	N= 26 women at term gestation admitted for IOL and 42 providers involved in the insertion and care of catheters. (Nullip vs Parous - Unspecified)	Clinical data were collected on women's views on the method and effectiveness of induction of labor, pain relief, artificial rupture of membranes, opinions on having the double balloon catheter in a future pregnancy as well as the option of the insertion as an outpatient. Data was also collected from clinicians on ease of insertion, effectiveness, insertion, and removal timing, and the option of the double balloon catheter as an outpatient measure.	Level 3, Quality C
Wang et al.	2021	Patient satisfaction with outpatient cervical ripening in parous women	Assess whether patient satisfaction differs between women beginning cervical ripening in the outpatient versus inpatient setting.	Planned secondary analysis alongside an RCT	N=129; Outpatient (n=65), Inpatient (n=64), Nullip (n=126), Parous (n=3) Eligibility Criteria: Low-risk, parous, English literate women, with a singleton pregnancy, vertex presentation, ≥18 y/o, between 39-42 weeks gestation	The primary outcome of this secondary analysis was patient satisfaction as measured by the individual scores of three different surveys.	Level 1, Quality B

Washburn et al.	2021	Outpatient Foley catheter provides clinical and cost benefits	The objective of this study was to examine the difference in health care costs, maternal and neonatal morbidity, and cesarean birth rates for inpatient versus outpatient Foley induction protocols.	Retrospective cohort study	N= 331; Nullip (n=227), Parous (n=54) Eligibility Criteria: Singleton pregnancy in vertex presentation, including diabetes and hypertension were included with controls for their conditions, >35 weeks gestation, within the Orange County service area	The difference in safety, cost, and c/s rates between outpatient Foley versus traditional inpatient IOL.	Level 2, Quality B
Wilkinson et al.	2015	A comparison of inpatient vs outpatient balloon catheter cervical ripening: a pilot RCT	Compare key labor and birth outcomes in inpatient compared with outpatient catheter ripening for the direction of effect and magnitude and assess the clinical pathways of the intervention and determine the acceptability from the perspective of both pregnant women and health care providers	RCT	N=48; Outpatient (n=33), Inpatient (n=15), Nullip (n=36), Parous (n=12) Eligibility Criteria: Low-risk term pregnancies	outcomes, clinical pathways, and acceptability to both women and clinicians of outpatient balloon catheter ripening compared with usual inpatient care.	Level 2, Quality B

Wollmann et al.	2017	Time-to-delivery and delivery outcomes comparing three methods of labor induction in 7551 nulliparous women: a population-based cohort study.	Determine time-to-delivery and mode-of-delivery in labor induction among women with unripe cervix.	A retrospective population-based cohort study	N=7551; Misoprostol (n=1424), Dinoprostone (n=3297), Transcervical single balloon catheter (n=2830) Eligibility Criteria: Nulliparous women with singleton pregnancies, ≥37 weeks, Bishop Score ⩽6, induced with dinoprostone, misoprostol, or transcervical single balloon catheter.	Mean time-to-delivery with β-estimates and 95% confidence intervals with adjustments. Multivariable logistic regression analysis was used to calculate the odds of cesarean delivery, instrumental vaginal delivery, and maternal and neonatal outcomes.	Level 2, Quality B

Table 2

Results

Authors	Length of Hospitalization	Patient Satisfaction	Safety/ Efficacy/ Adverse Outcomes	Cost Comparison
Ausbeck et al., (2020) Inpatient Foley catheter vs. Outpatient foley catheter	Decreased admission to delivery interval (17.467.4 vs 21.769.1 hours, P,.01, mean difference 4.3 hours, 95% CI 1.3–7.2).	Women in both groups were overall satisfied with their care, with no significant differences in scores and safety concerns between groups.	Cesarean delivery (24% vs 32%, RR 0.8, 95% CI 0.4–1.3, P5.32) and chorioamnionitis (22% vs 13%, RR 1.8, 95% CI 0.8–3.9, P5.16) were not significantly different between groups. Outpatient cervical ripening was not associated with an increase in adverse neonatal outcomes	Not addressed
Austin et al., (2015) Inpatient PGE2 vs. outpatient single balloon catheter	The outpatient balloon group experienced fewer predelivery inpatient hours, leading to a reduction of total inpatient hours from randomization to discharge (96 and 105 h, respectively)	Not addressed	OFC and IPG groups experienced similar cesarean section rates (34 and 29%, respectively). Neonatal inpatient hours and nursery admission rates were also similar between the groups	Mean hospital costs per woman were not significantly higher ($6524 OFC vs $5876 IPG) and the mean difference $643; 95% CI $366 to $1652. Reduction in total inpatient hours resulted in an incremental cost per inpatient hour prevented of $57 (95% CI $79.44 to $190.65).

Beckman et al., (2020) Inpatient PGE2 vs. Outpatient DBC	Not addressed	More women in the balloon-outpatient group reported they would choose IOL next pregnancy (49.2 % vs 38.4 %; p = 0.037) and desire the same method (72.4 % vs 61.1 %; p = 0.022). The balloon-outpatient group experienced higher pain scores at the start of IOL (median (IQR) 3(25) vs 2(14); p = 0.002) but lower scores at the time of rupture of membranes (3(15) vs 4(26); p = 0.007).	Not addressed	Not addressed

Beckman et al., (2020) Inpatient PGE2 vs. Outpatient DBC	Not addressed	Not addressed	There were no statistically significant differences in the primary outcome comparing balloon with PG (18.6% vs 25.8%; relative risk = 0.77, 95% CI 0.51–1.02; P = 0.070), cord arterial pH <7.10 (3.5% vs 9.2%; P = 0.072), nursery admissions (12.6% vs 15.5%; P = 0.379), neonatal antibiotic use (12.1% vs 17.6%; P = 0.103), or mode of birth. In a post hoc analysis to explore the relationship between parity, cervical favorability, and mode of birth, the likelihood of CS was no different among nulliparous women with either a favorable or an unfavorable cervix. There was also no statistically significant difference in the likelihood of CS for parous women with an unfavorable cervix. However, among parous women with a favorable cervix, those in the balloon group had higher rates of CS than those in the PG group (21.2% vs 2.4%; P = 0.009).	Not addressed

Blair et al., (2020) Outpatient Foley catheter vs. Outpatient PGE2	Time from insertion to delivery was not different between PGE2 and Foley catheter groups (median 27 vs. 33 h), controlling for parity, gestational age, initial dilation, and use of oxytocin (HR 1.13, 95% confidence interval 0.77−1.68).	Not addressed	Patients in the PGE2 group were more likely to experience uterine tachysystole (9% vs. 0%; P <0.01) and require another method of CR (34% vs. 1%; P < 0.001). There were no differences in neonatal or maternal adverse outcomes between groups.	Not addressed
Coates et al., (2020) Outpatient DBC vs. Outpatient PGE2 pessary	Not addressed	The balloon method was preferred as it was considered a gentler start to the process, although some women reported it was painful on insertion. 'Importance of place' reflected women's associations of the home with comfort, ease of support and distraction, and the hospital with safety yet also with discomfort and delays.	Not addressed	Not addressed
Crosland et al., (2022) Outpatient Foley vs. inpatient Foley	Not addressed	Mean (SD) cumulative post-induction survey scores for outpatient and inpatient study arms were 4.3 0.6 and 4.4 0.5, P1⁄40.5925.	Not addressed	Not addressed

Gidazewski et al., (2018) Pain during Foley catheter insertion	Not addressed	We found digital vaginal examination and speculum insertion (mean pain score = 4.6–4.7/10) to be significantly more uncomfortable than Foley catheter insertion (mean pain score = 3/10), while having the catheter in situ for a median of 14 h was mid-way in discomfort (mean pain score = 3.7/10). Only 12–13% of women experienced no discomfort during digital vaginal examination and speculum insertion, while about 40% experienced no discomfort during Foley catheter insertion.	Not addressed	Not addressed
Hamdan et al., (2021) Inpatient Foley catheter vs. outpatient Foley catheter	Duration of hospital stay and membrane rupture to delivery interval was significantly shorter in the outpatient arm: 35.8 ± 20.2 vs. 45.2 ± 16.2 h (p = 0.001) and 4.1 ± 2.9 vs. 5.3 ± 3.6 h (p = 0.020), respectively.	The median maternal satisfaction visual numerical rating score was 9 (interquartile range 9–9) vs. 9 (interquartile range 8–9, p = 0.134), respectively.	Other maternal and neonatal secondary outcomes were not significantly different.	Not addressed

Henry et al., (2013) Outpatient Foley catheter vs. Inpatient PGE2	OPC group had shorter hospital stay before birth (21.3 vs. 32.4 hrs, p < .001), and IP were more likely to achieve vaginal birth within 12 hours of presenting to the Birthing Unit (53% vs. 28%, p = .01). Total induction to delivery time (33.5 hrs vs. 31.3 hrs) and total inpatient times (96 hrs OPC Vs. 105 hrs IP) were similar.	The OPC group felt less pain (significant discomfort 26% Vs 58%, p = .003), and had more sleep (5.8 Vs 3.4 hours, p < .001), during cervical preparation	Vaginal birth rates (66% OPC Vs. 71% IP), were similar between groups.	Not addressed
Kruit et al., (2016) Inpatient Foley catheter vs. outpatient Foley catheter	Not addressed	Of the outpatients, 85.3% were satisfied.	No differences in the rates of cesarean delivery (P = 0.87, P = 0.85), postpartum hemorrhage ⩾ 1000 ml (P = 0.47, P = 0.38 in vaginal delivery, and P = 0.65, P = 1.00 in cesarean delivery, respectively), maternal intrapartum infection (P = 0.62, P = 0.40) or postpartum infection rates (P = 0.21, P = 1.00)	Not addressed

Kuper et al., (2018) Outpatient Foley catheter vs. Inpatient foley catheter	Outpatient cervical ripening did not significantly shorten the time from labor ward admission until delivery (12.467.4 vs 13.567.0 hours, P5.38).	Not addressed	There were no significant differences in neonatal outcomes between groups. The rate of cesarean delivery was not significantly different between the outpatient and inpatient groups (3% vs 5%, P5.68). The rates of chorioamnionitis, endometritis, maximum intrapartum maternal temperature, admission white blood cell counts, and readmission within 30 days of discharge were also similar between groups.	Not addressed
Lim et al., (2018) Inpatient DBC vs. Inpatient PGE2	Induction to vaginal delivery time and vaginal delivery rate were similar in both arms of the study.	Both groups expressed good satisfaction scores (CRB 3.4 ± 1.5 vs. PGE 3.2 ± 1.4; p = 0.465), and the majority of the women said they would recommend their method of IOL (CRB 71.0% vs. PGE 69.2%; p = 1.000). Pain score in the CRB group was significantly lower than in the PGE group during the induction process (4.5 ± 2.3 vs. 5.6 ± 2.4; p = 0.044)	The birth outcomes of both arms of the study were also similar, with no case of stillbirth.	Not addressed

Merollini et al., (2021) Inpatient PGE2 vs. Outpatient DBC	Not addressed	Not addressed	Similar health outcomes (0.75 vs 0.74 quality-adjusted life years gained)	lower mean costs ($7294 versus $7585) in the outpatient balloon (n = 205) compared to the inpatient-prostaglandin group (n = 243), and overall higher net monetary benefit ($30,054 vs $29,338).
Pierce-Williams et al.,(2022) Outpatient Foley catheter vs. inpatient Foley catheter	There was no significant difference in time from admission to delivery between outpatient and inpatient groups (14.5 6.1 versus 18.9 8.2 hours, P1⁄4.11). The total induction time was shorter for the inpatient group (24.9 6.8 versus 17.3 9.4 hours, P1⁄4.02).	Maternal satisfaction was similar between groups on a 1-10 scale (8.6 1.7 versus 8.9 1.0, P1⁄4.53), and all patients felt safe.	There were no differences in other maternal or neonatal outcomes (P>.05).	Not addressed
Policiano et al., (2016) Outpatient Foley catheter vs. inpatient Foley catheter	The outpatient group had a shorter average catheter application-to-delivery time than the inpatient (38.2 vs 44.9. hours, p = 0.01) and an average of 10 h less hospital stay than the inpatient group.	Not addressed	Outpatient group had a statistically significant lower rate of cesarean deliveries for failed induction of labor [2/65 (3%) vs 11/65 (17%), p = 0.02]. There were three cases of chorioamnionitis for each group with no significant maternal or neonatal morbidity.	Not addressed

Sciscione, et. al (2014) Timing of adverse events with Inpatient foley	Not addressed	Not addressed	No adverse outcomes were noted among term, singleton uncomplicated pregnancies receiving a Foley catheter for pre-induction cervical ripening who met inclusion criteria (relative risk, 0.0; 95% confidence interval, 0.0–0.002).	Not addressed
Sutton, et. al. (2016) Patient attitudes towards outpatient Foley catheter	Not addressed	33% of patients stated, both before the commencement of cervical ripening and after delivery, that they would feel happy to undergo outpatient cervical ripening.	no participants in this survey required emergency surgical intervention during the process of cervical ripening.	Not addressed

Ten Eikelder, et. al. (2018) Inpatient Foley vs. inpatient misoprostol	Not addressed	Not addressed	Not addressed	Mean costs per woman in the oral misoprostol group and Foley catheter group were €4470 versus €4158, respectively [mean difference €312, 95% confidence interval (CI) – €508 to €1063]. Multiple sensitivity analyses did not change these conclusions. However, if cervical ripening for low-risk pregnancies in the Foley catheter group was carried out in an outpatient setting, with admittance to the labor ward only at the start of active labor, the difference would be €4470 versus €3489, respectively (mean difference €981, 95% CI €225–1817).

Waldron et al., (2022) Patient and clinician perceptions of DBC	Not addressed	100% (n=23) reported that the insertion of the catheter was painful. Most of the women (87%, n=20) required pain relief post double balloon catheter insertion and 75% (n=15) stated that the pain relief was effective. The DBC appeared to be a well-accepted method of cervical ripening among women (61%) and clinicians (>82%). The success of DBC to achieve an artificial rupture of membrane post-removal directly correlates to women's acceptance (61%). While most clinicians (59–67%) perceived insertion of DBC in an outpatient setting and then women discharged home was appropriate, only 13% of women were in favor.	Not addressed	Not addressed

Wang et al., (2021) Inpatient vs. outpatient Foley catheter	Not addressed	There was no difference in satisfaction between outpatient and inpatient cervical ripening with transcervical Foley catheterization, with high satisfaction in both groups. Patients in both the outpatient and inpatient groups would choose the same type of care for their next pregnancy (on a scale of 1–7, median (25th–75th percentile): 7 [7–7] vs. 7 [6–7], respectively, p 1⁄4 0.75)and would be very likely to recommend their method of induction to a friend or family member (on a scale of 0–100, 99 [80–100] vs. 99 [65–100], respectively, p 1⁄4 0.60).	Not addressed	Not addressed
Washburn et al., (2021) Inpatient vs. outpatient Foley catheter	Outpatient inductions were more likely to have a shorter length of hospitalization from admission to discharge (a 7.17-hour difference, 95% CI, 71.00, 77.59)	Not addressed	In the univariate analysis, there was no difference in the rate of cesarean birth (OR 0.95, 95% CI, 0.61, 1.48). However, in the multivariate analysis, there was a decreased rate of cesarean for outpatient inductions (OR 0.5, 95% CI, 0.26, 0.97).	The outpatient group had lower costs of hospitalization ($408 per patient, 95% CI, 4305, 4714).

Wilkinson et al., (2015) Outpatient vs. inpatient DBC	Not addressed	Most women in both groups reported discomfort with insertion and wearing the catheter but were equally satisfied with their care and felt the baby was safe (91 % of both groups). Outpatient women reported feeling less isolated or emotionally alone.	Clinical and perinatal outcomes were similar. Most women required oxytocin (77 %). The outpatient group was 24 % less likely to require oxytocin (risk difference −23.6 %, 95 % CI −43.8 to −3.5). There were no failed inductions, infections, or uterine hyperstimulation attributable to the catheter in either group.	Not addressed
Wollmann et al., (2017) Inpatient Foley catheter vs. inpatient misoprostol vs. inpatient PGE2	Adjusted mean time-to-delivery was 6.9 and 1.5 h shorter, respectively, when inducing labor with a balloon catheter (mean 18.3 h, β − 6.9, 95% confidence intervals; − 7.6 to − 6.3) or misoprostol (mean 23.7 h, β − 1.5, 95% confidence intervals; − 2.3 to − 0.8) compared with dinoprostone (mean 25.2h).	Not addressed	There were no significant differences in adverse maternal or infant outcomes between induction methods.	Not addressed