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A comparison of maternal satisfaction with the use of osmotic dilators as opposed to balloons as a method of induction of labour: A literature review.

Bachelor Thesis

Hebammenwissenschaft B.Sc.

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Foreword

Love and thanks go to the many people who have supported and encouraged me throughout the past three and a half years of this adventure. You know who you are and I will be forever grateful to you.

This thesis is dedicated to Isaac, José and Lena without whom none of this would have been possible.

Please note:

In this thesis the terms woman, mother or maternal are used. This is done based on the evidence used in the research for this thesis with the awareness of including those who are pregnant, give birth and are parents of a newborn, and who do not (gender) identify as women or mothers.

Similarly, many studies refer to pregnant people and parturients as patients. It is explicitly acknowledged by the author of this thesis that the term “patients” is not an appropriate description of a population experiencing physiological pregnancy and birth.

Abstract

Introduction and objective: This thesis investigates whether the use of osmotic dilators as a method of mechanical induction of labour leads to increased maternal satisfaction when compared to balloon inductions at term.

Background: Up to 25% of births (185,000 pregnancies) are induced every year in Germany, using a range of pharmacological or mechanical methods. Pharmacological methods can lead to uterine hyperstimulation, requiring increased monitoring and inpatient management. Mechanical methods ripen the cervix through the endogenous release of hormones and can be managed in an outpatient setting. Most research concentrates on obstetric outcomes with little to no focus on maternal satisfaction.

Method: A literature review was conducted in September and October 2023 searching for keywords in the databases PubMed, CINAHL and Scopus, using current clinical guidelines and the principle of snowballing. Studies were included for review if they focussed on maternal satisfaction. Ten studies (eight RCTs and 2 cohort studies) are critically assessed in this thesis.

Results: Balloons and osmotic dilators are safe, effective, and accepted methods of mechanical cervical ripening. Their use is associated with higher maternal satisfaction when compared with pharmacological agents. In direct comparison osmotic dilators are superior to balloons in the areas of sleep, relaxing time and performance of daily activities.

Discussion: Most studies compare balloons and osmotic dilators with pharmacological agents; only few compare the mechanical methods with each other and, even fewer focus on satisfaction as an outcome.

Conclusions: There is currently insufficient evidence to categorically show the superiority of osmotic dilators over balloons. Further research is recommended looking specifically at direct comparisons between the Cook double balloon and Dilapan-S, focussing on standardised measurements of satisfaction as well as the acceptance of outpatient management. Providing evidence-based choices in cervical ripening procedures can facilitate shared decision making and ultimately lead to an increase in maternal satisfaction.

Table of Contents

List of Figures and Tables

List of Abbreviations

ACOG	American College of Obstetricians and Gynecologists
AWMF	Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (Association of the Scientific Medical Societies in Germany)
BMI	Body Mass Index
CEQ	Childbirth Experience Questionnaire
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CRB	Cervical Ripening Balloon
DGGG	Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (German Society of Gynecology and Obstetrics)
DGHWi	Deutsche Gesellschaft für Hebammenwissenschaft (German Society of Midwifery Science)
FDA	United States Food and Drug Administration
NICE	National Institute for Health & Care Excellence, United Kingdom
IOL	Induction of Labour
p/p-value	Probability Value
PG / PGE	Prostaglandins
PICO	Population, Intervention, Comparison, Outcome
RCT	Randomised Controlled Trials
RR	Relative Ratio
TOLAC	Trial of Labour after Caesarean
VAS	Visual Analogue Scale
VBAC	Vaginal Birth after Caesarean

1 Introduction

One of the most common interventions in obstetrics is the induction of labour (IOL). In Germany, the number of births which are induced stands currently at between 20-25%, with the indications for the intervention having increased in recent years (DGGG, 2020a). Care of pregnant people being induced has therefore become a daily routine and challenge for midwives and other healthcare professionals working in clinical settings.

The Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften / Association of the Scientific Medical Societies in Germany (AWMF) S2k Guideline “Induction of Labour” (DGGG, 2020a), the authors of which include the Deutsche Gesellschaft für Gynäkologie und Geburtshilfe / German Society of Gynecology and Obstetrics (DGGG) and the Deutsche Gesellschaft für Hebammenwissenschaft / German Society of Midwifery Science (DGHWi), lists potential indications for induction, yet the topic remains complex and necessitates an individual risk-benefit analysis reflecting both the mother’s and the foetus’s medical and pregnancy history.

Methods of cervical ripening and IOL can be broadly categorised into “mechanical” and “pharmacological”. Pharmacological methods using prostaglandin (PG/PGE) or oxytocin applications can increase the risk of uterine overstimulation and require an inpatient setting to regularly monitor the mother and foetus. Mechanical methods can be used in outpatient settings and offer a valid alternative to inducing labour when the cervix is assessed as unripe or unfavourable (having a low Bishop score). Their use supports the endogenous release of prostaglandins and or oxytocin. They are the preferred methods for women aiming for a vaginal birth after caesarean (VBAC / TOLAC) or for those who prefer a non-pharmacological method of induction with the option of outpatient cervical ripening.

The Bishop score is a system for predicting successful IOL which assesses, on a point scale of 0-3, cervix dilation, position, effacement and consistency together with foetal station. Generally, a score of $\leq$6 is considered to be unfavourable and therefore an indication for pre-induction cervical ripening.

The focus of this thesis is not to assess whether mechanical methods are superior in outcome compared to pharmacological ones but rather to compare two specific mechanical methods: cervical ripening balloons (CRBs e.g., Cook or Foley catheters) and synthetic osmotic cervical dilators (e.g., Dilapan-S). Both methods are approved for this purpose in Germany (DGGG, 2020a) as well as in other countries with similar health care systems, such as the United Kingdom (NICE, 2021). While many papers have been published focussing on obstetric outcomes, there is little research available on pregnant peoples’ acceptance of or satisfaction with these methods.

Using a structured search of databases, the existing literature is reviewed to explore maternal satisfaction with each method and to evaluate whether osmotic dilators can offer a satisfactory, or even a superior, alternative to balloon inductions in pregnancies with viable foetuses. The aim is to provide midwives, other healthcare professionals and those who are pregnant with evidence-based options, to open discussions on individual care models and ultimately to promote shared decision making by reflecting on first-hand experience and satisfaction.

2 Background

Balloons catheters are inserted into the cervix and are inflated with fluid thus holding them *in situ*. The tubes protruding from the introitus are then strapped to the inner thigh of the pregnant person, under tension in the case of the Foley catheter. Foley catheters inflate a single balloon on the uterine side (internal cervical os) and Cook balloons use a second balloon on the vaginal side (external cervical os). The pressure of the balloon(s) supports the endogenous release of hormones causing the cervix to dilate through, amongst other complex changes, an increase in collagen degradation.

Osmotic dilators are synthetic rods made of Aquacryl and are inserted into the cervical canal traversing the internal os. Due to their hydrophilic properties, they increase in diameter as they absorb moisture in the cervical canal. This gradual stretching of the cervical tissue encourages the same hormone release as with balloons, causing the cervix to soften and ripen. Multiple rods can be used at the same time.

In German hospitals the use of balloons is more widespread than osmotic dilators. Figures in Kehl et al. (2021) show that of 249 clinics who provided information on methods of induction 53% used balloons in an inpatient setting compared with only 38% osmotic dilators. However in outpatient settings in cases of unfavourable cervixes with a Bishop score of 0-3 the use of Dilapan-S is more frequent (8% rods, 4% balloons). (Kehl et al., 2021, p. 962).

There were 738,819 live births in Germany in 2022 (Destatis, 2023). If up to 25% of these births were induced, then the affected population per year numbers around 185,000. The target group of the AWMF guideline (DGGG, 2020a) is pregnant people, yet it dedicates only two pages to the evaluation of the two methods featured in this thesis and the statements are brief; balloon inductions are rated positively by pregnant people, and osmotic dilators are approved for use and are safe. It is not disputed that health providers should aim for the best possible health outcomes, but choice and satisfaction with the given care should be viewed as equally important. For example, midwives in both clinical and

community settings are in a unique position to use the available evidence to empower pregnant people to actively participate in their choices of care. Midwives also provide vital support once the procedure of IOL has commenced and can contribute positively to the experience (DGGG, 2000b; Place et al., 2022).

While it is admittedly difficult to assess satisfaction as it is, by nature, subjective, this should not be used as an excuse to negate it as a valuable research outcome. Qualitative studies could shine a light on factors which affect satisfaction. A systematic review on induction methods by the National Institute for Health Research in the United Kingdom (Alfirevic et al., 2016) found that less than 5% of the 613 studies included reported any data on maternal satisfaction and that furthermore "satisfaction was measured in such a number of different ways that meaningful analysis was not possible" (Alfirevic et al., 2016, p. 16). Their recommendations are for women's views to be explored as part of *any* future research. This is echoed by Dos Santos et al. (2018) who call for a core outcome set to include maternal satisfaction and facilitate standardised reporting in trials on IOL. Failure therefore to place value on these outcomes appears negligent. Ways of measuring experience through the use of tools such as the validated Childbirth Experience Questionnaire (CEQ) can help to improve satisfaction if lessons are learned from the responses. Negative experiences of childbirth can have not only an impact on the postpartum (mental) health of the parturient, but can also play a role in decisions concerning future family planning (Place et al., 2022).

To investigate these topics regarding cervical ripening methods and satisfaction further, the following research question is posed using the PICO (population, intervention, comparison, outcome) research framework:

> "Does the use of osmotic dilators as a method of mechanical induction of labour lead to increased maternal satisfaction when compared to balloon inductions at term?"

The *population* is those to be induced or needing cervical ripening at term, the *intervention* is the use of mechanical methods to induce labour, the *comparison* is between balloons and osmotic dilators, and the *outcome* is the level of maternal satisfaction with the method.

3 Method

3.1 Choice of research method

It was decided that a literature review would be the most appropriate method to best answer the research question. A review adds to the current knowledge of the researcher by identifying literature already available on a topic, highlighting current trends, and evaluating the

current level of research. It also enables the identification of gaps in research that may exist in the work to date. A study of the literature coupled with a critical analysis of the way the evidence is collected and analysed can therefore also help to focus and frame areas and questions where further studies or trials are needed.

The aim of this literature review is to provide clinical practice with the most up-to-date information to support evidence-based recommendations on the two mechanical methods. It is the author's opinion that such recommendations cannot be made without also taking into account the experiences of the primary care recipients.

3.2 Literature search

As the use of osmotic dilators and balloon catheters for cervical ripening as IOL takes place in a medical setting, a search was conducted in two of the most commonly used international scientific databases, PubMed and Scopus. Both databases are frequently favoured by further education establishments, PubMed being the primary resource for many reviews conducted by organisations such as the Cochrane Library. A third database, Cumulative Index to Nursing and Allied Health Literature (CINAHL), was also included to maximise the range of relevant research papers.

A matrix of keywords and terms provided the starting point for the initial search and is detailed in Table 1. It was decided to begin the search in PubMed and to use this database as the reference for the searches in the other databases. The language of this paper is English and as the majority of the articles and research studies available are also published in the English language, keywords and other terms used in the search were restricted to English only.

Table 1: Initial keyword and search criteria, own graphic, 2023

Operator AND →

Operator OR ↑

Keywords	**Osmotic dilator**	**Balloon**	**Satisfaction**
Similar search terms	Dilapan Hygroscopic	Cook Balloon Foley Balloon Cook Catheter Foley Catheter	Acceptance Comfort Invasiveness Experience

3.2.1 Keyword search – PubMed database

Use was made of the advanced search function on the PubMed website between 25th September and 2nd October 2023 using keywords and similar terms deemed to be relevant to the PICO question.

The keywords and terms “Osmotic dilator” were entered, combined with the Boolean operator OR to add the keywords “Dilapan” OR “Hygroscopic”. The terms were searched in “All fields”. The initial search generated 17,983 results for a period between the years 1877 and 2023. The pace of medical research is such that the validity of many studies is often related to how recently they have been published. As a consequence, the decision was taken to include the results from the last 10 years only in the search criteria. The restriction reduced the results to 12,741 possible articles, studies and reviews published between the years 2013 and 2024.

The process was repeated in the same way using the keywords and terms “Balloon” OR “Cook balloon” OR “Foley balloon” OR “Cook catheter” OR “Foley catheter”. This new search found 124,529 results (1862 – 2024). A restriction to the last 10 years reduced this number to 38,825.

The process was repeated using the keywords and terms “Satisfaction” OR “Acceptance” OR “Comfort” OR “Invasiveness” OR “Experience”. This search found 2,480,881 results (1787 – 2024). A restriction to the last 10 years reduced this number to 1,354,122.

The next step was to combine all the previous searches using the Boolean operator AND. This combined search found only five results, yet interestingly all these results were published between 2019 and 2023 indicating that a comparison of satisfaction with mechanical methods has only recently become an area for research.

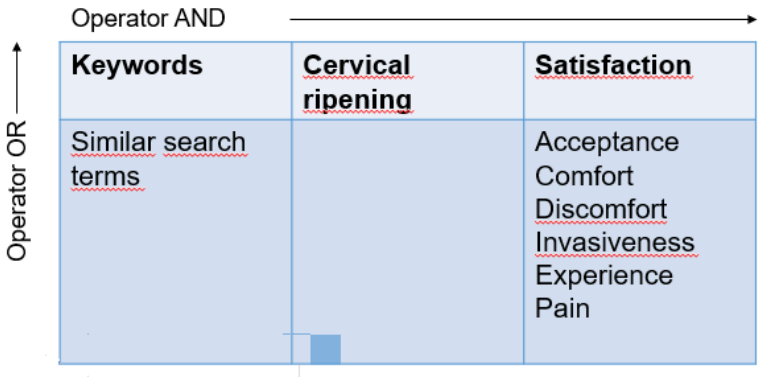
The five results were manually screened for their relevance with one Cochrane Systematic Review being excluded as it only compared home versus inpatient induction for improving birth outcomes (Alfirevic et al., 2020), and another Cochrane Systematic Review on mechanical methods for IOL from 2019 (Vann et al., 2019) was excluded as the 2023 update of the same review was also one of the five results found (Vaan et al., 2023).

Of the three remaining results only one randomised controlled trial (RCT) included a direct comparison between osmotic dilators and the (Foley) balloon (Saad et al., 2019). The other reports were a study protocol (MATUCOL) for which the results have not yet been published (Ducarme et al., 2022) and the final one was the aforementioned Cochrane systematic review (Vaan et al., 2023). Full-text documents were retrievable for all three results. Due to the nature of the focus of the thesis being satisfaction it was decided to analyse only primary

sources of evidence and the Vann et al. (2023) Cochrane review was therefore excluded from further evaluation. The lack of results found in this initial search confirmed the decision not to include terms such as cephalic presentation, singleton pregnancy, parity or at term pregnancies, as to do so would have restricted the results even further.

Due to the failure to find an appropriate quantity of literature it was decided to widen the search criteria with a view to evaluating the two methods either separately or in comparison with other methods of induction where the focus of the research was satisfaction (Table 2).

Table 2: Widened keyword and search criteria, own graphic, 2023



The phrase “Induction of labo*” was deemed to be too wide a search term whilst “Cervical ripening” would be more targeted as osmotic dilators and balloons are specifically used in this (pre)induction process. The subsequent search for “Cervical ripening” in “Title/Abstract”, using the filters from 2013 – 2023, and also “Clinical Trial, Randomized Controlled Trial” to exclude (systematic) reviews and articles retrieved 157 results. The second search using “Satisfaction” OR “Acceptance” OR “Comfort” OR “Discomfort” OR “Invasiveness” OR “Experience” OR “Pain” similarly restricted to 2013 – 2024 and “Clinical Trial, Randomized Controlled Trial” showed 58,947 results. The combination of these two searches with the Boolean operator AND retrieved 45 trials. (Appendix I.a shows history and search details, for all three databases).

The titles and abstracts were then manually screened to establish their relevance in answering the research question. The screening eliminated a further 32 results. Reasons for exclusion were mainly the use of pharmacological methods rather than osmotic dilators or balloons in cervical ripening, as well as the use of the methods in abortion and other gynecological procedures or in cases of foetal demise. Further reasons for exclusion were a focus on pregnancy complications such as oligohydramnios, hypertension, high maternal body mass index (BMI), accidental rupture of membranes, or a focus on the satisfaction of midwifes or clinical staff rather than the pregnant persons’, as well as comparisons in the

method of insertion and quantity of fluid used in the inflation of the balloons. All 13 remaining results were retrievable as full-text documents.

3.2.2 Keyword search – Scopus database

On 2nd October 2023 the identical search criteria and process followed for PubMed were used to search the Scopus database within the fields “Article title, Abstract, Keywords” . After restricting the search to years 2013 – 2023, the subject area to “Medicine”, “Nursing” and “Health Professions” and to the English language the total number of results was 1,252.

A cursory scan showed that the majority of the results diverged significantly from the PICO research question. The search was therefore narrowed using AND “Balloon” OR “Catheter” OR “Osmotic dilator” OR “Dilapan” OR “Hygroscopic” (Table 3). The two searches combined produced 93 results.

Table 3: Widened keyword and search criteria, Scopus, own graphic, 2023

Operator AND →

Operator OR ↓

Keywords	**Cervical ripening**	**Satisfaction**	**Balloon**
Similar search terms		Acceptance Comfort Discomfort Invasiveness Experience Pain	Catheter Osmotic dilator Dilapan Hygroscopic

A subsequent manual scan eliminated all but 12 documents based on the relevance of the title. The main reason for exclusion was use of the methods in abortion and other gynecological procedures. Three duplicates were manually excluded. The remaining nine documents were scanned by abstract and retrievability to leave two possible additional documents; one RCT (Saad et al., 2022) and one retrospective observational study (D’Indinosante et al., 2023).

3.2.3 Keyword search – CINAHL database

The search process was repeated a third time on 2nd October 2023 using the CINAHL database. Searching in “all fields” and without the need to include the additional keywords “Balloon” OR “Catheter” OR “Osmotic dilator” OR “Dilapan” OR “Hygroscopic” (Table 2), 81 documents were retrieved and manually scanned based on title and then on abstract. From the remaining 22 documents eight duplicates were identified and 13 further documents

rejected on grounds of scope. One possible prospective study remained for possible inclusion (Place et al., 2022).

3.2.4 Additional Sources

Between 3rd – 5th October 2023 use was made of snowballing for frequently referenced studies which were not identified in the database searches.

A review of the National Institute for Health & Care Excellence United Kingdom Guideline "Induction Labour" (NICE, 2021) and also of the website of the American College of Obstetricians and Gynecologists (ACOG) failed to retrieve additional studies or full-text access to evidence relevant to maternal satisfaction. A review of the evidence cited in the German AWMF Guideline "Induction of Labour" (DGGG, 2020a) found many systematic reviews but few studies evaluating satisfaction. One RCT looking at acceptance of balloons which was not found in the database search will be assessed in this thesis (Kehl et al., 2013). The literature on osmotic dilators had already been identified through the database searches.

Sources referenced on the Dilapan-S and Cook Medical websites were also assessed for evidence on maternal satisfaction, but no additional studies were found to be relevant for inclusion or accessible as full-text documents.

Through the principle of snowballing two conference presentations (McCue et al., 2023; Sidebottom et al., 2023) comparing osmotic dilators and balloons from the 71st Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists in Baltimore in May 2023 were identified. These demonstrate an interest in direct comparisons between the two methods however the research presented in these abstracts was not available as full-text documents and so unfortunately had to be excluded.

Finally a simple google.com search for "comparison balloon dilapan satisfaction" retrieved one retrospective cohort study (Koçak et al., 2020) which had not been previously identified.

3.3 Reasons for inclusion

With the focus on satisfaction, only primary sources are included in this thesis for detailed analysis. The decision to restrict the search timeframe to the last 10 years is confirmed by the volume of literature found, the increasing interest in mechanical methods (especially in outpatient settings) and the fact that Dilapan-S has only been approved by the US Food and Drug Administration (FDA) for third trimester cervical ripening since 2015.

When analysing the strength of the studies it is imperative to consider them within the pyramid of evidence. The strength of the data in systematic reviews is situated at the top of the pyramid indicating that the quality is high and the assessment of the studies rigorous (Polit

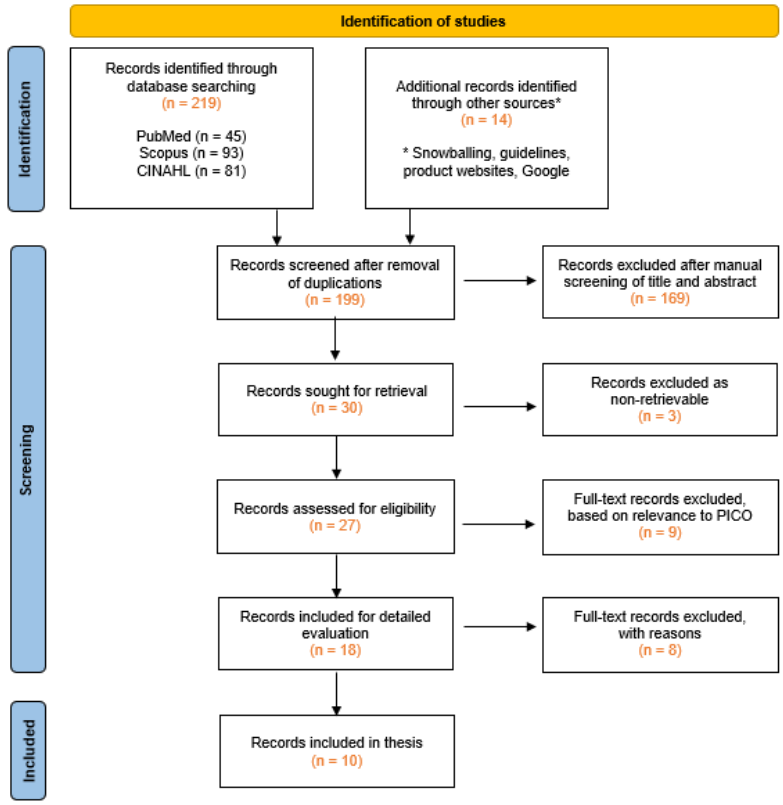
and Beck, 2021). The second highest strength is the RCT, followed by cohort studies. Fortunately, the studies found to have the most relevance to the PICO question were all such trials, with the majority being RCTs. Full-text retrievability was also a must for inclusion.

The original intention only to focus on studies which had maternal satisfaction as the primary outcome had to be widened as most investigated vaginal delivery and time in labour as primary outcomes and satisfaction as secondary. An analysis of maternal satisfaction in this thesis refers to mechanical induction as a “stand alone” intervention. Therefore, studies which subsequently made use of synthetic oxytocin, prostaglandins or an amniotomy to induce labour and then evaluated satisfaction were excluded from the analysis due to the risk of confounding in their results.

A brief overview regarding the final inclusion or exclusion of 18 of the most relevant studies (13 from PubMed, two from Scopus, one from CINAHL, one from google.com and one from the AWMF guideline) can be found in Appendix I.b. Ten studies are included in this thesis for detailed review.

3.4 PRISMA flow chart of identification of studies

A simplified, visual overview of the process of the selection of the studies is presented here:



Amended 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. For more information, visit: http://www.prisma-statement.org/

Figure 1: PRISMA Flow chart of identification of studies, own graphic, 2023

3.5 Instrument for evaluation of studies

The 10 studies included in this thesis will be reviewed in detail below applying Critical Appraisal Skills Programme checklists (CASP, 2022) suitable to the methodology of the individual studies.

The checklists provide a structure for appraising the method, results and clinical relevance of each study. They help to quickly identify the strengths, limitations and potential bias or confounding in the study results and design. The checking of boxes “yes”, “no” or “can’t tell” facilitates a rapid visual assessment of quality. The use of “hints” or “consider” in the explanation of the question prompts the assessor and helps analyse how robust the study and its results are by also looking for potential weaknesses in the work.

Particularly useful are the final questions asking whether the results help locally. These are extremely valuable in deciding whether the studies found can support recommendations to change existing care models in settings local to the assessor.

4 Results

As detailed above, due to the failure to find an appropriate quantity of literature it was decided to widen the review to consider the two methods either separately or in comparison with other (pharmacological) methods where the focus of the studies was satisfaction. The 10 studies selected for critical review are grouped below by the method of induction. Detailed CASP checklists for each study (including publication journals and their impact factors) can be found in Appendix I.c.

4.1 Satisfaction with balloon inductions

The majority of the studies found relating to satisfaction with mechanical methods focussed on satisfaction with balloons. The results of five studies are presented here:

Table 4: Summary of studies included on satisfaction with balloons, own graphic, 2023

Study Title	Author (year)	Study Design
Women’s experience of induction of labor using PGE2 as an inpatient versus balloon catheter as an outpatient	Beckmann et al. (2020)	RCT

Women's acceptance of a double-balloon device as an additional method for inducing labour	Kehl et al. (2013)	RCT
Patient satisfaction with the cervical ripening balloon as a method for induction of labour: a randomised controlled trial	Lim et al. (2018)	RCT
Comparison of primiparous women's childbirth experience in labor induction with cervical ripening by balloon catheter or oral misoprostol – a prospective study using a validated childbirth experience questionnaire (CEQ) and visual analogue scale (VAS)	Place et al. (2022)	Prospective cohort study
Double Foley catheter for labor induction: An alternative method	Obut et al. (2021)	RCT

The following graph shows the evaluation of the studies using the CASP checklists. The higher the number of "Yes" answers, and the lower the number of "Can't tell" or "No" answers, the higher the assessed quality of the study.

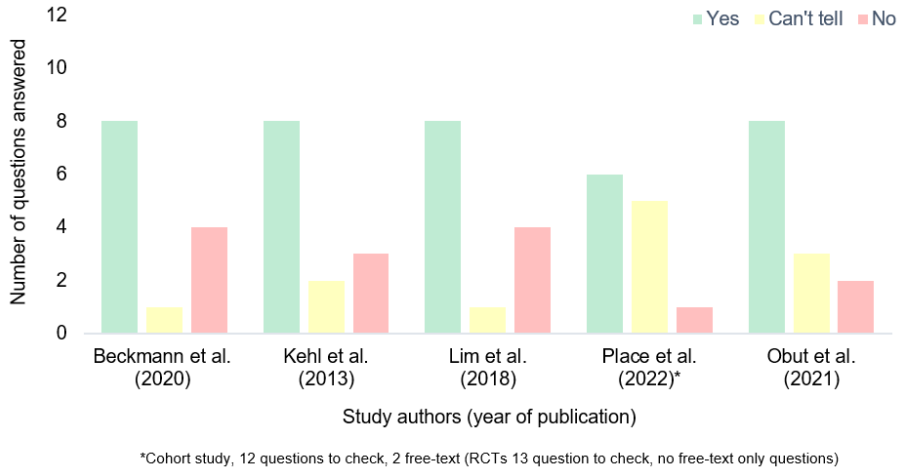


Figure 2: CASP evaluation of selected studies: Balloon inductions, own graphic, 2023

Having identified that little is known about parturients' preferences and the impact of outpatient IOL on their experience of healthcare, Beckmann et al. (2020) compare outpatient Cook balloon with inpatient vaginal PG inductions in a multi-centred, non-blinded RCT conducted across eight Australian maternity hospitals, ranging from secondary to quaternary levels. All participants had uncomplicated singleton cephalic presentation pregnancies, ≥ 37+0 weeks gestation and both groups had similar baseline characteristics thereby reducing selection bias. Data was collected using a written questionnaire following birth and

before discharge from hospital. A total of 366 questionnaires were analysed with both groups reporting similar experiences and no measurable differences in quality of life. Significantly more of the participants in the balloon group would however choose the method again in a subsequent IOL (p=0.022) despite the pain score at the start of IOL being higher than in the PG group (p=0.002). Strengths of the study include the multi-centred design to increase generalisability as well as a good sample size. Limitations are seen in the lack of qualitative analysis of the reasons for the responses and, as recognised by the authors, answering the questions prior to discharge may have been too soon to allow for proper reflection. They also concede that it is unclear if confounders such as the outpatient setting, coupled with potentially more realistic expectations of how long IOL could take, resulted in the more positive experiences as opposed to the method of IOL itself. The key message of the study is that where both options are available "evidence for differences in the patient experience should be shared with women alongside differences in clinical outcomes" (Beckmann et al., 2020, p. 6).

While Kehl et al. (2013) investigate the use of Cook balloons in addition to oral misoprostol and not as a stand-alone method this study is nevertheless included for analysis as it is referenced in the AWMF S2k Guideline (DGGG, 2020a) and is one of the few to evaluate parturient's acceptance of and satisfaction with the device as the primary outcome. This RCT included 122 women at a university hospital in Germany randomly assigned to a study group (both methods) or control group (only oral misoprostol) of whom 78 completed a standardised questionnaire after childbirth and before discharge. The inclusion criteria was a singleton pregnancy at term and an unfavourable cervix (Bishop score of <8). The study found that the women "were not bothered, or only moderately bothered by the placement of the CRB (*P*=0.017) or by the presence of the catheter (*P*=0.002)" (Kehl et al., 2013, p. 32). In addition, women in the study group were significantly more likely to select the method again or to recommend it to others (p=0.004). Very few negative side effects were noted with only three women reporting foreign-body sensations and problems urinating. The authors acknowledge limitations in their study being the small number of participants and the high proportion of women whose native language was not German. This factor reduced the number of questionnaires available for analysis as, despite translators being on hand to assist, many were returned incomplete (attrition and risk of possible publication bias).

The Lim et al. (2018) RCT looks at acceptance and satisfaction with the Cook balloon compared with intravaginal PGE. The participants were ≥37+0 weeks gestation with singleton pregnancies and cephalic presentation and there were no significant differences in their baseline characteristics. In interviews with 83 participants in a tertiary level maternity teaching hospital in Singapore pain was scored on a scale of 0-10 and satisfaction 0-5 with

additional opportunity given for comments. The pain score during induction was significantly lower in the CRB group (p=0.044). The results showed equal satisfaction with both methods and a likelihood to recommend the method they experienced to others, despite five participants describing discomfort with the catheter tube being strapped to their leg and pressure from the balloons. The authors' conclusion is similar to Beckmann et al. (2020) that having a choice of methods can help to tailor care to the individual with the aim of improving satisfaction. A limitation is again the small sample size and single-centre design. The survey sought to minimise bias towards either method through randomisation. The authors note that satisfaction is subjective as it "is influenced by one's expectations, perceptions, attitudes and personal values" (Lim et al., 2018, p. 424) which could be viewed as confounders.

Place et al. (2022) compare primiparous parturients' childbirth experience of balloons with oral misoprostol. This prospective cohort study was conducted at a tertiary centre in Finland with 8,500 deliveries a year and involved viable single pregnancies at $\geq$ 34 gestational weeks. The authors used the multidimensional and validated CEQ expanded to include non-validated questions on induction. Altogether 571 participants were recruited and 362 questionnaires evaluated of which 244 (67,4%) were returned from the balloon group and 118 (32,6%) from the oral misoprostol group. The authors do not say whether this is representative of the proportional use of both methods, nor do they provide information on the induction method used by the participants who did not return the questionnaire (attrition bias). The answers show those who received the balloon were significantly more satisfied with the method chosen for them (p=<0.001) and were more likely to select the same method in a future pregnancy (p=<0.001). It must however be noted that the participants in the balloon group were of a more advanced gestational age, had a riper cervix at the start of induction and usually had the option of outpatient care (performance bias). No randomisation was undertaken with the "preferences of the treating obstetrician and the patient determining the method of cervical ripening" (Place et al., 2022, p. 1157). These factors expose the results to bias within the population and possible confounding if patients had certain preconceptions of the procedure. The questionnaires were distributed upon admission and returned within one month of childbirth, giving time for reflection on the experience but simultaneously leaving the results open to recall bias. The strengths of the study are size of the population, the setting and a focus on satisfaction being a valuable measurement.

The RCT from Obut et al. (2021) compares the Cook balloon with the single Foley catheter and an adapted double Foley catheter. While Cook balloons are more commonly used in Germany, the RCT from Saad et al. (2019), which is reviewed below, uses a Foley catheter in the comparison and provides one of only two direct comparisons between balloons and osmotic dilators. It was deemed important to assess if satisfaction differs between single

and double balloons in order to be able to critically evaluate the results from the Saad et al. (2019) study. Participants at a training and research hospital in Turkey were randomly assigned to the three groups (74 per group, total of 222 participants). There were no significant differences in baseline characteristics between the participants who scored pain during insertion and ripening and satisfaction on a VAS from 1-10. The authors conclude that the pain score was higher during ripening in the single Foley group (p=0.011) and maternal satisfaction significantly lower (p=0.014). It should be noted that only the single Foley catheter was taped to the thigh under tension. The data shows the adapted double Foley catheter to be as acceptable as the Cook balloon with an added cost advantage especially in low-resource countries. The acceptability of a “homemade” device in a high-resource country such as Germany is however questionable.

4.2 Satisfaction with osmotic dilator inductions

Two recent studies compare osmotic dilator inductions with other methods of cervical ripening, while one other compares an inpatient with an outpatient setting.

Table 5: Summary of studies included on satisfaction with osmotic dilators, own graphic, 2023

Study Title	**Author (year)**	**Study Design**
Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term : A Randomized Controlled Trial	Gavara et al. (2022)	RCT
Outpatient Compared With Inpatient Preinduction Cervical Ripening Using a Synthetic Osmotic Dilator: A Randomized Clinical Trial	Saad et al. (2022)	RCT
A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert	Gupta et al. (2022)	RCT

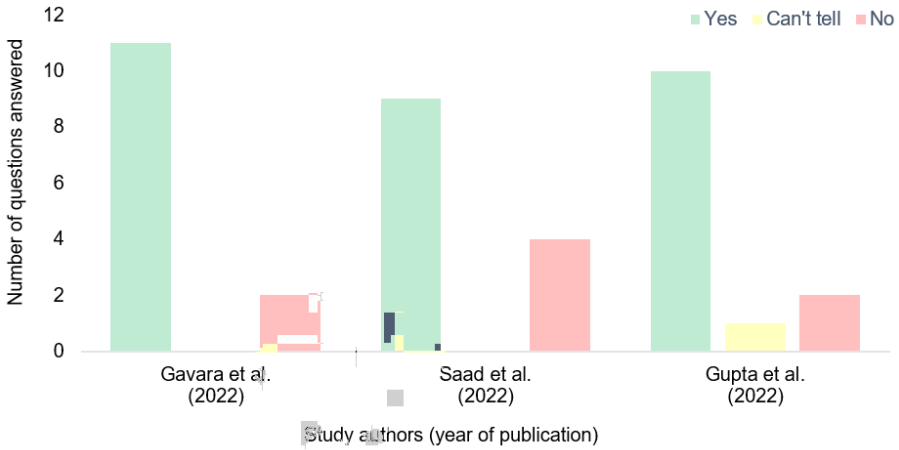


Figure 3: CASP evaluation of selected studies: Osmotic dilator inductions, own graphic, 2023

Gavara et al. (2020) conducted a prospective, open-label RCT at two medical centres in the US comparing the efficiency of cervical ripening with osmotic dilators and oral misoprostol together with a review of maternal satisfaction with the two methods. A total of 307 participants (≥ 37 gestational weeks, Bishop score of <6) with a planned IOL were randomised using stratification for parity and gestational age at a ratio of 1:1. Surveys on satisfaction scored on a scale of 1-5 were collected after delivery with three areas seeing significantly more satisfaction with the cervical dilator; being able to sleep (p=0.03), experiencing less pain (p=0.019) and less discomfort (p=0.04). The authors show consistency in the intention-to-treat and per protocol populations which they say confirm the robustness of the results and reduce the risk of attrition bias. Their results show the non-inferiority of osmotic dilators compared with oral misoprostol and several advantages (better safety profile, higher satisfaction). Strengths of the study are the sample size and two-centre design thereby increasing generalisability and the use of a single ripening method to eliminate confounding or performance bias. As with all the studies found, blinding of participants and investigators was not possible and while the two-centre design is a strength there may also have been differences in labour management at the hospitals and involvement of multiple clinicians could have affected outcomes. The study design and the power calculations conducted appear robust. It must however be noted that the manufacturer of Dilapan-S (Medicem, Inc.) funded the study and supplied the rods as well as having editorial input in the final draft of the results, leaving them potentially open to reporting bias. The authors claim that full disclosure has been made and that no conflict of interest exists.

Saad et al. (2022) used an open-label RCT in two academic centres in the US with 339 participants to look at the use of osmotic dilators in inpatient and outpatient settings. The study was again financed by Medicem, Inc. (the company is said to have had no role in the study or the drafting of the manuscript) and two of the authors have functioned as expert

consultants for the company. The primary focus of the RCT was to assess whether outpatient IOL with osmotic dilators can shorten hospital stays and improve satisfaction. Outpatient settings were either in the participant's home or at a hotel if their home was more than 60 minutes away from the hospital. Baseline characteristics were similar between the groups. Each participant completed a survey on satisfaction regarding sleep, rest, pain and activity. The participants in the outpatient group were more likely to walk, eat and shower (p=<0.01) and to support the statement that outpatient management is beneficial and a good idea (p=<0.01). They were also less likely to use analgesics during ripening (RR 0.23, 95% CI 01-0.54). This last statistic is open to confounding as analgesics are more readily available to inpatients. Strengths are once again sample size and randomisation. Limitations with regard to satisfaction are that only five questions were posed, and no separate analysis was undertaken between the results of the group who went home and those who went to a hotel. It could be hypothesize that satisfaction in a home environment would be higher than at a hotel. Although the primary outcome was to evaluate the length of hospital stay, the data on general satisfaction with the method of IOL (both groups strongly agree that they were pleased with Dilapan-S) and specifically with outpatient IOL, are valuable.

The most comprehensive look at maternal satisfaction can be found in Gupta et al. (2022) with a catalogue of 23 questions referring to insertion, ripening and overall satisfaction. Their open-label superiority RCT in four English hospitals compared Dilapan-S with vaginal dinoprostone inserts. Some 674 participants were randomised as close as possible to the start of IOL with a 1:1 ratio into the groups. Parity, BMI, maternal age and randomising hospital were thereby taken into consideration. Participants in the dinoprostone group had a significantly higher use of analgesia during ripening (p=<0.001). A higher degree of satisfaction was recorded in the Dilapan-S group in performing desired daily activities (walking, dressing, maintaining hygiene, showering, ability to sleep and relax) and the participants reported less frequent and less intense uterine contractions. Unfortunately, the analysis of these responses does not include p values and so the significance of the differences cannot be evaluated. The results could be affected by bias or indeed confusion when answering as the scale of 1-10 was used for all questions but some high scores indicated a more negative response and some more positive responses. Not all participants returned the questionnaire, and it is unclear how long after IOL the responses were provided. The authors make no mention of bias or confounding and assess the value of their study as providing "the best-quality evidence to date in support of allowing Dilapan-S to be considered as another method for induction of labor" (Gupta et al., 2022, p. 2). This study was also funded by Medicem, Inc.. It is stated that the views in the study are those of the authors and they declare no conflict of interest. Strengths of the study are the large sample size, the multi-

centred and randomised design as well as the concerted effort to assess satisfaction with the methods.

4.3 Comparison satisfaction with balloon and with osmotic dilator inductions

As previously noted, there are a lack of studies which make a direct comparison between both methods. The literature review in this thesis retrieved only two, the results of which are now presented.

Table 6: Summary of studies included on satisfaction with balloons compared with osmotic dilators, own graphic, 2023

Study Title	Author (year)	Study Design
The comparison of cervical ripening double balloon and higroscopic dilator (Dilapan–S®) in labor induction	Koçak et al. (2020)	Retrospective cohort study
A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial)	Saad et al. (2019)	RCT

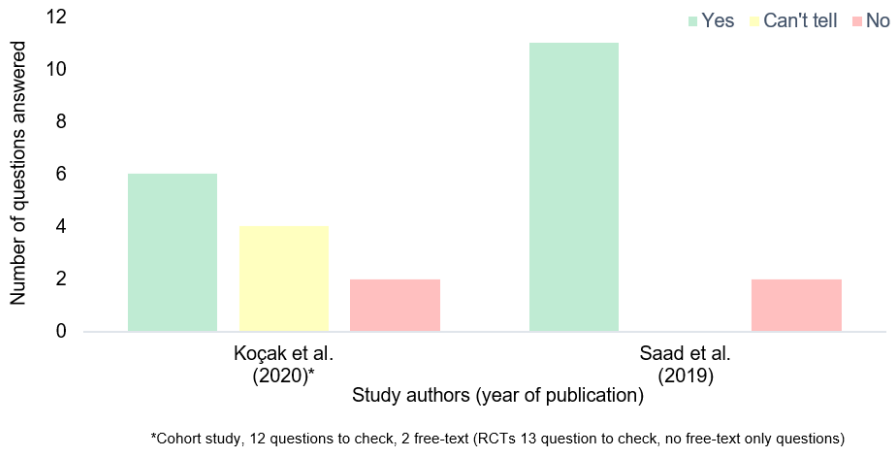


Figure 4: CASP evaluation of selected studies: Comparison balloon and osmotic dilator inductions, own graphic, 2023

Koçak et al. (2020) conducted a retrospective single-centre cohort study in a tertiary centre in Turkey involving 113 participants, comparing Dilapan-S and the Cook double balloon. The baseline characteristics of gestational age, BMI and parity were similar. They looked at patient comfort along with obstetric outcomes and found that comfort was significantly higher in the Dilapan-S group. Participants were asked to evaluate how much pain they felt during the application and at the end of IOL on a score of 1-10 (with 10 being the maximum). The average scores were 4.8 $\pm$ 0.7 (range 1-9) for the Dilapan-S and 7.6 $\pm$ 0.8 (range 5-10)

for the Cook double balloon. The authors calculated these results to be statistically significant (p=<0.001). Unfortunately, they do not provide any more detailed information on these figures. Moreover, the ranges, particularly for Dilapan-S, are extreme. It should be viewed as critical that the Cook group made up 63.7% and Dilapan-S only 36.3% of the population and that it is unclear when the participants were asked to evaluate pain or if they all responded. The results are therefore exposed to potential heavy reporting bias. The limitations of the study are the retrospective nature of the study, the small sample size as well as unclear reporting of the results. Furthermore, the study was only found via google.com, it does not appear in any of the databases searched and was published only locally in Turkey. The level of evidence presented is therefore questionable, but in the absence of other studies with a direct comparison the study is included in this thesis.

The final study to be evaluated is often cited as having the strongest evidence that Dilapan-S is an acceptable, even superior, alternative to balloons when considering maternal satisfaction. It is also referenced in the AWMF S2k Guideline (DGGG, 2020a) and is one of the few studies to evaluate acceptance of mechanical IOL methods. The RCT conducted by Saad et al. (2019) compares Dilapan-S for non-inferiority with the Foley single balloon catheter. Funding once again came from Medicem, Inc., however the manuscript states that the funder had no role in the trial, analysis or drafting of the results. The main author Antonio F. Saad narrates a video on the Dilapan-S website, raising questions of conflict of interest and bias in the trial and its results. Altogether 419 participants with similar baseline characteristics were included in this US single-centre, open label RCT. Patient satisfaction was assessed using a survey completed immediately after placement of the device and again after removal, but before leaving hospital. The 11 questions were scored on a 5-point Likert scale and a VAS. Both were available in English and Spanish owing to the Texan setting. Three of the questions scored Dilapan-S as significantly more satisfactory (p=<0.05) than the Foley balloon; ability to perform desired daily activities, able to find time to relax and time to sleep. None of the questions showed significantly more satisfaction with the Foley balloon. The size of the sample, the blind analysis of the results, the consistent management of labour in the single-centre, and analysis on intent-to-treat are strengths. The generalisability of the results are however reduced by the single-centre setting. The authors conclude that Dilapan-S has advantages over Foley including “FDA approval, no protrusion from the introitus, no need to keep under tension, and improved patient satisfaction” (Saad et al., 2019, p. 275.e8).

5 Discussion

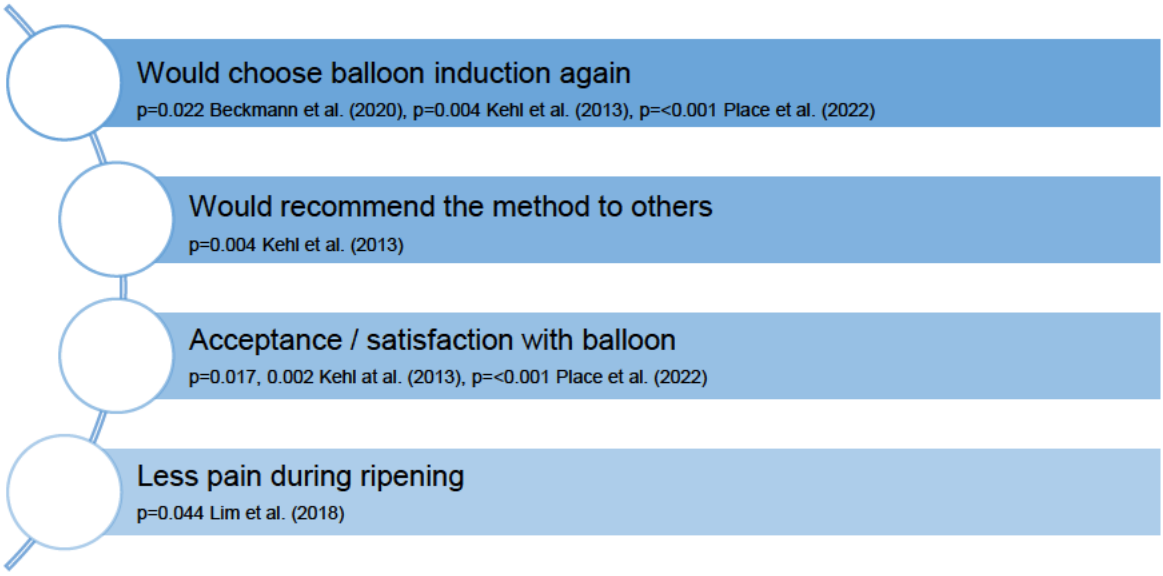
The key results of the studies presented above and the research method will now be discussed and applied to the PICO question posed in this thesis. Implications for midwifery and clinical practice will be considered and recommendations for further research proposed.

5.1 Results: Discussion and reflection

It should be noted that all the RCTs reviewed were unable to blind either the participants or those administering the intervention. While this lack of blinding somewhat downgrades the strength of the evidence due to possible selection bias, it is acknowledged that it is not possible to blind the participants or the clinicians in trials of this nature. The studies aimed to reduce the risk of selection bias in their trials through the randomisation of participants with similar baseline characteristics.

According to the studies, both balloons and osmotic dilators have certain advantages over pharmacological agents. Studies have repeatedly shown that mechanical methods of induction are not inferior to pharmacological ones (associated with a lower risk of hyperstimulation and pain during the ripening process) and can have a better safety profile (Vaan et al., 2023). Recommendations have been made that future research should therefore focus on maternal satisfaction.

All the studies which were looked at comparing balloons with pharmacological methods found high levels of satisfaction with the former.

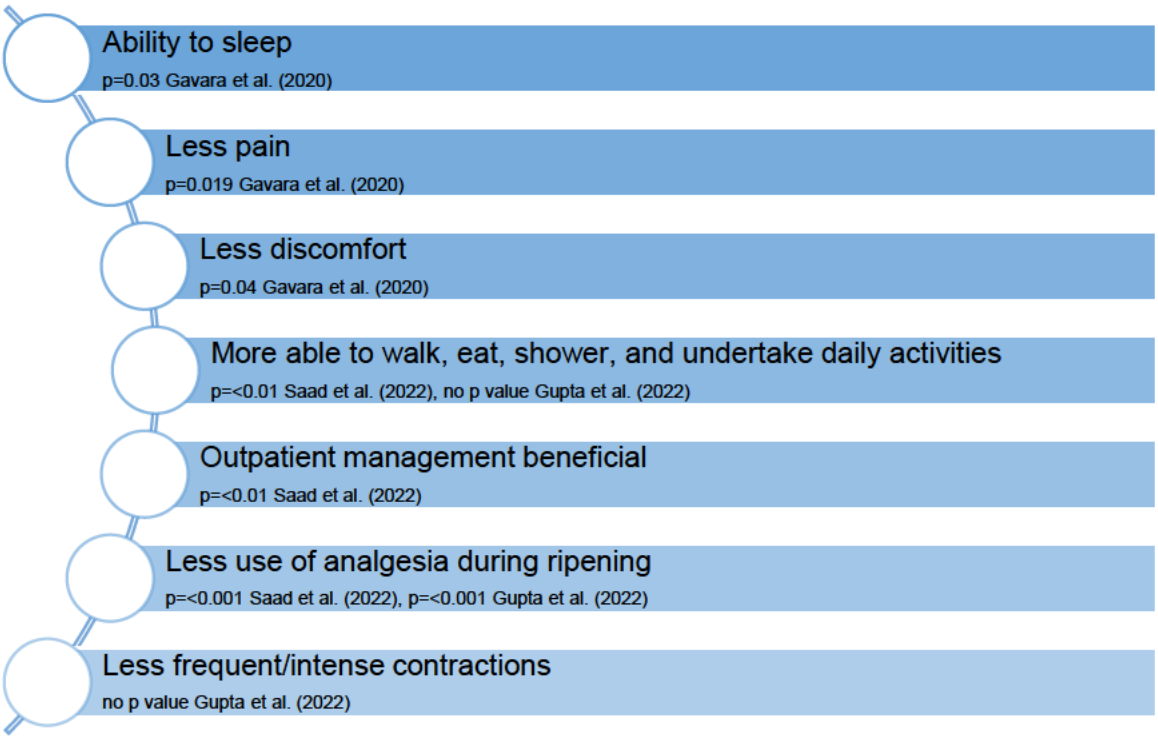


p=<0.05 = significant

Figure 5: Summary of key findings: Balloons compared with pharmacological methods, own graphic, 2023

The results from Obut et al. (2021) cannot be summarised in the same way as there was no comparison with a pharmacological method but rather a comparison of balloon designs. The results are still interesting as they significantly favour the double balloon over the single Foley under tension; pain score being higher in the single Foley group (p=0.011) and maternal satisfaction lower (p=0.014).

The studies comparing osmotic dilators similarly found more satisfaction with the mechanical method and outpatient management thereof.



p=<0.05 = significant

Figure 6: Summary of key findings: Osmotic dilators compared with pharmacological methods, own graphic, 2023

It is regrettable that the number of trials directly comparing balloons and osmotic dilators is so limited and that their quality is not more robust. Of the two studies showing a comparison one (Koçak et al., 2020) is retrospective, non-randomised and of low evidence and the other (Saad et al., 2019) is open to bias due to the involvement of the Dilapan-S manufacturer Medicem Inc. and the main authors prominence on the Dilapan-S website. The authors in Koçak et al. (2020) state that,

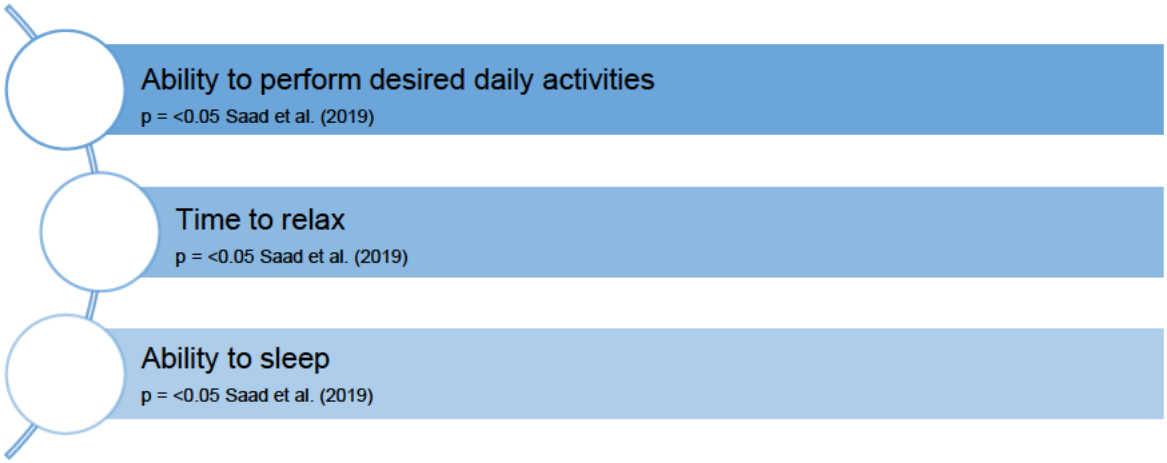
> "there is no study in the literature comparing Dilapan-S® and cervical ripening double balloon catheter (Cook®) in labor induction until this study […]. In this respect, this study is capable [of adding] new information to the literature." (Koçak et al., 2020, p. 77)

While this may be correct (it was also the only study found in the literature search for this thesis), it does not improve the quality of the evidence they present.

The evidence from Saad et al. (2019) comes closest to answering the research question of whether the use of osmotic dilators leads to more maternal satisfaction than balloons. It highlights Dilapan-S's superiority in performing daily activities and allowing for more relaxation and sleep (p=<0.05). The authors state that participants were more satisfied with Dilapan-S,

> "likely due to the difference in how the devices are handled after insertion. While the Foley protrudes from the introitus and is kept under tension, the Dilapan-S remains mostly in the cervical canal, allowing more patients to continue with daily activities." (Saad et al., 2019, p. 275.e6)

This would however appear to be somewhat speculative on the part of the authors as no qualitative responses were collected in the survey. The conclusions in the study are drawn from only three of eleven questions posed to participants immediately after placement and after extraction.



p=<0.05 = significant

Figure 7: Summary of key findings: Osmotic dilators compared with balloons, own graphic, 2023

The remaining eight questions showed no significant differences with satisfaction between the devices. These questions asked about worries prior to placement, anxiety at insertion, discomfort at insertion, amount of pain during insertion, discomfort whilst in situ and overall pain. Participants were also asked as to whether an alternative device would be considered. The question was posed prior to device placement and then again as a way to evaluate overall experience of cervical ripening.

It is not stated in Saad et al. (2019) why the study design chose the Foley catheter as a comparison and not the double Cook balloon. If the findings are considered in the light of

the subsequent findings of Obut et al. (2021), which show better satisfaction with double balloons, then it could be hypothesised that Dilapan-S could indeed be the inferior method.

With this in mind and based on the evidence currently available, it cannot be said with certainty that the use of osmotic dilators as a method of mechanical induction of labour leads to increased maternal satisfaction when compared to balloon inductions at term. The PICO question can therefore neither be affirmed nor refuted. What the research does however show is that they each offer a comparable alternative to pharmacological methods.

5.2 Method: Discussion and reflection

While the research for this thesis was conducted using a structured search for literature in renowned databases it does not provide a comprehensive systematic review of all the literature available on the topic of methods of cervical ripening and satisfaction with either balloons or osmotic dilators. It can therefore not be said with certainty that all the relevant literature has been found or assessed. The keywords for the database searches were selected in order to retrieve as many relevant results as possible. However, the decision to exclude the broad term “induction of labo* may, upon reflection, have been too restrictive. Excluding the term “laminaria” may also have reduced results for osmotic dilators, however the term “cervical ripening” was considered to be wide enough to find suitable results.

By only searching for “Clinical Trial, Randomized Controlled Trial” in PubMed, observational or qualitative studies which may have included more information on satisfaction will have been excluded. The exclusion of systematic reviews enabled a concentrated focus on primary sources but may have hindered finding other records by way of snowballing with the studies referenced therein. Whilst RCTs offer the next strongest evidence level with regard to the evidence pyramid and randomisation of participants in these trials does reduce possible risks of confounders and bias, they are still not always the perfect study design to investigate subjective factors.

A further critique is that the searches in the three databases (PubMed, Scopus and CINAHL) were not identical. As shown in the method chapter there were slight variations in the filters applied. The Scopus search required additional keywords to find results relevant to the PICO question. The subject area in which the search was conducted was also restricted to the areas “Medicine”, “Nursing” and “Health Professions”. No restriction as to the publication or study design was undertaken. The CINAHL search did not require additional terms and was conducted without any restriction to search field, subject area or study design.

The original intention of the literature review to only focus on studies which had maternal satisfaction as the primary outcome had to be widened as almost all the studies retrieved

during the searches investigated vaginal delivery, time to labour, maternal or neonatal health as primary outcomes and satisfaction, if measured at all, as a secondary outcome. It is possible that some studies which may have included secondary outcomes were overlooked during the manual screening if they did not include the word satisfaction or similar terms in either the title or the abstract. The term satisfaction is so subjective that it is possible that clinical trials are not the best framework within which to search for such evidence. The hope was to find as many studies as possible on patient-reported outcome measures (PROMS) or patient-reported experience measures (PREMS) by also using the broader terms acceptance, comfort, discomfort, invasiveness, experience and pain. These were terms which the author (subjectively) considered to be similar.

A certain publication bias could be levelled at this thesis through the concentration on studies which report positive experiences with mechanical methods of IOL. Especially data referring to pain scores would be typically lower in mechanical methods as they do not directly stimulate (painful) uterine contractions.

Access to full-text reports also hampered this literature review. In particular the conference presentations from Sidebottom et al. (2023) and McCue et al. (2023) would seem to include promising findings and could have provided up-to-date evidence. The abstracts are however unavailable as full-text studies and requests from the authors via the website Research Gate unfortunately remain unanswered.

The methodological choice of a literature review is seen as validated in the assessment of the current state of research on this topic. A prospective study could have been designed to address the PICO question. As shown in this thesis there is a gap in the current research which places too little emphasis on maternal satisfaction with cervical ripening methods. A study design would not have been able to answer the question of whether satisfaction is higher with osmotic dilators as opposed to balloons at this present time. It could however provide an opportunity to answer the question in the future by proposing a design using a standardised approach to the collection of evidence.

5.3 Implications for midwifery and clinical practice

Both balloons and osmotic dilators have been shown to be safe, effective and acceptable methods for cervical ripening in the induction of labour. Providing optimal care is a priority for midwives and they are uniquely placed to offer choice to those who are pregnant and to support evidence-based, shared decision making. The hypothesis is that if pregnant people actively participate in decisions concerning their care then their satisfaction levels will rise.

IOL and cervical ripening are areas where midwives can play a vital professional and care role. The CEQ includes specific questions on the professional support midwives provide during induction and childbirth demonstrating their importance (Place et al., 2022). More training in the insertion of balloons and Dilapan-S rods would add to midwives' competences. With reference to the insertion of Foley catheters, a 2018 study showed that,

> "only 8% of insertions were rated as difficult by staff while 70% were rated easy. This, together with the fact that the inserter's level of experience had no influence on women's discomfort, are reassuring for midwives who wish to teach and learn this common procedure." (Gidaszewski et al., 2018, p. 57)

Another study shows that,

> "the osmotic dilator is easy to apply and can be effortlessly inserted by a physician or midwife. Our patients had no complaints whatsoever, neither during insertion, dilation nor extraction of Dilapan-S." (Maier et al., 2015, p. 5)

An increase in outpatient IOL can also be an opportunity for midwives working in the community. Through an increased involvement in perinatal care the midwife profits from personal and professional development and can individualise more their postpartum care of families. With particular focus on German maternity provision, people who have taken advantage of antenatal midwifery care and who plan postnatal care with the same midwife could benefit from the support of a known and trusted professional during cervical ripening prior to labour, thus extending the continuous care model (Sayn-Wittgenstein, 2007).

The possibility of outpatient care is particularly attractive to hospitals already struggling with tight resources. In such situations, a comprehensive risk assessment is essential before discharge into outpatient care and it is also imperative to provide information as to when to revisit the hospital. Channels of communication need to be clear should questions or issues arise during outpatient management. Allowing those undergoing cervical ripening to be sent home can alleviate pressure on maternity units and increase patient satisfaction with the process (Beckmann et al., 2020; Saad et al., 2022). The option of outpatient care "appears to confer psychosocial benefit for women needing cervical priming before induction of labor" (Turnbull et al., 2013, p. 80).

There is also a growing population of pregnant people with caesarean sections in their case history for whom an increased choice and range of induction procedures would be advantageous, potentially reducing the rate of repeat caesareans (Koenigbauer et al., 2021; Maier et al., 2015). Risk pregnancies, such as those with small for gestational age foetuses and those affected by intrauterine growth restrictions, would also benefit from more research into these mechanical methods as there is no hyperstimulation of the uterus, potentially

reducing foetal stress and adverse foetal effects (Grace Ng et al., 2022; Gupta et al., 2022; Rath et al., 2023).

5.4 Recommendations for further research

The recommendations for areas for further research can be summarised as follows: direct comparisons of the Cook balloon with Dilapan-S, the recognition and inclusion of satisfaction in all trials concerning IOL and cervical ripening procedures, the development of standardised metrics for reporting satisfaction, and the value of outpatient management.

As highlighted by Alfirevic et al. (2016), it is unacceptable that only 5% of studies include maternal satisfaction as an outcome. The recommendations in Dos Santos et al. (2018) for the development of core outcomes to be reported in IOL were made after consultation with stakeholders from across the spectrum of healthcare, including midwives. The increased involvement of the DGHWi in the writing of German guidelines for obstetric care is also a positive development and shows the relevance of these topics for the midwifery profession. It also demonstrates an increased interdisciplinary approach to research and the implementation of recommendations.

Research appears to be being increasingly undertaken in this area and this is to be welcomed. However, some recent studies have seen opportunities missed. A retrospective study (Shindo et al., 2017) compared hygroscopic dilators with balloons and found them comparable for obstetric outcomes but did not investigate satisfaction. The prospective observational study (Ducarme et al., 2022) investigating experiences with cervical ripening methods seeks to answer important questions of satisfaction but fails to include the use of synthetic osmotic dilators in the study design, choosing to concentrate instead on balloons, vaginal dinoprostone and oral misoprostol.

The subjective nature of “satisfaction” makes a comparison or summary of the results of different studies difficult.

> “In order to improve a woman’s experience, it must be measurable. Reporting experiential outcomes accurately and consistently is challenging and often poorly performed, with many studies failing to report on a woman’s experience at all. Those that do, are limited by inconsistent reporting, non-validated metrics, recall bias and confounding factors. Future IOL researchers should be routinely measuring experiential alongside clinical outcomes and utilizing consistent metrics of patient experience to enable meaningful comparison of each method.” (Beckmann et al., 2020, p. 5)

Maier et al. (2015) agree that “the patient’s satisfaction concerning the ripening and induction method should be assessed in a standardized manner, as this is an important factor in daily clinical work” (Maier et al., 2015, p. 5). Furthermore, the current studies show inconsistencies at the point at which participants are asked to evaluate their experiences. The “right time” to ask needs to be considered in future research designs. Some researchers favour giving up to one month after birth to report on experience while others seek rapid feedback. Both approaches are valid but make comparisons problematic. Longer periods allow reflection, while shorter response times reduce recall bias and allow for a focus on cervical ripening as a separate event to childbirth itself.

> “We recognize […] that women have been asked about their experience in the days immediately postpartum, and for some this may have been too early to conclude how they felt about their healthcare experience” (Beckmann et al., 2020, p. 5).

It also remains questionable how reliable data on satisfaction with two different interventions can ever be. It is not possible to offer both methods of cervical ripening in the same pregnancy and hence to receive robust results comparing the methods. Should, for instance, the first round of Dilapan-S not result in a favourable cervix, should a balloon be subsequently used? Would the first method pre-dilate and make the second method more effective and potentially therefore more satisfying? Which method should be used first? A difference in experience between nulliparous and multiparous people is also to be expected, meaning that the experiences of the same individual could differ with each pregnancy.

More trials also need to be carried out to investigate the feasibility of outpatient care during cervical ripening. Outpatient management must not be driven by the desire for cost-savings alone but used as an opportunity to increase satisfaction with care. “Further research into the safety, acceptability, and cost-effectiveness of Dilapan-S in this [outpatient] setting is needed”. (Gupta et al., 2022, p. 19)

> “For future outpatient priming to be a viable option, it can only be offered to women within the framework of clinical efficacy and safety. These results should be confirmed in other studies in different patient populations and clinical settings; additional research is also needed to establish what choices women would actually make if they were routinely offered a choice as part of clinical care.” (Howard et al., 2014, p. 10)

The AWMF guideline (DGGG, 2020a) is in principle supportive of the option of outpatient management of IOL using mechanical methods in low-risk pregnancies. It recommends however only the balloon as a possible method and does not mention osmotic dilators as an alternative. It can be generally said that the use of osmotic dilators is inadequately

represented in the current guidelines issued by organisations such as the AWMF, NICE and ACOG (Rath et al., 2023). This demonstrates once again a lack of evidence-based data to recommend more use of the method and the urgent need to conduct more research.

6 Conclusions

The focus of this thesis is a comparison of maternal satisfaction with balloons and osmotic dilators as a mechanical method of IOL through cervical ripening. In the process of researching the PICO question the most important medical databases were searched and evidence from the last 10 years critically analysed using the evaluation instrument CASP. Five studies have been presented comparing balloons with other pharmacological agents and three comparing osmotic dilators. The limitations of those studies which were found are discussed in this thesis and bias and confounding factors identified. The studies show that mechanical methods are not inferior to the more common pharmacological ones and indeed have higher satisfaction levels. Those who have experienced cervical ripening would chose the method again in a subsequent pregnancy and would recommended the method to others. Pain scores are reported as lower with mechanical methods with less analgesia needed, and it is easier to undertake daily activities during priming with a mechanical intervention as opposed to a pharmacological one. It is to be regretted that not more evidence is available comparing the two mechanical methods directly with each other. An additional challenge is finding studies which focus on maternal satisfaction as a measure.

Despite a structured literature search and the evaluation of a range of studies it is not possible to categorially answer the PICO research question as to whether the use of osmotic dilators as a method of mechanical induction of labour leads to increased maternal satisfaction when compared to balloon inductions at term. It has been discussed that the most frequently cited study for the non-inferiority of Dilapan-S (Saad et al., 2019) is not without its limitations and bias, and that the results and evidence level of the other comparison (Koçak et al., 2020) are not robust. Neither study can offer the generalisability that can unequivocally support recommendations towards a change in clinical practice to favour osmotic dilators over balloons. The reassuring message from the analysis of all the studies however is that both methods are safe, effective and are accepted by those who are being induced. These findings are, in themselves, valid and valuable conclusions.

The evidence also shows that there are benefits for both hospitals and individuals in the outpatient management of cervical ripening. Where appropriate, this model of care could be expanded and could involve more midwives in the community providing support during

the procedure, alleviating pressure on hospital resources and clinical personnel. Additionally, more midwives could be trained in the insertion of the devices.

There is a fundamental need for medical science to place more focus on the needs of women and to recognise satisfaction as an essential outcome of research (Alfirevic et al., 2016; Dos Santos et al., 2018). The literature and analysis presented in this thesis highlight existing gaps in research which are potentially limiting choice. It is the view of the author that more studies are specifically needed to compare the satisfaction of Cook balloon inductions with Dilapan-S osmotic dilators as these devices are the most commonly used in German maternity units. Ideal research designs with clinical relevance for Germany would use multi-centred RCTs or well-designed prospective cohort studies to investigate both products in inpatient as well as outpatient settings. The development of a standardised approach to the measurement of satisfaction, as well as the timing of data collection, would ultimately enable future comparisons of studies to build a more robust body of evidence. It is imperative that high quality evidence be fed into clinical guidelines (e.g., AWMF, NICE, ACOG) to address the current underrepresentation of mechanical methods of cervical ripening within them.

As described in the introduction, the aim of this thesis is to provide midwives, other healthcare professionals and those who are pregnant with evidence-based options, to open discussions on individual care models and ultimately to promote shared decision making by reflecting on first-hand experience and satisfaction. There will always be situations in obstetrics where cervical ripening, and induction of labour are necessary to ensure a healthy outcome for all parties and it is fortunate that there are choices available as to the method to be used. The current evidence shows that both balloons and osmotic dilators are comparable methods of IOL with high levels of satisfaction. Consultations explaining these choices can enable an individual tailoring of care to the needs of the 185,000 individuals who experience this specific intervention every year.

Midwives are the original advocates for comprehensive and good quality maternity provision and can empower those who are pregnant to participate in shared decision making at every stage of their care. They are in a unique position to contribute to increased maternal satisfaction by providing advice, counselling and support all based on the latest evidence (DGGG, 2020b).

7 Bibliography

Alfirevic, Z., Gyte, G. M., Pileggi, V. N., Plachcinski, R., Osoti, A. O., & Finucane, E. M. (2020). Home versus inpatient induction of labour for improving birth outcomes. *Cochrane Database of Systematic Reviews*, (*8)*. Article CD007372. https://doi.org/10.1002/14651858.CD007372.pub4

Alfirevic, Z., Keeney, E., Dowswell, T., Welton, N. J., Medley, N., Dias, S., Jones, L. V., Gyte, G., & Caldwell, D. M. (2016). Which method is best for the induction of labour? A systematic review, network meta-analysis and cost-effectiveness analysis. *Health Technology Assessment*, *20*(65), 1–584. https://doi.org/10.3310/hta20650

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

CASP: Critical Appraisal Skills Programme (2022). *CASP Cohort Study Checklist.* Retrieved October 10, 2023, from https://casp-uk.net/casp-tools-checklists/

CASP: Critical Appraisal Skills Programme (2022). *CASP Randomised Controlled Trial Checklist.* Retrieved October 10, 2023, from https://casp-uk.net/casp-tools-checklists/

Cook (n.d.). Homepage: Cook® Cervical Ripening Balloon with Stylet. Accessed on October 5, 2023, from https://cookmedical.com/products/wh_crbs_webds/

DGGGa: Induction of Labour. Guideline of the German Society of Gynecology and Obstetrics (S2k, AWMF Registry No. 015-088, December 2020). https://register.awmf.org.de/leitlinien/detail/015-088

DGGGb: Vaginal Birth at Term. Guideline of the German Society of Gynecology and Obstetrics (S3, AWMF Registry No. 015-083, December 2020). https://register.awmf.org.de/leitlinien/detail/015-083

D'Indinosante, M., Vidiri, A., Giorgi, L., Turrini, I., Spanò, A., Perelli, F., Scatena, E., Mattei, A., Lanzone, A., Scambia, G., & Cavaliere, A. (2023). Pre-induction cervical ripening and hygroscopic cervical dilators in pre-labor induction. *The Journal of Maternal-Fetal & Neonatal Medicine*, *36*(2), Article 2239422. https://doi.org/10.1080/14767058.2023.2239422

Dos Santos, F., Drymiotou, S., Antequera Martin, A., Mol, B., Gale, C., Devane, D., van't Hooft, J., Johnson, M., Hogg, M., & Thangaratinam, S. (2018). Development of a core outcome set for trials on induction of labour: An international multistakeholder Delphi study. *BJOG: An International Journal of Obstetrics & Gynaecology*, *125*(13), 1673–1680. https://doi.org/10.1111/1471-0528.15397

Ducarme, G., Martin, S., Chesnoy, V., Planche, L., Berte, M.-P., & Netier-Herault, E. (2022). Prospective observational study investigating the effectiveness, safety, women's experiences and quality of life at 3 months regarding cervical ripening methods for induction of labor at term—The MATUCOL study protocol. *PLoS ONE*, *17*(1), Article e0262292. https://doi.org/10.1371/journal.pone.0262292

Gavara, R., Saad, A. F., Wapner, R. J., Saade, G., Fu, A., Barrow, R., Nalgonda, S., Bousleiman, S., Almonte, C., Alnafisee, S., Holman, A., Burgansky, A., & Heikkila, P. (2022). Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term: A Randomized Controlled Trial. *Obstetrics & Gynecology*, *139*(6), 1083-1091. https://doi.org/10.1097/AOG.0000000000004799

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

Grace Ng, Y. H., Aminuddin, A. A., Tan, T. L., Kuppusamy, R., Tagore, S., & Yeo, G. S. H. (2022). Multicentre randomised controlled trial comparing the safety in the first 12 h, efficacy and maternal satisfaction of a double balloon catheter and prostaglandin

pessary for induction of labour. *Archives of Gynecology and Obstetrics*, *305*, 11–18. https://doi.org/10.1007/s00404-021-06090-y

Gupta, J. K., Maher, A., Stubbs, C., Brocklehurst, P., Daniels, J. P., & Hardy, P. (2022). A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert. *American Journal of Obstetrics & Gynecology MFM*, *4*(4), Article 100628. https://doi.org/10.1016/j.ajogmf.2022.100628

Howard, K., Gerard, K., Adelson, P., Bryce, R., Wilkinson, C., & Turnbull, D. (2014). Women's preferences for inpatient and outpatient priming for labour induction: A discrete choice experiment. *BMC Health Services Research*, *14*, 330. https://doi.org/10.1186/1472-6963-14-330

Kehl, S., Weiss, C., Rath, W., Schneider, M., Stumpfe, F., Faschingbauer, F., Beckmann, M. W., & Stelzl, P. (2021). Labour Induction with Misoprostol in German Obstetric Clinics: What Are the Facts on Such Use? *Geburtshilfe und Frauenheilkunde*, *81*(8), 955–965. https://doi.org/10.1055/a-1538-2200

Kehl, S., Welzel, G., Ehard, A., Berlit, S., Spaich, S., Siemer, J., & Sütterlin, M. (2013). Women's acceptance of a double-balloon device as an additional method for inducing labour. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, *168*(1), 30–35. https://doi.org/10.1016/j.ejogrb.2012.12.018

Koçak, Ö., Yerebasmaz, N., Yalvaç, E. S., Yirci, B., Esin, S., & Kandemir, Ö. (2020). The Comparison of Cervical Ripening Double Balloon and Higroscopic Dilator (Dilapan–S®) In Labor Induction. *Bozok Tıp Dergisi, 10*(4), 76-83. https://doi.org/10.16919/bozoktip.651534

Koenigbauer, J. T., Schalinski, E., Jarchau, U., Gauger, U., Brandt, K., Klaucke, S., Scharf, J.-P., Rath, W., & Hellmeyer, L. (2021). Cervical ripening after cesarean section: A prospective dual center study comparing a mechanical osmotic dilator vs.

prostaglandin E2. *Journal of Perinatal Medicine*, *49*(7), 797–805. https://doi.org/10.1515/jpm-2021-0157

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

Maier, J. T., Schalinski, E., Gauger, U., & Hellmeyer, L. (2015). Cervical Ripening with an Osmotic Dilator (Dilapan-S) in Term Pregnancies. *Journal of Gynecology and Neonatal Biology*, *1*(2), 55–60. https://doi.org/10.15436/2380-5595.15.015

McCue, B., Demertzis, K., Lin, B., Lu, A. M., Muscat, J., & Shahani, D. P. (2023, May 19-21). *Efficacy of Transcervical Balloon Catheter Versus Hygroscopic Dilator for Outpatient Prelabor Cervical Ripening* [Conference presentation abstract ID: 1382587]. 71st Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists, Baltimore, MD, United States. *Obstetrics & Gynecology*, *141*(5S), 57S-57S. https://doi.org/10.1097/01.AOG.0000930484.90397.35

Medicem, Inc. (n.d.). Homepage: Dilapan-S® Cervical Dilator. Accessed on October 5, 2023, from https://www.dilapans.com/

National Institute for Health and Care Excellence, Inducing Labour (NG207), published November 4, 2021, available at https://www.nice.org.uk/guidance/ng207/resources/inducing-labour-pdf-66143719773637, accessed on November 10, 2023

Obut, M., Balsak, D., Sarsmaz, K., Tolunay, H. E., Varlı, E. N., Şahin, D., & Yücel, A. (2021). Double Foley catheter for labor induction: An alternative method. *International Journal of Gynecology & Obstetrics*, *155*(3), 496–504. https://doi.org/10.1002/ijgo.13807

Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D., Shamseer, L., Tetzlaff, J. M., Akl, E. A., Brennan, S. E., Chou, R., Glanville, J., Grimshaw, J. M., Hróbjartsson, A., Lalu, M. M., Li, T., Loder, E. W., Mayo-Wilson,

E., McDonald, S., … Moder, D. (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ,* 372(71), https://doi.org/10.1136/bmj.n71

Place, K., Kruit, H., & Rahkonen, L. (2022). Comparison of primiparous women's childbirth experience in labor induction with cervical ripening by balloon catheter or oral misoprostol – a prospective study using a validated childbirth experience questionnaire (CEQ) and visual analogue scale (VAS). *Acta Obstetricia et Gynecologica Scandinavica*, *101*(10), 1153–1162. https://doi.org/10.1111/aogs.14433

Polit, D. F., & Beck, C. T. (2021). *Nursing research: generating and assessing evidence for nursing practice.* Eleventh edition. Philadelphia: Wolters Kluwer

Rath, W., Kummer, J., Königbauer, J. T., Hellmeyer, L., & Stelzl, P. (2023). Synthetic Osmotic Dilators for Pre-Induction Cervical Ripening – an Evidence-Based Review. *Geburtshilfe und Frauenheilkunde (efirst)*. https://doi.org/10.1055/a-2103-8329

Saad, A. F., Gavara, R., Senguttuvan, R. N., Goncharov, A. D., Berry, M., Eid, J., Goldman, B., Nutter, A., Moutos, C. P., Wang, A. M., & Saade, G. R. (2022). Outpatient Compared With Inpatient Preinduction Cervical Ripening Using a Synthetic Osmotic Dilator: A Randomized Clinical Trial. *Obstetrics and Gynecology*, *140*(4), 584–590. https://doi.org/10.1097/AOG.0000000000004942

Saad, A. F., Villarreal, J., Eid, J., Spencer, N., Ellis, V., Hankins, G. D., & Saade, G. R. (2019). A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial). *American Journal of Obstetrics and Gynecology*, *220*(3), 275.e1-275.e9. https://doi.org/10.1016/j.ajog.2019.01.008

Sayn-Wittgenstein F zu. (Hrsg.) (2007). Geburtshilfe neu denken. Bericht zur Situation und Zukunft des Hebammenwesens in Deutschland. 1. Auflage. Bern: Hans Huber Verlag

Shindo, R., Aoki, S., Yonemoto, N., Yamamoto, Y., Kasai, J., Kasai, M., & Miyagi, E. (2017). Hygroscopic dilators vs balloon catheter ripening of the cervix for induction of labor in nulliparous women at term: Retrospective study. *PLoS ONE*, *12*(12), Article e0189665. https://doi.org/10.1371/journal.pone.0189665

Sidebottom, A., Colicchia, L., Drake, K., Goering, M., Vacquier, M., & Wunderlich, W. (2023, May 19-21). *Outpatient Cervical Ripening Program Evaluation: A Comparison of Osmotic Cervical Dilators and Foley Balloon* [Conference presentation abstract ID: 1377400]. 71st Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists, Baltimore, MD, United States. *Obstetrics & Gynecology*, *141*(5S), 47S. https://doi.org/10.1097/01.AOG.0000930340.82711.ca

Statistisches Bundesamt (Destatis). (2023). Daten der Lebendgeborenen, Totgeborenen, Gestorbenen und der Gestorbenen im 1. Lebensjahr. Accessed on November 10, 2023, from https://www.destatis.de/DE/Themen/Gesellschaft-Umwelt/Bevoelkerung/Geburten/Tabellen/lebendgeborene-gestorbene.html

The American College of Obstetricians and Gynecologists. (2009). ACOG Practice Bulletin No. 107: Induction of Labor. *Obstetrics & Gynecology, 114*(2 Part 1), 386-397. https://doi.org/10.1097/AOG.0b013e3181b48ef5

The American College of Obstetricians and Gynecologists. (2019). ACOG Practice Bulletin No. 205: Vaginal Birth after Cesarean Delivery. *Obstetrics & Gynecology, 133*(2),e110-e127. https://doi.org/10.1097/AOG.0000000000003078

Turnbull, D., Adelson, P., Oster, C., Bryce, R., Fereday, J., & Wilkinson, C. (2013). Psychosocial Outcomes of a Randomized Controlled Trial of Outpatient Cervical Priming for Induction of Labor. *Birth*, *40*(2), 75–80. https://doi.org/10.1111/birt.12035

Vaan, M. D. T., ten Eikelder, M. L. G., Jozwiak, M., Palmer, K. R., Davies-Tuck, M., Bloemenkamp, K. W. M., Mol, B. W. J., & Boulvain, M. (2023). Mechanical methods for

induction of labour. *The Cochrane Database of Systematic Reviews*, *(3)*. Article CD001233. https://doi.org/10.1002/14651858.CD001233.pub4

I Appendices

Appendix I.a Database search histories

PubMed search history, 29th September 2023:

History and Search Details — Download — Delete

Search	Actions	Details	Query	Results	Time
#7	•••	›	Search: **#2 AND #4 AND #6**	5	09:48:45
#6	•••	›	Search: **((((satisfaction) OR (acceptance)) OR (comfort)) OR (invasiveness)) OR (experience)** Filters: **from 2013 - 2024**	1,354,122	09:48:21
#5	•••	›	Search: **((((satisfaction) OR (acceptance)) OR (comfort)) OR (invasiveness)) OR (experience)**	2,480,881	09:48:11
#4	•••	›	Search: **((((balloon) OR (cook balloon)) OR (foley balloon)) OR (cook catheter)) OR (foley catheter)** Filters: **from 2013 - 2024**	38,825	09:47:23
#3	•••	›	Search: **((((balloon) OR (cook balloon)) OR (foley balloon)) OR (cook catheter)) OR (foley catheter)**	124,529	09:47:11
#2	•••	›	Search: **((osmotic dilator) OR (dilapan)) OR (hygroscopic)** Filters: **from 2013 - 2024**	12,741	09:46:27
#1	•••	›	Search: **((osmotic dilator) OR (dilapan)) OR (hygroscopic)**	17,983	09:46:16

Showing 1 to 7 of 7 entries

PubMed search history, 2nd October 2023:

History and Search Details — Download — Delete

Search	Actions	Details	Query	Results	Time
#7	•••	›	Search: **#4 AND #6** Filters: **Clinical Trial, Randomized Controlled Trial**	45	05:34:02
#6	•••	›	Search: **((((((satisfaction[Title/Abstract]) OR (acceptance[Title/Abstract])) OR (comfort[Title/Abstract])) OR (discomfort[Title/Abstract])) OR (invasiveness[Title/Abstract])) OR (experience[Title/Abstract])) OR (pain[Title/Abstract])** Filters: **Clinical Trial, Randomized Controlled Trial, from 2013 - 2024**	58,947	05:33:31
#5	•••	›	Search: **((((((satisfaction[Title/Abstract]) OR (acceptance[Title/Abstract])) OR (comfort[Title/Abstract])) OR (discomfort[Title/Abstract])) OR (invasiveness[Title/Abstract])) OR (experience[Title/Abstract])) OR (pain[Title/Abstract])** Filters: **Clinical Trial, Randomized Controlled Trial**	135,609	05:33:23
#4	•••	›	Search: **Cervical ripening[Title/Abstract]** Filters: **Clinical Trial, Randomized Controlled Trial, from 2013 - 2023**	157	05:31:33
#3	•••	›	Search: **Cervical ripening[Title/Abstract]** Filters: **Clinical Trial, from 2013 - 2023**	157	05:31:26
#2	•••	›	Search: **Cervical ripening[Title/Abstract]** Filters: **from 2013 - 2023**	793	05:31:17
#1	•••	›	Search: **Cervical ripening[Title/Abstract]**	2,050	05:31:08

Showing 1 to 7 of 7 entries

Scopus search history, 2nd October 2023:

ID	Name	Query	Documents	Date last run	Actions
#3	cervical ripening satisfaction extended	((cervical AND ripening) AND (satisfaction OR acceptance OR discomfort OR comfort OR invasiveness OR experience OR pain) AND PUBYEAR > 2012 AND PUBYEAR < 2024) AND (balloon OR catheter OR osmotic AND dilator OR dilapan OR hygroscopic AND PUBYEAR > 2012 AND PUBYEAR < 2024) AND (LIMIT-TO (LANGUAGE , "English")) AND (LIMIT-TO (SUBJAREA , "MEDI") OR LIMIT-TO (SUBJAREA , "NURS") OR LIMIT-TO (SUBJAREA , "HEAL")) View Less Edit query	93	02 Oct 2023	
#2	cervical ripening satisfaction	(cervical AND ripening) AND (satisfaction OR acceptance OR discomfort OR comfort OR invasiveness OR experience OR pain) AND PUBYEAR > 2012 AND PUBYEAR < 2024 AND (LIMIT-TO (SUBJAREA , "MEDI") OR LIMIT-TO (SUBJAREA , "NURS") OR LIMIT-TO (SUBJAREA , "HEAL")) AND (LIMIT-TO (LANGUAGE , "English")) View Less Edit query	1,252	02 Oct 2023	

CINAHL search history, 2nd October 2023:

Search ID#	Search Terms	Search Options	Actions
S3	S1 AND S2	**Expanders** - Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (81) | View Details | Edit
S2	satisfaction OR Acceptance OR Comfort OR Discomfort OR Invasiveness OR Experience OR Pain	**Limiters** - Published Date: 20130101- **Expanders** - Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (590,218) | View Details | Edit
S1	Cervical ripening	**Limiters** - Published Date: 20130101- **Expanders** - Apply equivalent subjects **Search modes** - Boolean/Phrase	View Results (572) | View Details | Edit

Appendix I.b Overview of shortlisted studies and key messages

Where found	#	Title	Authors	Year Pub.	Study Design	Where conducted	N	Focus	Key messages
PubMed	1	Outpatient cervical ripening: discomfort/pain during speculum and Foley catheter insertion.	Gidaszewski B, Khajehei M, McGee T.	2018	Prospective cohort study as part larger RCT	Single centre, Sydney, Australia	318	Discomfort / pain with Foley	Foley insertion and in situ less uncomfortable than vaginal examination. Visual analog scale, questionnaire
PubMed	2	Patient Satisfaction with Outpatient Cervical Ripening in Parous Women.	Wang MJ, Jauk VC, George DM, Kuper SG, Edwards RK, Szychowski JM, Mazzoni SE, Files P, Tita AT, Subramaniam A, Harper LM.	2021	Secondary analysis evaluating patient satisfaction from RCT	Single centre, outpatient clinic, Birmingham Alabama, USA	129	Outpatient Foley	Satisfaction measured using 3 different surveys, recommend to friend. Satisfaction does not differ between inpatient and outpatient using Foley.
PubMed	3	Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term: A Randomized Controlled Trial.	Gavara R, Saad AF, Wapner RJ, Saade G, Fu A, Barrow R, Nalgonda S, Bousleiman S, Almonte C, Alnafisee S, Holman A, Burgansky A, Heikkila P.	2022	Prospective, open-label, noninferiority randomized trial	2 medical centres in USA	307	Osmotic dilators (Dilapan-S) v. oral misoprostol, satisfaction	Synthetic osmotic cervical dilator is noninferior to oral misoprostol for cervical ripening. Advantages of synthetic osmotic cervical dilator include a better safety profile and patient satisfaction (sleep, lower pain score, less abdominal discomfort), less tachysystole, and U.S. Food and Drug Administration approval.
PubMed	4	Patient satisfaction with the cervical ripening balloon as a method for induction of labour: a randomised controlled trial.	Lim SE, Tan TL, Ng GYH, Tagore S, Kyaw EEP, Yeo GSH.	2018	Prospective RCT	Single centre, Singapore	83	Ballon v. PGE - satisfaction	Interviews: Patient experience of IOL with CRB or PGE was equally satisfactory, although pain during induction was lower in the CRB group. We found that both methods of IOL are acceptable to women and should be made available to provide more options. Both groups would recommend method.
PubMed	5	Double Foley catheter for labor induction: An alternative method.	Obut M, Balsak D, Sarsmaz K, Tolunay HE, Varli EN, Şahin D, Yücel A.	2021	Prospective randomized controlled trial	Single centre, Ankara, Turkey	222	DFC v FC v Cook	The maternal safety and success rate of labor induction were comparable between groups. However, the FC group had a higher pain score during catheter insertion and a lower maternal satisfaction rate. Moreover, considering the high cost of the Cook cervical ripening balloon, the DFC has an advantage, especially in low-resource countries.
PubMed	6	Use of the Foley catheter versus a double balloon cervical ripening catheter in pre-induction cervical ripening in postdate primigravidae.	Sayed Ahmed WA, Ibrahim ZM, Ashor OE, Mohamed ML, Ahmed MR, Elshahat AM.	2016	Interventional study (cohort?). prospective randomized interventional study	Single centre, Egypt	78	Efficiency Foley/Cook	No significant differences in other outcomes: pain during or after insertion and overall patient satisfaction. Pain on visual analog scale. Insertion ease. Cook greater cervical ripening, Foley significantly shorter insertion-expulsion-delivery, cheaper
PubMed	7	Multicentre randomised controlled trial comparing the safety in the first 12 h, efficacy and maternal satisfaction of a double balloon catheter and prostaglandin pessary for induction of labour.	Grace Ng YH, Aminuddin AA, Tan TL, Kuppusamy R, Tagore S, Yeo GSH.	2021	multicentre prospective cohort randomised controlled study	Multi-centre, 2 tertiary hospitals, Malaysia	394	DBC v. PGE - not too much on satisfaction	To evaluate the safety in the first 12 h, efficacy and maternal satisfaction of a double balloon catheter (DBC) with vaginal prostaglandin (PGE) for induction of labour (IOL). Pain scores similar, but less pain relief needed in DBC group, recommendation of method high in both groups.

Where found	#	Title	Authors	Year Pub.	Study Design	Where conducted	N	Focus	Key messages
PubMed	8	A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert.	Gupta JK, Maher A, Stubbs C, Brocklehurst P, Daniels JP, Hardy P; Synthetic Osmotic Cervical Dilator for Induction of Labor in Comparison to Dinoprostone Vaginal insErt (SOLVE) collaborative group.	2022	Open-label superiority RCT	Multi-centre, 4 English hospitals	674	Dilapan-S v. Dinoprostone	This study aimed to compare the efficacy, maternal and neonatal safety, and maternal satisfaction of a synthetic osmotic cervical dilator (Dilapan-S) with those of dinoprostone. Secondary outcome: Satisfaction, use of 23 questions to assess satisfaction during insertion, ripening and overall. Evaluation of pain relief needs. Dilapan - more satisfaction walking, dressing, hygiene, showering , sleep, relax, less frequent and less intense uterine contractions.
PubMed	9	Women's experience of induction of labor using PGE2 as an inpatient versus balloon catheter as an outpatient.	Beckmann M, Acreman M, Schmidt E, Merollini KMD, Miller Y.	2020	RCT, non-blinded	Multi-centre, 8 Australian maternity hospitals (secondary to quaternary facilities)	366	PGE inpatient v Cook Balloon outpatient	Little is known about women's preference and the impact of outpatient cervical priming on their healthcare experience. The objective was to compare women's healthcare experiences following IOL using a balloon catheter and going home, versus prostaglandin (PG) and remaining an inpatient. Written questionnaire after birth, prior to discharge. More women in balloon group would chose same method again. Where both options available involve not only clinical outcomes but also women's experience in decision-making process.
PubMed	10	Inner thigh taping vs traction for cervical ripening with a Foley catheter: a randomized controlled trial.	Gibson KS, Mercer BM, Louis JM.	2013	RCT	Single centre, tertiary hospital, USA	191	Taping v. traction Foley	Secondary outcomes were time to expulsion of the catheter, maternal discomfort (visual analog scale), but not enough information to include in final selection
PubMed	11	A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial).	Saad AF, Villarreal J, Eid J, Spencer N, Ellis V, Hankins GD, Saade GR.	2019	RCT	Single centre, USA	419	Dilapan-S v. Foley	The objective of the study was to test the hypothesis that Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term. Satisfaction survey (11 questions scored on 5-point Likert scale), more sleep, relaxing time, daily activities. Incl. In S2k guideline. Dilapan-S has advantages over Foley including “Food and Drug Administration approval, safe profile, no protrusion from the introitus, no need to keep under tension, and better patient satisfaction”
PubMed	12	A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial.	Wilkinson C, Adelson P, Turnbull D.	2015	RCT	Single centre, Adelaide, Australia	48	Cook Balloon - inpatient v. outpatient	Conducted a pilot randomised trial to assess the outcomes, clinical pathways and acceptability to both women and clinicians of outpatient balloon catheter ripening compared with usual inpatient care. Feedback on acceptability at insertion and 4 weeks after birth (and from midwives and doctors). Discomfort with insertion and in situ but satisfied with care, outpatients less isolated / emotionally alone.
PubMed	13	Efficacy and safety of oral misoprostol vs transvaginal balloon catheter for labor induction: An observational study within the SWEdish Postterm Induction Study (SWEPIS).	Alkmark M, Carlsson Y, Wendel SB, Elden H, Fadl H, Jonsson M, Ladfors L, Saltvedt S, Sengpiel V, Wessberg A, Wikström AK, Hagberg H, Wennerholm UB.	2021	Observation study based on RCT	Multicentre, Sweden	1213	Oral misoprostol v. Balloon - efficiency and safety. Not sufficient data for satisfaction with balloon, rather childbirth experience as whole	Evaluate if there are any differences regarding efficacy, safety, and women's childbirth experience between oral misoprostol and transvaginal balloon catheter. Results: experience positive overall and similar in both groups - assessed with Childbirth Experience Questionnaire (CEQ 2.0) and visual analog scale

Where found	#	Title	Authors	Year Pub.	Study Design	Where conducted	N	Focus	Key messages
Scopus	14	Pre-cervical ripening and hygroscopic cervical dilators in pre-labor induction	D'Indinosante, M., Vidiri, A., Giorgi, L., ...Scambia, G., Cavaliere, A.	2023	Retrospective observational study	Single centre, Italy	82	Satisfaction with osmotic dilators	None of patients reported discomfort during 24h where the dilators were in place. Secondary outcome: in absence of women's discomfort to propose outpatient pre-induction in low Bishop score pregnancies. No data to support to satisfaction. Missed chance (also to compare with balloons).
Scopus	15	Outpatient Compared with Inpatient Preinduction Cervical Ripening Using a Synthetic Osmotic Dilator: A Randomized Clinical Trial	Saad, A.F., Gavara, R., Senguttuvan, R.N., ...Wang, A.M., Saade, G.R.	2022	RCT	2 centres in USA	339	Outpatient / Inpatient preinduction using osmotic dilators	Use of osmotic dilators reduced hopsital stay without significant adverse outcomes, less likely to receive analgesics during ripening. Each patient completed satisfaction survey regarding sleep, rest, pain and activity. Outpatient more able to walk, eat and shower, felt was beneficial and a good idea.
CINAHL	16	Comparison of primiparous women's childbirth experience in labor induction with cervical ripening by balloon catheter or oral misoprostol – a prospective study using a validated childbirth experience questionnaire (CEQ) and visual analogue scale (VAS)	Place, Katariina	2022	Prospective study	Single-centre, Helsinki, Finland, tertiary centre, 8500 deliveries per year, induction rate 30%, cesarean rate 23%	362	Comparison balloon v oral misoprostol in primiparaous	Use of validated childbirth experience questionnaire (but inability to distinguish most neg and most pos experiences) and visual analogue scale (limited but its simplicity). Extra questions (non-validated) specifically on satisfaction with method of induction. Balloon more satisfied with method and would choose same method in a future pregnancy ($p<0.001$).
Google	17	The Comparison of cervical ripening double balloon and higroscopic dilator (DILAPAN–S®) in labor induction	Özgür KOÇAK, Neslihan YEREBASMAZ, Ethem Serdar YALVAÇ, Bülent YİRCİ, Sertaç ESİN, Ömer KANDEMİR	2020	Retrospective single-centre study	Tertiary center, Turkey	113	Comparison DBC and hygroscopic dilators for induction of labour	Patient comfort with Dilapan-S significantly higher, similar in terms of safety and efficiency. Only study to compare Dilapan with Cook. (Saad is with Foley). Question on pain during application and until removal. Stage 3 labour significantly shorter in hygroscopic dilator group
AWMF	18	Women's acceptance of a double-balloon device as an additional method for inducing labour	Sven Kehl, Grit Welzel, Anna Ehard, Sebastian Berlit, Saskia Spaich, Jörn Siemer, Marc Sütterlin	2013	RCT	Single centre, Germany	122	Satisfaction with balloon and oral misoprostol compared with oral misoprostol alone	Standardized questionaire to complete before discharge. Only 78 completed - high proportion of women with German not as their native language. Women not bothered by placement or presence of balloon and would recommend to others and use method in subsequent pregnancy.

Key	
	Excluded as not specific enough to answer PICO question
	Relevant to PICO question but still not specific enough
	Included in thesis as assessed as most relevant to answering PICO question

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Appendix I.c CASP Checklists used for the evaluation of the studies

The checklists are presented here in the order in which the studies were evaluated in the method chapter of this thesis.

Women's experience of induction of labor using PGE2 as an inpatient versus balloon catheter as an outpatient (Beckmann et al., 2020)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	"The objective was to compare women's healthcare experiences following IOL using a balloon catheter (Cook) and going home, versus prostaglandin (PG) and remaining an inpatient".
	Uncomplicated singleton pregnancies, cephalic presentation, ≥37 weeks, low risk indications. Balloon outpatient v. PG inpatient. Outcomes: primary – neonatal outcomes, secondary – healthcare experience (subject of this paper).

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ "Computer-generated random allocation list using block randomisation in a 1:1 allocation, stratified by participating centre", sealed sequentially numbered envelopes, randomised one day prior to IOL – allocation by telephone. No blinding to allocation for clinicians or participants.
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ All participants results included in analysis. See COSORT flow diagram in study

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ☐ No ■ ☐ Can't tell ☐ ☐ ■
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ Groups comparable, except that more women in the balloon group underwent an amniotomy.

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐ No ■ Can't tell ☐ 8 Australian maternity hospitals – cannot be sure all participants received same level of care as inpatients. Outpatients and inpatients by nature of the setting will have experienced 12 hours of different care, but that was part of the aim of the study to investigate these differences. Review after 12 hours in birth suite. Subsequent review (when?) amniotomy attempted and syntocinon infusion commenced as soon as possible. No clearly defined study protocol.

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ Written questionnaire following birth, prior to discharge – handed out by research midwife not involved in care (completion with help of interpreter if needed). Outcomes measured: 8-item modified Experience of Induction Tool (ExIT, 5 point Likert score) and 5 question validated assessment of health-state (EQ-5D-3L), and pain scores (10 point), VAS and responses presented as %. Chi-squared and Fisher exact tests for categorical outcomes and Student's t-test and Mann-Whitney U tests for data measured on a continuous scale. All questionnaires received included in analysis. Bias discussed in study: 80% provided responses and characteristics of responders and non-responders similar. And only low-risk pregnancies. Risk of confounding – is the more positive experience in outpatient group because of balloon or outpatient setting? No qualitative analysis on reasons included. P <0,05 significant and calculated.
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐ No ■ Can't tell ☐
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Likelihood of adverse clinical outcomes very low. Patients in outpatient setting were specifically told when to return to hospital. No cost-effectiveness analysis undertaken, but it can be assumed that outpatient care is cheaper than inpatient care.

Section D: Will the results help locally?	
10. Can the results be applied to your local population/in your context? *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Trial conducted over 8 hospitals (secondary to quarternary facilities) increasing generalisability of the results. Outpatient care will become more frequent with hospitals looking to reduce costs. Would have like to see qualitative responses to the questions and not just points of a scale.
11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions? *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ For low risk pregnancies where patients want to feel connected to the hospital but want more familiar and relaxed surroundings during cervix ripening, this is a great alternative. SDM – do you want to go home or do you feel more comfortable as inpatient? Must be given the option to stay even if more "expensive".

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Analysis of data accumulated during larger trial where primary outcome was a composite neonatal measure.

Published in European Journal of Obstetrics & Gynecology and Reproductive Biology, Impact Factor 2,6, peer reviewed.

Risk of confounding – is the more positive experience in outpatient group because of balloon or outpatient setting?
But chance for women to be more involved in decision making regarding IOL.

Study makes valid point that many studies fail to report of women's experience at all. Those that do are limited by inconsistent reporting, non-validated metrics, recall bias and confounding factors. "Future IOL researchers should be routinely measuring experiential alongside clinical outcomes and utilizing consistent metrics of patient experience to enable meaningful comparison of each method".

"Furthermore, the study methodology did not include any qualitative analysis of the reasons behind women's responses. Hence, there should be caution inferring that all women undergoing outpatient cervical priming using mechanical methods might have similar healthcare experiences".

Women's acceptance of a double-balloon device as an additional method for inducing labour (Kehl et al., 2013)

Section A: Is the basic study design valid for a randomised controlled trial?			

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■	No ☐	Can't tell ☐
			
			"The aim of this study was to investigate women's acceptance of and satisfaction with the induction of labour by administration of oral misoprostol (OM) and the combination of that with a double balloon device (Cook)".

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■	No ☐	Can't tell ☐ Study here just says "randomised" after enrolment into study group (OM + balloon) or control group (OM). Study was part of randomised CyCo trial - sealed envelopes with either 'study group' or 'control group' randomly chosen by the patient. "Neither the physicians in the labour ward nor the patient were aware of the envelope's content".
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■	No ☐	Can't tell ☐ 78 questionnaires from 122 analysed. Questionnaire to be completed before discharge.

Section B: Was the study methodologically sound?			
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ☐	No ■ ☐	Can't tell ☐ ☐ ■
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■	No ☐	Can't tell ☐ Baseline demographic and pregnancy characteristics similar (table 2) High percentage of immigrants (~40% in CyCo) – many questionnaires answered incompletely or not at all. These were excluded from analysis but results would have been interesting to see if experience differed when language an issue.

6.	**Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)?** *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐ No ☐ Can't tell ■ Both interventions in inpatient settings in same hospital so similar treatment of both groups would be expected.

Section C: What are the results?

7.	**Were the effects of intervention reported comprehensively?** *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ Power calculation made in CyCo trial. Birth experience was objectively evaluated using the German language version of Salmon's Item List (SIL-Ger). For statistical analysis, the chi-squared test, Fisher's exact test, the binomial test, the t-test, or the Mann–Whitney U-test for independent samples were used as appropriate. Not all questionnaires were returned or analysed. No evaluation of whether more exclusions in the study group or control group – potential for bias in results. P values used <0,05 significant
8.	**Was the precision of the estimate of the intervention or treatment effect reported?** *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐ No ■ Can't tell ☐
9.	**Do the benefits of the experimental intervention outweigh the harms and costs?** *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Only moderate side-effects reported by 2 (foreign body sensation, bladder dysfunction with balloon)

Section D: Will the results help locally?

10.	**Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Trial took place in Germany, Level 1 hospital (single centre trial). Hamburg also large city with high level of non-German speakers. Results can be generalised to a certain extent. Outcomes show balloons well accepted as method of induction. Would results have been different is tested against single Foley catheter? Limitations: limited no. of participants, may be underpowered for rare events. High % of immigrants – language issues. Some questions not fully understood or not completed – these were excluded, reducing the no. of questionnaires available for analysis.
11.	**Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Option to combine balloon with OM could increase options for people being induced, more SDM and satisfaction with care. No experience of combining balloon with OM in our hospital. Double costs? Or would costs be partially offset by potential shorter stay in hospital?

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Published in European Journal of Obstetrics & Gynecology and Reproductive Biology, Impact Factor 2,6 (2022), peer reviewed.

Study referenced in AWMF S2k Guideline "Induction of Labour" (DGGG, 2020) as positively regarded by pregnant persons.

An analysis of all parameters made more difficult as not all methods fully described (need to consider Kehl S, Ehard A, Berlit S, Spaich S, Sutterlin M, Siemer J. Combination of misoprostol and mechanical dilation for induction of labour: a randomized controlled trial. European Journal of Obstetrics Gynecology and Reproductive Biology 2011;159:315–9 where original CyCo trial is documented). Combination induction would need to be backed up by more evidence to recommend use.
This study is still important with regards to acceptance – "first study that has compared… focusing on women's degree of acceptance and satisfaction (2013)".

"The women were satisfied with the induction of labour using oral misoprostol and the combination of that with a double-balloon catheter. The double-balloon catheter was accepted by the women, and surprisingly was found to have a positive impact on the birth experience".

Patient satisfaction with the cervical ripening balloon as a method for induction of labour: a randomised controlled trial (Lim et al., 2018)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	"Prospective randomised controlled study to evaluate patient acceptance of the cervical ripening balloon (CRB) for IOL" – compared with prostaglandins.
	"Singleton term pregnancy, randomised to receive the CRB (Cook) or PGE on the day of IOL. Pain and satisfaction scores obtained by interviewing the women at IOL and after delivery. Main outcome measures were participant characteristics, labour and birth outcomes, pain score, satisfaction scores, and whether the participant would recommend the mode of IOL".

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ "Identical envelopes were prepared, each containing a folded paper; 75 envelopes had the words 'Cervical Ripening Balloon' and another 75 had the word 'Prostin'. The envelopes were shuffled and sealed. They were then labelled sequentially with an allocation number from 1 to 150. Recruited participants were allocated to the next random allocation number in sequence".
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ All accounted for – interviews conducted before discharge from hospital. Labour and birth outcomes obtained from medical case notes. Studied in assigned groups. Study not stopped early.

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ☐ No ■ ☐ Can't tell ☐ ☐ ■
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ See Table I, no significant differences

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐ No ■ Can't tell ☐ More CTG monitoring of PGE group during insertion and repeat doses. After 12 hours of CRB or PGE (2 doses) amniotomy and/or synotcinon infusion given as necessary. If amniotomy not possible, then patient left the study.

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ No power calculation. Outcomes measured: satisfaction, labour outcomes, birth outcomes. Well specified and presented. One participant (from 32) withdrew from CRB group as discomfort after 11 hours "too unbearable". Her results not included in the analysis – this could have affected the satisfaction results, but she did not complete induction as so was excluded. Confounding possible due to satisfaction being such a subjective measure (personal background, experience). Bias minimised as patients only recruited and uniformly counselled by a member of the study team, also randomised to reduce impact of preconceptions as to which method was better. P values, no OR/RR Tests used: Student's t-test, Pearson's chi-squared test
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐ No ■ Can't tell ☐
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ On average CRB was slightly cheaper as only one "dose" used, more doses of PGE meant more time on labour ward for monitoring. Both methods found to be safe and acceptable.

Section D: Will the results help locally?	
10. **Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Both PGE and CRB used in Germany. Singapore health system as developed as German. Results likely to be similar in Germany (see also Kehl et al. 2013, also quoted in Lim study) Satisfaction with care always an important outcome for our population. Limitations: small sample size, but similar to other studies. Single centre study. Need larger numbers at other locations to over more generalised results. Satisfaction subjective, not objectively measurable.
11. **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Authors state they found an unpublished study that showed that trainees with no previous experience could rapidly achieve competency when supported by lectures, simulation and supervision – cost effective. CRB in use already in our setting. Evidence showing that balloon can be better accepted than PGE provides pregnant people with a choice.

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Little info available about women's acceptance of balloons. Opportunity to tailor individual care.
Questionnaire completed with the women after delivery, scale of pain, satisfaction, recommend to others, free text field for qualitative responses.

Impact factor of Journal 2,7 (2022) - The *Singapore Medical Journal* (SMJ) is the monthly publication of the Singapore Medical Association. The Journal aims to advance medical practice and clinical research by publishing high-quality articles that add to the clinical knowledge of physicians in Singapore and worldwide. No mention of peer review in the study but the Journal says all studies are peer reviewed before publication.

Study value for thesis: Satisfaction with balloon, but no comparison with osmotic dilators.

Comparison of primiparous women's childbirth experience in labor induction with cervical ripening by balloon catheter or oral misoprostol - a prospective study using a validated childbirth experience questionnaire (CEQ) and visual analogue scale (VAS) (Place et al., 2022)

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes	X
Can't Tell	
No	

HINT: An question can be 'focused' In terms of
the population studied
the risk factors studied
is it clear whether the study tried to detect a beneficial or harmful effect
the outcomes considered

Comments: "Aim was to compare childbirth experience in primiparous women with cervical ripening by balloon catheter or oral misoprostol using the validated Childbirth Experience Questionnaire (CEQ)". Also to compare assessment of a negative childbirth experience by visual analogue scale (VAS) and CEQ.

2. Was the Cohort recruited in an acceptable way?

Yes	
Can't Tell	X
No	

HINT: Look for selection bias which might compromise the generalisability of the findings:
- Was the cohort representative of a defined population
- Was there something special about the cohort
- Was everybody included who should have been?

Comments: Analysis as separate cohorts according to BC or OM. Prospective study, cohorts similar in characteristics, 163 who underwent induction did not return questionnaire (which induction method?), more questionnaires received back from balloon inductions than misoprostol (ratio 2:1). Balloon inductions more advanced gestational age & higher Bishop score at induction start (p <0.001).

Is it worth continuing?

3. Was the exposure accurately measured to minimise bias?

Yes	
Can't Tell	X
No	

HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- were all the subjects classified into exposure groups using the same procedure

Comments: Possible recruitment bias: No randomization, not all women participated in the study and not all answered the questionnaire, preferences of treating obstetrician and patient determined method of ripening. Potential confounding if patients have informed themselves of options prior to induction and would have certain expectations of induction. No sample size calculations made as planned to run for 1 year.

4. Was the outcome accurately measured to minimise bias?

Yes	
Can't Tell	X
No	

HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- has a reliable system been established for detecting all the cases (for measuring disease occurrence)
- were the measurement methods similar in the different groups
- were the subjects and/or the outcome assessor blinded to exposure (does this matter))

Comments: Questionnaires (subjective measurement) available on admission to unit and to be returned within 1 month of childbirth by email or post. Possible recall bias. CEQ available in Finnish, Swedish and English – all validated. All women had understanding of one of these languages. Non - validated "Induction" section added to questionnaire. CEQ limited by inability to distinguish most neg and most pos experiences. VAS limited in its simplicity. 3-4-5-point Likert scale used depending on outcome to be measured. No mention of why so many questionnaires not returned or follow-up.

5. (a) Have the authors identified all important confounding factors?

Yes	X
Can't Tell	
No	

HINT:
- list the ones you think might be important, and ones the author missed

Comments: Balloon ripening often took place in outpatient setting, which may influence experience positively, as well as higher Bishop score at start of induction. Potential confounding if patients have informed themselves of options prior to induction, were actively involved in deciding which method and would have certain expectations of induction – "preferences of treating obstetrician and patient determined method".

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes	
Can't Tell	
No	X

HINT:
• look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments: "Multivariable analysis for possible confounding factors for negative experience not feasible due to sample size". Here reference is overall childbirth experience and not limited to induction.

6. (a) Was the follow up of subjects complete enough?

Yes	
Can't Tell	X
No	

HINT: Consider
the good or bad effects should have had long enough to reveal themselves
• the persons that are lost to follow-up may have different outcomes than those available for assessment
• in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort•

Comments: No reasons given as to why so many participants did not return the questionnaire. 2:1 ratio of BC to OM but no details given as to how many of those who did not return had which intervention, just that 163 did not return and 46 were induced using other methods after recruitment.

6. (b) Was the follow up of subjects long enough?

Yes	X
Can't Tell	
No	

HINT: Consider
• the good or bad effects should have had long enough to reveal themselves
• the persons that are lost to follow-up may have different outcomes than those available for assessment
• in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort

Comments: Follow up 1 month after birth. Time possibly too long with risk of recall bias and risk of assessment of birth in total and not specifically of induction.

Section B: What are the results?

7. What are the results of this study?

HINT: Consider
- what are the bottom line results
- have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference
- how strong is the association between exposure and outcome (RR)
- what is the absolute risk reduction (ARR)

Comments: Analysis using SPSS, Chi square test and Fisher's exact test, Mann-Whitney U-test. P value <0,05 significant, standard deviation and interquartile ranges provided. No OR/RR/ARR.
With regard to induction of labour (unvalidated bit of CEQ) women were more often satisfied with IOL with BC and would chose it again (p <0.001)
Large ceiling effect with questions on induction seen by authors as not useful in future assessments.

8. How precise are the results?

HINT: Look at the confidence intervals, if given

Comments: No confidence intervals given. Ranges given: Mean and Median, Interquartile and standard deviation. Ceiling effects seen as a problem in assessment of satisfaction.

9. Do you believe the results?

Yes	
Can't Tell	X
No	

HINT: Consider
- big effect is hard to ignore
- can it be due to bias, chance or confounding
- are the design and methods of this study sufficiently flawed to make the results unreliable
- Bradford Hills criteria (e.g. time sequence, dose-response gradient,
- biological plausibility, consistency)

Comments: Possible recall bias if completing after 1 month (or possibility to assess the experience thoroughly), outpatient balloon v. inpatient misoprostol, possible selection bias due to preferences of clinician and patient in choice of method.
Authors are however aware of limitations and open to criticism of chosen tools. Strengths: Large no of participants, single centre with uniform induction and management practices, meticulous data gathering in electronic patient databases.

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes	X
Can't Tell	
No	

HINT: Consider whether
- a cohort study was the appropriate method to answer this question
- the subjects covered in this study could be sufficiently different from your population to cause concern
- your local setting is likely to differ much from that of the study
- you can quantify the local benefits and harms

Comments: Study carried out in very large metropole (Helsinki, tertiary center, 8500 deliveries). Research in European setting, similar rates of induction, caesarean section.

11. Do the results of this study fit with other available evidence?

Yes	X
Can't Tell	
No	

Comments: See Kehl at el. 2013

12. What are the implications of this study for practice?

Yes	X
Can't Tell	
No	

HINT: Consider
- one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- for certain questions, observational studies provide the only evidence
- recommendations from observational studies are always stronger when supported by other evidence

Comments: Adds to options for women to choose mechanical method over pharmacological. Also to include evidence of satisfaction with methods when choosing the most suitable method of induction. Can support SDM.

Verdict on study:
362 participants good study size.
Assessment using validated questionnaire, even if questions on induction not validated.
Focus on satisfaction but main scope was comparison of methods to measure satisfaction CEQ/VAS.
Only small section concentrated on scores for induction of labour and these were based on non-validated questions. CEQ looks at whole childbirth experience as whole.
Research in European setting
Question of choosing same method again difficult to assess as didn't experience the other method.
Published in Acta Obstetricia et Gynecologica Scandinavica, peer reviewed
Impact Factor 4,3 (2023) https://obgyn.onlinelibrary.wiley.com/page/journal/16000412/journal-metrics

Double Foley catheter for labor induction: An alternative method (Obut et al., 2021)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	"To introduce a new handmade device, the double Foley catheter (DFC), and compare it with the Foley catheter (FC) and Cook cervical ripening balloon for its effectiveness in labor induction".
	222 patients with unfavourable cervixes scheduled for induction. Cook balloon / double Foley catheter / foley (single) catheter.
	Outcomes: Intrapartum, adverse maternal events and foetal outcomes, maternal pain and satisfaction scores

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ "Randomised sequence created by computer-generated randomised scheme with a 1:1:1 allocation". "Physicians who recruited participants blinded to random allocation sequence". "Medical caregiver collecting overall satisfaction questionnaires blinded to the allocation groups".
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ See Figure 3 flow diagram. Losses accounted for. Study not stopped early.

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ■ No ☐ ■ ☐ Can't tell ■ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ See Table 1 – "no significant differences between groups regarding baseline demographic characteristics, pregnancy complications or indication for labour pre-induction".

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ■ No ☐ Can't tell ☐ All catheters left in for 12 hours – no spontaneous expulsion. Oxytocin infusion started for patients not in labour after balloon expulsion.

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ Power calculation undertaken, actual no. of participants exceeded this calculation. Outcomes clearly specified in tables. Satisfaction measured after balloons in situ for 12 hours. Where balloons removed early at patient request or delayed removal, these results were not included in the outcomes. Overall satisfaction, pain scored on 0-10 VAS (during insertion and during entire ripening period). Data available for all 222 participants. Drop-outs/exclusions same in all groups but for different reasons. No standardised balloon volumes for labour – in this study all balloons inflated with 80ml – min. bias. Statistical tests: SPSS, x^2 test, paired t test, one-way analysis of variance checked with Levene's test and Bonferroni or Tamhane's T2 No OR / RR measured. P value <0,05.
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ☐ No ■ Can't tell ☐
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Interventions were all similar in procedure (all balloons) Satisfaction measured in all groups. No adverse effects attributed to the use of the balloons. Cost-effectiveness: Cook can be over 35 times more expensive than Foley. Example given (without evidence!) that in China the price for Cook exceeds the total delivery cost in public hospitals. Foley more readily available in health centres as also used for bladder catheterisation.

Section D: Will the results help locally?	
10. **Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ☐ No ☐ Can't tell ■ Study participants similar. Outcomes important but Foley catheters not frequently used in Germany – double balloons used Limitations: Cost more important for low income settings, opinion of high income not known Double not tested in patients with uterine scarring or intrauterine foetal death. Insufficient power to compare method of labour induction according to indication.
11. **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ☐ No ☐ Can't tell ■ Cook balloon already balloon of choice. Results support its continued use and not a concerted effort to change, unless cost is the main factor for a change. Adaptation and insertion of double Foley would not require substantial training.

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

One of very few studies which has maternal satisfaction as one of the primary outcomes to be measured.
Comparison of balloons and the lower satisfaction for Foley raises the question as to why Saad at al. (2019) compared Foley and Dilapan and not Cook and Dilapan.

Single study trial in Turkey at training and research hospital.
Published in International Journal of Gynecology & Obstetrics, Impact Factor (Clarivate) 3,8 (2023), peer reviewed according to author guidelines for the journal.

Results confirm the use of double balloons for cervix ripening – this is already current practice. The only reason to change to double Foley would be cost.

Cervical Ripening Efficacy of Synthetic Osmotic Cervical Dilator Compared With Oral Misoprostol at Term (Gavara et al., 2022)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	
	"To evaluate whether a synthetic osmotic cervical dilator is noninferior to oral misoprostol for cervical ripening".
	Pregnant women undergoing induction at 37 weeks gestation or more, Bishop score <6.
	Intervention: osmotic dilators or oral misoprostol.
	Comparator: Noninferiority of osmotic dilator
	Primary outcome: vag. Delivery within 36 hours.
	Secondary (among many) patient satisfaction

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ Prospective, open-label randomised trial, 2 medical centres in US. "Randomisation created independently using computer-generated sequence, concealed from staff responsible for recruiting and enrolling participants". Assigned 1:1 to groups with stratification. Not concealed from participants or healthcare professionals.
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ See Fig 1. Flow chart ITT and per Protocol analysis Study not stopped early

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes / No / Can't tell ☐ ■ ☐ ☐ ■ ☐ ■ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ No significant differences between 2 groups – see Table 1.

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ■ No ☐ Can't tell ☐ All study participants re-examined after 12 hours, oxytocin initiated and amniotomy performed as soon as clinically feasible. "Management of labour left to managing physicians discretion". However management during ripening was similar.

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ "On the basis of a noninferiority margin of 10%, an expected primary outcome frequency of 65% for misoprostol and 71% for mechanical methods, and 85% power, a sample size of 306 participants was needed." Outcome measures clearly specified. Satisfaction outcomes measured on survey of 7 questions with rating of 1 to 5 – results for all questions individually presented with all values and p value. Cochran-Armitage test for trend analysis of patient survey. Student test, Pearson's x^2 test and Mentel Hanzal test used as indicated. Delivery time presented using Kaplan-Meier curves. No OR but RR documented, use of ranges and SD. Likelihood of bias minimal as outcomes prespecified and not affected by subjective interpretation. P values reported
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ■ No ☐ Can't tell ☐ CI reported on all outcomes apart from satisfaction
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Both interventions had similar safety profiles, but uterine tachysystole was significantly higher in oral misoprostol group. No cost-effectiveness analysis made but in conclusion authors comment that osmotic dilators can be used safely in outpatient setting, therefore potentially reducing hospital costs.

Section D: Will the results help locally?	
10. **Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Similar study participants. Both methods of induction used in Germany. Outcomes important to be able to offer pregnant people options in induction of labour (mechanical or pharmacological). Limitations: 2 geographical locations (good for diverse study participants) but differences in managing labour and induction could have affected outcomes.
11. **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Provided evidence-based options to those being induced. Osmotic dilators used less, but balloons frequently – insertion not vastly different. Skills could be quickly acquired. Outpatient inductions attractive to over-stretched maternity unit

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Good study population size over 2 hospitals. Use of single cervical ripening method and RCT reduces risk of confounding in results. Specific questions on satisfaction welcomed (too few studies include this factor).
Together with other evidence of satisfaction with osmotic dilators (e.g. Saad et al., 2019) argument can be made to increase their use. Relatively simple implementation as dilators already in use for late abortions. No safety concerns in use of osmotic dilators.
Outpatient management interesting proposal for over-stretched maternity units.
Funded by Medicem (manufacturer of Dilapan-S). Possible conflict of interest as also involved in editorial input on final manuscript. Full disclosure apparently made but not included in study.
Results of study peer reviewed. Published in Green Journal, Obstetrics & Gynecology official publication of the American College of Obstetricians and Gynecologists (ACOG). Impact factor 2022 7,2, 6th highest impact factor out of all 82 obs & gyn journals https://journals.lww.com/greenjournal/Pages/AbouttheJournal.aspx
Study does not answer the PICO question in thesis, but does provide important satisfaction indicators with use of osmotic dilators.

Outpatient Compared With Inpatient Preinduction Cervical Ripening Using a Synthetic Osmotic Dilator (Saad et al., 2022)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	"To assess whether outpatient cervical ripening with a synthetic osmotic dilator shortens the length of hospital stay in term pregnancies undergoing labor induction".
	Population: induction at term with unfavourable cervix (<3cm dilated, <60% effaced)
	Intervention: Cervix ripening with Dilapan-S
	Comparator: Inpatient/Outpatient for 12 hours of ripening
	Outcome: Length of hospital stay, satisfaction survey also carried out and analysed

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ Open label randomised trial in 2 academic centres in USA. Exclusions where limited access to telephone, no support person or declined hotel placement if lived more than 60 mins from hospital (others see Box 1). Randomisation: computer generated random list of numbers assigning to groups, allocations in sealed envelope. Separate randomisation per site.
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ All analysis were on ITT See Fig 1 – flow diagram of eligible patients.

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ☐ No ■ ■ Can't tell ☐ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ Groups similar at start – see Table 1

6.	**Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)?** *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ■ No ☐ Can't tell ☐ Both groups to return 12 hours after insertion or sooner if needed. No other interventions were to occur during 12 hours unless clinically indicated. Reasons for early removal and management after 12 hours were identical in both groups. After first round of ripening, oxytocin and labour management left up to clinical health professionals. More foetal monitoring inpatient (based on standard of care at the hospital)

Section C: What are the results?

7.	**Were the effects of intervention reported comprehensively?** *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ☐ No ■ Can't tell ☐ Power calculation made, required sample size reached Wilcoxon rank-sum test, t test, Fisher exact test or x^2 test used as appropriate. Kaplan-Meier curves. Patient satisfaction questionnaire Cochrane-Armitage test for trend used. Graphs provided but no exact numbers – here not comprehensively reported. RR and CI used. Bias – caesarean rate would mean longer hospital stay. Payment in US system for no. of days care in hospital – may stay longer because paid for it rather than because need care.
8.	**Was the precision of the estimate of the intervention or treatment effect reported?** *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ■ No ☐ Can't tell ☐ CI reported for proportion of participants with stays longer than 48 hours and analgesics, not for satisfaction.
9.	**Do the benefits of the experimental intervention outweigh the harms and costs?** *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ No unintended effects reported. Low-level intervention in/outpatient when medical procedure otherwise the same. No cost-effectiveness undertaken, but outpatient care cheaper than inpatient.

Section D: Will the results help locally?	
10. Can the results be applied to your local population/in your context? *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Would have like to see a comparison between balloon in/out and Dilapan in/outpatient satisfaction but this was not part of study. Comparison of outpatient satisfaction between being in own home or hotel. Limitation: generalisability as included low-risk patients with stringent eligibility criteria. Evidence based on outpatient satisfaction limited as only 5 questions asked and only 2 of these were answered with significant differences (p<0.01)
11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions? *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Patients in the outpatient group were more able to walk, eat, and shower than those in the inpatient group. They felt that outpatient cervical ripening was beneficial and would choose the same approach for their subsequent pregnancy. Easy to introduce an outpatient management. Less resources needed than inpatient care. Enables more patient choice.

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Possible conflict of interest for Saad & Saade as have acted as expert consultants for the study sponsor (Medicem – manufacturer of Dilapan-S).

Results of study peer reviewed. Published in Green Journal, Obstetrics & Gynecology official publication of the American College of Obstetricians and Gynecologists (ACOG). Impact factor 2022 7,2, 6th highest impact factor out of all 82 obs & gyn journals https://journals.lww.com/greenjournal/Pages/AbouttheJournal.aspx

Focus on in/outpatient but data on satisfaction also recorded. Outpatient group less likely to receive analgesics during ripening – confounder though if at in outpatient setting with limited access to analgesics?

Satisfaction survey – only 2 of the 5 questions showed significantly (p <0,01) more outpatient satisfaction. But other questions indicate high satisfaction with Dilapan-S as method of cervix ripening independent of.

A randomized trial of synthetic osmotic cervical dilator for induction of labor vs dinoprostone vaginal insert (Gupta et al., 2022)

Section A: Is the basic study design valid for a randomised controlled trial?	

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■ No ☐ Can't tell ☐
	Aim to compare the efficacy, maternal and neonatal safety, and maternal satisfaction of a synthetic osmotic cervical dilator (Dilapan-S) with those of dinoprostone.
	≥37 weeks gestation (whatever reason), vertex presentation, intact membranes, intervention cervix ripening, comparing Dilapan-S and dinoprostone
	Outcomes: primary - failure to achieve vag. delivery, secondary – maternal, neonatal adverse events, satisfaction

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■ No ☐ Can't tell ☐ Randomly assigned using a telephone randomisation system as close as possible to start of IOL using a minimisation algorithm to ensure balance between the groups on variables and randomising hospital. Concealed until eligibility was confirmed and minimisation variables provided.
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■ No ☐ Can't tell ☐ See CONSORT diagram P4. No losses to follow-up, exclusions accounted for and listed as protocol deviation. All deviations/exclusions documented and not included in final results. ITT analysis regardless of protocol non-compliances. Recruitment had to be curtailed before original target of participants reached due to COVID-19 pandemic (research midwives redeployed to clinical work).

Section B: Was the study methodologically sound?	
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ■ No ■ ☐ ☐ Can't tell ☐ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■ No ☐ Can't tell ☐ Baseline characteristics well-balanced – see Table 1.

6. Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)? *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ☐ No ☐ Can't tell ■ 4 UK hospitals involved – local policy may have resulted in differences in care. If no spontaneous labour when Bishop Score ≥ 6 then amniotomy. Oxytocin infusion then commenced no sooner than 30 mins after removal of dinoprostone/Dilapan-S as per hospital protocols. Differences in no. of "series" of intervention.

Section C: What are the results?

7. Were the effects of intervention reported comprehensively? *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ Power calculation undertaken. Outcomes clearly specified and very detailed presentation of the results. %, mean (standard deviation) or median (interquartile range) presented, RR/Risk difference P values reported (but not for satisfaction) Difference in adherence levels between groups (more women in Dilapan-S group did not receive the allocated intervention but authors say sensitivity analysis suggest conclusions remain robust when excluding these women). No mention of bias or confounding in the study. Satisfaction: 23 detailed questions with scale 1-10. Possible bias (!) as some questions 10 was more negative response (pain) and sometimes 10 more positive (satisfaction) – confusion in answering questions? When were the questionnaires received? Not all participants completed the questionnaire.
8. Was the precision of the estimate of the intervention or treatment effect reported? *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ■ No ☐ Can't tell ☐ CIs reported
9. Do the benefits of the experimental intervention outweigh the harms and costs? *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Both methods of induction safe and approved. Interventions not really experimental but a comparison of existing methods. Participants were instructed to report excess bleeding, pain or concerns but not to remove the interventions themselves. No cost-effectiveness analysis

Section D: Will the results help locally?	
10. **Can the results be applied to your local population/in your context?** *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Study participants similar and interventions both used in Germany. Outcomes important for showing pregnant people options – SDM Need to know when the questionnaires were completed – how much time elapsed between intervention and questionnaires. Were non responses followed up in any way?
11. **Would the experimental intervention provide greater value to the people in your care than any of the existing interventions?** *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Additional choice for pregnant people being induced to labour. Staff already proficient in insertion of balloons and use of Dilapan-S in late abortions so training/skills development could be quickly achieved.

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

"This project was funded by Medicem Technology s.r. o., Czech Republic with an unrestricted research grant. Medicem did not have any influence on the day-to-day conduct of the trial and had no involvement in analysis, interpretation, or the decision to publish the SOLVE trial. The views expressed in this publication are those of the authors and not necessarily those of Medicem".

Published in AJOG MFM is one of two companion titles to the highly-respected American Journal of Obstetrics and Gynecology, and focuses on the latest research in the specialty of maternal-fetal medicine, or high-risk pregnancy. Peer reviewed. Impact factor 6,33 (2023).

"This trial provides the best-quality evidence to date in support of allowing Dilapan-S to be considered as another method for induction of labor". P2.

Questionnaire on maternal satisfaction: 23 comprehensive questions, but no information on when these were completed, bias for recall and also confusion in scoring. Still the only study found with such a big focus on satisfaction and not only a couple of questions.

The comparison of cervical ripening double balloon and higroscopic dilator (Dilapan–s®) in labor induction (Koçak et al., 2020)

Section A: Are the results of the study valid?

1. Did the study address a clearly focused issue?

Yes	X
Can't Tell	
No	

HINT: An question can be 'focused' In terms of
the population studied
the risk factors studied
is it clear whether the study tried to detect a beneficial or harmful effect
the outcomes considered

Comments: The aim of this study was to compare the cervical ripening double balloon and hygroscopic dilator in labor induction: obstetric outcomes (bishop score change, oxytocin requirement, vaginal delivery rate, delivery time, APGAR score) and patient comfort. Population: ≥37 weeks with induction indication Study started at same time as hospital initiated use of Dilapan as method of induction. Study aimed to add new information to the literature with a comparison of the methods.

2. Was the Cohort recruited in an acceptable way?

Yes	X
Can't Tell	
No	

HINT: Look for selection bias which might compromise the generalisability of the findings:
- Was the cohort representative of a defined population
- Was there something special about the cohort
- Was everybody included who should have been?

Comments: Retrospective single-centre study in a tertiary centre. No difference between groups in terms of age, BMI, gestational week or parity. Cohort was patients who underwent labour induction for whatever reason using either Dilapan or Cook balloon. However there is a large difference in the sizes of the groups.

Is it worth continuing?

3. Was the exposure accurately measured to minimise bias?

Yes	
Can't Tell	X
No	

HINT: Look for measurement or classification bias:
- did they use subjective or objective measurements
- do the measurements truly reflect what you want them to (have they been validated)
- were all the subjects classified into exposure groups using the same procedure

Comments: Cohort similar in terms of age, BMI, gestational week or parity - no selection bias
Subjective measurements for satisfaction, survey not subject to recall bias as carried out on completion of induction (?). But risk of confounding as to whether pain referred to method of induction or birth itself. No information on who inserted either method. Their experience could affect pain / satisfaction with method. 2:1 ratio Cook (n=72) v. Dilapan (n=41) with no explanation as to why the specific method was selected. Balloon and Dilapan left in for 12 hours

4. Was the outcome accurately measured to minimise bias?

Yes	
Can't Tell	X
No	

HINT: Look for measurement or classification bias:
• did they use subjective or objective measurements
• do the measurements truly reflect what you want them to (have they been validated)
• has a reliable system been established for detecting all the cases (for measuring disease occurrence)
• were the measurement methods similar in the different groups
• were the subjects and/or the outcome assessor blinded to exposure (does this matter))

Comments: See question 3, pain measurement for induction or birth. No blinding - retrospective study. Measurement methods same in both groups. Would have wanted to see how the pain question was framed and who presented the questions to the participants.
Assumption that all participants completed the survey but no evidence in the study to confirm or refute this assumption.

5. (a) Have the authors identified all important confounding factors?

Yes	
Can't Tell	
No	X

HINT:
• list the ones you think might be important, and ones the author missed

Comments: No confounding factors mentioned. Level of skill of clinician inserting balloon or Dilapan suspected to play large part in pain experience and also in obstetric outcome if not placed correctly. Did birth outcomes have an effect on the satisfaction with the method. Is pain the same as measuring satisfaction?

5. (b) Have they taken account of the confounding factors in the design and/or analysis?

Yes	
Can't Tell	
No	X

HINT:
• look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

Comments: No mention of confounding in study. See question 4 in respect to question of satisfaction.

6. (a) Was the follow up of subjects complete enough?

Yes	X
Can't Tell	
No	

HINT: Consider
the good or bad effects should have had long enough to reveal themselves
• the persons that are lost to follow-up may have different outcomes than those available for assessment
• in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort•

Comments: Satisfaction / pain with method of cervix ripening recorded on completion of induction and this was aim of the survey. Effects would have had long enough to reveal themselves. Assumption that all participants completed the survey but no evidence in the study to confirm or refute this assumption.

6. (b) Was the follow up of subjects long enough?

Yes	X
Can't Tell	
No	

HINT: Consider
• the good or bad effects should have had long enough to reveal themselves
• the persons that are lost to follow-up may have different outcomes than those available for assessment
• in an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort

Comments: See 6a. Retrospective study.

Section B: What are the results?

7. What are the results of this study?

HINT: Consider
- what are the bottom line results
- have they reported the rate or the proportion between the exposed/unexposed, the ratio/rate difference
- how strong is the association between exposure and outcome (RR)
- what is the absolute risk reduction (ARR)

Comments: Satisfaction scores significantly better for Dilapan. Methods are "equivalent and replaceable" - comparable effectiveness and safety characteristics. No mention of RR/OR/ARR in study, but use of p value for significance in duration of procedures and characteristics of study groups.

8. How precise are the results?

HINT: Look at the confidence intervals, if given

Comments:
No documentation on separate scores for insertion and "to the end" for both methods. Does the pain score include labour and birth? Risk of confounding. Significantly higher satisfaction scores $p<0.001$ for Dilapan.
Results given with an average score together with range and standard deviation. Stage 3 labour significantly shorter (slight, insignificant difference in oxytocin requirement in both groups) but no further details provided other than time. Overall balloon inductions quicker than Dilapan. Some % results not accurately reported - vaginal delivery rate 19/41 is 46,3% and not 50% as stated in the study. CI not given, p values given

9. Do you believe the results?

Yes	
Can't Tell	X
No	

HINT: Consider
- big effect is hard to ignore
- can it be due to bias, chance or confounding
- are the design and methods of this study sufficiently flawed to make the results unreliable
- Bradford Hills criteria (e.g. time sequence, dose-response gradient,
- biological plausibility, consistency)

Comments: Possible bias as Dilapan newly introduced to centre - desire for successful introduction? Retrospective analysis of data - outcomes were already there. Satisfaction scores given on completion of induction - reduces recall bias. No documentation on separate scores for insertion and "to the end". Does this include labour/birth? Risk of confounding. Significantly higher satisfaction scores p <0.001 for Dilapan.

Section C: Will the results help locally?

10. Can the results be applied to the local population?

Yes	X
Can't Tell	
No	

HINT: Consider whether
- a cohort study was the appropriate method to answer this question
- the subjects covered in this study could be sufficiently different from your population to cause concern
- your local setting is likely to differ much from that of the study
- you can quantify the local benefits and harms

Comments: Same products used in study as in local population in Germany (Cook and Dilapan). Questions of satisfaction can be answered using cohort study. Use of a scale to assess pain well established in Germany. No reports of harm caused by either balloon or Dilapan. Vaginal delivery or around 50% for both groups considered low. Turkey known to have high caesarean rate so this outcome is not unexpected.

11. Do the results of this study fit with other available evidence?

Yes	
Can't Tell	X
No	

Comments: Results on satisfaction concur with Saad et al., 2019 with regard to balloon v. Dilapan satisfaction / pain. But very few studies available which consider satisfaction at all, even fewer which compare balloon to Dilapan. Evidence is thin.

12. What are the implications of this study for practice?

Yes	
Can't Tell	X
No	

HINT: Consider
• one observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
• for certain questions, observational studies provide the only evidence
• recommendations from observational studies are always stronger when supported by other evidence

Comments: Satisfaction / pain hard to measure as subjective. An objective evaluation can only be made based on subjective findings. The only way to quantify / evaluate pain is to ask those who have been exposed to the intervention. Authors say that there is no other study comparing Dilapan with Cook balloon (Saad et al., 2019 Dilapan v. Foley) and that more research is needed. Study serves more as a point of discussion rather than a recommendation for clinical practice but does add new information to the literature. No harm to patients. Does a significantly shorter 3rd stage of labour be interpreted as being more satisfactory?

Verdict on study:

Relatively small number of participants, no power calculation.
Term "completion of induction" unclear – does this mean when participants were in active labour?
"after application to the end" also unclear definition.
Satisfaction survey (or description thereof in the study) not clearly defined, weakens the strength of the conclusion that Dilapan has a higher satisfaction level.
Study interesting as concurs with Saad et al. but generally studies comparing methods are hard to find.

Study published in Bozok Medical Journal by Yozgat Bozok University, Faculty of Medicine.
"Bozok Medical Journal is a national journal, based on peer-review consultation principles publishing clinic and basic science, original research articles, reviews, editor views and case reports in every field of medicine (https://dergipark.org.tr/en/pub/bozoktip/aim-and-scope)".
No impact factor found for the journal.
Level of evidence presented questionable, but in absence of other studies with a direct comparison included in the thesis for evaluation.

A randomized controlled trial of Dilapan-S vs Foley balloon for preinduction cervical ripening (DILAFOL trial) (Saad et al., 2019)

Section A: Is the basic study design valid for a randomised controlled trial?			

1. Did the study address a clearly focused research question?
CONSIDER:
• *Was the study designed to assess the outcomes of an intervention?*
• *Is the research question 'focused' in terms of:*
  • *Population studied*
  • *Intervention given*
  • *Comparator chosen*
  • *Outcomes measured?*
	Yes ■	No ☐	Can't tell ☐
			
			Objective to test the hypothesis that Dilapan-S is not inferior to the Foley balloon for preinduction cervical ripening at term ≥37 weeks scheduled for induction with unfavourable cervix ≤3 cm dilated ≤60% effaced), 12h Dilapan-S or Foley balloon inflated with 60ml saline. Primary outcome vaginal delivery, secondary (among many) patient satisfaction

2. Was the assignment of participants to interventions randomised? *CONSIDER:* • *How was randomisation carried out? Was the method appropriate?* • *Was randomisation sufficient to eliminate systematic bias?* • *Was the allocation sequence concealed from investigators and participants?*	Yes ■	No ☐	Can't tell ☐ (DS) or Foley balloon (FB), "randomization sequence was created independently using a computer-generated randomization and was concealed from those responsible for recruiting participants into the study by keeping it in a file cabinet with access restricted to research staff". Not concealed from participants.
3. Were all participants who entered the study accounted for at its conclusion? *CONSIDER:* • *Were losses to follow-up and exclusions after randomisation accounted for?* • *Were participants analysed in the study groups to which they were randomised (intention-to-treat analysis)?* • *Was the study stopped early? If so, what was the reason?*	Yes ■	No ☐	Can't tell ☐ See protocol analysis (flow chart) page 275. e3

Section B: Was the study methodologically sound?			
4. • **Were the participants 'blind' to intervention they were given?** • **Were the investigators 'blind' to the intervention they were giving to participants?** • **Were the people assessing/analysing outcome/s 'blinded'?**	Yes ☐ ☐ ■	No ■ ■ ☐	Can't tell ☐ ☐ ☐
5. Were the study groups similar at the start of the randomised controlled trial? *CONSIDER:* • *Were the baseline characteristics of each study group (e.g. age, sex, socio-economic group) clearly set out?* • *Were there any differences between the study groups that could affect the outcome/s?*	Yes ■	No ☐	Can't tell ☐ See Table 1 page 275 e.4

6.	**Apart from the experimental intervention, did each study group receive the same level of care (that is, were they treated equally)?** *CONSIDER:* • *Was there a clearly defined study protocol?* • *If any additional interventions were given (e.g. tests or treatments), were they similar between the study groups?* • *Were the follow-up intervals the same for each study group?*	Yes ■ No ☐ Can't tell ☐ "Pre- and post-placement procedures were identical" page 275e.2 Dilapan left for at least 12 hours, max 24, Foley for at least 12 hours. If after first round cervix still unfavourable, then second round of same method used. After that only pharmacological (dinoprostone gel or vaginal insert), misoprostol (tablet). If cervix ripe, but patient not in labour, oxytocin started for induction.

Section C: What are the results?

7.	**Were the effects of intervention reported comprehensively?** *CONSIDER:* • *Was a power calculation undertaken?* • *What outcomes were measured, and were they clearly specified?* • *How were the results expressed? For binary outcomes, were relative and absolute effects reported?* • *Were the results reported for each outcome in each study group at each follow-up interval?* • *Was there any missing or incomplete data?* • *Was there differential drop-out between the study groups that could affect the results?* • *Were potential sources of bias identified?* • *Which statistical tests were used?* • *Were p values reported?*	Yes ■ No ☐ Can't tell ☐ Sample size was based on a noninferiority margin of 10%, 90% power, and an estimated frequency of vaginal delivery of 71% in Foley balloon and 76% in Dilapan-S. Statistical tests: X^2 or Mann-Whitney rank sum Satisfaction - Cochran-Armitage test for trend method, 11 questions, scored on 5 point Likert scale, pain at placement and during ripening assessed on visual analog scale. No OR or RR documented, but use of ranges and mean values. Potential bias was failure to mask (minimised by pre-specified outcomes not subject to subjective interpretation, and independent management from the investigators). Higher drop out per protocol Dilapan group, data analysis still used based on ITT - possible effect on results for secondary outcomes (excl. satisfaction) p values reported for all outcomes.
8.	**Was the precision of the estimate of the intervention or treatment effect reported?** *CONSIDER:* • *Were confidence intervals (CIs) reported?*	Yes ■ No ☐ Can't tell ☐ CIs of 95% reported for primary outcome of route of delivery
9.	**Do the benefits of the experimental intervention outweigh the harms and costs?** *CONSIDER:* • *What was the size of the intervention or treatment effect?* • *Were harms or unintended effects reported for each study group?* • *Was a cost-effectiveness analysis undertaken? (Cost-effectiveness analysis allows a comparison to be made between different interventions used in the care of the same condition or problem.)*	Yes ■ No ☐ Can't tell ☐ Safety outcomes reported for both groups - no statistical difference found between the two groups. Satisfaction measured in survey and VAS for pain. No cost-effectiveness analysis made, but comment in the conclusion section that Dilapan-S may be slightly more expensive than Foley.

Section D: Will the results help locally?	
10. Can the results be applied to your local population/in your context? *CONSIDER:* • *Are the study participants similar to the people in your care?* • *Would any differences between your population and the study participants alter the outcomes reported in the study?* • *Are the outcomes important to your population?* • *Are there any outcomes you would have wanted information on that have not been studied or reported?* • *Are there any limitations of the study that would affect your decision?*	Yes ■ No ☐ Can't tell ☐ Similar study participants. Balloons more often used in practice, Dilapan-S currently used more frequently in late abortions. Limitation of single centre study, but large sample size and prespecified outcomes. Generalisation questionable as no variability in management. After the first round of the method (DS or FB) it would have been interesting to use the other method if the cervix was still unfavourable and then question the participants on their satisfaction. This would enable to a direct comparison of both methods in this regard. Primary outcome of route of delivery would have been impossible to analyse though. Satisfaction with care always an important outcome for our population.
11. Would the experimental intervention provide greater value to the people in your care than any of the existing interventions? *CONSIDER:* • *What resources are needed to introduce this intervention taking into account time, finances, and skills development or training needs?* • *Are you able to disinvest resources in one or more existing interventions in order to be able to re-invest in the new intervention?*	Yes ■ No ☐ Can't tell ☐ Dilapan-S is in use, just not at term (see above). Insertion of both methods are similar so little additional training would be required. Dilapan-S is cheaper than the Cook balloons in use in local setting and evidence for non-inferiority with Foley is possibly transferable to Cook?

APPRAISAL SUMMARY: *Record key points from your critical appraisal in this box. What is your conclusion about the paper? Would you use it to change your practice or to recommend changes to care/interventions used by your organisation? Could you judiciously implement this intervention without delay?*

Survey and analogue scales in English and Spanish (hospital in Texas, USA) - language barrier removed for many participants. Assumption has to be that those who evaluated the survey also understood both languages.

Dr. Saad is on Dilapan website with a video explaining to peers how the dilators work and presenting his research. His study was funded by Medicem (manufacturer of Dilapan-S) and there is therefore a high risk of conflict of interest. The study however appears to be robust in spite of this and states that Medicem had no role in the trial, analysis or drafting and that an independent third party performed all statistical analyses. The authors report no conflict of interest. There are also very little other studies available which compare the two methods or include satisfaction as one of the outcomes of the research so this is the major strength of the study.

Study included in AWMF guideline (S2K) in Germany as evidence that osmotic dilators are safe and approved and can be used for cervix ripening (also after caesarean section).

Question on design study: why compare Dilapan and Foley and not (also) with Cook?

Study could be used to raise awareness of an alternative to balloons, no safety concerns, potentially cheaper alternative. The research also calls for more clinical studies to evaluate outpatient management of cervix ripening. This would also reduce healthcare costs if shown to be a safe alternative to inpatient care. Giving patients an evidence based choice and through SDM processes would increase satisfaction.

Study published in American Journal of Obstetrics & Gynecology - "The Gray Journal", covers the full spectrum of Obstetrics and Gynecology. The aim of the Journal is to publish original research (clinical and translational), reviews, opinions, video clips, podcasts and interviews that will have an impact on the understanding of health and disease and that has the potential to change the practice of women's health care. Impact factor 9,8 rank #2 in Obstetrics and Gynecology journals.

II Declaration of Originality / Eidesstattliche Erklärung

Hiermit versichere ich, Charlotte Maguire, geboren am 03.08.1977 in West Runton, (Großbritannien), dass ich die vorliegende Bachelorarbeit mit dem Titel:

> "A comparison of maternal satisfaction with the use of osmotic dilators as opposed to balloons as a method of induction of labour: A literature review."

selbstständig und ohne fremde Hilfe, insbesondere ohne entgeltliche Hilfe von Vermittlungs- und Beratungsdiensten sowie ohne die Anwendung von KI-Sprachmodellen wie z.B. Chat-GPT, angefertigt und keine anderen als die von mir angegebenen Quellen und Hilfsmittel benutzt habe. Alle wörtlichen oder sinngemäßen Entlehnungen aus anderen Arbeiten sind an den betreffenden Stellen als solche kenntlich gemacht und im entsprechenden Verzeichnis aufgeführt, das gilt insbesondere auch für alle Informationen aus Internetquellen. Ich erkläre zudem, dass ich die an der Medizinischen Fakultät Hamburg geltende „Satzung zur Sicherung guter wissenschaftlicher Praxis und zur Vermeidung wissenschaftlichen Fehlverhaltens an der Universität Hamburg" in der jeweils gültigen Fassung eingehalten habe.

Des Weiteren versichere ich, dass ich die vorliegende Bachelorarbeit vorher nicht in dieser oder ähnlicher Form in einem anderen Prüfungsverfahren dieser oder einer anderen Fakultät bzw. Hochschule eingereicht habe.

Ich erkläre mich einverstanden, dass meine Bachelorarbeit zum Zweck der Plagiatsprüfung gespeichert und von meiner/-m Erst- und Zweitprüfenden mit einer gängigen Software zur Erkennung von Plagiaten überprüft werden kann.

Ich erkläre mich einverstanden, dass oben genannte Bachelorarbeit oder Teile davon von der Medizinischen Fakultät der Universität Hamburg oder von der HAW Hamburg veröffentlicht werden.

Hamburg, 20.11.2023