Digital versus speculum-based balloon catheter insertion for labor induction: a systematic review and meta-analysis

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OBJECTIVES: Induction of labor is commonly undertaken when ongoing pregnancy poses a risk to either the mother or fetus. Often cervical preparation is required with mechanical methods increasingly popular due to their improved safety. This study evaluates the efficacy, safety, and acceptability of digital versus speculum-based balloon insertion for cervical preparation, aiming to identify gaps and inform future research.

DATA SOURCE: PubMed, Ovid MEDLINE, EMBASE, and Scopus were searched from database inception until 30 June 2023.

STUDY ELIGIBILITY CRITERIA: Included studies were randomized controlled trials comparing digital versus speculum-based insertion of catheter-related balloons for labor induction in individuals with viable singleton pregnancies, in both inpatient and outpatient settings, written in English. Exclusions included studies not using cervical balloons, comparisons to nonballoon methods, nonhuman studies, and nonprimary literature like guidelines, reviews, commentaries, and opinion pieces.

METHODS: Title and abstract screening were performed by 4 authors. Full-text articles were assessed against inclusion criteria. Selection was agreed upon by consensus among 3 authors, with a fourth consulted for disputes. The risk of bias was assessed using the Cochrane Risk of Bias Tool 2.0 for randomized trials. A meta-analysis was also performed.

RESULTS: Out of 3397 studies, 4 met the inclusion criteria, all being randomized controlled trials with some concerns in at least one domain but no high risk of bias. Two studies found digital insertion significantly less painful than speculum-based insertion ($P<.001$), while one reported no difference ($P=.72$). Maternal satisfaction was comparable, with one study favoring digital insertion ($P=.011$). Meta-analysis findings for other outcome measures suggest no difference between speculum or digital insertion. However, due to substantial heterogeneity, findings for procedural time, time from induction to delivery, and epidural rate should be cautiously interpreted.

CONCLUSIONS: Digital insertion for cervical preparation appears associated with reduced pain and higher patient acceptability compared to speculum-based insertion. Additionally, efficacy and safety were comparable, indicating it is a preferable option for clinical use. There was no difference in other procedural, obstetric, or neonatal outcomes, however, more rigorous research employing standardized outcome measures is needed to facilitate a clinically meaningful interpretation.

Key words: cervical ripening, maternal satisfaction, obstetrics, pain assessment, patient preferences, procedural safety, procedural time

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AJOG MFM at a Glance

Why was this study conducted?

To assess the efficacy, safety, and acceptability of digital versus speculum-based balloon catheter insertion methods for cervical preparation in labor induction.

Key findings

Digital insertion is less painful, offers faster procedural times, and has higher patient acceptability compared to speculum-based insertion, with no significant differences in obstetric or neonatal outcomes.

What does this study add to what is already known?

Provides evidence that digital insertion could be a preferable option for clinical practice, offering benefits in patient comfort and procedure efficiency without compromising safety or effectiveness.

Introduction

Induction of labor (IOL) is commonly undertaken when ongoing pregnancy poses a risk to the mother, fetus, or both;[1] such as pregnancies with maternal hypertensive complications, pregnancies that progress beyond 41 weeks' gestation, or where concerns about fetal wellbeing exist. An average of 30% of pregnant patients undergo IOL in developed countries and the incidence is increasing worldwide.[2-4] Over the past decade alone, there has been a dramatic increase in IOL rates in both Australia (from 26% in 2010 to 44% in 2021 among first-time mothers) and the UK (almost 30% in 2016-17).[5-8] Whilst developing countries typically have lower IOL rates (9% in Ethiopia),[9] Sri Lanka, is similar to high-income countries (~35.5%).[10]

When an IOL is indicated but the patient's cervix is not favorable, cervical preparation is recommended prior to stimulating uterine contractions, commonly using either pharmacological (oxytocin or prostaglandin administration) or mechanical approaches, such as the insertion of single or double balloon catheters.[11] Balloons work by stimulating endogenous secretion of prostaglandins and oxytocin and directly dilating the cervical canal. Recent studies indicate, while balloon catheters and pharmacological methods, such as vaginal prostaglandins, achieve similar vaginal birth rates, balloon catheters are associated with fewer adverse perinatal events.[12,13] Importantly, an increase in maternal and perinatal safety when using the cervical balloon is driving its adoption in contemporary clinical practice as the preferred method for cervical preparation with IOL.[1,14] With the increasing adoption of the cervical balloon, it is important to identify any areas within the procedure that could be optimized to enhance the outcomes and experiences of pregnant patients and their care providers.

When inserting a cervical balloon prior to IOL, the clinician guides a balloon catheter into a patient's uterus through the cervical canal. This process can be undertaken either by employing a speculum to help directly visualize the cervix and then use forceps to advance the catheter (speculum insertion (SPI)), or as part of a vaginal examination where the catheter is manually guided along the fingers and into the cervix (digital insertion (DI)). However, to date, no systematic review has synthesized the literature comparing the efficacy, safety, and preferences of patients for speculum or digital insertion techniques.

Objectives

The purpose of this systematic review is therefore to understand the current evidence of these 2 approaches to cervical preparation in relation to efficacy, safety, and acceptability and identify any knowledge gaps to inform future research priorities.

Materials and methods

The following review was conducted in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 guidelines.[15] The study protocol and review were registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42022335338).

Study selection

The search was undertaken by RRW in 4 databases, PubMed, Ovid Medline, EMBASE, and Scopus. The included studies compared digital insertion with speculum-based insertion of balloon catheters in patients with viable singleton pregnancies undergoing IOL in either inpatient or outpatient settings. Papers were excluded based on specific criteria, such as those not utilizing a cervical balloon for induction, comparisons to nonballoon induction methods, nonhuman studies, and nonprimary literature including guidelines, reviews, commentaries, and opinion pieces.

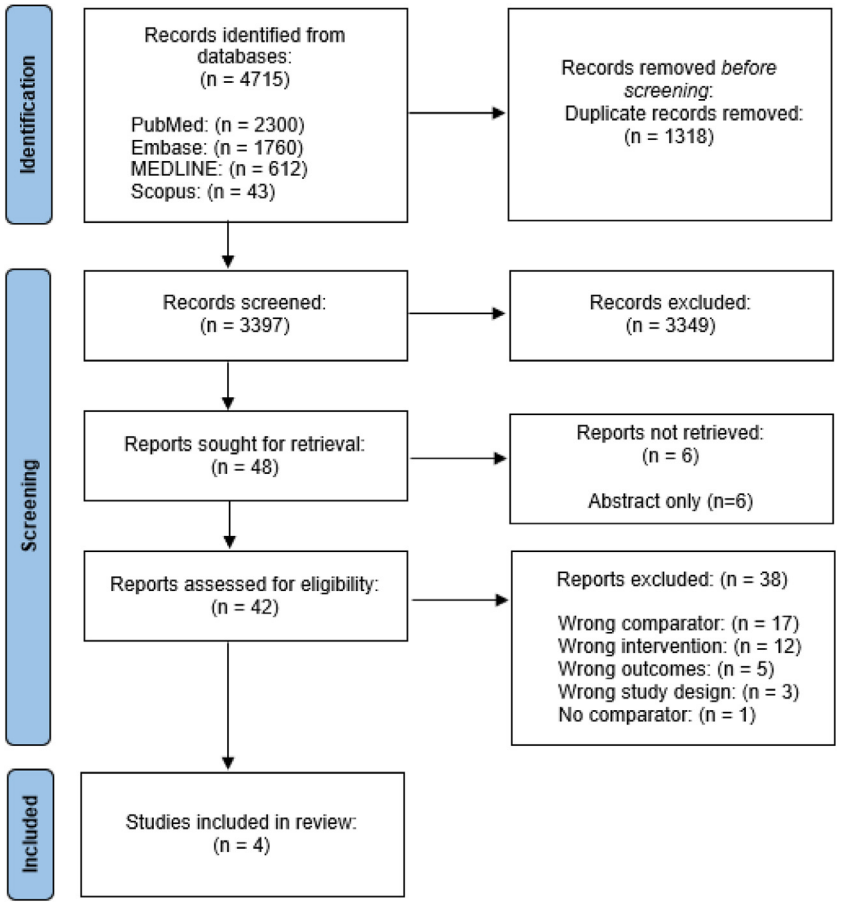
Articles were restricted to those in English and published anytime up to the end of June 2023. Title and abstract screening for each article was performed by 2 teams: KWS and MH; and MPP and RRW. Following screening, the full-text articles were assessed against the inclusion criteria. The reference lists of selected articles were also manually screened for suitable additional articles. The selection of articles was agreed upon by consensus between the screening authors (KWS, MH, and MPP) with a further author (DS) consulted in the event of disputes.

The outcomes of interest for this review are to compare the differences in efficacy (procedural time and procedural success rates), safety (obstetric and neonatal outcomes), and consumer preference (pain and maternal satisfaction rates) between both methods.

Search strategy

The following search criteria were utilized for this review: (foley* OR catheter OR balloon OR Cook OR Atad OR (single balloon) OR (double balloon)) AND (cervi* ripen* OR mechanical ripen* OR induction OR induce* OR cervi* priming OR bishop* score) AND (insertion OR digital OR speculum). Studies were then filtered manually as per the inclusion and exclusion criteria.

FIGURE 1
PRISMA flowchart for the systematic review. PRISMA, preferred reporting items for systematic reviews and meta-analyses.



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Data items

Data were extracted manually for analysis by KWS, MPP, MH, VS, and DS. Data extracted included:

1) Study characteristics, such as year, country, study design, study dates, study settings, interventions, comparators, number of participants
2) Participant demographics, such as age, BMI, relevant obstetric history
3) Features of the cervical balloon insertion process, including rates of insertion success, patient experience in terms of pain and discomfort, and clinician experience in terms of ease and duration of procedure

The findings of the studies were presented in tabular format.

Bias assessment

Two authors (KWS and MH) independently assessed each study for bias using the Cochrane Risk of Bias Tool 2.0 (ROB2) for randomized-controlled trials. Disagreements were resolved by consultation with a third author (RRW). ROB2 was selected as it is the preferred tool for assessing randomized-controlled trials—the design of all the included studies in this review.

Statistical analysis

For many outcomes, a meta-analysis was not feasible due to heterogeneity in outcomes and the low number of studies identified. The following outcomes were reported in 2 or more studies: time to place, induction to delivery, insertion to expulsion, procedure failure, epidural, maternal fever, umbilical arterial blood gas pH, hospital stay, and NICU admission. For the outcomes time to place, induction to delivery, insertion to expulsion, and hospital stay data were reported as mean and standard deviation (SD), median and interquartile range (IQR), or median, min, and max. Before undertaking the meta-analysis, means and standard deviations were estimated from medians, IQRs, and minimum and maximum values using the Wan et al, 2014 adapted equations.[16] Standardized differences in means, proportions, and standard errors were then calculated. Meta-analysis was then performed using a random effects model with study heterogeneity determined by assessing the I2 statistic with a value above 75% deemed high heterogeneity and guiding caution in interpretation. Funnel plots were also constructed to visualize publication bias. All analyses were undertaken using STATACorp 17.

Results

For this review, out of 3397 studies screened, a total of 4 studies were found to be suitable for inclusion.[17-20] This is reflected in the PRISMA diagram in Figure 1. On the risk of bias assessment (Figures 2 and 3), none of the studies demonstrated a domain or overall judgment of 'High Risk', though all 4 studies did have 'Some Concerns' for at least one domain. This was primarily due to the nature of the interventions as blinding the patient was not possible and could thus influence self-reported outcomes like pain and maternal satisfaction.

Tables 1 and 2 present the included studies, their characteristics and outcomes, and the findings of significance. All studies included were randomized controlled trials.

Pain experienced

Three studies reported pain experienced by pregnant individuals undergoing either digital or speculum insertion.[17,18,20] Two studies (Jonsson et al. (P=.03) and Shqara et al. (P<.001)) found that digital insertion was significantly less painful than speculum insertion, while Chia et al. reported no

FIGURE 2
Traffic light plot of bias assessment results using ROB2. Risk of bias assessment across 4 studies, illustrating comparative bias domains ROB 2: Risk of Bias 2.

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significant difference in pain between the 2 insertion techniques (P=.72).

Procedural times

Three studies in this review investigated procedural times. Jonsson et al. recorded cervical balloon insertion time, with significantly longer times for SPI compared to DI (P<.05).[17] Similarly, Shqara et al. used a stopwatch to measure insertion duration, revealing a statistically significant reduction (P<.001) in time with DI compared to SPI.[20] Chia et al. assessed the first attempt insertion duration, finding no significant differences between groups (P=.12).[18]

Procedural success

Two studies in this review investigated procedural success.[18,19] Kuhlmann et al. focused on the need for a secondary cervical balloon, while Chia et al. measured success via failure rates, defined as an insertion not achieved within 6 minutes, participant's request to stop, or investigator abandonment before the allocated time.

Kuhlmann et al. found no statistically significant differences in procedural success between DI and SPI but noted a higher need for a second round of mechanical dilation in the SPI group, with the relative risk ratio suggesting that DI may be a "protective factor" compared to SPI (RR: 0.19; 95% CI: 0.04-0.89).[19]

Chia et al. measured procedural success through the failure rate and

FIGURE 3
Summary of bias assessment results using ROB2. Summary of the risk of bias assessment based on a study's ability to fulfill a particular ROB2 domain.

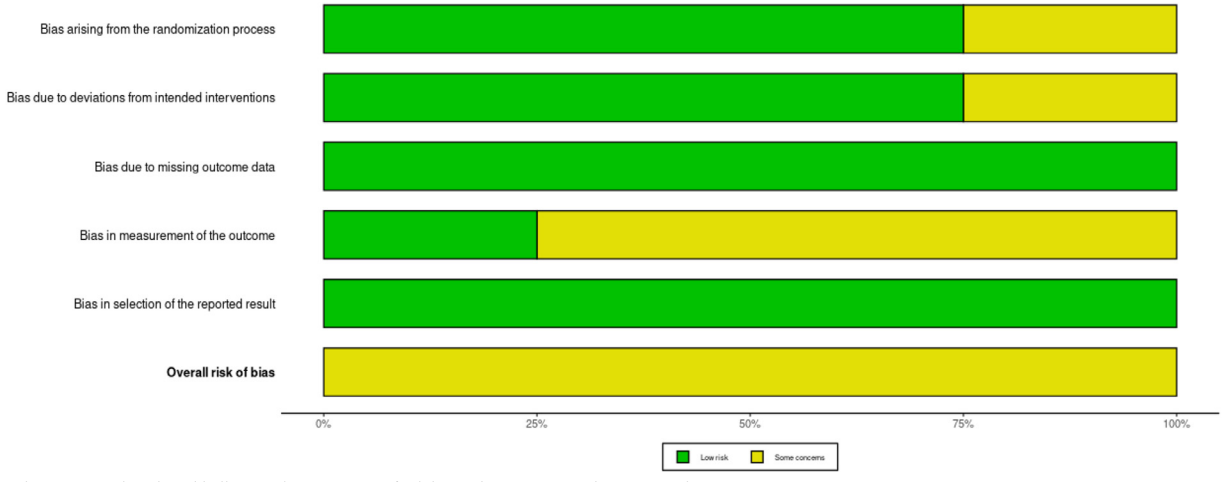

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TABLE 1
Descriptive summary of studies comparing speculum and digital insertion of catheter-related balloon.

Study/year	Sample size	Country/setting	Maternal age (years)		Gestational age (weeks)		Body Mass Index (BMI)		Gravidity (G), nulliparous (NP), parity (P)		Preinduction Bishop Score***		Catheter details
			SPI	DI	SPI	DI	SPI	DI	SPI	DI	SPI	DI	
Jonsson et al. (2011)	42	Sweden/Inpatient	32±4*	32±5*	39±2*	39±2*	25.5±4.6*	24.8±4.9*	NP: 11 (52) **	NP: 14 (67) **	4 (4–5)	4 (4–5)	18Fr Foley Latex catheters inflated with 50 mL saline
Chia et al. (2020)	86	Malaysia/Inpatient	29.3±4.3*	29.1±3.8*	38.4±1.1*	38.8±1.3*	29.8±6.1*	30.0±6.4*	–	–	2 (1.25–4) ***	3 (2–4) ***	16Fr Foley Latex catheters inflated with 60 mL sterile water
Kuhlmann et al. (2021)	372	USA/Inpatient	26.50± 5.45*	26.64±6.19*	39 (38–39) ***	39 (38–39) ***	29.2±6.53*	29.6±6.85*	G: 2 (1–4) *** P: 77 (41) **	G: 2 (1–3) *** P: 85 (46) **	3 (2–4) ***	3 (2–4) ***	16Fr Foley catheters inflated with 60 mL saline
Shqara et al. (2023)	100	Israel/Inpatient	30.98± 5.9*	31.0±5.7*	39.3 (37.3–41.3) ***	40.1 (37.0–41.7) ***	30.9±5.9*	32.5±5.9*	G: 3.0 (2–8) ***	G: 3.0 (2–10) ***	2.06±1.2*	2.04±1.3*	18Fr silicone-coated latex Foley catheters inflated with 60 mL sterile water

All patients across studies were considered statistically similar for demographic factors.
Data are presented as mean (standard deviation)*, number (percentage)**, or median (IQR)***.
SPI: Speculum Based Insertion, DI: Digital Insertion, IQR: Interquartile Range.
Seo. Digital versus speculum-based balloon catheter insertion for labor induction. Am J Obstet Gynecol MFM 2024.

reported no significant difference between DI and SPI (*P*=.24).[18] An arbitrary insertion duration of 10 minutes was assigned for penalizing failures, and the insertion attempt was abandoned after 6 minutes unless imminent success was anticipated.

Obstetric and neonatal outcomes

All studies (n=4) demonstrated no difference in obstetric or neonatal outcomes when comparing DI to SPI for any measure employed.[17-20]

Maternal satisfaction

All 4 studies assessed maternal satisfaction with the induction procedure and birth.[17-20] Three of which found maternal satisfaction rates to be comparable for DI and SPI.[17-19] Shqara et al., however, demonstrated superiority in maternal satisfaction rates for DI compared to SPI (*P*=.011).[20] Although nonsignificant, 90% of the DI group in Shqara et al. expressed a willingness to recommend DI to a friend or relative, compared to 80% in the SPI group (*P*=.261).[20] This 10% difference may be considered clinically meaningful despite statistically not being significant. Kuhlmann et al. also found a significantly higher proportion of patients from the SPI group would prefer DI over SPI should they have a subsequent pregnancy (37.6%, *P*=.02).[19]

Meta-analysis results

Table 3 presents the overall effect sizes for outcome measures: time to place, induction to delivery, insertion to expulsion, procedure failure, epidural, maternal fever, umbilical arterial blood gas pH, hospital stay, and NICU admission. The forest and funnel plots can be found in the supplementary materials. Overall, meta-analysis findings suggest no difference between speculum or digital balloon insertion on the outcomes assessed. It is important to note however, that due to the substantial heterogeneity, evidenced by the I2 scores >75%, findings for time to place, induction to delivery, and epidural rate should be interpreted with caution.

TABLE 2
Findings of studies comparing speculum and digital insertion of catheter-related balloons for cervical preparation.

Study, year	Outcomes/measures	Overall findings
Johnson et al. (2011)	Procedure time *(catheter insertion time-clinician dependent)*	• It took significantly longer to insert the catheter with SPI (3 min; 2.5−5 min***) compared to DI (2 min; 1.5 −3 min***), *P*<.05
	Pain *(Skin conductance, VAS-patient reported)*	• *During catheter placement:* Statistically significant difference reported between groups, with the SPI group having higher median VAS scores than the DI group, 5 vs. 3 (*P*=.03), and greater median skin conductance (AUC) measurements, 1840 vs. 823 μSv (*P*=.04) • *During cervical ripening:* No statistically significant difference between groups for skin conductance or VAS (*P*=.43 for both)
	Maternal satisfaction *(Questionnaire-patient reported)*	• Maternal satisfaction was comparable in DI and SPI
	Clinical outcome *(Maternal factors include length of labor, epidural analgesia rate, total time on oxytocin, temperature in labor, while fetal factors include birth weight, Apgar scores, umbilical arterial blood gases, base deficit, and admission to NICU)*	• The study found no statistically significant difference in clinical outcomes between the groups, considering both maternal and fetal factors • Length of hospital stay in days showed no statistically significant variation between the two groups
Chia et al. (2020)	Procedural time *(Duration between insertion into vagina of speculum or finger to removal measured with a digital stopwatch)*	• Comparing DI and SPI insertion, there were no statistically significant differences in procedural time: DI 2.72± 1.85 min* vs. SPI 2.25±0.55 min*, *P*=.12
	Failure rate *(Defined as an inability to achieve insertion within 6 min, a participant's request to stop, or investigator abandonment before the allocated time)*	• No statistically significant difference found between the two groups; 2/42 (5%)** cases for DI and 0/44 (0%)** cases for SPI, *P*=.24
	Pain *(VNRS-patient reported)*	• Pain rating: 3.5 (2−5)*** vs. 3(2−5)*** *P*=.72 for DI vs. SPI insertion respectively were not significantly different statistically
	Maternal satisfaction *(VNRS-patient-reported)*	• Women's satisfaction with their care from induction to birth, as measured by VNRS score, was similar between DI and SPI insertions; DI: 7 (6−8)*** vs. SI: 7 (7−8***), *P*=.97
	Clinical outcome *(Maternal factors include type of delivery, indications for different types of delivery, epidural analgesia rate, total time on oxytocin and postpartum outcomes (delivery blood loss, postpartum hemorrhage, length of hospital stay, and fever), while fetal factors include birth weight, Apgar scores, umbilical arterial blood gases, umbilical blood base excess and indications for neonatal admissions)*	• Labor, birth, and neonatal outcomes were not significantly different between groups
Kuhlmann et al. (2021)	Procedural success *(Need for secondary balloon placement)*	• SPI group had more frequent need for a second round of mechanical dilation DI: 2 (1)** vs. SPI: 10 (5)**; RR: 0.19, 95% CI: 0.04−0.89

(continued)

TABLE 2
Findings of studies comparing speculum and digital insertion of catheter-related balloons for cervical preparation.
(continued)

Study, year	Outcomes/measures	Overall findings
	Maternal satisfaction *(Questionnaire-patient reported)*	• Women had equal satisfaction with the explanation of both the methods of placements • More women would choose DI if optional; 37.6** vs. 25.7**; *P*<.02
	Clinical outcomes *(Maternal infection [fever, chorioamnionitis, endometritis], request for IV analgesia or epidural, vaginal bleeding, membrane rupture, neonatal infection, delivery modality)*	• Maternal infection rate was not different between the interventions (RR: 1.21, 95% CI: 0.37−3.91). Other outcomes did not differ between groups
Shqara et al. (2023)	Pain *(Visual analog scale [VAS]-patient-reported)* *VAS-1=scores at speculum or digital insertion* *VAS-2=Scores halfway through balloon filling* *VAS-3=Scores after speculum or digit removal*	• The median VAS 1−3 scores were lower in the DI group than in the SPI group; 2.67 (0−5.67)*** vs. 4.16 (1.33−8.33)***; *P*<.001 • Pain rating: 4 (0−10)***; vs. 7 (0−10)***; *P*<0.001 indicating statistically significant reduction in pain with DI vs. SPI insertion
	Maternal satisfaction *(Questionnaire-patient reported)*	• The maternal satisfaction score was greater for the DI vs. SPI, 5 (3−5)***; vs. 4(1−5)***; *P*=.011 • 90% would recommend their intervention to family member/friend for DI vs. 80% in SPI (*P*=.261)
	Procedural time *(Insertion duration recorded when the operator's fingers or speculum entered the vagina and ended at the removal of the fingers or the speculum)*	• Statistically significant reduction in time taken with DI in contrast to SPI: 2.1 (1.4−5.3 min)*** vs. 3.0 (1.4−5.0) ***; *P*<.001
	Clinical outcomes *(Maternal outcomes include intrapartum fever, delivery method, altered presentation [vertex to breech], need for other cervical ripening method, while fetal outcomes include Apgar score and birthweight)*	• No change in obstetric or neonatal outcomes • Cervical ripening, delivery mode, time to delivery, infections, and neonatal outcomes did not differ significantly between the groups

DI: Digital Insertion, RR: Relative Risk, SPI: Speculum Based Insertion, VAS: Visual Analogue Score, VNRS: Visual Numerical Rating Scale, AUC: Area Under Curve.

Data presented as: mean (standard deviation)*, number (percentage)**, or median (interquartile range)***.

Seo. Digital versus speculum-based balloon catheter insertion for labor induction. Am J Obstet Gynecol MFM 2024.

Discussion

This review examined 5 key aspects in comparing DI and SPI techniques for balloon insertion prior to IOL. These included pain, procedural duration, procedural success, obstetric and neonatal outcomes, and maternal satisfaction. In this discussion, we collectively discuss the first 4 aspects under the subheading of Efficacy and Safety, followed by a discussion of Patient Acceptability.

Efficacy and safety

In terms of pain experienced, 2 out of the 3 studies assessing pain as an outcome suggested that pain was significantly reduced by DI of the balloon compared to SPI. Shqara et al. was the only paper that defined time points at which pain was measured (time of insertion of the cervical balloon, time of balloon inflation, and time of speculum or finger removal).[20] Pain was lower at the time of insertion and inflation during DI compared to SPI, which suggests that DI offered reductions in discomfort associated with insertion. This is supported by Jonsson et al. in which more objective and validated measures of acute pain were collected using skin conductance.[17] These synchronously demonstrated a reduction in sympathetic activation in pain scores in line with reported pain scores for DI. These findings suggest that pain is reduced through DI in comparison to SPI for cervical ripening prior to IOL.

Half of the studies (2/4), assessing procedural time suggest that DI appears to be faster than SPI. Across studies, this amounted to a statistically significant ~60s difference between procedures. Although the clinical benefit of this may be arguable; this difference could be pertinent to a pregnant person undergoing IOL should this finding and options be discussed with them. However, procedural time should be considered alongside the effectiveness of the procedure and patient pain scores. The experience outcome reports indicate

TABLE 3
Meta-analysis findings.

Outcome	Number of studies	Overall effect size	I^2
Time to place catheter[a]	3	0.27 (−0.38 to 0.93)	82.9
Induction to birth[a]	4	0.17 (−0.37 to 0.71)	87.7
Insertion to expulsion[a]	4	0.23 (−0.07 to 0.53)	59.9
Procedure failure[b]	2	0.24 (−2.90 to 3.39)	72.2
Epidural[b]	2	−0.42 (−1.75 to 0.91)	86.5
Maternal fever[b]	4	−0.49 (−1.22 to 0.24)	0
Umbilical pH[a]	2	0 (−0.34 to 0.34)	0
Hospital stay[a]	2	0.02 (−0.17 to 0.20)	0
NICU admission[b]	2	0.28 (−0.40 to 0.96)	0

[a] Standardised mean diff (95% CI).; [b] Log risk ratio (95% CI).

Seo. Digital versus speculum-based balloon catheter insertion for labor induction. Am J Obstet Gynecol MFM 2024.

that DI was quicker to perform, less painful, equally effective, and possibly more preferred overall. While the shorter duration might benefit clinicians, patient preferences and comfort should remain a priority. From the perspective of the health service, the value is that DI does not take longer and requires fewer resources to achieve successful cervical balloon insertion.

Finally, while the evidence suggests no differences in procedural success rates, it is essential to acknowledge the heterogeneity in the definitions of success among the included studies. Variations in how success is defined, such as balloon retention rates, insertion time, or failure rates, limit the reader's ability to assess success in a clinically meaningful way. However, regardless of the definition of procedural success, the goal of cervical preparation is to advance cervical change ahead of the induction of uterine contractions. This heterogeneity underscores the need for a standardized and universally applicable outcome definition in future research to enhance the comparability and robustness of findings. To address this issue, correlating findings with the items included in the Core Outcome Set for Induction of Labour (COSIOL) would be beneficial.[21] The COSIOL, developed through an international multistakeholder Delphi study, provides 28 core outcomes across 4 domains: short-term maternal outcomes, short-term offspring outcomes, long-term maternal outcomes, and long-term offspring outcomes. Incorporating these outcomes, such as time from induction to delivery, mode of delivery, maternal satisfaction, and neonatal unit admission, would promote homogeneity in data collection, strengthen outcome

TABLE 4
Comparison of COSIOL core outcomes across 4 studies in cervical preparation and labor induction.

COSIOL core outcomes	Kuhlmann et al. (2021)	Jonsson et al. (2011)	Chia et al. (2020)	Shqara et al. (2023)
Short-term maternal outcomes (*n*=18)				
Hemorrhage	Vaginal bleeding	Blood loss at delivery	Postpartum hemorrhage	Not reported
Infection	Maternal infection composite	Endometritis	Maternal Infection	Chorioamnionitis
Length of hospital stay	Total hospital days	Maternal hospital stay	Induction to discharge interval	Not reported
Mode of delivery	Caesarean delivery rates	Caesarean delivery rates	Caesarean delivery rates	Caesarean delivery rates
Need for more than one induction agent	Second balloon catheter	Not reported	Additional cervical ripening methods	Not reported
Satisfaction with care	Maternal satisfaction survey	Maternal satisfaction	Maternal satisfaction	Maternal satisfaction
Time from induction to delivery	Balloon catheter placement for delivery	Induction-to-delivery interval	Induction-to-delivery interval	Not reported
Short-term offspring outcomes (*n*=8)				
Admission to the neonatal unit	NICU admission	Neonatal care unit	NICU admission	NICU admission
Meconium aspiration syndrome	Reported	Not reported	Reported	Reported
Infection	Neonatal infection	Not reported	Presumed sepsis	Neonatal sepsis

Summary of COSIOL core outcomes reported in studies by Kuhlmann et al. (2021), Jonsson et al. (2011), Chia et al. (2020), and Shqara et al. (2023) assessing short-term maternal and off-spring outcomes in cervical ripening and labor induction.

Seo. Digital versus speculum-based balloon catheter insertion for labor induction. Am J Obstet Gynecol MFM 2024.

reporting, and ultimately enhance the quality and comparability of research findings. Including the COSIOL outcomes would have strengthened our review and helped standardize future studies on the induction of labor, as evidenced by the detailed comparison in Table 4, which outlines the extent to which each study has implemented these core outcomes in its methodology.

An interesting finding in the Shqara et al. paper is that DI was utilized in cases where SPI had failed, raising questions about whether the DI method would be more useful in technically challenging cases of cervical balloon placement.[20]

Importantly, all studies in this review demonstrated equivalence between SPI and DI in terms of obstetric, neonatal, and maternal safety outcomes.

Patient acceptability

All studies in this review demonstrated comparable satisfaction rates across both procedures. A common theme highlighted was the need to provide pregnant individuals with options around their IOL and promote shared decision-making around the IOL method. Doing so would prioritize pregnant patients playing an active role in their care, showing greater respect to their bodily autonomy whilst allowing clinicians to offer more patient-centered care.[22] As demonstrated by Kuhlmann et al., pregnant patients were more likely to opt for DI when given a choice.[19] Achieving this objective may face constraints depending on the clinician's familiarity with digital placement as opposed to speculum-guided placement, influenced by prior experiences in performing cervical balloon insertion. To alleviate this potential obstacle, providing specific training to ensure that staff are proficient in both options would be beneficial.[23]

Limitations

This review is subject to several limitations. Firstly, the relatively small number of studies addressing the focal issue underscores the need for more high-quality research in approaches to labor induction that comprehensively evaluate the efficacy of interventions. This is pertinent given the subjective nature of the measures for pain perception, procedural outcomes, and maternal satisfaction; all of which influence the selection and optimization of cervical preparation procedures, such as DI and SPI. Furthermore, the heterogeneity in outcome measures among most of the data items included in this review limits the comparability of metadata, hindering the derivation of more widely applicable conclusions.

Furthermore, approximating means and standard deviations from medians, IQR, or minimum and maximum values have been criticized as they use estimated not direct effects which can introduce error, and these approaches assume a normal distribution of the data. New approaches to perform meta-analyses of medians have been proposed whereby pooled differences in medians are computed and then the confidence intervals are constructed by either inversing the sign test or via linear quantile regression approaches.[24] While these approaches may be superior, similar errors can be introduced if any means and SDs must be transformed into a median.

The absence of insights into provider experience and health economic data across studies is notable. For example, while all practitioners were trained in balloon placement, controlling for clinician competence reduces generalizability to other hospitals. Additionally, this lack of exploration means that it is difficult to assess the relationship between practitioner experience and the findings. This information would contribute to a more comprehensive assessment of the clinical and resource implications of the procedure. Additionally, there is a lack of clarity on the impact of a stylet on procedural feasibility for DI or SPI, with only Kuhlmann et al. explicitly reporting that no stylet was used. It was also noted that whilst Bishops' score was reported, the dilation at placement was not despite being a potential factor that affects the applicability of each insertion technique.

Addressing these limitations in future research will enhance the robustness and applicability of findings in this domain that may inform implementation and clinical guidelines. Future research should prioritize the acceptability of induction methods to generate more robust, patient-centered conclusions. This will ensure that findings are not only clinically relevant but also align closely with patient preferences and experiences.

Conclusion

Our review compared the DI and SPI of cervical balloons with a view to establishing efficacy, safety, and preference of pregnant individuals between both techniques utilized during the IOL process. Our findings suggest that DI is associated with reduced pain during insertion and inflation, was significantly faster than SPI, and was preferred by pregnant individuals. No differences were noted in procedural success rates and safety profiles across obstetric, neonatal, and maternal outcomes. These findings indicate that DI is a reasonable tool for clinical use and may be more acceptable by individuals requiring cervical preparation. This information is of value for clinicians to incorporate into shared decision-making around options for cervical balloon insertion through evidence-based clinical discussions and adequate training on available methods.

Declaration of generative AI in scientific writing

No specific tools or services were used during the preparation of this work. The authors independently conducted all research, analysis, and manuscript preparation. The authors reviewed and edited the content as needed and took full responsibility for the content of the publication.

Registration

This study was registered in the International Prospective Register of Systematic Reviews (protocol number: CRD42022335338). ■

CRediT authorship contribution statement

Densearn Seo: Writing — original draft, Validation, Formal analysis, Data curation, Conceptualization. **Rashvinder Kaur:** Writing — original draft, Validation, Formal analysis, Data curation.

Meghna Prasannan Ponganam: Investigation, Data curation. **Kah Wai Sam:** Investigation, Data curation. **Maclean Hill:** Investigation, Data curation. **Miranda Davies-Tuck:** Formal analysis, Methodology, Writing – review & editing. **Ritesh Rikain Warty:** Writing – original draft, Validation, Methodology, Formal analysis, Data curation, Conceptualization. **Vinayak Smith:** Validation, Methodology, Data curation, Conceptualization. **Thiam Chye Tan:** Writing – review & editing. **Deborah Fox:** Writing – review & editing, Validation, Supervision. **Kirsten R Palmer:** Writing – review & editing, Validation, Supervision. ■

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.ajogmf.2024.101519.

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