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Systematic Review

Single-balloon versus double-balloon catheters for cervical ripening before induction of labour in term singleton pregnancies: a systematic review of randomized controlled trials

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ABSTRACT

Mechanical balloon catheters are widely used for cervical ripening before induction of labour in women with an unfavourable cervix. The single-balloon Foley catheter and the double-balloon cervical ripening catheter are commonly used in clinical practice. However, evidence regarding their comparative effectiveness and safety remains inconsistent. A systematic review of randomized controlled trials was conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA 2020) statement. A systematic search of the PubMed database was performed from database inception to 31 May 2026. Randomized controlled trials comparing single-balloon and double-balloon catheters for cervical ripening and induction of labour in term singleton pregnancies were included. Data on maternal and neonatal outcomes were extracted and synthesized narratively because of clinical and methodological heterogeneity among the included studies. Five randomized controlled trials involving 835 women met the inclusion criteria. Both catheter types were effective for cervical ripening and labour induction. Improvements in bishop score, induction-to-delivery interval, and mode of delivery varied across the included studies. Some trials reported shorter induction-to-delivery intervals or greater cervical ripening with the double-balloon catheter, whereas others found similar outcomes between the two devices. Maternal and neonatal outcomes, including caesarean section rates, APGAR scores, and neonatal intensive care unit admissions, were generally comparable. Current evidence does not demonstrate consistent superiority of either the single-balloon or the double-balloon catheter for cervical ripening and induction of labour in term singleton pregnancies. Both devices appear to be safe and effective mechanical methods. Catheter selection should be guided by clinical judgement, patient characteristics, resource availability, local practice, and cost. Further well-designed multicentre randomized controlled trials with standardized outcome measures are needed to strengthen the available evidence.

Keywords: Cervical ripening, Foley catheter, Double-balloon catheter, Labour induction, Mechanical cervical ripening, Randomized controlled trial

INTRODUCTION

Induction of labour is one of the most frequently performed interventions in obstetric practice. It is recommended when the benefits of delivery outweigh the risks of continuing pregnancy for the mother or fetus. Successful induction depends largely on cervical readiness. Women with an unfavourable cervix are more likely to experience prolonged labour, failed induction,

and caesarean delivery. Cervical ripening before induction therefore plays an important role in improving labour outcomes.^{6,19,20}

Mechanical methods have become established alternatives to pharmacological agents for cervical ripening. Balloon catheters produce gradual cervical dilatation through direct mechanical pressure and stimulate the release of endogenous prostaglandins without increasing uterine

activity to the same extent as pharmacological methods. Because of their favourable safety profile, mechanical methods are widely used in women in whom excessive uterine contractions are undesirable.⁹⁻¹¹

The single-balloon Foley catheter has been used for several decades and remains an inexpensive, readily available method for cervical ripening. The double-balloon catheter was subsequently developed to apply pressure to both the internal and external cervical os, with the intention of improving cervical ripening and shortening the induction process. Despite these theoretical advantages, comparative studies have reported conflicting findings regarding cervical ripening, labour duration, mode of delivery, and maternal and neonatal outcomes.^{1-5,13-17}

Several professional organisations, including the World Health Organization, the National Institute for Health and Care Excellence, and the American College of Obstetricians and Gynecologists, recognise mechanical methods as acceptable options for cervical ripening. However, current recommendations do not favour one balloon catheter over another because the available evidence has not consistently demonstrated the superiority of either device.^{6,19,20}

Randomized controlled trials comparing single-balloon and double-balloon catheters have differed in study design, participant characteristics, catheter protocols, and reported outcomes. These variations have made interpretation of individual studies difficult and have contributed to differences in clinical practice. An updated synthesis of randomized evidence is therefore needed to provide a clearer comparison of these two mechanical methods.¹⁻⁵

The present systematic review was undertaken to evaluate the available randomized controlled trials comparing single-balloon and double-balloon catheters for cervical ripening and induction of labour in term singleton pregnancies. The review focused on maternal and neonatal outcomes to provide evidence that may support clinical decision-making.

Objectives

The objective of the study was to compare the effectiveness and safety of single-balloon and double-balloon catheters for cervical ripening and induction of labour in term singleton pregnancies by systematically reviewing evidence from randomized controlled trials.

METHODS

Study design

This systematic review was conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMA 2020) statement.⁷ The review aimed to compare the effectiveness and safety of single-

balloon and double-balloon catheters for cervical ripening and induction of labour in term singleton pregnancies.

Eligibility criteria

Studies were selected according to the population, intervention, comparator, outcomes and study design (PICOS) framework.

Population

Women with term (≥ 37 weeks) singleton pregnancies in cephalic presentation undergoing cervical ripening before induction of labour.

Intervention

Intervention used was single-balloon catheter (Foley catheter).

Comparator

Comparator was double-balloon cervical ripening catheter.

Outcomes

Maternal outcomes included Bishop score, induction-to-delivery interval, vaginal delivery, caesarean section, oxytocin augmentation, maternal complications and maternal satisfaction. Neonatal outcomes included Apgar score, neonatal intensive care unit admission, fetal heart rate abnormalities and other reported neonatal complications.

Study design

Only randomized controlled trials directly comparing single-balloon and double-balloon catheters were included.

Studies were excluded if they were observational studies, cohort studies, case-control studies, case series, review articles, conference abstracts, editorials or letters; evaluated pharmacological methods without a direct comparison between single-balloon and double-balloon catheters; involved animal studies; or included women with multiple pregnancies, preterm pregnancies or non-cephalic presentations.

Information sources and search strategy

A systematic literature search was conducted using the PubMed database from database inception to 31 May 2026. The search strategy combined medical subject headings (MeSH) and free-text terms related to cervical ripening and labour induction.

The search terms included Foley catheter, single-balloon catheter, double-balloon catheter, cook cervical ripening

balloon, cervical ripening, labour induction, and induction of labour.

The reference lists of eligible studies and relevant review articles were also screened manually to identify additional studies.

Study selection

Records retrieved from the PubMed search were screened by the author according to the predefined eligibility criteria. Titles and abstracts were reviewed, followed by full-text assessment of potentially eligible studies. Studies meeting the inclusion criteria were included in the qualitative synthesis. The study selection process is presented in the PRISMA 2020 flow diagram (Figure 1).⁷

Data extraction

Data were extracted by the author using a standardized data extraction form. The information collected included first author, year of publication, country, study design, participant characteristics, sample size, intervention and comparator, maternal outcomes, neonatal outcomes, and main findings.

The extracted data were checked for completeness and summarized in evidence tables.

Quality assessment

The methodological quality of the included randomized controlled trials was assessed by the author using the Cochrane risk of bias 2 (RoB 2) tool.⁸ The domains evaluated were the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result.

Each study was classified as having low risk of bias, some concerns, or high risk of bias.

Data synthesis

A narrative synthesis was performed because of differences among the included studies in participant characteristics, catheter protocols, outcome definitions and outcome reporting. The findings were summarized descriptively using text and tables. A meta-analysis was not undertaken because of the clinical and methodological heterogeneity of the included studies.

RESULTS

Study selection

The literature search identified 36 records in the PubMed database. As only one database was searched, no duplicate records were identified. After title and abstract screening, 29 records were excluded because they did not meet the

predefined eligibility criteria. The full texts of seven articles were assessed for eligibility. Two review articles were excluded after full-text assessment. Finally, five randomized controlled trials were included in the qualitative synthesis. The study selection process is illustrated in Figure 1.

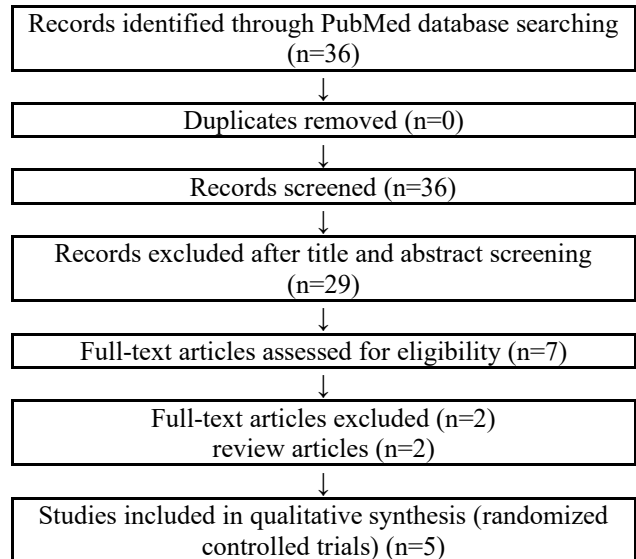


Figure 1: PRISMA 2020 flow diagram showing the study selection process.

Characteristics of the included studies

Five randomized controlled trials published between 2011 and 2021 met the eligibility criteria. Three studies were conducted in Israel, one in the United States, and one in Egypt. A total of 835 women were included in the review. The characteristics of the included studies are presented in Table 1.

Maternal outcomes

Bishop score

Four studies evaluated changes in Bishop score following cervical ripening. Mei-Dan et al reported similar cervical ripening success in both groups. Ahmed et al observed a greater increase in bishop score with the double-balloon catheter. Hoppe et al found better cervical ripening among nulliparous women receiving the double-balloon catheter, whereas Solt et al reported greater improvement among multiparous women.

Induction-to-delivery interval

All five studies reported the induction-to-delivery interval. Salim et al found no significant difference between the two catheter types. Mei-Dan et al and Solt et al reported a shorter induction-to-delivery interval with the double-balloon catheter, whereas Ahmed et al observed a shorter interval with the Foley catheter.

Mode of delivery

Mode of delivery was reported in all included studies. Vaginal delivery rates were generally comparable between the two catheter groups. Caesarean section rates varied across studies, with no consistent advantage for either catheter.

Maternal complications

Maternal complications and maternal satisfaction were generally similar between the two groups. The maternal outcomes reported in the included studies are summarised in Table 2.

Neonatal outcomes

Neonatal outcomes were reported in all five studies. Apgar scores, NICU admissions, fetal heart rate abnormalities,

and other neonatal outcomes were comparable between the single-balloon and double-balloon catheter groups.

The neonatal outcomes are summarised in Table 3.

Risk of bias assessment

The methodological quality of the included randomized controlled trials was assessed using the Cochrane risk of bias 2 (RoB 2) tool.

Overall, three studies were judged to have a low risk of bias, while two studies were classified as having some concerns, primarily because of insufficient reporting of the randomization process.

No study was considered to have a high risk of bias. The detailed assessment is presented in Table 4.

Table 1: Characteristics of the included studies.

Study	Coun-try	Study design	Population	Sample size	Single-balloon catheter	Double-balloon catheter	Primary outcomes	Main findings
Salim et al¹, 2011	Israel	Randomized controlled trial	Women with term singleton pregnancy, cephalic presentation, intact membranes, and an unfavorable cervix undergoing induction of labor	293 (145 versus 148)	Foley catheter	Cook cervical ripening balloon	Time from catheter insertion to delivery, mode of delivery, maternal and neonatal outcomes	No significant difference was found in the induction-to-delivery interval between the two groups. Fewer operative deliveries were reported in the single-balloon group. Maternal and neonatal outcomes were similar.
Mei-Dan et al², 2014	Israel	Randomized controlled trial*	Women with term singleton pregnancy undergoing induction of labor	186	Single-balloon catheter with extra-amniotic saline infusion (EASI)	Double-balloon catheter with EASI	Cervical ripening success, induction-to-delivery interval, cesarean section, maternal and neonatal outcomes	Cervical ripening success was similar in both groups. The double-balloon catheter group had a shorter induction-to-delivery interval and a lower cesarean section rate. No difference was reported in maternal or neonatal adverse outcomes.
Hoppe et al³, 2016	United States	Randomized controlled trial	Women with singleton vertex pregnancy requiring cervical ripening before induction of labor	98 (48 versus 50)	30 ml Foley catheter	80 ml double-balloon catheter	Cervical ripening success, vaginal delivery, maternal and	In nulliparous women, the double-balloon catheter achieved a higher rate of successful cervical ripening and vaginal

Continued.

Study	Coun-try	Study design	Population	Sample size	Single-balloon catheter	Double-balloon catheter	Primary outcomes	Main findings
							neonatal outcomes	delivery. Outcomes in multiparous women were similar between the two groups.
Ahmed et al⁴, 2016	Egypt	Rando-mized controlled trial	Postdate primigravid women with singleton pregnancy	78 (39 versus 39)	Foley catheter	Cook cervical ripening balloon	Bishop score improvement, induction-to-delivery interval, mode of delivery, maternal and neonatal outcomes	The Cook cervical ripening balloon resulted in a greater increase in Bishop score. The Foley catheter had a shorter induction process. Maternal and neonatal outcomes did not differ significantly between groups.
Solt et al⁵, 2021	Israel	Prospec-tive random-ized study	Women with an unfavorable cervix undergoing induction of labor	180	Foley catheter	Cervical ripening double balloon (CRDB) catheter	Bishop score improvement, induction-to-delivery interval, cesarean section, maternal and neonatal outcomes	The CRDB group had a shorter induction-to-delivery interval. Among nulliparous women, the cesarean section rate was lower in the CRDB group. Maternal and neonatal outcomes were comparable between the groups.

EASI: Extra-amniotic saline infusion, CRDB: cervical ripening double balloon

Table 2: Maternal outcomes reported in the included studies.

Study	Bishop score	Induction-to-delivery interval	Vaginal delivery	Caesarean section	Oxytocin use	Maternal complications	Maternal satisfaction
Salim et al¹, 2011	No significant difference reported	No significant difference	Similar between groups	Lower operative delivery rate in the single-balloon group	No significant difference reported	Similar between groups	Not reported
Mei-Dan et al², 2014	Similar cervical ripening success	Shorter in the double-balloon group	Similar between groups	Lower in the double-balloon group	Not reported	No significant difference	No significant difference
Hoppe et al³, 2016	Greater improvement with the double-balloon catheter in nulliparous women	No significant difference reported	Higher in the double-balloon group among nulliparous women	Similar between groups	Not reported	Similar between groups	Not reported
Ahmed et al⁴, 2016	Greater improvement	Shorter with the	Similar between groups	Similar between groups	Similar between groups	Similar between groups	Similar between groups

Continued.

Study	Bishop score	Induction-to-delivery interval	Vaginal delivery	Caesarean section	Oxytocin use	Maternal complications	Maternal satisfaction
	with the Cook balloon	Foley catheter					
Solt et al⁵, 2021	Greater improvement with the CRDB catheter among multiparous women	Shorter with the CRDB catheter	Similar between groups	Lower in the CRDB group among nulliparous women	Not reported	Similar between groups	Not reported

CRDB: Cervical ripening double balloon

Table 3: Neonatal outcomes reported in the included studies.

Study	Apgar score	NICU admission	Fetal heart rate abnormalities	Neonatal infection	Other neonatal outcomes
Salim et al¹, 2011	No significant difference	No significant difference	No significant difference	Not reported	Neonatal outcomes were comparable between the groups.
Mei-Dan et al², 2014	No significant difference	No significant difference	No significant difference	Not reported	No significant neonatal adverse outcomes were reported.
Hoppe et al³, 2016	No significant difference	No significant difference	No significant difference	Not reported	Neonatal outcomes were similar in both groups.
Ahmed et al⁴, 2016	No significant difference	No significant difference	No significant difference	Not reported	No significant neonatal complications were reported.
Solt et al⁵, 2021	No significant difference	No significant difference	No significant difference	Not reported	Neonatal outcomes were comparable between the Foley catheter and CRDB groups.

NICU: Neonatal intensive care unit, CRDB: cervical ripening double balloon

Table 4: Risk of bias assessment of the included randomized controlled trials using the Cochrane risk of bias 2 (RoB 2) tool.

Study	Randomization	Deviations from intervention	Missing outcome data	Outcome measurement	Selective reporting	Overall risk
Salim et al¹, 2011	Low	Low	Low	Low	Low	Low
Mei-Dan et al², 2014	Some concerns	Low	Low	Low	Low	Some concerns
Hoppe et al³, 2016	Low	Low	Low	Low	Low	Low
Ahmed et al⁴, 2016	Some concerns	Low	Low	Low	Low	Some concerns
Solt et al⁵, 2021	Low	Low	Low	Low	Low	Low

DISCUSSION

This systematic review synthesized evidence from five randomized controlled trials comparing single-balloon and double-balloon catheters for cervical ripening and induction of labour in women with term singleton pregnancies. Overall, both catheter types were effective for cervical ripening and labour induction. Although individual studies reported differences in selected maternal outcomes, the available evidence did not demonstrate

consistent superiority of either catheter across the maternal and neonatal outcomes assessed.¹⁻⁵

The effect of catheter type on cervical ripening varied across the included studies. Mei-Dan et al reported similar cervical ripening success with both catheters, whereas Ahmed et al found greater improvement in bishop score with the double-balloon catheter.^{2,4} Hoppe et al also observed better cervical ripening among nulliparous women managed with the double-balloon catheter, while Solt et al reported greater improvement in Bishop score in

women receiving the same device.^{3,5} These differences suggest that the effectiveness of mechanical cervical ripening may be influenced not only by catheter design but also by parity, baseline cervical status and variations in induction protocols.

The effect on the induction-to-delivery interval also differed among the included trials. Salim et al found no significant difference between the two catheter types, whereas Mei-Dan et al and Solt et al reported shorter induction-to-delivery intervals with the double-balloon catheter.^{1,2,5} In contrast, Ahmed et al observed a shorter interval with the Foley catheter.⁴ Variations in balloon inflation volume, duration of catheter placement, use of extra-amniotic saline infusion, oxytocin augmentation and local induction protocols are likely to have contributed to these inconsistent findings.

Mode of delivery was reported in all five trials. Vaginal delivery rates were generally comparable between women managed with single-balloon and double-balloon catheters. Although some studies reported lower caesarean section rates with the double-balloon catheter, Salim et al observed fewer operative deliveries in the single-balloon group.¹ Overall, the available evidence does not indicate that either catheter consistently improves the likelihood of vaginal birth or reduces the need for caesarean delivery.

Maternal and neonatal outcomes were also comparable across the included studies. No clinically important differences were observed in neonatal outcomes, including Apgar scores, neonatal intensive care unit admissions and fetal heart rate abnormalities. Likewise, maternal complications were uncommon and occurred at similar frequencies in both groups. These findings suggest that both single-balloon and double-balloon catheters are safe and effective mechanical methods for cervical ripening in appropriately selected women.¹⁻⁵

Our findings are consistent with previous systematic reviews and meta-analyses. Yang et al, Salim et al, Lajusticia et al, Liu et al and Peel et al likewise concluded that neither catheter demonstrated consistent superiority for clinically important maternal or neonatal outcomes.¹³⁻¹⁷ Similarly, the comprehensive review by Sanchez-Ramos et al reported that both balloon catheters remain effective options for cervical ripening and labour induction, with catheter selection depending largely on clinical circumstances, practitioner preference, local protocols and cost.¹²

Strengths

This review has several strengths. By restricting inclusion to randomized controlled trials that directly compared single-balloon and double-balloon catheters, the influence of confounding associated with observational studies was minimized. The review also evaluated clinically relevant maternal and neonatal outcomes that are commonly used to assess the effectiveness and safety of cervical ripening

methods. In addition, the methodological quality of the included studies was assessed using the Cochrane risk of bias 2 tool, and most studies were judged to have a low overall risk of bias.

Limitations

Several limitations should also be acknowledged. The literature search was limited to the PubMed database, and relevant studies indexed exclusively in other databases may not have been identified. Study selection, data extraction and quality assessment were performed by a single reviewer, which may have introduced reviewer bias despite the use of predefined eligibility criteria and standardized data extraction methods. The number of included studies was relatively small, and differences in participant characteristics, catheter protocols, balloon inflation volumes and outcome definitions limited direct comparison across studies. Because of this clinical and methodological heterogeneity, a meta-analysis was not performed. These limitations should be considered when interpreting the findings of this review.

CONCLUSION

Both single-balloon and double-balloon catheters are effective mechanical methods for cervical ripening before induction of labour in term singleton pregnancies. Although individual studies reported differences in cervical ripening, induction-to-delivery interval and mode of delivery, the available evidence does not demonstrate consistent superiority of either catheter. Maternal and neonatal outcomes were generally comparable with both methods. Catheter selection should therefore be guided by clinical judgement, patient characteristics, local practice and resource availability. Further well-designed multicentre randomized controlled trials with standardized outcome measures are needed to strengthen the evidence and support clinical decision-making.

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Ethical approval: Not required

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