Ripening of the Cervix Using the Balloon Catheter Prior to Induction of Labor

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Abstract

Background: Labour induction initiates uterine contractions to achieve vaginal delivery when continued pregnancy poses maternal or foetal risks. Indications include preeclampsia, diabetes, intrauterine growth restriction, post-term pregnancy, and premature rupture of membrane. Methods involve pharmacological or mechanical cervical ripening, notably balloon catheters. Proper candidate selection, informed consent, and balancing benefits with potential risks like failed induction or hyperstimulation are essential.

Objectives: This study aimed to evaluate the balloon catheter's role in cervical ripening, with an emphasis on safety, efficacy, and clinical applicability.

Methods: A cross-sectional study at Basra Maternity and Children Hospital from the 1st of October 2024 to the 1st of September 2025, involved 150 term pregnant women undergoing labour induction with intrauterine balloon catheter. Data included demographics, obstetric history, cervical status, induction details, delivery outcomes, and maternal/neonatal complications. Intrauterine balloon catheter was used for up to 12 hours, followed by oxytocin if needed. Ethical approval and informed consent were obtained.

Results: The study involved 150 women (mean age 30.5 years), mostly urban residents (58%) and housewives (68.7%). Over half were overweight, with a mean gestational age of 40.2 weeks. Post-term pregnancy (42%) and preeclampsia (26%) were the main induction indications. Bishop scores improved significantly post-catheter (2.6 to 7.5, $p<0.001$). Induction succeeded in 76%, with most requiring oxytocin. Failure was mainly due to lack of progress (75%). Most deliveries were vaginal (76%), with minimal complications. Neonatal outcomes included 19.3% low birth weight, 6.7% with low 1-minute Apgar, and 8.7% neonatal intensive care unit admissions. Overall, Intrauterine balloon catheter proved effective and generally safe.

Conclusions: Intrauterine balloon catheter is an effective, safe method for labour induction, achieving a 76% success rate with minimal complications, especially useful in unfavourable cervix cases and resource-limited settings.

Keywords: Labour induction; Cervical ripening; Balloon catheter; Pharmacological methods; Mechanical methods; Obstetric outcomes

INTRODUCTION

Labour induction is a widely practiced intervention in modern obstetrics, aiming to initiate uterine contractions before spontaneous labour to achieve vaginal delivery [(1)]. It is indicated when the risks of continuing pregnancy outweigh those of delivery, such as in post-term pregnancy, preeclampsia, gestational diabetes, intrauterine growth restriction, or other maternal and foetal complications [(2)]. The success of induction largely depends on cervical status, commonly assessed using the bishop score, which evaluates cervical dilation, effacement, consistency, position, and foetal station. A favourable score predicts a higher likelihood of vaginal delivery, while an unfavourable cervix often necessitates pre-induction cervical ripening [(3)].

Cervical ripening may be achieved pharmacologically or mechanically. Pharmacological methods, including prostaglandins like dinoprostone and misoprostol, act by softening and dilating the cervix, mimicking physiological processes of labour. These agents are effective but associated with adverse effects such as uterine hyperstimulation, foetal distress, and maternal side effects [(4)]. In contrast, mechanical methods exert local effects through physical cervical manipulation, with the most common techniques being balloon catheters and hygroscopic dilators. These methods are often associated with fewer systemic effects, making them useful in certain patient groups [(5)].

The balloon catheter is one of the most widely used mechanical methods. It facilitates cervical ripening by exerting pressure on the internal os, stimulating local prostaglandin release and promoting cervical effacement and dilation. The catheter is inserted into the cervix and inflated with sterile fluid, providing sustained pressure until expulsion or removal [(6)]. Evidence supports the efficacy of balloon catheters, demonstrating outcomes comparable to pharmacological methods in achieving vaginal delivery. Their advantages include lower risk of uterine

hyperstimulation, minimal systemic side effects, simplicity, and cost-effectiveness, making them particularly attractive in low-resource settings or in women with contraindications to prostaglandins [7].

Comparative studies suggest balloon catheters are as effective as prostaglandins in improving Bishop scores and facilitating vaginal delivery, though time to onset of active labour may be longer [8]. Combination regimens involving both mechanical and pharmacological approaches have also been explored, showing potential for enhanced efficacy but requiring careful monitoring to reduce complications. Importantly, maternal outcomes such as reduced uterine rupture and hyperstimulation, and neonatal outcomes including Apgar scores and NICU admission rates, appear comparable between balloon catheter and pharmacological methods [9].

Labour induction overall plays a critical role in improving maternal and neonatal outcomes, particularly in high-risk pregnancies [10]. Indications extend across maternal conditions (e.g., hypertensive disorders, diabetes, cardiac disease) [1], foetal complications (e.g., intrauterine growth restriction, oligohydramnios, non-reassuring foetal status) [10], post-term pregnancy [1], and premature rupture of membranes [12]. However, contraindications such as placenta previa, vasa previa, transverse lie, prior classical caesarean section, or active genital herpes must be carefully considered [4].

The bishop score remains the cornerstone for assessing cervical readiness, with scores ≥6 suggesting greater likelihood of successful vaginal delivery, while scores <6 indicate the need for cervical ripening prior to induction [13]. This assessment helps guide induction methods and anticipate potential challenges.

Pharmacological options for induction include prostaglandins [14], oxytocin [15], and emerging agents like mifepristone [16]. Mechanical options include balloon catheters [17], hygroscopic dilators [18], and membrane stripping [19]. Compared with pharmacological agents, mechanical methods have advantages of reduced hyperstimulation, fewer systemic side effects, and cost-effectiveness, though they may be less comfortable, slower, and require clinical expertise [20]. Alternative methods such as acupuncture, castor oil, and herbal remedies have been explored, though evidence of efficacy and safety remains limited [21].

The balloon catheter has evolved considerably since its introduction. Initially adapted from urological practice (Foley catheter), modern versions now include double-balloon devices designed to improve cervical dilation and reduce complications [22]. The mechanism of action involves both mechanical stretching and stimulation of endogenous prostaglandin release, with typical use spanning 12–24 hours or until expulsion occurs [7].

Comparative outcomes indicate both balloon catheters and prostaglandins are effective, though with distinct risk profiles. Mechanical methods tend to prolong the induction-to-delivery interval but reduce uterine hyperstimulation and systemic complications, making them safer options for high-risk pregnancies [23]. Conversely, pharmacological agents shorten induction time but increase risks of hyperstimulation and foetal compromise [6]. Combination protocols have shown promise in reducing induction duration and improving delivery outcomes but require cautious application [24].

Complications of induction include uterine hyperstimulation, foetal distress, and failed induction. Hyperstimulation is particularly associated with pharmacological agents and can compromise uteroplacental blood flow, increasing emergency caesarean rates [25]. Balloon catheters, while less likely to cause hyperstimulation, may result in discomfort or cramping. Failed induction, defined as lack of progression despite cervical ripening and contractions, can prolong hospitalization, increase operative delivery rates, and cause psychological stress. Careful patient selection, cervical assessment, and close monitoring remain essential [26].

Overall, the balloon catheter is a safe, effective, and cost-efficient option for cervical ripening. While comparable in efficacy to prostaglandins, it carries fewer risks of uterine hyperstimulation, making it a suitable choice for many women, especially those at higher risk or in resource-limited settings. However, further research is needed to optimize placement duration, evaluate its role in high-risk pregnancies, and assess patient satisfaction.

This study aimed to evaluate the balloon catheter's role in cervical ripening, with an emphasis on safety, efficacy, and clinical applicability.

METHODS

This research was designed as a cross-sectional study and was carried out in the gynecology outpatient clinics of Babylon over one year, from September 1, 2024, to A cross-sectional study was conducted at the obstetric department of Basra Maternity and Children Hospital in Basra City, Iraq, during the period from the 1st of October 2024 to the 1st of September 2025. The study aimed to evaluate the effectiveness, safety, and clinical outcomes associated with the use of the intrauterine balloon catheter (IUBC) in labour induction.

The study included 150 pregnant women admitted to the obstetric department who required labour induction for various obstetric indications. All participants were treated with IUBC, and the primary outcomes measured were the time to onset of active labour, rate of vaginal delivery, and occurrence of maternal or foetal complications.

The inclusion criteria were term pregnancy, a Bishop score ≤ 5, singleton pregnancy with cephalic presentation, and medical indications for labour induction such as post-term pregnancy, hypertensive disorders, or foetal growth restriction. Women were also required to provide informed consent to participate in the study. Exclusion criteria included multiple gestations, contraindications to vaginal delivery (such as placenta previa or transverse foetal lie), Bishop score ≥ 6 or established labour, history of uterine rupture or significant uterine surgery, and evidence of active infection or chorioamnionitis.

Data were collected using a structured questionnaire developed for the study. Information gathered included socio-demographic characteristics (age, residency, and occupation) and obstetrical history such as gestational age by last menstrual period (LMP), parity, previous caesarean section, and history of preterm labour. The primary indications for induction, including post-term pregnancy, hypertensive disorders (e.g., preeclampsia, gestational hypertension), diabetes in pregnancy, intrauterine growth restriction, and oligohydramnios, were documented. Anthropometric measurements such as weight, height, and BMI were calculated, while routine vital signs and blood investigations were also performed.

Before balloon insertion, the cervical status was carefully assessed and documented, including dilatation, effacement, station, consistency, position, Bishop score, and time of insertion. The IUBC was then inserted into the cervix and inflated with sterile saline to promote cervical ripening. The catheter remained in situ for a maximum of 12 hours or until spontaneous expulsion. Women were closely monitored for uterine contractions, foetal well-being, and any complications. Following removal of the catheter, the cervix was reassessed by the same observer, and changes in the bishop score were recorded. The volume of saline used for balloon inflation and the duration of catheter placement were also documented. In cases with favourable cervical changes, artificial rupture of membranes was performed and labor induction continued with oxytocin infusion.

Maternal complications during balloon placement, including vaginal bleeding or pain requiring analgesia, were recorded. The time from balloon insertion to delivery and mode of delivery—whether vaginal, assisted vaginal (forceps/vacuum), or caesarean section—were noted. Additional maternal complications during induction, such as uterine rupture and chorioamnionitis, were monitored. Neonatal outcomes included birth weight, Apgar scores at 1 and 5 minutes, and admission to the neonatal intensive care unit (NICU).

Ethical approval for the study was obtained from the Ethical Committee of the College of Medicine, Basrah University. Written informed consent was obtained from all participants, and confidentiality and anonymity of data were strictly maintained.

Data were entered and analysed using the Statistical Package for Social Sciences (SPSS), version 26. Quantitative variables were expressed as mean ± standard deviation, while qualitative variables were reported as frequencies and percentages. Statistical analyses included the Chi-square test for categorical variables, with Fisher's exact test applied where expected frequencies were less than five, and the independent samples t-test for continuous variables. A p-value ≤ 0.05 was considered statistically significant. Results were presented in tables and graphs for clarity.

RESULTS

The study included 150 women, their mean age was 30.5 years, and 40.7% of them were between 20-29 years. Regarding their residency, 58.0% of them were living in an urban area. 41.3% of women had a secondary education, and 68.7% were housewives. All these data were presented in Table 1.

Table 1: The demographic characteristics

Variables		No.	%
Age	Mean ± SD	30.5 ± 3.2	
	>20	15	10.0
	20-29	61	40.7
	30-39	50	35.3
	40	21	14.0
Residency	Rural	63	42.0
	Urban	87	58.0
Educational level	Illiterate	15	10.0
	Primary	29	19.3
	Secondary	62	41.3
	Higher education	44	29.4
Occupation	Housewives	103	68.7
	Employed	47	31.3
Total		150	100.0

Table 3.2 shows the clinical and obstetrical characteristics of participants. Regarding their parity, 52.7% had 1-4 children. The BMI was calculated, and 51.3% of them were

overweight. The mean gestational age at the time of presentation was 40.2 weeks.

Table 2: The clinical and obstetrical characteristics

Variables		No.	%
Parity	Nulliparous	53	35.3
	1-4	79	52.7
	5≥	18	12.0
BMI	Normal	30	20.0
	Overweight	77	51.3
	Obese	43	28.7
Gestational age	Mean ± SD	40.2 ± 1.1	
Total		150	100.0

The indications of labour induction are shown in Table 3. 42% of women had post-term pregnancy, 26.0% presented with preeclampsia, and only 4% of women underwent induction because of oligohydramnios.

Table 3: The indications for induction of labor

Indication	No.	%
Post-term pregnancy	63	42.0
Preeclampsia	39	26.0
Gestational diabetes	22	14.7
IUGR	20	13.3
Oligohydramnios	6	4.0
Total	150	100.0

Table 4 shows the change in Bishop score before and after catheter insertion. The mean score before insertion was 2.6 and increased to 7.5 after the catheter removal, and this difference is of statistical significance. P-value < 0.001.

Table 4: The change in Bishop score before and after catheter insertion

Variable	Pre-catheter Bishop score	Post catheter Bishop score	p-value
Change in Bishop score Mean ± SD	2.6 ± 1.4	7.5 ± 1.9	0.001

The success and failure rates are presented in Table 5. The induction succeeded in 76% of the women under study. 80.7% of them had vaginal delivery after catheter and oxytocin infusion, and 19.3 had vaginal delivery after catheter only. The induction failed in 24% of women.

Table 5: Induction success and failure rate

Variables	No.	%
Induction success	114	76.0
Vaginal delivery after catheter insertion only	22	19.3
Vaginal delivery after catheter and oxytocin infusion	92	80.7
Induction failure	36	24.0

The causes behind the failure of induction were no progress in 75% and foetal distress in 25% of women (Table 6).

Table 3.6: The causes of induction failure

Induction failure	No.	%
No progress	27	75.0
Fetal distress	9	25.0
Total	36	100.0

The maternal outcome among participants is presented in Table 7. The mean time from insertion to delivery was 18.2 hours. The mode of delivery was normal vaginal delivery among 76% and caesarean among 24%. The induction causes no complications for 92% of women, and 5.3% of them had bleeding, and 6.7% experienced pain.

Table 7: The maternal outcome among participants

Variables	No.	%
Time from insertion to delivery in hours Mean ± SD	18.2 ± 4.1	
Mode of delivery		
Normal vaginal delivery	114	76.0
Cesarean section	36	24.0
Maternal complication		
None	138	92.0
Bleeding	8	5.3
Pain	10	6.7
Infection	2	1.3

Table 8 shows the foetal outcomes; 19.3% of neonates had low birth weight <2.5 kg. 6.7% had a 1-minute APGAR score <7, and 3.3% had 5-minute APGAR score <7. And 8.7% had NICU admission.

Table 8: The foetal outcome

Variables	No.	%
Low birth weight < 2.5 kg	29	19.3
1 mint APGAR score <7	10	6.7
5-minute APGAR score <7	5	3.3
NICU admission	13	8.7

DISCUSSION

Labor induction is a common obstetric intervention, particularly when continuation of pregnancy poses risks to maternal or fetal health. Effective and safe cervical ripening methods are essential for improving delivery outcomes, especially among women with an unfavorable cervix [27]. This study aimed to evaluate the clinical effectiveness and safety of intrauterine balloon catheter (IUBC) for labor induction in term pregnant women with Bishop scores ≤ 5,

conducted at the Basra Maternity and Children Hospital. The rationale for this study lies in the increasing global and regional use of mechanical methods for cervical ripening due to their cost-effectiveness, minimal systemic side effects, and suitability in low-resource settings [28].

The mean age of participants was 30.5 years, with the majority aged 20–39 years. This age range is consistent with peak reproductive years and mirrors findings from similar studies conducted in the region. Most participants were urban residents (58%) and housewives (68.7%), which reflects the demographic profile typical of public hospital attendees in Iraq. Notably, 70.6% had secondary or higher education, suggesting a relatively well-informed population, which may positively influence compliance with antenatal and delivery care. This contrasts with findings from lower-income or rural populations where illiteracy and poor health awareness often complicate obstetric care [29].

Over half the women (52.7%) were multiparous (1–4 prior deliveries), while 35.3% were nulliparous. The mean gestational age at induction was 40.2 weeks, aligning with standard definitions of term pregnancy and consistent with WHO-recommended timelines for elective induction as reported by Gawrys et al. (2024) [30]. Most women were overweight (51.3%) or obese (28.7%), echoing regional trends and raising concerns given that increased BMI is associated with longer labor, reduced cervical responsiveness, and higher cesarean delivery rates as mentioned by Angeliki et al. (2018) [31].

Post-term pregnancy (42%) was the leading indication for labor induction, followed by preeclampsia (26%) and gestational diabetes (14.7%). These indications are consistent with both national and international guidelines that recommend induction when risks of continuing pregnancy outweigh the benefits [27, 32]. A smaller subset had IUGR (13.3%) and oligohydramnios (4%), conditions that are also valid reasons for timely intervention. These findings are in line with prior research by Chauhan et al. (2017) and Boers et al. (2010) where post-term pregnancy and hypertensive disorders accounted for the majority of induced labors [33, 34].

There was a statistically significant improvement in the bishop score post-catheter insertion, increasing from a mean of 2.6 ± 1.4 to 7.5 ± 1.9 ($p = 0.001$). This change confirms the effectiveness of the IUBC in promoting cervical ripening. Previous study by Li et al. (2024) demonstrated similar increases in cervical favorability following IUBC use, often matching or surpassing pharmaceutical agents like prostaglandins. The mechanical pressure exerted by the inflated balloon is thought to stimulate local prostaglandin release, promoting both effacement and dilation with minimal systemic effects [35].

Labor induction was successful in 76% of participants, with 80.7% requiring oxytocin augmentation after catheter removal. This high success rate supports existing evidence on the utility of IUBC in women with unripe cervices [25]. Of the 24% who experienced failed induction, the predominant cause was lack of cervical or labor progression (75%), while 25% were due to fetal distress. These findings are in line with those of Lawani et al. (2014), who reported non-progressive labor as the most common reason for cesarean following mechanical induction [1]. It is important to note that fetal distress in this context may be related to uterine hyperstimulation or pre-existing placental insufficiency, highlighting the need for continuous fetal monitoring during induction [36].

The mean time from catheter insertion to delivery was 18.2 ± 4.1 hours, indicating a reasonably efficient induction-to-delivery interval. The cesarean section rate was 24%, which falls within acceptable limits for induced labor and compares favorably with rates reported in studies using pharmacologic agents [18]. Maternal complications were minimal; most women (92%) had no adverse effects, while reported issues such as pain (6.7%), bleeding (5.3%), and infection (1.3%) were mild and manageable. This confirms the favorable safety profile of IUBC, as previously demonstrated by multiple randomized trials and meta-analyses [37].

Neonatal outcomes were generally favorable. Low birth weight was noted in 19.3%, which likely reflects the subgroup of patients induced to receive IUGR. APGAR scores were within safe limits, with only 6.7% having 1-minute score below 7 and 3.3% having low 5-minute scores. NICU admissions were 8.7%, consistent with other studies on induced labor in high-risk populations [38, 39]. Importantly, no neonatal deaths or severe morbidities were reported, underscoring the fetal safety of IUBC when combined with vigilant intrapartum monitoring.

The findings of this study support the use of intrauterine balloon catheter as a safe and effective method for cervical ripening in women with unfavorable cervices. Its high success rate, low complication profile, and relatively short induction-to-delivery interval make it a valuable tool in obstetric practice. Given the minimal systemic effects and affordability, IUBC is especially suited for resource-limited settings like Iraq, where pharmacologic agents may be expensive or poorly tolerated. Moreover, the mechanical method avoids risks associated with uterotonic overuse, such as hyperstimulation and uterine rupture, especially in multiparous women [40, 41].

The outcomes observed in this study align with the broader body of literature on mechanical labor induction. A Cochrane review by Jozwiak et al. (2012) concluded that balloon catheters are as effective as prostaglandins in achieving vaginal delivery and are associated with fewer adverse effects [42]. Similarly, de Vaan et al. (2023) found that mechanical methods resulted in comparable maternal and neonatal outcomes with reduced need for cesarean section [8]. Our success rate (76%) and low maternal morbidity reinforce these findings and provide region-specific evidence supporting broader adoption of mechanical induction in Iraq.

This study has some limitations. Being conducted in a single tertiary hospital limits the generalizability of the findings to other healthcare settings or rural populations. The sample size, while adequate for initial assessment, may not capture rare complications or outcomes. Additionally, the study design was observational and cross-sectional, which limits the ability to establish causal relationships. Variability in the clinical assessment of Bishop scores, despite being done by trained staff, may introduce subjective bias. Furthermore, the lack of a comparison group using alternative induction methods (e.g., prostaglandins) restricts the ability to directly compare efficacy and safety profiles.

CONCLUSION AND RECOMMENDATIONS

This study shows that the intrauterine balloon catheter (IUBC) is an effective and safe method for cervical ripening, achieving a 76% success rate with minimal maternal and neonatal complications. It is particularly useful in women with an unfavourable cervix and provides a reliable alternative to pharmacological methods. The IUBC is suitable for term pregnancies, especially in resource-limited settings or when prostaglandins are contraindicated. Based on the findings, we recommend promoting IUBC as a first-line option for women with a Bishop score ≤ 5. Healthcare providers should receive proper training in insertion and monitoring techniques, and standardized protocols for foetal surveillance and oxytocin use after catheter removal should be implemented. Further randomized controlled trials comparing IUBC with prostaglandins in diverse obstetric populations in Iraq are warranted. Finally, increasing public awareness and antenatal education on induction methods may help improve patient acceptance and satisfaction.

Conflicts of Interests: None

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Ethical Approvals: Ethical approval for the study was obtained from the relevant institutional review board, and informed consent was acquired from all participants prior to their inclusion in the study.

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