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Original Article

Safety and Efficacy of High-Volume (60 mL) Foley Catheter for Induction of Labour: A Prospective Descriptive Cohort Study from Swabi, Pakistan

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Abstract

Background: Mechanical methods of cervical ripening, particularly the Foley catheter, are widely used for labour induction due to their safety, low cost, and reduced risk of uterine hyperstimulation compared with pharmacological agents. In low-resource settings, high-volume Foley catheter use may offer additional advantages; however, local evidence from Pakistan remains limited.

Objective: To evaluate the safety and efficacy of a high-volume (60 mL) Foley catheter for cervical ripening and induction of labour, with a primary focus on the rate of vaginal delivery within 24 hours.

Methodology: This prospective descriptive cohort study was conducted at Bacha Khan Medical Complex, Swabi, from June to December 2024. A total of 86 term pregnant women with singleton cephalic pregnancies and unfavorable cervices underwent labour induction using a 20 Fr Foley catheter inflated with 60 mL of normal saline. Primary and secondary outcomes included induction-to-labour interval, induction-to-delivery interval, mode of delivery, and maternal and neonatal complications.

Results: The mean maternal age was 26.8 ± 5.3 years, and the mean pre-induction Bishop score was 4.0 ± 0.82. The median induction-to-labour interval was 250.5 minutes (IQR 198–416.2), while the median induction-to-delivery interval was 682.5 minutes (IQR 550.5–870). Vaginal delivery within 24 hours was achieved in 82.5% of participants, including 75.5% spontaneous and 6.9% instrumental vaginal deliveries. Cesarean section was required in 17.4% of cases. Maternal and neonatal complications were minimal, with no cases of uterine rupture, hyperstimulation, or severe morbidity.

Conclusion: High-volume (60 mL) Foley catheter induction is a safe and effective method for cervical ripening, achieving high rates of vaginal delivery within 24 hours with minimal maternal and neonatal complications. Larger multicenter randomized trials are recommended to further validate these findings.

Keywords: Cervical Ripening, Foley Balloon Catheter, Labour Induction.

Introduction

Labour is a physiological process characterized by coordinated uterine contractions leading to progressive cervical dilatation and eventual fetal expulsion. While spontaneous labour is preferred, approximately one-fifth of pregnancies require induction due to maternal or fetal indications such as post-term pregnancy, hypertensive disorders, pre-labour rupture of membranes, or intrauterine fetal compromise [1]. The success of labour induction is strongly influenced by cervical favourability, with an unfavorable cervix reflected by a low Bishop score being associated with prolonged labour, increased intervention rates, and higher likelihood of cesarean delivery [2].

Various methods are available for labour induction, including pharmacological agents such as prostaglandins and oxytocin, as well as mechanical techniques [3]. Mechanical methods, particularly the intracervical Foley catheter, promote cervical ripening by exerting direct mechanical pressure and stimulating endogenous prostaglandin release. Compared with pharmacological agents, mechanical methods are associated with lower rates of uterine hyperstimulation and fetal compromise, making them especially suitable in low-resource settings and in women with previous uterine scars [4].

The Foley catheter is widely used because of its simplicity, affordability, and favorable safety profile. Emerging evidence suggests that balloon volume may influence the effectiveness of cervical ripening, with higher volumes potentially resulting in greater cervical dilation and shorter induction-to-delivery intervals [5]. Randomized trials and observational studies have shown that high-volume balloons (50–60 mL) may be associated with faster cervical ripening, higher rates of spontaneous labour onset, and improved vaginal delivery outcomes without increasing maternal or neonatal complications [6–9].

Studies from South Asia and similar healthcare settings further support the tolerability and effectiveness of larger balloon volumes, reporting higher probabilities of delivery within 12–24 hours compared with standard 30 mL balloons [10]. Local data from Pakistan have also suggested that a 60 mL Foley catheter may be more effective than lower volumes for labour induction, particularly in achieving timely vaginal delivery [11]. Despite these encouraging findings, evidence from prospective cohort studies in the Pakistani population remains limited.

This study was therefore conducted to assess the safety and efficacy of a high-volume (60 mL) Foley catheter for labour induction in a prospective descriptive cohort at Swabi. By evaluating maternal and neonatal outcomes, this study aims to contribute locally relevant evidence to guide clinical practice and optimize induction strategies in resource-limited settings.

Methodology

Study Design

This study was designed as a prospective descriptive cohort study to evaluate the safety and efficacy of a high-volume (60 mL) Foley catheter for cervical ripening and induction of labour. The study followed women from induction through delivery, with outcomes assessed over a 24-hour period after catheter placement.

Ethics

Ethical approval was obtained prior to study initiation from the Institutional Ethical Review Committee of Bacha Khan Medical Complex, Swabi (Approval No. 2290/EB/GKMC). All eligible participants were informed about the purpose of the study, the procedure involved, potential benefits, and possible risks. Written informed consent was obtained from each participant or her accompanying relative before catheter placement and data collection. Confidentiality of patient information was strictly maintained throughout the study.

Setting

The study was conducted in the Department of Obstetrics and Gynecology at Bacha Khan Medical Complex, Swabi, Pakistan, a tertiary care referral hospital providing comprehensive maternal and neonatal services. Participant recruitment and follow-up were carried out from 10 June 2024 to 9 December 2024.

Participants

Pregnant women were enrolled through consecutive non-probability sampling based on predefined inclusion and exclusion criteria. Inclusion criteria comprised women with a singleton live pregnancy, cephalic presentation, gestational age ≥ 37 weeks, intact fetal membranes, and an unfavorable cervix defined as a Bishop score greater than 2 and less than 6. Women with a history of one previous cesarean section were also included, as mechanical methods of induction are considered safer in scarred uteri. Exclusion criteria included multiple pregnancies, preterm gestation, spontaneous labour, breech presentation, preterm rupture of membranes, previous myomectomy, placenta previa, and known fetal congenital anomalies.

Variables

The primary efficacy outcome was successful induction, defined as vaginal delivery within 24 hours of Foley catheter placement. Secondary efficacy outcomes included induction-to-labour interval, induction-to-delivery interval, change in Bishop score, spontaneous expulsion of the Foley catheter, need for oxytocin augmentation, and mode of delivery. Safety outcomes included maternal complications such as infection, uterine hyperstimulation, vaginal bleeding, uterine rupture, ICU admission, and neonatal outcomes including Apgar score at 5 minutes and NICU admission.

Data Sources/Measurement

Baseline maternal characteristics, obstetric history, and clinical parameters were recorded using a structured proforma. Cervical assessment was performed by a consultant gynecologist using the Bishop scoring system prior to induction and after catheter removal. Labour induction was initiated by inserting a 20 Fr Bardia® two-way Foley catheter into the cervical canal under strict aseptic conditions, with balloon inflation using 60 mL of normal saline. Participants were reassessed every 3–4 hours for uterine contractions, fetal heart rate, membrane status, cervical changes, bleeding, and spontaneous catheter expulsion. After 12 hours, if the catheter had not expelled, it was removed and cervical maturity reassessed. Oxytocin augmentation was administered according to institutional protocol when indicated. Labour monitoring was conducted using the World Health Organization Labour Care Guide.

Bias

To minimize observer bias, all clinicians and research assistants involved in data collection were trained on standardized assessment procedures, particularly for Bishop score evaluation and outcome measurement. Consecutive sampling was used to reduce selection bias. Although the descriptive design lacked a comparison group, uniform induction protocols and outcome definitions were applied to all participants to enhance internal consistency.

Study Size

Sample size was calculated using the World Health Organization sample size calculator for a single proportion. Assuming a 70% success rate of vaginal delivery within 24 hours, with a 95% confidence interval and a 10% margin of error, the minimum required sample size was 81 participants. To improve precision and account for potential exclusions, a total of 86 eligible women were enrolled.

Quantitative Variables

Continuous variables such as age, body mass index, gestational age, abdominal circumference, uterine height, Bishop score, and induction intervals were treated as quantitative variables. These were summarized using means with standard deviations or medians with interquartile ranges, depending on data distribution. Categorical variables such as parity, previous cesarean section, mode of delivery, and complication rates were expressed as frequencies and percentages.

Statistical Methods

Data analysis was performed using Statistical Package for Social Sciences (SPSS) version 23. Descriptive statistics were used to summarize baseline characteristics and outcomes. Comparisons between categorical variables were conducted using Chi-square or Fisher's exact test, while continuous variables were compared using Student's t-test or Mann–Whitney U test as appropriate. Multivariate logistic regression analysis was performed to assess the effect of parity and previous cesarean section on the likelihood of spontaneous vaginal delivery within 24 hours. A p-value of ≤ 0.05 was considered statistically significant.

Results

Participants

During the study period, a total of 541 pregnant women were assessed for eligibility for labour induction at Bacha Khan Medical Complex, Swabi. Of these, 86 women fulfilled the inclusion criteria and were enrolled in the study, undergoing induction of labour with a 20 Fr Foley catheter inflated with 60 mL of normal saline. One participant experienced rupture of membranes during catheter placement and was excluded from further analysis. The final cohort consisted of 86 women who were followed prospectively from induction through delivery, as illustrated in the patient flow diagram (Figure 1).

Descriptive Data

The mean age of the study participants was 26.8 ± 5.3 years, with an age range of 18 to 38 years. The mean body mass index was 25.0 ± 2.7 kg/m². Obstetric assessment revealed a mean abdominal circumference of 99.2 ± 3.5 cm and a mean uterine height of 35.3 ± 1.6 cm. The mean gestational age at induction was 272.4 ± 7.0 days. Cervical assessment prior to induction demonstrated an unfavorable cervix, with a mean Bishop score of 4.0 ± 0.82. Multigravida women constituted the majority of the cohort (61.6%), while 38.4% were primigravida. A previous cesarean section was documented in 24.4% of participants (Table 01).

Outcome Data

The median induction-to-labour interval was 250.5 minutes (interquartile range [IQR] 198–416.2), while the median induction-to-delivery interval was 682.5 minutes (IQR 550.5–870). Vaginal delivery was achieved in 82.5% of women, with 75.5% delivering spontaneously and 6.9% requiring instrumental vaginal delivery. Cesarean section was required in 17.4% of cases, primarily due to non-reassuring fetal heart rate patterns, non-progressive labour, or persistently unfavorable Bishop scores. Oxytocin augmentation was required in 31.3% of participants, predominantly among primigravida women. Neonatal outcomes were favorable, with 98.8% of newborns having an Apgar score ≥ 7 at five minutes, and only one neonate requiring NICU admission. Maternal complications were minimal, with postpartum fever observed in two cases, both resolving with antibiotic modification (Table 02).

Main Results

Successful induction, defined as vaginal delivery within 24 hours, was achieved in 82.5% of participants. Women with successful induction had significantly lower abdominal circumference and uterine height, higher gestational age, and higher pre-induction Bishop scores compared with those who experienced failed induction ($p < 0.05$). Post-induction Bishop scores increased substantially among women who achieved vaginal delivery (Table 03). Multivariate logistic regression analysis demonstrated that primigravida women had significantly higher odds of spontaneous vaginal delivery within 24 hours compared with multigravida women (OR 14.5; 95% CI 1.7–123.4; $p = 0.01$), while a history of previous cesarean section significantly reduced the likelihood of spontaneous vaginal delivery (OR 0.09; 95% CI 0.010–0.87; $p = 0.03$) (Table 04). Kaplan–Meier analysis showed that the majority of participants delivered within 24 hours of induction, confirming the efficiency of the high-volume Foley catheter for labour induction (Figure 2).

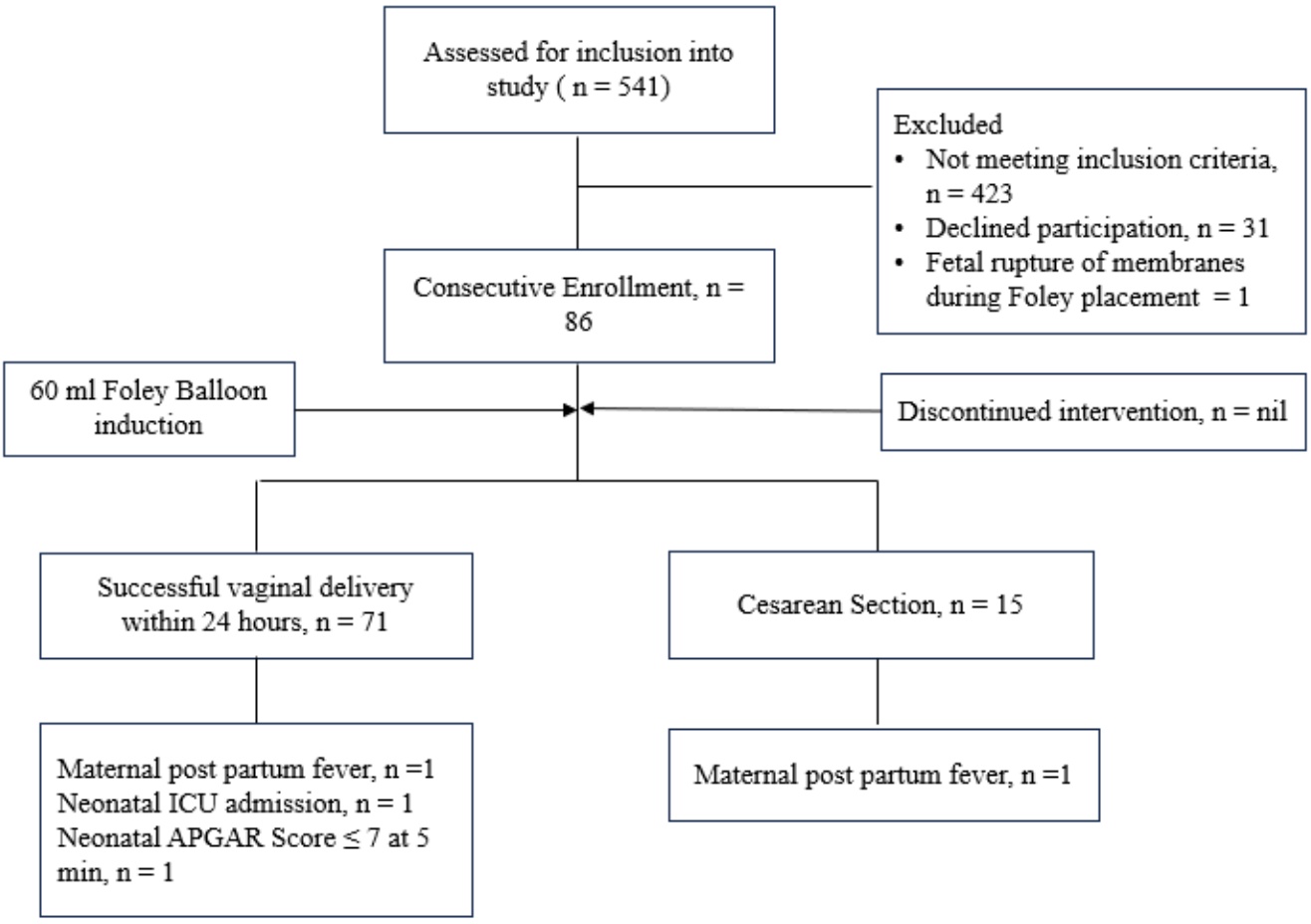


Figure 1: Patient flow diagram.

Table 1: Characteristics of patients and outcome of high-volume 20 Fr Foley catheter induction (N = 86).

Variable		N(%)
Age (years); Mean ± SD		26.86 ± 5.35
BMI; Mean ± SD		25 ± 2.7
Gravida	Primigravida	33 (38.37)
	Multigravida	53 (61.62)
Previous scar	Yes	21 (24.4)
	No	65 (75.5)
Abdominal circumference (cm); Mean ± SD		99.2 ± 3.5
Uterine height (cm); Mean ± SD		35.3 ± 1.6
Gestational age(days); Mean ± SD		272.4 ± 7.0
Bishop Score; Mean ± SD		4.0 ± 0.82
Induction-labour interval (Min); Median (IQR)		250.5 (198-416.2)
Induction-Delivery interval (Min); Median (IQR)		682.5 (550.5-870)
Mode of Delivery	Spontaneous Vaginal	65 (75.5)
	Instrumental vaginal	6 (6.9)
	Caesarean	15 (17.4)
Oxytocin augmentation		27 (31.3)
Repeat C- section in previously scarred		5 (23.8)
Indication for Caesarean section	Non reassuring fetal heart rate	4 (4.6)
	Non progressive Labor	6 (6.9)
	Poor Bishop Score	5 (5.8)
Neonatal APGAR score at 5 min ≥ 7		85 (98.8)
NICU admission		01 (1.1)
Maternal post-partum fever		02 (2.3)

Categorical data presented as frequency and percentages.

Table 2: Comparison of 20Fr high-volume Foley catheter induction in successful and failed vaginal delivery groups.

Variable		Successful vaginal delivery N (%) (N=71)	Failed vaginal delivery N (%) (N=15)	p-value
Age		27.3 ± 5.5	25.0 ± 3.9	0.20*
BMI		25.1 ± 2.8	25.1 ± 2.1	0.90*
Gravidity	Primigravida	21 (29.5)	9 (60)	0.03ł
	Multigravida	50 (70.4)	6 (40)	
Abdominal circumference (cm)		98.7 ± 3.4	102 ± 2.0	< 0.001 *
Uterine height (cm)		35.1 ± 1.6	36.2 ± 1.2	0.02*
Gestational age (days)		273.6 ± 6.6	266.6 ± 5.9	< 0.001 *
Bishop score	Pre-induction	4.2 ± 0.7	3.2 ± 0.4	< 0.001 *
	Post-induction	8.35 ± 0.8	4.27 ± 0.6	
Previous Caesarean section	No	55 (77.4)	10 (66.6)	0.50 ł
	Yes	16 (22.5)	5 (33.3)	
Indications for labor induction	Gestational Diabetes	12 (16.9)	3 (0.2)	0.70ł
	Hypertension	15 (21.1)	3 (0.20)	1.00ł
	Pre-eclampsia	13 (18.3)	2 (13.3)	1.00ł
	Cholestasis	13 (18.3)	2 (13.3)	1.00ł
	Post term pregnancy	11 (15.5)	1 (6.6)	0.60ł
	Fetal growth restriction	8 (11.2)	--	0.30ł
Induction-labour interval (Min)		316.3 ±151.4	--	< 0.001#
Induction-Delivery interval (Min)		710.6 ± 215.3	--	< 0.001#
Neonatal weight		3202.6 ± 127.7	3193.6 ± 153.6	0.8
Neonatal APGAR Score > 7 at 5 min		70 (98.6)	15 (100)	--
Neonatal APGAR Score ≤ 7 at 5 min		01 (1.4)	--	
NICU admission		01 (1.4)	--	--
Maternal post-partum fever		01 (1.4)	01 (6.6)	--

* Student- t test /ANOVA test applied

Mann–Whitney U test applied.

ł Chi square/ Fischer's exact test applied

Table 3: Comparison of 20Fr high-volume Foley catheter induction in patients with and without previous C- section.

Variable		No Previous C-section N (%) (N = 65)	History of previous C-section N (%) (N = 21)	p-value
Age		27.0 ± 5.2	26.6 ± 5.6	0.70 *
BMI		25.0 ± 2.9	25.5 ± 1.9	0.40 *
Gravidity	Primigravida	30 (46.1)	--	< 0.001 ǂ
	Multigravida	35 (53.8)	21(100)	
Abdominal circumference (cm)		99.3 ± 3.6	99.0 ± 3.1	0.50 *
Uterine height (cm)		35.3 ± 1.6	35.3 ± 1.3	0.80 *
Gestational age (days)		272.8 ± 7.1	271.0 ± 6.4	0.30 *
Bishop score	Pre-induction	4.2 ± 0.7	3.7 ± 0.9	0.01 *
	Post-induction	7.7 ± 1.6	7.3 ± 2.0	0.40
Indications for labor induction	Gestational Diabetes	12 (18.4)	3 (14.2)	1.00 ǂ
	Hypertension	14 (21.5)	4 (19)	1.00 ǂ
	Pre-eclampsia	11 (16.9)	4 (19)	1.00 ǂ
	Cholestasis	9 (13.8)	6 (28.5)	0.10 ǂ
	Post term pregnancy	11 (16.9)	1 (4.7)	0.20 ǂ
	Fetal growth restriction	13 (0.2)	3 (14.2)	0.70 ǂ
Induction-labour interval (Min)		316.3 ±151.4	--	0.60*
Induction-Delivery interval (Min)		710.6 ± 215.3	--	0.40*
Mode of delivery	Vaginal	55 (84.6)	16 (76.1)	0.50
	C- section	10 (15.3)	5 (23.8)	
Neonatal weight		3193.9 ± 137.1	3223.6 ± 113.0	0.30
Neonatal APGAR Score > 7 at 5 min		64 (98.6)	21 (100)	--
Neonatal APGAR Score ≤ 7 at 5 min		01 (1.5)	--	
NICU admission		01 (1.5)	--	--
Maternal post-partum fever		01 (1.5)	01 (4.7)	--

* Student- t test /ANOVA test applied

Mann–Whitney U test applied.

ǂ Chi square/ Fischer's exact test applied

Table 4: Multivariate logistic regression analysis for effect of parity and previous C-section on spontaneous vaginal delivery within 24 hours.

Variable	Odds ratio	95% CI	P value
Parity	14.5	1.7 – 123.4	0.01
Previous C-section	0.09	0.010 - 0.87	0.03

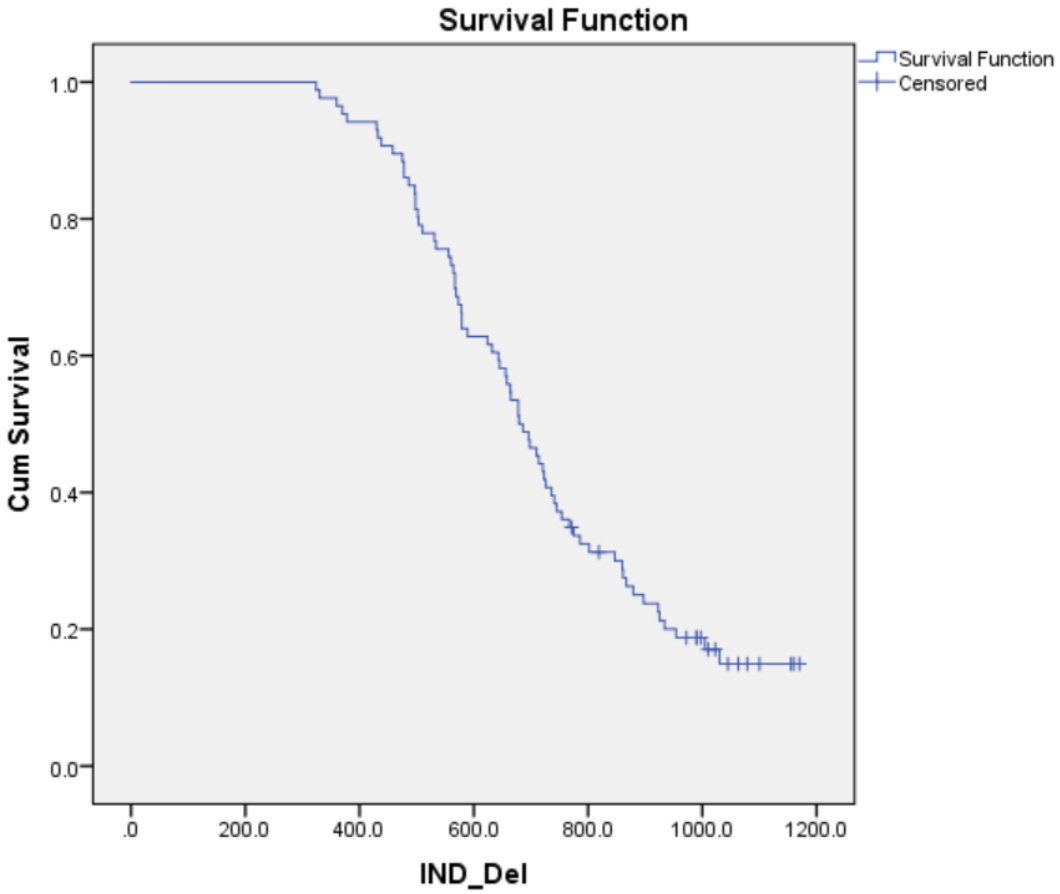


Figure 2: Kaplan–Meier figure for induction-to-delivery interval.

Discussion

Labour induction is undertaken in approximately one-fifth of pregnancies worldwide for maternal or fetal indications, and its success is closely linked to cervical favourability [12-15]. Mechanical cervical ripening using a Foley catheter has gained renewed attention due to its favorable safety profile, simplicity, and reduced risk of uterine hyperstimulation compared with pharmacological agents [16]. The present prospective cohort study demonstrates that induction of labour using a high-volume (60 mL) Foley catheter is both safe and effective, achieving a high rate of vaginal delivery within 24 hours with minimal maternal and neonatal complications.

In this study, successful vaginal delivery was achieved in 82.5% of participants, which is consistent with previously published data reporting high success rates with mechanical induction methods [17,18]. The high efficacy observed may be attributed to the greater mechanical stretching of the cervix produced by larger balloon volumes, which enhances endogenous prostaglandin release and accelerates cervical ripening. This finding supports the hypothesis that increasing balloon volume can improve induction efficiency without compromising safety. Delivery within 24 hours was achieved in the majority of women, aligning with findings from randomized and

observational studies that have demonstrated shorter induction-to-delivery intervals with high-volume Foley catheters compared with standard 30 mL balloons [19,20]. The rates of instrumental vaginal delivery observed in this study were comparable to those reported in the literature [21,22], suggesting that the use of a high-volume Foley catheter does not increase the likelihood of operative vaginal birth. Improved cervical preparedness likely contributed to the favorable mode-of-delivery outcomes observed.

Safety outcomes in the present study were reassuring. The Foley catheter insertion technique was well tolerated, with only one case of rupture of membranes during catheter placement, leading to exclusion from the study. No cases of uterine hyperstimulation, uterine rupture, or significant hemorrhage were observed. These findings are consistent with previous reports indicating the safety of Foley catheter use, even with balloon inflation beyond the manufacturer's standard volume [8]. In contrast, Sandberg et al. reported a higher rate of balloon rupture in the 60 mL group compared with the 30 mL group,[7] possibly due to structural variability in catheter material. No balloon ruptures occurred in the present study, suggesting that catheter integrity and careful insertion technique are critical determinants of safety.

The use of a high-volume Foley catheter was also found to be safe in women with a previous cesarean section, with no cases of uterine rupture or severe maternal morbidity. Oxytocin augmentation was required in approximately one-third of patients, predominantly among primigravida women, a finding consistent with prior observational studies [23]. Maternal infectious morbidity was minimal, with only two cases of postpartum fever that resolved with antibiotic adjustment and did not progress to sepsis. Neonatal outcomes were similarly favorable, with excellent Apgar scores and only one NICU admission. These findings are in line with recent studies reporting low maternal and neonatal complication rates following Foley catheter induction.

Limitations

Despite its strengths, this study has certain limitations. First, the single-center design may limit the generalizability of the findings to other healthcare settings. Second, the absence of a control group using a lower balloon volume or pharmacological induction method restricts direct comparative analysis. Third, data on analgesia use during labour were not collected, which may have influenced labour progression and maternal experience. Finally, although efforts were made to standardize Bishop score assessment, some degree of observer variability cannot be entirely excluded. Nevertheless, standardized training of research staff and consistent use of institutional protocols likely minimized this effect. These limitations should be considered when interpreting the findings.

Conclusion

High-volume (60 mL) Foley catheter induction is a safe and highly effective method for cervical ripening, resulting in a high proportion of vaginal deliveries within 24 hours and minimal maternal and neonatal complications. The technique is particularly well suited for resource-limited settings due to its low cost, ease of use, and favorable safety profile, including in women with a previous cesarean section. Multicenter randomized controlled trials are warranted to further validate these findings and to directly compare high-volume Foley catheter induction with alternative induction methods.

Authors' Contributions:

All authors meet the ICMJE criteria for authorship.

Author 1: Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 2: Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 3: Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.
Author 4: Analysis and interpretation of data, critical revision, final approval, agreed to be accountable for all the work.

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