

EFFECTIVENESS AND SAFETY OF A 16-GAUGE INTRACERVICAL FOLEY CATHETER FOR CERVICAL RIPENING AND INDUCTION OF LABOUR: A PROSPECTIVE STUDY

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ABSTRACT

Background: Osteoporotic vertebral compression fractures cause pain, disability, and reduced quality of life in the elderly. Percutaneous vertebroplasty stabilises fractures using polymethylmethacrylate cement. This study evaluated clinical and functional outcomes using the visual analogue scale (VAS) medication score, and overall clinical outcome assessment. **Materials and Methods:** This prospective observational study evaluated patients treated at the Tirunelveli Government Medical College from July 2015 to September 2017. All patients underwent clinical evaluation and radiological assessment using plain radiography and computed tomography. Percutaneous vertebroplasty was performed using a transpedicular approach under fluoroscopic guidance. Outcomes were assessed using the VAS, along with activity score and medication score to evaluate functional improvement and analgesic requirement. **Results:** Twenty patients were evaluated, including 15 women (75%) and five men (25%). Single-, double-, and triple-level vertebral involvement occurred in 14 (70 %), four (20 %), and two (10) patients, respectively. Excellent outcomes were achieved in 14 (70 %) patients, good outcomes in three (15%), fair outcomes in one (5%), and poor outcomes in two (10%). Cement leakage occurred in two (10 %) patients. Asymptomatic status improved from 14 (70%) patients' post-procedure to 18 (90%) at 12 months. Pain scores decreased from 6.26±1.75 to 1.59±1.99 immediately and to 0.24±0.99 at 3 months. Activity scores improved from 1.38±1.41 to 0.53±1.23 immediately and 0.26±0.79 at 3 months. Medication scores decreased from 1.15±0.99 to 0.41±0.56 immediately and 0.06±0.24 at 3 months. **Conclusion:** Percutaneous vertebroplasty is safe and effective, providing rapid pain relief, functional improvement, and reduced medication requirements in osteoporotic vertebral compression fractures with minimal complications.

INTRODUCTION

Labour is a physiological process that results in the delivery of the fetus, placenta and fetal membranes. Induction of labour is defined as the artificial initiation of uterine contractions before the spontaneous onset of labour, with or without rupture of membranes, to achieve vaginal delivery. It is one of the most commonly performed obstetric interventions worldwide and is indicated when the benefits of delivery outweigh the risks of continuing pregnancy. Common indications include postdated pregnancy, hypertensive disorders of pregnancy, oligohydramnios, fetal growth restriction, diabetes complicating pregnancy and other maternal or fetal

conditions requiring timely delivery. Successful induction aims to achieve vaginal birth with minimal maternal and neonatal morbidity.^[1-4]

The success of labour induction is closely related to the condition of the cervix before induction. An unfavourable cervix is associated with prolonged labour, failed induction and increased rates of operative delivery. The Bishop score, first described by Bishop in 1964, remains the most widely accepted clinical tool for assessing cervical favourability by evaluating cervical dilatation, effacement, consistency, position and fetal station. Women with a low Bishop score generally require cervical ripening before induction to improve the likelihood of successful vaginal delivery.^[11,13,14]

Cervical ripening is a complex physiological process involving biochemical, inflammatory and structural changes within the cervix that lead to softening, effacement and dilatation. Various methods are available to achieve cervical ripening, including pharmacological agents such as prostaglandins and mechanical methods such as membrane sweeping, hygroscopic dilators and transcervical Foley catheterization. Although prostaglandins are effective, their use may be associated with uterine tachysystole, hyperstimulation and fetal heart rate abnormalities. Mechanical methods have therefore gained increasing popularity because they provide effective cervical ripening with a lower risk of excessive uterine activity.^[6,10,12,15,16]

The transcervical Foley catheter is a simple, inexpensive and widely available mechanical method of cervical ripening. It acts by exerting direct pressure on the internal cervical os, causing mechanical dilatation and separation of the fetal membranes from the lower uterine segment. This stimulates endogenous prostaglandin release and enhances cervical remodelling, ultimately facilitating the onset of labour. Because of its ease of insertion, minimal systemic side effects and lower incidence of uterine hyperstimulation, the Foley catheter has become an attractive alternative to pharmacological agents, particularly in women with an unfavourable cervix and in resource-limited settings.^[6-8,18]

Several randomized controlled trials, systematic reviews and international guidelines have demonstrated that Foley catheter induction is associated with significant improvement in Bishop scores, satisfactory vaginal delivery rates and low maternal and neonatal complication rates. In addition, the method is cost-effective, does not require refrigeration, and can be safely used in women in whom prostaglandins are contraindicated or should be avoided. These advantages have contributed to its widespread use as a first-line cervical ripening method in many obstetric units. However, outcomes may vary depending on maternal characteristics, gestational age, indication for induction and cervical status at admission.^[5-10,17-20]

Despite the increasing use of the Foley catheter for cervical ripening, evidence from different populations and healthcare settings remains essential for optimizing induction protocols. The present prospective controlled study was therefore undertaken at Sri Venkateswara Medical College Hospital and Research Institute to evaluate the effectiveness and safety of a 16-Gauge intracervical Foley catheter as a cervical ripening agent in women undergoing induction of labour. The study assessed improvement in Bishop score, need for additional prostaglandin and oxytocin augmentation, induction-to-delivery interval, mode of delivery, and maternal and neonatal outcomes in 200 antenatal women.

MATERIALS AND METHODS

Study Design: This was a prospective controlled study conducted to evaluate the effectiveness and safety of a 16-Gauge intracervical Foley catheter for cervical ripening in women undergoing induction of labour. Participants were prospectively followed from the time of induction until delivery, and maternal and neonatal outcomes were recorded.

Study Setting: The study was conducted in the Department of Obstetrics and Gynaecology, Sri Venkateswara Medical College Hospital and Research Institute. The hospital serves as a major referral centre for high-risk obstetric cases in the region.

Study Duration: The study was carried out over a period of eight months, from January 2025 to August 2025. During this period, eligible pregnant women requiring induction of labour were consecutively enrolled and followed until delivery.

Study Population: The study population comprised pregnant women admitted for induction of labour with an unfavourable cervix (Bishop score <5). Eligible participants included women with singleton pregnancies in cephalic presentation and intact fetal membranes who required induction for obstetric or medical indications. All participants were recruited after obtaining written informed consent and were managed according to the institutional induction protocol.

Sample Size

A total of **200 antenatal women** meeting the eligibility criteria were included in the study. All eligible women admitted during the study period who consented to participate were enrolled consecutively.

Inclusion Criteria

1. Singleton pregnancy with a live fetus or a pregnancy requiring induction as per institutional indications.
2. Cephalic fetal presentation with intact fetal membranes.
3. Unfavourable cervix with a Bishop score <5 requiring cervical ripening.
4. Term, post-term, or selected preterm pregnancies scheduled for induction of labour.
5. Women with obstetric or medical indications for induction of labour, including hypertensive disorders of pregnancy, diabetes mellitus complicating pregnancy, oligohydramnios, abnormal Doppler studies, Rh isoimmunization, intrauterine fetal demise, or fetal anomalies.

Exclusion Criteria

1. Low-lying placenta (placenta previa).
2. Malpresentation.
3. Rupture of fetal membranes before induction.
4. Clinical evidence of maternal genital tract or systemic infection.
5. Any contraindication to vaginal delivery or intracervical Foley catheter insertion.

Patient Recruitment

Pregnant women admitted to the Department of Obstetrics and Gynaecology, Sri Venkateswara Medical College Hospital and Research Institute, for induction of labour during the study period (January 2025 to August 2025) were consecutively screened for eligibility. Women who fulfilled the predefined inclusion criteria and had no exclusion criteria were considered for enrolment. The study objectives, procedure, potential benefits, and possible risks were explained to each eligible participant in their native language, and written informed consent was obtained prior to recruitment. A total of 200 antenatal women were enrolled consecutively and followed prospectively from the time of induction until delivery. Participants underwent induction using a 16-Gauge intracervical Foley catheter according to the institutional protocol, and maternal and neonatal outcomes were recorded until hospital discharge.

Study Intervention (Intracervical Foley Catheter Procedure)

All enrolled participants underwent cervical ripening using a 16-Gauge intracervical Foley catheter under strict aseptic precautions. Prior to the procedure, baseline maternal vital signs, fetal heart rate, and cardiotocography (CTG) findings were recorded to exclude fetal compromise. The patient was placed in the lithotomy position, and after appropriate antiseptic preparation, the cervix was visualized using a sterile Cusco's speculum. The Foley catheter was gently introduced through the endocervical canal under direct visualization until the balloon passed beyond the internal cervical os.

The catheter was retained in situ for a maximum duration of 12 hours to facilitate cervical ripening. During this period, maternal pulse rate, blood pressure and fetal heart rate were monitored regularly. Following spontaneous expulsion or removal of the catheter after the designated period, the cervix was reassessed and the Bishop score was recalculated to determine the degree of cervical ripening. Women who failed to develop adequate uterine contractions after catheter removal received prostaglandin E₂ (PGE₂) for further cervical ripening whenever indicated, and oxytocin augmentation was administered according to labour progress and institutional protocol. Maternal and neonatal outcomes, including induction-to-delivery interval, mode of delivery, APGAR scores and maternal or fetal complications, were documented until delivery.

Labour Management Protocol

Following insertion of the 16-Gauge intracervical Foley catheter, all participants were observed in the labour ward for a maximum period of 12 hours. Cervical ripening was assessed by repeating the Bishop score after spontaneous expulsion or removal of the catheter. Women who failed to achieve adequate cervical ripening or effective uterine contractions received additional cervical ripening with prostaglandin E₂ (PGE₂) as indicated. Oxytocin augmentation was administered according

to the institutional labour management protocol in women with inadequate uterine contractions after cervical ripening.

The progress of labour was monitored throughout the induction process, and the mode of delivery was decided based on obstetric indications and maternal-fetal condition. Outcome measures included induction-to-delivery interval, induction-to-augmentation interval, augmentation-to-delivery interval, mode of delivery, and indications for caesarean section.

Maternal Monitoring

Maternal monitoring was performed before induction, during the cervical ripening process, throughout labour, and until delivery to ensure maternal safety and to identify any complications at the earliest stage. Baseline maternal pulse rate and blood pressure were recorded prior to Foley catheter insertion. A comprehensive clinical assessment, including general physical and obstetric examination, was carried out before induction. During the induction process, maternal vital signs, uterine activity, progress of labour and cervical changes were monitored at regular intervals. The response to cervical ripening was assessed by repeating the Bishop score following spontaneous expulsion or removal of the Foley catheter after the observation period.

Throughout labour, participants were closely observed for the development of maternal complications, including postpartum haemorrhage, puerperal sepsis and any adverse events related to induction. The requirement for additional prostaglandin administration, oxytocin augmentation and operative intervention was documented. Maternal outcomes, including the mode of delivery and complications occurring during labour and the immediate postpartum period, were recorded and analysed to evaluate the safety of intracervical Foley catheter induction.

Fetal Monitoring

Fetal monitoring was carried out before induction, during the cervical ripening process, throughout labour, and immediately after delivery to ensure fetal well-being and to identify early signs of fetal compromise. Prior to induction, cardiotocography (CTG) was performed to assess baseline fetal heart rate and exclude evidence of fetal distress. Obstetric ultrasonography was also performed to evaluate fetal biometry, presentation, and amniotic fluid volume before initiating induction.

Following insertion of the intracervical Foley catheter, fetal heart rate was monitored at regular intervals throughout the induction process and during active labour. Continuous clinical surveillance was maintained to detect fetal distress or other intrapartum complications requiring timely intervention. After delivery, neonatal well-being was assessed using the APGAR scores at 1 and 5 minutes, and the need for neonatal resuscitation or admission to the Neonatal Intensive Care Unit (NICU) was documented. Neonatal outcomes and fetal

complications were recorded as part of the study to evaluate the safety of intracervical Foley catheter induction.

Outcome Measures

Primary Outcome

The primary outcome of the study was the effectiveness of the 16-Gauge intracervical Foley catheter in cervical ripening, assessed by the improvement in the Bishop score. The Bishop score was recorded before Foley catheter insertion and reassessed after spontaneous expulsion or removal of the catheter following the 12-hour observation period. The change in Bishop score was used as the principal indicator of successful cervical ripening.

Secondary Outcomes

The **secondary outcomes** were evaluated to determine the effectiveness of labour induction and the safety of the intracervical Foley catheter. These included:

- Requirement for additional prostaglandin E₂ (PGE₂) for cervical ripening.
- Requirement for oxytocin augmentation during labour.
- Induction-to-delivery interval.
- Induction-to-augmentation interval.
- Augmentation-to-delivery interval.
- Mode of delivery (spontaneous vaginal delivery, assisted vaginal delivery, or lower segment caesarean section).
- Indications for caesarean section.
- Maternal complications, including postpartum haemorrhage, puerperal sepsis and other adverse events.
- Neonatal outcomes, including APGAR scores at 1 and 5 minutes, neonatal resuscitation, admission to the Neonatal Intensive Care Unit (NICU), and neonatal complications.

Data Collection

Data were collected prospectively using a predesigned and standardized case record proforma for all enrolled participants. Baseline information, including maternal age, parity, gestational age, indication for induction, associated obstetric or medical comorbidities, and pre-induction Bishop score, was recorded at the time of admission. Details of the intracervical Foley catheter insertion, duration of catheter placement, need for additional prostaglandin E₂ (PGE₂), oxytocin augmentation, and labour progression were documented throughout the induction process. Maternal outcomes, including mode of delivery, induction-to-delivery interval, indications for caesarean section, and maternal complications, were recorded. Neonatal data, including birth weight, APGAR scores at 1 and 5 minutes, neonatal complications, need for resuscitation, and admission to the Neonatal Intensive Care Unit (NICU), were collected immediately after delivery. All collected data were entered into a structured database for subsequent statistical analysis.

Ethical Considerations

The study protocol was prepared in accordance with the guidelines of The Tamil Nadu Dr. M.G.R. Medical University. Approval to conduct the study was obtained from the Sri Venkateswara Medical College Hospital and Research Institute - **Institutional Ethics Committee** before the commencement of the study. All eligible participants were informed about the purpose, study procedures, potential benefits, and possible risks in a language they could understand. Written informed consent was obtained from each participant prior to enrolment. Participation in the study was entirely voluntary, and participants were assured that refusal to participate or withdrawal from the study would not affect the standard of medical care received. Confidentiality and anonymity of patient information were maintained throughout the study by de-identifying all participant data and using the collected information solely for research purposes.

Statistical Analysis

The collected data were entered into Microsoft Excel and analysed using the Statistical Package for the Social Sciences (SPSS) software version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. The paired Student's *t*-test was used to compare pre- and post-induction Bishop scores. Associations between categorical variables were analysed using the Chi-square test or Fisher's exact test, wherever appropriate. Pearson's correlation coefficient was used to determine the relationship between continuous variables. A two-sided *p*-value <0.05 was considered statistically significant.

RESULTS

A total of 200 antenatal women with an unfavourable cervix (Bishop score <5) who underwent induction of labour using a 16-Gauge intracervical Foley catheter were included in the study. Maternal demographic characteristics, obstetric profile, effectiveness of cervical ripening, labour outcomes, and maternal and neonatal outcomes were analysed.

Baseline Characteristics of the Study Population

A total of 200 antenatal women who underwent induction of labour with a 16-Gauge intracervical Foley catheter were included in the study. The mean maternal age was 25.26 ± 4.10 years (range, 17–38 years). Nearly half of the participants (47.5%) were aged 21–25 years, and 60.0% were primigravidae. With respect to gestational age, 40.5% had postdated pregnancies, 40.0% were at term, and 19.5% were preterm. Most women had a normal amniotic fluid index (69.5%), while oligohydramnios was present in 23.0%. Overall, 65.5% of participants had no maternal comorbidities, whereas hypertensive disorders were the most common associated condition (25.5%). The most frequent indication for

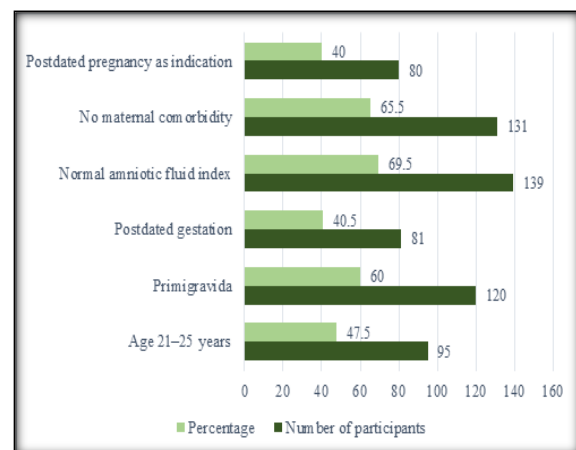
induction of labour was postdated pregnancy (40.0%), followed by hypertensive disorders (25.0%), oligohydramnios (15.5%), abnormal

Doppler studies (9.5%), and gestational diabetes mellitus (8.0%). [Table 1]

Table 1: Baseline demographic and obstetric characteristics of the study participants (N = 200)

Variable	Category	n (%)
Maternal age (years)	<20	24 (12.0)
	21–25	95 (47.5)
	26–30	62 (31.0)
	31–35	15 (7.5)
	>35	4 (2.0)
Parity	Primigravida	120 (60.0)
	Multigravida	80 (40.0)
Gestational age	Preterm	39 (19.5)
	Term	80 (40.0)
	Postdated	81 (40.5)
Amniotic fluid index	Normal	139 (69.5)
	Reduced (Oligohydramnios)	46 (23.0)
	Elevated (Polyhydramnios)	15 (7.5)
Maternal comorbidity	None	131 (65.5)
	Hypertensive disorders	51 (25.5)
	Other comorbidities	18 (9.0)
Primary indication for induction	Postdated pregnancy	80 (40.0)
	Hypertensive disorders	50 (25.0)
	Oligohydramnios	31 (15.5)
	Abnormal Doppler findings	19 (9.5)
	Gestational diabetes mellitus	16 (8.0)
	Other indications	4 (2.0)

Note: Data are presented as frequency (n) and percentage (%). Gestational age was categorized as preterm (<37 weeks), term (37–40 weeks), and postdated (>40 weeks). AFI = Amniotic Fluid Index; GDM = Gestational Diabetes Mellitus.



Note: The figure presents the most frequent baseline demographic and obstetric characteristics of the study population. Values are expressed as frequency (n) and percentage (%). AFI = Amniotic Fluid Index. The percentages represent the proportion of participants within each characteristic category and are not cumulative.

Obstetric Characteristics

The obstetric characteristics of the study population are presented in Table 2. Of the 200 participants, 81 (40.5%) had postdated pregnancies, 80 (40.0%) were at term, and 39 (19.5%) had preterm pregnancies. Assessment of the amniotic fluid index (AFI) showed that 139 women (69.5%) had a normal AFI, while 46 (23.0%) had oligohydramnios and 15 (7.5%) had polyhydramnios. The most common indication for induction of labour was postdated pregnancy (40.0%), followed by hypertensive disorders of pregnancy (25.0%), oligohydramnios (15.5%), abnormal Doppler studies (9.5%), and gestational diabetes mellitus (8.0%). [Table 2]

Table 2: Obstetric characteristics of the study participants (N = 200)

Characteristic	Category	n	%
Gestational age	Preterm	39	19.5
	Term	80	40.0
	Postdated	81	40.5
Amniotic Fluid Index (AFI)	Normal	139	69.5
	Reduced (Oligohydramnios)	46	23.0
	Elevated (Polyhydramnios)	15	7.5
Primary indication for induction of labour	Postdated pregnancy	80	40.0
	Hypertensive disorders of pregnancy	50	25.0
	Oligohydramnios	31	15.5
	Abnormal Doppler studies	19	9.5
	Gestational diabetes mellitus	16	8.0
	Other indications	4	2.0
Total		200	100.0

Note: Data are presented as frequency (n) and percentage (%). AFI = Amniotic Fluid Index; Preterm = <37 completed weeks of gestation; Term = 37–40 completed weeks; Postdated = >40 completed weeks.

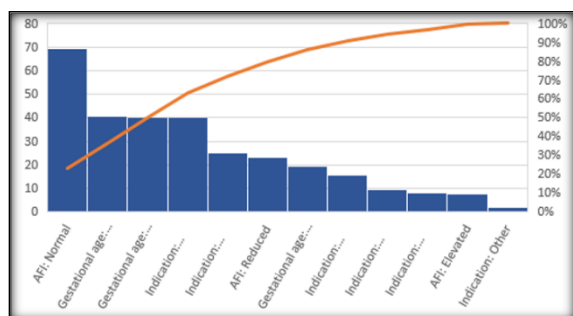


Figure 2: Distribution of obstetric characteristics among the study participants (N = 200)

Note: The figure illustrates the distribution of gestational age, amniotic fluid index (AFI), and the primary indications for induction of labour among the study participants. Values are presented as percentage (%). AFI = Amniotic Fluid Index;

Preterm = <37 completed weeks of gestation; Term = 37–40 completed weeks of gestation; Postdated = >40 completed weeks of gestation. The percentages for each variable are calculated independently within their respective categories and are not cumulative across the entire figure.

Effectiveness of Cervical Ripening

The effectiveness of cervical ripening was evaluated by comparing the Bishop score before and after induction with the 16-Gauge intracervical Foley catheter. As shown in Table 3, the mean pre-induction Bishop score was 1.81 ± 0.67 , which increased to 4.13 ± 1.07 following Foley catheter insertion. The mean improvement in Bishop score was 2.32 ± 0.06 . The increase in Bishop score was statistically significant ($t = 39.758$, $p < 0.001$), demonstrating that intracervical Foley catheterization effectively improved cervical favourability prior to induction of labour. [Table 3]

Table 3: Comparison of Bishop score before and after cervical ripening with intracervical Foley catheter (N = 200)

Variable	Mean $\pm$ SD
Bishop score before Foley catheter insertion	1.81 ± 0.67
Bishop score after Foley catheter insertion	4.13 ± 1.07
Mean improvement in Bishop score	2.32 ± 0.06
Statistical Test	Value
Paired Student's t-test	39.758
p-value	<0.001

Note: Data are presented as mean $\pm$ standard deviation (SD). Statistical significance was determined using the paired Student's t-test, with a p-value <0.05 considered statistically significant. SD = standard deviation.

Labour Induction Characteristics

The labour induction characteristics following cervical ripening with the 16-Gauge intracervical Foley catheter are presented in [Table 4]. Following Foley catheter insertion, 114 women (57.0%) required a single dose of prostaglandin E₂ (PGE₂)

for further cervical ripening, while 54 women (27.0%) required two or more doses. Additional prostaglandin was not required in 32 participants (16.0%). Furthermore, 103 women (51.5%) required oxytocin augmentation during labour, whereas 97 women (48.5%) progressed without augmentation. The mean induction-to-delivery interval was approximately 19.6 hours, indicating satisfactory progression of labour following cervical ripening with the intracervical Foley catheter. [Table 4]

Table 4: Labour induction characteristics following intracervical Foley catheter insertion (N = 200)

Variable	Category	n	%
Requirement for PGE ₂ instillation	None	32	16.0
	One dose	114	57.0
	Two or more doses	54	27.0
Oxytocin augmentation	Required	103	51.5
	Not required	97	48.5
Mean induction-to-delivery interval	Hours	19.6	—

Note: Data are presented as frequency (n) and percentage (%), unless otherwise specified. PGE₂ = Prostaglandin E₂.

Mode of Delivery

The mode of delivery following induction of labour with the 16-Gauge intracervical Foley catheter is presented in [Table 5]. The majority of women achieved spontaneous vaginal delivery (72.5%), demonstrating successful cervical ripening and labour induction. Assisted vaginal delivery was

performed in 8 women (4.0%), comprising 5 (2.5%) outlet forceps deliveries and 3 (1.5%) vacuum-assisted deliveries. A total of 35 women (17.5%) underwent lower-segment caesarean section (LSCS). Among women who required LSCS, fetal distress (60.0%) was the most common indication, followed by failed induction (25.7%). Other indications included deep transverse arrest, non-reactive cardiotocography (CTG), eclampsia, and cord prolapse. [Table 5]

A. Mode of delivery		
Mode of delivery	n	%
Spontaneous vaginal delivery	145	72.5
Outlet forceps delivery	5	2.5
Vacuum-assisted delivery	3	1.5
Lower-segment caesarean section (LSCS)	35	17.5

B. Indications for lower-segment caesarean section (n = 35)		
Indication	n	%
Fetal distress	21	60.0
Failed induction	9	25.7
Deep transverse arrest	2	5.7
Non-reactive CTG	1	2.9
Eclampsia	1	2.9
Cord prolapses	1	2.9
Total	35	100.0

Note: Data are presented as frequency (n) and percentage (%). LSCS = Lower-segment caesarean section; CTG = Cardiotocography.

Maternal and Neonatal Outcomes

The maternal and neonatal outcomes following induction of labour are summarized in [Table 6]. Maternal complications were uncommon, with 197 women (98.5%) experiencing no complications during labour or the immediate postpartum period. Postpartum haemorrhage occurred in 2 women

(1.0%), while 1 woman (0.5%) developed puerperal sepsis. Among the neonates, 153 (76.5%) had no complications after delivery. Transient tachypnoea of the newborn (TTN) was observed in 28 neonates (14.0%), whereas 18 neonates (9.0%) developed meconium aspiration syndrome (MAS). Of the 199 neonates for whom NICU data were available, 20 (10.1%) required admission to the Neonatal Intensive Care Unit, while 179 (89.9%) did not require intensive care. [Table 6]

Table 6: Maternal and neonatal outcomes following induction of labour (N = 200)

Outcome	Category	n	%
Maternal complications	No complications	197	98.5
	Postpartum haemorrhage	2	1.0
	Puerperal sepsis	1	0.5
Neonatal complications	No complications	153	76.5
	Transient tachypnoea of the newborn (TTN)	28	14.0
	Meconium aspiration syndrome (MAS)	18	9.0
NICU admission*	Required	20	10.1
	Not required	179	89.9

Note: Data are presented as frequency (n) and percentage (%). PPH = Postpartum haemorrhage; TTN = Transient tachypnoea of the newborn; MAS = Meconium aspiration syndrome; NICU = Neonatal Intensive Care Unit.

DISCUSSION

The present prospective study evaluated the effectiveness and safety of the 16-Gauge intracervical Foley catheter as a mechanical method of cervical ripening in women undergoing induction of labour with an unfavourable cervix. A total of 200 antenatal women were included in the study, and maternal, labour, and neonatal outcomes were analysed. The findings demonstrated that intracervical Foley catheterization effectively improved cervical favourability, reduced the need for operative delivery in most women, and was associated with a low incidence of maternal and neonatal complications. Similar findings have been reported in randomized controlled trials and systematic reviews evaluating mechanical methods of cervical ripening. [5–8,12]

The majority of women included in the present study were between 21 and 25 years of age (47.5%), with a mean maternal age of 25.26 ± 4.10 years. Most participants were primigravidae (60.0%), reflecting the higher frequency of labour induction among first-time mothers with an unfavourable cervix. Similar demographic characteristics have been reported by Jozwiak et al., Ten Eikelder et al., and Crane, who observed that primigravid women constituted a large proportion of patients undergoing induction of labour. [5,7,14]

Postdated pregnancy was the most common indication for induction of labour (40.0%), followed by hypertensive disorders of pregnancy (25.0%) and oligohydramnios (15.5%). This distribution is consistent with recommendations from the World Health Organization (WHO), ACOG, NICE, and RCOG, which identify post-term pregnancy and hypertensive disorders as common indications for induction of labour. [2–4,19]

The principal finding of this study was the significant improvement in cervical favourability following intracervical Foley catheter insertion. The mean Bishop score increased from 1.81 ± 0.67 before induction to 4.13 ± 1.07 after catheter removal, with

a mean improvement of 2.32 points ($p < 0.001$). Similar improvements in Bishop score have been reported in the PROBAAT trial, the PROBAAT-II trial, and the Cochrane review by Jozwiak et al., supporting the effectiveness of Foley catheter cervical ripening.^[5-7] The mechanism is believed to involve direct mechanical dilatation of the cervix together with stimulation of endogenous prostaglandin release, resulting in cervical softening and effacement.^[6,12,18]

Despite successful cervical ripening, 57.0% of women required one additional dose of prostaglandin E₂, while 27.0% required two or more doses, and 51.5% required oxytocin augmentation. These findings indicate that although the Foley catheter effectively improves cervical favourability, pharmacological augmentation may still be required in a proportion of women to establish adequate uterine contractions. Similar observations have been reported in previous systematic reviews comparing mechanical and pharmacological methods of induction.^[6,10,12,15,16]

A favourable mode of delivery was achieved in most participants, with 72.5% undergoing spontaneous vaginal delivery. Caesarean section was performed in 17.5% of women, and the most frequent indication was fetal distress (60.0%), followed by failed induction (25.7%). Comparable vaginal delivery rates have been reported by Jozwiak et al., Ten Eikelder et al., and Heinemann et al., demonstrating that Foley catheter induction is associated with satisfactory vaginal birth rates and acceptable caesarean section rates.^[5,7,8]

Maternal safety is an important consideration during labour induction. In the present study, 98.5% of women experienced no maternal complications. Postpartum haemorrhage occurred in only 1.0%, while puerperal sepsis occurred in 0.5% of participants. Similar low rates of maternal morbidity have been reported in randomized trials and systematic reviews evaluating transcervical Foley catheter induction.^[6-8,18]

Neonatal outcomes were similarly favourable. More than three-quarters of newborns (76.5%) experienced no neonatal complications, and only 10.1% required admission to the Neonatal Intensive Care Unit. These findings are comparable with those reported by previous randomized controlled trials and WHO recommendations, which have demonstrated no increase in neonatal morbidity associated with mechanical cervical ripening.^[5-7,17]

The study also identified several factors associated with successful cervical ripening. Multigravidae demonstrated significantly greater improvement in Bishop score than primigravidae, while women who achieved vaginal delivery also showed greater cervical improvement than those who underwent caesarean section. Similarly, women who did not require oxytocin augmentation demonstrated greater improvement in Bishop score. These findings are consistent with previous reports identifying parity,

cervical status, and Bishop score as important predictors of successful labour induction.^[11,13,14]

Overall, the findings of the present study indicate that the 16-Gauge intracervical Foley catheter is an effective, safe, and economical method of cervical ripening. The significant improvement in Bishop score, high rate of vaginal delivery, low incidence of maternal and neonatal complications, and acceptable requirement for additional pharmacological induction support its use as a reliable method of labour induction, particularly in resource-limited healthcare settings. These findings are consistent with recommendations from the WHO, FIGO, RCOG, and the Cochrane Database, which recognize mechanical methods as safe and effective options for cervical ripening in appropriately selected women.^[2,6,17-20]

Limitations

The present study has certain limitations that should be considered while interpreting the findings. First, the study was conducted at a single tertiary care centre, which may limit the generalizability of the results to other healthcare settings with different patient populations and clinical practices. Second, the study included a relatively small sample size of 200 participants, which may have reduced the statistical power to detect differences in less common maternal and neonatal outcomes. Third, the study evaluated only the 16-Gauge intracervical Foley catheter as a cervical ripening method and did not include a comparison group using other mechanical or pharmacological induction agents. Consequently, the relative efficacy and safety of the Foley catheter compared with alternative induction methods could not be determined. Finally, maternal and neonatal outcomes were assessed only until delivery and the immediate postpartum period, and long-term maternal and neonatal follow-up was not performed.

CONCLUSION

Percutaneous vertebroplasty is safe and effective, providing rapid pain relief, functional improvement, and reduced medication requirements in osteoporotic vertebral compression fractures with minimal complications.

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