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Comparison of PGE2 Gel and Transcervical Foley Single-Balloon Catheter for Induction of Labor in Term Pregnancy: An Open-Label Randomized Controlled Trial

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Abstract

Objective: This study aims to compare the efficacy and safety of transcervical Foley catheter and vaginal prostaglandin E_2 (PGE_2) gel for cervical ripening and induction of labor in women with an unfavorable cervix.

Materials and methods: This prospective randomized controlled trial was conducted at a tertiary care center. A total of 86 women requiring induction of labor with an unfavorable cervix were randomized to the Foley catheter induction group or the PGE_2 gel group, with 43 participants in each group. Cervical ripening was assessed using the Bishop's score before and after induction. Primary outcomes included change in Bishop's score and individual cervical parameters. Secondary outcomes included the induction-to-active labor interval, induction-to-delivery interval, mode of delivery, failed induction, requirement for oxytocin augmentation, and maternal and fetal adverse outcomes.

Results: Baseline characteristics and pre-induction Bishop's scores were comparable between groups. Post-induction mean increase in Bishop's score was significantly greater with Foley catheter induction (5.40 ± 0.23 vs. 3.81 ± 0.29; p = 0.001) compared to PGE2 gel. Foley catheter use resulted in significantly greater improvement in cervical length (1.35 ± 0.12 cm vs. 0.81 ± 0.16 cm; p < 0.01) and cervical dilatation (1.26 ± 0.43 cm vs. 0.95 ± 0.71 cm; p < 0.01). A higher proportion of women achieved a soft cervix following Foley catheter induction (81% vs. 55.8%; p = 0.011). Labor outcomes, mode of delivery, and adverse events were comparable between groups.

Conclusion: Foley catheter induction provides superior cervical ripening with comparable safety and labor outcomes, supporting its use as an effective method for labor induction.

Categories: Obstetrics/Gynecology
Keywords: bishops score, cervical ripening, foleys catheter, induction of labour, prostaglandin e2, vaginal delivery

Introduction

Induction of labor (IOL) is a frequently performed obstetric procedure when delivery is considered safer for the mother or fetus than continuing the pregnancy. The objective of IOL is to initiate uterine contractions and achieve vaginal delivery using pharmacological or mechanical methods. Globally, the prevalence of IOL varies widely, ranging from approximately 25% in high-income countries to 5-22% in low- and middle-income settings such as India, depending on institutional protocols and clinical indications [1]. IOL is commonly indicated in pregnancies complicated by prolonged gestation, oligohydramnios, fetal growth restriction, hypertensive disorders, gestational diabetes mellitus, or prelabor rupture of membranes.

A wide range of methods have been employed for labor induction, including pharmacological agents such as prostaglandins (PGE_1, PGE_2, and $PGF_2\alpha$ analogs) and oxytocin, as well as mechanical methods such as membrane sweeping, amniotomy, transcervical Foley catheter insertion, hygroscopic dilators, laminaria tents, dilapan, and saline infusion [2]. Among pharmacological agents, prostaglandin E_2 (PGE_2) gel is one of the most commonly used agents for cervical ripening and labor induction. It facilitates cervical softening and stimulates myometrial contractions [3]; however, its use has been associated with adverse effects, including uterine hyperstimulation with fetal heart rate abnormalities, gastrointestinal symptoms, postpartum hemorrhage, and backache [4,5]. Additionally, repeated intravaginal administration may lead to patient discomfort and an increased risk of infection.

The most commonly used mechanical method for cervical ripening is the transcervical Foley balloon catheter. It facilitates cervical ripening through mechanical pressure on the internal cervical os, which promotes cervical dilatation and triggers the local release of endogenous prostaglandins [6-8]. The Foley catheter is inexpensive, readily available, stable at room temperature, and requires fewer vaginal

examinations, making it particularly suitable for low-resource settings. While existing literature supports its use in women with a previous cesarean section and in high-risk pregnancies, evidence regarding its efficacy as a sole induction agent in term pregnancies with an unscarred uterus remains limited. Furthermore, mechanical methods have been associated with a theoretical risk of ascending infection, warranting further evaluation. Therefore, this study aims to compare the effectiveness and safety of transcervical Foley catheter with intracervical PGE_2 gel for labor induction at term in pregnant women with an unscarred uterus.

Materials And Methods

This was an open-label, parallel-arm randomized controlled trial with a non-inferiority margin, conducted at the Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences (AIIMS), Patna. The study was carried out over a 12-month period from February 2024 to February 2025, after obtaining approval from the Institutional Ethics Committee (AIIMS/Pat/IEC/PGTh/Jan23/92). The trial was registered prospectively at ClinicalTrials.gov (CTRI/2024/02/062843).

The sample size was calculated based on the findings of a previous study by Deshmukh et al. [9], considering the difference in mean Bishop's score between the two intervention groups as the primary parameter. Assuming a pooled standard deviation of 1.85, an expected mean difference of 1.07 units, a two-sided significance level (α) of 0.05, and a statistical power of 80% ($\beta = 0.20$), the minimum required sample size was estimated to be 76 participants (38 per group). To account for a potential dropout rate of 10%, the sample size was increased to 86 participants, with 43 participants allocated to each group.

All pregnant women admitted for IOL during the study period were screened for eligibility. A consecutive sampling technique was used, whereby all eligible women presenting during the study period were approached for participation until the required sample size was achieved. Women who met the inclusion criteria and provided written informed consent were enrolled in the study.

Inclusion criteria

The study included women with singleton pregnancies with cephalic presentation, gestational age of ⩾37 completed weeks, intact amniotic membranes, and an unfavorable cervix, defined as a Bishop's score of ⩽3, with no contraindication to vaginal delivery.

Exclusion criteria

Those with a history of previous cesarean section or other uterine surgery resulting in a uterine scar, antepartum hemorrhage, including placenta previa or suspected placental abruption, active vaginal or genital tract infection, known hypersensitivity, or any other contraindication to PGE_2 gel were excluded from the study.

Randomization and intervention

Eligible participants (n=90) were randomized using a computer-generated random block method into two groups: the Foley single catheter group and the intracervical PGE_2 gel group. Allocation concealment was ensured using sequentially numbered opaque envelopes, and the intervention was assigned upon opening the envelope.

After obtaining consent, eligible participants underwent an NST (non-stress test) and a sterile per vaginal examination to determine the modified Bishop's score before induction for patients with reactive NST.

Foley Catheter Group

With the woman in the lithotomy position and under aseptic precautions, an 18F single-balloon Foley catheter was inserted through the cervical canal into the extra-amniotic space. The balloon was then inflated with 60 mL of sterile normal saline and gently retracted until it rested against the internal cervical os. The catheter was secured to the medial aspect of the thigh and retained for a maximum of 18 hours or until spontaneous expulsion, whichever occurred earlier.

PGE_2 Gel Group

Participants received 0.5 mg of intracervical dinoprostone gel (pre-sterilized and refrigerated) under aseptic conditions in the lithotomy position. A maximum of three doses were administered at 6-hour intervals (0h, 6h, 12h), with monitoring for uterine activity and fetal well-being.

In both groups, post-intervention Bishop's scores were assessed at 18 hours or earlier if labor commenced or if the Foley catheter was expelled. Labor progression was monitored through hourly abdominal examinations and per vaginal examinations every four hours during the active phase of labor. Augmentation with oxytocin was done as and when required, as per institute protocol. Fetal heart rate monitoring was

performed as per NICE guidelines for all patients included in the study. Maternal side effects, fetal heart rate patterns, induction-to-active labor interval, induction-to-delivery interval, mode of delivery, rate of failed induction, APGAR score, NICU admission within the first 72 hours, and the rate of failed induction were systematically documented.

Active labor was defined as cervical dilatation ⩾5 cm with regular painful contractions (WHO Labour Care Guide 2022) [7]; failed induction was defined as failure to achieve 5 cm dilatation after at least 12 hours of oxytocin with ruptured membranes [7]; ⩾6 uterine contractions in 10 minutes averaged over 30 minutes were considered as tachysystole. Fetal distress was defined as abnormal CTG as per NICE 2022 (e.g., baseline <100 or >180 bpm, reduced variability <5 bpm for >50 mins, late decelerations, etc.). Postpartum hemorrhage is defined as blood loss ⩾500 mL after vaginal birth or ⩾1000 mL after cesarean. Puerperal pyrexia was defined as an oral temperature of ⩾38°C on two separate occasions (excluding the first 24-hour postpartum).

The primary outcome was the change in Bishop's score after 18 hours of induction, while secondary outcomes included the time from induction to active labor, time from induction to delivery, mode of delivery, rate of failed induction, and maternal and fetal side effects such as tachysystole, fetal distress, gastrointestinal symptoms, postpartum hemorrhage, and puerperal pyrexia.

Statistical analysis

We performed an intention-to-treat analysis. Data were recorded in Microsoft Excel 2021 (Microsoft Corporation, Redmond, Washington) and analyzed using Jamovi software (version 2.6.26). Continuous variables were expressed as mean ± standard deviation or median with interquartile range depending on data normality, which was assessed using Q-Q plots, whereas categorical variables were summarized as frequencies and percentages. Paired and independent t-tests were applied for normally distributed continuous variables, and categorical variables were compared using the chi-square test or Fisher's exact test as appropriate. A p-value of <0.005 was considered statistically significant.

Results

A total of 124 antenatal women were screened for eligibility. After excluding 34 participants (10 who did not meet inclusion criteria and 24 who declined to participate), 90 women were randomized equally into two groups: the Foley catheter group (n = 45) and the PGE_2 gel group (n = 45), and the final analysis was performed on 43 participants in each group. The CONSORT diagram summarizing participant flow is presented in Figure *1*.

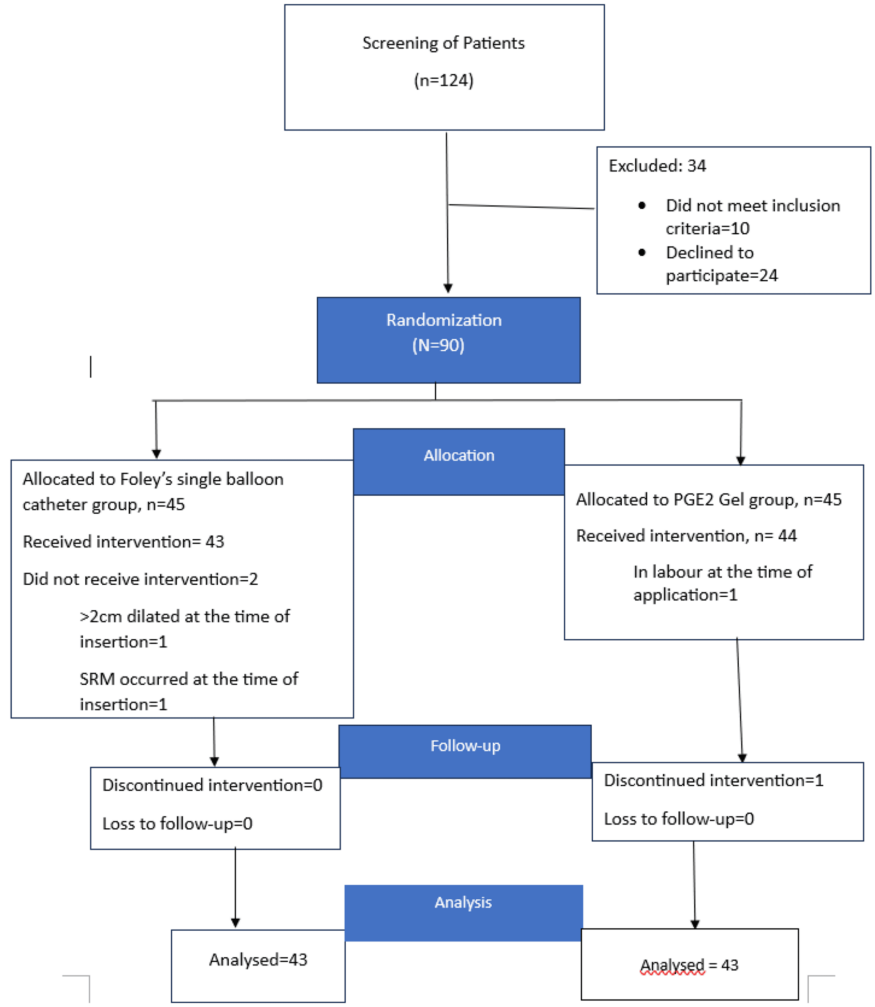


FIGURE 1: Flowchart of the study

CONSORT flowchart of patient recruitment.

Baseline maternal characteristics, gestational age at induction, and indications for IOL were comparable between the Foley catheter and PGE_2 gel groups, with no statistically significant differences observed (Table *1*).

Parameters	Foley Group (n=43; n %)	PGE_2 Gel Group (n=43; n %)
Age (mean ± SD)	24.48±3.42	23.4±2.84
Parity		
Primigravida	32 (74.4%)	36 (83.7%)
Multigravida	11 (25.5%)	7 (16.2%)
Gestational age at induction of labor (IOL)		
37–39	13 (30.2%)	18 (41.8%)
40–41	27 (62.8%)	21 (48.9%)
Postdated	3 (6.9%)	4 (9.3%)
Indications of IOL		
DM	12 (27.9%)	14 (32.5%)
HDP	7 (16.2%)	8 (18.6%)
FGR	11 (25.5%)	2 (4.6%)
Rh negative	0 (0%)	2 (4.6%)
Post-dated	3 (6.9%)	4 (9.3%)
Hepatic disorder	3 (6.9%)	2 (4.6%)
Other	7 (16.2%)	11 (25.5%)

TABLE 1: Clinical characteristics of the included patients

IOL: induction of labor; DM: diabetes mellitus; HDP: hypertensive disorders of pregnancy; FGR: fetal growth retardation; SD: standard deviation

Table 2 describes the primary outcome between the groups. Baseline pre-induction Bishop's scores were comparable between the Foley catheter group and the PGE_2 gel group (2.40 ± 0.82 vs. 2.42 ± 0.73). Following induction, the post-induction Bishop's score was significantly higher in the Foley group compared with the PGE_2 gel group (7.79 ± 1.47 vs. 6.23 ± 2.18; p = 0.01). The mean increase in Bishop's score was also significantly greater in the Foley group (5.40 ± 0.23 vs 3.81 ± 0.29; p = 0.001). Analysis of individual components of the bishop's score demonstrated a significantly greater improvement in cervical length and cervical dilatation in the Foley group compared with the PGE_2 gel group (mean change in cervical length: 1.35 ± 0.12 vs. 0.81 ± 0.16 cm; p < 0.01; mean change in cervical dilatation: 1.26 ± 0.43 vs. 0.95 ± 0.71 cm; p < 0.01). A significantly higher proportion of women in the Foley group achieved a soft cervical consistency after induction (81% vs. 55.8%; p = 0.011). Although a higher proportion of women in the Foley group demonstrated a change to an anterior cervical position, this difference did not reach statistical significance (46.5% vs. 25.5%; p = 0.072). There was no significant difference between the groups in fetal station advancement to −1 or 0 (18.6% vs. 11.6%; p = 0.632).

Primary Outcome	Foley Group (n=43)	PGE_2 Gel Group (n=43)	Statistical Test	p-value	Interpretation
Pre-induction Bishop's score (mean±SD)	2.40 ± 0.82	2.42 ± 0.73	Independent t-test	0.36	Not significant
Post-induction Bishop's score (mean±SD)	7.79 ± 1.47	6.23 ± 2.18	Independent t-test	0.01	Significant
Mean Difference (mean±SD)	5.40 ± 0.23	3.81 ± 0.29	Independent t-test	0.001	Significant
Change in individual Bishop's score parameter					
Mean change in cervical length (mean±SD, cm)	1.35±0.12	0.81±0.16	Independent t-test	<0.01	Significant
Mean change in cervical dilatation (cm)	1.26±0.43	0.95±0.71	Independent t-test	<0.01	Significant
Cervical consistency (change to soft consistency post-induction)	35 (81%)	24 (55.8%)	Chi-square test	0.011	Significant
Cervical position (change to anterior position post-induction)	20 (46.5%)	11 (25.5%)	Chi-square test	0.072	Not Significant
Station changes to -1/0	8 (18.6%)	5 (11.6%)	Chi-square test	0.632	Not Significant

TABLE 2: Comparison of primary outcomes among the groups

PGE_2: prostaglandin; SD: standard deviation

As described in Table *3*, there was no statistically significant difference between the Foley catheter group and the PGE_2 gel group in the mean induction-to-active labor interval (21.6 ± 7.87 vs. 19.6 ± 9.99 hours; p = 0.444) or induction-to-delivery interval (24.9 ± 8.34 vs. 23.2 ± 11.0 hours; p = 0.572). The proportion of women who entered spontaneous labor was comparable between the two groups (39% vs. 35%; p = 0.67). Although a higher proportion of women in the PGE_2 gel group required augmentation with oxytocin, this difference was not statistically significant (76% vs. 85%; p = 0.29). Rates of vaginal delivery (including unassisted and instrumental delivery) were identical in both groups (48.8% each; p = 1.00), and the rate of failed induction was also comparable among the groups (18.6% vs. 23.2%, p = 0.67). Adverse events were infrequent and did not differ significantly between the two groups. Tachysystole occurred only in the PGE_2 gel group (0% vs. 6.9%), but the difference was not statistically significant (p = 0.241). Neonatal outcomes were also comparable among the groups.

Parameters	Foley Group A (n=43; n,%)	PGE_2 Gel Group (n=43; n,%)	Statistical Test	p-value	Interpretation
Induction to active labor (mean±SD, hours)	21.6 ± 7.87	19.6 ± 9.99	Independent t-test	0.444	Not Significant
Induction to delivery (mean±SD, hours)	24.9 ± 8.3	23.2 ± 11.0	Independent t-test	0.572	Not Significant
Oxytocin augmentation	32 (76%)	36 (85%)	Chi-square test)	0.29	Not Significant
Vaginal delivery	15 (34.8%)	17(39.5%)	Chi-square test)	0.65	Not Significant
Instrumental delivery	6 (13.9%)	4 (9.3%)	Fisher's exact test	0.74	Not Significant
Failed induction	8 (18.6%)	10 (23.2%)	Chi-square test	0.67	Not Significant
Caesarean delivery	22 (51.2%)	22 (51.2%)	Chi-square test	1	Not Significant
Indications				0.57	Not Significant
Failed induction	8 (33.3%)	10 (45.1%)	Chi-square test	-	-
Meconium-stained liquor with NRCTG	9 (40.3%)	8 (33.3%)	Chi-square test	-	-
Non-progression of labor	5 (23.8%)	4 (19.0%)	Fisher's exact test	-	-
Maternal adverse event					
Tachysystole	0 (0%)	3 (6.9%)	Fisher's exact test	0.241	Not Significant
Fetal distress	2 (4.6%)	3 (6.9%)	Fisher's exact test	0.81	Not Significant
Meconium-stained liquor	11 (25.5%)	13 (32.2%)	Chi-square test	0.67	Not Significant
GI symptoms	1 (2.3%)	2 (4.6%)	Fisher's exact test	0.55	Not Significant
Postpartum hemorrhage	2 (4.6%)	4 (9.3%)	Fisher's exact test	0.67	Not Significant
Puerperal pyrexia	4 (9.3%)	0 (0%)	Fisher's exact test	0.152	Not Significant
Neonatal outcome					
APGAR at 1 minute <7	6 (13.9%)	5 (11.6%)	Chi-square test	0.31	Not Significant
APGAR at 5 minutes <7	2 (4.6%)	3 (6.9%)	Fisher's exact test	0.81	Not Significant
NICU admission within 48 hours of births	4 (9.3%)	3 (6.9%)	Fisher's exact test	0.53	Not Significant

TABLE 3: Comparison of secondary outcomes among the groups

PGE2: prostaglandin E2; NRCTG: non-reactive cardiotocography; SD: standard deviation; NICU: neonatal intensive care unit

Discussion

Inducing labor in women with an unfavorable cervix can be challenging, highlighting the importance of choosing a cervical ripening method that is both safe and effective. In this randomized controlled trial, Foley catheter induction resulted in significantly greater improvement in overall Bishop's score and key cervical parameters compared with PGE_2 gel, while labor outcomes and maternal-fetal safety profiles were comparable between the two methods.

Baseline pre-induction Bishop's scores were similar between groups, confirming adequate randomization. However, post-induction Bishop's scores and the mean change in Bishop's score were significantly greater in the Foley catheter group compared to the PGE_2 group (mean change: 5.40 vs. 3.81, $p < 0.005$). This highlights the superior efficacy of the Foley catheter in mechanical cervical ripening, indicating superior cervical ripening. The Foley catheter facilitates cervical ripening through mechanical dilatation and stimulation of endogenous prostaglandin release from the decidua and fetal membranes, thereby promoting cervical softening, remodeling, and effacement [10,11]. Previous randomized trials and meta-analyses have reported comparable cervical ripening efficacy and cesarean delivery rates with mechanical and prostaglandin-based methods, although Foley catheter use is generally associated with a lower risk of uterine hyperstimulation [11,12]. Analysis of individual Bishop's score components showed significantly greater improvement in cervical length, dilatation, and cervical consistency in the Foley catheter group. A higher proportion of women achieved a soft cervix following Foley induction, consistent with previous studies reporting superior cervical effacement with mechanical methods [9,13]. Engagement of the fetal head within the pelvis may be a key determinant influencing cervical ripening and the induction-to-delivery interval. While some studies have suggested that cervical ripening balloons may hinder fetal head engagement and increase the risk of cord prolapse [14], more recent evidence indicates that the ellipsoid and cylindrical configuration of the balloon allows it to function as a "cushion" for the presenting part, thereby facilitating safe apposition of the fetal head to the cervix [15,16]. Aligned with this finding, no significant difference in fetal station was observed between the groups.

Although the Foley catheter resulted in better cervical ripening, both groups had comparable induction-to-active labor and induction-to-delivery intervals, as well as similar rates of failed induction and modes of delivery, with no statistically significant differences. The mean induction-to-delivery interval in the Foley catheter group was 24.9 ± 8.34 hours compared with 23.2 ± 11.0 hours in the PGE_2 gel group ($p = 0.572$). Similar findings were reported by Deshmukh et al., who observed no significant difference in induction-to-delivery interval between the Foley catheter and PGE_2 gel groups, although the mean duration was shorter in both groups (15.32 hours and 14.2 hours, respectively) [9]. In contrast, Henry et al. reported longer mean induction-to-delivery intervals in both the Foley catheter and PGE_2 gel groups (33.5 hours vs. 31.3 hours) [17]. These variations across studies may be attributed to differences in gestational age at induction, indications for induction, and labor management protocols.

Brown et al. reported higher rates of unassisted vaginal birth with balloon catheter induction compared with PGE_2 gel (50.4% vs. 42.9%; $p = 0.028$). Similarly, vaginal delivery within 24 hours was more frequent in the balloon catheter group (33.7% vs. 25.8%; $p = 0.011$) [16]. In contrast, our study did not demonstrate a significant difference in cesarean delivery rates between the two groups. Similar findings have been reported in previous studies, which found comparable modes of delivery following mechanical and pharmacological methods of cervical ripening [9,17]. The requirement for oxytocin augmentation was higher in the PGE_2 gel group (76% vs. 85%; $p = 0.29$), although this difference was not statistically significant. This trend aligns with previous reports suggesting that mechanical cervical ripening may reduce dependence on pharmacological augmentation [9,16,17].

Although mechanical methods of cervical ripening have been associated with a theoretical risk of ascending infection, the present study did not demonstrate an increased incidence of puerperal pyrexia with Foley catheter induction. The absence of increased infectious morbidity in the Foley catheter group is consistent with the findings of McMaster et al., whose meta-analysis of 26 randomized trials involving 5,563 women found comparable rates of maternal and neonatal infections following mechanical and prostaglandin-based cervical ripening [18]. An additional advantage of Foley catheter induction is the avoidance of repeated vaginal examinations, which are often required with PGE_2 gel application.

In the present study, tachysystole occurred in 6.9% of women in the PGE_2 gel group, whereas none occurred in the Foley catheter group; however, this difference did not reach statistical significance. Nevertheless, this trend is consistent with findings from multiple meta-analyses demonstrating significantly higher rates of uterine hyperstimulation with prostaglandin analogs compared with Foley catheter use, with reported relative risks ranging from 2.3 to 4.0 [12,19]. Neonatal outcomes were comparable among the groups, which aligns well with previously reported literature [16,20].

Beyond its clinical efficacy, the Foley catheter offers practical advantages, particularly in resource-limited settings. Its low cost, ready availability, and lack of refrigeration requirements make it a feasible option for cervical ripening. Furthermore, its mechanical action avoids systemic prostaglandin-related adverse effects, supporting its use as an alternative to pharmacological methods. Although a formal cost-effectiveness analysis was not conducted in the present study, economic evaluations from randomized controlled trials

have shown that Foley catheter induction generates comparable overall costs to PGE_2 gel (mean €3297 vs. €3075) while offering similar clinical outcomes [21]. In addition, observational data suggest that the direct cost of Foley catheter induction is substantially lower than that of PGE_2 gel in routine clinical practice [22].

Strength and limitations

An important strength of our study is the detailed evaluation of individual components of the Bishop's score, which helped us better understand the effects of Foley catheters and PGE_2 gel on cervical ripening. The randomized design and similar baseline characteristics of the two groups add to the reliability of our findings. However, the study was conducted at a single center with a relatively small sample size, which may limit the generalizability of the results and the detection of uncommon maternal and neonatal complications. Blinding was also not possible because of the nature of the interventions.

Conclusions

Foley catheter induction provides superior cervical ripening compared with PGE_2 gel, with similar labor outcomes and a comparable safety profile. Given its effectiveness, low cost, and reduced risk of uterine hyperstimulation, the Foley catheter represents a valuable option for IOL, particularly in low-resource settings.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Sangam Jha, Supriya Subhi

Acquisition, analysis, or interpretation of data: Sangam Jha, Supriya Subhi, Raveena Bhagat, Pammy Pravina

Drafting of the manuscript: Sangam Jha, Supriya Subhi, Raveena Bhagat

Critical review of the manuscript for important intellectual content: Sangam Jha, Pammy Pravina

Supervision: Sangam Jha

Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), Patna, issued approval AIIMS/Pat/IEC/PGTh/Jan23/92. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

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