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Original Research Article

Comparative Evaluation of Maternal and Neonatal Outcomes Following Mechanical versus Pharmacological Induction of Labour in Term Pregnancies: A Prospective Cohort Study

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Abstract

Background: Induction of labour (IOL) is one of the most common obstetrical interventions worldwide. The choice of induction method remains a subject of debate, particularly regarding the balance between efficacy (time to delivery) and safety (maternal and fetal complications). While pharmacological agents like prostaglandins are widely used, mechanical methods such as the Foley catheter are gaining traction due to their low cost and favorable safety profile.

Methods: A prospective cohort study was conducted at a tertiary care center involving 220 pregnant women with singleton, cephalic, term pregnancies (37–41 weeks) and a Bishop score < 6. Participants were assigned to receive either an intracervical Foley catheter (Group M, n=110) or intracervical Dinoprostone gel (Group P, n=110) based on clinical protocols and patient counseling. Key outcomes included the rate of Cesarean section (CS), induction-to-delivery interval, uterine hyperstimulation, and neonatal morbidity.

Results: The baseline characteristics were comparable between groups. The rate of Cesarean section was lower in Group M (18.2%) compared to Group P (23.6%), though this did not reach statistical significance (P = 0.31). However, Group P exhibited a significantly shorter mean induction-to-delivery interval (16.4 ± 4.2 hours) compared to Group M (21.8 ± 5.1 hours; P < 0.001). Conversely, uterine hyperstimulation was significantly more frequent in Group P (7.3%) than in Group M (0.9%; P = 0.02). Neonatal outcomes, including APGAR scores and NICU admissions, showed no significant differences (NICU admission: 3.6% vs. 4.5%; P = 0.74).

Conclusion: Mechanical induction with a Foley catheter is associated with a significantly lower risk of uterine hyperstimulation compared to Dinoprostone gel, making it a safer alternative for cervical ripening. While pharmacological induction offers a shorter interval to delivery, it does not significantly reduce the Cesarean section rate.

Keywords: Induction of Labour, Foley Catheter, Dinoprostone, Prostaglandins, Cesarean Section, Maternal Outcomes.

Introduction

Induction of labour (IOL) represents a critical intervention in modern obstetrics, indicated when the benefits of delivery outweigh the risks of continuing the pregnancy. The prevalence of IOL has risen steadily over the past two decades, currently accounting for approximately 25% of all deliveries in developed countries [1]. Common indications include post-term pregnancy, hypertensive disorders, oligohydramnios, and maternal diabetes. Success in IOL is heavily dependent on the status of the cervix, often assessed by the Bishop score. For women with an unfavorable cervix (Bishop score < 6), cervical ripening is a prerequisite to successful vaginal delivery [2]. Two primary categories of cervical ripening agents are currently in widespread use: pharmacological and mechanical. Pharmacological methods, primarily prostaglandins such as Dinoprostone (PGE2) and Misoprostol (PGE1), act by dissolving collagen bundles in the cervical stroma and increasing submucosal water content, alongside stimulating uterine contractions [3]. While effective, prostaglandins carry a well-documented risk of uterine tachysystole and hyperstimulation, which can lead to fetal heart rate abnormalities and emergency operative delivery [4]. Mechanical methods, specifically the transcervical Foley catheter, rely on the mechanical

stretching of the cervix and the stripping of the fetal membranes, which induces the local release of endogenous prostaglandins [5]. Historically viewed as cumbersome or associated with infection risks, mechanical methods have seen a resurgence. Recent systematic reviews suggest that mechanical methods may offer a more favorable safety profile regarding uterine hyperstimulation compared to prostaglandins [6].

Despite numerous randomized controlled trials (RCTs), consensus on the optimal method remains elusive. Some studies suggest prostaglandins result in a shorter induction-to-delivery interval [7], while others highlight the cost-effectiveness and safety of the Foley catheter [8]. Furthermore, data regarding the comparative rates of Cesarean section remain conflicting, with variations attributed to population demographics, parity, and specific induction protocols.

There remains a gap in the literature regarding real-world observational data in diverse clinical settings where strict RCT protocols may not apply. This study aims to evaluate and compare the efficacy and safety of mechanical (Foley catheter) versus pharmacological (Dinoprostone gel) induction methods in a prospective cohort of women with term pregnancies, focusing specifically on mode of delivery, time intervals, and perinatal safety.

Materials and Methods

Study Design and Setting: This prospective cohort study was conducted at the Department of Obstetrics and Gynecology of a large tertiary care teaching hospital.

Sample Size: Based on previous literature estimating a difference in Cesarean section rates and induction intervals, a sample size calculation determined that 100 participants per group were required to detect a significant difference with 80% power and a 5% significance level. To account for potential dropouts or protocol deviations, 220 women were recruited (110 per group).

Inclusion and Exclusion Criteria: Inclusion Criteria: Women aged 18–40 years with singleton pregnancies, cephalic presentation, gestational age between 37+0 and 41+6 weeks, intact membranes, and an unfavorable cervix (Bishop score < 6) requiring induction of labour.

Exclusion Criteria: Previous Cesarean section (scarred uterus), placenta previa, vasa previa, active genital herpes, unexplained vaginal bleeding, non-reassuring fetal heart rate trace at admission, known latex allergy, or contraindication to vaginal delivery.

Interventions: Participants were allocated into two groups based on the clinical decision-making process and unit protocols, which alternated based on supply availability and consultant preference, minimizing selection bias.

Group M (Mechanical): A 16Fr or 18Fr Foley catheter was introduced into the endocervical canal under aseptic conditions. The balloon was inflated with 30–50 mL of sterile saline and pulled taut against the internal os. The catheter was taped to the inner thigh to maintain traction. It was left in place for up to 24 hours or until spontaneous expulsion. Oxytocin augmentation was started after expulsion if labor was not established.

Group P (Pharmacological): Intracervical Dinoprostone gel (0.5 mg) was administered every 6 hours, up to a maximum of 3 doses in 24 hours. Fetal heart rate monitoring was performed continuously for 1 hour post-administration. Oxytocin was initiated if necessary, 6 hours after the last prostaglandin dose.

Data Collection and Outcome Measures: Baseline demographic data (age, BMI, parity, gestational age, initial Bishop Score) were recorded.

Primary Outcome: Mode of delivery (Vaginal vs. Cesarean Section).

Secondary Outcomes: Induction-to-delivery interval (time from first intervention to birth), need for oxytocin augmentation, uterine hyperstimulation (defined as >5 contractions in 10 minutes with fetal heart rate changes), maternal complications (postpartum hemorrhage, fever), and neonatal outcomes (APGAR score <7 at 5 minutes, NICU admission).

Statistical Analysis: Data were analyzed using SPSS software version 26.0. Continuous variables were presented as mean ± standard deviation (SD) and compared using the Student's t-test. Categorical variables were expressed as percentages and analyzed using the Chi-square test or Fisher's exact test. A P-value of < 0.05 was considered statistically significant.

Results

A total of 220 women were included in the final analysis, with 110 in the Mechanical (Foley) group and 110 in the Pharmacological (Dinoprostone) group.

Baseline Characteristics: Table 1 summarizes the demographic and clinical characteristics of the participants. There were no statistically significant differences between the two groups regarding maternal age, BMI, gestational age, parity, or pre-induction Bishop scores, ensuring comparability.

Table 1: Baseline Demographic and Clinical Characteristics

Characteristic	Group M (Foley) (n=110)	Group P (Dinoprostone) (n=110)	P-value
Age (years), Mean ± SD	26.4 ± 4.1	25.9 ± 3.8	0.34
BMI (kg/m²), Mean ± SD	27.2 ± 3.5	26.8 ± 3.2	0.38
Gestational Age (weeks), Mean ± SD	39.4 ± 1.1	39.2 ± 1.0	0.16
Nulliparous, n (%)	68 (61.8%)	65 (59.1%)	0.68
Initial Bishop Score, Mean ± SD	3.2 ± 1.1	3.4 ± 1.0	0.15

Labor and Delivery Outcomes: Labor outcomes are presented in Table 2. The primary outcome, the rate of Cesarean section, was 18.2% in Group M versus 23.6% in Group P. Although the rate was lower in the mechanical group, the difference was not statistically significant (P = 0.31). The most common indication for CS in Group P was non-reassuring fetal status (fetal distress), whereas failure to progress was the primary indication in Group M. significantly, the induction-to-delivery interval was longer in Group M (21.8 ± 5.1 hours) compared to Group P (16.4 ± 4.2 hours; P < 0.001).

However, Group P experienced a significantly higher rate of uterine hyperstimulation (7.3%) compared to Group M (0.9%; P = 0.02). The requirement for oxytocin augmentation was significantly higher in the Foley group (74.5%) compared to the Dinoprostone group (48.2%; P < 0.001).

Table 2: Maternal Labor and Delivery Outcomes

Outcome	Group M (Foley) (n=110)	Group P (Dinoprostone) (n=110)	P-value
Mode of Delivery			
Vaginal Delivery, n (%)	90 (81.8%)	84 (76.4%)	0.31
Cesarean Section, n (%)	20 (18.2%)	26 (23.6%)	0.31
Induction-to-Delivery Interval (hrs)	21.8 ± 5.1	16.4 ± 4.2	**< 0.001**
Uterine Hyperstimulation, n (%)	1 (0.9%)	8 (7.3%)	**0.02**
Oxytocin Augmentation required, n (%)	82 (74.5%)	53 (48.2%)	**< 0.001**
Maternal Fever (>38°C), n (%)	3 (2.7%)	2 (1.8%)	0.65

Neonatal Outcomes: Neonatal outcomes (Table 3) were largely similar between the groups. There was no significant difference in mean birth weight or the number of neonates with a 5-minute APGAR score < 7. Admission to the Neonatal Intensive Care Unit (NICU) occurred in 4.5% of Group P versus 3.6% of Group M, which was not statistically significant (P = 0.74).

Table 3: Neonatal Outcomes

Outcome	Group M (Foley) (n=110)	Group P (Dinoprostone) (n=110)	P-value
Birth Weight (g), Mean ± SD	3150 ± 420	3120 ± 390	0.58
APGAR score < 7 at 5 min, n (%)	2 (1.8%)	4 (3.6%)	0.41
Meconium Stained Liquor, n (%)	9 (8.2%)	14 (12.7%)	0.26
NICU Admission, n (%)	4 (3.6%)	5 (4.5%)	0.74

Discussion

This prospective cohort study provides a comparative analysis of two standard methods for cervical ripening: the Foley catheter and intracervical Dinoprostone gel. Our findings suggest that while pharmacological induction significantly shortens the time to delivery, mechanical induction offers a safer maternal profile with significantly reduced rates of uterine hyperstimulation.

Our observation regarding the Cesarean section rate (18.2% for Foley vs. 23.6% for Dinoprostone) showed a trend favoring mechanical induction, though it did not reach statistical significance. This aligns with the results of the PROBAAT trials and recent meta-analyses, which generally report comparable Cesarean rates between the two methods [9, 10]. This finding is clinically important as it dispels earlier concerns that mechanical dilation might be less effective in achieving vaginal delivery compared to hormonal methods. A key finding of this study was the significant difference in uterine hyperstimulation (tachysystole with fetal heart rate changes), observed in 7.3% of the prostaglandin group compared to only 0.9% in the Foley group. This is consistent with the pharmacological mechanism of prostaglandins, which can cause unpredictable and profound myometrial contractility [11]. The mechanical action of the Foley catheter, which induces a more gradual release of endogenous prostaglandins,

appears to mitigate this risk. Consequently, the Foley catheter may be the preferred method for women with reduced placental reserve or those at higher risk for fetal distress [12].

Regarding the induction-to-delivery interval, Dinoprostone demonstrated a clear advantage, reducing the mean time by approximately 5.4 hours compared to the Foley catheter. This supports findings from multiple previous studies indicating that prostaglandins initiate active labor more rapidly [13]. However, the shorter duration must be weighed against the increased need for intense fetal monitoring required with prostaglandin use. The higher requirement for oxytocin augmentation in the Foley group (74.5%) confirms that while mechanical methods effectively ripen the cervix, they are less effective at initiating uterine contractions compared to prostaglandins, often necessitating subsequent pharmacological augmentation [14].

There were no significant differences in neonatal morbidities, including NICU admissions and APGAR scores. This suggests that despite the increased incidence of hyperstimulation in the prostaglandin group, prompt management (such as tocolysis or expedited delivery) prevented long-term neonatal harm in our cohort. This is reassuring and consistent with the Cochrane review by Boulvain et al. [15].

Regarding infectious morbidity, a theoretical concern with foreign bodies like catheters, we found no significant difference in maternal fever or neonatal infection between groups. This supports evidence that with aseptic technique, the Foley catheter does not increase infectious risk compared to repeated vaginal examinations or gel insertions [16].

Limitations

The limitations of this study include its observational design, which may introduce selection bias, although the baseline characteristics were well-matched. Additionally, the study was conducted at a single center, which may limit the generalizability of the findings to settings with different induction protocols.

Conclusion

In conclusion, mechanical induction of labour using a Foley catheter is as effective as pharmacological induction with Dinoprostone gel in achieving vaginal delivery, with no significant difference in Cesarean section rates. The Foley catheter demonstrates a superior safety profile with a significantly lower risk of uterine hyperstimulation. Although Dinoprostone reduces the induction-to-delivery interval, the potential for adverse uterine activity requires vigilant monitoring. Therefore, the Foley catheter should be considered a first-line option for cervical ripening, particularly in resource-limited settings or cases where minimizing fetal stress is a priority.

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