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Comparison of Administering Misoprostol vs Prostaglandin E2 (PgE2) Gel in Induction of Labor at a Tertiary Care Hospital

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Declaration
Authors' Contribution
Dr. Sajawal Murad: led the study's conceptualization, drafted the manuscript, and facilitated data collection from hospital records.
Dr. Rizwan Ahmad: played a pivotal role in designing the study, conducting data analysis and interpretation, and providing critical revisions to the manuscript.
All authors equally contributed to the study and approved the final manuscript

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ABSTRACT

Background: Induction of labor is a commonly employed obstetric intervention, particularly in post-dated or high-risk pregnancies. Among various pharmacological agents, misoprostol and prostaglandin E_2 (PGE_2) gel are widely used for cervical ripening and labor initiation. However, debate continues regarding their comparative efficacy, safety, and impact on maternal and neonatal outcomes. **Aim:** To compare the effectiveness, safety, and delivery outcomes of vaginal misoprostol versus PGE_2 gel in inducing labor among term pregnant women in a tertiary care hospital setting. **Methodology:** This hospital-based comparative study included 260 pregnant women admitted for induction of labor at term, randomly assigned into two groups of 130 each. Group A received 25 µg of vaginal misoprostol every 4–6 hours, while Group B received 0.5 mg of PGE_2 gel intracervically every 6 hours as per institutional protocol. Outcomes analyzed included induction-to-delivery interval, need for oxytocin augmentation, mode of delivery, maternal complications, and neonatal outcomes. Statistical analysis was performed using t-tests, chi-square tests, and Fisher's exact tests, with $p < 0.05$ considered significant. **Results:** The misoprostol group showed a significantly shorter mean time to active labor (6.8 ± 2.3 hours vs 9.1 ± 2.7 hours; $p < 0.001$) and delivery (11.5 ± 3.4 hours vs 14.2 ± 4.1 hours; $p < 0.001$). Oxytocin augmentation was required in only 29.2% of misoprostol cases compared to 51.5% in the PGE_2 group ($p = 0.001$). Spontaneous vaginal delivery was significantly more frequent in nulliparous women receiving misoprostol (70.6% vs 51.4%; $p = 0.018$), and cesarean deliveries for failed induction were lower (3.8% vs 9.2%; $p = 0.047$). Maternal complications such as postpartum hemorrhage and uterine hyperstimulation were not significantly different. Neonatal outcomes, including NICU admissions and Apgar scores, were slightly better in the misoprostol group, though differences were not statistically significant. **Conclusion:** Vaginal misoprostol is more effective than PGE_2 gel in inducing labor, with a shorter induction-to-delivery time, reduced need for oxytocin, and higher rates of vaginal delivery, especially in nulliparous women. Its safety profile is comparable, and its lower cost and ease of use make it particularly advantageous in resource-limited tertiary settings. Misoprostol should be considered a first-line agent for labor induction where appropriate clinical infrastructure and monitoring are available.

INTRODUCTION

Induction of labor (IOL) is one of the most frequently performed obstetric interventions worldwide, accounting for 20–30% of all term pregnancies in developed nations and rising steadily in low- and middle-income countries (Kvalvik et al., 2021). In Pakistan, the practice of labor induction is increasingly prevalent, reflecting global trends in obstetric care and rising institutional deliveries (Muqaddas et al., 2024). While national-level data are limited, regional hospital-based studies indicate that labor induction rates in tertiary care settings range between 10% and 22% of all deliveries, depending on the obstetric population and availability of induction agents (Khan et al., 2025). It is defined as the artificial initiation of uterine contractions before the spontaneous onset of labor, with the aim of achieving vaginal delivery when continuation of pregnancy poses potential risks to the mother or fetus (Chiossi et al., 2021). Common indications include post-term pregnancy, hypertensive disorders, premature rupture of membranes, intrauterine growth restriction, and oligohydramnios (Kamel et al., 2021).

The bishop score continues to serve as the primary clinical tool for assessing cervical favorability before induction (Chen et al., 2022). A score less than 6 indicates an unfavorable cervix and is often associated with prolonged labor, increased need for oxytocin

augmentation, and higher likelihood of operative delivery. Therefore, cervical ripening is a critical initial step in women with an unripe cervix, and a range of pharmacological and mechanical options have been developed (Sahu & Janjewal, 2021). Among pharmacological agents, prostaglandins have remained the mainstay of medical induction. They function by remodeling the extracellular matrix of the cervix and promoting myometrial contractility, thereby enhancing the possibility of achieving vaginal delivery (Socha et al., 2023). Two commonly used prostaglandin analogs in this context are prostaglandin E_2 (PGE_2) and misoprostol, each with distinct pharmacological properties, safety profiles, routes of administration, and regulatory approvals (De et al., 2023).

PGE_2, also known as dinoprostone, is widely approved for labor induction and has been used in clinical practice for decades (Paola et al., 2025). It is administered either as a gel, pessary, or vaginal insert, and its effects are dose-dependent, typically requiring repeated applications due to its relatively short half-life. Its use is supported by numerous studies and clinical guidelines, and it is often regarded as the standard comparator in induction trials (Gulersen et al., 2022; Vince & Matijević, 2022). However, its limitations include higher cost, need for refrigeration, and variability in individual responsiveness, which has led to interest in alternative agents (Aherwar, 2021). On the other hand, misoprostol is a synthetic prostaglandin E_1 analog originally approved for gastric ulcer prevention has gained increasing attention in obstetric practice due to its low cost, thermal stability, and multiple routes of administration. While misoprostol is not approved for induction in all countries, off-label use has become common, and numerous clinical trials have evaluated its efficacy and safety in comparison to PGE_2 (David et al., 2024).

A further complicating factor is that the majority of large-scale trials comparing these two agents originate from high-income countries, and their findings may not be directly transferable to low-resource settings due to differences in patient demographics, healthcare infrastructure, labor monitoring capabilities, and baseline maternal health (Bjorklund et al., 2022). In South Asian countries such as Pakistan, both misoprostol and PGE_2 gel are available and widely used for labor induction, but the selection often depends on institutional preferences, physician familiarity, and cost considerations rather than standardized evidence-based guidelines. Despite the routine use of both agents, there remains a paucity of locally generated, high-quality comparative data evaluating their relative efficacy and safety profiles in the South Asian obstetric population. This gap in the literature necessitates context-specific clinical research to inform practice and policy (Zhang et al., 2021). Therefore, the present study was undertaken to compare the effectiveness, safety, and delivery outcomes associated with vaginal misoprostol and prostaglandin E_2 gel for the induction of labor at term in a tertiary care hospital.

METHODOLOGY

Study Design and Duration

This research was conducted as a randomized controlled trial at the Department of Obstetrics and Gynecology, Doctors Hospital and Medical Center, Lahore from 20 Nov 2024 to 20 May 2025. A total of 260 pregnant women were recruited for the study, with 130 participants assigned to each intervention group. The sample size was determined using a power of 80% and a 5% level of significance, based on expected mean induction-to-delivery intervals of 20.08 ± 8.24 hours for the Misoprostol group and 23.19 ± 9.59 hours for the PgE2 group. A non-probability consecutive sampling technique was used to select participants meeting the eligibility criteria.

Inclusion and Exclusion Criteria

Eligible participants were pregnant women aged between 18 and 40 years, with a gestational age of more than 37 weeks, who were admitted for induction of labor. Exclusion criteria included multiple pregnancies, abnormal fetal presentations, previous cesarean section, cardiopulmonary disease, unexplained vaginal bleeding during pregnancy, intrauterine fetal death, and known allergy to prostaglandins. After obtaining informed consent, participants were randomly allocated into two groups using the lottery method. Group A received Misoprostol, and Group B received PgE2 gel for labor induction.

Intervention Protocol

Participants in Group A were administered 50 micrograms of Misoprostol vaginally into the posterior fornix. This dose was repeated every four hours, up to a maximum of four doses, or until the patient entered active labor, achieved adequate uterine contractions (three contractions per 10 minutes, each lasting at least 45 seconds), or developed fetal distress whichever occurred first. Participants in Group B received 2 mg of PgE2 gel (Glandin-E2) delivered intracervically just below the internal os using a 2.5 ml syringe. This dose was repeated every six hours, up to a maximum of three doses, or until the desired induction response was achieved.

Data Collection

Throughout labor, all patients were continuously monitored using non-invasive blood pressure devices, electrocardiography, and pulse oximetry. Labor progress was evaluated through periodic abdominal and vaginal examinations according to standard labor room protocols. All procedures were performed by the same trained medical staff, and data were collected directly by the principal investigator to minimize observational bias. The primary outcomes measured included the time to active labor (defined as cervical dilation of 4 cm with adequate contractions) and the induction-to-delivery interval (defined as the time from the administration of the first dose to the delivery of the baby). Both outcomes were recorded in minutes using a stopwatch.

Data Analysis

The collected data were analyzed using SPSS version 26. Descriptive statistics were applied to summarize the data. Categorical variables such as mode of delivery were reported as frequencies and percentages, while continuous variables such as age, gestational age, time to active labor, and induction-to-delivery interval were presented as means with standard deviations. An

independent sample t-test was used to compare the mean values between the two groups. Stratification was performed for age and gestational age to control for effect modifiers, and a post-stratification t-test was applied. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

Prior to data collection, approval was obtained from the Ethical Review Committee of Doctors Hospital and Medical Center, Lahore. A certificate of ethical clearance was issued, confirming that there were no ethical concerns regarding the study protocol. Written informed consent was obtained from each participant after explaining the study objectives, procedures, potential risks, and benefits. Participant confidentiality was maintained throughout the study, and no personally identifiable information was disclosed in any part of the research.

RESULTS

Baseline Characteristics:

The baseline characteristics across both intervention groups indicate that the two cohorts were well-matched, enhancing the internal validity of subsequent outcome comparisons. The mean maternal age and gestational age were statistically similar between groups (p = 0.544 and 0.287, respectively), suggesting no confounding effect of age or gestational maturity on labor outcomes. Parity distribution was also comparable (p = 0.774), with a near-equal split between nulliparous and multiparous women. Common indications for induction such as post-dated pregnancy and oligohydramnios were proportionately distributed, while the proportion of women presenting with a low Bishop score was slightly higher in the PGE_2 group but not statistically significant (p = 0.698). These homogeneities affirm that any observed differences in labor progression or delivery outcomes are attributable to the induction agents rather than baseline disparities (Table 1).

Table 1

Baseline Characteristics at Entry into the Trial

Characteristics	Immediate induction with misoprostol (n=130)	Immediate induction with PGE_2 gel (n=130)	P value
Maternal age (years)*	26.8 ± 4.3	27.1 ± 4.7	0.544⁺
Gestational age (weeks)*	39.1 ± 1.0	39.2 ± 0.9	0.287⁺
Parity			0.774[1]
0	68 (52.3%)	70 (53.8%)	
≥1	62 (47.7%)	60 (46.2%)	
Indication for induction			0.591[1]
Post-date	85 (65.4%)	87 (66.9%)	
Oligohydramnios	20 (15.4%)	18 (13.8%)	
PIH or mild preeclampsia	25 (19.2%)	25 (19.2%)	
Bishop score ≤ 4 at admission	88 (67.7%)	91 (70.0%)	0.698[1]

Methods of Induction

The misoprostol group required significantly fewer repeat doses compared to the PGE_2 gel group, with 44.6% of women achieving effective induction with a single dose versus only 23.1% in the PGE_2 arm (p = 0.003). Conversely, the PGE_2 group showed a higher requirement for multiple applications, with 26.2% needing three doses and 8.5% requiring four doses, compared to only 16.9% and 3.8% respectively in the misoprostol group. Furthermore, oxytocin augmentation was needed significantly less often in the misoprostol group (29.2%) compared to PGE_2 (51.5%; p = 0.001), underscoring the superior uterotonic potency of misoprostol (Table 2). This table strongly suggests that misoprostol provides a more efficient pharmacologic induction profile, with faster cervical ripening and reduced reliance on adjunctive uterotonics.

Table 2

Methods of Inducing Labor and Use of Oxytocin

PCG_2 gel application pattern	Misoprostol (n=130)	PGE_2 gel (n=130)	P value
Route of administration	Vaginal (all cases)	Vaginal (all cases)	—
Number of doses used			
One dose	58 (44.6%)	30 (23.1%)	
Two doses	45 (34.6%)	55 (42.3%)	
Three doses	22 (16.9%)	34 (26.2%)	
Four doses	5 (3.8%)	11 (8.5%)	0.003[1]
Oxytocin required during labor	38 (29.2%)	67 (51.5%)	0.001[1]

Timing of Labor Events

Women induced with misoprostol demonstrated significantly shorter times to both active labor and overall delivery compared to those receiving PGE_2 gel. The mean time to active labor was 6.8 hours in the misoprostol group versus 9.1 hours in the PGE_2 group (p < 0.001), while time to delivery was similarly reduced (11.5 vs 14.2 hours; p < 0.001). Although the duration of active labor was slightly shorter in the misoprostol group, the difference did not reach statistical significance (p = 0.091). Importantly, the rate of failed induction was significantly lower in the misoprostol group (3.8% vs 9.2%, p = 0.047), further reinforcing the clinical efficiency of misoprostol as a more reliable agent for labor initiation (Table 3). These findings illustrate the practical benefits of misoprostol in reducing inpatient labor duration and potential resource utilization.

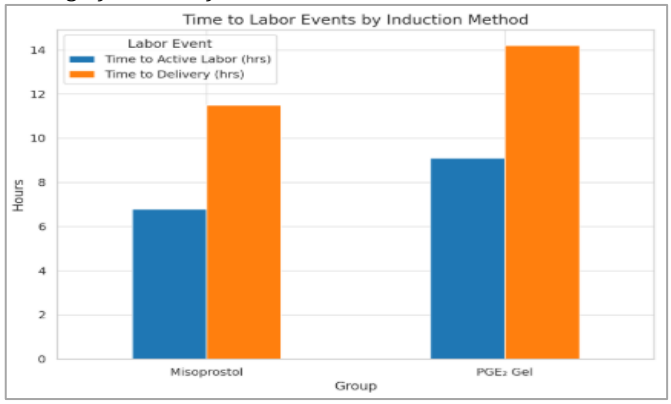
Table 3

Timing of Events After Induction

Event	Misoprostol (n=130)	PGE_2 gel (n=130)	P value
Time to active labor (hours)*	6.8 ± 2.3	9.1 ± 2.7	<0.001⁺
Time to delivery (hours)*	11.5 ± 3.4	14.2 ± 4.1	<0.001⁺
Duration of labor (active to delivery)	4.7 ± 1.8	5.1 ± 2.0	0.091⁺
Failed induction	5 (3.8%)	12 (9.2%)	0.047[1]

Figure 1

Timing of Events After Induction



Mode of Delivery

Mode of delivery analysis revealed that spontaneous vaginal delivery was significantly more common in nulliparous women who received misoprostol (70.6%) compared to those who received PGE_2 gel (51.4%; p = 0.018). Cesarean section rates were consequently lower in the misoprostol group among nulliparas (22.1% vs 38.6%), likely reflecting more efficient cervical ripening and labor progression. Among multiparous women, although the difference in spontaneous delivery (87.1% vs 78.3%) favored misoprostol, this was not statistically significant (p = 0.337), possibly due to the inherently higher responsiveness of multiparas to induction (Table 4). Overall, misoprostol was associated with more favorable delivery routes, particularly in nulliparous women, who typically pose greater challenges for induction success.

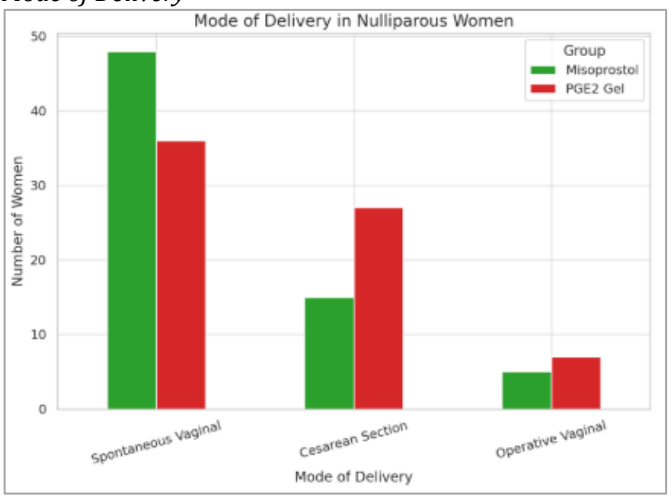
Table 4

Mode of Delivery

Mode of delivery	Misoprostol (n=130)	PGE_2 gel (n=130)	P value
Nulliparous women	68	70	
- Spontaneous vaginal delivery	48 (70.6%)	36 (51.4%)	
- Cesarean section	15 (22.1%)	27 (38.6%)	
- Operative vaginal delivery	5 (7.3%)	7 (10.0%)	0.018[1]*
Multiparous women	62	60	
- Spontaneous vaginal delivery	54 (87.1%)	47 (78.3%)	
- Cesarean section	6 (9.7%)	10 (16.7%)	
- Operative vaginal delivery	2 (3.2%)	3 (5.0%)	0.337[1]

Figure 2

Mode of Delivery



Maternal Outcomes

Maternal complications were generally low in both groups; however, the misoprostol group had marginally lower incidences of adverse outcomes. Hyperstimulation with fetal heart rate changes occurred less frequently in the misoprostol group (3.8% vs 7.7%), though this difference was not statistically significant (p = 0.171), indicating comparable safety profiles. Notably, cesarean deliveries for failed induction were significantly lower in the misoprostol group (3.8% vs 9.2%; p = 0.047), aligning with the findings from Table 3 and supporting its higher efficacy. Rates of postpartum hemorrhage, meconium-stained liquor, and chorioamnionitis were also modestly lower with misoprostol (Table 5). These results support the interpretation that misoprostol, while potent, does not increase maternal morbidity and may, in fact, reduce operative interventions associated with failed labor progress.

Table 5

Maternal Outcomes

Outcome	Misoprostol (n=130)	PGE_2 gel (n=130)	P value
Clinical chorioamnionitis	4 (3.1%)	8 (6.2%)	0.237[1]
Meconium-stained liquor	11 (8.5%)	14 (10.8%)	0.528[1]
Hyperstimulation with FHR change	5 (3.8%)	10 (7.7%)	0.171[1]
Uterine rupture	0 (0.0%)	0 (0.0%)	—
Postpartum hemorrhage	9 (6.9%)	13 (10.0%)	0.368[1]
Cesarean for failed induction	5 (3.8%)	12 (9.2%)	0.047[1]
Cervical laceration	3 (2.3%)	5 (3.8%)	0.471[1]

Neonatal Outcomes

Neonatal well-being indicators were comparable between groups, though the misoprostol group exhibited slightly better results across most measures. Fewer neonates in the misoprostol group had low Apgar scores at 1 and 5 minutes (6.2% and 1.5%, respectively) compared to the PGE_2 group (10.8% and 3.8%), although differences did not achieve statistical significance (p = 0.147 and 0.249). NICU admissions were also lower in the misoprostol group (4.6% vs 9.2%; p = 0.111), possibly reflecting smoother labor courses and fewer instances of birth asphyxia or infections. Perinatal mortality was negligible in both groups (Table 6). These findings suggest that misoprostol does not compromise neonatal safety and may offer marginally superior neonatal outcomes due to more efficient and timely deliveries.

Table 6

Neonatal Outcomes

Outcome Measure	Misoprostol (n=130)	PGE_2 gel (n=130)	P value
Apgar score <7 at 1 minute	8 (6.2%)	14 (10.8%)	0.147[1]
Apgar score <7 at 5 minutes	2 (1.5%)	5 (3.8%)	0.249[1]
NICU admission	6 (4.6%)	12 (9.2%)	0.111[1]
Neonatal infection (confirmed)	1 (0.8%)	3 (2.3%)	0.312[i]
Perinatal mortality	0 (0.0%)	1 (0.8%)	0.317[i]

DISCUSSION

The findings of this comparative study reinforce the growing body of evidence that supports the clinical superiority of misoprostol over prostaglandin E_2 (PGE_2) gel for induction of labor. In this study, the mean time to onset of active labor and overall delivery was significantly shorter among women induced with misoprostol (6.8 ± 2.3 and 11.5 ± 3.4 hours, respectively) compared to those receiving PGE_2 gel (9.1 ± 2.7 and 14.2 ± 4.1 hours), with p-values less than 0.001 in both cases. These findings align with the meta-analysis conducted by Gaudineau et al., (2021), who reported that misoprostol significantly reduces induction-to-delivery interval by approximately 3 hours when compared to dinoprostone across a pooled sample of 3,945 women (Gaudineau et al., 2021). The shorter labor course not only reduces maternal discomfort

but also optimizes bed utilization and staffing in resource-limited labor wards an operational advantage particularly relevant to tertiary care centers in low- and middle-income countries (Kumari, 2021).

Furthermore, the reduced need for oxytocin augmentation in the misoprostol group (29.2% vs 51.5%, p = 0.001) underscores its pharmacologic potency and more consistent efficacy in cervical ripening and uterine contractility. This observation is mirrored by the randomized trial conducted by Goswami et al., (2021), in which 32% of women receiving vaginal misoprostol required oxytocin compared to 56% in the dinoprostone arm (p < 0.01). The biological rationale is well established: misoprostol, a PGE_1 analog, binds more avidly to myometrial receptors than dinoprostone (a PGE_2 analog), leading to more synchronous uterine contractions and faster cervical effacement (Goswami et al., 2021; Shankarappa et al., 2021). While concerns have historically existed around misoprostol-induced hyperstimulation, our study showed a non-significant difference in uterine tachysystole (3.8% vs 7.7%, p = 0.171), indicating that with appropriate dosing (25 µg intervals), safety can be maintained without compromising efficacy.

Mode of delivery, an outcome highly valued in both clinical and patient-centered contexts, also favored misoprostol. Spontaneous vaginal delivery occurred in 70.6% of nulliparous women in the misoprostol group, compared to only 51.4% in the PGE_2 group (p = 0.018), and overall cesarean rates for failed induction were significantly lower in the misoprostol arm (3.8% vs 9.2%, p = 0.047). Similar trends have been reported by Sharma and Agarwal (2023) in a Cochrane review where misoprostol was associated with a higher vaginal delivery rate within 24 hours and lower incidence of cesarean delivery, particularly in nulliparous populations (Sharma & Agarwal, 2023). These results may stem from more rapid cervical changes induced by misoprostol, reducing the likelihood of dystocia or non-progressive labor, both common indications for surgical intervention in primigravida.

Despite enhanced efficacy, maternal safety remained uncompromised in the misoprostol group. Rates of postpartum hemorrhage (6.9% vs 10.0%), cervical laceration (2.3% vs 3.8%), and chorioamnionitis (3.1% vs 6.2%) were all lower in the misoprostol group, though differences did not reach statistical significance. Importantly, the rate of uterine rupture was zero in both groups, an encouraging outcome given historical fears surrounding uterotonic overactivity. Studies such as Agarwal et al., (2023) and more recently Gaudineau et al., (2021) have consistently demonstrated that low-dose misoprostol is not associated with increased uterine rupture in women without prior cesarean delivery (Agarwal et al., 2023; Gaudineau et al., 2021). Our findings reinforce this safety profile, highlighting that, when administered judiciously, misoprostol provides a favorable balance between effectiveness and maternal morbidity.

Neonatal outcomes also trended favorably in the misoprostol group. The incidence of NICU admission (4.6% vs 9.2%), low Apgar scores at 1 minute (6.2% vs 10.8%), and at 5 minutes (1.5% vs 3.8%) were consistently lower, although not statistically significant. This trend suggests that accelerated labor progression with misoprostol does not translate into fetal distress or compromise. A retrospective cohort study by Taliento et al., (2023) involving 5,312 deliveries similarly noted no increase in neonatal morbidity with vaginal misoprostol compared to dinoprostone, and even reported improved composite neonatal outcomes in the misoprostol cohort (Taliento et al., 2023). Importantly, the absence of perinatal mortality in the misoprostol group in our study further supports the assertion that rapid induction need not come at the cost of neonatal safety, provided fetal monitoring protocols are rigorously followed.

In this study, the superiority of misoprostol in terms of fewer induction failures (3.8% vs 9.2%, p = 0.047) also carries substantial clinical implications. Failed inductions not only prolong maternal hospitalization but often culminate in surgical deliveries, exposing mothers to anesthesia, hemorrhage, and infection risks. This efficiency advantage also translates into economic benefits. A cost-effectiveness analysis by Das et al., (2023) found misoprostol to be the most cost-effective pharmacologic agent for induction in nulliparous women, yielding both better health outcomes and reduced hospital resource utilization. In low-resource settings, these advantages become even more pronounced, positioning misoprostol as a preferred agent in public maternity services (Das et al., 2023).

Nonetheless, while our findings advocate for the widespread adoption of misoprostol, caution should be exercised in certain high-risk populations. For example, although our study excluded women with previous cesarean sections or uterine surgery, the extrapolation of findings to such populations should be guided by existing evidence, which continues to debate the safety of misoprostol in scarred uteri. Further, the difference in uterine hyperstimulation and meconium-stained liquor though not statistically significant warrants vigilance. As identified by Fatima et al., (2024), uterine sensitivity to prostaglandins varies based on parity, cervical status, and individual pharmacogenetics, reinforcing the need for personalized protocols rather than universal regimens (Fatima et al., 2024).

CONCLUSION

This study found that low-dose vaginal misoprostol more effective and clinically advantageous agent than PGE_2 gel for the induction of labor in term pregnancies. Misoprostol was associated with significantly shorter induction-to-delivery intervals, reduced need for oxytocin augmentation, and higher rates of spontaneous vaginal delivery, particularly among nulliparous women. Importantly, these benefits were achieved without a concomitant increase in maternal or neonatal morbidity, as evidenced by comparable rates of postpartum hemorrhage, uterine hyperstimulation, NICU admissions, and low Apgar scores. The incidence of failed induction and cesarean section for non-progression were also markedly lower in the misoprostol group, suggesting improved labor efficiency and fewer operative interventions. Given its low cost, ease of storage, and

clinical reliability, misoprostol represents a superior choice for labor induction in high-volume tertiary settings, especially in resource-constrained environments. However, careful patient selection, appropriate dosing, and vigilant monitoring remain essential to ensure safety, particularly in settings with limited intrapartum surveillance.

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