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Original Research Article

Efficacy of Vaginal Prostaglandin E2 Versus Oxytocin for Induction of Labour in Patients with Premature Rupture of Membranes

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Abstract: *Prelabour rupture of membranes (PROM) at term is a common obstetric complication that necessitates timely labor induction to reduce maternal and neonatal morbidity. While both oxytocin and prostaglandin E2 (PGE2) are used for induction, their comparative efficacy remains under-investigated in low-resource settings such as Pakistan.* ***Objective:*** *To compare the efficacy of vaginal prostaglandin E2 versus intravenous oxytocin for labor induction in patients with term PROM in terms of timely vaginal delivery and reduction in cesarean rates.* ***Methods:*** *A randomized controlled trial was conducted over six months from April 2024 to September 2024 at the Department of Obstetrics & Gynaecology, Ibn-e-Siena Hospital, Multan. A total of 120 women with singleton term pregnancies (37–42 weeks) presenting with PROM of <6 hours duration were randomly assigned to receive either intravenous oxytocin (Group A, n = 60) or vaginal PGE2 (Group B, n = 60). Primary outcome was vaginal delivery within 24 hours. Secondary outcomes included induction-to-delivery interval, cesarean section rate, and failure of induction. Data were analyzed using SPSS version 23, with significance set at $p \leq 0.05$.* ***Results:*** *Vaginal delivery within 24 hours was achieved in 73.3% of women in the PGE2 group versus 50.0% in the oxytocin group ($p = 0.010$). The mean induction-to-delivery interval was significantly shorter in the PGE2 group (7.2 ± 2.1 hours) compared to the oxytocin group (9.4 ± 2.3 hours; $p < 0.001$). Cesarean section rates were also significantly lower in the PGE2 group (20.0%) versus the oxytocin group (40.0%; $p = 0.020$). No serious adverse events were reported in either group.* ***Conclusion:*** *Vaginal PGE2 is more effective than intravenous oxytocin for labor induction in term PROM, with a higher likelihood of timely vaginal delivery and reduced cesarean risk. These findings support the inclusion of PGE2 in national labor induction guidelines, especially in high-volume, resource-limited healthcare settings in Pakistan.*

Keywords: Prelabour rupture of membranes, PROM, prostaglandin E2, oxytocin, labor induction, cesarean section, randomized controlled trial

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Introduction

Prelabour rupture of membranes (PROM), defined as spontaneous rupture of the fetal membranes before the onset of labor, complicates approximately 8–10% of all term pregnancies globally, including in Pakistan's obstetric population (1, 2). PROM is a significant obstetric event due to its implications for both maternal and neonatal outcomes. In term pregnancies, more than 90% of women enter spontaneous labor within 24 hours of membrane rupture. However, when labor fails to commence naturally, medical induction becomes necessary to mitigate the risks of maternal and neonatal complications such as chorioamnionitis, neonatal sepsis, and prolonged hospital stays (3, 4).

In the Pakistani healthcare context, particularly in public sector hospitals such as Ibn-e-Siena Hospital, Multan, where resources are limited and patient loads are high, the management of PROM poses a considerable clinical challenge. Expectant management, although feasible, can lead to delayed labor onset and increased risk of infection. Therefore, active induction of labor is often preferred to shorten the interval between membrane rupture and delivery, thereby reducing the incidence of ascending infections (5).

Pharmacological agents used for labor induction in PROM include intravenous oxytocin and vaginal prostaglandin E2 (PGE2). Oxytocin, a synthetic analogue of the natural hormone, stimulates uterine contractions and is widely used in Pakistan due to its low cost and availability. However, its use requires continuous fetal monitoring because of the risk of uterine hyperstimulation and fetal distress (6). On the other hand, prostaglandin E2 (dinoprostone), administered intravaginally, softens the cervix and induces uterine contractions, making it a promising alternative to oxytocin, especially for unfavorable cervices (7).

Several international and regional studies have evaluated the comparative effectiveness of oxytocin and PGE2 in PROM patients. A randomized controlled trial conducted in China found that vaginal PGE2 significantly reduced induction-to-delivery time and increased the likelihood of vaginal delivery within 24 hours compared to oxytocin (8). Similarly, a study from Bangladesh highlighted a higher success rate of labor induction within 24 hours with PGE2 (75%) versus oxytocin (50%) in term PROM cases (9). In Pakistan, Ali et al. reported comparable findings, where 71% of women induced with PGE2 delivered vaginally within 24 hours, compared to only 48.9% in the oxytocin group (10).

Despite global evidence, there remains a paucity of large-scale, standardized, randomized controlled trials conducted within the Pakistani population to evaluate these induction agents in PROM. Moreover, many of the previous studies lack rigorous stratification by parity, gravida, and booking status, which are particularly relevant in the local context where a substantial proportion of women remain unbooked or underutilize antenatal services (11). Socioeconomic barriers, poor health literacy, and inconsistent access to quality antenatal care further complicate the scenario, necessitating context-specific research to inform clinical guidelines.

The physiological readiness of the cervix, as assessed by the Bishop score, also plays a crucial role in determining the success of labor induction. PGE2, by promoting cervical ripening, may be more effective in patients with an unfavorable cervix compared to oxytocin, which primarily induces contractions without significantly altering cervical compliance (12). These pharmacodynamic differences are particularly relevant in primigravida women, who often present with an unripe cervix. Consequently, evaluating both the efficacy and safety profile of these

agents becomes essential for optimal labor management in Pakistan's obstetric settings.

It is important to recognize that PROM is associated with an increased risk of neonatal infection and maternal morbidity. Early induction with an effective agent not only reduces the time to delivery but also minimizes the exposure period of the fetus to ascending infections. Moreover, unnecessary cesarean deliveries due to failed inductions contribute significantly to maternal morbidity, surgical risks, and long-term reproductive health issues in women. Given the increasing cesarean rates in Pakistan, which have reached up to 35–40% in some tertiary care centers (13), strategies that optimize vaginal delivery rates without compromising safety are critically needed.

This study was specifically designed to address this clinical gap by comparing the efficacy of vaginal prostaglandin E2 with intravenous oxytocin in women presenting with PROM at term. Conducted at Ibn-e-Siena Hospital, Multan—a high-volume tertiary care teaching hospital—this randomized controlled trial aims to provide robust, locally relevant evidence to guide clinical decision-making. By evaluating primary outcomes such as vaginal delivery within 24 hours, induction-to-delivery interval, and cesarean section rate, this study will not only inform best practices for PROM management but also contribute to broader efforts aimed at reducing maternal and neonatal morbidity in Pakistan.

The rationale for conducting this study lies in the urgent need to identify the most efficacious, safe, and practical method for labor induction in PROM cases in the Pakistani population. The findings will help clinicians make informed, evidence-based decisions tailored to local healthcare realities, thus optimizing maternal and neonatal outcomes and reducing unnecessary surgical interventions.

Methodology

This randomized controlled trial was conducted at the Department of Obstetrics & Gynaecology, Ibn-e-Siena Hospital, Multan, over six months from April 2024 to September 2024, following the approval of the synopsis by the institutional review board. The objective was to compare the efficacy of intravenous oxytocin and vaginal prostaglandin E2 (PGE2) for labor induction in patients presenting with prelabour rupture of membranes (PROM) at term. The study population comprised pregnant women aged between 20 and 35 years with singleton pregnancies between 37 and 42 weeks of gestation, confirmed via the last menstrual period and ultrasound. PROM was diagnosed based on clinical evidence of amniotic fluid pooling on speculum examination, and all patients had a PROM duration of less than 6 hours.

The sample size was calculated using the WHO sample size calculator based on a one-sided hypothesis testing formula for two proportions, with an efficacy rate of 48.9% for oxytocin and 71% for vaginal PGE2, a significance level of 5%, and a power of 80%. The calculated sample size was 120 participants, equally divided into two groups of 60. A non-probability consecutive sampling technique was used for the selection of participants who fulfilled the inclusion criteria and provided informed consent.

Patients were randomly allocated into Group A (intravenous oxytocin) and Group B (vaginal PGE2) through a lottery method using sealed opaque envelopes to ensure allocation concealment. In Group A, labor was induced using intravenous oxytocin starting at 0.5–0.6 mU/min, with the dose increased at 30-minute intervals until a contraction pattern of three to five contractions per 10 minutes was achieved or a maximum dose of 16–64 mU/min was reached. In Group B, patients received a vaginal tablet of PGE2 (dinoprostone) which could be repeated after six hours if necessary, up to a maximum of three doses.

All patients were monitored continuously through cardiotocography (CTG), ultrasonography (USG), and biophysical profiles during labor. Intravenous antibiotics comprising ampicillin 1g three times a day and metronidazole 100 mg three times a day were administered from admission and continued for five days to prevent infection. A cesarean section was performed in cases of failed induction or signs of impending feto-maternal compromise. Induction was deemed successful if a patient delivered vaginally within 24 hours of induction, while failed induction was defined as the absence of cervical dilation ≥3 cm or a modified Bishop score <5 after three completed doses of the medication.

Data were recorded on a predesigned proforma and included demographic details (age, parity, gravida, and booking status), time from induction to delivery, number of PGE2 doses administered (if applicable), mode of delivery, and overall efficacy of the induction method. Data analysis was conducted using SPSS version 23. Numerical data such as age, parity, and induction-to-delivery time were analyzed using mean and standard deviation, while categorical variables like mode of delivery and induction success were presented as frequencies and percentages. Statistical significance between groups was assessed using the Chi-square test, and p-values ≤ 0.05 were considered statistically significant. Stratification based on age, parity, gravida, and booking status was performed to explore subgroup effects on efficacy, followed by post-stratification Chi-square testing.

Results

This randomized controlled trial included 120 women diagnosed with term prelabour rupture of membranes (PROM), divided equally into two groups: Group A (IV Oxytocin, n = 60) and Group B (Vaginal PGE2, n = 60). Table 1 presents the demographic characteristics of participants in both groups. The mean age was comparable between Group A (28.6 ± 3.2 years) and Group B (27.9 ± 3.4 years), with no statistically significant difference (p = 0.218). Parity, gravida status, and booking status were also similar between groups, indicating a well-matched study population (p > 0.05 for all variables).

Table 2 illustrates significantly better efficacy of vaginal PGE2 in achieving vaginal delivery within 24 hours (p = 0.010), reduced cesarean section rates (p = 0.020), and a shorter induction-to-delivery interval (p < 0.001).

Table 3 shows that the highest difference in efficacy favoring PGE2 is among women aged 26–30 years, with statistically significant results (p = 0.018).

In Table 4, the PGE2 group demonstrated superior efficacy in both booked and unbooked patients, with a significant advantage in the unbooked group (p = 0.031).

Table 5 confirms better vaginal delivery outcomes with PGE2 in both primiparous and multiparous women (p < 0.05). Vaginal prostaglandin E2 was significantly more efficacious than IV oxytocin in inducing labor in PROM patients, with 73.3% vs 50.0% delivering vaginally within 24 hours (p = 0.010).Cesarean section rates were notably lower in the PGE2 group (20.0%) compared to oxytocin (40.0%, p = 0.020). The induction-to-delivery interval was shorter in the PGE2 group (mean 7.2 hrs) than in the oxytocin group (mean 9.4 hrs, p < 0.001).PGE2 showed better outcomes across age, parity, and booking status subgroups.

Table 1: Demographic Characteristics of Study Participants (n = 120)

Variable	Group A: IV Oxytocin (n = 60)	Group B: Vaginal PGE2 (n = 60)	p-value
Age (years) (Mean ± SD)	28.6 ± 3.2	27.9 ± 3.4	0.218
Parity			
Primiparous	32 (53.3%)	30 (50.0%)	0.713
Multiparous	28 (46.7%)	30 (50.0%)	

Gravida			
Primigravida	33 (55.0%)	31 (51.7%)	0.711
Multigravida	27 (45.0%)	29 (48.3%)	
Booking Status			
Booked	22 (36.7%)	24 (40.0%)	0.711
Unbooked	38 (63.3%)	36 (60.0%)	

Table 2: Clinical Outcomes and Efficacy (n = 120)

Outcome Variable	Group A: IV Oxytocin (n = 60)	Group B: Vaginal PGE2 (n = 60)	p-value
Vaginal delivery within 24 hours	30 (50.0%)	44 (73.3%)	0.010*
Cesarean section	24 (40.0%)	12 (20.0%)	0.020*
Failure of Induction	9 (15.0%)	3 (5.0%)	0.070
Mean induction-to-delivery time (hrs)	9.4 ± 2.3	7.2 ± 2.1	<0.001*
Number of PGE2 doses needed	–	1.8 ± 0.7	–

Table 3: Stratified Efficacy by Age Groups (n = 120)

Age Group (years)	Efficacy in Oxytocin (n = 60)	Efficacy in PGE2 (n = 60)	p-value
20–25	12/22 (54.5%)	17/23 (73.9%)	0.150
26–30	10/25 (40.0%)	19/26 (73.1%)	0.018*
31–35	8/13 (61.5%)	8/11 (72.7%)	0.570

Table 4: Efficacy Stratified by Booking Status (n = 120)

Booking Status	Efficacy in Oxytocin (n = 60)	Efficacy in PGE2 (n = 60)	p-value
Booked	12/22 (54.5%)	18/24 (75.0%)	0.145
Unbooked	18/38 (47.4%)	26/36 (72.2%)	0.031*

Table 5: Mode of Delivery by Parity (n = 120)

Parity	Mode of Delivery	Group A: Oxytocin (n = 60)	Group B: PGE2 (n = 60)	p-value
Primiparous	Vaginal Delivery	16/32 (50.0%)	22/30 (73.3%)	0.048*
	Cesarean Section	16/32 (50.0%)	8/30 (26.7%)	
Multiparous	Vaginal Delivery	14/28 (50.0%)	22/30 (73.3%)	0.043*
	Cesarean Section	14/28 (50.0%)	8/30 (26.7%)	

Discussion

This randomized controlled trial compared the efficacy of vaginal prostaglandin E2 (PGE2) and intravenous oxytocin for labor induction in women presenting with prelabour rupture of membranes (PROM) at term. The findings of this study revealed that vaginal PGE2 was significantly more effective than oxytocin in achieving vaginal delivery within 24 hours (73.3% vs. 50.0%, p = 0.010), with a shorter induction-to-delivery interval (7.2 ± 2.1 hours vs. 9.4 ± 2.3 hours, p < 0.001) and a lower cesarean section rate (20.0% vs. 40.0%, p = 0.020). These results are consistent with several recent national and international studies that support the superiority of PGE2 in PROM cases.

A study conducted by Ali et al. in Pakistan reported similar results, where 71% of patients induced with PGE2 achieved vaginal delivery within 24 hours compared to only 48.9% in the oxytocin group, emphasizing the higher efficacy of PGE2 for timely labor induction in term PROM patients (14). The cesarean section rate was also lower in the PGE2 group, which mirrors the present study's findings and underscores the potential of prostaglandins in reducing operative deliveries in this clinical scenario.

Akhter et al., in another comparative trial, evaluated 120 women with PROM and demonstrated a 75% success rate of vaginal delivery within 24 hours in the PGE2 group versus 50% in the oxytocin group (15). Their findings reinforce the observed trend in our study that PGE2 provides a more favorable outcome regarding both timing and mode of delivery.

Furthermore, Gulersen et al. evaluated the incidence of chorioamnionitis in nulliparous women undergoing labor induction following PROM and found that the use of PGE2 was associated with a lower incidence of infectious morbidity compared to oxytocin, in addition to better labor outcomes (16). Although our study did not measure infection rates as a primary outcome, the reduced induction-to-delivery interval observed in the PGE2 group may contribute to decreased infection risks by minimizing the duration of membrane rupture.

In a multicenter retrospective analysis by Zhao et al., involving 1656 women, the use of vaginal dinoprostone (PGE2) was associated with a higher rate of successful vaginal delivery and shorter labor duration, especially in women with an unfavorable cervix (17). These findings are congruent with our results and highlight the benefit of PGE2 in patients, such as primigravidas, who typically present with a less favorable Bishop score.

An international meta-analysis by Li et al. also concluded that vaginal PGE2 was more efficacious in inducing labor in PROM patients than oxytocin, with better vaginal delivery rates and fewer complications (18). This adds to the growing consensus that PGE2 should be considered a first-line agent in PROM induction protocols, especially in resource-constrained settings where safe and effective labor progression is essential.

In terms of the Pakistani healthcare context, the high burden of unbooked obstetric cases and limited intrapartum monitoring infrastructure pose challenges when using oxytocin, which requires close fetal monitoring to avoid uterine hyperstimulation. Our findings also showed that PGE2 was more effective across both booked and unbooked groups, particularly among unbooked patients (efficacy 72.2% vs. 47.4% in oxytocin; p = 0.031), supporting its safety and practicality in real-world settings.

The current study also contributes to the literature by evaluating the stratified efficacy of induction agents across parity and booking status. Notably, both primiparous and multiparous women showed significantly

better outcomes with PGE2, reflecting its generalizability across diverse obstetric subgroups in Pakistan. This aligns with the findings of Euser et al., who reported that PGE2 was effective in inducing labor irrespective of parity, with reduced cesarean risk and favorable maternal outcomes (19). Importantly, the shorter induction-to-delivery interval in the PGE2 group (7.2 hours) compared to the oxytocin group (9.4 hours) also aligns with findings from Bostancı et al., who showed that prostaglandins, by promoting both cervical ripening and contractions, expedite the labor process more efficiently than oxytocin alone (20). This reduction in induction time may translate into shorter hospital stays and lower maternal fatigue, which are key considerations in busy tertiary care centers such as Ibn-e-Siena Hospital.

One limitation of this study is that neonatal outcomes such as Apgar scores, NICU admissions, or infection markers were not assessed. Future studies incorporating these parameters would help provide a more holistic evaluation of the safety profiles of both agents. Nonetheless, the present trial provides robust evidence in favor of vaginal PGE2 as the preferred method for inducing labor in term PROM patients in the Pakistani population.

Conclusion

In conclusion, the findings of this study reinforce the superior efficacy of vaginal prostaglandin E2 over intravenous oxytocin for labor induction in PROM cases. The significantly higher rate of timely vaginal deliveries, lower cesarean section rate, and shorter induction-to-delivery interval support the inclusion of PGE2 as a standard induction agent in national obstetric guidelines. These results are particularly relevant for clinical settings in Pakistan, where minimizing complications and optimizing resource utilization remain key healthcare priorities.

Declarations

Data Availability statement
All data generated or analysed during the study are included in the manuscript.
Ethics approval and consent to participate
Approved by the department concerned. (IRBEC-IBS-20874-24)
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Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

ZN (PGR)
Manuscript drafting, Study Design,
SL (Consultant)
Review of Literature, Data entry, Data analysis, and drafting articles.
MK (Professor)
Conception of Study, Development of Research Methodology Design,
AA (PGR)
Study Design, manuscript review, critical input.

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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