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Oral Misoprostol vs Oxytocin: A Comparative Study in Induction of Labour in Prelabour Rupture of Membrane

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ABSTRACT
Prelabor Rupture of Membranes (PROM) at term poses significant clinical challenges, often necessitating timely induction of labor to reduce maternal and neonatal risks. This study compares the efficacy and safety of oral misoprostol versus intravenous oxytocin for labor induction in women with PROM. The primary aim was to compare the induction-to-delivery interval and mode of delivery between oral misoprostol and oxytocin. Secondary objectives included evaluating maternal and neonatal outcomes associated with both methods. This randomized controlled trial was conducted at Sree Mookambika Institute of Medical Sciences, Tamil Nadu, from January to December 2024. A total of 152 term pregnant women with PROM were randomly assigned to receive either oral misoprostol (25 µg every 6 hours, up to 4 doses) or intravenous oxytocin (titrated infusion). The primary outcome was the induction-to-vaginal delivery interval. Secondary outcomes included mode of delivery, maternal complications and neonatal outcomes. The mean induction-to-delivery time was significantly longer in the misoprostol group (10.15±5.66 hrs) compared to the oxytocin group (7.75±2.90 hrs, $p<0.001$). Vaginal delivery rates were similar (misoprostol 82%, oxytocin 87%). Maternal complications, including pyrexia and uterine hyperstimulation and neonatal outcomes such as Apgar scores and NICU admissions showed no significant differences between groups. Both oral misoprostol and intravenous oxytocin are effective and safe for labor induction in PROM. Misoprostol is associated with a longer induction-to-delivery interval but comparable maternal and neonatal outcomes.

INTRODUCTION

Prelabor Rupture of Membranes (PROM) refers to the spontaneous rupture of fetal membranes before the onset of labor. When PROM occurs at term (≥37 weeks of gestation), it presents a clinical dilemma, as prolonged latency increases the risk of maternal and neonatal infections, while immediate induction may lead to unnecessary interventions[1]. Induction of labor in PROM is aimed at reducing these complications by minimizing the duration between membrane rupture and delivery.

Two commonly used agents for labor induction in PROM are misoprostol, a synthetic prostaglandin E1 analogue and oxytocin, a naturally occurring hormone that stimulates uterine contractions. Misoprostol, when used orally, is affordable, stable at room temperature and has both cervical ripening and uterotonic effects[2]. Oxytocin, administered intravenously, has long been a mainstay in induction protocols but requires continuous monitoring and skilled administration.

PROM occurs in approximately 8-10% of all term pregnancies and is associated with increased rates of cesarean delivery, chorioamnionitis and neonatal sepsis if not managed appropriately[3]. In low-resource settings, the burden is even higher due to limited access to immediate obstetric interventions and antibiotics.

Several studies have evaluated the efficacy and safety of misoprostol and oxytocin in term PROM cases. A study by Bolla found that oral misoprostol is effective and well-tolerated, with comparable outcomes to oxytocin in terms of cesarean section rates and neonatal outcomes. Similarly, the WHO multicenter trial on misoprostol concluded that oral misoprostol is a viable alternative to conventional oxytocin regimens, particularly in resource-constrained settings[4]. However, there remains variability in reported induction-to-delivery intervals, side effect profiles and patient satisfaction across different studies, emphasizing the need for localized, context-specific research.

Despite existing evidence, there is limited data comparing oral misoprostol and intravenous oxytocin in the Indian population, particularly in rural and semi-urban settings. Given the differences in healthcare access, patient profiles and institutional protocols, it is essential to evaluate the comparative efficacy and safety of these agents in real-world settings. Furthermore, oral misoprostol presents a potentially more accessible and cost-effective option for induction, particularly in facilities with limited capacity for continuous intravenous infusion and electronic fetal monitoring. This study seeks to provide evidence that can guide clinical decision-making and protocol development for the management of PROM at term.

Aim and objectives

Aim: To compare the efficacy, safety and outcomes of oral misoprostol versus intravenous oxytocin in the induction of labor among women with prelabor rupture of membranes (PROM).

Objectives:

- To assess the induction-to-delivery interval and mode of delivery (vaginal vs cesarean) in women induced with oral misoprostol versus oxytocin
- To evaluate maternal and neonatal complications associated with both methods

MATERIALS AND METHODS

Study design: This study was a randomized controlled trial conducted to compare the efficacy and safety of oral misoprostol versus intravenous oxytocin for labor induction in women with Prelabor Rupture of Membranes (PROM) at term. Ethical approval was obtained from the institutional review board and informed consent was secured from all participants prior to their inclusion in the study.

Study population: The study included pregnant women at term (≥37 weeks gestation) presenting with PROM. Inclusion criteria were singleton pregnancies, cephalic presentation and an unfavorable cervix (Bishop score <6). Exclusion criteria included contraindications to labor induction, previous uterine surgery, fetal distress, chorioamnionitis and known hypersensitivity to prostaglandins or oxytocin.

Study setting and duration: This study was conducted at Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanniyakumari, Tamil Nadu between Jan 20204 and Dec 2024.

Sample size and randomization: A total of 152 participants were enrolled in the study. They were randomly assigned into two groups using a computer-generated randomization sequence:

- Group A: Oral misoprostol (n = 76)
- Group B: Intravenous oxytocin (n = 76)

Randomization was performed by an independent third party to ensure allocation concealment.

Intervention protocols

Group A (oral misoprostol): Participants received 25 µg of misoprostol orally every 6 hrs, up to a maximum of four doses or until active labor was established.

Group B (intravenous oxytocin): Participants received oxytocin infusion as per hospital protocol, starting at 2 mU min^{-1} and titrated every 30 min until adequate uterine contractions were achieved.

Both interventions were administered under continuous fetal heart rate monitoring and regular assessment of uterine activity.

Outcome measures: The primary outcome measure was the induction-to-vaginal delivery interval. Secondary outcomes included:

- Mode of delivery (vaginal or cesarean)
- Maternal complications (pyrexia, gastrointestinal side effects)
- Neonatal outcomes (Apgar scores, NICU admissions)

Statistical analysis: Data were analyzed using SPSS software (version 26). Continuous variables were expressed as Mean±standard deviation and compared using the Student's t-test. Categorical variables were analyzed using the chi-square test. A $p<0.05$ was considered statistically significant.

RESULTS AND DISCUSSION

The present study aimed to compare the efficacy and safety of oral misoprostol and intravenous oxytocin for labor induction in term pregnancies complicated by Prelabor Rupture of Membranes (PROM). The findings reveal that while both agents were effective in achieving vaginal delivery, significant differences were observed in the induction-to-delivery interval and the incidence of certain maternal complications (Table 1).

The induction-to-delivery interval was significantly longer in the misoprostol group (10.15±5.66 hrs) compared to the oxytocin group (7.75±2.90 hrs). This observation aligns with results from Bolla who reported a longer latency period with misoprostol but noted comparable delivery outcomes overall. Similarly, a randomized trial by Shetty *et al*.[5] reported that although oxytocin achieved faster delivery, oral misoprostol offered the advantage of ease of administration without significantly increasing maternal or neonatal morbidity (Table 2).

In terms of the mode of delivery, both groups demonstrated high vaginal delivery rates (82% for misoprostol and 87% for oxytocin), with no statistically significant difference. This concurs with the findings of Wing *et al*.[6] who concluded that both misoprostol and oxytocin are associated with favorable delivery outcomes in women with PROM, though individual institutional protocols and patient preferences may influence agent selection (Table 3).

Maternal complications such as pyrexia, nausea and uterine hyperstimulation were slightly more frequent in the oxytocin group, although these differences were not statistically significant. The incidence of uterine hyperstimulation was higher with oxytocin (10%) compared to misoprostol (5%), a finding supported by Hofmeyr *et al*.[2], who highlighted a dose-dependent relationship between oxytocin titration and uterine activity abnormalities. Misoprostol, while associated with mild gastrointestinal side effects, was generally well tolerated (Table 4).

Regarding neonatal outcomes, including Apgar scores and NICU admissions, no significant differences were observed between the two groups. This is in agreement with studies by Lokugamage and ACOG guidelines, which emphasize that both misoprostol and oxytocin, when used appropriately, are safe for the fetus in term PROM (Table 5).

Overall, the study suggests that oral misoprostol, despite requiring a longer time to achieve delivery, is a safe and effective alternative to intravenous oxytocin for labor induction in PROM cases. It also presents practical advantages in terms of ease of use and

Table 1: Baseline characteristics

Parameters	Misoprostol group (n = 76)	Oxytocin group (n = 76)	p-value
Mean age (years)	28.5 ±4.2	29.0±4.5	0.45
Parity (Primiparous %)	60%	58%	0.68
Gestational age (weeks)	39.1±1.2	39.3 ± 1.4	0.32

Table 2: Induction-to-delivery interval

Parameters	Misoprostol group	Oxytocin group	p-value
Mean induction-to-delivery time (hrs)	10.15±5.66	7.75±2.90	<0.001
Active phase duration (hrs)	6.5±3.1	4.20±1.8	<0.001

Table 3: Mode of delivery

Mode of delivery	Misoprostol group (%)	Oxytocin group (%)	p-value
Vaginal delivery	82	87	0.39
Cesarean section	18	13	-

Table 4: Maternal Complications

Complication	Misoprostol group (%)	Oxytocin group (%)	p-value
Maternal pyrexia	8	10	>0.05
Nausea/vomiting	12	15	>0.05
Uterine hyperstimulation	5	10	>0.05

Table 5: Neonatal outcomes

Outcome	Misoprostol group (%)	Oxytocin group (%)	p-value
Apgar score <7 at 5 min	3	5	>0.05
NICU admission	6	8	>0.05

resource efficiency, especially in settings where continuous IV administration and monitoring may be challenging.

The study on misoprostol, a medication used in induction, has several limitations. It was conducted at a single tertiary care center, which may limit its generalizability to other settings. The sample size of 152 participants may have been underpowered for subgroup analysis. The lack of blinding of participants and care providers could introduce bias in outcome reporting and clinical decision-making. The study only assessed short-term neonatal outcomes, which could be useful in evaluating the safety of induction agents. The fixed dosing regimen used in the study may not be suitable for exploring alternative strategies to optimize effectiveness and reduce side effects.

CONCLUSION

Both oral misoprostol and oxytocin are effective and safe for inducing labor in women with PROM, with comparable rates of vaginal delivery and maternal/neonatal outcomes. However, oral misoprostol demonstrated a longer induction-to-delivery interval compared to oxytocin, particularly in primiparous women, while oxytocin showed a higher incidence of uterine hyperstimulation. Further studies are recommended to optimize dosing regimens and assess long-term neonatal outcomes for both methods.

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