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A Comparative Study of Efficacy and Safety of Oral Misoprostol with Intravenous Oxytocin for Induction of Labour in Nulliparous Women with Prematur Rupture of Membrane

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Abstract

Background: Prelabour rupture of membranes (PROM) complicates 8–10% of pregnancies and increases infection risk with delayed labour. Early induction is preferred to reduce complications. Misoprostol and oxytocin are commonly used agents. This study compares their efficacy and safety for labour induction in term PROM to determine the more effective and safer option.

Aim: To compare efficacy and safety of oral misoprostol with intravenous oxytocin for induction of labour in women with premature rupture of membrane.

Result: Both groups showed comparable demographic and obstetric profiles. Misoprostol achieved faster induction-to-delivery (p=0.02) with 86.7% vaginal deliveries versus 80% in Oxytocin. Neonatal outcomes, including mean birth weight (2.91 kg vs 2.86 kg) and APGAR scores, were similar, with no significant maternal complications.

Method: This randomized study at SMS Medical College, Jaipur, included women with term PROM meeting inclusion criteria. Participants were randomly assigned to oral Misoprostol (25 µg every 3 hours, max five doses) or intravenous Oxytocin (5 IU/500 mL Ringer's lactate). Detailed clinical evaluation, ultrasound, and laboratory investigations were conducted before induction.

Conclusion: The study concludes that both oral Misoprostol and intravenous Oxytocin are safe and effective for labour induction in nulliparous women with term PROM. Misoprostol showed a shorter induction-to-delivery interval and faster labour progression. However,

due to the limited sample size, larger multicentric studies are recommended to validate these findings.

Keywords: Prelabour rupture of membranes, oral Misoprostol, intravenous oxytocin, fetal infection, Antepartum and postpartum pyrexia, puerperal sepsis.

Introduction

Prelabour rupture of membranes (PROM) is the rupture of fetal membranes before labour onset, complicating about 8% of term pregnancies, with intrauterine infection being the major maternal risk increasing with rupture duration.[1] It occurs in around 10% of pregnancies, with 70% at term, and is linked to higher maternal and perinatal infection and mortality. Nearly 80% of women with term PROM enter labour within 24 hours and 95% within 72 hours.[2] As prolonged latency increases infection risk, induction is recommended. A 2017 Cochrane review found early induction lowers maternal infection without raising cesarean rates.

Delays in labour onset after membrane rupture expose the fetus to infection and complications.[3] Frequent vaginal examinations further elevate maternal and fetal infection risk, leading to higher postpartum morbidity. Therefore, the American College of Obstetricians and Gynecologists (ACOG) recommends induction if spontaneous contractions do not occur upon presentation.[4]

Induction of labour involves stimulating uterine contractions medically or surgically to achieve vaginal delivery. When performed with an unripe cervix, it may result in prolonged labour or failed induction.[5] Misoprostol and oxytocin are the most common agents used. Misoprostol, a synthetic prostaglandin E_1 analogue, promotes cervical ripening and contractions but may cause uterine hyperstimulation. Originally developed for gastric ulcer prevention, it is inexpensive, heat-stable, and ideal for low-resource settings.[6]

Vaginal misoprostol has a longer half-life, while oral misoprostol's shorter duration reduces uterine overstimulation and infection risk in PROM. Doses typically range from 50–100 µg every 4–6 hours, achieving high vaginal delivery rates within 24 hours.[7]

Oxytocin, a naturally occurring hormone from the posterior pituitary,[8] is a standard induction agent whose safety depends on cervical status. It induces effective contractions but may cause fetal distress or uterine rupture. Though sublingual misoprostol shows better efficacy and neonatal outcomes, ACOG still recommends oxytocin for PROM, and Kulhan found it superior to dinoprostone for 24-hour delivery.[9]

This study aims to compare the efficacy and safety of oral misoprostol versus oxytocin infusion for induction of labour.

Materials and Methods

Type of Study: Hospital-based interventional study

Study Design: Prospective comparative study

Study Location: Department of Obstetrics and Gynaecology, SMS Medical College, Jaipur

Duration: Conducted from July 2023 until completion of the required sample size, followed by two months for data analysis

Study Population: Nulliparous pregnant women with term PROM admitted to the labour room

Inclusion Criteria: The study included singleton live pregnancies between 37–42 weeks with PROM lasting under 12 hours, vertex presentation, no prior uterine surgery, reactive NST, and Bishop score <6. Participants gave informed consent and were not part of any other study.

Exclusion Criteria: Women with contraindications to vaginal delivery, prostaglandins, or oxytocin, including those with heart disease, severe asthma, renal insufficiency, glaucoma, or chorioamnionitis, were excluded from the study.

Ethical Clearance: Obtained from the institutional ethics committee

Sample Size: Based on a previous randomized trial, detecting a 1.18-hour difference in induction-to-delivery interval with 80% power

Method: Participants were randomly assigned by flip coin into Group A receiving 25 µg buccal misoprostol every 3 hours (max 5 doses) and Group B receiving oxytocin infusion starting at 1 mIU/mL/min, increased hourly up to 6 mIU/mL/min.

Monitoring: Labour progress was monitored using Bishop score, CTG, and partogram, with caesarean performed for meconium-stained liquor, non-reassuring CTG, or arrested labour.

Maternal Outcomes: Gastrointestinal effects, cervical/perineal tears, chorioamnionitis, hemorrhage, pyrexia, sepsis

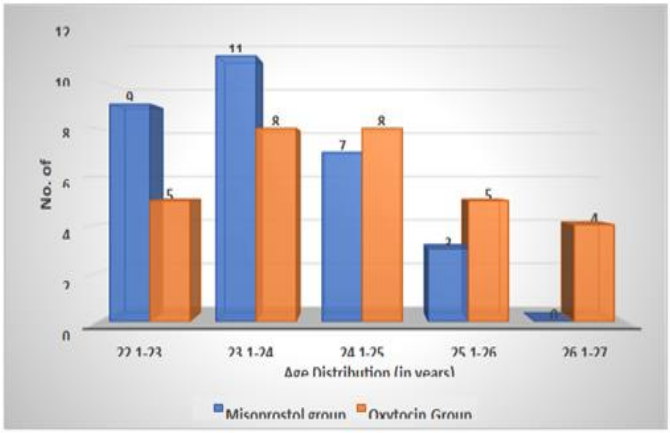
Neonatal Outcomes: Fetal weight, APGAR score (1 & 5 min), NICU admission, delivery mode, induction-to-delivery interval

Data Analysis: All data compiled and statistically analyzed.

Results & Observations

Both Misoprostol and Oxytocin groups showed comparable demographic, clinical, and obstetric profiles with no significant differences in religion (p=0.58), socioeconomic status (p=0.9), BMI (p=0.72), or Bishop score (p=0.74). Misoprostol led to a shorter induction-to-delivery interval (p=0.02). Vaginal delivery occurred in 86.67% (Misoprostol) and 80% (Oxytocin). Neonatal outcomes—including birth weight (p=0.85), APGAR scores, and NICU admissions—were similar. Maternal complications were mild and statistically insignificant (p=0.1).

Graph 1: Distribution of Cases according to Age.



The age distribution between the Misoprostol and Oxytocin groups was comparable. The mean age was 24.96 ± 1.21 years and 24.76 ± 1.40 years, respectively. Most participants were aged 23–25 years, and the difference between groups was statistically insignificant (p = 0.55).

Table 1: Comparison of mean time taken till active phase in two group.

Parameter	Misoprostol group		Oxytocin Group		P- Value
	Mean	SD	Mean	SD	
Time till active phase	4.98	0.69	5.69	0.58	0.0005

The mean time to reach the active phase was significantly shorter in the Misoprostol group (4.98 – 0.69 hours) compared to the Oxytocin group (5.69 – 0.58 hours), with the difference being highly significant (p = 0.0005). This indicates that oral Misoprostol was more

effective in initiating active labour than intravenous Oxytocin.

Table 2: Comparison of mean Ind.to del. Interval in two groups

Parameter	Misoprostol group		Oxytocin Group		P- Value
	Mean	SD	Mean	SD	
Ind.to del. interval	7.18	0.93	7.67	0.72	0.02

The mean induction to delivery interval was significantly shorter in the Misoprostol group at 7.18 hours with a standard deviation of 0.93, compared to 7.67 hours with a standard deviation of 0.72 in the Oxytocin group. This difference was statistically significant ($p = 0.02$), indicating a faster delivery process in the Misoprostol group.

Table 3: Comparison of cases according to Side Effects

Side Effects	Misoprostol group		Oxytocin Group		P-Value
	No. of Cases	Percentage	No. of Cases	Percentage	
Breathlessness	4	13.33	3	10.00	0.01
Headache	4	13.33	2	6.67	
Hypotension	0	0.00	1	3.33	
Palpitations	0	0.00	2	6.67	
Diarrhea	4	13.33	0	0.00	
Nausea	2	6.67	0	0.00	
Tachycardia	2	6.67	0	0.00	
Vomiting	4	13.33	0	0.00	

Side effects were more frequent in the Misoprostol group. Breathlessness (13.33% vs 10%, p=0.01), headache (13.33% vs 6.67%), diarrhea, nausea, tachycardia, and vomiting occurred only with Misoprostol, while hypotension (3.33%) and palpitations (6.67%) were seen only in the Oxytocin group.

Discussion

This study, A Comparative Study of Efficacy and Safety of Oral Misoprostol with Intravenous Oxytocin for Induction of Labour in Nulliparous Women with Premature Rupture of Membrane, found that misoprostol achieved a shorter induction-to-delivery interval and better cervical ripening than oxytocin, with comparable maternal side effects and neonatal outcomes between both groups.

The age distribution was comparable between the groups, with mean ages of 24.96 ± 1.21 years (Misoprostol) and 24.76 ± 1.40 years (Oxytocin),

showing no significant difference (p = 0.55). Similarly, Maskey S et al[10] reported mean ages of 25.32 ± 3.82 years and 25.94 ± 4.01 years (p = 0.10), while Rashmi et al[11] observed 25.19 ± 3.52 years and 24.99 ± 3.52 years (p = 0.737).

In the present study, the mean induction-to-active phase duration was significantly shorter with Misoprostol (4.98 ± 0.69 hrs) than with Oxytocin (5.69 ± 0.58 hrs, p = 0.0005). Similarly, Ahmed R H M et al[12] reported shorter duration with Misoprostol (5.86 ± 1.08 hrs) versus Oxytocin (6.74 ± 1.33 hrs, p < 0.001). However, Kashanian M et al[13] observed opposite findings, with Misoprostol requiring longer duration (12.9 ± 5.4 hrs) compared to Oxytocin (10.1 ± 6.1 hrs, p < 0.05).

In the present study, the mean induction-to-delivery interval was significantly shorter with Misoprostol (7.18 ± 0.93 hrs) than with Oxytocin (7.67 ± 0.72 hrs, p = 0.02). Similarly, Maskey S et al[10] reported comparable intervals between Misoprostol (8.67 ± 3.22 hrs) and Oxytocin (7.61 ± 2.84 hrs, p = 0.08). However, Rashmi et al[11] found a shorter interval with Oxytocin (4.33 ± 2.23 hrs) than with Misoprostol (5.0 ± 2.58 hrs, p = 0.048).

Side effects were mild, with breathlessness (13.33%) and headache (13.33%) more frequent in the Misoprostol group, while hypotension (3.33%) and palpitations (6.67%) occurred only with Oxytocin. Similarly, Maskey S et al[10] reported mild effects—vomiting, diarrhea, or chills in 6.15% (Misoprostol) and vomiting or fever in 4.62% (Oxytocin, p = 0.69). Ahmed R H M et al[12] found nausea in 4.7% and vomiting in 1.2% (Misoprostol) vs. 2.4% (Oxytocin), indicating comparable tolerability.

Conclusion

Both oral Misoprostol and intravenous Oxytocin were effective and safe for labour induction in nulliparous women with PROM. Demographic, neonatal, and maternal outcomes were comparable. Misoprostol showed faster labour progression and shorter induction-to-delivery interval. Side effects were mild. Although Misoprostol appeared more efficient, the small sample size limits conclusions—larger studies are needed to confirm these findings.

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