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Original Research Article

Misoprostol versus Dinoprostone for induction of labour in premature rupture of membranes

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ABSTRACT

Background: To compare the efficacy of misoprostol (PG E1 analog) and Dinoprostone (PGE2) for induction of labour in patients with premature rupture of membranes (PROM).

Methods: This prospective study was conducted at the Department of Obstetrics and Gynaecology, Dr. BVP Rural medical college, Loni, Ahmednagar, Maharashtra. A total of 120 women (60 in each group) presenting with PROM (premature rupture of membranes) within 48 hours with gestational age between 34 weeks to 40 weeks were included. Group A women received tab misoprostol 25 mcg orally and Group B women received Dinoprostone gel vaginally kept in posterior vaginal fornix for induction of labour. Dose was repeated every 4th hourly in Group A with maximum of 4 doses and it was repeated 6th hourly In Group B with maximum of 3 doses.

Results: Among 60 patients in Group A, 47 (78.33%) delivered vaginally and 13 (21.66%) were delivered by caesarean section. In Group B, 39(65%) patients delivered vaginally and 21(35%) were delivered by LSCS.

Conclusions: Oral misoprostol 25 mcg 4 hourly is efficient and cost-effective alternative to PGE2 gel for cervical ripening and induction of labour in PROM patients.

Keywords: Labour, Misoprostol, Dinoprostone

INTRODUCTION

Prostaglandins are essential mediators of labor, influencing cervical remodelling and myometrial contractions.^{1,2} Their role in cervical ripening and labor induction is well-established, with synthetic analogs like prostaglandin E1 (Misoprostol) and Prostaglandin E2 (Dinoprostone) widely used in clinical practice.³ However, the choice between these agents remains debated, particularly in pre-labor rupture of membranes (PROM) cases, where induction strategies must balance efficacy with the risk of infection and maternal-fetal complications.⁴ PROM, defined as the rupture of fetal membranes before labor onset, has an incidence of 5-10%, with 60% occurring at term.² The management of PROM is time-sensitive, as prolonged latency increases the risk of chorioamnionitis, neonatal sepsis, and adverse perinatal

outcomes.^{5,6} The American college of obstetricians and gynaecologists (ACOG) recommends labor induction in PROM at or beyond 34 weeks to mitigate these risks.^{7,8} However, the optimal prostaglandin choice, particularly in resource-limited settings, requires further evaluation.

Rationale for study

While both PGE1 (misoprostol) and PGE2 (dinoprostone) are used for labor induction, their mechanisms of action, administration routes, storage requirements, and safety profiles differ significantly.^{9,10} Misoprostol (PGE1 analog) is a low-cost, heat-stable agent available in oral, sublingual, and vaginal forms, making it particularly advantageous in low-resource settings where refrigeration is not feasible.¹¹ Dinoprostone (PGE2 gel or pessary) requires cold chain storage and carries a higher risk of

ascending infections due to repeated vaginal examinations.^{12,13} Given these differences, understanding the comparative efficacy and safety profiles of these agents in PROM cases is crucial for optimizing clinical outcomes.

Study objectives

Primary objective

To compare vaginal delivery rates in patients induced with misoprostol (PGE1) versus dinoprostone (PGE2) in PROM cases.

Secondary objectives

To evaluate LSCS rates and indications in both groups. To assess neonatal outcomes, including, incidence of meconium-stained liquor. Apgar scores at birth. NICU admissions.

METHODS

The present study is hospital based prospective study done at the Department of Obstetrics & Gynaecology, Dr. BVP Rural medical college, Loni, Ahmednagar, Maharashtra. All pregnant women with age group of 15-30 years and period of gestation between 34 to 40 weeks assessed by LMP irrespective of parity, presenting with PROM within 72 hours and cephalic presentation with bishop's less than 5 with no uterine contractions were included in the study.

Exclusion criteria

Non-cephalic presentation, twin pregnancy, cervix ≥ 3 cm dilatation, hypersensitivity to prostaglandins, history of any uterine surgery like previous LSCS, myomectomy, hysterotomy, placenta previa, grand multiparity, history of medical disorder like hypertensive disorders, asthma, heart disease, gestational diabetes, any evidence of chorioamnionitis like temperature $>37.5^{\circ}\text{C}$, uterine tenderness, $\uparrow\text{TLC}$, Fetal distress, Meconium-stained liquor. Sample size in the present study is 120 depending on the average number of PROM cases in two-year period from December 2022-November 2024. Study period was 24 months (18 months for data collection and 6 months for data compilation) of December 2022-November 2024.

All women meeting the inclusion criteria were enrolled in the study through labour ward. The purpose of the study was explained to the patients and written informed consent was obtained. A detailed history was taken regarding age, parity, and time since PROM. Obstetrical examination was done to confirm the PROM. All included patients were randomly allocated in two groups. Sampling technique was based on simple random sampling where patients receiving oral misoprostol 25 mcg drug were allocated in group A and patients receiving Dinoprostone gel vaginally were allocated in group B. Dose was repeated every 4th hourly in Group A with maximum of 4 doses and it was repeated 6th hourly In Group B with maximum of 3 doses.

RESULTS

120 patients were enrolled in the study. Group A had 60 patients and group B had 60 patients. Group A were induced with 25 mcg misoprostol tablet orally and group B were induced with dinoprostone PGE2 gel. Both the groups had comparable age wise distribution as seen in Table 1. In group A 71.67% of women were belonging to the age group of 18-25 while in group B it was 65%. In group A 28.33%. Both groups had comparable number of primigravida and multigravida. There were 33 primigravida in Group A and 40 in group B and 35 multigravidas in Group A and 39 in group B (Table 1).

Table 1: Age, parity, mode of delivery wise distribution.

		Group A	Group B
Age (years)	18-25	71.67%	65%
	>25	28.33%	35%
Parity	Primigravida	55%	73.33%
	Multigravida	45%	26.67%
Mode of delivery	Vaginally	78.33%	65%
	LSCS	21.67%	35%

Table 2: LSCS indications.

LSCS indication	Group A	Group B
Meconium-stained liquor	9	6
Failed induction	2	11
	2	4
Fetal distress	13 (100%)	21 (100%)

Among 60 patients in group A, 47(78.33%) delivered vaginally and 13(21.67%) were delivered by cesarean section. In group B, 39(65%) patients delivered vaginally and 21(35%) were delivered by LSCS (Table 1). The indications of LSCS were meconium-stained liquor, fetal distress and failed induction (Table 2).

Among 13 patients delivered through LSCS in group A 9 patients had meconium-stained liquor, 2 patients had failure of induction and 2 patients had fetal distress. In group B out of 21 patients delivered through LSCS, 6 patients had meconium-stained liquor, 11 patients had failure of induction and 4 patients had fetal distress.

Among 60 patients in group A, 47 (78.33%) delivered vaginally and 13 (21.66%) were delivered by cesarean section. In group B, 39 (65%) patients delivered vaginally and 21 (35%) were delivered by LSCS. Among the patients delivered, 12 had meconium-stained liquor in group A out of which, 3 delivered vaginally and 9 were delivered through LSCS. 7 had meconium-stained liquor in group B, out of which 1 was delivered vaginally and 6 were delivered through LSCS. 2 patients in group A had APGAR<5, and 1 in group B had APGAR<5. These babies needed NICU admission.

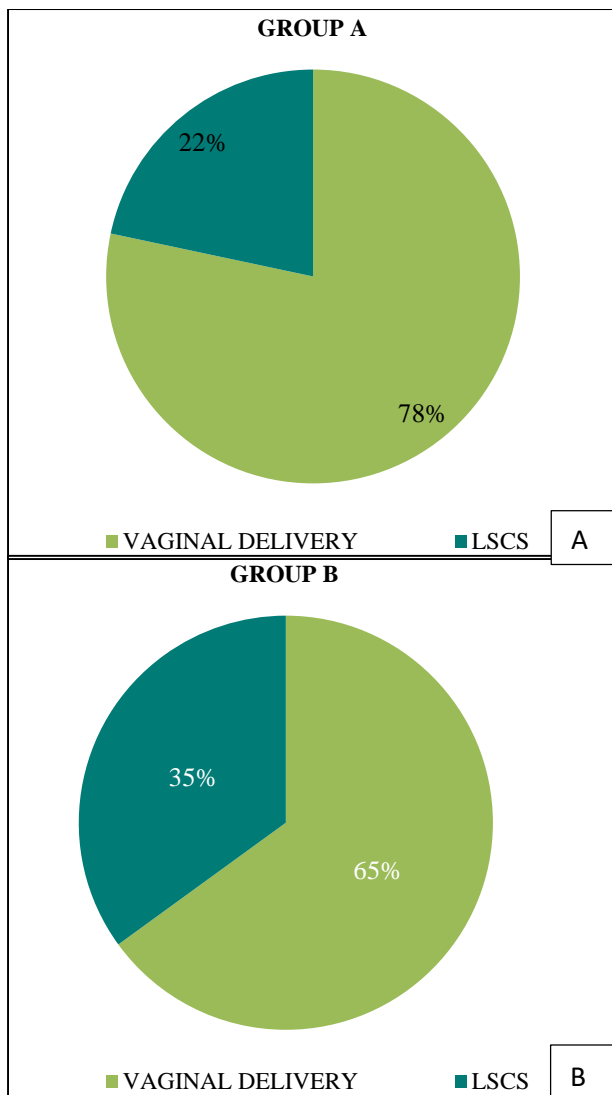


Figure 1 (A and B): Mode of delivery: vaginal and LSCS rates in group A and group B

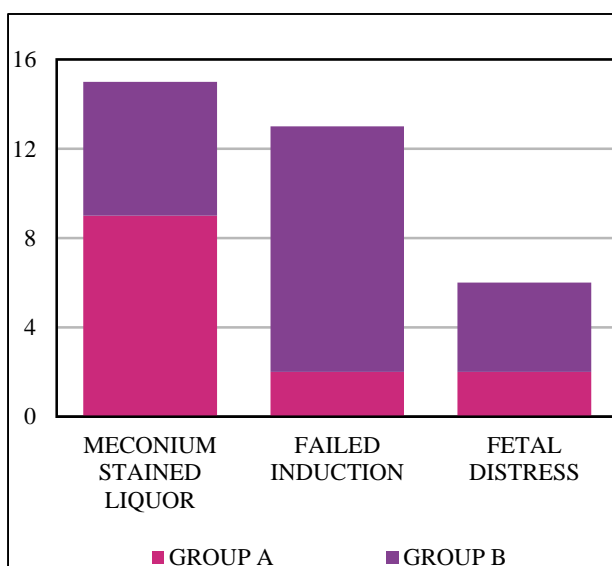


Figure 2: LSCS indications.

DISCUSSION

In the present study, the synthetic PGE1 analogue, oral misoprostol, was compared with PGE2 intracervical dinoprostone gel in patients with premature rupture of membranes (PROM). The study aimed to evaluate the vaginal delivery rate, mode of delivery, incidence of meconium-stained liquor, and APGAR scores in both groups.

Vaginal delivery

The vaginal delivery rate was 78.33% in the misoprostol group and 65% in the dinoprostone group. These findings align with those reported by Shetty et al, who found a similar success rate for misoprostol in PROM cases.¹⁴ Additionally, Kumari et al, observed a higher vaginal delivery rate of 73.97% with misoprostol compared to 47.22% with dinoprostone, further supporting the efficacy of misoprostol in improving labor outcomes.¹⁵

Several studies have demonstrated the advantages of oral misoprostol in labor induction, particularly its longer half-life, ease of administration, and cost-effectiveness compared to dinoprostone gel. Moreover, misoprostol has been found to produce a more sustained uterotonic effect, thereby increasing the likelihood of vaginal delivery without significantly increasing maternal or neonatal complications.

Caesarean section rate

The caesarean section rate was 21.66% in the misoprostol group and 35% in the dinoprostone group, indicating a lower need for surgical intervention with misoprostol. These findings are consistent with the studies conducted by Patil et al and Shetty et al, which also reported a reduced caesarean rate with misoprostol use.^{14,16}

The lower caesarean section rate in the misoprostol group may be attributed to its more effective cervical ripening and stronger uterotonic action, leading to a higher rate of spontaneous vaginal delivery. However, it is essential to consider factors such as uterine tachysystole and hyperstimulation, which have been associated with misoprostol use and may necessitate timely monitoring during labor induction.

Neonatal outcome

The mean APGAR score at 5 minutes was comparable between the two groups, suggesting that both misoprostol and Dinoprostone are safe for neonatal outcomes when used appropriately. The incidence of meconium-stained liquor was slightly higher in the misoprostol group, which aligns with some previous studies reporting an increased risk of fetal distress with misoprostol use. However, this difference was not statistically significant, indicating that both drugs are equally effective in ensuring fetal well-being. Additionally, neonatal NICU admissions and

perinatal complications did not show a marked difference between the two groups, reinforcing the safety profile of oral misoprostol in labor induction. However, given the potential risks of uterine hyperstimulation, careful dose titration and fetal monitoring remain crucial to optimizing neonatal outcomes.

Limitations

Clinical protocol differences variations in protocols and clinician preferences may affect induction success rate. Uncontrolled confounding factors like cervical status, Bishop score might influence labour induction outcomes. Mode of administration: differences in vaginal and oral administration could influence results.

CONCLUSION

Induction of labour confers benefits in various maternal and fetal conditions like PROM. Misoprostol and Dinoprostone have a significant role as inducing agents. However, both drugs have their pros and cons. This study concluded that efficacy of misoprostol is more than Dinoprostone for induction of labor in terms of rate of vaginal delivery among women with prelabour rupture of membranes & preterm premature rupture of membranes. Oral misoprostol 25 mcg 4 hourly is efficient and cost-effective alternative to PGE2 gel for cervical ripening and induction of labour in PROM patients.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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