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Comparison of effectiveness of oral misoprostol vs PGE2 gel in PPROM patients: A prospective study

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Abstract
Preterm premature rupture of membranes (PPROM) is the spontaneous rupture of the fetal membranes before 37 weeks of gestation in the absence of regular painful uterine contractions. Active induction of labour soon after PROM reduces the risks of maternal and fetal sepsis compared with conservative management, and is associated with a shorter interval from PROM to significant uterine contractions and delivery.

Materials and Methods: A prospective study was carried out in the Department of Obstetrics and Gynecology at Government Thiruvannamalai medical college, Tamil Nadu from October 2020 to October 2021. 147 PPROM patients were included in the study. Group A had 68 patients and group B had 79 patients. Group A were induced with 50µgm Misoprostol tablet and Group B were induced with 0.5 mg intracervical PGE2 gel**.**

Results: Among 68 patients in Group A, 58(85.30%) delivered vaginally and 10(14.70%) were delivered by cesarean section. In Group B, 63(79.74%) patients delivered vaginally and 16(20.25%) were delivered by LSCS (p value 0.379). 38 patients were delivered vaginally within 12 hours in Group A whereas it was 33 in Group B. 4 required LSCS in Group A in <12 hours and 6 in Group B. In Group A LSCS was done in 6 patients after 12 hours and in Group B, LSCS was done in 10 patients after 12 hours (p valueo.400)

Conclusion: Oral misoprostol 50µgm 4 hourly is safe, efficient and cost effective alternative to PGE2 gel for cervical ripening and induction of labour in PPROM patients in low resource settings.

Keywords: PGE1 (prostaglandin E1), PGE2 (prostaglandin E2), misoprostol, dinoprostone gel

Introduction

Premature rupture of membrane (PROM) is the rupture of the fetal membranes before the onset of labour. Preterm premature rupture of membranes (PPROM) is the spontaneous rupture of the fetal membranes before 37 weeks of gestation in the absence of regular painful uterine contractions [1]. Incidence of PPROM ranges from 3.0-10.0% of all deliveries [2]. It increases the risk of prematurity and leads to perinatal and neonatal complications with 1-2% risk of fetal death. An inverse relationship exists between gestational age at the time of rupture of membrane and latency.

In women with PPROM remote from term, 50% will go into labour within 24 to 48 hours and 70% to 90% within 7 days. PPROM is an important cause of perinatal morbidity and mortality because it is associated with brief latency from membrane rupture to delivery, perinatal infection and umbilical cord compression due to oligohydramnios. A prolonged interval from rupture of membrane to delivery is associated with an increase in incidence of chorioamnionitis and neonatal sepsis. Active induction of labour soon after PROM reduces the risks of maternal and fetal sepsis [3] compared with conservative management, and is associated with a shorter interval from PROM to significant uterine contractions and delivery [4].

Prostaglandin E2 (PGE2) gel can be used for induction, but it carries risk of ascending infection. Maintenance of cold chain & thus storage may be a problem for PGE2 gel at primary health centres & thus the need to study the safety aspect of misoprostol for use in low resource setting.

Misoprostol is a prostaglandin E1 analogue which is rapidly absorbed after oral administration. Its uterotonic and cervical ripening properties have become increasingly well known, and a wealth of information has emerged from studies investigating its potential use in obstetrics and gynaecology [5]. Misoprostol has been the drug of choice for induction of labour in developing countries for almost a decade, because it is cheap, stable at room temperature, does not require refrigeration prior to use, is easy to prepare and because the route of administration is convenient [6, 7].

In most studies prostaglandins have been used vaginally which results in long half-life than oral administration. However, low oral dosing may have an advantage in induction of labour because of the reduced risk of hyperstimulation and tachysystole [8, 9]. The advantage of oral misoprostol in reference to PROM is in the avoidance of repeated vaginal examinations and the subsequently reduced risk of sepsis for both mother and baby [10].

Aim and Objectives

Primary aim

The primary aim of the study was to determine the vaginal delivery rate in both groups and to compare induction - vaginal delivery interval in both groups.

Secondary aims

The secondary aims were to compare the following in both the groups

- Need for oxytocin augmentation
- Meconium stained liquor
- APGAR score

Materials and Methods

This prospective randomized study was conducted in the Department of Obstetrics & Gynaecology at Government Thiruvannamalai Medical College, Tamil Nadu from October 2020 to October 2021.

Inclusion criteria

- Gestational age ≥34 to <37weeks of gestation with PROM
- Cephalic presentation
- PROM ≥ 4 hours.
- Bishop score ≤ 5.
- No uterine contraction.

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 asthma, glaucoma, heart disease, gestational diabetes
- Any evidence of chorioamnionitis like temperature ≥ 37.5°c, uterine tenderness, ↑TLC
- Fetal distress
- Meconium stained liquor
- PROM more than 24 hour
- History of antepartum hemorrhage

Diagnosis of PPROM was based on clinical history of passage of liquor, pooling of fluid in posterior fornix as seen by speculum examination. In PPROM patients, bishop's score was recorded, following which patients were monitored for one hour to determine onset of labour and fetal wellbeing. If the woman was not in labour she was randomly allotted to either of the groups. Prophylactic antibiotic of a penicillin group was given.

In the group A, labour was induced by oral misoprostol 50 micrograms every 4 hours for maximum three doses and in group B, labour was induced by intracervical 0.5 mg PGE2 gel. Patients were observed for progress of labour. If labour had not established, oral misoprostol was repeated after 4 hours (maximum 3 doses) in group A and PGE2 gel after 6 hours (maximum two doses) in group B. Emergency LSCS was done in cases of failed induction, meconium stained liquor, fetal distress, tachysystole. Induction delivery interval, mode of delivery and NICU admissions were recorded in all patients.

Results

147 patients were enrolled in the study. Group A had 68 patients and group B had 79 patients. Group A were induced with 50µgm Misoprostol tablet and Group B were induced with 0.5 mg intracervical PGE2 gel. Both the groups had comparable age wise distribution as seen in table 1.

Table 1: Age wise distribution

Age (in years)	Group A (%)	Group B (%)	P value
21-25	42(61.76%)	48(60.75%)	0.900
>25	26(38.23%)	31(39.25%)	
	68(100%)	79(100%)	

Both groups had comparable number of primigravida and multigravida. There were 33 primigravida in Group A and 40 in Group B and 35 multigravida in Group A and 39 in Group B (table 2).

Table 2: Parity distribution

Parity	Group A (%)	Group B (%)	P value
Primigravida	33(48.52%)	40(50.64%)	0.799
Multigravida	35(51.48%)	39(49.36%)	
	68(100%)	79(100%)	

Among 68 patients in Group A, 58(85.30%) delivered vaginally and 10(14.70%) were delivered by cesarean section. In Group B, 63(79.74%) patients delivered vaginally and 16(20.25%) were delivered by LSCS (Table 3). The indications of LSCS were meconium stained liquor, fetal distress, failed induction and uterine tachysystole (Table 4).

Table 3: Mode of delivery

Mode of delivery	Group A (%)	Group B (%)	P value
Vaginal delivery	58(85.30)	63(79.74)	0.379
LSCS	10 (14.70)	16(20.25)	
	68(100%)	79(100%)	

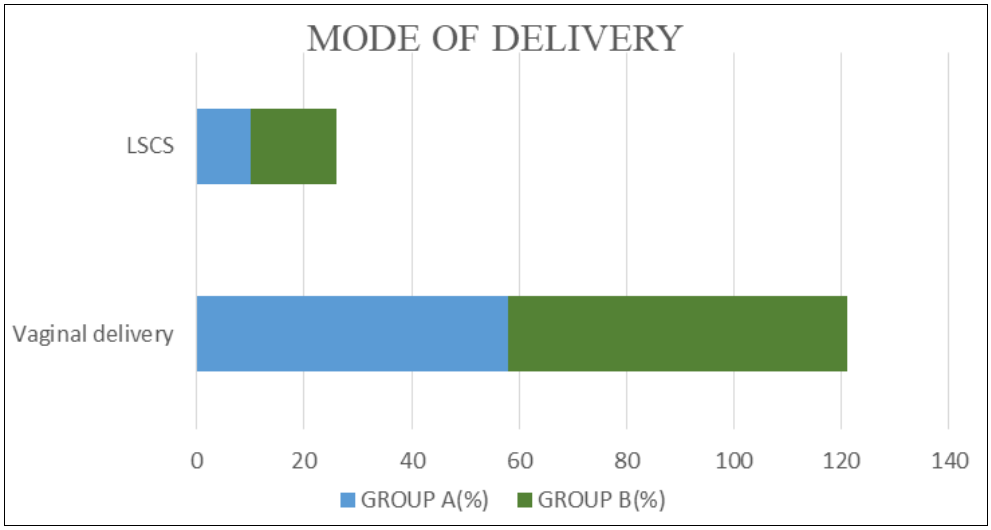

Fig 1: Mode in delivery in both groups

Table 4: Indications for LSCS in both groups

LSCS	Group A (%)	Group B (%)	P value
Meconium liquor	5(50%)	3(18.75%)	
Failed induction	2(20%)	8(50%)	
Fetal distress	2(20%)	3(18.75%)	0.329
Uterine tachysystole	1(10%)	2(12.5%)	
	10(100%)	16(100%)	

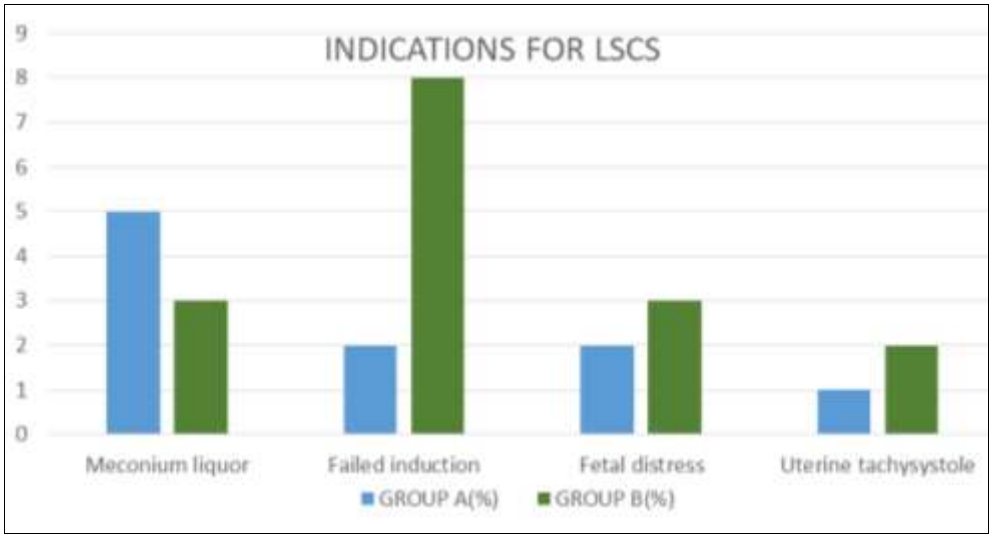

Fig 2: Indications for LSCS

38 patients were delivered vaginally within 12 hours in Group A whereas it was 33 in Group B. 4 required LSCS in Group A in <12 hours and 6 in Group B. In Group A LSCS was done in 6 patients after 12 hours and in Group B, LSCS was done in 10 patients after 12 hours (Table 5).

Table 5: Induction delivery interval

Mode of delivery	Induction delivery interval	Group A (%)	Group B (%)	P value
Vaginal delivery	<12 hours	38(55.88%)	33(41.77%)	
	>12 hours	20(29.41%)	30(37.97%)	
LSCS	<12 hours	4(5.88%)	6(7.60%)	0.400
	>12 hours	6(8.82%)	10(12.66%)	
		68(100%)	79(100%)	

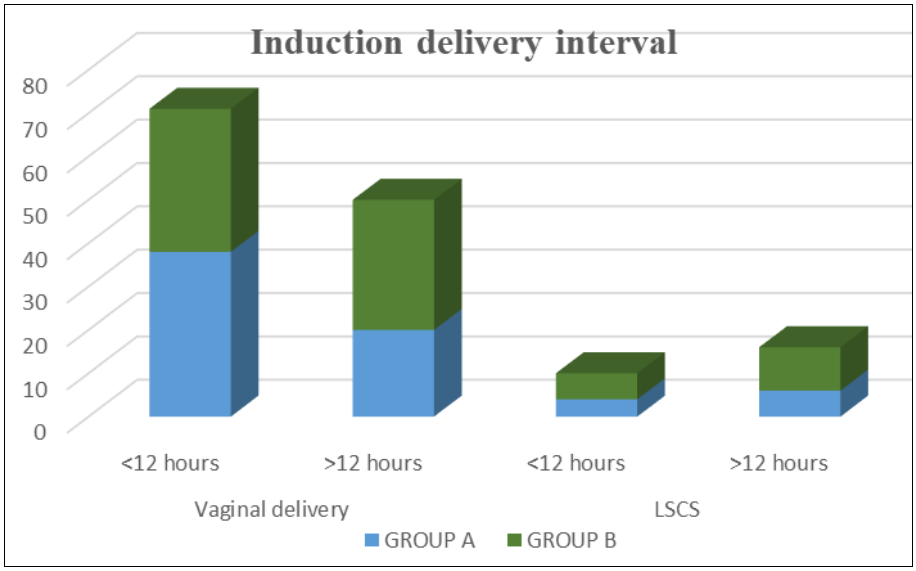

Fig 3: Induction delivery interval

Among the patients delivered vaginally, oxytocin was required in 19 patients in Group A and 36 in Group B which is statistically significant. 8 had meconium stained liquor in Group A out of which, 3 delivered vaginally. The results were not statitically significant 5 had meconium stained liquor in Group B, out of which 2 were delivered vaginally. 2 patients in Group A had APGAR<5, and 1 in Group B had APGAR<5. These babies needed NICU admission.

Table 6: Oxytocin augmentation, meconium liquor and APGAR in both groups

		Group A	Group B	P value
Oxytocin augmentation	Yes	19	36	0.002
	No	39	27	
Meconium stained liquor	Yes	8	5	0.243
	No	60	74	
APGAR	<5	2	1	0.47
	>5	66	78	

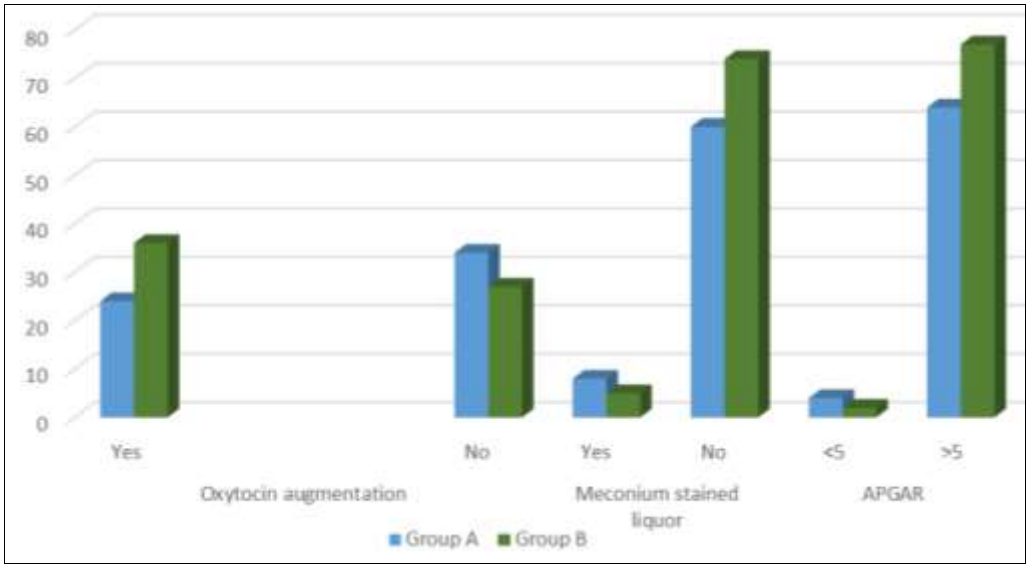

Fig 4: Comparison of oxytocin augmentation, meconium stained liquor and APGAR

Discussion

- In our study, synthetic PGE1 analogue oral misoprostol was compared with PGE2 intracervical dinoprostone gel in PPROM. Vaginal delivery rate in both groups was determined and induction vaginal delivery interval, mode of delivery, need for oxytocin augmentation, meconium stained liquor and APGAR score in both groups were studied and compared. In our study PPROM was more common in the age group of 21-25 years with an incidence of 61.2% (n=147) which is comparable to the study conducted by Noor *et al*. [11] in Ayub medical college which stated that higher incidence (58.8%) among younger age group.

- **Vaginal Delivery**

In our study, the rate of vaginal delivery was 85.30% in the misoprostol group and 79.74% the dinoprostone gel group. The result was comparable with Shetty A *et al*. (2004) [12] for the misoprostol group.

- **Induction to Delivery Interval**

In our study 55.88% in group A and 41.77% in group B delivered within 12 hours which is comparable to the study conducted by nadar *et al*. [13] in which 55.56% in misoprostol group and 44.44% in dinoprostone gel group delivered vaginally within 12 hours.In this study, induction to delivery interval was significantly shorter in group A (misoprostol) as compared to

group B (dinoprostone). It was 10.36 hours and 14.54 hours in group A and group B respectively. The present study is comparable to the observation of Frohn *et al*. (2002) [14] with respect to induction to delivery interval.

- **Oxytocin Augmentation**

In our study, only 19 (32.8%) women in group A (misoprostol) needed oxytocin augmentation as compared to 36 (45.6%) women in group B (dinoprostone).Also, the oxytocin dose required for augmentation was lesser in the former group. The result was comparable to the observation of Nagpal *et al*. (2009).

- **Caesarean Section Rate**

In the misoprostol group 14.70% women underwent emergency caesarean section whereas in dinoprostone group 20.25% women underwent emergency caesarean section. The results of our study were consistent with the observation of Patil P. *et al*. [16] (2013) and Shetty A *et al*. [12] (2004) with respect to rate of caesarean section.

- **Neonatal Outcome**

The mean APGAR score was compared at 5 mins in our study. There was no statistical difference in APGAR score in both group. The incidence of meconium stained liquor was comparable in both the groups. Birth asphyxia was seen in 3.4% in misoprostol group as compared to 1.27% in dinoprostone group. The difference was statistically not significant. The incidence of meconium aspiration syndrome in misoprostol was 1.47% as compared to 1.27% in dinoprostone group. Where as in Nagpal *et al*. (2009) [15] study meconium aspiration syndrome was 0 v/s 1 in misoprostol and dinoprostone group which is comparable to our study. NICU admissions were seen in 3.4% in misoprostol group as compared to 1.27% in dinoprostone group. In Nagpal *et al*. (2009) [15] study it was 1 v/s 2 which was comparable to our study.

Conclusion

Oral misoprostol 50µgm 4 hourly is safe, efficient and cost effective alternative to PGE2 gel for cervical ripening and induction of labour in PPROM patients in low resource settings.

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