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Original Research Article

Obstetric and perinatal outcomes of expectant management and immediate induction of labour in term premature rupture of membranes: promising outcomes from expectant management cohort

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ABSTRACT

Background: Premature rupture of membranes (PROM) is common obstetric entity, the management even at term is controversial and there is no consensus for definite protocol of management. Objective of the present study is to compare the effectiveness, safety of expectant management of 24 hours and immediate induction with PGE₂ gel in terms of maternal and fetal outcome in term PROM.

Methods: 200 women were randomized to group A expectant management and group B immediate induction, after strict Inclusion and exclusion criteria. In expectant group waiting period was 24 hours. Multiple end points were examined throughout management. Chi square test and independent t tests were performed for statistical analysis. P value<0.05 was considered significant.

Results: Demographic parameters of patients, maternal and gestational age were similar in both groups. Primigravidae were more in both groups A and B. Vaginal delivery rate is more in expectant group and Caesarean Section rate is high in immediate induction group. CS rate was 37% and 23% in group A and B respectively; the difference is statistically significant (p value=0.031). 'ROM to delivery interval' was more in group A (16.31±8.67 hrs and 13.85±5.46 hrs) (p value=0.0256). Hospital stay was comparatively more in group A (5.40±0.81 days and 4.11±0.86 days) (p value=0.435). Infective morbidity of mother and baby was low in both groups and no difference was seen.

Conclusions: An expectant management allows a good number of women to go into labour and deliver vaginally without an increase in CS rate and infectious morbidity for mother and fetus.

Keywords: Term PROM, Expectant management, Immediate induction, PGE₂ gel, Caesarean section rate

INTRODUCTION

'Premature rupture of membranes' (PROM) refers to the loss of integrity of membranes before onset of labor, with resulting leakage of amniotic fluid and establishment of communication between the amniotic cavity and the endocervical canal and vagina.¹

PROM occurs in approximately 5-10% of all pregnancies, of which approximately 80% occur at term (term PROM).² Causes like infection, trauma, APH, hydromnios, multiple

gestation and coitus in pregnancy contribute to PROM. However, it is often not possible to pin point the exact cause in an individual case. Interestingly, at term, PROM can be a physiological variation rather than a pathological event.³

Approximately 60-70% of term PROM cases are followed by the onset of labor within 24 hours and an additional 20-30% start within 72 hours.^{1,4} PROM is associated with increased risk of chorioamnionitis, unfavourable cervix and dysfunctional labour, increased caesarean rates,

postpartum haemorrhage and endometritis in the mother. In the fetus, depending on gestation there is increased occurrence of hyaline membrane disease, intraventricular haemorrhage, sepsis, cord prolapse, fetal distress, increased fetal wastage.

The management of a case of PROM has remained as one of the most difficult and controversial problems in obstetrics over the past several decades.

Expectant management is implicated for various maternal and fetal complications generally for infection. Hence induction of labour could be advised, but there remains associated risk of increased caesarean section rates.

Present study was a prospective study undertaken to compare maternal and neonatal outcomes of immediate induction with intracervical PGE₂ gel and expectant management (24 hours) in term PROM cases and hence to compare effectiveness and safety of both the modes of treatment.

METHODS

This was a prospective study conducted in 200 women at term gestation with PROM, admitted at conducted at department of obstetrics and gynaecology, St. Philomena's Hospital, Bangalore. Approval from Scientific committee and Ethics committee of hospital was obtained. Informed and written consent was obtained from women enrolled in the study.

Inclusion criteria set was- women diagnosed with PROM with singleton pregnancy with cephalic presentation, gestational age between 37 and 41 completed weeks, H/O of leaking PV-PROM<24 hrs, no signs and symptoms of labour, no evidence of fetal compromise, no evidence of infection-chorioamnitis. And exclusion criteria set was- women in labour, contraindications to induction of labour (e.g. placenta previa, Prev. LSCS), contraindications to expectant management (e.g. Meconium stained liquor, APH), medical or obstetric complications indicating prompt delivery (e.g. severe pre-eclampsia, IUGR), malpresentations, multiple gestations.

Patients were enrolled in the study after accurate history taking. A thorough, general and systemic examination were performed to exclude exclusion criteria. A detailed obstetric examination was done to note presentation, uterine contractions status, and fetal heart rate pattern. Speculum examination was done to confirm leaking-confirming gush of amniotic fluid draining from cervical OS and accumulating in posterior fornix.

In doubtful cases, further tests such as pH estimation of discharge- Litmus paper test, fern tests were done. High vaginal swab was sent for culture and sensitivity. Vaginal examination was done to note the dilatation and effacement and to confirm the presence of membranes and to exclude the women who have set into labour.

Total number of patients with term PROM recruited in the study was 200; they were assigned group A and group B randomly. Group A consisted 100 patients assigned to expectant management (24 hours) and group B consisted 100 patients assigned to immediate induction of labour by intracervical PGE₂ gel instillation. Randomization achieved by alternately recruiting the patients to individual group. They were kept under observation. Observations include PR, BP, uterine activity and FHR. Time interval from the time of administering PGE₂ gel to the onset of labour was also recorded. If labour did not supervene after 8 hours or there was no improvement in Bishop score, application of PGE₂ gel was repeated. Vaginal examination repeated every 6 hrs and progress noted with Bishop score.

Women in the expectant management group were closely observed for 24 hrs. Monitoring included temperature recording every 4th hourly, FHR hourly, digital examination was avoided until women were in active labour clinically, induction was planned if chorioamnionitis develops. If labour was not established after 24 hours reinduction with intracervical PGE₂ was performed depending on cervical ripening. Injection Oxytocin was used for augmentation of labour depending on intensity of contractions, it was not used as induction agent.

Investigations performed were haemoglobin, Total WBC count, differential count, CRP, HVS culture and sensitivity, urine routine, urine culture and sensitivity were done for all the patients on admission, apart from routine ante-natal investigations. All patients irrespective of duration of PROM were given injection Ceftriaxone 1 g IV 12th hourly and injection Metronidazole 500 mg IV 8th hourly till delivery. The data was statistically analysed using IBM SPSS version 22. Data was analysed by using Chi-square test, paired-t test, independent t test. P value<0.05 was considered as significant.

RESULTS

Basic demographic characters were similar in both the groups. The majority of patients in A and B belonged to 22-27 years of age with mean of 25.72±3.59 and 25.48±3.4 in A and B respectively. The mean gestational age was 38.08±0.98 and 38.30±0.82 weeks in group A and B respectively. 73% and 75% women in group A and B respectively were nulliparous; 27% and 25% were multiparous (parity >1) in group A and B respectively (Table 1).

The mean 'rupture of membranes' to 'admission' interval in group A and B was 5.33±3.14 hours and 4.90±5.22 hours respectively (p=0.421, not statistically significant). On admission the Bishop's score in women ranged mostly from 4 to 7. 34% and 42% had Bishop's score less than 6 in group A and B respectively. In expectant management group high vaginal swab for culture grew E. coli in one Patient and Pseudomonas in 2 patients. In immediate

induction group one was positive for E. coli, one for ‘group B streptococci’ and one showed Diphtheroid insignificant growth; Insignificant growth was considered culture negative, hence total two were positive in Immediate induction group. All other patients had no growth in the high vaginal swabs.

In expectant management group 89 patients (89%) went into spontaneous labour over given expectancy of 24 hours. Other 11 patients (11%) required induction by PGE₂ gel at 24 hours; out of them 2 patients (2%) required 2 doses of PGE₂; which were given 8 hours apart. In immediate induction group 84 patients (84%) responded to single application of PGE₂ gel and went into labour. Out of other 16 patients 11 patients (11%) required 2 doses and 5 patients (5%) required 3 doses of PGE₂. PGE₂ doses were repeated at 8-hour interval (Figure 1). 51 out of 77 patients in expectant group and 43 out of 63 patients in immediate induction group required augmentation with oxytocin. The difference was not statistically significant.

LSCS, operative delivery and spontaneous vaginal delivery rates in expectant group were 23%, 9% and 68% respectively. And the same in immediate induction group were 37%, 7% and 56% respectively. Spontaneous vaginal delivery rate is more in expectant group (Table 2); The comparison between LSCS rate and vaginal delivery as shown in Table 3 clearly states the difference with high rate of LSCS in immediate induction group. 77% women delivered vaginally in expectant group as compared to 63% in immediate induction group. LSCS rate being 23% and 37% in expectant group and immediate induction group respectively. The difference is statistically significant (p value was <0.05 by Chi square test) (Table 3). The association between LSCS rate and immediate induction group calculated by Odd’s ratio with 95% CI was 1.97 (logistic regression); i.e.; women in immediate induction group have 1.97 times risk of undergoing LSCS.

When mode of delivery was compared between nullipara and multipara, LSCS rate was high in immediate induction group in nullipara group; p value here was 0.052. The difference between the same in multipara group is not significant (Table 4). Indications for LSCS in both the groups were observed and compared. Fetal distress and failed induction were common indications in immediate induction group i.e.; 24.32%. CPD and non-progress of labour were major contributory factors for LSCS in both the groups. 3 cases in expectant group underwent LSCS in view of and at the earliest evidence of developing sepsis/chorioamnitis (13.04%). The differences when indications for LSCS are compared are not statistically

significant. Table 5 shows number of vaginal examinations conducted in both groups during the course of management. More number of vaginal examinations were conducted in expectant management group i.e.; 5-8 examinations in 26% and ≥9 examinations in 4% women. The same in immediate induction group were less i.e., 19% and 0% respectively. This difference is statistically significant, p value being 0.048. More number of vaginal examinations were performed in expectant management group.

Mean duration of active labour in group A and B was 7.31±1.38 hours and 6.49±1.70 hours respectively. All the women delivered within 12 hours of active labour. Difference was not statistically significant. Mean ROM to delivery interval in group A and B was 16.31±8.67 hours and 13.85±5.46 hours respectively. Duration is more in expectant management; the difference is statistically significant (p value by independent t test=0.025).

Most of the women in both the groups delivered within 12 to 24 hours interval. As explained, duration of ROM to delivery interval was more in expectant management group; 17 women in this group had ROM to delivery interval more than 24 hours. This proves definite risk of increased duration of ROM to delivery interval in expectant management group (p value by Chi square test=0.002). Induction to delivery interval in immediate induction group was 11.48±6.15 hours. In expectant management group 11 women required induction of labour at 24 hours interval from ROM who did not go into spontaneous labour. Out of 11 in only 2 women induction to delivery interval was beyond 12 hours. The details are shown in Table 6. Among other maternal factors; hospital stay was 5.40±0.81 days and 4.11±0.86 days in group A and B respectively. The duration is more in expectant management group.

As operative interventions increase the duration of hospital stay, the duration of hospital stay was on higher side in immediate induction group too. The difference was not statistically significant. Infective morbidity i.e., clinical chorioamnitis, puerperal pyrexia were less in both groups. These are more in expectant group, but differences are not statistically significant. Fetal distress was noted in 9% and 15% of patients in group A and B respectively. The observation more found in immediate induction group. Among others, the incidence of PPH was less. Active management of third stage of labour was followed for all the patients. No statistically significant difference noted. Neonatal factors in both the groups compared are depicted (Table 7); the differences were not statistically significant.

Table 1: Maternal age (years), gestational age (weeks) and parity.

Variables	Group		P value
	Expectant management (A)	Immediate induction (B)	
Age (years)	25.72±3.59	25.48±3.40	0.628
Gestational age (weeks)	38.08±0.98	38.30±0.82	0.088

Continued.

Variables	Group		P value
	Expectant management (A)	Immediate induction (B)	
Parity			
0	73 (73%)	75 (75%)	0.747
1,2,3	27 (27%)	25 (25%)	

Table 2: Mode of delivery.

Mode of delivery	Group A (%)	Group B (%)	P value
LSCS	23 (23)	37 (37)	0.096
Operative vaginal delivery	9 (9)	7 (7)	
Spontaneous vaginal delivery	68 (68)	56 (56)	

Table 3: Mode of delivery comparing caesarean section versus vaginal birth.

Mode of delivery	Group A (%)	Group B (%)	P value
LSCS	23 (23)	37 (37)	0.031
Vaginal delivery	77 (77)	63 (63)	

Table 4: Parity wise mode of delivery.

Mode of delivery	Group A (%)	Group B (%)	P value
Nullipara			
LSCS	20 (27.40)	32 (42.67)	0.052
Vaginal delivery	53 (72.60)	43 (57.33)	
Multipara			
LSCS	03 (11.11)	05 (20.00)	0.458
Vaginal delivery	24 (88.89)	20 (80.00)	

Table 5: Number of vaginal examinations.

No. of vaginal examinations	Group A (%)	Group B (%)	P value
≤4	70 (70)	81 (81)	0.048
5-8	26 (26)	19 (19)	
≥9	4 (4)	0 (0)	

Table 6: Rupture of membranes (ROM) to delivery interval and induction to delivery interval.

Variables	Group A (%)	Group B (%)	P value
ROM to delivery interval (hours)	16.31±8.67	13.85±5.46	0.0256
<12	36 (36)	29 (29)	0.0021
12-24	47 (47)	67 (67)	
>24	17 (17)	4 (4)	
Induction to delivery interval (hours)	NA	11.48±6.15	-
<12	-	54 (54)	-
12-24	-	43 (43)	-
>24	-	3 (3)	-

Table 7: Neonatal outcomes.

Neonatal outcome	Group A (%)	Group B (%)	P value
Apgar score ≤7 at 5 min	7 (7)	10 (10)	0.998
Resuscitation with PPV	4 (4)	6 (6)	1.06
NICU admission	7 (7)	5 (5)	0.767
Ventilatory support	1 (1)	2 (2)	1.00
Neonatal sepsis	4 (4)	2 (2)	0.683

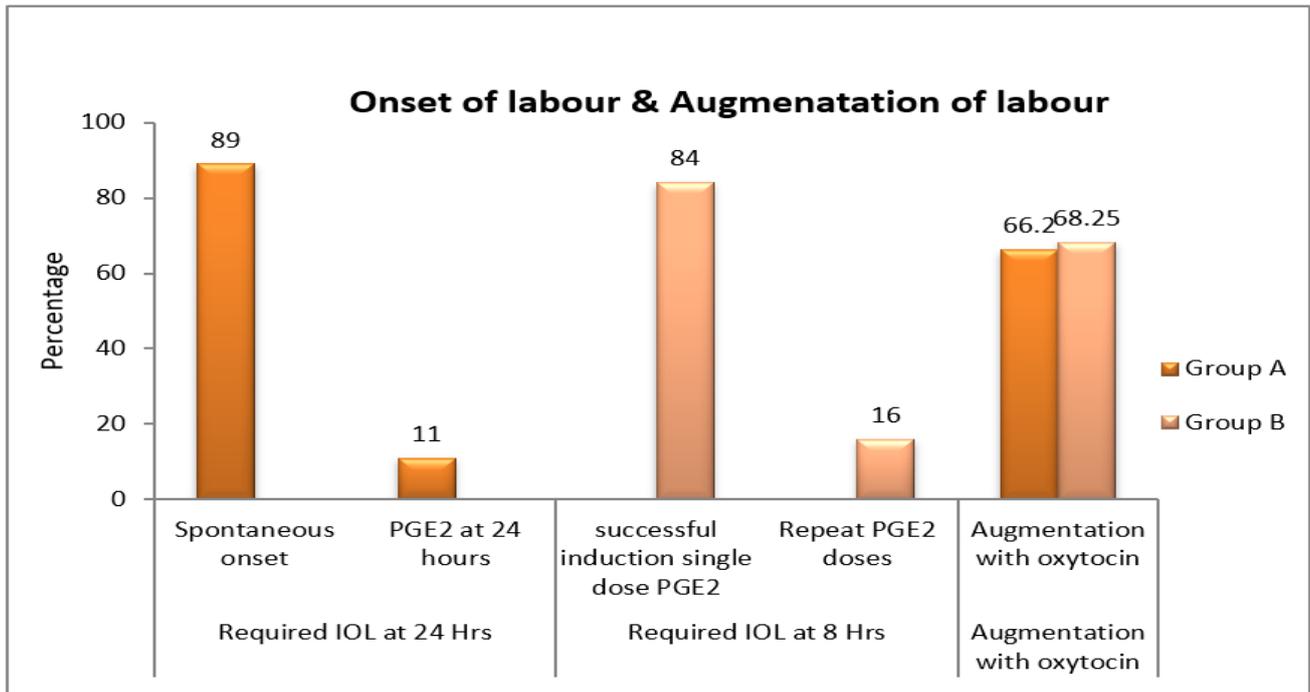


Figure 1: Onset of labour and requirement of oxytocin for augmentation of labour.

DISCUSSION

Though PROM is not uncommon, the management even at term is controversial and there is no consensus for definite protocol of management. Earlier reports favoured induction based upon findings that the risks of maternal or neonatal infection are increased with longer durations of ruptured membrane. But recent studies have shown that expectant management was safe and more successful in achieving vaginal delivery.

The baseline demographic characteristics were same as compared to the studies reviewed. In the comparative study by Chaudari et al 75.33% of women included were nullipara.⁵ In the present study too most of the women (about 68%) were primigravida. Total nullipara were 74%. It reflects that incidence is high in primigravida. In the present study 89% women in expectant group went into spontaneous labour within 24 hrs. In a study conducted by Shah et al 77.5% women in expectant group went into labour spontaneously within 24 hours.⁶ In a study conducted by Shalev et al total 45% women went into spontaneous labour within 12 hours and total 85% over a period of 3 days.⁷ While in a study by George SS et al 35.6% of primigravida women and 55.5% of multigravida went into spontaneous labour within 12 hours.⁸ Gonen et al reported that 93% women in immediate induction group went into labour after single application of PGE₂ gel.⁹ And in the studies by Chaudari et al and Shah et al 91.89 and 81% women went into labour respectively after single application of gel. This is comparable to the present study

where 84% went into labour after single application of PGE₂ gel.

In a study conducted by Meikle et al 64% women required augmentation of labour by oxytocin in immediate induction group.¹⁰ In the studies by Chaudari et al and Poornima et al, respectively 32.43% and 56% women in Induction group required augmentation by oxytocin; whereas respectively 82.14% and 65% women in expectant group required augmentation.^{5,11} This comparison was statistically significant ($p < 0.01$), but in both these studies criteria for expectant management was different from the present study, which was expectancy of 12 hours followed by immediate induction of labour by oxytocin. In the present study 66.20% women in expectant group (51/77) and 68.25% women in induction group (43/63) required augmentation of labour by oxytocin; statistically not significant. The rate of caesarean section in immediate induction group by Gibbs et al was 39%, 17.8% by Snehamay et al 22% by Krupa Shah et al and 37% in the present study.^{5,6,12} In the expectant group the rate of CS was 28.5% in Chaudari et al group, 24% by Shah et al and 23% in the present study.^{5,6} Recent study by Gupta et al in 2018 concluded that caesarean section rates and fetal distress are significantly less compared to active management group.¹⁵ In present study LSCS rate is more in immediate induction group compared to expectant group (37% vs 23%) giving us rate of vaginal deliveries as 63% vs 73% respectively, which is statistically significant ($p < 0.05$).

The operative vaginal delivery rate was 17% in expectant management group in a study by Conway et al and it was 19.1% in immediate induction group in a study by Chua et al, Arulkumaran et al.^{13,14} By Chaudhuri et al group operative vaginal delivery rate was significantly higher in expectant management group 14.2% as compared to immediate induction group of 3.5%.⁵ In the present study operative vaginal deliveries were 9% and 7% in expectant and immediate induction group respectively. The variation in the results may be attributed to the different format of expectant group in the various studies and institute-based variations in management of labour. Recent studies by Rawat et al in 2018 and Savitha et al in 2017 concluded that there were no statistically significant differences in the

rate of maternal and neonatal morbidity among major outcomes compared above among both the groups.^{16,17} Savitha et al had used tab. Misoprostol in immediate induction group and had high rate of vaginal deliveries.¹⁷ The results concur findings in the present study.

Limitations of the present study can be enumerated as- number of women included in the study were less, duration of study was only two years, randomization can become difficult considering obstetrician's choice of mode of management, number of vaginal examinations are high in expectant management group, increased hospital stay and high cost factor in expectant management group.

Table 8: Caesarean section rate compared in different studies.

Authors	Expectant management group (%)	Immediate induction group (%)
Gibbs et al (1982) ¹²	-	39
Chaudari et al (2006) ⁵	28.5	17.8
Shah et al (2012) ⁶	24	22
Gupta et al (2018) ¹⁵	2	16
Present study	23	37

Table 9: Maternal outcome in comparative studies.

Maternal outcome	George et al (2003) ⁸	Chou et al, Arulkumar et al (1991) ¹³	Chaudari et al (2006) ⁵		Present study	
	A	B	A	B	A	B
ROM to delivery interval	21.13±7.2	-	21±10.3	17±10.3	16.31±8.67	13.85±5.46
Duration of active labour	3.7±5	8.6±3.9	3.79±2	3.89±2.6	7.31±1.38	6.49±1.70
No. of vaginal examination>4 (%)	43	-	46	40	26	19

CONCLUSION

An expectant management allows a good number of women to go into labour without an increase in caesarean section rate and infectious morbidity for mother and fetus. Hence in Term PROM Expectant management with 24 hours of waiting is desirable, it gives good chance of spontaneous onset of labour in women and would help reducing caesarean section rate without increasing risk of infective morbidity. Prophylactic antibiotics must be administered to mother and neonate. Number of vaginal examinations must be restricted. Patients must be counselled adequately to relieve their anxiety about long period of expectancy and waiting.

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