

A Comparative Study of Feto-maternal Outcomes in Pre-labor Rupture of Membrane at Term

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Abstract

Aims and Objectives: To compare feto-maternal outcomes in patients with pre-labor rupture of membrane (PROM) at term with that of patients without PROM and also compare the efficacy of three different modes of induction.

Materials and Methods: In this study, 120 patients with PROM were included as cases and 120 patients without PROM were included as controls. We divided cases and controls into three subgroups (40 patients in each group) depending upon the mode of induction, i.e., with oxytocin only, with misoprostol only, with both misoprostol and oxytocin. The data were collected prospectively and analyzed statistically.

Results: Mean gestational age of cases and controls was 38.17 ± 0.83 and 38.60 ± 0.70 weeks, respectively. There were higher chances of instrumental delivery and lower segment cesarean section in patients with PROM. Most of the cases (84.17%) were belonging to lower socioeconomic class, so their babies were having low-birth weight. More percentage of cases gave birth to babies with Apgar score <7 at 1 and 5 min. There were higher chances of neonatal intensive care unit admission of babies born to patients with PROM than patients without PROM. There were higher chances of developing fever and wound infection in cases. The chances of fetal and maternal morbidity and mortality were increased in case of PROM and as the leaking to delivery interval increased, it further increased.

Conclusion: PROM leads to increased chances of fetal and maternal morbidity and mortality. Hence, early diagnosis and prompt management is required for better outcome of mother and baby. Induction to delivery interval with misoprostol and oxytocin is lesser and more number of cases delivered normally so this mode of induction is better than other modes of induction.

Key words: Feto-maternal outcomes, Lower segment caesarean section, Misoprostol, Neonatal intensive care unit, oxytocin, Pre-labor rupture of membrane

INTRODUCTION

Spontaneous rupture of membranes at any time beyond 37 weeks of pregnancy but before the onset of labor is called pre-labor rupture of membranes (PROMs) at term. The incidence of PROM is about 10% of all pregnancies and 70% of them occur at term. Most Indian studies

document incidence of 7-12% for PROM of which 60-70% occurs at term.¹

PROM is linked to significant maternal and fetal morbidity and mortality and is one of the most common complications of pregnancy that has a major impact on neonatal outcome.² It has been shown to be the cause of 18-20% and 21.4% of prenatal mortalities and morbidity, respectively.^{3,4} The three causes of fetal death associated with PROM are sepsis, asphyxia, and pulmonary hyperplasia. Women with intrauterine infection deliver earlier than non-infected women. Maternal complications include intra-amniotic infection, which occurs in 13-60% of women with PROM, placental abruption, and postpartum endometritis.^{5,6} Whereas, neonatal complications include

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higher incidence of non-reassuring cardiotocography patterns (7.9%) due to cord compression subsequent to leaking and higher incidence of sepsis.⁷ Moreover, infants born with sepsis have a mortality rate 4 times higher than those without sepsis.⁸ The chances of complication in PROM is increased if the mother has low body mass index, concomitant infection of the gestational tissues, and longer time elapsed between the rupture of membranes and delivery.⁹

Diagnosis and prompt management is very important to limit various fetal and maternal complications, generally due to infection. Management of PROM is still controversial and involves a balance between expectant management and intervention.¹⁰ Various agents are available for induction of labor, mainly prostaglandins, and oxytocin.¹¹

The current study was conducted to compare the feto-maternal outcome in patients with PROM at term and that in patients without PROM and to compare the efficacy of three different methods of induction, i.e., misoprostol only, oxytocin only, both misoprostol and oxytocin.

MATERIAL AND METHOD

After obtaining Institutional Ethical Committee approval and patient's written informed consent, present observational prospective case - control study was conducted on 240 pregnant women in the department of Obstetrics and Gynaecology, at Government medical college and Hospital, Nagpur, Maharashtra, India. Patients were divided into two groups, Group A (cases): 120 patients with PROMs and Group B (controls): 120 patients without PROMs. All the patients who were ≥ 37 weeks of gestation with PROM, confirmed by per speculum examination and fern test and with single fetus in cephalic presentation, having no contraindication for active management, cervical dilatation of ≤ 3 cm at time of admission were included in the study as cases. The patients with features of chorioamnionitis such as fever, tachycardia, uterine tenderness, and foul smelling per vaginal discharge at the time of admission, fetal distress, and meconium stained liquor at the time of admission, active labor at the time of admission, patients with previous cesarean section, antepartum hemorrhage, maternal medical diseases such as preeclampsia, diabetes or heart disease, and fetal anomalies were excluded from the study. The cases and control groups again subdivided into three groups (40 patients in each group) depending upon the mode of induction, i.e., with oxytocin only, with misoprostol only, with both misoprostol and oxytocin.

A detailed history, examination and all relevant investigations were done for all the patients. Maternal evaluation was done by doing complete blood counts and taking vaginal

swab. Fetal evaluation was done by doing non-stress test (NST). After recording a reactive NST, patient was either induced with misoprostol only or oxytocin only or with both misoprostol and oxytocin. Patients, induced with misoprostol only were given tablet misoprostol 25 μ g every 4 hourly, maximum of 6 doses or until labor was established. Patients induced with oxytocin only were given oxytocin intravenous in drip. The oxytocin drip was formed by adding 2 IU of injection pitocin in 500 ml of ringer solution and drip started at 8 drops/min. The oxytocin drip rate was doubled after every 30 min till 60 drops/min or until adequate contractions, i.e., 3-4 contraction were obtained in 10 min. If adequate contractions were not achieved with this then we started drip of 3 IU of injection pitocin in 500 ml of ringer solution at rate of 8 drops/min and again the drip rate was doubled after every 30 min till 60 drops/min and like this we escalated the oxytocin drip till 5 IU of injection pitocin in 500 ml of ringer solution at rate of 60 drops/min or until adequate contractions, i.e. 3-4 contraction were obtained in 10 min. Patients induced with both misoprostol and oxytocin were given first misoprostol 25 μ g 4 hourly, maximum of 3 doses then oxytocin drip started in the same way as described earlier.

Maternal vitals were monitored for chorioamnionitis. Fetal well-being surveillance was done by auscultating fetal heart rate every 30 min and color of liquor and by doing NST. Progress of labor was monitored by doing 4 hourly per vaginal examinations. Patients in whom signs of chorioamnionitis was developed or fetal heart rate was < 120 /min or liquor was meconium stained or there was protracted labor, were subjected for caesarean section. Maternal outcomes were studied in terms of fever, foul smelling vaginal discharge, wound infection, hospital stay, and mortality. Fetal outcomes studied in terms of birth weight, Apgar score at one and 5 min of birth, neonatal intensive care unit (NICU) admission, cause of NICU admission and neonatal mortality.

All the patients with PROM were given antibiotic prophylaxis of injection cefotaxime 1 g BD during antenatal period and patient having leaking to delivery interval more than 12 h, antibiotic prophylaxis was continued in postnatal period for 5 days (as per institutional protocols). All the babies of patients, who had leaking to delivery interval more than 12 h, received antibiotic prophylaxis of injection cefotaxime (50 mg/kg) BD and injection amikacin (15 mg/kg) OD for 5 days (as per institutional protocols). Efficacy of three modes of induction was compared by comparing induction to delivery interval.

Statistical Analysis

Continuous variable were presented as mean \pm standard deviation. The categorical variables were expressed in

frequency and percentages. Continuous variables were compared by performing independent *t*-test and categorical variables by performing Pearson's Chi-square test. For small numbers, Fisher exact test was used wherever applicable. All the tests were two sided. $P < 0.05$ was considered as statistically significant. Statistical software STATA version 14.0 was used for statistical analysis.

RESULTS

A total of 240 pregnant women were included in the study and divided into two equal groups, i.e., cases and control group. The mean age of cases was 25.20 ± 3.65 years and that of controls was 24.97 ± 3.40 . Among the cases (120), 45.83% (55) were primigravida and 54.17% (65) were multigravida while among the controls (120), 55% (66) were primigravida and 45% (54) were multigravida. Majority of women in cases (84.17%) and control (71.67%) were belonging to lower socioeconomic class. The mean gestational age of cases was 38.17 ± 0.83 weeks and that of controls was 38.60 ± 0.70 weeks. Most of the cases (94.17%) and controls (98.33%) were belonging to 37-40 weeks of gestation group. There were higher chances of instrumental delivery and lower segment cesarean section (LSCS) in patients with PROM and the fetal distress was the common cause leading to LSCS. Table 1 shows the distribution of cases according to mode of induction and mode of delivery.

Among the cases (120), 44.17% (53) delivered babies with birth weight between 2 and 2.5 kg and 55.83% (67) delivered babies with birth weight >2.5 kg. Among the controls (120), 13.33% (16) delivered babies with birth weight between 2 and 2.5 kg and 86.67% (104) delivered babies with birth weight >2.5 kg, ($P < 0.001$, HS). Out of 120 cases, 9.17% (11) delivered babies with Apgar score <7 and 90.83% (109) cases delivered babies with Apgar score ≥ 7 at 1 and 5 min. Among the controls (120), 1.67% (2) delivered babies with Apgar score <7 and 98.33% (118) delivered babies with Apgar score ≥ 7 at 1 and 5 min, ($P = 0.019$, S).

Out of total cases (120), 11.67% (14) cases delivered the baby who required NICU admission and 2.5% (3) cases had neonatal mortality while among the controls (120), 3.33% (4) delivered the baby who required NICU admission and there was no neonatal mortality which was statistically significant ($P = 0.025$). This indicates higher chances of NICU admission of babies born to patients with PROM at term than patients without PROM. 68.33% (82) cases delivered within 12 h of leaking and among them there was no neonatal morbidity or mortality. 30% (36) cases were delivered between 12 and 24 h of leaking and among them 10% (12) required NICU admission, neonatal mortality

was 1.67% (1). 1.67% (2) cases were delivered after 24 h of leaking and all required NICU admission and all got expired. The difference was statistically highly significant ($P < 0.001$). This shows that as the leaking to delivery interval increases, the chances of neonatal morbidity and mortality increases. Table 2 shows the distribution of cases and controls according to causes of NICU admission.

There was statistically highly significant difference observed in development of neonatal pneumonia ($P = 0.006$), jaundice ($P = 0.046$), and septicemia ($P = 0.001$) requiring NICU admission and leaking to delivery interval. This shows that as the leaking to delivery interval increases, there were higher chances of NICU admission due to pneumonia, neonatal jaundice, and septicemia (Graph 1).

Table 3 shows the distribution of cases and controls according to maternal morbidity and mortality. Table 4 shows that there was no maternal mortality among cases and controls. However, the difference in distribution of cases and controls according to developing fever and wound infection was statistically highly significant, i.e., there were higher chances of developing fever and wound infection in patients with PROM than patients without PROM.

Table 1: Distribution of cases and controls according to mode of induction and mode of delivery

Mode of induction	Mode of delivery (cases)		
	Normal (%)	Instrumental (%)	LSCS (%)
Oxtocin (40)	35 (87.5)	1 (2.5)	4 (10)
Misoprostol (40)	17 (42.5)	3 (7.5)	20 (50)
Misoprostol with oxytocin (40)	39 (97.5)	0 (0)	1 (2.5)
Total (120)	91 (75.83)	4 (3.33)	25 (20.83)
Mode of induction	Mode of delivery (controls)		
Oxtocin (40)	38 (95)	1 (2.5)	1 (2.5)
Misoprostol (40)	30 (75)	0 (0)	10 (25)
Misoprostol with oxytocin (40)	40 (100)	0 (0)	0 (0)
Total (120)	108 (90)	1 (0.83)	11 (9.17)
<i>P</i>	<0.0001 HS		

LSCS: Lower segment caesarean section

Table 2: Distribution of cases and control according to cause of NICU admission

Cause of NICU admission	Cases (%)	Controls (%)	<i>P</i> -value
Pneumonia	5 (4.17)	2 (1.67)	0.446, NS
Neonatal Jaundice	3 (2.5)	2 (1.67)	1.000, NS
Bronchial Asthma	2 (1.67)	0 (0)	0.498, NS
Septicemia	3 (2.5)	0 (0)	0.247, NS
Total	13	4	-

NICU: Neonatal intensive care unit

Among the cases (120), 68.33% (82) delivered within 12 h of leaking and no one developed any morbidity. 30% (36) cases delivered between 12 and 24 h of leaking and among those, 13.33% (16) developed fever, 2.5% (3) developed foul smelling per vaginal discharge and 0.83% (1) developed wound infection. 1.67% (2) cases delivered after 24 h and among them 0.83% (1) developed fever and all developed foul smelling per vaginal discharge and wound infection. This difference in distribution of cases according to leaking to delivery interval and maternal morbidities was statistically significant ($P = 0.026$, S). This shows that as leaking to delivery interval increases, chances of maternal morbidities increases.

Among the 120 cases, in only 5 (4.17%) cases growth was seen on vaginal swab culture and in 115 (95.83%) cases, no growth was seen on vaginal swab culture.

Table 4 shows the hospital stay of the patients. The difference in distribution of cases and controls according to hospital stay was statistically highly significant ($P < 0.001$).

Among the cases, the mean induction to delivery interval for oxytocin only was 8.42 ± 2.34 h, for misoprostol only was 10.62 ± 3.33 h and for both misoprostol and oxytocin was 8.10 ± 2.29 h while among controls, the mean induction to delivery interval for oxytocin only was 9.52 ± 1.79 h, for misoprostol only was 10.22 ± 1.71 h and for both misoprostol and oxytocin was 8.82 ± 1.54 h. In both groups, mean induction to delivery interval for both misoprostol and oxytocin was less than that of the other two modes of induction. Graph 2 shows the distribution of cases and controls according to mode of induction and induction to delivery interval.

Table 3: Distribution of cases and control according to maternal morbidity and mortality

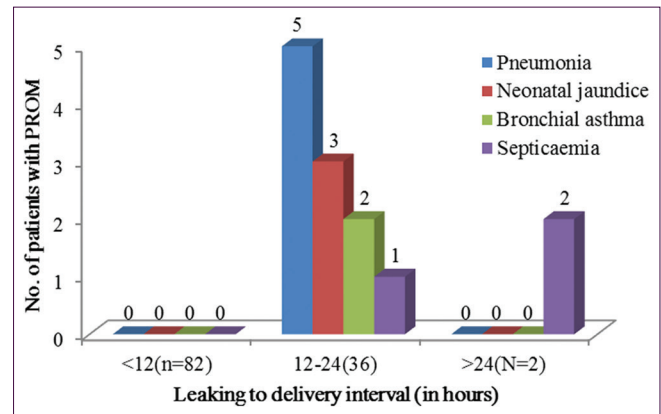
Maternal morbidity and mortality	Cases (%)	Controls (%)	P-value
Fever	17 (14.17)	3 (2.5)	0.006, HS
Foul smelling per vaginal discharge	5 (4.17)	2 (1.67)	0.446, NS
Wound infection	3 (2.5)	0 (0)	0.003, HS
Mortality	0 (0)	0 (0)	-
Total	25 (20.83)	5 (4.17)	-

Table 4: Distribution of cases and controls according to hospital stay

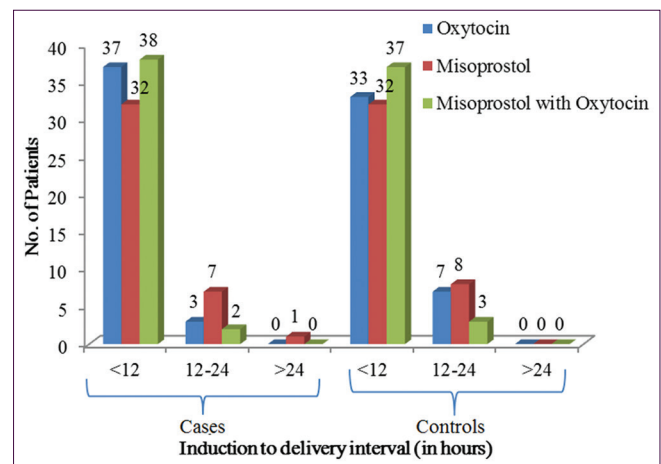
Hospital stay days	Cases (%)	Controls (%)	P
1-3	73 (60.83)	108 (90)	<0.001, HS
4-6	22 (18.33)	1 (0.83)	
>6	25 (20.83)	11 (9.17)	

DISCUSSION

In the present study, the majority of cases (52.5%) and controls (56.7%) were belonging to age group of 21-25 years and this was comparable with other studies.¹²⁻¹⁴ 45.83% cases were primigravida and 54.17% cases were multigravida. Most of the cases, i.e., 84.17% were belonging to lower socioeconomic class and 3.33% were belonging to upper class and 12.5% were belonging to middle class, this was comparable with study of Minnalkodi.¹⁴ Most of the cases, i.e., 94.17% were of gestational age between 37 and 40 weeks and 5.83% were of >40 weeks of gestation with mean gestational age of 38.17 ± 0.83 weeks. Among the controls, 98.33% were belonging to 37-40 weeks of gestation group and 1.67% were of >40 weeks of gestation with mean gestational age of 38.60 ± 0.70 weeks. As the number of patients with gestational age >40 weeks were very less so, conclusion cannot be made. Majority of cases (79.16%) delivered vaginally and 20.83% delivered by LSCS while 90.83% controls delivered vaginally and 9.17% controls



Graph 1: Distribution of cases according to cause of neonatal intensive care unit admission and leaking to delivery interval



Graph 2: Distribution of cases and controls according to mode of induction and induction to delivery interval

delivered by LSCS. This was comparable with previous studies.^{12,14,15}

Among the cases, who were induced with oxytocin only, overall 90% delivered vaginally and 10% delivered by LSCS. Among the cases, who were induced with misoprostol only, overall 50% delivered vaginally and 50% delivered by LSCS and among the cases who were induced with both misoprostol and oxytocin, 97.5% delivered vaginally, 2.5% delivered by LSCS. This shows that there were more chances of normal delivery if patients with PROM at term were induced with both misoprostol and oxytocin. In the study of Butt *et al.*,¹⁶ among the cases induced with oxytocin, 93.6% cases delivered vaginally, 6.4% cases delivered by LSCS, which was comparable. 18.33% cases were delivered by LSCS, with indication of LSCS was fetal distress and 2.5% cases delivered by LSCS, with indication of LSCS was protracted labor. In the study of Endale *et al.*,¹⁵ 7.6% cases were delivered by LSCS with indication of fetal distress and 3.2% cases delivered by LSCS with indication of protracted labor, which was comparable, as fetal distress was common indication in both studies.

Out of total cases, 44.17% gave birth to babies with birth weight between 2 and 2.5 kg and 55.83% gave birth to babies with birth weight >2.5 kg. Among the controls, 13.33% gave birth to babies with birth weight of 2-2.5 kg and 86.67% gave birth to babies with birth weight >2.5 kg. In our study, most of the cases were belonging to lower socioeconomic class and because of their nutritional status and some intrauterine stress of unknown etiology, there were higher chances of mild intrauterine growth restriction and that lead to PROM and low birth weight of babies born to them. 9.17% cases gave birth to babies having Apgar score <7 at 1 and 5 min, 90.83% cases gave birth to babies having Apgar score ≥7 at 1 and 5 min. 11.67% babies born to patients with PROM, got admitted in NICU and neonatal mortality was 2.5%. As per our institutional protocols, all the cases received antibiotic prophylaxis antenatally and babies of cases, who had leaking to delivery interval more than 12 h, also received injectable antibiotics prophylactically, so may be because of this, in our study, more percentage of cases gave birth to babies with Apgar score ≥7 at 1 and 5 min and lower percentage of babies developed morbidity and mortality as compared to other studies.^{12,14,15} In the present study, 14.17% of cases developed fever which is comparable with other studies.^{12,14} 60.83% of cases required ≤3 days of hospital stay and 39.16% cases required hospital stay for >3 days, this was comparable with the study of Endale *et al.*¹⁵ The longer duration of hospital stay among the cases was because of antibiotic prophylaxis to most of the babies and mothers

remain admitted in ward till the completion of baby's antibiotic prophylaxis, as per our institutional protocols.

Among the cases, induced with oxytocin only, 92.5% got delivered within 12 h with mean induction to delivery interval of 8.42 ± 2.34 h and among the cases, induced with misoprostol only, 80% got delivered within 12 h with mean induction to delivery interval of 10.62 ± 3.33 h. Our findings were comparable with study of Butt *et al.*¹⁶

CONCLUSION

The present study concluded that the chances of fetal and maternal morbidity and mortality increases in patients with PROM and as the leaking to delivery interval increases, the chances of fetal and maternal morbidity and mortality further increases. Hence, to decrease the feto-maternal morbidity and mortality, intervention at the earliest is must. As in our study, induction to delivery interval with misoprostol and oxytocin is lesser and more number of cases delivered normally so this mode of induction is better than other modes of induction, i.e., oxytocin only and misoprostol only.

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