

Outcome of Active versus Expectant Management in Preterm Premature Rupture of Membranes between 34 weeks to 36 weeks Six days: A Retrospective Study

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ABSTRACT

Introduction: An important cause of neonatal morbidity and mortality is the prelabour Preterm Rupture of the Membranes (PPROM) which refers to, the rupture of the membranes before 37 weeks. There are two modes of managing PPRM, active management (immediate delivery) and expectant management (therapy directed toward extending the pregnancy to improve neonatal outcome).

Aim: To compare neonatal outcomes following active and expectant (conservative) management in PPRM cases from 34 weeks to 36 weeks six days.

Materials and Methods: This retrospective study was conducted in the Department of Obstetrics and Gynaecology at Government Medical College (tertiary care teaching hospital), Thiruvananthapuram Kerala, India, from February 2021 to July 2021. The data collection period was from January 2013 to December 2014. PPRM cases between 34 weeks and 36 weeks and six days were retrospectively studied. A total of 62 patients among the Active Management (AM) group and 62 patients among the Expected Management (EM) group were selected. The neonatal outcomes (respiratory distress

syndrome, hypoglycaemia, neonatal sepsis) and maternal outcomes (caesarean section, chorioamnionitis) were compared. The latency period in conservative management and in active management was also compared. The data was analysed using the Chi-square test.

Results: In the AM group, 13 (21%) babies had respiratory distress syndrome, whereas, in the EM group it was 4 (6.5%) (p-value=0.019). In the AM group, 13 (21%) babies had hypoglycaemia, whereas, in the EM group, it was 5 (8.1%) (p-value=0.041). In the AM group, 3 (4.8%) women had signs and symptoms of chorioamnionitis, whereas, in the EM group, it was 7 (11.3%) (p-value=0.187). In the AM group, 16 (25.8%) of women had Caesarean section, whereas, in EM it was 9 (14.5%) (p-value=0.117). In AM group, 1 (1.6%) has neonatal sepsis and in EM it was 3 (4.8%) p-value=0.309. The latency period in conservative management was 119.5±31 hours and in active management, it was 51.5±13.2 hours.

Conclusion: The present study indicated that expectant management of PROM between 34 weeks to 36 weeks and six days leads to a statistically significant reduction of neonatal respiratory distress syndrome and hypoglycaemia.

Keywords: Amniotic fluid, Caesarean section, Chorioamnionitis, Hyperbilirubinaemia, Neonatal sepsis, Respiratory distress syndrome

INTRODUCTION

Preterm Premature Rupture of the Membranes (PPROM) refers to the rupture of the membranes before 37 weeks and before the onset of labour. PPRM is an important cause of neonatal morbidity and mortality. It complicates upto 3% of all pregnancies and is the cause of 40% of all preterm births [1,2]. The main risk factors for PPRM are previous preterm birth, nulliparity, multiple pregnancies, low Body Mass Index (BMI), infections, vitamin deficiency, antepartum bleeding and maternal habit of cigarette smoking [3].

The main neonatal complications in PPRMs include prematurity, neonatal sepsis, respiratory distress syndrome, hyperbilirubinaemia hypoglycaemia, hypokalaemia, and hypocalcaemia [4]. The maternal complications include endometritis, chorioamnionitis, increased rate of caesarean section and puerperal sepsis [5]. The management of PPRM is dependent upon the gestation at which rupture of the membranes occurs.

Royal College of Obstetricians and Gynaecologists recommend expectant management in women with PPRM upto 37 weeks of pregnancy [6]. American College of Obstetricians and Gynaecologists recommends either active management or expectant management in PPRM between 34 weeks to 36 weeks and six days [7]. Many studies have been conducted in the past with the aim of deciding whether expectant or active management is more beneficial in cases of near-

term PPRM. These studies concluded that in women with near-term PPRM, active and expectant management resulted in comparable rates of primary adverse neonatal outcomes (respiratory distress syndrome and neonatal sepsis). The effects on maternal outcomes (chorioamnionitis and mode of delivery) and secondary neonatal outcomes (hypoglycaemia and hyperbilirubinaemia) were mixed [8-10]. In a developing country like India preterm neonatal care poses a severe mental and financial burden on the patient and family. So the decision to terminate a preterm pregnancy needs to be done after careful consideration. The present study was conducted with an aim to find any difference in neonatal outcomes in active and expectant management of PPRM between 34 weeks to 36 weeks and six days.

MATERIALS AND METHODS

This retrospective analytical study was conducted in the Department of Obstetrics and Gynaecology in a tertiary care teaching hospital, Government Medical College, Thiruvananthapuram, Kerala, India, after taking the Institutional Ethical Committee clearance (IEC. No.36/1/2013 MCT). The case records of those patients who developed PPRM (between the gestational age of 34 weeks to 36 weeks and six days) between January 2013 and December 2014 were included in the study. The data analysis was done from February 2021 to July 2021.

Inclusion criteria: Singleton pregnancy, cephalic presentation, Bishop's score <5, patients not in active labour and who gave consent to participate were included in the study.

Exclusion criteria: Women who were in established labour, clinical evidence of chorioamnionitis at presentation, meconium-stained liquor, previous caesarean section, multiple pregnancies, antepartum haemorrhage, fetal/maternal distress and cephalopelvic disproportion were excluded from the study.

Participants' data were recorded from the database of the hospital. Every alternate patient file that matched the criteria for active and expectant protocols during the study period was included, till the required sample size was achieved. Those files with missing information were discarded, and further files were taken up that matched the criteria using the above selection process.

Study Procedure

In the present study, participants were taken as two groups:

- **Active Management (AM) group:** Patients who underwent induction of labour/caesarean section done within 48 hours of rupture of the membranes.
- **Expectant Management (EM) group:** Involved observation of the mother and baby, and awaiting the spontaneous onset of labour, in the absence of any complications that may necessitate delivery [9,11].

The diagnosis of PPRM was confirmed by sterile speculum examination of the vagina. The gold standard for diagnosis was considered the amniotic fluid leakage [12].

Chorioamnionitis diagnosis was based on the presence of one of the following signs and/or paraclinical changes, not explained by other associated conditions: foetal tachycardia, fever (above 37.8°C) present in two successive examinations at 4-6 hour intervals, maternal tachycardia (over 100 bpm) present on two successive examinations every four to six hours, foul smelling discharge pervagina and high maternal leucocytes value, over 15,000 leucocytes/mm [13].

The mode of delivery was recorded as caesarean section or vaginal delivery. Neonatal sepsis was assessed by C-reactive protein, absolute neutrophil count, micro Erythrocyte Sedimentation Rate (ESR), peripheral smear to look for band forms and blood culture or clinical signs of infection (apnoea, fever, intolerance for feeding, respiratory distress, and/or haemodynamic instability) [14].

Respiratory distress syndrome constituted tachypnoea, tachycardia, chest wall retractions, expiratory grunting, and nasal flaring during breathing efforts and who require oxygen for support [15]. As per the institutional protocol, hyperbilirubinaemia in the neonates was assessed by Cockington chart for premature infants [16]. Hypoglycaemia was defined as glucose values less than 40 mg/dL on the first day of life [17]. The following neonatal outcomes were recorded-respiratory distress syndrome, neonatal sepsis, hyperbilirubinaemia and hypoglycaemia. The maternal complications were also recorded (chorioamnionitis, caesarean section).

STATISTICAL ANALYSIS

Data was entered in an Microsoft Excel sheet and analysed using Statistical Package for the Social Sciences (SPSS) software version 27.0. The Chi-square test was used to compare the maternal and fetal outcomes in active and expectant management. Student's t-test was used to compare the interval between rupture of membranes and delivery in hours.

RESULTS

The baseline characteristics of women included in the study were analysed between the two groups and were found to be comparable [Table/Fig-1,2]. In the Active Management (AM) group, a majority of the 25 (40.3%) patients had amniotic fluid leaking between 35 weeks

to 35 weeks six days. In the expectant management (EM) group, 18 (29%) patients had amniotic fluid leaking between 35 weeks to 35 weeks six days. In active management mean gestational age at birth was 34 weeks six days and in expectant management, it was 36 weeks and two days [Table/Fig-3]. The mean interval between rupture of membranes and delivery in the AM group was 51.5 hours, while in the EM group this time interval was 119.5 hours [Table/Fig-4].

Age (years)	AM	EM
	n (%)	n (%)
<20	9 (14.5)	9 (14.5)
20-24	20 (32.3)	19 (30.64)
25-29	21 (33.9)	21 (33.87)
30-34	7 (11.3)	6 (9.7)
≥35	5 (8.1)	7 (11.3)
Mean±SD	25.48±5.31	25.85±5.947
p-value=0.7153 (Chi-square test)		
Obstetric score	AM	EM
	n (%)	n (%)
Primi	33 (53.2)	32 (51.6)
G2 (second gravida)	22 (35.5)	23 (37.1)
G3 (third gravida)	5 (8.1)	6 (9.7)
>G3 (more than third gravida)	2 (3.2)	1 (1.6)

[Table/Fig-1]: Age and obstetric score of the patients in both the groups.
SD: Standard deviation

Antenatal complications	AM	EM
	n (%)	n (%)
Gestational hypertension	10 (16.1)	12 (19.4)
Gestational diabetes mellitus	14 (22.6)	13 (21)
Unexplained polyhydramnios	9 (14.5)	6 (9.7)
Urinary tract infection	8 (12.9)	7 (11.3)
Gestational diabetes mellitus+urinary tract infection	5 (8.1)	5 (8.1)
Hypothyroidism	16 (25.8)	12 (19.4)
Nil	0	7 (11.3)

[Table/Fig-2]: Antenatal complications of the patients in both the groups.

Gestational age at leaking in weeks	AM	EM
	n (%)	n (%)
34 weeks-34 weeks six days	17 (27.4)	13 (21)
35 weeks-35 weeks six days	25 (40.3)	18 (29)
36 weeks-36 weeks six days	20 (32.3)	31 (50)
Gestational age at birth in weeks	AM	EM
	n (%)	n (%)
34 weeks-34 weeks six days	17 (27.4)	2 (3.2)
35 weeks-35 weeks six days	25 (40.3)	14 (22.6)
36 weeks-36 weeks six days	20 (32.3)	31 (50)
>37 weeks	0	15 (24.2)

[Table/Fig-3]: Frequency of patients of gestational age at leaking and birth in both the groups.

Interval between rupture of membranes and delivery in hours	N	Mean±SD	Min	Max
Active management	62	51.5±13.2	32	96
Expectant management	62	119.5±31.0	75	184

[Table/Fig-4]: Comparison of latency period between active and expectant management.
SD: Standard deviation; Min: Minimum; Max: Maximum; p<0.0001 (95%CI-59.52-76.47) (t-test)

In the AM group, eight patients and in the EM group, four patients reported between 11-12 hours of PPRM to the hospital (p-value

of 0.226 [Table/Fig-5]. In EM group respiratory distress syndrome (n=4, 6.5%) was less compared to AM group (n=13, 21%) with p-value of 0.019 which was statistically significant. In EM group hypoglycaemia (n=5, 8.1%) was less than in AM group (n=13, 21%) with (p-value=0.041). Suspected neonatal sepsis was less in AM (n=1, 1.6%) than in EM (n=3, 4.8%) with a p-value of 0.309 [Table/Fig-6]. Signs and symptoms of chorioamnionitis were less in AM group (n=3, 4.8%) than women and in the EM group (11.3%) with a p-value of 0.187. Caesarean section was more in AM group n=16 (25.8%) than in EM group (n=9,14.5%) with a p-value=0.117 [Table/Fig-7].

PPROM to admission interval (hours)	AM n (%)	EM n (%)	p-value (Chi-square test)
<2	12 (19.35)	10 (16.12)	0.639
2-4	14 (22.58)	16 (25.8)	0.67
5-7	16 (25.8)	18 (29.03)	0.688
8-10	12 (19.35)	14 (22.58)	0.659
11-12	8 (12.9)	4 (6.45)	0.226
Mean±SD	5.51±3.58	5.22±3.14	0.631

[Table/Fig-5]: Preterm Premature Rupture of the Membranes (PPROM) to admission interval.

Neonatal outcome	AM	EM
	n (%)	n (%)
No sepsis	61 (98.4)	59 (95.2)
Suspected neonatal sepsis	1 (1.6)	3 (4.8)
$\chi^2=1.033$, df=1, p-value=0.309 (Chi-square test)		
Respiratory distress syndrome	AM	EM
	n (%)	n (%)
Yes	13 (21)	4 (6.5)
No	49 (79)	58 (93.5)
$\chi^2=5.522$, df=1, p-value=0.019 (Chi-square test)		
Hypoglycaemia	AM	EM
	n (%)	n (%)
Yes	13 (21)	5 (8.1)
No	49 (79)	57 (91.9)
$\chi^2=4.159$, df=1, p-value=0.041 (Chi-square test)		
Hyperbilirubinaemia	AM	EM
	n (%)	n (%)
Yes	21 (33.9)	12 (19.4)
No	41 (66.1)	50 (80.6)
$\chi^2=3.345$, df=1, p-value=0.067 (Chi-square test)		

[Table/Fig-6]: Comparison of neonatal outcomes.

Signs and symptoms of chorioamnionitis	AM	EM
	n (%)	n (%)
Yes	3 (4.8)	7 (11.3)
No	59 (95.2)	55 (88.7)
$\chi^2=1.740$, df=1, p-value=0.187 (Chi-square test)		
Mode of delivery	AM	EM
	n (%)	n (%)
Vaginal delivery	46 (74.2)	53 (85.5)
Caesarean section	16 (25.8)	9 (14.5)
$\chi^2=2.455$, df=1, p-value=0.117 (Chi-square test)		

[Table/Fig-7]: Comparison of maternal outcomes.

DISCUSSION

Preterm premature rupture of the membranes is an important clinical problem and a dilemma for clinicians. On one hand, awaiting spontaneous labour may lead to an increase in infectious disease for both mother and child, whereas, induction of labour

leads to preterm birth with an increase in neonatal morbidity due to prematurity [6].

The present study showed that neonatal sepsis was more in the expectant management group than in active management, though not statistically significant. This is comparable with the study of Van Der Ham D et al., which also reported an increase in neonatal sepsis in expectant management compared to active management (4.6% vs 2.6%) [8]. The study by Ezzat L, also showed an increase in perinatal infection with expectant management than in active management (18% vs 10%) [18].

The present study showed that respiratory distress syndrome was less in the expectant management group compared to the active management (6.5% vs 21%) and was statistically significant (p-value=0.019). It is similar to the study by Morris J et al., [19] which showed decreased incidence of RDS (5% vs 8% with p-value=0.008) in the expectant management group when compared to the active management group. The Cochrane database systematic review by Bond D et al., also showed decreased incidence of respiratory distress syndrome in the expectant management group [5]. RDS was more in the active management group (RR 1.26, 95% CI 1.05 to 1.53, 12 trials). The study by Quist-Nelson J et al., also showed a decrease in respiratory distress syndrome in the expectant management group. RDS was more in the active management group (RR 1.47, 95% CI 1.10-1.97) [9].

The present study showed an increase of caesarean section in the active management group when compared to expectant management (25.8% vs 14.5%, p-value=0.117). In the study done by Biswas S et al., in India, the rate of caesarean section was higher in the actively managed group (32% vs 28%) than the expectant group [20]. The study by Bond DM et al., also showed that early birth was associated with an increased rate of caesarean section (RR 1.26, 95% CI 1.11 to 1.44, 12 trials) [5]. It is also similar to the study of Rawat R et al., which showed increase in Caesarean section in the active management group (32% vs 20% p-value=0.25) [10].

The present study showed a trend toward an increased risk of clinical chorioamnionitis in women receiving expectant management for PPRM when compared to active management, although not significant statistically (11.3% vs 4.8% p=0.187). It is similar to the study of Kayem G et al., which showed an increase in chorioamnionitis in expectant management (4.8% vs 0.9% p-value=0.07) [21]. The study by Sgayer I et al., also showed an increase in chorioamnionitis in the expectant management group when compared to active management (7.3% vs 2.6% p-value=0.61) [22].

In the present study, the expectant management policy was associated with a statistically significant reduction of hypoglycaemia compared with the active management policy (8.1% vs 21% p-value=0.041). The study by Kayam G et al., showed a reduction of hypoglycaemia in the expectant management group compared to active management (5.6% vs 12.3% p-value=0.07) [21].

In the present study, hyperbilirubinaemia was less in the expectant management group than in the active management group (19.4% vs 33.9% p-value=0.067). The study by Van Der Ham D et al., also showed a reduction of hyperbilirubinaemia in the expectant management group compared to active management (26% vs 38% p-value=0.004) [8]. The study by Elsayed E, also shows a reduction in hyperbilirubinaemia in expectant management compared to active management (11.9% vs 28.6% p-value=0.057) [23].

This retrospective comparative analysis compared the neonatal and maternal outcomes in near-term PPRM and observed that expectant management helps to reduce respiratory distress syndrome and hypoglycaemia in PPRM patients who are presenting near-term. However, there was an increase in chorioamnionitis and neonatal sepsis in the expectant management group which was not significant statistically.

Limitation(s)

Being a referral center, many patients had antenatal complications when they report. So, all patients with PPRM between 34 weeks to 36 weeks and six days could not be included in the conservative management group and hence sample size was limited. As this was a hospital-based study it was not generalisable to the population. As it was a retrospective study it lacks the methodologic validity of randomised controlled trials, hence, more studies are needed to arrive at a definite management protocol.

CONCLUSION(S)

The present study indicated that expectant management of preterm premature rupture of membranes between 34 weeks to 36 weeks and six days leads to a statistically significant reduction of neonatal respiratory distress syndrome and hypoglycaemia. A decrease in neonatal hyperbilirubinaemia was also noted in the expectant management group. Expectant management of pregnancies with PPRM seems to be more beneficial in terms of reducing short-term complications in premature infants between 34 weeks and 36 weeks and six days.

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