

Original Article

Fetomaternal Outcome with Active versus Expectant Management of Pre Labour-Rupture of Membranes at Term; A Randomized Controlled Trial

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Abstract

Objective: To compare fetomaternal outcome with immediate/active versus expectant management in pregnancies complicated with pre labour rupture of membranes at term.

Methodology: A randomized prospective controlled trial conducted in Obstetrics & Gynaecology department of Benazir Bhutto Hospital, Rawalpindi from 1st July 2022 to 31st December 2022. All women presenting with PROM at term and fulfilling the defined inclusion criteria were recruited and randomized equally to Group-A and Group-B for Active versus Expectant management. The latency period for onset of labour, mode of delivery, maternal and fetal complications were compared in two groups. The data was entered and analyzed by SPSS version 21. Comparison of maternal and fetal outcome variables was done using Chi square test. p value was calculated to measure the statistically significant differences at $p < 0.05$.

Results: During study period, 190 women were recruited. The mean maternal age was 26.16 years. Out of total, 45% were primigravidas, 40% multigravidas and 15% were grand multiparas. There was no statistically significant difference in mode of delivery between two groups (p-value 0.459). The latency period was significantly prolonged (>24 hours) in 57.9 % of the patients with expectant management (p-value <0.05). The rate of PPH (p-value 0.004) and chorioamnionitis (p-value 0.005) was higher in expectant group and while neonatal complications were comparable in both groups (p-value >0.05).

Conclusion: The active management of PROM is the preferred management option due to a shorter latency period, lesser maternal complications, without any significant increase in the rate of operative delivery.

Key words: Active management, Expectant management, Latency period, Premature rupture of membranes, PROM.

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Introduction

Pre-labour or Premature rupture of membranes (PROM) is the rupture of amniotic membranes after 28 weeks of gestation but prior to the onset of labor, resulting in leakage of amniotic fluid.^{1,2} When this happens before term (37 completed weeks of gestation) it is referred to as "Preterm Pre-labour rupture of membranes (PPROM) while after term it is termed as "Pre-labour rupture of membranes (PROM)".³

PROM is a common obstetric complication globally affecting 3-15% of all pregnancies, 30–40% of preterm labor, and 8–10% of term labor.³⁻⁵ The reported incidence for Pakistan is 3.27 %.⁶

PROM is a focus of concern worldwide, as a breach in amniotic membrane integrity can lead to significant fetomaternal complications, like; placental abruption, premature delivery, chorioamnionitis, post-partum haemorrhage (PPH), neonatal sepsis, neonatal

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respiratory distress syndrome and even mortality.⁷ Normally as pregnancy approaches term, various pathophysiological phenomena get activated in preparation for uterine contractions and amniotic membranes rupture during normal labor, however, membranes can get spontaneously ruptured even before labour, mainly due to a genetic defect in collagen of cervix and membranes leading to weakening and subsequent rupture of membranes.^{3,8}

Extensive research has been done on maternal and fetal risk factors associated with PROM and includes; low BMI, Interpregnancy interval <2 years, previous abortion/preterm birth or PROM, caesarean section (CS), gestational hypertension & diabetes mellitus, vaginal discharge and malpresentation.⁹⁻¹² A latest study by Benkia concludes the strong association of PROM with; primiparity, history of vaginal discharge and infection.¹³

The diagnosis of PROM requires a detailed history, speculum examination, ultrasound assessment of amniotic fluid, and at times diagnostic tests like; Nitrazin test (vaginal fluid PH examination), Ferning test, and fetal fibronectin tests, because of attendant false negative (10–20%) diagnosis.^{8,14}

The management of uncomplicated PROM remains controversial and an issue of debate since 1960's.¹⁵ There are two management options, each having its own pros and cons, leaving the obstetrician with the dilemma of whether; to wait for spontaneous onset of labour (expectant management), thereby limiting the chance of CS at the cost of an increased risk of ascending infections, or; to limit the risk of fetomaternal infection, and go for immediate delivery (Active management) by a planned CS or induction of labour with attendant increased risk of operative delivery.^{15,16}

The latest Cochrane systematic review by Middleton et al, concluded that expectant management of PROM is associated with an increased fetomaternal infectious morbidity (chorioamnionitis and/or endometritis combined), though no statistically significant difference in CS rate, serious maternal morbidity/mortality, definite neonatal sepsis, or perinatal mortality.¹⁷ Thereafter immediate delivery following term PROM was recommended and still being practiced widely. Nevertheless, a wait for spontaneous labour with informed consent, if patient and family wish so, was also permitted.¹⁸

National Institute of Healthcare and Excellence (NICE) guidelines, recommend expectant management for

initial 24 hours followed by stimulation, if patient does not go into spontaneous labour.¹⁹

The risk of infection is always present, even with intact membranes. Moreover, induction will increase the chance of CS, depriving the women and foetus to have a normal physiological birth with its long-term benefits. *Therefore, the recent systematic review declares the management of term PROM as still a controversial issue, recommending further RCT's to compare the outcome of both management options for term PROM.*¹⁵

Few local studies also have revealed same conflicting fetomaternal outcomes with the two management strategies for PROM.²⁰⁻²² Nevertheless, in developing countries like ours, the final outcome of either management strategy may get affected by various confounding factors like; peculiar demographics, lower socioeconomics; poor hygiene; late reporting to the hospital with a consequent prolonged latency period without fetomaternal surveillance; and insufficient neonatal care facilities.

In view of these unavoidable risk factors and the long-standing controversial management background, this study was undertaken to determine whether active or expectant management yields better outcomes for term PROM in our local settings. The outcomes will contribute to existing body of evidence and help inform generalizable management guidelines.

Methodology

After getting approval from Institutional Ethical Review Committee (ERB) and Board of Advanced Studies & Research (BASR), this prospective randomized control trial was conducted at the Department of Obstetrics & Gynecology, Benazir Bhutto Hospital, Rawalpindi from 1st July 2022 to 31st December 2022.

Inclusion Criteria: Women having single alive fetus in cephalic presentation and admitting with spontaneous PROM $\geq$ 37 weeks of gestation.

Exclusion Criteria: Gestational age less than 37 weeks; Meconium-stained liquor; Chorioamnionitis; Previous cesarean sections; Intrauterine deaths; Cephalopelvic disproportion; Multiple gestation; Mal-presentation; medical co-morbidities (hypertension, diabetes mellitus, cardiac Disease); Bishop score > 6.

All women presenting with complaint of PROM underwent a detailed history, speculum examination and Nitrazine/Fern test (if needed) to confirm PROM. Baseline investigations, obstetric ultrasound,

cardiotocography (CTG) and BISHOP scoring was done to rule out cases not fulfilling inclusion criteria. After informed consent, recruited women were randomly divided in two groups of matched parity (95 each); Group A (Immediate/Active Management) was stimulated with vaginal prostaglandin E2 tablet (Dinoprostone) 3mg, within 24 hours of PROM. In Group B (Expectant Management): spontaneous onset of labor was waited for first 24 hours. Those not accomplishing labour within 24 hours, were then stimulated as in group A. All participants were closely monitored per PROM protocol for pulse, blood pressure, temperature, and abdominal tenderness for early diagnosis of infection. Sterile pad was provided to monitor liquor-color. CTG was performed 4 hourly. Emergency caesarean delivery was reserved only for obstetric indications (chorioamnionitis, cord prolapse, meconium-stained liquor, fetal distress). Maternal and neonatal follow-up was done for one week. All data and outcome variables were recorded on specially designed proformas.

Outcome variables compared in two groups were; Mode of delivery; Latency Period (Duration from rupture of membranes till delivery); Maternal, fetal and neonatal complications (e.g., Chorioamnionitis, Primary postpartum hemorrhage (PPH), Stillbirth, Apgar Score, neonatal sepsis, NICU admissions, early neonatal death).

The data was entered and analyzed by SPSS version 21. Descriptive stats were applied for quantitative variables (age, gestational age, parity). Frequencies and percentages were calculated for qualitative outcomes (mode of delivery, latency period, primary postpartum hemorrhage, chorioamnionitis, NICU admission, early neonatal sepsis, stillbirth). Comparison of maternal and fetal outcome variables was done using Chi square test. p value was calculated to measure the statistically significant differences at $p < 0.05$.

Results

During study period, total 190 patients were recruited and randomized in two groups A and B for immediate and expectant management respectively. Mean maternal age (years) in Group A versus Group-B was 26.04 (SD 3.79) and 26.62 (SD 4.42), while mean gestational age (weeks) was 37.38 (SD 0.68) and 37.12 (SD 0.39), respectively. Average BISHOP score was 3.3 ± 1.4 .

Each group had equal number of matched parity i.e., 42 (44.2%) primigravida, 38 multigravida (40.0%) and grand multi para 15 (15.8%) in each group.

The mean time of stimulation in Group A was 6 ± 0.82 hours. In Group B (expectant management), 40 (42.1%) women went into spontaneous labour within 24 hours, while in remaining 55 (57.9%) cases, labour was stimulated after 24 hours with Tablet Prostaglandin E2.

Out of 190 patients, 27 (14.2%) had latency period of < 12 hours; while majority (45.8%) of women had latency period of more than 24 hours. In Group A, 63 (66%) were delivered within 24 hours compared with 40 (42%) in expectant group. Detailed split is shown in Table-1. Upon applying the chi-square test, the difference in latency period between two groups was statistically significant (p-value 0.003).

The SVD was accomplished in 142 (74.8%) cases, while instrumental vaginal deliveries and caesarean deliveries were 12 (6.3%) and 36 (18.9%) respectively. Difference in mode of delivery was not statistically significant between two groups (Figure 1 & Table I).

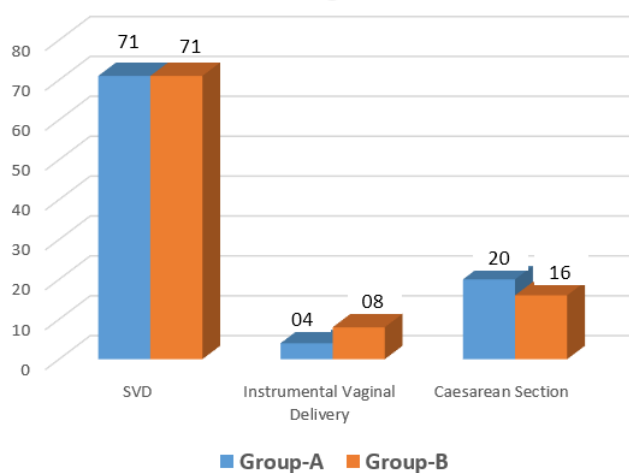


Figure 1. Mode of Delivery. (P value= 0.459)

Maternal outcomes revealed two main complications; primary PPH and chorioamnionitis (Table I). Both complications were more in expectant management group with a statistically significant difference of p-value 0.004 and p-value 0.005, respectively.

Neonatal outcomes analyzed were; Apgar Score (1st min, 10 min), early onset neonatal sepsis (Need to use antibiotics within 1st 7 days of birth), NICU admissions and stillbirth. All babies in two groups had a good APGAR score (>7), with no statistically significant difference (Table I). Similarly, all other perinatal outcomes were also statistically insignificant (Table I).

Table I: Comparison of Outcome Variables between Two Groups.

Outcome Variables		Group-A (Immediate Management)	Group-B (Expectant Management)	Total	P Value
LATENCY PERIOD					
< 12 Hours		15 (15.8%)	12 (12.6%)	27 (14.2%)	0.003
12-24 Hours		48 (50.5%)	28 (29.5%)	76 (40.0%)	
>24 Hours		32 (33.7%)	55 (57.9%)	87 (45.8%)	
MODE OF DELIVERY					
SVD		71 (74.7%)	71 (74.7%)	142 (74.7%)	0.459
Instrumental Delivery		04 (4.2%)	08 (8.4%)	12 (6.3%)	
Caesarean Delivery		20 (21.0%)	16 (16.8%)	36 (18.9%)	
MATERNAL COMPLICATIONS					
Post-partum Haemorrhage	Yes	12 (12.6%)	28 (29.5%)	40 (21.1%)	0.004
	No	83 (87.4%)	67 (70.5%)	150 (78.9%)	
Chorio- amnionitis	Yes	2 (2.1%)	12 (12.6%)	14 (7.4%)	0.005
	No	93 (97.9%)	83 (87.4%)	176 (92.6%)	
PERINATAL OUTCOMES					
APGAR Score (01 min)	< 7	6 (6.3%)	8 (8.4%)	14 (7.4%)	0.579
	> 7	89 (93.7%)	87 (91.6%)	176 (92.6%)	
APGAR Score (10 min)	< 7	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.579
	>7	95 (100.0%)	95 (100.0%)	190 (100%)	
Neonatal Sepsis & NICU Admission	Yes	17 (17.9%)	21 (22.1%)	38 (20.0%)	0.468
	No	78 (82.1%)	74 (77.9%)	152 (80.0%)	
Still Births		0 (0.0%)	0 (0.0%)	0 (0.0%)	--

Table II: Stratification of Outcome Variables in Relation to Latency Period.

Latency Period	Outcome Variable		Group-A (Immediate Management)	Group-B (Expectant Management)	Total	P Value
< 12 hours	Post-partum Haemorrhage	Yes	0 (0.0%)	3 (25.0%)	3 (11.1%)	0.255
		No	15 (100.0%)	9 (75.0%)	24 (88.9%)	
12-24 hours		Yes	3 (6.3%)	4 (14.3%)	7 (9.2%)	0.575
		No	45 (93.8%)	24 (85.7%)	69 (90.8%)	
>24 hours	Chorioamnionitis	Yes	9 (28.1%)	21 (38.2%)	30 (34.5%)	0.016
		No	23 (71.9%)	34 (61.8%)	57 (65.5%)	
< 12 hours		Yes	0 (0.0%)	1 (8.3%)	1 (3.7%)	0.314
		No	15 (100.0%)	11 (91.7%)	26 (96.3%)	
12-24 hours		Yes	2 (4.2%)	2 (7.1%)	4 (5.3%)	0.681
		No	46 (95.8%)	26 (92.9%)	72 (94.7%)	
>24 hours	APGAR (01min) Score	Yes	0 (0.0%)	9 (16.4%)	9 (10.3%)	0.031
		No	32 (100.0%)	46 (83.6%)	78 (89.7%)	
< 12 hours		<7	1 (6.7%)	1 (8.3%)	2 (7.4%)	0.869
		>7	14 (93.3%)	11 (91.7%)	25 (92.6%)	
12-24 hours		<7	3 (6.3%)	1 (3.6%)	4 (5.3%)	0.614
		>7	45 (93.8%)	27 (96.4%)	72 (94.7%)	
>24 hours	APGAR Score (10 min)	<7	2 (6.3%)	6 (10.9%)	8 (9.2%)	0.468
		>7	30 (93.8%)	49 (89.1%)	79 (90.8%)	
< 12 hours		>7	15 (100.0%)	12 (100.0%)	27 (100.0%)	--
		>7	48 (100.0%)	28 (100.0%)	76 (100.0%)	
12-24 hours	Early Onset Neonatal Sepsis & NICU Admission	>7	32 (100.0%)	55 (100.0%)	87 (100.0%)	--
		Yes	1 (6.7%)	0 (0.0%)	1 (3.7%)	
>24 hours		No	14 (93.3%)	12 (100.0%)	26 (96.3%)	0.362
		Yes	14 (29.2%)	3 (10.7%)	17 (22.4%)	
12-24 hours	NICU Admission	No	34 (70.8%)	25 (89.3%)	59 (77.6%)	0.063
		Yes	2 (6.3%)	18 (32.7%)	20 (23.0%)	
>24 hours		No	30 (93.8%)	37 (67.3%)	67 (77.0%)	0.005
		Yes	2 (6.3%)	18 (32.7%)	20 (23.0%)	

Latency period, the most important effect modifier was analyzed in relation to all outcome variables too among both groups (Table II). The significant differences seen were; frequency of PPH (p-value 0.016), chorioamnionitis (p-value 0.031) and early onset neonatal sepsis with subsequent NICU admission (p value 0.005) more in women having a latency period of more than 24 hours; All other outcome variables in

relation to latency period showed no significant difference.

Discussion

Spontaneous rupture of amniotic membranes is a normal physiological event during the natural process of labour and delivery but almost in 10% cases, it happens

before labour.¹⁵ Prolonged PROM can lead to significant maternal and perinatal morbidity, thereby needing a definitive management plan. However, management of PROM at term is still controversial, as active management while reducing the risk of fetomaternal sepsis, may lead to an increase in CS rate because of uterine hyperstimulation and fetal distress.²⁰ The objective of our study was to analyze whether immediate induction of labour to expedite the delivery in term PROM is better than to wait for spontaneous onset of labour.

The basic demographic profile (maternal age, gestational age, parity, socioeconomic status) were matched in both groups and the only parameter affecting the final outcome was a different management plan offered to each group.

The latency period (per our operational definition; PROM to delivery interval) is usually expected to affect the fetomaternal outcome in a direct manner. Longer the interval, more fetomaternal complications are anticipated. In our study active management (group-A) significantly shortened the latency period ($p=0.003$) compared with expectant management (group-B). In group A, majority of cases (66.3%) were delivered within a latency period of ≤ 24 hours compared to group-B (42%). This is quite comparable to a local study where 64.6% of women in active management group compared with 36.9% in expectant management group were delivered within 24 hours ($p=0.001$).²⁰ Consistently significant results were reported in another local study (Active: 13.49 hours vs. Expectant: 16.27 hours, $p=0.002$).²¹

Contrarily, a study done in Nepal have shared comparable outcomes between two groups in terms of PROM to delivery interval, CS rate, maternal and neonatal morbidity. The average PROM to delivery interval was 15.6 hours in group A, Vs. 16.8 hours in group B ($p>0.05$).²³ Similar outcome is reported by another recent study, where PROM to delivery interval within 24 hours (44% in active group vs. 63% in expectant group), mode of delivery and complications were comparable. Although active management significantly shortened the induction to delivery interval ($P=0.020$).⁸ Interestingly, a local study by Sheeraz et al. demonstrated no significant difference in mode of delivery and any of the fetomaternal outcome between two groups ($P>0.05$), with the conclusion that both management strategies can be employed for the term PROM.²² Multiple studies in literature have reported

though a shorter PROM-delivery interval with active management but no statistically significant difference regarding CS rate, maternal and neonatal morbidity with either management.^{8,20-24}

When mode of delivery was analyzed in our study, there was a slightly higher rate of caesarean delivery (Group A -21% vs. Group B-16.8%) but was statistically insignificant ($p=0.459$). Likewise, several other studies have shown that active management did not lead to significant rise in caesarean delivery; (30% vs. 21%. $P>0.05$);⁸ (35.4% vs. 63.1%, $p=0.001$);²⁰ (23.1% vs. 36.9%, $p=0.014$);²¹ (20.5% vs. 28.2%, $p>0.05$).²³

Maternal outcomes revealed two main complications in our study; primary PPH and chorioamnionitis. Both complications are associated with prolonged ruptured membranes⁷ and so were in our expectant management group with a statistically significant difference ($p=0.004$ and $p=0.005$, respectively). This result is much comparable to findings of Ashraf et al; Chorioamnionitis in 4.6% in induced Group and 21.5% in expectant management group ($P=0.004$),²⁰ and in an Indian study maternal infective morbidity was also significantly more in the expectant management group ($p=0.001$).²⁴ However, no significant difference was reported in several other studies.^{8,21,22}

All recent studies have shown no statistically significant difference in perinatal outcome in both groups in terms of rate of infection and NICU admission.^{8,20-24} Upon analyzing neonatal outcome; APGAR score in both groups was quite good (>7) at 1minute (93%) and 10 minute (100%), with no statistically significant difference ($p=0.579$) much comparable to Malla's study (1minute (91%) and 5 minute (94%).²³ The NICU admission of the babies from group A vs group B was 17.9% vs. 22.1% with an insignificant p value (0.468). This finding is consistent with the findings of two other local trials by Zia et al. (13.8% vs. 23.1%, $p=0.175$)²¹ and Sheeraz et al.; (23.3% vs. 36.7%. $p>0.05$).²² The studies from Nepal and India also showed statistically insignificant differences in the neonatal outcomes ($p=0.04$). The number of NICU admissions in both studies was low and identical in both groups (5%- $p>0.05$).^{23,24}

Neonatal mortality associated with PROM ranges from 2–4% to 7–20% in singleton and twin pregnancies, respectively.²⁵ There was no neonatal mortality in index study, consistent with results of other studies.^{8,23,24}

The latency period, most important effect modifier was also analyzed in relation to all outcome variables among both groups (Table.2). The significant differences were

seen in; frequency of PPH (p-value 0.016), chorioamnionitis (p-value 0.031) and early onset neonatal sepsis with subsequent NICU admission (p value 0.005) more in women having a latency period of more than 24 hours; All other outcome variables in relation to latency period showed insignificant difference. These results are consistent with a Nigerian study.⁸

A recent local study has recommended immediate induction of labour for PROM at term. However, an expectant management can be offered for a limited period of time, as nearly 80% of women establish spontaneous labour within 12 hours, and 95% within 24 hours, making a 12-24-hours period of expectant management reasonable, provided no fetomaternal concern arises.²¹

Conclusion

Owing to a shorter PROM – delivery interval (latency period) and less maternal complications, this study concludes that active management of term PROM is preferable to expectant management. Although existing literature suggests that active management reduces latency, it generally does not result in significant differences in most other fetomaternal outcomes. Consequently, there remains a continued need for further large-scale randomized controlled trials at national and global levels, particularly in major tertiary care centres, to establish standardized, evidence-based management protocols tailored to local population.

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