Original Article

Comparison of Active and Expectant Management for Fetomatenal Outcome Among Women Presenting with Premature Rupture of Membrane at Term

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Abstract

Objective: The objective of this study is to compare the feto-maternal outcome of active versus expectant management in women presenting with PROM at term in a tertiary care hospital.

Methodology: This was a randomized trial conducted at Department of Obstetrics and Gynecology, Azad Jammu and Kashmir Medical College, Muzaffarabad from January to December 2020. A total of 130 (65 in each group) women presenting with PROM at term were included in the study. Sample selection was done with the help of a predefined inclusion and exclusion criteria.

Results: Prom to admission interval was significantly higher for active management (Active: 6.26 vs. Expectant: 5.46, p-value=0.043) and lower for prom to delivery interval (Active: 13.49 vs. Expectant: 16.27, p-value=0.002). No significant difference was seen between fetal and maternal outcome in active management and expectant management group. i.e. C-section (Active:23.1% vs. Expectant:36.9%, p-value=0.140), APGAR score at 1 (Active: 9.2% vs. expectant: 13.8%, p-value=0.410) and 5 minutes (Active: 6.2% vs. expectant: 10.8%, p-value=0.344), fetal [Meconium (Active: 13.8% vs. Expectant: 18.5%), birth asphyxia (Active: 12.3% vs. Expectant: 16.9%) & hyperbilirubinemia (Active: 7.7% vs. Expectant: 12.3%)] and maternal outcome (p-value=0.142).

Conclusion: Results of this study demonstrate no significant difference for feto maternal outcome for active management and expectant management of women presenting with PROM at term. However, women in active management groups had shorter delivery interval and hospital stay as compared to women in expectant groups.

Keywords: Feto-maternal Outcome, Active Management, Expectant Management, Premature Rupture of Membrane.

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Introduction

Prelabour rupture of membranes (PROM) refers to the disruption of foetal membranes before the onset of labour, resulting in the leakage of amniotic fluid.[1] Premature rupture of membranes is more common in certain countries than others, and this may be because of the differences in the populations investigated. The prenatal, neonatal, and maternal deaths it causes are common in both wealthy and impoverished nations.[2] Early membrane ruptures are common in both industrialised and developing nations, regardless of country's socioeconomic status: Pakistan (3.27%)[3], Nigeria(2.5%)[4], USA(3%~4.5%)[5] and in China 2.5%.[6]

Preterm PROM is linked to morbidity and death in both the foetus and the mother including umbilical cord prolapse & compression[7], oligohydramnios, abruption of placenta[8], necrotising enterocolitis, respiratory distress syndrome, foetal mortality[9], maternal intra-amniotic and postpartum infection risks.[10,11] Chorioamnionitis is linked to preterm newborns'

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neurodevelopmental delays, early-onset sepsis, and severe intraventricular haemorrhage.[12, 13]

There are two management options for women with simple PROM. After a PROM diagnosis, active management (AM) entails inducing labour or preparing a caesarean delivery as soon as possible. Expectant management (EM), on the other hand, is waiting for labour to begin spontaneously if no complications arise.[14] AM aims to lower mother and newborn infection rates after term PROM, while EM aims to encourage spontaneous labour and hence limit the chance of caesarean delivery.[14]

Furthermore, PROM's economic impact is not limited to maternal and newborn death and morbidity, but also to the cost of drugs, hospitalisation, and the load on health personnel.[15] Despite advancements in prenatal care, there is an increasing worry about increased trends in unfavorable outcomes related with PROM. Pregnant women may be compelled to seek emergency treatment because to a PROM's iffy appearance. Term PROM management remains problematic despite several research studies. The present research was carried out in our population to compare the outcomes of both active and expectant management that we may use it on general population in future.

Methodology

This was a randomized comparative trial conducted at Department of Obstetrics and Gynecology Azad Jammu and Kashmir Medical College, Muzaffarabad, during time duration of one year from January to December 2020.

Sample size calculation was done with the help of C-section rate with active and expectant management in women presenting with term PROM. A total of 130(65 in each group) is calculated with 80% confidence level, 7.7% absolute precision and by taking expected percentage of C-section rate among women going active and expectant movement as 10% and 17% respectively.[16] We adopted the difference between two population formula from Sample size determination for health studies (WHO sample size calculation software).[17]

A total of 130 (65 in each group) women presenting with PROM at term were included in the study. Sample selection was done with the help of a predefined inclusion and exclusion criteria. Women presenting with Singleton pregnancy vertex presentation, gestational age >37 weeks (LMP or by early sonography with diagnosis of PROM), spontaneous PROM (≤6 hours of duration, sterile speculum examination of vagina). Women with following characteristics were not included in the study. Patients were randomly divided into two groups with the help of random number tables. Written informed consent was taken after explaining the aims and procedures. Detailed history, general physical, obstetrical and sterile speculum examination was carried out on all the patients. All women received broad spectrum antibiotics.

To induce labour, oral misoprostol 50 mcg was administered every four hours in the immediate induction group. If necessary, an oxytocin drip might be added to the labour process. Patients were closely watched for any signs of foetal discomfort, such as hyperstimulation, tachysystole, or hypertonus. Menstruating women who gave birth within 24 hours of starting an induction technique were judged to have successfully initiated labour, as were those women who had a noticeable change in their cervical score after a few hours of induction. Surgical procedures and their underlying causes were carefully scrutinized. Every difficulty that arose during or after delivery was recorded. The APGAR score was used to track the immediate foetal outcome.

In order to ensure the safety of the patients, they were constantly monitored. The mother's pulse, B.P., and temperature were measured every four hours. Symptoms and indicators of chorioamnionitis were a primary concern for the doctors. None of the P/V tests were deemed to be unnecessary. P/V was performed aseptically whenever necessary. Reassessment of cervical findings was done if labour did not begin within 12 hours, and oxytocin or oral misoprostol 50 mcg was used based on the patient's Bishop score. Group A patients received the same level of care and attention throughout induction and delivery. All cases were tracked for maternal and foetal outcomes, as well as the health of newborns for up to seven days after birth. For newborns hospitalised to the neonatal intensive care unit, full follow-up was conducted.

SPSS version-26 was used for data entry and analysis. Quantitative variables were presented with mean ± SD and qualitative variables were presented with frequency and percentage. Association between qualitative variables with study groups was assessed with chi square test while independent sample t-test was

applied to compare quantitative outcome variables. P-value ≤0.05 was considered statistically significant.

Results

In this study 130 women (65 in each group) were included. Mean age of women in active and expectant group was 26.32 ± 4.32 and 26.69 ± 4.08 years. No significant difference was seen for age and gestational age of women in both treatment groups. No significant difference was seen for gravida status of women in both treatment groups, however parity status showed signifying difference. Significant difference was seen for prom to admission and delivery time. (Table I)

Table I: Patients Characteristics in Study Groups

		Management		p-value
		Active	Expectant	
		65	65	
Age (Years)		26.32±4.32	26.69±4.08	0.618
Gestational Age (Weeks)		38.30±1.13	38.52±1.03	0.259
Gravida	1	42(64.6%)	31(47.7%)	0.134
	2	11(16.9%)	14(21.5%)	
	3	12(18.5%)	20(30.8%)	
Parity	0	25(28.5%)	7(10.7%)	<0.001
	1	8(12.3%)	22(33.8%)	
	2	21(32.3%)	19(29.2%)	
	3	11(16.9%)	17(26.2%)	
Prom to Admission Interval		6.26±2.53	5.46±1.87	0.043
Prom to delivery Interval		13.49±5.60	16.27±4.11	0.002

No significant difference was seen for type of delivery between study groups. Although C-section was higher in expectant management group but it was not statistically significant. i.e. (Active: 23.1% vs. Expectant: 36.9%, p-value=0.140) Indications for c0section did not show any significant difference between groups. Regarding neonatal outcomes, no significant difference was seen for APGAR score at 1 and 5 minutes between study groups. I.e. APGAR score 1 minute (<7: Active: 9.2% vs. Expectant: 13.8%, p-value=0.410) & APGAR score 5 minute (<7: Active: 6.2% vs. Expectant: 10.8%, p-value=0.344). Other neonatal outcome measures like meconium (Active: 13.8% vs. Expectant: 18.5%, p-value=0.475), birth asphyxia (Active: 12.3% vs. Expectant: 16.9%, p-value=0.456), hyperbilirubinemia (Active: 7.7 vs. Expectant: 12.3%, p-value=0.380) and NICU admission (Active: 13.8% vs. Expectant: 23.1%, p-value=0.175) did not show any significant difference between groups. However, women in expectant group had higher frequency for all these complications. Maternal outcome also did not show any significant difference between groups. i.e. p-value=0.142. Parameters regarding maternal outcome includes fever, PPH and wound discharge. Mean hospital stay was significantly higher for women in expectant group as that of active management group. i.e. (Active: 6.60 vs. Expectant: 7.96, p-value<0.001). (Table II)

Table II: Feto-maternal outcome in study Groups

	Management		p-value
	Active	Expectant	
	65	65	
Type of Delivery			
C-Section	15(23.1%)	24(36.9%)	0.140
NVD	44(67.7%)	33(50.8%)	
Instrumental	6(9.2%)	8(12.3%)	
Indications for Delivery			
Fetal distress	3(4.62%)	2(3.08%)	0.471
Prolong 2nd stage labour	2(3.08%)	4(6.15%)	
Cervical dystocia	2(3.08%)	9(13.85%)	
No progress of labour	4(6.15%)	5(7.69%)	
Failure of induction	4(6.15%)	4(6.15%)	
Not Applicable	50(76.9%)	41(63.1%)	
Fetal Outcome			
APGAR Score at 1 minute			
<7	6(9.2%)	9(13.8%)	0.410
>7	59(90.8%)	56(86.2%)	
APGAR Score at 1 minute			
<7	4(6.2%)	7(10.8%)	0.344
>7	61(93.8%)	58(89.2%)	
Meconium	9(13.8%)	12(18.5%)	0.475
Birth asphyxia	8(12.3%)	11(16.9%)	0.456
Hyperbilirubinemia	5(7.7%)	8(12.3%)	0.380
NICU Admission	9(13.8%)	15(23.1%)	0.175
Maternal Outcome			
Fever	10(15.4%)	15(23.1%)	0.142
PPH	3(4.6%)	5(7.7%)	
Wound Discharge	3(4.6%)	8(12.3%)	
None	49(75.4%)	37(56.9%)	
Hospital Stay	6.60±1.10	7.96±1.81	<0.001

Discussion

It is still a matter of debate among obstetricians as to the best way to treat PROM, which is linked to a wide range of complications for both mother and baby, including immediate complications like cord prolapse, cord compression, meconium-stained liquor, foetal distress, and placental abruption, as well as delayed complications like infections that affect both mother and baby.[5, 18]

Results of this study showed that prom to admission interval was significantly higher for active management (Active: 6.26 vs. Expectant: 5.46, p-value=0.043) and lower for prom to delivery interval (Active: 13.49 vs. Expectant: 16.27, p-value=0.002). No significant

difference was seen for C-section rate, indication for C-section. Regarding fetal complications, no significant difference was seen for APGAR score (At 1 and 5 minutes), Meconium, birth asphyxia, hyperbilirubinemia and NICU admission.

PROM to delivery interval, Caesarean section rate, and maternal and newborn morbidity were all found to be identical across active treatment and expectant management groups with a 24-hour cutoff in a newly published Nepal research.[19] Furthermore, a local Pakistani research found no difference between active and expectant care in patients with prelabor rupture of membranes at term.[16] Results of this study is in line with these studies showing no significant difference for maternal and fetal complications between active and expectant management among women with term PROM.

A local study from Multan Pakistan with induction of labour within twenty-four hours of premature rupture of membranes patients are usually delivered within 24 hours as compared to expectant management. With induction, active management reduces the requirement for oxytocin augmentation and the danger of choriolamennitis. The rate of caesarean sections, on the other hand, is not raised as a result of this strategy.[20]

Anjali Gupta in her study reported that fetal distress and lower (uterine) segment Caesarean section were comparatively higher in induction group (16%vs 2% p-value=0.038). Neonatal Sepsis was higher in expectant group but statistically insignificant (22% versus 16%, p-value=0.26).[21] These findings are contrary to the results of this study as showing significantly higher C-section rate with active management. Few other studies have also reported higher C-section rates with active management but their findings were not statistically significant. These findings are also in line of this study as in this study C-section rate was lower for active management group and prom to delivery interval was significantly shorter for active management group.[22, 23] Another recently published local study reported significantly higher C-section rate with expectant management which is in line with the results of this study. (Expectant: 63% vs. Active: 35.4%).[20]

In this study, neonatal complications did not show significant difference between study groups. Many other studies have reported similar trend for neonatal complications between active and expectant management for term PROM.[19, 21, 24, 25]

Delorme's review found that AM after term PROM reduces the risk of caesarean section but has no effect on the rate of caesarean section. Reducing rates of early-onset newborn sepsis is difficult to prove. When labour induction is not beneficial, EM may be an option for women who are prepared to wait a few days or who have had a previous caesarean delivery and are at a lesser risk of obstetric complications if they give birth naturally.[14]

Induction of labour is preferable to expectant treatment in patients with term PROM, according to a meta-analysis. As an alternative to caesarean delivery, an induction might assist to decrease infection in both mother and child.[26] Prompt labour induction should be recommended for women with PROM at 37 0/7 weeks or more, however the option of expectant management for a limited period of time may be adequately offered to those without a contraindication to labour. When expectant management is chosen, nearly 80% of women go into labour spontaneously within 12 hours, and 95% of women go into labour spontaneously within 24 hours, making a 12- to 24-hour period of expectant management reasonable if the clinical and foetal conditions are reassuring and the patient is adequately counselled on the risks of prolonged PROM and the limitations of available data. GBS prophylaxis should not be postponed when pregnant women who are GBS positive are anticipating labour, and immediate induction rather than expectant management is recommended for such women.[27]

Advantages and drawbacks exist with both management strategies for PROM. A woman with the term PROM may make an educated decision between two management alternatives: expectant 24-hour management and early induction that explains the advantages and disadvantages of both approaches.

Conclusion

Results of this study demonstrate no significant difference for feto maternal outcome for active management and expectant management of women presenting with PROM at term. However, women in active management groups had shorter delivery interval and hospital stay as compared to women in expectant groups.

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