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Original Research Article

Evaluation of Fetomaternal Outcome in Expectant and Active Management of Term Prelabour Rupture of Membranes

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Abstract: Background: PROM is a complex condition with multifactorial etiology, including factors like multigravida, low socioeconomic status, concomitant infections, late symptom presentation, and a history of preterm PROM. Conventional management strategies include expectant management, waiting for spontaneous labor, and active management, involving induction with oxytocin or prostaglandins. Objectives: This prospective cross- sectional observational study aimed to evaluate fetomaternal outcomes in both expectant and active management of term PROM. Methods: Conducted at the Obstetrics and Gynecology Department of Rangpur Medical College Hospital, the study included 50 pregnant women with a history of PROM, gestational age \geq 37 weeks, and spontaneous membrane rupture. Data were collected from March to September 2019 using purposive sampling. Demographic information was recorded, and clinical examinations were performed. Data were processed, analyzed, and compared between active management (Group-A) and expectant management (Group-B). *Results:* The study population's age ranged from 17 to 35 years, with a majority aged 20-25 years (42.0%). Most patients were from urban areas (52.0%), with 52% belonging to a socioeconomically disadvantaged class. Group-A, which underwent active management, showed a significantly higher rate of delivery within 12 hours (80.0%) compared to Group-B (48%). Both groups had similar induction-to-delivery intervals. Vaginal deliveries were more frequent in Group-A (84% vs. 64%), while Group-B had a higher rate of C-sections due to fetal distress. Group-B experienced more maternal complications, including puerperal sepsis, wound infections, and postpartum hemorrhage. Neonatal outcomes were better in Group-A, with higher Apgar scores at both 1 and 5 minutes. Conclusion: Active management was associated with better outcomes in term PROM cases compared to expectant management. Early antenatal diagnosis and risk factor identification are essential tools in the management of term PROM to prevent adverse outcomes.

Keywords: Prelabour Rupture of Membranes (PROM), Active Management, Fetomaternal Outcomes.

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INTRODUCTION

Prelabour rupture of membranes (PROM), defined as the spontaneous leakage of amniotic fluid from the amniotic sac, is a common occurrence in pregnancy, but it is associated with a high incidence of complications and risks [1]. Nearly two- thirds of PROM cases are spontaneous, with common risk factors including young maternal age, multiple pregnancies, genital tract infections, and a history of preterm delivery

[2]. Term PROM is diagnosed after thirty-seven completed weeks of gestational age, affecting approximately 8% to 10% of term pregnancies [3]. One of the most significant maternal risks associated with the term PROM is intrauterine infection, and the risk increases with prolonged membrane rupture. Fetal risks include umbilical cord compression and ascending infections [3]. The complications associated with PROM can range from the need for cesarean section to fetal

pulmonary morbidity and, in severe cases, neonatal mortality.

Despite extensive research, the etiology of PROM remains poorly understood. Some research suggests that PROM may result from a "programmed weakening process" in which the fetal membranes weaken prior to the onset of labor [4]. Other proposed mechanisms include mechanical forces, such as those exerted by conditions like polyhydramnios or multiple gestations [4]. While major complications associated with PROM are relatively rare, it is still linked to increased maternal and neonatal morbidity. Maternal health care providers often have differing opinions on the optimal management of women with PROM, particularly regarding the necessity and timing of labor inductions [5].

The management strategies for PROM can be broadly categorized into two approaches: expectant management, which involves waiting for spontaneous labor to begin within 24 hours, and active management, which includes the induction of labor using prostaglandin or oxytocin [6]. The choice between these two strategies depends on various factors and continues to be a subject of clinical debate. In recent decades, the induction of labor has become increasingly common worldwide. In developed countries, up to 25% of term deliveries now involve induced labor. In developing nations, the rates are generally lower but can be comparable in some settings. Induction of labor is defined as the artificial initiation of uterine contractions to initiate labor and delivery, which can be achieved by administering oxytocin, prostaglandins, or manually rupturing the amniotic membranes [7].

Patients with term PROM often experience issues such as fluid leakage and pelvic pressure without the presence of contractions. As the duration of membrane rupture increases, the risk of maternal and fetal infections also rises. Therefore, obstetricians often recommend labor induction if a pregnancy is at term and labor does not commence spontaneously following membrane rupture. The primary goal of induction is to achieve a successful vaginal delivery while minimizing discomfort and risks for both the mother and fetus. Successful induction of labor should achieve three primary objectives: the initiation of uterine contractions and cervical dilation, ultimately resulting in vaginal delivery, while minimizing discomfort and risks to both mother and fetus. Various agents are available for induction, including misoprostol, dinoprostone, and oxytocin, each with unique advantages and considerations.

Misoprostol, a synthetic analogue of prostaglandin E1 (PGE1), has gained attention for its efficacy in cervical ripening and labor induction. It is stable at room temperature, has a rapid onset of action, and can be administered through multiple routes, making

it a cost-effective alternative to other agents [8]. Oxytocin, on the other hand, is a well- established agent for labor induction but primarily stimulates uterine contractions and does not directly affect cervical ripening [9]. The choice of induction method depends on factors such as safety, efficacy, and cost- effectiveness. Various mechanical and pharmacological methods are available for cervical ripening, including balloon devices and prostaglandins. While prostaglandin E2 (PGE2) has demonstrated effectiveness in cervical ripening, misoprostol, a synthetic analogue of PGE1, has emerged as a versatile agent due to its stability, rapid action, and cost-effectiveness [10]. Oxytocin, administered intravenously, is widely used but primarily stimulates uterine contractions rather than cervical ripening [11].

Despite the availability of these induction methods, there is a need for further research to compare their effectiveness, especially in the context of PROM management. Clinical studies assessing the outcomes of expectant versus active management in the case of term PROM are relatively limited, particularly in Bangladesh. This study aims to evaluate fetomaternal outcomes in expectant and active management strategies for prelabour rupture of membranes at term. By examining the results of these different approaches, we can gain valuable insights into the optimal management of this complex obstetric condition and enhance the care provided to pregnant women experiencing PROM.

OBJECTIVES

General Objectives

• To evaluate the fetomaternal outcome in expectant and active management of prelabour rupture of membranes at term.

Specific Objectives

- To find out the fetal outcome in expectant management of PROM.
- To find out the maternal outcome in expectant management of PROM.
- To find out the fetal outcome in active management of PROM.
- To find out the maternal outcome in active management of PROM.
- To compare the fetal outcome between expectant and active management of PROM
- To compare the maternal outcome between expectant and active management of PROM

MATERIALS & METHODS

Study Design

This study employed a hospital-based prospective cross-sectional observational design to investigate the management of prelabour rupture of membranes (PROM). The research was conducted at the Department of Obstetrics & Gynaecology in Rangpur Medical College Hospital, Rangpur, Bangladesh, over a six-month period from March 28, 2019, to September 27, 2019.

Inclusion Criteria

- Pregnancy ≥37 weeks of gestation confirmed by LMP or early sonography with diagnosis of PROM.
- Single fetus with vertex presentation.
- Absence of active labour or features suggestive of fetal distress.
- No contraindication for vaginal delivery.
- No known hypersensitivity to prostaglandin
- No intervention outside the hospital

Exclusion Criteria

- Fetal distress or meconium stained amniotic fluid at admission.
- Patient with features of Chorioamnionitis like fever, tachycardia, uterine tenderness, or foul smelling liquor
- Cesarean section or major uterine surgery.
- Medical condition like heart disease, asthma, preeclampsia, DM, Twins, Rh incompatibility.
- Fetal abnormality like IUGR, fetal anomalies

Data Collection

Data collection for this study involved enrolling pregnant women with gestational age \geq 37 weeks and spontaneous rupture of membranes (PROM) before labor at Rangpur Medical College Hospital. After obtaining informed consent and assigning unique IDs, a structured Case Record Form (CRF) was used to gather data on sociodemographics, clinical history, and physical examination findings. Laboratory tests, including high vaginal swabs and blood samples, were conducted. The diagnosis of Chorioamnionitis followed predefined criteria. Patients received management based on their condition, and fetal assessments were performed. Data quality was ensured through careful checking and processing.

Data Analysis

Data analysis involved using a pre-designed questionnaire to collect sociodemographic and clinical data from participants. After verifying, editing, and coding the data, it was entered into SPSS vs 23.0 for analysis. Data cleaning and validation were conducted to ensure accuracy. Statistical analysis was performed using SPSS/PC software, including descriptive and inferential methods. Graphs and charts were created using MS Excel for visual representation. Results were presented in tabular form, and a significance level of P < 0.05 was applied to assess statistical significance.

Ethical Considerations

Ethical considerations in this study were paramount. Approval from the ethical committee at Rangpur Medical College Hospital was obtained. Patients were provided with comprehensive explanations of the study's objectives, procedures, and potential risks and benefits in a language accessible to them. Written informed consent was obtained from all patients or their parents/legal guardians if minors were involved. Strict confidentiality measures were assured, and patients were informed that the study aimed to benefit both physicians and patients in rational case management, adhering to ethical principles and respecting participants' rights and well-being.

RESULTS

Demographic features	Variables	Frequency	Percentage	
Age distribution				
	<20	8	16.0	
	20-25	21	42.0	
	26-30	12	24.0	
	30-35	9	18.0	
	Mean \pm SD	23.5 ± 9.54		
Residence				
	Rural	19	38.0	
	Urban	26	52.0	
	Sub-urban/slum	5	10.0	
Socioeconomic status				
	Poor class	26	52.0	
	Middle class	10	20.0	
	Upper class	14	28.0	

 Table 1: Sociodemographic characteristics of the study subject (n=50)

In this study, the age of the patients ranged between 17-35 years. Most of the patients were 20-25 years (42.0%). Next (24.0%) were 26-30 years of age group. Mean age was 23.5 ± 9.54 years. Maximum respondents came from urban area (52.0%), followed by rural area (38.0%) and sub-urban/slum area (10.0%).

Socioeconomically patients are grouped into three classes. Poor class GNI per capital income (In Tk.) : <7000, Middle-class GNI per capital income (In Tk.): 7000- 27000 and Upper-class GNI per capital income (In Tk.) : >27000. Among the patients the poor class 26(52%) comprising the major percentage of the

patients, which is followed by upper class 14(28%) and remaining are middle class 10(20%).

Obstetrics history, clinical features	Frequency	Percentage (%)		
Clinical features				
H/O gush of fluid from vagina	18	36.0		
Continuous leakage of fluid from vagina	32	64.0		
Fever	29	58.0		
Lower abdominal pain	42	84.0		
Tachycardia	26	52.0		
Leukocytosis	23	46.0		
Uterine tenderness	16	32.0		
Foul smelling vaginal discharge	13	26.0		
Fetal distress	17	34.0		
Less foetal movement	19	38.0		
Risk factors profile		·		
Anemia	14	28.0		
H/O preterm labour	5	10.0		
UTI	13	26.0		
No ANC	9	18.0		
Previous PPH	5	10.0		
Polyhydramnios	7	14.0		
Previous C/S	12	24.0		
Vulvovaginitis	5	10.0		
Multiple pregnancy	2	4.0		

 Construction of PROM women (n=50)

 Obstatrics history clinical features

 Frequency

 Percentage (%)

In this study we noted down the gestational week of evaluation of outcome of PROM and regular ANC, treatment received throughout the pregnancy. Present study shows that Lower abdominal pain, continuous leakage of fluid from vagina and fever was commonest presentation (84.0%, 64.0% & 58.0% respectively). Table also gives impression that history of gush of fluid from vagina was 36.0% of patients, Tachycardia (52.0%), leukocytosis (46.0%) patients of PROM women. The association of risk factors or

maternal complication is shown on Table 3.7. Among the all risk factors anaemia present in 28.0% cases; UTI were 26.0% cases and H/O previous C/S were 24.0% cases. Study shows most of the women delivered by LUCS (82.0%). Total 27 patients has been trial for vaginal delivery. Among them only 9(18.0%) patients progress to vagina delivery, but 18 patients not progress and Caesarean section was done. Occurrences of caesarean delivery in rural patients were much higher (89.47%) in relation to urban residing (77.41%).

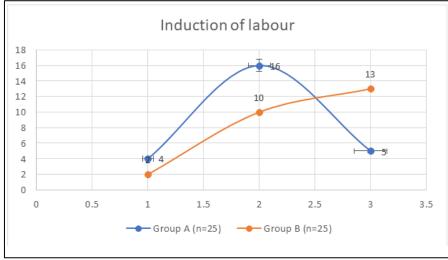


Figure 1: Induction to delivery time (n=50)

According to management protocol study populations were allocated into two groups, Group-A or

induction of labour with prostaglandin /oxytocin (active) and group-B or patients with waiting for spontaneous

onset of labour or expectant for 24 hours. Delivery was achieved within 12 hours of induction in 20 patients (80.0%) in group-A and 12 patients (48%) in group-B, the difference being significant (p value 0.0001). After drug administration, patients were monitored for progress of labour, maternal and fetal vital signs routinely. A partogram was strictly maintained in all patients. If labor not started within 24 hours, decision of operation was taken according to the clinical condition of patients. The mean interval from labor induction to delivery interval was similar between the two groups: 8.37 ± 5.3 hours and 14.23 ± 4.2 hours in group-A and group-B respectively.

Cable 3: Mode of delivery between study group (n=50)					
Mode of Delivery	Group A		Group B		p value
	(n=25)		(n=25)		
	Ν	%	Ν	%	
Vaginal delivery	21	84.0	16	64.0	
Caesarean section	4	16.0	9	36.0	0.110
Total	25	100	25	100	

Table shows the mode of delivery. In this study 21(84%) women in group-A and 16 women (64%) in group-B had vaginal delivery. Frequency of C- Section was high in group-B or patients or patients with waiting

for spontaneous onset of labour or expectant for 24 hours (18.0% patients). The difference was statistically non-significant (p value 0.110).

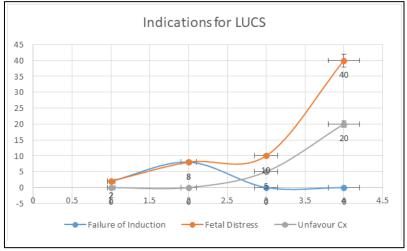


Figure 2: Indication for caesarean section (n=13)

Study indicates the indications for LUCS was failure of induction in 2 subjects, fetal distress 12 subject. Two patients was failure of Induction in group-A. Group-B has higher rate of fetal Distress. The difference being significant (p value ≤ 0.05), except failure of Induction.

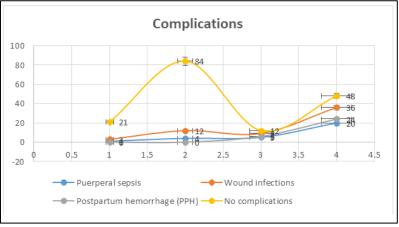


Figure 3: Maternal complications (n=50)

Shows that 33(66.0%) of PROM mothers was free from any complications and among them group-A predominant. Most cases of Group-B PROM women developed any sort of complication. Most common complication was Puerperal sepsis, wound infections and PPH. The difference being significant (p value ≤ 0.05).

Table 4: Neonatal outcome (n=50)						
Neonatal outcome	Group A (n=25)		<i>Group B</i> (<i>n</i> =25)		p value	
	Ν	%	Ν	%		
Good fetal & neonatal outcome	23	92.0	21	84.0	0.388 ^{ns}	
Need resuscitation	2	8.0	4	16.0	0.388 ^{ns}	
Admission in NICU	1	4.0	2	8.0	0.556 ^{ns}	
Death	0	0	0	0	-	

Table shows neonatal outcome of the study population. It was found that 92.0% neonates in group-A and 84.0% in group-B were found good fetal & neonatal outcome. Two (8.0%) baby in group A & 4(16.0%) baby in group-B required resuscitation. None of the neonate expired in this study.

DISCUSSION

In the present study 50 patients of term PROM were studied to evaluate the fetomaternal outcome in expectant and active management of prelabour rupture of membranes at term. In this study, the age of the patients ranged between 17-35 years. Most of the patients were 20-25 years (42.0%) with a mean age of 23.5 ± 9.54 years. Maximum respondents came from urban areas (52.0%), and socioeconomically poor class 26(52%) comprised the majority of the patients. The findings of our study align with those of previous research in the field of term prelabour rupture of membranes (PROM). Eftekhari et al., conducted a study in which they reported similar patient demographics and outcomes. In their study, the mean age of patients was 23.7 ± 3.6 in the misoprostol group and 24.3 ± 4.2 in the oxytocin group, which closely resembles the age distribution observed in our study. Furthermore, they found no significant differences in gestational age between the two groups, consistent with our findings [11].

Additionally, Eftekhari et al., noted Bishop scores at the initiation of induction in their study. They reported scores of 1.6 ± 1.6 for the misoprostol group and 16 ± 1.5 for the oxytocin group, indicating that the cervical readiness for induction was comparable between these groups, which mirrors our results. Another study, which investigated the expectant treatment group, reported a mean age of women of 23.8 ± 4.9 years, which is in line with our study's patient demographics. They also reported the mean duration of pregnancy, with women in the expectant treatment group having a mean gestational age of 38.5 ± 1.1 weeks, closely resembling our findings. The 2010 Jalilian, N analysis, which reviewed the advantages of early intervention with oxytocin or prostaglandin versus expectant management in term PROM cases, supports our study's rationale for active management. This analysis underlines the challenges associated with using oxytocin for induction before 28 weeks, necessitating multiple attempts, which

can be costly and frustrating, further reinforcing the benefits of active management [12].

In our study, we followed a specific management protocol, categorizing patients into two groups: Group-A, which received active management with prostaglandin/oxytocin induction, and Group-B, which followed an expectant approach. The significant difference in the time to delivery between these groups, with 80.0% of patients in Group-A delivering within 12 hours of induction compared to 48% in Group-B, corroborates the advantages of active management. Our rigorous monitoring of labor progress, maternal and fetal vital signs, and the strict maintenance of partograms in all patients ensure a comprehensive assessment of outcomes [1]. The dosage regimen for misoprostol in cervical ripening and labor induction has been a subject of interest and discussion in the field of obstetrics. The American College of Obstetricians and Gynecologists (ACOG) committee opinion recommends the use of a 25 µg dose of misoprostol for these purposes, based on the observation of a higher incidence of tachysystole with larger doses. This recommendation is in line with the principle of balancing efficacy and safety [13].

A review article by Sanchez-Ramos also examined the dosing of misoprostol, comparing doses of 25 μ g and 50 μ g. It was found that patients who received the 25 μ g dose experienced a lower incidence of tachysystole and hyperstimulation. However, they also had a longer interval to vaginal delivery compared to those receiving the higher dose. No significant differences were noted in cesarean delivery rates, cesareans performed for fetal heart rate abnormalities, operative delivery rates, or neonatal intensive care unit (NICU) admissions between the two dosing regimens [14].

A comprehensive 2021 Cochrane review encompassed 61 studies involving 12,819 women, focusing on cervical ripening and labor induction methods. The review found that when comparing oxytocin alone to vaginal prostaglandins, the former was associated with a higher rate of unsuccessful vaginal delivery within 24 hours (70% vs. 21%). Moreover, oxytocin versus intracervical prostaglandins resulted in fewer vaginal deliveries (51% vs. 35%) and increased cesarean sections (19.1% vs. 13.7%). These findings suggest that oxytocin may be less effective in achieving successful vaginal deliveries and may lead to higher cesarean section rates compared to prostaglandin- based methods. Notably, the review highlighted that cesarean section rates were elevated in women with an unfavorable cervix, regardless of membrane status [15].

In our study, we observed that 84% of women in Group-A underwent active management with prostaglandin/oxytocin induction had vaginal deliveries. In contrast, only 64% of Group-B women who followed an expectant approach achieved vaginal deliveries. This substantial difference in favor of active management suggests its effectiveness in promoting vaginal deliveries. Group-B had a higher frequency of cesarean sections (18.0% of patients), with indications including failure of induction and fetal distress. This aligns with previous studies that have consistently shown increased rates of failed induction and cesarean sections when women have an unfavorable cervix. Xenakis's prospective study of 597 pregnancies, which stratified women based on Bishop scores, found that the highest risk of cesarean sections was observed in both nulliparous and parous women with low Bishop scores (0 to 3) compared to those with higher scores. Even women with Bishop scores of 4 to 6 had a significantly higher risk of cesarean sections than those who spontaneous labor. These experienced findings emphasize the importance of cervical ripening in achieving successful vaginal deliveries and reducing the risk of cesarean sections [16].

The study observed no significant differences in age, parity, gestational period, mean Bishop's score, or leaking to admission interval between the groups. Most participants were between 37-40 weeks gestation, with only one woman in the misoprostol group at 41-42 weeks. Most patients (52%) in the misoprostol group responded to a single dose, while 36% required 2 doses and 12% required 3 doses. The mean misoprostol dose was similar in primigravida and multigravida patients. Among primigravidae, 39.39% required 10 units of oxytocin, while 47% of multigravida patients required 2.5 units. Additionally, 70% of misoprostol-induced patients did not require oxytocin augmentation. A prospective study demonstrated that misoprostol led to favorable cervix conditions faster than a Foley catheter, with lower oxytocin use due to a required 6-hour wait after the last misoprostol dose [17].

Maternal outcomes indicated that 66% of PROM mothers in group-A were free from complications. At the same time, most group-B PROM women experienced various complications, including puerperal sepsis, wound infections, and PPH. In terms of neonatal outcomes, a higher percentage of newborns in group-B had Apgar scores below 7 at both 1 and 5 minutes. The study findings aligned with previous research, emphasizing that induction success depended on cervical favorability. Misoprostol proved effective in ripening the cervix and initiating uterine contractions, leading to a lower rate of cesarean sections. Other studies also supported misoprostol's efficacy in reducing cesarean section rates compared to other induction methods, with shorter induction-to-delivery intervals and minimal adverse effects on neonatal outcomes [18].

CONCLUSIONS

The present study concluded that active management is better than expectant management in the case of term PROM. Prelabour membrane rupture is significant as it causes maternal complications, increased operative procedures, and neonatal morbidity. Therefore, early detection and appropriate management are mandatory for the reduction of the burden of PROM. PROM has a significant impact on perinatal outcomes. But our main target was a healthy mother and healthy baby. In managing PROM, timely use of proper antibiotics, steroids, and induction or augmentation of labor reduce the hospital stay and ultimately reduce perinatal and maternal complications.

RECOMMENDATIONS

- PROM is a high-risk obstetric condition. Active management should be conducted as soon as possible for better feto-maternal outcomes.
- Aseptic precaution & prophylactic antibiotics should be given to prevent neonatal infection.
- A large-scale, multi-center study will be conducted for precise and accurate outcome findings.

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