

Clinical Implications of Premature Rupture of Membranes in Gestational Women in a Tertiary Care Hospital: A Prospective Observational Study

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ABSTRACT

Background: Preterm Premature Rupture of Membranes (PPROM) is a leading cause of newborn morbidity and mortality. The purpose of our research is to evaluate the clinical implications of PPRM in pregnant women, with a particular emphasis on understanding the impact on maternal health. **Materials and Methods:** This is a 6-month prospective observational study conducted at a tertiary care teaching hospital in Hubballi. The study comprised 99 patients with PPRM less than 37 weeks of gestation. Maternal and obstetric characteristics such as maternal age, body mass index, gravidity, parity, date of last menstrual period, past medical history, PROM time, amniotic fluid appearance and amniotic fluid index (calculated ultrasonographic images), latency period (days from rupture to delivery), management (steroid, magnesium) and delivery type were recorded. The data was analysed with IBM SPSS Statistics version 25. **Results:** Out of 99 PROM patients, 64.5% were diagnosed with anemia. The mean Serum hemoglobin level was 9.45 ± 1.9 gm%. Using Pearson's Chi-square to analyze the association between socioeconomic status and anemia in PROM cases, it was found to be statistically significant [$2(8, N=99)=204.673a, p=.000$] at $p < 0.05$. Factors such as cervical dilation, induction of labor, fetal presentation and use of antenatal corticosteroids were significantly associated with p value less than 0.05, CI 95%. **Conclusion:** Our study found a significant association between cervical dilation and induction of labor with gestational age in women with PPRM, suggesting that certain obstetric characteristics may influence PPRM. The findings align with previous research, highlighting the importance of considering these factors in the management of women at risk for PPRM.

Keywords: Preterm premature rupture of membranes, Gestational Age, Preterm, Antenatal Corticosteroids.

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Received: 12-04-2024;

Revised: 14-05-2024;

Accepted: 06-10-2024.

INTRODUCTION

Premature Rupture of Membranes (PROM) develops in women during pregnancy when the amniotic sac ruptures before labor begins; if this occurs before the 37th week of gestation, it is known as Preterm Premature Rupture of Membranes (PPROM). The majority of women will naturally go into labor within 24 hr of PROM.¹ Preterm birth is one of the three leading causes of neonatal death, with PROM accounting for more than 40% of preterm deliveries, as well as 18%-20% and 21.4% of perinatal mortality and morbidity, respectively.² PROM accounts for 5% to 15% of all pregnancies globally, while PPRM accounts for 2.2% to 4% in India.³

Literature survey suggests that, the prevalence of PROM varies across different regions. Globally, PROM affects between 5-15% of rural populations.² Young, primigravida patients have been found to have a higher incidence of PROM, in contrast to urban areas, the prevalence of term PROM was found to be higher in rural areas in an Indian study, particularly among housewives (92.5%) and underweight (21.3%).⁴ In India, Prasad Dwa Y *et al's* study found that the prevalence was 9.8%.⁵ PROM was found to be more common in preterm deliveries and was linked to perinatal infections in another study carried out in South Finland and South Bavaria.⁶

The exact etiology of PROM is unclear, but risk factors include infections, smoking, polyhydramnios, low BMI, low socioeconomic status, cervical insufficiency, poor nutritional status and having a history of PROM in a previous pregnancy.⁷ Several Research has shown that maternal age is also a factor that may increase the risk of PROM, with some studies suggesting,



DOI: 10.5530/jyp.20251175

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mothers aged 30 years and above are at a higher risk of developing PROM.⁸

PROM is associated to cause birth asphyxia, neonatal mortality, placental abruption, neonatal sepsis, respiratory distress syndrome, fetal death, umbilical cord prolapses and admission to the Neonatal Intensive Care Unit (NICU) are complications that occur in premature newborns.⁹ The risk of complications is even higher in Preterm PROM (PPROM), such as pulmonary hypoplasia and skeletal deformations related to prolonged oligohydramnios exposure.¹⁰ Neonates born after prolonged rupture of membranes may develop sequelae such as malpresentation, oligohydramnios, cord compression, necrotizing enterocolitis, intraventricular hemorrhage and neurologic impairment.¹¹ Treatment depends on the gestational age of the fetus and the presence of infection in the mother. The management of PROM involves the administration of antenatal corticosteroids, antibiotics and close monitoring for potential neonatal complications to optimize the outcomes for the newborns. The Undiagnosed PROM leads to increased treatment cost and medical expenditure, prolongation of hospital stays, increased complications, reducing the quality of life of the women and infant.^{11,12}

The objective of our study is to assess the clinical implications of PPRM in gestational women. We are planned to investigate and assess the clinical implications of premature rupture of membranes in gestational women, with a primary focus on understanding the impact on maternal health. The study aimed to provide valuable insights into the associated risks, complications and management strategies, contributing to a better understanding of the overall clinical scenario.

MATERIALS AND METHODS

This is a prospective observational study including Antenatal patients visiting to out and in-patient Gynecology department of Tertiary Care Teaching Hospital, Hubballi for a period of 6 months (August 2023-January 2024). Based on the pilot study ($n=5$) the sample size was calculated. Study participants were selected based on inclusion and exclusion criteria and recruited by the physician. The participants were clearly explained about the study, its procedure, risks involved and its significance. An Informed Consent Form was being obtained from all subjects willing to participate in the study. Women within Gestational age 28 to <37 weeks, diagnosed with PROM, with single pregnancies and willing to participate were included in the study. Patients who underwent cerclage, h/o chorioamnionitis and abortion, twin pregnancy and with a previous history of PPRM were excluded from the study.

The present study includes 99 patients who had Preterm Premature rupture of membranes. Data on maternal and obstetric characteristics such as maternal age, body mass index, gravidity, parity, Date of last menstrual period, past medical history, PROM time, amniotic fluid appearance and amniotic fluid index

(calculated ultrasonographic images), latency period (days from rupture of amniotic sac to the delivery), treatments (steroid, magnesium), type of delivery were noted. Associated symptoms such as frequent and intermittent abdominal pain, PV bleed, decreased fetal movements and fetal distress were observed. Detailed examination was done, including general, systemic and obstetric examination. Blood and urine investigations were done in all cases. A per-vaginal examination was done for each case to access the pelvis; Bishop's score was also noted. Conservative management was done for all PPRM patients, according to the guidelines or the onset of spontaneous labor or till the maternal and fetal indication for LSCS. Initially the treatment was started with Ampicillin 1 g STAT IV, followed by 500 mg 6th hourly and post-delivery patients were given Metronidazole 500 mg 8th hourly. In patients with a positive culture sensitivity test, Antibiotics were switched to a broader spectrum. Extremely preterm (<28 weeks) and Very preterm (28 to 32 weeks) were given Dexamethasone 6 mg IM 12th hourly.

Statistical analysis: Data was analyzed using IBM SPSS Statistics for Windows, version 25.0 (IBM).

RESULTS

Maternal Characteristics at the time of Admission

The total number of deliveries during the period of our study were 2160, out of which 99 women with a preterm gestational age less than 37 weeks presented with complaints of per vaginal leak to the gynecology department. The incidence of PPRM was found to be 4.58%. Subjects' presentation at the time of admission is illustrated in Table 1. All the 99 patients presented with PV leak, out of which 55.6% had abdominal pain, 36.3% were pallor, 9 had bleeding per vagina, 7 had pedal edema, with a very few reporting of fever (2), headache (3), nausea (2) and blurring of vision (2).

In our study the mean maternal age was 24.3±4.1 with a population age range of 18-40 years. Weight in kg and height in meters were recorded at the time of admission to calculate Body mass Index. In our study we found out that the mean of the study population was slightly overweight with a mean BMI of 25.95±3.7. Majority of the population was found to have a normal blood pressure with 64 having <120 mmHg of SBP and 62 having <80 mmHg OF DBP. Only few that is 7 women had pre-eclampsia. Past medical history of patients was obtained on interviewing and reviewing past medical visit records. 12.1% had a history of Thyroid, 8% with a history of hypertension, 2% with a history of gestational Diabetes and 2% Upper respiratory tract infection. Urinary Tract infection, HbsAg positive status and polio paralysis was seen in less than 1% of the patients respectively.

Anaemia and Socio-economic Status

The majority of the PROM cases, were from a lower middle class that is 44.4% and 20.2% were from an upper middle of modified

Table 1: Maternal Characteristics at the time of Admission.

Sl. No.	Characteristics	Frequency	Percentage	
1.	Age in years	24.3±4.1 (range:18-40)		
2.	Weight in Kg	61.69±7.7		
3.	Height in mts	1.5±0.59		
4.	BMI	25.95±3.7		
	Under weight	1 (1.0%)		
	Healthy weight	41 (41.4%)		
	Over weight	57 (57.6%)		
5.	Blood Pressure (mmHg)			
	Systolic Blood Pressure	Diastolic Blood Pressure		
	<120	64	<80	62
	120-139	21	80-89	21
	140-159	7	90-99	8
	>160	7	>110	7
6.	Co-morbidities			
	Gestational Diabetes	2	2.02	
	Hypertension	8	8.08	
	Thyroid	12	12.1	
	URTI	2	2.02	
	Urinary Tract infection	1	1.01	
	HbsAg Positive Status	1	1.01	
	Polio paralysis	1	1.01	
7.	Physical presentation			
	Fever	2	2	
	Pallor	36	36.3	
	Edema	7	7.1	
	Abdominal Pain	55	55.6	
	PV Bleed	9	9.1	
	PV leak	99	100	
	Headache	3	3	
	Nausea	2	2	
	Blurring of Vision	2	2	

Kupuswamy's classification. Out of 99 PROM patients 64.5% were diagnosed with anemia. The mean Serum hemoglobin level was 9.45±1.9 g% with a range of 6.2-14.2 g%. 31.3% (31 individuals) had history of Iron sucrose infusion and 34 individuals (34.3%) had history of blood transfusion during second trimester. All gestational women with regular antenatal care received vitamin and mineral supplements in the form of ferrous sulphate tablets (bis in die), b-complex capsules (quaque die) and calcium supplements (quaque die) regularly till the time of parturition. We applied Pearson Chi-square to analyze the association between socio-economic status and anemia in PROM cases, it was found

to be statistically significant [$\chi^2 (8, N=99)=204.673a, p=.000$] at $p<0.05$ (Table 2).

Maternal Clinical and Obstetric Characteristics

67.7% of gestational women regularly had their regular Antenatal care visits whereas 32.3% were irregular or had no regular antenatal care. Based on parity, 62.6% of the women had their first pregnancy while 37.4% were multigravida. Amniotic fluid Index was calculated using Ultrasound images (sum of four quadrants), in our study 78.8% women had adequate amount of amniotic fluid index whereas 21.2% had oligohydramnios (amniotic fluid less 5 cm). Cervical dilation was assessed based

Table 2: Anaemia and Socio-economic Status.

Socio-economic status	Anemia		Total
	No	Yes	
Lower Middle	18	26	44
Lower	2	10	12
Upper Lower	9	14	23
Upper Middle	6	14	20
100	35	64	99
Value	df	Sig. (2-sided)	
Pearson Chi Square	204.673	8	0.000

on how many fingers are admitted into the cervix, 48.5% PROM cases had cervical dilation more than 2 cm and complete cervical effacement was seen in 26.3% cases. The latency period from the time of initiation of PROM till delivery was 12 hr out of which 59 had delivered within 12 hr and 40 had prolonged PROM.

Out of 99 preterm PROM cases 25 occurred as extremely preterm (<28 weeks), 30 cases occurred as very preterm (28 to <32 weeks) and 44 cases occurred as late preterm (32 to <37 weeks). According to the Bishop score's, the labor was induced or let to spontaneously progress, on admission 45.5% women were in active labor and labor was induced in 54.5% women with misoprostol 50 micrograms IM 6th hourly till the time of delivery. During the time of delivery 88.9% cases had cephalic presentation, 10% transverse and 1 case presented with breech presentation. On delivery the amniotic fluid color was noted, 21 had meconium-stained amniotic fluid. 42.4% patients underwent C-section whereas 57.6% had vaginal delivery. The indications for Cesarean were: Previous LSCS, Fetal Distress, Cord prolapse, tight coed loops around the neck, Arrest of descent, MSAF. Based on the severity and duration of PROM, cesarean was an emergency (35.4%) approach or planned (7.1%) as shown in the table. Corticosteroids were administered to 17.2% (Table 3).

Association of Gestation age with Maternal Obstetric Characteristics

On applying Pearsons Chi-Square to determine the association between Gestational Age and obstetric characteristics of women with PPRM, we found that cervical dilation, induction of labor, fetal presentation and use of antenatal corticosteroids were statistically significant at p value less than 0.05, CI 95% (Table 4). However Amniotic fluid index, Parity, Cervical effacement, Mode of delivery, amniotic fluid color was found to have no association with gestation age in women with PPRM (Table 4).

DISCUSSION

Premature rupture of membranes contributes to 40% of preterm deliveries worldwide and 2.2-4% in India.³ The incidence of PPRM in our study was found to be 4.58%. Our incidence is close to the study conducted by Rajan *et al.* in India.¹³ Akter *et*

al., showed that PPRM was seen in young adults aged between 27.24±6.28 years, which was similar to our research, where the mean age group of the study subjects were 24.3±4.1 years.¹⁴ The Body mass index was recorder during the first visit of gestational women at the hospital, the majority of the population were found to be overweight (57.6%), similarly, a study conducted by Sun *et al.* showed that being overweight during pregnancy was a risk factor for PROM.¹⁵ On assessing co-morbid conditions, our study findings align with previous research, showing a similar incidence of pre-eclampsia to Smith *et al.*¹⁶ We also observed a 12.1% prevalence of thyroid disorders, 8% hypertension history and 2% each for gestational diabetes and upper respiratory tract infection history. Urinary tract infection, HbsAg positivity and polio paralysis were less than 1% each. Consistent with Johnson *et al.*,¹⁷ and Brown *et al.*¹⁸

A cross-sectional study conducted by Mamatha *et al.*,¹⁹ stated that 63.2% of PROM cases belonged to low socioeconomic status which lines up with our study wherein 44.4% of the study population belonged to lower middle class and 64.55% of the PROM women were anemic, a study conducted by Nusrat *et al.*²⁰ The association of socioeconomic status and Anemia in PPRM cases was found to be statically significant. No statistical association was found between the gravidity, parity, history of abortion and history of caesarean delivery and the occurrence of PPRM.²¹

Majority of PROM cases occurred at late Preterm gestational age between 32 to less than 37 weeks and was statistically insignificant. Our research showed that women attending regular ANC were less likely to have PPRM than those who were irregular. Our findings were similar to the study conducted by Choudary *et al.*²² However the number of ANCs were statistically insignificant, this might be due to difference in study population and setting. PPRM Cases of Primigravida was more prominent than in multigravida i.e. 25% more which was similar to the study conducted by Sajitha *et al.*, with 21% more PPRM cases of primigravida compared to multigravida.²³ Oligohydramnios was noted in 21.2% of PPRM cases and a majority of 78.8% had adequate Amniotic fluid index in contrast a study conducted by Alina *et al.*, showed that oligohydramnios supports the diagnosis of PROM.²⁴ Cervical condition at the time of admission; 51.5%

Table 3: Maternal Clinical and Obstetric Characteristics.

Sl. No.	Characteristics	Frequency	Percentage
1.	Gestational Age		
	Extremely Preterm	25	25.3
	Late Preterm	44	44.4
	Very Preterm	30	30.3
2.	Antenatal Care		
	Regular	67	67.7
	Irregular	32	32.3
3.	Parity		
	Multigravida	37	37.4
	Primigravida	62	62.6
4.	Amniotic fluid Index		
	Adequate	78	78.8
	oligohydramnios	21	21.2
	polyhydramnios	0	0.0
5.	Cervical Dilation		
	< 2 cm	51	51.5
	> 2 cm	48	48.5
6.	Cervical Effacement		
	Fully Effaced	26	26.3
	Minimally Effaced	73	73.7
7.	Latency Period	12.6±12.6 hr (range: 2-72)	
	<12 hr	59	59.6
	>12 hr	29	29.3
	>24 hr	11	11.1
8.	Induction of labor		
	Yes	45	45.5
	No	54	54.5
9.	Presentation at time of delivery		
	Breech	10	10.1
	Cephalic	88	88.9
	Transverse	1	1
10.	Amniotic Fluid Color		
	Clear	78	78.8
	Meconium	21	21.2
11.	Mode of Delivery		
	LSCS	42	42.4
	Vaginal	57	57.6
13.	Cesarean		
	Emergency	35	35.4
	Planned	7	7.1
14.	Corticosteroids Administration		
	Yes	17	17.2

Sl. No.	Characteristics	Frequency	Percentage
	No	82	82.8

Table 4: Association of Gestation age with Maternal Obstetric Characteristics.

Variables	Value	d_f	Asymptotic significance (2-sided)
Gestational age and Amniotic fluid index	2.034	2	0.362
Gestational age and Parity	5.832	2	0.054
Gestational age and Cervical Dilation	6.078	2	0.048*
Gestational age and Cervical Effacement	1.641	2	0.440
Gestational age and Induction of Labor	10.483	2	0.005*
Gestational age and Fetal Presentation	9.236	4	0.045*
Gestational age and Mode of Delivery	1.269	2	0.530
Gestational age and Cesarean	5.824	4	0.213
Gestational age and Amniotic Fluid color	1.608	2	0.447
Gestational age and Corticosteroids administration	6.197	2	0.045*

* Significant $p < 0.05$

had less 2 cm of cervical dilatation and 48.5% had more than 2 cm. 73.7% resulted in minimally effaced Cervix, in contrast to Akter *et al.*, findings.¹⁴ Presentation at the time of delivery; Cephalic presentation was found in majority of PPRM cases constituting of 88.9% compared to breech and transverse, our study lines up with the results of Natnal *et al*'s study, i.e, 92.1% had cephalic presentation followed by breech and others.²⁵ Our research revealed that 68.2% patients had normal vaginal delivery, while 31.7% underwent LSCS in contrast with study conducted by Vloran *et al.*²⁶ whereas the rate of vaginal delivery in PROM was high in the study conducted by Diraviyam *et al.*¹²

The association between gestational age and various obstetric characteristics in women with PPRM was analyzed using Pearson's Chi-Square test. Johnson *et al.*, found a significant association between cervical dilation and earlier gestational age at rupture of membranes, consistent with our findings.²⁷ This suggests that advanced cervical dilation may predispose women to earlier rupture of membranes in preterm pregnancies. Similarly, our study identified induction of labor as a significant predictor of gestational age in women with PPRM, which aligns with findings from a study by Brown *et al.*, reported that induced labor was associated with earlier rupture of membranes in preterm pregnancies.²⁸ The significant association between fetal presentation and gestational age in our study corroborates findings from a prospective cohort study by Smith *et al.*, demonstrated that certain fetal presentations, such as breech or transverse lie, were associated with earlier rupture of membranes in preterm pregnancies, highlighting the importance of fetal position in the timing of PPRM.²⁹

However, our study did not find a significant association between factors such as amniotic fluid index, parity, cervical effacement, mode of delivery and amniotic fluid color with gestational age in women with PPRM, which contrasts with a study conducted by Jones *et al.*, reported a significant association between amniotic fluid color and gestational age at rupture of membranes in PPRM cases.³⁰

CONCLUSION

In conclusion, our study found out that socioeconomic status and Anemia were found to be statistically significant with preterm premature rupture of membranes. Most PPRM cases occurred in late preterm gestational age (32 to <37 weeks). Factors such as cervical dilation, induction of labor, fetal presentation and corticosteroid administration were significantly associated with gestational age. However, no significant association was found between gestational age and factors such as amniotic fluid index, parity, cervical effacement, mode of delivery and amniotic fluid color. The study is a prospective observational single centered with a modest sample size constraining our findings. These findings underscore the multifactorial nature of PPRM and highlight the importance of tailored management strategies based on individual patient profiles.

ACKNOWLEDGEMENT

We would like to express sincere thanks to the Management and Principal, KLE College of Pharmacy, Hubballi, Karnataka for providing necessary facilities to carry out research. We owe our hearty thanks to Dr. Udayashree, KLE Co-operate hospital, Hubballi.

ETHICAL CONSIDERATION

Ethical clearance for this study was obtained from the Institutional Ethical Committee KLE College of Pharmacy, Hubballi to carry out this research project. IEC Number: KLECOPH/IEC/2023-24/13.

ABBREVIATIONS

PROM: Premature Rupture of Membranes; **PPROM:** Preterm premature rupture of membranes; **BMI:** Body Mass Index; **NICU:** Neonatal Intensive Care Unit; **PV:** Per Vagina; **PA:** Per Abdomen; **LSCS:** Lower Segment Cesarean Segment; **URTI:** Upper Respiratory Tract Infect; **UTI:** Urinary Tract Infection; **MSAF:** Meconium-Stained Amniotic Fluid; **ANC:** Antenatal Care.

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Cite this article: Sridhar T, Shukla S, Hiremath N, Varghese LE, Nyamagoud SB, *et al.* Clinical Implications of Premature Rupture of Membranes in Gestational Women in a Tertiary Care Hospital: A Prospective Observational Study. *J Young Pharm*. 2025;17(1):194-200.