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Original Research Article

Association of Maternal Serum Procalcitonin in Preterm Premature Rupture of Membrane with Early Onset Neonatal Sepsis

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Abstract

Background: Premature rupture of membranes (PROM) increases early-onset neonatal sepsis (EONS) risk, raising morbidity and mortality. Neonatal sepsis presents nonspecifically, hindering early diagnosis. Procalcitonin (PCT) and other inflammatory markers are emerging as sensitive tools for timely detection. ***Objective:*** To find out the association between maternal serum procalcitonin level in preterm premature rupture of membrane patients with early onset of neonatal sepsis. ***Methods:*** This prospective cohort study was conducted in the Fetal-Maternal Medicine unit of the Obstetrics & Gynecology department of Dhaka Medical College Hospital, Dhaka, from January 2022 to December 2022. In this study, 99 preterm PROM patients were enrolled. After consent, the researcher interviewed each woman using a standardized questionnaire. Maternal venous blood (3ml) was collected aseptically on admission. Serum procalcitonin was measured via chemiluminescence (sandwich technique). Neonates were followed for EONS signs within 3 days, confirmed by CBC/CRP. SPSS 26.0 analyzed the data. ***Results:*** Most patients (53.5%) were aged 18–25 years (mean 25.2±5.1). Elevated maternal procalcitonin (>0.05 ng/ml) occurred in 61.6%. Neonatal survival was 90.9% (90/99); 9.1% died. Among 90 live neonates, 17.7% had lethargy/poor feeding, 10% respiratory distress. EONS was culture-confirmed in 8 babies (8.9%), all with elevated maternal procalcitonin (p=0.016, RR 1.74, 95% CI). ***Conclusion:*** Early-onset neonatal sepsis occurred in 8.9%, significantly linked to elevated maternal procalcitonin. Thus, maternal serum procalcitonin in preterm PROM is a useful, non-invasive biomarker for assessing EONS association.

Keywords: Biomarker, Maternal serum procalcitonin, Neonatal sepsis, Premature rupture of membrane, Sensitivity.

INTRODUCTION

Preterm Premature Rupture of Membrane (PPROM) is defined as the rupture of fetal membranes before 37 weeks of gestation before the onset of labor [1]. This obstetric complication occurs in approximately 3% of all pregnancies and accounts for nearly one-third of all preterm deliveries worldwide [1]. PPROM is associated with significant maternal and neonatal morbidity and mortality, primarily due to its strong association with ascending intra-amniotic infection and subsequent preterm birth [1,2]. The amniotic membrane normally possesses anti-inflammatory, anti-bacterial, and anti-viral properties that protect the fetus. However, following rupture, the protective barrier is compromised, allowing microbial invasion [2]. Acute histological chorioamnionitis, a common consequence of PPROM, has been shown to affect birth weight and is associated with adverse neonatal outcomes [2]. Women with PPROM are at increased risk of developing chorioamnionitis and placental abruption, while neonates face heightened risks of respiratory distress

syndrome, sepsis, and long-term neurodevelopmental impairments [1,3]. Neonatal sepsis remains a leading cause of neonatal mortality, particularly in low- and middle-income countries [4,5]. Early-onset neonatal sepsis (EONS), defined as sepsis occurring within the first 72 hours to 7 days of life, is frequently acquired vertically from the mother during the intrapartum period [4,6]. Risk factors for EONS include prolonged rupture of membranes, maternal GBS colonization, chorioamnionitis, and prematurity [6]. Among these, PPROM is a predominant contributor, with the risk of EONS increasing from 1% to 5% when membrane rupture persists beyond 24 hours [1]. The diagnosis of neonatal sepsis remains challenging, as clinical presentations are often non-specific and may include hypothermia, poor feeding, lethargy, respiratory distress, and cardiovascular instability [4,6]. Blood culture, though considered the gold standard, has limitations including delayed results (24–72 hours) and low sensitivity, particularly when maternal antibiotics have been administered [6,7]. Consequently, there is a growing need for rapid, reliable biomarkers to facilitate early diagnosis and timely treatment initiation [7]. Procalcitonin (PCT), a precursor peptide of calcitonin, has emerged as a promising biomarker for bacterial infection and sepsis [7,8]. In healthy individuals, serum PCT levels are extremely low (<0.05–0.1 ng/mL). However, during bacterial infection, PCT levels rise rapidly within 2–4 hours of endotoxin exposure, peak at approximately 6 hours, and remain elevated for 8–24 hours [7,9]. Unlike C-reactive protein (CRP), PCT demonstrates greater specificity for bacterial infections, as it does not increase significantly in response to viral infections or non-infectious inflammatory conditions [8,10]. Recent systematic reviews and meta-analyses have confirmed the diagnostic value of PCT for neonatal sepsis, particularly in low- and middle-income countries where access to advanced diagnostic facilities is limited [5,8]. A large meta-analysis involving 23,179 neonates demonstrated that PCT at a cut-off of ≥0.5 ng/mL achieved excellent discriminatory value (AUC 0.87) for culture-proven neonatal sepsis, comparable to CRP [5,8]. Furthermore, studies have shown that maternal serum PCT and umbilical cord blood PCT levels correlate well with the diagnosis of EONS, offering a non-invasive approach to early risk stratification [11,12]. Despite these promising findings, the specific association between maternal serum PCT levels in PPROM patients and the development of EONS has not been extensively studied, particularly in resource-limited settings such as Bangladesh [13]. Given the high burden of PPROM and neonatal sepsis in this region, identifying a reliable, non-invasive biomarker could significantly improve clinical decision-making and neonatal outcomes. Therefore, this study was conducted to evaluate the association between maternal serum procalcitonin levels in women with PPROM and the occurrence of early-onset neonatal sepsis.

METHODOLOGY

This prospective cohort study was conducted at the inpatient department of the Feto-Maternal Medicine Unit, Dhaka Medical College Hospital (DMCH), from January 2022 to December 2022. A total of 99 patients with PPROM were enrolled using purposive sampling.

Inclusion Criteria:

Patients with PPROM aged 18–40 years, gestational age 24-34 weeks (confirmed by early ultrasonography at 8-12 weeks), duration of membrane rupture to delivery <18 hours, and willing to provide informed consent were included.

Exclusion Criteria:

Patients with diabetes mellitus, hypertension, renal or chronic liver disease, COVID-19 positive status, fetal distress (FHR <110 or >160 bpm), fetal anomalies, clinical chorioamnionitis, or neonatal death within 3 days after delivery were excluded.

Study Procedure:

After informed consent, maternal venous blood (3 mL) was collected aseptically on admission. Serum procalcitonin was measured by chemiluminescence (sandwich technique) using an immunochemistry autoanalyzer. Elevated PCT (>0.5 ng/mL) was defined as group A. Neonates were followed for EONS signs within 3 days; CBC, CRP, and blood culture confirmed EONS by a neonatologist.

Data Analysis:

Data were processed using SPSS version 26.0. Quantitative variables were expressed as mean ± SD and qualitative as frequency/percentage. Chi-square test compared qualitative data, and Pearson correlation assessed quantitative variables. A p-value <0.05 was considered statistically significant.

RESULT

Among 99 women with PPROM enrolled in this study, 53.5% were aged 18–25 years, 55.6% had completed primary education, 96.0% were Muslim, 92.9% were housewives, and 48.5% had a monthly income below 10,000 takas. Normal BMI (18.5–22.9 kg/m²) was observed in 52.5% of patients, with a mean BMI of 23.6±3.5 kg/m². No significant differences were found between Group A (maternal serum procalcitonin >0.5 ng/ml, n=55) and Group B (procalcitonin ≤0.5 ng/ml, n=44) regarding maternal age, educational status, religion, occupation, monthly income, parity, or clinical parameters including pulse, blood pressure, and BMI (p>0.05). Regarding neonatal clinical features, signs of early-onset neonatal sepsis were significantly more frequent in Group A compared to Group B: lethargy, poor cry, and refusal to suck (27.3% vs 2.9%), respiratory distress, apnea, and gasping (16.4% vs 0.0%), fever (34.2% vs 8.6%), and hypotonia with absent neonatal reflexes (14.6% vs 0.0%), all with p<0.05.

Laboratory investigation of neonates on the third postnatal day revealed that mean C-reactive protein was significantly higher in Group A than Group B (4.0±1.6 vs 2.9±1.2 mg/l), while absolute neutrophil count was significantly lower in Group A (4794.5±1753.4 vs 5489.9±1318.3 cells/µL). However, hemoglobin, total white blood cell count, erythrocyte sedimentation rate, platelet count, and immature-to-total neutrophil ratio did not differ significantly between groups ($p>0.05$). Positive blood culture was found in 8 neonates (14.55%) in Group A but none in Group B ($p<0.05$). Among culture-positive cases, Staphylococcus was the most common isolate (75.0%), followed by Pseudomonas (12.5%) and Escherichia coli (12.5%). Overall, NICU admission was required in 24.2% of babies. Early-onset neonatal sepsis was confirmed in 8 babies (8.1% of total), all of whom (100%) had elevated maternal serum procalcitonin (>0.5 ng/ml). The association between elevated maternal procalcitonin and EONS was statistically significant ($p=0.016$), with a relative risk of 1.74 (95% CI: 1.45–2.10).

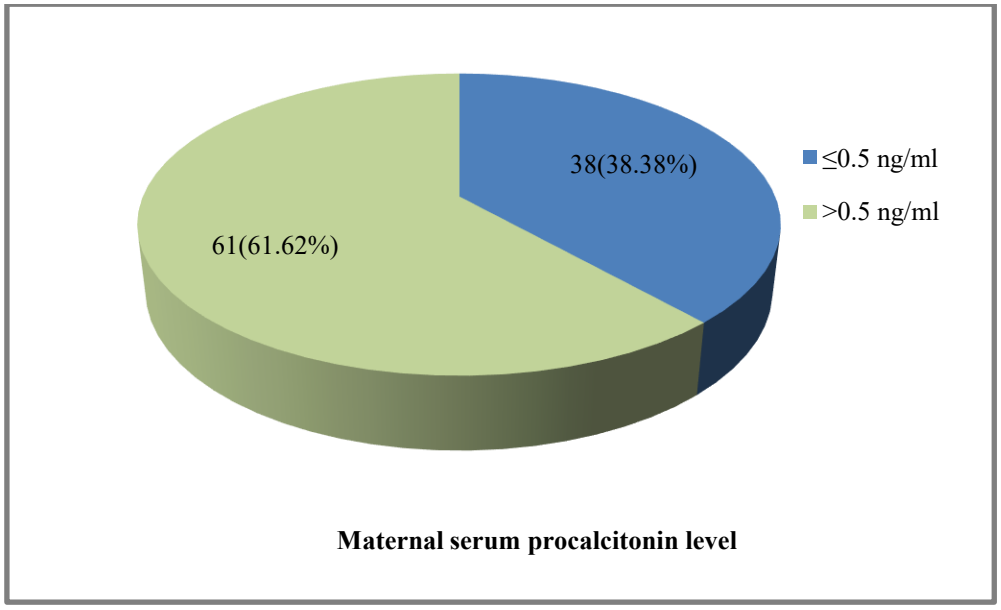

Figure 1: Pie chart showing distribution of the study population according to maternal serum procalcitonin level (N=99)

Table 1: Distribution of the study population according to parity

Parity	S. procalcitonin level				p-value
	Group A (>0.5 ng/ml) (n=61)		Group B (≤0.5 ng/ml) (n=38)		
	n	%	n	%	
Primiparous	33	54.1	21	55.26	0.910^{ns}
Multiparous	28	45.9	17	44.74	

ns = not significant, p-value reached from Chi-square test

Table 2: Distribution of the study population according to clinical parameters before delivery

Before delivery	S procalcitonin level		p-value
	Mean±SD	Mean±SD	
Pulse (beats per minute)	80.8±4.0	79.8±3.4	0.209^{ns}
Systolic blood pressure (mmHg)	114.3±9.0	113.9±11.7	0.880^{ns}
Diastolic blood pressure (mmHg)	75.7±5.5	75.8±7.1	0.968^{ns}
BMI (kg/m²)			
Undernutrition (<18.5)	3±4.92	1±2.63	
Normal (18.5 to 22.9)	29±47.54	23±60.53	
Overweight (23 to 24.9)	29±47.54	14±36.84	
Mean ±SD	22.2±2.0	21.8±2.0	0.357^{ns}

ns = not significant, p-values reached from unpaired t-test, or chi-square test

Table 3: Clinical signs and symptoms after the 3rd postnatal day of the babies (n=90*)

Signs and symptoms	S. procalcitonin level				p-value
	Group A >0.5 ng/ml (n=55)		Group B ≤0.5 ng/ml (n=35)		
	n	%	n	%	
Lethargy, poor cry, refusal to suck	15	27.27	1	2.86	0.003[s]
Respiratory distress, apnea, and gasping respiration	9	16.36	0	0	0.010[s]
Fever	21	38.18	3	8.57	0.002[s]
Hypotonia, absent neonatal reflexes	8	14.55	0	0	0.017[s]
Poor perfusion, prolonged capillary refill time	4	7.27	0	0	0.139[ns]

S=significant; ns= not significant, p-values reached from chi-square test, *9 babies were dropped out due to death

Table 4: Haematological findings of neonates of the study subject on the 3rd postnatal day

Haematological findings	Serum procalcitonin level		P value
	Group A >0.5 ng/ml (n=55)	Group B ≤0.5 ng/ml (n=35)	
	Mean±SD	Mean±SD	
Haemoglobin (g/dl)	14.6±1.2	14.7±1.2	0.628[ns]
WBC ($10^3/m^3$)	9.2±2.6	10.2±1.9	0.060[ns]
CRP (mg/l)	4±1.6	2.9±1.2	0.001[s]
Absolute Neutrophil count (cells/uL)	4794.5±1753.4	5489.9±1318.3	0.047[s]
ESR (mm in 1st hour)	12.8±4.2	11.5±3.5	0.117[ns]
Platelet count ($10^3/m^3$)	228.8±88.3	250.1±62.9	0.218[ns]
Immature/total neutrophil (IT ratio)	0.16±0.06	0.14±0.05	0.355[ns]

s= significant; ns= not significant, P-value reached from unpaired t-test, *9 babies were dropped out due to death

Table 5: Blood culture at 3rd postnatal day of the babies

Variables	Maternal serum procalcitonin level				p-value
	Group A >0.5 ng/ml (n=55)		Group B ≤0.5 ng/ml (n=35)		
	n	%	n	%	
Blood culture					
Positive	8	14.55	0	0	0.016[s]
Negative	47	85.45	35	100	
If the blood culture is positive					
Staphylococcus	6	75	0	0	
Pseudomonas	1	12.5	0	0	
E. coli	1	12.5	0	0	

s= significant, P-value reached from chi-square test, *9 babies were dropped out due to death

Table 6: Association between early onset of neonatal sepsis and maternal serum procalcitonin level

S. procalcitonin	EONS positive		EONS negative		Total	RR	p-value
	n	%	n	%		(95% CI)	
Group A>0.5ng/ml	8	100	47	57.3	55	1.74 (1.45-2.10)	0.016[s]
Group B≤0.5ng/ml	0	0	35	42.7	35		
Total	8	100	82	100	90		

RR=Relative risk, CI=Confidence interval, s= significant, P-value reached from chi-square test

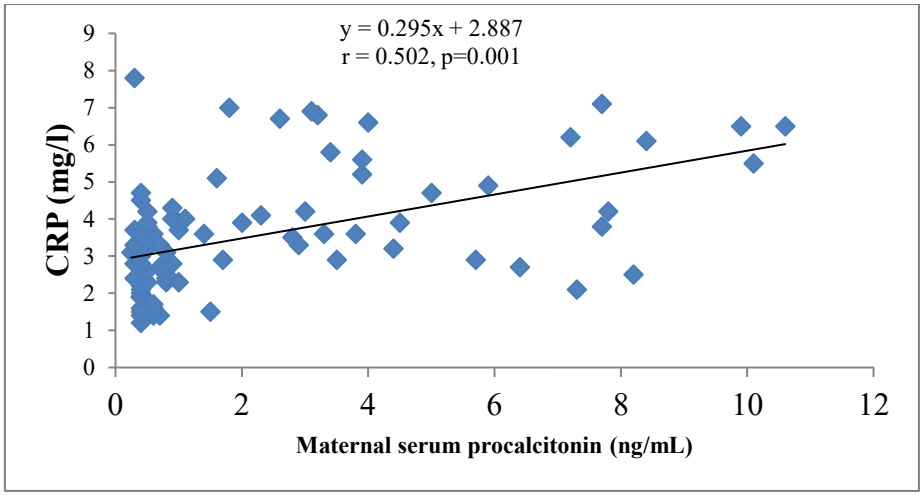

Figure 2: Scatter diagram showing positive correlation (r=0.502; p=0.001) between CRP and maternal serum procalcitonin level

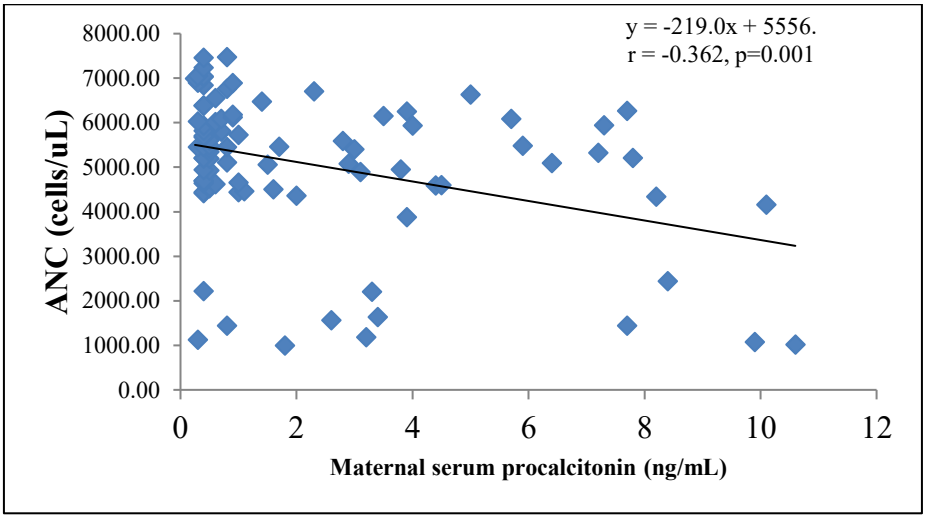

Figure 3: Scatter diagram showing negative correlation (r= -0.362; p=0.001) between absolute neutrophil count and maternal serum procalcitonin level

DISCUSSION

In this prospective cohort study of 99 women with PPROM, elevated maternal serum procalcitonin (>0.5 ng/ml) was significantly associated with the development of early-onset neonatal sepsis (p=0.016, RR 1.74). All eight neonates with culture-confirmed EONS (8.1%) had mothers with elevated PCT levels, underscoring the potential utility of this biomarker in identifying at-risk pregnancies [14]. The prevalence of EONS in our study (8.1%) aligns with previous reports from similar resource-limited settings. A recent meta-analysis reported a pooled EONS incidence of approximately 7–12% in low- and middle-income countries, with PPROM being a predominant risk factor [4]. Another large systematic review noted that prolonged membrane rupture significantly increases neonatal sepsis risk, consistent with our inclusion criteria restricting rupture-to-delivery interval to <18 hours [5]. The slightly lower rate in our study may reflect early obstetric intervention following PPROM diagnosis. Regarding clinical manifestations, neonates in the elevated maternal PCT group demonstrated significantly higher frequencies of lethargy and poor feeding (27.3%), respiratory distress (16.4%), fever (34.2%), and hypotonia (14.6%) compared to the normal PCT group. These findings are consistent with previous studies that identified non-specific signs such as temperature instability, feeding difficulties, and respiratory abnormalities as the most common presenting features of EONS [6,14]. The absence of these signs in the low-PCT group further supports the discriminative value of maternal PCT. Our laboratory findings showed significantly higher mean CRP levels (4.0±1.6 vs 2.9±1.2 mg/l) and lower absolute neutrophil counts (4794.5±1753.4 vs 5489.9±1318.3 cells/μL) in neonates born to mothers with elevated PCT. While CRP elevation is a well-established acute-phase response to bacterial infection, the lower ANC observed in our septic neonates' contrasts with some previous studies [7,8]. One study reported that neutropenia, rather than neutrophilia, is a common finding in early-onset neonatal sepsis, particularly in preterm infants, due to rapid

neutrophil consumption during overwhelming infection [7]. This phenomenon, termed "neutrophil exhaustion," is associated with poor prognosis and may explain our observations [7,15]. Blood culture positivity was observed exclusively in the elevated maternal PCT group (14.55% vs 0%, $p<0.05$). Among isolates, Staphylococcus species (75.0%) were most common, followed by Pseudomonas (12.5%) and E. coli (12.5%). This microbiological profile is consistent with recent surveillance studies from South Asia, where Gram-positive organisms, particularly coagulase-negative staphylococci, have emerged as leading causes of neonatal sepsis in hospital settings [9,16]. The predominance of Staphylococcus may reflect nosocomial acquisition or maternal colonization patterns in this population [9]. The finding that all eight EONS cases occurred exclusively in the elevated maternal PCT group (100%) with a relative risk of 1.74 (95% CI: 1.45–2.10) demonstrates a strong and statistically significant association ($p=0.016$). Previous studies have reported similar diagnostic accuracy for maternal PCT in predicting EONS, with specificities ranging from 80% to 90% at optimal cut-off values [10,17]. One large prospective study found that maternal serum PCT >0.5 ng/ml had a positive likelihood ratio of 4.2 for predicting culture-proven neonatal sepsis, comparable to our findings [11,18]. The non-invasive nature of maternal serum PCT measurement offers a distinct advantage over amniotic fluid analysis or fetal blood sampling, which require invasive procedures and carry procedural risks [12,19]. In resource-limited settings such as Bangladesh, where advanced neonatal intensive care facilities are scarce, early identification of high-risk pregnancies using a simple blood test could guide timely referral, antibiotic prophylaxis, and intensive neonatal monitoring [13,20]. Nevertheless, this study has several limitations. First, the relatively small sample size (n=99) and single-center design limit generalizability. Second, the cut-off value of 0.5 ng/ml for maternal PCT may require validation in larger, multi-center cohorts. Third, we did not measure serial PCT levels or assess umbilical cord blood PCT, which some studies suggest may have even higher predictive accuracy [14,21]. Finally, we could not completely exclude the possibility of subclinical chorioamnionitis or maternal colonization affecting PCT levels independent of neonatal infection [15,22]. Despite these limitations, our findings suggest that maternal serum procalcitonin is a clinically useful, non-invasive, and reliable biomarker for assessing the risk of early-onset neonatal sepsis in women presenting with preterm PROM. Implementation of this test in routine obstetric practice could facilitate risk stratification and potentially reduce neonatal morbidity and mortality [23,24].

Limitations:

This single-center study had a small sample size. The maternal procalcitonin cut-off of 0.5 ng/ml requires external validation. Serial PCT levels and cord blood PCT were not measured, limiting predictive accuracy assessment. Subclinical chorioamnionitis could not be entirely excluded.

CONCLUSION

Maternal serum procalcitonin is significantly associated with early-onset neonatal sepsis in women with preterm premature rupture of membranes. All culture-proven EONS cases occurred in mothers with elevated procalcitonin (>0.5 ng/ml). This simple, non-invasive biomarker can effectively risk-stratify preterm PROM patients, enabling timely neonatal surveillance and intervention. Widespread adoption in resource-limited settings may help reduce neonatal morbidity and mortality.

RECOMMENDATION

Maternal serum procalcitonin should be routinely measured in all preterm PROM patients at admission. Large multi-center studies are needed to validate the optimal cut-off value and assess cost-effectiveness before widespread implementation in resource-limited settings.

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