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Evaluation of the Role of Procalcitonin and D-Dimer Level in the Early Detection of Sepsis

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Abstract: *Sepsis is defined as the presence (probable or documented) of infection along with a systemic inflammatory response to that infection. It is a life-threatening condition that causes millions of deaths globally each year. Early identification of patients at high risk of dying from sepsis may help initiate rapid and appropriate therapeutic interventions, significantly impacting sepsis-related morbidity and mortality. However, accurately assessing patients at risk for poor clinical outcomes poses a challenge for clinicians. Objective: This study aims to evaluate the validity of Procalcitonin (PCT) and D-dimer in patients with sepsis. Methodology: This cross-sectional observational study was conducted in the Department of Anaesthesiology & ICU at Bangladesh Medical College Hospital, Dhaka, for six months following protocol acceptance. All data from the study were documented in a pre-formatted data collection sheet. The levels of Procalcitonin, D-dimer, lactate, and C-reactive protein were measured and compared in relation to the presence of sepsis. Subsequently, we calculated Sensitivity (%), Specificity (%), Positive Predictive Value (%), Negative Predictive Value (%), accuracy (%), and the correlation between sepsis and biochemical parameters for early diagnosis. The analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 22.0, where necessary. For all statistical tests, a p-value of <0.05 was considered statistically significant. Result: The biochemical parameters associated with sepsis were elevated in both sepsis and non-sepsis groups compared to their reference values. However, the levels of Procalcitonin (36.38± 11.61 vs 7.37±3.47 ng/mL), D-Dimer (3.46 ± 1.03 vs 2.11 ± 0.6 mg/L), CRP (329.5± 63.72 vs 329.5± 63.72 mg/L), and Lactate (5.38± 2.53 vs 3.17± 1.85 mmol/L) were markedly higher in sepsis patients than in non-sepsis patients. Procalcitonin demonstrated the best predictive value for diagnosing sepsis, with a cut-off value of 0.64 ng/mL (AUC 0.832), Sensitivity of 88.5 %, Specificity of 97.56%, Positive Predictive Value of 91.52%, Negative Predictive Value of 75.0%, and accuracy of 86.2%. Conclusion: Both Procalcitonin and D-dimer could be effective for early prediction of sepsis in the ICU, but Procalcitonin was a more reliable biomarker than the others.*

Keywords: *Antimicrobial Resistance (AMR), Antibiotic, ENT Infections, Otitis Media, Sinusitis, Tonsillitis, Bacterial Pathogens, Antibiotic Susceptibility, Drug Resistance, Public Health Threat*

1. INTRODUCTION

Sepsis, a syndrome of deregulated host response to infection leading to life-threatening organ dysfunction, is a substantial health burden worldwide [1]. According to 2020 data, 48.9 million cases and 11 million sepsis-related deaths worldwide, representing 20% of all global deaths [2]. The prevalence of deaths related to sepsis is recorded in the Low and Middle Income countries (LMIC) [3].

The prime cause of sepsis is an infection that triggers local inflammation and a spread of symptoms like fever, hypothermia, tachycardia, tachypnea, and either leukocytosis or leukopenia,

which is called the systemic inflammatory response syndrome (SIRS) [4]. Immune stimulation, late death of neutrophils, fast lymphocyte death, and tissue dying are behind the growth of sepsis. The inflammatory pathway acts on the coagulation pathway, resulting in an extra influence on the imbalanced systemic reaction [5]. Sepsis can be detected using biomarkers like CRP (C-reactive protein) and Procalcitonin (PCT), and these indicators may also help spot individuals who would benefit from immunomodulatory treatments [6]. Bacterial cultures in the lab are the gold standard method for precisely identifying bacterial infection, but this process is very slow and indicates the extent of inflammation in the body, besides may sometimes be negative in septic patients using antibiotics [7].

Alternative laboratory biomarkers included enzyme-linked immunosorbent assay (ELISA), flucitometry, polymerase chain reaction (PCR), fluorescence in situ hybridization (FISH), etc. Procalcitonin (PCT), which is a peptide precursor of calcitonin hormone, and a biomarker of bacterial infection with high diagnostic accuracy, but these are cost-effective and time-based assessments [8]. D-dimer is claimed as a potent biomarker for sepsis in several studies, as it elevates dramatically in sepsis patients due to fibrinolysis [9]. Considering D-dimer as a coagulation factor, this study aims to determine the validity of PCT and D-dimer biomarkers in the early diagnosis of sepsis.

2. METHODOLOGY

The cross-sectional observational study to compare the Procalcitonin and D-dimer levels in the early detection of Sepsis took place in the Department of Anaesthesia & Intensive Care Medicine, Bangladesh Medical College Hospital, Dhaka, over 6 months, from 1st May 2021 to 31st October 2021. With all ethical aspects, this study enrolled patients with study-specific inclusion and exclusion criteria.

2.1. Inclusion criteria

- Patients aged≥18 years, either sex.
- Patients admitted to the ICU fulfilling sepsis criteria (SIRS + Documented infection).
- The SOFA score ≥5 or APACHE II score ≥10 after admission to the ICU.
- Informed consent for inclusion in the study.

2.2. Exclusion criteria

- Patients aged <18 years.
- Patients with malignancy or haematological disorders.
- Patients on antitumor drug therapy.
- Patients with any kind of transplantation.
- Patients after a surgical treatment (less than 48h).
- Patients not fulfilling sepsis criteria.

Eligibility criteria were used for purposive sampling of patients with sepsis admitted to the ICU of BMCH. Data Analysis involved using MS Excel and SPSS v22; for quantitative data, the mean and standard deviation (SD) were used, while qualitative data were shown as frequencies and percentages. Statistical methods used were Chi-square, unpaired t-test, and ROC analysis to find the significance of the variables; p-value <0.05 was considered significant at a 95% confidence interval.

3. RESULT

Table 1. *Demographic and clinical characteristics of 87 sepsis patients*

Variable		Sepsis (n=68)	Non-sepsis(n=19)	p-value
Age		55.6±8.1	58.3±9.5	0.221
Gender	Male	35(51.5%)	11(57.9%)	0.118
	Female	33(48.5%)	8(42.1%)	0.103
MAP (mmHg)		68.5±4.6	70.8±4.7	0.631
Heart rate (beat/min)		104.6±9.8	101.8±8.7	0.251
Respiratory rate (breath/min)		24.5±2.3	21.5±1.9	0.128
Temperature (°C)		102.6±1.1	102.3±0.9	0.671
SpO2		97.4±1.2	98.5±1.3	0.217
GCS		11.7±1.4	12.4±1.6	0.538

Table 01 shows no significant differences were observed between sepsis and non-sepsis groups in age (55.6 ± 8.1 vs 58.3 ± 9.5 years; p = 0.221), MAP (68.5 ± 4.6 vs 70.8 ± 4.7 mmHg; p = 0.631), HR (104.6 ± 9.8 vs 101.8 ± 8.7 bpm; p = 0.251), RR (24.5 ± 2.3 vs 21.5 ± 1.9 breaths/min; p = 0.128), temperature (102.6 ± 1.1 vs 102.3 ± 0.9 °C; p = 0.671), SpO_2 (97.4 ± 1.2%

vs 98.5 ± 1.3%; p = 0.217), or GCS (11.7 ± 1.4 vs 12.4 ± 1.6; p = 0.538). All p-values were > 0.05.

Table 2. *Biochemical parameters, sepsis-related organ failure assessment (SOFA) score and acute physiology and chronic health evaluation (APACHE) II scores*

Parameter	Sepsis (n=68)	Non-sepsis(n=19)	p-value
Pro-calcitonin (ng/mL)	36.43± 11.61	11.37±3.47	0.007[ss]
D-Dimer(mg/L)	3.46 ± 1.03	2.11 ± 0.6	0.019[ss]
CRP (mg/L)	329.5± 36.72	223.7± 24.28	0.011[ss]
Lactate (mmol /L)	5.38± 2.53	3.17± 1.85	0.023[ss]
SOFA score	11.8± 3.64	7.5± 1.6	0.014[ss]
APACHE II score	22.4± 4.7	13.8± 3.9	0.008[ss]

According to Table 02, biochemical markers showed higher values in sepsis patients than in non-sepsis patients:Pro-calcitonin (36.43 ± 11.61 vs 11.37 ± 3.47 ng/mL; p = 0.007), D-Dimer (3.46 ± 1.03 vs 2.11 ± 0.6 mg/L. Septic patients showed a greater SOFA score (11.8 ± 3.64 vs 7.5 ± 1.6; p = 0.014) and higher APACHE II scores (22.4 ± 4.7 vs 13.8 ± 3.9; p = 0.008). All the research findings revealed that sepsis cases were statistically more severe (p < 0.05).

Table 3. *Blood culture results in the sepsis patients*

Blood culture results	Numbers (68)	Percentage (%)
Klebsiella	17	25%
E-Coli	11	16.2%
Pseudomonas	23	33.8%
Staph. aureus	8	11.8%
GBS	2	3%
others	7	10.3%

Table 03 compiles the blood culture results in sepsis patients. The positive cultures showed that Pseudomonas was the most common organism (33.8%). The other organisms were *Klebsiella* 25%, *E. coli* 16.2%, and *Staph. aureus* 11.8%, and GBS was less common (3%).

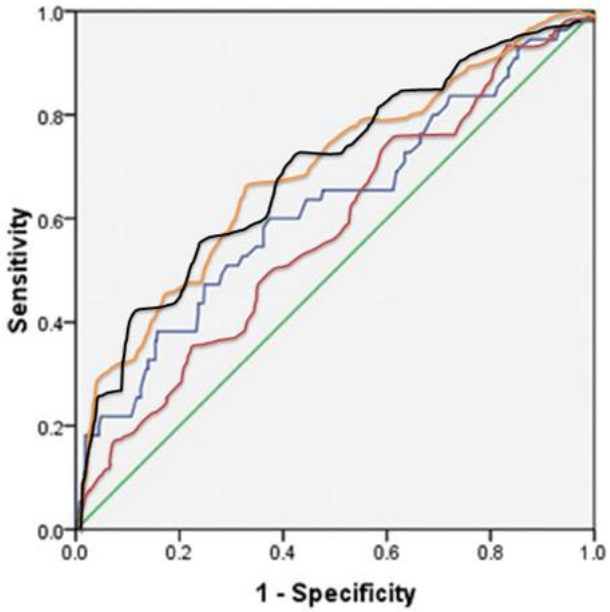

Figure 01. *ROC curve of Biochemical parameters for sepsis detection.*

Figure 01. ROC curve of Biochemical parameters for sepsis detection. (Black line – Lactate, Orange line- CRP, Blue line- D-Dimer, Red line- Pro-calcitonin, and Green line- reference values). demonstrates that the AUCs obtained by ROC analysis revealed that Pro-calcitonin and D-Dimer were the most effective in predicting sepsis. Sensitivity, specificity, and diagnostic precision were all high for both markers.

Table 4. *Receiver operating characteristic (ROC) for Biochemical parameters for prediction of sepsis.*

Parameter	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)	Accuracy (%)	AUROC (95%CI)	Cut-off Value
Procalcitonin	88.52%	97.56%	91.52%	75%	86.2%	0.832 (0.737.925)	>0.64 (ng/mL)
D-Dimer	78.94%	73.34%	84.9%	64.7%	77.01%	0.624 (0.5640.783)	>0.8 (mg/dL)
CRP	75.47%	73.52%	81.6%	65.8%	74.71%	0.472 (0.3280.582)	>236.5 (mg/L)
Lactate	70.07%	68.57%	75.55%	63.15%	71.26%	0.416 (0.3140.523)	>3.86 (mmol/L)

Table 04 figures out that the highest accuracy in diagnosing sepsis was seen with procalcitonin (AUC 0.832), at 88.5% sensitivity and 97.56% specificity with a cut-off >0.64 ng/mL. The overall performance of D-Dimer was good (AUC = 0.624), but CRP and Lactate demonstrated lower scores for detecting sepsis.

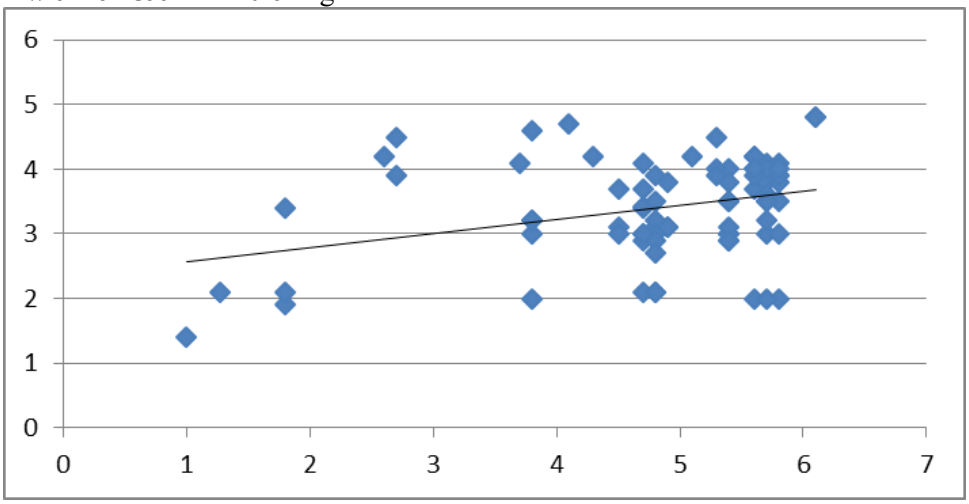

Figure 2(A). *Correlation between the measured Procalcitonin and Sepsis*

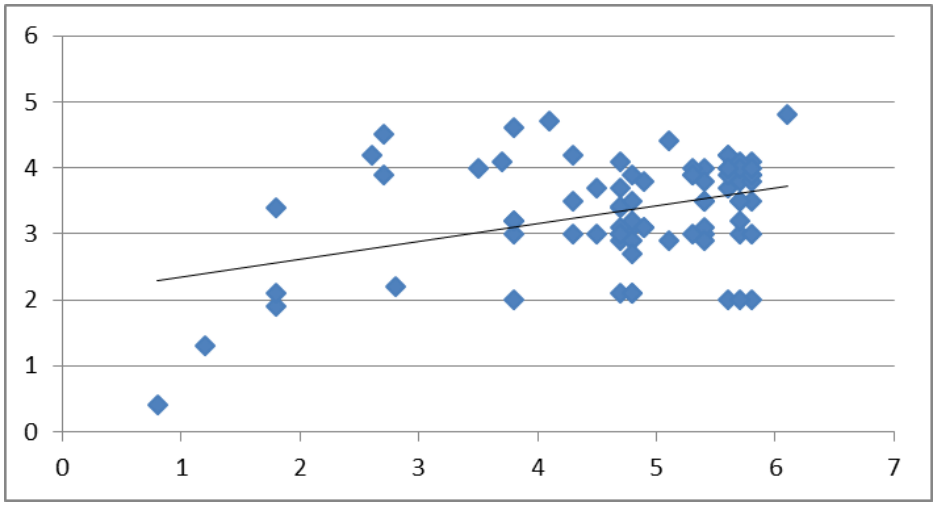

Figure 2(B). *Correlation between the measured D-Dimer and Sepsis*

Figure 2(A and B) shows the correlation between PCT and D-dimer in sepsis patients and non-sepsis patients. A significant direct (positive) correlation had been found between PCT and D-Dimer in both sepsis patients and non-sepsis patients. However, the correlation was stronger and more significant in sepsis patients (R=0.73, P<0.02) than in controls (R = 0.29, P=0.019).

4. DISCUSSION

Sepsis can be deadly because it causes organs to stop working normally when infection triggers a

harmful response and doctors use SOFA score to help with diagnosis. It is critical to detect Procalcitonin (PCT) and D-dimer early so that treatment can begin immediately. This research was designed to see how PCT and D-Dimer differed between patients diagnosed with sepsis and those without. It was shown in this study that both groups had high biochemical marker levels, but they were much higher in sepsis patients: procalcitonin (36.38 ± 11.61 vs 7.37 ± 3.47 ng/mL), D-Dimer (3.46 ± 1.03 vs 2.11 ± 0.6 mg/L), CRP (329.5

Patients with sepsis showed significantly higher scores for SOFA (11.8 ± 3.64) and APACHE II (22.4 ± 4.7) compared to patients without sepsis (7.5 ± 1.6 and 13.8 ± 3.9, respectively). A PCT level greater than 10.0 ng/mL suggests severe bacterial sepsis, while a level less than 0.5 ng/mL is not indicative of sepsis. The sensitivity and specificity of CRP and lactate markers were lower than those of other markers, measuring 75.47% and 73.52% for sensitivity, and 70.07% and 68.57% for specificity. D-Dimer showed a sensitivity of 78.94%, specificity of 73.34%, a positive predictive value of 84.9%, a negative predictive value of 64.7%, and an accuracy of 77.01% (AUC = 0.624; cut-off >0.8 mg/dL). PCT performed best, showing an 88.52% sensitivity, 97.56% specificity, 91.52% PPV, 75% NPV, and 86.2% accuracy (AUC = 0.832; cut-off >0.64 ng/mL).

In comparison, PCT exhibited a higher accuracy rate in diagnosing sepsis than in other studies. Kumar *et al.*, 2015 agreed with these findings by reporting that the specificity was modest (58%), D-dimer would detect sepsis in most cases (90% sensitivity), and had a negative predictive value of 84.4%. CRP had 80.8% sensitivity and 74.4% specificity, indicating it is a fair tool for finding sepsis [10]. While Brahmana AR *et al.*, 2019 found that D-dimer had a sensitivity value of 28%, specificity of 70%, positive predictive value of 40%, and negative predictive value of 58% [11]. According to Mustafić *et al.*, 2018 PCT was the best marker to predict sepsis (0.57 ng/mL) and bacteraemia (4.686 ng/mL), while lactate (3.25 mmol/L) and PCT (15.051 ng/mL) offered the highest predictive value for 28-day mortality along with the SOFA score (AUC 0.92), CRP (AUC 0.84), APACHE II (AUC 0.83) [12]. Another study found that D-dimer concentration >2 µg/mL was a powerful test for sepsis, with 97.8% accuracy, 100% sensitivity, and 95.6% specificity, while CRP greater than 6 mg/L indicated neonatal sepsis with 90.2% accuracy, 85% sensitivity, and 70.3% specificity [13]. Another study led by Al-Biltagi M found that a cut-off for D-dimer in neonatal sepsis is 0.75 mg/L, resulting in a sensitivity of 72.7% and specificity of 86.7%. In their analysis, D-dimer assay accuracy was similar to that of CRP [14]. A Spanish cohort study discovered that PCT at 2.54 ng/mL showed good ability to determine sepsis in adults, with AUC 0.705 (95% CI 0.653–0.758), outdoing lactate (4.1 mmol/L, AUC 0.654 [0.604–0.705]) and CRP (156 mg/L, AUC 0.579 [0.527–0.631]). PCT was sensitive 60.3% (52.3–67.7) and specific 70.5% (65.2–75.2), and the scores changed depending on the cutoff chosen (sensitivity increased with a lower cutoff; specificity with a higher cut off) [15]. In the study, sepsis patients had much higher levels of PCT (866.60±480.51 pg/mL) and 66.7% of them had elevated CRP values, compared to controls who had only 22.7% who had positive CRP (P=0.006). PCT had a better sensitivity (94%), specificity (77%), PPV (75%), NPV (85%), and AUC than CRP and white blood cell counts when measured at >250 pg/mL. Another similar study suggested the highest AUC (0.969) and best sensitivity (90%) and specificity (97.5%) for predicting septic shock were seen in a level of presepsin (PS) over 5500.6 pg/mL, compared to CRP (greater than 63 mg/L) and PCT (greater than 822.1 pg/mL) [16]. The study by Shijie L *et al.*, 2020 concluded that PCT with a cutoff of 4.13 ng/mL and D-dimer with a cutoff of 3.85 mg/L had AUCs of 0.939 and 0.832, respectively, which changed to AUC 0.947 when used together. The scores of the Youden indices were 0.741 (PCT), 0.557 (D-dimer), and 0.738 (combined), while the corresponding 95% CIs were 89.4–98.3%, 74.0–92.4%, and 90.4–98.9% [17].

5. Limitation

The best cutoffs for biomarkers in sepsis (for instance, PCT) may vary between populations and need to be higher or lower to balance how often patients are correctly identified or excluded from having the disease. Even with the use of a validated procedure for our ICU measurements, the subjective aspects show that more systematic scales will be necessary in future studies.

6. Conclusion

Procalcitonin is a better indicator of sepsis in the ICU than D-dimer. Still, using both inflammatory and anti-inflammatory markers can give better results in diagnosis. Current biomarkers are useful in discovering sepsis early, though even better ways to combine them are still being worked out. Developing precise ways to measure

biomarkers is important for targeted treatments and lowering the death rate from sepsis, over and above basic supporting treatments.

7. Abbreviation

SIRS: Systemic Inflammatory Response Syndrome

CRP: C-reactive protein

PCT: Procalcitonin

ELISA: Enzyme-Linked Immunosorbent Assay

PCR: Polymerase chain reaction,

FISH: Fluorescence in Situ Hybridization

GBS: Group B Streptococcus

Conflicts of Interest

The authors declare no conflicts of interest.

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