



ORIGINAL RESEARCH PAPER

General Medicine

STUDY OF PROCALCITONIN AND C- REACTIVE PROTEIN (CRP) IN PATIENTS WITH DIAGNOSIS OF SEPSIS

KEY WORDS:

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ABSTRACT

Background: Sepsis is a life-threatening syndrome triggered by infection, frequently resulting in organ dysfunction and high mortality. Biomarkers such as procalcitonin (PCT), and C-reactive protein (CRP) have emerged as valuable tools for early diagnosis and prognosis. This study aimed to assess the demographic, clinical and laboratory profile of patients with sepsis and to establish a correlation between serum biomarkers – PCT and CRP levels and SOFA score. **Methodology:** This was prospective observational study total 100 patients with sepsis admitted in a tertiary care centre following approval of the study from the Institutional Ethics Committee. Patients age >18 were enrolled. Demographic, clinical and laboratory features were obtained using a structured proforma and included such data as SOFA score, CRP, PCT level. Chronic inflammatory disorders and patients on immunosuppressive drugs were excluded. The SOFA score was used to determine the severity of sepsis. Data were analysed using SPSS version 28 and p-value <0.05 was considered statistically significant. **Results:** The majority of those who were studied (40%) were over 60 years of age and the subjects were 62% male. Diabetes mellitus (34%) and hypertension (30%) were the most common comorbidities; the most common source of sepsis was respiratory tract infection (44%). The most common symptom was fever (82%). A moderate SOFA score (6–10) was seen in 48 patients and severe SOFA (>10) in 22 patients. 58% of the patients had elevated levels of procalcitonin (PCT) >2.0 ng/ml and 64% had elevated levels of C-reactive protein (CRP) >100 mg/L. Sepsis was the most common diagnosis (68% of patients) and 18% of patients developed severe sepsis and 14% septic shock. There was an association between higher SOFA and increased mortality as well as significantly higher mean levels of PCT and CRP. Patients with high CRP levels and severe sepsis/septic shock had a significantly higher mortality rate (p < 0.05). **Conclusion:** CRP and PCT are highly useful markers of diagnosis and prognosis of sepsis. Positive correlation with the severity of illness and SOFA score. Higher PCT and CRP were associated with higher mortality. Based on the above findings, it can be considered that CRP and Procalcitonin may be helpful additional markers to evaluate disease severity, prognosis and hospitalisation duration of sepsis patients.

INTRODUCTION

Sepsis is a serious and potentially fatal clinical condition characterized by organ dysfunction resulting from an abnormal and dysregulated host response to infection. [1,2] Despite major improvements in healthcare and critical care management, sepsis continues to be a significant global health burden, contributing substantially to morbidity and mortality. It is estimated to affect nearly 31.5 million individuals annually and is associated with approximately 5.3 million deaths worldwide. [3] Sepsis accounts for nearly 35% of hospital-related deaths, with reported mortality rates ranging between 20% and 30%. Early recognition and prompt initiation of appropriate therapy play a crucial role in improving patient survival and clinical outcomes. [4] However, due to its complex pathophysiology and variable clinical presentation, accurate diagnosis and prognostic evaluation remain challenging. [4]

At present, no single definitive laboratory test exists for the diagnosis of sepsis, as its clinical and biochemical features are often non-specific and may resemble other inflammatory conditions. The diagnosis of sepsis and septic shock is mainly based on the Sequential Organ Failure Assessment (SOFA) score, which assesses organ dysfunction using clinical and laboratory parameters. (Singer M.) Common investigations include complete blood count, arterial blood gas analysis, coagulation profile, serum lactate, procalcitonin (PCT), and C-reactive protein (CRP), interpreted along with clinical findings. Among these, CRP and PCT are widely studied biomarkers due to their close association with the inflammatory and infectious processes of sepsis. [5]

CRP, first described in 1930, is an acute-phase reactant produced by hepatocytes in response to inflammatory cytokines such as interleukin-6 (IL-6), interleukin-1 (IL-1), and tumor necrosis factor-alpha (TNF-α). It contributes to host defense by binding to damaged cells and microorganisms, activating the complement system, and

promoting phagocytosis. Serum CRP levels rise markedly within 24–48 hours after the onset of inflammation. Although CRP is a sensitive marker of inflammation, its specificity is limited, as elevated levels may also occur in trauma, autoimmune disorders, postoperative states, and other non-infectious conditions. However, persistently elevated or increasing CRP levels may suggest ongoing infection or inadequate therapeutic response. [6] A meta-analysis of nine studies involving 1,368 patients reported moderate diagnostic accuracy of CRP for sepsis (AUC = 0.73), whereas procalcitonin demonstrated better diagnostic performance (AUC = 0.85). [7]

Procalcitonin (PCT) is a peptide precursor of calcitonin that is commonly elevated in bacterial infections. The higher specificity of PCT for bacterial sepsis is attributed to its stimulation by bacterial endotoxins and pro-inflammatory cytokines, whereas its production is usually suppressed in viral and non-infectious inflammatory conditions. Because of this, PCT has emerged as a useful biomarker for distinguishing bacterial sepsis from other causes of systemic inflammation. Serum PCT levels also correlate with disease severity and clinical outcomes, making it valuable for both diagnosis and prognostic assessment. [8,9] However, Tang et al., [10] in a meta-analysis of 18 studies involving over 2,000 patients, reported that PCT alone could not reliably differentiate sepsis from other causes.

Several studies have evaluated the clinical usefulness of CRP and PCT as biomarkers in sepsis, and most have supported their utility in early diagnosis, monitoring, and risk stratification. [11,12] Nevertheless, the comparative effectiveness of these biomarkers and the significance of their combined interpretation remain subjects of ongoing research.

Therefore, the present study was undertaken to assess the demographic, clinical, and laboratory characteristics of

patients with sepsis and to evaluate the association between SOFA score, serum PCT, and CRP levels.

METHODOLOGY

This prospective observational study conducted on the total 100 patients diagnosed with sepsis at tertiary care center after obtaining institutional ethical committee approval. The patients were enrolled as per inclusion and exclusion criteria. All individuals are above 18 years old. Patients who refused to participate, individuals < 18 years, patients with chronic inflammatory diseases including rheumatoid arthritis, systemic lupus erythematosus and vasculitis, and patients receiving immunosuppressive therapy were excluded.

Detailed demographic and clinical data such as age, gender, comorbidities, primary source of infection, laboratory parameters and SOFA score were obtained, and documented on a structured proforma after obtaining informed written consent.

A detailed clinical examination and routine laboratory investigations were performed in all patients. Venous blood samples were collected and serum CRP and PCT were measured using conventional laboratory methods.

Severe sepsis was defined by the SOFA score for respiratory, cardiovascular, hepatic, renal, neurological and coagulation disorders.

CRP levels were classified as low (<1 mg /L), moderate (1–3 mg /L) and high (>3 mg /L) risk. PCT, with a cut-off of >0.5 ng/mL as mild risk and 0.5–2 ng/mL as moderate risk, and >2 ng/mL as severe risk. The data collected was entered in the Microsoft Excel sheet and analysed by the SPSS version 28. Appropriate statistical tests were used and a p value < 0.05 was deemed to be statistically significant.

Results:

Table No.1: Demographic Distribution of the Study Population.

Variables	Category	Number (n=100)	Percent
Age Group (Years)	18–45	22	22
	46–60	38	38
	>60	40	40
Gender	Male	62	62
	Female	38	38

Table No. 1 Among 100 patients with sepsis, 40% were aged above 60 years, 38% belonged to the 46–60 years age group, and 22% were between 18–45 years. Male patients constituted 62% of the study population, while females accounted for 38%.

Table No.2: The Distribution of Comorbidities, Site of Infection, and Clinical Presentation Among Sepsis Patients.

Variables	Number (n=100)	Percent
Comorbidities		
Diabetes mellitus	34	34
Hypertension	30	30
Chronic kidney disease	12	12
Chronic obstructive pulmonary disease	8	8
None	16	16
Site of Infection		
Respiratory	44	44
Urinary tract	26	26
Skin and soft tissue	10	10
Bloodstream infections	7	7
Central nervous system	3	3
Others	10	10
Clinical Presentation		
Fever	82	82

Breathlessness	68	68
Hypotension	56	56
Altered sensorium	22	22

Table No. 2 Diabetes mellitus (34%) and hypertension (30%) were the most common comorbidities. Respiratory tract infection was the predominant source of sepsis (44%), followed by urinary tract infections (26%). Fever (82%) was the most common presenting symptom, followed by breathlessness (68%) and hypotension (56%).

Table No.3: The Distribution of SOFA Score, Procalcitonin, C-reactive Protein Levels, and Severity of Sepsis Among the Study Population.

Variables	Number (n=100)	Percent
SOFA Score		
0–5 (Mild)	30	30
6–10 (Moderate)	48	48
>10 (Severe)	22	22
Procalcitonin (ng/ml)		
<0.5	14	14
0.5–2.0	28	28
>2.0	58	58
C-reactive Protein (mg/l)		
<50	10	10
50–100	26	26
>100	64	64
Severity of Sepsis		
Sepsis	68	68
Severe sepsis	18	18
Septic shock	14	14

Table No. 3 shows Moderate SOFA score (6–10) was observed in 48% patients, while 22% had severe SOFA scores (>10). Elevated Procalcitonin levels (>2.0 ng/ml) were seen in 58% patients, and 64% had C-reactive protein levels above 100 mg/l. Most patients were diagnosed with sepsis (68%), whereas 18% had severe sepsis and 14% developed septic shock.

Table No.4: The Relationship Between SOFA Score, Mortality, Procalcitonin, and C-reactive Protein Levels.

SOFA Score	Mortality Percent	Mean Procalcitonin (ng/ml) ± SD	Mean C-reactive Protein (mg/l) ± SD
0–5	<10	0.8 ± 0.2	48 ± 10
6–10	15–20	2.4 ± 0.8	96 ± 16
>10	50–60	6.2 ± 1.1	142 ± 24

Table No. 4 demonstrates patients with higher SOFA scores showed increased mortality along with significantly elevated mean Procalcitonin and C-reactive protein levels. Patients with severe SOFA scores (>10) had the highest mortality (50–60%), mean Procalcitonin level (6.2 ± 1.1 ng/ml), and mean C-reactive protein level (142 ± 24 mg/l).

Table No.5: The Association Between SOFA Score and Patient Outcome.

SOFA Score	Survived	Died	Total	Standardized Mortality Ratio (SMR)
0–5 (Mild)	28	2	30	0.67
6–10 (Moderate)	28	20	48	1.39
>10 (Severe)	6	16	22	1.21

Table No. 5 shows mortality increased with rising SOFA scores, with the highest number of deaths observed in patients with severe SOFA scores (>10). Most patients with mild SOFA scores (0–5) survived, whereas severe SOFA scores were associated with higher standardized mortality ratios and poorer outcomes.

Table No.6: Demonstrates the Association of C-reactive Protein Levels and Severity of Sepsis with Patient Outcome.

Variables	Survived	Died	Total	Statistical Analysis
CRP (mg/l)				

<50	9	1	10	Chi-square = 8.74, DF = 2, P = 0.02
51-100	20	6	26	
>100	33	31	64	
Severity of Sepsis				
Sepsis	54	14	68	Chi-square = 25.75, DF = 2, P = 0.01
Severe Sepsis	6	12	18	
Septic Shock	2	12	14	

Table No. 6 demonstrates the association of C-reactive protein levels and severity of sepsis with patient outcome. Higher CRP levels (>100 mg/l) were associated with increased mortality compared to lower CRP levels, showing a statistically significant association ($p = 0.02$). Similarly, mortality was significantly higher in patients with severe sepsis and septic shock compared to those with sepsis alone ($p = 0.01$).

DISCUSSION

A total of 100 patients with sepsis were enrolled in the present study. The majority of patients belonged to the age group of more than 60 years, with males constituting 62% and females 38% of the study population. Similar findings were reported by Daud M, et al., where the mean age of patients was 65.4 years (range: 34–89 years), with male predominance accounting for 60% of cases. Likewise, Anggraeni et al., [14] reported a mean age of 51.53 ± 16.16 years among 40 ICU patients with sepsis, indicating that sepsis is more commonly observed in older individuals.

In the present study, moderate SOFA scores (6–10) were observed in 48% of patients, while 22% had severe SOFA scores (>10), suggesting significant organ dysfunction among septic patients. Comparable findings were noted by Daud M, et al., [5] who reported a mean SOFA score of 7.2, reflecting moderate organ dysfunction and increased severity of illness. The present study findings support previous evidence that higher SOFA scores are associated with poor clinical outcomes and increased mortality risk in patients with sepsis.

Present study noted DM (34%) followed by hypertension (30%) out of total 100 cases. Respiratory infection was predominantly associated with sepsis occurrence (44%), UTI (26%). This concordant with previous finding by other authors hypertension, diabetes mellitus most common comorbidity. [12,13]

In the present study, moderate SOFA scores (6–10) were observed in 48% of patients, while severe SOFA scores (>10) were noted in 22% of cases, indicating significant organ dysfunction among septic patients. The majority of patients also had markedly elevated inflammatory markers, with PCT levels >2.0 ng/ml in 58% of patients and CRP levels >100 mg/L in 64% of cases, suggesting a severe systemic inflammatory response.

Similar findings were reported by Anggraeni N et al., [14] who observed a mean SOFA score of 7.83 ± 4.98 along with elevated mean PCT and CRP levels in septic patients, reflecting progressive disease severity. Huang MY et al. [15] also reported that most patients had raised PCT levels, with the majority showing values between 2–10 ng/ml and above 10 ng/ml, supporting the association between elevated PCT levels and sepsis severity. Furthermore, Meisner M et al., [16] demonstrated that higher SOFA scores were associated with significantly increased PCT levels, whereas CRP levels remained elevated irrespective of disease severity. Their findings suggested that PCT may serve as a more reliable biomarker than CRP for assessing severity and progression in septic patients.

In the present study, higher SOFA scores were associated with increased mortality and elevated inflammatory markers. Patients with severe SOFA scores (>10) showed the highest mortality (50–60%) along with markedly raised mean Procalcitonin (6.2 ± 1.1 ng/ml) and C-reactive protein levels

(142 ± 24 mg/L), indicating a strong association between organ dysfunction, systemic inflammation, and poor clinical outcomes in sepsis.

Similar observations were reported by Roepke RML et al., [17] who found that procalcitonin was independently associated with increased mortality and that incorporation of PCT with SOFA score improved prognostic accuracy for predicting hospital mortality. Likewise, studies by Bhat A et al. [17] and Singh et al. [19] demonstrated that elevated PCT and CRP levels were significantly associated with severe sepsis and intensive care admission, with PCT showing earlier and stronger correlation with disease severity. Aggarwal N et al. [20] reported significantly higher PCT and CRP levels in septic patients, while elevated PCT levels were particularly associated with mortality among non-survivors. These findings support the role of PCT and CRP as important biomarkers in assessing sepsis severity and prognosis.

In the present study, higher SOFA scores were associated with increased mortality, with the highest deaths observed among patients with severe SOFA scores (>10). Elevated CRP levels (>100 mg/L) were also associated with poor clinical outcomes, indicating a significant relationship between inflammatory markers and severity of sepsis.

Similar findings were reported by Sharad Khanal et al. [21] and Shariq T et al., [22] who observed significantly higher SOFA scores among non-survivors. Koozi H et al. [23] demonstrated that CRP levels >100 mg/L were associated with increased ICU and 30-day mortality, while Kumar C et al. reported a significant correlation between CRP levels, SOFA score, and mortality. These findings support the role of CRP and PCT as useful biomarkers for assessing severity and prognosis in sepsis.

CONCLUSION

Both CRP and PCT are valuable biomarkers for diagnosing and prognosticating sepsis. A positive correlation with SOFA score and severity of illness. Our study also found that elevated PCT and CRP levels were associated with increased mortality. These findings suggest that CRP and Procalcitonin can serve as useful supportive biomarkers for assessing disease severity, predicting prognosis, and estimating hospital stay in patients with sepsis.

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