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Research Article

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Analysis between Serum Correlation of Procalcitonin and C-reactive Protein in Patients with Sepsis: An Observational Study

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ABSTRACT

Background: Physiological measures of malfunction in six organ systems (respiratory, cardiovascular, hepatic, coagulation, renal, and central nervous systems) were used to create the sequential organ failure assessment (SOFA) score. Each organ system is graded from 0 to 4 with increasing severity of dysfunction. Procalcitonin (PCT) and C-reactive protein (CRP) are recognised indicators of sepsis. Procalcitonin and C-reactive protein serum concentrations should be compared and correlated with the various degrees of organ dysfunction in the sepsis.

Methods: A total number of 75 patients admitted to ICU were selected for this study. Routine investigations like CBC, LFT, RFT, arterial blood gas analysis and Special investigations like Serum Procalcitonin and serum CRP were done in all patients. Based on the SOFA score, four groups of patients were chosen for the study, each with varying degrees of organ dysfunction in sepsis.

Results: In the study, 58.6% were males. About 60% of patients were above 50 years of age. In the study, the most common presentation in mild and severe sepsis was fever. The mean serum PCT levels were found to be significantly higher among patients with severe sepsis, i.e. 46.6±37 mg/mL, as compared to mild sepsis patients i.e.17.3±22.7 mg/mL with p-value of 0.001. The mean CRP value was found to be non-significantly lower among patients with severe sepsis.

Conclusion: The degree of infection is highly correlated with PCT and SOFA. Because PCT levels closely correlate with the severity of sepsis and its outcome, PCT has a greater capacity for diagnosis than CRP.

Key-words: Correlation of procalcitonin (PCT), Sepsis-related organ failure assessment (SOFA), C-reactive protein (CRP), Organ dysfunction, Sepsis

INTRODUCTION

In 2016, a third worldwide consensus definition of sepsis was released, which was described as "a dysregulated host response to infection resulting in life-threatening organ dysfunction."

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The sepsis-related organ failure assessment (SOFA) score and the use of "quick" SOFA for patients with suspected sepsis outside of the intensive care unit (ICU) are used by the consensus definition in place of the SIRS criteria [1,2]. PCT is a protein precursor with a molecular weight of about 13 kDa that is related to the hormone calcitonin. PCT has been induced in the plasma of patients suffering from severe bacterial, fungal, or septic diseases. PCT concentrations can exceed 1000 ng/ml in situations of septic shock and severe sepsis. PCT is not brought on by viruses, autoimmune conditions, or localised bacterial

infections [3].

Whether PCT is primarily impacted by the strength of the systemic inflammatory response or by inflammation brought on by microbial infections is still up for debate. The connection between PCT concentrations and multiorgan dysfunction independent to sepsis origin has not received much attention [4-6]. The majority of current research has focused on sepsis severity scores, such as the ACCP/SCCM criteria or values that are comparable. It is not always possible to assess whether a major infection is present in critically sick patients presenting indications of septic shock or systemic inflammation; for example, the number of positive bacterial cultures can increase as the disease develops [7,8]. Thus, in order to better understand the relationship between PCT concentrations and the degree of organ dysfunction in patients with multiple organ dysfunction syndrome (MODS) brought on by systemic inflammation, whether infectious or not, we looked at the sepsis-related organ failure assessment (SOFA) score [9]. Three criteria are included in the Quick SOFA clinical score, which is a straightforward bedside score.

- Alteration in mental status.
- Systolic blood pressure ≤100 mmHg.
- Respiratory rate ≥22 per min.

Each is given a score of 1. Score≥2 means poor outcomes. Sequential organ failure assessment (SOFA) score was constructed using physiological measures of dysfunction in six organ systems (respiratory, cardiovascular, liver, coagulation, renal and central nervous systems), each of which is graded from 0 to 4 with increasing severity of dysfunction [10]. The adoption of the SOFA score means that identifying septic patients can now be easier and faster without the requirements of laboratory investigation.[3,4] PCT is a precursor protein of the hormone calcitonin with a molecular weight of approximately 13 kDa. PCT is induced in the plasma of patients with severe bacterial or fungal infections or sepsis. [5,6] Both CRP and PCT are accepted sepsismarkers. But there is still some debate concerning the correlation between their serum concentrations and sepsis severity. Thus, analysis of serum concentrations of CRP and PCT in varied severity of organ dysfunction in sepsis as assessed by SOFA scores is being done [11].

MATERIALS AND METHODS

Research Design- Between September 2019 and August 2021, 75 patients were hospitalised to the critical care units of the Department of Medicine at S.C.B. Medical College and Hospitals in Cuttack as part of this prospective study. In this study, patients who were admitted to the intensive care unit (ICU) and had a provisional diagnosis of sepsis were included; patients who were younger than 15 years old or those who had post-operative or post-traumatic sepsis were not. All patients had both special and routine examinations, including serum procalcitonin and serum C-reactive protein (CRP), in addition to routine tests like CBC, LFT, RFT, and arterial blood gas analysis. Based on the SOFA score, patients who were chosen for the study are divided into four groups, each with varying degrees of organ dysfunction in sepsis.

SOFA score assesses organ dysfunction in critically ill patients, notably in intensive care units in Table 1. This score system includes respiratory, coagulation, hepatic, cardiovascular, CNS, and renal physiological characteristics. The degree of dysfunction in each organ system is scored from 0 to 4, with higher scores indicating more severe damage. In the respiratory component, PaO2/FIO2 is the ratio of arterial oxygen partial pressure to inspired oxygen. platelet count, liver function by bilirubin, cardiovascular condition by MAP and vasopressor needs, CNS function by Glasgow Coma Scale (GCS) score, and renal function by serum creatinine and urine output. The cumulative SOFA score aids healthcare workers in assessing organ dysfunction and making prognostication and management decisions for critically unwell patients.

Inclusion and Exclusion Criteria

Inclusion Criteria

- ✓ To qualify for participation, patients were required to be at least 15 years old and hospitalized in the intensive care unit (ICU) with a preliminary diagnosis of sepsis.
- ✓ A complete blood count (CBC), liver function tests (LFT), renal function tests (RFT), arterial blood gas (ABG) analysis, and special investigations
- ✓ In addition, serum procalcitonin and serum CRP were performed on every patient. Routine investigations were also performed when necessary.

Table 1: SOFA score

System	0	1	2	3	4
Respiration PaO_2/FIO_2 mm Hg (kPa)	≥ 400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) With respiratory support	<100 (13.3) With respiratory support
Coagulation Platelets $*10^2$/ul	≥150	<150	<100	<50	<20
Liver Bilirubin mg/dl (umol/L)	<1.2 (20)	1.2-1.9 (20-32)	2-5.9 (33-101)	6-11.9 (102-204)	>12 (204)
Cardiovascular	MAP ≥70 mmHg	MAP <70 mmHg	Dopamine <5 or Dobutamine (any dose)	Dopamine 5.1-15 or Epinephrine ≤0.1 or Norepinephrine ≤ 0.1	Dopamine .15 or Epinephrine .0.1 or Norepinephrine .0.1
CNS GCS Score	15	13-14	10-12	6-9	<6
Renai Creathinine, mg/dl (umol/L) Urine Output, ml/d	<1.2(110)	1.2-1.9 (110-170)	2-3.4 (171-299)	3.5-4.9 (300-440) <500	0.5 (440) <200

Serum PCT [by ECLIA, Cobas E411(Roche)] immune fluorescent assay (Germany) and CRP (Using SIEMENS) concentrations were estimated in all the patients. Serum PCT [by ECLIA, Cobas E411(Roche)] immune fluorescent assay (Germany) and CRP (Using SIEMENS) concentrations were estimated in all the patients.

Exclusion Criteria

- ✓ Patients under the age of 15 were not allowed to participate in the study.
- ✓ Furthermore, patients who developed sepsis because of post-operative or post-traumatic situations were excluded from the study.
- ✓ The purpose of this exclusion criterion was to ensure uniformity in the study population by specifically selecting patients with sepsis that was not caused by surgery or trauma.

Statistical Analysis- Data were entered in MS-Excel and analyzed in SPSS V25. Descriptive statistics of SOFA score, PCT concentration, CRP concentration was analyzed. These are represented with percentages, mean with SD or Median with IQR depending on the nature of the data. Shapiro-wilk test was applied to find normality. Chi-square test Fisher Exact test was applied to find significance in proportions. Independent T-test, and Mann-Whitney U test were applied to compare mean and median values between two groups (mild and severe sepsis) respectively. ROC curve was drawn. Area under the curve was calculated. Sensitivity and specificity were calculated and $p<0.05$ was considered statistically significant.

RESULTS

Table 2 shows the severity of Sequential Organ Failure Assessment (SOFA) scores for patients by age group. The age groupings are 18-30, 31-40, 41-50, 51-60, 61-70, and above 70. The table shows how many patients have "Mild" or "Severe" SOFA scores for each age group. The 18-30 age group scores 11 and the 31-40 age group scores 9, reflecting 16.9% and 13.8% of their age categories, respectively, in the "Mild" category. The "Severe" category has particular scores with percentages. The severity percentages rise with age, reaching 50% in the 61-70 age group. The overall distribution shows SOFA score variance across age groups, revealing the incidence of different organ failure levels in the examined patient population.

Table 2: Distribution of patients based on severity of SOFA score

Age (years)	SOFA Score			
	Mild		Severe	
	Number		Number	%
18-30	11	16.9	0	0
31-40	9	13.8	1	10
41-50	11	16.9	0	0

51-60	14	21.5	3	30
61-70	12	18.5	5	50
>70	8	12.3	1	10

p=0.18

Table 3 describes the severity of sepsis among male and female patients. A higher proportion of males i.e. 39 (60%), were suffering from mild sepsis. In contrast, an equal proportion of both genders were suffering from severe sepsis i.e. 05 in each group, but these results were not statistically significant.

Table 3: Severity of sepsis across both the sexes

Sex	SOFA			
	Mild		Severe	
	Number	%	Number	%
Male	39	60	5	50
Female	26	40	5	50

p=0.73

Table 4 shows the clinical presentation of sepsis patients admitted to the ICU. All the patients with mild and severe sepsis had fever. The next most common presentation of patients with mild sepsis was chills/rigor i.e. 50 (76.9%) followed by cough i.e. 29 (44.6%), expectoration i.e. 26 (40%) and myalgia i.e 24 (36.9%). Among the patients with severe sepsis, following fever, the next most common presentations were chills/rigour i.e. 09 (90%). Equal proportion of patients were having myalgia, cough, vomiting and abdominal pain i.e. 04 (40%) each. However, none of these findings were statistically significant.

Table 4: Clinical presentation of patients based on severity of sepsis

	SOFA				p-value
	Mild		Severe		
	No	%	No	%	
Fever	65	100	10	100	1
Chills/Rigor	50	76.9	9	90	0.68
Myalgia	24	36.9	4	40	1
Arthralgia	1	1.5	1	10	0.25
Bleeding	1	1.6	0	0	1
Cough	29	44.6	4	40	1
Expectoration	26	40	1	10	0.08
Cold/Rhinorrhoea	1	1.5	0	0	1
Dyspnea	20	30.8	3	30	1
Chest pain	1	1.5	0	0	1
Vomiting	19	29.2	4	40	0.48
Loose stool	12	18.5	1	10	1
Pain abdomen	17	26.2	4	40	0.45
Jaundice	8	12.3	0	0	0.59
Dysuria	7	10.8	3	30	0.12
Headache	5	7.7	2	20	0.23
Altered Sensorium	6	9.2	3	30	0.09

Table 5 describes the various clinical findings among patients suffering from mild and severe sepsis. Among the patients suffering from mild sepsis, the commonest clinical fining was pallor i.e. 13 (20%), followed by cyanosis i.e. 05 (7.7%) and icterus i.e. 04 (6.2%), while among patients with severe sepsis, the most common finding was icterus i.e. 04 (10.7%) followed by pallor with icterus i.e. 02 (6.7%).

Table 5: General physical examination of sepsis patients

GPE	SOFA			
	Mild		Severe	
	No	%	No	%
Asymptomatic	25	38.5	2	20
Pallor	13	20	0	0
Pallor and icterus	3	4.6	2	20
Pallor and dehydration	3	4.6	0	0
Pallor and pedal edema	1	1.5	0	0
Pallor and bleeding	1	1.5	0	0
Pallor and clubbing	1	1.5	0	0
Icterus	4	6.2	4	40
Icterus and pedal edema	1	1.5	0	0
Dehydration	2	3.1	1	10
Pedal edema	3	4.6	1	10
Cyanosis	5	7.7	0	0
Generalized Swelling	3	4.6	0	0

Table 6 shows the mean differences in routine blood and Arterial blood gas parameters among patients based on the degree of severity of sepsis. The patients with severe sepsis had a significantly lower total platelet count i.e. 79428.0±35609.4/ dL, than those with mild sepsis i.e. 171210.2±114077.2/ dL, with p-value 0.004. Upon ABG analysis, it was observed that patients with severe sepsis had a significantly lower blood pH value of SD 0.1 in contrast to 0.4 in mild sepsis patients. This finding was statistically significant, with p-value of 0.016.

Table 6: Routine blood investigations, coagulation profile and ABG analysis

Variable	SOFA	Minimum	Maximum	Mean	SD	Median	IQR	p-value
Hb	Mild	6.5	17.4	11.3	2.4	11.6	4.2	0.62
	Severe	7.6	13.9	10.9	2.1	11.4	3.8	
TLC	Mild	2400	46800	17175.5	7100.9	14930	6120	0.85
	Severe	12870	24570	16037	3631.9	15125	3897.5	
ESR	Mild	4	125	44.2	32	34	30.5	0.46
	Severe	9	52	31.9	13.5	31	22.5	
TPC	Mild	5554	452000	171210.8	114077.2	134820	182935	0.004
	Severe	20000	132540	79428	35609.4	90385	54497.5	
PT	Mild	11.1	59.7	16.5	6.5	15.1	5.3	0.13
	Severe	12.4	26.7	17.9	4.3	17.0	6.9	
INR	Mild	0.9	5.6	1.4	0.6	1.3	0.3	0.82
	Severe	1	1.8	1.3	0.3	1.3	0.6	
APTT	Mild	20.8	126	33.1	16.8	28.6	11.6	0.99
	Severe	18.6	77.9	35.6	18.4	31.6	25.0	
PH	Mild	4.3	7.5	7.3	0.4	7.4	0.1	0.016
	Severe	7.2	7.4	7.3	0.1	7.3	0.1	
PCO_2	Mild	16.9	52.3	33	8.4	32.7	12.1	0.63
	Severe	17.9	44.2	31.2	8.6	32.2	13	
PO_2	Mild	57	117	81.1	10.9	81.1	14	0.38
	Severe	70.4	92.7	78.5	7.8	75.9	12.4	
Lactate	Mild	0.3	6.3	1.4	1.3	0.9	1	0.24
	Severe	0.7	2.3	1.3	0.5	1.2	0.7	
HCO_2	Mild	6.4	29.4	19.3	4.9	19.3	6.3	0.39
	Severe	6.4	26.3	17.4	5.9	18.3	9	
SO_2C (%)	Mild	90.6	99.4	95.7	2.2	96	3.1	0.052
	Severe	89.7	98.6	94	2.7	94.3	4	
BUN	Mild	7.3	114.3	32.9	18.6	26	17.4	0.33

Table 7 depicts the various types of infections detected among patients admitted with mild and severe sepsis in the ICU. Pneumonia was the most common infection among patients with mild sepsis, i.e. 23 (35.4%). The second most common infection among them was UTI i.e. 10 (15.4%). The most common infection in patients with severe sepsis is UTI, i.e., 4 (40%). Equal proportion of patients with mild sepsis was suffering from pyogenic meningitis and diarrhea along with UTI i.e. 4 (6.2%) each. Each patient, those with mild sepsis was found to be suffering from malaria, viral meningitis, dengue, liver abscess, ARDS, SBP and splenic abscess while none of them with severe sepsis were found to be suffering from these infections.

Table 7: Common infections among sepsis patients

Infections	SOFA			
	Mild		Severe	
	No of patients	%	No of patients	%
UTI	10	15.4	4	40
Pneumonia	23	35.4	0	0
Pyogenic meningitis	4	6.2	2	20
Malaria	1	1.5	0	0
Diarrhea	5	7.7	1	10
Viral meningitis	1	1.5	0	0
Dengue	1	1.5	1	10
Enteric fever	2	3.1	0	0
Cellulites	3	4.6	0	0
Liver abscess	1	1.5	0	0
Scrub typhus	2	3.1	0	0
ARDS	1	1.5	1	10
Leptospirosis	2	3.1	0	0
SBP	1	1.5	0	0
Splenic abscess	1	1.5	0	0
Pneumonia with UTI	3	4.6	1	10
Diarrhea with UTI	4	6.2	0	0

Table 8 shows the proportion of patients developing MODS. Out of the 65 patients with mild sepsis, 26 i.e. 40% developed MODS in contrast to all the patients with severe sepsis, who developed the same. Table 9 shows the mean values of serum PCT among the sepsis patients admitted to ICU. The mean serum PCT levels were found to be significantly higher among patients with severe sepsis i.e. 46.6±37.6 mg/mL as compared to mild sepsis patients i.e. 17.3±22.7 mg/mL with p- value of 0.001.

Table 8: Multi Organ Dysfunction Syndrome among sepsis patients

MODS	SOFA			
	Mild		Severe	
	Number	%	Number	%
Yes	26	40	10	100
No	39	60	0	0

Table 9: Serum procalcitonin (PCT) among sepsis patients

V9p	SOFA	Minimum	Maximum	Mean	SD	Median	IQR	p-value
Ser.PCT	Mild	1.3	104	17.3	22.7	7.5	15.1	0.001
	Severe	5.9	132.6	46.6	37.6	36.3	41.3	

Fig. 1 shows the receiver operator characteristic curve and area under the curve for serum PCT levels among sepsis patients admitted to the ICU. AUC for PCT was found to be 0.82, which indicated it to be a good predictor of sepsis. After observing various cut-off levels, it was found that a cut-off of 0.2mg/mL provides the highest negative predictive value of 97.8%.

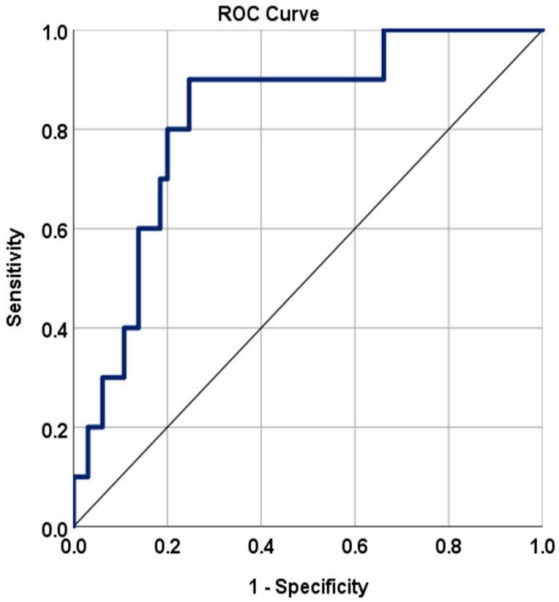

Fig. 1: Receiver operator characteristic curve and area under the curve for serum PCT levels

Table 10 describes the mean serum CRP values among varying grades of sepsis patients admitted to the ICU. The Mean CRP value was found to be lower among patients with severe sepsis i.e. 136.5±63.6 mg/L, as compared to their milder counterparts i.e. 157.8±57.2mg/L. However, this finding was not statistically significant.

Table 10: Serum C-reactive protein values among sepsis patients

Variable	SOFA	Minimum	Maximum	Mean	SD	Median	IQR	p-value
Ser. CRP	Mild	30	342.1	157.8	57.2	144.8	82.4	0.503
	Severe	40.9	222.9	136.5	63.6	137.7	111.9	

Table 11 shows the outcome of patients according to the severity of sepsis. More than half of the patients with severe sepsis i.e., 06 (60%) succumbed to death whereas only 09 out of 65 patients i.e., 13.8% with mild sepsis faced similar consequence. This finding was highly significant with p<0.001.

Table 11: Outcome of patients based on their severity of sepsis

Outcome	SOFA			
	Mild		Severe	
	Count	%	Count	%
Death	9	13.8	6	60
Survival	56	86.2	4	40
Total	65	100	10	100

p<0.001

DISCUSSION

According to the current study, severe sepsis is more likely to affect older adults. Ageing is a risk factor for sepsis, according to epidemiological literature [12]. Due to the lack of statistical significance in age-related differences in Sequential Organ Failure Assessment (SOFA) scores, greater sample sizes or research population variations are needed. This study found no gender difference in sepsis severity, contrary to some previous studies. Sepsis severity may be affected by gender-specific characteristics for further study [13]. The mean serum PCT levels were found to be significantly higher among patients with severe sepsis i.e., 46.6±37.6 mg/mL, as compared to mild sepsis patients i.e. 17.3±22.7 mg/mL, with p-value of 0.001. In contrast, the mean CRP value was found to be non-significantly lower among patients with severe sepsis i.e., 136.5±63.6 mg/mL, as compared to their milder counterparts i.e. 157.8±57.2mg/mL.

Fever, chills/rigor, and cough match sepsis symptoms in the literature. The absence of statistical significance between mild and severe sepsis groups shows that these symptoms may not accurately predict sepsis severity in this cohort. In many similar studies conducted by Chirouze *et al.* [7], Engel *et al.* [8], Bossink *et al.* [9], Hatherhill *et al.* [10], the mean serum PCT levels were significantly higher than CRP and ESR levels, thereby considering PCT to be a good predictor of bacteraemia among normal, neutropenia patients as well as pediatric patients with septic shock. However, studies by Tanriverdi *et al.* [11], and Meisner *et al.* [12] argued that there is no difference in predicting bacteraemia by using CRP and PCT.

As thrombocytopenia is linked to severe sepsis, severe sepsis patients have a lower total platelet count than mild sepsis patients [1]. Patients with severe sepsis have lower blood pH, which matches their physiological decline. In the current study, pneumonia predominated in mild sepsis cases, and urinary tract infections (UTIs) dominated severe cases. According to sepsis literature, these characteristics are consistent with varied infectious causes. The receiver operator characteristic curve and area under the curve for serum PCT levels among sepsis patients admitted to the ICU were calculated [5]. AUC for PCT was found to be 0.82, which indicated it to be a good predictor of sepsis. After observing various cut-off levels, it was found that a cut-off of 2.2mg/mL providesthe highest negative predictive value of 97.8%. These findings are similar to those of studies conducted by Sungurtekin *et al.* [13]. In another similar study conducted by Chirouze *et al.* [7]; it was observed that they have compared the diagnostic value of PCT with other inflammatory parameters like CRP and cytokine levels.

The high rate of MODS in severe sepsis patients supports the idea that organ failure is a hallmark. This emphasizes the importance of early detection and action to prevent MODS [8]. The much higher mean serum PCT levels in severe sepsis patients compared to mild sepsis patients support numerous studies highlighting PCT's potential as a biomarker for severity. ROC analysis with a high AUC supports PCT's predictive capacity. CRP readings are not statistically significant between mild and severe sepsis, contrary to some literature that suggests CRP is a less specific but generally available marker of inflammation [10]. Another study by Muller *et al.* [14]; it was found that a cut-off value of 1 mg/mL was used and PCT had better predictive values than both CRP and IL-6 for the diagnosis of sepsis in patients admitted in ICU. This value is higher than our finding. In another study by Simon *et al.* [15]; it was observed that the sensitivity of PCT [(92% [95% CI, 86%–95%] vs. 86% [95% CI, 65%–95%]) for differentiating bacterial from viral infection was higher than CRP.

The study's large correlation between sepsis severity and death supports the idea that severe sepsis is deadly. Therefore, risk classification and sepsis severity-based therapies are crucial. Hatherhill *et al.* [10] found that the area under the ROC curve was 0.96 for PCT compared with 0.83 for CRP and 0.51 for TLC at 95% CI with p value<0.001. in contrast to our findings, studies by Suprin *et al.* [16] and Ugarte *et al.* [17] found that PCT had poorer sensitivity, specificity and AUC than did CRP as a marker of sepsis. In another study conducted by Hausfater *et al.* [18], the optimal threshold for PCT was confirmed to be 0.2 μg/l and the accuracy of PCT was found to be 0.50 at 95% CI in predicting bloodstream infection. The sensitivity and specificity of PCT for detecting bloodstream infections varied from 0.62 to 0.69 and 0.65 to 0.88 in various other studies conducted on sepsis patients admitted to ICU like those by Chan *et al.* [19]; Fernandez *et al.* [20]; and Crain *et al.* [21].

CONCLUSIONS

According to the results of our investigation, PCT is a more reliable indicator than CRP for predicting the severity and prognosis of sepsis. The patients with severe organ dysfunction (SOFA groups 3 and 4) had higher mean serum PCT concentrations and SOFA scores than patients with mild organ failure. Sepsis-related deaths among patients were associated with greater mean SOFA scores and PCT concentrations than survival rates. In individuals with sepsis, there was no discernible relationship between the mean CRP concentration and the degree of organ failure or the prognosis. In contrast to CRP, which is frequently already in the upper concentration range with low SOFA scores, PCT can be triggered to very high blood concentrations during advanced stages of MODS. Because the degree of sepsis and its outcome are closely correlated with PCT levels, PCT has a greater capacity for diagnosis than CRP.

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