Section: General Surgery

Original Research Article

EVALUATION OF PROCALCITONIN AND INTERLEUKIN-6 LEVELS IN SEPSIS MANAGEMENT

S. Jagathesan[1], A. Muthuvinayagam[2], M. Senthilkumaran[3]

[1]Professor and Head, Department of General Surgery, Thanjavur Medical College, Thanjavur, Tamil Nadu, India
[2]Associate Professor, Department of General Surgery, Thanjavur Medical College, Thanjavur, Tamil Nadu, India
[3]Assistant. Professor, Department of General Surgery, Thanjavur Medical College, Thanjavur, Tamil Nadu, India

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Corresponding Author:
Dr. A. Muthuvinayagam,
Email: mrutmc@gmail.com

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ABSTRACT

Background: Sepsis ranks as a primary cause of mortality among patients in surgical intensive care units. Early diagnosis and swift administration of antibiotics are vital for enhancing patient outcomes. Procalcitonin (PCT) and Interleukin-6 (IL-6) have emerged as promising biomarkers for the early identification, monitoring, and prognosis of sepsis. This study explores the importance of procalcitonin and IL-6 as biomarkers in managing sepsis. Procalcitonin is crucial for distinguishing bacterial infections from nonbacterial ones, while IL-6 serves as a reliable predictor of mortality in sepsis cases. A prospective study was conducted with 40 surgical ICU patients showing signs of sepsis, admitted between 2023 and 2024. Clinical parameters, microbiological cultures, and biochemical markers, including PCT and IL-6, were assessed on Day 1 and Day 3. Additionally, a control group of 40 non-septic patients was evaluated. Most of the patients with sepsis were male, with an average age of 57 years. The predominant bacteria found in positive wound cultures were Klebsiella and E. coli. On the first day, septic patients exhibited significantly higher levels of PCT and IL-6 compared to the control group, but these levels decreased by the third day in patients who showed clinical improvement with medical and surgical interventions. Consistently elevated PCT and IL-6 levels were linked to unfavorable outcomes. PCT achieved 100% sensitivity and specificity in forecasting prognosis. In contrast, CRP exhibited less dynamic variation than PCT and IL-6. Piperacillin-Tazobactam was the main antibiotic administered and proved effective in most cases, as indicated by the trends in biomarkers. Procalcitonin and Interleukin-6 are dependable biomarkers for the early diagnosis, prognosis, moreover, monitoring of treatment response in surgical ICU patients exhibiting sepsis symptoms. Their application can enhance clinical decision-making and the judicious use of antibiotics, ultimately improving patient outcomes.

INTRODUCTION

Sepsis is one of the most pressing challenges in contemporary critical care medicine, defined as a life-threatening organ dysfunction resulting from a dysregulated host response to infection.[1] This clinical condition continues to place a significant burden on healthcare systems globally, leading to high rates of morbidity, mortality, and healthcare expenses. Despite advancements in medical care, sepsis remains a leading cause of death in intensive care units (ICUs), with mortality rates ranging from 10% to over 40%, depending on severity and patient demographics.[2] The primary challenge in managing sepsis lies in its diagnostic complexity. The clinical signs and symptoms of sepsis are often nonspecific and overlap with other inflammatory conditions, causing delays in recognition and treatment initiation. Traditional diagnostic methods rely on clinical assessment, vital signs, and laboratory parameters such as white blood cell count and blood cultures. However, these approaches have significant limitations, including delayed diagnosis, low sensitivity, nonspecific clinical signs, and heterogeneous presentation. These limitations highlight the urgent need for reliable, rapidly available biomarkers that can assist in early diagnosis, severity assessment, and treatment guidance.

Biomarkers can enhance clinical scores in identifying infections, assessing severity, and tracking treatment responses. Procalcitonin (PCT) and interleukin-6 (IL-

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6) are extensively researched candidates, as PCT levels increase with bacterial infections, while IL-6 indicates early inflammatory cytokine activation [3]. Procalcitonin is a peptide precursor of the hormone calcitonin, consisting of 116 amino acids. Under normal conditions, PCT is mainly produced by thyroid C-cells and is found in serum at very low levels (<0.05 ng/mL).[3] It is useful for distinguishing bacterial from viral infections, diagnosing sepsis and severe bacterial infections, guiding the initiation and duration of antibiotic therapy, and monitoring treatment response.

Interleukin-6 is a versatile cytokine with a molecular weight of about 26 kDa, playing a crucial role in inflammation, immune response, and blood cell formation.[4] IL-6 acts as a marker for detecting early inflammatory responses, assessing severity in sepsis and critical illnesses, monitoring short-term prognosis and treatment response, and identifying early complications in surgical and post-operative patients.[5] This study aims to assess the role of procalcitonin and interleukin-6 in managing sepsis by determining the sensitivity, specificity, and overall accuracy of PCT and IL-6 for diagnosing sepsis and evaluating their ability to predict clinical outcomes, including mortality and organ dysfunction.

MATERIALS AND METHODS

Study Populations: This study focuses on a prospective observational analysis of 40 adult patients with clinical signs indicative of sepsis, admitted to Thanjavur Medical College and Hospital's SICU between Jan 2023 and Jan 2024. The inclusion criteria for the study were: Age ≥ 18 years, patients of both genders, and patients with ≥ 2 of the following clinical indicators suggesting sepsis: i. Temperature > 100.4°F (38°C) or < 96.8°F (36°C) ii. Heart rate exceeding 100 beats per minute iii. Total leukocyte count > 11,000/µL or < 4,000/µL iv. Systolic blood pressure below 100 mmHg v. Respiration rate over 20 breaths per minute. Patients, who had undergone surgery or trauma in the previous 72 hours, as well as those with burns and acute pancreatitis, were excluded from this study and healthy person 40 used as a control.

Data Collection: The data collected included essential patient information such as age, demographic details, socioeconomic status, presenting complaints, and the duration of those complaints. Each patient underwent a comprehensive general physical examination followed by a focused systemic examination. Additionally, all patients were subjected to routine baseline investigations to support clinical evaluation and assist in diagnosis.

Blood Sample Collection: Blood samples were collected from patients within 24 hours of their admission to conduct basic biochemistry, complete blood count, coagulation profile, and other relevant tests for sepsis, such as CRP, IL-6, and Procalcitonin. Microbiological cultures from suspected infection sources were also performed upon admission before starting antibiotic treatment. Patients received antibiotics and underwent surgical wound debridement, and additional blood samples for IL-6 and Procalcitoninwere taken on the third day of admission.

Analysis of Blood PCT and IL-6 Levels: PCT and IL-6 levels were determined using sandwich ELISA kit (Human PCT ELISA Kit, Cat. No.: E-EL-H1492, Elabscience, Houston, TX, USA and Human IL-6 ELISA Kit, Cat. No.: E-EL-H6156, Elabscience, USA). CRP levelswere assessed using an immunoturbidimetric assay method.

Data Analysis: The data were analyzed based on patient history, clinical examination, and investigations. The data were entered into an Excel sheet and analyzed using SPSS v23. Frequency and percentage analyses were conducted, and cross-tabulation and Chi-square analyses were performed to explore the relationships and associations between various variables.

RESULTS

Demographic Level Outcome in Sepsis: Among sepsis patients aged 20 to 70 years, clinical observations noted mild fever, increased heart rates, and varying respiratory rates. Some patients exhibited decreased systolic blood pressure, indicating circulatory issues. Among the 40 sepsis patients, 33 were male and only 7 were female. Due to the small number of female participants, a detailed statistical analysis based on sex was not feasible. However, no significant differences in biomarker levels or clinical outcomes were observed between female and male patients, as shown in [Table 1].

The study divided participants into two age categories for comparison: Younger patients (under 55 years): 18 individuals and older patients (55 years and above): 17 individuals. The older group showed higher median levels of serum Procalcitonin (PCT) and Interleukin-6 (IL-6), which correlated with a higher mortality rate (5 out of 17; 29.4%) compared to the younger group (4 out of 18; 22.2%). However, the mortality difference between the age groups was not statistically significant ($p > 0.05$), as shown in [Table 2].

Biomarkers Levels and Outcome in Sepsis Patients: IL-6 levels measured on the first day of admission varied widely, reflecting different levels of systemic inflammatory response. Higher IL-6 levels were generally linked to worse outcomes, including deaths, mainly in patients aged 41 to 60 years, who also showed more physiological instability. Despite elevated inflammatory markers, most patients, particularly those aged 51 to 70, showed clinical recovery, suggesting that while age may influence outcomes, the degree of inflammation and timely medical intervention are more critical for prognosis. These findings indicate that IL-6 is a valuable marker

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for assessing sepsis severity and predicting outcomes across all ages, as shown in [Figure 1 and Table 3].

Serum Procalcitonin (PCT) levels on Day 1 and Day 3 differed significantly between the control group, deceased patients, and those who recovered. Patients who improved clinically had lower initial PCT values (average 0.83 ng/mL), which further decreased by Day 3 (average 0.37 ng/mL), indicating a positive treatment response and reduced infection burden. Conversely, those who did not survive had much higher PCT levels on Day 1 (average 2.20 ng/mL), with only a slight decrease by Day 3 (1.30 ng/mL), suggesting ongoing inflammation and a poor prognosis. The control group, consisting of uninfected individuals, had low PCT levels (around 0.02 ng/mL) on both days, as expected. These results underscore the high prognostic value of PCT in sepsis, as shown in [Figure 2 Table 3]. Significant differences were observed between the control group (n = 40) and septic patients ($p < 0.001$), confirming the diagnostic value of both biomarkers.

Correlation between Serum Procalcitonin (PCT) and Interleukin-6 (IL-6) Levels: The relationship between serum PCT and IL-6 levels was assessed on Day 1 and Day 3 in septic patients (n = 40). Both Pearson and Spearman correlations revealed a significant moderate positive association between PCT and IL-6 levels at both time points on Day 1 (Pearson and Spearman P value 0.67 (<0.001) and 0.64 (<0.001)), with slightly weaker correlations on Day 3 (P value 0.58 (0.002) and 0.55 (0.003)).

Utilizing Wilcoxon signed-rank tests, we evaluated changes in Serum PCT and IL-6 Levels within subjects. Both biomarkers exhibited a statistically significant reduction from Day 1 to Day 3, indicating a decrease in systemic inflammation following treatment showed in Table 4.

Comparison of Biomarker Levels Based on Clinical Outcome: Biomarker levels on Day 1 and Day 3 were notably higher in patients who did not survive compared to those who showed improvement (Mann-Whitney U test). Elevated levels of both biomarkers were strongly linked to mortality showed in [Table 5].

Antibiotic Treatment and Outcome: All participants in the study were administered a standardized antibiotic regimen of Piperacillin-Tazobactam. Among those diagnosed with sepsis, 25 patients (71.4%) showed clinical improvement, while 10 patients (28.6%) did not survive. Since the antimicrobial treatment was consistent for all patients, the differences in clinical outcomes seem to be more closely related to variations in inflammatory biomarker levels such as Procalcitonin and Interleukin-6, rather than differences in antibiotic management.

Clinical and Diagnostic Indicator of PCT and IL-6 in Predicting Sepsis Outcome: Receiver Operating Characteristic (ROC) curve analysis was conducted to evaluate the diagnostic accuracy of PCT and IL-6 levels (Day 1 and Day 3) in predicting mortality among septic patients. Both PCT and IL-6 showed excellent diagnostic accuracy, with IL-6 Day 1 having the highest AUC (0.941), sensitivity, and specificity for predicting mortality showed in [Figure 3 and Table 6].

Table 1: Gender wise outcome in sepsis patients

Parameters	Male (N= 33)	Female (N= 7)	Control(N= 40)
Age (years)	25 – 70	32 – 60	25 - 58
Temperature (°F)	99.0 - 100.8	98.0 - 100.0	96 - 99
Pulse Rate (bpm)	78 – 140	76 – 104	73 - 77
Systolic BP (mmHg)	80 – 140	110 – 120	90 - 120
Respiratory Rate (breaths/min)	14 – 24	12 – 16	12 - 16
Total Leukocyte Count (cells/mm³)	13,500 - 36,000	6,000 - 20,000	5500 - 8300
Urea (mg/dL)	25 – 102	30 – 63	15 - 40
Creatinine (mg/dL)	0.8 - 4.1	0.7 - 1.2	0.7- 1.3
CRP	Positive in all (sepsis)	Positive in sepsis patients	Negative
PCT Day 1 (ng/mL)	0.16 - 2.61	0.04 - 1.92	< 0.05
PCT Day 3 (ng/mL)	0.07 - 1.71	0.02 - 1.68	< 0.05
IL-6 Day 1 (pg/mL)	14.26 - 398.8	1.07 - 145.01	1.0 - 6.0
IL-6 Day 3 (pg/mL)	10.8 - 262.9	1.12 - 132.5	1.0 - 6.0
Outcome (Improved / Death)	33 / 6	6 / 1	nil

Table 2: Age group wise outcome in sepsis patients

Age (years)	No. of Patients		Temperature (°F)	Pulse Rate (bpm)	SBP (mmHg)	RR (breaths/ min)	PCT (pg/mL) Mean value	IL-6 (pg/mL) Mean value	Outcome (Improved / Death
	M	F							
20 – 30	1	0	99.6 - 99.6	100	110	16	0.16 – 2.10	59.61 - 138.8	2 / 0
31 – 40	6	2	99.0 - 100.2	78 - 124	110 - 120	12 – 16	0.19 – 1.44	1.56 - 228.4	3/ 1
41 – 50	5	3	99.2 - 100.6	102 - 116	80 - 120	16 – 18	0.20 – 1.95	24.34 - 278.5	5 / 2
51 – 60	14	2	99.8 - 100.6	102 - 120	100 - 140	14 – 20	0.23 – 0.52	14.26 - 257.7	13 / 3
61 – 70	7	0	100 - 100.8	98 - 118	100 - 120	16 – 22	0.21 - 2.35	23.07 - 288.3	6 / 1

Table 3: Biomarker levels and outcome

Outcome	No.of Patients	Mean PCT (ng/ml) Day 1	Mean PCT (ng/ml)Day 3	Mean IL-6 (pg/ml)Day 1	Mean IL-6 (pg/ml) Day 3
Improved	33	0.83 ± 0.44	0.37 ± 0.19	68.0 ± 53	42.0 ± 33.0

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Death	7	2.20 ± 0.70	1.30 ± 0.55	230.0 ± 80	180.0 ± 80.0
Control	40	0.02 ± 0.01	0.02 ± 0.01	2.4 ± 1.1	2.3 ± 1.0

Table 4: Trends in serum Biomarker levels

Biomarker	Median Day1	Median Day 3	Wilcoxon Statistics	P-Value
PCT (ng/mL)	0.65	0.22	91.5	0.0004
IL-6 (pg/mL)	28.47	19.60	88.0	0.0012

Table 5: Biomarker Levels Based on Clinical Outcome

Biomarker	Median (Improved)	Median (Death)	Mann-Whitney U Test	P-Value
PCT Day 1 (ng/mL)	0.41	2.35	18.0	<0.001
PCT Day 3 (ng/mL)	0.25	1.21	23.0	<0.001
IL-6 Day 1(pg/mL)	26.64	278.5	20.5	<0.001
IL-6 Day 3(pg/mL)	19.60	232.1	21.0	<0.001

Table 6: Biomarkers Receiver Operating Characteristic (ROC) curve analysis

Biomarker	AUC	95% CI	Sensitivity	Specificity	Cut-Off
PCT Day 1	0.912	0.821–0.998	88.9%	92.3%	>1.2 ng/mL
PCT Day 3	0.935	0.851–1.000	88.9%	96.1%	>0.9 ng/mL
IL-6 Day 1	0.941	0.863–1.000	100%	92.3%	>150 pg/mL
L-6 Day 3	0.918	0.814–0.999	100%	88.4%	>120 pg/mL

Figure 1: Mean IL6 levels and clinical Outcome

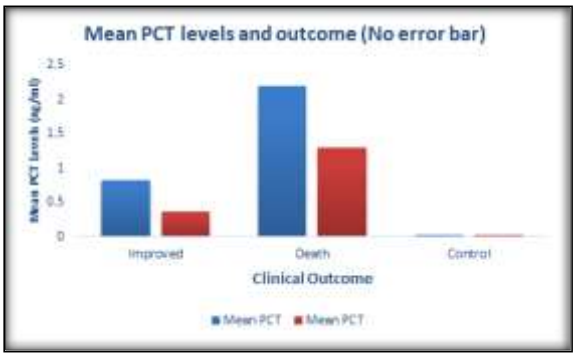

Figure 2: Mean PCT levels and clinical Outcome

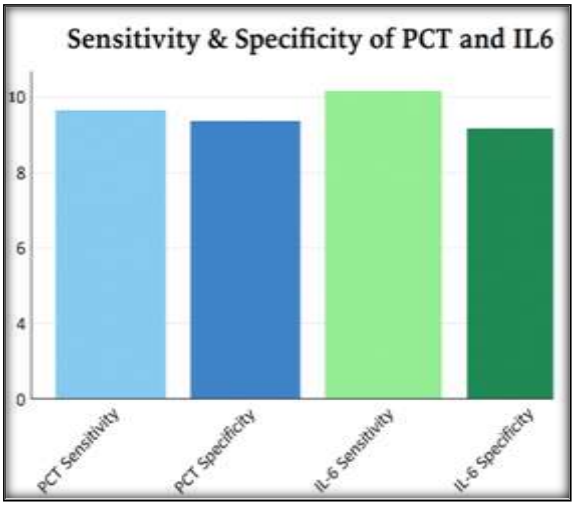

Figure 3: Sensitivity and Specificity of PCT and IL6

DISCUSSION

Over the course of a year, from January 2023 to January 2024, a study was carried out at Thanjavur Medical College and Hospital. This research involved a quantitative assessment of serum Procalcitonin (PCT) and Interleukin-6 (IL-6) levels on the first and third days in patients diagnosed with sepsis both clinically and microbiologically, compared to a control group without infection. In addition to biomarker levels, clinical parameters, culture results, antibiotic treatments, and patient outcomes were analyzed to evaluate the effectiveness of PCT and IL-6 in diagnosing, monitoring, and predicting sepsis outcomes.

All individuals in the sepsis group had positive pus cultures, confirming bacterial infection. Upon admission, serum PCT levels were significantly higher in septic patients (ranging from 0.16 to 2.61 ng/mL) compared to the control group, where levels were very low (0.01 to 0.04 ng/mL), reinforcing PCT's role as a sensitive and specific marker for bacterial infections. Similarly, IL-6 levels were markedly elevated in septic patients, reaching up to

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400 pg/mL in some instances, while control subjects maintained low baseline levels. These findings highlight IL-6's utility in the early detection of sepsis-induced systemic inflammation, given its role as an early mediator in the inflammatory process. A favorable outcome was observed in 65.5% of patients due to appropriate antibiotic use and removal of infection sources, while 12.5% of patients succumbed despite similar management, indicating the severity of sepsis, which was reflected in the elevated serum PCT and IL-6 levels in those with poor outcomes.

In patients who recovered, serial measurements showed a significant reduction in both PCT and IL-6 levels by Day 3, suggesting effective treatment and resolution of the infection. Conversely, patients who died from sepsis often had consistently high or only slightly reduced biomarker levels, indicating ongoing inflammation and a poor prognosis. This temporal trend underscores the importance of monitoring biomarker dynamics rather than relying solely on individual measurements.

The previous research concluded that a significant drop in PCT levels within 48 hours was a better predictor of survival than the initial level itself, indicating that dynamic trends in PCT are more informative than single-point measurements.[6] Earlier clinical study found that PCT had superior sensitivity (88%) and specificity (81%) in distinguishing bacterial from viral or non-infectious inflammation, establishing it as a more specific and earlier marker for bacterial infection.[7] In this study, all patients received the broad-spectrum antibiotic piperacillin-tazobactam, and the reduction in biomarker levels among survivors supports its effectiveness in treating the bacterial pathogens involved. This finding reinforces the dual role of IL-6 and PCT in detecting infection and evaluating treatment efficacy.

In the preceding clinical trial investigation, which included 621 ICU patients, the use of PCT to guide the cessation of antibiotics led to a reduction in overall antibiotic use and related complications, affirming PCT's importance in enhancing antibiotic management in sepsis care.[8] The prior longitudinal study involving 30 ICU patients with sepsis found that IL-6 levels remaining high beyond 72 hours were indicative of a poor prognosis and ineffective therapeutic response, highlighting its value in real-time disease monitoring.[9]

The prior Swiss ICU study showed that PCT levels exceeding 2ng/mL were highly suggestive of bacterial sepsis. A downward trend in PCT over 72 hours correlated with better outcomes, supporting the use of serial PCT measurements to monitor treatment response.[10] The specificity of these biomarkers for bacterial infections, as opposed to other inflammatory causes, was further validated by the stable biomarker levels in the control group. Overall, the study's findings support the clinical use of PCT and IL-6 for early sepsis detection, disease severity classification, and treatment monitoring.

CONCLUSION

This prospective observational study explored the diagnostic and prognostic value of procalcitonin (PCT) and interleukin-6 (IL-6) in sepsis patients admitted to the surgical intensive care unit. The study aimed to assess the utility of these biomarkers in routine sepsis management by comparing levels in septic and non-septic individuals and tracking changes during the first three days of admission. The results confirmed the diagnostic value of PCT and IL-6, showing significantly higher levels in septic patients on Day 1 compared to controls. Patients responding to antibiotics exhibited a notable decrease in biomarker levels, while persistently high levels were associated with poorer outcomes, including mortality. These findings suggest that serial measurements of PCT and IL-6 can be valuable tools in sepsis management. The reduction in biomarkers among survivors indicates effective antimicrobial treatment, although consistent antibiotic administration across all patients complicates comparisons of biomarker trends across different treatment regimens. Nevertheless, to enhance patient outcomes, guide treatment decisions, and improve diagnostic accuracy, the study advocates for the inclusion of PCT and IL-6 testing in sepsis protocols.

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