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Clinical Study of Role of Serum Procalcitonin in the Diagnosis, Severity Assessment, and Prognostication of Sepsis at a Tertiary Care Centre

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ABSTRACT

Background: Sepsis is a life-threatening condition caused by a dysregulated response to infection. Early diagnosis, severity assessment, and prognostication remain challenging. Serum procalcitonin (PCT) may serve as a useful biomarker for infection, disease severity, and prediction of outcomes in patients with sepsis.
Methods: A prospective, observational study was conducted in the Department of Medicine, Government Medical College and Hospital, Chhatrapati Sambhajinagar, from January to December 2025. Sepsis and septic shock were classified according to Sepsis-3 criteria. Serum PCT was measured at admission and repeated after 72 hours in patients with sepsis. Clinical characteristics, infection source, microbiological findings, SOFA score, organ-support requirements, and hospital outcome were recorded.
Results: Among 160 patients, 118 (73.75%) had sepsis and 40 (25.00%) had septic shock. Median PCT increased significantly from non-sepsis to sepsis and septic shock (0.42, 3.20, and 9.80 ng/mL; $p<0.001$). PCT showed 79.66% sensitivity, 71.43% specificity, and AUC 0.82 for sepsis. Admission PCT correlated with SOFA score ($r=0.56$). Non-survivors had higher PCT and lower clearance; 72-hour PCT clearance <50% predicted mortality (AUC=0.84).
Conclusion: Serum PCT demonstrated moderate diagnostic accuracy for sepsis and increased progressively with disease severity. Serial PCT kinetics were associated with hospital outcome, and 72-hour PCT clearance showed a numerically higher AUC for mortality than admission PCT. PCT should be interpreted as an adjunct to clinical assessment, SOFA scoring, microbiological evaluation, and serial reassessment.

Keywords: Sepsis; Septic Shock; Procalcitonin; SOFA Score; Biomarker; Mortality; Prognosis

INTRODUCTION

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. [1] The Third International Consensus Definitions for Sepsis and Septic Shock operationalize sepsis as suspected or documented infection associated with an acute increase of at least two points in the Sequential Organ Failure Assessment (SOFA) score. [1]

Septic shock represents a subgroup of patients with more profound circulatory and cellular-metabolic abnormalities and is associated with a substantially greater risk of death.[1] Early recognition and timely treatment are essential, but diagnosis remains challenging because clinical findings such as fever, tachycardia, leukocytosis, hypotension, altered mentation, and organ dysfunction are not specific for infection. Current sepsis guidelines therefore emphasize integrated clinical assessment, microbiological sampling, source identification, organ-dysfunction assessment, and repeated reassessment rather than reliance on a single diagnostic test. [2]

Procalcitonin (PCT) is the prohormone of calcitonin and is normally present at very low circulating concentrations. During systemic bacterial infection, widespread extra-thyroidal expression of the calcitonin precursor gene results in a rapid increase in serum PCT. This biological response has led to extensive evaluation of PCT as a diagnostic biomarker for bacterial sepsis. In a major systematic review and meta-analysis, Wacker et al., [3] reported pooled sensitivity of 77% and specificity of 79%, with an area under the summary receiver operating characteristic curve of 0.85. However, substantial heterogeneity was observed between studies, reflecting differences in patient population, infection site, assay, threshold, renal function, timing of sampling, and definitions of sepsis. Indian studies have similarly shown variable diagnostic performance, emphasizing that PCT is best interpreted in conjunction with clinical probability rather than used as a stand-alone diagnostic test. [4-8] The present study was therefore undertaken to evaluate serum PCT as an adjunct in the diagnosis of sepsis, assess its relationship with disease severity and SOFA score, and determine the prognostic significance of admission concentration and early PCT clearance.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Medicine, Government Medical College and Hospital, Chhatrapati Sambhajinagar, Maharashtra, India, from January 2025 to December 2025. Study was approved by institutional ethical committee. The study was explained in a language understood by the participant or legally authorized representative, and written informed consent was obtained before enrolment.

Inclusion Criteria

- Age ≥18 years, admitted under the Department of Medicine with suspected infection.
- Patients clinically evaluated for possible sepsis during the study period.
- Availability of admission serum PCT measurement.
- Availability of sufficient clinical and laboratory data to calculate the admission SOFA score.
- Written informed consent from the patient or legally authorized representative, as applicable.

Exclusion Criteria

- Age <18 years.
- Pregnancy.
- Major trauma or major surgery immediately preceding enrolment.
- Cardiogenic or haemorrhagic shock without evidence of infection.
- Known medullary thyroid carcinoma or other conditions known to substantially alter calcitonin precursor production.
- Inadequate clinical information for definitive Sepsis-3 classification.
- Absence of baseline serum PCT measurement.

The study size comprised all consecutive eligible patients enrolled during the predefined study period; therefore, no separate sample-size calculation was performed. Adult patients admitted with clinically suspected infection and possible sepsis were screened for enrolment. Detailed demographic data, symptoms, comorbidities, vital parameters, suspected focus of infection, laboratory findings, microbiological investigations, organ-support requirements, and hospital outcome were recorded.

Suspected infection was defined according to the treating physician's clinical assessment supported by initiation of antimicrobial therapy and/or microbiological sampling. Sepsis was defined according to Sepsis-3 criteria as suspected or documented infection associated with an acute increase in SOFA score of ≥2 points. [1] Septic shock was defined as sepsis associated with requirement for vasopressors to maintain a mean arterial pressure of at least 65 mmHg together with serum lactate >2 mmol/L despite adequate volume resuscitation. [1]

Patients presenting with suspected infection who did not fulfil Sepsis-3 criteria after complete clinical and laboratory evaluation constituted the non-sepsis comparison group. Final clinical classification was made independently of serum PCT concentration to avoid incorporation bias.

In patients without known pre-existing organ dysfunction, baseline SOFA was assumed to be 0. In patients with chronic organ dysfunction, baseline organ-specific SOFA was estimated from the most recent pre-illness clinical and laboratory values. Patients fulfilling Sepsis-3 criteria were further categorized as sepsis without shock or septic shock.

Serum PCT was measured at enrolment using the assay available in the institutional laboratory. A repeat measurement was obtained at approximately 72 hours among patients with sepsis who remained under active treatment.

PCT clearance was calculated as:

PCT clearance (%) = [(Admission PCT − 72-hour PCT) / Admission PCT] × 100

A positive value indicated a decline in PCT concentration. For prognostic analysis, a decline of ≥50% at 72 hours was considered adequate PCT clearance.

Appropriate blood cultures and cultures from clinically suspected infection sites were obtained before antimicrobial administration whenever clinically feasible. Antimicrobial therapy, haemodynamic support, mechanical ventilation, renal-replacement therapy, and source-control procedures were administered according to clinical indications and institutional protocols. PCT concentration was not used as the sole criterion for initiating antimicrobial treatment.

Categorical variables were expressed as frequency and percentage. Normally distributed continuous variables were summarized as mean±standard deviation, whereas skewed variables were expressed as median with interquartile range. Two independent groups were compared using the independent-samples t-test or Mann–Whitney U test as appropriate. Sensitivity, specificity, positive predictive value, negative predictive value, overall accuracy, and area under the ROC curve with 95% confidence intervals were calculated. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 160 patients with clinically suspected infection and possible sepsis were included. The mean age was 56.7±16.1 years. Ninety-four (58.75%) were male and 66 (41.25%) were female. Following complete clinical evaluation, 118 (73.75%) patients fulfilled Sepsis-3 criteria and 42 (26.25%) did not fulfil criteria for sepsis. Among the 118 patients with sepsis, 78 (66.10%) had sepsis without shock and 40 (33.90%) had septic shock. (Refer table 1)

Table 1. Baseline clinical characteristics of the study population (n=160)

Characteristic	n (%) / Value
Age, years, mean±SD	56.7±16.1
Male	94 (58.75)
Female	66 (41.25)
Hypertension*	66 (41.25)
Diabetes mellitus*	57 (35.63)
Chronic kidney disease*	24 (15.00)
Chronic obstructive pulmonary disease*	18 (11.25)
Ischaemic heart disease*	17 (10.63)
Non-sepsis	42 (26.25)
Sepsis without septic shock	78 (48.75)
Septic shock	40 (25.00)
Total fulfilling Sepsis-3 criteria	118 (73.75)

*Comorbidities were not mutually exclusive.

Among the 118 patients with sepsis, the most common source of infection was respiratory tract infection, observed in 45 (38.14%) patients, followed by urinary tract infection in 28 (23.73%) and intra-abdominal infection in 18 (15.25%) patients. Primary bloodstream infection was identified in 12 (10.17%), while skin and soft-tissue infections accounted for 9 (7.63%) cases. Other sources were noted in 6 (5.08%) patients. Positive blood cultures were obtained in 63 (53.39%) patients. Vasopressor support was required in 40 (33.90%) patients, while 47 (39.83%) required invasive mechanical ventilation. Acute kidney injury occurred in 49 (41.53%) patients, with 19 (16.10%) requiring renal-replacement therapy. Overall, 31 (26.27%) patients died during hospitalization.

Admission PCT increased progressively with clinical severity. Median PCT increased from 0.42 to 3.20 and 9.80 ng/mL across the three groups; the overall Kruskal–Wallis comparison was significant ($p<0.001$). Among patients with sepsis, admission PCT demonstrated a moderate positive correlation with admission SOFA score (Spearman $r=0.56$, $p<0.001$). (Refer table 2)

Table 2. Procalcitonin, SOFA score, and lactate according to sepsis severity

Parameter	Non-sepsis (n=42)	Sepsis without shock (n=78)	Septic shock (n=40)	p-value
PCT, ng/mL, median (IQR)	0.42 (0.18–0.96)	3.20 (1.70–6.40)	9.80 (5.60–21.40)	<0.001
SOFA score, median (IQR)	1 (0–2)	5 (3–7)	10 (8–12)	<0.001
Serum lactate, mmol/L, median (IQR)	1.5 (1.1–2.1)	2.2 (1.5–3.1)	4.5 (3.2–6.3)	<0.001

A serum PCT cut-off of 1.50 ng/mL showed moderate diagnostic performance. Wilson 95% CIs are: sensitivity 79.66% (71.52–85.93); specificity 71.43% (56.43–82.83); PPV 88.68% (81.25–93.40); NPV 55.56% (42.38–68.00); accuracy 77.50% (70.43–83.28). The relatively high positive predictive value reflected the high prevalence of sepsis within this clinically selected population. (Refer table 3)

Table 3. Diagnostic performance of admission serum PCT for Sepsis-3-defined sepsis

Diagnostic parameter	Result
PCT cut-off	1.50 ng/mL
True positive	94
False negative	24
True negative	30
False positive	12
Sensitivity	79.66%
Specificity	71.43%
Positive predictive value	88.68%
Negative predictive value	55.56%
Overall accuracy	77.50%
AUC	0.82
95% CI	0.75–0.88
p-value	<0.001

Admission PCT was approximately threefold higher among non-survivors. Differences became more pronounced at 72 hours, with survivors demonstrating substantial PCT decline and non-survivors showing persistent elevation. (Refer table 4)

Table 4. Procalcitonin and severity parameters according to hospital outcome among patients with sepsis

Parameter	Survivors (n=87)	Non-survivors (n=31)	p-value
Admission PCT, ng/mL, median (IQR)	3.10 (1.60–6.90)	9.40 (5.20–19.70)	<0.001
72-hour PCT, ng/mL, median (IQR)	1.40 (0.60–3.20)	8.10 (4.20–17.60)	<0.001
72-hour PCT clearance, %, median (IQR)	61.3 (42.5–78.6)	18.4 (−6.2–39.7)	<0.001
Admission SOFA score, median (IQR)	5 (3–8)	10 (8–12)	<0.001
Septic shock	19 (21.84)	21 (67.74)	<0.001
Mechanical ventilation	25 (28.74)	22 (70.97)	<0.001

The AUC was numerically higher for 72-hour PCT clearance (0.84) than for admission PCT (0.75) and was similar to that for admission SOFA score (0.83). (Refer table 5)

Table 5. Prognostic performance of PCT and SOFA score for in-hospital mortality

Marker	Cut-off	Sensitivity (%)	Specificity (%)	AUC (95% CI)	p-value
Admission PCT	>5.0 ng/mL	74.19	67.82	0.75 (0.65–0.84)	<0.001
72-hour PCT	>3.0 ng/mL	80.65	72.41	0.81 (0.72–0.89)	<0.001
72-hour PCT clearance	<50%	80.65	77.01	0.84 (0.76–0.91)	<0.001
Admission SOFA score	≥8	77.42	75.86	0.83 (0.75–0.91)	<0.001

DISCUSSION

The present study evaluated serum procalcitonin as a biomarker across three clinically relevant domains: diagnosis of sepsis, assessment of severity, and prediction of hospital outcome. Serum PCT was significantly higher among patients fulfilling Sepsis-3 criteria than in patients in whom sepsis was subsequently excluded. Concentrations increased progressively from sepsis without shock to septic shock and demonstrated a moderate positive correlation with SOFA score. Admission PCT showed moderate diagnostic discrimination, with an AUC of 0.82. Among patients with sepsis, non-survivors demonstrated markedly higher baseline and 72-hour PCT concentrations, while survivors demonstrated substantially greater PCT clearance. The dynamic change in PCT during the first 72 hours showed greater prognostic discrimination than a single admission concentration.

The diagnostic performance observed in the present study is consistent with the broader international literature. Wacker et al., [3] analysed 30 studies comprising 3,244 critically ill patients and reported pooled sensitivity of 77% and specificity of 79% for PCT in differentiating bacterial sepsis from non-infectious systemic inflammation, with an area under the summary ROC curve of 0.85. These values closely approximate the sensitivity of 79.66%, specificity of 71.43%, and AUC of 0.82 observed in the present cohort. The comparison supports PCT as a useful adjunctive diagnostic marker but also demonstrates that clinically important false-positive and false-negative results remain unavoidable.

Rowther et al. [4] compared eubacterial PCR and PCT with blood culture. For PCT, they reported a sensitivity of 100%, specificity of 61.66%, positive predictive value of 56.6%, and negative predictive value of 100% when blood culture was used as the reference standard.

Chivate et al., [5] prospectively evaluated PCT in 87 adults admitted to the ICU with symptoms of systemic infection. Their observations supported a significant relationship between increasing PCT concentration and sepsis. Although diagnostic criteria, PCT categorization, and assay methodology differed from contemporary Sepsis-3-based studies, the work remains relevant as Maharashtra-specific evidence that PCT can provide

early adjunctive information in critically ill patients.

Sinha et al., [6] evaluated 40 critically ill patients with suspected sepsis and reported that a PCT concentration ≥2 ng/mL had a sensitivity of 86% and specificity of 95% for sepsis. The higher specificity compared with the current study may partly reflect differences in assay, threshold, patient selection, and older sepsis definitions.

More contemporary Maharashtra data are provided by Jayara et al., [7] from Breach Candy Hospital Trust, Mumbai. Their prospective observational study included 100 ICU patients with Sepsis-3-defined sepsis and assessed PCT, neutrophil-to-lymphocyte ratio, and SOFA score serially on days 0, 2, and 4. PCT decreased significantly over time in the overall cohort, while patients who died had significantly higher PCT values on days 2 and 4. Serial SOFA scores were also higher among non-survivors. These findings closely support the present observation that PCT trajectory is more informative prognostically than an isolated baseline value.

The severity gradient observed in the present study is biologically plausible. Median PCT increased from 0.42 ng/mL among patients without sepsis to 3.20 ng/mL in sepsis without shock and 9.80 ng/mL in septic shock. This progression was accompanied by increasing SOFA score and serum lactate. Serum PCT also demonstrated a moderate positive correlation with SOFA score. Sudhir et al., [9] prospectively studied 100 adult patients with sepsis, severe sepsis, and septic shock and reported a significant association between serum PCT and SOFA score. Respiratory tract infection was the leading source of sepsis, and PCT demonstrated high sensitivity for sepsis in their cohort. Importantly, however, PCT did not predict mortality in that study, highlighting that diagnostic performance and prognostic performance are distinct properties.

Shinde et al., [10] prospectively studied 80 patients with suspected sepsis in a medical ICU and directly compared PCT with SOFA score. Mean PCT was 3.7±1.5 ng/mL among survivors and 6.4±3.13 ng/mL among non-survivors. The AUC for PCT was 0.77, compared with 0.78 for SOFA score. Their results support the present observation that baseline PCT is associated with outcome but does not clearly outperform an established organ-dysfunction score.

The prognostic value of serial PCT was stronger than that of baseline concentration. In the present study, survivors demonstrated median PCT clearance of 61.3% at 72 hours, compared with only 18.4% among non-survivors. A clearance threshold below 50% yielded an AUC of 0.84, exceeding the AUC of 0.75 for admission PCT. This finding is consistent with the broader concept that biomarker kinetics contain more prognostic information than a single measurement.

Liu et al., [11] in a systematic review and meta-analysis examining the prognostic role of PCT in adult sepsis, found that elevated PCT was associated with increased mortality but that the discriminatory performance of a single value was limited. Importantly, failure of PCT to decline was more strongly associated with death than baseline elevation alone. Serial PCT therefore appears to reflect the evolution of infection and host response more effectively than an isolated admission concentration.

Nevertheless, persistent PCT elevation should not be interpreted mechanistically without considering the clinical context. Chronic kidney disease and acute kidney injury may alter PCT kinetics, while major surgery, trauma, shock, burns, and certain malignancies can elevate PCT in the absence of bacterial infection. Conversely, localized infection, early infection, or partially treated infection may produce relatively low serum concentrations. A low PCT concentration therefore cannot safely exclude sepsis when clinical probability is high.

The 2026 Surviving Sepsis Campaign emphasizes that sepsis is a clinical diagnosis and should not be ruled in or ruled out on

the basis of a single biomarker or diagnostic test. [2] For adults with possible or probable sepsis or septic shock, the guideline suggests using clinical evaluation alone rather than PCT plus clinical evaluation to determine whether antimicrobial therapy should be initiated. Conversely, in patients with sepsis or septic shock who have adequate source control and in whom the optimal duration of antimicrobial therapy is uncertain, PCT may be used together with clinical evaluation to assist antimicrobial discontinuation. [2,12,13]

Predictive values in the present study require particular interpretation. The positive predictive value of 88.68% was considerably higher than the negative predictive value of 55.56%. This reflects, in part, the high prevalence of Sepsis-3-defined sepsis in a population selected because clinicians already suspected significant infection.

Gupta et al., [14] prospectively evaluated 305 patients at a tertiary-care centre and demonstrated that PCT distinguished culture-negative and culture-positive sepsis from non-infectious conditions. They reported an optimal PCT cut-off of 1.3 ng/mL for culture-negative sepsis, with sensitivity of 87.30% and specificity of 78.26%, while a threshold of 2.2 ng/mL for culture-positive sepsis yielded sensitivity of 98.47% and specificity of 89.13%. Their results demonstrate that the optimal threshold varies according to the diagnostic comparator and microbiological status, reinforcing the danger of treating any single cut-off as absolute.

The principal strength of the present study was the prospective evaluation of serum PCT across diagnostic, severity-assessment, and prognostic domains using contemporary Sepsis-3 definitions. Serial measurement at admission and 72 hours permitted evaluation of PCT kinetics, while concurrent SOFA assessment allowed comparison with an established measure of organ dysfunction.

However, the study was conducted at a single tertiary-care centre, which limits generalisability. The diagnostic and prognostic cut-offs were derived from the same cohort and require external validation. Renal dysfunction and other clinical conditions capable of influencing PCT concentrations may have resulted in residual confounding. The relatively small non-sepsis comparison group also resulted in limited precision of specificity and negative predictive-value estimates.

CONCLUSION

Among adults evaluated for suspected infection, admission serum procalcitonin showed diagnostic discrimination for Sepsis-3-defined sepsis and was positively associated with the severity of organ dysfunction. PCT concentrations were higher among patients with sepsis than among those not fulfilling Sepsis-3 criteria, increased further among patients with septic shock, and showed a moderate positive correlation with admission SOFA score.

Serial PCT kinetics provided additional prognostic information. The AUC for 72-hour PCT clearance was numerically higher than that for admission PCT and was similar to the AUC for admission SOFA score. Serum PCT should therefore be interpreted as an adjunct to clinical assessment, organ-dysfunction evaluation, microbiological findings, and serial clinical reassessment rather than as an isolated diagnostic or prognostic test.

Declaration

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