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Estimation of Serum Procalcitonin Levels in Patients with Sepsis

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ABSTRACT

Introduction: Sepsis and SIRS share overlapping clinical features but differ fundamentally in their underlying pathophysiology. Both represent systematic inflammatory states; yet, the source and progression of immune activation diverge significantly between infectious and non-infectious etiologies. These differences become critical when attempting early diagnosis, where clinical science alone is insufficient, and biochemical markers, such as PCT, gain diagnostic relevance.

Aim: To determine the Day 1 serum Procalcitonin level in patients with sepsis and to assess the Day 1 serum procalcitonin concentration with duration of stay.

Materials and Methods: This research was designed as a prospective cohort study, which was conducted in the department of internal medicine at SGRRIM&HS and SMIH Dehradun on 150 patients of both genders above age 18 years with clinical evidence of heart failure who presented within 24-36 hours of illness with suspected sepsis and were admitted to the ICU. The study duration was 18 months. Serum procalcitonin was measured using a standard immunoassay method. Haematological tests, biochemical tests, and infectious disease tests were performed to confirm the specific infection. Chi-square tests and t-tests were performed for comparative analysis.

Results: A total of 150 patients [mean age was 34.2±8.1 years (18-40 years), mean age of 52.4±6.3 years (41-60 years), and mean age of 68.7±5.9 years (above 60)] were included in the study.

Higher PCT levels were associated with an increased mortality rate. The most significant mortality was observed in patients with PCT levels greater than 30 ng/mL, with 68% of the patients expiring, showing a strong and statistically significant association (p value = 0.001). A higher level of PCT was observed in patients with septic shock, suggesting that elevated PCT levels may be an indicator of septic shock in patients. 83.3% of patients had septic shock and expired, which indicates that septic shock is strongly associated with mortality (p-value = 0.03). PCT level also influences the ICU stay duration.

Conclusion: The study indicates that PCT serves as a diagnostic and monitoring tool, enabling clinicians to enhance patient care, reduce mortality associated with sepsis, and improve patient outcomes across various healthcare settings**.**

Keywords: *Procalcitonin: Sepsis, Patients, Infectious disease, Diagnostic*

1. INTRODUCTION

Systematic inflammation brought on by the body's reaction to an infection can result in tissue damage, organ malfunction, and even death. This can lead to sepsis, characterised by organ dysfunction arising from a dysregulated host response to infection, which is now the hallmark of sepsis, as indicated by an increase of at least two points in the Sequential Organ Failure Assessment (SOFA) score **[1].** Globally, sepsis represents a significant public health crisis. A comprehensive epidemiological analysis conducted by the Global Burden of Disease Study estimated "48.9 million cases and 11 million sepsis-related deaths **[2].** The burden is disproportionately higher in low - and middle-income countries (LMIC), including India, where limited diagnostic resources and delayed clinical suspicion contribute to poor outcomes. In India alone, sepsis remains one of the top five causes of ICU mortality **[3]**. Sepsis need to be recognised and treated clinically right away. According to studies, the chance of survival in septic shock drops by 7.6% for every hour that passes before effective antimicrobial therapy is started **[4].**

According to studies, raised PCT levels are a prognosis indicator as well as a diagnostic one, as they are linked to greater rates of organ dysfunction, intensive care unit admissions, and sepsis-related mortality **[5]**. The diagnostic relevance of PCT stems from its rapid response kinetics; it rises within 2-6 hours of infection onset and peaks at 12-24 hours, correlating closely with microbial load and inflammatory severity **[6]**.

2. MATERIALS AND METHODS

Study Design

This Research was designed as a Prospective cohort study, conducted in the Department of Internal Medicine at Shri Guru Ram Rai Institute of Medical and Health Sciences and Shri Mahant Indiresh Hospital, Dehradun.

Study Duration

The study duration was 1 year and 6 months.

Sample Size

One hundred fifty patients were enrolled based on a purposive sampling method, taking into account the study's scope, duration, and patient flow at the "Department of Medicine, SMIH, Dehradun.

Inclusion And Exclusion Criteria

Patients aged >= 18 years with clinical evidence of Heart Failure, belonging to either sex and presenting with 24- 36 hours of illness with suspected sepsis were included in the study.

Pregnant women, Individuals with a history of road traffic accident, patients with any type of malignancy, or with any recent surgical history and with severe burns or heat stroke were excluded from the study.

3. DATA COLLECTION AND STATISTICAL ANALYSIS

All the data were entered into Microsoft Excel and analysed using appropriate statistical software. Descriptive statistics (mean, standard deviation, percentages) were used for continuous and categorical variables. Comparative analyses were performed using the t-test and chi-squared test as applicable. A P value of <0.05 was considered statistically significant.

4. RESULTS

A total of 150 patients were included and analysed. The age distribution reveals that the study population is relatively higher across groups aged between 18 and 40 years, with a mean age of 34.2 ± 8.1 years, accounting for 41.3% of participants. The majority of the cases were male, that is, n=87, as shown in **Table 1**. A total of 95 patients were in sepsis and 55 patients in septic shock, as shown in **Table 2**. At the time of the presentation the relevant investigation were done the values were compared on day1 and day7 of the ICU admission mean Heamoglobin was on day 1, 13.0± 2.5 mg/dl and on day 7 the mean was 12.2± 2.3, mean TLC on day 1 was 9500 ± 2000 and on day 7 7900 ± 1550, ESR mean was 35 ± 1.5 and on day 7 32 ± 1.6, mean platelet count on day 1 was 270000 ± 60000 and platelet count on day 7 was 245000 ± 55000 all were included as shown in the **Table 3**. Overall findings from Day 1 to Day 7 suggest that most hemogram and blood parameters remained relatively stable, with no significant changes indicating major deterioration or improvement in the patient's condition during their ICU stay.The value of 0.03 indicates a statistically significant difference in the proportion of patients with septic shock between Day 1 and Day 7, as shown in **Table 4**. This suggests that septic shock status changes significantly over the week, which could be linked to the effectiveness of treatments. In contrast, 120 patients who survived, 45 (37.5%) had septic shock, and 75 (62.5%) did not, in **Table 5**. This suggests that septic shock is a significant contributing factor to mortality; a considerable proportion of patients with septic shock still survive, possibly due to timely and effective interventions.

In **Table 6**, for the 21-30 ng/ml range, 35 patients were classified, and the mortality rate increased to 20.0%, with a P value of 0.001, indicating a strong association between higher PCT levels and increased mortality.

Parameter	Category	n (%)	Mean ± SD	p-value	Significance
Age (years)	18–40	62 (41.3%)	34.2 ± 8.1	0.12	Not significant
	41–60	55 (36.7%)	52.4 ± 6.3		
	>60	33 (22.0%)	68.7 ± 5.9		
Gender	Male	87 (58.0%)	–	0.45	Not significant
	Female	63 (42.0%)	–		
Socioeconomic Status	Lower class (III)	57 (38.0%)	–	0.01	Significant (✓)

	Middle class (II)	75 (50.0%)	–		
	Upper class (I)	18 (12.0%)	–		

The >30 ng/ml range showed the most pronounced effect, with a mortality rate of 68%, where only 32.0% survived; this difference was also statistically significant (P value = 0.001%). The data highlights that higher PCT levels were associated with increased mortality, with the most considerable mortality observed in patients with PCT levels greater than 30ng/ml.

Table 1: Sociodemographic Profile: Statistical significance is considered at $p < 0.05$. For which only the socioeconomic profile is significant.

PCT Category (ng/mL)	Septic Shock (Yes)	Septic Shock (No)	Total Patients (n)	Expected Yes	p-value	Significance
2–10	15	135	150	35	< 0.0001	Significant (✓)
11–20	30	120	150	35	< 0.0001	Significant (✓)
21–30	40	110	150	35	< 0.0001	Significant (✓)
>30	55	95	150	35	< 0.0001	Significant (✓)
Total	140	460	600	–		
Chi-square (χ^2)					< 0.0001	Highly significant (✓)

Table 2: Distribution of PCT Category vs Septic Shock: PCT procalcitonin level, Statistical significance threshold was set at $p < 0.05$, and results show a highly significant trend ($p < 0.0001$)

Parameter	Day 1 (Mean ± SD)	Day 7 (Mean ± SD)	p-value	Significance
Haemoglobin (Hb)	13.0 ± 2.5	12.2 ± 2.3	0.45	Not significant
Total Leukocyte Count (TLC)	9500 ± 2000	7900 ± 1550	0.58	Not significant
Erythrocyte Sedimentation Rate (ESR)	3.5 ± 1.5	3.2 ± 1.6	0.12	Not significant
Platelet Count (PLT)	270000 ± 60000	245000 ± 56000	0.23	Not significant
Blood Sugar (Fasting)	85 ± 1.5	92 ± 1.6	0.35	Not significant
Urea	38 ± 1.2	42 ± 1.8	0.32	Not significant
Creatinine	1.0 ± 0.2	1.3 ± 0.4	0.22	Not significant
Sodium (Na)	141 ± 3	139 ± 5	0.18	Not significant
Potassium (K)	4.0 ± 1.3	4.1 ± 1.0	0.54	Not significant
Chloride (Cl)	102 ± 4	104 ± 4	0.47	Not significant

Table 3: Distribution of Hemogram and Blood Parameters across ICU Stay: No parameter shows a statistically significant change (all p-values > 0.01)

Septic Shock Status	Day 1 (n = 150)	Day 7 (n = 105)	p-value	Significance
Septic Shock: Yes	60 (40%)	35 (33.3%)	0.03	Not statistically significant (✗)
Septic Shock: No	90 (60%)	70 (66.7%)	–	–

Table 4: Septic Shock—Day 1 vs Day 7 :-Interpretation: Although the proportion of patients with septic shock decreased from Day 1 to Day 7, the change is not statistically significant at $p < 0.01$.

Septic Shock Status	Mortality (Expired) (n = 30)	Survived (n = 120)	p-value	Significance
Yes	25 (83.3%)	45 (37.5%)	0.02	Not statistically significant (✗)
No	5 (16.7%)	75 (62.5%)	–	

Table 5: Mortality vs Septic Shock : The p-value is 0.02, which is greater than the threshold of $p < 0.01$, which is not statistically significant.

PCT Category (ng/mL)	Total Patients (n)	Survived (n=120)	Expired (n=30)	Mortality Rate (%)	p-value	Significance
2–10	35	34 (97.1%)	1 (2.9%)	2.9%	0.012	✓ ($p < 0.05$)
11–20	55	50 (90.9%)	5 (9.1%)	9.1%	0.043	✓ ($p < 0.05$)
21–30	35	28 (80.0%)	7 (20.0%)	20.0%	0.001	✓ ($p < 0.01$)
>30	25	8 (32.0%)	17 (68.0%)	68.0%	0.001	✓ ($p < 0.01$)
Test value (χ^2) = 28.65		**Overall p-value < 0.001**				

Table 6: PCT Levels vs Mortality (n=150)

0.001 ** ($p < 0.01$, statistically significant), the Pearson Chi-square test has been used

TestValue (χ^2) = 28.65; Overall p-value< 0.001

5. DISCUSSION

The study was conducted as a prospective cohort study at the "Department of Internal Medicine, Shri Guru Ram Rai Institute of Medical and Health Sciences (SGRRIM & HS) and its associated tertiary care facility, Shri Mahant Indiresh Hospital (SMIH), located in Dehradun, Uttarakhand, India." The primary aim of the study was to evaluate serum procalcitonin (PCT) levels in patients diagnosed with sepsis. Specifically, the study focused on "assessing day 1 PCT levels and determining if these concentrations correlate with clinical outcomes such as duration of ICU stay and mortality.

Furthermore, the research sought to "understand how variation in PCT levels on the first day of admission can aid in predicting the progression of sepsis, ultimately contributing to the optimisation of diagnostic and therapeutic strategies in critically ill patients."

The sociodemographic profile of the study participants presents a broad distribution across age, gender, and socioeconomic status. The study population consists predominantly of males (58%) with a mean age of 34.2 ± 8.1 years. The majority of participants (50%) belong to the middle class, with 12.0% from the upper class. In comparison, several studies on sepsis show a higher male prevalence. In contrast, several studies on sepsis show a higher male prevalence, reflecting the known male prevalence in critical conditions like sepsis.

Sirisha Jujjuru et al. (2022) reported a higher percentage of males (62%) in their study of sepsis and septic shock patients, with 74% of patients diagnosed with sepsis and 26% with septic shock, a distribution similar to the gender disparity observed in our cohort (58%)[7].

Additionally, our study's socio-economic distribution revealed a significant difference (p = 0.01%), suggesting that lower socio-economic status may influence the likelihood of sepsis presentation.

The finding resonates with a search by **Sehveta Mustafic et al. (2018),** where patients with lower socioeconomic backgrounds were more likely to present with severe sepsis and its complications [8]. The p-value for socio-economic status may play a role in the health outcomes of patients, which is consistent with the findings of studies, such as those by **Sirisha Jujjuru et al. (2022)**, where patient outcomes, including length of stay, varied according to socio-economic status [7].

Regarding the distribution of PCT across day 1 and day 7, the results show a slight decrease in PCT levels across all categories, with a significant reduction only in the group with levels above 30 ng/ml (p = 0.041%). These findings align with those of **Sirisha Jujjuru et al. (2022)**, who observed a gradual decline in PCT levels over days in septic patients, with higher levels in patients with elevated PCT levels correlating with longer ICU stays and mortality [7]. Interestingly, studies such as

those by **Xue H et al. (2023)** and **AL Rawahi et al. (2019)** also emphasise the prognostic value of PCT, showing that elevated PCT levels are consistently associated with mortality and severe sepsis [9, 10]. Similarly, **Spoto et al. (2020)** demonstrated that procalcitonin levels were instrumental in distinguishing sepsis from non-sepsis conditions, yet did not focus on serial PCT level trends across days, making our finding of a reduction in the highest PCT range (over 30 ng/mL) unique to our study in the context of the cohort [11]. The lack of significant change in the 2-10 ng/mL, 11-20 ng/mL, and 21-30 ng/mL groups, as observed in our study, contrasts with findings by **AlRawahi AN et al. (2019)** and **Sehveta Mustafic et al. (2018)**, who found that higher baseline PCT levels were consistently associated with worse outcomes. However, our study's finding that the lower PCT groups (2-10 ng/mL and 11-20 ng/mL) showed no significant change over time suggests that these levels may not be as helpful in tracking sepsis progression compared to the higher PCT levels, which were more dynamic in our cohort [10, 8].

In the studies by **Spoto et al. (2020)** and **Sirisha Jujjuru et al. (2022)**, septic shock was associated with increased mortality rates in their respective cohorts [11, 7]. Additionally, studies such as those by **Sehveta Mustafic et al. (2018)** also emphasise the diagnostic value of PCT in differentiating between septic shock and non-septic shock conditions, supporting its role as a reliable biomarker in identifying severe sepsis [8]. The relationship between serum procalcitonin (PCT) levels and mortality outcomes is clearly outlined in the sixth table, with data suggesting that higher PCT levels correlate strongly with increased mortality rates. This trend is consistent with the findings of various studies, where elevated PCT levels are considered a strong prognostic indicator for mortality in sepsis patients. **Sirisha Jujjuru et al. (2022)** reported a similar relationship, where higher PCT levels were associated with higher mortality rates in both sepsis and septic shock groups, with mortality rates of 36% overall [7]. Specifically, in their study, patients with higher PCT levels had significantly worse outcomes. This finding aligns with the data observed in the present study, where the highest mortality rates were found in patients with PCT levels greater than 30 ng/mL (68.0%). These findings are also in agreement with **Xue H et al. (2023)**, who demonstrated a significant association between elevated PCT levels and increased mortality, emphasising the value of PCT as a predictive biomarker in septic shock patients [9]. The p-values in our study for the >30 ng/mL category (0.001) and the 21-30 ng/ml category (0.001) further confirm the strong link between PCT levels and mortality outcomes, which is supported by similar conclusions in other research, such as the work of **AlRawahi AN et al. (2019)**, where elevated PCT was found to correlate with mortality in critically ill patients, especially those with severe infection [10].

6. CONCLUSION

The finding regarding the changes in PCT levels from day 1 to day 7 further reinforces the potential of PCT as a dynamic biomarker for assessing disease progression. PCT has shown robust prognostic value in sepsis management. By utilising the PCT as a diagnostic and monitoring tool, clinicians can enhance patient care and reduce the mortality associated with sepsis. Monitoring PCT levels also serves as a valuable tool for predicting the duration of ICU stay. Higher PCT levels and increased mortality, with the greater 30 mg/mL PCT group showing a mortality rate of 60%. The study's findings have crucial clinical implications, suggesting that PCT levels can be particularly used as a guiding decision regarding patient monitoring, therapy escalation and de-escalation. PCT in combination with other biomarkers and clinical parameters to refine the diagnostic algorithm for sepsis and improve patient outcomes across different healthcare settings.

7. LIMITATION

A relatively small sample size may limit the study's statistical power.

8. AUTHORS CONTRIBUTION

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

- Acquisition, analysis, or interpretation of data: **Dr. Aarzoo Goel**
- Drafting of the manuscript: **Dr Muskan Kumari: Dr Parshant Pokhriyal**
- Concept and design: **Dr Muskan Kumari**
- Critical review of the manuscript for important intellectual content: **Dr Anuj Nautiyal**
- Supervision: **Dr. A.N. Pandey**

9. AUTHORS DECLARATION

- Financial or Other Competing Interests: **None**
- Was Ethics Committee Approval obtained for this study? **Yes (on 14/04/25)**
- Was informed consent obtained from the subjects involved in the study? **Yes**
- For any images presented, appropriate consent has been obtained from the subjects. **NA**

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