Original Article

The role of Serum Procalcitonin (PCT) in Predicting 28 Days Mortality in Critically ill Patients with Sepsis Admitted to the Intensive Care Unit

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ABSTRACT

Objective: To assess the relationship between Serum Procalcitonin (PCT) and 28-day mortality in critically ill patients with sepsis admitted to the ICU.

Study Design: Cohort study.

Place and Duration of Study: This study was conducted at the High Definition Unit and Intensive Care Unit at Medical Unit 4, Jinnah Postgraduate Medical Centre Karachi from June 2023 to August 2024.

Methods: Total 142 male and female patients between 18-75 years of age, fulfilling the criteria of sepsis, septic shock, and being critically ill were included. Absence of critical illness, incomplete data and undergone dialysis before admission were not included. The patient was followed for the first seven days of his hospital stay with deterioration or improvement to be assessed till day 28 regardless of the patient being discharged.

Results: Association between PCT levels and mortality it was found that in patients with PCT >7 ng/dl, 48 hours mortality was found to be 25.35%, mortality within 7, 14 and 28 days was 42.25%, 52.11% and 57.75% respectively while in patients with PCT ≤7 ng/dl, it was found to be 12.68%, 23.94%, 29.58% and 33.80% respectively.

Conclusion: In patients hospitalized to the ICU, elevated PCT may be a sign of infection risk and infection-related death.

Key Words: Sepsis, Procalcitonin, Mortality

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INTRODUCTION

Sepsis is defined as life-threatening organ dysfunction leading to a dysregulated host response as a consequence of infection[1] The prevalence of sepsis recorded in patients at the time of admission or during ICU stay in ICU's worldwide is estimated to be 29.5%.[2] Biochemically PCT is a prohormone of calcitonin and is upregulated by microbial toxins and pro-inflammatory mediators, but is surprisingly reduced by cytokines released in response to viral infection (interleukin-gamma), which showcases its superiority as a marker of bacterial inflicted infection.[3,4] PCT has a rapid release rate of 2-4 hours, reaching a peak at 24 hours[5] as compared to microbial cultures that are most advantageous in aiding the diagnosis but at the cost of a significant time delay of more than 24 hours.[6,7]

A serious consequence of sepsis; septic shock occurs when abnormalities at the cellular and circulatory levels are severe enough to result in all-effect mortality.[8,9]

The sequential Organ Failure Assessment (SOFA Score) is a validated tool widely used to measure organ dysfunction with patients scoring 2 points or more serves as a marker of critical medical illness.[10]

Serum Procalcitonin (PCT) has a well-established role in the diagnosis and management of septic patients. Recruiting such a biomarker can aid in early diagnosis, risk stratification, and initiation of all possible resuscitative measures that pave the way towards a favorable outcome. No proven biomarker yet exists to establish the prognosis of septic shock,[11] and this is where it becomes pertinent to test Serum PCT's ability to serve as a prognostic marker in patients with sepsis in critically ill patients. Thus, the rationale of the present study is to establish the prognostic role of admission Serum PCT, early in the course of their disease in resource-limited settings.

METHODS

After receiving approval from the ethical review committee, this cohort study was carried out from June

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2023 to August 2024. By taking prevalence of 68.5% in PCT>7 ng/dL group and 43.6% in PCT<7 ng/dL of mortality with confidence interval 95% and power of test 80%, the sample size was calculated to be 142 with 71 in each group.[12] Male and female patients between 18-75 years of age, fulfilling the criteria of sepsis, septic shock, and being critically ill were included. Absence of critical illness as per the previous definition of organ dysfunction, incomplete data and undergone dialysis before admission as dialytic treatment tends to falsely reduce PCT levels were not included.

Informed written permission was taken from patients/attendants. Data was collected by retrospectively accessing patient's admission records including treatment sheets and monitoring sheets. Presenting complaint, comorbid conditions (such as HTN, DM, CKD, CLD, malignancy and/or autoimmune disorders but not limited to the following), vital signs, initial Serum PCT levels, physical status including organ or multisystem involvement, duration of hospital stay, and outcome (including death or discharge) were noted. The patient was followed for the first seven days of his hospital stay with deterioration or improvement to be assessed till day 28 regardless of the patient being discharged from ICU with follow-up to be acquired by telephonic communication or physical examination.

Data analysis was done on SPSS version 23. Descriptive analysis was done on variables, chi-square test and independent t-test was used to study the relationship between qualitative and quantitative variables respectively. p-value <0.05 as statistical significance. Effect modifiers included comorbidities such as hypertension, diabetes mellitus, and asthma, malignancy, previously known cardiac disease, previous stroke, malignancy, allergies and smokers. Relative Risk was calculated.

RESULTS

The average age of patients was 46.42 ± 11.43 years. There were 75 (52.82%) females and 67 (47.18%) males. The distribution of patients by various variables is shown in Table 1. Association between PCT levels and mortality it was found that in patients with PCT >7 ng/dl, 48 hours mortality was found to be 25.35%, mortality within 7, 14 and 28 days was 42.25%, 52.11% and 57.75% respectively while in patients with PCT ≤7 ng/dl, it was found to be 12.68%, 23.94%, 29.58% and 33.80% respectively. Despite 48 hours mortality values, all remaining statistics showed significant difference and positive association between PCT values and mortality rate (RR >1) as shown in Table 2. The mean SOFA score for this group was 9.15 ± 3.57, and the majority of patients had either an intra-abdominal infection (38.94%) or a pulmonary infection (47.85%). These patients' median PCT level at admission was 5.74 ng/ml, and those who did not survive had considerably higher PCT levels (p<0.001). Stratification of 28 days mortality with respect to effect modifiers is shown in Table 3.

Table No.1: Distribution of different variables (n=142).

		PCT >7 ng/dL (n=71)	PCT ≤7 ng/dL (n=71)
		Number (%)	Number (%)
Age (years)	18-45	46 (64.79%)	45 (63.38%)
	46-75	25 (35.21%)	26 (36.62%)
Gender	Male	34 (47.79%)	33 (46.48%)
	Female	37 (52.11%)	38 (53.52%)
HTN	Yes	26 (36.62%)	27 (38.03%)
	No	45 (63.38%)	44 (61.97%)
DM	Yes	22 (30.99%)	24 (33.80%)
	No	49 (69.01%)	47 (66.20%)
Asthma	Yes	14 (19.72%)	18 (25.35%)
	No	57 (80.28%)	53 (74.65%)
Malignancy	Yes	11 (15.49%)	15 (21.13%)
	No	60 (84.51%)	56 (78.87%)
Previous stroke	Yes	08 (11.27%)	10 (14.08%)
	No	63 (88.73%)	61 (85.92%)
Previous known cardiac disease	Yes	16 (22.54%)	13 (18.31%)
	No	55 (77.46%)	58 (81.69%)
Allergies	Yes	04 (5.63%)	06 (8.45%)
	No	67 (94.37%)	65 (91.55%)
Smoker	Yes	21 (29.58%)	20 (28.17%)
	No	50 (70.42%)	51 (71.83%)

Table No.2: Serum PCT in predicting mortality in critically ill patients (n=142).

Mortality	PCT >7 ng/dL (n=71)		PCT ≤7 ng/dL (n=71)		P-value	RR
	Yes	No	Yes	No		
Within 48 hours	18 (25.35%)	53(74.65%)	09(12.68%)	62 (87.32%)	**0.062**	**2.00**
Within 7 days	30 (42.25%)	41(57.75%)	17(23.94%)	54 (76.06%)	**0.025**	**1.76**
Within 14 days	37 (52.11%)	34(47.89%)	21(29.58%)	50 (70.42%)	**0.009**	**1.76**
Within 28 days	41 (57.75%)	30(42.25%)	24(33.80%)	47 (66.20%)	**0.006**	**1.71**

Table No.3: Stratification of 28 days mortality with respect to effect modifiers.

		PCT >7 ng/dL (n=71)		PCT ≤7 ng/dL (n=71)		P-value	RR
		28 days mortality		28 days mortality			
		Yes	No	Yes	No		
Age (years)	**18-45**	24 (52.17%)	22 (47.83%)	13 (28.89%)	32 (71.11%)	0.031	1.81
	46-75	17 (68.0%)	08 (32.0%)	11 (42.31%)	15 (57.69%)	0.076	1.61
Gender	**Male**	21 (61.76%)	13 (38.24%)	10 (30.30%)	23 (69.70%)	0.016	2.04
	Female	20 (54.05%)	17 (45.95%)	14 (36.84%)	24 (63.16%)	0.142	1.47
HTN	**Yes**	13 (50.0%)	13 (50.0%)	09 (33.33%)	18 (66.67%)	0.227	1.50
	No	28 (62.22%)	17 (37.78%)	15 (34.09%)	29 (65.91%)	0.012	1.82
DM	**Yes**	15 (68.18%)	07 (81.82%)	10 (41.67%)	14 (58.33%)	0.081	1.64
	No	26 (53.06%)	23 (46.94%)	14 (29.79%)	33 (70.21%)	0.027	1.78
Asthma	**Yes**	07 (50.0%)	07 (50.0%)	03 (16.67%)	15 (83.33%)	0.063	3.00
	No	34 (59.65%)	23 (40.35%)	21 (39.62%)	32 (60.38%)	0.042	1.50
Malignancy	**Yes**	06 (54.55%)	05 (45.45%)	02 (13.33%)	13 (86.67%)	0.048	4.09
	No	35 (58.33%)	25 (41.67%)	22 (39.29%)	34 (60.71%)	0.046	1.48
Previous stroke	**Yes**	05 (62.50%)	03 (37.50%)	01 (10.0%)	09 (90.0%)	0.063	6.25
	No	36 (57.14%)	27 (42.86%)	23 (37.70%)	38 (62.30%)	0.035	1.51
Previous known cardiac disease	**Yes**	11 (68.75%)	05 (31.25%)	07 (53.85%)	06 (46.15%)	0.426	1.28
	No	30 (54.55%)	25 (45.45%)	17 (29.31%)	41 (70.69%)	0.009	1.86
Allergies	**Yes**	02 (50.0%)	02 (50.0%)	01 (16.67%)	05 (83.33%)	0.291	3.00
	No	39 (58.21%)	28 (41.79%)	23 (35.38%)	42 (64.62%)	0.011	1.64
Smoker	**Yes**	12 (57.14%)	09 (42.86%)	07 (35.0%)	13 (65.0%)	0.172	1.63
	No	29 (58.0%)	21 (42.0%)	17 (33.33%)	34 (66.67%)	0.016	1.74

DISCUSSION

The current study set out to assess the association between serum PCT and 28-day mortality in patients with severe sepsis hospitalized in the ICU. A relationship exists between mortality and PCT levels. In patients with PCT >7 ng/dl, mortality was found to be 25.35% within 48 hours, 42.25%, 52.11%, and 57.75% within 7, 14, and 28 days, respectively, while in patients with PCT ≤7 ng/dl, the corresponding mortality rates were 12.68%, 23.94%, 29.58%, and 33.80%. These patients had a median PCT level of 5.74 ng/ml upon admission, and those who did not survive had considerably higher PCT levels ($p < 0.001$).

A retrospective cohort study that included 228 patients admitted to an ICU with a SOFA Score >2 and an overall mortality of 57.5% attempted to assess the prognostic ability of PCT by recording the SOFA scores of septic patients admitted to the ICU, monitoring them for 28 days, and evaluating them based on their life/death status. In order to ascertain whether PCT levels and death within 28 days are related, it was discovered that 40 (31.5%) of the patients with PCT≥7 ng/dl survived the first 28 days, whereas 87 (68.5%) died. In a similar vein, 44 (43.6%) of the patients with PCT≤7 ng/dl were declared expired, while 57 (56.4%) survived. These differences revealed a strong association between higher PCT and the death rate after 28 days (RR 1.572, p value <0.001).[12] Meng et al.'s study[6] found that mortality rates were relatively higher for higher levels of serum PCT on day 1 compared to their study, which found that PCT (day 1) with ranges of 10 ng/ml had a PPV and NPV of 57.1% and 81.8% for sensitivity and specificity of 75.0% and 66.0%, respectively. 78.05% of patients with a severe score of >10 died. It was considerably higher than serum PCT (ng/ml) of 20% of ≤0.5 (normal), 15.28% of >0.5 to 2 (mild), and 21.43% of >2 to 10 (moderate). Moreover, a significantly lower cut-off than that of Meng et al. at 6 ng/ml exhibited enhanced sensitivity and specificity of 72.0% and 79.0%, respectively.[6]

The association between PCT and SOFA scores was established by Suranadi et al., who found that the mean SOFA score was 2.279 higher for PCT> 7ng/dL and 5.85±2.7 for PCT<7ng/dL.[12] According to Sarkar D et al.[13], out of the 70 patients in the research, 87.1% had

serum PCT levels greater than 2 ng/mL, while 12.9% had serum PCT levels less than 2 ng/mL. The death rate among the 75 patients was 7.2% with PCT level <2 and 44.3% with PCT level >2. The specificity is 27.7% and the sensitivity is 96.4%. NPV is 92.9% and PPV is 44.2%. Patients with serum PCT levels more than 2 ng/mL had a statistically significant increased death rate than those with serum PCT levels below 2 ng/mL. The survivors' group had a median serum PCT level of 3.54 and a mean of 3.72±2.18. The group of non-survivors had a median serum PCT level of 8.75 and a mean of 8.8±3.80. The group of non-survivors had considerably higher serum PCT levels than the group of survivors.[13]

The current study's results, however, were different from those of Anand et al[14] who found that non-survivors had lower PCT levels than survivors (11.56 vs. 2.015). In their study, Huang P et al[15] examined PCT levels on the first, third, and fifth days of admission. They found that the group of non-survivors had greater serum PCT values than the survivors. Mustafic et al[16] found a strong correlation between the result and serum procalcitonin levels. Additionally, the study found that serum PCT had a 50% sensitivity and a 98.53% specificity in predicting mortality. The study population was split into three groups by Gupta S et al[17]: control, culture positive, and culture negative. In all three groups, non-survivors had greater serum PCT levels than survivors. Since the findings of this study and previous research are comparable, we may draw the conclusion that serum procalcitonin can be used as a prognostic marker in sepsis.

The highest sensitivity was shown 24 hours after the administration of antibiotics, according to Dolatabadi AA et al.[18] evaluation of procalcitonin serum levels in predicting the mortality. Twenty-four hours after starting treatment, the area under the curve for the 6.5 ng/mL cut-off point for serum procalcitonin levels was 0.789 (95% CI 0.717−0.862). It was able to make predictions with 80% specificity and 67% sensitivity.

The current study was limited in several ways. As this study was conducted at a single location, it may have been skewed by selection. Second, serum PCT levels in septic shock patients were only measured at the time of admission; no dynamic assessments of the relationship between PCT levels over time and mortality risk were performed.

CONCLUSION

In patients hospitalized in the intensive care unit, elevated PCT may be a sign of infection risk and is associated with infection-related death. For these patients, daily monitoring of PCT should be considered, which can help in the prompt diagnosis and treatment of infectious diseases.

Author's Contribution:

Concept & Design or acquisition of analysis or interpretation of data:	Anum Qader, Zeeshan Ali
Drafting or Revising Critically:	Shamim Kausar, Saliha Bano
Final Approval of version:	All the above authors
Agreement to accountable for all aspects of work:	All the above authors

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