

## Original Research Article

# Prognostic significance of serum pro-calcitonin level in paediatric intensive care unit patients

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**Received:** 22 March 2023

**Revised:** 14 April 2023

**Accepted:** 19 April 2023

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## ABSTRACT

**Background:** Serum procalcitonin (PCT) is already known predictive marker in serious bacterial infection and it is emphasized that these biomarkers can be used as a marker of increased mortality in critically ill patients. The aim of the study was to evaluate the serial PCT level and find out whether these biomarkers can be used to predict mortality.

**Methods:** This was a prospective observational study. Primary objective was to study the serum PCT as a prognostic marker in critically ill children (2 months to 12 years) admitted in PICU while secondary objective was to find out the association of level of serum procalcitonin with different organ system disease involvement and to compare the results of the serum procalcitonin with the PRISM-3 score in diagnosing the severity of illness in the patient. Patient outcome was assessed at hospital discharge, and the patients were divided into non-survivors and survivors. A p value of <0.05 will be considered statistically significant.

**Results:** A total of 185 patients were enrolled, the median age was 5 years (2 months to 12 years) with 56.76% being males. Majority (34.59%) of patients the primary diagnosis was of respiratory system. The median of serum PCT on day 1, day 3 and day 7 with outcome (p<0.05) in dead was significantly higher as compared to alive. The median PRISM score in dead was 21(13-33) which was significantly higher as compared to alive 11 (8-12.7). Serum PCT and PRISM score had significant discriminatory power to predict mortality.

**Conclusions:** In the present study serum PCT found to be a good prognostic marker for all cause mortality in critically ill patients admitted in PICU.

**Keywords:** PCT, Paediatric, PICU, PRISM

## INTRODUCTION

Procalcitonin (PCT) and C-reactive protein (CRP) are known predictive markers in serious bacterial infections and in critically ill patients these biomarkers can be used as a marker of increased mortality. PCT is a peptide hormone produced by parafollicular cells of thyroid gland and by the neuroendocrine cells in lung and intestine. PCT is commonly used in the early diagnosis of sepsis and infectious diseases.<sup>1-3</sup> Measurement of PCT can be used as a marker of severe sepsis caused by bacteria and generally

grades well with the degree of sepsis.<sup>4,5</sup> PCT is a stable marker than CRP and its concentration is not affected by neutropenia, immunodeficiency conditions and the use of non-steroid and steroid anti-inflammatory drugs.<sup>6</sup> The level of PCT follows the intensity of the inflammatory response and the severity of infection, so the increase in concentration or persistence of high values is considered as a prognostic indicator for severe forms of the disease with an adverse outcome. Currently, PCT assays are widely used in the clinical environment. Previous studies have suggested that patients with infections often have

increased levels of serum PCT level.<sup>7-9</sup> However, there was still no conclusive finding on the prognostic role of serum PCT level in critically ill patients. Patients in intensive care units (ICU) are at higher risk of mortality compared with those in general ward.<sup>10,11</sup> So, measurement of serum PCT on the day of admission may useful as a prognostic marker.

Most of the studies about serum PCT are comparing serum PCT as a prognostic marker either in sepsis in critically ill patients, pneumonia in critically ill patients or some other infection but very less studies are conducted serum PCT as a prognostic marker in critically ill patients in ICU as a general. There are very less studies on the association of level of rise in serum PCT level with different organ system disease. The aim of the study was to see the prognostic significance of serum PCT level in critically ill patients admitted in paediatric intensive care unit (PICU) and to correlate its level with different organ system disease. This study also compare the results with severity as per paediatric risk of mortality (PRISM) 3 scores.

## METHODS

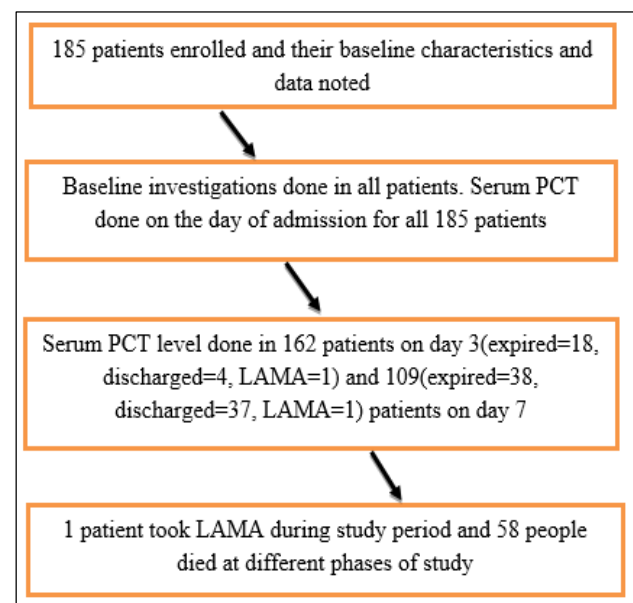
An observational study was conducted over 18 months from October 2018 to March 2020 in the PICU of Vardhman Mahavir Medical College and Safdarjung hospital, a tertiary care teaching hospital, New Delhi in collaboration with microbiology department after obtaining Institutional Ethical Committee's approval (IEC/VMMC/SJH/2020-11/CC-234) and patients were enrolled after receiving the informed written consent of the parents/guardians. Primary objective of the study was to study the serum PCT as a prognostic marker in critically ill children (2 months to 12 years) admitted in PICU based on its level at the time of admission, on day 3 and day 7 while secondary objective was to find out the association of level of serum procalcitonin with different organ system disease involvement and to compare the results of the serum procalcitonin with the PRISM-3 score in diagnosing the severity of illness in the patient. Critically ill children aged 2 months to 12 years admitted in PICU were included in the study, whereas postoperative/surgical patients, children who have been in the PICU prior to study and patients who clinically suspected of autoimmune disorders were excluded. Patient's name, address, contact number were taken, complete general and systemic examination were done. Immediately after admission into PICU serum PCT samples were sent on admission i. e.; day 1 and PRISM 3 score calculated for each patients admitted in PICU. Subsequently serum PCT levels observed on day 3 and day 7 and observed its relationship with different organ system involvement

Serum PCT level was done by BioVendor human PCT ELISA kits with the help of Infinite 200 Pro analyser. A level above 0.5 ng/ml is taken as raised PCT. A total of 185 patients were enrolled, of whom 1 patient took LAMA during study period and 58 people died at different phases of study. Baseline investigations were done in all patients.

Serum PCT was done on the day of admission for all 185 patients while serum PCT level done in 162 patients on day 3 and 109 patients on day 7.

## Statistical methods

Categorical variables will be presented in number and percentage (%) and continuous variables will be presented as mean $\pm$ SD and median. Normality of data will be tested by Kolmogorov-Smirnov test. If the normality is rejected then non-parametric test will be used. Quantitative variables will be compared using unpaired t-test/Mann-Whitney test (when the data sets were not normally distributed) between the survivors and non-survivors. Qualitative variables will be compared using Chi-Square test/Fisher's exact test. Receiver operating characteristic curve will be used to find out cut off point of PCT for predicting mortality. Diagnostic test will be used to calculate sensitivity, specificity, PPV and NPV. Univariate and multivariate cox proportional hazard regression will be used to find out significant risk factors of mortality. A p value of <0.05 will be considered statistically significant. The data will be entered in MS excel spreadsheet and analysis will be done using Statistical Package for Social Sciences (SPSS) version 21.0.



**Figure 1: Flow diagram.**

## RESULTS

A total of 185 patients were enrolled, the median age of the study population was 5 years (2 months-12 years) (Table 1) with 56.76% being males (Figure 2).

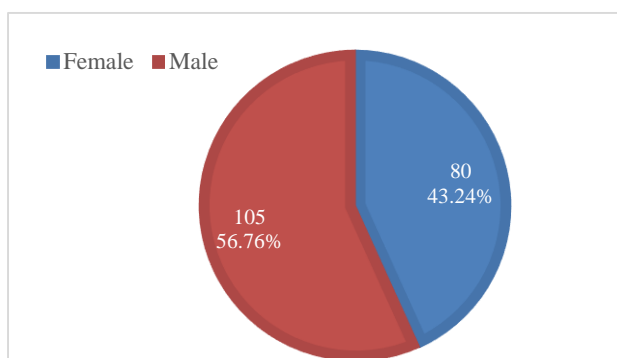
In 34.59% of patients the primary diagnosis was of respiratory system, 16.76% suffered from central nervous system disease, 15.4% suffered from gastrointestinal system, 11.89% of cardiovascular system, 6.49% suffered from multisystem others miscellaneous causes (Table 2).

**Table 1: Distribution of age (years) of study subjects.**

Age (years)	N	%
Up to 5	96	51.89
Above 5	89	48.11
Mean±SD	5.29±3.9	
Median (IQR)	5(1-9)	
Range	0.17-12	

**Table 2: Distribution of organic system involved of study subjects.**

Organic system involved	N	%
Blood	11	5.95
Cardiovascular system	22	11.89
Central nervous system	31	16.76
Endocrine system	8	4.32
Gastrointestinal system	28	15.14
Multisystem	14	7.59
Musculoskeletal system	3	1.62
Renal system	4	2.16
Respiratory system	64	34.59
Total	185	100.00

**Figure 2: Distribution of gender of study subjects.****Table 3: Association of serum PCT (ng/ml) with outcome.**

Serum PCT (ng/ml)	Alive N (%)	Died N (%)	Total N (%)	P value	Test performed
On day 1					
≤0.5 (normal)	12 (80)	3 (20)	15 (100)	<0.0001	Chi square test, 53.485
>0.5 to 2 (mild)	61 (84.72)	11 (15.28)	72 (100)		
>2 to 10 (moderate)	44 (78.57)	12 (21.43)	56 (100)		
>10 (severe)	9 (21.95)	32 (78.05)	41 (100)		
Mean±SD	3.93±5.05	16.68±15.73	7.95±11.39	<0.0001	Mann Whitney test; 1563
Median (IQR)	1.6 (1.2-5)	12 (4.25-24.5)	3 (1.2-8.6)		
Range	0.2-33	0.2-50	0.2-50		
On day 3					
≤0.5 (normal)	52 (96.30)	2 (3.70)	54 (100)	<0.0001	Chi square test, 97.458
>0.5 to 2 (mild)	54 (96.43)	2 (3.57)	56 (100)		
>2 to 10 (moderate)	13 (50)	13 (50)	26 (100)		
>10 (severe)	2 (7.69)	24 (92.31)	26 (100)		
Mean±SD	1.44±2.3	14.14±11.26	4.65±8.13	<0.0001	Mann Whitney test; 356
Median (IQR)	0.8 (0.3-1.5)	14 (7-16)	1.2 (0.3-4.4)		
Range	0.1-16	0.2-46	0.1-46		

Continued.

The overall median of the PCT on day 1, day 3 and day 7 were 3 (1.2-8.6), 1.2 (0.3-4.4) and 0.35 (0.2-2) whereas median of serum PCT on day 1, day 3 and day 7 with outcome ( $p<0.05$ ) in dead was 12 (4.25-24.5), 14 (7-16), and 22 (4-26) which was significantly higher as compared to alive 1.6 (1.2-5), 0.8 (0.3-1.5) and 0.3 (0.2-0.75) respectively (Table 3). The overall median PRISM score was 12 (8-18) but in dead it was 21 (13-33) which was significantly higher as compared to alive 11 (8-12.7). During the study period the patients were divided into 2 groups according to outcome, non-survivor group and survivor group, on discharge 68.11% survived.

No significant association found for age, gender, different organ system involvement with outcome and no significant association found for different organ system involvement and rise of serum PCT level. Serum PCT on day 1, day 3 and day 7 and PRISM score had significant discriminatory power to predict mortality. Interpretation of the area under the ROC curve showed that the performance of serum PCT on day 3 (ng/ml) (AUC 0.928; 95% CI: 0.877 to 0.963) and serum PCT on day 7 (ng/ml) (AUC 0.906; 95% CI: 0.835 to 0.954) were outstanding. Discriminatory power of serum PCT on day 1 (ng/ml) (AUC 0.786; 95% CI: 0.720 to 0.843) and PRISM-3 score (AUC 0.789; 95% CI: 0.722 to 0.845) was acceptable (Table 4). Among all the parameters, Serum PCT on day 3 (ng/ml) was the best predictor of mortality at cut off point of >3.2 with 92.80% chances of correctly predicting mortality (Figure 3). On comparing area under curve of serum PCT at different time intervals with PRISM-3 score for predicting mortality, serum PCT on day 3 and day 7 had significantly higher area under curve as compared to PRISM-3 score and on the other hand, area under curve of serum PCT on day 1 was comparable with PRISM-3 score (Figure 4). With the increase in serum PCT on day 1, day 3 and day 7 and PRISM-3 score, risk of mortality significantly increased with a hazard ratio of 5.789, 24.22, 23.575 and 5.352 respectively (Table 5).

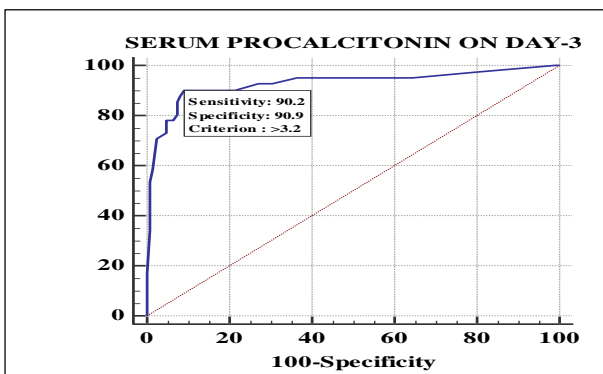
Serum PCT (ng/ml)	Alive N (%)	Died N (%)	Total N (%)	P value	Test performed
<b>On day 7</b>					
≤0.5(normal)	59 (96.72)	2 (3.28)	61 (100)	<0.0001	Fisher's exact test
>0.5 to 2 (mild)	21 (91.30)	2 (8.70)	23 (100)		
>2 to 10 (moderate)	5 (62.50)	3 (37.50)	8 (100)		
>10 (severe)	2 (12.50)	14 (87.50)	16 (100)		
Mean±SD	1.37±4.86	19.28±14.93	4.85±10.55	<0.0001	Mann Whitney test;171
Median (IQR)	0.3 (0.2-0.75)	22 (4-26)	0.35 (0.2-2)		
Range	0.1-40	0.2-44	0.1-44		

**Table 4: Receiver operating characteristic curve of serum PCT at different time intervals and PRISM-3 score for predicting mortality.**

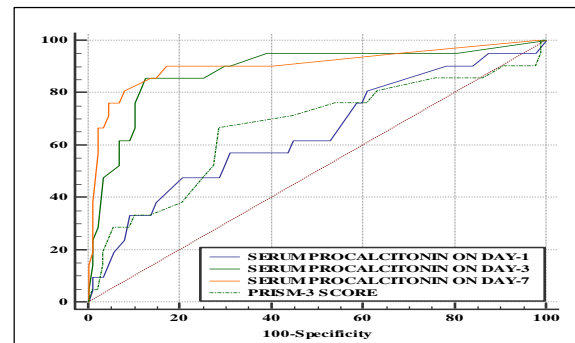
For predicting mortality	Serum PCT on day 1 (ng/ml)	Serum PCT on day 3 (ng/ml)	Serum PCT on day 7 (ng/ml)	PRISM-3 score
Area under the ROC curve (AUC)	0.786	0.928	0.906	0.789
Standard error	0.0402	0.0296	0.0464	0.0393
95%CI	0.720 to 0.843	0.877 to 0.963	0.835 to 0.954	0.722 to 0.845
P value	<0.0001	<0.0001	<0.0001	<0.0001
Cut off	>6	>3.2	>1	>12
Sensitivity (95%CI)	72.41% (59.1-83.3)	90.24% (76.9-97.3)	90.48% (69.6-98.8)	77.59% (64.7-87.5)
Specificity (95%CI)	79.37% (71.2-86.1)	90.91% (84.3-95.4)	82.76% (73.2-90.0)	74.6% (66.1-81.9)
PPV (95%CI)	61.8% (49.27-73.3)	77.1% (62.7-88.0)	55.9% (37.9-72.8)	58.4% (46.6-69.6)
NPV (95%CI)	86.2% (78.6-91.9)	96.5% (91.3-99.0)	97.3% (90.6-99.7)	87.9% (80.1-93.4)
Diagnostic accuracy (%)	77.17	90.74	84.26	75.54

**Table 5: Multivariate Cox proportional hazard regression to find out significant risk factors of mortality.**

Variables	Beta coefficient	Standard error	P value	Hazards ratio	Hazard ratio lower bound (95)	Hazard ratio upper bound (95)
<b>Serum PCT on day 1 (ng/ml)</b>						
≤6				1.000		
>6	-0.586	0.465	0.208	0.556	0.224	1.385
<b>Serum PCT on day 3 (ng/ml)</b>						
≤3.2				1.000		
>3.2	0.035	1.067	0.974	1.035	0.128	8.383
<b>Serum PCT on day 7 (ng/ml)</b>						
≤1				1.000		
>1	3.377	1.340	.012	29.286	2.118	404.883
<b>PRISM</b>						
≤12				1.000		
>12	0.136	0.488	0.781	1.146	0.440	2.980



**Figure 3: Receiver operating characteristic curve of serum PCT on day 3 for predicting mortality.**



**Figure 4: Comparison of receiver operating characteristic curve of serum PCT at different time intervals and PRISM-3 score for predicting mortality.**



## DISCUSSION

There is an increasing body of literature using PCT in the adults generally but in paediatric population the data is very limited and confined to the specific population like febrile neutropenia, sepsis, paediatric urinary tract infections, pneumonias etc. Usage of PCT is limited to neonatal sepsis and neonates post-cardiopulmonary bypass for surgical correction or palliation from congenital heart disease.<sup>12,13</sup> Most of the studies on this are retrospective studies although few prospective studies do exist in literature. In the study from day 1 to day 7 on serial evaluation of serum PCT it was found that in survivor's serum PCT value gradually improved when compared with the non-survivors. On performing univariate cox proportional hazard ratio, serum PCT on day 1, day 3 and day 7 were significant risk factors of mortality. With the increase in serum PCT on day 1, day 3, and day 7 risk of mortality significantly increased with hazard ratio of 5.789, 24.22 and 23.572 respectively, these findings match with the earlier studies of Meng et al and Cleh et al on contrary some did not find PCT to predict mortality.<sup>14-19</sup>

High median value of serum PCT on day 1 is 3 ng/ml and on day 7 is 0.35 ng/ml which is slightly lower than the results seen in study by Jain et al which was 5.4 ng/ml on day 1 and 3.1 ng/ml on day 7.<sup>20</sup> It was observed that serum PCT level decreased significantly in survivors over the course of 7 days than non survivors contrast to course of 28 days in study of Jain et al. Whereas study conducted by Jensen et al found that a high maximum PCT level and a pro-calcitonin increase for 1 day are early independent predictors of all-cause mortality during a 90-day follow-up period after ICU admission. Mortality risk increases for every day that PCT increases.

In the study of Meng et al on the day of admission PCT (day1) with ranges of <2, 2-10 and 10 ng/ml showed 6.25%, 8.75% and 75% mortality respectively over 28 days hospital course and a cut-off of serum PCT >10 ng/ml showed a sensitivity and specificity of 75 and 66 respectively and PPV and NPV were 57.1% and 81.8% whereas in this study relatively higher levels of mortality in mild, moderate and severe levels of serum PCT on day 1 was found. Proportion of died patients was 78.05% of >10 (severe). Serum PCT (ng/ml) which was significantly higher as compared to 20% of  $\leq 0.5$  (normal); serum PCT (ng/ml); 15.28% of >0.5 to 2 (mild); serum PCT (ng/ml) and 21.43% of >2 to 10 (moderate), serum PCT (ng/ml) and a cut-off of much lesser than Meng et al at 6 ng/ml showed higher sensitivity and specificity of 72 and 79, the same reflects in the PPV and NPV.

In the study serum PCT on day 1, day 3 and day 7 all of them found have significant discriminatory power to predict the mortality individually in critically ill children with a  $p < 0.005$ . All of the day 1, day 3 and day 7 serum PCT had significant discriminatory power to predict mortality. Interpretation of the area under the ROC curve

showed that the performance of serum PCT on day 3 (ng/ml) and serum PCT on day 7 (ng/ml) was outstanding. Discriminatory power of serum PCT on day 1 (ng/ml) acceptable. Among all the parameters, serum PCT on day 3 (ng/ml) was the best predictor of mortality at cut off point of >3.2 with 92.80% chances of correctly predicting mortality. These results of study were similar to the study conducted by Jain et al showing the level of PCT decreased significantly in survivors over 28 days. The median of PCT fell from 5.4 ng/ml on day 1 to 3.1 ng/ml on day-7 ( $p=0.002$ ) to 0.1 ng/ml on day-28 ( $p=0.01$ ). Another study conducted by Scheutz et al showed inability to decrease PCT by at least 80% is a significant independent predictor of mortality and may aid in sepsis care.<sup>21</sup>

Study conducted by Costa et al showed PRISM score showed adequate discriminatory capacity and calibration and thus constitutes a useful gizmo for the assessment of prognosis for paediatric patients admitted to a tertiary PICU with a median value of 15 in deaths and ROC curve yielded a value of 0.76 (CI 95% 0.69-0.83)  $p < 0.0001$  whereas our study showed a median value of slightly higher of 21 and acceptable discriminatory capacity and calibration for the assessment of prognosis in PICU patients ( $p < 0.0001$ ) and showed satisfactory discriminatory performance in differentiating survivors from non-survivors, supporting the conclusion that higher PRISM scores are correlated with increased risk of death, similar other studies.<sup>22-27</sup> Martha et al evaluated the PRISM scores of 421 patients and showed good discriminatory performance with proper calibration.<sup>23</sup> Brakel et al and Leuteurtre et al showed that the PRISM score provides good discriminatory power for patients with meningococcal disease and in children with meningococcal septic shock.<sup>25,26</sup>

In most of the studies PCT used as a marker of bacterial infection, sepsis, pneumonias but no study conducted regarding in which organ system involvement rises serum PCT level. In the study, on day 1 there is no significant association in distribution of organ system involvement. Significant association was seen in serum PCT on day 3 with organic system involved ( $p$  value < 0.05). Respiratory system involvement showed the highest increase in serum PCT elevation on day 3 followed by multisystem involvement and central nervous system. On day 7 statistically no significant association was seen between serum PCT and organ system involvement. So overall there is no significant association between the rise of serum PCT level and organ system involvement.

On comparing serum PCT on day 1, day 3 and day 7 with the PRISM score it was found that all of the parameters have significant discriminatory power ( $p < 0.005$ ). Serum PCT on day 3 and day 7 had significantly higher area under curve as compared to PRISM-3 score and on the other hand, area under curve of serum PCT on day 1 was comparable with PRISM-3 score. New evidences that came up in the study are (i) PRISM score found to be less effective than serum PCT on day 3 and day 7 in predicting

the mortality in critically ill PICU patients; (ii) no significant evidence found in rise in serum PCT level and different organ system involved; and (iii) serial PCT monitoring predicts mortality better than single day serum PCT.

Strength of the study are (i) this study was done in exclusively PICU patients thereby excluding postsurgical and trauma cases which have been shown to spuriously increase the level of PCT; (ii) prospective study; and (iii) PCT repeated at regular intervals to determine the trend in the course of PCT. While limitations are (i) single centre study; (ii) levels of PCT were measured using an ELISA based assay which is relatively less sensitive than time resolved amplified cryptate emission technology in which duration of assay is rapid but expensive; and (iii) levels of PCT were measured only at 3 points in the course of study and also levels of PCT of some patients could not be compared on serial measurement due to early mortality.

## CONCLUSION

In the present study serum PCT found to be a good prognostic marker for all-cause mortality in critically ill patients admitted in PICU. Serum PCT on day 3 with a cut-off of >3.2 ng/ml found to be the best predictor with a 92.80% chances of correctly predicting the mortality among all of them. When compared with PRISM score serum PCT on day 3 and day 7 found to be superior in predicting mortality. No significant association found between serum PCT and different organ system involved. Further studies required to establish guidelines for serum PCT as a prognostic marker in PICU critically ill patients.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Kumar PS, Kumar A, Belagodu MN, Gera R. Prognostic significance of serum procalcitonin level in paediatric intensive care unit patients. *Int J Contemp Pediatr* 2023;10:721-7.