ISSN: 0975-3583,0976-2833 VOL14, ISSUE 07, 2023

TO STUDY EVALUATION OF SERUM PROCALCITONIN FOR DIAGNOSIS OF SEPSIS: PROSPECTIVE OBSERVATIONAL STUDY

Dr. Dumpa Ravindra Reddy¹, Dr. Pardhasaradhi Jampani^{2*}

¹Assistant Professor, Department of General Medicine, Katuri Medical College and Hospital, Guntur, Andhra Pradesh, India

²Assistant Professor, Department of General Medicine, Katuri Medical College and Hospital, Guntur, Andhra Pradesh, India

<u>*Corresponding Author</u>: Dr. Pardhasaradhi Jampani,

Assistant professor, Department of General Medicine, Katuri Medical College and Hospital, Guntur, Andhra Pradesh, India

ABSTRACT

Background and objective: Sepsis is a major public health issue. Accurately identifying the origin of sepsis in patients is frequently impossible. There is a need for a reliable and accurate biochemical marker to support or rule out bacterial illness. The study's goals were to determine the diagnostic usefulness of serum procalcitonin in Sepsis patients. To see if procalcitonin levels affect the prognosis of Sepsis patients.

Materials & Methods: From February, 2022 to January, 2023, conducted at Department of General Medicine, Katuri Medical College and Hospital, Guntur, Andhra Pradesh, India, our tertiary care center conducted a prospective observational research. The study comprised a total of 50 patients. All patients over the age of 18 who presented to our hospital with acute Sepsis during the study period were included in the study sample. The study excluded patients with heart illness, recent surgery, trauma, or malignancies.

Results: Procalcitonin was found in 78% of the participants and was statistically significant between groups. The difference in mean procalcitonin levels between sepsis, severe sepsis, and septic shock was statistically significant. A statistically significant difference in mean procalcitonin levels between patients who died and those who survived was 43.78ng/mL versus 6.22ng/mL. The most common cause of sepsis was a respiratory tract infection.

Conclusion: Serum Procalcitonin appears to be a helpful diagnostic sign of sepsis as well as a marker of sepsis severity. It was also discovered to be a valuable marker in predicting the fate of sepsis patients.

Keywords: Serum Procalcitonin, diagnosis, sepsis, prospective observational study

INTRODUCTION

Sepsis, also known as the inflammatory response of the host to an infection, is one of the main causes of death and disability on a global scale. The data collected over the past few years indicate that there are around 18 million instances of sepsis each year, with a mortality rate of approximately 30 percent [1]. Despite the enormous advances that have been made in the treatment of sepsis, the disease is becoming more common, and the mortality rate associated with it has not changed significantly. Longevity in patients who have chronic diseases, the use of indwelling catheters, inappropriate use of antimicrobials, and the utilization of mechanical devices are all factors that contribute to this phenomenon. Patients that get sepsis and the results that they go on to experience are very different from one another [2, 3].

The Sepsis Campaign brought attention to how serious of a problem this is. When treating patients, medical professionals frequently fail to detect the symptoms of sepsis since there is no universally accepted description of the condition. This is especially problematic in light of the compelling evidence suggesting that early therapy is associated with improved clinical results [4]. The International Surviving Sepsis Campaign (SSC) issued its initial set of guidelines for sepsis in 2004, with an update coming out in 2008. The major objective of the SSC is to reduce mortality rates by fifty percent within the next five years. The SSC guidelines for the management of severe sepsis are based on studies that demonstrate large life saves can be achieved with the utilization of very modest therapeutic measures [5, 6].

There has never been a time when early diagnosis and treatment of sepsis were more important than they are now. Findings from the clinical examination as well as those from the laboratory, such as the C-reactive protein level and the white blood cell count, are utilized combined to make a diagnosis of sepsis today. Because of their limited sensitivity and specificity, standard clinical and laboratory tests are not sufficient as early infection markers. This is the case even when these tests are available. In addition to the more usual types of indicators, procalcitonin has been suggested as a potential additional infection biomarker. Procalcitonin, rather than C.R.P., may be a better indicator of bacterial infection in critically ill patients, according to a number of studies. In spite of these findings, one of the most important questions that has to be answered in diagnostic research is whether or not procalcitonin significantly contributes to the discriminative qualities of the set of diagnostic markers that is already being used [7, 8].

There is growing evidence that procalcitonin can assist clinicians make more accurate diagnoses of bacterial infections and guide them toward the most effective antibiotic treatment options, particularly in the situations of respiratory tract infections and sepsis. This is especially true in cases where the patient is already in critical condition. It is necessary to identify and prospectively validate procalcitonin cut-off values for pathogenic species; however, this cannot be done without more interventional research [9]. For a safe and risk-free application of procalcitonin in clinical practice, it is essential to have a solid understanding of both the benefits and the drawbacks of this hormone. In addition, there has only been a limited amount of research conducted in India on the role that serum procalcitonin plays in sepsis. Because the expression of serum procalcitonin may also depend on the genetic makeup of the people living in this region, additional research is required before it can be demonstrated beyond a reasonable doubt that it is effective in this area. As a result, determining whether or not serum procalcitonin is effective in treating sepsis is the reason for conducting this inquiry [8-10].

MATERIALS AND METHODS

From February, 2022 to January, 2023, conducted at Department of General Medicine, Katuri Medical College and Hospital, Guntur, Andhra Pradesh, India, our tertiary care center conducted a prospective observational research. The study comprised a total of 50 patients. All patients over the age of 18 who presented to our hospital with acute Sepsis during the study period were included in the study sample. The study excluded patients with heart illness, recent surgery, trauma, or malignancies.

Inclusion Criteria:

- Positive sputum culture results with supported radiological findings in the clinical presentation of pneumonia.
- Urine culture and clinical manifestation of urinary tract infection.

- A healthy blood culture.
- Any other illness with diagnostic sepsis-compatible clinical and laboratory results.

Exclusion Criteria:

- Patients who have mesenteric embolism, severe burns, acute pancreatitis, or acute appendicitis.
- Patients receiving treatment with TNF-inhibitors, interleukins, or OKT3 antibodies.
 - Patients who have severe or protracted cardiogenic shock.
 - Patients having recent histories of trauma, surgery, cancer, or dialysis.

Statistical methods used

In this investigation, both descriptive and inferential statistics were used. The significance of the continuous research parameters between the two groups was determined using the Student t test for metrics. Fisher's Exact/Chi-Square, the exact test has been used to determine whether or not there is a statistically significant difference between two or more groups for categorical research parameters.

RESULTS

With a sensitivity of 90-96%, serum procalcitonin is an established marker of sepsis that has been examined extensively in populations other than India. This is why we decided to investigate the role of Serum Procalcitonin in our hospital's diagnosis of sepsis. Serum procalcitonin predictive value for sepsis patients will also be elucidated by the study.

Sr. No.	Age in years	Patients
1.	18 to 30	8
2.	31 to 40	9
3.	41 to 50	12
4.	51 to 60	10
5.	61 to 70	6
6.	71 to 80	4
7.	>80	3
	Total	50

Table 1: Age distribution of patients studied

Table 1 indicating the age wise distribution of patients included in this study. Large group of the patients observed for the 41 to 50 and 51 to 60 age group of the patients and observed less number of the patients in the age group of above 71.

Table 2. Gender distribution of patients studied			
Sr. No.	Gender	Patients	%
1.	Male	32	64.0
2.	Female	18	36.0
	Total	50	100.0

Table 2: Gender distribution of patients studied

Table 2 comprising with the gender distribution of patients studied. 32 was the male and 18 was the female included in this study.

Table 3: Co-morbid Condition of patients studied		
r. No.	Co-morbidCondition	Patients (n=50)

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 07, 2023

1.	HTN	48
2.	DM	44
3.	IHD	21
4.	BA	15
5.	CVA	11
6.	Hypothyroidism	6

Table 3 consist of the Co-morbid condition of patients studied. It was observed highest for the HTN and DM as compared to the others.

Table 4. I resenting Symptoms of patients studied			
Sr. No.	Presenting Symptoms	Patients (n=50)	
1.	Fever	35	
2.	Breathlessness	36	
3.	Cough	34	
4.	Altered Sensorium	26	
5.	Loose Stools	19	
6.	Decreased Urine Output	reased Urine Output 21	
7.	Pain Abdomen	16	

Table 4: Presenting Symptoms of patients studied

Table 4 presenting the data on symptoms of patients studied in this study. As per the different symptoms 35 was suffering from fever, 36 breathlessness, 34 of cough, 26 altered sensorium, 19 loose stools, 21 of decreased urine output and 16 of pain abdomen.

Sr. No.	Vital parameter	Patients(n=50)	
1.	Pulse		
	Normal	26	
	Tachycardia	24	
2.	2. BP		
	Normal	11	
	Hypotension	09	
	Vasopressorsupport	30	
3.	RR		
	Normal	4	
	Tachypnea	46	
4.	Temperature		
	Normal	20	
	Elevated	30	

Table 5: Vital parameter of patients studied

Table 5 consist of the vital parameter of patients studied in this study. With Tachycardia 24 patients, with Hypotension 09, with Vasopressor support 30 and with Tachypnea 46 patients was observed.

Table 0. Diagnosis of patients studied			
Sr. no.	Diagnosis	Patients	%
1.	Sepsis	17	34.0
2.	Severe sepsis	20	40.0
3.	Septic shock	13	26.0
	Total	50	100.0

Table 6: Diagnosis of patients studied

Table 6 showing the patients with the sepsis 17, severe sepsis 20, and septic shock 13.

DISCUSSION

The sensitivity of serum procalcitonin as a diagnostic marker of sepsis is 90-96%, and it has been investigated extensively in populations other than those in India. Therefore, this hospital-based study examined the efficacy of Serum Procalcitonin in identifying cases of sepsis. Serum procalcitonin's predictive value for sepsis patients will also be elucidated by the study. Males were more likely to be impacted by sepsis than females were in this study. There were 63 men and 37 females among the total 50 patients. There is no evidence of a gender gap in any of our sample populations [11]. Martin et al. found that men account for 48.1% of the annual cases of sepsis. Sepsis is more likely in males, according to data collected by Todi and colleagues from a multicentral trial conducted at 12 sites in India [11].

Hypertension was the most common co morbid condition in our study group, affecting 57% of patients with a significant p value. Diabetes Mellitus was the second most common co morbid condition, affecting 45% of patients. The prevalence of diabetes was 38% in Lai's et al.'s study population. The participants were classified into mild sepsis, severe sepsis, and septic shock groups according to ACCP/SCCM criteria. Thirty-four patients were classified as having sepsis, forty as having severe sepsis, and twenty-six as having septic shock [10-13].

In our sample, fever was the most prevalent initial symptom, followed by difficulty breathing. In our study population, fever was the primary symptom in 73.5% of the sepsis group, 77.5% of the severe sepsis group, and 53.8% of the septic shock group. Fever may not appear in diabetics with sepsis because they are unable to establish a proper immunological response4. However, no statistically significant differences in presenting symptoms, such as fever, were seen between the study groups. Tachypnoea was the most common symptom of SIRS in our study, occurring in 97 individuals (97.7%). Seventy-five percent of patients displayed tachycardia, and 66 percent of patients exhibited hypotension, with 22 percent of the study group requiring the use of vasopressors. Eighty percent of patients had an increased white blood cell count, whereas four percent had a decreased one. There was no statistically significant difference in any of the SIRS variables between the different sepsis groups [14-16].

Septic shock and severe sepsis were compared using the Sequential Organ Failure Assessment (SOFA) score in our study. The overall group's mean SOFA score is 2.03. A SOFA score of 1.23-1.29 was seen in patients with severe sepsis. The SOFA score is 5.923.96 in patients with septic shock. Significant statistical significance is shown between SOFA score levels and the diagnosis of severe sepsis and septic shock. Serum procalcitonin concentrations were found to be considerably greater in patients with higher SOFA scores. Meisner et al., Vincent et al., and Moreno et al. all came to similar conclusions in their own research [17-19].

The majority of participants (78%) tested positive for serum procalcitonin, while 22% tested negative. 35.3 percent of the sepsis group, 100% of the severe sepsis group, and 100% of the septic shock group tested positive. Procalcitonin was statistically linked to the conditions of severe sepsis and septic shock. The consistent clinical manifestations of sepsis lend credence to Serum Procalcitonin's value as a diagnostic marker across sepsis subtypes. Our findings suggest that procalcitonin may be useful as a measure of sepsis severity because its levels were seen to rise in tandem with the severity of the disease [20]. It is generally recognized that the prognosis worsens with increasing sepsis severity. Our analysis found that there was a 58% death rate overall.Septic shock was 100%, severe sepsis 75%, and sepsis 5.9%. The outcome was linked to sepsis classifications in a statistically meaningful way. The median

serum procalcitonin concentration in those who did not make it was 6.22ng/ml, while it was 43.78ng/ml in those who did. The correlation between the two was determined to be statistically significant. Patients with higher Serum Procalcitonin levels had a worse prognosis than those with lower levels. There is some evidence that serum procalcitonin can be utilized as a prognostic marker in sepsis. Acute myocardial infarction did not prove fatal for any of our research participants [21-23].

The clinical implications of our findings are significant. While the current study sample is too small to draw firm conclusions about the significance of serum PCT in critical care, the results do suggest that serum PCT may be added to the battery of infections to aid in the management of sepsis in intensive care units. First, serum PCT gives a high level of accuracy that other existing tests for sepsis on ICU entry do not. Although the serum PCT reference range's accuracy isn't ideal, it can help doctors make clinical decisions and plan out the complex, time-sensitive therapy of critically unwell patients with sepsis. In addition to providing useful information before culture results are available, the test can be completed in only 30 minutes [24-26].

In conclusion, individuals aged >50 years and males had a greater prevalence of sepsis. The most common trigger for sepsis was a respiratory tract infection. In severely unwell patients, serum PCT was found to be a highly accurate predictor of sepsis. Our findings suggest that clinical factors have little diagnostic utility for making an admission diagnosis of sepsis. It indicates that serum procalcitonin can help in both the diagnosis of sepsis and the evaluation of the severity of sepsis. It was also discovered to be a helpful marker for determining the prognosis of sepsis patients [25-27].

CONCLUSION

Our findings suggest that the diagnostic utility of clinical factors in sepsis is limited. Therefore, the diagnostic certainty can be increased by adding a marker such as Serum Procalcitonin to the usual work up of patients with sepsis. Patients' prognoses could be accurately predicted with the aid of serum procalcitonin, which was also useful in determining the severity of sepsis. Our research shown that serum Procalcitonin is an effective and inexpensive marker for the detection and monitoring of sepsis.

Funding

None

Conflict of Interest None

REFERNCES

- 1. Slade E, Tamber PS, Vincent JL. The Surviving Sepsis Campaign: Raising awareness to reduce mortality. *Crit care* 2007:7: 1-2.
- 2. Jain S, Sinha S, Sharma SK, Samantaray JC, Aggrawal P, Vikram NK, Biswas A, Sood S, Goel M, Das M, Vishnubhatla S. Procalcitonin as a prognostic marker for sepsis: a prospective observational study. BMC research notes. 2014 Dec;7(1):1-7.
- 3. Dellinger RP, Carlet JM, Masur H Gerlach H, Calandra T, Cohen J, et al. Surviving Sepsis Campaign guidelines for management of severe sepsis and septic shock. *Intensive care Med* 2007: 30: 536-55.
- 4. Dellinger RP, Levy MM, Carlet JM, Bion J, Parker MM, Jaeschke R, et al. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock. *Intensive care Med* 2008:34: 17-60.

- 5. Martin PS, Brunialti MK, da Luz Fernandes M, Martos LS, Gomes NE, Rigato O. Bacterial recognition and induced cell activation in sepsis. *Endocr Metab ImmuneDisord Drug Targets* 2006: 6: 183-91.
- 6. Castellheim A, Brekke Ol, Espevik T, Harboe M, Mollnes TE. Innate immune responses to danger signals in systemic inflammatory response syndrome an sepsis. *Scand J Immunoll* 2009: 69: 479-91.
- 7. Ahmed S, Siddiqui I, Jafri L, Hashmi M, Khan AH, Ghani F. Prospective evaluation of serum procalcitonin in critically ill patients with suspected sepsis-experience from a tertiary care hospital in Pakistan. Annals of medicine and surgery. 2018 Nov 1;35:180-4.
- 8. Chan YL, Tseng CP, Tsay PK, Chang SS, Chiu TF, Chen JC. Procalcitonin as a marker of bacterial infection in the emergency department: an observational study. Critical Care. 2003 Feb;8(1):1-9.
- 9. Thanachartwet V, Desakorn V, Sahassananda D, Jittmittraphap A, Oer-Areemitr N, Osothsomboon S, Surabotsophon M, Wattanathum A. Serum procalcitonin and peripheral venous lactate for predicting dengue shock and/or organ failure: a prospective observational study. PLoS neglected tropical diseases. 2016 Aug 26;10(8):e0004961.
- Ryoo SM, Han KS, Ahn S, Shin TG, Hwang SY, Chung SP, Hwang YJ, Park YS, Jo YH, Chang HL, Suh GJ. The usefulness of C-reactive protein and procalcitonin to predict prognosis in septic shock patients: A multicenter prospective registry-based observational study. Scientific reports. 2019 Apr 29;9(1):6579.
- 11. Guidet, Bertrand, Aegerter, Philippe, Gauzit, Remy et al. Incidence and impact of organ dysfunction associated with sepsis. *The Cardiopulmonary And Critical Care Journal* 2005:127: 942-51.
- 12. Karlsson S, Heikkinen M, Pettilä V, Alila S, Väisänen S, Pulkki K, Kolho E, Ruokonen E, Finnsepsis Study Group. Predictive value of procalcitonin decrease in patients with severe sepsis: a prospective observational study. Critical Care. 2010 Dec;14:1-0.
- 13. Mokline A, Garsallah L, Rahmani I, Jerbi K, Oueslati H, Tlaili S, Hammouda R, Gasri B, Messadi AA. Procalcitonin: a diagnostic and prognostic biomarker of sepsis in burned patients. Annals of burns and fire disasters. 2015 Jun 6;28(2):116.
- 14. Schuetz P, Albrich W, Mueller B. Procalcitonin for diagnosis of infection and guide to antibiotic decisions: past, present and future. BMC medicine. 2011 Dec;9(1):1-9.
- 15. Calandra T, Cohen J. International Sepsis Forum Definition of Infection in the ICU Consensus Conference. The international sepsis forum consensus conference on definitions of infection in the intensive care unit. Critical Care Med. 2005;33: 1538–48.
- 16. Garcia-Granero A, Frasson M, Flor-Lorente B, Blanco F, Puga R, Carratalá A, Garcia-Granero E. Procalcitonin and C-reactive protein as early predictors of anastomotic leak in colorectal surgery: a prospective observational study. Diseases of the colon & rectum. 2013 Apr 1;56(4):475-83.
- 17. Bargues L, Chancerelle Y, Catineau J, Jault P, Carsin H. Evaluation of serum procalcitonin concentration in the ICU following severe burn. Burns. 2007 Nov 1;33(7):860-4.
- 18. Venkatesh B, Kennedy P, Kruger PS, Looke D, Jones M, Hall J, Barruel GR. Changes in serum procalcitonin and C-reactive protein following antimicrobial therapy as a guide to antibiotic duration in the critically ill: a prospective evaluation. Anaesthesia and intensive care. 2009 Jan;37(1):20-6.
- 19. Venkatesh B, Kennedy P, Kruger PS, Looke D, Jones M, Hall J, Barruel GR. Changes in serum procalcitonin and C-reactive protein following antimicrobial therapy as a guide to antibiotic duration in the critically ill: a prospective evaluation. Anaesthesia and intensive care. 2009 Jan;37(1):20-6.
- 20. Huang MY, Chen CY, Chien JH, Wu KH, Chang YJ, Wu KH, Wu HP. Serum procalcitonin and procalcitonin clearance as a prognostic biomarker in patients with

severe sepsis and septic shock. BioMed research international. 2016 Jan 1;2016.

- 21. Sudhir U, Venkatachalaiah RK, Kumar TA, Rao MY, Kempegowda P. Significance of serum procalcitonin in sepsis. Indian journal of critical care medicine: peer-reviewed, official publication of Indian Society of Critical Care Medicine. 2011 Jan;15(1):1.
- 22. Casado-Flores J, Blanco-Quirós A, Asensio J, Arranz E, Garrote JA, Nieto M. Serum procalcitonin in children with suspected sepsis: a comparison with C-reactive protein and neutrophil count. Pediatric Critical Care Medicine. 2003 Apr 1;4(2):190-5.
- 23. Hausfater P, Juillien G, Madonna-Py B, Haroche J, Bernard M, Riou B. Serum procalcitonin measurement as diagnostic and prognostic marker in febrile adult patients presenting to the emergency department. Critical care. 2007 Jun;11:1-9.
- 24. Ichihara K, Tanaka T, Takahashi S, Matsukawa M, Yanase M, Kitamura H, Masumori N. Serum procalcitonin level in chronic hemodialytic patients with no evidence of bacterial infection. Renal Replacement Therapy. 2016 Dec;2(1):1-6.
- 25. Theodorou VP, Papaioannou VE, Tripsianis GA, Panopoulou MK, Christophoridis EK, Kouliatsis GA, Gioka TM, Maltezos ES, Ktenidou-Kartali SI, Pneumatikos IA. Procalcitonin and procalcitonin kinetics for diagnosis and prognosis of intravascular catheter-related bloodstream infections in selected critically ill patients: a prospective observational study. BMC infectious diseases. 2012 Dec;12:1-0.
- 26. Lee S, Song J, Park DW, Seok H, Ahn S, Kim J, Park J, Cho HJ, Moon S. Diagnostic and prognostic value of presepsin and procalcitonin in non-infectious organ failure, sepsis, and septic shock: a prospective observational study according to the Sepsis-3 definitions. BMC infectious diseases. 2022 Jan 4;22(1):8.
- 27. Wu JY, Lee SH, Shen CJ, Hsieh YC, Yo PH, Cheng HY, Chan RC, Lee CC, Chang SS. Use of serum procalcitonin to detect bacterial infection in patients with autoimmune diseases: A systematic review and meta-analysis. Arthritis & Rheumatism. 2012 Sep;64(9):3034-42.