Study of Importance of Serum Pro Calcitonin as a Marker in Patients of Sepsis

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Abstract:-

➢ *Context*:

Sepsis is widely recognized as a significant global health issue. Identifying the cause of sepsis is a highly challenging task. It is crucial to identify biomarkers that are both accurate and effective in order to support or rule out a clinical diagnosis of bacterial illness. Serum Procalcitonin has been identified as a biomarker for sepsis. However, there is a scarcity of available studies to substantiate this claim. Therefore, this investigation was conducted with respect to this matter.

➢ *Objective* :

- **To identify the diagnostic value of Serum Pro calcitonin in patients suffering with sepsis.**
- **To assess if Pro calcitonin levels have a bearing on prognosis of patients with Sepsis.**

➢ *Settings & Design*:

The cross-sectional study was carried out at Katuri Medical College and Hospital in Guntur, from June 2022 to December 2022, spanning a period of 6 months. This study had a cohort of 100 patients. This study included exclusively adult patients, aged 18 years and above, who presented with acute sepsis. The study excludes patients who have a documented history of cardiac involvement, recent surgery, cancer, or trauma.

➢ *Materials & Methods*:

The study group conducts investigations on PROCALCITONIN and other related factors. The individuals were categorized into three distinct groups, namely Sepsis, Severe Sepsis, and Septic Shock. The statistical analysis was conducted using SPSS 15.0. The Fisher exact test and Chi-square test were utilized.

➢ *Results*:

The presence of PROCALCITONIN was detected in 78% of the subjects, and there was a statistically significant difference between the groups (p = 0.015). The mean values of PROCALCITONIN in sepsis, severe sepsis, and septic shock were 1.50ng/mL, 13.49ng/mL, and 55.66ng/mL, respectively. These differences were statistically significant with a p-value of less than 0.001. The average levels of PROCALCITONIN in patients who died were 43.78ng/mL, while in those who lived, the average levels were 6.22ng/mL. This difference is statistically significant (p<0.001). The most prevalent cause of sepsis was determined to be respiratory tract infection.

➢ *Conclusion*:

Serum Procalcitonin is a valuable diagnostic indicator for sepsis and is also effective in evaluating the seriousness of sepsis. Furthermore, it was discovered to be a valuable tool in forecasting the prognosis of individuals suffering from sepsis.

I. INTRODUCTION

Sepsis is a condition characterized by a severe and sometimes fatal inflammatory reaction of the body to infection, leading to organ failure and death, and causes considerable illness and death rates. Sepsis poses a significant strain on the healthcare system of any nation. The incidence rates of sepsis have reached up to 535 cases per 100,000 person-years and are currently increasing. The mortality rate within the hospital setting remains elevated, ranging from 25 to 30%. The bulk of these cases are seen in countries with low and moderate incomes (LMICs) [4]. A multicentre study unveiled a significant death rate associated with sepsis in Southeast Asia. There is a scarcity of data concerning sepsis in Sri Lanka. Recent data indicate an annual incidence of 18 million new cases of sepsis, with a death rate of 30%.One The global prevalence of sepsis is increasing, but the fatality rate remains high despite the continuous progress in sepsis care. One contributing factor to this is the demographic trend of an aging population, as

well as the longer lifespan of individuals with chronic illnesses. Additionally, the use of indwelling catheters, improper use of antimicrobial drugs, and mechanical devices also play a role.Two

The field of sepsis has undergone continuous progress and improvement in recent decades. Despite advancements in our comprehension of the etiology, pathophysiology, and immunological mechanisms of sepsis over the past thirty years, our ability to effectively and specifically treat the condition is limited or non-existent. Timely fluid resuscitation and early delivery of broad-spectrum antibiotics are the only interventions that have been proven to decrease death. The timing of accurate diagnosis and the implementation of causative, supportive, and adjunctive interventions are crucial determinants.

Prompt identification and treatment of sepsis is urgently required. The current diagnosis of sepsis relies on a mix of clinical characteristics and test data, such as C Reactive Protein (C.R.P) and Leucocyte counts. Due to the limited sensitivity and specificity of standard clinical and laboratory data, additional tests are necessary to provide an early indicator of infection. Procalcitonin has been proposed as a new biomarker for infections, alongside the traditional indicators. Multiple studies suggest that Procalcitonin is likely more effective than C-reactive protein (CRP) in identifying bacterial infection in critically unwell individuals. Although there is evidence, it is still uncertain whether Pro calcitonin contributes considerably to the distinguishing characteristics of the existing diagnostic markers. This is a crucial topic in diagnostic research.

An increasing amount of research literature provides evidence for the efficacy of Procalcitonin in enhancing the identification of bacterial infections and assisting clinicians in making more informed decisions regarding antibiotic treatment, specifically for respiratory tract infections and sepsis. Additional interventional studies are required to establish and confirm in advance the appropriate Procalcitonin threshold values for infectious conditions. Familiarity with the advantages and disadvantages of Pro calcitonin is essential for its logical and secure utilization in clinical practice. Furthermore, there has been a scarcity of research conducted on the significance of serum Procalcitonin in sepsis within the context of India. Given that the expression of Serum Procalcitonin may be influenced by the genetic makeup of the population, it is crucial to carry out additional research to definitively determine its effectiveness in this region. Therefore, this study aims to evaluate the efficacy of Serum Procalcitonin in diagnosing sepsis.

Sepsis is defined as the presence of a microbiologically confirmed or suspected infection along with systemic inflammatory response syndrome (SIRS). Severe sepsis refers to a condition where there is acute dysfunction of organs, reduced blood flow, or low blood pressure caused by sepsis (a severe infection). The low blood pressure is defined as having a systolic blood pressure below 90mm Hg or a decrease of more than 40mm Hg from the usual level.

Septic Shock is characterized by severe sepsis accompanied by low blood pressure that continues after receiving sufficient fluids or by indications of inadequate blood flow (such as lactic acidosis or reduced urine output) in patients undergoing vasoactive therapy. Multi Organ Dysfunction Syndrome (MODS) is a condition characterized by a disruption in physiological function, where the organs are unable to maintain a stable internal environment.[5] Within the hospital setting, it is important to recognize that patients' indwelling catheters, intravenous cannulas, and urine catheters might potentially serve as sources of infection.[6]

Exposure to endotoxins, exotoxins produced by gram positive bacteria, or other forms of microbial components initiates intracellular processes in immune cells, epithelium, endothelium, and the neuroendocrine system via microbial linked molecular patterns.[7]

➢ *Sepsis and Malfunction of Organs*
The pathophysiological mechanism behind sepsis-induced multiple organ failure is an intricate process. Both pro-inflammatory and anti-inflammatory chemicals are implicated in this process[8]. Two crucial reasons contributing to organ failure are sustained vasodilation resulting in low blood pressure, endothelial damage, and organ malfunction[9].

➢ *Acute Renal Failure and Sepsis*
The prevalence of acute renal failure with sepsis is roughly 19% in cases of sepsis, 23% in cases of severe sepsis, and 51% in cases of septic shock. The primary mechanism responsible for this is the induction of nitric oxide synthesis and vasodilation through cytokine mediation. Additionally, other agents such as catecholamine, angiotensin II, and endothelin contribute to peripheral vasoconstriction and an increase in systemic blood pressure. However, these agents also lead to renal vasodilation, which in turn contributes to the development of acute renal failure[9].

➢ *The Respiratory System and Sepsis*
Acute Respiratory Distress Syndrome (ARDS) is a prevalent type of Acute Lung Injury observed in patients exhibiting symptoms of sepsis. Approximately 50% to 70% of individuals in the United States succumb to ARDS. The occurrence is a result of damage caused by free radicals to the cells lining the alveolar capillaries and type I pneumocytes, which leads to the accumulation of fluid in the alveolar and interstitial spaces[10].

➢ *Cardiac Dysfunction Caused by Sepsis*
In 1981, Calvin and colleagues were the first to report on myocardial dysfunction in patients with septic shock who had been properly resuscitated with fluids. They observed a decrease in ejection fraction and an increase in end-diastolic volume index. Packer et al. showed that sepsis survivors experienced a decrease in ejection fraction and an increase in end-diastolic volume index, which returned to normal within 7 to 10 days after sepsis onset. In contrast, non-survivors maintained normal ejection fraction and end-diastolic volume, indicating that cardiac dysfunction in sepsis may serve as a compensatory mechanism to protect against myocardial dysfunction.

Furthermore, experimental studies have discovered that sepsis causes both structural and functional harm to the heart. A research investigation on a sheep model explored the impact of cecum ligation and puncture (CLP)-induced abdominal peritonitis on cardiac morphology. The study revealed that damage to the structure of mitochondria and impaired microcirculation, caused by edema in myocardial and vascular endothelial cells, could potentially lead to cardiac dysfunction in the initial phases of sepsis. These experimental experiments showed that there were both structural and functional injuries to the heart. However, in clinical conditions, the function of the heart could be adjusted by changing the preload and afterload.

➢ *Thrombocytopenia Caused by Sepsis*

The prevalence of thrombocytopenia in sepsis, defined as a platelet count of less than 1, 50, 000 cells/mm3, ranges from 35% to 44%. 12 - 15% of patients exhibit a count of ≤100,000. The underlying process involves the selective engulfment of megakaryocytes and other hematopoietic cells by monocytes and macrophages, known as emo-phagocytosis, together with temporary inhibition of bone marrow activity [14]

➢ *Study Objectives :*

- To identify the diagnostic value of Serum Pro calcitonin in patients suffering with sepsis.
- To assess if Pro calcitonin levels have a bearing on prognosis of patients with Sepsis.

II. MATERIALS & METHODS

The study group conducts investigations on PROCALCITONIN and other related factors. The individuals were categorized into three distinct groups, namely Sepsis, Severe Sepsis, and Septic Shock. The statistical analysis was conducted using SPSS 15.0. The Fisher exact test and Chi-square test were utilized.

➢ *Study Design : Cross Sectional Study*
➢ *Period : June 2022 to Dec 2022 (6 Months)*
➢ *Conflict of Interest: Nil*

➢ *Study Population:*

This study included exclusively adult patients, aged 18 years or older, who presented with acute sepsis. The study excludes patients who have a documented history of cardiac involvement, recent surgery, cancer, or trauma.

➢ *Inclusion Criteria:-*

- Patients who are 18 years of age or older and exhibit symptoms of sepsis:
- Pneumonia is characterized by a positive sputum culture and radiological evidence that corroborate the diagnosis.
- Exhibiting symptoms indicative of a urinary tract infection, as confirmed by a positive urine culture.
- Presence of bacteria in the blood sample.
- Any other illness exhibiting clinical and laboratory manifestations consistent with the diagnosis of sepsis.

➢ *Exclusion Criteria:*

- Individuals suffering from acute appendicitis, acute pancreatitis, severe burns, heat stroke, and mesenteric embolism.
- Patients receiving treatment with OKT3 antibodies, interleukins, or TNF-α inhibitors.
- Individuals experiencing prolonged or severe cardiogenic shock.
- Patients who have recently experienced trauma, undergone surgery, have a history of cancer, or are undergoing dialysis.

➢ *Methodology:*

The study included patients who had positive inclusion criteria features. The study only includes patients who were above 18 years of age and provided written informed permission.

The patients were interviewed to get a comprehensive medical history, after which a thorough physical examination and systemic assessment were conducted.

Various diagnostic tests were conducted including Complete Blood Picture, Complete Urine examination, Random Blood Sugar, Renal Function tests, Liver Function Tests, C-Reactive Protein, Chest X-Ray, Serum Electrolytes, ECG, 2D-ECHO, Sputum for Gram's Stain /Acid Fast Bacillus, Blood culture, Sputum culture, and urine culture as deemed necessary. Additionally, Serum Pro calcitonin was performed on all patients.

➢ *Statistical Methods Used :*

The current study involved conducting descriptive and inferential statistical analysis. Continuous measurements are reported as the mean plus or minus the standard deviation, along with the minimum and maximum values. Categorical measurements are reported as the number and percentage of occurrences. The significance is evaluated at a significance level of 5%.

The significance of research parameters on a continuous scale between two groups (intergroup analysis) has been determined using a two-tailed independent Student t-test. The Chi-square/Fisher Exact test was employed to determine the statistical significance of research parameters on a categorical scale across two or more groups.

➢ *Significant Figures*

- + Suggestive significance (P value: 0.05<P<0.10)
- Moderately significant (P value:0.01<P≤0.05)
- ** Strongly significant (P value : P≤0.01)

➢ *Statistical Software :*

The Statistical software namely SPSS 15.0, MedCalc 9.0.1,Stata 10.1, R environment ver.2.11.1, Systat 12.0 are used for the analysis of the data. Excel was used along with word for generating tables and graphs.

III. RESULTS

Table 1 Age Distribution of Patients Studied

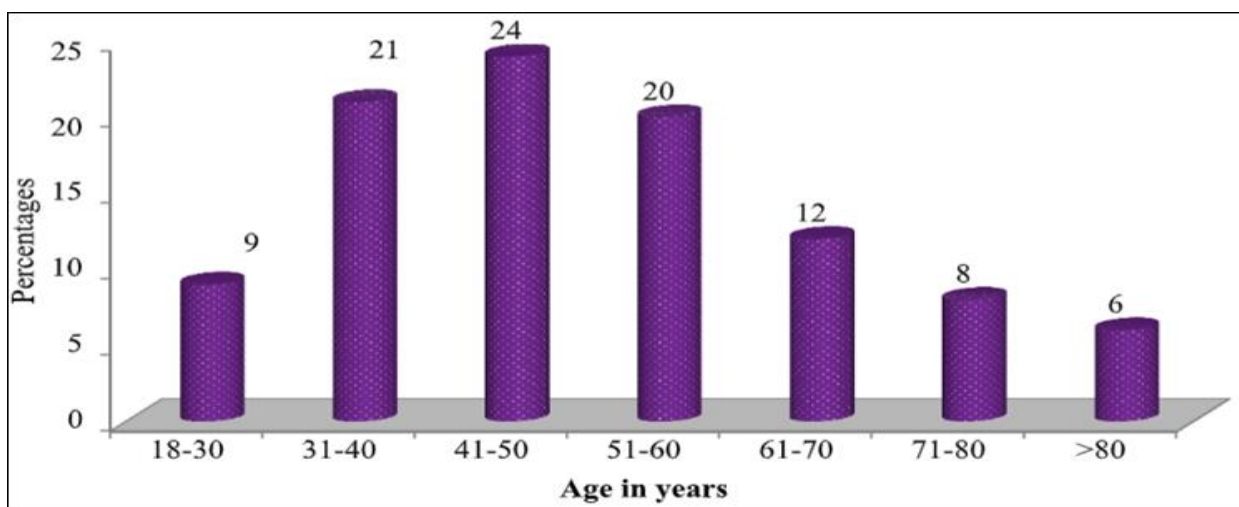| Age	No. of patients	%
18-30	9	9.0
31-40	21	21.0
41-50	24	24.0
51-60	20	20.0
61-70	12	12.0
71-80	8	8.0
>80	6	6.0
Total	**100**	**100.0**

Mean ± SD: 50.76±16.03

Fig 1 Age Distribution of Patients Studied

The average age in the study group was 50.76 ± 16.03 years. Among the population, 30% fell within the age range of 18-39 years, while 44% fell within the age group of 40-59 years. Additionally, 20% belonged to the age group of 60-79 years, and 6% were above the age of 80. The age of the individuals examined and its distribution closely align with comparable global research. A study conducted by Martin et al. in the United States revealed a greater prevalence of sepsis in patients above the age of 57. The average age in the survey conducted in India was 54.9 years.[17]

Table 2: Gender distribution of patients studied

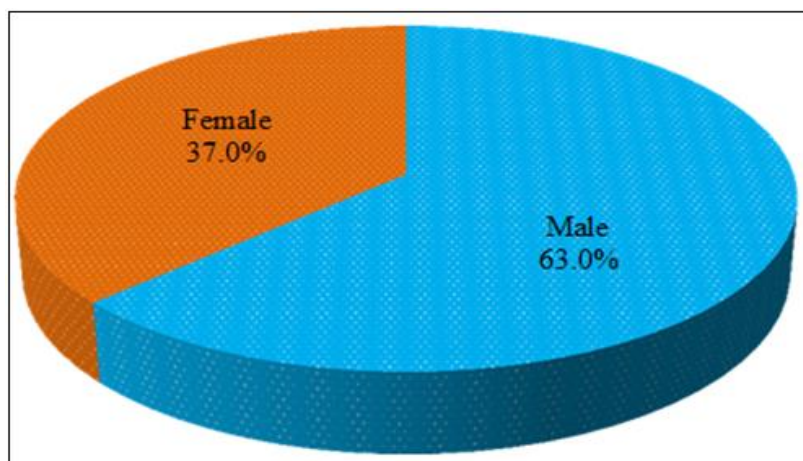| Gender	No. of patients	%
Male	63	63.0
Female	37	37.0
Total	**100**	**100.0**

Fig 2 Gender Distribution of Patients Studied

➢ *Gender*

A greater proportion of males were afflicted with sepsis in comparison to females in the study. Among the 100 patients, 63% are male and 37% are female. Our study groups do not exhibit any gender bias. Martin et al. (2016) found that the prevalence of sepsis was higher in males, constituting an average of 48.1% of cases per year. Todi and his research team conducted a multicenter trial at 12 different centers in India. Their findings revealed that sepsis is more prevalent in males than in girls.

Table 3 Co-Morbid Condition of Patients Studied

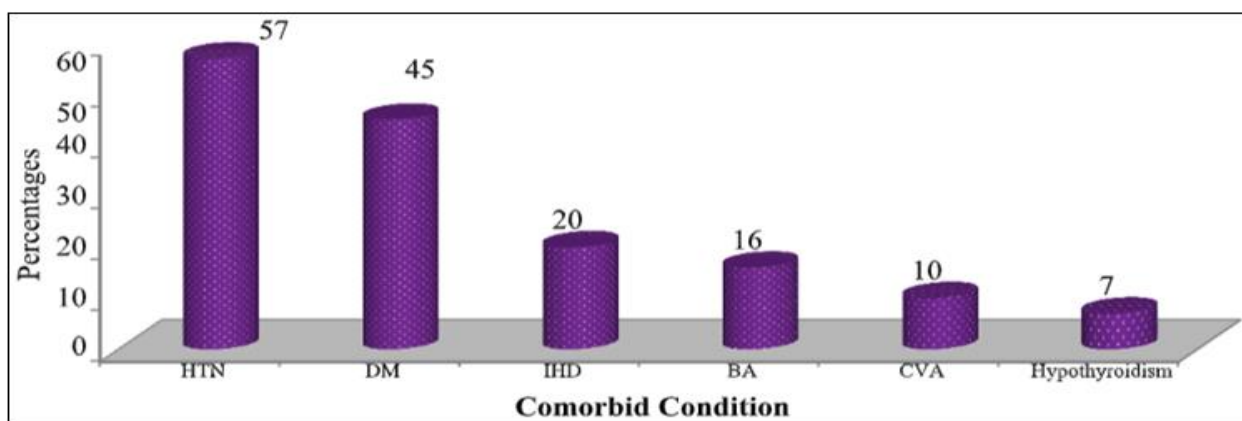| Co-morbidCondition	No. of patients(n=100)	%
HTN	57	57.0
DM	45	45.0
IHD	20	20.0
BA	16	16.0
CVA	10	10.0
Hypothyroidism	7	7.0

Fig 3 Co-morbid Condition of Patients Studied

In our study group, Hypertension was identified as the most prevalent co-morbid condition, affecting 57% of patients. This finding was statistically significant, as indicated by a p-value of 0.017. Diabetes Mellitus was the second most common co-morbid disease, affecting 45% of patients. A study conducted by Lai et al revealed that 38% of the population had diabetes.

Table 4 Presenting Symptoms of Patients Studied

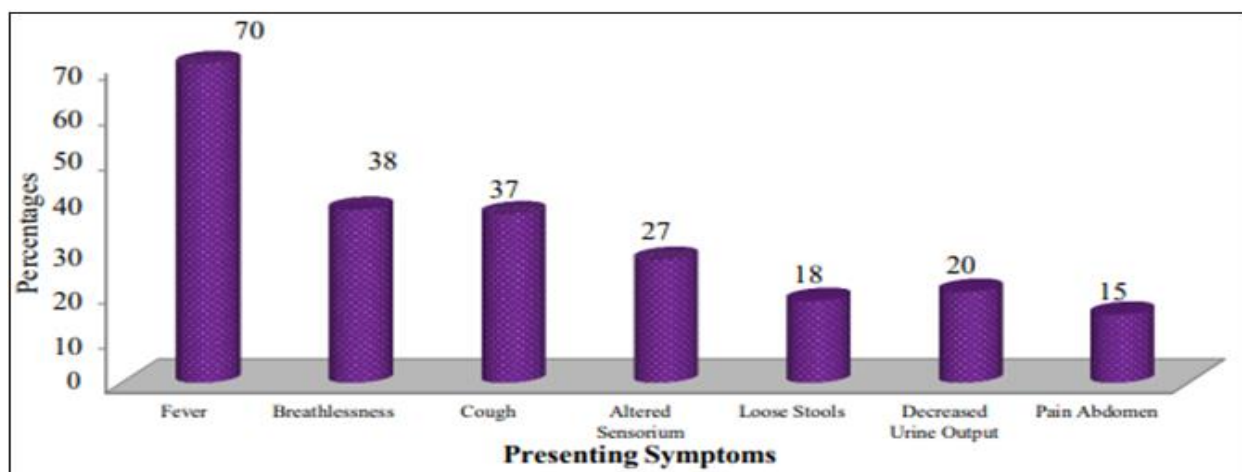| Presenting Symptoms	No. of patients(n=100)	%
Fever	70	70.0
Breathlessness	38	38.0
Cough	37	37.0
Altered Sensorium	27	27.0
Loose Stools	18	18.0
Decreased Urine Output	20	20.0
Pain Abdomen	15	15.0

Fig 4 Presenting Symptoms of Patients Studied

In our study group, fever was the predominant presenting symptom, observed in 70% of the cases, followed by dyspnea, which was reported by 38% of the participants. Among the participants in our study group, 73.5% of those with sepsis, 77.5% of those with severe sepsis, and 53.8% of those with septic shock exhibited fever as their initial symptom. Diabetic individuals with sepsis exhibit an insufficient immune response and may not experience fever. However, none of the observed symptoms, including fever, were determined to have a statistically significant impact among the groups being studied. Tachypnea was the predominant sign of systemic inflammatory response syndrome (SIRS) observed in 97 (97%) participants in our study. 75% of the patients exhibited tachycardia, and 66% of those patients experienced hypotension. Among the study group, 22% required Vasopressor assistance. 80% of the patients had leucocytosis, while leucopenia was observed in 4% of the patients. No statistically significant differences were found in any of the variables among the SIRS criteria between the sepsis study groups.

Table 5 Association of Vital Parameters with Diagnosis in Patients Studied

| Vital parameters	Diagnosis			Total (n=100)	P value
	Sepsis(n=34)	Severe sepsis (n=40)	Septic shock(n=26)		
Pulse					
• Normal	9(26.5%)	7(17.5%)	9(34.6%)	25(25%)	0.283
• Tachycardia	25(73.5%)	33(82.5%)	17(65.4%)	75(75%)	
BP					
• Normal	7(20.6%)	2(5%)	3(11.5%)	12(12%)	
• Hypotension	20(58.8%)	27(67.5%)	19(73.1%)	66(66%)	0.272
• Vasopressorsupport	7(20.6%)	11(27.5%)	4(15.4%)	22(22%)	
RR					
• Normal	1(2.9%)	2(5%)	0(0%)	3(3%)	0.781
• Tachypnea	33(97.1%)	38(95%)	26(100%)	97(97%)	
Temperature					
• Normal	22(64.7%)	29(72.5%)	20(76.9%)	71(71%)	
• Elevated	12(35.3%)	11(27.5%)	6(23.1%)	29(29%)	0.592
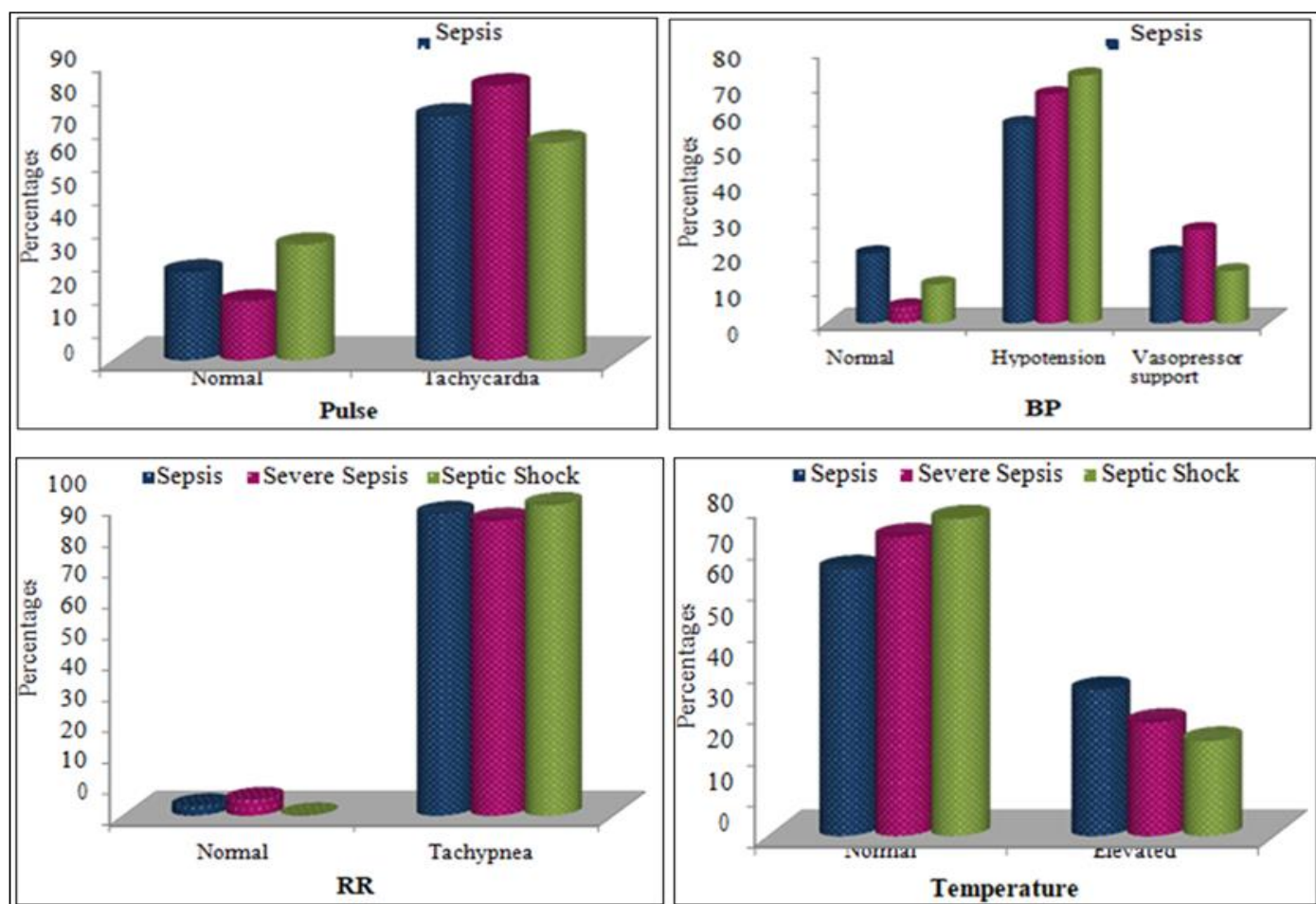
Fig 5 Association of Vital Parameters with Diagnosis in Patients Studied

Tachypnea was the predominant sign of systemic inflammatory response syndrome (SIRS) observed in 97 (97%) participants in our study. 75% of patients exhibited tachycardia, and among them, 66% also experienced hypotension. Furthermore, 22% of the study group required Vasopressor assistance. Leucocytosis was observed in 80% of patients, while leucopenia was observed in 4% of patients. No statistically significant differences were found in any of the variables among the SIRS criteria between the sepsis study groups.

Table 6 Diagnosis of Patients Studied

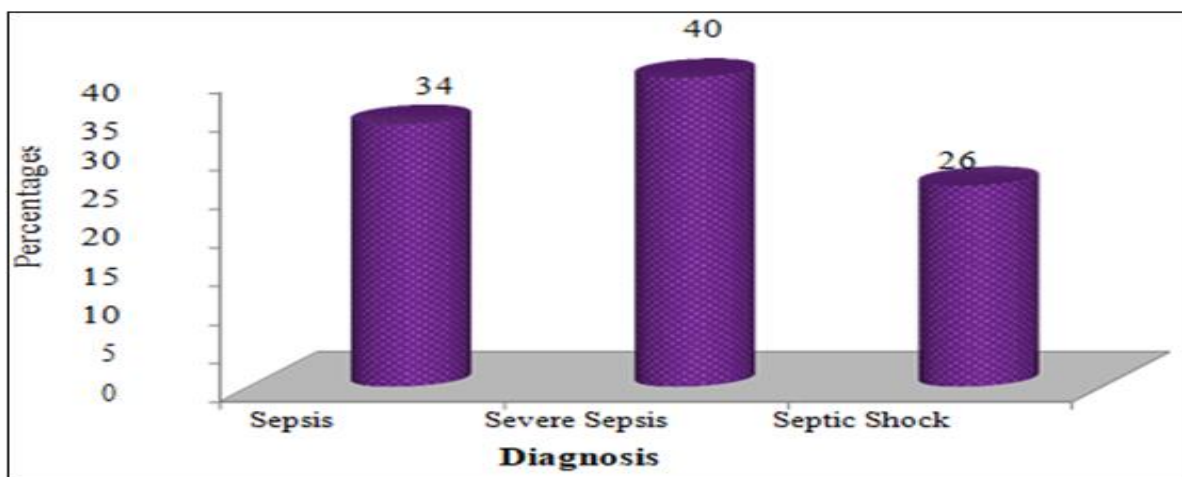| Diagnosis	No. of patients	%
Sepsis	34	34.0
Severe sepsis	40	40.0
Septic shock	26	26.0
Total	100	100.0

Fig 6 Diagnosis of Patients Studied

The study group was categorized into three groups, namely sepsis, severe sepsis, and septic shock, based on ACCP/SCCM criteria. The Sepsis group consisted of 34 patients, which accounted for 34% of the total. The severe sepsis group included 40 patients, representing 40% of the total. Lastly, the septic shock group had 26 patients, making up 26% of the total.

Table 7 Association of SOFA Score with Diagnosis in Patients Studied

SOFA score	Diagnosis			Total
	Sepsis	Severe sepsis	Septic shock	
0	34(100%)	19(47.5%)	0(0%)	53(53%)
1-5	0(0%)	21(52.5%)	13(50%)	34(34%)
6-10	0(0%)	0(0%)	10(38.5%)	10(10%)
>10	0(0%)	0(0%)	3(11.5%)	3(3%)
Total	**34(100%)**	**40(100%)**	**26(100%)**	**100(100%)**
Mean ± SD	**0.00±0.00**	**1.23±1.29**	**5.92±3.16**	**2.03±2.97**

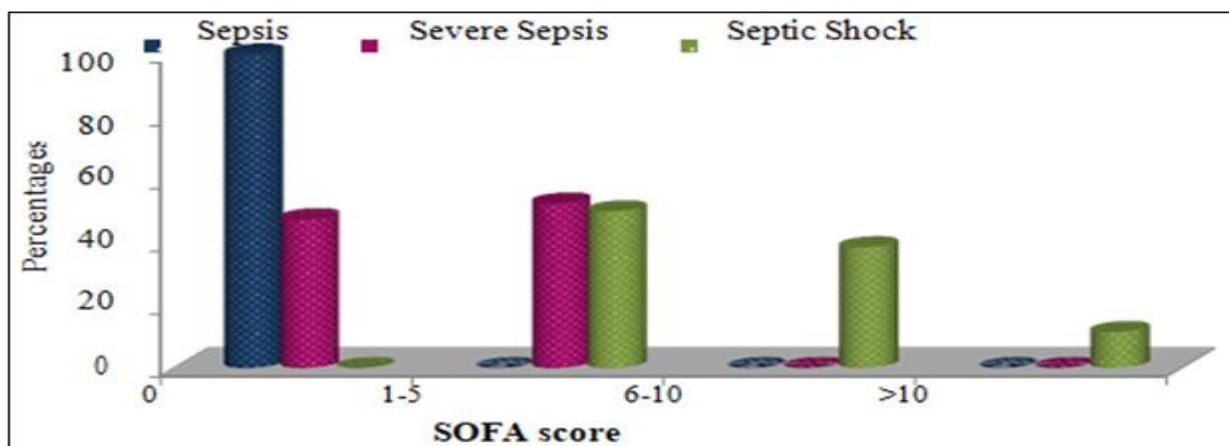SOFA score is significantly associated with septic shock with $P<0.001**$

Fig 7 Association of SOFA Score with Diagnosis in Patients Studied

We conducted an analysis of the SOFA score in groups of patients with severe sepsis and septic shock in our study. The average value of the SOFA score in the entire group is 2.03± 2.97. The SOFA score in the severe sepsis group was 1.23± 1.29. The SOFA score in septic shock patients is 5.92± 3.96. The levels of the SOFA score have a high level of statistical significance in diagnosing severe sepsis and septic shock (p value < 0.001). Elevated levels of SOFA scores were found to be substantially correlated with increased blood Procalcitonin concentrations. Consistent findings were seen in other investigations conducted by Meisner et al,[18] Vincent et al,[19] and Moreno et al.[20]

Table 8 Association of PCT with Diagnosis in Patients Studied

PCT	Diagnosis			Total
	Sepsis	Severe sepsis	Septic shock	
≤1	22(64.7%)	0(0%)	0(0%)	22(22%)
1-10	12(35.3%)	19(47.5%)	0(0%)	31(31%)
10.1-50	0(0%)	21(52.5%)	19(73.1%)	40(40%)
50.1-100	0(0%)	0(0%)	3(11.5%)	3(3%)
>100	0(0%)	0(0%)	4(15.4%)	4(4%)
Total	34(100%)	40(100%)	26(100%)	100(100%)
Mean ± SD	1.50±1.95	13.49±9.69	55.66±54.61	20.38±35.49

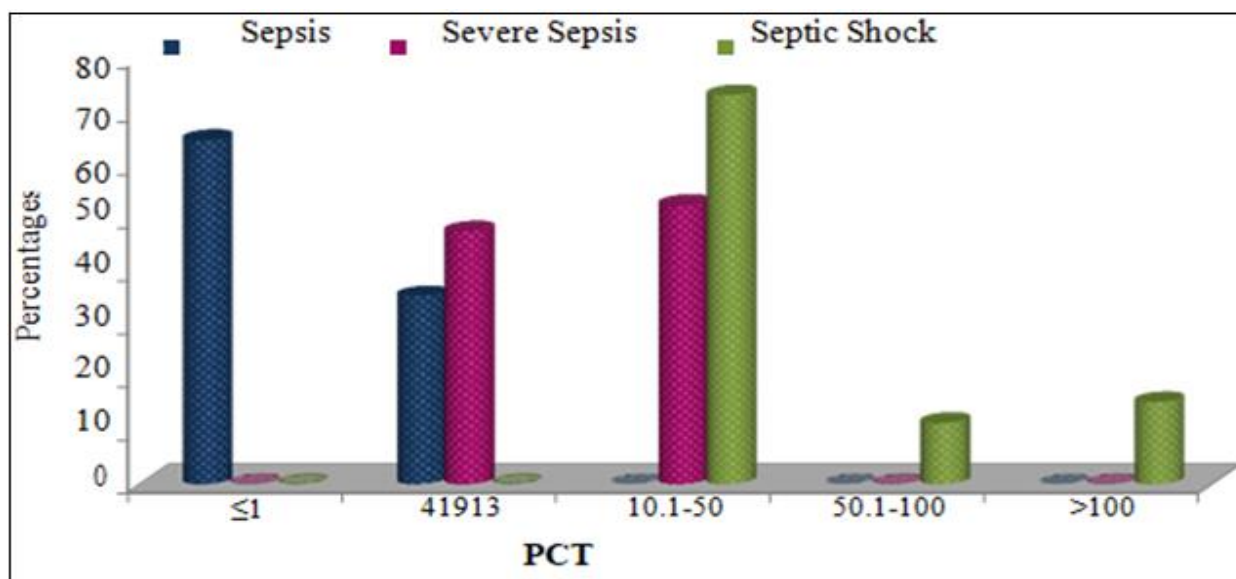Levels of PCT is Significantly Associated with Sepsis and Septic Shock with P<0.001**

Fig 8 Association of PCT with Diagnosis in Patients Studied

In the overall study population, the Serum Pro calcitonin test yielded positive results in 78% of cases and negative results in 22% of cases. In the sepsis group, it showed a positive result in 35.3% of cases, but in the severe sepsis and septic shock groups, it showed a positive result in 100% of cases. The average level of Procalcitonin in sepsis is 1.50±1.95ng/ml. In the severe sepsis group, the average level is 13.49±9.69ng/ml, and in the septic shock group, the average level is 55.66±54.61ng/ml. The average serum procalcitonin level in the entire study population is 20.38±35.49ng/ml. A strong statistical correlation was found between Pro calcitonin levels and the occurrence of severe sepsis and septic shock, with a p-value of less than 0.001. The unusual appearance of sepsis necessitates the use of Serum Pro calcitonin as a diagnostic marker in patients with different types of sepsis. The levels of Pro calcitonin in our study showed a positive correlation with the severity of sepsis, suggesting that Pro calcitonin may serve as a potential indicator of sepsis severity.

Table 9 Association of Duration with Diagnosis in Patients Studied

Duration	Diagnosis			Total
	Sepsis	Severe sepsis	Septic shock	
0	1(2.9%)	4(10%)	2(7.7%)	7(7%)
1-5	22(64.7%)	31(77.5%)	21(80.8%)	74(74%)
6-10	9(26.5%)	5(12.5%)	2(7.7%)	16(16%)
>10	2(5.9%)	0(0%)	1(3.8%)	3(3%)
Total	34(100%)	40(100%)	26(100%)	100(100%)
Mean ± SD	4.59±3.25	3.13±2.41	3.04±3.13	3.60±2.96

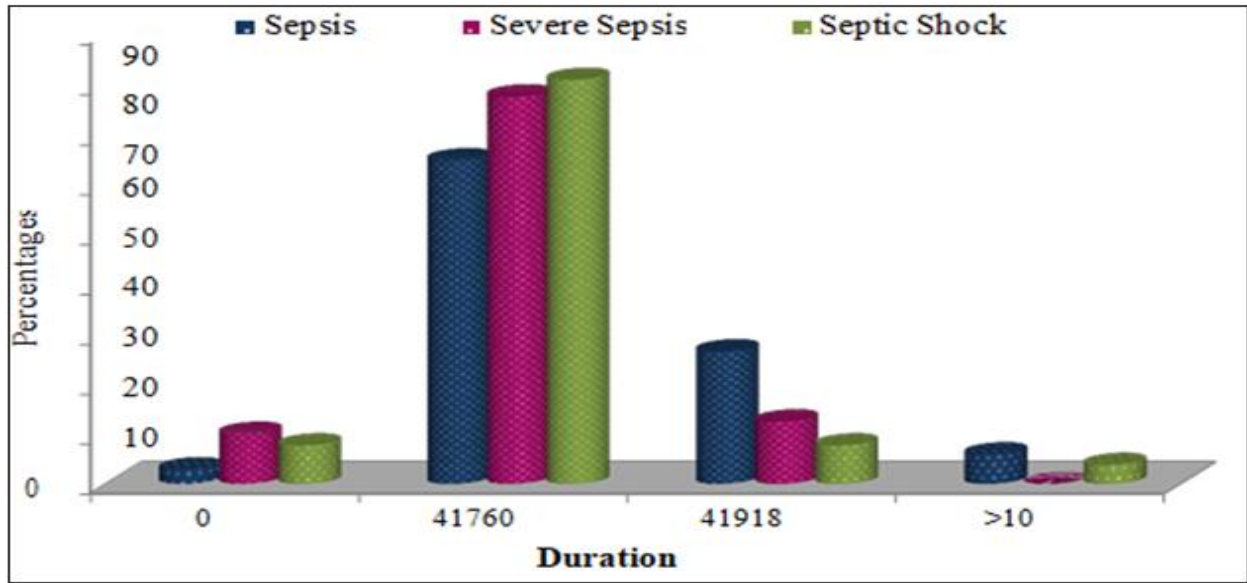Duration is Significantly Associated with Diagnosis with P=0.055+

Fig 9 Association of Duration with Diagnosis in Patients Studied

The average length of stay in our study is 3.60±2.96 days. The duration of the study is strongly correlated with different study groups, with a p-value of 0.055.

Table 10 Association of Outcome with Diagnosis in Patients Studied

Outcome	Diagnosis			Total
	Sepsis	Severe sepsis	Septic shock	
Death	2(5.9%)	24(60%)	21(80.7%)	50(50%)
Discharge	32(94.1%)	16(40%)	5(19.3%)	50(50%)
Total	34(100%)	40(100%)	26(100%)	100(100%)

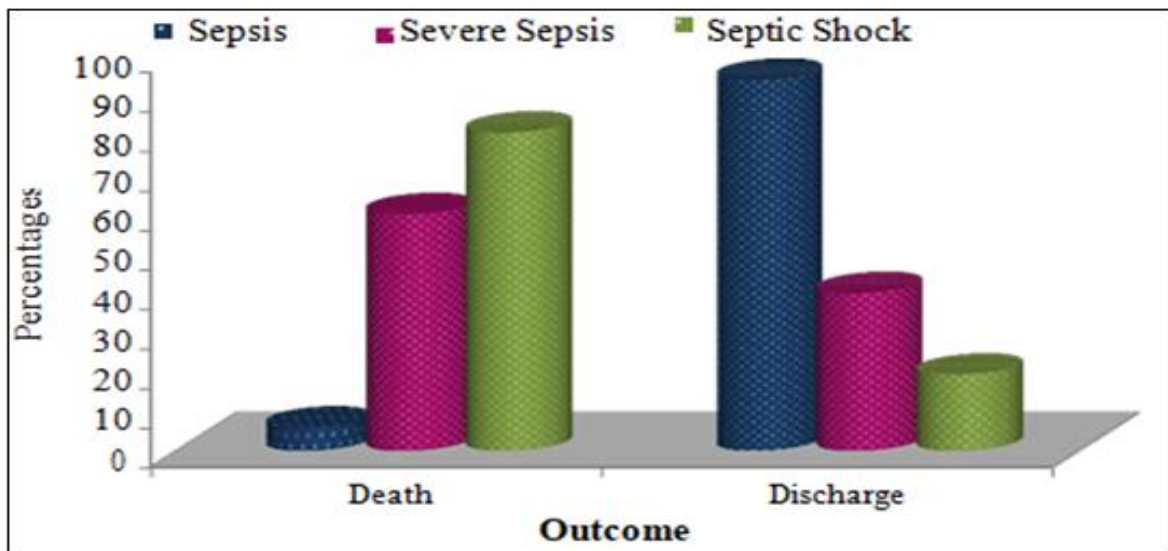Death is Significantly Associated with Septic Shock with P<0.001**

Fig 10 Association of Outcome with Diagnosis in Patients Studied

The study demonstrated a total death rate of 58%. The mortality rate was 5.9% in the sepsis group, 75% in the severe sepsis group, and 100% in the septic shock group. A strong statistical correlation was seen between the outcome and several categories of sepsis, with a p-value of less than 0.001. The average serum procalcitonin levels in patients who died was 43.78ng/ml, while patients who survived had an average of 6.22ng/ml. A significant statistical relationship was observed with a p-value of less than 0.001.

Patients with higher levels of Serum Procalcitonin (43.78ng/mL) had a worse prognosis compared to those with lower levels (6.22ng/mL) who survived. Serum Procalcitonin may be employed as a potential tool for forecasting the outcome and serving as a valuable indicator for the prognosis of sepsis. No fatalities occurred as a result of acute myocardial infarction among the individuals in our research group.

IV. DISCUSSION

Serum Procalcitonin is employed as a diagnostic indicator of sepsis in countries other than India and is a well-established indicator of sepsis, exhibiting a sensitivity ranging from 90% to 96%. Therefore, this study is being undertaken in Katuri hospital to investigate the efficacy of Serum Procalcitonin in diagnosing sepsis. The study will also investigate the efficacy of Serum Procalcitonin in predicting the prognosis of individuals diagnosed with sepsis.

We enrolled a cohort of 100 patients, aged 18 years and above, who were diagnosed with sepsis in our study. The study was conducted from June 2012 to June 2014 as a prospective observational study.

The average age in the study group was 50.76 ± 16.03 years. Among the population, 30% fell within the age range of 18-39 years, while 44% fell within the age range of 40-59 years. Additionally, 20% of the population fell within the age range of 60-79 years, and 6% of the population was above the age of 80. A study conducted by Martin et al. in the United States found a greater prevalence of sepsis in patients aged 57 years and above. The average age in an epidemiological study of sepsis in India conducted by Todi and colleagues was 54.9 years.[17]

In the current study, a greater proportion of males were found to be impacted by sepsis compared to females. Out of the total of 100 patients, 63% were males and 37% were girls. Our study groups do not exhibit any gender bias. Martin et al. (2016) found that sepsis was more prevalent in men, accounting for an average of 48.1% of cases per year. Todi and his team conducted a multicentral experiment at 12 centers in India, where they found that sepsis was more prevalent among males.[17]

In our study group, Hypertension was identified as the most prevalent co-morbid condition, affecting 57% of the patients. This finding was statistically significant, as indicated by a p-value of 0.017. Diabetes Mellitus was the second most common co-morbid condition, affecting 45% of the patients. A study conducted by Lai et al. found that 38% of the population had diabetes.

The study group was categorized into three groups, namely sepsis, severe sepsis, and septic shock, according to the ACCP/SCCM criteria. The Sepsis group consisted of 34 patients, which accounted for 34% of the total. The severe sepsis group included 40 patients, representing 40% of the total. Lastly, the septic shock group had 26 patients, making up 26% of the total.

In our study group, fever was the predominant presenting symptom, reported by 70% of participants, followed by dyspnea, reported by 38%. Within our study group, 73.5% of individuals in the sepsis group, 77.5% in the severe sepsis group, and 53.8% in the septic shock group exhibited fever as their initial symptom. Diabetic individuals suffering from sepsis exhibit an insufficient immune response and may not experience fever. However, none of the observed symptoms, including fever, were determined to have a statistically significant impact among the groups being studied. Tachypnea was the predominant sign of systemic inflammatory response syndrome (SIRS) observed in 97 (97%) participants in our study. Tachycardia was observed in 75% of the patients, and 66% of these individuals experienced hypotension. Among the study group, 22% required Vasopressor assistance. 80% of the patients had leucocytosis, while leucopenia was observed in 4% of the patients. No statistically significant differences were found in any of the variables among the SIRS criteria between the sepsis study groups.

Our study examined the SOFA score in groups of patients with severe sepsis and septic shock. The average value of the SOFA score for the entire group is 2.03± 2.97. The SOFA score in the severe sepsis group was 1.23± 1.29. The SOFA score in patients with septic shock is 5.92±3.96. The levels of the SOFA score have a high level of statistical significance in diagnosing severe sepsis and septic shock (p value < 0.001). Significant positive correlation was seen between higher levels of SOFA score and serum Procalcitonin concentrations. Consistent findings were seen in other investigations conducted by Meisner et al,[18] Vincent et al,[19] and Moreno et al.[20]

In the overall study population, the presence of Serum Procalcitonin was detected in 78% of individuals, while it was not detected in 22%. In the sepsis group, it had a positive rate of 35.3%, while in the severe sepsis and septic shock groups, it had a positive rate of 100%. The average Procalcitonin level in sepsis is 1.50±1.95ng/ml, whereas in the severe sepsis group it is 13.49±9.69ng/ml, and in the septic shock group it is 55.66±54.61ng/ml. The average serum procalcitonin level in the entire study population is 20.38±35.49ng/ml. A strong statistical correlation was seen between Procalcitonin levels and the occurrence of severe sepsis and septic shock, with a p-value of less than 0.001. Given the unusual nature of sepsis symptoms, Serum Procalcitonin serves as a valuable diagnostic indicator for patients across different sepsis groups. The study found that Procalcitonin levels rose in correlation with the severity of sepsis. Therefore, Procalcitonin may potentially serve as an indicator of sepsis severity. Severe types of sepsis are widely recognized to be linked with a less favorable result. The study revealed a total mortality rate of 58%.The mortality rate was 5.9% in the sepsis group, 75% in the severe sepsis group, and 100% in the septic shock group. A strong statistical correlation was seen between the outcome and several categories of sepsis, with a p-value of less than 0.001. The average serum procalcitonin levels in individuals who died were 43.78ng/ml, whereas those who survived had levels of 6.22ng/ml. A significant statistical relationship was observed with a p-value of less than 0.001. Patients with higher levels of Serum Procalcitonin (43.78ng/mL) had a worse prognosis compared to those with lower levels (6.22ng/mL) who survived. Serum Procalcitonin has the potential to be utilized for forecasting the outcome and can serve as a valuable indicator for the prognosis of sepsis. No fatalities resulting from acute myocardial infarction were

seen among the individuals in our research group.

A study conducted by Muller et al. found that Serum Procalcitonin demonstrated a sensitivity of 89% and specificity of 94% in diagnosing sepsis, with a concentration threshold of >1ng/ml. Elevated levels of serum were correlated with unfavorable outcome.The p-value is 0.01.

According to Brunkhorst22 et al, Procalcitonin levels were found to rise in correlation with the intensity of the inflammatory response to infection. The septic shock group had a mean Procalcitonin level of 12.89ng/ml, while the mean level in the severe sepsis group was 6.91ng/ml. In the sepsis group, Procalcitonin levels were 0.53ng/ml. The acquired results were similar to the outcomes obtained in our investigation.

Another study conducted by Harbarth23 et al yielded comparable findings, indicating median serum Procalcitonin levels of 3.5ng/ml for sepsis, 6.2ng/ml for severe sepsis, and 21.3ng/ml for septic shock, respectively.

The average length of stay in our study is 3.60±2.96 days. The duration of the study is strongly correlated with different study groups, with a p-value of 0.055.

In our research groups overall mortality was 47%, where in most of the cases are from septic shock (21) and severe sepsis (24). This is shown to be higher in comparison to other studies. The authors Martin et al documented a mortality rate ranging from 16.8% to 31.8%.Sixteen In another study done by Sands et al were sepsis in eight academic medical facilities was evaluated revealed a death incidence of 34%. The mortality can be ascribed to the process of aging and a multitude of risk factors that are more prevalent in that particular age cohort. Diabetes is an additional risk factor that can lead to higher mortality rates.

Although localized infections or infections without distinct systemic symptoms may not significantly elevate serum PCT levels, PCT is not considered a reliable measure of infection. While it is true that elevated levels of serum PCT (procalcitonin) with severe infections can fall significantly with proper treatment, this does not necessarily mean that the infection has been completely eliminated. It only indicates that the spread of the infection or the body's systemic response is being managed.

Elevations in serum procalcitonin (PCT) levels are also observed in systemic inflammatory syndrome caused by non-infectious factors. Patients who have experienced significant trauma or undergone surgery, as well as those who have undergone cardiopulmonary bypass, may exhibit elevated levels of procalcitonin (PCT) in their blood, even in the absence of serious infection. However, the average values under these settings are often lower than those observed during severe sepsis and septic shock.

To summarize, the occurrence of sepsis was more prevalent in those over the age of 50 and in males. Serum procalcitonin (PCT) has demonstrated exceptional efficacy as a diagnostic marker for sepsis in patients with critical illness. Our findings suggest that clinical factors have limited diagnostic efficacy in identifying sepsis upon admission. Serum Procalcitonin is a valuable diagnostic indicator for sepsis and can also be used to evaluate the severity of sepsis, including sepsis, severe sepsis, and septic shock. Additionally, it was shown that it serves as a valuable indicator for predicting the prognosis of individuals with sepsis.

V. SUMMARY

The objective of this study was to evaluate the efficacy of SERUM PROCALCITONIN as a diagnostic and prognostic indicator for sepsis.

The study was conducted at Katuri Medical Centre as a prospective observational study. A total of 100 patients, all of whom were over 18 years old and diagnosed with sepsis, were enrolled in the study conducted from June 2022 to December 2022.

The study population was categorized into three groups: sepsis (34%), severe sepsis (40%), and septic shock (26%), following the ACCP/SCCM recommendations for sepsis.

- The average age of the participants in the study was 50.76±16.03 years.
- The average length of stay was 3.60±2.96 days.
- Out of the entire study population, 63% were males and 37% were females.
- Hypertension was the most prevalent comorbid condition, affecting 57% of individuals. The prevalence of diabetes was 45%.
- Fever was the most often seen symptom among the participants in the study, with a prevalence of 70%.
- The most frequent indication of Systemic Inflammatory Response Syndrome (SIRS) was rapid breathing, observed in 97% of cases.
- Procalcitonin levels were positive in 78% of the entire study population and showed a statistically significant difference between the groups.

The mean serum procalcitonin levels were 1.50ng/mL in the sepsis group, 13.49ng/mL in the severe sepsis group, and 55.66ng/mL in the septic shock group. There was a statistically significant difference in procalcitonin levels between the groups. PROCALCITONIN may potentially assist in assessing the severity of sepsis.

The fatality rates in our study were 5.9% for sepsis, 60% for severe sepsis, and 80.7% for septic shock. These differences in mortality rates between the groups were statistically significant.

The mean serum procalcitonin levels were 43.78ng/mL in deceased patients and 6.22ng/mL in surviving patients, which was determined to be statistically significant.

Therefore Procalcitonin may be utilized to potentially forecast the prognosis of people suffering from sepsis.

Serum Procalcitonin has been identified as a cost-effective and dependable indicator for diagnosing and predicting the outcomes of patients with sepsis.

VI. CONCLUSION

The results suggest that clinical factors have limited diagnostic efficacy in identifying sepsis. Thus, incorporating an additional indicator such as Serum Procalcitonin into the routine evaluation of patients with sepsis can enhance the accuracy of diagnosis. Serum Procalcitonin was also useful in assessing the severity of sepsis and had a notable impact on predicting the patients' outcome. Our investigation revealed that serum Procalcitonin is a cost-effective and dependable indicator for the diagnosis and prognosis of sepsis.

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