Med. J. Cairo Univ., Vol. 89, No. 4, September: 1707-1714, 2021
www.medicaljournalofcairouniversity.net

Presepsin versus Procalcitonin as Diagnostic and Prognostic Markers in Sepsis

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Abstract

Background: Sepsis is a type of systematic inflammatory response syndrome caused by invasion of pathogens or conditional pathogenic bacteria into the blood circulation.

Aim of Study: To evaluate the value of the presepsin in early diagnosis of sepsis in comparison with procalcitonin (PCT) and assess prognostic significance of presepsin in sepsis evaluation in relation with PCT.

Patients and Methods: A prospective cohort study was conducted on 62 adult critically ill patients with sepsis and its related syndromes who were admitted to Ain Shams University hospital general intensive Critical Care Unite, from November 2017 to February 2018. Serum level of presepsin and procalcitonin were measured on admission, 24 and 72 hours after admission.

Results: There was positive significant correlation between procalcitonin and APACHE II score started from day 0 with p-value 0.011 and started to show strong direct correlation till day 3. Also, there was positive linear significant correlation between procalcitonin and values of SOFA score started from day 1 with p-value 0.005 and started to show strong direct correlation till day 3 with p-value 0.0001. While, there was significant correlation between presepsin and value of APACHE II score at day 0 with p-value 0.006 then insignificant correlation at day1 and started to show strong direct correlation at 3rd day with p-value 0.0001. Also, there was positive linear significant correlation between presepsin and values of SOFA score started from day 0 with p-value 0.035 and started to show strong direct correlation till day 3 with p-value 0.0001.

Conclusion: Presepsin cannot differentiate between sepsis and non-infective SIRS since admission; it can predict severity, prognosis and patient outcome. The accuracy of presepsin in this context was seen by our results to be superior to PCT.

Key Words: *CD14 – Presepsin – Procalcitonin – Prognostic – Sepsis.*

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Introduction

SEPSIS is a type of systematic inflammatory response syndrome caused by invasion of pathogens or conditional pathogenic bacteria into the blood circulation. It can develop into severe sepsis, septic shock and multiple organ failure. Sepsis occurs in 1%-2% of all hospitalized patients and accounts for as much as 25% of intensive care unit cases [1].

Despite advances in therapy, sepsis is the leading cause of death in critical care settings. To improve the survival, early recognition of severe sepsis and septic shock and subsequent introduction of an aggressive supportive therapy are mandatory. In routine clinical practice, early anti-infection treatment should be given before definitive diagnosis since blood culture, the gold-standard diagnostic method, usually takes several days to obtain the results and frequently yields low positive results [2].

Various biomarkers have been reported useful in sepsis diagnosis, such as procalcitonin and C-reactive protein. However, these biomarkers may also be elevated in non-septic conditions such as trauma, burn and postoperative settings. Some are slow to rise after the onset of sepsis. It thus remains necessary to find reliable biomarkers to replace or improve those that are currently available [3].

More recently, the soluble CD14 subtype, presepsin, appears to be an accurate sepsis diagnostic marker and rises up a great clinical interest. Levels of presepsin were found significantly higher in septic than in non-septic patients. Moreover, a specific increase was reported in the early stage of sepsis that also well correlated with severity. Accordingly, plasma presepsin levels could be

useful for diagnosis and prognosis of sepsis and also for monitoring the course of the disease [2].

Therefore, the aim of this study was evaluating the value of the presepsin in early diagnosis of sepsis in comparison with procalcitonin (PCT) and assess prognostic significance of presepsin in sepsis evaluation in relation with PCT.

Patients and Methods

A prospective cohort study was conducted on 62 adult critically ill patients with sepsis and its related syndromes who were admitted to Ain Shams University hospital general intensive Critical Care Unite, from November 2017 to February 2018.

Ethical consideration: Approval was obtained from the Departmental Ethical Committee of Ain Shams University Hospitals and obtaining a written informed consent from each patient (or his or her legally authorized surrogate) after explaining the aim of the study.

Inclusion criteria: Age ≥18 years, patients with suspected sepsis and patients who met 2 criteria at least of the following criteria (that was known before as SIRS) according to (American College of Chest Physicians/Society of Critical Care Medicine) ACCP/SCCM guidelines which include body temperature >38.5°C or <36°C, heart rate (HR) > 90/min, respiratory rate (RR) >20/min, or $PaCO_2$ <32mm Hg and leukocyte count >12 x 10^9/L or <4 x 10^9/L, levels >10% of immature neutrophils.

Exclusion criteria: Age ≤ 18 years, evident Sepsis, incapability to give informed legal consent and evidence of a clearly different diagnosis.

All patients included in this study were subjected to the following:

History taking: Including age, sex, smoking and chronic disease; diabetes mellitus or hypertension with stress on symptoms of presence or absence of infection and its site (e.g., fever, shortness of breath, purulent sputum, previous hospital/ICU admission... etc.), hemodynamic assessment: Including heart rate monitoring, blood pressure monitoring, temperature measurement, respiratory rate monitoring, central venous pressure monitoring and urine output monitoring every 6 hours and thorough clinical examination. Scoring System: Acute Physiology and Chronic Health Evaluation II score (APACHE II score) for all patients on admission and Sequential Organ Failure Assessment (SOFA) score [4].

Routine laboratory investigations: Complete blood counts with deferential count, renal function tests and blood, urine, and sputum cultures ± wound or drain culture, arterial blood gases, chest X-ray, urine analyses, presepsin, PCT and CRP plasma concentrations.

Special laboratory investigations: Including.

Serum level of presepsin: Serum level of presepsin was done on admission (day 0), 24 hours (day 1), and 72 hours (day 3) after admission [5].

Serum level of procalcitonin (PCT): Serum level of procalcitonin (PCT) was done on admission (day 0), 24 hours (day 1), and 72 hours (day 3) after admission.

Serum level of CRP: Serum level of CRP was done on admission (day 0), 24 hours (day 1), and 72 hours (day 3) after admission.

Statistical analysis: Data were collected, tabulated, statistically analyzed using Statistical Package of Social Science (SPSS) version 235 (SPSS Inc. Released 2015. IBM SPSS statistics for windows, version 23.0, Armnok, NY: IBM Corp.) Descriptive data were presented in the form of mean (X-), standard deviation (SD), range, and qualitative data were presented in the form numbers and percentages. Analytical statistics: Included Chi-Squared (χ^2), Spearman correlation and ROC (receiver operating characteristic) curves. Results were considered significant if $p \leq 0.05$ and highly significant if $p \leq 0.01$.

Results

In the current study, Patient's age ranged between 18-83 with mean 55.45 ± 16.264 years. The patients were 37 males (60%) and 25 females (40%). 28 patients had diabetes (45.2%) and 35 had hypertensive (54.8%). Also, in this study, SOFA score was comparable in patients who needed mechanical ventilation (7.39 ±4.61), inotropic support (8.2±4.8), dialysis (6.9±4.9) compared to those who did not need. On the other hand, the APACHE II score was significantly higher in patients who needed mechanical ventilation (87.96 ± 19.6 vs. 65.4± 16.5), inotropic support (93.4 ± 14.9 vs. 63.3± 15.5), dialysis (92.1 ± 10.9 vs. 75.4±22.0) compared to those who didn't need (Table 1).

In our study, the current study revealed that, the APACHE IV was significantly higher in non-survivors (95.17 ± 13.9) compared to survivors (64.59± 15.80), (p<0.001), (Table 2).

Table (1): SOFA score and APACHE II score in studied patients.

	Need (Mean±SD)	No need (Mean±SD)	*p*-value
SOFA score:			
- Mechanical ventilation	7.39±4.610	6.41±4.048	0.571
- Inotropic support	8.2±4.8	5.8±3.6	0.144
- Dialysis	6.9±4.9	7.0±4.3	0.787
APACHE II score:			
- Mechanical ventilation	87.96±19.6	65.4±16.5	0.001**
- Inotropic support	93.4±14.9	63.3±15.5	<0.001**
- Dialysis	92.1±10.9	75.4±22.0	0.049 *

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

Table (2): APACHE IV score in relation to survival.

	Non-survivors n=40	Survivors n=22	*p*-value
APACHE I score	17.7±4.8	12.7±2.8	0.0001**
APACHE II score	18 (11-22.5)	27 (17-32)	0.008 *
APACHE IV score	95.17±13.9	64.59±15.80	<0.001**

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

In our study, SOFA score was significantly higher at all assessments in non-survivors as compared to survivors with *p*-value 0.007 on admission and 0.0001 at day 1, and 3. While, mean CRP levels were insignificant on admission and day 1 then start to be more significant only from day 3 in non survivors compared to survivors. Also, mean procalcitonin levels were significantly higher from day 0 to 3 in non-survivors as compared to survivors with *p*-value 0.0001 on admission, day 1, and 3. While, mean presepsin levels were significantly and extremely higher from day 0 to 3 in non survivors as compared to survivors with *p*-value 0.0001 (Table 3).

In our study, there was a weak positive significant linear correlation between CRP with values of APACHE II score and SOFA score at day 3. While, there was no statistically significant correlation between CRP with values of APACHE II score and SOFA score on admission and first day. But There was positive linear significant correlation between procalcitonin and values of APACHE II score started from day 0 with *p*-value 0.011 and started to show strong direct correlation till day 3. Also, there was positive linear significant correlation between procalcitonin and values of SOFA score started from day 1 with *p*-value 0.005 and started to show strong direct correlation till day 3 with *p*-value 0.0001. While, there was significant correlation between presepsin and value of APACHE II score at day 0 with *p*-value 0.006 then insignificant correlation at day1 and started to show strong direct correlation at the 3 rd day with *p*-value 0.0001. Also, there was positive linear significant correlation between presepsin and values of SOFA score started from day 0 with *p*-value 0.035 and started to show strong direct correlation till day 3 with *p*-value 0.0001 (Table 4).

Table (3): Comparison between Non-survivors and survivors regarding SOFA, CRP, procalcitonin and presepsin.

	Non-survivors n=40	Survivors n=22	*p*-value
SOFA:			
Day 0	9.0±5.5	6.3±3.5	0.007*
Day 1	11.2±5.3	6.5±2.4	0.0001**
Day 3	13.1±5.4	5.8±2.1	0.0001**
CRP (mg/ml):			
Day 0	120.8±112.6	93.1±79.6	0.307
Day 1	153.6±109.9	112.6±81.2	0.132
Day 3	202.4±97.4	141.2±75.5	0.015*
Procalcitonin (pg/ml):			
Day 0	6.1±4.2	1.2±0.9	0.0001**
Day 1	7.7±5.4	1.1±0.9	0.0001**
Day 3	11.8±8.6	1.4±1.3	0.0001**
Presepsin (pg/ml):			
Day 0	1602.3±885.2	627.9±467	0.0001**
Day 1	1829.9±438.5	850.5±936.6	0.0001**
Day 3	2580.7±1280.6	827.6±651.2	0.0001**

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

Table (4): Correlation of CRP, procalcitonin and presepsin with APACHE II score and SOFA score.

	APACHE II		SOFA	
	r	*p*-value	*r*	*p*-value
CRP:				
Day 0	0.021	0.882	0.108	0.450
Day 1	0.099	0.488	0.129	0.367
Day 3	0.273	0.05*	0.284	0.44
Procalcitonin:				
Day 0	0.353	0.011*	0.263	0.063*
Day 1	0.387	0.005*	0.390	0.005*
Day 3	0.468	0.001*	0.549	0.0001*
Presepsin:				
Day 0	0.383	0.006 *	0.296	0.035*
Day 1	0.222	0.122	0.340	0.016*
Day 3	0.528	0.0001**	0.493	0.0001**

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

In our study, the area under ROC curve was the highest for serum presepsin on day 3 where it was 0.921. The best cutoff value of presepsin on day 3 was 1943pg/ml that could identify severe sepsis/septic shock by a sensitivity of 85% and a specificity of 82 % (Table 5, Diagram 1).

Table (5): The AUC for ROC analysis for identification of severe sepsis/septic shock in patients with sepsis.

	Area	*p*-value	Cutoff value	Sensitivity	Specificity
Presepsin (pg/ml) on day 1	0.789	<0.001**	1649.5	76%	73%
Presepsin (pg/ml) on day 3	0.921	<0.001**	1943	85%	82%
PCT (pg/ml) on day 1	0.717	0.007*	146.5	73%	55%
PCT (pg/ml) on day 3	0.871	<0.001**	182.5	85%	73%
CRP (mg/ml) on day 1	0.818	<0.001**	140	76%	82%
CRP (mg/ml) on day 3	0.897	<0.001**	140	85%	82%
APACHE II	0.686	0.02	18	79%	50%

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

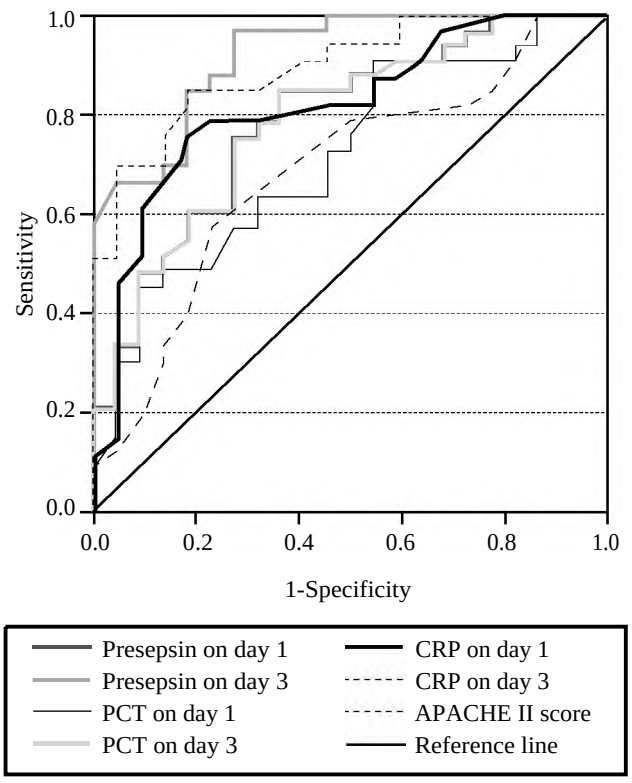

Diagram (1): ROC curve for the different variables for the identification of severe sepsis/septic shock.

In our study, CRP was high among sepsis patients than SIRS patients on admission till day 3 and the difference was found to be statistically significant. Also, procalcitonin level was higher among sepsis patients than SIRS patients on admission and first day and the difference was found to be statistically significant. While procalcitonin level showed no statistically significant difference between sepsis and SIRS patients at day 3 (Table 6).

Table (6): Comparison between SIRS and Sepsis group regarding CRP and procalcitonin level.

	SIRS	SEPSIS	*p*-value
CRP (mg/ml):			
Day 0	71.59±74.57	118.75±98.87	0.019*
Day 1	92.25±71.79	145.31±99.96	0.016*
Day 3	120.94±76.51	185.44±88.03	0.015*
Procalcitonin (pg/ml):			
Day 0	1.53±2.95	8.16±4.21	0.039*
Day 1	2.17±3.81	7.91±5.34	0.045*
Day 3	3.88±6.15	5.85±8.27	0.396

* *p*-value <0.05 is considered significant.
***p*-value <0.001 is considered to be statistically highly significant.

Discussion

In the current study, Patient's age ranged between 18- 83 years, 60% were males. DM was present in 45% of Patients and HTN in 56.7%. In the study by Tang et al., [6], found that there was increasing sepsis rate in younger population in thirties. Also, Men are more likely than women to develop sepsis, with a mean annual relative risk of 1.28 (95% CI 1.24-1.32). However, it is not clear whether this difference could be due to a higher prevalence of comorbidities in men, or whether women are protected against the inflammatory changes that occur in severe sepsis and septic shock [6].

In the current study, serum CRP levels were non-significant in non-survivors compared to survivors on days 0 and 1, and became significantly higher in non-survivors in day 3. On the other hand, mean procalcitonin and presepsin levels were significantly higher in non-survivors from day 0 to 3. Sands et al., [7] showed that patients with a decrease in CRP level 48h after admission to ICU was associated with a mortality rate of 15.4, while an increased CRP level was associated with a mortality rate of 60.9%. This study was conducted on a heterogeneous ICU patients rather than SIRS or sepsis patients. Liu et al., found that the presepsin and PCT were significantly higher in non-survivors

of sepsis [8]. Ulla et al., found that the presepsin was significantly higher in non-survivors while the PCT level was not related to survival [9]. Evaluating biomarkers for mortality prediction in burn patients found that the presepsin, PCT and CRP were elevated in non-survivors than survivors [10]. Also, Zhang et al., [11] found no significant difference in CRP and PCT levels between survivors and non-survivors. However, CRP and PCT were found to be significantly different between the two groups a day 10 and 14 after admission. The authors concluded that PCT was more of a diagnostic tool rather than a prognostic tool [11].

In the evaluation of the presepsin, for differentiating non-infective SIRS from sepsis, we found that presepsin levels were significantly higher from day 0 to 3 in non survivors as compared to survivors. While, in the study done by Nakamura and coworkers, they found that there was no difference in the presepsin level between non-infective SIRS and sepsis but this was in patients with renal failure [12]. In the study by Mearelli et al., found a significantly higher PCT level in sepsis patients compared to non-infective SIRS [13]. Other investigators also found a significantly higher CRP in sepsis patients compared to those with non-infective SIRS [14].

In a study measuring the concentration of presepsin in emergency patients on admission, presepsin was significantly higher in sepsis patients than in healthy people [15]. Also, in perioperative patients, found that the presepsin level is well correlated with culture results [16]. The increased presepsin with positive culture results was also seen in emergency department patients [17]. Other studies found that presepsin level is a powerful biomarker that helps to differentiate sepsis from the non-infective SIRS in critically ill patients [13]. This diagnostic significance was explained by its release in response to innate immune system to the microorganism component [18]. Whereas, Mearelli et al., also found that the presepsin level is higher in non-survivors than in survivors [13]. Kweon et al., found that it does not correlate with 30-day mortality in a Korean population [19].

Results of the current study showed that, there were weak positive significant linear correlation between CRP with values of APACHE II score and SOFA score at day 3. While, there was no statistically significant correlation between CRP with values of APACHE II score and SOFA score on admission and first day. Also, that there was positive linear significant correlation between procalcitonin and values of APACHE II score started from day 0 and started to show strong direct correlation till day 3. Also, there was positive linear significant correlation between procalcitonin and values of SOFA score started from day 1 and started to show strong direct correlation till day 3. Furthermore, Tschaikowsky et al., found that the PCT and CRP levels decreased steadily in both survivors and non-survivors while following day 7, an increase in PCT was associated with mortality. This was not observed with CRP [20]. Similar findings of persistent PCT elevation after 7 days and not the CRP were observed in patients with acute peritonitis [21].

Many studies found that the presepsin and PCT are higher in patients with infection versus those without, with a better diagnostic accuracy of presepsin [19]. Vodnik et al., found AUC of 0.916, 0.912 and 0.857 for presepsin, PCT, and CRP respectively for differentiating sepsis from SIRS [22].

Our results showed that there was significant positive correlation between presepsin and value of APACHE II score at day 0, then insignificant correlation at day 1 and started to show strong direct correlation at the 3 rd day. Also, there was positive linear significant correlation between presepsin and values of SOFA score started from day 0 and started to show strong direct correlation till day 3. The concentration of presepsin was found to be positively correlated with APACHE II and SOFA scores [23]. Also, presepsin level in emergency department was found to be significantly higher in severe sepsis patients than in sepsis patients [24].

These results support the enthusiasm resulting from the initial optimistic results of using the presepsin as a biomarker for sepsis diagnosis. Significant correlation was found between presepsin levels and SOFA score on admission, as a severity index of organ failure [25]. Moreover, the level of presepsin was seen in data from ALBIOS study to be correlated with SOFA score, and hemodynamic stability [26]. There was a strong significant positive correlation between presepsin levels and APACHE II score in our study that was also shown by Shirakawa et al., [18]; Shozushima et al., showed a significant correlation between presepsin values and both APACHE II and SOFA scores. These findings strengthened the hypothesis of presepsin use for prediction of more severe infection and reflecting patient condition [27].

In the current study, the AUC for the presepsin for survival prediction was the highest (0.910) compared to PCT (0.85), CRP (0.879). Also, we

detected a presepsin cutoff value of 1262pg/ml on day 3 to be 91% sensitive and 92% specific for survival prediction in SIRS patients. In the study by Behnes et al., found that the presepsin level had a significant 30 day and 6 months mortality prediction with AUC of 0.64 for 30-day mortality that was shown to be better than PCT and CRP. They found also that the APACHE II score is a significant prognostic indicator of 30-days and 6-months all-cause mortality, whereas AUC was not different from that of presepsin **[28]**. Liu et al., found an AUC that is slightly lower for presepsin than for PCT. They also found that the APACHE II score is higher in non-survivors within 28 days with an AUC of 0.722 which was higher than that of presepsin and PCT **[8]**. Rather than the absolute value of the biomarker, we studied its trend over time. We found that the decrease of the serum level of the three studied biomarkers was significantly associated with survival, with best sensitivity and specificity for presepsin. Endo et al., divided sepsis patients to favorable and unfavorable groups and found that the patients in favorable group exhibited significant decrease of presepsin, PCT, and CRP on day 3 while in the unfavorable group, only presepsin didn't decrease significantly **[29]**.

Also, Masson et al., showed that presepsin was higher in non-survivors while PCT revealed no relation to mortality. They showed also that the increasing concentration of presepsin from day 1 to day 2 predicted higher ICU mortality and the decrease of the presepsin was significantly higher in survivors while the decrease of PCT was similar in survivors and non-survivors **[30]**. Whereas, Magrini et al., reported that PCT increased in non-survivors during treatment but significantly decreased in survivors in patients admitted to emergency department with signs of infection **[31]**. Furthermore, Claeys et al., found a decreasing trend of PCT in survivors versus non-survivors within 2 days of septic shock as we found, but a longer time period of 120 hours for the decreasing trend of CRP in survivors was observed **[32]**.

Conclusion:

Presepsin cannot differentiate between sepsis and non-infective SIRS since admission; it can predict severity, prognosis and patient outcome. The accuracy of presepsin in this context was seen by our results to be superior to PCT. Also, our results demonstrated some mortality prediction value in presepsin in patients with sepsis. Further studies are needed to define the optimal cut-off point to predict mortality in sepsis.

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البريسيبسين مقابل البروكالسيتونين كدلالة لتشخيص ومعرفة تطور السميّة الدموية

المقدمة: السميّة الدموية هي إلتهاب مميت للجسم بأكمله (متلازمة الاستجابة الإلتهابية) الناجم عن عدوى شديدة. تتفاوت مظاهرها السريرية مع التقدم السريع. لا تقلل السميّة الدموية من جودة معيشة المريض فحسب، بل تزيد أيضاً من معدل الوفيات بشكل كبير.

الهدف من هذا البحث: هو التحقيق فى قيمة البريسيبسين التشخيصية والانذارية مقارنة بالبروكالسيتونين فى مرضى الرعاية المركزة الذين يعانون من متلازمة الاستجابة الإلتهابية الجهازية واشتباه السميّة الدموية أو الصدمة التسممية.

نوع الدراسة: دراسة كوهورت مستقبلية.

عينة الدراسة: تم إجراء البحث على ٦٢ مريض تم حجزهم بالرعاية المركزة العامة حيث عانى المريض على الأقل ٢ من خصائص متلازمة الإستجابة الإلتهابية الجهازية.

تم تحليل قياس نسبة البروكالسيتونين والبريسبيسين و CRP بالدم فى يوم دخول الحالة للرعاية المركزة وبعد ٢٤ ساعة ثم بعد ٧٢ ساعة.

ويمكن تلخيص نتائج هذه الدراسة على النحو الآتى :

- نسبة البروكالسيتونين أعلى بكثير من يوم دخول الحالة للرعاية المركزة إلى اليوم الثالث فى المجموعة الغير ناجية مقارنة بالمجموعة التى نجت.
- وكان البريسبسين أعلى بكثير من يوم دخول الحالة للرعاية المركزة إلى اليوم الثالث فى المجموعة غير الناجية مقارنة مع المجموعة التى نجت.
- كان مستوى البروكالسيتونين ذو دلالة إحصائية مميزة بين مرضى السميّة الدموية أكثر من المرضى ذو الاستجابة الإلتهابية الجهازية منذ دخول الحالة للرعاية المركزة وفى اليوم الأول. بينما، لم يكن مستوى البروكالسيتونين ذو دلالة إحصائية مختلفة بين مرضى السميّة الدموية والمرضى ذو الاستجابة الإلتهابية الجهازية فى اليوم الثالث.
- كان مستوى البريسبسين ذو دلالة إحصائية كبيرة بين مرضى السميّة الدموية أكثر من المرضى ذو الاستجابة الإلتهابية الجهازية وذلك منذ بداية دخول الحالة الرعاية المركزة وفى اليوم الأول. بينما، لم يكن مستوى البريسبسين ذو دلالة إحصائية كبيرة بين مرضى السميّة الدموية والمرضى ذو الاستجابة الإلتهابية الجهازية فى اليوم الثالث.

الإستنتاج: على الرغم من أن البريبسين لا يستطيع التفريق بين السميّة الدموية والاستجابة الإلتهابية الجهازية غير المعدية منذ القبول بالرعاية المركزة، إلا أنه يمكنه أن يتنبأ بالخطورة وتطور الحالة المرضية والنتائج المرضية متفوقاً على البروكاسيتونين ويمكنه التنبؤ بحدوث الوفاة فى المرضى الذين يعانون من السميّة الدموية.