

Presepsin as Sepsis Biomarker versus Procalcitonin in Early Sepsis Diagnosis

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Abstract

Background: Sepsis remains a major cause of death in critically ill patients. Early recognition of sepsis and timely therapeutic interventions are believed to be the cornerstone in outcome affection, however early identification of sepsis is not always straight forward since clinical signs and presentation can be misleading. Although blood culture remains the gold standard for diagnosis of bacterial infection, it still has several limitations and therefore the need for an early and specific diagnostic biomarker is mandatory. Procalcitonin is widely reported as a useful biochemical marker to differentiate sepsis from other non-infectious causes of systemic inflammatory response syndrome. Presepsin is a proposed early, sensitive, specific biomarker that may help early identification of sepsis.

Aim of Study: This study was performed to compare the clinical usefulness of monitoring Presepsin and Procalcitonin serum levels in early diagnosis of sepsis.

Patients and Methods: This prospective study was conducted at Ain-Shams University hospital, Cairo, Egypt. We included 50 sepsis patients (age from 18-60 years old), who fulfilled two or more of the criteria for sepsis as defined by the society of critical care medicine (SCCM). Full History taking, physical examination, baseline laboratory investigations and required imaging scans were collected and recorded for all patients on admission to ICU. Blood cultures were obtained before initiating antibiotic therapy. Presepsin and procalcitonin serum values were measured at 6 time points: On ICU admission (T0), after two hours (T1), after four hours (T2), after 8 hours (T3), after 24 hours (T4) and after 72 hours (T5). Sepsis was confirmed by the patient's cultures, and were then compared to the corresponding serum values of Procalcitonin and Presepsin. Results were analyzed to determine the diagnostic efficiency of both biomarkers.

Results: In the studied population, the mean age of all patients was (54.3±15.6) years, with (52%) of patients were females; and (48%) were males. Regarding the outcome data, (60%) of patients showed positive culture results, and (40%) showed negative culture results. In our study we found a significant increase in Presepsin level in the positive culture group compared to the negative culture group at all time

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points starting from T0 to T5. Concurrently we found marked increase in Procalcitonin in positive group compared to negative group starting from T2 to T5, while early measurements at T0 and T1 Procalcitonin rise was non-significant. ROC-curve analysis showed that early Presepsin level (after 2 hours) at a cutoff point (>379) showed a significant predictive power for early sepsis diagnosis, with good (82%) accuracy, sensitivity (100%) and specificity (80%) ($p<0.01$). Early Procalcitonin level showed comparable sensitivity (90%) to Presepsin but much lower specificity (35%), and poor (56%) accuracy ($p>0.05$), making its predictive value for early distinguishing patients with positive cultures compared to patients with negative cultures statistically non-significant.

Conclusion: To conclude, the present study suggests that Presepsin and Procalcitonin are valuable biomarkers for sepsis diagnosis. Furthermore, our findings demonstrate that Presepsin has proven to be a promising candidate for accurate and early prediction of sepsis compared to Procalcitonin, giving preliminary indications that Presepsin may play an important role in the early sepsis identification in suspected septic patients.

Key Words: Presepsin – Procalcitonin – Blood culture – Early sepsis diagnosis.

Introduction

DESPITE the advances in its diagnosis and management, sepsis remains a major cause of death in critically ill patients [1]. It is established now that early identification and timely therapeutic interventions are the cornerstone in outcome affection [2]. Prompt recognition of sepsis is not always straight forward and clinical signs and presentation can be misleading and very heterogeneous due to frequent comorbidities or variable demographics characteristic therefore, an urgent need for a reliable diagnostic procedure, allowing early discrimination between bacterial and non-bacterial infections is mandatory [3]. Although blood culture remains the gold standard for diagnosis of bacterial infection, its usefulness in early detection of infection is limited as it requires many days for obtaining the

This can delay proper intervention and consequently lead to increased adverse outcomes [2]. Biomarkers such as C-Reactive Protein (CRP) and Procalcitonin (PCT) introduced alongside the diagnostic criteria could help early recognition of patients affected by sepsis, severe sepsis and septic shock who could benefit from fast and proper therapy [3]. Procalcitonin (PCT) is widely reported as a useful biochemical marker to differentiate sepsis from other non-infectious causes of Systemic Inflammatory Response Syndrome (SIRS). Procalcitonin has been widely used as a sepsis biomarker, but it has poor specificity as it increases in many non-septic conditions (e.g. trauma, surgery, myocardial infarctions, stroke, pancreatitis) [4]. Presepsin [soluble CD14 subtype (Scd14-ST)] was first proposed in 2004 as a novel biomarker with high sensitivity and good specificity for sepsis diagnosis [5,6]. CD14 was identified to be glycoprotein expressed on the surface membrane of monocyte/macrophages (mcd14) and serves as a receptor for complexes of Lipopolysaccharides (LPS) and LPS Binding Protein (LPBP) and it co-localizes with Toll-Like Receptor (TLR4) [7]. The increase of Presepsin specifically in response to bacterial infection may be because its mechanism of secretion is related to phagocytosis against bacteria [8]. In this study we assessed the clinical performance of Presepsin and procalcitonin levels for early diagnosing sepsis.

Patients and Methods

Patients:

This prospective study was conducted after approval of the Research Ethics Committee, Faculty of Medicine, Ain Shams University, Cairo, Egypt (FMASU M S 363/2019) approved on 13/12/2019. The study was performed at Ain-Shams University Hospital, Cairo, Egypt, and was carried out during the period between November 2019 and June 2020. 50 patients suspected of having sepsis were randomly selected from the Intensive Care Unit (ICU).

Inclusion criteria:

- 1- Age > 18 years old.
- 2- Two or more of the following criteria suggestive of Sepsis as defined by SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference:
 - A- Temperature of more than 38°C or less than 36°C.
 - B- Pulse rate of more than 90 beats/min.
 - C- Respiratory rate of more than 20 breaths/min or hyperventilation with a partial pressure of arterial carbon dioxide of less than 32mmHg.

- D- White blood cell count of more than 12000/mm³ or less than 4000/mm³, or more than 10% immature cells [9].

Exclusion criteria:

- 1- Age <18 years.
- 2- Incapability to obtain informed consent from patient/relative.
- 3- Patients with end stage disease as: Malignancy, end stage liver or kidney disease, acquired immunodeficiency syndrome.
- 4- Documented different diagnosis as: Meningitis, thromboembolism, hemorrhagic shock etc.
- 5- Patients who had received anti-inflammatory drugs or corticosteroids before admission.

Methods:

Patients' demographic data, full medical history plus baseline clinical criteria, vital data, laboratory investigations and required imaging scans were collected and recorded on study enrolment. All patients were followed-up for 72 hours regarding: Heart rate, respiratory rate, mean arterial pressure and oxygen saturation, central venous pressure, urine output and random blood sugar as per standard ICU protocol. Daily recorded laboratory parameters included: Complete blood count, serum creatinine, serum liver enzymes (alanine transaminase, aspartate transaminase), Partial Thromboplastin Time (PTT), International Normalized Ratio (INR), serum electrolytes (sodium and potassium), blood gas analysis, CRP, total and direct bilirubin, total protein, serum albumin. Serum levels of Presepsin and procalcitonin were collected and recorded at five time points; on admission (T0), after 2 hours (T1), after 4 hours (T2), after 8 hours (T3), after 24 hours (T4) and after 72 hours (T5).

Details of Presepsin marker:

- *Method name:* Enzyme Immunoassay Technology.- *Specimen type:* Serum Red.
- *Collection container/tube:* Red top.
- *Specimen volume:* 100µL.
- *Specimen minimum volume:* 0.25mL.

Details of Procalcitonin marker:

- *Method name:* Homogeneous Time-Resolved Fluorescence.
- *Specimen type:* Serum Red.
- *Collection container/tube:* Red top.
- *Specimen volume:* 0.5mL.
- *Specimen minimum volume:* 0.25mL.

The normal value reference for Presepsin was 60-360pg/ml and for procalcitonin was 0.1-0.5ng/ml [10]. Before initiating antibiotic therapy, blood culture was obtained from each patient on admission. As well as cultures from any suspected site of infection such as urine, sputum or wound. The primary objective of our study was to evaluate the diagnostic value of Presepsin versus Procalcitonin in predicting the presence of infection in suspected septic patients.

Statistical analysis:

Data entry, processing and statistical analysis was carried out using MedCalc ver. 18.2.1 (MedCalc, Ostend, Belgium). Tests of significance (Mann-Whitney's, Chi square, tests, factorial ANOVA, and Receiver Operating Characteristic (ROC) curve analysis) were used.

Sample size:

Prior data indicate that sepsis patients had +ve blood cultures (57.5%) vs. (42.5%) who had -ve blood cultures (patient/control ratio was 1.35). Also, early Presepsin level in the patient group was (1453.78±372.5) pg/ml and in the control group was (800.6±169.4) pg/ml [11]. Then, we will need to study at least 5 experimental subjects and 4 control subjects (total 9 patients), to be able to reject the null hypothesis that the early Presepsin levels for experimental and control subjects are equal with probability (power) 80%. The Type I error probability associated with this test of this null hypothesis is 0.05. We used student's *t* statistics to evaluate this null hypothesis, and we enhanced sample power through studying 50 sepsis patients.

Results

In the studied population, the mean age of all patients was (54.3±15.6) years. Regarding gender of the patients, (52%) of patients were females; and (48%) were males. Regarding outcome data, (60%) of patients showed positive culture results, and (40%) showed negative culture results (Table 1).

Table (1): Outcome data among 50 sepsis patients.

Variables	Frequency (%)
<i>Culture and sensitivity:</i>	
-ve "Suspected Sepsis"	20 (40%)
+ve "Laboratory Confirmed Sepsis"	30 (60)

Comparative studies:

The 50 suspected septic patients were classified according to culture and sensitivity results into 2 independent groups:

- Negative "suspected sepsis" group (20 patients).
- Positive "laboratory confirmed sepsis" group (30 patients).

Follow-up data: We further analyzed and compared all 50 patients according to the serial Presepsin and Procalcitonin values at the six time points with entering a grouping factor (negative or positive cultures).

We found a marked increase in Presepsin level in the positive "laboratory confirmed sepsis" group; compared to the negative "suspected sepsis" group at all time points, starting from T0 to T5 ($p<0.01$) Fig. (1), (Table 2).

Table (2): Comparison between the 2 groups of patients regarding serial Presepsin assessments at different time points.

Presepsin	T0	T1	T2	T3	T4	T5
• -ve culture group (Median)	343.5	375.5	395.5	388.5	400.5	313.5
• +ve culture group (Median)	916	1764	3030	2169	1870	1349
• <i>p</i> -value	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01

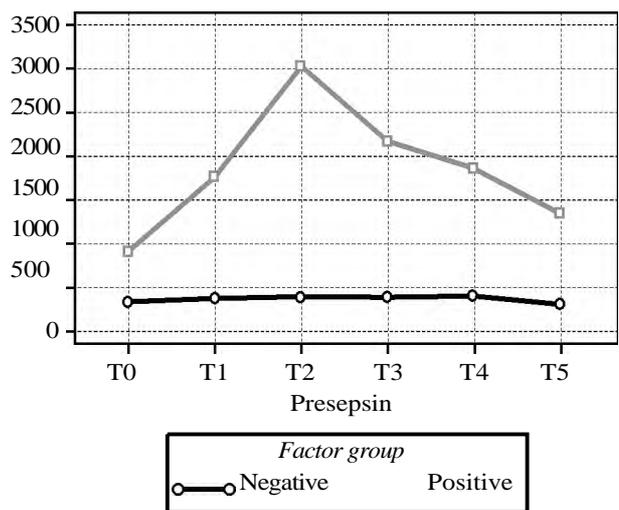


Fig. (1): Comparison between the 2 groups of patients regarding serial Presepsin assessments from T0-T5.

We found marked increase in Procalcitonin in positive "laboratory confirmed sepsis" group; compared to negative "suspected sepsis" group starting from T2 to T5 ($p<0.01$), while early measurements at T0 and T1 showed non-significant difference in Procalcitonin level between the two groups ($p>0.05$). Fig. (2), (Table 3).

Table (3): Comparison between the 2 groups of patients regarding serial Procalcitonin assessments.

Procalcitonin	T0	T1	T2	T3	T4	T5
• -ve culture group (Median)	0.45	0.5	1.55	1.57	1.9	0.9
• +ve culture group (Median)	0.5	0.5	3.3	10.05	12.9	8.55
• p-value	0.393	0.450	<0.01	<0.01	<0.01	<0.01

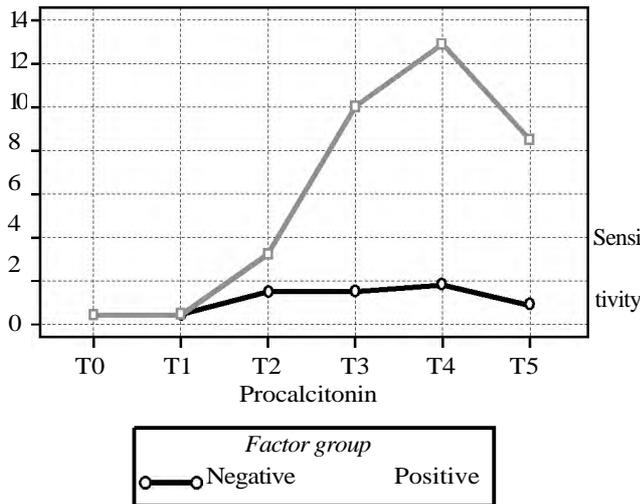


Fig. (2): Comparison between the 2 groups of patients regarding serial Procalcitonin assessments from T0-T5.

Correlation studies:

Receiver Operating Characteristic (ROC) curve analysis to detect the efficacy of early analysis (at 2 hours) of both laboratory biomarkers for early prediction of sepsis:

Table (4): Roc-curve of some laboratory markers to predict early sepsis diagnosis.

Variable	AUC	SE	Best cut off point (criterion)	Sens. (%)	Spec. (%)	p-value
Presepsin (2h)	0.820	0.081	>379	100	80	0.001**
Procalcitonin (2h)	0.562	0.086	>0.25	90	25	0.1627
ROC curve comparison between the 2 markers						=0.0026**
Difference between 2 ROC areas =						0.257

ROC: Receiver Operating Characteristic.
 AUC: Area Under Curve.
 SE: Standard Error.

Data obtained from ROC curve analysis in our study demonstrated that: Early Presepsin level at two hours at a cutoff point (>379) showed a significant predictive power for early sepsis diagnosis, with good (82%) accuracy, sensitivity= 100% and specificity=80% (p<0.01) Fig. (3), (Table 4).

Early Procalcitonin level at two hours showed a non-significant predictive power for early sepsis diagnosis with poor (56%) accuracy (p>0.05) Fig. (3), (Table 4).

Area Under the Curve (AUC) of both biomarkers confirmed the higher discriminating power of presepsin in distinguishing between bacterial and non-bacterial infections compared to procalcitonin (p=0.0026) (Table 4), Fig. (3).

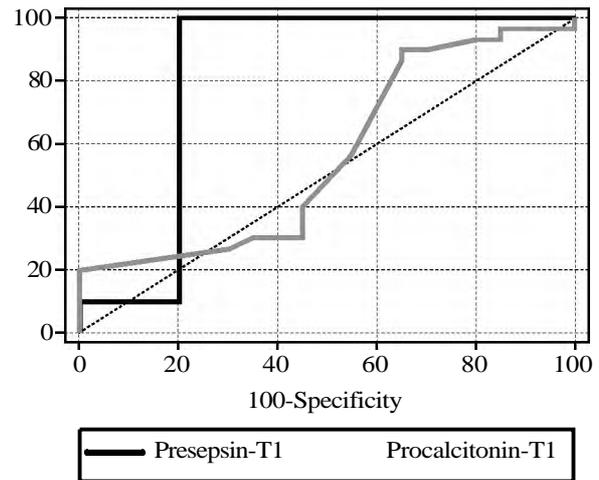


Fig. (3): ROC curve of early Presepsin vs Procalcitonin (early sepsis diagnosis).

Discussion

The biggest challenge when dealing with suspected septic patients is the difficulty in confirming an early diagnosis and subsequently timely intervention. Although conventional cultures are considered the gold standard of bacterial sepsis diagnosis, they still have several limitations. Early and specific biomarkers for sepsis diagnosis could contribute to proper identification of patients with sepsis and therefore have been widely studied in many clinical settings. The current study was designed to evaluate and compare the clinical usefulness of monitoring Presepsin and Procalcitonin levels for early sepsis diagnosis. 50 patients with suspected sepsis were enrolled in our study, sepsis was confirmed by the patient's cultures, and were then compared to the corresponding serum values of Procalcitonin and Presepsin. Results were analyzed to determine the diagnostic efficiency of both biomarkers. Regarding the demographics of our study population, we found that; the mean age of all patients was (54.3±15.6) years, including (52%) of patient's females; and (48%) males. In this study, out of the 50 patients enrolled there were 30 patients (60%) with positive culture results and 20 patients (40%) had negative culture results.

We found marked increase in Presepsin level on the first 3 days of admission in positive group; compared to negative group starting from T0 to T5 (p<0.01), in our study Presepsin level was

significantly higher in the positive group at 2 hours, peaked at 4 hours and started to decrease at 4-8 hours. Concurrently, we found marked increase in Procalcitonin in positive "laboratory confirmed sepsis" group; compared to negative "suspected sepsis" group starting from T2 to T5 ($p < 0.01$), while early measurements at T0 and T1, Procalcitonin rise was non-significant ($p > 0.05$), Procalcitonin started to increase 2-4 hours after infection and peaked at 24 hours. Our results came in agreement with a systematic review analysis and meta-analysis published in 2014 by Qi Zou et al., they found that Presepsin increased earlier in septic patients, it was high at 2 hours, peaked at 3 hours and decreased at 4-8 hours after infection. On the other hand, procalcitonin level increased in 4 hours following infection, slowly reached a plateau at 8-24 hours and its peak was 24 hours after infection [12]. Similar results were observed in several studies, they found that the concentration of Presepsin significantly increased at the early stage of sepsis. In a prospective study by El-Shafie et al., carried out on thirty-one Egyptian patients admitted to the ICU with suspected sepsis. They found that Presepsin level on days 0, 2, and 4 were significantly higher in the presence of infection [13].

Malaka et al., conducted another study at Ain Shams University and included seventy potentially septic patients and thirty apparently healthy individuals. Regarding the comparison between plasma Presepsin assay between the two groups, there was a statistically significant increase of Presepsin observed in the patient group [14]. Yaegashi et al., documented significant increase in levels of Presepsin in sepsis patients compared to its level in patients with no sepsis or healthy subjects [15]. Ulla et al., in a prospective study found that Presepsin levels significantly increased in early sepsis, its levels were higher than that in non-septic patients [16]. Liu et al., reported that Presepsin levels increased in early sepsis, and that the levels were significantly higher than in healthy controls and in SIRS patients [17]. Shozushima et al., noted that patients with local infection or sepsis had significantly higher Presepsin levels than the patients who did not have infection as a complication [18]. de Gadiana Romualdo et al., reported that, with regard to biomarkers, CRP, PCT and Presepsin values were significantly higher in bacteremia SIRS group [19]. Agilli et al., claimed that Presepsin is a new promising biomarker for diagnosis of sepsis. Presepsin levels of patients with sepsis were found significantly elevated in comparison with patients having SIRS and healthy people, in a clinical study [20]. The increase in Procalcitonin values in patients with positive culture compared

to patients with negative culture results during the serial measurements starting from T2 to T5 shown in our study, came in agreement with several studies e.g. Shozushima et al., and Romualdo et al., Yamamoto et al., 2019 and Tambo et al. Data from these studies found that procalcitonin have a good diagnostic performance, however when compared to Presepsin, the latter proved to have higher accuracy [10,18,19,21].

We studied ROC-curve analysis to evaluate the accuracy of both biomarkers for early prediction of sepsis. We found that early Presepsin level at a cutoff point (>379) predicted patients with negative cultures, with good (82%) accuracy, sensitivity=100% and specificity=80% ($p < 0.01$). PCT showed comparable sensitivity to Presepsin but much lower specificity and poor (56%) accuracy, making its predictive value in discriminating patients with positive cultures from patients with negative culture statistically non-significant. These findings came in agreement with several studies suggesting the superiority of Presepsin in early sepsis diagnosis compared to other biomarkers: In an Egyptian population, Malaka et al., study showed that Presepsin level of 320pg/ml has specificity 68% and the sensitivity 100%, while cut-off value of 395pg/ml has the same sensitivity (100%) but with better specificity (100%) [14]. Similarly, Shafie et al., found that the AUC was 1 for all Presepsin values at the three time points they measured. They identified a serum Presepsin value of 422pg/mL on admission, of 427.5pg/mL on day 2, and of 410.5 pg/mL on day 4 to have 100% sensitivity and specificity for diagnosis of sepsis [13]. Whereas Ulla et al., suggested Presepsin cut-off point at 600pg/ml for diagnosis of sepsis which gives 78.95% sensitivity and 61.9% specificity [16]. Liu et al., found that ROC analysis showed that the AUC of Presepsin (0.840) was statistically higher than that of PCT (0.741) ($p < 0.01$) and showed better sensitivity (82.4%) in predicting severe sepsis [17]. Ozdemir and Elgormus, reported that the cutoff value for Presepsin was 539pg/mL with 80% (95% CI: 75-85) sensitivity and 75% (95% CI: 71-79) specificity [22]. Shozushima et al., compared the AUC values of Presepsin, Procalcitonin and CRP, their results showed that the AUC value for Presepsin was the highest followed by CRP and then Procalcitonin (0.845 vs. 0.815 and 0.652 respectively). For differentiation between no sepsis and sepsis, they found a cutoff value of Presepsin of 415pg/to have a sensitivity and specificity of 80.1 % and 81 % respectively [18]. Endo and his colleagues also reported better sensitivity of Presepsin compared to Procalcitonin for the diagnosis of sepsis, sensitivity was 91.9% for

Presepsin, while for Procalcitonin was 89.9%. They found Presepsin cutoff value for discriminating bacterial and nonbacterial infectious diseases to be 600pg/ml, sensitivity was 87.8% and specificity was 81.4% [23]. Madenci et al., observed that the value of Presepsin in distinguishing the presence of bacterial infections was comparable to PCT, but the accuracy of Presepsin was much higher than PCT [24]. However, Ali et al., studied the diagnostic performance of Presepsin and PCT as assessed by ROC curve analysis in the septic versus non-septic groups, AUCs for Presepsin and PCT, were 0.805, 0.780 respectively, indicating that the usefulness of Presepsin to identify sepsis could be compared clinically to that of PCT (AUC, 0.805 vs. 0.780; $p = 0.755$) [25]. The variations in sensitivity and specificity between our study and other studies could be explained by different cut off values used. The current study was limited by the small sample size used, which may influence the accuracy of the ROC curve in calculating the cutoff values.

Conclusion:

More sensitive and specific biomarkers are needed for early diagnosis of sepsis particularly in such patients with atypical clinical picture and before the development of severe sepsis and septic shock. The present study suggests that Presepsin is a more accurate biomarker for early sepsis diagnosis compared to procalcitonin. Presepsin increases early in the first day of infection and therefore can effectively distinguish bacterial from non-bacterial infections. To conclude, Presepsin is a promising early, sensitive, specific marker that seems to play an important role in the early diagnosis of sepsis.

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مقارنة بين مستوى مادة البريسبس والبروكالستونين في التشخيص المبكر للإنتان

على الرغم من التقدم المحرز في تشخيص وعلاج إنتان الدم إلا أنه لا يزال سبب في وفاة كثير من مرضى الرعاية الحرجة. ولقد ثبت أن التدخل المبكر في التشخيص والعلاج في الوقت المناسب له تأثير فعال في السيطرة على حالات تعفن الدم. لكن التعرف المبكر على الإنتان لا يكون دائماً بشكل مستقيم وذلك نظراً لأن الحالات المرضية والأعراض قد تكون غير متجانسة ومتغيرة لذا كانت الحاجة الملحة من إيجاد تشخيص موثوق يسمح بالتمييز المبكر بين الإنتان ومتلازمة الإستجابة الجهازية الغير معدية ولذلك ظهرت التحاليل الحيوية التي قد تساعد في التشخيص مثل تحليل البروتين التفاعلي.

والبروكالستونين وبعده البروتين التفاعلي أحد أكثر العلامات الحيوية التشخيصية شيوعاً التي تستخدم في تشخيص حالات تعفن الدم وقد رأى الباحثون أن البروتين التفاعلي يظهر نتائج فعالة في التفريق بين الإنتان والإستجابة الإلتهابية الجهازية الغير معدية. حديثاً تم التعرف على بروتين جديد وهو عبارة عن بروتين سكري يوجد على الغشاء السطحي للخلايا أحادية البلاعم ويعمل CD14 يسمى كمستقبل للمجمعات السكرية الدهنية وأطلق عليه تحليل البريسبس. كما تم اعتبار البريسبس كعلامة حيوية ذات حساسية عالية وذو خصائص جيدة في تشخيص الإنتان والصدمة الإنتانية. كما يستخدم تحليل البروكالستونين للتمييز بين التسمم الإنتاني والمتلازمة الإستجابية الإلتهابية الجهازية الغير معدية. لذا قمنا في هذه المراجعة المنهجية بتقييم كل من منسوب البريسبس والبروكالستونين في المراحل المبكرة من التسمم الإنتاني.

الهدف من هذه الدراسة: هو مقارنة نتائج ومنسوب البريسبس والبروكالستونين في التشخيص المبكر للإنتان.

النتيجة العامة: تشير الدراسة الحالية إلى أن مادة البريسبس والبروكالستونين هما مؤشر حيوي وقوي للتشخيص المبكر للإنتان والتنبؤ بالوفيات على المدى القصير علاوة على ذلك تظهر النتائج التي توصلت إليها أن مادة البريسبس قد أثبتت نجاحاً في التنبؤ الدقيقة في تشخيص الإنتان ومدى وقياس مدى فعالية العلاج.