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Letter to editor

Pathfast POCT: Evaluation presepsin as a key biomarker in sepsis

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To the Editor,

Presepsin (PSEP), a known biomarker for sepsis but not widely adopted, is a protein anchored in the monocity membrane surface. It is involved in the immune response, specifically activated in the presence of bacterial infections (1). Its ability to early reflect the uncontrolled activation of the immune system makes it a valuable indicator for detecting sepsis in the initial stages.

Several studies have also explored the prognostic role of presepsin in patients with severe sepsis. For instance, Yoo et al. (2020) conducted a longitudinal study on a cohort of patients with severe sepsis, revealing a significant association between elevated levels of presepsin and increased 28-day mortality. These results suggest that presepsin could be a useful prognostic indicator, allowing for a more accurate assessment of mortality risk in patients with severe sepsis.

Existing Sepsis biomarkers such as C-reactive protein (CRP), procalcitonin (PCT) and lactate tests are universally used as early sepsis screening. Blood culture continues to be the gold standard for detecting and identifying pathogens, and in recent years, it has been extensively utilized in the differential diagnosis of sepsis. However, it still possesses significant limitations.

Several instruments have been identified in the literature, including enzymatic immunoassays (ELISA), chemiluminescence, and lateral flow immunoassays. Enzymatic immunoassays are among the most commonly used and are generally considered accurate and reliable (4). However, some studies have highlighted variations in results between different commercial kits, suggesting the need to standardise measurement methods.

Chemiluminescence-based and lateral flow immunoassay instruments offer advantages in speed of execution and ease of use but may have limitations in terms of sensitivity and specificity.

A novel, highly-sensitive, fully automated PATHFAST presepsin measurement system, based on the chemiluminescent enzyme immunoassay (CLEIA) principle, has been developed to analyse the entire blood samples that provides its result within 17 min. (5). This approach is applicable in the Emergency Department (ED), ICU, and surgical wards. No interference of presepsin has been detected with other analytes such as bilirubin, haemoglobin, lipids, triglyceride, or rheumatoid factors (6).

We assessed 23 consecutive patients who presented to the emergency room with suspected sepsis. Presepsin (PSEP), CRP, and PCT (BRAHMS) levels were measured in K3EDTA whole blood using Pathfast (POCT). Additionally, K3EDTA plasma samples from the same patients were collected and analyzed with DXI 800 Beckman Coulter to determine PCT and CRP.

All three biomarkers showed a statistically significant increase in different cutoff intervals (suspected, positive) during the Pathfast test. Additionally, the PCT and CRP values measured by DXI demonstrated overlap with those obtained through Pathfast.

Table 1. Evaluation criteria according to presepsin concentration.

Presepsin (pg/ml)	Diagnosis
< 200	Exclusion fo sepsis
< 300	Systemic infection not probable
< 500	Systemic infection (sepsis) probable
< 1000	Significat risk of the systemic infection progression (severe sepsis), increasing risk of unfavorable outcome
≥ 1000	High risk of the systemic infection progression (severe sepsis/septic shock). Hoigh risk for mortality after 30 day comparable with a SOFA score ≥8

Our results confirmed a strong agreement between the PCT and CRP values measured with Pathfast and those obtained using the Beckman Coulter DXI analyzer.

Considering values close to the cut-off, no significant differences were found.

For the early diagnosis and treatment of sepsis, presepsin appears to be a sensitive, specific, early, and prognostic biomarker, proving to be superior to other markers and, therefore, a valuable tool for ruling in or ruling out sepsis.

Since a positive likelihood ratio is clinically acceptable when it reaches higher values, PSEP cannot be used alone as a marker for sepsis diagnosis. It must be associated with the clinical context and other markers, such as procalcitonin (PCT), to confirm the diagnosis.

In the emergency department, P-SEP appears to be a promising sepsis marker, due to an earlier increase in plasma levels compared to PCT, thus allowing an early recognition and a rapid start of therapy in the ED.

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