

The PSP Biomarker Rises Earlier than CRP and PCT in Sepsis, a New Study Shows



Sepsis is a global healthcare problem, with 50 million cases each year and 11 million related deaths ¹. It's the life-threatening complication of an infection, in which the host's immune response to a pathogen damages its own organs. The clinical diagnosis of sepsis relies mostly on signs and symptoms that are neither sensitive nor specific enough to allow for timely and accurate diagnosis. Two biomarkers are routinely used today by clinicians as tools to support the diagnosis of sepsis: C-reactive protein (CRP) and procalcitonin (PCT), which have both been extensively studied and despite being the only two biomarkers established in clinical practice today, have important intrinsic limitations.

Is there another solution available?

The association of pancreatic stone protein (PSP) with sepsis is well established across various clinical situations and patient populations as an accurate sepsis biomarker (reviewed in 2). As of March 2020, PSP can now be readily measured at the patient's bedside on the point-of-care abioSCOPE device. To further define the utility of PSP in sepsis, and based on the true need to identify sepsis earlier, a study was designed to explore the association of PSP concentrations with the development of sepsis. It was hypothesized that increasing PSP levels could help identify sepsis before the onset of clinical signs. The results of this clinical study were recently published in *Critical Care*, the leading open access journal on intensive care medicine ³.

What was known before the study?

PSP has a high specificity for sepsis, since sterile inflammation caused by various types of traumas does not lead to an increase in PSP, but which is commonly seen with CRP, PCT and interleukin 6 (IL-6) ⁴⁻⁵. Consequently, PSP has a high accuracy for severe infection and the ability to distinguish between sterile inflammation and sepsis ⁶. Moreover, the PSP level at the time of sepsis diagnosis correlates with disease severity and predicts outcome ⁷⁻⁸.

What new evidence does this study provide?

Serial measurements prior to the identification of sepsis demonstrate that PSP rises continuously in the days preceding the clinical diagnosis of sepsis. Most importantly, patients without sepsis had constantly low PSP values. Therefore, daily measurements of PSP in patients at risk or suspected of sepsis can greatly help clinicians to identify the disease earlier. The design of this study including a heterogeneous ICU population supports the generalization of these findings to real life situations.

How was the study designed?

This was a multicentric, prospective, observational clinical study performed in fourteen hospitals in France, Italy, England and Switzerland. Adult patients admitted to the ICU without infection or sepsis and free of antibiotic therapy were included in the study, so as to observe the evolution of biomarkers before, during and after the development of a nosocomial sepsis, with PSP, CRP and PCT measured daily. Clinicians were blinded to biomarker results (if these were not part of standard routine), and an External Adjudication Committee (EAC) retrospectively determined whether a septic event had occurred or not, and, if yes, when, during the patient's ICU stay. PSP was measured on the point-of-care abioSCOPE device, while CRP and PCT were centrally measured in the clinical laboratory. 297 patients were recruited, of which 53 were identified as having sepsis. The association between each biomarker with the clinical development of sepsis was then investigated.

What are the implications of these results?

PSP demonstrated the strongest increase in the days preceding sepsis compared to PCT and CRP. In addition, patients who did not develop sepsis had stable levels of PSP, whereas PCT and CRP fluctuated irrespective of sepsis. Current guidelines emphasize the need for early

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recognition and aggressive management of sepsis, focusing on treating the infection and restoring homeostasis. Serial PSP measurements at the patient's side offers an unprecedented solution to improve the diagnosis of sepsis, meeting the needs of both patients and clinicians. This biomarker opens a window of opportunity to act earlier, before overt clinical signs and symptoms are visible, to mitigate the consequences of sepsis and to reduce the burden of this deadly disease.

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