INTENSIVE CARE UNIT | BURN UNIT

Sepsis Management in Burn Unit

abionic
Early Sepsis Detection

DETECT SEPSIS

7'

ACTIVATE BUNDLE

Reveal Sepsis Up To 72h Before Clinical Recognition

Sepsis Is A Global Emergency Requiring Immediate Diagnosis & Treatment

Pancreatic Stone Protein (PSP) for the Early Detection of Sepsis

An increase in PSP levels in the days preceding the clinical diagnosis of sepsis offers a unique window of opportunity for clinicians to initiate optimal treatment protocols **(Figure 1)**. PSP levels can be measured within minutes from a single drop of whole blood on Abionic's nanofluidic-based platform, the abioSCOPE®. This platform enables blood PSP concentration monitoring associated with the early development of sepsis.

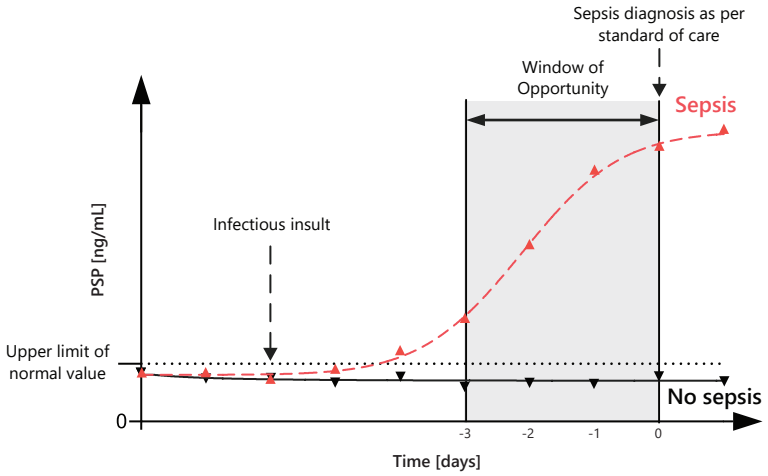

Figure 1. Schematized daily PSP biomarker readings in patients who develop nosocomial sepsis (dashed red line) or not (solid black line).

Early Sepsis Detection Within Minutes

abioSCOPE®

Reducing Time-To-Treatment by up to

72h

can dramatically improve patient outcomes

Lab-Quality Results

Interpretation Of PSP Measurements

Initiate The Right Treatment For Critically Ill Adults At Risk Of Developing Sepsis

PSP Concentrations	Interpretations	Suggested Measures
> 300 ng/mL	**Very High risk of sepsis**	Instantly apply sepsis bundle (surviving sepsis campaign guidelines)
Cut-off : 300 ng/ml	Sensitivity: 45% Specificity: 84%	
200 - 300 ng/mL	**High risk of sepsis**	Apply sepsis bundle (surviving sepsis campaign guidelines)
Cut-off : 200 ng/ml	Sensitivity: 55% Specificity: 77%	
100 - < 200 ng/mL	**Moderate Risk of Sepsis**	Decisions based on clinical evaluation
Cut-off : 100 ng/ml	Sensitivity: 83% Specificity: 53%	
< 100 ng/mL	**Low risk of sepsis** normal value	Reevaluate for possible sepsis if clinically indicated

The absolute values and relative changes of PSP should always be evaluated in the context of the patient's overall clinical picture. Value recommendations are based on clinical data.

Clinical Evidence

Early Sepsis Detection in Critical Care Workflows

Intensive care physicians must distinguish between systemic inflammatory response and sepsis for appropriate treatment. A 2021 multicentric study[1] found that the biomarker PSP significantly increases in the days preceding sepsis, strongly associating with subsequent sepsis development. This provides a crucial window for timely clinical intervention. PSP's effectiveness has been confirmed in various critically ill patient groups, including those with severe burns[2], polytrauma[3], post-cardiac surgery[4] and on admission to the intensive care unit (ICU)[5]. **Figure 2** shows PSP values in patients developing nosocomial sepsis peaked on day 7. PSP levels remained relatively stable in patients without nosocomial sepsis.

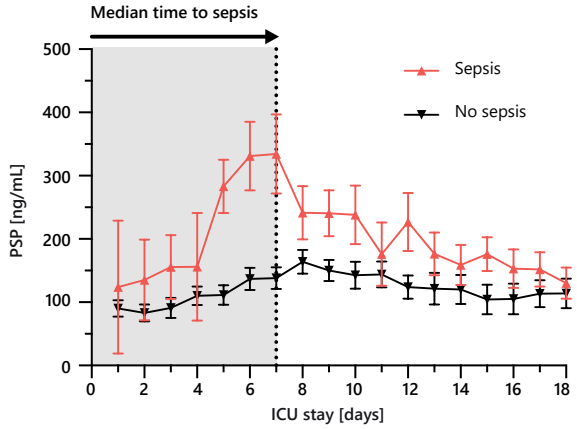

Figure 2. PSP trajectories of patients who did (red) or did not (black) develop sepsis. Data are median with SEM. Unpublished data from AB-PSP-001 (NCT: 03474809). SEM, standard error of the mean.

PSP Enables Early, High-Accuracy Sepsis Detection in Burn Patients

Key Clinical Facts:

- Severe burns increase the risk of sepsis
- Prolonged stays in Burn ICUs require judicious use of antibiotic

Burn victims often experience persistent hyperinflammation, metabolic disruption, and capillary leakage, which can obscure the clinical signs of sepsis, leading to delayed treatment. The prevalence of sepsis in these patients ranges from 8% to 43%[6]. A recent study[7] evaluated four biomarkers to diagnose sepsis based on three different definitions (Sepsis-3, Sepsis American Burn Association 2007, and Zurich Burn Center). The study found that PSP had the highest accuracy in distinguishing septic from infected patients according to all three definitions, particularly in the three days leading up to sepsis. Specifically, PSP's accuracy, measured by AUC, was 0.72 three days before sepsis, 0.88 two days before, and 0.85 one day before. Sensitivity ranged from 0.7 to 0.8, and specificity improved from 0.7 to 0.9. The diagnostic performance of the PSP progressively improves as the time of sepsis diagnosis approaches. (**Figure 3**)

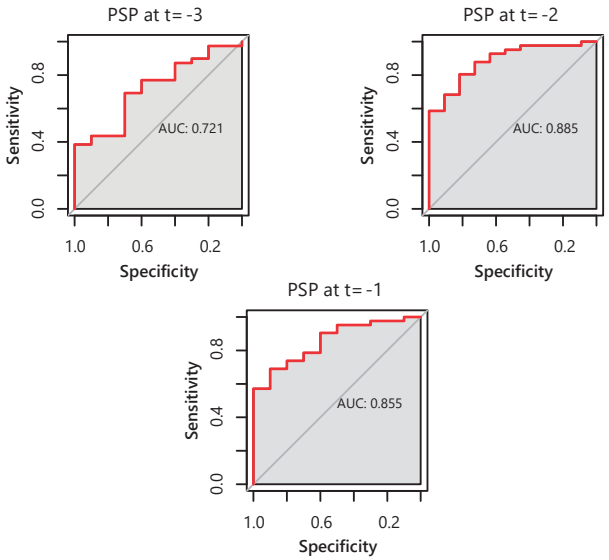

Figure 3. ROC-curve analysis with AUC for Sepsis-3 of PSP at t=-3,-2,-1 (days) before the onset of sepsis.

Early Sepsis Detection in Burn Patients

Figure 4 illustrates the evolution of PSP levels in severely burnt patients, showing distinct patterns before and after the onset of septic shock, sepsis, infection, or no infection. In a study[8] of 90 patients with severe burns, PSP levels increased three-fold in the 72 hours before sepsis appeared, confirming its value as an early sepsis biomarker. These findings underscore PSP's predictive power when it rises, making it a valuable tool for burn specialists in clinical decision-making.

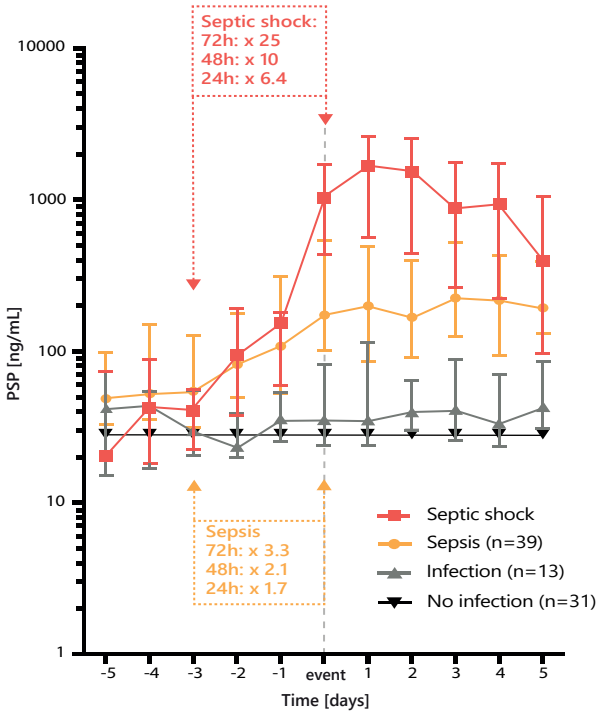

Figure 4. Evolution of PSP levels in severely burnt patients with septic shock, sepsis, infection, or no infection before and after the day of these events.

PSP in Burn Patients with Inhalation Injuries

Pulmonary inhalation injury in burn patients triggers a systemic immune and inflammatory response that complicates sepsis diagnosis and limits the effectiveness of standard biomarkers. However, pancreatic stone protein (PSP) levels rise significantly before sepsis develops, even with inhalation injury, making PSP a potentially useful marker. Current ICU burn treatments, including surgery and wound debridement, induce further tissue damage and stress, leading to increased pro-inflammatory cytokines and acute-phase proteins like C-reactive protein (CRP) which results in significant immune, hemodynamic, and endocrine changes. **Figure 5** demonstrates that PSP levels effectively differentiate between sepsis and non-sepsis patients, whereas CRP and procalcitonin (PCT) levels fail to distinguish sepsis in cases of inhalation injury[9].

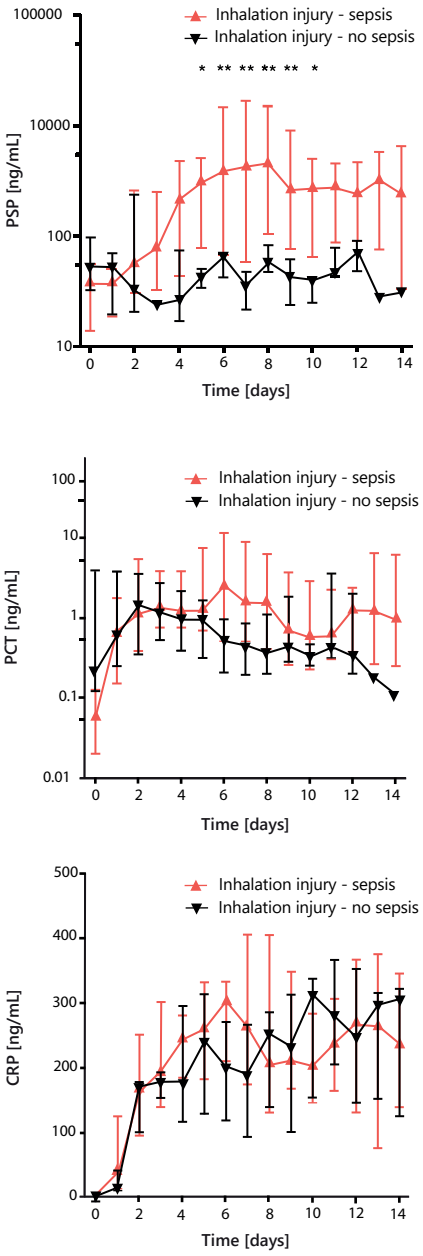

Figure 5. Daily PSP, PCT and CRP levels in severely burnt patients with inhalation injury[9].

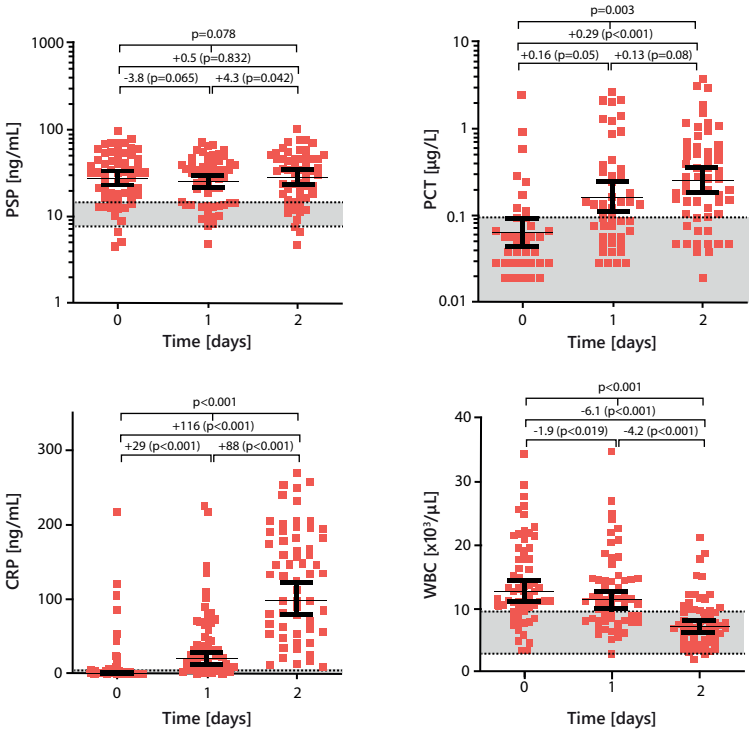

Figure 6. Time course of biomarker levels in the 2 days after admission to a burn center for patients without infection. Geometric mean with 95% confidence intervals are presented. Dotted lines with horizontal bars in light grey depict the range of normal values. Adapted from Klein et al., World J Surg 44,2020[10].

PSP, a Reliable Biomarker to Distinguish Immune from Inflammatory Changes

Following ICU admission, burn treatment protocols often involve surgery, extensive wound debridement, skin grafting, and sometimes limb amputation. These procedures cause significant tissue damage and stress, leading to the release of pro-inflammatory cytokines. This, in turn, triggers the synthesis of acute-phase proteins like CRP, resulting in substantial immune, hemodynamic, and endocrine disruptions.

Common biomarkers such as white blood cell count (WBC) and PCT levels also fluctuate in response to thermal injury and subsequent treatments, independent of infection. However, for patients without infection, only PSP levels remain consistently stable after the initial burn and subsequent interventions. This makes PSP a more reliable marker in this context[10] than PCT, CRP, or WBC, which tend to rise shortly after burn trauma and treatment, as shown in **Figure 6**.

Customer Story

As the Head of the Burn Center in Nuremberg, it is particularly important to me to ensure the best possible care for our patients with burn injuries. One of the key challenges in treating this patient group is the early detection and management of severe infectious complications. Measuring Pancreatic Stone Protein (PSP) levels in the blood has proven to be a promising diagnostic marker in this context: it allows for the detection of developing systemic infections significantly earlier than conventional methods. This diagnostic tool opens up valuable time windows for targeted and timely therapeutic intervention, a crucial factor in improving clinical outcomes and prognosis.

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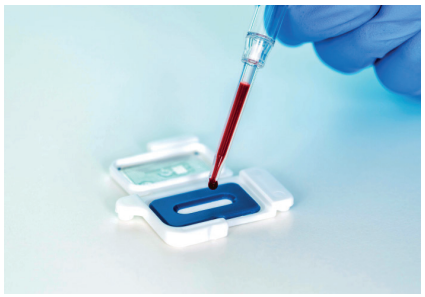
abioSCOPE® - Benchtop Rapid Diagnostic Platform

Lab-Quality Results, From A Drop Of Blood, Within Minutes

COLLECT



TRANSFER

MEASURE

Rapid Results
Accurate quantitative results
within minutes

Laboratory Quality Results
Performances equivalent to those
obtained in a laboratory

Easy To Use
3 simple steps with 1 drop of blood (50 µL)
from capillary, venous or arterial whole blood

Easy Device Handling
Low-maintenance
No sample-to-device contamination

abionic
Early Sepsis Detection

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CE 2797

The IVD CAPSULE PSP and the abioSCOPE® devices are compliant with the EU IVD Regulation 2017/746 and have received FDA clearance.

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