

Article

Pancreatic Stone Protein as an Early Biomarker of Sepsis in Critically Ill Non-Surgical Patients: A Retrospective Observational Study

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Abstract

Background: Timely identification of sepsis in critically ill patients remains challenging. Commonly used biomarkers, including C-reactive protein (CRP) and procalcitonin (PCT), show suboptimal diagnostic performance. Pancreatic stone protein (PSP) has recently been proposed as an early indicator of infection and sepsis. **Methods:** We performed a retrospective observational study involving 90 adult ICU patients, including septic and non-septic patients selected during the study period. Sepsis was defined according to Sepsis-3 criteria. Diagnostic accuracy was evaluated using receiver operating characteristic curves, and sensitivity, specificity, and predictive values were calculated. The association between PSP levels and in-hospital mortality was examined using multivariable logistic regression analysis. **Results:** Of the 90 patients included, 45 (50%) were diagnosed with sepsis. PSP levels were significantly higher in septic patients compared to non-septic patients (210 (175–265) vs. 105 (80–135) ng/mL; $p < 0.001$). PSP demonstrated the best diagnostic performance among the evaluated biomarkers (AUC 0.88, 95% CI 0.81–0.94), compared with PCT (0.82) and CRP (0.74). At a threshold of 150 ng/mL, PSP showed a sensitivity of 84% and a specificity of 80%. Higher PSP values were independently associated with increased in-hospital mortality and longer ICU stay. **Conclusions:** PSP appears to be a useful biomarker for early identification of sepsis in critically ill non-surgical patients, with better diagnostic performance than CRP and PCT. Its incorporation into clinical assessment may support earlier recognition and improved risk stratification. Further multicenter studies are needed to confirm these findings and to better define its role in clinical decision-making.

Keywords: sepsis; pancreatic stone protein; biomarkers; intensive care unit; procalcitonin; C-reactive protein



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1. Introduction

Sepsis continues to represent a major cause of morbidity and mortality in critically ill patients worldwide, with a substantial impact on healthcare systems [1–3]. Despite improvements in intensive care management, early identification of sepsis remains challenging, particularly in the initial phase of the disease when clinical signs may be subtle and organ dysfunction not yet fully evident [2].

The Sepsis-3 definition describes sepsis as a life-threatening condition caused by a dysregulated host response to infection [1]. However, in everyday clinical practice,

especially in emergency and intensive care settings, these criteria may be difficult to apply at an early stage [3]. This limitation highlights the need for additional tools capable of supporting timely diagnosis and improving early risk stratification.

Among currently available biomarkers, C-reactive protein (CRP) and procalcitonin (PCT) are the most frequently used. CRP is highly sensitive to inflammatory processes but lacks specificity, as it may increase in several non-infectious conditions [4]. PCT is more closely associated with bacterial infections and shows faster kinetics, although its levels may also rise in non-infectious clinical scenarios such as trauma or major surgery, limiting its reliability in heterogeneous ICU populations [5–8].

Pancreatic stone protein (PSP) has recently emerged as a potential biomarker of infection. It is involved in the innate immune response and is released during systemic inflammatory activation [9,10]. Previous investigations have suggested that PSP may increase earlier than traditional biomarkers, as reported in several clinical studies conducted in ICU populations [11,12]. In addition, higher PSP levels have been associated with disease severity and worse outcomes [13].

However, the clinical role of PSP remains to be fully clarified, particularly in specific patient populations. Most of the available evidence derives from heterogeneous populations, including surgical, trauma, and mixed ICU cohorts, as well as emergency department settings [14–16]. Evidence from systematic reviews further highlights the variability of study populations and clinical contexts [17,18].

The aim of the present study was to evaluate the diagnostic and prognostic performance of PSP in a cohort of critically ill non-surgical patients admitted to the intensive care unit. In particular, we compared its diagnostic accuracy with that of CRP and PCT and assessed its association with relevant clinical outcomes, including in-hospital mortality and ICU length of stay.

2. Methods

2.1. Study Design and Setting

This retrospective observational study was conducted in the intensive care unit (ICU) of Cardinale G. Panico Hospital, a tertiary-care center in Tricase, Italy. The study included adult patients admitted to the ICU for acute non-surgical conditions during the study period.

A comparative design was adopted, including patients with sepsis and non-septic ICU patients used as a control group to evaluate the diagnostic performance of pancreatic stone protein (PSP).

2.2. Study Population

Between March 2025 and November 2025, adult patients aged 18 years or older admitted to the ICU with suspected infection or clinical features suggestive of sepsis were screened for eligibility.

The final study population consisted of 90 patients, including 45 patients diagnosed with sepsis according to Sepsis-3 criteria and 45 non-septic ICU patients selected as a comparative control group during the same study period.

Patients were excluded in the case of recent surgery within the previous two weeks, acute pancreatitis, major abdominal trauma, or missing biomarker measurements at ICU admission.

2.3. Definitions

Sepsis was defined according to the Sepsis-3 criteria as infection-associated organ dysfunction resulting from a dysregulated host response to infection. The final classifica-

tion of patients was established through a comprehensive review of clinical presentation, laboratory findings, microbiological data, and ICU records.

2.4. Data Collection

All relevant clinical and laboratory data were recorded at ICU admission. The collected variables included demographic characteristics, comorbidity burden assessed by the Charlson Comorbidity Index, source of admission, and vital signs.

Laboratory parameters comprised white blood cell count, serum creatinine, lactate, CRP, and PCT. Plasma pancreatic stone protein (PSP) levels were measured using a validated point-of-care device abioSCOPE[®] platform (Abionic SA, Lausanne/Epalinges, Switzerland). Clinical outcomes included final diagnosis, in-hospital mortality, ICU length of stay, and total hospital length of stay.

Patients with missing key biomarker values were excluded, and analyses were conducted using a complete-case approach. Clinical data were retrospectively extracted from electronic medical records by the investigators. Data collection included demographic characteristics, comorbidities, admission source, laboratory findings, and clinical outcomes.

2.5. Biomarker Measurement

PSP levels were measured at ICU admission using a point-of-care immunoassay according to the manufacturer's instructions. CRP and PCT measurements were performed using standard automated laboratory methods routinely employed in clinical practice at our institution.

All biomarker measurements were performed at the time of ICU admission as part of routine clinical evaluation.

2.6. Outcomes

The primary endpoint was the diagnostic performance of PSP in identifying sepsis at ICU admission compared with CRP and PCT.

Secondary endpoints included the association between PSP levels and in-hospital mortality, the relationship with ICU length of stay, and the comparative diagnostic performance of the investigated biomarkers.

2.7. Statistical Analysis

Continuous variables were described using median and interquartile range, while categorical variables were expressed as counts and percentages. Comparisons between groups were performed using the Mann–Whitney U test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate.

Diagnostic accuracy was evaluated through receiver operating characteristic (ROC) curve analysis, with calculation of the area under the curve (AUC). Sensitivity, specificity, and predictive values were derived from predefined cut-off values. Differences between ROC curves were assessed using the DeLong method. The association between PSP levels and in-hospital mortality was analyzed using multivariable logistic regression adjusted for age, sex, and comorbidity burden.

A two-sided *p*-value below 0.05 was considered statistically significant. All analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY, USA).

2.8. Missing Data

Patients with missing key biomarker data were excluded from the final analysis. No imputation procedures were applied.

2.9. Ethics Statement

This study was conducted in accordance with the Declaration of Helsinki. Due to the retrospective design and the use of anonymized routinely collected clinical data, formal Institutional Review Board approval was waived according to institutional regulations. A formal ethical waiver was granted by the Ethics Committee of Cardinale G. Panico Hospital.

3. Results

3.1. Study Population

During the study period, 90 ICU patients were included in the analysis, including 45 patients with sepsis and 45 non-septic control patients selected according to the study design. Baseline characteristics of the study cohort are presented in Table 1. Patients with sepsis had a greater comorbidity burden, reflected by a higher Charlson Comorbidity Index (median 5 (3–7) vs. 3 (2–5)), and experienced higher in-hospital mortality (33% vs. 7%). In addition, both ICU and hospital length of stay were longer in the sepsis group.

Table 1. Baseline characteristics of the study population.

Variable	Total (N = 90)	Sepsis (n = 45)	Non-Sepsis (n = 45)	p-Value
Age, years, median (IQR)	68 (56–77)	70 (60–78)	65 (54–75)	0.12 (Mann–Whitney U = 840)
Male sex, n (%)	52 (58%)	28 (62%)	24 (53%)	0.39 ($\chi^2 = 0.74$)
Female sex, n (%)	38 (42%)	17 (38%)	21 (47%)	0.39 ($\chi^2 = 0.74$)
Charlson Comorbidity Index, median (IQR)	4 (2–6)	5 (3–7)	3 (2–5)	0.02 (Mann–Whitney U = 620)
ICU admission source, n (%)				0.78 ($\chi^2 = 0.50$)
– Emergency Department	48 (53%)	26 (58%)	22 (49%)	
– Medical wards	26 (29%)	12 (27%)	14 (31%)	
– Surgical wards	16 (18%)	7 (16%)	9 (20%)	
In-hospital mortality, n (%)	18 (20%)	15 (33%)	3 (7%)	$p = 0.005$ ($\chi^2 = 8.10$)
ICU length of stay, days, median (IQR)	7 (4–12)	9 (6–14)	5 (3–8)	0.01 (Mann–Whitney U = 590)
Hospital length of stay, days, median (IQR)	11 (7–18)	13 (9–20)	9 (6–13)	0.03 (Mann–Whitney U = 650)

Note: Data are presented as median (interquartile range) or number (%). Continuous variables were compared using the Mann–Whitney U test, while categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate. ICU: intensive care unit; IQR: interquartile range.

3.2. Biomarker Levels at ICU Admission

At the time of ICU admission, PSP, PCT, and CRP levels were all significantly elevated in septic patients compared to non-septic patients.

Median PSP concentrations were substantially higher in the sepsis group (210 (175–265) ng/mL) than in non-septic patients (105 (80–135) ng/mL; $p < 0.001$).

A similar pattern was observed for PCT (3.2 (1.5–5.4) ng/mL vs. 0.9 (0.4–1.8) ng/mL; $p < 0.001$) and CRP (145 (110–190) mg/L vs. 85 (60–120) mg/L; $p < 0.001$).

Detailed biomarker data are reported in Table 2.

Table 2. Biomarker levels at ICU admission according to final diagnosis.

Biomarker	Sepsis (n = 45)	Non-Sepsis (n = 45)	p-Value
PSP (ng/mL), median (IQR)	210 (175–265)	105 (80–135)	<0.001
PCT (ng/mL), median (IQR)	3.2 (1.5–5.4)	0.9 (0.4–1.8)	<0.001
CRP (mg/L), median (IQR)	145 (110–190)	85 (60–120)	<0.001

Note: Diagnostic performance was assessed using receiver operating characteristic (ROC) curve analysis. The area under the curve (AUC) with 95% confidence intervals was calculated. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were derived for predefined cut-off values.

3.3. Diagnostic Performance of Biomarkers

Analysis of diagnostic accuracy showed that PSP outperformed the other biomarkers in identifying sepsis at ICU admission.

The area under the ROC curve for PSP was 0.88 (95% CI: 0.81–0.94), compared with 0.82 for PCT and 0.74 for CRP.

At a cut-off value of 150 ng/mL, PSP achieved a sensitivity of 84% and a specificity of 80%, with a positive predictive value of 81% and a negative predictive value of 83%. For comparison, PCT (cut-off ≥ 2.0 ng/mL) showed a sensitivity of 78% and specificity of 76%, whereas CRP (cut-off ≥ 100 mg/L) showed a sensitivity of 70% and specificity of 68%.

A summary of diagnostic performance is provided in Table 3, and ROC curves are illustrated in Figure 1.

Table 3. Diagnostic performance of biomarkers for the diagnosis of sepsis.

Biomarker	Cut-Off	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	AUC
PSP	≥ 150 ng/mL	84	80	81	83	0.88 (95% CI: 0.81–0.94)
PCT	≥ 2.0 ng/mL	78	76	77	77	0.82
CRP	≥ 100 mg/L	70	68	71	67	0.74

Note: Diagnostic accuracy of PSP, PCT, and CRP for the identification of sepsis at ICU admission. Receiver operating characteristic (ROC) curve analysis was used to calculate the area under the curve (AUC). AUCs were compared using the DeLong test. AUC: area under the curve; CI: confidence interval; PPV: positive predictive value; NPV: negative predictive value.

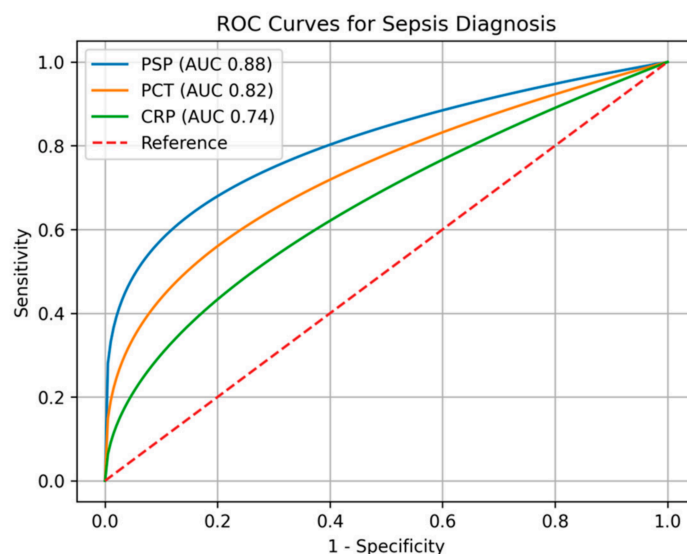


Figure 1. Receiver operating characteristic (ROC) curves showing the diagnostic performance of pancreatic stone protein (PSP), procalcitonin (PCT), and C-reactive protein (CRP) for the diagnosis of sepsis in critically ill patients. PSP demonstrated the highest discriminative ability (AUC 0.88), followed by PCT (AUC 0.82) and CRP (AUC 0.74).

3.4. Clinical Outcomes and Prognostic Value of PSP

Higher PSP concentrations were associated with worse clinical outcomes.

Patients with PSP levels ≥ 250 ng/mL had a significantly higher in-hospital mortality compared to those with lower values (42% vs. 18%, $p = 0.03$).

In addition, elevated PSP levels were associated with prolonged ICU stay (11 (8–15) days vs. 7 (5–10) days, $p = 0.01$).

In multivariable logistic regression analysis, PSP remained independently associated with in-hospital mortality after adjustment for age, sex, and the Charlson Comorbidity Index.

4. Discussion

In this retrospective observational study, we evaluated the role of pancreatic stone protein (PSP) as an early biomarker of sepsis in a cohort of critically ill non-surgical patients. Our findings show that PSP levels were significantly higher in septic patients at ICU admission and that its diagnostic performance exceeded that of commonly used biomarkers such as procalcitonin (PCT) and C-reactive protein (CRP). In addition, higher PSP concentrations were associated with worse clinical outcomes, including increased in-hospital mortality and prolonged ICU stay.

The diagnostic accuracy observed in our study suggests that PSP may represent a useful tool for early identification of sepsis in this specific clinical setting. Compared with traditional biomarkers, PSP showed better discriminative ability, which may be related to its earlier increase during the inflammatory response, as suggested by previous ICU-based studies [11,12]. This aspect is particularly relevant in critically ill patients, where early recognition of infection remains a key determinant of prognosis [2].

The biological mechanisms underlying PSP release may help explain its clinical performance. PSP is involved in the innate immune response and appears to be upregulated during systemic inflammation [9,10]. Previous studies have suggested that its levels may rise before the onset of clinically evident sepsis, potentially offering a temporal advantage over other biomarkers [11,12]. In this context, PSP may contribute to identifying patients at risk at a stage when clinical signs are still non-specific.

Beyond diagnosis, our data also indicate a potential prognostic role for PSP. Patients with higher PSP values showed increased mortality and longer ICU stays, even after adjustment for relevant clinical variables. This finding suggests that PSP levels may reflect the overall severity of the systemic response rather than simply the presence of infection. Similar findings have been reported in previous clinical studies evaluating the prognostic role of PSP in critically ill patients [13,15,19]. However, as with all biomarkers, PSP should not be interpreted in isolation but integrated with clinical assessment and other laboratory parameters.

Despite these findings, some limitations should be acknowledged. The study was conducted at a single center and included a relatively limited number of patients, which may affect the generalizability of the results. In addition, the study population was restricted to non-surgical ICU patients, and therefore, the results may not be directly applicable to surgical or mixed ICU settings. Another consideration is that PSP levels may also increase in non-infectious inflammatory conditions, as suggested by earlier experimental observations and more recent reviews [14,17].

From a practical perspective, PSP may represent a useful adjunct in the early evaluation of patients with suspected sepsis. Its availability as a point-of-care test and its rapid kinetics make it particularly suitable for time-sensitive environments such as emergency departments and intensive care units. The integration of PSP into clinical workflows may support earlier decision-making and improve risk stratification.

Future studies should aim to validate these findings in larger and more heterogeneous populations. In particular, further research is needed to explore the potential added value of PSP when combined with other biomarkers and clinical scoring systems, rather than its use as a standalone guide for therapeutic decisions [20].

Overall, our results support the use of PSP as a complementary biomarker for the early diagnosis and prognostic assessment of sepsis in critically ill non-surgical patients.

Future research should focus on validating PSP-based diagnostic and prognostic models in larger multicenter cohorts. The integration of PSP measurements with clinical variables, conventional biomarkers, and electronic health record data may further improve early sepsis recognition and risk stratification. In addition, emerging machine-learning approaches could help develop predictive models combining PSP with other clinical and laboratory parameters, potentially supporting personalized decision-making in critically ill patients. Although these applications remain exploratory, they represent promising areas for future investigation.

5. Conclusions

Pancreatic stone protein (PSP) demonstrated superior diagnostic performance compared to procalcitonin (PCT) and C-reactive protein (CRP) for the identification of sepsis in critically ill non-surgical patients. Its early increase and good discriminative ability support its potential role as a useful biomarker for early diagnosis and risk stratification in the intensive care setting.

Although PSP was associated with worse clinical outcomes, it should be considered an adjunct to clinical assessment and existing laboratory parameters rather than a standalone predictor. Further large-scale, multicenter studies are needed to confirm these findings and to better define its role in clinical practice.

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Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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