Diagnostic accuracy of procalcitonin for identifying paediatric sepsis: A retrospective study in a Malaysian tertiary hospital

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ABSTRACT

Introduction: Early diagnosis of paediatric sepsis remains challenging because clinical manifestations are non-specific and microbiological culture results are often delayed. Procalcitonin (PCT) has emerged as a promising biomarker for bacterial infection; however, its diagnostic performance varies across patient populations and clinical settings. This study evaluated the diagnostic accuracy of serum PCT for identifying paediatric sepsis in a Malaysian tertiary referral hospital.

Materials and Methods: A retrospective descriptive study was conducted at Hospital Sultanah Nur Zahirah, Terengganu, Malaysia, between June 2022 and June 2024. Children aged 1 month to 18 years who underwent serum PCT testing for suspected infection were included. Paediatric sepsis was classified according to the 2005 International Paediatric Sepsis Consensus Conference criteria, supported by microbiologically confirmed infection or a Phoenix Sepsis Score ≥2 in culture-negative cases. Serum PCT, C-reactive protein (CRP), and total white cell count (TWC) obtained at initial presentation were analysed. Diagnostic performance was evaluated using receiver operating characteristic (ROC) curve analysis, sensitivity, specificity, predictive values, likelihood ratios, and diagnostic odds ratio.

Results: A total of 242 children were included, of whom 129 (53.3%) were classified as having sepsis. Median PCT concentrations were significantly higher in the sepsis group than in the non-sepsis group (1.940 vs. 0.240 ng/mL; p < 0.0001). At a cut-off value of 0.5 ng/mL, PCT demonstrated a sensitivity of 76.0%, specificity of 73.5%, positive predictive value of 76.6%, negative predictive value of 72.8%, positive likelihood ratio of 2.86, negative likelihood ratio of 0.33, and diagnostic odds ratio of 8.75. ROC analysis showed moderate diagnostic accuracy with an area under the curve of 0.747 (95% confidence interval: 0.692–0.802). PCT demonstrated a moderate positive correlation with CRP (Spearman's r = 0.546) but no significant correlation with TWC.

Conclusion: Serum PCT demonstrated moderate diagnostic accuracy for identifying paediatric sepsis and may serve as a useful adjunctive biomarker for the early evaluation of children with suspected sepsis. However, PCT should be interpreted alongside clinical assessment and microbiological investigations rather than used as a standalone diagnostic test.

KEYWORDS:
Procalcitonin, Sepsis, Child, Biomarkers, Diagnosis, Sensitivity and Specificity, Paediatrics, Malaysia

INTRODUCTION

Sepsis is a clinical syndrome resulting from a dysregulated host response to infection and remains a significant cause of morbidity and mortality, particularly in the paediatric population.[1-2] Despite its clinical importance, the definition of paediatric sepsis remains a subject of ongoing debate and lacks consensus. Currently, a positive microbial culture remains the reference standard for confirming infection; however, obtaining culture results often requires several days. As outcomes in paediatric sepsis are highly time-dependent, delays in diagnosis may postpone timely treatment. Therefore, there is a critical need for reliable diagnostic biomarkers that enable earlier recognition and intervention.

Procalcitonin (PCT) is a 116-amino acid peptide with a molecular weight of approximately 14.5 kDa, encoded by the Calcitonin 1 (CALC-1) gene located on chromosome 11. It has emerged as a promising biomarker for bacterial sepsis because of its favourable kinetic profile compared with other inflammatory markers routinely used in clinical practice. Serum PCT concentration begin to rise within 2 to 4 hours following bacterial infection, peak at approximately 6 to 24 hours, and have a biological half-life of approximately 24 hours, allowing level to decline rapidly with resolution of infection or effective antimicrobial therapy. In contrast, C-reactive protein (CRP) typically begins to increase after 6 to 12 hours, reaches peak concentrations at 36 to 50 hours, and remains elevated for several days because of its continued hepatic synthesis during the inflammatory response, despite

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having biological half-life of approximately 19 hours. Total white cell count (TWC) may increase within a few hours of infection but demonstrates considerable biological variability and limited specificity, as it can be influenced by numerous non-infection condition, including physiological stress, corticosteroid therapy, and haematological disorders.[3–5] These differences in biomarker kinetics suggest that PCT may provide earlier and more specific evidence of bacterial infection than CRP or TWC.

Although globally PCT has been extensively evaluated as a biomarker for bacterial sepsis, variability in diagnostic performance across different patient populations and clinical settings makes it difficult to extrapolate evidence directly to routine paediatric practice. Consequently, validation in local real-world populations remains essential to determine its diagnostic utility within specific epidemiological and healthcare contexts.

Existing Malaysian studies have evaluated the diagnostic performance of PCT in neonatal sepsis, postoperative sepsis in paediatric cardiac surgery and infected adult diabetic foot ulcers.[6–8] However, evidence regarding its diagnostic performance in non-neonatal paediatric sepsis remains scarce. Although neonates represent the paediatric age group at greatest risk of sepsis, neonatal sepsis differs substantially from sepsis beyond the neonatal period in terms of immune system maturity, pathogen distribution, clinical presentation, and the interpretation of inflammatory biomarkers. Therefore, findings from neonatal studies cannot be directly applied to older children.

In current Malaysian practice, the diagnosis of paediatric sepsis continues to rely primarily on clinical assessment, conventional inflammatory markers, and microbiological investigations. Although blood culture remains the reference standard for confirming bloodstream infection, its clinical utility is limited by delayed turnaround time and suboptimal sensitivity, while CRP lacks specificity for bacterial infection. Therefore, this study evaluated the diagnostic accuracy of PCT in Malaysian children with suspected sepsis presenting to a tertiary referral hospital, with the aim of providing locally relevant evidence to support its appropriate use in routine paediatric practice.

MATERIALS AND METHODS

This retrospective descriptive study was conducted at Hospital Sultanah Nur Zahirah (HSNZ), Terengganu, Malaysia, a tertiary referral hospital, between June 2022 and June 2024. Children aged 1 month to 18 years who underwent serum PCT testing for suspected infection at Hospital Sultanah Nur Zahirah between June 2022 and June 2024 were eligible for inclusion. Patients with incomplete medical records or missing key laboratory investigations, including PCT, CRP, or TWC count, were excluded from the study.

Demographic, clinical, and laboratory data were retrospectively retrieved from the hospital electronic medical records and laboratory information system. Demographic variable included age. Clinical data included the presence of Systemic Inflammatory Response Syndrome (SIRS) criteria, suspected or confirmed infection, microbiological culture results, and the Phoenix Sepsis Score where applicable. Laboratory data included serum PCT, CRP and TWC count measured at the initial presentation. Microbial culture results from blood, cerebrospinal fluid, urine, or other normally sterile body sites were obtained from the culture collected closest to the PCT request during the same hospital admission.

Paediatric sepsis was classified according to the 2005 International Paediatric Sepsis Consensus Conference (IPSCC) criteria 9, defined as the presence of SIRS criteria with suspected or confirmed infection. According to the IPSCC criteria, SIRS was defined as the presence of at least two of four clinical criteria (abnormal temperature, heart rate, respiratory rate, or leukocyte count), one of which had to be abnormal temperature or leukocyte count, with age-specific thresholds applied.

Confirmed infection was established by the isolation of a pathogenic microorganism from blood, cerebrospinal fluid, urine, or another normally sterile body site. As microbiological cultures may be negative despite true infection, patients with clinically suspected infection and negative culture results were further evaluated using the Phoenix Sepsis Score 1. A Phoenix Sepsis Score of ≥2 was considered supportive of sepsis-associated organ dysfunction. Accordingly, patients who fulfilled the IPSCC criteria and had either microbiologically confirmed infection or clinically suspected infection with a Phoenix Sepsis Score ≥2 were classified as having sepsis. Patients who did not meet these criteria were classified as non-sepsis. The classification algorithm used in this study is illustrated in Figure 1

The diagnostic interpretation of PCT levels is based on established clinical guidelines and studies. A PCT level of 0.5 ng/mL is widely recognised as a critical threshold in distinguishing bacterial infection and possible sepsis from other non-bacterial causes of inflammation. Levels below 0.5 ng/mL are generally considered to indicate a low likelihood of systemic bacterial infection. Meanwhile, levels above 0.5 ng/mL suggest a higher probability of bacterial sepsis, warranting further clinical evaluation or initiation of antimicrobial therapy.[10-11]

The sample size was calculated based on Buderer's formula. Previous regional studies suggested an expected sensitivity of 83.3% and specificity of 56.3%[12] for PCT in identifying sepsis. The prevalence of paediatric sepsis in similar tertiary care settings was estimated at 52%.[13] A confidence level of 95% (Z=1.96) and a precision of ±10% were selected to ensure an acceptable margin of error for both estimates. The final minimum sample size was set at 197 patients, including 102 with sepsis and 95 without.

Serum PCT concentrations were measured using the UniCel DxI 800 Access Immunoassay System (Beckman Coulter, Brea, CA, USA), employing a sequential two-step chemiluminescent immunoenzymatic (sandwich) assay. The assay has an analytical measuring range of 0.01–100 ng/mL. Calibration was performed using manufacturer-provided calibrators in accordance with the manufacturer's

recommendations. Internal quality control (IQC) was performed daily using commercially available quality control materials at two concentration levels. The laboratory also participated in the Randox International Quality Assessment Scheme (RIQAS) for PCT throughout the study period, demonstrating satisfactory performance.

Serum CRP concentrations were measured using the AU680 Clinical Chemistry Analyser(Beckman Coulter, Brea, CA, USA) by an immunoturbidimetric latex assay calibrated according to the International Federation of Clinical Chemistry (IFCC) recommendations. Routine calibration and daily IQC were performed in accordance with the manufacturer's recommendations. The laboratory also participated in the RIQAS for CRP, achieving acceptable external quality assessment performance throughout the study period.

TWC counts were determined using the Sysmex XN-Series 5-Part Differential Haematology Analyser (Sysmex Corporation, Kobe, Japan) as part of the routine full blood count analysis. Internal quality control and routine analyser maintenance were performed according to the manufacturer's recommendations and the laboratory's quality management system.

Microbiological investigations, including aerobic and anaerobic blood culture and antimicrobial susceptibility testing were performed according to established laboratory protocols. All laboratory analyses were conducted in accordance with the manufacturers' instructions, the laboratory's quality management system, and standard operating procedures.

Microsoft Excel for Microsoft 365 (Microsoft Corporation, Redmond, WA, USA) was used for initial data collection, cleaning, and to identify missing values prior to statistical analysis. Data distribution was assessed using visual inspection and the Shapiro-Wilk normality test. As the numerical data were not normally distributed, continuous variables including PCT, CRP and WBC were summarised as medians with Interquartile Ranges (IQR) and compared between groups using the Mann-Whitney U test. The Hodges-Lehmann estimator was used to quantify the median difference (location shift) between groups, along with corresponding 95% Confidence Intervals (CI). A two-tailed p-value of <0.05 was considered statistically significant.

Diagnostic test parameters, including sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), Receiver Operating Characteristic (ROC) curves, and Area Under the Curve (AUC), were evaluated using Analyse-it software (Analyse-it Software Ltd, Leeds, UK), an Excel-based statistical add-in. CIs for diagnostic metrics were calculated using methods integrated within the software.

Correlation between PCT and other laboratory parameters was assessed using Spearman's rank correlation coefficient (r), due to the non-normal distribution of data. Correlation strength was interpreted as follows: r < 0.3 (weak), 0.3-0.7 (moderate), and > 0.7 (strong), with 95% CIs reported for each correlation coefficient.

RESULTS

Patient Characteristics

A total of 242 paediatric patients were included in the analysis. Among them, 129 (53.31%) were diagnosed with sepsis, and 113 (46.67%) were non-sepsis.

As summarised in Table I, both PCT and CRP levels were significantly elevated in patients with sepsis compared to those without. The median PCT level was 1.940 ng/mL (IQR: 0.470-12.527) in the sepsis group and 0.240 ng/mL (IQR: 0.120-0.843) in the non-sepsis group. The Hodges-Lehmann location shift was 1.100 ng/mL (95 % CI: 0.680 to 1.930), indicating a significant difference (p<0.0001).

Similarly, CRP levels were higher in sepsis (median 19.10 mg/L, IQR: 6.63-68.77) than in non-sepsis (median 14.20 mg/L, IQR: 2.90-36.57), with a Hodges-Lehmann shift of 4.70 mg/L (95% CI: 0.70 to 9.60; p=0.0159). In contrast, there were no statistically significant differences in age (p = 0.110) or WBC (p=0.472) between the groups.

Spearman's correlation analysis (Table II) revealed a moderate positive correlation between PCT and CRP (r=0.546, 95% CI: 0.448 to 0.631), indicating that higher PCT values were associated with higher CRP levels.

In contrast, there was no significant correlation between PCT and WBC (r=0.052, 95% CI: –0.079 to 0.180), indicating that WBC was not strongly associated with PCT levels in this cohort.

The diagnostic performance of PCT at a cut-off value of 0.5 ng/mL was evaluated using a 2 × 2 contingency table (Table III). PCT correctly identified 98 true-positive and 83 true-negative cases, while 31 cases were classified as false negatives and 30 as false positives. ROC curve analysis demonstrated moderate diagnostic accuracy, with an area under the curve (AUC) of 0.747 (95% CI: 0.692–0.802) (Figure 2). The corresponding sensitivity, specificity, predictive values, likelihood ratios, diagnostic odds ratio, and Youden Index are presented in Table III.

DISCUSSION

The present study demonstrated that serum PCT has moderate diagnostic accuracy for identifying paediatric sepsis, with an AUC of 0.747, sensitivity of 76.0%, and specificity of 73.5%. The observed diagnostic performance is broadly consistent with previous paediatric and adult studies, which generally report moderate-to-good discriminatory ability for PCT in bacterial sepsis.

Although our AUC of 0.747 was lower than the pooled AUCs reported in the systematic reviews by Wacker et al. (0.85) and Chairaj et al. (0.84),[14-15] it was comparable to the pooled AUCs reported by Ghatak et al. (0.77) in adult emergency department populations and Omar et al. (0.76) in neonatal population.[7,16] These findings suggest that the diagnostic performance of PCT varies across clinical settings and patient populations, with differences likely reflecting variations in study populations, sepsis definitions, and methodology rather than limitations of PCT itself.

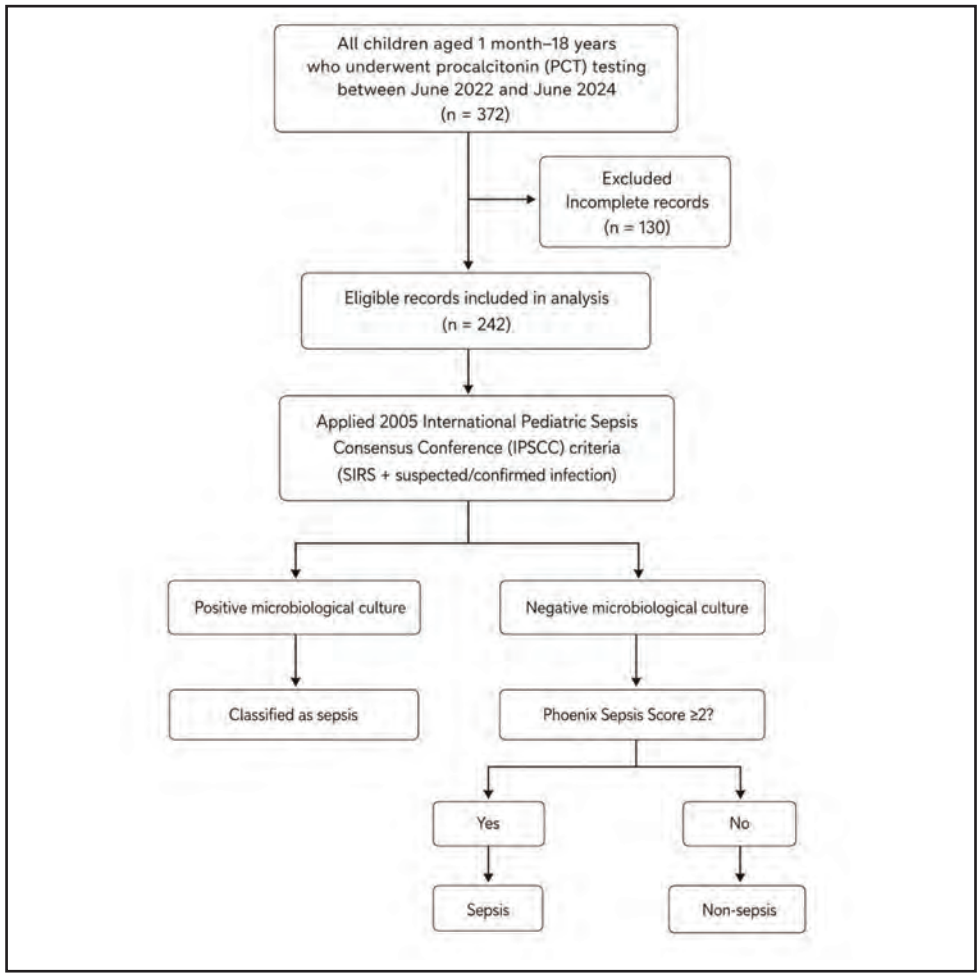

Fig. 1: Flowchart of patient selection and classification

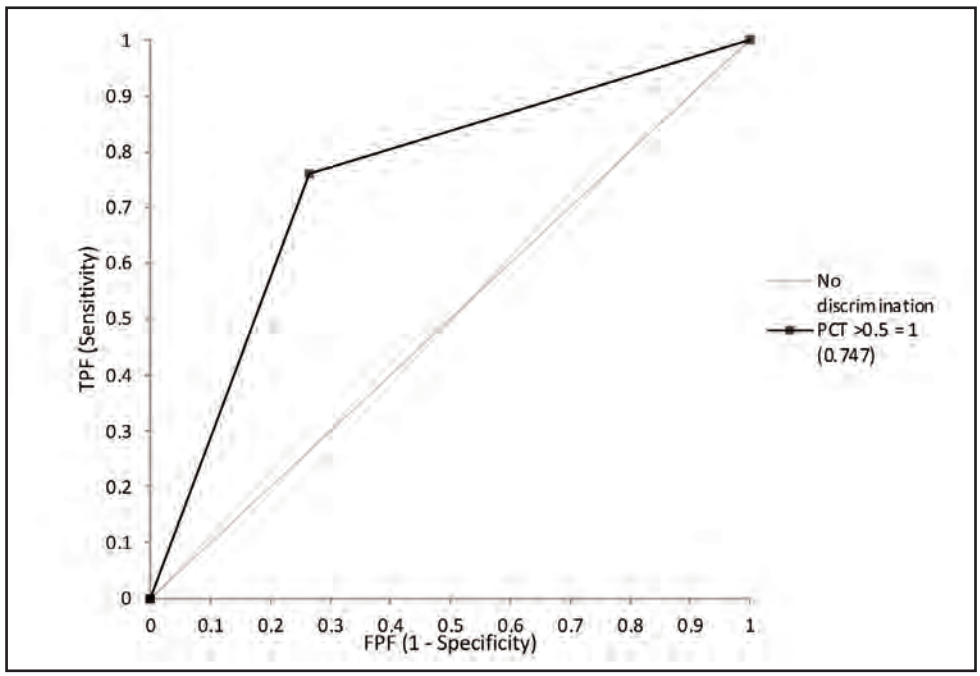

Fig. 2: Receiver Operating Characteristic (ROC) curve analysis

Table I: Comparison of laboratory findings between the sepsis and non-sepsis groups

Variables	Median (IQR)		Hodges-Lehmann Shift (95% CI)	p-value
	Sepsis	Non-sepsis		
PCT (ng/mL)	1.940 (0.470-12.527)	0.240 (0.120-0.843)	1.100 (0.680 to 1.930)	< 0.0001
CRP (mg/L)	19.10 (6.63-68.77)	14.20 (2.90-36.57)	4.70 (0.70 to 9.60)	0.0159
WBC ($\times 10^9$/L)	8.0 (2.0-49.0)	11.40 (7.37-17.57)	2.0 (0.0 to 5.0)	0.110

Table II: Spearman's correlation between PCT and selected laboratory parameters (n = 242)

Variable Pair	Spearman's (r)	95% Confidence Interval
PCT vs. CRP	0.546	0.448 to 0.631
PCT vs. TWC	0.052	–0.079 to 0.180

Table III: Diagnostic performance of procalcitonin in identifying paediatric sepsis

A. 2 x 2 Contingency table

Reference standard	PCT > 0.5 ng/mL (Positive)	PCT ≤ 0.5 ng/mL (Negative)	Total
Sepsis (yes)	98 (TP)	31(FN)	129
No Sepsis (No)	30 (FP)	83 (TN)	113
Total	128	114	242

B. Diagnostic performance indices

Parameter	Estimate (95% CI)
Sensitivity	75.97% (67.91–82.52)
Specificity	73.45% (64.64–80.72)
Positive predictive value	76.56% (68.52–83.06)
Negative predictive value	72.81% (64.00–80.13)
Positive likelihood ratio (LR+)	2.86 (2.07–3.95)
Negative likelihood ratio (LR–)	0.33 (0.24–0.45)
Diagnostic odds ratio	8.75 (4.89–15.64)
Youden's Index	0.494

Our study included a heterogeneous real-world paediatric population with diverse infection sources, disease severity, and underlying clinical conditions, whereas many previous studies evaluated more homogeneous cohorts, such as children admitted to paediatric intensive care units or adult in emergency department. Furthermore, differences in reference standards may also have contributed to variability across studies. While many contemporary adult studies have adopted organ dysfunction-based definitions, such as the Sequential Organ Failure Assessment (SOFA) or quick Sequential Organ Failure Assessment (qSOFA), these tools have not been validated for routine use in children. Accordingly, our study classified patients using the 2005 IPSCC criteria, which remain widely applied in paediatric sepsis research and were appropriate for this retrospective cohort.

The moderate sensitivity and specificity observed in this study may also reflect the occurrence of false-negative and false-positive PCT results in routine clinical practice. False-negative results may occur when blood samples are collected early in the course of infection before sufficient PCT production has occurred, in patients with localized bacterial infections, or in immunocompromised individuals with attenuated inflammatory responses. Previous antibiotic exposure before specimen collection may also reduce bacterial burden and culture positivity, potentially influencing both sepsis classification and circulating PCT concentrations. Conversely, false-positive PCT elevations have been reported in non-infectious inflammatory conditions, including major trauma, surgery, and severe systemic inflammation. Collectively, these factors may have reduced the observed sensitivity, specificity, and overall diagnostic performance of PCT in our retrospective cohort.

Although PCT demonstrated moderate overall diagnostic accuracy, the likelihood ratios (LR+ 2.86 and LR– 0.33) indicate that positive and negative test results produce only modest changes in the probability of sepsis. Similar likelihood ratios reported by Ghatak et al. (LR+ 2.80 and LR– 0.42) support this finding. 16 Therefore, PCT should be interpreted as an adjunct to clinical assessment and microbiological investigations rather than as a stand-alone diagnostic test.

We observed a moderate positive correlation between PCT and CRP, suggesting that both biomarkers increase in response to systemic inflammation during bacterial infection.

Although previous paediatric studies have primarily compared the diagnostic performance of PCT and CRP rather than their correlation, both biomarkers are recognised indicator of the host inflammatory response.[17] Despite this association, PCT is considered more specific for bacterial infection because its production is directly stimulated by bacterial endotoxins and pro-inflammatory cytokines, whereas CRP is a non-specific acute-phase reactant that may be elevated in a broader range of infectious and non-infectious inflammatory conditions. These findings support the use of PCT as a complementary biomarker alongside CRP, rather than as a replacement, in the diagnostic evaluation of paediatric sepsis.[18-19]

In contrast, no significant correlation was observed between PCT and TWC count. This finding is consistent with previous studies demonstrating that leukocyte counts are influenced by age, physiological stress, viral infections, and immune status, thereby limiting their specificity for bacterial infection.[5] Compared with conventional haematological indices, PCT appears to provide more specific information regarding bacterial infection and systemic inflammatory responses.

These findings have practical implications for paediatric sepsis management in Malaysia. As microbiological culture results typically require 24 to 72 hours and blood cultures may yield false-negative results, clinicians often initiate empirical antimicrobial therapy based on clinical suspicion. In this context, PCT may assist in the early recognition and risk stratification of children with suspected sepsis while awaiting microbiological confirmation, particularly in tertiary hospitals where rapid PCT testing is available. Nevertheless, PCT should be interpreted alongside clinical assessment and microbiological investigations rather than used as a standalone diagnostic test.

Despite its potential clinical utility, routine PCT testing remains largely confined to tertiary and selected secondary hospitals in Malaysia because of cost considerations and limited laboratory infrastructure. Consequently, clinicians in many district hospitals continue to rely primarily on CRP and TWC count despite their lower specificity for bacterial infection. In such settings, point-of-care (POC) PCT testing may represent a practical alternative, as previous studies have demonstrated good analytical agreement with central laboratory assays and shorter turnaround times, thereby facilitating earlier clinical decision-making in emergency and critical care settings.[20]

Beyond its diagnostic utility, previous studies have demonstrated that PCT-guided algorithms can support antimicrobial stewardship by reducing unnecessary antibiotic exposure and treatment duration. Although these outcomes were not evaluated in the present study, the moderate diagnostic performance observed suggests that PCT may contribute to more informed clinical decision-making when used alongside clinical assessment and other laboratory investigations.

Several emerging biomarkers, including presepsin and interleukin-6 (IL-6), have shown promising diagnostic performance for early sepsis detection. Nevertheless, these biomarkers require further validation in paediatric populations and are currently less accessible in routine clinical practice.[21-22] Compared with these novel biomarkers, PCT remains more widely available and better established, although its moderate diagnostic performance observed in the present study suggests that future research should evaluate whether multimarker approaches can further improve diagnostic accuracy in Malaysian children.

The strengths of this study include the use of real-world data from a Malaysian tertiary referral hospital, a sample size exceeding the calculated minimum requirement, and standardised laboratory analyses performed within an ISO 15189-accredited laboratory. Furthermore, inclusion of both culture-positive and culture-negative patients better reflects routine clinical practice and enhances the applicability of the findings to similar healthcare settings.

Nevertheless, several limitations should be acknowledged. The retrospective design limited control over important confounding factors, including prior antibiotic exposure, timing of biomarker measurement, patient comorbidities, and heterogeneity of infection sources, all of which may have influenced PCT concentrations and reduced the observed diagnostic performance. The use of the 2005 International Paediatric Sepsis Consensus Conference criteria together with microbiological findings and the Phoenix Sepsis Score for culture-negative cases may also have introduced classification bias. In addition, only the first PCT measurement obtained at presentation was analysed, whereas serial measurements may provide greater diagnostic and prognostic value.

CONCLUSION

Overall, the present study provides local evidence supporting the clinical utility of serum PCT as an adjunctive biomarker for the early evaluation of suspected paediatric sepsis. Despite demonstrating only moderate diagnostic accuracy, PCT may support clinical decision-making when interpreted in conjunction with clinical assessment and other laboratory findings. These findings highlight the potential role of PCT in routine paediatric sepsis evaluation while underscoring the need for larger prospective multicentre studies using contemporary paediatric sepsis definitions and the evaluation of combined biomarker models to further validate its diagnostic performance and optimise its clinical application.

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