ORIGINAL ARTICLE

Development and Validation of Pediatric Sepsis Score in the Prediction of Pediatric Septic Shock

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Background: Early recognition and identification of sepsis with appropriate resuscitation and prompt monitoring would improve the outcome of children with sepsis.

Objective: To develop and validate the new pediatric sepsis screening tool for predicting septic shock in children in all settings, including emergency departments, outpatient clinics, and inpatient settings.

Materials and Methods: This study was a retrospective, cross-sectional study. This study was divided into two phases: score development and validation. All eligible children aged one month to 15 years old who visited outpatient clinics, the emergency department, or were admitted to the hospital and who were at risk for sepsis were included. The new screening tool scoring system was derived from the abnormal physiological parameters according to age, from the consensus of the experts, with a decent content validity index. The final score for each participant was used to validate the prediction of septic shock using the area under the receiver operating curve (AUROC), sensitivity, and specificity.

Results: Seven hundred ninety-four screenings were done in this study. Of these, 15 episodes (1.89%) were diagnosed with septic shock. Abnormal parameters (including hypotension, abnormal pulse pressure, desaturation, abnormal capillary refill time, and decreased sensorium) were significantly associated with septic shock. The overall performance of the Thammasat University Hospital (TUH) pediatric sepsis screening tool in all settings to predict septic shock, as measured by the AUROC, was 0.990 (95% CI 0.981 to 0.998). With a sepsis score of at least 3, the sensitivity and specificity were 100% and 95.4%, respectively. The AUROC, sensitivity, and specificity were still excellent in the subgroup of inpatient and outpatient/emergency department settings.

Conclusion: This study showed that the TUH pediatric sepsis screening tool provided high sensitivity and specificity for the diagnosis of septic shock in inpatient and outpatient/emergency department settings.

Keywords: Pediatric sepsis screening tool; Sepsis score; Septic shock

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Sepsis remains a global burden due to high mortality and morbidity in children and neonates, despite advancements in medical technologies[1-4]. A large systematic review in 2018 demonstrated the aggregate estimates of sepsis and severe sepsis in children to be 48 per 100,000 person-years and 22 per 100,000 person-years, respectively. The mortality rates in sepsis and severe sepsis were 1 to 5% and 9 to 20%, respectively[2]. The major causes of death in children with sepsis are refractory shock and multiorgan failure, mostly occurring within 48 to 72 hours of treatment. Thus, early recognition of sepsis with appropriate resuscitation and monitoring promptly would lead to a major impact on the outcome of children with sepsis[5-7]. The Pediatric Surviving Sepsis Campaign (SSC) in 2020 suggested the implementation of a systematic screening tool for the early recognition of septic shock and sepsis-associated organ dysfunction for children who present with an acutely unwell condition, with a remark that the tool should be tailored to the type of patients and resources at each institution[7]. Nevertheless, the suggestion was based on very low-quality evidence. Most screening tools reported in the literature had limited reports on the accuracy of the screening for sepsis and the features of the screening tool. Furthermore, it was largely based on single-center studies in high-income settings and mostly conducted in the emergency department, which might not

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Table 1. TUH pediatric sepsis screening score

Age	Pulse	RR	SBP	PP	SpO_2	CRT	Consciousness
0 to <1 month	<100, >200	≥60	<60	<20 or DBP ≤50% of SBP	≤94% (room air) or need HHHFNC/MV	≥3 seconds/ mottling skin/ cold extremities/ erythema/ brisk CRT	Irritable/ drowsy/ stupor/ coma
1 to 12 months	<90, >190	≥50	<70				
1 to <5 years	>160	≥40	<70 + 2 × age (years)				
5 to <10 years	>140	≥35					
10 to <15 years	>120	≥30	<90				
15 to 18 years	>100	≥20					
Score	1	1	2	1	1	1	1

RR=respiratory rate; SBP=systolic blood pressure; PP=pulse pressure; CRT=capillary refill time; DBP=diastolic blood pressure; HHHFNC=heated humidified high flow nasal cannula; MV=mechanical ventilator

be practical in areas with limited resources and might not be applicable in an inpatient setting[4,8-12]. Furthermore, there are certain variations among different screening tools. Some screening tools are paper-based or electronic-based, some are based on abnormal vital signs per age, and some are based on risk factors and laboratory results. This further emphasizes the suggestion by the SSC that each institution should implement its screening tools based on the type of patients and resources. As of current, there is no validated screening tool for pediatric severe sepsis and septic shock in Thailand. Thus, the present study aimed to develop and validate the new pediatric sepsis screening tool for predicting septic shock in children in all settings, including emergency departments, pediatric outpatient clinics, and inpatient settings.

Materials and Methods

This study was divided into the score development and validation phases. This validation of the scoring system was conducted retrospectively in a tertiary care university hospital with seven pediatric intensive care unit (PICU) beds, pediatric outpatient clinics, and emergency departments. The Ethics Committee Board of the institution approved the study (MTU-EC-PE-0-147/66).

The development of a new pediatric sepsis screening tool

During the development phase, the new Thammasat University Hospital (TUH) pediatric sepsis screening tool was created based on abnormal vital signs per age (heart rate, respiratory rate, blood pressure, pulse pressure, capillary refill time, and consciousness), adapted based on Pediatric Advanced Life Support 2020[13]. All parameters were designed to be objective parameters to make the scoring simple and can be performed by all levels of healthcare providers. The sepsis screening tool contained two parts: 1) identification of the patients who were at risk of sepsis, and 2) evaluation for vital signs (pulse rate, respiratory rate, systolic blood pressure, pulse pressure, and oxygen saturation) and focused physical examination (capillary refill time and consciousness) to calculate the score. Content validity was assessed using the content validity index (CVI). An expert panel consisting of four subject-matter experts independently evaluated the relevance of each item using a 4-point Likert scale (1=not relevant to 4=highly relevant). Item-level content validity (I-CVI) was calculated as the proportion of experts rating an item as either 3 or 4. Scale-level content validity (S-CVI) was determined. The results demonstrated complete consensus among the four pediatric intensivist experts, with an I-CVI of 1.0, and the S-CVI further indicated high content validity, reflecting excellent agreement across all experts.

The abnormal systolic blood pressure was scored as 2, while other abnormal parameters scored 1, with the highest cumulative score of 8 (Table 1). During the validation phase, the final score for each participant was used to validate the prediction for the diagnosis of septic shock.

Population

Eligible subjects for validation included all children aged one month to 15 years old who visited outpatient clinics, the emergency department, or were admitted to TUH and were at risk for sepsis (at least one of the following criteria) between February 1 and June 31, 2023.

a) Body temperature of less than 36 or greater than 38.5°C.

b) Signs of infection such as chills, skin or organ infection, abscess, diarrhea, or alteration of consciousness.

c) Cancer patients who have been treated with

chemotherapy or radiation therapy, or the therapy has been completed within the last six months, accompanied by a fever of 38°C or higher.

d) White blood cell count of less than 5,000 or more than 15,000/cu.mm or band form greater than 10% or platelet of less than 80,000/cu.mm.

Because this tool is intended for screening, it is applied to all patients who meet the inclusion criteria. Therefore, no exclusion criteria are defined. A participant who was identified to fulfill the criteria for being at risk of sepsis more than once will be reevaluated according to the risk and will be included in the final analysis. For instance, if during the admission, the participant has a body temperature of greater than 38.5°C three times, the patient will be scored three times to obtain the score for each episode of the risk. Due to the retrospective nature of the study, informed consent was waived. With the expected sensitivity and specificity of 80% and the confidence level of 95%, at least 684 screenings were required to perform the validation.

Definitions

The operational definitions of sepsis, severe sepsis, and septic shock were based on the recent guideline from the pediatric SSC in 2020[7,14].

1. Sepsis: presumed or proven infection with systemic inflammatory response syndrome
2. Severe sepsis: sepsis with organ dysfunction
3. Septic shock: sepsis with cardiovascular dysfunction or hypotension for age

Moreover, abnormal pulse pressure was defined as pulse pressure of less than 20 mmHg or diastolic blood pressure of less than or equal to 50% of systolic blood pressure.

Outcome measurement and statistical analysis

For the validation of the pediatric sepsis score, septic shock will be used as the prediction endpoint using the area under the receiver operating curve (AUROC), sensitivity, and specificity, as well as positive and negative likelihood ratios. The univariate and multivariate analyses were also performed to outline which parameters of the score were associated with septic shock. All statistical analyses will be performed using IBM SPSS Statistics, version 24.0 (IBM Corp., Armonk, NY, USA).

Results

Participants

During the validation phase (February 1 to June 30, 2023), 587 patients fulfilled the pre-requisite criteria for risk of sepsis, with a total of 794 screenings being done. Of these, 15 episodes (1.89%) fulfilled the diagnostic criteria of septic shock. Age and gender were not significantly different between septic shock and non-septic shock patients. There was a significantly higher proportion of children with underlying diseases in the septic shock group at 80% versus 20.7% ($p<0.001$). No patient from the outpatient screening was diagnosed with septic shock. Several abnormal vital sign parameters, including hypotension, abnormal pulse pressure, desaturation requiring oxygen support, abnormal capillary refill time, and decreased sensorium, were found to be significantly higher among the septic shock group (Table 2).

Upon the evaluation of each factor by univariate analysis, underlying disease, hypotension, abnormal pulse pressure, abnormal capillary refill time, abnormal saturation or requiring respiratory support, and decreased sensorium were associated with the diagnosis of septic shock. Interestingly, after multivariate analysis, not only abnormal capillary refill time [adjusted odds ratio (aOR) 637.27, 95% confidence interval (CI) 47.03 to 8,634.83] but also the underlying disease (aOR 22.13, 95% CI 1.43 to 341.42) and abnormal pulse pressure (aOR 15.22, 95% CI 1.62 to 143.17) were significantly associated with septic shock. No patient without septic shock had hypotension. Univariate and multivariate analysis of factors for the development of septic shock is shown in Table 3.

Assessment of TUH pediatric sepsis screening tool

The overall performance of the TUH pediatric sepsis screening tool in all settings to predict septic shock, as measured by the AUROC, was 0.990 (95% CI 0.981 to 0.998). With a sepsis score greater than or equal to 3, the sensitivity and specificity were 100% and 95.4%, respectively. Among patients with or without underlying diseases, the AUROCs were 0.989 (95% CI 0.967 to 1.000) and 0.984 (95% CI 0.967 to 1.000), respectively. With a sensitivity of 100% in both with and without underlying disease groups, the specificity also remained high at 93.6% and 95.8% in both groups. As for inpatient settings and outpatient unit/emergency department settings, AUROCs were 0.986 (95% CI 0.968 to 1.000) and 0.992 (95% CI 0.980 to 1.000), respectively. Again, with the sensitivity of 100% in both the inpatient setting and outpatient/emergency department settings, the specificity was appreciatively high at 94.5% and 95.6% in each group, respectively. The overall

Table 2. Demographics and clinical characteristics of the children classified as "septic shock" and "non-septic shock"

	Overall (n=794)	Septic shock (n=15)	Non-septic shock (n=779)	p-value
Age (years); median (IQR)	2.6 (1.2 to 5.7)	3.0 (1.3 to 9.6)	2.6 (1.2 to 5.7)	0.992
Male sex; n (%)	242 (58.0)	7 (46.7)	238 (58.0)	0.603
Body weight (kg); median (IQR)	12.6 (9.4 to 19.8)	12.0 (8.0 to 25.0)	12.6 (9.4 to 19.2)	0.996
Underlying comorbidity; n (%)				<0.001
None	621 (78.2)	3 (20.0)	618 (79.3)	
Allergy	54 (6.8)	-	54 (6.9)	
Hematology	33 (4.2)	-	33 (4.2)	
Cardiology	31 (3.9)	3 (20.0)	28 (3.6)	
Oncology	14 (1.8)	5 (33.3)	9 (1.2)	
Neurology	9 (1.1)	-	9 (1.2)	
Genetic	8 (1.0)	1 (6.7)	7 (0.9)	
Rheumatology	5 (0.6)	2 (13.3)	3 (0.4)	
Nephrology	5 (0.6)	1 (6.7)	4 (0.5)	
Endocrinology	4 (0.5)	-	4 (0.5)	
Gastroenterology	3 (0.4)	-	3 (0.4)	
Developmental behavioral	3 (0.4)	-	3 (0.4)	
Pulmonology	3 (0.4)	-	3 (0.4)	
Plastic	1 (0.1)	-	1 (0.1)	
Setting; n (%)				<0.001
Outpatient	322 (40.6)	-	322 (41.3)	
Emergency department	336 (42.3)	6 (40.0)	330 (42.4)	
Inpatient	138 (17.1)	9 (60.0)	127 (16.3)	
Abnormal vital signs parameters; n (%)				
Tachycardia/Bradycardia for age	317 (39.9)	6 (40.0)	311 (39.9)	1.000
Tachypnea/ Bradypnea for age	186 (23.4)	3 (20.0)	183 (23.5)	1.000
Hypotension for age	10 (1.3)	10 (66.7)	-	<0.001
Abnormal pulse pressure	30 (3.8)	8 (53.3)	22 (2.8)	<0.001
Desaturation or requiring respiratory support	79 (9.9)	10 (66.7)	69 (8.9)	<0.001
Abnormal capillary refill	17 (2.1)	13 (86.7)	4 (0.5)	<0.001
Decreased sensorium	9 (1.1)	4 (26.7)	5 (0.6)	<0.001
28-day mortality; n (%)	8 (46.7)	8 (46.7)		
Shock recovery in 6 hours; n (%)	11 (73.3)	11 (73.3)		
Received fluids in 15 minutes; n (%)	14 (93.3)	14 (93.3)		
Received antibiotics in 1 hour; n (%)	13 (86.7)	13 (86.7)		

IQR=interquartile range

Table 3. Univariate and multivariate analysis of factors for the development of septic shock

Factors	Crude odds ratio (95% CI)	p-value	Adjusted odds ratio (95% CI)	p-value
Male sex	0.71 (0.25 to 1.97)	0.603	-	
Underlying disease	15.85 (4.42 to 56.84)**	<0.001	22.13 (1.43 to 341.42)**	0.027
Abnormal HR for age	1.00 (0.35 to 2.85)	1.000		
Abnormal RR for age	0.81 (0.23 to 2.92)	1.000		
Hypotension for age	2,976.27 (154.46 to 57,347.47)**	<0.001	-*	-
Abnormal pulse pressure	39.32 (13.10 to 118.07)**	<0.001	15.22 (1.62 to 143.17)**	0.017
Abnormal capillary refill	1,259.37 (211.60 to 7,495.52)**	<0.001	637.27 (47.03 to 8,634.83)**	<0.001
Abnormal saturation/RS support	20.58 (6.84 to 61.92)**	<0.001	0.53 (0.04 to 6.93)	0.630
Decreased sensorium	56.29 (13.29 to 238.35)**	<0.001	2.83 (0.07 to 120.33)	0.587

CI=confidence interval; HR=heart rate; RR=respiratory rate; RS=respiratory system

* Hypotension is not in the final model due to inadequate cell, ** p<0.05

Table 4. The overall performance of the TUH pediatric sepsis screening tool in all settings and subgroup analysis, as scored ≥3

Group	AUROC	95% CI	Sensitivity	Specificity
All settings	0.990	0.981 to 0.998	100%	95.4%
With underlying disease	0.989	0.976 to 1.000	100%	93.6%
Without underlying diseases	0.984	0.967 to 1.000	100%	95.8%
Inpatient setting	0.986	0.968 to 1.000	100%	94.5%
Outpatient/emergency room setting	0.992	0.980 to 1.000	100%	95.6%

AUROC=area under the receiver operating curve; CI=confidence interval

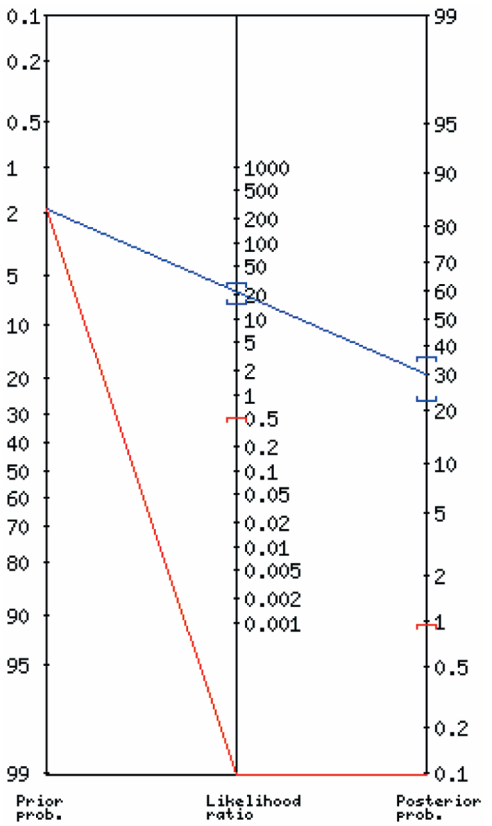

Figure 1. The positive and negative likelihood ratio of the predictive model.

performance of the TUH pediatric sepsis screening tool in all settings is summarized in Table 4.

In terms of likelihood ratios, the overall predictive model demonstrated excellent diagnostic performance, with a high positive likelihood ratio (PLR) of 22 (95% CI 15 to 29) and a negative likelihood ratio (NLR) approaching zero (Figure 1). As illustrated by the Fagan nomogram, a positive test result markedly increases the post-test probability even from a low pre-test probability, indicating strong rule-in capability. Conversely, a negative test result reduces the post-test probability to near zero, demonstrating excellent rule-out performance and supporting the clinical utility of this screening tool.

Discussion

According to the 2020 Pediatric SSC guidelines, systematic screening should be implemented in children who are acutely unwell for timely recognition of septic shock and sepsis-associated organ dysfunction. Systematic screening needs to be tailored to the context within each institution in the aspects of the types of patients, resources, and procedures[7]. Several studies demonstrated that systematic screening for sepsis in children leads to earlier recognition and, subsequently, more timely initiation of therapy. Thus, morbidity and/or mortality are supposed to be declining. Institutional sepsis bundles incorporated with screening tools have clear benefits to improve outcomes such as earlier recognition, initiation of treatment, shorter hospital length of stay, fewer days in the intensive care units (ICU), and lower mortality[9,15-24]. Moreover, the implementation of an automated sepsis screening tool in the pediatric emergency department lowers the costs for patients with sepsis[25].

In contrast to most of the previous studies conducted in high-income countries, this study was performed at a tertiary hospital in an upper-middle-income country. Like other previous studies, the authors selected the age-adjusted parameters involving cardiovascular, respiratory, and neurological signs in patients with sepsis risk to predict septic shock[4,12,26-30]. Based on some studies conducted in high-income countries, the screening tools used to identify at-risk patients to predict sepsis or septic shock contained subjective items such as parental concern, clinician concern, cool/pale skin, and pulse quality[12,26,27,30]. To avoid the subjectivity of the evaluation, all screening items within the score were designed to be objective measurements upon the consensus of experts with a decent CVI of 1.0. Since this screening tool was implemented and validated in a university hospital with different levels of staffing, the scoring system was designed to be objective

and simple. Therefore, it can be performed by healthcare providers at all levels, including medical students, residents, fellows, attending physicians, and registered nurses.

Furthermore, most of the previous studies implemented the sepsis screening tool in emergency departments[11,12,25,30,31]. A few studies were established in inpatient units, including ICU/outpatient units[24,26,28]. Of note, the authors tried to develop and establish a screening tool that can be implemented in all settings, including emergency departments, outpatient departments, and inpatient departments, to improve timely recognition and initiation of treatment.

As for the performance of the screening tool in this study, the model had AUROCs of more than 0.9 in all settings, even in the subgroup analysis of patients with or without underlying conditions, inpatient, or emergency/outpatient settings. With a score of 3 or more, the model yielded a sensitivity of 100% and a specificity of more than 90% in all settings. These statistical data demonstrated that this sepsis screening tool can effectively discriminate patients with septic shock from those without septic shock. Despite the limitations of comparison due to differences in model and settings, the findings are consistent with other studies. Scott et al. reported a model of the risk of septic shock among children with suspected sepsis, using data known in the electronic health record at hospital arrival in three different sets. The model had an area under the curve ranging from 0.75 to 0.87. The sensitivity was 82 to 90% with a specificity of 32 to 48%, which was lower than the current study[32]. Another study by Gilholm et al. was conducted in the emergency department in Australia to validate two pediatric sepsis screening tools to identify children with sepsis. First, the 32-item pediatric sepsis screening tool revealed good predictive performance with an AUROC of 0.8. Second, a simplified tool containing 16 of 32 criteria had comparable performance and retained an AUROC of 0.80. The final model achieved a sensitivity of 90% and a specificity of 51%. Moreover, AUROC for the outcomes of septic shock was 0.84[12]. Compared to the two previous studies, despite better prediction ability, sensitivity, and specificity, one of the limitations of this study was a smaller number of participants. Nevertheless, based on the calculation of sample size conducted before the initiation of the study, the current study has an adequate sample size to validate the novel sepsis screening tool. In addition, this study was performed in a single center, which is a tertiary hospital. Thus, the generalization of the data should be carefully considered.

Additionally, alarm fatigue can result from an excessive number of false positive alarms being triggered. This can cause clinicians to become desensitized and fail to respond to true alarms. A sepsis screening tool should accurately identify sepsis, with a sensitivity high enough to avoid missed cases and high specificity to reduce false positive alerts and the risk of alarm fatigue. The model in this study showed both excellent sensitivity and specificity with a high PLR of 22 (95% CI 15 to 29). Collectively, these findings indicate that the tool provides strong rule-in and rule-out performance, reinforcing its clinical applicability as a screening tool.

As this study was conducted before the publication of the new pediatric Phoenix score, the definition used in this study was based on the previous SSC definition in 2020. Nonetheless, in the publication of the new definition of pediatric sepsis, it is clearly stated that the Phoenix score should not be used as a screening tool, thus again emphasizing that each institution should implement and create its own screening tool[33]. Larger, multicenter trials are warranted to validate the pediatric sepsis screening tool in low and middle-income countries. An automated screening system should be developed and implemented to easily include all eligible patients for a larger sample size and more reliable data collection.

The limitation of this study is that it was conducted at a single tertiary care center, and the number of patients with septic shock was small, which may limit the generalizability of the findings.

Conclusion

The novel pediatric sepsis screening tool provided excellent sensitivity, specificity, and PLR for the prediction of septic shock and the prevention of alarm fatigue. This screening model could serve as a simple tool for advancing the development of a pediatric sepsis screening system in low- and middle-income countries to enhance the quality of treatment and, in turn, improve patient outcomes.

What is already known about this topic?

Sepsis continues to pose a significant global challenge, contributing to high rates of mortality and morbidity among children and newborns. The 2020 Pediatric SSC recommends implementing systematic, institution-specific screening to facilitate the early detection of septic shock and sepsis-

associated organ dysfunction in acutely ill children. However, most existing studies have been single-center investigations conducted in high-income countries, often within emergency department settings, conditions that may not reflect the realities of resource-limited environments or inpatient care contexts. Additionally, the 2020 Pediatric SSC stated that the new pediatric Phoenix score should not be used as a screening tool.

What does this study add?

This study aimed to develop and validate a screening tool applicable across various clinical settings, including emergency, outpatient, and inpatient departments, to enhance the timely recognition of sepsis and prompt initiation of treatment. Moreover, the study was conducted in a low to middle-income country with limited resources.

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Authors' contributions

Conceptualization: OP, DT. Data curation: OP, DT, CC. Formal analysis: OP, DT, CC. Methodology: OP, DT, CC. Project administration: DT. Visualization: OP, DT, CC. Writing-original draft: OP. Writing-review & editing: OP, DT, CC.

The authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

Data availability statement

The de-identified data analyzed in this study are available from the corresponding author upon reasonable request, subject to appropriate ethical approval. Public access to these data is restricted in accordance with the Ethics Committee board of the institution's requirements and to protect patient confidentiality.

Ethics approval and consent to participate

The study was approved by the Ethics Committee Board of the Thammasat University Hospital (MTU-EC-PE-0-147/66). Informed consent was not required for this study due to its retrospective chart review design.

Clinical trial registration

A clinical trial registration number was not obtained for this study because registration was not required by the ethics committee.

Use of artificial intelligence

Artificial intelligence (AI), assisted tools were used solely for English language editing and grammatical refinement during the revision of this manuscript. Specifically, ChatGPT 5.3 Instant (OpenAI) was employed to improve sentence clarity and readability only. No AI tools were used in the generation of scientific content, including study design, data collection, analysis, interpretation, or conclusions. The authors take full responsibility for the accuracy, integrity, and originality of the work. In accordance with ICMJE recommendations, AI tools are not listed as authors.

Conflicts of interest

The authors declare no conflict of interest.

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