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To Evaluate the Utility of Age-Adapted SOFA Score in Predicting Mortality in Paediatric Severe Sepsis: A Prospective Observational Cohort Study

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ABSTRACT

Objective: To determine the usefulness of repeated measurement the SOFA score for prediction of mortality in PICU patients. **Methods:** 235 patients were enrolled for study from October 2018 to January 2021 at Paediatrics department.Clinical characteristics of the patients were recorded and different systemic physiological parameters were also recorded. The highest and lowest values of these parameters during the first 24 hours of ICU admission (DAY1) were captured, and the recording was repeated at 72 hours (DAY 3) of PICU admission (i.e., from 48-72 hours) **Findings:** Significant correlation between mortality and SOFA score, with higher scores observed in non-survivors compared to survivors, consistent with previous studies. On day 1, the SOFA score showed good predictive ability with an AUROC of 0.842. A pSOFA score of 7.5 or higher predicted mortality with 80.9% sensitivity and 78% specificity. On day 3, a SOFA score of 9.5 or higher performed best in identifying patients at higher risk of mortality, with excellent sensitivity (93.6%) and specificity (88.2%). **Novelty:** SOFA score, particularly the age-adapted pSOFA score, is an excellent predictor of mortality in critically ill pediatric patients with sepsis. Implementing the pSOFA score may improve the management and outcomes of pediatric sepsis.

INTRODUCTION

Sepsis is defined as life-threatening organ dysfunction secondary to a dysregulated host response to infection. Organ dysfunction can be identified as an acute change in total SOFA score ≥2 points consequent to the infection. [1] Globally, there were around 60.2 million cases of sepsis per year in 1990 and 48.9 million cases of sepsis per year in 2017, representing a decrease of 18.8% in sepsis cases over 27 years. Out of the 48.1 million sepsis cases, the majority of cases (33.1 million) occurred in people with an underlying infectious cause, and the remaining 15.8 million occurred in people with underlying injuries or non-communicable diseases. [2] It is worth mentioning that the most common underlying cause of sepsis was diarrheal disease in all age groups, irrespective of sex, and the most common underlying injury to cause sepsis has been road traffic injury in males and maternal disorders in females throughout this period. [2] Data on the global burden of pediatric sepsis are limited, but it is important to implement necessary interventions and treatment with available resources. [2] In 2017, almost half of all global sepsis cases occurred among children, with an estimated 20 million cases and 2.9 million global deaths in children under five years of age. [2] The study by Martin et al. showed an increase in the incidence of sepsis from 164,000 to 660,000 from 1979 to 2000, with a decrease in mortality from 27.8% in 1979–1984 to 17.9% in 1995–2000. [3] In the United States, the case-fatality rate in neonates and children with sepsis decreased from 10.3% to 8.9% between 1995 and 2005. [4] A recent systematic meta-analysis identified 15 studies describing sepsis incidence in 12 middle-income and high-income countries on four continents. The authors estimated the aggregate pediatric sepsis incidence at 48 cases in children per 100,000 person-years. [5] ACCP/SCCM (American College of Chest Physicians/Society of Critical Care Medicine) Consensus Confeence Committee provided a definition of sepsis, which evolves over time

due to various drawbacks. To overcome all these drawbacks of old definitions of sepsis, the Third International Consensus Definitions for Sepsis and Septic Shock (SEPSIS-3, 2016) [1]

Offered a conceptual definition of sepsis as life-threatening organ dysfunction secondary to a dysregulated host response to infection. Sepsis is defined clinically as an increase of two or more Sequential Organ Failure Assessment (SOFA) points in the setting of infection. The current definition of sepsis is based on the 2005 International Pediatric Sepsis Consensus Conferences. [6] Sepsis is defined as SIRS (Systemic Inflammatory Response Syndrome) in the presence of or as a result of suspected or proven infection. Severe sepsis is defined as sepsis plus one of the following: cardiovascular organ dysfunction, acute respiratory distress syndrome, or two or more other organ dysfunctions. Typically, scoring systems are used to assess the severity of illness in order to take early intervention and predict outcomes based on them. [7] A few of the most commonly used scoring systems are Acute Physiology and Chronic Health Evaluation (APACHE), Sequential Organ Failure Assessment Score (SOFA), and Logistic Organ Dysfunction Score (LODS), etc. The SOFA (Sequential Organ Failure Assessment) score was developed following a consensus meeting in 1994, with the aim of creating a score "to describe quantitatively and as objectively as possible the degree of organ dysfunction /failure over time in groups of patients or even individual patients" [8]. The SOFA score is traditionally calculated on admission to the ICU and at each 24-hour period thereafter. The tool utilizes six criteria that reflect the function of different organ systems (respiratory, cardiovascular, renal, neurological, hepatic, and hematological) and assigns a score of 0-4, as shown in Table 1 [9]. However, one of the major limitations of the SOFA score is that it was developed for adult patients and includes parameters that vary significantly with age, making it difficult to use in children [8].

Recently, a pediatric version of the SOFA score (originally known as Sequential Organ Failure Assessment) called pSOFA was developed and retrospectively validated in critically ill children [10]. In the pSOFA score, the age-dependent cardiovascular and renal variables of the original SOFA score were modified. Additionally, the respiratory component was changed to the SpO2:FiO2 ratio because arterial sampling is not always available in pediatric patients. El-Mashada GM et al. [11] found that the pediatric SOFA score was useful for predicting 30-day mortality in the general PICU population and performed better than the PRISM and PIM2 scores in this regard, but its performance was only fair in predicting a prolonged PICU stay. Matics et al. [10] conducted a study to adapt and validate a pediatric version of the SOFA score (pSOFA) in critically ill children and to evaluate the Sepsis-3 definitions in patients with confirmed or suspected infection. Zhong M et al. [12] conducted a study to evaluate the prognosis of children with sepsis based on the degree of organ dysfunction. They assessed the predictive validity of the pSOFA score for in-hospital mortality in children with sepsis in a pediatric intensive care unit (PICU) in a developing country. Ramazani J et al. [13] conducted a study to predict mortality in critically ill patients in the intensive care unit using the SOFA (Sequential Organ Failure Assessment),GCS (Glasgow Coma Scale) and FOUR (Full Outline of Un Responsiveness) scores. This was an observational and prospective study in which a total of 90 consecutive patients, aged ≤18 years, admitted to the ICU, were enrolled. The researchers recorded the SOFA, GCS, and FOUR scores of all children on the first day of admission.

Table 1: SOFA Score (Adult)

Organ System	SOFA Score				
	0	1	2	3	4
Respiration PaO2/FiO2, mmHg	>400	<400	<300	<200 (with respiratory support)	<100(with respiratory support)
Coagulation Platelets $x10^3/mm^3$	>150	<150	<100	<50	<20
Hepatic Bilirubin, mg/dL (µmol/l)	<1.2 (<20)	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (<204)
Cardiovascular Hypotension	MAP>70 mmhg	MAP<70 mmHg	Dopamine ≤5 or dobutamine (any dose)**	Dopamine >5 or epinephrine ≤0.1or norepinephrine <0.1	Dopamine >15 or epinephrine >0.1or norepinephrine>0.1
Central Nervous System GCS	15	13-14	10-12	6-9	<6
Renal	<1.2	1.2-1.9	2.0-3.4	3.5-4.9	>5.0
Creatinine,	<110	(110-170)	(171-299)	(300-440)	(>440)
mg/dL (µmol/l) or Urine output				or <500 mL/day	or <200 L/day

MATERIAL AND METHODS

Study Design and Setting:

This prospective observational cohort study was conducted from October 2018 to January 2021 at the Pediatric Intensive Care Unit (PICU), Department of Pediatrics, Jawaharlal Nehru Medical College and Hospital, Aligarh, Uttar Pradesh, India a tertiary care hospital. The study was approved by the Institutional Ethics Committee (D.No. 246/FM).

Sample Size:

The PICU of the Department of Pediatrics, Jawaharlal Nehru Medical College and Hospital has an annual admission rate of around 2,200 cases per year, with severe sepsis cases accounting for approximately 5% of the total admissions, which amounts to 110 cases per year. Considering an expected attrition rate of 5%, the sample size over a period of two years was determined to be 235 patients.

Inclusion Criteria:

1. **Age 1 month to 14 years**

2. The inclusion criteria for the study included patients presenting with suspected or proven infection and meeting two or more SIRS criteria as defined in the International Pediatric Sepsis Consensus Conference definitions, with at least one of the criteria being abnormal temperature or abnormal counts. Additionally, patients needed to exhibit any of the organ dysfunction criteria as defined in the International Pediatric Sepsis Consensus Conference definition.

Exclusion criteria :

1. Patient deceased or transferred to other health facilities within 72 hours of admission.
2. Patients having any underlying chronic disease with organ dysfunction
3. Patients in which required lab investigations or clinical examination could not be done
4. Patient undergoing surgery within first 3 days of hospitalization
5. Patients whose parents did not give consent
6. Patients admitted post Cardio Pulmonary Resuscitation (CPR) to the hospital

Procedure:

Baseline clinical characteristics of the patients, including age, gender, anthropometry, relevant history, and examination findings, were recorded upon their presentation to the PICU. Physiological parameters related to cardio-respiratory, neurological, hepatic, renal, and hematological organ dysfunction were also recorded. The highest and lowest values of these parameters during the first 24 hours of ICU admission (DAY1) were captured, and the recording was repeated at 72 hours (DAY 3) of PICU admission (i.e., from 48-72 hours). An age-adapted SOFA score was utilized throughout the patients' stay in the PICU, and scoring was performed based on this score. In case of multiple recorded values, the worst value was selected for the purpose of predicting mortality.

Statistical analysis:

The predictive ability of both the D1 and D2 SOFA scores was evaluated using receiver operating characteristic (ROC) curve analysis generated on a standard statistical software such as SPSS. The area under the curve (AUC) was utilized to compare the discriminatory power of the scoring system or other clinical variables of interest. An AUC of 1.0 indicates perfect discrimination, while an AUC of 0.5 suggests discrimination equal to chance. Continuous data is presented as mean and standard deviation and was compared using unpaired Student's t-test or Mann-Whitney U test, as appropriate. Categorical data is presented as percentages and was compared using the chi-square test. A p-value less than 0.05 was considered statistically significant for all analyses.

RESULT

This observational cohort study aimed to investigate the performance of the age-adapted Sequential Organ Failure Assessment (SOFA) score in predicting mortality in pediatric patients with sepsis presenting in the emergency room. A total of 250 patients were initially enrolled to participate in the study. However, 47 patients were subsequently excluded based on the predefined exclusion criteria. Among the remaining patients, 28 patients died within 72 hours of admission, with 20 deaths occurring on Day 1 and 8 deaths on Day 2. Additionally, 10 patients were transferred to higher-level care centers, 7 patients underwent surgery within the first 72 hours, and consent was not provided by the parents of 2 other patients, as shown in Figure 1. All patients were evaluated on Day 1, and on Day 3, the SOFA score was calculated based on clinical and laboratory parameters.

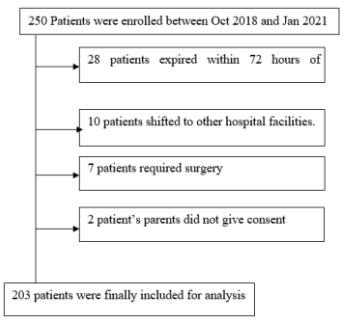

Figure 1: Consort Diagram

In this study, a total of 203 patients were enrolled, with a mean age of 37 months and a standard deviation of 46 months. Among these patients, the observed mortality rate was 110 (54.2%). Out of the total mortality cases, 61 were male patients (55%) and 49 were female patients (45%). It is worth noting that the mortality rate was slightly higher in the male population. Table 2 provides an overview of the baseline variables of the enrolled cases.

Table 2: Baseline Variables of Patients

Baseline Variables		
Age in Months, SD, IQR	37±46 , IQR 2-60	
Gender distribution		
Male	116	57.1%
Female	87	42.9%
Nutritional status		
Severe Acute Malnutrition	26	12.8%
Male	17	8.3%
female	9	4.43%

All enrolled patients in the study underwent investigation to identify the primary cause of sepsis. Among the enrolled patients, the majority had Central Nervous System (CNS) involvement as the primary cause of sepsis, with 102 patients in this category. The most common specific condition within the CNS category was acute pyogenic or partially treated meningitis, which was observed in 68 patients. Viral menin-goencephalitis was the cause in 28 patients. These patients were often hemodynamically unstable and exhibited invol-vement of other organ systems such as the renal and cardiovascular systems. Six patients had enteric ence-phalopathy.

Patients with the Gastrointestinal (GI) system (43 patients) and Respiratory system (41 patients) as the primary cause of sepsis were almost equally represented. Diarrhea was identified as the cause of sepsis in most of these patients, while a few patients presented with septic ileus and abdominal tuberculosis, numbering 4 and 3 respectively.

Pneumonia (bronchopneumonia and lobar pneu-monia) was the chief cause of primary sepsis in 34 patients, and 7 patients had sepsis associated with Acute Respiratory Distress Syndrome (ARDS). Six patients had sepsis related to skin or soft tissue infections, and in 11 patients, the primary cause of sepsis could not be identified. These patients were either malnourished or immunocompromised.

Assessment of organ dysfunction was conducted on Day 1 and Day 3. On Day 1, out of the 203 patients, 41 had only one organ dysfunction, 69 had two organ dysfunctions, and there were 49, 35, and 9 patients with three, four, and five organ dysfunctions respectively. No patients were enrolled with six organ dysfunctions. During the course of treatment, some patients showed clinical improvement and their organ dysfunction improved, while most patients deteriorated, leading to an increase in the number of patients with organ dysfunction on Day 3. On Day 3, there were 49 patients with only one organ dysfunction, 32 patients with two organ dysfunctions, and 26, 56, and 34 patients with three, four, and five organ dysfunctions respectively. Additionally, 6 patients had six organ dysfunctions. Different laboratory parameters are provided in Table 3.

Table 3: Lab Parameters

Baseline variables	**Survivors**	**Non-survivors**	**p-value**
Age In Months, Mean,SD) (over all -37±46)	46 ± 44	35 ± 40	0.382
GCS (mean value with SD)	12 ± 1.87	8.87 ± 3.59	<0.001
Malnourished Male Female	 55 38	 61 49	
Total Leucocyte Counts(in mm3/L)	20900 ± 27400	22700 ± 26000	0.631
Pao2/Fio2	260 ± 99	189 ± 133	<0.001
Platelets (in mm3/L)	269000 ±170000	176000 ±162000	<0.001
Creatinine (mg/dL)	0.48 ±1.54	2.61 ±4.08	0.235
Total Bilirubin (mg/dL)	0.89 ±1.54	2.61 ±4.08	<0.001
AST	79 ±176	259 ±833	<0.043
INR	1.10 ±0.21	1.76 ±1.00	<0.001
Lactate Levels (mmol/L)	3.46 ±2.85	5.58 ±3.97	<0.001
Inotropes Day 1 Day3	 23 21	 75 96	 <0.001 <0.001
Invasive Ventilation Day1 Day3	 3 10	 39 98	 <0.001 <0.001

The mean SOFA score on Day 1 for survivors was 5.84 (SD ± 2.97), while for non-survivors it was 10.81 (SD ± 3.84). On Day 3, the mean SOFA score for survivors was 5.46 (SD ± 4.14), and for non-survivors it was 15.21 (SD ± 3.32).

The age-adapted SOFA score was used to predict mortality on both Day 1 and Day 3. The comparison of SOFA scores onthese days is shown in Fig. 1 and Fig. 2 respectively. The performance of the age-adapted SOFA score in predicting mortality is depicted in the form of AUROC (Area Under the Receiver Operating Characteristic) curves, as shown in Fig. 3.

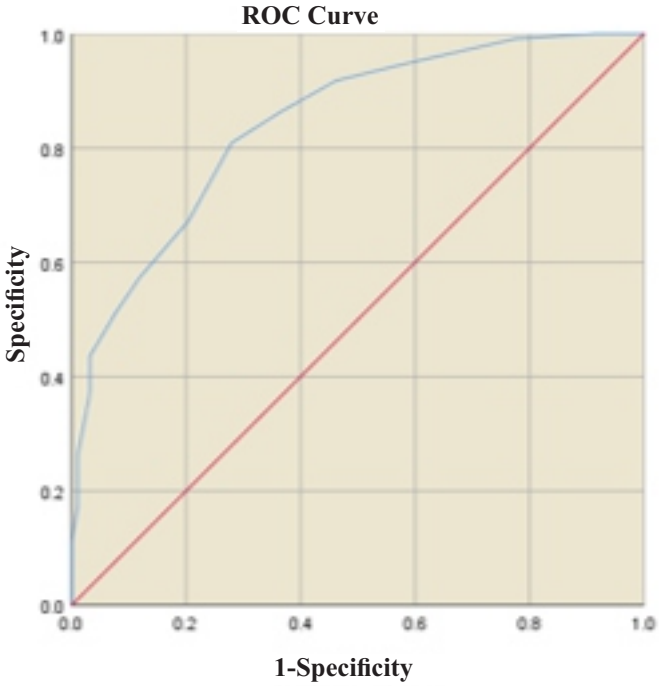

Figure 2: AUROC of SOFA Score On Day 1 =0.842 (0.790-0.950 with 95%CI)

When assessing organ dysfunction and mortality using the SOFA score, a cutoff value of ≥7.5, determined by applying Youden's index statistics, performed best in identifying patients with a higher risk of mortality. This cutoff had a sensitivity of 80.9% and specificity of 78%. The area under the receiver operating characteristic (AUROC) curve was 0.84, indicating good discriminative power of the SOFA score in predicting mortality.

The Hosmer-Lemeshow test, which assesses the goodness of fit of a model, yielded a $\chi 2$ value of -0.501 and a p-value of 0.479. These results indicate that the SOFA score had a good fit for predicting mortality in this study, as the p-value is greater than 0.05, suggesting no significant lack of fit.

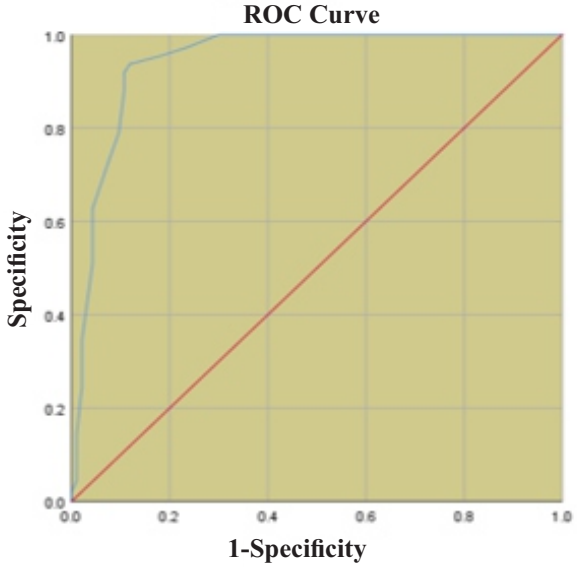

Figure 3: AUROC of SOFA score on day3= 0.944 (0.909 – 0.979 with 95%

When assessing organ dysfunction, mortality, or outcome using the SOFA score, a score of ≥9.5 performed best in identifying patients at a higher risk of mortality. This cutoff had a sensitivity of 93.6% and specificity of 88.2%. The area under the receiver operating characteristic (AUROC) curve was 0.944, indicating excellent discriminative power of the SOFA score in predicting mortality or outcome.

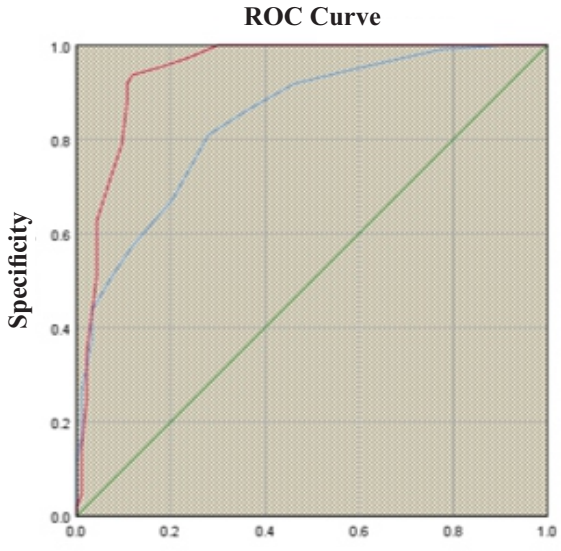

Figure 4: Comparison of SOFA Score on Day 1 and Day 3

On day 1 most of patients have SOFA score≤12 (159 out of 203 patients) in which 69 mortality occurred which was 43%. On the other hand in which SOFA score was high initially the mortality was also high in that group. 39 expired out of 42 patients in which in initial SOFA score was in the range of 13-18 (93% mortality) and 100% mortality observed in patients who had > 19 SOFA score. Only 2 patients had scores >19 and both of them expired. No survivor at or above 16 SOFA score as depicted in Table.4. On day 3, patients with SOFA score < 6 survived and no mortality observed in that particular group of patients, patients with SOFA score in range of 7-12 were 42 in which 23 expired (55%). 71 patients expired out of 79 (90%) in which SOFA score on day 3 was in the range of 13-18 and 16 patients expired out of 17 (94%) with SOFA score of ≥ 19. Only four survived at or above 16 SOFA score on Day 3 as shown in Table. 5. As we can withdraw inference from the above data that mortality increased with increased SOFA score.

Table 4: SOFA Score and Number of Mortality-Day 1

SOFA Score	Number of Patients	Total Number Non Survival	% Mortality
1-6	74	15	20%
7-12	85	54	63.5%
13-18	42	39	93%
19-24	2	2	100%

Table 5: SOFA Score and Number of Mortality-Day 3

SOFA score	Number of patients	Total number Non survival	% Mortality
1-6	65	0	0%
7-12	42	23	55%
13-18	79	71	90%
19-24	17	16	94%

Table 5: SOFA Score and Number of Mortality-Day 3

DISCUSSION

The aim of this study was to assess the efficacy of the age-adapted SOFA score in predicting mortality in patients with sepsis. The current definition of pediatric sepsis is primarily based on Sepsis-2, as the original SOFA score was not adapted for use in children. However, this poses limitations for clinical research [15]. To address this, Matics and Sanchez-Pinto proposed the pediatric version of the SOFA score (pSOFA), which incorporates age-adjusted cutoffs for the cardiovascular and renal systems, as well as expanded respiratory criteria to include non-invasive indicators of lung injury [10]. Previous studies have already validated the utilityof the SOFA score in large cohorts of critically ill patients [15][16].

In our study, we observed and followed 203 patients admitted for pediatric sepsis, ranging from 1 month to 14 years of age, in a tertiary level Pediatric inpatient department. Among the enrolled patients, 57% were males and 43% were females, resulting in a male-to-female ratio of 1.33:1. The mean age of the patients was 37 months with a standard deviation of ±46 months. Of the patients, 12% were malnourished. All 203 enrolled patients had at least one organ dysfunction, and some of them had two or more organ dysfunctions. The median duration of stay in the Pediatric Intensive Care Unit (PICU) was 4 days, with a range of 3-5 days, which is consistent with findings from studies conducted in different parts of the world [17][18][19].

The overall mortality rate in our study was 52.21%, which is comparable to the mortality rates observed in patients with sepsis and severe sepsis [20][21]. The median SOFA score was significantly higher in non-survivors compared to survivors, and there was a clear correlation between mortality and SOFA score, similar to the findings in the study conducted by El-Mashad et al. [11].On day 1, the area under the receiver operating characteristic curve (AUROC) for the SOFA score was 0.842 (95% CI: 0.790-0.950), indicating a good predictive ability. The Hosmer-Lemeshow test also showed a good fitness with a chisquare value of -0.501 and a p-value of 0.479. In comparison to similar studies, the AUROC of the SOFA score in our study was slightly lower but still within a reasonable range (0.937[12], 0.886(11), 0.829[15], 0.751[13].We found that a pSOFA score of 7.5 or higher predicts mortality with a sensitivity of 80.9% and specificity of 78% when applying Youden's index of statistics. A study conducted by Mianling Z et al. [12] in developing countries showed better prediction of mortality at a score of 5 or higher, while El-Mashad et al. [11] reported a cutoff of 7, and different pediatric studies have reported cutoffs of 8 [10]. In some adult studies, a cutoff of more than 8 has been recorded [22].On day 3, when assessing organ dysfunction and mortality, a SOFA score of 9.5 or higher performed best in identifying patients at higher risk of mortality, with a sensitivity of 93.6% and specificity of 88.2%. The AUROC for this cutoff was 0.944 (95% CI: 0.909-0.979), indicating excellent predictive ability. The Hosmer-Lemeshow test also showed a good fitness with a chi-square value of -0.32 and a p-value of 0.572.

CONCLUSION

In conclusion, our study aimed to evaluate the effectiveness of the age-adapted SOFA score in predicting mortality in pediatric patients with sepsis. The current pediatric sepsis definition is primarily based on Sepsis-2, as the original SOFA score was not specifically adapted for children, limiting its use in clinical research. To address this limitation, Matics and Sanchez-Pinto proposed the pediatric version of the SOFA score (pSOFA), which incorporates age-adjusted cutoffs for different organ systems and expands the respiratory criteria.

Our study included 203 pediatric sepsis patients, ranging from 1 month to 14 years of age, who were observed and followed up during their stay in a tertiary level Pediatric inpatient department. The male-to-female ratio was 1.33:1, with a mean age of 37 months. All patients had at least one organ dysfunction, and some had multiple dysfunctions. The median duration of PICU stay was 4 days, and the mortality rate was 52.21%, comparable to rates observed in sepsis and severe sepsis patients.

We found a significant correlation between mortality and SOFA score, with higher scores observed in non-survivors compared to survivors, consistent with previous studies. On day 1, the SOFA score showed good predictive ability with an AUROC of 0.842. A pSOFA score of 7.5 or higher predicted mortality with 80.9% sensitivity and 78% specificity. On day 3, a SOFA score of 9.5 or higher performed best in identifying patients at higher risk of mortality, with excellent sensitivity (93.6%) and specificity (88.2%).

In conclusion, our study demonstrates that the SOFA score, particularly the age-adapted pSOFA score, is an excellent predictor of mortality in critically ill pediatric patients with sepsis. These findings highlight the importance of using an age-specific scoring system to enhance the accuracy of prognostic evaluation in this patient population. Implementing the pSOFA score may improve the management and outcomes of pediatric sepsis by enabling early identification of high-risk patients and facilitating timely interventions.

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