

Clinical Profile and Pediatric Patterns in Predicting Sepsis Among Febrile Inpatients at an Indian Hospital: A Prospective Observational Study

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ABSTRACT

Background: Sepsis is a global perpetrator of pediatric morbidity and mortality. This research aims to analyze the clinical profile of febrile pediatric patients with a risk of sepsis to study underlying patterns involved and understand clinician perspectives to ensure diagnostic accuracy and assess the management and outcomes.

Methods: In this prospective cross-sectional descriptive study, 300 febrile inpatients of 1 month to 13 years of age with one or more sepsis warning signs were examined. Patient factors affecting progression towards sepsis were analyzed, along with age-related patterns of tachycardia and tachypnea. Risk of developing sepsis was compared with degree of elevation in TLC, patient admission and outcome on discharge. The study also extended towards segregating most relied markers of sepsis by comparing prevalence among various risk groups.

Results: Factors such as male gender, infancy, and incomplete vaccination status were found to increase the chances of developing sepsis. Diverse diagnoses heightened sepsis likelihood to varying extents. Tachycardia and tachypnea followed a pattern of manifesting most among infants. The study demonstrated a direct link between rising sepsis risk and elevating TLC levels. Quantification of PS6 interventions demonstrated that adrenaline

was the most commonly used ionotrope and IVF DNS was the most used isotonic fluid.

Conclusion: The unpredictable nature of pediatric sepsis can be tackled by an effective understanding of the patterns by which it manifests. Early detection of sepsis relies on pediatric patterns and established symptomatology approved commonly among clinicians which demands constant evaluation to ensure appropriateness and diagnostic consistency.

Keywords: Biomarkers, Acute febrile illness, Pediatric Intensive care Unit (PICU), Neonatal intensive care unit (NICU), SIRS

INTRODUCTION

Sepsis is a dynamic disease with a complex pathophysiology that has varied and unspecific clinical presentation and affects a heterogeneous group of people.^[1] Because of this sepsis is difficult to recapitulate to a simple definition. This pernicious subset of cytokine syndrome causes abnormal regulation of various cytokines and was described with regards to SIRS (Systemic Inflammatory Response Syndrome) with a suspected or proven infection source which can be life-threatening and lead to organ dysfunction when it is not recognized and treated early.^[2] Later Singer et al redefined sepsis as a life-threatening organ dysfunction caused by a dysregulated host

response.^[3] The burden of sepsis on survivors, their families, and the health care system is immense.^[4] Sepsis is the leading cause of death worldwide in the pediatric population resulting in an estimated 7.5 million deaths annually.^[5] When compared to its effect on the population, more studies on pediatric sepsis are necessitated. The clinical variables used to define SIRS are greatly affected by the normal physiologic changes that occur as children age.^[6] Pediatric sepsis studies claim increasing importance in light of emerging works related to its long-term outcomes. Collation and comparison of independent studies provide proof of long-term sequelae of sepsis affecting children in various aspects including physical and psychological health, cognitive abilities, and academic performance.^[7] Clinical assessment including history taking for symptoms and physical examination for signs is regarded as a cornerstone of clinical practice but has rarely been evaluated.^[8] Similarly, for the sepsis continuum, there are many criteria such as SIRS and SOFA containing a fixed set of signs and symptoms which enables early recognition and management of sepsis. The weightage awarded for individual signs and symptoms and biomarkers used vary with guidelines whereas the pattern in pediatrics and the predictors tends to be static. The importance of implementation of guidelines and their effectiveness is well supported by literature along with that they also point out the unwarranted discount in treatment and lack of importance awarded to signs and symptoms.^{[1],[2],[8],[4]} Most clinical algorithms are based on abnormal vitals such as heart rate, respiratory rate, temperature, capillary refill time, and altered sensorium. However, these abnormal vital parameters are also seen in a large proportion of children presenting with self-limiting infections.^[9] It is therefore essential to proficiently integrate clinical signs and symptoms, coupled with a thorough evaluation of their suitability as predictors of sepsis.

Our study aims to analyze the clinical profile of children with acute febrile illness, particularly those at risk of developing sepsis, directed towards the identification of underlying patterns, the effect of various factors in the progression to sepsis, and evaluation of management, furthermore, we intend to segregate the predictors of sepsis relied by the healthcare providers to escalate care and therapy.

MATERIALS & METHODS

Study design and study site: The research was conducted for a period of 6 months from March 2023 to September 2023 and adopted a prospective cross-sectional descriptive methodology. Each study participants were monitored closely from the day of admission till discharge. The ethical approval was obtained from the institutional ethics committee of Bapuji Pharmacy College. The investigation was undertaken at SSIMS & RC, a tertiary care academic medical institution situated in Davangere, Karnataka, India, boasting a bed capacity exceeding 720.

Selection of Study Participants: The study was conducted with a sample size of 300 volunteers. The study participants or bystanders were provided with an informed consent form describing the process and purpose of the study ensuring voluntary participation. Febrile pediatric in-patients from the NICU, PICU, and general wards of SSIMS & RC presenting with more than one warning sign of sepsis (according to SIRS criteria) were deemed eligible to participate in the study. The study population comprised both male and female patients between the ages of one month to 13 years. Patients who were diagnosed with sepsis at the time of admission and children with a complex medical history (cancer, HIV, TB) were excluded from the study. Any case with an ambiguous diagnosis or nonbacterial etiologies was excluded from the final cohort.

Outcome measures: The study aims to evaluate the views and approaches of clinicians on early recognition and

management of pediatric sepsis. For this, we segregated the signs and symptoms that the clinicians believed to be predictors of sepsis and escalated care grounded in it. We intended to identify the patterns of sepsis in pediatrics concerning age and disease severity comprising oddity in vitals and biomarkers. The risk of sepsis and its effect on care provided was analyzed and once the patient was discharged the outcome of patient was also contrasted against the chances of sepsis. The research extended towards prevalent bacterial cultures, common treatment strategies, with quantification of PS6 interventions.

Sample Size Calculation

Sample Size =	$Z\alpha^2$	P (1-P)
	d^2	
$Z\alpha^2$ = Std normal variation 1.96		
P = Expected proportion from population		
d = Absolute error		

Among hospitalized children, 26% had SIRS related to infection. Considering 26% as prevalence of sepsis in pediatric population with 5% margin of error, minimum sample needed to conduct the study is 298 cases. 300 cases will be selected.

Data Collection Process: The demographic details of each patient were collected from the case sheet along with any significant past medical history and immunization status. Patients were classified into various age groups according to the recommendations of Goldstein et al.^[6] We looked into the number of children fulfilling the suspected sepsis criteria based on NICE, SIRS, Goldstein et al, mental status evaluation, altered capillary refill time, and abnormal TLC and CRP levels. The presence of various signs and symptoms identified and confirmed by the treating physician that were considered markers of sepsis were subsequently registered as predictors of sepsis and the physician response was measured by the admission of the patient to the wards or ICU. The vital signs values utilized in the study were those collected upon admission. We segregated

the first obtained values of CRP and TLC for further analysis. The final diagnosis of serious bacterial infection was based on reference standards comprising positive cultures from sterile sites [blood, urine, and cerebrospinal fluid (CSF)] and consensus diagnosis by members of the health care team. The treatment expediency measures were the number of PS6 interventions each patient received and the timeliness of the intervention implemented. Details regarding IV fluids, ionotropic agents, and IV antibiotics given to patients were obtained from the patient medication chart. Patient health status on discharge (recovered, improved death) was keyed in based on the opinion of the treating physician.

STATISTICAL ANALYSIS

Statistical analysis was performed using Microsoft Excel and IBM SPSS version 28 for Windows. The collected data was summarized as frequency and percentage for categorical variables and were compared using the Chi-square test.

RESULT

Sepsis is conventionally described concerning SIRS criteria. In our study, the risk of sepsis was initially quantified by the number of SIRS parameters present. 102 members met all four (temperature, TLC, Tachycardia, and Tachypnea). 68 presented with 3 items positive and 89 patients with 2 SIRS parameters.

Of the 300 enrolled participants, 180 were male and 120 were female despite the gender-neutral recruitment. When participants were classified based on age as per the recommendations of Goldstein et al., 135 participants were infants contributing to 45% of the study population. The remainder comprised 29% of toddlers and 26% of school-age children.^[6]

Each patient was awarded a degree of sepsis risk based on the NICE published risk stratification tool, among which 133 possessed a high chance of developing sepsis and belonged to category red, 97 patients with moderate risk, were placed in

amber, and 70 low-risk patients were identified in the green category. The chance of developing sepsis was predominant among males and infants. Diverse diagnoses heightened sepsis likelihood to varying

extents. Immunization status was associated in a way that unimmunized or partially immunized patients exhibited higher chances of sepsis. (Table 1)

Table 1: Factors Influencing Sepsis

		Cases	Risk Stratification		
			Green	Amber	Red
Gender	Male	180	36	58	86
	Female	120	34	39	47
Age	Infants	135	26	44	65
	Toddlers	87	30	26	31
	School age children	78	14	27	37
Immunization status	Immunized	286	126	88	72
	Partially/ unimmunized	14	2	5	7
Diagnosis	Pneumonia	79	15	17	47
	Bronchiolitis	32	4	9	19
	UTI	40	12	17	11
	Gastroenteritis	32	11	11	10

Our study set apart and evaluated the incidence of various predictors involved in the early recognition of sepsis. We found that not all parameters are equally used and relied on by treating physicians and there is

variability in their degree of manifesting as well. Among patients with mild risk of sepsis and moderate to severe risk, incidence of certain signs and symptoms varied significantly. (Table 2).

Table 2: Most Relied Predictors Of Sepsis According To Prevalance Among Various Risk Groups

Parameters	Patients at mild risk of sepsis (n=70)	Proportion	Patients with moderate to severe risk of sepsis (n=230)	proportion
Pallor	13	18.57%	116	50.4%
Rashes	0	0	20	8.69%
Decreased Activity	26	37.14%	221	96%
Weak High Pitched Cry	2	2.8%	56	24.3%
Nasal Flaring	5	7.14%	92	40%
Abnormal Chest Sounds	7	10%	141	61.3%
Chest Indrawing	0	0	32	13.9%
Abnormal Spo ₂	4	5.71%	71	30.8%
Abnormal CRT*	0	0	32	13.9%
Reduced Urine Output	4	5.71%	44	19.1%
Poor Feeding	7	10%	77	33.4%
Grunting	0	0	17	7.3%
Cold Hands And Feet	10	14%	75	32.6%
Neck stiffness	0	0	16	6.95%

*CRT: Capillary refill time

A statistically significant association was exhibited between admissions to various care units and stratified risk. Patients were admitted to various units based on their

disease severity and the care warranted. The proportion of low risk patients admitted to wards were found to be 88% (n=70). In NICU, the proportion of low risk patients

were 0, but proportion of moderate and severe risks were 20% and 80% respectively. In PICU green category was 12%, amber category 26% and red category constituted 62%. The association was further proved using chi square test ($X^2=28.70, p=0.001$)

The study looked into the incidence of tachycardia and tachypnea in febrile pediatric patients at risk of sepsis concerning various age groups. Among the

300, 157 were affected by tachycardia. Infants contributed 44% of total tachycardia cases. The number of toddlers affected was comparatively lesser (36%) and school-age children comprised 33%. Tachypnea was more prevalent in our study compared to tachycardia, affecting 182 study participants, manifesting at peak among infants (46%) followed by 32% in toddlers and 22% in school-age children. (Figure 1)

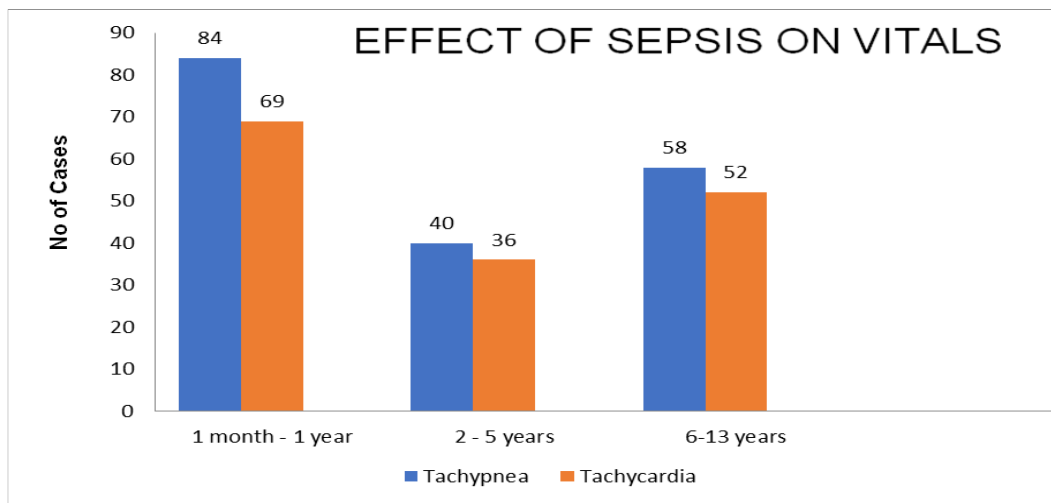


Figure 1: Incidence of tachycardia and tachypnea with respect to age

Since several studies endorse the credibility of TLC and CRP as predictors of sepsis, we intended to identify the pattern in which both TLC and CRP are dysregulated in patients with probable sepsis.^{[8], [4]} The study compared TLC values against the risk of developing sepsis by categorizing elevations in TLC as mild, moderate, and severe.

Results demonstrated that escalation in TLC was directly proportional to the amplification of sepsis risk (Figure 2). In contrast, CRP typically exhibited values ranging from 5-50mg/dl, emphasizing its heightened sensitivity irrespective of disease severity.

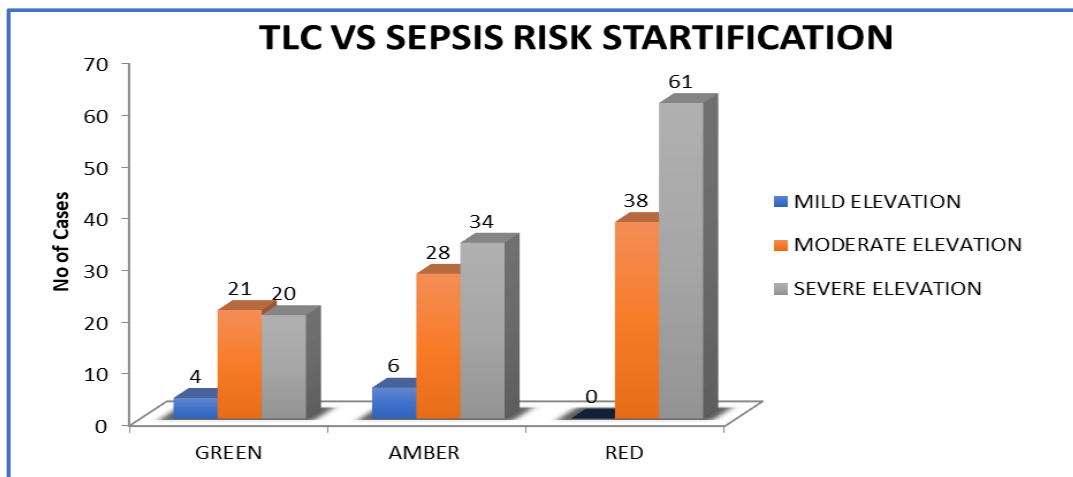


Figure 2: Relationship between stratified risk of sepsis and range of elevation in TLC

Evidence of invasive bacterial infection was obtained from positive culture reports. Among our study participants 113 had positive blood culture reports, 51 positive urine culture reports, and 8 for CSF. 37 patients had both urine and blood culture positive. When organisms were scrutinized, the most common isolates were found to be E.coli and Pseudomonas from NICU, E.coli and S. aureus from PICU followed by E.coli and S.aureus in the wards.

Another important objective of the study was to evaluate the management strategies. The number of PS6 interventions each patient received was analyzed (Table 3). Adrenaline was the most commonly used inotrope and IVF DNS was the most used isotonic fluid. 44% of our patients received all PS6 interventions within 1 hour of hospitalization.

Table 3: Evaluation of Extent of PS6 Intervention Received

PS6 INTERVENTION	NO. OF STUDY PARTICIPANTS
NO PS6 INTERVENTION RECIVED	6
HIGH FLOW OXYGEN FOR CLINICALLY INDICATED	234
OBTAIN IV ACCESS FOR BLOOD CULTURE, BLOOD GLUCOSE AND BLOOD GAS ASSESMENT	197
IV ANTIBIOTICS	274
IV FLUID BOLUS	255
SENIOR REVIEW	235
INOTROPE DRUGS	23
GOLDEN HOUR: all PS6 intervention within 1 st hour of hospital admission	132

The outcome of patients enrolled in our study was analyzed against their risk of developing sepsis. The outcomes were classified as recovered, improved, or death. The condition of the patient on discharge was statistically associated with their stratified risk of sepsis. This association was also substantiated using chi square test with a p value 0.01 ($X^2=12.76$).

DISCUSSION

Following specific trends and manifesting through versatile symptomatology, sepsis possesses certain patterns that can be understood when interlinked with patient characteristics. Our study started by categorizing patients by their risk of developing sepsis by using the NICE risk stratification tool and the SIRS criteria. Our initial focus was to analyze factors affecting the risk of sepsis and disease progression. There was a male preponderance in our study suggesting that the male gender has more susceptibility towards infections, with a heightened risk of disease progression to sepsis. The findings were overlapping with

many Indian studies and a Brazilian study. [10],[11] [18]. When classified according to age as per the recommendation of Goldstein et al, infants were afflicted most with intensified sepsis probability. A similar conclusion was shared by Jyotsna Mishra et al.[12] another prominent factor contributing to the risk of sepsis was the focus of infection. We deduced from our study that diseases of the respiratory system stood higher up on the table followed by UTI and GI illnesses. The findings were in agreement with research carried out elsewhere.[13] On comparing disease severity and management between immunized and partially/unimmunized children, our study found that the disease severity in children with incomplete immunization status was higher and their management required more antibiotics. We conclude that the male gender, infancy, incomplete immunization status, and diseases of the respiratory system have a detrimental influence on sepsis. We were able to identify the most relied predictors of sepsis leveraged by health

providers and sequestered 14 such. Each patient recruited to this study had a diagnosis of infectious etiology, meeting one or more warning signs of sepsis. But also their signs and symptoms vary largely. This may be attributed to the underlying disease condition, yet there is a repetition of certain physiological findings in majority concurrent with severity of disease condition. Regardless of the diagnosis certain physiological markers manifest repeatedly in moderate to severe risk patients and are absent or rarely present in low risk patients, supporting themselves as dependable markers of sepsis. Above all, it is the constellation of these symptoms that provides insight into a patient's risk of developing sepsis. Multicenter studies have demonstrated that, despite the recognition that variability exists among clinicians in identifying and managing sepsis, emergency physicians caring for children continue to rely heavily on clinical metrics for recognizing and monitoring sepsis.^[4] The validation of predictors ensures diagnostic consistency and effective allocation of resources along with improving collaboration between various disciplines including healthcare providers, researchers, and policymakers. Considering a future aspect, integrating valid predictors into electronic health records can alert physicians about the possibility of sepsis. Our study then looked into the patterns by which vitals and biomarkers are affected by sepsis. According to a 2015 study, tachycardia was the most relied clinical measure for defining sepsis, in our study tachypnea outnumbered tachycardia.^[4] Furthermore, both tachycardia and tachypnea predominantly affected infants. Similar results were demonstrated by researchers in 2020 and 2022.^{[9],[12]} This highlights the importance of clinicians to be prepared for initiating life support measures in infants without reluctance as they are most precarious. Even though many studies pronounce TLC as the most utilized biomarker for upgrading treatment and identifying sepsis, the pattern

of this correlation remains unclear.^{[4],[12]} Our study demonstrates a directly proportional link between degrees of elevation in TLC with patient disease severity. The rise in TLC was proportional to the awarded risk obtained from the NICE-published risk stratification tool, minimum among patients at lesser risk of sepsis and climbing according to the degree of risk. When IL6, serum lactate, and procalcitonin are not performed in every patient and pose a financial burden, reliable and routinely performed TLC can aid in early sepsis recognition and management among pediatric patients.

When the admission of patients to various care units was analyzed, the clinicians recognized the care each patient demanded and adjusted accordingly. Patients with higher sepsis risk were more likely to be admitted in specialized units like NICU or PICU. The clinical judgement of the severity of a disease process is subjective and is related to the experience and clinical ability of a physician. The culture isolates found most commonly in our PICU, NICU, and Wards were similar to what was found by various studies conducted locally and internationally, marking these organisms as worldwide propagators of sepsis.^{[11],[12],[14]}

The PS6 intervention is one of the standard protocols containing six critical actions for managing a patient at risk of sepsis. The bundle covers all critical aspects of sepsis management, ensuring no key area is neglected, from respiratory support to infection control and hemodynamic stability. The interventions are specifically tailored to meet the physiological and developmental needs of children, promising more effective and appropriate care. The timeliness and extent of each intervention delivered were analyzed. The IV fluid and ionotrope of choice agreed with studies conducted globally. According to some guidelines and studies, the success of resuscitation was measured using vitals, hemodynamic parameters, and mental status examination.^{[4],[17]} Our study didn't assess post resuscitation success and it was marked

as a limitation of our study. Another deficiency in our study was the short duration and excluding the effect of sepsis on biomarkers such as procalcitonin and serum lactates. When the outcomes of patients were analyzed there was a statistical significance between patient condition on discharge and presumed risk of sepsis. Our study found no proof of different care facilities influencing the outcome, despite several literatures claim of contradictory findings. ^[12]

CONCLUSION

The unpredictable nature of pediatric sepsis can be tackled by effective comprehension of underlying patterns by which it manifests. Endorsement of pediatric patterns; factors influencing risk of sepsis

and how patients of various clinical profiles are affected by sepsis, provide certainty for clinicians and give rationale for resource utilization. Risk stratification tools can be considered an innovative modality in individualized drug therapy because preventing sepsis is crucial to treating it. More studies on guidelines implemented in routine clinical practice can ensure accuracy, relevance, and credibility along with the identification and integration of novel sepsis predictors. Clinicians often extrapolate and follow most relied predictors from guidelines based on their practice. Periodic evaluation and validation of predictors and markers relied on by physicians ensure quality diagnostic and preventive strategies especially when facing rampant dynamics like sepsis.

LIST OF ABBREVIATIONS:

CRP	C- REACTIVE PROTEIN
CRT	CAPILLARY REFILL TIME
CSF	CEREBROSPINAL FLUID
E.COLI	ESCHERICHIA COLI
GI	GASTROINTESTINAL
HIV	HUMAN IMMUNODEFICIENCY VIRUS
ICU	INTENSIVE CARE UNIT
IVF DNS	DEXTROSE NORMAL SALINE INFUSION
NICE	NATIONAL INSTITUTE OF CARE AND HEALTH EXCELLENCE
NICU	NEONATAL INTENSIVE CARE UNIT
PICU	PEDIATRIC INTENSIVE CARE UNIT
PS6	PEDIATRIC SEPSIS SIX
S. AUREUS	STAPHYLOCOCCUS AUREUS
SIRS	SYSTEMIC INFLAMMATORY RESPONSE SYNDROME
SOFA	SEQUENTIAL ORGAN FAILURE ASSESSMENT
SPO2	PERIPHERAL CAPILLARY OXYGEN SATURATION
TB	TUBERCULOSIS
TLC	TOTAL LEUKOCYTE COUNT
UTI	URINARY TRACT INFECTION

Declaration by Authors

Ethical Approval: This study, titled Clinical Profile and Pediatric Patterns in Predicting Sepsis among Febrile Inpatients at an Indian Hospital: A Prospective

Observational Study has been approved by the BPC Institutional Ethics Committee (BPC/IEC NO. 92/2022-23). The committee is recognized by the Government of

Karnataka, AICTE, PCI, and affiliated with RGUHS, Karnataka, Bangalore.

For further details, please contact the BPC Institutional Ethics Committee at bapujipharmacycollege@yahoo.co.in

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