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Association between serum ferritin levels and sepsis severity and clinical outcomes in children with sepsis: a prospective observational study.

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Abstract

Background:
Sepsis remains a major cause of morbidity and mortality among children worldwide. Early identification of disease severity using reliable biomarkers is essential for timely intervention and improved outcomes.

Objectives:
To evaluate the association between serum ferritin levels and the severity of pediatric sepsis and to assess its relationship with clinical outcomes, including multiple organ dysfunction syndrome (MODS), recovery, and mortality.

Methods:
This prospective observational study was conducted in the Pediatric Intensive Care Unit of a tertiary care teaching hospital and included 50 children aged 1 month to 12 years diagnosed with sepsis. Serum ferritin levels were measured during sepsis, septic shock, MODS, and on the seventh day of recovery. Statistical analyses were performed to determine associations between serum ferritin, disease severity, and patient outcomes, with $p<0.05$ considered statistically significant.

Results:
The mean age of participants was 2.73±2.35 years, with equal representation of males and females. Mortality was 12%, while 88% recovered. Mean serum ferritin levels increased progressively from sepsis (501.88 ng/L) to septic shock (620.00 ng/L) and MODS (1716.67 ng/L), followed by a marked decline during recovery (131.70 ng/L), indicating a close association with disease severity. However, serum ferritin did not demonstrate a statistically significant association with mortality. Lower leukocyte and platelet counts were significantly associated with adverse outcomes, whereas hemoglobin and C-reactive protein were not significantly associated with mortality.

Conclusions:
Serum ferritin is a valuable biomarker for assessing disease severity and monitoring the clinical course of pediatric sepsis, although it may not independently predict mortality. Total leukocyte and platelet counts demonstrated greater prognostic significance for adverse outcomes.

Recommendation
Given the results of the present study, serum ferritin could be regarded as an adjunct biomarker for the evaluation of sepsis severity and prognosis in children in addition to clinical evaluation and routine laboratory tests.

Keywords: *Pediatric sepsis; Serum ferritin; Biomarker; Multiple organ dysfunction syndrome; Septic shock; Prognosis; Total leukocyte count; Platelet count.*
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Introduction
Sepsis is a life-threatening condition caused by a dysregulated host response to infection, resulting in organ dysfunction and high mortality. It remains a major global health challenge, accounting for an estimated 48.9 million cases and 11 million deaths worldwide in 2017[1]. In children, sepsis is a leading cause of morbidity and mortality, particularly in developing countries where

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delayed diagnosis and limited healthcare resources contribute to poor outcomes. Despite advances in intensive care, early identification of children at risk of severe disease remains difficult, highlighting the need for reliable biomarkers that can aid diagnosis, assess disease severity, and predict prognosis.[2]

The pathophysiology of sepsis involves a complex interaction between infection, inflammation, immune dysregulation, endothelial injury, and coagulation abnormalities. The initial inflammatory response is mediated by cytokines such as tumour necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6), leading to widespread tissue injury and organ dysfunction.[3] This is often followed by an anti-inflammatory phase characterized by immune suppression, increasing susceptibility to secondary infections and adverse outcomes. Owing to this complex disease process, biomarkers reflecting the inflammatory response have gained increasing clinical importance.

Serum ferritin, an intracellular iron-storage protein, has emerged as a promising biomarker in sepsis. Besides regulating iron homeostasis, ferritin functions as an acute-phase reactant, with serum concentrations increasing significantly during inflammation and infection.[4] Elevated ferritin levels have been associated with greater disease severity, multiple organ dysfunction, prolonged intensive care stay, and increased mortality in adult patients with sepsis. However, its prognostic value in paediatric sepsis remains uncertain because children exhibit distinct immune and inflammatory responses compared with adults.[5]

Previous studies evaluating serum ferritin in paediatric sepsis have produced inconsistent findings. [4,5,6]While some investigations have demonstrated a significant association between hyperferritinemia and poor clinical outcomes, others have reported limited or no prognostic significance. These conflicting observations underscore the need for further research to clarify the role of serum ferritin as a predictor of disease severity and outcomes in children with sepsis.

The present prospective observational study aims to evaluate the association between serum ferritin levels and the severity of paediatric sepsis, as assessed by validated clinical scoring systems, and to determine its relationship with important clinical outcomes including multiple organ dysfunction syndrome, duration of hospital stay, and mortality. Establishing serum ferritin as a reliable prognostic biomarker could facilitate early risk stratification, guide therapeutic decision-making, and improve monitoring of critically ill children with sepsis, ultimately contributing to better clinical outcomes.

Materials and Methods

Study Design

The research was conducted in a prospective observational study of a cross-sectional type that was aimed at assessing the relationship between serum ferritin level, sepsis severity, and outcomes in children suffering from sepsis. Children were recruited into the research prospectively, and information on demographics, clinical, and laboratory parameters was collected since the time of sepsis diagnosis. The assessment of the serum ferritin level was made at diagnosis and further in the course of treatment, even after overcoming multiple organ dysfunction syndrome (MODS), when it occurred.

Study Setting

The experiment was carried out in the Paediatric Intensive Care Unit (PICU) of Ballari Medical College and Research Centre, Ballari, Karnataka, India. The Paediatric Intensive Care Unit caters to the care of sick children who require close monitoring and intensive care. In addition, such patients require respiratory support, hemodynamic stability, and control of severe infections and sepsis. The hospital has paediatric emergency services, inpatient services, intensive care facilities, diagnostic laboratories, and other specialized medical services necessary to manage such children.

Study Population/Participants

The study population comprised children aged **1 month to 12 years** who were diagnosed with sepsis and admitted to the PICU during the study period.

Inclusion criteria:

- Children aged 1 month to 12 years.
- Children diagnosed with sepsis according to applicable consensus criteria.
- Children admitted to the PICU during the study period.
- Children whose parents or legal guardians provided written informed consent.

Exclusion criteria:

Patients suffering from chronic inflammation, iron overload disease, or hematological malignancy were not included in this study since their presence may independently affect serum ferritin levels and interfere with the association between serum ferritin levels and sepsis outcomes.

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Sampling Method

The study used a non-probability purposive sampling technique. All children who qualified on the set criteria were eligible to participate in the study. The children were recruited based on assessment of eligibility and provision of informed consent by their parents or guardians.

Sample Size Determination

The sample size needed was determined using nMaster statistical software version 2.0. This was done with reference to the published sensitivity for serum ferritin as a predictive biomarker of childhood sepsis. A 95% confidence interval and 13% margin of error were used to calculate the sample size. From this, a sample size of 50 was determined.

Variables and Outcomes

Exposure factors considered were the serum ferritin concentration, which was determined at the time of diagnosis of sepsis and repeated throughout the duration of illness. Clinical variables considered were age, sex, clinical features, total blood count, serum electrolyte concentrations, blood urea, creatinine, and coagulation profile.

The principal end point was the relationship between serum ferritin concentrations and sepsis severity. The secondary endpoints were the occurrence of MODS, length of stay in the hospital, and mortality. Mortality was death occurring during the hospitalisation period. MODS was assessed according to the appropriate International Paediatric Sepsis Consensus guidelines.

Minimizing Bias

Steps were taken to reduce any sources of bias wherever possible. Participants were recruited based on predefined inclusion and exclusion criteria to ensure consistency in patient selection. Demographic and clinical details were obtained via a structured case record form. Blood ferritin and other tests were conducted according to routine laboratory techniques in the hospital. Consistent criteria and definitions were employed across the entire study. Confounding due to known risk factors for increased serum ferritin concentrations was minimized by excluding children who had conditions such as chronic inflammation, iron loading diseases, and haematological cancers.

Data Collection

After obtaining written informed consent from the parents/guardians, demographic data, clinical history, physical examination, and laboratory investigation data were documented in a case record form. Levels of serum ferritin were determined at the time of diagnosis and repeatedly throughout the course of the disease. Further levels of ferritin were also taken after recovery from MODS, if any.

Laboratory investigation was carried out on full blood count, serum electrolytes, blood urea and creatinine levels, and ferritin levels. Where necessary, coagulation tests were done on PT, APTT, INR, and D-Dimer levels. Clinical outcomes like MODS, hospital stay period, and mortality were all documented prospectively.

Statistical Analysis

Analysis of data was done using [Insert Name of Software and Version]. Continuous data were presented as Mean ± SD, whereas categorical data were presented in terms of frequencies and percentages. Relationships between serum ferritin and categorical clinical outcomes were determined through the chi-square test wherever applicable. Relationship between serum ferritin and certain clinical outcomes was also determined by logistic regression analysis. P-value less than 0.05 was considered statistically significant.

Sample Size

The sample size was obtained through the use of nMaster software (version 2.0), taking into account the previously published data on the sensitivity of serum ferritin as a prognostic biomarker in childhood sepsis. This was done at the 95% confidence level and 13% precision. Given these considerations, the minimal sample size to be used in this research was found to be 50.

Ethical Considerations

Ethical clearance was obtained from the [full name of Institutional Ethics Committee] of Ballari Medical College and Research Centre before the conduct of the study (Approval No.: [insert number], date:[insert date]). Informed consent in writing was obtained from the parents/legal guardians of all children who participated in the study. Information confidentiality was ensured during the entire study period and was used only for the purpose of research. The study was carried out according to the Declaration of Helsinki and ICMR guidelines for ethics.

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Results

Participant Flow Diagram

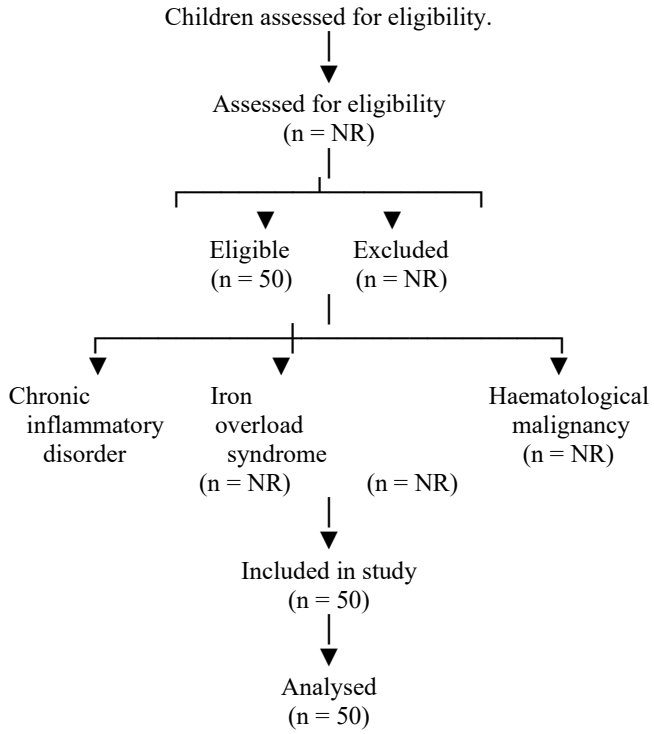

Table 1. Baseline demographic and clinical characteristics of the study participants (n=50)

Variable	Value
Age (years), Mean ± SD	2.73 ± 2.35
Male	25 (50%)
Female	25 (50%)
Fever	50 (100%)
Hurried breathing	27 (54%)
Convulsions	6 (12%)
Altered sensorium	6 (12%)
Cyanosis	2 (4%)
Hepatomegaly	7 (14%)
Respiratory findings (bilateral crepitations)	21 (42%)
Tachycardia	8 (16%)
Mortality	6 (12%)
Recovery	44 (88%)

The mean age of the study population was 2.73±2.35 years with equal gender distribution. Fever was present in all patients. Hurried breathing (54%) was the commonest associated symptom, while hepatomegaly (14%), altered sensorium (12%), and convulsions (12%) were less frequent. Overall mortality was 12%.

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Table 2. Baseline physiological parameters

Parameter	Mean ± SD
Pulse rate (beats/min)	126.46 ± 20.77
Respiratory rate (breaths/min)	37.26 ± 12.91
Systolic BP (mmHg)	95.19 ± 11.12
Diastolic BP (mmHg)	54.91 ± 7.36
Oxygen saturation (%)	94.77 ± 9.43

Children with sepsis demonstrated marked variability in vital parameters, reflecting heterogeneous disease severity.

Table 3. Laboratory parameters during different stages of sepsis

Parameter	Sepsis	Septic shock	MODS	Recovery (Day 7)
Total leukocyte count (cells/cumm)	23076.74	9964.00	6566.67	7449.77
Hemoglobin (g/dL)	11.03	9.36	9.37	10.94
CRP (mg/L)	124.05	107.70	191.33	31.75
Serum ferritin (ng/L)	501.88	620.00	1716.67	131.70

Serum ferritin increased progressively with disease severity, reaching its highest level in MODS, and decreased markedly after recovery. CRP demonstrated a similar pattern, while hemoglobin declined in severe disease.

Table 4. Comparison of laboratory parameters between recovered and deceased children

Variable	Death	Recovery
Age (years)	1.26 ±1.51	2.93 ±2.39
Serum ferritin in sepsis (ng/L)	410.20	511.61
Serum ferritin in septic shock (ng/L)	801.33	930.56
Serum ferritin in MODS (ng/L)	1080.90	2120.00
CRP during sepsis (mg/L)	95.33	124.58
Total leukocyte count (cells/cumm)	10098.33	15901.48

Children who died were younger and had lower total leukocyte counts than survivors. Ferritin concentrations were elevated in both groups and tended to be higher in severe disease.

Table 5. Comparison of laboratory parameters according to clinical outcome

Variable	Significant
Total leukocyte count (Sepsis)	Yes (p=0.002)
Total leukocyte count (Septic shock)	Yes (p<0.001)
Platelet count (Sepsis)	Yes (p=0.003)
Platelet count (Septic shock)	Yes (p=0.034)
Hemoglobin	No
CRP	No
Serum ferritin	No

Lower total leukocyte count and platelet count were significantly associated with mortality. Hemoglobin, CRP, and serum ferritin did not show statistically significant differences between survivors and non-survivors.

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Table 6. Summary of major findings

Finding	Result
Mortality	12%
MODS	12%
Septic shock	20%
Highest ferritin level	MODS (1716.67 ng/L)
Lowest ferritin level	Recovery (131.70 ng/L)
Highest CRP	MODS (191.33 mg/L)

Serum ferritin showed a progressive increase from uncomplicated sepsis to MODS and declined substantially during recovery, supporting its role as an indicator of disease severity.

Fifty children with sepsis were included in the study, with a mean age of 2.73±2.35 years and equal representation of both sexes. Fever was present in all children, followed by hurried breathing (54%), hepatomegaly (14%), convulsions (12%), and altered sensorium (12%). Six children (12%) died, while 44 (88%) recovered. Serum ferritin levels increased progressively with worsening disease severity, rising from 501.88 ng/L in sepsis to 620.00 ng/L in septic shock and 1716.67 ng/L in MODS, before declining to 131.70 ng/L during recovery. CRP demonstrated a similar trend, whereas hemoglobin levels decreased in severe disease. Children who died were younger and had significantly lower total leukocyte and platelet counts than survivors. Statistical analysis showed significant associations of leukocyte count and platelet count with mortality, whereas serum ferritin, hemoglobin, and CRP did not demonstrate statistically significant differences between survivors and non-survivors, although ferritin levels consistently increased with increasing severity of illness.

Discussion

The present prospective observational study evaluated the association between serum ferritin levels and disease severity in children with sepsis admitted to a pediatric intensive care unit.

The study population had a mean age of 2.73 years, and mortality was predominantly observed among younger children. This finding is consistent with previous reports demonstrating that infants and young children are particularly vulnerable to severe sepsis because of their immature immune system and limited physiological reserve. Equal representation of both sexes and the absence of sex-related differences in outcomes are also in agreement with earlier pediatric studies suggesting that sex has minimal influence on sepsis-related mortality in children.[7,8]

Fever was present in all patients, confirming its importance as the most common presenting feature of pediatric sepsis. Respiratory manifestations, particularly hurried breathing and bilateral crepitations, were frequently observed, whereas neurological manifestations such as convulsions and altered sensorium occurred less commonly. These findings emphasize that respiratory involvement is often an early clinical manifestation of pediatric sepsis, while neurological abnormalities may indicate more advanced disease. [9]

A major finding of this study was the progressive elevation of serum ferritin with worsening severity of illness. Mean ferritin concentrations increased from 501.88 ng/L in sepsis to 620.00 ng/L in septic shock and 1716.67 ng/L in MODS, followed by a substantial decline during recovery. Ferritin is a well-recognized acute-phase reactant released during systemic inflammation through activation of macrophages and cytokine-mediated pathways. Similar observations have been reported in previous studies, where hyperferritinemia was associated with severe inflammatory responses, septic shock, and organ dysfunction [9,10,11]. The marked reduction in ferritin during recovery observed in the present study further supports its usefulness as a marker of disease activity and response to treatment.

Despite its association with disease severity, serum ferritin did not demonstrate a statistically significant relationship with mortality. This finding suggests that although ferritin accurately reflects systemic inflammation, it should not be considered an independent predictor of survival. Mortality in pediatric sepsis is influenced by several factors including age, immune response, organ dysfunction, pathogen virulence, and timeliness of treatment. Therefore, serum ferritin is likely to provide greater clinical value when interpreted alongside established clinical severity scores and other laboratory parameters rather than as an isolated biomarker[12].

Among the hematological parameters evaluated, total leukocyte count emerged as a significant prognostic marker. Children who died had significantly lower leukocyte counts than survivors, particularly during sepsis and septic shock. Leukopenia may indicate immune exhaustion and impaired host defense against overwhelming infection, thereby contributing to poor clinical outcomes. Similarly, platelet counts were significantly reduced among non-survivors. Thrombocytopenia is a recognized manifestation of severe

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sepsis resulting from increased platelet consumption, disseminated intravascular coagulation, and bone marrow suppression. The significant association between thrombocytopenia and mortality observed in this study reinforces the importance of routine platelet monitoring in critically ill children.

Hemoglobin concentrations and C-reactive protein (CRP) levels did not differ significantly between survivors and non-survivors. Although CRP levels increased during severe disease and decreased during recovery, its inability to discriminate mortality suggests that CRP primarily reflects the inflammatory response rather than prognosis. Likewise, hemoglobin levels may be influenced by multiple factors including fluid resuscitation, anemia of inflammation, and blood transfusions, thereby limiting their predictive utility.[11,12]

Overall, the findings indicate that serum ferritin is a valuable biomarker for assessing disease severity and monitoring clinical recovery in pediatric sepsis. However, its prognostic utility for predicting mortality appears limited. Conversely, lower total leukocyte counts and platelet counts were significantly associated with adverse outcomes and may provide better prognostic information. Integrating serum ferritin with conventional hematological markers and clinical severity scoring systems may improve early risk stratification and facilitate timely therapeutic interventions in children with sepsis.

The study is limited by its relatively small sample size and single-center design, which may restrict the generalizability of the findings. Larger multicenter studies with serial biomarker assessment and long-term follow-up are required to further validate the prognostic role of serum ferritin and establish clinically useful cutoff values in pediatric sepsis.

Generalizability

The findings of the current research can be generalized for pediatric patients with sepsis who are admitted to the PICUs having the same clinical and laboratory infrastructure as that of the Ballari Medical College and Research Centre. However, the findings of this study are likely to lack generalizability on account of the fact that the present research is a one-site study which has been carried out on a very small number of participants through the use of non-probability purposive sampling. Different factors such as demographic characteristics of participants, severity of their conditions, availability of health care infrastructure, and clinical practices are likely to influence their serum ferritin levels and response to treatment.

Conclusion

The present study demonstrated that serum ferritin is a useful biomarker for assessing disease severity in pediatric sepsis, with levels increasing progressively from sepsis to septic shock and peaking in multiple organ dysfunction syndrome (MODS), followed by a marked decline during recovery. Although serum ferritin reflected the inflammatory burden and clinical course, it was not an independent predictor of mortality. Younger age was associated with poorer outcomes, while sex had no significant influence on disease severity or survival. Fever remained the most consistent clinical presentation, with respiratory and neurological manifestations serving as important indicators of severe illness. Among the hematological parameters evaluated, lower total leukocyte counts and platelet counts were significantly associated with mortality, highlighting their value as prognostic markers, whereas hemoglobin and C-reactive protein showed limited prognostic significance. Overall, these findings suggest that serum ferritin, when interpreted alongside total leukocyte count, platelet count, and clinical assessment, may improve early risk stratification, disease monitoring, and management of pediatric sepsis. Larger multicenter studies are warranted to validate these findings and establish the routine clinical utility of serum ferritin as a prognostic biomarker in children with sepsis.

Recommendation

Given the results of the present study, serum ferritin could be regarded as an adjunct biomarker for the evaluation of sepsis severity and prognosis in children in addition to clinical evaluation and routine laboratory tests. Ferritin levels can offer some more insights into the disease process and recovery. However, ferritin alone cannot be used as a diagnostic or prognostic tool until proven by multicenter studies.

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Conflict of Interest

The authors confirm that there is no conflict of interest in relation to this study.

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Author Contributions

Author 1: Conceptualization, study design, participant recruitment, data collection, data analysis, findings interpretation, and writing of the manuscript.
Author 2: Study supervision, methodology, clinical examination, findings interpretation, and manuscript revision.
Author 3: Laboratory investigation, data collection, findings interpretation, and manuscript revision.

Availability of Data and Materials

The data used to support the findings of this study are not publicly available due to privacy concerns, as they contain participants' details. De-identified data can be accessed from the corresponding author upon reasonable request.

List of Abbreviations

PICU Paediatric Intensive Care Unit
MODS Multiple Organ Dysfunction Syndrome
PT Prothrombin Time
aPTT Activated Partial Thromboplastin Time
INR International Normalised Ratio
D-dimer D-dimer
ICMR Indian Council of Medical Research
SD Standard Deviation
IEC Institutional Ethics Committee
CI Confidence Interval

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