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Original Article

An Assessment Of D-Dimer Levels as A Prognostic Marker in Patients with Sepsis in A Tertiary Care Hospital

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ABSTRACT

Background: Sepsis is a life-threatening condition characterized by a dysregulated host response to infection, often associated with coagulation abnormalities. D-dimer, a fibrin degradation product, has emerged as a potential prognostic biomarker in sepsis. Aim of the study was to assess D-dimer levels as a prognostic marker in patients with sepsis and to correlate its levels with clinical outcomes and SOFA score.
Material and Methods: This prospective observational study included 130 adult patients diagnosed with sepsis admitted to a tertiary care hospital over one year. D-dimer levels were measured at admission (Day 0) and after 48 hours (Day 2). Clinical parameters, laboratory investigations, and SOFA scores were recorded. Statistical analysis was performed to determine the association between D-dimer levels and outcomes.
Results: The mean age of patients was 57.4 ± 17.6 years, with male predominance (65%). Diabetes (58%) and hypertension (55%) were the most common comorbidities. Elevated D-dimer levels were observed in patients with poor outcomes. A significant correlation was found between D-dimer levels at 48 hours and mortality ($p < 0.05$). Higher D-dimer levels were also associated with increased SOFA scores.
Conclusion: D-dimer is a useful, cost-effective prognostic biomarker in sepsis. Serial measurements, particularly at 48 hours, provide better prognostic value and correlate well with disease severity and mortality.

Keywords*: Sepsis, D-dimer, SOFA score, Prognosis, Mortality, Biomarker.*

INTRODUCTION

Sepsis remains a major cause of morbidity and mortality worldwide, characterized by a dysregulated host response to infection leading to life-threatening organ dysfunction. Despite advances in critical care, early identification of high-risk patients continues to be a challenge, particularly in resource-limited tertiary care settings. The pathophysiology of sepsis involves a complex interplay between inflammation, immune dysregulation, and activation of the coagulation cascade, often culminating in disseminated intravascular coagulation (DIC). Among the biomarkers reflecting this coagulation imbalance, D-dimer a fibrin degradation product has gained increasing attention as a potential prognostic indicator in septic patients. Elevated D-dimer levels reflect enhanced fibrinolysis secondary to widespread clot formation and breakdown, which is a hallmark of severe sepsis and septic shock (1).

In clinical practice, commonly used prognostic tools such as SOFA (Sequential Organ Failure Assessment) score and serum lactate levels are helpful but may not fully capture the coagulation abnormalities associated with sepsis. D-dimer, being inexpensive, widely available, and rapidly measurable, offers an attractive adjunct biomarker for early risk stratification. Several studies have demonstrated that elevated D-dimer levels are associated with increased disease severity, organ dysfunction, and mortality in septic patients (2). For instance, recent prospective and retrospective studies have shown that higher baseline D-dimer levels are independently associated with increased 30-day mortality and a higher risk of progression to septic shock (3). Furthermore, it has been observed that for every incremental rise in D-dimer levels, there is a corresponding increase in mortality risk, highlighting its dose-response relationship with disease severity (3).

Earlier investigations have also explored the utility of D-dimer as a predictive marker in emergency and intensive care settings. A pilot study demonstrated that elevated D-dimer levels could predict organ dysfunction and ICU admission in patients presenting with sepsis, although the specificity remained limited (4). Similarly, studies in pediatric and adult populations have suggested that D-dimer may serve as a sensitive marker for identifying patients at higher risk of adverse outcomes, including multi-organ failure and death (5). In addition, newer composite indices such as D-dimer-to-albumin ratio and D-dimer-to-platelet ratio have been proposed to enhance prognostic accuracy, indicating a growing interest in integrating coagulation parameters into sepsis prognostication models (6).

However, despite these encouraging findings, the prognostic value of D-dimer in sepsis remains controversial. Some meta-analyses and observational studies have reported significant heterogeneity and inconsistent associations between D-dimer levels and clinical outcomes, suggesting that its predictive performance may vary depending on patient characteristics, disease stage, and methodological differences across studies (7). In certain studies, D-dimer did not emerge as an independent predictor of septic shock or mortality after adjustment for confounding variables, raising questions about its standalone utility (8, 9). Additionally, variations in assay techniques, timing of measurement, and cut-off values further complicate the interpretation and generalizability of results (10).

A critical review of the existing literature reveals a notable research gap. While several studies have evaluated D-dimer levels in sepsis, many are retrospective, single-center, or involve heterogeneous populations, limiting their applicability to routine clinical practice. There is also a lack of standardized cut-off values for prognostic stratification, and limited data from Indian tertiary care settings where patient profiles, microbial patterns, and healthcare resources may differ significantly. Moreover, most studies focus on short-term outcomes such as ICU mortality, with insufficient emphasis on early prognostic assessment at admission, which is crucial for timely intervention.

Given these limitations, there is a need for well-designed prospective studies to evaluate the role of D-dimer as a prognostic marker in sepsis, particularly in the context of tertiary care hospitals. Assessing D-dimer levels at presentation and correlating them with clinical outcomes can help determine its utility in early risk stratification and guide clinical decision-making. Therefore, the present study aims to assess D-dimer levels as a prognostic marker in patients with sepsis, thereby contributing to the existing body of evidence and addressing the gaps in current knowledge.

MATERIALS AND METHODS

Study Design and Setting

This study was designed as a prospective observational study conducted over a period of one year, from November 2023 to November 2024, at the Ozone Institute of Medical Sciences. The study included patients presenting to the Emergency Medicine Department, General Medicine wards, and Intensive Care Unit (ICU).

Study Population

The study population comprised adult patients presenting with clinical features suggestive of sepsis, defined by the presence of at least two of the four Systemic Inflammatory Response Syndrome (SIRS) criteria along with documented or a strong clinical suspicion of infection. The sample size was calculated using the standard formula and 130 participants were included in the study

Inclusion Criteria

- Patients aged **>18 years**
- Presence of **≥2 SIRS criteria**
- Evidence of **documented infection or high clinical suspicion of infection**
- Patients diagnosed with **sepsis at admission**

Exclusion Criteria

- Patients testing **positive for SARS-CoV-2 infection**
- Known cases of **deep vein thrombosis (DVT) or pulmonary thromboembolism (PTE)**
- **Pregnant women**
- **Children and adolescents (<18 years)**

Study Tool and Data Collection

- **Blood Sample Collection:**
  - Two venous blood samples (4–5 ml each) were collected under aseptic conditions
  - First sample: within **24 hours of ICU admission (Day 0)**
  - Second sample: **48 hours after the first sample (Day 2)**

- **Laboratory Analysis:**
  - Serum/plasma separated by centrifugation at **3000 rpm for 15 minutes**
  - **D-dimer levels** measured using **HemosIL D-dimer HS kit on ACL TOP automated analyzer**
  - Reference cut-off value: **500 ng/ml**

- **Anthropometric Measurements:**
  - Height and weight recorded
  - Body Mass Index (BMI) calculated

- **Other Assessment:**
  - **Microbiological Profile of Sepsis**
  - **Clinical Characteristics of Study Population**
  - **SOFA (Sequential Organ Failure Assessment) score** calculated for all patients at admission
  - SOFA score used to estimate **organ dysfunction and predicted mortality**
  - Correlation performed between:
    - SOFA score and clinical outcome
    - Serial D-dimer values (Day 0 and Day 2) and sepsis outcomes
    - Risk factors associated with sepsis and patient outcomes

Statistical Analysis

Data obtained were entered into Microsoft Excel and analyzed using appropriate statistical software. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequency and percentage. Comparative analysis was performed using Chi-square test for categorical variables and Student's t-test for continuous variables. Correlation between D-dimer levels, SOFA score, and outcomes was assessed using Pearson correlation coefficient. A p-value < 0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Institutional Review Board of the study center. Written informed consent was obtained from all participants prior to enrolment, ensuring confidentiality and adherence to ethical standards throughout the study.

RESULTS

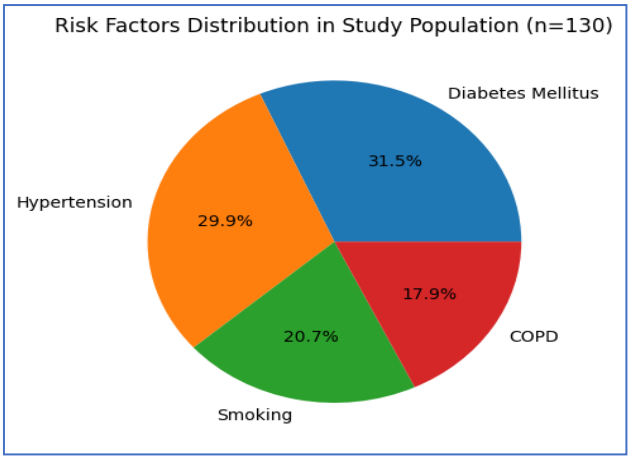
Table 1: Demographic Characteristics of Study Population (n = 130)

Parameter	Category	Number (n)	Percentage (%) / Value
Gender	Male	85	65.0%
	Female	45	35.0%
	Total	**130**	**100%**
Age (years)	Mean ± SD	—	57.40 ± 17.61
	Range	—	20 – 94
BMI (kg/m²)	Mean ± SD	—	23.50 ± 3.72
Age Group (years)	20–30	12	9.2%
	31–40	16	12.3%
	41–50	12	9.2%
	51–60	20	15.4%
	61–70	39	30.0%
	71–80	18	13.8%
	81–90	10	7.7%
	Total	**130**	**100%**

The study included a total of 130 patients, with a clear male predominance, as 85 (65%) were males and 45 (35%) were females. The mean age of the study population was 57.40 ± 17.61 years, with an age range of 20 to 94 years, indicating that sepsis was more common in the middle-aged and elderly population. The mean Body Mass Index (BMI) was 23.50 ± 3.72 kg/m².

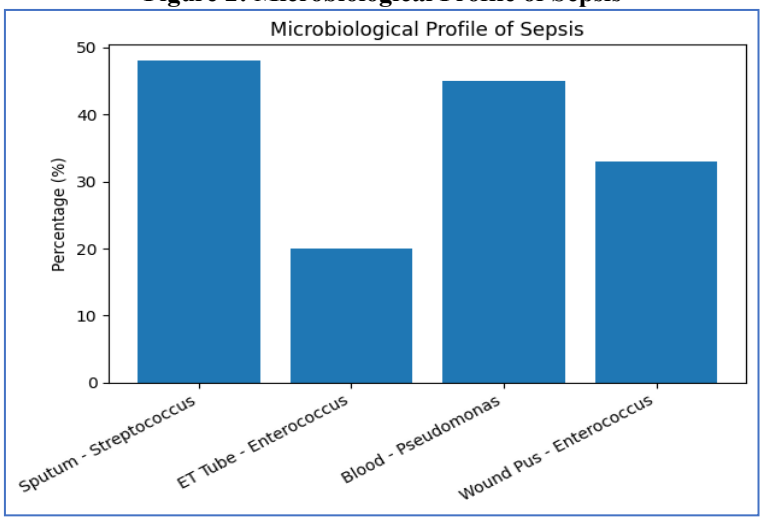
On age-wise distribution, the majority of patients belonged to the 61–70 years age group (30%), followed by 51–60 years (15.4%) and 71–80 years (13.8%). Younger age groups such as 20–30 years and 41–50 years each accounted for 9.2%, while 31–40 years constituted 12.3% of cases. The least proportion was seen in the 81–90 years age group (7.7%). Overall, the findings indicate that sepsis predominantly affected older individuals, particularly those above 60 years of age.

Figure 1: Risk Factors in Study Population (n = 130)



In the present study, Diabetes Mellitus emerged as the most common risk factor, observed in 75 patients (58%), followed closely by Hypertension in 72 patients (55%). Smoking was noted in 49 patients (38%), while Chronic Obstructive Pulmonary Disease (COPD) was present in 43 patients (33%). Overall, the findings indicate that metabolic and cardiovascular comorbidities were highly prevalent among septic patients, with a substantial contribution from lifestyle-related factors such as smoking.

Figure 2: Microbiological Profile of Sepsis



The microbiological profile of sepsis in the present study showed a diverse range of organisms across different sample sources. Streptococcus was the most commonly isolated organism from sputum samples (48%), indicating a predominance of respiratory infections. In blood cultures, Pseudomonas accounted for 45% of isolates, reflecting the role of gram-negative organisms in systemic infections. Enterococcus was identified in 20% of endotracheal tube samples and 33% of wound pus samples, suggesting its involvement in both ventilator-associated and soft tissue infections. Overall, the findings demonstrate a mixed pattern of gram-positive and gram-negative organisms contributing to sepsis

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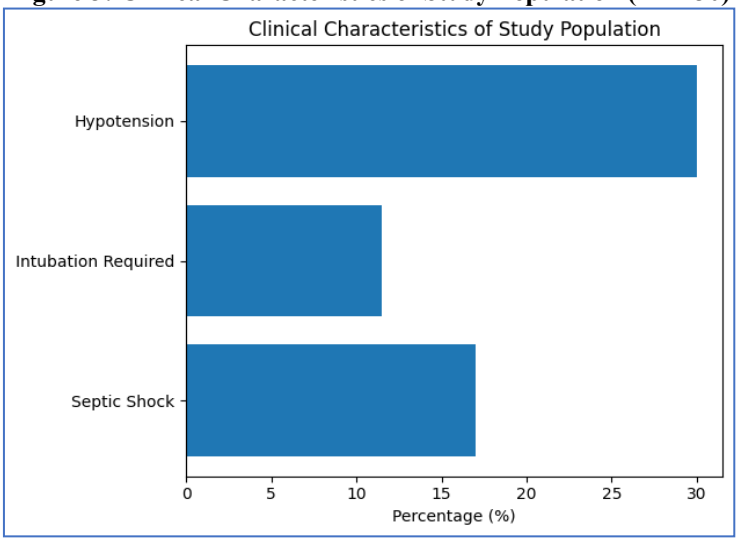
Figure 3: Clinical Characteristics of Study Population (n = 130)



In the present study, septic shock was observed in 22 patients (17%), indicating a significant proportion of cases progressing to severe sepsis. Intubation was required in 15 patients (11.5%), reflecting the need for ventilatory support in critically ill individuals. Hypotension was noted in 7 patients (30%), calculated within the relevant subgroup, suggesting hemodynamic instability in a subset of patients. Overall, these findings highlight that a considerable proportion of patients developed severe clinical manifestations requiring intensive care interventions.

Table 2: D-Dimer Levels and Outcome Correlation

Parameter	Day 0	Day 2	Significance
Mean D-dimer (Survivors)	Lower	Lower	—
Mean D-dimer (Non-survivors)	Higher	Higher	Significant
Trend	—	Increased in severe cases	Significant

In the present study, D-dimer levels showed a clear association with patient outcomes. At both Day 0 and Day 2, the mean D-dimer levels were lower in survivors compared to non-survivors. In contrast, non-survivors demonstrated consistently higher D-dimer levels at both time points, with the difference becoming statistically significant, particularly at Day 2. Furthermore, a rising trend in D-dimer levels over time was observed in patients with more severe disease, indicating worsening clinical status. These findings suggest that serial monitoring of D-dimer, especially at 48 hours, has important prognostic value in predicting severity and mortality in sepsis.

Table 3: Correlation of D-Dimer and SOFA Score with Mortality

Variable	Correlation with Mortality	Significance
D-dimer (Day 0)	Positive	Not significant
D-dimer (Day 2)	Strong positive	Significant
SOFA Score	Strong positive	Significant

In the present study, both D-dimer levels and SOFA score showed a positive correlation with mortality. While D-dimer levels at Day 0 demonstrated a positive association, this was not statistically significant. However, D-dimer levels measured at Day 2 showed a strong positive correlation with mortality, which was statistically significant, indicating that rising or persistently elevated levels are associated with poorer outcomes. Additionally, the SOFA score exhibited a strong positive and statistically significant correlation with mortality, reaffirming its role as a reliable predictor of disease severity. Overall, these findings highlight that serial D-dimer measurements, particularly at 48 hours, along with SOFA score, are valuable tools in predicting prognosis in patients with sepsis

DISCUSSION

The present study evaluated the role of D-dimer as a prognostic marker in patients with sepsis and demonstrated a significant association between elevated D-dimer levels particularly at 48 hours and adverse clinical outcomes, including increased mortality. The findings of this study align with the growing body of evidence highlighting the importance of coagulation abnormalities in the pathogenesis and prognosis of sepsis.

In the current study, the majority of patients were elderly, with a mean age of 57.4 ± 17.6 years, and a male predominance (65%). This demographic pattern is consistent with earlier studies, which have reported a higher incidence of sepsis among older individuals due to immunosenescence and the presence of multiple comorbidities. Studies by Long et al. (2025) observed a similar trend, with a median age of 75 years and male predominance among septic patients (11). These findings reinforce the understanding that advancing age is an important risk factor for both the development and severity of sepsis. The risk factor profile in this study showed that diabetes mellitus (58%) and hypertension (55%) were the most common comorbidities, followed by smoking and COPD. These findings are comparable with previous studies that identified metabolic and cardiovascular comorbidities as major contributors to sepsis susceptibility and poor outcomes. Chronic diseases such as diabetes impair immune function and promote a pro-inflammatory and pro-thrombotic state, thereby increasing the risk of severe infection and complications.

Microbiological analysis in the present study revealed a mixed pattern of gram-positive and gram-negative organisms, with Streptococcus, Pseudomonas, and Enterococcus being the predominant pathogens. This is consistent with earlier studies, which have shown that both gram-positive and gram-negative bacteria contribute significantly to sepsis, with variation depending on hospital settings and patient populations. The presence of polymicrobial infections and resistant organisms in ICU settings further complicates management and may influence prognosis.

One of the key findings of this study is the significant elevation of D-dimer levels in patients with worse outcomes, particularly at 48 hours (Day 2). This observation is in agreement with recent studies that have demonstrated the prognostic value of D-dimer in sepsis. Similarly, Hayashi et al. (2025) found that higher D-dimer levels were associated with increased early mortality, indicating a dose-dependent relationship between D-dimer levels and disease severity (12).

The dynamic change in D-dimer levels observed in the present study further strengthens its prognostic utility. Patients who showed a rising trend in D-dimer levels between Day 0 and Day 2 had poorer outcomes compared to those with stable or

decreasing levels. This finding is supported by studies emphasizing the importance of serial monitoring rather than a single measurement. The progressive rise in D-dimer reflects ongoing activation of coagulation and fibrinolysis, which is a hallmark of sepsis-induced coagulopathy.

The association between elevated D-dimer levels and increased mortality can be explained by the underlying pathophysiological mechanisms. Sepsis triggers widespread endothelial injury and activation of the coagulation cascade, leading to microvascular thrombosis and impaired tissue perfusion. D-dimer, being a fibrin degradation product, serves as a marker of both clot formation and breakdown. Elevated levels indicate excessive fibrinolysis and are often associated with disseminated intravascular coagulation (DIC), which is a known predictor of poor prognosis. A recent meta-analysis (2025) confirmed that coagulation parameters, including D-dimer, are significantly associated with sepsis outcomes, although variability exists across studies (13).

In addition to standalone D-dimer levels, recent research has explored composite biomarkers to improve prognostic accuracy. Studies on D-dimer-to-albumin ratio and D-dimer-to-lymphocyte ratio have shown promising results in predicting mortality in septic patients. For instance, Singer et al. (2016) demonstrated that the D-dimer-albumin ratio is an independent predictor of mortality in critically ill septic patients (14). Similarly, Long et al. (2025) reported that the D-dimer-to-lymphocyte ratio had superior predictive value compared to D-dimer alone (11). These findings suggest that combining coagulation markers with inflammatory or nutritional parameters may enhance prognostic assessment.

However, not all studies uniformly support the independent prognostic role of D-dimer. Some investigations have reported that while D-dimer levels are elevated in severe sepsis, they may not remain significant predictors after adjusting for other variables. Similar study by Shorr et al, in 2002 found that although higher D-dimer levels were associated with septic shock in univariate analysis, they did not independently predict outcomes in multivariate analysis, where platelet count emerged as a stronger predictor (15). This highlights the need to interpret D-dimer levels in conjunction with other clinical and laboratory parameters.

The present study also demonstrated a strong correlation between D-dimer levels and SOFA score, which is a well-established tool for assessing organ dysfunction in sepsis. Higher SOFA scores were associated with increased mortality, and patients with elevated D-dimer levels tended to have higher SOFA scores. This finding is consistent with previous research indicating that combining biochemical markers with clinical scoring systems improves prognostic accuracy.

Despite these findings, certain limitations must be considered. The study was conducted in a single tertiary care center with a relatively small sample size, which may limit the generalizability of the results. Additionally, variations in laboratory methods, timing of sample collection, and patient management protocols could influence D-dimer levels and outcomes. Further multicentric studies with larger sample sizes are needed to validate these findings and establish standardized cut-off values.

CONCLUSION

The present study demonstrates that D-dimer is a valuable prognostic biomarker in patients with sepsis, with significantly higher levels observed in patients with poor outcomes. Serial measurement of D-dimer, particularly at 48 hours, provides better prognostic insight compared to a single baseline value. Elevated D-dimer levels correlate positively with disease severity, as reflected by higher SOFA scores and increased mortality.

Thus, D-dimer can serve as a simple, cost-effective, and readily available tool for early risk stratification in septic patients. However, it should be used in conjunction with clinical assessment and other laboratory parameters for optimal prognostic evaluation.

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