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Original Research Article

THE ROLE OF ALBUMIN AND LIPID PROFILE AS BIOMARKERS FOR PREDICTING MORTALITY IN SEPSIS PATIENTS IN INTENSIVE CARE UNIT

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ABSTRACT

Background: Worldwide, sepsis continues to be one of the main reasons for intensive care unit (ICU) admissions and deaths, especially in low- and middle-income countries. There is an urgent need to quickly discover new, reliable and accessible biomarkers to improve patient care by enabling risk stratification. Researchers are now identifying serum albumin and lipid profile parameters as potential prognostic indicators in sepsis. The aim and objective is to assess the ability of serum albumin and lipid profile parameters in predicting death in sepsis patients admitted to an ICU, compared with two well-known severity scores (APACHE II & SOFA).

Materials and Methods: This study was performed in the course of twelve months in a tertiary hospital with patients who are were admitted to the intensive care level and have sepsis. The total population of patients included 150 and data collection included: demographic information, comorbid conditions, and number of clinical measurements performed on each patient. The APACHE II and the SOFA score were utilized as a way to measure the severity of the patient's illness. Serum albumin and lipid profile (total cholesterol, HDL-C, LDL-C and triglycerides) were obtained at the time of admission and through successive measurements every 24 hours for three days following admission. All patients were categorized as either survivors or non-survivors and subsequent analyses were performed on these two groups.

Results: Older adults (>70 years), people with diabetes mellitus, and those with chronic liver disease displayed considerably higher rates of mortality than younger individuals without diabetes or chronic liver disease. The authors found that non-survivors had considerably higher APACHE II (26.02 ± 5.62 vs 19.20 ± 5.59) and SOFA scores (11.93 ± 3.69 vs 7.34 ± 2.47; $p < 0.001$) than survivors. Serum albumin concentrations were consistently lower in non-survivors than survivors during their ICU stays. In addition total cholesterol, HDL-C, and LDL-C were significantly lower in non-survivors than in survivors at all study time points, while triglyceride levels had no appreciable relation to mortality.

Conclusion: The presence of low serum albumin levels and decreased levels of total cholesterol, high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) levels in individuals with sepsis have been shown to substantially improve prognostic accuracy through the use of previously established severity scores. These markers have also been suggested to be of significant utility in clinical decision making by giving the physician an accurate assessment of the patient's prognosis in a cost-efficient manner.

Keywords: Sepsis, ICU, Mortality, Albumin, Lipid Profile, HDL, LDL, Biomarkers, APACHE II, SOFA.

INTRODUCTION

Sepsis is a potentially fatal clinical syndrome characterized by an excessive inflammatory response by the host and resultant dysfunction of multiple organ systems, which contributes to a very high mortality rate associated with sepsis, particularly among patients who are admitted to the intensive care unit (ICU).[1] Despite advances in antimicrobials, organ support and critical care/nursing practice, sepsis continues to result in a significant global health burden, but not limited to, through significant levels of morbidity as well as mortality and the consumption of considerable health care resources.[2] Identifying patients who are at highest risk for adverse outcomes early in the management of sepsis remains very difficult. Traditional diagnostic laboratory tests and severity scoring systems such as the Acute Physiology and Chronic Health Evaluation II (APACHE II) and Sequential Organ Failure Assessment (SOFA) include many of the same physiological derangement; therefore, it is unlikely they are capturing all of the underlying biochemical and metabolic derangements that are involved with the progression of sepsis.[3]

In response to these difficulties, recent focus has been directed towards identification of simple, reliable, cost-effective biomarkers for early risk stratification and predicting outcomes. Among the most promising biomarkers for this application are those derived from serum albumin and lipid profile.[4] Albumin is the most abundant plasma protein produced in the liver and is responsible for maintaining oncotic pressure in plasma and for transportation of different chemical constituents dissolved in plasma, while also having an important role in modulating the inflammatory response and providing antioxidant defense.[5] In patients with sepsis, hypoalbuminemia is very common as a result of decreased albumin synthesis, increased albumin catabolism, capillary leakage of albumin and dilutional effects from fluid resuscitation. As a result, cumulative studies, confirm that hypoalbuminemia is associated with increased severity and poor clinical outcomes in patients with sepsis.[6]

The pathophysiology of patients with sepsis is also associated with major alterations in lipid metabolism. During the acute phase of sepsis, the level of total cholesterol (TC), high density lipoprotein (HDL), and low-density lipoprotein (LDL) are significantly decreased. These lipoproteins have demonstrated anti-inflammatory and endotoxin-neutralizing properties; therefore, the decrease observed in the acute phase of sepsis may contribute to the exaggerated inflammatory response associated with sepsis and subsequently worsen prognosis. The prognostic significance of triglycerides during sepsis varies, but remains poorly defined.[7]

Serum albumin and lipid profile biomarkers are easily and inexpensively measured in laboratory tests that are routinely performed; therefore, they take on increased value in resource-limited settings. When used in conjunction with traditional severity scoring systems, serum albumin and lipid profile biomarkers may further improve the accuracy of predicting patient prognosis and contribute to earlier clinical decision-making.[8]

The purpose of this study is to evaluate the utility of serum albumin and lipid profile biomarkers in predicting mortality in patients with sepsis who are admitted to the ICU, and to determine the added prognostic value of these biomarkers when used in conjunction with conventional severity scores.

MATERIALS AND METHODS

Study Design and Setting: This prospective cohort research conducted over a 12-month time frame on the basis of an Intensive Care Unit (ICU) at Government Omandurar Medical College and Hospital in Chennai was approved by the Institutional Ethics Committee. All participants gave their informed consent for participation in this study or their legally authorized representatives.

Patients and Methods: This cohort study was conducted on 150 adults in the intensive care unit with a diagnosis of sepsis who met the definition of sepsis as set forth by the clinical standards of infection and organ dysfunction. Various demographic data, comorbidities (diabetes mellitus and chronic liver disease), and relevant clinical parameters were recorded upon the patient's arrival for treatment. Disease severity was determined by the use of the APACHE II scoring system and the SOFA scoring system.

Laboratory tests performed included serum albumin and lipid panel: total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and triglycerides. Each of these was measured at entry into the hospital (day 0) and then re-measured every 24 hours for 72 hours or until the patient was discharged from the ICU.

The hospital stay for each of the 150 patients was monitored for either survival or death and all biochemical laboratory results were compared for patients who expired versus those who survived based on severity of illness as defined by their APACHE II and SOFA scores.

Inclusion Criteria

- Adult patients aged ≥18 years
- Patients diagnosed with sepsis and admitted to ICU
- Patients who provided informed consent (patient or attendant)

Exclusion Criteria

- Patients with pre-existing severe liver disease affecting albumin levels
- Patients with known lipid metabolism disorders
- Patients on lipid-lowering therapy (e.g., statins)
- Patients with chronic inflammatory or immunosuppressive conditions

- Patients who were lost to follow-up or discharged against medical advice

Sample Size Calculation: The sample size was calculated based on the expected difference in biomarker levels between survivors and non-survivors among sepsis patients, with a confidence level of 95% and power of 80%.

The sample size was determined using the formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Where:

n= required sample size

Z= standard normal variate at 95% confidence interval (1.96)

p= expected proportion (taken as 0.5 for maximum sample size)

q=1-p

d= allowable error (0.08)

$$n = \frac{(1.96)^2 \times 0.5 \times 0.5}{(0.08)^2}$$

$$n = \frac{3.84 \times 0.25}{0.0064} = 150$$

Thus, the calculated sample size was 150 patients, which were included in the study.

Randomization and Blinding: This study was a prospective observational cohort study; hence, no randomization was performed. Patients were enrolled consecutively based on predefined inclusion and exclusion criteria. However, for the purpose of analysis, patients were categorized based on clinical outcomes into two groups.

- Group I (Survivors): Patients with sepsis who improved clinically and were discharged from the ICU.
- Group II (Non-survivors): Patients with sepsis who succumbed during the ICU stay.

Blinding was maintained during data analysis, and the investigators analyzing laboratory parameters were not influenced by patient outcome status.

Procedure: All qualified patients who met inclusion criteria were recruited during their initial admission to the ICU. A total of 150 subjects participated in this investigation; there were systematic evaluations of all patients included in this study and a record of baseline demographic characteristics, comorbidities, and clinical parameters at the time of admission (day 0). The severity of an individual's illness was defined according to the APACHE II and SOFA scores.

Blood samples for the purpose of measuring serum and serum fat esters (total TC, HDL-C, LDL-C, triglycerides) were taken from all participants at four intervals (0 hours [time of admission], 24 hours, 48 hours, and 72 hours). The blood tests were performed in a standardized manner per laboratory protocol. Patients in this study were provided medical care according to their institution's ICU protocol and monitored continuously during the duration of their hospitalization.

Based on clinical outcome, patients were classified as alive or deceased; serial laboratory data were analyzed and compared between the two groups to determine the prognostic significance of the results.

Observations and Parameters Recorded:

- Age distribution
- Sex distribution
- Presence of comorbidities (Diabetes Mellitus, Chronic Liver Disease)
- Site of sepsis
- Source of infection
- Severity scores (APACHE II, SOFA)
- Serum albumin levels at 0, 24, 48, and 72 hours
- Lipid profile parameters (Total Cholesterol, HDL-C, LDL-C, Triglycerides)
- Clinical outcome (Survivor / Non-survivor)

Statistical Analysis: Appropriate statistical techniques were utilized in order to compile and analyze the data. Continuous variables (i.e., those measured on a continuous scale) were expressed in the format of mean ± standard deviation (SD), while categorical variables (i.e., those measured as yes/no variables) were presented as frequency and percentage by group. Comparison between the groups was conducted according to the appropriate test for either a quantitative variable or a qualitative variable. A p-value < 0.05 was deemed statistically significant.

RESULTS

This study included 150 patients admitted with sepsis to ICU; the majority were older and had higher mortality if ≥70 years. Males predominated in the patient population. Diabetes mellitus and chronic liver disease were associated with higher mortality in patients with sepsis.

Of the infection types, the two most frequent causes of death in patients with sepsis were bloodstream infections and primary septicemia. The analysis of severity demonstrated that non-survivors had a higher APACHE II score (26.02 ± 5.62) and SOFA score (11.93 ± 3.69) than survivors (19.20 ± 5.59 and 7.34 ± 2.47; $p < 0.001$).

Biochemical analyses performed serially on serum from patients demonstrated that serum albumin levels were lower for non-survivors at every sampling point (0, 24, 48, and 72 hours). In addition, total cholesterol, HDL-C, and LDL-C levels were lower among non-survivors, which corresponds to an increased incidence of a poor outcome; however, triglycerides showed no statistically significant difference in mortality.

Both hypoalbuminemia & hypolipidemia are associated with higher incidence & severity of illness & mortality in individuals experiencing sepsis.

Table 1: Demographic Distribution

Parameter	Category	Survivors n (%)	Non-survivors n (%)
Age	<30 yrs	4 (3.8%)	0 (0.0%)
	31–50 yrs	37 (34.9%)	12 (27.3%)
	51–70 yrs	57 (53.8%)	21 (47.7%)
	>70 yrs	8 (7.5%)	11 (25.0%)
Sex	Female	37 (34.9%)	16 (36.4%)
	Male	69 (65.1%)	28 (63.6%)

[Table 1] shows the distribution of patients according to age and sex, demonstrating higher mortality among elderly patients (>70 years) with a predominance of male patients.

Table 2: Comorbidities

Comorbidity	Survivors n (%)	Non-survivors n (%)
Diabetes Mellitus (Yes)	58 (54.7%)	35 (79.5%)
Diabetes Mellitus (No)	48 (45.3%)	9 (20.5%)
Chronic Liver Disease (Yes)	13 (12.3%)	10 (22.7%)
Chronic Liver Disease (No)	93 (87.7%)	34 (77.3%)

[Table 2] shows the distribution of comorbidities, demonstrating a higher prevalence of diabetes mellitus and chronic liver disease among non-survivors.

Table 3: Sepsis Characteristics

Site	Survivors n (%)	Non-survivors n (%)
None	2 (1.9%)	1 (2.3%)
Bloodstream	3 (2.8%)	9 (20.5%)
CNS	3 (2.8%)	2 (4.5%)
Intra-abdominal	2 (1.9%)	2 (4.5%)
Respiratory	44 (41.5%)	13 (29.5%)
Skin/Soft tissue	28 (26.4%)	8 (18.2%)
Urinary	24 (22.6%)	9 (20.5%)

[Table 3] shows the distribution of site of sepsis, demonstrating that bloodstream infections were more common among non-survivors, while respiratory infections were predominant among survivors.

Table 4: Severity Scores

Parameter	Survivors (Mean ± SD)	Non-survivors (Mean ± SD)	p-value
APACHE II	19.196 ± 5.591	26.020 ± 5.617	<0.001
SOFA	7.343 ± 2.470	11.932 ± 3.686	<0.001

[Table 4] shows the comparison of severity scores, demonstrating significantly higher APACHE II and SOFA scores among non-survivors.

Table 5: Serum Albumin Dynamics

Time	Survivors (Mean ± SD)	Non-survivors (Mean ± SD)	p-value
Baseline	2.8495 ± 0.5067	2.4955 ± 0.4730	<0.001
24 hrs	2.9445 ± 0.4987	2.4980 ± 0.4627	<0.001
48 hrs	3.0360 ± 0.4965	2.4536 ± 0.4794	<0.001
72 hrs	3.1417 ± 0.4986	2.4516 ± 0.4676	<0.001

[Table 5] shows the serial changes in serum albumin levels, demonstrating consistently lower levels among non-survivors at all time points.

Table 6: Lipid Profile Parameters

A. Total Cholesterol Trends			
Time	**Survivors (Mean ± SD)**	**Non-survivors (Mean ± SD)**	**p-value**
Baseline	126.159 ± 31.141	100.475 ± 30.645	<0.001
24 hrs	131.768 ± 30.814	98.798 ± 31.508	<0.001
48 hrs	132.893 ± 31.014	97.084 ± 30.733	<0.001
72 hrs	136.097 ± 31.800	95.389 ± 29.449	<0.001
B. Baseline Lipid Profile			
Parameter	**Survivors (Mean ± SD)**	**Non-survivors (Mean ± SD)**	**p-value**
HDL-C	32.959 ± 8.089	25.025 ± 7.856	<0.001
LDL-C	65.270 ± 21.762	52.927 ± 23.458	0.002
Triglycerides	132.903 ± 53.116	139.077 ± 51.810	0.515 (NS)

[Table 6] shows the lipid profile parameters, demonstrating significantly lower total cholesterol, HDL-C, and LDL-C levels among non-survivors, while triglycerides did not show a significant association with mortality.

As shown in [Table 1], patient demographics (age and sex) illustrate that there were more deaths in the elderly (>70 years) than in younger patients. Additionally, the majority of the population in this study were men. In [Table 2], patients were noted to have a variety of comorbidities; however, diabetes mellitus and chronic liver disease were more commonly seen in the patients that died than in the survivors. [Table 3] shows the type of sepsis in the patients and that bloodstream infection was more often seen in the patients that died than respiratory infection was seen in survivors. [Table 4] compares severity scores (APACHE II and SOFA) and shows that non-survivors have higher values. [Table 5] shows changes over time for serum albumin levels. The patients who died continued to have lower serum albumin values than the patients who survived at each time interval assessed. [Table 6] shows lipid profile parameters and shows lower levels for total cholesterol, HDL-C, and LDL-C in non-survivors than in survivors. No statistically significant association between triglyceride levels and mortality was found.

DISCUSSION

One of the principal causes of mortality and disability in an ICU is sepsis, therefore, reliable cost-effective and accessible biomarkers must be identified to provide clinicians with prognostic information regarding the clinical outcome of a patient at an earlier stage of disease severity. This study evaluated the use of serum albumin and lipid profile parameters as prognostic indicators related to the mortality rates of sepsis patients and identified statistically significant relationships between each of the biochemical markers and the mortality rates of sepsis patients.[9]

This study demonstrated that the advanced age (>70 years) of a sepsis patient increases their mortality risk, which is consistent with previous studies. Elderly sepsis patients have a decreased physiological reserve and immune response, and as a result, tend to have poorer clinical outcomes than younger sepsis patients. Many of the patients in this study who died had also been diagnosed with diabetes mellitus and chronic liver disease, indicating a relationship between the patients' comorbidities and their immune dysfunction and the severity of disease in sepsis patients.[10]

The APACHE II and SOFA scoring systems were validated in this study to be predictive of mortality in patients with sepsis, as both APACHE II [26.02±5.62 versus 19.20±5.59; $p<0.001$] and SOFA [11.93±3.69 versus 7.34±2.47; $p<0.001$] scores were significantly higher among patients that died compared to patients that survived. However, these scoring systems do not evaluate the underlying metabolic and inflammatory derangements/injuries that are present in sepsis patients; thus, they will not provide a total assessment of illness severity for sepsis.[11]

The most important finding of this study was the consistent relationship between low serum albumin levels and the mortality rates of patients with sepsis. There are multiple mechanisms whereby sepsis patients can develop hypoalbuminemia, including decreased hepatic production of albumin, increased proteolysis, increased capillary permeability and dilution of albumin resulting from fluid resuscitation.[12] In addition to being an indicator of nutritional status, albumin also maintains oncotic pressure, binds to both endogenous and exogenous substances, and has both antioxidant and anti-inflammatory properties in the human body. Therefore, low serum albumin levels likely increase disease severity and contribute to poor outcomes.[13]

In the present study, sepsis patients exhibited significant changes in their lipid profiles at the time of death, as patients that died had lower total cholesterol, LDL-C, and HDL-C levels than those that survived. The differential levels of these three markers in this study suggest that each of these lipid profile parameters has prognostic utility in sepsis patients.[14] Lipoproteins are generally regarded as playing a role in neutralising and modulating the inflammatory response to endotoxins through chemical reactions; thus, lower levels of lipoproteins likely impair the host response and increase the intensity of systemic inflammation and therefore contribute to poorer clinical outcomes. Among the lipid profile parameters examined, HDL-C is the most clinically significant due to its anti-inflammatory and antioxidant effects.[15]

In this study, triglyceride levels were shown to not have a significant correlation with mortality; therefore, triglyceride levels do not have prognostic utility in sepsis patients. These data support findings from other studies that show significant variability in triglyceride levels of sepsis patients based on their metabolic status; therefore, triglyceride levels cannot be considered reliable indicators of disease severity.[16]

The combination of serum albumin and lipid profile data, in conjunction with APACHE II and SOFA scoring systems, increases the accuracy of predicting mortality in sepsis patients and therefore, these four markers represent inexpensive, readily available, and reproducible clinical tests; thus, they are especially valuable for clinicians in resource-limited environments that do not have access to advanced prognostic markers.[17]

This study provides additional support for the growing body of literature that demonstrates the value of hypoalbuminemia and hypolipidemia as significant indicators of poor prognosis for sepsis patients and thus, their incorporation into routine clinical assessments of sepsis patients may serve to facilitate early detection of patients at risk for poor

clinical outcomes and to improve the overall clinical management of these patients.[18]

CONCLUSION

Patients with sepsis admitted to ICU are at increased risk of morbidity/mortality if they present with low serum albumin or impaired lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol). Routine assessment of these parameters would enhance early prognostication, when used with currently accepted severity scores/survivability indices, thus improving clinical decision making based upon accurate assessment of prognosis, especially in resource limited settings.

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