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Albumin: A Maverick or a Placebo? Study of Association of Serum Albumin and Albumin Therapy with Mortality in Sepsis

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ABSTRACT

Objectives: The study explores the relationship between serum albumin levels, heterogeneous (human-derived) albumin administration, and clinical outcomes in patients with sepsis. The aim is to ascertain whether Serum albumin levels can be a reliable surrogate for qSOFA in assessing mortality in patients with sepsis and whether systemic administration of Human albumin in those with serum levels <30 g/L has an impact on mortality. Methods: This retrospective study was conducted at Sohar Hospital in Oman and involved a random sample of 57 patients. The patients were initially categorized into three groups based on their predicted mortality risk using the qSOFA score: low, moderate, and high risk. The same sample was further divided into two groups according to serum albumin levels: ≥30 g/L and <30 g/L. Additionally, the patients were stratified based on whether or not they received human albumin administration. Results: Analysis revealed a non-significant trend toward better outcomes in patients with higher serum albumin levels (p = 0.097). Notably, patients with higher albumin levels experienced less clinical deterioration, whereas those with lower levels were more likely to worsen. In terms of heterogeneous (human-derived) albumin administration, results show no statistically significant association between human albumin administration and improved clinical outcomes (p = 0.222). We also analyzed the relationship between lactate: albumin ratio and qSOFA score, which showed no significant association (p=0.1994). Conclusions: Study findings suggest that while serum albumin may have a weak correlation with patient recovery, the therapeutic benefit of albumin administration remains inconclusive. This study found a weak, non-significant relationship between serum albumin levels, albumin administration, and clinical improvement in patients. Findings also indicate that while higher serum albumin levels may offer some protection against clinical decline, they are not strongly associated with improved outcomes. Conversely, patients with low serum albumin

level face a substantially higher risk of negative clinical progression. These findings highlight the need for further large-scale and controlled design research to better clarify the role of albumin in patient outcomes.

Keywords: Serum Albumin, Albumins/therapeutic use, Disease Progression.

INTRODUCTION

Hepatocytes produce approximately 10–15 grams of serum albumin daily, making serum albumin the most abundant protein in plasma. Serum albumin plays a crucial role in fluid distribution between body compartments by determining oncotic pressure. Moreover, it transports essential substances in the blood, such as hormones, nucleic acids, toxins, and drugs.[1] Serum albumin is a globular protein consisting of 585 amino acids. In addition to its transport functions, it exhibits antioxidant properties and possesses several (pseudo)-enzymatic activities, such as esterase, enolase, glucuronidase, and peroxidase-like actions.

Various studies have explored the prognostic outcomes of different disorders concerning albumin levels, including COVID-19[2], sepsis, heart failure, burns, chronic kidney injury[3], cancer and immunotherapy[4]. Our study aims to elucidate the correlation between serum albumin levels and whether administering exogenous human albumin influences patient outcomes. The study's conclusions can help us develop more effective protocols regarding the rationality of administering human albumin in sepsis. Additionally, we will determine if serum albumin can be used as a rapid mortality assessment in a busy setting, such as the emergency room, rather than relying on time-consuming scoring systems.

METHODS

This retrospective observational study was conducted at Sohar Hospital in Oman. A random sample of 57 adult patients admitted to the Department of Acute Medicine with various medical conditions were selected. Patients were eligible if they were 18 years or older, of any gender, and presented with signs of sepsis, defined by at least two criteria from the quick Sequential Organ Failure Assessment (qSOFA) score: altered mental status, systolic blood pressure ≤100 mmHg, or respiratory rate ≥22/min. Exclusion criteria included severe hepatic dysfunction, nephrotic syndrome, undrained surgical sources of sepsis, HIV/AIDS, pregnancy, administration of human albumin within three weeks prior to sepsis onset, pre-existing cardiac arrest, and known allergy to human albumin.

Patient data were obtained from electronic medical records, including demographic information (age, gender), clinical parameters (vital signs, comorbidities), serum albumin levels, administration of human-derived albumin, and clinical outcomes (improvement, deterioration, or mortality). The quick Sequential Organ Failure Assessment (qSOFA) score was used to stratify mortality risk into three groups: low risk, moderate risk, and high risk.

The same patient sample was categorized in three different ways for analysis: first, based on qSOFA scores to stratify patients into low, moderate, and high mortality risk groups; second, according to serum albumin levels, dividing patients into those with levels ≥30 g/L and those with levels <30 g/L; and third, based on whether or not the patients received human albumin therapy during their hospital stay.

Data was analyzed using SPSS version 20.v. Categorical variables were compared using the chi-square test. A p-value of less than 0.05 was considered statistically significant. The relationship between serum albumin level, albumin administration, and clinical outcomes was evaluated to assess the potential predictive value.

The study received ethical approval from the Research, Ethical Review and Approval Committee (RERAC), Ministry of Health, Oman, under the reference number MOH/CSR/24/28584. Potential confounding factors included the timing and selection of antibiotic therapy, choice of intravenous fluids, and the use of inotropic support.

RESULTS

In this retrospective study, 57 patients hospitalised at Sohar Hospital, representing various age groups and medical conditions, were categorised into three subgroups based on their Day 1 qSOFA scores: low mortality risk (n=18), intermediate mortality risk (n=20), and high mortality risk (n=19). When comparing these groups to their final clinical outcomes, all patients in the low-risk group showed no change (100%) with a statistically significant result (Chi-square p = 0.0001). In the intermediate-risk group, 60% of patients showed clinical improvement, 25% experienced deterioration, and 15% had no change. Notably, patients in the high-risk group demonstrated the highest rate of clinical improvement, with 84% showing positive progress, 16% remaining stable, and none experiencing deterioration (0%).

Variable	Category	No Change n (%)	Positive Progress n (%)	Negative Progress n (%)	Total	*p*-value
qSOFA Mortality Prediction	Low	18 (100%)	0 (0%)	0 (0%)	18	0.0001
	Intermediate	3 (15%)	12 (60%)	5 (25%)	20	
	High	3 (16%)	16 (84%)	0 (0%)	19	
Human Albumin Administration	Yes	5 (29%)	9 (53%)	3 (18%)	17	0.222
	No	19 (48%)	19 (48%)	2 (5%)	40	
Serum Albumin Level (g/L)	<30	7 (30%)	12 (52%)	4 (17%)	23	0.097
	≥30	17 (50%)	16 (47%)	1 (3%)	34	

The same cohort of 57 patients was divided into two groups based on their serum albumin levels: those with levels below 30 g/L (n = 23) and those with levels above 30 g/L (n = 34). Among patients in the low albumin group, 52% showed clinical improvement, 17% experienced deterioration, and 30% had no significant change in their condition. In the group with high albumin levels, 50% of the patients showed no change in their health status, while 47% experienced an improvement in therapeutic response, and the remaining 3% demonstrated a decline in their condition. The p-value (0.097) indicates a non-significant trend, suggesting that higher albumin levels may be modestly associated with reduced risk of clinical decline.

In another subgrouping of the 57 patients, 17 received intravenous human albumin. Among these patients, 53% exhibited clinical improvement, 29% showed no change, and 18% experienced clinical deterioration. In comparison, of the 40 patients who did not receive IV human albumin, 48% improved, 48% remained unchanged, and 5% showed a decline in their

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clinical condition. The p-value (0.222) indicates no significant association between human albumin administration and improvement outcome.

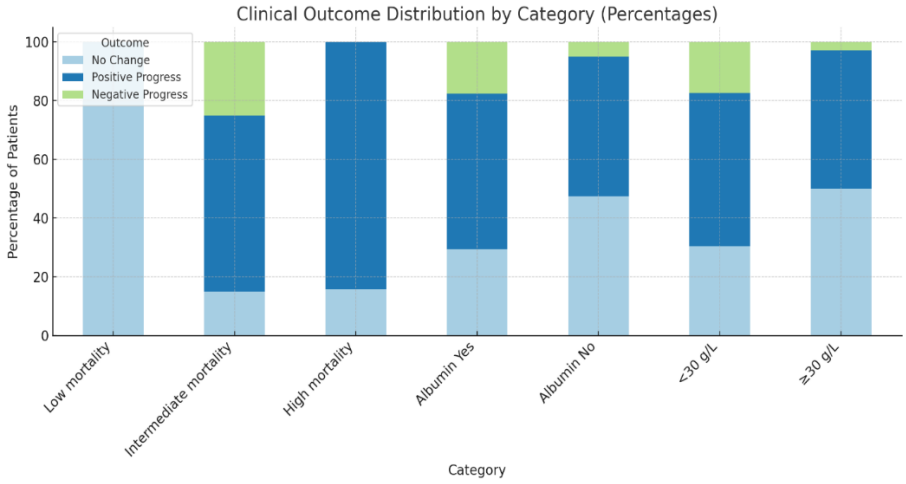

Figure 1: Clinical outcome distribution by category, expressed as percentages. Patient outcomes (no change, positive progress, or negative progress) are stratified by qSOFA-predicted mortality risk (low, intermediate, high), albumin administration status (yes/no), and serum albumin levels (<30 g/L vs. ≥30 g/L). The chart demonstrates that high-risk patients had the highest rate of clinical improvement, while patients with serum albumin levels <30 g/L or who received albumin therapy had a greater proportion of clinical deterioration, although differences were not statistically significant.

DISCUSSION

This study examined the association between serum albumin levels, human albumin administration, and clinical outcomes in patients with varying degrees of mortality risk. The findings indicate that patients classified as high risk on Day 1 demonstrated the highest rate of positive clinical progress (84%), suggesting that medical interventions may have contributed significantly to clinical improvement. The statistically significant Chi-square result ($p = 0.0001$) supports a strong association between early medical intervention and clinical improvement, particularly in patients with higher baseline risk.

Maintaining serum albumin levels ≥30 g/L was associated with reduced risk of clinical deterioration. However, this threshold did not show a statistically significant association with improved clinical progress ($p = 0.222$). In contrast, patients with albumin levels <30 g/L were more likely to experience negative outcomes, highlighting hypoalbuminemia as a potential risk factor for adverse clinical progression. Human albumin administration itself did not significantly alter outcomes ($p = 0.222$), suggesting limited therapeutic impact in this context.
To better interpret our results, we examined how they align with existing literature. A comprehensive meta-analysis that included 90 cohort studies involving 291,433 patients, along with 9 prospective controlled trials with 535 patients, found that hypoalbuminemia was strongly associated with poor clinical outcomes across diverse patient populations.[5] Additionally, a study investigating patients with community-acquired bacteremia reported that a single plasma albumin measurement taken on the day of diagnosis was a more accurate predictor of short-term mortality than traditional sepsis severity scores.[6] However, despite this association, a randomized study comparing the use of intravenous (IV) albumin in addition to

IV crystalloid versus IV crystalloid alone in patients with severe sepsis admitted to the intensive care unit (ICU) found no significant survival benefit at either 28 or 90 days.[7] These findings suggest that while hypoalbuminemia serves as a strong prognostic marker, albumin replacement therapy may not necessarily improve mortality outcomes in severe sepsis.

This study is limited by its small sample size, single-center design, and inability to adjust for all confounding factors, such as variability in antibiotic timing, type of fluid resuscitation, and dosage of albumin administered.

CONCLUSION

In conclusion, patients with serum albumin levels ≥30 g/L showed a reduced risk of clinical deterioration; however, the association with improved outcomes was weak and statistically non-significant. Administration of human albumin did not demonstrate a measurable therapeutic advantage. These findings highlight the potential prognostic value of albumin but also underscore the need for larger studies to assess its clinical utility.

Disclosure

The authors declared no conflicts of interest. No funding was received for this study.

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