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Predictive Value of Serum Albumin Levels for Prognosis of Severe Sepsis in Late Preterm Neonates Admitted in NICU in CMH Abbottabad

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ABSTRACT

Background: Severe sepsis remains a critical cause of neonatal morbidity and mortality, particularly in late preterm infants. Identifying cost-effective prognostic markers is essential for timely risk stratification and intervention. While serum albumin has been linked to adverse outcomes, its role in predicting mortality among late preterm neonates with sepsis requires further validation. **Objective:** To determine the diagnostic accuracy of serum albumin levels for poor prognosis of severe sepsis in late preterm neonates taking mortality as gold standard. **Study Design:** Cross-sectional validation study. **Duration and Place of Study:** The study was carried out from January 2024 to September 2024 in the Neonatal Intensive Care Unit of Combined Military Hospital, Abbottabad. **Methodology:** A total of 311 late preterm neonates (34 0/7 to 36 6/7 weeks gestation) diagnosed with severe sepsis were included through non-probability consecutive sampling. Serum albumin levels were measured within 24 hours of NICU admission. Neonates were followed until discharge or death. Diagnostic metrics and ROC curve were calculated to evaluate the poor prognostic value of serum albumin. **Results:** The mean GA at birth and birth weight were 35.37 ± 0.85 weeks and 2101.55 ± 272.22 g, respectively. The average serum albumin level was 3.15 ± 0.43 g/dL. Mortality occurred in 71 neonates (22.8%). Serum albumin demonstrated a sensitivity of 87.32%, specificity of 78.33%, diagnostic accuracy of 80.39%, PPV of 54.39%, and NPV of 95.43%. **Conclusion:** Serum albumin is a valuable, accessible biomarker with strong negative predictive ability for mortality in late preterm neonates with sepsis.

INTRODUCTION

Preterm neonates, i.e., neonates born less than 37 completed weeks of gestation, are high-risk groups with underdeveloped organ systems and poor immune responses that cause them to have a variety of issues.[1] Of these preterm infants, late preterm neonates born between $34^{0/7}$ to $36^{6/7}$ weeks of gestation—constituted a major proportion and in the past used to be considered as near-term.[2] But recently it emerged that late preterm infants have certain vulnerabilities in their physiology when compared to their term counterparts in that respiratory distress, thermoregulatory difficulty in maintenance, hypoglycemia, feeding difficulty, and higher susceptibility to infectious disease are increased in them.[3] Their transitional physiology while superior to that of their previous preterm counterparts but not strong enough to resist extrauterine stresses culminate in augmented neonatal mortality and morbidity.[4]

Severe sepsis in late preterm neonates remains a significant cause of admission to neonatal intensive care units and adverse outcomes.[5] It is a systemic inflammatory response to an infection with concomitant organ dysfunction and has an insidious presentation in neonates relative to adults and mature children.[6] Its presentation in late preterms can be subtle and nonspecific—e.g., poor feeding, temperature instability, or respiratory distress—such that diagnosis in an emergent timeframe and urgent intervention become critical.[7] Late preterm neonates, with their dysmature skin and mucosal barriers and their compromised immunity, are of particular risk for invasive disease through vertical and horizontal transmission of their pathogens.[8] Bacterial pathogens like Escherichia coli and Group B Streptococcus are among their most frequent culprits.[9] Prognosis in these situations depends significantly upon their being discovered soon enough, receipt of appropriate antimicrobial treatment and supportive care.[9]

Serum albumin, which is produced in the liver, is the major plasma protein in neonates and has various physiological functions including maintenance of oncotic pressure, transportation of various substances, and modulation of inflammatory states.[10] Preterm neonates have serum albumin concentrations that are generally lower than those of term infants due to hepatic immaturity and inefficient synthesis.[11] Stress, inflammation, or systemic disease can also cause hypoalbuminemia.[12] Hypoalbuminemia is therefore routinely observed in critically ill neonates.[13] Albumin levels are therefore associated with nutritional stores but also with the inflammatory state of the neonate and thus become a significant parameter not only for defining baseline nutritional status but for monitoring disease progression/recovery in neonatal ICU contexts.[14]

Serum albumin levels have increasingly shown to possess pro-babilistic value for severe sepsis prognosis in late preterm neonates in the form of an easily measurable yet inexpensive biomarker.[15] Neonatal sepsis-related hypoalbuminemia has been linked to increased disease intensities, hospitalization durations, respiratory support requirements, and mortality.[16] Inflammatory cytokines in sepsis suppress albumin synthesis and induce an increase in capillary permeability with resultant leak of albumin into the interstitial space, contributing to hypoalbuminemia.[17]

Zahid et al. reported in a study that serum albumin levels below 3.0 g/dL predicted mortality in late preterm neonates with severe sepsis a sensitivity of 80%, specificity of 75%, and observed a mortality prevalence of 20% among the study population.[18]

Severe sepsis remains a significant cause of mortality and morbidity in late preterm neonates, in which early stratification of risk can have immense value with regard to patient outcomes. Current biomarkers such as CRP and procalcitonin have limitations in terms of sensitivity, cost-effectiveness, and early prognostic capacity. Serum albumin in adult and pediatric sepsis has become a viable and inexpensive test that has shown promise in terms of being a prognostic factor. Its role in late preterm neonates remains to be fully understood. Conducting this study would help generate local evidence of serum albumin being of value in mortality prediction to inform appropriate clinical interventions in a timely manner and in maximizing NICU resource utilization.

METHODOLOGY

This cross-sectional validation study was conducted in the Neonatal Intensive Care Unit (NICU) of Combined Military Hospital (CMH), Abbottabad, from January 2024 to September 2024. A total of 311 neonates, born between 34 0/7 and 36 6/7 weeks of gestation, were enrolled. The sample size was calculated assuming a sensitivity of 80%, specificity of 75%, and an estimated mortality prevalence of 20%,[18] allowing for a 10% margin of error.

Neonates were eligible for inclusion if they met the clinical and laboratory criteria for severe sepsis, defined by the presence of systemic infection along with signs of cardiovascular instability, respiratory failure, or dysfunction of at least two organ systems. Exclusion criteria included neonates with major congenital anomalies, metabolic disorders, primary liver disease, or those who had received albumin therapy prior to admission.

A 2 mL venous blood sample was collected within the first 24 hours of NICU admission, and serum albumin levels were measured using an automated biochemical analyzer. A serum albumin threshold of <3.0 g/dL was used as the predictive cut-off for poor prognosis.

All neonates were followed until discharge or death, and the primary outcome was categorized as survival or non-survival. The prognostic ability of serum albumin was assessed by calculating its diagnostic accuracy, and the area under the receiver operating characteristic curve. SPSS version 27.0 was used to do statistical works, and subgroup analyses were performed based on birth weight, delivery mode, and gestational age at birth.

RESULTS

The mean gestational age at birth was 35.365 ± 0.854 weeks, and the mean birth weight was 2101.553 ± 272.215 g, with a mean serum albumin level of 3.152 ± 0.430 g/dL (as shown in Table-I). The cohort consisted of 148 males (47.6%) and 163 females (52.4%) neonates, with 143 (46%) delivered vaginally and 168 (54%) via cesarean section (as shown in Table 1).

Table 1

Demographics and Clinical Characteristics

Variables		Mean ± SD or n (%)
Gestational Age at Birth (weeks)		35.365 ± 0.854
Birth Weight (g)		2101.553 ± 272.215
Serum Albumin (g/dL)		3.152 ± 0.430
Gender	Male n (%)	148 (47.6%)
	Female n (%)	163 (52.4%)
Delivery Mode	Vaginal Delivery n (%)	143 (46%)
	C-section n (%)	168 (54%)

In terms of outcomes, 114 neonates (36.7%) had a poor prognosis based on serum albumin levels, while 197 (63.3%) did not, and 71 neonates (22.8%) died, with 240 (77.2%) surviving (as shown in Table 2).

Table 2

Overall Results of Poor Prognosis by Serum albumin and Mortality

Outcome	Positive n (%)	Negative n (%)	Total n (%)
Poor Prognosis by Serum albumin	114 (36.7%)	197 (63.3%)	311 (100%)
Mortality	71 (22.8%)	240 (77.2%)	311 (100%)

The chi-square test for the comparison of serum albumin and mortality in the diagnosis of poor prognosis yielded a value of 104.83 with a p-value of 0.000, indicating a statistically significant association (as shown in Table 3).

Table 3

Comparison of Serum albumin and Mortality in diagnosis of Poor Prognosis

Serum albumin	Mortality		Total
	Positive	Negative	
Positive	62 (TP)	52 (FP)	114
Negative	9 (FN)	188 (TN)	197
Total	71	240	311

Chi-square = 104.83, P value = 0.000

The diagnostic performance of serum albumin in predicting mortality showed a sensitivity of 87.32%, specificity of 78.33%, diagnostic accuracy of 80.39%, positive predictive value (PPV) of 54.39%, and negative predictive value (NPV) of 95.43% (as shown in Table 4).

Table 4
Sensitivity, Specificity, Diagnostic Accuracy, PPV and NPV of Serum Albumin in Predicting Mortality

Diagnostic Parameter	Result
Sensitivity	87.32%
Specificity	78.33%
Diagnostic Accuracy	80.39%
PPV	54.39%
NPV	95.43%

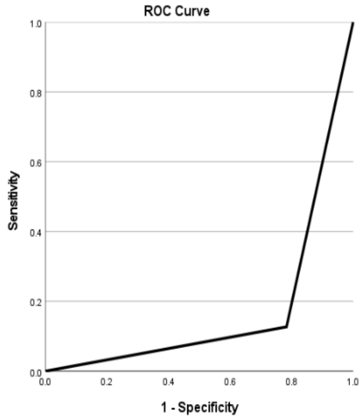
Stratified analyses revealed that for neonates with a gestational age ≤35 weeks, the sensitivity was 100%, specificity was 78.33%, diagnostic accuracy was 81.68%, PPV was 45.45%, and NPV was 100%. For those with a gestational age >35 weeks, the sensitivity was 82.35%, specificity was 78.21%, diagnostic accuracy was 80.00%, PPV was 60.00%, and NPV was 91.84% (as shown in Table-V). Among males, the sensitivity was 89.66%, specificity was 79.87%, diagnostic accuracy was 81.76%, PPV was 52.00%, and NPV was 96.97%. For females, the sensitivity was 85.71%, specificity was 77.08%, diagnostic accuracy was 80.37%, PPV was 56.25%, and NPV was 94.07% (as shown in Table-V). Neonates with a birth weight ≤2000 g had a sensitivity of 80.65%, specificity of 92.21%, diagnostic accuracy of 89.81%, PPV of 80.65%, and NPV of 92.21%. Those with a birth weight >2000 g had a sensitivity of 92.50%, specificity of 71.62%, diagnostic accuracy of 75.86%, PPV of 44.72%, and NPV of 97.50%. For vaginal deliveries, the sensitivity was 83.78%, specificity was 77.27%, diagnostic accuracy was 79.02%, PPV was 56.25%, and NPV was 93.02%. For cesarean deliveries, the sensitivity was 90.91%, specificity was 78.95%, diagnostic accuracy was 81.55%, PPV was 52.38%, and NPV was 97.22% (as shown in Table 5).

Table 5
Stratified Analysis of Sensitivity, Specificity, Diagnostic Accuracy, PPV and NPV of Serum Albumin in Predicting Mortality with Demographics

Variables	Groups	Diagnostic Parameter	Result
Gestational Age at Birth (weeks)	≤35	Sen	100%
		Spec	78.33%
		DA	81.68%
		PPV	45.45%
		NPV	100%
	>35	Sen	82.35%
		Spec	78.21%
		DA	80.00%
		PPV	60.00%
		NPV	91.84%
Gender	Male	Sen	89.66%
		Spec	79.87%
		DA	81.76%
		PPV	52.00%
		NPV	96.97%
	Female	Sen	85.71%
		Spec	77.08%
		DA	80.37%
		PPV	56.25%
		NPV	94.07%
Birth Weight (gm)	≤2000	Sen	80.65%
		Spec	92.21%
		DA	89.81%
		PPV	80.65%
		NPV	92.21%
	>2000	Sen	92.50%
		Spec	71.62%
		DA	75.86%
		PPV	44.72%
		NPV	97.50%
Delivery Mode	Vaginal Delivery	Sen	83.78%
		Spec	77.27%
		DA	79.02%
		PPV	56.25%
		NPV	93.02%
	C-section	Sen	90.91%
		Spec	78.95%
		DA	81.55%
		PPV	52.38%
		NPV	97.22%

The area under the curve (AUC) is 0.172, and the standard error is 0.028, with a 95% confidence interval ranging from 0.117 to 0.226. The p-value is less than 0.001, suggesting a statistically significant difference from the null hypothesis of an AUC of 0.5. The coordinates of the curve show that at a cutoff value of 1.5000, the sensitivity is 0.127 and 1-specificity is 0.783.

Graph 1
ROC Curve



DISCUSSION

The results indicate that serum albumin levels have significant prognostic potential, as evidenced by the high sensitivity (87.32%) and diagnostic accuracy (80.39%) in predicting mortality. The high NPV (95.43%) suggests that normal serum albumin levels can effectively rule out mortality risk in this population. However, the lower PPV (54.39%) indicates that elevated serum albumin levels are not as reliable in predicting poor outcomes, likely due to the presence of other confounding factors such as gestational age, birth weight, and delivery mode.

Stratified analyses revealed that serum albumin levels are more predictive in neonates with a gestational age ≤35 weeks, where the sensitivity was 100%. This may be attributed to the fact that younger gestational age is associated with more severe and prolonged inflammatory responses, making serum albumin a more reliable marker in this subgroup. Conversely, neonates with a gestational age >35 weeks had a lower sensitivity (82.35%) but a higher PPV (60.00%), suggesting that serum albumin levels may be more indicative of poor outcomes in this slightly more mature group.

The slightly higher sensitivity in males (89.66%) compared to females (85.71%) could be due to differences in immune responses and hormonal factors that influence albumin levels. Similarly, the higher sensitivity in neonates delivered via cesarean section (90.91%) compared to vaginal delivery (83.78%) might be related to the different stressors experienced during delivery, with cesarean deliveries potentially leading to more pronounced inflammatory responses.

Our results were consistent with Torer et al. [19] and Yang et al.[20] in indicating a good correlation between decreased serum albumin levels and a poor outcome in neonates. Consequently, we found that neonates who had a presentation of serum albumin levels of < 3.152 ± 0.430 g/dL were more likely to experience a poor outcome and die, similar to results that indicated hypoalbuminemia as a risk factor independent of mortality in preterm neonates.[19] Our mean serum albumin level was 3.152 ± 0.430 g/dL, similar to that reported by Yang et al.[20] and under which lower albumin levels were associated with a poor outcome in late preterm infants who were infected.

Based on demographic values, we investigated neonates with a mean gestation age of 35.365 ± 0.854 weeks and a mean birth weight of 2101.553 ± 272.215 g. These are higher when compared with preterm neonates identified by Torer et al. [19] who compared preterm neonates with a mean gestation age of 29.2 ± 2.2 weeks and a mean birth weight of 1,272 ± 390 g. This discrepancy in gestation age and birth weight may be due to the fact that our study encompassed late preterm neonates, while Torer's study comprised very preterm neonates. The higher gestation age and birth weight in our study may explain the slightly higher level of serum albumin observed.[21]

Our findings disclosed that 114 neonates (36.7%) had a poor outcome based on serum albumin level, and 71 neonates (22.8%) died. This proportion is comparable to that of Torer et al.[19] who noted a 17.6% proportion of preterm infant mortality in their population. The correlation between serum albumin level and mortality that we identified as being significantly different (chi-square test statistic 104.83, p-value 0.000) further strengthens our finding that hypoalbuminemia is a decisive risk variable that predisposes neonates to adverse outcomes, as noted by Torer et al. [19] and Yang et al.[20]

The diagnostic ability of serum albumin in our study to predict mortality revealed a sensitivity of 87.32%, specificity of 78.33%, diagnostic accuracy of 80.39%, PPV of 54.39%, and NPV of 95.43%. These are close to those of Torer et al.[19] who reported 71% sensitivity and 86% specificity of albumin levels smaller than 27.2 g/l in predicting mortality. The higher sensitivity and NPV in our study mean that neonates' serum albumin concentrations are a good predictor of neonates at risk of mortality, as also found by Torer et al.[19]

Among males, the sensitivity was 89.66%, specificity was 79.87%, diagnostic accuracy was 81.76%, PPV was 52.00%, and NPV was 96.97%. For females, the sensitivity was 85.71%, specificity was 77.08%, diagnostic accuracy was 80.37%, PPV was 56.25%, and NPV was 94.07%. These results suggest that serum albumin levels are slightly more effective in predicting mortality in male neonates compared to females, which is consistent with the findings of Torer et al.[19] and Yang et al.[20] who also reported higher rates of adverse outcomes in male neonates.

Neonates with a birth weight ≤2000 g had a sensitivity of 80.65%, specificity of 92.21%, diagnostic accuracy of 89.81%, PPV of 80.65%, and NPV of 92.21%. Those with a birth weight >2000 g had a sensitivity of 92.50%, specificity of 71.62%, diagnostic accuracy of 75.86%, PPV of 44.72%, and NPV of 97.50%. These results indicate that serum albumin levels are highly effective in predicting mortality in neonates with a birth weight ≤2000 g,[22] which is consistent with the findings of Torer et al. [19] and Yang et al. [20] who reported higher rates of adverse outcomes in neonates with lower birth weights.

For vaginal deliveries, the sensitivity was 83.78%, specificity was 77.27%, diagnostic accuracy was 79.02%, PPV was 56.25%, and NPV was 93.02%. For cesarean deliveries, the sensitivity was 90.91%, specificity was 78.95%, diagnostic accuracy was 81.55%, PPV was 52.38%, and NPV was 97.22%. These results suggest that serum albumin levels are slightly more effective in predicting mortality in neonates delivered via cesarean section compared to those delivered vaginally, which is consistent with the findings of Torer et al. [19] and Yang et al. [20] who also reported higher rates of adverse outcomes in neonates delivered via cesarean section.

Our investigation is also prone to a few limitations. Firstly, it is a single-center study whose results may not be applicable to different patient sets. The sample used in our investigation is also somewhat small and may undermine statistical power in our results. Lastly, we did not have long-term follow-up data whose inclusion would provide additional data on long-term neonatal outcomes as a result of hypoalbuminemia. Future investigations should make up for these limitations through the implementation of larger, multicenter trials with long-term follow-up in a quest to further establish our findings as well as seek plausible therapeutic interventions that could be implemented in neonates with hypoalbuminemia.

CONCLUSION

Our study has identified that serum albumin level is a strong predictor of neonatal demise and adverse outcome. Findings highlight that serum albumin measurement is a precious biomarker employed to foretell neonates who are exposed to adverse events. Future studies should focus on evaluating mechanisms responsible for hypoalbuminemia and designing individualized interventions to maximize outcome in such vulnerable population.

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