Section: General surgery

Original Research Article

# A PROSPECTIVE STUDY OF HYPOALBUMINEMIA AS RISK FACTOR OF WOUND HEALING IN DIABETIC FOOT

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## ABSTRACT

**Background:** Diabetic foot ulcer (DFU) is a common and serious complication of diabetes mellitus, often leading to prolonged hospitalization and amputation. Poor nutritional status, particularly hypoalbuminemia, has been implicated as a potential factor influencing delayed wound healing. This study aimed to evaluate the prevalence of low serum albumin levels in patients with diabetic foot ulcers and to assess their role in wound healing outcomes. **Materials and Methods:** This prospective study was carried out over a period of 12 months within the Department of General Surgery at Trichy SRM Medical College Hospital and Research Centre. A total of 250 adult patients presenting with diabetic foot ulcers were included in the study. The assessment of wound severity was conducted utilizing the Wagner grading system. All patients underwent standard wound care and received nutritional intervention to address hypoalbuminemia. After a period of three months, the levels of serum albumin and the status of wound healing were re-evaluated. Statistical analysis was conducted utilizing SPSS version 26.0, where a p-value of less than 0.05 was deemed significant. **Result:** The average age was 47.68 ± 8.67 years, with a higher prevalence of males at 67.2%. The majority of patients presented with Wagner grade 1, accounting for 62% of the total. The initial mean serum albumin level was 3.288 ± 0.48 g/dL, which showed a significant increase to 3.693 ± 0.47 g/dL at the three-month mark ($p < 0.001$). Initially, 71.2% presented with albumin levels below 3.5 g/dL, which decreased to 26.8% upon follow-up. Wound healing was achieved in 88.8% of cases, while 6.4% exhibited non-healing, and 4.8% necessitated amputation. A lower baseline albumin level was notably linked to unfavorable outcomes ($p = 0.002$). **Conclusion:** Hypoalbuminemia frequently occurs in patients with diabetic foot ulcers and is notably linked to impaired wound healing. Serum albumin serves as an important indicator of healing outcomes.

## INTRODUCTION

Diabetes is a chronic condition characterized by hyperglycemia resulting from β-cell dysfunction, and it is a significant risk factor for ischemic heart disease and stroke globally.[1] The prevalence of diabetes rose from 200 million in 1990 to 830 million in 2022, with countries with low or middle incomes experiencing a faster growth.[2]

A diabetic foot ulcer is characterized as a disruption in the epidermis that penetrates at least a portion of the dermis in patients with diabetes. Superficial or closed lesions that do not penetrate the dermis are classified as preulcerative and possess a significant risk of advancing to ulceration.3[3]Diabetic foot ulcers represent a significant source of preventable morbidity in adults with diabetes, resulting in infection, hospitalization, functional deterioration,

and mortality. The lifetime risk of developing an ulcer ranges from 19% to 34% and is on the rise. Recurrence rates attain 65% within 3–5 years, with an amputation incidence of 20% and a 5-year mortality rate ranging from 50% to 70%.[3]

The worldwide prevalence of diabetic foot is 6.3%, while Asia reports a prevalence of 5.5%. Diabetic foot is more prevalent in males and occurs more frequently in those with type 2 diabetes compared to those with type 1 diabetes.[4] The pooled prevalence of diabetic foot ulcers in India is 6.2%, with a greater prevalence in males (14.5%) compared to females (7.7%). Significant risk factors encompass prolonged diabetes duration, advanced age, concomitant conditions, male sex, and detrimental lifestyle choices.[5] Diabetic foot ulcers (DFUs) represent a considerable source of morbidity among individuals with diabetes and are a leading contributor to leg amputations in developed countries.[6]

Despite the progress made in various treatment modalities, including wound debridement, off-loading, medication, wound dressings, and infection prevention through maintaining infection control, the challenge of non-healing diabetic foot ulcers continues to be a notable clinical concern.[7] In the majority of patients with diabetic foot, serum concentrations of albumin, hemoglobin, iron, and zinc were found to be significantly reduced. The observed low values may be inversely associated with the process of wound healing. Nutrient replacements are essential for the wound healing process in patients with diabetic foot conditions.[7] Hypoalbuminemia, defined as serum albumin levels below 3.5 g/dL, is commonly observed in individuals with Diabetic Foot Ulcers (DFU), impacting more than 50–80% of affected patients. This factor serves as a notable indicator of suboptimal wound healing, elevated infection rates, extended hospitalizations, and an increased likelihood of amputations. This suggests the presence of chronic inflammation alongside significant malnutrition. Hence, this study aimed to determine low albumin levels among patients with Diabetic foot ulcer and their role in wound healing.

**Objective:** To determine low albumin levels among patients with Diabetic foot ulcer and their role in wound healing.

## MATERIALS AND METHODS

This prospective study was conducted over 12 months by the Department of General Surgery at Trichy SRM Medical College Hospital and Research Centre, Trichy. It encompassed both inpatient and outpatient cases. Throughout the study duration, all patients with diabetic foot ulcers were assessed for eligibility. Participants aged 18 and older with diabetic foot ulcers who provided written consent were included in the trial. Exclusions were made for individuals who did not give consent, those under 18 years of age, and those with non-diabetic ulcers. Further exclusion criteria included patients with chronic liver disease, chronic renal disease, underlying osteomyelitis, concurrent peripheral vascular disease, a history of ionizing radiation exposure, age over 80 years, deficiencies in vitamin C, vitamin A, zinc, or iron, and individuals administered exogenous medications known to impede wound healing, such as Adriamycin and glucocorticosteroids.

A total of 250 patients were enrolled in the study according to established inclusion and exclusion criteria. Patients who met the eligibility criteria and were admitted to the Department of General Surgery with diabetic foot ulcers were selected consecutively and monitored for a minimum duration of three months. Following the acquisition of informed consent, comprehensive demographic and clinical information was gathered utilizing a structured proforma. Data pertaining to age, gender, duration of diabetes, glycemic status, comorbidities, and prior occurrences of foot ulcers were documented. Baseline laboratory investigations include the measurement of serum albumin levels and the evaluation of glycemic status through fasting blood sugar, postprandial blood sugar, and HbA1c levels.

Hypoalbuminemia was characterized based on established laboratory reference values (serum albumin levels less than 3.5). An initial assessment of the wound was conducted upon admission or at the first point of presentation. Wound characteristics, including dimensions, depth, presence of slough, discharge, surrounding cellulitis, and indicators of infection, were meticulously recorded. Wagner's classification is a commonly utilized system for assessing diabetic foot ulcers, considering both the depth of the ulcer and the degree of tissue involvement.[8]

Throughout the follow-up period, all patients, including inpatients and outpatient underwent standard wound care management protocols. This encompassed daily cleansing of the wound with an antiseptic solution, application of sterile dressings, removal of slough, and comprehensive surgical debridement as clinically indicated. Glycemic control was enhanced through collaboration with the diabetology team, utilizing insulin or oral hypoglycemic agents as necessary. Patients diagnosed with hypoalbuminemia received nutritional intervention through a high-protein diet and oral protein supplementation. Nutritional guidance was provided to ensure adequate calorie and protein consumption. Serum albumin levels were evaluated, and a reassessment was conducted at the conclusion of three months. The wound status was re-evaluated at the three-month mark to assess healing progression, changes in ulcer size, granulation tissue development, and the necessity for additional surgical intervention.

Data were systematically entered into Microsoft Excel and subsequently analyzed utilizing the Statistical Package for Social Sciences (SPSS), IBM version 26.0. Age, HbA1c, FBS, PPBS, baseline


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serum albumin, and 3-month serum albumin levels were represented as mean and SD. Gender, diabetes duration, Wagner grade, albumin categories, and wound healing results were all provided as frequencies and percentages.

A paired Student's t-test was used to compare the means of two related groups (baseline and 3-month serum albumin levels). To compare mean values across different result groups, the independent Student's t-test or one-way analysis of variance (ANOVA) was used as applicable. The chi-square test was employed to determine relationships between categorical variables, such as the relationship between albumin status and wound healing outcomes, and the relationship between Wagner grade and healing status. A two-sided p-value of <0.05 indicated statistical significance. The study was carried out with consent from the Institutional Ethics Committee (IEC) of Trichy SRM Medical College Hospital and Research Centre in Tamil Nadu.

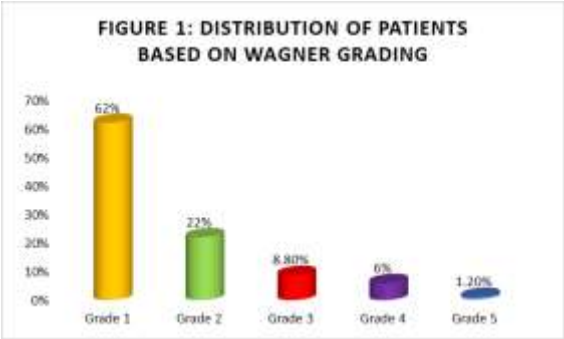
## RESULTS

This study was undertaken among patients with diabetic foot ulcers attending OPD and IPD to assess serum albumin levels and their role in wound healing. The mean age of the study population was 47.68 ± 8.68 years, with a range from 32 to 65 years, suggesting that diabetic foot ulcers were primarily observed in middle-aged individuals. Table 1 presents the descriptive statistics of the participants. Regarding age distribution, the predominant cohort was within the 41–50 years age range, accounting for 114 individuals (45.6%). The subsequent age group, comprising individuals aged 51 to 60 years, included 80 patients, representing 32% of the total population studied. Individuals aged 31 to 40 years represented 37 cases (14.8%), whereas the cohort of patients aged over 60 comprised the fewest, totaling 19 individuals (7.6%). The results demonstrate that diabetic foot ulcers were predominantly identified in individuals aged between 40 and 59 years. The study population exhibited a predominance of males in terms of gender distribution. Among the 250 participants, 168 (67.2%) were identified as male and 82 (32.8%) as female, resulting in a male-to-female ratio of roughly 2:1. This indicates an increased occurrence of diabetic foot ulcers in male patients within the study cohort. A total of 168 patients (67.2%) exhibited a duration of diabetes mellitus of 10 years or less, whereas 82 patients (32.8%) had a duration exceeding 10 years.

**Table 1: Descriptive data of participants (n = 250)**

| S No | Variables | | Frequency | Proportion |
|---|---|---|---|---|
| 1 | Age | 31 – 40 years | 37 | 14.8% |
| | | 41 – 50 years | 114 | 45.6% |
| | | 51 – 60 years | 80 | 32% |
| | | > 60 years | 19 | 7.6% |
| 2 | Gender | Male | 168 | 67.2% |
| | | Female | 82 | 32.8% |
| 3 | Duration of DM | > 10 years | 82 | 32.8% |
| | | ≤ 10 years | 168 | 67.2% |

[Figure 1] shows the proportion of DFU patients based on Wagner Grading. In the cohort of 250 patients participating in the study, a significant proportion was categorized as Wagner grade 1, comprising 155 individuals (62%). Wagner grade 2 ulcers were identified in 55 patients, representing 22% of the total cases, thus categorizing it as the second most prevalent type. Advanced ulcers were observed with reduced frequency. A total of 22 patients (8.8%) were identified with Wagner grade 3 ulcers, whereas 15 patients (6%) exhibited grade 4 ulcers. The most severe manifestation, classified as Wagner grade 5, was observed in a mere 3 patients, representing 1.2% of the study population.




The average HbA1c level was 7.919 ± 1.2662%, with a range of values from 6.6% to 12.1%. This suggests that a significant number of patients experienced inadequate long-term glycemic management. The average fasting blood sugar (FBS) was recorded at 142.55 ± 22.79 mg/dL, with observed values ranging from a minimum of 118.8 mg/dL to a maximum of 217.8 mg/dL. The average postprandial blood sugar (PPBS) was recorded at 197.98 ± 31.65 mg/dL, with values ranging from 165.0 mg/dL to 302.5 mg/dL.

Albumin levels

The mean baseline serum albumin level was recorded at 3.288 ± 0.4815 g/dL, with observed values ranging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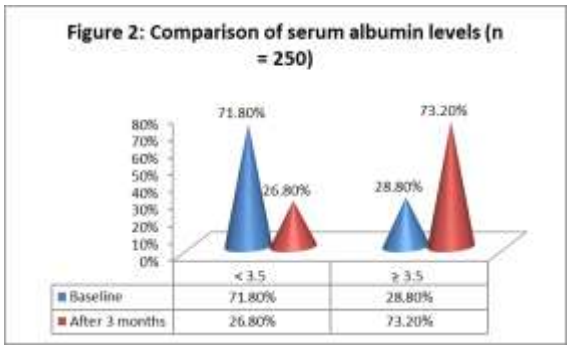
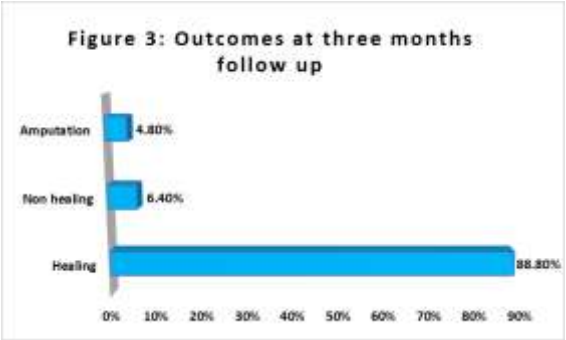
from 2.1 g/dL to 3.9 g/dL. This data suggests that a significant proportion of patients presented with hypoalbuminemia. After three months of follow-up and dietary intervention, the mean blood albumin level rose to 3.6932 ± 0.4734 g/dL, with a range of 2.5 g/dL to 4.3 g/dL. Among the 250 patients assessed, 178 individuals (71.2%) exhibited serum albumin levels below 3.5 g/dL, signifying the presence of hypoalbuminemia. A total of 72 patients (28.8%) exhibited albumin levels of 3.5 g/dL or higher, indicating a relatively normal nutritional status. Among the cohort of 250 patients, 67 individuals (26.8%) exhibited serum albumin levels below 3.5 g/dL at the three months, whereas 183 patients (73.2%) maintained albumin levels at or above 3.5 g/dL.




The average serum albumin level was 3.288 ± 0.4815 g/dL at baseline, but increased to 3.6932 ± 0.4734 g/dL after three months. The paired samples t-test showed a statistically significant rise in serum albumin levels after three months (t = -145.431, df = 249, p < 0.001).

**Outcomes:** [Figure 3] shows the outcomes at three months follow up period. A total of 222 patients (88.8%) experienced effective wound healing. During the follow-up period, sixteen patients (6.4%) exhibited no evidence of meaningful healing, which did not show any signs of the healing process during clinical examination. Twelve patients (4.8%) required amputation due to disease progression or the failure of conservative treatment.




[Table 2] shows serum albumin levels based on outcome data. Although albumin levels improved in all groups following nutritional intervention, persistently lower albumin levels were associated with poorer clinical outcomes. These findings support the role of serum albumin as an important predictor of wound healing in patients with diabetic foot ulcers.

**Table 2: Serum Albumin levels based on Outcome data (n = 250)**

| S No | Outcome | Baseline serum albumin levels | After 3 months | p value |
|---|---|---|---|---|
| 1 | Healing | 3.39±0.387 | 3.79±0.216 | 0.002 |
| 2 | Non healing | 2.419±0.19 | 2.9±0.228 | 0.002 |
| 3 | Amputation | 2.433±0.218 | 2.83±0.218 | 0.002 |

## DISCUSSION

This prospective observational study involved 250 patients diagnosed with diabetic foot ulcers (DFU), exhibiting a mean age of 47.68 ± 8.67 years. The largest proportion of patients was found in the 41–50-year age group, accounting for 45.6% of the total, with a notable predominance of males at 67.2%. The majority of participants exhibited a diabetes duration of 10 years or less, comprising 67.2% of the cohort, while early-stage ulcers, classified as Wagner grade 1 and 2, represented 84% of the total cases. The average HbA1c level was recorded at 7.919 ± 1.266%, accompanied by a mean fasting blood sugar (FBS) of 142.55 ± 22.79 mg/dL and a postprandial blood sugar (PPBS) of 197.98 ± 31.65 mg/dL, suggesting inadequate glycemic control within the study cohort.

The present study revealed that hypoalbuminemia is notably common in individuals with diabetic foot ulcers (DFU) and is significantly correlated with the outcomes of wound healing. The baseline mean serum albumin level observed in this study was 3.288 ± 0.4815 g/dL, with 71.2% of patients presenting with hypoalbuminemia, defined as levels below 3.5 g/dL. After three months of nutritional intervention combined with standard wound management, there was a significant improvement in mean serum albumin levels, which increased to 3.6932 ± 0.4734 g/dL (p < 0.001). Additionally, the percentage of patients classified as hypoalbuminemic decreased to 26.8%. The results indicate that nutritional correction may play a significant role in improving biochemical status and potentially facilitating wound healing.

The findings of our study align with those reported by Devaprashanth M et al,[9] who observed a mean albumin level of 3.3 ± 1.06 g/dL in patients with diabetic foot ulcers in Karnataka, where 53.14% of the subjects demonstrated hypoalbuminemia. The prevalence of hypoalbuminemia in their cohort was observed to be lower than that in our study (53.14% compared to 71.2%). Nevertheless, both studies corroborate that diminished serum albumin levels are frequently encountered in patients with diabetic foot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ulcers (DFU). Their observation regarding the increased prevalence of hypoalbuminemia in patients over 40 years is consistent with our findings, which indicate that the majority of patients fall within the 41–60-year age range. The observed increase in prevalence within our cohort may indicate variations in nutritional status, socioeconomic influences, or the degree of ulceration severity.

In a similar study, Lee et al,[7] from Korea observed that 37% of patients with diabetic foot exhibited low albumin levels. Although this proportion is lower than what was observed in our study, the consistent findings across geographically diverse populations strengthen the association between diabetic foot ulcers and compromised nutritional or inflammatory status. The variation in prevalence could be linked to factors such as patient selection criteria, accessibility to healthcare services, or foundational nutritional requirements. Yunir et al,[10] from Indonesia documented a prevalence of hypoalbuminemia at 83.7% among patients with diabetic foot ulcers, aligning closely with our findings. Their study additionally emphasized inadequate glycemic control in 82.7% of patients, which aligns with our finding of an elevated mean HbA1c level of 7.919 ± 1.266%. The observed consistency indicates that inadequate metabolic control and systemic inflammation could collaboratively lead to diminished albumin levels.

Albumin is essential in the process of wound healing. This component accounts for approximately 75% of the serum antioxidant capacity and serves as a scavenger of free radicals. The liver synthesizes albumin, which then diffuses into interstitial tissues, providing antioxidant and anti-inflammatory effects. In diabetic foot ulcers, chronic hyperglycemia and infection trigger a sustained inflammatory response, resulting in heightened oxidative stress and increased capillary permeability. While hepatic synthesis of albumin can be elevated due to inflammatory processes, the concomitant increase in degradation and capillary leakage may lead to a net decrease in serum albumin levels. This decrease may hinder collagen production, angiogenesis, and tissue repair processes, consequently prolonging the wound healing process.[11,12]

In this study, 88.8% of patients demonstrated wound healing within three months, whereas 6.4% presented with non-healing ulcers, and 4.8% necessitated amputation. Baseline serum albumin levels were notably elevated in the healing group (3.39 ± 0.387 g/dL) when contrasted with the non-healing (2.419 ± 0.19 g/dL) and amputation groups (2.433 ± 0.218 g/dL), with a statistically significant difference observed ($p = 0.002$). The results indicate a significant correlation between hypoalbuminemia and adverse wound outcomes in patients with diabetic foot ulcers (DFUs). The findings of our study align with those reported by Satriadinatha et al,[13] from Indonesia, who observed notably reduced median serum albumin levels in patients undergoing amputation (2.5 g/dL) in comparison to individuals undergoing debridement. The findings indicated significant positive correlations between serum albumin levels and both microvascular density and granulation tissue area, highlighting the biological importance of albumin in the process of tissue repair. In a similar study, Cheng et al.17 found that patients exhibiting hypoalbuminemia (<3.5 g/dL) faced a 2.5-fold increased risk of non-healing, with a preoperative albumin threshold of 3.44 g/dL serving as a predictor for wound healing outcomes. Xu et al further established the significant prognostic value of serum albumin, evidenced by an ROC area under the curve of 0.816, thereby reinforcing its predictive utility.[14-16]

The findings reported by Edakkepuram U et alin Kerala are consistent with those observed in our study.[17,18] The findings indicated markedly reduced healing rates and elevated amputation rates in patients exhibiting low serum albumin levels, thereby underscoring the correlation between nutritional status and wound healing outcomes. Similarly, the systematic review conducted by Mansoor et al,[14] indicated that a majority of patients undergoing amputation presented with albumin levels below 2.9 g/dL, which aligns with the low albumin levels noted in our amputation cohort.

Sun et al,[15] indicated that lower albumin levels were primarily linked to elevated Wagner grades, which aligns with our findings that severe cases exhibited worse outcomes and reduced albumin concentrations. In contrast, Vlad et al,[12] observed that initial albumin levels did not show significant differences between patients who healed and those who did not, and the monthly changes in albumin were found to have a weak correlation with wound healing outcomes. The observed discrepancy could be ascribed to variations in sample size, severity of ulcers, duration of follow-up, or the presence of confounding factors, including inflammatory status and comorbid conditions. Hypoalbuminemia results in a decrease in plasma oncotic pressure, which subsequently causes interstitial edema that hinders the diffusion of oxygen and nutrients. Deficiency in albumin adversely affects collagen synthesis, angiogenesis, and the functionality of immune cells, which in turn hinders re-epithelialization and the body's ability to manage infections. The results of our study indicate a credible causal link in which low serum albumin levels are associated with delayed healing and a heightened risk of amputation in patients with diabetic foot ulcers. Moreover, addressing hypoalbuminemia may improve wound healing outcomes.

## CONCLUSION

This prospective study revealed a high prevalence of hypoalbuminemia in patients with diabetic foot ulcers, which is significantly linked to adverse wound healing outcomes. A significant percentage of patients exhibited low baseline serum albumin levels, and individuals with reduced albumin levels


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demonstrated a higher likelihood of experiencing delayed healing or necessitating amputation. Hypoalbuminemia is an established, modifiable risk factor that adversely affects wound healing in diabetic foot ulcers (DFUs). This condition is primarily associated with malnutrition, greater inflammation, and inadequate granulation tissue formation. Serum albumin levels below 3.5 g/dL are consistently correlated with increased rates of non-healing and delayed recovery following both conservative and surgical interventions for DFUs. The integration of nutritional rehabilitation, which includes sufficient protein intake and, when necessary, oral or enteral supplements, alongside glycemic optimization and infection control, is essential in addressing non-healing ulcers in diabetes mellitus.

**Limitations:** A larger sample size may be deemed necessary for the generalization of results. The outcomes were assessed through clinical examination, including the presence of healing signs. The nutritional intervention involved providing health education to ensure that each patient adhered to a high protein diet; however, subjective findings may differ among individuals.

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