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Research Article

Role of HbA1c as a Predictor in Healing of Diabetic Foot Ulcer (DFU) at a Tertiary Care Hospital: A Prospective Observational Study

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) represent a significant complication of diabetes mellitus, often leading to amputation and substantial morbidity. Glycemic control, as measured by glycosylated hemoglobin (HbA1c), may influence wound healing outcomes in diabetic patients.
Objective: To assess the healing rate of diabetic foot ulcers in patients with different HbA1c levels and evaluate associated risk factors leading to delayed wound healing.
Methods: This prospective observational study was conducted at Mandya Institute of Medical Sciences over one year, involving 168 patients with type 2 diabetes mellitus and diabetic foot ulcers (Wagner grades 1 and 2). Patients were divided into three groups based on HbA1c levels: Group 1 (<7%), Group 2 (7-8%), and Group 3 (>8%). Wound healing was assessed by area reduction over 15 days using digital photography and tissue analytics software. The rate of wound healing was calculated as area reduction per day.
Results: The study included 127 males (75.6%) and 41 females (24.4%) with a mean age of 56±11 years. Group 1 (n=55) showed the highest mean area reduction (10.8±3.8 cm^2) and healing rate (0.72±0.26 cm^2/day), followed by Group 2 (n=60) with area reduction of 10.1±3.1 cm^2 and healing rate of 0.67±0.2 cm^2/day, and Group 3 (n=53) with the lowest area reduction (6.2±3.7 cm^2) and healing rate (0.4±0.24 cm^2/day) ($p<0.001$). Strong negative correlations were observed between HbA1c levels and both area reduction ($r=-0.566$, $p<0.001$) and healing rate ($r=-0.578$, $p<0.001$).
Conclusion: Higher HbA1c levels were significantly associated with slower diabetic foot ulcer healing. HbA1c can serve as a reliable predictor of wound healing outcomes in diabetic patients, emphasizing the importance of optimal glycemic control in DFU management.

Keywords*: diabetic foot ulcer, glycosylated hemoglobin, HbA1c, wound healing, diabetes mellitus, glycemic control.*

INTRODUCTION

Diabetes mellitus (DM) has emerged as one of the most pressing global health challenges of the 21st century, affecting approximately 537 million adults worldwide as of 2021, with projections indicating this number could reach 783 million by 2045 (1). The prevalence of diabetes in India has shown a particularly alarming trajectory, with current estimates suggesting that over 77 million individuals are living with the condition, making India the country with the second-highest number of people with diabetes globally (2). This epidemic proportions of diabetes have been accompanied by a corresponding increase in diabetes-related complications, among which diabetic foot ulcers (DFUs) represent one of the most devastating and costly manifestations.

Diabetic foot ulcers affect approximately 15-25% of individuals with diabetes during their lifetime and are responsible for more than 80% of non-traumatic lower limb amputations (3). The annual incidence of DFUs ranges from 1.0% to 4.1% globally, with significant variations across different populations and healthcare settings (4). The economic burden associated with DFU management is substantial, with treatment costs often exceeding those of many common cancers, primarily due to the chronic nature of these wounds and their propensity for recurrence (5).

The pathophysiology of diabetic foot ulceration is multifactorial, involving a complex interplay of neuropathy, peripheral arterial disease, immune dysfunction, and impaired wound healing mechanisms (6). Diabetic peripheral neuropathy, affecting up to 50% of individuals with diabetes, leads to loss of protective sensation, making patients vulnerable to repetitive trauma and mechanical stress. Concurrently, peripheral arterial disease, present in approximately 25-35% of diabetic patients, compromises tissue perfusion and oxygen delivery, creating an environment unfavorable for wound healing (7).

The wound healing process in diabetic patients is characterized by prolonged inflammatory phases, impaired angiogenesis, reduced collagen synthesis, and altered cellular migration and proliferation (8). These alterations are primarily attributed to the effects of hyperglycemia on various cellular and molecular processes. Persistent elevation in blood glucose levels leads to the formation of advanced glycation end products (AGEs), which cross-link with collagen and other matrix proteins, altering their mechanical properties and reducing their susceptibility to enzymatic degradation (9). Additionally, hyperglycemia impairs neutrophil function, reduces growth factor availability, and promotes the formation of reactive oxygen species, all of which contribute to delayed wound healing (10).

Glycosylated hemoglobin (HbA1c) has become the gold standard for assessing long-term glycemic control in diabetic patients, providing a reliable measure of average blood glucose levels over the preceding 8-12 weeks (11). The American Diabetes Association recommends maintaining HbA1c levels below 7% for most adult patients with diabetes to minimize the risk of microvascular complications (12). However, the relationship between HbA1c levels and wound healing outcomes in diabetic foot ulcers has yielded conflicting results in the literature, with some studies demonstrating a clear association while others have failed to establish a significant correlation.

Several landmark studies have investigated the relationship between glycemic control and diabetic complications. The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) established that intensive glycemic control significantly reduces the risk of microvascular complications, including neuropathy, which is a primary risk factor for DFU development (13). However, the direct impact of HbA1c on wound healing rates has been less consistently demonstrated.

A study by Christman et al. involving 183 diabetic patients found that for each 1% increase in HbA1c, the daily wound area healing rate decreased by 0.028 cm^2/day (14). Similarly, Markuson et al. demonstrated that while healing occurred regardless of HbA1c levels, ulcers in patients with higher HbA1c values took significantly longer to heal (15). Conversely, some studies have reported minimal or no association between baseline HbA1c levels and healing outcomes, suggesting that other factors may play more prominent roles in determining wound healing success.

The inconsistencies in the literature may be attributed to several factors, including variations in study design, patient populations, wound characteristics, treatment protocols, and outcome measures. Additionally, the complex nature of wound healing in diabetic patients involves multiple variables beyond glycemic control, including the presence of infection, arterial insufficiency, wound depth, patient age, and nutritional status.

Understanding the role of HbA1c as a predictor of wound healing in diabetic foot ulcers has significant clinical implications. If a clear relationship exists, HbA1c could serve as a valuable prognostic tool for healthcare providers, enabling them to stratify patients according to their likelihood of healing success and adjust treatment strategies accordingly. This could potentially lead to more personalized care approaches, with intensive glycemic management being prioritized in patients with poor wound healing prospects.

Furthermore, establishing HbA1c as a reliable predictor could inform clinical decision-making regarding the timing and extent of interventions, resource allocation, and patient counseling. In healthcare systems with limited resources, such predictive capabilities could help optimize the distribution of specialized wound care services and guide decisions regarding more aggressive interventions, including surgical debridement or advanced wound care products.

The current study aims to address the gaps in the existing literature by conducting a comprehensive prospective analysis of the relationship between HbA1c levels and wound healing rates in a well-characterized population of diabetic patients with foot ulcers. By employing standardized outcome measures and controlling for potential confounding variables, this research seeks to provide clarity on the predictive value of HbA1c in diabetic wound healing and contribute to evidence-based clinical practice guidelines for DFU management.

AIMS

The primary objectives of this study were:

1. To assess the healing rate of diabetic foot ulcers in patients with different levels of HbA1c
2. To evaluate the associated risk factors leading to delayed wound healing in diabetic patients
3. To establish the correlation between HbA1c levels and wound healing outcomes in diabetic foot ulcers

MATERIALS AND METHODS

Study Design and Setting
This prospective observational study was conducted in the Department of General Surgery at Mandya Institute of Medical Sciences (MIMS), Mandya, Karnataka, India, over a period of one year from 2022 to 2023. The study was approved by the Institutional Ethics Committee of MIMS, Mandya, and written informed consent was obtained from all participants in their preferred language.

Sample Size Calculation
The sample size was calculated using the formula: $N = 2[Z\alpha/2 + Z\beta]^2 \times \sigma^2/d^2$, where $Z\alpha/2 = 1.96$ (standard normal variable), $Z\beta = 0.84$ (power of test = 80%), $\mu1 = 39$, $\mu2 = 46.5$, $\sigma = 17.317$, and $d = \mu1 - \mu2$. The calculated sample size was 84 patients per group, totaling 168 patients distributed across three groups of 56 each based on HbA1c levels.

Sampling Method
Purposive sampling was employed to recruit patients meeting the inclusion criteria during the study period.

Inclusion Criteria
The inclusion criteria were: (1) patients with type 2 diabetes mellitus presenting with diabetic foot ulcers, (2) Wagner classification grades 1 and 2 ulcers, (3) age less than 80 years, and (4) provision of informed written consent.

Exclusion Criteria
Patients were excluded if they had: (1) pregnancy, (2) age greater than 80 years, (3) serum creatinine >2 mg/dl, (4) diabetic foot ulcers of Wagner grades 3, 4, or 5, (5) known peripheral vascular disease, (6) hypoproteinemia, (7) hemoglobin <10 g%, or (8) trophic ulcers of non-diabetic etiology.

Patient Grouping
Patients were stratified into three groups based on their admission HbA1c levels: Group 1 (HbA1c <7%), Group 2 (HbA1c 7-8%), and Group 3 (HbA1c >8%). HbA1c measurements were performed using high-performance liquid chromatography (HPLC) in the hospital's biochemistry laboratory.

Data Collection and Clinical Assessment
Comprehensive clinical histories were obtained, including demographic information, duration of diabetes, ulcer characteristics, and comorbidities. Physical examination included assessment of ulcer size, location, depth, and surrounding tissue condition. Neurological evaluation was performed using Semmes-Weinstein monofilament testing for protective sensation assessment.

Laboratory Investigations
All patients underwent comprehensive laboratory evaluation including complete blood count, fasting blood glucose, postprandial blood glucose, HbA1c, liver function tests, renal function tests, and wound culture and sensitivity testing where indicated.

Wound Assessment and Measurement
Digital photographs of ulcers were captured using the Tissue Analytics software application installed on an Android smartphone. A standardized green circular sticker of 1 cm^2 area was placed adjacent to each wound to serve as a reference scale. Photographs were taken on day 0 (study initiation) and day 14 (study completion). The software automatically calculated wound length, width, and area measurements.

Wound Management Protocol
All patients received standardized wound care consisting of daily normal saline irrigation followed by povidone-iodine application and appropriate dressing. Systemic antibiotic therapy was administered based on culture and sensitivity results when infection was present. All patients were maintained on insulin therapy for glycemic control during hospitalization.

Outcome Measures
The primary outcome measure was the rate of wound healing, calculated as area reduction per day using the formula: Rate of healing = (Initial area - Final area)/15 days. Secondary outcome measures included total area reduction and factors associated with delayed healing.

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using SPSS software version 22. Descriptive statistics including mean, standard deviation, and percentages were calculated for quantitative and categorical variables respectively. The correlation between HbA1c levels and healing parameters was assessed using Pearson correlation analysis. Analysis of variance (ANOVA) and Student's unpaired t-test were employed for group comparisons. Chi-square tests were used to assess associations between categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic Characteristics

The study included 168 patients with diabetic foot ulcers, comprising 127 males (75.6%) and 41 females (24.4%). The mean age of the study population was 56±11 years, with no significant difference observed between the three HbA1c groups (p=0.0961). Group 1 had a mean age of 57±13 years, Group 2 had 56±10 years, and Group 3 had 55±11 years.

HbA1c Distribution and Clinical Parameters

Among the 168 patients, 55 (32.7%) were classified into Group 1 (HbA1c <7%), 60 (35.7%) into Group 2 (HbA1c 7-8%), and 53 (31.5%) into Group 3 (HbA1c >8%). The mean HbA1c values were 6.5±0.4% for Group 1, 7.6±0.3% for Group 2, and 12.1±1.9% for Group 3 (p<0.001). Corresponding fasting blood glucose levels were 151±41 mg/dl, 160±38 mg/dl, and 212±58 mg/dl respectively (p<0.001).

Ulcer Characteristics and Distribution

Table 1: Demographic and Clinical Characteristics by HbA1c Groups

Characteristic	Group 1 (<7% HbA1c) n=55	Group 2 (7-8% HbA1c) n=60	Group 3 (>8% HbA1c) n=53	p-value
Age (years)	57±13	56±10	55±11	0.0961
Male gender	48 (87.3%)	41 (68.3%)	38 (71.7%)	0.0450
Duration of diabetes (years)	9±6	10±7	10±6	0.8366
Body Mass Index	25±4	24±3	24±3	0.0961
Hemoglobin (g/dl)	12.1±2.1	11.5±1.6	11.3±1.7	0.0672
Creatinine (mg/dl)	1.2±0.5	1.1±0.3	1.1±0.4	0.0664

The mode of ulcer onset showed significant variation between groups (p=0.0020). Spontaneous onset was most common in Group 1 (54.5%), while trauma-related onset predominated in Groups 2 and 3 (46.7% and 34.0% respectively). Pressure-related ulcers were more frequent in Groups 2 and 3 compared to Group 1.

Table 2: Ulcer Characteristics by HbA1c Groups

Characteristic	Group 1 (<7% HbA1c) n=55	Group 2 (7-8% HbA1c) n=60	Group 3 (>8% HbA1c) n=53	p-value
Onset Mode				0.0020
Spontaneous	30 (54.5%)	17 (28.3%)	21 (39.6%)	
Trauma	23 (41.8%)	28 (46.7%)	18 (34.0%)	
Pressure	2 (3.6%)	12 (20.0%)	14 (26.4%)	
Site				0.0090
Dorsum	31 (56.4%)	33 (55.0%)	16 (30.2%)	
Plantar	24 (43.6%)	27 (45.0%)	37 (69.8%)	
Wagner Grade				0.0150
Grade 1	26 (47.3%)	22 (36.7%)	11 (20.8%)	
Grade 2	29 (52.7%)	38 (63.3%)	42 (79.2%)	

The anatomical distribution of ulcers showed significant differences between groups (p=0.0090). Dorsal ulcers were more common in Groups 1 and 2 (56.4% and 55.0% respectively), while plantar ulcers predominated in Group 3 (69.8%). Wagner grading revealed a significant association with HbA1c levels (p=0.0150), with higher proportions of Grade 2 ulcers observed in patients with elevated HbA1c levels.

Comorbidities and Associated Factors

Hypertension was present in 78 patients (46.4%) with no significant difference between groups (p=0.8212). Diabetic neuropathy was diagnosed in 69 patients (41.1%), showing a trend toward higher prevalence in Groups 2 and 3, though this did not reach statistical significance (p=0.1700).

Table 3: Microbiological Profile by HbA1c Groups

Organism	Group 1 (<7% HbA1c) n=55	Group 2 (7-8% HbA1c) n=60	Group 3 (>8% HbA1c) n=53	Total n=168
No growth	38 (69.1%)	26 (43.3%)	14 (26.4%)	78 (46.4%)
Staphylococcus	6 (10.9%)	6 (10.0%)	2 (3.8%)	14 (8.3%)

Organism	Group 1 (<7% HbA1c) n=55	Group 2 (7-8% HbA1c) n=60	Group 3 (>8% HbA1c) n=53	Total n=168
MRSA	5 (9.1%)	1 (1.7%)	5 (9.4%)	11 (6.5%)
E. coli	1 (1.8%)	7 (11.7%)	6 (11.3%)	14 (8.3%)
Pseudomonas	3 (5.5%)	6 (10.0%)	8 (15.1%)	17 (10.1%)
Others	2 (3.6%)	14 (23.3%)	18 (34.0%)	34 (20.2%)

Microbiological analysis revealed significant differences in culture positivity between groups (p=0.0010). Group 1 showed the highest proportion of culture-negative cases (69.1%), while Groups 2 and 3 demonstrated increasing rates of bacterial colonization, with Pseudomonas aeruginosa showing a particularly notable increase in prevalence with higher HbA1c levels.

Wound Healing Outcomes

Table 4: Wound Healing Parameters by HbA1c Groups

Parameter	Group 1 (<7% HbA1c) n=55	Group 2 (7-8% HbA1c) n=60	Group 3 (>8% HbA1c) n=53	p-value
Initial area (cm²)	585.2±615.6	460.4±337.9	480.4±304.4	0.0832
Final area (cm²)	574.5±617.0	450.4±338.7	474.2±306.2	0.0592
Area reduction (cm²)	10.8±3.8	10.1±3.1	6.2±3.7	<0.001
Healing rate (cm²/day)	0.72±0.26	0.67±0.20	0.40±0.24	<0.001

The primary outcome measures demonstrated highly significant differences between groups. Group 1 achieved the highest mean area reduction of 10.8±3.8 cm² and healing rate of 0.72±0.26 cm²/day. Group 2 showed intermediate values with area reduction of 10.1±3.1 cm² and healing rate of 0.67±0.20 cm²/day. Group 3 demonstrated the poorest healing outcomes with area reduction of 6.2±3.7 cm² and healing rate of 0.40±0.24 cm²/day. Both parameters showed statistically significant differences between groups (p<0.001).

Table 5: Correlation Analysis Between HbA1c and Healing Parameters

Parameter	Pearson Correlation Coefficient	p-value
Area reduction	-0.566	<0.001
Healing rate per day	-0.578	<0.001
Initial wound area	-0.068	0.380
Final wound area	-0.063	0.418

Correlation analysis revealed strong negative correlations between HbA1c levels and both area reduction (r=-0.566, p<0.001) and healing rate per day (r=-0.578, p<0.001). No significant correlations were observed between HbA1c and initial or final wound areas, indicating that the association was specifically related to healing capacity rather than baseline wound characteristics.

Laboratory Parameters

Total leukocyte count showed a trend toward higher values in Groups 2 and 3 (13,480±5,595 and 13,377±6,499 cells/μL respectively) compared to Group 1 (11,376±6,033 cells/μL), though this difference did not reach statistical significance (p=0.0727). Hemoglobin levels were slightly higher in Group 1 (12.1±2.1 g/dl) compared to Groups 2 and 3 (11.5±1.6 and 11.3±1.7 g/dl respectively), with a trend toward significance (p=0.0672).

DISCUSSION

This prospective observational study provides compelling evidence for the role of HbA1c as a significant predictor of wound healing outcomes in diabetic foot ulcers. The findings demonstrate a clear inverse relationship between glycemic control and healing rates, with patients maintaining HbA1c levels below 7% achieving superior healing outcomes compared to those with suboptimal glycemic control.

The demographic characteristics of our study population align with previous epidemiological data on diabetic foot ulcers. The male predominance (75.6%) observed in our cohort is consistent with several large-scale studies, including the work by Singh et al., who reported a similar gender distribution with males accounting for approximately 70-80% of DFU cases

(16). This male preponderance has been attributed to occupational factors, lifestyle patterns, and potentially delayed healthcare-seeking behavior among men.

The mean age of 56±11 years in our study population corresponds with the peak incidence of diabetic complications, as reported in the International Diabetes Federation's global estimates (17). The absence of significant age differences between HbA1c groups suggests that the observed healing differences were primarily attributable to glycemic control rather than age-related factors, strengthening the validity of our findings.

Our primary finding of a strong negative correlation between HbA1c levels and wound healing rates ($r=-0.578$, $p<0.001$) is consistent with several recent investigations. Christman et al., in their retrospective analysis of 183 diabetic patients, reported that each 1% increase in HbA1c was associated with a 0.028 cm^2/day decrease in healing rate ($p=0.027$) (14). Similarly, our study demonstrated that patients with HbA1c levels above 8% had healing rates of 0.40±0.24 cm^2/day compared to 0.72±0.26 cm^2/day in those with HbA1c below 7%, representing an approximately 44% reduction in healing capacity.

The mechanistic basis for impaired wound healing in hyperglycemic conditions has been extensively studied. Falanga et al. demonstrated that elevated glucose levels interfere with multiple phases of wound healing, including inflammatory cell function, angiogenesis, collagen synthesis, and epithelialization (18). Advanced glycation end products (AGEs), formed through non-enzymatic glycation of proteins in hyperglycemic environments, have been shown to cross-link with collagen and alter the extracellular matrix composition, thereby impeding normal tissue repair processes (19).

Our observation of increased bacterial colonization in patients with higher HbA1c levels aligns with established knowledge regarding diabetes-associated immunosuppression. The culture positivity rate increased from 30.9% in Group 1 to 73.6% in Group 3, with a notable predominance of Gram-negative organisms, particularly Pseudomonas aeruginosa, in patients with poor glycemic control. This finding is consistent with the work of Citron et al., who reported that hyperglycemia impairs neutrophil chemotaxis, phagocytosis, and bacterial killing capacity (20).

The association between ulcer location and HbA1c levels observed in our study provides additional clinical insights. Plantar ulcers were significantly more common in patients with HbA1c levels above 8% (69.8% vs. 43.6% in Group 1), possibly reflecting the greater degree of neuropathy and altered foot biomechanics associated with prolonged hyperglycemia. This finding is supported by the work of Boulton et al., who demonstrated that peripheral neuropathy severity correlates with glycemic control duration and intensity (21).

The Wagner grading distribution in our study revealed a significant association between ulcer severity and HbA1c levels ($p=0.0150$). Grade 2 ulcers (involving tendon, bone, or joint) were more prevalent in patients with higher HbA1c levels, suggesting that poor glycemic control may predispose to deeper, more severe ulcerations. This observation is consistent with the findings of Oyibo et al., who reported that patients with HbA1c levels above 7.5% had a significantly higher incidence of severe foot complications requiring surgical intervention (22).

However, our findings contrast with some previous investigations. Fesseha et al., in a retrospective analysis of 270 participants with 584 wounds, found no significant association between baseline HbA1c and wound healing in either univariate or fully adjusted models (23). The authors suggested that factors other than glycemic control, such as arterial perfusion, infection status, and wound care protocols, might play more prominent roles in determining healing outcomes. These discrepancies may be attributed to differences in study design, patient selection criteria, wound management protocols, and outcome measurement methods.

The correlation between HbA1c variability and healing outcomes has been explored by Dhatariya et al., who found that patients with low HbA1c variability healed significantly faster than those with high variability (78.0 vs. 126.9 days, $p=0.032$) (24). While our study focused on single-point HbA1c measurements, the strong correlations observed suggest that even cross-sectional glycemic assessment can provide valuable prognostic information.

The clinical implications of our findings are substantial. The ability to stratify patients based on HbA1c levels could inform treatment planning, resource allocation, and patient counseling. Patients with HbA1c levels above 8% may benefit from more intensive glycemic management, frequent wound assessment, and early consideration of advanced wound care modalities. Conversely, patients with optimal glycemic control may be candidates for more conservative management approaches.

The economic implications of these findings are equally important. Given that DFU treatment costs can exceed $50,000 per episode in developed healthcare systems (25), the ability to predict healing outcomes could facilitate more efficient resource utilization. Patients with poor predicted healing based on HbA1c levels might benefit from early referral to specialized wound care centers or consideration of more aggressive interventions.

Our study has several limitations that merit consideration. The 15-day observation period, while providing standardized outcome assessment, may not capture long-term healing patterns or recurrence rates. Additionally, the single-center design

may limit generalizability to other populations or healthcare settings. The exclusion of patients with severe peripheral vascular disease, while reducing confounding variables, may limit applicability to the broader DFU population where vascular compromise is common.

Future research directions should include longer-term follow-up studies to assess healing completion rates, recurrence patterns, and amputation outcomes. Investigation of interventions to optimize glycemic control in the acute wound care setting could provide valuable therapeutic insights. Additionally, exploring the role of continuous glucose monitoring in wound care management represents an emerging area of interest.

CONCLUSION

This prospective observational study provides robust evidence that HbA1c serves as a reliable predictor of wound healing outcomes in diabetic foot ulcers. Patients with HbA1c levels below 7% demonstrated significantly superior healing rates compared to those with suboptimal glycemic control. The strong negative correlations observed between HbA1c levels and both area reduction and healing rates underscore the critical importance of maintaining optimal glycemic control in diabetic patients with foot ulcerations.

The findings support the implementation of HbA1c-based risk stratification in clinical practice, enabling healthcare providers to identify patients at risk for delayed healing and implement appropriate interventions. The increased bacterial colonization observed in patients with elevated HbA1c levels further emphasizes the multifactorial benefits of glycemic optimization in wound care.

Healthcare providers should prioritize intensive glycemic management as an integral component of diabetic foot ulcer treatment protocols. The establishment of HbA1c as a predictor of healing outcomes can facilitate evidence-based clinical decision-making, improve resource allocation, and ultimately enhance patient outcomes in this challenging clinical scenario.

These results contribute to the growing body of evidence supporting the central role of glycemic control in diabetic wound healing and provide a foundation for developing more personalized, predictive approaches to diabetic foot ulcer management. The implementation of these findings in clinical practice has the potential to improve healing rates, reduce complications, and decrease the substantial burden associated with diabetic foot complications.

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