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Exploring the Determinants of Diabetic Foot Ulcer Healing: A 12-Month Longitudinal Study

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Abstract

Background: Diabetic foot infections (DFI) are a major complication of diabetes mellitus, contributing significantly to morbidity, amputation, and mortality. Multiple factors, including glycemic control, smoking status, and comorbidities such as neuropathy and peripheral artery disease, influence the healing process of diabetic foot ulcers (DFU). While cross-sectional studies have explored these factors, longitudinal studies are needed to observe how these variables affect the healing process over time.

Purpose: To identify clinical, demographic, and lifestyle factors that influence the healing of diabetic foot infections over 12 months in patients at Hospital Nurhayati Garut.

Methods: This prospective longitudinal study included 130 diabetic patients diagnosed with type 1 or type 2 diabetes mellitus and a diabetic foot ulcer of Wagner grade 2 or higher. Patients were followed over 12 months with data collection at baseline, 3, 6, and 12 months. Variables collected included demographics (age, sex), clinical characteristics (glycemic control, smoking status, infection severity, comorbidities), and treatment regimens. Kaplan-Meier survival analysis, Cox proportional hazards regression, and Generalized Estimating Equations (GEE) were used to analyze predictors of wound healing.

Results: The mean age of participants was 58.7 years, with 53.8% male and 65.4% having type 2 diabetes. Smoking was present in 38.5% of patients. The analysis revealed that increased HbA1c levels (hazard ratio [HR], 1.22; 95% CI, 1.10-1.35) and smoking (HR, 0.58; 95% CI, 0.40-0.83) were significant predictors of delayed wound healing. Older age (HR, 1.04; 95% CI, 1.02-1.06) was also associated with a longer time to healing. Infection severity did not show a significant impact on healing. Advanced wound care therapies demonstrated a 10% reduction in healing time compared to standard care ($p = 0.04$).

Conclusion: Glycemic control, smoking cessation, and age were significant predictors of wound healing in diabetic foot ulcers. The findings emphasize the importance of managing modifiable risk factors, particularly glycemic control and smoking, to improve healing outcomes in diabetic patients. Advanced wound care therapies were beneficial, but optimal outcomes require comprehensive management addressing lifestyle factors.

Keywords: diabetic foot, glycemic control, smoking, wound healing

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Introduction

Diabetic foot infections (DFI) are a prevalent and severe complication of diabetes mellitus that significantly impacts patients' quality of life and healthcare systems globally (Boulton et al., 2021; Dinh et al., 2022). The increasing global prevalence of diabetes, with an estimated 15-25% of diabetic patients experiencing diabetic foot ulcers (DFU) during their lifetime, highlights the scale of the issue (Michaud et al., 2020; Singh et al., 2021). DFIs often lead to severe consequences such as amputation, prolonged hospitalization, and higher mortality rates, especially in cases where proper care and management are lacking (Faglia et al., 2021; Reiber et al., 2020). Diabetic foot infections are primarily caused by a combination of factors, including neuropathy, poor circulation, and immunosuppression, which make diabetic patients more susceptible to infections (Jing et al., 2021). Several factors influence the healing of diabetic foot ulcers, including glycemic control, infection severity, and comorbidities such as peripheral artery disease (PAD), neuropathy, and chronic kidney disease (Gutiérrez et al., 2022; Boulton et al., 2022).

Keywords: diabetic foot ulcer, glycemic control, insulin therapy, psychosocial support, wound

Glycemic control has been widely recognized as a critical determinant, as hyperglycemia impairs collagen synthesis and immune function, both essential for wound healing (Michaud et al., 2020). Smoking has also been identified as a significant risk factor for delayed wound healing, as it reduces blood flow, decreases oxygen supply to tissues, and impairs immune responses (Dinh et al., 2022; Palumbo et al., 2020).

Despite the known impact of these factors on wound healing, most studies have been cross-sectional, providing only a snapshot of the healing process (Gokce et al., 2020). Longitudinal studies are required to observe the dynamic changes in wound healing and to identify predictors of healing over time (Cukierman-Yaffe et al., 2021; Armstrong et al., 2021). This study aims to identify clinical, demographic, and lifestyle factors that influence the healing of diabetic foot infections by following 130 patients at Hospital Nurhayati Garut, Thailand, over a 12-month period. By doing so, we hope to fill the gaps in current knowledge and improve the management strategies for diabetic foot infections (Mahendra 2024; Burhan et al., 2023).

The findings from this study are expected to offer valuable insights into the management of diabetic foot infections, particularly in regions with limited healthcare resources. By focusing on modifiable factors such as glycemic control and smoking cessation, this study could inform more targeted interventions to enhance healing outcomes and reduce complications such as amputations (Boulton et al., 2021; Armstrong et al., 2021). These findings could have global implications, especially for healthcare systems facing challenges in treating chronic conditions like diabetes (Singh et al., 2022; Bakker et al., 2020).This longitudinal study is particularly relevant in Thailand, where diabetes prevalence is increasing rapidly, and healthcare resources for chronic disease management are often limited (Jing et al., 2021). The results of this study will contribute to the development of evidence-based practices that can improve patient outcomes globally (Turner et al., 2020).

Method

Study Design

This is a prospective longitudinal study conducted at Hospital Nurhayati Garut, Indonesia, where 350 diabetic foot ulcer patients were initially enrolled. After applying inclusion and exclusion criteria, a total of 130 patients were selected for final analysis. The patients were followed for a period of 12 months, with data collected at specific 12 months. The longitudinal nature of the study allows for tracking the healing process of diabetic foot ulcers over these key intervals, providing insights into how various factors impact healing rates over time.

Inclusion and exclusion criteria

The study included patients who met the following criteria: diagnosed with Type 1 or Type 2 diabetes mellitus for at least 5 years, ensuring that participants had a sufficient duration of diabetes to potentially experience chronic complications like diabetic foot ulcers. Additionally, participants had to have a diabetic foot ulcer classified as Wagner grade 2 or higher, which indicates ulcers that are deep and may involve more severe tissue damage. The study was restricted to individuals aged between 40 and 75 years, as this age group typically experiences a higher incidence of diabetes-related complications. Lastly, all participants had to be capable of providing informed consent, ensuring they understood the study's purpose and procedures. Exclusion Criteria: Patients were excluded from the study if they had active cancer or any life-threatening conditions, as these could significantly interfere with wound healing and introduce confounding variables. Additionally, patients who were unable to attend regular follow-up visits were excluded, as consistent follow-up is crucial for accurate monitoring of wound healing progress and adherence to the study protocol. This exclusion criterion ensured that only participants who could reliably comply with the study's demands were included.

Data Collection

Data were systematically collected at baseline and at three-month intervals over the course of the 12-month study. The data collection at 1 month, 3 months, and 6 months included several key variables: demographics such as age, sex, duration of diabetes, smoking status, and the presence of comorbidities like hypertension, dyslipidemia, and renal disease; clinical factors including ulcer size, infection severity, and laboratory measures such as HbA1c levels and C-reactive protein to assess glycemic control and systemic inflammation; and the treatment regimen, which included data on wound care interventions such as debridement, antibiotics, and advanced therapies. Key outcome measures were also recorded, including the time to wound healing, recurrence rates, amputation rates, and the incidence of complications, which were tracked at each of the three follow-up points.

Statistical Analysis

The data were analyzed using a range of statistical methods. Descriptive statistics were used to summarize the baseline characteristics of the study population at each time point, providing a clear overview of the participants' health status and risk factors. To analyze the time to wound healing, Kaplan-Meier survival analysis was employed,

which estimates the probability of wound healing over time at 1 month, 3 months, and 6 months. Cox proportional hazards regression was used to identify the significant predictors of wound healing, including variables such as age, glycemic control, smoking status, and infection severity. This regression model provided hazard ratios (HR), indicating the relative risk of delayed healing for each factor. Lastly, Generalized Estimating Equations (GEE) were used to account for repeated measures taken from the same patients over time. GEE is ideal for longitudinal studies with multiple measurements from each participant, as it adjusts for correlations within the data and provides robust estimates of the relationships between treatment, clinical factors, and healing outcomes

Results

Table 1. Demographics and Clinical Characteristics of Study Participants

Variable	Mean (SD) / n (%)	p-value (Homogeneity)
Age (Years)	58.7 (±8.9)	0.12
Gender (Male: Female)	70 (53.8%): 60 (46.2%)	0.25
Type of Diabetes (Type 1: Type 2)	45 (34.6%): 85 (65.4%)	0.11
Smoking Status (Yes: No)	50 (38.5%): 80 (61.5%)	0.04
Comorbidities (Hypertension: Renal Disease)	60 (46.2%): 45 (34.6%)	0.23

Interpretation: Table 1 shows the baseline characteristics of the 130 patients. The mean age of participants was 58.7 years, with a higher proportion of males (53.8%). Type 2 diabetes was more prevalent, comprising 65.4% of the participants. Smoking was present in 38.5% of patients, and 46.2% had comorbid hypertension, which is consistent with diabetes-related cardiovascular complications. The p-value for smoking status (0.04) indicates a significant difference between smokers and non-smokers in terms of wound healing, suggesting that smoking may hinder the healing process (Table 1)

Table 2. Cox Regression Model for Predictors of Wound Healing

Variable	Hazard Ratio (HR)	95% CI	p-value
Age	1.04	1.02-1.06	0.01
HbA1c	1.22	1.10-1.35	0.001
Smoking Status	0.58	0.40-0.83	0.004
Infection Severity	0.92	0.80-1.05	0.14

Interpretation: Table 2 reveals the key factors influencing wound healing. Age and HbA1c are significant predictors, with each additional year of age associated with a 4% increase in the time to wound healing. Higher HbA1c levels also significantly delay healing, with a 22% increased risk for slower healing. Smoking status was found to be a strong negative predictor, with smokers having a 42% lower chance of healing within the same time frame as non-smokers ($p = 0.004$). Infection severity, although negatively correlated, did not reach statistical significance (Table 2)

Table 3. Generalized Estimating Equation (GEE) Model for Wound Healing

Variable	Estimate (β)	Standard Error	p-value
Age	0.05	0.02	0.01
HbA1c	0.13	0.06	0.02
Infection Severity	0.08	0.04	0.06
Treatment Regimen (Advanced vs Standard)	-0.10	0.05	0.04

Interpretation: The GEE analysis (Table 3) further confirms that age and glycemic control are the most significant factors influencing wound healing. For every additional year of age, healing time is delayed by approximately 5%. Each 1% increase in HbA1c corresponds to a 13% longer healing time. The treatment regimen showed a small but significant advantage for advanced wound care techniques, reducing healing time by 10% compared to standard care ($p = 0.04$). Infection severity did not reach statistical significance, but the trend suggests it may influence healing in more complex cases (Table 3).

Table 4. Interaction of Variables with Hazard Ratios and Confidence Intervals

Variable	Hazard Ratio (HR)	95% CI	p-value
Age x Smoking Status	1.06	1.02-1.11	0.02
HbA1c x Smoking Status	1.28	1.10-1.49	0.002
Infection Severity x Treatment	1.12	1.01-1.25	0.04

Interpretation: Table 4 shows the interaction effects between key variables. The interaction between age and smoking status indicates that the negative impact of smoking on healing is greater in older patients, with a 6% increased risk of delayed healing for each additional year of age. The interaction between HbA1c and smoking

status also shows a significant compounded effect, with smokers having a 28% higher likelihood of delayed healing for every 1% increase in HbA1c. The interaction between infection severity and treatment regimen suggests that advanced therapies may help mitigate the negative effects of severe infections on healing times (Table 4)

Discussion

The results of this study align with previous research that suggests glycemic control, smoking, and age are critical factors influencing the healing of diabetic foot ulcers. Glycemic control remains one of the most significant predictors of wound healing, with elevated HbA1c levels consistently associated with delayed healing times (Michaud et al., 2020; Cukierman-Yaffe et al., 2021). Studies have shown that even small reductions in HbA1c levels can lead to improved wound healing and reduced complications, emphasizing the need for better blood glucose management in diabetic patients (Fried et al., 2020; Gutiérrez et al., 2022). Furthermore, smoking has been well-documented as a major risk factor for delayed wound healing due to its negative impact on blood circulation and immune function (Singh et al., 2021; Gokce et al., 2020). Our findings confirm that smoking significantly impairs wound healing, with smokers showing longer healing times than non-smokers.

The interaction between smoking and poor glycemic control in delaying wound healing is notable (Mahendra 2024; Elian 2024). As shown in previous studies, the combined effect of these factors exacerbates the impairment in wound healing (Dinh et al., 2022; Palumbo et al., 2020). Smoking not only reduces oxygenation but also increases the risk of infections, further complicating the wound healing process (Singh et al., 2021). Our study underscores the need for healthcare providers to focus on smoking cessation programs and tighter glycemic control in their treatment strategies for diabetic foot patients (Boulton et al., 2022; Gutiérrez et al., 2022).

Interestingly, infection severity, while a factor in delayed healing, did not show a significant statistical association with healing in our study (Sebayang et al.m 2024; Burhan et al 2021). This finding may be attributed to the effective infection management protocols implemented at Hospital Nurhayati Garut, including appropriate antibiotic therapy and debridement (Boulton et al., 2021). The role of advanced wound therapies, such as bioengineered skin substitutes and negative pressure wound therapy, was also examined (Burhan et al., 2022; Ariani et al., 2024). While these therapies have shown promise in promoting healing, our study suggests that their impact may be limited if basic factors like glycemic control and smoking are not adequately managed (Armstrong et al., 2021; Zubair et al., 2020).

Age remains a significant predictor of wound healing. Older patients have a slower healing process due to the natural decline in regenerative capacities and immune function with age (Boulton et al., 2022). The results from our study reinforce the importance of targeted care in older populations, such as advanced therapies and more frequent monitoring, to ensure optimal healing outcomes (Faglia et al., 2021; Gutiérrez et al., 2022). Our findings highlight the growing need for personalized treatment regimens that address the unique challenges faced by older diabetic patients (Turner et al., 2020).

Finally, the role of advanced wound care therapies, while beneficial, was not sufficient to overcome the combined negative effects of smoking and poor glycemic control in our study. This indicates that while technology and advanced therapies can support healing, comprehensive management of lifestyle factors is crucial to optimizing outcomes in diabetic foot care (Gutiérrez et al., 2022; Zubair et al., 2020). Further studies with larger sample sizes and multi-center designs are needed to confirm these findings and develop more effective, personalized treatment strategies for diabetic foot infections.

Strengths And Limitations of The Study

One of the main strengths of this study is its prospective longitudinal design, which allowed the researchers to monitor changes in wound healing over a full year. This approach provided more accurate insights into how factors such as blood sugar levels, smoking habits, and age affect healing outcomes over time. The use of statistical models, including Cox regression and Generalized Estimating Equations (GEE), also helped ensure reliable analysis. However, the study had some limitations. It was conducted in a single hospital, which may limit how well the results apply to other settings. In addition, the study did not include information on psychological or behavioral aspects that may influence healing, such as patient motivation or treatment adherence

Implications on patient care and the profession

These findings have meaningful implications for both patient care and clinical practice. The results clearly show that controlling blood sugar and helping patients quit smoking can significantly improve the healing of diabetic foot ulcers. This suggests that healthcare providers should place more focus on lifestyle interventions alongside medical treatment. For nurses and other health professionals, the study highlights the importance of patient education, regular monitoring, and teamwork in managing diabetic wounds. These approaches can lead to better healing outcomes and reduce the risk of complications such as amputation

Conclusions

In conclusion, this study found that poor glycemic control, active smoking, and older age are key factors that delay the healing of diabetic foot ulcers. While advanced wound care methods offer some benefits, they are not enough on their own to ensure successful healing. To achieve better results, it is essential to address the root

causes, particularly blood sugar management and smoking cessation. These findings support the need for more comprehensive and personalized care strategies in diabetic wound management.

Author contribution

Hanan Ansari designed the study, coordinated data collection, and led the writing of the manuscript. Intan Habibi contributed to the study design, performed the statistical analysis, and reviewed relevant literature. Munafirah supported participant recruitment, data entry, and critical revision of the draft. All authors reviewed and approved the final version of the manuscript.

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None

Conflict of Interest Statement

The authors declare that there is no conflict of interest.

Data Availability

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request. Due to privacy concerns, individual patient data cannot be shared publicly.

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