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Clinical outcomes of an integrated wound care protocol for diabetic foot ulcers – a prospective study

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ABSTRACT

Introduction and aim. Diabetic foot ulcers (DFUs) are serious complications of diabetes, often leading to infection and amputation. This study evaluated the clinical outcomes of an integrated wound care protocol in patients with DFUs.

Material and methods. A prospective cohort study was conducted among 225 patients with type 2 diabetes and Wagner grade 1–3 DFUs at PKU Muhammadiyah Hospital, Indonesia, between February and September 2024. All patients received a standardized integrated wound care protocol, including wound bed preparation, debridement, infection control, moisture balance, nutritional counseling, patient education, and ulcer offloading. The primary outcome was complete wound healing at 12 weeks; secondary outcomes were wound area reduction, BWAT score improvement, pain reduction, and infection control.

Results. By week 12, 157 patients (69.8%) achieved complete healing. Mean wound area decreased from $6.8 \pm 3.2 \text{ cm}^2$ to $1.2 \pm 1.5 \text{ cm}^2$ ($p < 0.001$), BWAT scores improved from 28.4 ± 4.1 to 13.6 ± 3.8 ($p < 0.001$), and pain scores declined from 5.8 ± 1.6 to 2.1 ± 1.1 ($p < 0.001$). Infection prevalence dropped from 45.3% to 12.4% ($p < 0.001$). Healing was highest in Wagner grade 1 (83.1%), compared with grade 2 (69.7%) and grade 3 (47.1%).

Conclusion. The integrated wound care protocol significantly improved healing, reduced wound size and pain, and controlled infection in DFU patients. These findings support its incorporation into routine multidisciplinary DFU management.

Keywords. clinical outcomes, diabetic foot ulcer, integrated wound care, prospective study, wound healing

Introduction

Diabetes mellitus (DM) is a long-term metabolic condition marked by sustained elevation of blood glucose levels resulting from defects in insulin production, insulin function, or a combination of both.¹ Long-standing hyperglycemia leads to structural and functional vascular changes, neuropathy, and impaired immune function, which collectively increase the risk of chronic complications.^{2,3} Among these, diabetic foot ulcers (DFUs) are one of the most debilitating and costly complications, often resulting in infection, prolonged hospitalization, reduced quality of life, and, in severe cases, lower limb amputation.⁴ The underlying mechanisms of diabetic foot ulcers (DFUs) are complex and multifactorial, encompassing peripheral neuropathy, vascular insufficiency, delayed tissue repair, and a heightened risk of infection.^{5,6} Globally, DFUs affect approximately 15–25% of individuals with diabetes during their lifetime, and their incidence is rising in parallel with the increasing prevalence of diabetes.^{7,8} According to the International Diabetes Federation (IDF), more than 537 million adults were living with diabetes in 2021, a number projected to reach 643 million by 2030.⁹ DFUs account for up to 85% of diabetes-related lower limb amputations, and mortality rates following amputation are as high as 50% within five years, exceeding many cancer prognoses.¹⁰ In Indonesia, DFUs remain a significant public health burden, with limited access to specialized wound care services, especially in resource-constrained settings.

Despite advances in modern wound care, healing rates for DFUs remain suboptimal due to multiple challenges: inadequate glycemic control, delayed diagnosis, lack of systematic wound assessment, inconsistent adherence to evidence-based care, and limited patient education.^{11–14} Standard facility-based care may not be sufficient to address these multifaceted needs, particularly in patients who require continuous monitoring, individualized education, and psychosocial support.¹⁵ Previous studies have examined various wound care modalities, but few have evaluated an integrated wound care protocol that combines systematic wound assessment, targeted debridement, infection control, moisture balance, nutritional optimization, and patient education into a single structured approach.¹⁶ Moreover, most available research has been conducted in specialized tertiary care settings, limiting generalizability to broader clinical practice.¹⁷ There is a paucity of prospective studies assessing the real-world clinical outcomes of such integrated protocols in diverse patient populations.

The distinctive contribution of this research is its implementation of a standardized, comprehensive wound care protocol that incorporates nutritional guidance and patient education within a cohesive clinical system, prospectively assessed in a real-world hospital environment with limited resources in Indonesia. Unlike

most previous investigations that emphasized isolated components of wound treatment or were confined to tertiary facilities, this study provides one of the few prospective cohort evaluations demonstrating the efficacy of a fully integrated and multidisciplinary strategy within routine clinical practice.

Aim

Accordingly, this study aimed to assess the clinical effectiveness of an integrated wound care protocol among patients with diabetic foot ulcers during a specified follow-up duration, focusing on wound healing rate, reduction in ulcer area, infection management, and alleviation of pain. In this study, an 'integrated wound care protocol' is defined as a structured, multidisciplinary approach that combines clinical wound management with nutritional counseling and patient education, aiming to optimize both local wound healing and systemic health factors.

Material and methods

Study design

This research employed a prospective cohort design to examine the clinical outcomes associated with the application of an integrated wound care protocol in individuals with diabetic foot ulcers (DFUs). Participants were monitored from the initial assessment through a 12-week treatment phase, during which regular evaluations were performed to record wound healing progress and accompanying clinical indicators.

Population and sample

The study enrolled adult participants with a confirmed diagnosis of type 2 diabetes mellitus who exhibited diabetic foot ulcers (DFUs) categorized as Wagner grades 1 to 3. Recruitment was carried out at the outpatient wound care unit of PKU Muhammadiyah Hospital in Gombong, Indonesia, over the period from February to September 2024.

Baseline demographic and clinical characteristics of the participants are presented in Table 1. A total of 225 patients were included using a consecutive sampling method. Patient eligibility screening was performed consecutively at the outpatient wound care clinic using standardized inclusion and exclusion criteria. Sample size estimation was calculated using the single-proportion formula for an expected wound healing rate of 50%, 95% confidence interval, and 5% precision. The minimum required sample was 218 participants, and the number was increased to 225 to compensate for an anticipated 5% attrition during follow-up. Sample size was determined based on the estimation of wound healing proportion in DFU patients, with a 95% confidence level, an expected healing rate of 50%, and a 5% margin of error, resulting in a minimum required sample of 218; this was increased to 225 to account for potential loss to follow-up. Inclusion criteria were: 1) Adults aged ≥ 18 years, 2) Clinical diagnosis of type 2 diabetes mellitus, 3) Presence of diabetic foot ulcer for ≥ 2 weeks and ≤ 6 months, and 4) Able to provide informed consent.

Exclusion criteria included: 1) Critical limb ischemia requiring immediate surgical intervention, 2) Severe systemic infection or sepsis, and 3) Cognitive impairment limiting participation. Peripheral arterial disease was identified based on prior clinical diagnosis and documented comorbidities in patients' medical records. Advanced vascular imaging (e.g., Doppler ultrasound, ABI, or CT angiography) was not routinely performed due to resource constraints.

Instruments

Data collection utilized validated clinical instruments. The Bates-Jensen Wound Assessment Tool (BWAT) was employed to assess wound parameters such as size, depth, edge condition, necrotic and granulation tissue, exudate characteristics, periwound skin status, and epithelialization. The Numerical Pain Rating Scale (NPRS) was used to quantify the intensity of wound-associated pain reported by patients. An Infection Assessment Checklist was used to document clinical signs of infection (redness, swelling, warmth, purulent exudate). Digital planimetry was employed for precise wound area measurement (cm²). A Patient Education and Adherence Questionnaire was administered to assess compliance with wound care instructions, glycemic control, and foot care practices. All assessment tools used in this study were validated and standardized for clinical wound evaluation. The Bates-Jensen Wound Assessment Tool (BWAT) has demonstrated high inter-rater reliability (Cronbach's $\alpha = 0.89\text{--}0.95$) in chronic wound populations, while the Numerical Pain Rating Scale (NPRS) is widely validated for assessing subjective pain intensity. Wound assessments were performed by two certified wound care nurses who had undergone inter-rater reliability training before data collection. Periodic calibration sessions were conducted to maintain consistency in scoring and measurement across assessors.

Data collection

At baseline, demographic data, diabetes duration, ulcer characteristics, and comorbidities were recorded. All patients received the integrated wound care protocol, which consisted of: 1) Wound bed optimization was carried out following the TIME framework, which encompasses tissue management, infection control, maintenance of moisture balance, and promotion of wound edge advancement, 2) Debridement (sharp or autolytic) when indicated, 3) Infection control with culture-guided topical or systemic antibiotics, 4) Moisture balance using appropriate modern dressings (hydrogel, foam, or silver-containing dressings), 5) Nutritional counseling to optimize glycemic control and protein intake, and 6) Patient education on self-care, footwear selection, and foot hygiene. The integrated wound care protocol was delivered by a multidisciplinary team consisting of wound care nurses, diabetes educators, and physicians trained in diabetic foot management. Wound assessments and dressing changes were conducted twice weekly during outpatient visits, with interim reviews if complications occurred. The protocol adhered to the principles outlined in the International Working Group on the Diabetic Foot (IWGDF 2023) and the TIME framework

(Tissue management, Infection control, Moisture balance, Edge advancement). Adherence to the protocol was monitored through weekly documentation and patient self-reports verified during follow-up visits. Wounds were assessed weekly for 12 weeks, with documentation of BWAT scores, wound size, infection status, and pain level. Any complications or adverse events were recorded. The primary outcome of the study was complete wound healing, defined as full epithelialization without drainage within 12 weeks. Secondary outcomes were changes in wound size, BWAT scores, pain intensity (NPRS), and infection prevalence. The flow of participant recruitment, screening, enrollment, and follow-up throughout the 12-week study period is summarized in Figure 1.

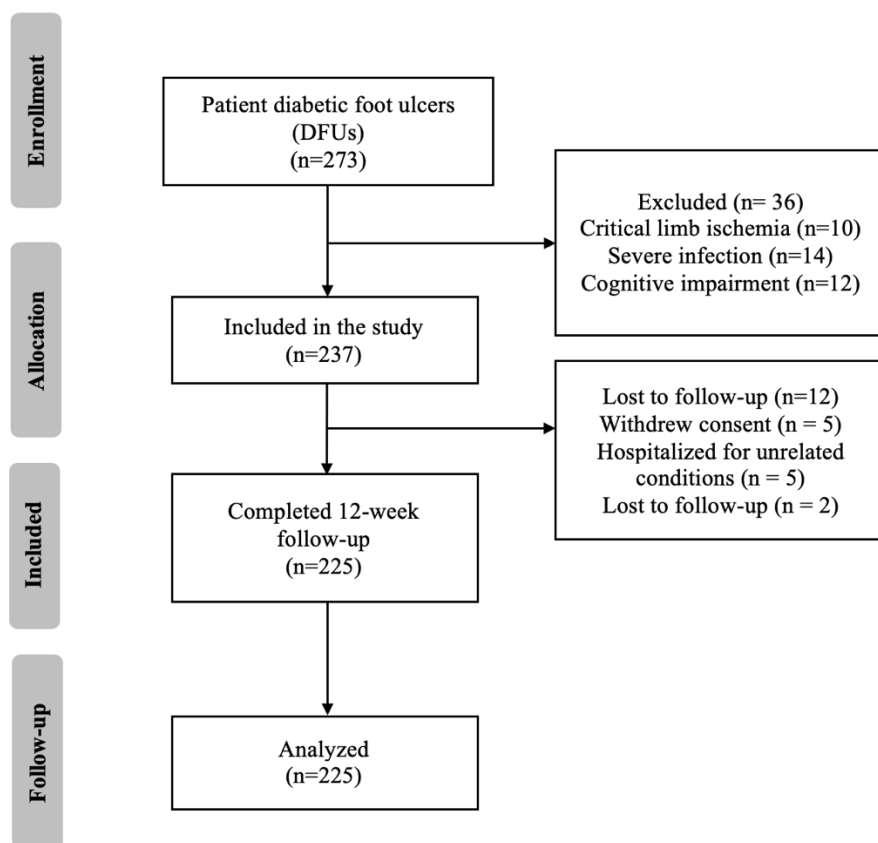


Fig. 1. Flow diagram of participant recruitment and follow-up in the prospective cohort study on diabetic foot ulcers

The integrated wound care protocol in this study consisted of a structured combination of evidence-based interventions, including: wound bed preparation with the TIME framework (tissue management, infection control, moisture balance, edge advancement); debridement when indicated; infection control with culture-guided topical or systemic antibiotics; maintenance of moisture balance using modern dressings (e.g., hydrogel, foam, silver dressings); nutritional counseling to optimize glycemic control and protein intake;

ulcer offloading using customized felt padding, removable cast walkers, or therapeutic footwear; and patient education on daily foot care and treatment adherence.

Data analysis

Statistical analyses were performed using SPSS software version 26.0 (IBM Corp., Armonk, NY, USA). Continuous data were presented as mean \pm standard deviation (SD) or as median with interquartile range, depending on the distribution assessed for normality. Categorical variables were described in terms of frequencies and percentages. Variations in wound area, BWAT scores, and pain intensity between baseline and week 12 were evaluated using either the paired t-test or the Wilcoxon signed-rank test. The percentage of participants who achieved complete wound healing within 12 weeks was computed with corresponding 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant.

Ethical approval

Ethical clearance for this research was granted by the Ethics Committee of the Faculty of Health Sciences, Universitas Muhammadiyah Gombong, Indonesia (Approval No. 12/EC/KEPK-FKUMS/I/2024). Written informed consent was obtained from all participants before inclusion in the study, and all procedures were conducted in accordance with the ethical standards of the Declaration of Helsinki.

Results

In total, 225 individuals diagnosed with diabetic foot ulcers (DFUs) participated in this study. The participants had a mean age of 58.4 ± 9.6 years, with males comprising 56.9% of the cohort. The median duration of diabetes was 10 years (IQR 6–15), and the average HbA1c level was $8.4 \pm 1.2\%$, reflecting inadequate glycemic control. The majority of ulcers were found on the forefoot region (63.1%) and were predominantly classified as Wagner grade 2 (48.4%), followed by grade 1 (28.9%) and grade 3 (22.7%). Hypertension was the most common comorbidity (69.3%), followed by peripheral artery disease (36.4%) and chronic kidney disease (15.1%), shown in Table 1.

Table 1. Baseline characteristics of study participants (n=225)

Variable	n (%) or Mean \pm SD
Age (years)	58.4 \pm 9.6
Sex	
Male	128 (56.9)
Female	97 (43.1)

Diabetes duration (years)	10 (6–15)
HbA1c (%)	8.4±1.2
Ulcer duration (weeks)	8.2±3.6
Wagner grade	
Grade 1	65 (28.9)
Grade 2	109 (48.4)
Grade 3	51 (22.7)
Ulcer location	
Forefoot	142 (63.1)
Midfoot	48 (21.3)
Heel	35 (15.6)
Comorbidities	
Hypertension	156 (69.3)
Peripheral artery disease	82 (36.4)
Chronic kidney disease	34 (15.1)

Table 2. Clinical outcomes before and after 12 weeks of integrated wound care protocol

Outcome	Baseline	Week 12	p
Wound area (cm ²)	6.8±3.2	1.2±1.5	<0.001
BWAT score	28.4±4.1	13.6±3.8	<0.001
Pain score (NPRS)	5.8±1.6	2.1±1.1	<0.001
Infection present (%)	102 (45.3)	28 (12.4)	<0.001
Complete healing (%)	–	157 (69.8)	–

By the end of the 12-week intervention, 157 patients (69.8%) achieved complete wound healing. The detailed comparison of wound area, BWAT score, pain score, and infection prevalence between baseline

and week 12 is shown in Table 2, while the trend of progressive wound area reduction over time is illustrated in Figure 2. The mean wound area decreased significantly from $6.8 \pm 3.2 \text{ cm}^2$ at baseline to $1.2 \pm 1.5 \text{ cm}^2$ at week 12 ($p < 0.001$). The temporal pattern of wound area reduction across the 12-week period is depicted in Figure 2, showing a continuous decline with statistically significant improvement compared to baseline ($p < 0.001$). BWAT scores improved from 28.4 ± 4.1 to 13.6 ± 3.8 ($p < 0.001$), pain scores declined from 5.8 ± 1.6 to 2.1 ± 1.1 ($p < 0.001$), and the proportion of patients with clinical signs of infection decreased from 45.3% to 12.4% ($p < 0.001$) (Table 2, Fig. 2). When analyzed by ulcer severity, healing rates differed significantly according to Wagner grade, as detailed in Table 3.

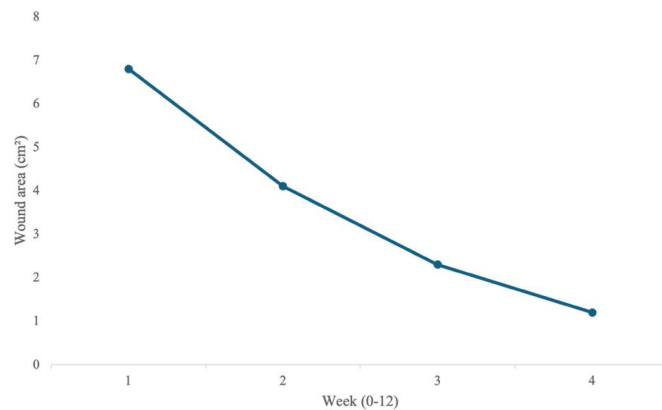


Fig. 2. Mean wound area reduction from baseline to week 12 among patients receiving the integrated wound care protocol ($n=225$), error bars represent standard deviation, statistical significance compared to baseline: $p < 0.001$

Table 3. Complete healing rates according to Wagner grade

Wagner grade	n	Healed n (%)	p
Grade 1	65	54 (83.1)	<0.001
Grade 2	109	76 (69.7)	
Grade 3	51	24 (47.1)	

Discussion

This prospective cohort study evaluated the clinical outcomes of an integrated wound care protocol in 225 patients with DFUs over a 12-week follow-up period. The main findings indicate that the protocol was associated with a high overall healing rate of 69.8%, significant reduction in mean wound area (from 6.8 cm^2 to 1.2 cm^2), substantial improvement in wound characteristics as measured by BWAT scores, and a

notable decrease in pain intensity and infection prevalence. Healing rates varied according to ulcer severity, with the highest rates observed in Wagner grade 1 ulcers and the lowest in grade 3.

The observed healing rate of nearly 70% aligns with previous studies evaluating multidisciplinary or protocol-driven wound care in DFUs, which have reported healing rates ranging from 60% to 80% over comparable follow-up periods. A standardized wound care regimen, including regular debridement, offloading, infection control, and moisture balance, significantly improved healing outcomes in DFUs, a finding consistent with our results.¹⁸ Furthermore, the marked reduction in infection prevalence mirrors findings from previous research, who noted that structured antimicrobial strategies within an integrated protocol reduced infection risk by more than half.^{19–21} However, the healing rates observed in Wagner grade 3 ulcers in this study (47.1%) were slightly higher than those reported in some tertiary care settings, where advanced ulcers often heal in less than 40% of cases within three months. This difference may reflect the comprehensive approach of our protocol, which integrated nutritional counseling and patient education alongside clinical interventions.^{22,23}

The consistent decrease in wound dimensions, especially the marked reduction observed within the initial six weeks, suggests that the integrated care protocol successfully targeted the early stages of the wound healing process.^{24–26} The combination of evidence-based wound bed preparation, appropriate dressing selection, and individualized patient education likely accelerated the healing process.^{11,27}

Clinically, the results highlight the significance of adopting a coordinated and multidisciplinary strategy in managing diabetic foot ulcers, one that not only focuses on local wound treatment but also encompasses broader systemic aspects including blood glucose regulation and nutritional optimization. Importantly, the stratification of healing rates by Wagner grade underscores the need for early intervention to prevent ulcer progression to more severe stages, where healing potential is markedly reduced.^{28,29}

Improvements in glycemic control during the follow-up period may have contributed to the favorable wound healing outcomes observed. Hyperglycemia impairs multiple aspects of wound repair, including leukocyte function, collagen synthesis, and angiogenesis.³⁰ The nutritional counseling component of our protocol, combined with regular clinical contact, likely promoted better dietary adherence and glycemic monitoring, which could enhance tissue repair and infection control. However, because glycemic indices (e.g., HbA1c, fasting glucose) were not systematically recorded at each follow-up visit, we cannot quantify the extent to which improved metabolic control influenced healing outcomes. Future studies should integrate longitudinal glycemic measurements to clarify this relationship.

One of the principal strengths of this research is its prospective study design combined with a comparatively large sample size for a single-center cohort of DFU patients, thereby improving the robustness of the results. The application of validated instruments such as the BWAT and NPRS, along with objective techniques for wound evaluation, contributes to strong methodological validity. In addition, conducting the study in an

actual clinical environment enhances the external applicability of the findings to comparable healthcare settings.

This research acknowledges several limitations. Firstly, the lack of a control group constrains direct comparisons between the integrated wound care protocol and alternative management approaches. Secondly, being conducted at a single institution may reduce the extent to which the findings can be generalized to different clinical environments. Thirdly, the 12-week observation period provides only short-term insights and may not reflect longer-term healing trajectories or outcomes. Finally, advanced vascular assessments such as Doppler ultrasonography or ABI were not systematically performed, which could limit the accuracy of vascular status evaluation. Despite these limitations, the study provides valuable evidence for the effectiveness of an integrated wound care protocol in DFU management.

Future studies should incorporate randomized controlled designs to strengthen causal inference and compare integrated wound care protocols with standard care or alternative interventions. Multicenter trials would enhance external validity, and longer follow-up periods are needed to evaluate recurrence rates, cost-effectiveness, and patient-reported quality-of-life outcomes. Additionally, subgroup analyses focusing on patients with severe DFUs (Wagner grades 3–4) could help refine protocol adaptations to optimize healing in this high-risk group. The main novelty of this study lies in demonstrating that combining clinical wound care, infection control, nutritional counseling, and patient education into a single structured protocol can achieve high healing rates even in a limited-resource setting. This evidence fills an important gap between guideline-based multidisciplinary recommendations and their implementation in daily hospital practice, particularly in low- and middle-income countries. Our results therefore extend previous findings from tertiary centers to more generalizable, real-world contexts.

Conclusion

This prospective cohort investigation showed that the application of an integrated wound care protocol led to notable improvements in clinical outcomes among individuals with diabetic foot ulcers. Throughout the 12-week monitoring period, the protocol resulted in a high rate of complete healing, marked reductions in wound dimensions, enhanced wound condition, lower pain scores, and diminished infection rates. Healing outcomes were most favorable in patients with lower Wagner grades, underscoring the importance of early intervention. These findings support the adoption of structured, multidisciplinary wound care protocols as part of routine clinical practice to optimize healing and reduce complications in diabetic foot ulcer management. This study adds new evidence supporting the real-world effectiveness of a multidisciplinary integrated wound care protocol for diabetic foot ulcers, emphasizing that even in non-specialized hospital settings, coordinated care can achieve high healing rates and effective infection control. For clinical practice, we recommend adopting an integrated wound care protocol as a standard approach for diabetic foot ulcer management. Its implementation in outpatient wound care clinics, supported by multidisciplinary

teams, may improve healing rates, enhance infection control, reduce patient pain, and ultimately decrease the risk of lower limb amputation.

Declarations

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Author contributions

Conceptualization, D.S. and R.K.M.; Methodology, D.S.; Software, D.S.; Validation, D.S. and R.K.M.; Formal Analysis, P.A.W.S.; Investigation, D.S. and R.K.M.; Resources, D.S.; Data Curation, D.S.; Writing – Original Draft Preparation, D.S. and P.A.W.S.; Writing – Review & Editing, D.S. and P.A.W.S.; Visualization, P.A.W.S.; Supervision, D.S. and R.K.M.; Project Administration, D.S. and P.A.W.S.; Funding Acquisition, D.S.

Conflicts of interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request. Due to patient confidentiality, raw data are not publicly shared.

Ethics approval

The study was approved by the Ethics Committee of the Faculty of Health and Sciences, Universitas Muhammadiyah Gombong, Indonesia (Approval No. 12/EC/KEPK-FKUMS/I/2024).

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