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Clinical Outcomes in Two Non-Randomized Cohorts of Patients with Diabetic Foot Ulcers Managed Using Guideline-Based or Traditional Care

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Abstract **Background:** Diabetic foot ulcers (DFUs) are associated with delayed healing and substantial morbidity. This study compared healing outcomes between structured, guideline-based wound care and traditional wound care according to WIfI clinical stage. **Methods:** The guideline-based cohort (n = 78) was recruited prospectively between Jun. and Nov. 2026, as eligible patients became available at different times. Each patient was followed individually for 12 weeks to assess wound-healing outcomes and determine healing time. The traditional-care cohort (n = 90) was identified through hospital records covering the same January–July 2026 period. Only patients with complete records documenting their wound-healing outcomes over the 12-week period were included. Wound healing outcomes were compared between the two groups over 12 weeks for each patient. **Results:** Complete wound healing within 12 weeks was achieved in 65/78 patients (83.3%) receiving guideline-based care, compared with 30/90 (33.3%) receiving traditional care ($p<0.0001$; OR 10.00, 95% CI 4.77–20.95). The observed healing rate was approximately 2.5 times higher with guideline-based care. Stage-specific healing rates were significantly higher with guideline-based care in WIfI Stage 1 (100.0% vs 19.0%, $p<0.0001$), Stage 2 (90.9% vs 48.0%, $p = 0.0248$), and Stage 3 (93.1% vs 42.1%, $p<0.0002$), but not Stage 4 (50.0% vs 24.0%, $p = 0.1167$). Among patients who achieved complete healing, mean healing time was shorter with guideline-based care overall (52.06±22.87 vs 66.52±16.58 days, $p = 0.0025$), with significant differences in Stage 1 (29.11±13.89 vs 50.64±7.82 days, $p = 0.0077$), Stage 2 (42.40±18.56 vs 59.27±18.40 days, $p = 0.0455$), and Stage 3 (63.04±16.95 vs 75.89±9.24 days, $p = 0.0492$). The difference in Stage 4 was not statistically significant (73.40±12.48 vs 79.09±5.92 days, $p = 0.3168$). **Conclusion:** Structured, guideline-based wound care was associated with significantly higher healing rates and shorter healing time, particularly among patients with WIfI Stages 1–3. Prospective multicentre studies are needed to confirm these findings.

Key Words Diabetic Foot Ulcer, WIFI Classification, Wound Healing, Guideline-Based Care, Multidisciplinary Team, Comparative Study

INTRODUCTION

Diabetic foot ulcer (DFU) is among the most serious complications of diabetes and one of the most prevalent chronic metabolic disorders worldwide with a lower pooled global prevalence of 6.4% reported across diabetic populations [1, 2]. Overall, up to 34% of individuals with type 1 or type 2 diabetes are expected to experience a foot ulcer at some point during their lifetime [3]. About 20% of people with diabetic foot ulcers require a lower-limb amputation, mainly due to infection and gangrene [4,5].

Diabetic foot ulcers (DFUs) develop through a multifactorial process, primarily driven by peripheral neuropathy, peripheral arterial disease, foot deformities, and impaired wound healing [6]. Diabetic neuropathy affects sensory, motor, and autonomic nerves, sensory neuropathy leads to loss of protective sensation, while motor neuropathy causes muscle imbalance, foot deformities, and abnormal biomechanics [7]. Autonomic neuropathy results in reduced sweating and skin dryness, producing viscoelastic skin changes that predispose to callus formation [8].

Diabetic foot ulcer classification systems primarily support clinical description and communication, whereas scoring systems quantify severity for prognostic and treatment decisions, as no single system effectively serves both purposes [9, 10]. The Meggitt–Wagner classification system was the first diabetes-specific system to be introduced and remains one of the most widely known [11]. The University of Texas (UT) classification system was developed that uses ulcer depth as the main grading factor but adds information about infection and ischemia by staging each ulcer [12]. The Society for Vascular Surgery (SVS) developed the Wound, Ischemia, and Foot Infection (WIfI) classification system to evaluate wound extension, ischemia, and foot infection [13,14]. This classification system is recognized as a suitable approach for evaluating clinical decision-making in DFU management [15].

The primary goal of diabetic foot ulcer (DFU) management is timely wound closure while preventing the development of new ulcers on the same or contralateral limb and ultimately preserving the limb [16]. Early identification and treatment of DFUs are critical, as prompt intervention significantly improves healing outcomes [17]. International guidelines support structured multidisciplinary care combining debridement, infection control, offloading, glycaemic control, appropriate dressings, and patient education to promote healing and reduce amputation risk [18-20]. This study aimed to compare complete wound healing rates and mean healing time, stratified by WIfI clinical stage, between patients managed with structured, guideline-based wound care and a comparator cohort managed with traditional wound care in the same region.

METHODS

Study Design and Setting

This non-randomized comparative cohort study included 168 patients with diabetic foot ulcers (DFUs) in Erbil, Kurdistan Region of Iraq. DFU was defined as a foot wound associated with diabetes, including neuropathic, ischemic, infected, or combined ulcers. Eligible patients had DFUs suitable for assessment and management under the study protocols. Patients with extensive foot involvement that could not be objectively standardized, advanced infection, critical limb ischemia as determined by multidisciplinary team (MDT) assessment, terminal illness (e.g., advanced malignancy or end-stage organ failure), severe psychiatric or cognitive impairment, or concurrent participation in other interventional trials were excluded. All included patients presented with a single ulcer.

The guideline-based cohort (n = 78) was prospectively enrolled at the Wound Care Unit, Erbil International Hospital, between Jun. and Nov. 2026 and managed using a structured multidisciplinary protocol [21]. Each patient was followed for 12 weeks to assess wound-healing outcomes. The traditional-care cohort (n = 90) was identified retrospectively from hospital records of patients treated at other regional hospitals during the same calendar period using routine wound care. Only records with complete documentation of patients' wound-healing outcomes over the 12-week period were included. No a priori sample-size calculation was performed; the sample size was based on available eligible cases and feasible recruitment. Therefore, the study may have limited statistical power for stage-specific analyses, particularly in smaller subgroups.

Wound Care Protocols and Outcome Assessment

The guideline-based protocol followed a multidisciplinary approach to diabetic foot ulcer (DFU) management [21]. Comprehensive foot and wound assessments included ulcer classification as neuropathic, ischemic, or neuroischemic; evaluation of intrinsic and extrinsic factors affecting wound healing; examination of the ulcer and surrounding skin; assessment of musculoskeletal deformities; measurement of ulcer dimensions; and evaluation of wound-bed tissue characteristics, classified as black (necrotic), yellow (slough), red (granulation), or pink (epithelialization). Signs of infection were assessed, and the Wound, Ischemia, and foot Infection (WIfI) classification system was used to evaluate ulcer severity and amputation risk.

Wound management was individualized according to clinical findings and wound characteristics using the TIME framework, addressing Tissue management, Infection or inflammation, Moisture balance, and Epithelial-edge advancement. Appropriate debridement, dressing selection, and pressure releveling strategies were incorporated into care. Patient education covered wound self-care, adherence to treatment, and prevention of recurrence. Additional components by a multidisciplinary team included glycaemic control, systemic infection treatment, and vascular assessment with referral when clinically indicated. When infection was clinically suspected, tissue samples were collected for culture when appropriate, and antibiotic therapy was selected according to infection severity and adjusted based on culture and susceptibility results. Advanced therapies, including Negative Pressure Wound Therapy (NPWT), NPWT with Instillation (NPWTi), and hyperbaric oxygen therapy, were considered when clinically indicated and available.

The traditional-care cohort received routine hospital-based wound care, with treatment decisions guided primarily by individual clinicians rather than a standardized, protocol-driven approach. Based on the available clinical records, traditional care did not consistently document or incorporate systematic assessment of intrinsic and extrinsic healing factors, standardized measurement of ulcer dimensions, or treatment selection explicitly guided by individual wound characteristics and the TIME framework. Although routine wound care could include dressings, debridement, and treatment of infection according to clinical judgment, these interventions were not delivered through the same standardized management pathway as in the guideline-based cohort. Offloading education and implementation were less structured, and the advanced therapies used in the guideline-based protocol, including

NPWT, NPWTi, and hyperbaric oxygen therapy, were not routinely incorporated into traditional care. Infection management and vascular assessment or referral were undertaken according to clinicians' decisions and the information available in the medical records. The frequency of follow-up visits and the specific dressing regimens used in the traditional-care cohort were not consistently standardized.

Outcome Assessment and Follow-Up

The primary outcome was complete wound healing within 12 weeks, defined as complete epithelialization corresponding to W0I0fI0. Healing time was recorded for ulcers that achieved complete healing. WIfI staging by the researchers was used to classify wound, ischemia, and foot infection severity and estimate amputation risk.

Complete wound healing within 12 weeks was determined using documented clinical assessments and follow-up records, applying the same definition of complete epithelialization to both cohorts. The guideline-based cohort was assessed at baseline and weeks 3, 6, and 12, whereas outcomes in the traditional-care cohort were determined retrospectively from available hospital records. Outcome assessment was based on documented clinical findings. Patients with incomplete 12-week follow-up records were excluded from the analysis. Amputation and death during follow-up were recorded as non-healing outcomes where applicable.

Ethical Considerations

Ethical approval for this study was obtained from the Research Ethics Committee of Hawler Medical University, College of Nursing, Kurdistan Region, Iraq (Approval No. 2608/2026). Written informed consent was obtained from all participants in the prospective guideline-based cohort before enrollment. For the retrospective traditional-care cohort, the use of existing patient records was conducted in accordance with the ethics committee's requirements regarding informed consent and authorization for record review. Patient confidentiality was maintained throughout the study by restricting access to clinical records, removing identifying information from the research dataset, and using the data solely for research purposes. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical Analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS version 25; IBM Corp., Armonk, NY, USA). Continuous variables were compared between cohorts using independent-samples t-tests, while categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. The odds ratio (OR) and 95% confidence interval (CI) were calculated for the overall association between care approach and complete wound healing. All tests were two-tailed, with statistical significance set at $p < 0.05$. No adjustment for multiple comparisons was applied.

RESULTS

Baseline Characteristics

A total of 168 patients with diabetic foot ulcers were included, comprising 90 patients managed with traditional wound care and 78 treated according to the guideline-based approach. The two cohorts were comparable in age, sex distribution, diabetes duration, and BMI, with no statistically significant differences observed for these variables (all $p > 0.05$). The overall distribution of baseline WIfI stages was also comparable between cohorts, although a borderline difference was observed ($p = 0.058$), with a higher proportion of Stage 3 ulcers in the guideline-based cohort (37.2 vs. 21.1%) and a higher proportion of Stage 2 ulcers in the traditional-care cohort (27.8 vs. 14.1%). Detailed baseline characteristics are presented in Table 1 and Figures 1 and 2.

Healing Outcomes

Complete wound healing within 12 weeks was achieved in 65 of 78 patients (83.3%) receiving guideline-based care, compared with 30 of 90 patients (33.3%) receiving traditional care ($p<0.0001$; OR 10.00, 95% CI 4.77–20.95). This OR indicates higher odds of healing and should not be interpreted as a tenfold increase in the probability of healing. The observed healing rate was approximately 2.5 times higher with guideline-based care.

Stage-specific healing rates were higher in the guideline-based cohort across all four WIfI stages (Table 2, Figure 3). For Stage 1, healing occurred in 18/18 patients (100.0%) receiving guideline-based care versus 4/21 (19.0%) receiving traditional care ($p<0.0001$). The conventional OR was not estimable because no non-healing events occurred in the guideline-based group. For Stage 2,

Table 1: Baseline Characteristics of the Traditional-Care and Guideline-Based Cohorts

Characteristic	Traditional Care (n = 90)	Guideline-Based Care (n = 78)	p-value
Age, years (Mean±SD)	60.9±11.3	61.5±11.9	0.738
Male sex, n (%)	58 (64.4%)	42 (53.8%)	0.207
Female sex, n (%)	32 (35.6%)	36 (46.2%)	0.207
Diabetes duration, years (Mean±SD)	17.3±5.8	16.8±6.7	0.605
BMI, kg/m² (mean±SD)	27.9±7.3	28.2±6.1	0.774
Baseline WIfI Stage 1, n (%)	21 (23.3%)	18 (23.1%)	0.058*
Baseline WIfI Stage 2, n (%)	25 (27.8%)	11 (14.1%)	
Baseline WIfI Stage 3, n (%)	19 (21.1%)	29 (37.2%)	
Baseline WIfI Stage 4, n (%)	25 (27.8)	20 (25.6)	

*p-value represents the overall chi-square test comparing the distribution of all four WIfI stages between cohorts

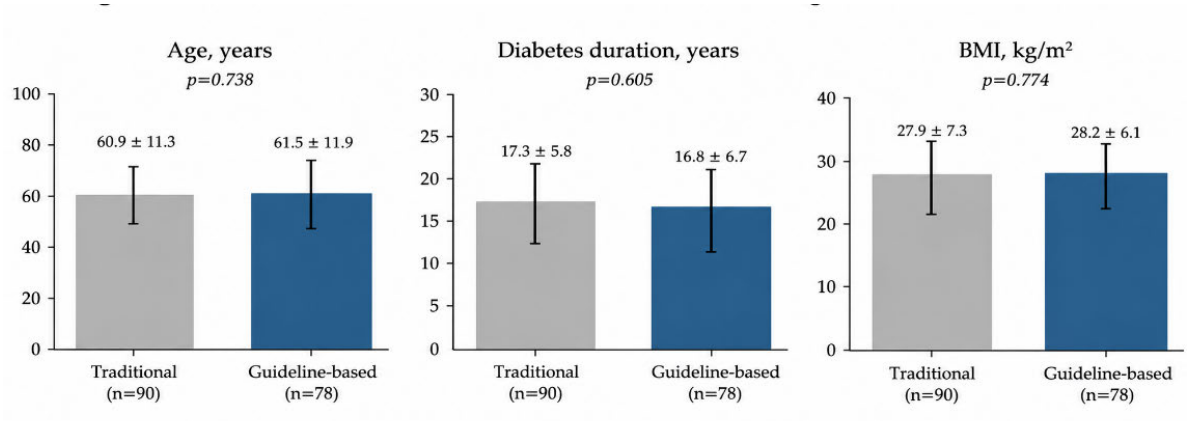


Figure 1: Baseline Continuous Characteristics (Age, Diabetes Duration, BMI) of the Traditional-Care and Guideline-Based Cohorts. Bars Show Mean±SD; p-Values from Independent-Samples t-Tests

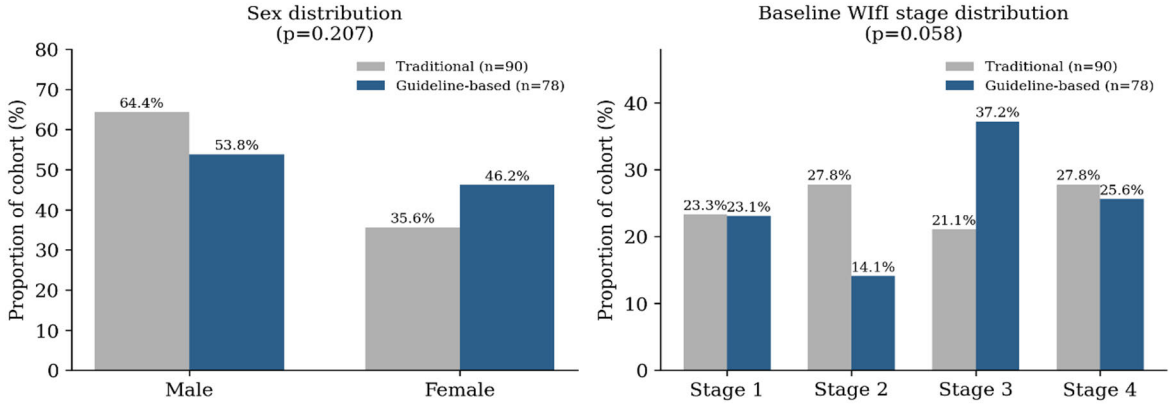


Figure 2: Baseline Sex Distribution and WIfI Stage Distribution of the Traditional-Care and Guideline-Based Cohorts. p-Values from Chi-Square Tests

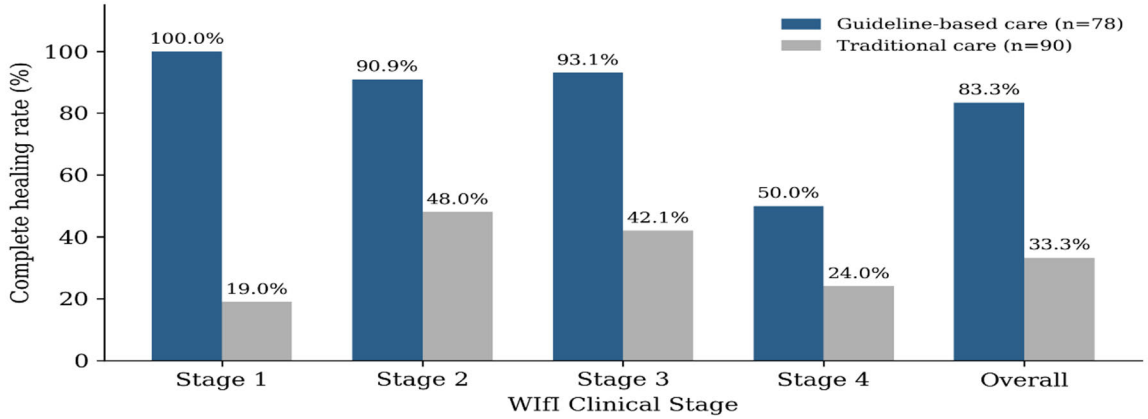


Figure 3: Complete Wound Healing Rate by WIfI Stage: Guideline-Based Versus Traditional Wound Care

Table 2: Comparative Healing Outcomes by WIFI Stage: Guideline-Based Versus Traditional Wound Care

	Guideline-Based Care (N = 78)		Traditional Care (N = 90)			
Wifi Stage	Case, healed n (%)	Healing time, days (mean±SD)	Case, healed n (%)	Healing time, days (mean±SD)	p (Rate)	p (Time)
Stage 1	18, 18 (100.0%)	29.11±13.89	21, 4 (19.0%)	50.64±7.82	<0.0001	0.0077
Stage 2	11, 10 (90.9%)	42.40±18.56	25, 12 (48.0%)	59.27±18.40	0.0248	0.0455
Stage 3	29, 27 (93.1%)	63.04±16.95	19, 8 (42.1%)	75.89±9.24	0.0002	0.0492
Stage 4	20, 10 (50.0%)	73.40±12.48	25, 6 (24.0%)	79.09±5.92	0.1167	0.3168
Overall	78, 65 (83.3%)	52.06±22.87	90, 30 (33.3%)	66.52±16.58	<0.0001	0.0025

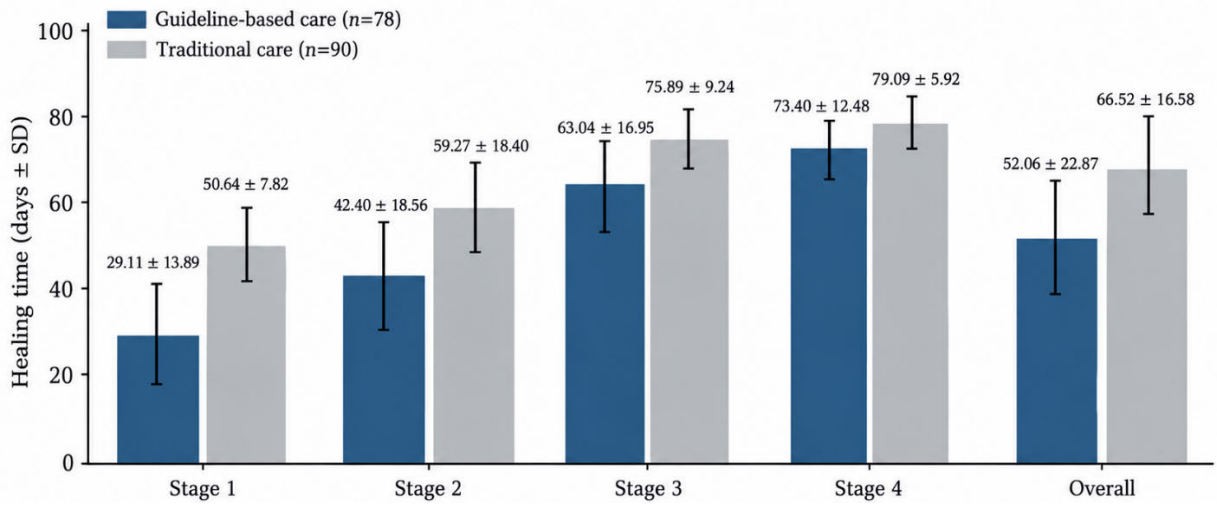


Figure 4: Mean Time to Complete Healing (Among Healed Patients Only) by Wifi Stage, with Error Bars Representing ±1 SD

(p=0.0248; OR 10.83, 95% CI 1.20–97.80). For Stage 3, the rates were 93.1% (27/29) versus 42.1% (8/19) (p<0.0002; OR 18.56, 95% CI 3.39–101.69). For Stage 4, healing occurred in 50.0% (10/20) versus 24.0% (6/25) (p=0.1167; OR 3.17, 95% CI 0.89–11.27). The differences were statistically significant in Stages 1–3, whereas the Stage 4 comparison was not statistically significant.

Among patients who achieved complete healing, mean healing time was shorter with guideline-based care overall (52.06±22.87 vs 66.52±16.58 days, p=0.0025). This difference was also observed in Stage 1 (29.11±13.89 vs 50.64±7.82 days, p=0.0077), Stage 2 (42.40±18.56 vs 59.27±18.40 days, p=0.0455), and Stage 3 (63.04±16.95 vs 75.89±9.24 days, p=0.0492). In Stage 4, the difference was not statistically significant (73.40±12.48 vs 79.09±5.92 days, p=0.3167) (Table 2, Figure 4).

DISCUSSION

Guideline-based care was also associated with faster healing among patients who achieved complete wound closure. Overall, mean healing time was significantly shorter in the guideline-based cohort than in the traditional-care cohort (52.06±22.87 vs. 66.52±16.58 days, p = 0.0025). This difference remained significant for WIfI Stage 1 (29.11±13.89 vs. 50.64±7.82 days, p = 0.0077), Stage 2 (42.40±18.56 vs. 59.27±18.40 days, p = 0.0455), and Stage 3 (63.04±16.95 vs. 75.89±9.24 days, p = 0.0492), but not Stage 4 (73.40±12.48 vs. 79.09±5.92 days, p = 0.3168). Thus, the observed benefit of structured care was evident not only in the proportion of ulcers achieving complete healing but also in the time required for healing among patients who healed. These findings are consistent with previous evidence supporting coordinated multidisciplinary management of DFUs. In a retrospective cohort study from Australia, implementation of a multidisciplinary approach in a high-risk foot clinic was associated with a 6.2-week reduction in time to complete ulcer healing (p = 0.021) [22]. Similarly, introduction of a multidisciplinary diabetic-foot service in a UK hospital reduced ulcer healing time from 300 to 244 days (p = 0.0375), while the proportion of healed ulcers increased from 64% to 74% [23]. An earlier Canadian study evaluating integration of podiatric care into a multidisciplinary diabetic-foot service reported healing of 73.2% of ulcers within a mean of 19.8 weeks, compared with 27.3% healing within 44.6 weeks in the pre-integration group [24]. More recently, a 2026 retrospective cohort study comparing a one-stop multidisciplinary clinic with traditional sequential care found that multidisciplinary management was independently associated with faster ulcer healing after adjustment for baseline characteristics (adjusted HR 1.41, 95% CI 1.04–1.90; p = 0.027) [25].

The present findings therefore extend previous evidence by demonstrating shorter healing times within specific WIfI severity strata, particularly among Stage 1–3 ulcers. The potential benefit of the guideline-based pathway may be related to the coordinated application of several evidence-based components, including systematic WIfI assessment, wound debridement, appropriate cleansing and dressing selection, pressure offloading, infection management, glycaemic and vascular optimization, patient education, and scheduled reassessment. Such coordinated pathways can facilitate earlier recognition of complications and more consistent delivery of appropriate interventions. A systematic review of multidisciplinary DFU teams found that successful models commonly incorporated coordinated management of glycaemic control, local wound care, vascular disease, and infection, with clear referral pathways and care algorithms facilitating timely treatment [26]. A more recent systematic review and meta-analysis conducted for the development of Italian diabetic-foot guidelines likewise found that patients managed by multidisciplinary teams had better outcomes for healing and time to healing than those managed using other organizational approaches, although the authors noted heterogeneity across the available evidence [27].

The relationship between WIfI severity and healing time in our study is also consistent with previous research. In a multidisciplinary DFU cohort, WIfI stage was significantly associated with wound healing, with Stage 4 ulcers having a mean healing time of approximately 190 days, substantially longer than less severe stages [28]. Another study demonstrated that increasing WIfI severity independently predicted poorer wound healing, supporting the use of WIfI classification when comparing healing outcomes across DFU populations [29]. These findings provide context for the progressive increase in healing time observed across WIfI stages in the present study.

The lack of a statistically significant difference in Stage 4 healing time should therefore be interpreted cautiously. Although mean healing time remained numerically shorter with guideline-based care (73.40 vs. 79.09 days), the difference was not significant ($p = 0.3168$). The relatively small Stage 4 subgroups (20 vs. 25 patients) may have limited the statistical power to detect a between-group difference. In addition, Stage 4 ulcers represent more advanced disease and are generally associated with prolonged healing and greater treatment complexity [28]. Importantly, the absence of statistical significance should not be interpreted as evidence of equivalence between care models.

Stage-specific analyses were exploratory and should be interpreted with caution because no correction for multiple comparisons was applied. Conducting multiple subgroup tests increases the risk of false-positive findings. Therefore, borderline p-values should not be considered definitive evidence of a treatment benefit within individual WIfI stages. These findings should be regarded as hypothesis-generating and confirmed in larger studies with prespecified subgroup analyses and appropriate control for multiple testing.

These findings should be interpreted in the context of the study design. The two cohorts were broadly comparable in baseline demographic and diabetes-related characteristics, with no significant differences in age, sex, diabetes duration, or BMI. Although the overall WIfI-stage distribution did not reach statistical significance ($p = 0.058$), some variation in stage composition was observed between cohorts. The non-randomized design and retrospective assessment of the traditional-care cohort may nevertheless have introduced residual confounding. The consistent differences in healing outcomes across WIfI Stages 1–3 support the robustness of the observed association; however, prospective multicentre studies with standardized baseline assessment are warranted to confirm the effectiveness of WIfI-based, multidisciplinary guideline care.

CONCLUSION

Structured, guideline-based wound care was associated with higher complete healing rates and shorter healing time than traditional wound care among patients with diabetic foot ulcers, particularly at WIfI Stages 1–3. These findings support the potential value of standardized, multidisciplinary wound-care pathways and WIfI-based assessment in clinical practice.

Limitations

This study has several limitations. The non-randomized design and recruitment from different hospitals may have introduced selection bias and residual confounding. Retrospective WIfI staging and differences in outcome documentation and assessment between cohorts may have led to misclassification or ascertainment bias. The analyses were not adjusted for potential confounders, and small sample sizes in some WIfI stage subgroups may have limited statistical power. In addition, multiple comparisons were performed without correction, increasing the risk of false-positive findings. Healing-time analysis was restricted to patients who achieved complete healing within 12 weeks, which may have introduced selection bias. Therefore, the findings indicate an association between guideline-based care and improved healing outcomes but do not establish causation. Generalizability may also be limited to settings with similar patient populations and wound-care resources.

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