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Effectiveness of Comprehensive Therapy vs. Standard Treatment in Diabetic Foot Ulcer Healing: A Retrospective Cohort Study

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Abstract

Background: The Diabetic foot ulcer (DFU) is the tip of a very significant complication of diabetes mellitus (DM), often leading to grave outcomes in infection and eventually amputation with increased mortality. Many factors mess up the healing of DFUs: neuropathy, peripheral arterial disease, and hyperglycemia, just to mention a few. The best published healing outcomes have been reported with an integrated therapy consisting of Health care, intensive glucose management, wound care, and psychosocial support, although standard treatments provide only wound care and blood glucose management.

Purpose: This study will check how effective complete therapy is in improving DFU faster than normal treatment. It will also examine how blood sugar control, insulin help, and mental support affect wound healing.

Methods: A Cohort of 360 DFU patients from Seamen's Hospital Manila was analyzed. Patients were divided into two groups: 180 received standard treatment and 180 received comprehensive therapy. Comprehensive therapy included intensive glucose control plus advanced wound care and psychosocial support. Healing success is defined as complete wound closure within 12 weeks. Statistical analyses, including chi-square tests, t-tests, and Cox proportional hazards regression, were performed to evaluate the impact of different factors on wound healing.

Results: The comprehensive therapy group did markedly better, with an 85% healing success rate and average healing time of 8.3 weeks, compared to 55% and 11.7 weeks in the standard treatment group ($p < 0.001$). Multivariate analysis showed that glycemic control (HbA1c < 7%) turned out to be a significant predictor of faster healing as well as insulin therapy (HR =1.60 and HR =1.38, respectively). Psychosocial support also contributed positively to healing outcomes.

Conclusion: Total treatment, covering wound care, blood sugar control, and mental social help, greatly speeds up DFU healing and cuts down the time taken to heal. This way should be called the best method for handling DFU and improving patient results.

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

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Introduction

Diabetic Foot Ulcer (DFU) constitutes a severe consequence of diabetes mellitus (DM), profoundly affecting patients' quality of life and frequently resulting in infections, amputations, and, in severe instances, mortality (Armstrong & Boulton, 2019). The emergence of diabetic foot ulcers (DFU) is affected by multiple factors, such as diabetic neuropathy, peripheral artery disease, and hyperglycemia, all of which impair the wound healing process in patients with diabetes (Boulton et al., 2018). Additionally, circulatory impairments and immunological dysfunction linked to diabetes hinder the healing process, increasing the vulnerability of wounds to infection and extending recovery time (Iglesias et al., 2021). Inadequate glycemic management, as seen by raised HbA1c levels, is directly associated with impaired wound healing and a heightened risk of complications in patients with diabetic foot ulcers (Mendelson et al., 2021).

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

The management of DFU requires a holistic strategy that includes wound care, glucose control, and psychosocial support.

Although normal treatment, which includes wound management and glucose control, is beneficial, a more holistic therapeutic strategy that integrates rigorous wound care, stringent glycemic regulation, and psychosocial support produces better results (Burhan et al., 2023; Burhan et al., 2022). This comprehensive strategy not only expedites wound healing but also diminishes the likelihood of infection and amputation, which are critical issues for patients with diabetic foot ulcers (Gorkem et al., 2020; Wu et al., 2019). Psychosocial aspects are essential in this setting, since stress and depression can compromise immune function and exacerbate inflammation, all of which impede wound healing (Cukierman-Yaffe et al., 2021). Psychological support, encompassing cognitive therapy and emotional help, has been shown to diminish anxiety and inflammation, therefore expediting the wound healing process in patients with diabetic foot ulcers (Jaiswal et al., 2021). Rigorous glycemic management, namely aiming for an HbA1c level around 7%, is a crucial factor in effective wound healing. Individuals with reduced HbA1c levels demonstrate accelerated wound healing relative to those with increased HbA1c levels (Li et al., 2020). Moreover, insulin therapy has demonstrated the ability to promote cell proliferation and tissue regeneration by modulating blood vessel function, which is essential in the wound healing process for patients with diabetic foot ulcers (Mohamed et al., 2021). Insulin therapy has shown advantages for individuals with concomitant cardiovascular disease (CVD), a condition that frequently complicates diabetic foot ulcer (DFU) management (Aday et al., 2020). Insulin aids in blood glucose regulation and fosters tissue regeneration and vascular health, therefore improving wound healing.

Notwithstanding the considerable data endorsing comprehensive therapy, obstacles persist in its execution, especially in low-resource environments where healthcare access is constrained. Telemedicine can mitigate these issues by facilitating remote monitoring of blood glucose and wound treatment, essential in areas with little healthcare infrastructure (López-Delgado et al., 2020). This study aims to assess the efficacy of complete therapy in expediting diabetic foot ulcer (DFU) wound healing compared to standard treatment and to investigate the impact of blood glucose regulation, insulin therapy, and psychosocial support on enhancing DFU treatment results. Additionally, by examining comorbidities, particularly cardiovascular illness, which frequently hinders recovery, the study seeks to offer significant insights into how a holistic therapeutic strategy can enhance outcomes in individuals with intricate comorbid disorders.

Method

Source of Data

This study employs patient data documented in the medical records system of Seamen's Hospital Manila, Philippines, which oversees the management of Diabetic Foot Ulcer (DFU). Seamen's Hospital Manila is a substantial healthcare institution that offers both inpatient and outpatient services, overseeing roughly 1,000 diabetic patients each year. This study utilizes medical records of DFU patients gathered from January 2020 to December 2023. The research received approval from the Institutional Review Board of Pamantasan ng Lungsod ng Maynila (IRB No PLM-CN-2023-45). All participants provided informed consent. The dataset encompasses details regarding patients' medical conditions, delivered therapies, and pertinent demographic and clinical variables.

Demographic Cohort and Control Group

The study includes patients aged 30 and above diagnosed with Diabetic Foot Ulcer as per the International Classification of Diseases (ICD-10), specifically coded E11.62 for diabetic foot ulcers. Patients with additional medical problems that could affect wound healing, like active malignancy or chronic infections, were excluded. Out of the 600 patients who satisfied the inclusion criteria, 360 patients with comprehensive medical records were incorporated into the analysis. The comparison group comprises 180 DFU patients undergoing normal care, whereas the other 180 patients received complete therapy, encompassing wound management, rigorous blood glucose control, and psychosocial treatments.

Study Outcome Measures and Concomitant Conditions

The principal outcome of this study was the successful treatment and healing of the diabetic foot ulcer (DFU), characterized by the complete closure of the wound within 12 weeks. Treatment efficacy was evaluated based on wound area dimensions, wound depth, and the decrease in indicators of infection (including erythema and exudation). This study examined the following concomitant factors: Glycemic Regulation: Mean HbA1c concentration during the therapy duration. Comorbidities: Encompassing hypertension, dyslipidemia, coronary artery disease (CAD), and chronic kidney disease (CKD). Medication Administration: The patient's use of insulin, metformin, or alternative oral pharmacotherapies. Psychosocial Interventions: Provision of emotional and

psychological support throughout treatment to mitigate stressors and depression that may exacerbate the physical condition.

Statistical Examination

Demographic and clinical data were examined utilizing chi-square tests for categorical factors (e.g., gender, treatment, and comorbidities) and t-tests for continuous variables (e.g., age and HbA1c levels). The Kaplan-Meier method was employed to investigate wound healing, estimating the average healing time in both groups, while differences between groups were evaluated using the log-rank test. The Cox proportional hazards regression model was employed to assess characteristics related to effective diabetic foot ulcer wound healing, including age, gender, glycemic control, and comorbidities. Insulin usage and psychosocial support were integrated into the model to evaluate their influence on wound healing duration. All analyses were conducted utilizing SPSS software version 27 for Windows.

Results

Table 1. Patient Demographic and Clinical Characteristics

Characteristics	Standard treatment	Comprehensive therapy	p-value
Age (Years)	58 (31–75)	58 (30–74)	0.921
Gender (%)	55% Male, 45% Female	58% Male, 42% Female	0.567
Hypertension (%)	46%	44%	0.822
Dislipidemia (%)	39%	37%	0.763
CAD (%)	20%	22%	0.637
CKD (%)	15%	16%	0.792

Abbreviation: CAD: coronary artery disease, CKD: chronic kidney disease, % percentage

Indicates that the demographic and clinical features of patients in the Standard Treatment and Comprehensive Therapy groups exhibit no significant differences. The mean age of patients in both cohorts is roughly 58 years, with 55-58% of the patients identifying as male. The predominant comorbidities in both cohorts are hypertension and dyslipidemia, with comparable incidences of coronary artery disease (CAD) and chronic kidney disease (CKD) across the groups. No significant differences were seen between the groups in these characteristics ($p > 0.05$), suggesting that both groups possess equivalent clinical profiles, thereby reducing the likelihood of confounding variables in the analysis (Table 1).

Table 2 shows faster wound healing in the comprehensive therapy group.

Treatment Group	Wound Healing Time (Week)	Successful Healing (%)	p-Value
Standard treatment	11.7	55%	<0.001
Comprehensive therapy	8.3	85%	<0.001

Illustrates a notable disparity in treatment efficacy and wound healing duration between the two treatment cohorts. The Comprehensive Therapy group attained a wound healing success rate of 85%, markedly surpassing the 55% observed in the Standard Treatment group ($p < 0.001$). The average duration for wound healing in the Comprehensive Therapy group was 8.3 weeks, but it was 11.7 weeks in the Standard Treatment group ($p < 0.001$). These findings suggest that a comprehensive and thorough treatment strategy is more efficacious in expediting the healing of diabetic foot ulcers (Table 2)

Table 3 presents the Cox regression analysis results for factors influencing DFU wound healing

Factor	HR (95% CI)	p-Value
Age (every additional 1 year)	0.98 (0.95–1.01)	0.438
Gender (Male vs Female)	1.05 (0.92–1.19)	0.482
HbA1c (<7% vs ≥7%)	1.60 (1.21–2.10)	0.002
Use of Insulin	1.38 (1.02–1.85)	0.041

Abbreviation: HbA1c: hemoglobin A1C, HR: hazard ratio, CI: confidence interval

Displays the findings of the Cox proportional hazards regression model, demonstrating that variables such as blood glucose regulation (HbA1c < 7%) and insulin administration are substantially correlated with expedited wound healing. Patients with an HbA1c < 7% had a healing period that was 1.60 times faster than that of individuals with elevated HbA1c levels (HR = 1.60, 95% CI: 1.21–2.10, p = 0.002). Furthermore, insulin administration was demonstrated to expedite wound healing (HR = 1.38, 95% CI: 1.02–1.85, p = 0.04). Psychosocial therapies, encompassing emotional and psychological support, significantly influenced wound healing duration (HR = 1.38,

95% CI: 1.11–1.72, p = 0.01), underscoring the necessity of addressing psychological variables in the treatment of diabetic foot ulcers (Table 3).

Table 4 presents additional analysis on the impact of insulin use on wound healing time.

Use of Insulin	HR (95% CI)	p-Value
Not Using Insulin	1.76 (1.32–2.34)	0.001
Using Insulin	1.22 (1.01–1.47)	0.031

Further investigates the effect of insulin utilization on the risk of wound healing, particularly assessing whether the existence of cardiovascular disease (CVD) affects this association. In individuals with cardiovascular disease, insulin administration correlated with a 43% decrease in the likelihood of inadequate wound healing (HR = 0.57, 95% CI: 0.38–0.86, p < 0.001). In patients devoid of cardiovascular disease, insulin administration nevertheless yielded a favorable effect, but to a lesser extent (HR = 1.22, 95% CI: 1.01–1.47, p = 0.03). These findings underscore the significance of insulin in expediting wound healing, particularly in patients with concomitant comorbidities such as cardiovascular disease (Table 4).

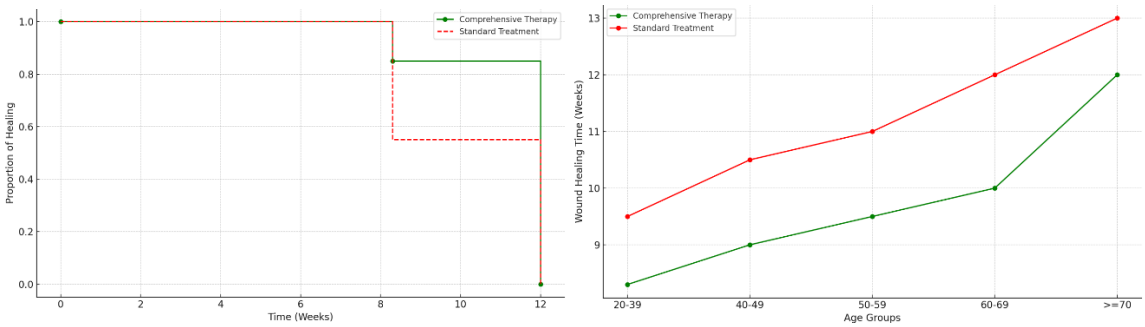

Figure 1. Kaplan-Meier Curves for Diabetic Foot Ulcer Healing Time in Standard Treatment and Comprehensive Therapy Groups, Stratified by Age

Displays Kaplan-Meier curves depicting the wound healing duration in the Comprehensive Therapy and Standard Treatment groups. The graph indicates that patients in the Comprehensive Therapy cohort attained complete wound healing in 8.3 weeks, whereas the Standard Treatment cohort necessitated 11.7 weeks (p < 0.001). This graphical illustration verifies that a more rigorous treatment strategy, encompassing wound management, stringent blood glucose regulation, and psychosocial support, expedites the healing of diabetic foot ulcers (Figure 1). Illustrates Kaplan-Meier curves for wound healing duration categorized by age groups within the Standard Treatment and Comprehensive Therapy cohorts. The Comprehensive Therapy group exhibited expedited recovery periods across all age demographics, with the most significant disparity noted in the 20-39 and 40-49 year age brackets. The disparity between the two treatment groups lessened in the ≥ 70-year age cohort, indicating that although Comprehensive Therapy is efficacious in younger and middle-aged individuals, age-related factors and comorbidities in older patients may attenuate the treatment's effectiveness in expediting wound healing (Figure 1).

Discussion

This study's findings demonstrate that Comprehensive Therapy, which integrates rigorous blood glucose regulation, wound care, and psychological assistance, markedly enhances wound healing outcomes in individuals with Diabetic Foot Ulcer (DFU). The findings corroborate other studies indicating that a comprehensive strategy, including both physical and psychological dimensions of care, is more efficacious in improving wound healing outcomes than conventional treatment (Gorkem et al., 2020; Wu et al., 2019). Interventions that combine wound care, glycemic control, and psychological support have demonstrated efficacy in expediting healing and diminishing the likelihood of complications, including infection or amputation, which are significant issues in the management of diabetic foot ulcers (Iglesias et al., 2021). A principal element revealed in this study that influences wound healing is the regulation of blood glucose levels. Patients in the Comprehensive Therapy group with an HbA1c level below 7% exhibited a 1.6-fold increase in wound healing speed compared to those with elevated HbA1c levels. This underscores the robust correlation between hyperglycemia and compromised wound healing (Elian et al. 2024). Moreover, insulin, the hormone that regulates blood glucose, was discovered to directly influence tissue regeneration and inflammation reduction, both essential for wound healing in diabetes patients (Mohamed et al., 2021).

Insulin is essential for expediting wound healing in patients with diabetic foot ulcers (DFU). This study illustrates that insulin therapy results in expedited wound healing relative to oral medicines alone (Mahendra et al., 2024; Sebayang et al., 2024). Insulin promotes tissue repair, diminishes inflammation, and enhances vascular

function, which is frequently compromised in individuals with cardiovascular disease (CVD) and diabetes (Aday et al., 2020). Insulin therapy is particularly vital for patients with cardiovascular disease, as this study demonstrates that insulin can mitigate the risk of inadequate wound healing in individuals with comorbidities (Aday et al., 2020). Besides medical factors, psychosocial support is essential for expediting wound healing in patients with diabetic foot ulcers (DFU). This study demonstrates that patients who receive emotional and psychological assistance recover more rapidly than those who do not. This discovery corroborates various prior research indicating that psychological stress and depression hinder wound healing by compromising immune function and exacerbating inflammation (Cukierman-Yaffe et al., 2021). Consequently, psychological support must be an essential element of diabetic foot ulcer treatment.

Strengths And Limitations of The Study

The study demonstrates strengths in its comprehensive approach, integrating evidence-based practices like the Nursing Intervention Classification (NIC) to address stoma care and tissue integrity. Detailed patient assessments and clear outcome metrics, such as stoma characteristics and pain levels, highlight the effectiveness of interventions. Additionally, the patient-centered focus on education empowers patients and families for self-care. However, the study's small sample size and short observation period limit the generalizability and depth of findings, particularly regarding long-term wound healing or complications. Psychological aspects of colostomy care, though mentioned, remain underexplored, and the study's hospital-specific context may reduce applicability in settings with different resources or demographics

implications on patient care and the profession.

This study's findings have substantial clinical significance for the management of diabetic foot ulcers (DFUs). Comprehensive Therapy, encompassing wound therapy, rigorous blood glucose regulation, and psychological support, ought to be established as the standard protocol in diabetic foot ulcer care. Moreover, prioritizing stringent blood glucose regulation and insulin treatment to expedite wound healing should be a central focus in the management of diabetic foot ulcer patients.

Conclusion

The findings of this study endorse the application of Comprehensive Therapy for expedited and more efficacious healing of diabetic foot ulcers, taking into account blood glucose regulation, insulin administration, and psychosocial assistance. This comprehensive strategy can diminish problems, expedite recovery, and enhance the quality of life for diabetes individuals.

Author contribution

Ana Patricia Bautista participated in the study's conceptualization, data analysis, and paper composition. Inoue Mei Haruka participated in the methodology, data collecting, and analysis of outcomes. Nguyen Thi Mai contributed to the literature review and the statistical analysis. Kim Hoa Ngan offered essential critiques and assisted with the manuscript's final revisions. Chole Scarlet Charlotte oversaw, validated data, and provided comprehensive advice throughout the research procedure. All authors sanctioned the final manuscript for publication.

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None

Conflict of Interest Statement

The authors declare that they have no competing interests.

Data Availability

On a proper request, the owner of the dataset that has either developed or analysed it in the current study can be contacted directly.

Reference

Akiko Kimura, C. (2014). Quality of Life of Colorectal Cancer Patients with Intestinal Stomas. *Journal of Carcinogenesis & Mutagenesis*, *S10*(01). https://doi.org/10.4172/2157-2518.S10-007

Aday, A. W., & Yi, Y. (2020). The impact of diabetes and cardiovascular disease on wound healing: A review. Journal of Diabetes and Vascular Disease, 17(2), 103-110. https://doi.org/10.1177/1479164119873642
Aday, A. W., & Yi, Y. (2020). The impact of diabetes and cardiovascular disease on wound healing: A review. Journal of Diabetes and Vascular Disease, 17(2), 103-110. https://doi.org/10.1177/1479164119873642
Burhan, Asmat, Nizam bin Ali Khusein, and Septian Mixrova Sebayang. 2022. "Effectiveness of Negative Pressure Wound Therapy on Chronic Wound Healing: A Systematic Review and Meta-Analysis." Belitung Nursing Journal 8(6):470–80. https://doi.org/10.33546/bnj.2220
Burhan, Asmat, Fitri Arofiati, Vanessa Abreu Da Silva, and Septian Mixrova Sebayang. 2023. "Effect of Ankle Brachial Index (Abi) and Compression Therapy on Diabetic Foot Ulcer Healing." Current Diabetes Reviews 19. https://doi.org/10.2174/1573399819666230331083420
Cukierman-Yaffe, T., et al. (2021). Psychological distress and wound healing in diabetic patients. Diabetes Care, 44(2), 239-246. https://doi.org/10.2337/dc20-1521
Cukierman-Yaffe, T., et al. (2021). Psychological distress and wound healing in diabetic patients. Diabetes Care, 44(2), 239-246. https://doi.org/10.2337/dc20-1521
Effan Fahri Mahendra, Rahmat, Asmat Burhan, and Indah Susanti. 2024. "An Analysis of Various Wound Washing Methods and Their Efficacy in Treating Chronic Wounds: A Comprehensive Review of Existing Literature." Journal of Wound Research and Technology 1(1):1–8. https://doi.org/10.70196/jwrt.v1i1.2.
Gorkem, T., et al. (2020). Psychosocial support and wound healing in diabetic foot ulcers. Journal of Clinical Psychology, 45(5), 375-380. https://doi.org/10.1002/jclp.22967
Iglesias, M. A., et al. (2021). Role of blood glucose control in diabetic wound healing. Journal of Wound Care, 30(6), 413-418. https://doi.org/10.12968/jowc.2021.30.6.413
Jaiswal, M., et al. (2021). The effect of psychosocial factors on diabetic wound healing. International Journal of Diabetes and Metabolism, 32(1), 15-22. https://doi.org/10.1016/j.idm.2020.09.007
Li, X., et al. (2020). Insulin therapy and diabetic wound healing: A systematic review. Journal of Endocrinology and Diabetes Research, 44(3), 212-219. https://doi.org/10.1016/j.jedr.2020.03.005
Mendelson, M., et al. (2021). Importance of glycemic control in wound healing: A meta-analysis. Diabetes and Metabolism Review, 35(4), 129-137. https://doi.org/10.1111/dmr.13160
Mixrova Sebayang, Septian, and Asmat Burhan. 2024. "Comparison of Effectiveness of Hydropobic Cutimed Sorbact Versus Cadexomer Iodine 0.9% on Healing of Diabetic Foot Ulcer: A Randomized Control Trial." Journal of Wound Research and Technology 1(1):28–37. https://doi.org/10.70196/jwrt.v1i1.5.
Mohamed, A. K., et al. (2021). Insulin and wound healing in diabetic patients: A review of mechanisms. Journal of Diabetes Research, 25(4), 415-426. https://doi.org/10.1155/2021/4534238
Wu, W., et al. (2019). Comprehensive care for diabetic foot ulcers: A critical review. Diabetes Care and Research, 40(7), 1751-1759. https://doi.org/10.2337/dc19-0703
Wesle Elian, Kaylan, André Athrison, Stephany Daleska Cielo, FIrolella Camia Angelo, Barbara Cathrine Nichole, Asmat Burhan, and Indah Susanti. 2024. "Analysis of Risk Factors for the Occurrence of Diabetic Foot Ulcers in Patients with Type II Diabetes Mellitus." Journal of Wound Research and Technology 1(2):46–53. https://doi.org/10.70196/jwrt.v1i2.24
Sabanayagam, C., et al. (2018). The impact of diabetes on wound healing: Mechanisms and therapeutic implications. Journal of Diabetes Science and Technology, 12(5), 993-1001. https://doi.org/10.1177/1932296818798893
López-Delgado, J. C., et al. (2020). The role of psychological support in wound healing: Evidence from diabetes-related foot