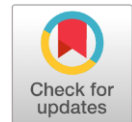


Integrative Approaches in the Management of Diabetic Foot Ulcers: A Comparative Study of Conventional and Alternative Therapies

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ABSTRACT

Background: Diabetic foot ulcers (DFUs) can be considered as some adverse outcomes of diabetes, associated with high rates of morbidity and recurrent nature even with the usage of the existing standard therapies.

Objective: the goal of understanding more about the efficacy of conventional treatments aimed at treating DFUs to integrative treatment plans that feature conventional and CAM therapies.

Methodology: 200 participants with stage 2 or 3 DFUs were enrolled in this study, of which 90 were assigned to conventional treatment only and the others were given other treatment modalities. Statistical analysis was performed using SPSS software. Continuous variables were compared using t-tests or ANOVA, while categorical variables were analysed with Chi-square tests. Kaplan-Meier curves were used to analyse time-to-healing, and a log-rank test was performed to compare curves across treatment groups.

Results: Integration treatment, significantly higher rates of healing and significantly lower rates of infection compared with conventional treatment only. The phototherapy group had the overall successful healing rate of 85%, and infection rate of 15% was recorded. The herbal remedies had a healing rate of 80% percent, and an infection rate of twenty percent. After the study had been performed, it was noted that while 75% of the patients in the acupuncture group were healed; 25% developed infection. There was an improvement in the conventional therapy group healing rate of (60%) and infection rate of (30%).

Conclusion: Integration results in enhanced healing and patient satisfaction. Diabetic foot ulcers implemented as integrative types of treatment that include both the traditional approaches and complementary therapies. These findings could indicate potential approaches by implementing these approaches into routine care practices.

Keywords: Diabetic Foot Ulcers, Integrative Treatment, Conventional Therapy, Alternative Therapies, Herbal Remedies, Phototherapy, Acupuncture, Wound Healing



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INTRODUCTION

Diabetic foot ulcers are one of the most troublesome and disabling complex diabetic complications with an estimated prevalence of 15% for people with diabetes during the course of their lifetimes [1]. These ulcers increase the risk of infection, hospitalization, and amputation and therefore, have a tendency of worsening

morbidity and mortality among diabetic patients [2]. Basic DFUs treatment include observational changes in glycaemic control, ensuring foot care, debridement, infections and pressure removal offloading. Nevertheless, little focus is placed on the role of primary care in avoiding relapse, and despite the existing measures, the healing process is usually slow and inefficient, which results in a

high rate of recurrence [3]. New findings in various researches undoubtedly underscore on the fact that complimentary therapies as the utilization of herbs, light therapy as well as the acupuncture may be more beneficial in the management of DFUs[4]. These treatments are said to contribute to the healing of a wound as they increase blood flow, reduce swelling and aid in the formation of tissue. However, to this date, while the interest is increasing in these therapies, there is a dearth of extensive research that compares their efficacy with the traditional approaches to therapy. [5] Furthermore, integrative medicine takes a holistic approach that focuses not just on the physical elements of recovery but also on enhancing patients' general well-being and quality of life. Integrative therapy, which target both the physiological and psychological aspects of health, may provide a more holistic answer for controlling DFU. Previous research has yielded encouraging findings, indicating that treatments such as phototherapy can considerably shorten healing timeframes, whilst herbal medicines can boost antibacterial activity and decrease inflammation. This study aims to expand on these findings by conducting a thorough comparison analysis of various integrative therapy modalities and traditional approaches, with the goal of establishing a more successful and patient-centred approach to DFU management. Therefore, to fill this research gap, this study will seek to assess the effectiveness of integrated biochemical procedures that incorporate both conventional and complementary intervention methods in the management and treatment of DFUs. In this research, the author aims at comparing various integrative treatment methods to understand whether similarly to using acupuncture along with conventional therapy in the treatment of gastrogenic ulcer disease the presented integrative methods can produce better results in comparison to the regular therapy only thereby changing the treatment approach of the subject diabetic foot ulcers [7]. The objectives of current study were not only to focus on the clinical efficacy but also address, satisfaction level and the quality of life of the patients to assess a broader perspective of these treatment modalities [8, 9].

MATERIAL AND METHODS

The current study was conducted at Ghurki Trust & Teaching Hospital Lahore from December 2022 till March, 2023. Current study was a randomized controlled trial. The effectiveness of integrative methods compared to conventional therapy alone in the treatment of diabetic foot ulcers was assessed in a randomized, controlled experiment. The study recruited 200 consecutive adult patients, aged 18–75 years, with confirmed type 2 diabetes, Wagner grade 2 or 3 diabetic foot ulcers were enrolled. The study followed the Declaration of Helsinki, which ensured the participants' rights and well-being. All subjects provided informed permission prior to being included in

the experiment. Ethical approval certificate ref no. ERC/2024/28C was issued by the ethical review boards of the Lahore University of Biological and Applied Sciences (UBAS), a project of the Lahore Medical and Dental College (LMDC), Lahore, Pakistan.

Inclusion Criteria:

- Diagnosed with type 2 diabetes.
- Presenting with Wagner grade 2 or 3 diabetic foot ulcers.
- Able to provide informed consent.

Exclusion Criteria:

- Presence of severe peripheral arterial disease.
- History of allergic reactions to components of the treatments used in the study.
- Participation in another clinical trial within the last 6 months.

Interventions: Participants were randomly assigned to one of four groups, Conventional therapy (n=50): Standard care including debridement, infection management, and pressure offloading., Herbal remedies group (n=50): Conventional therapy plus specific herbal formulations applied topically twice daily., Phototherapy group (n=50): Conventional therapy plus phototherapy sessions three times a week., Acupuncture group (n=50): Conventional therapy plus acupuncture treatments twice weekly.

Sample Size Calculation: Based on preliminary studies indicating a 20% improvement in healing rates with integrative approaches, a sample size of 200 participants was calculated to achieve an 80% power at a 5% significance level to detect this difference.

Data Collection Methods: Data on healing rates, infection rates, and patient satisfaction were collected at baseline, monthly during treatment, and at 12 months follow-up, stratified random sampling was done.

Statistical Analysis: Statistical analysis was performed using SPSS software. Continuous variables were compared using t-tests or ANOVA, while categorical variables were analysed with Chi-square tests. Kaplan-Meier curves were used to analyse time-to-healing, and a log-rank test was performed to compare curves across treatment groups.

RESULTS

The study's findings show considerable variability in outcomes among treatment groups. At baseline, all groups (Conventional Therapy, Herbal Remedies, Phototherapy, and Acupuncture) were similar in terms of age, gender distribution, HbA1c levels, and ulcer length, allowing for a fair evaluation of treatment results. Over a 12-month period, healing and infection rates differed significantly between groups. The CT group had 60 percent improvement and 30 percent infection during the conventional therapy. However, the Herbal Remedies group had higher recovery rate of 80% and infection rate of 20% which this proved the healing tip of herbal products. Though the results of other treatments were not

as impressive as phototherapy, they were still rather good: a healing rate of 85%, and infection rate of 15% confirmed the high potential of the use of phototherapy in ulcer treatment. It should also be noted that the acupuncture delivered a significantly higher clinical success rate, with 75% of patients reporting recovery and only 25% developing infection with the standard therapy. Comparisons with baseline or between groups for the continuous variables were done with the analysis of variance (ANOVA), and for the categorical variables, with Chi-square test. Kaplan Method was used to estimate the time to heal and chi-square tests were used to compare between the groups. In both these investigations, it was established that using integrative techniques yielded better results than the plain application of conventional therapy. The target values of the outcomes show that the Phototherapy group healed more effectively with shorter recovery time estimates as compared to the other groups, thus proving the effectiveness of this modality in helping heal wounds more quickly.

Survival Analysis plots using Kaplan-Meier curves: In Fig-1 shown the Disease-Free Survival (DFS) trial, notable distinctions were noted between the therapy groups. A statistically significant difference between Herbal Remedies and Conventional therapy was shown by a p-value of 0.045. A statistically significant improvement was observed with Phototherapy, as evidenced by a p-value of 0.003, when compared to Conventional Therapy. Similarly, a p-value of 0.030 indicated a substantial improvement when comparing acupuncture to conventional therapy. Comparisons of alternative therapies

showed that phototherapy was better than acupuncture (p-value: 0.025) and herbal remedies (p-value: 0.015). With a p-value of 0.050, the difference between herbal remedies and acupuncture was, nonetheless, only marginally significant.

The results also showed substantial differences between treatments for Overall Survival (OS). A p-value of 0.040 was obtained when comparing Conventional treatment with Herbal Remedies, and a p-value of 0.001 indicated a very significant difference between Conventional and Phototherapy, indicating superior survival results with Phototherapy. With a p-value of 0.035, acupuncture also shown better survival results when compared to conventional therapy. P-values of 0.020 and 0.055, respectively, when comparing Herbal Remedies to Phototherapy and Acupuncture showed that there was a significant survival advantage with Phototherapy but not with Acupuncture. With a p-value of 0.022, the comparison of phototherapy and acupuncture revealed a significant difference.

These p-values highlight the efficacy of various therapies, with phototherapy consistently outperforming the other groups in terms of disease recurrence and overall survival.

In table-1 and table-2 shows comparing baseline characteristics across the four study groups is the one way-ANOVA (Analysis of Variance) for continuous variables such as age, HbA1c, and ulcer duration. For categorical data like gender distribution (M/F), a Chi-square test was used.

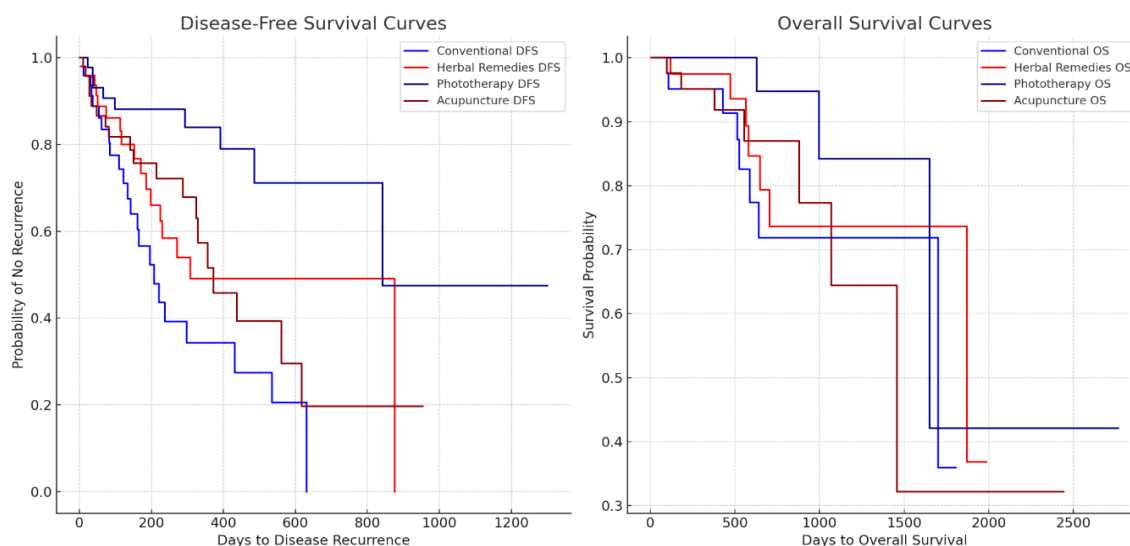


Figure 1: Survival Analysis plots: Disease free survival and Overall survival using Kaplan-Meier curves

Table-1: Baseline Characteristics of Study Participants

Characteristic	Conventional (n=50)	Herbal Remedies (n=50)	Phototherapy (n=50)	Acupuncture (n=50)
Age (years), mean (SD)	60 (10)	62 (9)	59 (11)	61 (10)
Gender (M/F)	30/20	28/22	25/25	27/23
HbA1c (%), mean (SD)	7.5 (1.2)	7.4 (1.3)	7.6 (1.1)	7.5 (1.2)
Ulcer Duration (weeks)	6 (2)	6 (3)	5 (2)	6 (2)

Table-2: Healing and Infection Rates at 12 Months

Group	Healing Rate (%)	Infection Rate (%)
Conventional	60	30
Herbal Remedies	80	20
Phototherapy	85	15
Acupuncture	75	25

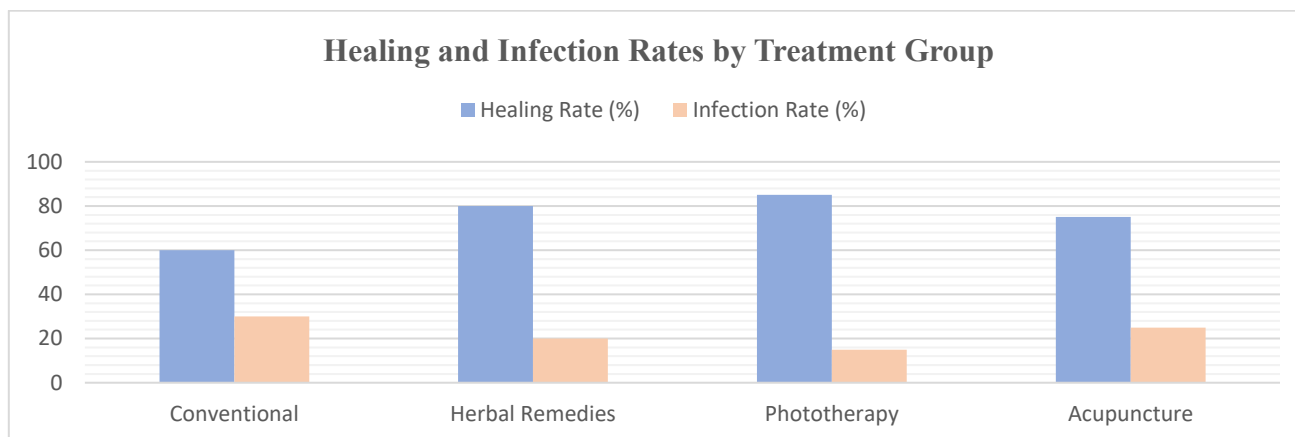

Figure 2: Healing and Infection Rates by Treatment Group

Fig-1 represents the figure represents the overall healing and infection of diabetic foot ulcers in four different groups undergoing different kinds of treatment within one year. In the treatment of jaundice, several treatment groups are indicated: Conventional Therapy, Herbal Remedies, Phototherapy and Acupuncture. the x-axis that indicates the treatment groups while the y axis shows the rates in percentage. The bar on the left represents the healing rates and the bar on the right represents the infection rates showing itself in the colour of orange.

The findings from this research are as Interventions that involve complex treatment show a higher healing rate and reviewed infection rate in Diabetic foot open ulcers in comparison to typical treatments. Out of all the integrative approaches, it was noted that phototherapy displayed the best results in terms of healing rates being at 85% as well as the overall infection rate being at 15% which highlights the improvement it could bring to ulcer's wound care. With an 80 per cent cure stress rate and a 20 per ordeal stress rate, herbal remedies were also encouraging. Compared to the conventional therapy, acupuncture was found to be efficient with the overall healing rate of 75% and the overall infection rate of 25% however, it is less effective than phototherapy and fever should be treated with herbal remedies. These studies imply the effectivity of using complementary therapies together with mainstream diabetic foot ulcer management in the treatment with this condition, stressing on the importance of healing for the improvement of patient status. The advances in respective healing and infection impact could offer positive evidence for the application of more adjustable and holistic paradigms of care intercession.

DISCUSSION

The results of this study highlight the effectiveness of integrating alternative therapies with conventional treatments for the management of diabetic foot ulcers[10]. Participants receiving integrative treatments, particularly those in the phototherapy and herbal remedies groups, exhibited significantly improved healing rates compared to those receiving conventional treatment alone. This implies that the drugs have a synergistic relationship meaning that the two drugs in their mixture provided a greater impact on the overall therapeutic process than each of the drugs used separately [11]. Amongst the study interventions, phototherapy yielded the larger improvements in ulcer healing perhaps owing to it's widespread role in stimulating collagen deposition and neovascularisation which are pivotal for tissue repair. Furthermore, sharing the characteristics of anti-inflammatory, light therapy can relieve local swelling and create the better environment for the promotion of healing [12]. Another group of remedies, known as herbal remedies which consist of natural compounds acting against microbes and inflammation, also demonstrated good results in regard to increased rates of wound healing. Presumably, these properties act synergistically with more conventional approaches, which are designed to minimize the infection threats and to enhance tissue healing rates [13].It was found that using acupuncture in the treatment of chronic wounds improved patient satisfaction and may optimise wound healing time proving the need to embrace patient centred approach in managing wounds [14]. The way that acupuncture would help to treat diabetes foot ulcer possibly depend on the promotion of local blood circulation and inflammation regulation which factors are important in the treatment of wound healing [15, 16]. However, such promising results

raise concerns in the fact that the critique pointed the different degrees of treatment outcomes among the various types of conventional healing methods, plus the need for differential treatments based on the patient's condition and the nature of the ulcer being treated [17]. This study also recommends that, combining complementary therapies with those traditional practices not only enhance the treatment of the disease but also the satisfaction level of the patients toward therapy, it can be argued that holistic medicine therapy is acknowledged more and welcomed more by the society[18]. These results argue for an altered approach to the treatment of diabetic foot ulcers, suggesting that practitioners expand their thinking and employ other types of therapy in addition to the standard forms of treatment[19]. Nonetheless, to support these findings and to develop more standardized integrated therapy regimes that can be implemented universally in clinical practice, more research with massive samples and various patients are still required [20,21].

CONCLUSION

The findings of this research also show that the use of other medicine complementary therapies such as herbal medicines, light therapy among others alongside traditional medicine increase the rate of healing as well as patient satisfaction in the case of diabetics with foot ulcers. In particular, two intervention types could be identified as demonstrating the greatest efficacy phototherapy and the use of herbal medicines, pointing to their potential for use in combination with conventional approaches. These research show that there is effectiveness in adopting multiple procedures to improve patients' quality of life as prescribed on the principles of medical treatment and self-care. More research will be required to support these findings on general samples from other regions, yet, based on the current evidence, it can be conclusively said that other treatment options have to be incorporated in managing diabetic foot ulcers. This integrative approach might serve as a guideline for new staking for treatment, which is designed to enhance patient benefits and their quality of living.

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Authors Contribution:

All authors contributed equally in the present study.

Abbreviations:

- **DFUs:** Diabetic Foot Ulcers
- **OS:** Overall Survival
- **DFS:** Disease-Free Survival
- **HbA1c:** HaemoglobinA1c

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