Research article

Efficacy of microcurrent therapy versus laser therapy for diabetic foot ulcer on size of the wound

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ABSTRACT

Introduction and Aim: Diabetes mellitus (DM) will increasingly contribute to years of life and disability worldwide. Approximately 25% of individuals with diabetes will develop diabetic foot ulcers. This study aimed to assess the effectiveness of microcurrent therapy compared to low-level laser therapy in terms of wound healing and quality of life among patients with diabetic foot ulcers.

Materials and Methods: This study followed a prospective randomized open blinded endpoint assessment (PROBE) design with two parallel groups allocated in a 1:1 ratio. Participants meeting the selection criteria and having diabetic foot ulcers were included. Baseline measurements were taken before randomly assigning participants to the treatment groups. Pre-test and post-test data were collected to evaluate the wound size.

Results: The t-test analyses demonstrated significant improvement in both treatment groups (LLLT: $t = 41.818$, $p < 0.001$; Micro-Current Group: $t = 32.787$, $p < 0.001$). To compare the groups, One-Way Analysis of Variance (ANOVA) was conducted, indicating a significant difference in ulcer size between the LLLT group (mean value: 62.600, SD=3.035) and the microcurrent therapy group (mean value: 51.933, SD= 6.938).

Conclusion: This study concludes that microcurrent therapy is more effective than low-level laser therapy for managing diabetic foot ulcers. The findings suggest that a 3-week intensive physiotherapy therapeutic approach, combined with conventional medical treatment, yields the best results in terms of wound healing.

Keywords: Diabetic ulcer; microcurrent; LLLT; diabetic foot ulcer; acetate tracing.

INTRODUCTION

According to the World Health Organization (WHO), Diabetes Mellitus (DM) is a clinical condition characterized by high blood sugar levels due to insufficient insulin production or utilization. Projections indicate that DM will have a growing impact on mortality and disability worldwide, with it expected to become the 7th leading cause of death by 2030, up from its current position at 11th. Around 15-25% of individuals with diabetes will develop diabetic foot ulcers, a complication that increases the risk of amputation and mortality (1-4).

Type 1 diabetes, previously known as insulin-dependent or juvenile diabetes is characterized by inadequate insulin production, requiring daily insulin administration. The cause of type 1 diabetes is unknown, and it cannot be prevented with current knowledge. Symptoms may include frequent urination (polyuria), excessive thirst (polydipsia), increased hunger, weight loss, vision changes, and fatigue, which can occur suddenly (5). On the other hand, type 2 diabetes, previously called non-insulin-dependent or adult-onset diabetes, arises from the body's ineffective use of insulin. It is prevalent worldwide and is often associated with excess body weight and physical inactivity. Symptoms of type 2 diabetes may resemble those of type 1 but are typically less pronounced. Consequently, type 2 diabetes is often diagnosed after complications have already developed, and it is now increasingly seen in children as well (6).

Foot ulcers in individuals with diabetes develop due to various risk factors and not spontaneously. Preventing ulceration is crucial to avoid costly and debilitating amputations. Diabetic foot complications are considered life-threatening and can lead to a condition known as diabetic foot 'attack'. The risk of amputation in people with diabetes is significantly higher, up to 40 times greater than in those without diabetes. Wagner's classification is a widely accepted grading system for diabetic foot ulcers, which categorizes ulcers into six grades based on their depth (grades 0-5). However, this classification does not adequately account for independent risk factors such as ischemia and infection in all grades.

Low-level laser therapy (LLLT), also known as soft laser, involves delivering low-energy laser light directly to body cells to stimulate bioactivity. LLLT devices emit light at a specific distance from the treatment area, and it is also used in laser acupuncture known as laser needle (7).

Microcurrent therapy has shown successful results in promoting healing, particularly in soft tissue healing. It involves the application of very low-intensity

electrical stimulation in the microampere (μA) range or one-millionth (10-6) of an Ampere and is below the sensation threshold with ranging from 0.5Hz -1565 Hz. Microcurrent therapy produces minute pulsating currents which mimic the currents generated in the body at the cellular level resulting in these currents penetrating the cells unlike other electrical stimulation devices which bypass the cell to focus on muscle, tissue and fascia. This form of stimulation has Pulsed High-voltage, damped sinusoidal asymmetrical waveforms.

MATERIALS AND METHODS

Study design

This research study followed a prospective randomized open blinded endpoint assessment (PROBE) design, consisting of two parallel groups with a 1:1 allocation. The participants were recruited from Saveetha Medical College and Hospital, and individuals with diabetic foot ulcers who met the specified selection criteria were included. Prior to enrollment, all participants provided their consent using the approved consent form from the institution.

The inclusion criteria for this study were as follows: patients diagnosed with Type II DM and having a diabetic foot ulcer for a minimum duration of 4 weeks, along with a Wagner grade 2 classification of the foot ulcer. Participants exhibiting clinical signs of infection, those with exposed bone in the target wound, and individuals with other concurrent illnesses or conditions that could potentially hinder wound healing (such as carcinoma, vasculitis, connective tissue disease, or immune system disorders) were excluded. Moreover, individuals with ulcers in locations other than the foot and those with multiple diabetic ulcers on the same foot were also excluded from participation. The participants were randomly assigned to two groups, namely Group A receiving low-level laser therapy and Group B receiving microcurrent therapy.

Procedure

From the population, a total of 125 potential participants were screened for this study. Among them, 60 participants who met the inclusion and exclusion criteria were enrolled. The researchers thoroughly explained the study's objectives and treatment procedures to all participants, and informed consent was obtained prior to their enrolment in the study. Baseline measurements were taken for all participants before they were randomly assigned to their respective treatment groups. Pre-test and post-test data were collected to assess the size of the wounds, using acetate tracing as the outcome measure. An independent physiotherapist with appropriate qualifications evaluated the pre-test and post-test data. To calculate the ulcer area, an impression of the ulcer floor was obtained on a sheet of cellophane paper and then transferred onto graph paper. The ulcer size was measured on day 0 and day 21.

The intervention period lasted for 3 weeks. Each treatment session lasted an average of 30-50 minutes for both Group A (LLLT) and Group B (Microcurrent therapy). Data collection occurred before the study commenced and at the end of the study. In Group A, patients received LLLT treatment along with conventional treatment, including daily wet saline or betadine dressings and antibiotic therapy. The LLLT device used in the study was equipped with a Scanning mode (Techno med Electronics Ltd). The duration of exposure was calculated based on the size of the ulcer to deliver 3-5 J/cm2 at 632.8 nm, with continuous emission of a visible beam administered daily for 3 weeks. The ulcer floor and edge were irradiated, and the ulcer was then covered with conventional moist dressing. In Group B, patients received Microcurrent therapy in addition to conventional treatment, which included daily wet saline or betadine dressings and antibiotic therapy. Microcurrent device with a modulate .5:1 and VASO modes (Avazzia Inc., USA) were used in this group. Modulate mode outputs pulses with frequency from 139 Hz to 147 Hz with two pulses per output packet. VASO stands for variable sophisticated mode frequency where the frequency ranges from 4Hz to 99Hz with four to six pulses per packet.

Outcome measures: Acetate tracing

The acetate method used in this study involved placing a two-layer transparent acetate sheet over the wound. The wound was then traced using an indelible marker on a grid pattern. The bottom layer of the acetate, which was in direct contact with the wound, was disposed of as clinical waste, while the top layer was stored with the patient's medical records. The acetate sheets used in this method typically come pre-printed with $1cm^2$ measurements. The number of complete squares within the perimeter of the wound was counted as $1cm^2$ (8). For incomplete squares that covered the entire wound area, an approximation was made. The number of 1-mm squares within the traced area was also counted, taking into account only the full 1-mm squares inside the perimeter. The area was then converted to square centimetres. The data collected through this method was recorded in an Excel spreadsheet (9).

Statistical analysis

The data in this study consists of pre-test and post-test measurements from the LLLT (Low-Level Laser Therapy) Group. Each measurement was obtained from a sample size of 30. The statistical analysis used for this comparison is the paired t-test. For the LLLT Group, the paired t-test yielded a t-value of 41.818 and a corresponding p-value of less than 0.001. These values indicate a statistically significant difference

between the pre-test and post-test measurements within the LLLT Group.

The Microcurrent therapy Group underwent a pre-test and post-test assessment, with each group comprising a sample size of 30. The statistical analysis employed for comparing these measurements is the paired t-test. For the Microcurrent therapy Group, the paired t-test resulted in a t-value of 32.787 and a corresponding p-value of less than 0.001. These findings indicate a highly significant difference between the pre-test and post-test measurements within the Microcurrent therapy Group.

RESULTS

The data was collected by a blinded assessor which was interpreted with statistical analysis. The principal investigator first analyzed the demographic and clinical baseline data by using mean and SD of all variables. The Acetate tracing was analyzed with the parametric test, t-test was used to compare within-group significance and one-way ANOVA was used to compare the significance between the groups. The t-test analyses have shown significant improvement in all the two groups (LLLT t= 41.818 p<0.001 and Micro-Current Group t = 32.787, p<0.001). Between groups, the analysis was done with One Way Analysis of Variance (ANOVA) to analyse the size of ulcer difference where LLLT group with the mean value of 62.600, SD=3.035 and micro-current therapy group with the mean value of 51.933, SD= 6.938.

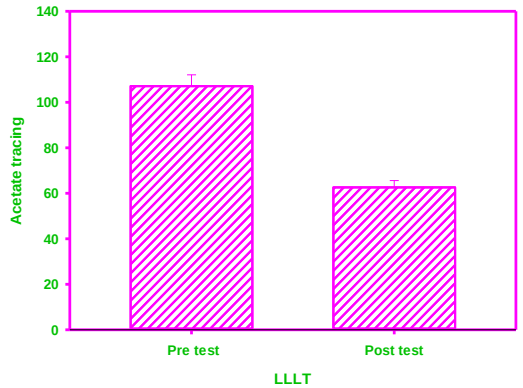

Fig. 1: Effectiveness of LLLT in wound size measured by acetate tracing-pre-test and post-test

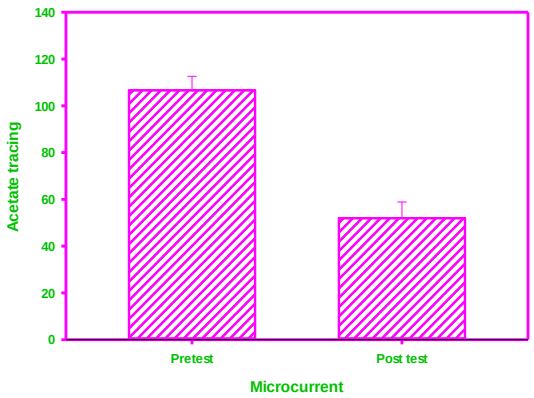

Fig. 2: Effectiveness of microcurrent in wound size measured by Acetate tracing- pre-test and post-test.

DISCUSSION

Type 1 affects the younger age group and type 2 affects in middle age. Type 1, diabetes needs insulin and the type 2 needs hypoglycemic drugs and in case of any stressful situation there may arise the need of insulin. Type 2 affects mostly male rather than females (10). The diabetes and DFU put the patient at risk and imposes economic burden on the patient. A common man cannot reach out the high cost and difficulty to cope up with the high technological changes especially the medications, injection insulin with various modes of administration especially coming for regular dressing (11).

The importance of prevention over cure is emphasized, particularly for diabetic patients. Regular foot examinations are crucial, focusing on aspects such as colour, sensation, numbness, temperature, reflexes, and practicing proper nail and skin care, personal hygiene, and wearing appropriate shoes (12-15). According to a study, diabetic foot ulcers (DFUs) are predominantly found in patients who have had diabetes for an extended period, typically exceeding 10 years. Around 50% of individuals with diabetes develop critical limb ischemia, which can progress to DFUs. A high percentage of diabetic patients, approximately 92%, experience retinopathy, while 74% develop DFUs. Among those with the same type of ulcer, 42% have peripheral neuropathy and complete loss of sensation when tested with a monofilament, and 100% exhibit loss of vibration (16-19). Age, sex, diabetic nephropathy, obesity (determined by BMI), abnormal ankle reflexes, and elevated serum creatinine were not identified as risk factors for DFUs. The term "diabetic foot" refers to foot issues in patients with diabetes mellitus (DM), characterized by arterial abnormalities, diabetic neuropathy, delayed wound healing, and an increased susceptibility to foot infections and gangrene (20-24).

In this study, baseline clinical measures were recorded for all participants after random allocation, and there were no significant differences in baseline demographics, anthropometrics, and clinical characteristics between the treatment groups, indicating comparability. The outcome measures focused on ulcer size, which was assessed using acetate tracing. The results of this study contribute to the growing body of evidence supporting the effectiveness of microcurrent therapy in reducing ulcer size and improving the quality of life for individuals with DFUs. Promising improvements were observed in terms of fibrosis formation, granulation tissue, and reduction in inflammatory cells. One of the strengths of this study is its design, which explores the effects of both low-level laser therapy and microcurrent therapy on healing time and quality of life (25).

This study proved that the intensive dosage of microcurrent therapy was effective in improving these study outcomes. The improvement not only seen in the outcome measures, the participants also self-reported improved confidence. The present study demonstrated that 4 weeks of Microcurrent therapy can effectively reduce wound size and improve quality of life than LLLT and conventional treatment programs in patients with diabetic foot ulcers.

CONCLUSION

Diabetic foot ulcer is a challenging one where the wound healing and quality of life is more predominant. The extent of wound healing depends upon the early diagnosis and proper wound care management. LLLT and microcurrent therapy were found to be effective therapeutic treatment in wound care but none of the studies compared these two modalities in terms of fast healing and the outcome used in this study is a gold standard in measuring size of diabetic foot ulcer. This study concludes that microcurrent therapy was effective when compared with low level laser therapy for diabetic foot ulcer population. The major findings from this study indicate that the 3-week of intensive physiotherapy therapeutic management along with conventional medical treatment will produce best effects in terms of wound healing. The microcurrent intervention is beneficial in improving these study outcomes.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

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