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Original Research Paper

General Surgery

PHOTOTHERAPY IN THE TREATMENT OF DIABETIC FOOT ULCERS

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ABSTRACT Foot ulcers are a disabling complication that affect 15% to 25% of people with diabetes mellitus (DM) at some point in their lives. The nature of diabetic foot ulcers makes them difficult to manage and treat. A dynamic management plan is required to treat diabetic lower limb ulcerations. This involves a strategic approach, including mechanical offloading, wound debridement, wound dressing, patient education and surgical intervention. Phototherapy is a relatively new, non-invasive, and pain-free treatment method, which promotes the ulcer repair process through multiple mechanisms such as increased cell growth and vascular activity. Phototherapy can be used as an alternative approach to conventional wound management, for the treatment of foot ulcers in people with diabetes (DM). Phototherapy, or low-level laser therapy (LLLT), is a therapeutic treatment modality that has been found to enhance wound healing, decrease the level of secondary complications, improve wound regeneration, and ultimately improve patient quality of life. **Objectives:** To assess the effects of phototherapy for the treatment of foot ulcers in people with diabetes. **Methodology:** A randomized cross sectional study was conducted among 80 patients with diabetic foot ulcer. They were divided into two groups A and B, each consisting of 40 patients. Group A were subjected to phototherapy and Group B to conventional wound dressings. Patients were followed up to observe for change in ulcer size, complications and hospital stay. **Results:** The wounds in subjects treated with LLLT contracted significantly more than the wounds in the Group B (37.2% for the LLLT group versus 15.12% for the control group, $p < 0.001$), which indicates that LLLT is an effective modality to facilitate wound contraction in patients suffering from diabetes and can be used as an adjunct to conventional mode of treatment for healing of diabetic wounds.

KEYWORDS : PHOTOTHERAPY, DIABETIC FOOT ULCERS, LLLT

INTRODUCTION

Diabetes mellitus (DM) is the most common health problem in modern society with >422 million people affected worldwide, making it an extremely important medical, social, and economic problem. If left untreated, or poorly treated DM carries a risk of several complications, including Diabetic foot ulcers (DFU). DFU occurs in approximately 6.5% of patients with DM [1]. It is one of the most feared complications of DM, with mortality and amputation rates being 16% and 25% respectively.

Etiopathogenesis of DFU:

There are several components that cause the emergence of diabetic foot ulcers in diabetic patients, and can be divided into two major factors.

Causative factors : Peripheral neuropathy, High plantar foot pressure, trauma

Contributing factors : Atherosclerosis

Pathogenesis of DFU is due to complex interaction of multiple risk factors working together. A study by Reiber et al concluded that 63% of foot ulcers are due to a combination of neuropathy, trauma and deformity [2]

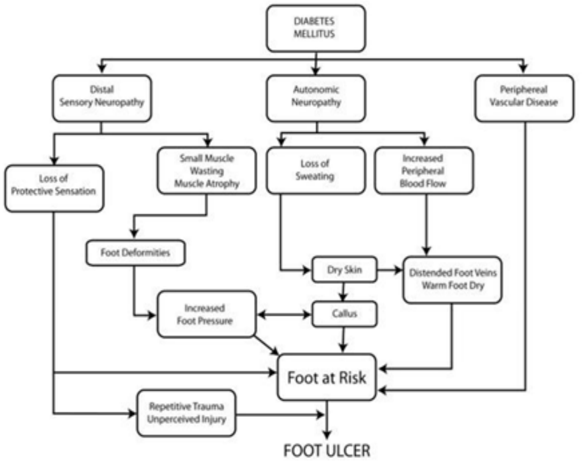

Figure 1: Pathways to DFU

Classification of DFU:

Of the multiple classifications present, Meggitt-Wagner system was considered gold standard.

Grade	Description of the ulcer
0	Pre- or postulcerative lesion completely epithelialized
1	Superficial, full-thickness ulcer limited to the dermis, not extending to the subcutis
2	Ulcer of the skin extending through the subcutis with exposed tendon or bone and without osteomyelitis or abscess formation
3	Deep ulcers with osteomyelitis or abscess formation
4	Localized gangrene of the toes or the forefoot
5	Foot with extensive gangrene

Figure 2 : Meggitt-Wagner system of DFU classification

Management Of DFU:

The basis of DFU therapy is: debridement, reducing the load/pressure on the area of the injury (offloading), managing the infection, providing adequate antibiotics and ulcer treatment using regular wound dressings. Despite the proposed advances in the areas of antiseptics, antimicrobial applications, wound dressing agents, bioengineered skin matrices, negative pressure devices, hyperbaric oxygen, and electrical stimulation devices, the treatment of DFU remains a challenge, and continues to pose a substantial concern and financial strain to the healthcare system often with unsatisfactory results. Phototherapy is a relatively new, non-invasive, and pain-free treatment method that has received clearance from the US Food and Drug Administration for its beneficial effects on tissue healing and pain relief.

MATERIAL AND METHOD:

This was an institution based observational study with cross sectional study design, conducted in the Department of General Surgery, MGM Hospital, Warangal, Telangana. Patients presenting with Type II diabetes (diagnosed) with Wagner's grade 1, 2 and 3 DFU admitted during August 2020 to September 2022, were counseled. Of those, 80 patients admitted with DFU were chosen for the study.

Inclusion Criteria

DFU of grade 1, 2 and 3 according to Wagner's Classification. These would be superficial ulcers with no subcutaneous involvement (grade 1), or deeper sores reaching the subcutaneous tissue level in which the ulcer extension involves ligament, tendon, joint capsule, or fascia (grade 2).

Exclusion Criteria:

- Severe infection.
- Having received antibiotic treatment during the week prior to the study.
- Severe vascular illness, characterized by an ankle brachial index of < 0.5, being a candidate for vascular surgery, or having undergone revascularization surgery within 10 weeks prior to the study.
- Photosensitive diseases.
- Malignancies or renal dysfunction.
- Being on immunosuppressive medications
- Pregnancy.
- Being on dialysis or having a creatinine level of > 2 mg%.
- Anaemia (hemoglobin of < 9 g%)
- A serum albumin level of < 3 mg

METHODOLOGY:

In the current study , The Light Emitting Diode (LED) lamps for phototherapy with LED lights of wavelengths 635 nm (red), or no light (control group) were used. All LED devices had a peak irradiation intensity of 80 mW/cm^2. Taking into account the pulse rate of 50% and the repeat frequency = 2.5 Hz, the average irradiation intensity reached 40 mW/cm^2. The administered daily dose amounted to 24 J/ cm^2.Irradiation was carried out at room temperature for 10 min from a distance of 2 cm. The tracing technique was utilized for estimating the area of each wound. A transparent film was applied to the area in order to trace each wound boundary and the traced film was placed on a 1 mm chart sheet. The square millimeters were counted and transformed into square centimeters, and the area for each wound was recorded. Additionally, the wound contraction rate at (X) day was calculated by the following equation: [(area of 1st day – area of (X) day) /area of the 1st day] × 100.For each wound, area as well as the rate of wound contraction, was measured at the end of each week of treatment and 3 measures provided.

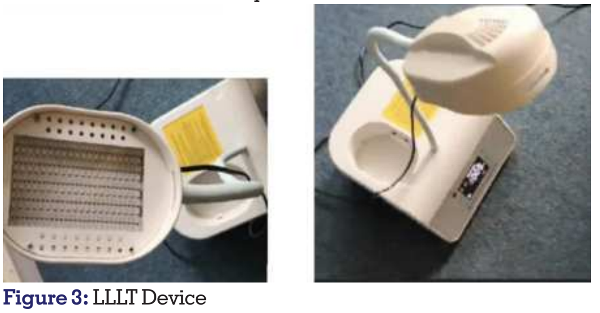

Figure 3: LLLT Device

Statistical Analysis:

After collecting data, data analysis was carried out by the SPSS (v.16) as means plus standard deviations were estimated. The data for our study was a parametric type, so comparing mean values between groups as well as within each group was achieved through the use of one-way ANOVA, as well as repeated measures, respectively. P values less than 0.05 were considered statistically significant.

RESULT:

The results in Table 1 indicate a highly significant increase in wound healing throughout three measures within each group.

After 1st week of treatment as shown in Table 1 , the mean values of both wound area and healing rate in ; in laser group (A) were 2.8±0.81 cm^2 and 44.66±13%, respectively; and in control group (B) were 3.1±0.77 cm^2 and 38.6±18.5%, respectively. On analysis of the results of the 1st week, it was revealed that there were no statistically significant differences among groups as p value = 0.52. Furthermore, there were no significant differences in the mean values of either wound surface area or healing rate between the 2 groups when data were further analyzed by post-hoc test as p value is more than 0.05 for all.

Table 1: Comparing Wound Surface Area (WSA) and Rate of Healing (RH) between Group A(LLLT) and Group B(control) at the end of week 1,2 and 3 in terms of Mean±Standard Deviation

	1^{st} week WSA R.H	2^{nd} week WSA R.H	3^{rd} week WSA R.H	p value
GROUP A (LLLT)	2.8±0.81 44.6±13	0.95±0.61 81.6±9.2	0.1±0.12 97.5±2.0	0.0001
GROUP B	3.1±0.77 38.6±18.5	1.4 ±0.7 72.5± 13	0.3± 0.2 94± 3.56	0.0001
p value	0.52	0.038	0.048	

After 2nd week of treatment as also shown in Table 1 , the mean values of both wound area and healing rate in laser group (A) were 0.95±0.61 cm^2 and 81.6±9.2%, respectively; and in control group (B) were 1.4±0.7 cm^2 and 72.5±13%, respectively. Upon analysis of data, there were significant differences among the two groups (p-value = 0.038). More data analysis elicited that there was a statistically significant difference for laser group (A) versus control group (B)as p-values equal 0.042 and 0.022, respectively.

After 3rd week of treatment as shown in Table 1 , mean values of both wound surface area and healing rate in laser group (A) were 0.1±0.12 cm^2 and 97.5±2%, respectively; and in control group (B) were 0.3±0.2 cm^2 and about 94.0±3.56%, respectively. Analysis of data provided that there were significant differences among the groups as p-value = 0.048. Further data analysis indicated that there was significant differences for group (A) versus group (B) as p values equal 0.046 and 0.003, respectively.

Figure 4: Pictures of DFU treated with LLLT, on day 1,7 and 14.

Figure 5: Pictures of DFU treated with LLLT, Day 1 and 7

DISCUSSION:

Our study demonstrated an improvement in the wound healing after three weeks of treatment. There was significant shrinkage of wound surface areas and increase of healing rates in (A) in comparison with those in group (B). These results are in agreement with previously published studies which found that the laser healing effect may be related to its biomodulatory effects. This relies on the theory that energy of the photon is ingested by photo acceptor elements which is converted to chemical energy type inside the cells. Cytochrome m. oxidase accepts photons and enhances alteration in the mitochondrial redox resulting in the alteration of the ions across the mitochondrial membrane as well as an increase in ATP formation . Additionally, intracellular calcium (Ca^{2+}) increases, resulting in hastening of DNA and RNA formation[2,3].

All previous events facilitate DNA duplication, protein formation, oxidative stress regulation, and different cytokines modulation . All these lead to production of various cellular bio-modulations which are involved in tissue build-up. These bio-modulations include fibroblast mitosis , angiogenesis, cytokines activity changes, and fibroblasts transformation into myofibroblasts.

LLLT plays a role in facilitating the healing process of chronic skin ulcers. Laser therapy reduces the inflammatory response and provokes the greater proliferation of myofibroblasts in experimental skin wounds. No adverse effects of the therapy were observed[4,5].

CONCLUSION:

Those wounds in subjects treated with LLLT contracted significantly more than the wounds in the nontreated group (37.2% for the LLLT group versus 15.12% for the control group, $p < 0.001$), which indicates that LLLT is an effective modality to facilitate wound contraction in patients suffering from diabetes and can be used as an adjunct to conventional mode of treatment (dressings and debridement) for healing of diabetic wounds. Due to its stimulatory effect and no reported side effects, LLLT can be used to treat chronic wounds, including diabetic ulcers.

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