Diabetic Foot, Conservative Management.

1. Dr. Hasanain Moayad Husain  
M.B.Ch.B. \ F.I.B.M.S. \ (General Surgery)  
Ministry of Health, Department of Health Nineveh, Alsalam Teaching Hospital, Nineveh, Iraq.  
hasanainm.husain@gmail.com  
2. Dr. Sadoon Jehad Abdaljabar  
M.B.Ch.B. \ C.A.B.S. \ (General Surgery)  
Ministry of Health, Department of Health Nineveh, Alsalam Teaching Hospital, Nineveh, Iraq.  
sadoonalubaidy@gmail.com  
3. Dr. Shakir Mahmood Abboosh Alsultan  
M.B.Ch.B. \ C.A.B.S. \ (General Surgery)  
Ministry of Health, Department of Health Nineveh, Alsalam Teaching Hospital, Nineveh, Iraq.  
Shakiraljurayse@yahoo.com

Abstract:  
Background: Diabetic foot ulcers are serious complications of Diabetes Mellitus and are known to be resistant to conventional treatment; they may herald severe complications and may lead to lower limb amputation if not treated wisely. Objectives: To assess the efficacy of conservative management and Low-Level Laser Therapy (LLLT) in the treatment of diabetic foot ulcers. Setting: Baghdad Teaching Hospital. Time, from January 2015 through April 2020. Patients and methods: A prospective randomised study included (45) patients who were proved to have a diabetic foot ulcer, the ulcers were graded according to Wagner classification into six grades from (0 to 5), and patients with Wagner grades 1, 2, and 3 were treated conservatively by wound cleaning, controlling of blood sugar in the ward and send for laser therapy.  
Results: There were six patients with grade 1 ulcers, and all of them (100%) showed complete healing over a period of 3 weeks of conservative treatment and laser therapy. Also, 22 patients out of 25 (88%) with grade 2 ulcers and 11 patients out of 14 (78.6%) with grade 3 ulcers showed complete healing in about six weeks of treatment. Forty-five patients were treated by laser, and only six patients (13.3%) showed minor complications (itching, numbness, erythema, or even blisters), which were reported after the 2nd. Weak of treatment.  
Conclusion: Diabetic foot ulcers are a common problem in Baghdad Teaching Hospital; it is most commonly occure in patients with long-standing uncontrolled diabetes. Conservatie treatment by wound cleaning, controlling of blood sugar, and laser therapy (LLLT) was proved to be effective in treating grade 1,2 and 3 ulcers and decreasing the time of ulcer healing.

Keywords: Low-level laser therapy, Treatment of diabetic foot ulcer. Diabetic foot, conservative management

Introduction  
Diabetic foot ulcers, as one of the most common complications of diabetes mellitus, are defined as non-healing or long-lasting chronic skin ulcers in the diabetic patient, and it is one of the most prevalent causes of non-traumatic limb amputations. Hyperglycemia state lead to an increase in the action of the enzymes (aldose reductase and sorbitol dehydrogenase). This results in the conversion of intracellular glucose to sorbitol and fructose, and the accumulation of these sugar products results in a decrease in the synthesis of nerve cell myoinositol which is required for normal neuron conduction, additionally the chemical conversion of glucose, result in a depletion of nicotinamide adenine dinucleotide phosphate stores which are necessary for the detoxification of reactive oxygen species and for the synthesis of vasodilator nitric oxide this result in an increase in oxidative stress on the nerve cell and increase in vasoconstriction leading to ischemia. Also, oxidative stress contributes to abnormal glycation of nerve cell proteins and resulting in further nerve dysfunction and ischemia. Interaction of the sequels of diabetic neuropathy and circulatory impairments in the foot of diabetic patients lead to a number of functional and structural ulcerations’ that give rise to neuropathic and /or ischemic ulcer, Picture (1). [1,2,3]
Also, recurrent mechanical stress upon osseous protuberances on the deformed foot of a patient with the sensory deficit is one of the most important causes of ulceration, neuropathic lesions are prone to infection in a foot with poor circulation, and the spread of infection is fast leading to tissue devitalization, ulceration and gangrene frequently with consequential amputation [4,5]. Evaluation of vascular, neurologic, musculoskeletal, cutaneous, and soft tissue alterations are very important and must be done frequently, especially in high-risk patients (patients with a history of peripheral vascular disease, hyperlipidemia, or uncontrolled long-standing diabetes...), so in these patient proper and frequent foot examination should be performed and health care for these patients should be provided by a trained medical team experienced in diabetic patients [6,7]. LLLT, also called endolaser or soft laser on wound area consider as a noninvasive pain-free method with minor side effects, which include simple erythema, numbness, and itching arround the site of exposure to laser therapy, also eye damage to both the patients and therapist so special glasses should be applied for eye protection [8,9,10]. It is considered as a possible treatment option for the diabetic foot syndrome; it is usually applied by a doctor, therapist, or technician; Treatment typically takes 1-10 minutes for each session and could be applied for two or more times a week. This study aims to study to assess the efficacy and complications of conservative management and Low-Level Laser Therapy (LLLT) in the treatment of diabetic foot ulcers in relation to its Wagner grade at Baghdad Teaching Hospital. [11,12]

**Patients and Methods**

A prospective randomized study included (45) patients were conducted at Baghdad Teaching Hospital from the 4th of January 2020 until the 1st. of April 2020. All patients with diabetic foot ulcer (DFU) of grades 1, 2, and 3 according to Wagner classification were included in the study, and the clinical records of these patients were reviewed and assessed. The nature of therapy to be given was topically explained to the patients, and informed consent was obtained from them before enrolment; all patients were admitted to the ward and subjected to detailed evaluation, and also good glycemic control was done as advised by the physician, photos were taken for ulcers at day 0 and after completion of treatment. Ulcers with evidence of slough were subjected to repeated wound cleaning before starting of laser therapy, and objective assessment of vascularity was done by careful palpation of peripheral pulses, and Color Doppler imaging of arterial circulation was performed in patients with weak or absent pulsations. Systemic antibiotics were administered based on culture and sensitivity tests. Low-Level Laser Therapy was commenced to all patients, in a dose of 5kHz for each session, and each patient was given three sessions/week (10 minutes for each session), in which the ulcer floor and edge were irradiated, the ulcer was then covered with a conventional moist dressing, the duration of treatment for each ulcer depends on the grade of ulcer and its response to laser therapy. Endolaser 422 devise was used for laser therapy (pictures 1 & 2). Microsoft Excel was used for data entry and analysis.

![Endolaser device](picture1.jpg)

Picture 1. Endo laser device
Picture 2- Red laser by Endo laser device.

Results:

Figure 1 - Distribution of patients by Gender

<table>
<thead>
<tr>
<th>Gender Distribution</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36%</td>
<td>64%</td>
</tr>
</tbody>
</table>

Figure 2 - Distribution of patients by Age

<table>
<thead>
<tr>
<th>Relative Frequency distribution of Patients by Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>41-45</td>
</tr>
<tr>
<td>46-50</td>
</tr>
</tbody>
</table>
Patients with uncontrolled diabetes were 31 (69%), and most of them, 23 patients (74%), had other risk factors such as PVD., long-standing diabetes, trauma, foot deformity, immunocompromised patients, and smoking, while the remaining 14 patients (31%) had controlled diabetes but all of them had other risk factors for DFUs as shown in figures (3, 4).

![Figure 3- Relative Frequency Distribution of Patients by Diabetic control](image)

![Figure 4- Relative Distribution of patients with uncontrolled diabetes and other co-morbidity](image)

*Patients with diabetic ulcers were classified according to Wagner classification, as shown in figure (5).

![Figure 5- Frequency Distribution of patients by Grading of Ulcers (Wagner Classification)](image)
All patients with grade I DFUs showed complete healing in response to conservative treatment and Laser Therapy; also, 22 patients (88%) with grade II DFUs and only 11 patients (78.6%) with grade III DFUs showed complete healing in response to this treatment modality as shown in figure (6).

Figure 6- Relative Frequency of Patients responsiveness to conservative treatment and LASER therapy according to Grade of Ulcer

* From all patients who were subjected to conservative treatment and laser therapy, only six patients (13.3%) with grade II & III DFUs were not responded to treatment, four of them had DFUs with severe infection, and the other two had poor vascularity and improper wound care (slough tissue) as shown in figure (7&8).

Figure 7- Responsiveness for Laser Therapy according to Wagner Grades
Figure 8- Frequency distribution of patients not responds to Laser Therapy according to the cause

*Most of the patients with grade I DFUs start their response to Laser Therapy after the 2nd. Week, and show complete healing at 3rd. Week, while patients with grade II and III ulcers start their response after the 3rd. A week and most of them showed complete healing within (4 to 6) Weeks, as shown in Figure (9)

Figure 9- Complete healing of ulcers by the time according to their grade

*Of all patients treated by laser therapy there is only six patients (13.3%) showed minor side effects (numbness, erythema, itching, and blisters), Figure 10,11

Figure 10- Relative Frequency Distribution of Patients by the presence of side Effects
Main side effect due to Laser Therapy was erythema

![Frequency Distribution of Patients by side effects]

Twenty-nine patients (64.4%) with DFUs have had diabetes mellitus for more than 15 years. Also, 13 patients (28.8%) had diabetes mellitus for (10-15) years, and only three patients (6.6) had diabetes mellitus for less than ten years.

![Patients distribution according to the duration of diabetes mellitus in years.]

OF all patients with DFUs, there were 33 patients (73.3%) complaining of ulcers for less than one mouth duration and these patients responded very well to conservative treatment and laser therapy, while other 12 patients (26.7%) had DFUs for (1 to 3) mounths and those patients showed fair or no respnce to this treatment modality.

<table>
<thead>
<tr>
<th>Duration of DFUs</th>
<th>No. of patients</th>
<th>Response to treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than one month</td>
<td>33 (73.3%)</td>
<td>Good</td>
</tr>
<tr>
<td>one to three months</td>
<td>12 (26.7%)</td>
<td>Fair or no</td>
</tr>
</tbody>
</table>
Discussion

Diabetic foot ulcers are a common problem, and it poses a major healthcare problem as a significant cause of morbidity and mortality. The healing process in DFUs is arrested in the stage of inflammation, and it is not known why it does not progress further.

The healing properties of LLLT are likely to be due to photobiomodulation resulting in increased granulation tissue, fibroblast proliferation, collagen synthesis, neovascularization, and early epithelialization. Low doses of laser are stimulatory, and higher doses are suppressive for wound healing. [13,14] In this study, patients ranged in age from 40 to 70 years, with a highest frequency of patients were at the age group of 56-60 years (35.6%); this is understandable since these age groups are more liable to have other co-morbidities which increase the incidence of diabetic complications and may exacerbate DFUs.

Thirty-one patients (69%) had uncontrolled diabetes, which is a risk factor for the development of DFUs. Also, 29 patients (64%) with DFUs were complaining of diabetes mellitus for more than 15 years, and this may be due to an increase in the incidence of other complications such as neuropathy and PVD that may increase with time and may increase the risk of DFUs. All patients with grade 1 (6 patients) and 22 patients (88%) with grade 2 DFUs showed complete healing within 3 to 5 weeks, and only 11 patients (78.6%) with grade 3 ulcers showed complete healing within 4 to 6 weeks of treatment by laser therapy, so this treatment modality was very effective in the treatment of DFUs of Wagner grade 1 and 2, and less effective in grade 3 ulcer. Among the various non-invasive treatment modalities, LLLT is gaining increasing interest; research findings to date based on animal, human, and in vitro studies have shown that LLLT can play a useful role in healing chronic diabetic ulcers resistant to conventional treatment. A study by Hopkins et al. has reported results in 22 healthy subjects and shown 55% greater wound contraction in cases as compared to controls. Gupta et al. have demonstrated a significantly greater reduction (p < 0.002) in the surface area of leg ulcers treated with red light and infrared light than in sham-irradiated controls [15,16,17,18]. The leg ulcers were given three treatments per week for ten weeks, by which time LLLT-treated ulcers showed an average reduction in surface area of 193.0 mm², whereas, in controls, it was only 14.7 mm². In our study (45) patients with DFUs were treated conservatively and subjected to laser therapy of them, (39) patients (87%) showed a significant reduction in the percentage of wound area and a decrease in the time for wound healing. [19,20]

Conclusion

Conservative management in combination with Low-Level Laser Therapy (LLLT) is a highly effective and limb-preserving procedure in treating DFUs of Wagner grade (1), (2), and (3) and can improve or accelerate the healing process giving positive results and encourage further investigations. This study is recommended to 1) All patients with DFUs of Wagner grades 1, 2, and 3 should be subjected to laser therapy in addition to conservative management. 2) Patients with Wagner grade (3) may need wound debridement before being subjected to Laser Therapy. 3) Good glycemic control, appropriate antibiotic, and proper wound care are very important and accelerate the healing process. 4) Patients who do not respond to laser therapy within three weeks may need further investigations or even surgical interventions.

References

5. Gebrekirstos Kahsu, Solomon Gebrekiros, Fantahun Atsede. Prevalence and factors associated with diabetic foot ulcer among adult patients in ayder referral hospital diabetic clinic Mekelle, North Ethiopia. J. Diabetes Metab. 2015;6(68)