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Original Research Article

Effect of low level laser therapy on diabetic foot ulcers: a randomized control trial

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ABSTRACT

Background: Nearly 15 % of diabetic patients will suffer from DFU in their life span. Conventional treatment is not effective against the non-healing DFUs so in recent days so many adjuvant therapies which have been tried to stimulate healing process are in use. LLLT, is a non-invasive, pain-free method is considered as a possible treatment option for the diabetic foot syndrome. Aim of this study is to study the role of low level laser therapy on diabetic ulcers, i.e. Reduction in size of the ulcer, faster wound healing, control of infection, cost effectiveness and if secondary procedures like split skin grafting can be avoided.
Methods: A total of 100 patients with Diabetic foot ulcer fitting the inclusion criteria was included in the study and they were randomly categorized into control and study group. Patients in the study group received treatment with LLLT. Ulcer bed with edge was irradiated locally with red light (660nm), about 4-8J/cm^2 for 20 minutes was delivered for 15 days on daily basis. Conventional dressing was preferred for covering after irradiation and controls were treated with conventional therapy alone which includes dressings with betadine or wet with saline, Course of antibiotic treatment and sloughs removed whenever needed. The size, grade and culture status of the ulcer was assessed on Day 1 and day 15. Duration of stay in hospital was noted to assess cost effectiveness.
Results: In LLLT group, after completing 15 days treatment complete wound healing was achieved in 66.6% of grade-1 ulcers and 4.4% of grade-2 ulcers and 96.6% of grade-2 ulcers improved to grade-1. In contrary only 3.4% of grade-2 ulcers improved to Grade 1 and a majority of ulcers remained as such. Reduction in Mean area of ulcer at day-15 was statistically significant in LLLT group (13.74±11.88 to 3.97±5.41cm^2 and P<0.001) whereas reduction of mean ulcer area among controls was statistically not significant (19.09±15.03cm2 to 18.80±17.70cm^2 and P=0.859). Mean total cost of the treatment was less compared to conventional treatment group. (2264.3±140 Vs 3588.4±68 Rs).
Conclusions: Laser therapy is painless, cost effective procedure which induces faster granulation, wound contraction and reepithelialisation, thus accelerates complete wound healing hence avoiding secondary procedures like split skin grafting. Control of infection was also better compared to control group.

Keywords: Diabetic foot ulcers, Low level laser therapy

INTRODUCTION

Worldwide, diabetes mellitus (DM) has become a major public health interest because of its incidence, which is raising day to day remarkably.[1] Available epidemiological data on the prevalence of DM reported that there was a raise in DM cases. In the year 1985 recorded cases were 30 million cases and were reached to 285 million in 2010 and as per the expectation it may reach to 360 million by 2030.[2] In majority of DM cases

more frequently faced complications were foot ulcers (DFUs).[3,4]

Nearly 15% of diabetic patients will suffer from DFU in their life span.[5,6] Proper wound caring is very important for DFU otherwise they are the greater source for morbidness, gangrene, amputation. Improper management of DFUs may leads to mortality in some cases.[7,8] DFUs may cause notable physical, psychological stress and also affects the productivity which may leads to financial problems and also lowers the patients quality of life.[9]

Still there is a uncertainty about basic pathophysiological factors leading to DFUs, the triad of neuropathy, ischaemia and infections are treated as the routine and most important cause.[10] Low angiogenic response and deficiency of growth factors may be responsible for delayed healing of wounds in DFUs.[11] In recent days so many adjuvant therapies which have been tried to stimulate healing process are in use which includes ultrasound, laser therapy and other forms of photo bio modulation, electrical stimulation, hyperbaric oxygen and vacuum-assisted closure.[12] Although laser therapy has been investigated since the 1990s for possible improvements in the healing of wounds, reproducible results not available in literature may stops its wide range of usage in wound healing.[13,14] Most of the study findings stated that laser therapy, or low-level laser therapy (LLLT), modulates the expression of inflammatory mediators and leads to a reduction in edema, leukocyte influx, and oxidative stress.[15] Further, LLLT has been shown to stimulate neo vascularization and collagen remodeling[16] to heal the wounds in faster way. Few of the studies shows that 660nm wave length shows more viability than longer wavelength.[17] A study supports that the better results are found with a dose of 3J/cm^2 by changing doses of 632.8nm He-Ne laser irradiation.[18]

LLLT was invented since 1990s to induce wound healing process of different ulcers but its implementation in India is still at budding stage because of less research in this field. Even though many studies have listed in literature on the efficacy of low level laser therapy to treat DFUs, but in Indian scenario there are minimum number of studies.[14,19-24] There is a need in India to accelerate the research on the viability of low level laser therapy to avoid the backlogging in its implementation. The aim of this study was to study the role of LLLT on diabetic ulcers, i.e. reduction in size of the ulcer, faster wound healing, control of infection, cost effectiveness and if secondary procedures like split skin grafting can be avoided.

METHODS

The current study was randomized open labelled control study, with randomized two treatment groups and total sample size of 100.

- Group A: Intervention group (who received laser therapy in addition to standard management)
- Group B: Control group (standard treatment group)

Study setting: The study was conducted in the department of general surgery, Chettinad hospital and research institute, which is a tertiary care teaching hospital

Study duration: The recruitment of the participants was conducted over a period of 1 year from june 2016 to july 2017. All the subjects were followed up after 15 days of administering the intervention

Inclusion criteria

Diabetic foot ulcer patients aged between 30 to 80. Good glycemic control patients with fasting blood sugar (FBS) levels measured on two occasions 24 h apart between 90 and 200mg/dl with glycosylated haemoglobin (HbA1c) levels between 6% and 9% will be included. Wound size below 10cm and diabetic ulcers from grade 1 to 2.

Exclusion criteria

- Presence of osteomyelitis.
- Those with clinical signs of ischemia and ABI less than 0.9.
- Patients associated with critical illness who needs intensive care.

Study procedure

After obtaining the informed written consent, relevant demographic and clinical parameters were documented in a structure proforma. The exact dimensions of the ulcer were noted, and each ulcer was graded using the warner grading system as follows.

Wagner grading system

- Grade 1: Superficial diabetic ulcer
- Grade 2: Ulcer extension, involves ligament, tendon, joint capsule or fascia
- Grade 3: Deep ulcer with abscess or osteomyelitis
- Grade 4: Gangrene to portion of forefoot
- Grade 5: Extensive gangrene of foot

All patients were admitted in the surgical ward and evaluated thoroughly. Both acute as well as chronic ulcers were included in the study. The size of the ulcer was measured with ruler. Objective assessment of vascularity was done by careful palpation of peripheral pulses and calculation of Ankle brachial index. Colour Doppler imaging of the arterial circulation of lower limbs was performed in patients with feeble or absent and those with signs of ischemia and cases with <0.9 ABI were excluded from the study. Plain radiographs were used to find the presence of osteomyelitis and those cases were excluded from the study.

Administration of intervention

All patients in both the groups received the required, conventional treatments of diabetic wound care, including dressing, antibiotics, controlling diabetes, cholesterol, and blood pressure along with aggressive drug treatment and wound debridement when needed, before, after and during the laser therapy procedure.

Patients in the study group received treatment with LLLT. Ulcer bed with edge was irradiated locally with red light (660nm). Ulcer size and its depth were used as basis to calculate the duration of exposure to deliver 4-8J/cm^2 for 20 minutes, for 15 days on daily basis. Conventional dressing was preferred for covering after irradiation and controls were treated with conventional therapy alone which includes dressings with betadine or wet with saline, course of antibiotic treatment and slough removed whenever needed.

Figure 1: Application of low level laser therapy.

At baseline and day 15, size of the ulcer was measured with a ruler. Wound swab for culture and sensitivity was taken both in control and study group on day 0 and day 15. Grade of ulcer assessed before starting the treatment and on day 15. Systemic antibiotics were suggested to use with the help of culture sensitivity reports. Good glycemic control was maintained by having Insulin/oral hypoglycaemic agents (OHA) on the advice of physician.

Informed consent was obtained from each study participant, after explaining the risks and benefits involved in the study and voluntary nature of participation, in a language participant can understand.

Statistical analysis

Area of the ulcer was considered as primary outcome variable. The mode of treatment standard vs Intervention) was considered as primary explanatory variable. Various demographic, diabetes disease related, and treatment related parameters were considered as other potential confounding variables. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

Both the study groups were compared at the baseline with respect to all potential confounders. The area of the ulcer was compared between the two groups, using independent sample t-test. The mean differences along with their 95% CI were presented. Association between quantitative explanatory and outcome variables was assessed by calculating person correlation coefficient and the data was represented in a scatter diagram. P value <0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

RESULTS

Among the study participants, 50 (50.00%) were Cases and 50 (50.00%) were Controls. The mean Age was 52.1±8.940 in cases and mean Age was 52.48±11.57 in controls. The mean difference across the group is (-0.38) and it is statistically not significant (p value 0.855). The proportion of male in cases was 26 (52%) and female was 24 (48%) whereas the proportion of male in controls was 31 (62%) and female was 19 (38%). The association of gender with the study groups was statistically not significant (p value 0.31).

Table 1: Comparison of mean area across study groups on day 1 and 15 (N=100).

Parameters	Cases (G1) Mean±STD	Control (G2) Mean±STD	Mean difference	95% CI		P value
				Lower	Upper	
Day-1 area	13.74±11.88	19.09±15.03	-5.3490	-10.72	0.028	0.051
Day-15 area	3.97±5.41	18.80±17.70	-14.8330	-20.02	-9.638	<0.001
Changes in area	9.77±7.83	0.28±11.37	9.4836	5.607	13.359	<0.001

The proportion of males was slightly higher than females in both cases and controls. The mean BMI was 27.19±2.554 among cases and mean BMI was 26.29±2.457 among controls. The mean difference across the group is (0.89) and it is statistically not significant. The mean duration of ulcer in weeks was 4.72±3.625 in cases and mean duration of ulcer in weeks was 4.62±4.115 in controls. The mean difference across the group is (0.10).

It is statistically not significant (p value 0.898). The mean day-1 area was 13.74±11.88 in cases and 19.09±15.03 in

controls. The mean difference across the group is (-5.349). It is statistically significant (p value 0.051). The mean day-15 area was 3.97±5.41 in cases and 18.80±17.70 in controls. The mean difference across the group is (-14.83). It is statistically significant (p value <0.001) the mean changes in area was 9.77±7.83 in cases and 0.28±11.37 in controls.

The mean difference across the group is (9.48). It is statistically significant (p value <0.001) (Table 1).

Table 2: The change in the grade of ulcer in group A.

Day-1	Day-15		
	Grade 2	Grade 1	Complete healed
Grade 2 (N=29)	0(0.00%)	28(96.6%)	1(3.4%)
Grade 1 (N=21)	0(0.00%)	7(33.33%)	14(66.67%)

In study group A, among the 50 subjects 29 were grade 2 ulcers and 21 were grade 1 ulcers on day 1. At the end of 15 days, number of grade 2 ulcers that remained in grade2 was nil. Out of 29 grade 2 ulcers 28 (96.6%) improved to grade1 and 1 ulcer was completely healed at day 15. Among 21 grades 1 ulcers, 7 (33.33%) remained in grade 1, 14 (66.67%) ulcers completely healed at the end of 15 days (Table 2).

Table 3: The change in the grade of ulcer in group B.

Day-1	Day-15		
	Grade 2	Grade 1	Complete healed
Grade 2 (N=26)	23(88.46%)	3(11.53)	0
Grade 1 (N=24)	0(0.00%)	24(100%)	0

In study group B, among the 50 subjects 26 were grade 2 ulcers and 24 were grade 1 ulcers on day 1. At the end of 15 days, number of grade2 ulcers that remained in grade 2 was 23 (88.46%) and 3 ulcers (11.53%) improved to grade 1.

Among 24 grade1 ulcers all remained in grade1 and no (0.00%) ulcers healed completely at the end of 15 days (Table 3).

Table 4: Culture positive status on day 1 and day 15 in group A (N= 50).

Day-1	Day-15	
	Growth	No growth
Growth (N=31)	10(32.25%)	21(67.74%)
No growth (N=19)	0(0.00%)	19(100%)

In group A, 31 subjects had bacterial growth on day- 1 and the remaining 19 had no bacterial growth. Out of the 31 subjects with bacterial growth, 10 people still had growth at the end of 15 days and 21 had no growth. Among 19 people with no growth, none of them developed new growth on day 15 (Table 4).

Table 5: Culture positive status on day 1 and day 15 in group B (N= 50).

Day-1	Day-15	
	Growth	No growth
Growth (N=34)	29(85.25%)	5(14.71%)
No growth (N=16)	3(18.75%)	13(81.25%)

In group B, 34 subjects had bacterial growth on day-1 and the remaining 16 had no bacterial growth.

Out of the 34 with bacterial growth, 29 (85.25%) still had growth at the end of 15 days and 5 (14.71%) had no growth. Among 16 people who had no growth, 3 (18.75%) cases developed new bacterial growth (Table 5).

Figure 2: Grade 2 ulcer before laser therapy.

Figure 3: Grade 1 ulcer after laser therapy on day 15.

Figure 4: Grade 1 ulcer before laser therapy.

Figure 5: Completely healed ulcer after laser therapy on day 15.

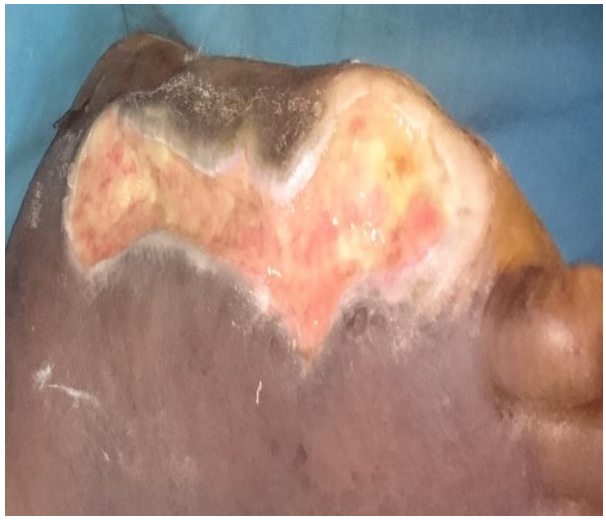

Figure 6: Grade 2 ulcer before laser therapy.

Figure 7: After laser therapy on day 15.

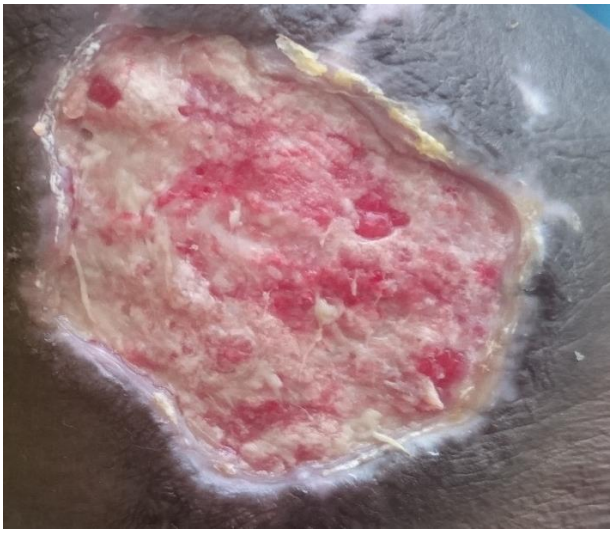

Figure 8: Before laser therapy.

Figure 9: After laser therapy on day 15.

Figure 10: Grade 2 ulcer before laser therapy and grade 1 ulcer after laser therapy on day 15.

Figure 11: Before laser therapy.

Figure 12: After laser therapy on day 15.

Figure 13: Before laser therapy.

Figure 14: Completely healed ulcer after laser therapy on day 15.

DISCUSSION

Diabetic foot ulcers are the most common complications of diabetes mellitus and conventional wound healing therapies are not that much effective for DFUs and if proper treatment was not given to the DFUs they may herald severe complications. Wound healing can be initiated by treating with a beam of electromagnetic radiations or laser. In the existing literature, few studies are available in this area.[14,19-24] The current study was aimed to assess the adequacy of a treatment modality with LLLT for diabetic foot ulcers.

Ulcer grade

In the current study, among 50 subjects of a group A study participants 29 were grade-2 ulcers and remaining 21 were grade 1 ulcers at baseline. Among 29 grade 2 ulcers, 28 (96.6%) improved to grade-1 and 1 ulcer healed completely on15 th day. On day 15, in 21 grade 1

ulcers majority (66.67%) of ulcers healed completely and 33.33% remained as such. Of 50 group B participants,26 were grade-2 ulcers and remaining 24 were grade 1 ulcers on day1. After 15 days of treatment, 88.46% of grade-2 ulcers remained as such and 11.53% of wounds improved to grade-1, out of 24 grade -1 ulcers all remained as grade-1 and no wound got healed completely. In the past literature, very minimal number of studies have shown interest on grades of ulcers. Saltmarche AE et al, study have shown findings similar to present study.[26] 21 open wounds were treated with low level laser therapy and at the end of 9 weeks of treatment, the major proportion of wounds (61.9%) improved significantly. 42.8% were closed completely, minimum improvement was found in 14.3% cases and no change was reported in 23.8% wounds.

Bacterial growth status

In present study among group A participants, at base line 31 subjects had bacterial growth and remaining 19 had no bacterial growth. At the end of 15 days in 31 cases with bacterial growth, growth was absent in 67.74% cases and in 32.25% cases growth still remained. In 19 cases with no growth on day-1, no new growth developed even after 15 days. Among group-B study participants, at base line 34 subjects were having bacterial growth and the remaining 16 had no growth. On day 15 in 34 subjects with bacterial growth 85.25% of cases still showrd growth and 14.7% had no growth. In 16 cases with no growth at day-1, 81.25% of cases had no growth but in 3 subject's growths was observed after 15 days of treatment. A study conducted by Tubachi P et al, findings were also in agreement with current study findings.[27] He studied 60 patients of diabetic foot ulcer and positive for culture. After 10 days of treatment, among treatment group subjects 66.66% were showing culture positive results and 33.3% were with negative culture reports. In controls (N=30) 80% of subjects had positive cultures and in 20% of subject s were culture negative.

Ulcer size

In present study reported that the mean area of the ulcer was 13.74±11.88 among cases, which reduced to 3.97±5.41cm^2 on day 15, statistically significance (p value <0.001). Among the controls, the mean area of the ulcer reduction was very minimal from 19.09±15.03cm^2 on day 1 to 18.80±17.70 on day 15, which was statistically not significant (p value 0.859). Like present study findings Kajagar BM et al, have reported in his findings as the mean initial area of the ulcer was 2608.03mm^2 in cases and was reduced to 1564.79mm^2 after 15 days of treatment whereas in controls initial area was 2747.17mm^2 and reduced to 2424.75mm^2.[14]

Mean reduction was minimal in controls when compared to cases. Study of Hopkins et al agreed with the current study findings and shows that after conducting follow up tests for days 6,8 and 10 days observed that wound size was reduced in laser group than the sham group for both treated as well as untreated wounds and the difference in size reduction between the two groups was statistically significant.[21] Gupta AK et al, have reported that there was a great reduction in ulcer area of LEPT group than the placebo group (193.0mm^2 Vs 14.7mm^2) with statistically significant difference in ulcer area between two study groups (P=0.0002).[28]

CONCLUSION

In conclusion, Laser therapy is painless, cost effective procedure which induces faster granulation, wound contraction and re-epithelialization, thus accelerates complete wound healing hence avoiding secondary procedures like split skin grafting. Control of infection was also better compared to control group.

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