Original Research Article

Low level red laser therapy using wavelength 635nm for diabetic foot ulcers: a prospective study

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Received: 15 November 2018

Accepted: 01 January 2019

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ABSTRACT

Background: Diabetic foot ulcer is one of the important complications of diabetes. After effective debridement and antibiotic therapy, lasers are used to hasten the healing process. Red laser of wavelength 635nm promotes wound healing. This study will aid us to find out the efficacy of red laser wavelength 635nm in healing of diabetic foot ulcers.

Methods: After obtaining informed consent, diabetic foot ulcer patients admitted to Rajiv Gandhi government hospital were selected based on non-probability convenience sampling. Necessary history obtained, clinical examination of the ulcer done, investigations done. Cases are given 30minutes of laser therapy by non-contact method before regular ulcer dressing. Controls are given saline dressing. Ulcer area measured before initiation of therapy and measured at 1st week, 2nd week and 3rd week after initiation of therapy.

Results: Wound contraction rate was 39.65% with laser and 11.26% with saline dressing alone ($p < 0.001$). The data were statistically significant; thus, laser have wound healing property.

Conclusions: Cases have more mean contraction percentage than controls (37.99% versus 11.68%, $p < 0.001$). So LLLT is an effective therapy to heal diabetic ulcers. Need for additional surgeries can be avoided by using LLLT.

Keywords: 30minutes, 635nm, Avoided, Non-contact, Red laser

INTRODUCTION

Diabetes mellitus is the most common metabolic disorder in general population. Diabetic foot ulcer is one of the important complications of diabetes leads to major mortality and morbidity.¹ Even a trivial trauma to foot ends in major amputation. Quick healing of foot ulcer is necessary to prevent morbidity and mortality. Diabetic foot ulcer is caused by activities like barefoot walking, inadequate facilities for diabetes foot care and education, and low socioeconomic conditions. Limb amputation creates major impact on the individual distorting body image, loss of productivity, increasing dependency,

unemployment and loss of money.²⁻⁵ Use of laser therapy to heal non-healing ulcers of lower extremity is documented. After effective debridement and antibiotic therapy, lasers are used to hasten the healing process.⁶ Red laser of wavelength 635nm promotes wound healing by bio-stimulation effect, increased granulation formation and re-epithelialization.⁷

This study will aid us to find out the efficacy of red laser wavelength 635nm in healing of diabetic foot ulcers in Madras medical college and Rajiv Gandhi government general hospital. This study will mainly determine the wound contracture after red laser therapy. Use of laser

therapy to treat a diabetic ulcer of the lower extremity is profiled. Laser therapy applied over a course of two weeks stimulates granulation tissue formation in the wound bed and re-epithelialization of the ulcer thus enhancing wound healing. Laser therapy is a useful tool to heal ulcers in a short time.

The aim of the study was to use the wound healing effect of red laser wavelength 635nm in healing of diabetic foot ulcers in Rajiv Gandhi government General Hospital and the objectives of the study was to determine the wound healing effect of red laser in diabetic foot ulcer, determine the effect of red laser on diabetic foot ulcers after 3weeks of therapy and to determine mean percentage reduction in wound area.

METHODS

Present study was a randomized control study done in Madras medical college and Rajiv Gandhi government General Hospital in patients with diabetic foot ulcers admitted to various surgical wards in the period of 7months from October 2017 to April 2018. Patients were selected based on non-probability convenience sampling. After obtaining informed consent from diabetic foot ulcer patients fulfilling the inclusion criteria, necessary history obtained, clinical examination of the ulcer done, investigations done.

The patients with all diabetic foot ulcers with ulcer size <8cm in greatest dimension, ulcer depth <1cm, ulcer with good vascularity, ulcer with no slough/infection and ulcer within one-year duration were included. The patients having renal failure, liver dysfunction, malnutrition, peripheral vascular disease, osteomyelitis, deep ulcers involving tendons, ligaments, joint capsule or fascia, bed sores, marjolin ulcer and ulcer >1yr duration.

Total 164 cases were randomized into 2 groups (cases=82, controls=82). Patients age, sex was recorded, clinical examination was done. Preformed pro-forma filled. CBC, RFT, LFT, HBA1C were done in all cases. Pus culture, X-ray of the affected part done. Blood sugar controlled with insulin and OHA. Ulcer area was measured by scale in cm. Peripheral pulses were palpated to rule out peripheral vascular diseases. Antibiotics were given as per culture and sensitivity.

Cases were given 30minutes of red laser therapy of wavelength 635nm by non-contact method before regular ulcer dressing. Controls were given saline dressing. Patients were followed up to 3weeks after initiation of laser therapy. Ulcer area measured by scale in cm before initiation of therapy and measured at 1st week, 2nd week and 3rd week after initiation of therapy.

Data obtained were entered in Microsoft excel spreadsheet. Data were entered as rates, percentages and ratios. Comparison was done by using chi square test, unpaired t-test. Intragroup comparison was done by

ANOVA test. P Value equal or less than 0.05 was taken as significant.

RESULTS

Randomized control study to test the efficacy of low-level red laser 635nm wavelength on diabetic foot ulcer healing done at RGGGH, Chennai over 7months period from October 2017 to April 2018. Total of 164 patients studied and divided into study and control groups of 82 each.

Before the initiation of LLLT, the mean initial ulcer area in study group was $2625.6 \pm 669.74 \text{mm}^2$ and in control group was $2774.8 \pm 603.39 \text{mm}^2$. The minimum and maximum ulcer area in study group was 1293.95mm^2 and 3598.94mm^2 respectively whereas in the control group it was 1344.99mm^2 and 3364.98mm^2 respectively (Table 1).

Table 1: Initial ulcer area in study group and control group.

Ulcer area (mm ²)	Study group (n=82)	Control group (n=82)
Mean	2625.60	2774.80
SD	669.74	603.39
Median	2536.84	2778.39
Minimum	1293.95	1344.99
Maximum	3598.94	3364.98

After the end of 3weeks of LLLT, the mean final ulcer area in study group was $1580.8 \pm 426.12 \text{mm}^2$ and in control group was $2450.6 \pm 552.32 \text{mm}^2$. The minimum and maximum final ulcer area in study group was 687.22mm^2 and 2282.74mm^2 respectively whereas in the control group it was 1153.01mm^2 and 3217.04mm^2 respectively (Table 2).

Table 2: Final ulcer area in study group and control group.

Ulcer area (mm ²)	Study group (n=82)	Control group (n=82)
Mean	1580.80	2450.60
SD	426.12	552.32
Median	1555.16	2411.97
Minimum	687.22	1153.01
Maximum	2282.74	3217.04

After three weeks of LLLT, the minimum and maximum reduction in ulcer area in study group was 550.75mm^2 and 1486.79mm^2 respectively whereas in the control group it was only 145.96mm^2 and 490.01mm^2 respectively. The mean reduction in ulcer area in study group was $1044.80 \pm 264.09 \text{mm}^2$ and $324.20 \pm 84.81 \text{mm}^2$ in control group. Difference between two groups was statistically significant ($p < 0.001$). LLLT for diabetic foot ulcers is an adjunctive therapy can be recommended to all

diabetic foot ulcers (Table 3). After three weeks of LLLT, the minimum and maximum percentage reduction in ulcer area in study group was 35.23% and 46.89% respectively whereas in the control group it was only 8.13% and 17.34% respectively. The mean percentage reduction in ulcer area in study group was 39.79% and 11.68% in control group. Difference between two groups was statistically significant ($p < 0.001$). Thus, laser have wound healing property (Table 4).

Table 3: Reduction in ulcer area in study group and control group.

Ulcer area (mm ²)	Study group (n=82)	Control group (n=82)
Mean	1044.80	324.20
SD	264.09	84.81
Median	1024.45	329.60
Minimum	550.75	145.96
Maximum	1486.79	490.01
	$p < 0.001$	

Table 4: Percentage reduction in ulcer area or wound contraction in study group and control group.

Ulcer area (%)	Study group (n=82)	Control group (n=82)
Mean	39.79	11.68
SD	3.04	2.52
Median	39.65	11.26
Minimum	35.23	8.13
Maximum	46.89	17.34
	$p < 0.001$	

DISCUSSION

Present study was done at Madras medical college and Rajiv Gandhi government general hospital to test the efficacy of low-level red laser 635nm wavelength in healing of diabetic foot ulcers. Diabetes mellitus is a most common metabolic disorder. About 15% of diabetic patients will develop diabetic foot. 85% of non-traumatic amputations of lower limbs are due to diabetic foot.^{1,2} Most of the diabetic foots are caused by neuropathy, ischemia and sepsis.³ Progression of infection is quick in diabetes due to poor healing process and poor vascularity. Control of hyperglycemia is the important wound healing factor. Along with this wound debridement, antibiotics, regular dressings are mandatory. So many adjunctive therapies have been tried like LLLT, Hyperbaric oxygen therapy, vacuum assisted closure, application of growth factors.^{4,5} Healing of clean diabetic wounds are quickened by low level red laser is profiled in history.^{6,7} Need of skin grafting is avoided in large ulcers. Laser stimulates angiogenesis, bio stimulation and fibroblast proliferation.^{8,9} Size of the ulcers is greatly reduced by lasers.¹⁰ A study of Hopkins JT et al, studied 22 healthy subjects and reported 55 percentage greater wound contraction by using lasers.¹¹ Total 125seconds of 700Hz

was given for 20days. Drawback of this study was artificially induced wounds in small samples.

Gupta K et al, demonstrated significant reduction of wound surface area by lasers on venous ulcers.¹² Weekly three times treatment given for 10weeks. Average reduction in surface area is 193mm², in controls it was only 14.7mm². Drawback is small sample size. Landau Z et al, demonstrated effects of hyperbaric oxygen along with laser.¹³ Treatment time was 20mins for 2-3weeks. 81% of refractory diabetic foot ulcers were healed by this method. In this study, diabetes is more common in males. Diabetic foot ulcers were also common among males when compared to females. Prevalence of is increasing with the age. Diabetic foot ulcers are more common in 6th decade of life. In this study most of the diabetic foot ulcers were caused by trauma which is secondary to neuropathy. Most of them were treated by insulin for achieving glycemic control. Most of them were non-hypertensive. Common risk factors for diabetic foot ulcers in this study were male sex, diabetes >10yrs, neuropathy and smoking.

Most of the ulcers were in plantar aspect (55.49%) than dorsal aspect (44.51%). Thus, appropriate footwear can prevent plantar related ulcers. In this study, wound contraction rate was 39.65% with laser and 11.26% with saline dressing alone. The data were statistically significant; thus, laser have wound healing property. With the use of 635nm wound contraction percentage was 40.30. In this study, ulcers on the dorsal aspect were healed quickly than plantar aspect. Ulcers on the plantar aspect are mainly due to neuropathy. Mean contraction of wound was less in diabetics with hypertension.

It is a light therapy using low power laser or LED light. It operates between 1-500milliwatts, surgical lasers are between 3000-10000mw. Also known as soft lasers or lower intensity level lasers. High energy lasers are used to cutting and welding. Low level lasers are monochromatic, coherent and polarized. It penetrates the skin surface without any side effects. It has bio stimulatory effects, thus promotes wound healing.¹⁴ Red or infrared lasers are commonly used for therapy (Figure 1).

Figure 1: Low level red laser.

Red laser using 635nm wavelength is used for wound healing because of its high penetrance power of 10mm.¹⁴ It acts by promoting ATP release from mitochondria, angiogenesis, increased protein synthesis, increased blood flow, improved fibroblast proliferation, increased collagen formation, reduced oxidative stress, increased vasodilation, decreased edema and inflammation.

In contact method, probe was placed directly over the target site.¹⁵ Penetration of laser was increased by this method. Cross infection and tenderness elicited by this method are the drawbacks. In non-contact method, probe was placed at distance from target site. Multidiode cluster units are used in open wounds non-contact method was beneficial (Figure 2).

Figure 2: Methods of laser delivery.

CONCLUSION

Diabetic foot is one of the most common complications of diabetes if not treated properly at time leads to fatality. Glycemic control and other therapies are available to heal ulcers effectively. Among these LLLT has shown promising results in the past studies. Cases have more mean contraction percentage than controls (37.99% versus 11.68%, $p < 0.001$). So, LLLT is an effective therapy to heal diabetic ulcers. Additional surgeries can be avoided by using LLLT.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Swaminathan SP, Velayutham M, Karthikeyan SM, Pakkiriappan M. Low level red laser therapy using wavelength 635nm for diabetic foot ulcers: a prospective study. *Int Surg J* 2019;6:527-30.