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Original Research Article

Efficacy of low level infrared light therapy on wound healing in patients with chronic diabetic foot ulcers: a randomised control trial

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ABSTRACT

Background: A total of 52-patients with Type-2 Diabetes Mellitus having Meggitt-Wagner Grade-I of foot ulcers of at least more than 4-weeks duration, less than 6×6 cm, with negative culture were studied. Diabetic foot ulcers are serious complications of diabetes mellitus and are known to be resistant to conventional treatment. It also causes a significant cause of morbidity, mortality and financial burden. If the ulcer is left untreated they can create a severe complications. This study was designed to examine the effect of infrared radiation on the healing of diabetic foot ulcer.
Methods: This clinical trial was performed on 52 patients with diabetic foot ulcer Wagner Grade-I. Patients were classified into 26 control and 26 study group. Electromagnetic radiations in the form of photons are delivered to the ulcer site by infrared light to stimulate healing.
Results: Male preponderance was found with ratio of 2:1. Mean age of the patients was 58.82 years in control group and 52.44 years in study group. The mean HbA1C levels in the control groups were 7 (range 6.2-8.3%) and 7.2 (range 7-8%) in the study group, suggesting no biochemical differences between two groups. Mean reduction in the ulcer area was 375.30 mm in the control group and 893.56 mm in the study group and this differences between the two groups was statistically significant ($p<0.010$).
Conclusions: It is shown that using infrared plus routine dressing is more effective than merely routine dressing in diabetic foot ulcers and there was a significant difference in reduction of ulcer size in study group.

Keywords: Diabetic foot ulcer, Infrared rays, Wound healing

INTRODUCTION

Diabetic foot ulcers (DFU) as one of the most common complications of Diabetes Mellitus (DM) are defined as non-healing or long lasting chronic skin ulcers in diabetic patients.[1] More than 60% of all non-traumatic lower limb amputations are due to diabetic foot ulcer complications.[2] About 15% of patients with DM are likely to develop foot ulcers during their lifetime and about 6-40% of them may require an amputation.[3] Multidisciplinary care for the diabetic foot is common but treatment results are often unsatisfactory.[1] Non-healing DFU are resistant to conventional treatment. Low level infrared light therapy on wound areas, as a non-invasive, pain free method with minor side effects, has been considered as a possible treatment option for diabetic foot syndrome.[1] The clinical efficacy of low level infrared light therapy or low energy photon therapy in wound healing has been reported and it has been found to significantly decrease the time of wound healing.[4,5] The aim of the study is to assess the

efficacy of low level infrared light therapy in patients with diabetic foot ulcers.

METHODS

This is an interventional study of randomised control trial. The study involves chronic diabetic foot patients. The inclusion criteria is all diagnosed Type II diabetes mellitus Wagner Grade-1 Diabetic foot Ulcer of at least more than 4 weeks duration, less than 6×6 cm, with negative culture were studied. The exclusion criteria is clinical signs of ischaemia, osteomyelitis and uncontrolled diabetes with FBS >200 mg. We use Low level Infrared Light as an intervention.

After explaining the procedures and taking consent from chronic diabetic foot ulcer Wagner grade 1, 52 patients were divided into 26 control and 26 study group. 26 patients received conventional method of treatment dressing of ulcer and 26 patients received additional treatment with low level infrared light therapy through local irradiation of the ulcer bed and ulcer margins. On the basis of the ulcer size, the duration of exposure was calculated to deliver 2–4 J/cm^2 at 60 mW, 5 kHz, daily for 15 minutes in 15 days. The ulcer was then covered with conventional moist dressing

On day 0 and day 15 the ulcer area were calculated by obtaining the impression of ulcer floor on a sheet of cellophane paper and then transferring the imprint onto a graph paper. Total surface area of both control and study group were calculated and compared to assess the difference in reduction of ulcer size. The study were conducted in the department of surgery Indira Gandhi Medical College & Research Institute Pondicherry for a period of 12 months from October 2016 to October 2017.

Statistical analysis

Statistical analysis was performed using Student's t-test for paired samples using SPSS v.21.0. Values were expressed as a mean±standard deviation or as percentages. A p value <0.05 was considered statistically significant.

RESULTS

A total of 52 patients were included in the study. Ratio between male and female was 2:1. Mean age of the patients was 58.82 years in control group and 52.44 years in study group. No significant difference was found in demographic characteristics (Table 1). Majority of the patients were housewife (30.8%) in the study group, labourer (53.8%) and employed (23.1%) in the control group [Figure 1(A)]. In most of the patients symptoms were insidious / spontaneous in onset (84.6%) in the control group [Figure 1(B)].

The mean FBS levels among controls were 122 mg/dl (range 90-167 mg/dl). The mean HbA1C levels in the control groups were 7 (range 6.2-8.3%) and 7.2 (range 7-8 %) in the study group, suggesting no biochemical differences between two groups. Median duration of ulcer at the time of enrolment is 5 weeks in both the study and control group. Median duration of oral hypoglycaemic agents intake was 8 years in the control group and 6 years in the study group. Insulin intake was 5 months in the control group and 3.5 months in the study group. Mean initial size of the ulcer was 2320.44 mm in the control group and 2100.16mm in the study group (Table 2). Majority of the ulcer were in the planter region in the control group (57.7%) and on the dorsum region in the study group (61.5%).

Table 1: Demographic characteristics.

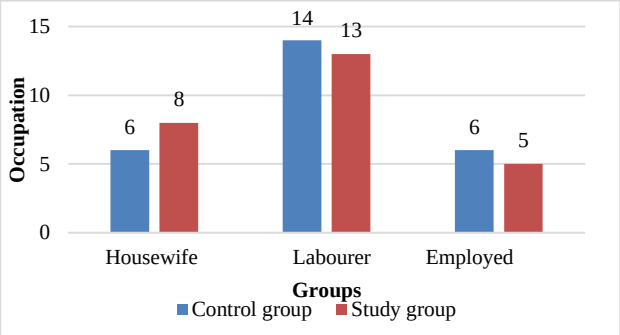
Characteristics	Control group (n=26)	Study group (n=26)	Mean
Male:Female ratio	2:1	2:1	
Mean age in years	58.82 years	52.44 years	55.63± 4.51
Occupation			**P value**
Housewife	06 (23.1%)	08 (30.8%)	0.264
Labourer	14 (53.8%)	13 (50%)	0.389
Employed	06 (23.1%)	05 (19.2%)	0.363
95% confidence interval	-9.836 to 9.836		
F test to compare variances F, DFn, Dfd	1.306, 2, 2		
Onset			
Insidious/spontaneous	22 (84.6%)	20 (76.9%)	P<0.241
Traumatic	04 (15.4%)	06 (23.1%)	P<0.241
95% confidence interval	-49.06 to 49.06		
F test to compare variances F, DFn, Dfd	1.653, 1, 1		
Duration of ulcer at presentation	5 weeks	5 weeks	
Duration of diabetes in years	10	10	P<0.5

Table 2: Ulcer characteristics.

Clinical features	Control group	Study group	Mean
Initial ulcer area (mm^2)	2320.44	2100.16	2210.3±155.7
Site of the ulcer			**P value**
Plantar	15 (57.7%)	10 (38.5%)	0.082
Dorsum	11 (42.3%)	16 (61.5%)	0.082
Meggitt Wagner Grade	1 (3.8%)	1 (3.8%)	0.5
Depth of the ulcer in mm	5 (19.2%)	5 (19.2%)	0.5
95% confidence interval	-10.99 to 10.99		
F test to compare variances F, DFn, Dfd	1.086, 3, 3		

Table 3: Outcome of the study.

Results	Control group (n=26)	Study group (n=26)	Mean	P value
Initial ulcer area (mm^2)	2320.44	2100.16	2210.3±155.76	0.5382
Final ulcer area (mm^2)	1945.14	1206.60	1575.8±522.2	0.318
Mean reduction in ulcer area (mm^2)	375.30	893.56	634.43±366.4	<0.010
Percentage ulcer area reduction	16.17%	42.54%		
95% confidence interval	-1788 to 2081			
F test to compare variances F, DFn, Dfd	2.716, 2, 2			



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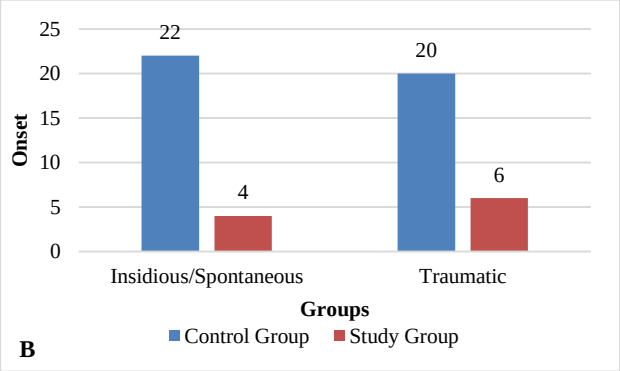

B

Figure 1 (A): Occupation characteristics; (B) onset of symptoms in control and study group.

All ulcers in both groups belong to Meggitt-Wagner grade 1 and had a depth of 5 mm (Figure 2). There is no significant difference between the two groups. After completion of 15 days of infrared therapy, the final area of the ulcer was 1945.14 mm in the control group and 1206.60 mm in the study group (Table 3, Figure 3). Mean reduction in the ulcer area was 375.30 mm in the control group and 893.56 mm in the study group and this differences between the two groups was statistically significant (p<0.010).

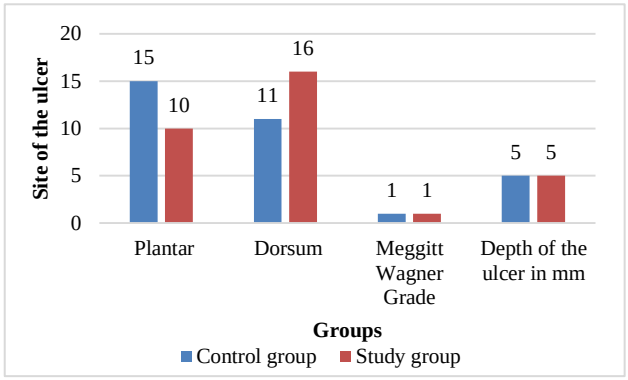

Figure 2: Site of ulcer

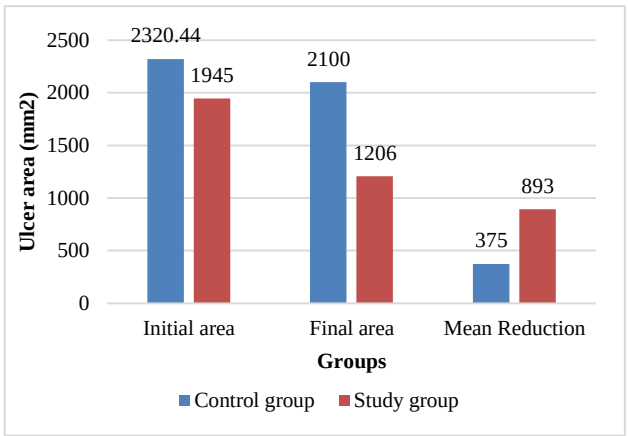

Figure 3: Ulcer area in control and study group.

DISCUSSION

To achieve a complete healing of chronic diabetic foot ulcers require a longer period of treatment even after a multidisciplinary approach which may include a proper control of blood sugar, local foot care on a daily basis, pressure off-loading, proper antibiotic therapy, revascularization surgery etc. but the results are not encouraging.[6] Diabetic foot ulcers are a significant cause of morbidity, mortality, causing lots of burden financially and pose a major healthcare problem to the society.[7] Low level infrared light therapy has been shown to promote chronic wound healing in conditions of reduced microcirculation. Kaviani et al conducted a double-blind, placebo controlled randomized control trial and found no significant difference in (i) complete healing of ulcers between treatment arm (8 of 13) and placebo arm (3 of 9); (ii) mean time of complete healing between treatment arm (11 weeks) and placebo arm (14 weeks); whereas Kajagar et al in their study found a significant reduction in ulcer area between treatment arm (1,043.20 mm^2) and control arm (322.44 mm^2), which is similar to our findings.[2,6] Landau et al also found significantly higher rate of wound closure in treatment arm (9 of 10) compared with placebo arm (2 of 6); wound size reduction achieved significant results between treatment arm (89%) compared with placebo arm (54%) and a mean time to wound closure for treatment and placebo arm was 7.14 weeks and 11.16 weeks, respectively.[8]

Minatel et al also found that the treatment arm achieved significantly higher rate of mean ulcer healing and granulation.[9] They reported that at 90 days, placebo arm had only one fully healed ulcer and none achieved >90% healing in comparison to 58.3% of treatment arm ulcers which were fully healed with 75% of ulcers achieved 90–100% healing. Studies done by Posten et al and Zand et al have reported that more than 70% of the chronic wound, especially diabetic foot ulcers have responded to the effect of infrared radiation therapy.[10,11] In our study, 26 ulcers treated with Infrared light therapy showed significant reduction in percentage wound area, that is, 42.54% mm^2 compared to 16.17% mm^2 in control groups. These results show significant benefit following the use of Infrared light therapy. The limitation of the study was the time limit and the strength of this present study was the high percentage of partial recovery and cost effectiveness of infrared radiation in patients with diabetic foot ulcers.

CONCLUSION

From the present study, it is evident that using infrared plus routine dressing is more effective than merely routine dressing in diabetic foot ulcers and there was a significant difference in reduction of ulcer size in study group compared to the control group.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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