A Randomized Clinical Trial on Efficacy of Low-Level Laser Therapy in Healing of Ulcers

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ABSTRACT

BACKGROUND
Wound healing is a complex and changing process with the wound environment changing along with the changing health status of the individual. Laser light, when reduced in its energy output to a low level, may be utilized for tissue healing and repair, cutting as in surgery, shrinking tumours, unblocking clogged arteries, eradicating infections, and other therapeutic purposes. For bringing about health enhancement, the application of these amazing beams of light is called “Low Level Laser Therapy”. Biological effects caused by low level lasers are due to the energy deposited into tissues results in many therapeutic effects. This results in the analgesic and anti-inflammatory effects as well as in improvement in healing.

METHODS
This study was conducted in 50 patients, who were randomized into two groups. Group 1 (LLLT) and Group 2 (control) with 25 patients in each group. Initial condition of the ulcer was recorded, and adequate wound debridement was done if necessary in both the groups. Patients in group A underwent LLLT once in three days along with regular dressings, whereas patients in group B underwent only conventional dressings. Observations were made during dressing and examination of the patients. Data was recorded on every third day from the date of admission till the 12th day. The efficacy evaluation was based on the size of ulcer, discharge from the wound, granulation tissue, and presence of epithelialization at the site of the wound.

RESULTS
The wound was assessed on every third day up to 12 days of treatment. In group 1, reduction in size of ulcer started within a minimum of 3 days to a maximum of 6 days with a mean period of 3.84 days. In group 1, granulations were seen in the ulcer from 3rd day to 9th day with a mean period of 4.32 days; whereas, in group 2 granulations started to appear from 3rd day to 9th day with a mean period of 6.12 days. In group 1, epithelialisation started within 3rd day to 9th day and mean period was 4.92 days. Altogether in this group, the mean time for the healing process to start was 3.84 days to 8.4 days whereas in group 2, Epithelialisation started within 3rd day to 9th day and mean period was 6.72 days.

CONCLUSIONS
LLLT helps in wound healing by decreasing the time taken for healing, promoting granulation and early epithelialization and can also be used as an adjunct to conventional treatment in treatment of ulcers. Patients treated with LLLT did not develop any complications during the study period and hence can be safely used.

KEYWORDS
Wound Management, Laser
Wound healing is a complex and changing process with the wound environment changing along with the changing health status of the individual. The knowledge of the physiology of the normal wound healing process through the phases of haemostasis, inflammation, granulation and maturation is essential for understanding of the basic principles of wound healing.

Through with this understanding the doctor can develop the skills required to care for a wound and the body can be assisted in the complex task of tissue repair. Healing a chronic wound requires care that is patient centered, holistic, interdisciplinary, and cost effective and evidence based. For proper healing, wound bed has to be well vascularized, no slough, with no evidence of infection. Wound dressings material should help in achieving proper environment for the wound to heal and should also be cost effective and also easy to use. Wounds closure can be done once the wound bed shows good granulation tissue. Many topical agents and alternative therapies are available to improve the wound healing environment. A variety of other therapies are used in treatment of ulcer and have shown good results such as low frequency ultrasound, electrical stimulation, electromagnetic therapy, and phototherapy.

The word LASER, an acronym for Light Amplification by Stimulated Emission of Radiation. The laser light, when reduced in its energy output to a low level, may be utilized for tissue healing and repair, cutting as in surgery, shrinking tumours, unblocking clogged arteries, eradicating infections, and other therapeutic purposes. "Low Level Laser Therapy" is used for many health enhancements. The effects caused by low level lasers are because of low energy deposited into tissues where deposited energy results in various therapeutic effects. This results in the analgesic and anti-inflammatory effects as well as in improvement in healing. LLLT act as a good analgesic since they improve endorphin release and therefore inhibit nociceptive signals and control pain mediators. These lasers act on cellular reduction-oxidative potential. In redox state the cells are in acidic form after the activity of low level laser therapy the cells shift to alkaline medium with then promotes the optimum functioning of the cell. The low level laser therapy does not affect healthy cells. It is well known that LLLT stimulate lymphocytes, activate mast cells, and increase production of adenosine-triphosphate in the mitochondria and proliferation of various cell types and stimulates microcirculation therefore acting as anti-inflammatory and promotes healing.

We wanted to compare the effect of Low Level Laser Therapy and conventional methods in management of ulcers with regard to time taken for healing, reduction in size, formation of granulation tissue, reduction in discharge and epithelialisation.

This is a prospective study conducted from November 2012 to November 2013 among 50 patients aged between 20 and 60 years diagnosed with ulcer. Diabetic ulcer patients with uncontrolled diabetes, critically ill patients and patients with pregnancy were excluded from the study. Low level laser therapy with standardized exposure with He-Ne laser of wavelength 632.8 nm was given.

The 50 study patients were randomized into two groups- Group 1 (LLLT) and Group 2 (control) with 25 patients in each group. In all cases, a detailed history and clinical examination was done by me and data was recorded as per protocol, after getting informed and written consent. The initial condition of the ulcer was recorded and adequate wound debridement was done if necessary in both the groups. Patients in group A underwent LLLT once in three days along with regular dressings whereas patients in group B underwent only conventional dressings. Observations were made during dressing and examination of the patients. Data was recorded on every third day from the date of admission till the 12th day. The efficacy evaluation was based on the size of ulcer, discharge from the wound, granulation tissue, and presence of epithelialization at the site of the wound.

Ethical Consideration
1. Informed and written consent for the study process was obtained from patients who are included in the study in a language which they understand.
2. Approved by the PIMS ethical committee.

Statistical Analysis
Data was entered in MS-excel 2010 & analysed by SPSS 17.0 version. Independent t test was used for the analysis.

### RESULTS

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Sex</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Male</td>
<td>16-64%</td>
<td>17-68%</td>
</tr>
<tr>
<td>2.</td>
<td>Female</td>
<td>9-36%</td>
<td>8-32%</td>
</tr>
</tbody>
</table>

*Table 1. Sex Distribution*

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Age Groups</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>20-30</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>31-40</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>3.</td>
<td>41-50</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>4.</td>
<td>51-60</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>5.</td>
<td>Mean Age</td>
<td>48.68</td>
<td>45.48</td>
</tr>
</tbody>
</table>

*Table 2. Age Distribution*

<table>
<thead>
<tr>
<th>Type of Ulcer</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Foot Ulcer</td>
<td>15 - 60%</td>
<td>18 - 72%</td>
</tr>
<tr>
<td>Traumatic Ulcer</td>
<td>6 - 24%</td>
<td>4 - 16%</td>
</tr>
<tr>
<td>Bed Sores</td>
<td>4 - 10%</td>
<td>3 - 12%</td>
</tr>
</tbody>
</table>

*Table 3. Distribution According to Type of Ulcers*
Results Group 2
- Reduction in size of ulcer within a minimum of 3 days to a maximum of 6 days with a mean period of 5.16 days.
- Reduction in discharge from ulcer started to reduce subsequently from 6th day to 9th day with a mean period of 7.92 days.
- Granulations were started to appear from 3rd day to 9th day with a mean period of 6.12 days.
- Epithelialization was started within 3rd day to 9th day and mean period was 6.72 days.
- Altogether in this group the mean time for the healing process to start was 5.16 days to 7.92 days.

LLLT has produced statistically significant results in terms of parameters such as time taken for reduction in size of the ulcer, time taken for granulation tissue and epithelialisation with a ‘p’ values of 0.001, 0.014 and 0.011 respectively.

**DISCUSSION**

Chronic wounds affect a substantial proportion of the population and contribute to a significant burden in the hospital setting. Certain patients are at risk for development of a non-healing wound such as those with impaired arterial or venous circulation, immunocompromised states, the elderly, those with diabetes, and any patient with neuropathy or spinal cord injury. The most common nonhealing wounds affecting the lower extremities are associated with peripheral artery disease, diabetes and chronic venous insufficiency.11,12 Non healing ulcers are managed by adequate debridement and suitable dressing with antiseptic solutions and topical applications which enhance wound healing. There is a continuous search for an ideal method to accelerate wound healing which does not have any ill effects on the patient. LLLT can be used as an adjuvant therapy in patients receiving conventional therapy in order to accelerate wound healing.

50 patients including both males and females with a diagnosis of non-healing ulcer were admitted under surgery department in Pondicherry Institute of Medical Sciences. Patients were randomized into two groups Group 1 (LLLT) and Group 2 (control). Their wound condition at the time of presentation was assessed, patients in both the groups underwent debridement if necessary and daily saline dressings were carried out for patients in both groups. Patients in Group 1 received LLLT twice in a week or once in three days. Demographic distribution in this study showed out of 50 patients 33(66%) were male and 17(34%) were females. Most of the patients were in the age group between 40 and 60. Out of all the patients, most of them were farmers and daily labourers rest of the others include teachers, shopkeepers, conductors and housewives. Majority of the patients included in the study had diabetes mellitus (39 patients), yet again proving that DM is a major risk factor associated with chronic wounds. Other risk factors
and comorbidities associated with the patients included in the study are HTN, dyslipidaemia, smoking, alcoholic and obesity.

The wound was assessed on every third day up to 12 days of treatment. The parameters which were observed are 1) Reduction in size of the ulcer, 2) Appearance of granulation tissue, 3) reduction in discharge and 4) epithelialisation. In group 1, reduction in size of ulcer started within a minimum of 3 days to a maximum of 6 days with a mean period of 3.84 days, whereas in group 2, Reduction in size of ulcer started within a minimum of 3 days to a maximum of 6 days with a mean period of 5.16 days. In group 2, reduction in discharge started to reduce from 3rd day to 9th day with a mean period of 8.4 days, whereas in group 2, Reduction in discharge from ulcer started to reduce subsequently from 6th day to 9th day with a mean period of 7.92 days. In group 1, granulations were started to see in the ulcer from 3rd day to 9th day with a mean period of 4.32 days, whereas in group 2 Granulations were started to appear from 3rd day to 9th day with a mean period of 6.12 days. In group 1, epithelialisation was started within 3rd day to 9th day and mean period was 4.92 days. Altogether in this group the mean time for the healing process to start was 3.84 days to 8.4 days whereas in group 2, Epithelialisation was started within 3rd day to 9th day and mean period was 6.72 days. The mean time for the healing process to start in group 1 was 3.84 days to 8.4 days compared to 5.16 days to 7.92 days in group 2.

A study by Hopkins et al. has reported results in 22 healthy subjects and shown 55% greater wound contraction in cases as compared to control group.13 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. The leg ulcers were given three treatments per week for 10 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).14 In a study conducted by Basavaraj et al on wound healing in diabetic foot ulcers, the wounds in subjects treated with LLLT contracted significantly more than the wounds in the non-treated group (40.24% vs 11.87%, 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.15

**CONCLUSIONS**

LLLT helps in wound healing by decreasing the time taken for healing, promoting granulation and early epithelialization and can also be used as an adjunct to conventional treatment in treatment of ulcers. Patients treated with LLLT did not develop any complications during the study period and hence can be safely used.

**REFERENCES**