Research Article CODEN: IJPRNK IMPACT FACTOR: 1.862 ISSN: 2277-8713
A Vishwanath Reddy, IJPRBS, 2014; Volume 3(2): 707-715 IJPRBS

INTERNATIONAL JOURNAL OF
PHARMACEUTICAL RESEARCH AND BIO-SCIENCE

A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL ON THE EFFECTIVENESS OF LOW INTENSITY LASER THERAPY ON THE WOUND HEALING DYNAMICS IN PRESSURE ULCERS

DR. A. VISWANATH REDDY[1], DR. B. C. M. PRASAD[2], DR. G. RAVINDRA REDDY[3], DR. ARUN G. MAIYA[4]

1. Associate Professor, Department of Microbiology, Sri Venkateswara Institute of Medical Sciences, Tirupati. Andhra Pradesh.
2. Professor & H.O.D, Dept. of Neurosurgery, SVIMS , Tirupati.
3. Senior Asst. Professor, Dept. of Plastic surgery, S. V. Medical college, Tirupati.
4. Associate Dean, MCOAHS, Manipal University, Manipal.

Accepted Date: 19/04/2014; Published Date: 27/04/2014

Abstract: **INTRODUCTION:** Pressure ulcers are a challenge to humanity as they are the wounds, initiated by continuous pressure on the insensate skin, causing the skin and underlying tissues to wither. They are one of the major complications of spinal cord injury and diabetic patients.This study has been done to assess the efficacy of Low intensity laser therapy (LILT) on the wound healing dynamics in human subjects with pressure ulcers. **METHODS:** A total of 130 subjects were enrolled for the study and after randomization the subjects were allocated to control and experimental groups each consisting of 65 subjects. The subjects of the control group received conventional wound dressing for the pressure ulcer for 3 weeks where as the subjects of the experimental group underwent LILT and conventional wound dressing for 3 weeks. On Day 1 and after 3 weeks, the PUSH score of the pressure ulcer was recorded. **RESULTS:** The results showed a significant difference between pre and post intervention values in experimental group compared to control group ($p < 0.05$). **CONCLUSION**: The study has brought out that LILT has better healing of pressure ulcers when compared to the conventional wound management to compare the wound healing dynamics among diabetic and non-diabetic subjects in the control and experimental groups.

Keywords: Pressure ulcers, LILT, PUSH score, Diabetes

PAPER-QR CODE

Corresponding Author: DR. A. VISWANATH REDDY

Access Online On:

www.ijprbs.com

How to Cite This Article:

A Vishwanath Reddy, IJPRBS, 2014; Volume 3(2): 707-715

INTRODUCTION

Pressure ulcers are a challenge to a physician as they are the wounds, initiated by continuous pressure on the insensate skin, causing the skin and underlying tissues to wither. Without proper attention, pressure ulcers continue to grow in diameter and depth thereby enhances morbidity.[1]In the United States, the annual number of patients who develop a pressure ulcer is estimated at 1.7 million. An overall prevalence of 9.2% among institutionalized patients and 5 to 10% in hospitals, about 30% in geriatric clinics and homes for the elderly.[2]

Pressure ulcers are complex wounds that result from one or more contributing factors. Stress, time, spasticity, infection, edema, denervation, moisture and poor nutrition contribute to the development of pressure ulcers.[3,4,] The loss of cutaneous sensitivity contributes to ulceration by removing one of the important warning signals about excess pressure, pain.[5] Paralysis leads to atrophy of the skin with thinning of this protective barrier, making the skin more susceptible to minor traumatic forces, such as friction and shear forces.[6,7,] Loss of surface epithelium leads to water loss across the skin, creating maceration and adherence of the skin to clothing and bedding, which raises the coefficient of friction for further insult.[8]Pressure ulcers are one of the major complications of spinal cord injury and diabetic patients. Ulcers are usually accompanied by an inflammatory reaction and secondary infection due to local bacterial colonization or by systemic infection. Exudation from large areas of damaged skin leads to fluid and protein loss.[9]

Low intensity laser therapy (LILT) is classified under class 3 B with a power varying between 5 to 500mW. It has been used as promising adjunctive treatment for the pressure ulcers and is a non-thermal modality which does not raise the subcutaneous tissue temperature greater than 36.5℃. Therefore the therapeutic effects of LILT are due to photochemical response and not due to thermal response. Laser therapy is associated with increased collagen synthesis, rate of healing and wound closure, tensile strength, tensile stress, number of degranulated mast cells and reduced wound healing time.[10]

In view of absence of large scale prospective, randomized, controlled clinical trials in human subjects, this study has been done to assess the efficacy of LILT on the wound healing dynamics in pressure ulcers.

MATERIALS AND METHODOLOGY:

A total of 130 subjects with pressure ulcers who are admitted in the SVIMS hospital, BIRRD hospital and SVRRG hospital, Tirupati, A.P are taken up for the study. A total of 117(excluding 13 dropouts) samples, male-66 number that is 56.4%, female-51 number that is 43.6% are finally selected for the study. The mean age group of the samples is 45.26±15.88 in the experimental group. In control group, mean age of samples is 45.98±14.12. The control group is

represented by 63 samples (drop outs = 2) while the experimental group consists of 54 samples (drop outs = 11). A prospective, randomized, controlled protocol approved by the Institutional ethics committee is conducted and informed consent is obtained from all subjects or their families.

Subjects with grade II pressure ulcers are included in the study. Patients are then randomly assigned to one of the two groups, and are treated for 3 weeks or until the ulcer healed whichever occurred first.

Control group (n=63) Subjects are randomized to receive only conventional wound dressing. Ulcers are cleansed gently with topical substance with physiological normal saline, moistened gauze and dried. Regular change of dressing is done and patients are given instructions not to lie on the pressure ulcer to diminish the pressure effects on skin microcirculation. Pressure ulcer is assessed on first day and PUSH score is calculated. Conventional wound therapy is done regularly and re-assessment of the wound is done at the end of 3rd week and statistical analysis done. Among 63 subjects, 26 were diabetic and 37 were non diabetic. Experimental group (n=54) Subjects are randomized to receive both the conventional wound dressing and a regimen of LILT for 3 weeks for the pressure ulcers. A total of six sessions of laser therapy is given per week. The equipment used is TECH LASER THERAPY SS (Laser therapy unit) which is a versatile, solid state laser, continuous output with visible red at 632.8 nm wavelength and power output of 10 mW.

Scanning mode is used which is very useful for treating larger areas such as sacrum, buttocks etc., Laser therapy has the advantage of short treatment and the ability to be applied without touching the wound, thus minimizing the cross- infection risk. During the treatment, protective goggles are given to the subject. The subject made lie down on the bed and the scanner is used to treat the pressure ulcer. The distance of 70 cm is maintained between and the scanner and the subject. The treatment is given with a frequency of 6 days per week and dosage of 9.54 J/cm^2 to 13.35 J/cm^2. Among 54 subjects, 23 were diabetic and 31 were non diabetic.

Dosage calculation:

Laser power output (W) = 10 mW = 0.01 W

The size of the beam aperture of the laser therapy unit is 0.314 cm²

$$\text{Power Density (W/cm}^2\text{)} = \frac{\text{Laser Output Power (W)}}{\text{Beam area (cm}^2\text{)}}$$

Power Density (W/cm^2) = 0.01W/0.314 cm²

= 0.0318 W/cm²

Energy Density (Joule/cm^2) **=** Power Density (W/cm^2) x Time (Secs)

= 0.0318 x 300 sec (5 min) or (7 min)

= 9.54 J/cm² to 13.35 J/cm²

Both groups are given the same preventive information and local ulcer therapy. The pressure ulcers of these samples are assessed on day 1 and after 3 weeks by using PUSH tool. All statistical computations have been done using IBM SPSS 19.0 version. The data has been analyzed by the following standard statistical methods. Mean values have been calculated for PUSH scores of the pressure ulcers of day 1 and after 3 weeks of the control and experimental groups separately. This has been done using paired t- test. Further mean differences and percentages of change between control and experimental groups for various variables have been done and its significance from the angle of study of thesis using independent sample t-test. The differences are found to be statistically significant at $p < 0.05$ level.

Table 1: PUSH scores of day1 and after 3 weeks among subjects with pressure ulcers in control and experimental groups

Group	PUSH Score	Mean	N	Std. Deviation	t- statistic	p-value
Control	Day1	12.08	63	1.825	32.224	0.000*
	After 3weeks	8.52	63	1.900		
Experimental	Day1	12.48	54	2.561	38.153	0.000*
	After 3weeks	7.13	54	2.111		

Table 2: Mean difference of PUSH scores of control and experimental groups

Group	Mean	N	Std. Deviation	t- statistic	p-value
Control	3.55	63	0.8758	10.19	0.000*
Experimental	5.35	54	1.0308		

Table 1 reflects the PUSH scores of day1 and after 3 weeks among subjects with pressure ulcers in control and experimental groups. The mean PUSH score of control group decreased from 12.08±1.82 to 8.52±1.90, where as the mean PUSH score of experimental group decreased from

12.48±2.56 to 7.31±2.11. Table 2 quotes the mean difference of PUSH scores between the control and experimental groups which is significant at p<0.05 level.

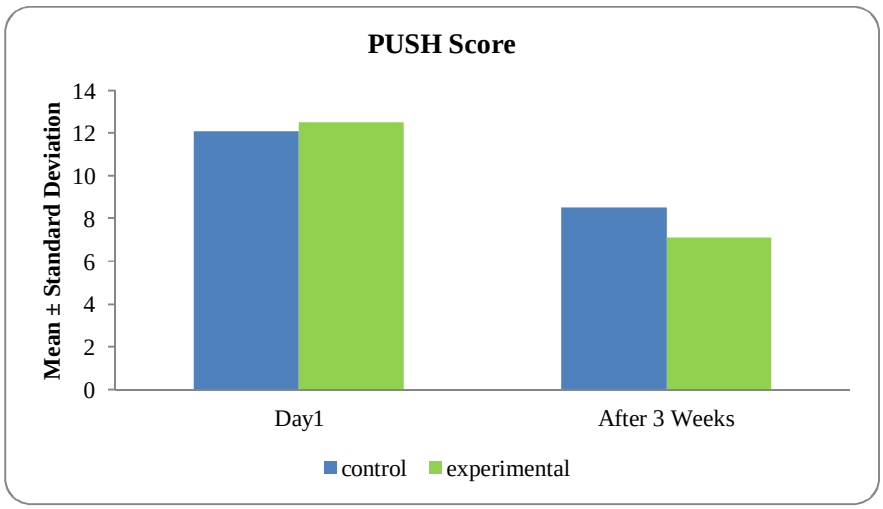

Fig 1: Comparison of PUSH scores of day1 and after 3 weeks among subjects with pressure ulcers in control and experimental groups

Further, to observe whether there is any influence of diabetes in healing of pressure ulcers, the following tables 3 and 4 reports the statistical summary. The non-diabetic subjects have better wound healing when compared to that of diabetic subjects in both the control and experimental groups.

Table 3: Mean percent change of PUSH scores in diabetic and non diabetics in the control and experimental groups

Group	Diabetic	N	Mean	Std. Deviation	t- statistic	p-value
Control	No	37	3.9459	0.66441	4.959	0.000*
	Yes	26	3.0000	0.84853		
Experimental	No	31	5.8065	0.94585	4.353	0.000*
	Yes	23	4.7391	0.81002		

Table 3 shows the mean percent change of PUSH scores of 3.94±0.66 in non diabetic subjects when compared to diabetic subjects of 3.00±0.84 in the control group. The mean percent change of PUSH scores is 5.80±0.94 in non diabetic subjects when compared to diabetic

subjects of 4.73±0.81 in experimental group. The mean difference of PUSH scores between non diabetic and diabetic subjects is significant at p=0.05 level.

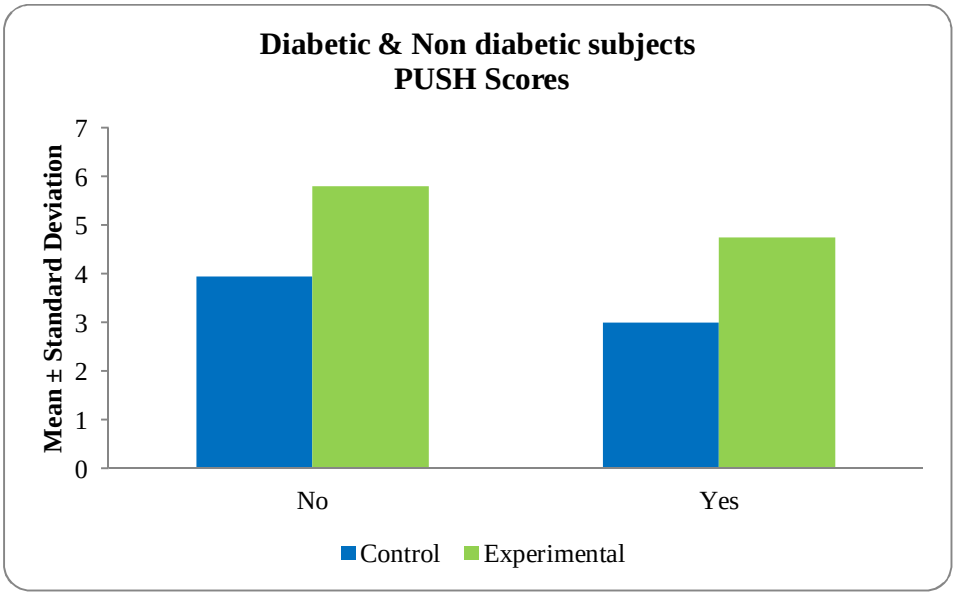

Fig 2: Comparison of mean percent change of PUSH scores among non diabetic and diabetic subjects in the control and experimental groups

DISCUSSION:

The demographic data includes a total number of 117 subjects. The control group consisted of 63 subjects including 36 male and 27 female subjects with a mean age group of 45.98±14.12. Among 63 subjects, 26 were diabetic and 37 were non diabetic. The experimental group consisted of 54 subjects including 30 male and 24 female subjects with a mean age group of 45.26±15.88. Among 54 subjects, 23 were diabetic and 31 were non diabetic. In the present study, the mean PUSH score of experimental group decreased from 12.48±2.56 (Day 1) to7.13±2.11 (after 3 weeks) where as the mean PUSH score of control group decreased from 12.08±1.82 (Day 1) to 8.52±1.90 (after 3 weeks). The mean difference between the control and experimental groups is significant at p<0.05 level.

In this study, LILT resulted in significant reduction of wound size, decrease in the amount of exudation and improvement of tissue type which suggests the effectiveness of LILT on the wound healing which is evident in the reduction of PUSH scores in a marked level from day 1 to after 3 weeks. Similar results were found in the study done by Ratliff and Rodeheaver in which 23 participants experienced a decrease in their PUSH score over the 2 month study period.

A prospective study done by Gardener and Colleagues, out of 32 pressure ulcers, 21 ulcers (66%) healed during the study period with reduction of PUSH scores. Thus, the PUSH tool was

shown to be a valid instrument for measuring healing in a clinical setting. A similar study done by A.E. Saltmarche et.al (2008), reveals that PUSH scores were reduced in the experimental group when compared to the control group which support the above statistical data where in the data was also significant at p< 0.001 level.[11]

During wound healing, the inflammatory process involves a vascular response, a hemostatic response, a cellular response and a immune response which are controlled by a complex interaction of neural and humoral mediators. During proliferative phase, the epithelial tissues have a high regenerative capacity and undergo a process known as re-epithelialization followed by remodeling phase.

The proposed mechanism of action of laser therapy is associated with the ability of the cell to absorb the photon and transform the energy into A.T.P which is used by the cell for its function. The light absorbing components of the cells are termed chromophores or photoacceptors and are contained within the mitochondria and cell membrane. Laser stimulation has been shown to enhance the production of ATP by forming singlet oxygen, reactive oxygen species (ROS) or nitric oxide, all which influence the normal formation of ATP (Derr and Fine 1965; Lubart et al. 1990). The increased ATP prompts homeostatic function of the cells to resume. Furthermore, the ATP energy may drive the messenger RNA to foster cell mitosis and proliferation.

The mean percent change of PUSH scores is 5.80±0.94 in non diabetic subjects when compared to diabetic subjects of 4.73±0.81 in the experimental group in table 15. The mean difference of PUSH scores between non diabetic and diabetic subjects is significant at p<0.05 level. The results shows the evidence of better wound healing in non diabetic subjects when compared to diabetic subjects. The factors which may delay the wound healing might be arterial insufficiency and peripheral neuropathy which are most common among diabetic subjects. Subjects with diabetes are prone to peripheral vascular disease in both macrovessels and microvessels. They also have dampened immune response which compromises the ability to combat infection. A study done by Maiya GA et al on “effect of low intensity helium-neon laser irradiation on diabetic wound healing dynamics” concluded that laser photostimulation promotes the tissue repair process of diabetic wounds.[12]

Byrnes et al in their study “photobiomodulation improves cutaneous wound healing in an animal model of type II diabetes” concluded that an energy density of 4 J/cm2 is effective in improving the healing of chronic cutaneous wounds. A study done by Sylvia.B.R et al(2006) “comparison between wound healing in induced diabetic and non diabetic rats after low level laser therapy” concluded that irradiation of rats with helium neon (632.8 nm), at the tested dose promoted efficient wound healing in both non diabetic and diabetic rats as, compared to the control group.

In the present study, the wound healing is evident in both the diabetic and non diabetic subjects and the rate of healing is better in the non diabetic subjects in both the control and experimental groups. Biochemical and histological analysis of the pressure ulcers were not done in this study which might be incorporated in future studies.

CONCLUSION: The study has brought out that LILT has better healing of pressure ulcers when compared to the conventional wound management. The rate of healing was better in non diabetic subjects when compared to that of diabetic subjects in both the control and experimental groups. Improvement of wound healing with LILT has increased the quality of life in the subjects with pressure ulcers thereby enhancing the self esteem of the subjects. Good interdisciplinary approach among the physiotherapists, nursing professionals, surgeons and physicians helped in the holistic rehabilitation of the subjects with pressure ulcers in this study.

REFERENCES

1. Damien P Kuffler. Techniques for Wound Healing with a Focus on Pressure Ulcers Elimination. The Open Circulation & Vascular Journal 2010;3:72-84.

2. Eberhardt.S, Heinemann.A, Kulp.W. Health Technology Assessment report 2004.

3. Bennet L, Kavner D, Lee BK, Trainor FA. Shear versus pressure as causative factors in skin blood flow occlusion. Arch Phys Med Rehabil 1979;60:309-314.

4. Gosnell DJ. Pressure Sore Risk Assessment, Part II: Analyses of Risk Factors. Decubitus 1989;2:40-43.

5. Holewski J.J, Stess R.M, Graf P.M, Grunfeld C. Aesthesiometry: quantification of cutaneous pressure sensation in diabetic peripheral neuropathy. J Rehabil Res Dev 1988;25:1-10.

6. Jay R. Pressure and shear: their effects on support surface choice. Ostomy Wound Manage 1995;41:36-38,40-32,44-35.

7. Daniel R.K, Wheatley D, Priest D. Pressure sores and paraplegia:an experimental model. Ann. Plast. Surg 1985;15:41-49.

8. Anders J, Heinemann A, Leffmann C, Leutenegger M, Pröfener F, von Renteln-Kruse W**.** Decubitus ulcers: Pathophysiology and primary prevention. Dtsch Arztebl Int 2010;21:371-81.

9. Kosiak M, Kubicek WG, Olson M. Evaluation of pressure as a factor in the production of ischial ulcers. Arch Phys Med Rehabil 1958;39:623-29.

10. Edmonton AB. Regional Wound care Guidelines Working Group Capital Health authority. 2001.

11. Anita E Saltmarche. Low level laser therapy for healing acute and chronic wounds-the extendicare experience. International wound journal. 2008;5(2):351-360.

12. Maiya GA, Kumar P, Rao L. Effect of low intensity (He-Ne) laser irradiation on diabetic wound healing dynamics. Photomedicine and laser surgery 2004; 23(2):187-90.