

Low Level Laser Therapy in the Treatment of Pressure Ulcers in Spinal Cord Handicapped Veterans Living in Tehran

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Abstract

Pressure ulcers result from immobility and continuous pressure on an area of body. Besides imposing further restriction of movements and thus creating a vicious circle in the healing process, these ulcers are of significant importance in decreasing the life quality and increasing the costs of treatment in these patients. In this study we compared the outcome of treatment of pressure ulcers with GA-AL-AS (Gallium- Aluminium -Arsenide) & Gal-AL-In-Ph (Gallium- Aluminium-Indium – Phosphate) - diode lasers, on contact, continuous emission mode at an every other day dose of 4-6 J/cm² for 3 weeks plus conventional treatments of pressure ulcers, with that of conventional treatment alone in two groups of veterans with spinal cord paralysis who reside in Tehran. The study was a triple blind clinical trial conducted among 16 veterans who were randomly divided into case and control groups.

The diameter of the ulcers was measured and staged by one person who was unaware of the subjects' allocation. Digital photographs of the ulcers were initially taken and a combination of conventional treatment (wet dressing, irrigation) with Low Level Laser and conventional treatment alone was performed for the case and control groups respectively. After 3 weeks the subjects were evaluated again and photographed with the same method. The results demonstrated a statistically significant enhancement of the healing process by combination of Low Level Laser with conventional treatments of pressure ulcers.

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Keywords • Low level laser • pressure ulcers • healing • spinal cord injury • veterans

Introduction

Pressure ulcers generally result from immobility or continuous pressure on an area of body. Previously known as bed sores, these ulcers are currently named after their underlying mechanism. Pressure causes local derangement of blood supply, which results in ischemia. Such nomenclature makes them distinguishable from ulcers with other etiologies such as venous stasis and vascular disorders including diabetes mellitus.¹

In patients with spinal cord injury, induced paralysis, increased local pressure due to persistent immobility and the resulting ischemia as well as less understood mechanisms arising from the cord injury itself are believed to be responsible for the pathogenesis of pressure ulcers. Pressure ulcer is a major

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health problem, which causes severe restriction of movements in patients with spinal cord injuries.²

The significance of pressure ulcers is that besides imposing further restriction of movements and thus creating a vicious circle in the healing process, these ulcers are of significant importance in decreasing the life quality and increasing the costs of treatment in these patients. It is worth mentioning that the treatment expenditure of a single ulcer alone at high stages is about US \$ 58 K which is irrespective of the economical burden resulting from the reduced functionality.³

In Iran, based on the results of a 1998 survey, 21% of spinal cord injury veterans are suffering from pressure ulcers.⁴ It is generally held that most of these patients require surgical treatments for their ulcers. The current treatment of pressure ulcers accompanies pains, and prolonged period of time for natural healing process, which is only effective if pressure is lifted from the site of ulcer.¹ Relapse can only be avoided if sufficient perfusion and blood supply of the underlying tissues is maintained otherwise any kind of treatment would be temporary and the ulcers are to re-appear with the restoration of pressure.¹ Conventional treatments encompass measures such as irrigation with normal saline and sterile dressing, while more expensive methods employ the use of platelet growth factors, recombinant DNA or newer thermal and other physical modalities such as ultrasound and ultra violet (UVS).² Few high stage ulcers (stage III and above) require surgical procedures such as skin graft.¹

The consensus of opinion is that pressure ulcers must be avoided by preventive measure in the first place however if developed, every effort must be made to halt its progress because earlier recovery means less debility.³

In view of neurovascular pathophysiology of pressure ulcers in patients with spinal cord injury and positive effects of laser in enhancing the tissue perfusion and stimulating cellular metabolism, low level laser has recently been used for treatment of pressure ulcers.⁵ The evidence regarding the positive effects of laser on the healing process through induction of local vasodilatation and enhanced tissue perfusion, its relative feasibility and lack of significant side effects and cultural conflicts made us carry out this study among a population of spinal cord veterans in Tehran and compare its efficacy with routine ulcer treatments (irrigation with normal saline and sterile dressing).

Materials and Methods

The experimental study was designed as a randomized clinical trial with control and intervention

groups in a triple blind setting. The subjects were all veterans with spinal cord injury living in Tehran who were afflicted with pressure ulcers. They were selected in a convenient method and were randomly divided into case and control groups. The subjects were introduced by veteran's hospitals or spinal cord Veterans' care homes for treatment and checkups.

Based on previous studies,² the cure rate of pressure ulcers with routine treatment was estimated at 75%. If we consider a cure rate of 100% with low level laser therapy enough to deem its effect as statistically significant when $\alpha=0.05$ and test power is set at 80%, a sample size of 15 subjects was calculated. The subjects were given the necessary information and written informed consent was obtained.

The inclusion criteria were as follows:

- 1) Spinal cord injured veterans with stage I, II, and III pressure ulcer in sites such as knee, ankle, occiput, and around pelvis, which confirmed by primary clinical examination.
- 2) Lack of any history or signs for diabetes mellitus, vascular disorder, vasculitis, and chronic renal failure according the clinical examination and previous medical records.
- 3) Lack of indicative signs of ulcer infection (malodorous, yellow secretion, fever).
- 4) Negative history for consuming any immunity compromising drugs.
- 5) Lack of any laser treatment contraindications such as seizure, cancer, and hypersensitivity to light.

The patients who develop ulcer infection during the course of treatment and those with non-compliance or unwillingness to continue treatment were excluded from the study.

The minimum 50% reduction of ulcer size and at least one stage as reported by an examiner in a blind setting or failure to achieve any improvement in the size and stage of the ulcer after a 10-session course of treatment was considered as final outcome.

GA-AL-AS laser (Gallium-Aluminium-Arsenide) and GA-AL-IN-PH (Gallium-Aluminium-Indium-Phosphate) laser (Azor-2k, Russia) with probes:

Infra red; 980 nm, 200 mw continuous (GA-AL-AS), and red; 650 nm, 30 mw continuous (GA-AL-IN-PH) with the dose: 4-6 J/cm² were used.

The data were filled into a form and were analyzed by a statistician in a blind setting using the SPSS software version 12.

Data regarding the size and stage of ulcer in spinal cord veterans before and after treatment was evaluated by paired *t* test while the size and stage of ulcers in both case and control groups were compared using the Mann Whitney test. Considering the small sample

size, we preferred to use a non-parametrical statistical test such as Wilcoxon as well.

Results

In this study in a triple blind setting, 16 subjects were randomly divided into two groups.

Table 1 shows the demographic characteristics of the participants. The most common anatomical site for ulcers in both groups was ischial region (62.5%) (table2).

Table 1: Demographic characteristics of the participants

group variables	Supportive therapy		Supportive therapy+ laser	
	mean	Standard deviation	mean	Standard deviation
Age/year	41.1	9.4	38.2	5
Duration of Injury/year	19.3	3.8	18	2.7
Duration of Ulcer/month	36.4	7.2	36.8	3.9

Comparing the 3 stages of ulcers before and after treatment in the control group demonstrated that most patients remained at the same stage (P=0.317).

Statistical analysis regarding the ulcer size before and after treatment in the control group demonstrated decreased size of the ulcer in six subjects, expansion of ulcer in one subject, and unchanged size in the remaining one subject.

The Wilcoxon test indicated that there was not sufficient evidence in favour of the efficacy of treatment in downsizing the ulcers (P=0.236).

The comparison of ulcer stage before and after treatment with laser demonstrated regression of stage in five subjects while the stage in the remaining three did not change. It can be elicited that this treatment was effective in reducing the stage of ulcer (P=0.025).

Ulcer size was reduced in seven subjects after treatment with laser but did not change in the remaining one (table 3). It shows that laser was effective in reducing the size of pressure ulcers (P=0.016). Comparing the ulcer stage before and after treatment in both case and control groups did not demonstrate a statistically significant change (P=0.238).

Ulcer stage before and after treatment in both groups showed a statistically significant effect which was more pronounced in the laser treatment group (P=0.005).

Comparing the ulcer size before and after treatment in both groups indicated a statistically significant effect, more pronounced in the laser group (z=2.79, P=0.003).

Comparing the effect of treatment in reducing the size of ulcer in both groups indicated a statistically significant effect, which was more pronounced in the laser group (P=0.010).

Stage downgrade in both groups was not statistically significant (P=0.119).

Table 2: Anatomical distribution, type of ulcers and level of spinal cord injury in subjects

Variable	Treatment groups	Supportive therapy+ laser		Supportive therapy alone	
		percentage	Frequency	frequency	percentage
Site of ulcer					
Ischial		4	50	6	75
Sacral		2	25	2	25
Ankle		2	25	0	0
sensory distribution					
Cervical		1	12.5	3	25
Thoracic		3	37.5	4	62.5
Lumbar		4	50	1	12.5
Motor distribution					
Cervical		1	12.5	2	25
Thoracic		5	62.5	5	62.5
lumbar		2	25	1	12.5
Stage before treatment					
I		6	75	3	37.5
II		1	12.5	3	37.5
III		1	12.5	2	25
Stage after treatment					
0		3	37.5	1	12.5
I		4	50	3	37.5
II		1	12.5	2	25
III		0	0	2	25

Table 3: Frequency of decreased and non-decreased and increased ulcer size after treatment

Study group	Supportive treatment + laser		Supportive treatment alone		P=0.007
	Frequency	percent	Frequency	percent	
Decreased	7	87.5	6	75	
Unchanged	1	12.5	1	12.5	
Increased	0	0	1	12.5	
Total	8	100	8	100	

The analysis of the minimum 50% reduction in ulcer size in the studied groups with showed that the reduction in ulcer size was statistically significant ($P=0.007$).

Also the difference of cure rate (the minimum 50% reduction of ulcer size and at least one stage) in the two groups was statistically significant ($P=0.001$).

Discussion

Taking the results of this study into consideration, it is possible to state that combined use of GA- Al- Ar (infrared) and GA Al, (red) lasers is effective in healing of pressure ulcers in spinal cord veterans of our country.

A regimen of low level laser administered in alternate days for 3 weeks, has produced a statistically significant reduction in the size of ulcers as compared with the control group ($P=0.007$). Despite the eventual healing of ulcers in both groups after one month of treatment, it appears that low level laser has facilitated the healing process.

The observed results were in line with numerous previously reported cases and also clinical trials on the effect of low level laser treatment on healing process of ulcers.^{1,3,5-12} The results were also supported by the previously conducted studies on the use of low level laser therapy in animals.^{8,9}

This effect has not been confirmed by a number of studies,¹⁰ however those studies were either carried out on a small number of subjects or differed from our study in their employed method of low level laser therapy or the ulcer types.

Beckerman et al identified a number of methodological biases that existed in the previous studies, which failed to establish the therapeutic effects of laser.^{10,11} Such shortcomings such as lack of precise control or blind methods in clinical trials, may explain the difference in the observed results.

Also in numerous studies several treatment modalities were concomitantly employed, rendering attribution of the result to one almost impossible.⁸

When considering an interventional study on treatment of pressure ulcers, it is important to bear in mind that several intrinsic factors are also important in the form of inflammatory responses.¹² To this end, the results of previous studies on certain groups of subjects can not be applied to other patients and this study was specifically designed to evaluate the treatment of pressure ulcers in spinal cord veterans of our country.

Possible shortcomings of this study include its relative small sample size and short follow up period. Such flaws were imposed by lack of

sufficient information about the prevalence of pressure ulcers among the target population (Iranian spinal cord veterans) which resulted in limited number of them volunteering to participate in this project.

To avoid the previously encountered biases (poor study design, lack of control group or non-specificity of the employed treatment) in substantiating the efficacy of laser treatment, we selected an equal number of subjects for both the case and control groups from a similar population of patients and conducted all phases of the study (observation, evaluation, treatment) in a blind setting.

Despite the success of this study in demonstrating the efficacy of combining laser with supportive treatments, the poor interest of veterans in volunteering for this project and lack of harmony between the two groups in terms of other factors such as level of injury and age which are effective in the healing process, can be regarded possible flaws for his study.

Nevertheless it seems that combination of low level laser with irrigation and dressing in treatment of pressure ulcers in spinal cord veterans is more effective than irrigation and dressing alone. Furthermore, adequate physical activity, controlling blood sugar, cessation of smoking and proper nutrition are of great importance in enhancing the healing process in these patients.¹³ Given the lack of harmony between the case and control groups in terms of other important factors in the healing process and the obtained results of this study, further studies with larger and more harmonised samples may be necessary to substantiate the positive effect of laser in the treatment of pressure ulcers. Finally we wish that presentation of the results of this study will encourage our spinal cord veterans to adopt this treatment modality and thus pave the way for future studies.

Conclusion

The healing process of pressure ulcer in spinal cord injured enhances by combination of Low Level Laser with conventional treatments of pressure ulcers. Further research might focus on the other important factors such as adequate physical activity, controlling blood sugar, cessation of smoking and proper nutrition in enhancing the healing process in these patients.

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