

Efficacy of Negative Pressure Therapy Versus Monochromatic Infrared Energy (MIRE) on Healing of Venous Ulcer: A Randomized Controlled Trial

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Abstract : Background: Venous ulcers are one of the major health problems of the industrial world. **Objective:** The aim of this study was to compare between the efficacy of Negative Pressure therapy and Monochromatic infrared energy (MIRE) in accelerating the healing of lower limb venous ulceration. **Patients and methods:** Forty patients with lower limb venous ulcer selected from department of surgery, Cairo University Hospitals between Dec 2015 and May 2016, with age ranged from 30-50years. Patients were randomly assigned into two equal groups. Group (A) received monochromatic infrared energy in addition to routine medical treatment, while Group (B) received Negative Pressure therapy in addition to routine medical treatment. All treatment interventions were applied at a frequency of 3 days per week for 6 weeks. Outcome measures included Ulcer Surface Area (USA). USA was measured for all patients before treatment and after 6 weeks from the beginning of treatment. **Results:** There was a significant reduction of ulcer surface area ($p < 0.05$) at both groups. percent of improvement of ulcer surface area " between both groups showed there was significant differences ($p < 0.05$) and this significant reduction in group B (Negative Pressure therapy). **Conclusion:** From the results of our study it was concluded that Negative Pressure therapy accelerates the healing of lower limb venous ulceration as compare to Monochromatic infrared energy (MIRE) in patients with lower limb venous ulceration. **Key words;** Monochromatic infrared energy, Negative Pressure therapy, Ulcer Surface Area, and, Venous ulcers.

Introduction

The skin is a lively organ of the body that directly affects the capacity of different organ systems to feature usually. It serves as a defensive barrier that prevents internal tissues from exposure to trauma, ultraviolet radiation, temperature extremes, pollution and bacteria. Other vital features include sensory perception, immunologic surveillance, thermoregulation and control of insensible fluid loss ¹.

Venous ulcers are an incredible trouble among older and overweight populace. There were numerous researches approximately the aetiology, natural records, and epidemiology of pores and skin breakdown. There's exceptionally little information approximately elements that stimulate the repair of body tissues after break down ².

Venous ulcers are wounds which are thought to occur due to improper functioning of valves within the veins commonly of the legs. They may be the important purpose of continual wounds, happening in 70% to

90% of chronic wound instances. Venous ulcers are expensive to treat, and there is a substantial risk that they'll reoccur. After healing; up to 48% of venous ulcers had recurred by means of the fifth year after healing³.

Venous ulcers have exceptional characteristics, which can be differentiated by using the records and clinical examination of the patients. But, objective documentation for the ulcer etiology is necessary previous to beginning remedy. The methods for diagnosing the causes for the ulcers include plethysmography, ultrasound, angiography, computed tomography, magnetic resonance imaging, and skin biopsy. Some of these tests should be used at the side of the medical presentation of the patient. They ought to be performed in a value-powerful manner to keep away from delays in prognosis and decrease charges and usage of sources⁴.

Venous skin ulcers develop on either side of the lower leg, above the ankle and beneath the calf as that is wherein the ankle vessels perforate, locally increasing the venous pressure. Immobility, abnormality of the calf muscle pump, or valvular disorder of the venous system because of thrombotic damage, trauma or congenital absence causes venous insufficiency. Venous ulcers generally fashioned when these elements combine to some degree, inflicting occlusion or distortion of capillary network⁵.

Negative Pressure Wound Therapy has emerged as non-pharmacological treatment for acute and chronic wounds, including venous ulcers, diabetic wounds, abdominal wounds and traumatic wounds. It is primarily used for more complex chronic wounds⁶.

Vacuum therapy (VAC remedy) has been used for the treatment of open wounds for almost a century. Beginning in 1908 with Bier's Hyperemic treatment, clinicians has applied vacuum suction to contamination and all types of chronic, stressful and post-surgical wounds. Greater current uses of vacuum suction have been described in 1970 in Russian literature and Fleischmann's work accompanied with the aid of case research described by means of Chariker, Jetter and Tintle in 1989. In1993, the US food and administration (FDA) cleared "VAC therapy" for marketing purposes and use in wounds remedy⁷.

The Negative Pressure device is comprised of: 1) a gauze or wound dressing to fill the hollow space, 2) a drainage tube held near the location of harm, sometimes interior of the dressing,3) an adhesive sealant located atop the dressing to create an airtight seal, 4) a box or outlet for the fluid drained from the injured vicinity, and 5) a low-pressure (round 40 to 200 mmHg, depending on severity) vacuum to create negative pressure. The dressing of the wound is probable to final no extra than three days⁸.

The Anodyne® therapy device is a non-invasive scientific tool that provides Monochromatic Infrared Energy/ (MJRE™) through infrared light-emitting diodes. those diodes are set up in bendy remedy Pads, and emit infrared mild at a wavelength of 890 nm, increasing local circulation and decreasing pain, stiffness and muscle spasm in which applied⁹.

It has been suggested that Monochromatic Infrared power (MIRE™) is best suitable for the management of stage 2 and stage 3 ulcers with inadequate or terrible granulation tissue and heavy exudates¹⁰.

Wound healing includes a relatively complicated set of physiological processes regulated by using many distinctive cell and humeral factors; MIRE therapy stimulate the endogenous purification by way of elimination of infectious microorganisms and mobile particles thru the following; growing stimulation of macrophages, increasing bacterial phagocytosis activity and bacterial phagocytosis ability by using increasing formation of the scavenger cells, increasing stimulation of neutrophils, growing range of neutrophils and phagocytosis activity¹¹.

Patients and Methods

Randomized clinical trial was conducted between December 2015 and May 2016, at department of surgery, Cairo University Hospitals, forty patients who had lower limb venous ulcer enrolled into this blinded randomized-controlled trial. The patients participated in the study after signing an informed consent form prior to data collection. Recruitment began after approval was obtained from the Ethics Committee of the Faculty of Physical Therapy, Cairo University.

Exclusion criteria: sufferers had been excluded if they had a history of sensory impairment, systemic sickness or photosensitive. Further sufferers were excluded if they suffered from any skin sicknesses which can intrude with the targets of the study.

Within the first contact with the sufferers, they had been allowed to finish the assessment form. Ulcer surface area evaluated for all sufferers. Sufferers have been selected from department of surgery, Cairo university Hospitals, after preliminary evaluation, patients have been randomly divided into equal groups in wide variety (n=20), Negative Pressure therapy group and Monochromatic infrared power (MIRE) group.

The sufferers had been randomly assigned to the Negative Pressure therapy group or Monochromatic infrared strength (MIRE) group (n=20) by way of an unbiased character who took a sealed opaque envelope from a box following a numerical series; the envelope contained a letter indicating whether the patient would be allotted to the Negative Pressure therapy group or Monochromatic infrared energy (MIRE) group.

Treatment Procedures

Every affected person in Negative Pressure therapy group turned into placed right into a comfortable position according to the site of the ulcer, the wound cleaned before everything .some report abscesses opened and pus drained, and necrotic tissue eliminated. Scrubbing the wound with a tender tooth brush followed with the aid of hydrogen peroxide, saline rinse and betadine. Negative Pressure application: vacuum assisted closure (VAC) device. Frequency of application: use intermitted (5min on, 2min off) Negative Pressure Therapy will be applied every other day for six weeks for 20 minutes¹².

While sufferers in Monochromatic infrared strength (MIRE) group received the radiation thru Anodyne® remedy systems-version 480 that provides monochromatic Infrared energy/ (MIRE™) which acquired clearance from the united states FDA in 1994, obtained CE Marking in 2005. The remedy pads placed the area to be treated, with clear plastic barrier among the pads and the patient's skin to avoid the spread of bacteria, viruses and different microorganisms from one person to another, session last for 12 minutes¹³.

Outcome measures

The outcome measure for determining treatment assessment was ulcer surface area, The measurement of ulcer surface area was conducted by tracing method, A sterilized transparency film was placed on the ulcer. The ulcer perimeter was traced using the fine-tipped marker pen. Each wound area was traced three times to establish measurement reliability.

After tracing, the transparency sheet face, which faced the venous ulcer wound, was leaned by a piece of cotton and alcohol. A separate transparency sheet was used for each wound. The tracing was then placed over the metric graph paper and the number of square millimeters inside the trace perimeter was only counted and the area was then converted to cm²¹⁴.

Sample size:

By using G power program a preliminary power analysis [power (1 α error P) = 0.85, α = 0.01, effect size = 0.5] determined a sample size of 40 for this study. This effect size was chosen because it yielded a realistic sample size.

Statistical Analysis:

Statistical analysis was conducted using SPSS for windows, version 20 (SPSS, Inc., Chicago, IL). The current test involved two independent variables. The first one was the tested group that had two levels (group A receiving monochromatic infrared energy in addition to routine medical treatment and group B receiving Negative Pressure therapy in addition to routine medical treatment). The second one was the treatment periods, within subject factor which had two levels (pre- treatment, post treatment). In addition, this test involved one tested dependent variable (ulcer surface area). Prior to final analysis, data were screened for normality assumption, homogeneity of variance, and presence of extreme scores. This exploration was done as a pre-requisite for parametric calculations of the analysis of difference.

Descriptive analysis using histograms with the normal distribution curve showed that the ulcer surface area was normally distributed and not violates the parametric assumption for the measured dependent variable. Additionally, testing for the homogeneity of covariance revealed that there was no significant difference with p values of > 0.05 . The box and whiskers plots of the tested variable were done to detect the outliers. Normality test of data using Shapiro-Wilk test was used, that reflect the data was normally distributed for ulcer surface area. All these findings allowed the researchers to conduct parametric analysis. Accordingly, "paired t test" was used to compare between "pre" and "post" tests for each dependent variables for each group. "Unpaired t test" was conducted to compare percent of improvement of ulcer surface area between both groups with the alpha level 0.05.

Results

Ulcer surface area:

The mean \pm SD values of ulcer surface area in the "pre" and "post" tests at both groups shown at (table 1). "Paired t test" revealed that there was a significant reduction of ulcer surface area ($p < 0.05$) at both groups. Considering the effect of the tested group (first independent variable) on percent of improvement of ulcer surface area, "unpaired t test" revealed that the mean values of the " percent of improvement of ulcer surface area " between both groups showed there was significant differences ($p < 0.05$) and this significant reduction in favor of group B(Negative Pressure therapy) (table 2).

Table (1): Mean \pm SD and p values of ulcer surface area pre and post- test at both groups.

Ulcer surface area	Pre test	Post test	MD	t-value	p- value
	Mean \pm SD	Mean \pm SD			
Group A	10.1 \pm 1.8	1.9 \pm 1.2	8.2	28.88	0.0001*
Group B	18.38 \pm 5.8	1.37 \pm 1.02	17	11.84	0.0001*

*Significant level is set at alpha level < 0.05

SD: standard deviation

MD: Mean difference,

p-value: probability value

Table (2): Mean of percent of improvement of ulcer surface area and p value between both groups.

Ulcer surface area	Group A	Group B	MD	t-value	p- value
Percent of improvement	82.45 \pm 11.33	92.28 \pm 4.60	-9.83	-3.112	0.004*

*Significant level is set at alpha level < 0.05

SD: standard deviation

MD: Mean difference,

p-value: probability value

Discussion:

This study was to compare the efficacy of Negative Pressure therapy and Monochromatic infrared energy (MIRE) as a method of accelerating the healing of lower limb venous ulceration.

Results of this study showed that there was a significant reduction of ulcer surface area ($p < 0.05$) at both groups. Considering the effect of the tested group (first independent variable) on percent of improvement of ulcer surface area, "unpaired t test" revealed that the mean values of the " percent of improvement of ulcer surface area " between both groups showed there was significant differences ($p < 0.05$) and this significant reduction in favor of group B(Negative Pressure therapy) .

The findings of this study are in agreement with those, Fleck and Frizzell, ¹⁵ who proved Negative Pressure Wound Therapy may be taken into consideration in a chronic wound if the wound size decreases less than 30% after 4 weeks following debridement or if immoderate exudates can't be managed effectively with daily dressing changes.

The primary suggested mechanisms of action for negative pressure remedy are the availability of a wet wound healing environment, elimination of fluids and infectious substances, assisted perfusion, reduced bacterial colonization and more advantageous formation of granulation tissue. It includes speedy mobile division, increase in local blood flow, discount in bacteria levels and removal of harmful proteases¹⁶.

Negative pressure therapy can be correctly utilized in expedited wound closure effects in shorter hospitalizations, decreased costs and reduced risks of contamination. Complications which include infection normally prolong hospitalization, requiring next processes for patients. treatment with Negative pressure therapy lets in patients to be discharged from hospital and treated at domestic, where they can preserve extra mobility with advanced nice of lifestyles. Inside home healthcare settings, it is able to assist to enhance affected person care and reduce prices associated with numbers of visits¹⁷.

Negative pressure therapy can help to hold sufferers from returning to medical institution, as its function has been evaluated for its impact on clinic readmissions. In a retrospective evaluation of it in open foot wounds with sizeable tissue defects discovered that the danger of complications, subsequent foot surgeries and hospital readmissions (secondary consequences) had been all reduced by 70% or extra for the sufferers handled with it, compared with sufferers dealt with trendy saline soaked gauze dressings¹⁸.

Till the wound is closed, the Negative pressure therapy does now not best increase affected person's exceptional of existence due to much less regularly wanted painful modifications of dressings, however it improves the wound after debridement in order that we will close the wound extra quickly and extra thoroughly. This doesn't relate to skin transplants best however additionally to coverage with pedicled and unfastened micro vascular flaps. Elements of infection and vascularization of the wound (or limb) continually need to be clarified before any technique can take place¹⁹.

Wound healing entails a surprisingly complicated set of physiological approaches regulated by using many distinct cell and humeral factors; MIRE therapy stimulate the endogenous purification by using elimination of infectious microorganisms and mobile debris thru the subsequent; increasing stimulation of macrophages, growing bacterial phagocytosis and bacterial phagocytosis capacity through growing formation of the scavenger cells, growing stimulation of neutrophils, growing quantity of neutrophils^{20,21}.

Additionally the outcomes of this study at concerning the efficacy MIRE therapy on recovery of lower limb venous ulcers became in consistence with studies that mentioned that MIRE therapy stimulate the discharge of growth factors ends in boom bFGF, stimulation cellular growth fibroblasts; growth EGF, growth stimulation of epithelium cells. MIRE remedy stimulate the quicker epithelialization through accelerating the proliferation and migration of epithelium cells, that can originate from the wound periphery and probably from the wound bed, all the aforementioned mechanisms eventually cause wound closure^{22,23}.

MIRE remedy stimulate the higher pleasant of granulation via revascularization and collagen manufacturing via the following sequence; release of mediators leading to release of cytokines (IL1&IL VI) and release of growth elements, the discharge of cytokines (IL1&IL VI) leads to stimulation of fibroblasts, increase collagen production, stimulation of keratinocytes, increasing formation of epithelium, stimulation of endothelium cells and stimulation of the angiogenesis^{24,25}.

Limitations of the study:

A lot of efforts become exerted with each affected person to reduce impact of viable errors inherent within the study. This examine turned into constrained with the aid of the subsequent factors: bodily and mental situation of the affected person all through length of remedy, viable human error in application of measurement or therapeutic procedures, Cooperation of the affected person, affected person lifestyles fashion& practicing physical games, and variability among patients and their response consequences of recovery.

Conclusion:

From the results of our study it was concluded that Negative Pressure therapy accelerates the healing of lower limb venous ulceration as compare to Monochromatic infrared energy (MIRE) in patients with lower limb venous ulceration.

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