International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.10 No.5, pp 427-434, 2017

Polarized light Versus Pulsed Electromagnetic Field Therapy On Healing of Venous Ulcers

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Abstract : Venous leg ulcer is a common problem, frequently leads to disability. The aim of this work to evaluate efficacy of polarized light versus pulsed electromagnetic field therapy in accelerating venous ulcers healing. Forty five patients (both sexes) with leg venous ulcers, their age from 45-60 years were randomly divided into three groups. Group (I) received pulsed electromagnetic field therapy **PEMF**. Group (II) received the polarized bioptron light **BLT**; both groups also received conservative traditional ulcer care. Group (III) (Control group) received only the conservative traditional medical care. Measurement of wound surface area was used as a method of assessment. The results showed that both pulsed electromagnetic field therapy and the polarized were effective in accelerating healing of venous ulcers ($p<0.05$), while pulsed electromagnetic field therapy was more beneficial than polarized light in decreasing ulcer surface area and improving healing of the venous ulcers.
Key words : Polarized light; Pulsed electromagnetic field therapy; Venous ulcer; Wound surface area.

1. Introduction:

Venous ulcers are a one of common chronic diseases that demand ongoing therapeutic close observation, seriously affects quality of life of the involved sufferers because of concurrent edemas, dermatitis, shallow purulence and thrombophlebitis[1].

Venous ulcer is the ulcer occurred due to chronic venous deficiency of the lower limb. Venous ulcer has the nature of a full thickness wound including the fat and subcutaneous tissues. Chronic vascular leg ulcers can be considered as sever inflammatory processes caused by insufficient blood supply, edema, tissue ischemia, cell end, and infection, among differentvariables[2].

Venous ulcers are wounds that may be happen because of inappropriate functioning of venous valves mostly of the legs. They are the main reason of chronic damages, occurring in 70% to 90% of chronic wound conditions. Venous ulcers are expensive to treat, and there is a critical possibility that they will recurrent again after healing; about 48% of venous ulcers had recurrent again by the 5thyear after healing[3].

Venous ulcers represent a significant value of chronic wounds. Many compound variables promote to venous ulcer development, however the main cause is venous inadequacy that lead to tension in deep veins falls to lower than normal, so named venous hypertension which causes consequently to venous ulceration. Venous ulcers happen in soft tissue as a result of nonstop, unrelieved microcirculatory changes causing tissue death. After time prolonged closure of the capillaries decreased exchange of O_2 and nutrients causing ischemia, cell death and ulcer formation[4.]

Venous ulcers can be occurred on either side of the lower leg, above the ankle and underneath the calf because this is the place where the ankle vessels divided and locally elevate the venous tension. Immobility, variation from norm of the calf muscle mechanism, or valvular insufficiency of the venous network because of thrombotic affection, injury or congenital absence leads to venous deficiency. Venous ulcers frequently occurred when these elements combine to some degree, leading to closure or disturbance of capillary system[5-6.]

Venous ulcers are a serious problem between geriatric people and obese population. There are many researches about the causes, normal history, and epidemiology of skin ulceration. Generally there is a few data about variables that stimulate the healing of body tissues after injury[7.]

Pulsed electromagnetic field therapy (PEMF) is a conservative treatment that has been broadly utilized to increase blood circulation and the permeability of cell membrane, improving O_2 supply, increasing ATP formation, promoting healing process and epithelialization of the harmed tissues, enhancing bone healing, stimulating osteoblastic and fibroblastic functions, as well as its anti-inflammatory and pain reliving effects [8-9.]

Studies have utilized PEMF stimulators to improve the healing process, however the outcomes differ significantly between them and there were differences between the applications of PEMF parameters. More researches should be done to detect the best PEMF parameters for enhancing of tissues healing [10.]

The effects of magnetic fields on living organisms are extremely complicated. It is too early to set the mechanism, more studies should be done to explain the phenomena, however the recent data about the magnetic field effects on the biological and living systems are effects of the magnetic fields on criteria of the biological liquid crystals and ionic movement[11.]

Different musculoskeletal problems can be treated by Polarized light from low power lasers and non-laser devices that are considered a non-invasive therapy, stimulation of tissues healing and repairing of skin ulcers, in spite of the fact that the polarized light is known to have many photo-biostimulatory influences involving cell proliferation, improved collagen formation, enhancing the circulatory system and anti-inflammatory function, the exact mechanism of its action still a mystery. The present non-laser optical machines are the Bioptron products which produce a wide beam of polarized, polychromatic,non-coherent, low energy light that include wavelengths from the visible spectrum (480-700nm) and infrared radiation (700-3400nm); this range gives maximum penetration and stimulation of the tissues without the hazards of DNA harm[12.]The incidence of burns is present with the laser therapy, while not possible with the Bioptron light therapy[13.]

2. Materials and Methods:

2.1. Subjects

This study was conducted over 45 patients ***(both sexes),*** who had venous leg ulcers just above medial malleolus, their ages were ranged from 45 to 60 years, they were excluded if they had cardiac pacemaker, metal implants, pregnancy ,after steroid therapy, or have any disease that can affect healing process and/or influences the results of the study (diabetes or blood problems), common cause for all ulcers was the venous insufficiency and with persistence time ranged from 20-35 weeks, Their ankle brachial pressure index (ABPI) less than 1 (mean 0.98).and they were selected from inpatient department of vascular surgery unit at Teaching Hospitals in Cairo. Treatment was conducted for 2 months.

Patients were randomly divided into 3 equal groups in number: 2 study groups and one control group: ***Group I:*** (first study group) this group was composed of 15 patients who received pulsed electromagnetic therapy(PEMF) and regular ulcer care through the treatment period. ***Group II:*** (second study group), this group was composed of 15 patients who received polarized light therapy (BLT) Bioptron Compact III polarized light

therapy system (PAG-860 manufactured in Switzerland) and regular ulcer care through the treatment period**.** ***Group III:*** (control group) that was composed of 15 patients who received only the same regular medical ulcer care through the treatment period. Assessment was conducted at the beginning of the study pre ;(after 2 months of developing ulcer), post I after 1month and post II after 2 months of study.

2.2. Material for treatment:

The following are the technical characteristics and specifications of PEMF:

The treatment protocol was achieved by using JAMAVA® Pro *Magneto therapeutic Device,* with Power supply 230v/50 Hz, Unit of Power15w, frequency of 1.6-25 Hz, Diameter 160 mm, Length 320mm, Active surface 200cm² ,and Maximum induction of magnetic field 7mT.

The following are the technical characteristics and specifications of the BLT:

A single unit emitting a broad range of light wavelengths at constant intensity for safe light therapy, thereby providing effective, clinically proven solutions in wound healing and pain treatment [17.]BLT with Power supply of 100-230 V, 50/ 60 Hz, Power consumption: 56 VA, Rated power of halogen: 20 W, Protective class: Class II, IP 20, Wavelength: 480-3400 nm, Degree of polarization: > 95% (590-1550 nm), Specific power density: av. 40 mW/ cm², Light energy per minute: av. 2.4 Joule/ cm², Distance from skin surface 10cm, Dose (energy density) 24 Joule / cm² and Spot size 254 cm².

2.3. Ulcer surface area assessment

Ulcer surface area (USA) was calculated by placing a piece of sterilized transparency film over the ulcer and tracing the ulcer perimeter on the film with fine tipped transparency marker. A separate transparency was used for each ulcer. The tracing was then placed over metric graph paper and the number of 1mm in the tracing was counted (only full 1 millimeter squares inside the perimeter was counted and the area was converted into square centimeters) [14.]

Ulcer surface area was measured before the beginning of the experiment as a first record and at the end of the first month as a second record as well as at the end of the second month of therapy as a third final record, this process was repeated a minimum of three times for each measurement with the value obtained two or more times was reported.

2.4. Proceduresof Pulsed electromagnetic field (PEMF)

PEMF was applied once daily, three times per week for 2 months. Each session was conducted for 20 minutes with frequency 50 Hz on the wound perimeter directly over sterile Vaseline gauze (sofa-tulle dressing) that covers the wound to prevent germs or similar form being transmitted to other patients and avoid any allergic sensitization.

2.5. Procedures of the polarized light Therapy (BLT)

BLT application: point the light beam at the area to be treated, holding the device at right angle (90°) perpendicular to the surface of the venous ulcer and maintaining a distance of 10 cm from the surface of the venous ulcer and applying the BLT for about 10 minutes. Frequency of application: applied once daily three times a week for 2 months [20.] Unplug the device after use and it is advisable to prolong the BLT for one or two weeks if wound closure occurred before the end of the treatment 2 months in order to strengthen the treated area.

Data Analysis:

Data analysis was performed using SPSS for windows; version 18 (Statistical Package for the Social Sciences).Level of significance was set at $P \leq 0.05$.

4. Results

Data concerning the patient demographic data (age, sex, weight) as well as Ulcer Surface Area had been collected at the beginning of the study. Follow up evaluation had been performed after one month of treatment (pre I) and after 2 months post II.

Demographic and clinical characteristic of the patients:

As shown in table (1), There were no statistical significant differences between the groups concerning general characteristics (age, sex, weight). As well as clinical characteristics (USA), and wound volume at the beginning of the study (P>0.05).

Table (1): Statistical analysis of the demographic& clinical characteristics of patients between 3 groups at the beginning of the study.

Variables	Group I(GI) (n=15)	Group II(GII) (n=15)	Group III(GIII) (n=15)	P- value
Age (years)	52.06±3.0234	52±3.229	52.133± 3.335	0.843*
Sex(male/ female)	9/6	6/9	7/8	0.561*
Weight (Kg)	72±9.9	76±11.23	75 ±10.46	0. 0.31*
Cigarette smoking	10 smokers 5 non smokers	9 smokers 6non smokers	8 smokers 7 non smokers	>0.05
USA (cm^2)	6.71 + 1.406	6.79±1.363	6.64 + 1.426	0.7*

X= Mean, SD= Standard deviation, P-value = Probability level, USA= Ulcer surface area and *Non- Significant

Ulcer surface area for all groups (before and after treatment):

Table (2): Comparison of USA (cm^2) between pre, post I and post II of treatment within group and between groups.

Groups	X±SD (cm^2)			F-value	P-value	Significance
	pre	Post I	Post II			
G I	6.79±1.363	4.02±1.28	1.234±1.12	72.965	0.001*	S
G II	6.71 ±1.41	4.719±1.64	1.882 ±1.55	38.613	0.000*	S
G III	6.64 ±1.43	6.13 ±1.39	5.63 ±1.33	1.997	0.148	NS
P-value	0.958	0.015	0.000			
Significance	NS	S	S			

X= Mean, SD= Standard deviation, P-value = Probability level, NS=Non- Significant And S= Significant

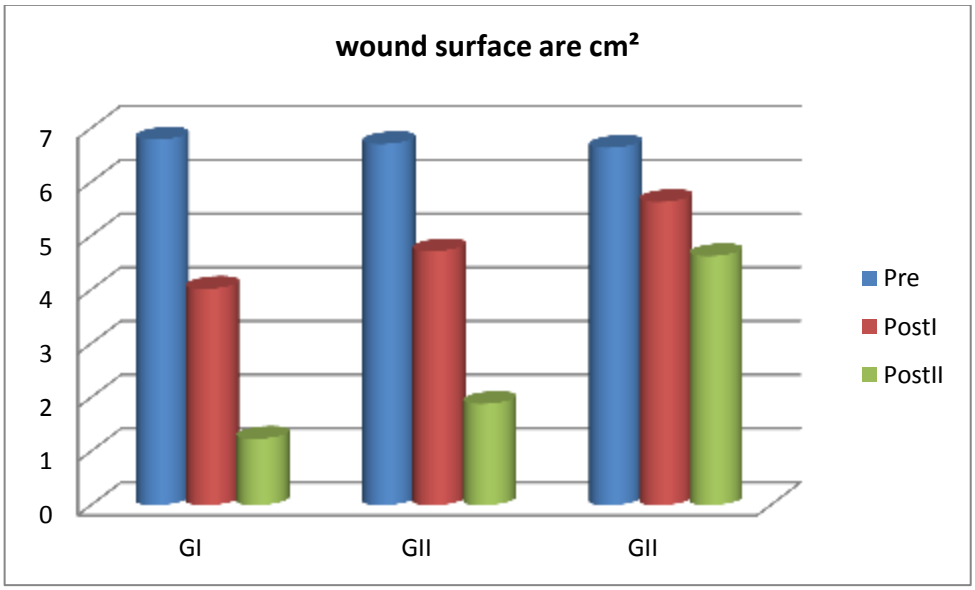

Fig. (1):Comparison of ulcer surface area before and after treatment for the three groups.

Percentage of improvement in all groups: table 3 fig 2

Table (3): Percentage of improvement in all study groups.

Groups	Mean		Percentage of improvement %
	Before treatment	After treatment	
G I	6.79cm²	1.234cm²	81.8%
G II	6.71 cm²	1.882 cm²	71.9%
G III	6.640 cm²	5.63 cm²	15.2%

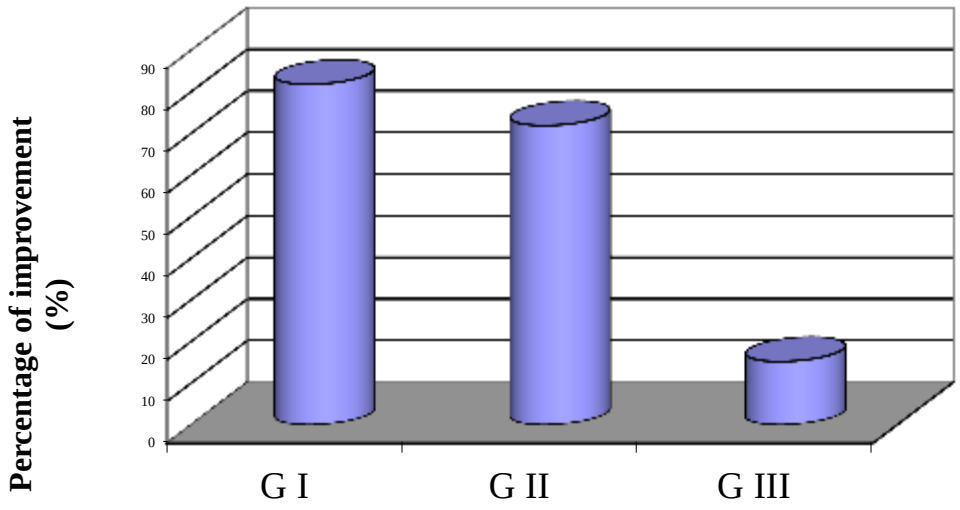

Fig. (2): Percentage of improvement in WSA in GI, GII, and GIII.

5. Discussion

Venous ulcers are wounds that are thought to occur due to improper functioning of valves in the veins usually of the legs. They are the major cause of chronic wounds, occurring in 70% to 90% of chronic wound cases.

Venous ulcers are costly to treat, and there is a significant chance that they will reoccur after healing; up to 48% of venous ulcers had recurred by the fifth year after healing [7.]

Venous ulcers, as with all superficial ulcers, are a breakdown of the cutaneous and sub-cutaneous tissues. The venous part of the title indicates the etiology of the ulcer. With increased venous pressure from venous insufficiency, there is also increased pressure in the microvasculature, resulting in edema. As such, there is decreased perfusion of tissues, with absence of nutrition and build-up of toxic metabolites. These factors reduce the resistance of the tissues, rendering them susceptible to breakdown from minor trauma.[6.]

The most common site for a venous ulcer is just proximal to the medial malleoli, as this is where the ankle vessels perforate, locally increasing the venous pressure. Venous ulcers usually present as shallow, irregular to oval in shape, with macerated borders. Size varies from pinhead to extensively covering the distal-medial aspect of the leg [15.]

Weakness of the calf muscle is the equivalent of heart failure. The calf muscles rapidly waste and weaken with disuse. Disuse accompanies major injuries, neurological disease, and vascular insufficiency, debilitating diseases, myositis, bone and joint pain. If the veins and their valves are normal, a weak calf muscle alone rarely causes symptoms of venous insufficiency but, if there is a pre-existing venous abnormality and the muscle becomes weak, symptoms are exacerbated. But venous disease itself can cause calf muscle wasting as a result of avoiding painful ankle movement [16.]

Venous ulcers are often large but shallow, with prominent granulation tissue in their bases. Incompetent perforating branches (blowouts) between the superficial and deep veins are best felt with the patient standing. Under favorable conditions the exudative phase gives way to a granulating and healing phase, signaled by a blurring of the ulcer margin, ingrowth of skin from it, and the appearance of scattered small grey epithelial islands over the base. Prolonged ulceration, with lipodermatosclerosis, gives the leg the look of an inverted champagne bottle[17.]

Bioptron light therapy system has a low energy density (fluency) of an average of 2.4 J/cm². Bioptron light reaches the area to be treated with a constant, steady intensity; this energy density has biostimulative effects. With Bioptron light therapy, the energy density dosage can be precisely determined. Furthermore, the effect exerted by light is also defined by its power density. As it is measured at the skin's surface, it varies depending both on the intensity of the light's source and its distance from the area to be treated. The specific power density of Bioptron light is approximately 40 mW / cm² at a treatment distance of 10 cm; this is equivalent to an energy density (fluency) of an average of 2.4 J/ cm² per minute. These properties of Bioptron light allow it to penetrate the surface of the skin with minimum heating effect, no damage to skin and no known side-effects [18.]

BLT devices emit light containing a range of wavelengths that correspond to visible light plus infrared radiation, both of which have been reported to stimulate the biological reactions and importantly no harmful ultraviolet radiation is present in the BLT[19.]

The Bioptron light therapy can be used both as a complementary treatment to support conventional medical methods and as a monotherapy for specific indications [20.]

Low pulsed magnetic field (LPMF) is a very effective biophysical modality used in physical therapy and utilized for acceleration therapeutic purposes as well as in the area of diagnoses [21.]

Electromagnetic field has been shown to influence epidermal cell proliferation and migration (i.e. closure) and dermal fibroblastic activity (collagen secretion). It is believed that electromagnetic fields play its role in healing by guiding cellular movements that close wounds. It has been shown that fields can affect orientation, migration and proliferation of cells such as fibroblasts, my fibroblasts and keratiocytes, which are of key importance in healing[22-23.]

Initial acceleration of wound healing with anon-invasive method, such as PEMF, may be important in reducing bacteria accumulation stimulating growth factors, cytokine production, and reducing early inflammation, thus creating an appropriate environment to facilitate tissue regeneration[24.]

Magnetic and electric field stimulation have been associated with increased collagen deposition, enhanced ionic transport , amino acid uptake, fibroblast migration , and adenosine triphosphate (ATP)protein synthesis, including an increased rate of synthesis of protein and DNA [25-26.]

Pulsed electromagnetic field found to be effective in wound healing as it enhanced wound epithelization in open cutaneous wounds and provide indications of early contraction without significant short – term changes in other variable [27.]

The effect of exposure to pulse extremely –low- frequency magnetic field on skin wounds in rats with skin wounds surgically created on their backs was examined. Significant increase in the rate of wound contraction was found in rats treated with magnetic fields. Forty two days after surgery all treated animal showed fully closed wounds. The treated rats showed earlier cellular organization, collagen formation and maturation, and Avery early appearance of newly formed vascular network[28.]

A randomized, double-blinded, placebo-controlled study to evaluate the effect of pulsing electromagnetic fields on the biomechanic strength of rat Achilles' tendons at 3 weeks after transection and repair was applied. The results showed that the animals receiving PMF exposure, showed an increase in tensile strength of up to 69% was noted at the repair site of the rat Achilles' tendon at 3 weeks after transection and repair compared with non-stimulated control animals. So the conclusion was that the application of electromagnetic fields, configured to enhance Ca (2+) binding in the growth factor cascades involved in tissue healing, achieved a marked increase of tensile strength at the repair site in this animal model. If similar effects occur in humans, rehabilitation could begin earlier and the risk of developing adhesions or rupturing the tendon in the early postoperative period could be reduced[29.]

On the other hand there were also results opposed our finding as in:

In a study to investigate the effect of high intensity, short duration pulsed electromagnetic fields (PEMF) on the healing of full thickness skin wounds in rats, Full thickness skin wounds were surgically created in two groups of Sprague-Dawley male rats. The rats were randomly divided into two groups, each containing 20 rats. Animals in the treatment group received treatments with the PEMF device on day 0, 3, 7, 9, 12, 14, 17, and 22, while the rats in the control group were subjected to the same procedure, but with the PEMF device not activated. Photographs of the surgically created wounds were obtained on day 0, 3, 7, 9, 12, 14, 17, and 22. Wound contraction (WC), wound epithelialization (WE), non-healed wound, and contraction-epithelialization (CE) ratio were calculated for each wound. No significant difference was found between the two groups for the parameters of WC, WE, non-healed wound, and CE ratio. This type of PEMF did not have a significantly beneficial effect on wound healing [30.]

6. Conclusions

Both pulsed electromagnetic field therapy and the polarized were effective in accelerating healing of venous ulcers ($p<0.05$). But pulsed electromagnetic field therapy was superior decreasing wound surface area.

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