Pneumatic Compression versus Pulsed Ultrasound for Venous Leg Ulcer Treatment

Haidy N. Ashem* MD. and Mohamed Yehia**MD.
Department of surgery-Faculty of physical therapy-Cairo University.*
Department of surgery-Faculty of medicine-Cairo University.

ABSTRACT

Chronicleg ulcers due to venous insufficiency, atherosclerosis, diabetes mellitus, or small vessel disease affect approximately 1% of the general population and up to 10% of individuals who are in health care facilities. ***The purpose****of this study was to determine which therapeutic method out frompneumatic compression (PC)versus pulsed ultrasound current (US) obtains the best improvement in healing rate of venous leg ulcers. Thirtymale patientscomplicated with venous leg ulcer.Their ages ranged from 50 to 60 years. They were randomized into 2 equal groups of equal number; group (A)received (PC)while group (B) received(US) ,in addition toexercises therapy andmedical treatment.* ***Measurements*** *of ulcer surface area and volume in addition to ankle dorsi flexion muscle force for all patients in the two groups were done before treatment and after two months of the treatment program. There was no statistically significant difference between mean levels of the investigated parameters in (PC)and (US) group (p<0.05).****Conclusion****: Both(PC)and (US)are effective in the treatment of leg venous ulcer.*
Key words*: venous leg ulcers,ultrasound therapy, pneumatic compression.*

INTRODUCTION

Venous ulceration is the most common type of leg ulceration. Sixty to 80% of leg ulcers have a venous component.It is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence ofvenous disease.[(1)]. Also it arise from venous valve incompetence and calf muscle pump insufficiency whichleads to venous stasis and hypertension. This results in microcirculatory changes and localized tissue ischaemia.[(2)]

Also, risk factors for development of venous ulcers include venous disease, obesity, immobility, family history of varicose veins, deep vein thrombosis, previous surgery for varicose veins, and congestive cardiac failure. Up to 50% of patients with chronic venous insufficiency have a history of leg injury[(3)]

Treatment goals for patients with chronic venous insufficiency include reduction of edema, alleviation of pain, improvement of lipodermatosclerosis, healing of ulcers, and prevention of recurrence[(4)]. Better understanding of the pathophysiology of venous disease and leg ulceration has in turn suggested new approaches to the management of ulcer disease with new types of wound dressings, compression bandages, topical and systemic therapeutic agents, and surgical modalities [(5)]

Clinical studies have examined the efficacy of compression therapy on leg ulcers. There are many methods of applying external graduated compression, such as elasticated bandages, Unna's boots, multilayer elastic compression bandages, short stretch bandages and elastomeric hosiery [(6,7,8)]

As, venous ulcers are caused by venous hypertension; thus some steps should be taken to decrease hypertension and its consequences in the macro and microcirculations. Compression treatment is mandatory for thatsince it acts on the macrocirculation, increasing deep venous return, decreasing pathologic reflux during ambulation and increasing stroke volume during the activation of the calf muscles.[(9)]

The compression methods available are compression dressings, elastic stockings and pneumatic compression. Intermittent pneumatic compression is useful when the patient does not respond to conventional compression[(10)].

Ultrasound can improve tissue repair by increasing protein synthesis, mast cell degranulation and growth factor production, uptake of calcium and fibroblast mobility. It may work at several levels in the early stages of healing, it may decreases edema, increases blood

flow, increases the delivery of oxygen & macrophages to the area, stimulates collagen deposition and remodeling.[11]

Also, Ultrasound therapy increases intracellular calcium and permeability of cell membrane which lead to faster tissue healing at intensities of 0.5 to 0.75 w/cm 2 with pulsed frequency of 20%. Ultrasound therapy applied at pulsed mode, frequency 3 MHz, intensity 0.5 w/cm2, duration of 5 minutes per session and for three weeks can promote healing of diabetic foot ulcers.[12]

the aim of this study was to determine the effect of pneumatic compression (PC) versus pulsed ultrasound current (US) in venousleg ulcers healing.

PATIENTS & METHODS

Thirtymale patients complicated with venous leg ulcerparticipated in this study. They had no more than one ulcer. All of them were non-smokers and were under meticulous control of blood glucose, and controlled diet therapy. exclusion criterion was: Significant musculoskeletal disorders in the lower extremities, including injury, fracture, and surgery and rheumatoid arthritis.Their ages ranged from 50 to 60 years. All patients consented to measurements and availability for re-assessments. They were however, informed of their freedom to withdraw from the study at any point in time.A complete history was taken and routine physical examination as well as laboratory tests routinely performed by physicians to assess the cases and all patients were diagnosed as a venous ulcer.

They were randomized (by odd number selection method) into two equal groupsof equal number; group (A) thatreceived (PC)and group (B) received(US), in addition toexercises therapy andmedical treatment.Assessment was done before, and after 2 monthsof treatment for all patients by measurement of ulcer surface area, wound volumeand Ankle dorsiflexor muscles forceare done to all patients.

Measurement procedures

1- Wound surface area measurement: The measurements of the ulcer surface area was conducted by tracing the ulcer perimeter and was drawn on sterilized transparency, then the side which faced the ulcer was cleaned by alcohol. The traced transparency film was placed over metric graph paper and number of square millimeter on the metric graph paper with the wound tracing were counted to determine the ulcer surface area.[13]
2- Wound volume measurement: Patient was seated in a position according to the site of ulcer allowing complete filling of the ulcer. A 5 cm2 syringes with removal needle was filled with normal saline (3). The ulcer was injected with saline to measure ulcer volume[5].
3- Ankle dorsiflexor muscles force was measured by the dynamometer, the patient was in a sitting position at the edge of a plinth. The end piece of dynamometer was fixed on the dorsum surface of the foot which was tested in mid-range of ankle joint, proximal to the metatarsophalangeal joints, and the patient was asked to exert his maximum force during the test. Three trails were used and the mean was calculated for dataanalysis.[14]

Treatment procedures

For group (A) Pneumatic compression therapy:

First, each patient was instructed that the limb treated should be completely bared. The leg was placed in a cotton gauze sleeve before putting into the compression sleeve. The sleeve was connected by plastic or rubber tubing to the machine which switched off.Each patient was positioned in comfortable bed with his back supported. The involved lower extremity was elevated by using pillows just above the level of the heart 30°.The intermittent compression was given at a pressure of 30-40 mmHg for half of hours, five times weekly for two months.

For group (B) Ultrasound treatment:

First, the ultrasonic therapy was applied to the intact skin surrounding the wound using coupling gel for contact for 5 minutes 5 times per week, for a total period of two months, treatment was delivered at a frequency of 3 MHZ, at spatial average intensity of 0.5 w/cm2 and the pulse ratio was set at 1:5. The ultrasound head was cleaned with alcohol to avoid any infection transmitted to the patient.Then, procedures were performed in a water bath with a temperature of 34°C. 1 MHz frequency was used. The ultrasound probe had an area of 10 cm2 and was placed 2 cm above the wound. The time duration of a single procedure was dependent on the ulcer size – one minute on

each 1 cm2 of ulcer area. The procedures were repeated once daily for five times a week over eight weeks (two months)

Also, for both groups physiotherapeutical active exercises program for lower extremities directed mainly to ankle muscles was done.they were instructed for a home routine that focus on education and regular foot examinations, every patient was advised to wash, dry and examine his feet daily and avoid excessive heat and cold, as well as trauma and optimal use of therapeutic footwear. Patients were advised to repeat these exercise at home, warm up, and active ankle ROM exercises.Also, patients were advised to apply a bandage or a medical compression stockings providing pressure 25–32 mmHg at the ankle to the affected leg as a form of compression therapy.

Statistical procedures:

The mean values of ulcer surface area and volume were measured before treatment and after two months at the end of the study for the two groups, then the t test was used for comparison between the two groups ($p<0.05$).

Also, thet test was used for comparison between the two groups to analyze the ulcer surface area and volume as measured before treatment and after two months.

RESULTS

Table (1) presents the characteristics of the patients completing the study. Both groups were comparable at the baseline regarding to the demographic and clinical characteristics.

Table 1: Demographic and clinical characteristics

Variables	PC group	US group	P values
Age (years) (mean ±SD)	56.9± 2.24	56.87± 1.94	0.246*
Height (cm)	1.317± 10.56	1.318± 7.87	0.973*
Weight (Kg)	76.65± 14.64	78.01±14.14	0.304*
Duration of venous ulcer (months)	8.50± 0.81	8.27±0.80	0.383*

* No significant differences between groups pretreatment. SD; standard deviation

Measurement of wound surface area, wound volume andankle dorsiflexion force:

In table (2), (3) and (4);the results of study showed a non-significant difference of wound surface area, wound volume and ankle dorsiflexion force,pre- treatment and post- treatment when compare between both groupsas p value >0.05. While when compare between the pre-treatment and post treatment values ofwound surface area, wound volume and ankle dorsiflexion force, there were asignificant difference betweenpre-treatment and post treatment values in each group as p value <0.05

Table 2: Measurement of wound surface area:

	PC Group	USGroup	*P value between both groups*
Pre	7.45±0.899	7.30± 0.879	***> 0.05****
Post	1.5± 0.4342	1.6±0.515	***> 0.05****
P value	<0.05**	<0.05**	
Percentage of improvement	79.86%	78.08%	

** No significant difference * * Significant difference*

Table 3: Measurement of wound volume:

	PC Group	USGroup	*P value between both groups*
Pre	2.59± 0.562	2.49± 0.489	***> 0.05****
Post	0.30± 0.223	0.40±0.231	***> 0.05****
P value	<0.05**	<0.05**	
Percentage of improvement	88.41%	83.39%	

** No significant difference * * Significant difference*

Table 3: Measurement of ankle dorsiflexion force

	PC Group	US Group	*P value between both groups*
Pre	12.32±0.821	12.8± 1.211	***> 0.05****
Post	19.53±0.912	20.13±3.155	***> 0.05****
P value	<0.05**	<0.05**	
Percentage of improvement	57.26%	58.52%	

** No significant difference * * Significant difference*

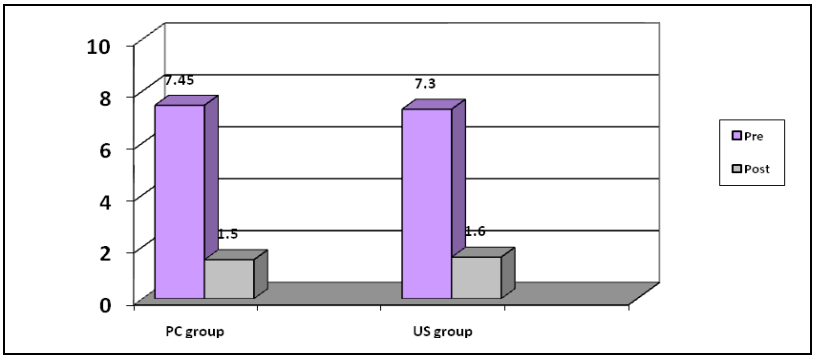

Fig (1)Statistical differences of ulcer surface area pre and post treatment in both groups

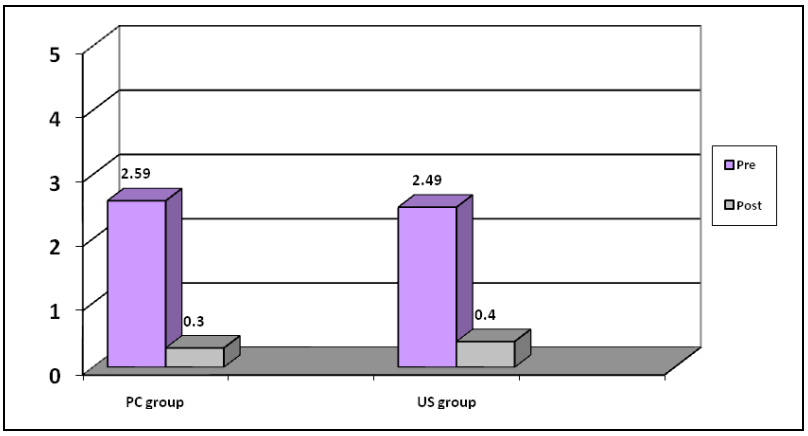

Fig (2) Statistical differences of ulcer volume pre and post treatment in both groups

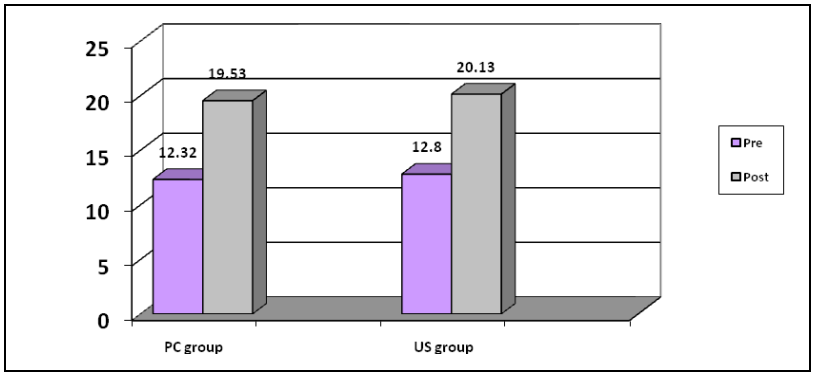

Fig (3) Statistical differences of ankle dorsi flexion force pre and post treatment in both groups

DISCUSSION

The results of this study indicated that there was a significant improvement in values of ulcer surfacearea,wound volume and ankle dorsiflexion forcefor all patients in the two groups after treatment. There was a non-statistically significant difference between mean levels of the investigated parameters in both groups after treatment.

Many studies proved that, compression therapy is an important part of treatment for venous leg ulcers. Such as, [15] who studied the effect of a sequential gradient compression device used 4 hours per day in a RCT of 45 patients ranging in age from 42 to 78 years. Patients in the experimental and control groups received compression stockings (30 to 40 mm Hg compression at the ankle) and were instructed to wear stockings during pumping sessions. One of 24 patients had healing within 3 months in the control group compared with 10 of 22 patients in the pneumatic compression group (*P* =.009). The median healing rate was 2.1% of ulcer area per week in the control group compared with 19.8% of ulcer area per week in the pneumatic compression group (*P* =.046). This was an intention-to-treat analysis.

Also, [10] studied the effect of a single-chamber device in a prospective controlled study of 21 patients with an age range from 50 to 82 years. No indication was given on how patients were chosen for treatment or control. Patients used the device once daily for 2 to 3 hours at "comfortable" pressure settings (30 to 80 mm Hg). Most control patients had no change or worsening of ulcers; several pneumatic compression patients had improved ulcers, and a few of those who reported low compliance had ulcers that did not change or increased in size.

On the other hand,Ultrasound has been used for many years to help tissue repair and it is commonly given by physiotherapists to help joint and muscle repair, using ultrasound treatment regimens of treatment three to seven times a week. Ultrasound may work at several levels in the early stages of healing, it may decreases edema, increases blood flow, increases the delivery of oxygen & macrophages to the area, stimulates collagen deposition and remodeling[1].

The use of ultrasound therapy to enhance and augment healing of venous leg ulcers has been supported by the literature. Based on some research from conservative therapy, ultrasound strongly accelerates the healing process.[1-11]

Ultrasound appeared an efficient method in conservative treatment of venous leg ulcers. The healing rate was30.1% after ultrasound therapy (only 11.4% in control group). For surgically-treated patients these physical therapies are efficient only in superficial plus deep reflux cases. The healing rate was and 36% after ultrasound therapy (only 22.2% in control group). Ultrasound can be alternative methods for compression therapy in extreme cases[8].

In the clinical trial of[14], they found that after 12 weeks of treatment the control group showed a mean decrease of 16.5% in the ulcerated area. In contrast the mean ulcerated area decreased by 55.4% in the ultrasound group (p<0.007). The daily ulcer reduction in the ultrasound-treated patients was 0.08 mm+/-0.04 mm and in the placebo patients 0.03 mm+/-0.03 mm. Patients recorded only minor side-effects such as a tingling feeling and occasionally pinhead-sized bleeding in the ulcer area. So they concluded that the application of low-frequency and low-dose ultrasound is a helpful treatment option in chronic venous leg ulcers, especially if they do not respond to conventional ulcer treatment

On the other hand,in the presence of limited joint mobility, the foot is unable to provide its shock-absorbing mechanism and may lose its ability to maintain normal plantar pressures. The presence of limited joint mobility can result in abnormally high intrinsic plantar pressures and lead to plantar ulceration[10]. The results in this study agreed with the results of[16], it showed that, improvement in ankle dorsiflexion ROM may be attributed to wound healing and increased strength of ankle dorsiflexors.

That could be explained as that, supervised calf muscle exercise has been shown to increase calf muscle pump function and improve haemodynamics. So, brief exercise may results in an improvement in cutaneous perfusion and so[17].

CONCLUSION

PC and US are useful methods in thetreatment of venous leg ulcers in addition to medical treatment and exercises therapy.

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