Change in the great saphenous vein diameter in response to contrast baths and exercise: a randomized clinical trial.

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Abstract: The purpose of the present study was to investigate the effect of contrast baths on varicose vein and to compare its effect with that of calf muscle exercises on the improvement of varicose vein. A randomized clinical trial was performed on 70 patients with varicose vein of the lower limb. Their age was (40-50) years. Patients were randomly divided into three groups; Group (1) (30 patients) used a contrast bath and compression stocking. Group (2) (30 patients) performed pedal ergometer exercise and the compression stocking. Group (3) (10 patients) used compression stocking. Venous Duplex ultrasound scanning was conducted for evaluating the cross-section of great saphenous vein (CsGSV) at the knee and ankle levels. There was significant reduction in the mean value of CsGSV at the ankle and knee levels in group one and two with non-significant difference in group three. The result revealed a non-significant difference between contrast baths and pedal ergometer exercise groups. Both contrast baths and strengthening exercise to calf muscle are effective methods in the treatment of varicose veins.

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1. Introduction:

Chronic venous insufficiency (CVI) is a recalcitrant medical problem that affects millions of people around the world causing substantial morbidity and medical expenditure (Magnusson et al., 2001). Varicose veins are the most common manifestations of chronic venous disease, with widely varying estimates of prevalence (Jones and Carek, 2008).

There is no universally accepted definition of a varicose vein however it is commonly taken to mean enlarged tortuous subcutaneous veins. The condition is caused by poorly functioning (incompetent) valves within the veins and decreased elasticity of the vein walls, which allow de-oxygenated blood to be pumped back to the heart, leading to a backward flow and pool of blood in the superficial veins, causing them to enlarge and become varicose (Tisi, 2007).

Effective venous return requires the interaction of a central pump, a pressure gradient, a peripheral venous pump mainly through the calf muscle, and competent venous valves (Eberhardt and Raffetto, 2005). When the calf muscle contract, it cannot determine the direction in which the blood will flow. This is achieved by the presence of one way valves within the vein that allow the flow of blood only proximally out of the leg. Failure or incompetence of the one way valves that present in the lower limb vein leads to decreased calf muscle pump efficiency and the eventual development of lower extremity venous hypertension and varicose vein are the visible results of this process (Recek, 2004).

When a calf muscle pump function is impaired in accordance with the presence of venous valvular incompetence, the residual venous volume in the calf increases immediately after muscle contraction and causes the ambulatory venous pressure to rise (Padberg et al., 2004).

It is likely that the pathogenesis of varicose veins in an individual is the combination of a number of factors. Factors such as hormones and aging acting on the vein wall, hereditary factors such as the number and position of the veins and the original strength of the vein wall and the effect of lifestyle factors such as pregnancy, occupation and obesity will all interact to produce the pattern of varicosities found in that individual. These actors are exacerbated by muscle pump dysfunction in the lower extremity (Criqui et al., 2007). Treatment modalities for varicose veins include conservative management, medical therapy, external laser treatment, injection sclerotherapy, endovenous interventions, and surgery (Edwards et al., 2009).

Conservative treatment includes avoidance of prolonged standing and straining, elevation of the affected leg, an exercise program that stimulates the calf muscle pump mechanism, external compression, loosening of restrictive clothing, modification of cardiovascular risk factors, reduction of peripheral edema, and weight loss (Subramonia and Lees, 2007).

It can be stressed that exercise plays a vital role in the treatment of varicose veins, as it helps the muscle pumps of the calves to return blood from the veins in legs back to the heart, so keeps the legs healthy and comfortable. In fact, as far as the treatment of varicose veins is concerned, the more activity is the better (Trappe et al., 2001).

Contrast baths constitute a thermal modality whereby the limb is alternately immersed in hot and cold water to a specified temperature, time, and duration to therapeutically decrease edema, stiffness, and pain (Breger et al., 2003). This procedure is commonly described in textbooks (Cameron, 2003) and continues to be used in practice (Petrofsky et al., 2006). Contrast baths are a commonly used modality in rehabilitation. Although it is considered as an everyday tool in clinical practice and has an old history of application (Woodmansey et al., 1938, Engel et al., 1950) up till now some therapists prefer not to use contrast baths and stated that there was no evidence to support its use (Breger, 2003).

There was a noticeable variation in which modality is delivered first: hot versus cold; and the type of modality used; for example: running water, pooled water poured into a basin or sink, tap water, or ice water (Breger et al., 2009).

A number of studies discuss the effect of exercises in the treatment of varicose veins (Subramonia and Lees, 2007, Trappe, 2001) but no study up till now, for the available literature, discuss the effect of contrast baths on varicose veins. So, the purpose of the present study was to investigate the effect of contrast baths and to compare it with the effect of calf muscle exercises in patients with varicose vein.

2. Subjects and Methods:

Subjects

Patients were referred from the vascular departments of the Kasr El Aini Hospital, Cairo, Egypt, and selected according to the inclusion and exclusion criteria. Changing in cross-section of great saphenous vein (CsGSV) was the outcome measure.

Power analysis

In order to calculate a sample size, a preliminary power analysis was applied with power = 0.80, α = 0.05, using one way analysis of variance (ANOVA), expected effect size = 0.80 with a result of sample size of total 66 patients at least. The expected effect size chosen based on the results of the previous studies. The high effect size was also recommended in order not to observe except the major difference between groups so; it yielded a realistic sample size and major observed differences in variables measured.

70 patients; 32 male and 38 female with their age ranging from 40-50 years with a mean (45.5 ± 2.5) were randomly selected and participated in this study with ethical committee approval as shown in the patient flowchart in figure 1.

Inclusion criteria

Patients were diagnosed by a vascular specialist as they had a primary varicose vein of the lower limb. Their age ranged from 40-50 years.

Exclusion criteria

Patients were excluded when they had the following problems: Peripheral arterial insufficiency based on ankle – brachial index (ABI) measurements less than 1.0, incompetent sapheno-femoral junction, restricted ankle mobility, pregnancy, cancer, patients with ischemic heart disease, uncontrolled diabetic patients, patients with skin diseases, and patients that did not complete the treatment program.

Treatment groups

Patients were randomized into three groups: Group one (contrast bath group) included 20 patients who used a contrast bath and compression stocking. Group two (exercises group) included 20 patients who performed pedal ergometer exercise and used compression stocking. Group three (stocking group) included ten patients who used only the compression stocking.

A randomized trial was used as the patients did not know in which group was assigned and which treatment would be taken. Randomization was performed simply by adding a specific identification number for each patient. These numbers were randomized by SPSS program into three groups. All patients were given a full explanation of the treatment protocol and a written informed consent form to sign their agreement for participation in the study and publication of the results. The study was approved by the departmental council of the Faculty of Physical Therapy, Cairo University, Egypt.

Venous Duplex Measurements

Venous Duplex ultrasound scanning was conducted for providing an anatomical and functional data of the venous system through evaluating the luminal diameter of the great saphenous vein in millimeters at the knee and ankle levels (Simens-Sonoline-Versa Plus-Germany) (Coleridge-Smith et al., 2007). The long saphenous vein was evaluated in the relaxed supine position. The vein was imaged during repeated valsalva maneuvers and calf compressions (Magnusson et al., 2001).The entire duplex ultrasound scan had been done by the same specialist and during the same time of the day. The examiner was completing blinded and did not have any detail of the experiment.

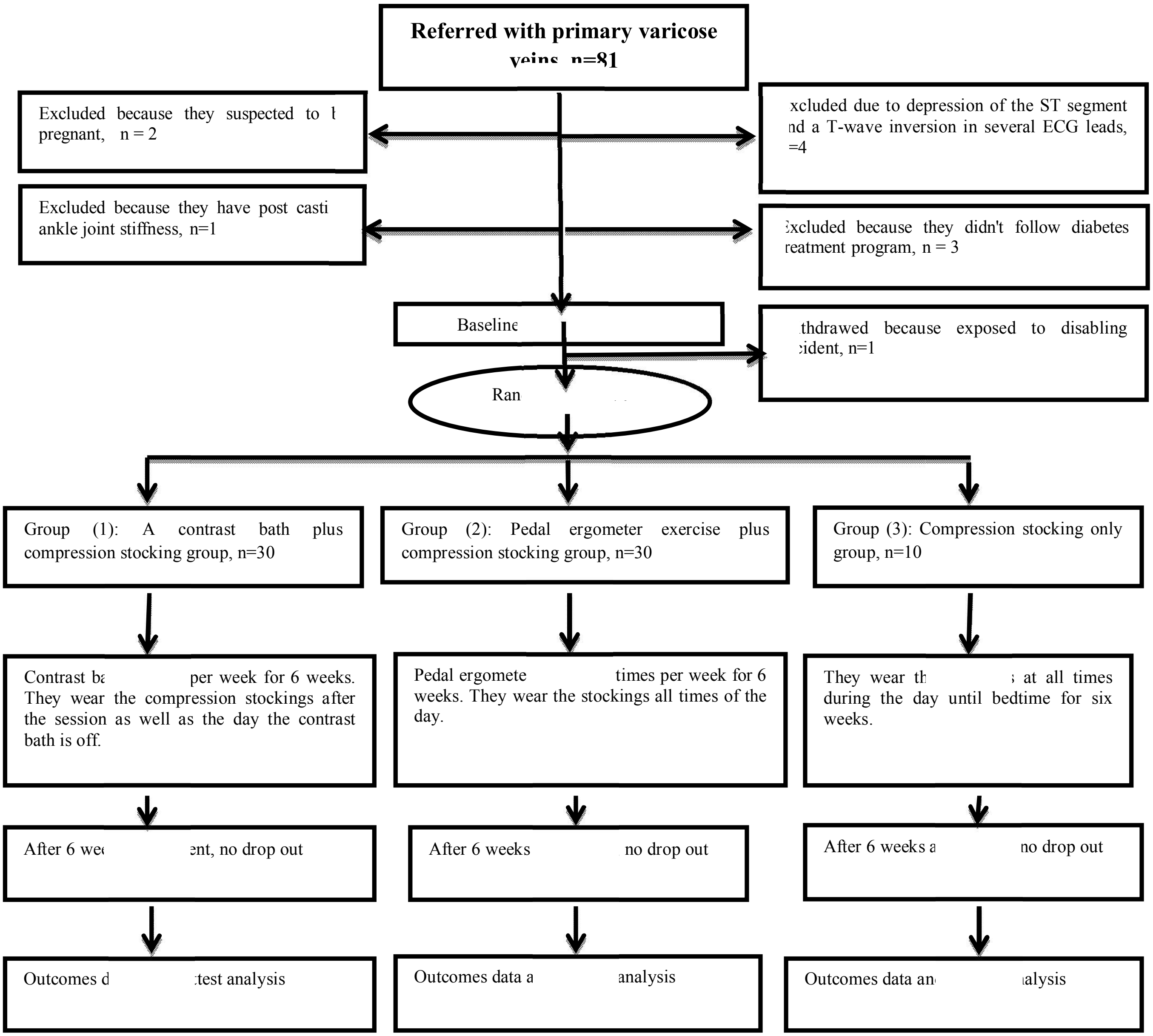

Figure 1. patient's flowchart.

Exercise Intervention

Standard 6.5 Kg resistance pedal ergometer (Made in Egypt, and calibrated in the Integrated Calibration services) was used as the calf muscle mechanical strengthening and endurance exercise (determined by the maximal number of planter flexion performed against a fixed 6.5 Kg resistance during six minutes) (Kan and Delis, 2001).

Patients in the exercise group were asked to set on an examination couch with their knee in slight flexion resting on a pillow and their heel firmly placed on the backrest of the ergometer pedal. Before commencing the exercise program, patients were assessed individually to determine the maximum number of flexion during the six minutes at the rate of one flexion per second. In the first three weeks, each training session had been conducted by half of the maximum number of flexion reached at the base line, and then the number of flexion increased up to 360 repetition of flexion in next three weeks. In each session patients were completed three sets of flexion of six minutes, each at the rate of one flexion per second (with five-minutes rest were allowed between consecutive sets) (Kan and Delis, 2001). The exercise had been conducted three times per week for six weeks, figure 2.

Figure 2. Foot ergometer exercise

Elastic compression stocking

Open-toe mid-thigh elastic compression stocking: (Care medical stocking. Healthy Co. 34 – 46 mm.Hg.) had been selected to provide continuous pressure gradient throughout the calf, crossing the knee to eliminate the possibility of any constricting elastic band across the upper calf (Benko et al., 2001). The patients were fitted with the stocking according to the manufacture's recommendations based on leg circumferences, leg length and shoe size. The patients should put on the stockings in the morning before getting out of bed, and the limb should first be raised to reduce the swelling before stockings are put on and wear them all day until bedtime.

Contrast Baths

Two whirlpool baths (stainless steel tanks) were used to store water. Leg was submerged in each tank with no rest time between two tanks. First, the patient is instructed to start with hot water then, cold water. Constant temperature was monitored with thermostat probe. One bath maintained cold water 10^0 C and the other warm water 40^0C (Cameron, 2006). The patient submerge the examined leg to level of knee at first in hot water for 10 minutes and then one minute cold then starting three to four minutes in hot water then one minute in the cold. This process was repeated four times. The frequency of treatment was three times per week for six weeks (Breger et al., 2009).

Outcome measure

The cross-section of the great saphenous vein (CsGSV) at the knee and ankle levels was measured in millimeters and the data were taken for all groups pre-treatment and at the end of treatment after six weeks.

Data analysis

The data were analyzed using paired t-test to compare between pre and post treatment values. One way analysis of variance ANOVA is used to compare within and between treatment groups. The level of significance was set at 0.05 for all tests.

3. Results:

81 patients with primary varicose veins were recruited to the present study. A number of 11 patients were excluded from the participation for different reasons as shown in the flow chart in figure (1). So, only 32 male (45.7%) and 28 female patients (54.3%) with primary varicose vein of the lower limb were included in this study. There was a non-significant difference in the mean of patient's age between treatment groups.

The paired t-test was applied to compare pre-test and post-test values in all groups. The result showed that there was a significant decrease in the mean value of (CsGSV) at the ankle and knee levels in group one and two and a non-significant decrease in group three as shown in table 1 and figures 3 & 4.

Table 1. Comparison of pre-test and post-test values of CsGSV at ankle level and knee level among test groups.

	Contrast Baths		Exercise group		Compression stocking	
	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test
CsGSV (Ankle)	2.82 ± 0.22	2.51 ± 0.23	2.80 ± 0.20	2.54 ± 0.24	2.80 ± 0.16	2.77 ± 0.17
	Rate of change= -10.99		Rate of change= -9.29		Rate of change = -1.07	
	t value = 24.372		t value = 17.379		t value = 1.96	
	P value = 0.0001[a]		P value = 0.0001 [a]		P value = 0.081[b]	
CsGSV (knee)	3.43 ± 0.19	3.17 ± 0.17	3.43 ± 0.25	3.16 ± 0.27	3.48 ± 0.24	3.44 ± 0.27
	Rate of change = - 7.58		Rate of change= - 7.82		Rate of change= -1.25	
	t value = 9.381		t value = 18.76		t value = 1.30	
	P value= 0.0001[a]		P value = 0.0001[a]		P value = 0.22 [b]	

a : Significant b: Non significant

ANOVA was applied to pre-test values and result showed that there was no significant difference in pre-test value in all groups at the ankle (f = 0.08222 and P value = 0.9212) and knee levels (f=0.2125 and P value = 0.8091). Also, ANOVA was applied to post-test values and the result showed that there was a significant difference in post treatment value in all groups at the ankle (f= 5.105 and P value =0.0086) and knee levels (f = 6.032 and P value = 0.0039) as shown in table 2 and figure 5.

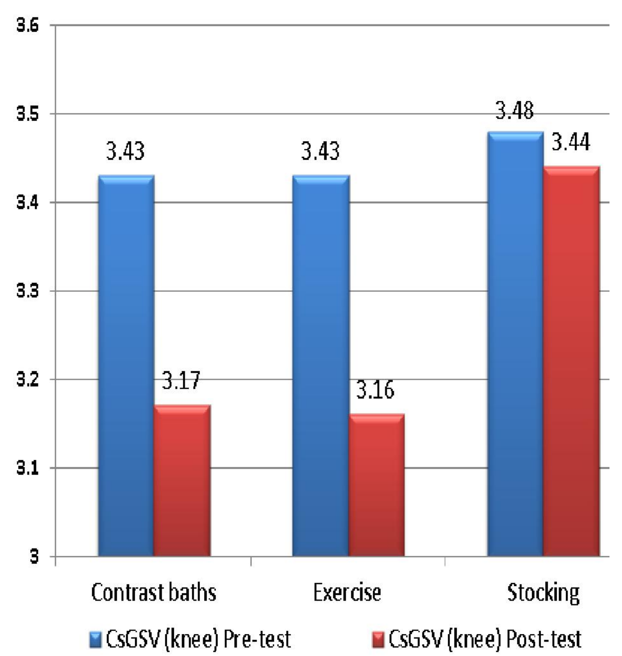

Figure 3. Comparison of pretest and posttest values of (CsGSV) at knee level.

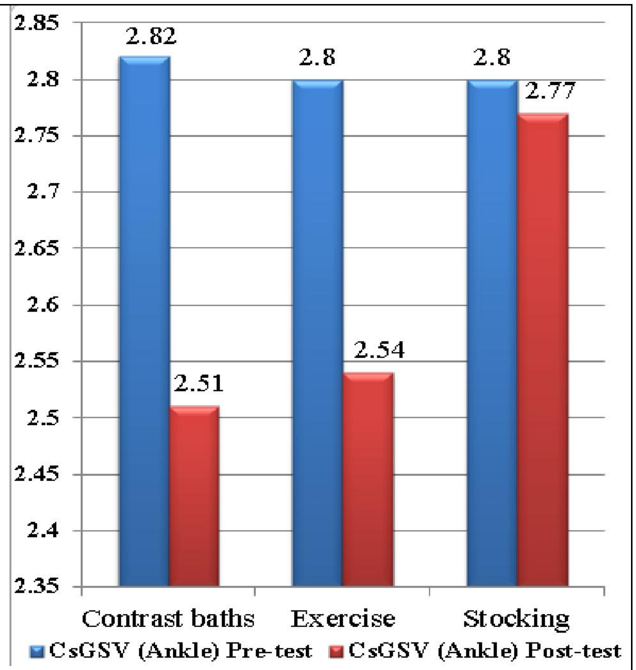

Figure 4. Comparison of pretest and posttest values of (CsGSV) at ankle level.

The post hoc Bonferroni test showed that there were significant differences between the results of group three and the results of group one (P< 0.01) and group two (P< 0.05), and there was non-significant difference between group one and two in both ankle (t= 0.5109 , P > 0.05) and knee levels (t = 0.1669 , P> 0.05) as shown in Table 2.

The relative changes in the mean value of (CsGSV) at the ankle level were calculated in each group and it revealed that in contrast bath group was (-10.99) while in exercise group the relative change was (-9.29) and in stocking group was (-1.07). At knee level, relative change in contrast baths group was (- 7.58), while in exercise group was (- 7.82) and in stocking group was (-1.25) as shown in table 1.

Although there was no significant difference between contrast baths group and exercises group, the relative change of the contrast baths group was higher than that of the exercise group in the ankle level while the relative change of the exercise group was higher than that of contrast bath group at knee level; shown in table 1.

Table 2. Post hoc Bonferroni test.

	(I) Group	(J) Group	Mean differences	t-value	P value
CsGSV (Ankle)	Contrast Baths	Exercise	-0.03000	0.5109	P > .05[b]
	Contrast Baths	Stocking	-0.2600	3.131	P< .01[a]
	Exercise	Stocking	-0.2300	2.770	P< .05[a]
CsGSV (knee)	Contrast Baths	Exercise	0.01000	0.1669	P> .05[b]
	Contrast Baths	Stocking	-0.2700	3.186	P< .01[a]
	Exercise	Stocking	-0.2800	3.304	P< .01[a]

a: significant b: non-significant

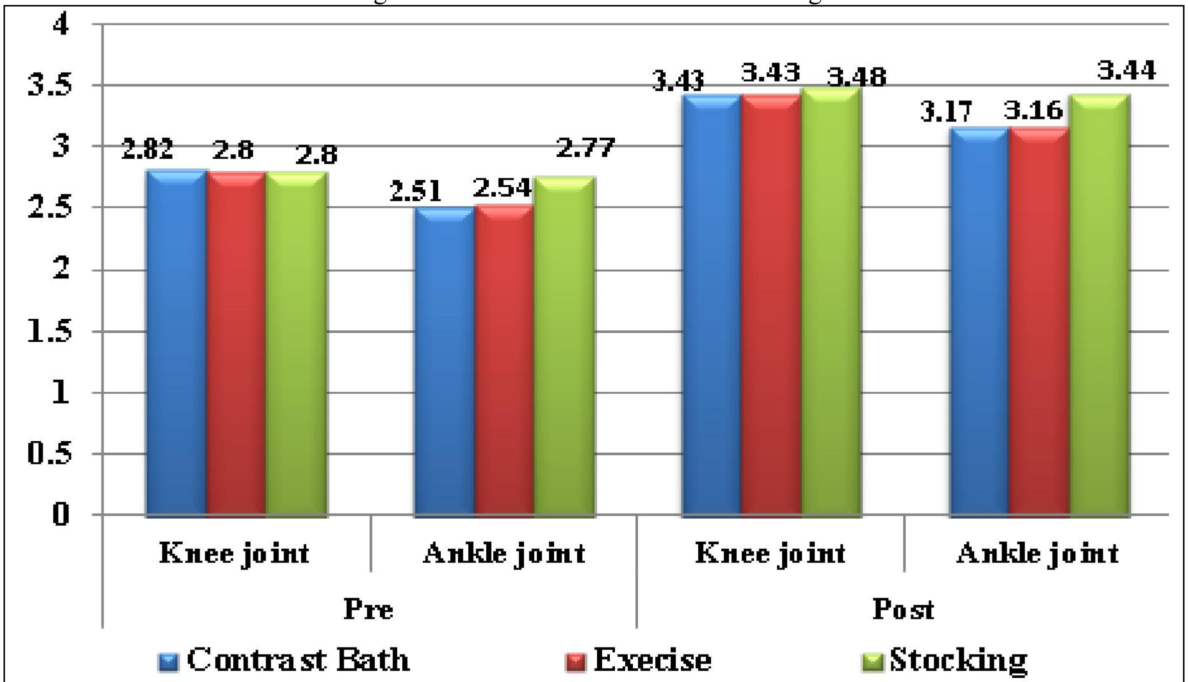

Figure 5: Comparison of pretest and posttest values of (CsGSV)

4. Discussion:

Hydrotherapy is a common physical therapy modality (Breger et al., 2003). It is believed that by alternating hot and cold baths, additional vasodilatation occurs in the limb and creates a pumping action that will allow edema to decrease in the cells (Cameron, 2003). Recent studies have shown that there is better blood flow in the limb after immersion in contrast baths compared with continuous immersion in warm water at the same temperature as the warm water temperature used in the contrast baths (Petrofsky et al., 2006, Fiscus et al., 2005).

The result of the present study was agreed with studies that investigated the physiological changes after contrast baths on peripheral vascular pumping and on blood flow (Woodmansey et al., 1983, Engel et al., 1950) and also with the studies that investigated the use of contrast baths to increase tissue temperature at the intramuscular level (Fiscus et al., 2005, Myrer et al., 1994, Myrer et al., 1997). All these studies demonstrated an increase in the superficial tissue temperature and blood flow with heat compared with cold.

More recent studies support the use of contrast baths to increase superficial blood flow, particularly when subjects were exposed to a warm room before the procedure (Petrofsky et al., 2007, Petrofsky et al., 2007). Petroskfy et al., found that contrast baths were more effective to increase blood flow after each succeeding warm water immersion alternated with cold immersion over time compared to warm water immersion alone (Petrofsky et al., 2007).

Although there were no significant differences in the mean values of contrast baths group and the exercise group in the present study , there was a higher tendency of the contrast baths to decrease the mean value of CsGSV at ankle level and a higher effect was observed (not statistically significant) with exercise more than that of contrast baths at knee level.

One explanation for these results that the timing regimen of starting contrast baths was immersion in hot water for 10 minutes, followed by alternate immersion of four minutes in hot and one minute in cold for another three or four repetitions for a total duration of 30 minutes (Breger et al., 2009). Other protocols described did not include the initial 10 minutes of warm water immersion and the ratio suggested was alternate immersion in either four or three minutes warm water and one minute cold water immersion (ratio of 4:1 or 3:1) to variation depending upon the protocol used (Petrofsky, et al., 2007).

In the present study, the starting of the contrast baths with 10 minutes hot before a ratio of 4:1 hot to cold ratio might explain the potent higher relative change of contrast baths over the exercise at ankle level despite of the lack of any significant differences between their effects. While, at knee level , the effect of strengthening exercise tends to be higher due to the action of muscle pump produced by bulky of the calf muscles.

Venous return is dominated by the action of the three natural muscle pumps of the lower limb: those of the foot, calf, and thigh. The calf muscle pump is the most effective hemodynamically because of its high capacitance, the high pressures it can generate, and its positioning in the lower half of the limb, where the venous pressure is maximal (Padberg et al., 2004).

When the calf muscle pump function is impaired, the residual venous volume in the calf increases immediately after muscle contraction, in the presence of venous valvular incompetence, causes the ambulatory venous pressure to rise and a resultant venous hypertension (Recek, 2006).

Venous hypertension caused by CVI is known to produce three types of morphological injuries of the skeletal muscle tissue: (1) atrophy of type 2 muscle fibers, which become angular; (2) denervation (neurogenic atrophy) manifested by grouping of atrophic fibbers and (3) myopathic abnormalities, noted by fibre degeneration, inflammation, and necrosis (Labropoulos, 1996).

Calf muscle exercise, on the other hand, produces hyperaemia and promotes conditioning of the striated muscle cells, resulting in an increase in the skeletal muscle fibre size, capillary density, and succinate dehydrogenase activity, which reflects an enhancement in the cellular oxidative capacity (Saltin et al., 1998).

The present study was similar to some previous studies that recommended and supported the isotonic strength of calf muscle and the use of elastic compression stocking in the treatment of varicose vein. Clarke et al., found a significant increase in venous blood flow after neuromuscular electrical stimulation to the calf muscle (Clarke et al., 2006).

Also, Van Uden et al., pointed to the possible role of gait and strength training in the rehabilitation process of patients with severe chronic venous insufficiency (Van Uden et al., 2005). Yang et al., concluded that poor calf muscle pump function in patients with chronic venous ulceration can be improved by a six-week intensive tiptoe exercise program (Yang et al., 1999).

Furthermore, Faghri et al., concluded that periodic single electrical stimulation to calf muscle produced a significant improvement in the muscle pump function and could be used to improve venous blood flow and reduce stasis in the lower leg (Faghri et al., 1998).

Hartmann et al., stated that physical factors are known to influence homodynamic in the veins of the lower extremities. They concluded that, a combined physical therapy program was shown to be of long-term therapeutic value, improving venous function and reducing patients' symptoms (Hartmann et al., 1997).

Conclusion:

Both contrast baths and strengthening exercise to calf muscle are effective methods in the treatment of varicose veins. However, contrast bath is a new safe and useful physical therapy method that can be used effectively as an alternative to traditional conservative ways of varicose vein treatment especially in patients who are unable to follow an exercise program.

Recommendation:

Contrast baths are innovative, non-invasive and non-expensive method that can be used as a new physical therapy modality in the treatment of varicose vein.

Practical applications:

Both Contrast baths have been shown to be effective in improving venous return in patients with varicose vein. The contrast baths are effective tools that could be used separately or in combination with strengthening exercises.

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