Evaluation of efficiency of compression therapy in enhancement of venous leg ulcer healing in patients after surgical treatment

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Abstract The objective of this study was to evaluate efficiency of compression therapy in enhancement of venous leg ulcer healing after surgical treatment. Two comparative groups of patients, 1 and 2, were formed at random from patients with venous leg ulcers, which had been earlier operated by modified Babcock stripping of great or small saphenous vein. Both group 1 and 2 consisted of 30 patients. Patients in two comparative groups were treated pharmacologically in the same way. Patients in group 1 were additionally treated with use of two elastic short stretch bandages made by Sigvaris. We evaluated to what degree compression therapy causes changes of the surface, length, width and volume of tissue defect, as well as Gilman index. The weekly rate of changes of the surface and volume were also calculated. After completion of the study, significant progression of healing was noted in both comparative groups. In patients provided with compression therapy we observed an increased Gilman index and wound surface decrease and ulcers were also better debrided , compared with the control group. Faster weekly surface change was noticed too. Other results also appeared to be better than in the control group, although the difference was not statistically significant. Compression therapy is an efficient method in enhancement of venous leg ulcer healing after surgical treatment.

Key words compression therapy • venous leg ulcers

Introduction

Venous leg ulcerations constitute 80% of all leg ulcers and are a serious medical and socio-economical problem. It is estimated that in the countries of Western Europe the rate of people suffering from this condition is about 0.3-1% of population, with proportion women to men 3:1. It is worth noting that the occurrence of this condition increases with age and in the range of 65-80 years reaches 6%. Moreover, occurrence is higher in childbearing women, especially in multiparas [9, 13, 14].

The most typical causes of venous ulcers are chronic venous insufficiency and elevated venous pressure of peripheral vessels and microcirculation. Changes appearing in the process of chronic venous insufficiency make it impossible to maintain normal haemodynamics, leading to reflux and blood congestion, resulting in prolonged maintenance of venous hypertension (above 90 mm Hg). There are several theories explaining the mechanism of formation of venous ulcerations. Those most usually cited are the theory of leucocytic trap, fibrin collar and too high blood viscosity in microcirculation [4, 5, 20].

Lowering venous pressure in the vessels of the extremities is the aim of treatment and condition for effective healing of ulceration. Treatment includes causative and conservative methods. Treatment consists of surgery of superficial veins, including stripping of great or small saphenous vein (e.g. according to Babcock), crossectomy and Muller's phlebectomy. Treatment also includes surgery of perforating branches: endoscopic incision of perforators under fascia and paratibular incision of fascia (Hach's method), as well as surgery of deep veins, including modification of venous valves, transposition of veins and bypass by Palma and Warren's method [11, 12, 15, 17, 19, 20].

Table 1. Inclusion and exclusion criteria for the clinical study. API – ankle/arm pressure index.

Inclusion criteria	Exclusion criteria
Venous leg ulcer (API>0.9)	Arterial leg ulcer (API<0.9) Ulcer of other etiology not venous Diabetes Atherosclerosis Rheumatoid arthritis Cardiac pacer Heart arrhythmia Metal implants Corticosteroid therapy Pregnancy

In spite of surgical removal of causative factors, it is difficult to achieve full healing of venous ulceration. On top of that, defect closure by performed surgical intervention does not assure lack of recurrence. Rate of recurrences after surgical procedure presented by various authors may reach even 20% to 33% in five-year follow-up [20]. This shows the need to continue effective conservative treatment in order to maintain the result of surgery and prevent the possibility of recurrence. This is why effective methods of pharmacological support during the postoperative period are still being investigated.

According to standards set by the Polish Society for Wound Healing [10] and Polish Phlebological Society [16], compression therapy is a basic and first-line treatment after surgical intervention, because application of appropriate external force in the form of gradual compression decreases local volume of venous blood, by pushing it towards the heart. However, there are many recommended methods of compression therapy. Compression therapy usually requires application of elastic or non-elastic bandages, Unna boot, regulated compression bands (CiraAid boot), elastic knee-length socks, compression tights, multi-layered compression systems or equipment assuring dynamic compression (rhythmic pneumatic massage). Selection of the method and appropriate compression class depends on the symptoms reported by the patient (intensity), etiology and location of lesion as well as degree of clinical advancement [1, 9, 18]. A Variety of compression therapy methods assures a broad range of selection, but hinders decisive clinical assessment as to which method is the most effective.

In Poland, economic cost is also one of the important factors influencing selection of the compression therapy method. Long-term follow-up of patients with venous leg ulcers shows that most patients are usually treated with compression bandages. Also, in our experience, application of this form of compression is a standard procedure (at least until the time of lesion healing). Our team has decided to assess efficiency of compression therapy with use of two compression bandages with short stretch, as an adjunctive treatment of venous ulcers in patients after surgical intervention.

Material and methods

Treatment modalities, plan and scope of treatments, selection of patients into groups and other necessary procedures of controlled clinical study were analyzed, approved and accepted for application by the Bioethics Committee of Silesian Medical University in Katowice, Poland. Before the beginning of the research, all the patients were subjected to detailed randomization (basic inclusion and exclusion criteria are presented in Table 1). Eventually, 60 patients with venous shin ulcers were recruited for the study. These patients were randomized into two comparative groups, 1 and 2.

Table 2. Characteristics of patients and ulcers.

Parameter	Group 1	Group 2	*p*
Number of patients	30	30	>0.05
Age (years) Average (years)	43-78 61.43	40-79 60.93	>0.05
Sex: Women Men	 18 12	 16 14	>0.05
Body mass (kg) Average (kg)	63-95 70.42	60-99 74.44	>0.05
Height (cm) Average (cm)	156-188 172.34	152-186 170.54	>0.05
Localization of ulcers: Medial ankle Lateral ankle Anterior part of shin Posterior part of shin	 17 4 8 1	 18 3 8 1	>0.05
Duration of condition Average	6 months – 14 years 2.8 years	2 months – 10 years 2.7 years	>0.05
Primary area of ulcer (cm^2) Average (cm^2)	9.11-35.90 22.39	7.89-42.17 25.27	>0.05
Primary volume of ulcer (cm^3) Average (cm^3)	0.29-5.18 2.77	0.44-8.11 3.56	>0.05

Table 3. Epicrisis and clinical signs of patients with venous shin ulcers.

Parameter	Group 1	Group 2	*p*
	n (%)	n (%)	
Oedema, hyperpigmentation, lipodermatosclerosis	30 (100)	30 (100)	>0.05
Postphlebitic syndrome	12 (40)	12 (40)	>0.05
Obesity	2 (7)	4 (13)	>0.05
Smoking	5 (17)	6 (20)	>0.05
Number of ulcers covered with purulent exudate	30 (100)	30 (100)	>0.05

Table 4. Classification of patients according to CEAP scoring system.

Classification	Group 1	Group 2	*p*
$C_6E_PA_{S2,3}P_R$	12	13	>0.05
$C_6E_PA_{S4}P_R$	4	3	>0.05
$C_6E_PA_{S2D13}P_R$	4	2	>0.05
$C_6E_PA_{S3D13}P_R$	4	5	>0.05
$C_6E_PA_{S2,3D13,14P18}P_R$	3	3	>0.05
$C_6E_SA_{S2,3D13,14P18}P_R$	3	3	>0.05

Group 1 included 30 patients: 18 women and 12 men. Patients' age ranged from 43 to 78 years (average 61.43). Patients from group 1 were subjected to compression therapy and pharmacological treatment. Group 2 also included 30 patients: 16 women and 14 men. Patients' age ranged from 40 to 79 years (average 60.93). Patients from group 2 were subjected to the pharmacological treatment alone , identical to the one used in group 1. Detailed characteristics of patients in both comparative groups are presented in Tables 2-3. Patients were also classified according to CEAP scoring system for chronic venous insufficiency (Table 4).

All ulcers in comparative groups were diagnosed as venous ulcers. In order to eliminate the arterial component and to localize venous insufficiency, patients were subjected to Doppler ultrasound examination with use of EUB 555 (Hitachi) machine. Linear 7.5 MHz head and sector 2.5 MHz head were used. In all patients surrounding tissues of the ulcers showed features of chronic venous insufficiency (oedema, discoloration, lipodermatosclerosis). Body mass index was calculated according to the formula:

$BMI = m/h^2$ [kg/m^2]

m – mass of patient in kilograms;
h – height of patient in meters.

Fig. 1. Compression therapy with use of two bandages with short stretch.

Fig. 2. Digital planimetry kit.

According to assumed norm, body mass index above 30 kg/m^2 signified obesity. Also the number of smoking patients was recorded.

All the patients were hospitalized in the Department of General, Vascular and Transplantation Surgery, Public Autonomous Clinical Hospital, Katowice, Poland, where surgery according to modified Babcock's method was performed. This technique included cutting off of all veins at the branching of great or small saphenous vein, subcutaneous tearing of great saphenous vein (stripping from the groin to proximal 1/3 of shin bone) or small saphenous vein (stripping from the knee to the level of gastrocnemius muscle of the calf), ligation and incision of insufficient perforators. The aim of the surgery was to remove the cause of venous reflux and normalize pressure in the venous system. In the first group,

surgery of great saphenous vein was performed in 26 patients, while in the remaining four cases patients underwent surgery of small saphenous vein. In the second group surgery of the great saphenous vein was performed in 27 patients, and surgery of small saphenous vein in three cases. Patients were hospitalized for several days after the intervention. Further evaluations were performed in the out-patient setting, in surgical ambulatory.

After surgical intervention, patients in group 1 were treated with compression therapy. Treatment was performed with use of two elastic Sigvaris bandages, with short stretch. Compression was applied at the level of ankle joint. In the case of insufficiency of superficial veins we used compression of 30 mm Hg, and in the case of co-existing insufficiency of deep veins 40 mm Hg (in cases of patients with deep system insufficiency a Sigvaris stocking of the first class of compression was additionally worn on the bandaged lower leg). Before application of the dressing, the sitting patient put his ankle joint at the angle of 90º. The first bandage (8 cm wide and 5 m long) was put from the shank (from the level of metatarsophalandeal articulations) through the heel, to the beginning of the calf. Another bandage (10 cm wide and 5 m long) was put above median ankle (overlapping with the last layer of the first bandage), obliquely crossing from top to bottom, to the level of the head of fibula (Fig. 1). Compression was graduated and decreased in the proximal direction. Patients remained in bandages put on the ulcerated shin for 8-10 hours daily. Duration of compression therapy was seven weeks.

During the postoperative period patients from both groups were also treated pharmacologically. They received phlebotropic drugs, micronized flavone fraction (450 mg of diosmin and 50 mg of hesperidin) in the form of two 500 mg tablets once a day. Standard gauze with physiological saline was also used on the wound. Duration of treatment was also seven weeks. Assessment of treatment progression for venous ulceration was made with a subjective method, on the basis of daily evaluation of individual phases of healing (epithelialization, amount of granulation tissue, purulent exudate etc.) Lesions were also photographed

Planimetry of one-plane, adjunct projections of lesions onto a transparent film with use of a digitizer was used as an objective method of assessment. Measuring kit included Mutoh Kurta XGT digitizer (tablet 57 x 44 cm and four-button cordless mouse), personal computer with installed modified C-GEO program (Fig. 2). The program allowed calculation of parameters like total area, areas of individual parts (purulent area) and volume. Gilman index was calculated [7]. Moreover, maximal length and perpendicular length were measured in order to assess regularity of wound healing. Thus, measurements were performed at baseline and once a week, during the treatment, in both groups.

Relative values of total surface, purulent area and volume, as well as relative indices of weekly changes of total area and volume were calculated. For this purpose the following formulas were used:

$$d = \frac{\Delta S}{P} = \frac{S_2 - S_1}{(Ob_2 + Ob_1)/2} = \frac{2(S_2 - S_1)}{Ob_2 + Ob_1}$$

d – Gilman index (in cm);
S_1, S_2 – primary and final surface of ulceration;
Ob_1, Ob_2 – primary and final circumference of ulceration.

$$dS\% = \frac{(S_1 - S_n) \times 100\%}{S_1}$$

dS% – change of relative surface of ulceration (in %);
S_1 – primary surface of ulceration;
S_n – final surface of ulceration.

$$dV\% = \frac{(V_1 - V_n) \times 100\%}{V_1}$$

dV% - change of relative volume of ulcerations (in %);
V_1 – primary volume of ulceration;
V_n – final volume of ulceration.

The degree of slough (dR%) was calculated from percentage indices of changes of relative sloughy areas (R_1, R_n):

$$dR\% = \frac{(R_1 - R_n) \times 100\%}{R_1}$$

$$R_1 = \frac{S_{inf\ p}}{S_1 \times 100\%}$$

R_1 – relative slough on the surface of ulceration before treatment (in %);
S_{infp} – primary slough on the surface of ulceration;
S_1 – primary surface of ulceration.

$$R_n = \frac{S_{inf\ n}}{S_n \times 100\%}$$

R_n – relative slough on the surface of ulceration after the end of treatment;
S_{infn} – final slough on the surface of ulceration;
S_n – final surface of ulceration.

Percent weekly rate of changes T_x, calculated for measured parameters, was derived from the formula:

$$T_x = \frac{dX\%}{t}$$

dX% - relative percent changes of measured parameters;
X – measured parameter: S (surface area),
V (volume);
t – time (7 weeks).

In order to evaluate regularity of distribution of features characterizing patients in group 1 and 2, independence test χ^2 was used, in the version of the highest confidence (NW). Significant differences were assumed at the level of $p \leq 0.05$. The average size of surface area, length, width, volume and sloughy area before and after treatment, were compared in both groups with use of non-parametric matched pairs Wilcoxon test (confidence level $p \leq 0.05$). Comparison of Gilman index and average changes of relative area, volume and purulent area in relation to the primary value in both groups were assessed with use of non-parametric U Mann-Whitney test (confidence level $p \leq 0.05$). Comparison of average weekly rate of changes of lesion area and volume between groups 1 and 2 was also performed with use of non-parametric U Mann-Whitney test (confidence level $p \leq 0.05$).

Results

Treatment of patients in both group 1 and 2 was effective. In patients from both groups statistically significant decrease of total surface and wound area, as well as length, width and volume of lesions, were recorded (Table 5).

Comparison of Gilman index demonstrated a significant difference in favour of the group undergoing compression therapy, compared to the control group (Fig. 3, $p=0.03$). Patients in group 1 also achieved more effective (Fig. 4, $p=0.04$) and faster (Fig. 5,$p=0.04$) decrease of sloughy areas, compared to group 2. Moreover, in patients treated with compression bandages, improved removal of purulent exudate from the lesions was also observed (Fig. 6, $p=0.02$).

In the case of change of relative volume of ulceration, some therapeutic benefit of compression therapy was also noted compared to the control group; relative volume was 90.40% in group 1 and 81.71% in group 2. However, these differences were not significant. Weekly rate of volume changes in both groups turned out to be similar (12.91%/week in group 1 and 11.67%/week in group 2). Comparison of ulcer area changes and linear results (width and length) demonstrated regularity of the ulceration healing process in both comparative groups.

Table 5. Results of treatment in group 1 and 2.

Parameter	Group	Average value ± standard deviation		*p*
		Before treatment	After treatment	
Total surface area (cm^2)	1 2	22.39±13.11 25.27±18.00	7.66±9.61 14.12±16.51	p(1)=0.00001 p(2)=0.00001
Volume (cm^3)	1 2	2.77±2.66 3.56±2.80	0.27±0.43 0.75±1.16	p(1)=0.00001 p(2)=0.00001
Length (cm)	1 2	6.52±2.13 6.86±2.95	3.23±2.77 4.03±3.52	p(1)=0.00001 p(2)=0.00001
Width (cm)	1 2	4.62±1.61 4.69±1.59	2.05±1.83 2.81±2.18	p(1)=0.00001 p(2)=0.00001
Purulent area (cm^2)	1 2	19.48±13.19 22.57±14.77	0.11±1.12 0.63±1.18	p(1)=0.000002 p(2)=0.000003

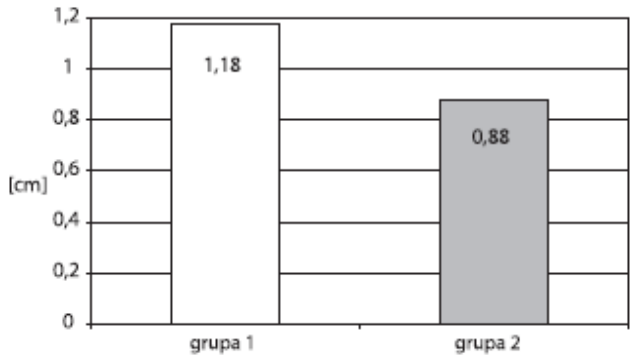

Fig. 3. Comparison of Gilman index.
grupa 1 = group 1

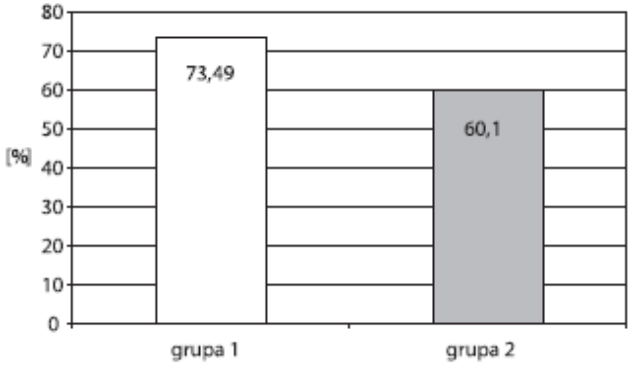

Fig. 4. Comparison of changes of relative ulceration area.

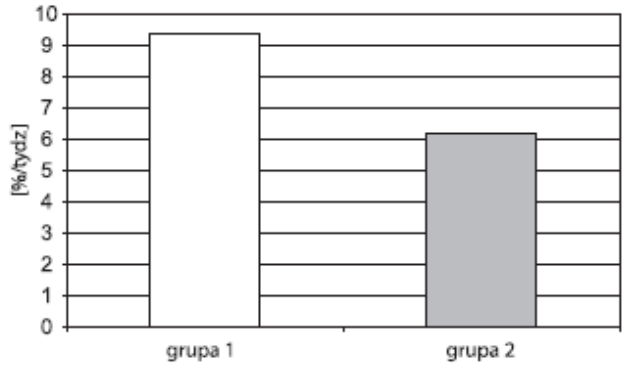

Fig. 5. Comparison of weekly rate of changes of relative ulceration area. [%/week]

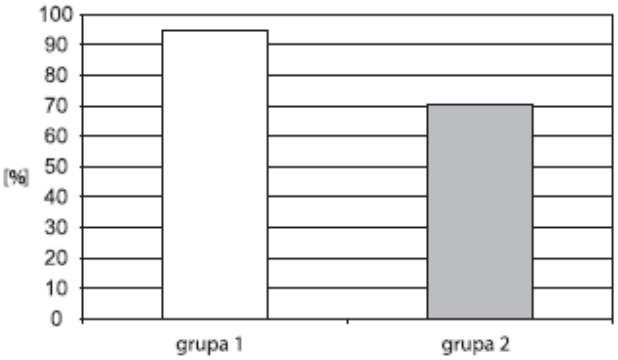

Fig. 6. Comparison of changes of purulence level in ulcerations.

Discussion

On the basis of this clinical study we confirmed significant efficacy of compression therapy in adjunctive therapy of venous leg ulcer healing in patients after surgical intervention. This result is confirmed by most measured parameters. Only in the case of change in lesion volume was the benefit of compression therapy not statistically significant when compared with the control group.

Compression therapy in the presented form is one of the most frequently used in Poland. One of the advantages of elastic bandages is the significantly lower financial cost, which has to be borne by the patients with venous leg ulcers. Moreover, this method allows daily cleansing of the wound as a result of daily dressing replacement. Nevertheless, patients require constant medical care during the first period, and then thorough training, in order to properly apply the bandages. This may be an organizational disadvantage for the everyday work of a vascular clinic.

Positive results of compression therapy in the form of compression bands are also reported by other authors [2, 3, 6, 8]. Blecken et al., after using elastic bandages with short stretch

for three months in 12 patients, recorded an average decrease of venous leg ulceration area from 50.08 cm^2 to 18.30 cm^2 (p=0.02) [3].

At the same time, Danielsen et al. managed to completely heal 45% of patients after six months, and after a year 71% of patients [6]. These patients had not been treated surgically prior to compression therapy.

On the other hand, Barwell et al. compared compression therapy after surgical intervention with compression therapy alone [2]. After 12 weeks of compression therapy, counting from the time of surgical intervention, healing was achieved in 82% of patients. At the same time, after 12 weeks of compression therapy alone, healing was noted in as many as 76% of patients. Care was continued for 12 subsequent weeks, after which the measurement was repeated. Obtained differences in results between groups still were not statistically significant. From the review of literature and our results, it seems that surgical intervention and compression therapy in the postoperative period is currently the best way to manage venous leg ulcers.

Conclusions

1. Compression therapy with use of two elastic bandages with short stretch is an effective method of adjunctive therapy in venous leg ulcers, in patients after surgical intervention.
2. Further research on use of different forms of compression therapy in chronic venous insufficiency is necessary in order to objectively and positively compare therapeutic efficiency of individual forms of therapy.

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