The influence of different sub-bandage pressure values on venous leg ulcers healing when treated with compression therapy

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Background: **Venous leg ulcers (VLU) have a huge social and economic impact. An estimated 1.5% of European adults will suffer a venous ulcer at some point in their lives. Despite the widespread use of bandaging with high pressure in the treatment of this condition, recurrence rates range between 25% to 70%. Numerous studies have suggested that the compression system should provide sub-bandage pressure values in the range from 35 mm Hg to 45 mm Hg in order to achieve the best possible healing results.**

Methods: **An open, randomized, prospective, single-center study was performed in order to determine the healing rates of VLU when treated with different compression systems and different sub-bandage pressure values. One hundred thirty-one patients (72 women, 59 men; mean age, 59-years-old) with VLU (ulcer surface >3 cm^2; duration >3 months) were randomized into three groups: group A – 42 patients who were treated using an open-toed, elastic, class III compression device knitted in tubular form (Tubulcus, Laboratoires Innothera, Arcueil, France); group B – 46 patients treated with the multi-component bandaging system comprised of Tubulcus and one elastic bandage (15 cm wide and 5 cm long with 200% stretch, Niva, Novi Sad, Serbia); and group C – forty-three patients treated with the multi-component bandaging system comprised of Tubulcus and two elastic bandages. Pressure measurements were taken with the Kikuhime device (TT MediTrade, Soro, Denmark) at the B1 measuring point in the supine, sitting, and standing positions under the three different compression systems.**

Results: **The median resting values in the supine and standing positions in examined study groups were as follows: group A – 36.2 mm Hg and 43.9 mm Hg; group B – 53.9 mm Hg and 68.2 mm Hg; group C – 74.0 mm Hg and 87.4 mm Hg. The healing rate during the 26-week treatment period was 25% (13/42) in group A, 67.4% (31/46) in group B, and 74.4% (32/43) in group C. The success of compression treatment in group A was strongly associated with the small ulcer surface (<5 cm^2) and smaller calf circumference (CC; <38 cm). On the other hand, compliance in group A was good. In groups B and C, compliance was poor in patients with small CC, but the healing rate was high, especially in patients with large ulcers and a large CC (>43 cm).**

Conclusion: **The results obtained in this study indicate that better healing results are achieved with two or multi-component compression systems than with single-component compression systems and that a compression system should be individually determined for each patient according to individual characteristics of the leg and CC. Target sub-bandage pressure value (B1 measuring point in the sitting position) of the compression system needed for the ulcer healing could be determined according to a simple formula, CC + CC/2. (J Vasc Surg 2010;51:655-61.)**

Compression therapy remains the most widely used treatment for venous leg ulcer (VLU), and it has been utilized in different forms for more than 4 centuries. The application of external pressure to the calf muscle raises the interstitial pressure resulting in improved venous return and reduction in the venous hypertension. Published healing rates of venous ulcers obtained with compression therapy vary widely from 40% to 95%[1-4] and numerous studies have suggested that compression systems with sub-bandage pressure values from 35 mm Hg to 45 mm Hg provide the best possible healing results.[5-7] Unfortunately, until today, there is no standard compression therapy that is universally successful in the treatment of patients with VLU. Although many studies have proved the efficacy of compression therapy in the treatment of these patients, there is still no agreement on what type of compression and sub-bandage pressure values should be used in order to achieve the best possible healing results.

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METHODS

An open, randomized, prospective, single-center study was performed in order to determine healing rates of VLU when treated with three different compression systems and three different sub-bandage pressure values.

Patients aged at least 18-years-old with leg ulceration of suspected venous etiology were screened for inclusion in the trial. Before inclusion in the study, all patients underwent a color Duplex scan (CDS) examination and ankle-brachial pressure index (ABPI) measurements. The CDS examinations were performed using Siemens (Erlangen, Germany) Sonoline Sienna ultrasonography device with a 7-MHz probe. Venous compressibility and flow characteristics were the key elements to exclude thrombosis. The direction of flow was assessed in a 20-30° reverse Trendelenberg position during the Valsalva maneuver. A cuff inflation-deflation method with rapid cuff deflation in the standing position was performed to induce reflux. The presence of reflux was determined by retrograde flow of a duration >0.5 seconds.[8] The evaluation of vein segments for obstruction was performed using the compression method while the patient was in a supine position.[9] Evaluation of the pelvic outflow was not performed, and only vein segments below the inguinal ligament were examined. If the examined vein segment was compressible, it was classified as a "normal finding"; if there was failure to approximate the vein wall completely, but there was color flow with augmentation, it was classified as a "partial obstruction", and if the examined segment could not be compressed at all with high echoes in the lumen, irregular thick wall, and no flow with color imaging, even with augmentation, it was classified as an "obstruction".

Venous etiology was verified according to CDS findings and only patients with verified VLU (ulcer surface >3 cm^2; duration >3 months) were included in the study. The study excluded patients with ABPI <0.8 (11 patients), patients with heart insufficiency with ejection fraction (EF) <35 (1 patient), pregnancy (1 patient), cancer disease (1 patient), and diabetes (11 patients). Also, 12 patients with an unidentified cause of leg ulcer were excluded from the study. All limbs were classified according to the CEAP classification.[10]

Randomization was computer generated, and patients were randomized into three groups:

Group A – Patients who were treated using a heel-less, open-toed, elastic class III compression device knitted in tubular form (Tubulcus; Laboratoires Innothera, Arcueil, France);

Group B – Patients treated with a multi-layer bandaging system comprised of Tubulcus and one elastic bandage (15 cm wide and 5 cm long with 200% stretch; Niva, Novi Sad, Serbia); and

Group C – Patients treated with a multi-layer bandaging system comprised of Tubulcus and two elastic bandages.

The standard regimen was to debride the wound. This was normally a simple mechanical debridement with sterile gauze in order to remove slough and other dead tissue. According to the extent of wound exudation, dressings were changed every 1 to 7 days. Extensive wound exudation was treated with crystal acidum boricum (after debridement, acidum boricum was applied over the wound in a thin layer), and in patients with no exudation, dry dressings were performed. After wound debridement and dressing, bandaging systems were applied. The bandaging system was applied by clinical staff as follows:

- The first and second layers were comprised of cotton gauze without tension (50% overlap) and cotton crepe bandage.
- The third layer in treatment group A consisted of a ready-made tubular compression device (Tubulcus) that exerts graduated pressure with the highest compression (30-40 mm Hg) at the ankle, diminishing up the calf, and corresponds to class III compression stockings. It is open-toed and has no heel. Because it is a tubular, knitted, ready-made device, the appropriate pressure is exerted regardless of the fitter's skill. Tubulcus can be reused and laundered at 60°C. The device size was determined for each patient according to the circumferences of the leg measured at the ankle and the largest part of the calf (5 sizes – S, M, L, XL, and XXL – were available). The circumference of the limb was measured every 4 weeks during the treatment and according to these measurements a new pair of Tubulcus was applied. If the measurements of the limb stayed in the initial size, Tubulcus was changed after 6 months.
- In group B, the above-mentioned system was wrapped over by an additional component of one elastic bandage and in group C by a second elastic bandage. The elastic bandages were applied in a spiral with a 50% overlap with the patient in the recumbent position and the foot in dorsal flexion. The bandages were 15 cm wide and 5 m long and had long stretch characteristics (200% stretch; Niva, Novi Sad, Serbia). One pair of elastic bandages was renewed regularly every 3 months. The patient was advised to walk for 30 minutes after bandaging. The bandaging systems were worn day and night. The patients were treated at the Clinic for Vascular Surgery, Clinical Centre Nis (Serbia), on an ambulatory basis. The endpoint in this study was healing of the VLU, which is complete epithelization of the ulcer at 26 weeks. In cases in which the original ulcer closed but a new area developed on the same limb while the original ulcer was still present, the limb was considered to be open until this new area of ulceration had also closed. After ulcer healing, patients were instructed to continue to wear the Tubulcus elastic stockings in order to avoid recurrence.

The study protocol included the measurement of ulcer size, calf, and ankle circumference, and sub-bandage pressure values.

1. Ulcer size was determined by the measured area (cm^2), using a computerized process that consisted of mapping the two-dimensional digital image onto the polygonal mesh. The margins of a wound were outlined on a computer screen, and the enclosed wound area was automatically determined. Digital images were taken

with a Sony Cyber Shot digital camera T10. The digital image included a 5-cm-long calibration marker positioned below the wound surface. The wound area was evaluated every 2 weeks.
2. Calf and ankle circumference were measured in the recumbent position with the maximal (calf) and minimal (ankle) point determined visually.
3. Using a pressure transducer (Kikuhime small probe; MediTrade, Soro, Denmark) the sub-bandage pressure was measured on the medial aspect of the lower leg at the transition of the gastrocnemius muscle into the Achilles' tendon (B1 measuring point) in the supine, sitting, and standing position under the three different compression systems. The pressure difference between active standing and lying is defined as the static stiffness index (SSI). The sub-bandage pressure measurements were taken in all patients at the same time right after the compression system was applied. The pressure transducer was removed immediately after measurement took place. The measurements were performed on three occasions: at the beginning of the treatment, and at 4 and 10 weeks after the first measurement. The median value for each patient was taken for statistical analysis.

Factors independently associated with ulcer healing, such as different sub-bandage pressure values, age, gender, ulceration surface, calf circumference (CC), time since ulcer onset, previous operations, and history of deep vein thrombosis (DVT) were analyzed. In addition, the rate of healed ulcers and compliance was assessed in regard to CC of the affected leg and ulcer size.

According to the CC of the affected leg obtained before the beginning of the compression treatment, all patients were divided into four subgroups: CC <33 cm, CC = 33-38 cm, CC = 38-43 cm, and CC >43 cm. In regard to ulcer size (US), patients were also divided into four subgroups: US <5 cm^2, US = 5-10 cm^2, US = 10-20 cm^2, and US >20 cm^2.

This study was approved by relevant authorities, and written consent was obtained by all patients included in the study. The same treatment team comprised of three doctors and five medical nurses treated all patients.

Statistical methods. The healing rate in each group was calculated up to 26 weeks. The time to heal was compared using the log-rank test. Cox regression analysis with backward method was performed to determine whether covariates (different sub-bandage pressure values, age, gender, ulceration surface, CC, time since ulcer onset, previous operations, and history of DVT) significantly influenced the cumulative rate of ulcer healing.

To compare the median healing times from the three groups, a median test was performed. Fisher's exact test was used to compare categoric parameters between the groups. One-way analysis of variance (ANOVA) with Dunnett's T3 post hoc test was used to compare values of noncategoric parameters. Analyses were done using SPSS 10.0 statistical package (SPSS Inc, Chicago, Ill).

RESULTS

One hundred sixty-eight patients with VLUs were considered for the study, and 131 patients (72 women, 59 men; mean age 59-years-old) were randomized into 3 groups (group A – 42 patients; group B – 46 patients; and group C – 43 patients). During the treatment period, 1 patient in group A, 1 patient in group B, and 9 patients in group C dropped out of the study due to noncompliance to compression treatment. The mean patient's age at the first office visit was 58.6-years-old (range, 32-77-years-old).

The median number of previous episodes of ulceration was 3.2 (range, 2-6), the median size of the ulcer was 12.7 cm^2 (range, 3.0-35.0 cm^2), and 77.1% of ulcers were medial, 13.7% were lateral, 6.1% were circumferential, and 3.1% were a combination. The median duration of the ulcer was 3.9 years (range, 3 months-18 years). Forty-seven patients (35.9%) had previous DVT.

Pain, edema, pigmentation, and lipodermatosclerosis were present in all 131 patients (100%). Thirty-five patients (26.7%) had previously undergone some surgical procedure (stripping of great saphenous vein [GSV] was performed in 32 patients [24.4%] and 3 patients [2.3%] underwent a superficial endoscopic perforator vein surgery [SEPS] procedure). Mean time from operation until inclusion in the study was 7.6 years (range, 18 months-22 years). During the study period, neither surgery nor sclerotherapy was performed. There were no deaths or major complications during the treatment period. There were no statistical significant differences in the above parameters between the study groups (Table I).

The CEAP classification was as follows:

1) Clinical: all included limbs had active ulceration (C6);
2) Etiologic: 53.4% of the patients had primary chronic venous insufficiency (CVI), while 46.6% of the patients were classified as secondary CVI. Secondary etiology was based on ultrasound scan findings.
3) Anatomic: perforating vein reflux was documented at duplex scanning in 66 patients (50.4%). Association of perforating vein reflux with superficial venous reflux was noted in 24 patients (18.3%). The combination of both superficial and deep reflux with perforating vein reflux was observed in 11 patients (8.4%). Deep vein reflux was noted in 30 patients (22.9%).
4) Pathophysiologic: the pathophysiology identified was reflux in all 131 limbs (100%). Reflux and obstruction were present in 27 patients (20.6%).

There were no statistical differences in examined groups in regard to CEAP classification.

Sub-bandage pressure values. The median resting sub-bandage pressure values at the B1 measuring point in the supine and standing position in examined study groups are presented in Table II. The resulting resting pressure ranges correspond to the groups of "moderate", "strong", and "very strong", as defined in an international consensus document.[11]

Table I. Characteristics of the patients by groups

Characteristic	*Group*			P *value*
	A (n = 42)	*B (n = 46)*	*C (n = 43)*	
Female gender	22 (52)	25 (54)	24 (56)	>.05
Previous episodes of ulceration	42 (100)	46 (100)	43 (100)	>.05
Previous operations	11 (26)	12 (26)	12 (28)	>.05
History of deep vein thrombosis	15 (36)	16 (35)	16 (37)	>.05
Age (yrs)	60 (33-76)	55 (35-77)	57 (32-77)	>.05
Size of the ulcer (cm^2)	9 (4-160)	9 (3-160)	11 (3-150)	>.05
Duration of the ulcer (yrs)	4.5 (.3-28)	3.5 (.3-42)	4 (.3-31)	>.05
Calf circumference (cm)	37.5 (28-47)	40 (29-49)	40 (29-52)	>.05

Values are given as number (percent) or median (range).

Table II. Sub-bandage pressure values by groups

Position	*Group*		
	A (n = 42)	*B (n = 46)*	*C (n = 43)*
Supine	36.2 (31.2-39.3)	53.9 (47.8-58.9)	74.0 (67.9-78.7)
Standing	43.9 (37.7-46.1)	68.2 (62.3-74.2)	87.4 (81.6-91.3)
SSI	<10	>10	>10

SSI, Static stiffness index.
Values are given as median (range).

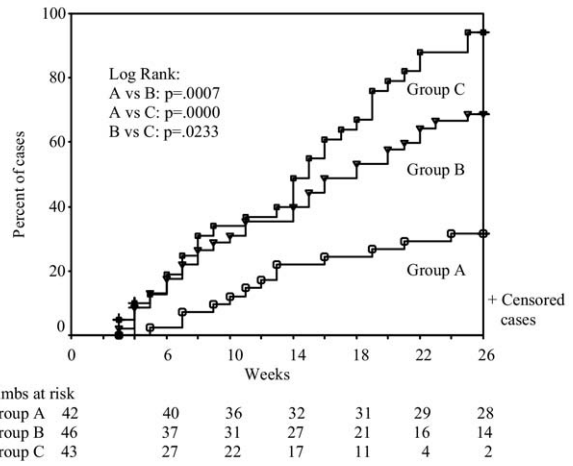

Fig. Time to leg ulcer healing analysis, the Kaplan Maier method.

Healing rate and noncompliance in regard to calf circumference and wound size. The healing rate calculated based on intent-to-treat analysis was 25% in group A, 67% in group B, and 74% in group C. Median healing time in group A was 12 weeks (range, 5-24 weeks), 11 weeks (range, 3-25 weeks) in group B, and 14 weeks (range, 5-24 weeks) in group C (median test: $P > .05$) (Fig).

The rate of noncompliance was 2% in groups A and B and 21% in group C (Fisher's exact test: $P < .05$ and $P < .01$, respectively). If the patient was noncompliant with the compression treatment, we had considered such a case as a drop out from the study.

Table III. Predictor variables included in Cox regression model

Variables in the equation	*OR*	*95% CI*	P *value*
Treatment group A	.102	.051-.203	<.001
Treatment group B	.538	.323-.895	.017
Calf circumference (cm)	.943	.902-.986	.010
Size of the ulcer (cm^2)	.851	.809-.894	<.001
Previous operations	.619	.361-1.059	.080
Variables not in the equation			
Age (yrs)	.992	.413-1.094	.110
Female gender	.672	.562-1.427	.643
Duration of the ulcer (yrs)	1.004	.967-1.043	.826
History of deep vein thrombosis	.934	.582-1.500	.778

OR, Odds ratio; *CI,* confidence interval.

Cox regression model identified that different sub-bandage pressure values, CC, and ulcer size were independent predictors of ulcer healing. The chance of healing was lower among patients in groups A and B than in group C. Higher values of CC and ulcer size also decreased the odds of healing. Previous operations, age, gender, ulcer duration, and history of DVT were not associated with 26-week healing status (Table III).

In group A, the ulcer healing rate was significantly higher among the patients with a CC of the affected leg of <33 cm (75%) than in patients with a CC of 33-38 cm (31%; $P < .05$) and >43 cm (13%; $P < .05$). In group B, the healing rates among the patients with a CC of 33-38 cm (86%) and 39-43 cm (79%) were significantly higher than in patients with a CC of >43 cm (30%; $P < .05$). In group C, the ulcers' healing rate among the patients with a CC of <33 cm (14%) was significantly lower than in patients with a CC of 33-38 cm (79%; $P < .05$), 39-43 cm (92%; $P < .01$), and >43 cm (89%; $P < .01$; Table IV).

The ulcer healing rate among the patients with a CC of <33 cm was higher in group A (75%) than in group C (14%; $P < .05$). Among the patients with a CC from 33-38 cm and 39-43 cm, the healing rates in groups B (86% and 79%, respectively) and C (79% and 92%, respectively) were

Table IV. Outcome by group in regard to calf circumference of affected leg

	Calf circumference (cm)				
Outcome ratio by group	*<33*	*33 to 38*	*39 to 43*	*>43*	*Comparison*
Healed/Non-healed					
Group A	6 (75)/2 (25)	4 (31)/9 (69)	2 (15)/11 (85)	1 (13)/7 (87)	a*, c*
Group B	5 (63)/3 (37)	12 (86)/2 (14)	11 (79)/3 (21)	3 (30)/7 (70)	d*, e*
Group C	1 (14)/6 (86)	11 (79)/3 (21)	12 (92)/1 (8)	8 (89)/1 (11)	a*, b†, c†
Comparison	g*	f*, g*	f†, g‡	g†, h*	
Compliance/Non-compliance					
Group A	8 (100)/0 (0)	12 (92)/1 (8)	13 (100)/0 (0)	8 (100)/0 (0)	n.s.
Group B	8 (100)/0 (0)	13 (93)/1 (7)	14 (100)/0 (0)	10 (100)/0 (0)	n.s.
Group C	3 (43)/4 (57)	11 (79)/3 (21)	12 (92)/1 (8)	8 (89)/1 (11)	b*
Comparison	g*, h*	n.s.	n.s.	n.s.	

a, <33 cm vs 33 to 38 cm; *b*, <33 cm vs 39 to 43 cm; *c*, <33 cm vs >43 cm; *d*, 33 to 38 cm vs >43 cm; *e*, 39 to 43 cm vs >43 cm; *f*, group A vs group B; *g*, group A vs group C; *h*, group B vs group C.
n.s., Not significant.
*$P < .05$; †$P < .01$; ‡$P < .001$.

Table V. Outcome by group in regard to ulcer size

	Ulcer size (cm^2)				
Outcome ratio by group	*<5*	*5 to 10*	*11 to 20*	*>20*	*Comparison*
Healed/Non-healed					
Group A	10 (83)/2 (17)	3 (25)/9 (75)	0 (0)/11 (100)	0 (0)/7 (100)	a*, b‡, c‡
Group B	10 (100)/0 (0)	9 (64)/5 (36)	8 (57)/6 (43)	4 (50)/4 (50)	b*, c*
Group C	7 (78)/2 (22)	9 (75)/3 (25)	8 (62)/5 (38)	8 (89)/1 (11)	n.s.
Comparison	n.s.	d*, e*	d†, e†	e†	
Compliance/Non-compliance					
Group A	12 (100)/0 (0)	11 (92)/1 (8)	11 (100)/0 (0)	7 (100)/0 (0)	n.s.
Group B	10 (100)/0 (0)	13 (93)/1 (7)	14 (100)/0 (0)	8 (100)/0 (0)	n.s.
Group C	7 (78)/2 (22)	10 (83)/2 (17)	9 (69)/4 (31)	8 (89)/1 (11)	n.s.
Comparison	n.s.	n.s.	f*	n.s.	

a, <5 cm^2 vs 5 to 10 cm^2; *b*, <5 cm^2 vs 11 to 20 cm^2; *c*, <5 cm^2 vs >20 cm^2; *d*, group A vs group B; *e*, group A vs group C; *f*, group B vs group C.
n.s., Not significant.
*$P < .05$; †$P < .01$; ‡$P < .001$.

significantly higher than in group A (31% and 15%, respectively).

Among the patients with a CC >43 cm, the healing rate in group C (89%) was higher than in groups A (13%; $P < .01$) and B (30%; $P < .05$; Table IV).

Noncompliance was registered in 4 patients (57%) with a CC <33 cm in group C, which was a significantly higher rate in comparison to groups A and B ($P < .05$; Table IV).

In group A, the ulcer healing rate among the patients with a wound area <5 cm^2 (83%) was significantly higher than in patients with an ulcer surface from 5-10 cm^2 (25%; $P < .05$), 11-20 cm^2, and >20 cm^2 (0%; $P < .001$). All ulcers with a wound area <5 cm^2 in group B healed, which was a significantly higher healing rate in comparison to larger ulcers in this group (11-20 cm^2; 57%; $P < .05$) and >20 cm^2 (50%; $P < .05$; Table V).

The ulcer healing rate among the patients with a wound area of 5-10 cm^2 was lower in group A (25%) than in groups B (64%; $P < .05$) and C (75%; $P < .05$). None of the ulcers with a surface of 11-20 cm^2 and >20 cm^2 among the patients in group A healed, and this healing rate was significantly lower in comparison with groups B and C ($P < .01$; Table V).

DISCUSSION

The goals of compression therapy in the treatment of VLUs are ulcer healing, reduction of pain and edema, and prevention of recurrence.[12] According to numerous studies, it has been suggested that the best healing results are achieved in the treatment of VLUs with sub-bandage pressure values of 35-45 mm Hg.[7-9] There is no standard compression therapy that is universally successful in the treatment of patients with VLU and it is possible that we shall never find such an ideal compression system that could be used in patients with VLU regardless of many variables such as ulcer size, duration of venous ulcer, CC, fixed ankle joint, and reduced range of motion. An ideal compression device should have a relatively low pressure in a resting position, especially during bed rest, which is well tolerated by the patient. A higher pressure is required when patients stand up in order to compensate for the increase in the hydrostatic load.

Clinical studies have shown that the effect of compression therapy in chronic venous insufficiency depends mainly on two factors: (1) the interface pressure of the fabric on the affected leg, and (2) on the elastic property (stiffness) of the material that determines the performance of the product during standing and walking.[13,14] The pressure increase occurring with standing up from the supine position is a simple parameter for stiffness (SSI). The compression systems with SSI >10 are defined as inelastic, and compression systems with SSI <10 are defined as elastic. Higher stiffness is obtained by wrapping several layers of elastic material over each other thereby increasing the friction between the different layers. However, the obtained SSI values are still much lower than those of inelastic material.

Not only that there is no consensus among the experts concerning which compression systems and materials provides best possible results in the treatment of VLU, but there is a direct conflict in the opinions. For example, a recently published Cochrane review on Compression for VLUs[15] states that an elastic bandage appears more effective than those composed mainly of inelastic constituents. The reason for this may be the fact that inelastic compression loses its sub-bandage pressure during the time (loss of 25% after 30 to 60 minutes).[16] The measurements obtained in one study[17] showed that the working pressure at ankle level after 7-8 hours dropped to approximately 75% of the initial resting pressure. This means that a short stretch bandage should be applied with an initial resting pressure that is higher for approximately 25%. In contrast to these findings, measurements showed that the long stretch bandage is very stable in terms of pressure. The working pressure at ankle level after 7-8 hours only dropped to approximately 95% of the initial resting pressure.[17]

On the other hand, there are many published articles stressing that inelastic materials provide better hemodynamic and clinical outcome on VLU healing compared to elastic material.[18,19] Despite the drop in the interface pressure, Partsch[20] demonstrated that in patients with deep venous incompetence, "inelastic" material achieves better control of venous reflux than "elastic" bandages applied at the same interface pressure. Therefore, it is clear that material plays a decisive role influencing the efficacy of the compression system.

The other important characteristic of compression systems is sub-bandage pressure value, and despite the fact that there are many published studies, there were no suggestions by the authors that sub-bandage pressure would provide the best possible results in the treatment of VLU. These studies were mainly related to measuring the interface pressure of different compression systems.[21,22] It is also interesting that there are no clinical trials describing treatment modality for venous ulcers according to individual characteristics of the affected leg. From clinical experience, it is well known that patients with larger CCs need a much higher sub-bandage pressure in order to achieve healing of venous ulcer compared to patients with smaller CC. However, there are no data regarding this matter.

The results in our study show that the best healing results of VLU are achieved with compression systems that are exerting higher sub-bandage pressure value. The highest healing rate was in group C and especially a high healing rate was obtained in patients with large CC. On the other hand, the vast majority of patients with small CC in group C were noncompliant to the compression treatment due to bandage discomfort, indicating that it may be prudent to determine sub-bandage pressure values of compression system for each patient according to their CC. A median resting pressure of >70 mm Hg exerted by elastic material is very high and frequently not tolerated. This explains the high rate of noncompliance in group C patients, which was noted especially in the first 6 weeks of the treatment. The low-pressure compression system that was applied in group A gave some results in the healing of VLU in patients with small CC and no results in patients with large CC. Our results also indicate that higher healing rates are achieved with higher SSI (Group B and C with SSI >10). By using high enough levels of compression, venous hypertension during walking can be reduced in patients with chronic venous insufficiency. A high working pressure may be able to intermittently compress incompetent deep veins, so that venous reflux is hindered.

Taking into account the results from our study, we are suggesting a simple formula that could be used as a starting point for establishing optimal sub-bandage pressure value (at B1 measuring point in the standing position) of compression systems used for ulcer healing: sub-bandage pressure value = CC + CC/2. The formula is suggested as a starting point in determining a compression system and sub-bandage pressure value for the treatment of VLU that will have the best balance between the high pressure needed for VLU healing and noncompliance due to bandage discomfort. The formula correlates well to the results obtained in our study.

CONCLUSION

The results obtained in this study indicates that better healing results are achieved with two or multi-component compression systems than with a moderate pressure device. It is clear from these results that a compression system should be individually determined for each patient according to their CC. This is especially true for legs with large CC (>38 cm) and extensive ulcers. Good healing results with a moderate pressure device could be achieved in legs with small venous ulcers (<5 cm^2) and small CC (<33 cm).

AUTHOR CONTRIBUTIONS

Conception and design: DM, SZ, DB, DS
Analysis and interpretation: DM, SZ, DB, MJ, RJ, DS
Data collection: DM, SZ, ZM, MT
Writing the article: DM, DB, RJ, ZM, MT
Critical revision of the article: SZ, MJ, RJ, DS
Final approval of the article: DM, SZ, DB, MJ, RJ, ZM, DS, MT
Statistical analysis: DB, ZM

Obtained funding: MJ, DS
Overall responsibility: DM

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