

**COMPARISON OF TWO-LAYER AND FOUR-LAYER BANDAGE SYSTEMS IN
TREATMENT OF VENOUS ULCER****Emin Can Ata* and Metin Onur Beyaz**

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ABSTRACT

Chronic venous insufficiency frequently causes the leg ulcers, pain, unpleasant smell, and decrease of life quality. Multi-layer bandage systems are the cornerstone of the treatment of venous ulcers. We aimed to compare the efficacy of the 2-layer and 4-layer bandage systems that we commonly use in our clinic. This retrospective study was conducted at our University Hospital during December 2017 and March 2019. A total of 81 (21 females, 60 males) patients with venous ulcers were included in the study. Two-layer and four-layer bandage systems were used for compression therapy according to the bandage availability, patient willingness, and ulcer exudation. The sub-bandage pressure was measured and fixed to 30-35 mmHg. Bandages were renewed every three days until the venous ulcer completely healed. The ulcer exudation disappeared after the first or 2nd bandaging. The mean time required for the closure of the venous ulcer was not statistically significant between the two groups (48.9 ± 13.9 vs. 54.3 ± 15.1 , $P=0.438$). Sub-bandage pressure change after 8-10 hours between the group was not statistically significant (6.1 ± 2 vs. 5.11 ± 1.29 , $P=0.289$). At the end of the treatment, the patients who had improvement in deep venous reflux were also similar in both groups (22.7% vs. 35%, $P=0.220$). No recurrent venous ulcer was observed during the follow-up period. In the treatment of venous ulcers caused by chronic venous insufficiency, the 2-layer and 4-layer bandages have similar effectiveness. The 2-layer bandage might be recommendable owing to its low cost and ease of use.

KEYWORDS: venous insufficiency; venous ulcer; multi-layer bandage; sub-bandage pressure;**INTRODUCTION**

Chronic venous insufficiency (CVI) is seen in 25-33% of adult women and 10-20% of men. Leg ulcers caused by CVI is quite common disturbing complication since it affects approximately 0.2% to 1% of the population.^[1,2] Moreover, chronic venous pathologies is also a significant health problem with epidemiological and socio-economic consequences, as it causes cosmetic concerns and physical activity limitations due to the leg ulcers, pain, unpleasant smell, and decreased life quality.^[3,4]

Its treatment is extremely complicated and challenging. Compression to the lower extremities is the gold standard in the treatment of venous ulcers caused by CVI. Therefore, inelastic bandages can be used, but efficacy is not satisfying. The pneumatic compression devices that provide intermittent pressure is not preferred due to the limited applicability and total loss of the labor force caused by the treatment.^[5] Multi-layer compression bandage treatment has been the fundamentals of compression treatment since last decade. It is recommended that the results would be more satisfying if the non-adherent wound dressings applied additionally.^[6]

This study aims to compare the 4-layer compression bandage system with a diminished 2-layer compression bandage system in terms of the effectiveness of venous leg ulcers caused by CVI.

MATERIAL AND METHOD**Ethical consideration**

Ethical Committee approval was not required due to this is a retrospective study. Informed consent was obtained from each patient before the procedures. The hospital authorities and all the authors approved the study results.

Study design

This retrospective study was conducted at our University Hospital during December 2017 and March 2019. All the patients were examined with Doppler US for superficial, deep venous insufficiency, and deep vein thrombosis (DVT) before procedure.

Inclusion and exclusion

A total of 81 (21 females, 60 males) patients followed with chronic venous ulcers were included in the study. Patients with ipsilateral arterial pathology (ABI <0.8) and DVT were not included in the study

Bandage procedures

The patients were subjected to two different bandage types according to the bandage availability, patient willingness, and ulcer exudation. "Hartmann twopress two-layer compression bandaging systems" was used as two-layer bandages treatment, and "Hartmann veno 4 layer two cotton creep bandages" was used as four-layer bandage treatment. The under-bandage pressures of the patients were measured and adjusted at 30-35 mmHg. Pressure changes were noted after 8-10 hours of daily activity following the bandage application. Standard silver dressing was routinely used to cover the venous ulcers before bandages applied. Bandages were renewed every three days until the venous ulcer completely healed. We applied RF ablation if there was superficial venous insufficiency. Besides, patients with perforating vein insufficiency were also treated with a mini surgical incision. After these procedures, Doppler US was routinely performed to confirm the success of the intervention. In the treatment of concomitant chronic venous thrombosis, one of the new generation oral anticoagulants was used. Patients were also prescribed calcium dobesilate or diosmin hesperidin 500mg twice daily for six months. After the bandage treatment, patients were evaluated by Doppler US every four months to prevent new emerging venous pathology in time. Regardless of the etiological factor, class II upper the knee elastic compression socks and the effected extremity elevation as possible were strongly advised after the ulcer was healed.

Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics software (SPSS Inc. Chicago Illinois, United States of America), version 24.0. The normal distribution of the variables was examined by histogram graphs and the Kolmogorov-Smirnov test. Mean and standard deviation values were used to present descriptive analyses. Pearson's chi-squared and Fisher's exact tests were compared with 2x2 tables. When normally distributed (parametric) variables were evaluated among the groups, Student's t-test was used. Mann-Whitney U test was used to evaluate nonparametric variables. P-values < 0.05 were considered statistically significant results.

RESULTS

The mean age was 44.7±9, and the female was 21 (25.9%). The clinical characteristics and the risk factors of the patients were similar between the groups before the bandage (Table 1). However, there were more ulcer exudation in group B (P = 0.039). That is because we aimed to keep the ulcer area dry with four-layer bandage. Radiofrequency (RF) ablation was applied to a similar number of patients with severe great saphenous vein insufficiency in both groups (13.6% vs. 21.6%, P = 0.347) before the bandage treatment. Although more perforating vein ligation was performed in group B, it was not statistically significant (20.5% vs. 40.5%, P = 0.052).

Table 1: Patient characteristics before bandage treatment.

	Two layer bandage N=44	Four layer bandage N=37	P value
Mean age	44.1±9.8	45.5±8.6	0.917
Female	12 (27.3%)	9 (24.3%)	0.763
Family history of leg ulcer	9 (20.5%)	4 (10.8%)	0.246
Obesity	8 (18.2%)	5 (13.5%)	0.569
Superficial vein insufficiency	13 (29.5%)	15 (40.5%)	0.301
Deep vein insufficiency	37 (84.1%)	33 (89.2%)	0.507
Deep vein thrombosis	5 (11.4%)	6 (16.2%)	0.527
Recurrence ulcer	7 (15.9%)	5 (13.5%)	0.762
Ulcer exudation	16 (36.4%)	22 (59.5%)	0.039
Ulcer diameter >5cm ²	13 (29.5%)	12 (32.4%)	0.779

Sub-bandage pressure measured after 8-10 hours daily activity was lower than the application pressure, this pressure change was not statistically significant between the groups (6.1±2.0 vs. 5.11±1.29 mmHg, P=0.289). Regarding this pressure change, it can be conclude that patients are treated with an average of 25-30mmHg bandage pressure.

In 31 (81.6%) patients, it was found that the ulcer exudation disappeared after the first bandaging, and the rest of 7 (18.4%) patient recovered after the 2nd ing.

There was no statistical difference about the length of follow-up between the groups (P=438). The mean time required for the complete closure of the venous ulcer was 51.4±15 days in overall patients, and this duration determined the length of the treatment (Fig I. and Fig II.). This period was not statistically significant between the two groups (48.9±13.9 vs. 54.3±15.1, P=0.438). There were about 30% patient that ulcer diameter more than 5 cm in both groups, which was the main reason for prolonged treatment (Fig III.).



Fig I. Venous ulcer on the right foot thumb and metatarsal-phalangeal joints
Left: before treatment
Right: after two months of treatment



Fig II. Venous ulcer of the left foot thumb and metatarsal-phalangeal joints
Left: before treatment
Middle: after three weeks of treatment
Right: healed ulcer after seven weeks of treatment



Fig III. Approx. 7cm leg ulcer with exudation
Left: before treatment
Right: healed ulcer after eleven weeks of treatment

At the end of the bandage treatment, the reduction in the ankle and calf circumferences were similar between the groups ($P=0.091$ and $P=0.433$). As a result of the Doppler US evaluation after bandage treatment, the

patients who had > 0.5 second improvement in the deep venous reflux were also similar in both groups (22.7% vs. 35%, $P=0.220$) (Table 2). No recurrent venous ulcer was observed in any patient during the follow-up period.

Table 2: Procedures and outcomes of two different bandage systems.

	Two layer bandage N=44	Four layer bandage N=37	P value
Saphenous vein ablation	6 (13.6%)	8 (21.6%)	0.347
Perforator vein ligation	9 (20.5%)	15 (40.5%)	0.052
Length of bandage treatment (day)	48.9±13.9	54.3±15.1	0.438
Mean follow-up (week)	46.9±4.7	44.5±5.3	0.578
Sub-bandage pressure change* (mmHg)	6.1±2.0	5.11±1.29	0.289
Ankle circumference decrease (cm)	1.92±0.50	1.52±0.44	0.091
Calf circumference decrease (cm)	2.74±0.77	3.03±0.79	0.433
Deep vein reflux decrease**	10 (22.7%)	13 (35%)	0.220
*Pressure differences between the first application and 8-10 hours after daily activation			
**Patients who's deep venous reflux decreased at least of 0.5 second after bandage treatment			

DISCUSSION

Venous ulcer caused by CVI is associated with venous hypertension, more than 50% of it may reoccur in lifetime, and should be treated to prevent recurrence.^[7] The etiology of nearly 2/3 of the non-healing lower limb ulcers is CVI. Treatment of CVI is a very complicated and challenging. Compression therapy is the gold scenario of the CVI and venous ulcers. The primary function of compression therapy is to prevent gravity, which is the critical factor for the disruption of venous and lymphatic return of the lower limb, and to ensure the elimination of chronic venous hypertension. Multi-layer bandages used for compression therapy not only increase the pressure falling in cm^2 , but also increase the stiffness of the total applied compression. In this way, the treatment efficiency is increased.^[8,9] Studies have shown that even at approximately 6 mmHg pressure applied to the calf, a decrease in femoral vein caliber has been observed.^[10] Since the ideal pressure value in the multi compression bandage application is 35-40 mmHg on average, it is possible to reduce venous hypertension effectively, thereby shortening the recovery time and reducing hospital cost.^[11]

There is no precise data on the superiority of a particular bandaging technique. However, an ideal compression bandage should allow intermittent compression of the veins and allow a tolerable resting pressure, and also show pump activity by showing enough massage effect to the calf muscles during walking.^[12] Bandages should be washable and reusable for economic reasons.^[13] One of the most important problems with bandages is that the bandage pressure decreases during the day and the treatment effectiveness decreases. In our study, we evaluated the sub-bandage pressure in both patient groups before and after 8-10 hours of activity. The average sub-bandage pressure decrease was around 5-6 mmHg, and no statistical difference was found between the two types of bandage systems.

In this study, we found that the first positive finding after applying the bandage was the cessation of the ulcer exudation regardless of the bandage type. In majority cases, this period is within the first three days, the exudation was completely disappeared in all patients after second bandaging. This is an indication of the effectiveness of bandage treatment, and precondition of the ulcer healing. Clinical studies have shown that when elastic multi-layer compression bandages reach the correct pressure values, they overcome the venous hypertension, which forms the basis of the disease, and accelerates wound healing.^[14]

However, the multi-layer bandage treatment have two disadvantages which lead to abandon by the patients. First of all, today's busy business world and its socioeconomic and sociocultural negative effects.^[7] The other one is the inadequate patient compliance. The patient education and evaluation before the procedure is crucial to preclude interruption of the treatment.

In this study, we found out that the 2-layer bandages were preferred due to their ease of use and quite thin appearance. The 2-layer bandages are also as convenient as the single-layer bandage for use, but unlike the single-layer bandage, the pressure difference at the end of daily activation was found to be the same as the four-layer bandage.^[15] However, we believe that the use of a 4-layer bandage at the beginning is important for the patients with excessive ulcer exudation to keep the ulcer dry.

CONCLUSION

In the treatment of venous ulcers caused by CVI, the 2-layer and 4-layer bandages have similar excellent treatment effectiveness. Due to its low cost and ease of use, the 2-layer bandage might be recommended for patients without excessive ulcer exudation. Treatment of the underlying superficial and perforating venous insufficiency by RF or surgically before bandage may be accelerated ulcer healing.

limitation

This as a retrospective, non-randomized study and includes a limited number of patients. A large scale prospective and randomized study should be required.

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Conflict of interest

We declare no conflict of interest in this study.

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