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Original Research Article

Outcome of combined surgery with compression therapy for management of venous leg ulcer

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ABSTRACT

Background: Venous leg ulcers (VLUs) are late indicators of chronic venous insufficiency (CVI) and venous hypertension. Compression therapy (CT) with multilayer bandage is the first line of treatment modality of ulcer management. But CT has a slow ulcer healing rate and high chance of recurrence. The present study was conducted to identify the outcome of combined surgery with compression therapy to manage VLU.
Methods: In this prospective study, 60 patients were included who presented to the department of cardiovascular surgery of Dhaka Medical College and Hospital between January 2021 to December 2023. The patients were divided into two groups. Group A included the patients who underwent surgery combined with compression therapy while Group B patients received only compression therapy (CT). Ulcer healing time, recurrence rate and Venous Clinical Scoring System (VCSS) were analysed to determine the outcome.
Results: There was no significant difference in the demographic variables between two groups. 30 limb ulcers healed in the combined treatment group with a median healing time of 1.6 months (95% CI, 1.42–1.82), while 24 limb ulcers healed in the CT alone group with a median healing time of 2.15 months (95% CI, 1.92–2.45). The ulcer healing time was shorter in the combined treatment group than in the CT alone group (HR for ulcer healing 1.98, 95% CI, 1.474–2.309, $p<0.05$). Recurrence rate was higher in CT group (16.66% vs 53.33%). Besides VCSS was lower in Combined group that CT group after 1month, 6 month and 12 month of follow-up which was statistically significant. ($p<0.05$)
Conclusions: The present study has demonstrated combined treatments can shorten the ulcer healing time and reduce the ulcer recurrence rate compared with CT alone for treating VLU. Further randomized large scale multicenter study is recommended to provide a better management to the patients.

Keywords: Compression therapy, Surgery, Venous leg ulcer

INTRODUCTION

Venous leg ulcers (VLUs) are late indicators of chronic venous insufficiency (CVI) and venous hypertension. Calf muscle contraction and intraluminal valves helps to prograde blood flow while preventing blood reflux in normal conditions.[1] However, when venous reflux, obstruction or both co-exist, the resultant chronic ambulatory venous hypertension is responsible for the dermatologic and vascular complications resulting in forming a VLU.[2] CVI will give rise to both macro and microcirculatory dysfunction.[3] The increased intraluminal

pressure causes protein extravasation and fibrin cuff formation, which impedes the diffusion of oxygen and growth factors and activates the inflammatory response.[3] In addition leucocyte also migrates to extravascular space and release their chemical mediator's also known as leucocyte entrapment. Chronic inflammation and incompetent blood flow ultimately favor thrombus formation, causing further fibrosis and valvular destruction. Together, this inflammatory cascade of events impairs healing processes, which results in ulcer formation upon wounding.[4] An epidemiological survey from Asia, Eastern Europe, Latin America, and Western Europe showed that 2.21% of 99,359 CVI patients had an active or healed VLU when visiting their primary care physician for various reasons.[5] Common risk factors for VLU are family history, advanced age, female sex, previous deep vein thrombosis, multiparity, obesity.[6]

The initial manifestations of CVI are telangiectasia and reticular veins. Varicose veins, brown-orange hyperpigmentation, chronic leg edema, stasis dermatitis, atrophie blanche and lipodermatosclerosis are late indicators of venous insufficiency.[7] Color-flow duplex ultrasound is an inexpensive, non-invasive, and highly informative diagnostic test useful for superficial vein assessment. The technique can identify presence of thrombus and valve incompetence. Valve incompetence in superficial venous system is declared when reflux time is >0.5s. The commonly accepted criterion for significant reflux in perforating veins is 0.35 second of retrograde flow after release of compression of a vein segment below the perforator veins in the lower calf that with a diameter of more than 3.5 mm.[8,9]

Compression therapy (CT) with multilayer bandage is the first line of treatment modality of ulcer management. Various kinds of interventions like Flush ligation and stripping with phlebectomies(FLSP), ultrasound-guided foam sclerotherapy (UGFS), Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) have good effects on eliminating or reducing superficial venous hypertension and promoting ulcer healing.[10] In the Effect of Surgery and Compression on Healing and Recurrence (ESCHAR) study, CT combined with surgery had a lower ulcer recurrence rate.[11] Recently, another clinical trial (EVRA ulcer trial) concluded that CT combined with early endovenous ablation treatment could promote ulcer healing, reduce ulcer recurrence and prolong the patients' ulcer-free time.[12]

In the present study we tried to analyze the outcome of surgery combined with four-layer compression therapy for management of VLU.

METHODS

Study place

This prospective study was conducted in cardiovascular center of Dhaka Medical College and Hospital.

Study duration

The period of study was from 2021 to 2023.

Sample size

Total 60 patients were included in the study who were divided into two groups. Each group consists of 30 members.

Group A

Patients who underwent flush ligation and striping of great saphenous vein (GSV)and/or short saphenous vein with multiple phlebectomies with compression therapy

Group B

Patients who received only compression therapy (CT)

All the patients received phlebotonic agents like diosmin and hesperidin for ulcer management.

Inclusion criteria

The inclusion criteria were, age≥18 years, Active venous ulcer of the lower extremity due to venous reflux evidenced by imaging modalities (C6), Recurrent venous ulcers who did not receive compression therapy or any surgical intervention.

Exclusion criteria

The exclusion criteria were, leg ulcers from other causes, such as arterial ulcers, diabetic ulcers, malnutrition ulcers, and malignant ulcers, patient with reflux from deep veins, serious systemic disease, patients who could not tolerate compression therapy, patients with VLUs who had chosen other therapies and patients with deep vein thrombosis.

Eligible patients' personal and clinical details, including gender, age, body mass index (BMI), history of diabetes, smoking history, course of varicose veins, ulcer site, ulcer duration, ulcer diameter, venous reflux pattern and preoperative (Venous Clinical Severity Score) (Table 1) were recorded. Venous reflux was identified as isolated superficial venous reflux (ISVR), superficial venous reflux (SVR), segmental deep venous reflux (SDVR), full-length deep venous reflux (FLDVR) and calf perforator veins reflux (CPVR) according to the location of reflux aided by duplex ultrasonogram.

All surgical interventions were performed under spinal anesthesia. All the varicose veins were marked before surgery including perforator veins. Then flush ligation and stripping of GSV or short saphenous vein (SSV) with was done. Besides, multiple phlebectomies were performed including the incompetent perforator veins.

Four-layer compression bandage (Velfour) was used for CT. The target pressure at ankle was 30-40 mm hg. Group A received the CT after removal of stitches in the postoperative period. The bandage was changed after one week to observe the outcome. On the other hand, group B received only CT as a part of management of Venus ulcer.

Patients with active VLUs followed up monthly at outpatient visits after the intervention. The patients assessed at 1 month, 6 months and 12 months, respectively, after the intervention for venous clinical severity score (VCSS) scoring. Repeat duplex ultrasonogram was done if necessary. Patients with healed ulcer continued to follow up for 12 months to detect recurrence. The primary outcome was ulcer healing time. Secondary outcomes included the changes in VCSS at 1 month, 6 months and 12 months, the 12-month and recurrence rates in the two groups.

Statistical analysis

Statistical analysis was performed using SPSS software version22.0 IBM Corp, USA. The continuous variables were presented by mean±standard deviations (SDs) while categorical data were presented as percentages. We analyzed results with Kaplan-Meier curve to compare ulcer healing time and recurrence time between two groups. The VLCC scoring of two groups were compared by t-test. The Hazard ratio (HR) for time to ulcer healing and recurrence of the two interventions was also calculated with 95% confidence interval. A p value less than 0.05 was considered statistically significant.

RESULTS

A total number of 60 patients were included in the study who fulfilled the inclusion criteria from January 2021 to December 2023.

There were no significant differences noted among the demographic variables of the patients. Factors considered to affect ulcer healing such as gender, age, BMI, duration of varicose veins, ulcer duration, ulcer diameter and venous reflux pattern did not demonstrate any statistically significant difference between two groups. 30 limb ulcers healed in the combined treatment group with a median healing time of 1.6 months (95% CI, 1.42–1.82), while 24 limb ulcers healed in the CT alone group with a median healing time of 2.15 months (95% CI, 1.92–2.45). The rest of the patients in group-B required further treatment including surgery or endovascular management (Table 2).

The ulcer healing time was shorter in the combined treatment group than in the CT alone group (HR for ulcer healing 1.98, 95% CI, 1.474–2.309, P<0.05). (Figure 1) VCSS was lower in Combined group that CT group after 1 month, 6 month and 12 month of follow-up which was statistically significant (P<0.05).

Recurrence of ulcer was identified after 12 months of follow-up. The number of ulcer recurrence in the combined treatment group was 5 (16.66%) while it was 14 (53.33%) in the CT alone group. The combined treatment group had obviously lower ulcer recurrence than the CT alone group (HR for ulcer recurrence, 0.316, 95% CI, 0.258 to 0.477) which was statistically significant (Figure 2).

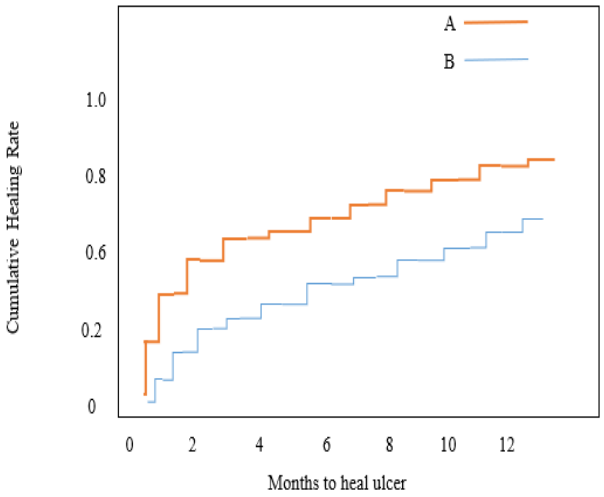

Figure 1: Kaplan-Meier analysis of ulcer healing (HR=1.98, 95% CI, 1.474-2.309).

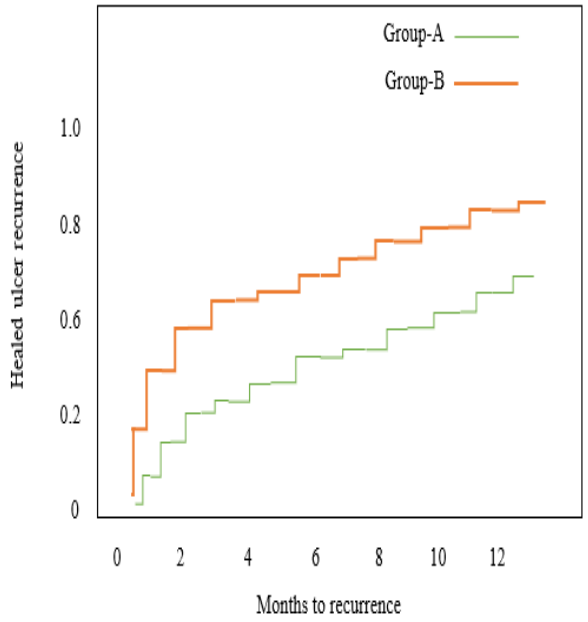

Figure 2: Kaplan-Meier analysis of ulcer 12-month recurrence (HR=0.316, 95% CI, 0.258 to 0.477).

Table 1: Venous severity scoring system.

Attribute	Absent (0)	Mild (1)	Moderate (2)	Severe (3)
Pain	None	Occasional	Daily	Daily with meds
Varicose veins	None	Few	Multiple	Extensive
Venous edema	None	Evening only	Afternoon	Morning
Skin pigmentation	None	Limited, old	Diffuse, more recent	Wider, recent
Inflammation	None	Mild cellulitis	Moderate cellulitis	Severe
Induration	None	Focal <5 cm	<1/3 gaiter	>1/3 gaiter
No. of active ulcers	None	1	2	>2
Active ulcer size	None	<2 cm	2-6 cm	>6 cm
Ulcer duration	None	<3 months	3-12 months	>1 year
Compression	None	Intermittent	Most days	Fully compliant

Total score=30

Table 2: Baseline characteristics of the study patients according to treatment group.

Characteristics	Compression with surgery (n=30)	Compression alone (n=30)	P value
Gender			
Male	25	22	0.126**
Female	5	8	
Age (in years)	35±2.6	42±5.4	0.321*
Hospital stays (days)	5.2±5.3	3.8±5.7	0.456*
BMI (kg/m^2)	25.4±5.69	24.4±4.73	0.118*
History of diabetes	12 (40.0%)	10 (33.33%)	0.443**
Smoking history	61 (30.5%)	55 (31.1%)	0.667**
Duration of varicose vein/CVI (months)	14±12.55	12±5.76	0.754*
Ulcer duration(months)	6.5±12.4	7.3±8.77	0.189*
Ulcer diameter(cm)	3.09±4.36	2.51±3.72	0.09*
Ulcer site			
Right medial malleolus	13 (43.33%)	11 (36.67%)	
Right lateral malleolus	4 (13%)	2 (6.67%)	
Left medial malleolus	10(33.33%)	14(46.67%)	
Left lateral malleolus	3 (10.00%)	3 (10.00%)	
Venous reflux			
GSVR	25 (83.33%)	26 (86.67%)	
SSVR	2 (6.67%)	3 (10.00%)	
Combined GSVR and SSVR	3 (10.00%)	1 (3.33%)	
CPVR			
The VCSS of pre-intervention	12.5±5.31	12.6±2.73	0.265*

*Independent-sample t-test, **Pearson Chi-Square, BMI-body mass index, GSVR- Great saphenous vein reflux, SSVR- short saphenous venous reflux, CPVR-Calf perforator veins reflux.

Table 3: The changes in VCSS at 1 month, 6 months and 12 months after intervention.

Time	Compression plus surgery	Only compression	P value*
1 month post-intervention	5.77±3.62	11.3±2.73	0.006
6 months post-intervention	4.36±2.92	8.60±2.88	0.002
12 months post-intervention	2.55±1.81	7.76±2.61	0.004

*Independent-sample t-test.

DISCUSSION

The venous leg ulcer (VLU) is a manifestation of progressive chronic venous disease (CVD). VLUs are often associated with increased resource usage resulting increased economic burden to both patients and society.[13] The higher recurrence rates are often due to incomplete management of chronic superficial venous insufficiency. Persistent chronic VLUs are also associated with higher incidence of cellulitis and repeated hospitalizations.[14]

The mainstay of treatment of VLU is correction of underlying venous disease. Adequate multilayer compression for VLUs has been the standard treatment for many years. But compression therapy does not eliminate the venous reflux despite its association with healing 65% of the ulcers within almost 24 weeks.[15] So ulcer healing time is prolonged and recurrence rate is high. On the other hand, surgical correction eliminates the pathological superficial venous system. So combined therapy provides a better outcome by reducing ulcer healing time and preventing recurrence.[16] In our study, combined surgery with compression therapy has demonstrated better outcome by reducing ulcer recurrence and faster healing time. Duplex ultrasound is still considered as main modality of diagnostic tool to diagnose underlying venous pathology.[17] In our study we also used duplex ultrasound to detect venous reflux which was responsible for VLU.

Most studies primarily evaluate the success of VLU treatment based on technical criteria, such as healing time and recurrence with limited consideration of clinical criteria related to patients' symptoms and quality of life.[18] Venous Clinical Severity Score (VCSS) is an important tool to assess the quality of life after different intervention for VLU. In our study, we have showed that combined surgical and compression therapy has produced a better VCSS score which coincides with other studies.[18,19]

There were some limitations of current study. The sample size was short. It has a short study period which was conducted in a single center. Patient selection was not randomized.

CONCLUSION

The first line of treatment for VLU is CT unless contraindicated. But CT alone cannot reduce ulcer recurrence. Besides Ulcer healing time is more in CT alone therapy which leads to a huge economic burden to the patients. The present study has proved that combined surgery and CT has provided a better outcome in managing VLU. So, in conclusion, we can say that combined treatments can shorten the ulcer healing time and reduce the ulcer recurrence rate compared with CT alone for treating VLU. Further randomized large scale multicenter study is recommended to provide a better management to the patients.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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