

Healing of venous ulcers by four layer bandage versus single layer short stretch bandage: a prospective randomised study.

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Abstract: Compression therapy is widely accepted as the corner-stone of venous leg ulceration treatment and often has a dramatic effect on outcome, with patients reporting reduced pain and improved mobility and improved quality of life as a result of ulcer healing. The present study has been done to evaluate the efficacy and safety of four layer compression bandage in comparison to short stretch compression bandage for healing of venous ulcer. The study was done in 40 patients of venous ulcer divided in two groups of 20 each by draw of ballots. Group A was treated with four layer compression bandage and Group B patients were treated with single layer short stretch bandage. Level of exudates decreased and surrounding skin showed improvement in both the groups. At 12 weeks ulcers healed in 45% patients in four layer bandage group while healing was seen in 35 % patients in single layer group. It was observed that healing was better in ulcers with short duration and lesser size in both groups as compared to long standing and large size ulcers.

Key words: Venous ulcer, Four layer bandage, Single layer short stretch bandage, Leg ulcer.

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I. Introduction

Venous disease is responsible for 60-70% of all ulcers in the lower leg. Venous ulcer is the most severe form of venous disease. The estimated life time prevalence for leg ulceration in developed countries is 1% and the point prevalence is 0.1 to 0.2 %. The resultant venous hypertension is associated with skin pigmentation, lipodermato-sclerosis and ulceration.¹

Compression therapy is widely accepted as the corner-stone of venous leg ulceration treatment. Antibiotics do not speed up ulcer healing in the absence of cellulitis and all other specific ulcer healing drugs are of dubious validity.² By applying an adequate level of compression, the diameter of veins may be reduced in both the superficial and deep system, although this does not occur in all the patients. The four layer bandage system is the standard method in the United Kingdom which comprises of orthopaedic wool, crepe bandage, elastic bandage and a final cohesive retaining layer. The short stretch system used as standard treatment in Europe and Australia comprises of orthopaedic wool covered by elastic bandage.³ The present study has been done to evaluate the efficacy and safety of four layer compression bandage in comparison to short stretch compression bandage in healing of venous leg ulcer.

II. Material And Methods

This study was conducted on 40 patients of venous ulcer presenting to Department of Surgery and Venous disease clinic at Pt. B.D. Sharma PGIMS, Rohtak over a period of 2 years from January 2015 to January 2017. All patients were divided into 2 groups- Group A and Group B. Twenty cases were allocated to each group. The allocation of patients to each group was done by randomization by draw of lots. Group 'A' patients were treated by Four Layer Bandage and Group 'B' patients were treated by Short Stretch Bandage.

Written and informed consent was taken from all the participants and a detailed history was taken with history of predisposing factors for varicose veins. Patients were examined for venous insufficiency and Ankle-Brachial Pressure Index was calculated to assess the arterial supply of the target limb. Only patients with ABI more than 0.8 were included in the study. Routine laboratory investigations and color doppler examination was done to assess the status of deep veins and superficial and perforator incompetence in all the patients. The target ulcer was assessed for quality of ulcer bed tissue , surrounding skin and level of exudates . The swab for culture

sensitivity was sent and antibiotics were given as per culture report. Venous ulcers of patients were bandaged according to their random number allocation. The target ulcer and limb was thoroughly cleansed with saline and povidone iodine solution. The wound debridement was done in sloughy and exudative wounds.

III. Application Of Bandages:

Group A (Four Layer Compression Bandages): In the four-layer bandage, the elastic layers were applied with pressure from the base of the toes. It consisted of f

Layer 1 (Orthopaedic wool): Orthopaedic wool provides a layer of padding that protects areas at risk of high pressure.

Layer 2 (Crepe Bandage): This layer adds extra absorbency and smoothes down the orthopaedic layer prior to the application of the two outer compression bandages.

Layer 3 (Elastic Extensible Bandage): This is the first of the two outer elastic bandages. It is a highly extensible bandage that provides a sub-bandage pressure of approximately 17 mm Hg when applied at 50% extension with a 50% overlap using a figure-of-eight technique.

Layer 4 (Elastic Cohesive Bandage): This layer provides the higher level of compression (sub-bandage pressure approximately 23 mm Hg) and must not be over-extended. Bandaging should extend over the upper portion of the gastrocnemius muscle to prevent slippage. The two outer elastic bandages, when used in combination, provide a sub-bandage pressure of approximately 40 mmHg.

GROUP B: All Group B patients were given short stretch bandage. Short-stretch bandages are inelastic bandages which comprise of orthopaedic wool layer covered by stretch bandage to create a firm ‘tube-like’ structure around the calf. When the calf muscle contracts the firmness of the tube discourages the backflow of blood that causes hypertension, thereby reducing ankle oedema. Short-stretch bandaging has a low resting pressure, with only temporary high levels of compression present when the patient is active.

Treatment Period was designated to be 1 to 12 Weeks. Participants came to venous disease clinic weekly following Day 1 for bandage and were assessed for healing of ulcer, target ulcer assessment, tolerability of product (very comfortable, comfortable, uncomfortable, very uncomfortable). Additional visits were advised if clinically indicated especially in earlier stages where the amount of discharge was more. Once a wound has been judged to be completely healed participants were advised fitting of long-term compression stockings and were advised to come for follow up monthly for 3 months. Statistical analysis was performed using Chi-Square and Student-T Test .

IV. Observations

Mean age of total patients in our study was 49.67 years. 18 patients (45%) were above 50 years of age. The youngest patient being 18 years old and oldest was 65 years old. Most of the patients had prolonged standing occupation and 12 patients (30%) were housewives. In the present study, left side was involved in 20 (50%) and right side was involved in 13 (32.5%) while bilateral ulcers were seen in 7 (17.5%) patients. Fifteen patients (37.5%) had ulcer of less than 6 months duration, 12 patients (30%) had ulcer duration between 7-12 months and 13 patients had duration of ulcer more than 12 months.

At the time of presentation, in Group A, maximum 9 patients (45%) had medium exudate level, 7 patients (35%) had copious discharge and four patients had minimal discharge while at 12th week, 19 patients (95%) had no discharge and only 1 patient (5%) had minimal discharge. In Group B, 8 patients (40%) had medium exudate level, while 5 patients (25%) had copious discharge and 7 patients had minimal discharge. At 12th week, only 3 patients (15%) had minimal discharge while rest 17 patients (85%) had no discharge from ulcer. This showed that exudate level decreases significantly after application of both types of bandages. Amount of discharge also went on decreasing in both types of bandages Statistically the difference between the two groups was not significant.

In Group A patients at the time of presentation, 9 patients (45%) had wet eczema in skin surrounding the ulcer area, 7 patients (35%) had dry eczema, 2 (10%) had erythema while no eczema changes were seen in two patients (10%). In Group B patients, at presentation, 8 patients (40%) had dry eczema, 5 (25%) had wet eczema, 5 patients (25%) had erythema and only 2 (10%) had no significant skin changes surrounding the ulcer area. At 12th week, most of the patients had improvement in skin condition surrounding the ulcer area and there was complete resolution of eczema and erythema. Significant improvement was seen in surrounding skin status after application of both types of bandages over ulcer area but there was no difference between two groups statistically.

Ulcer size and healing rate in Group A (Four Layer Bandaging):

In Group A, complete healing was seen in 9 patients (45%). At 12 weeks it was observed that all 4 ulcers which had size less than 5 cm² were completely healed (100%) and 5 out of 8 ulcers (62.5%) having size between 5 to 10 cm² showed complete healing. None of ulcers which had initial size more than 10 cm² healed

completely, though their size went on decreasing with less healing rate as compared to smaller sized ulcers.

Ulcer size and healing rate in Group B (Short Stretch Bandaging):

In Group B, at 12th weeks, complete healing was seen in 7 patients. It was observed that all ulcers (100%) which had size less than 5 cm² were completely healed . Only 5 out of 11 patients (45.45%) which had ulcer size between 5 to 10 cm² showed healing. No ulcer healed which had size more than 10 cm² at the time of presentation (Table 1)

Table 1: Comparison of results in Group A and Group B.

Parameter	Four layer bandage (Group A)		Short Stretch Bandage (Group B)	
	At presentation	At 12 weeks	At presentation	At 12 weeks
Number of patients with discharge from ulcer	20	1	20	3
No. of patients with healthy skin surrounding the ulcer area	2	14	2	14
Percentage of granulation	<25	15	0	16
	25-50	4	0	3
	50-75	1	1	0
	>75	0	10	1
	Healed	0	9	0
Ulcer size (cm ²)	No. of ulcers at presentation	No. of healed ulcer at 12 weeks	No. ulcers at presentation	No. of healed ulcers at 12 weeks
0-5	4	4	2	2
>5-10	8	5	11	5
>10-15	5	0	4	0
>15-20	3	0	3	0

Comparision of healing between two Groups:

It was observed that in the four layer bandage group, 9 patients (45%) showed complete healing while 7 patients (35%) showed complete healing in short stretch bandage group at 12 weeks. None of the ulcers healed which had initial size more than 10 cm² in either group.

On application of chi-square test, there was a statistically significant better healing in patients on using four layer bandage as compared to short stretch bandage (p= 0.003, i.e. p<0.05).

Ulcer healing in terms of chronicity of ulcers in both Groups (Four Layer Bandage And Short Stretch Bandage):

Ulcer healing in the two groups was dependent on the chronicity of the ulcers. In Group ‘A’, ulcer healing was highest in the ulcers which were present for less than 6 months duration; with 5 out of 7 ulcers healing at 12 weeks, whereas 3 out of 6 ulcers healed in the 6-12 months group and only 1 out of 7 ulcers healed which was present for more than one year duration.

Similarly in Group ‘B’, ulcer healing was highest in patients who had ulcers with less than 6 months’ duration viz. 3 out of 8.

V. Discussion

Venous leg ulcers are a common and recurring chronic wound caused by damage to the veins and consequent high venous pressure.¹ When compared with short stretch bandage, the four layer bandage increases the chance of healing in venous ulcer by around 30% when independent prognostic factors are taken into account. Multilayer bandage increases the stiffness and subbandage pressure as compares to single layer bandage.⁴ In the present study mean age of patients was 49.67 years. Other studies in the literature reported a mean age of 64 yrs to 77 years.⁵⁻¹⁰ Mean age in our study was less as compared to reported in literature possibly because young patients have to spend lot of time in standing occupation specially in developing countries as most of the patients in the present study had prolonged standing occupation. There is no systematic literature review regarding occupational risk factors for varicose veins. One prospective study has addressed occupational factors and it concluded that women who reported spending >8 hours a day in sedentary activities had a significantly higher incidence of varicose veins than those who spent <4 hours a day in such activities.¹¹⁻¹⁶ There were 27 males and 13 females in our study. In the literature there is female preponderance of venous ulcer.⁵⁻¹⁰ This may be due to geographical variations in the sex incidence of venous ulcer.

In our study, left side was involved in 20 patients (50%) while right side was involved in 13 patients (32.5%). Bilateral involvement was seen in 7 patients (17.5%). It is reported in literature that right side is involved in 32% to 41%, left side in 43% to 56% and bilateral involvement in 9% to 21% of patients.^{5,7-9}

Duration of symptoms varied from less than 6 month to 10 yrs in the present study. Maximum 15 patients (37.5%) had ulcer of less than 6 month duration while 12 patients (30%) had duration of 7-12 months and other patients had longer duration of ulcer. Various authors in the literature have reported varying duration

of presentation of ulcers ranging from less than 6 months to more than 5 years.⁵⁻¹⁰ In developing countries patients tend to neglect their symptoms specially in rural areas and may present very late.

Healing rates in four layer and short stretch bandaging at 12 Weeks:

The preferred treatment for leg ulcers in the United States is Unna's boot, in parts of Europe other than in the United Kingdom, short stretch bandaging is more popular, whereas four-layer bandaging is increasingly advocated in the United Kingdom.¹⁷ Different studies have given different healing rates with two types of bandages.

In the present study, healing rate was 45% and 35% in 'Four layer bandaging' and 'Short Stretch bandaging' respectively. Various studies on four layer bandaging have shown ulcer healing rates varying from 40 to 61%. Whereas the ulcer healing rates of short stretch bandaging in various studies has varied from 34 to 53.1% as shown in table 2.

Table 2: Comparison of healing in various studies

Sr. No.	Study	Year	Study Type	Results (Healing Rate)	
				Four Layer	Short Stretch
1	Duby et al ¹⁸	1993	Prospective & Randomized	44%	40%
5	Partsch et al ¹⁹	2001	Prospective & Randomized	No significant difference in healing rate.	
6	Moffatt et al ²⁰	2003	Prospective & Randomized	70%	58%
7	Frank et al ²¹	2004	Prospective & Randomized	No significant difference in healing rate.	
8	O'Brien ¹⁰	2003	Prospective & Randomized	54%	34%
9	Harrison ²²	2011	Prospective & Randomized	No significant differences in healing rate	
10	Susan ⁶	2009	Meta-analysis	Significantly shorter average healing times in four layer bandaging	
11	Present study	2017	Prospective & Randomized	45%	35%

Most of the studies reported in literature showed better healing with four layer bandage.^{6,10,18-20} However a few studies have reported equal healing rates with both types of bandages.^{19,21-22}

Ulcer healing in terms of chronicity of ulcers:

Ulcer healing in the two groups was dependent on the chronicity of the ulcers. In both groups healing was better in patients who had ulcers of less than 6 months duration and was poor in long standing ulcers. Franks et al also reported that chronic ulcers had slower healing rates.²¹ Susan et al conducted a meta-analysis comparing the two methods of compression bandaging which included 887 patients from seven trials. They concluded that larger ulcers and ulcers of longer duration took longer time to heal independently of one another and of treatment.⁶

VI. Conclusion

It is concluded that four layer bandaging has better results in healing of venous ulcers as compared to single layer short stretch bandage. Large size ulcers and chronic ulcers take long time to heal. Four layer bandaging is easy to apply in outpatient department (OPD) basis and leads to early healing of ulcers hence should be used in all patients of venous ulcers.

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