FOUR LAYER BANDAGE VERSUS CONVENTIONAL TREATMENT IN VENOUS LEG ULCERS

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ABSTRACT

BACKGROUND

Venous ulcers cause great disability and reduced quality of life if not managed appropriately. Venous leg ulcers significantly affect patients' physiologic and psychosocial well-being. Reducing the ambulatory limb venous pressure is the cornerstone for the management of venous leg ulcers. For venous ulcers, compression therapy has been called the gold standard of wound healing. Objective of this study was to compare the effectiveness of four-layer compression bandage with conventional single layer bandage in the treatment for venous ulcer in terms of healing status, reduction in size of ulcer area at follow up points and time taken for healing.

MATERIALS AND METHODS

A prospective study was carried out during the study period of 12 months, from April 2016 to April 2017 among 120 patients with venous leg ulcers (60 patients with four-layer bandaging (case) and other 60 patients with conventional management (control) in the Department of General Surgery, in our institution.

RESULTS

The study analysis showed significantly better healing status with four-layer bandage compared to conventional management. There was significant reduction in size of ulcer area at follow up points. Time taken for complete healing was also less with four-layer bandaging but not found to be statistically significant.

CONCLUSION

From this study, it can be concluded that four-layer bandage is effective in attaining better healing status and achieves better reduction in size of ulcer area compared to conventional management. Time taken for healing of the ulcer was also less among the four-layer bandage group but not found to be statistically significant.

KEYWORDS

Venous ulcer, Compression therapy, Four Layer Bandage.

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BACKGROUND

Venous disease is responsible for about 65 percent of all ulcers in the lower leg. Ambulatory venous hypertension is the cause for venous ulcer.[1] Compression therapy is the cornerstone of venous leg ulcer treatment and it has a dramatic effect on outcome, with patients having reduced pain and improved mobility and general quality of life as a result of their ulcer healing.[2]

Four-layer bandaging is a high-compression bandaging system (sub-bandage pressure 35-40 mmHg at the ankle) that incorporates an elastic layer which helps to achieve a sustained level of compression over time.

Four-layer bandaging was developed by a clinical group at Charing Cross Hospital, London. The group used Stemmer's theoretical framework, which suggested that an external pressure of at least 40mmHg at the ankle is required to achieve ulcer healing in patients with chronic venous insufficiency.[3]

The concept underlying the development of this system was the requirement for sustained compression, which could be achieved using a multi-layer bandage system. Compression therapy acts on the venous system in a number of ways to improve healing. In patients with venous disease the valves are damaged, which may cause the blood to flow back into the veins of the lower leg (venous reflux), producing high ambulatory pressures in the venous circulation in the upright position (ambulatory venous hypertension). Patients with venous disease and ulceration have got ambulatory pressures in excess of 90mmHg, compared with 10-20 mmHg in individuals with functioning valves.[4] Compression treatment increases the healing of venous ulcers compared with no compression. High compression is effective than low compression but it should only be used in the absence of significant arterial disease.[5] Four-layer bandage is very effective in reducing the ambulatory venous pressures.[6]

It is proven that multilayer compression bandaging aids in venous ulcer healing.[7] Compression with adhesive plaster bandaging is inadequate (30 mm Hg), and it depends on the

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technique of application, and dissipate rapidly after a few hours while the four-layer bandage achieves pressures of about 40 mm Hg, which depends less on the person applying it, and sustaining it for at least one week. Compression is related to the diameter of the ankle and it is greater in patients with small ankles. This is predicted from Laplace's law; the pressure in a cylinder exerted by uniform tension in the wall is inversely proportional to the radius. Graduated compression is therefore applied automatically when the same tension and overlap is used, as the radius of the leg increases from ankle to calf. The consistency in compression with the four-layer bandage is due to the overlap and elasticity of the bandages, which is achieved when bandages are applied at mid-stretch. Four-layer bandaging is associated with a rise in pressure of up to 45mmHg during walking, but at rest the pressure did not fall below 40mmHg.[8]

MATERIALS AND METHODS

This study was done at Government Medical College, Kottayam, in the Department of General Surgery. Government Medical College Kottayam is a tertiary care center in central Kerala in India.

The research was conducted after receiving approval from Institutional Review Board and Ethical committee. Patients admitted to general surgery wards or treated as outpatients with venous leg ulcers were taken up for study after obtaining informed written consent. Patients with POVD, rheumatoid arthritis, diabetes mellitus and other established dermatological conditions were excluded from the study. A total of 120 patients were included in this study. Patients were alternatively allotted to case and control groups. 60 of them to undergo four-layer bandaging& 60 to undergo conventional management. In Four Layer Bandage group, weekly the ulcers were re-bandaged after cleaning with saline. Conventional management includes daily cleaning and dressing of the wound with application of a single elastic bandage over it. Both groups received antibiotics according to culture and sensitivity. The total area of ulceration on each leg was measured every week. For the measurement of area of ulceration sterile gauze was applied over the ulcer and cut according to the shape of ulcer. The cut gauze piece was then applied over a graph paper containing 1cm x 1cm squares. The number of squares covered by the gauze piece were calculated. The patients were followed up every week for a period of 12 weeks or till the ulcer healed (whichever was earlier). Ulcers that do not start healing at 12 weeks or with less than 50% epithelialisation are considered to be treatment failures.

Four-layer bandage includes an innermost sterile gauze dressing to cover the ulcer. The first two layers of four-layer bandage consists of a soft cotton role and a non-elastic crepe bandage. Both these layers do not provide any compression. The third layer is the elastic bandage which provides a sub bandage pressure of 17mmHg at the ankle. The fourth layer is the cohesive bandage (Coban) which retains the bandage position and adds 23mmHg of pressure providing a total sub bandage ankle pressure of 40mmHg.

The ulcer healing is defined as complete when there is full epithelialization, partial when there is more than 50% epithelialization and nonhealing when less than 50% epithelialization. Ulcers that do not start healing at 12 weeks are considered to be treatment failures.

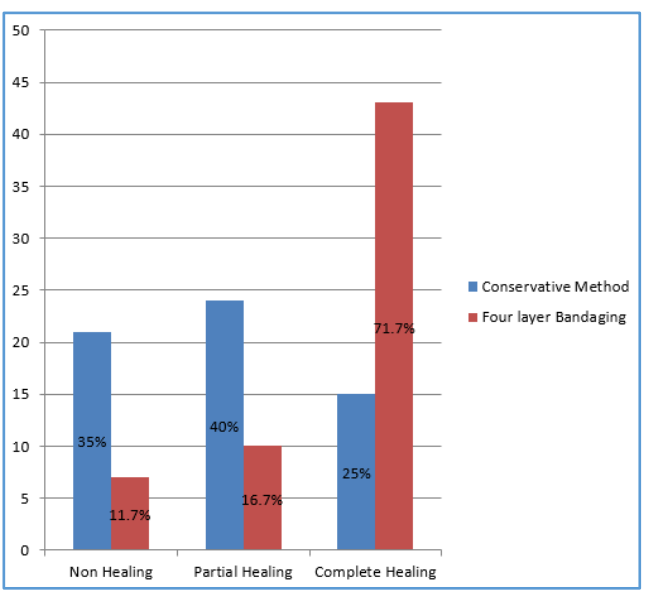
Demographic data such as age, address, gender and co morbidities were collected. For recording the progress of healing of ulcers, patients were followed up every week. The study results obtained as qualitative variables were analysed using Chi-square test and quantitative using independent sample t test. Data entered in Excel work sheet and analysed with SPSS-16 software.

RESULTS

The study included 120 patients of which 53.3% were males (n=96) and 46.7% were females. Among 120 patients in study population 72.4% belonged to productive age group of 20-60.

Age Group	Frequency	Percent
10-20	2	1.67
20-30	4	3.33
30-40	16	13.33
40-50	25	20.83
50-60	42	35.0
60-70	23	19.167
70-80	8	6.67
Total	**120**	**100.0**

Table 1. Distribution of Study Population based on Age

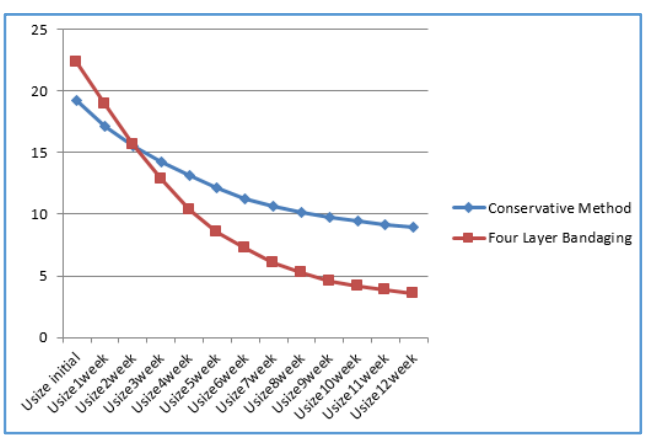


Graph 1. Comparison of Healing Status between Four Layer Bandaging and Conventional Management

Among the four-layer bandage group 71.7% (43 patients) had complete healing and 16.7% (10 patients) had partial healing.

	Conservative Method				Four Layer Bandaging			
Ulcer size(cm^2)	**Mean (SD)**	**Minimum**	**Maximum**	**Range**	**Mean (SD)**	**Minimum**	**Maximum**	**Range**
Initial	19.28 (11.745)	2	57	55	22.32 (13.809)	2	65	63
1st week	17.12 (11.115)	1	56	55	18.98 (13.413)	0	61	61
2nd week	15.57 (10.814)	0	56	55	15.68 (13.026)	0	60	60
3rd week	14.28 (10.605)	0	54	54	12.86 (12.820)	0	60	60
4th week	13.19 (10.386)	0	54	54	10.35 (12.245)	0	58	58
5th week	12.13 (10.230)	0	53	53	8.58 (11.538)	0	56	56
6th week	11.29 (10.131)	0	52	52	7.21 (10.825)	0	54	54
7th week	10.63 (9.851)	0	50	50	6.08 (10.014)	0	52	52
8th week	10.19 (9.594)	0	50	50	5.22 (9.499)	0	50	50
9th week	9.78 (9.419)	0	49	49	4.59 (8.895)	0	48	48
10th week	9.41 (9.143)	0	47	47	4.15 (8.198)	0	44	44
11th week	9.13 (8.939)	0	46	46	3.84 (7.834)	0	42	42
12th week	8.92 (8.736)	0	45	45	3.6 (7.352)	0	40	40

Table 2. Comparison of Reduction in Ulcer Size between Four Layer Bandaging and Conventional Management



Graph 2. Comparison of Mean of Ulcer Size between Four Layer Bandaging and Conservative Method

General Linear Model was the method adopted for assessing whether there was any significant reduction in size of ulcer at follow up points. The change in ulcer size at each week was found to be statistically significant between the four-layer bandaging group and the conservatively managed group. (p<0.001).

Treatment Method	Healing Status			Total
	Non-Healing	Partial Healing	Complete Healing	
Four Layer Bandaging	7 (11.66%)	10 (16.66%)	43 (71.66%)	60
Conservative Method	21(35%)	24 (40%)	15 (25%)	60

Table 3. Comparison of Healing Status between Four Layer Bandaging and Conventional Management

Chi square test was the method adopted for assessing healing status of patients. There is statistically significant difference in healing status between Four Layer Bandaging and conservative method (p value < 0.001). While comparing the time taken for healing, only those who had complete healing were included in the analysis.

Treatment Method	n (No. of Patients with Complete Healing Status)	Time for Complete Healing in Weeks	
		Mean	S.D.
Four Layer Bandaging	43	5.81	2.538
Conservative Method	15	6.73	2.463

Table 4. Comparison of Time Taken for Complete Healing in Weeks between Four Layer Bandaging and Conventional Management

Student T test was the method adopted for assessing time for healing of ulcer in patients. There is no statistically significant difference in time for healing in weeks between four-layer bandaging and conservative method (p value = 0.23).

Serial Photographs Showing Ulcer Healing with Four Layer Bandaging in a 54-year-old Male Patient

DISCUSSION

A prospective study was conducted in our institution, to assess the effectiveness of four-layer bandaging compared to conventional management. Study was conducted for a duration of 12 months among total of 120 patients. Total study population was divided into two groups of 60 each and labelled as case and control group respectively. Both case and control group comprised 60 numbers of venous ulcers. Cases were treated with four-layer bandaging while the control group was managed with conservative treatment.

Out of total population, 56 were females (46.7%) while the rest were males comprising of 53.3%. Entire population was divided into 7 age classes from 10-20 to 70-80. 35% belonged to age class 50-60. Data was analyzed by comparing healing status using chi square test, time taken for healing of ulcer using Student T test and reduction in ulcer size using general linear model.

Analysis of healing status between test and control group showed that in the control group, the number of non-healing, partial healing and complete healing were 21 (35%), 24 (40%) and 15 (25%) respectively while that of test group were 7 (11.66%), 10 (16.66%) and 43 (71.66%) respectively. A total of 88.32% showed healing with four-layer bandaging. Statistical analysis using chi square test found this difference to be significant with p-value of <0.001 for all the three healing status, indicating a better healing status among the case group which was treated with four-layer bandaging.

When comparing the time taken for healing in weeks, of cases with that of controls, it was found that the mean and standard deviation were 5.81 and 2.538 while that of controls were 6.73 and 2.463. Statistical analysis using Student T test shows that there is no statistically significant difference with p values 0.23.

When comparing the reduction in ulcer size area in weeks of cases with that of controls, it was found that the mean were 22.32, 18.98, 14.68, 12.86, 10.35, 8.58, 7.29, 6.08, 5.22, 4.59, 4.15, 3.84 and 3.6 while that of controls were 19.28, 17.12, 15.57, 14.28, 13.19, 12.13, 11.29, 10.63, 10.19, 9.78, 9.41, 9.13 and 8.92. Also, it was found that the standard deviations of cases were 13.809, 13.413, 13.026, 12.820, 12.245, 11.538, 10.825, 10.014, 9.499, 8.895, 8.198, 7.834 and 7.352. While that of controls were 11.745, 11.115, 10.814, 10.605, 10.386, 10.230, 10.131, 9.851, 9.594, 9.419, 9.143, 8.939 and 8.736. Statistical analysis using general linear model shows that there is statistically significant difference with p values <0.001.

In the study a total of 88.32% healed with four-layer bandaging. This is comparable to a retrospective study "Four-layer dressing in the management of chronic venous ulcers in the outpatient setting of a tertiary hospital in India done by Albert Abhinav and et al at department of Vascular Surgery, CMC, Vellore, India. Of the 170 patients studied, healing was seen in 87.6%.[9]

Similar results with better healing for four-layer bandage were seen in a study done by K. K. Tiwari et al in 2015. This prospective study included 20 patients [group A] with chronic venous ulcers on lower limbs for four-layer bandage and Other 15 patients [group B] with conventional wound dressing. Four-layer bandaging were done once weekly for three weeks. Majority of patients were having left sided chronic venous ulcers and the mean duration of the ulcers were 15.6 vs 10.86 months (Group A vs. Group B). 55% wounds in Group A were healed completely at the end of three weeks except few big and deep wounds remained. Most of these wounds also became smaller with minimal discharge. Size of wounds significantly decreased in Group A vs. Group B patients (0.7±0.81 cm vs. 1.73±0.77 cm, p<0.00031). They concluded that four-layer compressive bandage is an easy, effective, and reproducible method of treatment for the chronic venous ulcer.[6]

In our study 43 out of 60 patients (71.66%) with four-layer bandaging showed complete healing. This result was comparable to the prospective randomised study done by C J Moffatt et al. Patients were randomized to receive either four-layer or two-layer high-compression elastic bandage systems. A total of 112 patients were included in this study. After 12 weeks, 40 out of 57 (70%) patients randomized to the four-layer bandage system with follow-up had ulcer closure (full epithelialisation) compared with 30 out of 52 (58%) on the two-layer bandage, odds ratio = 4.23 (95% confidence interval 1.29-13.86), p = 0.02.[5]

Similar to our studies, better results in healing of ulcers with four-layer bandaging was seen in a randomized clinical trial done by O'Brien et al with regard to economic analysis of four-layer compression bandaging for venous ulcers. This study compared the cost-effectiveness of four-layer compression bandaging for venous leg ulcers with that of other available treatments. In this pragmatic trial, 200 patients with a venous leg ulcer were randomized either to four-layer bandaging (intervention group; n = 100) or to continue their usual system of care (control group; n = 100).

The follow-up for each patient was 12 weeks. Analysis was by intention to treat; the main outcome measures were time to healing and cost to the health board per leg healed. The Kaplan–Meier estimate of the healing rate at 3 months was 54 per cent with four-layer bandaging and 34 per cent in the control group. Throughout the 3 months, four-layer bandaging healed leg ulcers significantly earlier (P = 0·006). There was a significant reduction in the median cost per leg healed with four-layer bandaging (P = 0·040).[10]

Regarding the cost effectiveness of four layer bandaging, in 1998, C J Morrell et al done a prospective randomised trial of four-layer versus usual care provided by district nurses for the treatment of venous leg ulcer to establish the relative cost effectiveness of community leg ulcer clinics that use four layer compression bandaging .In this study with 1 year follow up, 233 patients with venous leg ulcers allocated at random to intervention (120) or control (113) group. Every week treatment with four-layer bandaging in a leg ulcer clinic (clinic group) or usual care at home by the district nursing service (control group). The main outcome measures studied were time to complete ulcer healing, patient health status, and recurrence of ulcers. Satisfaction with care, use of services, and personal costs were also monitored. The result of the study was that ulcers of patients in the intervention group Healed sooner than those in the control group over the whole 12 month follow up (log rank P = 0.03). At 12 weeks, 34% of patients in the intervention group were healed compared with 24% in the control. The crude initial healing rate of ulcers in intervention compared with control patients was 1.45 (95% confidence interval 1.04 to 2.03). Mean total NHS costs were £878.06 per year for the clinic group and £859.34 for the control. Community based leg ulcer clinics with trained nurses using four-layer bandaging is more effective than traditional home based treatment.[11]

In 2005 Clarke Moloney et al did a study to compare the effects of four-layer compression bandaging (4LB) for treating venous leg ulcers with other available treatments on health-related quality of life during treatment. In this trial, 200 patients with venous leg ulceration were randomised either to 4LB (intervention group; n = 100) or to continue their usual system of care (control group; n = 100). Analysis was done by intention to treat; quality of life measurements were taken at random and after six weeks of treatment. Study concluded that 4LB provided greater quality of life benefits than the control group particularly in the area of physical activity and social functioning. This study showed that 4LB significantly improves the quality of life of patients during treatment for venous leg ulceration.[12]

In our study majority of the patients (72%) were in productive age group of 20-60. These patients are the earning members of the family. With conventional treatment (daily dressing with single layer elastic bandage) patients have to spend time for ulcer care from nearby health care facility. Moreover, venous ulcer causes restriction of mobility and work capacity. Social activities are limited due to fear of injury to ulcer and negative body image. This profound psychosocial impact reduces the quality of life. Four-layer bandage need to be changed only once in a week and with these patients were able to do their routine activities. The health-related quality of life improved significantly with four-layer bandaging.

CONCLUSION

Venous ulcers, increase the social and economic burden of the society. For reducing the ambulatory venous hypertension, which is the underlying pathophysiology behind venous ulcers, four-layer compression bandage plays a significant role.

This prospective study was conducted at Government Medical College, Kottayam over a period of 1 year with 120 patients. This study demonstrated better outcome in terms of healing status and reduction in size of ulcer area among those who were treated with four-layer bandage compared to conventional management ($p<0.001$). The time taken for complete healing among those who were treated with four-layer bandage was one week lesser when compared to conventional management, but it was not found to be statistically significant.

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