

Research Article

A Comparative Study to Know the Efficacy of Four Layer Dressing Plus Hydrocolloid Patch with Four-Layer Dressing only in the Management of Chronic Active Venous Ulcer Patients

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Abstract

Background: Venous leg ulcers cause long-term suffering to the patients and will take more time to heal. There is a significant socioeconomic burden to the patients and community due to these active non healing venous ulcers. Many patients with venous ulcers lack economical & social support. Venous ulcers cause great disability and reduce quality of life. Compression therapy like four-layer dressing has been called the gold standard treatment of choice for healing of venous ulcers. We have done one study at our Institution to know the efficacy of four-layer dressing comparing with addition of hydro-colloid patch adding to four-layer dressing in the process of healing of venous ulcers in terms of time taking for early healing.

Methods: We have conducted a prospective randomized clinical study at Department of general surgery in our institution on Outpatient Department (OPD), services between October 2022 to June 2024. Out of total 70 patients with chronic active venous leg ulcers, 35 patients (Group-A) were treated with four-layer bandaging dressing with hydro-colloid patch and other 35 patients (Group-B) were treated with four-layer dressing only. We have compared the efficacy of both types of dressing systems, in promoting early healing rate of venous ulcers by comparing demographic details, size of venous ulcers and time taken for healing of ulcers.

Results: The study analysis showed significantly early healing of venous ulcers in term of duration (weeks) with four-layer bandage dressing with adding extra hydrocolloid patch over venous ulcer. There was significant reduction in size of ulcer area at early follow up visits in patients treated with four-layer dressing plus hydrocolloid patch. The duration was also taken less in fast healing of venous ulcers in the group of patients treated with four-layer bandaging with hydro-colloid patch, when compared with the group of patients treated with only four-layer dressing.

Conclusion: Our study concludes that four-layer dressing with hydro-colloid patch (Group-A) is effective in attaining better healing rate and achieves better reduction in size of ulcer area when compared with the group of patients (Group-B) treated only with four-layer dressing.

Keywords: Active venous ulcer; Compression bandage system; Four-layer bandage dressing (system); Hydro-colloid dressing patch; Venous doppler

Introduction

Chronic venous ulcers are very slow to heal and it causes long term suffering and intensive use of health care resources [1]. The quality of life of many patients with chronic venous ulcers will be changed due to long term problem. The expenditure towards this condition is substantial. Long standing chronic venous insufficiency with ambulatory venous hypertension cause non healing active venous ulcers in around 70% of the patients [2]. In previous many

studies shows that compression therapy is an effective treatment. The underlying mechanism which supported by compression therapy is that, it will narrow the veins and restores valve competence and reduces ambulatory venous pressure, thus reducing venous re-flux and helps in the healing process of ulcers [3]. However, the lack of evidences regarding exact type of compression therapy comparing a along with topical dressing is limited and it can lead to uncertainty and inconsistency in treatment decisions. Many primary wound contact dressings are often applied to ulcers beneath compression therapy to aid healing, promote comfort and control exudates and promotes in healing.

There are many dressing materials available for venous leg ulcers and hydrogel dressing is often prescribed for this venous disease. However, occlusive hydrocolloid dressings promote re-epithelization, enhances autolytic debridement, reduce pain and provide a barrier against bacteria [4]. Even though, some evidence bases are already present but exact type of topical agent usage in active venous ulcers with exudates is sparse.

The aim of the study is to compare the healing rate and area of reduction of size of venous ulcers in both groups of patients treated with four-layer dressing plus hydrocolloid patch in one group and four-layer dressing only in another group.

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Materials and Methods

This was a prospective open-label, randomized clinical trial conducted at our department of general surgery, All India Institute of Medical Sciences (AIIMS), Bibinagar, Hyderabad, Telangana, India. We have obtained ethical clearance to conduct the study from the institutional ethics committee's (AIIMS/BBN/IEC/109-A) prior to start the study. Study was conducted on outpatient department basis according to our inclusion criteria. Study sample was calculated based previous study and we have confined total of up to 70 patients based on our out-patient census of chronic venous insufficiency cases. Inclusion and exclusion criteria of our study participants included was given below.

Inclusion Criteria:

1. Patients with venous ulcer according to CEAP classification of varicose veins.
2. Age above 18 -70 years.
3. Male and female with chronic venous ulcers.
4. Ulcers between region of knee and ankle joint.
5. Patients with congestive heart failure, renal failures, malignancy, ulcers with chronic other skin disease, exposure to radiation will not be taken in the study.

Exclusion Criteria:

1. Above 70 years
2. Diabetic ulcers
3. Tropic ulcer
4. Patients with POVD, rheumatoid arthritis, diabetes mellitus and other established dermatological conditions will be excluded.
5. Arterial ulcers with ABI index less than 0.9.

The Venous Doppler of bilateral lower limbs of patients was done at Department of Radiology at our institution before starting the dressing. Venous Doppler duplex scan showing reflux >1 sec at Sapheno-femoral, >0.5 sec at sapheno-popliteal junction and perforators considered as significant. We divided them into two groups (Group-A and Group-B) 35 patients in each group and section done randomly. Randomization was done according to alternate pickup method. We had a total of 70 patients divided in to two groups (35 patients in Group-A & 35 patients in Group-B). According to inclusion criteria of the study, total number of 70 patients were enrolled in the study. After obtaining informed written consent, demographic data, a detailed clinical history, and physical findings, were recorded. Size of ulcer was measured by planimetry with sterile gauze or graph paper. All the patients underwent required blood investigations and venous Doppler of bilateral lower limb to check the competency and reflux of Sapheno-Popliteal Junction (SFJ) valves, Sapheno-Popliteal Junction (SPJ), perforator valves as well as to rule out deep venous thrombosis.

We have compared the below mentioned factors in both groups of patients:

1. Demographic data.
2. Co morbidity.

3. Total duration for complete/partial wound healing in both groups.
4. SFJ, SPJ incompetence status & culture of wound.
5. Rate of linear wound healing growth.
6. Patients' satisfaction.

In group-A patients (35) were subjected to four-layer dressing with hydrocolloid patch and other groups of patients (group-B) were subjected to only four-layer dressing every week with sterile gauze as protective layer over the ulcer. We have used same brand of four-layer dressing material throughout our study.

In group-B, patients were followed up every week up to 8 weeks in our hospital on outpatient day basis. According to ulcer size at the time of first presentation the hospital, the patients were included and divided into sub groups like 1 cm to 5 cm, 5 cm to 10 cm & more than 10 cm size of ulcer according initial size of ulcer. In the follow up period, the ulcer size of both the group of patients was calculated with sterile gauze and graph paper. The cut gauze piece was be then applied over a graph paper containing 1 cm × 1 cm squares and the number of squares covered by the gauze piece calculated.

Both the group of patients (Group-A and Group-B) were compared after 8-10weeks of follow up duration. According to our study we have defined, complete healing is, when there is full epithelization, partial, when there is more than 50% epithelization and non-healing when less than 50% epithelization. Ulcers that do not start healing at 8 weeks considered as treatment failures.

The working principle of Four Layer Dressing is as mentioned below,

1. Plain Stockinet: For securing the wound dressing.
2. Orthopedic Bandage: Absorbs exudates. Redistributes pressure around limb.
3. Cotton Compression Bandage: This is considered to be the second layer of the system. This will flatten the padding layer and aid absorbency of the orthopedic bandage.
4. Cotton and Rubber Elastic Bandage: Provides higher pressure at the ankle, with decreasing pressure exhibited at the calf to help improve upward blood flow. It is essential that the correct technique and pressure is used while applying the bandage.
5. Cohesive Bandage: This layer provides the higher level of compression. Sub-bandage pressure approximately 23mmHg.

Descriptive statistics were done using chi-square test, student t test and Mann-Whitney U test to analyze the results. Continuous variables were presented as mean for parametric data and median if the data are non-parametric or skewed. $p < 0.01$ was taken to calculate statistical significance.

Results

During the 16months of study period, we have applied four-layer dressing with hydrocolloid patch to group-A (35) patients and only four-layer dressing to Group-B (35) patients. The mean age group of the study subjects was 59.9 (9.78%) years in group-A (four-layer dressing plus hydrocolloid patch) and 57.9 (8.97%) in group-B (four-layer dressing group). The gender distribution showed 54 (77.1%) males as compared to 16 (22.8%) females in the study. The 12/35 patients out of 35 diabetics in Group-A and 14/35 (45.7%) in

Group-B. The 17/35 (42.8%) subjects were hypertensive in Group-A and 21/35(46.6%) in group-B.

In our study wound culture showed streptococcus 8/35 (22.5), staph aureus 11/35(31.4%) & E-coli 2/35 (5.7%) in group-A patients. In group-B (four-layer dressing only) patients streptococcus showed positive in 6/35 (17.1%) and staph aureus positive in 13/35 (11.11%).

In Group-A, the incompetence of SFJ valve (Sapheno-femoral junction) was present in 29/35(82.8%) patients and 30/35(85.7%) in group-B patients. In group-A 27/35(77.1%) subjects had SPJ (Sapheno-popliteal junction) incompetence and 28/35(80%) subjects in group-B.

The patients with venous ulcer in both male and females in Group-A having early healing rate in weeks as compared with Group-B patients (Table 1 and 2).

The patients with SFJ (Sapheno-femoral junction) incompetence and SPJ (Sapheno-popliteal junction) incompetence in Group-A had early healing in weeks as compared to Group-B patients having SFJ & SPJ incompetence (Table 3).

According to ulcer size, in our study the number of patients having less than 5 cm ulcer size was 7/35(20%), less than 10 cm size was 12/35(34.2%) and above 10 cm size was 16/35(45.7%). In group-B, the patients having ulcer size less 5 cm size was 8/35(22.8%), up to 10 cm size was 13/35(37.1%) and more than 10 cm was 15/35(42.8%). The mean healing time in group-A four-layer dressing with hydrocolloid patch was 4.2 weeks in less than 5cm ulcer size. In group-B the mean healing time was 5.3 weeks for ulcer less than 5 cm size. The mean healing time in group -A four-layer dressing with hydrocolloid patch was 5.7 weeks in less than 10 cm ulcer size. In group-B the mean healing time was 6.5 weeks for ulcer less than 10 cm. In both groups, it took more than 7 weeks to decrease the maximum size of ulcer if the ulcer size more than 10 cm size. In group-A patients the with ulcer size more than 10 cm with slight discharge had an early response to the hydrocolloid dressing.

As above mentioned, table the healing duration in weeks in different size ulcer patients in Group-A mainly in ulcer size group more than 5 cm to 10 cm and 10 cm had faster healing duration when compared to Group-B patients and significant(p-value<0.001) (Table 4).

Discussion

Chronic venous ulcer of lower extremity is a long-standing clinical condition that can cause disability and serious complications. Venous leg ulcers are late manifestations of chronic venous insufficiency. The management of chronic venous ulcers is very challenging and the condition is accompanied by varying degree of chronic pain. It can affect sleep and quality of life of many patients [5]. In our study, according to the ulcer size at first visit to the hospital and incompetence of venous segments involved, the mean healing duration in four layers with hydro-colloid dressing group (group-A) is 5.36 weeks in smaller size of ulcers (less than 5 cm) and 7.41 weeks in only four-layer dressing group (group-B) for patients with small size ulcers (less than 5 cm) with SFJ incompetence. Even though many previous studies suggested application of topical agents prior to compression therapy will have good results in early healing of the venous ulcers, but in our study, we have applied hydro-colloid dressing direct over the ulcer then we have applied compression therapy adding to it helps in early healing of venous ulcers mainly with some exudation. According to our study, the adding of hydro-colloid dressing to four-layer dressing for active venous ulcer patients had a good result in early healing rate when compare without adding any topical agents to compression therapy. In our prospective study we defined the effectiveness of adding hydro-colloid patch to four-layer compression therapy in chronic non healing ulcer patients in view of decreased ulcer size in a particular duration of weeks. Many previous studies shown that using of layered compression therapy will take more than 10 weeks to complete healing of the ulcer [6]. But in our study, adding the hydro-colloid patch to the four-layer compression therapy having good result (takes less than 7-8 weeks) in view of fast healing rate.

Hydro-colloid dressings contain an inner layer that is self-adhesive, gel forming, and composed of hydrophilic colloid particles such as Carboxy-Methylcellulose (CMC), pectin, gelatin, or an elastomer [7]. This layer absorbs exudate and swells into a gel-like mass over the wound. This allows for a moist healing environment and also provides thermal insulation to the wound bed. The outer layer, which usually consists of polyurethane, seals and protects the wound from bacteria, foreign debris, and shearing. These dressings are available in a variety of sizes/shapes and also come in a paste, powder, or granule form. The effectiveness of these dressings lies in their ability to provide a moist healing environment, prevent contamination, promote

Table 1: Distribution of study participants as per baseline characteristics (n=70).

Sr. No	Variable		Group A n= 35 No. (%)	Group B n= 35No. (%)	Total No. (%)
1	Age in years	Mean Age (SD)	59.9 (9.78)	57.9 (8.97)	58.9 (9.37)
		40-50	7(43.8)	9(56.2)	16 (100)
		50-60	9(37.5)	15(62.5)	24 (100)
		60-70	12(63.2)	7(36.8)	19 (100)
		>70	6(60)	4(40)	10 (100)
2	Gender	Male	24(44.4)	30(55.6)	54 (100)
		Female	11(68.8)	5(31.2)	16 (100)
3	Co-Morbidity	HTN	17/35	21/35	38/70
		DM	13/19	14/35	26/70
4	Ulcer size	0-5 cm	6 (37.5)	10(62.5)	16 (100)
		5-10 cm	10 (45.5)	12 (54.5)	22 (100)
		>10 cm	19 (59.4)	13 (40.6)	32 (100)
5	SFJ incompetence	Yes	29 (49.2)	30 (50.8)	59 (100)
		No	6 (54.5)	5 (45.5)	11 (100)
6	SPJ Incompetence	Yes	27 (48.2)	29 (51.8)	56 (100)
		No	8 (57.1)	6 (42.9)	14 (100)
7	Follow up duration in weeks	Mean (SD)	5.94 (0.99)	6.71 (1.13)	6.33 (1.13)

Table 2: Comparison of Mean Healing Duration in weeks in group- A and group-B as per gender distribution.

Group	Gender	N	Mean duration for healing in weeks	Standard deviation	U- statistics	P-Value*
Group-A	Male	24	5.55	0.93	250	<0.001
	Female	11				
Group-B	Male	30	6.63	0.97		
	Female	5				

*Mann-Whitney U test used for statistics.

Table 3: Comparison of healing duration in patients having SFJ and SPJ Incompetence in both groups (Group-A & Group-B).

	Group	Mean (SD) duration required for healing in weeks	t- value	P value
Patients having SFJ incompetence	Group A (n=29)	5.64 (0.913)	-4.46	<0.001*
	Group B (n=6)	6.75 (0.991)		
Patients having SPJ incompetence present	Group A (n=30)	5.61 (0.845)	-5.61	<0.001*
	Group B (n=5)	6.87(0.823)		

*Students t test.

Table 4: Comparison of duration required for healing in weeks as per different ulcer size in both groups (Group-A & Group-B).

Baseline Ulcer size	Mean (SD) duration required for healing in weeks		Statistic	p-value
	Group-A	Group-B		
0-5cm	4 (0)	5.6 (0.64)	3	0.002*
5-10cm	5.41(0.41)	6.53(0.49)	4.5	<0.001*
>10cm	6.12 (0.63)	7.52 (0.59)	-6.37	<0.001 [§]

*Mann-Whitney U test § Student's t test.

autolytic debridement, and not require a secondary dressing [8]. They can remain in place for up to 7 days or until drainage is noted from beneath the dressing. They are indicated for partial and full-thickness wounds with low-moderate exudates, granular and necrotic wounds, minor burns, and pressure ulcers. They must be avoided in clinically infected wounds. Caution should also be taken in fragile peri wound skin as the adhesive may cause further damage.

In some previous studies like, Meyer FJ, et al. [9,10] in their prospective randomized study of 133 patients, compared four-layer dressing with 3-layer paste bandages in the treatment of venous leg ulcers. They Concluded that, three-layer paste bandages were significantly more effective at healing venous ulcers than four-layer regimen.

In another study like, in 1990, Darkovich, et al. [11] compared (Biofilm) a hydro-gel dressing, compared with normal gauze in a total number of 90 patients. The authors of this study concluded that hydrogel dressing facilitated healing of pressure ulcers by promoting more rapid epithelization.

As many previous studies showed the effectiveness of four-layer dressing along with some topical usage of adhesive ointments and dressings. But in our study, we have added hydro-colloid patch in extra to four-layer dressing as a compression therapy in the management of chronic non healing active venous ulcers and had significant result over with topical agent. As per our study it showed that adding hydrocolloid patch having benefit in the early healing of venous ulcers in terms of duration and decreased size of ulcer in less duration.

Conclusion

We conclude that (after this study), adding topical hydro-colloid dressing with four-layer dressing reduce the discharge and helps early healing of ulcer as well as reduces the size of ulcer early. We conclude that the hydro-colloid patch adding to four-layer compression therapy is very effective over only four-layer compression therapy in the management of chronic active venous ulcers.

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