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THE EFFECTIVENESS OF 4-LAYER COMPRESSION DRESSING ON HEALING IN PATIENTS WITH CHRONIC LEG ULCERS

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ABSTRACT

Objective: To provide a comprehensive descriptive analysis of the healing outcomes in patients with chronic leg ulcers treated with a four-layer compression dressing over a 24-week study period.

Study Design: A descriptive case series.

Settings and Duration of Study: Department of General Surgery, Sir Ganga Ram Hospital Lahore, from 22-06-2024 to 21-12-2024.

Methods: Total 80 patients of 15-70 years age, having venous leg ulcers of >1cm^2 and ankle-brachial index >0.8 were selected and consent taken. Demographic data, PUSH score, and history of diabetes, hypertension and smoking were documented. All patients underwent a standardized treatment by application of a four-layer compression dressing with 40mmHg compression pressure. Patients were followed up for 3 months. Endpoint was determined based on the PUSH tool. The grades of 0,1 and 2 were labelled as healing. All data collected in this study was analyzed using SPSS v.27.0. To account for potential effect modifiers like age, gender, ulcer area, duration, weight, diabetes, hypertension, and smoking, stratification was employed and Chi-square test was applied and p≤0.05 was significant.

Results: Mean PUSH score after 3 months of treatment was 3.07±2.60 and ulcer healing was observed in 49 (61.3%) of the patients.

Conclusion: The 4-layer compression dressing had significant role in chronic venous ulcer healing over 12 weeks period, especially in younger age groups as well as non-diabetic, normotensive and non-smoker patients with less than 12 weeks duration of ulcers.

Keywords: *venous leg ulcers, PUSH score, 4-layer compression dressing, healing.*

INTRODUCTION

Venous leg ulcers typically show a slow healing process, leading to prolonged misery and substantial use of healthcare funds.[1,2] Beyond the direct financial burden on the healthcare system, these chronic wounds impose significant hidden problems on the community. These include productivity losses, dependance on social support systems -either funded by community or government- for individuals with limited mobility, and high personal expenses related to homebased care of chronic leg ulcers.[3] Patients frequently report that venous leg ulcers result in persistent pain, reduced functional capacity, restricted movement, social separation, and a poor quality of life.

Approximately 70% of leg ulcers are attributed to venous pethology,[4] and evidence demonstrates that compression therapies are good management options. However, with the development of numerous compression systems, along with inadequate data regarding the comparison of their effectiveness, there is much uncertainty and incomplete information available during decision making for treatment of the patients. Variations in cost, availability of expertise for application, patient comfort, and ease of use further highlight the need for detailed information

regarding these systems for clinicians as well as patients. A 2009 systematic review[5] concluded that multilayered high-compression dressings were more effective as compared to single-layered low-compression dressings. They further demonstrated that multilayered systems integrating the elastic components outperformed the systems which integrated the non-elastic alternatives.[5]

The debate over the ideal type of multilayered compression systems is still in progress, with several trials comparing long- and short-stretch systems conducted.[6-8] However, studies to compare other types of compression dressings are limited, and even less focus on compression hosiery, despite its common use by the clinicians. An analysis of two studies comparing two-layer compression hosiery with short-stretch dressings found higher healing rates with hosiery.[9,10] Contrarywise, two other studies evaluating compression hosiery to other modalities in the management of chronic venous ulcers observed no significant difference in the healing outcomes.[11,12]

Koksal et al.'s study [13] compared the compression dressing group (Group A) with hydrocolloid dressing group (Group B), with 15 patients each. The ulcer duration was
16.6±5.8 and 16.9±6.2 weeks in Group A and B, respectively ($p > 0.05$). Ulcer recurrence rates were 74% and 73% in Group A and B, respectively ($p > 0.05$). Complete healing was observed in 74% of Group A and in 81% of Group B, showing no statistically significant differences between the groups. However, ease-of-use scores were 9.04±2.38 and
17.27±3.27 in group A and B, respectively, with statistically significant difference ($p < 0.001$).

Finlayson KJ et al.[14] performed a study to assess the efficiency of four-layer compression dressings compared to Class-3 compression hosiery in improving healing and quality of life for patients with chronic leg ulcers. Data from 103 participants were composed over a period of 24 weeks, which included demographics, ulcer characteristics, pain, depression, and QoL. After 24 weeks, healing rates were 86% for the compression bandage group and 77% for the hosiery group ($P = 0.24$). The median time of healing was 10 and 14 weeks in bandage and hosiery group, respectively ($P = 0.018$). Cox proportional hazards regression analysis revealed that the participants who were using the four-layer bandages had 2.1 times the potential to heal (95% CI 1.2–3.5) than those who were using hosiery. Larger ulcer size and longer duration, were significantly associated with late healing of leg ulcers.

This study is important for addressing knowledge gaps and providing evidence-based guidance in managing the chronic venous ulcers. The introduction points out the challenges and inconsistencies in the available data associated with various compression systems while highlighting the lack of specific data on the effectiveness of four-layer compression dressings used in chronic ulcers. Given their potential benefits, such as ease of application and improved patient comfort, it was essential to evaluate the effectiveness of four-layer compression dressings. Current study aimed to provide evidence in order to promote patient care, informed clinical decision-making, and also contribute towards the ongoing discussion about the best treatment for chronic venous leg ulcers. By bridging the current knowledge deficit, it sought to offer a comprehensive descriptive analysis of the healing outcomes in patients with chronic leg ulcers treated with a four-layer compression dressing over a period of 24-week, including healing rates, and the impact of effect modifiers.

Material and Methods:

This is a descriptive case series conducted at Department of General Surgery, Sir Ganga Ram Hospital Lahore, from 22-06-2024 to 21-12-2024, over a period of six months. Ethical approval was taken from Institutional review board. Sample size was calculated taking 95% confidence level, 8% margin of error, and healing frequency of 86% in four-layer dressing taken from the study conducted by Finlayson et al.[14] Total 80 patients were selected by nonprobability consecutive sampling technique according to the inclusion criteria. All patients of 15-70 years age, having venous leg ulcers of > 1 cm and ankle-brachial index>0.8 were included in the study. Venous ulcers were defined as open lesions between the knee and ankle joint that occurred in the presence of venous disease confirmed by doppler USG. Patients who were immobilized, having deep venous thrombosis on duplex scan, infectious non-healing ulcer on examination, history of coagulation profile impairments, chronic pulmonary disease (Asthma, ILD), and congenital heart lesions, and/or refusal to participate in the study were excluded. To gauge the effectiveness of the treatment and track wound healing, we employed the "Pressure Ulcer Scale for Healing (PUSH) tool for ulcer healing." This tool provided objective measurements of the healing process.

Informed consent was diligently obtained from each eligible patient. Age, gender, weight, ulcer area, duration in weeks, PUSH score at inclusion, and history of diabetes, hypertension and smoking were documented for all the patients. Subsequently, all enrolled patients underwent a standardized treatment protocol, which included the application of a four-layer compression dressing with a consistent compression pressure of 40mmHg. To monitor progress and facilitate healing, patients were regularly assessed in the OPD, and the four-layer compression dressing was replaced every two days until complete wound healing was achieved. To monitor changes in edema, we conducted ankle and calf circumference measurements at regular intervals of every two weeks. These measurements were taken at two specific points: 2 cm above the medial malleolus and 5 cm below the tibial tuberosity. Patients were followed up for a duration of 3 months, with monthly appointments scheduled for each participant. The study's endpoint was determined by whether the wound had successfully healed or not by the conclusion of the 3-month study period, based on the PUSH tool. The grades of 0,1 and 2 were labelled as healing. This data collection procedure was designed to ensure thorough and systematic monitoring of patients' progress and treatment outcomes in the context of chronic venous leg ulcers.

All data collected in this study was diligently recorded and analyzed using SPSS v.27.0. Categorical variables, such as gender, DM, HTN, smoking and healing outcomes were presented as frequencies and percentages. For continuous variables, including age, weight, ulcer area, ulcer duration, and PUSH scores at inclusion and 3 months, descriptive statistics were provided, reporting mean values accompanied by standard deviations (mean ± SD). To account for potential effect modifiers like age, gender, ulcer area, duration, weight, diabetes, hypertension, and smoking, stratification was employed. Subgroup analyses was conducted, and the Chi-squared test was used for categorical comparisons. Statistical significance was determined at a significance level of $p \leq 0.05$. This rigorous analysis approach enabled us to explore the impact of potential effect modifiers and assess the effectiveness of the four-layer compression dressing in treating chronic venous leg ulcers comprehensively.

Results:

Total 80 patients with mean age of 43.96 ± 13.18 years were included in the study. Study group included 49 (61.3 %) males and 31 (38.8 %) females. Mean weight of all the patients was 56.61 ± 4.99 kg. Mean ulcer area was 14.77 ± 8.45 cm^2 with a mean duration of 18.37 ± 6.94 weeks. Study population included 34 (42.5 %) diabetics, 39 (48.8 %) hypertensive patients and 28 (35.0 %) smokers. PUSH score at presentation was 12.70 ± 2.11. Table-I

Mean PUSH score after 3 months of treatment was 3.07 ± 2.60 and ulcer healing was observed in 49 (61.3 %) of the patients. Table-II

Patients were divided on the basis of age i.e., 15-35 years group included 22 patients; 36-50 years group included 28 patients; 51-70 years group included 30 patients. Healing of ulcers was observed in 100% patients in 15-35 years group; in 75% of the patients in 36-50 years group; and in 20% of the patients in 51-70 years age group. The observed difference was statistically significant ($p < 0.001$). Healing was seen in 65.3 % of the males and in 54.8 % of the females ($p=0.349$). Ulcer healing was seen in 54.3 % of the patients with ≤55kg weight and in 66.7 % of the patients with >55kg weight ($p=0.259$). Healing was seen in 63.6% of the patients with ≤12 weeks of ulcer duration and in 60.3% of the patients with >12 weeks of ulcer duration ($p=0.787$). In patients with ulcer ≤ 10 cm^2, 76.7 % patients healed, while in those with >10cm^2 ulcer area 52% patients healed, with statistically significant difference ($p=0.028$). Healing ratio was 47.1% in diabetics and 71.7% in non-diabetics ($p=0.025$); 46.2% in hypertensives and 75.6% in normotensives ($p=0.007$); 42.9% in smokers and 71.2% in non- smokers ($p=0.013$). Table-III

Table-I Demographic data

Variable	Value (n=80)
Age, years	43.96 ± 13.18
Gender, Male / Female, N (%)	49 (61.3 %) / 31 (38.8 %)
Weight, kg	56.61 ± 4.99

Diabetes, N (%)	34 (42.5 %)
Hypertension, N (%)	39 (48.8 %)
Smoking, N (%)	28 (35.0 %)
Duration, weeks	18.37 ± 6.94
Ulcer area, cm^2	14.77 ± 8.45
PUSH score at presentation	12.70 ± 2.11

Data is entered as mean ± S.D. unless mentioned otherwise

Table-II Outcome data

Variable	Value (n=80)
PUSH score at 3 months	3.07 ± 2.60
Ulcer healing, N (%)	49 (61.3 %)

Data is entered as mean ± S.D. unless mentioned otherwise

Table-III
Assessment of ulcer healing after stratification of data

Effect modifier	Subgroup	Healing	P value
Age, years	15-35 (N = 22)	22 (100.0 %)	<0.001
	36-50 (N = 28)	21 (75.0%)	
	51-70 (N = 30)	6 (20.0%)	
Gender	Male (N = 49)	32 (65.3 %)	0.349
	Female (N = 31)	17 (54.8 %)	
Weight, kg	≤55 (N = 35)	19 (54.3 %)	0.259
	>55 (N = 45)	30 (66.7 %)	
Duration, weeks	≤12 (N = 22)	14 (63.6 %)	0.787
	>12 (N = 58)	35 (60.3 %)	
Ulcer area, cm^2	≤ 10 (N = 30)	23 (76.7 %)	0.028
	> 10 (N = 50)	26 (52.0%)	
Diabetes	Yes (N = 34)	16 (47.1 %)	0.025
	No (N = 46)	33 (71.7 %)	
Hypertension	Yes (N = 39)	18 (46.2 %)	0.007
	No (N = 41)	31 (75.6 %)	
Smoking	Yes (N = 28)	12 (42.9 %)	0.013
	No (N = 52)	37 (71.2 %)	

Discussion:

The four-layer compression bandage is classified as high compression which gives an ankle sub-bandage pressure of 35–40 mmHg. However, its clinical efficacy can vary depending on the practitioner's proficiency and the skill to apply the correct pressure. As a result, meta- analyses or review articles may not fully capture real-world outcomes.[10,15,16] The four-layer bandage has shown significant effectiveness in promoting the ulcer healing. In our experience, all patients achieved improvement in chronic ulcers to a variable degree, with majority achieving proper wound healing. For these patients, additional interventions, such as endovenous ablation or surgery, may augment the healing process and decrease the recurrence rates. Nevertheless, evidence on the superiority of open surgical or endovenous procedures over compression bandage therapy remains inconclusive.[16]

Current study found out that majority of the patients were of 50-70 years age. The findings were consistent with those presented by Berenguer Pérez et al.[17] who stated that the incidence of chronic venous ulcers rises after the age of 65 years. Current study also observed that wound healing after 3 months of 4-layer compression dressing was observed in 61% of the patients. Healing rates were higher in patients who were younger than 50 years. Finlayson KJ et al.[14] observed in their study that 84% of the patients experienced venous ulcer healing after 24 weeks duration of treatment with 4 layered compression dressing. Their results were better than those of current study most likely due to the longer duration of treatment. They also observed that the percentage reduction in ulcer area was 96% among this group of patients.

In the study conducted by Shah B et al. [18], the mean age of the patients was 45.76 years, with males (67%) predominance. Their observations were close to those observed in current study (mean age = 43.96 years, 61% males). They observed that the patients who were given four- layer compression bandage needed significantly fewer follow-up visits (mean=4.88) as compared to those prescribed two-layer compression dressing (mean=6.46) (p <0.001). A study by O'Meara S et al. [19] found that four-layer bandage improved the probability of ulcer healing by approximately 30%, even when the independent prognostic factors were taken into account.

A 2023 Turkish study[20] observed that ulcers of less than 10 cm needed a 4-week treatment with 4-layer compression bandage, whereas >10cm sized ulcers required 11 weeks long treatment with 4-layer compression bandage for proper healing. In that study, mean duration of ulcer healing was significantly higher in larger ulcers (32 weeks) as compared to in smaller ulcers (12 weeks) ($p<0.001$).[20] Their results are similar to those observed in current study as we observed significantly higher healing rates in those patients with ulcer of less than or equal to 10cm2 surface area i.e.,77% as compare to in those with >10cm2 size ulcers (52%) (p=0.028). in a study by Jaiswal A et al.[21], when patients were evaluated after 3 months of treatment, mean ulcer size was 1.66±1.55 cm in 4-layer bandage groups as compared to 4.22±3.59 cm in those without any treatment with compression bandage (p=0.001).

Current study also observed that the higher healing rates were present in non-smokers, normotensive and non-diabetic patients. This observation warrants the need for further extensive clinical trials and observational studies to find out the impact of comorbidities on the incidence and healing of chronic leg ulcers. These findings also reflect that life style modification can significantly impact chronic ulcer healing among the patients of venous insufficiency.

Conclusion:

The 4-layer compression dressing had significant role in chronic venous ulcer healing over 12 weeks period, especially in younger age groups as well as non-diabetic, normotensive and non- smoker patients with less than 12 weeks duration of ulcers.

Conflict of interest:

No conflict of interest.

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