

Combination of hydrocolloid dressing and medical compression stocking versus Unna's boot for the treatment of venous leg ulcers

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Summary

Background: Various therapeutic approaches have been developed to manage venous ulcers. In this study the effectiveness of a hydrocolloid dressing (Comfeel Ulcer Dressing) in comparison to the Unna boot, the prototype of rigid bandages, was evaluated.

Methods: Design: Prospective, comparative study. **Setting:** University hospital. **Patients:** Sixty patients diagnosed with post-thrombotic chronic venous insufficiency with venous ulcers were randomly assigned to two groups of 30 patients. **Interventions:** In group A, the Unna boot, and in group B, hydrocolloid dressing in addition to the elastic compression were used. **Measures:** The two groups were compared in terms of 1) complete healing, 2) weekly wound surface reduction, 3) time to complete healing, 4) performance characteristics (ease-of-use score), 5) pain during application and at home, 6) application time.

Results: The duration of the ulcers was 16.6 ± 5.8 weeks in group A and 16.9 ± 6.2 in group B ($p > 0.05$). Previous ulcer recurrence was 74% (20/27 patients) in group A and 73% (19/26 patients) in group B ($p > 0.05$). The initial ulcer size was 6.38 ± 1.2 cm² in group A and 6.19 ± 0.8 cm²

in group B ($p > 0.05$). The complete healing rates were 74.07% (20/27) in group A and 80.76% (21/26) in group B ($p > 0.05$). The weekly wound surface reductions were 1.28 ± 0.72 cm²/week and 1.16 ± 0.38 cm²/week in groups A and B, respectively ($p > 0.05$). The ulcer healing time was 6.85 ± 3.60 weeks in group A, whereas it was 6.65 ± 3.31 weeks in group B ($p > 0.05$). Ease-of-use score was 9.04 ± 2.38 in group A and 17.27 ± 3.27 in group B and the difference was significant ($p < 0.0001$). A higher degree of pain was reported by the patients who were treated with the Unna boot, both during application (group A 3.69 ± 1.35 , group B 1.88 ± 1.48 , $p < 0.0001$) and at home (group A, 3.27 ± 1.08 , group B, 1.88 ± 1.11 , $p < 0.0001$). The average time spent on Unna boot changes was 150.59 ± 34.73 min, compared to 134.54 ± 43.39 min in group B ($p > 0.05$).

Conclusions: These results demonstrate the superiority of hydrocolloid dressing plus elastic compression treatment in terms of patient convenience.

Key words: venous ulcer; hydrocolloid dressing; Unna boot; patient compliance

Introduction

Venous ulcers have a significant impact on quality of life, and the cost associated with the care of these chronic wounds is substantial. It is estimated that 24 million United States citizens have varicose veins, 6 million to 7 million have leg stasis changes, and 400 000 to 500 000 have present or previous venous ulcers [1]. Nelzen et al. reported leg ulcers in 827 of 270 800 inhabitants of Skorabury, Sweden. Fifty-four percent of these ulcers were purely venous in origin, giving a prevalence of 0.16% [2]. The estimated annual cost of ulcer treatment is \$ 25 million in Sweden and may

be between \$ 1.9 billion and \$ 2.5 billion in the United States [3, 4].

The optimal clinical management of venous ulcers is not clear. A better understanding of the pathophysiology has led to the development of new approaches, such as new types of wound dressings, topical and systemic therapeutic agents and growth factors. However, the mainstay of the therapy is the relief of venous hypertension by external compression that is the "gold standard" [5, 6]. The traditional Unna boot which is the choice of our clinic, is a popular and effective form of ther-

apy. It is a moist zinc-impregnated paste bandage and provides both compression and topical treatment [7]. However, occlusive hydrocolloid dressings have been used for many years as an adjunct to elastic compression for the treatment of venous ulcers. They promote re-epithelialisation, enhance autolytic debridement, reduce pain and provide a barrier against bacteria [6].

Our current study aimed to compare two different modalities; a hydrocolloid dressing (Comfeel Ulcer Dressing, Coloplast A/S, Espergaerder, Denmark) in conjunction with elastic compression versus The traditional Unna boot in the treatment of venous ulceration.

Materials and methods

Sixty consecutive outpatients, 37 women and 23 men diagnosed with post-thrombotic chronic venous insufficiency, with venous leg ulcers were recruited to the study. The inclusion criterion was venous leg ulceration on the "gaiter area" of the leg ranging between 5–8 cm². The diagnosis was made by clinical criteria alone. Exclusion criteria were: 1) patients with significant arterial disease (ankle/brachial pressure index <0.8), 2) clinical signs of infection requiring treatment, 3) patients with diabetes mellitus, 4) patients with other causes of leg ulceration such as malignant ulcer and rheumatoid vasculitis. All the patients who participated to the study were fully informed and written consent was obtained. The patients were randomly assigned into two groups, each group consisting of 30 patients with an average age of 51 years in group A (range 24–70) and 49 years in group B (range 20–72).

The treatment modality was classical Unna boot in group A and hydrocolloid dressing plus elastic stocking (with 30–40 mm Hg pressure, class II) in group B. The patients were instructed to wear the stockings at all times while ambulatory and to remove them upon going to bed. The Unna boot contained calamine, zinc oxide, glycerine, sorbitol, gelatine and magnesium aluminium silicate and was prepared in the hospital pharmacy. A commercially available hydrocolloid dressing was consistently used during the study in group B (Comfeel Ulcer Dressing, Coloplast A/S, Espergaerder, Denmark). The patients in group B wore elastic stockings at all times between dressing changes. Two dedicated and trained outpatient nurses applied both treatment modalities. Dressing changes were carried out every 3 to 7 days depending on the amount of wound exudates.

The efficacy parameters of the study were: 1) the complete healing of the ulcer; 2) weekly wound surface-area reduction; 3) time to healing; 4) performance characteristics graded by the nursing staff (ease-of-use score); 5) pain during application of the treatment modality and during the time period spent at home; 6) application time.

The patients visited the outpatient clinic 1 or 2 times a week unless the ulcer was exuding very heavily. At each outpatient clinic visit, the outer margins of the ulcers were traced on a transparent plastic film and, were cleansed with normal saline and debrided when necessary. After the study was completed, all tracings and area determinations were performed planimetrically by a technician who was unaware of the modality with which the respective wounds had been treated. The weekly wound surface reduction was calculated according to the percentage decrease in the area of the ulcer formula.

The performance characteristics included: 1) ease of application, 2) ease of removal, 3) patient comfort during wear, 4) patient comfort during removal, 5) dressing flexibility. The evaluations were performed by one of the two outpatient nurses using a rating scale of 1 (poor) to 5 (excellent). Ease-of-use score was calculated by the summation of these five characteristics. The intensity of pain experienced by the patient during dressing changes and at home was measured at the 3rd week of therapy on a linear analogue scale of 0–10, where 0 represents "no pain" and 10 represents "the worst imaginable pain". The application time of the modality was reported as the cumulative application time during the entire treatment (min).

For the initial ulcer sizes which were expressed as cm², for the ulcer duration which was expressed on a weekly basis and for the previous ulcer recurrence which was expressed as a percentage, the chi-square test was used. The complete healing rates were expressed as a percentage, evaluated by chi-square test and represented as a Kaplan-Meier curve. For the healing time, which was expressed on a weekly basis, and for weekly wound surface reduction (cm²/week) The Mann-Whitney U test was used. Ease-of-use score characteristics, pain assessed by linear analogue scale and application time were evaluated by student t test. P values of less than 0.05 were considered to be significant.

Results

Of the 30 patients who enrolled in group A, 27 completed the study and 3 withdrew; two ulcers became infected, and one patient was withdrawn due to hospitalisation. Four patients in group B were withdrawn; one due to infection, one had to suspend the treatment because of the onset of severe erythema due to contact dermatitis around the lesion attributable to the dressing, one did not attend outpatient clinic appointments, and one patient was lost to follow-up. The demographic data and the initial size of the ulcers are summarised in

table 1. The two groups were similar in respect of age, gender and initial ulcer size. The duration of ulcers was 16.6 ± 5.8 weeks and 16.9 ± 6.2 weeks in group A and B, respectively. Previous ulcer recurrence was 74% (20/27 patients) in group A and 73% (19/26 patients) in group B (table 1). None of the patients experienced a serious adverse event related to the study during the trial. A treatment-related adverse event was reported in group B.

The complete healing rates were found to be 74.07% (20/27) in group A and 80.76% (21/26)

Table 1

Demographic data, initial size of ulcers, previous ulcer duration and previous ulcer recurrence (mean, average, SD).

	Age (years)	Sex (M/F)	Initial ulcer size (cm ²)	Ulcer duration (week)	Previous ulcer recurrence
Group A	51 (24–70)	9/21	6.38 ± 1.2	16.6 ± 5.8	74%
Group B	49 (20–72)	11/19	6.19 ± 0.8	16.9 ± 6.2	73%

Table 2

Complete healing rates, healing time, Weekly wound surface reduction of the treatment modality.

	Complete healing rate (%)	Weekly wound surface reduction (cm ² /week)	Healing time (week)
Group A	74.07	1.28 ± 0.72	6.85 ± 3.60
Group B	80.76	1.16 ± 0.38	6.65 ± 3.31

Table 3

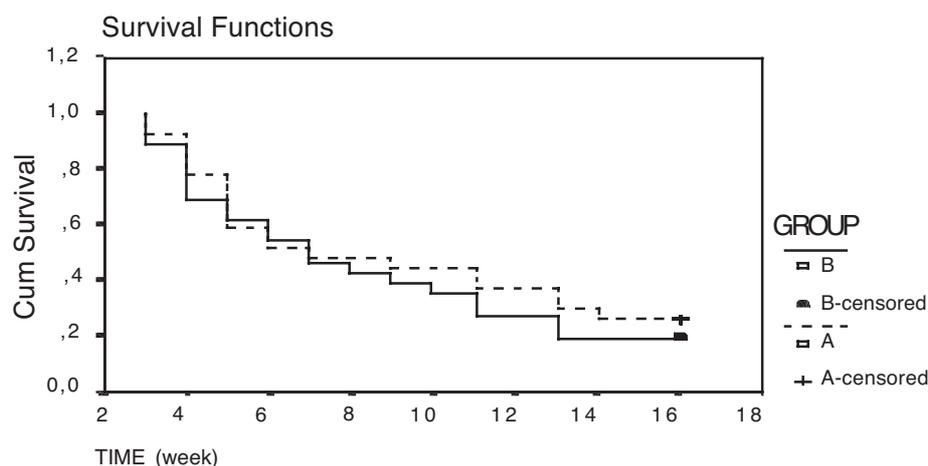
Overall performance, pain during application and at home, and time spent on application.

	Ease-of-use score	Pain during application	Pain at home	Application time(min)
Group A	9.04 ± 2.38	3.69 ± 1.35	3.27 ± 1.08	150.59 ± 34.73
Group B	17.27 ± 3.27*	1.88 ± 1.48*	1.88 ± 1.11*	134.54 ± 43.39

*p <0.0001.

Figure 1

Complete healing rate per week with Kaplan-Meier graph.



in group B at the end of 4 months. The comparison of both groups according to the complete healing rates showed no significant difference ($p > 0.05$, table 2, figure 1). When both groups were compared according to weekly wound surface reduction, the difference was also not significant (1.28 ± 0.72 cm²/week in group A and 1.16 ± 0.38 cm²/week in group B, $p > 0.05$, table 2). The ulcer healing time was 6.85 ± 3.60 weeks in group A, whereas it was 6.65 ± 3.31 weeks in group B, which also revealed no significant difference ($p > 0.05$, table 2). Ease-of-use score was 9.04 ± 2.38 in group

A, and 17.27 ± 3.27 group B, and this difference was statistically significant ($p < 0.0001$, table 3). The pain scores are summarized in table 3. A significantly higher degree of pain was reported in patients who were treated with Unna boot, both during application (group A 3.69 ± 1.35 , group B 1.88 ± 1.48 , $p < 0.0001$) and at home (group A 3.27 ± 1.08 , group B 1.88 ± 1.11 , $p < 0.0001$). The average time spent on Unna boot changes was 150.59 ± 34.73 min, whereas it was 134.54 ± 43.39 min in group B ($p > 0.05$); this was not a significant difference (table 3).

Discussion

Venous disease accounts for 1% to 2% of the health care budgets of European countries [8]. Thus, the morbidity and associated economic burden have led to a growing interest in the develop-

ment of new approaches to accelerate healing [6]. However, compression therapy has remained the standard treatment [9–11]. In fact, the problem facing clinicians today may be in deciding what

treatments to use as an adjunct to compression therapy. Fletcher and Sheldon reviewed 24 randomised trials and found that compression alone is superior to a moist interactive dressing without compression [12]. In a prospective study, Partsch et al evaluated the efficiency of medial compression stockings compared with short stretch bandages for treating leg-ulcers. After 3 months 21 cases (84%) were healed in the compression stocking-group, and 13 (52%) in the bandage-group. This significant difference was partly explained by the maintenance of a more stable compression pressure [5].

Rigid inelastic bandages can be used in the acute phase to reduce oedema and to heal venous ulcers [6]. After the invention of the Unna boot by the German dermatologist Unna in 1896, it became the prototype for rigid bandages [7]. The Unna boot is a moist zinc-impregnated paste bandage which is designed to provide both compression and topical therapy [7]. Unfortunately, it does not accommodate changes in the volume of the leg. An other disadvantage is the operator dependent nature of the compression achieved. In many studies no clear differences in the effectiveness of different types of compression systems have been shown [13].

It is generally accepted that the maintenance of a moist wound environment underneath the compression bandaging accelerates wound healing [14]. Occlusive dressings help to keep fluid-rich growth factor activity in contact with healing tissues [15]. There are five basic types of occlusive dressings: 1) hydrogels, 2) alginates, 3) hydrocolloids, 4) foams, 5) films (5). Comfeel belongs to the group of occlusive hydrocolloid dressings and contains sodium carboxymethylcellulose.

Several studies have been reported comparing Unna boot with different types of hydrocolloid dressings. Cordts et al compared Duoderm (a hydrocolloid dressing) plus elastic compression with Unna boot and encountered no significant difference in terms of healing rate at 12 weeks [16]. Kikta et al. demonstrated that ulcer healing was not different in patients treated with Unna boot or occlusive hydrocolloid dressing, but patient compliance was better in the latter group [17]. Similarly Alvares et al. compared Unna boot with hydrocolloid dressing plus elastic compression in a clinical study and encountered no significant difference between the groups in terms of the healing rates. However, hydrocolloid dressing plus elastic compression was found to be more comfortable for the patients [18].

We were unable to find any study comparing Comfeel Ulcer Dressing and classical Unna boot in the treatment of venous ulcers, and conducted this prospective research. Unna boot and hydrocolloid dressing plus elastic compression groups showed no significant difference when compared in terms of complete healing rates, weekly wound surface reduction, healing time, and time spent on application. But performance characteristics were found to be significantly superior for the hydrocolloid dressing plus elastic compression group. Similarly, the pain reported by the patients in group B was significantly lower both during application and at home. The summation of all data indicated the efficacy of both modalities in management of venous ulcers. However, the main advantages observed with hydrocolloid dressing plus elastic compression were better patient compliance and convenience, reflected by the performance characteristics and pain intensity.

Venous ulcers are more common with increasing age, with peak prevalence between 60–80 years [19]. As the shift in the population to a higher percentage of elderly individuals increases, clearly the number of patients with venous ulcers will rise significantly. The mean age of the patients in this study is lower than that in other studies. This fact can be explained by the relatively younger average age of population in our country. Interestingly, the Framingham Study also reported that varicose veins are more prevalent in women than in men and the highest rates were seen in the age range of 40 to 49 years for women and the age range of 70 to 79 years for men [20].

Conclusion

This study demonstrated that Comfeel hydrocolloid dressing in conjunction with elastic compression is superior to Unna boot in terms of patient convenience. However, further controlled clinical studies are necessary to ascertain the effectiveness of different treatment modalities in venous ulcer management in different patient care settings.

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