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Title

The effectiveness of a four layer compression bandage system in comparison to Class 3 compression hosiery on healing and quality of life for patients with venous leg ulcers: A randomised controlled trial.

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ABSTRACT

There are an increasing number of compression systems available for treatment of venous leg ulcers and limited evidence on the relative effectiveness of these systems. The purpose of this study was to conduct a randomised controlled trial to compare the effectiveness of a 4-layer compression bandage system with Class 3 compression hosiery on healing and quality of life in patients with venous leg ulcers. Data were collected from 103 participants on demographics, health, ulcer status, treatments, pain, depression and quality of life for 24 weeks. After 24 weeks, 86% of the 4-layer bandage group and 77% of the hosiery group were healed ($p=0.24$). Median time to healing for the bandage group was 10 weeks, in comparison to 14 weeks for the hosiery group ($p=0.018$). Cox proportional hazards regression found participants in the 4-layer system were 2.1 times (95% CI 1.2–3.5) more likely to heal than those in hosiery, while longer ulcer duration, larger ulcer area and higher depression scores significantly delayed healing. No differences between groups were found in quality of life or pain measures. Findings indicate these systems were equally effective in healing patients by 24 weeks, however a 4-layer system may produce a more rapid response.

Key Words

compression, quality of life, varicose ulcer, wound healing

Key Points

- Venous leg ulcers are slow to heal and result in intensive use of health care resources.
- Around 70% of chronic leg ulcers are caused by venous disease and evidence shows compression therapy is an effective treatment.

- The increasing variety of compression systems, wide variation between systems with regards to costs and ease of application, and limited evidence on comparative effectiveness can lead to uncertainty and inconsistency in treatment decisions.
- This study compared the effectiveness of a four layer compression bandage system and a Class 3 compression hosiery system
- The study found that although healing rates were similar after 24 weeks of treatment, the four layer bandage system had a significantly shorter time to healing.
- No differences were found in quality of life or pain measures between the two compression groups.
- Participants with longer ulcer duration and higher depression scale scores were significantly less likely to heal.

INTRODUCTION

Venous leg ulcers are often slow to heal and result in long term suffering and intensive use of health care resources (1,2). In addition to direct costs to the health care system, chronic leg ulcers are associated with significant hidden burdens on the community. These include costs associated with lost productivity, the social support systems (both community and government funded) necessary for people who are unable to mobilise freely, and high personal costs associated with home care of the ulcers (3). Patients report that leg ulcers are associated with prolonged periods of restricted mobility, decreased functional ability, pain, social isolation and decreased quality of life (4-6).

Around 70% of chronic leg ulcers are caused by venous disease and evidence shows compression therapy is an effective treatment (7). However, the ever increasing variety of compression systems and limited evidence on comparative effectiveness can lead to uncertainty and inconsistency in treatment decisions. In addition, the wide variation between differing compression systems with regards costs, requirement for expertise to apply, comfort and ease of application point to an urgent need for information on the relative effectiveness of these systems for both clinicians and consumers.

A systematic review in 2009 found the use of multilayered high compression systems were more effective than single layered low compression systems, and multilayered systems including an elastic component were more effective than non-elastic systems (7). Debate continues on the optimal type and level of multilayered compression systems, and a number of trials comparing short stretch and long stretch multilayered systems have been undertaken (8-10). However, there are few

comparisons of other types of systems and even fewer looking at compression hosiery, despite the frequent use of compression hosiery in clinical practice. One combined analysis of two studies comparing two layered compression hosiery and short stretch bandaging (11,12) found compression hosiery resulted in higher healing rates (7), while two other studies comparing compression hosiery with paste bandages found no significant differences in healing (13,14).

The purpose of this study was to compare the effectiveness of a four layer compression bandage system and a Class 3 (30–35mmHg) compression hosiery system on healing and quality of life outcomes.

Hypothesis

There will be no difference in healing or quality of life outcomes at 24 weeks between patients receiving a four layer bandage compression system and those receiving a Class 3 compression hosiery system.

METHODS

A randomised controlled trial was undertaken to determine the effectiveness of a four layer compression bandage system in comparison to a Class 3 compression hosiery system on healing and quality of life at 24 weeks in patients with venous leg ulcers. Recruitment and data collection occurred from September 2006 – August 2009.

Sample

All patients fitting the inclusion and exclusion criteria and admitted to outpatient leg ulcer clinics run by metropolitan hospitals or two community nursing services were invited to participate in the study.

Inclusion Criteria

- Patients with leg ulcers of venous aetiology
- Ankle Brachial Pressure Index >0.8 and <1.3
- Ulcer size of $\geq 1\text{cm}^2$
- When more than one ulcer was present, the largest ulcer was identified as a target ulcer for the purpose of the study

Exclusion Criteria

- Patients unable to mobilise i.e. completely bed or wheelchair bound
- Ankle Brachial Pressure Index ≤ 0.8 or ≥ 1.3
- Patients with cognitive impairment
- Presence of clinical signs of infection on admission

Sample size calculations found that a sample of 154 participants would be required to detect a 20% difference in proportions of participants healed, as determined by power analysis with a type I error of 5% and 90% power, and allowing for 20% attrition (64 completing participants/group). Power analysis for the secondary outcomes (pain, depression, quality of life), based on identifying a significant clinical difference of 20/100 between mean group scores, with a type I error of 5% and 90% power and allowing for 20% attrition, found required samples sizes ranging from 52 (26/group for quality of life) to 80 (40/group for pain scale) participants required.

Data Collection and Measures

Data on demographics, health, medical history and ulcer characteristics were collected from medical records and patient questionnaires at baseline. Information on variables known to influence ulcer healing, i.e. ulcer size, duration and age

(15,16), were collected to include in the final analysis. Data on progress in healing and treatments were collected second weekly for 24 weeks from baseline. A 'healed' leg ulcer was defined as full epithelialisation of the wound which was maintained for two weeks. Data on quality of life measures were collected via a patient questionnaire at baseline, 12 weeks and 24 weeks from recruitment.

Instruments and Measures

Progress in wound healing was measured with the following methods:

- ulcer area was calculated from acetate wound tracings and use of a portable digital planimetry device to determine ulcer areas and percentage area reduction;
- the PUSH tool for ulcer healing (17) was used to provide a broader measure of healing than examining area alone, covering area, exudate and the type of wound bed tissue (i.e. epithelial, granulating, slough or necrotic);
- clinical data related to healing progress such as presence of oedema, eczema, inflammation and signs of infection were also collected. Ankle and calf circumference measurements were taken to check for changes in oedema every two weeks at two points: 2cm above the medial malleolus and 5cm below the tibial tuberosity.

Quality of Life measures included:

- Quality of Life Index (18): The QL Index was developed for chronically ill patients and consists of five items measuring the domains of activity, daily living, health support and psychological outlook. Evidence of good validity and reliability has been reported in studies from Australia, Canada and the USA (19). Spitzer et al. (18) reported co-efficient $\alpha=0.77$ for internal consistency and correlations from 0.74–0.84 for inter-rater reliability (18).

- Medical Outcomes Study Pain Measures (20): This seven item questionnaire measures the intensity, frequency and duration of pain and records the impact of pain on daily living. The self-report items cover two factors, severity and pain effects. Good internal consistency has been reported (21).
- Geriatric Depression Scale (22): This screening scale was designed to be easily completed by older adults in an outpatient setting. The abbreviated 15-item scale avoids problems of fatigue. Studies in varying settings have shown good reliability and high sensitivity (84%) and specificity (95%) among cognitively intact elderly people (21).

Procedure and protocol

On admission to the outpatient leg ulcer clinics, patients were assessed and if fitting the inclusion and exclusion criteria, were invited to participate in the trial. An information package on the study was provided by a Research Assistant and explained to potential participants and signed consent obtained. Baseline data were collected prior to randomisation and thus blinded.

Following collection of baseline data, the Research Assistant at the clinical site opened a sequentially numbered envelope containing the randomised group. Randomisation was undertaken centrally generated via a computerised randomisation program for the total expected sample size. An independent administration assistant assembled sealed sequentially numbered envelopes containing the randomised group allocation. These envelopes were divided into 4 sets (one for each recruitment site). Participants were randomised to either a four layer compression bandage system or a Class 3 (30 – 35mmHg) compression hosiery system. A core team of wound care nurses at the clinics were trained in the

protocol assessment, wound care and compression techniques for consistency. New staff members were also trained in study protocols throughout the study data collection phase.

The ulcers were cleansed with warm tap water and dressed with a non-adherent, non-medicated dressing. Patients with clinical signs of infection on admission were excluded from the study, however, if signs of infection developed during the course of the study, the clinician treated the infection appropriately and the patient continued in the study. All such events were documented to enable checks for confounders in analysis of data. Although the nurses assessing the ulcers and providing care were unable to be blinded from the type of compression being applied, the acetate ulcer tracings and wound photographs were assessed and area calculated by an independent research assistant, who was blinded to group allocation.

Participants randomised to the bandage group had a four layer compression bandage system applied, while participants randomised to the Class 3 compression hosiery group were fitted for the correct hosiery size and shown how to apply and remove the hosiery with appropriate applicators if needed. Participants who were unable to manage their hosiery alone were referred to community nursing services or their General Practitioner Practice Nurse for assistance (n=2, 4%). Compression hosiery could be removed at night, as long as it was replaced first thing in the morning.

Participants with very oedematous legs who were randomised to the compression hosiery group were placed in short stretch bandaging for 1–4 weeks until the

oedema subsided prior to commencement of Class 3 compression hosiery (n=9, 18%). A record was kept each week on how many days/week the compression systems were worn.

Analysis

Data were analysed with SPSSv15 (SPSS Inc., Chicago II). Analysis was conducted following intention to treat guidelines. Data were double entered and inconsistencies checked and corrected according to the original records. Analysis was undertaken by an investigator not involved in data collection at the clinical sites using a group coded database. Baseline demographic, health, psychosocial, treatments and ulcer characteristics were analysed to check for comparability of the two compression groups. Descriptive analyses were undertaken for all variables. Median times to healing were calculated and compared using the Kaplan-Meier method and log-rank test. A Cox proportional hazards regression model was used to adjust for potential confounders and analyse the effect of the two types of compression on healing. Plots of the survival curves for each variable were checked to test for proportionality of hazards. Multicollinearity checks were undertaken using a correlation matrix and examining Pearson or Spearman coefficients, and checking squared multiple correlations among covariates. A general linear model with repeated measures analysis was undertaken to investigate differences in pain and quality of life measures over data collection points and between groups.

Ethical Considerations

Ethical approval for the study was obtained from the Human Research Ethics Committee at each of the organisations involved and complied with the Helsinki

Declaration ethical rules for human experimentation. Informed consent was obtained from all participants.

Trial Registration No. ACTRN12611000224921 (Australian New Zealand Clinical Trials Registry)

RESULTS

A sample of 103 patients was recruited to participate in the study. The flow of participants through the study and reasons for loss to follow-up are shown in Figure 1. There was an overall attrition rate of 9.7% (n = 10) of participants over the 24 weeks. Participants who withdrew or were lost to follow-up did not differ significantly from those who completed the study on baseline demographics, co-morbidities or ulcer characteristics, however, they reported significantly lower Quality of Life scale scores ($p = 0.01$) and higher average pain scores ($p = 0.005$) on admission to the study in comparison to those who completed the study. There were no missing data in the demographic, health or ulcer variables; however, missing data were identified in the Geriatric Depression Scale items. The pattern of missing data were checked by testing differences between cases with missing data and cases with no missing data and no significant differences were found. Cases with more than five of the scale items missing were removed from the analysis (n = 4), while cases with 4 or less scale items missing had their total score calculated according to the scale authors' algorithm (22). There were two adverse effects in the compression hosiery group (local sensitivity reactions) and three adverse effects in the four layer bandage group (two local sensitivity reactions, one bandage trauma).

Baseline demographic characteristics, co morbidities, and ulcer characteristics are displayed in Table 1. There were no significant differences between groups for age, gender, living arrangements, health variables or ulcer characteristics. Looking at adherence to the compression protocols, 85% (n = 39) of those randomised to Class 3 hosiery reported they were adherent (i.e. remained in compression six or more days/week) for at least three-quarters of their time in the study and 15% (n = 7) for less than 75% of the study period. Of the participants randomised to the four layer bandage system, 88% (n = 43) reported they were adherent for at least three-quarters of their time in the study, and 12% (n = 6) for less than 75% of the study period.

Ulcer healing outcomes

After 24 weeks of treatment, 84% of participants in the 4-layer system and 72% of those in Class 3 hosiery were healed (χ^2 2.16, p = 0.14). Mean percentage reduction in ulcer area was 96% (SD 15.6) for those in the four layer bandage group, and 93% (SD 14.9) for those in the Class 3 hosiery group (p = 0.27).

A survival analysis approach was taken to determine multivariable relationships between the compression groups, potential confounders and differences in proportions of ulcers healed, as recommended by Cullum et al. (23) and more recently O'Meara et al. (7), who noted that survival analysis provides a more meaningful estimate of treatment effect and that all trials assessing ulcer healing should adopt this analysis. At the bivariate level, Kaplan-Meier survival curve analysis found median time to healing for the 4-layer group was 10 weeks, in

comparison to 15 weeks for those in Class 3 hosiery ($p=0.003$). Time to healing was also found to be significantly delayed for participants with an ulcer duration over 24 weeks on admission ($p < 0.001$), baseline ulcer area over 10cm^2 ($p=0.03$), a PUSH score higher than 10 ($p=0.005$), and scores >4 on the Geriatric Depression Scale ($p=0.012$). Time to healing was significantly shorter for those taking diuretic medications ($p=0.002$) at the bivariate level. There were no significant relationships found between healing and age, gender, comorbidities (diabetes, osteoarthritis, rheumatic disease, cardiovascular disease, autoimmune disease, past deep vein thrombosis), types of medications, restricted mobility (requiring a walking aid) and dressing type.

Cox proportional hazards regression model

All variables associated with healing at the bivariate level ($p < 0.05$) or identified in the literature as impacting on healing were entered simultaneously in the regression model. After mutual adjustment for all variables, analysis found the type of compression, ulcer duration, and Geriatric Depression Scale scores remained significantly associated with healing. Participants in the 4-layer system were 2.4 times more likely to heal (95% CI 1.4–4.3) than those in Class 3 compression hosiery. In addition, patients with an ulcer duration >24 weeks were 2.3 times less likely to heal (95% CI 1.4–4.0), and those scoring at risk of depression were 2.1 times less likely to heal (95% CI 1.1–4.3). The proportional hazards regression model is shown in Table 2.

Quality of life outcomes

The two compression groups' mean scores and standard deviations for the Quality of Life Index, MOS Pain Measures Pain Severity scale and Geriatric Depression Scale

at baseline and at 24 weeks from baseline are displayed in Table 3. General linear model repeated measures analysis found no significant interaction effect or main effect for the Quality of Life Index scores. There were no significant interaction effects for the Geriatric Depression Scale scores or the MOS Pain scores, however, there were significant main effects for the Geriatric Depression Scale scores, with a small improvement over time from a mean score of 3.94 (SD 3.94) at baseline down to 3.88 (3.65), $F = 4.72$, $p = 0.035$; and for the MOS Pain Severity scores, which improved from an overall mean score of 50.8 (SD 27.1) at baseline (on a scale of 0 – 100, where 0 = no pain and 100 = worst pain possible) to a mean score of 28.9 (SD 23.1) at 24 weeks from baseline ($F = 35.2$, $p < 0.001$).

DISCUSSION

This study aimed to compare the effectiveness of a four layer compression bandage system and a Class 3 (30–35mmHg) compression hosiery system on healing and quality of life outcomes. Results found the four layer compression bandage system achieved significantly faster healing times, although there were no significant differences between the two groups in the proportions of healed patients after 24 weeks of treatment. Quality of life and pain outcomes were similar for both compression groups.

These findings provide important evidence on the comparative effectiveness of these two compression systems for patients, their carers and health professionals. Previously reported evaluations of compression hosiery have had varying results, including favourable comparisons with short stretch compression bandages (11,12), and no differences in healing found in comparisons with paste bandages (13,14). As

both multilayered bandage systems and compression hosiery are widely used, further studies are important to build a strong body of evidence in this area and enable patients and health professionals to make informed choices.

Ulcer duration remained significantly associated with healing in this sample, as is frequently reported in the literature (16,24-26). For example, Meaume et al. (25) specified an ulcer duration over three months as associated with prolonged healing; and Margolis et al. (16) reported that ulcers over 10cm² in size and lasting over 12 months had a 78% chance of not healing after 24 weeks of treatment. This consistent risk factor demonstrates the urgent need for early identification of ulcers at high risk of poor healing outcomes in order to implement early interventions and break the long duration – hard to heal cycle that develops.

Ulcer size has also been previously identified as a risk factor. In general the larger the ulcer, the more delayed the healing process (16,25,27,28). This trend was demonstrated in this sample, although ulcer area did not quite reach statistical significance in the multivariable model.

Importantly, depression was found to be significantly independently associated with healing in this study. Although depression and anxiety have been shown to delay acute wound healing (29,30), there is an absence of research on the relationship between poor mental health and healing in chronic leg ulcers. It is known that a significant number of patients with leg ulcers have problems with depression and anxiety and significant correlations have been found between patients' psychological and spiritual well being and the number of venous ulcers experienced (6,31,32).

Moffatt et al. (33) found patients with leg ulcers were more likely to be depressed than matched controls without leg ulcers, and Wong and Lee (34) found there was a significant correlation between patients with better emotional status and a higher likelihood of healing. These findings suggest that all patients with leg ulcers may benefit from screening and appropriate interventions for depression and further research is indicated in this area.

Limitations

Although only a small number of participants were lost to follow-up (10%), participants who withdrew or were lost to follow-up reported significantly lower quality of life and higher levels of pain on admission to the study in comparison to those who completed the study, suggesting that a small sub-group of patients may not be suitable for these treatments. Measures of health-related quality of life and pain were obtained from self-report questionnaires, with the possibility of response bias.

Conclusions

From a clinical care perspective, findings indicate these two compression systems are equally effective in healing patients after 24 weeks, although a four layer system may produce a more rapid response. The study provides an improved understanding of wound healing in venous leg ulcers to facilitate development of improved treatment regimes and inform the practice of health care professionals caring for patients with venous leg ulcers. This new information has the potential to improve ulcer healing rates and quality of life and reduce healthcare costs.

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why some heal and others don't? Psychosocial determinants of wound healing in older people 2008;16:71-6.

TABLES

Table 1. Baseline demographic, health and ulcer characteristics

Characteristic	4 layer bandage Group (n = 53)	Class 3 hosiery Group (n = 50)	Total (n = 103)
<i>Demographic</i>			
Age, mean \pm SD [†]	67 \pm 15.7	68 \pm 14.1	68 \pm 14.8
Female (n, %)	29, 55%	22, 44%	51, 50%
Lived alone (n, %)	18, 34%	13, 26%	31, 30%
<i>Comorbidities / Health</i>			
Cardiac disease (n, %)	16, 30%	9, 18%	25, 24%
Osteoarthritis (n, %)	23, 43%	16, 32%	39, 38%
Rheumatoid disease (n, %)	7, 13%	4, 8%	11, 11%
Diabetes (n, %)	8, 15%	7, 14%	15, 15%
Previous DVT (n, %)	10, 19%	12, 24%	22, 21%
Previous leg ulcers (n, %)	38, 72%	33, 69%	71, 70%
Required aid to mobilise (n, %)	16, 30%	10, 20%	26, 25%
Body Mass Index (mean \pm SD [†])	34 \pm 11.5	33 \pm 9.7	33 \pm 10.7
<i>Ulcer Characteristics</i>			
Ulcer area (median, range)	4.6 cm ² (1–170)	4.0 cm ² (1–114)	4.1 cm ² (1–170)
Ulcer duration (median, range)	19 weeks (1–312)	25 weeks (1–364)	23 weeks (1–364)
PUSH score (mean \pm SD [†])	10.7 \pm 2.89	10.0 \pm 2.56	10.4 \pm 2.75

[†]SD = Standard Deviation

Table 2. Hazard Ratios for healing - Cox proportional hazards regression model

	β	Hazard Ratio	95% CI	p
Age	0.015	1.02	0.99–1.03	0.101
Taking diuretic medications	0.311	1.37	0.76–2.43	0.291
Ulcer area >10cm ²	0.677	1.97	0.99–3.88	0.051
Ulcer duration >24 weeks	0.950	2.58	1.48–4.51	0.001
Compression type				
Class 3 compression hosiery		referent group		
4 layer bandage system	-0.91	0.402	0.23–0.69	0.001
Depression (score >4*)	0.762	2.14	1.05–4.39	0.037

*Geriatric Depression Scale Short Form – scale from 0 – 15, where scores of 5 or higher suggest depression

Table 3. Quality of life measures at baseline and at 24 weeks from baseline.

	Mean (SD) at baseline		Mean (SD) at 24 weeks		<i>Interaction effect</i>		<i>Main effect</i>	
	Class 3	4 layer	Class 3	4 layer	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
	hosiery	bandages	hosiery	bandages				
Quality of Life ¹	8.33 (1.72)	7.56 (2.20)	8.36 (2.43)	8.00 (2.36)	1.19	0.278	1.51	0.223
Depression ²	3.87 (3.84)	4.04 (2.75)	3.71 (3.76)	4.13 (3.58)	0.02	0.892	4.72	0.035
Pain Severity ³	50.0 (26.4)	51.8 (28.3)	34.0 (23.3)	23.0 (22.1)	2.42	0.124	35.2	<0.001

¹ Range 0–10, where 0 = poor quality of life and 10 = excellent quality of life

² Geriatric Depression Scale: Range 0–15, where 0= no depression and 15 = high risk of depression

³ MOS Pain Measures, Range 0–100, where higher scores indicate higher levels of pain

FIGURE LEGENDS

Figure 1: Flow of participants through study

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