

Is it time to re-appraise the role of compression in non-healing venous leg ulcers?

- **Objective:** To evaluate the role of compression in non-healing venous leg ulcers (VLUs) of > 3 months' duration.
- **Method:** Patients' records from three independent data sets of non-healing VLUs of > 3 months' duration were re-analysed. Two data sets were separate audits of clinical practice and the third comprised patients' records from a randomised controlled trial. Some patients in each data set were never treated with compression. The effect of compression on healing at 6 months was tested with logistic regression.
- **Results:** In each data set, patients in the compression and no-compression groups were matched according to ulcer size and duration; there were no differences in comorbidities. Comparing the no-compression with the compression groups, the healing rate at 6 months was 68% vs 48% in study 1, 12% vs 6% in study 2, and 26% vs 11% in study 3. Use of compression was found to be an independent predictor of not healing with an odds ratio of 0.422, 0.456 and 0.408 in studies 1, 2 and 3 respectively.
- **Conclusion:** The healing rate of non-healing VLUs of > 3 months' duration in the no-compression groups was double that of VLUs in the compression groups. These findings have the potential for treatment modification if confirmed in a prospective trial.
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Commentary by Professor Hugo Partsch on page 461

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The management of venous leg ulcers (VLUs) is a significant clinical problem, which imposes huge demands on limited health-care resources.^{1,2} Venous disease, or chronic venous insufficiency (CVI), is the result of ongoing pooling and congestion of venous blood. This may be due to a number of features including, but not limited to, varicosities, obesity and calf muscle pump impairment. The congestion of blood in the deep veins increases ambulatory pressures and results in venous hypertension, which subsequently increases the hydrostatic pressure in the superficial veins. This alteration in pressure dynamics leads to capillary fluid loss and soft tissue oedema.

Venous pressure in a standing individual is largely hydrostatic;³ hence, the external pressure necessary to counteract this effect progressively reduces up the leg, as the hydrostatic head is effectively reduced.³ Consequently, external compression is usually applied to a VLU in a graduated fashion, with the highest pressure at the ankle and reducing below the knee.^{3,4}

The application of graduated external compression has been shown to minimise or reverse the

vascular changes that occur in a VLU, by forcing fluid from the interstitial spaces back into the vascular and lymphatic compartments.⁴ However, there is less agreement about the precise level of pressure required. Pressures of about 40mmHg at the ankle are widely quoted in the literature for the prevention or treatment of VLUs, but some recommend values significantly higher than this.⁴⁻⁶

In clinical practice, the optimum pressure varies according to a number of factors, including the severity of the wound and the height and limb size of the patient. The majority of newly-presenting VLUs can be induced to heal by applying adequate levels of sustained, graduated compression.⁷ In such situations compression bandages currently represent the treatment of choice.

Several different types of compression bandaging systems are available, each of which may have advantages over the others for particular applications. Moreover, they vary greatly in their ability to provide sustained compression, owing to differences in their structure and content of elastomeric yarns.⁴ Other factors, such as limb circumference and shape, also

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affect the pressure produced beneath a compression bandage.⁴ However, there is some anecdotal evidence that nurses in the community have difficulty determining which type to apply.

High compression bandaging (30–40mmHg) is an effective treatment, healing over 70% of uncomplicated VLUs in 3 months.^{5,6} A systematic review of different compression bandages for VLUs concluded that the rate of ulcer healing was increased with compression bandages compared with no compression.⁴ It also found multicomponent compression systems more effective than single-component systems, and those with elastic bandages were more effective than inelastic systems. However, there were no clear differences in the effectiveness of different types of high compression.⁴

We recently conducted a study on >400 highly-exuding VLUs of ≥ 3 months' duration using patients' records from The Health Improvement Network (THIN) database, a nationally representative database of patients registered with general practitioners (GPs) in the UK.⁸ Surprisingly, we found that 20% of the wounds were never treated with compression. We then reviewed the data sets from two other chronic VLU analyses^{9,10} and found that >20% of patients in both studies never received any compression.

The aim of this present analysis was to elucidate the effect of no compression on wound healing and wound-size reduction in these patients with chronic wounds of ≥ 3 months' duration.

Method

Study 1

The THIN database contains computerised information on >9 million anonymised patients entered by GPs from 500 practices across the UK.¹¹ General practices across the UK using Vision Practice Management Software are invited to participate in the database, and are self-selecting. The patient data within THIN has been shown to be representative of the UK population in terms of demographics and disease distribution.^{12,13}

Information contained in the THIN database includes patients' demographics, details from GP consultations, specialist referrals, nurse and other clinician visits, hospital admissions, diagnostic and therapeutic procedures, laboratory tests and prescriptions issued by GPs, which are directly generated by the general practice's IT system. The information contained in the THIN database reflects real clinical practice, as it is based on actual patient records. Moreover, GPs are the gatekeepers to health care in the UK, and patients' entire medical history is theoretically stored in their primary-care record.

The anonymised records of a randomised sample of 414 patients in the THIN database, who were treated with one of five absorbent dressings for their

VLU between 1 January 2010 and 30 June 2011, were analysed. To be included in the data set, patients had to have been 18 years of age or over, had one of the following read codes for a VLU: 14F5.00 H/O, M271500 or G837.000, had their VLU for at least 3 months before treatment with an absorbent dressing and had at least 6 months' follow-up data in their case record following the start of treatment with an absorbent dressing. Patients in the five groups were matched according to age, gender, their general practice, date of diagnosis of their VLU and treatment start date.⁸

Twenty per cent (n=82) of these patients never received any compression. Those who died or had missing data were excluded from the sample, yielding 74 patients who never received compression. These patients were then matched with 74 patients who received compression based on:

- The time with their VLU before treatment with an absorbent dressing
- The initial VLU size at treatment start date.

Study 2

The population of study 2 was also extracted from the THIN database. It comprised the anonymised records of 255 patients who were treated with a skin protectant for their VLU between 1 January 2008 and 31 December 2009 and the records of 255 matched patients who never received a skin protectant for their VLU over the same period. To be included in the data set, patients had to have been 18 years of age or over, had one of the following Read codes for a VLU: 14F5.00 H/O, M271500 or G837.000 and had at least 6 months' follow-up data in their case record following treatment with a skin protectant or the matched start date. Patients in the two groups were matched according to age, gender, the general practice where they were treated and the date of diagnosis of their VLU.⁹

Thirty two per cent (n=164) of these patients never received any compression. These patients were then matched with 164 patients who received compression based on:

- The time with their VLU before the study start date
- The initial VLU size at treatment start date.

Study 3

The population of study 3 comprised the anonymised records of patients who participated in a multi-centred, controlled clinical trial, which was conducted in 2005/2006. Patients with a chronic VLU were randomised to receive either an advanced topical treatment (amelogenin [Xelma; Mölnlycke]) combined with standard dressings, or standard dressings alone. Patients were followed-up weekly for 3 months with one follow-up assessment at 6 months in a hospital clinic.¹⁰ To be included in the study, a patient's ulcer

Table 1. Patient characteristics

Study 1	Compression	No compression	p-value
No. of patients (n)	74	74	N/S
Mean age (years)	74.2 ± 14.4	69.72 ± 17.0	N/S
Female/male	51%/49%	47%/53%	N/S
Mean wound duration (months)	5.8 ± 11.9	5.8 ± 12.1	N/S
Mean initial wound size (cm ²)	156.0 ± 158.7	153.3 ± 166.0	N/S
Study 2			
No. of patients (n)	164	164	N/S
Mean age (years)	77.0 ± 10.5	76.9 ± 12.2	N/S
Female/male	59%/41%	64%/36%	N/S
Mean wound duration (months)	4.3 ± 7.1	3.1 ± 5.4	N/S
Mean initial wound size (cm ²)	95.6 ± 76.1	86.6 ± 64.5	N/S
Study 3			
No. of patients (n)	19	19	N/S
Mean age (years)	75.7 ± 9.9	67.4 ± 10.6	N/S
Female/male	79%/21%	68%/32%	N/S
Mean wound duration (months)	30.8 ± 26.6	30.2 ± 26.3	N/S
Mean initial wound size (cm ²)	19.9 ± 11.1	18.9 ± 10.4	N/S

Table 2. Patient comorbidities for compression/no compression

Comorbidity (%)	Study 1		Study 2		Study 3	
	Compression	No compression	Compression	No compression	Compression	No compression
Cardiovascular	65%	61%	73%	72%	58%	79%
Musculoskeletal	49%	39%	57%	51%	37%	42%
Psychiatric	42%	36%	12%	19%	—	—
Endocrinological/metabolic	30%	34%	30%	37%	21%	16%
Respiratory	18%	15%	18%	22%	—	—
Dermatological	16%	26%	7%	10%	0%	5%
Cancer	14%	20%	15%	14%	5%	11%
Neurological	12%	18%	10%	17%	21%	0%
Gastrointestinal	12%	16%	23%	20%	26%	32%
Peripheral vascular	11%	15%	17%	19%	16%	16%
Genito-urinary	8%	12%	20%	27%	0%	11%
Cerebrovascular	0%	5%	11%	9%	<5%	<5%
Ophthalmological	<5%	<5%	12%	14%	0%	5%

had to be at least 6 months old, have a surface area of 10–30cm² and not demonstrate excessive exudate or signs of infection. All patients were meant to have received high compression bandaging one month before and during the 3-week run-in period, although this cannot be verified.¹⁰

Eighty three patients were recruited into the study of which 23% (n=19) seemed to have never received any compression during the trial. The 19 patients who never received any compression were matched with 19 patients who received compression based on:

- The time with their VLU before recruitment into the trial
- The initial VLU size at the start of the trial.

Data analysis

For studies 1 and 2, the following information was extracted from patients’ records: age, gender, symptoms, comorbidities and duration of symptoms, and community-based and secondary-care VLU-related resource use over a period of 6 months following the treatment start date. Specific wound size estimates for all patients were not available for every dressing change. In those instances, patients’ wound size was estimated to be 80% of the size of the primary dressing, as previously described.^{8,9}

For study 3, the following information was extracted from patients’ clinical trial case report forms: age, gender, symptoms, comorbidities and duration of symptoms, health-care resource use over a period of 6 months following the trial start date. Specific wound size estimates were available for all patients, using tracings taken and analysed with planimetry.¹⁰

Patient outcomes were quantified for the compression and no-compression groups over a 6-month follow-up period. Differences between groups were tested for statistical significance using a Mann–Whitney U-test or Chi-squared test. Logistic regression was performed to identify independent predictors of healing. All statistical analyses were performed using IBM SPSS Statistics (v21.0; IBM Corporation).

Results

Patients in the compression and no-compression groups in each study were well matched in terms of their age, gender, duration of wound and initial wound size (Table 1). Using a Chi-squared test, no significant differences in patients’ comorbidities were detected between the groups (Table 2). All the patients in study 1 had a highly-exuding chronic VLU, whereas in study 2 only 34% and 38% of patients in the compression and no-compression groups, respectively, had a highly-exuding chronic VLU.

Patient management and outcomes

In studies 1 and 2, patients’ wounds were managed in the community by practice nurses or community

References

1 Moffatt, C., Martin, R., Smithdale, R. Leg Ulcer Management. Blackwell Publishing, 2007.

2 Gottrup, F., Apelqvist, J., Price, P. Outcomes in controlled and comparative studies on non-healing wounds: recommendations to improve the quality of evidence in wound management. *J Wound Care*. 2010; 19: 237–268.

3 Meissner, M.H., Moneta, G., Burnand, K. et al. The hemodynamics and diagnosis of venous disease. *Vasc Surg*. 2007; 46: (Suppl. S), 4S–24S.

4 O’Meara, S., Cullum, N., Nelson, E.A., Dumville, J.C. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. 2012; 11: CD000265.

5 Stemmer, R., Marescaux, J., Furdere, C. Compression treatment of the lower extremities particularly with compression stockings [in German]. *Hautarzt*. 1980; 31: 355–365.

6 Burnand, K.G., Layer, G.T., Graduated elastic stockings. *Br Med J (Clin Res Ed)*. 1986; 293: 224–225.

7 Backhouse, C.M., Blair, S.D., Savage, A.P. et al. Controlled trial of occlusive dressings in healing chronic venous ulcers. *Br J Surg*. 1987; 74: 626–627.

8 Panca, M., Cutting, K., Guest, J.F. Clinical and cost-effectiveness of absorbent dressings in the treatment of highly exuding VLU. *J Wound Care*. 2013; 22: 109–118.

9 Guest, J.F., Taylor, R.R., Vowden, K., Vowden, P. Relative cost-effectiveness of a skin protectant in managing venous leg ulcers in the UK. *J Wound Care*. 2012; 21: 389–398.

10 Guest, J.F., Nagy, E., Sladkevicius, E. et al. Modelling the relative cost-effectiveness of amelogenin in non-healing venous leg ulcers. *J Wound Care*. 2009; 18: 218–224.

11 The Health Improvement Network (THIN) Database. Cegedim, 2011.

12 Hipsley-Cox, J., Coupland, C., Vinogradova, Y. et al. Performance of the QRISK cardiovascular risk prediction algorithm in an independent UK sample of patients from general practice: a validation study. *Heart*. 2008; 94: 34–39.

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Table 3. Patients’ use of dressings and compression bandages

	Study 1			Study 2			Study 3		
	Compression/ no compression	p-value		Compression/ no compression	p-value		Compression/ no compression	p-value	
Dressing (%)									
• Absorbent	56%	43%	N/S	19%	22%	N/S	75%	75%	N/S
• Activated charcoal	4%	3%	N/S	6%	2%	N/S	0%	0%	N/S
• Alginate	8%	13%	N/S	3%	3%	N/S	0%	0%	N/S
• Antimicrobial	51%	25%	<0.001	15%	9%	N/S	0%	0%	N/S
• Hydrocolloid	5%	13%	N/S	6%	9%	N/S	0%	0%	N/S
• Hydrogel	23%	4%	<0.001	2%	8%	N/S	0%	0%	N/S
• Impregnated gauze	<1%	<1%	N/S	1%	3%	N/S	0%	0%	N/S
• Knitted viscose	<1%	<1%	N/S	13%	3%	<0.02	0%	0%	N/S
• Low adherence	25%	16%	N/S	<1%	<1%	N/S	0%	0%	N/S
• Polyurethane foam	32%	16%	<0.03	14%	23%	N/S	0%	0%	N/S
• Povidone iodine	<1%	<1%	N/S	3%	6%	N/S	0%	0%	N/S
• Protease modulating matrix	79%	65%	N/S	8%	1%	<0.05	0%	0%	N/S
• Soft polymer	36%	14%	0.002	3%	10%	N/S	0%	0%	N/S
• Soft silicone	<1%	<1%	N/S	14%	<1%	<0.002	50%	50%	N/S
• Vapour-permeable films and membranes	1%	12%	N/S	<1%	<1%	N/S	0%	0%	N/S
Compression bandaging (%)									
• Compression hosiery	62%	—	—	58%	—	—	0%	—	—
• Conforming retention bandages	13%	—	—	31%	—	—	44%	—	—
• High compression bandages	5%	—	—	10%	—	—	29%	—	—
• Multi-layer compression	31%	—	—	33%	—	—	11%	—	—
• Short stretch bandages	13%	—	—	40%	—	—	16%	—	—

nurses. However, in study 3, patients’ wounds were managed in specialist centres by clinical trial investigators comprising physicians and nurses.

In study 1, significantly more patients in the compression group received an antimicrobial dressing, or a hydrogel, foam or soft polymer dressing than patients in the no-compression group (Table 3). However, every patient in this study was prescribed an antibiotic.⁸ In study 2, significantly more patients in the compression group received knitted viscose, soft silicone or a protease-modulating matrix than patients in the no-compression group (Table 3). There were no significant differences in the use of dressings between the two groups in study 3, as this was determined by the trial protocol.

Significantly more patients healed in the no-compression groups than the compression groups (Table 4). However, there were no differences in the time to healing or the percentage change in wound size over 6 months between the groups. Analgesic use and antibiotic use differed between the groups, which was indicative of the different patient cohorts in each study.

Logistic regression showed that use of compression was an independent predictor of not healing in all three studies. The odds ratios (ORs) were 0.422 (95% confidence interval [CI]: 0.210; 0.846); 0.456 (95%CI: 0.239; 0.869) and 0.408 (95%CI: 0.036; 4.61) in studies 1, 2 and 3, respectively.

Logistic regression also showed that, in study 1, the wound duration was an independent predictor of not healing (OR: 0.032 [95%CI: 0.032; 0.033] for each month). However, healing was not affected by a patient’s age, gender or initial wound size. Additionally, patients receiving compression were more likely to require analgesics (OR: 2.48 [95%CI: 1.21; 5.11]) and antibiotics (OR: 2.43 [95%CI: 1.22; 4.86]), over the 6-month study period.

In study 2, a patient’s age was an independent predictor of healing (OR: 0.942 [95%CI: 0.919; 0.966] for each additional year); however, healing was not affected by a patient’s gender, level of exudate or initial wound size. Patients using compression were more likely to use an antibiotic over the 6-month study period (OR: 1.34 [95%CI: 0.94; 2.01]).

In study 3, a patient’s age was an independent predictor for the use of compression (OR: 10.98 [95%CI: 10.08; 11.96] for each additional 10 years). However, healing was not affected by a patient’s age, gender, length of time with wound or initial wound size. Moreover, the healing rate at 6 months among amelogenin-treated patients who did not receive compression was 44% compared with 11% among those who did receive compression.

Among the patients who received compression, the VLU healing rate was higher in those using class II hosiery followed by short stretch compression, class I compression hosiery, multi-layer

compression, conforming retention bandage and high-compression bandages (Table 5).

Discussion

The cohorts of patients in these three studies were different from one another in terms of their wound duration, wound size and the dressings used to manage the wounds. Additionally, there were inconsistencies between the studies in the levels of exudate produced. Nevertheless, in these three distinct studies on non-healing VLU of >3 months' duration proportionally fewer patients healed if they received compression compared with those who did not receive any compression. The analysis also found that the healing rate following use of single-component compression systems was higher than that associated with use of multi-component compression systems.

These observations may be explained, in part, if patients were experiencing popliteal vein incompetence, as this has been reported to be an indicator of poor response to compression therapy.¹⁴ Additionally, healing of chronic VLUs could be affected by an interaction of the haemochromatosis gene polymorphism HFE H63D, since the healing of VLUs carrying this gene has been shown to be impaired by high-strength compression.¹⁵ Furthermore, insufficient arterial supply to the wounds in studies 1 and 2 cannot be excluded, in which case high levels of compression applied to these limbs, or inexperienced application of bandages, can exacerbate the wound, leading to tissue damage.¹⁶ Patients in studies 1 and 2 may have been treated with compression for some or all of the time, but this may not have been documented in their records. However, even if patients did not receive compression, it does not imply that the nurses were not attempting to manage their patients to the best of their ability. This is evidenced to some extent by the dressing choices between the compression and no-compression groups being different in both studies 1 and 2.

Notwithstanding this, these observations are contrary to the findings of a systematic review on the use of compression in VLU management.⁴ However, the review⁴ only evaluated controlled trials, hence the population in each study is likely to be a more homogenous cohort of patients, who fulfilled the study's admission criteria, than that seen in clinical practice. Also the follow-up period in many of the studies was typically 12 weeks. In contrast, two of our studies evaluated a cohort of patients managed in clinical practice without any exclusion criteria and followed them up for 6 months. Therefore, clinical effectiveness was evaluated at 6 months in clinical practice, rather than clinical efficacy at 3 months within a controlled framework. Notwithstanding this, study 3 was a multi-centred controlled trial in which patients

Table 4. Patient outcomes at 6 months

Study 1	Compression	No compression	p-value
Healed (%)	47%	68%	<0.02
Time to healing (months)*	2.7 ± 1.6	2.0 ± 1.5	N/S
Size of unhealed wounds (cm ²)*	144.1 ± 127.3	141.8 ± 121.0	N/S
Percent change in wound size (%)	-8%	-8%	N/S
Analgesic use at baseline (%)	46%	24%	<0.01
• Reduction in analgesic use (%)	6%	39%	<0.001
Antibiotic use at baseline (%)	100%	100%	N/S
• Reduction in antibiotic use (%)	30%	51%	<0.01
Study 2			
Healed (%)	6%	12%	0.05
Time to healing (months)*	5.3 ± 0.6	4.8 ± 1.0	N/S
Size of unhealed wounds (cm ²)*	79.2 ± 53.1	66.3 ± 41.0	<0.01
Percent change in wound size (%)	-17%	-23%	N/S
Analgesic use at baseline (%)	41%	38%	N/S
• Reduction in analgesic use (%)	10%	11%	N/S
Antibiotic use at baseline (%)	58%	51%	N/S
• Reduction in antibiotic use (%)	47%	50%	N/S
Study 3			
Healed (%)	11%	26%	0.03
Time to healing (months)*	3.0 ± 1.0	4.4 ± 1.7	N/S
Size of unhealed wounds (cm ²)*	22.9 ± 27.0	20.3 ± 20.2	N/S
Percent change in wound size (%)	15%	8%	N/S
Analgesic use at baseline (%)	42%	47%	N/S
• Reduction in analgesic use (%)	N/A	N/A	—
Antibiotic use at baseline	N/A	N/A	—
• Reduction in antibiotic use (%)	N/A	N/A	—

* Results presented as mean ± standard deviation

were followed-up for 6 months and the endpoint was clinical efficacy at that time point, but within a controlled framework.

An additional confounding factor is the unknown microbiological status of these wounds. Although some patients received antimicrobial dressings and/or systemic antibiotics, the authors were unable to comment on the need for, or the specific impact of, these interventions on individual wounds and their healing/non-healing status. The science underpinning the level and composition of wound bio-burden in relation to its impact on healing lacks clarity. In addition, chronic wounds will host biofilm

Table 5. Healing rate of different compression systems as a proportion of the healing rate in the no-compression group in each study

	Study 1 (n=332)	Study 2 (n=346)	Study 3 (n=64)	Mean
Class 2 compression hosiery	0.87	0.50	N/A	0.68
Short-stretch compression bandage	0.49	0.08	0.77	0.45
Class 1 compression hosiery	0.46	0.25	N/A	0.35
Multi-layer compression	0.40	0.08	0.58	0.35
Conforming retention bandage	0.28	0.00	0.38	0.22
High compression bandage	0.00	0.00	0.31	0.10

13 Blak, B.T., Thompson, M., Dattani, H., Bourke, A. Generalisability of The Health Improvement Network (THIN) database: demographics, chronic disease prevalence and mortality rates. *Inform Prim Car.* 2011; 19: 251–255.

14 Brittenden, J., Bradbury, A.W., Allan, P.L. et al. Popliteal vein reflux reduces the healing of chronic venous ulcer. *Br J Surg.* 1998; 85: 60–62.

15 Blättler, W., Lüscher, D., Brizzio, E. et al. Healing of chronic venous leg ulcers could be affected by an interaction of the hemochromatosis gene polymorphism HFE H63D with the strength of compression treatment—a re-analysis of patients from previous studies. *Wound Repair Regen.* 2012; 20: 123–124.

16 Nelson, E.A. Venous leg ulcers. *BMJ Best Practice Document.* 2011; Available from: bit.ly/199V8zy [Accessed March 2013].

17 Cutting, K.F., Wolcott, R., Dowd, S.E., Percival, S.L. Biofilms and significance to wound healing. In: Percival, S.L., Cutting, K.F. (eds). *The Microbiology of Wounds.* CRC Press, 2010.

18 Percival, S.L., Dowd, S.E. The microbiology of wounds. In: Percival, S.L., Cutting, K.F. (eds). *The Microbiology of Wounds.* CRC Press, 2010.

phenotypic bacteria.¹⁷ These multispecies bacterial communities have been frequently associated with delayed healing¹⁸ and as their presence in wounds is occult and no diagnostic test for biofilm exists it is difficult to directly attribute (other than a potential for delayed healing) the clinical implications of biofilm presence to the VLU included in this study.

Limitations

This analysis has a number of limitations. The studies were not powered to detect the effect of no compression. Hence, these studies have <80% power to detect significant differences with a type I (alpha) error of 0.05 between the two groups. The results were censored at 6 months and exclude the consequences of managing patients beyond this period. The analysis only considered the ‘average patient’ and no attempt was made to stratify the results according to gender, comorbidities, suitability of patients for different treatments and other disease-related factors. The uncertainty surrounding the microbiological status of the wounds is an additional study limitation. This is an unaccounted-for variable where the status of the wound bioburden will have an unknown positive or negative impact whether or not the patients received compression.

There are many outcomes that could be used to assess the effect of an intervention on a wound including wound healing, wound-size reduction, granulation, exudate reduction and epithelialisation. However, in studies 1 and 2 the records in the THIN database did not include all of this information for all patients. Reduction in wound surface area was the only outcome that could be estimated from all the patients’ records. In study 3, wound surface area was measured at each dressing change. Hence, reduction in wound surface area was the metric used to assess the effect of no compression.

As study 3 was a controlled trial, compression should have been applied correctly by the clinical investigators. However, studies 1 and 2 are an assessment of actual clinical practice in which compression was applied in the community by practice nurses and community nurses; therefore, it is questionable whether therapeutic levels of compression would have been consistently applied at all times. Indeed, it has been reported that the effectiveness of compression is likely to be influenced by the ability of those applying the bandage to generate safe levels of compression and by the fitting of appropriately sized compression stockings or leggings.¹⁶

Nevertheless, this analysis provides a provisional assessment of the clinical outcomes attributable to compression versus no compression. While the study results are surprising and compelling, the analyses were based on clinicians’ entries into their patients’ records and may be subject to a certain amount of imprecision and lack of detail. Moreover, the computerised information in the THIN database is collected by GPs for the purposes of clinical care for their patients and not for research purposes. Hence, some information may be required for research purposes that was not recorded since it was not required for clinical reasons.

This analysis raises the questions of whether the findings reflect:

- Correct use of compression bandaging?
- Improper use of compression bandaging?
- Influence of dressings under compression?
- Patient concordance?
- Lack of training among nurses?
- Lack of continuity/consistency of care of patients between clinicians at each dressing change?
- Differential effects between compression systems?
- Lack of mobility among patients treated with compression?
- Correct differential diagnosis of VLUs, or do some of these ulcers have an arterial involvement?

This study’s observations now need to be evaluated in a controlled trial comparing no compression with different compression systems in patients with a non-healing VLU of >3 months’ duration in which wound size, infection, healing and other clinical outcome measures, health-related quality of life and cost-effectiveness metrics are measured prospectively. Our observations have the potential for treatment modification, if confirmed in a prospective trial.

Conclusion

The healing rate of non-healing VLUs of >3 months’ duration in the no-compression groups was double that of VLUs in the compression groups. These findings have the potential for treatment modification if confirmed in a prospective trial. ■



Commentary

Should we forget compression therapy in long-standing, recalcitrant venous leg ulcers?

Following the data presented by Julian Guest et al. this question is open for discussion. At least in a real-life scenario, with predominantly old patients (mean age >70 years) suffering from many comorbidities and with the large majority being treated by staff who are not specifically trained, the authors have demonstrated that different compression modalities may cause more harm than benefit.

My usual suggestions in a patient whose leg ulcer does not show improvement after 4 weeks of compression are:

- Reconsider the diagnosis 'venous ulcer' and rule out potential additional pathologies (such as arterial occlusions)
- Check the quality of compression therapy.

These two points could also be crucial for explaining the unexpected results reported here:

At least in non-specialised centres, the diagnosis of 'venous' leg ulcer is usually made by exclusion of other underlying disease. Venous pathology, which is the main target of compression therapy, is rarely verified (by Duplex ultrasound) and even concomitant arterial occlusive disease may frequently be overlooked. In the above article, studies 1 and 2 seem to fall into this category.

Even more important is the quality of the compression therapy that has been used.

In studies 1 and 2, compression hosiery was applied in the majority of cases (62% and 58%, respectively), a rather disputable form of management in patients over 70 years old with large leg ulcers (mean size $\geq 10 \times 10$ cm), especially concerning applicability and concordance. However, it is amazing to see that, in study 1 after 6 months, 47% of these large ulcers were healed with compression and 68% without compression. The fact that such large ulcers, active for a mean duration of 5.8 months, were healed 6 months later just by local dressings comes close to a miracle. Maybe the antibiotics given to all patients in this study had a positive influence. Since the routine application of antibiotics in leg ulcers is not recommended in modern guidelines, this could be one issue to be investigated more closely in the future. Interestingly, much less favourable outcomes are demonstrated in study 2, despite similar baseline conditions, with healing rates after 6 months of only 6% in the compression group and 12% without compression.

In study 3, based on a randomised controlled trial (RCT) performed in a specialised centre, which compared different local dressings, 44% of the ulcers received 'conforming

retention bandages' and 29% 'high-compression bandages'. After 6 months, 26% were healed without but only 11% with compression. While the healing rate without compression comes close to recently-published data from an RCT,¹ the significantly worse result with compression shows that the chosen forms of compression have caused damage in a considerable portion of patients.

We are grateful to the authors for their article pointing to the challenge of treating recalcitrant leg ulcers in elderly patients in the community. The most important issue would be to avoid, or at least to reduce, the number of recalcitrant ulcers by early intervention targeted at reflux abolition and by adequate compression. In general, I believe that most non-healing ulcers are due to inadequate care, mainly because of poor compression.

So my answer to the initial question is clear: NO, we need compression therapy since we cannot escape from gravity. But there is a need for better knowledge of effective forms of compression to counteract gravity and especially better skills in performing proper bandaging learned and trained in qualified hands on courses, in order to improve the regrettable real life situation reflected in the article.

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References

- 1 Wong, I.K., Andriessen, A., Charles, H.E. et al. Randomized controlled trial comparing treatment outcome of two compression bandaging systems and standard care without compression in patients with venous leg ulcers. *J Eur Acad Dermatol Venereol.* 2012; 26: 102–110.

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