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Effective Health Care

Bulletin on the effectiveness of health service interventions for decision makers

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Compression therapy for venous leg ulcers

- Venous leg ulcers are a major cause of morbidity, especially in older people. There is wide variation in practice, and evidence of unnecessary suffering and costs due to inadequate management of venous leg ulcers in the community.
- Routine application of high compression therapy using one of a number of systems such as 3-, or 4-layer or short stretch bandages, Unna's boot or compression stockings, possibly with the addition of intermittent pneumatic compression, can significantly improve healing rates.
- Use of compression stockings should be encouraged to prevent the recurrence of venous leg ulcers. However, there is little evidence to support the use of drug therapy using stanozolol or oxerutins.
- Patients with arterial disease are not suitable for high compression therapy. Arterial disease can be diagnosed more accurately if highly trained operators measure the ratio of ankle to brachial systolic pressure (ABPI) rather than feel for foot pulses alone.
- Community nurses should be adequately trained in leg ulcer management, including patient assessment and bandage application.
- The issues raised in this bulletin should be discussed with providers of primary care and community nursing services and relevant hospital specialists so as to co-ordinate services, ensure adequate nurse education and establish systems to monitor standards of care.

The contents of this bulletin are likely to be valid for around one year, by which time significant new research evidence may have become available.

A. Background

A.1 The importance of leg ulceration: Leg ulcers are areas of *"loss of skin below the knee on the leg or foot which take more than 6 weeks to heal"*.[1] Leg ulceration is a common chronic recurring condition and a major cause of morbidity and suffering (Fig. 1).[2,3] Annual costs to the NHS of leg ulceration have been estimated to be as high as £230–400 million (1991 prices) of which nursing time is a major element.[4]

Fig. 1 A venous ulcer

About 1.5–3.0 per 1,000 population have active leg ulcers and prevalence increases with age up to around 20 per 1,000 in people over 80 years.[5–7] Leg ulceration is strongly associated with venous disease (e.g. varicose veins and a history of deep vein thrombosis).[8] Arterial disease is present (alone or with venous problems) in approximately 20% of cases of leg ulceration.

Leg ulcer disease is typically chronic and patients with active ulceration for more than 60 years have been documented.[9] There is wide variation in reported recurrence with re-ulceration rates of 26%[10] to as high as 69% at one year being reported.[11] People at higher risk of recurrence include those with a previous ulcer size greater than 10cm^2, a history of deep vein thrombosis and those unable to wear compression stockings.[10]

A.2 The management of venous leg ulceration: Most people with leg ulcers are managed by GPs and community nurses but a significant number are managed in hospital settings.[5,6] Audits have shown wide variation in the clinical management of leg ulcers.[3,12] Numerous types of wound dressings, bandages and stockings are used in the treatment of venous leg ulcers and the prevention of recurrence. A survey of 301 patients with leg ulcers in the Wirral found 26 different primary dressings in use and 42 different preparations being applied to the surrounding skin. A similar audit in Stockport identified 31 different dressings, 28 bandages and 59 topical preparations in use.[13]

This issue of *Effective Health Care* summarises the results of research on the effectiveness and cost-effectiveness of different forms of compression in the treatment of venous ulceration;[14] on interventions to prevent recurrence; and on methods of diagnosing venous ulceration. The methods used in this systematic review[15] are outlined in the appendix and given in more detail in the *Cochrane Library*. The bulletin does not consider the effectiveness of dressings, debridement or skin grafts which are the subject of future review work.

B. Compression therapy

Below-knee compression graduated from toe (highest) to knee (lowest), in the form of bandaging or stockings, is viewed as a key component of treatment when venous leg ulceration occurs in the absence of significant arterial disease (Fig 2). A range of compression systems are used (see Box), which apply varying levels of compression, using different materials with varying degrees of elasticity. There is considerable uncertainty however, as to the most effective method. The preferred treatment for leg ulcers in the USA is Unna's boot; in other parts of Europe short stretch bandaging is more popular, whilst 4-layer bandaging is increasingly advocated in the UK. Twenty randomised controlled trials (RCTs) evaluated different forms of compression bandaging on venous ulcer healing in a wide range of age groups.[16–35] Two of these incorporated economic evaluations,[17,35] 2 compared compression stockings with compression bandages,[36,37] and 2 evaluated intermittent pneumatic compression.[38,39] Overall, the quality of trials is poor; a summary is available elsewhere.[14]

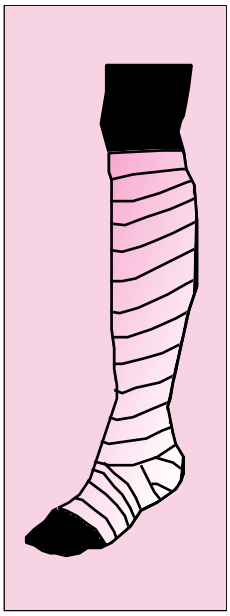

Fig. 2 Compression bandaging from toe to knee

B.1 Compression versus no compression: Six RCTs assessed whether compression therapy was better than no compression (Table 1).[16–21] These show that compression provided either by Unna's boot,[19,20] 2-layer,[16] 4-layer[17] or short stretch bandages[18] improve healing rates compared to treatments using no compression. One study showed that compression therapy was more cost-effective because the faster healing rates saved nursing time.[17]

B.2 High compression versus low compression: Three RCTs compared elastic high compression 3-layer bandaging (two using Tensopress and one Setopress as a component) with low compression (using

Box Examples of compression bandages commonly used in the management of venous leg ulcers. Adapted from Morison[57]

Type of Compression	Examples	Performance Characteristics
High elastic compression	Tensopress* (Smith & Nephew) Setopress* (Seton) Surepress* (Convatec)	Sustained compression; can be worn continuously for up to 1 week; can be washed and reused
Light compression/ light support	Elastocrepe* (Smith & Nephew)	Low pressures obtained; used alone it only gives light support; a single wash reduces pressures obtained by about 20%
Light support only	crepe* (many manufacturers)	For holding dressings in place, as a layer within a multilayer bandage, for light support of minor strains and sprains; pressures from crepe alone are too low to be effective in management of venous ulcers; 40-60% of pressure lost in first 20 minutes after application
Cohesive bandages	Co-Plus* (Smith & Nephew) Tensoplus* (Smith & Nephew) Coban* (3M)	Self-adherent so preventing slippage; useful over non-adhesive bandages such as Elastocrepe and paste bandages; compression well sustained
Multilayer high compression	'Charing Cross' 4 layer bandage comprising: orthopaedic padding; crepe; Elset; Coban. Other multilayer systems are in use e.g. orthopaedic padding; Tensopress; shaped tubular bandage.	Designed to apply 40 mmHg pressure at the ankle, graduating to 17 mmHg at the knee, sustainable for a week.
Inelastic compression	Short-stretch bandage e.g. Comprilan (Beiersdorf) Unna's boot	Principal bandage in mainland Europe. Reusable with slight stretch giving low resting pressure but high pressure during activity. Non compliant, plaster-type dressing used in USA.
Compression stockings	Class 1 - light support Class 2 - medium support Class 3 - strong support	Used to treat varicose veins Used to treat more severe varicosity and to prevent venous ulcers in patients with thin legs For treatment of severe chronic venous hypertension and severe varicose veins and to prevent ulcers in patients with large-diameter legs

*often used as component of multi-layer system

Elastocrepe) (Table 2).[22–24] More patients were healed at 12–15 weeks with high compression (Odds Ratio = 2.26; 95% CI: 1.4, 3.65). The advantage of higher compression was confirmed in another RCT in which patients with either 4-layer or short stretch bandaging healed faster than those receiving a paste bandage with outer support.[25]

B.3 Different types of high compression: Several types of high compression systems are available, some of which have been compared directly in RCTs. The original 'Charing Cross' 4-layer bandage (see Box) has been compared with both a kit that provides all the constituents to make up a 4-layer bandage,[29] and a regimen adapted to achieve similar levels of compression using materials available on prescription.[30] No statistically significant difference in outcome was found in either study, although the latter trial was very small (Table 3).

Four-layer bandaging has also been compared with short stretch[25, 26] and with Unna's boot[27, 28] in 4 RCTs. No differences were found in the healing rates. However, because these studies were small in size, we cannot be confident that there are not clinically important differences in effectiveness (Table 4).

The advantage of multilayer high compression systems over single layer systems is shown by 1 large and 2 small trials which found more ulcers healed at 24 weeks using 4-layer bandaging than were healed using a single layer, adhesive compression bandage (Table 5).[31–33]

Even though 3-layer, 2-layer and other compression bandages have been shown to be effective, they appear not to have been directly compared with 4-layer bandaging in RCTs. A trial comparing 4-layer with 3-layer bandaging is however, being carried out at St. Thomas's Hospital, London.

Compression stockings have also been used to treat current ulcers.[40] A combination of 2 compression stockings has been shown to increase the rate of healing compared to a short stretch bandage (Odds Ratio = 4.9, 95%CI: 1.3, 18.3) (Table 6).[37]

B.4 Intermittent pneumatic compression treatment: Two small studies showed that more ulcers healed when intermittent pneumatic compression was used in addition to compression stockings or Unna's boot (pooled OR = 10.0; 95% CI: 2.96, 33.8) (Table 7).[38, 39]

C. Prevention of recurrence

Seven RCTs comparing interventions to prevent recurrence were identified; their quality is summarised in Table 8.

C.1 Compression stockings: No RCT was found which compared recurrence rates achieved with and without compression stockings in people with healed ulcers. One trial however, showed that 3–5 year recurrence rates were lower in patients using strong support from class 3 compression stockings (21%) than in those randomised to receive medium support from class 2 compression stockings (32%) (p=0.034); class 2

Table 1 RCTs of compression versus no compression (alone/usual treatment) I = Intervention

Study	Patients and interventions	Initial ulcer size & duration	Results
Charles 1991[18] UK	53 community-based patients from inner London I1: short stretch bandage applied by project nurse (Rosidal K) I2: 'usual treatment' applied by district nurse Follow up: 3 mths	Mean ulcer area (cm^2) I1: 12; I2: 15 Mean duration (mths) I1: 32; I2: 25	Complete healing I1: 71%; I2: 25% Ulcers increased in size I1: 0%; I2: 21% Attrition: I1:3; I2: 3
Eriksson 1984[16] Sweden	44 patients, setting unclear I1: Skintec porcine skin dressing (no compression) I2: Metallina aluminium foil dressing (no compression) I3: double layer bandage (ACO paste bandage + Tensoplast) Follow up: 2 mths	Not stated	No statistical analysis reported. Decrease in ulcer area and volume I1: 60%, 67%; I2: 10%, 0%; I3: 80%, 90% Atttrition: I2:6 In the 'middle' of the trial, patients in the porcine skin group were crossed over to double layer bandage
Kikta et al 1988[19] USA	84 patients from vascular surgery clinics with 87 ulcers I1: Unna's boot I2: Duoderm hydrocolloid dressing Follow up: 6 mths	Mean ulcer area (cm^2) I1: 9 I2: 8.6 Mean duration (wks) I1: 45 I2: 51	N.B. 69 ulcers in 66 patients; I2 group contained 3 patients with 2 ulcers Completely healed at 6 mths I1: 21/30 (70%); I2: 15/39 (38%) Life table analysis - ulcers healed at 15 wks I1: 64%; I2: 35% [p=0.01] Complication rate I1: 0%; I2: 26% Attrition: I1: 12; I2: 16
Rubin et al 1990[20] USA	36 consecutive ambulatory patients I1: Unna's boot I2: polyurethane foam dressing (Synthaderm) Follow up: unclear possibly 1 yr	Mean ulcer area (cm^2) I1: 76; I2: 32.2 Mean duration: not stated	Completely healed I1: 18/19 (94.7%); I2: 7/17 (41.2%) [p = 0.005] Attrition: I2: 9
Sikes 1985[21] USA	13 male patients (42 ulcers), a convenience sample from outpatient vascular surgery clinic I1: Unna's boot I2: polyurethane moisture vapour permeable, transparent film dressings (OpSite) Follow up: 1 yr	Mean ulcer area not stated but I1 had a mean of 3 ulcers and I2 had a mean of 3.5 ulcers. Mean duration I1: 3.5 yrs; I2: 6.9 yrs	Completely healed I1: 17/21 (81%); I2: 15/21 (71%) [p>0.05] Attrition: none
Taylor et al[17] UK	30 patients referred to the clinic by GPs Community setting I1: 4 layer bandage I2: conventional treatment (FP10 non-compression) Follow-up: 3 mths	Mean ulcer area (cm^2) I1: 5.4; I2: 4.2 Mean duration I1: 7 ulcers <6 mths; 9 ulcers >6 mths I2: 9 ulcers <6 mths; 5 ulcers >6 mths	Complete healing I1: 12 (75%); I2: 3 (21%) [p = 0.003] Median time to healing (days) I1: 55; I2: >84 [p = 0.003] Total average wkly treatment costs and cost of district nursing time were less in I1 [p = 0.04]

stockings however, were better tolerated by patients (Table 9).[41]

C.2 Pharmacological and surgical interventions: Two drugs have been investigated for their effects on leg ulcer recurrence: stanozolol, an anabolic steroid which increases fibrinolysis; and rutoside (Paroven) an oxerutin which is said to decrease capillary permeability. These drugs have been compared with placebo in 2 RCTs in which all patients also received class 2 compression stockings.[42,43] Both trials found that neither drug reduced recurrence.

Surgery in which incompetent communicating veins are ligated and varicose veins are eradicated has been compared in 2 small trials with the drug stanozolol (both combined with compression stockings) (Table 10). These gave conflicting results; one showing a lower recurrence rate with surgery within 1 year[44] and the other showing reduced recurrence with drug therapy at 5 years.[45]

One trial appeared to show a moderately reduced rate of recurrence when surgery was carried out in addition to the use of elastic stockings, however the study was small and poorly reported (see Table 9).[58]

Table 2 RCTs of elastic high compression bandaging *versus* low compression

Study	Patients and interventions	Initial ulcer size & duration	Results
Callam et al 1992[22] UK	132 patients from leg ulcer clinics (multicentre) Male and female I1: elastic compression: Soffban+ Tensopress+ Tensoshape I2: non-elastic compression: Soffban + Elastocrepe + Tensoplusforte Follow up: 3 mths	Mean ulcer area (cm^2) I1: 8.2 I2: 11.0 Mean duration (mths) I1: 11.3 I2: 11.5	Complete healing I1: 35/65 (54%); I2: 19/67 (28%). [$p = 0.01$] However, patients were only followed up for 12 wks and at this point a large number of I2 patients were almost healed. Attrition: I1:8; I2: 20
Northeast et al 1990[23] UK	106 patients presenting to outpatient clinic I1: 3-layer bandage (Calaband + Elastocrepe + Tensogrip) I2: 3-layer bandage (Calaband + Tensopress + Tensogrip) Follow up: 3 mths	Not stated	Complete healing I1: 51%; I2: 64% [$p = 0.01$] Attrition: 3
Gould et al[24] UK	39 ambulatory patients (46 ulcers) from general practices attending outpatient clinic I1: elastic compression (Setopress) + medicated paste bandage + elasticated viscose stockinette I2: inelastic bandage (Elastocrepe) + medicated paste bandage + elasticated viscose stockinette 1 wk prior to treatment patients wore Setopress bandage Follow up: 16 wks	Mean ulcer area (cm^2) 7.44 Median duration (mths) 10	Healed or progressed I1: 11 (58%); I2: 7 (35%) [$p>0.05$] Attrition: 7 patients (10 ulcers)
Duby et al 1993[25] UK	67 patients (76 legs) I1: orthopaedic wool + short stretch bandage (Comprilan) + Tricofix net covering I2: 4-layer bandage (orthopaedic wool + crepe bandage + Elset + Coban) I3: paste bandage (Icthopaste) + support bandage (Elastocrepe and Tubigrip) Follow up: 3 mths	Mean ulcer area (cm^2) I1: 13.1 I2: 11.9 I3: 12.3 Mean duration (mths) I1: 26.7 I2: 20.5 I3: 34.5	Complete healing (ulcers) I1: 40%; I2: 44%; I3: 23% Attrition: none

Table 3 Comparing between different multilayer high compression systems

Study	Patients and interventions	Initial ulcer size & duration	Results
McCollum et al[29] UK	232 patients from community leg ulcer services I1: 'original' Charing Cross 4-layer I2: new proprietary 4-layer (Profore system) Follow up: 6 mths	Percentage <10cm^2 I1: 82%; I2: 84% Median duration: (wks) I1: 8; I2: 7	Complete healing I1: 82%; I2: 84% ($p>0.05$) Attrition: I1: 16%; I2: 15%
Wilkinson et al 1997[30] UK	35 legs in 29 patients recruited through district and practice nurses I1: Charing Cross 4-layer bandage I2: "Trial bandage": Tubifast + separate strips of lint applied horizontally + Setopress + Tubifast (to secure bandage) [Patients were stratified by ulcer size] Follow up: 3 mths	Mean ulcer area (cm^2) I1: 11.2; I2: 8.6	Complete healing I1: 8/17 (47%); I2: 8/18 (44%) Odds Ratio = 1.1; 95% CI: 0.2–5.2 Attrition: I1: 4; I2: 2

D. Diagnosis

The high rates of co-morbidity in patients with leg ulceration mean that careful assessment of all patients is important. This is particularly the case as considerable damage can be caused by inappropriately applying high compression in patients with arterial and small vessel disease.[46] There is debate about how arterial status should be assessed and whether this assessment should be undertaken routinely by nurses. Research into the precision and accuracy of the nursing assessment of leg ulcer patients is lacking.

Table 4 RCTs of elastic high compression bandaging *versus* inelastic compression

Study	Patients and interventions	Initial ulcer size & duration	Results
Duby 1993[25]	See Table 2		
London and Scriven[26] UK	30 ambulant patients I1: 4-layer bandage (orthopaedic wool, crepe, Elset, Coban) I2: short stretch (orthopaedic wool, short stretch, Coban) Follow up: 1 yr	Median ulcer area (cm^2) I1: 12.4; I2: 8.16 Median duration (mths) I1: 18; I2: 24	Healing rate I1: 60%; I2: 60% Attrition: I1: 4
Colgan et al[27] Ireland	30 patients at routine venous ulcer out-patient clinic I1: modified Unna's boot (paste bandage + Elastocrepe + Elastoplast + class II compression sock) I2: 4-layer bandage (Profore) (4LB) I3: Lyofoam dressing + Setopress compression bandage Follow up: 3 mths	Median ulcer area (cm^2) I1: 7; I2: 9; I3: 20 Median duration (mths) I1: 24; I2: 10; I3: 12	Complete healing: I1: 6/10 (60%) I2: 7/10 (70%) I3: 2/10 (20%) Mean bandage costs in IR£ I1: £82.54 I2: £66.24 I3: £58.33
Knight & McCulloch 1996[28] USA	10 patients randomly chosen from patients at a wound care centre I1: 4-layer bandage (Profore) I2: Unna's boot Follow up: 6 wks	Not stated	Average rate of ulcer healing (cm^2/ wk) I1: 1.14 ; I2: 0.34 Attrition: not stated
Inelastic compression versus single layer bandage			
Cordts et al 1992[34] USA	43 patients, >18 yrs, male and female, outpatient clinic I1: Hydrocolloid dressing (Duoderm) + graduated compression (Coban wrap) I2: Unna's boot Follow up: 3 mths	Median ulcer area (cm^2) I1: 9.1 I2: 6.0 Mean duration (wks) I1: 95 I2: 96	Complete healing I1: 8/16 (50%); I2: 6/14 (43%) [p = 0.18] Attrition: I1: 7; I2: 6

Table 5 RCTs of multilayer high compression systems versus single-layer bandage systems

Study	Patients and interventions	Initial ulcer size & duration	Results
Nelson et al 1995[31] UK	200 patients referred by GPs and community nurses, age > 18 years, attending leg ulcer clinic I1: 4-layer bandage (orthopaedic wool + crepe + Elset + Coban) I2: single layer bandage (Granuflex adhesive compression bandage) [Primary dressing randomised to knitted viscose dressing or hydrocolloid dressing. Patients were also randomised to oxpentifylline or placebo] Follow up: not stated	Mean ulcer area (cm^2) I1: 7.8; I2: 12.4 Mean duration (mths) I1: 15.5; I2: 11	Complete healing I1: 69%; I2: 49% Odds ratio = 2.4; 95% CI: 1.3–4.3 Attrition: greater in I1 than I2
Kralj & Kosicek[32] Slovenia	40 in- and outpatients I1: 4-layer bandage (Profore) I2: single layer bandage (Porelast) + hydrocolloid dressing (Tegasorb) Follow up: 6 mths	Mean ulcer area (cm^2) I1: 18.6; I2: 17.2 Mean duration (mths) I1: 7.9; I2: 6.9	Complete healing I1: 7/20 (44%); I2: 8/20 (44%) Attrition: I1: 4; I2: 2
Travers et al 1992[33] UK	27 patients attending leg ulcer clinic I1: self adhesive 1-layer bandage (Panelast Acryl) I2: 3-layer bandage (Calaband + Tensopress + Tensogrip) Follow up: 6 mths	Mean ulcer area (cm^2) I1: 31 I2: 23 Mean duration (mths) I1: 23 I2: 35	Reduction in ulcer area I1: 86%; I2: 83% [no sig. diff.] Bandage costs equivalent Attrition: none

Table 6 RCTs of compression stockings *versus* compression bandaging

Study	Patients and interventions	Initial ulcer size & duration	Results
Hendricks & Swallow 1985[36] USA	21 patients attending outpatients clinic I1: Unna's boot + Kerlix roll + elastic bandage I2: open toe, below knee graduated compression stockings Follow up: 18 mths	Median ulcer area (cm^2) 2.55 Median duration 4.5 yrs	Complete healing I1: 7/10 (70%); I2: 10/14 (71%) but 3 of these were transferred from I1 Patients cross between arms depending on progress. No intention to treat analysis carried out.
Horakova & Partsch 1994[37] Austria	59 patients attending a dermatology clinic I1: Short stretch bandage (Rosidal K) I2: Thrombo stocking + compression stocking (Sigvaris– removed at night) Follow up: 3 mths	Mean ulcer area (cm^2) I1: 3.2; I2: 6.0 Mean duration (mths) I1: 2; I2: 5 [p<0.05]	Complete healing I1: 13/25 (52%); I2: 21/25 (84%) [p < 0.05] Attrition: I1:6; I2:3

Table 7 RCTs of intermittent pneumatic compression treatment

Study	Patients and interventions	Initial ulcer size & duration	Results
Coleridge Smith et al 1990[38] UK	45 patients (48 ulcers) attending venous ulcer outpatient clinic I1: graduated compression stockings I2: I1 + intermittent sequential gradient pneumatic compression used daily in the home Follow up: 3 mths	Median ulcer area (cm^2) I1: 17.3; I2: 49.8 Median duration (yrs) I1: 3.5; I2: 3.9	Completely healed I1: 1/24 (4%) patients; I2: 10/21 (48%) patients [p = 0.009] I1 contained patients with 2 ulcers Attrition: none
McCulloch et al 1994[39] USA	22 patients attending vascular surgery clinic I1: Unna's boot only I2: I1 + intermittent one cell pneumatic compression applied for one hour, twice a week after cleansing Follow up: 6 mths	Mean ulcer area (cm^2) I1: 0.4 - 59.4 I2: 0.4 - 45.0	Completely healed I1: 8/10 (80%); I2: 12/12 (100%) Attrition: none

Arterial disease of the leg is most commonly detected by a combination of general clinical examination and either manual palpation of foot pulses or by measuring the ratio of the systolic blood pressure at the ankle to that in the arm (the ankle:brachial pressure index ABPI).[47] The ABPI ratio is measured using a hand-held Doppler ultrasound together with a sphygmomanometer. An ABPI ratio of less than 1.0 is viewed as indicative of some arterial impairment. The cut-off point below which compression is generally not applied in clinical practice is often quoted as 0.8[47] however, many trials use the higher cut-off of 0.9.

There is generally poor agreement between manual palpation of foot pulses and ABPI. Two large studies have shown that 67% and 37% of limbs respectively with an ABPI <0.9 had palpable foot pulses, with the consequent risk of applying compression to people with arterial disease.[47, 48] Even though ABPI measurement appears to be better than manual palpation for excluding arterial disease, ABPI measurement has been shown to be unreliable when carried out by inexperienced operators.[49] Reliability can however, be significantly improved if people are highly trained.[50, 51]

E. Organisation of care

A recent trial in Sheffield (Table 11) showed that care delivered in leg ulcer clinics, by trained nurses, following a treatment protocol which included use of 'Charing Cross' 4-layer bandaging resulted in better healing at 1 year (65%) than in patients who continued their usual treatment at home provided by their district nurse, who did not routinely have access to the 4-layer bandage (55%).[35] The clinic was also more cost-effective. Improved healing associated with specialist clinics using 4-layer bandaging was also shown in a second small trial.[17] These 2 trials do not however, provide information on the relative impact of, or interactions between, the various elements of setting, nurse training, compression bandaging, and protocols for treatment and referral. It is possible for example, that similar improvements in healing could be achieved without the use of clinics or by using other high compression therapies.

A survey in Leeds found that district nurses' knowledge of the assessment and management of leg ulcers was often inadequate.[52] Another survey reported that 50% of nurses made a diagnosis of the cause of the ulcer based on visual assessment alone.[53]

Table 8 Quality of RCTs of interventions to prevent recurrence of venous ulcers

Study	Clear inclusion and exclusion criteria reported	Sample size [arms]	A priori sample size calculation?	Method of randomisation	Baseline comparability or treatment groups	Blinded outcome assessment	With-drawals reported by group with reasons	Analysed by intention to treat/life table method
Franks et al 1995[10]	✓	166 [2]	✓	not stated	✓	not stated	none stated	✓
Harper et al 1995[41]	×	300 [2]	not stated	concealed	not stated	×	×	✓
McMullin et al 1991[42]	✓	48 limbs [2]	not stated	not stated but double blind so assume allocation concealment	not stated for previously ulcerated limbs	✓	✓ but no individual details for previously ulcerated limbs	unclear
Lagatolla et al 1995[45]	brief	105 [2]	not stated	not stated	not stated	not stated	X (reasons given for 22 withdrawals but a further 19 people are missing from the data)	✓
Stacey et al 1988[61]	✓	30 (41 limbs) [2]	not stated	not stated	only for venous status	not stated	not stated	unclear
Stacey et al 1990[44]	brief	55 (68 limbs) [2]	not stated	not stated	✓	not stated	✓	×
Wright et al 1991[43]	brief	138 [2]	✓	concealed randomisation code	✓	✓	not stated	✓

Table 9 RCTs of prevention of recurrence of venous ulceration using compression stockings and venous surgery

Study	Patients and interventions	Initial ulcer size & duration	Results
Franks et al 1995[10] UK	166 patients from community leg ulcer clinics with newly healed ulcers, mean age 72 yrs I1: class 2 below knee stockings (Medi, UK) I2: class 2 below knee stockings (Scholl) New stockings prescribed every 3 months Follow up: 18 mths	Median ulcer (cm^2) I1: 3.3; I2: 3.5 Median ulcer duration: (mths) I1: 5.7; I2: 2.0 Mobility (chairbound; walk+aid; walk freely I1: 4(4%): 27(29%); 61(67%) I2: 1(1%): 23(31%); 50(68%)	Recurrence rate at 18 mths I1: 24% I2: 32% Adjusted RR = 1.16; 95% CI 0.65–2.04] Attrition: none stated Overall 83% all day wear (no difference)
Harper et al 1995[41] UK	300 patients with newly healed venous leg ulcers I1: Class 2 stockings I2: Class 3 stockings Refitting and supply of new stockings every 4 months Follow up: 5 yrs	Not stated	recurrence within 36–60 mths I1: 32%; I2: 21% [p=0.034]
Stacey et al 1988[58] UK	30 patients with 41 previously ulcerated limbs attending surgical outpatients I1: surgery – ligation of incompetent communicating veins and ablation of incompetent superficial veins plus permanent below-knee elastic stockings (Sigvaris) I2: stockings – below-knee stockings (Sigvaris) NB. Limbs rather than patients were randomised Follow up: 1 yr	I1: 8 had evidence of past DVT I2:10 had evidence of past DVT	Ulcer recurrence: I1: 1 (5% limbs); I2: 5 (24% limbs) Attrition: not stated

Table 10 RCTs of pharmacological interventions for the prevention of recurrence of venous ulceration

Study	Patients and interventions	Initial ulcer size & duration	Results
Lagatolla et al 1995[45] UK	136 patients with healed venous ulcers attending outpatients clinic I1: Stanozolol 5mg bd for 12 months plus compression stockings I2: surgery – ligation of calf, perforating veins plus compression stockings Follow up: 5 yrs	Not stated	I1: 10/42 recurrences (24%) I2: 13/41 recurrences (32%) Life table analysis: increased ulcer-free survival in surgery group (NS) Attrition: I1: 9; I2: 13
McMullin et al 1991[42] UK	48 limbs with healed venous ulcers out of a total of 85 limbs in 60 patients being treated for lipodermatosclerosis I1: Stanozolol 5 mg bd + below knee class II graduated compression stocking (Venosan, Switz) I2: placebo tablet + stockings as in I1 Follow up: not stated how much beyond 6 mths treatment	Not stated	Recurrence of ulceration: I1: 7/25 limbs (20%) I2: 4/23 limbs (17%) [p>0.6] Attrition: I1: 6/30; I2: 3/30
Stacey et al. 1990[44] UK	68 limbs of 54 patients with healed venous ulcer I1: Stanozolol 5 mg bd for 9 months + below knee graduated stockings (Sigvaris) I2: Ligation of the incompetent communicating veins and eradication of all visible varicose superficial veins + stockings as I1 (stockings worn continuously and replaced every 6 mths) Follow up: 12 mths	Number of limbs with normal deep veins I1: 9/49; I2: 13/49 Number of limbs with post-thrombotic changes: I1: 15/49; I2: 12/49	Limbs in which ulcers recurred within 12 mths I1: 6/24 limbs (5/17 pts) I2: 1/25 limbs (1/20 pts) Attrition: I1: 8; I2: 9
Wright et al 1991[43] UK	138 patients with recently healed venous ulcer recruited at first follow up appointment I1: Oxerutins (Paroven, Zyma, UK) 500 mg bd + below knee class II graduated elastic stockings I2: identical placebo + stockings as in I1 Stockings replaced where necessary at 3-monthly intervals, equal numbers in each group randomised to surgery Follow up: 18 mths	Mean duration (mths) I1: 8.9; I2: 8.8 Additional illnesses No significant differences between groups	Cumulative recurrence at 18 mths I1: 34%; I2: 32% [p = 0.93 log rank test] Attrition: not stated

Table 11 RCTs of compression from trained nurses and/or specialised clinics versus usual district nurse treatment

Study	Patients and interventions	Initial ulcer size & duration	Results
Morrell et al[35] UK	233 ambulant patients from 8 clinics who had suspected venous ulcers I1: 4-layer bandaging delivered by project nurses in clinic I2: 'usual care' from district nurses at home Follow up: 1 yr	Mean ulcer area (cm^2) I1: 16.2 ; I2: 16.9 Mean duration (mths) I1: 27.5; I2: 29.7	Complete healing at 12 mths I1: 65%; I2: 55% Difference in percentage healed = 11; 95% CI: -0.02 – 0.24. Overall there is a statistically significant difference in healing rate p = 0.03 log rank test Attrition: I1: 16; I2: 13
Taylor et al[17]	See Table 1		

Large variability in the way bandages are applied and the pressures achieved have also been observed. More experienced or well trained bandagers obtained better and more consistent pressure results.[54] Training of nurses can result in improved bandaging technique,[55] but there is some evidence that maintenance of good practice requires monitoring, feedback and supervision.[52, 55]

F. Implications

- Diagnosis of arterial status (to determine eligibility for compression therapy) is more accurate when based upon the ABPI measurement than manual palpation of foot pulses alone. However, unless operators are well trained, ABPI measurements can be unreliable.
- The most effective intervention for the treatment of venous leg ulcers is high compression provided by 4- or 3-layer (multilayer) or short stretch bandages, Unna's boot or compression stockings, possibly with the addition of intermittent pneumatic compression. Routine application of one of these high compression techniques in

people with venous ulcers should have a significant impact on healing rates and save time spent by community nurses. Despite the promotion in the UK of 4-layer bandaging, there is little reliable evidence for its superiority over other high compression techniques.

- High compression bandage systems and their components vary in their availability in the community. Orthopaedic wool padding, a component of most high compression systems, is not available on prescription, and purchasers and providers should consider how this can be made readily available to community nurses.

- Whichever high compression approach is employed, it is important that it is used correctly so that sufficient (but not excessive) pressure is applied. Community nurses and other practitioners should be better trained and monitored in leg ulcer management, including patient assessment, and bandage application.

- Use of compression stockings should be encouraged for the prevention of recurrence. However, there is little evidence to support the use of drug therapy using stanozolol or oxerutins.

- Systems should be put in place to monitor standards of care as measured by *structure* (e.g. the proportion of appropriately trained staff); *process* (e.g. the proportion of patients whose arterial status has been determined by ABPI measurement, and the proportion with uncomplicated venous ulcers receiving high compression therapy); and *outcome* (e.g. the prevalence of active ulceration, proportion of patients healed, rates of healing and adverse outcomes due to incorrectly treated arterial disease or excessive compression).[56]

- The issues raised in this bulletin should be discussed with providers of primary care and district nurse services and relevant hospital specialists so as to co-ordinate services, ensure nurse training and supervision and establish systems to monitor standards of care.

- Further RCTs of sufficient size and follow-up are necessary. In particular there is a need to determine the most cost-effective high compression systems, whether surgery for certain groups of patients confers any added benefit, and the additional importance (if any) of the organisation of care once proper compression systems are in place.

- The Royal College of Nursing is leading the development of a clinical guideline on leg ulcer assessment and management, based on this *Effective Health Care* bulletin. It is expected that the guideline will be available in mid-1998.

Appendix: Methods used to review the research

A systematic review of research with no restriction on date or language was carried out using 18 electronic databases including MEDLINE, CINAHL and EMBASE. Relevant journals and conference proceedings were handsearched and experts consulted. Published and unpublished RCTs which measured ulcer healing were included because in RCTs statistically significant differences in outcomes can be more confidently attributed to a particular treatment. Studies which compared healing rates using a new treatment with historical controls were excluded as this design is more susceptible to bias. The methodological quality of each study was assessed using a checklist, by two reviewers working independently.

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