



SIGN

Scottish Intercollegiate Guidelines Network

Part of NHS Quality Improvement Scotland



120

Management of chronic venous leg ulcers

A national clinical guideline



August 2010

KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

LEVELS OF EVIDENCE

1 ⁺⁺	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 ⁺	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1 ⁻	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2 ⁺⁺	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2 ⁺	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2 ⁻	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, eg case reports, case series
4	Expert opinion

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A	At least one meta-analysis, systematic review, or RCT rated as 1 ⁺⁺ , and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1 ⁺ , directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2 ⁺⁺ , directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1 ⁺⁺ or 1 ⁺
C	A body of evidence including studies rated as 2 ⁺ , directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2 ⁺⁺
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2 ⁺

GOOD PRACTICE POINTS

- | | |
|-------------------------------------|---|
| <input checked="" type="checkbox"/> | Recommended best practice based on the clinical experience of the guideline development group |
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Scottish Intercollegiate Guidelines Network

Management of chronic venous leg ulcers
A national clinical guideline

This guideline is dedicated to the memory
of Dr Susan Morley



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SIGN consents to the photocopying of this guideline for the
purpose of implementation in NHSScotland

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1 Introduction

1.1 BACKGROUND

Venous ulceration is the most common type of leg ulceration. Sixty to 80% of leg ulcers have a venous component.¹⁻⁷ The Lothian and Forth Valley Study examined 600 patients with leg ulceration and found that 76% of ulcerated legs had evidence of venous disease and 22% had evidence of arterial disease. Ten to 20% of cases had both arterial and venous insufficiency. Nine per cent of ulcerated legs were in patients with rheumatoid arthritis. Five per cent of the patient group had diabetes.⁸

Chronic venous leg ulceration has an estimated prevalence of between 0.1% and 0.3% in the United Kingdom.^{1-6,9} Prevalence increases with age.⁸ Approximately 1% of the population will suffer from leg ulceration at some point in their lives.¹⁰

Venous ulcers arise from venous valve incompetence and calf muscle pump insufficiency which leads to venous stasis and hypertension. This results in microcirculatory changes and localised tissue ischaemia.^{11,12} The natural history of the disease is of a continuous cycle of healing and breakdown over decades and chronic venous leg ulcers are associated with considerable morbidity and impaired quality of life.¹³ Leg ulcers in patients from the most deprived communities (social classes IV and V) take longer to heal and are more likely to be recurrent.¹⁴

Treatment of this major health problem results in a considerable cost to the NHS. The cost of treating one ulcer was estimated to be between £1,298 and £1,526 per year based on 2001 prices and in the context of a trial conducted within a specialist leg ulcer clinic.¹⁵

1.1.1 THE NEED FOR A GUIDELINE

Evidence of variation in both healing rates and recurrence rates of venous leg ulcers highlights the need for an updated evidence based guideline to support practice. Healing rates in the community, where 80% of patients are treated, are low compared to rates in specialist clinics. In the Scottish Leg Ulcer Trial, the six months healing rate for community based treatment was 45%.¹⁶ In specialist clinics (see section 6.3), healing rates of around 70% at six months have been achieved.¹⁷ Twelve month recurrence rates vary between 26% and 69%.¹⁸

1.1.2 REMIT OF THE GUIDELINE

This guideline provides evidence based recommendations on the management of venous leg ulcers and examines assessment, treatment and the prevention of recurrence. Evidence on provision of care is also presented. The guideline does not cover detailed management of patients with chronic leg ulcer in the specialist fields of diabetes, vascular surgery or rheumatoid disease, although indications for referral are considered.

1.1.3 DEFINITION

In this guideline, chronic venous leg ulcer is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease. Studies reviewed in this guideline included patients with venous leg ulcers, irrespective of the method of diagnosis of venous insufficiency.

1.1.4 TARGET USERS OF THE GUIDELINE

This guideline will be of particular interest to patients, general practitioners (GPs), nursing staff (district nurses, practice nurses and specialist nurses in dermatology, wound management, tissue viability and rheumatology) dermatologists, vascular surgeons and plastic surgeons, as well as pharmacists. It may also be of interest to podiatrists and physiotherapists.

1.2 UPDATING THE EVIDENCE

This guideline updates SIGN 26 to reflect the most recent evidence on chronic venous leg ulceration. Where no significant new evidence was identified to support an update, text and recommendations are reproduced from SIGN 26. The original supporting evidence was not re-appraised by the current guideline development group. The key questions used to develop this guideline are displayed in Annex 1.

The evidence in SIGN 26 was appraised using an earlier grading system. Details of how the grading system was translated to SIGN's current grading system are available on the SIGN website (www.sign.ac.uk).

1.2.1 SUMMARY OF UPDATES TO THE GUIDELINE

1 Introduction	Minor update
2 Key recommendations	New
3 Assessment - The ankle brachial pressure index (3.2.1) and dermatitis/eczema (3.3.4)	Minor update
4 Treatment	Completely revised
5 Prevention	Completely revised
6 Provision of care - Specialist leg ulcer clinics (6.3)	Minor update
7 Provision of information	New
8 Implementing the guideline	Minor update

1.3 STATEMENT OF INTENT

This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.

1.3.1 PRESCRIBING OF LICENSED MEDICINES OUTWITH THEIR MARKETING AUTHORISATION

Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the marketing authorisation (product licence). This is known as “off label” use. It is not unusual for medicines to be prescribed outwith their product licence and this can be necessary for a variety of reasons.

Generally the unlicensed use of medicines becomes necessary if the clinical need cannot be met by licensed medicines; such use should be supported by appropriate evidence and experience.¹⁹

Medicines may be prescribed outwith their product licence in the following circumstances:

- for an indication not specified within the marketing authorisation
- for administration via a different route
- for administration of a different dose.

Prescribing medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescribers’ professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.¹⁹

Any practitioner following a SIGN recommendation and prescribing a licensed medicine outwith the product licence needs to be aware that they are responsible for this decision, and in the event of adverse outcomes, may be required to justify the actions that they have taken.

Prior to prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF).¹⁹

1.3.2 ADDITIONAL ADVICE TO NHSSCOTLAND FROM NHS QUALITY IMPROVEMENT SCOTLAND AND THE SCOTTISH MEDICINES CONSORTIUM

NHS QIS processes multiple technology appraisals (MTAs) for NHSScotland that have been produced by the National Institute for Health and Clinical Excellence (NICE) in England and Wales.

The Scottish Medicines Consortium (SMC) provides advice to NHS Boards and their Area Drug and Therapeutics Committees about the status of all newly licensed medicines and any major new indications for established products.

No relevant SMC advice or NICE MTAs were identified.

2 Key recommendations

The following recommendations were highlighted by the guideline development group as the key clinical recommendations that should be prioritised for implementation. The grade of recommendation relates to the strength of the supporting evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

2.1 ASSESSMENT

D Leg ulcer patients with dermatitis/eczema should be considered for patch-testing using a leg ulcer series.

2.2 TREATMENT

A Simple non-adherent dressings are recommended in the management of venous leg ulcers.

A High compression multicomponent bandaging should be routinely used for the treatment of venous leg ulcers.

A Use of pentoxifylline (*400 mg three times daily for up to six months*) to improve healing should be considered in patients with venous leg ulcers.

2.3 PREVENTING ULCER RECURRENCE

A Below-knee graduated compression hosiery is recommended to prevent recurrence of venous leg ulcer in patients where leg ulcer healing has been achieved.

2.4 PROVISION OF CARE

B Specialist leg ulcer clinics are recommended as the optimal service for community treatment of venous leg ulcer.

3 Assessment

An example patient assessment proforma is given in Annex 2.

3.1 ASSESSING THE PATIENT

Venous leg ulcers are caused by venous insufficiency. The associated clinical signs are discussed in section 3.2. Initial assessment should cover any history of prior deep venous thrombosis or previous treatment for varicose veins.

Management of a patient with chronic venous leg ulcer will often be influenced by the patient's comorbidity. Factors such as obesity, malnutrition, intravenous drug use and co-existing medical conditions will affect both prognosis and suitability for invasive venous surgery.

In the initial assessment, the patient's mobility should be considered as well as the availability of help at home, as many elderly patients find graduated compression hosiery difficult to put on.

The following conditions require specific treatment and should be looked for in initial assessment:

- **Peripheral arterial disease:** approximately 22% of patients with leg ulcer will have arterial disease.⁸ A history of intermittent claudication, cardiovascular disease, or stroke may indicate that the patient has arterial disease. Absence of symptoms does not exclude the presence of peripheral arterial disease. This may be excluded by performing the ankle brachial pressure index (see section 3.2.1). 3
- **Rheumatoid arthritis and systemic vasculitis:** around 9% of patients with leg ulcer have rheumatoid arthritis.³ These patients may have venous, arterial or vasculitic ulcers. Those with vasculitic ulcers will have clinical features of established disease which may be associated with systemic vasculitis. If this is the case there will be evidence of vasculitic lesions elsewhere, eg nail fold infarcts or splinter haemorrhages. Rarely, ulceration will be due to Felty's syndrome or pyoderma gangrenosum. Systemic vasculitis occurs as a feature of several collagen vascular diseases when leg ulcers will usually be multiple, necrotic, deep and have an atypical distribution. 3
- **Diabetes mellitus:** approximately 5% of patients will have diabetes.³ These patients may have venous, arterial or neuropathic ulcers, or may have diabetic bullae which subsequently ulcerate. Necrobiosis lipoidica may be present, and can also ulcerate. 3

3.2 ASSESSING THE LEG

The leg should be assessed for signs of venous disease, in particular, varicose veins, venous dermatitis (see section 3.3.4), haemosiderin deposition, lipodermatosclerosis and atrophie blanche. A venous duplex scan may aid assessment of the leg.

Oedema should be assessed and non-venous causes of unilateral and bilateral oedema ruled out.

Joint mobility, particularly that of the ankle, is an important component of calf muscle pump function and should be carefully recorded.

It is important to assess arterial supply with respect to safety of compression therapy, which is the standard treatment for venous leg ulcers. Palpation of pulses alone is not adequate to rule out peripheral arterial disease. Measurement of the ankle brachial pressure index (ABPI) of both lower limbs by hand held Doppler device is the most reliable way to detect arterial insufficiency.²⁰⁻²³ 2+

- ☑ All patients with chronic venous leg ulcer should have an ABPI performed prior to treatment.

3.2.1 THE ANKLE BRACHIAL PRESSURE INDEX

Objective evidence to substantiate the presence or absence of significant peripheral arterial disease (PAD) may be obtained reliably (except in those with heavily calcified vessels) by obtaining an ankle brachial pressure index (ABPI) in both legs at the initial visit. This is the ratio of the ankle to brachial systolic pressure and can be measured using a sphygmomanometer and hand held Doppler device.²⁴ Appropriate training is required due to the complexity of clinical reporting and methodological issues around interpretation and reproducibility of results.²⁵

4

A resting ABPI cut-point of 0.9 has been shown in several clinical studies to be highly sensitive and specific for peripheral arterial disease (positive predictive value of 95% and negative predictive value of 99%), and, in practice, an ABPI of < 0.9 is considered to be abnormal.²⁶ An observational study of 24 healthy young adults highlighted a higher normal range for ABPI in young patients (mean ABPI = 1.14). This may be of significance to the treatment of leg ulcers in young adults, such as intravenous drug users.²⁷

3

A review concluded that compression therapy may be safely applied in patients with an ABPI greater than 0.8.²³

3

Care must be taken in interpreting ABPI results in patients with heavily calcified vessels, such as in some patients with diabetes and advanced chronic renal failure, where they may be misleadingly high. For values above 1.5, the vessels are likely to be incompressible, and the result cannot be relied on to guide clinical decisions.²⁴

4

D Measurement of ankle brachial pressure index should be performed by appropriately trained practitioners who should endeavour to maintain their skills.

D Compression therapy may be safely used in leg ulcer patients with ABPI ≥ 0.8.

D Patients with an ABPI of < 0.8 should be referred for a specialist vascular assessment.

Patients with an abnormal ABPI should have their cardiovascular risk factors treated according to the SIGN guideline on management of peripheral arterial disease (SIGN 89).

3.2.2 PULSE OXIMETRY

One single centre open study of 195 legs showed that pulse oximetry may be a useful alternative technique for assessing peripheral arterial disease, with positive linear association and some agreement with ABPI measurement (kappa = 0.303).²⁸

3

There is insufficient evidence on which to base a recommendation for routine use of pulse oximetry in patients with chronic venous leg ulcer.

Pulse oximetry is not routinely recommended, but may be a useful adjunctive investigative tool in specialist leg ulcer clinics.

3.3 ASSESSING THE ULCER

3.3.1 CLINICAL ASSESSMENT

Deep ulcers which involve deep fascia, tendon, periosteum or bone may have an arterial component to their aetiology. The depth should be described in terms of the tissue involved in the ulcer base.

Serial measurement of the surface area is a reliable index of healing. Appropriate techniques include photography, tracing of the margins and measuring the two maximum perpendicular axes.²⁹

2+

C The surface area of the ulcer should be measured serially over time.

Although there is no evidence relating to other aspects of the clinical description of the leg ulcer, the guideline development group recommends the following.

- The ulcer edge often gives a good indication of progress and should be carefully documented (eg shallow, epithelialising, punched out).
- The base of the ulcer should be described (eg granulating, sloughy).
- The position of the ulcer(s), medial, lateral, anterior, posterior, or a combination, should be clearly described.

3.3.2 BIOPSY

Neoplastic ulcers or neoplastic change in pre-existing ulcers are uncommon, but may give rise to diagnostic difficulty. Referral to a specialist unit for biopsy should be considered if the appearance of the ulcer is atypical or if there is deterioration or failure to progress after 12 weeks of active treatment.³⁰

3

D Patients with a non-healing or atypical leg ulcer should be referred for consideration of biopsy.

3.3.3 BACTERIOLOGICAL SWABS

In the absence of clinical signs of infection (eg cellulitis, pyrexia, increased pain, rapid extension of area of ulceration, malodour, increased exudate), there is no indication for routine bacteriological swabbing of venous ulcers.³¹ All ulcers will be colonised by micro-organisms at some point, and colonisation in itself is not associated with delayed healing.²⁹

2+

C Bacteriological swabs should only be taken where there is clinical evidence of infection.

3.3.4 DERMATITIS/ECZEMA

Venous ulcers are commonly associated with varicose eczema which is characterised by erythema, weeping, scaling and pigmentation, and may be misdiagnosed as infection. Venous ulcers are also prone to being complicated by allergic contact dermatitis (see section 4.4). The clinical appearance of varicose eczema and allergic contact dermatitis is similar, but the distribution and response to treatment provide useful diagnostic information.

The incidence of contact allergy increases with the duration of ulceration.³² Two studies in which patients with venous leg ulcer were patch-tested for a range of allergens contained in current ulcer dressings (as additions to the European standard series), found that in one, 46% and in the other, 61% of reactions were to these additional allergens.^{33,34} Several large patch-test studies have demonstrated that the principal sensitisers are ingredients of applications, dressings, and bandages, with common sensitisers being lanolin, antibiotics, antiseptics, preservatives, emulsifiers, resins and latex.³²⁻³⁷

3

D Leg ulcer patients with dermatitis/eczema should be considered for patch-testing using a leg ulcer series.

3.4 RE-ASSESSMENT

The active management of leg ulcers may be required over many months or years and may be carried out by several different healthcare professionals. Re-assessment should be carried out at 12 weeks if no progress and thereafter at 12 weekly intervals. Likewise, when an ulcer recurs, a full assessment should be carried out even though the patient may be well known to the nurse or doctor.

The following should be considered:

- is the ulcer healing?

If not:

- is the aetiology of the ulcer confirmed?
- are there new comorbidities?
- should the ulcer be biopsied?
- is the management consistent and appropriate?
- is the patient complying with treatment?

3.5 CRITERIA FOR SPECIALIST REFERRAL

D Patients who have the following features should be referred to the appropriate specialist at an early stage of management:

- suspicion of malignancy
- peripheral arterial disease ($ABPI < 0.8$)
- diabetes mellitus
- rheumatoid arthritis/vasculitis
- atypical distribution of ulcers
- suspected contact dermatitis or dermatitis resistant to topical steroids
- non-healing ulcer.

Detailed indications and procedures for referral should be discussed at a local level for inclusion in local guidelines.

4 Treatment

4.1 INTRODUCTION

The primary treatment outcome examined in this guideline was leg ulcer healing. This is expressed in a range of study-specific measures such as time to complete healing, proportion of ulcers completely healed at various time points, commonly three and six months, and reduction in ulcer area.

The mainstay of treatment of a venous ulcer involves compression therapy (see section 4.5) to reduce venous hypertension. Dressings are required to prevent the bandage or compression hosiery from adhering to the wound (see section 4.3).

Treatment of the skin surrounding the ulcer is discussed in section 4.4.

Patient concordance with treatment is likely to improve if they are properly informed about the disease and its management (see the checklist for provision of information in section 7).

4.2 CLEANSING AND DEBRIDEMENT

4.2.1 CLEANSING

There is no contraindication to regular cleansing of the leg.

- Ulcerated legs should be washed normally in tap water and carefully dried.

4.2.2 DEBRIDEMENT

NICE guidance on the management of surgical site infections states that 'necrotic material or slough within a wound margin acts as a medium for bacterial proliferation and therefore should be removed by debridement'.³⁸ No studies were identified which compare debridement with no debridement in the management of venous ulcers.

4

Debridement methods

Various debridement methods have been examined on a wide variety of outcomes including degree of desloughing, wound size, healing rates, pain and infection. There is a lack of data to clarify whether mechanical, chemical or biosurgical methods are most appropriate in this patient group.

Sharp debridement

Sharp debridement is a relatively swift method of debridement, but must be undertaken by someone with specific training in this skill, as it is essential that underlying structures are not damaged.³⁹

4

- D** Sharp debridement should only be carried out by appropriately trained practitioners.

A double blind placebo controlled study in 69 patients investigated the use of EMLA® (lidocaine 2.5%, prilocaine 2.5%) as a topical anaesthetic for the repeated mechanical debridement of venous ulcers. Those with active treatment had fewer episodes of debridement, wounds were cleaned faster and better pain relief was experienced. No comparisons were made with other therapies.⁴⁰

2+

Use of EMLA for pain reduction in debridement of venous ulcers is an unlicensed indication.

- C** Local anaesthetic cream (EMLA®) should be used to reduce the pain of sharp debridement in patients with venous leg ulcer.

Hydrosurgery versus sharp debridement

A small randomised controlled trial (RCT), (n=41), which compared Versajet Hydrosurgery with sharp debridement on venous leg ulcers and diabetic foot ulcers, found shorter procedural time for the Versajet system but no overall benefit to healing rates.⁴¹ 1+

Given the uncertain relationship between debridement and healing no recommendation for hydrosurgery can be made.

Manuka honey versus hydrogel

One RCT (n = 108) compared the desloughing effect of hydrogel (IntraSite gel®) versus Manuka honey (WoundCare 18+) over a four week period on ulcers with greater than 50% of the wound area covered with slough. The mean percentage reduction in slough was 67% in the patients allocated to honey, compared to 53% in the hydrogel group (p=0.054). Median reduction in wound size was 34% in the Manuka honey group compared to 13% in the hydrogel group (p<0.001).⁴² There were no significant differences between the two groups in terms of wound infection rates, number of bacterial species or pain scores.⁴³ 1+

Given the uncertain relationship between debridement and healing no recommendation for Manuka honey, as a debridement agent, can be made.

Larval therapy versus hydrogel

A large randomised controlled trial (n = 267) compared larval therapy and hydrogel for sloughy leg ulcers in patients with at least one venous or mixed venous arterial ulcer with at least 25% coverage of slough. Larval therapy produced significantly faster debridement, median 14 days for loose larva and 28 days for bagged larvae compared with 72 days for hydrogel, but this did not result in faster ulcer healing or improved rates of ulcer healing nor did it reduce bacterial load.⁴⁴ 1+

Given the uncertain relationship between debridement and healing no recommendation for larval therapy can be made.

4.3 DRESSINGS

The effectiveness of a range of dressing types in promoting healing was examined. They were compared with inexpensive, simple non-adherent dressings which are most commonly used.

A systematic review identified 42 studies where non-adherent dressings were compared to alginate dressings (60 patients), hydrocolloids (792 patients), hydrogels (151 patients), and foams (253 patients). No evidence was identified to support superiority of any dressing type over another when applied under appropriate multilayer bandaging. No evidence was identified on the effectiveness of different dressings in patients unable to tolerate multilayer bandaging.⁴⁵ 1++

A Simple non-adherent dressings are recommended in the management of venous leg ulcers.

4.3.1 TOPICAL ANTIMICROBIALS AND ANTISEPTICS

Studies on dressings incorporating topical antimicrobials and antiseptics were examined in the context of routine venous leg ulcer care. Study populations varied. A number of trials used systemic antibiotics prior to the start of the study to resolve clinical infection or excluded participants with signs of clinical infection. Most studies did not differentiate between infected and colonised ulcers.

Iodine

A Cochrane systematic review identified 10 trials of variable quality evaluating the effect of cadexomer iodine in treatment of leg ulcer.⁴⁶ Only three trials specifically incorporated compression for all patients. Two of these were pooled (132 patients) and showed that cadexomer iodine was associated with improved frequency of complete healing at 4-6 weeks, (relative risk (RR) 6.72, 95% confidence interval (CI) 1.56 to 28.95), reduction in ulcer size and reduction in *Staphylococcus aureus* colonisation. This suggests some evidence of benefit for cadexomer iodine as an adjunct to compression.

1++

Four trials included in the systematic review compared use of cadexomer iodine with standard care. Of these one suggested improved healing rates due to cadexomer iodine, but this trial had poor external validity due to the intensive setting of the intervention which included bed rest and hospital inpatient care.

Three poor quality trials compared cadexomer iodine with dextranomer paste or hydrocolloid dressing/paraffin gauze and found no differences between interventions.

Five trials assessing the effect of povidone iodine were identified. No significant improvement in healing rates was found. Meta-analysis was not possible due to variations in the outcome measures used.⁴⁶

There is insufficient consistent evidence on which to base a recommendation for either cadexomer iodine or povidone iodine.

Manuka honey

As well as investigation into its use as a potential debridement agent (see section 4.2.2), the use of honey as a wound treatment, based on its antimicrobial properties, has also been explored.

A Cochrane systematic review identified 19 trials using Manuka honey as a wound treatment. Although only two trials were in patients with chronic venous ulcers, these were combined (total n = 476) and showed that there was no significant benefit of honey on ulcer healing at 12 weeks.⁴⁷

1++

B Honey dressings are not recommended in the routine treatment of patients with venous leg ulcers.

Mupirocin

A systematic review identified one small RCT (n = 30) of patients with leg ulcer which compared topical mupirocin with placebo, in addition to standard compression for all. There was no significant difference between groups in rates of complete healing, or eradication of gram positive bacteria.⁴⁶

1+

There is insufficient evidence on which to base a recommendation for mupirocin.

Peroxide

A Cochrane systematic review identified three small trials recruiting a total of 83 participants, either using hydrogen peroxide or benzoyl peroxide.⁴⁶ Compression was used in two of the three trials and these found statistically significant beneficial effects of hydrogen peroxide (1% cream) on ulcer area reduction at 10 days.

1++

There is insufficient evidence on which to base a recommendation for peroxide.

Phenytoin

A systematic review identified three trials comparing topical phenytoin treatment with a placebo or control dressing. Only one of the trials was blinded and all were small and of short duration.⁴⁸

1++

There is insufficient evidence on which to base a recommendation for topical phenytoin.

Silver

A Cochrane systematic review reviewed three RCTs comparing silver dressings with hydrocellular foam, alginate or best practice. Two studies showed no difference between products and one reported statistically faster healing rates but did not report complete healing. All three studies were small and of short duration and could not be combined for a meta-analysis.⁴⁹

1++

An RCT (n = 213) comparing, silver dressings and non-adherent dressings (in addition to standard compression), found no significant differences in median time to complete healing or healing rates at three, six and 12 months.⁵⁰

1++

A Silver dressings are not recommended in the routine treatment of patients with venous leg ulcers.

Routine long term use of topical antiseptics and antimicrobials is not recommended.

4.4 SURROUNDING SKIN

General care of the skin surrounding an ulcer is essential to maintain skin integrity and minimise the risk of further ulceration. The peri-ulcer skin should be treated routinely with a bland emollient, and ulcer margins should be coated with a barrier preparation to prevent maceration of surrounding skin.

Uncomplicated venous dermatitis usually responds to emollients, but often topical corticosteroids may be required. Failure to respond to a moderately potent steroid is an indication for patch-testing (see section 3.3.4). Dressings, applications, and bandages should be chosen as far as possible to avoid the most frequent sensitisers, and care should be taken to avoid further exposure to allergens identified by patch-testing in individual patients. Dressings which have not been reported as frequent sensitisers include paraffin gauze, zinc paste, alginates and paraffin based emollients. Latex-free brands of compression bandages and stockings are available.

Latex-free brands of compression bandages should be used routinely.

4.5 COMPRESSION

4.5.1 EFFECTIVENESS OF COMPRESSION

Compression therapy aims to improve venous return and reduce venous hypertension.

A Cochrane review examining the role of compression in healing of venous leg ulcers identified seven RCTs comparing compression with no compression.⁵¹ Two trials included in the review compared compression with dressings alone and one trial compared compression with a non-compression bandage. These were limited by small size and/or poor design. Four studies compared compression performed within specialist leg ulcer community clinics (using four component systems in three of the studies) with usual treatment by the GP and district nurse. All found greater healing rates in patients treated within the specialist service. It should be noted that some of the patients who were allocated to treatment as usual may have received compression therapy. The review concluded that compression increases ulcer healing rates compared to no compression.

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Compression therapy does have potential risks, some of which may not become evident in the structured context of clinical trials. High pressures may cause pressure damage to skin particularly in patients with impaired arterial supply who make up 20% of patients with leg ulcers. The use of compression in patients with an ABPI less than 0.8 should only be initiated under specialist advice and requires very close monitoring and review (see section 3.2.1). It should also be used with caution in patients with diabetes, who may have unreliable ABPIs due to arterial calcification as well as an underlying sensory neuropathy.⁸

Compression is usually graduated, such that the magnitude is greatest at the ankle and gaiter area and diminishes towards the knee.

4.5.2 TYPES OF COMPRESSION

Graduated compression is achieved by compression bandages or by compression stockings (see Annexes 3 and 4). Class 3 compression bandages are the ones most commonly used to treat active ulcers. Compression bandages may be made of elastic, extensible materials or inelastic, relatively inextensible fibres.^{51,52}

Multicomponent high compression versus single or two component high compression

High compression is defined as providing compression of 23-35 mmHg. In a Cochrane review, most of the trials comparing single layer systems with multicomponent systems were small and underpowered.⁵³ A single large RCT (n = 245) suggested a benefit for four layer bandage (4LB) when compared with elastic adhesive single component compression.⁵⁴ One trial compared two components with four components and found a statistically significant difference in frequency of complete healing in favour of the 4LB at six months.⁵⁵

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Multicomponent systems incorporating elastic bandage (4LB) versus multicomponent inelastic bandage systems (SSB)

Traditionally, elastic multicomponent bandages such as four layer bandaging (4LB) are used in the United Kingdom. These consist of an initial layer of orthopaedic wool, a crepe bandage to smooth the wool layer, an elastic bandage and an elastic cohesive bandage as the outer layer. The 4LB can sustain high pressure for a considerable time thus allowing for a weekly change of dressings.⁵²

Short stretch inelastic compression bandages (SSB) are widely used in Europe and Australasia. These consist of orthopaedic wool, one or two SSBs and sometimes a retaining layer (eg cohesive bandage or tubular device). They have the advantage of applying very high pressure only when the patient is active. The pressure falls when the patient is resting. They are made of cotton, are reusable and have a reduced risk of associated contact dermatitis.

A Cochrane systematic review identified six trials comparing the 4LB with systems which included SSB.⁵¹ Most of the trials did not identify significant differences between patient groups. One large study (VenUS, n = 387) found no difference between groups at three months but found significantly greater proportion of patients healed at six months with 4LB. This study was conducted in the UK where there is likely to be greater experience with 4LB.⁵² There was no difference in generic and disease-specific quality of life between the two groups. Meta-analysis of four trials suggested a higher probability of healing with 4LB but there was significant heterogeneity reducing the certainty of the effect.⁵¹

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A meta-analysis of RCTs with pooling of individual patient data from five trials comparing 4LB with short stretch bandage found that the 4LB was associated with a significantly shorter time to healing.⁵³

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The VenUS study, found that 4LB was less expensive than non-cohesive SSB which required more re-applications and changes of dressings. However, the SSB could have been reused or replaced by cohesive SSB which can stay in place for up to a week and the cost of nurse training in 4LB was not considered.⁵²

Compression hosiery

No studies were identified comparing compression hosiery with 4LB for treatment of leg ulcers.

A Cochrane review compared compression stockings and tubular compression devices with compression bandage systems.⁵¹ Data comparing two layer stockings with SSB were pooled and showed that significantly more patients achieved complete healing with stockings at three months. Results should be interpreted with caution since there were differences in the groups at baseline and compression was applied by the patients or relatives which may have biased the studies in favour of compression stockings.

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A meta-analysis of eight RCTs concluded that compression with stockings is more effective than compression with bandages. Studies were small and there was heterogeneity with regard to the types of bandages and stocking used. Four studies used a two-stocking system. The meta-analysis only included one comparison with a multicomponent bandage system.⁵⁶

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There is insufficient evidence on which to base a recommendation for use of compression hosiery.

4.5.3 CONCORDANCE/COMPLIANCE WITH COMPRESSION THERAPY

Studies of patient concordance (some studies use the concept of compliance rather than concordance) with therapy are hampered by the lack of a uniform definition and objective assessment.

Pain, discomfort and lack of valid lifestyle advice have been cited by patients as the main reasons for non-concordance. The belief that compression was unnecessary and uncomfortable had a significant detrimental effect on concordance. In contrast, the belief that compression was worthwhile and prevented recurrence improved concordance.⁵⁷

A systematic review found that patient-reported compliance was higher in patients allocated to class 3 stockings compared to short stretch compression bandage.⁵⁸

4.5.4 RECOMMENDATIONS FOR COMPRESSION THERAPY

- A High compression multicomponent bandaging should be routinely used for the treatment of venous leg ulcers.**
- Patients should be offered the strongest compression that maintains patient concordance.
- At initiation of compression, patients should be assessed for skin complications within 24-48 hours.
- In patients with an ABPI <0.8, and in patients with diabetes, compression should only be used under specialist advice and with close monitoring.
- When considering the type of compression to use, practitioners should take into account:
 - patient preference, lifestyle and likely concordance
 - required frequency of application
 - practitioner level of expertise
 - size and shape of leg.
- Compression should only be applied by staff with appropriate training and in accordance with the manufacturer’s instructions.

4.6 SYSTEMIC THERAPY

4.6.1 ANTIBIOTICS

A Cochrane systematic review included five small RCTs of variable quality examining healing rates of ulcers with a range of systemic antibiotics given for a variable period of time (10 days to 20 weeks). Studies did not differentiate between infected and colonised ulcers. There was insufficient evidence to support routine use of antibiotics, and two placebo-controlled studies suggested increased bacterial resistance with antibiotic usage.⁴⁶

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Current prescribing guidelines recommend that antibacterial preparations should only be used in cases of clinical infection and not for bacterial colonisation.¹⁹

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C In patients with chronic venous leg ulcers, systemic antibiotics should not be used unless there is evidence of clinical infection.

4.6.2 PHARMACOLOGICAL AGENTS USED TO INCREASE HEALING RATES

Despite compression therapy, typically 30% of ulcers will not have healed at one year.⁵⁹ This has led to the evaluation of a number of potential pharmacological agents which may prevent or reduce damage to the microcirculation which occurs as a result of the underlying venous hypertension, and thus promote healing.

Aspirin

A single RCT involving only 20 patients assessed the effectiveness of aspirin (300 mg daily) on healing of venous leg ulcers. Some of the patients received other interventions including antibiotics.⁶⁰ Four months treatment led to ulcer healing in 38% of patients compared with 0% of patients in the placebo group ($p < 0.007$). A significant reduction in ulcer size was seen in 52% of patients in the aspirin group compared with 26% of those in the placebo group ($p < 0.007$). The low healing rate in the placebo group, in this study, is concerning and there are also unaddressed issues around randomisation, blinding and the use of other treatment interventions.

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There is insufficient evidence on which to base a recommendation for aspirin in chronic venous leg ulcer.

Micronized purified flavonoid fraction

A meta-analysis incorporating five poor quality RCTs, with a range of follow-up periods, of which only two were placebo controlled reported benefit of micronized purified flavonoid fraction (MPFF) (Daflon[®] 500 mg twice daily) on healing rates. Of the controlled studies, one is unpublished and the other had a follow up period of only two months.⁶¹

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There is insufficient good quality evidence on which to base a recommendation for MPFF in chronic venous leg ulcer.

Mesoglycan

One multicentre RCT compared mesoglycan (30 mg administered as daily intramuscular injection for three weeks followed by 100 mg orally daily) with placebo in 183 patients with venous ulceration who received compression therapy. The primary end point was time to healing of the target ulcer. At 24 weeks the relative risk of healing was 1.48 (95% CI 1.05 to 2.09) in favour of mesoglycan. Compared with other studies, the ulcers were of relatively short duration and the healing rate high. There were also differences at baseline between the groups and the use of compression bandaging was not standardised.⁶²

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There is insufficient evidence on which to base a recommendation for mesoglycan in chronic venous leg ulcer.

Pentoxifylline

Pentoxifylline is believed to increase microcirculatory blood flow although the exact mechanism of action is unknown.

A well conducted systematic review identified 11 RCTs comparing pentoxifylline with placebo or no treatment. Treatment with pentoxifylline (400 mg three times daily) improved venous leg ulcer healing rates by 21% (RR 1.56, 95% CI 1.14 to 2.13) when used as an adjuvant to compression or by 23% when used alone where compression not possible.⁶³ More people taking pentoxifylline reported adverse effects than those taking placebo, although the difference was not significant. Almost half of the adverse effects were gastrointestinal.

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Medications with potential interactions with pentoxifylline include non-steroidal anti-inflammatorys (NSAIDS). Details of interactions and contraindications can be found in the British National Formulary.¹⁹

The use of pentoxifylline in the treatment of venous leg ulcers is an unlicensed indication.

A Use of pentoxifylline (400 mg three times daily for up to six months) to improve healing should be considered in patients with venous leg ulcers.

Zinc

A Cochrane review identified five small RCTs of zinc therapy which varied substantially in terms of duration of treatment and follow up and baseline comparability.⁶⁴ The evidence provided is limited and the studies were all too small to be able to detect a moderate effect of zinc.

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There is insufficient evidence on which to base a recommendation for zinc therapy in chronic venous leg ulcer.

4.7 ANALGESIA

Leg ulcers are frequently painful, particularly if they have an arterial component or are associated with cellulitis or deep infection and strong analgesics are likely to be required. Assessment of pain is complex and outwith the remit of this guideline, but a structured discussion and frequent re-assessment are important.

4.8 SKIN GRAFTING

A skin graft is a shaving of skin of variable thickness transferred to a distant site (bed) where, once applied, it establishes a new blood supply. Graft 'take' depends upon transfer to an adequately debrided bed that is well vascularised and non-infected. Skin grafts can be classified according to the source of the donated skin, for example autograft (skin taken from another site on the same individual) and allograft (skin taken from a donor).

A Cochrane systematic review identified seven trials of skin grafting (autograft and fresh or frozen allograft) compared with standard care in patients with 'hard to heal' venous leg ulcers. Trials were generally small and of poor methodological quality and there was large variation in the definition of ulcer severity, characteristics of standard care and in trial duration. The review found no firm evidence of benefit for skin grafting.⁶⁵

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A number of skin substitutes (also called tissue engineered skin, bioengineered skin, human skin equivalents or dermal replacements) are available. These are single layer or bilayer products which feature a matrix into which cells important for skin repair are 'seeded'.

The Cochrane review identified two small studies comparing single layer dermal replacement. There was insufficient evidence of benefit.

When two trials comparing bilayered skin equivalents in addition to compression therapy with standard care were pooled (n = 345) there was a relative risk of healing with the artificial skin compared with simple dressings of 1.51 (95% CI, 1.22 to 1.88) at six months. The certainty of this beneficial effect was reduced by the lack of an intention to treat analysis in the larger of the two studies (n = 309) and, in this study, recurrence rates did not differ significantly between the two groups during the 12-month study period.

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There is insufficient evidence on which to base a recommendation for skin grafting.

4.9 OTHER THERAPIES

4.9.1 ELECTROMAGNETIC THERAPY

A Cochrane review identified three trials on the use of electromagnetic therapy in the treatment of chronic venous leg ulcers.⁶⁶ One trial was non-randomised, and had less than six weeks follow up, the other two trials were RCTs but were of poor methodological quality and had small patient numbers. None of the trials showed a significant increase in healing with electromagnetic therapy.

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There is insufficient evidence on which to base a recommendation for electromagnetic therapy in chronic venous leg ulcer.

4.9.2 HYPERBARIC OXYGEN THERAPY

A Cochrane review identified one small RCT involving 16 patients with venous ulcers. Although a significant reduction in wound area was observed at six weeks in those patients allocated to hyperbaric oxygen therapy, this was not maintained at 18 weeks and the study reported a high drop-out rate.⁶⁷

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There is insufficient evidence on which to base a recommendation for hyperbaric oxygen therapy in chronic venous leg ulcer.

4.9.3 INTERMITTENT PNEUMATIC COMPRESSION

A Cochrane review identified four randomised controlled trials addressing the use of intermittent pneumatic compression (IPC) in the treatment of patients with chronic venous leg ulcers. These studies were small and underpowered. IPC did not improve healing rates when compared to standard compression bandaging alone. It may however improve healing compared to no compression bandaging. Further research is required to determine whether IPC should be recommended in patients who cannot tolerate standard compression bandaging.⁶⁸

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There is insufficient evidence on which to base a recommendation for IPC in chronic venous leg ulcer.

4.9.4 LASER THERAPY AND INFRA-RED LIGHT THERAPY

The local application of energy from low-level lasers to accelerate the healing of venous leg ulcers was assessed in a Cochrane systematic review. Four RCTs were identified. There was no evidence of benefit associated with low-level laser therapy on venous leg ulcer healing. The review identified one small study which suggested that combining laser therapy and/or infra-red light therapy may promote healing but more evidence is required.⁶⁹

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There is insufficient evidence on which to base a recommendation for laser therapy and infra-red light therapy in chronic venous leg ulcer.

4.9.5 TOPICAL NEGATIVE PRESSURE THERAPY/ VACUUM-ASSISTED CLOSURE

One small RCT (n = 60) conducted in a hospital setting suggests that vacuum assisted closure (VAC) decreases wound bed preparation time ahead of skin grafting in patients with venous leg ulcers. Following application of split thickness skin graft, time to complete healing was 29 days in the intervention group and 45 days in the control (compression) group (p = 0.0001). There was no significant difference in ulcer recurrence up to one year.⁷⁰

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No studies were identified where topical negative pressure (TNP)/VAC was assessed as a primary therapy.

There is insufficient evidence on which to base a recommendation for TNP/VAC in chronic venous leg ulcer.

4.9.6 ULTRASOUND

A Cochrane review of eight randomised controlled trials found that no individual trials identified a significant difference in healing rates associated with therapeutic ultrasound.⁷¹ When pooled, however, there was a beneficial effect on ulcer size. The trials considered were of a small size and poor quality.

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There is insufficient evidence on which to base a recommendation for therapeutic ultrasound in chronic venous leg ulcer.

4.10 VENOUS SURGERY

Venous surgery is covered in section 5.2.

4.11 LIFESTYLE ISSUES

There are few intervention studies which address the effects of lifestyle modification on rates of healing of venous leg ulcers or the prevention of recurrence.^{13,58,72}

4.11.1 EXERCISE

Supervised calf muscle exercise has been shown to increase calf muscle pump function and improve haemodynamics.^{73,74} Further studies are required to determine whether this may have a beneficial effect on ulcer healing.

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Supervised calf muscle exercise should be considered in patients with venous leg ulcer.

4.11.2 NUTRITIONAL INTERVENTION

No good quality evidence was identified on the effectiveness of nutrition interventions or nutritional supplementation in the treatment of patients with venous leg ulcer.

5 Preventing ulcer recurrence

Chronic leg ulcers almost always recur unless secondary prevention is maintained.^{6,8}

3

5.1 GRADUATED COMPRESSION FOR HEALED VENOUS ULCERATION

In a systematic review of patients with chronic venous insufficiency and a history of leg ulcer, well fitted graduated compression hosiery (below knee) restored venous function and reduced recurrence rate. The review concluded that patients should be offered the strongest compression with which they can comply.¹⁸

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The effectiveness of graduated compression stockings in achieving and maintaining healing is dependent on the correctness of fit and the pressure generated beneath the stocking. In clinical and laboratory testing, not all stockings produce an adequate pressure or pressure gradient although they may be described as of a similar class.⁷⁵

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Two RCTs assessing ulcer recurrence rates were identified which compared class 3 single layer hosiery with class 2 (see Annex 4). Both studies found no differences in recurrence rates, but a higher rate of non-compliance with class 3 was shown (42% for class 3 versus 28% for class 2).⁷⁶

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No evidence was identified on the use of class 3 dual layer hosiery, which consists of a compression stocking and liner, for prevention of ulcer recurrence.

A Below-knee graduated compression hosiery is recommended to prevent recurrence of venous leg ulcer in patients where leg ulcer healing has been achieved.

Patients should be offered the strongest compression which they can tolerate to prevent ulcer recurrence.

Patients should be informed that it is likely that compression will be required indefinitely.

If a patient finds a stocking uncomfortable, changing the brand of stocking within the same class may improve compliance.⁷⁷ Made to measure hosiery is available and should be offered when fitting is otherwise difficult. Devices are available which may be useful for patients who find the application of stockings difficult. The gradient of pressure achieved is as important as the absolute maximum pressure and the stocking or bandage should extend from toes to knee. Prescriptions should specify the class and generic type of stocking and be of a quantity to allow for frequent washing.

The concepts, practice, and hazards of graduated compression should be fully understood by those prescribing and fitting compression stockings.

5.2 VENOUS SURGERY

One large RCT on the use of surgery in ulcerated or recently healed legs was identified.⁷⁸ Five hundred patients with isolated superficial venous reflux and mixed superficial and deep reflux were randomised to either compression treatment alone or compression in combination with superficial venous surgery. Surgery did not improve ulcer healing rates but did significantly reduce 12 month recurrence rates after healing (12% versus 28%, hazard -2.76 (95% CI -1.78 to -4.27). Benefit was demonstrated for those patients with superficial venous reflux and segmental deep venous reflux. Patient numbers were insufficient to assess benefit for those with total deep venous reflux. The applicability of surgery is limited by the high prevalence of comorbidities in this patient group. Prior to randomisation 46% of patients assessed were unsuitable for surgery.

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No good quality trials of deep venous reconstruction, subfascial endoscopic perforator surgery (SEPS), minimally invasive long saphenous laser ablation or foam sclerotherapy were identified.

B Patients with chronic venous leg ulcer and superficial venous reflux should be considered for superficial venous surgery to prevent recurrence.

Assessment of venous reflux should be undertaken using duplex ultrasound.

6 Provision of care

6.1 BACKGROUND

A survey of a population of around one million individuals found that in 83% of cases of leg ulcer the care was carried out entirely in the community, in 12% it was a joint effort between hospital and the community, and in 5% of cases patients were hospital inpatients.³ Scottish data from 2002 showed that the average case load for a community based nurse is 2-4 leg ulcer patients annually.¹⁶

6.2 TRAINING

A review of studies addressing the effectiveness of training found that a large number of community nurses perform bandaging inadequately. In two of the studies, technique improved following appropriate training. This improvement was sustained at 2-4 weeks following training, but diminished to near baseline levels at 6-10 weeks.⁷⁹

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A large RCT of training (Scottish Leg Ulcer Trial) randomised community nurses to cascade training and release of (SIGN) guidelines or release of guidelines alone. There was no measurable impact in either group with the three month healing rate of leg ulcers being 30% both at baseline and after the interventions.¹⁶

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6.3 SPECIALIST LEG ULCER CLINICS

A specialist leg ulcer clinic involves nurses who are specially trained in the assessment and management of patients with leg ulcers.

A Cochrane review identified four RCTs which compared compression bandaging (4LB in three trials, SSB in one) within a specialised leg ulcer care setting with usual management by the general practitioner and district nurse. Overall, healing rates were significantly increased in the patients receiving compression within a specialist leg ulcer care setting, a contributing factor of which was likely to be the higher level of staff expertise which resulted in better management of leg ulceration overall.⁵¹

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Cost data was outlined for the three trials which used 4LB. In the first there were significantly lower costs in the specialist leg ulcer group when compared on the basis of consumables, district nurse time and mileage both per week and for the three month trial duration. The second found no difference in the mean NHS costs per patient. The third trial found costs per leg healed were significantly lower for the compression group within the specialist leg ulcer clinic setting.

A locality based observational study used the setting up of a specialist clinic as the intervention. The ulcer healing rate improved in the area of intervention (six and 12 week healing increasing to 8% and 22% respectively versus 4% and 12% for the control area). However, only 40% of the ulcers diagnosed in the intervention locality were referred to the new clinic and for these patients the 6 and 12 week healing rates were 24% and 48% respectively. There was also a significant reduction in the recurrence rates in the intervention group.⁸⁰ Another comparison study demonstrated similarly improved healing rates associated with attendance at a specialist clinic. A greater proportion of the clinic group received compression bandaging, (81% compared with 42% in the control group).⁸¹

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The improvement in care and outcomes observed in specialist clinics may in part be due to the more stringent delivery of evidence-based recommendations. One study involving specially trained nurses following an evidence based protocol found no significant difference in outcomes for patients receiving treatment at home when compared to clinic treatment and concluded that organisation of care, and not the setting where care is delivered, is the factor which most influences healing rates. This study has limited applicability to current practice.⁸²

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No studies were identified on the role of case load in acquisition and maintenance of healthcare practitioner skills in leg ulcer management. It is likely that skill development around measurement of ABPI and application of compression is likely to be better facilitated where practitioners operate in a specialist leg ulcer setting due to the larger case loads to which they are exposed.

B Specialist leg ulcer clinics are recommended as the optimal service for community treatment of venous leg ulcer.

6.4 LEG CLUBS

Regular (eg weekly) meetings of clients and healthcare workers (leg clubs) offer support to patients and, in a small number studies, have demonstrated improved concordance with treatment.⁵⁸ Definitions and assessments of concordance vary widely and are often dependent on self reporting or nurse-administered questionnaires.

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In a small Australian RCT pilot, n=67, patients were randomised to either the Lindsay Leg Club[®] model of care (n=34), or the traditional community nursing model (n=33) consisting of individual home visits by a registered nurse. Participants who received care under the leg club model had better ulcer healing outcome as well as benefits in terms of pain, quality of life, self esteem and functional ability.⁸³

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7 Provision of information

This section reflects the issues likely to be of most concern to patients and their carers. These points are provided for use by health professionals in their discussions with patients and carers and in guiding the production of locally produced information materials.

7.1 CHECKLIST FOR PROVISION OF INFORMATION

Assessment
<ul style="list-style-type: none"> ▪ Explain to patients that the ABPI test will be carried out to decide if compression treatment is appropriate. ▪ Advise patients who experience pain in their calf when walking that this may be an indication of arterial disease and may affect their treatment options. ▪ Explain to patients that taking a swab from the ulcer to look for bacteria is not usually helpful, as most leg ulcers have bacteria which do not delay healing. ▪ Advise patients that it may be useful to take a swab if the ulcer becomes more painful or there are signs of infection.
Treatment
<ul style="list-style-type: none"> ▪ Explain the results of the ABPI test and any swab tests to patients. ▪ Explain to patients that compression treatment with bandages or with a stocking is the single most important treatment for a leg ulcer, and is far more important than the ulcer dressing. ▪ Ensure that patients are aware of the need for a weekly change of bandage and that more frequent changes may be required in certain circumstances. ▪ Encourage patients to wash their leg gently in warm tap water when bandages are being changed. ▪ Advise patients that antibiotic tablets are only needed very occasionally. ▪ Explain to patients that they may be offered pentoxifylline tablets to help improve their blood flow which may help their leg ulcer to heal. ▪ The following advice should be offered to patients and carers during treatment of leg ulcers: <ul style="list-style-type: none"> - regular ankle/calf exercises may be of value - when resting try to keep the ankles up higher than the heart - raising the foot of their bed at night if tolerable will help to assist venous return - it is important to maintain a normal sleeping pattern in bed rather than in a chair - waterproof protectors for bathing/showering are available. ▪ Explain to patients that skin irritation (dermatitis) near or around the leg ulcer may be due to leaky veins, but occasionally may be due to the treatments being used. Referral to a specialist for assessment and possible patch-testing may be required. The following advice should be offered to patients: <ul style="list-style-type: none"> - use emollients to help keep the skin supple - avoid perfumed soaps - dry the leg carefully - avoid trauma. ▪ Explain to patients that leg ulcers can sometimes cause pain. If pain is experienced, advice should be sought from their GP or district nurse. ▪ Advise patients that they may be referred to a specialist if their ulcer is not responding to treatment or if there are features which require investigation. ▪ Inform patients who have a long-standing leg ulcer that it may have to be reassessed. This might involve a sample (biopsy) of the ulcer being taken for microscopic analysis.

Prevention of recurrence

- Emphasise to patients that compression stockings are available on prescription and ensure they are aware of the importance of wearing well fitting compression stockings during the day once the leg ulcer has healed. Advise them that these are known to improve considerably the chances of the leg remaining healed and are well worth any inconvenience.
- Explain to patients that there might be the possibility of surgical treatments to prevent ulcer recurrence, but that this is not suitable for everyone.
- Explain to the patients about:
 - the benefits of exercise
 - the need to wear compression hosiery from the time you get up in the morning until going to bed at night
 - renewing hosiery every 3-6 months
 - keeping mobile
 - elevating their legs when resting
 - showering as normal
 - using emollients.

7.2 SOURCES OF FURTHER INFORMATION

Leg Ulcer Forum Scotland (LUFS)
 PO Box 641, Huntingdon, PE29 9GU
 Tel: 01480 412381
www.legulcerforum.org

Affiliated to the Leg Ulcer Forum UK, this forum provides educational materials and runs local and national educational events. The committee of the forum represents the different models of care that are available in Scotland.

Lindsay Leg Club
 PO Box 689, Ipswich, IP1 9BN
 Tel: 01473 749565
www.legclub.org

The Lindsay Leg Club Foundation exists to help patients alleviate suffering and stigma caused by leg ulcers. Leg Clubs aim to provide leg ulcer management in a social environment, where patients (members) are treated collectively and the emphasis is on social interaction, participation, empathy and peer support where positive health beliefs are promoted.

There is a Leg Club in Scotland for patients in Speyside and information can be provided to patients in other areas of Scotland.

7.3 SAMPLE INFORMATION LEAFLET

An example information leaflet for patients with venous leg ulcer is given below. Healthcare professionals may wish to adapt this for use in their own departments, and insert relevant local details.

What is a venous leg ulcer?

A leg ulcer is an area of damaged skin where the tissue underneath is exposed. Leg ulcers develop when there is poor blood circulation in the veins of your legs. In healthy leg veins, blood pressure is kept at the right level by the valves in your veins. These valves prevent blood from flowing backwards and keep blood moving through your veins. When the valves become damaged, the blood pressure in the veins of your legs will rise. This causes fluid to leak out of them leading to swelling, irritation, tenderness and eventually the formation of an ulcer.

What is the treatment for leg ulcers?

Compression bandaging is the most effective treatment for venous leg ulcer.

The bandages work by helping push the blood in your leg veins back up to your heart.

The type of bandage you wear will be decided by your health care professional following discussion with you. Different strengths are available and your healthcare professional will help select the best one for you – aiming to find the strongest that you are able to wear.

A dressing is worn under the bandage. This will be changed when required, usually once a week, by your healthcare professional. When the dressing is changed, you should take the opportunity to gently wash your leg in warm tap water. Waterproof protectors are available for bathing/showering at home between dressing changes.

Elevation (raising your legs)

When resting, you should try to keep your ankles up higher than your heart. This allows the fluid to drain from your legs.

At night time it is important that you keep to your normal sleeping habits – you should sleep in your bed rather than in a chair. Raising the foot of your bed at night may also help.

Exercise

You should keep mobile and continue with your everyday activities. Taking a walk each day can help. You should avoid standing still but if you have to stand you could exercise on the spot by moving your toes inside your shoes. You can also do some exercises when you are sitting, for example you can rotate your ankles and bend your toes towards you then away from you.

Moisturising

Dry scaly skin needs to be treated with a non-perfumed moisturiser (emollient) to keep the skin moist. If you have been prescribed a moisturiser, you should use it as often as possible, ideally once or twice a day. You should also avoid perfumed soaps and dry your legs carefully to prevent irritation.

Skin irritation (dermatitis) near a leg ulcer is usually caused by the leaky veins, but may sometimes be due to treatments such as creams, dressings and bandages. You may need to be referred to a dermatologist (skin-care specialist) who may investigate this by doing skin patch tests.

Are leg ulcers painful?

You may or may not experience pain from your leg ulcer. If you do have pain and it prevents you from carrying out your normal daily activities, you should speak to your GP, district nurse or healthcare professional about this.

How should I care for my legs once my leg ulcer has healed?

Venous leg ulcers result from a chronic condition of the veins and even when they have been treated successfully are likely to return. You can help to prevent this by wearing compression stockings.

Compression stockings apply constant pressure to your leg to improve the circulation through your veins and can help prevent the ulcer returning. It is important that you put your stockings on first thing in the morning and remove them before going to bed at night. Applicators to help you apply the stocking are available on prescription. You should talk to your GP or district nurse for advice on applicators.

There are a number of other things you can do to stop your leg ulcers from coming back again:

- wear loose fitting socks and well fitting footwear
- keep your legs raised at night
- exercise regularly, for example, take a 30 minute walk each day
- avoid bumps to the legs which could cause the ulcer to come back, for example, bumps from supermarket trolleys
- keep your feet warm but avoid hot temperatures such as sitting too close to the fire or having the bath water too hot
- take care when washing your legs
- use a non-perfumed moisturiser regularly on your legs
- examine your legs regularly for broken skin and swelling.

When should I seek help?

You must tell your healthcare professional if you have any of the following problems:

- broken skin, irritation or redness
- swelling of the leg
- pain becoming worse
- compression stocking becoming worn or torn or not fitting comfortably.

8 Implementing the guideline

This section provides advice on the resource implications associated with implementing the key clinical recommendations, and advice on audit as a tool to aid implementation.

Implementation of national clinical guidelines is the responsibility of each NHS Board and is an essential part of clinical governance. Mechanisms should be in place to review care provided against the guideline recommendations. The reasons for any differences should be assessed and addressed where appropriate. Local arrangements should then be made to implement the national guideline in individual hospitals, units and practices.

8.1 AUDITING CURRENT PRACTICE

A first step in implementing a clinical practice guideline is to gain an understanding of current clinical practice. Audit tools designed around guideline recommendations can assist in this process. Audit tools should be comprehensive but not time consuming to use. Successful implementation and audit of guideline recommendations require good communication between staff and multidisciplinary team working.

The guideline development group has identified the following as key points to audit to assist with the implementation of this guideline:

- time from presentation to Doppler assessment
- access to specialist leg ulcer clinic
- appropriate use of compression
- inappropriate use of Manuka honey
- inappropriate use of silver dressings
- prescribing of pentoxifylline
- healing rate at 12 and 24 weeks
- time to complete healing
- recurrence rate at one and three years.

8.2 RECOMMENDATIONS WITH POTENTIAL RESOURCE IMPLICATIONS

Key recommendation	Section	Likely resource implication
B Honey dressings are not recommended in the routine treatment of patients with venous leg ulcers.	4.3.1	Disinvestment opportunity
A Silver dressings are not recommended in the routine treatment of patients with venous leg ulcers.	4.3.1	Disinvestment opportunity
A Use of pentoxifylline (400 mg three times daily for up to six months) to improve healing should be considered in patients with venous leg ulcers.	4.6.2	Increased prescribing costs
B Patients with chronic venous leg ulcer and superficial venous reflux should be considered for superficial venous surgery to prevent recurrence.	5.2	Potential increase in number of patients referred for surgery

9 The evidence base

9.1 SYSTEMATIC LITERATURE REVIEW

The evidence base for this guideline was synthesised in accordance with SIGN methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Information Officer. Databases searched include Medline, Embase, CINAHL, and the Cochrane Library. The year range covered was 1997-2008. The main searches were supplemented by material identified by individual members of the development group. Each of the selected papers was evaluated by two members of the group using standard SIGN methodological checklists before conclusions were considered as evidence.

9.1.1 PATIENT SEARCH

At the start of the guideline development process, a SIGN Information Officer conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to the management and prevention of venous leg ulcers. Databases searched include Medline, Embase, CINAHL and PsycINFO, and the results were summarised and presented to the guideline development group. A copy of the Medline version of the patient search strategy is available on the SIGN website.

9.2 RECOMMENDATIONS FOR RESEARCH

The guideline development group was not able to identify sufficient evidence to answer all of the key questions asked in this guideline. The following areas for further research have been identified:

- Comparison of ABPI and pulse oximetry as assessment tools in leg ulcer
- Models of provision of care*
- Primary prevention of venous insufficiency*
- Pathogenesis of venous ulceration
- Use of dual layer hosiery treatment compared to multicomponent bandaging in initial treatment of leg ulcer
- Use of dual layer hosiery compared to single layer hosiery in recurrent leg ulcer
- Use of alternatives to surgery for the treatment of varicose veins.

* An economic evaluation should be included

9.3 REVIEW AND UPDATING

This guideline was issued in 2010 and will be considered for review in three years. Any updates to the guideline in the interim period will be noted on the SIGN website: www.sign.ac.uk

10 Development of the guideline

10.1 INTRODUCTION

SIGN is a collaborative network of clinicians, other healthcare professionals and patient organisations and is part of NHS Quality Improvement Scotland. SIGN guidelines are developed by multidisciplinary groups of practising clinicians using a standard methodology based on a systematic review of the evidence. Further details about SIGN and the guideline development methodology are contained in “SIGN 50: A Guideline Developer’s Handbook”, available at www.sign.ac.uk

10.2 THE GUIDELINE DEVELOPMENT GROUP

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The membership of the guideline development group was confirmed following consultation with the member organisations of SIGN. All members of the guideline development group made declarations of interest and further details of these are available on request from the SIGN Executive.

Guideline development and literature review expertise, support and facilitation were provided by the SIGN Executive.

10.2.1 ACKNOWLEDGEMENTS

SIGN would like to acknowledge the guideline development group responsible for the development of SIGN 26: The care of patients with chronic leg ulcer, on which this guideline is based.

10.3 CONSULTATION AND PEER REVIEW

10.3.1 PUBLIC CONSULTATION

The draft guideline was available on the SIGN website for a month in September 2009 to allow all interested parties to comment.

10.3.2 SPECIALIST REVIEWERS INVITED TO COMMENT ON THIS DRAFT

This guideline was also reviewed in draft form by the following independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. The guideline group addresses every comment made by an external reviewer, and must justify any disagreement with the reviewers' comments.

Mrs Irene Anderson	<i>Senior Lecturer, University of Hertfordshire, Hatfield</i>
Mrs Margaret Armitage	<i>Vascular Liaison Nurse Specialist, Gartnavel General Hospital, Glasgow</i>
Ms Janice Bianchi	<i>Lecturer in Tissue Viability, Glasgow Caledonian University</i>
Dr Alison Bryden	<i>Consultant Dermatologist, Ninewells Hospital, Dundee</i>
Mr Hector Campbell	<i>Consultant Vascular Surgeon, Wishaw General Hospital</i>
Mrs Arlene Coulson	<i>Principal Clinical Pharmacist, Ninewells Hospital, Dundee</i>
Dr Sara Davies	<i>Public Health Consultant, Scottish Government Health and Wellbeing Directorate, Edinburgh</i>
Mr Gareth Griffiths	<i>Consultant Vascular Surgeon, Ninewells Hospital, Dundee</i>
Mrs Anne Lee	<i>Principal Pharmacist, Horizon Scanning, Scottish Medicines Consortium, Glasgow</i>
Ms Bridget Nuttall	<i>District Nurse, Pentland Medical Centre, Edinburgh</i>
Ms Celia Macaskill	<i>Dermatology Nurse Specialist, Southern General Hospital, Glasgow</i>
Mrs Margaret MacDougall	<i>Link Leg Ulcer Nurse, Clydebank Health Centre</i>
Mrs Isobel MacIver	<i>Tissue Viability Nurse Specialist, NHS Western Isles, Isle of Lewis</i>
Ms Joyce O'Hare	<i>Professional Advisor Tissue Viability, Care Commission, Dundee</i>
Mrs Anne Ritchie	<i>Leg Ulcer Specialist Nurse, Ninewells Hospital, Dundee</i>
Mr Paul Rodgers	<i>Consultant Surgeon, Gartnavel General Hospital, Glasgow</i>
Mr Rob Smith	<i>Consultant Surgeon, Falkirk and District Royal Infirmary</i>
Mr Paul Teenan	<i>Consultant Vascular Surgeon, Glasgow Royal Infirmary</i>
Mr James Watson	<i>Consultant Plastic Surgeon, St John's Hospital, Livingston</i>
Mrs Ethel Wilson	<i>Community Team leader in District Nursing, Peterhead Health Centre</i>

10.3.3 SIGN EDITORIAL GROUP

As a final quality control check, the guideline is reviewed by an editorial group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised. The editorial group for this guideline was as follows.

Dr Keith Brown	<i>Chair of SIGN; Co-Editor</i>
Ms Beatrice Cant	<i>Programme Manager, SIGN</i>
Mr Andrew de Beaux	<i>Royal College of Surgeons of Edinburgh</i>
Dr Roberta James	<i>Acting Programme Director, SIGN</i>
Dr Sara Twaddle	<i>Director of SIGN; Co-Editor</i>

Abbreviations

4LB	four layer bandaging
ABPI	ankle brachial pressure index
BNF	British National Formulary
CI	confidence interval
EMLA	eutectic mixture of local anaesthetics
GP	general practitioner
IPC	intermittent pneumatic compression
MPFF	micronized purified flavonoid fraction
MTA	multiple technology appraisal
NHSQIS	NHS Quality Improvement Scotland
NICE	National Institute for Health and Clinical Excellence
NSAID	non-steroidal anti-inflammatory drug
PAD	peripheral arterial disease
QoL	quality of life
RCT	randomised controlled trial
RR	relative risk
RRR	relative risk reduction
SEPS	subfascial endoscopic perforator surgery
SIGN	Scottish Intercollegiate Guidelines Network
SMC	Scottish Medicines Consortium
SSB	short stretch bandage
TNP	topical negative pressure
VAC	vacuum-assisted closure
VenUS	Venous Leg Ulcer Study

Annex 1

Key questions addressed in this update

This guideline is based on a series of structured key questions that define the target population, the intervention, diagnostic test, or exposure under investigation, the comparison(s) used and the outcomes used to measure efficacy, effectiveness, or risk. These questions form the basis of the systematic literature search.

THE KEY QUESTIONS USED TO DEVELOP THE GUIDELINE

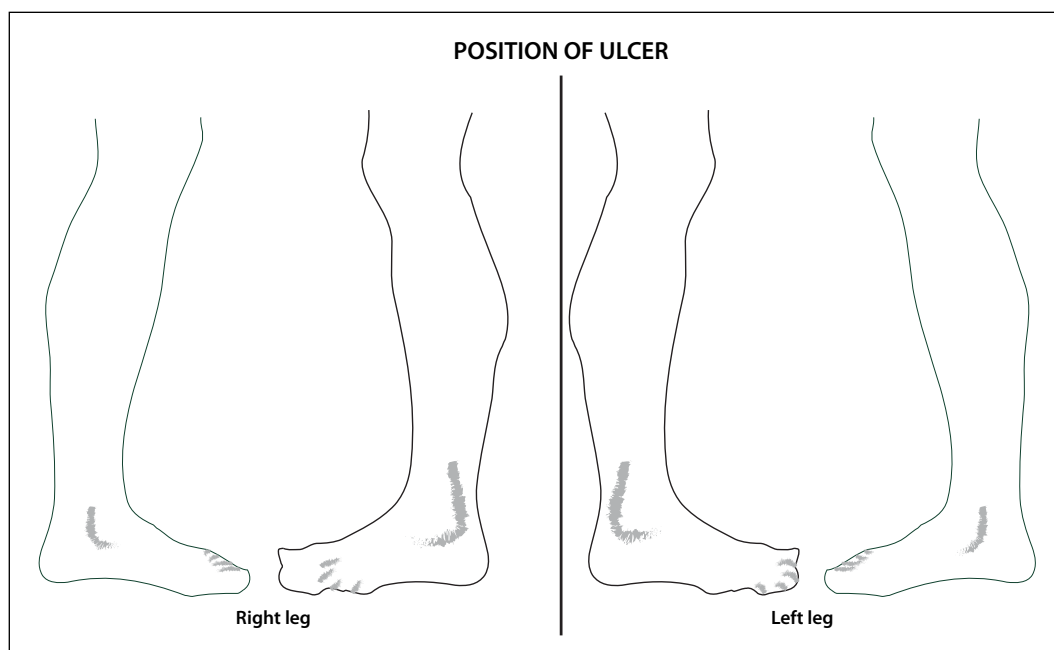
ASSESSMENT		
Key question	Inclusion/exclusion criteria	See guideline section
1. What investigation should a patient with a leg ulcer undergo to exclude a diagnosis of arterial disease/arterial insufficiency?	ankle brachial pressure index, pulse oximetry, (photo) plethysmograph, duplex scan	3.2
TREATMENT		
Key question	Inclusion/exclusion criteria	See guideline section
2. In patients with venous leg ulcer, is there any evidence for the benefit of ulcer debridement on healing rates or recurrence?	larvae, hydrocolloid dressings, hydrogels, hydrocolloids, hydrofibre, alginates, surgical, saline jets, ultracision, honey	4.2
3. Is there any evidence that adherent dressing is more effective than simple non-adherent dressing under compression in healing venous leg ulcers and improving quality of life and concordance?	hydrocolloid dressings, hydrogels, hydrocolloids, hydrofibre, alginates, honey, growth factor (topical)	4.3
4. What is the evidence that topical agents assist wound healing in patients with venous leg ulcer?	antiseptics, antimicrobial dressings, iodine, peroxide, silver, honey, phenytoin	4.3.1
5. What is the evidence that antibiotics (topical or systemic) assist wound healing in patients with venous leg ulcers?		4.3.1 4.6.1
6. In patients with venous leg ulcer, what form of compression bandaging improves healing rates (at 12 weeks/24 weeks), recurrence rates, concordance, quality of life and practitioner satisfaction?	elastic/non-elastic compression; multilayer/single-layer bandages, short stretch, pro-guide, zip-on bandages	4.5

Key question	Inclusion/exclusion criteria	See guideline section
7. What evidence is there for the effectiveness of specialist compression hosiery systems compared to compression bandaging in treatment and in secondary prevention of venous leg ulcer with regard to healing rates, recurrence rates, concordance, quality of life and practitioner satisfaction?		4.5
8. What is the evidence that systemic drug therapy improves healing rates, recurrence rates, and quality of life in patients with venous leg ulcers?	statins, pentoxifylline, cilostazol, prostacyclin, aspirin, zinc, horsechestnut	4.6
9. What is the evidence that skin grafting under compression bandaging improves healing rates, recurrence rates and QoL in patients with venous leg ulcers compared with non-adherent dressings and compression?	pinch grafts, split skin grafts, tissue engineering grafts	4.8
10. Is there any evidence that the following interventions are effective for treating venous leg ulcer with regard to healing rate, recurrence rate and quality of life?	ultrasound, infra-red, electromagnetic current, vacuum assisted closure, hyperbaric oxygen, pneumatic compression, passive exercisers, biophysical	4.9
11. Is there any evidence that lifestyle modifications have an effect on the healing rates or recurrence of venous leg ulcers?	physical activity, lifestyle advice, weight loss, nutritional intervention,	4.11
12. What is the evidence that direct venous intervention is effective in healing venous ulcers, preventing recurrence and improving quality of life?	laser therapy, venous surgical techniques, foam sclerotherapy	5.2
MODELS OF CARE		
Key question	Inclusion/ exclusion criteria	See guideline section
13. Is there any evidence that patients with venous leg ulcer managed in a specialist care setting (community leg ulcer clinic, nurse specialists, one stop clinics) have improved ulcer healing rates and less recurrence than patients managed in a traditional primary care setting (district nurse, community nurse, GPs)?		6.3

Annex 2

Example leg ulcer assessment sheet (continued)

LEG ULCER ASSESSMENT SHEET PAGE 2



OTHER COMMENTS

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Annex 3

Compression bandages - classification and use

Compression Bandages

All bandages used in compression must be applied on top of padding (subcompression wadding bandage) to prevent friction and pressure damage over bony prominences by spreading pressure across a greater area. Bandages should generally be applied toe to knee at 50% stretch and with 50% overlap but specific manufacturers instructions should be followed for each bandage. Products currently available are outlined in the British National Formulary.^{19,84}

- **Light compression bandages**
These provide low levels of compression (Class 3a, 14-17 mmHg at the ankle). These Class 3a bandages can be applied in a spiral or a figure of eight, according to manufacturer's instructions, and can be used as a component of a layered system.
- **High compression bandages**
These provide and maintain high levels of compression (Class 3c, 25-35 mmHg at the ankle). Class 3c bandages are useful for bigger legs or more active patients. They can be used over padding on their own or as part of a layered system, and should be applied in a spiral, according to manufacturer's instructions.
- **Cohesive compression bandages**
These provide light support. The cohesive bandages adhere to themselves but not to skin. They are useful as an outer layer in layered systems and to prevent slippage.
- **Short stretch compression bandages**
These bandages have limited extensibility and should be applied at full stretch, and according to manufacturer's instructions. They are applied over padding in one or two layers.
- **Short stretch cohesive compression bandages**
These bandages have limited extensibility and should also be applied at full stretch and according to manufacturer's instructions. They are applied over padding in one or two layers and have a cohesive component to prevent slippage.
- **Two layer systems**
These are two layer compression systems comprising an inner layer, and an outer compression or cohesive compression layer. These vary in type and should be applied according to manufacturer's instructions.
- **Multilayer compression systems**
These are usually four layer systems which are commercially available as kits. Different kits are available comprising slightly different components for different ankle sizes. These should be applied according to manufacturer's instructions. Four layer kits commonly comprise:

A wound contact low adherent dressing

- | | |
|---------|---|
| Layer 1 | subcompression wadding bandage (one or two rolls depending on ankle size) |
| Layer 2 | support bandage |
| Layer 3 | compression bandage, class 3a or class3c, depending on ankle size |
| Layer 4 | cohesive compression bandage |

Annex 4

Compression hosiery - classification and use

Compression hosiery

Compression hosiery is available in different sizes, lengths, and compression/class. Legs should be measured and hosiery prescribed according to each manufacturer's own measuring guide as sizes vary according to manufacturer. Hosiery can also be made to measure. Current suppliers are outlined in the Scottish Drug Tariff published by the Scottish Government.⁸⁵

Hospitals tend to supply hosiery in line with the European classification of compression testing. Hosiery classified according to British Standard tends to be supplied in the Community (although European classification products are available on GP prescription).⁸⁶

Compression class	British standard	European classification
class 1	14–17 mmHg	18–21 mmHg
class 2	18–24 mmHg	23–32 mmHg
class 3	25–35 mmHg	34–46 mmHg
class 4	not available	49–70 mmHg
class 4 super	not available	60–90 mmHg

Hosiery kits

Two layer hosiery kits comprise a liner stocking, with an outer stocking applied on top. Commonly the liner stocking will apply approx 10 mmHg compression and should be worn 24 hours. The outer stocking should be removed when the person is in bed. The combination of the hosiery kit stockings is 40 mmHg compression and it is available in different sizes.

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