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The Care of Patients with Chronic Leg Ulcer

A National Clinical Guideline

July 1998

KEY TO EVIDENCE STATEMENTS AND GRADES OF RECOMMENDATIONS

The definitions of the types of evidence and the grading of recommendations used in this guideline originate from the US Agency for Health Care Policy and Research¹ and are set out in the following tables.

STATEMENTS OF EVIDENCE

Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

GRADES OF RECOMMENDATIONS

A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation <i>(Evidence levels Ia, Ib)</i>
B	Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation <i>(Evidence levels IIa, IIb, III)</i>
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates the absence of directly applicable clinical studies of good quality <i>(Evidence level IV)</i>

GOOD PRACTICE POINTS

<input checked="" type="checkbox"/>	Recommended best practice based on the clinical experience of the guideline development group
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The Care of Patients with Chronic Leg Ulcer

A National Clinical Guideline

July 1998



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NOTES FOR USERS OF THE GUIDELINE

DEVELOPMENT OF LOCAL GUIDELINES

It is intended that this guideline will be adopted after local discussion involving clinical staff and management. The Area Clinical Audit Committee should be fully involved. Local arrangements may then be made for the derivation of specific local guidelines to implement the national guideline in individual hospitals, units and practices and for securing compliance with them. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

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STATEMENT OF INTENT

This guideline is not intended to be construed or to serve as a standard of medical care. Standards of medical 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.

These parameters of practice should be considered guidelines only. Adherence to them 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 regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment options available.

Significant departures from the national guideline as expressed in the local guideline should be fully documented and the reasons for the differences explained. Significant departures from the local guideline should be fully documented in the patient's case notes at the time the relevant decision is taken.

A background paper on the legal implications of guidelines is available from the SIGN secretariat.

REVIEW OF THE GUIDELINE

This guideline was issued in 1998 and will be reviewed in 2000 or sooner if new evidence becomes available. Any updates to the guideline in the interim period will be noted on the SIGN website. Comments are invited to assist the review process. All correspondence and requests for background information regarding the guideline should be sent to:

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Summary of recommendations

ASSESSMENT

- B** Measurement of ankle brachial pressure ratio (index) (ABPI) by hand-held Doppler is essential in the assessment of chronic leg ulcers.
- B** Patients with an ABPI < 0.8 should be assumed to have arterial disease.
- B** The surface area of the ulcer should be measured serially over time.
- The ulcer **edge** often gives a good indication of progress and should be carefully documented (e.g. shallow, epithelialising, punched out, rolling).
- The **base** of the ulcer should be described (e.g. granulating, sloughy, necrotic).
- The **position** of the ulcer(s)—medial, lateral, anterior, posterior or a combination—should be clearly described.
- The **morphology** is helpful in the diagnosis of less common causes, e.g. carcinoma and tuberculosis.
- C** A non-healing or atypical leg ulcer should be referred for biopsy.
- B** Bacteriological swabs should only be carried out where there is clinical evidence of infection such as cellulitis.
- B** Leg ulcer patients with associated dermatitis should be referred for patch-testing with a specific series for leg ulcer.
- C** Patients with the following features should be referred to the appropriate specialist at an early stage of management:
 - diabetes mellitus
 - peripheral arterial disease (ABPI < 0.8)
 - rheumatoid arthritis/vasculitis
 - suspicion of malignancy
 - atypical distribution of ulcers
 - contact dermatitis or dermatitis resistant to topical steroids
 - patients who may benefit from venous surgery
 - failure to progress despite following this guideline.

TREATMENT

- B** Graduated compression should be used to improve venous insufficiency.
- A** Graduated compression should be used for healing uncomplicated venous ulcers.
- A** Elastic compression is the treatment of first choice for uncomplicated venous leg ulcers.
- A** Multilayer bandaging is recommended.
- Correct application of graduated compression is essential.
- Ideally, leg oedema should be reduced by elevation of the limb before graduated compression is applied.

It is strongly recommended that all the components of multilayer bandage systems should be available on the Drug Tariff.

- A** Ulcerated legs should be washed normally in tap water and carefully dried.
- A** Simple non adherent dressings are recommended in the treatment of venous ulcers, as no specific dressing has been shown to improve healing rates.
- A** Hydrocolloid or foam dressings may be of value in painful ulcers.
- A** Antibiotics should be reserved for evidence of cellulitis or active infection before grafting.
- B** Topical antibiotics are frequent sensitisers and should be avoided.
- A** Systemic therapy in the treatment of leg ulcers is not recommended.
- B** Venous surgery followed by graduated compression should be considered in patients with chronic venous ulceration.

REASSESSMENT

- C** Formal reassessment should be carried out 12 weeks after the start of treatment and thereafter at 12-week intervals.

SECONDARY PREVENTION

- A** Correctly fitted graduated compression hosiery should be prescribed for at least five years for all patients who have successfully healed their venous leg ulcer.

1 Introduction

1.1 BACKGROUND

Chronic leg ulcer is a major health problem in the UK, affecting principally the elderly and costing up to £600m per annum.² The natural history of the disease is of a continuous cycle of healing and breakdown over decades.

In Western countries, ten per thousand of the adult population are likely to have a chronic leg ulcer at some time.³ The point prevalence seems to be between 1.1 and 3.0 per thousand, this range being partly explained by age differences in the populations studied and the inclusion of foot ulcers in those nearer the higher figure. Otherwise there is a remarkable similarity in the findings of a number of large population studies.^{4-10,12} These studies found that about 60-80% of chronic leg ulcers had a venous component, 10-30% were associated with arterial insufficiency and that other factors included diabetes mellitus and rheumatoid disease. Arterial and venous insufficiency combined in 10-20% of cases. However, more recently a comparative study has shown that arterial insufficiency is no more prevalent in patients with chronic leg ulcer than in the population at large.¹¹

1.2 THE NEED FOR A GUIDELINE

Most of the clinical management of chronic leg ulcer falls to primary care: over 80% of chronic leg ulcers are cared for in the community, although a number will be found in hospital.¹² Healing rates in the community are low.¹³ In specialised clinics the healing of smaller ulcers may be improved to 70% at three months in some circumstances.¹⁴ It is known that recurrence rates are certainly in excess of 67% and may be much higher.^{7, 10} Available treatments can reduce recurrence rates to between 20% and 30%.^{15,16}

There is at present no published clinical guideline on management of chronic leg ulcer based on a systematic literature review, although there is a consensus-based clinical guideline from the British Association of Dermatologists.¹⁷ The Scottish Health Purchasing Information Centre have completed an evidence-based report on leg ulcer care.¹⁸

1.3 REMIT OF THE GUIDELINE

The purpose of this guideline is to make recommendations based on evidence of effective practice in the management of this common and costly condition. The guideline is aimed primarily at informing the initial management of these patients.

The guideline deals first with the assessment of patients with leg ulcer before considering treatment. Following this is a section on secondary prevention, perhaps the greatest challenge. The guideline does not discuss the detailed management of patients with chronic leg ulcer in the specialist fields of diabetes, vascular surgery, rheumatoid disease, etc., although indications for referral are considered.

1.4 DEFINITION

For the purpose of this guideline, chronic leg ulcer is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks.

2 Assessment of the patient with leg ulcer

An example patient assessment proforma which may form the basis of discussion in development of local guidelines is illustrated at Annex 2.

2.1 THE PATIENT

The management of chronic leg ulcer will often be influenced by the patient's co-morbidity, e.g. cardiac failure, and other causes of limb swelling such as renal disease, lymphoedema and osteoarthritis.

Initial assessment of the patient should exclude:

- **Rheumatoid arthritis and systemic vasculitis**

Approximately 8% of patients with leg ulcer have rheumatoid arthritis.¹² These patients may have venous, arterial or vasculitic ulcers. Those with vasculitic ulcers will have clinical features of established disease. They may be associated with systemic vasculitis, in which case there will be evidence of vasculitic lesions elsewhere, e.g. nail fold infarcts or splinter haemorrhages. Rarely, ulceration will be due to Felty's syndrome or pyoderma gangrenosum.

Evidence level III

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.

- **Diabetes mellitus**

Diabetes is present in approximately 5% of patients with leg ulcer.¹² The diagnosis should be established according to current World Health Organisation (WHO) criteria.¹⁹

Evidence level III

- **Peripheral arterial disease**

A history of intermittent claudication, cardiovascular disease, or stroke may indicate that the patient has arterial disease.

In the initial assessment, the patient's mobility should be assessed. The availability of help at home may be important, especially when bed rest or compression therapy is recommended. Many elderly patients find good quality graduated compression hosiery difficult to put on and there are devices available to help with this.

The incidence of leg ulcer is spread evenly across social class, but leg ulcers in patients in social classes IV and V take longer to heal and are more likely to be recurrent.²⁰

2.2 THE LEG

It is the treatment of the leg as a functional unit which will achieve the best results for ulcer healing and the initial assessment of the leg is crucial. Oedema should first be assessed, ruling out non-venous causes of unilateral and bilateral oedema. Joint mobility, particularly that of the ankle, is an important component of calf muscle pump function and so this too should be carefully recorded. The leg should also be assessed for signs of venous disease, in particular, varicose veins, venous dermatitis (see section 2.3.4), or symptoms and signs of previous deep vein thrombosis (DVT).

Finally, and most importantly, the state of the arterial supply requires to be assessed. Palpation of pulses alone is not adequate to rule out peripheral arterial disease. Measurement of the ankle brachial pressure ratio (index) (ABPI) of both lower limbs by hand-held Doppler is the most reliable way to detect arterial insufficiency.^{21-23, 25}

*Evidence level
IIa and IIb*

B Measurement of ABPI by hand-held Doppler is essential in the assessment of chronic leg ulcers.

Studies have indicated that an ABPI of 0.9 is up to 95% sensitive in detecting angiogram positive disease.²⁴ However, a ratio of ≥ 0.8 may be considered to exclude significant peripheral arterial disease.²⁵ The ABPI is not useful in assessing the presence of microvascular disease associated with rheumatoid arthritis, systemic vasculitis and diabetes mellitus. Similarly, medial sclerosis of calf vessels (as in patients with diabetes) can cause the ABPI to be spuriously high and so misleading.

Evidence level III

B Patients with an ABPI < 0.8 should be assumed to have arterial disease.

2.3 THE ULCER

2.3.1 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 tracing of the margins, measuring the two maximum perpendicular axes,²⁶ or photography.

Evidence level IIb

B 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 recommend that the following should be described:

- The ulcer **edge** often gives a good indication of progress and should be carefully documented (e.g., shallow, epithelialising, punched out, rolling).
- The **base** of the ulcer should be described (e.g., granulating, sloughy, necrotic).
- The **position** of the ulcer(s)—medial, lateral, anterior, posterior, or a combination—should be clearly described.
- The **morphology** is helpful in the diagnosis of less common causes, e.g. carcinoma and tuberculosis.

2.3.2 BIOPSY

Neoplastic ulcers or neoplastic change in pre-existing ulcers are uncommon, but may give rise to diagnostic difficulty. Referral 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.²⁷

C A non-healing or atypical leg ulcer should be referred for biopsy.

2.3.3 BACTERIOLOGICAL SWABS

In the absence of clinical signs of infection (e.g. cellulitis) there is no indication for routine bacteriological swabbing of venous ulcers.²⁸ All ulcers will be colonised by micro-organisms at some point, and colonisation in itself is not associated with delayed healing.²⁹

Evidence level IIb

B Bacteriological swabs should only be carried out where there is clinical evidence of infection, such as cellulitis.

2.3.4 DERMATITIS

Dermatitis (eczema) is commonly associated with chronic ulceration, especially venous ulceration. It is characterised by erythema, weeping, scaling and pigmentation, and is frequently misdiagnosed as infection. Venous (stasis) dermatitis is frequently complicated by allergic contact dermatitis which occurs in > 50% of patients with leg ulcers and 60-80% of those with associated dermatitis.

Several large patch-test studies have demonstrated that the principal sensitisers are ingredients of applications, dressings, and bandages.³⁰⁻³⁵ The incidence of contact allergy increases with the duration of ulceration.³⁵ Two recent studies in which venous leg ulcer patients were patch-tested to a range of allergens contained in current ulcer dressings in addition to the European standard series, showed that 46% and 61% of reactions were to these additional allergens^{33,34}

Evidence level III

B Leg ulcer patients with associated dermatitis should be referred for patch-testing. Standard series patch-testing is inadequate: a leg ulcer series is recommended.

2.3.5 THE MIXED ULCER

A mixed ulcer is one in which more than one factor may be operative, e.g. a venous ulcer associated with arterial insufficiency, diabetes mellitus, or rheumatoid arthritis.^{7, 10} Often such ulcers first appear in the middle years and are venous in origin. As the patient ages, arterial insufficiency leads to further breakdown or inhibition of healing. Compression may be hazardous in such patients with reduced ABPI,³⁶ although mild compression under strict supervision may be of value where the ABPI is between 0.5 and 0.8. Patients with venous ulcers and diabetes mellitus may be at risk with compression. No studies are available to give guidance as to the most appropriate care of mixed ulcers and more research is required in this area.

2.3.6 ARTERIAL ULCERS

Arterial ulcers are those in which there is evidence of arterial insufficiency and no evidence of other associated conditions such as venous insufficiency, diabetes mellitus, or connective tissue disorders. Where the ABPI is below 0.5 then compression treatment is contraindicated. Full vascular investigation is required. Where appropriate, vascular surgery may help to heal the ulcer and prevent recurrence, but there are no controlled studies to underpin this strategy.

2.4 CRITERIA FOR SPECIALIST REFERRAL

- C** Patients with the following features should be referred to the appropriate specialist at an early stage of management:
- diabetes mellitus
 - peripheral arterial disease (ABPI < 0.8)
 - rheumatoid arthritis/vasculitis
 - suspicion of malignancy
 - atypical distribution of ulcers
 - contact dermatitis or dermatitis resistant to topical steroids
 - patients who may benefit from venous surgery
 - failure to progress despite following this guideline.

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

3 Treatment of patients with leg ulcer

3.1 THE PATIENT

As stressed in section 2 on assessment, the patient's co-morbidity and the control of cardiac failure, diabetes mellitus, and other causes of leg swelling should be reviewed as routine. In addition, exercise with graduated compression support, if appropriate, may be of benefit. Patients are more likely to comply with treatment if they are properly informed about the disease and its management (see *key points for patients at Annex 1*).

As with all wounds, patients with chronic leg ulcers should have optimum nutrition, but specific evidence relating to this patient group is lacking.

3.2 THE LEG

3.2.1 GRADUATED COMPRESSION FOR VENOUS ULCERS

Treatment directed at the leg will depend on the aetiology of the ulcer. Patients with arterial disease to a degree that reduces their ABPI to less than 0.8 may be harmed by graduated compression, as may people with diabetes, in whom the ABPI may be unreliable because of arterial calcification. Neuropathy may confer an additional risk. Although graduated compression may be harmful in these patients it is an essential treatment for venous ulceration (*vide infra*) uncomplicated by other factors.³⁷

It is well established from a number of physiological studies that graduated compression (i.e. a compression which delivers the highest pressure at the ankle and gaiter area and progressively diminished as it ascends the leg) controls or reverses venous insufficiency.³⁸⁻⁴⁵

*Evidence level
IIa and IIb*

B Graduated compression should be used to improve venous insufficiency.

The correct application of graduated compression is the single most effective means of healing venous ulcers. A systematic review of 24 randomised controlled trials of compression treatment for venous ulcers demonstrated that compression improves healing and should be used routinely.⁴⁶

Evidence level Ia

A Graduated compression should be used for healing uncomplicated venous ulcers.

Many venous patients may have leg swelling on presentation and this is best reduced by bed rest and elevation *before* bandages or hosiery are applied.

Ideally, leg oedema should be reduced by elevation of the limb before graduated compression is applied.

3.2.2 TYPE OF COMPRESSION

Graduated compression may be achieved by bandages or by compression stockings. Unfortunately, not all hosiery products are equally effective⁴⁵ and the *in vivo* assessment of graduated compression hosiery remains unsatisfactory. Bandages may provide elastic or non elastic graduated compression.

The type of compression applied has been studied in a number of clinical trials with healing rates of as high as 70% at three months, but these results have not been duplicated outside specialist nursing clinics or clinical trials.^{47,48} The nature of the graduated compression was investigated by the Lothian and Forth Valley Leg Ulcer Study in a randomised controlled study of 132 leg ulcers. Patients were randomised to either multilayer elastic or multilayer non elastic (short stretch) compression and an advantage for those given elastic compression was established.⁴⁹

Evidence level Ib

A Elastic compression is the treatment of first choice for uncomplicated venous leg ulcer.

A clinical study on the effect of a four layer bandage in 148 ulcerated legs demonstrated a 74% healing rate within three months, but ulcers greater than 10 cm² were excluded.⁴⁷ Pressure studies in a subset of 20 patients confirmed that the four layer technique maintained better compression than an adhesive plaster bandage for a week after application.⁵⁰ It was found that compression of over 40 mm Hg at the ankle was associated with a 74% healing rate in three months. Similar results were reported in a clinical study involving closely supervised application of a four layer graduated compression system in community clinics¹⁴

Evidence level IIb

Pooling the results of studies of multilayer compression compared to single layer compression demonstrates an increase in complete healing when a multilayer high compression system is used.⁴⁵

Evidence level Ia

A Multilayer bandaging is recommended.

There is no direct evidence regarding the number of layers required to produce an optimum healing rate. Briefly, a multilayer system might include an inner generous wool layer for padding, an elastic or non elastic bandage to provide compression, and an outer covering to keep the bandaging in place. Some practitioners recommend a further layer to consolidate the wool layer.

This potentially complex but effective treatment requires training in its application.

Correct application of graduated compression is essential.

It is strongly recommended that all the components of multilayer bandage systems should be available on the Drug Tariff.

3.3 THE ULCER

3.3.1 DEBRIDEMENT AND CLEANSING

Many ulcers present with a clean base but some may require debridement when there is adherent slough, although there is no evidence whether this is of benefit or otherwise. There have been no large well-conducted trials of topical agents or debridement on leg ulcer healing. Neither has there been any comparative trial of mechanical and chemical debridement. Entrapped pus should be drained. There is no contraindication to regular cleansing of the leg.

A randomised study using tap water or sterile saline to clean acute traumatic soft tissue wounds found a lower rate of infection in those wounds cleaned with tap water.⁵¹

Evidence level Ib

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

3.3.2 DRESSINGS

There is good evidence that the type of dressing has no effect on ulcer healing.⁵² The Lothian and Forth Valley Leg Ulcer Study carried out a randomised clinical trial in 132 patients with venous ulcers where the type of graduated compression was standardised and found no significant advantage for hydrocellular over simple non adherent dressings.⁵³ In another randomised controlled trial 30 patients were randomised to a hydrocolloid, 30 to silver sulphadiazine and 60 to a non adherent dressing as control. All had standardised compression and there was no difference between the three groups in ulcer healing.⁵⁴ This suggested that the type of dressing added nothing to the beneficial effects of good graduated compression. A number of smaller trials have come to the same conclusion or have been considered inadequate.

Evidence level Ib

A Simple non adherent dressings are recommended in the treatment of venous ulcers as no specific dressing has been shown to improve healing rates.

3.3.3 ANTIBIOTICS

There is evidence that routine use of antibiotics in the management of a clinically uninfected leg ulcer is of no benefit (*evidence level Ib*),⁵⁵ and some evidence that it may be harmful by encouraging the growth of and subsequent colonisation by resistant organisms (*evidence level III*).^{56, 57}

Evidence level Ib and III

Wound swabs should be taken only when there is clinical evidence of infection, e.g. cellulitis, and the appropriate systemic antibiotic treatment instituted. An increase in the amount of pain is often an indication of underlying infection.

A Antibiotics should be reserved for evidence of infection, e.g. cellulitis.

Topical antibiotics are frequent sensitisers³⁴ and have no effect on healing.

Evidence level III

B Topical antibiotics should not be used in the treatment of leg ulcers.

(An exception might be a short course of metronidazole gel for the odoriferous ulcer.)

3.3.4 THE PAINFUL ULCER

Leg ulcers are frequently painful, particularly if they have an arterial component or are associated with cellulitis or deep infection. Assessment of pain is complex and outwith the remit of this guideline, but a structured discussion and frequent reassessment are important. Pain may occur in venous ulcers, but is a particular feature of arterial ulceration and strong analgesics such as opiates are likely to be required. The pain associated with a dressing change can be reduced by adequate soakage before the dressing is removed.

In two trials, one of a hydrocolloid and the other of a foam dressing, the ulcer pain was less when compared with a non-adherent dressing.^{53, 54}

Evidence level Ib

A Hydrocolloid or foam dressings should be used in painful ulcers.

3.3.5 PLASTIC SURGERY

Skin grafting may speed the closure of the ulcer but will not address the underlying pathology. Rates of recurrence will therefore be unaltered.

Split skin grafting, preferably meshed, should be considered in the management of leg ulcers in order to accelerate healing.

- ☑ Graduated compression should be fitted following grafting.
- ☑ It is important to identify and exclude organisms inimical to graft survival such as β -haemolytic streptococcus and pseudomonas.

Pinch skin grafts have been shown to give an early increase in the healing rate over compression alone, but this is not sustained.⁵⁸

3.3.6 VENOUS SURGERY

Patients with chronic venous leg ulcers should be considered for surgery either while the ulcer is present or as a method of secondary prevention after healing. The guideline development group was unable to find evidence which favours one or other course. For such surgery to be effective, careful and detailed identification of the venous pathology is required. There is a consensus of opinion that if the deep venous system is normal, superficial venous surgery may be helpful. Usually the chronic venous insufficiency has several components of valvular incompetence—superficial, deep and perforator. However, many of these exist in the outwardly normal contralateral limb of patients with venous leg ulcers.⁵⁹ It is not surprising therefore that the place of surgery for this complex condition is not yet clear from the evidence.

Studies in this area consist mainly of uncontrolled clinical series which cannot be compared. However, good results were associated with the combined use of surgery and graduated compression.⁶⁰⁻⁶² Calf muscle pump function was shown to be improved only where these were combined.⁶³

Evidence level IIb

- B Venous surgery followed by graduated compression should be considered in patients with venous ulceration.**

There are no randomised clinical controlled trials in this area and further research about the place of surgery and compression is required.

3.3.7 ARTERIAL SURGERY

In ulcerated legs where the ABPI is below 0.8, referral to a vascular surgeon is advised. In suitable cases revascularisation may be advised if an arterial ulcer is associated with critical ischaemia. In cases where a venous ulcer co-exists with significant arterial disease, revascularisation may restore the ABPI to a degree which allows the application of the appropriate graduated compression.

3.3.8 SURROUNDING SKIN

Uncomplicated venous (stasis) dermatitis responds to topical corticosteroids. Failure to respond to a medium potency steroid is an additional indication for patch-testing (see section 2.3.4). Common sensitisers include lanolin, antibiotics, antiseptics, preservatives, emulsifiers, resins (in hydrocolloid dressings and paste bandages), and rubber.³⁰⁻³⁵ 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. Rubber-free brands of compression bandages and stockings are available.

3.4 SYSTEMIC THERAPY

For patients with venous ulceration, there is no clear evidence at present of benefit from any drug over placebo. Oxpentifylline (Trental) was shown to improve healing rates in a small trial using non standardised compression,⁶⁴ but in a large-scale trial of this drug, in which compression was standardised, the improvement with oxpentifylline failed to reach statistical significance.⁶⁵

Evidence level Ib

There have been no well-conducted trials of other drug treatments with large enough numbers of patients to be conclusive.

A Systemic therapy in the treatment of venous leg ulcer is not recommended.

Diabetic, vasculitic and rheumatoid leg ulcers may reflect a lack of control of the underlying condition but the effect of systemic therapy on the ulcer specifically is not known.

4 Reassessment

The active management of leg ulcers may be required over many months or years and may be carried out by several different health care professionals. It is important to reassess progress 12 weeks after the institution of treatment. This assessment should follow the recommendations for the initial assessment (see *section 2*). 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 co-morbidities?
- should the ulcer be biopsied?
- is the management consistent and appropriate?
- is the patient complying with treatment?

C Formal reassessment should be carried out 12 weeks after the start of treatment and thereafter at 12-week intervals.

5 Secondary prevention

Chronic leg ulcers almost always recur unless secondary prevention is maintained.^{7,10} Secondary prevention presently takes the form of graduated compression, surgery or drugs.

Evidence level III

5.1 GRADUATED COMPRESSION FOR HEALED VENOUS ULCERATION

In patients with chronic venous insufficiency it has been demonstrated that well fitted graduated compression hosiery restored venous function (as assessed by the venous refilling time) in 35 of 36 limbs studied.⁶⁶ Two recent studies have shown that properly fitting below knee graduated compression stockings reduce the recurrence rate over a period of five years.^{15, 16}

Evidence level Ib

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.⁴⁵ Class III stockings are more effective than Class II, even when patient compliance is taken into account.¹⁶ The hazards of incorrectly fitting stockings are the same as those of improperly applied compression bandages—the problem of leg swelling has already been referred to in section 3.

Evidence level Ib

A **Correctly fitted graduated compression hosiery should be prescribed for at least five years for all patients who have successfully healed their venous leg ulcer.**

It is likely that compression will be required indefinitely unless the underlying haemodynamic abnormality has been fully corrected.

If a patient finds a stocking uncomfortable, changing the brand of stocking within the same class may improve compliance.⁶⁷ 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 (these are presently not available on Drug Tariff). 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 SURGERY

The role of surgery in the secondary prevention of venous leg ulcers (or as treatment for open venous ulcer—see section 3.3.6) is not established. Such evidence as does exist suggests that combination of appropriate surgery carried out at an early stage in the clinical course and graduated compression is associated with good outcomes. There is scope for further controlled research in this area.

Surgery has a more established place in the treatment of advanced peripheral vascular disease, of which arterial ulceration may be a manifestation. Although, again, there are no studies looking specifically at leg ulcer, patients with leg ulcer and a significant reduction in ABPI should be referred for vascular assessment.

5.3 DRUG THERAPY

No drugs have established a significant role in the prevention of recurrence of leg ulcer.

6 Provision of care

A survey of a population of 1 million carried out in 1985 found that in 83% of leg ulcers the care was carried out entirely in the community, in 12% it was a joint effort between hospital and the community, and 5% were hospital inpatients.¹²

6.1 COMMUNITY LEG ULCER CLINICS

More recently, the development of community leg ulcer clinics in an urban area has been studied and found to be effective, allowing overall healing rates of 67% at 12 weeks and 81% at 24 weeks compared with a rate at 12 weeks of 22% previously.¹⁴ This study not only used effective standardised graduated compression but also indicated a need for a reorganisation of services, (particularly transport) and integration with secondary care. The support of community clinics by secondary care, particularly dermatology, vascular investigation and surgery is important. Many of these patients will require patch-testing, physiological studies and imaging, and others may benefit from surgery. This approach has been successfully implemented elsewhere.⁶⁸⁻⁷⁰ This particular pattern of care improves patient outcomes when compared to historical controls: comparative studies of other patterns of provision are awaited.

Evidence level IIIb

6.2 PATIENT COMPLIANCE

Patient compliance can improve patient outcomes considerably. One study found a two-fold rate of leg ulcer recurrence in those patients unable to comply with treatment compared with patients successfully carrying out their treatment regimen.¹⁵ Another study recorded a recurrence rate as low as 16% in patients complying with treatment.⁷¹ Patient compliance may be improved by patient information such as that included in Annex 1, although evidence of benefit has not been established.

7 Recommendations for audit and research

7.1 IMPLEMENTATION OF THE GUIDELINE

Implementation of local guidelines derived from this national guideline may be supported by a variety of activities, including continuing education and training, and clinical audit. Patient specific reminders could take the form of an assessment record as illustrated in Annex 2.

7.1.1 OUTCOME INDICATORS

- healing rate at twelve weeks
- time to healing
- recurrence rate at 3 years

7.1.2 CLINICAL AUDIT MARKERS

- compliance with guideline/protocol
- specialist nurse or consultant referral rate

7.2 RECOMMENDATIONS FOR FURTHER RESEARCH AND AUDIT

- Models of provision of care*
- Primary prevention of venous insufficiency*
- Pathogenesis of venous ulceration
- Influence of vascular reconstruction in arterial ulcers*
- Influence of the implementation of the SIGN guideline on management of diabetic foot disease on management of diabetic leg ulcer⁷²
- Role of venous surgery in primary healing and secondary prevention*
- Management of mixed and non venous ulcers*
- Audit of the prescription and fitting of graduated compression hosiery*
- Role of bacterial contamination in leg ulcer healing

* *An economic evaluation should be included*

Annex 1

KEY POINTS FOR PATIENTS

The following key points for patients, based on the recommendations in the guideline, might be included along with further information and explanation in patient information materials developed to facilitate local implementation of the guideline.

- For most patients, compression treatment with bandages or with a stocking is the single most important treatment for your ulcer, and is far more important than the ulcer dressing.
- Pain in your calf when walking may prevent your leg ulcer being treated with compression.
- There are no tablets available at present that have been shown to help the healing of leg ulcers.
- 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. Antibiotic tablets are only very occasionally needed.
- Antibiotic treatment applied to your skin or to the ulcer may do more harm than good.
- When resting, try to keep your ankles up higher than your heart. Raising the foot of your bed at night by about 4 inches (10 cm) will also help.
- When your ulcer is being dressed you should take the opportunity to wash your leg normally in tap water.
- Skin irritation (dermatitis) near a leg ulcer will most likely be due to the treatment and may need to be investigated.
- A long-standing leg ulcer may have to be reassessed. This might involve a sample of the ulcer being taken for analysis.
- Your nurse or doctor may wish you to see a specialist if your ulcer is not responding to treatment or if there are features which require investigation.
- Three months after treatment has started, you should let your doctor/nurse know if the ulcer has healed (if they don't already know). They need this information for their records.
- Once your ulcer has healed, in most cases you should wear compression stockings during the day. These are known to improve considerably the chances of the leg remaining healed and are well worth the possible inconvenience.

EXAMINATION			DOPPLERS	RIGHT	LEFT
Circumference (cm)	R	L	Brachial (mm Hg)		
Calf			DP or PT (mm Hg)		
Ankle			ABPI:		

Ankle movement	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Oedema	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Cellulitis	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Dermatitis	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

ULCER <i>(indicate on diagram)</i>	SIZE (mm)	
No. 1:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	
No. 2:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	
No. 3:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	
No. 4:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	
No. 5:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	
No. 6:	<input type="text"/> × <input type="text"/> = <input type="text"/> mm ²	

Slough:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Odour:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
Depth:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

INVESTIGATIONS	Glucose
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Annex 3

DETAILS OF SYSTEMATIC REVIEW UNDERTAKEN FOR THIS GUIDELINE

The evidence base for this guideline was synthesised in accordance with SIGN methodology (see *inside front cover for definitions of the types of evidence and grading of recommendations*).

A systematic review of the literature was carried out in association with the Scottish Health Purchasing Information Centre (SHPIC) and the Lothian & Forth Valley Leg Ulcer Study. An explicit search strategy, based on the highly sensitive strategy developed by the UK Cochrane Centre, was used to search the Cochrane Peripheral Vascular Diseases Group database and Medline (1980-1996).

Papers were only included if they adhered to recognisable methodological principles, including adequate sample size, a clearly identified hypothesis and measure of outcome, and accurate reporting of results. Whenever possible randomised trials have been discussed but, due to the paucity of sound randomised controlled trials work in this area, a number of clinical studies have been included.

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