



clinical practice

G U I D E L I N E S

**The management of patients
with venous leg ulcers**

*Recommendations for
assessment, compression therapy,
cleansing, debridement, dressing,
contact sensitivity,
training/education and
quality assurance*

1998

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Notes for users of these guidelines

Evidence base

The evidence base for these recommendations came from the Effective Health Care Bulletin, Compression Therapy for Venous Leg Ulcers, NHS CRD and updated sections of an original systematic review (Cullum 1994). Recommendations without a strong evidence base were informed by expert opinion and are thought to reflect current good clinical practice.

This document contains recommendation statements which were graded as follows:

- I Generally consistent finding in a majority of multiple acceptable studies;
- II Either based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies;
- III Limited scientific evidence which does not meet all the criteria of acceptable studies or absence of directly applicable studies of good quality. This includes published or unpublished expert opinion.

(adapted from Waddell et al 1996)

The evidence grade alerts the reader to the type of evidence supporting each statement. However, this grading should not be interpreted as indicative of the strength of recommendation. All of the recommendations are equally strongly endorsed and are not regarded as optional, despite the strength of evidence grade accorded to them.

Updating of the guideline

The guideline was completed in mid-1998. Resources permitting, it is envisaged that the guideline will be updated 2-yearly.

Audit

Audit criteria based on this guideline are being piloted in 1999 and will be available in 2000. This work is being undertaken as part of a national sentinel audit project funded by the NHS Executive, in partnership with the Royal College of Nursing, Centre for Evidence Based Nursing, Eli Lilly National Clinical Audit Centre, the Royal College of Physicians, The Royal College of General Practitioners and the Tissue Viability Society.

Disclaimer

Guideline users should be mindful that, as with any clinical guideline, recommendations may not be appropriate for use in all circumstances. Clearly, a limitation of any guideline is that it simplifies clinical decision-making processes and recommendations (Shiffer 1997). Decisions to adopt any particular recommendation must be made by the practitioner in the light of available resources, local services, policies and protocols, the particular patient's circumstances and wishes, available personnel and equipment, clinical experience of the practitioner and knowledge of more recent research findings.

The reader is referred to the document: *Clinical practice guidelines. The management of patients with venous leg ulcers. Technical report: guideline objectives and methods of guideline development* for further information on the methods used to develop the guideline and its evidence base. Evidence tables and the Effective Health Care Bulletin on Compression Therapy for Venous Leg Ulcers that summarise the evidence base of the guideline are appended to this document. The Technical Report can be obtained from RCN Publishing, Nursing Standard House, 17-19 Peterborough Road, Harrow HA1 2AY.

Summary recommendations

	Strength of Evidence		Strength of Evidence
Assessment of leg ulcers		Assessment of leg ulcers <i>continued</i>	
Assessment and clinical investigations should be undertaken by a health care professional trained in leg ulcer management	III	A formal record of ulcer size should be taken at first presentation, and at least at monthly intervals thereafter	III
A full clinical history and physical examination should be conducted for a patient presenting with either their first or recurrent leg ulcer and should be ongoing thereafter	III	Specialist medical referral may be appropriate for: treatment of underlying medical problems; ulcers of non-venous aetiology; suspected malignancy; diagnostic uncertainty; reduced ABPI; increased ABPI; rapid deterioration of ulcers; newly diagnosed diabetes mellitus; signs of contact dermatitis; cellulitis; healed ulcers with a view to venous surgery; ulcers which have received adequate treatment and have not improved after 3 months; recurring ulceration; ischaemic foot; infected foot; pain management	III
Record the following, which may be indicative of venous disease: family history of venous disease, varicose veins; proven deep vein thrombosis in the affected leg; phlebitis in the affected leg; suspected deep vein thrombosis; surgery/fractures to leg; episodes of chest pain, haemoptysis or history of a pulmonary embolus	III	Management of venous leg ulcers	
Record the following, which may be indicative of non-venous aetiology: family history of non-venous aetiology; heart disease, stroke, transient ischaemic attack; diabetes mellitus; peripheral vascular disease/intermittent claudication; cigarette smoking; rheumatoid arthritis; ischaemic rest pain	III	Graduated multi-layer high compression systems (including short-stretch regimens), with adequate padding, capable of sustaining compression for at least a week, should be the first line of treatment for uncomplicated venous leg ulcers (ABPI must be ≥ 0.8)	I
In mixed venous/arterial ulcers, patients may present with a combination of the features described above		The compression system should be applied by a trained practitioner	II
The person conducting the assessment should be aware that ulcers may be arterial, diabetic, rheumatoid or malignant, should record any unusual appearance and if present refer the patient for specialist medical assessment	III	Health professionals should regularly monitor whether patients experience pain associated with venous leg ulcers and formulate an individual management plan, which may consist of compression therapy, exercise, leg elevation and analgesia to meet the needs of the patient	II
Information relating to ulcer history should be recorded in a structured format and may include: year first ulcer occurred; site of ulcer and of any previous ulcers; number of previous episodes of ulceration; time to healing in previous episodes; time free of ulcers; past treatment methods; previous operations on venous system; previous and current use of compression hosiery	III	Use of compression stockings reduces venous ulcer recurrence rates	II
Examine both legs and record the presence/absence of the following to aid assessment of ulcer type:	III	Other strategies for the prevention of recurrence may also include the following, depending on the needs of the patient:	III
venous disease: usually shallow (usually on gaiter area of leg); oedema, eczema; ankle flare; lipodermatosclerosis; varicose veins; hyperpigmentation; atrophie blanche		Clinical: venous investigation and surgery; lifetime compression therapy; regular follow-up to monitor skin condition for recurrence; regular follow-up to monitor ABPI	
arterial disease: 'punched out' appearance; base of wound poorly perfused and pale; cold legs/feet; shiny, taut skin; dependent rubour; pale or blue feet; gangrenous toes		Patient education: compliance with compression hosiery; skin care; discourage self-treatment with over-the-counter preparations; avoidance of accidents or trauma to legs; early self-referral at signs of possible skin breakdown; encouragement of mobility and exercise; elevation of the affected limb when immobile	
mixed venous/arterial: features of venous ulcer in combination with signs of arterial impairment		Cleansing, debridement, dressing, contact sensitivity	
The presence of oedema, eczema, hyperkeratotic skin, maceration, cellulitis, degree of granulation tissue, signs of epithelization, unusual wound edges (eg rolled), signs of irritation and scratching, purulence, necrosis, slough, granulation and odour should be recorded at first presentation and as part of routine monitoring thereafter	III	Cleansing of the ulcer should be kept simple: irrigation of the ulcer, where necessary, with warmed tap water or saline is usually sufficient. Dressing technique should be clean and aimed at preventing cross-infection - strict asepsis is unnecessary	III
Blood pressure measurement, weight, urinalysis and Doppler measurement of ankle: brachial pressure index (APBI) should be recorded on first presentation	III	Removal of necrotic and devitalized tissue can be achieved through mechanical, autolytic, chemical or enzymatic debridement	III
Routine bacteriological swabbing is unnecessary unless there is evidence of clinical infection such as: inflammation /redness/evidence of cellulitis; increased pain; purulent exudate; rapid deterioration of the ulcer; pyrexia	I	Dressings must be simple, low adherent, low cost and acceptable to the patient	I
All patients presenting with an ulcer should be screened for arterial disease by Doppler measurement of ABPI	I	Health professionals should be aware that patients can become sensitized to elements of their treatment at any time	II
Doppler measurement of ABPI should be done by staff who are trained to undertake this measure	II	Products which commonly cause skin sensitivity such as those containing lanolin and topical antibiotics should not be used on any patient	III
Doppler ultrasound to measure ABPI should also be conducted when: an ulcer is deteriorating; an ulcer it not fully healed by 12 weeks; patients present with ulcer recurrence; before recommencing compression therapy; patient is wearing compression hosiery as a preventive measure; there is a sudden increase in size of ulcer; there is a sudden increase in pain; foot colour and/or temperature of foot change; and, as part of ongoing assessment (3 monthly)	II	Patients with suspected sensitivity reactions should be referred to a dermatologist for patch testing. Following patch testing, identified allergens must be avoided and medical advice on treatment should be sought	III
		Education/training	
		Health care professionals with recognized training in leg ulcer care should cascade their knowledge and skills to local health care teams	III
		Quality assurance	
		Systems should be put in place to monitor standards of leg ulcer care as measured by structure, process and outcome	III

1.0 The assessment of patients with leg ulcers

Who should assess the patient?

- 1.1 Assessment and clinical investigations should be undertaken by a health care professional trained in leg ulcer management

Rationale

Surveys of reported practice of leg ulcer care by nurses have demonstrated that knowledge often falls far short of that which is ideal (Bell 1994; Roe et al 1994) and that there is wide variation in the nursing management, including assessment of leg ulcers, in areas of the UK (Elliott et al 1996; Roe et al 1993). One audit found that over 80% of patients known to the district nursing services had not been assessed using Doppler ultrasound to determine ulcer aetiology prior to treatment (Stevens et al 1997) and another study (Elliott et al 1996) found that 50% of district nurses used visual assessment alone to diagnose a leg ulcer. There is also debate about whether leg ulcer assessment should be undertaken routinely by nurses (Cullum et al 1997). Insufficient training, as well as lack of equipment and referral criteria (Griffey 1992; Stevens et al 1997) may also contribute to variation in assessment practices by nurses. The UKCC gives little guidance on the matter of what constitutes adequate training levels for nurses involved in leg ulcer care. Consequently, this recommendation states 'health care professional': referring to a nurse or a practitioner other than a nurse. The essential point is that the person conducting the assessment (and who is responsible for the care and treatment of the patient and the application of these recommendations) must be trained and experienced in leg ulcer care. The consensus group view is that there needs to be a commitment to make training in the assessment and management of patients with leg ulcers a mandatory part of general practitioner, district nurse and practice nurse training courses.

Strength of the evidence (III)

The recommendation is consensus rather than evidence-based. No trials were found which assess and compare the reliability and accuracy of nursing assessment or which compare the cost-effectiveness of general practitioner (or other health professional) with nurse assessment of patients with leg ulcers or compare other models of assessment. Surveys of knowledge and reported practice were of variable quality (four cross-sectional and one before and after design) but gave fairly consistent results.

1.0 The assessment of patients with leg ulcers

Clinical history and inspection of the ulcer

- 1.2 A full clinical history and physical examination should be conducted for a patient presenting with either their first or recurrent leg ulcer and should be ongoing thereafter

Rationale

Lack of appropriate clinical assessment of patients with limb ulceration in the community has often led to long periods of ineffective and often inappropriate treatment (Cornwall et al 1986; Elliott et al 1996; Roe et al 1993; Stevens et al 1997). There is evidence that danger occurs if arterial ulcers are not properly diagnosed and receive compression (Callam et al 1987b). It is therefore advisable that diagnosis of ulcers should be based on a thorough clinical history and physical examination, as well as appropriate laboratory tests and haemodynamic assessment. This will assist identification of both the underlying cause and any associated diseases and will influence decisions about prognosis, referral, investigation and management. If the practitioner is unable to conduct a physical examination, they must refer the patient to an appropriately trained professional.

Strength of evidence (III)

This recommendation is consensus-based as there are no studies which examine patient outcomes comparing patients given or not given the benefit of a full clinical history and physical examination.

- 1.3 Record the following which may be indicative of venous disease
- family history
 - varicose veins (record whether or not treated)
 - proven deep vein thrombosis in the affected leg
 - phlebitis in the affected leg
 - suspected deep vein thrombosis (for example, a swollen leg after surgery, pregnancy, trauma or a period of enforced bed rest)
 - surgery/fractures to the leg
 - episodes of chest pain, haemoptysis, or history of a pulmonary embolus

Record the following which may be indicative of non-venous aetiology

- family history of non-venous aetiology
- heart disease, stroke, transient ischaemic attack
- diabetes mellitus
- peripheral vascular disease/intermittent claudication
- cigarette smoking
- rheumatoid arthritis
- ischaemic rest pain

In mixed venous/arterial ulcers patients may present with a combination of the features described above

Rationale

Patients with venous and non-venous leg ulcers often have a readily recognized clinical syndrome comprising some of the above features and staff should be trained to recognize these. This will assist the accurate identification of aetiology, which has major implications for treatment choice. However, observation alone is insufficient to determine the aetiology (refer to recommendations 1.10;1.11).

1.0 The assessment of patients with leg ulcers

Strength of evidence (III)

Although the methods employed and population structures examined are not comparable, there is relative concordance of data on aetiological factors and the medical criteria used to define venous, non-venous and mixed aetiology ulcers are well-defined (Alexander House Group 1992). Well-designed, prospective, epidemiological studies are needed to determine risk factors for venous disease and venous ulceration so that prevention strategies can be developed (Cullum & Roe 1995).

1.4 The person conducting the assessment should be aware that ulcers may be arterial, diabetic, rheumatoid or malignant, should record any unusual appearance and refer the patient for specialist medical assessment*

* if there is any doubt about aetiology the patient should be referred to the appropriate specialist

Rationale

Arterial ulcers

Arterial leg ulcers are caused by an insufficient arterial blood supply to the lower limb, resulting in ischaemia and necrosis (Belcaro et al 1983; Carter 1973). A vascular assessment is required in order to establish the location and extent of the occlusion and the presence of small vessel disease (Cullum 1994). The specialised assessment will determine whether the patient is suitable for angioplasty or major vascular surgery.

Rheumatoid ulcers

These are commonly described as deep, well-demarcated and punched-out in appearance. They are usually situated on the dorsum of the foot or calf (Lambert & McGuire 1989) and are often slow to heal. Patients with rheumatoid arthritis might also develop ulcers associated with venous disease.

Diabetic ulcers

These are usually found on the foot, often over bony prominences such as the bunion area or under the metatarsal heads and usually have a sloughy or necrotic appearance (Cullum & Roe 1995).

An ulcer in a diabetic patient may have neuropathic, arterial and/or venous components (Browse et al 1988; Nelzen et al 1993). It is essential to identify underlying aetiology. Consequently, all diabetic patients with leg ulcers should be referred to a diabetologist or diabetic clinic, particularly if diabetes is poorly controlled. Specialist assessment is essential as Doppler measurement of ABPI may be unreliable in this group of patients.

Malignant ulcers

Malignancy is a rare cause of ulceration and more rarely, a consequence of chronic ulceration (Ackroyd & Young 1983; Baldursson et al 1995; Yang et al 1996). Malignant ulcers can be confused with venous ulcers and longstanding venous ulcers may become malignant (Ackroyd & Young 1983; Yang et al 1996). Ulcers with atypical site and appearance such as rolled edges, or non-healing ulcers with a raised ulcer bed should be referred for biopsy and medical attention (Ackroyd & Young 1983; Baldursson et al 1995; Yang et al 1996).

Strength of evidence (III)

This recommendation is based on expert opinion although as referenced above, there are a number of studies (mainly prevalence surveys and case studies) which have examined the prevalence and/or clinical features of these type of ulcers.

1.0 The assessment of patients with leg ulcers

1.5 Information relating to ulcer history should be recorded in a structured format and may include

- year first ulcer occurred
- site of ulcer and of any previous ulcers
- number of previous episodes of ulceration
- time to healing in previous episodes
- time free of ulcers
- past treatment methods (both successful and unsuccessful)
- previous operations on venous system
- previous and current use of compression hosiery

Rationale

Collection of these data in a structured format will enable consideration of clinical factors that may impact on treatment and healing progress, as well as provide baseline information on ulcer history. However, diagnosis of ulcer type should not be made solely on this information.

Strength of evidence (III)

This statement is consensus based as no research was identified which examined whether a structured approach for recording ulcer history results in improved management and patient outcomes.

1.6 Examine both legs and record the presence/absence of the following to aid assessment of type of ulcer

Venous disease

- usually shallow ulcers (situated on the gaiter area of the leg)
- oedema
- eczema
- ankle flare
- lipodermatosclerosis
- varicose veins
- hyperpigmentation
- atrophie blanche

Arterial disease

- ulcers with a 'punched out' appearance
- base of wound poorly perfused and pale
- cold legs/feet (in a warm environment)
- shiny, taut skin
- dependent rubor
- pale or blue feet
- gangrenous toes

Mixed venous/arterial

These will have the features of a venous ulcer in combination with signs of arterial impairment

Rationale

All of the above are well-recognized signs respectively of chronic venous insufficiency and arterial disease (as indicated). However, these signs do not construct a diagnosis per se (refer to recommendations 1.10; 1.11)

Strength of evidence (III)

Consensus statements and literature reviews concur on well known features of these conditions (Alexander House Group 1992; Browse et al 1988).

1.0 The assessment of patients with leg ulcers

- 1.7 The presence of oedema, eczema, hyperkeratotic skin, maceration, cellulitis, degree of granulation tissue, signs of epithelization, unusual wound edges (e.g. rolled), signs of irritation and scratching, purulence, necrosis, slough, granulation, odour should be recorded at first presentation and as part of routine monitoring thereafter

Rationale

The condition of the ulcer and surrounding skin will influence skin care and will provide baseline information for evaluating treatment outcomes. For example, if eczema with itching is present, a topical steroid may be required; if there is no eczema the surrounding intact skin can be moisturized. If the ulcer is odorous and sloughy frequent dressing changes may be considered. Also, fragile, oedematous skin will need careful application of compression bandages (although, not necessarily decreased compression).

Strength of evidence (III)

Although the exact role that a systematic and comprehensive skin inspection plays in improving care has not been empirically tested, there is general expert agreement that skin inspection is a fundamental part of assessment.

Clinical investigations

- 1.8 Blood pressure measurement, weight, urinalysis and Doppler measurement of APBI should be recorded on first presentation

Rationale

Blood pressure is taken to monitor arterial disease, weight is taken at baseline to monitor weight loss if the patient is obese and urinalysis is taken to screen for undiagnosed diabetes mellitus. The need for additional blood and biochemical investigations will depend on the patient's clinical history and local protocols. Measurement of ABPI is essential to rule out arterial disease (refer to recommendations 1.10, 1.11).

Strength of evidence (III)

This recommendation is supported by consensus opinion.

- 1.9 Routine bacteriological swabbing is unnecessary unless there is evidence of clinical infection such as
- inflammation/redness/cellulitis
 - increased pain
 - purulent exudate
 - rapid deterioration of the ulcer
 - pyrexia

Rationale

Chronic leg ulcers are usually colonized by micro-organisms, but how this affects healing is debatable (Skene et al 1992; Trengove et al 1996). The influence of bacteria on ulcer healing has been examined in a number of studies (Ericksson 1984; Ericksson et al 1984; Skene et al 1992; Trengove et al 1996) and most have found that ulcer healing is not influenced by the presence of bacteria.

Strength of evidence (I)

1 RCT and 1 prospective study.

1.0 The assessment of patients with leg ulcers

Doppler measurement of ankle/brachial pressure index (ABPI)

1.10 All patients presenting with an ulcer should be screened for arterial disease by Doppler measurement of ABPI, by staff who are trained to undertake this measure

The importance of assessing the blood supply to the leg

Rationale

All patients should be given the benefit of Doppler ultrasound measurement of ABPI to ensure detection of arterial insufficiency which could result in the commencement of inappropriate and even dangerous therapy. Absent or very weak foot pulses indicate poor peripheral blood supply and are regarded as signs of arterial disease. However, there is a body of research, which suggests that diagnosis should not be solely based on the absence or presence of pedal pulses because there is generally poor agreement between manual palpation and ABPI (Brearley et al 1992; Callam et al 1987b; Magee et al 1992; Moffatt et al 1994). Two large studies have shown respectively that 67% and 37% of limbs with an ABPI of <0.9 had palpable foot pulses, with the consequent risk of applying compression to people with arterial disease (Callam et al 1987b; Moffatt & O'Hare 1995). One survey of surgeons found that 32% reported at least one instance of necrosis induced or aggravated by compression bandages of stockings (Callam et al 1987c).

The importance of making an objective aetiological diagnosis by measuring ABPI, *in addition* to visual inspection of the ulcer, pedal pulse palpation and a thorough clinical history and physical assessment, is highlighted by a number of studies (Moffatt et al 1994; Nelzen et al 1994; Simon et al 1994). Furthermore, venous and arterial disease can and often do, co-exist in the same individual (Callam 1987c; Scriven et al 1997; Sindrup et al 1987) and Doppler ultrasound can aid diagnosis in such cases.

Strength of evidence (I)

The evidence for this recommendation is mainly from a number of cross-sectional studies; one controlled study and one cohort study.

ABPI training

Rationale

Unless operators have undergone formal training in Doppler ultrasound technique, ABPI measurements can be unreliable (Brearley et al 1992; Callam et al 1987b; Cornwall et al 1986; Magee et al 1992; Ray et al 1994). Reliability of Doppler measurements can be considerably improved if operators are highly trained (Fisher et al 1996; Fowkes et al 1988).

Training should also emphasize that ABPI measurements in patients with diabetes or atherosclerosis may not be reliable. Patients with these conditions may have deceptively high pressure readings (Callam et al 1987b; Corson et al 1986; Dealey 1995) and such patients should be referred for specialist assessment (refer to recommendation 1.4).

Strength of evidence (II)

One before-after, four cross-sectional and one controlled study.

1.0 The assessment of patients with leg ulcers

1.11 Doppler ultrasound to measure ABPI should also be conducted when

- an ulcer is deteriorating
- ulcer is not fully healed by 12 weeks
- patients present with ulcer recurrence
- before recommencing compression therapy
- patient is wearing compression hosiery as a preventive measure
- there is a sudden increase in size of ulcer
- there is a sudden increase in pain
- foot colour and/or temperature of foot change
- and, as part of ongoing assessment (three monthly)

Rationale

Arterial disease may develop in patients with venous disease (Callam 1987c; Scriven et al 1997; Sindrup et al 1987) and significant reductions in ABPI can occur over relatively short periods of time (3–12 months) (Simon et al 1994). Estimates of between 13%–29% of legs with venous ulcers which also had detectable arterial insufficiency have been reported (Nelzen et al 1994; Scriven et al 1997; Simon et al 1994). ABPI will also fall with age. The regularity with which Doppler studies are repeated as part of ongoing assessment may be determined by local protocols.

Strength of evidence (II)

One cohort and two cross-sectional studies.

Ulcer size/measurement

1.12 A formal record of ulcer size should be taken at first presentation, and at least at monthly intervals thereafter

Rationale

The literature demonstrates a variety of methods used to measure wounds which mainly focus on wound area rather than depth (Ahroni et al 1992; Buntinx et al 1996; Etris et al 1994; Liskay et al 1993; Majeske 1992). Many of the described measurement techniques (Johnson & Miller 1996) may be too cumbersome and invasive for everyday use in the clinical setting where rapid assessment is required and where monitoring of progress rather than accurate measurement is the priority.

Therefore, the choice of a measurement method should be based primarily on the local expertise available to perform and interpret the measurement and the availability of equipment. Monitoring progress can be done cheaply and easily using serial tracings; placing a current tracing over a previous tracing, ideally, by the same practitioner each time. However, the practitioner should be mindful that wound state should also be regularly monitored (refer to recommendation 1.7).

Strength of evidence (III)

Design, setting, personnel and statistical differences in the six cross-sectional studies prevent adequate comparison of the reliability of measurements obtained with the various wound measurement procedures. There was consensus agreement that sophisticated measuring devices are unnecessary in everyday clinical practice.

1.0 The assessment of patients with leg ulcers

Referral criteria

- 1.13 Specialist medical referral may be appropriate for
- treatment of underlying medical problems
 - ulcers of non-venous aetiology (rheumatoid; diabetic; arterial; mixed-aetiology)
 - suspected malignancy
 - diagnostic uncertainty
 - reduced ABPI (for example, <0.8 – routine vascular referral; <0.5 – urgent vascular referral)*
 - increased ABPI (for example, >1.0)*
 - rapid deterioration of ulcers
 - newly diagnosed diabetes mellitus
 - signs of contact dermatitis (spreading eczema; increased itch)
 - cellulitis
 - healed ulcers with a view to venous surgery
 - ulcers which have received adequate treatment, and have not improved after three months
 - recurring ulceration
 - ischaemic foot
 - infected foot
 - pain management

* may vary according to local protocols

Rationale

There is some research which shows that patients may not be referred appropriately for specialist assessment. One study of district nurse records indicated that only 35% of leg ulcer patients were referred at any stage for a specialist assessment and 7% had been examined by a vascular surgeon (Lees & Lambert 1992). However, most of the nurses felt that further investigation of the patients was necessary. Another study found that only six out of 146 nurses would refer patients with rheumatoid or diabetic ulcers for specialist advice (Roe et al 1993).

Local protocols will dictate if the patient is to be referred to a vascular surgeon, dermatologist, rheumatologist, diabetologist or other medical specialist.

Strength of evidence (III)

Principal criteria for referral are widely agreed by experts although no studies examining the outcomes of patients with leg ulcers referred from primary to secondary care or between health professionals within primary care were found. Trials are being established to evaluate the effectiveness of early surgery before ulcer healing.

2.0 The management of venous leg ulcers

Compression therapy

This guideline does not address compression bandaging in patients with mixed aetiology. Patients with this condition usually require some form of reduced compression, which requires expertise in application and close monitoring.

- 2.1 Graduated multi-layer high compression systems (including short-stretch regimens), with adequate padding, capable of sustaining compression for at least a week* should be the first line of treatment for uncomplicated venous leg ulcers (ABPI must be ≥ 0.8)

* if wound large and heavily exuding, more frequent dressing changes will be required

Patient suitability for compression bandaging

Rationale

Patients with arterial disease are not suitable for high compression therapy as it can decrease perfusion and worsen ischaemia. People with venous ulcers usually have an ABPI equal to or greater than 0.8. Arterial involvement is suggested by an APBI of less than 0.8 (the presence of the latter readings do not necessarily diagnose an ulcer as arterial); mixed venous/arterial ulcers may have an ABPI of 0.6–0.8. Although the cut-off point below which compression is not recommended is often quoted as 0.8, vascular surgeons may use a lower cut-off point, for example 0.6/0.7 (Moffatt et al 1995) and in one study reduced compression was used in patients with an ABPI of 0.5 (Moffatt et al 1995). However, the use of compression on patients with a reduced APBI requires assessment and supervision by an experienced and trained leg ulcer care expert. Again, the importance of adequate assessment, correct interpretation of that assessment, prescription of appropriate compression systems and their meticulous application cannot be over-stressed (Cullum 1994).

Strength of evidence (III)

This recommendation is based mainly on the logic and principles of pathophysiology, consensus group views and two studies (Callam et al 1987b; Moffatt et al 1992).

Compression vs. no compression

Rationale

Randomised controlled trials (RCTs) have shown that compression provided either by Unna's boot (Rubin et al 1990; Sikes 1985), two-layer (Eriksson et al 1984), four-layer (Taylor et al 1998); or short stretch bandages (Charles 1991) improved healing rates compared to treatments using no compression. Furthermore, compression therapy is more cost-effective because the faster healing rates saved nursing time (Taylor et al 1998).

Strength of evidence (I)

This recommendation is based on six RCTs.

High compression vs. low compression

Rationale

Three RCTs compared elastic high compression three-layer bandaging (two using Tensopress and one Setopress as a component) with low compression (using Elastocrepe) (Callam et al 1992; Gould et al, unpublished; Northeast et al 1990). More patients were healed at 12–15 weeks with high compression. The advantage of higher compression was confirmed in another RCT in which patients with either four-layer or short stretch bandaging healed faster than those receiving a paste bandage with outer support (Duby et al 1993).

Strength of evidence (I)

There is reliable evidence that high compression achieves better healing rates than low compression (four RCTs).

Multi-layer vs. single-layer

Rationale

The advantage of multilayer high compression systems over single layer systems is shown by one large and two small trials which found more ulcers healed at 24 weeks using four-layer bandaging than were healed using a single layer, adhesive compression bandage (Kralj et al unpublished; Nelson et al 1995b; Travers et al 1992).

Strength of evidence (I)

This recommendation is based on one large and two small trials

2.0 The management of venous leg ulcers

Four-layer vs. other types of compression bandaging

Rationale

Even though 3-layer, 2-layer and other compression bandages have been shown to be effective, they appear not to have been directly compared with 4-layer bandaging in RCTs. 4-layer bandaging has been compared with short stretch and with Unna's boots in 4 RCTs (Colgan et al unpublished; Duby et al 1993; Knight & McCulloch 1996; Scriven et al 1998). No differences were found in healing rates. However, because these studies were small in size, there cannot be confidence that there are not clinically important differences in effectiveness. A trial comparing 4-layer with 3-layer bandaging is being carried out at St. Thomas's Hospital, London. When clinics have specifically promoted the delivery of 4-layer high compression treatment, their healing rates have improved compared with results for the usual care given by community nurses (Morrell et al 1998; Taylor et al 1998). However, the 2 available trials do not provide information on the relative impact of, or interactions between the various elements of setting, nurse training, compression bandaging and protocols for treatment and referral (Morrell et al 1998; Taylor et al 1998) and a trial comparing 4-layer with short stretch is under way coordinated by the CEBN.

Strength of evidence II

Currently, there is little reliable evidence which directly compares 4-layer with other types of compression bandaging in RCTs.

2.2 The compression system should be applied by a trained practitioner

Rationale

Whichever high compression approach is employed, it is important that it is used correctly so that sufficient (but not excessive) pressure is applied. Incorrectly applied compression bandages may be harmful or useless and may predispose the patient to cellulitis or skin breakdown. In the presence of diabetes or any other condition that compromises arterial circulation, compression must be applied with extreme caution. The consensus group was able to give several examples where staff are not trained in applying compression bandaging.

Inexperienced nurses or those without additional training in compression bandaging apply bandages at inappropriate and widely varying pressures (Logan et al 1992, Nelson et al 1995a, Stockport et al 1997). More experienced or well trained bandagers obtain better and more consistent pressure results (Logan et al 1992; Nelson et al 1995a). One study found that multilayer compression bandage systems were easier to apply correctly than single-layer bandages (Stockport et al 1997). It is difficult to ascertain from existing studies if these results are maintained over time. Whether nurses who consistently find it difficult to apply a compression bandage should be given additional training or whether it is more appropriate to promote the use of a core team of nurses skilled in bandaging to provide a compression therapy service requires formal evaluation.

Strength of evidence (II)

There is fairly reliable research evidence supporting the recommendation (a one-sample follow-up study, one cross-sectional study). However, more research is needed to see what training strategies improve compression bandage techniques and if the effects of training are maintained over time. The consensus group view was that it is essential that only properly trained staff apply compression bandages.

2.0 The management of venous leg ulcers

Pain assessment and relief

2.3 Health professionals should regularly monitor whether patients experience pain associated with venous leg ulcers and formulate an individual management plan, which may consist of compression therapy, exercise, leg elevation and analgesia, to meet the needs of the patient

Rationale

A significant proportion of patients with venous ulcers report moderate to severe pain (Cullum & Roe 1995; Dunn 1997; Hamer et al 1994; Hofman et al 1997; Stevens et al 1997; Walshe 1995). Yet, one survey found that 55% of district nurses did not assess patients' pain (Roe et al 1993). Increased pain on mobility may be associated with poorer healing rates (Johnson 1995) and may also be a sign of some underlying pathology such as arterial disease or infection (indicating that the patient requires referral for specialized assessment - refer to recommendation 1.13).

Leg elevation is important since it can aid venous return and reduce pain and swelling in some patients. However, leg elevation may make the pain worse in others (Hofman et al 1997). Compression counteracts the harmful effects of venous hypertension and compression may relieve pain (Franks et al 1995). Exercise maintains the venous calf pump function.

Fifty per cent of patients with purely venous aetiology reporting severe pain were taking either mild analgesia or none at all (Hofman et al 1997). Analgesics containing opioids may be necessary in some patients.

Strength of evidence (II)

Although the research is quite heterogeneous, the results consistently report that patients with venous leg ulcers can experience considerable pain (one prospective, one matched and two cross-sectional studies). There is also some evidence that pain relief occurs with compression and healing (Franks et al 1995). No research could be identified that examined the use of a pain assessment method specifically designed for patients with venous leg ulcers or compared different methods of relief. There is very little conclusive research on other pain relief strategies such as exercise and leg elevation.

Prevention of recurrence of ulceration

2.4 Use of compression stockings reduces venous ulcer recurrence rates

Rationale

The EHCBC Compression therapy for venous leg ulcers (NHSCRD1997) found no RCT which compared recurrence rates achieved with and without compression stockings in people with healed ulcers. One RCT however, showed that three – five year recurrence rates were lower in patients using strong support from class three compression stockings (21%) than in those randomized to receive medium support from class two compression stockings (32%) ($p=0.034$); class two stockings however, were better tolerated by patients (Harper et al 1995).

Drug tariff recommendations for compression hosiery

Class I 14-17mmHg at the ankle for light support

Class II 18-24mmHg at the ankle for medium support

Class III 25-33mmHg at the ankle for strong support

Strength of evidence (II)

Although no RCTs were found, there is fairly strong evidence in support of the recommendation from one controlled trial.

2.0 The management of venous leg ulcers

- 2.5 Other strategies for the prevention of recurrence may also include the following, depending on the needs of the patient

Clinical

- venous investigation and surgery
- lifetime compression therapy (see 2.4)
- regular follow-up to monitor skin condition for recurrence
- regular follow-up to monitor ABPI

Patient education

- compliance with compression hosiery
- skin care
- discourage self-treatment with over-the-counter preparations
- avoidance of accidents or trauma to legs
- early self-referral at signs of possible skin breakdown
- encouragement of mobility and exercise
- elevation of the affected limb when immobile

Rationale

A variety of strategies have been proposed, largely based on expert opinion, which range from medical investigation to health education. The recommended approach will depend on the particular patient and likely compliance with suggested strategies.

Strength of evidence (III)

There is little evidence evaluating the effectiveness of each of these strategies - much of the published research is based on what is judged to be current best practice and clinical common-sense. There is some evidence for the importance of early self-referral from a trial (Moffatt & Dorman 1995), which showed that the more quickly someone re-attends to receive 4-layer compression bandaging after recurrence, the shorter the time to rehealing.

3.0 Cleansing, debridement, dressings, contact sensitivity

Cleansing

- 3.1 Cleansing of the ulcer should be kept simple:
- irrigation of the ulcer, where necessary with warmed tap water or saline is usually sufficient
 - dressing technique should be clean and aimed at preventing cross-infection: strict asepsis is unnecessary

Rationale

There is no evidence that use of antiseptics confers any benefit and some evidence from studies of animal models and cell culture that it might be harmful. Cleansing traumatic wounds with tap water was associated with a lower rate of clinical infection when compared to sterile isotonic saline (Angeras et al 1992).

Wounds and skin are colonized with bacteria and these do not appear to impede healing. The purpose of the dressing technique is not to remove bacteria but rather to avoid cross-infection with sources of contamination, e.g. other sites of the patient or other patients. A trial of clean versus aseptic technique in the cleansing of tracheotomy wounds failed to demonstrate any difference in infection rates between the two methods (Sachine-Kardase et al 1992). There are no trials comparing aseptic technique with clean technique in chronic wounds, including leg ulcers.

Strength of evidence (III)

There are no trials comparing aseptic technique with clean technique in chronic wounds, including leg ulcers.

Debridement

- 3.2 Removal of necrotic and devitalized tissue can be achieved through mechanical, autolytic, chemical or enzymatic debridement

Rationale

A systematic review (Bradley et al, in press) concluded that there have been no trials which measure the impact of debridement on the time wounds take to heal. It is acknowledged, however, that clinicians may wish to remove sloughy or necrotic tissue from the ulcer bed and this should be accomplished in a manner unlikely to delay healing. Sharp debridement is a relatively swift and inexpensive 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.

The chemical agents 1% providone iodine, 0.25% acetic acid, 3% hydrogen peroxide and 0.5% hypochlorite have been shown to damage cells in vitro (Lineaweaver et al 1985), however, there are no trials of these solutions in leg ulcers. Nevertheless, the consensus view is that they should not be used.

The second generation chemical debriding agents dextranomer and cadexomer iodine have been compared to a variety of standard treatments, usually involving saline or antiseptic-soaked gauze, and may facilitate healing compared to these alternatives.

The use of maggots as biological debriding agents is enjoying a resurgence in the UK, however there have been no randomized controlled trials of their use and current evidence does not support their use, and patients' perceptions of this therapy have not been researched.

Autolytic debridement, the breakdown and removal of dead tissues by the body's own cells and enzymes, can be facilitated through the maintenance of a moist wound environment. In patients wearing compression bandages, it is possible to maintain a moist wound environment under simple non-adherent dressings as moisture is retained beneath the bandage.

Strength of the evidence (III)

Moist wound environment aids debridement—no trial evidence could be found.

Chemical debridement is harmful to cells—in vitro studies for example, Lineaweaver et al (1985).

3.0 *Cleansing, debridement, dressings, contact sensitivity*

Dressings

3.3 Dressings must be simple, low adherent, low cost and acceptable to the patient

Rationale

A recent systematic review (Bradley et al in press) has concluded that there is no evidence that any particular dressing or dressing type is more effective in healing venous leg ulcers. The most important aspect of treatment for uncomplicated venous ulcers is the application of high compression using a stocking or bandage. In the absence of evidence, dressings should be low cost and low or non-adherent to avoid any damage to the ulcer bed. For this reason, wet to dry gauze is not recommended.

Strength of the evidence (I)

A recently completed systematic review (Bradley et al in press) identified 42 randomised trials of dressings and topical agents in patients with venous ulcers and concluded there was insufficient evidence to promote the use of any particular dressing.

3.4 Health professionals should be aware that patients can become sensitized to elements of their treatment at any time

Rationale

Patients can develop allergies after using a product over time. Cameron (1998) found that more than 20% of patients previously patch tested had developed at least one new allergy at retesting 2 and 8 years later.

Strength of evidence (II)

One cohort study (Cameron, 1998)

Contact sensitivity

3.5 Products which commonly cause skin sensitivity such as those containing lanolin and topical antibiotics should not be used on any patient

Rationale

Patients with venous leg ulcers have high rates of sensitivity to these products. Preparations commonly used as part of leg ulcer treatment reported to cause contact sensitivity in certain individuals are listed below. Frequency of contact sensitivity and the commonest sensitizers in leg ulcer patients have been examined in a number of studies (Blondeel et al 1978; Cameron 1990; Cameron et al 1991; Dooms-Goossens et al 1979b; Fraki et al 1979; Kulozik et al 1988; Malten et al 1973; Malten & Kuiper 1985; Paramsothy et al 1988). Given that skin condition can be improved using products without lanolin, that there is no evidence that topical antibiotics aid healing and that patients may develop a sensitivity after using the product for a while, the safest course is to avoid these products wherever possible.

Strength of the evidence (III)

The evidence for the recommendation is based on observation and clinical experience.

3.6 Patients with suspected sensitivity reactions should be referred to a dermatologist for patch testing. Following patch testing, identified allergens must be avoided and medical advice on treatment should be sought

Rationale

A large proportion of patients with venous leg ulcers are allergic to a number of commonly used products (Dooms-Goossens et al 1979a; McLelland & Shuster 1990). It is important that these are identified so that they may be avoided in future. Treatment will vary and may consist of elevation of the affected limb and application of steroid ointment.

Strength of evidence (III)

The evidence supporting this recommendation is based on observation and clinical experience.

3.0 *Cleansing, debridement, dressings, contact sensitivity*

Table 1: Common allergens and their importance in the care of venous ulcers

Name of allergen	Type	Potential sources
wool alcohols, amerchol L 101,	lanolin	bath additives, creams, emollients, barriers and baby products
neomycin, framycetin, bacitracin	antibiotic	medicaments, tulle dressing, antibiotic creams and ointments
parabens (hydroxybenzoates)	preservative	medicaments, creams and paste bandages
cetyl alcohol, stearyl alcohol, cetylstearyl alcohol, cetostearyl alcohol	vehicle	most creams, including corticosteroid creams, aqueous cream, emulsifying ointment and some paste bandages
colophony/ester of rosin	adhesive	adhesive backed bandages and dressings
mercapto/carba/thiuram mix	rubber	elastic bandages and supports, elastic stockings, latex gloves worn by carer
chlorocresol	biocide	corticosteroid creams and some moisturizers
quinoline mix	biocide	antiseptic and antifungal creams and ointments
chlorhexidene	biocide	antiseptics, tulle dressing
tixocortal pivalate	steriod	steroid preparations, eg.hydrocortisone
fragrance mix/balsam of Peru	perfume	bath oils, over the counter preparations such as moisturizers and baby products

4.0 Education/training in leg ulcer care

- 4.1 Health care professionals with recognized training in leg ulcer care should cascade their knowledge and skills to local health care teams. This should include providing education on the following
- pathophysiology of leg ulceration
 - leg ulcer assessment
 - use of Doppler ultrasound to measure ABPI
 - normal and abnormal wound healing
 - compression therapy - theory, management, application
 - dressing selection
 - skin care and management
 - health education
 - preventing recurrence
 - criteria for referral for specialised assessment

Rationale

To reduce variation in practice, research-based information and knowledge about aetiology, assessment and management is required (Morrell et al 1998; Simon et al 1998). Research using non-randomised comparison groups or pre- and post-test designs has shown that community nurses' knowledge of leg ulcer management is often inadequate, but that knowledge can be improved by provision of training (Dealey, in press; Luker & Kenrick 1995). There is also some evidence to suggest that information packs and videos are a valuable adjunct to study days (Nelson & Jones 1997). However, there is little research on the impact of different training programmes on patient outcomes and the long-term impact on nursing knowledge. Hence, a specific training approach is not recommended.

Strength of evidence (III)

Most existing research in this area is presented within the context of a poorly reported audit study, utilizing one-sample, before-after designs and often fail to describe in adequate detail the education programme or baseline skill mix of the participants. However, there is some evidence from pre- and post-test analysis of non-randomized comparison groups that knowledge of leg ulcer care is improved by training (two studies). There is a need for well-designed, prospective studies which evaluate the impact of well-described educational interventions on nursing practice and patient outcomes. In the absence of such research, this recommendation is based on consensus opinion.

5.0 Quality assurance

- 5.1 Systems should be put in place to monitor standards of leg ulcer care as measured by structure, process and outcome

Rationale

Measurement by structure (for example, the proportion of patients treated by appropriately trained staff); process (for example, the proportion of patients whose arterial status has been determined by ABPI measurement, and the proportion with uncomplicated venous ulcers receiving high compression therapy) and outcome (for example, the prevalence of active ulceration, proportion of patients healed, rates of healing and adverse outcomes due to incorrectly treated arterial disease or excessive compression) ensures that appropriate performance indicators are monitored. From the EHCBC Compression therapy for venous leg ulcers (NHSCRD 1997).

Concern was expressed by a consensus group member that for audit to be of benefit in leg ulcer care, a large number of variables (eg., healing rates, recurrence rates, time to complete healing, patient health status, patient-centred outcomes (such as an ulcer free leg), ulcer size etc. adjusted for case-mix, setting etc.) would need to be collected to assess whether meaningful change has taken place. Another comment was that many audits have revealed that patient outcomes were much poorer than staff expected, consequently, standards require continual monitoring.

Strength of evidence (III)

Much of the published audit-related research has used weak designs that have not sufficiently examined the impact of monitoring systems on patient outcomes. The recommendation is consensus based.

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