improving practice: improving care

clinical practice G U I D E L I N E S

The nursing management of patients with venous leg ulcers

Recommendations



clinical practice g u i d e l i n e s

The nursing management of patients with venous leg ulcers

Recommendations

Recommendations for assessment, compression therapy, cleansing, debridement, dressings, skin grafts and skin replacements, contact sensitivity, therapeutic ultrasound, laser, electrotherapy, topical negative pressure and pharmacological agents, training/education and quality assurance

Published by the Royal College of Nursing, 20 Cavendish Square, London, W1G 0RN

© 2006 Royal College of Nursing. All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means electronic, mechanical, photocopying, recording or otherwise, without prior permission of the Publishers or a licence permitting restricted copying issued by the Copyright Licensing Agency, 90 Tottenham Court Road, London W1T 4LP. This publication may not be lent, resold, hired out or otherwise disposed of by ways of trade in any form of binding or cover other than that in which it is published, without the prior consent of the Publishers.

September 2006

Publication code: 003 020

ISBN: 1-904114-22-9

Acknowledgements

Ian Bullock** Claire Collins** Nicky Cullum*

Yolanda Ferguson**

Will Gray**

Martin Henriksson*

Cynthia Iglesias*

E Andrea Nelson*

Emily Petherick*

First published 1998; updated 2005 and 2006.

First edition: RCN Institute, Centre for Evidence-Based Nursing, The University of York and the School of Nursing, Midwifery and Health Visiting, The University of Manchester.

Second edition: RCN Institute, Centre for Evidence Based Nursing, The University of York.

- * Centre for Evidence Based Nursing, Department of Health Sciences, The University of York, York, UK.
- ** Royal College of Nursing Institute, Radcliffe Infirmary, Woodstock Road, Oxford OX2 6HE. UK.

Contents

Notes for users of these guidelines		
Evidence base		
Updating the guideline Audit		
Prin	ciples of practice	3
1.0	The assessment of patients with leg ulcers	4
	Patient considerations	4
	Clinical history and inspection of the ulcer	6
	Clinical investigations	10
	Doppler measurement of ankle/brachial pressure index (ABPI)	11
	Ulcer size/measurement	12
	Referral criteria	13
2.0	Compression therapy	14
	Patient suitability for compression bandaging	14
	Compression versus no compression	14
	High compression versus low compression	15
	Elastomeric versus non-elastomeric multi-layer compression	15
	Multi-layer high compression versus short stretch bandages	15
	Comparisons between different elastomeric multi-layer high compression systems	15
	Inelastic compression versus compression hosiery	16
	Multi-layer versus single layer	16
	Four-layer versus other types of compression bandaging	16
	Intermittent pneumatic compression versus compression bandaging	17
	Intermittent pneumatic compression plus compression versus compression alone	17
3.0	Pain assessment and relief	19
4.0	Cleansing of the leg ulcer	20
5.0	Debridement	21
6.0	Dressings and topical agents	22
	Simple dressings versus simple dressings, in the presence of compression	22
	Foam, film or alginate (semi-occlusive)	

	dressings versus simple dressings, in the presence of compression	22
	Hydrocolloid (occlusive) dressings compared with foam, film or alginate (semi-occlusive) dressings, in the presence of compression	22
	Hydrocolloid (occlusive) dressings compared with simple low adherent dressings, in the presence of compression	22
	Hydrocolloid (occlusive) dressings compared with hydrocolloid (occlusive) dressings, in the presence of compression	22
	Hydrocolloid (occlusive) dressings compared with cadexomer iodine paste and paraffin gauze	23
	Comparisons between occlusive or semiocclusive dressings	23
	Antimicrobial agents versus placebo or standard care	23
	Topical agents (e.g. growth factors) compared with inert comparators	23
7.0	Contact sensitivity	25
8.0	Skin grafts and skin replacements	27
9.0	Topical negative pressure	28
10.0	Drug treatments	29
	Pentoxifylline	29
	Oral zinc	29
	Aspirin	30
11.0	Low level laser treatment	31
12.0	Electromagnetic therapy for treating venous leg ulcers	32
13.0	Electrical stimulation	33
14.0	Ultrasound therapy	34
15.0	Prevention of recurrence of ulceration	35
	Drug tariff recommendations for compression hosiery	35
16.0	Education and training for leg ulcer care	37
17.0	Quality assurance	38
18.0	References	39

Notes for users of these guidelines

Evidence base

The evidence base for the original recommendations came from the *Effective health care bulletin* on compression therapy for venous leg ulcers, NHS Centre for Research and Dissemination, 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.

The evidence base for the updated guideline came from systematic reviews and systematic literature searches to update the review evidence, as well as from clinical evidence.

This document contains recommendation statements that 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 that 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 original full guideline was completed in mid-1998 and this first update completed in 2006.

Resources permitting, it is envisaged that the guideline will be updated two to four yearly, and depending on the change in the evidence base. This guidance, which includes all the recommendations for practice, is supported by the full technical report that is currently being updated. Further information can be obtained by contacting the Quality Improvement Programme at qip.hq@rcn.org.uk

Audit

The Sentinel Audit Project, led by the RCN, developed and piloted an audit tool in 1999 to compliment this clinical practice guideline. The results showed an increase in concordance with the guideline recommendations, an increase in venous leg ulcers healed within 12 weeks and a 35 per cent decrease in costs per ulcer healed between first and second audits. With the benefit of Healthcare Commission funding, further work has been undertaken that builds on these previous findings, aiming to improve outcomes of care for people with venous leg ulcers by reducing variations in practice and to develop state of the art IT infrastructure to support this work and future national audits. By utilising a web-based data management strategy, independent of the IT infrastructure of individual NHS organisations, this approach enables a vast increase in data handling capacity, and moves away from the previous paperbased system, making results more immediately available.

The RCN Quality Improvement Hub houses a freely accessible patient/public area and a restricted access area for audit participants. It can be accessed at: www.rcn-audit.org.uk

- The patient/public area includes information on current audits, including published results. It also contains patient information leaflets that can be downloaded.
- The participants' zone of the site is strictly controlled and password protected. Only designated individuals from participating sites have access. In addition to housing the audit tool, this area also enables access to bespoke training materials on relevant aspects of good practice. There is also a discussion forum. This promotes networking and sharing between the participants, providing a mechanism to capture best practice and enabling the needs of participants for specific additional materials to be evaluated.

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 (Schiffer & Ullrich, 1997).

Notes for users of these guidelines

Decisions to adopt any particular recommendation must be made by the health care team in the light of available resources, local services, policies and protocols, the particular patient's circumstances and wishes, available personnel and equipment, clinical experience and skills of the practitioner, and knowledge of more recent research findings.

The reader is referred to the document *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. The technical report is available from RCN Direct by calling telephone 0845 772 6100 and quoting publication code 000 989.

Principles of practice

The principles outlined below describe the ideal context in which to implement the recommendations in this guideline. They reflect original research and development work previously produced by the RCN. They also enable clinicians using evidence-based guidance to contextualise and understand the importance of preparation and planning before using this evidence-based tool.

Person-centred care

- Patients and carers should be made aware of the guideline and its recommendations, and be referred to the patient and public zone on the Quality Improvement Hub.
- Patients and carers should be involved in shared decision-making about the management of leg ulcers.
- Health professionals are advised to respect and incorporate the knowledge and experience of people who have had, or have, a leg ulcer.
- Patients and carers should be informed about any potential risks, and/or complications of having leg ulcers.

A collaborative interdisciplinary approach to care

- All members of the interdisciplinary team should be aware of the guideline and all care should be documented in the patient's health care records.
- The approach to care should be interdisciplinary, involving all those needed in the management of leg ulcers.

Organisational issues

- There should be an integrated approach to the management of leg ulcers, with a clear strategy and policy supported by management.
- Care should be delivered in a context of continuous quality improvement, where improvements to care following guideline implementation are the subject of regular feedback and audit.
- Commitment to, and availability of, education and training are needed to ensure that all staff, regardless of profession, are given the opportunity to update their knowledge and are able to implement the guideline recommendations.
- The health care team should have undergone appropriate training and demonstrate competence in leg ulcer management.
- Staffing levels and skill mix should reflect the needs of patients, and are paramount to providing high-quality services for individuals with leg ulcers.
- Priority should be given to the provision and allocation of resources in the management of patients with leg ulcers.

Patient considerations

There is a growing body of research on the impact of leg ulcers on patients' quality of life (Chase et al., 2000; Cullum & Roe, 1995; Douglas, 2001; Flett et al., 1994; Franks et al., 1995; Hareendran et al., 2005; Hopkins, 2004; Jull et al., 2004; Lindholm et al., 1993; Phillips et al., 1994; Price & Harding, 1996; Rich & McLachlan, 2003; Walshe, 1995; Wissing et al., 2002). A study conducted by Husband (2001) found that pain was the key symptom of venous ulceration that led patients to seek medical consultation. Leg ulcer patients have much in common with patients with other chronic diseases. This may include social isolation, loss of income and reduced self-esteem. Although the considerations raised by these studies are not amenable to clinical practice recommendations, it is expected that the health professionals using this guideline are sensitive to these issues. Importantly, the practitioner should be aware the effective treatment (high compression therapy for venous ulcers resulting in improved healing rates) may help diminish those factors that affect quality of life (Cullum & Roe, 1995) and ensure that decisions regarding therapy are discussed with the patient.

Factors influencing patient concordance and acceptability of compression bandaging have been examined in a few studies (Edwards, 2003; Johnson, 1995; Jull et al., 2004; Moffatt, 2004; Samson & Showalter, 1996; Taylor, 1998; Travers et al., 1992). Patients' reasons for non-concordance with compression therapy include heat and discomfort; a perception that the dressing is more than the compression therapy; expense; and difficultly in applying compression stockings. However, there have been no studies of the extent to which patients may be able to participate in the management of their ulcers, or of the most effective method of maximising concordance with venous leg ulcer therapy. There have been only a few studies of patient acceptability of compression bandaging. Again, the practitioner should have an understanding of the factors that may hinder patient compliance with therapy.

In terms of patient information and education, although studies have found that patients may not remember or know the cause of their leg ulcer (Douglas, 2001; Edwards et al., 2002; Hamer et al., 1994) and that patients lack knowledge of wound care for venous therapy, particularly compression therapy (Chase et al., 1997; Edwards, 2003), further research is needed to develop and evaluate psychosocial (including educational) interventions for leg ulcer patients (Hamer et al., 1994). Rich & McLachlan (2003) suggested setting up specific support networks for venous ulcer patients. One study reported limited value of information leaflets for patients with leg ulcers (Clarke Moloney, 2005). The study had a small sample size and therefore the results need to be interpreted with caution. Further research is required to fully understand the value of information for patients and carers. In the absence of such research, it was suggested by consensus group members that education of the patient by the health professional delivering their care should not be 'one-off'. Instead, patients should be offered ongoing education about leg ulcer disease and rationale for treatment, appropriate to their treatment stage.

Who should assess the patient?

1.1 The assessment and clinical investigation of leg ulcer patients should be undertaken by health care professionals 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; Moffatt & Franks, 2004; Roe et al., 1994) and that there is wide variation in the nursing management, including the assessment, of people with leg ulcers in areas of the UK (Elliot et al., 1996; Moffatt & Franks, 2004; Roe et al., 1993). One audit found that more than 80 per cent 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). Another study (Elliot et al., 1996) found that 50 per cent of district nurses used visual assessment alone to diagnose a leg ulcer. Insufficient training, as well as lack of equipment and referral criteria (Griffey, 1992; Stevens et al., 1997; Schofield et al., 2000) may also contribute to variation in assessment practices by nurses. One study examined the characteristics of the caseload and the attitudes and training of practice nurses in relation to leg ulcer management in one region as a precursor to guideline implementation (Schofield et al., 2000). The nurses expressed lack of knowledge, equipment

and confidence in relation to assessing patients using Doppler and applying compression bandaging. The majority of practice nurses managing leg ulcers received two hours training or less in Doppler ABPI measurement and compression bandaging; a few nurses received between a half and full day of training. Typically, training was provided by specialist nurses and company representatives within the practice, since the practice nurses complained that GPs were reluctant to release them from clinical duties to attend educationally approved leg ulcer training (Schofield et al., 2000).

Following the publication of the first edition of these guidelines, the RCN led a two-year project involving facilitated development of audit protocols based on the guideline content (Morrell et al., 2001). Using a pre/post study design, an improvement in compliance with audit recommendations was observed over the two audit periods. These recommendations included assessment of patients using Doppler ABPI and undertaking pain assessment, as well as use of compression.

There is no national guidance on the matter of what constitutes adequate training levels for nurses involved in leg ulcer care. Consequently, this recommendation uses the term 'health care professional' in reference to a nurse or other practitioner. 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 and community nurse (including practice nurse) training.

Strength of the clinical evidence (III)

The recommendation is consensus rather than evidence-based. No studies were found that assessed the reliability, validity or accuracy of nursing assessments, nor trials that compared general practitioner (or other health professional) and nurse assessment of patients with leg ulcers. Surveys of knowledge and reported practice were of variable quality, but gave fairly consistent results.

No eligible economic research was identified.

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 assessment 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 even inappropriate treatment (Cornwall et al., 1986; Elliott et al., 1996; Roe et al., 1993; Stevens et al., 1997). Serious damage to the limb can occur if arterial insufficiency in the leg is not properly diagnosed and the leg receives compression (Callam et al., 1987a). Therefore it is advisable that assessment of the patient and diagnosis of the cause of ulceration 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 clinical evidence (III)

This recommendation is consensus-based, as there are no studies that compare the outcomes of patients given or not given the benefit of a full clinical history and physical examination, nor of different approaches to examination.

No eligible economic evidence was identified.

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

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

- family history of non-venous ulcers
- history of:
 - heart disease
 - stroke
 - transient ischaemic attack
 - diabetes mellitus
 - peripheral vascular disease/intermittent claudication
 - cigarette smoking
 - rheumatoid arthritis.

Patients with mixed venous/arterial ulcers may present with a combination of the features described above.

Rationale

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

Strength of clinical evidence (III)

Although epidemiological studies have varied in the methods employed and populations examined,

there is some consensus regarding possible risk factors and diagnostic criteria for venous, nonvenous and mixed aetiology ulcers (Alexander House Group, 1992, Kurz et al., 1999). Well designed, prospective, epidemiological studies are needed to better determine risk factors for venous disease generally and ulcers specifically, so that prevention strategies can be developed (Cullum & Roe, 1995).

No eligible economic evidence was identified.

1.4 The person conducting the assessment should be aware that leg ulcers may be due wholly or in part to arterial disease, diabetes, rheumatoid arthritis and malignancy. Practitioners should record any unusual appearance and if there is any doubt or concern refer the patient for specialist medical assessment.

Rationale

Arterial ulcers

Arterial leg ulcers are caused by an insufficient arterial blood supply to the lower limb, resulting in ischaemia and tissue 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. People with rheumatoid arthritis might also develop ulcers associated with venous disease.

Ulcers due to diabetes

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 patient with diabetes 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 people with diabetes and leg ulcers should be referred to a diabetes specialist, 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 clinical evidence (III)

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

- 1.5 The following factors have been shown to be independently associated with failure of venous leg ulcers to heal within 24 weeks:
 - initial wound area
 - wound duration at presentation
 - history of venous ligation/venous stripping
 - history of knee or hip replacement
 - ankle: brachial pressure index (ABPI) of <0.8
 - >50 per cent of wound surface covered in fibrin at baseline.

Information relating to these factors and others (for example, those below) should be recorded in a structured format:

- 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.

Margolis et al. (2000) have analysed cohorts of patients with venous leg ulcers, treated with compression bandaging and shown that:

- initial wound area
- wound duration at presentation
- history of venous ligation /venous stripping
- history of knee or hip replacement
- ankle: brachial pressure index (ABPI) of <0.8
- >50 per cent of wound surface covered in fibrin at baseline

are all independently associated with failure of the

ulcer to heal within 24 weeks. This group developed a prediction rule from a cohort of 260 patients treated with compression and validated it in an independent cohort of 219 patients. This simple rule (1 point if ulcer duration greater than 6 months; 1 point if baseline ulcer area greater than 5cm²; score of 0 predicted healing; score of 2 predicted failure to heal) discriminated between ulcers healed or not healed at 24 weeks in 87 per cent of cases (Margolis et al., 2000). More recent work showed that it is the percentage change in ulcer area during the first period of treatment that distinguishes between healers and non-healers at 24 weeks. A wound whose area increases by 3 per cent or more over the first four weeks of treatment has a 68 per cent probability of failing to heal by 24 weeks. Conversely, an ulcer whose area increases by less than 3 per cent in the first four weeks has a 75 per cent chance of healing (Kantor & Margolis, 2000).

Strength of clinical evidence (II)

Several of the factors listed were identified from good quality prospective epidemiological studies. However, no research was identified that examined whether a structured approach for recording ulcer history results in improved management and patient outcomes.

No eligible economic evidence was identified.

Clinical bractice curpe

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-recognised signs of either chronic venous insufficiency or arterial disease, as indicated. However, these signs do not construct a diagnosis per se (refer to recommendations 1.10; 1.11)

Strength of clinical evidence (III)

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

No eligible economic evidence was identified.

Rationale

The condition of the ulcer and surrounding skin influences skin care and provides 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 moisturised. If the ulcer is odorous and sloughy, frequent dressing changes may be considered. In addition, fragile, oedematous skin will need careful application of compression bandages (although, not necessarily decreased compression).

Strength of clinical 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 Measurement of blood pressure, weight, urinalysis and Doppler measurement of ABPI should be recorded on first presentation.

Rationale

Blood pressure is taken to monitor cardiovascular disease, weight is measured at baseline to monitor weight loss if the patient is obese, and urinalysis is undertaken to detect any 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 insufficiency in the ulcerated limb (refer to recommendations 1.10, 1.11).

Strength of clinical evidence (III)

This recommendation is based on consensus of opinion.

No eligible economic evidence was identified.

- 1.9 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
 - foul odour.

Rationale

Chronic leg ulcers are usually colonized by microorganisms, but how these affect healing is unclear (Skene et al., 1992; Trengove et al., 1996). The influence of bacteria on ulcer healing has been examined in a number of studies (Eriksson, 1984; Eriksson et al., 1984; Skene et al., 1992; Trengove et al., 1996) and most studies in humans with chronic wounds have not demonstrated an association between bacteria and impaired healing. However, most of the research has been in small groups of patients and more research is needed.

Strength of clinical evidence (II)

One randomised controlled trial (RCT) and one prospective study.

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. Compression applied to legs with arterial insufficiency could result in pressure damage, limb ischaemia and even amputation. Absent or very weak foot pulses indicate poor peripheral blood supply and are regarded as signs of arterial disease. However, research 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., 1987a; Magee et al., 1992; Moffatt et al., 1994). Two large studies have shown that 67 per cent and 37 per cent respectively 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., 1987a; Moffatt and O'Hare, 1995). In one survey, 32 per cent of surgeons reported at least one instance of necrosis induced or aggravated by compression bandages or stockings (Callam et al., 1987b).

The importance of making an objective assessment of the leg 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 does, co-exist in the same individual (Callam et al., 1987b; Scriven et al., 1997; Sindrup et al., 1987) and Doppler ultrasound can aid diagnosis in such cases.

Strength of clinical evidence (I)

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

No eligible economic evidence was identified.

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., 1987a; 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 emphasise 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., 1987a; Corson et al., 1986; Dealey, 1995) and such patients should be referred for specialist assessment (refer to recommendation 1.4).

Strength of clinical evidence (II)

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

- 1.11 Doppler ultrasound to measure ABPI should also be conducted when:
 - an ulcer is deteriorating
 - an ulcer is not fully healed by 12 weeks
 - patients present with ulcer recurrence
 - before recommencing compression therapy
 - patient is to commence 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
 - ongoing assessment (three monthly).

Rationale

Arterial disease may develop in patients with venous disease (Callam et al., 1987b; Scriven et al., 1997; Sindrup et al., 1987) and significant reductions in ABPI can occur over relatively short periods of time (three -12 months) (Simon et al., 1994). Estimates suggest that 13-29 per cent of legs with venous ulcers also have detectable arterial insufficiency (Nelzen et al., 1994; Scriven et al., 1997; Simon et al., 1994). ABPI will also reduce with age. The regularity with which Doppler studies are repeated as part of ongoing assessment may be determined by local protocols.

Strength of clinical evidence (II)

One cohort and two cross-sectional studies. No eligible economic evidence was identified.

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

A variety of methods of wound measurement are described in the literature; these 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. Wound healing progress can be monitored cheaply and easily by observing serial tracings of wound area; ideally, by the same practitioner each time. However, practitioners should be mindful that the general condition of the wound should also be regularly monitored (refer to recommendation 1.7).

Strength of clinical evidence (III)

Differences (in terms of design, setting, personnel and statistical approaches) between the several cross sectional studies identified, prevent adequate comparison of the reliability of measurements obtained with the various wound measurement procedures. There was consensus that sophisticated measuring devices are unnecessary in everyday clinical practice.

Referral criteria

- 1.13 Specialist medical referral may be appropriate for:
 - treatment of underlying medical problems
 - ulcers of non-venous aetiology (rheumatoid; diabetes-related; 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 that shows that patients are not always referred appropriately for specialist assessment. One study of district nurse records indicated that only 35 per cent of leg ulcer patients were referred at any stage for a specialist assessment and 7 per cent had been examined by a vascular surgeon (Lees & Lambert, 1992). However, most of the nurses in this study 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 diabetes-related ulcers for specialist advice (Roe et al., 1993). Local protocols will dictate the types of patients to be referred to vascular surgeons, dermatologists, rheumatologists, diabetes specialists or other medical specialists. Similarly, local protocols will determine which patients should be referred for specialist nursing assessment.

Strength of clinical evidence (III)

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. The effectiveness of venous surgery and other specialist medical interventions is beyond the scope of this guideline.

This guideline does not address compression bandaging in patients with mixed aetiology ulcers. Such patients are likely to require a reduced level of compression, since they have a degree of arterial insufficiency. The application of compression in these patients requires expertise and the patients must be closely monitored.

- 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 greater than 0.8) in all settings.
- 2.2 There is currently insufficient evidence to support the routine use of intermittent pneumatic compression, either as a replacement or an adjunct to compression bandaging.
 - * If ulcers are large and heavily exuding, more frequent dressing changes will be required.

Patient suitability for compression bandaging

Rationale

Patients with arterial insufficiency in their leg(s) are not suitable for high compression therapy as compression may decrease perfusion and worsen ischaemia. People with venous ulcers usually have an ABPI equal to or greater than 0.8. Arterial insufficiency is suggested by an APBI of less than 0.8 (a reduced APBI does not necessarily diagnose an ulcer as 'arterial' in origin); mixed venous/arterial aetiology ulcers may have an ABPI of 0.6 to 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 - and in one study compression was only reduced for patients with an ABPI of 0.5 or less (Moffatt & O'Hare, 1995). However, the use of compression for 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, appropriate choice of compression systems and their meticulous application cannot be over stressed (Cullum, 1994).

Strength of clinical evidence (III)

This recommendation is mainly derived from pathophysiological principles, consensus views and two studies (Callam et al., 1987a; Moffatt et al., 1992).

Compression versus no compression

Rationale

Two systematic reviews of randomised trials and one subsequent trial conclude that more people heal their ulcers under compression than without compression. The first review (Cullum et al., 2001) - search date 2000, six randomised controlled trials (RCTs), 260 people - compared all forms of compression with no compression. The second systematic review (Alberta Heritage for Medical Research, 2001) - search date 2001, two RCTs, 263 people - studied four-layer elastomeric high compression versus no compression and included one additional trial. The conclusion of these reviews was that compression (for example, elastomeric multi-layer high compression bandages, short stretch bandages, double layer bandages, compression hosiery, or Unna's boot) healed more venous leg ulcers than no compression (for example, dressing alone, non-compressive, palliative regimens). The subsequent trial (200 people) also found that compression (elastomeric multi-layer high compression) healed more ulcers than non-compressive treatments (O'Brien et al., 2003). The RCTs were heterogeneous, using different forms of compression in different settings and populations, and as such were not combined in a meta-analysis. However the results of individual trials consistently favour the use of compression.

Strength of clinical evidence (I)

This recommendation is based on two systematic reviews of RCTs and a subsequent RCT.

High compression versus low compression

Rationale

The systematic review (Cullum et al., 2001) identified three RCTs (273 patients) that compared elastic, three layer, high compression bandaging – two using Tensopress and one Setopress as a component – with low compression, using Elastocrepe (Callam et al., 1992; Gould et al., 1993; Northeast et al., 1990). More patients were healed at 12-15 weeks with high compression (RR 1.54, 95% CI 1.19 – 1.99).

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 clinical evidence (I)

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

Elastomeric versus non-elastomeric multilayer compression

Rationale

Two systematic reviews (Cullum et al., 2001; Alberta Heritage for Medical Research, 2001) identified three RCTs (273 people), and one subsequent RCT was identified of 112 people (Meyer et al., 2002), which compared elastomeric, multi-layer high compression bandages with nonelastomeric multi-layer compression. Metaanalysis of the first three RCTs found a statistically significant increase in healing with elastomeric compression bandaging (RR 1.54, 95% CI 1.19 to 2.0; NNT 5, 95% CI 3 to 12), with treatment times in these trials ranging from 12 to 15 weeks. Meyer et al., (2002) reported no significant difference in healing rates between elastomeric and nonelastomeric layered compression regimes at 26 weeks (healing 58 per cent and 62 per cent of ulcers respectively).

Strength of clinical evidence (I)

This recommendation is based on four RCTs.

Multi-layer high compression versus short stretch bandages

Rationale

One systematic review (Cullum et al., 2001) identified four small RCTs (search date 2000, 167 people), and we identified three subsequent RCTs (588 people) (Partsch et al., 2001; Ukat et al., 2003; Iglesias et al., 2004). The systematic review found no significant difference in healing rates between multi-layer high compression and short stretch bandages (RR 1.10, 95% CI 0.78 to 1.55). Partsch et al., (2001) (112 people) found no difference in healing rates between four-layer and short stretch bandages (62 per cent and 73 per cent healed at 16 weeks respectively). Ukat et al., (2003) (89 people) reported higher healing rates with four-layer than short stretch (30 per cent and 22 per cent of ulcers healed at 12 weeks respectively). The largest trial comparing four-layer and short stretch bandages (Iglesias et al., 2004) (387 people) reported a statistically significant increase in ulcer healing associated with the four-layer bandage (hazard ratio for healing with short stretch compared with four-layer 0.72, 95% CI 0.58 - 0.91). However, overall there is no clear evidence of a difference in healing rates between four-layer and short stretch bandages. Further, it is difficult to pool the data and draw robust conclusions, given that most of the trialists have only reported the proportion of ulcers healed at various arbitrary time points and there is no survival data.

Strength of clinical evidence (I)

This recommendation is based on seven RCTs.

Comparisons between different elastomeric multi-layer high compression systems

Rationale

One systematic review (Cullum et al., 2001) identified three RCTs (285 people) comparing different elastomeric multi-layered bandage regimens with four-layer bandage regimens, and two subsequent RCTs have been identified (Vowden et al., 2000, 149 people; Meyer et al., 2000, 133 people). The original meta-analysis (Cullum et al., 2001) found no difference in the number of people healed in four-layer versus other high compression

multi-layer regimens (RR 1.02, 95% CI 0.87 to 1.18). Meyer et al., (2000) found that ulcers healed more quickly (median 12 weeks versus 16 weeks) with three-layer paste than a four-layer bandage (p=0.040). Vowden et al., (2000) found no difference in healing rates between the original four-layer system and two commercial 'kits' making a four-layer system (proportion of ulcers healed at 20 weeks – 87 per cent, 84 per cent and 83 per cent). There is little evidence that any particular multi-layer high compression regimen is more effective than any other.

Strength of clinical evidence (I)

This recommendation is based on seven RCTs.

Inelastic compression versus compression hosiery

Rationale

One RCT (Koksal & Bozkurt, 2003, 60 people) compared the use of hydrocolloid dressing and medical compression stocking (class 2) with Unna's boot for the treatment of venous leg ulcers. No differences were observed between the two groups in terms of proportion of ulcers healed, nor in weekly mean wound surface area reduction.

Strength of clinical evidence (II)

This recommendation is based on one small RCT

Multi-layer versus single layer

Rationale

A systematic review identified four RCTs (280 people) that compared multi-layer, high compression with a single layer of bandage (Cullum et al., 2001). A meta-analysis of these trials identified a statistically significant increase in the proportion of people whose reference ulcer healed with multi-layer compression compared with single layer bandages (RR 1.41, 95% CI 1.12 to 1.77; NNT for variable periods of treatment 6, 95% CI 4 to 18).

Strength of clinical evidence (I)

This recommendation is based on four RCTs.

Four-layer versus other types of compression bandaging

Rationale

Four-layer bandaging compared with short stretch is covered above. The four-layer bandage has also been compared with Unna's boots in four 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, it is not possible to exclude the possibility of clinically important differences in effectiveness. A trial comparing four-layer with three-layer paste compression bandage (133 patients) found ulcers healed more quickly with the three-layer bandage than the four-layer bandage (median time to healing 12 weeks for three-layer and 16 weeks for four-layer, p=0.040) (Meyer et al., 2003).

When clinics have specifically promoted the delivery of four-layer high compression treatment, their healing rates have improved, compared with results for the usual care given by community nurses (Morrell et al., 1998a and b; Taylor et al., 1998). However, the two 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., 1998a & b; Taylor et al., 1998).

Strength of clinical evidence (I)

Currently, there is no strong evidence of a difference in healing rates between the four-layer bandage and short stretch bandages, Unna's boot or three-layer bandages (five RCTs of bandages and two RCTs of four-layer bandaging as one component of a complex intervention).

2.3 Any graduated multi-layer high compression system that can remain inplace for up to a week is likely to be cost-effective.

Rationale

Evidence from four randomised controlled studies (Ukat et al., 2003; Moffatt et al., 2003; O'Brien et al., 2003; Iglesias et al., 2004) and one observational study (Torra i Bou et al., 2003) suggested that, on average, four-layer compression systems result in a slightly higher proportion of patients healed. There is also a reduction in number of nurse visits required for the treatment of venous leg ulcer patients, compared with alternative high compression systems. The cost effectiveness of the four-layer system, compared with alternative high compression systems, has been calculated on the basis of reductions in nursing time associated with its use. While the four-layer system requires one weekly bandage change on average, alternative compression systems have been reported to require replacing more frequently (1.25 times to four times per week) (Torra i Bou et al., 2003; Ukat et al., 2003; Moffatt et al., 2003; O'Brien et al., 2003; Iglesias et al., 2004).

Similar clinical effectiveness to that of the fourlayer system has been associated with other types of multi-layer high compression systems, such as the short stretch, and two-layer bandages. While on average the proportion of ulcers fully healed with the four-layer system at 12 weeks has been approximately 9 per cent higher than that associated with alternative high compression systems, the difference is not statistically significant (Iglesias et al., 2004; Moffatt et al., 2003; Ukat et al., 2003). In settings where the fourlayer bandage is not current practice, an audit of the frequency of bandage changes is recommended to investigate the cost-effectiveness of the service provided.

Evidence from three cost consequence studies (Bosanquet et al., 1993; Kerstein and Gahtan, 2000; Vickery et al., 2000) and one cost effectiveness study (Morrell et al., 1998a) suggests that managing patients with venous leg ulcers in coordinated community leg ulcer clinics, using multilayer high compression systems, is likely to be a cost effective strategy, if not cost saving.

Strength of the economic evidence (II)

This recommendation is based on nine studies: seven partial (Ukat et al., 2003; Kikta et al., 1988; O'Brien et al., 2003; Moffatt et al., 2003; Torra i Bou et al., 2003; Carr et al., 1998; Taylor et al., 1998) and two full economic evaluations (Iglesias et al., 2004; Schonfeld et al., 2000). Six trial-based partial economic evaluations compared the fourlayer compression system to a number of alternative multi-layer high compression systems i.e. short stretch bandage, two layer system - and usual care with and without compression (Carr et al., 1998; Ukat et al., 2003; Moffatt et al., 2003; O'Brien et al., 2003; Iglesias et al., 2004; Taylor et al., 1998). One study compared four-layer bandage with crepe bandage (Torra i Bou et al., 2003); one compared Unna's boot with a human skin construct (Schonfeld et al., 2000); and finally, one study compared Unna's boot with a hydrogel (Kikta et al., 1988).

The economic evidence is based on four studies: three partial and one full economic evaluation.

Intermittent pneumatic compression versus compression bandaging

Rationale

Two systematic reviews (Mani et al., 2001; Berliner et al., 2003; search dates 2001) were located that each found one RCT (16 people). The RCT found no significant difference between intermittent pneumatic compression and compression bandaging in the proportion of ulcers healed over two-three months.

Strength of clinical evidence (II)

Based on one small RCT.

No eligible economic evidence was identified.

Intermittent pneumatic compression plus compression versus compression alone.

Rationale

Two systematic reviews (Mani et al., 2001; Berliner et al., 2003; search date 2001) each identified three RCTs (115 people). The first RCT (45 people) found that intermittent pneumatic compression (IPC), plus

graduated compression stockings, significantly increased the proportion of people with healed ulcers at three months, compared with graduated compression stockings alone (48 per cent for IPC compared with 4 per cent without IPC; RR 11.4, 95% CI 1.6 to 82). The second RCT (53 people) found no significant difference between intermittent pneumatic compression plus elastic stockings (71 per cent healed) and Unna's boot (75 per cent healed) in the proportion of people healed at six months (RR 0.95, 95% CI 0.67 to 1.34). The third RCT (22 people) also found no significant difference in healing at six months between intermittent pneumatic compression plus Unna's boot (100 per cent healed) and Unna's boot alone (80 per cent healed); RR 1.25, 95% CI 0.92 to 1.70 (Mani et al., 2001).

Strength of clinical evidence (II)

Based on three RCTs.

2.4 The compression system should be applied by a trained practitioner. However the level of training required, and the best method of training is unclear.

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 had not been properly trained in the application of compression bandages. Research has shown that, for example, practice nurses managing people with leg ulcers typically receive only two hours training or less on the assessment and management of people with leg ulcers (Schofield et al., 2000).

Inexperienced nurses or those without additional training in compression bandaging may apply bandages at inappropriate and widely varying pressures (Logan et al., 1992; Nelson et al., 1995a; Stockport et al., 1997; Feben, 2003). 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 multi-layer 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 bandaging skills are maintained over time. It is unclear 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. Feben (2003) completed a systematic review examining the effectiveness of training in compression bandaging techniques. Three studies (uncontrolled before and after studies involving small numbers of nurses) met the inclusion criteria. The nurses in the studies varied in terms of previous experience, the time period over which the training was given, the type of bandaging used and the follow-up period also varied. All studies showed an improvement both immediately after training and weeks after training. One study followed nurses up to six to ten weeks and observed only a marginal benefit at this time. The authors of this study concluded that there is a need to assess the skill level of current practitioners to provide training to those with inadequate technique, and to assess the effect of that training over the long term (Feben, 2003).

Strength of clinical evidence (II)

There is some research evidence supporting the recommendation, however there are no RCTs evaluating the impact of training programmes on practice and patient outcomes. 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.

3.0 Pain assessment and relief

- 3.1 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.
- 3.2 EMLA cream is an effective treatment for leg ulcer pain due to procedures such as debridement.

Rationale

A significant proportion of patients with venous ulcers report moderate to severe pain (Cullum & Roe 1995; Dunn et al., 1997; Hamer et al., 1994; Hofman et al., 1997; Stevens et al., 1997; Walshe, 1995). Yet one survey found that 55 per cent 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 specialised 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) or even exacerbate it.

Fifty per cent of patients with purely venous actiology who reported severe pain were taking either mild analgesia or none at all (Hofman et al., 1997). A systematic review (Briggs & Nelson 2003; search date 2002) found no trials evaluating interventions for persistent pain in venous leg ulcer patients. However they identified six RCTs (317 people) comparing a eutectic mixture of local anaesthetic (EMLA cream) with placebo for pain during debridement. Meta-analysis showed that EMLA cream was associated with an average reduction in pain scores (measured on a 100mm scale) of 20.6mm (95% C.I. 29.11-12.19). Only one of these trials measured healing as an outcome and found no difference in the numbers healed at the end of the study period.

Analgesics containing opioids may be necessary in some patients.

Strength of clinical evidence (II)

Although the research is quite heterogeneous, the results consistently report that patients with venous leg ulcers may experience considerable pain. There is also some evidence that pain relief may occur 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. One systematic review and meta-analysis of six RCTs concluded that EMLA cream is effective in reducing pain during debridement, however no trials were found of interventions for persistent pain from leg ulcers.

4.0 Cleansing of the leg ulcer

- 4.1 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

Wounds and skin are colonised with bacteria and currently there is a lack of evidence that the presence of colonising bacteria impedes healing.

There is no evidence that antiseptics confer any benefit and some evidence from studies in animals and cell culture suggests that antiseptics may be harmful. A systematic review of the effects of antimicrobials, including topical antiseptics, on the healing of chronic wounds was conducted by O'Meara et al., (2000; search date January 2000). The review identified no RCTs of antiseptic wound cleansers for venous leg ulcers.

A second systematic review looked at the effects of using water as a wound cleanser (Fernandez et al., 2001; search date May 2001). The review identified six RCTs (1864 participants). Three trials compared rates of infection in wounds cleansed with water and normal saline (two of which evaluated tap water), two compared cleansing with no cleansing and one compared cleansing with procaine spirit and water. There was no evidence of a difference in infection or healing rates as a result of using distilled, boiled or tap water as a cleanser.

The purpose of the dressing technique is not to remove bacteria but rather to avoid cross-infection with sources of contamination, for example, 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).

Strength of clinical evidence (II)

There are no trials comparing aseptic technique with clean technique in chronic wounds, including leg ulcers. Two systematic reviews have identified some RCTs but there is a lack of evidence for or against cleansing leg ulcers versus not cleansing them; cleansing with tap water versus cleansing with sterile saline or water; and cleansing with antiseptics.

5.0 Debridement

5.1 Removal of necrotic and devitalised tissue can be achieved through mechanical, autolytic, chemical, biosurgical or enzymatic debridement, however the impact of active debridement techniques on healing times is unknown.

Rationale

A systematic review (Bradley et al., 1999; search date October 1997) concluded that there have been no trials which measure the impact of debridement on the time wounds take to heal. The review concluded that there was insufficient evidence to conclude that any one debriding agent is more effective at debridement than another. Three subsequent RCTs have been identified. One RCT (Ortonne et al., 1996) (50 people) examined the use of hyaluronic acid gauze pad, compared to dextranomer paste applied daily for 21 days. Patients who had the hyaluronic gauze pad had a significant reduction in ulcer area, compared with the group receiving dextranomer paste. The second RCT (Nowak et al., 1996) (31 people) compared the effectiveness of a hydrogel with gauze, in terms of debridement of necrotic venous ulcers with low to medium exudate levels. This study found no difference between the two groups for the number of patients achieving successful debridement by 21 days. The third RCT (Wayman et al., 2000) (12 people) compared larval therapy (also known as 'biosurgery') with hydrogel for the debridement of sloughy venous ulcers. Whilst larval therapy was significantly more effective at debriding the ulcers in this trial (and was associated with lower costs), the impact on time to ulcer healing is not known.

However, it is acknowledged 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 per cent povidone iodine, 0.25 per cent acetic acid, 3 per cent hydrogen peroxide and 0.5 per cent hypochlorite have been shown to damage cells in vitro (Lineweaver 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 with a variety of standard treatments, usually involving saline or antiseptic-soaked gauze, and may facilitate healing compared with these alternatives.

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 clinical and economic evidence (III)

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

There is no evidence from RCTs randomising between debridement and no debridement that ulcer debridement speeds ulcer healing.

There is currently insufficient evidence to recommend one debriding agent over another.

Chemical debriding agents are harmful to cells in vitro, but their effect on wound healing in vivo is not known.

6.0 Dressings and topical agents

6.1 Dressings must be simple, low adherent, low cost and acceptable to the patient. 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. For those patients not requiring frequent bandage re-application, the cost effectiveness of leg ulcer dressings will be determined by their ability to remain in situ for up to a week.

Rationale

A systematic review (Bradley et al., 1999; search date October 1997) identified 51 randomised trials of dressings and topical agents in patients with venous ulcers. It concluded there was insufficient evidence to promote the use of any particular dressing. Since the completion of the review, a further 13 trials have been identified and these are summarised below.

Strength of the clinical evidence (I)

64 RCTs comparing different dressings and topical agents.

Simple dressings versus simple dressings, in the presence of compression

Two RCTs were identified that examined the use of different types of simple dressings in the presence of compression (Andersen et al., 2002; Vin et al., 2002). Neither of these studies found any difference in the proportion of healed patients at the completion of the study, with more than a third of patients in each group healing regardless of treatment method.

Foam, film or alginate (semi-occlusive) dressings versus simple dressings, in the presence of compression

The systematic review (Bradley et al., 1999; search date October 1997) found five RCTs comparing semi-occlusive dressings (foam, film, alginates) with simple dressings (such as paraffin-tulle or knitted viscose dressings). Two comparisons of foam dressings with simple dressings; two of film dressings with simple dressings; and one comparing an alginate with a simple dressing found no evidence of benefit. However, the RCTs were too small (10-132 people, median 60) to detect anything but a very large difference in effectiveness.

Hydrocolloid (occlusive) dressings compared with foam, film or alginate (semi-occlusive) dressings, in the presence of compression

Two RCTs compared hydrocolloid dressings with foam, film or alginate dressings. One RCT (Schulze et al., 2001) (113 people) compared hydropolymer dressing with alginate and film or alginate and swabs all used in the presence of compression found no difference in the mean rate of ulcer reduction per day. Complete ulcer healing was not an outcome of this study. The second RCT (Thomas et al., 1997) compared the use of hydrocolloid dressings with hydropolymer (foam) dressings, both in the presence of compression. The proportion of patients healed in both groups was similar, with 38 per cent in the hydrocolloid group and 34 per cent in the hydropolymer group. No further analysis was performed in this study.

Hydrocolloid (occlusive) dressings compared with simple low adherent dressings, in the presence of compression

We found one systematic review (search date 1997), which identified nine RCTs comparing hydrocolloid dressings versus simple dressings in the presence of compression (Bradley et al., 1999). Within the review, a pooled analysis of seven RCTs (714 people) found no evidence of benefit.

Hydrocolloid (occlusive) dressings compared with hydrocolloid (occlusive) dressings, in the presence of compression

We found two RCTs that compared various hydrocolloid dressings in the presence of compression. Limova & Troyer-Caudle (2002)

6.0 Dressings and topical agents

compared the use of Tegasorb with Duoderm CGF plus medicopaste, both used in conjunction with compression therapy. This study found a higher proportion of patients in the Tegasorb group was able to achieve wound closure than in the Duoderm group (59% vs. 15%, p=0.03). The second trial (Charles et al., 2002) compared the use of three different hydrocolloid dressings (Comfeel, Cutinova and Granuflex) in the presence of compression. No differences were observed between the groups with respect to the percentage of the ulcer healed, with all three groups achieving at least a 54 per cent decrease in initial ulcer area (range 54.8-58.6%). Nor was any difference observed between the groups in the time to achieve complete healing (range 6-7.5 weeks).

Hydrocolloid (occlusive) dressings compared with cadexomer iodine paste and paraffin gauze.

Hannson (1998) compared the use of hydrocolloid dressings, cadexomer iodine paste and paraffin gauze dressing. No statistically significant differences were observed between the groups in terms of mean ulcer reduction at 12 weeks. Rates of ulcer healing or time to healing were not reported as outcomes in this study.

Comparisons between occlusive or semi-occlusive dressings

The systematic review (Bradley et al., 1999; search date 1997) identified 12 small RCTs comparing different occlusive or semi-occlusive dressings. The studies found failed to show significant differences between the treatments, or the data provided was insufficient to calculate any differences between the groups. One subsequent RCT was identified (Seely et al., 1999) that compared hydrocolloid to hydrocellular dressings. This did not find a significant difference in healing rates.

Antimicrobial agents versus placebo or standard care

One systematic review (O'Meara et al., 2000, search date 1997, 14 RCTs) compared antimicrobial agents with either placebo agents or standard care. The RCTs were small (25-153 people, median 56), of poor quality, and no firm conclusions could be drawn.

Topical agents (e.g. growth factors) compared with inert comparators

The systematic review (Bradley et al., 1999, search date 1997) identified 16 RCTs comparing topical agents (such as growth factors, cell suspensions, oxygen free-radical scavengers) with either placebo or standard care in the treatment of venous leg ulcers. There was insufficient evidence to recommend any particular topical agent. The studies were small (9-233 people, median 45) and heterogeneous; therefore, results could not be pooled. Five subsequent RCTs were identified, which are described below (Falanga et al., 1998; Gherardini et al., 1998; La Marc et al., 1999; Stacey et al., 2000 and Robson et al., 2001).

The first subsequent RCT (293 people) found that a cultured allogenic bilayer skin replacement significantly increased the proportion of ulcers completely healed at six months, compared with a non-adherent dressing (92/146 [63%] vs. 63/129 [49%]; RR 1.29, 95% CI 1.04 to 1.60; NNT for six months' treatment 7, 95% CI 4 to 41) (Falanga et al., 1998). The second subsequent RCT (66 people) compared calcitonin gene-related peptide plus vasoactive intestinal polypeptide, administered by iontophoresis, with placebo iontophoresis and found no significant difference in the proportion of people with healed ulcers after 12 weeks' treatment (11/33 [37%] vs. 6/33 [28%]; RR 1.83, 95% CI 0.77 to 4.38) (Gherardini et al., 1998). The third subsequent RCT (40 people) found no benefit associated with topically applied mesoglycan, a profibrinolytic agent (La Marc et al., 1999). A fourth RCT (86 people) found no difference in time to healing between topical autologous platelet lysate and placebo (Stacey et al., 2000). The fifth RCT (94 people) compared topically applied recombinant human keratinocyte growth factor 2 (Repifermin at doses of 20 or 60 \lg/cm^2) with placebo and found no significant difference in proportions of ulcers completely healed at 12 weeks (32% with 20lg/cm² dose, 38% with 60lg/cm² dose, 29% with placebo). Note that some of these may not be available in the UK.

6.0 Dressings and topical agents

Economic evidence – rationale

Whilst there is no strong trial evidence in favour of any particular dressing or topical agent, the cost effectiveness of one dressing over another is primarily based on the reduction in nursing time associated with its use compared to alternative dressings or topical agents. For example, the costeffectiveness of hydrocolloid dressings compared with saline gauze has been investigated in four economic evaluation studies. The evidence suggests hydrocolloid dressings are associated with fewer weekly dressing changes [range 1.5 to 2.3] than saline gauze [range 4 to 9.8] thus reducing treatment costs (Ohlsson et al., 1994; Capillas Perez et al., 2000; Meaume et al., 2002; Augustin et al., 1999). When compared with povidone iodine plus paraffin tulle, hydrocolloids were associated with fewer weekly changes in ulcers of diameter less than 6cm (one change per week), whilst patients with larger ulcers required approximately the same number of dressing changes per week in both dressing groups (approx 4.2 changes per week) (Smith et al., 1992).

In patients with moderate to heavily exuding ulcers, the use of hydrocolloids was associated with similar clinical effectiveness and costs as alginate dressing plus cadoxemer iodine (Hannson, 1998; Harding et al., 2001; Schulze et al., 2001).

In a comparison of a hydrocolloid with impregnated gauze and human skin construct, hydrocolloids were economically dominant, i.e. they were associated with lower costs and higher numbers of ulcers healed (Kerstein & Gahtan, 2000).

Strength of economic evidence (II)

The evidence for this recommendation is from nine studies: five partial and four full economic evaluations, reporting on the clinical effectiveness and cost effectiveness of different dressings available in the treatment of venous leg ulcers. Seven studies were trial-based and two were model-based economic evaluations.

7.0 Contact sensitivity

7.1 Health professionals should be aware that patients may become sensitised 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 per cent of patients previously patch tested had developed at least one new allergy at retesting two and eight years later.

Strength of clinical evidence (II)

One cohort study (Cameron, 1998).

No eligible economic evidence was identified.

7.2 Products that commonly cause skin sensitivity, such as those containing lanolin and topical antibiotics, should not be used on any leg ulcer patient.

Rationale

Patients with venous leg ulcers have high rates of sensitivity to many of the products commonly used in leg ulcer treatment (see Table 1). Frequency of contact sensitivity and the commonest sensitisers 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 (for example, paraffin based products), that there is no evidence that topical antibiotics aid healing, and that patients may develop a sensitivity, the safest course is to avoid these products wherever possible.

Strength of the clinical evidence (III)

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

No eligible economic evidence was identified.

7.3 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 clinical evidence (III)

The evidence supporting this recommendation is based on observation and clinical experience. There are no randomised trials evaluating the impact on ulcer healing of patch testing and avoidance policies.

7.0 Contact sensitivity

TABLE 1: COMMON ALLERGENS AND THEIR IMPORTANCE IN THE CARE OF VENOUS ULCERS

Name of allergen	Туре	Potential sources
Wool alcohols, Amerchol L-101	Lanolin	Bath additives, creams, emollients, barriers and some 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 cream	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 moisturisers.
Quinoline mix	Biocide	Antiseptic and antifungal creams and ointments.
Chlorhexidene	Biocide	Antiseptics and tulle dressing.
Tixocortal pivalate	Steroid	Steroid preparations, for example – hydrocortisone.
Fragrance mix/balsam of Peru	Perfume	Bath oils, over-the-counter preparations such as moisturisers and baby products.

8.0 Skin grafts and skin replacements

8.1 There is insufficient evidence that skin grafts (allografts or autografts) or skin replacements (artificial skin) hasten the healing of venous leg ulcers.

Rationale

One systematic review (Jones & Nelson, 2000; search date 1999) identified six RCTs (involving 197 people) that examined the effects of skin grafts (autografts or allografts) for venous leg ulcers. In five of the RCTs, people also received compression bandaging; two RCTs (98 people) evaluated split thickness autografts, and one RCT (seven people, 13 ulcers) compared tissue-engineered skin (artificial skin) with split thickness skin grafts. The results of these studies provided insufficient information to determine whether skin grafting increased the healing of venous ulcers (Jones & Nelson, 2000). A subsequent RCT (Krishnamoorthy et al., 2003) compared the safety and effectiveness of a range of different skin grafting regimens, used in the presence of compression bandaging, with compression therapy alone in 53 participants. This study found that at 12 weeks, complete healing of the ulcer was achieved in 15 per cent of those receiving compression alone, 7 per cent of those using a single application of Dermagraft and 38 per cent of those receiving multiple applications of Dermagraft. This difference was not statistically significant.

Strength of the clinical evidence (II)

Seven small RCTs; evidence inconclusive.

9.0 Topical negative pressure

9.1 There is no research evidence that the application of topical negative pressure speeds wound healing generally, or the healing of venous ulcers specifically.

Rationale

One systematic review (Evans & Land, 2001; search date 2000) identified two small RCTs involving 34 participants. One RCT included some people with venous leg ulcers, however people with venous leg ulcers were not the sole focus of either study. The review found no clear evidence of benefit of topical negative pressure, but the RCTs were too small to exclude a clinically important difference in outcomes.

Strength of the evidence (III)

Two small RCTs.

10.0 Drug treatments

Pentoxifylline

10.1 Pentoxifylline appears to be a costeffective adjunct to compression bandaging for treating venous ulcers, and may be considered for prescription in appropriate clinical circumstances. Pentoxifylline may also be effective for treating venous leg ulcers in the absence of compression, however there is a lower level of evidence.

Rationale

One systematic review (search date 2001, nine RCTs, 572 people) (Jull et al., 2002) and two subsequent RCTs (Belcaro et al., 2002; De Sanctis et al., 2002). The systematic review compared pentoxifylline (1200mg or 2400mg daily) versus placebo or versus other treatments, with or without compression (Jull et al., 2002). It found that, in the presence of compression, pentoxifylline significantly increased the proportion of people with healed ulcers over 8 to 24 weeks, compared with placebo (five RCTs: 155/243 [64%] vs. 96/204 [47%]; RR 1.30, 95% CI 1.10 to 1.54; NNT for six months' treatment 6, 95% CI 4 to 14). One RCT identified by the review found no evidence of benefit for pentoxifylline, compared with defibrotide, in people receiving compression (Jull et al., 2002). The two subsequent RCTs compared pentoxifylline (400mg three times daily) and placebo in people receiving compression (Belcaro et al., 2002; De Sanctis et al., 2002). The first RCT (172 people, 160 analysed) found that pentoxifylline for six months significantly increased rates of complete healing, compared with placebo (55/82 [67%] with pentoxifylline vs. 24/78 [30.7%] with placebo; P=0.02) (Belcaro et al., 2002). The second subsequent RCT (85 people, 80 analysed) found that pentoxifylline for 12 months significantly increased rates of complete healing, compared with placebo (complete healing: 36/41 [88%] with pentoxifylline vs. 17/39 [44%] with placebo; P=0.02) (De Sanctis et al., 2002).

One RCT (Nikolovska et al., 2002) was found that compared the effectiveness of pentoxifylline taken orally (400mg three times daily) and local therapy, compared to local therapy alone in 80 people. A statistically significant difference was observed between the groups at 24 weeks with 58 per cent of patients in the pentoxifylline group healed at 24 weeks, compared with 28 per cent receiving only local therapy (p=0.013).

An economic evaluation study (Iglesias et al., 2001) provided evidence of the cost-effectiveness of oral pentoxifylline in the treatment of venous leg ulcers. The analysis of the value for money of conducting further research to reduce the uncertainty associated with the cost-effectiveness of pentoxifylline study suggests further research will not be worthwhile. Given current information, pentoxifylline is associated with a high probability of being cost-effective.

Strength of the clinical evidence (I)

Twelve RCTs.

Strength of the economic evidence (III)

The evidence for this recommendation is based on one model-based, full economic evaluation study.

Oral zinc

10.3 There is no evidence that oral zinc supplementation improves the healing of venous leg ulcers.

Rationale

One systematic review (Wilkinson & Hawke, 1998) – search date 2001, six RCTs, 183 people – was found that compared daily doses of 440-660mg oral zinc sulphate versus placebo. The review did not find any evidence of benefit for oral zinc in terms of ulcer healing.

Strength of the clinical evidence (I)

Six RCTs.

10.0 Drug treatments

Aspirin

10.4 There is no evidence that aspirin increases the healing of venous leg ulcers.

Rationale

One small RCT was located that compared aspirin (300mg daily, enteric coated) with placebo. It found aspirin increased ulcer healing rates (38 per cent of ulcers healed, compared with 0 per cent), but due to methodological weaknesses, the results need to be interpreted cautiously (Layton et al., 1994).

Strength of the clinical evidence (III)

One small, flawed RCT.

11.0 Low level laser treatment

11.1 There is no evidence that low level laser therapy speeds the healing of venous leg ulcers.

Rationale

Two systematic reviews (Flemming & Cullum, 1999, search date 1999; Schneider & Hailey, 1999, search date 1999) and two subsequent RCTs (Lagan et al., 2002; Franek et al., 2002) were identified. The first review identified four RCTs (139 people) (Flemming & Cullum, 1999). Two RCTs compared low level laser treatment versus sham treatment and found no significant difference in healing rates over 12 weeks (17/44 [39%] vs. 14/44 [32%]; RR 1.21, 95% CI 0.73 to 2.03). One three-arm RCT (30 people) identified by the review compared laser treatment versus laser treatment plus infrared light or versus non-coherent, unpolarised red light. It found that significantly more ulcers healed completely after nine months' treatment in the group receiving a combination of laser and infrared light, compared with non-coherent, unpolarised red light (12/15 [80%] vs. 5/15 [33%]; RR 2.4, 95% CI 1.12 to 5.13). The fourth RCT identified by the review compared laser and ultraviolet light and found no significant difference in healing over four weeks (Flemming & Cullum, 1999). The second review (five RCTs, Schneider & Hailey, 1999) identified, but did not fully describe the four RCTs identified by the first review. The review did not perform a meta-analysis. The additional RCT identified by the review (9 people, 12 venous leg ulcers) compared low-level laser treatment with sham treatment. It found limited evidence that ulcer area reduction was greater with laser over 10 weeks (25 per cent of ulcer area remained unhealed in people receiving laser versus 85 per cent in people receiving sham treatment) (Schneider & Hailey, 1999). The RCT did not assess complete ulcer healing. The first subsequent small RCT (15 people) compared laser therapy plus phototherapy once weekly for four weeks, versus sham therapy (Lagan et al., 2002). It found no significant difference between laser and sham in ulcer area at 12 weeks. The second small subsequent RCT (65 people) compared laser, sham laser, and no treatment, although it is unclear if the 'no additional treatment' was established by randomisation (Franek et al., 2002). It found no significant difference between treatments in the change in area of ulceration (reduction in area:

4.25 cm² (27 per cent) with laser v 5.21 cm² (39 per cent) with sham laser vs. 2.98 cm² (18 per cent) with no treatment; P value not reported).

Strength of the clinical evidence (I)

Based on seven RCTs.

12.0 Electromagnetic therapy for treating venous leg ulcers

12.1 There is no evidence that electromagnetic therapy increases the healing of venous leg ulcers.

Rationale

One systematic review was found (Cullum et al., 2001) (three RCTs; 94 people; search date 1999). Two trials compared the use of electromagnetic therapy to sham and one compared it to standard topical treatments. No statistically significant differences were observed in the included trials, although individual numbers in trials may have meant that they were underpowered to detect a difference between therapies.

Strength of the clinical evidence (II)

Three small RCTs.

13.0 Electrical stimulation

13.1 There is insufficient evidence that electrical stimulation increases the healing of venous leg ulcers.

Rationale

One RCT (Houghton et al., 2003, 27 people) was located that compared the use of a high voltage pulsed current to sham therapy, using a deactivated device. A statistically significant difference was observed between the groups in terms of reduction of wound area from baseline ($57\pm15\%$ vs. 20 ± 18.6 ; p<0.05). The exact p value and confidence intervals were not reported.

Strength of the clinical evidence (II)

One small RCT.

14.0 Ultrasound therapy

14.1 The available evidence suggests a possible benefit of ultrasound therapy in the healing of venous leg ulcers but more research is needed.

Rationale

One systematic review was found (search date 1999, seven RCTs, 470 people) comparing therapeutic ultrasound with no ultrasound or sham ultrasound for venous leg ulcers (Flemming & Cullum, 2000). Ultrasound improved ulcer healing in all studies, but a significant difference was found in only four of the seven RCTs, and heterogeneity precluded pooling the seven RCTs. One additional RCT (Peschen et al., 1997, 24 patients) was found that was not included in the systematic review. This study found a significant difference in mean percentage ulcer size decrease between the group treated with ultrasound compared with placebo (55.4% vs. 16.5%, p<0.007).

Strength of the clinical evidence (II)

Eight RCTs.

15.0 Prevention of recurrence of ulceration

15.1 Use of compression stockings reduces venous ulcer recurrence rates and is costeffective. Patients should be encouraged to wear class III compression, if this is not contraindicated and they can tolerate it; otherwise the highest level of compression they will tolerate.

Rationale

A systematic review identified no trials comparing recurrence in people randomised to compression hosiery or no compression hosiery (Nelson et al., 2000; search date 2000). However such an RCT has since been published (153 people, Vandongen & Stacey, 2000) and reported that wearing class 3 compression stockings significantly reduced ulcer recurrence at six months, compared with not wearing compression stockings (21% vs. 46%; RR 0.46, 95% C.I. 0.28 to 0.76).

The review identified two RCTs. One showed that three to five year recurrence rates were lower in patients using strong support from class 3 compression stockings (21 per cent) than in those randomised to receive medium support from class 2 compression stockings (32 per cent) (p=0.034); however, class 2 stockings were better tolerated by patients (Harper et al., 1995). The second RCT found no difference in recurrence between two alternative UK class 2 stockings, although not wearing the allocated compression stockings was associated with greater recurrence.

Evidence from a cost utility analysis (Korn et al., 2002) suggests that providing patients with compression stockings and an educational programme focused on the importance of wearing stockings was less costly and more effective than doing nothing – i.e. stocking provision was associated with lower lifetime costs and high quality adjusted life years than no stocking provision.

Strength of the clinical evidence (I)

One RCT found that leg ulcer recurrence was significantly more likely in people not allocated compression, compared with those allocated class 3 compression hosiery. A further RCT found that recurrence was more likely in those people who did not wear their stockings.

Strength of the economic evidence (II)

One model-based, full economic evaluation.

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.

15.2 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

- concordance with compression hosiery
- skin care
- discourage self-treatment with overthecounter 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, ranging from medical investigation and surgery to health education. These strategies are based largely on expert opinion. The recommended approach will depend on the individual patient and likely concordance with suggested strategies.

15.0 Prevention of recurrence of ulceration

Strength of clinical 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 reattends to receive four-layer compression bandaging after recurrence, the shorter the time to re-healing.

16.0 Education and training for leg ulcer care

- 16.1 Health care professionals with recognised 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., 1998b; Simon et al., 1996). 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, 1998; Luker et al., 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 clinical evidence (III)

Most existing research in this area is presented within the context of poorly reported audit studies, utilising one sample, before-after designs and often fails 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-randomised comparison groups that knowledge of leg ulcer care is improved by training. There is a need for well designed, prospective studies that 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.

17.0 Quality assurance

17.1 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, rates of healing and adverse outcomes due to incorrectly treated arterial disease or excessive compression) ensures that appropriate performance indicators are monitored.

Concern was expressed by a consensus group member that for audit to be of benefit in leg ulcer care, a large number of variables (for example, healing rates, recurrence rates, time to complete healing, patient health status, patient-centred outcomes (such as an ulcer free leg, ulcer size) 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 clinical 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.

Ackroyd JS and Young AE (1983) Leg ulcers that do not heal, *British Medical Journal (clinical research edition)*, 286(6360), pp.207–208.

Ahroni JH, Boyko EJ and Pecoraro RE (1992) Reliability of computerized wound surface area determinations, *Wounds*, 4(4), pp.133–137.

Alberta Heritage Foundation for Medical Research (2001) *Technote: 2001 'Profore compression bandage treatment of venous leg ulcers'*, Alberta: AHFMR.

Alexander House Group (1992) Consensus paper on venous leg ulcers, *Phlebology*, 7, pp.48–58.

Andersen KE, Franken CPM, Gad P et al. (2002) A randomized, controlled study to compare the effectiveness of two foam dressings in the management of lower leg ulcers, *Ostomy Wound Management*, 48(8), pp.34–36.

Augustin M, Siegel A, Heuser A and Vanscheidt W (1999) Chronic leg ulcers: cost evaluation of two treatment strategies, *Journal of Dermatological Treament*, 10(Suppl 1), pp.S21–S25.

Baldursson B, Sigureirsson B and Lindelof B (1995) Venous leg ulcers and squamous cell carcinoma: A large-scale epidemiological study, *British Journal of Dermatology*, 133(4), pp.571–574.

Belcaro G, Sager P, Borgwardt A et al. (1983) Arterial pressure measurements correlated to symptoms and signs or peripheral arterial disease, *Acta Chirurgica Belgica*, 83(5), pp.320–326.

Belcaro G, Cesarone MR, Nicolaides AN et al. (2002) Treatment of venous ulcers with pentoxifylline: A six-month randomized, doubleblind, placebo controlled trial, *Angiology*, 53(Suppl 1), pp.S45–S47.

Bell M (1994) Nurses' knowledge of the healing process in venous leg ulceration, *Wound Care*, 3(3), pp.145–150.

Berliner E, Ozbilgin B and Zarin DA (2003) A systematic review of pneumatic compression for treatment of chronic venous insufficiency and venous ulcers, *Journal of Vascular Surgery* 37(3), pp.539–544.

Blondeel A, Oleffe J and Achten G (1978) Contact allergy in 330 dermatological patients, *Contact Dermatitis*, 4(5), pp.270–276. Bosanquet N, Franks P, Moffatt C et al. (1993) Community Leg ulcer clinics: cost-effectiveness, *Health Trends*, 25(4), pp.146–148.

Bradley M, Cullum N and Sheldou T (1999) The debridement of chronic wounds: a systematic review, *Health Technology Assessment*, 3(17 (pt 1)).

Brearley SM, Simms MH and Shearman CP (1992) Peripheral pulse palpation: an unreliable physical sign, *Annals of the Royal College of Surgeons of England*, 74, pp.169–171.

Briggs M and Nelson EA (2003) Topical agents or dressings for pain in venous leg ulcers, *The Cochrane Library*, Issue 1, Chichester: John Wiley & Sons, Ltd.

Browse NL, Burns KG and Lea Thomas M (1988) Diseases of the veins: pathology, diagnosis and Treatment, London: Edward Arnold.

Buntinx F, Beckers H, De Keyser G et al. (1996) Inter-observer variation in the assessment of skin ulceration, *Journal of Wound Care*, 5(4), pp.166–170.

Callam MJ, Harper DR, Dale JJ et al. (1987a) Arterial disease in chronic leg ulceration: an underestimated hazard? Lothian and Forth Valley leg ulcer study, *British Medical Journal (clinical research edition)*, 294(6577), pp.929–931.

Callam MJ, Ruckley CV, Dale JJ and Harper DR (1987b) Hazards of compression treatment of the leg: an estimate from Scottish surgeons, *British Medical Journal (clinical research edition)*, 295(6610), p.1382.

Callam MJ, Harper DR, Dale JJ et al. (1992) Lothian Forth Valley leg ulcer healing trial – part 1: elastic versus non-elastic bandaging in the treatment of chronic leg ulceration, *Phlebology*, 7, pp.136-141.

Cameron J (1990) Patch testing for leg ulcer patients, *Nursing Times*, 86(25), pp.63–64.

Cameron J, Wilson C, Powell S et al. (1991) *An update on contact dermatitis in leg ulcer patients,* Symposium on Advanced Wound Care: San Francisco.

Cameron J (1998) *Contact sensitivity in relation to allergen exposure in leg ulcer patients.* Unpublished M.Phil. Liverpool: The University of Liverpool.

Capillas Perez R, Cabre Aguilar V, Gil Colome V et al. (2000) Comparison of the effectiveness and cost of treatment with humid environment as compared to traditional cure. Clinical trial on primary care patients with venous leg ulcers and pressure ulcers, *Revista de Enfermería*, 23(1), pp.17–24.

Carr L, Phillips Z and Posnett J (1998) *Evaluation of the relative cost-effectiveness of Profore*, York: York Health Economics Consortium, The University of York.

Carter SA (1973) The relationship of distal systolic pressures to healing of skin lesions in limbs with arterial occlusive disease, with special reference to diabetes mellitus, *Scandinavian Journal of Clinical and Laboratory Investigation*, 128, pp.239–243.

Charles H, Callicot C, Mathurin D et al. (2002) Randomised, comparative study of three primary dressings for the treatment of venous ulcers, *British Journal of Community Nursing*, 7(Suppl 6), pp.48–54.

Chase SK, Melloni M and Savage A (1997) A forever healing: the lived experience of venous ulcer disease, *Journal of Vascular Nursing*, 15(2), pp.73–78.

Clarke Moloney M, Moore A, Adelola OA et al. (2005) Information leaflets for venous leg ulcer patients: are they effective? *Journal of Wound Care*, 14(2), pp.75–82.

Colgan MP, Teevan M, McBride C et al. *Cost comparisons in the management of venous ulceration*. Unpublished.

Cornwall JV, Dore CJ and Lewis JD (1986) Leg ulcers: epidemiology and aetiology, *British Journal of Surgery*, 73(9), pp.693–696.

Corson JD, Jacobs RL, Karmody AM et al. (1986) The diabetic foot, *Current Problems in Surgery*, 23(10), pp.721–788.

Cullum N (1994) *The nursing management of leg ulcers in the community: a critical review of research,* Liverpool: The University of Liverpool, Department of Nursing.

Cullum N and Roe B (1995) *Leg ulcers nursing management – a research-based guide*, London: Bailliere Tindall.

Cullum N, Nelson EA, Fletcher AW and Sheldon TA (2001) Compression for venous leg ulcers, *The*

Cochrane Library, Issue 2, Chichester: John Wiley & Sons, Ltd.

Dealey C (1995) Wound assessment may delay healing, *British Journal of Nursing*, 4(10), p.603.

Dealey C (1998) *The importance of education in affecting change in leg ulcer management,* 7th European conference on advances in wound management, London: EMAP Healthcare Ltd.

De Sanctis MT, Belcaro G, Cesarone MR et al. (2002) Treatment of venous ulcers with pentoxifylline: a 12-month, double-blind, placebo controlled trial. Microcirculation and healing, *Angiology*, 53(Suppl 1), pp.S49–51.

Dooms-Goossens A, Degreef HC, Parijs M and Kerkhofs L (1979a) A retrospective study of patch test results from 163 patients with stasis dermatitis or leg ulcers. I. Discussion of the patch test results and the sensitization indices and determination of the relevancy of positive reactions, *Dermatologica*, 159(2), pp.93–100.

Dooms-Goossens A, Degreef H, Parijs M and Maertens M (1979b) A retrospective study of patch test results from 163 patients with stasis dermatitis or leg ulcers. II. Retesting of 50 patients, *Dermatologica*, 159(3), 231–238.

Douglas V (2001) Living with a chronic leg ulcer: an insight into patients' experiences and feelings, *Journal of Wound Care*, 10(9), pp.355–360.

Duby T, Hoffman D, Cameron J et al. (1993) A randomized trial in the treatment of venous leg ulcers comparing short stretch bandages, four layer bandage system and a long stretch paste bandage system, *Wounds*, 5, pp.276–279.

Dunn C, Beegan A and Morris S (1997) *Towards Evidence-based practice. Focus on venous ulcers. Mid-term review progress report compiled for King's Fund PACE project*, London: King's Fund.

Edwards LM, Moffatt CJ and Franks PJ (2002) An exploration of patients' understanding of leg ulceration, *Journal of Wound Care*, 11(1), pp.35–39.

Edwards LM (2003) Why patients do not comply with compression bandaging. *British Journal of Nursing*, 12(Suppl 11), pp.S5–6, S8, S10 passim.

Elliot E, Russell B and Jaffrey G (1996) Setting a standard for leg ulcer assessment, *Journal of Wound Care*, 5(4), pp.173–175.

Eriksson G, Eklund AE and Kallings LO (1984) The clinical significance of bacterial growth in venous leg ulcers, *Scandinavian Journal of Infectious Diseases*, 16(2), pp.175–180.

Etris MB, Pribble J and LaBrecque J (1994) Evaluation of two wound measurement methods in a multi-center, controlled study, *Ostomy Wound Management*, 40(7), pp.44–48.

Evans D and Land L (2001) Topical negative pressure for treating chronic wounds, *The Cochrane Library*, Issue 1, Chichester: John Wiley & Sons, Ltd.

Falanga V, Margolis D, Alverez O et al. (1998) Rapid healing of venous ulcers and lack of clinical rejection with an allogeneic cultured human skin equivalent. Human Skin Equivalent Investigators Group, *Archives of Dermatology*, 134(3), pp.293–300.

Feben K (2003) How effective is training in compression bandaging techniques? *British Journal of Community Nursing*, 8(2), pp.80–84.

Fernandez R, Griffiths R and Ussia C (2003) Water for wound cleansing, *The Cochrane Library*, Issue 4, Chichester: John Wiley & Sons, Ltd.

Flemming K and Cullum N (1999) Laser therapy for venous leg ulcers. *The Cochrane Library*, Issue 1, Chichester: John Wiley & Sons, Ltd.

Flemming K and Cullum N (2000) Therapeutic ultrasound for venous leg ulcers, *The Cochrane Library*, Issue 4, Chichester: John Wiley & Sons, Ltd.

Fisher CM, Burnett A, Makeham V et al. (1996) Variation in measurement of ankle-brachial pressure index in routine clinical practice, *Journal of Vascular Surgery*, 24(5), pp.871–875.

Flett R, Harcourt B and Alpass F (1994) Psychosocial aspects of chronic lower leg ulceration in the elderly, *Western Journal of Nursing Research*, 16(2), pp.183–192.

Fowkes FG, Housley E, MacIntyre CCA et al. (1988) Variability of ankle and brachial systolic pressures in the measurement of atherosclerotic peripheral arterial disease, *Journal of Epidemiology and Community Health*, 42(2), pp.128–133.

Fraki JE, Peltonen L and Hopsu-Havu VK (1979) Allergy to various components of topical preparations in stasis dermatitis and leg ulcer, 5(2), pp.976–1000. Franek A, Krol P and Kucharzewski M (2002) Does low output laser stimulation enhance the healing of crural ulceration? Some critical remarks. *Medical Engineering and Physics*, 24(9), pp.607–615.

Franks PJ, Oldroyd MI, Dickson D et al. (1995) Risk factors for leg ulcer recurrence: a randomized trial of two types of compression stocking, *Age and Ageing*, 24(6), pp.490–494.

Gherardini, G, Gurlek A, Evans GR et al. (1998) Venous ulcers: improved healing by iontophoretic administration of calcitonin gene-related peptide and vasoactive intestinal polypeptide, *Plastic and Reconstructive Surgery*, 101(1), pp.90–93.

Gould DJ, Campbell S and Harding EF (1993) Short stretch vs. long stretch bandages in the management of chronic venous leg ulcers, *Phlebology*, 8(1), p.43.

Griffey M (1992) Reach for the highest standard. Comparison of leg ulcer management in two practices, *Professional Nurse*, 8(3), pp.189–192.

Hamer C, Cullum NA and Roe BH (1994) Patients' perceptions of chronic leg ulcers, *Journal of Wound Care*, 3(2), pp.99–102.

Hannson C (1998) The effects of cadexomer-Iodine paste in the treatment of venous leg ulcers compared with hydrocolloid dressing and paraffin gauze dressing, *International Journal of Dermatology*, 37(5), pp.390–396.

Hareendran A, Bradbury A, Budd J et al. (2005) Measuring the impact of venous leg ulcers on quality of life, *Journal of Wound Care*, 14(2), pp.53–57.

Harding KG, Price P, Robinson B et al. (2001) Cost and dressing evaluation of a hydrofiber and alginate dressing in the management of community-based patients with chronic leg ulceration, *Wounds*, 13(6), pp.229–236.

Harper DR, Nelson EA, Gibson B et al. (1995) A prospective randomized trial of class 2 and class 3 elastic compression in the prevention of venous ulceration, *Phlebology*, 11(S), pp.872–873.

Hofman D, Ryan TJ, Arnold F et al. (1997) Pain in venous leg ulcers, *Journal of Wound Care*, 6(5), pp.222–224.

Hopkins A (2004) Disrupted lives: investigating coping strategies for non-healing leg ulcers, *British Journal of Nursing*, 13(9), pp.556–563.

Houghton PE, Kincaid CB, Lovell M et al. (2003) Effect of electrical stimulation on chronic leg ulcer size and appearance, *Physical Therapy*, 83(1), pp.17–28.

Husband LL (2001) Shaping the trajectory of patients with venous ulceration in primary care, *Health Expectations*, 4(3), pp.189–198.

Iglesias C, Claxton K et al. (2001) The value of clinical trials of Trental in the treatment of chronic venous leg ulcers, *Medical Decision Making*, 21(6), p.531.

Iglesias C, Nelson EA, Cullum NA and Torgerson DA (2004) VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers, *Health Technology Assessment*, 8(29), pp.1–105.

Johnson M (1995) The influence of patient characteristics and environmental factors in leg ulcer healing, *Journal of Wound Care*, 4(6), pp.277–282.

Johnson M and Miller R (1996) Measuring healing in leg ulcers: practice considerations, *Applied Nursing Research*, 9(4), pp.204–208.

Jones JE and Nelson EA (2000) Skin grafting for venous leg ulcers, *The Cochrane Library*, Issue 2, Chichester: John Wiley & Sons, Ltd.

Jull AB, Walker N et al. (2004) Leg ulceration and perceived health: a population based case-control study, *Age and Aging*, 33, pp.236–241.

Jull AB, Waters J and Arroll B (2002) Pentoxifylline for treatment of venous leg ulcers, *The Cochrane Library*, Issue 1, Chichester: John Wiley & Sons, Ltd.

Kantor J and Margolis DJ (2000) A multicentre study of percentage change in venous leg ulcer area as a prognostic index of healing at 24 weeks, *British Journal of Dermatology*, 142(5), pp.960–964.

Kerstein MD and Gahtan V (2000) Outcomes of venous ulcer care: results of a longitudinal study, *Ostomy Wound Management*, 46(6), pp.22–6, 28–9.

Kikta M, Schuler J, Meyer J et al. (1988) A prospective, randomized trial of Unna's boot versus hydroactive dressing in the treatment of venous stasis ulcers, *Journal of Vascular Surgery*, 7(3), pp.478–483. Knight CA and McCulloch J (1996) *A comparative study between two compression systems in the treatment of venous insufficiency leg ulcers.* Presented at Symposium of Advanced Wound Care and Medical Research Forum on Wound Repair, 117. Pennsylvania, Health Management Publications.

Koksal C and Bozkurt AK (2003) Combination of hydrocolloid dressing and medical compression stocking versus Unna's boot for the treatment of venous leg ulcers, *Swiss Medical Weekly*, 133(25–26), pp.364–368.

Korn P, Patel ST, Heller JA et al. (2002) Why insurers should reimburse for compression stockings in patients with chronic venous stasis, *Journal of Vascular Surgery*, 35(5), pp.950–957.

Krishnamoorthy L, Harding K, Griffiths D et al. (2003) The clinical and histological effects of Dermagraft in the healing of chronic venous leg ulcers, *Phlebology*, 18(1), pp.12–22.

Kulozik M, Powell SM, Cherry G and Ryan TJ (1988) Contact sensitivity in community-based leg ulcer patients, *Clinical and Experimental Dermatology*, 13(2), pp.82–84.

Kurz, X, Kahn SR, Abenheim L et al. (1999) Chronic venous disorders of the leg: epidemiology, outcomes, diagnosis and management. Summary of an evidence-based report of the VEINES task force. Venous insufficiency epidemiologic and economic studies, *International Angiology*, 18(2), pp.83–102.

La Marc G, Pumilia G and Martino A (1999) Effectiveness of mesoglycan topical treatment of leg ulcers in subjects with chronic venous insufficiency, *Minerva Cardioangiolica*, 47(9), pp.315–319.

Lagan KM, McKenna T, Witherow A et al. (2002) Low-intensity laser therapy/combined phototherapy in the management of chronic venous ulceration: A placebo-controlled study, *Journal of Clinical Laser Medicine and Surgery*, 20(3), pp.109–116.

Lambert E and McGuire J (1989) Rheumatoid leg ulcers are notoriously difficult to manage. How can one distinguish them from gravitational and large vessel ischaemic ulceration? What is the most effective treatment? *British Journal of Rheumatology*, 28(5), p.421.

Layton AM, Ibbotson SH, Davies JA et al. (1994) Randomised trial of oral aspirin for chronic venous leg ulcers, *Lancet*, 344(8916), pp.164–165.

Lees TA and Lambert D (1992) Prevalence of lower limb ulceration in an urban health district, *British Journal of Surgery*, 79(10), pp.1032–1034.

Limova M and Troyer-Caudle J (2002) Controlled, randomized clinical trial of two hydrocolloid dressings in the management of venous insufficiency ulcers, *Journal of Vascular Nursing*, 20(1), pp.22–34.

Lineaweaver W, McMorris S, Soucy D and Howard R (1985) Cellular and bacterial toxicities of topical antimicrobials, *Plastic and Reconstructive Surgery*, 75(3), pp.394-396.

Lindholm C, Bjellerup M, Christensen OB and Zederfeldt B (1993) Quality of life in chronic leg ulcer patients. An assessment according to the Nottingham Health Profile, Acta Dermato Venereologica, 73(5), pp.440–443.

Liskay AM, Mion LC and Davis BR (1993) Comparison of two devices for wound measurement, *Dermatology Nursing*, 5(6), pp.437–440.

Logan RA, Thomas S, Harding EF and Collyer G (1992) A comparison on sub-bandage pressures produced by experienced and inexperienced bandagers. *Journal of Wound Care*, 1(3), pp.23–26.

Luker KA, Nurs B and Kenrick M (1995) Towards knowledge-based practice; an evaluation of a method of dissemination, *International Journal of Nursing Studies*, 32(1), pp.59–67.

Magee TR, Stanley PRW, Al Mufti R et al. (1992) Should we palpate foot pulses? *Annals of the Royal College of Surgeons of England*, 74, pp.166–168.

Majeske C (1992) Reliability of wound surface area measurements, *Physical Therapy*, 72(2), pp.138–141.

Malten KE, Kuiper JP and van der Staak WB (1973) Contact allergic investigations in 100 patients with ulcis cruris, *Dermatologica*, 147(4), pp.241–254.

Malten KE and Kuiper JP (1985) Contact allergic reactions in 100 selected patients with ulcus cruris. *Vasa*, 14(4), pp.340–345.

Mani R, Vowden K and Nelson EA (2001) Intermittent pneumatic compression for treating venous leg ulcers, *The Cochrane Library*, Issue 4, Chichester: John Wiley & Sons, Ltd.

Margolis DJ, Berlin JA and Strom BL (2000) Which venous leg ulcers will heal with limb compression bandages? *American Journal of Medicine*, 109(1), pp.15–19.

McLelland J and Shuster S (1990) Contact dermatitis with negative patch tests: the additive effect of allergens in combination, *British Journal of Dermatology*, 122(5), pp.623–630.

Meaume S, Faucher N et al. (2002) A randomised controlled study to compare a sequential treatment using alginate-CMC and hydrocolloid dressing to hydrocolloid dressing alone in decubitus ulcers management, 12th conference of the European Wound Management Association, Granada: GNEAUPP-EWMA.

Meyer FJ, Burnand KG et al. (2000) *More venous leg ulcers are healed by three-layer paste than by four-layer bandages: a randomised, controlled, prospective study,* Australia: First World Wound Healing Congress, Australian Wound Management Association.

Meyer FJ, Burnand KG, Lagatolla NR and Eastham D (2002) Randomised clinical trial comparing the efficacy of two bandaging regimens in the treatment of venous leg ulcers, *British Journal of Surgery*, 89(1), pp.40–44.

Meyer FJ, McGuinness CL, Lagatolla NR et al. (2003) Randomised clinical trial of three-layer paste and four-layer bandages for venous leg ulcers, *British Journal of Surgery*, 90(8), pp.934–940.

Moffatt CJ, Franks PJ, Oldroyd M et al. (1992) Community clinics for leg ulcers and impact on healing, *British Medical Journal*, 305(5), 1389–1392.

Moffatt CJ, Oldroyd MI, Greenhalgh RM et al. (1994) Palpating ankle pulses is insufficient in detecting arterial insufficiency in patients with leg ulceration, *Phlebology*, 9, pp.170–172.

Moffatt CJ and O'Hare L (1995) Ankle pulses are not sufficient to detect impaired arterial circulation in patients with leg ulcers, *Journal of Wound Care*, 4(3), pp.134–137.

Moffatt CJ and Dorman MI (1995) Recurrence of leg ulcers within a community ulcer service, *Journal of Wound Care*, 4(2), pp.56–62.

Moffatt CJ (2004) Factors that affect concordance with compression therapy, *Journal of Wound Care*, 13(7), pp.291–294.

Moffatt CJ and Franks PJ (2004) Epidemiology and health services research. Implementation of a leg ulcer strategy, *Journal of Dermatology*, 151(4), pp.857–867.

Morrell CJ, King B and Brereton L (1998a) Community based leg ulcer clinics: organization and cost effectiveness, *Nursing Times*, 94(9), pp.51–54.

Morrell CJ, Walters SJ, Dixon S et al. (1998b) Cost effectiveness of community leg ulcer clinics: randomised controlled trial, *British Medical Journal*, 316(7143), p.1487–1491.

Morrell C, Liao XH, Cheater F et al. (2001) The management of venous leg ulcers: a project to improve care, *Nursing Standard*, 15(30), pp.68–73.

Nelson EA, Bell-Syer SEM and Cullum NA (2000) Compression for preventing recurrence of venous ulcers, *The Cochrane Library*, Issue 4, Chichester: John Wiley & Sons, Ltd.

Nelson EA, Ruckley CV and Barbenel JC (1995) Improvements in bandaging technique following training, *Journal of Wound Care*, 4(4), pp.181–184.

Nelson EA and Jones JE (1997) *The development, implementation and evaluation of an educational initiative in leg ulcer management.* Liverpool: Research and Development Unit, Department of Nursing, The University of Liverpool.

Nelzen O, Bergqvist D and Lindhagen A (1993) High prevalence of diabetes in chronic leg ulcer patients: a cross-sectional population study, *Diabetes Medicine*, 10(4), pp.345–350.

Nelzen O, Bergqvist D and Lindhagen A (1994) Venous and non-venous leg ulcers: clinical history and appearance in a population study, *British Journal of Surgery*, 81(2), pp.182–187.

Nikolovska S, Pavlova L, Petrova N et al. (2002) Pentoxifylline – efficient in the treatment of venous ulcers in the absence of compression? *Acta Dermatovenerologica Croatia*, 10(1), pp.9–13. Northeast A, Layer G, Wilson N et al. (1990) *Increased compression expedites venous ulcer healing*, presented at Royal Society of Medicine Venous Forum. London, RSM.

Nowak, A, Bowszyc J et al. (1996) 'A comparison of a new polyurethane foam dressing versus a calcium alginate dressing in the treatment of moderately to heavily exuding varicose leg ulcers', in Cherry GW, Gettrup F, Lawrence JC et al. (eds.) *Proceedings of the 5th European conference on advances in wound management,* London: Macmillan Magazines.

O'Brien JF, Grace PA, Perry IJ et al. (2003) Randomised clinical trial and economic analysis of four-layer compression bandaging for venous ulcers, *British Journal of Surgery*, 90(7), pp.794–798.

Ohlsson P, Larsson K, Lindholm C and Moller M (1994) A cost effectiveness study of leg ulcer treatment in primary care. Comparison of saline-gauze and hydrocolloid treatment in a prospective, randomized study, *Scandinavian Journal of Primary Health Care*, 12(4), pp.295–299.

O'Meara SM, Cullum N, Mahid N and Sheldon T (2000) Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration, *Health Technology Assessment*, 4(21), pp.1–237.

Ortonne JP (1996) A controlled study of the activity of hyalouronic acid in the treatment of venous leg ulcers, *Journal of Dermatological Treatment*, 7(2), pp.75–81.

Paramsothy Y, Collins M and Smith AG (1988) Contact dermatitis in patients with leg ulcers. The prevalence of late positive reactions and evidence against systemic ampliative allergy, *Contact Dermatitis*, 18(1), pp.30–36.

Partsch H, Damstra RJ, Tazelaar DJ et al. (2001) Multicentre, randomised controlled trial of fourlayer bandaging versus short stretch bandaging in the treatment of venous leg ulcers, *Vasa*, 30(2), pp.108–113.

Peschen M, Weichenthal M, Schopf E and Vanscheidt W (1997) Low frequency ultrasound treatment of chronic venous leg ulcers in an outpatient therapy, *Acta Dermato Venereologica*, 77(4), pp.311–314.

Phillips T, Stanton B, Provan A and Lew R (1994) A study in the impact of leg ulcers on the quality of life: financial, social and psychological implications, *Journal of the American Academy of Dermatology*, 31(1), pp.49–53.

Price P and Harding K (1996) Measuring healthrelated quality of life in patients with chronic leg ulcers, *Wounds*, 8(3), pp.91–94.

Ray SA, Srodon PD, Taylor RS and Dormandy JA (1994) Reliability of ankle:brachial pressure index measurement by junior doctors, *British Journal of Surgery*, 81(2), pp.188–190.

Rich A and McLachlan L (2003) How living with a leg ulcer affects people's daily life: a nurse-led study, *Journal of Wound Care*, 12(2), pp.51–54.

Robson MC, Phillips TJ, Falanga V et al. (2001) Randomized trial of topically applied repifermin (recombinant human keratinocyte growth factor 2) to accelerate wound healing in venous ulcers, *Wound Repair and Regeneration*, 9(5), pp.347–352.

Roe BH, Griffiths JM, Kenrick M et al. (1994) Nursing treatment of patients with chronic leg ulcers in the community, *Journal of Clinical Nursing*, 3(3), pp.159–168.

Roe BH, Luker KA, Cullum NA et al. (1993) Assessment, prevention and monitoring of chronic leg ulcers in the community: report of a survey, *Journal of Clinical Nursing*, 2(5), pp.299–306.

Sachine-Kardase A, Bardake Z, Basileiadou A et al. (1992) Study of clean versus aseptic technique of tracheotomy care based on the level of pulmonary infection, *Noseleutike*, 31(141), pp.201–211.

Samson RH and Showalter DP (1996) Stockings and the prevention of recurring venous ulcers, *Dermatological Surgery*, 22(4), pp.373–376.

Schiffer C and Ullrich J (1997) Starting in Cologne: the initiative: chronic wounds. Guideline: decubitus ulcer, *Krankenpflege Journal*, 35(9), pp.333-334. [German]

Schneider WL and Hailey D (1999) *Low level laser therapy for wound healing*, Alberta: Alberta Heritage Foundation for Medical Research.

Schofield J, Flanagan M, Fletcher J et al. (2000) The provision of leg ulcer services by practice nurses, *Nursing Standard*, 14(26), pp.54–60. Schonfeld WH, Villa KF, Fastenau JM et al. (2000) An economic assessment of APLIGRAF (Graftskin) for the treatment of hard-to-heal venous leg ulcers, *Wound Repair and Regeneration*, 8(4), pp.251–257.

Schulze HJ, Lane C, Charles H et al. (2001) Evaluating a super absorbent hydropolymer dressing for exuding venous leg ulcers, *Journal of Wound Care*, 10(1), pp.511–518.

Scriven JM, Hartshorne T, Bell PRF et al. (1997) Single-visit venous ulcer assessment clinic: the first year, *British Journal of Surgery*, 84, pp.334–336.

Scriven JM, Taylor LE, Wood AJ et al. (1998) A prospective randomised trial of four-layer versus short stretch compression bandaging for the treatment of venous leg ulcers, *Annals of the Royal College of Surgeons of England*, 80(3), pp.215–220.

Seeley J, Jensen JL and Hutcherson J (1999) A randomized clinical study comparing a hydrocellular dressing to a hydrocolloid dressing in the management of pressure ulcers, *Ostomy Wound Management*, 45(6), pp.39–44, 46–7.

Simon DA, Freak L, Williams IM and McCollom CN (1994) Progression of arterial disease in patients with healed venous ulcers, *Journal of Wound Care*, 3(4), pp.179–180.

Simon DA, Freak L, Kinsella A et al. (1996) Community leg ulcer clinics: a comparative study in two health authorities, *British Medical Journal*, 312(7047), pp.1648–1651.

Sindrup JH, Groth S, Avnstorp C et al. (1987) Coexistence of obstructive arterial disease and chronic venous stasis in leg ulcer patients, *Clinical and Experimental Dermatology*, 12(6), pp.410–412.

Skene AI, Smith JM, Dore CJ, Charlett A and Lewis JD (1992) Venous leg ulcers: a prognostic index to predict time to healing, *British Medical Journal*, 305(6862), pp.1119–1121.

Smith JM, Doré CJ, Charlett A and Lewis JD (1992) A randomized trial of Biofilm dressing for venous leg ulcers, *Phlebology*, 7(3), pp.108–113.

Stacey MC, Mata SD, Trengrove SA and Mather CA (2000) Randomised double-blind placebo controlled trial of topical autologous platelet lysate in venous ulcer healing, *European Journal*

of Vascular and Endovascular Surgery, 20(3), pp.296–301.

Stevens J, Franks PJ, Harrington M (1997) A community/ hospital leg ulcer service, *Journal of Wound Care*, 6(2), pp.62–68.

Stockport JC, Groarke L, Ellison DA and McCollom C (1997) Single-layer and multilayer bandaging in the treatment of venous leg ulcers, *Journal of Wound Care*, 6(10), pp.485–488.

Taylor AD, Taylor RJ and Marcuson RW (1998) Prospective comparison of healing rates and therapy costs for conventional and four layer high compression bandaging treatments of venous leg ulcers, *Phlebology*, 13, pp.20–24.

Thomas S, Banks V, Bales S et al. (1997) A comparison of two dressings in the management of chronic wounds, *Journal of Wound Care*, 6(8), pp.383–386.

Torra i Bou J, Rueda Lopez J et al. (2003) Varicose ulcers: the use of a system of multilayered compresses or a crepe bandage? *Revista de Enfermería*, 26(6), pp.59–66.

Travers J, Dalziel K and Makin G (1992) Assessment of new one-layer adhesive bandaging method in maintaining prolonged limb compression and effects on venous ulcer healing, *Phlebology*, 7, 59–63.

Trengove NJ, Stacey MC, McGechie DF and Mata S (1996) Qualitative bacteriology and leg ulcer healing, *Journal of Wound Care*, 5(6), pp.277–280.

Ukat A, Konig M, Vanscheidt W and Munter C (2003) Short stretch versus multi-layer compression for venous leg ulcers: a comparison of healing rates, *Journal of Wound Care*, 12(4), pp.139–143.

Vandongen YK and Stacey MC (2000) Graduated compression elastic compression stockings reduce lipodermatosclerosis and ulcer recurrence, *Phlebology*, 15(1), pp.33–37.

Vickery L, Coe N and Pearson NJ (2000) The impact Of Somerset leg ulcer service developments, *Journal of Clinical Excellence*, 2(1), pp.55-59.

Vin F, Teot L and Meaume S (2002) The healing properties of Promogran in venous ulcers, *Journal of Wound Care*, 11(9), pp.335–341.

Vowden KR, Mason A, Wilkinson D and Vowden P (2000) Comparison of the healing rates and complications of three four-layer bandage regimens, *Journal of Wound Care*, 9(6), pp.269–272.

Waddell G, McIntosh A, Hutchinson A, Feder G and Lewis M (1996) *Low back pain evidence review*. London, Royal College of General Practitioners.

Walshe C (1995) Living with venous leg ulcer: a descriptive study of patients' experiences, *Journal of Advanced Nursing*, 22(6), 1092–1100.

Wayman J, Nirojogi V, Walker A et al. (2000) The cost effectiveness of larval therapy in venous ulcers, *Journal of Tissue Viability*, 10(3), pp.91–94.

Wilkinson EA and Hawke CI (1998) Does oral zinc aid the healing of chronic leg ulcers? A systematic literature review, *Archives of Dermatology*, 134(12), pp.1556–1560.

Wissing U, Ek A and Unosson N (2002) Life situation and function in elderly people with and without leg ulcers, *Scandinavian Journal of Caring Sciences*, 16(1), pp.59–65.

Yang D, Morrison BD, Vandongen YK et al. (1996) Malignancy in chronic leg ulcers, *Medical Journal of Australia*, 164(12), pp.718–721. improving practice: improving care



Published by the Royal College of Nursing 20 Cavendish Square, London W1G 0RN

Telephone: 020 7409 3333

ISBN: 1-904114-22-9

September 2006

Publication code: 003 020

