

## WORKSHOP REPORT

# Guidelines for the management of chronic venous leg ulceration. Report of a multidisciplinary workshop

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### Summary

This document is the product of a multidisciplinary workshop held in November 1991 between the audit subcommittee of the British Association of Dermatologists and the Research Unit of the Royal College of Physicians. Participants included dermatologists, vascular surgeons, general practitioners, community nurses and physicians involved in care of the elderly. The text is based on papers submitted to, and presented and discussed at, the workshop, and on comments received in response to subsequent wide dissemination of the proceedings to speciality associations. Participants in the workshop, and contributors to the guidelines are: Dr B.R.Allen (Nottingham), Sister S.Bainsborough (Exeter), Professor K.Burnand (London), Professor D.Burrows (Belfast), Mr M.J.Callam (Bedford), Dr G.W.Cherry (Oxford), Dr R.P.R.Dawber (Oxford), Dr W.S.Douglas (Airdrie), Dr A.Y.Finlay (Cardiff), Dr D.Gawkrodger (Sheffield), Dr D.J.Gould (Truro), Dr A.Hopkins (Royal College of Physicians, London), Dr D.McGibbon (London), Dr A.M.Middleton (London), Dr L.Millard (Nottingham), Dr L.Rhodes (Liverpool), Professor T.J.Ryan (Oxford), Dr N.B.Simpson (Newcastle), Dr F.D.Skerrett (Fowey), Dr J.M.Sowden (Nottingham), Miss L.A.Stone (London), Dr R.Williams (Rhyl).

Papers presented to the workshop (copies available from the Royal College of Physicians of London):

- 1 Callam M.J. Epidemiology, natural history and rate of recurrence of leg ulcers.
- 2 Ryan T.J. Pathology of venous leg ulcers.
- 3 Gould D.J. Assessment of severity; process and outcomes of care.
- 4 Millard L. The role of infection.
- 5 Cherry G. Treatment of known effectiveness.
- 6 Burnand K. Indications for surgical treatment.

### Introduction

The management of leg ulcers comprises a significant portion of the work-load of community and hospital nurses, general practitioners, dermatologists, surgeons and physicians involved in care of the elderly. Among the myriad regimens employed in ulcer treatment, few have scientific validity. The total cost to the National Health Service has been estimated at £600 million per annum.<sup>1</sup> A number of initiatives to improve community-based nurse management of leg ulcers<sup>2,3</sup> suggest that there is considerable potential for improved outcome, and for considerable saving in costs, especially of nursing time, by the more widespread adoption of techniques of proven efficacy. These guidelines summarize published evidence and consensus views from the disciplines involved in management of leg ulcers on

the best treatment, identify several stages in the clinical process at which critical management decisions are made, and list audit points to aid the assessment of the quality of care in community and hospital practice. Their implementation will require initiatives to improve training, especially of community nurses, improved liaison between community and hospital nurses, availability on prescription of some of the more effective bandages, and some expenditure on equipment.

### Definition

A chronic venous leg ulcer is an area of discontinuity of epidermis, persisting for 4 weeks or more, occurring as a result of venous hypertension and calf muscle pump insufficiency. Exclusion of arterial disease is a prerequi-



Figure 1. Gaiter area. From bulge of gastrocnemius to lower border of malleolus. An ulcer with its centre or origin outwith the gaiter area is extremely unlikely to be of venous aetiology.

site for appropriate management. Other causes of leg ulceration should be excluded on clinical grounds, or by investigation, including biopsy. Leg ulcers are frequently multifactorial in origin. Common among non-venous causes are: arterial insufficiency, neuropathy, diabetes mellitus, rheumatoid arthritis, haemoglobinopathies, and tumours, especially squamous cell carcinoma and basal cell carcinoma.

## Diagnosis

The most important criteria for the diagnosis of chronic venous leg ulcer are: (i) origin or centre of the ulcer sited within the 'gaiter' area<sup>4</sup> of the lower leg (Fig. 1); ulceration of the forefoot is extremely unlikely to be of venous origin; (ii) pigmentation of the skin (the principal feature of lipodermatosclerosis) within the gaiter area; (iii) exclusion of arterial disease by either the presence of full and bounding dorsalis pedis and posterior tibial pulses, or normal pressure gradient as measured by Doppler ultrasound (a ratio of systolic BP at the ankle to that in the arm of  $> 0.8$ ).

Other important clinical features include venous flare, telangiectasia, and atrophie blanche. Criteria such as the presence or absence of oedema, slough or granulation tissue, may determine some of the finer points of management.

Portable Doppler ultrasound instruments are inex-

pensive (approximately £300), and skill in their use is easily acquired. Caution is required in the interpretation of Doppler pressures in diabetic patients, and where there is arterial calcification. The most consistent results are obtained by staff who use the technique regularly in ulcer or other vascular assessment.

## Epidemiology and natural history

U.K. studies suggest that 10 per 1000 of the population will suffer leg ulceration at some time.<sup>5</sup> This figure fits with the point prevalence for open leg ulcers in European studies, which is 1–4 per 1000.<sup>6</sup> Prevalence increases with age, 60% of patients developing their first ulcer after the age of 50. Fifteen to 25 per 1000 people over 85 years of age have open ulcers. Overall, the preponderance of females is approximately 2:1, but before the age of 40 males are more commonly affected.

In the developing world, malnutrition and infection are major contributing factors in the aetiology of leg ulceration,<sup>7</sup> but in the developed world circulatory problems prevail, with venous ulcers representing 75–90% of all leg ulcers.<sup>4</sup> The Forth Valley survey showed that 50% of venous ulcers were open for up to 9 months, 20% were unhealed after 2 years, and 8% were still open at 5 years. Approximately one-third of patients were suffering from leg ulceration for the first time, one-third were on their second or third episode, and one-third were on their fourth episode or more.<sup>1</sup> Where the deep veins of the leg are abnormal, the recurrence rate at 5 years is virtually 100%.<sup>8</sup> In one study, the median duration of individual ulcers managed by care in the community was 9 months,<sup>4</sup> but in specialist centres clinical trials on selected small ulcers have shown that a 70% healing rate can be achieved in 3 months.

## Infection

Colonization of leg ulcers by potentially pathogenic bacteria is universal. In the absence of clinical signs of infection there is little evidence that bacteria impair healing,<sup>9</sup> although  $\beta$ -haemolytic *Streptococcus pyogenes* and *Pseudomonas pyocyanea* may prejudice the outcome of skin grafting. There is insufficient evidence that bacterial synergism or colonization by anaerobic organisms are relevant to the outcome of leg ulceration. There is a need for further quantitative studies.<sup>10</sup> On present evidence, routine swabbing of leg ulcers for bacteriological culture is unnecessary, and intervention should be considered only if one or more of the following signs or

symptoms is present, suggestive of spreading infection (cellulitis): (i) pyrexia; (ii) increase in pain; (iii) increasing erythema of the surrounding skin; (iv) lymphangitis; (v) rapid increase in the size of the ulcer.

Acute dermatitis (see later text) may also present with erythema and an increase in ulcer size, and may be misdiagnosed as infection. Some characteristic features of dermatitis which may be helpful in distinguishing it from cellulitis are: (i) itch; (ii) weeping; (iii) scaling; (iv) bilateral involvement. Slough on the surface of an ulcer is not a sign of infection. When infection is suspected swabs must be sent in a suitable transport medium, e.g. Stuart's medium.

#### *Treatment of infection*

Infection of an ulcer with  $\beta$ -haemolytic streptococci should be treated with systemic penicillin, e.g. intramuscular benzylpenicillin or oral phenoxymethylpenicillin. Apparent cellulitis caused by other infecting organisms should be treated systemically, according to bacteriological sensitivity.

### **Treatment of leg ulceration**

#### *Bandaging*

Support or compression bandaging, properly applied, and combined with exercise, is the treatment of choice for most cases. Community clinics which provide adequate compression therapy can achieve high rates of healing.<sup>5</sup> Venous ulcers worsen in the absence of such bandaging,<sup>11</sup> and failure to use it represents inadequate treatment. Arterial insufficiency is a contraindication to the use of compression,<sup>12</sup> except in a modified form under specialist observation.

Support bandages form a passive casing for the lower leg, enhancing muscle pump function. These include: (i) medicated paste bandages (e.g. Ichthopaste<sup>™</sup>, Ichthaband<sup>™</sup>, Viscopaste<sup>™</sup>); (ii) short-stretch bandages (e.g. Comprilan<sup>™</sup>).

Compression bandages and hosiery provide active counter-pressure, with maximum compression at the ankle, in order to enhance venous return. Examples include: (i) elastic web bandages (blue- and red-line webbing); (ii) extensible bandages (e.g. Setopress<sup>™</sup>, Tensopress<sup>™</sup>); (iii) multilayer compression using padding (Soffban<sup>™</sup>, Velban<sup>™</sup>), light support (crêpe, Elset<sup>™</sup>), and cohesive bandages (Coban<sup>™</sup>, Cohepress<sup>™</sup>, Secure<sup>™</sup>), according to the Charing Cross technique;<sup>13</sup> (iv) compression hosiery (class I–III according to strength).<sup>14</sup>

With the exception of shaped bandages (such as Tubigrip SSB<sup>™</sup>), crêpe bandages and elasticated tubular bandages do not, on their own, provide adequate support or compression, but may form part of a multi-layer compression system.

Although the majority of patients can, with adequate instruction, apply compression bandages, as a result of immobility or disability some require nursing help.

#### *Elevation*

Reduction of oedema<sup>11,15</sup> by elevation of the legs above the level of the heart is a helpful adjuvant therapy. For maximum efficacy, compression bandaging should be applied immediately after prolonged elevation, for example, while still in bed, following overnight elevation of the legs.

#### *Dressings*

No dressing of any type has been proved to enhance the healing rate of venous ulcers.<sup>16</sup> There is some evidence from clinical trials that occlusive and semi-occlusive dressings may relieve pain. Gel and hydrocolloid dressings absorb exudate, protect the surrounding skin, and require reduced frequency of application.<sup>17</sup> Topical antimicrobial agents, e.g. metronidazole, and activated charcoal dressings, may reduce odour in a heavily colonized ulcer. There is evidence that the prolonged use of antiseptics may be harmful.<sup>18</sup> Topical antibiotics are frequent sensitizers.<sup>19–21</sup> During the course of its evolution, an ulcer may require several different dressings, or no dressing. Dressings and applications should be chosen on an individual basis as aids to: (i) the control or absorption of exudate; (ii) the reduction of pain; (iii) the control of odour; (iv) the care of the surrounding skin; (v) the optimum use of nursing time; (vi) debridement; (vii) the promotion of re-epithelialization.

The principles of matching dressing to ulcer are outlined in an article in *Drug and Therapeutics Bulletin*.<sup>19</sup>

#### *Treatment of dermatitis*

Uncomplicated venous dermatitis may require the application of barrier preparations such as zinc oxide paste, emollients or topical steroids. Allergic contact dermatitis is a common complication, affecting up to 70% of cases.<sup>20</sup> Failure to improve may be a pointer to contact allergy,<sup>21</sup> and patch testing is indicated if dermatitis is inadequately controlled by a moderately potent topical

steroid. The commonest contact allergens are ingredients of topical medicaments, and include lanolin, neomycin, cetylstearyl alcohol, parabens, colophony and rubber.<sup>20,21</sup> Topical applications containing antibiotics and other common allergens should be avoided as far as possible in the management of leg ulceration.

### Drugs

In a controlled trial, oxpenthylline was reported to be of benefit,<sup>22</sup> but standard compression therapy was not used, and there was a surprisingly low healing rate in the control group. Further studies are required before it can be recommended. There is no adequate trial evidence for the efficacy of any other drug. There have been a number of trials of enhancers of fibrinolysis, with inconclusive results.<sup>23</sup> There is a single study suggesting efficacy for ultrasound therapy.<sup>24</sup>

### Surgery

Skin grafting may be required to complete the healing of ulcers, but should normally be reserved for cases in which there is failure to heal after 12 months of properly applied support or compression bandaging. Earlier grafting may be justified in the management of very large ulcers. Valid techniques include pinch grafting<sup>25</sup> and split-skin grafting, but mesh grafting<sup>26</sup> is now the treatment of choice. Grafting should be employed, where possible, on a day-patient basis.<sup>27,28</sup> Grafting with cultured keratinocytes<sup>29</sup> is not yet established as a standard treatment.

Whether debridement alone enhances healing has not been assessed, but in one study it improved the results of grafting.

Superficial vein surgery (ligation or sclerosis of the long and short saphenous systems, with or without communicating vein ligation or sclerosis) has been shown to be of value in decreasing the rate of recurrence if the deep veins are competent, but this benefit is not obtained when the deep veins are incompetent.<sup>8</sup> However, superficial vein surgery has not been shown to improve the healing rate of venous ulcers. The place of newer surgical techniques such as internal and external valvuloplasty has yet to be established.

Assessment for venous surgery includes tests of the integrity of the deep venous system and of calf muscle pump function by one or more of the following techniques: (i) colour flow duplex scanning; (ii) phlebography;

(iii) ambulatory venous pressure measurements; (iv) plethysmography; (v) volumetry.

### Patient education

An educational programme should be devised for each patient, to include: (i) knowledge of the condition; (ii) prescribed treatment; (iii) health promotion measures. Oral education should be reinforced by written information.

### Assessment of severity

Assessment of severity should be carried out monthly in community practice, or at each hospital out-patient clinic attendance. Important measurements to be recorded in the initial assessment and follow-up of patients with venous leg ulcer include:

- 1 Estimation of the surface area of the ulcer by one of the following methods: (i) the product of the two maximum perpendicular diameters<sup>30</sup> (the simplest reproducible method); (ii) serial tracings of the ulcer margin; (iii) photography, e.g. Polaroid prints or colour slides taken from a standard distance or including a scale; (iv) planimetry.
- 2 Pain is best estimated by the use of a simple scale, e.g. 0 = absent; 1 = slight; 2 = severe.
- 3 Complicating factors which may influence the outcome of treatment, and should be recorded if present include: obesity, malnutrition (including anaemia), joint disease (especially rheumatoid arthritis), heart disease, diabetes, and neurological disorders.
- 4 Signs of cellulitis.
- 5 A complete list of topical applications, including cleansers.
- 6 The Dermatology Life Quality Index may prove to be a useful measurement of improvement or deterioration.<sup>31</sup>
- 7 Social circumstances may have a major influence on outcome, and should be evaluated by the community nurses. An assessment form has been developed in Nottingham (enquiries to Department of Dermatology, University Hospital, Queen's Medical Centre, Nottingham NG7 2UH).

Other criteria, such as the presence or absence of oedema, slough, or granulation tissue are much less important.

### Criteria for specialist referral

The principal criterion for referral to a specialist centre

is non-healing of the ulcer, defined as failure to decrease in surface area in a 3-month period, or to heal completely in 1 year. Other acceptable criteria for referral include: (i) diagnostic uncertainty; (ii) cellulitis; (iii) arterial insufficiency; (iv) dermatitis failing to respond to moderate potency (British National Formulary group III) topical steroid; (v) suspected adverse reaction to dressings/bandages; (vi) post-healing referral for assessment for venous surgery.

### Equipment and resources

All specialized centres should have facilities for Doppler assessments, phlebography and biopsies, as well as full laboratory facilities for the exclusion of unusual causes of ulceration.

Surgical centres should also have colour flow duplex scanning, grafting facilities and plethysmography.

Dermatological centres should have full patch testing facilities (including standard and medicament batteries), and some may undertake grafting.

### Outcome

The principal aim of treatment is complete healing of the ulcer(s). It is not possible to achieve this goal in some patients, in whom limited mobility and/or the severity of complicating conditions dictate the secondary goals of relief of pain, resolution of cellulitis, control of dermatitis and complicating disorders, and improvement in social circumstances and disability.

### Statement on recurrence and prevention

Deep vein reflux can be demonstrated in approximately 50% of patients with venous leg ulcer.<sup>32</sup> In 95% reflux is due to valve damage from previous deep vein thrombosis (DVT). As a sizeable proportion of venous ulcers are due to DVT, it is likely that the prevention of DVT will prevent ulcers. The Thromboembolic Risk Factors Consensus Group's published recommendations on the identification of 'at-risk' individuals and prophylaxis of DVT<sup>33</sup> are being further developed into guidelines on the prevention of thromboembolism, implementation of which should contribute to a reduction in venous ulceration. The possible role of treatment for acute DVT in the prevention of ulceration needs to be examined by controlled studies of, for example, the use of thrombolytic drugs. There is now controlled trial evidence, from the Amsterdam Post-Thrombotic Syndrome Study, that the use of graduated compression elastic stockings may reduce the incidence of

ulceration and other late sequelae of DVT by approximately 50% (unpublished observations). In established venous hypertension where the deep veins are normal, superficial vein surgery will prevent ulceration in a high proportion of cases.

### Audit measures for venous leg ulcers

The sets of audit questions in Appendix 1 are intended to provide tools for clinical audit for anyone involved in the care of patients with leg ulcers. The most appropriate subset of questions should be chosen according to the group carrying out the audit—the emphasis will be different for community or practice nurses, general practitioners, dermatologists, surgeons, and physicians caring for the elderly. It is recommended that, where possible, the assessment should be made in the presence of the patient.

The guidelines, with an expanded set of audit tools and assessment forms, will be published in booklet form by the audit subcommittee of the British Association of Dermatologists, as a resource from which Regional Audit Groups can set standards against which to measure their practice, and derive audit protocols. The results of such audit projects contribute, along with new research, to the processes of keeping guidelines up to date and the encouragement of continuous improvement in clinical practice. We exhort colleagues to test and refine these audit tools, and to feed back their views and results.

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## Appendix 1

### Patient-centred audit measures

#### 1 Arterial supply

- 1a Have pulses been checked and found to be adequate? YES/NO

#### If the answer to 1a is NO,

- 1b Have Doppler studies been performed? YES/NO  
 1c If Doppler studies show a low pressure index (< 0.8) has the opinion of a vascular surgeon been obtained? YES/NO

#### 2 Assessment of severity

- 2a Has the size of the ulcer(s) been measured at appropriate intervals? YES/NO  
 2b Has there been complete healing of the ulcer within a year of its onset? YES/NO

#### OR

- Has there been a decrease in the size of the ulcer in the past 3 months? YES/NO

#### If the answer to 2b is NO,

- 2c Has a general medical assessment been made? YES/NO  
 2d Has specialist advice been obtained? YES/NO

#### 3 Associated medical conditions

##### In the event of non-healing

- 3a Has a full physical examination been carried out? YES/NO  
 3b Has the patient's weight been recorded? YES/NO  
 3c Has the urine been tested for glucose? YES/NO  
 3d Has a full blood count been checked? YES/NO

#### If an abnormality has been identified,

- 3e Have associated conditions been adequately investigated and treated? YES/NO

#### 4 Bandages and dressings

- 4a Was the adequacy of the arterial supply assessed before compression therapy was begun? YES/NO  
 4b Does the bandage/stocking in use give adequate compression? YES/NO

- 4c Has the bandage/stocking been properly applied to provide adequate compression? YES/NO
- 4d If the patient or a member of the family is unable to apply the bandage/stocking properly, has nursing help been arranged? YES/NO
- 4e Is the patient exercising when the bandage/stocking is in place? YES/NO

#### 5 Elevation

- 5a Are the legs being elevated above the level of the heart for at least 2 h twice daily? YES/NO

#### 6 Dermatitis

- 6a If dermatitis is resistant to a moderate potency topical steroid, has patch testing been carried out? YES/NO
- 6b Have relevant positive patch tests been recorded and communicated to all those involved in management of the ulcer? YES/NO
- 6c Are known allergens absent from topical medications, dressings, bandages and stockings? YES/NO

#### 7 Infection

- 7a Are there symptoms or signs of cellulitis? YES/NO

#### If the answer to 7a is YES,

- 7b Has a swab been taken for bacteriology? YES/NO
- 7c Has an appropriate systemic antibiotic been prescribed? YES/NO

#### 8 Pain

- 8a Does the patient complain of significant pain? YES/NO

#### If the answer to 8a is YES,

- 8b Has there been reassessment of the arterial supply? YES/NO
- 8c Has there been exclusion of infection? YES/NO
- 8d Has there been assessment of pain control? YES/NO

#### 9 Oedema

- 9a Is the leg oedematous? YES/NO

#### If the answer to 9a is YES,

- 9b Does the patient sleep all night in a chair? YES/NO
- 9c Have cardiac and other systemic causes of oedema been excluded? YES/NO
- 9d Is compression therapy adequate (in type and application)? YES/NO

#### 10 Odour

- 10a Is there an offensive odour from the ulcer? YES/NO

#### If the answer to 10a is YES,

- 10b Has appropriate treatment been offered, e.g. metronidazole or charcoal dressing? YES/NO

#### 11 Communication

- 11a Have the condition and its treatment been discussed with the patient? YES/NO
- 11b Has the patient been advised about preventive care? YES/NO
- 11c Has the patient been given written/printed guidance? YES/NO

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