

The Diagnosis and Management of Mixed Arterial/Venous Leg Ulcers in Community-based Clinics

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Objectives: to assess a management protocol for mixed arterial/venous leg ulcers in a community service

Design: two-year prospective study of outcome with intention of assessing limbs with mixed arterial/venous ulcers when managed by a new protocol.

Method: limbs were assessed for venous reflux by duplex and arterial insufficiency by ankle-brachial pressure index (ABPI) and defined into three categories ABPI > 0.85, 0.5 > ABPI ≤ 0.85 (moderate), ABPI ≤ 0.5 (severe). Four-layer compression was applied to limbs with normal arteries. Modified compression was applied to limbs with venous and moderate arterial disease with treatment failure triggering arterial imaging and revascularisation. Limbs with venous and severe arterial disease were investigated for revascularisation.

Results: of 267 consecutive limbs, 221 had pure chronic venous ulcers and 46 had mixed arterial/venous ulcers with 33 having moderate and 13 having severe arterial disease. Thirty-six week healing rates for chronic venous, moderate arterial/venous and severe arterial/venous ulcers were 70%, 64% and 23%, respectively.

Conclusion: limbs with mixed moderate arterial/venous ulcers achieved rates comparable with venous ulcers with this protocol although nurse-led surveillance was required. Limbs with mixed severe arterial/venous ulcers healed slowly despite an aggressive approach to correct arterial disease.

Key Words: Leg ulcers, Duplex; Mixed leg ulcers

Introduction

Chronic leg ulceration affects 1–2 per cent of the population and is a major cause of prolonged morbidity with frequent delay in healing and multiple recurrences.^{1–7} Significant venous disease exists in over 70 per cent of ulcerated limbs, but a variety of other aetiologies have been identified.^{8–10} Arterial disease, which may coexist with venous dysfunction, is important in over 20 per cent of affected limbs but is often underestimated.^{10–11} Correct determination of the vascular abnormalities is important as it allows a logical approach to ulcer management and influences overall prognosis.

Community leg ulcer clinics have become an effective means of delivering treatment to patients.^{3,12} The weekly application of high compression bandaging to ulcers of venous aetiology within these community clinics has significantly improved healing rates.^{5,12–14} However, application of compression therapy to venous ulcers with a component of arterial insufficiency compromises tissue viability and may cause critical

deterioration with the risk of limb loss.¹⁵ Nonetheless, modifying the amount of compression may allow successful treatment of some ulcers of mixed arterial/venous aetiology.⁵

Clinical assessments alone have proved unreliable in determining vascular abnormalities.^{15–17} More objective arterial assessment using resting ankle-brachial pressure index (ABPI) and venous assessment by colour-venous duplex ultrasonography offer validated methods of identifying vascular abnormalities and can be achieved at a one-stop clinic.¹⁸

As vascular assessment of leg ulcer patients in our previous study excluded a large number of ulcerated limbs with both arterial and venous disease,¹⁸ we defined a management protocol for ulcers of mixed aetiology with the aim of assessing whether it could be safely and effectively incorporated into our community ulcer practice.

Patients and Methods

Consecutive patients with chronic leg ulcers referred to five community-based leg ulcer clinics in East Gloucestershire were invited to attend for a one-stop non-invasive vascular assessment at Cheltenham General

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Hospital. Chronic leg ulcers were defined as >1 month duration and excluded foot ulcers. The population of East Gloucestershire was 215 289, with 39371 (18%) more than 65 years old.¹⁹ In addition to a full clinical assessment, the resting ABPI was measured by a trained specialist nurse or the vascular research fellow using a hand-held Doppler (Huntleigh, Cardiff, U.K.). Arterial disease in compressible vessels, for the purposes of this study, was classified according to the ABPI as follows: normal arteries (ABPI >0.85; group I), moderate arterial disease (0.5 <ABPI ≤0.85; group II) and severe arterial disease (ABPI ≤0.5; Group III) Venous disease was confirmed by a trained vascular technologist using colour-venous duplex ultrasonography (H.P. Sonos 2000, Hewlett Packard, Mass, U.S.A.). Deep and superficial veins were assessed above and below the knee with the patient sitting on the edge of a variable height couch with the examined limb slightly flexed.¹⁸ We defined venous reflux as significant if retrograde blood flow persisted for longer than 1s following manual calf compression and release.²⁰ The following segments of vein were imaged: common/superficial femoral, popliteal, saphenofemoral and saphenopopliteal junctions, long and short saphenous, and perforator segments

Patients with coexisting diabetes mellitus, rheumatoid arthritis or malignancy were excluded from the study. Patients with no current episode of ulceration were also protocol exclusions.

Ulcerated limbs in group I were managed with the weekly application of standard four layer graduated compression bandaging (Profore, Smith & Nephew, Hull, U.K.) and limb elevation with exercise at home. Those in group II were managed with modified compression bandaging achieved by applying the same four-layer bandaging but at half the usual stretch (25% extension) by the specialist vascular nurse and were also advised limb elevation with exercise at home.

The two compression methods were quantitated using the Oxford Talley Pressure Monitor (Talley Group Ltd, Hampshire, U.K.) in 10 limbs with full compression (50% stretch) and modified compression (25% stretch) until a repeatable reduction from 40mmHg to 30mmHg at the ankle was achieved with modified compression.²¹

During modified compression, ulcerated limbs were carefully observed for adverse effects including increasing ulcer size, development of rest pain or ulcer pain, or a reduction in a repeated ABPI measurement to ≤0.5. Development of adverse effects at any stage of treatment or failure to show signs of ulcer improvement after 3 months prompted further investigations with arteriography and consideration for

Table 1. Baseline characteristics of the three study groups (median values with range shown).

	Group I	Group II	Group III
Patients	202	30	12
Male/female	74/128	11/19	5/7
Age/years	76 (27–93)	82 (50–94)	82 (70–91)
Limbs	221	33	13
Duration/months	6 (1–480)	4 (1–108)	6 (1–240)
Recordable ABPI	1.1 (0.86–1.5)	0.73 (0.57–0.85)	0.46 (0.31–0.5)
Ulcer diameter/cm	2.5 (0.5–14)	2.5 (0.5–12)	3.5 (0.5–14)
Deep venous insufficiency	117 (53%)	5 (15%)	6 (46%)

revascularisation. Those patients with ulcerated limbs in group III were offered immediate arteriography with a view to revascularisation.

Outcome was determined by the time taken for full ulcer re-epithelialisation from the start of treatment. Pinch skin grafting was performed on all ulcers greater than 3cm diameter which failed to improve when a clean granulating base was achieved.¹⁴ Full (group I) or modified (group II) compression was applied after grafting and patients advised to elevate their limbs and limit their exercise at home. Any unusual ulcers which failed to improve by 12 weeks were biopsied to exclude malignancy.

Statistics

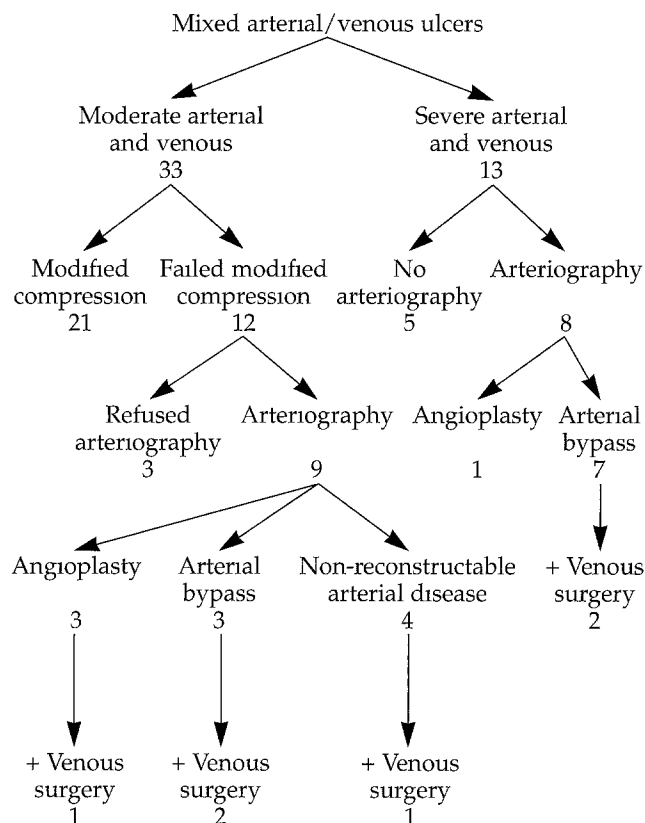
All statistical analyses were performed on a PC using the SPSS for Windows Advanced Statistical Package (version 7.0; Statistical Packages for the Social Sciences Inc, Chicago, U.S.A.) Time-dependent data was analysed by Kaplan–Meier survival analysis. Significant differences in outcome were determined with the log rank statistic.

Results

Demographic data

Three hundred and forty-five patients with 398 affected limbs were assessed during the 2 years. Two hundred and sixty-seven limbs, confirmed to have vascular abnormalities, were entered into the study. One hundred and thirty-one limbs were protocol exclusions: 32 diabetes mellitus, 33 rheumatoid arthritis, two diabetes mellitus and rheumatoid arthritis, two malignancies, 10 pure arterial, 41 healed and 11 failures to attend clinics. The baseline characteristics of all the groups are summarised in Table 1. The flow chart in Table

Table 2. Flow chart illustrating vascular intervention in the mixed arterial/venous ulcers.



Moderate arterial disease

Thirty-three limbs had ulcers with mixed venous and moderate arterial disease (group II). Twenty-one (64 per cent) healed at 36 weeks. Twelve of the 33 limbs (36 per cent) failed to improve with modified compression and arteriography was offered. Nine patients with nine ulcerated limbs agreed to proceed to arteriography. Two limbs proceeded to successful angioplasty with one having concomitant superficial venous reflux correction. Both angioplasty limbs healed at 9 and 34 weeks. Three limbs had bypass surgery, with two having their concurrent superficial venous reflux corrected. Two of the bypass limbs healed at 23 and 25 weeks but the third patient died of myocardial infarction at 18 weeks with the ulcerated limb improving. Four limbs had distal vessel disease and were not suitable for reconstruction, although one proceeded to venous surgery for superficial venous disease alone. Two of these four non-reconstructed limbs healed including the operated limb.

In the 21 limbs that improved without further investigation in group II, the mean ABPI was 0.71 ± 0.09 and eight (38 per cent) had deep venous insufficiency, whilst in the 12 that failed to improve the mean ABPI was 0.73 ± 0.09 and seven (58 per cent) had deep venous insufficiency.

2 illustrates the vascular intervention in the mixed arterial/venous ulcers. The healing rates of all the groups assessed so far are summarised in the Kaplan–Meier survival curves shown in Fig. 1.

Severe arterial disease

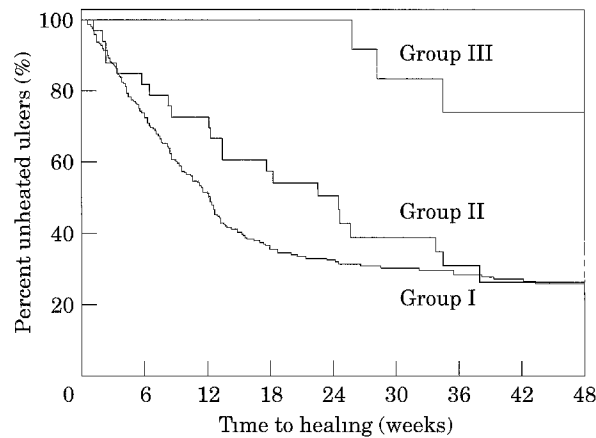
Thirteen limbs had ulcers with mixed venous and severe arterial disease (group III). Only three ulcerated limbs (23 per cent) healed at 36 weeks. One 91-year-old lady with bilateral ulceration declined arteriography with one limb healing after 28 weeks of conservative treatment, one high-risk patient was managed conservatively from the outset and two patients died prior to investigation. Thus, eight limbs underwent arteriography. One proceeded to angioplasty and is healing slowly after 28 weeks. Seven had arterial bypass, of which four healed at 26, 35, 60 and 74 weeks. Three of these limbs required femoropopliteal vein grafts and, as two of these limbs had venous reflux confined to the long saphenous vein, their venous abnormality was corrected concurrently. The other healed limb, in a patient who refused surgery for a year, underwent an emergency bypass when toe gangrene developed. The leg ulcer healed 4 weeks after surgery but the bypass failed following surgery to a fractured hip. Three bypass limbs have not healed and deep vein reflux was present in two of these cases. One femorodistal PTFE graft failed despite subsequent

Pure chronic venous ulcers

Two hundred and two patients had 221 ulcerated limbs of venous aetiology (group I). Of these limbs, 155 (70 per cent) healed at 36 weeks. Thirty-five (16 per cent) ulcers had been skin grafted.

Mixed arterial/venous ulcers

Forty-two patients had 46 ulcerated limbs of mixed arterial/venous aetiology with either moderate arterial disease or severe arterial disease. There was a trend for slower healing in the larger mixed ulcers >3cm, that is 45% versus 20% at 24 weeks; however, nine (20 per cent) ulcers had been skin grafted.



Number remaining						
Time (weeks)	0	12	24	36	48	
Group I	221	106	61	47	37	
Group II	33	22	13	7	6	
Group III	13	11	11	7	7	

Fig. 1. Differences in healing rates of mixed arterial/venous ulcers according to the management protocol based upon the degree of arterial insufficiency: group I is venous ($ABPI > 0.85$), group II is mixed arterial/venous ($0.5 < ABPI \leq 0.85$), and group III is mixed arterial/venous ($ABPI \leq 0.5$). Healing: group I versus group III, $p < 0.01$ (Kaplan-Meier, log rank test), group II versus group III, $P < 0.01$ (Kaplan-Meier, log rank test), group I versus group II, not significant.

thrombectomy and anticoagulation. The two remaining grafts remain patent with both ulcers and symptoms improved but unhealed 18 months after surgery.

Discussion

Management strategy in ulcerated limbs with different degrees of mixed arterial and venous dysfunction has not been accurately defined despite these ulcers being relatively common.⁹⁻¹⁰ The management of these ulcers provides a dilemma to the vascular surgeon – whilst improved arterial inflow is achieved by revascularising the ischaemic limb, compression therapy – the treatment of choice in those with venous ulceration – reduces arterial inflow.²² No objective data exists to guide the management of these limbs in terms of the relative importance of each process.

Poor healing of leg ulcers in the community often reflects ineffective assessment and inappropriate treatment. Our results show that arterial disease may be implicated in the aetiology of some “venous” ulcers. Our finding of mixed venous and arterial disease in 17 per cent of ulcerated limbs with a venous component is consistent with other reports.⁹⁻¹¹ Ulcerated limbs of mixed arterial/venous aetiology are now readily identified in substantial numbers following practical non-invasive arterial and venous assessment and a management strategy is required to deal with this group of patients.^{18,23}

Complete exclusion of compression therapy neglects the treatment of the venous component of mixed arterial/venous ulcers. Previous reports have shown that modified compression may promote healing in patients with mixed disease where arterial insufficiency is only moderate.^{5,24,25} However, unsupervised or inappropriate compression bandaging for the venous component may convert a moderately ischaemic limb into a critically ischaemic one.¹⁵ Management decisions regarding conservative or surgical intervention require further elucidation in these ischaemic limbs.

In our study, limbs with mixed disease were treated according to the resting ankle-brachial pressure index. Understandably, better healing occurs in limbs with venous ulcers compared to those with mixed venous/severe arterial ulcers, but improvement in healing is also observed in mixed venous/moderate arterial ulcers compared to mixed venous/severe arterial ulcers. The ABPI limits of 0.5–0.85 were selected after a literature review. An index of 0.9 is commonly used to identify significant arterial disease,^{4,11,26} but 0.8 is the lowest index recommended for full four-layer compression in the community.^{5,13} It was felt that 0.85 represented a safe compromise in our community protocol for the identification of arterial disease and the use of full compression. An index of 0.5 was the lowest published for reduced compression bandaging and indices below this (0.3–0.4) approach critically ischaemic levels.⁵ These limits were practical guidelines for safe and effective management within a com-

munity protocol and were evaluated within a full clinical assessment.

We have demonstrated that the use of modified compression bandaging under specialist nurse-led surveillance is appropriate initial treatment in the community for those limbs with mixed venous/moderate arterial ulcers. The outcome in this group was not significantly worse than that of pure venous ulcers, although a trend for slower healing was observed. No patients suffered any major adverse effects, but when limbs showed mild adverse effects with modified compression, the patients were transferred from the care of the specialist nurse in the ulcer clinic to the vascular surgeon who proceeded to arterial imaging with a view to revascularisation. The limbs that did not respond to appropriate modified compression did not have a lower ABPI than those that did improve; however, a greater proportion (58 per cent vs. 38 per cent) did have deep venous insufficiency. It may be that this group of mixed venous/moderate arterial limbs with deep venous insufficiency are a difficult group to treat with only modified compression.

Although ulcerated limbs with superficial venous reflux alone may benefit from superficial venous surgery, this was offered with caution to our patients with mixed venous/arterial ulcers to prevent the unnecessary removal of a potentially suitable conduit for possible future arterial bypass.^{27,28} In those limbs with significant arterial disease and saphenofemoral reflux, the long saphenous vein was used as the bypass conduit, thus removing an underlying cause of venous hypertension whilst improving the arterial inflow. This dual correction was possible in six of our ulcerated limbs, with five subsequently healing.

Ulcers with venous and a severe arterial component responded disappointingly slowly despite early aggressive revascularisation. This may reflect the reluctance to apply full standard compression to treat a limb with deep vein reflux after a distal arterial bypass even though the limb had been fully revascularised. Thus, the venous hypertension may have been inadequately treated even though the arterial disease had been corrected. Nevertheless, five of the 11 limbs in surviving patients did eventually heal. In principle, revascularisation of limbs with mixed arterial/venous ulcers should then facilitate the safe use of appropriate compression to manage the underlying venous disease and promote ulcer healing.

Whilst resting ankle-brachial pressure index is an acceptable and efficient means of assessing the severity of ischaemia in ulcerated limbs seen at specialised community clinics, venous duplex is essential in identifying accurately coexisting venous dysfunction

which may be present in the absence of any visible varicosities.²³ Using our ulcer management protocol, we have achieved healing rates in ulcerated limbs of mixed venous/moderate arterial aetiology comparable to those of pure venous aetiology. We have confirmed that supervised modified compression bandaging in ulcerated limbs with mixed venous and moderate arterial disease is safe and effective and may be used to select a subgroup of limbs which require further arterial intervention. The use of such defined protocols in nurse-led specialised clinics can offer a safe approach to ulcer management in the community.

Acknowledgements

The authors would like to thank the South West Regional Research & Development Directorate, Smith & Nephew U K Ltd, Medi U K Ltd and East Gloucestershire NHS Trust for their support

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Accepted 27 May 1998