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Title: Prescribing for the management of venous leg ulceration

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## **Abstract**

Venous leg ulceration affects a significant proportion of the elderly population and can have a profound impact on quality of life. Most patients with leg ulcers receive care from community nurses who are principally responsible for the prescribing decisions for managing venous leg ulceration. There is evidence to support the use of potable tap water for cleansing. To promote good venous blood flow, there is good evidence to support the use of compression bandaging or compression hosiery for all patients with adequate arterial supply to the lower leg. There is also good evidence to support the prescription of oral pentoxifylline, preferably as an adjunct to compression or, for patients unable to tolerate compression, as a stand alone therapy. The evidence base for dressings is less robust but simple low cost low adherent dressings are a reasonable first line choice for under compression.

## **Introduction**

Leg ulceration affects between 0.6% and 3.6% of the population (Graham et al., 2003) with 38% - 85% of ulcers due to venous insufficiency (Callam et al., 1987, Cornwall et al., 1986, Srinivasaiah et al., 2007, Vowden and Vowden, 2009). Venous leg ulceration (VLU) can have a profound negative impact on quality of life in terms of in terms of pain, malodour and leakage, impaired mobility, anxiety, sleep disturbance and social isolation (Briggs and Flemming, 2007) and care is costly for the NHS (Posnett and Franks, 2008). Most patients with leg ulcers receive care provided by community nurses (Posnett and Franks, 2007) and thus nurses are either responsible as a nurse prescriber or non-medical prescriber, or heavily influential, in the prescribing decisions for these patients.

Venous leg ulceration is a chronic long term condition which is characterised by one or more lesions in the lower limb due to high pressure of blood in the leg veins (British Association of Dermatologists, 2008). In the venous circulation, blood flows towards the heart in response to increased pressure from the pumping of the heart combined with the calf and foot pump mechanisms which function when the ankle flexed (such as during walking). Back flow is prevented by a series of valves within the deep, superficial or perforator vein systems but failure of these valves can cause venous overload (Morison and Moffat, 1997). Some people are born with poor valves while others acquire valve damage following venous thrombosis, limb trauma or reduced mobility due to illness, aging or an occupation which involves long periods of standing. When these valves fail to close properly there is backflow pressure which leads to increased pressure within the veins. It is not known exactly how this venous hypertension leads to skin breakdown but eventually the skin may fail to heal following an injury or it may break down spontaneously.

Interventions to promote healing can be categorised in terms of therapies to:

- Cleanse
- Promote venous blood flow
- Dress the wound bed

This article will focus on the information needed to be able to make evidence-based prescribing decisions for the management of venous leg ulceration.

## **Prescribing for Cleansing**

Venous leg ulceration is often characterised by heavy exudate which can lead to maceration and skin damage. Furthermore, venous leg ulcers often have sloughy wound beds which are thought to potentially hamper healing by becoming a focus of infection and which may act as a barrier to migration of new epithelial cells across the surface of the wound. Therefore, maintaining good hygiene of both the wound bed and the surrounding skin is regarded as good practice. Cleansing is thought to remove excessive debris that may delay healing or harbour bacteria, keep surrounding skin clean, facilitate wound assessment, minimise wound trauma when removing dressings, reduce malodour and promote patient comfort .

In terms of prescribing decisions, there is discussion around fluids for cleansing and methods of debridement. A Cochrane systematic review (Fernandez and Griffiths, 2008) which compared water with other preparations for cleansing acute wounds found no evidence to suggest that using drinkable tap water increased infection rates. Although this review focussed on acute wounds it is reasonable to apply the results to chronic wounds such as venous leg ulcers.

Wound debridement is another form of wound cleansing. Methods of debridement include the application of enzymatic agents topically to a wound bed and larvae therapy. A systematic review of found no convincing evidence that enzymatic agents are effective in reducing slough and promoting healing (Raymundo and Gray, 2008). Similarly, a large randomised controlled trial of patients with leg ulcers found that although larvae increased the rate of debridement, this was not associated with improved healing times but was linked with greater pain (Dumville et al., 2009).

## **Prescribing for Promoting Venous Blood Flow**

### *Compression*

Compression is the mainstay of treatment for managing venous leg ulceration. Compression is usually applied in the form of tight bandaging or hosiery. The aim is to apply greater pressure at the ankle than at the calf thus reversing venous hypertension and promoting blood flow back to the heart. A Cochrane systematic review (O'Meara et al., 2012) found evidence that compression more than doubles the chances of healing venous leg ulcers. It is important to note that high compression is contraindicated for patients with significant arterial disease and therefore all patients with leg ulceration should receive Doppler assessment of their ankle brachial pressure index (ABPI) to rule out significant arterial disease (SIGN, 2010). It is usually recognised as safe to apply compression to a limb with an ABPI  $\geq 0.8$  (SIGN, 2010). It is worth noting that the beginning of compression therapy can be painful and patients are likely to require analgesia to help them cope with the initial experience of compression. It has been noted that pain levels usually reduce once compression is established (Closs et al., 2008).

There are many different ways of applying compression. In the UK, elastic four-layer bandaging has become the gold standard treatment. Four-layer bandaging systems are supplied by a number of manufacturers and are available in a variety of kits to suit different ankle circumferences. On the continent, inelastic short-stretch bandaging is the standard approach. Both these methods are available for prescription in the UK along with a variety of other elastic bandages which are often

marketed as being 'easier' to apply in terms of achieving the required amount of pressure applied to the limb.

There is evidence to inform prescribing decisions about different types of compression bandaging. An earlier version of the Cochrane review cited above (O'Meara et al., 2009a) reported no difference in effectiveness between elastic systems such as four-layer bandaging and inelastic systems such as short stretch. However, a subsequent meta-analysis of patient level data (O'Meara et al., 2009b) found that ulcers healed more quickly with four-layer bandaging than with short stretch bandaging although the difference was small. The median time to healing for four-layer bandaging was 90 days compared to 99 days for short stretch which only equates to one or two more nursing visits which may not be of interest to clinicians, patients or healthcare providers.

Another recent randomised controlled trial which compared short stretch bandaging to four layer bandaging found no significant difference between the two groups in terms of time to healing, pain or health related quality of life (Harrison et al., 2011). It seems likely that the active ingredient of care is compression plus the skill of the bandager, rather than the type of bandage system. Therefore, when prescribing compression bandaging it would appear best to develop skills in a small number of bandage systems in order to maintain skill levels while offering some patient choice.

An alternative means of applying compression is through the use of compression hosiery. Compression is manufactured in a range of levels with 'Class 1' compression providing less compression than 'Grade 2' or 'Grade 3'. It is important to note that compression hosiery can be classified to British Standard or other standards: British standard is less tight than other standards. As with compression bandaging, compression hosiery is contra-indicated for patients with an ABPI < 0.8. Compression hosiery is available in a range of styles (below knee, full length, open toe etc) and sizes and colours.

A recently published randomised controlled trial compared two-layer compression hosiery with four layer bandaging for promoting healing of venous leg ulcers (Ashby et al., 2014). There was no difference in healing rates between the four-layer bandaging and the hosiery groups but more patients changed from hosiery to bandaging than from bandaging to hosiery so hosiery may be less acceptable to more patients than bandaging. It also appeared likely that hosiery is more cost-effective than four-layer bandaging. The results suggest that two-layer compression hosiery is a viable alternative to four-layer bandaging.

Intermittent pneumatic pressure (IPC) has also been proposed as a method of delivering compression to limbs. A Cochrane systematic review (Nelson et al., 2011) found evidence to suggest that IPC may lead to better healing compared to no compression but it was not clear whether there is increased healing when used as an adjuvant therapy with compression. It is possible that IPC may be useful when other forms of compression are not possible but there is insufficient evidence to recommend it as a first line treatment.

### *Oral medication*

Another approach to improving venous blood flow is through medication. Oral pentoxifylline is known to influence the blood flow of the micro-circulation and has been evaluated in a Cochrane review (Jull et al., 2012). The results found good evidence that oral pentoxifylline promotes healing

in venous leg ulceration as both an adjunct to compression bandaging and in the absence of compression bandaging. The most common side effects of oral pentoxifylline are gastro-intestinal disturbances such as nausea, indigestion and diarrhoea. Although more adverse events occurred in people receiving oral pentoxifylline and compression than in those receiving compression alone, most people were able to tolerate these side effects. The economic analysis suggests that prescribing oral pentoxifylline may be cost-effective but further research is required.

### **Prescribing Dressings**

A range of dressings have been considered for promoting healing in venous leg ulceration. Dressings are an obvious therapeutic intervention since it is customary to apply a dressing to a wound to absorb excess exudate, to protect the wound bed from physical damage and infection, and for cosmetic reasons (Bale, 1997). While compression systems cover the wound and often offer absorbency and thermal insulation, a low-adherent wound contact layer is still required to minimise the risk of the compression bandaging or hosiery sticking to the wound. Dressings impregnated with therapeutic agents may have the potential to actively promote healing.

Three Cochrane systematic reviews have considered the comparative effectiveness of dressings and topical agents. One review included comparisons of hydrocolloids, alginates, hydrogels and other miscellaneous dressings (Palfreyman et al., 2010). Hydrocolloids were reported to be no more effective than simple low adherent dressings when used under compression. There was insufficient evidence to compare other dressing types.

A second Cochrane review considered antibiotics and antiseptics for healing venous leg ulcers (O'Meara et al., 2010) but the trials of systemic antibiotics were too small to reliably detect any difference in effectiveness. The trials of topical antiseptics included one study which reported the use of cadexomer iodine to be effective in promoting healing but this intervention required daily dressings. This result is of limited usefulness in current UK community nursing practice where recommended practice is weekly reapplication of compression. An HTA review of antimicrobials is due to be published in 2015 and will update the evidence. The third Cochrane review considered the topical use of honey (Jull et al., 2013) but found no evidence that honey significantly increased healing when used as an adjunct to compression bandaging.

Therefore, at present no particular type of dressing is supported by research findings and this coupled with concerns about the increasing problem of bacterial resistance to antibiotics (O'Meara et al., 2010) and the increased risk of allergy in patients with venous leg ulceration (Cameron, 1998) supports the use of simple, low cost, low adherent dressings under compression.

### **Conclusion**

In conclusion, an evidence-based approach to prescribing for venous leg ulceration might take a tiered approach. With regard to cleansing, there is no evidence to support the use of fluids other than potable tap water although sterile fluids may be preferred for patients with compromised immunity. With regard to promoting blood flow, all patients with adequate arterial supply to the lower leg should be offered high compression therapy but the choice of type of compression should be negotiated between the patient and the clinician. It is likely that patients commencing compression therapy will require analgesia. Oral pentoxifylline is likely to be a clinically and cost

effective treatment both as an adjunct to compression or alone for patients unable to tolerate compression. With regard to dressings, simple low cost low adherent dressings are a reasonable first line choice for under compression. Together, these therapies offer an evidence-based approach to prescribing for venous leg ulceration which is likely to benefit patients, clinicians and health care providers.

### Key points

1. Potable tap water will usually be adequate for wound cleansing
2. Compression therapy should be offered to all patients with an ABPI  $\geq 0.8$
3. Compression bandaging and two-layer compression hosiery appear to be equally effective in promoting healing
4. Oral pentoxifylline is effective for promoting healing
5. Simple low cost, low adherent dressings are a reasonable first line choice for under compression.

### Key words

- Leg Ulcer
- Varicose ulcer
- Skin ulcer
- Compression bandages
- Compression
- Stockings

### Further reading

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