

Innovations in venous leg ulcer management



Author:
Hugo Partsch

This paper describes recent research in the field of venous leg ulcer management. It provides an overview of the most important randomised clinical trials and meta-analyses of studies in this specialty. It suggests that compression therapy remains the most effective treatment, but that clinicians should be open to other therapies, particularly those that seek to correct an individual's underlying condition and prevent recurrence.

References

1. Perrin, M. Rationale for surgery in the treatment of venous ulcer of the leg. *Phlebology* 2004; 45: 276-80.
2. Humphreys ML, Stewart AH, Gohel MS, et al. Management of mixed arterial and venous leg ulcers. *Br J Surg* 2007; 94(9): 1104-7.
3. O'Meara S, Cullum NA, Nelson EA. Compression for venous leg ulcers. *Cochrane Database Syst Rev* 2009; 1: CD000265.
4. Leaper D. Evidence-based wound care in the UK. *Int Wound J* 2009; 6(2): 89-91.
5. Harding K, Queen D. Cochrane's legacy and its impact on wound care. *Int Wound J* 2009; 6(5): 316-7.
6. Amsler F, Willenberg T, Blättler W. In search of optimal compression therapy for venous leg ulcers: a meta-analysis of studies comparing diverse bandages with specifically designed stockings. *J Vasc Surg* 2009; 50(3): 668-74.
7. Partsch H, Horakova MA. [Compression stockings in treatment of lower leg venous ulcer.] [Article in German] *Wien Med Wochenschr* 1994; 144(10-11): 242-9.
8. Milic DJ, Zivic SS, Bogdanovic DC, et al. The influence of different sub-bandage pressure values on venous leg ulcers healing when treated with compression therapy. *J Vasc Surg* 2010; 51(3): 655-61.

INTRODUCTION

The majority of venous leg ulcers are characterised by venous reflux and/or obstruction, impeding normal venous return from the lower extremities. Duplex examinations have demonstrated reflux in approximately 80% of leg ulcer patients, half in the superficial venous system only and half with additional deep reflux^[1]. Additional incompetent perforators are frequent, while isolated perforator incompetence is rare. 'Hydrostatic' leg ulcers without venous reflux and/or obstruction, for example in morbidly obese patients, may also be considered as 'venous' ulceration. About 15% of patients with venous leg ulcers have concomitant arterial occlusive disease, and their ulcers are commonly termed 'mixed'^[2].

Research developments

Several studies have recently been published highlighting best clinical practice in venous leg ulcer management.

There is level 1 evidence of the efficacy of compression (using bandages or stockings) in achieving ulcer healing, as well as in maintaining healing. In a Cochrane review, 39 randomised controlled trials (RCTs) reported on 47 comparisons of treatments. The authors concluded:

- Compression increases ulcer healing rates compared with no compression
- Multi-component systems are more effective than single-component systems
- Multi-component systems containing an elastic bandage appeared more effective than those composed mainly of inelastic constituents^[3].

A stimulating discussion has been started concerning the principal question of whether wound-healing RCTs lead to better care of the individual patient^[4,5].

Some problems with meta-analyses are also evident from a recent paper that concluded that 'leg compression with stockings is clearly better than compression with bandages, has a positive impact on pain, and is easier to use'^[6]. Such generalising statements need to be regarded with suspicion.

On analysing the article, it was found that some of the quoted studies were wrongly described and that, in most of the trials reported, good compression stockings had been compared with inadequate bandages. However, the concept of applying two stockings on top of each other is a pragmatic solution for many patients with small ulcers for whom self-management is a preferable option^[7]. The basic 'liner' keeps the wound dressing in place and stays in place day and night on the leg; the outer stocking is worn during the daytime only and provides a certain amount of pressure.

In an RCT involving 132 patients with large and long-standing leg ulcers, Milic and co-workers compared:

- **Group A: compression stockings**
- **Group B: compression stockings plus one compression bandage**
- **Group C: compression stockings plus two compression bandages^[8].**

The authors found that the healing rate after 26 weeks was correlated with the bandage pressure: the highest healing rate (74%) was seen in group C (resting pressure 74mmHg), while the lowest (25%) was seen in group A (resting pressure 36mmHg)^[8].

In another Cochrane review including seven RCTs and involving 367 people, the efficacy of intermittent pneumatic compression (IPC) for ulcer healing was analysed^[9]. The authors concluded that IPC may increase healing compared with no compression, but that it is not clear whether it increases healing when added to treatment with bandages, or if it can be used instead of compression bandages. Rapid IPC was more effective than slow IPC in one trial^[9].

In a study comprising 2011 consecutive ulcerated legs, 15 (8%) had a reduced ankle-brachial pressure index (ABPI) of <0.8. Supervised modified compression and selective revascularisation achieved good healing rates for mixed arterial and venous leg ulceration^[2].

A meta-analysis looking at the efficacy of local wound management could not demonstrate that a particular dressing type was more effective in speeding up ulcer healing^[10]. A systematic review reported that some growth factors and tissue-engineered artificial skin products may have favourable cost-effectiveness ratios in selected patient groups with chronic ulcers^[11].

Further studies have shown that frequent debridement may increase wound healing rates and rates of closure^[12] and that some drugs such as diosmin and micronised purified flavonoid fraction or pentoxifyllin may help to promote leg ulcer healing^[13].

Cochrane reviews regarding the effects of electromagnetic therapy^[14], low level laser therapy^[15] and hyperbaric oxygen therapy^[16] did not find reliable evidence to show that any of these methods were beneficial. Some weak evidence was found that ultrasound therapy could increase the healing of venous leg ulcers^[17].

Important clinical guidance

Position documents and guidelines regarding best clinical practice in managing venous leg ulcers have been published^[18,19]. Guidelines have also been developed for the important problem of how venous ulcers should be prevented^[20].

Proposals concerning a classification of compression bandages for use in clinical practice have been made by a group of experts with the aim of finding a common language in defining pressure, layers, components and the elastic property of different compression materials (PLaCE)^[21].

Research points

1. There is level 1 evidence of the efficacy of compression bandaging and stockings in achieving healing of venous leg ulcers
2. Multi-component compression systems are more effective than single-component systems
3. Clinical studies have reported a higher bandage pressure is correlated with a higher healing rate in patients with longstanding ulcers
4. A systematic review has reported that some advanced wound therapies may provide cost-effective treatment in selected patients
5. There are proposals for a classification of compression bandaging using a common language
6. Case studies have reported that, in patients with superficial saphenous reflux, surgery or other less invasive interventions to prevent reflux may promote ulcer healing and/or prevent recurrence when combined with compression
7. Accurate diagnosis of underlying vascular pathology has led to more targeted treatment
8. New compression devices and research into advanced wound care therapies and surgical approaches will lead to improved treatment and reduction in incidence of venous leg ulcers

References

9. Nelson EA, Mani R, Vowden K. Intermittent pneumatic compression for treating venous leg ulcers. *Cochrane Database Syst Rev* 2008; 2: CD001899.
10. Palfreyman S, Nelson EA, Michaels JA. Dressings for venous leg ulcers: systematic review and meta-analysis. *BMJ* 2007; 335(7613): 244.
11. Langer A, Rogowski W. Systematic review of economic evaluations of human cell-derived wound care products for the treatment of venous leg and diabetic foot ulcers. *BMC Health Serv Res* 2009; 9: 115.
12. Cardinal M, Eisenbud DE, Armstrong DG, et al. Serial surgical debridement: a retrospective study on clinical outcomes in chronic lower extremity wounds. *Wound Repair Regen* 2009; 17(3): 306-11.
13. Nicolaidis AN, Allegra C, Bergan J, et al. Management of chronic venous disorders of the lower limbs: guidelines according to scientific evidence. *Int Angiol* 2008; 27(1): 1-59.
14. Ravaghi H, Flemming K, Cullum NA, Olyae Manesh A. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev* 2006; 2: CD002933.
15. Flemming K, Cullum NA. Laser therapy for venous leg ulcers. *Cochrane Database Syst Rev* 1999; 1: CD001182.
16. Kranke P, Bennett MH, Debus SE, et al. Hyperbaric oxygen therapy for chronic wounds. *Cochrane Database Syst Rev* 2004; 1: CD004123.
17. Al-Kurdi D, Bell-Syer SEM, Flemming K. Therapeutic ultrasound for venous leg ulcers. *Cochrane Database Syst Rev* 2008; 1: CD001180.
18. World Union of Wound Healing Societies (WUWHS). *Principles of Best Practice: Compression in venous leg ulcers. A consensus document*. London: MEP Ltd, 2008.
19. Barrett S, Cassidy I, Graham MM. National survey of Irish community nurses' leg ulcer management practices and knowledge. *J Wound Care* 2009; 18(5): 181-6.
20. Robson MC, Cooper DM, Aslam R, et al. Guidelines for the prevention of venous ulcers. *Wound Repair Regen* 2008; 16(2): 147-50.
21. Partsch H, Clark M, Mosti G, et al. Classification of compression bandages: practical aspects. *Dermatol Surg* 2008; 34(5): 600-9.

References

22. Bergan JJ, Schmid-Schönbein GW, Coleridge-Smith PD, et al. Chronic venous disease. *N Engl J Med* 2006; 355(5): 488-98.
23. Danielsson G, Arfvidsson B, Eklof B, et al. Reflux from thigh to calf, the major pathology in chronic venous ulcer disease: surgery indicated in the majority of patients. *Vasc Endovascular Surg* 2004; 38(3): 209-19.
24. Schmeller W, Gaber Y. Surgical removal of ulcer and lipodermatosclerosis followed by split-skin grafting (shave therapy) yields good long-term results in 'non-healing' venous leg ulcers. *Acta Derm Venereol* 2000; 80(4): 267-71.
25. Obermayer A, Göstl K, Walli G, Benesch T. Chronic venous leg ulcers benefit from surgery: long-term results from 173 legs. *J Vasc Surg* 2006; 44(3): 572-9.
26. Obermayer A, Göstl K, Partsch H, Benesch T. Venous reflux surgery promotes venous leg ulcer healing despite reduced ankle brachial pressure index. *Int Angiol* 2008; 27(3): 239-46.
27. Gohel MS, Barwell JR, Taylor M, et al. Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial. *BMJ* 2007; 335(7610): 83.
28. Darvall KA, Bate GR, Adam DJ, et al. Ultrasound-guided foam sclerotherapy for the treatment of chronic venous ulceration: a preliminary study. *Eur J Vasc Endovasc Surg* 2009; 38(6): 764-9.
29. O'Hare JL, Earnshaw JJ. Randomised clinical trial of foam sclerotherapy for patients with a venous leg ulcer. *Eur J Vasc Endovasc Surg* 2010; 39(4): 495-9.
30. 6th Pacific Vascular Symposium, Hawaii, November 2009. *J Vasc Surg* (Suppl). In press.

Main innovations

Promising new concepts concerning a more rational treatment of venous leg ulcers are based on the fact that more than 80% of venous leg ulcers present with superficial valve incompetence, creating an axial reflux projecting into the ulcer area^[22].

Case series have shown that patients with superficial saphenous reflux, with or without perforation and deep vein incompetence, may benefit from the prevention of superficial venous reflux by surgery or other interventional methods^[23]. Additional ulcer excision or 'shaving' of the ulcer bed^[24], with skin grafting, accelerates ulcer healing^[25].

Favourable results have even been found in patients with mixed ulceration and with a reduced ABPI after such procedures^[26].

One RCT revealed that reflux surgery alone does not shorten ulcer healing time but is effective at preventing recurrence after healing with compression^[27].

A less invasive method to abolish venous reflux is foam sclerotherapy performed under ultrasound guidance. This method can be undertaken in an adequately equipped medical practice and is a feasible adjunct to compression therapy for venous ulcers^[28, 29].

The use of Duplex ultrasound to provide a clear diagnosis of venous reflux is a diagnostic prerequisite to all these procedures.

Developments that changed my practice

A detailed diagnosis of the underlying vascular pathology has led to more targeted treatment.

The wide spectrum of differential diagnoses of leg ulcers requires treatment strategies that can be adjusted to the main components of the underlying disease in each individual patient. Therefore a proper diagnosis is essential in patients with open wounds. Doppler ultrasound is very helpful for assessing the main vascular components causing venous, arterial or mixed leg ulcers [Fig 1]. Experienced investigators are able to use simple pocket Doppler instruments not only for the assessment of the arterial inflow, but also for screening of refluxes in the veins. Referral to specialised centres is usually necessary in order to clearly localise arterial occlusions and/or venous flow abnormalities and to propose adequate therapeutic solutions.

Since compression therapy counteracts gravity it will continue to be the gold standard treatment for most leg ulcers. However, its routine use should not prevent the use of

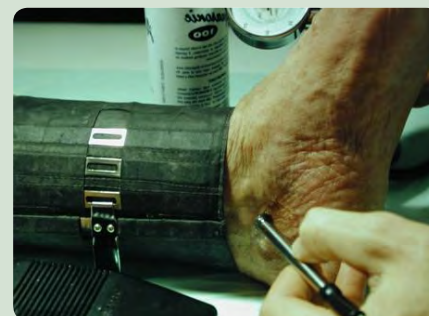


Figure 1 – Doppler ultrasound can be used for the measurement of the arterial systolic ankle pressure (see above) and also for the detection of venous flow and venous refluxes

additional therapeutic modalities that may treat the patient's condition by correcting the underlying problem.

FUTURE FOCUS

New compression devices allowing the application of standardised pressure in a sustained and intermittent mode are being developed. Basic research is under way concerning gene therapy, growth factors and bioengineered skin substitutes. A recent initiative led by a group of vascular surgeons in the US has proposed to reduce the incidence of venous ulcers in the next ten years to one half by the introduction of several measures^[30]. Two main targets in this plan are:

- **The reduction of post-thrombotic syndrome using better treatment modalities for deep vein thrombosis in the acute phase and improvement of the compliance with compression for the following years.**
- **Earlier and better treatment of severe disturbances of venous drainage by eradication of venous reflux and desobliteration of outflow obstructions.**

AUTHOR DETAILS

Hugo Partsch, Professor of Dermatology, University of Vienna, Austria.

Useful links and further reading

- EWMA Position Document. Understanding Compression Therapy
- WUWHS. Principles of best practice: Compression in venous leg ulcers