

Landmark EVRA trial: the evidence for interventional venous leg ulcer management



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The results of the Early Venous Reflux Ablation (EVRA) trial were presented last month in London (Gohel et al, 2018). The world of venous leg ulcer (VLU) management has finally gained significant Level 1 evidence with the potential to change future practice. EVRA's primary outcome was to research the effects of venous intervention on ulcer healing. The main conclusions were that early venous ablation of superficial venous reflux resulted in faster healing of VLUs, increased time free from ulceration and significant cost savings. These are important outcomes for patients, healthcare professionals and commissioners.

WHAT IS EVRA?

The EVRA trial was a non-commercial study conducted in 20 NHS centres across the UK. It randomised 450 patients with active venous ulceration of less than 6 months duration in two groups; the first received therapeutic compression therapy and early endovenous intervention within 2 weeks of randomisation and the other group received compression alone. They received deferred venous ablation once healed. The high-quality data produced from the trial clearly demonstrate that receiving early endovenous intervention outperforms conservative management and deferred treatment, with regards to healing times.

INTERVENTIONAL MANAGEMENT

Modern endovenous ablation techniques, such as radiofrequency ablation, endovenous laser therapy and ultrasound-guided foam sclerotherapy have essentially replaced traditional varicose veins surgery over the last decade (Gohel, 2015). These are straightforward, minimally invasive techniques, that are usually performed under local anaesthesia in an outpatient setting, and do not require any convalescence period. Subsequently, they have allowed a wider group of patients, especially the elderly, to receive treatment of their

superficial venous reflux. Not every individual referred with venous leg ulceration will require, be suitable for or indeed wish to proceed with endovenous intervention. Assessment with duplex colour ultrasound would determine if the underlying problem was a superficial or a deep venous problem, or a combination of both. If their subsequent management remained conservative in practice, then they could be prescribed a therapeutic level of compression to facilitate effective healing, and their long-term compression needs assessing to help prevent recurrence.

The ESCHAR trial (Gohel et al, 2007) previously demonstrated that surgical correction of superficial venous reflux reduced the recurrence of ulcers at 4 years and a greater time free from ulceration. Conservative compression therapy has been the mainstay of VLU management for many years and this is reflected in National Policies and pathways (Scottish Intercollegiate Guidelines Network, 2010). Although compression therapy temporarily treats venous hypertension and improves ulcer healing rates, it does not permanently treat the underlying cause of venous hypertension, and that is an important consideration for clinicians. We must consider that recurrence in this group of patients remains high and concordance with long-term compression hosiery is often poor (Carpentier et al, 2011).

THE IMPORTANCE OF EARLY REFERRAL

The National Institute for Health and Care Excellence (NICE, 2013) advocated early referral of patients with VLUs to a vascular specialist within 2 weeks. A third of the patients screened for the EVRA trial had had ulceration for greater than 6 months before being referred to secondary care. The usual pathway for a patient with a VLU is conservative management in primary care. Early onward referral to secondary care for interventional management is not always

standard practice and is inconsistently applied. The recent NHS RightCare Pathway of *Betty's Story* (NHS England, 2017) was introduced to reduce unwarranted variation in care and brought national recognition of the potential impact of mismanagement of VLUs both in terms of quality of life and costs. Betty's story highlights that some patients do not receive therapeutic compression in a timely manner and are subject to sub-optimal wound care. Only at the end of this story does the practice nurse mention the possibility of venous intervention. Evidence from Guest et al (2015) highlighted that too many patients languish in sub-optimal compression without a clear diagnosis in primary care. The evidence from EVRA now challenges this conservative management.

CALLING FOR A CHANGE IN PRACTICE

The use of venous intervention has often been previously considered to be of low value for varicose veins and chronic venous disease and is, indeed, considerably rationed in many areas of the UK. Patients with venous bleeding from varicose veins are usually referred and swiftly treated in secondary care. In the light of the EVRA results, this situation must now be challenged by healthcare professionals and patients to empower a change in routine practice. On clinical examination, patients with VLUs may not have obvious varicose veins but may have significant underlying truncal incompetence, and this can only be assessed with colour duplex ultrasound, to aid diagnosis and management.

Venous disease is a chronic condition that is often progressive in nature and wellrepresented by the Clinical, Etiology, Anatomy, Pathophysiology (CEAP) classification (Eklöf et al, 2004). The endpoint of this continuum is ulceration or tissue loss, which should be considered and subsequently treated as a clinical priority with a clear well-defined prescriptive care pathway for patients, ensuring that evidence-based care is integrated into clinical practice. The recent Best Practice Document (Wounds UK, 2016) provides an excellent summary of VLU management for healthcare professionals and alludes to vascular referral if healing has not occurred somewhere between 4 and 12 weeks. This could now be

consequently reviewed in the light of the EVRA results to provide further clarity regarding onward vascular referral.

WHAT NOW?

The results from the EVRA trial clearly provide the evidence to be prescriptive in our daily practice and must empower clinicians and patients to embrace and call for change in practice. A future challenge will be if vascular services in secondary care are prepared and able to meet this major change in management. The unequivocal evidence, now before us as practitioners, means that standard or best practice VLU management must be early endovenous ablation combined with therapeutic compression.



REFERENCES

- Carpentier PH, Becker F, Thiney G et al (2011) Acceptability and practicability of elastic compression stockings in the elderly: a randomized controlled evaluation. *Phlebology* 26(3): 107–13
- Eklöf BG, Rutherford RB, Bergan JJ et al (2004) Revision of the CEAP classification for chronic venous disorders: Consensus statement. *J Vasc Surg* 40(6): 1248–52
- Gohel MS, Barwell JR, Taylor M et al (2007) Long-term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial. *BMJ* 335(7610): 83
- Gohel MS (2015) *Endovenous Treatment Options in Patients with Chronic Venous Disease and Lower Limb Ulcers*. Available at: <https://www.wounds-uk.com/resources/details/endovenous-treatment-options-in-patients-with-chronic-venous-disease-and-lower-limb-ulcers> (accessed 06.05.2018)
- Gohel MS, Heatley F, Liu X et al (2018) *A Randomized Trial of Early Endovenous Ablation in Venous Ulceration*. Available at: <https://www.nejm-org.plymouth.idm.oclc.org/doi/pdf/10.1056/NEJMoa1801214> (accessed 06.05.2018)
- Guest JF, Ayoub N, McIlwraith T et al (2015) Health economic burden that wounds impose on the National Health Service in the UK. *BMJ Open* 5(12): e009283
- NHS England (2017) *NHS RightCare Scenario: The Variation Between Sub-optimal and Optimal Pathways Betty's Story: Leg Ulcer Wound Care*. Available at: <https://www.england.nhs.uk/rightcare/wp-content/uploads/sites/40/2017/01/nhs-rightcare-betys-story-narrative-full.pdf> (accessed 06.05.2018)
- National Institute of Health and Care Excellence (2013) *Varicose Veins in the Legs. Clinical Guideline 168*. Available at: <https://www.nice.org.uk/guidance/cg168> (accessed 06.05.2018)
- Scottish Intercollegiate Guidelines Network (2010) *Management of Chronic Venous Leg Ulcers. Clinical Guideline No. 120* at: <http://www.sign.ac.uk/assets/sign120.pdf> (accessed 06.05.2018)
- Wounds UK (2016) *Best Practice Statement: Holistic Management of Venous Leg Ulceration*. Available at: <https://www.wounds-uk.com/resources/details/best-practice-statement-holistic-management-of-venous-leg-ulceration> (accessed 27.06.2018)

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