

Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins

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Background: This randomized trial compared four treatments for varicose great saphenous veins (GSVs).

Methods: Five hundred consecutive patients (580 legs) with GSV reflux were randomized to endovenous laser ablation (980 and 1470 nm, bare fibre), radiofrequency ablation, ultrasound-guided foam sclerotherapy or surgical stripping using tumescent local anaesthesia with light sedation. Miniphlebectomies were also performed. The patients were examined with duplex imaging before surgery, and after 3 days, 1 month and 1 year.

Results: At 1 year, seven (5.8 per cent), six (4.8 per cent), 20 (16.3 per cent) and four (4.8 per cent) of the GSVs were patent and refluxing in the laser, radiofrequency, foam and stripping groups respectively ($P < 0.001$). One patient developed a pulmonary embolus after foam sclerotherapy and one a deep vein thrombosis after surgical stripping. No other major complications were recorded. The mean(s.d.) postintervention pain scores (scale 0–10) were 2.58(2.41), 1.21(1.72), 1.60(2.04) and 2.25(2.23) respectively ($P < 0.001$). The median (range) time to return to normal function was 2 (0–25), 1 (0–30), 1 (0–30) and 4 (0–30) days respectively ($P < 0.001$). The time off work, corrected for weekends, was 3.6 (0–46), 2.9 (0–14), 2.9 (0–33) and 4.3 (0–42) days respectively ($P < 0.001$). Disease-specific quality-of-life and Short Form 36 (SF-36[®]) scores had improved in all groups by 1-year follow-up. In the SF-36[®] domains bodily pain and physical functioning, the radiofrequency and foam groups performed better in the short term than the others.

Conclusion: All treatments were efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping.



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Introduction

Varicose veins are common and affect approximately 25 per cent of Western adults¹. The condition is most often associated with great saphenous vein (GSV) reflux. Until recently, standard treatment has been surgery, with high ligation and stripping to knee level, combined with phlebectomies. Such treatment efficiently reduces symptoms, improves quality of life (QoL), and reduces the rate of reoperation compared with high ligation and phlebectomies only^{2–4}. However, the operation may occasionally be associated with significant postoperative morbidity, including bleeding, groin infection, thrombophlebitis and saphenous nerve

damage. Major complications are rare⁵. Conventional surgery is most often performed in hospital and using general or regional anaesthesia, which may increase costs.

In the past decade, alternative treatments such as endovenous ablation of the GSV with laser (EVLA), radiofrequency ablation (RFA) and ultrasound-guided foam sclerotherapy (UGFS) have gained popularity. Performed as office-based procedures using tumescent local anaesthesia, the new minimally invasive techniques have been shown in numerous studies to eliminate the GSV from the circulation safely and effectively^{6–9}. A few randomized trials have compared the endovascular methods with conventional surgery. The first-generation RFA device, VNUS