

FOCUS ON : FLEBOLOGIA

Le procedure interventistiche

Ruggiero CURCI

Direttore UOC di chirurgia vascolare ed endovascolare

ASST Lodi

Ospedale Maggiore



Efficacia
Tollerabilità
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Costo

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e della
Società Italiana di Flebologia



SICVE

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Raccomandazione 12.1.2

Per le varici degli arti inferiori è indicato lo stripping radicale della safena interna/esterna in caso di incontinenza safenica e/o di varici extrasafeniche. In caso di safena interna incontinente è da preferire, se possibile, lo stripping corto fino sopra o sotto il ginocchio, associato o meno a varicectomie extrasafeniche. Qualora lo stripping radicale non sia possibile per motivi tecnici, è indicata la crossectomia safenica con varicectomie.

Classe IIa, Livello B

Raccomandazione 12.1.3

Per le varici degli arti inferiori da incontinenza della safena, in alternativa allo stripping, in centri e con operatori con adeguata esperienza, in casi selezionati può essere indicato l'intervento termoablattivo, meno invasivo, mediante laser o radiofrequenza.

Classe IIa, Livello B

Raccomandazione 12.1.4

Per le varici degli arti inferiori da incontinenza della safena, in alternativa allo stripping, in centri e con operatori con adeguata esperienza, in casi selezionati può essere indicato l'intervento di CHIVA, la valvuloplastica esterna safeno-femorale e/o legatura di perforanti, associato o meno a varicectomie.

Classe IIa, Livello C

Raccomandazione 12.1.5

L'intervento di CHIVA non è indicato in caso di safena di calibro giudicato eccessivo alla coscia o aplasica/ipoplasica nel tratto sottostante all'origine delle collaterali.

Classe III, Livello C



The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II

Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine

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Continued

1. Evaluation of patients with varicose veins			
Consensus statements			
151.	In asymptomatic patients with telangiectasias or reticular veins (CEAP Class C1) DUS evaluation of the lower extremity veins should not be routinely performed, since testing could result in unnecessary saphenous vein ablation procedures.		
152.	In symptomatic CEAP Class C1 patients with bleeding or with severe symptoms of pain or burning due to moderate to severe telangiectasias or reticular veins, DUS evaluation may be performed to exclude associated venous incompetence; however, saphenous ablation for C1 disease without bleeding is rarely required.		
153.	In symptomatic patients with varicose veins (CEAP Class C2) the deep venous system should be routinely evaluated for infrainguinal obstruction or valvular incompetence		
154.	In symptomatic patients with varicose veins (CEAP Class C2) evaluation for iliofemoral venous obstruction with DUS or with other imaging studies should be performed if suprapubic or abdominal wall varicosities are present and in patients with symptoms of proximal obstruction, including thigh and leg fullness, heaviness, swelling and venous claudication. CEAP Classes 3-6 warrant DUS or other imaging studies to evaluate for iliofemoral obstruction.		
155.	In patients with medial thigh or vulvar varicosities evaluation of pelvic venous pathology with DUS or other imaging studies is not indicated if they have no symptoms of pelvic venous disease.		
2. Compression therapy			
2.1 Compression therapy vs. intervention			
Guidelines		Grade of recommendation	Quality of Evidence
2.11.	For patients with symptomatic varicose veins and axial reflux in the superficial truncal veins, we suggest compression therapy for primary treatment if the patient's ambulatory status and/or underlying medical conditions warrant a conservative approach, or if the patient prefers conservative treatment for either a trial period or definitive management.	2 (weak)	C (low to very low)
2.12.	For patients with symptomatic varicose veins and axial reflux in the GSV or SSV who are candidates for intervention, we recommend superficial venous intervention over long-term compression stockings.	1 (strong)	B (moderate)
2.13.	For patients with symptomatic varicose veins and axial reflux in the AAGSV or PAGSV, who are candidates for intervention, we suggest superficial venous intervention over long-term compression stockings.	2 (weak)	C (low to very low)
2.14.	In patients with symptomatic varicose veins who are candidates for endovenous therapy and wish to proceed with treatment, we suggest against a 3-month trial of compression therapy before intervention.	2 (weak)	B (moderate)
2.2 Compression therapy after intervention			
2.21.	In patients undergoing thermal ablation for saphenous incompetence, with or without concomitant phlebectomy, we suggest postprocedure compression therapy for a minimum of 1 week for pain reduction.	2 (weak)	B (moderate)
3. Pharmacological treatment			
Guidelines		Grade of recommendation	Quality of Evidence
31.	In symptomatic patients with varicose veins who are not candidates for intervention, or who are waiting for intervention or have symptoms after intervention, we suggest micronized purified flavonoid fraction or Ruscus extracts for treatment of vein-related pain, leg heaviness and/or sensation of swelling.*	2 (weak)	B (moderate)
32.	In symptomatic patients with varicose veins who are not candidates for intervention, or who are waiting for intervention or have symptoms after intervention, we suggest hydroxyethylrutosides, calcium dobesilate, horse chestnut extract, red vine leaf extract, or sulodexide for treatment of vein-related pain, leg heaviness, night cramps and/or sensation of swelling.*	2 (weak)	C (low to very low)
*These products are not approved drugs by the U.S. Food and Drug Administration (FDA). The FDA does not approve medical food or nutritional supplements (https://www.fda.gov).			
4.1. Endovenous ablation vs high ligation and stripping (HLAS)			
Guidelines		Grade of recommendation	Quality of Evidence
4.11.	For patients with symptomatic varicose veins and axial reflux in the GSV, who are candidates for intervention, we recommend treatment with endovenous ablation over HLAS of the GSV.	1 (strong)	B (moderate)

(Continued on next page)



Review

A Systematic Review and Meta-analysis of Randomised Controlled Trials Comparing Endovenous Ablation and Surgical Intervention in Patients with Varicose Vein **CME**

B. Siribumrungwong^{a,b}, P. Noorit^c, C. Wilasrusmee^d, J. Attia^e, A. Thakkestian^{a,*}^a Section for Clinical Epidemiology and Biostatistics, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Rama VI Road, Rachatevi, Bangkok, 10400, Thailand^b Department of Surgery, Faculty of Medicine, Thammasat University Hospital, Thammasat University (Bangsit Campus), Pathumtani, Thailand^c Department of Surgery, Chonburi Hospital, Chonburi, Thailand^d Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand^e Center for Clinical Epidemiology and Biostatistics, The University of Newcastle, Newcastle, NSW, Australia**WHAT THIS PAPER ADDS**

- A systematic review and meta-analysis of randomised controlled trials was conducted, which aim to compare clinical outcomes between concurrent minimally invasive procedures and surgery for treating varicose veins. All relevant randomised controlled trials published up to August 2011 were included. Treatment comparisons were endovenous laser ablation, radiofrequency ablation, ultrasound-guided foam sclerotherapy and surgery. Clinical relevant outcomes, that is, primary failure, clinical recurrence, post-operative complications, pain and return to normal activities were covered. Evidence and recommendation suggested from our study were provided.

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Endovenous laser

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Recurrence

Complication

Systematic review

Meta-analysis

ABSTRACT

Objectives and design: A systematic review and meta-analysis was conducted to compare clinical outcomes between endovenous laser ablation (EVLA), radiofrequency ablation (RFA), ultrasound-guided foam sclerotherapy (UGFS) and surgery.

Methods: We searched MEDLINE and Scopus from 2000 to August 2011 to identify randomised controlled trials (RCTs) comparing EVLA, RFA, UGFS, and surgery or combinations of these for treatment of varicose veins. Differences in clinical outcomes were expressed as pooled risk ratio and unstandardised mean difference for dichotomous and continuous outcomes, respectively. Methodological quality was assessed using Cochrane tools.

Results: Twenty-eight RCTs were included. The primary failure and clinical recurrences were not significantly different between EVLA and RFA versus surgery with the pooled RR of 1.5 (95%CI: 0.7, 3.0) and 1.3 (95%CI: 0.7, 2.4) respectively for primary failure, and, 0.6 (95%CI: 0.3, 1.1) and 0.9 (95%CI: 0.6, 1.4) respectively for clinical recurrences. The endovenous techniques had advantages over surgery in lowering wound infections (RR = 0.3 (95%CI: 0.1, 0.8) for EVLA), haematoma (RR = 0.5 (95%CI: 0.3, 0.8) and 0.4 (95%CI: 0.1, 0.8) for EVLA and RFA), and return to normal activities or work (mean differences = -4.9 days (95%CI: -7.1, -2.7) for RFA).

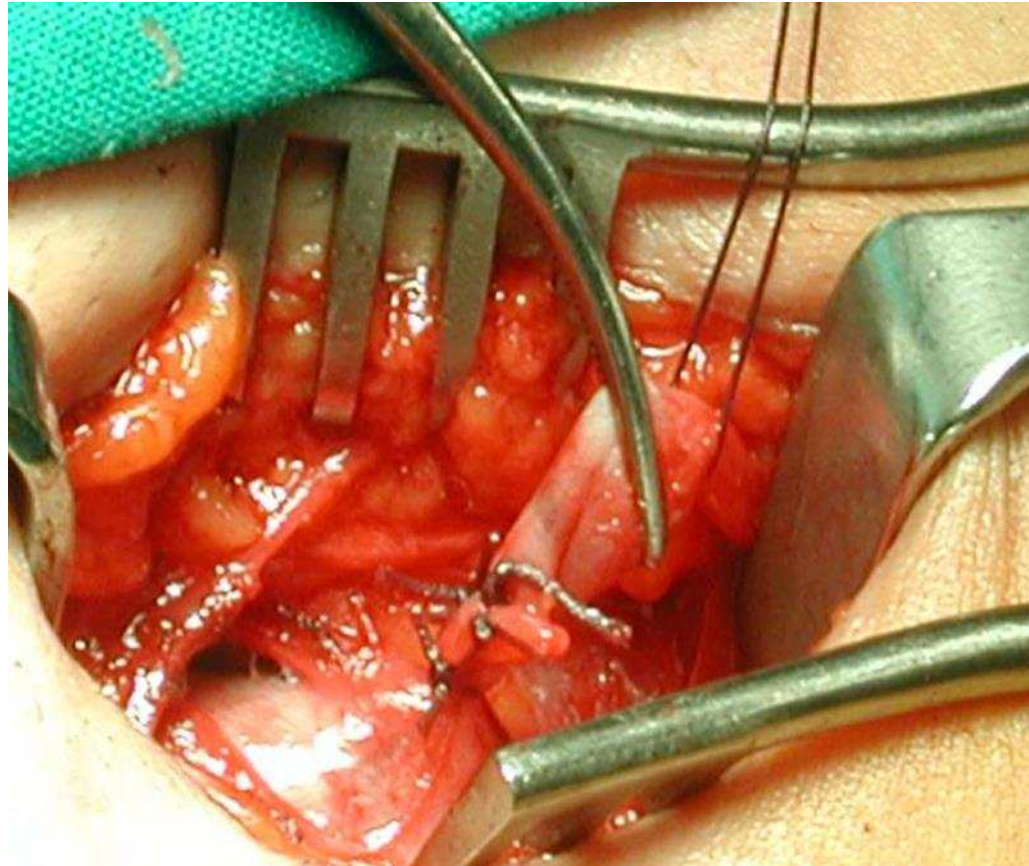
Conclusions: The primary failure and recurrence in EVLA and RFA were non-significantly different compared with surgery. However, they had lower haematoma, less wound infection, less pain and quicker return to normal activities.

Surgical options

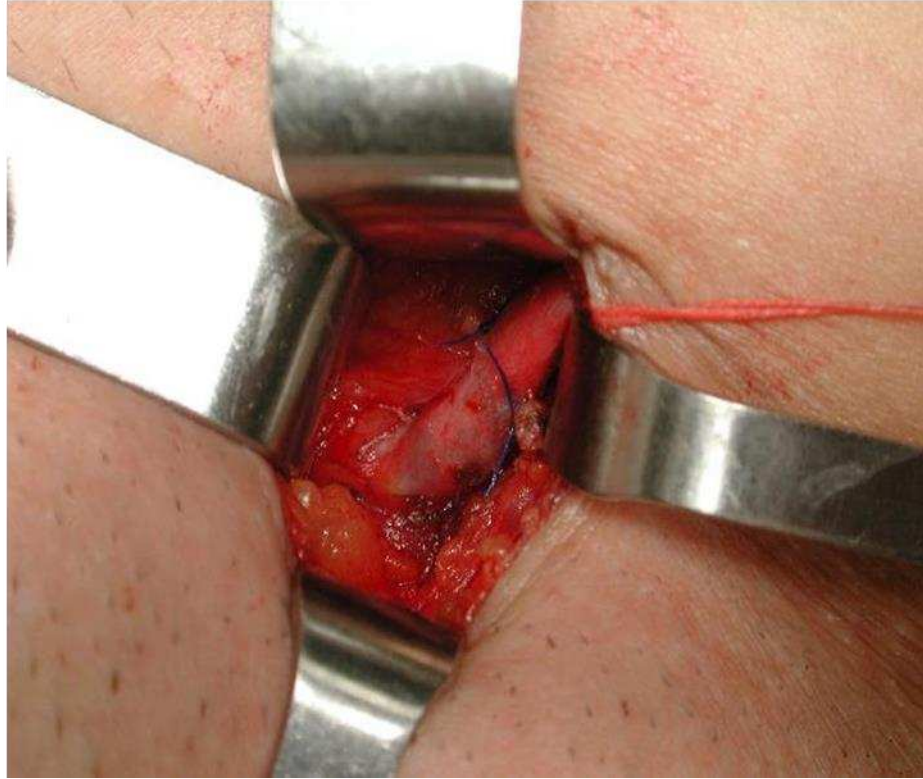
- Saphenectomy stripping
- Muller phlebectomies
- EVLT (endo venous laser treatment)

Saphenectomy stripping





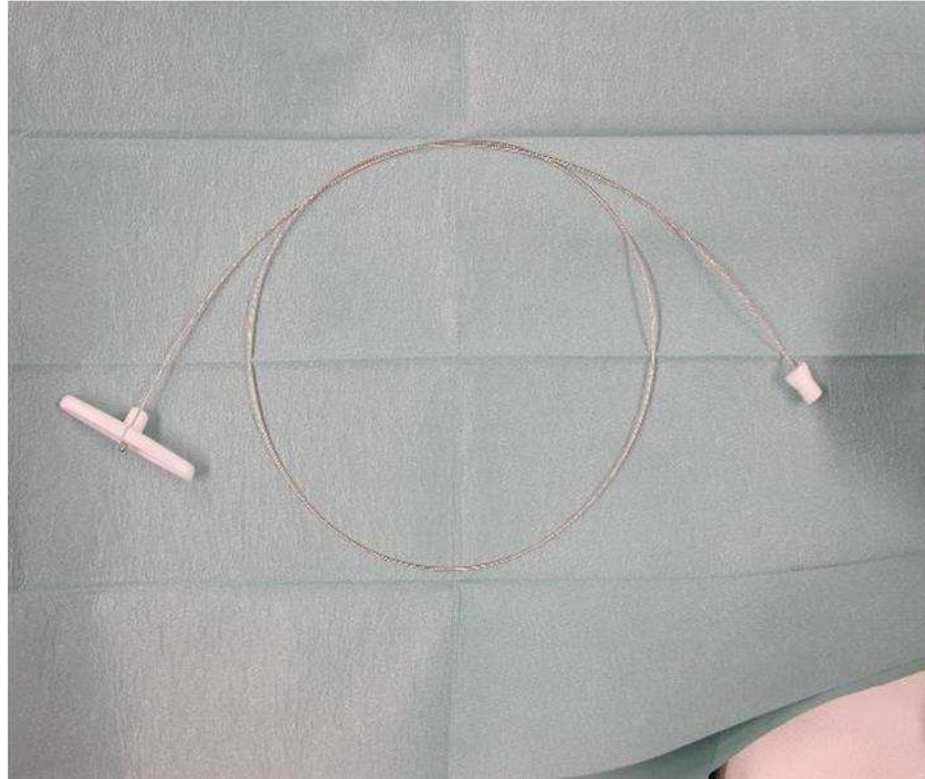
Saphenectomy stripping



Crossectomy



Stripper

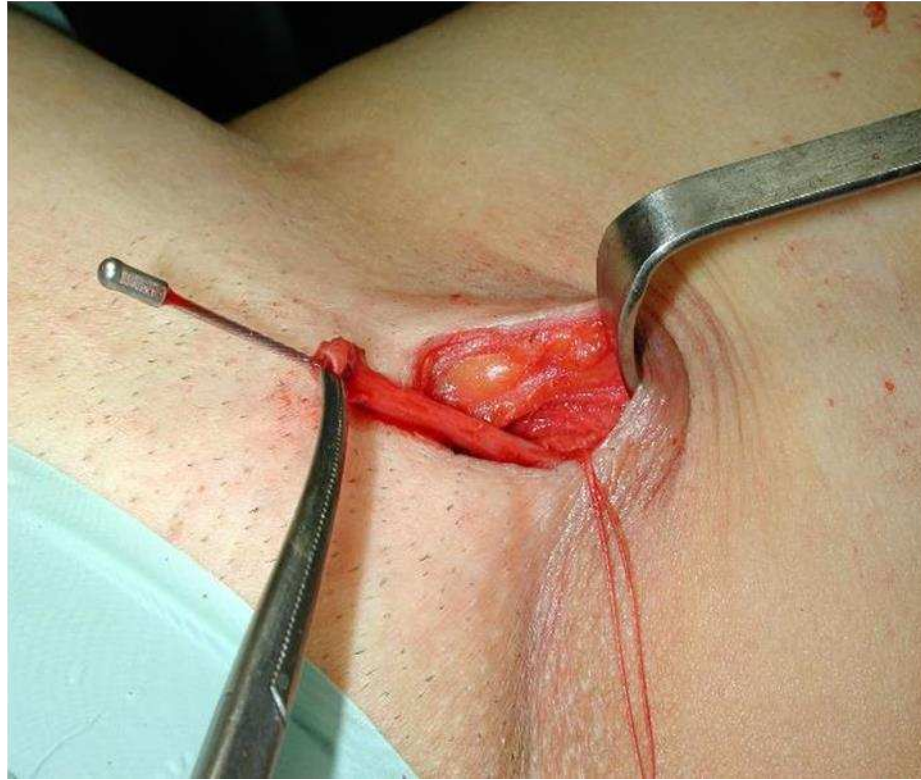




Saphenectomy stripping



Saphenectomy stripping

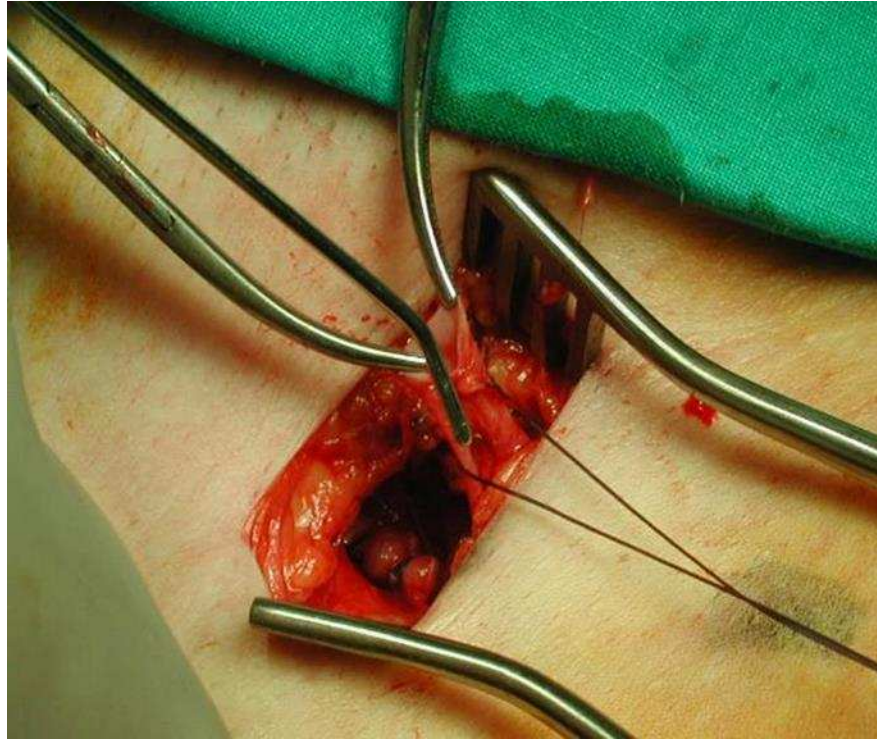


Saphenectomy stripping











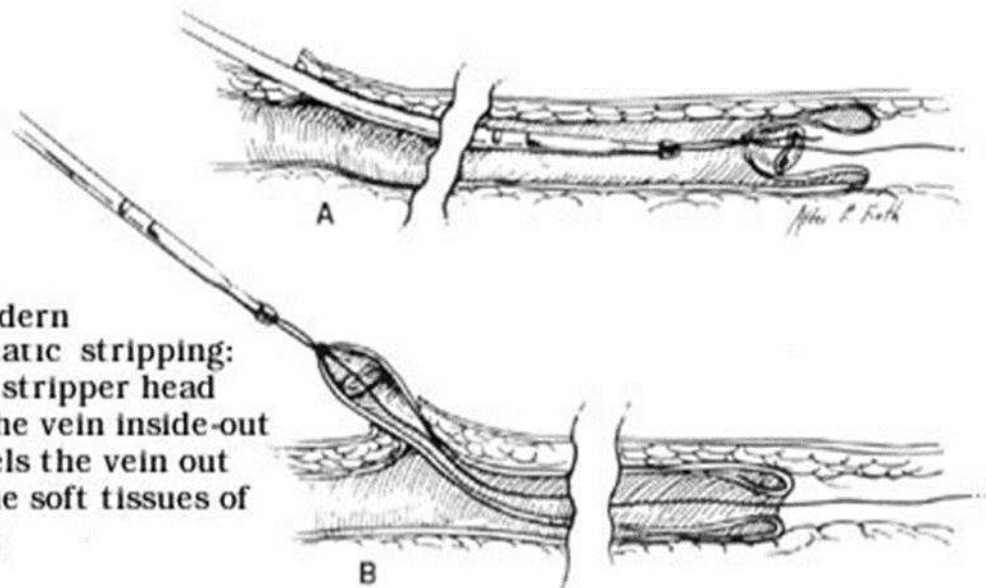








The modern
atraumatic stripping:
a small stripper head
turns the vein inside-out
and peels the vein out
from the soft tissues of
the leg.



Muller phlebectomies

- Local anesthesia
- Removal of varicose veins with micro-incisions of 1-2 mm using hooks

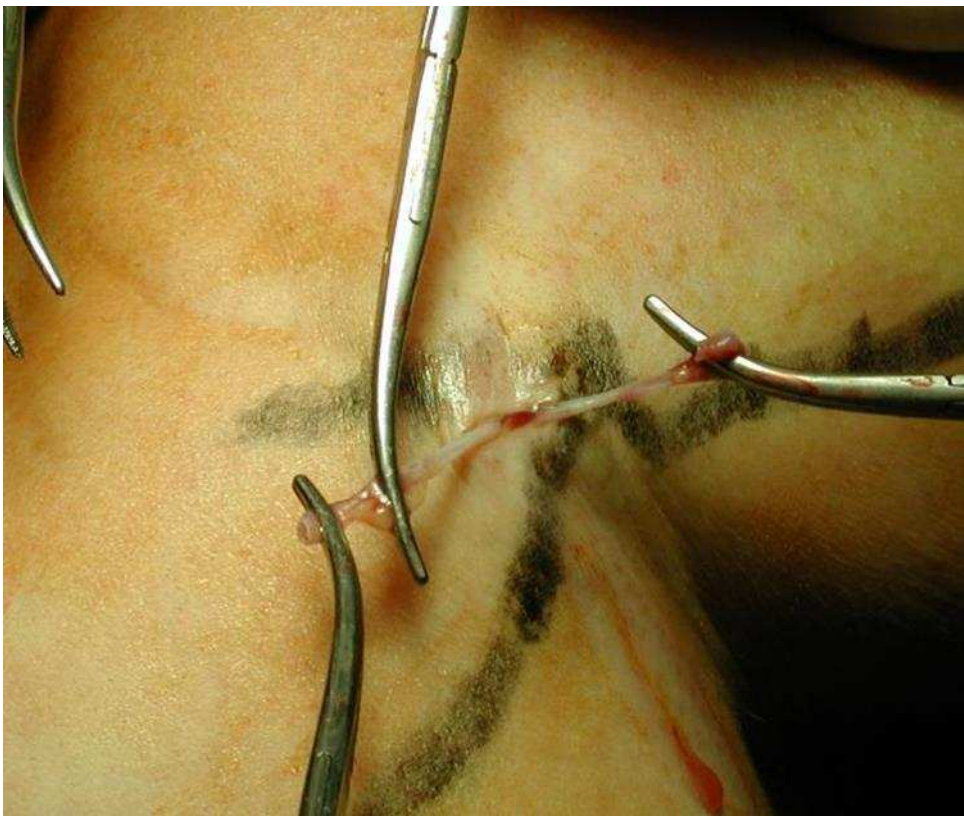




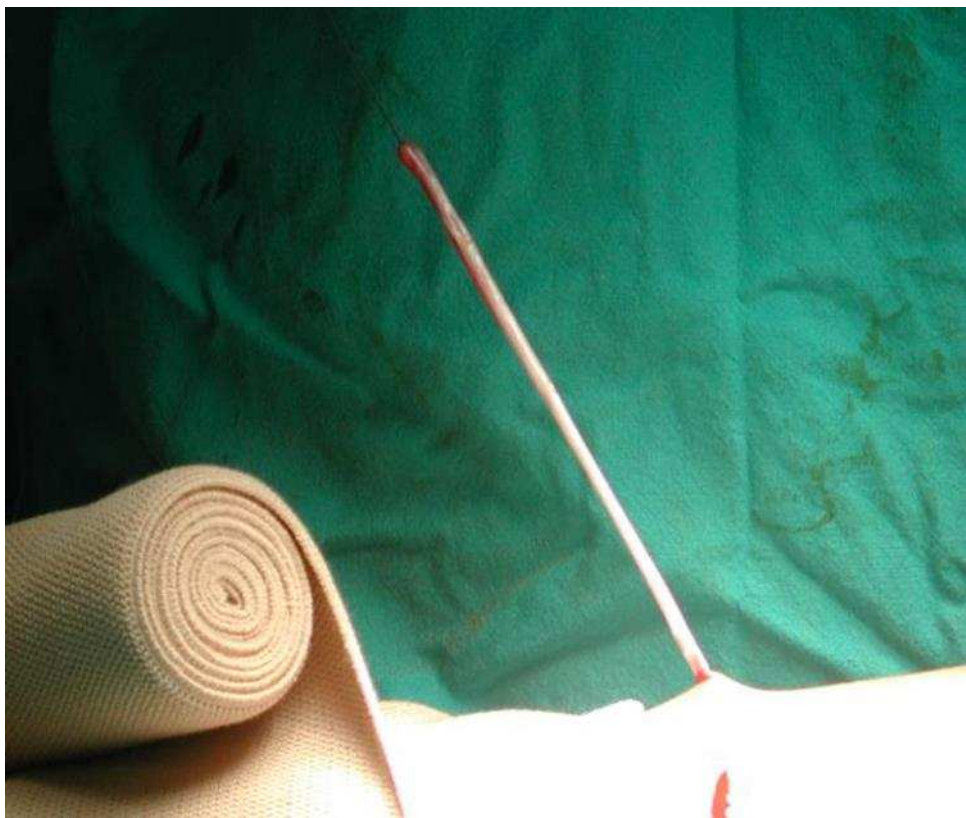






















Trattamenti mini-invasivi

Ablazione con radiofrequenza- Closure

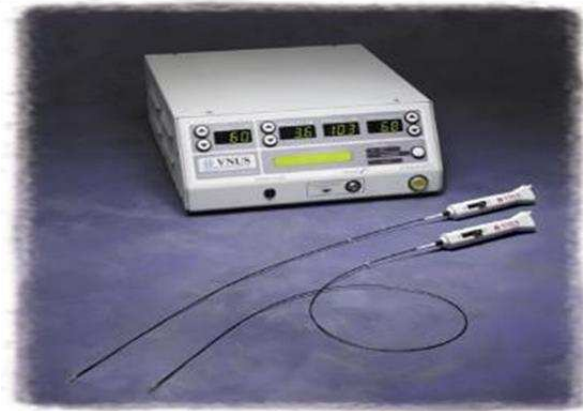
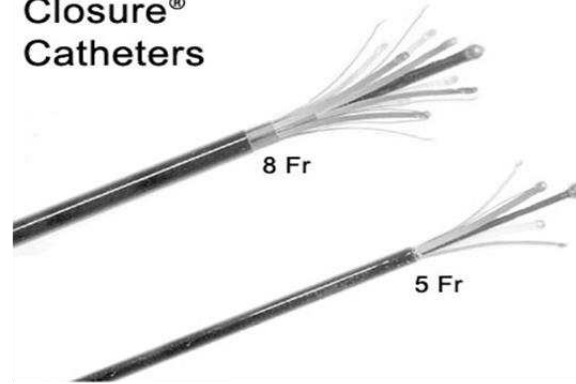
Scleroterapia mediante SCLEROMOUSSE

Ablazione termica con Laser -Elves

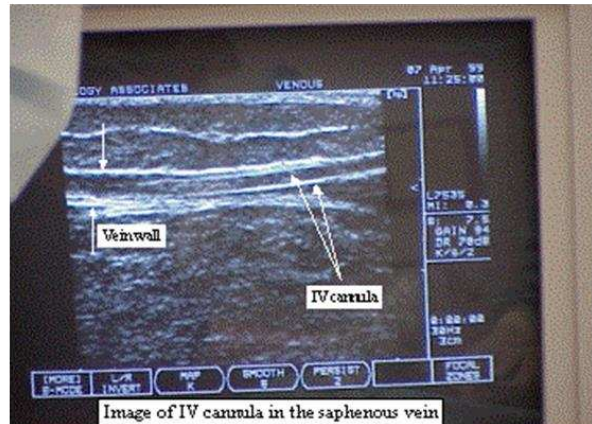
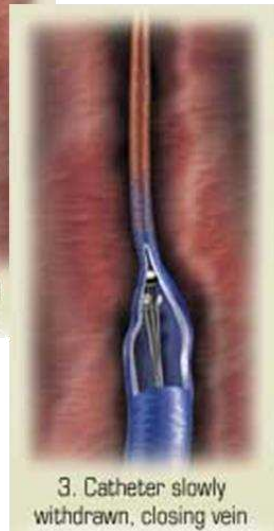
CLOSURE System



Closure[®]
Catheters



CLOSURE System

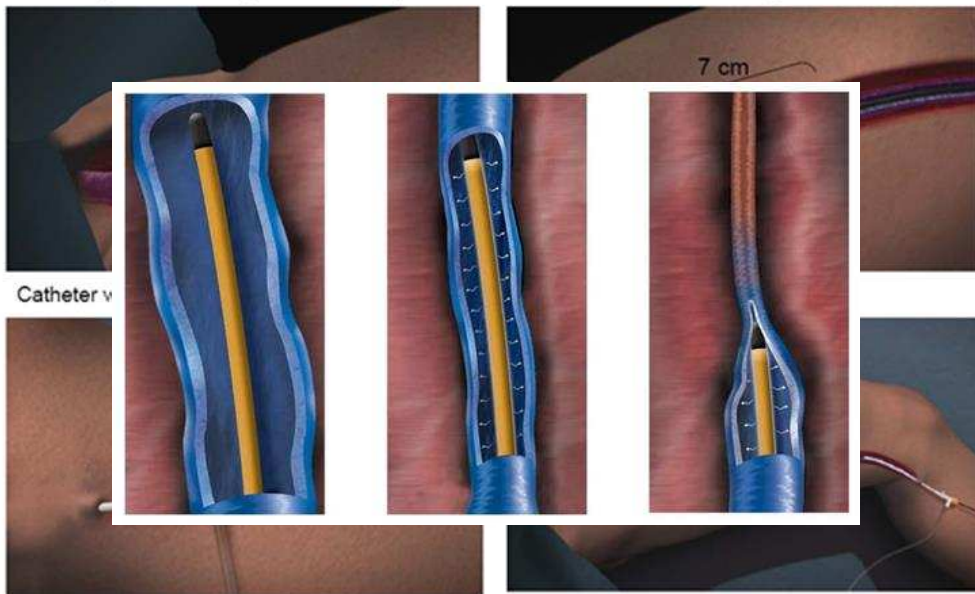


The VNUS Closure Procedure

Using the ClosureFAST™ Catheter

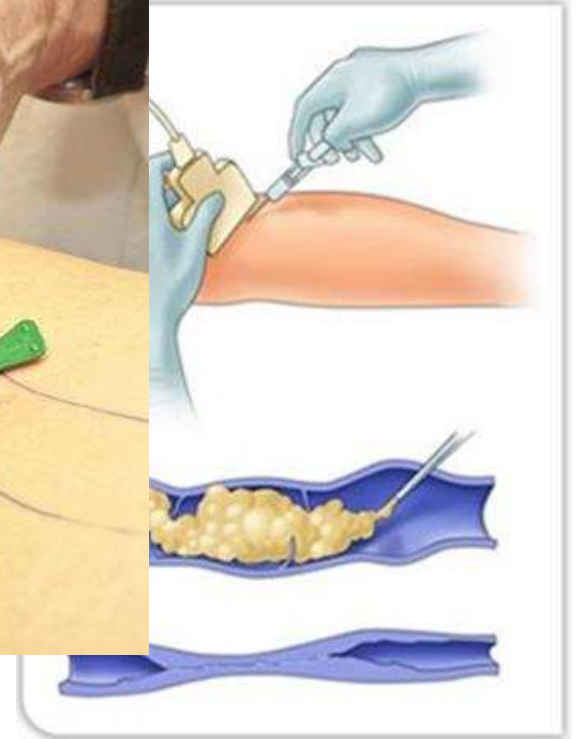
Catheter positioned at highest treatment point

Vein treated in 7cm vein segments

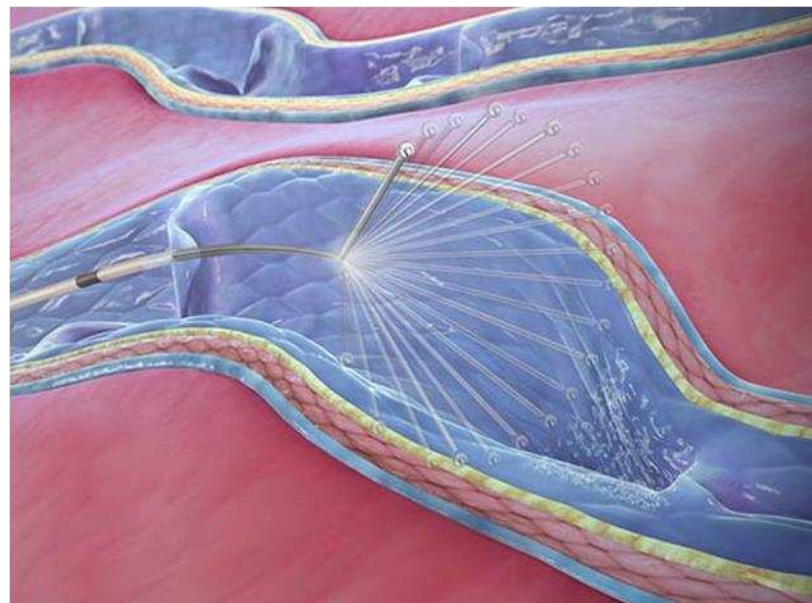
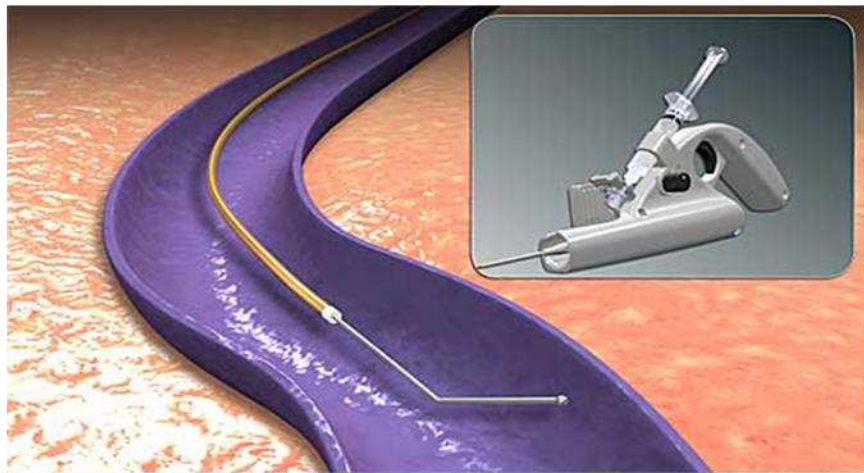


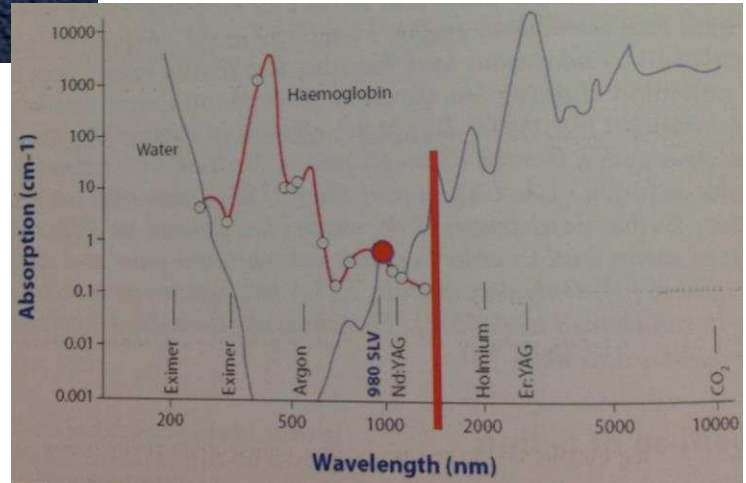
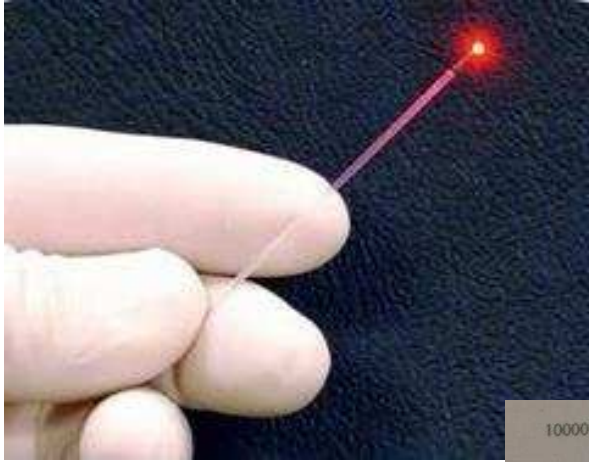
5. Introducing the ClosureFAST catheter

SCLEROMOUSSE

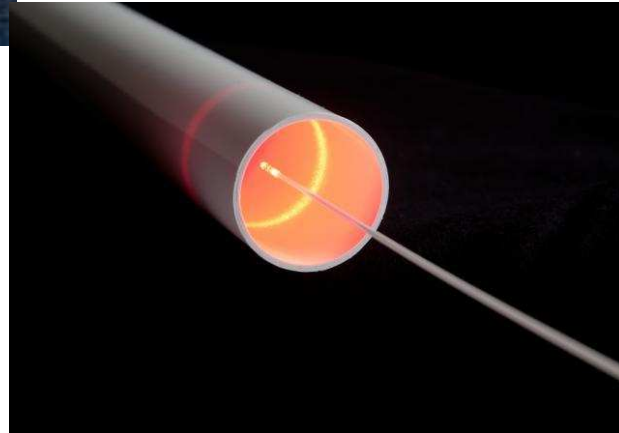
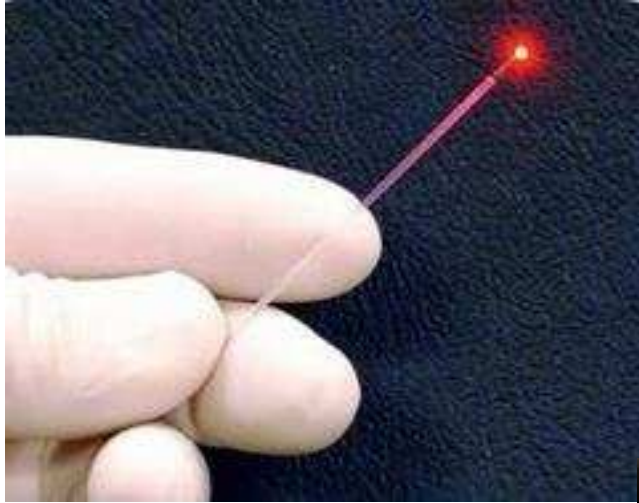


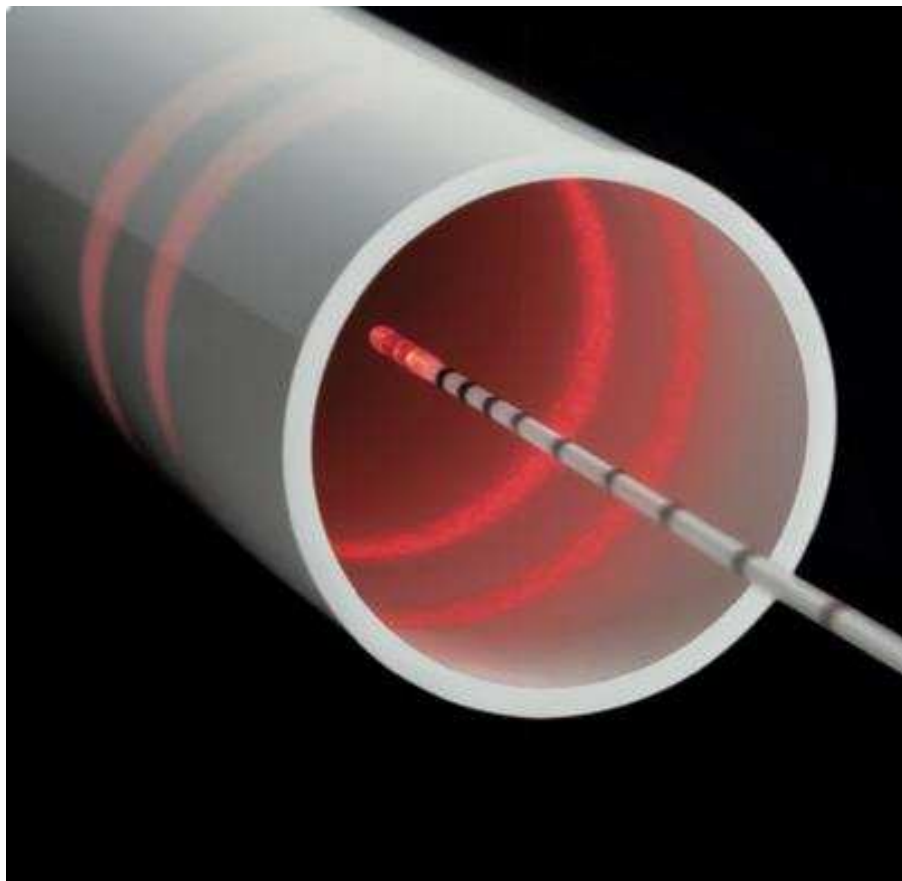
CLARIVEIN - MOCA











Influence of fibers and wavelengths on the mechanism of action of endovenous laser ablation

Takashi Yamamoto, MD, and Masahiro Sakata, MD, *Osaka City, Japan*

Objective: This study aimed to investigate the different mechanisms involved in the use of bare, radial, and two-ring fibers, operating at 980- or 1470-nm wavelengths, by analyzing the histological changes caused to irradiated human great saphenous veins (GSVs).

Methods: GSVs were removed by invaginated stripping and were prepared for irradiation. Irradiation was performed using bare, radial, and two-ring fibers, combined with 980- and 1470-nm laser wavelengths, operating at powers of 6 to 12 W. The fibers moved through the GSVs at a speed of 1 mm/s. The circumferences of the irradiated veins were measured, and the histological changes were examined.

Results: The use of the bare fibers resulted in an average shrinkage ratio that increased with increasing laser power, regardless of the wavelength. Microscopic changes were heterogeneous and included carbonization and ulceration at the side where the heated fiber tip contacted the vessel wall, and sparse low-temperature changes were evident more distant from the fiber, regardless of the wavelength of the laser used. Using radial or two-ring fibers, the thermal changes were circumferentially uniform, but the shrinkage ratio and microscopic changes varied according to the laser wavelength combined. With the 1470-nm laser, the average shrinkage ratio did not vary significantly between different outputs. Mid-temperature changes were spread across the intima and superficial layer of the media, without causing carbonization.

With the 980-nm laser, the average shrinkage ratio increased depending on the output. Conducted heat caused carbonization of the superficial part of the intima, with a thin layer of additional mid-temperature changes. Although adhesion of the hot fiber to the vessel wall was an annoying phenomenon during endovenous laser ablation and occurred frequently in the radial-1470 experiments, it rarely occurred in the two-ring-1470 experiments.

Conclusions: Using bare fibers, direct contact between the unevenly placed heated tip and the vessel wall results in heterogeneous heating of the vein. Radial and two-ring fibers, combined with 1470-nm light, can heat vessel walls circumferentially and uniformly with the laser light emitted radially penetrating into the vessel wall. Regarding the longitudinal uniformity, two-ring fibers provide a greater uniformity with a reduced incidence of sticking. (*J Vasc Surg: Venous and Lym Dis* 2014;2:61-9.)

Clinical Relevance: This study aimed to investigate the mechanisms of heat conduction during endovenous laser ablation using different fiber types (bare, radial, and two-ring) and different laser wavelengths (980 nm and 1470 nm) by analyzing the histological changes caused to irradiated human great saphenous veins. The results of the study indicated that a combination of two-ring fibers and 1470-nm laser light enables homogeneous, circumferential heating of the vessel wall.

» **Original Article** «

Comparison of Bare-Tip and Radial Fiber in Endovenous Laser Ablation with 1470 nm Diode Laser

Masayuki Hirokawa, MD, PhD and Nobuhisa Kurihara, MD, PhD

I

Objective: Major side effects after endovenous laser ablation (EVLA) are pain and bruising. The aim of this study was to compare outcome and side effects after EVLA for primary varicose veins with 1470 nm diode laser using bare-tip or radial fiber.

Methods: From October 2007 to December 2010, 385 patients (453 limbs) with primary varicose veins treated with 1470 nm laser were studied. Bare-tip fiber was used in 215 patients (242 limbs) (BF group) and radial fiber (ELVeS™ Radial, Biolitec AG, Germany) was used in 177 patients (211 limbs) (RF group). This study is a retrospective study and radial fiber was started for use from November 2008. Laser energy was administered at 6–12 W of power in the BF group and 10 W of power in the RF group with constant pullback of laser fiber under tumescent local anesthesia. The patients were assessed by clinical examination and venous duplex ultrasonography at 24–48 h, one week, one month, 4 months and one year follow-up postoperatively.

Results: Mean operating time, length of treated vein and linear endovenous laser energy of all cases were 42.6 min, 36.2 cm and 83.4 J/cm, respectively. Major complications such as deep vein thrombosis and skin burns were not noted. Bruising (1.9% vs. 19.4%) and pain (0.9% vs. 7.4%) were significantly lower in the RF group. Cumulative occlusion rates by Kaplan-Meier method were 100% at 32 months in the RF group and 99.5% at 4 years in the BF group.

Conclusion: EVLA using 1470 nm laser with the radial fiber minimized adverse effects compared with bare-tip laser fiber. (*English translation of Jpn J Vasc Surg 2013; 22: 615-621)



Comparison of 980 nm Laser and Bare-tip Fibre with 1470 nm Laser and Radial Fibre in the Treatment of Great Saphenous Vein Varicosities: A Prospective Randomised Clinical Trial[☆]

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Gulhane Military Academy of Medicine, Department of Cardiovascular Surgery, Ankara, Turkey

Submitted 29 August 2009; accepted 11 April 2010
Available online 23 May 2010

KEYWORDS

Endovenous laser
ablation;
Bare-tip fibre;
Radial fibre;
1470 nm;
980 nm;
Varicose veins

Abstract *Objectives:* The aim of this study is to compare efficacy, early postoperative morbidity and patient comfort of two laser wavelengths and fibre types in treatment of great saphenous vein (GSV) incompetence resulting in varicosities of the lower limb.

Design: Prospective randomised clinical trial.

Materials and Methods: Sixty patients (106 limbs) were randomised into two groups. They were treated with bare-tip fibres and a 980 nm laser in group 1 and radial fibres and 1470 nm laser in group 2 in order to ablate the GSV. Local pain, ecchymosis, induration and paraesthesia in treated regions, distance from skin, vein diameter, treated vein length, tumescent anaesthesia volume, delivered energy and patient satisfaction were recorded. Follow-up visits were planned on the 2nd postoperative day, 7th day, 1st, 2nd, 3rd and 6th months.

Results: Mean GSV diameters at saphenofemoral junction and knee levels were 12.1 S.D. 4.3 mm and 8.2 S.D. 2.4 mm, and 11.8 S.D. 4.1 mm and 7.9 S.D. 2.6 mm respectively in groups 1 and 2. There were 14 patients with induration, 13 with ecchymosis and nine minimal paraesthesia in group 1 and no or minimal local pain, minimum ecchymosis or induration in group 2. Duration of pain and need for analgesia was also lower in group 2 ($p < 0.05$). There was significant difference on postoperative day 2, day 7 and 1st month control in favour of group 2 in venous clinical severity scores (VCSS).

Conclusion: Treatment of the GSV by endovenous laser ablation using a 1470 nm laser and a radial fibre resulted in less postoperative pain and better VCSS scores in the first month than treatment with a 980 nm laser and a bare-tip fibre.

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[☆] Presented at the XXIII Annual Meeting 3–6 September, 2009, European Society for Vascular Surgery, Oslo, Norway.

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Histological damage of saphenous venous wall treated *in vivo* with radial fiber and 1470 nm diode laser

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P. PAVEI¹, E. GIRALDI¹, M. FERRINI¹, A. NOSADINI¹, U. BACCAGLINI¹

¹Center of Multidisciplinary Day Surgery, University Hospital of Padua, Padua, Italy
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Aim. Aim of this study was to evaluate the histological damage to the saphenous trunk after a 1470nm diode laser treatment performed by using a radial fiber.

Methods. At the end of an endovenous laser procedure, five patients underwent a biopsy of a segment of the saphenous trunk, including a treated as well as a non-treated part of the vein. Such segments were all colored with Hematoxylin-eosin, and some of them also with Azan Mallory, Trichrome Masson, Van Gieson, Weigert, Alcian and Alcian-PAS.

Results. Through microscopic analysis, the intimal layer was recognizable around all the vessel circumference, though with clear signs of coagulative necrosis also detectable in the tunica media, at a progressively deeper location correlated with the amount of delivered energy. Inside the tunica media, cavities and fissures were present. No histological signs of carbonization, vaporization or perforation were observed either on the intimal or media layers. All the described damage was widespread, uniform and constant around the whole vein wall circumference.

Conclusion. Endovenous treatment of the saphenous trunks with a 1470 nm laser and radial fiber causes no contact damage. Vice versa, this procedure results in deep and uniform coagulation injury getting deeper as the delivered energy increases. The presence of cavities and separations in the tunica media suggests that a significant dose of energy is absorbed by the water of this layer and transformed into vapour, hence creating both thermal and mechanical damage.

KEY WORDS: Lasers - Histology - Optic fiber technology.

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Since 2001, when endovenous laser started to be used in the treatment of lower limbs varices,¹ a lot of clinical experience has confirmed both efficacy and safety of the procedure.^{2,3}

Over these years materials employed in the laser field as well as optical fiber have increasingly been developed.

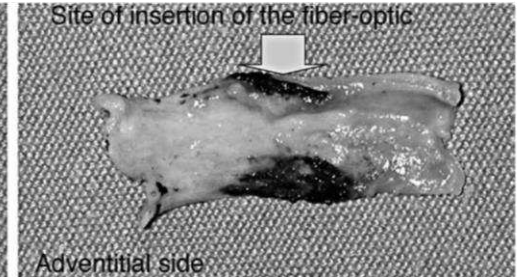
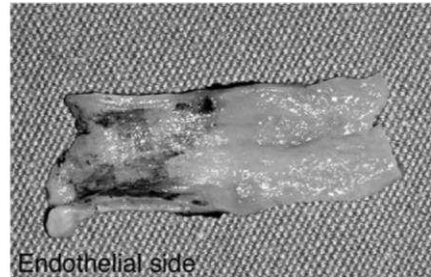
In addition to 810, 940 and 980 nm lasers, which have hemoglobin as chromophore, a 1470 nm laser with water as chromophore is now available. In the same way, besides flat fibers with frontal light emission, a radial fiber with 360° lateral light emission has been devised.⁴

The use of a 1470 nm laser with a radial fiber has significantly changed the postoperative course, resulting in less pain and less ecchymosis.^{5,6}

This evidence suggests that the mechanism of action and the type of damage to the venous wall are different from those obtained with a 980 nm laser and flat fibers, the patterns of which were detailed in an article published in 2006.⁷

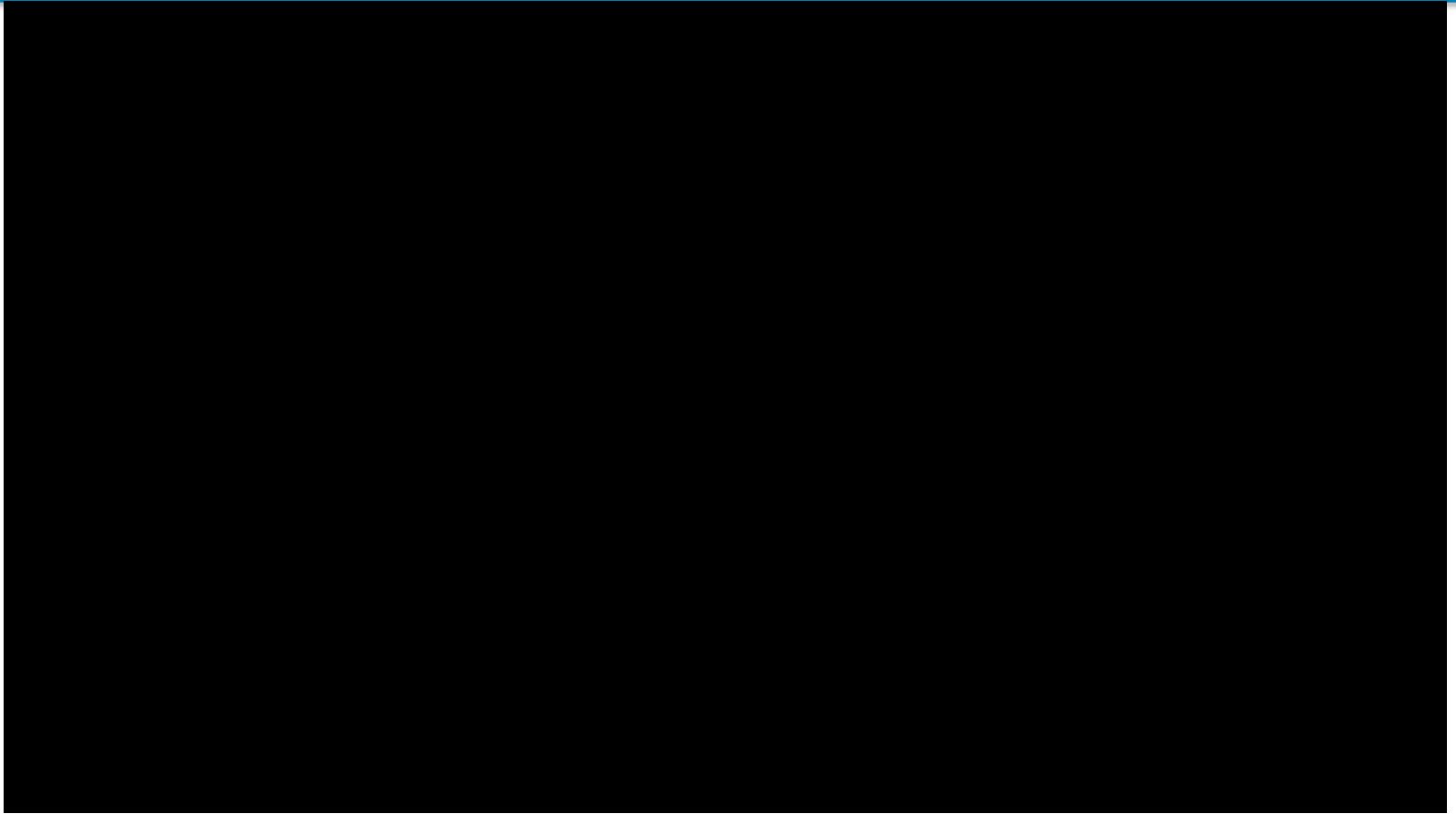
Materials and methods

Five patients, two women and three men with a mean age of 47 years, presenting great saphenous



Saphenous Vein Treatment Alternatives

	Surgery (Ligation & Stripping)	Endovenous Laser	Radiofrequency (RF)	Sclerotherapy
FDA Clearance	Grandfathered (in use for >30 years)	2002	1999	Foam – Not Cleared Liquid (Sotradecol) – 2004 Liquid (Other) – Not Cleared
Anesthesia	General Anesthesia	Local	Local	Local
Success Rate	77-82% ^{1,2}	93-100% ³⁻⁸	86-92% ⁵⁻⁸	9-26% (liquid) ^{18,20} 68-80% (foam) ^{18,19,21}
Complications Deep Vein Thrombosis (DVT) or Saphenous Thrombus Extension	5.3% ⁹	0.3% ^{10,11}	2.1% ^{10,12}	Foam – Documented embolism and stroke (with PFO) ^{22,23}
Pulmonary Embolism (PE)		None Reported ¹³	7 Cases ¹³	
Side Effects Ecchymosis/ Hematoma	Significant (>50%) ¹⁴	Mild to Moderate (<35%) ^{3,7,15}	Mild to Moderate (<35%) ^{7,14,15}	
Pain/Tenderness	Moderate (28%) ¹⁴	Mild to Moderate (<25%) ^{7,15}	Mild to Moderate (<25%) ^{7,14,15}	
Paresthesia	14% ¹⁴	0.08% ^{3,8}	11% ^{8,14,16,17}	
Recovery Return to Normal Activity	3.9 days ¹⁴	1-2 days	1.2 days ¹⁴	





Role of compression stockings after endovenous laser therapy for primary varicosis

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Turnover pazienti
Valore percepito dell'atto chirurgico
Prevenzione secondaria efficace con ottimi risultati estetici, funzionali e
sulla progressione della malattia

Systematic review, network meta-analysis and exploratory cost-effectiveness model of randomized trials of minimally invasive techniques *versus* surgery for varicose veins

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FS is slightly higher in the first few years compared with surgery (HR 1.02 at 1 year), potentially resulting in fewer QALYs for intermediate model time spans. In the longer term (between 10 years and life), FS has a lower failure rate than surgery and leads to a small QALY gain (Fig. 3).

Summary of cost-effectiveness

Differences between treatments are negligible in terms of clinical outcomes, so the treatment with the lowest cost appears to be most cost-effective. The central estimate is that total FS costs are the lowest and this procedure is marginally more effective than surgical stripping (+0.0015 QALYs), with a probability of being the most cost-effective treatment above 90 per cent for willingness-to-pay thresholds in the range £20 000–50 000. This result is, however, sensitive to the model time horizon (cost-effectiveness is reduced in the shorter term because of the early failure rates for this technique). EVLA and RFA both cost more than surgery, and with little difference in QALYs they cannot be considered cost-effective at the usual threshold of £20 000–30 000, a result that is robust to parameter variation and model time horizon. There is considerable uncertainty in the cost differences between treatments arising from different reported costs of the procedures, and in fact these are likely to vary with setting, and may also vary over time. Threshold analysis showed that the additional costs of EVLA and RFA would have to be no more than £50 and £24 respectively greater than the costs of surgery to be considered cost-effective at a

as the less invasive nature of some options, and the opportunity to avoid larger scars and general anaesthesia, may be important in the choice of procedure. Furthermore, if wider social benefits, such as speed of recovery and return to work, were to be considered in costs, the minimally invasive techniques might demonstrate further benefits over surgery; the majority of studies evaluating time to return to work or normal activity report a significant reduction for the minimally invasive techniques compared with surgical stripping²¹.

All of the effectiveness analyses presented here used only technical rather than symptomatic recurrence data, so the true proportion of treated individuals likely to present with symptoms of recurrence requiring retreatment is not certain. The rates of technical recurrence are therefore higher than those encountered in clinical practice, because non-symptomatic patients would not report, even if they were experiencing technical recurrence. The findings on initial failure and retreatment, symptomatic recurrence and retreatment for recurrence, given in the full report²¹, are affected by a high degree of uncertainty owing to the relative infrequency with which such data were reported, as well as the limitations of the reporting of these data in primary studies. Based on projections from trial data, the long-term risk of a technical recurrence is less for all of the minimally invasive treatments compared with surgery, although the time-to-treatment-failure curves are quite similar.

Varicose veins in the legs

The diagnosis and management of varicose veins

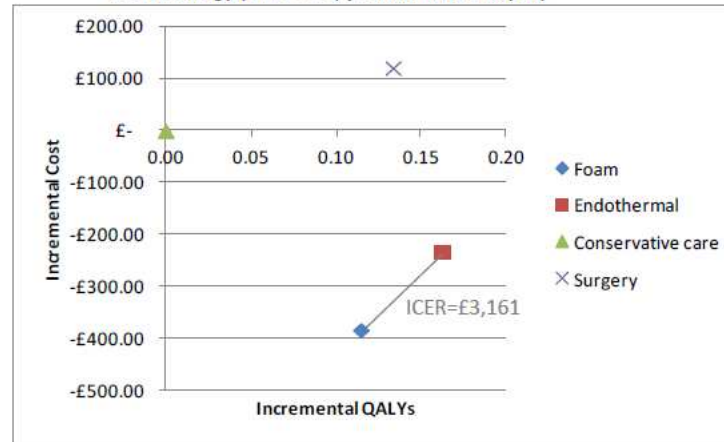
Clinical guideline

Methods, evidence and recommendations

12 February 2013



Figure 5: Cost effectiveness plane showing incremental cost and QALYs per patient expected with each strategy (Base case, probabilistic analysis)



The strategy which provided the most QALYs, and was therefore the most clinically effective, was endothermal treatment. However, this came at an additional cost compared to foam sclerotherapy. Using the mean costs and QALYs generated over the probabilistic sensitivity analysis, the ICER of the endothermal treatment compared to foam was £3,161 which is below the NICE threshold of £20,000 per QALY gained, therefore endothermal treatment was the cost-effective strategy. Endothermal treatment had a probability of being cost-effective of 71%, followed by foam which had a lower chance of being the most cost-effective option of 23%.



EDITORIAL

A New Gold Standard for Varicose Vein Treatment?

The current principles of surgical treatment of varicose veins were established at the beginning of the 20th century by Parfies, Keller, Mayo, Backeck and others. They include ligation of the incompetent sapheno-femoral or sapheno-popliteal junction, stripping of the refluxing saphenous vein and phlebectomy of varicose branches. These principles have been increasingly challenged since the advent of thermal ablation by laser or radio-frequency around the turn of the millennium. Furthermore, sclerotherapy has gained renewed interest due to improved results by ultrasound guidance and the use of foam instead of liquid agents.

Two randomised controlled trials (RCTs) comparing endovenous laser ablation (EVLA) of refluxing saphenous veins with surgical high ligation and stripping were published by Rasmussen et al.¹ and by Dorsovi et al.² Furthermore, Dsouffri et al.³ published an RCT comparing EVLA with cyanoacrylate. All studies used laser light with a wavelength of 980 nm. In all trials, abolition of reflux was marginally superior after EVLA, but the differences were not significant. Improvement of symptoms according to AVOS (the Aberdeen Varicose Vein Symptom Severity Score) or VCS (the Venous Clinical Severity Score) was similar after EVLA and surgery. Return to normal activities was earlier after EVLA than after surgery, according to the Dorsovi and Dsouffri trials, but not in the Rasmussen study. However, all trials found a tendency towards less pain and bruising after EVLA.

Early in 2009, Van den Bos et al.⁴ published a large meta-analysis of results of all current treatment modalities. EVLA, radio-frequency ablation (RFA) and ultrasound-guided foam sclerotherapy (UGFS) were compared with surgical high ligation plus stripping. As many as 64 clinical trials that used ultrasound examination as an outcome measure with a total of 12 320 limbs and an average follow-up of 21.2 months were included.

After 3 years, the estimated pooled success rate was highest after EVLA with 94%, followed by RFA (84%), surgery (78%) and foam sclerotherapy (77%).

After adjusting for the duration of follow-up, endovenous laser therapy was significantly superior to all other treatments in terms of abolition of saphenous reflux. Foam

therapy and radio-frequency ablation were equally effective as surgery. The authors concluded that minimally invasive techniques were “at least as effective as surgery” in the treatment of varicose veins.

Superior rates of abolition of saphenous reflux after EVLA using 980-nm technology in the meta-analysis come mostly from non-randomised trials published by enthusiasts of thermal ablation. However, recent studies by Probstle et al.⁵ Favier et al.⁶ and others suggest that laser light with longer wavelengths may reduce side effects without compromising abolition of reflux. Another recent development provides a fibre with a radial distribution of laser light as in top Ebers by Biedtke,⁷ which may positively affect the balance between desired and undesired effects.

RFA technology has evolved as well. RFA procedures that were included in the meta-analysis⁴ used the original VNUS Closure catheter with umbrella-shaped electrodes. They heated the vein up to barely 90°C in a rather tedious procedure with a slow, continuous withdrawal of the catheter. A more recent variation (Celian by Olympus) features bipolar radio-frequency from a sleek catheter with two integrated electrodes that are 15 mm apart.

A further recent development is named VNUS Closure Fast.⁸ The catheter’s sleek tip integrates a heating coil of 7 cm length, producing temperatures up to 120°C. After a heating cycle of 20 s, the catheter is withdrawn one step of 6.5 cm before the next cycle begins. Large vein diameters are compensated for by double dosage. One small RCT was published earlier this year. It suggests that Closure Fast is superior to the conventional 980-nm laser in terms of post-procedural recovery and quality-of-life parameters. At Klinik Wietzen, until last April, we have treated 155 patients with 232 refluxing saphenous veins using Closure Fast. All procedures were carried out under tumescence local anaesthesia only and spicose branches were removed by hook phlebectomy in the same session. The outcomes were examined by an independent team from the Zurich University Hospital using questionnaires and ultrasound examination (Lemare-Vosté E et al., publication in preparation). Among the responders (56% to date), patient

Table 3. Percentage of diameter reduction after four methods of endovenous thermal ablation

	10 days	6 months
RFA	24%	51%
EVLA980 nm	10%	46%
EVLA810 nm	15%	50%
EVLA1470 nm	42%	80%



A randomized clinical trial of endovenous laser ablation versus conventional surgery for small saphenous varicose veins

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Background: This randomized clinical trial compared endovenous laser ablation (EVLA) and surgical ligation with attempted stripping in the treatment of small saphenous vein (SSV) insufficiency. The early results demonstrated that EVLA was more likely to eradicate axial reflux and was also associated with a faster recovery, lower periprocedural pain, and fewer sensory complications. The aim of this 2-year follow-up was to establish whether these benefits remained stable over time and whether these improved technical outcomes were associated with less clinical recurrence.

Methods: Patients with primary saphenopopliteal junction and SSV reflux were randomized to EVLA or saphenopopliteal junction ligation and attempted stripping/excision. Outcomes assessed at 2 years included the presence of residual or recurrent reflux, clinical recurrence, sensory complications, the need for secondary intervention, and patient-reported quality of life on the Aberdeen Varicose Veins Questionnaire, SF-36, and EuroQol.

Results: Of 106 patients who were equally randomized and successfully treated according to the protocol, 88 (83%) were successfully assessed at 2 years. The groups were comparable at baseline. At 2 years, EVLA remained superior to surgery in eradicating axial reflux in 36 patients (81.2%) compared with 29 (65.9%) in the surgery group ($P = .002$). There was no significant difference in clinical recurrence (EVLA: seven of 44 [16%] vs surgery: 10 of 44 [23%]; $P = .736$), sensory disturbance (EVLA: one [2.4%] vs surgery vs three [6.8%]; $P = 1.000$) or any quality of life domain.

Conclusions: The results of treatment of SSV insufficiency with EVLA appear durable up until 2 years. The study does not appear to suggest that the improved abolition of reflux after EVLA compared with surgery is associated with superior outcomes than those seen after surgery by this time point, because equal effect was shown in both groups. The sensory disturbance associated with surgery appears to settle over this time frame. EVLA is therefore superior in the short-term and not inferior by 2 years. (*J Vasc Surg* 2015;61:741-6.)

A systematic review and meta-analysis of the treatments of varicose veins

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Objectives: Several treatment options exist for varicose veins. In this review we summarize the available evidence derived from comparative studies about the relative safety and efficacy of these treatments.

Methods: We searched MEDLINE, Embase, Current Contents, Cochrane Central Register of Controlled Trials (CENTRAL) expert files, and the reference section of included articles. Eligible studies compared two or more of the available treatments (surgery, liquid or foam sclerotherapy, laser, radiofrequency ablations, or conservative therapy with compression stockings). Two independent reviewers determined study eligibility and extracted descriptive, methodologic, and outcome data. We used random-effects meta-analysis to pool relative risks (RR) and 95% confidence intervals (CI) across studies.

Results: We found 39 eligible studies (30 were randomized trials) enrolling 8285 participants. Surgery was associated with a nonsignificant reduction in the risk of varicose vein recurrence compared with liquid sclerotherapy (RR, 0.56; 95% CI, 0.29-1.06) and all endoluminal interventions (RR, 0.63; 95% CI, 0.37-1.07). Studies of laser and radiofrequency ablation and foam sclerotherapy demonstrated short-term effectiveness and safety. The quality of evidence presented in this review was limited by imprecision (small number of events), short-term follow-up, and indirectness (use of surrogate outcomes).

Conclusion: Low-quality evidence supports long-term safety and efficacy of surgery for the treatment of varicose veins. Short-term studies support the efficacy of less invasive treatments, which are associated with less periprocedural disability and pain. (J Vasc Surg 2011;53:49S-65S.)