CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

## JANUARY 19-21 2017 MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE

varicose veins surgery: what is more important, the technique or the strategy?

Armando Mansilha MD, PhD, FEBVS S. João University Hospital - Porto





### **Disclosure**

Speaker name: Armando Mansilha

- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- □ Other(s)
- X I do not have any potential conflict of interest

### INTERVENTIONAL OPTIONS

- evidence-based
- skills of the specialist
- national health care system reimbursement policies
- patient's ability to pay for a treatment that is not reimbursed
- patient's preference



modern surgical treatment of varicose veins: do we have evidence that supports one single technique?

### INTERVENTIONAL OPTIONS

- Classic Stripping
- > EVLT
- Radiofrequency
- > Foam Sclerotherapy
- > Glue
- Steam
- > ASVAL
- > CHIVA
- > Stab Avulsion
- > MMIASVV
- Mechanochemical Ablation

Evidence ???

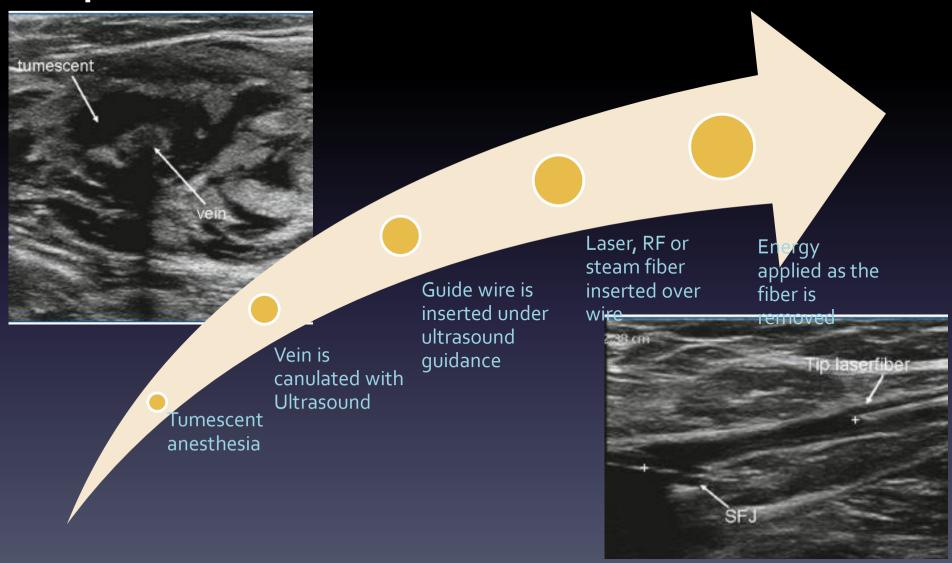
or

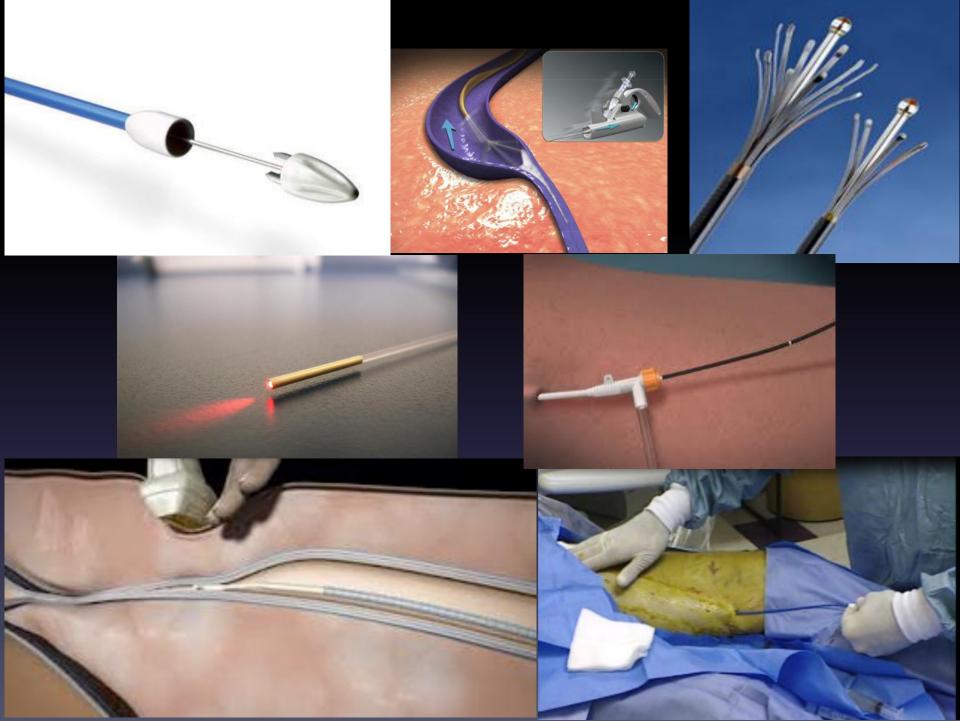
Fashion ???

## Disclosures

- With the Patients
- With the National Health System
- With the Evidence

# Catheter-based treatments for saphenous vein ablation





## C2 ... C6





## GSV



## SSV







## ASCENDING ... DESCENDING





PRESERVE ... REMOVE

### INTERVENTIONAL OPTIONS

- Classic Stripping
- > EVLT
- Radiofrequency
- > Foam Sclerotherapy
- > Glue
- Steam
- > ASVAL
- > CHIVA
- Stab Avulsion
- > MMIASVV
- Mechanochemical Ablation

Technique ???

and/or

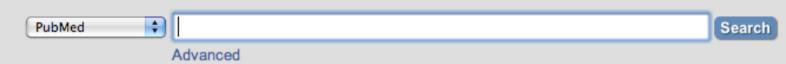
Strategy ???

### **COST-EFECTIVENESS**

- procedure complications
- loss of working days
- costs
- QoL
- recurrence rate
- recanalization rate
- cosmetic satisfaction
- CEAP/VCSS improvement
- relief of symptoms
- venous pain
- •

Gold Standard





Vascular. 2015 Jun;23(3):285-296. Epub 2014 Jul 15.

#### Surgical management of great saphenous vein varicose veins: A meta-analysis.

Lynch NP1, Clarke M2, Fulton GJ3.

Author information

#### Abstract

**PURPOSE:** The purpose of this systematic review and meta-analysis is to synthesise the available evidence of randomised controlled trials comparing endovenous laser therapy to traditional open surgery, high ligation and stripping, for the treatment of great saphenous vein varicose veins in terms of clinical effectiveness, patient satisfaction and peri-operative complications.

METHODS: MEDLINE, CINAHL, EMBASE and the Cochrane library were searched to identify eligible studies. All randomised controlled trials comparing endovenous laser therapy to high ligation and stripping that used ultrasound examination as an outcome measure and had follow up of one year or more were included. The Cochrane Collaboration's tool for assessing risk of bias was also used to assess the methodological quality of the included studies. Pooled risk ratios with 95% confidence intervals were used as the measure of effect for each dichotomous outcome.

FINDINGS: Nine eligible publications relating to six randomised controlled trials were identified. The total enrolment of the studies was 1289 limbs. The clinical efficacy of endovenous laser therapy is comparable to that of surgery in the relatively short follow up period described in the studies. Meta-analysis revealed a trend towards a higher risk of ultrasound recurrence after endovenous laser therapy at 12 months. Quality of life questionnaires reveal similar outcomes for endovenous laser therapy and surgery. There is low quality evidence to suggest surgery is associated with more pain, sensory complications and infection.

**CONCLUSION:** Endovenous laser therapy is a safe alternative to traditional open surgery. There is some weak evidence to suggest that endovenous laser therapy has a higher risk of ultrasound-detected recurrence at 12 months following treatment compared to open surgery. However, it may be associated with less sensory complications, pigmentation and infection.



#### Contents lists available at ScienceDirect

#### Reviews in Vascular Medicine





#### Review

### Review of randomized controlled trials comparing endovenous thermal and chemical ablation



Bo Eklöf a,\*, Michel Perrin b

#### ARTICLE INFO

Article history: Received 27 September 2013 Accepted 15 October 2013

#### ABSTRACT

In the past decade, the development of minimally invasive correction of primary venous reflux of the great saphenous vein (GSV) by endovenous techniques has provided a patient-friendly means to treat this disorder as an office- based procedure with ablation of the GSV using radiofrequency (RFA), laser (EVLA), or scienotherapy. What do the randomized controlled trials (RCT) teach us about these new endovenous procedures? There are 7 RCT's (493 patients) in 9 papers comparing RFA with open surgery (OS); 12 RCT's (2327 patients) in 16 papers comparing EVLA with OS; 5 RCT's (570 patients) comparing RFA with EVLA; 6 RCT's (699 patients) with modifications of EVLA; 2 RCT's (153 patients) in 3 papers comparing EVLA with cryostripping; 6 RCT's (1406 patients) in 7 papers comparing foam sclerotherapy with OS; 2 RCT's (166 patients) comparing EVLA with foam sclerotherapy; 1 RCT (580 patients) in 2 papers comparing RFA versus EVLA versus foam sclerotherapy versus OS.

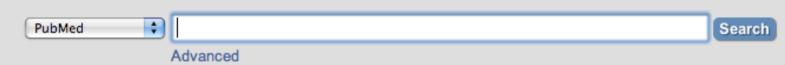
Conclusion: Based on the presented RCT's with caveats mentioned in the paper, the differences between modern open surgery and the new endovenous procedures are insignificant and no treatment modality can be recommended as superior to another. Nevertheless it is established that chemical ablation is the cheapest, but redo-treatment is more frequent related to recurrence.

© 2013 Elsevier GmbH. All rights reserved.

<sup>\*</sup> Botterhorget 8, 25270 Helsingborg, Sweden.

<sup>26</sup> Chemin de Decines, 69680 Chossieu, France





Br J Surg. 2014 Aug;101(9):1040-52. doi: 10.1002/bjs.9566. Epub 2014 Jun 25.

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

Carroll C1, Hummel S, Leaviss J, Ren S, Stevens JW, Cantrell A, Michaels J.

#### Author information

#### Abstract

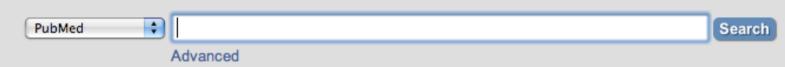
**BACKGROUND:** A Health Technology Assessment was conducted to evaluate the relative clinical effectiveness and cost-effectiveness of minimally invasive techniques (foam sclerotherapy (FS), endovenous laser ablation (EVLA) and radiofrequency ablation (RFA)) for managing varicose veins, in comparison with traditional surgery.

**METHODS:** A systematic review of randomized clinical trials (RCTs) was undertaken to assess the effectiveness of minimally invasive techniques compared with other treatments, principally surgical stripping, in terms of recurrence of varicose veins, Venous Clinical Severity Score (VCSS), pain and quality of life. Network meta-analysis and exploratory cost-effectiveness modelling were performed.

RESULTS: The literature search conducted in July 2011 identified 1453 unique citations: 31 RCTs (51 papers) satisfied the criteria for effectiveness review. Differences between treatments were negligible in terms of clinical outcomes, so the treatment with the lowest cost appears to be most cost-effective. Total FS costs were estimated to be lowest, and FS was marginally more effective than surgery. However, relative effectiveness was sensitive to the model time horizon. Threshold analysis indicated that EVLA and RFA might be considered cost-effective if their costs were similar to those for surgery. These findings are subject to various uncertainties, including the risk of bias present in the evidence base and variation in reported costs.

**CONCLUSION:** This assessment of currently available evidence suggests there is little to choose between surgery and the minimally invasive techniques in terms of efficacy or safety, so the relative cost of the treatments becomes one of the deciding factors. High-quality RCT evidence is needed to verify and further inform these findings.





Cochrane Database Syst Rev. 2014 Jul 30;7;CD005624. doi: 10.1002/14651858.CD005624.pub3.

### Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices.

Nesbitt C1, Bedenis R, Bhattacharya V, Stansby G.

Author information

#### Abstract

BACKGROUND: Minimally invasive techniques to treat great saphenous varicose veins include ultrasound-guided foam sclerotherapy (UGFS), radiofrequency ablation (RFA) and endovenous laser therapy (EVLT). Compared with flush saphenofemoral ligation with stripping, also referred to as open surgery or high ligation and stripping (HL/S), proposed benefits include fewer complications, quicker return to work, improved quality of life (QoL) scores, reduced need for general anaesthesia and equivalent recurrence rates. This is an update of a review first published in 2011.

**OBJECTIVES:** To determine whether endovenous ablation (radiofrequency and laser) and foam sclerotherapy have any advantages or disadvantages in comparison with open surgical saphenofemoral ligation and stripping of great saphenous vein varices.

**SEARCH METHODS:** For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched January 2014) and CENTRAL (2013, Issue 12). Clinical trials databases were also searched for details of ongoing or unpublished studies.

**SELECTION CRITERIA:** All randomised controlled trials (RCTs) of UGFS, EVLT, RFA and HL/S were considered for inclusion. Primary outcomes were recurrent varicosities, recanalisation, neovascularisation, technical procedure failure, patient QoL scores and associated complications.

**DATA COLLECTION AND ANALYSIS:** CN and RB independently reviewed, assessed and selected trials which met the inclusion criteria. CN and RB extracted data and used the Cochrane Collaboration's tool for assessing risk of bias. CN and RB contacted trial authors to clarify details as needed.

MAIN RESULTS: For this update, eight additional studies were included making a total of 13 included studies with a combined total of 3081 randomised patients. Three studies compared UGFS with surgery, eight compared EVLT with surgery and five compared RFA with surgery (two studies had two or more comparisons with surgery). Study quality, evaluated through the six domains of risk of bias, was generally moderate for all included studies, however no study blinded participants, researchers and clinicians or outcome assessors. Also, nearly all





Cochrane Database Syst Rev. 2014 Jul 30:7:CD005624, doi: 10.1002/14651858.CD005624.pub3.

### Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices.

Nesbitt C1, Bedenis R, Bhattacharva V, Stansby G.

Author information

OBJECTS' CONCLUSIONS: Currently available clinical trial evidence suggests that UGFS, EVLT and RFA are at least as effective as authors in the treatment of great contends using Due to long incompatibilities between trials and different time said. Surgery in the treatment of great saphenous varicose veins. Due to large incompatibilities between trials and different time point. surgery in the treatment or great saphenous varicose veins. Due to large incompatibilities between that and different time point and measurements for outcomes, the evidence is lacking in robustness. Further randomised trials are needed, which should aim to report and produce regulate in a construct manner to facilitate future materials.

analyse results in a congruent manner to facilitate future meta-analysis.

unpublished studies.

SELECTION CRITERIA: All randomised controlled trials (RCTs) of UGFS, EVLT, RFA and HL/S were considered for inclusion. Primary outcomes were recurrent varicosities, recanalisation, neovascularisation, technical procedure failure, patient QoL scores and associated

DATA COLLECTION AND ANALYSIS: CN and RB independently reviewed, assessed and selected trials which met the inclusion criteria. CN and RB extracted data and used the Cochrane Collaboration's tool for assessing risk of bias. CN and RB contacted trial authors to clarify details as needed.

MAIN RESULTS: For this update, eight additional studies were included making a total of 13 included studies with a combined total of 3081 randomised patients. Three studies compared UGFS with surgery, eight compared EVLT with surgery and five compared RFA with surgery (two studies had two or more comparisons with surgery). Study quality, evaluated through the six domains of risk of bias, was generally moderate for all included studies, however no study blinded participants, researchers and clinicians or outcome assessors. Also, nearly all

### INTERNATIONAL GUIDELINES

- > American Venous Forum
- European Venous Forum
- European Society for Vascular Surgery
- > Latin American Venous Forum
- European College of Phlebology?

### INTERNATIONAL GUIDELINES

- American Venous Forum
- European Venous Forus
- Do we need so many different international guidelines??? Europe
- European College of Phlebology?

## INTERNATIONAL GUIDELINES

- > American Venous Forum
- > La Why different levels of evidence for the

  - European College of Phlebology?



modern surgical treatment of varicose veins: do we have evidence that supports one single technique?



## NO

according to the evidence ...

## WHAT'S IN

- minimally invasive
- ambulatory setting



- according the hemodynamic specific pattern of each patient
- without general anaesthesia
- able to return to work the day after the procedure
- cost-effective
- cosmetic satisfaction of the patient
- able to spares all the potential venous capital



CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

## JANUARY 19-21 2017 MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE

varicose veins surgery: what is more important, the technique or the strategy?

Armando Mansilha MD, PhD, FEBVS S. João University Hospital - Porto