

Interventions for Chronic Venous Disease: Immediate/Near Term Outcomes

Peter Gloviczki, MD

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Forum**

**Meeting of the Medicare Evidence Development and Coverage
Advisory Committee on Lower Extremity Chronic Venous Disease**

**July 20, 2016
Baltimore, MD**

SVS

Society for
Vascular Surgery



Conflict of Interest

None

SVS

Society for
Vascular Surgery



Founded in 1947

Mission

**Seeks to advance
excellence and
innovation in vascular
health.**

Membership

>5400

Founded in 1987

Mission

**Fosters cutting edge
research, clinical
innovation and education
of venous and lymphatic
diseases.**

Membership

>750

PRACTICE MANAGEMENT

From the Society for Vascular Surgery

A survey of current practice of vascular surgeons in venous disease management

Ruth L. Bush, MD, MPH,^a and Peter Gloviczki, MD,^b Round Rock, Tex; and Rochester, Minn

Objective: Acute venous thromboembolism and chronic venous diseases are common conditions that affect a large proportion of the United States population. The diagnosis of venous disease has improved, and the treatment options have rapidly evolved over the past decade. To date, it is unclear to what extent vascular surgeons have become involved in the modern management of venous disorders. This survey was undertaken to explore the current interest and practice of vascular

surgeons in the com

Methods: A survey to active and cand Surgery (SVS). Th the characteristics practice. Open-en commentary.

Results: A total of nationwide, 20.5%). The p 37.7% practicing practice. The resp and deep veins (85 their own vascular la

tions for superficial (91.9%), deep (85.8%), and perforator veins (52.7% endovenous, 19.4% subfascial endoscopic

perforator surgery) are being performed by respondents. Only 26.2% had learned endovenous thermal ablation in their training program; however, over 96% of those performing venous interventions utilized this technique. Overall, the majority (85.5%) devoted 50% or less of practice to venous disorders. Respondents indicated that limitations to expansion of vein practices mainly involved challenges with third party payers, local competition, and existing large volumes of

93% of 386 responders treated superficial veins and 86% treated deep veins

patients with venous disease. (J Vasc Surg: Venous and Lym Dis 2013;1:90-5.)

Guidelines for Management of Chronic Venous Disease



The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

Peter Gloviczki, MD,^a Anthony J. Comerota, MD,^b Michael C. Dalsing, MD,^c Bo G. Eklof, MD,^d David L. Gillespie, MD,^e Monika L. Gloviczki, MD, PhD,^f Joann M. Lohr, MD,^g Robert B. McLafferty, MD,^h Mark H. Meissner, MD,ⁱ M. Hassan Murad, MD, MPH,^j Frank T. Padberg, MD,^k Peter J. Pappas, MD,^k Marc A. Passman, MD,^j Joseph D. Raffetto, MD,^m Michael A. Vazquez, MD, RVT,ⁿ and Thomas W. Wakefield, MD,^o Rochester, Minn; Toledo, Ohio; Indianapolis, Ind; Helsingborg, Sweden; Rochester, NY;

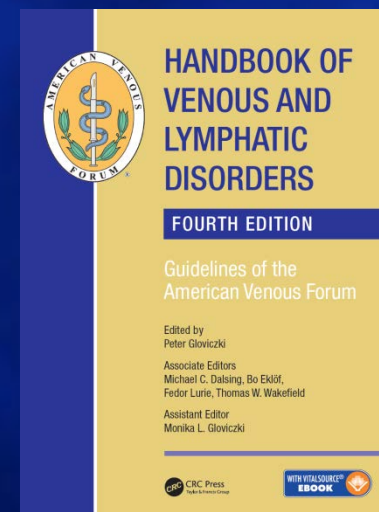
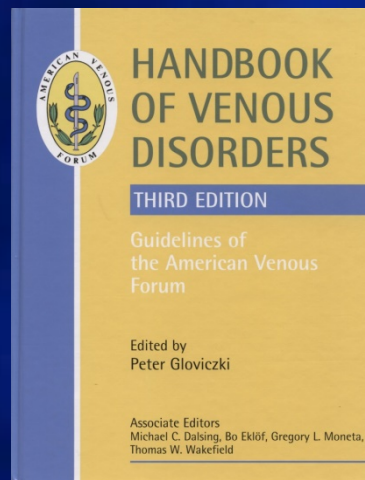
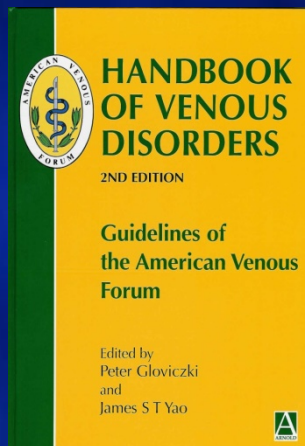
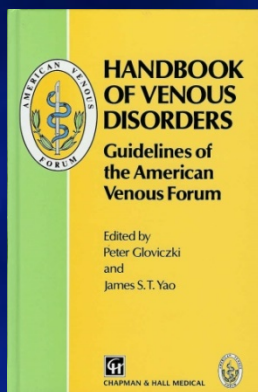
Management of venous leg ulcers: Clinical practice guidelines of the Society for Vascular Surgery[®] and the American Venous Forum

Endorsed by the American College of Phlebology and the Union Internationale de Phlébologie

Thomas F. O'Donnell Jr, MD, Marc A. Passman, MD, William A. Marston, MD, William J. Ennis, DO, Michael Dalsing, MD, Robert L. Kistner, MD, Fedor Lurie, MD, PhD, Peter K. Henke, MD, Monika L. Gloviczki, MD, PhD, Bo G. Eklof, MD, PhD, Julianne Stoughton, MD, Sesadri Raju, MD, Cynthia K. Shortell, MD, Joseph D. Raffetto, MD, Hugo Partsch, MD, Lori C. Pounds, MD, Mary E. Cummings, MD, David L. Gillespie, MD, Robert B. McLafferty, MD, Mohammad Hassan Murad, MD, Thomas W. Wakefield, MD, and Peter Gloviczki, MD

J Vasc Surg 2011;53:2S-48S.

J Vasc Surg 2011;53:2S-48S.



Randomized clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins

J. A. Michaels¹, J. E. Brazier², W. B. Campbell³, J. B. MacIntyre³, S. J. Palfreyman¹ and J. Ratcliffe²

¹Sheffield Vascular Institute, Northern General Hospital, and ²Health Economics and Decision Science, University of Sheffield, Sheffield and ³Royal Devon and Exeter Hospital, Exeter, UK

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Background: Surgical treatment of varicose veins improves quality of life and effectiveness remains to be established.

Methods: A randomized controlled trial was conducted in two hospitals in the UK. 536 consecutive patients were randomized to either surgery or conservative treatment. The primary outcome was the Short Form (SF) 6D and EuroQol (EQ) 5D scores at 1 and 2 years. Secondary outcomes were symptom improvement, anatomical extent of disease, and complications.

Results: In the first 2 years, the mean difference in the SF-6D score and 0.083 (95 per cent confidence interval 0.033 to 0.133) were also seen in symptom improvement.

Conclusion: Surgical treatment of varicose veins improves quality of life in patients referred to a specialist clinic.

REACTIVE TRIAL

- 246 patients randomized
- Clinical Outcome assessed at 1 and 2 years
 - Short Form (SF) 6D
 - EuroQol (EQ) 5D
 - SF-36
 - EuroQol
 - Complications
 - Symptom improvement
 - Anatomical extent

Randomized clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins

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¹Sheffield Vascular Institute, Northern General Hospital, and ²Health Economics and Decision Science, University of Sheffield, Sheffield and ³Royal Devon and Exeter Hospital, Exeter, UK
Correspondence to: Prof. J. A. Michaels, Acad (e-mail: j.michaels@shef.ac.uk)

Background: Surgical treatment of uncomplicated varicose veins remains uncertain.

Methods: A randomized controlled trial comparing surgery with conservative treatment in 536 consecutive referrals for surgical treatment. Conservative treatment (flush ligation and phlebectomies, as appropriate) was compared with surgery. SF-6D and EuroQol (EQ) 5D were used to measure quality of life. At 1 year post-treatment, symptoms of varicose veins were assessed.

Results: At 1 year post-treatment, the mean SF-6D score was 0.083 (95% CI: 0.005-0.16) for surgery and 0.016 (95% CI: 0.000-0.032) for conservative treatment. Similar improvements were also seen in symptoms of varicose veins.

Conclusion: Surgical treatment of uncomplicated varicose veins improves quality of life in patients referred to a vascular clinic.

RESULTS

At 1 and 2 years significant benefit of surgery in QoL:

- 0.083 QALY (95% CI:0.005-0.16, SF-6D)
- 0.13 QALY (95% CI: 0.016-0.25, EQ-5D)

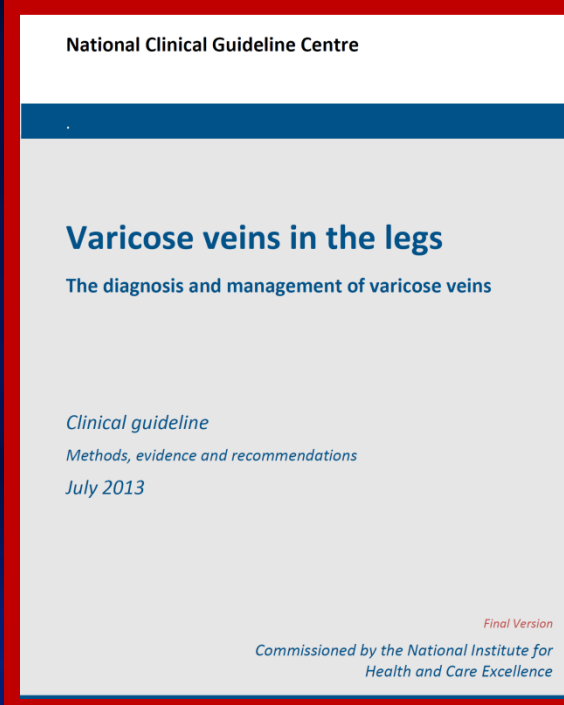
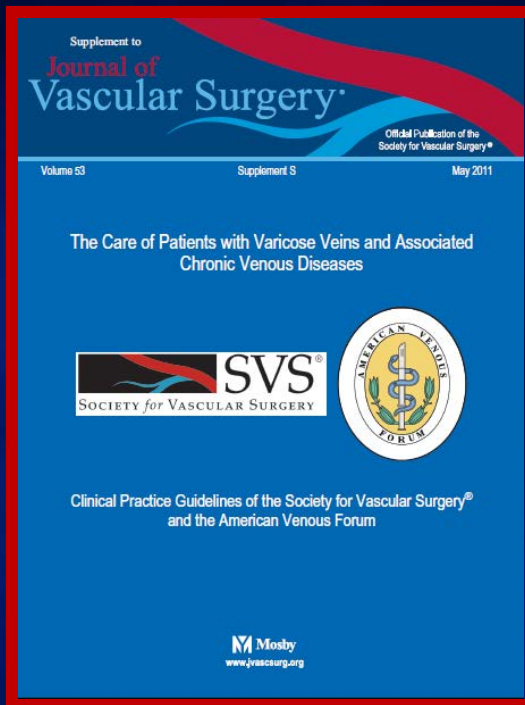
In symptomatic improvement

aching, heaviness, itching, swelling, cosmetic concerns (P <0.05 for all at 1 year)

In anatomical extent of Varicose Veins (VVs) at 1 year

Cons tx: NO CHANGE in VVs: 100%

Surgery: NO VVs: 70% (p <.0.010)



The SVS/AVF, the UK NICE and the European Guidelines

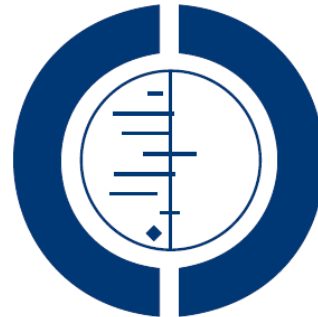
Recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation

Grade of recommendation: 1 (Strong)

Level of Evidence: B (Moderate Quality)

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

Nesbitt C, Bedenis R, Bhattacharya V, Stansby G



**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 7

<http://www.thecochranelibrary.com>

- **13 RCTs , 3081 patients**
- **3 RCTs UGFS with surgery**
- **8 RCTs EVLT with surgery**
- **5 RCTs RFA with surgery**

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

Nesbitt C, Bedenis R, Bhattacharya V, Stansby G



**THE COCHRANE
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- **UGFS, EVLT and RFA are as effective as surgery**
 - **The evidence is lacking in robustness.**

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 (Rangsit Campus), Pathumtani, Thailand

^c Department of Surgery, Chonburi Hospital, Chonburi, Thailand

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^e Center for Clinical Epidemiology and Biostatistics, The University of Newcastle, Newcastle, NSW, Australia

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- 28 RCTs
- EVLA and RFA had less hematoma, less pain, less wound infection and earlier return to normal activities than surgery

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

L. H. Rasmussen, M. Lawaetz, L. Bjoern, B. Vennits, A. Blemings and B. Eklof

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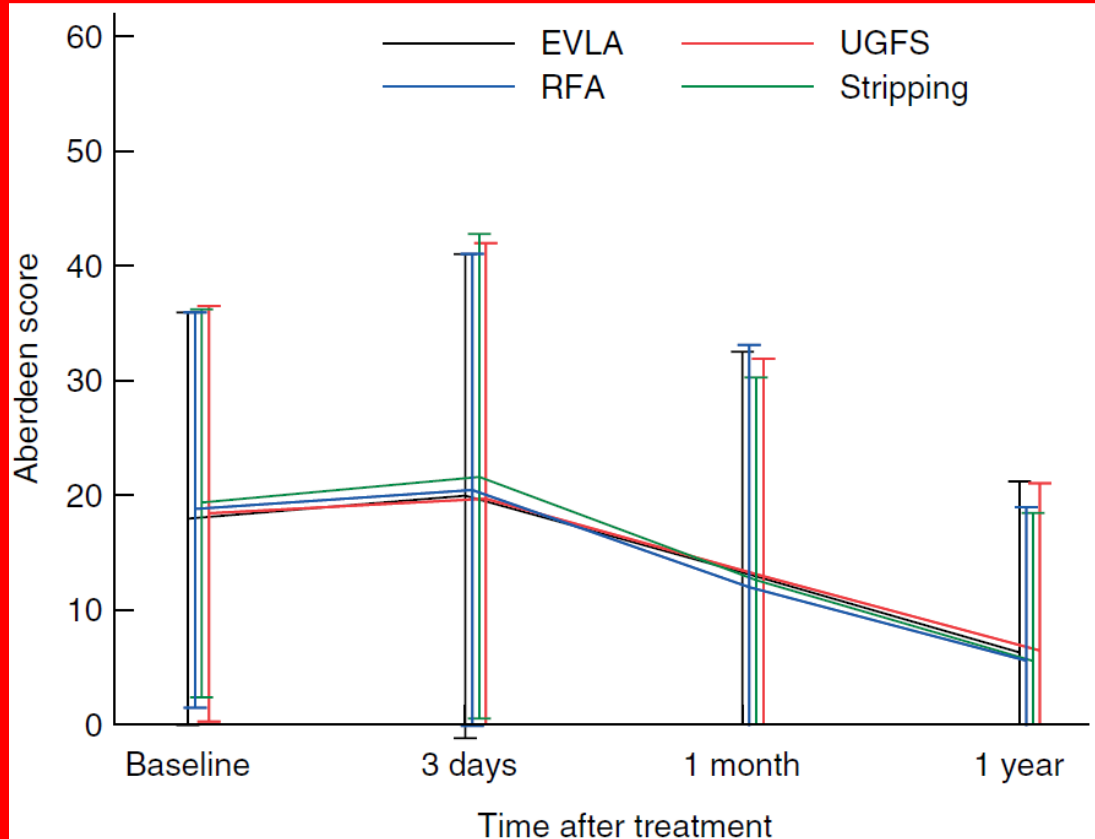
Correspondence to: Dr L. H. Rasmussen, Danish Vein Centres, Eskadronsvej 4A, 4700 Naestved, Denmark (e-mail: lhr@varix.dk)

Background: This randomized trial compared four

Methods: Five hundred consecutive patients underwent endovenous laser ablation (980 and 1470 nm, balloon foam sclerotherapy or surgical stripping using Miniphlebotomies were also performed. The primary outcome was pain, and after 3 days, 1 month and 1 year.

Results: At 1 year, seven (5.8 per cent), six (4.8 per cent) of the GSVs were patent and refluxing in the EVLA and RFA groups, respectively ($P < 0.001$). One patient developed one a deep vein thrombosis after surgical stripping. The mean (s.d.) postintervention pain scores (scale 0–46) were 2.25 (2.23) respectively ($P < 0.001$). The median (range) SF-36 scores were 1 (0–30), 1 (0–30) and 4 (0–30) days respectively ($P < 0.001$). The mean (s.d.) quality-of-life and Short Form 36 (SF-36®) scores were 3.6 (0–46), 2.9 (0–14), 2.9 (0–33) and 4.3 (0–46) respectively ($P < 0.001$). SF-36® domains bodily pain and physical function were better in the short term than the others.

Conclusion: All treatments were efficacious. Stripping and foam sclerotherapy, but both radiofrequency ablation and endovenous laser ablation had less postoperative pain than endovenous laser ablation.

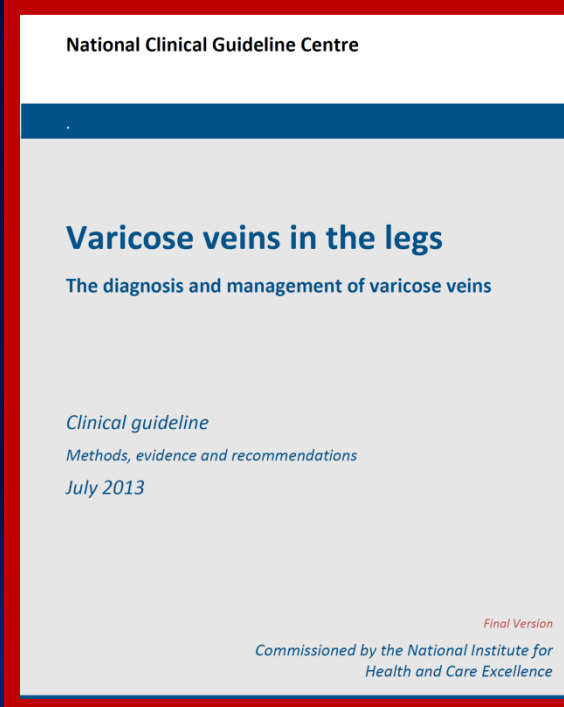
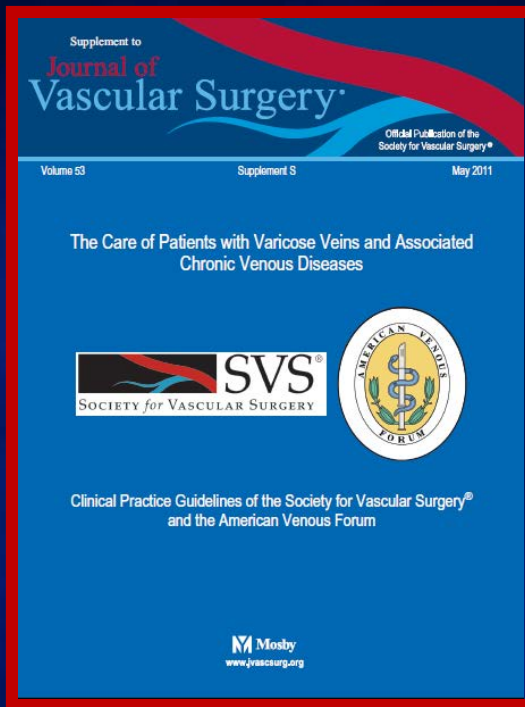


Secondary Outcomes

	EVLA	RFA	UGFS	Stripping	P value
Time to resume normal activity (days) *	2 (0–25)	1 (0–30)	1 (0–30)	4 (0–30)	<.001
Time to resume work (days) *	3.6 (0–46)	2.9 (0–14)	2.9 (0–33)	4.3 (0–42)	<.001

*: Median (range)

- Venous Clinical Severity Score
Improved in all ($P<.001$), no difference between groups



The SVS/AVF, the UK NICE and the European Guidelines

Recommend endovenous thermal ablation (RF or laser)

over high ligation and stripping

Grade of recommendation: 1 (Strong)

Level of Evidence: B (Moderate Quality)

A review of randomised controlled trials comparing ultrasound-guided foam sclerotherapy with endothermal ablation for the treatment of great saphenous varicose veins

Huw OB Davies¹, Matthew Popplewell¹, Katy Darvall², Gareth Bate¹ and Andrew W Bradbury¹

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Abstract

Objective: The last 10 years have seen the introduction into everyday clinical practice of a wide range of novel non-surgical treatments for varicose veins. The following review compares the effectiveness of the most commonly recommended treatments: endothermal ablation (ETA), ultrasound-guided foam sclerotherapy (UGFS), and surgery.

Methods: A systematic review of randomised controlled trials comparing ETA, UGFS, and surgery.

Results: ETA and UGFS were found to be safe and effective, with low complication rates and low morbidity.

Conclusions: Both ETA and UGFS are safe and effective, with low complication rates and low morbidity.

Keywords: Varicose veins, endothermal ablation, ultrasound-guided foam sclerotherapy, surgery.

Introduction: For almost 100 years, surgery has been the mainstay of treatment for varicose veins (VV). However, over the last 10 years a wide range of novel non-surgical, local and tumescent anaesthetic, treatment modalities have been described, evaluated and entered clinical practice around the world.

In July 2013, the UK National Institute for Health and Care Excellence (NICE) recommended (Clinical Guideline, CG, 168) the following treatment hierarchy for VV: endothermal ablation (ETA), ultrasound-guided foam sclerotherapy (UGFS), surgery and

- All endovenous treatments are safe, with low complication rate and morbidity
- Interventions resulted in significant and clinically important improvement in symptoms and signs
- All interventions result in significant improvement in QoL!

(VSOBT) and Royal College of Surgeons (RCS) Commissioning Guide published in December 2013²

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A Randomized Trial Comparing Treatments for Varicose Veins

Julie Brittenden, M.D., Seonaidh C. Cotton, Ph.D., Andrew Elders, M.Sc., Craig R. Ramsay, Ph.D., John Norrie, M.Sc., Jennifer Burr, M.D., Bruce Campbell, M.B., B.S., Paul Bachoo, M.B., Ch.B., Ian Chetter, M.B., Ch.B., M.D., Michael Gough, M.B., Ch.B., Jonathan Earnshaw, D.M., Tim Lees, M.B., Ch.B., M.D., Julian Scott, M.B., Ch.B., M.D., Sara A. Baker, M.Sc., Jill Francis, Ph.D., Emma Tassie, M.Sc., Graham Scotland, Ph.D., Samantha Willeman, Ph.D., and Marion K. Campbell, Ph.D.

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

L. H. Rasmussen, M. Lawaetz, L. Bjoern, B. Vennits, A. Blemings and B. Eklof

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Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins

Anke A. M. Biemans, MD,* Michael Kockaert, MD,* George P. Akkersdijk, MD,^{b,*} Renate R. van den Bos, MD, PhD,* Marianne G. R. de Maesseneer, MD, PhD,^{a,c} Philip Cuypers, MD, PhD,^d Theo Stijnen, PhD,* Martino H. A. Neumann, MD, PhD,^a and Tamar Nijsten, MD, PhD,^a Rotterdam, Eindhoven, and Leiden, The Netherlands; and Antwerp, Belgium



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Cost and Effectiveness of Laser with Phlebectomies Compared with Foam Sclerotherapy in Superficial Venous Insufficiency. Early Results of a Randomised Controlled Trial[®]

C.R. Lattimer^{a,*}, M. Azzam^a, E. Kalodiki^a, E. Shawish^a, P. Trueman^b, G. Geroulakos^a

1.a. For adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for an intervention that improves immediate/near-term health outcomes?

Confidence level: 4 (High/Intermediate)

(Without symptoms: 1 , Low)

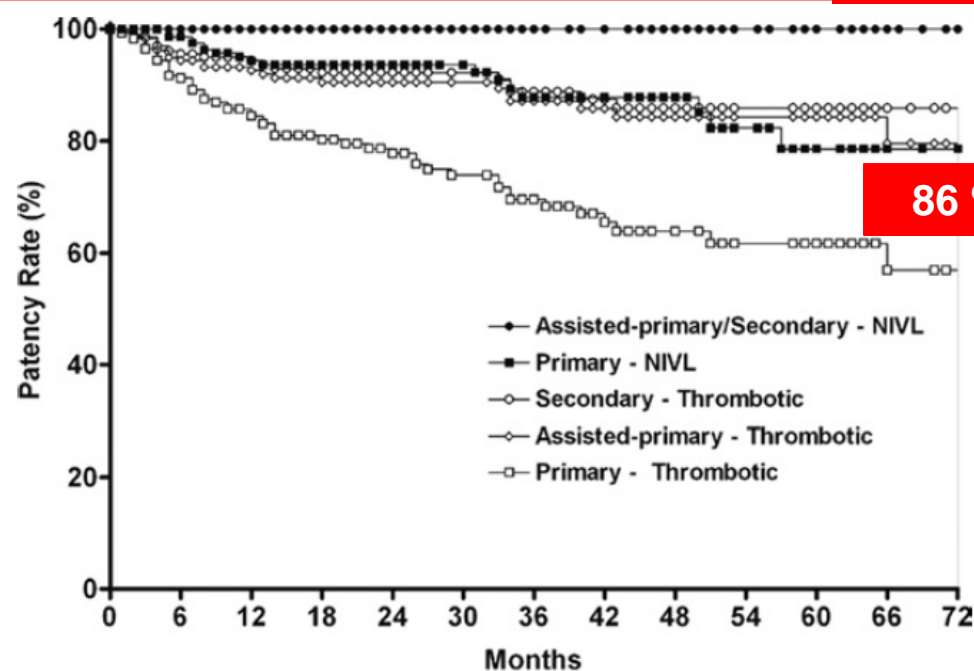
Stenting of the venous outflow in chronic venous disease: Long-term stent-related outcome, clinical, and hemodynamic result

Peter Neglén, MD, PhD,^a Kathryn C. Hollis, BA,^a Jake Olivier, PhD,^b and Seshadri Raju, MD,^b
Jackson, Miss

Background: Stenting of chronic nonmalignant obstruction in the venous outflow tract started in earnest in 1997. Data sets are now available to perform long-term analysis of stent-related outcome and clinical and hemodynamic results of this intervention.

Materials: From 1997 to 2005, 982 chronic nonmalignant obstructive lesions of the femoroiliocaval vein were stented under intravascular ultrasound guidance. Median patient age was 54 years (range, 14 to 90 years), the female/male was 2.6:1, and left/right limb symptoms, 2.4:1. Clinical score of CEAP was 2 in 7%, 3 in 47%, 4 in 24%, 5 in 5%, and 6 in 17%; primary/secondary etiology was 518:464. Stent-related outcome (no recurrent stenosis), clinical outcome, quality of life (QOL) as assessed by

Questionnaire (CIVIQ), and hemodynamics were evaluated before and after stenting. **Result:** Monitoring for 94% of patients lasted a mean 22 months (range, 0 to 72 months). There was no mortality (<30 days) and low morbidity. Thrombotic events were rare (3%) and during later follow-up (3%). At 72 months, primary, assisted, and secondary patency were 79%, 100%, and 100% in nonthrombotic disease and 57%, 80%, and 86% in thrombotic limbs. Cumulative rate of severe in-stent restenosis (>50%) occurred in 5% of limbs in nonthrombotic limbs. The main risk factors associated with stent-related thrombosis were secondary etiology and thrombotic disease; thrombophilia by itself was not a risk factor. The main symptom was leg pain, which was significantly poststent. Severe leg pain (visual analogue scale >5) and leg swelling were present to 11% and 18% poststent, respectively. At 5 years, cumulative ulcer healing was 62% and 32%, respectively, and ulcer healing was 58%. The mean CVC categories. Mean hand-foot pressure differential decreased and mean ankle-brachial index was similar in limbs with no concomitant reflux. The hemodynamic response was similar in superficial reflux in subsets of patients with adjunct saphenous procedure. **Conclusions:** Venous stenting can be performed with low morbidity and low rate of in-stent restenosis. It resulted in major symptom relief in patients with chronic venous disease, which was consistently reflected in any substantial hemodynamic improvement. Clinical outcome occurred regardless of presence of remaining reflux or obstruction. (J Vasc Surg 2007;46:979-90.)



100 %

86 %

302	192	143	120	96	80	65	55	43	34	24	16
302	189	135	110	87	72	54	45	36	26	18	11
303	191	147	123	99	87	74	59	45	35	29	18
303	189	144	122	99	87	74	59	45	35	29	18
303	184	132	107	89	74	59	45	32	26	21	13

REVIEW

Editor's Choice — A Systematic Review of Endovenous Stenting in Chronic Venous Disease Secondary to Iliac Vein Obstruction

M.J. Seager, A. Busuttil, B. Dharmarajah, A.H. Davies *

Department of Surgery and Cancer, Imperial College London, Charing Cross Hospital, London, UK

WHAT THIS PAPER ADDS

This review demonstrates that quality of evidence behind the use of deep venous stenting to treat obstructive chronic venous disease is weak. However, the consistent effects and marked changes to disease course mean that it should be considered as an acceptable treatment option. Vascular teams are aware of this, and it is

Objectives: Deep endovenous stenting for non-thrombotic iliac vein obstruction. This review reports systematic reviews on the topic and analysis of the available data, reported in the Cochrane Analyses guideline.

Methods: MEDLINE, EMBASE, and the Cochrane references were searched.

Results: Sixteen studies were included (10 case series) encompassing successful treatment of thrombotic limbs and patients respectively. There were significant improvements in quality of life. Persistent ulcer healing rate was improved. Primary and major complication rates were low. The quality of the evidence for the treatment was weak.

Conclusions: The quality of the evidence for the treatment is currently weak. The treatment should be considered as a treatment option while the evidence is weak.

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Article history: Received 7 June 2015, Accepted 10 July 2015

Keywords: Venous insufficiency, Iliac vein obstruction, Angioplasty, Systematic review

- Evidence from 16 studies to support the use of stenting venous obstructions is weak
- Stenting is safe, promising and should be considered acceptable treatment for proximal venous obstruction

1.a. For adults with clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for stenting to improve immediate/near-term health outcomes in patients presenting with symptoms?

Confidence level: 2 (Low/Intermediate)

(Without symptoms: 1 , Low)

THANK YOU!