

Interventions for Chronic Venous Disease: **Long Term** Outcomes

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**- Lower Extremity Chronic-
Venous Disease**

SVS

Society for
Vascular Surgery



- *Disclosures:*
 - *Research Support for BTG – Minor – less than \$10,000*

Key Question 1B

- 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 long-term health outcomes in patients presenting with symptoms?

Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy, and surgical stripping for great saphenous varicose veins with 3-year follow-up

Lars Rasmussen, DMSC, Martin Lawaetz, MS, Julie Serup, MS, Lars Bjoern, MD, Bo Vennits, MD, Allan Blemings, MSc, and Bo Eklof, MD, *Naestved, Denmark*

Introduction: This study compares the outcome 3 years after treatment of varicose veins by endovenous laser ablation (EVLA), radiofrequency ablation, ultrasound-guided foam sclerotherapy (UGFS), or surgery by assessing recurrence, Venous Clinical Severity Score (VCSS), and quality of life (QOL).

Methods: A total of 500 patients (580 legs) were randomized to one of the three endovenous treatments or high ligation and stripping of the great saphenous vein (GSV). Follow-up included clinical and duplex ultrasound examinations and VCSS and QOL questionnaires. Kaplan-Meier (KM) life-table analysis was used. *P* values below .05 were considered statistically significant.

Results: At 3 years, eight (KM estimate, 7%), eight (KM estimate, 6.8%), 31 (KM estimate, 26.4%), and eight (KM estimate, 6.5%) of GSVs recanalized or had a failed stripping procedure (more than 10 cm open refluxing part of the

treated GSV; CLF, EVLA, UGFS, and stripping, respectively; *P* < .01). Seventeen (KM estimate, 14.9%), 24 (KM estimate, 20%), 20 (KM estimate, 19.1%), and 22 (KM estimate, 20.2%) legs developed recurrent varicose veins (*P* = NS). The patterns of reflux and location of recurrent varicose veins were not different between the groups. Within 3 years after treatment, 12 (KM estimate, 11.1%), 14 (KM estimate, 12.5%), 37 (KM estimate, 31.6%), and 18 (KM estimate, 15.5%) legs were retreated in the CLF, EVLA, UGFS, and stripping groups, respectively (*P* < .01). VCSS, SF-36, and Aberdeen QOL scores improved significantly in all the groups with no difference between the groups.

Conclusions: All treatment modalities were efficacious and resulted in a similar improvement in VCSS and QOL. However, more recanalization and reoperations were seen after UGFS. (J Vasc Surg: Venous and Lym Dis 2013;1:349-56.)

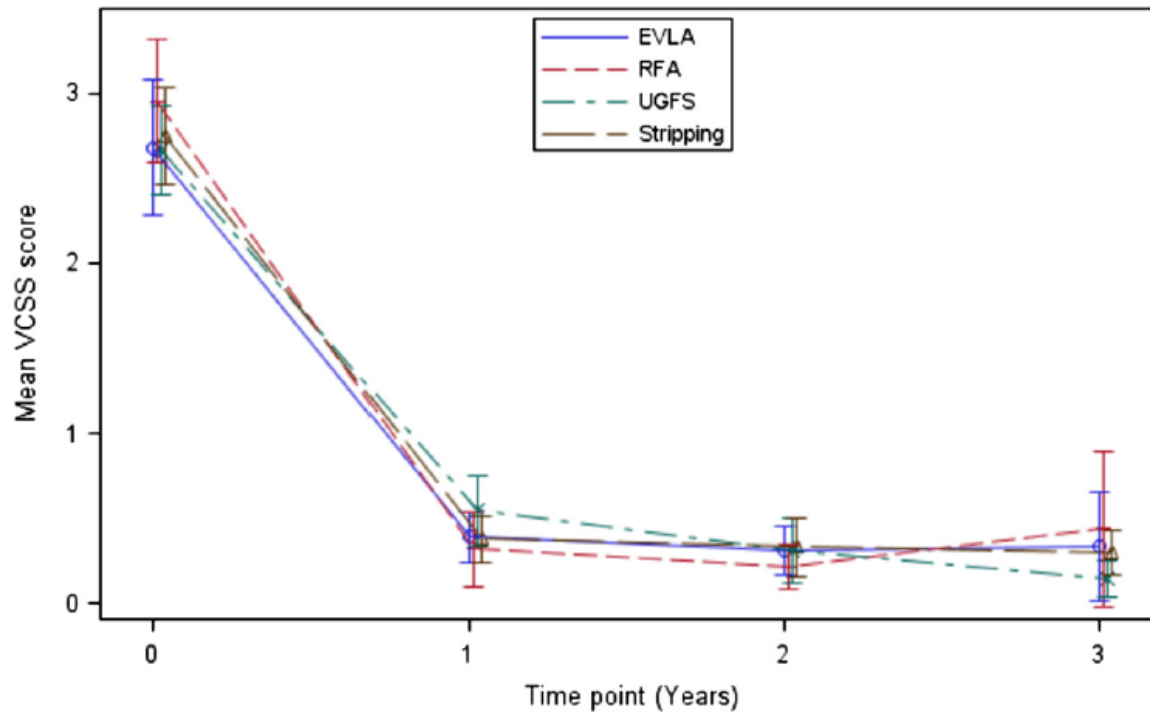


Fig 5. Venous radiofrequency

3 year VCSS scores show sustained equivalent improvement

5 year follow up data

Randomized clinical trial comparing endovenous laser ablation and stripping of the great saphenous vein with clinical and duplex outcome after 5 years

Lars Rasmussen, MD, Martin Lawaetz, MB, Lars Bjørn, MD, Allan Blemings, MSc, and Bo Eklof, MD, PhD, Naestved, Denmark

Objective: This is the first randomized controlled trial with a 5-year follow-up comparing endovenous laser ablation (EVLA) with high ligation and pin-stripping in patients with great saphenous vein (GSV) incompetence.

Methods: One hundred twenty-one consecutive patients (137 legs) with GSV incompetence were randomized to EVLA (980 nm bare fiber) or high ligation and stripping using tumescent local anesthesia with light sedation. Mini-phlebectomies were performed in all patients. The patients were examined with duplex scanning before treatment and after 12 days, and then after 1, 3, and 6 months, and yearly thereafter for up to 5 years. The primary end point was open refluxing GSV. Secondary end points were recurrent varicose veins, frequency of reoperations, Venous Clinical Severity Score, and quality of life scores (Aberdeen Varicose Vein Symptoms Severity Score and Short Form-36).

Results: In the EVLA and stripping group, nine (Kaplan-Meier [KM] estimate, 17.9%) and four (KM estimate, 10.1%) of GSVs had open refluxing segments of 5 cm or more (ns). Clinical recurrence was recorded in 24 (KM estimate, 46.6%) and 25 (KM estimate, 54.6%), whereas reoperations were performed in 17 (KM estimate, 38.6%) and 15 (KM estimate, 37.7%) legs (ns). Venous Clinical Severity Score and Aberdeen Varicose Vein Symptoms Severity Score improved whereas Medical Outcomes Study Short Form-36 quality of life score improved in several domains in both groups with no difference between the groups.

Conclusions: Five-year follow-up of our randomized controlled trial comparing EVLA with open surgery in patients with GSV incompetence did not show any significant difference between the two groups in primary or secondary end points, perhaps because of the small sample size. EVLA seems to be a valid alternative to open surgery. (J Vasc Surg 2013;58:421-6.)

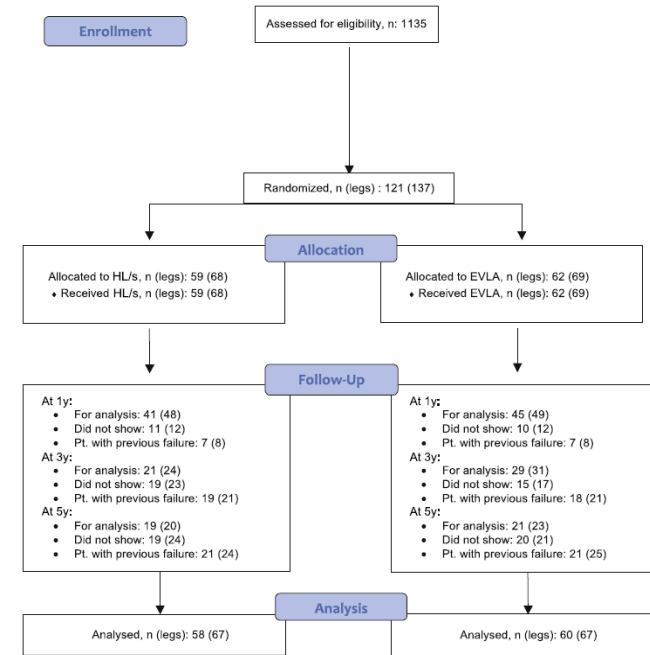


Fig 1. Consort diagram. EVLA, Endovenous laser ablation.

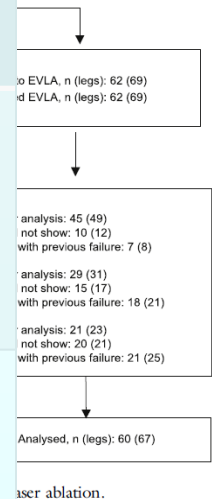
5 year follow up data

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laser ablation
vein with c

Lars Rasmussen, MD
Bo Eklof, MD, PhD,

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	EVLA	Surgery
Pre op	2.8 ± 1.7	2.4 ± 1.4
5 year f/u	0.4 ± 0.9	0.4 ± 0.7



At 5 yrs both modalities show sustained, equivalent improvement in VCSS scores

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,^l Joseph D. Raffetto, MD,^m Michael A. Vasquez, MD, RVT,ⁿ and

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Gloviczki et al 31S

Guideline 11. Endovenous thermal ablation

Guideline No.	11. Endovenous thermal ablation	GRADE of recommendation	Level of evidence
		1. Strong	A. High quality
		2. Weak	B. Moderate quality C. Low or very low quality
11.1	Endovenous thermal ablations (laser and radiofrequency ablations) are safe and effective, and we recommend them for treatment of saphenous incompetence.	1	B
11.2	Because of reduced convalescence and less pain and morbidity, we recommend endovenous thermal ablation of the incompetent saphenous vein over open surgery.	1	B

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Guideline	JOURNAL OF VASCULAR SURGERY Volume 53, Number 16S Gloviczki et al 21S		
Guideline No.	Guideline 9. Compression treatment		
	Guideline No.	9. Compression treatment	GRADE of recommendation Level of evidence
11.1			1. Strong 2. Weak
11.2	9.1	We suggest compression therapy using moderate pressure (20 to 30 mm Hg) for patients with symptomatic varicose veins.	2 A. High quality B. Moderate quality C. Low or very low quality
	9.2	We recommend against compression therapy as the primary treatment of symptomatic varicose veins in patients who are candidates for saphenous vein ablation.	1 B

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Guideline No.	Guideline No.	Gloviczki et al 35S	
11.1	Guideline 9	JOURNAL OF VASCULAR SURGERY Volume 53, Number 16S	
11.2	Guideline No.	Guideline 12. Sclerotherapy of varicose veins	
		Guideline No.	12. Sclerotherapy of varicose veins
			GRADE of recommendation
			Level of evidence
			1. Strong
			2. Weak
			A. High quality
			B. Moderate quality
			C. Low or very low quality
		12.1	We recommend liquid or foam sclerotherapy for telangiectasia, reticular veins, and varicose veins.
		12.2	For treatment of the incompetent saphenous vein, we recommend endovenous thermal ablation over chemical ablation with foam.

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

Endorsed by the

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SVS/AVF Joint

Superficial Venous Reflux and Venous Leg Ulcer

Guideline 6.1 Superficial Venous Reflux and Active Venous Leg Ulcer—Ulcer Healing

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we suggest ablation of the incompetent veins in addition to standard compressive therapy to improve ulcer healing. [GRADE - 2; LEVEL OF EVIDENCE - C]

Guideline 6.2 Superficial Venous Reflux and Active Venous Leg Ulcer—Prevent Recurrence

In a patient with a venous leg ulcer (C6) and incompetent superficial veins that have axial reflux directed to the bed of the ulcer, we recommend ablation of the incompetent veins in addition to standard compressive therapy to prevent recurrence. [GRADE - 1; LEVEL OF EVIDENCE - B]

Phlébologie

John J. Ennis, DO,
MD,
Sri Raju, MD,
MD,

Effectiveness and Cost Effectiveness

Randomized clinical trial

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

Correspondence to: Prof. J. A. Michaels, Academic Vascular Unit, Coleridge House, Northern General Hospital, Herries Road, Sheffield S5 7AU, UK (e-mail: j.michaels@shef.ac.uk)

Background: Surgical treatment of medically uncomplicated varicose veins is common, but its clinical effectiveness remains uncertain.

Methods: A randomized clinical trial was carried out at two large acute National Health Service hospitals in different parts of the UK (Sheffield and Exeter). Some 246 patients were recruited from 536 consecutive referrals to vascular outpatient clinics with uncomplicated varicose veins suitable for surgical treatment. Conservative management, consisting of lifestyle advice, was compared with surgical treatment (flush ligation of sites of reflux, stripping of the long saphenous vein and multiple phlebectomies, as appropriate). Changes in health status were measured using the Short Form (SF) 6D and EuroQol (EQ) 5D, quality of life instruments based on SF-36 and EuroQol, complications of treatment, symptomatic measures, anatomical extent of varicose veins and patient satisfaction.

Results: In the first 2 years after treatment there was a significant quality of life benefit for surgery of 0.083 (95 per cent confidence interval (c.i.) 0.005 to 0.16) quality-adjusted life years (QALYs) based on the SF-6D score and 0.13 (95 per cent c.i. 0.016 to 0.25) based on the EQ-5D score. Significant benefits were also seen in symptomatic and anatomical measures.

Conclusion: Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients referred to secondary care with uncomplicated varicose veins.

Effectiveness and Cost Effectiveness

Randomized clinical trial

- REACTIV Trial Group

- A systematic review that included data from 34 RCTs:

J. A. Michaels¹, J. E. Brazier², W. B. Campbell³, J. B. Macintyre¹, S. J. Fairhead¹ and J. Kitchell¹
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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- Recurrence rates: lower for EVLA, RFA and FS, for longer follow-up periods

Background: Surgical treatment of medically uncomplicated varicose veins is common, but its clinical effectiveness remains uncertain.

- VCSS score: lower for EVLA and FS than for stripping, higher for RFA

Methods: A randomized clinical trial was carried out at two large acute National Health Service hospitals in different parts of the UK (Sheffield and Exeter). Some 246 patients were recruited from general practice referrals to a venous clinic with uncomplicated varicose veins suitable for surgical treatment. Conservative management, consisting of lifestyle advice, was compared with

- Higher quality-of-life scores for all evaluated interventions than for stripping

Endovenous laser treatment of the great saphenous vein (EVLA), radiofrequency ablation of the great saphenous vein (RFA), or stripping of the great saphenous vein (FS), as appropriate. Changes in health status were measured using the Short Form (SF)-36 and EuroQol (EQ)-5D quality of life instruments, and SF-36 and EuroQol, complications of treatment, symptomatic measures, anatomical extent of varicose veins and patient satisfaction.

- EVLA and RFA might be considered cost-effective if their costs are equivalent to stripping

Results: In the first 2 years after treatment there was a significant quality of life benefit for surgery of £0.81 (95 per cent c.i. £0.41 to £1.21) based on the EQ-5D score and £0.13 (95 per cent c.i. £0.016 to £0.25) based on the SF-6D score. Significant benefits were also seen in symptomatic measures and anatomical extent of varicose veins.

Conclusion: Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients referred to secondary care with uncomplicated varicose veins.

ESCHAR Trial

BMJ

RESEARCH

Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial

Manjit S Gohel, specialist registrar,¹ Jamie R Barwell, consultant vascular and transplant surgeon,² Maxine Taylor, leg ulcer nurse specialist,¹ Terry Chant, vascular nurse specialist,³ Chris Foy, medical statistician,⁴ Jonathan J Earnshaw, consultant surgeon,⁵ Brian P Heather, consultant surgeon,⁵ David C Mitchell, consultant surgeon,³ Mark R Whyman, consultant surgeon,¹ Keith R Poskitt consultant surgeon¹

ABSTRACT

Objective To determine whether recurrence of leg ulcers may be prevented by surgical correction of superficial venous reflux in addition to compression.

Design Randomised controlled trial.

Setting Specialist nurse led leg ulcer clinics in three UK vascular centres.

Participants 500 patients (500 legs) with open or recently healed leg ulcers and superficial venous reflux.

Interventions Compression alone or compression plus saphenous surgery.

INTRODUCTION

In recent years the importance of the effect of venous leg ulceration on healthcare expenses and patients' quality of life has been recognised.¹⁻⁴ European studies have reported a prevalence of 1% in the adult population, increasing dramatically in those aged more than 80.⁵⁻⁷ The precise pathophysiological mechanisms causing ulceration remain debatable, although chronic venous hypertension (usually as a result of venous reflux) is generally accepted to play a major part.^{5,8}

Chronic venous hypertension may be countered by high elevation of the leg and multilayered compression

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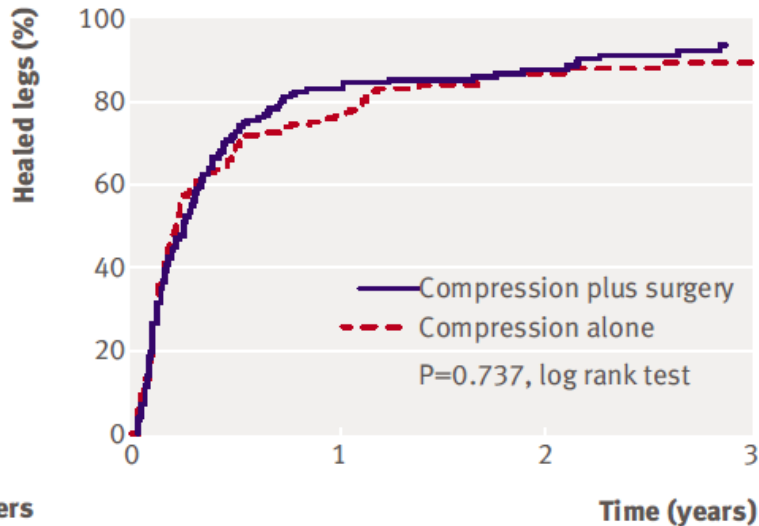
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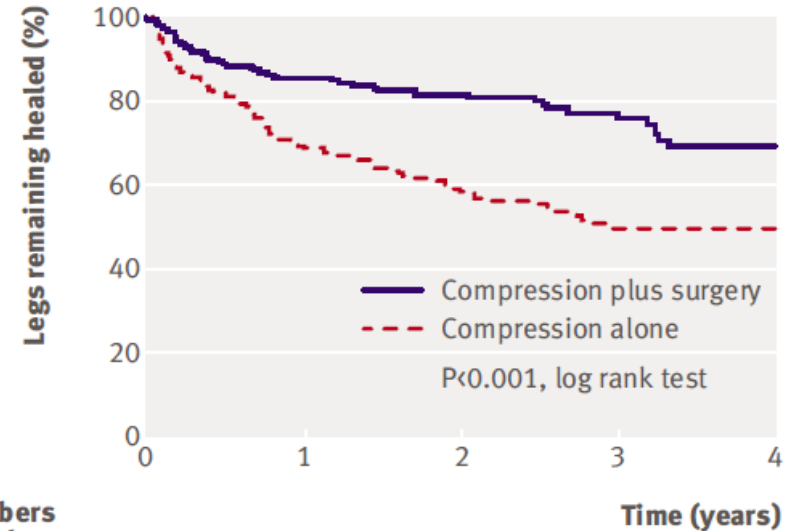
doi: 10.1136/bmj.39216.542442.BE

ESCHAR Trial



Numbers at risk

Compression plus surgery	185	33	13	6
Compression alone	156	24	15	5



Numbers at risk

Compression plus surgery	216	166	124	68	27
Compression alone	226	139	98	45	10

Ulcer healing and recurrence rates at 4 years:

- Compression alone (median age 72, 10% PTS): **56%**
- GSV surgery were (median age 74, 8% PTS): **31%**
- Elimination of superficial reflux disease lowers recurrence rates in C6 patients

Fig 2 | Kaplan-Meier survival analysis showing ulcer healing at three years

Fig 3 | Kaplan-Meier survival analysis showing ulcer recurrence at four years

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doi: 10.1136/bmj.39216.542442.BE

Setting: Specialist nurse led leg ulcer clinics in three UK vascular centres.

Patients: 500 patients (50% male, 50% female) with healed leg ulcers and superficial venous reflux.

Intervention: Randomised to either compression plus saphenous surgery.

increasing venous pressure in the leg more than 80%.^{5,7} The precise pathophysiological mechanisms of this reflux are still unclear, but chronic venous hypertension (usually as a result of venous reflux) is generally accepted to play a major part.^{5,8} Chronic venous hypertension may be countered by high elevation of the leg and multilayered compression

Iliac-Caval Outflow Obstruction

Iliac Vein Stenting

EVIDENCE SUMMARY

Peter F. Lawrence, MD, Section Editor
From the Society for Vascular Surgery

Best management options for chronic iliac vein stenosis and occlusion

Seshadri Raju, MD, FACS, *Jackson, Miss*

Background: Iliac vein stenting technology is rapidly emerging as a minimally invasive alternative to traditional open venovenous bypass procedures for iliac vein stenoses and chronic total occlusions.

Methods: Peer-reviewed publications meeting eligibility criteria were retrieved and reviewed from public domain databases.

Results: Reviewed reports encompass ~1500 patients. Evidence quality was judged moderate, with a grade 1B recommendation (benefits outweigh risks) for patients with disabling symptoms in whom conservative therapy had failed. A grade 2B recommendation was assigned for patients with less severe symptoms. Iliac vein stenting is safe, with negligible morbidity (<1%). Patency was 90% to 100% for nonthrombotic disease and 74% to 89% for post-thrombotic disease at 3 to 5 years. Clinical relief of pain was 86% to 94%, and relief from swelling was 66% to 89%. From 58% to 89% of venous ulcers healed. Procedural success in recanalization of chronic total occlusions was 83% to 95%. Hybrid techniques for complex cases are in evolution.

Conclusions: Iliac vein stenting is emerging as a safe and effective alternative to traditional open surgery to correct iliac vein obstruction. (J Vasc Surg 2013;57:1163-9.)

Iliac-Caval Outflow Obstruction

Iliac Vein Stenting

EVIDENCE SUMMARY

Peter F. Lawrence, MD, Section Editor
From the Society for Vascular Surgery

- A review of worldwide iliac and IVC stent series:
Best management options for chronic iliac vein stenosis and occlusion
 - cumulative patency at 3 to 5 years:

Seshadri Raju, MD, FACS, *Jackson, Miss*

- 90% to 100% for non-thrombotic
- 74% to 89% for post-thrombotic disease

Background: Iliac vein stenting technology is rapidly emerging as a minimally invasive alternative to traditional open venovenous bypass or iliac vein stent placement.

Methods: Peer-reviewed publications meeting eligibility criteria were retrieved and reviewed from public domain databases.

Results: Reviewed reports encompass ~1500 patients. Evidence quality was judged moderate, with a grade 1B recommendation (benefit outweighs risk) for patients with disabling symptoms in whom conservative therapy had failed. A grade 2B recommendation was assigned for patients with less severe symptoms. Iliac vein stenting is safe, with negligible morbidity (<1%).

Conclusions: Iliac vein stenting is emerging as a safe and effective alternative to traditional open surgery to correct iliac vein obstruction. (J Vasc Surg 2013;57:1168-9.)

- Clinical relief of:
 - Pain: 86% to 94%
 - Swelling: 66% to 89%
 - Venous ulcers healed: 58% to 89%

Key Question 1B

- 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 long-term health outcomes in patients presenting with symptoms?
- The SVS and the AVF have a high (score 4) level of confidence that for adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency interventions **to ablate refluxing superficial veins** improve long-term health outcomes.
- The SVS and the AVF have a intermediate (score 3) level of confidence that for adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency interventions **to stent stenotic iliocaval lesions** improve long-term health outcomes.

Key Question 1B

- How confident are you that there is sufficient evidence for an intervention that improves long-term health outcomes in patients presenting without symptoms but with signs?
- There is no evidence that interventions to treat patients with asymptomatic varicose veins is medically necessary
- The SVS has a low (score 2) level of confidence that interventions improves long-term health outcomes in asymptomatic patients.



THANK YOU!

SVS

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Vascular Surgery

