IMAP
International Meeting on Aesthetic Phlebology 2017

Radiofrequency ablation for perforators veins

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GRAND HYATT SÃO PAULO

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Disclosures

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Agenda

- When and How did the radiofrequency ablation for perforators veins be created?
- How is this surgery done?
- What is the surgery outcome?
- VUERT trial

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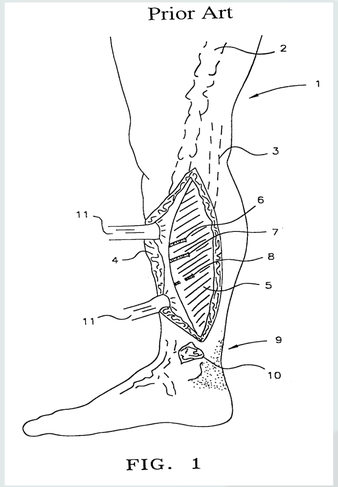
When and How did the radiofrequency ablation for perforators veins be created?



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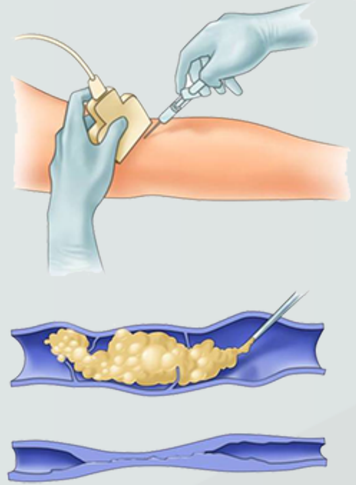

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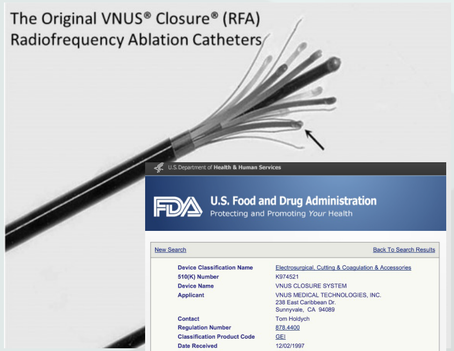
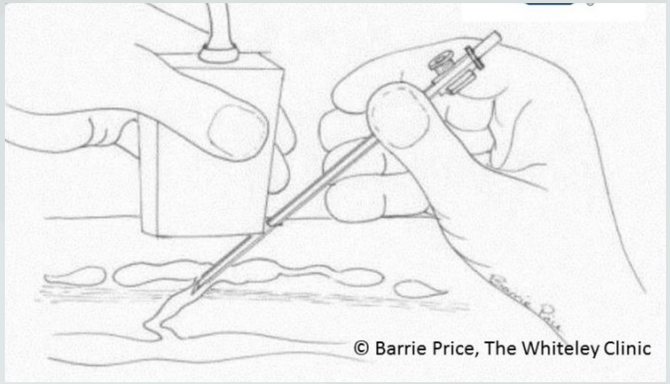
When and How did the radiofrequency ablation for perforators veins be created?



1999 – FDA allowance



Whiteley MS, Price BA, Scott MJ, Gallagher TM. Radiofrequency ablation of refluxing great saphenous systems, Giacomini veins, and incompetent perforating veins using VNUS closure and TRLOP technique. Phlebology 2003;18:52

2004– FDA allowance

Agenda

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How is this surgery done?

1. Patient prepare
2. US : identify perforator vein
3. Local anesthesia
4. Incision with n. 11 blade
5. Puntion
6. Checking:
   - Blood scape
   - Impedance <400
   - US image
7. Infiltration w/ tumescent solution
8. Tremdelemburg position
9. Compression w/ US probe
10. Ablation – 1 minute per quadrant

Peden E, Lumsden A. Radiofrequency Ablation of Incompetent Perforator Veins. Perspectives in vascular surgery and endovascular therapy. 2007;19(1):73-7.

Agenda

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What is the surgery outcome?

Original article

Five-year results of incompetent perforator vein closure using TRans-Luminal Occlusion of Perforator

J L Bacon, A J Dinneen, P Marsh, J M Holdstock, B A Price and M S Whiteley
The Whiteley Clinic, Stirling Road, Guildford, UK

Abstract
In 2000, we developed a percutaneous method of treating incompetent perforator veins (IPV) using ultrasound-guided radiofrequency ablation (RFA), which we termed TRansluminal Occlusion of Perforator (TRLOP).
Objective: To audit the five-year outcome of the TRLOP technique as indicated by the rate of IPV closure on duplex ultrasound (DUS).
Methods: Patients underwent DUS five years post-TRLOP. Experienced vascular technologists documented the presence of IPVs using a two co-ordinate system, blinded to previous results. Results were then compared with preoperative scans. IPVs were classified as: closed; not closed/reopened; or *de novo*. Closed IPVs were defined as the absence of any IPV at or within 5 cm of a previous IPV in the vertical and horizontal plane. Any IPVs found outside the delineated area were defined as *de novo* IPVs.
Results: Of 67 patients invited, 37 attended DUS (55% participation rate; men to women ratio of 14:23, age 40–84; mean 64). Preoperative clinical, aetiological, anatomical and pathological classification: C2, 36.2%; C3, 27.6%; C4, 34.5%; C6, 1.7%. From 125 IPVs analysed, 101 were closed (81%), 24 were not closed/reopened (19%) and 14 *de novo* IPVs were found.
Discussion: Despite these results representing our learning curve for the procedure, we found TRLOP to be an effective treatment for IPVs. The closure rates described are comparable with the published clinical series data for subfascial endoscopic perforator surgery.

Keywords: TRLOP; perforator; radiofrequency ablation

Introduction

Perforator veins connect the superficial and deep venous systems in the lower limbs, conducting venous flow from superficial to deep layers under normal circumstances. However, these veins may become incompetent, exhibiting reverse flow on duplex ultrasound (DUS). Incompetent perforator veins (IPVs) are more commonly found in patients with recurrent varicose veins than primary varicose veins.[1] Over half of the limbs with reflux in the great saphenous system after saphenofemoral ligation have been associated with IPVs.[2] Indications for perforator vein surgery are controversial, but an association has been shown between the presence of IPVs and recurrent varicose veins. Recurrent varicose veins have IPVs more commonly and a larger number present per leg.[3]

In the early part of the twentieth century, IPV surgery was performed using open techniques such as the Linton procedure.[4] High complication rates led to the development of subfascial endoscopic perforator surgery (SEPS) in 1985 by Hauer.[5] SEPS is a minimally invasive technique usually clipping IPVs under direct vision using video-endoscopy with general or regional anaesthesia. This technique is favoured for its small incision, remote from the site of venous disease where skin is often compromised. Success rates are high; we have reported closure rates of 92% at one-year post-procedure,[3] with rates of 78% found by others after longer follow-up (mean 3.7 years).[6]

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Accepted: 15 July 2008

Bacon JL, et al. Five-year results of incompetent perforator vein closure using TRans-Luminal Occlusion of Perforator. Phlebology 2009;24(2):74-8.

Observational

37 patients/ 58 limbs
Axial ablation + TRLOP procedure
5y follow up

125 perforators are treated
- 81% closed
- 19% not closed/reopened

Observational

53 patients/ 67 limbs
Axial ablation + ClosureRFS stylet
1y follow up

124 perforators are treated
- 82% closed
- 18% not closed/reop

Original article

One-year outcomes of radiofrequency ablation of incompetent perforator veins using the radiofrequency stylet device

P Marsh, B A Price, J M Holdstock and M S Whiteley
The Whiteley Clinic, 1 Stirling House, Stirling Road, Guildford, GU2 7RF, UK

Abstract
Objectives: Early success treating incompetent perforator veins (IPVs) with radiofrequency ablation (RFA) and the trend to move varicose vein surgery into a walk-in walk-out service led to the design of a specific device enabling RFA of IPVs using local anaesthesia (ClosureRFS™ stylet). Our aim was to assess one-year outcomes of a clinical series of patients undergoing treatment with this device. Truncal reflux, where present, was treated initially, and RFA of IPVs was performed as a secondary procedure.
Method: Duplex ultrasound examinations were performed and the presence of IPVs documented. Results were compared with preoperative scans. IPVs were classified as closed, not closed/reopened or *de novo*.
Results: Of the 75 patients invited for follow-up, 53 attended at a median time of 14 months (range 11–25). Sixty-seven limbs were analysed (M:F 1:2.1, median age 62, range 25–81). Of the 124 treated IPVs, 101 were closed (82%). Clinical, aetiological, anatomical and pathological clinical score was improved in 49.3% limbs. IPV closure was reduced in patients with recurrent varicose veins compared with primary varicose veins (72.3% versus 87%, $P = 0.056$).
Conclusion: These results demonstrate the radiofrequency stylet device to be an effective treatment for IPVs.

Keywords: incompetent perforator vein; radiofrequency ablation; varicose veins; venous insufficiency

Introduction

The importance of incompetent perforator veins (IPVs) in the pathogenesis of chronic venous insufficiency has long been recognized since classic studies by Linton[1] and Cockett[2], yet their treatment remains controversial. There appears to be a particular association with recurrent varicose veins, with studies demonstrating that IPVs are more common in patients with recurrent varicose veins and with larger numbers present in these patients.[4,5] Numerous authors have noted clinical benefits of treatment.[6,7]

Subfascial endoscopic perforator surgery (SEPS) was developed by Hauer[8] in 1985 in light of high complication rates after open surgery for IPVs. Success rates of 78% at three years have been reported.[9] With the advent of minimally invasive 'office-based' procedures for varicose veins, new technical developments have enabled the treatment of IPVs in this setting.

Recently, we reported an 81% closure rate for TRans-luminal Occlusion of Perforator (TRLOP), a technique that uses radiofrequency ablation (RFA) to treat IPVs under general anaesthesia, at five years.[10] The early success of this technique led to the design of a purpose-built stylet for the procedure. The aim of this study was to assess the one-year outcomes of patients undergoing treatment using this new device. We believe this is the first published study of treatment outcomes.

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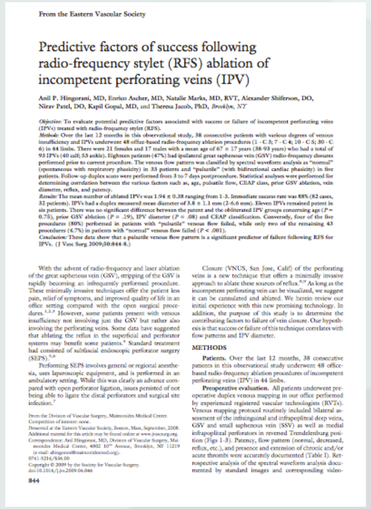
This study was presented at the Spring Meeting of the Venous Forum at the Royal Society of Medicine and subsequently published in abstract format.[3]

Accepted 14 April 2009

Marsh P et al. One-year outcomes of radiofrequency ablation of incompetent perforator veins using the radiofrequency stylet device. Phlebology 2010;25(2):79-84.

What is the surgery outcome?



From the Eastern Vascular Society

Predictive factors of success following radio-frequency stylet (RFS) ablation of incompetent perforating veins (IPV)

Anil P. Hingorani, MD, Enrico Ascher, MD, Natalie Marks, MD, RVT, Alexander Shiferson, DO, Nirav Patel, DO, Kapil Gopal, MD, and Theresa Jacob, PhD, *Brooklyn, NY*

Objective: To evaluate potential predictive factors associated with success or failure of incompetent perforating veins (IPVs) treated with radio-frequency stylet (RFS).

Methods: Over the last 12 months in this observational study, 38 consecutive patients with various degrees of venous insufficiency and IPVs underwent 48 office-based radio-frequency ablation procedures (1: C 3; 7: C 4; 10: C 5; 30: C 6) in 44 limbs. There were 21 females and 17 males with a mean age of 67 ± 17 years (38-93 years) who had a total of 93 IPVs (40 calf; 53 ankle). Eighteen patients (47%) had ipsilateral great saphenous vein (GSV) radio-frequency closures performed prior to current procedure. The venous flow pattern was classified by spectral waveform analysis as "normal" (spontaneous with respiratory phasicity) in 33 patients and "pulsatile" (with bidirectional cardiac phasicity) in five patients. Follow-up duplex scans were performed from 3 to 7 days postprocedure. Statistical analyses were performed for determining correlation between the various factors such as, age, pulsatile flow, CEAP class, prior GSV ablation, vein diameter, reflux, and patency.

Results: The mean number of ablated IPVs was 1.94 ± 0.38 ranging from 1-3. Immediate success rate was 88% (82 cases, 32 patients). IPVs had a duplex measured mean diameter of 3.8 ± 1.1 mm (2-6.6 mm). Eleven IPVs remained patent in six patients. There was no significant difference between the patent and the obliterated IPV groups concerning age ($P = 0.75$), prior GSV ablation ($P = .19$), IPV diameter ($P = .08$) and CEAP classification. Conversely, four of the five procedures (80%) performed in patients with "pulsatile" venous flow failed, while only two of the remaining 43 procedures (4.7%) in patients with "normal" venous flow failed ($P < .001$).

Conclusion: These data show that a pulsatile venous flow pattern is a significant predictor of failure following RFS for IPVs. (J Vasc Surg 2009;50:844-8.)

With the advent of radio-frequency and laser ablation of the great saphenous vein (GSV), stripping of the GSV is rapidly becoming an infrequently performed procedure. These minimally invasive techniques offer the patient less pain, relief of symptoms, and improved quality of life in an office setting compared with the open surgical procedures.[1,2] However, some patients present with venous insufficiency not involving just the GSV but rather also involving the perforating veins. Some data have suggested that ablating the reflux in the superficial and perforator systems may benefit some patients.[3] Standard treatment had consisted of subfascial endoscopic perforator surgery (SEPS).[4,5]

Performing SEPS involves general or regional anesthesia, uses laparoscopic equipment, and is performed in an ambulatory setting. While this was clearly an advance compared with open perforator ligation, issues persisted of not being able to ligate the distal perforators and surgical site infection.[6]

From the Division of Vascular Surgery, Maimonides Medical Center.

Competition of interest: none.

Presented at the Eastern Vascular Society, Boston, Mass, September, 2008.

Additional material for this article may be found online at www.jvascsurg.org.

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Closure (VNUS, San Jose, Calif) of the perforating veins is a new technique that offers a minimally invasive approach to ablate these sources of reflux.[7,8] As long as the incompetent perforating vein can be visualized, we suggest it can be cannulated and ablated. We herein review our initial experience with this new promising technology. In addition, the purpose of this study is to determine the contributing factors to failure of vein closure. Our hypothesis is that success or failure of this technique correlates with flow patterns and IPV diameter.

METHODS

Patients. Over the last 12 months, 38 consecutive patients in this observational study underwent 48 office-based radio-frequency ablation procedures of incompetent perforating veins (IPV) in 44 limbs.

Preoperative evaluation. All patients underwent preoperative duplex venous mapping in our office performed by experienced registered vascular technologists (RVTs). Venous mapping protocol routinely included bilateral assessment of the infrainguinal and infrapopliteal deep veins, GSV and small saphenous vein (SSV) as well as medial infrapopliteal perforators in reversed Trendelenburg position (Figs 1-3). Patency, flow pattern (normal, decreased, reflux, etc.), and presence and extension of chronic and/or acute thrombi were accurately documented (Table I). Retrospective analysis of the spectral waveform analysis documented by standard images and corresponding video-

Observational

38 patients/ 44 limbs _CEAP 3-6
ClosureRFG stylet
1 month follow up

93 perforators are treated
- 88% closed after 1month

Pulsatile venous flow -> unsuccessful
- 5 pulsatile x 43 non-pulsatile procedures
- 4 failed x 2 failed (p<0,001)

Hingorani AP, Ascher E et al. Predictive factors of success following radio-frequency stylet (RFS) ablation of incompetent perforating veins (IPV). Journal of vascular surgery. 2009;50(4):844-8.

Observational

12 patients/ 13 limbs
ClosureRFG stylet
3 months follow up

14 perforators are treated
- 100% closed (immediately)
- 64% closed after 3 months

Original article

Treatment of incompetent perforating veins using the radiofrequency ablation stylet: a pilot study

R R van den Bos, T Wentel, M H A Neumann and T Nijsten
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Abstract

Background: Although the role of incompetent perforating veins (IPV) in chronic venous insufficiency remains controversial, they are often treated by surgical or by minimal invasive techniques.

Objectives: To describe the procedure of radiofrequency ablation (RFA) of IPV and to evaluate its short-term effectiveness and safety.

Methods: In a clinical pilot study, 14 IPV in 12 patients were treated with a radiofrequency stylet. After three months, ultrasound (US) examination was used to assess anatomical success rate and exclude deep venous thrombosis. Also, self-reported side-effects were investigated.

Results: Of the 14 treated IPV, nine (64%) were obliterated on US examination and the others showed remaining reflux. Two patients reported localized paresthesia, but no deep venous thrombosis was recorded.

Conclusion: RFA of IPV may be a promising procedure, but patient and incompetent perforator vein selection is important and further standardization of the procedure is required. Comparative clinical trials between RFA and other therapies are warranted.

Keywords: perforating veins; radiofrequency ablation; varicose veins

Introduction

By perforating the fascia generalis, about 150 perforating veins (PV) in the lower extremity connect the superficial with the deep venous system (reviewed by Van Neer *et al.*).[1] PV larger than 1 mm diameter have valves and appear to function as pressure valves when high pressures occur in the muscular compartment and avoid an outward flow from the deep to superficial system. Incompetent PV (IPV) show reflux on ultrasound (US) examination of more than 0.5 second and often have a larger diameter (Figure 1). Because of its close association with deep or superficial venous incompetence, it is difficult to assess the contribution of isolated IPV in the development of chronic venous insufficiency (CVI).

Because of the controversial role of IPV in CVI,[2] the need to treat IPV remains somewhat unclear.[3] Some authors suggest that PV are part of a compensatory mechanism in venous return and have shown that selective ligation of IPV did not improve venous haemodynamics. The increased venous limb volume diameter is correlated with the largest IPV diameter and may be responsible for and precede IPV development.[4] In clinical practice, IPV have often been treated in conjunction with the treatment of the superficial venous system.[5] The most traditional therapy of IPV is surgical subfascial ligation or subfascial endoscopic perforator surgery (SEPS).[3,6–8] Surgical ligation and, even more, Linton's procedure and its modifications leave a noticeable scar and have a high complication rate such as wound infection, nerve injury and postoperative pain, especially in patients with CVI-induced skin changes (≥C4 level of clinical, aetiological, anatomical and pathological elements [CEAP] classification).[9] Because the incision made

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van den Bos RR et al. Treatment of incompetent perforating veins using the radiofrequency ablation stylet: a pilot study. Phlebology 2009;24(5):208-12.

What is the surgery outcome?

Case control – retrospective review

112 patients w/ treated trunck reflux plus symptoms

296 perforators are treated

- 93 – radiofrequency ablation (ClosureRFS Stylet)
- 62 – endovenous laser (1470nm, 400-µm fiber)
- 141 – polidocanol 1% foam (Asclera) – max 10 cc

2 weeks follow up

Closure rate	
RFA	73%
EVLA	61%
UGFS	57%

RFA versus UGFS (p<0,05)

CrossMark

From the American Venous Forum

Journal of Vascular Surgery
Venous and Lymphatic Disorders

Factors that influence perforator vein closure rates using radiofrequency ablation, laser ablation, or foam sclerotherapy

Eric S. Hager, MD, Christopher Washington, MD, Amy Steinmetz, RDMS, RVT, Timothy Wu, MD, Michael Singh, MD, and Ellen Dillavou, MD, *Pittsburgh, Pa*

Objective: Perforator vein closure for the treatment of advanced chronic venous insufficiency has been shown to be effective using radiofrequency ablation (RFA), endovenous laser ablation (EVLA), or ultrasound-guided foam sclerotherapy (UGFS). The objective of the study was to compare these three modalities and attempt to identify factors that might predict treatment failure.

Methods: A retrospective review of a prospectively managed database of perforator vein treatments performed at a three centers within a single institution from February 2013 to July 2014. The modality for perforator closure was left to the discretion of the treating physician. A Duplex scan was performed at 2 weeks after the procedure. Standard statistical methods were used to compare subgroup characteristics. Univariate and multivariate analyses were performed using SAS v9.3.

Results: We performed 296 perforator ablations on 112 patients. Superficial venous reflux was appropriately treated before perforator ablation. Of the 296 procedures, 62 (21%) underwent EVLA, 93 (31%) RFA, and 141 (48%) UGFS. The indications for intervention in most patients were C5 and C6 disease (67%). At 2 weeks, closure rates were significantly lower for UGFS (57%) compared with RFA (73%; $P = .05$) but failed to reach significance compared with EVLA (61%; $P = .09$). When patients were first treated with UGFS and closure failed, thermal ablation was then successful in 85% ($P = .03$) of EVLA and 89% ($P = .003$) of RFAs as a secondary procedure, compared with initial closure rates. Systemic anticoagulation, perforator size, and presence of deep vein reflux did not affect closure rates for any modality. Factors that were predictive of failure were body mass index >50 with closure rates of only 37% for all modalities. There were five postprocedure deep venous thromboses found (5%). One patient had an isolated gastrocnemius thrombus after undergoing UGFS and the other four had focal tibial vein thrombosis without extension into the popliteal vein.

Conclusions: In this study we compared EVLA, RFA, and UGFS for the treatment of incompetent perforating veins. RFA was found to be the most reliable means of perforator closure and was significantly better than UGFS. Morbid obesity (body mass index >50) predicted failure of perforator closure in all groups. Failure of UGFS as an initial treatment led to increased perforator closure when thermal ablation was used as a secondary technique. (J Vasc Surg: Venous and Lym Dis 2016;4:51-6.)

Chronic venous insufficiency (CVI) affects millions of people worldwide. Patients with venous ulceration often suffer for years without proper treatment. In addition to loss of work hours, patients can develop significant psychosocial issues surrounding chronic ulceration, because significant pain and disability can be associated with wounds and wound care. Genetic factors have been implicated in the development of CVI.[1] Other factors that increase risk of CVI include history of deep venous thrombosis, multiple pregnancies, and advanced age. Although compression has long been the primary treatment, aggressive procedures to relieve venous hypertension have been shown to improve wound healing and risk of recurrence.[2-6]

CVI arises from the venous hypertension caused by valvular incompetence. Increased venous pressure can cause aching, heaviness, fatigue, and pain. In the most severe cases, this can progress to inflammatory changes, lipodermatosclerosis, hemosiderosis, stasis dermatitis, and ultimately venous ulcers. With the advent of improved techniques to study flow and advances in the imaging capabilities of duplex ultrasonography, insufficiency within the superficial system and perforating veins has also become recognized as pathologic. Treatment of these veins helps to relieve venous hypertension and facilitates ulcer healing.[3,7]

Incompetent perforating veins (IPVs) play a role in the development of CVI and ulceration.[8,9] With improvements in technology, traditional open surgical options have been supplanted by minimally invasive techniques. Current societal recommendations include perforator closure in clinical

From the Division of Vascular Surgery, University of Pittsburgh Medical Center.

Author conflict of interest: none.

Presented at the Twenty-seventh Annual Meeting of the American Venous Forum, Palm Springs, Calif, February 25-27, 2015.

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Factors that predicted failure for RFA:

- BMI > 50 (p<0,05)

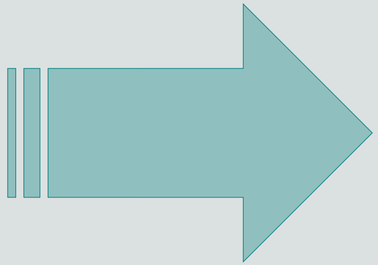
- Perforator size
- Deep veins insufficiency
- Pulsatile flow
- Anticoagulation
- Diabetes
- CEAP class
- Sex
- Age
- Malignancy
- Congestive Heart Failure
- Obstructive sleep apnea
- Obstructive pulmonary disease

NS

Hager ES, Washington C, Steinmetz A, Wu T, Singh M, Dillavou E. Factors that influence perforator vein closure rates using radiofrequency ablation, laser ablation, or foam sclerotherapy. Journal of vascular surgery Venous and lymphatic disorders. 2016;4(1):51-6.

What is the surgery outcome?

Author/year	Number of perforating veins treated	Follow up	Outcome: closure rates
Bacon et al., 2009	125	5 years	81%
Marsh et al., 2010	124	1 year	82%
Hingorani et al, 2009	93	1 month	88%
Van den Bos et al., 2009	14	3 months	64%
Hager et al., 2016	141	2 weeks	73%



Radiofrequency ablation for perforating veins

Closure rate: 64-88%

What is the surgery outcome?

What about complications?

Author/year	Number of participants	Outcome: closure rate	Complications
Bacon et al., 2009	37	81%	eroneal nerve injury- foot drop rest cnemius vein) riovenous fistula itis
Ma		32%	1 D terior tibial vein) 7 neuropraxias 1 phlebitis 1 wound infection
Hingorani et al, 2	93	88%	1 phlebitis
Van den , 2009	14	64%	2 paresthesias 1 localized pain
Hager et al., 2016	112	73%	2 DVT (tibial veins)

SAFE

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Venous

Ulcer

Endovenous

Radiofrequency

Treatment

TRIAL

Multilayer Compressive Bandages

VS

RFA saphenous and perforating veins
plus
Multilayer Compressive Bandages

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END-POINTS

Primary :
Ulcer healing rate
Ulcer recurrence

Secondary:
Cost-effectiveness
Cost-utility
Quality of life

Venous

Ulcer

Endovenous

Radiofrequency

Treatment

TRIAL

Until now:
61 included
19 excluded

(goal 84 participants)
36 treated
6 under treatment

Preliminary Results	Bandage	RFA + bandage	
Number of Participants	18	17	
Ulcer size – mean (cm2)	8,10	7,44	NS
Ulcer healing time (week)	19,24	11,66	p=0,06
Ulcer Healing Rates (%)			
6 weeks	16,67%	17,65%	NS
12 weeks	27,78%	52,94%	p=0,03
24 weeks	50,00%	94,12%	p=0,03
52 weeks	94,44%	100,00%	NS
Ulcer recurrence (%)	33,33%	5,88%	p=0,01

36 perforators veins treated

Occlusion 1 week – 94%

Occlusion 3 months – 80,5%

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Take-Home Message

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Radiofrequency ablation is a safe and effective way to treat perforating veins even in advanced CEAP classes .

Occlusion rate: 64 to 88%

Low complications rate

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Thank you for your attention !

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