

Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency

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Background: Endovascular radiofrequency obliteration has been used as an alternative to conventional vein-stripping surgery for elimination of saphenous vein insufficiency. A clinical registry was established in 1998, and its mid-term results have been reported previously. This study is to demonstrate the long-term treatment outcomes and to determine the risk factors that affect treatment efficacy.

Methods: Data were collected in an ongoing multicenter, prospective registry. Patients were treated before October 2004. Clinical and duplex ultrasound follow-up was performed 1 week, 6 months, 1 year, and yearly thereafter to 5 years. Treatment efficacy and clinical improvement after the procedure were analyzed. Three types of anatomical failure were identified. Logistic regression analysis was performed to determine the existence of any significant risk factors associated with anatomical failure. Risk factors considered were age, gender, body mass index, vein diameter, and pullback speed. The impact of anatomical failure on clinical symptoms and varicose vein recurrence was also analyzed.

Results: There were 1,006 patients (1,222 limbs) treated, their mean age was 47.4 ± 12.1 years, and 78.1% were female. Veins treated included 89.1% great saphenous vein above-knee segments, 1.2% great saphenous vein below-knee segments, 4.1% great saphenous vein groin-to-ankle, 4.3% small saphenous veins, and 1.3% accessory saphenous veins. Mean vein diameter was 7.5 mm, with a maximum of 24 mm. Vein occlusion rates were 87.1%, 88.2%, 83.5%, 84.9%, and 87.2%, and reflux-free rates were 88.2%, 88.2%, 88.0%, 86.6%, and 83.8% at each annual follow-up. Clinical symptom improvement was seen in 70% to 80% of limbs with anatomical failures and in 85% to 94% of limbs with anatomical success from 6 months to 5 years after the radiofrequency obliteration. Logistic regression analysis showed that catheter pullback speed ($P < .0001$) and body mass index ($P < .0333$) were risk factors for anatomical failure. Limbs that had type II and type III anatomical failures were found to be more prone to varicose vein recurrence.

Conclusions: Endovascular radiofrequency obliteration of saphenous vein reflux exhibits enduring efficacy. Adequate pullback speed during the procedure should be emphasized to ensure the proper thermal dose delivery. A whole treatment strategy to address hemodynamically significant tributaries and perforators can further improve treatment outcomes. Body mass index is a risk factor for anatomical failure, indicating the impact of hemodynamic factors on disease progression and recurrence. (J Vasc Surg 2005;42:502-9.)

Great saphenous vein (GSV) reflux is an important component of the pathophysiology of primary venous insufficiency and is customarily treated with surgical stripping of the GSV from the groin to just below the knee. For

nearly a century, vein stripping, with minimal modifications, has remained the standard of care for symptomatic varicose veins despite the observation of recurrence rates ranging from 20% to 80%, depending on the definition of recurrence.^{1,2}

Endovenous radiofrequency obliteration (RFO), also known as the Closures procedure (VNUS Medical Technologies, Inc, San Jose, Calif), was introduced in Europe in 1998 and to the United States in 1999. The clinical benefits of this technique have been demonstrated through three separate randomized clinical studies comparing RFO with conventional vein stripping.³⁻⁵ The short- and mid-term treatment outcomes have been reported by several groups.⁶⁻⁹ In this study, we report the 5-year follow-up results of a multicenter registry. Factors related to treatment failure and later varicose vein recurrence were also analyzed.

MATERIALS AND METHODS

Data were collected in an ongoing multicenter, prospective registry. This report includes the results from all patients in the registry treated without concomitant high ligation. Patients were treated before October 2004 at 34

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Competition of interest: R.F.M. has been paid a consulting fee as a member of the advisory board for VNUS Medical Technologies, Inc, owns shares in the company, is on its speakers bureau, and receives a stipend when providing educational opportunities for physicians. O.L. has been paid consulting fees for VNUS Medical Technologies, Inc. VNUS Medical Technologies, Inc, designed the original data collection forms, collected the data forms from the registry centers, arranged for statistical analysis as needed, assisted in the technical aspects of manuscript preparation, and provided nominal funds to assist in defraying physicians' costs associated with collection of long-term data including follow-up ultrasound studies. R.F.M. reviewed the data personally, and the decision to submit the manuscript was made by the authors.

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centers worldwide, with 12 centers contributing 5-year follow-up data.

Patients with superficial venous insufficiency confirmed by duplex ultrasound scanning were considered as candidates for RFO treatment. Saphenous vein incompetence was diagnosed with saphenofemoral, saphenopopliteal, or truncal vein reflux in response to manual compression and release with patient standing or with Valsalva maneuver in a 15° reverse Trendelenburg position. Exclusions for saphenous vein aneurysm and vein diameters >12 mm were initially established as a conservative measure and were later discontinued after reports of routinely successful treatment in patients with these anatomical features.

Technical details of the RFO procedure have been described elsewhere.⁹ In brief, vein access was achieved through either percutaneous access or a small cut down. A Closure catheter was advanced to the saphenofemoral junction (SFJ) or the saphenopopliteal junction (SPJ), and the electrodes were placed distal to the SFJ or SPJ under ultrasound guidance. Procedure evolution included the gradual introduction of subcutaneous saline infiltration and later perivenous tumescent infiltration. The treatment temperature was set at 85°C. After starting radiofrequency energy delivery and achieving treatment temperature for 15 seconds, the catheter was withdrawn at approximately 2 to 3 cm/min along the length of the vein while maintaining the target temperature \pm 3°C. Adjunctive procedures at the time of treatment included phlebectomy and sclerotherapy of visible varicose veins. Patients were advised to ambulate and return to normal activities shortly after the procedure.

After the procedure, a duplex ultrasound examination was routinely performed \leq 1 week (preferably \leq 72 hours) to check for any evidence of thrombus extension from the SFJ or SPJ into the deep system and to document the occlusion status of the treated veins. Further follow-up ultrasound scans and physical examinations were performed at 6 months, 1 year, and each year thereafter.

Reflux was defined as any evidence of reverse flow >0.5 seconds in any treated vein segment or in the area of the SFJ (or SPJ). As reported, RFO often started 1 to 2 cm below the SFJ, and the most common duplex finding after the treatment was a short patent terminal GSV segment conducting prograde tributary flow through the SFJ.¹⁰ Vein occlusion was defined as the absence of any blood flow 3 cm inferior to the SFJ or SPJ along the length of treated vein segments. Symptom severity and clinical assessment according to CEAP clinical classification were recorded at each visit.

Three types of failure mode were identified based on duplex ultrasound examination results. To differentiate these failures from actual clinical failure, failure identified by the duplex ultrasound was referred to as anatomical failure. Risk analysis was performed to determine any factors associated with anatomical failure. The clinical implication of anatomical failure was analyzed based on clinical symptoms and signs as well as varicose vein recurrence.

Statistical analysis. Measurable values were expressed as mean \pm standard deviation, and the Student's *t* test was

Table I. Maximum preoperative CEAP clinical class distribution

CEAP clinical class	% each CEAP
0	0.5%
1	2.5%
2	69.6%
3	10.1%
4	13.1%
5	1.2%
6	1.1%
Not recorded	1.9%

used to determine the statistical significance. Ratios were expressed as mean (95% confidence interval [CI]), and the χ^2 or Fisher's test was used to determine statistical significance. Considering that the data series included the early experience and several procedural changes were incorporated during the study period that improved clinical outcomes, survival analysis was not performed. Vein occlusion, absence of reflux, and varicose vein recurrence were thus analyzed at each follow-up time point.

Stepwise logistic regression analysis for analyzing dichotomous response data (eg, success or failure, present or not present) while accommodating adjustments for one or more explanatory variables (risk factors) was performed for anatomical failure and varicose vein recurrence. Risk factors considered in the anatomical failure analysis were gender, age, body mass index (BMI), vein diameter, and catheter pullback speed. For varicose vein recurrence, the three types of anatomical failure mode were considered as risk factors. The regression parameter (β) of a risk factor in the logistic model was tested for significance at the level of 5% using Wald χ^2 method. The corresponding odds ratios (OR = e^β) were calculated and the 95% confidence limits (Wald) were presented in brackets. Statistical Analysis System (SAS) software (SAS Institute, Cary, NC) was used for the data analysis.

RESULTS

There were 1,006 patients (1,222 limbs) treated from 34 centers (see Appendix) consisting of 23 private practice centers, 10 university hospitals, and 1 state hospital. The average age was 47.4 ± 12.1 years (range, 15 to 97 years) with a BMI of 24.8 ± 4.9 , and 78.1% of the patients were female. The CEAP clinical class distribution before the treatment is listed in Table I. The most common symptoms in the limbs were pain in 85.3%, fatigue in 78.6%, and edema in 39.2%.

All of the veins treated had reflux >0.5 seconds before the treatment documented by duplex ultrasound examination as described previously in the *Methods* section. Among the veins treated, 89.1% were GSV limited to the thigh segment (access at above the knee or just below the knee), 4.1% GSV from groin to ankle, 1.2% GSV limited to the below-knee segment, 4.3% SSV, and 1.3% accessory saphenous veins. The mean diameter, measured with the patient

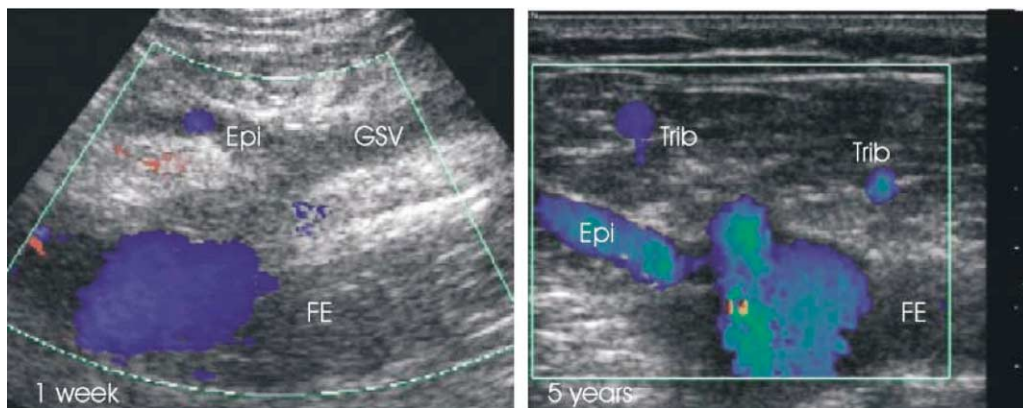


Fig 1. On the left, a duplex ultrasound image of the area near the saphenofemoral junction 1 week after radiofrequency obliteration of the great saphenous vein (GSV). The image on the right was recorded at the 5-year follow-up. Transverse views of patent tributaries (Trib) are seen. There are no longer any discernible landmarks for the GSV, Epi, Superficial epigastric vein; FE, femoral vein. (Images courtesy of Olivier Pichot, MD)

Table II. Vein occlusion and hemodynamic outcomes

	1 wk	6 mo	1 yr	2 yr	3 yr	4 yr	5 yr
Limbs at risk	1,222	1,220	1,206	1,141	991	833	406
Limbs available for follow-up	985	518	473	263	133	119	117
Vein occlusion	96.8%	89.2%	87.1%	88.2%	83.5%	84.9%	87.2%
Absence of reflux	96.6%	91.3%	88.2%	88.2%	88.0%	86.6%	83.8%

supine, was 7.5 mm (range, 2 to 24 mm). Adjunctive phlebectomy was performed in 52% of limbs and sclerotherapy in 11% of limbs at the time of RFO treatment.

Vein occlusion and hemodynamic outcomes. Limbs at risk and limbs available for follow-up at each time point are summarized in Table II. Immediate vein occlusion was achieved in 96.8% of limbs confirmed by duplex ultrasound examination ≤ 1 week after the procedure. The vein occlusion rate at 6 months, 1, 2, 3, 4, and 5 years was 89.2%, 87.1%, 88.2%, 83.5%, 84.9%, and 87.2%, respectively; and the absence of reflux rate was 91.3%, 88.2%, 88.2%, 88.0%, 86.6%, and 83.8%, respectively, at each time point. A duplex image taken at 5 years of an occluded GSV is shown in Fig 1.

For those 30 limbs (3.2%) that did not achieve immediate occlusion, subsequent intervention to the GSV was done in three limbs, two with sclerotherapy and one with high ligation. As of the last reported follow-up, 24 limbs received no further GSV treatment, seven of the 24 had spontaneous occlusion at a later time point, and another three limbs had no further follow-up information.

Anatomical failure mode and risk factors. Over a 5-year follow-up on 1,222 limbs treated, duplex ultrasound examination identified 185 limbs that had either one of the following: flow in a segment of or the entire treated vein, or developed groin reflux despite a completely occluded GSV trunk. These findings were defined as anatomical failure. The mode of anatomical failure can be categorized into three types, illustrated in Fig 2:

- Type I (nonocclusion) failure referred to veins that failed to occlude initially and never occluded during the follow-up. There were 23 limbs belonging to this category, consisting of 12.4% (23/185) of all anatomical failures. Among these 23 limbs, eight (34.8%) were significantly narrowed, with no reflux irrespective of a patent trunk.
- Type II failure (recanalization) referred to veins that were initially occluded but recanalized, partly or completely, at a later time point. There were 129 limbs in this category, accounting for 69.7% (129/185) of the total anatomical failure. Among the 129 type II limbs, 44 (34.1%) exhibited no reflux. There was documentation in 30 (23.3%) type II limbs that the recanalization was directly related to either a refluxing tributary or an incompetent thigh perforator.
- Type III failure (groin reflux) referred to the situation in which the vein trunk was occluded, but reflux was detected at the groin region, often involving an accessory vein. There were 33 type III limbs, which made up 17.8% (33/185) of the total anatomical failure.

Only 19 (10.3%) of 185 limbs received reintervention to address the anatomical failure: 11 limbs with sclerotherapy resulting in secondary occlusion in 9 limbs, 2 limbs with RFO and veins closed, 1 vein stripping, 2 high ligations, and 3 nonspecified.

Logistic regression analysis found that the two risk factors of pullback speed ($P < .0001$) and BMI ($P < .0333$)

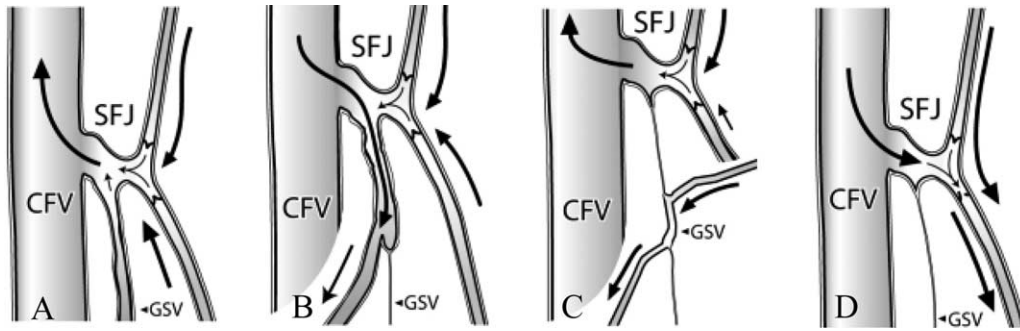


Fig 2. The types of anatomical failure are illustrated in the panels (left to right). A, Type I, great saphenous vein (GSV) failure to completely occlude, with or without reflux present. B and C, Type II, partially recanalized GSV. D, Type III, the treated GSV is occluded, but reflux is present involving branches near the saphenofemoral junction (SFJ). CFV, Common femoral vein.

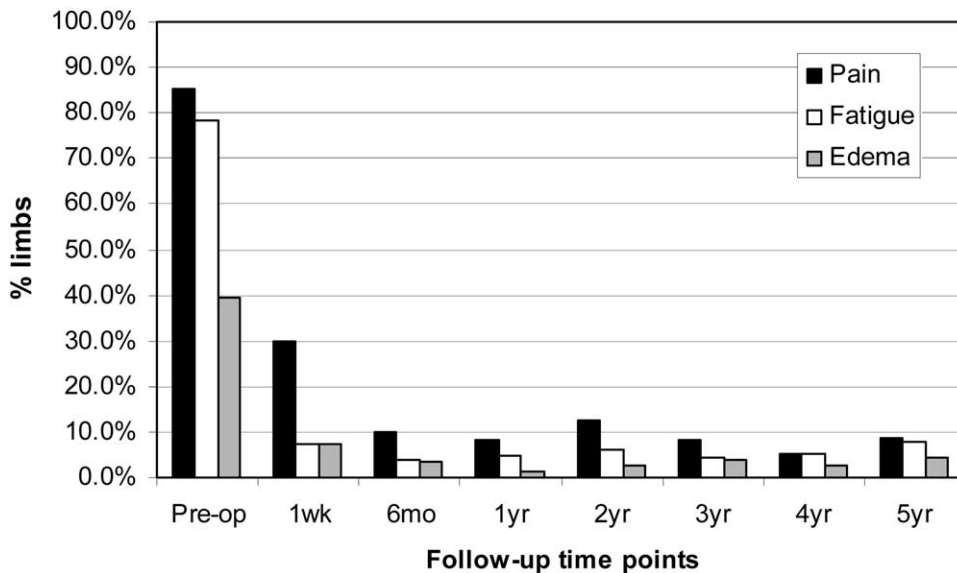


Fig 3. As a measure of symptom relief following treatment, presence or absence of limb pain, fatigue or edema was recorded.

were significant for anatomical failure. The fitted logistic regression model, adjusted for the normal pullback speed of 3 cm/min and BMI of 25 kg/m², was as follows:

$\text{logit}(p^{\wedge}) = -1.5979 + 0.2464 \times (\text{pullback speed} - 3) + 0.0356 \times (\text{BMI} - 25)$. The p^{\wedge} indicates an estimated probability of anatomical failure.

The estimated slope coefficients indicated that the probability of anatomical failure increased by 1.28 times (95% CI: 1.13, 1.45) for each unit (1 cm/min) increase over 3 cm/min in pullback speed using a target treatment temperature of 85°C; and the probability of anatomical failure increased by 1.04 times (95% CI: 1.00, 1.07) for each unit (1 kg/m²) increase over 25 kg/m² in BMI.

When further identifying which risk factor was associated with which type of anatomical failure, it was found that the pullback speed was a risk factor for only type I and type II failure but not type III failure. The BMI, however, failed

to show significance for any individual failure type, likely because of the small sample size that resulted in insufficient statistical power in each failure category.

It is important to point out that anatomical failure does not necessarily result in clinical failure. As detailed below, most patients experienced symptom relief after the procedure and remained asymptomatic in spite of anatomical failure.

Clinical symptoms and signs. Patient symptom improvement was observed as early as 1 week after the treatment (Fig 3). The percentage of limbs exhibiting pain decreased from 85.3% pretreatment to 29.9% by 1 week, 10.0% by 6 months, and 8.5% by 5 years after the RFO treatment. Limb fatigue was improved from 78.6% of limbs before RFO to 7.3% at 1 week and 3.9% at 6 months after treatment. The percentage of limbs with edema reduced to 7.5% at 1 week and 3.3% at 6 months after RFO compared

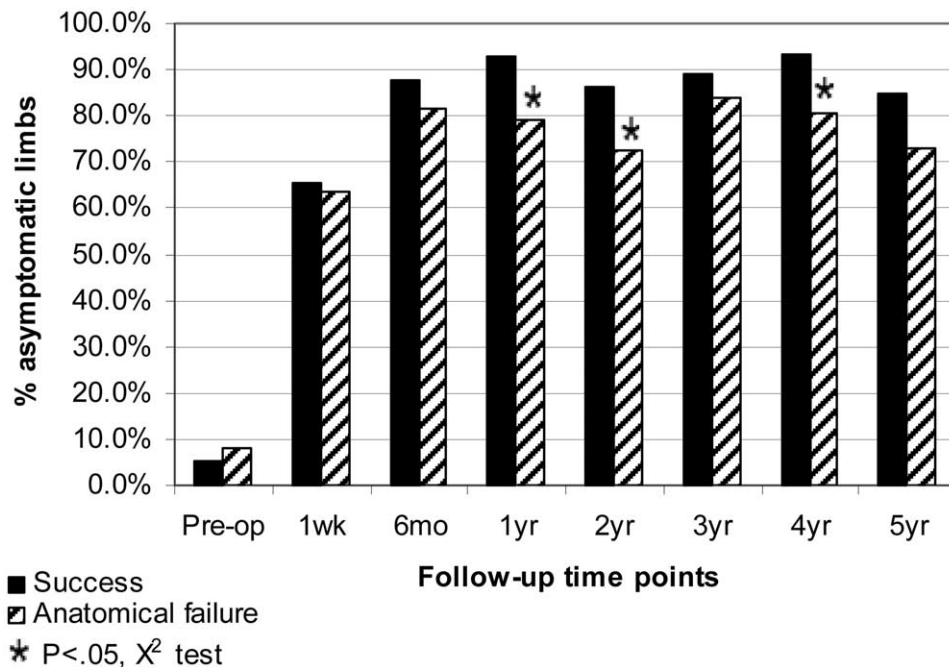


Fig 4. Limbs that were asymptomatic at each time point for limb pain, fatigue, or edema were separated into two groups: those for which treatment was categorized as successful and those categorized as anatomical failure.

with 39.2% pretreatment. As shown in Fig 3, the treatment effect on patient symptom improvement persisted over 5 years.

Significant symptom improvement was also seen in patients with anatomical failures. As shown in Fig 4, even in the anatomical failure patients, 70% to 80% of limbs remained asymptomatic up to 5 years after the treatment, suggesting the clinical benefit of the procedure even in patients with a treated limb judged as an anatomical failure. When the percentage of asymptomatic patients at each follow-up time point was compared, no statistical significance was found among the type I, II, or III patients (χ^2 test). The data from these patients with anatomical failure were thus combined and compared with anatomically successful patients. As expected, the percentage of asymptomatic limbs was slightly lower in the anatomical failure group compared with the anatomical success group (Fig 4).

CEAP clinical classification improvement is illustrated in Fig 5. Before treatment, 92.8% of limbs were CEAP clinical class 2 to 4. One week after the procedure, 66.2% of limbs were CEAP clinical class 0 to 1. The percentage increased to 77.0% by 6 months, maintained stable through 3 years, and showed a slight decrease at 4 and 5 years.

Overall varicose vein recurrence rates at 6 months, 1, 2, 3, 4, and 5 years were 7.7% (40/518), 13.1% (62/473), 14.8% (39/263), 14.3% (19/133), 22.7% (27/119), and 27.4% (32/117), respectively. When the impact of anatomical failure on varicose vein recurrence was examined, it was found that type II ($P < .0001$) and type III ($P = .0009$) failures were risk factors for varicose vein recurrence. The odds ratio for varicose vein recurrence was 3.8 (95% CI:

2.5, 5.9) when there was a type II failure and 4.0 (95% CI: 1.8, 9.2) where there was a type III failure.

Complications. Complications associated with the RFO procedure were reported and discussed in detail previously.^{7-9,11} The first published report on RFO recommended a follow-up duplex evaluation ≤ 72 hours, and this has been standard follow-up protocol since 1999.¹¹ Early complications in this series included 0.9% deep venous thrombosis (DVT) or clot extension into the common femoral vein, 1.2% skin burn, 2.9% clinical phlebitis, and 0.2% infection at the vein access site. No limbs exhibited lymphedema at any follow-up visits. A pulmonary embolism developed in one of the patients with DVT, as reported elsewhere.^{9,11} All thrombotic episodes were successfully treated with anticoagulation therapy or thrombectomy ($n = 1$). Skin burn complications occurred primarily before the implementation of tumescent infiltration to protect the skin.

Paresthesia, often presenting as focal hypoesthesia, was observed in 121 (12.3%) of 985 limbs at the initial 1-week follow-up. The incidence decreased to 7.3% by 6 months and was 2.6% at 5 years. For GSV below-knee treatment, the paresthesia rate was 13.3%, 11.6%, and 7.7% at 1 week, 6 months, and 5 years, suggesting a trend towards a higher paresthesia rate with below-knee GSV treatment. The paresthesia rate associated with SSV treatment was 8.9% and 9.5% at 1 week and 6 months.

DISCUSSION

Vein stripping and high ligation has been the standard of care for superficial venous insufficiency for many dec-

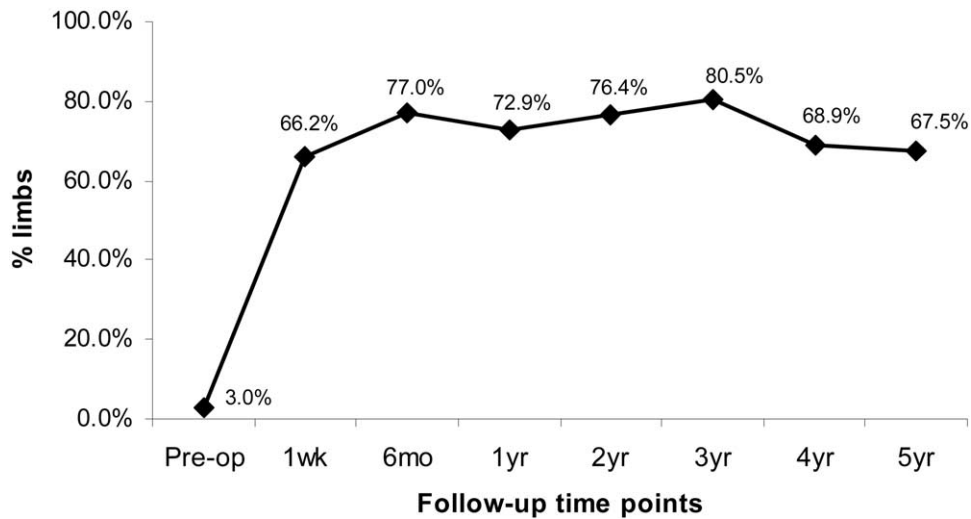


Fig 5. Percentages of limbs presenting with CEAP clinical classification 0 to 1.

caes. Efficacy assessment of stripping and ligation was often performed by using varicose vein recurrence as the primary end point. Only recently, because of the wide availability of duplex ultrasound scanning, has the significance of recurrent reflux been recognized. The prevalence of recurrent reflux increases over time, with a 28.8% incidence at 5 years¹² and 60% at a mean follow-up of 34 years.¹³

The mechanism responsible for recurrence has been the topic of a long-standing discussion. Recent published studies have provided sufficient evidence supporting neovascularization as one of the major mechanisms for SFJ recurrence.¹³⁻¹⁹ In our study, 83.8% of GSVs were free from reflux 5 years after RFO, and ultrasound evidence of neovascularization was detected in only two limbs through the follow-up period, suggesting a significant advantage of this procedure over conventional vein stripping. It is speculated that avoiding a groin incision and preservation of physiologic flow from junctional tributaries draining the abdominal and pudendal areas diminish angiogenic stimuli and thus reduce neovascularization.²⁰

Anatomical failure after an RFO procedure can be categorized into three types. Type I failure (nonocclusion) refers to the situation when a vein fails to occlude and is often due to less than optimal procedural techniques, such as a too fast pullback speed that results in an insufficient thermal dose. Type I failures can be reduced by following a recommended and standardized procedural methodology. It has also been observed that in a very small percentage of patients, veins were nonresponsive to thermal obliteration, even after repeated treatment attempts. It has been speculated that the collagen structure might be different or that inflammatory swelling after vein wall heating is attenuated in these patients, but there is no evidence as yet to prove these hypotheses. Despite this, frequently the open vessel has shrunk in diameter, often without reflux.

Recanalization (type II failure), 23.3% of which were associated with either tributary or perforator incompetence, accounted for 69.7% of the total anatomical failures. The significance of tributary or thigh perforator incompetence and its relationship to the durability of endovenous obliteration has not been given much attention in the past. Results from this study suggest that proactively addressing tributary and perforator incompetence may further improve long-term RFO treatment outcomes. A thorough preoperative ultrasound study and diligent ultrasound follow-up to identify refluxing tributaries and thigh perforators can lead to a carefully designed treatment plan to address all refluxing sources, with either endovenous ablation or surgical ligation.

In addition to type I and II failure, groin reflux developed in 33 limbs (17.8% of total failures) despite complete occlusion of the GSV trunk (type III). The reflux often involved an accessory saphenous vein associated with or "feeding" varicosities. This type of failure likely reflects disease progression associated with persistent hypertension of the venous system, but a contributing factor may also be an undiagnosed accessory vein incompetence that existed at the time of GSV treatment.

Risk analysis revealed that the pullback speed was a risk factor for type I and II failures. It is understandable that the thermal dose delivered at a specific vein segment is related to both the treatment temperature and the time, the latter being a function of pullback speed. A certain level of thermal dose is required to efficiently occlude the vein. An insufficient thermal dose may result in short-term vein occlusion, probably through formation of thrombosis in the treated segment. However, the thrombotic occlusion is subject to recanalization (type II), particularly when the segment is associated with incompetent tributaries or perforators.

BMI was also identified as a risk factor for anatomical failure, although we were unable to further stratify whether it was associated with all the types or only a specific type because of small sample size in the failure group. Nevertheless, it is reasonable to suggest that preventive measures, such as compression, should be provided after the treatment to patients with a higher BMI. The mechanism by which a high BMI results in anatomical failure remains unclear. However, patients with high BMI values tend to pose more procedural challenges such as inadequate compression during RFO and incomplete removal of varicose veins that result in incomplete relief of venous hypertension.²¹

It is important to note that anatomical failure does not necessarily result in clinical recurrence. Most patients experienced clinical improvement, and 70% to 80% were asymptomatic, irrespective of anatomical failure, during the 5-year follow-up period. This suggests that the anatomical failure may not be significant enough to cause pressure-related symptoms.

On the other hand, type II and type III failures were risk factors for varicose vein recurrence. Type II failure patients were 3.8 times and type III 4.0 times as likely to develop varicose vein recurrence compared with anatomical success patients. Type I failure did not reach statistical significance in this analysis. One possible explanation is that fewer of these patients had longer than 3 years follow-up, may have been treated by other methods, or were lost to follow-up, and therefore, the impact of early failure on varicose vein recurrence may not be identified.

Surveillance monitoring, early recognition of anatomical failure, and taking further corrective action that may include RFO retreatment²¹ may prevent some of the varicose vein recurrence. However, it should be recognized that the disease progression is likely to play a major role in type III failure and may also account for some of the type II failure. This may contribute to the increase in varicose vein recurrence at 4 and 5 years.

In addition to the GSV, RFO has also been used to treat SSV and accessory saphenous vein incompetence in clinical practice. In this series, 4.3% veins treated were SSV and 1.3% were accessory saphenous veins. Although there were not enough samples and follow-up to demonstrate their long-term efficacy, one would not expect a dramatic difference between them and the GSV treatment. In this series, no serious adverse event such as motor nerve damage was reported with SSV treatment. The paresthesia rate in the SSV group was 8.9% at 1 week and 9.5% at 6 months, similar to that with the GSV treatment. The technical aspects of perivenous tumescent infiltration, catheter tip placement, and patient response monitoring during the procedure demand special attention with the SSV treatment to protect the sural nerve and other surrounding nerves. When these elements were applied to SSV procedures, the paresthesia incidence dropped to as low as 0.3% (1/30) at one center.

Application of tumescence during endovenous obliteration is one of the most important procedural advancements during the last several years. It has been shown previously that tumescent infiltration can significantly decrease procedure complications.²² With perivenous tumescence, RFO can be used effectively to treat larger diameter veins (>12 mm in diameter) without compromise of treatment efficacy.²² In the current series, the largest vein that was treated effectively was 24 mm in diameter.

CONCLUSION

Five-year follow-up on patients treated with endovenous radiofrequency obliteration has demonstrated that vein occlusion and clinical improvement are durable. Risk analysis in this international multicenter registry identified catheter pullback speed and body mass index as the two risk factors associated with RFO anatomical failures. Although historical data on traditional vein stripping can only serve as a reference and not a direct comparison, the clinical recurrence and neovascularization appear to be low in RFO patients. The data from this report and from randomized trials of RFO versus vein stripping clearly indicate that RFO provides long-term efficacy and is better for the patients. The combination of positive level-one evidence and 5-year confirmation of procedure efficacy with RFO indicates that it has been evaluated extensively enough to be considered at least a comparable standard of care alongside traditional surgery.

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INVITED COMMENTARY

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Endovenous treatment to obliterate the saphenous vein may be performed by several techniques, including radiofrequency ablation, laser treatment, or foam sclerotherapy. In this study, Dr Merchant reports the data from an ongoing multicenter prospective registry of radiofrequency ablation treatment. Clinical and duplex follow-up was performed within 1 week, at 6 months, at 1 year, and yearly thereafter. A total of 1006 patients and 1222 limbs were treated; most involved the greater saphenous vein above the knee. Vein occlusion rates ranged from 83.5% to 88.2%. Clinical symptom improvement was noted in 70% to 80% of limbs with anatomic failure and in 85% to 94% of limbs with anatomic success.

There is no question that endovenous saphenous vein ablation is here to stay. The stage was set for such a procedure by the determination that patients had better results with varicose vein surgery if the saphenous vein was removed along with saphenofemoral ligation, rather than with ligation alone.¹ Saphenous vein ablation, even in the presence of deep venous insufficiency, can improve the manifestations of chronic venous insufficiency.² As indicated by the authors, three randomized trials have established the superiority of endovenous radiofrequency ablation to saphenous vein surgery. The importance of the current study is to show the durability of endovenous radiofrequency closure over 5 years. Two disappointing aspects of the report include the fact that patient symptoms did not correlate with anatomic success or failure

and that body mass index correlated with anatomic failure. It is exactly in this type of patient that endovenous ablation is most appealing as opposed to operative ligation and stripping. Additionally, before radiofrequency ablation is embraced as the best method for saphenous vein ablation, more comparisons to laser and foam sclerotherapy, techniques that have shown excellent results, should be performed.^{3,4} Nonetheless, this study is an important contribution to our understanding of the durability and efficacy of this new modality for the treatment of saphenous vein reflux.

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APPENDIX. Closure study group

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