Prospective study of safety and effectiveness in the use of radiofrequency ablation for incompetent great saphenous vein ≥12 mm

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ABSTRACT

Objective: The objective of this study was to assess the outcomes of radiofrequency ablation (RFA) in incompetent great saphenous vein (GSV) according to its diameter.

Methods: This was a prospective single-center study including all patients treated with RFA from September 2014 to December 2015. The sample was divided according to the maximum GSV diameter measured on duplex ultrasound scan (A, <12 mm; B, ≥12 mm). Second-generation catheters (ClosureFast; Covidien, Mansfield, Mass) and tumescent anesthesia were used. Clinical stage (according to Clinical, Etiology, Anatomy, and Pathophysiology [CEAP] classification), quality of life (measured by the 14-item Chronic Venous Insufficiency Questionnaire), and pain on visual analog scale were recorded before the procedure and during follow-up. Technical success was defined as GSV occlusion on duplex ultrasound scan. Safety was defined as incidence and type of adverse events at 10 days, 1 month, 6 months, and 12 months.

Results: There were 257 patients included, 183 (71%) with GSV diameter <12 mm and 74 (29%) with GSV diameter ≥12 mm. Mean GSV diameter was 8 ± 2 mm (4-11 mm) and 14 ± 2 mm (12-21 mm), respectively. Before the procedure, although a tendency toward greater clinical severity was observed in group B, no significant differences were found in the percentage of patients in C4 and C5 categories (A, 10%; B, 22%), median pain perception (A, 40; B, 39), or median quality of life value on the 14-item Chronic Venous Insufficiency Questionnaire scale (A, 27; B, 27). The rate of GSV occlusion at 1 month (n = 221) was 97% in group A and 100% in group B ($P = .325$); at 6 months (n = 158), it was 97% and 98%, respectively ($P > .999$); and at 12 months (n = 90), it was 99% and 96% ($P = .481$). There was a significant improvement in pain and quality of life in both groups, without differences between them. Finally, no differences between groups were found in terms of adverse events. Paresthesias were the most frequent event (A, 4%; B, 5%; P = NS), which disappeared during follow-up in half of the cases. Regarding major adverse events, there was only one case of deep venous thrombosis in group B.

Conclusions: RFA is safe and effective for the treatment of GSV ≥12 mm at midterm. (J Vasc Surg: Venous and Lym Dis 2017;■:1-7.)

For many years, the treatment of varicose veins consisted of ligation and stripping of the incompetent saphenous vein. Since the introduction of radiofrequency ablation (RFA)[1] in 2000 and endovenous laser ablation[2] in 2001, minimally invasive endovenous ablation therapy has become an alternative to open surgery for the management of great saphenous vein (GSV) incompetence.[3] These new options have advantages over traditional surgery proven in recent randomized clinical trials, including lower postoperative pain and recurrence rates, better quality of life, and faster recovery times.[4-10]

The RFA technique consists of producing an endofibrosis of the saphenous vein walls through the application of heat by conduction from the intravenous catheter. Initially, the first-generation device ClosurePlus (VNUS Medical Technologies, San Jose, Calif) was used. However, its clinical trials excluded GSVs that were >12 mm in diameter because they did not allow the catheter to be positioned in contact with the vein walls.

In 2000, tumescent anesthesia became routine with RFA as reported by Manfrini et al.[11] This allows the compression of the vein walls against the RFA catheter and the creation of a thermal and mechanical barrier between the saphenous vein and the surrounding tissues. It has been suggested that RFA could be used safely and effectively in veins of greater diameter[12,13] using tumescent anesthesia and the ClosureFast catheter (Venefit; Covidien, Mansfield, Mass).

Despite the extended use of radiofrequency on incompetent GSVs ≥12 mm, few studies have compared the influence of the diameter on the effectiveness and safety of this technique. Therefore, the main objective of our

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study was to assess the effectiveness and safety of this treatment in the subgroup of patients with saphenous veins ≥12 mm.

METHODS

Study design and setting. This was a prospective, single-center study including all patients who underwent RFA of the GSV from September 2014 to December 2015.

Variables. Patients were selected consecutively with an age range between 18 and 75 years and clinical stage of chronic venous insufficiency between C2 and C5 according to the Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) classification (developed in 1994[14] and revised in 2004[15]). GSV incompetence (defined as reflux ≥0.5 second after calf compression or Valsalva maneuver) was demonstrated using duplex ultrasound in all cases. Individuals with a clinical history or ultrasound findings of deep venous thrombosis (DVT), phlebitis of the GSV, or double GSV and those with incompetence of the deep venous system or peripheral arterial disease were excluded from the study.

Initially, a clinical assessment and duplex ultrasound examination were carried out. Pain intensity and clinical stage data were collected using the 100-mm visual analog scale (VAS)[16] and CEAP classification, respectively. Data on quality of life in the last month were collected using the 14-item Chronic Venous Insufficiency Questionnaire (CIVIQ-14). In addition, ultrasound mapping was performed in the standing position to reveal GSV incompetence and to measure its maximum diameter. This diameter was recorded at the level of the thigh, in a tubular part of the trunk, according to the International Union of Phlebology consensus document on duplex ultrasound.[17] The sample was divided into two groups according to the main variable: group A, GSV <12 mm; and group B, GSV ≥12 mm.

Procedure. All the procedures were carried out using tumescent anesthesia, with duplex ultrasound guidance. The second-generation device, VNUS ClosureFast catheter with a 7-cm thermocouple, was used; 10 mL of tumescent anesthesia was injected into the saphenous compartment for each centimeter of vein to be treated. The tumescence used consisted of 500 mL of cold physiologic saline solution at 0.9%, 30 mg of lidocaine, 0.5 mg of epinephrine, and 10 mL of bicarbonate (1M). According to the manufacturer's instructions, the first cycle of RFA (a 20-second radiofrequency cycle in which the catheter reaches 120°C) was performed 2 cm distal to the saphenofemoral junction. At this location, it is compulsory to apply a second cycle in all cases. Then, the catheter is removed 7 cm, and a single new cycle of 20 seconds is applied every 7 cm. As an exception, in those GSV segments larger than 12 mm, a second cycle was performed.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective nonrandomized study
- **Take Home Message:** There was no difference in great saphenous vein (GSV) occlusion rate or quality of life at 1 year after radiofrequency ablation between 74 patients with GSV diameter ≥12 mm and 183 patients with GSV diameter <12 mm.
- **Recommendation:** The study suggests that radiofrequency ablation of the GSV with a diameter ≥12 mm is safe and effective at 1 year after treatment.

In the same surgical procedure, a Müller miniphlebectomy of collateral veins was performed on all patients. All the procedures were performed on an outpatient basis.

With regard to postoperative care, early mobilization and quick return to normal life were recommended to patients. Analgesics were used subject to the patient's needs, with 1 g of acetaminophen (maximum of 1 tablet every 6 hours) or 600 mg of ibuprofen (maximum of 1 tablet every 8 hours). All patients received a prophylactic dose of subcutaneous low-molecular-weight heparin (usually 40 mg of enoxaparin or 3500 units of bemiparin daily) during the 7 days after surgery. Last, they all used an elastic support with a medium-compression long stocking (22-29 mm Hg).

The effectiveness of treatment was defined as the complete occlusion of the vein with no reflux on the duplex ultrasound scan in the treated GSV segment. Safety was defined as the incidence and type of complications observed during follow-up.

The first postoperative checkup was carried out at 10 days, recording the potential complications. Hematoma, paresthesias, pigmentation of the skin, and cellulitis were considered to be minor complications; and the appearance of skin burns, DVT, and pulmonary thromboembolism were considered to be major complications. Recurrence was defined as one or more new varicose branches of the ablated GSV on physical examination with duplex ultrasound scan-confirmed patency and reflux, excluding those dependent on perforating veins, nonablated GSV, saphenous veins separate from the GSV, and incompetent pelvic collateral veins. In this visit, the patient handed in a diary with the quantity of analgesics taken and the degree of pain experienced according to the VAS during this period.

Subsequently, an ultrasound scan was performed at 1 month, 6 months, and 12 months. The objective of these visits was to assess the effectiveness of the treatment, complications, pain (according to the VAS), clinical stage (CEAP), and quality of life (using the CIVIQ-14).

Statistical methods. Groups A and B were compared and differences tested using Student *t*-test or

Table I. Baseline characteristics of the sample

	<12 mm (n = 183)	≥12 mm (n = 74)	*P*
Female	118 (65)	43 (58)	.42
Age, years	49 ± 12	52 ± 11	.10
Side, right	93 (52)	31 (44)	.25
CEAP			.10
C2	79 (50)	28 (42)	
C3	62 (40)	24 (36)	
C4	13 (8)	11 (16)	
C5	3 (2)	4 (6)	
CIVIQ-14 score	27 (15)	27 (23)	
VAS pain score	40 (39)	39 (52)	

CEAP, Clinical, Etiology, Anatomy, and Pathophysiology; *CIVIQ-14*, 14-item Chronic Venous Insufficiency Questionnaire; *VAS*, visual analog scale.
Categorical variables are presented as number (%). Continuous variables are presented as mean ± standard deviation or median (interquartile range).

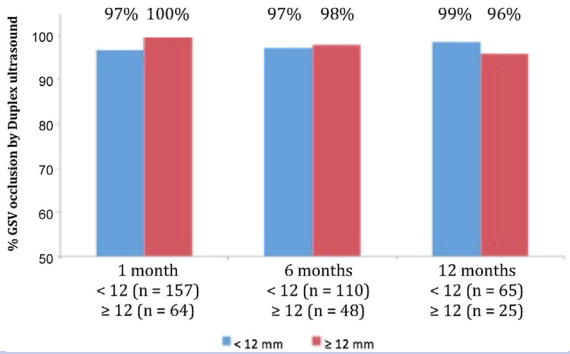

Fig 1. Efficacy of the treatment. Effectiveness is defined as the correct occlusion of the treated great saphenous vein (*GSV*) by duplex ultrasound scan. Assessed at 1 month, 6 months, and 12 months after the intervention.

Mann-Whitney for continuous variables and χ^2 or Fisher exact test for qualitative ones. The VAS score was compared using the Wilcoxon signed rank test. The differences between the groups in the baseline CIVIQ-14 were analyzed using the Student *t*-test; the change in values during follow-up with respect to baseline was compared using the repeated-measures analysis of variance test.

The results of continuous variables are shown as mean ± standard deviation and median and quartiles for variables not thought to be normally distributed.

The statistical analysis was carried out using the software SPSS 20.0 (IBM Corp, Armonk, NY) and Stata 12.0 (StataCorp LP, College Station, Tex) and supervised by a statistician from the hospital's department of preventive medicine. The assumed significance level was $P < .05$.

Ethics. This study was performed in accordance with the Declaration of Helsinki. The protocol was revised and approved by the Ethics Committee of our hospital, and all patients signed an informed consent.

RESULTS

Patients. During the study period, a total of 257 patients were treated with RFA for GSV incompetence. There were 183 (71%) with a GSV diameter <12 mm (group A), and 74 (29%) had a GSV diameter ≥12 mm (group B). The mean diameter of the treated GSVs was 10 ± 2 mm (range, 4-21 mm), with 8 ± 2 mm (4-11 mm) in group A and 14 ± 2 mm (12-21 mm) in group B.

Regarding the demographic characteristics (Table I), 161 patients were women (63%), with a mean age of 50 ± 12 years (18-75 years) and no differences between groups. Although a tendency toward greater clinical severity was observed in group B, no significant differences were found in the percentage of patients in C4 and C5 CEAP categories (A, 10%; B, 22%), median pain perception (A, 40; B, 39), or median quality of life value on the CIVIQ-14 scale (A, 27; B, 27).

Procedure. In total, 93% of the interventions were performed percutaneously in the overall cohort, with no differences between groups (A, 91%; B, 94%; $P = .475$). The remaining 7% required a small incision for insertion of the catheter through the GSV. Tumescent anesthesia was used in all cases. The technical success of the procedure was 100% in both groups, with a complete occlusion of the treated GSV and with no complications in the common femoral vein in any case at the time of the end of the intervention, assessed with duplex ultrasound scan.

Early control. Few patients experienced pain in the days after the intervention, especially from the second day after surgery. From this point, <50% of patients needed to take any type of analgesics. In the overall cohort, the median (interquartile range) pain scores on the first, third, and fifth days after surgery were 18 (49), 9 (31), and 2 (18), respectively, with no differences observed between groups for this variable or in the need for analgesics.

With regard to complications at 10 days, there was only one case of inflammation of the treated GSV in group A and one of DVT in group B. No skin burns or complications at the puncture site were recorded.

Follow-up. Of the 257 patients included in the study, 221 had a checkup at 1 month (A, 157; B, 64), 158 at 6 months (A, 110; B, 48), and 90 at 12 months (A, 65; B, 25).

The success of the complete ablation of the treated vein (Fig 1) in the group with GSV <12 mm was 97%, 97%, and 99% at 1 month, 6 months, and 12 months, respectively; in the group with GSV ≥12 mm, it was 100%, 98%, and 96%, respectively. No statistically significant differences were observed between the two groups. The overall occlusion rate 1 year after the intervention was 96%.

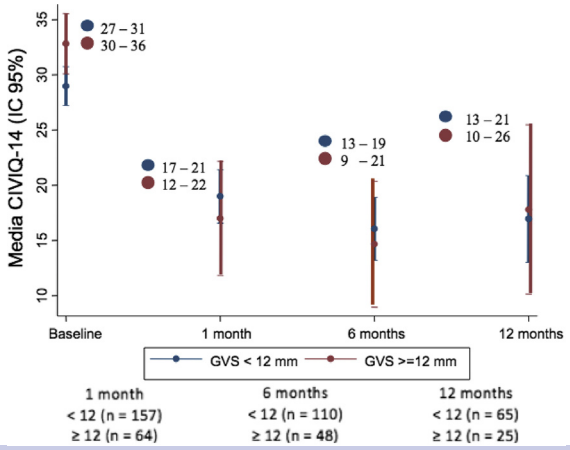

Fig 2. Changes in quality of life according to the 14-item Chronic Venous Insufficiency Questionnaire (*CIVIQ-14*). Collected preoperatively and 1 month, 6 months, and 12 months after surgery. *IC,* Confidence interval; *GSV,* great saphenous vein.

The five patients who presented with patency of the GSV on the duplex ultrasound scan performed at the checkup at 1 month belonged to the group with the smaller GSV. Of these cases, at 6 months, one of them became occluded and three continued to be patent (in two of them, the persistent patency was due to perforating veins). The duplex ultrasound scan performed at the second checkup was not yet available for the remaining case.

During follow-up, two of the occluded GSVs on the duplex ultrasound scan performed at the first visit (one from each study group) became patent during the following 5 months, with varicose veins appearing in one of the recurrent cases. No cases of recanalization were observed after 1 year of being occluded in the previous two Doppler ultrasound scans (at 1 month and 6 months).

Fig 2 shows the changes in quality of life in both groups, with a significant improvement in the postoperative CIVIQ-14 values with regard to the baseline at 1 month ($P < .001$), 6 months ($P < .001$), and 12 months ($P < .001$). However, there were no significant differences in the improvement obtained in group A vs group B ($P = .240$). Similar results were obtained by analyzing the changes in pain during follow-up, with improvement observed in both groups compared with the baseline but with no differences between them. One month after the intervention, the median pain score was 8 (20) in group A and 0 (20) in group B. These differences were not statistically significant.

Complications during follow-up are shown in Table II. The percentage of complications in the overall cohort was 8% at 1 month, 9% at 6 months, and 6% at 12 months, with no differences between the groups. The most common complication after treatment of the GSV was paresthesias, being present at 1 month in seven (4%) patients from group A and in three (5%) from group B. Paraesthesia disappeared progressively in most cases; at 6 months, it persisted in only three of the seven patients from group A and two from group B.

With regard to recurrent varicose veins, few patients suffered from this complication, with no differences between the two groups. At 6 months, two patients from group A suffered from recurrent varicose veins, accounting for 2% of these patients, with no evidence of recurrent cases in group B. At 12 months, one patient from each group presented with recurrent varicose veins.

DISCUSSION

The radiofrequency system VNUS Closure (VNUS Medical Technologies) was used for the first time in 1998, and it was approved by the Food and Drug Administration in 1999. Since then, there have been many studies showing its safety and effectiveness. Merchant

Table II. Radiofrequency ablation (RFA) complications during follow-up

	1 month (n = 221), No. (%)		6 months (n = 158), No. (%)		12 months (n = 90), No. (%)	
	<12 mm (n = 157)	≥12 mm (n = 64)	<12 mm (n = 110)	≥12 mm (n = 48)	<12 mm (n = 65)	≥12 mm (n = 25)
Total complications	12 (8)	5 (8)	12 (11)	2 (4)	3 (5)	2 (8)
Minor complications						
Hematoma	1 (1)	—	—	—	—	—
Paresthesia	7 (4)[a]	3 (5)	3 (5)	2 (4)	3 (5)	2 (8)
Hyperpigmentation	5 (3)[a]		5 (5)	—	—	—
Cellulitis	—	—	—	—	—	—
Superficial phlebitis		1 (2)	2 (2)	—	—	—
Major complications						
Skin burn	—	—	—	—	—	—
DVT	—	1 (2)	—	—	—	—

DVT, Deep venous thrombosis.
[a]The same patient presented with hyperpigmentation and paresthesia at 1 month in group A.

et al[6] published a prospective, multicenter study of 319 cases treated with this technique. In terms of effectiveness, 83.6% presented with complete occlusion of the treated GSV at 1 year and 85.2% at 2 years, with a paresthesia rate of 3.9% and 5.6% at 1 year and 2 years, respectively. At 2 years, 94.5% of the patients were satisfied with the treatment. These good results were confirmed at 5 years by the same authors.[18] Furthermore, RFA has been associated with less need for analgesics, less postoperative pain, more rapid recovery, and better quality of life compared with the other endoluminal treatment, endovenous laser ablation.[19-21]

The first-generation radiofrequency catheter VNUS ClosurePlus consisted of a bipolar electrode that had a treatment temperature of around 85°C to 90°C. It had to be retrieved manually, carrying out a pullback to a speed of 1 to 3 cm/min. During the ablation, heparinized saline had to be instilled through the catheter lumen to prevent the formation of a blood clot at the electrode tip. The main drawbacks associated with this catheter were slowness, variability in removal speed, need to add saline, and having to remove the catheter to prevent or to remove the clot forming at the tip of the thermocouple.

The second-generation catheter VNUS ClosureFast, which was first used in 2006, aimed to correct the drawbacks of the previous device, converting RFA into a faster, simpler, and more effective treatment. In this case, the thermocouple measures 7 cm or 3 cm, and the ablation is not continuous but segmental instead, being applied in 20-second cycles at 120°C. The thermocouple is also enclosed in a lubricated sheath that prevents the formation of clots and renders irrigation with heparinized saline unnecessary during the procedure. In addition, this sheath and its better flexibility have facilitated its navigability. Moreover, it allows the use of a 0.025-inch guidewire through the light to redirect it.

Both the first-generation[6,7,9-11,18] and the second-generation[3,12,13,22-24] catheters have proven their effectiveness and safety in the treatment of incompetent GSV. A comparative study by Zuniga et al[25] showed the superiority of the second-generation device in immediate results. A total of 312 patients treated with ClosurePlus and 355 with ClosureFast were enrolled. The total occlusion rate was 88% and 98%, respectively, on the duplex ultrasound scan at 1 week. With regard to major complications, there was a DVT rate of 3.5% and 0%, respectively. All these differences were statistically significant.

Although the GSVs >12 mm were excluded from first-generation RFA instructions, several studies have suggested its potential use in this group; when the RFA data were analyzed by subgroups, the effectiveness in these patients was >96% at 6 months.[9,10,12,13] Currently, with the availability of second-generation RFA catheters and tumescent anesthesia, its use in GSVs >12 mm is no longer considered a contraindication.

In terms of efficacy, initial studies with the second-generation catheters showed good results in spite of including GSVs >12 mm. Thus, an occlusion rate of 99.6% at 6 months and 86.4% at 36 months was obtained by Proebstle et al.[22,23] Creton et al[24] reported an efficacy of 98.6% at 6 months and 96.9% at 1 year. The result in our series concurs with these previous ones, with an overall occlusion rate at 1 year of 96.4%. However, the studies of Proebstle and Creton did not analyze comparatively the subgroups according to GSV diameter.

One of the most relevant studies intending to extend the use of RFA to large veins was published by Calcagno et al[12] in 2009. This was the first study to compare the outcomes according to GSV diameter (>12 mm or <12 mm). This prospective study included 246 veins in the first group and 96 in the second one. The second-generation ClosureFast catheter was used with a reported effectiveness of 94% and 96%, respectively, at 1 month and 98% and 100% at 6 months, without differences between groups and concluding that larger diameters were not associated with worse occlusion rates. Our results, with occlusion rates >97% for both groups at 1 month and 6 months, agree with those of Calcagno et al, whereas our study adds longer term follow-up data, confirming that these good results remain at 1 year (with 99% and 96% rates, respectively).

The only study to date to report comparative results at 1 year for smaller and larger GSVs was published in Russian by Shaidakov et al.[13] In this prospective, multicenter, nonrandomized study with 218 enrolled patients comparing the results of stripping and RFA according to GSV diameter, an overall efficacy of 95.3% without differences between groups was reported.

Regarding safety, this is a technique with a low rate of major complications, which occur in around 2.5% of the patients during follow-up. Among these major complications, the one most commonly reported in the literature is DVT, which accounts for 1.8%, followed by skin burns (0.3%), neuralgia (0.27%), and pulmonary thromboembolism (0.02%).[26] In our cohort, there was only one major complication at 1 month of follow-up, one case of DVT in group B, which represents 2% within this group. These data coincide with those described in the literature.[26-28] Jacobs et al identified a history of DVT as the only known risk factor for the development of a new DVT after this procedure. Among the minor complications, paresthesias represented the most common adverse event in most studies. It was found to vary from 3.2% in the study by Proebstle et al[22,23] to 3.4% in that by Creton et al[24] and 12.1% in that by Merchant et al.[6] This last study identified a change in the frequency of paresthesias in the periods before and after tumescence, with a frequency of 14.5% and 9.1%, respectively. Paresthesia occurred in 5% of our cohort 1 month after the intervention. However, it disappeared 1 year

after surgery in most patients. The rest of the potential complications (hematoma, superficial phlebitis, cellulitis, infection, skin pigmentation, and skin burns) are not common, and in our cohort, they had all disappeared 1 year after the intervention. There were no differences in our study or in that carried out by Calagno et al[12] in the frequency of individual or overall complications based on the diameter of the GSV vein to be treated.

Our study adds information to the previous literature on efficacy and safety too. Postoperative pain, use of pain medication, and quality of life have been thorough analyzed. The need for pain medication after this intervention was low, with <50% of the patients requiring analgesia after the second postoperative day, in relation to the low rate of pain experienced during the postoperative period for this type of intervention in our series. Previous studies such as the one published by Shepherd et al[20] obtained a mean pain score at the third postoperative day of 26 ± 22 of 100, using the VAS, whereas Creton et al[24] reported a mean pain score of 7 ± 16, both similar to the outcomes in our cohort (17 ± 20). These studies show that RFA is a comfortable technique for patients from the first postoperative days, allowing a quick return to normal life; however, none of these previous studies had analyzed these results in relation to GSV diameter before. From a clinical point of view, an improvement in quality of life with a decrease in pain was obtained in both groups after treatment. These variables are difficult to compare directly with other studies because of the different scales used and their validation in different populations. However, this is the first study to date to compare quality of life according to the GSV diameter.

Limitations. This study presents some limitations. First, some variables, such as skin depth, volume on tumescence, presence of perforating veins in the treated GSV segment, and previous use of antiplatelet or anticoagulant drugs, which may alter the patient's postoperative pain or the presence of one of the complications, had not been collected. New studies to analyze the different risk factors associated with the complications would therefore be necessary. Second, the patients in our study received low-molecular-weight heparin for 7 days after the intervention, but they were not routinely studied by ultrasound until 1 month after surgery, which might have had an influence on the incidence of DVT observed. Finally, follow-up was limited to 12 months in our series. A longer follow-up is therefore needed to confirm these results.

CONCLUSIONS

Radiofrequency thermal ablation is safe and effective for the treatment of GSV incompetence, regardless of its diameter.

AUTHOR CONTRIBUTIONS

Conception and design: MC, IM, IC, FS
Analysis and interpretation: MC, IM, MH, PM, FS
Data collection: MC, IC
Writing the article: MC, IM, PM
Critical revision of the article: IM, MH, PM, IC, FS
Final approval of the article: MC, IM, MH, PM, IC, FS
Statistical analysis: MC, MH
Obtained funding: Not applicable
Overall responsibility: MC

REFERENCES

1. Goldman MP. Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow-up. Dermatol Surg 2000;26:452-6.
2. Navarro L, Min RJ, Bone C. Endovenous laser: a new minimally invasive method of treatment for varicose veins—preliminary observations using an 810 nm diode laser. Dermatol Surg 2001;27:117-22.
3. Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, et al. 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. J Vasc Surg 2011;53:2S-48S.
4. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg 2011;98:1079-87.
5. Siribumrungwong B, Noorit P, Wilasrusmee C, Attia J, Thakkinstian A. A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein. Eur J Vasc Endovasc Surg 2012;44:214-23.
6. Merchant RF, De Palma RG, Kabnick LS. Endovenous obliteration of saphenous reflux: a multicenter study. J Vasc Surg 2002;35:1190-6.
7. Wagner WH, Levin PM, Cossman DV, Lauterbach SR, Cohen JL, Farber A. Early experience with radiofrequency ablation of the greater saphenous vein. Ann Vasc Surg 2004;18:42-7.
8. Rautio T, Ohinmaa A, Perälä J, Ohtonen P, Heikkinen T, Wiik H, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. J Vasc Surg 2002;35:958-65.
9. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomised study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVeS study). J Vasc Surg 2003;38:207-14.
10. Nicolini P; Closure Group. Treatment of primary varicose veins by endovenous obliteration with the VNUS closure system: results of a prospective multicentre study. Eur J Vasc Endovasc Surg 2005;29:433-9.
11. Manfrini S, Gasbarro V, Danielsson G, Norgren L, Chandler JG, Lennox AF, et al. Endovenous management of saphenous vein reflux. J Vasc Surg 2000;32:330-42.
12. Calcagno D, Rossi JA, Ha C. Effect of saphenous vein diameter on closure rate with ClosureFAST radiofrequency catheter. Vasc Endovascular Surg 2009;43:564-70.

13. Shaidakov EV, Grigorian AG, Iliukhin EA, Bulatov VL, Gal'chenko MI. Analysis of efficacy of radiofrequency obliteration with due regard for the target vein's diameter. Angiol Sosud Khir 2014;20:87-94.
14. Nicolaides A, Bergan JJ, Eklof B, Kistner RL, Moneta G; Ad Hoc Committee of the American Venous Forum. Classification and grading of chronic venous disease in the lower limbs: a consensus statement. In: Gloviczki P, Yao JS, editors. Handbook of venous disorders: guidelines of the American Venous Forum. London: Chapman & Hall Medical; 1996. p. 652-60.
15. Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL, et al. Revision of the CEAP classification for chronic venous disorders: consensus statement. J Vasc Surg 2004;40:1248-52.
16. Faiz KW. [VAS—visual analog scale]. Tidsskr Nor Laegeforen 2014;134:323.
17. Maeseneer M, Pichot O, Cavezzi A, Earnshaw J, van Rij A, Lurie F, et al. Duplex ultrasound investigation of the veins of the lower limbs after treatment of varicose veins—UIP consensus document. Eur J Vasc Endovasc Surg 2011;42:89-102.
18. Merchant RF, Pinchot O. Long-term outcomes of endovenous radiofrequency obliteration of saphenous reflux as a treatment for superficial venous insufficiency. J Vasc Surg 2005;42:502-9.
19. Goode SD, Chowdhury A, Crockett M, Beech A, Simpson R, Richards T, et al. Laser and radiofrequency ablation study (LARA study): a randomised study comparing radiofrequency ablation and endovenous laser ablation (810 nm). Eur J Vasc Endovasc Surg 2010;40:246-53.
20. Shepherd AC, Gohel MS, Brown LC, Metcalfe MJ, Hamish M, Davies AH. Randomized clinical trial of VNUS ClosureFAST radiofrequency ablation versus laser for varicose veins. Br J Surg 2010;97:810-8.
21. Nordon IM, Hinchliffe RJ, Brar R, Moxey P, Black SA, Thompson MM, et al. A prospective double-blind randomized controlled trial of radiofrequency versus laser treatment of the great saphenous vein in patients with varicose veins. Ann Surg 2011;254:876-81.
22. Proebstle TM, Vago B, Alm J, Göckeritz O, Lebard C, Pichot O. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. J Vasc Surg 2008;47:151-6.
23. Proebstle TM, Alm J, Göckeritz O, Wenzel C, Noppeney T, Lebard C, et al. Three-year European follow-up of endovenous radiofrequency powered segmental thermal ablation of the great saphenous vein with or without treatment of calf varicosities. J Vasc Surg 2011;54:146-52.
24. Creton D, Pichot O, Sessa C, Proebstle TM. Radiofrequency-powered segmental thermal obliteration carried out with the ClosureFast procedure: results at 1 year. Ann Vasc Surg 2010;24:360-6.
25. Zuniga JM, Hingorani A, Ascher E, Shiferson A, Jung D, Jimenez R, et al. Short-term outcome analysis of radiofrequency ablation using ClosurePlus vs ClosureFast catheters in the treatment of incompetent great saphenous vein. J Vasc Surg 2012;55:1048-51.
26. Health Quality Ontario. Endovascular radiofrequency ablation for varicose veins: an evidence-based analysis. Ont Health Technol Assess Ser 2011;11:1-93.
27. Marsh P, Prince BA, Holdstock J, Harrison C, Whiteley MS. Deep vein thrombosis (DVT) after venous thermoablation techniques: rates of endovenous heat-induced thrombosis (EHIT) and classical DVT after radiofrequency and endovenous laser ablation in a single centre. Eur J Vasc Endovasc Surg 2010;40:521-7.
28. Jacobs C, Pinzon MM, Orozco J, Hunt PJ, Rivera A, McCarthy WJ. Deep venous thrombosis after saphenous endovenous radiofrequency ablation: is it predictable? Ann Vasc Surg 2014;28:679-85.

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