Prospective comparative cohort study evaluating incompetent great saphenous vein closure using radiofrequency-powered segmental ablation or 1470-nm endovenous laser ablation with radial-tip fibers (Varico 2 study)

James A. Lawson, MD, PhD,[a] Stefanie A. Gauw, CRC,[a] Clarissa J. van Vlijmen, MD, PhD,[a] Pascal Pronk, MD,[a] Menno T. W. Gaastra, MD,[a] Marco J. Tangelder, MD, PhD,[b] *and* Michael C. Mooij, MD,[a] *Alkmaar and Haarlem, The Netherlands*

CME Activity

Purpose or Statement of Need The purpose of this journal-based CME activity is to enhance the vascular specialist's ability to diagnose and care for patients with the entire spectrum of circulatory disease through a comprehensive review of contemporary vascular surgical and endovascular literature.

Learning Objectives At the end of this activity, participants should be able to:

- Know the short- and long-term success rates of laser and radiofrequency ablation of the saphenous vein.
- Know the complications and recovery of patients treated by either radiofrequency or laser ablation of the saphenous vein.

Target Audience This activity is designed for vascular surgeons and individuals in related specialties.

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ABSTRACT

Background: Endovenous laser ablation (EVLA) and radiofrequency-powered segmental ablation (RPSA) of the incompetent great saphenous vein (GSV) are both known for their excellent technical and clinical outcomes for the treatment of varicose veins. RPSA has reduced postprocedural pain and morbidity with shorter recovery time for the patient compared with EVLA using bare-tip fibers. However, new-generation EVLA devices with less traumatic radial-tip fibers (RTFs) operating at longer wavelengths up to 1470 nm also reduce postprocedural pain. The objective of this study was to compare long-term effectiveness of GSV thermal ablation and postprocedural recovery using RPSA or 1470-nm EVLA with RTF (EVLA-RTF).

Methods: In a comparative prospective monthly altering-treatment cohort study of 311 patients (346 treated legs), each leg with incompetence of the GSV was treated with either RPSA (158 patients, 175 legs) or EVLA-RTF (153 patients, 171 legs). The primary outcome was anatomic occlusion of the GSV, assessed at 12, 24, 36, 48, and 60 months using Kaplan-Meier statistics and compared using the log-rank test. Secondary outcomes included freedom of varicose vein recurrence,

From the Centrum Oosterwal, Alkmaar[a]; and the Panta Rei Cardiovascular R&D Consultancy, Haarlem.[b]

Dutch Nederland Trial Register: NTR2854.

Author conflict of interest: J.A.L. conducted ClosureFast and VenaSeal workshops and on-site clinical training worldwide supported by Covidien and Medtronic. A nonrestricted grant is issued by Biolitec for an ongoing randomized study about cranial tip location as a starting point during endovenous laser ablation with radial fibers in our center.

Correspondence: James A. Lawson, MD, PhD, Centrum Oosterwal, Comeniusstraat 3, Alkmaar 1817 MS, The Netherlands (e-mail: jalawson@me.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

http://dx.doi.org/10.1016/j.jvsv.2017.06.016

clinical success measured by Venous Clinical Severity Score (VCSS), disease-specific quality of life determined using the Aberdeen Varicose Vein Questionnaire (AVVQ), postoperative pain scores, and time to return to work.

Results: The total primary obliteration rate after 36 and 60 months was 96.2% with RPSA and 96.7% with EVLA-RTF ($P = .81$). Freedom of symptomatic anterior accessory vein recurrence after 5 years was 85% after RPSA and 87% after EVLA-RTF ($P = .50$). VCSS and AVVQ score presented similar and durable improvements in both groups between 6 weeks and 60 months. There was no difference in postoperative pain scores after both treatments during the first 14 days (mean visual analog scale score, 0.54-2.19). The median time for return to work was 1 day after both treatments. No severe adverse events were observed.

Conclusions: RPSA and EVLA-RTF have similarly high GSV obliteration rates in the long term, and the treatments are equally effective clinically. Both treatments are associated with similar minimal postprocedural pain scores and short recovery times. (J Vasc Surg: Venous and Lym Dis 2018;6:31-40.)

Saphenous reflux is a contributing factor to symptoms and progression of venous disease.[1] Endovenous thermal ablation (EVTA) is a minimally invasive and efficacious technique for the treatment of saphenous incompetence. EVTA replaces the classic high ligation and stripping of the saphenous vein as treatment of first choice following recommendations of the guidelines of the Society for Vascular Surgery, American Venous Forum, and European Society for Vascular Surgery.[2,3] Several randomized studies concluded that endovenous laser ablation (EVLA) had advantages over open surgery, such as less postprocedural pain, fewer complications, and limited downtime.[4-7] However, most of these randomized studies compared open surgery under general anesthesia with EVTA under local anesthesia. In only a few studies, tumescent anesthesia was used in both treatment modalities.[8-11] These studies showed no differences in postoperative pain and recovery between open surgery and EVLA using a bare-tip fiber (EVLA-BTF). A recent systematic review comparing endovenous ablation and surgical intervention showed no significant difference in postoperative pain between open surgery and EVLA-BTF.[12] Radiofrequency ablation (RFA) is considered significantly less painful in the postoperative period than open surgery and 980-nm EVLA-BTF.[13,14] The primary reason that EVLA-BTF (810 nm and 980 nm) is more painful is the use of sharp BTFs that easily cause vein wall perforations and hematoma. This can be avoided by ablation catheters using radiofrequency as a heating mechanism. This led to the development of a new 1470-nm EVLA (ELVeS Radial; Biolitec, Jena, Germany) with a blunt radial-tip fiber (RTF) that circumferentially heats up the vein wall with lower power density than EVLA-BTF. A small prospective pilot study in our center (presented at European Venous Forum, Antwerp, 2010) showed less postoperative pain after both radiofrequency-powered segmental ablation (RPSA) by ClosureFast (Medtronic, Santa Rosa, Calif) and 1470-nm EVLA with RTF (EVLA-RTF; Biolitec) compared with EVLA with a 980-nm BTF (Biolitec).[15]

The objective of this study was to compare the two ablation techniques, RPSA and EVLA-RTF, regarding postoperative recovery, long-term anatomic and clinical results, recurrence rate at the groin, and health-related quality of life (QOL).

METHODS

The study protocol was approved by the Regional Ethics Review Board. The study complied with the Declaration of Helsinki. Patients with symptomatic primary varicose veins due to great saphenous vein (GSV) incompetence attending the vascular outpatient clinic of Centrum Oosterwal Alkmaar were invited to participate in the study in the period from October 1, 2010, to September 31, 2012.

All patients were examined by a phlebologist and underwent duplex ultrasound (DUS) scanning to assess suitability for both treatments and entry into the study. All patients gave written informed consent.

Inclusion criteria were age 18 years or older, presence of primary symptomatic varicose veins and incompetent GSV with a diameter of >3 mm, duration of reflux >0.5 second, and length of incompetence >15 cm. Exclusion criteria were current deep vein occlusion, acute superficial vein thrombosis, and tortuous veins considered to be unsuitable for endovenous treatment.

Study design. This was a comparative prospective monthly altering-treatment cohort study. Both treatments were already performed in our normal clinical practice, so the trial was consistent with usual clinical care. Every consecutive month, the treatment was switched from ClosureFast (RPSA) to EVLA-RTF, or vice versa. Procedures in patients who required bilateral treatment were performed at different sessions with a time interval >6 weeks; thus, patients could have received either treatment in each leg. The total follow-up duration was 60 months after treatment.

Interventions. Both interventions were performed under tumescent anesthesia (35 mg of lidocaine diluted in 500 mL of saline) in an outpatient setting by one of three surgeons who were experienced in both techniques. For both techniques, the GSV was cannulated near the most distal point of venous reflux, and the catheter tip was positioned 1.5 to 2 cm from the saphenofemoral junction under ultrasound guidance. Tumescent

anesthesia was delivered along the length of the vein under ultrasound guidance. All patients received thromboprophylaxis with a single dose of nadroparin 0.3 mL (9.5 IU anti-Xa/mL) before the procedure. During the RPSA procedure, the 7-cm radiofrequency-powered heat-generating coil is passed up the saphenous vein under ultrasound guidance. After infiltration of the tumescent anesthesia solution around the catheter, thermal energy to the vein wall was delivered by conductive heating in segments, resulting in venous spasm and collagen shrinkage with minimal thrombus formation. The first segment was treated with two conductive heating cycles of 20 seconds each, and the remainder of the vein was treated with one RPSA cycle per 7-cm segment with a 0.5-cm overlap. Extrinsic pressure was applied over the vein during treatment cycles while the leg was in a Trendelenburg position. In patients who underwent thermal ablation with EVLA-RTF (Biolitec), the treatment was performed in a continuous mode with a power setting of 10 W. The linear endovenous energy density was radially dosed by controlling pullback time through signals of the generator and was calculated at approximately 80 J/cm. After both procedures, a stocking exerting 23 mm Hg of pressure at the ankle region was applied before discharge. Patients were instructed to wear a compression stocking continuously for the first 24 hours. After 24 hours, we advised patients to continue to wear the stocking on a voluntary basis during the day for 1 week if it felt more comfortable to them. All patients were discharged without pain medication and instructed to take acetaminophen 500 mg only if required. All patients were instructed to mobilize immediately after the procedure and were advised to return to work and normal activities as soon as possible. Patients with varicose tributaries were treated after 1 week with foam sclerotherapy, if necessary.

Primary outcome measure. The primary outcome measure was anatomic occlusion of the treated GSV. Anatomic success was assessed postoperatively during follow-up visits using DUS.

Secondary outcome measures. Clinical success was measured using the revised Venous Clinical Severity Score (VCSS).[16] Other secondary end points were postprocedural pain measured by a 10-point visual analog scale (VAS) score in the first 2 postoperative weeks, time to return to daily activities and work (in days), postoperative events, and disease-specific QOL using the Dutch translated Aberdeen Varicose Vein Questionnaire (AVVQ).[17]

Follow-up visits and outcomes assessment. During the patient's initial visit, information on medical history was collected, followed by physical examination and DUS.

ARTICLE HIGHLIGHTS

- **Type of Research:** Prospective nonrandomized study
- **Take Home Message:** In 311 patients, great saphenous vein ablation using both radiofrequency and laser with a 1470-nm radial-tip fiber had similar low postprocedure pain and short recovery with equally high (96.2% vs 96.7%) 5-year saphenous occlusion rates and similar improvements in quality of life.
- **Recommendation:** Endovenous great saphenous vein ablation with radiofrequency catheter and 1470-nm radial-tip laser fiber had excellent and similar 5-year results, suggesting similar clinical efficacy for the two techniques.

DUS was performed with the patient in the upright position, using manual compression of the calf and the Valsalva maneuver to detect flow and reflux. Incompetence was defined as DUS demonstrable reflux of >0.5 second after a distal augmentation maneuver. After inclusion, classification of the severity of the disease was reported using the validated revised VCSS and comprehensive classification system (Clinical, Etiology, Anatomy, and Pathophysiology). During and after treatment, pain scores were measured using a VAS ranging from 0 (no pain) to 10 (most severe pain). Disease-specific QOL was measured by the Dutch translated AVVQ.[17] Treatment failure and post-treatment complications were documented. Complications could include prolonged bleeding, wound infection, skin burns, paresthesia, thrombus at saphenofemoral junction protruding in the femoral vein, and deep venous thrombosis.

Follow-up visits were scheduled at 1 week and 6 weeks and at 12, 24, 36, 48, and 60 months after treatment. During all follow-up visits, clinical outcomes were assessed by symptoms, physical examination, and DUS. Treatment success of GSV was defined as complete occlusion of the treated GSV segment. According to multisociety consensus, any patency or recanalization, with or without reflux, in any treated segment >5 cm in length beyond the junction or initiation of the treatment point after EVTA as documented by DUS is considered to be a treatment failure.[18]

VCSS and AVVQ classification were documented every year. Clinical recurrence of varicose veins was defined as visible or palpable branch varicosities. Patients were further classified with the Clinical, Etiology, Anatomy, and Pathophysiology score. After endovenous ablation, recurrence of the GSV was defined as the ability to compress the GSV during DUS or as reflux >0.5 second in a vein originating from the saphenofemoral junction or another connection with the femoral vein.

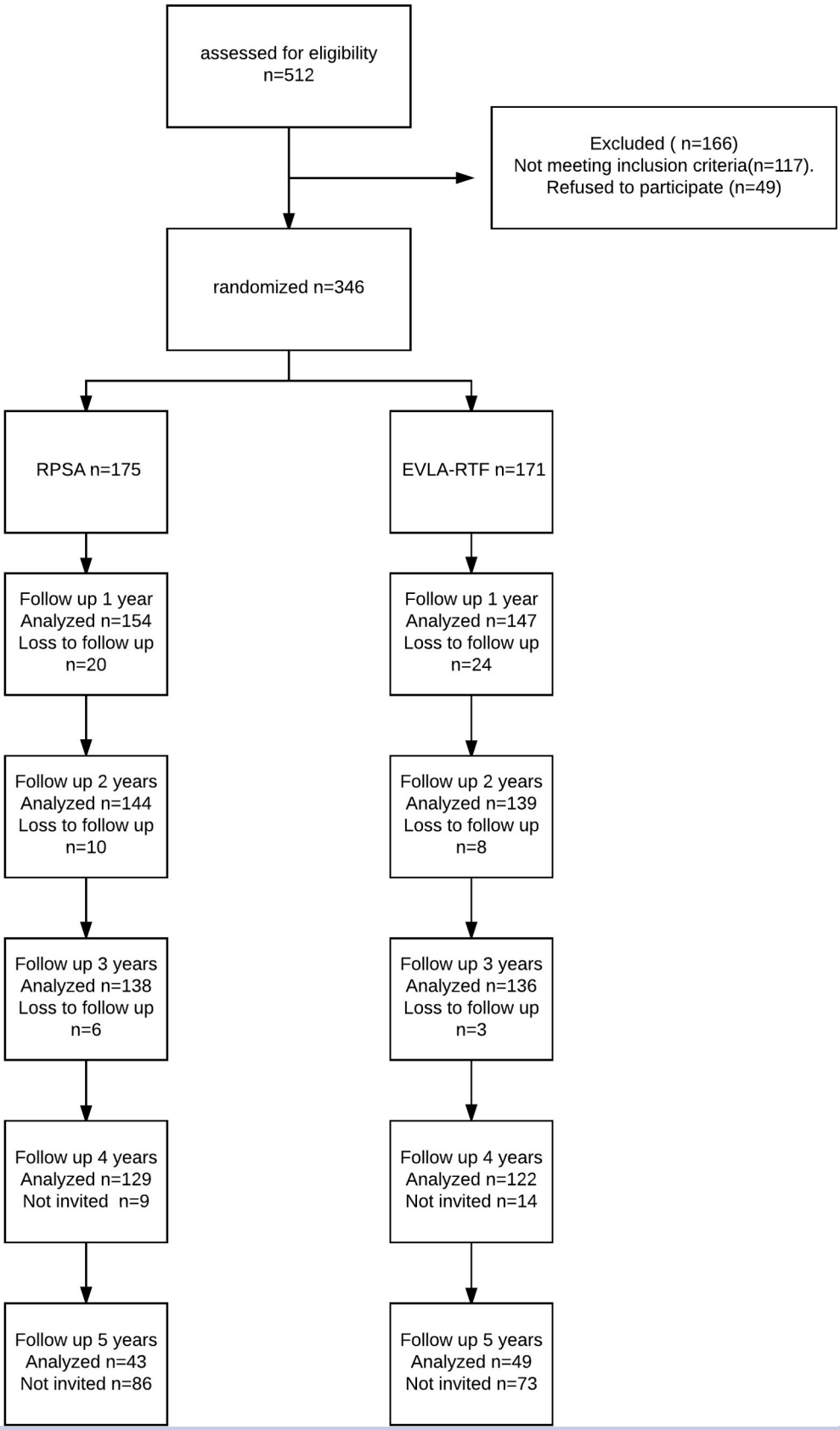

Fig 1. Consolidated Standards of Reporting Trials diagram. Trial recruitment, treatment allocation, and follow-up, in terms of legs. *EVLA-RTF,* Endovenous laser ablation with radial-tip fiber; *RPSA,* radiofrequency-powered segmental ablation.

Table I. Demographics and preoperative clinical characteristics

	RPSA (n = 158; n = 175 legs)	EVLA-RTF (n = 153; n = 171 legs)	*P* value
Left/right legs	86/89	84/87	
Female	120 (76)	110 (72)	.44
Age, years	49.9 (21-76)	50.0 (22-77)	.88
Length, cm	174.6 (155-196)	174.1 (154-196)	.59
BMI	25.2 (18-39)	25.7 (19-43)	.53
VCSS	3.73	4.04	.21
AVVQ	11.4	12.9	.13
CEAP class			
C1	0	0	
C2	40	35	
C3	115	116	
C4	18	18	
C5	2	3	
C6	0	0	
Length of treated vein, cm	39.6 (16-62)	39.1 (16-58)	.78
Midthigh diameter, mm	5.5 (3.0-10)	5.9 (2.7-11.0)	.04
GSV with incompetent terminal valve	125 (71)	122 (70)	

AVVQ, Aberdeen Varicose Vein Questionnaire; *BMI,* body mass index; *CEAP,* Clinical, Etiology, Anatomy, Pathophysiology; *EVLA-RTF,* endovenous laser ablation with radial-tip fiber; *GSV,* great saphenous vein; *RPSA,* radiofrequency-powered segmental ablation; *VCSS,* Venous Clinical Severity Score. Continuous data are presented as mean (minimum-maximum), and categorical data are presented as number (%).

Sample size and statistical analysis. The primary outcome was GSV occlusion. Previous data from a meta-analysis showed a 3-year occlusion rate of 84% with RFA and 95% with EVLA.[19] Sample size calculations were based on detecting a 10% to 12% difference in occlusion rate after 3 years between the treatment groups. With α (type I error) of .05 and β (type II error) of .20, 150 patients were required in each group. Anticipating a dropout of 10%, 350 patients were planned to be included in this study.

Differences in nominal variables were tested by the χ^2 test. For group comparisons of the ordinal variables, the Mann-Whitney *U* test or the Kruskal-Wallis test was used. Continuous variables were compared with a *t*-test or analysis of variance; for comparison of two ordinal variables, a Wilcoxon test was performed. Cumulative occlusion and recurrence incidences in accessory veins were calculated with Kaplan-Meier survival analysis and statistically compared with the log-rank test. Hazard ratios were calculated with Cox regression models, adjusted for possible confounding variables.

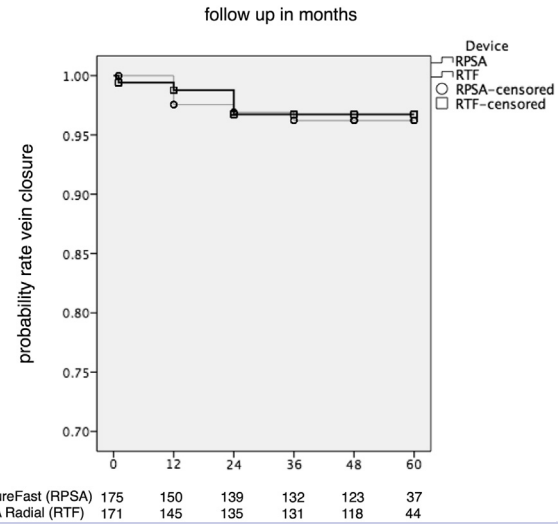

Fig 2. Kaplan-Meier plots for freedom from recanalization of great saphenous vein (GSV) observed by duplex ultrasound (DUS). *EVLA,* Endovenous laser ablation; *RPSA,* radiofrequency-powered segmental ablation; *RTF,* radial-tip fiber. Standard error of the mean <10 (*P* = .81).

RESULTS

A total of 457 patients with 512 legs treated were assessed for eligibility. Of these, 311 patients with 346 legs were included between October 2010 and September 2012 and received treatment as intended (Fig 1). Reasons for excluding 146 patients were not fulfilling the inclusion criteria (n = 97) and refusing to participate (n = 49). Details are shown in Fig 1. The mean age of the patients was 50 years, and 76% were women. The mean treated GSV length was 39.4 cm.

Demographic and preoperative clinical and anatomic characteristics were comparable in both groups, except for the preoperative mean diameter of the treated GSV measured 10 cm above the knee (Table I).

Table II. Preoperative and postoperative Venous Clinical Severity Score (*VCSS*)

	P value	No.	Mean	95% Confidence interval for mean	
				Lower bound	Upper bound
VCSS preoperative					
RPSA		173	3.75	3.43	4.06
EVLA-RTF	.24	171	4.04	3.66	4.42
VCSS 12 months					
RPSA		161	1.98	1.68	2.27
EVLA-RTF	.24	155	1.96	1.62	2.30
VCSS 24 months					
RPSA		150	2.11	1.81	2.40
EVLA-RTF	.67	147	2.01	1.71	2.31
VCSS 36 months					
RPSA		142	1.88	1.57	2.19
EVLA-RTF	.64	139	1.78	1.47	2.09
VCSS 48 months					
RPSA		134	1.81	1.51	2.12
EVLA-RTF	.47	121	1.64	1.26	2.01
VCSS 60 months					
RPSA		62	1.77	1.29	2.26
EVLA-RTF	.33	64	2.13	1.60	2.65

EVLA-RTF, Endovenous laser ablation with radial-tip fiber; *RPSA,* radiofrequency-powered segmental ablation; *VCSS,* Venous Clinical Severity Score. *P* values are derived from repeated-measures analysis of variance.

Primary outcome

Technical outcome. In patients treated with EVLA-RTF, five of the treated GSVs eventually recanalized (two partial and three total). In patients treated with RPSA, six of the treated GSVs eventually recanalized (three partial and three total) in a period of 5 years. The primary

Table III. Postoperative pain scores of radiofrequency-powered segmental ablation (*RPSA*) vs endovenous laser ablation with radial-tip fiber (*EVLA-RTF*)

	P value	No.	Mean	95% Confidence interval for mean		Minimum	Maximum
				Lower bound	Upper bound		
Pain day 1							
RPSA		163	2.05	1.74	2.36	0	8
EVLA-RTF	.57	158	2.18	1.84	2.53	0	8
Pain day 2							
RPSA		162	1.57	1.29	1.85	0	7
EVLA-RTF	.99	157	1.55	1.24	1.86	0	10
Pain day 3							
RPSA		162	1.25	1.01	1.50	0	8
EVLA-RTF	.58	157	1.15	0.89	1.41	0	9
Pain day 7							
RPSA		160	1.22	0.94	1.49	0	8
EVLA-RTF	.16	152	0.96	0.72	1.20	0	8
Pain day 10							
RPSA		157	1.13	0.84	1.41	0	8
EVLA-RTF	.05	152	0.78	0.56	0.99	0	7
Pain day 14							
RPSA		154	0.99	0.70	1.27	0	8
EVLA-RTF	.06	146	0.65	0.44	0.86	0	8

P values are derived from repeated-measures analysis of variance.

Table IV. Postoperative pain medication in first 14 days

Postoperative pain medication	RPSA	%	EVLA-RTF	%
No medication	124	76.1	116	73.4
1-5 units	29	17.8	32	20.3
6-10 units	7	4.3	5	3.2
>10 units	3	1.8	5	3.2

EVLA-RTF, Endovenous laser ablation with radial-tip fiber; *RPSA,* radiofrequency-powered segmental ablation.

persistent obliteration rate was 96.2% (confidence interval, 86-100) with RPSA at 36 and 60 months and 96.7% (confidence interval, 86-100) with EVLA-RTF at 36 and 60 months. There was no significant difference in failure between the treatments ($P = .81$). Comparison of persistent obliteration rate of both treatments during a period of 5 years is graphically presented in Fig 2. The results were similar after adjustment for the difference in preoperative GSV diameter between the groups.

Secondary outcomes

Clinical outcome. In both groups, there was significant improvement after treatment in the median VCSS scores after 12, 24, 36, 48, and 60 months. There were no significant differences between the groups at different time points (Table II).

Symptomatic groin recurrence. Symptomatic recurrence with recanalization of the GSV as a cause of varicose veins was not observed. The most important pattern of recurrence was disease progression at the groin with reflux in the pre-existent anterior accessory vein (23 RPSA legs vs 18 EVLA-RTF legs). After 5 years, 85% of RPSA legs and 87% of EVLA-RTF legs had no symptomatic anterior accessory vein reflux ($P = .50$). Stump length was measured in 270 legs after 12 months. The mean stump length was almost equal in both groups (RPSA, 8.3 mm; EVLA-RTF, 7.5 mm; $P = .60$).

Periprocedural pain and return to normal functioning. In general, the VAS postoperative pain scores were low in both groups (mean, 1-2.5). In the first 14 postoperative days, there was no significant difference in VAS pain scores between the groups (Table III). There was no difference in the frequency of analgesic drug intake; 61% of RPSA and 64% of EVLA-RTF patients did not use any pain medication (Table IV). Patients returned to daily activities in an equally short amount of time in both groups. After EVLA-RTF, the median (minimum-maximum) time was 1 day (0-5 days) compared with 1 day (0-8 days) after RPSA. The median time for return to work was equal after both treatments. After EVLA-RTF, the median (minimum-maximum) time was 1 day (0-14 days) compared with 1 day (0-11 days) after RPSA.

Postoperative complications. No serious adverse events occurred. Minor complications are listed in Table V.

QOL outcomes. QOL was assessed preoperatively, at 6 weeks after treatment, and at 12, 24, 36, 48, and 60 months after treatment. In both groups, treatments produced similar durable health gains in disease-specific QOL scores (AVVQ) during the study period (Table VI).

DISCUSSION

This trial demonstrated safety and long-term effectivity for both RPSA and EVLA-RTF endovenous treatments. Both procedures showed similar low postoperative pain scores and short postoperative recovery. The study confirms the results from recent long-term follow-up studies with ClosureFast, showing 3- to 5-year GSV occlusion rates >92%.[20-22] The results indicate that claims for superiority of EVLA over RFA regarding anatomic occlusion or other definitions of success rate are unjustified if it concerns the radiofrequency-powered ClosureFast procedure.[19] The conclusions of these meta-analyses were all based on comparisons between bare-tip EVLA and out-of-date bipolar radiofrequency catheters.

Bipolar radiofrequency catheters such as ClosurePlus (VNUS Medical Technologies, San Jose, Calif) and radiofrequency-induced thermotherapy pass electric current into tissue of the vein wall from one pole of the electrode to the other. This results in resistive heating proportional to power density and therefore decreases rapidly with increasing distance from the electrode source. Most tissue heating, in turn, is not due to direct resistive heating but rather is a result of conducted heat from the narrow rim of resistive heating into deeper tissue layers.[23] Especially bipolar radiofrequency catheters need a lower withdrawal rate in larger diameters, which causes carbonization on the poles more frequently, and in some cases, the catheter has to be pulled out several times for cleaning and then reintroduced.[24]

Table V. Postoperative complications

	RPSA (n = 175), No. (%)	EVLA-RTF (n = 172), No. (%)	*P* value
Bruising	26 (14.9)	32 (18.7)	.39
Temporary paresthesia	3 (1.8)	4 (2.3)	.72
Permanent paresthesia	1 (0.5)	5 (2.9)	.21
Deep venous thrombosis	0	1 (0.6) crural vein	

EVLA-RTF, Endovenous laser ablation with radial-tip fiber; *RPSA,* radiofrequency-powered segmental ablation.

Table VI. Preoperative and postoperative Aberdeen Varicose Vein Questionnaire (*AVVQ*) scores

	P value	No.	Mean	95% Confidence interval for mean	
				Lower bound	Upper bound
AVVQ preoperative					
RPSA		166	11.45	10.18	12.71
EVLA-RTF	.13	157	12.97	11.43	14.50
AVVQ 1 year					
RPSA		158	5.00	4.18	5.83
EVLA-RTF	.96	153	4.98	4.10	5.85
AVVQ 2 years					
RPSA		149	5.43	4.59	6.27
EVLA-RTF	.90	143	5.50	4.56	6.45
AVVQ 3 years					
RPSA		135	5.28	4.38	6.18
EVLA-RTF	.95	125	5.32	4.33	6.31
AVVQ 4 years					
RPSA		131	5.50	4.56	6.43
EVLA-RTF	.97	117	5.48	4.33	6.62
AVVQ 5 years					
RPSA		59	5.20	3.68	6.73
EVLA-RTF	.48	62	5.98	4.39	7.57

EVLA-RTF, Endovenous laser ablation with radial-tip fiber; *RPSA,* radiofrequency-powered segmental ablation.
P values are derived from repeated-measures analysis of variance.

The next-generation catheter with a 7-cm radiofrequency-powered heat-generating coil, called ClosureFast, delivers direct thermal energy to the vein by segmental conductive heating, remaining stationary every 7 cm during its 20-second energy cycle. The heat damages the intima and denatures the vein wall collagen, resulting in contraction and obliteration of the GSV lumen.[25]

The RPSA catheter eliminates heating during pullback, which will make the procedure easier, faster, and more consistent, avoiding treatment variability and operator failure. Rasmussen et al concluded in a randomized controlled trial that the technical outcome of GSV ablation with RPSA is not different from that with EVLA-BTF after 3 years' follow-up.[22] However, patients in the RPSA group reported significantly less postoperative pain than those in the EVLA-BTF group using 980 nm. Also, the time of returning to normal activities and work was significantly shorter in the groups treated with RPSA compared with the EVLA-BTF group.

EVLA has undergone many innovations since its introduction at the end of the past century. Higher dosing improved the occlusion rate of treated veins but resulted in more side effects, such as postoperative pain and collateral damage through perforations, despite the growing use of tumescent anesthesia.[9]

Different nontraumatic fiber tip architecture and higher laser wavelengths could not further increase efficacy as achieved with the existing BTF fibers but improved patient-related outcomes, such as less postprocedural pain and faster recovery after the procedure.[26-31]

Lower wavelengths have their chromophore in blood and are hemoglobin specific. The blood absorbs the energy and is heated easily above its boiling point. Carbonization of the bare tip is unavoidable and results in fast heating in excess of 1000°C. Direct contact of the bare tip with the vein wall causes local injury and perforations and contributes to side effects, such as postoperative pain and bruising.[30,32] Tulip-tip fibers (TTFs) and jacket-tip fibers (JTFs) try to prevent direct contact of the bare tip with the vein wall by means of geometric constraints.[30,33] The TTF has the same surface area of light emission (irradiance) as the BTF. A disadvantage of the TTF is the trapping of coagulum inside the tulip construction, blocking direct radiation to the vein wall.[31] A JTF design has been constructed to sheath the energy-emitting tip of the laser fiber, diminishing the chance of perforations of the vein wall. The JTF significantly expands the emitting surface of the fiber that causes diffusion of the laser beam. The delivered energy is spread out over a greater surface area with a lower power density.[30,34]

The EVLA-RTF emits the laser light circumferentially through a prism slanted sideways and directed to the vein wall. This causes a more homogeneous and effective way of heating up the different layers of the vein wall. The fluency rate is reduced below the ablation threshold. Experiments using an ox foot showed homogeneous

shrinkage of the vessel due to thickening, loss of flexibility, and change in color as a sign of effective treatment.[35] Carbonization of the tip, which is an adverse effect of BTFs, does not occur. The tip of the radial fiber is blunt as well. Altogether there is a minimal risk for vein perforations and bruising in comparison with BTFs. Randomized studies in which EVLA-RTF was compared with EVLA-BTF showed less postoperative pain and less bruising with EVLA-RTF.[27,36]

In our study, we did not find a difference in postoperative recovery and adverse events between RPSA and EVLA-RTF. The postoperative pain scores are similarly low in both procedures, and there is a fast recovery, resulting in a short back-to-work time.

Strengths and limitations of the study. For reasons of feasibility, this single-center study was not designed as a randomized controlled trial. Both treatments were standard care in our center. The study was set up as a high-quality pragmatic, real-life, comparative prospective cohort trial with good adherence to the study protocol. The independent allocation of participants was carried out in consecutive months in which the two treatments were alternately switched every new month. We achieved an adequate sample size, although we had a loss of follow-up rate of 20%. We did not expect that the loss of follow-up influenced the study's validity because we found no difference in the amount and reasons for loss of follow-up between the groups. Although there was no randomization of individual patients, we found no meaningful differences in baseline variables between the two treatment groups. Indeed, the hazard ratio for the primary efficacy outcome, the only small difference between the groups, remained similar after adjustment for GSV diameter. The study was not blinded, but the outcome was assessed by phlebologists who did not perform the endovenous procedure. This trial was performed in a high-volume vein clinic with experienced surgeons. Thus, the results are probably valid and useful in similar health care settings.

CONCLUSIONS

Endovenous GSV ablation with ClosureFast or 1470-nm EVLA with RTF had similarly high long-term obliteration rates and were equally effective clinically with durable gains in disease-specific QOL. The treatments were equally associated with minimal postprocedural pain scores and short recovery times.

The authors gratefully acknowledge the support of T.J. van der Ploeg, who assisted in the statistical analysis for this study.

AUTHOR CONTRIBUTIONS

Conception and design: JL, SG, CV, MG, MM
Analysis and interpretation: JL, SG, CV, MT
Data collection: JL, SG, CV, MG, PP, MM
Writing the article: JL
Critical revision of the article: JL, SG, CV, MG, MT, PP, MM
Final approval of the article: JL, SG, CV, MG, MT, PP, MM
Statistical analysis: JL, SG, MT
Obtained funding: Not applicable
Overall responsibility: JL

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Submitted May 19, 2017; accepted Jun 20, 2017.

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