

Research Article

Endoluminal Thermal Ablation of Varicose Great Saphenous Vein - A Randomized Single Center Application Comparison of Laser Ablation (EVLA 1470nmTM), Radio Frequency Ablation (RFITT and ClosureFastTM) and Superheated Steam with Average Post-Operative Follow-up of 3.8 Years

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- Great saphenous vein
- Endothermal ablation
- Laser ablation
- Radio frequency ablation

Abstract

Objectives: In addition to combined high ligation and stripping or pure sclerotherapy, various endovenous thermal procedures are now available for treatment. Laser ablation (EVLA 1470nmTM), Radio frequency ablation (RFITT and ClosureFastTM) and superheated steam are compared in the present study.

In this prospective study between 2009 and 2013, the GSV was ablated in 297 patients using one of four methods: EVLA 1470nm (n=75), Closure Fast (n=94), RFITT (n=81) or superheated steam (n=47). The recurrence rate after treatment was defined as the primary endpoint. Follow-up examinations with duplex ultrasound took place 14 days, 3 months and 1 year post-operatively, and thereafter annually with average follow-up time of 3.8 years and a follow-up rate of 81%.

Results: At the time of the last follow-up examination, the following complete closure rates of treated GSV were found: EVLA 89%, RFITT 57%, superheated steam 56% and Closure Fast 94%. Serious complications occurred only with superheated steam (necrosis at the puncture site). The median pain intensity recorded 14 days post-operatively was 1-3 on a scale of 1-10 in all groups. Both the CIVIQ score and the VCSS were significantly improved by all endovenous thermal methods. In 5-12% of cases, reflux was found in the previously non-reflexive AASV.

Conclusions: EVLA and Closure Fast are indicated for the treatment of GSV incompetence with high success rates, comparable to the results with high ligation and stripping. The RFITT and superheated steam methods presented with significantly lower closure rates.

ABBREVIATIONS

EVLA: Endovenous Laser Ablation; RFA: Radiofrequency Ablation; RFITT: Radiofrequency Induced Thermal Therapy; GSV: Great Saphenous Vein; VCSS: Venous Clinical Severity Score; AASV: Anterior Accessory Saphenous Vein; PAD: Peripheral Arterial Disease; DVT: Deep Vein Thrombosis; BMI: Body Mass Index; SFJ: Sapheno Femoral Junction; CEAP: Clinical Etiologic Anatomic Pathophysiologic; LMH: Low Molecular Weight Heparin; CIVIQ: Chronic Venous Insufficiency Questionnaire; EHIT: Endovenousheat Induced Thrombosis; PASV: Posterior Accessory Saphenous Vein

INTRODUCTION

Large studies evaluating the long-term effects of endovenous procedures are still lacking. A comparative study of EVLA and RFA in 2016 showed comparably good results from the two procedures, with RFA presenting slightly lower post-operative pain [1]. A recently published meta-analysis by Haman showed comparable results between crossectomy and stripping and endovenous procedures; however, only EVLA and RFA were included [2].

MATERIALS AND METHODS

A prospective randomized single center observational study was performed on the closure rates after ablation of incompetent GSVs using 4 different endovenous thermal procedures: EVLA 1470nm, Closure Fast, RFITT and superheated steam. Randomization was performed with a randlist: patients who gave their consent to participate in the study were given consecutively the next free endovenous technique on the randlist. No patient or doctor was allowed to know which technique was the next on the list before consent to the study was given. Only a study nurse had access to the list. All treatments were performed by four phlebologists in one centre where endovenous procedures have been used regularly since 2007. The superheated steam process was performed by only one very experienced surgeon. By the start of observation in 2009, more than 1000 endovenous treatments had been performed in the centre.

All patients included in the study gave their written consent to the use of the data collected. Ethical approval was received.

Inclusion criteria

Apart from the minimum age of 18 years, the only inclusion criterion was diagnosis of GSV incompetence suitable for treatment with one of the four procedures in the study.

Exclusion criteria were: severe systemic disease, unsuitability for anaesthesia, acute febrile illness, inflammatory skin diseases, acute superficial or deep vein thrombosis, severe generalized infections, bed-ridden state, advanced stage II PAD, pregnancy, lactation, late diabetic complications, known hypercoagulability, post-DVT thrombophilia, known thrombophilic diathesis, involvement in another clinical trial within the last 4 weeks.

Objective

The primary endpoint of the observational study was the recurrence rate in the ablated vein. To assess the safety of each procedure, we examined the acute and medium-term complications (thrombosis, ecchymosis, sensory disturbances). The secondary endpoints were the improvement in the quality of life measured by VCSS and CIVIQ.

Patients

All patients enrolled in the study presented incompetent GSV, diagnosed by duplex ultrasound examination.

The inclusion period was between 2009 and 2013, with a total of 297 patients enrolled; 18 patients underwent bilateral operations, and these patients were treated statistically as two independent cases. 232 of the patients were women, 65 men. The average BMI was 24.5 for women and 27.2 for men. The average age of the women was 46.2 years, and of the men 49.8 years. The average diameter of the GSV 3 cm below SFJ was 7.4 mm (min 4.0 mm, max 8.6 mm).

Patients were assigned consecutively to one of the 4 treatment methods. In 291 patients the terminal valve was insufficient with complete GSV incompetence; eight patients presented incomplete GSV incompetence with intact terminal valve, and two of them also had an incompetent Dodd perforating vein.

The distribution of the C classification according to CEAP showed mainly C2 and C3 stages, in male patients also C4 stages.

Pre-operatively, the men had an average VCSS of 5.6, the women of 4.5. Table 1 shows an overview of all patients included, Table 2 shows the intraoperative data for the individual procedures.

Ablation techniques

EVLA systems release energy through a glass fibre tip, in this study with a wavelength of 1470nm. The energy is absorbed in the haemoglobin and water content of the vein wall and converted into thermal energy at a temperature higher than 120°C [3].

In RFA (Closure Fast), the entire region surrounding the 7 cm-long catheter tip is heated to 120°C. The temperature is applied to the corresponding segment for 20 seconds before the catheter is retracted to the next segment to be closed.

The RFITT method delivers radio frequency current into the tissue via an electrode inserted into the vein. Heating of the blood causes it to coagulate. The Celon method used here measures the resistance continuously, and adjusts the required energy automatically [4].

In the superheated steam method, superheated steam is released into the vein under pressure at a temperature of 120°. Denaturation of the wall structures causes the vein to contract to the point of definitive occlusion [5].

All patients underwent tumescent local anaesthesia, combined with analgesic sedation or intubation anaesthesia depending on the patient's preference or expression of tributary vein varicosity.

In all cases, the saphenofemoral junction was ablated under ultrasound guidance as proximal as possible without allowing the 'catheter shadow' to affect the deep vein. When Closure Fast was used, the SFJ region was ablated with at least 2 sequences, and in some cases 3 or more, depending on the diameter. The next section of the saphenous vein was also treated with several cycles per section; a single cycle was used only in a few cases, where the vein diameter was very small. Where EVLA was used, the energy was selected according to the vein diameter using the formula $7 \text{ J} / \text{mm vein diameter per second}$.

After ablation of the GSV, depending on the extent of the varicose veins, foam sclerotherapy and/or miniphlebectomy were performed via mini-incisions. LMWH was administered post-operatively for 10 days in all patients. A compression bandage was applied directly to the leg post-operatively. The next day it was removed and replaced by a Class II compression stocking (23-34mmHg) for 3 weeks.

Follow-ups

The follow-up visits took place 14 days, 3 months and 1 year post-operatively and then annually, according to the study protocol. The following parameters were queried or measured during each follow-up visit:

Ultrasound assessment of the condition of the treated vein (GSV): A closed or later invisible vein was considered to be a complete therapeutic success. Open or partially closed veins

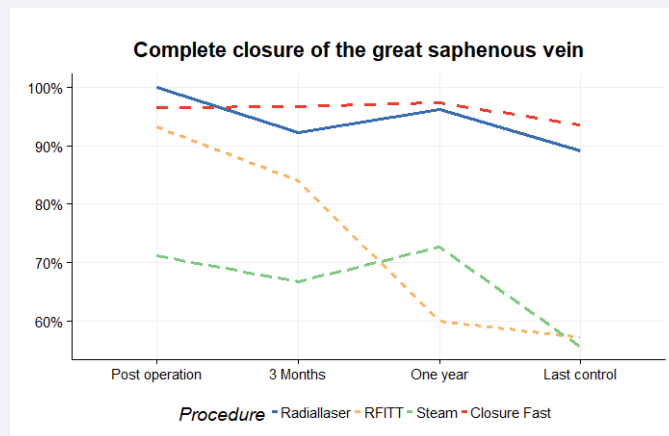


Figure 1 Complete closure of the treated GSV by surgical method, post operation= 14 days postoperatively.

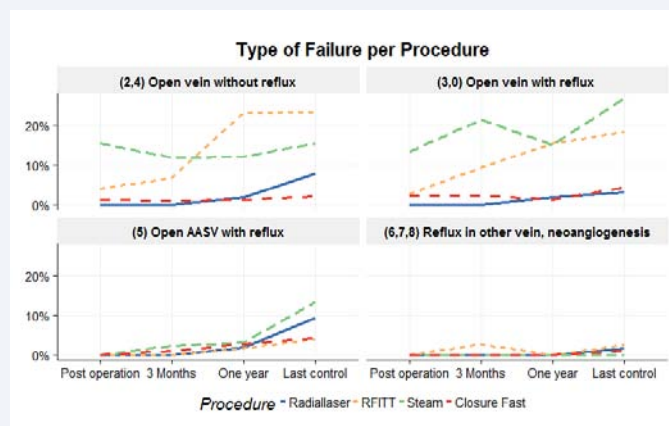


Figure 2 Results in the SFJ region in ultrasound examination, Post operation = 14 days postoperatively.
 Top left: In 22% of patients treated with RFITT, recanalisation of the vein without reflux was found 1 year after surgery
 Bottom left: Reflux through the untreated AASV was found in 5% for Closure Fast and RFITT, 10% for EVLA and 12% for superheated steam
 Top right: Ultrasound examination at the last control showed the following rates of recurrence by recanalisation of the vein with reflux: EVLA 2%, RFITT 19%, superheated steam 28% and Closure Fast 3%
 Bottom right: Recurrence by neoangiogenesis or through other vessels is rare (1-3%)

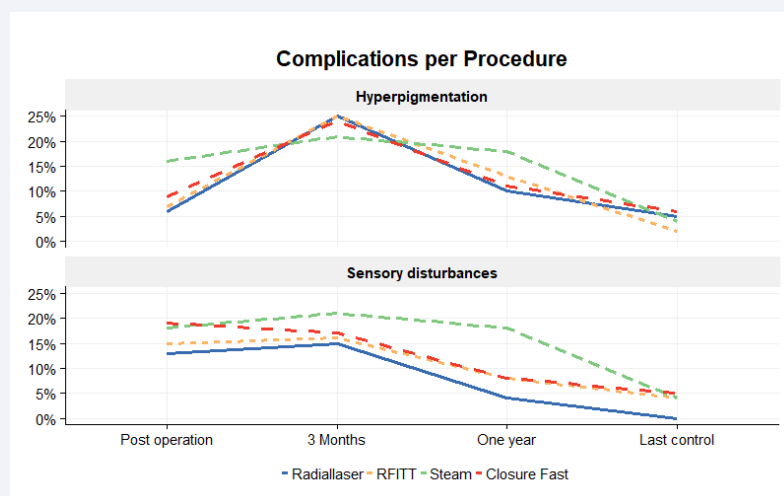


Figure 3 Representation of the incidence of hyper pigmentation and sensory disturbances, Post operation= 14 days postoperatively.

without reflux, in which the treatment outcome was not achieved as planned but clinically no reflux was present, were described separately. Open veins with reflux were rated as recurrence or treatment failure. Measurable reflux episodes in the remaining untreated AASV, as well as recurrences via untreated veins were also described separately.

In addition, patients were asked to evaluate pain intensity and pressure pain intensity on a scale of 1-10, and patient satisfaction on a scale of 1-5. The presence of ecchymosis, hyperpigmentation and sensory disorders was documented each time. Quality of life was assessed by VCSS and CIVIQ. The CIVIQ score is a combined score from 20 areas of life and reflects a better quality of life directly proportional to an increase in the score [6]. The highest possible score is 100 [7].

The following follow-up rates were obtained during the study: 91% of patients attended for follow-up 14 days post-operatively, 88% after 3 months and 72% after one year. The last control occurred on average after 3.8 years, in the longest case after 6.9 years, with a follow-up rate of 81%. For the purposes of objectivity, the last follow-up was done in all patients by the same phlebologist, who was not a surgeon.

Statistics

All parameters measured or requested were documented in an Excel spread-sheet. The R (Version 3.4.0) and Statistix statistical programmes were used to analyse the data. The Shapiro Wilk test was used to check the distribution of the variables. The inferential statistics for comparison of the different surgical methods were evaluated with the Kruskal Wallis test; the confidence interval was set at 95%, significant p value <0.05. Statistical evaluation was carried out by an external statistician.

End of inclusion of further patients

In October 2012, the last patient treated by the superheated steam method was included. Since too many complications were associated with this procedure during post-operative check-ups, the method was ruled out prematurely. This explains why fewer patients were treated with superheated steam.

RESULTS

The definition of successful treatment was a closed vein or one no longer visible in later follow-up examinations. Figure 1 shows the percentages of complete closure of the treated GSV during the follow-up examinations with the different surgical methods.

As can be seen in Figure 1, the following complete closure rates of the treated vein were recorded for the various procedures at 14 days, 3 months and 1 year post-operatively and at the last follow-up: EVLA 100%, 92%, 96%, 89%; RFITT 93%, 84%, 60%, 57%; superheated steam 71%, 68%, 72%, 56%; Closure Fast 96%, 97%, 98%, 94%.

Figure 2 shows the different results in the SFJ region in ultrasound examination. RFITT and steam show more open veins with or without reflux over time. After one year rates of recurrence through an AASV are raising in all endovenous methods. Neoangiogenesis in the groin seems to be not relevant in endovenous techniques.

The statistical significance calculations in Table 3 confirm the results shown in the graphical representation of the Figures 1 and 2:

Even at the first control, 14 days post-operatively, there is a significant difference in GSV treatment by superheated steam in comparison to the other methods.

The RFITT method also shows decreasing closure rates in subsequent examinations, so that at the time of the last control, superheated steam and RFITT performed significantly worse than EVLA or Closure Fast. The heat-intensive EVLA and Closure Fast processes show equally high success rates at the time of the last control. If Closure Fast and EVLA are compared against each other at each check-up, neither method is superior to the other.

Significance calculations of the results at the different follow-up examinations show the following: The post-operative results for Closure Fast show no significant changes over time. The results for superheated steam present a significant deterioration between the 1-year control and the last control. The occlusion rate after RFITT decreases continuously and significantly at each control.

COMPLICATIONS

Necrosis/burns at the puncture site

Six of the 47 patients (13%) treated with superheated steam presented burns or necrosis at the puncture site at the first post-operative control, sometimes with ulcer formation. Since the method was performed by just one very experienced surgeon in all cases, lack of experience in the application of the method cannot to be assumed. For this reason, the treatment of patients by this method was terminated prematurely.

Deep Vein Thrombosis

Deep Vein Thrombosis or EHIT occurred in only one case, after ablation with Closure Fast (0.01%).

Hyper pigmentation, ecchymosis and sensory disturbances are shown in Figure 3.

Hyper pigmentation occurred mainly in the superficial course of the treated saphenous vein. Typically, hyper pigmentation did not occur immediately post-operatively, but during the first 3 months. It subsequently declined slowly, as the body degrades blood pigment over time. It is not clear to what extent the hyper pigmentation was exclusively due to the endovenous heat process, as almost all patients underwent foam sclerotherapy of remaining tributaries. Sensory disturbances in the course of the GSV occurred in most cases after about 3 months; at the time of the last control the frequency of sensory disturbances was between 0 and 5%.

Pain

At each follow-up, patients were asked to evaluate the pain currently experienced in the area of the operated limb, the greatest pain since the last visit, the current pressure pain and the most severe pressure pain since the last visit on a scale of one (no pain) to ten (severe pain).

At the first post-operative control after 14 days, on the pain

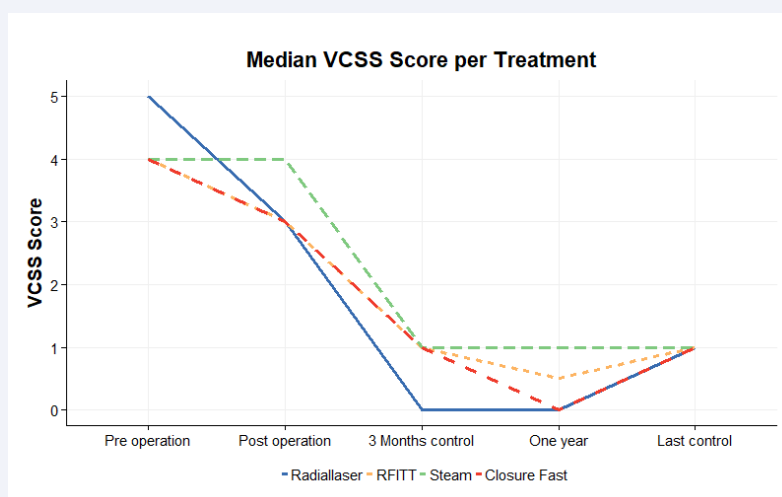


Figure 4 Comparison of VCSS from pre-operative values to the Last Control, Post operation = 14 days postoperatively.

scale “greatest pain since the last visit”, there was a significantly higher indication of pain after EVLA compared to RFITT ($p = 0.02$); significantly higher pain was also reported after the superheated steam method compared to RFITT ($p = 0.006$) and Closure Fast ($p = 0.04$).

CIVIQ score

To assess the quality of life, the CIVIQ score was assessed pre-operatively, 3 months post-operatively, 1 year post-operatively and at the last control. All four surgical methods show a significant improvement in the CIVIQ score compared to the pre-operative values as early as three months post-operatively.

VCSS

In the pre-operative VCSS evaluation (Figure 4), patients assigned at random to the EVLA method presented higher VCSS than patients in the other groups. (EVLA-RFITT $p = 0.009$)

A significant improvement between the pre-operative data and the 3-month control is evident in VCSS, as in the CIVIQ score, with all surgical methods. No significant changes were found in later check-ups.

A significant improvement in values at the 14-day post-operative control was found only after EVLA ($p = 0.02$); this could be an indicator that laser leads to a faster improvement in symptoms than the other methods, but it could also be due to the higher pre-operative values.

The renewed increase in VCSS over a longer period of time can be explained by the progression of the patients’ chronic varicosis.

Patient satisfaction

Significant differences in satisfaction with the operation could be shown at the first follow-up after 14 days between EVLA and RFITT ($p = 0.03$) and between Closure Fast and RFITT ($p = 0.05$). At this early stage, RFITT and superheated steam present the highest patient satisfaction. In the course of further follow-up examinations, however, this difference no longer exists.

DISCUSSION

High closure rates following endoluminal thermal ablation of the saphenous veins have been reported in numerous studies. Good tolerance of the intervention with few side effects is described for all the procedures, but there is no previous comparative study to investigate the superiority of any one of the four endoluminal thermal methods compared in this study.

Several studies report a comparable success rate for stripping versus endovenous ablation, with most studies using EVLA or RFA. Van der Velden showed comparable data for EVLA and stripping versus worse results for foam sclerotherapy in the 5-year results of a comparative trial [8].

Sporbert et al., studied the results after GSV ablation by EVLA and RFA in a 5-year comparison with a large number of patients. Out of 643 veins, 86% of those treated by RFA and 93% of those treated by EVLA were closed after 5 years. The results showed similar recurrence rates to those of our study, and likewise reflected no significant difference between EVLA and RFA. Secondary incompetence of a previously untreated section of the GSV or an accessory vein was found in 133 patients in Sporbert’s study. A more detailed description of the reflexive vein does not exist, so that the reflux rates of untreated AASV cannot be compared with the results in our study.

In 2014 van den Bos et al., showed that the 1-year treatment success of superheated Steam Ablation (EVSA) was not inferior to that of EVLA [9].

In our study, it quickly became clear that superheated steam treatment is associated with more complications (burns and necrosis at the puncture site) and presents significantly worse results compared to the other methods. This method is therefore clearly inferior to the EVLA and RFA methods. Why there is such a big difference between van den Bos and our study cannot be explained.

The recurrence rate with the RFITT procedure, applied according to the manufacturers’ protocol, was significantly higher than with EVLA and Closure Fast. It would appear that

Table 1: Overview of patient data at inclusion.

Procedure	Number of patients	Mean Age	Mean BMI	Mean Length Vein	Mean VCSS
Radial laser	75	49.28	25.24	48.35	5.56
RFITT	81	47.95	24.49	48.67	4.16
Steam	47	44.72	25.11	46.51	4.72
Closure Fast	94	45.56	25.60	48.57	4.70

Abbreviations: RFITT: Radiofrequency Induced Thermal Therapy; BMI: Body Mass Index; VCSS: Venous Clinical Severity Score.

Table 2: Technical intra-operative data of individual procedures.

Procedure	LEED J/cm	Closure Fast (Cycles)	OP Time (sec)
Radial laser	54.78	-	254.11
RFITT	53.84	-	142.85
Steam	118.98	-	-
Closure Fast	-	12.17	244.36

Abbreviations: RFITT: Radiofrequency Induced Thermal Therapy; J/cm: Joule per Centimeter, OP Time (sec): Operation Time in Seconds.

Table 3: Significance calculations of the results in post-operative follow-up, comparison of surgical methods. Dunn test adjusted with Benjamini-Hochberg method, only the statistically relevant p values (<0.05) are presented.

Post OP	Comparison	P	
	Radial laser - Steam	<0,0001	
	Steam - Closure Fast	<0,0001	
	RFITT - Steam	<0,0001	
3 Months	Radial laser - Steam	<0,0001	
	RFITT - Steam	<0,05	
	RFITT - Closure Fast	<0,05	
	Steam - Closure Fast	<0,0001	
	1 Year	Radial laser - RFITT	<0,0001
		Radial laser - Steam	<0,05
RFITT - Closure Fast		<0,0001	
	Steam - Closure Fast	<0,05	
	Last Control	Radial laser - RFITT	<0,001
		Radial laser - Steam	<0,001
RFITT - Closure Fast		<0,0001	
	Steam - Closure Fast	<0,0001	

Abbreviations: Post OP: Postoperative; RFITT: Radiofrequency Induced Thermal Ablation.

the energy and duration of treatment recommended by the manufacturers are not sufficient to ensure occlusion of the vein. In the RFITT procedure, it is particularly noticeable that there is an above-average frequency of recanalization of the GSV without reflux, i.e. restoration of the vein's normal function; however, this outcome is not reliable enough to be considered an advantage of the method. Both the EVLA and the Closure Fast procedures are equally well suited for the treatment of incompetent GSV, while the superheated steam method is restricted to special situations where the other procedures are not suitable, for example due to the tortuous course of the vein.

The energy applied in EVLA in our study was below the currently recommended energy of 60J/cm. This is because in our study the energy was selected according to the formula 7J/mm

vein diameter per second. Today we apply energy of 10J/mm, which results in total energy of over 60J/cm. With this energy, even higher occlusion rates might perhaps have been achieved with EVLA.

Rates of recurrence through the AASV when it is not treated in the first intervention are strikingly high at 5% for RFITT and Closure Fast, 10% for EVLA and 12% for superheated steam. These recurrences were usually found at the last follow-up, but in some cases as early as the 2-year control. Proebstle and Möhler reported a reflexive AASV four years after RFA in up to 70% of patients [10]. Our data showed only around 10% of cases: this might be due to our treatment regime of placing the endovenous catheter as proximal as possible into the SFJ without allowing the 'catheter shadow' to affect the deep vein. In the Proebstle study,

secondary reflux via a primarily untreated PASV appeared to be negligible, which was also observed in our study.

The AASV is not a vein which is needed for bypasses and in open surgery it is disconnected from the SFJ during crosssectomy so therefore, we recommend endovenous treatment of non-refluxive AASV in the same session in order to prevent long-term recurrence, as discussed in earlier works [11]. In our opinion, "endovenouscrosssectomy" with placing the catheter right before the femoral vein and treatment of SFJ-side branches (especially the AASV) endovenously in the same session will produce the lowest recurrence rates [12]

In our study, there was only one case of post-operative deep vein thrombosis (0.01%), so the risk is considered very low. Whether this low risk is due to the routine administration of LMH for 10 days, we cannot say for sure. A 2017 study by Keo compared the effects of rivaroxaban and fondaparinux given 3 days post-operatively. Deep venous thrombosis occurred with both treatments in this study, in 0.6 and 0.9% of cases respectively, so the incidence after 3 days of prophylaxis was also very low, albeit slightly higher than in our study [13].

CONCLUSION

Both the EVLA 1470nm and the CLOSURE FAST procedures show very good results in the treatment of incompetent saphenous veins, superior to the other thermal procedures.

Superheated steam should only be used in special situations when other methods are not suitable.

A competent AASV should, if possible, be co-treated endovenously in the same session, even if it presents no reflux at the time of surgery, as recurrence often occurs through this accessory vein in the long term.

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