Recurrence rates and form of recurrence after endoluminal ablation of the great saphenous vein

A comparison of laser ablation (EVLA) 1470 nm, radio frequency (RFITT and ClosureFast) and superheated steam with an average follow-up time of 3.8 years

Rezidivraten und Form des Rezidivs nach endoluminaler Ablation der Vena saphena magna

Ein Vergleich von Laserablation (EVLA) 1470 nm, Radiofrequenz (RFITT und ClosureFast) sowie Heißdampf mit einer durchschnittlichen Nachbeobachtungszeit von 3,8 Jahren

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Key words
varicose veins, great saphenous vein, endothermal ablation, recurrence rate

Schlüsselwörter
Varikose, Vena saphena magna, endothermale Ablation, Rezidivhäufigkeit

published online 08.05.2020

Bibliography
Phlebologie 2020; 49: 222–230
DOI 10.1055/a-1033-2736
ISSN 0939-978X

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ABSTRACT

Objectives In addition to combined crossectomy and stripping or pure sclerotherapy, various endovenous thermal procedures are now available for treatment, which are compared in the present study.

Methods Between 2009 and 2013, the GSV was ablated in 297 patients using one of four methods: EVLA 1470 nm, ClosureFast, RFITT or superheated steam. 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: ClosureFast 95 %, EVLA 97 %, RFITT 79 % and superheated steam 71 %. 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. 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-refluxive AASV.

Conclusions EVLA and ClosureFast are indicated for the treatment of GSV incompetence with high success rates, comparable to the results with crossectomy and stripping. The RFITT and superheated steam methods present significantly lower closure rates. Particular attention should be paid to the presence of an initially non-refluxive AASV. Since there was an increased recurrence rate over this vein, it seems reasonable to treat the AASV primarily.

ZUSAMMENFASSUNG

Einleitung Erkrankungen des Venensystems, insbesondere auch die Insuffizienz der Vena saphena magna (VSM), gehören zu den häufigsten Krankheitsbildern in unserer Gesellschaft. Zur Behandlung stehen neben Krossektomie und Stripping sowie reiner Sklerosierungstherapie verschiedene endovenöse thermische Verfahren zur Verfügung, die in der vorliegenden Studie untereinander verglichen werden sollten.

Methoden Zwischen 2009 und 2013 wurde bei insgesamt 297 Patienten die insuffiziente VSM mit einer der 4 Methoden EVLA 1470 nm, ClosureFast, RFITT oder Heißdampf abladiert. Als primärer Endpunkt wurde die Rezidiv-Häufigkeit definiert. Die Nachkontrollen mit Duplexsonografie fanden 14 Tage postoperativ, 3 Monate postoperativ, nach 1 Jahr und schließlich jährlich mit einer durchschnittlichen Nachbeobachtungszeit von 3,8 Jahren und einer Follow-up-Rate von 81 % statt.

Ergebnisse Zum Zeitpunkt der letzten Nachkontrolle zeigten sich folgende anatomische Erfolgsraten der behandelten

VSM: ClosureFast 95 %, EVLA 97 %, RFITT 79 % und Heißdampf 71 %. Schwerwiegende Komplikationen traten nur beim Heißdampf auf (Nekrosen an der Punktionsstelle), die Schmerzintensität lag bei allen Methoden 14 Tage postoperativ bei einem Median von 1–3 auf einer Skala von 1–10, bei den nachfolgenden Kontrollen lag der Median bei allen Methoden bei 1. Sowohl der Global Index Score (CIVIQ-Score) als auch der Venous Clinical Severity Score (VCSS) ließen sich durch alle endovenösen thermischen Methoden signifikant verbessern. In 5–12 % der Fälle trat ein Reflux der zuvor suffizienten Vena saphena magna accessoria (VSAA) auf.

Diskussion EVLA und ClosureFast sind zur Behandlung von Insuffizienzen der VSM mit hoher Erfolgsrate und vergleichbaren Ergebnissen zu Krossektomie und Stripping geeignet. Die Verfahren RFITT und Heißdampf zeigen im Vergleich signifikant niedrigere Verschlussraten und sind damit besonderen Situationen vorbehalten. Besonderes Augenmerk sollte auf das Vorhandensein einer zunächst nicht refluxiven VSAA gerichtet werden. Da sich hier eine erhöhte Rezidivrate bei dieser Vene zeigte, erscheint es sinnvoll, die VSAA primär mit zu abladieren.

Introduction

With a prevalence of 30–40 %, diseases of the venous system are amongst the most common conditions occurring in developed countries. In order to counteract the associated complications and sequelae of chronic venous insufficiency, such as skin changes, venous leg ulcers, deep vein thrombosis and pulmonary embolism, as much as possible, both the German and the NICE guidelines recommend early surgical or interventional treatment of the epifascial venous system [1–3].

Surgical high saphenous ligation and stripping was considered the gold standard of treatment for trunk varicose veins until the end of the last century [4], but minimally invasive methods have been steadily increasing in popularity in the meantime. The treatment spectrum has now expanded to include thermal and non-thermal endovenous procedures in addition to surgical techniques [5].

Endovenous laser ablation (EVLA™) was introduced in 1998 and radiofrequency ablation (RFA) in 1999, while superheated steam for the treatment of varicose veins has been approved in Germany since 2009.

The available thermal procedures work in different ways:

EVLA systems release energy via the tip of the glass fibre; this energy is subsequently absorbed in the haemoglobin and aqueous component of the vein wall and converted to thermal energy of more than 120 °C [6].

Using the ClosureFast™ procedure for radiofrequency ablation (RFA), the entire surroundings of the 7 cm-long catheter tip are heated to 120 °C; the temperature is maintained for 20 seconds in the corresponding segment before the catheter is retracted to the next segment to be occluded.

When the radiofrequency-induced thermotherapy RFITT© method is used for RFA, the radiofrequency current is released from the electrode into the tissue. Heating then causes coagulation. The Celon method that we use here continuously measures the resistance and automatically adjusts the energy required [7].

Superheated steam at a temperature of 120 °C is introduced into the vein under pressure, so that it contracts and closes due to denaturation of the wall structures [8].

As yet, there are hardly any data on which to evaluate the effects of steam, although a proof-of-principle study gave a success rate of 13 out of 20 treated trunk veins [9].

Large-scale studies to evaluate the long-term effects of endovenous procedures are still lacking. A 2016 study comparing EVLA with RFA gave similarly good outcomes for the two procedures, although RFA resulted in slightly less postoperative pain [10]. A meta-analysis published by Hamann showed results that were comparable for high saphenous ligation and stripping as well as for the endovenous procedures, which, however, included only EVLA and RFA [11].

Methods

We carried out a prospective comparative study on the occlusion rate of incompetent great saphenous veins (GSVs) with four different endovenous thermal procedures: EVLA 1470 nm, ClosureFast, RFITT, and superheated steam. All treatment sessions were carried out by four phlebologists at a centre that has used endovenous procedures on a regular basis since 2007. The superheated steam procedure was performed by just one of our experts. More than 1000 endovenous treatments had been carried out at the centre prior to the start of the observational study in 2009.

All the patients enrolled gave their written informed consent to use the data collected.

Inclusion criteria

Apart from a minimum age of 18 years, the main inclusion criterion was the diagnosis of an incompetent GSV that was suitable for treatment with one of the four available procedures.

Exclusion criteria

Severe systemic disease, unsuitability for a general anaesthetic, acute pyrexial illness, inflammatory skin disease, acute superficial or deep vein thrombosis, severe generalised infections, confinement to bed, advanced peripheral arterial occlusive disease (stage II onwards), pregnancy, breast-feeding, late complications of diabetes, known hypercoagulability, thrombophilia with a history of deep vein thrombosis, known thrombophilic diathesis, and participation in another clinical study within the previous four weeks.

Objectives

The primary endpoint of the observational study was the success rate of the ablation divided into A: complete anatomical occlusion

▶ **Table 1** Overview of patient data at enrolment.

procedure	number of patients	mean age	mean BMI	mean length of the vein	mean VCSS
radial laser	75	49.28	25.24	48.35	5.56
RFITT	81	47.95	24.49	48.67	4.16
superheated steam	47	44.72	25.11	46.51	4.72
ClosureFast	94	45.56	25.60	48.57	4.70

of the treated vein; B: functional success, i. e. no reflux seen in the vein on ultrasound scanning after the ablation; and C: recurrence of varicose veins at the saphenofemoral junction (SFJ) with reflux seen on duplex ultrasound. We examined the safety of the procedures based on the immediate and medium-term complications after the procedure (thrombosis, ecchymosis, disorders of sensation). Secondary endpoints were the superiority of a method and the improvement in quality of life as measured with the VCSS and CIVIQ scores.

Patients

All the enrolled patients had an incompetent GSV diagnosed on duplex ultrasound scanning.

Recruitment was carried out between 2009 and 2013, enrolling 297 patients. As both legs were treated in 18 patients, they were considered as two independent cases. The study included 232 women and 65 men. The mean Body Mass Index (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 mean diameter of the GSV measured 3 cm below the SFJ was 7.4 mm (minimum 4.0 mm, maximum 8.6 mm).

The patients were allocated consecutively, i. e. alternately in a predefined order, to one of the four treatment methods, with the exception of 22 patients who preferred a specific method because of previous treatment of the other leg or the experience of friends or relations. 291 patients had complete GSV insufficiency with incompetent terminal valves and eight patients had incomplete GSV insufficiency with intact terminal valves, two of which also had incompetent Dodd perforators.

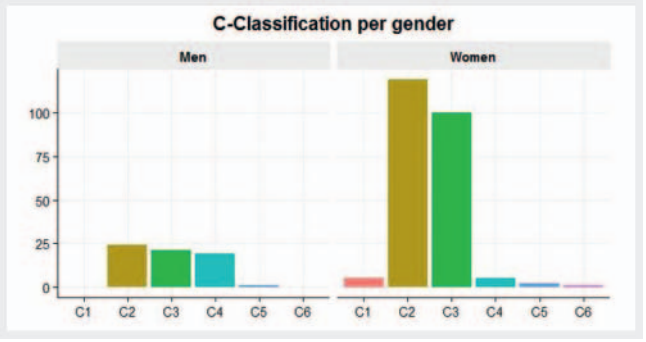
The C category according to the CEAP classification gave the following distribution (▶ **Fig. 1**).

The mean Venous Clinical Severity Score (VCSS) was 5.6 for the men, and 4.5 for the women (▶ **Table 1**).

Interventional techniques

All patients were treated with tumescent local anaesthesia (TLA), combined with sedation/analgesia or a general anaesthetic, depending on the patient's wishes and the extent of the tributary varicose veins.

In all cases, the saphenofemoral junction was ablated under ultrasound guidance as proximally as possible without creating a 'catheter shadow' in the deep vein. With ClosureFast, the SFJ was ablated with at least two sequences, but sometimes with three or more, depending on the diameter. The remaining trunk vein segments were likewise treated with several cycles per segment; just one cycle was used in only a few cases if the vein had a particularly small diameter. A single-ring radial fibre from Biolitec was used for EVLA. The energy was selected according to the diameter of the vein, using the formula 7 J/mm vein diameter per centimetre of treated vein, and 10 Watt. Following ablation of the trunk vein, foam sclerotherapy and/or miniphlebectomy of tributary branches was carried out according to the extent of the varicose veins. Low molecular weight heparin (LMWH) was administered for 10 days after the intervention. A compression bandage extending up to the groin was applied directly after the procedure. The bandage was removed the following day and exchanged for a class II compression stocking worn for the next three weeks (▶ **Table 2**).



▶ **Fig. 1** Distribution of the C category of the CEAP classification according to sex.

Follow-up

In accordance with the study protocol, follow-up took place 14 days, 3 months and 1 year after the intervention, and annually thereafter. At each follow-up, the following parameters were recorded after questioning or measurement:

Ultrasound assessment of the condition of the treated GSV: an occluded or subsequently no longer visible vein was considered as complete anatomical treatment success (A). Patent or partially occluded veins without reflux, in which the planned therapeutic results had not been achieved but clinically no longer showed signs of reflux were described separately and considered as functional success (B). Open veins with reflux were designated as recurrence or treatment failure (C). Measurable reflux in untreated anterior

▶ **Table 2** Technical data for the individual procedures during the intervention.

procedure	energy J/cm	ClosureFast (cycles)	duration (sec)
radial laser	54.78	–	254.11
RFITT	53.84	–	142.85
superheated steam	118.98	–	–
ClosureFast	–	12.17	244.36

accessory saphenous veins that were still present was also described separately, as well as recurrences in other vessels.

In addition, the patients reported pain intensity and tenderness on a scale of 1–10, as well as their satisfaction on a scale of 1–5. The presence of ecchymosis, hyperpigmentation, and disorders of sensation were documented each time. The VCSS and CIVIQ scores were calculated to demonstrate the quality of life. After points were allocated in 20 different areas of life, the CIVIQ score showed an improvement in the quality of life directly proportional to the increase in the score [12]. The highest possible score is 100 [13].

Statistics

All the parameters that were measured or enquired about were recorded in an Excel table. We used the statistics program R (Version 3.4.0) and Statistix to analyse the data. The Shapiro-Wilk test was used to check the normal distribution of the variables. The Kruskal-Wallis test with 95 % confidence intervals was used to compare the different interventional techniques; $p < 0.05$ was taken to be significant. External statisticians performed the statistical analysis.

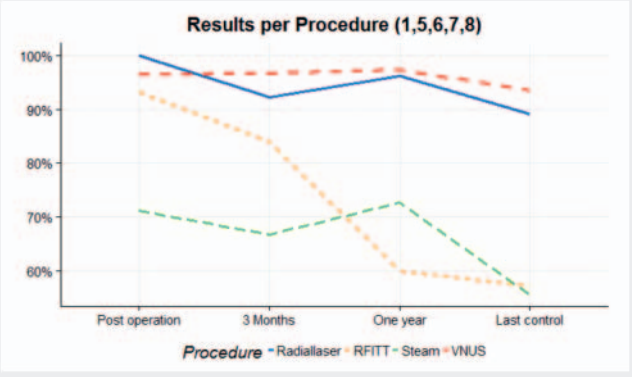
End of recruitment of further patients:

The last patient for the superheated steam procedure was enrolled into the trial in October 2012. As considerably more complications were found at follow-up with this procedure, we ceased to use the method before the end of the study. This explains why fewer patients out of the total number were treated with superheated steam.

Results

Follow-up rate

The follow-up rates during the study were: 91 % at 14 days post-intervention and 88 % at three months, while 72 % of the patients came for the visit after one year. **The final check-up took place after 3.8 years on average, with the longest interval being 6.9 years** and an overall follow-up rate of 81 %. To ensure objectivity, the final check-up of all patients was performed by the same phlebologist, who herself had not performed any of the interventions.



▶ **Fig. 2** Rate of complete occlusion of the treated GSV using the different treatment methods.

Occlusion rates

Occlusion was classified into the following groups:
A: complete anatomical occlusion of the treated vein
B: functional success, i. e. after ablation the vein no longer showed signs of reflux on ultrasound
C: evidence of recurrence at the SFJ seen on duplex ultrasound scanning

Only an occluded vein or one no longer visible at later follow-up visits was considered to be complete treatment success.

▶ **Fig. 2** shows the percentages for complete closure (A: complete anatomical occlusion) of the treated GSV with the different methods.

As can be seen from ▶ **Fig. 2**, the different procedures had the following complete occlusion rates of the treated vein at follow-up of 14 days, 3 months and 1 year after treatment and at the final check-up: EVLA 100 %, 92 %, 96 %, and 89 %, RFITT 93 %, 84 %, 60 %, and 57 %, superheated steam 71 %, 68 %, 72 %, and 56 %, ClosureFast 96 %, 97 %, 98 %, and 94 % respectively (see ▶ **Table 3**).

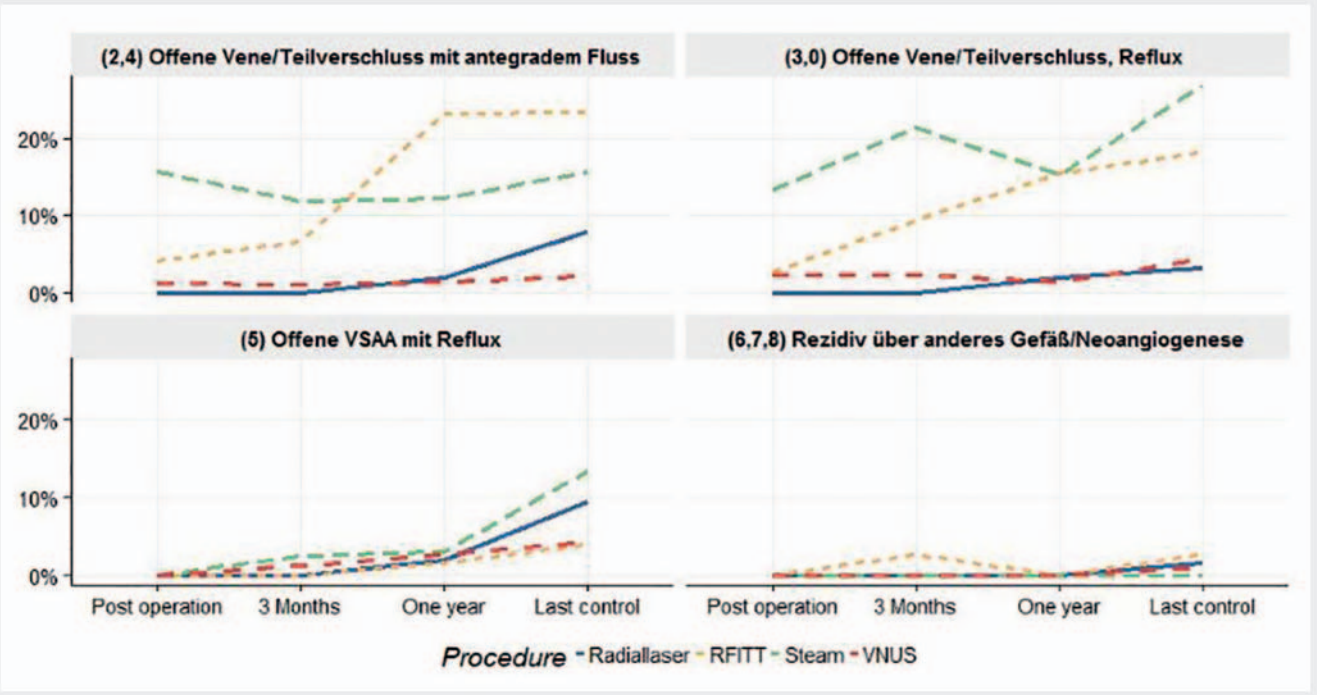
▶ **Fig. 3** shows the different patterns that could be seen on ultrasound around the SFJ and along the course of the ablated vein.

The calculations in ▶ **Table 3** confirm the statistical significance of the results shown graphically in ▶ **Fig. 2, 3**.

Even at the first follow-up 14 days post-intervention, there was a significant difference in treatment of the GSV with superheated steam compared with the other methods.

With time, the RFITT method showed falling occlusion rates, so that those of superheated steam and RFITT were significantly worse at the final check-up than EVLA or ClosureFast. The heat-intensive EVLA and ClosureFast methods showed similarly good success rates at that time. Comparing ClosureFast and EVLA at each time of follow-up showed that neither method was superior to the other.

The calculated significance of the results at the different times of follow-up showed the following: the results after ClosureFast showed no significant changes in the post-interventional course. Superheated steam showed a significant deterioration in the results between the 1-year follow-up and the final check-up. The closure rate after RFITT fell progressively and significantly at each follow-up visit.



▶ **Fig. 3** Above left: One year after the procedure, 22 % of patients treated with RFITT had recanalisation of the vein without reflux. Cases corresponding to functional success (B): ClosureFast 95 %, EVLA 97 %, RFITT 79 %, superheated steam 71 %. Below left: Reflux over the untreated AASV was seen on duplex ultrasound in 5 % each after ClosureFast and RFITT, 10 % after EVLA, and 12 % after superheated steam. Above right: Demonstrable recurrence with recanalisation of the vein (C) at the time of final check-up were found in EVLA 2 %, RFITT 19 %, superheated steam 28 %, and ClosureFast 3 %. Below right: Recurrence due to neogenesis or in other vessels was generally rare (1–3 %).

Complications

Necrosis/burning at the puncture site

Six of the 47 patients (13 %) who were treated with superheated steam showed signs of burning or necrosis at the puncture site even at the first follow-up visit, sometimes with ulceration. As the method was carried out by only one surgeon, this finding cannot be attributed to a lack of experience in the procedure. Patients were therefore no longer allocated to this method.

Deep vein thrombosis (DVT)

A DVT occurred in only one case after treatment with ClosureFast (0.01 %).

Hyperpigmentation, ecchymosis, disorders of sensation

Ecchymosis in terms of bleeding in the thermally treated area following puncture of the vein for the endovenous procedure occurred only immediately after treatment.

Hyperpigmentation occurred especially over the more superficial course of the treated trunk vein. The hyperpigmentation typically did not appear immediately, but over the first three months (the hyperpigmentation develops as haemosiderin is deposited). It then regresses slowly with time, as the body gradually breaks down the haemoglobin. The exact extent to which the hyperpigmentation is due solely to the thermal endovenous procedure is not completely clear, as all patients had foam sclerotherapy of residual tributary varicose veins at the same time as the endothermal ablation or at follow-up, and this procedure may also cause hyperpigmentation on occasion.

In most cases, disorders of sensation along the course of the GSV resolved after about three months. Sensory disorders were present in 0–5 % at the time of the final check-up.

Even though the statistical analysis did not show any significant difference between the methods with respect to the two most common post-interventional complications, there is a difference in frequency particularly between EVLA and superheated steam, as can be seen from ▶ **Fig. 4**. Larger case numbers would be necessary for us to make any more precise statements on the statistical relevance of complications occurring with the different treatment methods (▶ **Table 4**).

Pain

At each follow-up visit, the patients reported any current pain in the treated leg, the worst pain they had experienced since the last visit, existing tenderness, and the worst tenderness they had experienced since the last visit, each rated on a scale of one (no pain/tenderness) to ten (severe pain/tenderness).

At the first follow-up visit after 14 days, the pain score for ‘the worst pain experienced since the last visit’ was significantly higher for EVLA than RFITT ($p = 0.02$); the superheated steam procedure also gave significantly higher pain scores than RFITT ($p = 0.006$) and ClosureFast ($p = 0.04$). One year after treatment, there was a

▶ **Table 3** Significant differences (primary endpoints) in the results during follow-up, comparing the methods with each other.

post-intervention	comparison	p
	EVLA – superheated steam	< 0.0001
	superheated steam – ClosureFast	< 0.0001
	RFITT – superheated steam	< 0.001
3-month follow-up	EVLA – RFITT	< 0.05
	EVLA – superheated steam	< 0.05
	RFITT – superheated steam	< 0.05
	RFITT – ClosureFast	< 0.05
	superheated steam – ClosureFast	< 0.05
1-year follow-up	EVLA – RFITT	< 0.05
	EVLA – superheated steam	< 0.05
	RFITT – ClosureFast	< 0.05
	superheated steam – ClosureFast	< 0.05
final check-up	EVLA – RFITT	< 0.05
	EVLA – superheated steam	< 0.05
	RFITT – ClosureFast	< 0.05
	superheated steam – ClosureFast	< 0.05

significant difference between EVLA and RFITT (p = 0.01) and between RFITT and ClosureFast (p = 0.01) with respect to the worst tenderness experienced since the last visit. Overall, RFITT had the lowest pain scores.

All the other data on pain/tenderness showed no differences between the individual methods. In comparison with the other procedures, therefore, RFITT caused the least pain/tenderness (▶ **Table 5**).

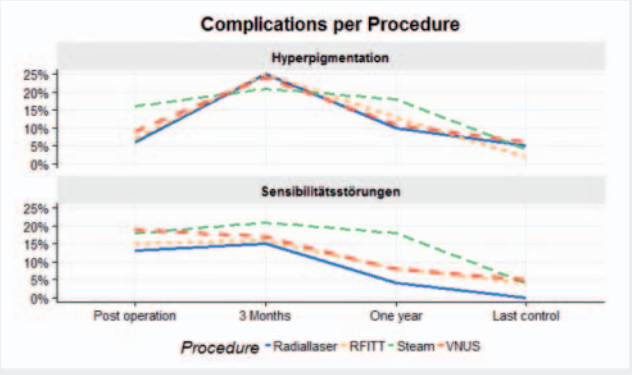
CIVIQ score (secondary objective)

The CIVIQ questionnaire was evaluated before treatment, three months after treatment, at the one-year follow-up, and the final check-up, in order to assess the quality of life.

As can be seen from ▶ **Fig. 5**, all four methods already showed a clearly significant improvement in the CIVIQ three months after treatment, when compared with the pre-treatment baseline. For EVLA and RFITT there was no further improvement in the CIVIQ score at later visits. The improvement in the scores was not significantly different for any of the individual methods.

VCSS (secondary objective)

Patients randomly allocated to receive the EVLA procedure had higher pre-treatment baseline VCSS scores than patients in the other groups (EVLA-RFITT p = 0.009), as can be seen in ▶ **Fig. 6**.



▶ **Fig. 4** Incidence of hyperpigmentation and disorders of sensation.

Like the CIVIQ score, there was a significant improvement in the VCSS after treatment with all methods when comparing the three-month follow-up data with the pre-treatment scores. No further improvement was seen with time.

Fourteen days after treatment, scores showed a relevant improvement only after EVLA. This may indicate that EVLA leads to a more rapid improvement of the symptoms than the other methods, but may also be due to the higher pre-treatment scores.

The increase in the VCSS occurring in the long term can be explained by the progression of the chronic condition of 'varicose veins'.

Discussion

Numerous studies have reported high occlusion rates after endoluminal thermal ablation of the trunk veins. Although all procedures are said to be well tolerated with a small number of adverse effects, no previous study has compared the four methods we used to ascertain whether any one of them is superior to the others.

Several studies report similar success rates for surgical stripping versus endovenous ablation, with most studies using EVLA or RFA. Van der Velden gave similar data for EVLA and stripping, with a poorer outcome for foam sclerotherapy over five years [14].

Sporbert et al. compared the five-year outcomes of GSV ablation using EVLA 1470 nm and RFA [15]. With a larger patient population and 643 trunk veins, 86 % of the treated veins were anatomically occluded 5 years after RFA and 93 % after EVLA. These results are therefore in line with the recurrence rates found in our study, although there was no significant difference between EVLA and RFA even in Sporbert's study. The 133 patients in that study revealed secondary incompetence of previously untreated segments of the GSV or an accessory vein. As there were no further details on the refluxing veins, the reflux rate of untreated AASVs cannot be compared with the results of our study.

Our study quickly found that superheated steam treatment was associated with more complications (burning and necrosis at the puncture site) and clearly worse results in comparison with

▶ **Table 4** Complications after treatment; 95 % confidence interval, $p < 0.05$ in all comparisons of the individual methods with each other.

time	complications	EVLA	RFITT	ClosureFast	steam
14 day follow-up	hyperpigmentation	6 %	7 %	9 %	16 %
	ecchymosis	19 %	16 %	16 %	27 %
	disorders of sensation	13 %	15 %	19 %	18 %
3-month follow-up	hyperpigmentation	25 %	25 %	24 %	21 %
	disorders of sensation	15 %	16 %	17 %	21 %
1-year follow-up	hyperpigmentation	10 %	13 %	11 %	18 %
	disorders of sensation	4 %	8 %	8 %	18 %
final check-up	hyperpigmentation	5 %	2 %	6 %	4 %
	disorders of sensation	0 %	4 %	5 %	4 %

▶ **Table 5** Descriptive statistics of the significant differences in pain since the last visit (pain LV) 14 days after treatment and tenderness since the last visit (tenderness LV) at the one-year follow-up.

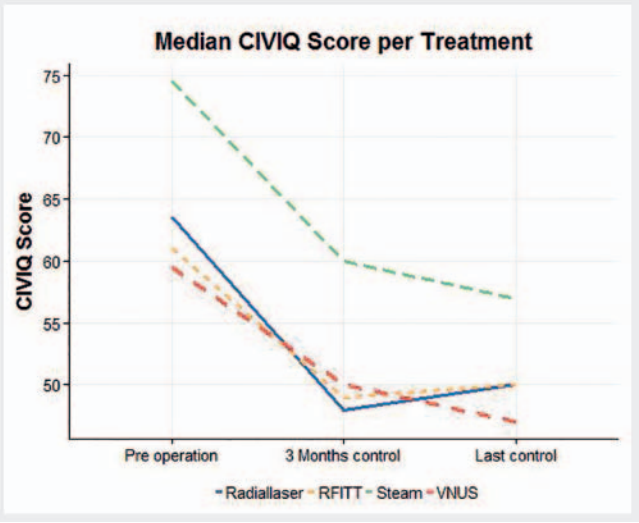
14-day follow-up	variable	n	median	SD	min	max	Q1	Q3
radial laser	pain LV	66	3	2.06	1	8	1	4
RFITT	pain LV	72	1	1.52	1	7	1	3
steam	pain LV	46	3	2.48	1	10	1	4
ClosureFast	pain LV	85	2	1.88	1	8	1	3
1-year follow-up	**variable**	**n**	**median**	**SD**	**min**	**max**	**Q1**	**Q3**
radial laser	tenderness LV	49	1	1.37	1	9	1	1
RFITT	tenderness LV	79	1	0.83	1	7	1	1
steam	tenderness LV	17	1	0	1	1	1	1
ClosureFast	tenderness LV	83	1	0.92	1	5	1	1

the other methods. This method is thus clearly inferior to EVLA or the radiofrequency ablation procedure.

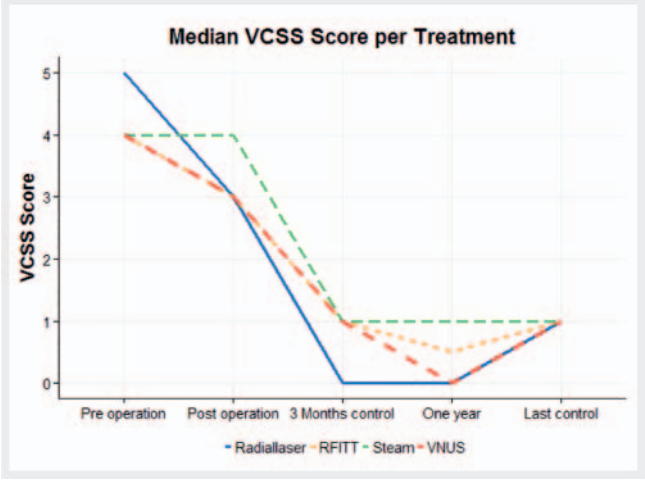
The recurrence rate with RFITT, used according to the manufacturer's instructions, was significantly higher than with EVLA and ClosureFast. This is possibly due to the manufacturer's recommendations for the energy to be applied and treatment duration being too inadequate to ensure reliable closure of the vein. But as all the techniques are constantly being developed further due to the great demand, the instructions for use that we used at the time are no longer the latest version. This means that more studies would be necessary to compare the updated techniques. With the RFITT procedure, however, it was particularly noticeable that recanalisation of the GSV without reflux occurred more than the average, i. e. 'normal functioning' of the vein returned, but not reliably enough to be considered an advantage of the method. Our results show that EVLA and the ClosureFast procedure are similarly suitable for the treatment of an insufficient GSV, while superheated steam procedures should be reserved for specific situations in which the other methods are not appropriate, for example with a particularly tortuous serpentine vein.

The energy applied with EVLA in our study was less than the energy of 60 J/cm required at the present time. This can be explained by the fact that we chose to calculate the energy to be applied according to the formula of 7 J/mm vein diameter per centimetre of treated vein. Today we use an energy of 10 J/mm. It is possible that we could have achieved even higher occlusion rates for EVLA if we had used this energy.

The recurrence rates in AASVs not treated in the first procedure is also striking: 5 % with RFITT and ClosureFast, 10 % with EVLA and 12 % with superheated steam. These recurrence rates were found mostly at the final check-up, but not before two years had elapsed after treatment. Once the first AASV recurrences appeared, we switched to including the AASV in the initial endothermal treatment. This may explain why our data, giving a rate of only 10 %, are much lower than the results found in other studies. Proebstle, for example, reported reflux in the AASV of up to 70 % four years after treatment with RFA [15]. Regular sclerotherapy of newly appearing tributary varicose veins (disease progression) at follow-up visits may also have contributed to preventing AASV recurrence. In Proebstle's study, secondary reflux in an initially



▶ **Fig. 5** Changes in the CIVIQ score over time – from before treatment to the final check-up.



▶ **Fig. 6** VCSS scores before and after treatment, until the final check-up.

untreated posterior accessory saphenous vein (PASV) could be ignored, as we also observed in our study.

Previous studies with low wavelengths (EVLA 810–980 nm) are available to compare recurrence rates with surgical high saphenous ligation and stripping. These show a somewhat higher rate of SFJ recurrence for endovenous procedures, but the long-term results after endovenous ablation with higher wavelengths remain to be seen. Further studies are required to address this aspect [16]. The first 5-year data with respect to the 1470 nm laser with radial probe and segmental RFA showed similar anatomical success rates (97 % for EVLA vs 96 % for RFA). In that study, SFJ recurrence in the AASV was demonstrated on ultrasound scanning in 15 % of cases after 5 years (n ~ 171 per group) [17].

We therefore recommend that an AASV without reflux should also be treated with an endovenous procedure during the initial treatment session, in order to prevent the long-term development of recurrence, as has already been discussed in earlier publications [18].

In addition, complete endovenous treatment of the SFJ is essential to achieve a low recurrence rate [19].

As there was only one post-treatment DVT in our study (0.01 %), the risk can be considered to be very low. We cannot say for sure whether this low rate is related to the routine administration of LMWH for 10 days. A study by Keo in 2017 compared the effects of rivaroxaban and fondaparinux given for 3 days after treatment. DVTs occurred in the two study arms in 0.6 and 0.9 % respectively, and the incidence after three days' prophylaxis was thus also extremely low, even if in a somewhat higher range than in our study [20].

In one of our own retrospective analyses on the occurrence of post-ablation thrombosis between 2015 and 2017, the routine administration of LMWH for 10 days was reduced to a single post-interventional administration from 2017 onwards, unless the patient's risk profile indicated that longer thromboprophylaxis was necessary (past history of DVT, thrombophilia, hormonal therapy). Since we reduced this prophylaxis, however, all our patients have had a duplex ultrasound scan 10 days after treatment to ensure that there was no post-ablation thrombus (PATE) [21].

Comparing all four endovenous thermal methods, there is significantly less pain 14 days after RFITT than the other procedures, and this method shows the significantly lowest tenderness at the one-year follow-up. However, pain was slight with all methods, with a median score between one and three after 14 days and a median score of one for all methods at follow-up after one year. How far the reports of pain one year after treatment could be attributed to the procedure itself or rather to another cause (disease progression, swelling with tenderness for another reason) cannot be said with any certainty, so the reports of pain should be interpreted with reservation.

The different baseline CIVIQ scores for the different treatment methods can be considered incidental thanks to the random allocation of the methods. The decrease in values after treatment is decisive, however, as there was no significant difference between the individual methods.

Summary for practice

Both EVLA 1470 nm and the ClosureFast procedure showed very good results in the treatment of incompetent GSVs and were superior in performance to the other thermal procedures.

Superheated steam should be used only in exceptional circumstances if other procedures are not appropriate.

Recurrence after endovenous thermal ablation most often develops in an accessory vein, especially the AASV. We therefore recommend an endovenous procedure in all competent AASVs during the same treatment session whenever possible, as this accessory vein is frequently responsible for the long-term development of recurrence. Only in this way can complete endovenous treatment of the SFJ be achieved. But further studies will have to be carried out to confirm this approach. Before the procedure, the patient must be informed that the SFJ will be treated and a short segment of a normal vein in the region will also be closed.

The statistical analysis was performed with the help of Nicolás Carbonare, MSc, and María Belén Gagliardi Reolón, MSc.

The study was supported financially with a grant of EUR 5900 from the German Society of Phlebology (DGP) for the time taken to collect the data and for the statistical analysis.

The study was approved by the Baden-Württemberg Ethics Committee (Ref. No. 2009–115-f).

Interessenkonflikt

Die Firmen Biolitec und Medtronic haben in den letzten 2 Jahren für den in Freiburg durchgeführten, von Dr. Hartmann organisierten Berliner Venenworkshop Sponsorengelder gezahlt.

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