Great Saphenous Vein Ablation with Steam Injection: Results of a Multicentre Study

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WHAT THIS PAPER ADDS?
Steam ablation of the great saphenous vein was first described in animals in 2006. This paper presents the 1-year results of the first clinically important study on the efficacy and safety of steam vein sclerosis in 75 treated patients (88 veins). Its role alongside other thermal ablation techniques is also discussed.

Objective: To assess the safety and efficiency of steam vein sclerosis (SVS) of the great saphenous vein (GSV) in a multicentre open prospective cohort study.
Design: 75 consecutive adult patients with GSV reflux, CEAP C2—C5 and vein diameter 4—13 mm.
Methods: Patients treated using an SVS™ generator delivering homogenous pulses of superheated steam were followed up at 8 days and 1, 3, 6 and 12 months (clinical, duplex ultrasound, quality of life [QoL] with SF12).
Results: 88 veins were treated in 75 patients. At 6 months, 72/75 (96%) veins were obliterated (95% CI: 89—99) and Kaplan—Meier analysis found an obliteration rate of 96.1% at 12 months. QoL increased at 6 months for both the physical and mental components ($p = 0.049$ and $p < 0.001$ respectively). SVS was well tolerated: no major complications were reported. Adverse events occurred mainly at day 8 and incidents amounted to ecchymosis ($n = 60$) and pain ($n = 7$).
Conclusions: SVS achieved an obliteration rate similar to that of other thermal ablation techniques. It was well tolerated with minimal post-operative pain.

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INTRODUCTION

Conventional surgical treatment of truncal superficial venous insufficiency consists of destroying the affected vein, with high ligation and stripping of the saphenous veins. It has been credited with satisfactory long-term effectiveness, with 77% of patients reporting to be asymptomatic at 10 years,[1] and is therefore still considered the gold standard of care. Complications (major and minor) are reported in 18—20% of patients and include wound complications (infection, haematoma and abscess formation), thigh haematomas and nerve injury.[2] This approach is associated with a 20%—37% rate of recurrent varicosities at 3—5 years[1,3] and up to 70% at 10 years.[1] Furthermore, patients frequently require 2—4 weeks off work or daily activities to recover.

Less invasive techniques have been developed with the aim of lowering the rates of surgical adverse events and reducing disability after intervention.[4] Endoluminal thermal therapies, such as endovenous laser treatment and radiofrequency ablation (RFA), involve exposing the vein wall to heat-based energy and destroying the endothelium.[5]

Endovenous laser treatment with a bare fibre requires high levels of heat and can induce blood carbonisation, or perforation of the venous wall.[6] The histopathologic examination of laser-treated veins revealed perforation of the vein wall at the site of direct laser impact and thermal damage of adjacent vein wall areas.[7,8] However, tulip fibres and radial fibres can reduce perforations.[9]

To avoid these drawbacks, it was hypothesised that homogeneous wall heating, and thus obliteration, could be obtained by injecting steam directly into the veins. The Steam Vein Sclerosis (SVS™) system (cermaVEIN, Archamps,

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France) is a medical device used to perform steam ablation. Micropulses of steam are injected into a catheter to deliver the steam into the vein.[10]

This technique might therefore have the same advantages as other endovenous procedures, such as quick recovery time. It was first assessed in sheep where pulsated steam ablation established SVS as an effective technique,[10] and its potential efficacy was confirmed in a pilot patient study in 20 veins (19 patients) with 13 being completely obliterated at 6 months.[10] Pilot studies used insufficiently low energy levels (one pulse of 60 J/cm); in the present study energy delivery was therefore increased to two to three pulses of 60 J/cm.

The results of the pilot study needed to be confirmed in a larger population. The objective of the present study was to report the obliteration rate of the great saphenous vein (GSV) in an open prospective cohort of 75 patients treated using the SVS system with higher energy levels.

MATERIAL AND METHODS

Design

This open multicentre prospective cohort study was carried out in four French centres.

Patients

Patients aged between 20 and 80 years old were included in the study if they presented reflux at the sapheno-femoral junction (SFJ) and/or from the sub-terminal valve of the GSV of more than 0.5 s. The other inclusion criteria were vein diameter of between 4 and 13 mm (measured 3 cm distal to the SFJ) and a Clinical Etiologic Anatomic Pathophysiologic (CEAP) clinical class from C2 to C5.[11] Patients had to be able to understand and complete a quality of life (QoL) questionnaire.

Patients were not included if they presented one of the following criteria: recurrent varicose veins in the affected territory; a vein less than 5 mm from the skin along the thigh; the presence of a collateral vein on the thigh with a vestigial underlying saphenous vein; an anterior accessory saphenous vein with junction reflux; aneurismal dilation of the SFJ, or a prior history of deep or superficial vein thrombosis; ipsilateral deep venous reflux; pregnancy or breastfeeding; known thrombophilia; or a relevant severe pathology (cancer, cardiac or renal insufficiency, lower limb arteriopathy, progressive hepatitis).

Patients were treated for one or both legs.

Treatment procedure

A pre-operative duplex ultrasound scan (DUS) was performed on patients while standing and the region to be treated was marked.

Anaesthesia. Patients were operated under anaesthetic according to local practices. Tumescent anaesthesia was administered around the vein, in between the fascias, using a 21 gauge needle to inject a solution of 1.4% bicarbonate 500 ml, plus 20 ml 1% lidocaine with adrenaline. This was also performed in patients undergoing general anaesthesia or loco-regional spinal anaesthesia to provide a heat sink and protect the saphenous nerve. Compression with the ultrasound probe was applied at the SFJ.

Procedure. A tiny surgical incision or echo-guided percutaneous puncture was made to gain access to the GSV under the knee (the catheter is not long enough to enter at the ankle) and a 16G infusion catheter was placed in the vein. Then, a flexible stainless steel SVS catheter, covered with Teflon® and with a diameter of 1.2 mm (cermaVEIN), was inserted through the infusion catheter and forwarded under ultrasound guidance to a level of 2—3 cm below the SFJ. No guide wire was necessary because the stainless steel catheter acts as a guide wire by itself. The catheter was taped to the skin to secure the correct position. The SVS generator was calibrated at the factory to emit one pulse of steam with 60 J of energy every 1.8 s. The steam temperature delivered at the tip was 120 °C.[10] On activation of the SVS generator by a foot-operated switch, two pulses of steam were delivered to dispel condensed water in the catheter. Then, three pulses were delivered at the catheter tip. The catheter was then withdrawn by 1 cm and two or three pulses emitted for every centimetre of vein treated with the catheter stationary. The number of steam pulses was based on pre-operative vein diameter: two pulses for up to 7 mm, three pulses for over 7 mm and four pulses for large trunks over 12 mm. Absence of blood flow was verified by colour ultrasound scan before removing the catheter. Steam generation was stopped 2 or 3 cm before fully removing the catheter from the vein to avoid burning the skin. Although some patients underwent simultaneous phlebectomies for bulging tributaries, the number so treated was not recorded.

Post-operative treatment consisted of 2 weeks of compression by class II stockings worn during the day and pain killers (ibuprofen) at the patient's discretion.

Eight days of prophylactic low molecular weight heparin was given systematically in two centres and in patients with a personal or familial history of thrombosis in the two others.

Patient follow-up

A clinical examination and DUS were performed 8 days post surgery. In three centres this was done by an independent angiologist and in one centre by the surgeon himself. Patients were then followed up at 1, 6 and 12 months with clinical examination, duplex ultrasound scanning, QoL and safety assessments. CEAP was recorded at inclusion. Reflux was tested at four levels: SFJ, thigh, leg and ankle.

Study endpoints

The primary endpoint was full length vein obliteration at 6 months measured by the absence of a DUS signal at 3 cm below the junction and at mid-thigh. This level was chosen because it is representative of the reopening of the terminal segment of the GSV.

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The secondary endpoints were: obliteration of the vein at 12 months, evolution of functional stage and symptoms between inclusion and 6 months, and evolution of QoL measured using the SF-12 questionnaire between inclusion and 6 months. At inclusion, the SF-12 questionnaire was filled out by the patient in the consultation room and after the surgeon had explained the treatment modalities. The results were compiled into a mental component score and a physical component score.[12]

Safety evaluations were performed during the treatment procedure, at 8 days, and at 1 month, 6 months and 12 months post-operation, and consisted of recording: ecchymosis, haematoma, pain greater than 5 on visual analogic scale (VAS), pain as mentioned by patient, hypoaesthesia, paraesthesia, skin burn, bleeding, inflammation of the venous pathway, thrombo-embolic event. Any other adverse events were recorded. The duration of the operation was also recorded.

Ethics

The research adhered to the Declaration of Helsinki. Patients gave written informed consent before inclusion, and the study was authorised by the competent authority (*Agence Française de Sécurité Sanitaire des Produits de Santé*, 01-08-2008) and approved by the research ethics committee (*Comité de Protection des Personnes Est II*, 14-08-2008).

Statistics

A descriptive analysis was performed on inclusion and per-operative data, giving the mean, standard deviation, median (and range) for quantitative data, and number and percentage for qualitative measures (and exact 95% confidence interval for obliteration rate).[13] Obliteration rate was also studied by Kaplan—Meier survival analysis.

The McNemar test and the Wilcoxon signed rank test were used for comparison of paired qualitative and quantitative data.

Analyses were performed with SAS 9.2.

RESULTS

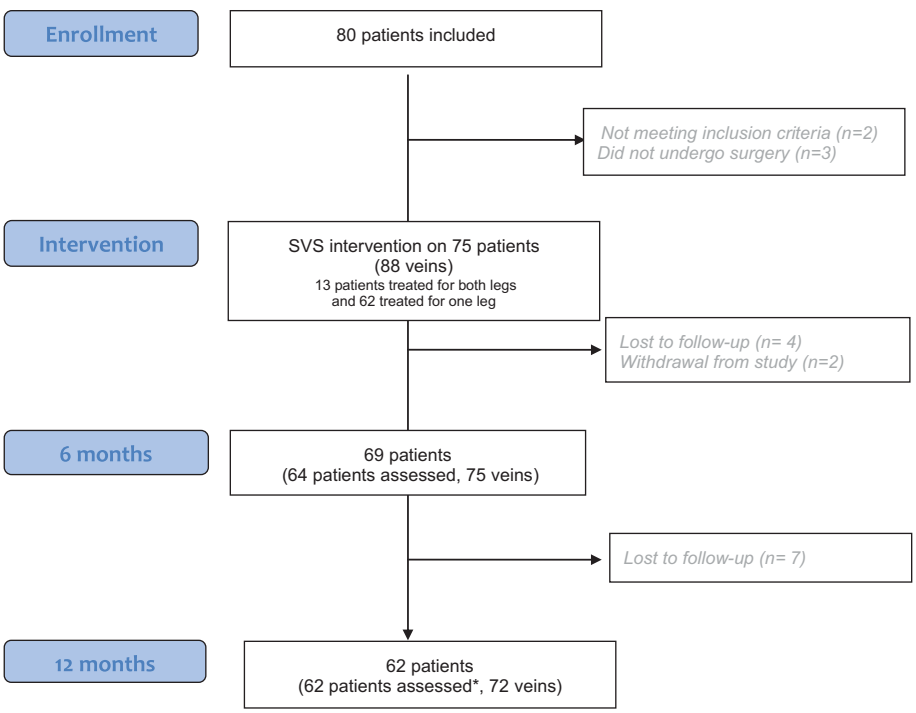
A total of 75 patients underwent surgery (Fig. 1). The patients were mostly women ($n = 52$; 69%), and the median age was 48 years (range: 28—75). These patients represented 88 limbs (13 patients treated for both lower limbs). Pre-operative DUS found that 81 (92%) had saphenofemoral incompetence and 64 (73%) reflux down to the leg. The CEAP and the clinical presentation are set out in Table 1.

Treatment procedure

The median treatment time was 35 min (range 12—85) including patient preparation time; the median length of vein treated was 42 cm (range 15—57 cm).

Efficacy analysis

Primary endpoint. The analysis was performed on 75 veins from 64 patients with a 6-month visit available; the obliteration rate was 96% [95% CI: 89—99]. Absence of reflux was also found in 96% of patients (2 saphenofemoral incompetencies and 1 thigh reflux).



* 5 patients (6 veins) were assessed more than 16 months after procedure.

Figure 1. Patient inclusion in the study.

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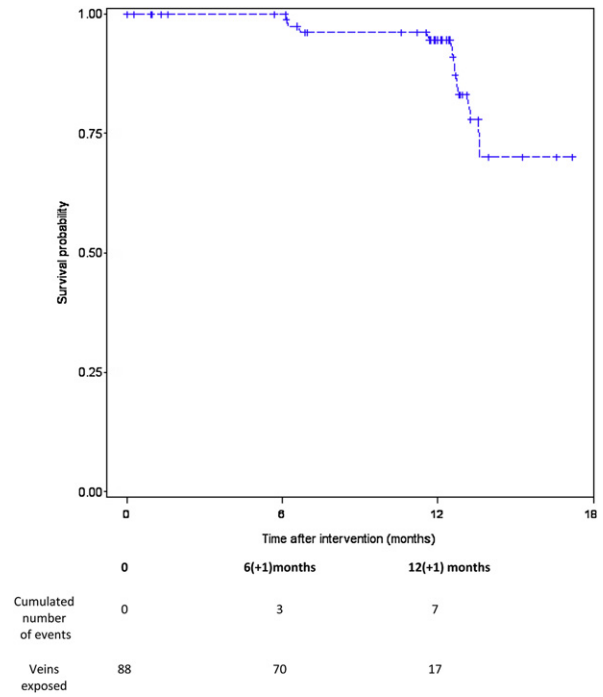

Figure 2. Kaplan—Meier survival analysis. Legend: Patients were considered as obliterated at the operation date and occurrence of non-obliteration was considered as an event. Patients were considered as censored when remaining obliterated (=success at latest news).

Secondary endpoints. Crude obliteration rate was 92% [95% CI: 83—97] at 12 months. Kaplan—Meier analysis revealed an obliteration rate of 96.1% at 6 months (±1 month) and 83.0% at 12 months (±1 month) (Fig. 2).

Vein diameter improved at 6 months from a median of 8 mm (range: 4—12 mm) to 1 mm (range: 0—9 mm) at mid-thigh at the treated vein level. Functional stage and symptoms were also improved at 6 months (Table 1).

The SF12 scores had improved 6 months after surgery both for the physical component score (48.79 at inclusion vs 51.27 at 6 months for the 45 patients with questionnaires filled at inclusion and 6 months; $p = 0.049$) and for the mental component score (46.29 vs 52.05; $p < 0.001$).

Safety analysis

SVS treatment was well tolerated (Table 2); pain during follow-up is reported in Table 3. There were no adverse events either during or after the surgical procedure. The majority of adverse events occurred by day 8, the most common being ecchymosis at the entry site and pain cited or pain with a VAS score >5 occurred in seven patients. Skin burn at entry site occurred in one patient and this was considered by the surgeon to be due to removal of the catheter before the steam had cooled.

At 1 month, inflammation of the venous pathway occurred in two patients and hypoaesthesia in one patient. Both of these conditions resolved over time. A haematoma developed in one patient at the cutaneous access site and this resolved quickly.

Other adverse events were rare (Table 2) and most resolved without treatment. One protrusion of thrombus in the femoral vein (less than 1 cm) occurred. It resolved fully in 8 days under treatment by low molecular weight heparin.

Table 1. Initial characteristics of treated patients at inclusion and 6 months.

	Inclusion *n* (%) 75 Patients	6 Months *n* (%) 64 Patients	*p*-Value
C-Class of CEAP stage			
C0 no evidence of venous disease (yes)	0 (0.0)		
C1 superficial reticular veins (yes)	0 (0.0)		
C2 simple varicose veins (yes)	67 (89.3)		
C3 oedema of venous origin (yes)	4 (5.3)		
C4 skin pigmentation in the ankle area (yes)	4 (5.3)		
C5 healed venous ulcer (yes)	0 (0.0)		
C6 open venous ulcer (yes)	0 (0.0)		
Functional stage			
No possible activity (yes)	0 (0.0)	0 (0.0)	—
Normal activity with compression stockings (yes)	57 (76.0)	46 (71.9)	0.2668
Normal activity without compression stockings (yes)	58 (77.3)	57 (89.1)	0.0768
No sign (yes)	7 (9.3)	38 (59.4)	<0.0001
Symptoms			
Heaviness (yes)	68 (90.7)	24 (37.5)	<0.0001
Oedema (yes)	39 (52.0)	10 (15.6)	<0.0001
Restless (yes)	20 (26.7)	6 (9.4)	0.0043
Pruritus (yes)	16 (21.3)	0 (0.0)	—
Phlebalgia (yes)	30 (40.0)	5 (7.8)	<0.0001
Symptoms worsened by heat (yes)	52 (70.3)	8 (12.5)	<0.0001
Improvement with the cold (yes)	31 (41.9)	6 (9.4)	0.0001
Improvement by walking (yes)	39 (52.7)	15 (23.4)	0.0002

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Table 2. Related adverse events.

	8 Days $n = 74$	1 Month $n = 73$	6 Months $n = 64$	12 Months $n = 57$
At least one adverse event (yes)[b]	**63**	**10**	**9**	**2**
At least one ecchymosis (yes)[c]	60	1	0	0
Haematoma (yes)	0	1	0	0
Pain (cited or greater than 5 on VAS[a]) (yes)	7	2	4	1
Hypoaesthesia (yes)	0	1	1	0
Paraesthesia (yes)	0	0	0	0
Dysaesthesia (yes)	0	0	0	1
Skin burn at entry point (yes)	1	0	0	0
Bleeding (yes)	0	0	0	0
Inflammation of the venous pathway (yes)	0	2	0	0
Deep vein pathology (yes)	0	0	0	0
Superficial thrombosis (yes)	2	2	0	0
Others	**5**	**4**	**6**	**1**

[a] VAS = visual analogic scale

[b] Patients could present more than one related adverse event.

[c] Information missing for 2 patients at 8 days and 1 month.

DISCUSSION

This is the first phase II study of the new SVS technology developed for treating superficial venous insufficiency. The technique was shown to be consistent and successfully obliterated the pathologic vein in 96% of cases.

Occlusion can be measured using different parameters. In this study, obliteration at 3 cm below the SFJ was used, whilst others may use different distances, or measure absence of reflux, which was absent in 96% of patients treated with SVS at 6 months.

Obliteration rates at 1 year using RFA techniques vary from 83% to 97%, the latter being observed with the newest RFA segmental ablation device.[14–16] RFA has been in use for a number of years and many of the surgeons participating in clinical trials are highly experienced in endovenous procedures. Consistent temperature delivery has been called into question regarding traditional RFA devices as repeat procedures were required due to a high proportion of unsatisfactory results.[17]

Endovenous laser ablation occlusion rates at 1 year are usually in the range of 91–95%, but the widely differing wavelength and power settings mean it is difficult to make direct comparisons with this study.[14,18]

Although the development of this technology is still in the early stages, several practical issues have been brought to light. In the study by Van den Bos et al., some veins re-opened between 6 and 12 months after steam therapy.[10] These patients had received one pulse per centimetre of steam rather than two or three pulses.

The SVS protocol has been developed to optimise patient outcomes and, when adhered to, maintainable obliteration rates of more than 94% can be expected with no adverse events.

QoL was improved in this patient group. However, most patients were staged C2 at inclusion and their venous insufficiency, although symptomatic, did not greatly reduce their QoL. One feature of the study was the inclusion of venous symptom evaluation: patients assessed their complaints and not the obliteration of their saphenous vein. The value of venous symptoms is disputed, but most authors agree that leg heaviness and leg pain relate to venous insufficiency in patients who present with this condition.[5,19,20] Therefore, even if the SF12 questionnaire score is only slightly better, the symptoms, which are the main reason why patients undergo surgery, are significantly improved. One of the weaknesses of the QoL analysis is the choice of the SF12 tool, which is not disease specific. Although the majority of patients had varicosities only, post-procedural aesthetics were not evaluated in this study, but do have an impact on the patient's determination of outcome. Another critical point may be the absence of evaluation of residual or recurrent varicose veins owing to the short follow-up time of patients. In this respect the study would have been enhanced by assessing these issues with the Aberdeen varicose vein severity questionnaire.

Post-procedural pain with SVS was rare, as observed with RF segmental ablation using ClosureFast® (VNUS Medical Technologies Inc., San Jose, CA, USA), whilst pain following bare fibre laser treatment is generally higher and may be associated with wavelength used and thermal injury.[2,10,14] Ecchymosis is reported frequently in the days immediately following most endovenous procedures and is thought to be partly related to the tumescent anaesthesia.[2,14]

The main incident was one protrusion of thrombus in the femoral vein (less than 1 cm) recorded in one of the first patients treated at this centre. The event occurred because

Table 3. Pain during follow-up (visual analogic scale).

	8 Days $n = 66$	1 Month $n = 72$	6 Months $n = 63$	12 Months $n = 52$
Median pain (range)	0.75 (0.00–7.00)	0.63 (0.00–5.38)	0.00 (0.00–7.31)	0.00 (0.00–4.06)

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the catheter was positioned too close to the SFJ. This would be avoided with correct positioning, and will be monitored in future studies as venous thrombotic extension has been associated with other endovenous techniques in a number of studies.[21]

The SVS catheter does not require a guide wire and is flexible, which makes it easy to navigate tortuous veins. The current catheter is 60 cm long which may not be enough when entry is from mid-calf or ankle. Thus, longer catheters are being developed. However, when entering at ankle level, it is advisable to stop heating at the upper third of the leg in order to avoid any nerve damage, as the sensitive nerve is close to the vein at this level.

One of the limitations of the study is that comparative measures were not made in patients in whom both legs or multiple veins were treated. Comparative studies with alternative thermal ablation techniques are ongoing.

In conclusion, SVS is a new thermal technique for the obliteration of varicose veins. Successful venous obliteration, with little pain and minimal adverse events, has been obtained at 6 months in 96% of treated veins. Another ongoing study is focused on the treatment of tributaries. This could be a significant improvement as it allows an all-in-one endovenous procedure. This study was the first step of SVS clinical evaluation; thus comparative studies are underway to establish more evidence and the advantages of steam ablation in terms of efficiency, versatility, cost, and tolerance.

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CONFLICT OF INTEREST STATEMENT

René Milleret is a consultant with cermaVEIN, the company manufacturing the devices. None of the other investigators have any conflicts of interest.

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