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## ORIGINAL ARTICLE

# Is endovascular treatment of the great saphenous vein (with immediate foam sclerotherapy of superficial tributary veins) in an outpatient clinic really safe and profitable?

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## ABSTRACT

**BACKGROUND:** This preliminary study aimed to evaluate the safety of radiofrequency (RF) thermoablation of the great saphenous vein (GSV) with immediate foam sclerotherapy of superficial tributary veins performed in the outpatient clinic (Hospital Department). Further, we also evaluated the cost reduction compared to the same procedure performed in the operating room.

**METHODS:** Thirty patients were evaluated for RF thermoablation of the GSV. Foam sclerotherapy was performed with 1-3% sodium-tetradecyl-sulphate foam (Tessari's method). We evaluated the possible risks of the procedure and methods to resolve them. We compared the costs of both procedures performed in the operating room and in the outpatient clinic.

**RESULTS:** We had complete occlusion of the GSV in 28/30 patients (93.3%). Periodic check-up revealed a reflux through an anterior lateral saphenous vein in one patient and a long saphenous stump in another patient. There were no severe intraoperative complications. In two cases, it was necessary to convert the radiofrequency procedure into foam sclerotherapy (using the hollow probe as a long catheter in one case and using needle injection in the second case). In another case, it was necessary to perform surgical cannulation of the GSV. There were no severe postoperative complications. Moreover, the cost of the operating room procedure was € 1226.50, while that of the outpatient clinic procedure was € 1082.65 (cost reduction, 12.5%).

**CONCLUSIONS:** This procedure is safe and sufficiently cost-effective to perform in an outpatient clinic and the operating room can hence be reserved for patients with more serious pathologies. These results should be validated in further studies with larger sample size.

(Cite this article as: Orsini C. Is endovascular treatment of the great saphenous vein (with immediate foam sclerotherapy of superficial tributary veins) in an outpatient clinic really safe and profitable? Acta Phlebol 2021;22:79-83. DOI: 10.23736/S1593-232X.21.00498-7)

**KEY WORDS:** Varicose veins; Radiofrequency therapy; Outpatient clinics, hospital.

Endovascular techniques such as radiofrequency (RF) or endovenous laser ablation (EVLA) are the first choice<sup>1,2</sup> of treatment for saphenous trunk insufficiency. Usually, the surgeon completes the procedure by surgical ablation of the superficial tributary veins.<sup>3</sup> The procedure is performed under tumescent local anesthesia for RF and with additional local anesthesia for the surgical ablation. The procedure is often performed in the operating room but, more rarely, in an outpatient clinic.<sup>4-7</sup>

Foam sclerotherapy is the second choice of treatment for saphenous trunk insufficiency<sup>2</sup> and is frequently utilized for treatment of superficial varicose veins. This procedure does not require any anesthesia.

## Materials and methods

The RF thermoablation was performed with Medtronic ClosureFast™ (Medtronic; Dublin, Ireland) or RF medical VeinClear™ (VER SAN & Dafne; Verona, Italy) and an echo-color-Doppler Logiq S8 (GE Healthcare; Chicago, IL, USA). The sequence of operating times was as recommended by the manufacturer. Echo-guided sclerotherapy was performed with foam prepared with 1-3% sodium-tetradecyl-sulphate (STS) with Tessari's method (liquid:air 1:4), and with the use of short catheters.<sup>8</sup> We treated at the origin of tributary veins when they come out from Egyptian eye. The injection was made after local tumescent an-

esthesia (Klein's formula) of the GSV, but before activation of the generator. The foam remained in contact with the vein wall for more than 10 min.<sup>9</sup>

The outpatient clinic (hospital department) must be authorized for simple surgical procedures. The patient must be monitored, and an emergency trolley must always be available. The procedure can be done with one surgeon and three nurses. The anesthesiologist should be easily contactable.

Low-risk patients preoperatively completed an anesthesia-related assessment test to assess their suitability for the procedure. High-risk patients underwent the procedure only in the operating room and were excluded from this study. All patients were treated with paracetamol 1 g i.v. and midazolam 2 mg i.v. The patients were discharged within 2 hours with eccentric compression and a KKL1 elastic stocking.<sup>8</sup> Enoxaparin 2000 U.I./day was prescribed for one week. We also prescribed oral micronized and purified diosmin for a week.

Clinical and echo-color-doppler checks were carried out one day after the procedure, and thereafter on days 7 and 30. The costs were elaborated from the local Management Control Office.

### Results

From December 2016 to December 2018, more than 100 patients were treated with RF thermoablation of GSV and surgical tributary veins ablation.

From January 2003 to December 2020, just under 1000 major sclerotherapy procedures (for saphenous trunk insufficiency or recurrent varicose veins) were performed.

From January 2019 to December 2020, thirty patients were treated with RF thermoablation of GSV with immediate foam sclerotherapy of the superficial tributary veins. Patient recruitment was challenging, because it was hindered by the ongoing COVID-19 pandemic.

The patients were 17 males and 13 females, median age: 45.5 years (range: 37-67 years), twenty-one ASA-1 and nine ASA-2 grade patients were selected after physical ex-

amination, echo-color-doppler reflux study. The diameter measurements of S-F junction was median 0.91 (range: 0.72-1.2cm) and GSV median: 0.69 (range: 0.51-0.95cm). Patients were treated with 10.7 cycles of RF (range: 5-13), and they were treated with 3 cc (range: 2-4) of sclerosing foam with 1-3% STS (median: 2.4%)

In this preliminary study, the safety of the procedure was evaluated. The procedure was performed in an operating room, recreating the same environment that would be found in an outpatient clinic. The procedure was performed by one surgeon and three nurses without an anesthesiologist, perioperative nurse, or specific surgical instruments. For each patient, all dangerous situations or situations that could make it difficult to perform the procedure, and the possible solutions were recorded (Table I).

No major intraoperative complications were noted. In one case, the probe did not reach correctly up to the 2-cm distance from the S-F junction and hence, it was deemed more appropriate to perform a chemical ablation with 4 cc 3% STS foam by using the hollow probe as a long catheter.<sup>8</sup> In the patient converted from RF to foam sclerotherapy, the saphenous vein was perfectly occluded at the 7-month control.

In another case the GSV was not cannulated for anatomical anomalies, and we performed a direct needle injection echo-guided foam sclerotherapy of the GSV. In one case, the GSV was surgically cannulated.

No risk was encountered that could not be resolved in an outpatient clinic. In one case, the onset of pain required a second dose of midazolam.

Periodic checks revealed a complete GSV occlusion within 2-3 cm (without S-F Junction reflux) was observed in 28/30 patients (93.3%).

We revealed the S-F junction reflux in one patient through an anterior lateral saphenous vein. We treated this accessory saphenous vein with a foam sclerotherapy session with 4 cc 3% STS mousse and had complete occlusion after 6 months. Periodic checks also revealed a 5-cm long saphenous stump in one patient. We check the patient periodically.

TABLE I.—Anesthetic complications, device problems and their resolution in 30 patients treated with RF thermal ablation of GSV with immediate foam sclerotherapy of the superficial tributary veins.

Patients	Anesthesia complications	Resolution	Device problems	Resolution	30-day check	Follow-up
N.=30 (17 males, 13 females)	1 pain	Midazolam	1 failed percutaneous cannulation 1 failed percutaneous cannulation 1 S.F-J not reached	Surgical cannulation Echosclerosis of GVS with needle injection Echosclerosis of the ©GSV with the probe	2 chemical phlebitis treated with paracetamol 6 thrombi <1 cm from S.F-J treated with EBPM	1 patient with reflux in anterior saphenous vein was treated with echosclerosis 1 patient with long saphenous stump was periodical checked

In six cases, the GSV occlusion was within 1 cm with occlusion of epigastric artery; thus, we continued enoxaparin for two-three weeks. No patient had a really DVT.

No patient had major complications, neurologic disturbances, or complained of any pain. Only two patients had minor chemical phlebitis that was treated with paracetamol for few days.

The cost of performing the procedure in the operating room was € 1226.50, while the cost of performing the same procedure in the outpatient clinic (Hospital Department) was € 1082.65. The cost reduction was 12.5%. The difference was due to the higher cost of the operating room and the absence of the anesthetist. The materials used were the same (Table II).

### Discussion

The endovascular technique for saphenous trunk insufficiency treatment is a painless procedure, with excellent patient comfort, rapid discharge, and early resumption of work. Thus, the possibility of performing that in an outpatient clinic (hospital department) allows further reduction of costs. We aimed to perform the endovascular technique with immediate foam sclerotherapy of the tributary veins without skin incisions or blood loss instead of the usual surgical ablation of the same. We did not compare the effectiveness of the two procedures (*i.e.* alone or in association) because those have been studied better in several previous trials.

TABLE II.—Cost analysis for the procedure performed in the operating room vs. outpatient clinic.

Variables	Operating room	Operating room costs (€)	Outpatient clinic costs (€)	Outpatient clinic
Usage of operating room/ clinic (1.5-2 hours)	Depreciation of sanitary equipment	2.46	1.39	Depreciation of sanitary equipment
	Depreciation of movable property	0.60	0.55	Depreciation of movable property
	Maintenance material	2.21	0.12	Maintenance material
	Fees and rentals	2.22	0.00	Fees and rentals
	Maintenance services	4.47	4.12	Maintenance services
	Employees' laundry		1.13	Employees' laundry
	Employees' canteen		1.69	Employees' canteen
	Cleaning		12.65	Cleaning
	Waste		1.15	Waste
	Heating		4.80	Heating
	Phone		0.82	Phone
	Electricity		3.38	Electricity
	Water and gas		0.68	Water and gas
	Total		38.26	32.48
Staff costs	1 surgeon		128.80	1 surgeon
	1 anesthesiologist	150.92	37.73	1 available anesthesiologist
	3 nurses	149.25	124.37	3 nurses
	Total	428.97	290.91	Total
Materials	RF probe Versan	79.04	0.36	Perfalgan 1 f
	Midazolam 1f	0.22	11.15	Fibrovein 3% 1 f
	Augmentin 1 f	1.08	2.88	Disposable scalpel
	Syringes 5/10/20 mL	0.46	2.72	Betadine
	Bicarbonate 8.4%	0.26	0.37	Foley catheter
	Cannula needle 20 G	0.31	14.54	Tumescence tubes kit
	Butterfly needle 21 G (1/3)	0.15	0.56	Lidocaine 1 f
	Local anesthesia set for tumescence (peristaltic pump, connection bag)	29.66	7.32	Ultrasound probe cover
	Adrenaline 1 f	0.15	0.43	Extension cord (30 cm)
	Needles 23 G	0.17	31.46	Peripheral vascular kit
	Three-way tap	0.24	6.50	RF generator
	Cefazoline 1 f	0.91	0.40	Physiological 50 cc
	Introducer kit (free)	0.00	371.11	RF Ablation catheter
	Total	562.44	562.44	Pump Dispenser DP 30 Biolitec (free)
	Total			Total
Hospitalization	1-2 hours D-H local	4.40	4.40	1-2 hours D-H local
General costs		192.43	192.43	
Total costs		€ 1226.50	€ 1082.65	Total costs

Instead, we aimed to understand whether these two associated procedures were safe to perform even in an outpatient clinic (Hospital Department).

In a randomized study, Varetto *et al.* compared 57 patients operated with laser thermoablation in a day-hospital setting with 55 patients operated with the same technique in an outpatient setting. The two groups showed no differences in the 30-day results and complications. The study on the comparison of approval of the procedure in the two admission regimens showed a slight preference for outpatient regimen in patients aged >65 years.<sup>4</sup>

In a multicenter retrospective study, Keo *et al.* compared 829 patients, 747 patients <75 years old (group 1) and 82 patients ≥75 years and older (group 2). All the patients were treated with EVLA of truncal varicose veins in outpatient setting. Complete occlusion of the ablated varicose veins was achieved in 98,9% in the group 1 and 97.6% in group 2 (P=0.295). The incidence of DVT was similar 0.3% in group 1 vs. 1.2% in group 2 (P=0.215). Propensity score-matched analysis revealed no significant difference in efficacy and safety outcomes.<sup>5</sup>

In a retrospective study, Somasundaram *et al.* showed that endovenous radiofrequency ablation of truncal veins without concomitant phlebectomies or sclerotherapy resulted in resolution of symptoms in >75% of patients. A total of 429 limbs were treated in 394 patients in outpatient setting. No major complications were encountered in more of 400 procedure. Three endovenous heat induced thromboses (EHIT) were recognized immediately and treated with an appropriate therapeutic anticoagulation. The average cost of each procedure done in the outpatient setting was £ 691. The average cost of unilateral day case EVRFA combined with phlebectomies done under general anesthesia was £ 1301.<sup>6</sup>

In this preliminary study, the procedure was performed in the operating room, recreating the same organization that would be found in an outpatient clinic. Thus, we studied the feasibility of the procedure without reducing patient safety.

The procedure was performed by one surgeon and three nurses without an anesthesiologist, perioperative nurse, or specific surgical instruments. We also analyzed potentially dangerous or challenging situations to carry out a correct procedure in all patients.

In one case, pain onset required a further dose of midazolam. In another case, the GSV was surgically cannulated. In yet another case, we had to convert the procedure to foam sclerotherapy with a long catheter owing to an anatomical complication<sup>8</sup> with good occlusion of the saphenous trunk after 7 months. In another case the GSV

was not cannulated for anatomical anomalies, and we performed a direct needle injection echo-guided foam sclerotherapy of the GSV.

And so, we can say that foam sclerotherapy is not only the treatment of tributary veins, but also the resolution of device problems.

The use of flavonoid drugs with oral micronized and purified Diosmin in these patients confirmed what we already knew from published literature<sup>10</sup> and our experience.<sup>8</sup> The patient's edema and discomfort after the procedure were reduced with the oral micronized, purified Diosmin, and hence, the use of pain killers was insignificant.

The results obtained by analyzing this small group of patients are quite similar to available data in literature.<sup>1-3</sup>

Periodic check-up revealed a reflux through an anterior lateral saphenous vein in one patient. We treated this accessory saphenous with a foam sclerotherapy session with 4 cc 3% STS mousse and achieved complete occlusion after 6 months.

After one month, follow-up revealed a long saphenous stump in one patient we check him periodically.

In six cases, the GSV occlusion was within 1 cm with occlusion of epigastric artery; thus, we prolonged enoxaparin for three weeks. I preferred to be careful and prolong the prophylaxis even if it was not a real DVT.

This small group of patients was considered sufficient to evaluate the safety of the outpatient clinic procedure. The reduction of costs between the two procedures performed in an operating room *versus* an outpatient clinic was modest (12.5%). The cost reduction was essentially due to the possibility of not having the anesthetist present, who was only available (Table II).

We can perform the endovascular procedure in an Outpatient Department not only to reduce costs but above all to allow the use of the operating room for patients with more serious pathologies.

## Conclusions

In conclusion, in selected patients with low operation risk, the radiofrequency thermoablation of the great saphenous vein with immediate foam sclerotherapy of superficial tributary veins can be performed even in the outpatient clinic (Hospital Department). The anesthesia was simple, and the pain was well controlled. There were no intraoperative complications that could not be resolved in the outpatient clinic setting. It is important for the patients to be well selected preoperatively in terms of both anatomical features and the type of great saphenous vein reflux and must have



a low operative risk. As an additional benefit, the reduction of costs between the two procedures performed in an operating room *versus* an outpatient clinic was 12.5%. We believe it is very important to perform these endovascular procedures (in selected outpatient patients) in an outpatient clinic to reserve the operating room for patients with more serious pathologies. The results of this preliminary study will need to be validated by analyzing a larger group of patients.

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*Conflicts of interest.*—The author certifies that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

*Authors' contributions.*—The author read and approved the final version of the manuscript.

*Acknowledgements.*—The author acknowledges Monica Callegaro (Operating room staff) for her help in data collection, Fabio Zorzetto (Management Control Office) for his help with data analysis, and Federico Orsini for his help with proofreading.

*History.*—Manuscript accepted: March 5, 2021. - Manuscript received: February 16, 2021.