Eur J Vasc Endovasc Surg (2019) 58, 244–248

Safety and Effectiveness of Endovenous Thermal Ablation for Incompetent Saphenous Veins with an Aneurysm Close to the Junction

Sterre A.S. Hamann [*], **Simone K. van der Velden, Marianne G.R. De Maeseneer**

Department of Dermatology, Erasmus MC, Erasmus University Rotterdam, Rotterdam, the Netherlands

WHAT THIS PAPER ADDS

This is the first study concentrating on the effectiveness and safety of endovenous thermal ablation (EVTA) of saphenous aneurysms close to the saphenofemoral or saphenopopliteal junction. With adequate application of tumescent anaesthesia, saphenous aneurysms can easily be treated with EVTA.

Objective: The aim was to evaluate the safety and effectiveness of endovenous thermal ablation (EVTA) with or without adding high ligation (HL) for the treatment of incompetent saphenous veins with an aneurysm (>20 mm for the great saphenous vein, >15 mm for the small saphenous vein) close to the junction.

Methods: This was a prospective observational cohort study in a single centre. All patients presenting with saphenous aneurysms close to the junction were included. Those with a venous aneurysm more distally, at >2 cm from the junction, or with associated deep venous aneurysms were excluded. Patients were treated with EVTA alone or combined with HL in cases of an aneurysm with a diameter >30 mm. Phlebectomies were performed during the same treatment session. Patients were followed up one and six weeks, and one year after treatment. Duplex ultrasound (DUS) was performed to evaluate occlusion of the vein and aneurysm as well as possible complications such as endovenous heat induced thrombosis (EHIT) or deep vein thrombosis (DVT). Venous clinical severity scores (VCSS) were registered before and one year after treatment.

Results: Thirteen patients (15 limbs) were included between February 2012 and January 2015. Eleven limbs were treated with EVTA alone, the remaining four limbs with EVTA and HL. No severe adverse events occurred (no EHIT, no DVT). After one year none of the aneurysms was still visible on DUS and the truncal obliteration rate was 80% (two partial, one segmental recanalisation). Both treatment strategies showed significant improvement of the VCSS at the one year follow up, from a median score of 6 (interquartile range [IQR] 5–7) to 2 (IQR 1–3) ($p = .001$).

Conclusion: EVTA with or without HL appeared to be a safe and effective treatment for patients presenting with incompetent saphenous veins with an aneurysm close to the junction.

Keywords: Venous insufficiency, Saphenous vein, Aneurysm, Ablation techniques, Varicose veins
Article history: Received 10 September 2018, Accepted 5 December 2018, Available online 29 May 2019

INTRODUCTION

Aneurysms of the great saphenous vein (GSV), anterior accessory saphenous vein (AASV), or small saphenous vein (SSV), also known as saphenous aneurysms, are rare and may be associated with symptoms and signs of chronic venous disease (CVD). Such aneurysms are larger in size than focal dilatations (defined as >1.5 times the diameter of the saphenous trunk).[1,2] According to Labropoulos *et al.*,[1] saphenous aneurysms have a diameter exceeding 20 mm for the GSV and 15 mm for the SSV. They are often situated close to the saphenofemoral or saphenopopliteal junction (SFJ or SPJ). Saphenous aneurysms may present as a soft tissue mass in the groin (Fig. 1) or popliteal fossa, or may be an incidental finding during duplex ultrasound (DUS) examination.[1,3,4]

One of the main problems of venous aneurysms is the increased risk of local thrombosis of the aneurysm[5,6] and subsequent venous thromboembolism, in particular if it is situated close to the SFJ or SPJ. Although the risk of pulmonary embolism (PE) is higher in patients with deep venous aneurysms, this has also been reported in patients with large saphenous aneurysms (with a diameter ≥30 mm).[5,7] Therefore it is important to evaluate the best and safest treatment options for these types of aneurysms. In the past, the only available treatment option consisted of high ligation (HL) and stripping. Nowadays classic surgery has largely been replaced by endovenous thermal ablation (EVTA), which is the treatment of choice for saphenous incompetence, according to

* Corresponding author. Department of Dermatology, Erasmus MC, Erasmus University Rotterdam, Dr. Molewaterplein 40, 3015 GD Rotterdam, the Netherlands.
E-mail address: s.hamann@erasmusmc.nl (Sterre A.S. Hamann).

https://doi.org/10.1016/j.ejvs.2018.12.007

Figure 1. Fifty-four year old woman presenting with chronic venous disease (right, C4a; left, C3) and prominent bilateral great saphenous vein aneurysms close to the saphenofemoral junction.

current guidelines and practice worldwide.[8–11] The question is whether EVTA can also be performed safely and effectively in the presence of a saphenous aneurysm close to the junction. Literature on saphenous aneurysms is scarce and mainly consists of case reports in which surgical treatment has been reported.[4–7,12] With the routine use of DUS, saphenous aneurysms seem to be diagnosed more often and hence the clinician may have to face this problem more frequently and have to decide on treatment options in these patients.[4,12]

For this reason it was decided to study a cohort of patients with saphenous aneurysms of the GSV, AASV, and SSV close to the junction who were treated with EVTA with or without additional HL. The primary objective of the study was to evaluate the safety of EVTA in these patients, looking at the rate of adverse events, mainly endovenous heat induced thrombosis (EHIT),[13] deep vein thrombosis (DVT), and PE. The secondary objective was to evaluate the effectiveness of EVTA in the case of pre-operative presence of such saphenous aneurysm close to the junction, including obliteration rate and improvement of the venous clinical severity score (VCSS).[14]

METHODS

This was a small prospective observational study of a selected cohort of patients investigated for symptomatic CVD because of superficial venous incompetence which either presented with a visible or palpable aneurysm in the groin or popliteal fossa, further confirmed by DUS, or in which a superficial venous aneurysm of the GSV, AASV, or SSV close to the junction was diagnosed on pre-operative DUS. The indication for EVTA treatment was based on a combination of symptoms, clinical signs of CVD, and DUS findings. Patients at a single centre (Erasmus MC, Rotterdam, The Netherlands) were included from February 2012 onwards and all data were entered in a database. Exclusion criteria were age younger than 18 years, pregnancy, extreme tortuosity of the saphenous trunk, and the presence of an aneurysm at >2 cm from the junction or associated deep venous aneurysms. The study protocol was approved by the Medical Ethics Committee (MEC-2016-017).

Pre-operative evaluation

Baseline demographics (age, sex), clinical class 'C' of the CEAP classification and VCSS were registered. All patients underwent a comprehensive DUS of the superficial and deep venous system in the standing position.[10] When there was any suspicion of deep venous post-thrombotic lesions, additional DUS was performed with the patient supine to verify normal patency of the deep veins, including the iliac veins. Reflux, defined as abnormally reversed flow in a saphenous trunk lasting >500 ms on calf compression—release or Valsalva, was registered in the GSV, AASV, or SSV and the inner diameter of the refluxing trunk was measured in a standardised way at mid-thigh, 15 cm from the SFJ for the GSV, at least five cm from the SFJ for the AASV, or at mid-calf for the SSV. When a large focal dilatation was present close to the SFJ or SPJ, the diameter was measured at this site (avoiding compression of the vein with the transducer), and if it was ≥ 20 mm for the GSV and AASV, or >15 mm for the SSV, it was considered a saphenous aneurysm.[1] If the aneurysm had an oval shape in transverse view, two diameters were measured (the smallest and the largest) and only the largest diameter was taken into account.

Procedure

After pre-operative marking of the saphenous trunk with DUS and indicating prominent varicosities on the skin, EVTA was performed either by means of endovenous laser ablation (EVLA), using a tulip tip fibre (Tobrix®) or radiofrequency ablation (RFA) with Venous Closure Fast (Medtronic®). The tip of the laser fibre or RFA catheter was positioned at 1—2 cm from the junction, which was usually in the actual aneurysm. Patients were treated with local tumescent anaesthesia only (consisting of 0.5 mg of epinephrine, 4.2 mg of bicarbonate and 350 mg of lidocaine diluted in 500 mL of saline 0.9% solution) without additional sedation. An extra amount of tumescent fluid was applied at the site of the aneurysm under ultrasound guidance to reduce the size of the aneurysm as much as possible. Extra laser or radiofrequency energy was applied at the site of the

aneurysm, 100 J/cm or three RF cycles respectively. For GSV or AASV treatment, patients were placed in the supine position and for SSV treatment in prone position.

The agreement in the department was to proceed to additional HL only in those cases where the aneurysm was situated near the SFJ with at least one of the measured diameters exceeding 30 mm. In these cases, after EVTA of the affected saphenous trunk, a classic flush HL was performed through a 3–4 cm long transverse incision in the skin crease of the groin under local tumescent anaesthesia. The aneurysm was carefully dissected free and the GSV was ligated with a non-absorbable suture (Mersilene 2.0) at the junction. The aneurysm was excised and the GSV trunk was then ligated distally with an absorbable suture (Vicryl 2.0).

Phlebectomies of varicose tributaries, also with tumescent anaesthesia, were performed during the same intervention. Wound dressings were fixed with an adhesive inelastic bandage (Elastomull Haft–BSN Medical®) and an elastic stocking with 15–20 mmHg ankle pressure on top. After the intervention patients were kept in the clinic for one or 2 h and then could leave the hospital after verifying there was no post-operative bleeding. They were instructed to mobilise as much as possible, and to resume normal activities one day after surgery. Thromboprophylaxis with low molecular weight heparin (LMWH) was only prescribed if indicated, in cases of a history of venous thromboembolism or superficial venous thrombosis (SVT).

In cases of bilateral saphenous aneurysms, limbs were operated with an interval of at least four weeks.

Follow up

Patients were asked to come back to the phlebology clinic after one and six weeks, and one year for clinical and DUS follow up. At the early visits (one and six weeks) patients were checked for symptomatic PE and EHIT at DUS of the junction and asymptomatic or symptomatic DVT. The EHIT classification was used as previously described: Class 1, thrombus visible to superficial to deep junction (SFJ or SPJ) but not extending into the deep venous system; Class 2, extension of thrombus into the deep venous system to less than 50% of the cross section; Class 3, extension of thrombus into the deep venous system to more than 50% of the cross section; Class 4, occlusive DVT of the common femoral or popliteal vein.[13] One year after the intervention VCSS was registered again and DUS was performed to check for post-operative disappearance of the aneurysm and obliteration of the treated saphenous trunk. Partial recanalisation was defined as the presence of a visible lumen, and segmental recanalisation as the reopening of a segment (at least five cm long) of the vein.

Statistical analysis

Owing to the small number of patients, median with interquartile range (IQR) was used to present continuous data. To test improvement of the VCSS before and after treatment, the Wilcoxon sign ranked test was used. All analyses were performed using IBM SPSS Statistics version 24 (IBM Corporation, Armonk, NY, USA).

RESULTS

The main demographic data and study findings are summarised in Table 1. During the study period, between February 2012 and January 2015, 14 patients were diagnosed with unilateral ($n = 11$) or bilateral ($n = 3$) saphenous aneurysm. One patient presenting during the study period with bilateral GSV aneurysms at the SFJ was excluded because he presented with multiple superficial and deep venous aneurysms that appeared to be related to hypereosinophilic syndrome. This exceptional case was published separately.[15] No other patients were excluded. Hence, 15 limbs with saphenous aneurysms in 13 patients were scheduled for EVTA. During this three year study period, a total of 540 EVTA procedures were performed, which results in a prevalence of saphenous aneurysms close to the junction of 2.8%. All saphenous aneurysms were situated close (0.5–2 cm) to the SFJ or SPJ. Thirteen were located close to the SFJ, 10 in the GSV and three in the AASV. Two were found in the SSV, both very close to the SPJ. In all limbs the affected saphenous trunk had reflux from the junction, including terminal valve incompetence. Preoperatively the median VCSS for all 15 limbs was six (IQR 5–7). Three patients (four limbs, all GSV) were treated with

Table 1. Characteristics of patients and limbs treated for incompetent GSV, AASV, or SSV with an aneurysm

Patients	13
Sex ratio – Female:Male	8:5
Median age – y (IQR)	53.0 (48.0–64.0)
Limbs	15
Side	
Left	12 (80)
Right	3 (20)
Clinical class	
C2 or C3	8 (53)
C4 or C5	7 (47)
Saphenous vein	
GSV	10 (67)
AASV	3 (20)
SSV	2 (13)
Median diameter of saphenous vein – mm (IQR)	9.3 (8.5–11.9)
Median diameter of aneurysm – mm (IQR)	22.6 (21.2–28.2)
Median length of treated vein segment – cm (IQR)	23 (16–36)
Type of device used for EVTA	
1470 nm laser	4
Median energy delivered – J/cm (IQR)	78 (70–91)
RFA	11
Median number of RF cycles (IQR)	7 (7–13)
Median VCSS at baseline (IQR)	6 (5–7)
Median VCSS at one year follow up (IQR)	2 (1–3)

Data are given as *n* (%) unless stated otherwise. AASV = anterior accessory saphenous vein; EVTA = endovenous thermal ablation; GSV = great saphenous vein; IQR = interquartile range; RF = radiofrequency; RFA = radiofrequency ablation; SSV = small saphenous vein; VCSS = venous clinical severity score.

combined EVTA (all RFA) and HL of the SFJ because of the large size of the aneurysm (diameter ≥30 mm). The largest diameter was 39.7 mm. Thromboprophylaxis was prescribed in two patients due to history of PE ($n = 1$) and SVT ($n = 1$). One patient had to be bridged with LMWH because of oral anticoagulants use (i.e., acenocoumarol).

At the early post-operative visits there were no patients with symptoms of PE, no cases of EHIT two, three or four (i.e., no thrombus bulging at the SFJ or extension into the common femoral vein) and no cases of DVT, confirmed by thorough DUS screening. Some patients temporarily felt a small, painless lump in the groin for a few weeks, which corresponded to the thrombosed aneurysm on DUS.

At one year follow up, achieved in all 13 patients, saphenous aneurysms were absent in the 15 limbs treated. The median VCSS had improved significantly in all limbs to two (IQR 1—3), with a median improvement of four points (IQR 2—6) and $p = .001$ Twelve of 15 treated saphenous trunks (80%) were completely obliterated after one year. In three limbs (3 patients) partial or segmental recanalisation with reflux in the treated vein occurred during the first year of follow up. One patient with an initial aneurysm of 3.16 × 2.50 cm and a GSV with a diameter of 1.53 cm treated with RFA and concomitant HL developed segmental recanalisation with GSV reflux just below the knee because of inflow from an incompetent perforating vein that had not been detected pre-operatively. This GSV segment was successfully treated with additional ultrasound guided foam sclerotherapy (UGFS) because of minor recurrent symptoms. A second patient who had an aneurysm of 2.12 × 1.71 cm and a GSV diameter of 1.25 cm developed partial recanalisation with reflux of the GSV and SFJ after initial treatment with RFA. Because of recurrent symptoms of heaviness, this patient underwent additional successful EVLA of the GSV after an interval of one year. In a third patient, who was initially treated with RFA of the SSV with a diameter of 1 cm and an aneurysm of 2 cm, recurrent partial SSV and SPJ reflux was detected on DUS 10 days and 11 months after treatment and this patient was treated with UGFS twice in view of minor complaints.

DISCUSSION

This small case series of patients presenting with a saphenous aneurysm close to the junction and an incompetent GSV, AASV, or SSV illustrates that EVTA, or EVTA with HL and aneurysm resection in the case of an aneurysm larger than 30 mm, offers a safe and efficacious treatment option. The prevalence of saphenous aneurysms close to the junction is unknown. In a recent report, Bush and Bush[16] found saphenous aneurysms of the GSV, AASV, or SSV in 18 of 330 patients evaluated for CVD (C2C6) over a two year period. Of these, 11 were situated close to the SFJ or SPJ, which represents a prevalence of 3.3% in patients suffering from C2C6 disease. This corresponds with the prevalence of 2.8% found in the present study.

In this case series, no major complications occurred and no patient developed post-operative venous thromboembolism. Moreover there were no cases of EHIT, even if the diameters of the involved saphenous trunks were all ≥8 mm, which has been considered a risk factor for developing EHIT after EVTA.[13,17] As mentioned previously, thromboprophylaxis (LMWH) was not routinely prescribed but only when there was a history of DVT/PE or SVT ($n = 2$) or for the purpose of bridging ($n = 1$). Hence this study cannot answer the question whether routine thromboprophylaxis with LMWH (or direct anticoagulants) should be advocated when treating patients with saphenous aneurysms close to the junction by means of EVTA. Nevertheless, this may be a wise strategy also for medicolegal reasons. In any case, patients had been encouraged to mobilise early and repeatedly, which is known to enhance natural fibrinolysis, in this way preventing thrombus extension from the previous aneurysm site through the junction. In the four limbs where HL with resection of the aneurysm had been added to EVTA, EHIT was obviously not an issue.

The effectiveness of EVTA alone and EVTA with HL, both with concomitant phlebectomies, was good with obvious improvement of the VCSS, conform to the available literature and recent meta-analysis.[18] Obliteration rates were somewhat inferior to what has been reported in randomised clinical trials. However, in this small series it is difficult to identify the cause of recanalisation. The diameters of the refluxing trunks were obviously larger than in most studies. In addition, development of a saphenous aneurysm usually points to severe venous hypertension and this may explain why ablation was not effective in all cases. In the present series, 47% of limbs indeed presented with skin changes (C4 or C5), which is much higher than in usual case series of patients suffering from CVD.

The decision to treat limbs, in which the size of the aneurysm exceeded 30 mm, with EVTA + HL instead of EVTA alone was taken arbitrarily, mainly on empirical grounds ("eminence based"), as there are no guidelines for handling these exceptional cases. Future studies will have to investigate whether this is indeed a good threshold for adding HL for these large aneurysms, and if confirmed, this could be integrated in a further revision of the existing guidelines, in which no particular strategy has been mentioned in the case of such large aneurysms.[10] The advantage of opening the groin (or popliteal fossa) is that the aneurysm can be completely excised, as such avoiding further complications because of thrombus formation in the aneurysm sac. The disadvantage of groin surgery may be an increased risk of wound infection, even if this did not occur in the present patient cohort.

Limitations

The main limitation of the present study is the small number of patients and limbs. Even though the study was performed in a tertiary referral centre in a department with special focus on complex venous disease, there were only 13 patients (15 limbs) with saphenous aneurysms. For this study, it had been decided to adhere strictly to the definition of saphenous aneurysm according to Labropoulos

et al.[1] and not to older definitions, which include all kinds of focal dilatations, >1.5 times the size of the saphenous trunk above or below it.[12]

As EVTA + HL was carried out only in a pre-defined, selected group of limbs, comparison between adding or not adding HL was not possible in the present study. Collaboration between different high volume centres, setting up a larger prospective study, would be needed to further unravel this issue.

CONCLUSION

In this small cohort of patients presenting with incompetent saphenous trunks and uni- or bilateral saphenous aneurysms, EVTA alone, or combined with HL and excision of the aneurysm, if its diameter exceeded 30 mm, appeared to be a safe and effective treatment.

CONFLICTS OF INTEREST

None.

FUNDING

None.

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