Original communication

Lower prevalence of stump reflux after endovenous laser flush ablation of the great saphenous vein

A single center prospective randomized study

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Summary: *Background:* This single center prospective randomized study was performed to compare the effect of endovenous laser flush ablation (EVLAf) of the great saphenous vein (GSV) close to the sapheno-femoral junction (SFJ) with a standard ablation (EVLAs) up to two cm distally of the SFJ on reflux in the GSV stump. *Patients and methods:* Between April 2013 and January 2016, 146 legs in 146 consecutive patients, meeting the inclusion/exclusion criteria, were treated by EVLA. All patients were randomized into 2 groups. In group 1 EVLAf started from the SFJ level, and in group 2 EVLAs started two cm below the SFJ. The primary endpoint was reflux in the GSV stump after 900 days. Secondary endpoints were reflux in the anterior accessory saphenous vein (AASV), proximal clinically recurrent varicose veins related to reflux in the stump and/or the AASV. *Results:* At day 900, 27 patients were lost to follow-up. Reflux in the stump was detected in 3.6% in group 1 and in 22.2% in group 2 ($p<0.05$). Reflux in the AASV was present in 7.1% in group 1 and in 17.46% in group 2 ($p=0.09$). Proximal clinically recurrent varicose veins were observed in 8.9% in group 1 and in 19.1% in group 2 ($p=0.12$). The greatest diameter of the stump was significantly larger in group 2 (group 1: 0.41 cm, group 2: 0.6 cm, $p<0.001$). *Conclusions:* EVLAf is associated with a significantly lower incidence of reflux in the GSV stump, with a trend to a lower incidence of reflux in the AASV and with a lower incidence of proximal recurrent varicose veins after 900 days follow-up compared to EVLAs. EVLAf may improve the clinical recurrence rate after EVLA of the GSV.

Keywords: Endovenous thermal ablation, flush ablation, stump reflux, great saphenous vein, anterior accessory saphenous vein

Introduction

Endovenous laser ablation (EVLA) is an effective method to treat incompetent great saphenous veins (GSV) [1, 2, 3]. Occlusion rates were demonstrated to reach about 95% after 1 year [1]. Despite good results for the occlusion rate, the role of the untreated proximal segment close to the sapheno-femoral junction (SFJ) on the development of reflux and recurrence after thermal ablation remains unclear [4, 5, 6, 7]. Higher rates of stump reflux after EVLA compared to high ligation and stripping have been reported [4, 5]. Flessenkämper demonstrated a significant higher incidence of reflux from the SFJ into the GSV after EVLA alone compared to high ligation and stripping (HL/S) and HL plus EVLA [4]. Rass et al reported 17.8% reflux in the GSV stump after EVLA and 1.3% after HL/S [5]. In consequence the authors reported a higher incidence of recurrent VV in the groin compared to HL/S after 5 years [5].

Modern laser fibers like the radially emitting fibers can reduce postoperative pain and improve results [8, 9]. A modified radial fiber (ELVeS Radial 2ring^{TM}, Biolitec) is emitting the laser energy in two separate rings radially around the tip. By this it is thought to have a more homogenous thermal effect on the venous wall leading to less pain and bruising after the procedure [10]. These fibers allow to ablate the GSV close to the SFJ and may achieve results comparable to high ligation [11]. With the 1-ring fiber a similar effect is possible with a linear energy density (LEED) which is a little bit higher at the junction with the deep vein. In this study we used the 2-ring fiber as we preferred a slightly reduced LEED at the tip to reduce the risk of

damage to the deep vein. The aim of this study was to demonstrate the influence of flush ablation at the level of the SFJ (EVLAf) compared to the standard ablation up to 2 cm distally of the SFJ (EVLAs) on the prevalence of reflux in the stump and in the anterior accessory saphenous vein (AASV) as well as on the development of proximal clinically recurrent varicose veins.

Patients and methods

Between April 2013 and January 2016, 146 legs in 146 patients, meeting the inclusion/exclusion criteria, attending the Dr. Maurins Vein Clinic in Riga, Latvia, where treated by EVLA for GSV incompetence in this single center unblinded prospective randomized study. Inclusion criteria were age 18 to 80 years, GSV reflux of more than 0,5 sec, length of the incompetent part of the GSV minimum of 25 cm, SFJ fits well 0 cm or 2 cm from the femoral vein for EVLA, CEAP classification C_{2S} – C_{5S}, E_P, A_S, $P_{R,}$ signed informed consent. Exclusion criteria were history of or acute deep or superficial venous thrombosis (DVT, SVT), incompetent AASV, superficial epigastric vein or other proximal varicose veins, any former vein treatment in the study leg, any planned interventions during the next 90 days, severe comorbidities or medical conditions that could influence the outcome of planned surgery, phlebotonic drugs one month before and during study duration.All patients agreed to be included in a prospective randomized study in accordance with the Declaration of Helsinki. We obtained permission from an independent ethics committee in Riga *(Ārstniecības līdzekļu klīnisko pētījumu Ētikas komiteja, Aizkraukles 21-113, Rīga, Latvija, LV – 1006).*

All patients were examined clinically and by duplex ultrasound according to a standardized protocol by one of six experienced phlebologists prior to the intervention (screening visit), on the day of the intervention (D0) and at follow-up visits at day 14 (D14), 90 (D90) and 900 (D900) after the procedure for side effects, complications, occlusion, reflux, and recurrences. No relevant differences could be found for the patient's general and technical data between the two groups at the time of the intervention (Table I).

Duplex was performed in the upright position (Imagic Agile, KONTRON MEDICAL). The standardized evaluation included the complete superficial and deep venous system. This included the exclusion of refluxing veins in the SFJ area. Flow was defined as being antegrade. Reflux was defined as retrograde flow of >0.5 sec duration after a semi-standardized Valsalva maneuver with manual control of correct pressure increase in the abdomen or manual compression and decompression of the distal vein. Pre- and postoperatively the entire treated vein and more extensively the sites 3 cm, 25 cm, 50 cm, and the point of puncture distally to the SFJ were assessed. Even a slight marginal flow or reflux in a largely occluded vein was assessed as not occluded. The entire deep venous system was checked before the procedure for postthrombotic changes or reflux and occlusion and during follow-up for deep venous thrombosis (DVT) and endothermal heat-induced thrombosis (EHIT) [12]. All participants were checked for clinical signs of pulmonary embolism. In the case of clinical suspicion, a pulmonary scan was possible. The clinical evaluation included the clinical classification (CEAP) [13]. The venous clinical severity score (VCSS), and the specific quality of life and outcome response – venous (SQOR-V) questionnaire were used to calculate QOL improvement. Patient data according to QOL were collected at D0, D90, and D900 visits [14, 15].

Randomization into the two groups was performed using sealed envelopes that were shuffled and opened by the patient in the operating room just before the intervention. There were two options for the patient to be in group 1 or group 2 and it was not possible to change the group after the selection. In the study each patient underwent only one intervention on one leg according to the study protocol. An ultrasound image of the fiber position in EVLAf with flush ablation (Figure 1A) and of the classical EVLAs (Figure 1B). No compression therapy was applied after study operation.

EVLA was performed with a 1470 nm Diode laser (Ceralas E, Biolitec). The entire procedure was performed under duplex guidance using cold (5°C) tumescent local anesthesia with 0.05% lidocaine [16]. No additional treatment like phlebectomy or sclerotherapy for insufficient tributaries was performed in the same session or during follow-up up until D90. GSV was accessed at the most distal insufficient point with a 17 gauge needle. The 600 µm Radial 2ring^{TM} fiber was introduced through a micro puncture set and the tip was positioned at the level of the SFJ or 2 cm below (Figures 1A and 1b). The positioning was monitored by duplex. The tumescent local anesthesia was then applied under duplex guidance. Laser treatment was carried out in a continuous mode with a power of 10 Watt. The average Laser Energy Equivalence Density (LEED) was 63.5±15.42 J/cm in group 1, 64.29±18.04 in group 2. The average Energy Fluence Equivalent (EFE) was 36.39 ±10.41 J/cm^2 in group 1 and 35.53±7.76 J/cm^2 in group 2.

The patients were mobilized immediately after the intervention. The NSAID Ibuprofen 400 mg, was prescribed to be taken in case of postoperative pain.

The primary outcome parameter was reflux in the SFJ stump after 900 days. Secondary endpoints were length of the GSV stump (Figures 2A and 2B), reflux in the AASV, proximal clinical recurrent varicose veins, occlusion rate of the GSV, C of CEAP, VCSS, SQOR-V improvement, pain, use of analgesics, time off work and/or return to normal activities and patient's satisfaction. Patient's satisfaction was assessed by a scale ranging from 0 to 4 points for the questions: "are you satisfied with the method being used?" (0=very satisfied, 1=satisfied, 2=fairly satisfied, 3=not satisfied, 4=extremely unsatisfied) and "would you choose laser op. again?" (0=yes, definitely, 1=yes, probably, 2=I don't know, 3=probably not, 4=definitely not). The incidence of deep venous thrombosis (DVT) and endovenous heat

Table I. Patient's general and technical treatment data at intervention (D0)

Parameter	Group 1	Group 2	p
Patients/GSV (n)	71	75	ns
Female (n)	64	63	ns
Right leg (n)	38	36	ns
Age mean±SD (range) (years)	50.8±14.07 (min 20, max 81)	51.34±15.88 (min 22, max 78)	ns
BMI mean±SD (range) (kg/cm^2)	26.79±4.92 (min 18.87, max 39.92)	27.41±5.63 (min 18.81, max 48.33)	ns
CEAP Clinical Class C			
C2 (CEAP) (n)	45 (63.4%)	36 (48%)	ns
C3 (CEAP) (n)	11 (15.5%)	19 (25%)	ns
C4 (CEAP) (n)	15 (21.2%)	20 (26.6%)	ns
C5/C6 (CEAP) (n)	0	0	
GSV diameter 3cm distally to SFJ mean±SD (mm)	.70±.26	.75±.31	ns
Treated GSV length mean±SD (cm)	56.9±11.2	56.97±10.69	ns
LEED mean±SD (J/cm)	63.5±15.42	64.29±18.04	ns
EFE mean±SD (J/cm^2)	36.39±10.41	35.53±7.76	ns

Notes. GSV: great saphenous vein; BMI: Body-Mass-Index; C: clinical class according to CEAP classification; SFJ: sapheno-femoral junction; LEED: linear endovenous energy density; EFE: endovenous fluence equivalent; min: lowest value; max: highest value; ns: difference not statistically significant.

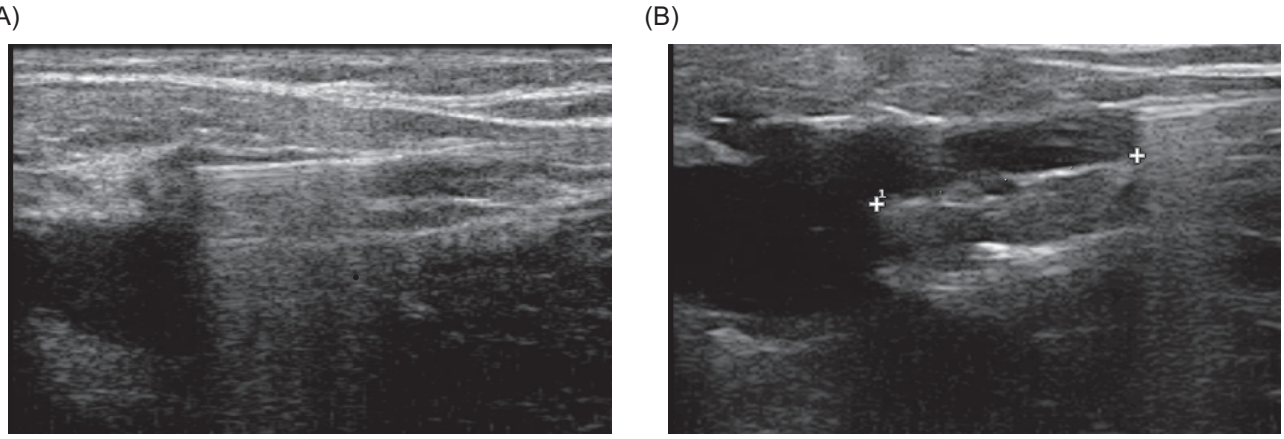


Figure 1. (A) Visual description of the fiber position in group 1 (tip of the fiber at the level of SFJ). (B) Visual description fiber position in group 2 (tip of the fiber 2 cm distally from the level of SFJ).

induced thrombosis (EHIT) as well as ecchymoses and other potential adverse events where recorded [17]. EHIT was defined according to the American Venous Forum recommendations [18]. For EVLAf EHIT stage 1 is not applicable as the goal of this treatment is occlusion of the GSV up to the junction.

Statistics

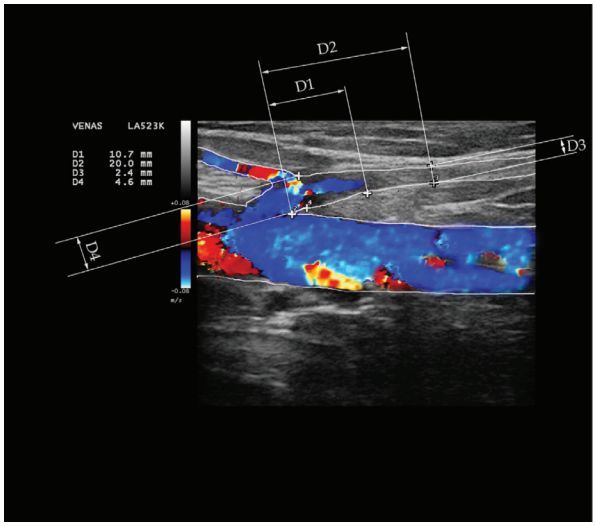
The primary endpoint of the study is reflux in the GSV stump. The incidence of stump reflux after EVLAs is likely to be close to 19% as demonstrated after EVLA or HL/S with persisting GSV stump [4, 5, 19]. The incidence of reflux after EVLAf is expected to decrease to below 5%. This would represent a clinically important improvement. Thus, the sample size has been calculated to test the null hypothesis that the proportion of reflux in the stump $\geq$5% against the alternative hypothesis the proportion of reflux in the stump <5% with a two-sided Mann-Whitney test. The sample size has been calculated at 80% power and 5% significance level, assuming a 20% dropout rate and equal sized treatment groups. The required total sample size was 144 patients.

Analysis was done by SPSS software (Version 24.0 IBM Company, Chicago, IL, USA). One way ANOVA test was used to assess difference between reflux after EVLAf (expected to be below 5%) and EVLAs (likely to be close to 19%).

Results

The patient's clinical and technical follow-up data is shown in Table II. Mean follow-up at D900 was 1183.2±473.1 days. Twenty-seven (18.49%) patients were lost to follow-up, 15 (21.13%) in group 1 and 12 (16.00%) in group 2. Patients were lost to follow-up mainly due to changes of contact phone number and/or contact address. A primary successful procedure was achieved for all enrolled patients. The initial occlusion rate was 100% and at D900 98.21% in

(A)



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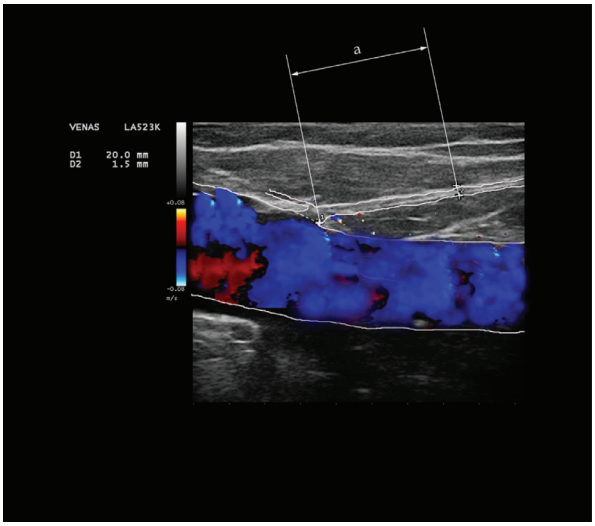

Figure 2. (A) Dupex image of the sapheno-femoral junction (SFJ) with measuring points at D900: D1 length of the stump, D2 the point 2 cm distally from the SFJ, D3 vein diameter 2 cm distally from the SFJ, D4 max. diameter of the stump. (B) Dupex image of the SFJ with measuring points at D900 if the occlusion is on the 0 level: D1 (A) the point 2 cm distally from the SFJ, D2 vein diameter 2 cm distally from the SFJ.

group 1 and 96.83% in group 2. No severe complications such as deep venous thrombosis (DVT), pulmonary embolism (PE), skin damage, infection, severe nerve damage or hematoma could be detected. Asymptomatic EHIT 2 was observed in one patient from group 1 at the D14 visit. The patient was treated with rivaroxaban 10 mg once daily for two weeks. The EHIT resolved completely and was not observed in future follow-up visits.

At D900 there was a statistically significant difference in the length (group 1: 8.04 mm, group 2: 15.03 mm; p<0.001; Figure 3 and Table III) and in the incidence of reflux (group 1: 3.56%; group 2: 22.22%; p<0.05) in the GSV stump (Table II). There was a trend for a higher incidence of reflux in the AASV in group 2 which did not reach statistical significance (group 1: 7.14%; group 2: 17.46%; p=0.09; Table II). There was a statistically significant difference according to the greatest diameter of the GSV stump (group 1: 3.65 mm; group 2: 6.05 mm; p<0.001) but no significant difference in the diameter of the GSV 3 cm below the SFJ (Table II).

The incidence of clinically visible proximal new VV at D 900 related to reflux in the GSV stump and/or the AASV appeared more often in group 2 but did not reach statistical significance (group 1: 8.93%; group 2: 19.05%; p=0.12; Figure 4).

At D900 there was no statistically significant difference in VCSS (Table III) and C class improvement of CEAP classification between the two groups at D900 (Table II).

The results from the SQOR-V patient's questionnaire did not show any differences between the two groups but showed a QOL improvement after treatment in both groups (Table IV).

Group 1 improved from 44.97 (±11.32) at D0 to 33.86 (±9.61) at D90 (p<0.001) and to 36.85 (±13.64) at D900 (p=0.004). Group 2 improved from 46.01 (±12.69) at D0 to 34.79 (±10.08) at D90 (p<0.001) and to 33.59 (±10.42) at D900 (p<0.001). There are no statistically significant differences between group 1 and group 2 at D0 (p=0.725), D90 (p=0.685) and D900 (p=0.296).

Characteristics of pain and the use of painkillers did no differ significantly between the groups. 76% of patients did not take any painkiller at any time after the procedure. There was no relevant difference between the two groups according to satisfaction with treatment at any time point or on the question if the method would be chosen again (Table II).

Additional treatment (sclerotherapy) from D90 to D900 were performed in both groups (Table II), and there was no significant difference comparing both groups.

Discussion

Recent randomized controlled studies have demonstrated that 5 years after treatment of the incompetent GSV the incidence of clinical recurrent varicose veins is similar after high ligation and stripping (HL+S) or EVLA [4, 5, 20]. However, the nature of the recurrence often differs. After HL+S there is more often neovascularization but after EVLA stump reflux and AASV incompetence plays a more important role [3, 4, 5, 21, 22].

The role of a residual GSV stump after HL+S for inguinal varicose vein recurrence has been demonstrated already [23]. Using bare fibers for EVLA the distance of the fiber tip to the deep vein was suggested to be about 2 cm to avoid damage to the femoral vein. This caused a GSV stump left over after the procedure with a high rate of residual or recurrent reflux [4, 21, 24]. Disselhoff compared EVLA of the GSV with and without high ligation and could not demonstrate significant differences in recurrent varicose veins after 5 years [5]. Flessenkämper compared HL/S, EVLA and HL/EVLA and found more GSV stump reflux

Table II. Clinical and technical results after EVLA at follow-up

Parameter ($D_{follow-up}$)	Group 1	Group 2	p
Patients/GSV (n) (D900)	56	63	ns
Lost to follow-up (n) (D900)	15	12	ns
Female gender (n) (D900)	51	51	ns
Right leg treated (n) (D900)	29	29	ns
Reflux GSV stump (n/%) (D900)	2 (3.56%)	14 (22.22%)	=.003
Reflux AASV (n/%) (D900)	4 (7.14%)	11 (17.46%)	=.09
Proximal recurrent VV (n/%) (D900)	5 (8.93%)	12 (19.05%)	=.12
GSV occlusion rate (n/%) (D900)	55 (98.21%)	61 (96.83%)	ns
C2 (CEAP) (D0/D900)	45/19	36/21	ns
C3 (CEAP) (D0/D900)	11/3	19/4	ns
C4 (CEAP) (D0/D900)	15/2	20/4	ns
C5/6 (CEAP) (D0/D900)	0/0	0/0	ns
Greatest diameter of the GSV stump (mm) mean±SD (D900)	3.65±2.15	6.05±1.95	<.001
GSV diameter 3 cm distally to SFJ (mm) mean±SD (D900)	.31±.16	.34±.12	ns
Length of the GSV stump (mm) mean±SD (D900)	8.04±7.08	15.03±6.75	<.001
Mean pain score ±SD (D14)	.74±1.08	.94±1.11	ns
Use of analgesic tablets ±SD (D14)	.99±2.6	1.11±3.07	ns
Time-off work ±SD (D14)	.91±1.5	.97±1.3	ns
Return to normal activity ±SD (D14)	.6±.8	.6±.6	ns
DVT (D14)	0	0	ns
EHIT 2-4 (D14)	1	0	ns
Ecchymoses (D14)	18 (25.4%)	14 (18.7%)	.310
Other AE (D14)	0	0	ns
Additional VV therapy D90 to D900	8 (14.3%)	7 (11.1%)	ns
Satisfaction with treatment D900			
Very satisfied	37 (66.1%)	40 (63.5%)	ns
Satisfied	15 (26.8%)	21 (33.3%)	ns
Fairly satisfied	4 (7.1%)	1 (1.6%)	ns
Not satisfied	0	1 (1.6%)	ns
Would you choose laser op. again with current experience D900?			
Definitely	39 (69.6%)	40 (63.5%)	ns
Possibly yes	12 (21.4%)	22 (34.9%)	ns
Not sure	3 (5.4%)	1 (1.6%)	ns
Rather no	2 (3.6%)	0	ns
Never	0	0	ns

Notes. GSV: great saphenous vein; AASV: anterior accessory saphenous vein; n: number of patients; D0: day of the intervention; D900: day 900 after the intervention; VV: varicose veins; C: clinical class according to CEAP classification; SFJ: sapheno-femoral junction; DVT: deep vein thrombosis; EHIT: endovenous heat-induced thrombosis; AE: adverse event; ns: difference not statistically significant.

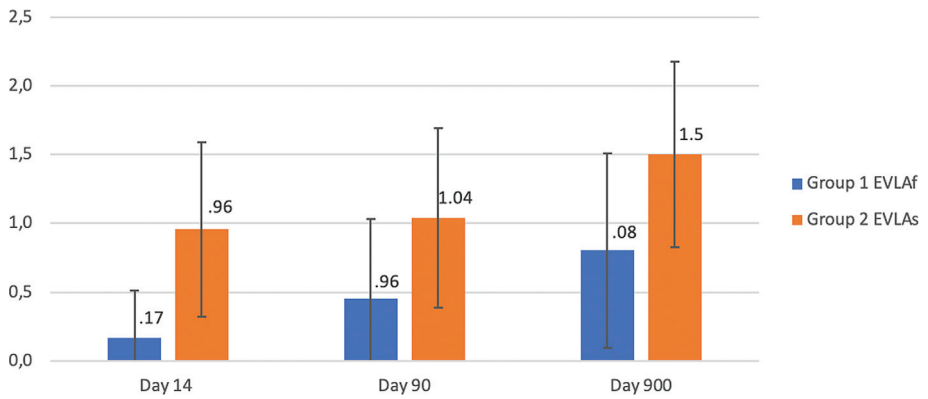

Figure 3. Length of the GSV stump after EVLA (EVLAf: endovenous laser ablation flush, EVLAs: endovenous laser ablation standard).

Table III. VCSS improvement (mean±SD)

$D_{follow-up}$	Group 1	Group 2	p
D0	3.92±2.38	5.54±3.38	.001
D90	1.10±1.76	1.43±1.83	ns
D900	1.89±2.14	1.86±1.87	ns

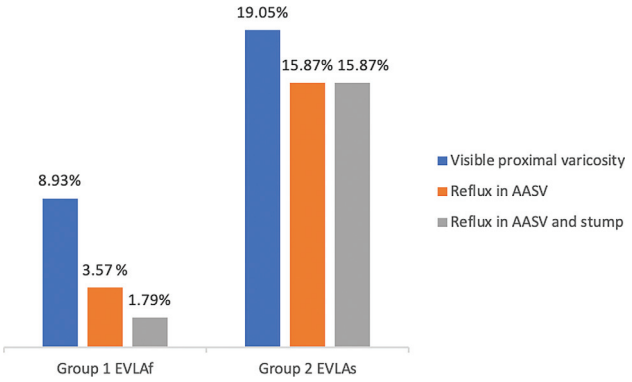

Figure 4. Proximal varicosity and reflux at SFJ day 900.

and more reflux from the SFJ into side branches in the EVLA group compared to EVLA with additional HL [4]. With new radial emitting fibers, a closer approach to the deep vein seems more applicable.

In our study we could demonstrate that a flush ablation of the GSV using a 2-ring radial fiber is safe and applicable with no higher rate of adverse events compared to the standard position 2 cm below the junction. During follow-up some recanalization of the proximal GSV may occur after EVLAf but the length of the stump and the incidence of reflux in the GSV stump remains significantly lower after flush ablation compared to EVLAs. In our study this is related to a higher incidence of proximal clinical recurrent varicose veins after EVLAs compared to EVLAf. In a retrospective study Bihari and co-workers could demonstrate beneficial results one year after flush closure of the SFJ by EVLA [25]. Incompetent AASV was present in 1.2%. In a single-center, retrospective analysis of 113 patients who underwent a flush closure of the GSV by EVLA using a radial fiber Spinedi et al. could demonstrate that the method was feasible and safe [26]. EHIT 2 appeared only in one case. Our study confirms that it is safe and effective to ablate GSV up to the SFJ level without a higher rate of complications. Flush occlusion rate was 95.3% at day 10 and 88.2% after 6 weeks.

As demonstrated in previous studies stump reflux does not influence the improvement of quality of life, clinical severity or patient's satisfaction for up to 5 years [4, 5, 20]. In our study EVLAf of the GSV showed the same patient reported outcome at D900 as after EVLAs.

Limitations

The limitations of our study are the relatively small number of patients and the limited follow up time. The reflux duration was measured by a semi-standardized Valsalva and compression-decompression maneuver and not in a completely standardized way by using additional tools. None of the participants in the study showed clinical signs of pulmonary embolism and therefore we did not perform additional pulmonary scans.

Table IV. SQOR-V improvement (mean±SD)

$D_{follow-up}$	Group 1	Group 2	p
D0	44.97±11.32	46.01±12.69	ns
D90	33.86±9.61	34.79±10.08	ns
D900	36.85±13.64	33.59±10.42	ns

Conclusions

Flush ablation of the incompetent GSV by EVLAf using a 2-ring radial fiber is associated with significantly less GSV stump reflux after 900 days compared to the ablation 2 cm below the SFJ. A trend towards a higher incidence of reflux in the AASV and proximal clinical recurrent VV after EVLAS did not reach statistical significance. Flush ablation was safe and effective in our study with no higher rate of adverse events. There is no significant difference between the two groups according to VCSS, SQOR-V or CEAP improvement, pain, use of analgesics and patient's satisfaction.

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