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CLINICAL STUDY

A comparative study of 1,470-nm endovenous laser ablation and segmental radiofrequency ablation in the treatment of saphenous veins insufficiency

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ABSTRACT

BACKGROUND: Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are safe and minimally invasive techniques used in the treatment of saphenous veins insufficiency. We compare a 1,470-nm EVLA and RFA in the treatment of patients with insufficiency of the great or small saphenous vein.

MATERIAL AND METHODS: Six hundred and twenty-six consecutive patients presenting to our department with insufficiency of the great or small saphenous vein and treated between January 2017 and January 2020 were included in the study. The randomly selected 301 patients (group 1) received 1,470-nm EVLA and the other 325 patients (group 2) received RAF. Patients were assessed on the second day after the procedure, two and six months after procedure and then semiannually (not included in the study). Major and minor complications were recorded as well as VCSS.

RESULTS: There was no difference between groups as to inclusion criteria as age, diameter of GSV and SSV, predominance of extremity and diameter of the treated vein. Also, clinical stages of CVI in both groups were similar and without statistical significance. VCSS was similar, however at 6 months after the procedure the inter-group difference in VCSS became clinically significant. In terms of the comparison of procedural pain and pain relief on the first postoperative day, the statistical level of difference was less than 0.05. The operative time was shorter in patients from group 1 with statistical significance, but the quantity of tumescent solution and length of GSV was also statistically lower than in group 2. Minor complications in EVLA and RFA were ecchymosis which occurred in 23.6 % of patients in group 1 and 33.8 % of patients from the RFA group, and local puncture inguinal hematoma with spontaneous resolution in 2 weeks, which occurred in 1% of patients in both groups. The frequency of all minor complications was similar in both groups. One months after the procedure, one patient from EVLA group was admitted to the hospital with signs of pulmonary embolism and thrombosis of VFC. The return to normal daily activity was similar in both groups, it took place on the next day after the procedure. The return to work took place earlier in RFA patients *(Tab. 5, Fig. 2, Ref. 19)*. Text in PDF *www.elis.sk*

KEY WORDS: radiofrequency ablation, endovenous laser ablation, tumescence, great saphenous vein, short saphenous vein, endovenous heat-induced thrombosis.

Abbreviations: CVI – chronic venous insufficiency, GSV– great saphenous vein, SSV – short saphenous vein, VFC – common femoral vein, VCSS – Vein clinical severity score, EVLA – endovenous laser ablation, RFA – radiofrequency ablation, US – ultrasound, LMWH – low molecular weight heparin, RCT – randomized controlled trial, CEAP – classification system of CVI, SF – sapheno-femoral

Introduction

In the last decade, endovenous ablation procedures have become a frequently used therapy for saphenous varicose veins. The endovenous thermal ablation techniques currently available are endovenous laser ablation, radiofrequency ablation and endovenous steam ablation. All endovenous techniques act by destroying the inner lining of the vein or intima allowing the vein to seal off and turn into fibrous tissue which is gradually removed by the body. Endovenous procedures are recommended for the great saphenous vein, short saphenous vein, accessory saphenous veins, Giacomini vein, cranial extension of the short saphenous vein, other superficial veins situated in the subcutaneous tissue, insufficient perforating veins, residual intrafascial veins after previous treatment and some of venous malformations. Absolute contraindications of endovenous procedures are acute deep vein thrombosis, acute superficial phlebitis, acute infections at the puncture sites and deep venous obstruction in case that the vein to be treated is a functional collateral. Relative contraindications are immobility or state close to being non-ambulatory, significant peripheral arterial disease with the ankle-brachial index being lower than 0.5, pregnancy, elevated

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thromboembolic risk (thromboprophylaxis should be considered in such case), significant uncompensated leg edema that cannot be adequately monitored by ultrasound for thrombosis, and allergy to local anesthetics (tumescence without local agent or another agent should be used in such case). Relative contraindications from the local point of view are tortuous veins difficult to catheterize, diameter of the vein at the accessing segment <3 mm, partly occluded venous segment and vein segment to be treated being shorter than it is necessary for catheter placement.

For tumescent (or heat) methods, it is inevitable to inject the anesthetic locally with the physiologic solution around and along the vein (so-called tumescence) by using ultrasound imaging.

Material and methods

Six hundred and twenty-six consecutive patients presenting to our department with insufficiency of great or small saphenous vein treated between January 2017 and January 2020 were included in the study. The randomly selected 301 patients (group 1) received 1,470-nm EVLA and the other 325 patients (group 2) received RAF. Patients were assessed on the second day after the procedure, two and six months after the procedure and then semiannually (not included in the study). Major and minor complications were recorded as well as VCSS.

For EVLA procedure, we used 1,470-nm wave-length system from Biolitec, Germany (Fig. 1). For the purpose of this study, we treated all patients with one-ring catheter and this radial fiber reflects the laser beam by means of a prism and the laser energy is emitted in a 360-degree manner, thus allowing a homogenous irradiation of the vein wall and making it possible to prevent perforation.

For RFA procedure, we used VNUS ClosureFast System, Medtronic, USA (Fig. 2). Segmental RFA has a 7-cm therapeutic distal segment that heats to 120 °C. Alike endovenous laser therapy, perivenous tumescent anesthesia is applied to optimize the surface contact and to decrease pain and risk of dysesthesia.

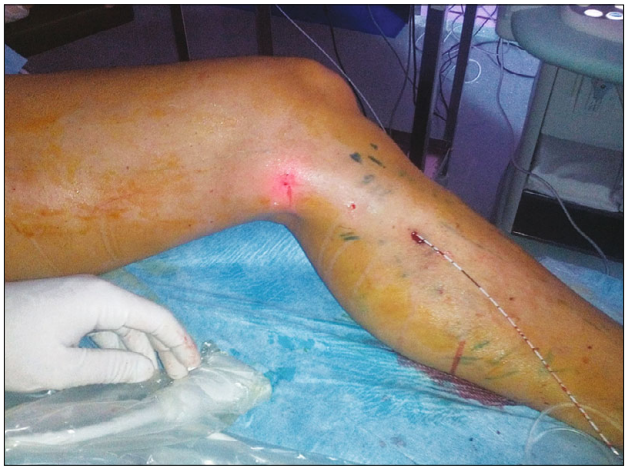

Fig. 1. EVLA 1,470-nm catheter just before the completion of the procedure (lights indicate the tip of catheter, sheath already pulled out)

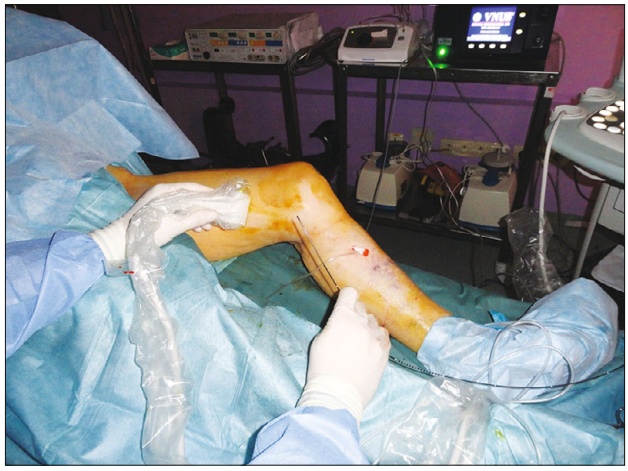

Fig. 2. Just prior Radiofrequency catheter insertion (sheath inserted inside the GSV).

Both groups of patients were similar as to age, GSV and SSV diameter, predominance of extremities, and reflux time (Tab. 1). Both groups of patients are similar also from the point of clinical (C) stage of CEAP classification of CVI. Total operating time, i.e, time from puncturing the vein to applying compression bandages, was similar in both groups (Tab. 2). This total time includes also the treatment of the collateral system that we performed in one stage procedure. In addition to ablation of the main vein, it consists also surgical extirpation of arched superficial veins and foam sclerotherapy of collaterals. Net operating time, i.e, time of the ablation of a truncal or main straightforward vein was significantly shorter in the EVLA group.

Tab. 1. Inclusion criteria of patients.

	EVLA	RFA	p
Age /years)	47.5±23.6	42.7±19.6	NS
GSV diameter (mm)	11.5±4.6	10.9±5.1	NS
SSV diameter (mm)	8.9±3.1	9.0±4.0	NS
Extremities (right)	165	154	NS
Reflux time (s)	4.27±1.8	5.2±2.4	NS

Tab. 2. Duration of procedures and consumption of solution.

	EVLA (12,5W, 75J)	RFA	p
Net operative time (min)	6.3±2.3	9.8±4.6	<0.001
Total operative time (min)	23.7±12.7	31±14.6	NS
Tumescent solution(ml)	245±52	296±62	<0.001
GSV length (mm)	36±12	43±14.7	<0.001
SSV length (mm)	14±5.6	12±4.6	NS

Tab. 3. VCSS and pain score.

	EVLA	RFA	p
VCSS			
Preoperative	16.9±2.6	15.9±2.9	NS
Postoperative (2nd month)	13.8±1.9	13.6±2.1	NS
Postoperative /6th month	11.9±0.7	12.1±1.1	<0.001
Pain			
Periprocedural	3.9±1.1	3.8±2.0	NS
1st postoperative day	2.1±1.9	2.5±1.7	NS

Tab. 4. Amounts of minor complications.

%, patients	EVLA	RFA	p
Ecchymosis	23.2% (77)	33.8% (104)	NS
Oedema	33.1% (110)	42.3% (130)	NS
Paresthesia	3% (10)	6% (19)	NS
Burns	0% (0)	0% (1)	NS
Hematoma	1% (3)	1% (4)	NS

VCSS score in our groups of patients was similar in both groups however the statistically significant difference between both groups appeared 6 months after the procedure. We regularly checkup all patients on the first day after the procedure, then 2 months and 6 months after the procedure (Tab. 3). When comparing VCSS results between each checkup, there was a significant waning of clinical difficulties ($p < 0.01$). Periprocedural pain and day 1 postprocedural pain relief were also significant in both groups of patients ($p < 0.05$).

Minor complications, hematoma and bruising were similarly present in our patients from both groups, albeit without statistically significant differences (Tab. 4). We did not have any wound infections in our group of patients.

Discussion

Varicose veins are a disease which significantly affects the quality of life wherefore different approaches have been applied to treat this condition in recent years. Ligation and stripping of great and short saphenous veins were for long years the most frequently used procedure in the treatment of saphenous insufficiency. First thermal endovenous procedure was published by Navaro in 2001 and since then a lot of other techniques were described. To date, five RCTs conducted in USA and UK/Europe and associated with compression in all groups reported comparisons of EVLA and RFA. A majority of patients had a baseline CEAP class C2–C3 and two C3–C4 (1, 2, 3). In the final RCT class, CEAP was not reported (4,14). One fair-quality observational study reported a comparison of EVLA and RFA with 979 patients. (5) The average age of the patients was 53.2 years, with female predominance of 74 % and with baseline CEAP class of C2–C3. One poor-quality observational study reported a comparison of EVLA and RFA (6, 13). This study involved 36,096 patients and was conducted in 84 centers in Germany/Europe on patients with average age of 52.8 years, female proportion of 69 %, CEAP baseline class C2 and without racial and ethnic composition of study population.

It is clear from Table 2 that also the length of GSV was shorter in comparison to RFA group. This length disproportion can explain the longer net operating time in the RFA group and higher average consumption of tumescent solution. Even though SSV was a little bit longer in the EVLA group, the difference was not significant and this disproportion influenced neither the net operating time nor the tumescent solution consumption. The consumption of the solution is higher in more dilatated veins to ensure good contact of the catheter with the vein wall. In both groups of patients the diameter of the vein is similar and does not influence the consumption of the solution.

Four of above mentioned RCT studies presented VCSS data following EVLA and RFA. One poor-quality study reported day 2 and month 1 VCSS data with the inter-group difference at 2 days being statistically significant (7, 11). One fair-quality study reported changes in VCSS at week 1, month 1 and year 1. There was a statistically significant difference between the groups at week 1. One-good quality observational study presented the mean change in VCSS at year 3, with a statistically significant difference in favor of EVLA group (5, 15). One fair-quality study reported patients with CEAP score ≥ C3 (8, 16). There was a statistically significant difference between the groups at year 1, but there was no difference in CEAP improvement between the groups during the follow-up.

One-good quality RCT and one fair-quality observational study reported on patients with the presence of hematoma and wound infection. In the RCT study, 2 patients in the EVLA group had hematoma (0 in RFA group) and the numbers of wound infection in EVLA and RFA groups were 2 and 4, respectively (1, 2). The observational study reported 45 hematomas in the EVLA group and 55 hematomas in the RFA group with a statistical significance in favor of RFA group (5). One fair-quality RCT study reported on patients with bruising at week 1 and month 1. There was significantly more bruising in EVLA group at week 1 and the inter-group difference at month 1 was not statistically significant (8, 10).

Three RCTs reported on patients with venous thromboembolic events (3, 7, 8). In all studies, one patient presented with DVT in the EVLA group. One good-quality RCT reported that 1 patient presented with PE in the RFA group (1, 2, 12). A fair-quality observational study reported venous thromboembolic events for each group (5, 17). There were six cases of deep venous thrombosis in the RFA group and 19 in the EVLA group with one case of PE in EVLA group. The observational study also reported the presence of EHIT in 26 patients in the EVLA group and in 10 patients in the RFA group, but without statistically significant difference between the groups (5, 18). The same study reported on superficial venous thrombosis with statistically significant difference between the groups in favor of the RFA group (19). In our study, we noticed one pulmonary embolism with deep vein thrombosis. The patient with the signs of pulmonary embolism was admitted to the hospital one month after the procedure. We found thrombosis of VFC which was partially occluded. This was the result of EHIT, type III (Tab. 5). Therapeutic LMWH was initialised with total dissolving of the thrombus. During hospitalization, Leiden V thrombophilia was diagnosed by blood examination, and after LMWH therapy, maintenance treatment with antithrombotics was continued. Patient is regu-

Tab. 5. Types of EHIT.

Type	Localisation
I	Venous thrombosis to superficial deep junction, not extending into deep system
II	Non-occlusive venous thrombosis extending into the deep venous system, but in cross sectional area less than 50 %
III	Non-occlusive venous thrombosis extending into the deep venous system, in cross sectional area more than 50 %
IV	Occlusive deep venous thrombosis of femoral or popliteal vein

larly checked and currently is healthy with no other symptoms of the disease. Other possible complications include nerve injuries, bruising/hematoma, skin burns, superficial and deep venous thrombosis.

Apart from minor limitations caused by bandages and postprocedural discomfort, the full return to daily activity was reported to take place on the next day after the procedure, i.e, after the first postprocedural follow-up of patients at the out-patient clinic. The return to work took place significantly sooner in the RFA group. After the interviews with patients, we believe that this was affected by their occupational status and social system in our country, and that it was not influenced by the ablation method.

In our opinion, both methods are applicable in patients with insufficiency of truncal veins. In recurrent venous insufficiency, both catheters are very practical to treat insufficiency of the main insufficient, straightforward vein with suitable diameter and length and additional procedures on the collateral venous system. We prefer EVLA catheter in patients with short insufficient stumps after previous procedures on SF junctions and for acute-angled (kinking) veins less than 10 cm away from the SF junction point. This proximity of SF junction kinking is unsuitable for RFA catheter which should be tucked minimally 10 cm under the skin and in the vein.

Endovenous thermal ablation methods are minimally invasive interventions serving as an alternative to vein stripping in the treatment of varicose veins and their common underlying cause, i.e, venous reflux. As compared to traditional procedures, they offer the patients effective results with less pain and bleeding, and earlier recovery. This procedure can be performed for cosmetic or medical purposes, depending on each patient's individual condition and goals for the treatment.

Recommendation for practice

Endovenous techniques in the treatment of saphenous veins incompetence have become very popular as a minimally invasive alternative to classical surgery. For the treatment of GSV reflux in patients with symptoms and signs of CVI, endovenous thermal ablation techniques are recommended in preference to surgery by European Society for Vascular Surgery; GRADE IA (9). An American college of phlebology recommends treating insufficiency of GSV, SSV and accessory saphenous veins by the endovenous thermal ablation method as a preferred treatment. Open surgery is appropriate in veins not amenable by endovenous methods GRADE 1B (10). Endovenous heat treatment methods represent an effective treatment of the varicose reflux while being less invasive and slightly more effective as compared to conventional surgical methods.

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