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Original Article

Great saphenous varicose vein treatment with endovenous ablation techniques: A comparison of EVLA and RF

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Abstract

Aim: In this study, we compared the clinical follow-up results and complication and success rates of patients undergoing 1470 nm wavelength endovenous laser ablation (EVLA) or radiofrequency ablation (RFA) in our clinic.

Material and Methods: The records of 581 patients treated in our clinic due to clinical symptoms arising from great saphenous vein insufficiency between January 2014 and September 2018 were examined retrospectively. Three hundred fifty-seven of these patients treated with EVLA or RFA and with no deficient data were included in the study. Patients with reflux in the saphenofemoral junction lasting at least 0.5 sec, with a great saphenous vein diameter of at least 7 mm, 2 cm distal to the saphenofemoral junction, and of at least 5.5 mm at knee level, and with CEAP stage C2-C5 were scheduled for endovenous ablation. The patients were randomly distributed between the established EVLA and RFA treatment groups. Data for patients' diagnostic and therapeutic processes were recorded and evaluated in the light of information in the literature.

Results: The EVLA group consisted of 86 patients (42 male, 44 female; mean age 46 years, range 26-71), and the RFA group of 271 (113 male, 158 female; mean age 43.3 years; range 20-77). The mean follow-up time was 27.2 months. No significant differences were determined in terms of patients' demographic data, preoperative additional diagnoses, CEAP classification values, duration of reflux, or proximal and distal great saphenous vein diameter values. Thrombophlebitis developed in 14 patients and ecchymosis/hematoma in 32. No significant difference was observed between the groups in terms of complications. Great saphenous vein occlusion rates at Doppler ultrasonography six months after treatment were 91.8% in the EVLA group and 94% in the RFA group (p=0.46).

Conclusion: Our results suggest that neither of the two endovenous ablation methods is superior to the other.

Keywords: Laser ablation; radiofrequency ablation; venous insufficiency

INTRODUCTION

Chronic venous insufficiency (CVI) is a widespread, important health problem resulting in high costs due to manpower losses and severely reducing patients' quality of life. CVI adversely affects the quality of life of approximately 20-40% of individuals (1,2). Varicose veins in the great saphenous vein (GSV) and its branches, associated with clinical symptoms such as pain and restlessness, and with cosmetic problems, are frequently associated with underlying CVI (2,3).

Until recently, the traditional treatment of CVI consisted of ligation alone of the GSV or stripping with ligation and removal of varicose packs. Recently developed minimally invasive endovenous thermal ablation (EVTA) methods that have since become widely employed are based on the principle of occlusion of the GSV with thermal energy (1,3). These less traumatic and shorter procedures have the advantages of early mobilization and return to daily life, high patient comfort, and low complication rates (1-5). Two main EVTA methods are currently applied; endovenous laser ablation (EVLA) and radiofrequency ablation (RFA). However, the current guidelines make no indication which method should be preferred. Although numerous studies have compared the effectiveness of these two methods, it is still unclear whether or not EVLA is superior to RFA (6). The purpose of this study is to contribute to the literature by comparing the clinical results of patients undergoing 1470 nm wavelength EVLA or RFA in our clinic.

MATERIAL and METHODS

Study design

Approval was granted by our hospital's local ethical committee (no. 40986104-799), and the study was planned to comply with the principles of the Declaration of Helsinki. The records of 581 patients treated in our clinic due to clinical symptoms arising from GSV insufficiency between January 2014 and September 2018

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were examined retrospectively. Three hundred fifty-seven of these patients treated with EVLA or RFA and with no missing data were included in the study. All patients with symptomatic complaints such as burning sensations in the legs, cramp or cosmetic concerns due to varicose packs, were evaluated before surgery by a specialist radiologist using Doppler ultrasonography (DUSG) in terms of presence and duration of reflux in the GSV and proximal and distal GSV diameters. Patients evaluated in the clinic were classified based on the Clinical, Etiological, Anatomic, and Pathophysiological (CEAP) classification. Patients with reflux in the saphenofemoral junction lasting at least 0.5 sec, with a GSV diameter of at least 7 mm 2 cm distal to the saphenofemoral junction, and of at least 5.5 mm at knee level, and with no contraindication for ablation such as elongation or dilatation etc. along the track of the GSV above the knee, and with CEAP stage C2-C5 were scheduled for endovenous ablation. The type of treatment to be applied was based on the preference of the surgeon. Patients meeting the specified criteria were included in the study and were randomly distributed between the treatment groups. Two groups, EVLA and RFA, were thus established. Patients' demographic data, preoperative additional diagnoses, pre- and post-treatment DUSG findings, CEAP classification data, complication data, and follow-up durations were recorded and compared for statistical significance between the groups. Obesity was defined as a body mass index greater than 30.

Operative technique

Before the operation, the varicose veins were evaluated and marked with indelible ink with the patient in a standing position. All procedures were performed under operating room conditions. Twenty-one patients (5.8%) received general anesthesia by laryngeal mask airway insertion, either at the recommendation of the anesthetist or due to reluctance to undergo spinal anesthesia, while all the remaining patients underwent spinal anesthesia. In patients undergoing EVLA (Biolas, Ankara, Turkey), the GSV was first cannulated using the Seldinger technique at the medial level with DUSG guidance, after which a 7F sheath was installed. A radial laser catheter was then advanced through the sheath, the tip being inserted such as to emerge 2 cm distal to the saphenofemoral junction. Next, tumescent local anesthesia was prepared with the addition to 1000 mL cold 0.9% isotonic solution of 40 mL 8.4% sodium bicarbonate, 1 mg adrenalin, and 10 mL 2% lidocaine. This was then applied, with DUSG guidance, around the GSV using a 19-21G needle. The installed 1470 nm radial laser catheter was then retracted at a speed of 2 cm/sec, and 15W and 60-120 J/cm energy was applied to the saphenous vein. Compression was applied along the track of the GSV throughout EVLA. In case of patients undergoing RFA (Closure FAST, Covidien, Mansfield MA, USA), the tip of the RFA catheter was similarly advanced through a 7F sheath advanced inserted in the GSV at medial knee level such as to emerge 2 cm distal to the saphenofemoral junction. Tumescent local anesthesia prepared in the same manner was then applied around the GSV. RFA was completed with each 7-cm segment being exposed to 120°C thermal energy for 20 sec. Compression was applied along the track of the GSV during RFA.

Varicose pack excision with miniphlebectomy was performed on 71 patients (82%) in the EVLA group and 233 (86%) in the RFA group. In patients with varicose packs, incisions no greater than a few millimeters in size, leaving the maximum distance between them, were made with the tip of a No. 11 scalpel. The packs were then removed through these. Following the procedure, moderate compression was applied with a 15-cm width elastic bandage wrapped around the leg from the ankle to the thigh. Care was taken that patients should not be dehydrated, and patients were mobilized immediately once the effects of the spinal anesthesia had passed. Patients with previous venous thromboembolism and risk factors such as advanced age or obesity received single-dose deep vein thrombosis (DVT) prophylaxis with low molecular weight heparin after the procedure. The bandages were removed on the morning of the first postoperative day, dressings were applied, and patients were discharged. Oral venotonic drugs were given during discharge. Patients were advised to use moderate pressure compression stockings (28-32 mmHg) for the first three months postoperatively. Patients were invited to clinical controls after 10 days, when the sutures were removed. Controls were performed with venous DUSG in the sixth postoperative month.

Statistical analysis

Categorical variables were expressed as frequency and percentages, and continuous variables as mean ± standard deviation. Descriptive statistics were applied to elicit information concerning age and smoking status in the EVLA and RFA groups, presence of diabetes, hypertension and obesity, CEAP clinical classification data, and thrombophlebitis, ecchymosis and hematoma complications were determined as percentages. Since these data were nominal values, the chi-square test was applied to determine whether differences between groups were statistically significant. In addition, descriptive statistics were applied in EVLA and RFA group data for age, preoperative reflux duration and GSV diameter (minimum, maximum, mean and standard deviation). We then investigated whether these values in the two groups were normally distributed. Since the values were not normally distributed, the non-parametric Mann-Whitney U test was applied to determine whether differences between the groups were significant. p values ≤0.05 were regarded as statistically significant.

RESULTS

The EVLA group consisted of 86 patients (42 male, 44 female; mean age 46 years; range 26-71 years), and the RFA group of 271 (113 male, 158 female; mean age 43.3 years; range 20-77 years). Mean length of follow-up was 27.2 months. No statistically significant difference was determined between the groups in terms of demographic data or preoperative additional diagnoses (Table 1).

Table 1. Study groups demographic data and preoperative additional diagnoses

	EVLA (n=86)	RFA (n=271)	P
Sex, n (% male)	42 (48.83)	113 (41.69)	0.24*
Age, years (mean±SD)	46.06±10.15	43.35±10.08	0.05**
HT, n (%)	8 (9.30)	16 (5.90)	0.39*
DM, n (%)	3 (3.48)	14 (5.16)	0.77*
Smoking, n (%)	30 (34.88)	73 (26.93)	0.20*
Obesity, n (%)	4 (4.65)	19 (7.01)	0.59*

*chi-square.**Mann-Whitney U test
EVLA: Endovenous Laser Ablation, RFA: Radiofrequency Ablation, SD: Standard Deviation, HT: Hypertension, DM: Diabetes Mellitus

No significant difference was also determined between the groups in terms of preoperative CEAP classification values, reflux durations, or proximal and distal GSV diameters (Table 2). No skin burn, DVT or pulmonary embolism complications developed in any patient. Thrombophlebitis developing in 14 patients and ecchymosis/hematoma developing in 32 patients resolved entirely during follow-up with medical treatment. No statistically significant difference was observed between the groups in terms of postoperative complications (Table 3). GSV occlusion rates at control DUSG performed after six months were 91.8% in the EVLA group and 94% in the RFA group. The difference in occlusion rates between the groups was not statistically significant (p=0.46).

Table 2. Preoperative clinical and ultrasonographic data

	EVLA (n=86)	RFA (n=271)	P
GSV proximal diameter (mm)	7.71±1.22	7.90±1.23	0.21**
GSVdistal diameter (mm)	5.50±0.81	5.60±1.05	0.65**
Reflux duration (sec)	2.48±1.30	2.70±1.31	0.16**
CEAP classification			
C2, n (%)	36 (41.86)	103 (38.00)	0.52*
C3, n (%)	35 (40.69)	117 (43.17)	0.73*
C4, n (%)	10 (11.62)	42 (15.49)	0.52*
C5, n (%)	5 (5.81)	9 (3.32)	0.31*

*chi-square, **Mann-Whitney U test
EVLA: Endovenous Laser Ablation, RFA: Radiofrequency Ablation, GSV: Great Saphenous Vein, CEAP: Clinical Etiological Anatomic and Pathologic Classification

Table 3. Postoperative complications

	EVLA (n=86)	RFA (n=271)	P
Thermal skin injury, n (%)	0	0	
Thrombophlebitis, n (%)	3 (3.48)	11 (4.05)	1*
Deep venous thrombosis	0	0	
Ecchymosis/hematoma, n (%)	10 (11.62)	22 (8.11)	0.43*

*chi-square
EVLA: Endovenous Laser Ablation, RFA: Radiofrequency Ablation

DISCUSSION

Function loss in the GSV and its branches, an important component of the superficial venous system, represents the basic mechanism involved in CVI (7). The principal disposing factors are obesity, pregnancy, spending long periods standing, a history of thrombophlebitis, and genetic predisposition (1). Studies have shown that surgical treatment is more effective in symptomatic CVI than other therapeutic options such as venoactive drugs and compression stockings (7). Endovascular techniques have begun widely replacing traditional surgery due to advances in technology, particularly in the last decade. EVLA and RFA, both thermal endovenous treatment methods, represent two widely accepted such techniques (3-8). Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum recommend EVTA techniques in preference to high ligation and stripping in the treatment of incompetent GSVs due to advantages such as fewer complications, high patient comfort, and a short healing time (9).

The mechanisms by which the two methods result in occlusion in the lumen through the damage caused by thermal energy differ. In EVLA, the energy transmitted to the blood components by the laser catheter produces indirect thermal damage in the endothelium (7,8). In contrast, in RFA, the heating element at the tip of the catheter transfers energy all around the endothelium by making direct contact with it. This difference in the effect mechanisms of EVTA techniques can also affect the clinical outcomes. Current guidelines contain no information concerning which of the two methods should be preferred. It is also unclear whether or not there is any difference between the two techniques' clinical outcomes (8). This study compared the two EVTA techniques most frequently employed in the treatment of GSV insufficiency, and concluded that there is no significant difference between EVLA and RFA in terms of complication development or occlusion rates.

Reported complication rates in previous studies were ranging between 0% and 10% after EVLA and between 4% and 23% after RFA (10-12). Puggioni et al. reported a mean total complication rate of 15.4% with the two methods, and that the rate of complication development was significantly higher in EVLA (20.8% after EVLA and 7.6% after RFA, p=0.03) (12). No statistically significant difference in total complication development rates were observed between the two techniques in the present study (15.1% after EVLA and 12.1% after RFA, p=0.60). A wide spectrum of complications have been described as capable of developing after treatment using EVTA methods, including deep vein thrombosis (DVT), pulmonary embolism, thermal skin injury, superficial thrombophlebitis, cellulitis, paresthesia, excessive pain, hematoma, ecchymosis, and even urinary retention (3-7,12,13).

DVT, pulmonary embolism, and thermal skin injury are classified as major complications (3,7,12). The Clinical Practice Guidelines of the European Society for Vascular

Surgery reported that the incidence of DVT developing following application of EVTA methods ranges between 0.2% and 1.3%, and is more common in patients treated with RFA compared to EVLA. In addition, an incidence of 0.3-7.8% has been reported in patients undergoing EVTA from the saphenofemoral junction to the femoral vein (generally as endovenous heat-induced thrombosis [EHIT]) (13). In contrast, Yalçın et al. reported encountering DVT at rates of 2.9% following EVLA and 1.7% after RFA (3). Puggioni et al. compared the two methods and reported encountering EHIT in 2.3% of patients undergoing EVLA, that all patients were treated with anticoagulant application, and that no pulmonary embolism developed in any case (12). On the other hand, an incidence of 0-3% has been reported for pulmonary embolism following EVLA (13).The guidelines state that the role of pharmacological prophylaxis directed toward DVT is uncertain, and have stressed that thrombo-prophylaxis can be applied in high-risk conditions such as a previous history of venous thromboembolism, obesity, advanced age, immobility and neoplasm. Evaluation of every patient in terms of thrombosis using a specific risk assessment score, such as the Caprini score, has also been recommended (13). No DVT or pulmonary embolism complication developed in any patient in this study. We think that our application of a single dose of low-weight molecular heparin as a prophylactic after surgery in patients in the risk group in our clinic may have contributed to this.

Among other complications developing after EVTA therapy, thrombophlebitis has been reported at a rate of 7%, thermal skin injury at<1%, ecchymosis at 5%, paresthesia at 1-2%, and hematoma at 0-7% (13). Failure to administer tumescent anesthesia in sufficient quantities and at sufficient coolness has been described as an important factor in the development of complications in EVTA therapies (3-5). Complications such as pain, ecchymosis, and hematoma have also been reported to be more common in EVLA than in RFA (3-5). The high level of energy applied per centimeter in EVLA and the use of low wavelength laser affect the development of these side-effects (3-5,13). Since low wavelength laser light is less absorbed by hemoglobin, water and proteins in blood than high wavelength laser light, more side-effects may occur. Different fiber tips and higher laser wavelengths have therefore been developed in order to reduce potential side-effects in EVLA (13). In contrast to these data, despite using a high wavelength laser (1450 nm), Eroğlu et al. observed a significantly higher ecchymosis rate following RFA compared to EVLA (14). In the present study employing a 1470 nm wavelength laser, we determined no significant difference between the groups in terms of ecchymosis or hematoma (11.62% after EVLA and 8.11% after RFA, p=0.43). On the other hand, Yalçın et al. reported that thrombophlebitis was more frequently seen in EVLA due to lack of complete emptying of the thrombus in the lumen (3). One study comparing five different methods including EVLA and RFA reported observing no thrombophlebitis in any patient (7). In the present study, thrombophlebitis developed in three patients in the EVLA group and in 11 in the RFA group, but the difference between the groups was not statistically significant (Table 3).

Several studies have reported high GSV occlusion rates in both EVLA and RFA, with no statistically significant difference between the two, and that both are as successful as surgical treatment (3,13-16). Yalçın et al. reported occlusion rates of 92.7% for EVLA and 93.2% for RFA after six-month follow-up (3). Another study reported slightly higher GSV occlusion rates after EVLA (94.4%) than after RFA (90.9%), but that more complications also occurred in EVLA (12). Uncu et al. observed a high GSV occlusion rate at controls after one year in a group undergoing RFA. That study also stressed that RFA was superior to EVLA in terms of complication rates, treatment costs, and patient comfort (4). In the present study, GSV occlusion rates observed at DUSG six months postoperatively were 91.8% in the EVLA group and 94% in the RFA group. The difference in occlusion rates between the two groups was not statistically significant (p=0.46).

The principal limitations of this study are its retrospective nature and the fact that it was not randomized. Other limitations include the unequal sample sizes, variation in follow-up times, and lack of long-term follow-up data. However, despite these limitations we think that our study will make a significant addition to our knowledge concerning EVTA.

CONCLUSION

In conclusion, this study comparing EVLA and RFA techniques in terms of postoperative complications and occlusion rates in the GSV during follow-up indicated that there is no significant difference between the two methods. The fact that neither technique requires wide incisions, lower development of post-procedural ecchymosis and hematoma, the reliability of the outcomes, and an early return to daily life make both techniques preferable to traditional surgery. Our conclusions also suggest that neither method is superior to the other. Our results now need to be confirmed with further prospective studies with larger numbers of participants.

Competing interests: The authors declare that they have no competing interest.

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Ethical approval: Approval was granted by our hospital's local ethical committee (no. 40986104-799).

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