Comparison of Two Different Endovenous Ablation Techniques for Greater Saphenous Vein Insufficiency: A Prospective Randomised Clinical Trial

Vena Safena Magna Yetmezliğinde İki Farklı Endovenöz Ablasyon Tekniğinin Karşılaştırılması: Prospektif Randomize Klinik Çalışma

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ABSTRACT Objective: The improvements in minimally invasive procedures for the treatment of varicose veins aim to reduce operative trauma and bruising associated with standard surgical techniques. There are two major thermal endovenous treatments in use; Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA). The aim of the current study was to compare the efficacy, early postoperative morbidity, patient comfort and effects on venous clinical severity score (VCSS) of EVLA and RFA. **Material and Methods:** In this study, 134 patients presented with symptomatic unilateral primary venous insufficiency due to great saphenous vein (GSV) incompetence were analyzed. The patients were classified according to the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification. Patients were randomised into two groups. Group 1 (n=82) was treated with the radial laser fiber, and group II (n=52) was treated by endovenous radiofrequency. Patients were called for control visits at the end of the first week, the first month, and sixth month. Routine postoperative duplex scanning was performed in the follow up visits. Limbs were examined for successful obliteration, pain, bruising, erythema, and hematoma at each postoperative visit. CEAP clinical class and VCSS scores were recorded. **Results:** There was more bruising and painful eryhtema in the RF group at the end of the first week (p=0.001), painful erythema was reported in 7 patients in RF and 1 patient in EVLA group, and 5 bruise in RF and 2 bruises in EVLA group. However, there was no difference in bruising and erythema among the groups at the end of the first month. There was no statistically significant difference among the groups for complications such as skin necrosis, edema and minor paraesthesia. Returning to daily activities and the workplace was similar in two groups. **Conclusion:** We may conclude that RFA and EVLA both effectively reduce superficial venous insufficiency from incompetent GSVs. EVLA was associated with less bruising in the periprocedural period.

Key Words: Endovenous laser treatment; radiofrequency ablation; saphenous vein; venous reflux

ÖZET Amaç: Minimal invaziv tekniklerin (endovenöz termal tedavi yöntemi) geliştirilmesindeki amaç standart cerrahi yönteme oranla hastaya ameliyat esnasında uygulanan travmanın ve zedelenmenin azaltılması ile ameliyat sonrası konforun arttırılmasıdır. Endovenöz termal tedavi yöntemlerinin en sık kullanılanları ise endovenöz lazer ablasyon (EVLA) ve radyofrekans ablasyondur (RFA). Bu çalışmanın amacı venöz yetmezlik tedavisinde kullanılan endovenöz termal tedavi yöntemlerinin etkinlik, ameliyat sonrası erken morbidite, hasta konforu ve venous clinical severity score (VCSS) olan etkisinin karşılaştırılmasıdır. **Gereç ve Yöntemler:** Vena safena magnada tek taraflı yetmezliğe bağlı şikayetleri olan toplam 134 hasta çalışmaya dahil edilmiştir. Tüm hastalar klinik, etiyolojik, anatomik ve patofiyolojik (CEAP) olarak sınıflandırılmıştır. Hastalar randomize olarak seçilmiştir. Grup 1'e (n=82) dahil hastalar EVLA ile tedavi edilirken, grup 2'ye (n=52) dahil hastalar RFA ile tedavi edilmiştir. Hastaların 1. hafta, 1. ay ve 6. ayda takipleri yapılmıştır. Takiplerde hastalara rutin Doppler ultrasonografi yapılmıştır. Ayrıca tüm takiplerde hastalar, opere edilen ekstremitelerdeki ağrı, zedelenme, eritem ve hematom açısından incelenmiştir. Bu değerlendirmelere göre CEAP klinik sınıflaması ve VCSS skorlaması yapılıp kayıt altına alınmıştır. **Bulgular:** Birinci haftada yapılan kontrollerde RFA grubunda 7 hastada ağrılı eritem mevcut iken, EVLA grubunda sadece 1 hastada ağrılı eritem mevcuttu. İki grup arasındaki bu fark anlamlı bulundu. Aynı takipte RFA grubunda 5 hastada zedelenme saptanırken, EVLA grubunda 2 hastada zedelenme saptandı. İki grup arasında istatistiksel olarak anlamlı fark saptandı. Buna rağmen 1. ay takiplerinde iki grup arasında zedelenme ve ağrılı eritem arasında fark saptanmadı. İki grup arasında komplikasyon açısından istatistiksel olarak fark saptanmadı. **Sonuç:** Perioperatif periodda zedelenme EVLA'da daha az olmasına rağmen, iki tedavi yönteminin etkinlik açısından birbirine karşı herhangi bir üstünlükleri olmadığı kanatine vardık.

Anahtar Kelimeler: Endovenöz lazer tedavisi; radyofrekans ablasyon; safen ven; venöz reflü

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The improvements of minimally invasive procedures for the treatment of varicose veins aim to reduce operative trauma and bruising associated with standard surgical techniques.[1] There are two major thermal endovenous treatments in use: Endovenous Laser Ablation (EVLA) and Radiofrequency Ablation (RFA). Those procedures ablate the great saphenous vein (GSV) through percutaneous approach to minimize the complications associated with conventional stripping. Randomized clinical trials comparing EVLA with surgery have shown that EVLA is an equally effective treatment, however it produces less pain and bruising, and it offers a significantly better quality of life. Randomized studies comparing RFA and open surgery have shown that RFA causes less pain, bruising and fewer complications with less time off from work.[2-5] Studies of the individual techniques do not show differences in patient safety, and overall success rates appear similar. However, there may be differences in comfort, degree of bruising, and vein obliteration degrees.

The aim of the current prospective randomized study was to compare two different major thermal endovenous treatments available (EVLA and RFA) for efficiency, early postoperative morbidity, patient comfort and effects on venous clinical severity score (VCSS).

MATERIAL AND METHODS

This study included 134 patients that presented with symptomatic unilateral primary venous insufficiency due to GSV incompetence between June 2011 and February 2014. All patients were classified according to the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification. Clinical data, operative details, postoperative course, and follow up data were recorded and analyzed. The study was approved by our institutional ethics committee, and informed written consents were obtained from all patients. Each patient had a preoperative duplex ultrasound examination to identify the site of reflux, and suitability for endovenous ablation. Ultrasonography was performed by two vascular technologists using GE Logic 9 scanners (General Electric ultrasound, Milwaukee, USA). Reflux in the superficial (GSV and small saphenous vein) and deep (femoral vein and popliteal vein) venous systems was assessed with patients in the standing position by inflation/deflation of a calf with a plethysmographic cuff. Reversed flow lasting for 0.5 seconds was defined as reflux. Patients with a history of previous deep venous thrombosis (DVT), concomitant peripheral arterial disease (Ankle Brachial Pressure Index <0.8), difficulty in ambulation, recurrent varicose veins, pregnant or breast-feeding ones, those who had reflux in other axial veins (anterior accessory great saphenous vein, small saphenous vein) or perforators, and the patients who underwent bilateral endovenous ablation procedures were excluded from the study in order to maintain a homogenous patient population. All the operations were carried out by the same surgical team.

A total of 134 patients were randomized into two groups according to a computer-generated randomization list. Group 1 (n=82) was treated with the radial laser fiber (Elves radial, Bolitec AG, Bonn, Germany), and group II (n=52) was treated with endovenous radiofrequency ablation (Covidien ClosureFast, San Jose, California).

Operative procedures were performed in the operating room under spinal anesthesia supplemented with local tumescent anesthesia. The patients were placed in the supine position, and under duplex ultrasound guidance, the GSV was punctured with an 18-gauge needle and a guide-wire inserted through the needle and a 6-F introducer sheath was placed over the guide-wire into the GSV. In EVLA, a radial catheter was directly inserted through the sheath, and its position confirmed to be distal to the saphenofemoral junction (SFJ), 1 cm below the intersection of the inferior epigastric vein. An RF sheath was inserted in a similar way for the patients undergoing RFA. The saphenous subcompartment along the GSV was infiltrated with tumescent anesthesia (50 mL of 1% lidocaine and 1 mL of

epinephrine [1:1,000] diluted in 1L of normal saline) under duplex ultrasound guidance from knee to groin around the catheter. The patient was then placed in Trendelenburg position, and the GSV was treated with either RFA or EVLA. Laser energy was applied using the laser's continuous mode and a constant pullback with a rate corresponding to at least 80 J cm- 1 linear endovenous energy density (LEED). Laser power was set according to the vein diameter changing from 9 to 13 W power and total laser energy were recorded. In ClosureFAST RFA, the catheter has white spacing markers every 6.5 cm, which indicate the pullback distance for each treatment cycle. Pullback during ablation is segmental.

Successful obliteration and absence of common femoral vein (CFV) thrombus were confirmed by intraoperative duplex ultrasound scans. Stab avulsion phlebectomies and other concomitant procedures were performed when indicated.

After the procedure, the legs of the patient were wrapped with elastic compression bandages for 24 hours. The patients were encouraged to ambulate, and to continue ongoing compression therapy with 18 to 21 mmHg knee-high gradient compression hose for at least 3 weeks.

At time of discharge, all patients were prescribed a standard dose of analgesics. Postoperative pain was defined as excessive when this required an additional prescription of analgesic or caused significant limitation of activities on everyday living. Thrombophlebitis was defined as the presence of an indurated cord at the site of the treated GSV, associated with localized hyperemia, edema, and tenderness requiring treatment with anti-inflammatory agents. Edema was defined as the new-onset of swelling in the treated lower extremity that exacerbated by ambulation, and relieved by leg elevation.

Patients were called back after 1 week, 1 month, and 6 months for follow-up. Routine early postoperative duplex scanning (7^{th} postoperative day, and 1 month and 6 months after from surgery) was performed. Successful obliteration was confirmed by the evidence of a noncompressible GSV with thickened walls and no flow on color duplex ultrasound analysis. The limbs were examined for pain (visual analog scale), bruising, erythema, and hematoma at each postoperative visit. CEAP clinical class and VCSS scores were recorded. Bruising was assessed using a scale from 0 (no visible bruising) to 5 (excessive bruising).

STATISTICAL ANALYSIS

In this study, distributed continuous variables were displayed as mean±standard deviation, and two samples t test was performed. Categorical variables were shown as frequencies and percentages, and continuity correction Chi-square, and Fisher's exact tests were applied. All statistical analyzes were performed using the SPSS for Windows version 15.0 (SPSS, Chicago, IL, USA) package program. Statistical significance was determined at the level of $p<0.05$.

RESULTS

Successful access, endovenous placement and obliteration of VSM by EVLA and RF fibers were achieved in all patients. A total of 82 limbs of 82 patients in group I and 52 limbs of 52 patients in group II were treated. A hundred and ten patients were women (83.7%), and 24 patients were men (16.3%), with a mean age of 46±3.4 years (range 32 to 54 years) in group I, and 48±4.1 (range 34 to 59) in group II. All patients had symptomatic varicose veins, with or without skin changes (C1 ,C2, C3, C4). The primary etiology was valvular incompetence in all limbs. The demographic data is shown in Table 1.

Length of GSV treated by EVLA ranged between 20 and 45 cm (mean 34±2.7 cm). The mean diameter of the treated vein was 10.2±2.1 mm. The mean laser power used was 84.6±2.7 J/cm, and 3468±374 J/limb was delivered as the total energy. Mean tumescent anesthesia volume per limb was 425±52 (ml). Mean procedure duration/limb (min) was 42.8±2.4 minutes. The number of flebectomies per limb was 4.7±1.3.

TABLE 1: Demographic data.

	Group I (EVLA) n=82 patients 61.1%)	Group II (RF) n=52 patients 38.9%)	p
Female gender	68 (82.9%)	42 (80.7%)	0.931
Age	46±3.4 (32-54)	48±4.1(34- 59)	0.004
Smoking	38 (46.3%)	26 (50%)	0.814
Hypertension	18 (21.9%)	12 (23%)	1.000
Hyperlipidemia	13 (15.5%)	8 (15.3%)	1.000
CEAP II	32 (39%)	21 (40%)	1.000
CEAP III	12 (14.6%)	9 (17.3%)	0.864
CEAP IV	7 (8.5%)	5 (9.6%)	1.000

EVLA: Endovenous Laser Ablation; RFA: Radiofrequency Ablation; BP: Blood pressure; CEAP: Clinical, etiologic, anatomic, pathophysiologic classification.

Length of GSV treated with RF ranged between 25 and 47 cm (mean 35±1.97 cm). The mean diameter of the treated vein was 9.8±1.7 mm. Mean tumescent anesthesia volume per limb was 637.3±48.1 (ml). Mean procedure duration/limb (min) was 34.3±3.7 minutes. The number of flebectomies per limb was 4.1±3.4 in EVLA group, and 4.3±2.1 in RF group.

The mean follow up period was 5.2±1.2 months.

There was more bruising and painful eryhtema in the RF group on 1 week (p=0.001), and painful erythema was reported in 7 patients in RF, and 1 patient in EVLA groups, and bruise was seen in 5 patients in RF and 2 patients in EVLA group. However 1 month later, there was no difference between the groups for bruising or erythema. Superficial vein thrombosis developed in 1 RF patient on week 1. This patient, who was obese and had a history of smoking, was given anticoagulation (enoxaparin, followed by warfarin) for 6 weeks, and later there was no further evidence of deep vein thrombosis.

There was no statistically significant difference between the groups for complications such as skin necrosis, edema or minor paraesthesia. The complications are summarized in Table 2.

TABLE 2: Operative data.

Complications	Group I (EVLA) n=82 patients (61.1 %)	Group II (RF) n=52 patients (38.9 %)	p
Thrombophlebitis	0	1	0.388
Urinary retention	1	0	1,000
Paresthesia	0	1	0.388
Hematoma	0	0	-
Erythema	1	7	0.006
Edema	2	3	0.376
Pain	3	4	0.430
Cellulitis	1	0	1,000
Deep vein thrombosis	0	1	0.388
Skin Necrosis	0	2	0.149
Postoperative analgesic duration	3±1.1 hours	4.2±1.3 hours	0.256
Recanalization	1	2	0.560

EVLA: Endovenous Laser Ablation; RFA: Radiofrequency Ablation.

Returning to daily activities and the workplace was similar in both groups. This period was 2.1±0.8 days in EVLA group, and 2.5±1.2 days in RF group (p=0.079).

VCSS scores improved significantly in both groups at follow up visits. The venous clinical severity scores were 8.4±2.6 preoperatively, 4.9±1.8 on the third day, 4.5±1.3 at the first week and 3.9±1.3 in the first month in EVLA group. The venous clinical severity scores were 8.1±2.9 preoperatively, 5.2±1.7 on the third day, 4.7±1.1 at the first week and 4.1±2.2 in the first month in RF group.

DISCUSSION

Ablation of saphenous vein with endovascular techniques have been introduced as a minimally invasive alternative to high ligation and open surgical stripping of the incompetent saphenous vein. Stripping may lead to painful and prolonged postoperative recovery in some patients, carries the risk of infection, hematoma, and nerve injury. The field has grown rapidly since the introduction of radiofrequency ablation (RFA) into the venous therapeutic armamentarium in 1998 to 1999, followed by endovenous laser treatment (EVL) in 2002. A number of different laser systems and two generations of radiofrequency catheters are available. Both techniques report successful obliteration of the great saphenous vein (GSV), small saphenous vein, saphenofemoral junction (SFJ) branches, and perforators.

Studies of the individual techniques have not shown differences in patient safety, and overall success rates appear similar. Nevertheless, there may be differences in comfort, degree of bruising, and completeness of vein obliteration. In this randomized study we tried to evaluate objective outcomes of VCSS, clinical class of CEAP, patient-related outcomes of pain, bruising, paresthesia, and efficient outcomes of vein obliteration after 1 week and 1 year in patients undergoing endoluminal saphenous vein ablation with RFA or EVLA.

The mechanisms of luminal ablation are fundamentally different in these two methods. The radiofrequency catheter has probes that contact the vein wall. When activated, radiofrequency energy is delivered to the vein wall and converted to heat. The heat produces tissue damage in the form of endothelial denudation, denaturation of proteins within the vein wall (collagen), stimulation of inflammation, vein shrinkage, and thrombosis.

In the former studies with EVLA treatment, laser wavelengths of 810 to 1064 nm were absorbed by the hemoglobin of red blood cells, which led to the formation of steam bubbles that produced convective heat transfer to the vein wall. The heat damaged endothelium and subendothelial collagen, causing shrinkage of the vein wall, inflammation, thrombosis, and subsequent fibrosis. When the tip of the laser catheter is in contact with the vein wall, high-energy absorption by small volumes of tissue can lead to tissue vaporization, resulting in vein perforation. Blood leaking from these perforations leads to ecchymosis.

Some studies reported long-term results with EVLA with a 980-nm diode laser, and reported 60% ecchymosis and 7% transient paresthesia following treatment.[6] In our study, we used radial fiber laser. Several studies concluded that laser fiber reduced tissue vaporization, leading to less pain and ecchymosis. This may explain the low incidence of painful ecchymosis in our EVLA group.

Recanalization is another issue in endovenous treatment. In 2006, Almeida et al. reported a greater number of cases (819 EVL and 128 RF) and a longer follow-up (1.5 years).[7] The recanalization rate was somewhat greater for RFA, 5.5% versus 1.7% for EVL. The rate of extension of the thrombus into the common femoral vein was 0.2% for EVL, and absent for RFA. Gale et al. published another prospective randomized study comparing RFA ClosurePlus (obsolete) (n=46) and EVL (810 nm) (n=48), reporting results at one month and at one year.[8] Both methods were very effective for reducing symptoms (VCSS, CEAP, CIVIQ-2). RFA showed a higher rate of late recanalization (11 for RFA and 2 for EVL, p=0.002). Therefore, EVL was

more effective than ClosurePlus, in exchange for a higher rate of ecchymosis and discomfort during the perioperative period.

After the improvement in the radiofrequency technology, second generation RF devices took place in the treatment. In 2009, RECOVERY study was published by Almeida et al.[9] It was a multicenter, randomized comparative study of 87 veins in 69 patients. The groups were EVL (980 nm) (n=41) and RFA ClosureFAST (n=46), with a one-month follow-up. The primary objectives were postoperative pain, ecchymosis, swelling and complications from the procedure. The secondary objectives were the venous clinical severity score and quality of life score (VCSS and QOL scores). The authors concluded that RFA was significantly superior to EVL in terms of postoperative recovery and quality of life parameters, and the complications were significantly more prevalent in the EVL group (22.0% vs 4.4%, p=0.02).

Shepherd et al. published a comparative study on 131 patients using RFA ClosureFAST (n=67) and EVL (980 nm) (n=64). Postoperative pain and quality of life in the postoperative period were analyzed.[10] The study showed less pain in patients undergoing RFA for the first 10 days (p=0.001). Returning to daily activities and the workplace was similar in both groups, with an overall rate of return to work within the first week of 70%. In another study by the same author, the patients with RFA returned to work sooner than those treated with EVL (5 days vs 9 days, p=0.022).[11]

In our study, side effects such as pain, induration and ecchymosis were significantly low with the 1470 nm laser and radial catheter system. This may be due to reduced vein-wall perforations in the last generation laser system. In our study, returning to daily activities and the workplace was similar in both groups, and this result was similar with the other studies in the literature.[7-11]

In our study, the mean amount of tumescent anesthesia was higher than the studies in literature (more than 600 ml). We used more amount of tumescent anesthesia in order to gain better results in terms of pain and bruise.[1,7-9] In other studies, 400-500 ml of tumescent anesthesia were used.[1,7-9] We did not observe any side effects due to tumescent anesthesia.

This prospective study compared the early success and complications of two endovenous procedures of GSV ablation, performed in a single institution. We may conclude that RFA and EVL both effectively reduce superficial venous insufficiency from incompetent GSVs. EVLA was associated with less bruising in the periprocedural period.

Conflict of Interest

Authors declared no conflict of interest or financial support.

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