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# A Comparison of 1,470-nm Endovenous Laser Ablation and Radiofrequency Ablation in the Treatment of Great Saphenous Veins 10 mm or More in Size

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**Background:** To compare 1,470-nm endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) in the treatment of patients with great saphenous vein diameters of 10 mm or more.

**Methods:** One hundred twenty consecutive patients presenting to the cardiovascular surgery department with a great saphenous vein diameter exceeding 10 mm at the saphenofemoral junction between January and December 2013 were included in the study. The first randomly selected 60 patients (group 1) received 1,470-nm EVLA and the other 60 patients (group 2) received RFA. Patients were assessed on the second day, the first week, and the first, third, and sixth months. Major and minor complications were recorded.

**Results:** Minor complications in EVLA and RFA were hyperemia at 20% and 30% ($P = 0.50$), ecchymosis at 16.7% and 48.3% ($P = 0.02$), and edema at 40.0% and 65.5% ($P < 0.08$), respectively. No major complication was observed in any patient. Recanalization developed during monitoring in 3 patients in the RFA group, a rate of 5%. No recanalization was observed in the EVLA group. Success rates in the EVLA and RFA groups were 100% and 95%, respectively. Mean time to return to daily activity was 0.7 days in the EVLA group and 1.4 days in the RFA group ($P < 0.006$), whereas mean time to return to work was 1.8 days in the EVLA group and 2.2 days in the RFA group ($P < 0.07$). There was no statistically significant difference between the groups in terms of pain during the procedure or postoperatively. Less pain was reported in the EVLA during both ($P < 0.02$).

**Conclusions:** EVLA using a 1,470-nm radial fiber is superior to RFA in the treatment of saphenous veins larger than 10 mm in diameter.

## INTRODUCTION

Lower extremity superficial venous insufficiency is a common disease that can progress to venous ulcers unless the clinical symptoms are treated.[1] Primary treatment of varicose veins was surgery for many years, although thermal ablation techniques have become increasingly popular in recent years. Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are safe and minimally invasive techniques used in the treatment of saphenous vein insufficiency. Thermal endovenous ablation using an 810-nm diode laser was the first reported in 2001, by Navarro et al.[2] Weiss et al.[3] reported cases in which they performed thermal ablation

*Conflict of Interest: The authors declare that there is no conflict of interest.*

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using radiofrequency energy. EVLA and RFA produce similar histopathologic changes in the varicose saphenous vein.[4] Damage in the venous wall associated with the heat energy emitted by the tip of the catheter occurs in both techniques, and venous structures are broken down. The vein thus assumes a fibrotic structure. However, although the results are similar, the mechanisms involved in the 2 techniques are different. When laser light is used, heat develops in the optic penetration zone with direct absorption of laser energy (radiation). This intraluminally emitted light energy is absorbed by various substances known as chromophores. These cause tissue damage through photochemical and photothermolytic mechanisms by reflecting this energy back to the tissues. In the radiofrequency technique, on the other hand, when the radiofrequency waves make contact with tissue by producing electromagnetic energy, this causes the collagen in connective tissue to break down by setting up vibration and abrasion. The most characteristic property of RFA is that it exhibits this effect at much lower temperatures (90−120°C) compared with other sources of energy. The radiofrequency catheter therefore has to be in direct contact with the tissue to produce effective thermal destruction. Because laser catheters are capable of reaching temperatures up to 700°C, they can cause perforation when they come into direct contact with tissue. There is therefore a prevailing opinion that because the radiofrequency catheter will not be able to make direct contact with the vein wall when the diameter of the saphenous vein exceeds 10 mm, its effectiveness may be quite low. The purpose of this study was to test that hypothesis by comparing 1470-nm EVLA and RFA in the treatment of superficial venous insufficiency in patients with a saphenous diameter of 10 mm or more in the saphenofemoral region.

## MATERIALS AND METHODS

One hundred twenty patients presenting to the cardiovascular surgery department between January and December 2013, and with a saphenous vein diameter of 10 mm or more at the level of the saphenofemoral joint (SFJ) were enrolled. Patients were randomly assigned into 1 of 2 groups after local ethical committee approval. Patients in group 1 received laser ablation and those in group 2 received RFA. Patients with a saphenous vein diameter less than 10 mm at the SFJ were excluded. Before the procedure, patients were classified on the basis of the clinical severity, etiology, anatomy, and pathophysiology (CEAP) classification. Patients' venous clinical severity score (VCSS) values based on the clinical severity and findings scoring system were recorded before the procedure. EVLA and RFA procedures were decided based on existing insufficiency in the vena saphena magna (VSM) at colored Doppler ultrasound (CDUSG) performed for diagnostic purposes. No advanced insufficiency or obstruction was determined in the deep veins in any extremity. A 1,470-nm wavelength 12-W diode laser source (Biolas-15D; Del YCHI GMBH, Duisburg, Germany) and radial fiber (EVLAS Circular-2; FG Group, Ankara, Turkey) were used for the EVLA procedure, and an EVRF® Endo Venous Radio Frequency CR45i device and catheter (F-Care Systems NV; Antwerp, Belgium) were used for RFA. USG-guided percutaneous entry with a 21G needle was performed on the saphenous vein with reflux under local anesthetic in all patients. USG-guided tumescent local anesthesia consisting of 20-mL 2% prilocaine, 500-mL 0.9% isotonic solution (+4 C), 20-mL 8.4% sodium bicarbonate, and 0.5-mg adrenalin was administered around the saphenous vein with 19−21G needles. Laser energy was applied by adjusting the laser parameters based on the vein diameter and the depth of the vein beneath the skin (12 W, 1.2−1.8 mm/sec retraction speed), higher in those parts close to the SFJ, in pulse mode (0.2 sec interval). The RFA procedure was performed by applying radiofrequency energy to the saphenous vein in the form of 25 W every 0.5 cm (50 W/cm) from the distal aspect of the SFJ. Analgesics (paracetamol) were prescribed for all patients after the procedure. Pain felt during and after the procedure was evaluated using a visual analogue scale (VAS) on a scale of 1−5. Patients' painkiller requirements were recorded. An elastic bandage was applied to the leg receiving the procedure for 2 days after which compression stockings were recommended for 3 months. Patients were advised to return to their daily activities as early as possible. Times to return to day-to-day activities were recorded. Clinical follow-ups were performed on the second after the procedure and clinical checkup together with CDUSG were performed on the first week and the first, third, and sixth months. Saphenous vein occlusions, perforating veins, and residual varicosities were recorded at CDUSG. Major and minor complications were investigated. No varicose veins excision was performed on any patient during the procedure.

### Statistical Analysis

Data were expressed as mean ± standard deviation or as median and range. Demographic and clinical

measures were tested using paired samples *t*-tests for parametric variables and Wilcoxon signed-rank tests for non-normally distributed data. The McNemar test was used to analyze the quantitative data. All calculations were performed using SPSS version 17.0 (SPSS Inc., Chicago, IL). $P < 0.05$ was considered statistically significant.

## RESULTS

All patients had primary etiology, and pathophysiology in the entire extremity was associated with reflux. There was no statistical difference between extremities on the basis of CEAP and VCSS classifications at preoperative assessments. Mean duration of reflux in the SFJ was 3.7 sec in the EVLA group and 4.1 sec in the RFA group. EVLA and RFA procedures were performed on a total of 60 saphenous veins each. The mean diameter of the saphenous vein at the level of the SFJ was 11.3 mm and the mean diameter at knee level 9.9 mm in the EVLA group, whereas in the RFA group the values were 11.6 and 9.7 mm, respectively. Length of the saphenous vein undergoing procedure was 26.4 cm in the EVLA group and 25.9 cm in the RFA group. Saphenous vein depth beneath the skin was 18.5 mm in the EVLA group and 17.1 mm in the RFA group. Length of procedure was 32.5 min in the EVLA group and 34.8 min in the RFA group. There was no significant difference between the groups. Detailed demographic and clinical data are shown in Table I. Mean perioperative pain score based on VAS was 1.3 in the EVLA group and 1.7 in the RFA group. The difference was statistically significant ($P < 0.02$). Postoperative pain score was 1.0 in the EVLA group and 1.5 in the RFA group. The difference was again significant ($P < 0.03$). Postoperative analgesic use was 1.5/day, compared with 2.0 in the RFA group. This was also statistically significant ($P < 0.04$). Postoperative time to starting activity was 0.6 days in the EVLA group and 1.4 days in the RFA group. The difference was also significant ($P < 0.006$). Time to return to work was 1.8 days in the EVLA group and 2.2 days in the RFA group. This difference was not significant. Postoperative data are shown in Table II. Enduration, ecchymosis, and edema were identified as minor complications. Enduration developed in 69.0% of the EVLA group and 80.0% of the RFA group. The difference was not statistically significant. Ecchymosis developed in 16.7% of the EVLA group and 48.3% of the RFA group, and the difference was statistically significant ($P = 0.02$). Edema developed in 40.0% of the EVLA group and 65.5% of the RFA group. This difference was not significant. Enduration, ecchymosis, and edema all subsided at the end of 2 weeks. No major complication (deep vein thrombosis [DVT], pulmonary embolism, skin burn, etc.) was observed in any patient. Complications after endovenous laser therapy and RFA are shown in Table III. Recanalization developed in 3 patients in the RFA group during monitoring, a level of 5.0%. Complete occlusion was determined in 60 saphenous veins (100%) receiving EVLA at 6-month checkup. Occlusion levels were not significantly different ($P > 0.05$).

## DISCUSSION

The 2 most commonly used alternatives to surgery in the treatment of varicose veins in recent years are EVLA and endovenous RFA. Both methods involve similar mechanisms, are safe, effective, minimally invasive, and easy to perform with high occlusion rates in saphenous vein insufficiency. The absence of any requirement for general anesthesia or hospitalization, early mobilization, low complication and recurrence rates, and high patient satisfaction compared with surgery mean that EVLA and RFA have today replaced surgical treatment. A meta-analysis by Van Den Bos et al.[5] examined 119 studies and reported the results for 12,320 legs. Success rates in the treatment of superficial venous insufficiency of 78% for classic surgical stripping, 77% for foam sclerotherapy, 84% for RFA, and 94% for EVLA were reported. Many studies involving EVLA report that clinical outcomes improve together with the laser wavelength used. This is attributed to its chromophore effect. In their double-blinded, randomized study, Kabnick et al. compared 810-nm and 980-nm wavelength laser therapies for VSM ablation. Occlusion levels were similar, but fewer symptoms such as phlebitis, ecchymosis, and pain were seen in the 980-nm group. They attributed this to high wavelength lasers directly affecting the vein wall, rather than hemoglobin.[6] Another similar randomized study compared 940-nm and 1,320-nm wavelength lasers and determined significantly less pain, ecchymosis, and analgesia requirement when longer wavelength lasers were used.[7] Although several studies have compared the endovenous thermal ablation techniques EVLA and RFA, the number of studies comparing 1,470-nm EVLA and RFA in varicose veins of 10 mm or more is limited. The radial fibers that have entered into use in recent years permit a more homogeneous distribution of laser light to the venous wall compared with bare fibers. This is important in terms of both procedural success and

**Table I.** Demographic and clinical data

| Variables | EVLA ($n = 60$) | RFA ($n = 60$) | $P$ |
|---|---|---|---|
| VCSS | 11.6 ± 2.1 | 10.8 ± 2.0 | 0.137 |
| CEAP | 3.5 ± 0.8 | 3.3 ± 0.5 | 0.213 |
| VSM diameter (SFJ) mm | 11.3 ± 0.9 | 11.6 ± 1.4 | 0.339 |
| VSM diameter (knee) mm | 9.9 ± 0.9 | 9.7 ± 1.7 | 0.478 |
| Mean SFJ reflux time (sec) | 3.7 ± 1.3 | 4.0 ± 1.2 | 0.300 |
| Distance beneath the skin | 18.5 ± 8.5 | 17.1 ± 7.2 | 0.750 |
| Saphenous vein length | 26.4 ± 5.1 | 25.9 ± 3.9 | 0.385 |
| Length of procedure | 32.5 ± 6.9 | 34.8 ± 5.8 | 0.148 |

**Table II.** Postoperative clinical data

| Variables | EVLA ($n = 60$) | RFA ($n = 60$) | $P$ |
|---|---|---|---|
| Pain (intraoperative)/days | 1.4 ± 0.6 | 1.7 ± 0.8 | 0.026* |
| Pain (postoperative)/days | 1.2 ± 0.4 | 1.4 ± 0.5 | 0.038* |
| Analgesic requirement (tablet/day) | 1.7 ± 0.6 | 1.9 ± 0.4 | 0.063 |
| Time to return to activity (days) | 0.9 ± 0.8 | 1.3 ± 1.1 | 0.001* |
| Time to return to work (days) | 1.8 ± 0.8 | 2.1 ± 1.2 | 0.549 |

*Indicates statistical significance.

**Table III.** Complications after endovenous laser therapy and RFA

| Variables | EVLA ($n = 60$), % | RFA ($n = 60$), % | $P$ |
|---|---|---|---|
| Enduration | 20.7 | 31.0 | 0.508 |
| Ecchymosis | 31.0 | 27.6 | 0.146 |
| Edema | 27.6 | 65.5 | 0.007* |
| Paresthesia | 0.0 | 0.0 | — |
| Deep vein thrombosis | 0.0 | 0.0 | — |
| Pulmonary embolism | 0.0 | 0.0 | — |

*Indicates statistical significance.

minor complications in varicose veins. Almeida et al.[8] reported recanalization rates of 5.5% for RFA and 1.7% for EVLA. Puggioni et al.[9] reported success rates of 100% for EVLA and 96% for RFA at 1-month follow-up. This is because during ablation with RFA, the catheter tip has to touch the venous wall, whereas laser able energy is able to perform ablation without direct contact. This is even more significant in saphenous veins of 10 mm or more in diameter. The recanalization observed in 3 patients in the RFA group in this study may suggest that RFA is insufficient in veins with a large diameter. Saphenous vein diameters in the 3 patients in whom recanalization developed exceeded 12 mm, confirming this thesis. In addition, better results were obtained in this study in the EVLA group compared with the RFA groups in terms of such criteria as intraoperative and postoperative pain, postoperative analgesia requirement, and times to return to activity and return to work. The differences in intraoperative and postoperative pain and times to return to activity between the groups were statistically significant ($P < 0.026$, $P < 0.038$, and $P < 0.001$, respectively). Almost all those studies reporting better results for RFA than for EVLA have used both low wavelength laser and naked-tip laser catheters.[10–13] Because high wavelength laser rays use water as a chromophore, they penetrate the vein wall better. The radial emission of the rays also permits more homogeneous contact with the vein wall and reduces perforation levels. We therefore used a high wavelength and radial fiber in this study. No procedure-related major complications (DVT, pulmonary embolism, or skin burn) occurred in this study. Minor complication levels were lower in the EVLA group. In conclusion, EVLA and RFA have similar success rates. In terms of intraoperative and postoperative pain, however, EVLA using a wavelength of 1,470 nm and radial fiber is superior to RFA in veins of 10 mm and above.

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