Comparison of ultrasound results following endovenous laser ablation and radiofrequency ablation in the treatment of varicose veins

Ann Ital Chir, 2019 90, 5: 457-642
pii: S0003469X19029658
Epub Ahead of Print - September 25
free reading: www.annitalchir.com

Hakan Öntas*, Turhan Yavuz**, Altay Nihat Acar**, Dinçer Uysal**

**Department of Cardiovascular Surgery, Balıkesir Atatürk City Hospital, Turkey*
***Cardiovascular surgery Department, Suleyman Demirel University Medicine Faculty, Turkey*

Comparison of ultrasound results following endovenous laser ablation and radiofrequency ablation in the treatment of varicose veins

PURPOSE: *Superficial venous insufficiency is a common problem associated with varicose veins. In addition to classical symptoms, it may result in skin changes, venous ulcers and has a great impact on patients' health-related quality of life. In the last decade, minimally invasive techniques such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) have been developed as alternatives to surgery in an attempt to reduce morbidity and improve efficiency. The aim of this study is to evaluate the efficacy of EVLA and RF therapies in superficial venous insufficiency.*
MATERIAL AND METHODS: *Fifty legs belonging to 50 patients with symptomatic primary venous insufficiency were treated. 25 saphenous veins treated with 1470 nmdiode laser, while 25, saphenous veins treated with bipolar Radiofrequency Induced Thermotherapy (RF). All patients underwent postoperative duplex scanning within 6 month after the procedure and followed clinically, to determine the severity of the venous disease. Complications and occlusion rates were recorded.*
RESULTS: *Total occlusion rates in RF and EVLA groups were 100% and was 100%, respectively. There was no significant difference between groups (p=0,140). Major complications such as skin burns, deep venous thrombosis have not been detected for both groups. 2 patients treated with EVLA had erythema (8%) and 1 patient had a pain sensation (4%). 1 patient in the RF group had erythema (4%), 1 had pain (4%) and 1 had a burning sensation (4%).*
CONCLUSION: *EVLA and RF therapies in saphenous vein insufficiency are effective, minimally invasive, safe, easy to use treatment modalities with good patient satisfaction and high occlusion rates.*

KEY WORDS: EVLA, Radiofrquency, Venous insufficiency

Introduction and Objective

Venous insufficiency (VI) is a common disease that may be accompanied by varicose veins, causing a wide range of clinical symptoms if left untreated. Varicosis is seen in about 1/3 of males and females who are aged between 18-64. Lower extremity varicosities are divided into 3 groups depending on their size and distance to skin as spider veins, reticular veins and varicose veins. While they may be asymptomatic, they can also cause severe symptoms such as pain with standing for a long time, itching, burning sensation, tingling, nocturnal cramps, edema, skin changes and venous ulcers [1,3,6]

Varicose veins are often caused by vena saphena magna (VSM) reflux associated with insufficiency in the saphenofemoral junction. Gender, pregnancy, hormonal balance, age, gravity and standing or sitting for a long time are also factors contributing to the formation and progression of primary varicose veins [2,3,5,23].

Venous diseases can be diagnosed by listening to the clinical complaints of the patient and examination. However, diagnostical methods used in the evaluation are quite important for planning the right treatment. Ultrasonography (US), venography, computed tomogra-

Pervenuto in Redazione Ottobre 2018. Accettato per la pubblicazione Novembre 2018.
Correspondence to: Hakan Öntas, Balıkesir Atatürk City Hospital, Bahçelievler, Balıkesir, Turkey (e-mail: maestrohakan@hotmail.com)

phy (CT), magnetic resonance venography are diagnostic methods that are still applied [1,3].

The conventional treatment of varicosities is surgery with the ligation of saphenofemoral or saphenopopliteal junction, stripping of the saphenous vein showing insufficiency and excision of varicose veins. In recent years, methods such as endovenous laser ablation (EVLA), radiofrequency ablation (RFA) and sclerotherapy have been used in the treatment of varicose veins. These methods, which are performed under local or spinal anesthesia and US guidance, are alternatives to surgical methods. EVLA, RF, sclerotherapy are current treatment modalities that are applied today due to being minimally invasive and the low rates of complications [1-6].

The aim of this study to investigate the differences between the Doppler USI and clinical results following endovenous laser ablation therapy and Radiofrequency therapy, which are used in the treatment of lower extremity superficial venous insufficiency and associated varicosities that are frequently seen in society and may present itself in different forms ranging from cosmetic problems to venous ulcers.

Material and Methods

This study was conducted in a 6-month period in 2014 at the Cardiovascular Surgery Department, Faculty of Medicine, Suleyman Demirel University. The study enrolled 50 patients (25 males, 25 females) with symptomatic saphenofemoral insufficiency aged between 28-65 with a VSM diameter ≥ 5.5 mm. 25 patients were treated with EVLA and the other 25 patients were treated with RF. Doppler USG was performed in patients at 6 months post-operatively. The study protocol and clinical method were approved by the Ethics Board of Suleyman Demirel University. (Board decision dated 02.07.2014 and no. 101). Patients aged <18, pregnant and breastfeeding women, and patients requiring emergency interventions and treatment were excluded from the study.

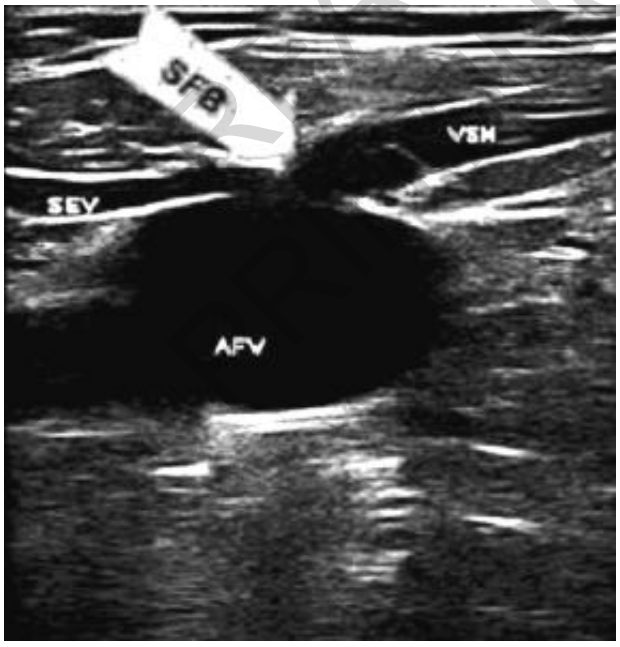

Fig. 1: SFB where VSM discharge into AFV, SEV: Superficial epigastric vein.

EVLA procedure was performed after administering spinal anesthesia by giving the appropriate position with entry using 21G micro puncture needle generally from above the knee into the venous segment to be treated under ultrasound guidance and appropriate sterile conditions. After gaining venous access, venous sheath and fiber in the laser kit were placed into the saphena magna, 1-2 cm inferior to the saphenofemoral junction, and tumescent anesthesia was started. A mixture of 500 cc serum physiological solution, 20 cc prilocaine and 20 cc sodium bicarbonate was used for each extremity during tumescent anesthesia. Tumescent anesthesia was injected with 21 G needle around the venous segment to be treated under US. The necessary amount of the prepared mixture was used. Then, the ablation stage was started. After the optimum application of tumescent anesthesia, ablation stage was performed. During ablation, the target venous segment was burned with 15 watt in the continuous mode. Generally, the pullback speed of the laser fiber was determined to provide 50-100 joule power per centimeter of the vein segment in proportion to the dilatation degree in the vein. A lower energy amount was used for superficial segments to avoid skin burns. After the operation, the treated venous segment was evaluated with ultrasonography for control purposes, and the operation was finished.

For RF operation, the catheter was placed into the saphenous vein, generally at knee level, under spinal anesthesia with US guidance. After the catheter tip was advanced to the top of the saphenous vein with insufficiency, tumescent anesthesia was injected around the vein under ultrasonography in order to prevent heat damage. The tumescent anesthesia method prevents heat damage and helps both the vein spasm and the easier performance of the operation. After it was ensured under ultrasonography that the catheter tip was in the right place, radiofrequency energy was started to be delivered. At this point, the heat inside the vein was raised to a maximum 120 °C. While delivering energy, the catheter was slowly withdrawn. In the radiofrequency method, the catheter was pulled down by giving energy for 20 seconds per 7 cm.

The patients in both groups wore a Class 2 (25-32 mmhg) thigh high varsity socks for three months following the operation.

Statistical Analysis

T test and chi-squared Fisher's test were used in the statistical evaluation of the obtained data. The mean of two

Table I - Summary Values

	GROUPS	N	Mean	Std. Deviation	Std. Error Mean
Preop VSM Diameter	EVLA	25	8.2960	2.54893	.50979
	RF	25	7.2200	1.44712	.28942
Postop VSM Diameter	EVLA	25	3.3560	.48997	.09799
	RF	25	3.1720	.63804	.12761

Table II - Post-op Minor complication

	Postop Minor Complication	N	Mean	Std. Deviation	Std. ErrorMean
Preop VSM Diameter	No	41	7.7683	2.24827	.35112
	Yes	9	7.7111	1.51859	.50620
Postop VSM Diameter	No	41	3.1902	.55444	.08659
	Yes	9	3.6000	.55000	.18333

dependent masses and the mean of two independent masses in the groups were compared. If the p-value obtained from the comparisons is <0.05, then there is a difference between the compared groups or situations.

Results

The study enrolled 50 patients planned to be treated with EVLA and RF. The mean age was 28-65. 50% of the patients were female. During the diagnosis of venous insufficiency, CEAP clinical classification for the extremities was detected to be C2 in 11 extremities, C3 in 34 extremities and C4 in 5 extremities. During the DU examination before the operation, all patients (100%) had SFY while no patients had DVY and perforating vein insufficiency.

Intragroup comparison for EVLA and RF (Table I).

Comparison of the Previous VSM Diameter Values for the Two Groups:

As t=1.836, p=0.073>0.05, there is no difference in the previous VSM values between the two groups.

Comparison of the Next VSM Diameter Values for the Two Groups:

As t=1.144, p=0.258>0.05, there is no difference in the next VSM values between the two groups.

There was no significant difference in the pre-op and post-op VSM diameters between the EVLA and RF treated groups. Both groups had full occlusion in the post-op VSM diameters (Table II).

Comparison of the Previous VSM Diameter Values for the groups that had or did not have Post-op Minor Complications

As t=-0.720, p=0.943>0.05, there is no difference in the previous VSM values between the two groups that had or did not have Post-op Minor Complications.

Comparison of the Next VSM Diameter Values for the groups that had or did not have Post-op Minor Complications

As t=-2.014, p=0.051>0.05, there is no difference in the next VSM values between the two groups that had or did not have Post-op Minor Complications.

With regard to post-op minor complications, 2 EVLA-treated patients had erythema and 1 patient had a pain sensation. 1 RF-treated patient had erythema, 1 had a pain sensation and 1 had a burning sensation. Almost all patients in both groups had ecchymose. These patients had no such complaints during the post-op 10-day controls. Neither group experienced a major complication (DVT, Pulmonary embolism).

Discussion and Conclusion

Varicosis is a frequent disease affecting 25% of the female population and 15% of the male population. Age, gender, pregnancy, hormonal balance, gravity, and standing or sitting for a long time are primary factors affecting the formation of varicose veins or deterioriation of the existing clinical picture. Patients generally seek treatment with aesthetical concerns related to varicose veins but many patients also have severe accompanying symptoms [7,8].

If left untreated, about 50% of patients with superficial venous insufficiency develop chronical venous insufficiency signs such as edema, eczema, pigmentation and ulceration in the lower extremity [9,19].

RF and EVLA therapies show many technical similarities. Both techniques deploy vein entry under US, catheter placement into the lumen to be treated, application of tumescent anesthesia and delivering energy by continuously withdrawing the catheter along the treated vein. However, there are some differences affecting

patient and practitioner comfort during the procedure, and the duration and success of the operation.

As the first endovenous thermal ablation technique, RF (VNUS Closure Plus) was performed [10]. Later, EVLA technique came into use and laser systems with varying wavelengths became the most frequently used endovenous ablation methods. [2,23]In recent years, two more new RF systems were manufactured. These are Segmental EVRFA(VNUS Closure Fast) and RFITT (Olympus Celon) systems.

There are publications stating that the 18G needle and 0.035 guidewire and sheath with a thicker diameter used in RF increase venospasm during canulation, potentially making canulation harder [4,5,21].

There are also studies suggesting that performing the catheter placement in EVLA in several steps (sheath placement, advancing guidewire, removal of the sheath, placement of the dilatator, and positioning of the fiber) increase the likelihood of error [8].

In our study, we observed in 4 cases (11.7%) that RF catheter was stuck in the lumen despite the vein not being convoluted when advancing the RF catheter but this segment could be passed with dilatation manoeuvres (valsalva, reverse Trendelenburg position, massage). We think that the RF catheter being relatively thicker in diameter (5.4F) and thus triggering venospasm more may be the reason for this situation. Also, the micro introducer set we used in RF consisted of a thicker sheath, punction needle and guidewire, which caused more venospasm during vascular entry compared to EVLA. In cases treated with EVLA, there was no technical difficulty. In our opinion, manufacturing RF catheters with thinner diameters and use of introducer sets may provide a faster and more comfortable procedure compared to EVLA. Furthermore, considering the fact that the saphenous vein lengths we treated were significantly shorter in the RF group, the use of a thick catheter may be considered as one of the criteria that may direct the clinician in deciding for a therapy. EVLA therapy may be firstly preferred due to the use of a thinner catheter for the ablation of more distal segments.

Minor complications like pain, erythema were rarely observed in our study. There is no significant difference in terms of minor complications between EVLA and RF. Major complications like DVT were not seen.

Krnic et al. reported in their retrospective study where they comparatively evaluated both treatments (RFITT and 1064 nm Nd: Yag Lazer) that operation could not be completed due to the catheter being stuck during advancing in 2 cases treated with RFITT (4.5%), and this problem did not occur in EVLA-treated cases [12].

Braithwaite et al. reported in their multi-centre study that clot was accumulated on the RFITT catheter tip in some cases and thus operation could be continued only after withdrawing and cleaning the catheter [13]. The problem with advancing the catheter was also indicated for Closure catheters in a study by Gohel et al. [4].

Puggioni et al. reported in their retrospective study comparing both methods (Closure Fast and 810 nm EVLA) that repeating catheter entry was required in 9 RF-treated cases (17%) after recanalization under RDUS but such a problem was not experienced in EVLA-treated cases [11].

There are reasons for choosing one method over the other in the studies with EVLA and RF because of superiorities in terms of application, frequency of minor complications and different occlusion rates [14,15,10]. However, the frequency of minor complications in cases treated with EVLA and RF was at a statistically tolerable level in our study. (2 patients treated with EVLA had erythema and 1 patient had a pain sensation. 1 RF-treated patient had erythema, 1 had pain and 1 had a burning sensation.)

Application of tumescent anesthesia in endovenous thermal ablation treatment is known for its importance in many aspects, such as a painless procedure, ability to walk in the shortest time post-operatively, prevention of thermal effect by removing perivenous tissues, increased contact of the laser or radiofrequency catheter with the vein lumen, and minimization of thrombus formation by removing the blood inside the lumen [3,20]. There are studies in the literature reporting that complications such as paresthesia, skin burns and DVT, and post-operative dysesthesia complaints are high in EVLA and RF treatments performed without tumescent anesthesia but these rates become considerably lower following the use of tumescent anesthesia [15,22].

Tumescent anesthesia was applied in all operations in our study. It was observed that complaints such as pain sensation, ecchymose and erythema were at low or acceptable levels in the post-op period in our cases, and major complications like DVT did not develop. Therefore, we think that tumescent anesthesia should be particularly used in thermal ablation techniques.

Similar studies conducted [17-19] mention the superiority of RF and EVLA applications to each other in terms of occlusion rates and frequency of minor complications. However, our study concluded that there was no statistical superiority for occlusion rates and frequency of minor complications in cases treated with EVLA and RF. 2 patients treated with EVLA had erythema (8%) and 1 patient had a pain sensation (4%). 1 RF-treated patient had erythema (4%), 1 had pain (4%) and 1 had a burning sensation (4%). Therefore, differing from the other studies in the treatment of varicose veins, it was observed that there was no superiority between EVLA and RF therapies, and they could be used safely.

Conclusion

EVLA and RF are safe and effective treatment methods in saphenous vein insufficiency and have become a serious alternative to the conventional surgical treatment in

recent years because of easy application and more patient comfort. Early and mid-term outcomes spread their use with lower complication and recurrence rates. Comparing RF and EVLA therapies, we think that the two methods are not superior to each other in terms of saphenous vein occlusion rates and frequency of minor complications.

Riassunto

L'insufficienza venosa superficiale è un problema comunememte associato alle vene varicose. Oltre ai sintomi classici, può causare alterazioni cutanee, ulcere venose ed ha un grande impatto sulla qualità della vita della salute dei pazienti. Nell'ultimo decennio sono state sviluppate come alternative alla chirurgia tecniche mininvasive, come l'ablazione laser endovenosa (EVLA) e l'ablazione con radiofrequenza (RFA), nel tentativo di ridurre la morbilità e migliorare l'efficienza. Con questo studio si è inteso valutare l'efficacia delle terapie sia EVLA che RF nell'insufficienza venosa superficiale.

Sono state studiate cinquanta gambe appartenenti a 50 diversi pazienti con insufficienza venosa primaria sintomatica. 25 vene safene sono state trattate con laser nm diode 1470, mentre 25 vene safene sono state trattate con termoterapia indotta da radiofrequenza bipolare (RF). Tutti i pazienti sono stati sottoposti a scansione duplex postoperatoria entro 6 mesi dalla procedura e seguiti clinicamente, per determinare la gravità della malattia venosa, e sonio stati registrati le complicazioni ed l'incidenza dell'occlusione.

Le percentuali di occlusione totale nei gruppi RF ed EVLA sono state in entrambi i gruppi del 100% senza alcuna differenza significativa tra loro (p = 0,140). Non sono state rilevate complicanze importanti come bruciature della pelle, trombosi venosa profonda per entrambi i gruppi. 2 pazienti (8%) trattati con EVLA hanno presentato eritema, e 1 paziente (4%) ha dichiarato una sensazione di dolore. 1 paziente (4%) nel gruppo di RF ha presentato eritema, 1 ha lamentato dolore (4%) ed 1 una sensazione di bruciore (4%).

Si conclude che le terapie EVLA e RF nell'insufficienza venosa della safena sono modalità di trattamento efficaci, minimamente invasive, sicure e facili da usare con una buona soddisfazione del paziente e alti tassi di occlusione.

References

1. Padberg FT Jr*: CEAP classification for chronic venous disease.* Dis Mon, 2005; 51:176-82.

2. RJ, Gough MJ: *Treatment options for primary varikose veins-a review*. Eur J Vasc Beale Endovasc Surg, 2005; 30:83-95.

3. Brown K, Moore CJ: *Update on the Treatment of Saphenous Reflux: Laser, RFA, or Foam?* Perspect Vasc Surg Endovasc Ther, 2009.

4. Ravi R, Rodriquez-Lopez JA, Trayler EA, et al.: *Endovenous ablation of incompetent saphenous veins: A large single-center experience.* J Endovasc Ther, 2006; 13:244-48.

5. Davies R: *Buffering the pain of local anaesthetics: A systematic review*. Emerg Med, 2003; 15:81-88.

6. Merchant RF, Pichot,O, Myers, KA: *Four-year follow-up on endovascular radiofrequency obliteration of great saphenous reflux.* Dermatol Surg, 2005; 31(2): 129-34.

7. Vasquez, M.A., et al.: *The utility of the venous clinical severity score in 682 limbs treated by radiofrequency saphenous vein ablation.* Dermatol Surg, 2007; 45(5): 1008-14; discussion 1015.

8. Van den BOS RRDM, M.M.G: *Endovenous thermal ablation for varicose veins: Strengths and weaknesses.* Phlebolymphology, 2012; 19(4):163-69.

9. Van den Bos, R.R., et al.: *Proof-of-principle study of steam ablation as novel thermal therapy for saphenous varicose veins.* Dermatol Surg, 2011; 53(1):181-86.

10. Goldman MP: *Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: Preliminary 6-month follow-up.* Dermatol Surg, 2000; 26(5): 452-56.

11. Puggioni A., et al.: *Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: Analysis of early efficacy and complications*. Dermatol Surg, 2005; 42(3): 488-93.

12. Krnic,A, Sucic Z: *Bipolar radiofrequency induced thermotherapy and 1064 nm Nd:Yag laser in endovenous occlusion of insufficient veins: Short term follow up results*. Vasa, 2011; 40(3):235-40.

13. Goldman MP, Guex JJ, Weiss RA: *Sclerotherapy: Treatment of varicose and telangiectatic leg veins.*, Mosby, St. Louis, 1995; 85-117.

14. Puggioni A, Kalra M, Carmo M, et al.: *Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: Analysis of early efficacy and complications*. J Vasc Surg, 2005; 42:488-93.

15. Theivacumar NS, Dellagrammaticas D, Beale RJ, et al.: *Fate and clinical significance of saphenofemoral junction tributaries following endovenous laser ablation of great saphenus vein.* Br J Surg, 2007; 94:722-25.

16. Hingorani AP, et al.: *Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: A word of caution*. Dermatol Surg, 2004; 40(3): 500-04.

17. Proebstle TM, Lehr HA, Kargl A, et al.: *Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles*. J Vasc Surg, 2002; 35:729-36.

18. Beebe-Dimmer JL, Pfeifer JR, Engle JS, et al.: *The epidemiology of chronic venous insufficiency and varicose veins*. Ann Epidemiol, 2005; 15:175-84.

19. Yılmaz S: *Alt Ekstremite Venöz Sistem Anatomisi ve Ultrasonografi İncelemesi. 27.* Ulusal Radyoloji Kongresi Kurs Kitabı s: 94-100.

20. Depalma RG, Kowalek DL, Barcia TC ve ark.: *Target selection for surgical intervention in severe chronic venous insufficiensy: Comparison of duplex scanning and phlebography*. J Vasc Surg, 2000; 32(5): 913- 20.

21. Nordon IM, et al.: *A prospective double-blind randomized con-*

trolled trial of radiofrequency versus laser treatment of the great saphenous vein in patients with varicose veins. Ann Surg, 2011; 254(6): 876-81.

22. Kara KA, Hafız E, Deniz H, Arı M, Polat M, Güzel G: *Successfully surgical repair of giant unruptured aneursym of the sinus of valsalva.* J Clin Case Rep, 7:985. Doi: 10.4172/2165-7920.1000985.

23. Quarto G, Amato B, Giani U: *Comparison of traditional surgey and laser tretment of incotinent great saphenous vein.Result of meta-Analysis*. Benassai GE, Apperti M, Furino E.: Ann Ital Chir, 2016; 87:61-67.