

## A comparison of four different endovenous ablation techniques

### *Dört farklı endovenöz ablasyon tekniğinin karşılaştırılması*

Kemal Korkmaz,<sup>1</sup> Ali Ümit Yener,<sup>2</sup> Serhat Bahadır Genç,<sup>1</sup> Hikmet Selçuk Gedik,<sup>1</sup>  
Ali Baran Budak,<sup>1</sup> Kerim Çağlı<sup>1</sup>

*Institution where the research was done:*

Ankara Numune Training and Research Hospital, Ankara, Turkey

*Author Affiliations:*

<sup>1</sup>Department of Cardiovascular Surgery, Ankara Numune Training and Research Hospital, Ankara, Turkey

<sup>2</sup>Department of Cardiovascular Surgery, Medical Faculty of Çanakkale Onsekiz Mart University, Çanakkale, Turkey

#### ABSTRACT

**Background:** This study aims to investigate the efficacy of radiofrequency ablation and endovenous laser ablation techniques and the impact on the quality of life of patients.

**Methods:** Between October 2011 and October 2012, 472 extremities of a total of 368 patients (258 females, 110 males; mean age 41.2 years; range 24 to 62 years) who were admitted to our Cardiovascular clinic and underwent endovenous ablation for symptomatic varicose veins were included in the study. Of the patients, 1470 nm wavelength diode laser in 34.1% (n=161), 980 nm wavelength diode laser in 20.1% (n=95), radiofrequency ablation in 26.3% (n=124), and 1470 nm wavelength radial fiber laser in 26.3% (n=124) was applied. These techniques were compared in terms of the postoperative complications, complete occlusion, recanalization rates, and patient comfort.

**Results:** Any major complication such as deep venous thrombosis, pulmonary embolism, and skin burn was observed in none of the patients. Postoperative pain and paresthesias were similar in the endovenous laser ablation groups. Radiofrequency ablation group had lesser postoperative pain and ecchymosis (n=9; n=2; p<0.05). Ecchymosis were mostly seen in 1470 nm wavelength radial diode laser group (n=12; p<0.05) and 980 nm wavelength diode laser group (n=15; p<0.05). At six months, recanalization was observed in the 1470 nm wavelength diode laser group (n=2) and in the 980 nm wavelength diode laser group (n=2). At one year, we observed recanalization in four patients in the radiofrequency ablation group, which did not statistical significance.

**Conclusion:** Considering the same recanalization rates with endovenous laser ablation, lower need for tumescent anesthesia, effective use of thermal energy, and low complication rates, we recommend radiofrequency ablation technique in the treatment of superficial venous insufficiency.

**Keywords:** Complication; endovenous ablation; great saphenous vein.

#### ÖZ

**Amaç:** Bu çalışmada radyofrekans ablasyon ve endovenöz lazer ablasyon tekniklerinin etkinliği ve hastaların yaşam kalitesi üzerine etkisi araştırıldı.

**Çalışma planı:** Ekim 2011 - Ekim 2012 tarihleri arasında, Kalp ve Damar Cerrahisi kliniğimize başvuran ve semptomatik variköz venler nedeniyle endovenöz ablasyon yapılan toplam 368 hastanın (258 kadın, 110 erkek; ort. yaş 41.2 yıl; dağılım 24-62 yıl) 472 ekstremitesi çalışmaya dahil edildi. Hastaların %34.1'ine (n=161) 1470 nm dalga boyu diod lazer, %20.1'ine (n=95) 980 nm dalga boyu diod lazer, %26.3'üne (n=124) radyofrekans ablasyonu ve %26.3'üne (n=124) 1470 nm dalga boyu radyal fiber lazer uygulandı. Bu teknikler ameliyat sonrası komplikasyonlar, tam kapanma, tekrar akım oluşumu oranları ve hasta konforu açısından karşılaştırıldı.

**Bulgular:** Hiçbir hastada derin ven trombozu, pulmoner emboli, cilt yanığı gibi önemli komplikasyonlar gözlenmedi. Ameliyat sonrası ağrı ve his kaybı, endovenöz lazer ablasyon gruplarında benzerdi. Radyofrekans ablasyon grubunda ağrı ve ekimoz daha az görüldü (n=9; n=2; p<0.05). Ekimoz en fazla 1470 nm radyal diod lazer grubunda (n=12; p<0.05) ve 980 nm diod lazer grubunda (n=15; p<0.05) görüldü. Altıncı ayda 1470 nm dalga boyu diod lazer grubunda (n=2) ve 980 nm dalga boyu diod lazer grubunda (n=2) tekrar akım oluşumu izlendi. Birinci yılda radyofrekans ablasyon grubunda dört hastada istatistiksel olarak anlamlı olmayan tekrar akım oluşumu izlendi.

**Sonuç:** Endovenöz lazer ablasyon ile aynı rekanalizasyon oranlarına sahip olması, tümesan anestezi gereksiniminin daha az olması, termal enerjinin verimli kullanımı ve düşük komplikasyon oranları dikkate alındığında, yüzeysel venöz yetmezlik tedavisinde radyofrekans ablasyon tekniğini önermekteyiz.

**Anahtar sözcükler:** Komplikasyon; endovenöz ablasyon; büyük safen ven.



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Correspondence: Kemal Korkmaz, MD. Ankara Numune Eğitim ve Araştırma Hastanesi, Kalp ve Damar Cerrahisi Kliniği, 06230 Altındağ, Ankara, Turkey.

Tel: +90 312 - 508 42 85 e-mail: kemalkorkmaz44@hotmail.com

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Chronic venous insufficiency (CVI) leading to varicose veins is one of the most common diseases in the Western society.<sup>[1,2]</sup> Although no clear data has been demonstrated in the Turkish population, symptoms due to varicose veins have been most common condition presenting to physicians.<sup>[3]</sup> In developing countries long working hours and less physical activity are considered to contribute to the formation of the disease.

The great saphenous vein (GSV) ligation and stripping was earlier the treatment of choice; however, the development of catheter-based minimally invasive techniques such as radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) has evolved the surgical management of CVI. Since there has been a lack of data comparing the results of different EVLA techniques in the Turkish population in the literature, we aim to compare the effects of different EVLA techniques performed in our recently established cardiovascular clinic in the Turkish population with regard to postoperative complications, patient comfort, and occlusion/recanalization rates.

## PATIENTS AND METHODS

Between October 2011 and October 2012, 472 extremities of a total of 368 patients (258 females, 110 males; mean age 41.2 years; range 24 to 62 years) who were admitted to our Cardiovascular outpatient clinic and underwent EVLA for symptomatic varicose veins were included in this retrospective study.

A written informed consent was obtained from each patient. The study protocol was approved by the local Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki. Demographic data, physical examination notes, preoperative venous Duplex ultrasound (US) imaging notes of the lower extremity veins data were recorded.

The Comprehensive Classification System for Chronic Venous Disorders (CEAP) classification, venous severity scores and length of ablation, tumescent volume were noted for all patients using the surgery forms. Procedure-related major complications such as deep vein thrombosis (DVT), pulmonary embolism, and skin burns were noted using the patient files. In addition, minor complications including thrombophlebitis, paresthesia, ecchymoses, and postoperative pain were recorded using the patient files.

Clinical examination was performed at each visit and Duplex US (Aloka Prosound Alpha 7, linear array, 5-7 MHz [Hitachi Aloka Medical, Japan])

was performed on the sixth month and first year postoperatively by a single vascular surgeon.

All patients were applied a questionnaire for early and late postoperative period and quality of life (QoL) at six months and at one year. The Chronic Venous Insufficiency Quality of Life Questionnaire 14 (CIVIQ-14) which was translated into Turkish was used to assess the patients complaints. We added two new questions to the questionnaire: "Would you prefer the same surgery again?" "If yes, why?"

## Statistical analysis

Statistical analysis was performed using the IBM SPSS version 19.0 software (IBM Corporation, Armonk, NY, USA). The data were given in the mean and standard deviation, while the enumerated values were expressed in percentages. For the statistical analyses, frequency tables, descriptive statistics, chi-square analysis, one-way analysis of variance, paired-samples t-test, and the least square difference tests were used. A *p* value of 0.05 was considered statistically significant.

## RESULTS

According to the CEAP classification, 472 extremities were examined. Of these, C2 was identified in 351 (74.2%) extremities, C3 in 68 (14.4%) extremities, C4 in 45 (9.5%) extremities, and C5-C6 in eight (1.6%) extremities (Table 1).

Four EVLA types were used in all patients. The techniques were grouped as: group A (1470 nm wavelength diode laser, n=161 [34.1%]), group B (980 nm wavelength diode laser, n=95 [20.1%]), group C (radiofrequency catheter, n=124 [26.3%]), and group D (1470 nm wavelength radial fiber laser, n=124 [26.3%]) (Table 1).

The GSV diameter at the saphenofemoral junction (SFJ) and 3 cm above the knee were measured preoperatively. No statistically significant difference was found in the diameter of the GSV above the knee among the groups (*p*>0.05).

A tumescent anesthetic solution was instilled percutaneously during the surgery. Tumescent anesthesia solution was prepared with 1000 mL 0.9% NaCl, 20 mL 2% prilocain, 60 mL 8.4% NaHCO<sub>3</sub>, 1 mg adrenaline. The linear energy density (LEED) values were used to calculate the laser energy based on the GSV diameter. The GSV diameters between 5.5 to 7.5 mm 60j/cm-70j/cm and for diameters above 7.5 mm 70j/cm-90j/cm were used. Even for the diameter above 15 mm, these LEED values were

**Table 1. Demographic data**

	Group A		Group B		Group C		Group D	
	n	Min-Max	n	Min-Max	n	Min-Max	n	Min-Max
Extremities (n=472)	161		95		124		124	
Age (year)	42		38		33		40	
Gender								
Female (n=258)	91		48		74		45	
BMI >30	85		50		84		75	
BMI <30	76		45		40		49	
CEAP classification								
C2 (n=351)	105		75		90		91	
C3 (n=68)	20		12		18		18	
C4 (n=45)	14		9		10		12	
C5-6 (n=8)	3		1		2		2	
Great saphenous vein diameter								
SFJ (mm)	8	5.5-14	7.6	5.5-17	8.4	5.5-19	8.3	5.5-21
Above knee (mm)	5	3.4-8.5	5.4	2.7-7.8	5.2	3.6-8.2	5.5	4.1-9.3
Ablation length (cm)		38		36		38		36
VCSS		7.1		7.3		6.9		7.0
Tumescent anesthesia volume (mL)		500-1000		500-1000		<500		500-1000

BMI: Body mass index; CEAP: Comprehensive classification system for chronic venous disorders; SFJ: Saphenofemoral junction; VCSS: Venous clinical severity score; Min: Minimum; Max: Maximum.

used as maximum 90j/cm. Group C required less volume of tumescent anesthesia than the other groups (<500 mL,  $p<0.05$ ).

No major complication was seen in any of the groups; however, thrombophlebitis was observed in three patients in group A ( $p<0.05$ ). In these patients, the CEAP scores were above four and two of them suffered from active ulceration before surgery.

Postoperative pain complaint was not statistically different among the EVLA groups: 18 patient in group A, 14 patients in group B, and 15 patients in group D suffered postoperative pain ( $p=0.32$ ). The number of patients who complained about postoperative pain

in group C was significantly lower than the other ( $n=9$ ,  $p<0.05$ ).

Postoperative paresthesia was mostly seen in group A; however, the difference was not statistically significant ( $p=0.42$ ).

Ecchymosis was observed more frequently in group A and group B than the other groups ( $p<0.05$ ) (Table 2).

The CIVIQ-14 questionnaire results were also similar in all groups ( $p=0.12$ ). On the other hand, most patients responded ‘Yes’ to the question ‘Would you prefer the same surgery again?’ ( $p<0.05$ ) (Table 3).

**Table 2. Complications**

	Group A (n=161)		Group B (n=95)		Group C (n=124)		Group D (n=124)		p
	n	%	n	%	n	%	n	%	
Minor complications									
Ecchymosis	15	9.3	12	12.6	<b>2*</b>	1.6	9	7.2	<b>&lt;0.05*</b>
Thrombophlebitis	<b>3*</b>	-	0	0	0	0	0	0	<b>&lt;0.05*</b>
Paresthesia	8	5	4	4.2	5	4	6	4.8	
Postoperative pain	18	11	14	13.7	<b>9*</b>	7	15	12	<b>&lt;0.05*</b>
Major complications									
Skin burns	0	0	0	0	0	0	0	0	
Deep venous thrombosis	0	0	0	0	0	0	0	0	
Pulmonary tromboembolism	0	0	0	0	0	0	0	0	

\* Statistically significant.

The Duplex US study at six months revealed recanalization in two patients in group A and two patients in group B. At one year of follow-up, we observed recanalization in four patients in group C. However, no significant difference was found in the recanalization rates at the postoperative first year among the groups ( $p>0.05$ ) (Table 4).

**DISCUSSION**

To date, the long-term results of various minimally invasive methods for the ablation of GSV have been compared and published in the literature.<sup>[4-6]</sup> Nevertheless, in this study, we aimed to report our initial results in a recently established cardiovascular clinic, to compare the success rates, and to investigate the impact of these four techniques on the quality of life of the Turkish patients.<sup>[4]</sup>

As a state hospital and as a recently established clinic, we have addressed the most common problems in the community in order to develop optimal treatment strategies. Chronic venous insufficiency constitutes a large majority of patients admitted to our clinic. When patients with such a condition choose an invasive procedure as a treatment, they often prefer less pain and return to their daily activities as soon as possible. However, the states policy is to prefer the treatment methods, which are cost-effective.

In our clinic, these four EVLA types have been performed in accordance with our policies. Although not mentioned, a blind randomization was carried out for the patients who underwent endovenous ablation for varicosity treatment. This randomization occurred because of sequentially administration of patients and

**Table 3. The Chronic Venous Insufficiency Quality of Life Questionnaire 14**

Dimension	Item
Pain	Pain in the legs
	Impairment at work
	Sleeping poorly
Physical	Climbing several floors
	Squatting/kneeling
	Walking at a good pace
	Going to parties
	Performing athletic activities
Psychological	Feeling nervous
	Having the impression of being a burden
	Being embarrassed to show legs
	Becoming irritable easily
	Having the impression of being disabled
	Having no desire to go out

**Table 4. Quality of life and recanalization rates (The Chronic Venous Insufficiency Quality of Life Questionnaire 14)**

	Group A			Group B			Group C			Group D			p	
	n	Median	Min-Max	n	Median	Min-Max	n	Median	Min-Max	n	Median	Min-Max		
Total scores														
6 <sup>th</sup> month		68	55-85	91	72	51-83	123	83	50-87	117	72	56-85		>0.05
1 <sup>st</sup> year		67	60-72	4	71	63-84	1	78	55-89	7	68	56-74		>0.05
Would you prefer the same surgery again?														
Yes	150													
No	11													
Recanalization														
6 <sup>th</sup> month	2			2			0			0				<0.05
1 <sup>st</sup> year	2			2			4			0				>0.05

Min: Minimum; Max: Maximum.

catheter buying procedure. Therefore, we aim to report our clinic experience, although randomized controlled trials were published previously.<sup>[4-6]</sup>

It is a necessary practice for patients with venous insufficiency to assess their complaints with at least two scoring systems during their first visit to the clinic. VSSC and CEAP scoring are effective and useful methods in evaluating lesions with the duration of the patient's complaints.<sup>[7,8]</sup> We think that patients are better evaluated by the combined use of these two scoring systems. The reassessment of the saphenofemoral junction and the puncture site by Duplex US even after the first visit and a few hours before the procedure is the most important reason for our successful results.<sup>[9]</sup> Continuation of the assessment with Duplex US may be an effective reason for the reduction of recanalization, if necessary, by adjusting of the compression treatments.<sup>[9]</sup>

In the present study, all patients were under general anesthesia in order to complete in single session, although consecutive patients had ablation without the surgeon's catheter preference and had simultaneous phlebectomy. Our study demonstrated that RFA resulted in significantly less minor complications and higher patient comfort than other EVLA techniques, consistent with the literature data.<sup>[4-6]</sup>

Postoperative ecchymosis was more frequent in EVLA groups but postoperative pain and ecchymosis were the lowest in the RFA group, even the volume of the tumescent anesthesia was lower. This result can be explained by the effects of the laser on the vessel wall and the perivascular region. EVLA primarily targets hemoglobin or water according to wave length. Thermal damage to the vein wall occurs by the absorption of photon energy (radiation), or by conduction of vapor bubbles and by heated conduction. This multiple energy ablates the vessel wall by affecting the perivascular space. Together with this, the thermal damage to the perivascular area can be minimized by the tumescent anesthesia. Despite adequate tumescent anesthesia, pain and ecchymosis can be seen after EVLA procedures.<sup>[4-6,10]</sup>

Complications seen in our clinic have rarely been seen in terms of post-procedural complications, and no pulmonary embolism has been seen.<sup>[11-13]</sup> Furthermore, we conducted a new operative protocol to prevent all undesired complications such as pain, bruise, and ecchymosis, which are common in almost 20 to 60% of patients.<sup>[4-5,10,14]</sup> To prevent bruise and ecchymosis, in addition to tumescent anesthesia, we applied topical ice-pack and dampened the skin with saline (+4 °C)

before the delivery of the energy. Cooling the skin with local hypothermia was helpful to prevent the undesired damages to the perivascular structures leading to ecchymosis and pain after the procedure. In addition, immediately after the ablation of the GSV, an ointment containing chondroitin sulfate was applied. The patients continued to use this ointment for the next one week and additional ointments containing NSAID to decrease the pain. A compression bandage was wrapped around the treated limb, which remained for three hours. Then, the patients wore Class II thigh-high compression stockings.

Among the four groups, the body mass index was greater than 30 in approximately half of the patients. This finding is important, as these patients had thicker subcutaneous fat tissues; in other words, the distance of the GSV from the skin was longer. As a result, the volume of tumescent anesthesia was higher to prevent the radiation of thermal energy to the surrounding tissues and skin. We also observed that most patients suffering from postoperative pain and ecchymosis had a BMI value of <30. Based on this finding, we conclude that thick subcutaneous fat tissue may be a factor which prevents cutaneous complications acting like a barrier similar to the tumescent anesthesia. In group B, we observed postoperative ecchymosis in 12.6% of the patients, indicating a higher rate than the other studies,<sup>[15]</sup> which can be explained by this factor. Applying topical ice-pack and dampening the skin with saline (+4 °C) before the delivery of the energy can also lower the perivascular damage in patients with a BMI value of <30.

On the other hand, some of our patients complained about the stiffness in the ablated area of the leg, which was caused by the application of the tumescent anesthesia. To solve this problem, a compression bandage was wrapped around the treated limb for three hours. This bandage resolved the discomfort and patients re-gained ability to ambulate early.

Furthermore, application of the tumescent anesthesia requires multiple patient needle-sticks which may cause bruising. In addition, adjustment of the accurate amount of the tumescent solution is difficult. This conflict can be solved by lowering the tumescent volume. Patients in group C required lower volumes of the tumescent solution. This finding can be explained by the technological development in the RF generators and catheters. Latest generation RF generators and catheters provide transmural heating of the venous wall and limiting the heating up of the surrounding tissue

using lower energy.<sup>[5,6,10,14]</sup> In a previous study, we published our satisfactory and encouraging results with the tumescentless RFA.<sup>[16]</sup>

Based on our findings, we suggest that RFA and EVLA are both appear to be effective for the treatment of GSV insufficiency. However, EVLA was found to be more cost-effective with a shorter duration of procedure was shorter than RFA. However, after RFA, the patients felt more comfortable and the required amount of tumescent anesthesia was lower.<sup>[16]</sup>

Agus et al.<sup>[17]</sup> reported a complete occlusion rate of 97% during three-year follow-up and found no major complications during the EVLA treatment, which was administered with 810 nm and 980 nm wavelength diode laser.

In another study, Doganci et al.<sup>[15]</sup> compared 980 nm wavelength diode and 1470 nm wavelength radial fiber lasers and found that the number of patients suffering from pain and ecchymosis in 980 nm wavelength diode laser group was higher. In our study, EVLA techniques did not differ statistically with regards to complications.

Discrepancies between studies can be because of pain data collection and additional applications used in our EVLA groups. We also had same occlusion rates individually in our 980 nm wavelength diode laser group; however, we found more pain in the 1470 nm wavelength diode laser group. In addition, we observed lesser complications in 1470 nm wavelength radial fiber laser group, which did not reach statistical significance. No major complication was observed thanks to the expert US guidance.

Follow of the quality of life before and after ablation procedure, CIVIQ-14 is a system that is currently being used.<sup>[18]</sup> In our clinic, we preferred to apply this scoring system. We translated questions for the Turkish population in the manner of Islamic and cultural additions. Such as for “kneeling”, we asked questions as “praying difficulties” or “going to parties” as “neighbourhood visits”.

The patients reported variable answers to the additional questions. The patients who had a complication after the procedure, such as ecchymosis and thrombophlebitis, answered the question negatively. The quality of life questionnaire and additional questions revealed that RFA was more favor than the EVLA procedures.

Based on this finding, we recommend tumescentless RFA with local hypothermia and compression technique under general anesthesia.<sup>[16]</sup>

Although the sample size was sufficient, the short follow-up period of 12 months was a limitation. Therefore, further long-term, large-scale studies are required to confirm these findings.

In conclusion, catheter-based minimally invasive techniques such as endovenous laser ablation and radiofrequency ablation have been widely adopted in modern surgical management of great saphenous vein insufficiency and varicose veins. Preoperative evaluation of patients with expert ultrasound imaging, identification of the differences between the techniques, and recognition of the patients expectations are mandatory. Additional applications such as topical cooling and using postoperative ointments may also helpful to prevent minor and major complications. Considering the same recanalization rates with endovenous laser ablation, lower need for tumescent anesthesia, effective use of thermal energy, and low complication rates, we recommend radiofrequency ablation technique in the treatment of superficial venous insufficiency.

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