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Evaluation of great saphenous vein occlusion rate and clinical outcome in patients undergoing laser thermal ablation with a 1470-nm bare fiber laser with low linear endovenous energy density

Avaliação da taxa de obliteração da veia safena magna e da evolução clínica de pacientes submetidos a termoablação com laser 1470 nm, fibra linear e baixa densidade de energia endovenosa linear

Walter Junior Boim Araujo¹, Jorge Rufino Ribas Timi¹, Carlos Seme Nejm Júnior¹, Filipe Carlos Caron¹

Abstract

Background: Water-specific 1470-nm lasers enable vein ablation at lower energy densities and with fewer side effects because they target interstitial water in the vessel wall. **Objectives:** To determine great saphenous vein (GSV) occlusion rate after thermal ablation with 1470-nm laser using 7W power and to evaluate clinical outcomes and complications. **Method:** Nineteen patients (31 GSVs) underwent thermal ablation. Follow-up duplex scanning, clinical evaluation using the Venous Clinical Severity Score (VCSS), and evaluation of procedure-related complications were performed at 3-5 days after the procedure and at 30 and 180 days. **Results:** Mean patient age was 46 years and 17 of the patients were female (89.47%). Of 31 limbs treated, 2 limbs were clinical class C2, 19 were C3, 9 were C4, and 1 limb was C5 according to the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification. Mean linear endovenous energy density was 33.53 J/cm. The GSV occlusion rate was 93.5% immediately after treatment, 100% at 3-5 days and 100% at 30 days after treatment and 87.1% 180 days after treatment. There was a significant reduction in VCSS at all time points. **Conclusions:** The data from this study support the possibility that the incidence of complications can be reduced without significantly affecting the clinical outcomes, by using lower energy density. However, this appears to be at the cost of reduced efficacy in terms of GSV occlusion rates.

Keywords: ablation techniques; laser therapy; varicose veins.

Resumo

Contexto: O laser de diodo 1470 nm, com comprimento de onda específico para água, tendo como alvo a água intersticial da parede venosa, poderia causar ablação venosa a densidades de energia menores e com menos efeitos colaterais. **Objetivos:** Determinar a taxa de obliteração da veia safena magna (VSM) após termoablação com laser 1470 nm utilizando 7 W de potência e avaliar a evolução clínica e as complicações. **Métodos:** Dezenove pacientes (31 VSMs) foram submetidos a termoablação e reexaminados através de ecodoppler, avaliação clínica utilizando o Venous Clinical Severity Score (VCSS) e avaliação das complicações do procedimento entre 3 e 5 dias e aos 30 e 180 dias de pós-operatório. **Resultados:** A média de idade dos pacientes foi de 46 anos; 17 eram mulheres (89,47%). De acordo com a classificação de Clinical-Etiology-Anatomy-Physiopathology (CEAP), 2 dos 31 membros tratados eram C2, 19 eram C3, 9 eram C4 e 1 membro era C5. A densidade de energia linear endovenosa média foi de 33,53 J/cm. A taxa de obliteração da VSM foi de 93,5% no pós-operatório imediato, de 100% entre 3 e 5 dias e aos 30 dias, e de 87,1% aos 180 dias. Houve uma redução significativa dos valores de VCSS em todos os momentos de avaliação. **Conclusões:** Os dados deste estudo apoiam a possibilidade de que, utilizando baixa densidade de energia, podemos reduzir a incidência de complicações sem afetar significativamente o resultado clínico. No entanto, isso parece ocorrer às custas da diminuição da eficácia em termos de taxa de obliteração da VSM.

Palavras-chave: técnicas de ablação; terapia a laser; varizes.

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INTRODUCTION

Chronic venous insufficiency (CVI) caused by varicose veins is a common medical condition and prevalence rates in adults can be as high as 28% to 35%.¹ The impact of CVI on patients' quality of life is comparable to that of other common chronic diseases, such as arthritis, diabetes, and cardiovascular disease.²

Conventional treatment of great saphenous vein (GSV) insufficiency includes high ligation at the saphenofemoral junction (SFJ) combined with stripping of the GSV. However, the morbidity and patient dissatisfaction associated with this treatment have prompted development of alternative techniques.³

The first study investigating endovenous laser ablation (EVLA) was published by Charles Boné⁴ in 1999 and an 810-nm diode laser was used. However, it was only in 2001, when Navarro et al.⁵ published the first major study on the use of endovenous laser for saphenous vein ablation, that this technique attracted the attention of phlebologists. Many studies have been published subsequently and, since then, endovenous laser treatment, which aims to irreversibly destroy the vein with reflux, has become a minimally invasive alternative to surgery.

The 1470-nm diode laser operates at a wavelength that is relatively new to thermal ablation therapy and has been in use since 2006. The first successful results were published by Pannier et al.⁶ In comparison with the 980-nm wavelength, the 1470-nm wavelength is 40 times more preferentially absorbed by water. In theory, targeting the interstitial water in the vessel wall should achieve vein ablation at lower energy densities and with fewer side effects.⁷ Given the recent commercial release of the 1470-nm diode laser, there are currently no well-defined protocols for treatment with this laser system.

The objectives of this study were to 1) determine the occlusion rate, diameter changes, and flow of the

GSV after thermal ablation with 1470-nm laser at a power of 7 W, using duplex ultrasound scanning, and 2) evaluate clinical outcomes and complications in patients undergoing treatment.

METHODS

This prospective, nonrandomized study is part of a research stream investigating early detection methods and evaluation of prognostic factors in surgical conditions run by the Graduate Program in Clinical Surgery at the university where the study was conducted. The study was approved on October 21, 2012 by the chairperson of the Research Ethics Committee at a tertiary care teaching hospital affiliated with the university and was conducted in accordance with the provisions of the Declaration of Helsinki.

Participants were recruited from among patients receiving care at our institution on the Brazilian National Health Service (SUS) from January 2013 to December 2014. Eligible participants were all patients aged 18 or over who had been diagnosed with unilateral or bilateral varicose veins of the lower extremities, with diseases clinical class C2-C6, according to the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification, and who had been referred for surgical treatment. Exclusion criteria were a previous history of deep vein thrombosis, concomitant peripheral arterial disease, difficulty walking, pregnancy, breastfeeding, or previous surgical treatment of varicose veins. All participants provided written informed consent prior to enrollment on the study.

EVLA was performed after an 8-hour fast. Patients were given spinal anesthesia for lower limb blockade. The GSV was punctured with a 16- or 18-gauge Abbocath needle at the middle third or distal part of the thigh, at the knee level, or at the middle third or proximal part of the leg, depending on the technical difficulties encountered (Figure 1).

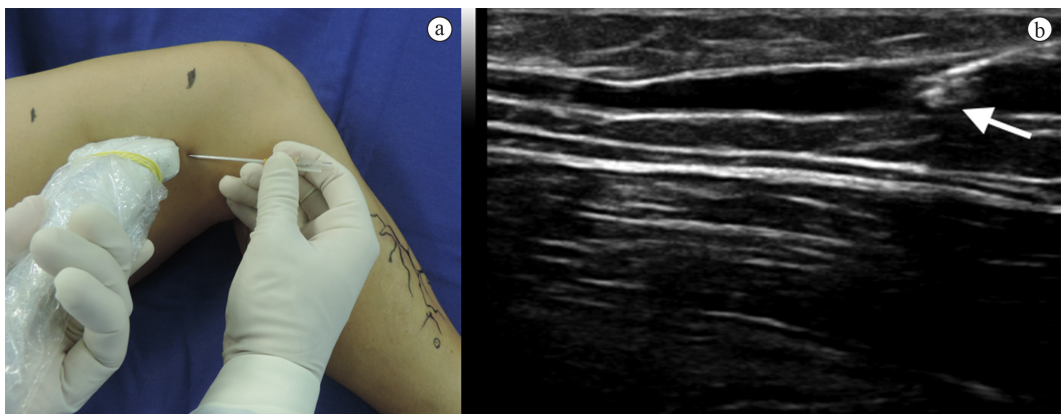


Figure 1. Ultrasound-guided puncture at the left mid-thigh (a) and image of the ultrasound-guided puncture (b).

With the patient in the Trendelenburg position to reduce the amount of blood inside the vein, a conventional bare-tip 600- μ m optical fiber connected to a laser device (Quanta System, Solbiate Olona, Province of Varese, Italy) was inserted through the needle puncture into the affected vein. The laser was set to a wavelength of 1470 nm and power of 7 W. The optical fiber was advanced through the vein under ultrasound guidance in the anterograde direction until it reached the inguinal region, and the tip of the fiber was positioned approximately 2-3 cm from the SFJ (Figure 2).

With the laser fiber in place, at room temperature, 0.9% saline solution was injected into the saphenous fascia surrounding the saphenous vein to achieve tumescence. This was not performed for anesthetic purposes, but rather to induce vasospasm and reduce fiber eccentricity, thereby providing more uniform application of laser energy. The laser was delivered by manually pulling the optical fiber in a caudal direction until the planned treatment was complete. No automatic pull-back device was employed. The optical fiber was then withdrawn through the needle puncture. The total energy used was recorded as the sum of energy delivered per linear centimeter, and the mean linear endovenous energy density (LEED, in J/cm) that had been needed to achieve the occlusion of the treated saphenous vein was calculated.

Varicose tributaries were treated intraoperatively (phlebectomy). In the immediate postoperative period, an occlusive dressing was applied to the insertion site and a semi-compressive dressing with orthopedic stockinette and crepe bandage was applied to the lower limbs. Patients were encouraged to walk after recovery from anesthesia. The bandages were usually removed on the third day after the operation, and patients began using below-knee, above-knee or long-leg graduated (20-30 mmHg) compression stockings. Patients were

then asked to wear their stockings every day for 7 days and allowed to return to their usual daily activities, avoiding physical exercises for 15 days.

Follow-up duplex scanning was performed with the patient in an upright position at 3-5 days after the procedure and at 30 and 180 days, for assessment of GSV occlusion rate and to observe any changes in the deep venous system, to rule out venous thrombosis. All measurements were performed by an independent examiner who had not taken part in the surgical procedure. The GSV diameter was measured at different segments along the treated vein (SFJ, thigh, knee, leg, and ankle). At each follow-up examination, possible procedure-related complications were evaluated and treated according to a protocol for postoperative symptoms. Follow-up examinations included clinical evaluation using the Venous Clinical Severity Score (VCSS).

Quantitative variables are expressed as means, standard deviations (SD), medians, and minimum and maximum values. Qualitative variables are expressed as frequencies and percentages. Values obtained at different time points were compared using the nonparametric Friedman test. For each GSV assessment site, we tested the null hypothesis that results would be equal at all time points against the alternative hypothesis that at least one of the time points would have a different result. When the null hypothesis was rejected, a Friedman post hoc test was used for pairwise comparison of time points. The nonparametric Mann-Whitney test (for two independent groups) was used to test for associations between the length of ablated GSV and occlusion rate at 6 months. Results for which $p < 0.05$ were considered statistically significant. Data were analyzed using SPSS, version 20.0.

RESULTS

From January 2013 to December 2014, 19 patients were enrolled on the study, 2 male (10.53%) and 17 female (89.47%). Mean patient age was 46 years (SD, 9.71 years; minimum, 30 years; maximum, 69 years). Mean body mass index (BMI) was 27.19 (SD, 3.76; minimum, 21.5; maximum, 34.25), and mean duration of operations was 93.42 min (SD, 25.08 min; minimum, 45 min; maximum, 150 min).

A total of 31 GSVs were treated, 15 in the right lower limb (48.39%) and 16 in the left lower limb (51.61%). Of 31 limbs treated, 2 limbs were CEAP clinical class C2, 19 were C3, 9 were C4, and 1 limb was C5.

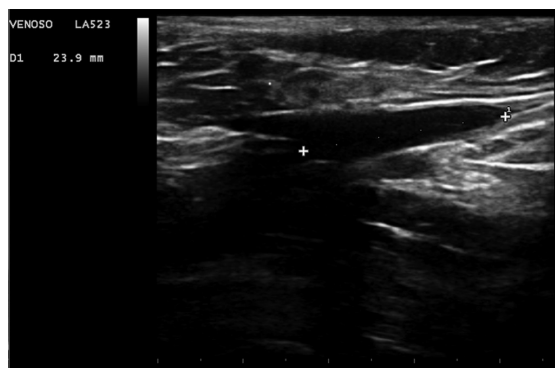


Figure 2. Duplex scan showing the fiber positioned 2-3 cm from the saphenofemoral junction.

The technique of fiber insertion through the needle puncture was used in all 31 GSVs treated (100%). With regard to puncture site, 4 GSVs (12.90%) were punctured at the mid-thigh, 16 (51.61%) at the distal thigh, and 11 (35.48%) at the proximal leg.

The mean LEED was 33.53 J/cm (SD, 4.56 J/cm; minimum, 23 J/cm; maximum, 39.86 J/cm).

The GSV diameters measured in different segments along the treated vein at different time points are shown in Table 1. Table 2 lists the results of pairwise comparisons of the GSV diameters obtained at different time points.

The GSV occlusion rate was 93.5% immediately after treatment, 100% at 3-5 days and 100% at 30 days, and 87.1% at 180 days after treatment. Four GSVs had recanalized by 6 months (Figure 3).

The patients exhibited statistically significant reductions in VCSS at all time points (Figure 4).

There were no associations between the length of ablated GSVs and occlusion rate at 6 months (Table 3).

With regard to procedure-related complications, no patients had deep vein thrombosis, one had thrombophlebitis of the varicose vein at the level of the knee, and three reported symptoms of paresthesia in one of the limbs at the first follow-up examination. In two of these patients, symptoms persisted over the first month, but by 180 days symptoms had resolved in all three patients (Table 4).

DISCUSSION

Varicose veins of the lower extremities are a common medical problem. Recently, EVLA has been shown to be a minimally invasive treatment with excellent results in terms of a high technical success rate and low complication rate.⁸ However, there is still no consensus on the optimal energy level that will provide the highest rate of technical success and the lowest rate of complications when performing EVLA.

The reported recurrence rates following EVLA depend on the LEED used. When EVLA is conducted with low energy densities it results in lower occlusion rates and higher recurrence rates than higher energy

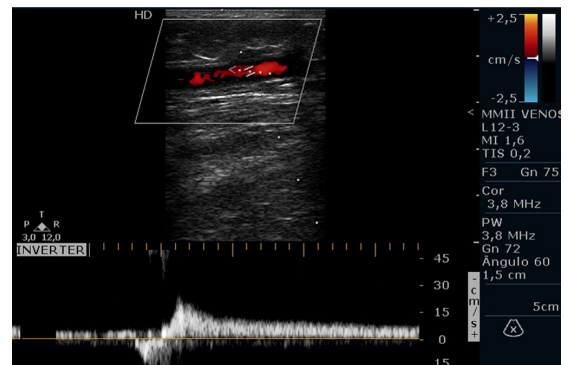


Figure 3. Duplex scan showing recanalization with great saphenous vein reflux at 6-month follow-up.

Table 1. Saphenous vein diameters.

Variable	Time of assessment	n	Mean	Median	Minimum	Maximum	SD	p-value*
SFJ	Preoperative	31	8.2	7.6	5.5	12.1	2.09	<0.001
	3-5 days	31	8.6	8.0	5.0	15.4	2.47	
	1 month	31	7.5	6.7	1.3	14.1	2.45	
	6 months	31	6.6	6.3	3.7	13.0	1.85	
Thigh	Preoperative	31	5.6	5.3	2.4	11.0	1.88	<0.001
	3-5 days	31	5.6	4.8	3.0	12.3	2.09	
	1 month	31	4.6	4.0	0.0	8.8	2.08	
	6 months	31	2.3	2.9	0.0	6.5	2.16	
Knee	Preoperative	31	4.3	4.3	0.0	7.3	1.70	<0.001
	3-5 days	31	4.3	4.1	0.0	7.7	1.55	
	1 month	31	3.9	3.8	0.0	7.0	1.55	
	6 months	31	3.0	3.1	0.0	6.4	1.67	
Leg	Preoperative	31	3.0	2.9	0.0	6.0	1.11	0.635
	3-5 days	31	2.8	2.8	0.0	4.9	0.87	
	1 month	31	2.7	2.7	0.0	4.2	0.83	
	6 months	31	2.9	2.9	0.0	5.0	1.00	
Ankle	Preoperative	31	2.8	2.8	0.0	4.8	0.96	0.991
	3-5 days	31	2.8	2.8	0.0	5.6	0.99	
	1 month	31	2.7	2.9	0.0	4.2	0.91	
	6 months	31	2.6	2.8	0.0	3.8	0.99	

SD: standard deviation; SFJ: saphenofemoral junction. *Nonparametric Friedman test; p<0.05.

EVLA.^{9,10} However, use of higher LEED significantly increases the incidence of paresthesia. It therefore seems appropriate to use LEED below 100 J/cm in future trials.

The efficacy of energy delivered at different ranges of energy density has also been evaluated. Timperman et al.¹¹ conducted a study using 810-nm

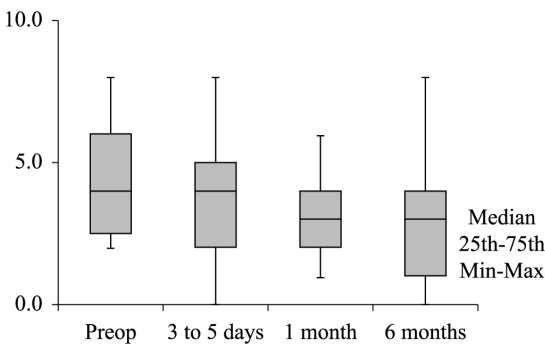


Figure 4. Venous Clinical Severity Scores (VCSS) over time.

Table 2. Pairwise comparison of GSV diameters measured at the SFJ, thigh, and knee at different time points.

Time points compared	SFJ	Thigh	Knee
Preop × 3-5 days	0.330	0.902	0.476
Preop × 1 month	0.386	0.110	0.091
Preop × 6 months	0.001	<0.001	0.001
3-5 days × 1 month	0.068	0.140	0.017
3-5 days × 6 months	<0.001	<0.001	<0.001
1 month × 6 months	0.014	<0.001	0.091

GSV: great saphenous vein; SFJ: saphenofemoral junction.

and 940-nm laser treatment and reported a significant difference in energy delivery between the “success” and “failure” groups (63.4 J/cm vs. 46.6 J/cm, p<0.0001). They also concluded that there was no significant difference in outcomes between patients treated with different wavelengths.¹¹

Bueno et al.¹² published a case series report showing that use of 1470-nm laser is a good method for treating saphenous veins, with results similar to those obtained with 980-nm laser treatment, but with lower energy densities and power.

Park et al.¹³ concluded that EVLA conducted using a 1470-nm laser and low energy (LEED of 80 J/cm or lower) is an effective, safe, and technically successful option for the treatment of incompetent saphenous veins. In the current study, use of low-energy parameters with a mean LEED of 33 J/cm resulted in a GSV occlusion rate of 87.1% after 6 months.

Because recanalization can also occur after high-energy EVLA of saphenous veins, energy is probably not the only problem. If recanalization occurs, the ablated GSV may have incompetent collateral veins in the distal part of the reflux segment. If incompetent collateral veins are visualized preoperatively using duplex scanning, they should be removed by phlebectomy during the same procedure, thus preventing some cases of recanalization. In the current study, phlebectomy of incompetent collateral veins was performed concomitantly with EVLA of the saphenous vein to minimize recanalization rates related to this factor.

Table 3. Length of ablated GSV versus occlusion rate at 6 months.

Occlusion at 6 months	Length of ablated GSV						p-value*
	n	Mean	Median	Minimum	Maximum	SD	
No	4	35	35	30	40	5.8	0.237
Yes	27	31	28	15	50	9.8	

GSV: great saphenous vein; SD: standard deviation. *Nonparametric Mann-Whitney; p<0.05.

Table 4. Procedure-related complications.

Variable	No		Yes		Total
	n	%	n	%	
DVT – 3-5 days	31	100.0%	0	0.0%	31
DVT – 1 month	31	100.0%	0	0.0%	31
DVT – 6 months	31	100.0%	0	0.0%	31
Phlebitis – 3-5 days	31	100.0%	0	0.0%	31
Phlebitis – 1 month	30	96.8%	1	3.2%	31
Phlebitis – 6 months	31	100.0%	0	0.0%	31
Paresthesia – 3-5 days	28	90.3%	3	9.7%	31
Paresthesia – 1 month	29	93.5%	2	6.5%	31
Paresthesia – 6 months	31	100.0%	0	0.0%	31

DVT: deep vein thrombosis.

Moreover, in this study recanalization of the GSV occurred in four limbs at 6 months, three of which exhibited reductions in VCSS. Only one limb exhibited an increase in VCSS, from 2 (preoperative, 3-5 days, and 1 month) to 4 at 6-month follow-up. It is of note that patients with excess BMI appear to be among those who have higher recanalization rates. However, it was not possible to perform a multivariate analysis taking into account the incidence of recanalization and BMI in this study.

The Trendelenburg position should always be used when performing EVLA, especially for veins with diameters greater than 8 mm, in which the amount of intravenous blood is very important. In such cases laser irradiation is not sufficient to heat the vessel wall because the light energy is almost entirely absorbed by the blood. The initial success rate is therefore mainly the result of a thrombotic effect that, after thrombus dissolution, leads to recanalization of the GSV.¹⁴ Therefore, in the present study all patients were placed in the Trendelenburg position for ELVA, in order to reduce the diameter of the GSV and, consequently, prolong vein contact with the laser fiber, thereby avoiding thrombotic effects that could lead to subsequent recanalization.

The bare fiber used for EVLA in this study has some technical shortcomings of its own, mainly because it is a rigid fiber that emits the laser beam in a forward direction straight out of the tip, rather than emitting the laser energy in 360° around the tip, as is the case with radial fibers. When the bare fiber is introduced into a GSV, which normally has some small tortuosities, it always has a tendency to stretch. As a consequence of stretching, the fiber tip often occupies an eccentric position, with the tip touching the vein wall. In an *ex vivo* model, the use of bare fibers was found to result in uneven application of light energy, requiring greater energy to ensure the destruction of the vein wall and prevent recanalization. Additionally, if the vein wall is carbonized by direct contact, a great amount of energy is emitted, increasing the likelihood of vein perforation.¹⁵

Hirokawa and Kurihara¹⁶ conducted a study using 1470-nm laser treatment, reporting that the incidence rates of bruising and pain were significantly reduced by using a radial fiber, when compared with a conventional bare-tip fiber. In the current study, we decided to use the bare fiber because of the lower per-unit cost and the possibility of reuse by simply trimming the tip of the fiber, which can be tested for effectiveness in the device and then sterilized. Notwithstanding, precautions were taken to minimize the disadvantages of the bare fiber, adopting measures to produce more

uniform contact between the fiber tip and the vessel wall, such as the Trendelenburg position, perivenous tumescence, and local compression as thermal ablation was occurring. These measures resulted in higher occlusion rates at 6-month follow-up.

In general, EVLA is a well-tolerated technique with a low incidence of complications and side effects, and most cases of such effects are transient and resolve within a few days without affecting normal walking or return to work. The main complications are bruising, saphenous nerve injury, skin burns, infection, and deep vein thrombosis/pulmonary embolism.

With the increasing popularity of endovenous GSV ablation, the possibility of endovenous heat-induced thrombosis (EHIT) of the saphenous vein extending to the femoral vein in the perioperative period has become a clinical reality. Although this occurrence has not been commonly reported in previous studies, all patients should be evaluated for this condition and treatment options should be discussed with them. Factors that may increase the risk of EHIT include patient age, unknown hypercoagulable states, and the severity of chronic venous disease.¹⁷

Sufian et al.¹⁸ conducted a prospective study on the incidence and factors contributing to the occurrence of EHIT after EVLA (1470 nm) and concluded that the following risk factors were associated with EHIT after EVLA: vein size, age, and multiple concomitant phlebectomies. EHIT usually resolves within 2 to 4 weeks in most patients, but it may worsen in some cases.¹⁸ In the current study, there was one case of EHIT with minimal thrombus protrusion through the SFJ into the common femoral vein (involving 25% of the vein lumen). The patient was treated with anticoagulation. Duplex scanning was repeated after 4 weeks and showed that the thrombus had regressed and been resolved, and anticoagulation was then withdrawn. The risk of EHIT-related pulmonary embolism remains to be defined, but it is unlikely to occur after EVLA.

The risk of nerve injury during EVLA is directly related to the proximity of several nerves to the ablated veins. The site associated with the greatest risk of saphenous nerve injury is the middle/distal third of the leg. At the distal leg, the saphenous nerve may be directly damaged by the puncture needle or burned by laser energy transfer causing skin paresthesia, which is usually transient. Most nerve injuries can be prevented by performing ultrasound-guided puncture and avoiding EVLA on sites at high risk for nerve injury.¹⁹ In the current study, three patients reported symptoms of paresthesia in one of their limbs at the first follow-up visit. The symptoms persisted over the

first month in two patients, but by 6 months symptoms had resolved in all patients.

One limitation of this study is the lack of long-term follow-up. However, the mean follow-up of 6 months is consistent with that reported in previous studies.²⁰ Min et al.²¹ reported that most failures in their study occurred within the first 3 months of follow-up, and all had occurred by 9 months. It therefore seems reasonable to assume that most failures that occurred in our study would have been detected within our follow-up period. Furthermore, a relatively small number of failures were observed in our sample, thereby precluding a multivariate analysis. Nevertheless, we only used nonparametric statistical tests, which are suitable for evaluation of variables that are not normally distributed or when the sample size is small. The sample size (31 cases) was considered adequate, and nonparametric methods were adopted mainly because the data did not fit the normal distribution. An additional factor to be considered is that, when significant differences are detected for a particular sample, we can conclude that the sample size is sufficient to support the results (differences) obtained in the analysis.

■ CONCLUSION

The thermal ablation therapy investigated in this study, using a 1470-nm water-specific laser, allowed ablation at lower laser fluence, leading to a reduction in the energy required for successful treatment. Our data support the possibility that, by using low energy density, the incidence of complications can be reduced without significantly affecting the clinical outcomes in the whole study group. However, this appears to be at the cost of reduced efficacy in terms of GSV occlusion rates.

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