

Outcome of 1470nm laser diode ablation for superficial venous insufficiency

Resultado do tratamento da insuficiência venosa superficial com Laser Diodo 1470 nm

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Abstract

Background: Endovenous laser ablation is a minimally invasive procedure that can be used to treat superficial venous insufficiency. We believe that using a longer wavelength will reduce the frequency of the most common adverse effects associated with the use of shorter wavelengths. **Objectives:** To report the results of an initial series of patients with chronic superficial venous insufficiency treated using a 1470 nanometer diode laser and to compare results using linear and radial laser fibers. **Methods:** We conducted an observational cohort study. Seventy-four patients, for whom at least two postoperative Doppler ultrasonography scans were available, were recruited with a total of 121 saphenous veins treated (92 great and 29 small saphenous veins). There were 57 patients in Group A (treated with the linear fiber) and 17 in Group B (radial fiber). Follow-up ideally comprised clinical consultation and Doppler ultrasonography at 1 month, 6 months and 12 months after the procedure. Success was defined as total occlusion of the venous segment that had been treated. **Results:** Success rates at mean follow-up of 13.4 months (range 7 - 27) were 83% for great saphenous veins and 89% for small saphenous veins. Patients treated with the radial fiber required less energy to achieve occlusion of the small saphenous vein and exhibited fewer adverse reactions, with statistical significance. **Conclusions:** Treatment of great and small saphenous vein insufficiency using the 1470 nm diode laser is safe and effective. The radial fiber was associated with fewer intercurrent conditions than the linear fiber, although success rates were similar.

Keywords: venous insufficiency; varicose veins; laser treatment.

Resumo

Contexto: A ablação endovenosa com laser consiste em um procedimento minimamente invasivo e é aplicada no tratamento da insuficiência venosa superficial. Acreditamos que o uso de uma onda de maior comprimento irá propiciar a diminuição dos principais efeitos adversos, relacionados com ondas de menor comprimento. **Objetivos:** Demonstrar o resultado de uma série inicial de pacientes com insuficiência venosa crônica superficial, tratados com o uso do Laser Diodo 1470 nanômetros, e comparar as fibras linear e radial. **Métodos:** Conduzimos um estudo observacional do tipo coorte histórico. Setenta e quatro pacientes, com no mínimo dois eco-Doppler pós-operatórios, foram incluídos, totalizando 121 veias safenas tratadas (92 magnas e 29 parvas). Tivemos 57 pacientes pertencentes ao Grupo A (fibra linear) e 17 ao Grupo B (fibra radial). O follow-up foi idealmente realizado com uma consulta clínica e eco-Doppler em um mês, seis meses e 12 meses, após o procedimento. O sucesso foi definido como a oclusão total do segmento venoso tratado. **Resultados:** O sucesso no follow-up médio de 13,4 meses (7 - 27) foi de 83% para veias safenas magnas e 89% para veias safenas parvas. Pacientes submetidos ao uso de fibra radial necessitaram de menos energia para oclusão da veia safena parva e apresentaram menos reações adversas, com significância estatística. **Conclusão:** O tratamento da insuficiência de veias safenas magna e parva com o Laser Diodo 1470 nm é seguro e eficaz. A utilização da fibra radial foi associada a menos intercorrências em relação à fibra linear, apesar de sucesso semelhante.

Palavras-chave: insuficiência venosa; varizes; terapia a laser.

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■ INTRODUCTION

Chronic venous insufficiency is one of the most prevalent vascular diseases in the Western world. It is a disorder of venous system transport and the most widely-accepted theory is based on insufficiency of the valves in communicating veins, with the result that they allow the pressure in the deep vein system to be transmitted to the superficial system, which, under physiological conditions, is a low pressure system.¹ Over the years, countless risk factors have been identified as associated with this disease, including family history, age, obesity, female sex, lifestyle, diet and pregnancy.^{1,2} In Brazil, the prevalence of venous disease is also elevated and is equivalent to rates in developed countries, affecting as many as 37.9% of men and 50.9% of women.³ The consequences of this disease often compromise patient quality of life, and complications can develop if appropriate treatment is not provided.⁴ Management of patients with this condition should draw in multidisciplinary expertise, with the objective of intervening in modifiable risk factors and thereby preventing a large number of different diseases with shared risk factors.

Surgical treatment is an important pillar of the management approach to these patients, especially when conservative treatment is not successful, when there are significant symptoms, the disease is at an advanced stage, or patients are dissatisfied with aesthetic aspects. Conventional surgery basically consists of ligation and/or excision of the venous segments involved. When both the great and small saphenous veins are involved, they are ligated at the saphenofemoral junction (JSF) or saphenopopliteal junction (JSP), followed by total or partial resection, which improves patient quality of life.⁵⁻⁷ However, conventional treatment can be associated with injuries to the saphenous nerve, thrombophlebitis, bleeding and infection of the surgical wound.⁸ Currently, less-invasive techniques, such as microfoam, radio frequency ablation and endovenous laser ablation, are being introduced in order to take advantage of the intrinsic benefits of minimally invasive procedures, which include lower rates of postoperative intercurrent conditions, improved esthetic results and shorter recovery times, without losing the benefits of conventional surgery's success rates.⁹ All of the different techniques for saphenous vein ablation are effective for exclusion of the affected vein, but each technique has its peculiarities and offers advantages and disadvantages.^{8,10}

Specifically with relation to ablation using lasers (Light Amplification by Stimulated Emission of

Radiation), the first report in the literature describing its use for superficial venous insufficiency was published in 1999.¹¹ Randomized studies comparing the technique with conventional surgery have found similar efficacy, with the added advantage that patients treated using lasers enjoy an earlier return to daily activities.¹²⁻¹⁵ Recently, new generation lasers with longer wavelengths, such as 1470 nanometers (nm), and different types of fiber optics, such as radial fibers, have begun to be adopted and are achieving even more promising results.^{4,16-18}

The primary objective of this study is to report results of treatment for superficial venous insufficiency using a 1470 nanometer (nm) diode laser. A secondary objective is to conduct a comparative assessment of two groups of patients, one treated using the linear laser fiber and the other using a radial laser fiber.

■ METHODS

Patients

This is an observational study of a historic cohort. A total of 74 patients who had been treated with ablation of saphenous veins using a 1470 nm laser between March 2011 and May 2013 were recruited and signed free and informed consent forms. Exclusion criteria were refusal to sign the consent form and fewer than two postoperative control examinations available for analysis.

Preoperative, transoperative and follow-up data were recorded on a predefined form (protocol) that was completed prospectively (Figure 1). The study was approved by the Human Research Ethics Committee at the Universidade Federal de Santa Catarina (UFSC) and all patients read and signed an informed consent form.

We divided the patients into two groups in order to achieve the study's secondary objective. Group A (n=57) comprised patients who had been treated using a linear fiber for ablation, and Group B (n=17) comprised patients treated with the radial laser fiber. In view of the fact that several patients had treatment on more than one vein simultaneously, where appropriate, success rates and adverse reaction rates are calculated with relation to the total numbers of veins treated, which were 87 veins in Group A and 34 veins in Group B.

Technique

All patients underwent clinical assessment and Doppler ultrasonography preoperative examinations, thereby enabling Clinical, Etiologic, Anatomical and Pathological classification (CEAP). The Doppler

the level of the JSF or JSP and on the view provided by Doppler ultrasonography. Patients were given elastic bandages for the lower limbs and instructed to return to walking soon after recovering from the anesthetic.

Follow-up

Patients were seen between 7 and 10 days after the operation and prescribed elastic compression stockings. At this consultation, patients were asked about ecchymosis, pain, burning sensations, paresthesia and edema and these were recorded as either present or absent. Control examinations using Doppler ultrasonography were conducted to assess hemodynamic status of the saphenous veins, to check for signs of deep venous thrombosis (DVT) and to measure diameters at 30 days, 6 months and 1 year. Cases were defined as successful when total occlusion of the treated segment had been achieved. Partial occlusion was defined as when the first postoperative Doppler ultrasonography showed flow through part of the treated segment and re-canalization was defined as when flow was observed in a segment that had been considered occluded on the basis of a prior Doppler ultrasonography. Both of these scenarios were defined as treatment failure.

Statistical analysis

Data were analyzed retrospectively, using information harvested from the predefined protocol. Excel 5.0 and the Primer of Biostatistics (McGraw-Hill Inc.) were used for statistical analysis. Procedure success rates and general adverse reactions were expressed as percentages and compared with the results of studies in the literature, to indicate the extent to which previously published efficacy and adverse reaction rates were reproducible. For comparisons between groups, quantitative variables were analyzed as means and standard deviations and using the *t* test for independent samples, with 95% confidence intervals. Associations between qualitative variables were analyzed using the chi-square test and Fisher's test. Results with $p < 0.05$ were considered statistically significant.

RESULTS

Seventy-four patients who had been treated with saphenous ablation using the 1470 nm Laser were enrolled on the study. Twenty-six were male and 48 were female and the mean age of patients was 52 years. Ninety-five limbs and a total of 121 treated veins (92 great saphenous veins and 29 small saphenous veins) were analyzed. Patients were stratified by CEAP

classification, as follows: CEAP II - 16.9%; CEAP III - 59.3%; CEAP IV - 16.9%; and CEAP V - 6.7%.

The mean power for the great saphenous vein was 6.8 Watts in the thigh and 6.4 Watts in the leg, while for the small saphenous vein mean power was 6.1 Watts in the more proximal segment of the vein and 6 Watts in the distal leg. A mean energy of 2,146 Joules was used for great saphenous veins and 898 Joules for small saphenous veins, equating to a mean linear energy of 30.9 J/cm in the great saphenous veins and 22.65 J/cm in the small saphenous veins. Eight great saphenous veins required additional punctures because the fiber could not be advanced. A total of 52 dissections of the great saphenous vein were performed at the JSF because of the following conditions: inability to advance the fiber, JSF with diameter greater than 8 mm, difficulties viewing the fiber on Doppler ultrasonography and/or very intense reflux at the JSF.

Transoperative control Doppler ultrasonography scans showed that the lumen of the vessel had disappeared in all 121 veins treated. There were no significant intercurrent conditions and all patients were discharged on the same day as the procedure, with elastic bandages and instructions for early mobilization.

At the first clinical follow-up, conducted from 7 to 10 days after the operation, we detected ecchymosis, pain and local paresthesia in 7 cases (5.7%) along the paths of veins that had been treated. There were no cases of skin burns. Four of the 95 limbs analyzed exhibited edema (4.2%). One patient with significant edema was examined using Doppler ultrasonography, which confirmed a diagnosis of DVT involving the popliteal vein, after ablation of the great and small saphenous veins in the same limb.

All patients were examined with Doppler ultrasonography for follow-up at 30 days, and 91 great saphenous veins had undergone total occlusion, while one exhibited partial occlusion (98.9% success for great saphenous veins), and 29 small saphenous veins exhibited total occlusion (100% success). On this occasion two cases of DVT were observed. One of these was symptomatic and was the same case diagnosed at the 1-week consultation, while the other was an asymptomatic thrombosis of the solar plexus in a patient who had been treated with ablation of the great saphenous vein. Both of these patients received outpatient care and exhibited [ou showed] full resolution with no later repercussions.

The 6-month control Doppler ultrasonography examinations detected 80 totally occluded great saphenous veins, one that was partially occluded and

Table 1. Characteristics of patients by type of fiber employed.

	Distribution of patients		p
	Group A (linear fiber) n=57	Group B (radial fiber) n=17	
Age (years)	52.23 ± 13	55.3 ± 13.2	0.397
Sex (M:F)	21:36	5:12	0.784
Follow-up (months)	14.23 ± 5.6	11 ± 4.12	0.032
LEED GSV (J/cm)	31.33 ± 10.03	30.17 ± 16.48	0.722
LEED SSV (J/cm)	30.6 ± 5.04	18.68 ± 2.89	<0.05*

LEED: linear endovenous energy density, calculated by dividing total energy delivered (in Joules) by the length of the vein segment treated (in centimeters). GSV: great saphenous vein, SSV: small saphenous vein. *Statistically significant.

Table 2. Adverse reactions by type of fiber employed.

	Group A (n=87)	Group B (n=34)	p
Ecchymosis (Yes : No)	7:80	12:34	0.204
Pain (Yes : No)	7:80	0:34	0.204
Paresthesia (Yes : No)	5:82	2:32	0.686
DVT (Yes : No)	2:85	0:34	0.922
Adverse reactions (Yes : No)	21:66	2:32	<0.05*

DVT: deep venous thrombosis. *Statistically significant.

Table 3. Success rates by type of fiber used for treatment.

	Group A (n=87)	Group B (n=34)	p
GSV (success : failure)	57:13	20:2	0.5
SSV (success : failure)	14:3	12:0	0.246
Total (success : failure)	71:16	32:2	0.146

GSV: great saphenous vein, SSV: small saphenous vein.

11 veins with partial recanalization (86% success for great saphenous veins), in addition to 27 small saphenous veins with total occlusion and two with partial recanalization (93% success for small saphenous veins). All patients who had exhibited adverse reactions during the immediate postoperative period were actively questioned about that progress and all exhibited improvement. At a later follow-up consultation, an average of 13.4 months (range: 7 – 27, median: 12) after the procedure, we observed 77 totally occluded great saphenous veins, one that was partially occluded and 14 that had undergone partial recanalization, in addition to 26 small saphenous veins with total occlusion and three with partial recanalization. As such, the procedure's success rate at 13.4 months was 83% for great saphenous veins and 89% for small saphenous veins.

With regard to the comparison of patients treated with linear fiber (Group A, n=57) and radial fiber (Group B, n=17), both groups were similar, with no statistical differences in terms of age, sex, follow-up (Table 1) or diameter of veins treated. There was a statistically significant difference in terms of linear energy (J/cm) used to ablate small saphenous veins, with more energy delivered in the linear fiber group (Table 1). In contrast, there was no relevant statistical

variation between energy delivered to treat great saphenous veins in each group (Table 1). There were also no statistically significant differences between the two groups in terms of specific adverse reactions (ecchymosis, pain, paresthesia and DVT). However, analysis of total adverse reactions for each group indicated that group B (radial fiber) had a lower frequency and that the difference was statistically significant, as shown in Table 2. Finally, there were no statistically significant differences when great saphenous veins, small saphenous veins and all veins were analyzed separately (Table 3).

DISCUSSION

Endovenous laser ablation was developed with the objective of offering the inherent benefits of less invasive procedures whilst preserving or even improving on the success rates offered by conventional treatment. In the present study, treatment using a 1470 nm diode laser and either linear or radial fibers resulted in high success rates even when low quantities of energy were delivered, with the result that there were few adverse reactions or complications.

The 1-year follow-up success rate observed in this study is similar to figures reported by earlier

publications.^{9,12,13,19} Notwithstanding, some articles have reported superior success rates than those observed here.^{8,20} This may be the result of different definitions of success and/or variations in the quantity of energy delivered. The quantity of energy delivered is dependent on the power setting (Watts = J/s) and duration of exposure.⁴ Timperman et al. have recommended that the linear energy density should be 80 J/cm to ensure that the procedure is successful and have identified this parameter as an independent factor in successful venous occlusion.^{21,22} Proebstle et al. also showed that success rates were higher for procedures using more energy.¹⁹ Notwithstanding, these findings were reported in studies that employed shorter wavelengths and there is evidence to show that the energy delivered can be reduced, without reducing efficacy, when longer wavelengths are used.¹⁶ Our results are similar to these reports, with satisfactory success rates associated with a mean energy density of just 30.9 J/cm for great saphenous veins and 22.65 J/cm for small saphenous veins. This was the result of administering a very low power level, of around 6 to 8 W. It is however probable that our occlusion rate would have been better if we had used higher power settings, which would also probably have led to a greater number of adverse reactions.

The adverse event rates observed in this study are low and are in line with previous studies.^{8,20} With regard to DVT rates, our findings are also similar to other studies of laser treatment and rates are similar, if not lower than, those for patients treated using conventional surgery.^{23,24} With regard to less serious intercurrent conditions, we believe that longer wavelengths may benefit patients in terms of reduced postoperative pain and lower degree of ecchymosis when compared with patients treated with shorter wavelengths.^{4,17} The explanation for this is the fact that shorter wavelengths have a greater affinity for deoxygenated hemoglobin and so heat up the intraluminal blood, leading to significant transmission of heat to adjacent tissues. Furthermore, the ideal conditions involve a layer of hemoglobin between the optical fiber and the vein wall, protecting the wall. This condition is often lacking in diseased veins that are tortuous and have variations in caliber. The result is acute, localized temperature increases, causing microperforations, and as a consequence more ecchymosis and pain.^{4,16,17} In contrast, longer wavelengths have a more specific action on the vessel wall, meaning that the less energy is required to achieve occlusion.¹⁷

With regard to this study's secondary objective, we demonstrated that it was necessary to deliver smaller quantities of energy to treat the small saphenous vein

if the radial fiber was used (Group B) and that this difference was statistically significant. Notwithstanding, the results achieved in Group B were similar to those for Group A (there were no statistical differences). This difference was not detected in the comparison of great saphenous veins. We also observed a statistically significant difference in overall adverse reactions, with fewer reactions in Group B (radial fiber). We believe that these findings are indicative that radial fibers can indeed contribute to more uniform distribution of energy across the surface of the vein, avoiding points of extreme heating and causing fewer side effects.¹⁶

Some authors have questioned the fact that the laser does not occlude tributary veins, which are traditionally ligated during conventional surgical procedures.²⁵ However, Min et al. have demonstrated over a two-year follow-up that laser ablation offers lower recurrence rates than saphenectomy with ligation of collateral veins and that non-ligation of tributaries is not a factor in recurrence.²⁶ At our Clinic we continue to perform the traditional ligation or sclerotherapy of tributaries with the aim of reducing recurrence.

While we used linear energy density as the reference measure for energy delivered, Proebstle et al. have stated that the fluence (J/cm²) applied to the lumen of the vessel is an important parameter.^{19,27} However, the difficulty, or even impossibility, of measuring the internal surface area of the vein along the entire segment has led the majority of studies to employ the linear endovenous energy density parameter to analyze their results, which means that our results can be compared with the literature. Another possible limitation of this type of study, with reference to the literature, is failure to standardize the volume of tumescent anesthesia, which could lead to differences in diameter with relation to preoperative examinations. This limitation does not affect our study, since none of the patients were given this type of anesthesia. These factors are the main limitations of this study.

In conclusion, we have demonstrated that treatment of great and small saphenous vein insufficiency using a 1470 nm diode laser is both safe and effective. Use of a radial fiber was associated with fewer intercurrent conditions than using a linear fiber.

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