

## ORIGINAL ARTICLE

# Prospective randomized trial comparing radiofrequency ablation and complete saphenous vein stripping in patients with mild to moderate chronic venous disease with a 3-year follow-up

Ensaio clínico randomizado prospectivo comparando a ablação por radiofrequência e a retirada completa de veia safena em pacientes com doença venosa crônica leve à moderada com seguimento de 3 anos

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**ABSTRACT**

**Objective:** To compare the use of the radiofrequency thermoablation of the saphenous vein with the ligation technique, and complete removal of the saphenous vein, from the saphenofemoral junction to the ankle. **Methods:** A total of 49 patients with chronic venous disease in the Comprehensive Classification System for Chronic Venous Disorders (CEAP) classes 2 to 4 for clinical signs, etiology, anatomic distribution and pathophysiology, were assessed at baseline, after 4 weeks, and after 1 year. The parameters assessed were complications, period of absence from activities, Venous Clinical Severity Score (VCSS) and quality of life scores according to Aberdeen Varicose Veins Questionnaire (AVVQ). They were re-examined 1 and 3 years after treatment to evaluate recurrence rates. **Results:** The success rate per limb ( $p=0.540$ ), VCSS ( $p=0.636$ ), AVVQ ( $p=0.163$ ), and clinical complications were similar in the two treatment groups. Nevertheless, the radiofrequency thermoablation group had significant shorter length of hospital stay ( $0.69\pm 0.47$ ) and absence from activities ( $8.62\pm 4.53$ ),  $p<0.001$ . **Conclusion:** Patients submitted to radiofrequency thermoablation had an occlusion rate, clinical recurrence and improvement in quality of life comparable to removal of the saphenous vein. However, these patients spent less time hospitalized and away from their daily activities during recovering.

**Keywords:** Catheter ablation/methods; Saphenous vein/surgery; Radio waves; Quality of life

**RESUMO**

**Objetivo:** Comparar o uso da termoablação por radiofrequência da veia safena com a técnica de ligação e retirada completa da veia safena da junção safeno-femoral ao tornozelo. **Métodos:** Foram avaliados 49 pacientes com doença venosa crônica nas categorias 2 a 4 (*Comprehensive*

*Classification System for Chronic Venous Disorders – CEAP* para classificação clínica, etiológica, anatômica e fisiopatológica, no início do estudo, 4 semanas e 1 ano após o procedimento. Os parâmetros analisados foram complicações, período de ausência de atividades, *Venous Clinical Severity Score* revisado (R-VCSS) e escore de qualidade de vida de acordo com o *Aberdeen Varicose Veins Questionnaire* (AVVQ). Os pacientes foram reexaminados 1 e 3 anos após o tratamento, para avaliar as taxas de recorrência. **Resultados:** As taxas de sucesso por membro ( $p=0,540$ ), VCSS ( $p=0,636$ ), AVVQ ( $p=0,163$ ) e complicações clínicas foram semelhantes nos dois grupos. No entanto, o grupo termoablação por radiofrequência teve períodos de internação significativamente mais curtos ( $0,69\pm 0,47$ ) e ausência de atividades ( $8,62\pm 4,53$ ), com  $p<0,001$ . **Conclusão:** Pacientes submetidos à termoablação por radiofrequência apresentaram taxa de oclusão, recidiva clínica e melhora da qualidade de vida comparáveis à retirada completa da veia safena. No entanto, esses pacientes passaram menos tempo internados e ausentes de suas atividades diárias durante a recuperação.

**Descritores:** Ablação por cateter/métodos; Veia safena/cirurgia; Ondas de rádio; Qualidade de vida

## INTRODUCTION

Chronic venous disease (CVD) affects approximately 23% of population of the United States and 35% of Brazil, with a male: female ratio ranging from 1:2 to 1:4.<sup>(1)</sup> Up to 6% of cases are in the advanced stage of disease, with trophic changes in the skin and open or healed ulcers, which substantially impacts the patients' quality of life.<sup>(2,3)</sup>

Reflux in the great saphenous vein (GSV) is the most common cause for varicose veins and CVD.<sup>(4)</sup> However, this reflux may be segmental, especially in patients in the clinical category 2 (Comprehensive Classification System for Chronic Venous Disorders – CEAP), and is a reason for complaints regarding aesthetic aspects.<sup>(5,6)</sup>

The conventional techniques to treat chronic venous insufficiency (CVI) of the GSV and small saphenous vein (SSV) are the high ligation of the saphenofemoral junction (SFJ) or saphenopopliteal junction (SPJ), and the vein stripping. Recommendations to treat GSV are to strip the above-knee GSV due to saphenous nerve injury caused by complete GSV stripping.<sup>(2)</sup> However, in Brazil, the complete removal of the GSV is considered a standard treatment.<sup>(7)</sup> Theivacumar et al.,<sup>(8)</sup> showed greater satisfaction of patients, and Gifford et al.,<sup>(9)</sup> noted better long-term outcomes of patients undergoing complete stripping of the venous incompetence segment. Several authors recommend removing the entire GSV if a venous duplex evaluation confirms reflux to the ankle of over 1 second.<sup>(9-11)</sup> The SSV is usually removed from the SPJ to the mid-third

of the leg, but it can be completely excised, especially in patients with severe disease.<sup>(12)</sup> This procedure usually requires hospitalization, has a high rate of recurrence and the patient may need at least 1 week to recover.<sup>(13)</sup>

Percutaneous techniques have significantly evolved, especially in the last decade, because they are safe, outpatient procedures. These techniques have medium-term outcomes similar to the conventional treatment, but cause less pain and postoperative discomfort, allow an earlier return to work and have a lower rate of recurrence.<sup>(14,15)</sup> However, most studies compare ablative techniques to the stripping of the GSV limited to the knee, even though, in several countries, including Brazil, the standard technique to treat GSV reflux is high ligation and stripping of the SFJ to the ankle.<sup>(1,7,16-18)</sup>

The aim of this study was to compare the treatment of saphenous vein reflux using radiofrequency ablation (RFA) to treatment using ligation and complete stripping of the saphenous vein (S&T), in patients with CVD CEAP classes 2-4.

## OBJECTIVE

To compare the use of the radiofrequency thermoablation of the saphenous vein with the technique of ligation and complete stripping of the saphenous vein, from the saphenopopliteal junction to the ankle.

## METHODS

Patients with CVD requiring treatment of the saphenous vein at *Hospital Geral de Carapicuíba*, of *Organização Social de Saúde São Camilo*, Carapicuíba (SP) Brazil, were recruited from February to September of 2013. All patients who met the inclusion criteria and were interested in volunteering were invited to participate in the study. The study was approved by the Research Ethics Committee of *Hospital Geral de Carapicuíba* (protocol number 021/12), and all procedures were performed in accordance with the Declaration of Helsinki and good practices in clinical research. All participants signed Informed Consent forms, and were free to leave the study at any moment, without interference in treatment.

The patients were examined in the vascular outpatient clinic. A detailed history was taken and a complete physical examination was made. All patients had an Ankle-Brachial Index (ABI) measured and underwent color-Doppler venous ultrasound of the superficial and deep veins in the lower limbs. Age, sex, weight, comorbidities and body mass index (BMI) were recorded. The same physician determined the score

for each patient by using the revised Venous Clinical Severity Score (R-VCSS).<sup>(19-22)</sup> Furthermore, all patients filled in the Aberdeen Varicose Vein Questionnaire (AVVQ) for quality of life.<sup>(19-22)</sup>

Doppler venous ultrasound for reflux evaluation was performed by a vascular surgeon with experience in imaging examination of CVD patients, using a portable system (MySono 6 Samsung Medison Co., Seoul, Korea) with a 7 to 12MHz multi-frequency linear transducer. The examination was performed in the standing position with the body weight put on the contralateral limb. The deep venous system was evaluated for acute thrombophlebitis and post-thrombotic changes. The number and location of refluxing perforator veins were recorded. Reflux was induced by manual compression followed by sudden release. Retrograde flow lasting >0.5 second was used as cut-off for reflux in the saphenous vein. In this study, only patients with >1 second reflux (diffused throughout the entire GSV) were included to avoid treating minimal disease. GSV diameters were measured 3cm away from the SFJ, at mid-thigh and at the knee. Small saphenous vein diameter was measured at the popliteal fossa, and at 10cm below that level before beginning of treatment. The same measurements were taken 12 and 36 months after surgery. The ultrasound pattern of the treated saphenous vein flux was classified as with occlusion (or non-visualized); patent saphenous vein with reflux; and patent saphenous vein without reflux.

The inclusion criteria were as follows: age between 18 and 70 years; CEAP classes C2, C3 or C4 and presence of symptoms; ABI  $\geq 0.9$ ; GSV reflux of >1 second (diffused throughout the entire GSV), with a minimum diameter of 5mm and maximum diameter of 12mm; and SSV reflux of >1 second, with a minimum diameter of 3mm and maximum diameter of 12mm.

The exclusion criteria were patients unable to undergo Duplex ultrasound examination; presenting with acute thrombophlebitis or chronic obstruction of the saphenous vein detected in the duplex ultrasound exam; history of deep venous thrombosis; absence of clinical conditions for surgical treatment, even under local anesthesia; CEAP 0, 1.5 or 6; restricted mobility; pregnancy; peripheral arterial disease; saphenous vein diameter <5mm or >12mm; non-compliance with postoperative treatment protocol; and technical failure of the procedure.

Bilateral treatment was performed, and each limb received the same treatment. Both limbs were treated and in the same surgery. For the statistical analysis, each leg of the patients who underwent bilateral treatment was considered a distinct individual. Multiple

treatments were allowed in the same procedure, such as thermoablation of GSV and anterior saphenous vein.

### Randomization

Patients were randomized using the website sealedenvelope.com (<https://www.sealedenvelope.com/>). Two groups were generated: the first one received saphenous thermoablation (RFA Group) and the second group was treated with conventional stripping (S&T Group).

### Analyzed outcomes

The outcomes were assessed at baseline, 4 weeks, 1 year, and 3 years after treatment. Criteria for technical success were closed or absent saphenous vein with no flow. A recanalized saphenous vein or treatment failure were defined as an open part of the treated vein segment with more than 10cm in length; or a residual SFJ and SPJ with reflux. The primary outcome measured was recanalization rate for RFA Group, and saphenous vein neovascularization or surgical failure for the S&T Group, which were analyzed only at the 1- and 3-year follow-up. Secondary outcomes measured were length of hospital stay, period of absence from work or domestic activities, clinical recurrence rate, and R-VCSS and AVVQ, which were both analyzed at baseline (14 to 30 days after the procedure), and in the 1-year follow-up. AVVQ is a change-responsive tool, which has been internationally validated to assess quality of life in varicose vein patients.<sup>(19-22)</sup>

Furthermore, we evaluated demographic indices, comorbidities, BMI and adverse events associated to the methods used, such as infection, phlebitis, deep venous thrombosis, pulmonary embolism, or need for hospitalization.

### Surgical procedure and operative technique

All patients from both groups were treated in the operating room. For the S&T Group, all procedures were performed under spinal block, through exposure of the SFJ in the groin, dissection and ligation of all tributaries, and ligation of the GSV next to the common femoral vein. Later, the GSV was dissected through a 1-cm incision at the ankle level, and the phleboextractor was inserted in the cephalad direction. Saphenous stripping was performed from proximal to distal and hemostasis was obtained by compression for 10 minutes. The SSV was surgically treated through ligation of the SFJ and stripping of the segment with reflux up to the origin of the Achilles tendon. We avoided complete

stripping of the SSV due the risk of sural nerve injury.<sup>(17)</sup> The suture of incisions and phlebectomy healing were followed by extrinsic compression through a compressive tubular gauze bandage. Analgesics and non-steroid anti-inflammatory drugs were prescribed for 3 to 5 days.

The RFA Group was mostly treated under local anesthesia – only four patients, who did not agree to tumescent anesthesia, were given spinal blockage. With the patient in supine position, the GSV was punctured under echography, preferably in the middle third of the leg. A 7F-sheath was inserted, and the Closure FAST™ 100 cm (Medtronic™, USA) catheter was placed 2 to 3cm away from the terminal valve of the SFJ. Tumescent anesthesia was applied under ultrasound-guidance in the saphenous compartment and in the perivenous tissues. The tumescent solution was composed of 1,000mL of saline and 120mg of methylprednisolone. For those who chose for local anesthesia, the tumescent solution was composed of 1,000mL of saline, 40mL of lidocaine with epinephrine at 1%, 20mL of sodium bicarbonate at 8.4%, and 120mg of methylprednisolone. On average, 400mL of the solution were used in each limb, never exceeding the maximum dose of 7mg/kg of lidocaine. The patients were maintained in the Trendelenburg position for the ablation. Pressure over the treated area during ablation was made both by the ultrasound transducer and by hand. Small saphenous vein ablation was similar to that of the GSV. Varicose tributaries were treated during the same surgery using micro-incisions in both groups. Adjuvant procedures on varices and perforator vessels were limited to anesthesia sites.

All patients were encouraged to use compression stockings and return to their routine physical activity as soon as possible.

### Statistical analysis

Numerical variables were expressed as mean and standard deviation, or median and interquartile range, and minimum and maximum values. Categorical variables were described as absolute and relative frequencies. Both groups were compared in relation to demographic data, comorbidities and outcomes using Fisher's exact test or  $\chi^2$  test for categorical variables, and the Student's *t*-test or Mann-Whitney's test for numerical variables.

Models of generalized estimating equations were adjusted considering the relation between the two evaluations performed in the same patient, and the results were presented by estimated means and a 95% confidence interval. The models were adjusted by the

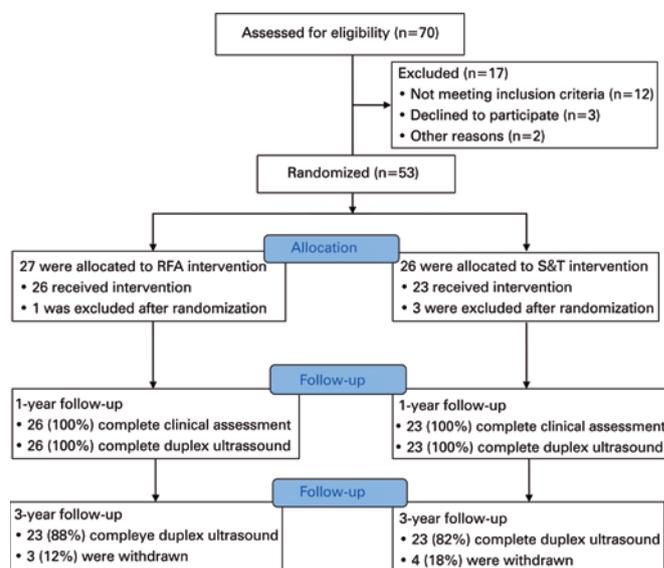
Poisson distribution in the case of the R-VCSS, and by normal distribution for the quality of life score. For the CEAP classification, the adjustment was performed with multinomial distribution, and binomial distribution was used for the recanalization of treated saphenous vein in all patients analyzed.

The analyses were conducted using the IBM Statistical Package for the Social Sciences (SPSS) for Windows, version 19.0 (IBM Corp., Armonk, NY, USA), and significance level was set at 0.05.

## RESULTS

A total of 186 patients were referred to primary outpatient care and, of those, 70 (37.6%) met the eligibility criteria and 53 (28.6%) consented to participate. Four patients were excluded after randomization. The final analysis included 49 patients with primary CVD of the saphenous vein. A total of 26 patients were randomly assigned to the RFA Group and 23 to the S&T Group (Figure 1). After 4 weeks of treatment, all patients underwent clinical evaluation and duplex scan to identify any complications. There was no statistical difference in demographic data and clinical characteristics between the groups, as indicated in table 1.

The incidence of complications was similar between the groups (Table 2). They included thrombophlebitis in a thigh tributary and popliteal vein thrombosis in the



RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein.

Figure 1. Assessment for eligibility, randomization, and outcomes

**Table 1.** Comparison of epidemiological data between both groups

	Total (n=49)	Groups		p value
		RFA (n=26)	S&T (n=23)	
Sex, n (%)				
Female	39 (79.6)	20 (76.9)	19 (82.6)	0.731*
Male	10 (20.4)	6 (23.1)	4 (17.4)	
Age, years				
Mean ± SD	46.6±11.9	44.1±11.7	49.3±11.7	0.128 <sup>†</sup>
Minimum-maximum	21-70	21-68	23-70	
BMI, kg/m <sup>2</sup>				
Mean±SD	26.6±3.6	26.4±3.5	26.7±3.7	0.776 <sup>‡</sup>
Minimum-maximum	19.6-36.7	19.6-32.0	20.8-36.7	
Unilateral involvement, n (%)	31	17 (65.4)	14 (60.9)	
Saphenous-vein involvement, n				
Great saphenous vein	63	34	29	0.596 <sup>§</sup>
Small saphenous vein	6	3	3	0.948 <sup>§</sup>
CEAP classification, n (%)				0.268 <sup>§</sup>
C2, varicose veins >3mm	19 (38.8)	9 (34.6)	10 (43.5)	
C3, edema	19 (38.8)	11 (42.3)	8 (34.8)	
C4, skin or subcutaneous change	11 (22.4)	6 (23.1)	5 (21.7)	
Comorbidities, n (%)				
SAH	13 (26.5)	7 (26.9)	6 (26.1)	0.947 <sup>§</sup>
DM	5 (10.2)	1 (3.8)	4 (17.4)	0.173*
Smoking	8 (16.3)	6 (23.1)	2 (8.7)	0.254*
OAC	4 (8.2)	2 (7.7)	2 (8.7)	1.000*
Recurrence of varicose veins within 3 years, n (%)				
No	37 (88.1)	21 (91.3)	16 (84.2)	0.638*
Yes	5 (11.9)	2 (8.7)	3 (15.8)	

\* Fisher's exact test; <sup>†</sup> two sample t-test; <sup>‡</sup> generalized estimating equations; <sup>§</sup> Pearson  $\chi^2$ .

RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein; SD: standard deviation; BMI: body mass index; CEAP: Comprehensive Classification System for Chronic Venous Disorders; SAH: systemic arterial hypertension; DM: diabetes mellitus; OAC: oral anticoagulants.

**Table 2.** Surgery outcomes according to treatment

	Total (n=49)	Groups		p value
		RFA (n=26)	S&T (n=23)	
Complications				
No	45 (91.8)	24 (92.3)	21 (91.3)	1.000*
Yes	4 (8.2)	2 (7.7)	2 (8.7)	
Length of hospital stay, days		0.69±0.47	1.48±1.67	0.001 <sup>†</sup>
Absence from work, days		8.62±4.53	20.13±18.76	<0.001 <sup>†</sup>

Results expressed as n (%) or mean±standard deviation. \* Fisher's exact test; <sup>†</sup> Mann-Whitney test.

RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein.

RFA Group, while one patient developed cellulitis and another developed deep venous thrombosis in the S&T Group (Table 2).

Patients in the S&T Group reported a longer time of absence from work or from house activities (20.13±18.76) than those in the RFA Group (8.62±4.53). Length of hospital stay was also significantly longer for the S&T Group (1.48±1.67) than for the RFA Group

(0.69±0.47). Moreover, the RFA Group stayed at the hospital for a maximum of 1 day, whereas hospitalization ranged from 1 to 9 days for patients in the S&T Group. In the S&T Group, one patient had a secondary infection (cellulitis) and required hospitalization for antibiotic therapy.

Both R-VCSS and AVVQ significantly improved ( $p<0.001$ ) between pre- and postoperative evaluations for all patients (Table 3), but there was no difference in R-VCSS ( $p=0.636$ ) or AVVQ scores ( $p=0.163$ ) between the RFA and S&T Groups (Tables 3 and 4). Both procedures significantly improved CEAP classification ( $p<0.001$ ) of all participants, but there was no difference ( $p=0.268$ ) in CEAP classifications between the groups.

Twelve months after treatment, on average, 67 limbs of 49 patients (35 from the RFA Group and 32 from the S&T Group) were evaluated by ultrasound (Table 5). Overall technical failure rate was 5.2%,

with one recanalization in the RFA Group (2.9%) and three surgical failures in the S&T Group (9.4%). In the latter, there were two cases of reflux in residual segments of GSV, and one case of incomplete ligation of SSV, maintaining venous reflux to gastrocnemial and superficial varicose veins.

**Table 3.** Results of Aberdeen Varicose Veins Questionnaire in study participants, before and after the procedure, according to the treatment performed after 1-year follow up

	Total (n=49)	Groups	
		RFA (n=26)	S&T (n=23)
Evaluation			
Preoperative	24.2 (20.7-27.6)	22.6 (18.7-26.6)	25.7 (20.1-31.3)
Postoperative	14.7 (12.7-16.6)	13.0 (10.4-15.7)	16.3 (13.5-19.2)
Tests of model effects*			
Technique <i>versus</i> evaluation	p=0.964		
Technique	p=0.163		
Evaluation	p<0.001		
Difference (pre-post)	9.5 (6.1-12.8) p<0.001	9.6 (5.5-13.6) p<0.001	9.4 (4.1-14.8) p<0.001

Results expressed as estimated means and 95% confidence intervals. \* Generalized estimating equations.  
RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein.

**Table 4.** Results of the Revised Venous Clinical Severity Score in patients analyzed, according to treatment performed after 1-year follow-up

	Total (n=49)	Groups	
		RFA (n=26)	S&T (n=23)
Evaluation			
Preoperative	7.68 (6.81-8.55)	7.58 (6.37-8.79)	7.78 (6.52-9.04)
Postoperative	4.17 (3.49-4.85)	4.00 (2.91-5.09)	4.35 (3.56-5.13)
Tests of model effects*			
Technique <i>versus</i> evaluation	p=0.737		
Technique	p=0.636		
Evaluation	p<0.001		
Difference (pre-post)	3.51 (2.60-4.42) p<0.001	3.58 (2.22-4.94) p<0.001	3.43 (2.24-4.63) p<0.001

Results expressed as estimated means and 95% confidence intervals. \* Generalized estimating equations.  
RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein.

**Table 5.** Estimated proportion of recanalization within 1 and 3 years/limb treated

	Total	Groups		p value
		RFA	S&T	
Failure rate 1 year	5.2 (0.0-11.0)	2.9 (0.0-8.4)	9.4 (0.0-19.4)	0.266*
Limbs treated	67	35	32	
Failure rate 3 year	8.6 (1.2-16.0)	6.6 (0.0-15.5)	11.2 (0.0-23.1)	0.540*
Limbs treated	58	31	27	

Results expressed as 95% confidence interval and n. \* Generalized estimating equations.  
RFA: radiofrequency ablation; S&T: complete stripping of the saphenous vein.

In the next follow-up session (37.1 months, on average), in which 42 study participants returned for ultrasound and medical evaluation, a total of 58 limbs were analyzed (31 from the RFA Group and 27 from the S&T Group), resulting in the identification of one new technical failure (saphenous recanalization) in the RFA Group. Thus, the success rate per limb was 93.4% for the RFA Group and 88.8% to the S&T Group (p=0.540).

The clinical recurrence of varicose veins in 3 years was not significantly different in the two groups (p=0.638), with only two cases in RFA Group (8.7%) and three cases in the S&T Group (15.8%).

## DISCUSSION

This study shows that RFA allows for a shorter period of hospitalization and absence from work when compared to the S&T Group, as previously demonstrated by Lurie et al.,<sup>(13)</sup> and other studies.<sup>(23,24)</sup> Furthermore, the data presented here confirm the good clinical results of RFA regarding venous occlusion rates and impact on quality of life of patients treated, during the medium-term follow-up. We found a 93.4% occlusion rate per limb in the RFA group after 3 years, similar to the results described by Proebstle et al.,<sup>(25)</sup> who reported a 95% reflux-free rate, 5 years after RFA. We identified two cases of saphenous vein recanalization after RFA: one partial recanalization at knee level, and one neovascularization of the saphenous vein trunk at mid-thigh. However, one of the patients had no complaints about venous insufficiency, corroborating the recent publications that have demonstrated ablation of the saphenous vein improves VCSS, despite failing to close it completely.<sup>(26)</sup> Recently, the results of the original VNUS closure device to eliminate truncal venous reflux at 15 years were reported, demonstrating excellent long-term technical success in truncal veins with the first-generation device.<sup>(27)</sup>

In the S&T Group, we believe most recurrences are due to the current standard technique, with no intraoperative ultrasound assessment. Additionally, there was no permanent clinical nerve injury detected in any of the groups, even in those patients who underwent stripping from the SFJ to the ankle. Although we did not perform a specific protocol for nerve injury evaluation, our results are similar to those described by Morrison et al.<sup>(10)</sup> The authors suggest that saphenous nerve deficits after stripping of the GSV to the ankle have little clinical significance. In contrast, other reports found in the literature showed a risk of nerve injury after stripping below the knee as high as 39%.<sup>(17)</sup>

Furthermore, clinical dynamics such as surgical time, perioperative and temporary post-operative care, and antibiotic therapy were similar between the RFA and S&T Groups.

In the first two decades of the this century, there were significant advances in techniques used to treat saphenous trunk reflux, especially in the ultrasound-guided minimally invasive techniques.<sup>(28)</sup> There are numerous studies demonstrating encouraging results with these techniques.<sup>(24,29)</sup> The earlier return to daily activities and the decrease in postoperative pain, in comparison to the conventional technique, have been well established since the use of the first radiofrequency catheters.<sup>(13)</sup> After technological advances in the ablation device, radiofrequency started to present even better results.<sup>(30)</sup> This led the American Venous Forum guidelines to recommend endovenous thermoablation instead of the conventional technique.<sup>(2)</sup> Since then, several publications recommending the same treatment to vascular specialist have been published, especially in developed countries.<sup>(31)</sup> A recent survey with surgeons, who are members of the American Venous Forum (mostly US residents), identified that 47% of them favor radiofrequency ablation and 40% prefer laser ablation of the GSV.<sup>(32)</sup> However, this paradigm change in CVD treatment through endovenous thermoablation is not yet globally disseminated.

Our main objective was to compare the standard of care in Brazil (complete stripping) to the standard of care in developed countries (thermoablation).<sup>(2)</sup> We focused on the most prevalent group of CVD (CEAP classes 2, 3 and 4) for a better data analysis, and our results were corroborated by most data previously published.<sup>(22,25,33)</sup>

This is the first randomized Brazilian trial with mid-term follow-up (3 years) that compared the complete stripping of saphenous vein for CVD treatment with a minimally invasive technique. This study reproduced the good results reported in the literature in the last 20 years, opening a new perspective for the treatment of axial saphenous reflux in developing countries. Since this technology requires additional equipment and supplies, it is necessary to perform a detailed economic analysis of the financial impact of the endovenous technique on the public health system. Lower hospitalization rates and shorter work absence periods must be considered when assessing the cost of implementing the new techniques, since they may be beneficial to society.

## CONCLUSION

Patients submitted to radiofrequency thermoablation had an occlusion rate, clinical recurrence and improvement

in quality of life that were comparable to those of patients who underwent complete stripping of the saphenous vein. However, the patients who underwent radiofrequency thermoablation showed an improvement in quality of life, spent significantly less time at the hospital and were absent from work for a shorter period of time in comparison to those who underwent the traditional technique. Further studies should evaluate the cost-benefit ratio of these minimally invasive techniques.

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## REFERENCES

- Maffei FH, Magaldi C, Pinho SZ, Lastoria S, Pinho W, Yoshida WB, et al. Varicose veins and chronic venous insufficiency in Brazil: prevalence among 1755 inhabitants of a country town. *Int J Epidemiol.* 1986;15(2):210-7.
- Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW; Society for Vascular Surgery; American Venous Forum. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* 2011;53(5 Suppl):2S-48S.
- Biemans AA, Kockaert M, Akkersdijk GP, van den Bos RR, Maeseneer MG, Cuyper P, et al. Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. *J Vasc Surg.* 2013;58(3):727-34. e1.
- Labropoulos N, Leon M, Nicolaidis AN, Giannoukas AD, Volteas N, Chan P. Superficial venous insufficiency: correlation of anatomic extent of reflux with clinical symptoms and signs. *J Vasc Surg.* 1994;20(6):953-8.
- Engelhorn CA, Engelhorn AL, Cassou MF, Salles-Cunha SX. Patterns of saphenous reflux in women with primary varicose veins. *J Vasc Surg.* 2005; 41(4):645-51.
- Labropoulos N, Kokkosis AA, Spentzouris G, Gasparis AP, Tassiopoulos AK. The distribution and significance of varicosities in the saphenous trunks. *J Vasc Surg.* 2010;51(1):96-103.
- Sociedade Brasileira de Angiologia e de Cirurgia Vasculare (BACV). Projeto Diretrizes SBACV. Insuficiência Venosa Crônica Diagnóstico e Tratamento [Internet]. São Paulo: SBACV; 2015 [citado 2017 Nov 20]. Disponível em: <http://www.sbacv.org.br/lib/media/pdf/diretrizes/insuficiencia-venosa-cronica.pdf>

8. Theivacumar NS, Darwood R, Gough MJ. Neovascularisation and recurrence 2 years after varicose vein treatment for sapheno-femoral and great saphenous vein reflux: a comparison of surgery and endovenous laser ablation. *Eur J Vasc Endovasc Surg.* 2009;38(2):203-7.
9. Gifford SM, Kalra M, Gloviczki P, Duncan AA, Oderich GS, Fleming MD, et al. Reflux in the below-knee great saphenous vein can be safely treated with endovenous ablation. *J Vasc Surg Venous Lymphat Disord.* 2014;2(4):397-402.
10. Morrison C, Dalsing MC. Signs and symptoms of saphenous nerve injury after greater saphenous vein stripping: prevalence, severity, and relevance for modern practice. *J Vasc Surg.* 2003;38(5):886-90.
11. Theivacumar NS, Darwood RJ, Dellagrammaticas D, Mavor AI, Gough MJ. The clinical significance of below-knee great saphenous vein reflux following endovenous laser ablation of above-knee great saphenous vein. *Phlebology.* 2009;24(1):17-20. Erratum in: *Phlebology.* 2015;30(7):500.
12. Bergan JJ. Saphenous vein stripping and quality of outcome. *Br J Surg.* 1996;83(8):1027-7.
13. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVE Study). *J Vasc Surg.* 2003;38(2):207-14.
14. Leopardi D, Hoggan BL, Fitridge RA, Woodruff PW, Maddern GJ. Systematic review of treatments for varicose veins. *Ann Vasc Surg.* 2009;23(2):264-76.
15. Murad MH, Coto-Yglesias F, Zumaeta-Garcia M, Elamin MB, Duggirala MK, Erwin PJ, et al. A systematic review and meta-analysis of the treatments of varicose veins. *J Vasc Surg.* 2011;53(5 Suppl):49S-65S. Review.
16. Mendes CA, Martins AA, Fukuda JM, Munia MA, Fioranelli A, Teivelis MP, et al. Randomized trial of radiofrequency ablation versus conventional surgery for superficial venous insufficiency: if you don't tell, they won't know. *Clinics (São Paulo).* 2016;71(11):650-6.
17. Sam RC, Silverman SH, Bradbury AW. Nerve injuries and varicose vein surgery. *Eur J Vasc Endovasc Surg.* 2004;27(2):113-20. Review.
18. Cheatle T. The long saphenous vein: to strip or not to strip? *Semin Vasc Surg.* 2005;18(1):10-4. Review.
19. Garratt AM, Macdonald LM, Ruta DA, Russell IT, Buckingham JK, Krukowski ZH. Towards measurement of outcome for patients with varicose veins. *Qual Health Care.* 1993;2(1):5-10.
20. Smith JJ, Garratt AM, Guest M, Greenhalgh RM, Davies AH. Evaluating and improving health-related quality of life in patients with varicose veins. *J Vasc Surg.* 1999;30(4):710-9.
21. Vasquez MA, Rabe E, McLafferty RB, Shortell CK, Marston WA, Gillespie D, Meissner MH, Rutherford RB; American Venous Forum Ad Hoc Outcomes Working Group. Revision of the venous clinical severity score: venous outcomes consensus statement: special communication of the American Venous Forum Ad Hoc Outcomes Working Group. *J Vasc Surg.* 2010;52(5):1387-96.
22. Brittenden J, Cotton SC, Elders A, Ramsay CR, Norrie J, Burr J, et al. A randomized trial comparing treatments for varicose veins. *N Engl J Med.* 2014;371(13):1218-27.
23. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. *Br J Surg.* 2011;98(8):1079-87.
24. Siribumrungwong B, Noorit P, Wilasrusmee C, Attia J, Thakkinstian A. A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein. *Eur J Vasc Endovasc Surg.* 2012;44(2):214-23. Review.
25. Proebstle TM, Alm BJ, Göckeritz O, Wenzel C, Noppeney T, Lebard C, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. *Br J Surg.* 2015;102(3):212-8.
26. Jin HY, Ohe HJ, Hwang JK, Kim SD, Kim JY, Park SC, et al. Radiofrequency ablation of varicose veins improves venous clinical severity score despite failure of complete closure of the saphenous vein after 1 year. *Asian J Surg.* 2017;40(1):48-54.
27. Whiteley MS, Shiangoli I, Santos SJ, Dabbs EB, Fernandez-Hart TJ, Holdstock JM. Fifteen year results of radiofrequency ablation, using VNUS closure, for the abolition of truncal venous reflux in patients with varicose veins. *Eur J Vasc Endovasc Surg.* 2017;54(3):357-62.
28. Coleridge-Smith P, Labropoulos N, Partsch H, Myers K, Nicolaides A, Cavezzi A. Duplex ultrasound investigation of the veins in chronic venous disease of the lower limbs—UIP consensus document. Part I. Basic principles. *Eur J Vasc Endovasc Surg.* 2006;31(1):83-92.
29. Harlander-Locke M, Jimenez JC, Lawrence PF, Derubertis BG, Rigberg DA, Gelabert HA. Endovenous ablation with concomitant phlebectomy is a safe and effective method of treatment for symptomatic patients with axial reflux and large incompetent tributaries. *J Vasc Surg.* 2013;58(1):166-72.
30. Zuniga JM, Hingorani A, Ascher E, Shiferson A, Jung D, Jimenez R, et al. Short-term outcome analysis of radiofrequency ablation using ClosurePlus vs ClosureFast catheters in the treatment of incompetent great saphenous vein. *J Vasc Surg.* 2012;55(4):1048-51.
31. Joh JH, Kim WS, Jung IM, Park KH, Lee T, Kang JM; Consensus Working Group. Consensus for the Treatment of Varicose Vein with Radiofrequency Ablation. *Vasc Specialist Int.* 2014;30(4):105-12.
32. Aziz F, Diaz J, Blebea J, Lurie F; American Venous Forum. Practice patterns of endovenous ablation therapy for the treatment of venous reflux disease. *J Vasc Surg Venous Lymphat Disord.* 2017;5(1):75-81.e1.
33. van Eekeren RR, Boersma D, Konijn V, de Vries JP, Reijnen MM. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. *J Vasc Surg.* 2013;57(2):445-50.