Radiofrequency thermal ablation versus conventional saphenectomy

Ablação térmica por radiofrequência versus safenectomia convencional

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Abstract

Background: Varicose veins of the lower limbs have a high prevalence worldwide. New treatment techniques have been developed with the objectives of improving patients' quality of life and reducing recovery times. **Objective**: To evaluate patients with incompetent saphenous veins treated using conventional saphenectomy or radiofrequency ablation (RF), in terms of postoperative status. **Methods**: From May 2012 to April 2013 146 varicose veins patients with saphenous insufficiency, 90 of whom were treated with conventional surgery (G1) and 56 with RF ablation (G2), were evaluated prospectively. **Results**: In G1, 88.61% of patients complained of postoperative pain and needed to take analgesics, compared with 28.85% in G2 ($p<0.05$). Mean pain rating on an analog scale from 0 to 10 was 3.91±2.13 points for G1 and 1.76±3.01 points for G2 ($p<0.05$). Recovery periods ranged from 26.63±13.3 days to 18.26±19.37 days, for G1 and G2 respectively. Mean time taken to become totally asymptomatic was 66.78±60.9 days for G1 and 38.38±46.8 days for G2 ($p<0.05$). **Conclusions**: The RF treatment method caused less postoperative pain and resulted in earlier recovery, when compared to conventional saphenectomy.

Keywords: varicose veins; radiofrequency; saphenectomy.

Resumo

Contexto: As varizes dos membros inferiores têm elevada prevalência mundial e as técnicas convencionais de tratamento têm seus resultados bem definidos há décadas. O advento de novas tecnologias nos obriga a avaliar os resultados e compará-los com métodos tradicionais. **Objetivo**: Avaliar o tratamento de pacientes com varizes dos membros inferiores e insuficiência de safenas por safenectomia convencional (SF) ou ablação por radiofrequência (RF), quanto aos sintomas pós-operatórios. **Materiais e Métodos**: Entre maio/2011 e abril/2013, foram avaliados prospectivamente 146 pacientes com varizes dos membros inferiores e insuficiência de safenas, sendo 90 por SF (G1) e 56 por RF (G2). **Resultados**: Quanto aos quesitos avaliados, o G1 evidenciou 88,61% dos pacientes com queixa de dor pós-operatória com necessidade do uso de analgésicos e o G2, 28,85% ($p<0,05$). A média da graduação da dor através da escala analógica – de 0 a 10 – foi de 3,91±2,13 pontos no G1 e de 1,76±3,01 pontos no G2 ($p<0,05$). O período de recuperação variou de 26,63±13,3 dias para o G1 e 18,26±19,37 dias para o G2. O tempo médio até tornar-se assintomático foi 66,78±60,9 dias para G1 e 38,38±46,8 dias para G2. **Conclusão**: A RF propiciou menor dor pós-operatória e recuperação mais precoce quando comparada à SF.

Palavras-chave: varizes; radiofrequência; safenectomia.

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INTRODUCTION

Varicose veins of the lower limbs are dilated, elongated and tortuous veins and they have an elevated prevalence worldwide, making them one of the most important causes of discomfort and work incapacity.[1] They affect 10 to 15% of men and 20 to 25% of women in the Western world.[2] If multiple points of reflux are also included, in addition to the saphenous veins, prevalence can reach 43%[3] and if cases of reticular veins and telangiectasia are also included, then more than 80% of the population has the disease.[4]

The etiology of primary varicose veins of the lower limbs is linked to changes to the veins walls and changes to the structure of collagen and/or elastin, to localized or segmental valve incompetence and/or the presence of arteriovenous fistulas at the level of the microcirculation.[2] Secondary varicose veins are related to post-phlebitic syndrome, traumatic arteriovenous fistulas, angiodysplasias and causes of extrinsic compression.[2]

In Brazil, chronic venous insufficiency of the lower limbs is the 14th most common disease for which the country's social security system (INSS) makes sickness benefit payments. According to the Brazilian National Health Service (SUS - Sistema Único de Saúde) statistical office, DATASUS, in 2004 the service spent 43 million Reais on surgical treatment for varicose veins of the lower limbs.[5] In 2013, expenditure was 36.6 million Reais.[6]

New treatment techniques for varicose veins of the lower limbs have been developed with the objectives of reducing the length of hospital stays and recovery times,[7] including thermal ablation using lasers[8] or radiofrequency,[9] mechanical ablation[10] and administration of sclerosant agents such as ultrasound-guided foam.[11] It should be borne in mind that the results and complications of conventional surgery are well-defined, leading to an unpleasant situation in terms of cost and benefit, which are in constant conflict.

Radiofrequency (VNUS Medical Technologies Inc., San José, California, and, more recently, Covidien, Mansfield, Maryland) ablation is an intervention guided by catheter, in which energy is released in continuous or sinusoidal waves with frequencies of 200 to 3000 kHz causing tissues in contact with the catheter to heat up.[12] The procedure's activity is concentrated against the vessel wall, destroying the endothelium and denaturing the collagen, causing fibrosis of the lumen. The treatment protocol includes a standardized rate of traction, determined by the manufacturer of the catheter, so that it travels through a 7 cm segment of the vessel during each 20-second burst of energy, which makes it easier to reproduce the technique and offers more consistent results than treatment with laser, which focuses on transmission of energy into blood or water and has traction velocities that vary depending on the manufacturer or the service.[12]

One feature of minimally invasive techniques that can make them preferable to conventional surgery is the possibility of using color Doppler ultrasonography, which enables real-time evaluation of status in the immediate postoperative period and identification of tributaries or anomalous trajectories that have not been correctly treated or which may appear immediately after exclusion of the diseased saphenous vein.[13]

It is understood that an ideal treatment for varicose veins of the lower limbs should be minimally invasive, possible to be repeated when necessary, free from significant complications and inexpensive and should also improve esthetics while effectively eliminating points of reflux and allowing a rapid return to work.[14] However, in practice this ideal treatment does not exist because each of the available techniques has its advantages and disadvantages, so it is up to the vascular surgeon to consult the scientific evidence and choose the treatment that will achieve the best results for each patient.

OBJECTIVE

To evaluate postoperative results in a sample of patients with varicose veins of the lower limbs, with incompetent saphenous veins, who were treated either by conventional surgery or by radiofrequency ablation.

MATERIALS AND METHODS

This prospective study was conducted in the city of Cascavel, state of Paraná, Brazil, at the Instituto Vascular, between May 2012 and April 2013. Since this study constitutes research involving human beings, it was conducted in accordance with the provisions of National Health Council resolution 196/96 and was approved in advance by the Research Ethics Committee at the Faculdade Assis Gurgacz – FAG (Approval number: 085 / 2012).

The sample comprised a total of 146 people, selected according to a set of inclusion and exclusion criteria. Inclusion criteria were as follows: both sexes; any age, as long as clinically healthy; symptoms of chronic venous insufficiency or varicose veins of

the lower limbs; with ultrasonographic diagnosis of insufficiency of at least one of the internal saphenous veins along at least 50% of its course; with indications for surgery; CEAP classes 2 to 5; free and spontaneous consent for the patient's chosen procedure, plus signature of a form accepting responsibility for the costs incurred for use of the VNUS Closure FAST radiofrequency equipment. Patients with varicose veins of the lower limbs were excluded from the study if they did not have a saphenous vein that was incompetent along at least 50% of its length, if they had high surgical risk or CEAP classes 1 or 6, or if they did not consent to taking part in the study.

Patients were allocated to one of two groups: group 1 (G1) received conventional surgery and group 2 (G2) was treated with radiofrequency ablation. Allocation was based on the patients' own preferences, in view of the additional costs involved if RF is used.

Data were collected at initial consultations, from lower limb Doppler ultrasound reports, both preoperative and postoperative, and during telephone calls made to ask about postoperative signs and symptoms.

The following data were acquired from the Doppler ultrasound studies: diameter, in millimeters, at the arch, thigh, leg and ankle, and presence of significant reflux, greater than 0.5 s, involving more than 50% of the total extent of an internal or external saphenous vein.

Both groups underwent the same preoperative procedures, consisting of initial consultation, evaluation using color Doppler ultrasonography, preoperative evaluations including laboratory tests and cardiological and anesthetic assessments, verification that informed consent had been understood, trichotomy and demarcation of the legs using a percutaneous transilluminator. Perioperative procedures were similar for both groups, with spinal anesthesia, with the only difference between groups being the open saphenectomy administered to G1 patients versus the RF ablation method used for G2 patients, followed by removal of reticular veins using mini-incisions and sclerotherapy and dressing with micropore and 20 cm crepe bandages. During the postoperative period all patients were given the same prescription, consisting of 6 hours' fasting; hydration with 500 mL of 0.9% saline solution; analgesia with tenoxicam and dipyrone when necessary; rest with legs raised and prophylaxis 4 hours after anesthesia with 20 mg of enoxaparin. Patients were discharged after 12 to 24 hours. Both groups were instructed to remove their bandages after 3 days and start wearing elastic stockings, if possible. Seven days after the operation, the micropore dressings were removed for both groups and G1 patients' saphenectomy sutures were also removed. Patients' progress was monitored at 30, 90 and 180 days and in the most recent assessment available.

Patients were contacted by telephone and asked questions about the following: time in hospital (days); recovery time (days); time until asymptomatic; burns/discoloration (and, if they occurred, the number of days until they disappeared); pain and pain rating (on a scale from 0 to 10), use of medication (NSAIDS, Analgesics or opiates).

Statistical analysis was conducted using Epi Info 7 from the Centers for Disease Control and Prevention (CDC), Atlanta, USA.

RESULTS

The surgical group, G1, comprised 90 patients, 19 men (21.11%) and 71 women (78.89%), with mean age of 51.4 years (varying from 23 to 78). The RF group, G2, comprised 56 patients, 14 men (25.0%) and 42 women (75.0%), with mean age of 54.7 years (varying from 25 to 84).

The most common risk factors were arterial hypertension (28.77%), diabetes mellitus (8.22%) and smoking (6.85%). There was a higher incidence of risk factors in G1 and this difference was statistically significant.

In G1, mean diameters at arch, thigh, leg and ankle were 7.42 mm, 5.27 mm, 4.92 mm and 3.72 mm, respectively, and in G2 the same measures were 7.06 mm, 5.30 mm, 4.94 mm and 3.69 mm, with no statistically significant difference between groups 1 and 2 (Table 1).

There were no major complications such as deaths, deep venous thrombosis or clinically detectable infections in either group. In G2 there were two cases of skin burns (3.57%), one of which left a hyperchromic discoloration.

In G1, 88.61% of the patients complained of postoperative pain and required analgesics and

Table 1. Mean diameters of saphenous veins in G1 and G2 (mm).

n	G1	G2	*p*-value
	90	56	-
Arch	7.42±2.78	7.06±1.51	
Thigh	5.27±2.25	5.30±1.32	
Leg	4.92±1.11	4.94±1.57	0.301
Ankle	3.72±0.87	3.69±0.63	
Mean	5.33±1.75	5.24±1.25	

anti-inflammatories, whereas in G2 this percentage was 28.85% ($p<0.05$). The mean pain rating on the analog scale was 3.91 points in G1 (varying from 0 to 8), with a mode of 4 (20.25%). In G2, mean pain rating was 1.76 (varying from 0 to 10), with a mode of 0, chosen by 70.59% of the group ($p<0.05$). The relative risk of suffering pain during the postoperative period was 3.07 times greater for patients in G1 ($p<0.05$) (Table 2).

Recovery time (return to normal physical activities) was 26 days for G1 and 18 days for G2. The mean time taken for patients to become entirely asymptomatic was 66.78±60.9 days in G1 and 38.38±46.8 days in G2 ($p<0.05$) (Table 2).

Skin discoloration affected 37.33% of patients in G1 during the postoperative period and 63.46% of the G2 patients ($p<0.05$). Furthermore, 45.10% of all patients with discoloration were in G1 and 54.10% were in G2 ($p<0.05$). Mean time taken for discoloration to disappear varied from 98.61±249.8 days in G1 to 83.32±135.0 in G2. The relative risk of discoloration on the lower limbs was 1.69 times greater for patients treated with RF (G2) ($p<0.05$) (Table 2).

A combination of economic reasons and healthcare providers' regulations meant that the study protocol only included serial Doppler ultrasonography for patients in G2. This showed that immediate and late success rates of RF ablation were 99% and 92% respectively.

DISCUSSION

This study assessed a population seen at a private clinic and, therefore, did not offer any advantage with regard to the procedures proposed. The proportion of men to women was in line with the tendencies reported in several Brazilian publications,[15,16] with higher prevalence among the female population.

The criteria for 'incompetence' of the saphenous veins were based on the literature, and were defined as reflux time evidently greater than 0.5 in the segments assessed combined with patients' clinical complaints.[17] The mean diameters of internal saphenous veins observed in this study are similar to results published by Engelhorn et al.,[18] who found that veins larger than 8 mm at the arch, 6 mm at the thigh and 4 mm at the leg had a greater than 90% positive predictive value for reflux, and are also in line with data from our service that have been analyzed previously.[19] In that study, assessment of 2,471 internal saphenous vein segments revealed a strong correlation between increased diameter and the presence of reflux and showed that more than 50% of cases in which veins were larger than 6.1 mm exhibited reflux.[19]

The fact that patients were responsible for covering the cost of the radiofrequency catheter constitutes a financial limitation to formation of the groups, although it did not significantly affect the populational characteristics of either, since statistical analysis showed that the groups had very similar data.

As has been described, the only differences between the procedures were the method used to treat internal saphenous vein reflux. All of the other elements involved in the operations were conducted in the same manner for both groups. In general, countries in Europe and North America tend to conduct ablation in outpatient settings,[20,21] and do not attempt to resolve other aesthetic venous problems which, to a certain extent, delayed acceptance of endovascular techniques by Brazilian vascular surgeons because they felt that, initially, the procedure did not address all of the problems presented by patients, i.e., saphenous vein reflux disease and the aesthetic problems caused by reticular and truncal veins and telangiectasias.

Introduction of a new technique is based on the constant need for improvement. Although the majority of vascular surgeons consider it to be well-defined, conventional surgery also has its prerequisites. Obese patients are always a challenge, for example. Additionally, postoperative complaints related to conventional saphenectomy

Table 2. Comparison of results for G1 and G2.

Criteria	G1	G2	RR G1/G2	*p*-value
n	90	56	-	-
Pain (%)	88.61%	28.85%	2.67	0.000000
Mean pain rating (0 to 10)	3.91±2.13	1.76±3.01	-	0.000005
Mode pain rating (0 to 10)	4 (21.92%)	0 (63.64%)	-	0.00352
Discoloration (%)	37.33%	63.46%	0.58	0.00375
Time for discoloration to disappear (days)	98.61±249.8	83.32±135.0	-	0.008
Time to return to normal activities (days)	26.63±13.3	18.26±19.37		0.00432
Time for symptoms to disappear (days)	66.78±60.9	38.38±46.8		0.00507

have become a cause of growing concern among vascular surgeons. Subramonia and Lees[22] state that around 40% of patients who undergo conventional saphenectomy suffer neuropathic symptoms during the postoperative period. Notwithstanding, radiofrequency ablation is not entirely complication free, and cases of neuropathic pain have been described along the path of the saphenous nerve and the sural nerve[12] and even neuropathy of the fibular nerve with foot drop.[23]

Rasmussen et al.[24] compared a number of different methods for treatment of saphenous vein incompetence, including radiofrequency, intravenous laser, dense foam and conventional surgery. According to these authors, all treatments were effective, but radiofrequency and foam caused less pain during the postoperative period when compared with laser or conventional surgery. According to a randomized study conducted by Rautio et al.,[20,25] patients subjected to conventional saphenectomy suffered paresthesia in 23% of cases, whereas 13% of patients treated with RF suffered neuropathic symptoms.

Patients subjected to radiofrequency thermal ablation had less pain during the postoperative period and many of these patients did not even take the analgesics they were offered. Several different studies have compared the incidence of postoperative symptoms in patients subjected to varicose vein treatments,[20] with less pain and reduced consumption of analgesics. According to Rautio et al.,[20] patients treated with conventional surgery took a mean of 1.6 600 mg ibuprofen tablets per day, whereas patients treated with radiofrequency only took 0.4 tablets. According to Shepherd et al.[26] patients treated with RF had a mean score of 26.4 points (0-100) and took 8.8 ibuprofen tablets over the first three days, in contrast with patients treated with conventional surgery who had a mean score of 36.8 points (0-100) and took a mean of 20.4 tablets over the first three days.

The time taken for recovery (return to normal physical activities) varied from 26 days in G1 to 18 days in G2. The mean time to become entirely asymptomatic was 66.78±60.9 days in G1 and 38.38±46.8 days in G2 ($p<0.05$). It should be remembered that if these patients had only been treated for saphenous reflux they would have recovered more rapidly, but regardless of this the RF group recovered more quickly, as had already been demonstrated by some North-American studies, where, for example, the time taken to return to normal activities varied from 4.7 to 6.5 days after RF ablation and 12.4 to 15.6 days after conventional treatment.[20]

Skin discolorations were more common in G2, primarily at the sites of repeated punctures made to conduct pre-ablative expansion, and consisted of ecchymosis along the paths of the saphenous veins, in contrast with saphenectomy which initially caused a lower incidence of ecchymosis, because the majority of the hematoma is confined to the saphenous compartment. On the other hand, this may also explain why the G2 patients, who exhibited more discoloration during the postoperative period, also exhibited faster disappearance of this discoloration, since it was more superficial. With regard to burns, both occurred during the learning curve. One case was caused by overheating of the introducer kit sheath and the other was caused by a very superficial path combined with excessive compression. Both cases were treated with local measures, but the first case resulted in a hyperchromic scar.

The results of this study are similar to data reported in the current literature, such as research by Lurie and Highlife, 2006,[10] confirming that the radiofrequency technique has a greater impact in terms of improved patient quality of life – with less postoperative pain and rapid return to daily activities– when compared with conventional saphenectomy. The challenge that remains is to develop a less expensive technology so we can make it available to all patients with indications for saphenectomy.

CONCLUSIONS

This study has shown that radiofrequency thermal ablation caused less postoperative pain and offered faster recovery, when compared with conventional saphenectomy.

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