# Real time echo-guided endolaser for thermal ablation without perivenous tumescence

*Endolaser ecoguiado em tempo real para termoablação sem intumescência perivenosa*

Ricardo José Gaspar[1,2,3], André Nóbrega Castro[4], Manuel de Jesus Simões[5], Hélio Plapler[6]

## Abstract

**Background:** There is no consensus in the medical literature on the ideal procedure for endovenous laser application. **Objective:** To assess the safety and efficacy of real time echo-guided endovenous laser for thermal ablation of great saphenous vein (GSV) incompetence, without perivenous tumescence. **Methods:** Thirty-four limbs of patients with CEAP clinical scores of 2 to 6 and bilateral incompetence of the saphenofemoral junction (SFJ) and GSV, confirmed by Echo-Doppler, underwent endovenous laser therapy and were followed for 1 year. Laser ablation was performed using a 600 µ bare optical fiber introduced endovenously close to the malleolus along the full extent of the GSV in an anterograde direction, using a standardized echo-Doppler-guided AND? 15 watt continuous mode 980 nm diode laser with real-time monitoring of thermal ablation of the whole target vein. Adverse effects and complications were recorded. **Results:** Hyperesthesia, cellulitis, and fibrous cord, all transitory, developed in 2.9% of the 34 limbs treated; 8.8% developed hypoesthesia in the perimalleolar region, which was transitory and had no clinical consequences; there were no cases of deep venous thrombosis. Immediate occlusion was achieved in 100% of the 34 saphenous veins that underwent photocoagulation, although one exhibited recanalization without reflux at 1-month follow-up. After 6 months and 1 year, occlusion was 100% according to echo-Doppler findings. **Conclusions:** Real-time echo-guided 980 nm endovenous laser ablation without perivenous tumescence provided controlled thermal ablation with safe, effective, immediate and medium-term GSV occlusion and can therefore be recommended as a method for the treatment of chronic venous disease.

**Keywords:** varicose veins; venous insufficiency; saphenous vein; laser therapy.

## Resumo

**Contexto:** Não há consenso na literatura médica sobre qual técnica é a ideal para aplicação do endolaser. **Objetivos:** Avaliar a segurança e a eficácia do endolaser ecoguiado em tempo real para termoablação da veia safena magna (VSM) insuficiente, sem intumescência perivenosa. **Métodos:** Trinta e quatro membros de pacientes em estágio clínico CEAP 2 a 6, com incompetência bilateral da junção safeno-femoral e da VSM, confirmada por eco-Doppler, foram submetidos à terapia por endolaser e acompanhados por um período de um ano. A aplicação foi feita por meio de fibra condutora de 600 µ, introduzida por via endovenosa, ao nível da região perimaleolar por toda VSM, sentido anterógrado, utilizando laser diodo com 15 w de potência e 980 nm de comprimento de onda, no modo contínuo, guiado por eco-Doppler, e forma padronizada para monitoração em tempo real da termoablação de toda a veia-alvo. Foram anotados os efeitos adversos e as complicações. **Resultados:** Dos 34 membros tratados, 2,9% apresentaram hiperestesia, celulite e cordão fibroso, todos transitórios; em 8,8%, constatou-se hipoestesia perimaleolar, transitória e sem repercussão clínica; não houve relato de trombose venosa profunda. Das 34 safenas fotocoaguladas, houve 100% de oclusão imediata, uma recanalização sem refluxo no controle de um mês e 100% de oclusão após seis meses e um ano, mostrado pelo eco-Doppler. **Conclusões:** Ablação utilizando endolaser 980 nm, ecoguiado em tempo real, sem intumescência perivenosa, promoveu fotocoagulação suficientemente controlada, com oclusão imediata e em médio prazo da VSM, de forma segura e eficaz, e configura-se como método terapêutico recomendável para o tratamento da doença venosa crônica.

**Palavras-chave:** varizes; insuficiência venosa; veia safena/cirurgia; terapia a laser.

[1] Universidade Federal de São Paulo – UNIFESP, São Paulo, SP, Brazil.
[2] Sociedade Brasileira de Angiologia e Cirurgia Vascular, São Paulo, SP, Brazil.
[3] Instituto Vascular Ricardo Gaspar, São Paulo, SP, Brazil.
[4] Sociedade Brasileira de Angiologia e de Cirurgia Vascular – SBACV, São Paulo, SP, Brazil.
[5] Universidade Federal de São Paulo – UNIFESP, Department of Histology and Structural Biology, São Paulo, SP, Brazil.
[6] Universidade Federal de São Paulo – UNIFESP, Department of Surgery, São Paulo, SP, Brazil.
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## INTRODUCTION

There is no consensus in the medical literature on the ideal procedure for endovenous laser application and there are no descriptions of a standard method capable of managing all physical and biological variations using different devices and techniques.

Studies have been conducted to analyze thermal damage caused by endoluminal lasers of different wavelengths and have shown that the main component responsible for vein wall damage is blood vaporization.[1-4] Additionally, a small number of histological studies have observed the changes to the great saphenous vein (GSV) caused by the action of heat.[5] Some preliminary findings from investigations of limbs that have undergone endovenous laser treatment appear to indicate that endovenous laser irradiation is always followed by thrombosis.[2,3,6,7] Changes to the vein wall caused by the heat generated by the laser have been described as shrinking by myoglobin contraction,[5,8,9] collagen retraction,[6,10-15] and thrombosis and fibrosis,[2,7,15] and results are apparently fluence dependent.[14] Other factors that also appear to influence the practical outcomes of the selective thermal action of endovenous lasers include vein wall diameter and thickness and optical fiber conditions and pull-back speed, venous tone, immediate spasm, blood volume and blood vaporization,[12,14] as well as the presence of reflux points caused by incompetent tributary and perforating veins.[3]

In view of the above, this study investigated whether use of a real-time echo-guided endovenous laser thermal ablation method would increase safety and efficacy and reduce adverse effects and recanalization prevalence. Parameters were recorded over a 1-year follow-up period, during which patients were evaluated at regular intervals.

## MATERIALS AND METHODS

This study was performed under supervision by the Graduate Course in Surgery and Experimentation at the Universidade Federal de São Paulo – Escola Paulista de Medicina (UNIFESP-EPM) and was approved by the Research Ethics Committees at UNIFESP-EPM and the Santa Catarina, Bandeirantes and Igesp Hospitals, where the procedures were performed. Patients were enrolled on the study after signing informed consent forms. All surgical procedures were performed by the same surgery team. Patients with suspected lower limb chronic venous disease underwent clinical assessment. Those with confirmed diagnoses of venous disease and indications for surgical treatment were selected to receive endovenous laser therapy. Inclusion criteria were age greater than 21 years, indications for surgical treatment of primary varices, bilateral GSV and saphenofemoral junction (SFJ) reflux confirmed by color echo-Doppler findings and clinical stage 2 to 6 according to the Clinical Etiology Anatomy Pathophysiology (CEAP) classification, which sets standards for stratification of chronic venous diseases.[16] Exclusion criteria were valve insufficiency in deep veins or post thrombotic syndrome, mental conditions, severe ongoing infectious diseases, uncontrolled hypertension and severe heart disease. All 17 patients (100%) underwent bilateral endovenous laser treatment. All incompetent tributary and perforating veins mapped by echo-Doppler were recorded and those topographically related to the GSV were marked with an arrow drawn with a pen specifically designed for writing on skin, containing ink that cannot be removed by antiseptics. After spinal anesthesia, patients were positioned on the operating table in the horizontal dorsal position. An incision was then made at the inguinal fold and the SFJ was dissected, followed by high ligation, crossectomy and ligature of tributary veins. The GSV was catheterized via the malleolus region, where a 600-micron-wide bare optical fiber, connected to the 980 nm diode laser (Model Ceralas D15, Biolitec brand, manufacturer Biolitec Biomedical Technology) with 15W power density, was inserted using either needle cannula or vein dissection. The equipment used is approved and regulated by the Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária [ANVISA], registration number 80162040002). After GSV catheterization via the malleolus region, the laser fiber was introduced in the ascending direction, with real-time visualization using echo-Doppler in B mode, until it reached the level of the vein ligation in the SJF. Its position was also confirmed by direct observation of the laser light by trans-illumination through the skin near the inguinal incision. Thermal exposure time was determined according to thrombosis parameters on the basis of echo-Doppler findings. After visualization by ultrasound of the fiber tip inside the vein lumen in a longitudinal section, laser light was applied in continuous mode, and blood boiling was confirmed by the presence of steam bubbles (Figure 1). As echo-Doppler showed the complete occlusion by thrombosis of each centimeter of the treated segment (Figure 2), the optical fiber was manually withdrawn caudally in a gradual motion without using any type of mechanical device. After photocoagulation of each 20 cm, laser discharges were interrupted to perform a proximal sweep of a cross-section and reconfirm obliteration by detection of hyperechogenic material,

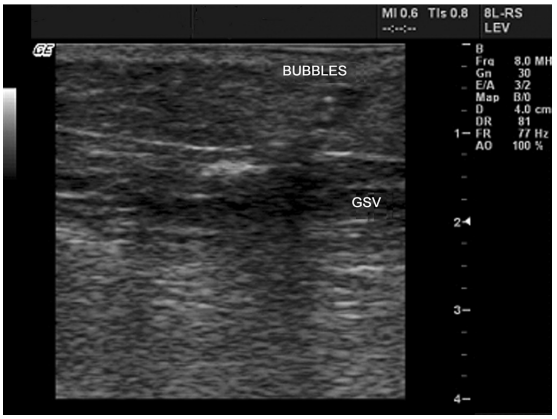


Figure 1. Real-time echo-guided photoablation. Blood vaporizes inside the great saphenous vein (GSV) lumen, with steam bubbles migrating to tributary vein.

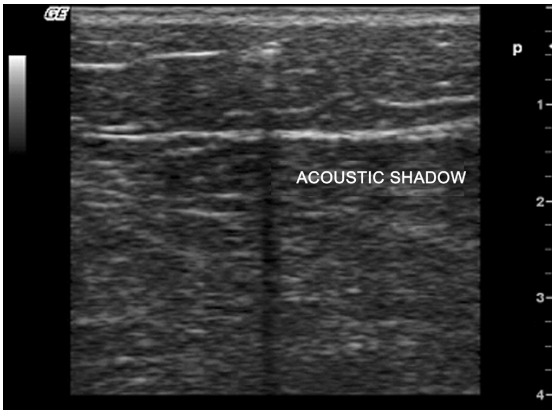


Figure 3. Total occlusion of the great saphenous vein was confirmed in cross-section with hyperechogenic material and acoustic shadow.

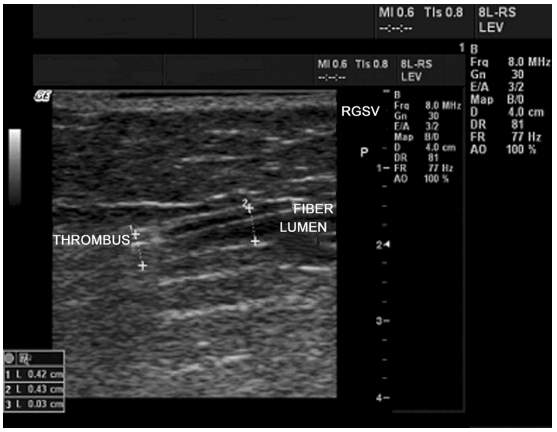


Figure 2. Real-time echo-guided photoablation. Thrombus occludes the target-vein lumen during optical fiber pull-back.

acoustic shadow, and vein incompressibility (Figure 3). If any segments remained patent, the optical fiber was advanced cranially once more for another laser application. The laser power used for each venous segment ranged from 4W to 15W, depending on the lumen diameter (with maximum densities of two times the vessel diameter in the thigh and no more than one and a half times in the leg)[17] and the depth from the skin. Therefore, different energy emissions and optical fiber pull-back speeds were used. Laser pulses were interrupted when a point about five centimeters cranial of the malleolus had been reached. The following additional surgical procedures were performed with patients placed in the Trendelemburg position: phlebectomy and/or ligature of varicose and incompetent perforating-communicating veins via mini-incisions, and closure of the inguinal and perimalleolar incisions using polyamide suture and semi-compressive occlusive dressing with cotton stockinettes and crepe bandage for the full length of the lower limbs. All patients were discharged from hospital on the same day, after recovery from anesthesia, and none of them needed to stay in hospital overnight. The following day, all dressings were removed and the patients were instructed to wash the area, rest for 1 hour and then put on medium compression elastic support stockings (20-30 mm Hg), after which they were to begin walking immediately. The patients were then instructed to wear elastic support stockings daily for 15 days and perform their usual daily activities, but avoid exercising for 15 days. A return appointment was set for 7 days later, when possible adverse effects such as infection of the incision sites, cellulitis, erysipelas, thrombophlebitis, fibrous cord, hyperchromic spots and paraesthesia were recorded and treated. Post-operative control echo-Doppler examinations were conducted after 1, 6 and 12 months and included assessment of the deep venous system to exclude the possibility of venous thrombosis. Remaining tributary veins in the SFJ were sought, and presence or absence of reflux was confirmed using color or spectral mode. Cross-sectional B mode echo-Doppler scanning was used to map the whole GSV to evaluate complete occlusion, which was confirmed when the vein was completely filled with hypoechogenic content that could not be compressed by the transducer and also when no flow was detected in the venous lumen using color mode. When a patent segment was detected, reflux was assessed and mapped to check whether surgical treatment was indicated.

## RESULTS

Table 1 lists the anatomical features of the saphenous veins treated. All 34 of the saphenous veins that underwent endovenous laser therapy were

Table 1. Diameter and length variability of the 34 saphenous veins treated.

| | Variation |
|---|---|
| Diameter in the SFJ (mm) | 4.1-12 |
| Diameter in the knee (mm) | 2.3-11 |
| Diameter in the leg (mm) | 1.7-5.8 |
| Length in the thigh (cm) | 29-40 |
| Length in the leg (cm) | 26-39 |

Table 2. Variability of technical parameters for laser application in the 34 saphenous veins treated.

| | Variation |
|---|---|
| Exposure time in the thigh (s) | 233-932 |
| Exposure time in the leg (s) | 118-736 |
| Energy in the thigh (J) | 1,926-1,188 |
| Energy in the leg (J) | 1,014-5,510 |
| Energy per linear centimeter in the thigh (J/cm) | 52-290 |
| Energy per linear centimeter in the leg (J/cm) | 31-163 |
| Power density in the thigh (J/s) | 7.67-13.35 |
| Power density in the leg (J/s) | 5.40-11.03 |
| Optical fiber pull-back speed in the thigh (mm/s) | 0.42-1.54 |
| Optical fiber pull-back speed in the leg (mm/s) | 0.44-2.14 |

Table 3. Distribution of adverse effects by prevalence in 34 limbs.

| | n | Percent (%) |
|---|---|---|
| Limbs treated | 34 | 100 |
| Hyperpigmentation | 1 | 2.9 |
| Hypoesthesia | 3 | 8.8 |
| Hyperesthesia | 1 | 2.9 |
| Cellulites | 1 | 2.9 |
| Fibrous cord | 1 | 2.9 |
| Deep venous thrombosis | 0 | 0 |
| Infection | 0 | 0 |

completely occluded after the final intraoperative control scan, according to the echo-Doppler parameters adopted. After surgery and recovery from anesthesia, none of the patients complained of bruising or pain requiring prolonged hospitalization. All patients were therefore discharged from hospital on the same day of the procedure and none needed to stay in hospital overnight. Table 2 shows the range of variation in all of the technical parameters obtained after saphenous vein ablation, separately for thighs and legs. Table 3 lists the rates of adverse effects in the 34 limbs treated. Table 4 shows the rates of recanalization after control by echo-Doppler at 1, 6 and 12 months after the procedure. Recanalization without reflux was observed in a short 6-cm segment of one saphenous vein at 1-month follow-up, but this finding was not observed at subsequent follow-ups. At 1-year follow up, no cases of recurrent or persistent varicose veins were observed.

Table 4. Distribution of recanalization in saphenous veins treated, at periodic echo-Doppler follow-ups.

| Control with eco-Doppler examinations | n | Percent (%) |
|---|---|---|
| Treated saphenous veins followed | 34 | 100 |
| Recanalized saphenous veins (after 1 month) | 1 | 2.9 |
| Recanalized saphenous veins (after 6 months) | 0 | 0 |
| Recanalized saphenous veins (after 12 months) | 0 | 0 |

## DISCUSSION

Developments in biotechnology engineering have brought substantial advances in the medical field, with the emergence of new surgical techniques that may be alternatives for or even replace the old ones permanently. Endovascular techniques are capable of offering patients minimally invasive interventions, as is also the case with video surgery, thereby reducing the risks of such procedures.[18] Therefore, based on evidence from investigations conducted by Boné Salat[19] and supported by more recent studies,[20-22] endovenous laser ablation has evolved into a safe and effective alternative for treatment of incompetent GSVs, when compared to conventional surgery (radical phlebectomy). Its major advantage is much faster and more comfortable patient recovery, with an early return to work activities.[23,24] Most papers analyzing endovenous laser treatment have focused on the GSV and/or on the small saphenous vein (SSV). The indications for the procedure are the same as those for the traditional surgical procedure, i.e. SFJ incompetence with venous reflux, except in cases with a history of deep venous thrombosis. Endovenous lasers have been employed in non-hospital settings using perivenous tumescent local anesthesia along the GSV or the SSV. In these settings, neither crossectomy nor ligature of SFJ tributary veins is performed.[6,10,25] Most investigators have used 810, 940 or 980 nm diode laser in continuous or pulsed mode and power density between 6 and 15 W. However, some studies have reported use of other types of endovenous laser, such as Nd:Yag and helium/neon, with longer wavelengths (1,320 and 1,470 nm) and other choices of chromophores and their respective absorbed energy spectra, which enabled use of much lower energy densities and increased the safety of the procedure

even further.[1,20,26,27] Similarly, new radial and tulip fibers have been developed with the aim of providing greater efficacy.[27,28] It was very important to determine the anatomic variability of saphenous veins, in order to demonstrate the highly significant heterogeneity of the lumens in each segment of the vein and of their lengths in thigh and leg (Table 1). Additionally, these data were critical for establishing the best laser power density for the different segments, together with vein-skin distance detected by echo-Doppler. Vein-skin distances were not recorded, because of their great variability, but they were always higher in the thigh than in the leg, due to the presence of a thicker fat pad, usually measuring ≥ 1cm on the thigh. Both diameter and length had a strong influence on the energy released per linear centimeter in thigh and leg segments (Table 2).

There are a very large number of biological variants and physical parameters in the medical literature about endovenous laser application. However, there was previously no method to effectively control the quantity of energy released in the GSV lumen in each segment of the vein.[14,18,21] Several studies reviewed by Corcos et al.,[17,29] in addition to their own findings, have shown that high energy density used for short periods of time generally leads to an increase in blood and tissue vaporization on the inner wall of the vein. In contrast, low energy density released for long periods of time may decrease vaporization and increase tissue coagulation. There is, therefore, an inverse relationship between the fluence and the area of internal surface that undergoes irradiation, which suggests that different vein diameters require variable exposure times for the same energy density to release the same fluence. In their studies, the variations in energy density were less significant than the variations in optical fiber pull-back speed in vein segments with different diameters and surface areas.

According to Corcos et al.,[17,29] the ideal results of the procedure were obtained in vein segments < 10 mm diameter. Reduced thermal damage and less penetration was detected in veins > 10 mm and < 17 mm, although activation of the thrombotic and healing processes was equally satisfactory. The authors therefore inferred that in wider veins a lower degree of wrinkling of the wall should be expected due to less extensive thermal damage in the lumen and a greater massive thrombotic process, with a less satisfactory clinical result. Real-time echo-Doppler-guided endovenous laser application offers several advantages and allows more freedom with regard to several pre-established criteria. In veins with wider segments according to vein-skin distance, power density that was twice the vein diameter was used safely in the thigh; in the leg, power density was calculated as one and a half times the vein diameter; most procedures used 10 to 12 W in the thigh and 6 to 8 W in the leg (Table 2). Optical fiber pull-back speed was controlled using echo-Doppler while the thrombotic process to fully occlude the vein was observed, as stated in the method, proving that it is unnecessary to use mechanical devices or equipment for this purpose. In this study, there was evident variation in the linear endovenous energy density (LEED) released and the greatest increase was found in the thigh segments, where applications exceeded the prescribed LEED of 80 J/cm (Table 2),[17,18,29] confirming that this parameter cannot be kept steady. In certain cases, the optical fiber had to be advanced cranially once more for a supplementary reapplication because of partial thrombosis, which was seen using echo-Doppler. Additionally, the safety margin to identify exteriorization of the optical fiber was optimal, and the fiber could be accurately pulled back into the lumen and repositioned. According to one study in the literature,[17] inability to advance the optical fiber should be used as a parameter to confirm total vein thrombosis and, conversely, if it is possible to push it back, this should be taken as a parameter indicating incomplete thrombosis. In such cases, the study recommends repositioning the optical fiber in the reverse direction for supplementary endovenous laser application in the same segment, with no real-time echo-Doppler control. These maneuvers may be less safe, because perforation may occur and go undetected, and less effective, because it is not possible to control whether a single reapplication is sufficient, especially in wider segments, Most authors[21] prefer to perform endovenous laser treatment in outpatient settings rather than in hospitals. Therefore, perivenous tumescent local anesthesia has to be used to ensure three advantages for the patient: pain reduction; perivenous tissue protection against high temperatures, decreasing the risk of burns; and increased surface area contact between the fiber tip and the vein wall.[6,10,25] The reason participants in this study were given spinal anesthesia in a hospital setting and were admitted for daytime hospitalization using a "day clinic" system was because they were recruited to a study for a doctoral dissertation.[30] The objective was to perform a comparative bilateral histological evaluation of GSV fragment segments collected after SFJ ligation and divided into two groups that were compared with one another: one comprising fragments assessed before laser application and the other comprising fragments assessed after laser application. This is also the reason why this article only describes patients with bilateral

GSV incompetence. Undoubtedly, the treatment with endovenous laser proposed in this study has the disadvantages of requiring hospital admission, spinal anesthesia, and SFJ ligation. However, the patients benefited from phlebectomy of all collateral varicose veins and incompetent perforating veins at the same time, which avoids having to attend several ambulatory sessions.[31] Another benefit from spinal anesthesia is that perivenous tumescent anesthesia precludes clear vein visualization and distorts echographic parameters needed for real-time endovascular laser control. When the present study was conducted, 980nm diode laser was the endovascular laser available in the market. Additionally, the reason for accessing the GSV via the perimalleolar region was that since patients underwent spinal anesthesia we could treat the vein as extensively as possible. However, this decision may have led to higher rates of paresthesia, especially hypoesthesia (Table 3), a situation that could be minimized by obtaining access to the middle third of the leg via puncture, as occurs in most ambulatory settings.[32] In Brazil, the decision to perform a hospital or an ambulatory procedure depends mostly on the patient's profile and the fact that ambulatory procedures are not usually covered by health insurance plans should also be taken into consideration.Other types of endovenous lasers with different active media that produce longer wavelengths have been tested, and some papers have already been published.[1,20,26,27] Their findings suggest that certain specific chromophores and their respective absorption spectra increase efficiency and efficacy but establish new variables. The results of this study, without complications and with a negligible rate of recanalization and adverse effects at 1-year control (Tables 3 and 4), suggest that real time echo-guided ablation without perivenous tumescence is a safe and effective procedure that offers standardization for endovenous laser application and better control of those variables that are already known and of other variables that may emerge as a result of inexorable technological advances.

## CONCLUSIONS

In our series, ablation using continuous mode 980 nm endovenous laser without perivenous tumescence resulted in photocoagulation with effective occlusion of the GSV under real-time echo-Doppler guidance in a sufficiently controlled way, regardless of vessel diameter.

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Correspondence
Ricardo José Gaspar
Rua Itapeva, 240, CJ 1407/ 1408, Bela Vista
CEP 01332-000 - São Paulo (SP), Brazil
Tel.: +55 (11) 3266-8959 / Fax: +55 (11) 3262-0336
E-mail: ricardojgaspar@terra.com.br

Author information
RJG - MD, PhD, vascular and endovascular surgeon, Head of the Vascular and Endovascular Surgery Service, Hospital São Camilo Pompéia, São Paulo, SP, Brazil. Director, Instituto Vascular Ricardo Gaspar.
ANC - Vascular surgeon, Sociedade Brasileira de Angiologia e Cirurgia Vascular.
MJS - MD, PhD, Associate Professor at the Department of Histology and Structural Biology, Universidade Federal de São Paulo-Escola Paulista de Medicina (UNIFESP-EPM).
HP - MD, PhD Associate Professor at the Department of Surgery, Universidade Federal de São Paulo, Escola Paulista de Medicina (UNIFESP-EPM).

Author contributions
Conception and design: RJG, HP
Analysis and interpretation: RJG, MJS
Data collection: RJG, ANC
Writing the article: RJG
Critical revision of the article: HP
Final approval of the article*: RJG, ANC, MJS, HP
Statistical analysis: RJG, MJS, RJG
Overall responsibility: RJG

*All authors should have read and approved of the final version of the article submitted to J Vasc Bras.