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Risk factors associated with recanalization of incompetent saphenous veins treated with radiofrequency ablation catheter

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KEYWORDS
Saphenous vein;
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Abstract
Purpose: The purpose of this study was to determine the occlusion rate of incompetent great saphenous veins (GSVs) and small saphenous veins (SSVs) treated with radiofrequency ablation (RFA) and individualize variables associated with recanalization.
Materials and methods: A retrospective review of 311 veins (256 GSVs and 55 SSVs) in 211 patients [177 women, 34 men; mean age, 45 years ± 12 (SD) (range: 18—75 years)] with incompetent GSVs and/or SSVs who were treated using new-generation RFA catheters was performed. The clinical results, occlusion rates, and variables associated with recanalization for the incompetent GSVs and SSVs were analyzed.
Results: No major complications were observed in the study population. Ten months after RFA, the occlusion rate was 89% (227/256) for GSVs and 91% (50/55) for SSVs. An increased pre-procedure diameter of the incompetent GSVs was associated with a higher rate of recanalization (OR: 0.825; 95% CI: 0.715—0.952) ($P < 0.05$). No significant differences in age, gender, and side of treated veins were found between patients with recanalization of treated veins and those without recanalization.
Conclusion: Our results show that pre-procedure diameter of the GSV is the single risk factor for recanalization after RFA.

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Varicose veins affect almost 25% of Western adults [1]. Until recently, the preferred treatment has been surgery involving high ligation and stripping of the saphenous veins [2—4]. However, substantial morbidity and inconveniences have been reported after surgery [2,5]. In the last decade, alternative minimally invasive treatments, such as endovenous thermal ablation of the saphenous veins using endovenous laser ablation (EVLA), radiofrequency ablation (RFA), or mechanochemical ablation (MOCA), have been introduced [2,6—10].

Endovenous techniques have been recommended for the treatment of saphenous incompetence by the Society for Vascular Surgery and the American Venous Forum because they are safer, more effective, require a shorter recovery time, involve less pain, and yield less morbidity than open surgery [4]. Furthermore, the National Institute for Health and Care Excellence in the United Kingdom has recommended endothermal ablation (RFA or EVLA) as the first-line treatment for saphenous incompetence, followed by ultrasound-guided foam sclerotherapy when endothermal ablation is unsuitable, with surgery being the last option when foam sclerotherapy is unsuitable [11].

Whereas the occlusion rates of RFA reported in the literature are often > 90%, the factors that could affect post-procedure recanalization have been rarely reported [12—18]. To date only two English-language studies are available regarding factors associated with recanalization for saphenous veins treated with the new-generation RFA device using the ClosureFAST™ catheter (Covidien, Mansfield MA, USA). Calcagno et al. evaluated the great saphenous vein (GSV) and the small saphenous vein (SSV) [13]. These researchers reported that vein diameters > 12 mm had no effect on closure rate with the ClosureFAST™ catheter for the GSV [13].

The purpose of this retrospective study was to determine the occlusion rates of incompetent GSVs and SSVs treated with RFA and individualize the factors associated with recanalization of incompetent saphenous veins after RFA.

Material and methods

Patients

A retrospective study was conducted on a cohort of 211 consecutive patients who underwent saphenous vein thermal ablation via endovenous RFA between June 2013 and July 2014. There were 177 women and 34 men, with a mean age of 45 years ± 12 [standard deviation (SD)], (range: 18—75 years). Patient demographics and clinical data are reported in Table 1.

Demographic, procedural, and follow-up data were obtained from the hospital charts. All patients had cosmetic or clinical complaints of varicose veins with documented saphenous vein incompetence. Patients older than 18 year-old with symptomatic GSV/SSV incompetence were enrolled in the study. Patients with any of the following criteria were excluded from the study: allergy to the sclerosing agent, thrombus in the vein of interest or deep vein thrombosis, deep venous reflux, previous surgical or nonsurgical SV treatment, significant peripheral arterial disease, pulmonary embolism, pregnancy, or known malignancy. The study protocol was approved by the local ethics committee.

Table 1 Characteristics of the study population.

	Number
Total number of limbs/total number of veins	276/311
Number of patients	211
Gender	
Women	177 (84%)
Men	34 (16%)
Age (years)	45 ± 12 (SD) [18—75]
Clinical presentation	
C 1—3[a]	264/311 (85%)
C 4—6[a]	47/311 (15%)

[a] C corresponds to the ''C'' component of CEAP (Clinical, Etiologic, Anatomic, Pathophysiologic).

Pre-procedure evaluation

Baseline examinations, including color Doppler ultrasonography (CDUS) and a brief, focused physical examination, were performed at the outpatient clinic. Insufficiency of the truncal veins was evaluated using US (Antares; Siemens, Erlangen, Germany) with a linear multifrequency transducer (9.4- or 13.5-MHz), and the CDUS exams were performed in the standing position. The superficial (GSVs, SSVs, and other truncal) veins and deep (femoral and popliteal) veins were evaluated in detail for the presence of insufficiency or previous venous thrombosis. The diameters of GSVs and SSVs were measured 3—5 cm below the saphenofemoral junction (SFJ) or the saphenopopliteal junction (SPJ), in the standing position. Reflux with a duration of > 0.5 s in the superficial veins or > 1 s in the deep veins while squeezing and releasing (or performing the Valsalva maneuver) was considered to be pathological. In addition, a venous map of the related leg was obtained via CDUS. The goal of the CDUS evaluation was to map out all the incompetent venous pathways responsible for the patient's condition. Such a map is necessary to determine the best combination of treatments appropriate for eliminating the abnormal refluxing veins while preserving the normal veins.

Patients on antiplatelet therapy (e.g., acetylsalicylic acid, clopidogrel) and chronic anticoagulation therapy (e.g., warfarin) were instructed to continue taking the medication through the perioperative period.

Procedure

All procedures were performed in the interventional radiology treatment room. Legs were prepared in a sterile fashion before the procedure. The patient was then placed supine or prone (depending on the saphenous veins treated) on the table, allowing full access to the treated segments. All procedures were performed under local anesthesia supplemented with intravenous sedation and analgesia using dormicum and fentanyl citrate. Most commonly, the