Eur J Vasc Endovasc Surg (2018) ■, 1–7

Pre-operative Color Doppler Ultrasonography Predicts Endovenous Heat Induced Thrombosis after Endovenous Radiofrequency Ablation☆

Chiara Lomazzi [a,*], Viviana Grassi [a], Sara Segreti [a], Marta Cova [a], Daniele Bissacco [a], Ruth L. Bush [b], Santi Trimarchi [a]

[a] Vascular Surgery II and Thoracic Aortic Research Centre, IRCCS Policlinico San Donato Teaching Hospital, University of Milan School of Medicine, Milan, Italy
[b] Baylor College of Medicine and the Centre for Innovations in Quality, Effectiveness, and Safety, Houston, TX, USA

WHAT THIS PAPER ADDS

This cohort study offers a specific analysis of endovenous heat induced thrombosis (EHIT), occurring after radiofrequency ablation (RFA) of the great and small saphenous veins. In particular, it was found that the distance between the epigastric vein and the sapheno-femoral junction (dEV–SFJ) introduced a novel measurement variable to be included during the pre-operative color Doppler ultrasound of the great saphenous vein (GSV). In this study, this variable reliably predicted the occurrence of EHIT. This new measurement will assist vein surgeons in identifying which patients may be at higher risk of EHIT after RFA of the GSV. Accordingly, these higher risk patients would benefit from meticulous follow up after their ablation procedure to assess for EHIT.

Objectives: The aim was to identify pre-operative color Doppler ultrasound (CDUS) variables predictive of post-operative endovenous heat induced thrombosis (EHIT) after radiofrequency ablation (RFA) of the saphenous veins.

Design: This was a single centre, observational study with retrospective analysis of consecutive patients treated from December 2010 to February 2017.

Materials and methods: Pre-operatively, the diameter of the sapheno-femoral junction (dSFJ), distance between epigastric vein and SFJ (dEV–SFJ), maximum great saphenous vein (GSV) diameter (mdGSV), diameter of the saphenous–popliteal junction (dSPJ), and mean small saphenous vein (SSV) diameter (adSSV) were measured. All patients received low molecular weight heparin (LWMH) at a prophylactic dose for a week. Post-operatively, CDUS was performed after 72 h, 1 week, and 3 months.

Results: Venous interventions on 512 patients were performed: 449 (87.7%) underwent RFA of the GSV (Group 1), and 63 (12.3%) of the SSV (Group 2). At Day 3 post-operatively, CDUS documented 100% complete closure of the treated saphenous vein segment. Overall, 40 (7.8%) cases of post-operative EHIT were identified: 29 in Group 1, and 11 in Group 2 (6.4% vs. 17.5%, $p = .005$). Deep venous thrombosis or pulmonary embolism did not occur in either group. At the 1 month follow up, all cases of EHIT regressed. In Group 1, on multivariate analysis, dEV–SFJ (OR, 1.13, $p = .036$; 95% CI 1.01–1.27) was the only statistically significant predictor for EHIT. A dEV–SFJ distance of 4.5 mm yielded an 84% of sensitivity for EHIT prediction with a 72.4% positive predictive value. In Group 2, univariate analysis did not identify independent risk factors for EHIT occurrence.

Conclusions: EHIT was higher than previously reported. The dEV–SFJ was the most significant predictor for EHIT in the GSV group. A greater distance between the tip of the radiofrequency catheter and the SFJ may decrease the risk of developing this complication.

Article history: Received 2 July 2017, Accepted 19 February 2018, Available online XXX

Keywords: Endovenous heat induced thrombosis, Radiofrequency ablation

INTRODUCTION

In the past 15 years, endovenous ablation techniques have drastically revolutionised the treatment of chronic superficial venous insufficiency, providing a minimally invasive approach with excellent post-operative outcomes, patient satisfaction, and quality of life.[1–6] New techniques bring new types of complications: endovenous heat induced thrombosis (EHIT), which is defined as the extension of thrombosis at the sapheno-femoral junction (SFJ), is a recognised unique complication secondary to radiofrequency

☆ Presented at the Twenty-eighth Annual Meeting of the American Venous Forum, Orlando, FL, February 24–26, 2016.

* Corresponding author. Vascular Surgery II and Thoracic Aortic Research Centre, IRCCS Policlinico San Donato Teaching Hospital, University of Milan School of Medicine, Piazza "E. Malan" 2, 20097 San Donato Milanese, Milan, Italy.

E-mail address: doc.chiara@libero.it (Chiara Lomazzi).

https://doi.org/10.1016/j.ejvs.2018.02.025

Please cite this article in press as: Lomazzi C, et al., Pre-operative Color Doppler Ultrasonography Predicts Endovenous Heat Induced Thrombosis after Endovenous Radiofrequency Ablation, European Journal of Vascular and Endovascular Surgery (2018), https://doi.org/10.1016/j.ejvs.2018.02.025

ablation (RFA).[2,3] Both endothelial modifications and local injury triggered by endovenous thermal ablation may generate the formation of thrombosis beyond the target treatment area, potentially leading to deep venous thrombosis (DVT) and/or pulmonary embolism (PE).[6–8] Although there are studies that describe EHIT management and treatment, there are few data regarding the risk factors of this potentially dangerous complication.[9–12] The aim of this study was to evaluate both clinical and color Doppler ultrasound (CDUS) parameters to identify potential risk factors associated with EHIT after RFA of either the great saphenous vein (GSV), or the small saphenous vein (SSV).

MATERIALS AND METHODS

Patient cohorts

This was a single centre, observational study. The patients were maintained in a prospectively created database which was analyzed retrospectively. It included consecutive patients treated with RFA for chronic superficial venous insufficiency. Patients treated from December 2010 to February 2017 were included; for the final analysis, the end of study was March 1, 2017. During the study period, venous interventions were performed on 512 patients: 449 (87.7%) underwent RFA of the GSV (Group 1), and 63 (12.3%) of the SSV (Group 2). All patients were identified from a computerised database registry that remained consistent over the study period. Information about demographics, comorbidities, medical and surgical history, operative details, and post-operative events during the hospital stay and follow up were all registered.

Pre-operative venous assessment

All patients considered for endovenous thermal ablation underwent clinical and CDUS evaluation. Pre- and post-operative ultrasound assessments were performed by vascular surgeons who were certified in the examination of the deep and superficial venous circulation, with more than 10 years experience with CDUS examinations for both venous and arterial disease detection and follow up. A set protocol for the CDUS examination was used: it was consistent for all assessments with the same scanner (MyLab 50; Esaote, Genova, Italy). The technique of venous duplex scanning complies with the technique accepted by the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF).[3] Briefly, pulsed wave Doppler with a 4–7 MHz linear array transducer was used. Evaluation with duplex scanning was performed with the patient upright, started below the inguinal ligament, and the veins were examined at 3–5 cm intervals. In every examination both the deep and superficial systems, as well as tributaries/accessories and perforating veins were evaluated. The following features were evaluated: visibility, compressibility, venous flow, measurement of the duration of reflux, and augmentation. Flow characteristics and waveform patterns were evaluated using respiratory variations (e.g., Valsalva manoeuvre, or manual compression of the limb distal to the point of examination). The cut off value for abnormally reversed venous flow (reflux) in the saphenous, tibial, and deep femoral veins was 0.5 s. Pre-operatively, the following parameters during CDUS of the GSV were collected:

- diameter of the sapheno-femoral junction (dSFJ);
- distance between epigastric vein and SFJ (dEV–SFJ);
- maximum GSV diameter (mdGSV);
- mean GSV diameter (adGSV) obtained from the mean of three measurements taken at the proximal, middle, and distal thirds of the thigh.

For the SSV, the following parameters were collected during CDUS:

- diameter of the sapheno–popliteal junction (dSPJ);
- maximum SSV diameter (mdSSV).

Indication for operative intervention with RFA were as follows:

- classification 2–6, accordingly to the Clinical, Etiology, Anatomy and Pathophysiology (CEAP) grading system[2];
- venous incompetence with reflux time $>$ 0.5 s over a segment length of at least 10 cm (both GSV and SSV);
- failure of conservative medical therapy (e.g., persistence or worsening of venous symptoms despite lifestyle changes including exercise, leg elevation, management of weight and diet, the use of compression hosiery, and venotonic agents).

Exclusion criteria for RFA for chronic superficial venous insufficiency included:

- deep or superficial vein thrombosis of the lower limbs, or previous ones with endoluminal thrombotic remnant;
- pregnancy.

The superficial vein to be ablated was mapped and marked on the skin at the end of examination. Informed consent was signed by each patient; approval for the study was obtained from the local Institutional Review Board, accordingly to the National Policy in the matter of the Privacy Act on retrospective analysis of anonymised data. Also, each patient received adjunctive treatment in the form of elastic compression stockings, and venotonic agents, or periodic evaluation with complex wound dressings in case of ulcers.[2]

Operative management

All procedures were performed by one of four trained vascular surgeons (C.L., V.G., S.S., M.C.) in the operating theatre in compliance with the national health system rules. A standard protocol was used for tumescent anaesthesia (lidocaine 2%, 20 mL; sodium bicarbonate 8.4%, 5 mL), made easier with the use of an infiltration pump (roller pump), and mild sedation (intravenous remifentanyl 0.02 μg/kg at 0.75 μg/kg/min). Tumescent anesthesia was

Please cite this article in press as: Lomazzi C, et al., Pre-operative Color Doppler Ultrasonography Predicts Endovenous Heat Induced Thrombosis after Endovenous Radiofrequency Ablation, European Journal of Vascular and Endovascular Surgery (2018), https://doi.org/10.1016/j.ejvs.2018.02.025