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Success rate and factors predictive of redo radiofrequency ablation of perforator veins

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ABSTRACT

Objective: Radiofrequency ablation (RFA) is increasingly being employed for treatment of perforator vein insufficiency and venous ulcer healing. Previous studies have shown a closure rate of 60% to 80% in incompetent perforator veins (IPVs) with RFA. The purpose of the study was to determine the utility of a redo RFA for symptomatic recanalized perforators and to predict factors associated with recanalization.

Methods: A retrospective analysis of 642 procedures in 256 patients with venous insufficiency due to IPVs from 2009 to 2015 was conducted. All 642 procedures were performed using RFA in patients who failed to respond to initial conservative management. Postoperative duplex ultrasound scans were performed within 3 to 7 days. Successful obliteration was defined as lack of color flow on postoperative scan. Recanalization was defined as presence of reflux on duplex ultrasound in symptomatic patients in the targeted vessel at follow-up. Follow-ups were conducted every 3 months in the first year and every 6 months thereafter.

Results: Among the 642 procedures, redo ablation was performed in 52 IPVs (29 patients, 37 extremities) including 14 women, with mean age of 65 years (standard deviation [SD], ±15 years). The Clinical, Etiology, Anatomy, and Pathophysiology class of the patients was as follows: C1, 0; C2, 0; C3, 3; C4a, 11; C4b, 7; C5, 0; and C6, 16. The distribution of the targeted IPVs included the calf (40) and ankle (12). The mean maximum diameter of the targeted veins was 4.6 mm (SD, ±1.1 mm). The initial technical success rate was 64.9%. Redo procedures had an early closure rate of 67.3%. At follow-up after a mean duration of 24 months (SD, ±16.8 months), the closure rate was 65.38%. No clinical correlation was found between successful obliteration in the redo procedure and age ($P = .54$), sex ($P = .14$), clinical class ($P = .82$), laterality ($P = .84$), or location of the vein ($P = .54$). When data were compared to predict factors associated with a redo procedure, IPVs located in mid and distal calf areas tended to recanalize more compared with the ankle ($P = .04$). Temperature of the radiofrequency stylet also showed a linear association, with patients treated at 85°C having higher probability of recanalization compared with patients treated at 90°C and 95°C ($P = .01$).

Conclusions: The rates of successful closure for IPVs on initial and redo procedures are comparable. The data validate the utility of performing redo perforator ablations and suggest that temperature of the radiofrequency stylet and location of the IPVs may be predictive of a successful outcome or recanalization. (J Vasc Surg: Venous and Lym Dis 2018;■:1-5.)

Keywords: Perforator veins; Incompetent perforator veins; IPVs; Radiofrequency ablation; Venous ulcer healing; Redo ablation

Incompetent perforator veins (IPVs) have been known for their contribution to chronic venous insufficiency (CVI) along with the saphenous veins. Previous literature has discussed the role and impact of management of perforator vein reflux on ulcer healing.[1-3] The Society for Vascular Surgery and American Venous Forum guidelines currently recommend the treatment of IPVs in patients with Clinical, Etiology, Anatomy, and Pathophysiology (CEAP) class C4 to C6 with duplex ultrasound confirmation of axial reflux >500 milliseconds and vein diameter >3.5 mm after failed conservative management.[4] Currently, available treatment options for perforator vein closure include open perforator surgical repair, subfascial endoscopic perforator surgery (SEPS), and the more popular minimally invasive techniques of endovenous thermal ablation (ETA) and ultrasound-guided foam sclerotherapy (UGFS).

ETA of perforator veins has been reported to have a technical success rate of 60% to 80%.[1,5-8] In a recently published review article by Dillavou et al[9] that performed a meta-analysis comparing the current treatment options, ETA using radiofrequency ablation (RFA) or endovenous laser ablation (EVLA) was reported to have a higher successful closure rate compared with UGFS,

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especially with redo ablation procedures in symptomatic recanalized veins. The objective of the study was thus to determine the utility of performing a redo ablation to treat recanalized IPVs and to predict factors associated with recanalization.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective single-center cohort study
- **Take Home Message:** Technical success of redo radiofrequency ablations (RFAs) of 52 incompetent perforating veins in 29 patients was 67.3%, with a closure rate of 65.4% at 24 months, unrelated to age, sex, laterality, presenting clinical class, or vein location.
- **Recommendation:** Redo RFA should be considered for recurrent symptomatic incompetent perforator veins after failure of initial RFA treatment of incompetent perforator veins.

METHODS

A retrospective analysis of 642 RFA procedures in 256 patients with CVI due to IPVs from 2009 to 2015 was conducted. All procedures were performed by three vascular surgeons in a single outpatient vascular office, with assistance from registered vascular technicians. Patients with symptomatic veins or signs of venous insufficiency were initially treated with conservative management in the form of leg elevation and grade II (20-30 mm Hg) knee-high compression stockings for a minimum of 3 months consecutively. All patients were offered venous ablation procedures for other incompetent superficial refluxing veins including the great, small, and accessory saphenous veins. If symptoms still failed to improve, RFA of IPVs was offered. Incompetence of perforator veins was confirmed in symptomatic patients by duplex ultrasound visualization of reflux (>350 milliseconds) or maximum vein diameter of >2.5 mm of the targeted perforator vein. The vein and CEAP criteria we used in the study differ from the current Society for Vascular Surgery and American Venous Forum guidelines as the data collected include patients since 2009, which was before the guidelines were published. Our current approach for patients with IPV was changed in accordance with the guidelines after their publication.[4] The clinical severity of venous insufficiency in each patient was determined by the CEAP classification for CVI as defined by the American Venous Forum.[10]

The radiofrequency stylet (RFS) was used for thermal ablation in all 642 procedures. We used the ClosureFast (Medtronic, Dublin, Ireland) RFS catheter. The vein was marked by duplex ultrasound, and a stab incision was made over the vessel. The catheter was then advanced under ultrasound guidance into the perforator vein to a position above the fascia. The vein was treated using temperature and impedance (<200 Ω) to monitor the procedure. Postoperative duplex ultrasound scans were performed after 3 to 7 days. Successful obliteration was defined as lack of color flow on postoperative scan. Recanalization was defined as presence of reflux in the targeted perforator vein on duplex ultrasound on subsequent follow-up visits. Follow-ups were conducted every 3 months in the first year and every 6 months thereafter. Longitudinal follow-up was performed by using anatomic landmarks to identify the targeted perforator veins as accurately as possible. The clinical indication for performing a redo procedure was recurrence or persistence of symptoms (swelling, healed ulcers, and recurrent ulcer) along with positive ultrasound characteristics with a pathologic perforator. The redo procedure was carried out in a similar routine manner in symptomatic patients as described before.[11] No other adjunct sclerotherapy procedures were performed otherwise.

Data collection included age, sex, laterality, vein location, vein diameter, and CEAP class. Statistical analysis was performed with the χ^2 test, Fisher exact test, independent samples *t*-test, and logistic regression using generalized estimating equations to explore the relationship between the variables and result using the SPSS software (version 22; IBM Corp, Armonk, NY).

The data collection and interpretation conformed to the principles set by the Declaration of Helsinki. The Institutional Review Board of Vascular Institute of New York granted a waiver for informed consent as the study is of minimal risk and the data are blinded and retrospective.

RESULTS

Among the 642 ablation procedures performed during the course of 6 years, 416 procedures (175 patients) with successful closure were excluded from this study. Recanalized perforator veins were noted in the remaining 226 procedures (80 patients). Among them, 52 patients were clinically asymptomatic and hence not treated. Redo ablation was performed in 52 symptomatic IPVs (29 patients, 37 lower extremities). The mean age of the study population was 65 years (standard deviation [SD], ±15 years); 14 were women. The CEAP classes of the patients are summarized in the Table. The targeted IPVs were distributed in the calf (40) and ankle (12). The mean maximum diameter of the targeted IPVs after recanalization was 4.6 mm (SD, ±1.1 mm). The initial technical success rate for all 642 procedures was 64.9%. The mean time to recanalization was 368 days (SD, ±257 days). A redo procedure performed in the 52 recanalized perforator veins had an early closure rate of 67.3%. At follow-up after a mean duration of 24 months (SD, ±16.8 months), the closure rate was 65.38%. No complications (burns, skin necrosis, wound infection, artery or nerve injury) were observed. The rate of deep venous