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Factors Associated with Recanalization and Reintervention Following Below Knee Polidocanol Endovenous Microfoam Ablation for Great Saphenous and Small Saphenous Veins

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Factors associated with recanalization and reintervention following below knee polidocanol endovenous microfoam ablation for great saphenous and small saphenous veins

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ABSTRACT

Background: Polidocanol endovenous microfoam (PEM) has been used to treat lower extremity venous reflux for almost one decade with specific advantages for below knee (BK) truncal veins where thermal ablation poses a risk of injury to adjacent nerves. The current literature of the BK segment often examines short-term outcomes with modest sample sizes. We aim to identify factors associated with recanalization and reintervention in this subset of patients.

Methods: We performed a retrospective study of a prospectively maintained database of patients from a single institution who underwent 1% PEM ablation for BK great saphenous vein (GSV) and small saphenous vein (SSV) reflux. Patients underwent duplex ultrasound (DU) within 7 days after injection, every 3 to 6 months for 1 year, and every 6 to 12 months thereafter. Patients with symptomatic recanalization underwent reintervention. The 26 patients lost to follow-up without DU after ablation were excluded. The factors associated with recanalization and reintervention were examined by multivariate and nonparametric analyses.

Results: Between March 2018 and July 2023, 411 patients (166 male, 245 female) with 573 treated limbs (284 right, 289 left) met the study criteria. Of the 573 included limbs, 457 (79.8%) had undergone prior above knee saphenous ablations. A total of 554 BK GSV and 42 SSV ablations were performed. The most recent DU was performed at a mean of 231 ± 329 days. The overall recanalization rate was 10.6% (55 GSVs and 8 SSVs) at a mean follow-up of 104 ± 180 days. Comparing the closed and recanalized veins, we found no significant difference in age ($P = .90$), treated laterality ($P = .14$), patient body mass index ($P = .59$), preprocedural CEAP (clinical-etiology-anatomy-pathophysiology) score ($P = .79$), recanalization rate in GSVs vs SSVs ($P = .06$), or administered PEM volume ($P = .24$). The recanalized veins had significantly larger preprocedural diameters than the veins that remained closed (recanalized, 4.9 mm; closed, 4.3 mm; $P = .001$). Men had higher incidence of recanalization than women (men, 14.2%; women, 8%; $P = .015$). Anticoagulation use was associated with recanalization (odds ratio, 1.96; 95% confidence interval, 1.1-3.6; $P = .03$). Early recanalization at the first DU accounted for 31 failures (49.2%) and had a significantly lower administered PEM volume compared with later recanalization (early, 4 mL; late, 5 mL; $P = .025$). There were no significant differences between the 33 recanalized patients requiring reintervention (52.4%) and the 30 who did not. Twenty-four reinterventions were performed with PEM, 100% of which remained closed at a median of 160 days (interquartile range, 257 days).

Conclusions: PEM is successful for the treatment of BK GSV and SSV reflux with a closure rate of 89% at a mean of 231 days and shows promise as salvage therapy. Most cases of recanalization were noted in the early postprocedure period and were associated with a lower PEM volume. A larger vein diameter, male sex, and anticoagulation use are associated with higher rates of recanalization. (J Vasc Surg Venous Lymphat Disord 2024;12:101886.)

Keywords: Microfoam; Polidocanol; Recanalization; Reflux; Truncal

Refractory lower extremity venous reflux is recognized as a multilevel disease process with specific directed treatments for the above knee (AK) and below knee (BK) great saphenous vein (GSV). AK-GSV reflux is conventionally treated with minimally invasive thermal ablation, which is the favored modality due to the shorter

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return to normal activity compared with surgical vein stripping.[1] However, approximately one half of patients continue to have symptomatic BK-GSV reflux after adequate AK-GSV reflux treatment.[2-4] Since the Food and Drug Administration (FDA) approval of commercially available 1% polidocanol endovenous microfoam (PEM; Varithena; Boston Scientific) in 2014, the proprietary microfoam sclerotherapy preparation method has been a favored nonthermal, nontumescent antireflux therapy for BK-GSV, with off-label use in the small saphenous vein (SSV) due to the consistent effectiveness in symptom improvement and apparent avoidance of rare adverse neurologic outcomes reported with physician-compounded foam sclerotherapy.[5-8] Microfoam ablation also avoids the risk of injury to intimately adjacent nerves and the pain associated with surgical and thermal techniques.[9,10]

Surveillance of vein closure using duplex ultrasound (DU) has served as an approximate metric for ablation success, along with the established metrics for subjective improvement (VVSymQ instrument) and venous ulcer healing.[11-13] Several modestly sized prospective and observational PEM outcome studies after FDA approval have demonstrated high short- and mid-term closure rates on DU that parallels the effective symptom relief outcomes reported in the initial VANISH (efficacy and safety study of polidocanol injectable foam for the treatment of saphenofemoral junction incompetence) trials.[5-7,12-15] However, substantial mid- to long-term closure outcomes and characterization of anatomic failure in the BK saphenous segment remain scarce. In this study, we aimed to identify patient and treatment demographics associated with recanalization and the need for reintervention in the BK-GSV and SSV after 1% PEM ablation.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective analysis of a prospectively maintained patient database
- **Key Findings:** A total of 596 ablations were performed with 1% polidocanol endovenous microfoam in 411 patients for symptomatic below knee saphenous vein reflux. Vein recanalization was found in 10.6% of patients on follow-up duplex ultrasound at a mean of 231 days after ablation. Of the recanalized patients, 52.4% required reintervention.
- **Take Home Message:** Recanalization after ablation is associated with male sex, larger vein size, and anticoagulation use. The predictive factors of symptomatic and asymptomatic recanalization remain unclear.

METHODS

We performed a retrospective study of a prospectively maintained database of patients treated at the Vascular Institute of New York (Brooklyn, NY). The institutional review board waived the requirement for patient informed consent and publication consent due to the retrospective nature of the study. All collected patient data were de-identified to provide patient data confidentiality and compliance with the Declaration of Helsinki. In our practice, venous reflux patients receive a trial of 3 months of compression stocking use before invasive intervention. Patients with continued symptoms of heaviness, aching, swelling, throbbing, itching (HASTI) or venous ulcers were selected for ablation. Microfoam ablation is our preferred treatment modality for BK venous reflux. Patients with persistent symptoms 3 months after endovenous ablation would be considered for phlebectomy or foam sclerotherapy of residual varicose veins. All the patients in this study underwent 1% PEM ablation of the BK-GSV or SSV. The patients were aged ≥18 years with and without a prior AK antireflux procedure. All but three patients with prior AK antireflux interventions had had their prior AK ablations performed at our institution with thermal techniques.

All BK-GSV and SSV ablations were performed by three operators with direct injection of 1% PEM under ultrasound guidance with a 25-gauge needle. Local or tumescent anesthesia was not routinely required, because most ablations were performed with a single percutaneous needle stick. The FDA-labeled instructions for use, including preprocedural ultrasound vein mapping, identification of perforators, Trendelenburg positioning, extrinsic compression of the distal vein target during injection, limiting the administered microfoam volume to <15 mL per treatment session, and postprocedural compression wrapping, were implemented with each treatment session.[16] The volume of PEM administered was determined by direct visualization on DU to ensure complete filling of the target vein. Consistent adherence to these adjunctive measures minimizes the incidence of neurologic and venous thromboembolic (VTE) events.[17] All treated patients underwent immediate postprocedure DU to survey treatment-induced vasospasm and cessation of endovenous flow in the target segment and to screen for adverse VTE events. No activity restrictions were imposed after ablation. DU was repeated within 7 days, every 3 to 6 months for 1 year after intervention, and every 6 to 12 months thereafter. Patients experiencing recurrence of reflux symptoms were evaluated by DU sooner. A patient was considered to have recanalization if patency, endovenous flow, or reflux (>500 ms) was observed in the previously treated segment on DU. Patients with persistent HASTI symptoms or recurrent or persistent ulcers and found to have recanalization of the treated vein underwent reintervention and were selected for additional analysis. A total of 26 patients who did not have documented DU after ablation or who were lost to follow-up were excluded from this study.

Table I. Characteristics of study cohorts stratified by ablation

Characteristic	All ablations (n = 597)	Ablation outcome		
		Closed (n = 533)	Recanalized (n = 63)	*P* value
Age, years	68 ± 14	68 ± 14	68 ± 12	.90
Sex				.015
Male	246 (41.3)	211 (35.4)	28 (4.7)	
Female	350 (58.7)	322 (54)	35 (5.9)	
BMI, kg/m^2	31 (8.4)	32.3 (8.2)	32.8 (10)	.59
Treated laterality				.14
Right	297 (49.6)	260 (43.6)	37 (6.2)	
Left	299 (50.4)	273 (45.8)	26 (4.4)	
Clinical severity score				.79
2	18 (3)	12 (2.5)	3 (0.5)	
3	257 (44.5)	235 (39.5)	30 (5)	
4	196 (33.4)	181 (30.4)	18 (3)	
5	3 (0.5)	3 (0.5)	0 (0)	
6	99 (18.6)	99 (16.6)	12 (2)	
Vein diameter, mm	4.3 ± 1.2	4.3 ± 1.2	4.9 ± 1.3	.001
Truncal vein type				.06
GSV	554 (93)	499 (83.7)	55 (9.2)	
SSV	42 (7)	34 (5.7)	8 (1.3)	
Microfoam volume, cm^3	4.3 ± 1.1	4.3 ± 1.1	4.6 ± 1.4	.24
Antithrombotic medication				
None	287 (48.2)	265 (44.4)	22 (3.7)	
Anticoagulation	95 (15.9)	79 (13.3)	16 (2.7)	.03
Antiplatelet	214 (35.9)	189 (31.7)	25 (4.2)	.51

BMI, Body mass index; *GSV,* great saphenous vein; *SSV,* small saphenous vein.
Data presented as mean ± standard deviation, number (%), or median (interquartile range).

The collected demographics included patient age, sex, body mass index (BMI), preprocedural clinical score using the CEAP (clinical-etiology-anatomy-pathophysiology) classification, maximum vein diameter before ablation, PEM volume administered, concurrent use of antithrombotic medications, and interval to the last documented DU after treatment. The outcomes of interest were the incidence of adverse VTE events, recanalization of treated BK truncal vein on DU, time to recanalization on DU, and need for reintervention after recanalization. Interoperator variability was not examined, because the patients were managed in a first-available provider, first-to-treat manner. Patient age and maximum vein diameter were analyzed using a two-tailed *t* test. The BMI and PEM volume were analyzed using the Mann-Whitney *U* test. CEAP score, patient sex, use of antithrombosis, laterality, and GSV vs SSV comparison were performed using χ^2 testing. Multivariable linear and logistic regression analysis was performed on significant factors associated with recurrence. Recanalization was regarded as a time to event variable for Cox proportional hazard analysis. All statistical calculations were performed using SPSS, version 29.0 (IBM Corp).

RESULTS

Between March 2018 and July 2023, 596 ablations (554 BK-GSV and 42 SSV) in 573 treated limbs (284 right, 289 left) were performed in 411 patients (166 male, 245 female), with a mean age of 68 ± 14 years (Table I). The treated patients represented a broad range of body sizes (median BMI, 31 kg/m^2; interquartile range [IQR], 8.4 kg/m^2) and clinical reflux severity (C2, n = 18; C3, n = 257; C4, n = 196; C5, n = 3; C6, n = 99). The target veins had a mean diameter of 4.3 ± 1.2 mm (range, 1.6-10.2 mm). Of the 573 limbs, 457 (79.8%) had prior ipsilateral AK antireflux treatment. Ablation was performed with a mean PEM volume of 4.3 ± 1.1 mL. Patients had received their most recent follow-up DU at a mean of 231 ± 329 days (range, 2-1758 days) and a median of 91 days (IQR, 298 days) after treatment.

Two patients (0.5%) experienced venous thrombosis after ablation. One patient experienced thrombus extension into the posterior tibial vein through a perforating vein at the level of the ankle, and the other developed superficial venous thrombosis in the proximal segment of the treated GSV. Both patients were successfully treated with oral antithrombotic medication. There was no incidence of

Table II. Cox proportional hazard model of covariables

Covariable	B	SE	Wald statistic	df	Sig	Exp(B)	95% CI for Exp(B)
Sex	0.595	0.259	5.276	1	.022	1.812	1.091-3.010
Vein size	0.250	0.090	7.706	1	.006	1.285	1.076-1.533
Antiplatelet	0.193	0.295	0.427	1	.513	1.213	0.680-2.164
Anticoagulation	0.673	0.330	0.4160	1	.041	1.960	1.027-3.742

B, Estimated coefficient; *df,* degrees of freedom; *Exp(B),* exponential value of B; *SE,* standard error; *Sig,* significance.

adverse pulmonary embolisms, transient ischemic attacks, or lower extremity paresthesia. Of the 111 patients with preprocedural C6 disease, 60 (54%) experienced ulcer healing after the procedure. The overall anatomic failure rate in BK truncal veins was 10.6% (GSV, 55; SSV, 8) observed on serial follow-up DU scans (mean, 104 ± 180 days; median, 16 days; IQR, 139 days). There were no significant differences in patient age ($P = .90$), patient BMI ($P = .59$), preprocedural CEAP score ($P = .79$), treated laterality ($P = .14$), recanalization rate in GSVs vs SSVs ($P = .06$), or PEM volume administered ($P = .24$) between veins that recanalized and those that remained closed after ablation. The mean maximum diameter of recanalized veins was significantly larger than that of closed veins (recanalized, 4.9 mm; closed, 4.3 mm; $P = .001$). Of the recanalized veins, 14.2% were in men compared with 8% in women ($P = .015$). Patients taking anticoagulation medication during treatment were more likely to have recanalization than were patients not taking such medication (odds ratio, 1.96; 95% confidence interval, 1.1-3.6; $P = .03$). The use of antiplatelet medications was not associated with increased failure of vein closure on DU (odds ratio, 1.21; 95% confidence interval, 0.7-2.2; $P = .51$; Table II). Of the 13 patients taking anticoagulation medication with recanalization in 16 treated limbs, 4 were using prophylactic apixaban, 3 therapeutic apixaban, 3 therapeutic warfarin, and 3 therapeutic rivaroxaban.

Early recanalization observed on DU within 7 days after ablation accounted for 49.2% (31 of 63) of all treatment failures and was associated with a significantly lower administered PEM volume compared with later recanalization (early: median, 4 mL [IQR, 1.5 mL]; late: median, 5 mL [IQR, 2 mL]; $P = .025$). The need for subsequent reintervention was not associated with early or late recanalization ($P = .16$). Of the 63 patients with recanalization, no significant differences were found between the 33 (52.4%) requiring reintervention and the 30 (47.6%) who did not. Of the interventions, 24 were performed with PEM, and 100% of the PEM reinterventions remained closed at a median follow-up DU of 160 days (IQR, 257 days).

DISCUSSION

Vein closure and elimination of venous reflux on DU has served as an approximate metric of ablation success with a positive, albeit unrefined, correlation with symptom improvement in the AK and BK saphenous segments after ablation.[4-7,13,15,18,19] In our study, nearly one half of patients incidentally found with anatomic failure of their BK ablation were asymptomatic and did not require reintervention. Improvement in HASTI symptoms, including lower extremity edema, after BK ablation was generally positive for treated patients but was not captured with the conventionally used patient-reported outcome metrics and is a limitation of this study.[5-7,11] Prior studies of thermal ablation in the GSV have also demonstrated a similarly dichotomous relationship between recanalization on DU and refractory symptoms.[20,21] The implications of ultrasound-determined recanalization on reflux symptoms require further study. However, DU after ablation continues to serve an important prognostic and safety measure when used adjunctively with symptom assessment tools in clinical practice.[13,19]

Our findings of high PEM efficacy and a low incidence of adverse VTE events for the treatment of BK-GSV and SSV reflux are consistent with the established literature.[7,12-15] The DU surveillance schedule performed after ablation is part of our institutional protocol, which has previously demonstrated variable utility in the surveillance of AK-GSV after thermal ablation.[22] Serial DU evaluations in this study demonstrated an 88% anatomic closure rate at midterm follow-up and revealed two distinct subpopulations of patients: those with early recanalization (captured within 7 days on first follow-up DU) and those with late recanalization (captured on subsequent DU scans). A prior observational study examining reflux in the BK saphenous segment found an excellent early closure rate of 95% using DU (within 48-72 hours) that was achieved with a mean PEM volume of 7.6 mL in veins with an average diameter of 5 ± 2 mm.[15] In contrast to our study protocol, asymptomatic patients were not routinely evaluated again after the first DU, which did not allow for effective capture of late anatomic failures. We found a comparable closure rate during the first 7 days after ablation (94.8%; 565 of 596) with a subsequently reduced closure rate as patients were followed up further after ablation. We achieved this early closure rate with a lower mean PEM volume than that previously advocated.[15] The judicious use of PEM for the BK segment is recommended to minimize adverse VTE events but must be weighed against the association with early recanalization.[14,15] In comparison to our study, on multivariate logistic regression analysis, a larger preablation BK vein diameter, male sex, and the concurrent use of

anticoagulation medication were all found to be independently associated with vein recanalization on DU. These factors were adjusted for their previously observed associations.[23,24] All anticoagulation use was continued perioperatively by the patients. The deleterious effect of anticoagulation use on the durability of antireflux sclerotherapy has been alluded to in prior studies and is demonstrated again in our study.[15,25] Additionally, no patient (0 of 95) using anticoagulation at the time of ablation were found to have any complications of adverse VTE events at follow-up. Thermal AK saphenous ablation has a reported anatomic failure rate at 1 year comparable to an observed failure rate of BK PEM ablation in this study.[20,21] Recanalization on DU after thermal ablation was also shown to be associated with a larger vein diameter but had a mixed association with patient sex.[20,21] This similarity in recanalization patterns suggests that venous recanalization possibly occurs under shared hemodynamic influences after both thermal and microfoam ablations. Ultimately, a patient's reflux symptoms, in conjunction with anatomic failure, provides the impetus for reintervention after ablation. Further study of the risk factors predictive of reintervention is required and might clarify the implications of recanalization on DU on the treatment success for lower extremity venous reflux.

AUTHOR CONTRIBUTIONS

Conception and design: JF, AM, EA, AH, NM
Analysis and interpretation: JF, AH
Data collection: JF, CF
Writing the article: JF
Critical revision of the article: JF, CF, AM, EA, AH, NM
Final approval of the article: JF, CF, AM, EA, AH, NM
Statistical analysis: JF, AM
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Overall responsibility: JF

DISCLOSURES

None.

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