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Thrombus Extension After Great Saphenous Vein Mechanochemical Ablation

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Abstract

Objective: To examine factors associated with thrombus extension after early experience with mechanochemical ablation, which combines mechanical damage to the venous endothelium with infusion of a sclerosant.

Methods: A retrospective review was performed of patients who underwent mechanochemical ablation to treat saphenous vein insufficiency in the thigh including the saphenofemoral junction. Data abstracted included patient demographics, procedural details, and post-procedural outcomes. Thrombus extension was determined by post-procedural duplex ultrasound and classified as flush closure with the femoral vein and any extension of thrombus into the femoral vein.

Results: 73 patients met inclusion criteria. The mean age of the population was 60, 17.8% were female, and the mean BMI was 30.7. Seven (9.6%) patients who underwent mechanochemical ablation experienced saphenous vein closure flush with the femoral vein. Eleven (15%) patients experience extension of thrombus to less than 50% of the diameter of the femoral vein and one patient experienced complete thrombosis of the femoral vein. There was no significant difference in age, sex, or comprehensive classification system for chronic venous disorders (CEAP) between the group with thrombus extension and the group without, with the exception of body mass index (BMI). The mean BMI in the group with thrombus extension was 26.8 vs 32 in the group without ($p=0.02$). There was no significant difference between the two groups in sclerosant volume used, distance between catheter tip and SFJ, and mean diameter of GSV in the thigh.

Conclusions: In this cohort, the incidence of thrombus extension into the femoral vein with mechanochemical ablation was high relative to rates of thrombus extension associated with reported rates of thermal ablation. Further investigation with larger cohorts, and standardized reporting is required to characterize the true rate of thrombus extension after mechanochemical ablation and identify maneuvers which may prevent thrombus extension.

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Declarations of interest: none

Introduction:

Vein ablation for symptomatic venous insufficiency, not relieved by compression stockings, has become standard of care. Endothermal ablation using radiofrequency or laser techniques has been shown to result in earlier return to work and less post-procedural pain compared to vein stripping.¹ While endothermal ablation results in a closure rate near 100%, endothermal methods do require the use of tumescent anesthesia and are associated with complications including ecchymosis, skin burns (1%) and nerve injury in up to 22%.²

Mechanochemical ablation of the great saphenous vein (GSV) is a relatively new treatment option for patients with venous insufficiency that does not require tumescent anesthesia and eliminates the risk of skin burn and nerve injury.³ Simultaneously, mechanochemical ablation is associated lower procedure-related pain scores, shorter procedure times, and an earlier return to work than endothermal techniques.^{3,4} However, mechanochemical ablation can still result in extension of thrombus into the femoral vein, the equivalent of endovenous heat-induced thrombosis (EHIT) associated with endothermal methods.

While the short-term benefits of mechanochemical ablation are well-described, data regarding complications, specifically thrombus extension, is lacking in the literature. Available publications on the outcomes of mechanochemical ablation focus on saphenous vein closure and recanalization rates. Two studies report thrombus extension rates after mechanochemical ablation at 0.2–1.8% as secondary outcomes.^{5,6} The objective of this study is to examine factors associated with thrombus extension after mechanochemical ablation.

Methods:

This study was a retrospective review of patients who underwent mechanochemical great saphenous vein (GSV) ablation in the thigh using the Clarivein device (Merit Medical, South Jordan, UT) from 2015–2018. The procedures were performed at two sites associated with the Division of Vascular Surgery of the University of California, Los Angeles (Gonda Vascular Center and West Los Angeles Veterans Affairs). Inclusion criteria was treatment of the thigh GSV up to the sapheno-femoral junction (SFJ). Patients with symptomatic venous insufficiency were treated with established mechanochemical ablation techniques.⁷ Briefly, all procedures were performed using ultrasound guidance. The tip of the device was placed within the GSV several centimeters proximal to the epigastric vein. The catheter wire rotation was activated while infusing sclerosant (polidocanol or sotradecol, type and concentration at clinician's discretion) and pulling back the catheter. The treated lower extremity was wrapped with an elastic bandage after the procedure.

All patients underwent venous duplex ultrasound two to three days after the procedure to evaluate for thrombus extension into the deep venous system (which will going forward be referred to as "EHIT"). This is our standard practice after venous ablation using any method. EHIT class 1 was defined as thrombus extending flush with the SFJ.⁸ EHIT class 2 was defined as extension into the femoral vein of <50% of the cross-sectional area. EHIT class 3 was defined as >50% cross sectional area extension and class 4 was complete occlusion of

the femoral vein. Patients who were found to have EHIT were started on anticoagulation at the surgeon's discretion and followed with serial venous duplex studies. Data regarding demographics, comorbidities, Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification, procedural details, and post-procedural outcomes were abstracted from the medical record.⁹

Summary results were presented as mean \pm standard deviation for continuous variables and as frequency (percent) for categorical variables. Two-group comparisons were assessed by the independent samples t-test or the Wilcoxon rank sum test, as appropriate of continuous variables and by Chi-Squared test or Fisher's exact test for categorical variables. SAS 9.4 (SAS, Cary, NC) was used for all analyses. This study was approved by the Institution Review Board of both participating institutions.

Results:

A total of 73 patients who underwent mechanochemical ablation using the ClariVein device met inclusion criteria. One limb was included per patient. The mean age was 60 and 13 (17.8%) were female. The majority of the patients had hypertension and hyperlipidemia (Table I). The mean body mass index (BMI) was in the obese range. The majority of patients had a CEAP clinical classification of C2 or C3 (Table I). Before attempted GSV closure, 54 (74%) of patients had documented use of compression stockings prior to ablation. (A small portion of patients were cash-pay and did not require insurance approval or the documentation of compression therapy and the remainder likely were not well documented in the chart.)

The tip of the ClariVein catheter was positioned at a mean of 2.7cm from the saphenofemoral junction. Polidocanol at a concentration of 1.5% was used in the majority of cases (86%) with a mean amount of 6.4cc of sclerosant per case. Sotradecol was used in the remainder of cases at a mean concentration of 1.8% and mean amount of 4.7cc of sclerosant per case. All patients had a post-procedure duplex scan 2–3 days after the procedure. Complete GSV closure was achieved on post-procedure duplex in 66 (90.4%) patients.

On post-procedure duplex, 19 (26%) cases demonstrated evidence of EHIT, when EHIT was defined as class 1 or greater. (Table I) There was no significant difference in sclerosant volume used, distance measured between catheter tip and SFJ, and mean diameter of the GSV were similar between the EHIT and non-EHIT group. Patients in the non-EHIT group had a higher BMI compared to the EHIT group. (Table I)

Of the 19 patients with EHIT, 13 were treated with anticoagulation and underwent duplex scans until thrombus resolution. Of these 13, 3 received rivaroxaban, 1 received apixaban, and 9 received lovenox. (Supplemental Table 1) Of the 7 patients with EHIT level 1, 3 were treated with anticoagulation; three remained stable at level 1 at day 10, 52 and 59. (Supplemental Table 1) Three resolved to a level 0 closure at day 13, 16 and 46, and one was lost to follow up after the initial post-procedure scan. Of the 11 patients with EHIT level 2, 9 were treated with anticoagulation; they had variable time to resolution with a median of 29 days (range 10–298). The single patient with complete femoral vein occlusion post-

procedure had residual partial thrombus extension into the femoral vein and was placed on lifelong anticoagulation. No patient experienced a post-procedure pulmonary embolus.

A sensitivity analysis was performed defining EHIT as class 2 or greater, excluding thrombus flush with the femoral vein. In this sensitivity analysis, there was no association of BMI with EHIT. No pre-operative variables or patient characteristics were associated with an increased incidence of EHIT.

Discussion:

Mechanochemical ablation has been shown to have high closure rates of up to 97% after eight weeks in a study of 333 GSV procedures.¹⁰ However, there is little data available in the literature regarding the association of mechanochemical ablation and EHIT. In this retrospective review of our initial experience with mechanochemical ablation of the thigh GSV, we found an EHIT rate that was significantly higher than that reported in the literature ranging from 0.2–1.8%.^{5,6}

Most reports of mechanochemical ablation outcomes focus on GSV closure rates. This may be related to the fact that the majority of studies examining the outcomes of mechanochemical ablation do not use routine protocols examine for post-procedure deep venous thrombosis.¹¹ In fact, the previously mentioned study of 333 procedures performed only an immediate post-procedure venous duplex to rule out deep venous thrombosis.¹⁰ Other authors perform venous duplex of the deep system up to 30 days after superficial venous ablation.¹² In contrast, in our practice, we routinely obtain a post-procedure venous duplex 2–3 days after GSV ablation by any method. Our surveillance protocol may result in a higher rate of EHIT compared to others who perform duplex at a further time point from the procedure, due to detection bias. In our cohort, 42% of the thrombi had regressed by post-op day 30; thus, if the surveillance duplex had been performed later, they would not have been detected.

We classified thrombus extension in this study according to reporting recommendations.⁸ One other study of 365 mechanochemical ablation procedures on the GSV used the same classification scheme and identified an EHIT rate of 1.8% at the 1-week post-operative visit.⁶ However, in this study, their protocol was to prescribe anticoagulation with fondaparinux until the first post-operative visit, which we do not do in our practice. Other studies in the literature simply report “deep venous thrombosis” rates after mechanochemical ablation.⁵ These differences in treatment protocol and reporting make it difficult to compare our findings to the findings of the previously published studies.

We did not identify any variables that were significantly associated with risk of EHIT, except for a higher BMI in the group without EHIT. Increasing BMI has been shown to be associated with less improvement in clinical severity score and quality of life after venous ablation.¹³ However, based on the literature, the association between BMI and risk of thrombus extension after superficial venous ablation is unclear. Some authors consider only EHIT of class 2 or higher to be clinically significant.¹⁴ For this reason, we performed a sensitivity analysis defining EHIT presence as class 2 or greater. In the sensitivity analysis,

BMI became no longer significantly associated with risk of EHIT, suggesting that the BMI association may be spurious and related to the small sample size.

Mechanochemical ablation is associated with technical issues that are unique to the device. Some authors stress the importance of listening for the motor slowing down, as this may represent catching of the device on a valve, or scar tissue.⁶ Other authors recommend applying external pressure over the SFJ, especially in veins with large diameters.¹⁵ However, these maneuvers are not included in the device instructions for use and it is unclear if they are necessary or beneficial.

The primary limitation of the study is the relatively small sample size. The lack of association between the studied variables and EHIT may represent a Type II error related to the small sample size. The procedures were performed by multiple surgeons with varying experience at two different institutions. This experience represents our initial limited experience with mechanochemical ablation. Given the small sample size and limited experience, our outcomes may not be generalizable to other practices. However, these findings may serve as a cautionary tale for those who consider initiating use of mechanochemical ablation in a limited fashion. We have extensive experience with radiofrequency ablation. Using the same post-procedure venous duplex surveillance protocol, radiofrequency ablation was associated with an EHIT level 1 or greater rate of 6.6% in a series of 498 cases.¹⁶ In addition, our complete closure rates with radiofrequency ablation are 99.6%, compared to the 90% we experienced with mechanochemical ablation.¹⁶ Based on these findings, we made the decision to use radiofrequency as our primary ablation technique. We reserve mechanochemical ablation for cases with special circumstances, such as when the vein is very close to the skin and the risk of skin burn with thermal ablation may be higher.

Conclusion:

The initial experience with mechanochemical ablation in this cohort was associated with a relatively high rate of thrombus extension as identified with an post-procedure surveillance protocol starting at 2–3 days post-procedure. In addition, the rate of complete closure was lower than with radiofrequency ablation. Further investigation with larger cohorts, and standardized reporting is required to characterize the true rate of thrombus extension after mechanochemical ablation and identify maneuvers which may prevent thrombus extension.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1:

Patient and procedure Characteristics

Patient Characteristic	Total (%) (n=73)	no EHIT (%) (n=54)	EHIT (%) (n=19)	<i>P value</i>
Mean Age	60	58	63	0.16
Female	13 (17.8)	9 (16.7)	4 (21)	0.73
Mean BMI	30.7	32	26.8	0.016
Deep System Reflux	33 (45.2)	25 (46.3)	8 (42.1)	
Clinical Characteristics				
C2	26 (35.6)	19 (35.2)	7 (36.8)	
C3	18 (24.7)	12 (22.2)	6 (31.6)	
C4a	12 (16.4)	10 (18.5)	2 (10.5)	
C4b	4 (5.5)	3 (5.6)	1 (5.3)	
C5	2 (2.7)	1 (1.9)	1 (5.3)	
C6	11 (15.1)	9 (16.7)	2 (10.5)	
Sclerosant volume	6.1cc	6.3cc	5.8cc	0.45
Mean distance between catheter tip and SFJ	2.7cm	2.7cm	2.7cm	0.98
Mean diameter of GSV in upper thigh	6.9cm	7.1cm	6.5cm	0.58
Concomitant phlebectomies	32 (43.8)	21 (38.9)	11 (57.9)	0.19