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Mechanochemical Endovenous Ablation of the Saphenous Vein: A Look at Contemporary Outcomes

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Background: Endovenous ablation techniques have replaced greater saphenous vein (GSV) ligation and stripping for treatment of venous insufficiency. Our objective was to investigate our initial procedural experience and clinical presentation of patients undergoing mechanochemical ablation (MOCA) at a single institution. We hypothesized that closure level and success rate improved over time and were comparable to other endovenous ablation techniques.

Methods: We retrospectively reviewed all MOCA procedures performed at the Greater Los Angeles Veterans Affairs Hospital from 2015 – 2020. Variables included CEAP and VCSS scores, patient symptoms, post procedure duplex ultrasound, closure level, and need for anticoagulation. Success was defined as GSV thrombosis on initial post procedure duplex ultrasound. Procedure associated extension of thrombus into the deep veins was defined using the American Venous Forum (AVF) endothermal heat induced thrombosis (EHIT) classification.

Results: 104 venous ablation procedures were performed on 86 patients. Eleven (12.8%) patients received bilateral interventions, and six (7%) patients had asynchronous interventions on the same leg. The average age was 58.4 years (SD 12) and 93% were male. Pre-procedural symptoms included pain (102, 98.1%), varicose veins (87, 83.7%), edema (58, 55.8%), and active ulcers (19, 18.3%). A CEAP category of C2 was the most common indication (34.6%), followed by C3 (22.1%) and C6 (21.2%). Forty-five (43.2%) patients had deep system reflux, and 53% had concomitant phlebectomies. Average VCSS score was 7.5 (SD 3.5).We observed a GSV ablation rate of 92.7% ($n = 89$) in the 96 procedures which had post-procedure follow up, with no temporal evidence of a learning curve. On post procedure duplex of the 89 technically successful ablations, 77 (86.5%) patients had AVF EHIT level 1 closure, three (3.4%) had level 2 closure, eight (8.9%) had level 3 closure, and one had a level 4 closure. Fourteen (15.7%) patients were newly started on anticoagulation for an average of 33.2 days (SD 34.1). Of the 19 legs treated for active venous ulcers, 13 (68.4%) had improvement or resolution of their venous ulcers. No pulmonary embolic complications were reported.

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Conclusions: We observed a successful GSV thrombosis rate of 92.7% using MOCA without evidence of a learning curve and comparable to that reported in the literature. The rate of thrombus extension into the deep veins was 14.6%, with no adverse effects associated with anticoagulation or clinically significant sequelae of AVF EHIT level 2 or greater. Comparisons with MOCA associated thrombus extension into deep veins in the literature are limited as post procedure screening duplex are not standard of care. However, we demonstrated that MOCA ablation of the GSV is a safe procedure that may be performed with good technical success.

INTRODUCTION

Chronic venous insufficiency of the lower extremity is a common condition with a wide range of symptoms from purely cosmetic complaints to non-healing ulcers.[1] A cross-ethnic study of patients in San Diego, California estimated that the prevalence of clinically serious venous disease is approximately 28%, making it the most prevalent vascular disease.[2] In 2019, over $290 million in Medicare was spent on invasive therapy to treat chronic lower extremity venous disease.[1]

For over a century, the gold standard surgical treatment was ligation and stripping of the great saphenous vein (GSV). However, this technique has several limitations including the need for general or spinal anesthesia, high symptom recurrence rate of 18 – 40% after 5 years, significant postoperative pain, and bleeding complications.[3, 4] More recently, endovenous thermal techniques such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) have been adopted as widely accepted treatment options with less risk of hematoma formation, pain, and faster recovery time compared to traditional surgical stripping. However, thermal ablation techniques still require tumescent anesthesia and carry the risk of secondary thermal injury to perivascular structures.[5] Mechanochemical endovenous ablation (MOCA) is a technique that uses a rotating wire to cause mechanical damage to the endothelium with a simultaneous infusion of a liquid sclerosant. No heat is generated in this process, so tumescent anesthesia is not required. This is associated with faster recovery time, lower postprocedural pain, and spares the adjacent nerves from possible injury.

Studies have reported comparable occlusion rates ranging from 80 – 84% using MOCA.[5] The MARADONA trial demonstrated MOCA to have an equal anatomic and clinical success rate compared with RFA, with less postprocedural pain.[5] While successful closure rate for MOCA has been previously reported, minimal research to date has characterized the early anatomic location of the thrombus, which helps guide postoperative management.

This study was designed to describe real-world experience with MOCA and assess early complication rates, initial closure level as defined by the American Venous Forum (AVF), and initial technical success rate.

METHODS

This study was a retrospective review of all mechanochemical ablation procedures of the GSV using the ClariVein device (Merit Medical, South Jordan, UT) performed at the Greater Los Angeles Veterans Affairs Medical Center from 2015 – 2020. Procedures were performed under ultrasound guidance with the tip of the ClariVein device positioned approximately 2 centimeters distal to the saphenofemoral junction as recommended in the literature,[6] confirmed by ultrasound in transverse and longitudinal views. Sclerosant used was 1.5% sodium tetradecyl sulphate (STS), and volume was calculated using a combination of vein diameter and length of vein to be treated per the ClariVein instructions for use. Wire rotation was activated with simultaneous infusion of sclerosant while pulling back on the device at a rate of approximately one centimeter every 6 seconds. The vein was compressed as it was treated, and after treatment, gauze pads were placed over the tract of the GSV. The lower extremity was then wrapped with inelastic gauze wrap, followed by an elastic compression wrap. Patients underwent venous duplex ultrasound within 1 week after the procedure to evaluate for thrombus extension into the deep venous system. Initial classification was completed using the UCLA Lawrence system,[7] and subsequently changed to the nomenclature used by the AVF for endovenous treatment induced thrombosis as described in 2020 by Kabnick et al. and is referred to as Endothermal Heat-Induced Thrombosis (EHIT).[8] During the study period (2015 – 2020) EHIT events were classified and treated according to the UCLA Lawrence criteria. In preparation of this manuscript, these values were converted to comply with the AVF EHIT reporting

Table I. Patient characteristics

Patient characteristic	(Total patients = 86)
Age, avg (SD)	58.4 (12.0)
Gender, Male *n* (%)	80 (93)
BMI, avg (SD)	32.1 (7.7)
Tobacco, *n* (%)	54 (62.8)
Concurrent Anticoagulant Use, *n* (%)	9 (10.5)
History of venous intervention, avg (SD)	21 (24.4)
Total patients with bilateral treatment, *n* (%)	11 (12.8)
Total patients with multiple ipsilateral interventions leg, *n* (%)	6 (7.0)
Deep System Reflux, *n* (%)	45 (43.2)
Comorbidities, *n* (%)	
Coronary artery disease	8 (9.3)
Diabetes Mellitus	26 (30.2)
Deep Vein Thrombosis	5 (5.8)
Prior Pulmonary Embolism	2 (2.3)
Hypertension	45 (52.3)
Hyperlipidemia	49 (57.0)
Peripheral artery disease	5 (5.8)

Avg,average; SD,Standard Deviation.

standards. UCLA levels 1, 2, and 3 were collapsed into AVF EHIT class 1. UCLA level 4 was changed to AVF EHIT class 2. UCLA level 5 was changed to AVF EHIT class 3, and UCLA level 6 was changed to AVF EHIT class 4.

Primary outcome measures were initial greater saphenous vein closure rate, defined as thrombosis of the treated vein on initial post-procedure duplex, and venous closure level defined using the AVF EHIT criteria.[8] Secondary outcome measures were the number of patients with EHIT class greater than 1, number of patients newly started on anticoagulation and postoperative complications. Inclusion criteria for calculation of final closure rate were treatment of the GSV up to the saphenofemoral junction, and completion of a duplex ultrasound within 1-week post-procedure.

Summary statistics are presented as mean, standard deviation for continuous variables and as frequency for categorical variables. Two group comparisons were assessed by the Chi-Squared test for categorical variables. This study was approved by the Institutional Review Board of the participating institution.

RESULTS

A total of 104 MOCA procedures performed in 86 patients were identified within our study period. The average age was 58, and 93% ($n = 80$) were male. Five patients had prior deep vein thrombosis (DVT) and two had history of pulmonary embolism (PE) (Table I). 24% ($n = 21$) of patients had prior venous interventions. The cohort had a wide distribution using CEAP clinical classification, most commonly with C2 varicose veins, C3 edema, and C6 active venous ulcer (Table II). Average Venous Clinical Severity Score (VCSS) was 7.5.

Of the 104 total ClariVein procedures, 101 completed a postoperative duplex ultrasound. Of these, three procedures were performed in the calf only, one procedure was aborted due to GSV spasm, and one patient requested not to remove the compression wrap for imaging. Thus, 96 procedures were included in final calculation of success rate. Final GSV ablation rate was 92.7%. Using EHIT classification, 86% had closure class 1 (Table III). 13 (14.6%) patients were identified with closure greater than EHIT class 1, and 14 (15.7%) patients were newly started on anticoagulation for an average of 33 days. A patient with AVF EHIT class 1 who was previously classified as UCLA Lawrence level 3 was anticoagulated per provider preference. Follow-up of the 13 patients who presented with deep vein thrombosis showed that five patients were treated with anticoagulation with subsequent resolution of the DVT, one patient discontinued anticoagulation after 1 week due to adverse side effects, but the DVT was not clinically significant and remained unchanged despite anticoagulation, and seven patients had asymptomatic DVT that were not treated with anticoagulation. The CEAP distribution for the 13 patients with EHIT class greater than 1 is as follows: two patients with C2 varicose veins, five patients with C3 edema,

Table II. Clinical characteristics

CEAP score distribution	*n* (%) = 104 (total number of limbs)
C1	0 (0.0)
C2	36 (34.6)
C3	23 (22.1)
C4a	18 (17.3)
C4b	2 (1.9)
C5	3 (2.9)
C6	22 (21.2)

Table III. Operative and postoperative details

Procedure Details	
Volume of sclerosant, avg (SD)	6.27 (2.2)
Concomitant phlebectomy, *n* (%)	55 (52.9)
Section of GSV treated, *n* (%):	
Thigh	93 (89.4)
Below Knee	3 (2.9)
Both	4 (3.8)
Post-procedure duplex completed, *n* (%)	101 (97.1)
Days to first post-procedure duplex, avg (SD)	4.1 (4.1)
Number meeting inclusion criteria	96
Successful GSV ablations, *n* (%)	89 (92.7)
AVF EHIT Classification, *n* (%)	
Class 1	76 (85.6)
Class 2	4 (4.4)
Class 3	8 (8.9)
Class 4	1 (1.1)
Newly Started on Anticoagulation, *n* (%)	14 (15.6)
Duration (average days, SD)	33.2 (34.1)

three patients with C4 skin and subcutaneous tissue change, one patient with C5 healed venous ulcer, and two patients with C6 active venous ulcer.

Notably, the three patients who underwent calf ablation only demonstrated closure on postprocedural imaging. 53% (n = 55) of patients underwent concomitant phlebectomy. Postoperatively, 97% (n = 101) of patients completed a primary post-procedure duplex within 1 week at our institution.

No major complications including pulmonary embolism, saphenous nerve injury, valve entrapment, or tear were reported. Sensitivity analyses were performed between vein diameter >7.5, prior DVT, concomitant phlebectomies, and EHIT class 2 or higher. There was no association between any of these factors and an EHIT closure class of 2 or higher.

Finally, the distribution of EHIT closure levels was plotted by year of procedure, and no discernable trend toward lower EHIT closure levels over time was observed (Fig. 1).

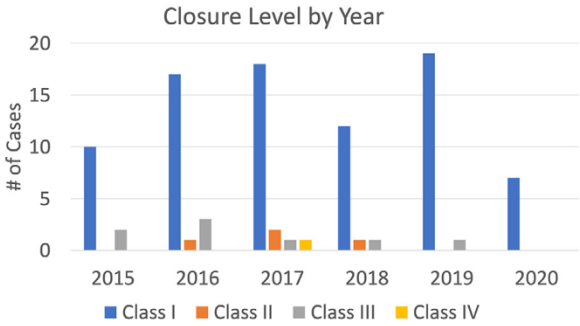

Fig. 1. EHIT closure level by year of procedure.

DISCUSSION

Mechanochemical ablation has been shown to have closure rates comparable to other endovenous techniques. However, there is a paucity of data regarding the association of mechanochemical ablation and EHIT. Most studies of mechanochemical ablation outcomes focus on GSV closure rates and simply report rates of postprocedural "deep venous thrombosis."

In this retrospective review of our initial experience with mechanochemical ablation of the thigh GSV, we found an EHIT rate of 14.6% that was higher than that reported in the literature ranging from 0.2 – 1.8%.[9, 10] This may be a result of our surveillance protocol that calls for early postoperative ultrasound within 1 week, before the thrombus has had time to fully regress, as compared to other studies which perform follow-up imaging up to 30 days postoperatively,[11] depending on the local ultrasound surveillance protocol.

Additionally, we had a low threshold for anticoagulation. At our institution, patients were initially classified using the UCLA Lawrence criteria, which we converted to AVF EHIT classification by equating UCLA levels 1 through 3 to EHIT class 1, UCLA level 4 to EHIT class 2, UCLA level 5 to EHIT class 3, and UCLA level 6 to EHIT class 4. This conversion was performed to comply with current reporting standards, and nomenclature for thrombus extension. Of note, because our patients were treated based on the UCLA Lawrence criteria, our threshold for anticoagulation was much lower and some AVF EHIT class 1 closures that do not meet criteria for anticoagulation were still treated with systemic anticoagulation. Importantly, we had no anticoagulation-associated bleeding complications, despite a high rate of anticoagulation within our cohort. While the rates of bleeding complications following venous ablation are low in the literature, it is known that patients anticoagulated for venous thromboembolism still have significant risk of major bleeding (7.2 events per 100 person-years) with a case-fatality rate of 13.4% from major bleeding.[12]

The principal limitation of this study is that wide differences in reporting and treatment protocol make it difficult to compare our results with those that have been previously published. A systematic review of endovenous thermal ablations demonstrated considerable variation in timing of postprocedural ultrasound, despite guidelines from the AVF recommending ultrasound within 1 week of the procedure.[8, 11] Furthermore, at our institution, these early ultrasounds demonstrating high closure levels likely led providers to have a low threshold for anticoagulation to prevent possible embolic complications in our relatively high-risk Veteran population, with ensuing unnecessary anticoagulation. An additional consideration is that these procedures were performed by multiple surgeons with trainee participation; however, we did not observe clear evidence of a learning curve or higher EHIT closure levels relating to provider experience with ClariVein. When we observed EHIT closure level distributions by year of procedure, we identified no discernable trend in EHIT rate over time. Our study was conducted in a Veteran population and the small number of females in this study may not be generalizable to the public. In addition, we had limited clinical follow-up for patients, and although we had a comparable closure rate, we were unable to document postoperative VCSS scores to measure clinical improvement.

CONCLUSIONS

We identified the rate of initial closure of the GSV using MOCA to be comparable to other commonly used techniques, despite a relatively high rate of thrombus extension identified on early postprocedural ultrasound. Anticoagulation was prescribed with a low threshold, but patients did not have any bleeding complications. Further investigation following standardized treatment guidelines based on EHIT is required to characterize the utility of documenting EHIT in the early postoperative period after mechanochemical ablation.

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