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Original Article

Mechanochemical ablation versus thermal ablation as a management modality for primary great saphenous varicose veins

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Abstract

Background

Chronic venous insufficiency is one of the most common conditions in the world. The WHO defines varicose veins (VV) of the lower limbs as dilated superficial veins presenting as baggy or cylindrical in shape and possessing damaged valves. In 70% of cases saphenous veins are affected.

Objective

This is a comparative, prospective study to compare thermal ablation versus maechanochemical ablation in the management of VV.

Patients and methods

This study was conducted on 40 patients who had primary great saphenous VV in the form of incompetence of saphenofemoral junction and/or great saphenous presented to the Vascular Department of Ain Shams University Hospitals, El-Sahel Teaching Hospitals (and other authorized hospitals under supervision of thesis supervisors). The study is a prospective, clinical trial (interventional comparative analytical study).

Results

This study compares between mechanochemical ablation (MOCA) versus radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) as the new managing modality for treatment of VV. This study shows no statistically difference in age and sex between the three groups. It shows statistically difference in obesity. There is statistical difference between three groups in great saphenous vein length preintervention. Most of the patients are C3 and C4.

Conclusion

MOCA is associated with less postoperative pain and faster recovery and work resumption compared with RFA and EVLA in the treatment of primary great saphenous VV. But recanalization was more in MOCA compared with RFA and EVLA.

Keywords: Mechanochemical ablation, primary great saphenous varicose veins, thermal ablation

Introduction

Chronic venous insufficiency is one of the most common conditions in the world. The WHO defines varicose veins (VV) of the lower limbs as dilated superficial veins presenting as baggy or cylindrical in shape and possessing damaged valves. In 70% of cases saphenous veins are affected [1].

It is reported that 40–60% of women and 25–30% of men will present with symptoms of venous insufficiency during their lifetime [2].

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Major risk factors include age and family history for both sexes. Pregnancy is an additional risk factor along with standing for long periods, obesity and female sex [3].

The severity of symptoms of VV can range from occasional discomfort and itching to severe skin ulceration, absence

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from work, pain, and decline in quality of life. About 10% of patients with VV develop skin changes, such as pigmentation or eczema, and about 3% may develop venous ulcers [4].

The clinical signs and symptoms of venous disease may be classified using the CEAP (clinical status, etiology, anatomy, and pathophysiology) classification. The degree of severity of pain and other clinical signs or symptoms can be measured using the Venous Clinical Severity Score (VCSS); the change of VCSS before and after intervention can be used to measure the efficacy of intervention [5].

Primary VV are mostly caused by the failure of at least a single valve in a critical location, whereas secondary VV occur when deep vein thrombosis (DVT) causes deep system and perforators' valve damage. In primary VV, the retrograde venous inflow (reflux) allows high-pressure, blood to pass into unsupported superficial veins. These veins become dilated, tortuous, and incompetent. Untreated venous hypertension has significant morbidity [6].

Venous duplex imaging is the favored technique for the evaluation of chronic venous insufficiency to confirm the diagnosis and assess its etiology and anatomy. Reversal of flow in the superficial venous system lasting more than 0.5 s indicates valvular incompetence. Deep system reflux is considered abnormal when reversal of flow exceeds 1 s. Longer durations of reflux and higher reflux velocities and volumes have been used to assess the severity of reflux [7].

The management of VV has changed drastically over recent years, but the ideal treatment remains elusive. Invasive treatments include traditional open surgery and minimally invasive endovenous ablation. The new treatments for VV developed in the last 25 years have primarily focused on ablation of the saphenous trunk [8].

Conventional open surgical management of long saphenous veins varicosities consists of high saphenofemoral ligation and stripping of the great saphenous veins (GSVs). This treatment is generally reserved for patients with most severe symptoms. Recurrence remains a significant problem of open surgery; recurrence rates are reported to be up to 20% at 2 years and 28% at 5 years [9].

Endovenous therapy, a minimally invasive procedure, offers potential benefits such as faster recovery, reduced complications, fewer physical limitations, and increased health-related quality of life. It can be classified into thermal techniques and nonthermal techniques. Thermal ablation includes endovenous laser ablation (EVLA), radiofrequency ablation (RFA), and steam vein sclerosis. Nonthermal ablation includes foam sclerotherapy, mechanochemical ablation (MOCA), and injection of cyanoacrylate glue [10].

EVLA induces a permanent, nonthrombotic occlusion of a refluxing vein using intraluminal application of laser energy. The laser energy induces mural inflammation and fibrosis with resultant vein obliteration. It is performed as an outpatient procedure using tumescent anesthesia [11]. Duplex ultrasound (US) examination at 5-year follow-up of EVLA and surgery was 93.3 versus 79.7% recurrence rate [12].

RFA is similar to EVLA. Follow-up after 5 years showed durable and high occlusion rates of 91.9%, with 94.9% free of reflux [13].

Because of EVLA and RFA favorable side effect profile in conjunction to sustained efficacy, in many countries they already replaced high ligation and stripping in the treatment of refluxing saphenous veins as well as for the treatment of perforators and selected tributaries [14].

Nonthermal, nontumescent ablation of saphenous veins is another method for the management of VV. MOCA is a catheter based system which strips off the endothelium of the vein using a rotating wire at its tip while liquid sclerosant is administered concomitantly [15].

Mechanochemical truncal ablation offers the patients reduced intraprocedural pain with equivalent technical success compared with radiofrequency truncal ablation at 6 months. Patients have equivalent disease-specific quality of life and clinical outcomes, and returned to work and normal activities at similar times [16].

Aim

The study is a comparative prospective study to compare thermal ablation versus maechanochemical ablation in the management of VV.

Patients and methods

This study was conducted on 40 patients who had primary great saphenous VV in the form of incompetence of saphenofemoral junction (SFJ) and/or great saphenous and presented to the Vascular Department of Ain Shams University Hospitals, El-Sahel Teaching Hospitals (and other authorized hospitals under supervision of thesis supervisors). The study is a prospective clinical trial (interventional comparative analytical study).

The patients were divided into two groups:

(1) First group: 20 patients will be treated using either EVLA or RFA.
(2) Second group: 20 patients will be treated using MOCA.

Inclusion criteria

(1) Age: the study included patients between 18 and 70 years.
(2) Primary GSV and or SFJ reflux on duplex imaging. (Definition of reflux: retrograde flow lasting more than 0.5 s in the superficial venous system, deep femoral veins and calf veins and lasting for more than 1 s in the common femoral vein, femoral vein, and the popliteal vein and more than 0.35 s in perforating veins.)
(3) Venous duplex scan confirmed suitability of GSV to be ablated with RFA, EVLA, and MOCA.
(4) The patient is able to ambulate following the procedure.
(5) The patient is able to give informed consent.

(6) Requirement for intervention agreed between the patient and the surgeon.
(7) Availability of patients for follow-up visits.

Exclusion criteria

(1) Patients with VV with neither GSV incompetence nor SFJ on venous duplex imaging.
(2) Patients who have associated small saphenous or deep venous incompetence on venous duplex imaging.
(3) Patients who have tortuous GSV above the knee which is unsuitable for catheterization.
(4) Patients who have GSV diameter by duplex of less than 3 mm or more than 12 mm in the supine position.
(5) Patients who have thrombus in the GSV.
(6) Patients who have concomitant peripheral arterial disease (ankle brachial pressure index < 0.9).
(7) Pregnant patients.
(8) Patients on oral anticoagulant.
(9) Patients with known allergy for foam sclerosing agents (athoxyscalerol).

Methods

Patient evaluation

All included patients will be evaluated by:

(1) Full history.
(2) Clinical examination.

Presenting symptoms and signs are classified according to:

(1) CEAP classification:

CEAP classification is currently the most commonly used assessment tool for venous disease. The CEAP classification system includes not only clinical (C) aspects of venous disease, but also etiological (E), anatomical (A), and pathophysiological (P) components, for the assessment of severity of venous disease.

Congenital factors are present from birth, and are related to disorders in the development of the venous system. Klippel–Trenaunay syndrome, Parkes–Weber syndrome, and vascular malformations are examples of congenital anomalies.

Primary venous disease commonly results in superficial venous incompetence, particularly located at the connecting points between deep and superficial veins, SFJ, saphenopopliteal junction, or perforating veins. Incompetence (or reflux) of the superficial venous system may result in venous hypertension and the development of signs and symptoms of chronic venous disease (CVD).

Secondary venous disease usually occurs as a result of previous deep venous thrombosis, although trauma and intra-abdominal masses may also result in impaired venous drainage and the development of CVD.

(2) Venous clinical severity score:

VCSS offers a broad quantification of the severity of venous disease and is not a detailed descriptive tool for CVD in an individual patient. It has also been found to be a useful screening tool because of its correlation with severity on imaging.

(3) Laboratory investigations required for the intended procedure.
(4) Venous duplex US commenting on:
SFJ competency, GSV competency and time of reflux, GSV diameter, short saphenous vein, and saphenopopliteal junction competency, deep vein status, and status of LL perforators.
(5) All patients who were included – according to inclusion and exclusion criteria – were asked to sign an informed consent explaining the nature of the intended procedure, benefits, and all its possible known complications. Only patients who were able to sign the consent agreed to be part of the study and agreed for postprocedural follow-up visits were included in the study.
(6) Selected patients were divided into two groups according to the intended procedure.

Endovenous laser ablation

(1) Preoperative planning:
  (a) On the day of the procedure, the patient should be well hydrated to achieve maximum distention of the leg veins.
  (b) Duplex US is performed to mark the skin overlying the target vein.
  (c) The patient should be kept warm and comfortable in the procedure room to further avoid vasospasm.
(2) Positioning:
  (a) The patient was placed in supine position on the operating room table.
  (b) Table positioned in reverse Trendelenburg.
(3) Anesthesia: spinal anesthesia.
(4) Technique:
  (a) The region treated is sterilely prepared and isolated with sterile barriers.
  (b) With the patient in reverse Trendelenburg position, vein is punctured at or below the knee using a micropuncture venous access kit (micropuncture sheath, needle, and guidewire) duplex guided.
  (c) A needle is advanced percutaneously into the vein lumen and a 0.18-inch guidewire is advanced through the needle once the intravascular position is confirmed.
(d) A small skin incision is performed at the puncture site and the needle is exchanged for the micropuncture sheath over the guidewire.
(e) The guidewire and inner stiffener of the micropuncture sheath are then removed and a 0.35-inch guidewire is advanced through the sheath.
(f) The micropuncture sheath is then exchanged over the wire for the long vascular sheath through which the laser fiber will be inserted.
(g) The wire and inner stiffener of the vascular sheath are removed and the position of the sheath is assessed by US.

(h) Under direct US guidance, the tip of the vascular sheath is positioned in the superficial venous system, typically 2 cm distal to the SFJ.
(i) At this point, the laser fiber is advanced through the vascular sheath and the position of the laser tip is confirmed by US.
(j) Confirmation of the laser tip position in the superficial venous system distal to the SFJ before laser activation to avoid damage to the deep venous system.
(k) At this point, the patient is then repositioned to a flat position to facilitate vein emptying, and tumescent anesthesia (0.1% lidocaine solution) is delivered under real-time US guidance in the perivenous sheath and the surrounding subcutaneous tissue of the entire length of the anatomic region to be ablated.
(l) During EVLA, the thermal energy is delivered by the device utilized.
(m) Continuous delivery of 80 J/cm at 12 W for 810 nm fibers and 70 J/cm at 14 W for 980 nm fibers.

Radiofrequency ablation

(1) Preoperative planning and positioning:
Same as EVLA.
(2) Device used:
ClosureFAST system consists of two main components: ClosureFAST catheter and closure RFG generator. The catheter is a sterile, single-used, disposable device. The catheter provides thermal energy to the desired treatment site via radiofrequency heating of the catheter heating element and relay temperature back to the generator. The generator is not sterile during the procedure with the catheter connected to it via a cable connector.
(3) ClosureFAST catheter:
   (a) Handle.
   (b) Shaft.
   (c) Heating element.
(4) Parameters of an RFG generator:
Device temperature: 120°C. with maximum power: 40 W.
(5) Technique:
   (a) Using Duplex US, the vein access site is selected, and the vein is entered percutaneously.
   (b) An introducer sheath is placed to allow catheter insertion into the target vein.
   (c) A 6-Fr introducer sheath for 6 Fr catheter was applied.
   (d) The catheter is navigated to the SFJ and positioned using US guidance 2 cm distal to the SFJ.
   (e) The vein must be anesthetized circumferentially along the entire treatment length with a diluted solution of 0.1% lidocaine.
   (f) Anesthetic solution is infused into the intrafascial perivenous plane with US visualization until the saphenous canal begins to swell.
   (g) Putting the patient in the Trendelenburg position and applying external compression by tumescent, initiation of radiofrequency energy delivery to the electrodes, the catheter is slowly withdrawn.
   (h) The patients are encouraged to ambulate immediately after the procedure. Duplex US scan performed within 72 h postoperatively to confirm vein closure and rule out the presence of DVT.

Endovenous mechanochemical ablation with Flebogrif

(1) Preoperative planning and positioning:
Same as EVLA.
(2) Device used: Flebogrif catheter.
Set elements of the catheter:
   (a) Straight needle: 18 G.
   (b) Guidewire: J.035.
   (c) Vascular sheath with a dilator: 6 Fr.
   (d) Catheter Flebogrif: 6 Fr.
   (e) Flebogrif catheter calibrated 1 cm with an available length of 90 and 60 cm.
(3) Anesthesia:
Local anesthesia (lidocaine 1% solution).
(4) Technique:
   (a) Under US guidance, the site of GSV puncture was evaluated and then chosen, usually below the knee joint and at the site of the lowest reflux level to provide maximum technical success.
   (b) The puncture was performed using the Seldinger needle provided with the kit, through which the guidewire w was inserted so that its end was located in the region of SF.
   (c) Before insertion of the 6-Fr introducer sheath, the skin was locally anesthetized with 1% lignocaine at the puncture site.
   (d) Using the guiding wire, the Flebogrif system was inserted placing its working part 2 cm below the SFJ.
   (e) The system was freed by sliding the external sheath in relation to the internal mandrile. The five arms of the working part with sharp hooks on the ends were released and directed toward the wall of the vessel and scarification of the vein was performed from the positioning site to the puncture site by withdrawing the system with a continuous movement. The speed at which the system was slid amounted to 5 cm/s and the volume of the injected foam amounted to 1 ml/5 cm of the vein prepared with the Tessari method. For veins with a diameter of 15 mm 2% polidocanol was used, and for veins of larger diameter 3% polidocanol. (The volume of the sclerosant used for saphenous vein ablation ranged from 3 to 10 ml with an average of 6.5 ml.)
   (f) After the operation, compression therapy was used with second-grade compression stockings for a minimum of 10 days. Enoxaparin is given for patients with an increased risk of thromboembolism at a dose of 1 × 40 mg subcutaneously for 10 days. Follow-up visits were scheduled at 1, 3, 6 months after the procedure.

(g) Postoperative data protocol included:
   (i) Patients should wear compression therapy for 7 days.
   (ii) Patients should mobilize as soon as possible following the procedure.
   (iii) Patients should come for follow-up visits 1 and 6 months after the procedure in the outpatient clinics to assess them clinically.
   (iv) Patients should have a venous duplex of the limb treated 6 months after the procedure.

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± SD. Qualitative data were expressed as frequency and percentage. *P* value less than or equal to 0.05 was considered significant, *P* value less than or equal to 0.001 was considered as highly significant; *P* value more than 0.05 was considered insignificant.

Results

Table 1 shows statistically significant difference between groups according to obese.

Table 2 shows statistically significant difference between groups according to length of GSV (cm).

Table 3 shows highly statistically significant difference between groups according to 2 cm distal to SFJ and Px, mid, distal thigh and leg in diameter of GSV (mm) before the procedure.

Table 4 shows statistically significant difference between groups according to 2 cm distal to SFJ and Px, mid, distal thigh and leg in diameter of GSV (mm) after the procedure.

Table 5 shows statistically significant difference between groups according to change before and after procedure in 2 cm distal to SFJ.

Table 6 shows highly statistically significant difference between groups according to before and after procedure according to the diameter of GSV (mm) in group I.

Table 7 shows highly statistically significant difference between groups according to before and after procedure according to diameter of GSV (mm) in group IIa.

Table 8 shows highly statistically significant difference between groups according to before and after procedure according to diameter of GSV (mm) in group IIb.

Table 9 shows statistically significant difference between groups according to before diameter and after diameter.

Table 10 shows statistically significant difference between groups according to operative time (min).

Table 11 shows statistically significant difference between groups according to time to return to normal work (days).

Table 12 shows statistically significant difference between groups according to edema, burning pain, infection, and nerve injury.

Discussion

VV and CVD is a benign but progressive and pervasive disease. The treatment options have been transformed with endovenous

Table 1: Comparison between groups according to comorbidity

Comorbidity	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	χ^2	*P*
Smoker					
No	15 (75.0)	9 (90.0)	7 (70.0)	1.290	0.525
Yes	5 (25.0)	1 (10.0)	3 (30.0)		
HTN					
No	19 (95.0)	10 (100.0)	10 (100.0)	1.026	0.599
Yes	1 (5.0)	0 (0.0)	0 (0.0)		
DM					
No	18 (90.0)	9 (90.0)	9 (90.0)	0.000	1.000
Yes	2 (10.0)	1 (10.0)	1 (10.0)		
Obese					
No	18 (90.0)	10 (100.0)	6 (60.0)	7.059	0.029*
Yes	2 (10.0)	0 (0.0)	4 (40.0)		

DM: Diabetes mellitus; EVLA: Endovenous laser ablation; HTN: Hypertension; MOCA: Mechanochemical ablation; RFA: Radiofrequency ablation. *P*>0.05, NS.**P*<0.05, significant.

Table 2: Comparison between groups according to length of great saphenous vein (cm)

Length of GSV (cm)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
Mean±SD	20.95±13.46	12.50±1.72[a]	40.90±32.05[a,b]	6.350	0.004*
Range	12-60	10-15	12-90		

EVLA, endovenous laser ablation; *F*, one-way analysis of variance; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation.Post-hoc: [a]Significant with group I (*P*<0.05).[b]Significant with group IIa (*P*<0.05).**P*<0.05, significant.

Table 3: Comparison between groups according to the diameter of great saphenous vein (mm) before the procedure

Diameter of GSV 'before procedure' (mm)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
2 cm distal to SFJ					
Mean±SD	5.10±1.17	4.10±1.10[a]	3.10±1.29[a,b]	9.859	<0.001**
Range	3-7	2-6	2-5		
Px, mid, distal thigh					
Mean±SD	6.45±1.15	6.10±1.29	5.30±1.42[a]	2.817	0.043*
Range	5-8	4-8	4-8		
Px, mid, distal leg					
Mean±SD	4.45±1.00	3.80±0.63[a]	2.90±0.57[a,b]	11.740	<0.001**
Range	3-6	3-5	2-4		

EVLA, endovenous laser ablation; F, one-way analysis of variance; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction. *P*>0.05, NS.Post-hoc: [a]Significant with group I (*P*<0.05). [b]Significant with group IIa (*P*<0.05). **P*<0.05, significant, ***P*<0.001, highly significant.

Table 4: Comparison between groups according to the diameter of great saphenous vein (mm) after the procedure

Diameter of GSV 'after procedure' (mm)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
2 cm distal to SFJ					
Mean±SD	1.90±1.17	1.45±0.59	1.20±0.42[a]	2.192	0.026*
Range	1-6	1-2.4	1-2		
Px, mid, distal thigh					
Mean±SD	3.67±1.16	2.70±0.67[a]	2.70±0.82[a]	4.892	0.013*
Range	2-7.4	2-4	2-4		
Px, mid, distal leg					
Mean±SD	2.25±1.12	1.70±0.67	1.10±0.32[a]	5.807	0.006*
Range	1-6	1-3	1-2		

EVLA, endovenous laser ablation; *F*, one-way analysis of variance; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction. *P*>0.05, NS. Post-hoc: [a]Significant with group I (*P*<0.05). [b]Significant with group IIa (*P*<0.05). **P*<0.05, significant.

Table 5: Comparison between groups according to the difference between before and after procedure diameter of great saphenous vein (mm)

Difference between before and after procedure diameter of GSV (mm)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
2 cm distal to SFJ					
Mean±SD	−3.20±1.20	−2.65±1.10	−1.90±1.29[a]	3.965	0.028*
Range	−5-0	−4 to−1	−4 to−1		
Px, mid, distal thigh					
Mean±SD	−2.78±1.05	−3.40±0.97	−2.60±0.70	2.029	0.146
Range	−4 to−0.6	−5 to−2	−4 to−2		
Px, mid, distal leg					
Mean±SD	−2.20±1.11	−2.10±0.99	−1.80±0.63	0.557	0.578
Range	−4-0	−4 to−1	−3 to−1		

EVLA, endovenous laser ablation; *F*, one-way analysis of variance; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction. *P*>0.05, NS.Post-hoc: [a]Significant with group I (*P*<0.05). [b]Significant with group IIa (*P*<0.05). **P*<0.05, significant.

ablation and MOCA allowing movement from the operating theater to the outpatient suite.

This study compares between MOCA versus RFA and EVLA as the new managing modality for the treatment of VV.

This study shows no statistical difference in age and sex between the three groups. It shows statistical difference in obesity. There is statistical difference between three groups in GSV length preintervention. Most of the patients are C3 and C4. Diameter of GSV (mm) before procedure 2 cm distal to SFJ and Px, mid, distal thigh, and leg are larger in patients with the MOCA technique than RFA and EVLA and larger in patients with EVLA than RFA, whereas diameters postintervention show statistical difference in the three groups. There is statistically difference between diameters of GSV 2 cm distal to SFJ and Px, mid, distal thigh and leg before and after intervention in MOCA, RFA, and EVLA groups.

Table 6: Comparison between before procedure and after procedure according to the diameter of great saphenous vein (mm) in group I: mechanochemical ablation (*n*=20)

Diameter of GSV (mm)	Before procedure	After procedure	Mean difference	Paired *t*-test	*P*
2 cm distal to SFJ					
Mean±SD	5.10±1.17	1.90±1.17	−3.20±1.20	11.961	<0.001**
Range	3-7	1-6	−5-0		
Px, mid, distal thigh					
Mean±SD	6.45±1.15	3.67±1.16	−2.78±1.05	11.885	<0.001**
Range	5-8	2-7.4	−4 to−0.6		
Px, mid, distal leg					
Mean±SD	4.45±1.00	2.25±1.12	−2.20±1.11	8.904	<0.001**
Range	3-6	1-6	−4-0		

EVLA, endovenous laser ablation; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction; *t*, paired sample *t*-test.*P<0.05, significant.**P<0.001, highly significant.

Table 7: Comparison between before procedure and after procedure according to the diameter of great saphenous vein (mm) in group IIa: endovenous laser ablation (*n*=10)

Diameter of GSV (mm)	Before procedure	After procedure	Mean differecne	Paired *t*-test	*P*
2 cm distal to SFJ					
Mean±SD	4.10±1.10[a]	1.45±0.59	−2.65±1.10[a]	7.599	<0.001**
Range	2-6	1-2.4	−4 to−1		
Px, mid, distal thigh					
Mean±SD	6.10±1.29	2.70±0.67[a]	−3.40±0.97	11.129	<0.001**
Range	4-8	2-4	−5 to−2		
Px, mid, distal leg					
Mean±SD	3.80±0.63[a]	1.70±0.67[a]	−2.10±0.99	6.678	<0.001**
Range	3-5	1-3	−4 to−1		

EVLA, endovenous laser ablation; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction; *t*, paired sample *t*-test. [a]significant.*P<0.05, significant. **P<0.001, highly significant.

Table 8: Comparison between before procedure and after procedure according to the diameter of great saphenous vein (mm) in group IIb: radiofrequency ablation (*n*=10)

Diameter of GSV (mm)	Before procedure	After procedure	Mean difference	Paired *t*-test	*P*
2 cm distal to SFJ					
Mean±SD	3.10±1.29[a,b]	1.20±0.42	−1.90±1.29[a,b]	4.670	0.004*
Range	2-5	1-2	−4 to −1		
Px, mid, distal thigh					
Mean±SD	5.30±1.42	2.70±0.82[a]	−2.60±0.70	11.759	<0.001**
Range	4-8	2-4	−4 to −2		
Px, mid, distal leg					
Mean±SD	2.90±0.57[a,b]	1.10±0.32[a,b]	−1.80±0.63	9.000	<0.001**
Range	2-4	1-2	−3 to −1		

EVLA, endovenous laser ablation; GSV, great saphenous vein; MOCA, mechanochemical ablation; RFA, radiofrequency ablation; SFJ, saphenofemoral junction; *t*, paired sample *t*-test.*P<0.05, significant.**P<0.001, highly significant.

After intervention all GSV in duplex in three groups appear hyperechoic.

Postintervention in the MOCA group 15% of the cases have partially compressible GSV with a flow less than 1 s. Recanalization of one segment about 5 cm in length in MOCA which is less in RFA and EVLA operative time was less in MOCA than RFA and EVLA. Also return to normal activity was faster in MOCA than the other two groups.

About postintervention complications, DVT and hyperpigmentation is higher in MOCA than RFA and EVLA. Edema, cellulitis, hyperemia, burning pain, and thrombophlebitis are more in the RFA group than the other two groups, whereas infection and nerve injury are more common in the EVLA group. Compression postoperative was less in RFA than the other two groups.

MOCA is associated with a significant reduction in postprocedural pain after treatment. Pain after endothermal ablation is considerable and probably an underreported complication in the literature. Recent studies have shown less postprocedural pain after RFA compared with EVLA [17].

Table 9: Comparison between groups according to common femoral vein

CFV	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
Before					
Reflux	0 (0.0)	0 (0.0)	0 (0.0)	0.000	1.000
Diameter (mm)					
Mean±SD	2.75±0.72	5.10±0.88[a]	3.80±0.79[a,b]	31.055	<0.001**
Range	2-4	4-7	3-5		
After					
Reflux	0 (0.0)	0 (0.0)	0 (0.0)	0.000	1.000
Diameter (mm)					
Mean±SD	2.75±0.72	4.50±0.85[a]	3.40±0.70[a,b]	18.321	<0.001**
Range	2-4	3-6	3-5		

CFV, common femoral vein; EVLA, endovenous laser ablation; *F*, one-way analysis of variance; MOCA, mechanochemical ablation; RFA, radiofrequency ablation.Post-hoc: [a]Significant with group I (*P*<0.05).[b]Significant with group IIa (*P*<0.05).**P*<0.001, highly significant.

Table 10: Comparison between groups according to the operative time (min)

Operative time (min)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
Mean±SD	44.25±14.17	61.50±11.07[a]	57.00±9.49[a]	7.596	0.002*
Range	30-60	45-90	30-60		

EVLA, endovenous laser ablation; *F*, one-way analysis of variance; MOCA, mechanochemical ablation; RFA, radiofrequency ablation. Post-hoc: [a]Significant with group I (*P*<0.05). [b]Significant with group IIa (*P*<0.05). **P*<0.05, significant.

Table 11: Comparison between groups according to time to return to normal work (days)

Time to return to normal work (days)	Group I: MOCA (*n*=20)	Group IIa: EVLA (*n*=10)	Group IIb: RFA (*n*=10)	*F*	*P*
Mean±SD	5.15±1.50	8.10±2.08[a]	18.20±15.06[a,b]	4.767	0.014*
Range	2-8	6-12	7-60		

EVLA, endovenous laser ablation; *F*, one-way analysis of variance; MOCA, mechanochemical ablation; RFA, radiofrequency ablation.Post-hoc: [a]Significant with group I (*P*<0.05).[b]Significant with group IIa (*P*<0.05).**P*<0.05, significant.

Table 12: Comparison between groups according to adverse events

Adverse events	Group I: MOCA (*n*=20) [*n* (%)]	Group IIa: EVLA (*n*=10) [*n* (%)]	Group IIb: RFA (*n*=10) [*n* (%)]	χ^2	*P*
Deep vein thrombosis	1 (5.0)	0 (0.0)	0 (0.0)	1.026	0.599
Edema	4 (20.0	0 (0.0)	4 (40.0)	5.997	0.042*
Cellulitis	1 (5.0)	0 (0.0)	2 (20.0)	3.243	0.198
Ecchymosis	2 (10.0)	0 (0.0)	1 (10.0)	1.081	0.582
Hyperpigmentation	5 (25.0)	2 (20.0)	1 (10.0)	0.938	0.626
Hyperemia	1 (5.0)	0 (0.0)	1 (10.0)	1.053	0.591
Burning pain	1 (5.0)	0 (0.0)	3 (30.0)	6.111	0.047*
Thrombophlebitis	1 (5.0)	0 (0.0)	2 (20.0)	3.243	0.198
Infection	0 (0.0)	2 (20.0)	0 (0.0)	6.316	0.043*
Nerve injury	0 (0.0)	2 (20.0)	0 (0.0)	6.316	0.043*

EVLA, endovenous laser ablation; MOCA, mechanochemical ablation; RFA, radiofrequency ablation.*P*>0.05, NS.**P*<0.05, significant.

MARADONA trial is a multicenter randomized controlled trial that aims for a reduction in postprocedural pain after MOCA compared with RFA, with a similar anatomical and clinical success [18].

The Flebogrif system provides high efficiency, high occlusion rate, and technical success after 3 months of follow-up reaching 96%. The system is also characterized by good cosmetic effect and low complication rate. The procedure performed with the Flebogrif catheter seems to improve quality of life of the patient in the postoperative period [19].

MOCA has also been successful in patients with small saphenous vein reflux. Twelve-month follow-up of 50 patients treated for small saphenous vein incompetence had a closure rate of 94% with minimal complications [18]. In addition, a small study in six patients with persistent ulcers found improved ulcer healing rates after MOCA of the below-knee GSV [20].

MOCA is associated with significantly less postoperative pain and a faster recovery and work resumption, compared with RFA in the treatment of great saphenous incompetence [21].

Recanalization was higher in the MOCA-treated group than in the EVLA-treated group. In both groups, the postoperative pain duration and return time to normal activity were less than a week in most patients. Although patient satisfaction in the MOCA and EVLA groups was not significantly different, more patients in the EVLA group expressed satisfaction than in the MOCA group. Minimally invasive EVLA surgery can be considered the gold standard for the management of VV of the limbs, especially VV with a diameter of more than 7 mm [22].

Conclusion

MOCA is associated with less postoperative pain and faster recovery and work resumption compared with RFA and EVLA in the treatment of primary great saphenous VV. But recanalization was more in MOCA compared with RFA and EVLA.

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Conflicts of interest

There are no conflicts of interest.

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