

Evaluation of Versatility of Mechanochemical Ablation (MOCA) in the Management of Great Saphenous Vein Reflux: A Day-Case Intervention with Good Outcomes

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Abstract:

Background: To find out outcomes of the day-case MOCA in the management of great saphenous vein (GSV) reflux. There is a rapid change in the management of great saphenous vein reflux in recent years. MOCA being minimal invasive instead of vein surgery, can be performed by percutaneous catheter ablation without incisions.

Patients and methods: This prospective randomized controlled study was conducted on 78 cases (93 limbs); 63 cases with unilateral limb and 15 cases with bilateral limbs with GSV reflux. All patients were treated with MOCA using the Flebogrif catheter using duplex guidance without tumescent anesthesia. Follow-up period was for 6-months. **Results:** There was satisfactory results and marked improvement of patients' symptoms. Patients experienced significantly less postoperative pain at 1st 2 days (VAS: 1.9 ± 0.6). Patients were discharged within hours and returned back to work within few days. There were 1-week PO minor complications that disappeared by time except only 1 (3.3%) limb of DVT was treated conservatively. At 3-6 months there was residual varicosities only in 6 (6.6%) and treated by foam

sclerotherapy. **Conclusions:** MOCA utilizing Flebogrif catheter and completion foam sclerotherapy are considered very promising interventions to treat GSV reflux; being less invasive, highly effective with good quality of life, less pain, satisfactory cosmeses and rapid return to work.

Key words: Great saphenous vein reflux; MOCA; Outcomes.

Introduction:

Varicose veins are defined as “subcutaneous veins in the lower extremities which are dilated to ≥ 3 mm in diameter in the upright position”. They can occur in the axial superficial veins (GSV and SSV) and/or in any of their tributaries (1-3).

Current thinking is that they represent primary venous disease and occur as a result of structural weakening of the vein wall, which can be focal or diffuse. This weakening is most likely the result of underlying morphologic or biochemical abnormalities. Valvular incompetence in the superficial veins is usually present, which may represent an inciting factor or a secondary result of vein wall dilation. Varicose veins can also occur as a result of secondary venous disease (post-thrombotic) (4-6).

Varicose veins constitute a progressive disease; remission does not occur except after pregnancy. Venous disease produces symptoms which frequently prompt the patient to seek medical care. Symptoms and signs include lower extremity pain and swelling, particularly after prolonged standing and a feeling of heaviness in the lower extremities (7-9).

The most frequent complications are superficial thrombophlebitis, bleeding

from thin-walled varices, eczema and skin ulceration. Depending on his or her age, general health condition and symptomatology, a patient with varicose veins may be offered one or more of the following: no treatment, conservative management with compression, venotonic medications, sclerotherapy or surgical treatment (open or endovascular, i.e. thermal or non-thermal ablation) (10-13).

Over the last decade, interventional progress by using new less invasive techniques has been developed such as VNUS Closure endovenous radiofrequency ablation (RFA), endovenous laser ablation and non-thermal, non-tumescent (NTNT) techniques. All of them should be followed by compression therapy (14-17).

The newer treatments that do not require the use of tumescent anesthesia are referred to as the non-thermal, non-tumescent (NTNT) techniques. Chemical ablation using foam sclerotherapy represents perhaps the longest-standing NTNT ablation technique. Physician-compounded foam using the Tessari method has a large body of literature supporting its safety and efficacy. Successful ablation rates range from 60%–95%.75–80 Varithena (polidocanol injectable foam) represents the first

proprietary foam sclerosant to gain FDA approval (18-21).

The aim of this prospective study is to find out outcomes of the day-case MOCA in the management of great saphenous vein (GSV) reflux; being less invasive and pain, early return to normal activities and better cosmetic results...

Patient and methods:

The present study was conducted after obtaining fully written informed patients consent and local ethical committee of Benha University Hospital approval at vascular unit, General surgery Department, Benha University from June 2021 till October 2022 so as to allow 6 months follow-up. This prospective randomized controlled study was conducted on 78 cases (93 limbs); 63 cases with unilateral limb and 15 cases with bilateral limbs with GSV reflux. All patients were treated with MOCA using the Flebogrif catheter (Balton company, Sp.z.o.o., ul. Nowy Swiat 7/14, 00-496 Warszawa, Poland) using duplex scan guidance without tumescent anesthesia.

This study included cases suffering from symptomatic GSV reflux, CEAP above c2 grade (Clinical, etiological, anatomical, pathological (CEAP) classification) and either unilateral or bilateral GSV reflux. All were fit for regional/general anesthesia. Cases were excluded if they

had previously undergone GSV stripping, having secondary varicose veins or vein diameter outside 0.2-1.2cm, severely tortuous veins, coagulation abnormalities, pregnancy, peripheral arterial diseases,, moribund obesity and difficult ambulation. All cases were admitted at vascular unit, General Surgery ward for clinical evaluation, routine hematological tests, and venous duplex of both lower limbs to mark the highest point of reflux. On the day of the procedure, each patient was hydrated efficiently for proper vein distention. The patient was kept warm, and the ultrasound gel was heated to avoid venospasm.

Mechanochemical Ablation (MOCA) technique:

The procedure was performed under spinal or local anesthesia without tumescence. The access site was detected by duplex guidance and initiated one hand breadth below popliteal crease; in the reverse Trendelenberg's position, lidocaine was administered at the selected site, and a percutaneous Seldinger needle was used to gain access. A small cut down was used in few cases. A 0.035-inch guide wire was inserted into GSV, and the needle was removed. Next, a 6F × 10-cm or 8F × 10-cm sheath was advanced over the wire then mechanochemical ablation (MOCA) was performed using the flebogrif catheter

(Balton, Poland). The device consists of a single-use catheter with wire that protrudes from its tip, which causes mechanical damage to the endothelium and vein wall spasm. The treatment was initiated 2 cm peripheral to the SFJ and, as the catheter was withdrawn, a sclerosant; Polidocanol injectable foam; 10mg or 20mg/2ml; (Amoun company, Egypt) was dispersed onto the vessel wall.

Completion treatment of residual tributaries was performed immediately; using foam sclerotherapy; Polidocanol, it was aspirated in a 10-mL syringe and connected to a 3-way cannula with a 10-mL syringe containing 8 mL of air; the syringes were rapidly depressed sequentially to create the foam (1:4) sclerosant to air volume ratio.

The foam was injected through the needle while observing the foam displace the blood from the vein. After all injections were completed, thigh and knee were wrapped with an elastic compression bandage for 5 days continuously, taking it off only to shower; then thigh high class II graduated compression stocking was applied for 2 weeks to minimize post procedure bruising. Clinical evaluation was performed on all subjects at 1 week, 3 and 6 months.

Outcome items:

Patients were discharged 1 day after intervention and followed up 1-week for (Nerve trauma (manifesting as numbness, decreased or altered sensation or paraesthesia), Thrombosis (thrombophlebitis or DVT), skin pigmentation, return to daily activities and post-operative pain was evaluated using a visual Analog Score (VAS). Patients ranked the level of pain from 0 (no pain) to 10 (very severe pain). Patients completed questionnaires dealing with analgesic use to detect the level of pain over the previous 24 hours. To assess postoperative outcome; Duplex scanning was done to assess obliteration procedure and to exclude DVT or extension of thrombus from saphenous vein into femoral vein (Fig.1-3).

Statistical analysis:

Analysis of data was done by using SPSS version 16 (SPSS; SPSS Inc., Chicago, Illinois, USA). Means of all continuous variables were compared by appropriate parametric or non-parametric tests ($SD < 50\%$ mean). Categorical variables and proportions were analyzed using Chi-square and Fisher exact tests. Results were expressed as medians, percentages and as means \pm SD.



Fig. (1): Needle and sheath insertion.



Fig. (2): Flebogrif catheter at SFJ (Mickey-mouth appearance) and Foam.



Fig. (3): Flebogrif catheter withdrawal and catheter hooks.

Fig. (1-3): Steps of MOCA of the Great Saphenous Vein (GSV) with immediate foam sclerotherapy injection of the residual tributaries.

Results:

This prospective randomized controlled study was conducted on 78 cases (93 limbs); 63 cases with unilateral limb and 15 cases with bilateral limbs with GSV reflux. All patients were treated with MOCA using the Flebogrif catheter. Table

1 showed that 60 (76.9%) females and 18 (23.1%) males were enrolled in this study with age range of 25- 35 years (21 (26.9%), 36-45 years: 42 (53.8%) and >45 years: 15 (19.3%)).

Table (1): Patients' preoperative data: (N=93 limbs in 78 patients)

	Data	Findings	
		Number	(%)
Age (years)	Strata	25- 35	21 (26.9%)
		36-45	42 (53.8%)
		>45	15 (19.3%)
Gender	Females	60	(76.9%)
	Males	18	(23.1%)
CEAP classification	C ₂ : Varicose Veins (V.V.).	51	(65.4%)
	C ₃ : V.V. with edema.	12	(15.4%)
	C ₄ : V.V. with skin changes without ulcer.	12	(15.4%)
	C ₅ : V.V. with healed ulcer.	3	(3.8%)
	C ₆ : V.V. with active ulcer.	0	(0%)
Patients' complaint	Heaviness	78	(100%)
	Visible varicose vein	75	(96.2%)
	Skin pigmentation	15	(19.3%)
	Muscle cramps	6	(7.7%)
	Bleeding	3	(3.8%)
	Total	78	(100%)
Managed limbs (93)	Left limb	27	(34.6%)
	Right limb	36	(46.1%)
	Both lower limbs	15	(19.3%)
	Total	93	(100%)
Anatomical	GSV along the whole length	51	(54.8%)
	GSV above the knee	39	(41.9%)
	Short Saphenous Vein (SSV)	3	(3.3%)
Vein reflux	GSV reflux	90	(96.7%)
	SSV reflux	3	(3.3%)
Diameter of GSV (mm)	At 5 cm Below SFJ		9.4±0.3
	Above knee		6.3±0.2
GSV puncture	At the knee	60	(64.5%)
	Below the knee	30	(32.3%)

Data are presented as numbers & percentages are in parenthesis.

Regarding to the patient complaint; the most common symptoms were heaviness and visible varices which were present in

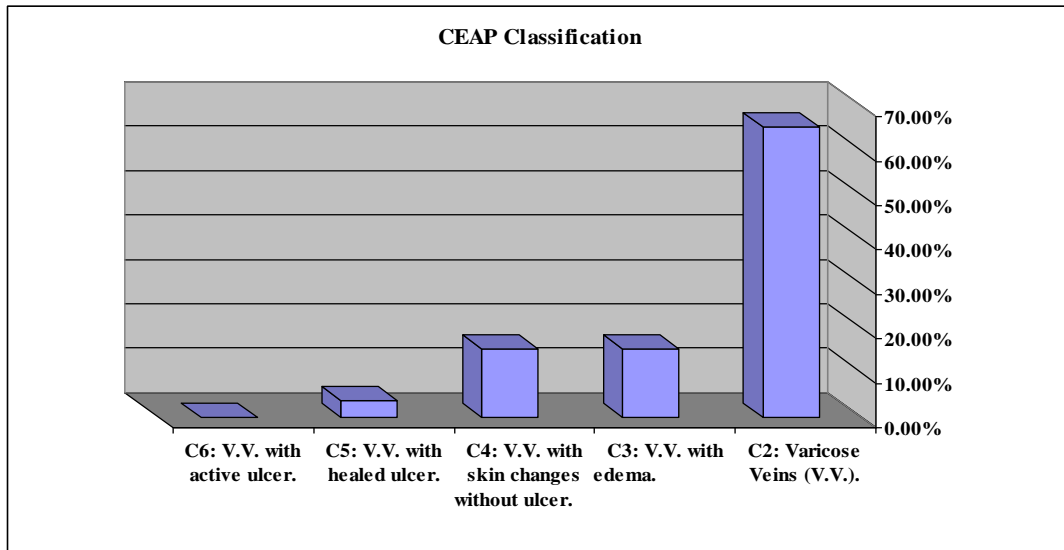
most cases, other symptoms included muscle cramps, bleeding and skin pigmentation were also detected. The

studied patients were classified according to CEAP classification which entails clinical, etiological, anatomical and pathophysiological classification. Upon review of characters of the affected veins; anatomical classification of varicose veins of the 78 patients (93 limbs) were mainly seen in great saphenous vein (GSV) reflux using duplex ultrasound that was used also to determine site of puncture of GSV either at level of the knee or at the ankle

and to detect site of SFJ (Table, 1 and graph 1).

Injection sclerotherapy was performed for some cases for residual dilated tributaries in the same session of MOCA (Table, 2).

By using a visual analog score (VAS); patients experienced significantly less postoperative pain at 1st 2 days (1.9 ± 0.6 , $p=0.001$) and to a great extent less pain at 7th day (0.8 ± 0.7 , $p= 0.001$, table 3).



Graph (1): CEAP classification.

Table (2): Sclerotherapy in the studied patients: (N=93 limbs in 78 patients)

Type of varicose vein	Type of procedure	Number (%)
GSV reflux without dilated tributary	MOCA alone	72 (77.4%)
GSV reflux with dilated tributaries	MOCA with sclerotherapy	18 (19.3%)
SSV reflux without dilated tributary	MOCA alone	3 (3.3%)

Data are presented as numbers & percentages are in parenthesis.

Table (3): Pain assessment using a visual analog score (VAS):

Variables	MOCA	p-value
1 st 2 days	1.9 ± 0.6	0.001 HS
7 days	0.8 ± 0.7	0.001 HS

Data are presented as numbers & mean ± SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test.

No mortality was reported but three patients of SSV reflux did not come for follow-up and data collection was applied on 75 patients (90 limbs) only. At 1-week PO, 3 (3.3%) had erythema, 3 (3.3%) hematoma, 6 (6.6%) bruising & ecchymosis. Residual varicosities were

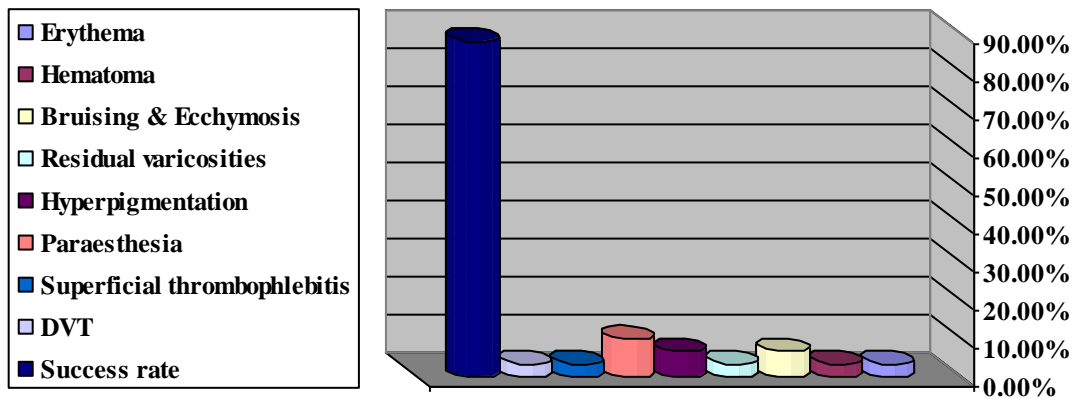
treated immediately by foam sclerotherapy, DVT and superficial thrombophlebitis was observed in 3 (3.3%); both were treated by conservative measures. Hyperpigmentation and paraesthesia were observed in 6 (6.6%) and 9 (10%) respectively (Table, 4 and graph, 2).

Table (4): Outcomes of 1-week postoperative intervention: (N=90 limbs in 75 patients)

Variables	MOCA	X ²	P-Value
Erythema	3 (3.3%)		
Hematoma	3 (3.3%)		
Bruising & Ecchymosis	6 (6.6%)		
Residual varicosities	3 (3.3%)		
Hyperpigmentation	6 (6.6%)	21	0.01 Significant
Paraesthesia	9 (10%)		
Superficial thrombophlebitis	3 (3.3%)		
DVT	3 (3.3%)		
Success rate	66 (88%)		

Data are presented as percentages and by using chi-square test

Outcomes of first week postoperative intervention



Graph. (2): Outcomes of first week postoperative intervention.

Table (5) Shows that the mean time to return back to work was 9.2 ± 1.7 days. At 3-6 months post-operative follow-up; there were skin pigmentation noticed in 3 (3.3%); residual varicosities in 6 (6.6%) and treated by foam sclerotherapy but

recurrence was noticed only in 3 (3.3%). Paraesthesia was markedly declined and observed in 3 (3.3%) limbs. Overall, no complications were reported in 42 (93.3%) (Table, 6) and graph, 3).

Table (5): Return back to work:

Variables	MOCA	<i>p</i> -value
Mean \pm SD	9.2 ± 1.7	0.001 HS
Range (days)	7-14	

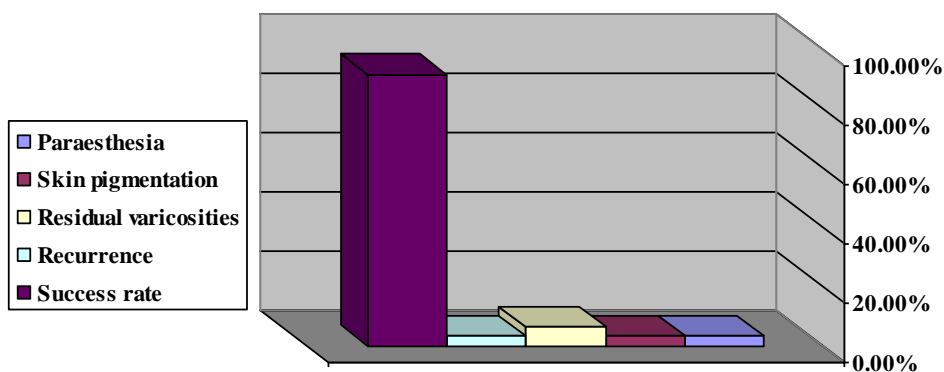
Data are presented as numbers & mean \pm SD; ranges are in parenthesis.

Table (6): Outcomes of 3-6 months post-operative: (N=90 limbs in 75 patients)

Variables	MOCA	χ^2	<i>p</i> -value
Paraesthesia	3 (3.3%)	20	0.01 Significant
Skin pigmentation	3 (3.3%)		
Residual varicosities	6 (6.6%)		
Recurrence	3 (3.3%)		
Success rate	69 (92%)		

Data are presented as percentages and by using chi-square test.

Outcomes of 3-6 months post-operative



Graph. (3): Outcomes of 3-6 months post-operative.

Discussion:

Minimal invasive intervention for GSV reflux has been available for more than a decade. Many methods of this intervention were reported like endovenous thermal ablation as laser therapy (EVLT) and radiofrequency ablation (RFA), foam sclerotherapy, glue and MOCA in addition to others. These modalities have been mentioned in many national guidelines as the surgical “gold standard” for the management of varicose veins, given their safety profile and efficacy (22-24).

Thermal with local anesthesia, such as radiofrequency ablation (RFA) and endovenous laser ablation (EVLA), have replaced the traditional stripping. However, the use of these ablation procedures has the risk of skin burns, nerve trauma and pain. Furthermore, tumescent injection is painful. To avoid these complications and decrease pain,

nonthermal treatment methods, such as ultrasound-guided foam sclerotherapy (UGFS) and mechanochemical ablation (MOCA), have been accepted (25-27).

A new NTNT methodology utilizes a combination of both mechanical and

chemical treatments, again foregoing the use of heat energy entirely. A new catheter, Flebogrif (Balton, Warsaw, Poland), has entered the market. It combines endothelial damage done by radial retractable cutting hooks with chemical ablation through foam injection. The benefit of MOCA is, decrease of pain intra and post intervention, because no heat or tumescence injection are required (28,29).

In the present study, all patients were treated with MOCA using the Flebogrif catheter. Foam sclerotherapy was

performed for some cases for residual dilated tributaries in the same session. 60 (76.9%) females and 18 (23.1%) males were enrolled in this study with age strata; 25- 35 years: 21 (26.9%), 36-45 years: 42 (53.8%) and >45 years: 15 (19.3%). This data was more than that reported by Ammollo et al (30) and Tawfik et al (31) but less than that mentioned by Ilzecki et al. (32).

Regarding to the patients' complaints, the most common symptoms were heaviness and visible varices which were present in most cases, other symptoms like muscle cramps, bleeding and skin pigmentation were also seen. The studied patients were classified according to CEAP classification, most of cases were C₂ despite most of cases in other studies were C₄ (30-32).

Upon review of characters of the affected veins, anatomical classification of varicose veins of the 78 patients (93 limbs) were mainly seen in great saphenous vein (GSV) reflux using duplex ultrasound. This data was comparable to the study done by Ammollo et al (30).

By using a visual analog score (VAS), patients experienced significantly less postoperative pain at 1st 2 days and to a great extent less pain at 7th day. This data was similar to Van Eekeren et al. (33) and Shepherd et al. (34) who approved less post intervention pain after MOCA. This

less pain depends upon the fact that Flebogrif is done without thermal ablation or tumescent injection (25-27).

Annoying complications, such as deep venous thrombosis and superficial thrombophlebitis were observed in 3 (3.3%) and treated by conservative measures i.e., anticoagulation and there were no skin burns just skin pigmentation that decreased to a great extent after 6 months of follow up 3 (3.3%). This data was comparable to study done by Yücel et al. (35).

No mortality was reported and success rate at 1-week PO and 3-6 months follow up was 66 (88%) and 69 (92%) respectively. These results were comparable to the studies The VANISH-1 and VANISH-2 trials; where the ablation rates at 6-12 months in MOCA group were 77% and 85% respectively (36).

Conclusion:

MOCA utilizing Flebogrif catheter and completion foam sclerotherapy are considered very promising interventions to treat GSV reflux; being less invasive, highly effective with good quality of life, less pain, satisfactory cosmeses and rapid return to work.

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