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Original article

Comparative Study Between Antegrade vs Retrograde Mechano-Chemical Ablation (MOCA) of Great Saphenous Vein Reflux

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Abstract:

Background: Varicose veins are the commonest problem that causes significant morbidity in the lower limbs and thus lead to increased healthcare cost. Symptoms include pain, itching, burning, discomfort, swelling, postural cramps, night cramps and further it may lead to ulcer formation which is difficult to heal. Surgery is the gold standard in the treatment of varicose veins but Mechano-Chemical Ablation is a newer minimally invasive technique that is available for the treatment of varicose veins.
Objective: To compare the results, advantage, disadvantage and complications of Antegrade vs. Retrograde Mechano-Chemical Ablation of Great Saphenous Vein Reflux. **Patients and Methods:** This was a prospective randomized clinical trial that was conducted on 60 patients diagnosed with GSV reflux in Department of surgery - vascular unit of Benha University Hospitals and Department of Vascular surgery - Maadi Armed Forces Hospital to compare between antegrade and retrograde mechanochemical ablation (MOCA). **Results:** DVT after procedure was significantly higher in antegrade mechanochemical ablation group (p =0.04). There was no significant difference between both groups as regards patients' satisfaction and postoperative complications (itching, ulcers, superficial thrombophlebitis, hematoma) between the studied groups. **Conclusion:** Antegrade MOCA seems to be superior to retrograde MOCA for treating primary varicose veins, as it is technically feasible, with short operative time, good clinical results, short recovery time, early return to work and better clinical outcomes although DVT after procedure was significantly higher in antegrade than retrograde mechanochemical ablation (MOCA). Both antegrade and retrograde mechanochemical have a positive impact on the patients' quality of life.

Keywords: Mechano-chemical ablation; coronary artery bypass graft; antegrade

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Introduction

Varicose veins are the commonest problem that causes significant morbidity in the lower limbs and thus leads to increased healthcare cost. Symptoms include pain, itching, burning, discomfort, swelling, postural cramps, night cramps and further it may lead to ulcer formation which generally is difficult to heal. Surgery is the gold standard in the treatment of varicose veins but Mechano-Chemical Ablation is a new minimally invasive technique that is available for the treatment of varicose veins [(1)].

Up to 60% to 70% of varicose veins result from great saphenous vein (GSV) incompetence. Varicose veins have traditionally been treated with high ligation at the sapheno-femoral junction (SFJ) followed by stripping (high ligation and stripping [HLS]). However, recurrences after conventional surgery have been frequent (range, 13%-65% at 5 years) [(2)].

High ligation and stripping (HLS) of the GSV have achieved good clinical results and is still done nowadays. Traditionally, a varicose vein was treated with Trendelenburg and stripping for many decades. Since the start of the last century, a new technique was introduced with subsequent refinement and advance in technology [(3, 4)].

Multiple techniques for treating saphenous reflux have been developed over the years, including high ligation of the saphenous vein, saphenous vein stripping and ultrasound-guided sclerotherapy, as well as various combinations of these procedures. Most recently, endo-venous thermal ablation has also been identified as a viable treatment option for patients with saphenous reflux [(5)].

Over the last decade, technological progress has enabled the development and application of new minimally invasive therapies such as VNUS Closure endo-venous radiofrequency ablation (RFA) and endo-laser [(6)].

Radiofrequency ablation (RFA) and endo-venous laser therapy (EVLT) has gone to the same result. These methods have many benefits including fewer complications, quicker return to work and improved quality of life. Fast rack recovery entails reduced need for postoperative analgesia and improved cosmetic outcome. So, the National Institute of Clinical Excellence (NICE) 2015 guidelines recommends the use of endo-venous thermal ablation techniques (RFA and EVLA) as first-line treatment for truncal vein reflux [(7)] .

Mechano-chemical ablation is a new minimally invasive closure technique. It works by the mechanism of endothelial mechanical damage and chemical injury with a foam sclerosant infusion. Tumescent anesthesia is not required and no risks of heat-related injury to the surrounding tissue and structures [(8).]

Non-thermal, non-tumescent 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. Mechano-chemical truncal ablation offers the patients reduced intra-procedural 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 [(9).]

Aim of the work

The aim of the work was to compare the results, advantage, disadvantage and complications of Antegrade Vs. Retrograde Mechano-Chemical Ablation (MOCA) of Great Saphenous Vein Reflux.

Patients and methods

This prospective interventional study included 30 patients with primary lower limb varicose veins at the Vascular surgery unit of Benha university hospitals and Vascular surgery departments of Military hospitals during the period from June 2022

to June 2023. The study was done after approval from the Ethical Committee Benha Faculty of Medicine (approval code: M.S. 14.6.2021).

Prior to the study an informed written consent was obtained from the patients and every patient received an explanation of the purpose of the study and had a secret code number.

Inclusion criteria: Patients (male or female) with primary uncomplicated varicose veins, age from 18 to 60 years old, with incompetent great saphenous vein, intact deep venous system, vein diameter at the GSV ≥5.5 mm and ≤15mm, reflux in GSV >0.5 second, CEAP classification between C2 and C4.

Exclusion criteria: Patients with history of deep venous thrombosis, patients with recurrent varicose veins, patients with connective tissue disorders, pregnant women with varicose vein, patients refuse to be included in the study, arterial disease of lower limb (ABPI less than 0.8).

Patients were divided into two groups:

Group A: 15 patients were treated with Antegrade mechano-chemical ablation (MOCA) of GSV. **Group B:** 15 patients were treated with Retrograde mechano-chemical ablation (MOCA) of GSV.

All studied cases were subjected to the following:

Detailed history taking, including: Full history taking (Age, sex, weight, height, and BMI). Presence of other comorbidities such as HTN, DM, hyperlipidemia, and obesity. Full clinical examination. General examination (Heart rate, blood pressure, temperature). Local examination of the lower limbs (unilateral or bilateral).

Laboratory Assessment: CBC, coagulation profile, liver and kidney functions.

Radiological Assessment:

Doppler/duplex scan was done for all patients: Duplex scanning was performed to document the patency of the deep veins and to evaluate the extent and severity of the reflux in the superficial venous system (GSV, small saphenous vein and perforators) of patients.

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.

Antegrade mechano-chemical ablation of GSV:

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In this group of patients, a catheter was used to deliver a scelerosant agent simultaneously with the hooks of internal mandrile causes intimal damage leading to venous spasm and sclerosing of the GSV percutaneously the procedure was done in either Angio suite or an operating theatre using local anesthesia (Figure 1).

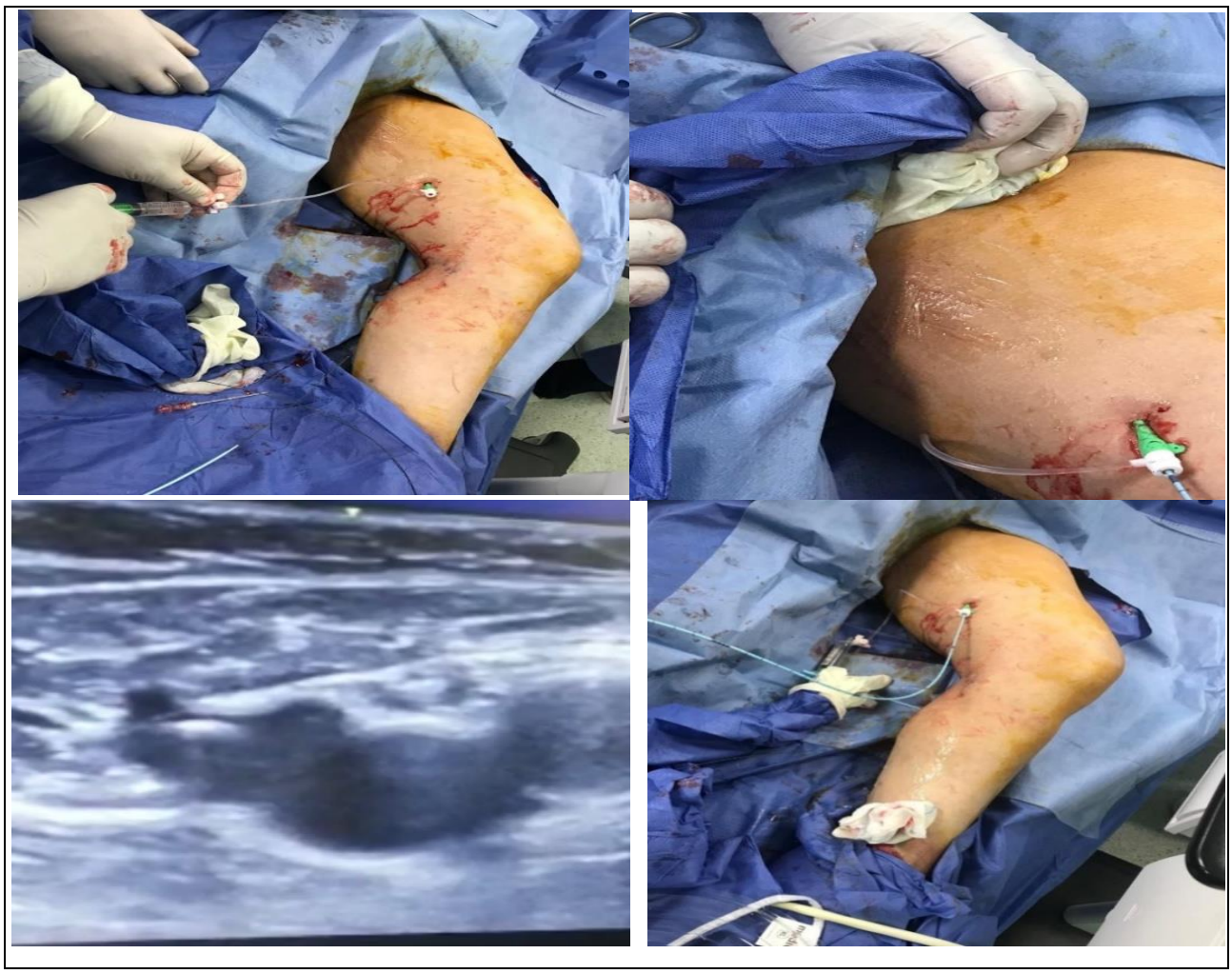

Figure 1: Antegrade mechano-chemical ablation of GSV

Retrograde mechano-chemical ablation of GSV:

In this group of patients, a catheter was used to deliver a scelerosant agent simultaneously with the hooks of the internal mandrile causes intimal damage leading to venous spasm and sclerosing of the GSV while open surgical ligation of sapheno-femoral junction is done, the procedure was in an operating theatre using spinal regional anesthesia (Figure 2).

Postoperative management:

Following our intercessions, patients were wrapped for multi weeks then clinical pressure stockings over the knee for1 month. Appendages treated with retrograde mechano-synthetic removal of the GSV were given prophylactic portion of anti-microbials for 5 days.

Follow up:

All patients were followed for: Operative, hospitalization and recovery time. Post operative pain, quick return to work and patients' satisfaction.

Clinical evaluation was performed on all subjects at 1 week, 3and 6 month.

Complication: DVT, pigmentation, itching, ulcers, and superficial thrombophlebitis. recurrence

Figure 2: Retrograde mechano-chemical ablation of GSV

Sample size:

This study was carried out to calculate the sample size by considering the following assumptions: - 95% two-sided confidence level, with a power of 80%. & an error of 5% odds ratio calculated= 1.115. The final maximum sample size taken was 30. Thus, the sample size was increased to 30 cases to assume any drop out cases during follow up.15 were treated with Antegrade Mechano-Chemical Ablation and 15 were treated with Retrograde Mechano-Chemical Ablation.

Ethical considerations:

The study was approved by the Ethics Committee of Faculty of Medicine, Benha University (approval code :{M.S. 14.6.2021}). There are adequate provisions to maintain privacy of participants and confidentiality of the data are as follows: The patients were given the option of not participating in the study if they did not want to. We put code numbers to each participate with the name and address kept in a special file. We hide the patients' names when we use the research. We used the results of the study only in a scientific manner and not to use it in any other aims.

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Statistical analysis

All data were collected, tabulated and statistically analyzed using SPSS 26.0 for windows (SPSS Inc., Chicago, IL, USA). Qualitative data were described using number and percentage. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. All statistical comparisons were two tailed with significance Level of *p*-value ≤ 0.05 indicates significant, *p* <0.001 indicates highly significant difference while, *p*> 0.05 indicates non-significant difference.

The used tests were Chi-square (X^2) test of significance was used to compare proportions between qualitative parameters. Independent T-test was used to compare between two independent groups with parametric quantitative data.

Results

Table (1): Comparison between both groups as regard demographic data

	Group A	**Group B**	**Test**	***p***
Age (years)			1.8	0.08
Mean ± SD	31.73 ± 2.55	33.67 ± 1.95		
Median (Minimum - Maximum)	32 (28-36)	34 (30-37)		
Sex			-	1
Male	8	8		
Female	7	7		
Side			0.08	0.43
Unilateral	10	9		
Bilateral	5	6		

X2: Chi Square; T: Two-Sample Independent t Test; *p* value >0.05: nonsignificant; *p* value <0.05 significant

This table shows that in group A, the mean age was 31.73 ± 2.55 years old, 8 of 15 were male and 10 of 15 had unilateral VV. In group B, the mean age was 33.67 ± 1.95 years old, 8 of 15 were male and 9 of 15 had unilateral VV. There was no significant difference between both groups as regard demographic data.

Table (2): Comparison between both groups as regards venous clinical severity score and operative time.

	Group A	**Group B**	**Test**	***p***
Venous clinical severity score			2	0.22
Mean ± SD	2.87 ± 1.46	3.13 ± 1.19		
Median (Minimum - Maximum)	3 (0-5)	3 (0-5)		
Operative Time (minutes)			9.1	**<0.001**
Mean ± SD	27.27 ± 0.88	35.27 ± 1.98		
Median (Minimum - Maximum)	27 (26-29)	36 (32-38)		

T: Two-Sample Independent t Test; *p* value >0.05: nonsignificant; *p* value <0.05 significant

This table shows that in group A, the mean venous clinical severity score was 2.87 ± 1.46, and the mean operative time was 27.27 ± 0.88 minutes.

In group B, the mean venous clinical severity score was 3.13 ± 1.19, and the mean operative time was 35.27 ± 1.98 minutes. There was a highly significant difference between both groups regarding operative time.

Table (3): Comparison between both groups as regard post operative pain, recovery time and return to work

	Group A	**Group B**	**Test**	***p***
Post operative pain (VAS)			8.5	**<0.001**
Mean ± SD	0.67 ± 0.49	2.07 ± 0.8		
Median (Minimum - Maximum)	1 (0-1)	2 (1-3)		
Recovery time, days			7.5	**<0.001**
Mean ± SD	6.88 ± 0.71	10.2 ± 1.18		
Median (Minimum - Maximum)	13 (12-14)	17 (14-18)		
Return to work, days			10.5	**<0.001**
Mean ± SD	5.5 ± 0.72	10.67 ± 1.59		
Median (Minimum - Maximum)	8 (7-9)	11 (8-13)		

T: Two-Sample Independent t Test; *p* value >0.05: nonsignificant; *p* value <0.05 significant

This table shows that in group A, the mean post operative pain (VAS) was 0.67 ± 0.49, the mean recovery time, was 6.88 ± 0.71 days, the mean return to work was 5.5 ± 0.72 days. In group B, the mean post operative pain (VAS) was 2.07 ± 0.8, the mean recovery time, was 10.2 ± 1.18 days, the mean return to work was 10.67 ± 1.59 days. There were high significant differences between both groups as regard post operative pain, recovery time and return to work.

Table (4): Comparison between both groups as regard patients' satisfaction

	Group A	**Group B**	**Test**	***p***
Patient satisfaction			3.333	0.06
Good	1	5		
Excellent	14	10		

X2: Chi Square; *p* value >0.05: nonsignificant; *p* value <0.05 significant

This table shows that in group A, 1 out of 15 had good results while 14 had excellent. In group B, 5 out of 15 had good results while 10 had excellent. There was no significant difference between both groups as regard patients' satisfaction.

Table (5): Comparison between both groups as regard complication

	Group A	**Group B**	**Test**	***p***
DVT	3	0	4.0	**0.04**
Pigmentation	2	1	1.1	0.55
Itching	2	1	1.1	0.55
Ulcers	1	0	1.4	0.4
Superficial thrombophlebitis	3	1	1.154	0.28

X2: Chi Square; *p* value >0.05: nonsignificant; *p* value <0.05 significant

This table shows that in group A, 3 out of 15 had DVT, 2 out of 15 had pigmentation, 2 out of 15 had itching while 3 had superficial thrombophlebitis. In group B, 0 out of 15 had DVT, 1 out of 15 had pigmentation, 1 out of 15 had itching while 1 had superficial thrombophlebitis. There was significant difference between both groups as regard DVT.

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Table (6): Correlations, univariate correlations, multivariate correlations, between DVT and risk factors

DVT				
Correlations		**Group A**	**Group B**	
Age	***r***	**0.495****		
	p	**<0.0001**		
"Venous clinical severity score "	***r***	**.560****		
	p	**<0.0001**		
Univariate Correlations				
			Group A	**Group B**
Age		**Correlation**	**0.348**	
		Significance	**<0.0001**	
"Venous clinical severity score"		**Correlation**	**0.412**	
		Significance	**<0.0001**	
		Multivariate Correlations		
Variable			**Group A**	**Group B**
Age		**Correlation**	**71.305**	
		Significance	**<0.0001**	
"Venous clinical severity score "		**Correlation**	**25.595**	
		Significance	**<0.0001**	

p value <0.05: statistically significant difference ; *p* value <0.001: statistically high significant difference; correlation regression: ANOVA

In univariate correlation regression, there were strong significant correlations (*p*>0.001) between DVT and Age and Venous clinical severity score.

This table shows that there were strong significant correlations between DVT, age and venous clinical severity score

In multivariate correlation regression, there were strong significant correlations (*p*>0.001) between DVT, age and Venous clinical severity score.

Discussion

Primary varicose veins have a profound effect on patients' quality of life. It affects about one third of the total population [from 20- 60%]. It presents with pain and discomfort, or venous ulcer, leading to a marked reduction in the quality of life with subsequent costs attributed to healthcare delivery [(10)].

Varicose veins are a common problem in the Western world. Epidemiological studies show that 21% of adults have some form of varicose veins, with women being more affected than men. The incidence of varicose veins increases steadily with age and is among the top ten complaints for which people visit their general practitioner. The main risk factors include prolonged standing or sitting, pregnancy, sex and age. The symptoms of varicose veins range from cosmetic complaints to venous ulcers [(11)].

High ligation and stripping of the great saphenous vein (GSV) has been the gold standard for GSV incompetence for more than 100 years. Surgery is performed under general or spinal anesthesia and is related to a high recurrence rate of 18 to 40% after five years. In addition, surgery may lead to significant postoperative symptoms (particularly pain and hematoma) and carries a risk of injury to the saphenous nerve [(12)].

Mechanochemical ablation [MOCA] is one of the newer treatment objectives to match the effectiveness of thermal ablation, but using a gentle sclerotherapy technique, with no need for tumescent anesthesia. A catheter was introduced into the vein; physical destruction to the endothelium of the vein occurs by the catheter positioned within the vein, and the spasm developed. Concurrently, injecting a sclerosing material through the hollow wire into the vein leads to protein denaturation, endothelial destruction, and endo-luminal fibrosis [(13)].

Mechanochemical ablation (MOCA) induces endo-venous vein occlusion by combined mechanical and chemical (liquid sclerosant) injury to the endothelium. It does not require tumescent anesthesia, because it does not heat the vein or adjacent tissues. There is also no risk of skin burns, nerve or muscle damage, and postoperative pain and the risk of thrombotic complications are significantly lower [(14)].

The safety and efficacy of MOCA was shown among 30 patients with primary GSV insufficiency who were treated using sodium tetradecyl sulfate (Sotradecol). At six months the anatomical success was 97%. After a follow-up period of two years, 27 of the 28 (anatomical success 96%) treated GSV were occluded [(15)].

Several reports have confirmed the efficacy of MOCA, with occlusion rates varying from 94 to 97%. No major complications such as deep vein thrombosis, pulmonary embolism or nerve injury were observed in all previous studies. Moreover, MOCA was associated with lower post-procedural pain and faster recovery than RFA [(16)].

It was indicated that this procedure has a very high effectiveness, reaching 97% in the first 6 weeks after the procedure. Effectiveness is maintained at the level of 96% over 2 years of follow-up. Elias estimated the effectiveness at 96.7% in a follow-up lasting 260 days. He also did not report complications, such as skin or nerve damage. A total of 28% of patients presented with small hematomas, 17% had local skin hardening, and 18% felt discomfort for more than a week after the procedure. High effectiveness of this method over follow-up periods ranging from 6 to 24 months has been confirmed in several other studies [(17,18)] .

The aim of the current work was to compare the results, advantage, disadvantage and complications of Antegrade Vs Retrograde Mechano-Chemical Ablation (MOCA) of Great Saphenous Vein Reflux.

In this study we found that in group A, the mean age was 31.73 ± 2.55 years old, 8 of 15 were male and 10 of 15 had unilateral VV. In group B, the mean age was 33.67 ± 1.95 years old, 8 of 15 were male and 9 of 15 had unilateral VV. There was no significant difference between both groups as regard demographic data.

Another study [(18)] found no significant difference when comparing demographics and procedural details between the antegrade group and those treated by the retrograde technique.

Another study [(19)] found that the groups were similar in terms of age, BMI, initial GSV size, C classification, and clinical disability score.

In this study, we demonstrated that in group A, the mean venous clinical severity score was 2.87 ± 1.46, and the mean operative time was 27.27 ± 0.88 minutes. In group B, the mean venous clinical severity score was 3.13 ± 1.19, and the mean operative time was 35.27 ± 1.98 minutes. There was a highly significant difference between both groups regarding operative time.

It was found that the median venous clinical severity score decreased significantly among antegrade MOCA group from 3.0 (IQR 2.0–4.75) to 1.0 (IQR 0.25–3.0) 6 weeks after treatment ($p<0.001$)[(20)] .

It was found that operative time ranged from 22 to 44 minutes and there a statistically significant decrease in time of

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antegrade group when compared to retrograde group [25.36±1.80 vs. 35.30±2.47 respectively, $p < 0.001$[21].

It was found that the Venous Clinical Severity Score significantly improved in both groups over the follow-up period and showed significantly lower levels in the antegrade MOCA group. The cases treated with antegrade MOCA had significantly shorter operative times when compared with the retrograde group (29.6±9 minutes vs. 36.9±10 minutes; p<0.001)[22] .

In this study we illustrated that in group A, the mean post operative pain (VAS) was 0.67 ± 0.49, the mean recovery time, was 12.93 ± 0.7 days, the mean return to work was 8.27 ± 0.7 days. In group B, the mean post operative pain (VAS) was 2.07 ± 0.8, the mean recovery time, was 16.4 ± 1.18 days, the mean return to work was 10.67 ± 1.59 v. There were high significant differences between both groups as regard post operative pain, recovery time and return to work.

It was demonstrated that antegrade MOCA is associated with a significant reduction in post-procedural pain after treatment [23].

Other researchers also described an antegrade technique for mechano-chemical endo-venous ablation (MOCA) of the GSV below the knee, which significantly improved the rates of healing of venous ulcers in their patient population (24).

Another study [25] found that antegrade MOCA is associated with significantly less postoperative pain and a faster recovery and work resumption compared with retrograde MOCA in the treatment of great saphenous incompetence.

It was demonstrated that antegrade MOCA group was associated with less pain at first postoperative day, and an early return to work (MOCA 3.5 ± 2.3 days vs. OS 14.2 ± 3.8 days, $p < 0.0001$) [26].

Another study confirmed these results, as they reported that there was minimal pain associated with the MOCA procedure [21].

In this study we cleared that in group A, 1 out of 15, had good results while 14 had excellent result. In group B, 5 out of 15 had good results while 10 had excellent. There was no significant difference between both groups as regard patients' satisfaction.

It was found that 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% among retrograde group and 96% among antegrade group and minimal complications [18] .

Another study [20] found that the median patient satisfaction with the treatment was 8.5 (IQR 8–9) on a 10-point scale among the antegrade group and 8 (IQR 7–9) among the retrograde group, with no significant difference between the two studied groups.

Another study [12] demonstrated that the clinical efficacy of antegrade MOCA is like that of the retrograde technique, at least at one to two years.

In this study we found that in group A, 2 out of 15 had DVT, 2 out of 15 had pigmentation, 2 out of 15 had itching while 3 had superficial thrombophlebitis. In group B, 0 out of 15 had DVT, 1 out of 15 had pigmentation, 1 out of 15 had itching while 1 had superficial thrombophlebitis. There was no significant difference between both groups as regards complication.

Another study [18] found that there was no significant difference between antegrade and retrograde MOCA regarding complications. No major complications such as nerve damage, deep vein thrombosis, or infection were observed. Thrombophlebitis was found in 10%, ecchymosis in 9%, and one patient developed a hematoma at the access site, all of which were managed conservatively and resolved without requiring further treatment.

Another study [27] found that there was significant improvement after treatment, as shown by the marked reduction in the CEAP class and the VCSS in both

antegrade and retrograde techniques of MOCA.

It was demonstrated that postoperative complication during the first week tended to be lower with MOCA [12] .

In this study we demonstrated that there were strong significant correlations between DVT and age and venous clinical severity score.

Another study [28] found that the venous clinical severity score was strongly associated with the presence of DVT ($p < 0.0001$).

A previous study reported that DVT is more common with increasing age [29].

An association between increasing age and a higher incidence of DVT was also reported. Patients >40 years of age are at significantly increased risk compared with younger patients, and risk approximately doubles with each subsequent decade [30].

Another study [31] found that women with prolonged prothrombin time have an increased risk of developing DVT by about 16 times.

Another study [32] found that VCSS showed a strong positive correlation with DVT, indicating that a higher VCSS is associated with a greater impact on the quality of life.

In a study done on 60 patients, it was found that increased VCSS values directly correlate with increased CEAP scores [33] .

Conclusion

Antegrade MOCA seems to be superior to retrograde MOCA for treating primary varicose veins, as it is technically feasible, with short operative time, provides good clinical results, short recovery time, early return to work and better clinical outcomes although DVT after procedure was significantly higher in antegrade than retrograde mechanochemical ablation (MOCA). Antegrade and retrograde mechanochemical ablation (MOCA) are both related to an improvement in quality of life.

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