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## Original article

# LASER versus Mechanochemical Ablation in Treatment of Primary Varicose Vein of Lower Limb

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## ABSTRACT

**Background:** Endovenous thermal techniques, such as endovenous laser ablation [EVLA], are the recommended treatment for varicose veins. Non-thermal techniques such as Mechanochemical ablation [MOCA] have potential benefits.

**Aim of the work:** To compare EVLA with MOCA in the treatment of primary varicose vein of the lower limb.

**Patients and Methods:** 40 patients who had primary great saphenous varicose veins [VV] admitted at the Vascular Surgery Department, Al-Azhar University Hospital, New Damietta, Egypt. They randomized into two equal groups each one included 20 patients group [1] treated by EVLA and group [2] treated by MOCA.

**Results:** The time of operation of studied patients ranged from 22 to 44 minutes, and there a statistically significant decrease in time of group 2 compared to group 1. [25.36±1.80 vs. 37.30±2.47 respectively]. Postoperative pain in studied patients ranged from 0 [no pain] to 7 [severe pain], there statistically significant decrease in pain of group 2 compared to group 1. As regard to induration, it was reported in 4 patients, representing 20% of group 1 [4] patients, were significant differences between groups 1 and 2 [20% vs. 0% respectively]. At the end of the sixth month postoperatively, as regard complete occlusion of the great saphenous vein [GSV] vein, there was statistically no significant difference between group 2 when compared to group 1 [92.5% vs. 95% respectively].

**Conclusions:** MOCA was associated with better results on short-term follow-up.

**Keywords:** Mechanochemical ablation; Phlebogriffe; thermal ablation; Treatment; Varicose veins.

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\* Main subject and any subcategories have been classified according to the research topic

## INTRODUCTION

Primary varicose veins have a profound effect on patients Quality of life<sup>[1]</sup>. It affects about one-third of the total population [from 20- 60%]<sup>[2-3]</sup>. It presents with pain and discomfort, or venous ulcer, leading to a marked reduction of the quality of life<sup>[4]</sup> with subsequent costs attributed to healthcare delivery<sup>[5]</sup>. Many proposed conservative management with compression hose; however, strong evidence that this alone is sufficient is lacking. Furthermore, patients have a higher rate of intolerance with this therapy<sup>[6]</sup>. Endovenous laser Ablation [EVLA], is a commonly accepted treatment modality and is recognized as the first-line management option for truncal varicose veins<sup>[7,8]</sup>. This approach improves recovery with less pain, leading to improvement of the life quality when compared with traditional surgical ligation with stripping, and had been associated with improved efficacy when compared with injection of foam sclerotherapy<sup>[9,10]</sup>. However, EVLA carry the risk of soft tissue and/or nerves damage. Thus, patients are treated with EVLA require tumescent anesthesia, which requires multiple injections around the length of the target vein. However, postoperative pain was reported by some patients for many postoperative weeks<sup>[11]</sup>.

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<sup>[12-13]</sup>. According to researchers' best of knowledge, to date, limited studies have been performed to compare MOCA with EVLA in the treatment of primary varicose veins of the lower limb. For example, Tawfik *et al.*<sup>[14]</sup> conducted a randomized controlled trial [RCT] to compare EVLA [50 patients] and MOCA [50 patients] and reported that MOCA is superior than EVLA for treatment of primary varicose veins, as it is feasible, safe and effective with a lower rate of postoperative complications and superior clinical

outcome. In addition, Mohamed *et al.*<sup>[15]</sup> conducted another RCT to compare MOCA and EVLA for superficial venous incompetence and concluded that both are highly effective, but axial occlusion rates were better with EVLA.

## AIM OF THE WORK

The current trial had been designed to compare EVLA with MOCA in the management of lower limb primary varicose veins.

## PATIENTS AND METHODS

The present study included 40 patients; the number calculated by Epi Info™ version: 7.2.3.1 using Fleiss formula to achieve a power of 80.0% and type-I error of 5%. All patients were presented by the primary lower limb varicose veins and underwent operative intervention at Al-Azhar University Hospital, New Damietta, Egypt, from December 2018 to October 2019. They were divided into two equal groups [randomized by closed envelop method]: Group 1 included patients treated by EVLA, and Group 2 included patients' treatment by MOCA. Inclusion criteria were: patient age ranged between 18 and 45 years, both sexes, with the primary symptomatic varicose vein, reflux of great saphenous vein [GSV] diameter <10 mm, reflux more than 0.5 seconds in the saphenous veins, and clinical grades from C2 to C6 according to Clinical-Etiological-Anatomical-Pathophysiological [CEAP] classification. On the other side, exclusion criteria were: <sup>[1]</sup> known allergy to medications and/or dressings used in the treatment <sup>[2]</sup> right to left circulatory shunt, evidence of acute deep vein thrombosis [DVT] or ipsilateral occlusion, <sup>[3]</sup> pelvic vein insufficiency, <sup>[4]</sup> active or recent superficial thrombophlebitis [within 6 weeks], <sup>[5]</sup> impalpable foot pulses with the Ankle Brachial Index 0.8 or less<sup>[6]</sup>, pregnancy or breastfeeding <sup>[7]</sup>, active malignancy, and <sup>[8]</sup> immobility.

### Pre-operative evaluation and preparation:

Each patient was subjected to history taking, clinical examination [systematic general & local examinations] and different investigations. Investigations were laboratory [complete blood count [CBC], serum creatinine, alanine amino-transferase [ALT], aspartate aminotransferase

[AST], total bilirubin, serum albumin, prothrombin time [PT] and International Normalized Ratio [INR]] and radiological in the form of Duplex ultrasound on the venous system of the lower limb. All patients had normal values of laboratory investigations, and all had a primary lower limb varicose vein, incompetent saphenofemoral junction [SFJ], their reflux was more than 0.5 seconds, and GSV diameter <10 mm. All patients received data about the indications of intervention and alternatives procedure, [e.g., continued medical management], risks, and benefits [relief of symptoms attributable to the venous insufficiency.... etc.].

No preoperative analgesics or anticoagulants were received. However, antibiotics were administered to all patients. All patients were informed that unforeseen anatomic issues might cause failure [i.e., the inability to perform an endovenous procedure], in which case the patient needs to be treated by surgical treatment. Despite the successful technical application of the endovenous device, non-closure vein or late vein recanalization could occur and may be more common in larger diameter veins. Associated varicosities that have not been treated at the time of the EVLA or MOCA should become less noticeable but may not completely disappear. Whether simultaneous versus delayed sclerotherapy or phlebectomy was performed should be understood before the procedure.

**Compression stockings:** Patients had Class II after EVLA or MOCA.

**Schedule duplex appointment:** A post scheduled appointment was done for follow up duplex examination two weeks and 6 months after EVLA and MOCA to assess DVT and recanalization of the vein.

**Vein mapping/markings:** On the day of the procedure, the veins to be ablated was marked [i.e., marked with permanent ink] with duplex ultrasound to guide the administration of tumescent anesthesia.

#### **Operation [procedure and technique]:**

**EVLA group:** Different materials had been prepared in advance [Laser generator, Laser fibers, Duplex US, **Figure 1**], tools for skin preparation, and sterile gloves. In addition, draping materials [sterile drape, bag for a foot, 10 ml syringe sized 16 to 20- gauge needles to draw up anesthetic, 25 to 30- gauge needles to inject] were also prepared. The sheath kit included wire [0.035"], 5F or 6 F device dilator/sheath, and an additional guidewire [0.018"]. Prepared wound dressings were gauze and elastic wrap or thigh-high elastic stocking with gauze pads, or adhesive strips or bandages. The laser generator machine had been checked for proper function. A local anesthetic was then delivered for the puncture site [1% lidocaine without epinephrine]. Sometimes, bicarbonate was added to help more reduction of pain caused by multiple injections. Tumescent anesthesia was then delivered in the form of 500 ml saline, 25 ml 2% lidocaine, and 10ml sodium bicarbonate 8.4%.



**Figure [1]:** [ARC LASER, FOX III]: Laser generator and Laser fibers



**Figure [2]:** Peri-venous tumescent anesthesia was injected into the fascial space surrounding the GSV under cross-sectional sonographic guidance along its length.

Peri-venous tumescent anesthesia was injected into the fascial space around the GSV under cross-sectional ultrasound guidance along its length. The amount of tumescent anesthetic was about 400–500cc. A needle puncture obtains access to the great saphenous vein. The first attempt at annulation of the vein was the most likely to be successful. Just below the knee and with the patient's operative leg externally rotated, this site

becomes more suitable than in the distal or mid-thigh. To avoid multiple punctures, we punctured the veins without local anesthesia, which can cause vein spasm. Then the needle unspheres from the vein, and at the entry of the guidewire, a small incision was made to permit the passage of the introducer sheath 5 / 6 Fr and the dilator over the wire. The guidewire and the dilator were removed, and the sheath remains.



**Figure [3]:** The GSV is punctured just below the knee, and the guidewire is located within J-tip 0.035 inch guidewire was passed under ultrasound guidance up towards the SFJ.

A5-F long introducer sheath was placed into the GSV over the guidewire. The sheath's interred length ranged from 35 cm to 50 cm, depending on the length of GSV to be treated. Then, the LASER fiber, which mostly has a diameter of 600µm, was passed under US guidance through the sheath and advanced at the SFJ. The perfect position of the tip of the laser fiber was at 2 mm from the junction and that usually just below the inferior superficial epigastric vein. This vein was an

important landmark for the site of the fiber tip in order to have a safe distance from the SFJ, avoiding major complications, such as DVT, also, the direction of blood flow from the abdominal wall vein towards the femoral vein through the superficial inferior epigastric. Thus, keeping the patency of this vein is important for the maintenance of the patency of the femoral vein. Then allowing the laser energy to be fired and after that the laser fiber and sheath were slowly pullbacks till, they reached one centimeter above

the site of puncture to avoid skin burn. For example, the 1470 nm wavelength the treated veins with a proper energy reduction. The continuous mode could be used. In the continuous mode, the delivered energy depends on the pullback speed and the wattage. A withdrawal rate of laser fibers depends on the equipment and the delivered energy but was ranged from 1 to 4 mm/s. Laser energy delivery ranged from 50 to 150 J/cm. After setting parameters to achieve a bloodless vein, the patient was positioned into the Trendelenburg position. This maneuver is accompanied by the tumescent administration helps to increase the contacted surface area between laser tip and wall of the vein and to reduce the amount of blood which could absorb even a small part of the energy stimulating clot formation. Then the fiber was pulled back as a nonstop in continuous mode. After the complete withdrawal of the catheter, a follow up US examination was performed to reveal the absence of flow and lack of compression on the vein at operative theater.

**MOCA group:** Preparation materials: [Phlebogriffe catheter, Aethoxeskelrol 2% [2 ampoules], Duplex US] skin prep, sterile gloves. Draping materials: sterile drape, bag for the foot. 10 ml sized syringe with 16 to the 20-gauge needle to draw up anesthetic. Sheath kit: wire [0.035"], 5F or 6 F device dilator/sheath. Additional guide wires: glide

wire [0.035. Wound dressing: Gauze and elastic wrap or thigh-high elastic stocking with gauze pads, or adhesive strips or bandages. The use of the Phlebogriffe catheter was attic. After sterilization of the skin, the great saphenous vein [GSV] is punctured with a needle-sized 18G, distally from its incompetent part or in the most distal part of the incompetent vein. In the case of a failed puncture, a venesection can be done.

Then, a 0.035" J-type guide wire was introduced into the vein, and over this guidewire, the sheath was introduced. Through this introducer, the Phlebogriffe was inserted over the guidewire. The catheter should be clearly visible on ultrasound, enabling precise placement of its terminal part in the SFJ before "opening" in the saphenofemoral junction. While the metal shank of the Phlebogriffe remains in the ideal position, the catheter was pulled distally, which allows the deployment of the claws in the saphenofemoral junction. Then, the whole device – catheter and shank with open claws were pulled distally with a fixed speed of about 1 cm per second. Simultaneously, beginning at the level of about 3 cm distally from the saphenofemoral junction, the sclerosing foam was administered [3% polidocanol], similarly to the standard foam sclerotherapy using a long catheter.



Figure [4]: Phlebogriffe set



Figure [5]: Guided US insertion of the needle most distal part of GSV



Figure [6]: Injection of foam

During the injection of foam, the pressure was applied at the bulb of the GSV in order to reduce the risk of rapid migration of foam to the femoral vein, approximately 1cm foam along 5cm vein distance. Mechanical injury of venous endothelium concomitant with the administration of sclerosing foam was continued along the entire treated vein, if necessary, up to the area of vascular access. In the end, the catheter was removed, manual pressure was applied at the venous puncture site, and when there was no more bleeding, a slightly compressing dressing was done.

**The primary outcomes** included postoperative pain [measured by Numeric Rating Scale [NRS-11]], induration, and the duration to return to the work.

**The secondary outcomes** were efficacy at 2 weeks and 6 months using duplex ultrasound to show complete occlusion or recanalization of the treated vein.

**Statistical analysis:** The collected data were designed, tabulated and analyzed statistically by Statistical Package for Social Science [SPSS], version 16 [SPSS Inc., USA] for windows. For numerical data, arithmetic mean [measure of central tendency], standard deviation [SD] [measure of dispersion], minimum and maximum [indicate range] were calculated, while for qualitative findings, the frequency [number] and percentages were calculated. Comparison between groups done by student [t] test for normally distributed numerical variables and Chi-square test for qualitative data. For comparison between two different points of time, the paired-

samples [t] test was used for normally distributed numerical variables, and the Wilcoxon test was used for non-parametric data.  $P < 0.05$  was considered significant.

## RESULTS

In the present work, age ranged from 18 to 45 years, and there was no significant difference between groups 1 and 2 [ $26.05 \pm 3.88$  vs.  $27.10 \pm 3.64$  respectively,  $p = 0.38$ ] [Table 1].

Males were 16 patients [40.0%], and females were 24 [60.0%], and there were no significant differences between groups 1 and 2 [males were 45% and 35% of groups 2 and 1 respectively,  $p = 0.51$ ]. Operative time ranged from 22 to 44 minutes, and there a statistically significant decrease in time of group 2 when compared to group 1 [ $25.36 \pm 1.80$  vs.  $37.30 \pm 2.47$  respectively,  $p < 0.001$ ] [Table 2].

Post-operative pain in studied patients ranged from 0 [no pain] to 7 [severe pain], and there was a statistically significant decrease in pain in group 2 when compared to group 1 from the 1<sup>st</sup> day till the 7<sup>th</sup> day [Figure 7].

At the end of the second postoperative week, complete occlusion was observed among 95% [19 patients] of group 1 and in 90% [18 patients] of group 2 with no significant difference [ $p = 0.54$ ]. At the end of the sixth month postoperatively, there was no significant difference between groups 2 compared to group 1 regarding complete occlusion of the GSV [92.5% vs. 95% respectively] [Table 3].

**Table [1]:** Comparison between groups as regards to patient age [year]

	Mean	SD	Min.	Max.	P value
Group 1	26.05	3.88	18.0	15.0	0.38 [ns]
Group 2	27.10	3.64	19.00	33.0	
Total	26.57	3.75	18.0	45.0	

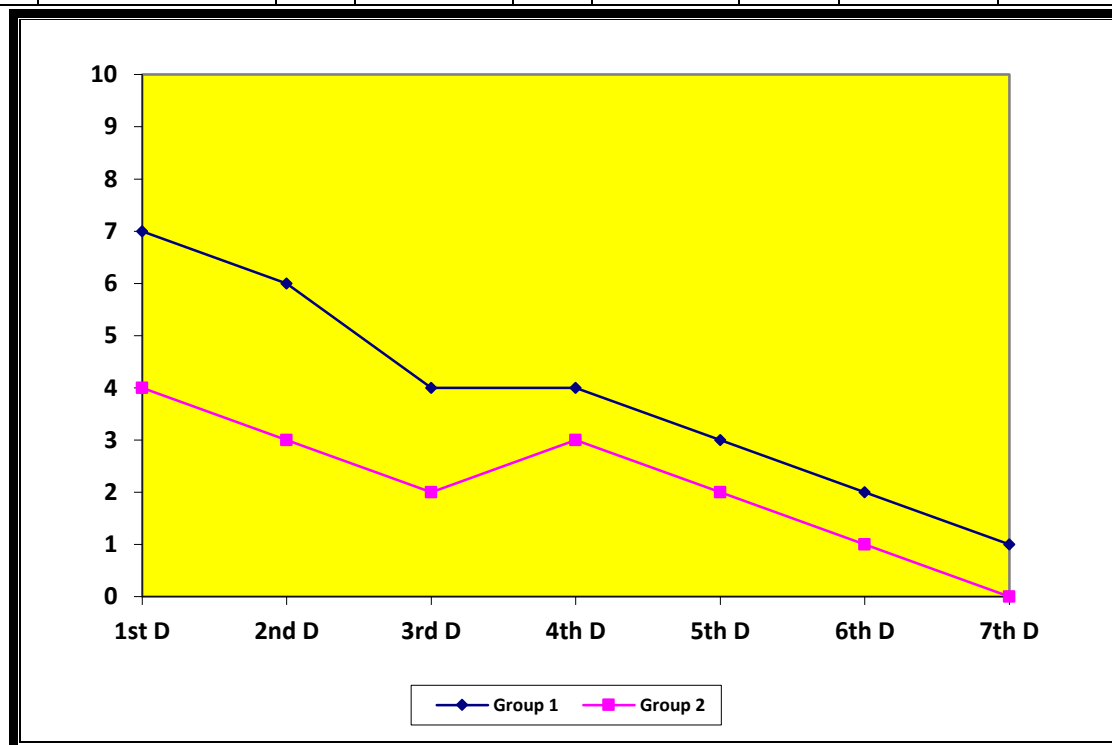
SD: standard deviation, Min.: minimum, Max.: Maximum, ns: non-significant

**Table [2]:** Comparison between groups as regard operative time [minute]

	Mean	SD	Min.	Max.	t	P
Group 1	37.30	2.47	33.00	44.00	21.29	<0.001
Group 2	25.36	1.80	22.00	27.00		
Total	31.33	6.39	22.00	44.00		

**Table [3]:** Comparison between groups as regard to postoperative outcome after 6 months:

		Groups				Total		P-value
		Group 1		Group 2				
		N	%	N	%	N	%	
Complete occlusion		19	95%	18	90%	37	92.5%	0.54 [ns]
Recanalization		1	5%	2	10%	3	7.5%	
Total	Yes	19	95%	18	90	37	92.5%	0.54 [ns]
	No	1	5%	2	10 %	3	7.5%	

**Figure [7]:** Postoperative pain measuring based on the Numeric Rating Scale [NRS-11] from 0 to10 for 7 days.

## DISCUSSION

Results of this study according to recanalization after EVLA after the sixth month postoperatively is 1 of 20 patients [5%] agree with **Myers and Jolley** [16] who reported recanalization after EVLA in 29 of 509 patients [5.6%] over a 5-year period. The Flebogrieff catheter provides high efficiency, a high occlusion rate, and technical success at the end of

six months [92.5%], which parallels **Zubilewicz et al.** [17] who reported a 96.0% success rate after three months of follow-up. The system is also characterized by good cosmetic effect and a low complication rate. The procedure performed with the Flebogrieff catheter seems to improve the quality of life [due to its low complications and good cosmetic effects] in the postoperative period. **Zubilewicz et al.** [17] study agree with that.

Postoperative pain was lower in the MOCA with significant reduction compared to the EVLA group from the first to the seventh days. However, **Tawfik *et al.***<sup>[14]</sup> reported non-significant difference between both groups, as pain improved significantly postoperatively in the two groups.

In addition, **Mohamed *et al.***<sup>[15]</sup> reported non-significant difference between both groups regarding procedural and postoperative pain.

Overall, **Suhartono *et al.***<sup>[18]</sup> revealed that, the EVLA group, total recanalization occurred in [1/19] [5.2%] and in MOCA group [2/24] [8.3%], which seems to be analogous to the current work [in EVLA group total recanalization [1/20] extremities [5%] and MOCA group, total recanalization occurred in [2/20] extremities [10%]].

There were no major complications; specifically, no DVT was encountered in our study, even without any prophylactic anticoagulant being used.

**Tawfik *et al.***<sup>[14]</sup> compared MOCA to LASER ablation and reported that both groups were comparable regarding short-term recurrence rate. However, MOCA was associated with lower rates of phlebitis. Moreover, patients in the MOCA group had been returned to work faster than their counterparts treated using EVLA.

In addition, **Park *et al.***<sup>[19]</sup> conducted a study on 355 limbs [236 patients] treated by EVLA and reported a 100% success rate. The treatment effect was sustained in 100.0%, 99.5%, and 99.3% after one week, one month, and three months, respectively. However, and in contradiction to the results of the present work, they reported a higher rate of complications [bruising [21%], pain [15%], and paresthesia [4%]].

The potential safety and high success rate obtained by MOCA in the present trial is discovered in previous studies.

For example, **Elias and Raines**<sup>[20]</sup> reported that the primary closure rate was 96.7%, respectively, with no side effects.

Other studies confirmed these results, as **Bootun *et al.***<sup>[21]</sup>, who reported that there was minimal pain associated with the MOCA procedure.

Moreover, **Kim *et al.***<sup>[22]</sup> showed that MOCA's primary high occlusion rate was sustained till the end of 2 years of follow up.

**In conclusion**, MOCA seems to be superior than EVLA for treating primary varicose veins, as it is technically feasible, with short operative time, provides good clinical results, and better clinical outcomes. But, due to the small number of patients included in the current work [a limiting step of the current study], future larger studies are required to generalize results. Another limiting step is the shorter duration of follow-up [6 months].

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