

Post ablation recanalization of varicose veins of the limbs: Comparison ablation method of mechanochemical and laser procedure

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Abstract. Endovenous ablation has been performed for varicose veins of the limbs in Indonesia since 2010. Endovenous laser ablation (EVLA) therapy has been performed in Cipto Mangunkusumo Hospital (RSCM) in Jakarta, and mechanochemical ablation (MOCA) has been conducted in Fatmawati Hospital. This was a descriptive analytical study, with a cross-sectional design to analyze post-ablation recanalization after MOCA and EVLA procedures. Patients who had undergone MOCA or EVLA treatment were interviewed 3–18 months after the procedures. All the patients underwent vascular ultrasonography (USG) of the operated limb to assess recanalization. Secondary presurgery data were obtained from the patients' medical records. The clinical characteristics of the subjects were recorded to compare the potential correlation between these characteristics and recanalization post-MOCA and EVLA procedures. All the data were analyzed using SPSS ver. 20.0. The study consisted of 43 limbs: 24 treated by MOCA and 19 treated by EVLA. Most subjects in the MOCA group were <60 years (20/24), and 16 of the subjects were women. In the EVLA group, nine patients were <60 years, and 19 were ≥60 years, 15 of whom were women. The body mass index (BMI) of the majority (18/24) of the subjects in the MOCA group was normal, whereas most of the patients in the EVLA (10/19) group were overweight. In the MOCA group, the largest diameter of the vena saphena magna (VSM) in 20/24 extremities prior to treatment was VSM 4–7 mm, whereas the largest diameter in the EVLA group prior to treatment was >7 mm in 13/19 extremities. In the MOCA group, total recanalization occurred in 2/24 extremities, and partial recanalization occurred in 8/24 extremities. In the EVLA group, total recanalization occurred in 1/19 extremities, and partial recanalization occurred in 3/19 extremities. The association between the clinical characteristics of the patients and recanalization was not statistically significant ($p > 0.05$). The recanalization tendency was higher in the MOCA group than in the EVLA group. Although there was no statistically significant association between the clinical characteristics of the patients and recanalization, the largest diameter of the VSM presurgery (>7 mm) was higher in 3/4 extremities in the MOCA group, as compared to 3/13 extremities in the EVLA group.

1. Introduction

The management of varicose veins of the limbs began in the early 20th century in the form of sapgenofemoral junction ligation, vein stripping, sclerotherapy, and phlebectomy. Nonsurgical management included graduated compression stockings and drug therapy aimed at symptom



alleviation [1,2]. In the last decade, developments in minimally invasive intravenous ablation surgery have led to its use in cases of reflux disease affecting the saphenofemoral junction and vena saphena magna (VSM) [2,3].

In the U.S., minimally invasive intravenous therapies, such as radiofrequency ablation, have been in use since 1999, and endovenous laser ablation (EVLA) treatment has been available since 2001. Both methods use thermal energy to perform ablation of varicose veins [4,5]. In Indonesia, endovenous surgery for varicose veins of the limbs began in 2010 at Cipto Mangunkusumo Hospital and other hospitals in Jakarta. EVLA was first performed at Fatmawati General Hospital in 2013, and mechanochemical ablation (MOCA) was first conducted at the same hospital in 2014. To date, there have been no studies of the success or recurrence of varicose veins of the limbs treated by MOCA and EVLA in Indonesia.

2. Materials and Methods

This was an analytical descriptive study, with a cross-sectional design of patients with venous reflux disease affecting the saphenous magna vein treated by MOCA or EVLA. The study population consisted of patients with reflux of the saphenous magna vein treated by MOCA or EVLA. The inclusion criteria were patients with reflux of the saphenous magna vein treated by MOCA or EVLA for the first time in more than three weeks, in addition to willingness to be interviewed and undergo a vascular ultrasonography (USG) examination. The exclusion criteria were patients with reflux of the saphenous magna vein who had been treated by MOCA or EVLA previously, patients who had been undergone MOCA or EVLA less than three weeks earlier, and patients who were not willing to be included or to be re-examined after MOCA or EVLA.

Data were obtained from the patients' medical records, interviews with the patients, and vascular USG examinations. Primary data recorded included the duration of post-treatment pain, return time to normal activity, and the patient's satisfaction with the treatment. Secondary data recorded were the patient's age, sex, and body mass index (BMI), as well as the largest diameter of the vena saphena magna (VSM) before treatment. Data on vascular recanalization was based on the results of the USG examination. This study was approved by the Medical Research Ethics Committee of the Faculty of Medicine, Universitas Indonesia, and all the patients included in the study sign written informed consent forms prior to participating in the study. All the data were processed using SPSS, version 20. A paired samples t-test was conducted for data with a normal distribution, and Wilcoxon's test was conducted for data without a normal distribution. The data distribution was assessed by the Kolmogorov–Smirnov test. Statistical significance was accepted at a p value < 0.05.

3. Results and Discussion

3.1 Results

In this study, there were 43 patients with sphenous magna venous insufficiency, 24 of whom were treated by MOCA and 19 of whom were treated by EVLA. The patients were stratified according to age (<60 years and ≥ 60 years). In the MOCA group, most of the patients (20/24) were <60 years. In the EVLA group, the majority of the patients (10/19) were ≥ 60 years. The majority of patients in the MOCA group (16/24) and EVLA group (15/19) were females. The BMI was categorized according to the classification of the World Health Organization (WHO). In the MOCA group, most of the patients (18/24) were in the normal category, whereas most of the patients (10/19) in the EVLA group were classified as overweight. Prior to treatment, the largest diameter of the VSM in the MOCA group was 4–7 mm in 20/24 limbs, and it was >7 mm in 4/24 limbs. In the EVLA group, prior to treatment, the largest diameter was >7 mm in 13/19 limbs. Postoperative pain of less than one week's duration was reported by 12/24 subjects in the MOCA group and 12/19 patients in the EVLA group. The return time to normal activity was less than one week in 15/24 patients in the MOCA group and 18/19 subjects in the EVLA group. In the MOCA group, 22/24 patients expressed satisfaction with the surgery, whereas 18/19 patients in the EVLA group were satisfied. The details are presented in Table 1.

Table 1. Characteristics of the MOCA and EVLA groups

Variables	Frequency (<i>n</i> %)	
	MOCA	EVLA
<i>N</i>	24 (55.8%)	19 (44.1%)
Age		
<60 years	20 (83.3%)	9 (47.3%)
≥60 years	4 (16.6%)	10 (52.6%)
Sex		
Male	8 (33.3%)	4 (21.05%)
Female	16 (66.6%)	15 (78.9%)
BMI		
<25 kg/m ²	18 (75%)	9 (47.3%)
≥25 kg/m ²	6 (25%)	10 (52.6%)
Preoperative venous diameter		
4–7 mm	20 (83.3%)	6 (31.5%)
>7 mm	4 (16.6%)	13 (68.4%)
Duration of postoperative pain		
≤1 week	12 (50%)	12 (63.1%)
>1 week	12 (50%)	7 (36.8%)
Return time to normal activity		
≤1 week	15 (62.5%)	18 (94.7%)
>1 week	9 (37.5%)	1 (5.2%)
Patient satisfaction score		
1–3	2 (8.3%)	1 (5.2%)
4–5	22 (91.6%)	18 (94.7%)

Recanalization of varicose veins occurred in some of the patients in both the MOCA and EVLA groups within 6–18 months. Total recanalization occurred in 2/24 limbs in the MOCA-treated group, whereas it occurred in only 1/19 limbs in the EVLA-treated group. Partial recanalization occurred in 2/24 limbs in the MOCA-treated group, and it occurred in 3/19 limbs in the EVLA-treated group. The proportion of recanalization is shown on Table 2.

Table 2. Post-MOCA and -EVLA recanalization

Variables	MOCA	EVLA
Recanalization	24	19
Total	2 (8.3%)	1 (5.2%)
Partial	8 (33.3%)	3 (15.7%)

The age, sex, BMI, and largest preoperative diameter of the VSM showed no significant association with post-MOCA recanalization. As shown in Table 3, recanalization occurred in three of four MOCA-treated limbs in cases where the preoperative diameter of the VSM was >7 mm. Recanalization also occurred in 7 of 20 limbs where the diameter of the VSM was 4–7 mm. The association between the patients' clinical characteristics and recanalization in the MOCA-treated group is shown on Table 3.

Table 3. Association of the Clinical Characteristics of the MOCA-treated Group with Recanalization

Variables	Post-MOCA Recanalization		p-value	OR (95% CI)
	Yes	No		
N	10 (41.6%)	14 (58.3%)		
Age				
<60 years old	7 (35%)	13 (65%)	0.178	0.179 (0.016-2.065)
≥60 years old	3 (75%)	1 (25%)		
Sex				
Male	4 (50%)	4 (50%)	0.439	1.667 (0.3-9.272)
Female	6 (37.5%)	10 (62.5%)		
BMI				
<25 kg/m ²	6 (33.3%)	12 (66.6%)	0.170	0.250 (0.035-1.775)
≥25 kg/m ²	4 (66.6%)	2 (33.3%)		
Preoperative venous diameter				
4–7 mm	7 (35%)	13 (65%)	0.178	0.179 (0.016-2.065)
>7 mm	3 (75%)	1 (25%)		

Table 4 shows the association of the clinical characteristics of the patients in the EVLA-treated group with recanalization. The patient's age, sex, BMI, and largest preoperative diameter of the VSM showed no significant association with post-EVLA recanalization. In most EVLA-treated patients (13/19), the largest preoperative diameter of the VSM was >7 mm. As shown in Table 4, recanalization seems to have occurred in only one EVLA-treated patient (where the preoperative VSM diameter was 4–7 mm) and in three EVLA-treated patients (where the preoperative VSM diameter was 7 mm).

Table 4. Association of the clinical characteristics of the EVLA-treated group with recanalization

Variables	Post-EVLA Recanalization		p-value	OR (95% CI)
	Yes	No		
N	4 (21%)	15 (78.9%)		
Age				
<60 years old	3 (33.3%)	6 (66.6%)	0.249	4.500 (0.374-54.115)
≥60 years old	1 (10%)	9 (90%)		
Sex				
Male	1 (25%)	3 (75%)	0.728	0.917 (0.073-11.577)
Female	3 (20%)	12 (80%)		
BMI				
<25 kg/m ²	2 (22.2%)	7 (77.7%)	0.667	1.143 (0.126-10.386)
≥25 kg/m ²	2 (20%)	8 (80%)		
Preoperative venous diameter				
4–7 mm	1 (16.6%)	5 (83.3%)	0.627	0.667 (0.054-8.161)
>7 mm	3 (23%)	10 (76.9%)		

3.2 Discussion

In the present study, the proportion of females was higher than that of males. This finding is in accordance with that of a previous study, in which females and males accounted for 25% and 15% of limb varicose vein patients, respectively [2]. These findings indicate that females appear to have a higher risk than males of varicose veins. Lack of physical activity was previously reported to be a risk factor of varicose veins of the limbs [2]. Hormonal factors have also been reported to play an important role in the occurrence of varicose veins. The use of hormonal contraceptives was shown to affect venous wall relaxation. Most women also tend to wear high heels, which have been demonstrated to be a risk factor for varicose veins [1].

In the present study, overall, the patients who were treated by MOCA or EVLA felt satisfied, as their clinical complaints, such as pain and a poor cosmetic appearance, were resolved after the treatment. Two MOCA patients and one EVLA patient expressed dissatisfaction due to the return of pain in the treated limbs, although the pain was not as bad as prior to the surgery. In these cases, total recanalization of the ablated limb and recurrence of the varicose veins occurred. However, the posttreatment venous diameter of the vein was not as large as the preoperative diameter. Thus, the complaints that arose were not as bad as before the surgery. As reported earlier, recanalization can cause the return of reflux and pose a risk of the recurrence of varicose veins [6].

In the present study, the incidence of total and partial recanalization in the MOCA-treated group was higher than that in the EVLA-treated group. In a previous study, Rasmussen reported that the rate of recanalization four months after EVLA was 4.3% [5]. Van Eekeren reported complete occlusion in 26 of 30 (87%) post-MOCA patients who were followed up for six weeks after surgery [7]. In the same study, the incidence of recanalization was 13.3%, with partial recanalization in three limbs (9.75%) and total recanalization one limb (3.25%) [7]. In the present study, the rate of recanalization in post-MOCA limbs was higher than that of EVLA-treated limbs. This finding is in accordance with that reported in previous studies in other countries. The rate of recanalization after MOCA and EVLA treatment in the present study was also higher than that reported in other countries. The latter can be attributed to the low number of cases included in this study. In addition, different surgeons performed the treatments in the present study.

The results showed that age, sex, BMI, and a large preoperative VSM diameter did not show a statistically significant association with the incidence of post-MOCA or post-EVLA recanalization. This was probably due to the small number of samples included in the study. Nevertheless, a preoperative venous diameter > 7 mm affected the incidence of recanalization in the MOCA-treated group (three of four limbs) as compared to the EVLA-treated group (3 of 13 limbs). The aforementioned finding in the MOCA-treated group is likely attributed to the rotation diameter and size of the catheter tip, so it cannot reach a large diameter of vein tunica intima. A large venous diameter also requires a higher volume of sclerosan agents to obtain the expected inflammatory reaction. This study has a number of limitations. These include the small number of patients due to the relatively recent introduction of minimally invasive treatments for varicose veins of the limbs in Indonesia. Another limitation was the lack of patients' education regarding the importance of control after venous ablation. In addition, a number of potential subjects refused to participate because they resided in remote locations far from the hospitals or experienced no complaints as a result of the varicose veins. In addition, the hospitals used different instruments to examine post-MOCA and post-EVLA recanalization. Studies containing higher numbers of MOCA and EVLA procedures performed by the same surgeon, in addition to USG performed using the same type of machine and the same examiner, would help to validate the findings of the present study.

4. Conclusion

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. Age, sex,

BMI, and the largest preoperative diameter of the VSM showed no statistically significant association with post-MOCA or post-EVLA recanalization. However, the rate of recanalization in patients in the MOCA-treated group with a preoperative VSM diameter of >7 mm was higher than in the EVLA group. The findings point to the need for continuous monitoring of post-MOCA and post-EVLA recanalization. The medical records of all patients should contain complete information on the preoperative, intraoperative, and postoperative conditions. They should also record the patients' education after MOCA and EVLA of postoperative control in accordance with the right time. Minimally invasive EVLA surgery can be considered the gold standard for the management of varicose veins of the limbs in RSCM, especially varicose veins with a diameter >7 mm.

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