Al-Azhar International Medical Journal

Volume 4 | Issue 2 Article 17

2023

Assessment of Endovenous Microwave Catheter Ablation in the Treatment of Primary Lower Limb Varicose Veins

Abd El Fattah Ali Ismael
General and vascular surgery, Faculty of Medicine – Al-Azhar University-Cairo

Abd El Aziz Ahmed Abd El Hafez
General and vascular surgery, Faculty of Medicine – Al-Azhar University-Cairo

Mohamed Hassan Mohamed Hassan
General and vascular surgery, Faculty of Medicine – Al-Azhar University-Cairo, ahmalal@gmail.com

How to Cite This Article

Ismael, Abd El Fattah Ali; El Hafez, Abd El Aziz Ahmed Abd; and Hassan, Mohamed Hassan Mohamed (2023) "Assessment of Endovenous Microwave Catheter Ablation in the Treatment of Primary Lower Limb Varicose Veins," *Al-Azhar International Medical Journal*: Vol. 4: Iss. 2, Article 17.
DOI: https://doi.org/10.58675/2682-339X.1671

ORIGINAL ARTICLE

Assessment of Endovenous Microwave Catheter Ablation in the Treatment of Primary Lower Limb Varicose Veins

Abdelfatah Ali Ismael*, Abdelaziz Ahmed Abdelhafez, Mohamed Hassan Mohamed

Department of General and Vascular Surgery, Faculty of Medicine, Al-Azhar University, Cairo, Egypt

Abstract

Background: **Many adults often have varicose veins, and the clinically, etiologically, anatomically, and pathophysiological (CEAP) classification is a widely used method of staging the condition. Surgery is the standard course of therapy, which comprises saphenofemoral and/or saphenopopliteal junction disconnection, along with or without superficial axial vein stripping. Endovenous ablation treatment is now the most popular and has an occlusion rate of 95%. Endovenous microwave ablation (EMA), an endovenous ablation method, operates by producing radiofrequency radiation. The MICROTAZE OT-110 M device produces radiofrequency radiation.**

Aim: **The aim of this study was to use EMA as a new technique in treating lower limb varicose veins according to the results, advantages, disadvantages, and complications.**

Patients and methods: **Thirty patients with lower limb varicose veins participated in this study. It was conducted at the Vascular Surgery Department of Al-Azhar University hospitals (Al-Hussein and sSayed-Galal). Patients were exposed to a clinical assessment and a duplex ultrasound after providing written permission.**

Results: **Those overweight and patients in the age group of 30−50 years were the most affected. A statistically significant improvement was observed in Aberdeen varicose vein questionnaire at different follow-up intervals.**

Conclusion: **This prospective, single-center study found EMA of the great saphenous vein to be safe and effective. There were few complications, no DVT or paresthesia, little postoperative discomfort, and positive midterm radiological and clinical data.**

Keywords: Catheter, Endovenous, Lower limbs, Microwave, Varicose veins

1. Introduction

Adults often have lower body varicose veins, which are among the most prevalent vascular illnesses, impacting up to one-third of the population in industrialized nations and negatively affecting patients' quality of life.[1]

Women are more vulnerable than males, and additional risk factors include being older, getting pregnant, standing for lengthy periods of time, and being obese. Ineffective venous valves reduce the amount of blood that returns from the legs, which in turn predisposes to the development of dilated and convoluted veins from the leg to the thigh, which mainly raises esthetic concerns.[2]

Symptoms not only include pain but also itching, burning discomfort, heaviness, swelling, postural cramps, night cramps, cosmetic disfigurement; and further it may lead to thrombophlebitis or ulcer formation which generally is difficult to heal. Varicose vein disease is often staged using the CEAP classification (Clinical, Ethiological, Anatomical, and Pathophysiological). The clinical severity ranges from C0, which represents no skin alteration, to C5/C6, which includes healed or active leg ulcers.[3]

Accepted 9 September 2022.
Available online 15 May 2023

* Corresponding author.
E-mail address: ahmalal@gmail.com (A.A. Ismael).

https://doi.org/10.58675/2682-339X.1671

Surgery is the standard course of therapy, which comprises saphenofemoral and/or saphenopopliteal junction disconnection, along with or without superficial axial vein stripping. The standard anesthetic for surgery is general or spinal. It necessitates hospitalization, is linked to wound-related issues, and is connected with the phenomena of neovascularization/recurrence as a consequence of groin dissection raising the risks of bleeding, paresthesia, infection, scarring, higher hospital expenses, and extended recovery.[4]

The development of less invasive treatments to substitute surgical intervention received more focus. By inserting a specific catheter into the blood vessel lumen to cause endothelial and vein wall damage with subsequent fibrosis, the endovenous ablation procedure, which is less invasive than the conventional procedure due to its lower complication rates and greater tolerance, is currently the most popular. It can achieve an occlusion rate of ~95%.[5]

Endovenous microwave ablation (EMA), which uses the MICROTAZE OT-110 M machine to produce radiofrequency radiation, is one of the endovenous ablation procedures. EMA was compared with the traditional surgery in a randomized controlled experiment to address great saphenous vein (GSV) incompetence. Damage to the inner lining of the veins causes fibrosis and localized inflammation. This stops superficial reflux and causes vein blockage. EMA demonstrated its effectiveness with a 97% vein occlusion rate and no recurrence.[6]

Complications of endovenous ablation included the following: deep vein thrombosis, pulmonary embolism, pain syndrome, abscess, seroma, hyperpigmentation, and burning of the skin.[7]

The aim of this study was to use EMA as a new technique in treating lower limb varicose veins according to the results, advantages, disadvantages, and complications.

2. Patients and methods

This prospective randomized controlled trial was conducted at the Vascular Surgery Department of Al-Azhar University Hospitals (Al-Hussein and Sayed-Galal), between January and July 2022.

The study included 30 patients, there were 12 (40%) males, while females were 18 (60%), who presented with primary varicose veins of the lower limbs.

According to the CEAP categorization, all patients exhibited symptomatic varicose veins with proven GSV incompetence.

Using duplex scanning, the degree and scope of GSV reflux were assessed before surgery. With patients upright, the GSV and deep (femoral vein and popliteal vein) venous systems were evaluated for reflux. The presence of incompetent perforators was not routinely evaluated.

Inclusion criteria: patients with primary uncomplicated lower limb varicose veins, age from 18 to 55 years, incompetent GSV and saphenofemoral junction, intact deep venous system, vein diameter at the GSV greater than or equal to 5.5 mm and less than or equal to 15 mm, reflux in GSV greater than 0.5 s on duplex study, and CEAP classification between C2 and C5.

Exclusion criteria: patients with a history of deep venous thrombosis, patients with recurrent varicose veins, GSV diameter greater than or equal to 15 mm, patients with contraindications or allergy to anesthesia, pregnant women with varicose veins, patients who refuse to be included in the study, and patients with connective tissue disorders or inflammatory skin disorders in the punctured area.

Patient evaluation: clinical evaluation and Duplex ultrasound.

All patients underwent clinical examinations in accordance with the following plan: detailed history (disfigurement, pain, bleeding, deep venous thrombosis, drug allergy, anticoagulant therapy, etc.). Detailed general examinations and local examination of the lower limbs to detect distribution of veins affected, incompetent perforators and shape (spider, serpentine, or saccular).

2.1. Statistics

Data collected and maintained: age, sex, right or left lower limb or bilateral.

Preprocedural assessment: for all patients, complete blood count, coagulation profile, hepatic and renal function assessments, viral indicators, and Doppler/Duplex scan.

Preoperative duplex scanning: Duplex scanning will be 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 and sapheno-femoral junction (SFJ)) of patients.

The procedure: performed with the patient under local tumescent anesthesia.

Position: supine.

Sterilization: sterilization of the affected limb with povidone iodine and then putting sterilized towels.

Postoperative: early discharge out of hospital (~2 h after the ablation, compression by medical stockings Above Knee grade 2 from 2_to 4 weeks, diosmin tab

twice daily for 4 weeks, and anti-inflammatory drugs were advised for 3 days.

Every patient was advised to:

For the first month, refrain from straining, vigorous exercise, or Valsalva maneuvers as these may hasten recanalization.

To reduce the frequency of thromboembolic events during the first month after therapy, avoid extended vehicle or airline trips of more than 4 h.

Follow-up of patients: Patients will be evaluated and followed up immediately, during a week and after a month up to 6 months clinically and Duplex ultrasound scanning for the occurrence of complications or recurrence.

Ethical considerations: before enrolling the participants, written agreement was obtained to participate in the trial. The aims of the study and any possible risks were discussed with all patients. Privacy of the collected data is assured. Investigations were delivered to patients. Follow-up of the patients will is done after the procedure.

3. Results

A total of 30 patients identified with primary lower limb varicose veins undergoing EMA were enrolled in our study. Table 1 demonstrates the basic CERAP classification data of enrolled patients.

By ultrasonographic examination (Table 2), the mean diameter of GSV was 7.82 ± 1.56 mm (range: 6–15). The median reflux time was 2.8 ± 1.04 s (range: 0.7–4). Twenty-one (70%) patients had two or less perforators, while nine (30%) patients had more than two perforators.

Table 1. Patient CERAP characteristics (N = 30).

	Value [*n* (%)]
CEAP	
C2	7 (23.3)
C3	10 (30.3)
C4	10 (30.3)
C5	3 (10)

CEAP, clinical, etiological, anatomical, and pathophysiological.

Table 2. Ultrasound characteristics (N = 30).

	Value
Diameter of GSV (mm)	7.82 ± 1.56
Reflux time of GSV (s)	2.8 ± 1.04
Number of perforators [*n* (%)]	
>2 per limb	9 (30)
≤2 per limb	21 (70)

GSV, great saphenous vein.

As demonstrated in Table 3, the median procedure time was 40.5 ± 14.6 min (range: 30–50). The power was adjusted to 50 W. The mean time for ambulation postoperatively was 2.4 ± 1.8 h, ranging from 2 to 3 h. The median duration for hospital stay was 0.5 ± 0.35 days (range: 0.5–1). The mean postoperative Venous assessment score (VAS) for pain was 2 ± 1.3 (range: 1–4). The median time for ulcer healing was 3.67 ± 1.3 weeks, ranging from 2 to 5 weeks.

Table 4 illustrates the preintervention values of venous clinical severity score (VCSS) and the Aberdeen varicose vein questionnaire (AVVQ) and follow-up values at 1 and 6 months.

Table 5 shows that the GSV diameter ranged between 4.50 and 9.50 with a mean value of 6.52 ± 1.271 and it decreased significantly at postoperative time to reach after 6 months of follow-up to be at a mean value of 0.52 ± 0.252.

Table 6 summarizes the reported complications in our series. Six (20%) patients developed induration, four (13.3%) patients had ecchymosis, three (10%) patients had accidental skin burns, and none developed an infection at the incision site. One patient (3.3%) had fat liquefaction and two (6.7%) complained of paresthesia. At the 1-month follow-up, two (6.7%) patients showed residual veins. None developed DVT or pulmonary embolism (PE). No cases of death were reported either. The recurrence rate at the 6-month follow-up was 3.3%. However, GSV recanalization was not reported.

Table 3. Surgical outcomes (N = 30).

	Value
Procedure time (min)	40.5 ± 14.6
Power for GSV (Watt)	50
Time to ambulation (h)	2.4 ± 1.8
Length of hospital stay (days)	0.5 ± 0.35
VAS for pain	2.0 ± 1.3
Time to ulcer heal (weeks)	3.67 ± 1.3

Table 4. Clinical assessment (N = 30).

	VCSS	AVVQ
Preintervention	5.6 ± 1.3	18.5 ± 4.3
1-month follow-up	2.1 ± 0.6	8.1 ± 2.4
6-month follow-up	1.2 ± 0.3	4.5 ± 1.2
P value[a]	0.013	0.020
P value[b]	0.000	0.000
P value[c]	0.000	0.000
P value[d]	0.041	0.005

ANOVA, analysis of variance; AVVQ, Aberdeen varicose vein questionnaire; VCSS, venous clinical severity score.

[a] Repeated measure ANOVA.

[b] Post-hoc test preintervention versus 1 month.

[c] Post-hoc test preintervention versus 6 months.

[d] Post-hoc test 1 month versus 6 months.

Table 5. GSV diameter pre and post during follow up.

GSV diameter	Preoperative	Follow-up			
		1 week	1 month	3 months	6 months
Minimum–maximum	4.50–9.50	3.20–8.50	1.30–6.40	0.60–4.30	0.10–0.90
Mean ± SD	6.52 ± 1.271	5.31 ± 1.273	3.50 ± 1.070	1.88 ± 0.731	0.52 ± 0.252

Table 6. Complications (N = 30).

	Frequency	%
Induration	6	20
Ecchymosis	4	13.3
Skin burns	3	10
Incision infection	0	0
Fat liquefaction	1	3.3
Paresthesia	2	6.7
Residual varicose at 4 weeks	2	6.7
DVT	0	0
Pulmonary embolism	0	0
Death	0	0
Recurrence	1	3.3
Recanalization of GSV	0	0

GSV, great saphenous vein.

4. Discussion

According to CEAP classification in our study, seven (23.3%) patients were C2, 10 (33.3%) patients were C3, 10 (33.3%) were C4, and three (10%) patients were C5.

While the mean preprocedural CEAP classification in the study of Karnabatidis *et al*[5] was 3.3 ± 0.72 (median: 3; range: 2–6). According to the CEAP classification, the disease's baseline severity was C2: 7.8% (5/64), C3: 64% (41/64), C4 (a–b): 23.5% (15/64), C5: 3.1% (2/64), and C6: 1.6% (1/64).

The present study showed that the median diameter of GSV was 7.82 ± 1.56 mm (range: 6–15). The median reflux time was 2.8 ± 1.04 s (range: 0.7–4). Twenty-one (70%) patients had two or less perforators, while nine (30%) patients had more than two perforators.

Our results were supported by the study of Subwongcharoen and Chitwiset,[8] as they reported that the mean diameter of GSV was 9.5 + 1.1 mm.

The current study showed that as regards procedure outcomes, the median procedure time was 40.5 ± 14.6 min (range: 30–50). The power was adjusted to 50 W. The mean time for ambulation postoperatively was 2.4 ± 1.8 h, ranging from 2 to 3 h. The median hospitalization was 0.5 ± 0.35 days (range: 0.3–1). The mean postoperative VAS for pain was 2 ± 1 (range: 1–4). The mean time for ulcer healing was 3.67 ± 1.3 weeks, ranging from 2 to 5 weeks.

The procedure outcomes were very close to the study of Subwongcharoen and Chitwiset,[8] as the procedure time was 35 ± 15 min (range: 25–45). The power was adjusted to 50 W. The mean time for ambulation postoperatively was 2 ± 1 h, ranging from 2 to 3 h. The mean duration of hospital stay was 1 ± 0.35 days (range: 1–2). The mean postoperative VAS for pain was 1.5 ± 1 (range: 1–4). The mean time for ulcer healing was 3 ± 1 week, ranging from 2 to 5 weeks.

In this study, as regards preintervention values of VCSS and AVVQ and follow-up values at 1 and 6 months, the mean preintervention VCSS was 5.6 ± 1.3. After 1 month, the VCSS improved to 2.1 ± 0.6. At the 6-month follow-up, the median score was 1.2 ± 0.3. A statistically significant improvement was observed in VCSS at different follow-up intervals (repeated measure ANOVA, $P < 0.05$). The mean preintervention AVVQ was 18.5 ± 4.3. After 1 month, the VCSS improved to 8.1 ± 2.4. At 6-month follow-up, the mean score was 4.5 ± 1.2. A statistically significant improvement was observed in AVVQ at different follow-up intervals (repeated measure ANOVA, $P < 0.05$).

In the study of Yang et al.[9] after the procedure, the AVVQ and VCSS scores both decreased (improved) in the same way ($P < 0.001$), and there was no discernible change in the scores at any other time point ($P > 0.05$). After 2 years, the rise in AVVQ and VCSS scores was still noticeable.

Our results showed that as regards the complications in our study, six (20%) patients developed induration, four (13.3%) patients had ecchymosis, three (10%) patients had accidental skin burns, and none developed an infection at the puncture site. One patient (3.3%) had fat liquefaction, and two (6.7%) complained of paresthesia. At 1-month follow-up, two (6.7%) patients showed residual veins. None developed DVT or PE. No death cases were reported either. The recurrence rate at 6-month follow-up was 3.3%. However, GSV recanalization was not reported.

Our results were supported by the study of Karnabatidis et al.[5] as they reported that two little puncture site scars were the only minor issues that developed, and they automatically disappeared after 3 months, proving the device's safety. No serious consequences were detected.

4.1. Conclusion

The present trial confirmed that EMA is highly efficacious resulting in substantial reductions in

venous disease severity with reduced CEAP values after therapy.

What has been shown conclusively is that effective treatment of venous insufficiency leads to substantial improvements in quality of life.

Complications of endovenous ablation include the following: pain, abscess, seroma, hyperpigmentation, and burning of the skin is shown and explained in detail in our study.

There are no reports of direct comparisons of EMA and other endovenous ablation techniques. However, the published data shows slightly higher occlusion rates for microwave ablation.

However, long-term follow-up and quantification of 5 to 10-year recurrence rates will be important.

Conclusively, this single-center, single-arm, prospective research found that EMA of the GSV was safe and effective for treating symptomatic lower leg varicose veins. It also found that the procedure had very low complication rates, no instances of DVT or persistent paresthesia, low levels of postprocedural discomfort, and exceptionally positive radiological and clinical midterm results. For these findings to be confirmed, a larger comparative research is necessary.

Conflict of interest

None declared.

References

1. Evans CJ, Fowkes FG, Ruckley CV, Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh vein study. *J Epidemiol Community Health*. 2015;53:149–153.
2. Lohr JM, Bush RL. Venous disease in women: epidemiology, manifestations, and treatment. *J Vasc Surg*. 2013;57, 37S–45S.
3. Marsden G, Perry M, Kelley K, Davies AH, Guideline Development Group. Diagnosis and management of varicose veins in the legs: summary of NICE guidance. *BMJ*. 2013;347:f4279.
4. González C, Salvador F, Roser V, Kerbi A, Marta S, José R. A randomized controlled noninferiority trial comparing radiofrequency with stripping and conservative hemodynamic cure for venous insufficiency technique for insufficiency of the great saphenous vein. *J Vasc Surg Venous Lymphat Disord*. 2021;9:1.
5. Karnabatidis D, Papageorgiou C, Kitrou P, Spiliopoulos S. One-year duplex ultrasound–assessed closure outcomes of percutaneous endovenous microwave ablation for the treatment of varicose veins of the lower limbs. *Vascular*. 2022;57: 37S–45S.
6. Wang X, Wei Z, Zhu C, Liu J, Han Y. The clinical outcomes of endovenous microwave and laser ablation for varicose veins: a prospective study. *Surgery*. 2020;168. https://doi.org/10.1016/j.surg.2020;06.035.
7. Mao J, Zhang C, Wang Z, Gan S, Li K. A retrospective study comparing endovenous laser ablation and microwave ablation for great saphenous varicose veins. *Eur Rev Med Pharmacol Sci*. 2019;16:873e87.
8. Subwongcharoen S, Chitwiset S. Chronic venous disease treated with endovenous microwave ablation: long-terms results and quality of life. *J Med Assoc Thai*. 2014;97:S76–S80.
9. Yang L, Wang X, Wei Z, Zhu C, Liu J, Han Y. The clinical outcomes of endovenous microwave and laser ablation for varicose veins: a prospective study. *Surgery*. 2020;168:909–914.