Endovenous Microwave Ablation (MWA) for Varicose Veins: A Promising Minimally Invasive Treatment

Running Title: Microwave ablation

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Abstract

Objective: To evaluate the efficacy and outcomes of patients who underwent microwave ablation (MWA) to treat the lower limb's truncal varicose veins (VVs).

Patients and Methods: The study included all adult patients with truncal VVs of clinical, aetiological, anatomical, and pathological (CEAP) classification (C 2-6) who underwent MWA of the great saphenous vein (GSV) and /or short saphenous vein (SSV) with vein diameter 5.5-15mm and reflux time > 0.5 sec.

Results: The study included 20 patients with a mean age of 33 ± 10.4 years. The majority of patients (70%) were females. A history of prolonged standing was the most common risk factor (70%). The mean diameter of GSV was 9.2. ± 0.08 mm. According to the CEAP classification, C2 was the most common presentation. The mean time of the procedure was 56.9 ± 3.3 minutes, while the mean time to ambulation was 3.9 ± 0.3 hours. Technical success was achieved in all patients. There was a significant improvement in VAS score from 3.4 preoperatively to 2.4 at 24 hours postoperatively, P = <0.001. Complete occlusion was noticed in all patients undergoing a duplex ultrasound examination one month postoperatively. Over the 1-year follow-up period, there was a highly significant reduction in the Aberdeen Varicose Vein Questionnaire (AVVQ) score (7.6 vs 33.9, P =< 0.001). Patients with venous ulcers showed complete ulcer healing within 3 months. The occlusion rates at 3,6 and 12 months were 95.0%, 90.0%, and 85.0%, respectively.

Conclusion: MWA is a safe and effective minimally invasive treatment for truncal VVs. MWA offers advantages like short operation times, minimal postoperative pain sensation, and fast recovery.

Keywords: Microwave, Thermal ablation, Varicose Veins, Endovenous.

Introduction:

Varicose veins (VVs) are identified by subcutaneous, dilated, and twisted veins measuring at least 3 millimeters and involving the saphenous veins, branches, or non-saphenous superficial leg veins. Important risk factors include age and family history.1 VV entity encompasses various clinical and pathological manifestations, from aesthetic appearance or limited leg discomfort to non-healing ulcers. 1 Treatments to improve cosmetic appearance and reduce venous hypertension and the chronic inflammation that can lead to ulceration.2

When conservative treatments such as lifestyle modifications, medications, and compression therapy fail to produce the desired outcomes, surgical and endovascular options may be considered. Over the past two decades, the shift toward minimally invasive approaches is further highlighted by the United Kingdom's National Institute of Health and Care Excellence (NICE) guidelines, published in 2013, advising the

use of endovenous treatments ahead of open surgery for the treatment of VV.3

Microwave ablation (MWA) has emerged as a minimally invasive technique for treating VVs, offering an effective and satisfactory new technique for VV treatment. During MWA, the microwave radiator directly contacts the vein wall, causing it to solidify rapidly at a high temperature in the targeted area, thus facilitating the quick closure of VVs. 4 This makes MWA particularly effective for treating large VVs and significant perforator veins. Its high thermal efficiency, rapid heating, moderate thermal penetration, and controllable ablation range contribute to a lower risk of thermal injury complications than other ablation methods.4

This study evaluates the effectiveness and outcomes of patients who underwent MWA to treat truncal VV in the lower limbs at our local institution.

Patients and Methods

This prospective study was conducted between October 2021 and November 2022 at the Vascular and Endovascular Surgery Department, Faculty of Medicine, Assiut, Egypt. The study was approved and monitored by the local institutional Medical Ethics Committee of the Assiut Faculty of Medicine (IRB NO#17101861). The study included all adult patients with truncal VVs with clinical, aetiological, anatomical, and pathological (CEAP) classification (C2-C6) who underwent MWA of the great saphenous vein (GSV) and /or short saphenous vein (SSV) with a vein diameter range of 5.5 to 15mm and a reflux time > 0.5 sec. We excluded patients with suspected or proven deep venous thrombosis (DVT), acute phlebitis of GSV or SSV, pregnancy, recanalized GSV, contraindication to anesthesia or surgery, and severe skin infection.

All patients underwent thorough medical history assessments and detailed examinations of both lower limbs to identify typical or atypical VVs. DUS examinations were performed with patients in the standing position. DUS evaluation included documentation of reflux time and the pathway of the GSV and SSV, measurements of vein diameter and depth, assessment of other reflux pathways, identification of any refluxing perforators, evaluation of the deep venous system, and preoperative marking of GSV and atypical tributaries.

Technique

All procedures were performed under spinal anesthesia, with the patient positioned in a reverse Trendelenburg position to enhance vein distension. Under DUS guidance, the GSV was punctured below the knee using an 18G puncture set (Chongqing New World Trading, Jiangsu, China). A 6F introducer sheath (Hangzhou Wehere Medical Technology, Xiaoshun Town, Jinhua, Zhejiang, China) was placed over the guidewire. The 2-mm microwave catheter (Microwave Coagulation System, Shanghai Medical Electronics, Shanghai, China) was guided to a location 2 cm below the saphenofemoral junction (SFJ) using the Seldinger technique with DUS scanning. In cases of SSV incompetence, the puncture was performed at the lower calf, near the lateral malleolus, and the catheter was positioned 2 cm below the saphenopopliteal junction (SPJ).

Tumescent anesthesia was administered, consisting of a mixture of 50 mL of 1% lidocaine with epinephrine in 450 mL of normal saline, neutralized with 5 to 10 mL of 8.4% sodium bicarbonate, under ultrasound guidance. This technique helps prevent thermal injury to the skin and compresses the vein for successful occlusion. The GSV above the knee was ablated using a pulse mode with a power setting of 50W for 7 seconds. Below the knee, the GSV was treated with 30W to 35W for 7 seconds. If the vein diameter exceeded 10 mm, each cycle was extended to 9 seconds. The first segment near the junction was treated twice to ensure proper sealing. In cases of SSV incompetence, the vein was treated with pulse mode power settings of 35 to 40 W for 7 seconds. The catheter was then retracted by 1 cm after each cycle using microwave

catheter markers. Upon reaching the end of the catheter marked by three dots, the sheath was removed, and the final segment of the vein was ablated. DUS concluded the procedure to confirm successful vein ablation. Any residual tributaries were treated with mini phlebectomy or foam sclerotherapy using a polidocanol solution.

After the procedure, the limb was wrapped in a compression bandage for 48 hours. Patients were observed in the recovery room for 2 to 4 hours before discharge. All patients were instructed to begin walking as soon as possible after surgery. Upon discharge, patients were advised to replace the compression bandages with class 2 compression stockings to maintain compression for two weeks. Postoperative pain assessment was done within 24 hours of the procedure using the Visual Analog Scale (VAS), which ranges from 0 to 10, where 0 indicates no pain, and 10 represents the highest pain level.[5]

Follow-up

All patients were followed up 1, 3, 6, and 12 months after the intervention through clinical evaluations and DUS examinations. Any recurrence of varicosities and/or complications were documented. The patient's quality of life (QoL) was assessed using the Aberdeen Varicose Vein Questionnaire (AVVQ).[6]

Outcome Measures

Primary

1. Technical success is defined as achieving post-ablation noncompressible veins with no evidence of flow upon DUS for the entire length of the ablated vein segment and absence of vein recanalization of more than 2 cm at one month postoperatively.
2. Recanalization detected an open segment of the treated vein ≥5 cm long after one month.
3. Quality of life as assessed by AVVQ at 12 months compared to preoperative readings.

Secondary

1. Recurrent VVs were defined as all newly visible VVs post-ablation.
2. Procedure-related adverse events include thrombophlebitis, infection, skin burns, and ecchymosis.
3. Improved pain severity according to the VAS scale.

Statistical Analysis

Data were collected, coded, and entered into the Statistical Package for Social Science (IBM SPSS) version 20. Qualitative data were presented as numbers and percentages, while quantitative data were presented as mean, standard deviations, and ranges. P-value < 0.05 was considered significant.

Results

Baseline Demographic Data

The study included 20 patients, mainly women (70%), with an average age of 33 ± 10.41 years and a mean weight and height of 77.26 ± 0.05 kg and 1.65 ± 3.79m, respectively. Prolonged standing was the most common risk factor observed in 70% of the patients. According to the CEAP classification, C2 was the most frequent clinical presentation in 50% of cases. The GSV was the only vein affected in 55% of the patients. All patient baseline characteristics and clinical presentation are illustrated in **Table 1**.

Table 1: Demographics and comorbidities of the studied patients

	Number	Percentage
Age, years (Mean ± SD)	33.10 ± 10.41	
Female sex	14	70.0%
Long-standing	14	70.0%
Hypertension	2	10.0%
DM	1	5.0%
Smoking	8	10.0%
Weight (kg) (Mean ± SD)	77.26 ± 3.79	
Height (m) (Mean ± SD)	1.65 ± 0.05	
BMI (Kg/m²) (Mean ± SD)	28.59 ± 2.47	
CEAP classification		
C2	10	50.0%
C4	6	30.0%
C5	2	10.0%
C6	2	10.0%
Preoperative VAS score (Mean ± SD)	3.38 ± 0.66	

SD, Standard deviation; **DM**, Diabetes mellitus; **BMI**, body mass index; **CEAP** classification clinical, etiological, anatomical, and pathological classification; **VAS**, visual analog score

Procedural Details

The mean diameter of refluxing saphenous veins was 9.27 ± 0.84 mm with a mean reflux time of 2.38 ± 0.49 sec. The mean procedural time was 56.9 ± 3.3 min. The mean duration of hospital stay was 3.93 ± 0.39h. Other procedural details are shown in **Table 2**.

Table 2: Procedural details in the study patients

Procedural details	N (%)
Treated Vein GSV SSV Both	 11 (55.0%) 6 (30.0%) 3 (15.0%)
	Mean ± SD
Vein diameter (mm)	9.27 ± 0.84
Reflux time (sec)	2.38 ± 0.49
Procedure time (min)	56.90 ± 3.35
Time to ambulation (h)	3.93 ± 0.39
Hospital stay (h)	8.29 ± 1.05
Duration of return to activity (days)	3.31 ± 0.67

SD, standard deviation; **GSV**, Great saphenous vein; **SSV**, Short saphenous vein

Procedural Outcomes:

Immediate Outcomes

Technical success was achieved in all patients. There was a significant improvement in VAS score from 3.4 preoperatively to 2.4 at 24 hours postoperatively, p =< 0.001. The mean duration of hospital stay was 8.29 ± 1.05 h.

The encountered procedural-related complications included ecchymosis (3, 15%), skin burns (4, 20%), and sensory impairment in 3 patients (15%), which was resolved within one month in two patients but resolved in the third patient during the third month postoperatively. All complicated patients with ecchymosis or skin burns were resolved within 4 weeks after the procedure, as shown in **Table 3**.

Table 3: Complications of the procedure in the study patients

Complications		Number	Percentage
Ecchymosis		3	15.0%
Skin burn		4	20.0%
Sensory impairment (Paresthesia)	One Month	3	15.0%
	Three Months	1	5.0%
	Six Months		0.0%
	12 Months		0.0%

Short-term Outcomes

All study patients continued the 1-year follow-up. There was a highly significant reduction in the mean values of the AVVQ score, reaching 7.6 at 12 months compared to the preoperative AVVQ score of 33.9 (P=< 0.001), as shown in **Table (4)** and **Figure (1)**.

Table 4: The AVVQ assisted before and after the procedure at 1,3,6 and 12 months

AVVQ score	**Mean ± SD**	**Range**	**P-value**
Preoperative	33.95 ± 4.29	28 – 42	<0.001
Postoperative			
One Month	21.90 ± 2.73	18 – 28	
Three Months	18.35 ± 2.80	15 – 24	
Six Months	11.45 ± 3.43	7 – 18	
Twelve Months	7.60 ± 2.68	4 – 13	

AVVQ, Aberdeen Varicose Vein Questionnaire; **SD**, standard deviation.

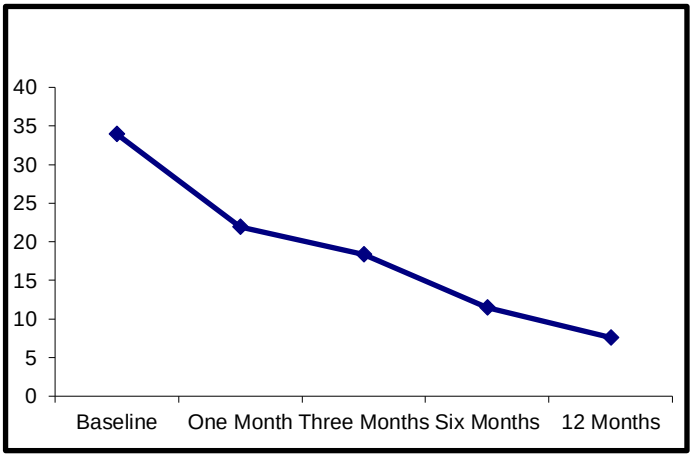

Figure (1): The AVVQ assisted before and after the procedure

At one month postoperatively, complete occlusion was achieved in all patients with DUS. However, at 3,6 and 12 months, the occlusion rates were 95.0%, 90.0%, and 85.0%, respectively. Of the three patients with recanalization, two patients (10%) had asymptomatic recanalization in a short vein segment (more than 5 cm). They did not require additional treatment, while the third patient experienced clinically recurrent varicose veins due to a refluxing anterior accessory saphenous vein that was not observed before the procedure. This patient was successfully treated with foam sclerotherapy. The two patients presenting with venous ulcers showed complete ulcer healing at 2 and 3 months.

Discussion

Endovenous methods like radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) have gained significant popularity as minimally invasive alternatives to traditional surgeries, such as high ligation (HL) and vein stripping, for treating saphenous vein incompetence.[7] According to the Society of Vascular Surgery, endovenous thermal ablation is recommended over HL and stripping for the treatment of the incompetent GSV.[8]These newer techniques offer better clinical outcomes, reduced pain, and faster recovery compared to conventional surgery.[7,9]

MWA is another effective method, a newer thermal ablation therapy that differs from EVLA in how it generates heat.[10] Several studies have shown that MWA is a safe and effective option.[11–14] Research comparing MWA and RFA found both to be equally effective in alleviating symptoms and improving quality of life.[13] MWA may have some benefits; for instance, one study reported that MWA leads to shorter operative times, less postoperative pain, fewer complications, better occlusion rates, and lower recurrence rates than EVLA.[4]

In the current study, the mean duration of the procedure was 56.9 minutes, with a mean hospital stay of 8.3 hours and resuming normal activities after approximately 3.3 days. These results are consistent with the findings of other studies comparing MWA combined with high ligation versus traditional surgery. They observed that the MWA group had a shorter average operation time and quicker return to daily activities.[15,16]

Several studies have evaluated the effectiveness of MWA and other endovenous ablation techniques.[4,12,13] In a study comparing MWA vs. EVLA, MWA demonstrated a shorter procedure time (42.58 ±15.62 min vs 65.46 ± 24.38 min, respectively, $P < 0.05$); however, the time to ambulation, length of hospital stay post-procedure were comparable between the two procedures.[4] Also, MWA and EVLA were found to have similar operating times and lengths of hospital stay.[12] One study highlighted that MWA was associated with shorter operation times, less postoperative pain, and fewer complications than EVLA.[4] Comparing MWA vs RFA, researchers observed that both techniques effectively reduced symptoms and improved QoL with comparable vein closure and symptom improvement rates.[13]

In terms of complications, 3 (15%) patients were complicated with ecchymosis, 4 (20%) patients with skin burns, and 3 (15%) patients with temporary sensory impairment. These findings are consistent with those of Yang et al., who reported a lower incidence of induration and ecchymosis with MWA than EVLA.[4] Specifically, they observed a reduction in sensory impairment at 1 and 6 months after MWA (from 10.7% to 3.6%), which aligns with our results where the rate of sensory impairment decreased from 15% to 0% during the same time points.

During the 12-month follow-up of the study patients, only one patient (5%) experienced clinically recurrent VVs. In earlier studies, the recurrence rate of VV after MWA has been reported to range from 2.8% to 13% at 12 months.[15]

In the current study, the technical success and occlusion rate one month after

the procedure was achieved in all patients with complete occlusion of the treated veins with no evidence of recanalization. At one year, the occlusion rate was 85%. This aligns with another study that reported 100% vein occlusion in the MWA group at one month and 86.9% occlusion at one year.[15] Yang et al. reported that, at the 12-month follow-up, the GSV closure rate was similar in both MWA and EVLA groups.[4]

In our study, the two patients with venous ulcers showed complete ulcer healing within 2 and 3 months postoperatively, indicating a 100% ulcer healing rate in the present study. This rate compares favorably to the 81.5% rate reported in the study using EVLA and compression therapy for VV treatment [17] Regarding the time of ulcer healing, both the MWA and EVLA groups had shown similar durations for healing times of venous ulcers.[4]

Our study's mean preoperative VAS Score was 3.4 compared to 2.41 postoperatively (P=< 0.001). The time of ambulation was 3.9 hours. This agrees with Ghweeba and Ghweeba, who showed that MWA had a lower postoperative pain score (mean 2.4 ±0.7) than the surgical group (2.78 ±0.6).[15] Similarly, low post-MWA VAS scores have been reported by other authors to be as low as two measured 24 hours postoperatively, with 90% of their patients returning to normal activities the next day.[18] These outcomes are considered satisfactory and comparable to the reported rates following RFA or EVLA.[18]

Our study's QoL assessment by AVVQ score revealed a significant improvement at one year compared to the preoperative score (7.6 vs 33.9, P = < 0.001, respectively). This agrees with Yang et al., who reported that the AVVQ score of the patients improved from 33.7 preoperatively to 8.1 postoperatively in one year, with equal patient satisfaction rates for both MWA and EVLA groups.[4] A study by Yang et al. used AVVQ, venous clinical severity score (VCSS) in patients treated with MWA showed improved AVVQ and VCSS scores postoperatively[16] In a study using chronic venous disease quality of life questionnaire (CIVIQ-2) scoring system reported that QoL improved to 24 after operation compared to 32 scores recorded before operation (P< 0.001).[11]

There are several limitations in the present study, including the small sample size with all inherent limitations that precluded direct comparisons of the outcomes in the different patient subgroups. However, our results demonstrate our early experience with this relatively new technique, which still shows acceptable outcomes compared to the established endovenous thermal ablation techniques reported in the literature. Another important limitation of the present study is lacking a comparative group to compare the outcomes of MWA versus open surgical and other endovenous techniques. Large-scale, randomized controlled trials with larger patient cohorts and longer follow-up duration are still needed to better evaluate MWA outcomes in treating VV and identify the patient subgroups who will benefit best from this technique.

Conclusion

MWA is a safe and effective minimally invasive surgical treatment of truncal VVs. MWA offers advantages like short operation times, minimal postoperative pain sensation, and fast recovery.

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Conflicts of Interest

The authors declare no conflicts of interest.

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