Microwave versus endovenous laser in great saphenous vein ablation: a randomized controlled clinical study

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Background
Due to the global burden of varicose veins (VVs) and the impact on the quality of life (QoL) of patients, it is essential to search for better treatment modalities.
Objectives
The main objective of this research was to compare the efficacy, safety, and impact on the QoL of endovenous microwave ablation (EMA) and endovenous laser ablation (EVLA) for the management of varicose veins of the great saphenous vein (GSV).
Methods
A comparative, multicenter, single-blinded, parallel randomized controlled study conducted on 340 patients confirmed to have primary VVs of the GSV who were further randomized into two groups. The study group (n=170) received EMA, and the control group (n=170) received EVLA.
Results
Both the study group and the control group were comparable with regard to their baseline characteristics (P values $>$ 0.05). The study group and the control group were comparable with regard to the limb affected (P=0.184). Only 14.7% and 10.0% of the study group and the control group have both limbs affected. Both the study group and the control group were comparable with regard to CEAP classification (P=0. 068). The study group and the control group were significantly different with regard to operating time (P$<$0.001).
The operating time is less in the study group than in the control group. The median (IQR) and the mean±SD of the operating time was 7 (4) and 8.7±4.1 min in the study (microwave) group and 9 (5) and 10±3.9 min in the control group. Also, the study group and the control group showed 100% success at the 1-week evaluation as none of the cases in both groups suffered recanalization. At 6-month evaluation, only 1 case in the study group and 2 cases of the control group experienced recanalization; however, the difference is not significant (P=0.537). At the 12-month evaluation, the study group and the control group showed 100% success as none of the cases in both groups suffered recanalization.
QoL is better in the study group than the control group at 6 months Aberdeen score (P=$<$ 0.001). The median IQR and the mean±SD of the postoperative Aberdeen score were 9 (2.7) and 9.3±1.7 in the study (microwave) group and 10.8 (3.4) and 10.8±1.8 in the control group. Moreover, the study group and the control group were comparable (P values $>$ 0.05) with regard to adverse events except for paresthesia (P-value = 0.025). About 11.2% of the control group experienced paresthesia versus only 2.9% of the study group.
Conclusion
In conclusion, EMA has a lower operating time than EVLA. EMA is as effective as EVLA for treating VVS of the GSV. EMA has fewer adverse events than EVLA. EMA has better QoL than EVLA ablation. However, the choice of treatment should be based on individual patient characteristics and the expertise of the treating physician.

Keywords:
adverse events, endovenous laser ablation, endovenous microwave ablation, great saphenous vein, quality of life, recanalization, varicose veins

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Introduction

Varicose veins are a common medical condition that affects many people worldwide. They involve more than 30% of the adult population. In addition to the cosmetic concerns, varicose veins can cause a range of

symptoms, including chronic leg pain, fatigue, itching, and swelling. In more severe cases, they can also lead to nonhealing ulcers, skin discoloration, and other complications. For many people, varicose veins can significantly impact their quality of life (QoL), making it difficult to perform daily activities or enjoy leisure activities [1].

Endovenous thermal ablation has revolutionized the treatment of varicose veins, providing a minimally invasive alternative to traditional surgical procedures. These techniques use heat energy to destroy the damaged vein from the inside, causing it to collapse and eventually be reabsorbed by the body. Catheter-based radiofrequency ablation and endovenous laser ablation (EVLA) are two of the most commonly used endovenous thermal ablation techniques. Both of these procedures involve inserting a catheter into the affected vein under ultrasound guidance and then using heat energy to seal the vein shut. Compared with traditional surgical techniques, endovenous thermal ablation is associated with a lower risk of complications, shorter recovery time, and better cosmetic outcomes. These procedures can be done on an outpatient basis and typically do not require general anesthesia [2]. Endovenous thermal ablation means heating the vein sufficiently to ablate it (permanently closing it) from within [3].

Endovenous microwave ablation (EMA) is the latest treatment for varicose veins in legs. It uses heat like other laser ablation techniques to permanently destroy refluxing veins. However, unlike EVLA where temperatures are up to about 800°C, the temperature in EMA is around 50–80°C, significantly lowering the risk of skin burn and saphenous nerve injury [4].

Endovenous microwave varicose vein treatment is a form of endothermal ablation. Hence, it should be as effective as EVLA with more advantages. The microwave method does not require direct contact with the vein wall, and it can ablate all varicose veins even if it is more than 14 mm in diameter. The microwave ablation catheter can pass easily through tortuous veins. It also does not require laser protection or strict laser regulations. It has a higher occlusion rate and lesser operation time; these are advantages over the EVLA [5].

To the best of our knowledge only two studies compared EMA and EVLA in the management of VVs. One of them is a retrospective study of Mao and colleagues who aimed to compare the effectiveness and complications of EMA and EVLA for treating varicose veins of lower limbs. The other one was in a nonrandomized comparative study by Yang and colleagues, who compared the clinical outcomes of EMA and EVLA. It also assessed clinical outcomes, complications after the procedure, and evaluated the effect on QoL [6,7].

Therefore, the main objective of this study was to compare the efficacy, safety, and impact on QoL of EMA and EVLA of the great saphenous vein.

Methods

This current parallel multicenter single-blinded randomized controlled trial (RCT) was conducted on patients confirmed to have primary VVs of the great saphenous vein (GSV) attending the vascular surgery outpatient clinic at Ain Shams University Hospitals, Ahmed Maher Teaching Hospital and two authorized private hospitals under supervision in Cairo, Egypt from July 2020 to December 2022. The research ethics committee of the Institutional Review Board of Ain Shams University approved the study. The purpose of this study was clearly explained in the Arabic language to all patients before their enrollment in the study, and a written informed consent form was signed by and obtained from all of those enrolled.

All cases aged greater than 18 years diagnosed as VVs by the clinical pathway containing detailed inquiry of history, Doppler's inspection, and the clinical severity of the varicose disease is graded according to the clinical, etiological, anatomical, and pathophysiological (CEAP) scoring system. CEAP classes C:2–6, E: p, A: s (2 and 3), and P: reflux were included in the study.

Patients with a history of deep vein thrombosis (DVT), patients with active superficial thrombophlebitis of GSV, or peripheral artery diseases, serious systemic diseases, or pregnant patients, patients with recurrent VVs, patients with CEAP classification who do not meet the previous score and patients who declined to participate in this study were excluded.

Randomization and blinding

A computer-generated list of random numbers was used to assign participants. A block size of four was used for block randomization, with a 1 : 1 ratio between the study group and the control group.

The researcher evaluating the patients was not told the allocation sequence of the patients, so he was unaware

of the relationship between the patient numbers and the allocation sequence. As a result, the allocation was hidden from the trial's outcome evaluator.

Patients were randomized into two groups: the control group (EVLA) (n=170) comprised patients who underwent EVLA, and the study group (Microwave EMA group) (n=170) comprised patients who received microwave ablation.

Procedures

Before randomization all participants were subjected to full history, clinical examination, full blood count with differential as well as prothrombin time and INR.

After randomization, all participants were subjected to

For all patients in both groups, the procedures performed under spinal anesthesia, regional anesthesia (nerve block), local infiltration anesthesia (Tumescence anesthesia), or general anesthesia based on patient satisfaction and general condition, anesthetist preference, and operator preference. In cases undergoing spinal, regional, or general anesthesia there was no need for tumescence anesthesia, just cold saline injection perivenous was sufficient. All patients were adjusted to a supine position with slight flexion of the knee joint with abduction and external rotation of the hip joint and thigh. Then, saphenous vein mapping was the initial step to identify the diameter of the saphenous vein at different sites above and below the knee and also to assess saphenofemoral junction (SFJ) incompetence, sites of reflux and incompetent perforators, and sites of tortuosity to determine the perfect puncture site for the patient. The site of puncture depended on the diameter of the GSV, the affected segment of the vein, sites of incompetent perforators, blowouts at the course of GSV, and sites of tortuosity of the GSV.″ The least tortious or nearly straight segment of the vein was better to allow easy access and good working distance. The preferred point of the puncture was just below the knee because at this point the diameter of the vein is large and the risk of thermal injury of the saphenous nerve is low. The great saphenous vein was cannulated percutaneously using the Seldinger technique puncture under duplex ultrasonography (US) guidance. First, a guidewire was introduced into the vein through the needle and the sixth French (Fr) sheath was inserted into the great saphenous vein at a site, which can permit enough working distance The 5-Fr catheter (name, city, country) was introduced through the sheath under US guidance, and the catheter tip was localized 2 cm below the SFJ. Tumescence anesthesia was injected just between the GSV and its overlying sheath in the perivenous tissue under US guidance with multiple syringe hand injections or with the use of a foot pump system. The administration started distally and proceeded proximally till SFJ so that blood did not get trapped. The solution included 500 ml saline or Ringer's lactate, 25 ml 2% lidocaine with or without 10 ml sodium bicarbonate (8.4%). Its temperature was set at 4°C. It causes local anesthesia and significant collapse of the vein. Ablation of the GSV was done under US guidance by energy generated from the device to target vascular tissues with withdrawal of the catheter distally until the whole target vessel had been ablated. Then the sheath was removed and the skin puncture was closed with a medical adhesive.

For patients in the study group (microwave EMA group), the seventh French (Fr) sheath is better. The EMA was performed using a microwave ablation therapeutic apparatus (Sanhe Dingye Technology Co., Ltd., Beijing, China). The device consisted of a microwave generator, with a frequency of 2450 MHz, a power output of 10–120 W, a flexible low-loss cable, and an 18-gauge cooled-shaft antenna. The cooled-shaft antenna is 160 cm long, 2 mm in diameter with a 1 cm long active tip coated with polytetrafluoroethylene and emits an energy of between 45 and 65 W. Great saphenous vein access was performed safely below the knee distal to the most distal incompetent perforator or tributary with no fear about saphenous neuralgia with an injection of enough amount of cold saline or tumescence anesthesia perivenously. The catheter had a good ability to pass through tortious segments and can be safely adjusted to about 1 cm distance from SFJ with no fear of energy transmission to the deep system. Microwave catheter did not require direct contact with the vein wall to ablate the vein. The diameter of GSV did not hinder ablation of the vein even if exceeded 14 mm. The microwave energy was adjusted to 50 W which was proved to be effective and safe by previous experiments in vitro and in vivo. The catheter was withdrawn at an average speed of 1 cm/cycle; each cycle lasts ~5 s until the whole target vessel was treated including the most distal 1 cm before the puncture site.

For patients in the control group (EVLA group), the semiconductor laser treatment apparatus and disposable laser fiber (EUFOTON S. R. L., Trieste, Italy) were used for EVLA. Laser is a monochromatic diode laser which means that it emits light of a single wavelength (1470 nm). Radial laser fibers have combine a 1470 nm diode laser with a patented

radial (360°) design. The new radial double-ring laser fibers with a 2-phase radiation provide an even more homogenous and tissue-friendly light emission.

The laser fibers have two diameters: standard 1.8 mm and slim fiber which is about 1 mm in diameter which has a better advantage in passing tortious segments despite major risk of easy perforation of the vein. The active tip is 2.5 mm in length with a ring light fiber and an emission angle 60°. To achieve damage to all layers of the vein, the vein wall must absorb enough energy to generate a significant amount of heat. If the vein cannot absorb enough energy, it will recanalize. All of the heat generated will disperse to nearby tissues that have sustained undesired damage if the energy absorbed is too great. Because of the larger vein diameter and lower risk of thermal injury to the saphenous nerve, the ideal location for the puncture was just below the knee. The laser fiber was advanced at the SFJ with US guidance after passing through the sheath. The laser fiber's tip should have been positioned 2 cm away from the junction, or slightly below the inferior superficial epigastric vein. The administration of tumescent anesthesia was of paramount importance to achieve an external compression of the vein, posing in strict contact with the vein wall with the fiber tip located within the lumen and having a direct transmission of the laser energy to the vein wall. It was useful to increase the quantity of tumescent solution injected at the level of the SFJ to achieve a better compression of the junction and avoid a possible extension of a thrombotic phenomenon into the femoral vein. The energy delivered by the vein depended on the pullback speed and the wattage. The fiber was withdrawn at a constant speed of 10 mm per second or pulsed for 0.1–25 s until the entire GSV was treated. Repetition of ablation of vein segments occurred frequently to achieve complete ablation of the vein lumen.

After the intervention, for all patients in both groups, the limb was wrapped with an elastic bandage for continuous compression. Then compression stocking (30 mmHg) was applied to replace bandage for 1 month. The patients were asked to mobilize as soon as they were resumed from the state of anesthesia. A prophylactic dose of low molecular weight heparin was given to all patients for 3 days to avoid deep vein thrombosis. All patients were asked to visit the department at 1 week, 6 months, and 1 year after the procedure. Doppler ultrasound examination was repeated to identify whether the treated veins were recanalized or not.

Assessments

The primary outcome variable was the occlusion rate in both groups 6 months after the procedure. The secondary outcome variables were the occlusion rate in both groups at 1 week and 12 months after the procedure, the change in QoL as measured by the Aberdeen score, operating time, diameter reduction, visual analog scale (VAS) scores, and adverse events.

The disease-related effect on the QoL was assessed using the Aberdeen varicose veins questionnaire (AVVQ) a patient-reported, disease-specific QoL questionnaire, which is a validated tool for the assessment of QoL in patients with VVs. The assessments were conducted preprocedure and at 6 months postprocedure. The AVVQ assessed the specific effect on QoL and was scored from 0 to 100, with higher scores indicating a worse QoL [8].

Sample size justification and statistical analysis

According to the data reported in the relevant literature, the effective occlusion rate of GSV at 6 months after the treatment ranges from 92 to 98% (average 95%) (Bozkurt and Yılmaz MF; Desmyttère and colleagues). After comprehensive consideration, the effective rate in this trial is preset as 98%. With significance level $\alpha=0.05$ and 80% power ($\beta=0.20$), 141 cases in each arm will be needed. Assuming an equal sample size in each group, the total sample needed was $141\times2=282$, with an expected dropout rate of 15%, so the sample size is 340 cases [9,10].

The statistical analysis for efficacy and safety was made on the intent-to-treat (ITT) population. All statistical tests were done using a significance level of 95%. Statistically, a *P*-value less than0.05 was considered significant. The Statistical Package for the Social Sciences (SPSS, version 25.0, SSPS Inc, Chicago, IL, USA) was used for the statistical analyses. Data was presented as (mean±SD) for continuous variables, median (IQR) for ordinal and nonparametric data, and frequency and percentage for categorical variables. Comparisons were made using Pearson Chi-square or Phi test for categorical variables and the unpaired Student's *t*-test for continuous variables and other relevant tests.

Results

A total of 377 patients with confirmed primary varicose veins of great saphenous veins were recruited to participate in this study. Eight patients refused to participate, and 19 patients were excluded before randomization because they did not meet the

inclusion criteria, leaving 340 participants for randomization with 170 assigned to each group as follows:

The study group (the microwave group) (n=170) included patients who underwent microwave ablation. The control group (n=170) included patients who underwent EVLA. None were excluded after randomization. The dispositions of these patients are shown in Figure 1. Hence, the ITT population comprised of 340 individuals: the microwave group (n=170) and the control group (n=170)

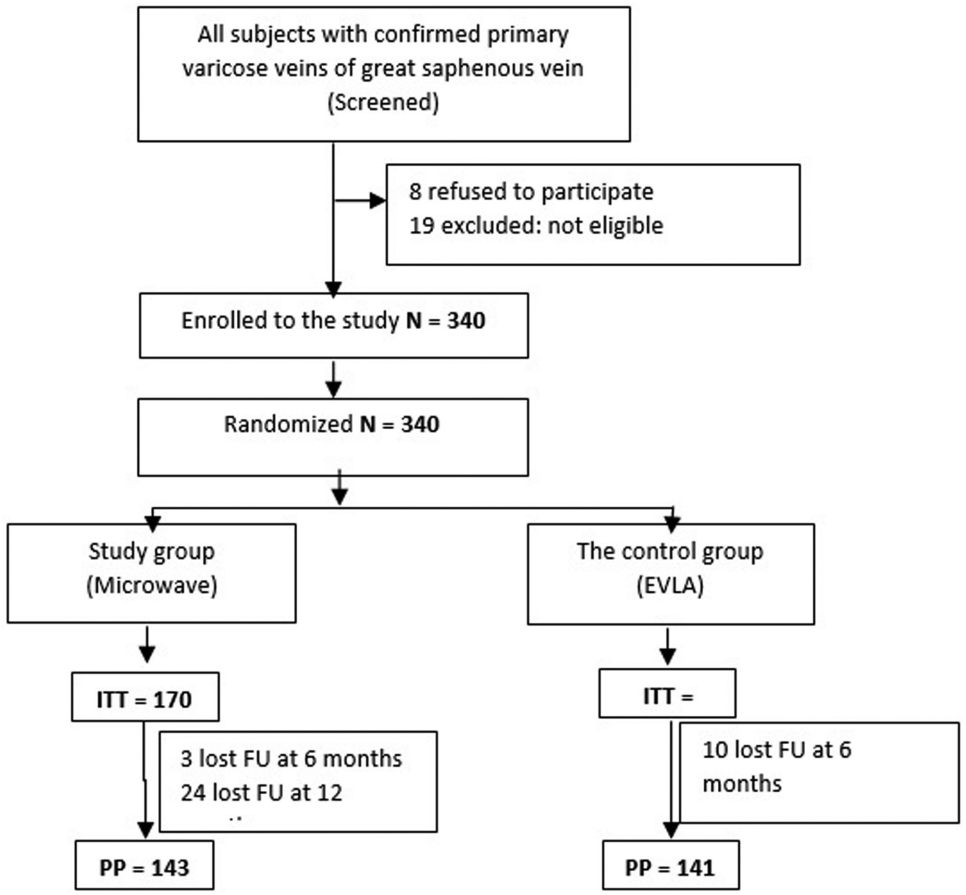
Baseline characteristics

Both the study group and the control group were comparable with regard to their baseline characteristics (P values > 0.05) as shown in Table 1. The microwave group has more females (51.8%) than the EVLA group (47.1%); however, the difference is not significant (0.386). Both the study group and the control group were comparable with regard to age (P=0. 454). The median IQR and the mean±SD of age was 38 (14.3) and 40.2±9 in the study (microwave) group and 42 (13.3) and 40.8±8.8 years in the control group.

Also, both the study group and the control group were comparable with regard to BMI (P=0. 514). The median IQR and the mean±SD of BMI was 25 (4) and 24.7±3.1 in the study (microwave) group; and 25 (4) and 24.5±3.2 Kg/m^2 in the control group. Both groups were comparable with regard to the limb affected (P=0.184). Only 14.7% and 10.0% of the study group and the control group have both limbs affected. The right limb was affected in more than 50% of each group, as shown in Table 1. Both groups were comparable with regard to CEAP-classification (P=0.068). The most frequent CEAP classification is C4a Ep As Pr, accounting for 38.8% in the study group 47.1% in the control group as shown in Table 1.

The study group and the control group were comparable with regard to GSV preoperative diameter (P=0. 054). The median IQR and the mean±SD of the preoperative GSV diameter were 7.9 (1.7) and 8.4±1.6 in the study (microwave) group and 8.5 (1.4) and 8.5±1.2 mm in the control

Fig. 1



CONSORT diagram.

Table 1 Baseline characteristics

	Endovenous microwave ablation		Endovenous laser ablation		
Intent-to-treat population	170		170		
Sex	*N* (%)		*n* (%)		*P*-value
Female	88 (51.8%)		80 (47.1%)		0.386
Male	82 (48.2%)		90 (52.9%)		
Limb affected					
Bilateral	25 (14.7%)		17 (10.0%)		0.184
Left	52 (30.6%)		66 (38.8%)		
Right	93 (54.7%)		87 (51.2%)		
CEAP classification					
C3s Ep As Pr	22 (12.9%)		26 (15.3%)		0.068
C4a Ep As Pr	66 (38.8%)		80 (47.1%)		
C4b Ep As Pr	47 (27.6%)		37 (21.8%)		
C4s Ep As Pr	2 (1.2%)		0		
C5s Ep As Pr	26 (15.3%)		14 (8.2%)		
C6s Ep As Pr	7 (4.1%)		13 (7.6%)		
	Mean	**Median (IQR)**	**Mean±SD**	**Median (IQR)**	*P*
Age, years	40.2±9	38 (14.3)	40.8±8.8	42 (13.3)	0.454
BMI, Kg/m^2	24.7±3.1	25 (4)	24.5±3.2	25 (4)	0.514
Preoperative diameter, mm	8.4±1.6	7.9 (1.7)	8.5±1.2	8.5 (1.4)	0.054
Preoperative Aberdeen score	22.6±2.4	23.1 (3.9)	22.4±2.5	22.6 (3.7)	0.468

group. Both groups were comparable with regard to preoperative Aberdeen score (P=0.468). The median IQR and the mean±SD of the preoperative Aberdeen score was 23.1 (3.9) and 22.6±2.4 in the study (microwave) group and 22.6 (3.7) and 22.4±2.5 in the control group.

Operative and postoperative characteristics

Both the study group and the control group were significantly different with regard to operating time (P<0.001). The operating time is less in the study group than in the control group. The median IQR and the mean±SD of the operating time were 7 (4) and 8.7 ±4.1 min in the study (microwave) group; and 9 (5) and 10±3.9 min in the control group as shown in Table 2 and Figure 2.

Also, both the study group and the control group were comparable with regard to the treated length of the GSV (P=0. 863). The median IQR and the mean±SD of the GSV length treated were 56 (22) and 60.5 ±27.1 cm in the study (microwave) group and 56 (19) and 61.9±26.9 cm in the control group as shown in Table 2. In addition, both the study group and the control group were comparable with regard to the percentage of diameter reduction (P=0. 254). The median IQR and the mean±SD of the percentage of diameter reduction was 98 (3) and 98.2±1.6% in the study (microwave) group and 98 (2) and 98±1.7% in the control group, as shown in Table 1.

The postoperative stay in both groups was the same; it was 1 day in all cases. Also, both the study group and the control group were comparable with regard to postoperative VAS score (P=0. 223). The median IQR and the mean±SD of the postoperative VAS score were 1 (2) and 1.10±1.03 in the study (microwave) group and 1 (2) and 1.06±1.28 in the control group, as shown in Table 1.

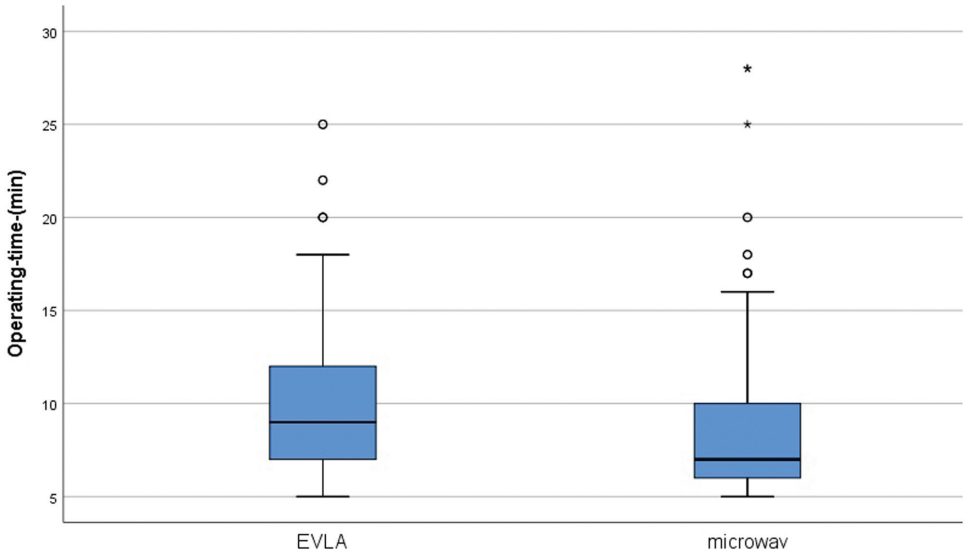
Recanalization and success rate

As depicted in Table 3, both the study group and the control group showed 100% success at 1-week evaluation as none of the cases in both groups

Table 2 Operative and postoperative details

	Microwave		Endovenous laser ablation		
	Mean	Median (IQR)	Mean±SD	Median (IQR)	*P*
Operative details					
Length treated, cm	60.5±27.1	56 (22)	61.9±26.9	56 (19)	0.863
Operating time, min	8.7±4.1	7 (4)	10±3.9	9 (5)	< 0.001
Postoperative details					
Diameter, %reduction	98.2±1.6	98 (3)	98±1.7	98 (2)	0.254
VAS scores	1.10±1.03	1 (2)	1.06±1.28	1 (2)	0.223

Fig. 2



Operating time.

Table 3 Recanalization at 1 week, 6 months, and 12 months

	Number of cases	Microwave		Endovenous laser ablation		*P*-value
Recanalization-1-week	340	0/170	0	0/170	0	NA
Recanalization-6-months	327	1/167	0.6%	2/160	1.3%	0.537
Recanalization-12-months	284	0/143	0	0/141	0	NA

suffered recanalization. At a 6-month evaluation, only 1 case in the study group and 2 cases of the control group experienced focal segmental recanalization; however, the difference is not significant (P=0.537). At the 12-month evaluation, the study group and the control group showed 100% success as none of the cases in both groups suffered recanalization.

Postoperative QoL

Both the study group and the control group were significantly different with regard to the 6-month Aberdeen score (P=< 0.001). The study group has a lower score than the control group. The median IQR and the mean±SD of the postoperative Aberdeen score were 9 (2.7) and 9.3±1.7 in the study (microwave) group and 10.8 (3.4) and 10.8±1.8 in the control group, as shown in Figure 3.

Safety results

As depicted from Table 4, both the study group and the control group were comparable (P values > 0.05) with regard to adverse events except for paresthesia (P-value = 0.025). About 11.2% of the control group experienced paresthesia versus only 2.9% of the study group.

Discussion

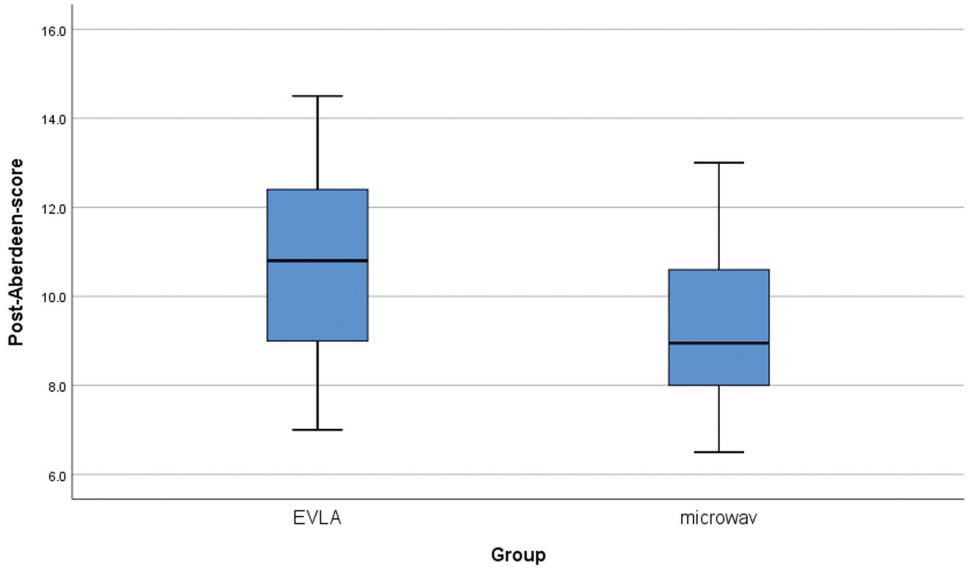
Guidelines and systematic reviews propose EVLA and EMA as the initial thermal ablation procedures for patients with VVs; however, the outcomes of these two operations have not yet been compared [11,12]. To the best of our knowledge, a literature search revealed no randomized controlled trial comparing both treatment modalities. Therefore, the main objective behind the current randomized controlled single-blind study was to compare both treatment modalities in terms of efficacy, safety, and QoL.

The ITT analysis in our study was carried out on 340 individuals, group 1 (active group) included 170 patients who underwent EMA, and group 2 (control group) had 170 patients who underwent EVLA.

The present research verified the relative short-term results of EMA and EVLA, fully ablated the GSV trunk, and showed no recanalization with either technique at the 1-week evaluation (100% success rate).

In the current study, both the EMA group and the EVLA group were comparable as regards gender, age, and BMI (P values > 0.05). In addition, both groups

Fig. 3



Postoperative 6-months' Aberdeen score.

Table 4 Adverse events

	Microwave	Endovenous laser ablation	
Intent-to-treat population	170	170	*P*-value
Adverse events	*n* (%)	*n* (%)	
Ecchymosis	6 (3.5%)	10 (5.9%)	0.067
Skin burns	0	3 (1.8%)	0.5
Paresthesia	**5 (2.9%)**	**19 (11.2%)**	**0.025**
Inflammation	5 (2.9%)	3 (1.8%)	0.311
Scleroma	0	0	
DVT	0	0	

are comparable as regards the limbs affected, CEAP classification, preoperative diameter, and preoperative Aberdeen score (P values > 0.05).

VVs of the GSV were more unilateral (85.3% and 90.0% in the EMA and EVLA groups, respectively) than bilateral (14.7% and 10.0%), according to the findings of this study. This was in line with a study by Yang and colleagues, which examined the clinical results of endovenous laser ablation against EMA for varicose veins in 145 patients and 139 patients who received EMA. In additionally, using the AVVQ and the EuroQol Group 5-Dimension Self-Report Questionnaire, it analyzed the impact on QoL and assessed clinical outcomes and complications at 1, 6, and 12 months following the procedure. According to Yang and colleagues, unilateral groups (EMA and EVLA, respectively) reported higher rates of 90% and 89% than bilateral groups (10% and 11%) [13].

In addition, in our study, there were more VVs on the right side (30.6% and 38.8%) than on the left side (54.7% and 51.2% EMA and EVLA, respectively). This was not the issue with the retrospective study conducted by Mao and colleagues, which compared the risks and benefits of endovenous laser ablation versus EMA in the treatment of varicose veins in the lower limbs. They comprised 259 cases in all, with 306 limbs allocated to EMA or EVLA. The study's findings showed that there were more VVs on the left side (52% and 53% EMA and EVLA, respectively) than on the right (48% and 47%) [14].

Our study depicted that more cases were in the CEAP classification C3 and C4. It was 81% and 84% in the EMA and EVLA groups, respectively. Also, the study by Yang and colleagues demonstrated more cases in the C3 and C4 (76% and 79%). However, the study of Mao and colleagues showed a lower rate than ours (45% and 43%) [14].

The results of our study showed that the preoperative diameter of the GSV was 8.4±1.6 and 8.5±1.2 mm for the EMA and EVLA groups, respectively (P=0.054). However, the study of Yang and colleagues demonstrated preoperative diameter of the GSV of 6.78+2.05 and 6.12+286 mm, for the EMA and EVLA groups, respectively (P=0.58) [13].

In the current RCT, the preoperative Aberdeen score for the EMA and EVLA groups was 22.6±2.4 and 22.4 ±2.5, respectively (P=0.468). Furthermore, Mao and colleagues revealed that the EMA and EVLA groups had preoperative Aberdeen scores of (13.76±1.32 and 13.44±1.29), respectively (P>0.05) [14].

The EMA and EVLA groups had VAS scores of 1.10 ±1.03 and 1.06±1.28, respectively (P=0.223). The VAS scores for the EMA and EVLA groups in the Yang *et al.* (2020) study were 2.16±1.25 and 2.35±1.06, respectively (P=0.62) [13].

In our research, the EMA group's operating time was 8.7±4.1 min, while the EVLA group's operating time was 10±3.9 min (P<0.001). This indicates that EMA could ablate VVs with a shorter procedure time when compared with the EVLA procedure used in this study. Compared ith our findings, Mao and colleagues reported an operating time that was similar, but longer than ours (27.5±6.3 EMA and 26.7±5.6 EVLA) (P>0.05) [14].

The length of hospital stay was 1 day in both groups in our study. However, the length of hospital days was comparable but more than in ours (2.3±0.3 EMA and 2.1±0.4 EVLA; P> 0.05) in the study of Mao and colleagues. Length of hospital stay in the study of Yang and colleagues was close to ours as it was 1.15±0.45 and 1.20±0.62 days (P= 0.33) [13].

The results of the current study showed that the QoL as demonstrated by the postoperative Aberdeen score is significantly (P=< 0.001) better in the EMA group than in the EVLA group. The EMA group has a lower score of 9.3±1.7 than the EVLA group (10.8±1.8). In contrast to the results of our study, Mao and colleagues showed a comparable (P>0.05) postoperative Aberdeen score (EMA 10.8±1.3 and EVLA 11.1 ±1.2) [14].

Heat-related complications, including skin burns, nerve damage, and induration, are frequently indicated by the thermal ablation procedures used to treat VVs. The current study's safety analysis revealed that the safety of the EMA and EVLA groups was comparable (P values > 0.05). However, paresthesia is significantly (P=0.025) lower in the EMA (2.9%) than in the EVLA group (11.2%) and reversible within 1–3 months maximum with medical treatment and adjusting the EMA machine settings during the procedure, so further research study is being done for this finding. In contrast to the results of our study, Mao and colleagues showed that paresthesia was higher in the EMA group (10.74%) than in the EVLA group (5.8%) (P<0.01) [14]. This was due to the heat conduction effect, which suggests that thermal injury may result in irreversible nerve damage. Nonetheless, we think that a complete GSV thermal ablation is required; thermal insult could be minimized using less energy and tumescent anesthesia immediately before ablation. Furthermore, ablation of the GSV trunk above the knee is advised for patients classified as mild-to-moderate, as this may lower the risk of thermal injury. Because residual varicose veins are giving rise to debate regarding endovenous therapy, we think it is critical to perform injection sclerotherapy or a completion phlebectomy for GSV ablation procedures [15].

In our study, ecchymosis is nonsignificantly lower in the EMA (3.5%) than in the EVLA group (5.9%) (P=0.067). In contrast to the results of our study, Mao and colleagues showed a higher rate of ecchymosis in the EMA group (17.4%) than in the EVLA group (21.5%) (P< 0.05). Also, in our study, skin burns are nonsignificantly lower in the EMA (0%) than in the EVLA group (1.8%) (P=0.5). However, in the Mao and colleagues study skin burns were significantly higher in the EMA group (9.9%) than in the EVLA group (6.5%) (P<0.01) [14].

Comparing these findings with the EVLA procedure confirmed that the EMA procedure exhibits a lower incidence of complications. Given the disparity in thermal temperatures between microwaves (70–100°C) and lasers (>100°C), we determined that EMA, as a novel thermal ablation technique, would be more appropriate for treating VVs [16,17].

Thermal injury is a less common complication of microwave ablation than other ablation procedures because of its features, which include rapid heating, moderate thermal penetration, inconspicuous carbonization, high thermal efficiency, and controllable thermal ablation range [18,19].

As depicted from the results of our study, both the EMA group and the EVLA group showed 100% success at the 1-week evaluation as none of the cases

in both groups suffered recanalization. At 6-month evaluation, only one case in the EMA group and two cases of the EVLA group experienced focal segmental recanalization; however, the difference is not significant (P=0.537). At the 12-month evaluation, the EMA group and the EVLA group showed 100% success as none of the cases in both groups suffered recanalization.

In contrast to the results of our current RCT, Mao and colleagues showed less canalization after 1 week postoperatively in the EMA group (0.76%) than in the EVLA group (2%) (P<0.01). Also, their study showed less canalization after 6 months postoperatively in the EMA group (5.5%) than in the EVLA group (9.9%) (P<0.01). However, the retrospective nature of this study does not allow for drawing a conclusive evidence [14].

Meanwhile, the success rate was 100% in the study of Yang and colleagues and recanalization of GSV did not occur at 12 months' follow-up. However, the local recurrence rate was lower in the EMA group than in the EVLA group at 12 months (2.34% vs. 8.46%, P=0.03). It is important to note that the study of Yang and colleagues is a non-randomized trial, which can be subjected to selection bias that jeopardizes reaching a conclusive evidence[13].

These outcomes proved that EMA is a new and satisfactory method for treating VVs with good effectiveness in ablation. Different thermal mechanisms are used in the EMA procedure than in the EVLA procedure. Heat is produced by microwave ablation using molecular vibrations within the tissue. While the laser thermal effect only affects the vessel wall, the tissue is instantly (within a few seconds) solidified at a high temperature in a small range by the microwave radiator, which contacts the venous wall directly during treatment. This can quickly close the VVs [17,18].

The current study had the advantage of being the first randomized trial to tackle this research question. Also, the sample size is quite enough and had the power to give a conclusive evidence. However, the follow-up time was not long enough beyond the first year. The long-term outcomes of this study still need to be confirmed by additional randomized trials. Another limitation of the study is that it used the AVVQ for content validity, including the weighting of the AVVQ questions, based on the opinion of clinicians; the instrument had poor acceptability [8].

In conclusion, the study suggests that EMA is an effective alternative to laser ablation for treating varicose veins, with a higher occlusion rate and fewer serious complications. However, the choice of treatment should be based on individual patient characteristics and the expertise of the treating physician.

In conclusion, EMA has a lower operating time than laser ablation. EMA is as effective as laser ablation for treating varicose veins. EMA has fewer adverse events than laser ablation. EMA demonstrates a higher QoL than laser ablation.However, the choice of treatment should be based on individual patient characteristics and the expertise of the treating physician.

From our work, we recommend routine uses of EMA in primary VVs. Also, we recommend further studies with long follow-up times of 2 years or more to study the long-term outcomes of EMA in primary VVs, and to use other QoL measurement tools other than AVVQ with more content validity and better reliability.

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Conflicts of interest
There are no conflicts of interest.

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