

Below-Knee Endovenous Microwave Ablation of Great Saphenous Vein: A Prospective Single-Arm Study

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ABSTRACT

Background: Intervention on the Great Saphenous Vein (GSV) has traditionally been limited to the above-knee (AK-GSV) segment for fear of saphenous nerve damage. Nonhealing ulcers and skin discoloration may persist and significantly impacting individuals' quality of life (QOL) and hindering daily activities.

Objectives: Studying the effectiveness, safety, and effects on quality of life using below-knee endovenous microwave ablation (EMA) for the treatment of varicose veins of the greater saphenous vein (GSV) was the primary goal of this study.

Methods: A non-comparative, single-arm, multicenter trial was carried out on 87 individuals who had been verified to have primary GSV VVs. They were all given below-knee EMA.

Results: Males accounted for half of the sample 37(50%). The mean±SD of age was 40.8±8.6. The most frequent CEAP classification is (C4a Ep As Pr). The mean±SD of the preoperative GSV diameter was 8.2±1.6. The mean±SD of the preoperative Aberdeen score was 22.7±2.2. The mean±SD of the GSV length treated was 82.1±32.1cm. The mean±SD of the percentage of diameter reduction was 98.2±1.8%. The mean±SD of the postoperative VAS score was 0.9±0.8.

The study's one-week review revealed 100% success as none of the instances that attended the follow-up appointment had recanalization. The study showed that none of the cases developed skin burns, scleroma, or DVT. About 30 cases (40.5%) developed transient mild paresthesia which disappeared in an average of 5.4±1.6 week with a minimum of 2 and a maximum of weeks 8.

Conclusion: With a greater occlusion rate and fewer problems, the study concludes that endovenous microwave ablation is a successful method for ablation of below-knee varicose veins. Nonetheless, the features of each patient and the treating physician's experience should guide the therapy decision.

Key Words: Adverse events, endovenous microwave ablation, great saphenous vein, quality of life, varicose veins.

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INTRODUCTION

Intervention on the Great Saphenous Vein (GSV) has traditionally been limited to the above-knee (AK-GSV) segment for fear of saphenous nerve damage. In severe cases, with refluxing below knee great saphenous vein segment complications like nonhealing ulcers and skin discoloration may arise, significantly impacting individuals' quality of life and hindering daily activities. These residual symptoms of chronic venous insufficiency may be in need for reintervention were reported to result in nearly half the patients if the refluxing BK-GSV is ignored^[1].

The introduction of endovenous thermal ablation techniques has transformed VVs treatment, offering a minimally invasive alternative to traditional surgeries^[2]. Catheter-based radiofrequency and endovenous laser ablation (EVLA) are commonly used, utilizing heat energy to collapse and reabsorb damaged veins. Compared

to surgical methods, these thermal ablation techniques present lower complication risks, shorter recovery times, and improved cosmetic outcomes, often performed on an outpatient basis without general anesthesia^[3].

The recent addition to these techniques is endovenous microwave ablation (EMA), which operates at significantly lower temperatures while using heat to permanently destroy veins, minimizing the risk of skin burn and nerve injury^[4,5].

Despite the potential advantages of EMA, only a few studies investigated its efficacy and safety at the Below-knee ablation Yang *et al.*, (2020)^[6,7].

Therefore, the purpose of our study is to evaluate the effectiveness, safety, and effect on quality of life (QoL) of greater saphenous vein VVs placed below the knee.

The findings of an *in vitro* research conducted from January to March 2006 at Rajavithi Hospital in Bangkok, Thailand, served as the foundation for our investigation. Greater saphenous vein (GSV) stripping was used to treat varicose veins in two individuals. The greater saphenous vein (GSV) specimens, each measuring around 30cm in length after stripping, were employed in this research, divided to 6 equal length pieces and were ablated by microwave catheter. Nine out of ten pieces with 20% extraluminal tissue damage had the burning depth to tunica adventitia in the 50 Watt group (mean distance was less than one millimeter)^[8].

Those who visited the vascular surgery outpatient clinic at Ain Shams University Hospitals, Ahmed Maher Teaching Hospital, and two approved private hospitals under supervision in Cairo, Egypt, between July 2021 and November 2022 and were confirmed to have primary below-knee varicose veins (VVs) were the subjects of this prospective case-series study. The study received approval from Ain Shams University's institutional review board's research ethics committee. Prior to their registration, all subjects were told in Arabic of the study's aim, and each participant provided signed informed consent.

The clinical severity grading system, which uses the clinical, etiological, anatomical, and pathophysiological (CEAP) scoring system, Doppler's inspection, and a thorough history inquiry were all part of the clinical route that led to the diagnosis of VVs in all cases involving patients older than 18. For the study, those who fit within CEAP classes C: 2-6, E:p, A:s (2 and 3), and P: reflux were specifically taken into consideration.

DVT, active superficial thrombophlebitis of the great saphenous vein (GSV), peripheral artery diseases, systemic severe illnesses, pregnancy, recurrent VVs, CEAP classification that did not meet the specified score, persistent paresthesia or other peripheral neuropathy, and refusal to participate were among the exclusion criteria.

The patients were then assigned to the Microwave Endovenous Microwave Ablation (EMA) group, which underwent microwave ablation as part of the study.

METHODS

Procedures:

All participants underwent a comprehensive evaluation, including a detailed medical history, clinical examination, complete blood count with differential, prothrombin time, and INR. The procedures were performed under various types of anesthesia (spinal anesthesia, regional anesthesia, local infiltration anesthesia, or general anesthesia) based on patient preference, general condition, anesthesiologist preference, and operator preference. Patients undergoing spinal, regional, or general anesthesia did not require tumescence anesthesia; cold saline injection perivenous

was sufficient. Patients were positioned supine with a slight flexion of the knee joint, abduction, and external rotation of the hip joint and thigh.

Saphenous vein mapping was conducted as the initial step to assess the diameter of the vein at different sites above and below the knee, evaluate saphenofemoral junction (SFJ) incompetence, and identify reflux sites, incompetent perforators, and sites of tortuosity.

The puncture site selection was based on the diameter of the great saphenous vein (GSV), the diseased segment, and sites of incompetent perforators, blowouts, and tortuosity. The least tortuous or nearly straight segment below the knee was preferred for easy access and a reasonable working distance. Percutaneous cannulation of the GSV was performed using the Seldinger technique under duplex ultrasonography guidance.

Tumescence anesthesia was injected into the perivenous tissue under ultrasonography guidance, and the administration started distally and proceeded proximally. The anesthesia solution included saline or ringer lactate, lidocaine, and sodium bicarbonate. Microwave endovenous ablation (EMA) was performed using a therapeutic apparatus with a microwave generator, a flexible low-loss cable, and an 18-gauge cooled-shaft antenna with built in pump system From ECO Medical Technology (Nanjing) CO., LTD. The cooled-shaft antenna, 160cm long, emitted energy between 45-65W. Access to the GSV was made safely below the knee, distal to the most distal point of reflux, ensuring no saphenous neuralgia. The catheter could pass through tortuous segments and was adjusted to about a 1-2cm distance from SFJ.

Until the whole target vein was treated, the catheter was pulled at an average rate of 1cm each cycle using microwave radiation that had been adjusted to 50W.

Following the intervention, an elastic bandage was placed over the affected limb, and compression stockings (30mmHg) were worn for a month. Patients were discharged shortly after recovering from anesthesia, given three days of prophylactic low molecular weight heparin, and had Doppler ultrasonography exams one week, six months, and a year following the treatment.

Assessments:

Six months following the surgery, the occlusion rate served as the main outcome measure. Occlusion rates at one week and twelve months following the surgery, variations in quality of life as measured by the Aberdeen score, operating time, diameter reduction, VAS ratings, and adverse events, such as persistent paresthesia, were all considered secondary outcome measures.

The Aberdeen Varicose Veins Questionnaire (AVVQ), a validated, illness-specific QoL questionnaire, was used

to assess how the condition affected people's quality of life (QoL). This evaluation instrument was used prior to the surgery and six months following it. With higher scores signifying a more markedly negative influence, the AVVQ score, which ranges from 0 to 100, offers insight into the precise consequences on QoL^[9].

Sample size justification and statistical analysis:

The effective occlusion rate of GSV after 6 months following treatment varies from 92% to 98%, based on data presented in pertinent literature (Bozkurt and Yilmaz MF. (2016); Desmytère *et al.*, (2007). Following careful analysis, the study's efficacy rate was determined to be 90%. 37 examples will be required with 80% power ($\beta=0.20$) and a significance threshold of $\alpha=0.05$. The sample size is 51 instances, assuming a 30% dropout rate^[10,11].

A 95% significance threshold was used for all statistical tests. A *P*-value of less than 0.05 was deemed statistically significant. The statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS, version 25.0, SSPS Inc, and Chicago, IL, USA). The data was shown as frequency and percentage for categorical variables, mean $\pm$ SD for continuous variables, and median (IQR) for ordinal and non-parametric data. For continuous variables, the paired Student's *t*-test was used for comparisons.

RESULTS

For this study, 87 individuals with verified primary varicose veins of the great saphenous vein were included. Seventy-four individuals had microwave ablation after five subjects declined to participate and eight patients were eliminated before to the intervention due to their failure to satisfy the inclusion criteria.

Baseline characteristics:

Males accounted for 37(50%) of cases. The mean $\pm$ SD of age was 40.8 $\pm$ 8.6. The mean $\pm$ SD of BMI was 24.9 $\pm$ 2.6Kg/m². 41(55.4%) of patients had Right side vv, 22(29.7%) Left side and 11(14.9%) bilateral. The most frequent CEAP classification is (C4a Ep As Pr) as it accounted for 28(37.8%) followed by C4b Ep As Pr 24(32.4%), C3s Ep As Pr 14(18.9%) and C5s Ep As Pr 8(10.8%).

The preoperative GSV diameter ranged from 6.4mm to 12mm, with a mean $\pm$ SD of 8.2 $\pm$ 1.6. The preoperative Aberdeen score ranged from a minimum of 16.8 to a maximum of 26.1, with a mean $\pm$ SD of 22.7 $\pm$ 2.2.

Operative and post-operative details:

The procedure duration had a minimum of 7 minutes and a high of 28 minutes, with a mean $\pm$ SD of 10.7 $\pm$ 4.7 minutes. Additionally, the GSV length treated ranged from 60 to 200cm, with a mean $\pm$ SD of 82.1 $\pm$ 32.1cm. The percentage of diameter decrease ranged from 95% to 100%, with a mean $\pm$ SD of 98.2 $\pm$ 1.8%.

With a minimum of 0 and a maximum of 4, the postoperative VAS score had a mean $\pm$ SD of 0.9 $\pm$ 0.8. For all cases, the hospital stay lasted just one day.

Recanalization and success rate:

Since none of the 74 instances had recanalization, the research demonstrated 100% success at the one-week evaluation point. None of the 73 patients that attended the follow-up appointment (one instance was discontinued) had recanalization at the 6-month assessment. One of the 66 patients that attended the follow-up visit (the other eight cases were dismissed) experienced recanalization at the 12-month assessment.

Postoperative QoL:

The 6-months mean Aberdeen score 9.6 $\pm$ 1.7 was significantly ($p<0.001$) lower than the preoperative score 22.7 $\pm$ 2.2, as shown in Table (1) and Figure (1).

Table 1: Aberdeen score: pre and post-operative:

	Preoperative Aberdeen score	Postoperative Aberdeen score
Minimum	16.8	6.5
Lower quartile	21.5	8.4
Median	23.0	10.0
Upper quartile	24.6	11.0
Maximum	26.1	13.0

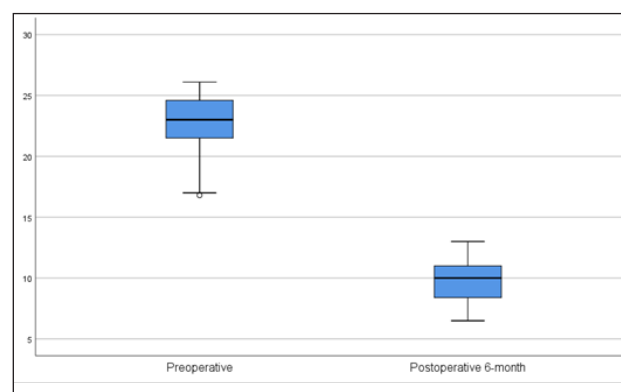


Fig. 1: Aberdeen score.

Safety results:

The study showed that there were few postoperative complications in the cases. Two cases developed and another two cases developed inflammation. None of the cases developed skin burns, scleroma, or DVT.

About 30 cases (40.5%) developed transient mild paresthesia which disappeared in an average of 5.4 $\pm$ 1.6 week with a minimum of 2 and a maximum of weeks 8.

Only three cases (4.1%) developed long time moderate paresthesia, resolved with medical treatment for 3-6 months. No patients suffered from chronic paresthesia.

DISCUSSION

Although the standard approach is the primary choice for treating VVS, it is linked to problems and recurrences often^[9,10]. Recent guidelines state that because EMA, EVLA, and other thermal ablation procedures are more successful in many nations, they have supplanted previous methods^[13]. The present single-arm study's primary goal was to assess the below-knee EMA's effectiveness, safety, and quality of life.

In the current study, right side VVs (55.4%) were more than left side (29.7%), and bilateral VVs was detected in 14.49%. That was in disagreement to the retrospective study of Mao *et al.*, (2012) which demonstrated VVs more in the left side (52%) than the right side (48%)^[6].

Our study depicted that more cases was in the CEAP classification C3 and C4. It was 89.1%. Also, the study of Yang *et al.* (2020) demonstrated more cases in the C3 and C4 (76%)^[13]. However, the study of Mao *et al.*, (2012) showed a lower rate than ours (45%)^[6].

The results of our study showed that preoperative diameter of the GSV was 8.2 ± 1.6 mm. However, the study of Yang *et al.*, (2020) demonstrated preoperative diameter of the GSV of 6.78 ± 2.05 mm^[13].

The preoperative Aberdeen score in the current RCT was (22.7 ± 2.2). In contrast, Mao *et al.*, (2012) reported a lower preoperative Aberdeen score (13.76 ± 1.32)^[6]. VAS scores were 0.9 ± 0.8 . The VAS scores in the study of Yang *et al.*, (2020) was higher 2.16 ± 1.25 than ours^[13].

Operating time in our study was (10.7 ± 4.7 min). In contrast to the results of our study, Mao *et al.*, (2012) reported a comparable - but more than ours - operating time (27.5 ± 6.3 min)^[6].

Th length of hospital stay was one day in all cases in our study. However, length of hospital days was more than in ours (2.3 ± 0.3 days) in the study of Mao *et al.*, (2012)^[6]. Length of hospital stay in the study of Yang *et al.*, (2020) was (1.15 ± 0.45 days)^[13].

Our study showed that below-knee EMA is effective and safe for treatment of the below knee segment of refluxing saphenous veins. It has a 100% success rate without recanalization at first week and at 6-month follow-up visit. However, only one case out of the 66 cases attended the visit (1.5%) suffered recanalization at 12-month follow-up visit.

EMA therapy may effectively block the tortuous veins around ulcers, reduce the pathological state of the ulcers, and then encourage ulcer healing^[14].

Heat-related problems are frequently indicated by the thermal ablation treatments used to treat VVs. Problems

including skin burns, nerve damage, and induration are commonly seen while treating VVs with these methods. According to our research, the EMA method is safe^[15].

None of the instances experienced lasting paresthesia, even though all of them experienced temporary paresthesia. Additionally, the study's findings demonstrated that the cases had little postoperative problems. While two individuals experienced ecchymosis and two more experienced inflammation, none of the cases experienced DVT, scleroma, or skin burn. Because microwaves (70°C to 100°C) and lasers (>100°C) have different thermal temperatures, EMA is regarded as a novel ablation technique^[13].

Also, out work showed that 40.5% of cases developed transient mild paresthesia which disappeared in an average of 5.4 ± 1.6 week. Only three cases (4.1%) developed resolved 2-6 months paresthesia.

Mao *et al.*, (2012) demonstrated that paresthesia was greater in the EMA group (10.74%)^[6], which is in contrast to the findings of our investigation. This was due to the fact that thermal injury might result in irreversible nerve damage due to the heat conduction effect. Nonetheless, we think that the entire GSV must be thermally ablated; this might lessen the thermal damage by using less energy and tumescent anesthesia.

Thermal damage is less common with microwave ablation than with conventional ablation procedures because of its high thermal efficiency, rapid heating, gentle thermal penetration, undetectable carbonization, and customizable thermal ablation range^[5]. Furthermore, the vast majority of thermal ablation issues may be resolved quickly and don't need further care^[16]. This concurred with Yang and colleagues^[3]. One and six months following surgery, EMA showed a reduction in the incidence of sensory impairment. Without therapy, these persons recovered in three to six months. Only minor complaints of sensory impairment should be treated with medication and physical therapy^[17].

According to our research, EMA was able to provide a positive clinical result and success rate, which had an impact on patients' quality of life. Our study's findings demonstrated that the mean Aberdeen score after six months was substantially less than the preoperative score. This is consistent with the findings of Mao *et al.*, (2012) and Yang *et al.*,^[13,6].

According to these findings, EMA was a novel and successful method of treating VV. Using the tissue's molecular vibrations, microwave ablation produces heat. The microwave radiator makes direct contact with the venous wall and instantaneously (within a few seconds) solidifies the tissue at a high temperature in a narrow region, which can swiftly seal the VVs^[18,19].

Our study had the limitation that it non comparative study. However, it is to the best of our knowledge the first clinical study reporting the results of EMA in below-knee ablation. Also, the follow up period is quiet enough to state its safety. Again, of course randomized controlled trial is warranted to further develop the evidence. Our study was just a pilot study to generate the hypothesis.

CONCLUSION

In conclusion, the study suggests that endovenous microwave ablation is an effective for ablation of below-knee varicose veins, with a higher occlusion rate and fewer complications. However, the choice of treatment should be based on individual patient characteristics and the expertise of the treating physician.

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

CONFLICT OF INTERESTS

There is no conflict of interests.

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