Randomized Clinical Trial of Endovenous Microwave Ablation Combined with High Ligation Versus Conventional Surgery for Varicose Veins

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WHAT THIS PAPER ADDS

This study was designed to evaluate the outcome of patients who underwent endovenous microwave ablation (EMA). This new endovenous therapy technique was compared with high ligation and stripping. Our results demonstrate that the EMA technique showed favourable short- and medium-term clinical outcomes. This technique showed similar results to other endovenous techniques, and is an effective and technically feasible new technique for the treatment of varicose veins.

Objective: To evaluate the efficacy of endovenous microwave ablation (EMA) in treatment of varicose veins (VVS).

Methods: The patients were randomly divided into EMA and high ligation and stripping (HLS) groups. Clinical outcomes and complications were assessed at 1, 3, 6, 12, and 24 months after surgery, and the effect on quality of life was also assessed using the Aberdeen Varicose Vein Questionnaire (AVVQ) and Venous Clinical Severity Score (VCSS) respectively.

Results: EMA occluded VVS completely, with a shorter operative time, less bleeding and smaller incisions than the HLS procedure. In the EMA group, skin burns were found on 11 limbs (10.2%); sensory alteration and ecchymosis were less; and the recurrence rate of VVS was relatively lower compared with the HLS group. Both groups had significant improvement in VCSS and disease-specific quality of life (AVVQ) postoperatively. There was no significant difference in AVVQ and VCSS scores between the groups.

Conclusion: EMA is an effective new technique for the treatment of VVS, and had a more satisfactory clinical outcome than HLS in the short term.

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Keywords: Endovenous microwave ablation, High ligation and stripping, Varicose vein

INTRODUCTION

Varicose veins (VVS) is a common disease in adults, and VVS without skin changes are present in about 20% of the population, while active ulcers are found in 0.5%.[1] The traditional surgical treatment of VVS is high ligation of the great saphenous vein (GSV), axial stripping and phlebectomy, but the postoperative clinical recurrence is as high as 60%.[2] Recently, minimally invasive techniques, such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), have become widely used for the treatment of VVS.[3–7] Several reports have shown that endovenous techniques are as effective as traditional procedures.[5–7] However, there are no reports concerning endovenous microwave ablation (EMA) for the treatment of VVS. We used the intracavity microwave coagulation system to treat the VVS in this study.

EMA for the treatment of VVS differs from the other endovenous methods, and no specific dose regime has been established for this system. Thus, it is unclear if EMA is more or less effective than conventional surgery, or whether it has any additional benefits. In this study, we compared the clinical outcome of high ligation and stripping (HLS) with EMA. Postoperative quality of life (QoL) analysis was assessed using the Aberdeen Varicose Vein Questionnaire (AVVQ) and Venous Clinical Severity Score (VCSS).[8,9]

PATIENTS AND METHODS

Patients

The patients with VVS were enrolled between May 2007 and June 2009. Suitable patients were assessed, and the selection of patients was considered (Fig. 1). All patients were randomized to undergo either EMA with high-tie or conventional surgery (via random digits table).

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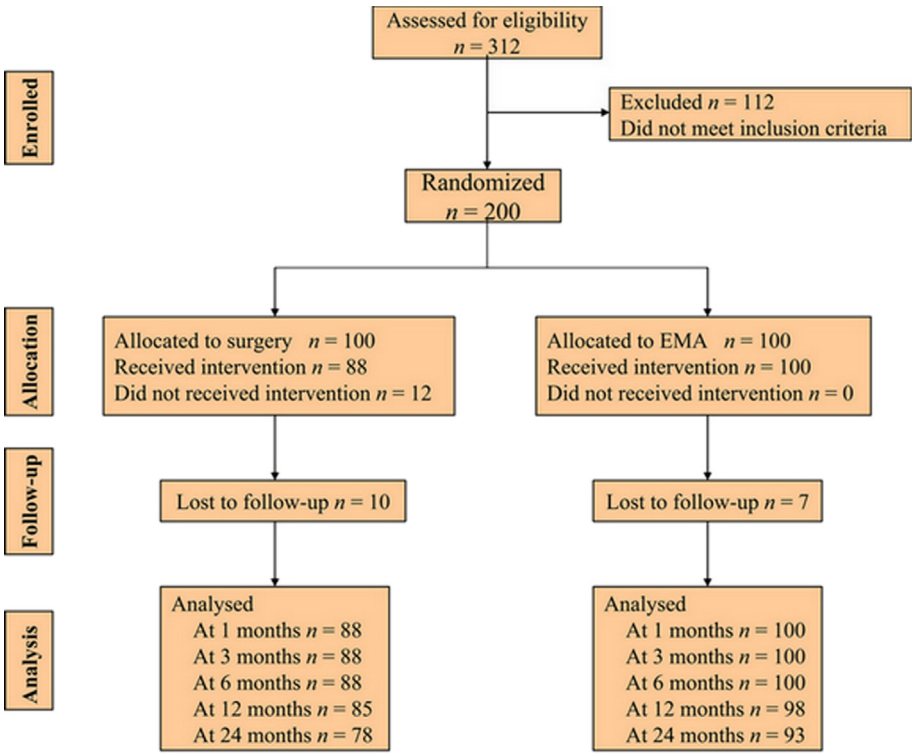

Figure 1. CONSORT chart showing the flow of patients through the trial of surgery (high ligation and stripping) versus endovenous microwave ablation (EMA).

Inclusion criteria were primary symptomatic VVS (CEAP, C3—C6), sapheno-femoral junction (SFJ) incompetence, GSV reflux from the groin to below the knee (retrograde flow lasting longer than 0.5 s on duplex scanning), and reflux of deep vein not going beyond the knee.

Exclusion criteria included a history of venous surgery, suspected or proven deep venous thrombosis, reflux of deep veins to distal limb, duplication of GSV, and patients' refusal to participate in the trial.

The patients were examined by duplex ultrasound (ATL 3500 HDI; ATL Ultrasound, Bothell, WA, USA), and the number of incompetent perforators and the presence of deep venous reflux were documented (Table 1). Before surgery, the sites of varices, incompetent perforators, and the SFJ were marked on the skin.

This trial was approved by the local ethics committee and institutional review board, and all patients provided written informed consent.

Treatment

In both groups, all treatments were performed under epidural anaesthesia by two experienced surgeons.

HLS group. Conventional surgical procedures were carried out through a 3—4 cm incision in the groin. The trunk of GSV and the tributaries were ligated and divided. The GSV was removed using a pin-stripper, and all varices and incompetent perforators were removed by phlebectomy. VVS underneath an ulcer were also removed by stab phlebectomies performed through normal skin at an angle.

EMA group. First, the SFJ was ligated in the same way as in the HLS group. Then, the microwave treating wire (Microwave Intracavity Coagulation System; Shanghai Medical Electronics, Shanghai, China) (Fig. 2; length is 150 cm from proximal to distal) was inserted into the GSV until it reached the medial aspect of ankle. This was guided by a light that illuminated the tip of the wire. Then, GSV was ablated using pulse mode at 20—30 W. The treating wire was withdrawn at 2—4 mm/s, with the ablation time lasting 2 s (energy delivery to the GSV was estimated at around 80 J/cm); the treatment parameters were based on a previous report and our own experience.[10] Tumescence was used in all patients with 0.9% saline containing 20 mL 2% lidocaine with 1: 200,000 adrenaline and 20 mL 0.5% levobupivacaine in 1 L 0.9% saline. Total local anaesthetic did not exceed the recommended maximum safe dose per patient. When the

Table 1. Demographics and CEAP classification in the endovenous microwave ablation (EMA) and high ligation and stripping (HLS) groups.

	EMA	HLS	*p*
Patients/limbs	100/108	88/98	
Age (y)	59 (43—69)	58 (46—70)	NS
Gender (F/M)	51/49	48/40	NS
Course of disease (y)	10 (2—40)	10 (3—33)	NS
No. of perforators			NS
Below the knee	195	168	
Above the knee	71	64	

Note. Values in parentheses indicate the range. y = year; F = female; M = male; NS = not statistically significant.

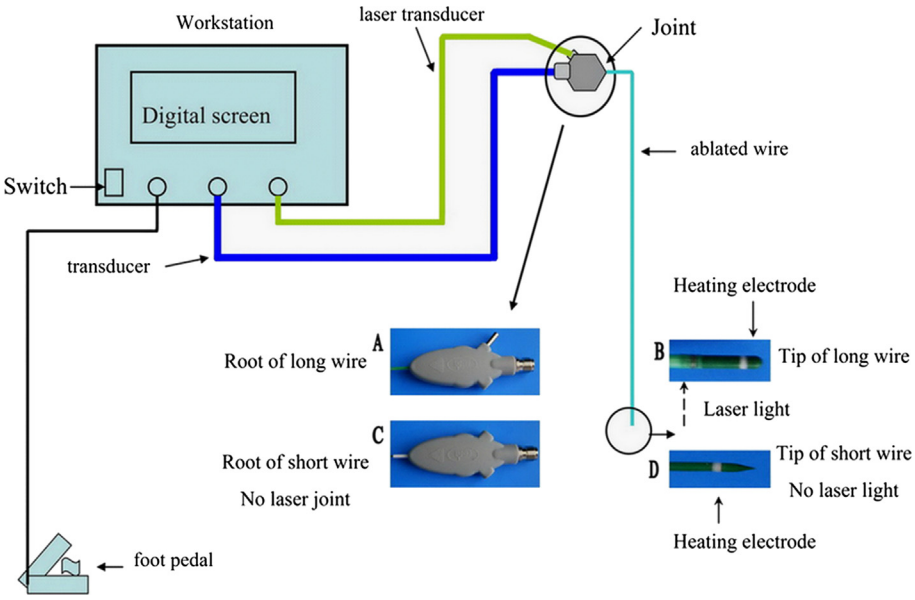

Figure 2. Diagram of the microwave ablation system. The work station generates microwave energy at 2,450 MHz, and the energy current is transmitted through transducer catheter (deep blue), which connects with the microwave wire (light blue). The laser light wire connects with the root of the great saphenous vein (GSV)-treating wire (A), the heating electrode (arrow), and the laser light (dashed arrow), located at the tip of wire (B). There is no laser light in the short wire (C, D), which connects with the transducer catheter. Then, GSV and tributary varices were ablated using the treating wire. The temperature of the microwave heating effect was about 90—100 °C in this study.

treating wire could not be passed to the ankle using this method (because of the tortuosity of the veins; 20 limbs, 16.4%), the treating wire was inserted into the GSV from the ankle puncture and was ablated from groin to ankle with the main trunk (the tip of the wire was placed 0.5—1 cm away from the ligation point of GSV to avoid unwanted damage). All superficial VVS and perforators were ablated successfully using a short wire (power was 10—15 W and the withdrawal speed was 2—4 mm/s, with the ablation time lasting 1 s), this short microwave wire could be inserted into varices 2—12 cm. Very large varices were excised through a small incision.

In the EMA group, VVS under ulcers were punctured through normal skin around the ulcer and ablated. The perforators were ablated under the guidance of duplex ultrasound in the EMA group (Fig. 3A), which is different from that of GSV and superficial VVS.

After surgery, the limbs were wrapped with sterile absorbent bandages and covered with a cohesive compression bandage for 48 h; thereafter, patients were instructed to wear a medical compression stocking (25 mmHg, ankle) during the day for at least 6 weeks. Ulcers were covered with sterile gauze, which was changed once every 3 days.

Follow-up

Criteria for technical success were closed or absent GSV with lack of flow. A re-canalized GSV or treatment failure was defined as an open segment of the treated vein segment of >10 cm in length. All patients were followed as outpatients up at 1, 3, 6, 12, and 24 months after surgery.

The operation time, number of incisions, intraoperative blood loss (determined by the swabs weighed pre- and postoperatively), and recurrence of varicosities were

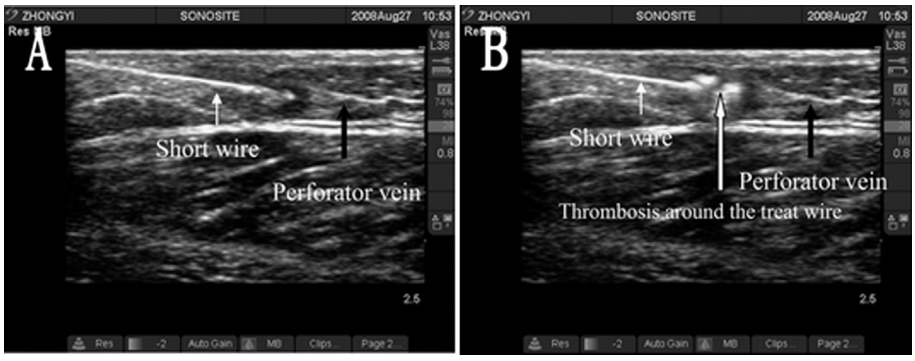

Figure 3. Treating the tributary veins under the guidance of ultrasound. (A) By inserting the short wire (white arrow) into the tributary veins (black arrow), and then (B) ablating the veins, we could find the thrombotic change around the tip of the treat wire on (long arrow) the ultrasound image.

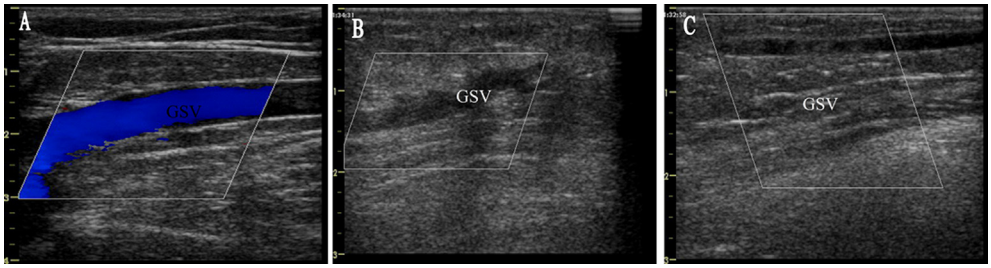

Figure 4. The ultrasound image of the great saphenous vein (GSV) perioperatively. (A) Two-dimensional image of GSV before treatment, and detection of treated veins at 1 month (B) and 6 months postoperatively (C).

recorded, as well as any complications, were recorded. The criteria for assessment were as follows.

1. Ecchymosis was confirmed 72 h after operation when the lividity and congestion area was >1 cm^2 in the affected limbs.
2. Skin burns were identified 72 h after operation when the skin was red and oedematous according to the criteria for burns.
3. Recurrence was defined by both duplex ultrasound and the clinical examination. A varicose vein that had not been observed before or previously been marked by the patient on the AVVQ form was considered to be a recurrent varicose vein (owing to neo-vascularization or dilation of pre-existing veins).[7,11]
4. Sensory impairment (numbness) that occurred around incisions was recorded based on the patient's history and physical examination.

QoL assessment

The diseased relation effect on QoL was determined using the AVVQ (Chinese version), which assessed the specific effect on QoL and was scored from 0 (no effect of VVS on QoL) to a theoretical maximum of 100.[8] The VCSS (Chinese version) was also completed (for the VCSS, 0 represents no significant venous disease and 30 is the maximum score), which is a valid sensitive and responsive measure of the severity of VVS.[9]

Statistical analysis

All data were analysed using SPSS v. 11.0 (SPSS, Chicago, IL, USA) and $p < .05$ was considered statistically significant. Categorical data were analysed using a chi-square test or, continuous data were first tested for normality. Normally distributed data were presented as mean (SD), and hypothesis significance testing was performed with paired and unpaired *t* tests. If the data were not normally distributed, median (interquartile range) values were presented, analysed using the Mann–Whitney *U* test for unrelated samples and the Wilcoxon signed rank test for paired data.

RESULTS

Clinical data (Table 1)

A total of 200 patients was randomized, as intended (Fig. 1).

EMA group. The EMA group consisted of 100 patients (108 limbs) with a median age of 59 years (range: 43–69 years), including 49 men (54 limbs) and 51 women (54 limbs). The median duration of disease prior to treatment was 10 years (range: 2–40 years). Moreover, 28 affected limbs had an ulcer (CEAP classification: C3, 27 limbs; C4, 33 limbs; C5, 20 limbs; C6, 28 limbs), with an ulcer of more than 2 cm^2 in 16 limbs. There were 195 perforator veins below the knee, and 71 perforator veins above the knee.

HLS group. In the HLS group 12 patients did not undergo surgery; thus, there were 88 patients (98 limbs) with a median age of 58 years (range: 46–70 years), including 40 men (45 limbs) and 48 women (53 limbs). The median duration of disease was 10 years (range: 3–33 years). Moreover, 23 affected limbs had an ulcer (CEAP classification: C3, 30 limbs; C4, 25 limbs; C5: 20 limbs; C6: 23 limbs), with an ulcer of more than 2 cm^2 in 14 limbs. There were 168 perforator veins below the knee, and 64 perforator veins above the knee.

Clinical outcomes

The demographics and CEAP classification were comparable between the two groups (Table 1). In both groups, treatment was successful, and most participants completed follow-up as outpatients. In the EMA group, two patients (two limbs) were lost to follow-up at 12 months and five patients (eight limbs) at 24 months, respectively. Three patients (four limbs) and seven patients (nine limbs) were lost to follow-up at 12 and 24 months in HLS group, respectively.

The mean operation time was significantly longer in the HLS group than in the EMA group (99 $\pm$ 31 min vs. 78 $\pm$ 25 min, $p < .01$), and more operative incisions were needed to complete the procedure in the patients in the HLS group than those in the EMA group (4 $\pm$ 1.2 vs. 1.5 $\pm$ 0.7, $p < .01$). Compared with patients in the HLS group, those in the EMA group had less intraoperative bleeding (116 $\pm$ 42 mL vs. 28 $\pm$ 9.8 mL, $p < .01$). Moreover, the postoperative healing time of the ulcer was faster in patients in the EMA group than in those in HLS group (45 $\pm$ 9.1 days vs. 74 $\pm$ 16 days, $p < .01$).

Ultrasound outcomes were assessed using duplex ultrasound 1, 3, 6 and 12 months postoperatively. In the EMA group, complete occlusion was noted in 116/122 limbs (95.1%) after 1 month. All treated veins showed shrinkage

immediately after ablation, and thrombosis signals were detected at the tip of the wire (Fig. 3B). The hyperechoic signal and organized thrombosis signals were detected in ablated vein lumen by duplex ultrasound (Fig. 3B). The ablated veins developed fibrosis and then occluded completely at 6 and 12 months postoperatively (Fig. 4), with the occlusion rates being 99% (121/122) and 97% (116/120), respectively. Few patients showed small recanalization in superficial veins, and the incidence rates were 1.6%, 0.9%, and 3.3% at 1, 6, and 12 months, respectively. In the HLS group, no GSV or perforator veins were detected in the treated area.

Complications

No deep vein thrombosis or wound infection developed after surgery in either treatment group (Table 2). The incidence of ecchymosis was higher in the HLS group than in the EMA group (31.6% vs. 14.8%, $p = .004$). In contrast, skin burns occurred on 11 limbs in the EMA group (10.2%), which was the main adverse effect of EMA. These skin burns usually developed at the puncture sites. In the HLS group, the incidence of sensory impairment was higher than in the EMA group 1 month postoperatively (28.6% vs. 15.7%, $p = .03$), but in most patients symptoms of altered sensation had resolved by 6 months after surgery. Sensory impairment was found in seven limbs in the EMA group and 16 limbs in the HLS group (6.5% vs. 16.3%, $p < .001$) at the 6-month follow-up examination; most sensory impairment occurred along the GSV and the ablation sites below the knee.

Recurrence

Recurrence was the main long-term complication, and EMA had a lower recurrence rate than HLS after 6 months (2.8% vs. 10.2%, $p = .03$). The recurrence rates increased gradually from 6 months to the 2-year follow-up. Recurrence was found in 14 and 24 limbs in the EMA and HLS groups, respectively (14.3% vs. 28.2%, $p = .02$). In the EMA group, six limbs were found with recurrence of neovascularization in the superficial veins of the thigh. Recurrence of incompetent tributary veins below the knee was found in eight limbs. In the HLS group, neovascularization occurring at the treated sites was found in 14 limbs, and recurrence at new sites was found in 10 limbs, which might correlate, among other reasons, with incompetent veins.

Table 2. Incidence of complications in the endovenous microwave ablation (EMA) and high ligation and stripping (HLS) groups.

	EMA	HLS	*p*
Ecchymosis (%)	16 (14.8)	31 (31.6)	.004
Sensory impairment (%)			
1 mo	17 (15.7)	28 (28.6)	.03
6 mo	7 (6.5)	16 (16.3)	<.001
Skin burns (%)	11 (10.2)	0 (0)	.001
Recurrence (%)			
6 mo	3 (2.8)	10 (10.2)	.03
2 y	14 (14.3)	24 (28.2)	.02
Others	0	0	

Note. Values in parentheses indicate the percentage. mo = months; y = years.

QoL assessment

Both groups had the same decrease (improvement) in AVVQ (Fig. 5A) and VCSS (Fig. 5B) scores after operation ($p < .001$), there was no significant difference in AVVQ and VCSS scores between the groups at any time point ($p > .05$). The improvement in AVVQ and VCSS scores was still present after 2 years (Fig. 5).

DISCUSSION

HLS is a conventional method for treatment of VVS; however, this procedure is associated with frequent recurrence (60%), complications, and longer operation time.[12,13] This study demonstrated that EMA resulted in a shorter operation time, fewer incisions, and less intraoperative bleeding than HLS. These findings suggest that EMA outstrips the traditional HLS in that it could achieve a favourable clinical outcome and success rate. The present study confirmed that both surgery and EMA are highly efficacious, and both result in significant improvements in the objective severity of venous disease, with lower VCSS values and decreased AVVQ scores postoperatively. There was no significant difference in clinical efficacy between the two groups with regard to QoL at the same time point after treatment.

In this study, the clinical success of ablation is defined according to that used in earlier publications.[14] EMA, which was combined with SFJ ligation, showed a high occlusion rate, similar to that of the EVLA and RFA procedures.[15,16] The difference in occlusion rate might correlate with the mechanisms of the device in which the efficacy of RFA was obtained by heat-induced venous spasm due to venous wall shrinkage. EMA induces direct and indirect thermal damage to the vessel walls by heating blood components. In this study, the EMA wire used was modified from the microwave probe used for upper gastrointestinal ablation,[10] which was specifically manufactured for the treatment of VVS (Fig. 1). The VNUS Closure system used the specifically designed catheter and electrode, but most Chinese patients cannot afford the expensive treatment fee. Our results showed that the clinical outcomes and QoL of EMA were similar to those of the RFA and EVLA techniques.[17,18]

In China, most patients with VVS present when their conditions are at an advanced stage and accompanied by limb ulcers. Traditional HLS is of limited value for the treatment of venous ulcers unless reflux adjacent to the ulcer is also treated. In our study, the short wire could be passed into perforators and tributaries 2–12 cm, and could puncture the varices and perforators from different directions; thus, the varices could be ablated completely. The EMA procedure could effectively occlude the tortuous varices around the ulcers, and improve the pathological state of ulcers, and then promoting the healing of ulcers.[19]

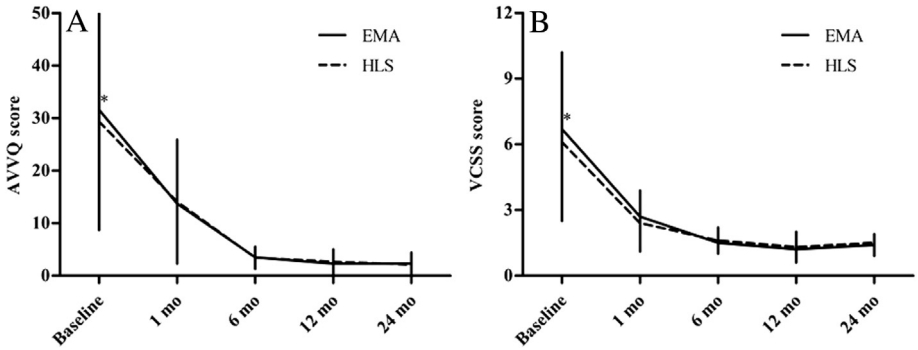

Figure 5. Aberdeen Varicose Vein Questionnaire (AVVQ) (A) and Venous Clinical Severity Score (VCSS) (B) score in patients treated with endovenous microwave ablation (EMA) and high ligation and stripping (HLS). For improvement over time $p < .001$. There was no significant difference between groups at the same time point. *Note*. Error bars indicate mean ± SD. mo = months after operation.

Superficial skin burns were the most common adverse event following EMA and were presumably the result of either energy levels that were too high or slow withdrawal of the wire. According to our results and a previous report,[10] the energy level used in EMA procedure was safe and effective. The temperature of microwave ablation (90—100 °C)[20] was markedly lower than that used for EVLA (800 °C).[4] Previous reports have suggested that microwave ablation was relatively safe in terms of thermal effect compared with RFA and EVLA.[20,21] Infiltration of adequate volumes of tumescence are important in preventing skin burns, and they have become less common as experience has increased at our centre.

However, the heat conduction of the microwave might lead to skin burns when using EMA; thus, the tumescent fluid technique was recommended for patients, which protected the skin from the thermal damage. As experience of using EMA at our centre has increased, skin burns are no longer common at our clinic. Thermal and physical damage to the saphenous nerve can result in the sensory impairment of limbs, which is a major adverse effect of HLS (7—40%).[20] Most sensory impairment occurred along the GSV and at ablated sites below the knee, which might correlate with temporary damage of the branches of the saphenous nerve. Compared with HLS, EMA showed lower incidences of sensory impairment at 1 and 6 months after surgery. These patients recovered after 3—6 months without treatment. Few patients who complain about sensory impairment should be treated with physical and medicine therapy.

Ecchymosis is often caused by perforation of veins by the EMA wire or by surgical trauma during HLS. In addition, overly tight elastic bandages might also result in ecchymosis. In our study, the incidence of ecchymosis was higher in the HLS group than in EMA group. Proper compression with an elastic bandage could minimize the ecchymosis, and most patients may recover within 2 weeks without further treatment. Other adverse effects, such as deep venous thrombosis, and infection of ulcers and wound infection, were not observed in our series. Clinically, we believed that the GSV should be ligated first and then ablated; this procedure could avoid the damage of deep vein by ablation and thrombosis extension into the femoral vein (one patient developed a deep vein thrombosis due to thermal damage of a deep vein during our early experience).

The main adverse effect was recurrence after surgery, which was associated with many factors.[22] In our study, recurrent varices occurred in the thigh and below the knee, which may have been the result of neovascularization, potential incompetent tributaries veins, and/or other sites of reflux. HLS could not remove these potential perforator veins and the small varices completely, but EMA could ablate these veins effectively, and may have contributed to the lower frequency of recurrence. When EMA is combined with high ligation, recanalization could be less common, although we have not examined this hypothesis in our study. While there is some evidence that high ligation in combination with another endovenous procedures could improve outcomes,[23,24] it is likely that neovascularisation will be more common. Thus, most studies rely on EVLA or RFA alone to treat GSV reflux. In order to examine our hypothesis further, a randomized trial of EMA with or without high ligation is required. There were three types of recurrence in the groin after SFJ ligation; however, the clinical relevance depended on the reconnection type, with single lumen direct connection to the common femoral vein being, by far, the most likely to be associated with a need for further treatment;[2] however, most of the neovascularization had no evidence of clinical recurrence.[25] Some data have suggested that preservation of groin tributaries during endovenous technique avoids stimulating angiogenesis.[26]

In conclusion, this study indicates that EMA with high ligation provides a satisfactory outcome for patients with VVS and GSV reflux. To examine its efficacy further a trial with or without high ligation should precede a larger, multicentre study.

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CONFLICT OF INTEREST

None.

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