

Comparative Study between Microwave Ablation versus Radiofrequency Ablation of Great Saphenous Vein in Primary Varicose Veins

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ABSTRACT

Background: The treatment of varicose veins is challenging, with public hospitals often facing long surgical wait times. Endovenous Microwave Ablation (EMA) and Radiofrequency Ablation (RFA) are outpatient options that can increase patient throughput without requiring inpatient admission. **Purposes:** This study aimed to compare the therapeutic efficacy and safety of EMA versus RFA in the treatment of primary varicose veins. **Patients and methods:** This prospective, randomized interventional study included 40 patients diagnosed with great saphenous vein (GSV) reflux. Patients were randomized into two groups (1:1) using a computer-generated randomization table: Group I (EMA, n=20) and Group II (RFA, n=20). Each patient underwent clinical assessment, hematological profiling, and duplex ultrasonography. Follow-up was conducted for 12 months post-procedure. **Results:** All patients had uneventful intraoperative courses. Spinal anesthesia was required by 85% in the EMA group and 75% in the RFA group. Mean operative times were 76.8 minutes for EMA and 69.1 minutes for RFA. No significant differences were observed in postoperative complications or recurrence rates between the groups over the 12-month follow-up period. **Conclusions:** Both EMA and RFA are safe and effective for treating primary varicose veins. EMA may offer advantages with fewer thermal-related complications and reduced short-term recurrence, indicating its potential as a preferred method in varicose vein management.

Keywords: Great saphenous Vein reflux, EMA, RFA, Efficacy.

INTRODUCTION

Great saphenous vein (GSV) varicosis represents a common peripheral vascular pathology, predominantly arising from insufficient venous valve closure. This insufficiency facilitates retrograde blood flow and stagnation within distal veins, subsequently leading to dilation, distension, and tortuosity of the GSV [1]. GSV varicosis impacts nearly one-third of the adult population, with a higher incidence observed among individuals whose occupations require prolonged standing, intense physical exertion, or extended immobility in a reclined position. This condition can significantly impair quality of life, as patients may experience intermittent pain, skin irritation, hyperpigmentation, and ulcerative lesions [2].

The conventional therapeutic approach for this condition entails saphenofemoral ligation, typically followed by excision of the GSV and, when indicated, of varicosities. However, despite over a century of clinical application, a definitive consensus regarding the optimal treatment modality for varicose veins remains elusive within the scientific community. There has been an increasing pivot toward minimally invasive techniques, aiming to reduce incision sites, while providing more localized and precise ablation of affected veins [3].

Endovenous thermal ablation modalities, such as endovenous laser ablation (EVLA) and radiofrequency ablation (RFA), have emerged as advancements driven by the demand for less invasive therapeutic options [4]. RFA operates through a radiofrequency generator and a dedicated electrode catheter, which emit thermal energy to elevate temperatures in adjacent tissues. This localized heating inflicts endothelial damage on contact with the catheter, effectively targeting the venous lining [5]. In

EVLA, laser energy transmitted through an optical fiber is transformed into thermal energy, leading to targeted thermal damage of the vein's endothelial layer, ultimately causing vein occlusion [6]. Both RFA and EVLA have demonstrated strong efficacy and a favorable safety profile [7]. EMA represents a comparatively recent approach within thermal ablation therapies. Unlike RFA, EMA operates without utilizing a thermocouple to regulate the temperature at the venous wall [8].

This study aimed to compare between EMA and RFA of great saphenous vein in primary varicose veins.

PATIENTS AND METHODS

This prospective randomized interventional study was carried out within The Vascular Surgery Unit of the Department of General Surgery at the Faculty of Medicine, Benha University Hospitals through the period from October 2022 to October 2024. This timeline was designed to ensure a 12-month follow-up for the final case operated on. Approval of Local Research Ethics Committee of Department of Surgery, Benha Faculty of Medicine was taken before proceeding in the study. This randomized clinical trial was conducted on 40 patients diagnosed with GSV reflux and patients were randomly allocated by using a computer generated random number table (Central Randomization System) into one of the two parallel treatment groups in a 1:1 ratio according to the intervention performed. Group I: Endovenous Microwave Ablation (EMA); (N=20 (50%)) and group II: Radio frequency ablation (RFA): (N=20 (50%)).

Inclusion criteria: Individuals aged 18 to 80 years with a clinical diagnosis of primary GSV insufficiency,

evidenced by Doppler ultrasonography indicating reflux duration exceeding 0.5 seconds.

Exclusion criteria: Patients with a target vein diameter less than 2 mm or greater than 15 mm, individuals with acute systemic infections, those with a history of superficial or deep vein thrombosis, and patients who had undergone previous surgical intervention on the target lesion. Patients who had contraindications to anesthesia, uncorrectable bleeding disorders or severe coagulopathy, significant hepatic or renal impairment (alanine aminotransferase levels exceeding three times the normal upper limit, or creatinine levels above 225 $\mu\text{mol/L}$), poorly managed hypertension (systolic ≥ 160 mm Hg and/or diastolic ≥ 100 mm Hg), or uncontrolled diabetes mellitus (fasting glucose ≥ 10.0 mmol/L). Additionally, patients with secondary varicose veins due to conditions such as post-thrombotic syndrome, Klippel-Trenaunay syndrome, or arteriovenous fistula. Also, conditions that could interfere with study participation or evaluation such as AIDS, mental illness, malignant tumors, cardiac insufficiency, liver disease, and a life expectancy of less than one year. In addition, pregnant or lactating women, as well as women planning pregnancy during the study period. Each patient underwent comprehensive clinical assessment, standard hematological testing, and bilateral lower limb venous duplex imaging. Following these evaluations, patients were then referred to the interventional unit for further management.

Interventions: In both groups, patients were operated under general, regional or local anesthesia on a morning list. In all instances where foam injection sclerotherapy was administered, it was crucial to designate the patient in the standing position with an indelible marker prior to the procedure. Visualizing varicose tributaries may be impossible after the patient has been prepared and the limb has been elevated, which is why such marking was necessary. To minimize vein shrinkage, patients were positioned in a supine anti-Trendelenburg posture with the leg slightly flexed, abducted, and externally rotated. Preoperatively, the leg was shaved using a clipper and disinfected with an appropriate surgical preparation solution, such as 10% aqueous povidone iodine. The entire limb was then draped, leaving it exposed from above the groin down to just above the ankle.

To verify and chart all reflux zones and delineate the course of the refluxing GSV from the saphenofemoral junction down through the lower thigh or proximal calf, duplex ultrasonography was utilized. The saphenofemoral junction, the GSV pathway, and the anticipated entry point were all precisely marked on the skin. GSV was accessed with a 16-gauge needle introducer under real-time ultrasound guidance. In cases where vasospasm occurred prior to successful cannulation, applying a tourniquet proximal to the access site and positioning the leg in a dependent manner proved beneficial. Alternatively, a

direct cut-down technique could be performed, wherein 1% lidocaine was infiltrated at the site, followed by a 1 cm skin incision over the GSV. Cannulation was subsequently conducted under direct visualization. The ideal entry point was positioned just distal to the lowest point of reflux, avoiding locations more than 10-15 cm below the knee, given the proximity of the saphenous nerve to the vein below this level. Subsequently, duplex ultrasonography was utilized to guide precise needle puncture of the target vessel. An introducer sheath was then advanced over the guidewire, which was subsequently withdrawn, and the Seldinger technique was applied to insert the guidewire into the vessel.

After gaining the great saphenous vein in both groups by the catheter, tumescent anesthesia was used (200 to 500 mL) to fully surround the saphenous vein. A combination of 25-40 mL of 1-2% lidocaine with 1 mL epinephrine (1:100000), 10 mL of sodium bicarbonate, and 450 mL of cold (4°C) normal saline in the tumescent mixture, which was administered peri-venously under duplex scanning using an infusion injector of microwave device in group I and infusion pump in group II until collapse of the GSV and non-echogenic halo of fluids were observed around the main trunk of GSV. A tourniquet was applied to enhance the administration of tumescent anesthesia, which was delivered intravenously. The patient was positioned in Trendelenburg's position to achieve optimal vascular collapse.

The procedure of group I (EMA):

To minimize the potential for DVT or central vein injury, the microwave treatment fiber (Microwave Intracavity Coagulation System; Shanghai Medical Electronics, Shanghai, China) was introduced into the GSV through a 6F or 7F vascular sheath and advanced up to the saphenofemoral junction. Subsequently, the fiber was retracted approximately 2 cm distal to the saphenofemoral junction, with positioning monitored by duplex ultrasonography and an illuminated tip at the end of the wire. Subsequently, pulse mode was utilized to ablate the GSV, applying power levels between 20 and 30 W. Each ablation pulse lasted 2 seconds, with the treatment wire retracted at a speed of 2-4 mm/s. The estimated energy delivered to the GSV was around 80 J/cm. These treatment parameters were established based on prior literature. Each patient received tumescent anesthesia via a 1 L solution of 0.9% saline infused with 20 mL of 2% lidocaine with 1:200,000 adrenaline and 20 mL of 0.5% levobupivacaine. The microwave fiber induces ablation over 3 cm of the vein per pulse, with 1 cm markings on the catheter shaft to ensure a 2 cm overlap between treated sections. The 6- to 7-foot catheter features an integrated tumescent injector. Similar to laser fibers, microwave fibers require an adequate blood volume around them to form vapor bubbles. However, they function by heating intracellular water to 80-100°C, leading to protein

denaturation, and do not emit light, negating the need for protective eyewear. The fiber tip, made of 1 cm PTFE, prevents adherence to the vein and maintains a clean contact surface.

The procedure of group II (RFA):

Procedure Setup; includes movable operation table (Anti Trendelenburg/ Trendelenburg), Sheath 7F., puncture needle 18G, yellow spinal needle, tumescent ingredient (Saline, lidocaine, & sodium bicarbonate) and Duplex device, Tumescent injector, ClosureFast system & bandage. System includes ClosureFAST catheter specifications. 7F catheter (7F heating coil; 4F catheter shaft), 7 cm length heating coil, available in 60 or 100 cm, catheter shaft markings every 6.5 cm. Ensures ½ cm overlap between treated segments. Catheter lumen accepts 0.025" guide wire, Segmental Ablation Technology, 7 cm vein segments treated at once. No energy delivery during repositioning and energy delivery does not vary by pullback speed. A 0.025-inch guidewire was introduced into the GSV, followed by the removal of the needle. The VNUS catheter was then advanced over the guidewire to the designated location, and a 7F × 10-cm sheath was placed over it. To minimize the risk of deep vein thrombosis or central venous injury, the catheter tip was positioned 2 cm distal to the saphenofemoral junction under ultrasound guidance. Prior to commencing treatment, the catheter tip's position was confirmed via ultrasound, after which the energy generator was activated. Radiofrequency treatment was delivered in 20-second intervals, raising the great saphenous vein's temperature to 120 °C. In the initial segment, treatment could be repeated up to three times, with no single segment receiving more than three applications. A 0.5-cm overlap was maintained between each adjacent segment, with a continuous pullback performed until the desired vessel length had been treated. During treatment of the final segment, the catheter's thermal element was left outside the sheath to prevent potential sheath degradation. Once the generator was deactivated, both the sheath and closure catheter were removed, and hemostasis was achieved through manual compression at the access site. A compressive bandage was then applied following catheter and sheath removal.

The saphenous vein is subjected to another ultrasound evaluation in both groups following the withdrawal of the fiber or catheter to the venotomy site. A successful endovenous saphenous vein obliteration procedure is typically indicated by the absence of flow, concentric narrowing, and thickening of the vessel wall. Additionally, the compressibility and absence of thrombus of the common femoral vein are assessed.

Immediately after the RFA procedure, residual tributaries were addressed with ultrasound-guided sclerotherapy using Aethoxysklerol 2% as the sclerosant. The target areas were disinfected with a 10% povidone-iodine solution. For foam sclerotherapy, the sclerosing

agent was prepared and drawn into a 10-mL syringe, which was then connected to a 3-way stopcock alongside a second 10-mL syringe containing 7 mL of air. The syringes were rapidly exchanged back and forth to produce foam with a sclerosant-to-air volume ratio of 1:4.

A 26-G needle was inserted into the vein, confirmed by blood return, and reticular veins under 5 mm were identified with a vein light. Once foam was injected, the needle was withdrawn, and foam displacement of venous blood was observed. In certain cases, foam was administered through multiple cannulas placed in dilated tributaries. Following all injections, pressure dressings were applied to the treated vessels, and the leg was elevated to a 90-degree hip flexion. Continuous elastic compression bandaging was applied to the thigh and knee for five days, except during showering. Afterward, a thigh-high, Class II graduated compression stocking was worn for two weeks to reduce post-procedural discoloration.

Post-intervention follow up:

All participants underwent clinical evaluations at intervals of one week, three months, six months, and twelve months. During these follow-up assessments, patients were asked about symptom relief, with particular attention to any reduction or improvement in lower-extremity pain linked to venous insufficiency. Patients also evaluated changes in the appearance of the leg, noting decreases in visible varicosities, edema, pigmentation, or other skin alterations associated with chronic venous insufficiency (CVI). Comparisons were made using pre-treatment photographs obtained for all treated subjects. At each follow-up visit, potential adverse effects related to the procedures were assessed. Minor complications were categorized as those without significant clinical impact, such as mild discoloration, while major complications were identified as those necessitating a higher level of care, surgical intervention, or hospitalization.

Ethical considerations: This study was conducted following approval from The Research Ethics Committee of the Faculty of Medicine, Benha University. Written informed consents were obtained from all participants before their enrollment, with the consent form clearly detailing their voluntary participation and consent for the publication of data while ensuring confidentiality and privacy. This study adhered to the ethical principles outlined in the World Medical Association's Declaration of Helsinki for research involving human subjects.

Statistical analysis:

Collected data were displayed in tables and appropriate graphs and analyzed using SPSS version 26 (IBM, Armonk, New York, United States). Qualitative variables were represented as frequencies and percentages, while quantitative variables were presented as mean ± standard deviation (SD) and range. The level of significance was set at $p \leq 0.05$.

These all data were shown in Figures (1) and (2):



Figure (1): Fiber withdrawal while generator off and on using pedal maneuver.

Steps of the procedure of group I (EMA)



Figure (2): A) Before and B) After 2 weeks.

A case of group I (EMA):



Figure (3): Probe + finger compression & generator off and on.

Steps of the procedure of group II (RFA):

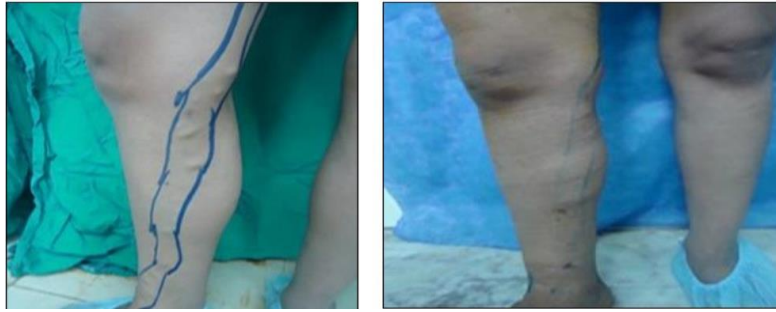


Figure 4: A case of group II (RFA).

RESULTS

This was a prospective randomized clinical trial that was conducted on 40 patients diagnosed with GSV reflux in Department of Surgery, Vascular Unit of Benha University Hospitals to compare between microwave ablation and radiofrequency ablation. Patients were divided into two groups: Group I (EMA); (N=20 (50%)), Group II (RFA): (N=20 (50%)). The age of studied cases ranged from 24 to 59 years with a mean age of 33.7 in group (I) and in group (II) was 35.4 years. There were 12 female patients and 8 male patients in group (I) where in group (II), there was 13 females and 7 male patients. There was no statistical difference between both groups regarding demographic data (Table 1).

Table (1): Patients' demographic data

Variables		Group I N=20 (50%)	Group II N=20 (50%)	P-Value
Age (years)		33.7±6	35.4±3.1	0.44
Gender	Male ♂	8 (40%)	7 (35%)	0.23
	Female ♀	12 (60%)	13 (65%)	

Data are presented as numbers & mean ± SD; percentages & ranges are in parenthesis

As regards CEAP and VCSS, there was no significant difference in clinical class and VCSS between the studied groups (Table 2).

Table (2): Clinical class (CEAP) and VCSS in both groups

		Group I	Group II	P value
Clinical class	C2	2 (10%)	1 (5%)	0.859
	C3	12 (60%)	13 (65%)	
	C4	7 (35%)	6 (30%)	
	C5	1 (5%)	2 (10%)	
VCSS	Mean ± SD	6.9 ± 1.93	7.1 ± 2.1	0.289
	Range	5 - 14	5 - 11	

CEAP: Clinical, Etiology, Anatomy, Pathophysiology class. **VCSS:** Venous Clinical Severity Score.

Data are presented as numbers & mean ± SD; percentages & ranges are in parenthesis

All of them passed uneventful intra-operative course without complications. Most patients needed spinal anesthesia, 17 (85%) in group (I) and 15 (75%) in group (II). Mean operation time was 76.8 ± 4; range: 60-91 minutes in group (I) and 69.1 ± 3 range: 53-79 minutes in group (II). Mean intra-operative blood loss was 56 ± 5.5; range: 50-60 ml in group (I) and 47.2 ± 5.1 range: 40-50 ml in group (II). There was no significant difference in procedure data (length of vein treated and duration of procedure) between the studied groups (Table 3).

Table (3): Operative data

Variables		Group I	Group II	t	P-Value
Tumescent and spinal and general		17 (85%)	15 (75%)		0.723
		2 (10%)	3 (15%)		
		1 (5%)	2 (10%)		
Operative time * (minutes)	Mean ± SD	76.8±4	69.1±3	3.5	0.11
	Range	60-91	53-79		
Intra-Operative blood loss (ml)	Mean ± SD	56±5.5	47.2±5.1	7.1	0.01
	Range	50-60	40-50		
Length of vein treated (cm)	Mean ± SD	40.6 ± 13.9	36.3 ± 14.8		0.254
	Range	15 - 61	11 - 53		
Intra-operative VAS score **	Mean ± SD	2.9 ± 1	4.1 ± 1.5	9	0.01
	Range	2 - 5	2 - 6		

*Operative time: defined as time between initiations of the ablation after the device is inserted into the vein and the time after the ablation is completed.
**VAS: Visual Analogue Score.

Data are presented as numbers & mean ± SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test.

Upon review of the results in this study post-operative pain was assisted for both groups by using the (0-10) Numeric Pain Rating Scale and relating doses of analgesic drugs, significant difference between both groups was noticed. Group (I) average doses was 11.3 ± 0.9 and pain rate was 6.3 ± 1.99 Vs 7.4 ± 2.3 for group (II) and pain rate was 4.05 ± 1.06 ; $t=10.9$ & $t=4.5$ P-value: 0.001. EMA patients had moderate to severe pain and received more analgesic drugs than RRA patients who had mild to moderate pain (Tab 4).

Tab. (4): Post-operative pain assessment using "0-10 Numeric Pain Rate"

Variables	Group I	Group II	t	P-Value
Doses of pain analgesic (mean \pm SD)	11.3 \pm 0.9	7.4 \pm 2.3	7.3	0.01 S
PO Numeric Pain Rate (mean \pm SD)	6.3 \pm 1.99	4.05 \pm 1.06	5.4	0.01 S

Data are presented as numbers & mean \pm SD; ranges are in parenthesis and statistically significant difference by using unpaired t-test.

Patients in group (I) were discharged 1-3 days post-operative (PO), But in group (II) they were discharged 1-2 days PO. There was no significant difference in post-operative outcomes (recovery time, return to work, and failure of procedure) between the studied groups. Failed case was due to tortuosity (Table 5).

Tab. (5): Post-Operative (PO) data

Variables		Group I	Group II	P-Value
Duration of PO hospital stay (days)	Mean \pm SD	2.1 \pm 0.5	1.9 \pm 0.4	0.01 S
	Range	1-3	1-2	
Recovery time (days)	Median (IQR)	2 (1-3)	2 (1-2)	0.068
	Range	1-7	1-6	
Return to work (days)	Median (IQR)	2 (1-4)	3 (1-5)	0.411
	Range	0-12	0-13	
Failure of procedure	Failure	1 (5%)	0	1.000

Data are presented as numbers & mean \pm SD; ranges are in parenthesis and statistically.

There was no significant difference in postoperative complications after one week between the

studied groups. Also, there was no significant difference in number of patients who didn't have any complications between the studied groups (Table 6).

Tab. (6): Postoperative complications after 1 week in both groups

	Group I	Group II	P value
Pigmentation	5 (25%)	3 (15%)	0.532
Paresthesia	3 (15%)	5 (25%)	0.532
Burn (Ulcers)	0 (0.00%)	1 (5%)	0.567
Superficial thrombophlebitis	4 (20%)	3 (15%)	0.748
Hematoma	3 (15%)	4 (20%)	0.748
Erythema	1 (5%)	1 (15%)	1.000
No complications	13 (65%)	15 (75%)	0.398

Data are presented as numbers & mean \pm SD; ranges are in parenthesis and statistically.

After 6-12 months, there was no significant difference in postoperative complications (Pigmentation, paresthesia, and recurrence) between the studied groups. Also, there was no significant difference in number of patients who didn't have any complications between the studied groups (Figure 4).

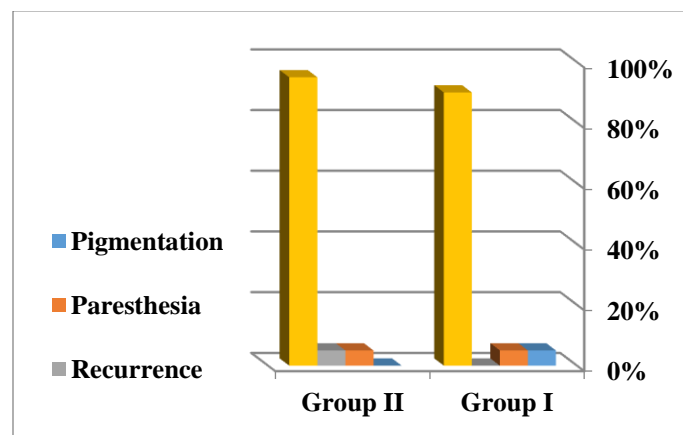


Figure (4): Postoperative complications after 6-12 months in both groups.

Severity and QoL were assessed using VCSS system, with no statistically significant differences observed between the two groups at baseline. Postoperatively, both groups showed a reduction in VCSS, but apart from the scores at the 6-month mark, no significant differences were noted between the groups at any other time point. Throughout follow-up, no significant variation was found in VCSS or patient satisfaction between the studied groups (Figure 5).

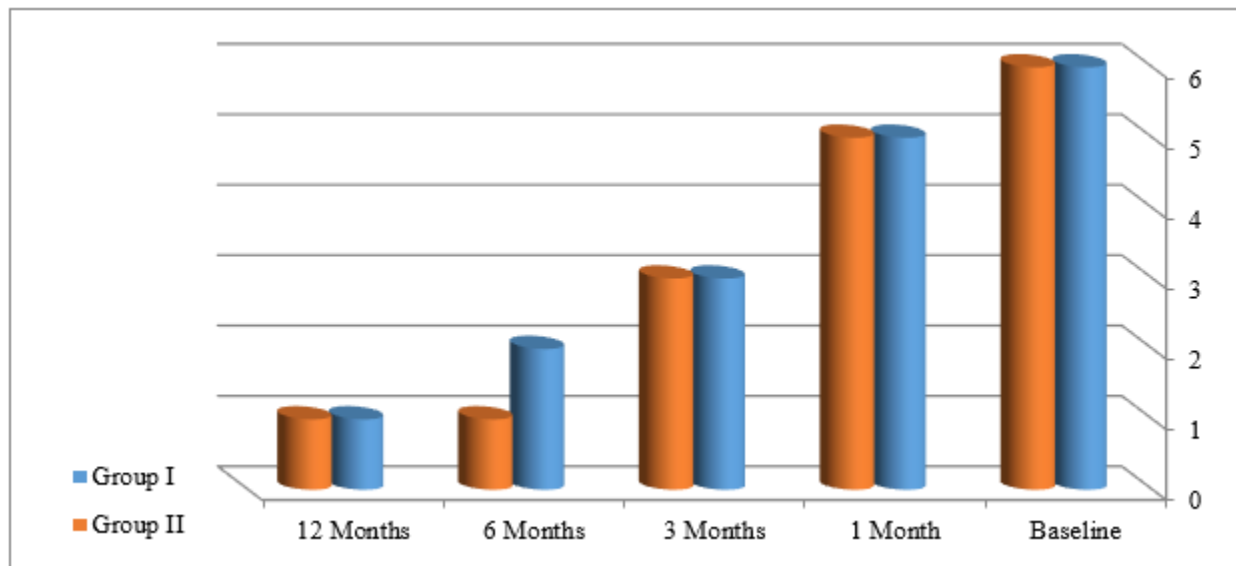


Figure 5: Venous clinical severity score (VCSS) for both groups.

DISCUSSION

In GSV reflux the patients may complain discomfort, itching, color change and ulceration, interfering with quality of life. The common traditional surgical treatment for GSV reflux is high ligation and stripping (HLS), but it causes high postoperative apparent recurrence, long time recovery and bad wound scar [2-4].

Endovenous thermal ablation interventions, including EMA, RFA, and Endovenous laser ablation (EVLA), have been developed in response to the demand for less invasive and cosmetic treatments. The generator and specialized electrode of RFA produce thermal energy, which causes extensive heating of the surrounding tissues that come into contact with the electrode, thereby causing endothelial injury [5, 9-11].

The current prospective randomized clinical trial was conducted on 40 patients diagnosed with GSV reflux to compare between microwave ablation and radiofrequency ablation. Patients were divided into two groups: Group I (EMA); (N=20 (50%)) and group II: Radio frequency ablation (RFA): (N=20 (50%)). The age of studied cases ranged from 24 to 59 years, mean age in group (I) was 33.7 years and in the group (II) was 35.4 years. There were 12 female patients and 8 male patients in group (I) where in group (II), there were 13 females and 7 male patients. There was no statistical difference between both groups in demographic data. This aligns with the findings of **Zhao et al.** [12] who examined the clinical outcomes of EMA and RFA in treating lower limb GSV reflux. Their study reported no statistically significant differences in baseline and demographic characteristics between the two groups ($P > .05$).

In this study, tumescent local anesthetic solution was used in all cases (100%) beside spinal or general

anesthesia, this technique provided excellent anesthesia. In addition, vasoconstriction from epinephrine and direct compressive effects of the instilled volume resulted in rapid hemostasis, a marked reduction in postoperative ecchymosis and pain and allowed separation of the superficial aspect of the GSV by at least 1.0 cm deep to the skin surface along its entire length to reduce the likelihood of skin burns and collapse of GSV to improve the transfer of thermal energy to the vessel wall. Performing the procedure under tumescent local anesthesia facilitates a prompt return to routine activities, yielding high levels of patient satisfaction alongside favorable medical and cosmetic results [15].

Our results revealed that, there was no significant difference in clinical class (CEAP classification) and VCSS between the studied groups, C3 and C4 were the most predominant in our patients. These results are nearly similar to other researches, which mentioned that CEAP classification and other details were similar between the two groups [12-14].

In the present study, postoperative VAS scores were higher for the EMA group compared to the RFA group. Additionally, the EMA group showed a greater incidence of pigmentation, which may have led to longer hospital stays and lower CIVIQ scores during follow-up. However, the EMA system still lacks a standardized dosage protocol, and no cases of skin injury were reported within the EMA cohort. Thermal ablation techniques used for LLVVs often induce heat-related adverse effects, including nerve damage, skin burns, induration, and postoperative discomfort. The findings of this study indicate that the EMA technique has a similarly low incidence of ecchymosis, paresthesia, and induration,

comparable to that observed with the RFA technique [7, 11, 16, 17].

There was no significant difference in postoperative complications during post intervention follow up for 12 months between the studied groups. Also, there was no significant difference in number of patients who didn't have any complications between the studied groups. But there was more pigmentation and pain in EMA group (I). These results closely align with those reported by **Zhao *et al.*** [12]. The variations in pigmentation and the degree of postoperative pain may be attributed to the differing mechanisms of the devices used in the procedures.

CONCLUSIONS

Both ablation techniques are safe and effective. However, the findings of this study suggest that the EMA procedure is a safe and effective ablation approach for patients with VVs and it leads to fewer thermal-related complications and short-term recurrences.

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Conflict of Interest: Nil.

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