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Outcomes of Endovenous Microwave Ablation (EMA) Versus Surgical Stripping in the Treatment of Saphenous Vein Reflux

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ABSTRACT

Background: Varicosities can be definitively treated by either conventional surgery or endovenous ablation techniques, which involve the abortion of venous reflux sources and the removal of significant refluxing segments and varicose reservoirs

Objectives: To compare outcomes of endovenous microwave ablation **(**EMA) versus surgical stripping in the treatment of saphenous vein reflux.

Patients and methods: In this retrospective analysis, 108 participants with primary varicose veins were categorized into two intervention groups. Group A (n=54) underwent conventional great saphenous vein stripping, whereas Group B (n=54) received EMA. Outcomes were monitored for 6 months.

Results: The age of studied cases was 33.2±4.6 and 35.4±3.9 years in Groups A and B, respectively. Post-operative (PO) discharge timelines mean was 2.8±0.6 days for group (A), whereas patients in group (B) were discharged after a mean time of 0.8 ±0.3 days. Two cases in group (A) experienced femoral vein hemorrhage.

At 6-monthes post-operative follow-up; there were skin discoloration (pigmentation) noticed in 16 cases of group (A) and in only 2 cases of group (B), scarring was noticed only in group (A); and recurrence (Recanalization) was noticed only in group (B); The overall results were better in group (B).

Conclusions: EMA of the Great saphenous vein (GSV) is a minimally invasive, efficient, and safe alternative, characterized by reduced complications, brief hospitalization, faster recovery, and rapid return to normal activities. Its cosmetic benefits make it an especially attractive option for female patients when compared to traditional surgical stripping.

Keywords: Saphenous Vein Reflux, EMA, Stripping, Outcome.

INTRODUCTION

Veins constitute intricate biological structures, comparable to arteries, optimally designed for their physiological functions. Venous pathologies constitute a significant health challenge within populations, arising from a complex interplay of genetic predispositions, environmental factors, and pathological conditions. Comprehensive insight into the fundamental physiological and molecular mechanisms underlying venous damage is critical for developing targeted, efficacious therapeutic interventions [(1)].

The superficial system typically exhibits valve incompetence, which could be a primary cause or a later effect of vein wall dilatation. Secondary venous disease (post-thrombotic) can also result in varicose veins. Varicose veins are a progressive condition that only goes away after pregnancy. The symptoms of venous illness often lead the patient to seek medical attention [(2,3)]. Patients with great saphenous vein (GSV) reflux may experience discomfort, itching, ulceration, and color changes, all of which can negatively impact their quality of life. Skin ulceration, dermatitis, bleeding from delicate veins, and superficial thrombophlebitis are common side effects [(1)].

Varicosis can be definitively treated by either conventional surgery or endovenous ablation techniques, which involve the abortion of venous reflux sources and the removal of significant refluxing segments and varicose reservoirs. The conventional surgical treatment for GSV reflux comprises high ligation and stripping (HLS). Nevertheless, causes high post-operative apparent recurrence, long time recovery and bad wound scar [(4,5)].

In response to the growing demand for minimally invasive and aesthetically considerate treatments, endovenous thermal ablation techniques have emerged, including endovenous microwave ablation (EMA), radiofrequency ablation (RFA), and endovenous laser ablation (EVLA). Radiofrequency ablation employs a specialized generator and electrode to create thermal energy, which induces comprehensive heating of the adjacent tissue in direct contact with the electrode, ultimately causing targeted endothelial injury [(6,7)].

EMA represents an innovative thermal ablation approach for addressing GSV reflux. Unlike endovenous laser ablation (EVLA), EMA generates thermal energy through a distinct mechanism. During the procedure, an EMA catheter is percutaneously introduced into the venous system, where the antenna emits penetrable microwave energy. This energy induces rapid molecular vibration of polar molecules within the vascular tissues under the influence of the microwave field, directly producing localized thermal effects [(8,9)].

This retrospective study's objective was to evaluate the benefits and effectiveness of EMA in

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comparison to surgical stripping for managing saphenous vein reflux.

PATIENTS AND METHODS

Study design:

The present retrospective study was conducted at the vascular units within the General Surgery Departments of Benha and Cairo Universities. This study included 108 patients diagnosed with primary varicose veins throughout the period from January 2022 till June 2024 and allocated into 2 groups: Group A underwent conventional surgical stripping of the great saphenous vein, and Group B, comprising patients receiving EMA.

Participants recruited in this study were suffering from symptomatic great saphenous vein incompetence; pain, visible varicose veins, night cramps, restless leg, bleeding, skin discoloration, and patients were having GSV with reflux >1 second on duplex ultrasound, GSV incompetence along its whole length with or without active ulcer and clinical, etiological, anatomical, and pathological (CEAP) c_2, c_3, c_4, c_5 grades.

All participants were deemed suitable for regional or general anesthesia. However, specific exclusion criteria were rigorously applied, eliminating patients presenting with active deep or superficial vein thrombosis, post-thrombotic syndrome, great saphenous or small saphenous veins measuring less than 3 mm or exceeding 15 mm in diameter, excessively tortuous veins incompatible with endovascular intervention, coagulation disorders, peripheral arterial pathologies, pregnancy, limited ambulation capacity, and morbid obesity.

Interventions:

Pre-operative marking was performed while the patient was in a standing position.

For both groups, tumescent anesthesia was used; (200 to 500 mL) to fully surround the saphenous vein; A mixture of 25–40 mL of 1–2% lidocaine, 1 mL epinephrine (1:100,000), 10 mL sodium bicarbonate, and 450 mL cold (4°C) normal saline was prepared for tumescent anesthesia. It was delivered peri-venously via an infusion pump under duplex ultrasound monitoring until the GSV showed complete collapse and a fluid-induced non-echogenic halo around its main trunk.

Following the standard protocols, EMA was carried out under local tumescent anesthesia[10]. However, light intravenous sedation or spinal anesthesia might be used while patients in GSV stripping group underwent surgery under general or spinal anesthesia.

Group A: Surgical Stripping (Figure 1):

The great saphenous vein was accessed via a strategically placed oblique incision, positioned 1 cm above and parallel to the groin crease. This approach optimized both cosmetic outcomes and reliable access to the saphenofemoral junction. Commencing over the palpable femoral artery, the incision extended medially, carefully balancing aesthetic considerations with the imperative of comprehensive visualization of the saphenofemoral junction and its associated tributaries. A high double ligation of the great saphenous vein was executed in proximity to the femoral vein, with the second ligation performed using a suture technique. Meticulous care was exercised to prevent femoral vein constriction and to minimize the risk of generating a prolonged venous stump that could potentially precipitate thrombus formation and subsequent embolism [11,12].

The great saphenous vein was subsequently stripped employing wire or disposable plastic strippers, extending from the knee to the groin through an additional incision. This standard stripping procedure constituted the fundamental element of the traditional varicose vein intervention. Clinical evidence demonstrated significantly diminished recurrence rates when complete vein stripping was done, as opposed to isolated high ligation. Concomitant varicose tributaries, when present, were excised via multiple phlebectomies utilizing small surgical access points. Post-procedurally, all limbs were dressed with cotton padding applied along the entire great saphenous vein tract, subsequently secured utilizing a crepe bandage [13,14].

Figure (1): Conventional surgical stripping of GSV.

Group B: EMA technique (Figure 2):

Participants were positioned in an anti-Trendelenburg configuration to minimize venous shrinkage. A microwave treating fiber was introduced into the great saphenous vein via a 6F or 7F vascular sheath, advanced to the saphenofemoral junction, then deliberately withdrawn approximately 2 cm distally to mitigate deep vein thrombosis and central venous injury risks. This procedure was guided by duplex ultrasound and a wire-tip illumination system.

The great saphenous vein ablation was executed utilizing pulse mode at 20-30 W, with the treating wire withdrawn at 2-4 mm/s and an ablation duration of 2 seconds, estimating energy delivery around 80 J/cm. Treatment parameters were predicated on prior research. Tumescence anesthesia was administered to all patients, comprising 0.9% saline solution containing 20 mL 2% lidocaine with 1:200,000 adrenaline and 20 mL 0.5% levobupivacaine in 1 L 0.9% saline.

This fiber induces vein ablation 3 cm each time. Catheter shaft markings every 1 cm, ensure 2 cm overlap between treated segments. 6-7F catheter has its own injector for tumescence. The same as LASER; it needs amount of blood around the fiber to induce got steam bubbles but heat water (80-100ºC) in cells so denature proteins; it doesn't emit light so no need protective eyewear and the tip of microwave fiber (1 cm) is PTFE to be smooth and not to be sticky with the vein.

Complementary ultrasound-guided sclerotherapy was carried out on residual tributaries immediately following the EMA, utilizing aethoxysklerol 2% as the sclerosant. Aspirating the sclerosing agent into a 10-mL syringe and connecting it to a 3-way cannula with another 10-mL syringe that contained 7 mL of air produced foam with a 1:4 sclerosant to air volume ratio for foam sclerotherapy.

A vein illumination device identified reticular veins less than 5 mm in diameter. A 26-G needle was inserted, with blood return confirmation, and foam was injected to displace blood from the vein. In select cases, multiple cannulas were utilized for injecting foam into dilated tributaries. Upon completion of injections, pressure dressings were applied, and the leg was elevated to achieve 90-degree hip flexion. Thigh and knee were encompassed by an elastic compression bandage for continuous 5-day wear, removed solely for showering, followed by thigh-high class II graduated compression stockings for a subsequent 2-week period to mitigate post-procedural bruising.

Figure (2): EMA technique in the treatment of saphenous vein reflux.

Outcomes

The 1ry outcome was effective treatment of varicose veins with minimal post-operative complications.

2ry was decrease hospital stay and early return to daily activities.

Post-intervention follow up:

The "0-10 Numeric Pain Rating Scale" was utilized for evaluating post-operative pain in both groups, supplemented by analgesic dosage records. Patients provided three separate ratings: current pain, best pain, and worst pain over the last 24 hours. The average of these ratings was utilized as the overall pain score, classified into four categories: 0 (No pain), 1–3 (Mild pain), 4–6 (Moderate pain), and 7–10 (Severe pain).

Patients were discharged 1-3 day post-operatively. Both groups were followed up 1-week for (Bleeding, hematoma in the subcutaneous along the stripped vein or in the groin, bruising and ecchymosis, wound infection, manifestations of nerve injury include numbness, altered or diminished sensation, and paraesthesia, superficial thrombophlebitis, DVT, and skin burn) and at 3- and 6-months for (Skin discolouration or pigmentation, residual varicosities, scarring and recanalization); to estimate post-operative outcome. For verifying the success of the obliteration, a duplex ultrasound was executed, checking for any signs of deep vein thrombosis (DVT) or thrombus migration from the saphenous vein to the femoral vein, especially in Group B. Bruising was monitored along the thigh where the stripping or ablation took place, while calf bruising was considered a result of the avulsions.

Ethical Approval:

This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Benha University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis:

Sample size was calculated by G-power 3.1 software (Universities, Dusseldorf, Germany). SPSS version 16 was used to process the data (IBM, Chicago, USA). The unpaired t-test was used to compare quantitative variables in parametric datasets (standard deviation <50% of the mean), and quantitative data were reported as mean and standard deviation. The Chi-square and Fisher exact tests were used to examine the qualitative data, which were expressed as numerical frequencies and percentages. Median and interquartile range to represent data was used to compare Venous clinical severity score (VCSS)   A p-value <0.05 was considered statistically significant, whereas a p-value <0.01 indicated substantial significance.

Results:

This retrospective study included 108 patients with GSV varicosities who were randomly allocated into 2 groups: Group A underwent conventional surgical stripping of the great saphenous vein, and Group B, comprising patients receiving EMA.

The age of studied cases was 33.2±4.6 and 35.4±3.9 years in Groups A and B, respectively. Both groups revealed no significant differences in demographic data and the presenting symptoms **(Table 1).**

Table (1): Patients' data:

Variables		Group A N=54	Group B N=54	P-Value
Age	**Mean ± SD**	33.2±4.6	35.4±3.9	0.009*
Sex				
Male	**N (%)**	25 (46.3%)	24 (44.5%)	0.85
Female		29 (53.7%)	30 (55.5%)	
Symptoms				
Pain	**N (%)**	52 (96.3%)	51(94.4%)	1.00
Visible varicose vein	**N (%)**	50 (92.6%)	49 (90.8%)	1.00
Night cramps	**N (%)**	1 (1.85%)	1 (1.85%)	1.00
Restless leg	**N (%)**	43 (79.6%)	44 (81.5%)	0.81
Bleeding	**N (%)**	2 (3.7%)	2 (3.7%)	1.00
Skin discoloration	**N (%)**	5 (9.3%)	4 (7.4%)	1.00

*: Significant.

The average operative duration, intra-operative blood loss was, and post-operative (PO) discharge timelines were significantly higher in group A than in group B. Surgical stripping had moderate to severe pain and received more analgesic drugs than EMA patients who had mild to moderate pain. There was a statistically significant difference between both groups, regarding all the other operative and immediate post-operative parameters **(Table 2).**

The intra-operative period was uneventful for all participants, except for two cases in group (A) that experienced femoral vein hemorrhage.

Table (2): Operative and immediate post-operative (PO) data:

Variables		Group A (N=54)	Group B (N=54)	P-Value
Type of anesthesia				
Spinal	**N (%)**	39 (72.2%)	0 (0%)	<0.001*
General	**N (%)**	11 (20.4%)	0 (0%)	<0.001*
Tumescent and spinal	**N (%)**	2 (3.7%)	14 (25.9%)	<0.002*
Tumescent and general	**N (%)**	2 (3.7%)	13 (24.1%)	<0.004*
Tumescent alone	**N (%)**	0 (0%)	27 (50%)	<0.001*
Operative time (minutes)	**Mean ± SD**	82.8±3	72.1±2	<0.001*
Intra-operative blood loss (ml)	**Mean ± SD**	59±3.2	43.6±3.2	<0.001*
Duration of PO hospital stay (days)	**Mean ± SD**	2.8±0.6	0.8 ±0.3	<0.001*
Doses of pain analgesic	**Mean ± SD**	13.2±2.1	5.4±2.1	<0.001*
PO numeric pain rate	**Mean ± SD**	7.06±1.078	3.9±1.6	<0.001*
Return back to normal activity	**Mean ± SD**	8.5±2.4	4.8±1.5	<0.001*

*: Significant

At 1-week PO, in group (A); there was hemorrhage at the saphenofemoral junction during surgery due to slipped ligature by retractor that was discovered intra-operatively in two cases. Hematoma was noticed in the subcutaneous along the stripped vein and in the groin in 13 cases. In group (B); there were complications limited to bruising and ecchymosis in 11 cases, superficial thrombophlebitis in 5 cases (9.3%). Other complications are reported in **table 3.**

At 6-monthes post-operative follow-up; there were skin discoloration (pigmentation) noticed in 16 cases of group (A) and in only 2 cases of group (B), scarring was noticed only in group (A); and recurrence (Recanalization) was noticed only in group (B); The overall results were better in group (B) **(Table 3)**.

Table (3): Post-operative complications:

Variables		Group A (N=54)	Group B (N=54)	P-Value
Post-operative 1-week complications:				
Saphenofemoral slipped ligature	**N (%)**	2 (3.7%)	0 (0%)	<0.50
Hematoma	**N (%)**	13 (24.1%)	0 (0%)	<0.001*
Ecchymosis	**N (%)**	15 (27.8%)	11 (20.4%)	<0.37
Wound infection	**N (%)**	5 (9.3%)	0 (0%)	<0.057
Paraesthesia	**N (%)**	5 (9.3%)	0 (0%)	<0.057
Phlebitis	**N (%)**	0 (0%)	5 (9.3%)	<0.057
Deep venous thrombosis	**N (%)**	0 (0%)	5 (9.3%)	<0.057
Cutaneous burn	**N (%)**	0 (0%)	2 (3.7%)	<0.50
No complications	**N (%)**	33 (61.1%)	39 (72.2%)	0.22
6-monthes post-operative outcomes:				
Skin pigmentation	**N (%)**	16 (29.6 %)	2 (3.7%)	<0.001*
Scarring	**N (%)**	14 (25.9%)	0 (0%)	<0.001*
Recurrence	**N (%)**	0 (0%)	4 (7.4%)	<0.12
No complications	**N (%)**	34 (63.5%)	49 (90.8%)	<0.001*

*: Significant

Severity was measured utilizing the VCSS system, with baseline comparisons showing no significant differences across the groups. Post-operatively, both groups experienced a reduction in VCSS scores, and no statistically significant differences were noted (**Table 4)**.

Tab. (4): Venous clinical severity score (VCSS) for both groups:

Variables	Group A	Group B	P value
Baseline	6 (4-7)	6 (4-8.5)	0.592
1 Month	5 (4-7)	4 (3-7)	0.271
3 Months	3 (2-4.5)	2 (2-4)	0.221
6 Months	2 (1-3)	1 (1-2)	0.029

DISCUSSION

GSV high ligation traditionally served as the primary treatment for superficial venous reflux. Initially, clinicians evaluated the procedure's effectiveness by tracking varicose vein recurrence. However, the advent of duplex ultrasound technology has shifted focus towards understanding recurrent reflux as a more meaningful clinical outcome. Research demonstrates that the prevalence of recurrent reflux progressively increases over time, with documented incidence rates of 28.8% at 5 years and escalating to 60% during extended follow-up periods averaging 34 years [15].

In recent years, the landscape of GSV incompetence treatment has evolved with the emergence of minimally invasive alternatives to traditional surgical stripping. These innovative techniques include EMA, RFA, EVLA, and foam sclerotherapy (FS). Additionally, two cutting-edge, non-tumescent non-thermal endovenous ablation (NTNT) methods have been introduced: mechanochemical ablation (MOCA) and cyanoacrylate injection. These novel approaches have demonstrated promising preliminary outcomes, offering potential advancements in the management of venous insufficiency [16,17].

In the recent past, medical professionals frequently underestimated the significance of venous disease, often subjecting patients to prolonged periods of extremity elevation and compression, which left individuals significantly impaired. The contemporary approach now recommends endovenous ablations as the preferred method for addressing GSV incompetence, replacing traditional surgical interventions. These modern techniques offer substantial advantages, including reduced post-operative discomfort, diminished surgical site infection rates, accelerated return to daily activities and work, and improved patient outcomes. Nevertheless, these innovative treatments are associated with elevated equipment expenses in comparison with conventional surgical approaches [16-19].

This investigation was on the EMA utilization in primary varicose veins treatment group (B) compared to stripping group (A), it included 108 patients and the mean follow up period was 6 months. As regard to EMA group (B) that included 54 patients; this was smaller than recent studies done by **Shi *et al.*** [20] who studied 132 patients (156 limbs) with EMA among a total of 311 patients (376 limbs) for a duration of 12 months, and **Brittenden *et al.***[21] who treated 212 out of 798 patients in a long term follow up 5 years duration.

The GSV reflux presenting symptoms were pain, visible varicose vein, night cramps, restless leg, bleeding, and skin discoloration These findings were consistent with the research conducted by **Campbell *et al.***[6]**,** which examined 151 limbs across 100 patients; reporting almost the same presentations.

In this study; in all cases (100%), tumescent local anesthetic solution was applied alongside general or spinal anesthesia within the group (B) and tried in combination with spinal or general anesthesia (A); this technique provided excellent anesthesia and allowed in group (A) vein stripping to be executed under straight local anesthesia. Epinephrine's vasoconstriction, combined with the compressive effects of the instilled tumescent solution, ensured rapid hemostasis of avulsed tributaries, leading to reduced post-operative bruising and pain. In group (B), this approach created a separation of at least 1.0 cm between the superficial GSV and the skin, preventing burns and ensuring better thermal energy transfer to the vein wall by avoiding vein collapse. Additionally, epinephrine reduced the occurrence of hematomas and hyperpigmentation. Utilizing tumescent local anesthesia allowed patients to quickly return to daily routines whereas achieving optimal cosmetic and medical results, contributing to high levels of patient satisfaction [10].

In the present study; mean operative time was 82.8±3; in group (A) and 72.1±2 in group (B). This is against **De Maeseneer *et al.***[22] who mentioned that; the total theatre time was significantly longer for EMA. But our results came in line with **Yang *et al.*** [23].

Upon review of the results in this study post-operative pain**;** surgical stripping patients had moderate to sever pain and received more doses of analgesic drugs than EMA patients who had mild to moderate pain; P- value: 0.001; as in EMA patients there were no multiple skin incision. In accordance with **Sharif *et al.*** [24] patients experienced pain between 5- and 8-days post-procedure, attributed to inflammation caused by successful endovenous ablation. This pain was unrelated to ecchymosis or peri-venous tissue damage.

The mean time for returning to normal activity in surgical group was higher than in EMA group; similar results were mentioned by many authors[22-25] who mentioned that following EVLA, patients resumed normal household activities, driving, and work significantly faster compared to those who underwent conventional surgery.

At 1-week PO, there was less post intervention complications in group (B) This is consistent with previous researches [23,26]

EMA represents an innovative ablation technique characterized by distinctive thermal properties, with temperature ranges between 70-100°C, contrasting with laser approaches that exceed 100°C. Microwave ablation offers notable advantages, comprising high thermal efficiency, rapid heating capabilities, subtle thermal penetration, minimal carbonization, and reduced thermal tissue damage. Furthermore, the majority of thermal ablation-related complications tend to resolve spontaneously within a relatively brief period, enhancing the procedure's overall clinical safety and efficacy [27,28].

The overall results especially recurrence rate were better in group (B) which is similar to promising results published by many authors [28,29] as the technical success rate of EMA was 100% in their evaluation of the effect of endovenous laser ablation of incompetent GSV in primary venous disease patients.

CONCLUSIONS

EMA of GSV being simple to perform; is a safe and effective intervention with less complications, one day hospitalization, short recovery time and rapid return to activities. So, this method is very promising techniques especially in female patients for cosmetic reason as compared to surgical stripping.

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