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"Assessment of Endovenous Microwave Ablation with High Tie versus Traditional Surgery for Primary Varicose Veins"

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Abstract:

Background: The high ligation and stripping (HLS) of great saphenous vein (GSV) is the traditional method for surgical treatment of varicose vein (VVs) with high postoperative recurrence rate up to 60%, slow recovery, and obvious scar. Endovenous microwave ablation (EMA) with high tie is considered a new technique of thermal ablation. We aimed to compare between (EMA) with high tie versus traditional surgery for lower limb VVs regarding return to activity, complications, recurrence rate, and affection the Quality of Life (QoL).

Methods: This prospective comparative study was conducted on 50 cases, presented with symptomatic VVs, classified into two equal groups, EMA with high tie group and traditional surgery group. The complications and possibility of recurrence were evaluated during 3, 6, and 12 m post intervention. The effect on QoL was assessed by the Aberdeen Varicose Vein Questionnaire.

Results: Operative incision was significantly fewer in EMA with high tie group (P value <0.001). Return to activity was significantly faster in microwave ablation group (P value <0.001). Incidence of Ecchymosis and sensory impairment were significantly lower in MA with high tie group. EMA is more Recurrence at 12 m was significantly lower in MA with high tie group compared to traditional surgery group with hazard ratio (95% confidence interval) 0.2836 (0.08855 to 0.9085) (P =0.033). AVVQ was insignificant between both groups during assessment.

Conclusions: MA with high tie is an effective ablation method for VVs patients, that provides shorter time with less incisions, faster recovery with lower thermal-related complications, and recurrence rate.

Keywords: Varicose Veins, Endovenous Microwave Ablation, Traditional surgery.

Introduction:

Varicose veins (VVs) is a common disease in adults as detected in about 25% of adults without skin changes while active ulcers are occurred in 0.5% [1]. The common causes of VVs in the lower extremities are the venous insufficiency of the great saphenous vein (GSV) by incompetency of saphenofemoral junction (SFJ) and insufficiency of small saphenous vein (SSV) by incompetency of sapheno-popliteal junction (SPJ) [2].

The symptoms can range greatly from little discomfort and swelling to the development of a non-healing venous stasis ulcer [3]. Clinical Etiological

Anatomic and Pathologic (CEAP) Classification is mostly recommended for characterizing the degree of VVs [4].

Patients complaining of lower limb VVs might have unsightly appearance, burning, heaviness, itching and easily fatigue. The limb condition deteriorates with prolonged standing and relieved by elevation and mild edema could be appeared. Superficial veins thrombosis, hyperpigmentation, bleeding tributaries and skin ulceration could be happened in advanced conditions [5].

The traditional treatment surgery of VVs is high tide of GSV at sapheno femoral junction (SFJ), axial stripping with or without phlebectomy [6]. This is recommended therapy for patients with large veins > 2 cm in diameter, but has high recurrence rate up to 60%, slow recovery, and a noticeable incision scar [7].

Treatment has been shifted to the less invasive techniques as radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) that have been developed with better clinical outcomes, lower pain and earlier return to daily activities compared with traditional surgery [8, 9].

The other techniques such as microwaves has considered to be safe with good clinical outcomes in treatment of VVs. EMA is a relatively new technique for thermal ablation therapy that produces thermal energy in a manner differ from EVLA [10].

In EMA technique The microwave ablation catheter is inserted percutaneously into the VVs and the antenna radiation released penetrating microwave energy that causes vibration of the polar molecules in the vascular tissues at high frequency under the effect of the microwave field to generate direct heat [11]. There are few studies that discussed the efficiency and safety of EMA with high tie for management of lower limb VVs; therefore we conducted this study to compare between EMA with high tie versus traditional surgery for primary lower limb VVs regarding return to activity, complications, recurrence rate, and affection the Quality of Life (QoL).

Patients and Methods:

This prospective pilot clinical trial was conducted on 50 cases age <50 presented with symptomatic VVs (CEAP), incompetence SFJ and GSV refluxing along the limb (the refluxing flow > 0.5 S.) with or without skin pigmentation or ulceration. The study was performed after approval from Ethical Research Committee (ERC), According to ethical research bylaws in Faculty of Medicine, Port Said University, Egypt. (ERN :MED (2/7/2022) s.no (47) SPS/VSC_003). The study was done in Omar Ibn El-Khattab hospital and El-Rahma hospital in Port Said, Egypt within three years. All patients provided their informed written consent.

Patients who had previous surgical intervention for VVs, deep venous thrombosis (DVT) or occlusion; deep vein reflux (incompetent valves) along the limb, GSV diameter greater than 12 mm, skin infection, contraindicated to anaesthesia or surgery because of general condition, or recent diagnosis of malignancy, and pregnant ladies were excluded.

Before intervention all patients underwent to:

1) Full history taking, risk factors such as (smoking, diabetes mellitus, hypertension, ischemic heart disease, history of DVT, and history of pulmonary embolism).

2) Clinical presentation: primary symptomatic of VVs (CEAP:), dilatation of superficial veins > 5 m in diameter, burning sensation in the leg, congested leg veins, skin pigmentation, and leg venous ulcer were recorded. 3) Routine laboratory and radiological investigations such as (Duplex ultrasound of venous system of the lower limb with the determination of GSV, SSV, and extra-axial varicosities (patency and diameters) were measured.

Patients presented with venous ulcer should be managed first for infection and the ulcer to be cleaned. If the ulcer was not healed, patients were excluded.

Randomization

Randomization was conducted by a computer-generated random list and opaque, sealed envelopes denoting the assignment group. Cases were classified into two equal groups: MA with high tie group (n=25) and traditional surgery group (n=25). All procedures were done in fully equipped operating rooms under spinal anaesthesia, supine in position with continuous monitoring of vital parameters. All patients received prophylactic antibiotic with intravenous ceftriaxone (1 g)

Endovenous microwave ablation with high tie group:

For ligation of SFJ, a transverse incision on the base of the femoral triangle was made. Needle and wire below knee access is more safe to avoid risk of neuralgia of long saphenous at the ankle by ultrasound- guided technique to cannulate the microwave catheter, till reaching the end of the vein. GSV was ablated using pulse mode at 50 W. The microwave catheter was manipulated till passing through whole length of GSV and controlled by withdrawn at 2-4 mm/s, lasting 2 s. The parameters of management were depended on all data gained before intervention by duplex or surgeon expertise.

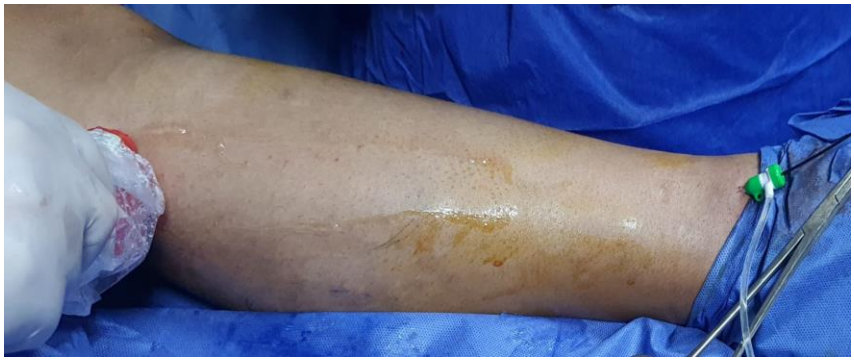
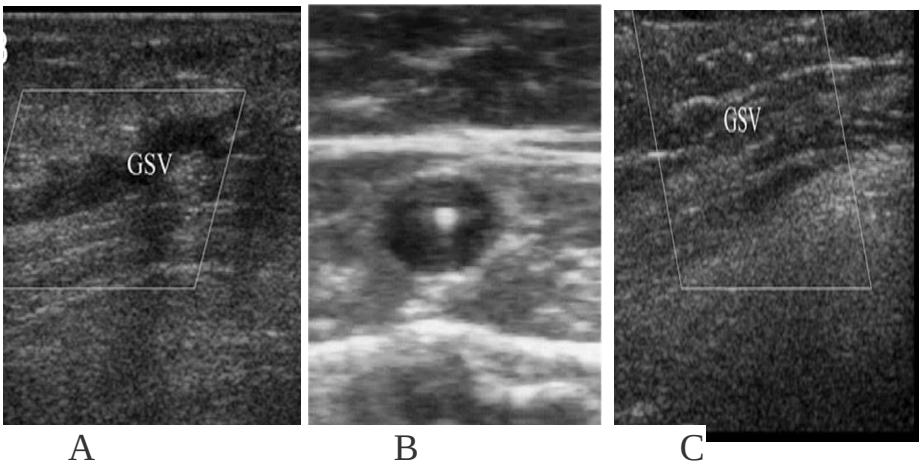


Figure (1): Insertion of the sheath in left GSV above the ankle and insertion the catheter guided by ultrasound along the limb (US).

Figure (2): Microwave catheter insertion in right GSV through below knee sheath.

Figure (3): the device used for microwave ablation.

Tumescence was injected in all cases with 0.9% saline. Superficial veins and perforators were ablated by using a catheter (power 10- 15 W and mobilizing 2-4 mm/s, for 1 s), and the catheter was inserted to 2-12 cm varices. The veins and perforators under the ulcer were entered within healthy skin close to the ulcer and ablated using a catheter guided by duplex ultrasound [12].



A B C

Figure (4): Ultrasound pictures of the great saphenous vein (GSV), A) perioperatively dilated vein. B) the micro-wave catheter inside GSV before treatment. C) post-operative obliterated GSV.

The limbs were wrapped postoperatively and covered with compression bandages for 48 hrs. Later, all cases informed to use elastic compression stocking (25 mmHg, ankle) at the day of maneuver for 3 months. The ulcer was dressed and covered with gauze.

Traditional surgery

Surgical approach was carried out through transverse incision about 3-4 cm in the groin. Flush ligation and transection of SFJ with non-absorbable suture (Ethicon, New Brunswick, New Jersey) 0-0 suture at the junction with deep system was performed. The tributaries in the groin were ligated and transected. The GSV was removed using a stripper till the level of below the knee, and varices and incompetent leg perforators were ligated, and superficial branches were removed by multiple stab avulsions (MSA) at the same time.

For both groups, after finishing the procedure, limb was wrapped with absorbent soft bandages and covered with compression bandages for a week. Later on, all cases were informed to wear a medical elastic compression stocking (class II compression stockings, 25 mmHg, at ankle) for at least 3 months. Dressing of the Ulcer and was covered with gauze. Analgesics were be prescribed (paracetamol 500 mg or ibuprofen 400 mg twice daily) for the first week. Procedure time, number of incision and postoperative pain score, hospital stay, time to ambulation and duration of return to daily activities were recorded.

Follow-up

The technical success was determined when obliterated or absorbed GSV with flow reduction. Failure of the maneuver through detection of recanalization of GSV was occurred if segment >10 cm in length. Follow up in out-patient clinic at 3, 6 and 12 months post-surgery. Any complication such as ecchymosis

was evaluated 72h postoperatively when the affected limbs had lividity and congestion area was >1 cm^2, skin burns were evaluated 72h postoperatively.

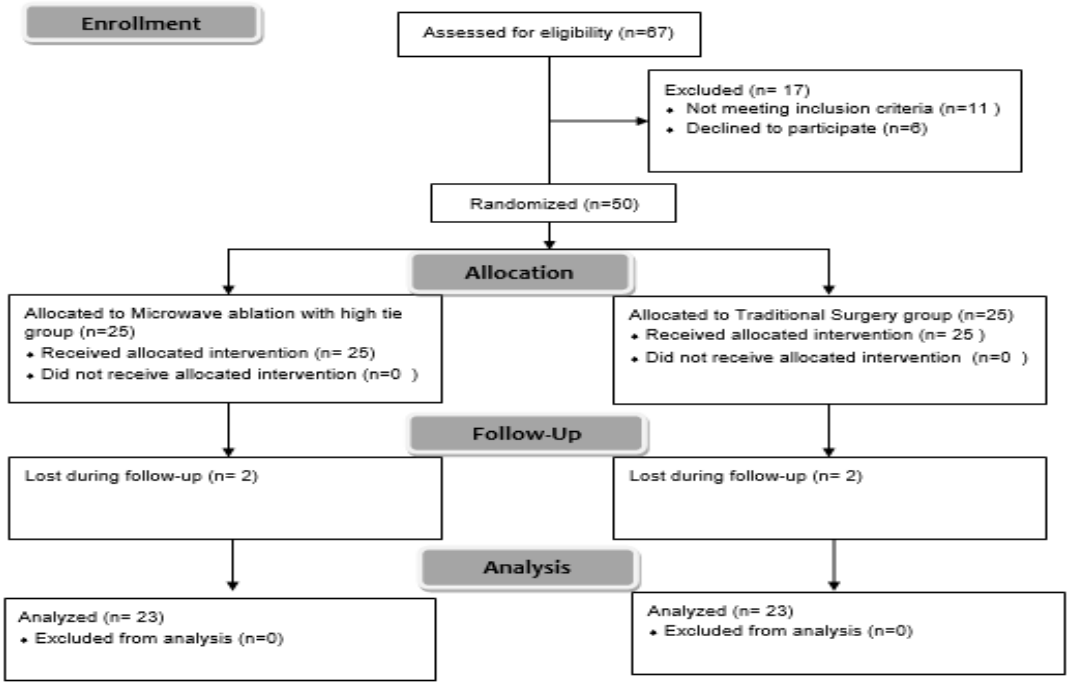
Sensory impairment (numbness) was recorded at 3,6,12 m). Recurrence of varicosities or incompetent perforators were evaluated at 3, 6 and 12m and managed by another phlebectomies or sclerotherapy. The diseased relation effect on QoL was measured by the AVVQ (Arabic version), which determined the effect on QoL that had a score ranged from 0 (no effect of VVS on QoL) to a theoretical maximum of 100 [13].

Our primary outcome was the hospital stay in MA with high tie versus traditional surgical approach for primary lower limb VVs. Our secondary outcome was assessment of complications, recurrence, and QoL.

Sample size:

The sample size calculation was done by G*Power 3.1.9.2 (Universitat Kiel, Germany). By performing a pilot study on 10 cases in each group and found that the mean (± SD) of hospital stay hours (the primary outcome) was 8.33±1.32 in MA with high tie and 9.44 ±1.24 in traditional group. Based on the following: 0.866 effect size, 95% confidence limit, 80% power of the study, group ratio 1:1 and 3 cases were added to each group for dropout. Therefore, we enrolled 25 patients in each group.

Figure 5: Consort flow chart of the enrollment patients



Statistical analysis

SPSS v26 (IBM, Chicago, IL, USA) was used for statistical analysis. Using the Shapiro-Wilks test and histograms, the normality of the data distribution was determined. Parametric quantitative data were presented as mean and standard deviation (SD) and compared using unpaired student t-test. Categorical variables were expressed as frequency and percentage (percent) and compared with the Chi-square test. To establish the total recurrence rate, a Kaplan Meier analysis was used. A two-tailed P value of ≤ 0.05 was considered statistically significant.

Result:

Across over study period, 61 cases were assessed for eligibility (four cases did not meet the inclusion criteria, seven cases refused to contribute in the study, therefore, 50 cases: 25 patients were randomized into two equal groups. In the MA with high tie and traditional surgery group, two patients dropped out during follow-up period and 23 cases were analyzed. **Figure 5**

characters		MA with high tie group n=23	Traditional surgery group n=23	P value
Age (years)		39.91 ± 6.03	41.26 ±6.55	0.472
Sex (Female)		16(69.57%)	12(52.17%)	0.365
Marital status	Single	4(17.39%)	7(30.43%)	0.525
	Married	19(82.61%)	16(69.57%)	
Weight (kg)		77.74 ±6.22	74.39 ±5.32	0.056
Height (m)		1.63 ±0.05	1.62 ±0.06	0.474
BMI (kg/m^2)		29.35 ±2.39	28.54 ±2.29	0.249
Hypertension		13(56.52%)	10(43.48%)	0.555
DM		9(39.13%)	8(34.78%)	0.760
Smoking		2(8.7%)	7(30.43%)	0.134
Long standing		16(69.57%)	14(60.87%)	0.766
LSV diameter (mm)		9.43 ±1.44	10.22 ±2.19	0.160
Reflux time (sec)		2.48 ±0.59	2.57 ±0.51	0.596
CEAP classification	C3	11 (47.8%)	9 (39.1%)	0.944
	C4	7 (30.4%)	8 (34.8%)	
	C5	4 (17.4%)	5 (21.7%)	
	C6	1 (4.4%)	1 (4.4%)	
Duration of the disease (y)		3.91 ±1.41	4.43 ±1.62	0.250
Vein affected	LSV	13(37.14%)	14(40%)	0.676
	SSV	4(11.43%)	2(5.71%)	
	Both	6(17.14%)	7(20%)	
Preoperative VAS score		3.35 ±1.02	3.96 ±1.23	0.075

Table (1): demographic data for all patients in the study.

Data are presented as mean±SD, or frequency (%). BMI: body mass index, LSV: Long saphenous vein, CEAP: Clinical-Etiological-Anatomical-Pathophysiological, DM: diabetes mellitus, SSV: small saphenous vein, VAS: Visual analogue scale.

Demographic data, clinical presentation and preoperative VAS score were insignificantly different between both groups. **Table 1**

Time of the procedure was significantly shorter in MA with high tie group compared to traditional surgery group (P value<0.001). The operative incisions needed to complete the procedures were fewer in MA with high tie group than traditional surgery group.

Postoperative VAS score and hospital stay were insignificantly different between both studied groups. Time to ambulation was significantly shorter in MA with high tie group compared to traditional surgery group (P value<0.001).

Duration of return to activity was significantly faster in MA with high tie group than traditional surgery group (P value < 0.001). **Table 2**

	MA with high tie group **n=23**	**Traditional surgery group** **n=23**	**P value**
Time of the procedure (min)	**56.65 ±5.18**	**73.17 ±8.17**	**<0.001***
Operative incisions	**1.65 ±0.49**	**4.09 ±1.41**	**<0.001***
Postoperative VAS score	**2.43 ±0.74**	**2.78 ±0.66**	**0.099**
Time to ambulation (h)	**3.96 ±0.71**	**4.7 ±1.18**	**0.014***
Hospital stay (h)	**8.22 ±1.44**	**9.09 ±1.68**	**0.066**
Duration of return to activity (weeks)	**3.26 ±0.99**	**6.57 ±0.81**	**<0.001***

Table 2: The procedure-related parameters of the studied patients

Data are presented as mean±SD:*:significant as P value ≤ 0.05.

In MA with high tie group, at 3 m 23 (100%) cases were occluded, at 6 m 22 (95.65%) cases were occluded and 1(4.35%) was partially occluded (recurrence) and at 12m 20 (86.96%) cases were occluded and 3 (13.04%) cases were partially occluded.

Duration	Events	MA with high tie group n=23	Traditional Surgery group n=23	P value
3 m	Removed	0(0.0%)	22 (95.65%)	<0.001
	occluded	23(100.0%)	0(0.0%)	
	Partial occluded	0(0.0%)	0(0.0%)	
	Reformed	0(0.0%)	1(4.35%)	
6 m	Removed	0(0.0%)	19(82.61%)	<0.001
	Occluded	22 (95.65%)	0(0.0%)	
	Partial occluded	1(4.35%)	0(0.0%)	
	Reformed	0(0.0%)	4 (17.39%)	
12 m	Removed	0(0.0%)	14(60.87%)	<0.001
	occluded	20(86.96%)	0(0.0%)	
	Partial occluded	3(13.04%)	0(0.0%)	
	Reformed	0(0.0%)	9(39.13%)	

Table 3: The occlusion and removal rate of the studied patients.

In traditional surgery group, 22 (95.65%) cases were fully removed, and 1(4.35%) case was reformed, at 6 m 19 (82.61%) cases were fully removed and4 (17.39%) cases were reformed, at 12m14 (60.87%) cases were fully removed and 9(39.13%) cases were reformed. Occlusion rate was significantly different between both groups. **Table 3**

Table 3: The occlusion and removal rate of the studied patients.

Regarding complications, Ecchymosis occurred in 3(13.04%) cases in MA with high tie group versus 14(60.87%) cases in traditional surgery group. Skin burn occurred in 5(21.74%) cases in MA with high tie group and did not occur in traditional surgery group. Sensory impairment occurred in 3(13.04%) cases MA with high tie group versus 11(47.83%) cases in traditional surgery group at 3 months, occurred in 1(4.35%) cases versus 6 (26.09%) cases in traditional surgery group at 6 months and occurred in (0.0%) versus 2(8.70%) cases in MA with high tie group compared to traditional surgery group respectively. Skin burn was significantly higher in MA with high tie group than traditional surgery group (P=0.049).

Incidence of Ecchymosis and sensory impairment at 3 months were significantly lower in MA with high tie group compared to traditional surgery group (P=0.001, and 0.023 respectively). Sensory impairment was insignificantly different between both groups at 6, and 12 months.

Recurrence was found in 0(0.0%) in MA with high tie group versus 1(4.35%) case in traditional surgery group after 3 m, was 1(4.35%) case in MA with high tie group versus 4 (17.39%) cases in traditional surgery group after 6 m. Recurrence was insignificantly different between both groups at 3m and 6m. in **Table 4**

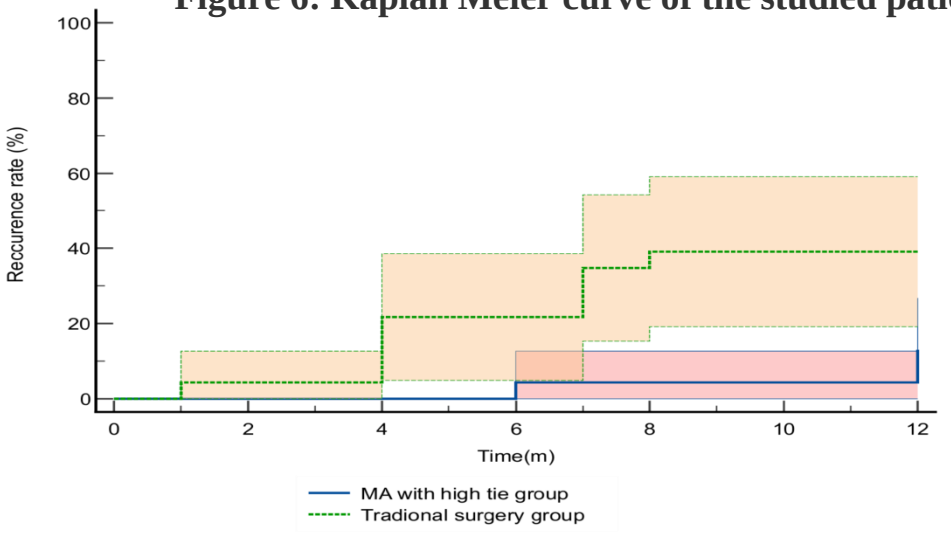
complications		MA with high tie group n=23	Traditional Surgery group n=23	P value
Ecchymosis		3(13.04%)	14(60.87%)	0.001*
Skin burn		5(21.74%)	0(0%)	0.049*
Sensory impairment	3 m	3(13.04%)	11(47.83%)	0.023*
	6 m	1(4.35%)	6(26.09%)	0.095
	12 m	0(0.0%)	2(8.70)	0.488
Recurrence	3 m	0(0%)	1(4.35%)	0.312
	6 m	1(4.35%)	4(17.39%)	0.155
	12 m	3(13.04%)	9(39.13%)	0.043*

Table 4: Complications of the studied patients

Data are presented as frequency (%),*:significant as P value <0.05

The overall recurrence at 12 m was 3(13.04%) cases in MA with high tie group versus 9(39.13%) cases in traditional surgery group after 12 m. Recurrence at 12 m was significantly lower in MA with high tie group compared to traditional surgery group with hazard ratio (95%confidence interval) (0.2836 (0.08855 to 0.9085) (P =0.033). **Figure 6**

Figure 6: Kaplan Meier curve of the studied patients for one year



AVVQ was insignificantly different between both groups at all times of measurements (P value > 0.05). **Figure 7**

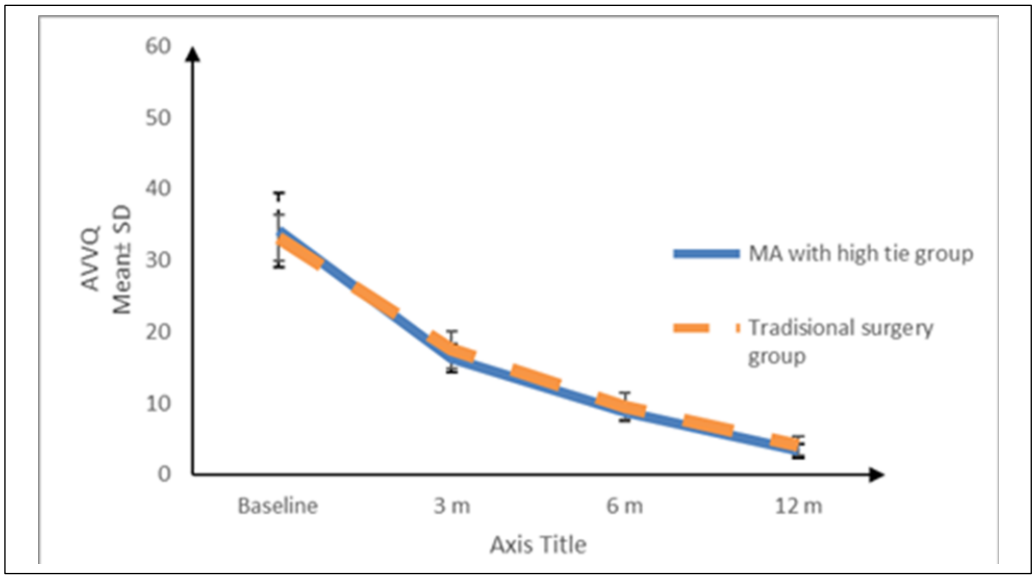


Figure 7: Aberdeen Varicose Vein Questionnaire (AVVQ) of the studied patients

Discussion

The traditional method is the first option for treatment of VVS but associated with frequent recurrence and complications [14, 15]. According to recent guidelines, EVLA and other thermal ablation techniques have replaced traditional method due to their higher effective in many countries [16].

Our trial showed that EMA had shorter operation time, lower postoperative pain score, and less operative incision compared to traditional surgery which

came in line with Yang et al. [17].

Our findings revealed that postoperative pain score was insignificantly different between both studied groups while return to activity was significantly more rapid in MA with high tie group compared to traditional surgery group.

In Agena et al., [18] who compared between traditional surgery and EVLA for VVs and showed that return to daily activity is significantly faster in patients treated with laser (3.92±1.99)days than traditional surgery group (10.71±2.56) days.

The importance of returning to normal activities after surgery cannot be overstated. Typically, they are concerned with the time required to resume their normal lifestyle prior to surgical intervention.Similarly to Kabnick et al[19] who reported that cases underwent laser ablation needed less time to return to daily activities than those who underwent surgical ligation SFJ.

In MA with high tie group, at 3 m all cases were occluded, at 6 m 22 (95.65%) cases were occluded and at one year 20(86.96%) cases were occluded. In traditional surgery group, 22 (95.65%) cases were fully removed, while 19(82.61%) cases were fully removed at 6 m and 14(60.87%) cases were fully removed at 12m. The difference in occlusion rate may connect with the mechanisms of the device, in which the efficacy of RFA was achieved via heat-induced venous spasm resulting from venous wall shrinkage. EMA induces direct and indirect thermal damage to the vessel walls by heating blood components. This came similarly to Yang et al [20] who found that EMA displayed a similar occlusion rate compared with EVLA.

Moreover, Agena et al., [18] found a significant difference in occlusion rate between traditional group and laser group. After 12 m, when duplex US was performed for all patients they reported that 6 cases (24.0%) were revascularized in traditional group, while 20 cases (80.0%) occluded and 5 cases (20.0%) with partially occluded in laser group.

Also, EMA treatment might efficiently occlude the tortuous veins around ulcers, alleviate the ulcers' pathological condition, and subsequently promote ulcer healing [21].

When using thermal ablation techniques to treat VVs, heat-related problems including as skin burns, nerve damage, and induration are frequently observed. Our findings reported the MA procedure had lower rates of ecchymosis, and sensory impairment after 1 month compared to traditional surgical method but higher incidence of skin burns occurred in MA procedure were presumably the result of either energy levels.

Our trial showed that EMA technique has a lower complication rate compared to traditional surgery. Incidence of Ecchymosis and sensory impairment at 3 months were significantly lower in MA with high tie group compared to traditional surgery group (P=0.001, and 0.023 respectively). Sensory impairment was insignificantly different between both groups at 6, and 12 months.

EMA is considered a new ablation approach because of the difference in thermal temperatures between microwaves (70 ˚C e100 ˚C) and lasers (>100C). [22]. With microwave ablation's high thermal efficiency, quick heating, mild thermal penetration, inconspicuous carbonization, and adjustable thermal ablation range, thermal damage is less frequent than with traditional ablation techniques. In addition, the majority of thermal ablation problems may be cured within a short time and do not require additional treatment [23]

This agreed with Yang et al.,[17] EMA demonstrated decreased occurrences of sensory impairment one and six months after surgery compared to HLS. These individuals healed within three to six months without therapy only little people with sensory impairment complaints should have physical and medicinal treatment.

In a previous study compared between EMA and ELVA and they stated that EMA resulted in lower ecchymosis complications, but higher skin burns

compared to EVLA [10].

Mao et al., [24] conducted a retrospective study comparing between EVLA and EMA and their results showed that EMA resulted in lower ecchymosis incidence, but higher skin burn than EVLA.

Prior research indicated that high ligation is not required for ablation operations; yet the vast majority of surgeons conducted high ligation [25, 26]. It was assumed that high ligation might prevent trunk recanalization and possible DVT, and this choice could be influenced by nonclinical variables. EMA, when paired with SFJ ligation, had a high occlusion rate comparable to those of EVLA and RFA [27].

The recurrence rates increased gradually from 3 months to the one-year follow-up. Recurrence was insignificantly different between both groups at 3m and 6m. The overall recurrence at 12 m was 3(13.04%) cases in EMA with high tie group versus 9(39.13%) cases in traditional surgery group after 12 m. Recurrence at 12 m was significantly lower in EMA with high tie group compared to traditional surgery group with hazard ratio (95%confidence interval) (0.2836 (0.08855 to 0.9085) (P =0.033). Novak et al [28], showed that the recurrence of VVs was higher after 1 year in the traditional surgery group compared to EVLA group.

These recurrences may be caused by neovascularization, inadequate tributary veins, and venous reflux. However, most recurrences diagnosed by ultrasonography lacked clinical recurrence indicators. Only clinical recurrence may necessitate further treatment [29].

Yang et al reported that EMA had a lower recurrence rate than HLS after 6 months (2.8% vs. 10.2%, $P < 0.03$). This difference may be due to our small ample size to prove the secondary outcomes.

Our findings reported that MA better than the traditional surgery in that it could achieve a favourable clinical outcome and success rate. AVVQ was insignificantly different between both groups at the same time point after treatment which came similarly with Yang et al. [17]. The thermal ablation procedures to treat VVs often indicate heat-related complications.

Our study had some limitation small sample size to prove our secondary outcomes. Further studies with larger population and longer follow up period are needed

Conclusions:

MA with high tie is a safe and effective ablation method for VVs patients that provide shorter operative time with fewer operative incisions, faster return to activity with lower thermal-related complications, and recurrence rate.

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Conflict of Interest: Nil

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