

Original Research Article

In the era of endo-venous ablation of varicose veins, is surgery still competitive?

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ABSTRACT

Background: There are different evolving minimally invasive surgical options for varicose veins (VV) treatment. This study compared Endo-venous Laser Ablation (EVLA) and foam sclerotherapy Vs high tie and multiple phlebectomy / ligation without vein stripping.

Methods: 185 lower limbs with primary VV and sapheno-femoral junction (SFJ) incompetence were included. Patients were divided into two groups. Group A: 85 limbs in 78 patients (4 had chronic venous ulcers) were treated by EVLA & foam sclerotherapy under tumescent anesthesia. Group B: 100 limbs in 100 patients (5 had chronic venous ulcers) were treated by high tie and multiple phlebectomy/ ligation under local anesthesia. All patients had duplex ultrasound preoperative and 4 weeks and 1 year postoperatively. Postoperative outpatient follow-up was 4 weeks, 3, 6 and 12 months.

Results: All procedures were successful. Early postoperative recurrence in 3 limbs (3.52%) in EVLA and no early recurrence in group B. Patients with venous ulcers healed within 3-5 weeks in both groups. Postoperative pigmentation was higher in group B. Mean time of procedure was 60-90 min and 60-150 min respectively. Significant pain in first week was more in group A (40 patients) than group B (22 patients) $p < 0.05$. No DVT, wound infection, permanent nerve affection nor skin burn was recorded in both groups. Return to normal activities was quicker in Group B compared to group A but mean cost per limb was higher in Group B (1000 -1500 US \$) versus Group A (500-750 US\$).

Conclusions: Both procedures are effective and safe in treating varicose veins. Minimally invasive surgery was less costly, more postoperative pain and was associated with longer operative time. EVLA was associated with more postoperative pigmentation and 1 year VV recurrence.

Keywords: Endovenous ablation, Minimally invasive varicose veins surgery, Sapheno-femoral junction, Varicose veins

INTRODUCTION

Lower limb venous disease is a very common condition, affecting about 25% of adults in western societies. The spectrum of disease presentation is ranging from simple telangiectasia to venous ulceration. Usually, the discomfort and disability is progressive. The treatment of early condition, traditionally, has been ignored or considered less important clinically because it is

frequently not life-threatening and interferes minimally with work or pleasure activities.¹

However, ignoring the condition can result in further progression to chronic venous insufficiency and leg ulceration. The recent EVRA trial concluded that early endovenous ablation of superficial venous reflux resulted in faster venous ulcers healing and more free time from ulcers than deferring endovenous ablation. This would be

associated with substantial saving in expenditure in dressings in this patients group.²

Therefore, treatment for varicose veins can offer substantial health- related quality-of-life improvements to patients. There are well established treatments of varicose veins include conservative management (inform of compression stockings), high-ligation surgery with or without stripping and ligation of the great and small saphenous veins), EVLA, radiofrequency ablation and ultrasound-guided foam sclerotherapy in addition to the emerging technologies of mechano-chemical ablation and cyanoacrylate glue occlusion.³

There are many studies comparing different modalities of treatment of varicose veins. Comparison of treatment options for varicose veins (CLASS trial) reported similar clinical efficacy between endovenous ablation treatment (apart from foam sclerotherapy) versus open surgery on the short term.⁴

There has been long-standing controversy about whether to strip GSV after flush SFJ ligation. Stripping is thought to reduce recurrence rates by removing contact with thigh perforators which may be, or will be, become incompetent. However, stripping is associated with discomfort, bruising and may results in damage the saphenous nerve resulting in paraesthesia.⁵

Therefore, authors adopted an open surgical technique which includes SFJ ligation and triple ligation for incompetent perforators and multiple phlebectomy/ ligation to keep benefits of treatment of incompetent SFJ and incompetent perforators but avoiding greater saphenous vein stripping complications.

The aim of this study is to compare the results of EVLA followed by foam sclerotherapy versus high tie, triple ligation for incompetent perforators and multiple phlebectomy/ ligation without vein stripping in treatment of varicose veins of the lower limb.

METHODS

The current work is non-randomized prospective study. It included all patients who had primary varicose veins

surgery for GSV incompetence in Menoufia University hospital and Delta hospital, Shebin El Kom, El Menoufia in the period of January 2012 to January 2014. All recurrent cases, secondary varicose veins and short saphenous varicose veins were excluded from the study.

The study included 2 groups. The first group included 100 patients who had sapheno-femoral junction ligation (SFJL), triple ligation for incompetent perforators, multiple phlebectomies and ligation of the vein ends without GSV stripping under local anesthesia (group A). SFJL involved dissection of the SFJ with exposing 2cm of common femoral vein with disconnection of all small lateral tributaries. Group B included 85 patients who had EVLA under Tumescant anaesthesia. Laser energy (11 W) was delivered during stepwise retraction of the optic fibre which was followed by foam sclerotherapy with 3% polidocanol in a separate session 4 weeks post ablation in patients with remaining varicose veins.

Both groups were comparable regarding patients' demography and comorbidities with no statistical significance as shown in Table 1.

All patients were assessed preoperatively regarding presenting symptoms, signs and preoperative duplex ultrasound as presented in Table 2. Postoperatively, all patients had Class II stockings full length for 1 week continuously then during day time only for another 2 weeks

Follow up was planned in outpatients after completion of treatment 4weeks then 3, 6 and 12 months postoperatively. Duplex ultrasound was done in the 4 weeks and 12 months visits. The aim of first appointment is to detect deep venous thrombosis and failure of treatment whereas the aim of the latter visit is to detect early recurrence of varicose veins.

Statistics: Data was collected prospectively. Statistical analysis of tables was performed using statistical Package for Social Sciences (SPSS for Windows, v.19.0; Chicago, IL, USA). Data is presented as mean / standard deviation. Continuous variables were analysed with t test and categoric variables using the X² test. A value of p<0.05 was considered statistically significant.

Table 1: patients' demography and comorbidities.

Pre-operative data	EVLA (n=85)	Surgery (n=100)	P value
Age	18-60 31.5±7	20-58 32±6	>0.05
Gender			
Male	34 40%	38 38%	>0.05
Female	51 60%	62 62%	
Long standing jobs	55 64%	66 66%	>0.05
Diabetes	5 5.9%	8 8%	>0.05
Hypertension	10 11.7%	15 15%	>0.05
Ever Smoking	17 20%	23 23%	>0.05

Table 2: Preoperative presented signs, symptoms and duplex ultrasound.

Pre-operative data	EVLA (n=85)	Surgery (n=100)	P value
Clinical presentation			
Pain	60 70%	72 72%	>0.05
Disfigurement	85 100%	100 100%	>0.05
Edema	32 37%	40 40%	>0.05
Pigmentation	22 26%	29 29%	>0.05
Eczema	4 4.7%	5 5%	>0.05
Ulcer	3 3.5%	5 5%	>0.05
Pre-operative duplex			
SFJ incompetence	85 100%	100 100%	>0.05
Incompetent leg perforators	53 62%	100 100%	<0.05
Diameter of GSV	<1 cm	0.8-2.2 cm	<0.05

RESULTS

All cases in Surgery group were done under local anaesthesia in one session whereas EVLA group patients had one session for EVLA under tumescent anaesthesia which was enough for VVs treatment in 32 patients without any further interventions. The other 53 patients

required foam sclerotherapy in separate sessions. The mean of foam sclerotherapy session was 1.8 (range 1-5) because not all patients required foam sclerotherapy as described above. Total treatment time was less in EVLA group without statistical significance however, the number of treatment sessions were significantly less in surgery group. Time required to heal venous ulcer was similar in both groups as demonstrated in Table 3.

Table 3: Operative details.

	EVLA (n=85)	Surgery (n=100)	P-value
Operation time	33 (20-90 min)	42 (60-150 min)	>0.05
Treatment sessions	1.8 (1-5)	1	<0.05*
Cost	1000-1500 USD	500-750 USD	<0.05*
Return to normal daily activity	2.5 days	4.2 days	<0.05*
Healing of ulcer	4 (3-5 weeks)	4.2(3-5 weeks)	>0.05

Table 4: Post-operative complications.

Complications	EVLA (n=85) N (%)	Surgery (n=100) N (%)	P-value
Significant pain (1 st 4 weeks)	22 (25.9)	40 (40)	<0.05*
Early failure (4weeks)	3 (3.5)	0 (0)	>0.05
Pigmentation	20 (23.5)	0 (0)	<0.01*
Bruises and ecchymosis	10 (11.7)	15 (15)	>0.05
DVT	-	-	
Skin burn	-	-	
Wound infection	-	-	
Early recurrence (1 year):	12 (14.1)	0 (0)	<0.05*
A) LSV incompetence	3 (3.5)	0 (0)	>0.05
B) Leg varicosities	9 (10.6)	0 (0)	<0.05*

Treatment cost was significantly less in surgery group however, mean time of return to daily working activities was less in EVLA group with statistical significance. Regarding postoperative complications, there was no

mortality or significant morbidity and procedures were well tolerated in both treatment groups. Three cases had failure of GSV ablation found in the 4 weeks outpatient appointment versus no GSV incompetence detected in surgery group.

Pigmentation is a well-known complication of foam sclerotherapy. That was highly significant in EVLA group. Post-operative bruises were less in surgery group compared to EVLA group however there was no associated statistical significance. No cases were complicated by skin burn or deep venous thrombosis (DVT). All post-operative complications are presented in Table 4.

One year recurrence was diagnosed in the 12-month outpatient follow up visit in 12 patients in EVLA group. Three patients had recanalization of GSV with duplex ultrasound (radiological diagnosis) and recurrent varicosities were seen clinically in 9 patients only. In those who had recurrent varicose veins, 1 foam sclerotherapy session was provided. No early recurrence was found in surgery group.

DISCUSSION

The main finding of this study is that both EVLA and open surgery were safe and effective in treatment of varicose veins however; as shown above, each option has its own advantages and disadvantages.

Recurrent varicose veins causes are still considered a mystery. Surgery if done correctly is unlikely to be associated with early recurrence for the simple fact the LSV vein itself is taken out. However, this is not the case in late recurrence. A recent meta-analysis studied causes and pathogenesis of recurrence of varicose veins after open surgery.⁶ This included: Tactical and technical error, inexperienced surgeons, disease progression and neovascularization.

Stripping versus no stripping has been studied for years. A good quality randomized controlled trial (RCT) studied effect of vein stripping or not on late recurrence.⁷ They found that stripping the GSV is recommended as an essential part of varicose vein surgery as it reduced the reoperation risk by 60% after 11 years. However interestingly, it did not reduce the rate of visible recurrent veins. Authors could not find RCT to compare SFJL plus routine stripping versus selective triple ligation of incompetent perforators without stripping. In our study, the incidence of postoperative bruises and significant pain was similar in both our treatment groups.

An older RCT, as many older studies, concluded that Recurrence was reduced from 43 to 25% in patients who had their GSV stripped ($p=0.04$).⁵ Neovascularisation was the commonest cause of recurrence and was detected in 52% in non-stripped group.

Our early recurrence after 1 year in group B was 14.1%. High success rates after EVLA have been reported. A 2-year recurrence rate of 10% was reported by Min et al.⁸

Authors used fixed laser energy application in all our patients in group B (11W). There are reports that the

energy delivery had an important effect on recurrence, where low-energy delivery had worse results and more recurrences than higher-energy doses.⁹

Other reports blamed large vein diameter to be the main cause of early and late recurrence when moderate energy delivery was used and was associated with non-occlusion of GSV.^{9,10}

Neovascularization is an interesting cause of recurrence in the literature. Although one of the theories that promoted EVLA because of the known relation between open surgery and neovascularization, a recent RCT from the Netherlands compared SFJL + stripping versus EVLA. Compared with the 1 year follow-up, after 5 years there is a significantly higher recurrence rate, mainly caused by neo-reflux from the SFJ in the anterior accessory saphenous vein after EVLA in comparison with the surgical arm.¹¹

In present study EVLA was associated with almost double the cost of treatment compared to open surgery. This was calculated with the net cost of surgery only without taking into consideration the benefit of early return to normal activities postoperatively and consequently less time off work and less interference of patient work productivity and income which was significantly high in the EVLA group. A recent cost analysis study assessed the overall cost and quality of life per person over 5 years; Radiofrequency ablation was the treatment with highest median rank for net benefit, with mechanochemical ablation second, EVLA third and surgical treatment came forth.³

The current study assessed 2 different modalities that are not entirely typical method of treatment of varicose veins. Our study is of prospective design with associated accurate recording of all steps of management and analysis of data. Follow up although was not for a long period, it was focused on the effectiveness of both treatment arms on the short and medium term and would be interesting when longer follow up results of the current study is available. Although our study is a prospective study, it would have been of better design if it was randomized. The number of patients involved in our study is average, but a higher number might have revealed more significant results and discrepancy between both treatment groups.

CONCLUSION

Both procedures are effective and safe in treating varicose veins. Minimally invasive surgery was less costly and required fewer operative sessions. EVLA and completion foam sclerotherapy was associated with less time required to resume regular activities but also was associated with more incidence of pigmentation and early 1-year recurrence.

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