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Abstract

Varicose veins is a major problem among adult population. It has a major effect on life quality as well as healthcare system resources, we aim in this study to compare ultrasound guided foam sclerotherapy (UGFS) with surgery in management of primary varicose veins patients and to measure patients' satisfaction with either modalities.

Lower limbs of 100 patients with great saphenous vein (GSV) incompetence were prospectively randomized to undergo either surgical treatment or foam sclerotherapy. Clinical, etiological, anatomical and SDWKRKSK\VLRRJLFDQ &(\$3 &ODVVL¿FDWLRQ DQG WKH 9HQRXV &OLQLFDQ 6HY investigated with a follow-up period of 1 year.

Total occlusion of great saphenous vein (GSV) was 88% in foam group as well as in the surgery group, recurrence rate in the foam group was 6% as well as in surgery group. Patient satisfaction at 1 year was 94% in IRDP JURXS ZKLOH LQ VXUJHU\ JURXS LW ZDV 7KHUH ZHUH QR VWDWLVLWLFDO VCSS, recurrence, patient satisfaction between both groups at 1 month, 6 months and 1 year (p value>0.001).

Surgical treatment and UGFS achieved elevated rates of total occlusion of GSV incompetence with QR VLJQL¿FDQW GLIIHUHQFH %RWK WUHDWPHQWV OHG WR VLJQL¿FDQW LPSURYH clinical outcomes. UGFS is a valid noninvasive modality in management of great saphenous vein incompetence and is comparable to surgery.

Keywords: Ultrasound guided foam sclerotherapy; Varicose veins surgery; VCSS; CEAP

Introduction

Multiple studies show that at least one quarter of the adult population have varicose veins [1]. This condition is often correlated with great saphenous vein (GSV) reflux [1,2]. Varicose veins disease has a major effect on quality of life, as well as on the resources and budgets of healthcare systems [3]. For decades, the ideal management was surgical removal of the GSV. Research comparing liquid sclerotherapy and surgery for treatment of GSV incompetence showed that surgery was more effective [4,5].

Long-term results of surgery indicated recurrence rates of between 21 and 26% after 3 years of follow-up and 60% after 34 years [6-8]. However, recently there is an increased demand for minimally invasive and less expensive procedures such as ultrasound-guided foam sclerotherapy (UGFS), endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) [9].

UGFS is a variant of liquid sclerotherapy, in which the liquid-air mixture (foam) is injected into varicose veins under ultrasound guidance. In comparison with liquid sclerotherapy, UGFS is more efficient [10,11]. UGFS has a reported successful result of 75-85% at 1 year and 69% after 2 years of follow-up [12-14]. Advantages of this treatment are that it is less invasive, reduces healthcare costs, and is associated with a shorter recovery time than surgery [15,16], making UGFS an appealing substitution to operations for varicose veins management.

The aim of our work is to compare ultrasound guided foam sclerotherapy (UGFS) with surgery in treatment of patients with primary chronic venous insufficiency.

Materials and Methods

This prospective randomized controlled study was carried out in Department of vascular surgery, Qena University Hospital, South Valley University, comparing the effectiveness of surgery and UGFS in management of patients with incompetent saphenofemoral junction. Patients attending to the vascular surgery outpatient clinic in Qena University hospital were included in the study. Patients were chosen based on clinical history, physical examination, duplex ultrasound and CEAP classification and patients who gave written consent were recruited in the study.

Inclusion criteria

Patients of age between 18 and 60 years were recruited. No previous management of varicose veins and patients with primary varicose veins only with the following criteria (the clinical C2-C3, Etiological reflux, Anatomic superficial long saphenous and Pathophysiologic reflux) according to (CEAP) classification.

Exclusion criteria

Patients with primary varicosities involving both the long saphenous

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vein (LSV) and short saphenous vein (SSV), acute deep vein thrombosis (DVT), thrombophilia, allergy to sclerosant agent, bronchial asthma, post-thrombotic syndrome, morbid obesity, pregnancy, peripheral arterial insufficiency (ankle brachial index <0.8), diabetic patients with peripheral neuropathy or ulceration, those with a patent foramen ovale and malignancy.

All the selected patients provided with detailed information related to conventional surgery and UGFS. Only one leg per patient will be involved in the study and in subjects with bilateral varicose veins the most severely affected limb was chosen and suspected to randomization.

Patients who agreed to take part in the study and who gave (informed) consent were randomly allocated to one of the treatment groups, the study was approved by local medical ethics committee of Qena University Hospital and randomization was done by asking the patients to choose from sealed envelopes. The patients classified to:

Group 1: 50 patients managed by conventional surgical treatment.

Group 2: 50 patients managed by duplex-guided foam sclerotherapy.

### Conventional surgery

Saphenofemoral junction ligation combined with saphenous stripping and phlebectomy for saphenous tributaries and ligation of incompetent perforating veins were done. The treated limbs will be bandaged at once postoperative by inelastic bandages. After 2 days, the bandages will be replaced by above knee elastic compression stockings with a compression for 3 months.

### Ultrasound-guided foam sclerotherapy

Pretreatment skin marking over incompetent truncal veins and superficial varicosities will be marked on the skin using duplex ultrasound. The patient then put in a flat position for GSV cannulation. Peripheral intravenous catheters will be inserted under direct duplex guidance. According to the size and depth of the target vein, 18-22G cannulae (green, pink or blue) will be used. Once all cannulae were secured, the leg will be elevated (to empty the veins) for injection of the foam.

All cannula should be flushed with normal saline to ensure that they were not dislodged during the changes in leg position. Sclerosant foam will be prepared by Tessari's method using two 5 mL syringes connected by a three-way stopcock and comprised 1 mL of sclerosant agent (ethanolamine oleate) and 4 mL of air.

Foam injected in 5 mL, and its distribution and resultant venous spasm observed by duplex ultrasound, minimum 30 seconds between each injection. After each injection patients will be asked for dorsi- and plantar- flexion of their ankle many times to get rid of any foam that might have passed to the deep venous system.

When all the trunks, tributary veins and the varices were in spasm and filled with foam, the cannulae will be removed and compression was applied with the leg still elevated. A roll was put in directly along the line of the previously marked saphenous trunk and superficial varices and kept in place using bandage. The bandage then secured with 100 mm wide adhesive tape, this regimen produce direct compression over the truncal veins.

Above knee class II compression stocking was put in over the bandage. The bandaging is left in place for five to ten days, depending

on the veins' size then it was removed and the class II stocking used alone for further three weeks. After the procedure the patients were asked to walk for around 10 minutes and then were informed to walk for five minutes at least during every waking hour while the bandages will be in place. Patients had been given a contact telephone number to use if they experienced severe discomfort or had any other matters following treatment.

### Follow-up

All patients had been seen at 1, 6 and 12 months post management in the outpatient clinic, comparing the effect of foam sclerotherapy with operation on venous symptoms (varicose vein severity score), comparing complications and side-effects after the incompetent great saphenous vein treatment such as early infection, hematoma, paraesthesia, pain at the site of injection, headache, visual disturbance, thrombo-phlebitis, DVT, pulmonary embolism, hyperpigmentation, telangiectasia matting. Patients also have been asked about their satisfaction regarding the procedure done and their answers were recorded.

Post-sclerotherapy follow-up using duplex ultrasound to measure the effectiveness of foam sclerotherapy was also done. The results will be classified as follows: complete occlusion: the GSV had shrunk and was occluded; partial GSV recanalization with no reflux, partial GSV recanalization with reflux and complete GSV recanalization with no reflux. VCSS estimated duplex were done to evaluate occlusion of the desired veins.

### Statistical analysis

Differences between the 2 groups of patients with a specific outcome at 1 month, 6 months and 1 year post treatment were tested for statistical significance. Ninety-five percent confidence intervals around the difference in proportions were calculated.  $P < 0.05$  was considered to indicate statistical significance. Only patients who underwent the allocated intervention were included in the analysis. All data were analyzed with SPSS version 17.0.

### Results

The chosen outcome measures were complete occlusion of, and abolition of incompetence in the GSV on duplex ultrasound (DUS) (defined as technical success), and the complete absence of any visible varicose vein (VV) (defined as clinical success). Regarding patients' satisfaction, they were asked whether they are satisfied with the results of maneuver done or not and their answers whether yes or no were recorded.

### Demographic data and patient characteristics

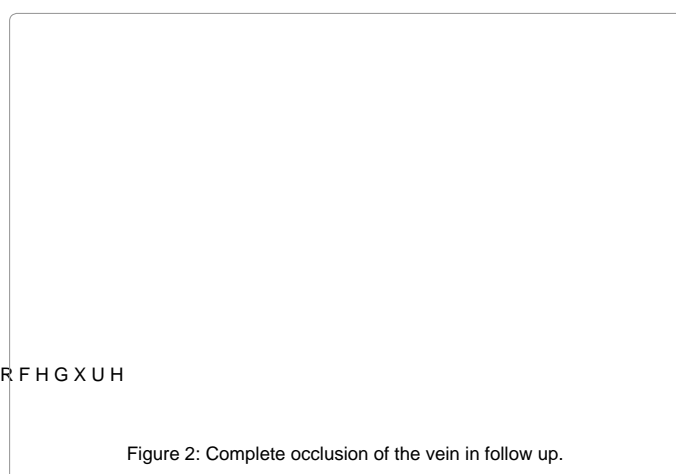
100 patients were randomized in this study, 50 patients for foam sclerotherapy and 50 patients to surgery, mean age was 35.97. All subjects were assessed by CEAP, VCSS and duplex ultrasound. All patients had incompetent long saphenous vein, 92 patients classified as C2s and 8 classified as C3s, VCSS mean was 7.68, (maximum was 10 and minimum was 6). Only one limb per patient was included in this study. Regarding gender, the study included 50 males and 50 females. In the foam group 24 patients with Lt lower limb and 26 with Rt lower limb varicose veins were treated and 46 patients were CEAP class C2 and only 4 patients classified as C3. While in surgery group 26 patients with Lt lower limb varicose veins and 24 patients with Rt lower limb varicose veins were operated and 46 patients were classified as C2 and 4 patients as C3d as shown in Table 1.

	All	Foam	Surgery	
Randomized number	100	50	50	
Age (M, M, M, SD)	Minimum	Maximum	Mean	Std. Deviation
	20	65	35.97	11.60847
Male	50	25 (50%)	25 (50%)	25 (50%)
Female	50	25 (50%)	25 (50%)	
Lt	50	24 (48%)	26 (52%)	
Rt	50	26 (52%)	24 (48%)	
Ceap (n, %)	100			
C2		46 (92%)	46 (92%)	
C3		4	4	
VCSS (M, M, M, SD)	Minimum	Maximum	Mean	Std. Deviation
	6	11	7.68	1.46942
Duplex pre				
Incompetent long saphenous vein	100	50	50	

Table 1: Demographic data and patient characteristics.

Follow up	Total occlusion	Partial recanalization without re ux	Partial recanalization with re ux	Total recanalization
1 month				
Foam	46 (92%)	1 (2%)	2 (4%)	1 (2%)
Surgery	50 (100%)	0	0	0
6 month				
Foam	49 (98%)	1 (2%)	0	0
Surgery	50	0	0	0
1 year				
Foam	44 (88%)	3 (6%)	2 (4%)	1 (2%)
Surgery	44 (88%)	3 (6%)	3 (6%)	0
	Minimum	Maximum	Mean	Std. Deviation
VCSS 1 month	2	4	2.92	0.67689
VCSS 6 month	0	2	0.49	0.55949
Vcss 1 year	0	3	0.2	0.60302
Satisfaction	Foam	Surgery		P value >0.001
				-0.466
6 D W L V ç H G	47 (94%)	45 (90%)		
1 R Q V D W L V ç H G	3 (6%)	5 (10%)		

Table 2: Follow up data.



## Patients Follow Up

### At 1 month follow up

In foam group, 92% of patient achieve total occlusion, 2% partial recanalization without re ux, 4% partial recanalization with re ux

and 2% total recanalization of these patient 3 patient receive another session of UGFS and one was satis ed with result and refuse to take another session. In surgery group 100% achieve total occlusion at month follow up (Figures 1 and 2).

### At 6 months follow up

In the foam group, 98% of subjects achieve total occlusion of GSV and 2% partial recanalization without re ux and 3 of patients who received another injection session achieve total occlusion. In surgery group 100% of patients achieve total occlusion.

At 1 year follow up

In foam group, 88% show total occlusion, 6% show partial recanalization without re ux, 4% show partial recanalization with re ux and 2% show total recanalization. In surgery group, 88% show total occlusion, 6% show partial recanalization without re ux and 6% show partial recanalization with re ux. All patients with complete recanalization and partial recanalization with re ux both considered treatment failure in foam group the failure was 6% and it is the same in surgery group probably because of neorevascularization or patient return to previous activities. Recurrence rate in foam group is 6% as well as in surgery group (Table 2 and Figure 3).

Follow up of VCSS

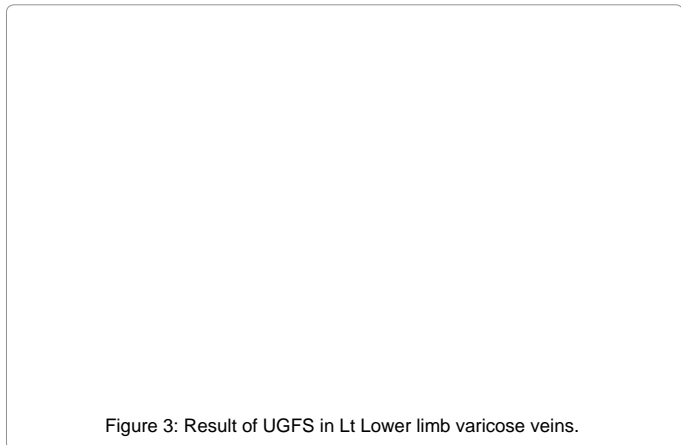
- At 1 month mean value was 2.92, (minimum 2 and maximum 4)
- At 6 months mean value was 49, (minimum 0 and maximum 2)
- At 1 year mean value was 2, (minimum 0 and maximum 3)

Patient satisfaction

In foam group, patient satisfaction at 1 year was 94% while 6% were unsatisfied while in surgery group 90% of patients were satisfied while 10% were unsatisfied with no significant difference as p value >0.001 (0.466).

Differences between groups

No significant differences between groups were found in preoperative duplex examination, side, VCSS, CEAP classification or sex. No significant difference between groups in follow up parameters (Table 3 and Figure 4).



Complications

Regarding complication there is statistically significant difference between groups regarding complications as hyperpigmentation, telangiectasia matting, headache, thrombophlebitis, infection, pain at site of injection, parathesis and haematoma, but not statistically significant difference regarding DVT and PE. These differences between groups are because those complications are technique specific (Table 4).

Discussion

Varicose veins constitute a chronic, frequently relapsing event that develops secondary to valvular failure. It is, therefore, unrealistic to expect the complete and constant removal of superficial re ux in all patients subjected to a single treatment whether it was operative, UGFS, or another minimally invasive alternative [17].

Although still considered by many surgeons as the 'gold standard', the efficacy of operation is limited by fear of damaging the saphenous nerve, to strip the below knee great saphenous vein BK-GSV - a common cause of residual and recurrent disease as well. Furthermore, a redo surgery for residual or recurrent re ux is usually difficult, often morbid, and frequently associated with suboptimal patient outcomes [17].

For many years, high ligation and stripping of the GSV are the most commonly used and effective method for varicose veins management [18]. The operation is a traumatic experience for patients. Surgery may



		Sum of Squares	Df	Mean Square	F	Sig.
VCSS	% H W Z H H Q * U R X S V	1.440	1	1.440	0.665	0.417
VCSS at 1 month	% H W Z H H Q * U R X S V	0.160	1	0.160	0.347	0.557
VCSS at 6 month	% H W Z H H Q * U R X S V	0.090	1	0.090	0.285	0.594
VCSS at 1 year	% H W Z H H Q * U R X S V	0.000	1	0.000	0.000	1.000
Follow up at 1 month	% H W Z H H Q * U R X S V	0.490	1	0.490	2.713	0.103
Follow up at 6 months	% H W Z H H Q * U R X S V	0.010	1	0.010	1.000	0.320
Follow up at 1 year	% H W Z H H Q * U R X S V	0.010	1	0.010	0.031	0.860
Recurrence	% H W Z H H Q * U R X S V	0.010	1	0.010	0.100	0.752
Patient satisfaction	% H W Z H H Q * U R X S V	0.040	1	0.040	0.536	0.466

Table 3: Difference between groups in follow up.

Complication	Surgery	Foam
DVT	0	1
PE	0	1
Telangectatic matting	0	4
Haematoma	4	0
Groin infection	2	0
Parathesia	5	0
Pain at injection site	0	6
Headache	0	3
Hyperpigmentation	0	5
Thrompophlipitis	0	5

Table 4: Complications.

also be followed by many complications as bleeding, groin infection, thrombophlebitis, saphenous nerve injury or even life-threatening conditions [19]. Additionally, postoperative recovery is quite long. General or regional anesthesia during a conventional operation increases the costs of treatment [12].

In recent years many less aggressive methods of endovenous treatments of varicose veins, such as sclerotherapy, thermo ablation (radiofrequency, laser, steam ablation) and intravascular glue have been used. The first one who used foam sclerosant was Orbach in 1944 [20,21]. Cabrera et al. in 1997 performed ultrasound-guided sclerotherapy. Finally, Tessari presented the newest method of producing a foamy sclerosant in 2000. He used two syringes and a three-way tap [22]. This method gave the opportunity to achieve stable foam formed of small bubbles. New treatment methods should be compared to surgery in order to measure their credibility and safety. The significance of randomized clinical trials for clinical decision making has been widely recognized [23].

Following surgery, recurrence rates after 2-5 years vary between 20 and 50% [24-26] and recurrence following FS re-ux was reported in 31% of the patients after 2 years [27]. We considered re-ux combined with symptoms as the most relevant measure because it best reflects clinical practice, where patients are treated only if they exhibit a combination of venous re-ux and symptoms [28,29].

The VCSS has been introduced only after 2004 therefore few studies are available for comparing outcomes after treatment using this scoring system [30].

In 2006 study shows VCSS, venous disability score VDS and CEAP clinical score were equally sensitive and better for measuring response to superficial venous surgery [31]. Very few studies have compared UGFS with surgery in a randomised study [32,33]. The study by Masuda et al. they compared the change in VCSS after foam sclerotherapy and found that median score changes from 8 to 2 (75% change in score) [34]. Iafrati et al. compare the change in VCSS after surgery and found that mean VCSS change from 9.8 to 4.2 (57% change in score) [35].

Gloviczki et al. also compared the change in VCSS after surgery and found that mean VCSS change from 8.93 to 3.98 (55% change in score) after the treatment [36].

Figueiredo et al. compared the result of foam sclerotherapy with surgery on the basis of VCSS they found improvement in both groups in VCSS in 1 month and 6 months follow up [32].

However, there is very little data in literature directly comparing UGFS with surgery on the basis of VCSS, in our work both treatment modalities were directly compared by using VCSS and both modalities

were equally effective in improving the VCSS score at 1 and 6 months and 1 year with no significant difference between foam and surgery groups.

Regarding vein occlusion rate, based on 69 studies in systematic review done by Jia et al. [37], the median rate of target vein occlusion was 87% (range 60-98). In another study done by Cabrera et al. [38], 81% of the treated GSV with foam therapy remained occluded after 3 years or more. Also, Comasset et al. [39] reported that, with 3 months as a median time of follow up 79% of cases showed complete occlusion of desired veins, 14% showed partial occlusion and the rest 6% showed complete patency. Figueiredo et al. shows the obliteration rate of 90% in surgery group and 78% in foam sclerotherapy group after 6 months of follow up [32]. Our study also, reported that the great saphenous vein treated vessels in sclerotherapy group showed a success rate 80%. In the study done by O'Hare et al. [40] the target vein occlusion was 93% by Doppler at 2 weeks follow up and 74% by Duplex at six month follow up. The treated veins in their study included the great saphenous vein (GSV), small saphenous vein (SSV), anterior accessory saphenous vein (AASV) or other recurrent veins with significant proximal incompetent deep venous connection. In the Tessari group, they found immediate success in 93.3%.

Hamel-Desnos et al. [41] reported the outcome of comparing liquid and foamed 3% polidocanol. In the foam group, 84% of the 45 patients had no residual re-ux at 3 weeks. At 6 months, there were two recanalization in the foam group. A recent meta-analysis reported the outcome of 13 studies that assessed surgery and 10 studies where patients with VV underwent USGFS with an average follow-up of 32.2 months [27]. The estimated pooled success rates (with 95% confidence intervals) were 78% (70-84%) for surgery and 77% (69-84%) for USGFS. It concluded that in the absence of large, comparative randomized clinical trials, foam sclerotherapy appears to be at least as effective as surgery in the treatment of lower extremity VV.

Dwerryhouse et al. did a follow-up study of 78 patients (110 limbs) who had primary GSV varicosities and underwent saphenofemoral ligation (SFL) alone or combined with stripping. At 5 years they found that stripping decreased the risk of redo surgery by two-thirds. Although surgery is highly effective in the short-term, the long-term recurrence rates are approximately 30% [42]. In another trial [43], saphenous re-ux was abolished in 85% of surgery patients and 84% of foam sclerotherapy patients 1 year after treatment. Bountouroglou et al. found an obliteration rate of 89% in surgery and 78% in foam sclerotherapy group after 12 months of follow up [44].

Several large case series and one multicenter study have been published. UGFS in 1411 limbs showed occlusion in 88% of GSVs after a mean follow-up of 11 months [45-47]. Few studies showed 69% complete sclerosis in 99 limbs after 24 months of follow-up [48], 44% occlusion in 211 limbs after 5 years of follow-up [43] and 88% occlusion in 143 limbs after 6 weeks of follow-up [49].

Our study compared 1 year results of surgery and ultrasound guided foam sclerotherapy but we should notice that all our patients as mentioned in inclusion criteria had been diagnosed as C2-3 EpAsPr. Our results were as follow at 1 year follow up both foam and surgery groups achieved 88% total occlusion of GSV and our result are comparable with some other studies.

## Complications

Some complications were exclusive to surgery group and not found on UGFS group. These included stitch infection in 3 (12%)

patients, seroma in 3 (12%) and hematoma in 2 (8%) subjects at 1 week follow up Figueiredo et al. in 2009 describes infection, hematoma and suture dehiscence in surgery group respectively in 3%, 7% and 38% patients [32]. In the present study surgical complications were groin haematoma in 4 patient 8%, groin infection in 2 patient 4% and parathesis in 5 patients 10% and all these complication were transient and managed in conservative way while in foam group complications in were pain at injection site in 6 patient 12%, hyperpigmentation and thrombophlebitis seen in 5 patients 10%, telangiectasia matting seen in 4 patients 8%, headache in 3 patients 6% and deep venous thrombosis and pulmonary embolism seen in one case 2%. In our work, complications in the foam UGFS group were tolerable and transient and did not need any active intervention, which are again comparable to the published studies [37,50,51].

Except for one case of DVT and pulmonary embolism which was managed medically without intervention and after 3 months anticoagulant complete resolution was achieved. The 2% frequency of thromboembolic events in our subjects corresponds to reported thromboembolic event rates between 0.02% and 1.25% [52,53].

In a study by Myers et al. [54], the only complication observed was deep venous thrombosis DVT, which occurred in 3.2% of the patients. This is somewhat higher than what has been reported in our study. Jia et al. [37] showed pain and pigmentations were the two most important complications in foam group which is in accordance with the literature, pain in 4 (16%) patients and pigmentation 5 (20%) patients [51,52].

Ouvry et al. show Pain and pigmentations were the most two important complications in foam [50]. Guex et al. Pain and pigmentations were the most two important complications in foam sclerotherapy [51].

omasset et al. show that the most common side effects associated with foam sclerotherapy were skin discoloration in 30% patients, superficial thrombophlebitis in 16%, and an allergy to the foam sclerosant in 2.5% [39].

In a study by Smith [55], the reported complications were as follows. thrombophlebitis occurred in a small number of patients (5%), and was managed by using analgesia, compression, and aspiration of the thrombus. Calf vein thrombosis was confined to isolated gastrocnemius veins or to part of the posterior tibiae vein (1.23%), which was managed with compression by stocking, or bandage and exercise without using anticoagulants.

## Limitation

The main limitations of the present study are the few number of patients assessed and the short period of follow-up. On the other hand, the fact that we were working with a homogeneous sample (all patients classified as Cc2-3 EpAsPr) allowed discussing the treatment of this specific type of patients. Further work should be done with the aim of defining a more accurate classification protocol.

## Conclusion

Our study declared that UGFS is effective in obliterating saphenous trunks. Follow-up treatment modalities foam and surgery accomplished similar results in the VCSS. The anatomical success rate was similar for both modalities. However, these early results cannot be relied on to determine definitive recommendations varicose veins management as late recurrence rates and the need for further management also required to be considered.

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