Duplex Guided Catheter Directed Foam Sclerotherapy versus Surgery in Primary Varicose Veins

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Abstract: Background: Varicose veins are a very common problem all over the world. Surgery has been the gold standard treatment for many years, however now other less invasive options are available, we aim in this study to compare ultrasound guided foam sclerotherapy (UGFS) with surgery in management of primary varicose veins. **Methods:** 40 lower limbs of 40 patients with great saphenous vein (GSV) incompetence were prospectively randomized to undergo either surgical treatment or foam sclerotherapy. Clinical, etiological, anatomical and pathophysiological (CEAP) Classification and the Venous Clinical Severity Score (VCSS) were completed and investigated with a follow-up period of 1 year. **Results:** Total occlusion of great saphenous vein (GSV) was 88% in foam group & 100% 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 foam group while in surgery group it was 90%. There were no statistical significant differences in follow up regarding VCSS, recurrence, patient satisfaction between both groups at 1 month, 6 months and 1 year (p value>0.001). **Conclusion:** Surgical treatment and UGFS achieved elevated rates of total occlusion of GSV incompetence with no significant difference. Both treatments led to significant improvements in VCSS, demonstrating improvements in clinical outcomes. UGFS is a valid noninvasive modality in management of great saphenous vein incompetence and is comparable to surgery.

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1. Introduction

Varicose veins are a very common problem all over the world. An estimated 15% of men and 25% of women suffer symptoms from varicose veins. Surgery has been the gold standard treatment for many years, however now other less invasive options are available and sometimes more efficient 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**].

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 [**6,7**]. UGFS has a reported successful result of 75-85% after 1 year and 69% after 2 years of follow-up [**8-9**]. Advantages of this treatment are that it is less invasive, reduces healthcare costs, and is associated with a shorter recovery time than surgery [**10,11**], 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.

2. Materials and Methods

This Prospective randomized controlled study was carried out in Department of vascular surgery, **AL-zahraa** University Hospital, cairo, Egypt and **Benha** Teaching Hospital, kalyobia governorate, Egypt comparing the effectiveness of surgery and UGFS in management of patients with incompetent saphenofemoral junction. Patients attending to the vascular surgery outpatient clinic 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 20 and 50 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

Acute deep vein thrombosis (DVT), allergy to

sclerosant agent, bronchial asthma, post-thrombotic syndrome, morbid obesity, pregnancy, Patients with primary varicosities involving both the (LSV) and (SSV), peripheral arterial insufficiency (ankle brachial index <0.8), diabetic patients with peripheral neuropathy or ulceration, those with a patent foramen ovale and malignancy.

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.

The study was approved by local medical ethics committee of A Lzhraa University Then patients classified to:

Group 1: 20 patients managed by conventional surgical treatment.

Group 2: 20 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 **[12].** 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

The maneuver was done in operating room. The limb was scrubbed by Betadine (povidone iodine 7.5 %). The long saphenous vein was cannulated under ultrasound vision with (18G cannulae. The GSV was routinely cannulated immediately above, or just below the knee., the leg will be elevated (to empty the veins) for injection of the foam **[13-15].**

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 syringes connected by a three-way stopcock and comprised sclerosing agent. 5ml 3% polidocanol in one syringe with 9 ml air in another syringe.

Foam injected in 5 mL, and its distribution and resultant venous spasm observed by duplex ultrasound, minimum 30 seconds left 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. 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.

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 and operation on venous symptoms (varicose vein severity score), comparing complications and side-effects after the incompetent great saphenous vein treatment.

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 reflux. VCSS estimated duplex were done to evaluate occlusion of desired veins.

3. 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

40 patients were randomized in this study, 20 patients for foam sclerotherapy and 20 patients to surgery, mean age was 30. All subjects were assessed by CEAP, VCSS and duplex ultrasound**.** All patients had incompetent long saphenous vein,. Only one limb per patient was included in this study.

Patients Follow Up

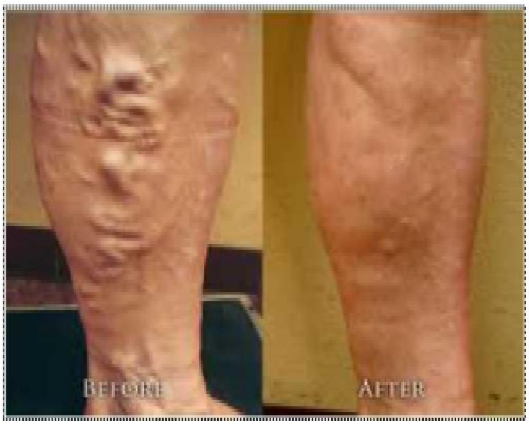
One week follow up. post intervention; duplex assessment revealed a radiologic success with complete obliteration of GSV and collaterals in **14** patients (70%). **3** patients (15%) underwent direct re-injection for further one or two injection sessions over the following two weeks until complete occlusion of GSV and collaterals was obtained. **2** patients (10 %) had thrombophlebitis (one of them had posterior tibial vein thrombosis) and only **one** of the patient (5%) needed re-intervention but refused reinjection.

One month follow up showed complete occlusion of all 19 patients. **Table 1** shows the improvement in the mean VS scores at 1 week and 6 months compared to pre-intervention scores.

Items	Pre-treatment mean (SD)	1 week mean (SD)	6 months mean (SD)
VS	5.78 (3.91)	3.20 (3.71)	1.39 (2.55)
Pain	1.77 (0.65)	0.58 (0.68)	0.20 (0.46)
Oedema	0.73 (0.81)	0.47 (0.69)	0.09 (0.29)
V V	2.18 (0.61)	1.27 (0.72)	0.55 (0.54)

At 6 months follow up

19 out of 20 patients presented for follow-up and were assessed by duplex examination. There was complete occlusion of treated veins in 16 patients (84%) and partial occlusion in 3 patients (15%). two of these three patients showed recanalization following complete occlusion obtained after the 1st week and one patient had partial occlusion which was present since the 1st week and remained during the follow-up at 6 months because the patient refused reinjection after the first week



At 1 year follow up

In foam group, 88% show total occlusion, 6% show partial recanalization without reflux, 4% show partial recanalization with reflux and 2% show total recanalization**.** In surgery group, 88% show total occlusion, 6% show partial recanalization without reflux and 6% show partial recanalization with reflux**.** All patients with complete recanalization and partial recanalization with reflux 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.

Complications

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.

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 reflux in all patients subjected to a single treatment whether it was operative, UGFS, or another minimally invasive alternative **[16].**

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 reflux is usually difficult, often morbid, and frequently associated with suboptimal patient outcomes **[16].**

For many years, high ligation and stripping of the GSV are the most commonly used and effective method for varicose veins management **[16].** The operation is a traumatic experience for patients. Surgery may

Conclusion

Our study declared that UGFS is effective in obliterating saphenous trunks. Follow-up treatment modalities foam and surgery accomplished similar refinements 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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