

## Original Research Article

# Comparing ultrasound guided foam sclerotherapy with surgical treatment in patients of varicose veins

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**Received:** 01 September 2016

**Accepted:** 30 September 2016

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### ABSTRACT

**Background:** Venous disorders of lower limbs are frequently encountered problem. This study compares conventional surgery and (UGFS) ultrasound guided foam sclerotherapy for treatment of varicose vein.

**Methods:** This study was conducted over a period of 18 months. Minimum of 50 patients with primary varicose vein due to SFJ (saphenofemoral junction) incompetence were selected and randomly assigned in each arm i.e. surgical and foam sclerotherapy.

**Results:** Mean age of patients was 35.32 (p = 1) in both groups. Overall more than 90% of patients were male. Mean venous clinical severity score (VSCC) score dropped from 7.84 to 1.72 (p <0.001) in surgery and 7.48 to 1.40 (p <0.001) in foam group at 3 month. Mean venous disability score (VDS) dropped from 1.40 to 0.00 (p <0.001) in surgery and 1.36 to 0.20 (p <0.000) in foam group. Average procedure time was 103.2 min surgery and 29 min in foam group (p <0.001). Complications in both groups were comparable. Mean hospital stay was 31 hours in surgery and 2 hours (p <0.001) in foam group. Both groups shows 100% obliteration rate 0% pathological reflux at 1 month post treatment colour duplex. Mean time to return to normal activity was 9.88 days in surgery and 1 day (p <0.001) in foam group. Mean analgesic use was 4.46 days in surgery and 0.46 in foam group.

**Conclusions:** Foam sclerotherapy come up as safe, promising and reliable method of treatment of varicose vein with ease of administration, no hospital stay, no risk of anesthesia, no interference to daily activity, immediate return to work and equally effective as surgery.

**Keywords:** CEAP classification, UGFS, VCSS, VDS, Varicose vein

### INTRODUCTION

Chronic venous insufficiency (CVI) of lower limbs is a frequently encountered problem, affecting 25% to 30% of women and approximately 15% of men in Western world with slightly lower incidence in developing world.<sup>1</sup>

Over last several years attempts have been made to optimally treat this condition by conservative, surgical or minimally invasive techniques. They have been shown to control reflux and improve calf muscle pump function in the setting of CVI.<sup>2</sup> Compliance with treatment is a significant clinical limitation and identifying patients

with surgically treatable venous incompetence remains an essential component of CVI management.<sup>3,4</sup>

The REACTIV trial involved 1,009 CVI subjects and prospectively demonstrated significant improvement in health care related quality of life when managed with surgery or sclerotherapy compared to conservative management.<sup>1</sup>

Any treatment for primary varicose veins should aim at being minimally invasive and capable of being used on primary and recurrent varicose veins so that it can be repeated as required. There should be few significant

complications and the treatment should have good efficacy in abolishing venous reflux in saphenous trunks, perforating veins and varices. Such a treatment should restore normal venous function and cure the clinical features of venous hypertension.

The treatment should be accomplished at little cost and be capable of achieving both functional and cosmetic improvement with little time away from the patient's usual occupation.<sup>5</sup> Surgical treatment does not comply with this definition, since it is relatively invasive and necessitates time away from work. The rate of recurrence of varicose veins after 5 years of surgery has been reported to vary from 20% to 80%.<sup>6</sup>

Ultrasound-guided foam sclerotherapy has been considered particularly attractive because it avoids the need for general anesthesia, hospital admission and long recovery times. However it has low success rate compared to surgery.<sup>7,8</sup>

## **METHODS**

The study was conducted in the department of surgery, VMMC and Safdarjung Hospital over a period of 18 months. All patients who presented with varicose veins were assessed based on clinical history, physical examination and duplex ultrasound and randomly assigned in each arm of the study i.e. surgical and UGFS groups fulfilling the inclusion criteria (Minimum of 25 patients in each group). All patients were informed about the intervention technique and written informed consent was taken.

### ***Inclusion criteria***

- Clinically symptomatic patients CEAP Class 2 to Class 5
- Age : >12 and < 70 years.

### ***Exclusion criteria***

- History of deep vein thrombosis
- CEAP Class-0, 1 and 6
- Severe systemic disease
- Local site infection
- Severe systemic infection
- Peripheral arterial insufficiency (Ankle-brachial Index < 0.8)
- Pregnancy
- Thrombophilia
- Allergy to polidocanol
- Bronchial asthma
- Post thrombotic syndrome
- Immobility or confinement to bed
- Severe lower limb edema and cellulitis
- Diabetic foot (peripheral neuropathy of ulceration).
- Patent foramen ovale on echocardiography
- BMI > 35

- Previous surgery / treatment for varicose veins.

## ***Treatment***

### ***Surgery***

The surgical approaches employed was saphenofemoral (trendelenberg) saphenopopliteal ligation combined with saphenous stripping and phlebotomy for varicose saphenous tributaries and incompetent perforator was done.

### ***Ultrasound guided foam sclerotherapy***

Pre operatively doppler study was done to mark the incompetent perforators and incompetent saphenofemoral junction (SFJ) and sapheno popliteal junction (SPJ) and also the course of GSV(greater saphenous vein) and SSV(short saphenous vein). Parts cleaned and then patient was ask to stand on operation table and accessory veins were cannulated using 23-25 gauge butterfly needles and were secured in position after it patient was laid supine on table and parts draped. GSV or SSV was hocked out by a small incision guided by marking just below the knee and a ureteric catheter of 5 or 6 Fr. Size is inserted up to SFJ or SPJ after measuring the required length to be inserted by marking. Soon after it patients was placed in Trendelenburg's position.

Tessari's method was used to produce foam.<sup>9</sup> The foam was made from polidocanol 3 % with room air at a 1:4 ratio.

Now catheter was withdrawn to about 2-3 cm so that the tip of the catheter lie about 2-3 cm from SFJ or SPJ. First assistant now compress the SFJ or SPJ (as it is already marked).

Foam was injected and at the same time catheter was withdrawn so that about 1-1.5 ml of foam is injected per 5 cm of vein. After the complete removal of catheter open end of the vein was ligated and gentle massage was given along the vein. Catheter can be inserted in the reverse direction and process repeated toward the foot. Now foam was injected in butterfly needle with about 1 ml of foam per needle. Any incompetent perforators which were not in the course of main vein were injected using 22-gauge 1.25" needles directly by diluted 1% polidocanol.

A maximum of 10-12 ml of foam was injected per session. At the same time patients was asked to perform ankle dorsiflexions to prevent the foam to enter deep veins. Manual compression of the SFJ or SPJ was continued for 10-15 min.

After 15 min of compression of the SFJ or SPJ, the limb was bandaged using crepe bandage and patient was asked to walk for a minimum of 30 minutes before discharge.

Crepe bandage was replaced by graduated elastic compression stockings with a compression of 30 - 40 mmHg after 7 days.

**Treatment assessment**

All patients followed up on 7<sup>th</sup> day, 1 month and 3 month post treatment at each follow up complete physical examination done, reassessment of CEAP score and severity score VCSS (venous clinical severity score), VDS (venous disability score) done, clinical photographs taken and any complication noted. Duplex ultrasound was performed at one week and one month to assess treatment effectiveness. In the surgery group, failure was defined as presence of pathological reflux in any of the segments assessed. In the foam sclerotherapy group, success was assigned to one of the four grades<sup>10</sup>

- Total occlusion
- Partial recanalization without reflux
- Partial recanalization with reflux
- Total recanalization.

The procedure was considered to be successful in cases presenting total occlusion or partial recanalization without reflux; the two remaining categories was considered to reflect treatment failure.<sup>11</sup>

**Statistical analysis**

Statistical analysis was performed by the SPSS program for window. Appropriate statistical test were used for

significance testing. Significance was considered to have been reached when  $p < 0.05$ .

**RESULTS**

The present study was conducted on 50 patients randomized into two groups of 25 patients in each group. The surgery group was taken as control group and the foam sclerotherapy group as the study group.

**Age of the patients**

Mean age in surgery group was  $35.32 \pm 9.29$  and in foam group is  $35.32 \pm 12.6$  ( $p = 1.00$ ).

**Sex of the patients**

In surgery group 24 (96%) are male and in foam group 23(92%) are male ( $p = 1.00$ ). Assesment of venous clinical severity score (VCSS) and its components.

**Venous clinical severity score (VCSS)**

Both the treatment modalities were equally effective in improving the VCSS scores with UGFS group showing better improvements on 7<sup>th</sup> post treatment day ( $p=0.017$ ) (Table 1).

Both the treatment modalities showed a significant improvement in VCSS compared to the preoperative values ( $p < 0.001$ ) (Table 2).

**Table 1: Mean VCSS scores in both groups on applying unpaired t-test.**

VCSS Score	Surgery group (No. of patients = 25)	UGFS group (No. of patients = 25)	p-value	Confidence limits ( 95 %)	
				Lower	Upper
Pre Op	7.84±2.08	7.48±1.87	0.523	-0.760	1.480
7 <sup>th</sup> day post Op	4.04±1.40	3.12±1.24	0.017	0.170	1.670
1 month post Op	1.80±1.12	1.72±1.24	0.8119	-0.590	0.750
3 month post Op	1.72±0.98	1.40±1.12	0.287	-0.280	0.920

**Table 2: Change in mean VCSS scores in each group on applying paired t-test.**

Observation	Surgery group (mean scores)			UGFS group (mean scores)		
	Before	After	'p' Value	Before	After	P- value
7 Day	7.84±2.08	4.04±1.40	$p < 0.000$	7.48±1.87	3.12±1.24	$< 0.000$
30 Day	7.84±2.08	1.8±1.12	$p < 0.000$	7.48±1.87	1.72±1.24	$< 0.000$
90 Day	7.84±2.08	1.72±0.98	$p < 0.000$	7.48±1.87	1.40±1.12	$< 0.000$

**Pain score**

The pain was assessed on the visual analogue scale (VAS) and converted to VCSS score. Pre-operative scores are comparable in both groups ( $p = 0.097$ ). Post treatment there is more pain in surgery group on 7<sup>th</sup> post treatment day ( $p = 0.001$ ) and more pain in sclerotherapy group on 1 month ( $p = 0.020$ ).

Pain score reduced significantly in both groups before and after treatment ( $p < 0.001$ ).

**Varicosity score**

Pre-operative scores were not comparable and the Surgical group had more patients with severe varicosities in their legs ( $p = 0.001$ ). Post treatment there was no

statistical difference in mean varicosities scores between the two groups.

Varicosity scores reduced significantly in both groups before and after treatment ( $p < 0.000$ ).

#### *Venous edema score*

Pre-operative scores were similar in the two groups ( $p = 0.887$ ). Postoperatively the resolution of edema was satisfactory in both the groups. This difference was not significant statistically.

**Table 3: Mean VDS scores in both groups applying unpaired t-test.**

VDS score	Surgery group (no. of patients = 25)	UGFS group (no of patients = 25)	P-value	Confidence limits ( 95 %)	
				Lower	Upper
Pre op	1.40±0.50	1.36±0.49	0.776	-0.240	0.320
7 <sup>th</sup> day post op	0.96±0.20	0.58±0.50	0.002	0.140	0.580
1 month post op	0	0.20±0.41	0.018	-0.360	-0.040
3 month post op	0	0.20±0.41	0.018	-0.360	-0.040

Edema score reduced significantly in both group before and after treatment ( $p < 0.000$ ).

#### *Pigmentation score*

Pre operatively both group had similar severity and extent of leg pigmentation ( $p = 0.414$ ). After treatment, there was small improvement in pigmentation score in UGFS group at three months. But it is non-significant ( $p = 0.187$ ).

Pigmentation score improve more in UGFS group at 3month ( $p < 0.014$  at 3 months).

#### *Compression score*

It was found that the need to use compression stockings in both the groups was same pre-operatively ( $p = 0.183$ ) and upto 7th post treatment day ( $p = 0.085$ ). At 1 month follow up significantly more patients in UGFS were using compression treatment ( $p = 0.039$ ). Due to small sample size Wilcoxon signed ranks test for comparing the difference in compression score individually in each group was not applicable.

#### *Venous disability score*

VDS scores were comparable in both the groups before the start of treatment ( $p = 0.776$ ). UGFS group showed significantly better improvements in VDS score on first follow up at 7th day ( $p = 0.002$ ), but at the end of 1 and 3 months the scores improved in favour of patients undergoing surgery (at 1 month and 3 month  $p = 0.018$ ) (Table 3). VDS scores were reduced significantly in both groups ( $p < 0.000$ ).

#### *Procedure time*

Average procedure time was 103.2±17.79 min in surgery group and 29±5.59 min in foam sclerotherapy group ( $p < 0.001$ ).

#### *Complication associated*

No major or life threatening complication such as anaphylaxis/cardio-respiratory arrest was noted in any of the groups during and immediately within few hours of the procedure.

Early complication noted at 7<sup>th</sup> post-operative day like pain, bruise, stitch infection, seroma and hematoma all were more in surgery group. Late complications noted at 1 month and 3 month follow up were as follows pain, pigmentation, neuralgia and deep vein thrombosis (DVT). No DVT found rest complication were less and comparable in both groups.

#### *Hospital stay*

Mean hospital stay for the patients in the surgery group was 31±7.52 hours and 2±0 hour for UGFS group ( $p < 0.001$ ).

#### *Follow up Doppler*

Follow up Doppler was done at 1 month postoperatively to see for the success of the treatment any complication (DVT) or any remaining disease. None of the patients in either group was found to have any pathological reflux in greater saphenous vein, and DVT.

#### *Time to return to normal and resume work*

The patients in the surgery group were able to resume their daily activity of living after mean of 9.88±2.24 days whereas those in the UGFS group resumed their work the very next day ( $p < 0.001$ ).

#### *Analgesic use*

The mean analgesic requirement in surgery group was more 4.46±2 days compared to UGFS group where it was 0.46±0.83 days ( $p < 0.001$ ).

## DISCUSSION

Most patients in our study were male with resultant M:F (male:female) = 16:1. The M:F ratio found in our study is in sharp contrast to the ratio mentioned in most of the western literature, where more females were suffering from this disease.<sup>8,11,12,18,21,26</sup> However in the study conducted by Jain et al, 41 of the 42 patients were males; by Masuda et al. 42 of the 68 patients were males.<sup>12,13</sup>

Majority of our patients were young with a mean age of 35.32 years in both group. This is less in comparison to most of the patients in western world where most patients present in their late 50s and early 60s.<sup>14,15</sup> As more males are involved in heavy labor, the fact may explain predominantly younger and male patients suffering from the disease.

The VCSS score has been introduced only after 2004 therefore not many studies are available for comparing outcomes after treatment using this scoring system.<sup>16</sup> In 2006 study shows VCSS, VDS and CEAP clinical score were equally sensitive and better for measuring response to superficial venous surgery.<sup>17</sup> Very few studies have compared UGFS with surgery in a randomised study.<sup>11,18</sup>

The mean disease VCSS scores was similar in the two groups in our study before the start of treatment ( $p = 0.523$ ). Both the treatment modalities were equally effective in improving the VCSS score at 1 and 3 month although patients in UGFS showed better improvements in total VCSS score in early postoperative period at day 7 ( $p = 0.017$ ).

In the study by Masuda EM 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).<sup>13</sup> Iafrati MD 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).<sup>19</sup> Gloviczki P 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.<sup>20</sup> However there is very little data in literature directly comparing UGFS with surgery on the basis of VCSS and VDS.

Figueiredo M et al compared the result of foam sclerotherapy with surgery on the basis of VCSS.<sup>11</sup> He does not take in to the account the total score change but only the mean score change in three components of VCSS namely: pain, edema and inflammation. They noted a significant improvement in the mean score of each of the above components of VCSS in both the groups. In our study we also observed that both the modalities were equally effective in relieving edema and pain after treatment.

There is a paucity of data in the literature to compare other three parameter studied; varicosity, pigmentation and compression therapy scores. We found that

pigmentation score did not improve significantly in subsequent follow ups. The reason behind it is that skin changes and lipodermatosclerosis of varicose vein limb are irreversible changes even if they change it takes very long time to change significantly. The need for compression therapy changed significantly in surgery group. This was because in foam group two patients had mild pain after sclerotherapy and they felt comfortable wearing a stocking for longer than recommended.

The functional capability as assessed by VDS showed that both the modalities showed a significant improvement after treatment and were equally effective. (For surgery pretreatment =  $1.40 \pm 0.50$ , after treatment = 0 and for UGFS pretreatment =  $1.36 \pm 0.49$ , after treatment =  $0.20 \pm 0.41$ ) It was definitely lower than that reported in the study by Masuda et al ( for UGFS pretreatment = 4, after treatment = 1).<sup>13</sup> This was probably because of the fact that this score is very much dependant on the ability of the patient to carryout activities. Most of our patients were daily wage earners where earning the daily livelihood and were keen to resume activities earlier in order to support the family.

### Procedure time

In our study it took significantly less time to do UGFS than the conventional surgery. Also our foam sclerotherapy was an OPD procedure. This is similar to many studies which have quoted a significantly less time in doing UGFS compared to surgery.<sup>11,18,21,22</sup>

### Complications

Some complications were exclusive to surgery group and not seen on UGFS group. These included stitch infection in 3 (12%) patients, seroma in 3 (12%) and hematoma in 2 (8%) patients at 1 week follow up. Figueiredo M et al in 2009 describes infection, hematoma and suture dehiscence in surgery group respectively in 3%, 7% and 38% patients.<sup>11</sup> Also comparing the local wound related complication in surgery group with work of Michaels JA et al who found wound related complication in only 2.4% of patients our study group had more of local wound related complications.<sup>18</sup>

In our study complications in the foam sclerotherapy group were tolerable and transient like discomfort in walking, tenderness etc. and did not require any active intervention, which are again comparable to the published studies.<sup>23-25</sup> Pain and pigmentations were the two most important complication in foam group in our study which is in accordance with the literature. Pain in 4 (16%) patients and pigmentation 5 (20%) patients.<sup>23-25</sup>

No major complication was found in UGFS group which is also established in literature.<sup>23-25</sup> So foam sclerotherapy is quite a safe procedure if done with proper USG guidance and care.

### **Hospital stay**

We discharged our patients after mean stay of  $30.6 \pm 7.56$  hours (1.3 days) after surgery; Iafrati et al discharged their patients after 1.3 days.<sup>19</sup> Jain et al discharged their patients after a mean duration of 4.5 days, the reasons for keeping the patients for this much of time was not specified.<sup>12</sup>

After the foam sclerotherapy, almost all the patients were discharged the same day after a short period of observation in most of the studies.<sup>11,18,22,26</sup> We are currently discharging the patients within 2 hour of the procedure.

### **Return to normal work**

Mean time to return to normal activity in our study is found to be  $9.9 \pm 2.3$  in surgery group and 1 day in foam group.

Bountouroglou DG et al shows mean time for return to normal activity was 8 days in surgery group and 2 days in foam group.<sup>26</sup> Which is quite comparable to our finding. Darvall KL et al found that about 50% of foam sclerotherapy patients returned to work within 24 hours where-as surgery patient takes about 4 days to return to work.<sup>22</sup>

### **Analgesic requirement**

In our study we found the mean analgesic requirement in surgery group  $4.46 \pm 2.00$  days and in foam group it is  $0.46 \pm 0.83$  days. Abela R et al found that 83% of patient undergoing standard surgery need analgesia postoperatively whereas only 23% of foam sclerotherapy patient occasionally need analgesia postoperatively.<sup>21</sup> Darvall KA et al found that after foam sclerotherapy 70.8% of patients required no analgesia compared with 24 % after surgery in immediate post op period.<sup>22</sup> After 1 week only 4.1% were still using analgesia in foam sclerotherapy group compared with 30 % in surgery group.

### **Follow up doppler**

We have done the doppler follow up of all patient done at 1 month post operatively. At 1 month post operatively we found no case of DVT (deep vein thrombosis) in either group and found 100% obliteration rate of greater saphenous vein (GSV). Figueiredo M et al shows the obliteration rate of 90% in surgery group and 78% in foam sclerotherapy group after 6 month of follow up.<sup>11</sup> Bountouroglou DG et al found a obliteration rate of 89% in surgery and 78% in foam sclerotherapy group after 12 month of follow up.<sup>26</sup> High obliteration rate found in our study may be explained by very short time of follow up in our study compared to above studies and another reason may be the use of catheter guided foam sclerotherapy in our study which is more efficacious than

conventional sclerotherapy.<sup>27</sup> We also did not found any case of recanalization of vein with reflux in both groups which we considered as failure of treatment.

### **CONCLUSION**

Foam sclerotherapy has come up as safe and reliable method of the treatment of the varicose veins. This does not require any other setup to be established, except for a Doppler, as the facility of the duplex ultrasound are available in all the major hospitals the cost of the treatment becomes very economical. UGFS can be done as an outpatient under local anesthesia and therefore saving a lot in terms of cost and hospital stay.

As far as the outcomes of the therapy are considered in terms of the immediate postprocedure complications, improvements of severity/disability scores, recurrence and overall clinical and radiological outcomes; all are comparable to the surgical management. The therapy was highly satisfying to the patients in terms of its ease of administration, no hospital stay, no risk of anesthesia, low in cost, no interference of daily activity, immediate return to work, and outcomes very similar to those after surgery. The technique was well tolerated both locally and generally, with no major complications, and very acceptable to the patients. However, it must be emphasized that study needs to be done on larger number of the patients with longer follow-up to arrive at any firm conclusion and opinion that, this form of therapy can be the gold standard treatment in the future.

### **ACKNOWLEDGEMENTS**

Authors would thankful to Dr. Gulshanjeet Singh, head of department of surgery. VMMC and Safdarjung hospital for his constant support and encouragement. They are also thankful to Dr. Jayashree Bhattacharjee, Principle of Vardhman Mahavir Medical College and Dr. B.D. Athani, medical superintendent VMMC and Safdarjung Hospital, New Delhi for their valuable support in conduction of this study. They would also like to thanks staff of department of surgery and department of radiology for their support during the study.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the institutional ethics committee*

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**Cite this article as:** Verma V, Mohil RS, Kumar S, Gupta A. Comparing ultrasound guided foam sclerotherapy with surgical treatment in patients of varicose veins. *Int Surg J* 2016;3:2239-45.