

**A study on saphenofemoral junction ligation, stripping and perforator ligation versus saphenofemoral junction ligation with ultrasound guided foam sclerotherapy of saphenous vein, perforators and superficial veins in lower limb varicose veins.**

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**Type of Publication:** Original Research Article

**Conflicts of Interest:** Nil

**Abstract**

**Background:** Surgery has been the standard treatment for lower limb veins but newer techniques such as Ultrasound guided Foam Sclerotherapy (UGFS) had become increasingly popular for treatment of varicose veins. These newer techniques are less time consuming and has less complications.

**Objectives of the study:** To compare saphenofemoral junction ligation, stripping and perforator ligation versus saphenofemoral junction ligation with ultrasound guided foam sclerotherapy of saphenous vein, perforators and superficial veins in terms of:

1. Surgical/ procedure time.
2. Duration of hospital stay.
3. Days required to return to work/ normal activity.
4. Postoperative complications.

5. Postoperative recurrence of varicosities (6 month follow up).

**Methods:** Patients satisfying inclusion criteria are enrolled and given admission after informed consent. All the patients with lower limb varicose veins will be evaluated through clinical examination, radiological and laboratory investigations. Proposed surgery will be performed and analyzed for in term of operative time, hospital stay, number of days to resume normal activities, post-op complications and follow-up for 6 months.

**Results:** Majority of patients belonged to the age group 41- 50 years. M: F is 52% males and 48% females. Mean operative time in Surgery group and sclerotherapy group is 68.33, 54.4 (p=0.02) Mean days of hospital stay among surgery group is 2.5 days and in sclerotherapy group is 1.12(p=0.01). Mean number of days to resume

normal activity among surgery group is 9.47 and sclerotherapy group is 6.83(p=0.01). Minor Postoperative complications are seen in both groups. 2% in sclerotherapy group and 1% in surgery had recurrent varicosities on 6-month follow-up.

**Interpretation and conclusion:** SFJ ligation with UGFS is associated with less operative time, shorter duration of hospital stay, earlier return to work and not associated with major postoperative complications and is equally effective compared to SFJ ligation +GSV stripping +perforator ligation + phlebectomies. Hence it can be considered as treatment option for lower limb varicose veins.

**Keywords:** Ultrasound guided Foam Sclerotherapy, venous clinical severity scoring system, Recurrent Varicose Veins, Sapheno-femoral Junction. GSV stripping.

### Introduction

Adult prevalence of visible varicose veins is between 30% to 50%<sup>1</sup>. According to The Edinburgh Venous study (EVS)<sup>2</sup> published in 2013 the overall incidence of C2 varicose veins was same in both males and females and the incidence increases with increase in age.

Most studies show prevalence in females more than males but the community prevalence differs. Prevalence of varicose veins increases with increase in the age of the patient, increase in body mass index of the patient. Evidence also supports familial susceptibility to varicose veins. Pregnancy increases the risk of varicose veins.

Varicose veins cause symptoms such as aching, heaviness, itching and skin changes in legs. The symptoms increase on prolonged standing. It can also cause complications such as pigmentation of skin, lipoderma to sclerosis and venous ulcers etc. Symptoms can

be so severe that it interferes the patient daily activities such as work and recreation etc.

There is clear evidence that in patients with severe symptoms and complications, there is a significant quality of life benefit from treatment. The maximal benefit is seen in those with symptomatic uncomplicated varicose veins as skin changes and a proportion of associated morbidity are frequently irreversible.

Initially surgery involving saphenofemoral junction ligation, stripping and perforator ligation is considered as standard treatment for varicose veins. The procedure is generally done under general anaesthesia and needs prolonged hospitalisation and return to normal activity is delayed when compared to newer methods of treatment. Hence newer techniques with minimal intervention and less complications are needed.

Ultrasound guided foam sclerotherapy is a newer modality. It has gained popularity as simple, minimally invasive technique that allows patients to return rapidly return to baseline activity level.

Sclerotherapy is defined as introduction of a chemical into the lumen of a vein to induce endothelial damage that results in thrombosis and eventually fibrosis<sup>3</sup>.

### Materials & Methods

**Type of study:** Prospective comparative longitudinal study Ethical clearance from the institute was obtained prior to commencement of the study.

**Sample size:** A minimum of 96 will be collected.

**Study period:** From March 2021 to August 2022

### Inclusion criteria

- 1 Patient willing to give informed consent.
- 2 All patients of age 18 and above with varicose veins of lower limbs with clinical grade C3 to C5 according to CEAP Classification.

### Exclusion criteria

1. Patient not willing to give informed consent.
2. Patient with DVT of effected lower limb.
3. Varicose veins in pregnant female.
4. Patient who are unfit for surgery due to other co morbidities.
5. Patients who are allergic to sclerosing agent.

### Methods

- After obtaining approval and clearance from the institutional ethics committee, the patients fulfilling the inclusion criteria will be enrolled for the study after obtaining informed consent.

- Considering the inclusion and exclusion criteria, patient with varicose veins constitute the study group. A total of 96 cases will be selected from outpatient department.

□ Categorization into two groups will be Open model. All 96 patients will be explained the advantages and disadvantages of both the procedures and the patient is allowed to choose the type of treatment he wants to undergo and further the patient will undergo the chosen procedure.

### Preoperative preparation

Revised Clinical Etiology Anatomy Pathophysiology (CEAP) assessment to be done.

Location of varicosities, presence or absence of skin pigmentation, oedema, dermatitis, ulceration, venous eczema and lip dermatosclerosis to be documented.

A duplex study to be carried out to assess extent of varicosities like presence or absence.

of saphenofemoral and Sapheno popliteal incompetence, perforator incompetence and to rule out DVT.

Routine blood investigations such as CBC, RFT, COAGULATION PROFILE,

Bleeding and clotting time, serology, serum

Electrolytes. Chest Xray and electrocardiogram

### SFJ ligation and USG guided Foam Sclerotherapy Group

Patients in this group after detailed physical examination, routine investigations and Doppler are taken up for the procedure. Under Local Anaesthesia (2%Lidocaine with Adrenaline 1:10000) the patient undergoes Sapheno-Femoral Junction ligation after ligation of all named tributaries of GSV. Then the wound is closed using Monocryl 3- 0 by subcuticular technique. Then Ultrasound is used to identify the pathological target veins and one to three access sites are identified 10 cm apart for intravenous access.

The vein is accessed under ultrasound guidance with a micro puncture needle or butterfly. A small volume (<5 mL) of 0.25-2% (based on the size of the target veins) foam sclerosant (polidocanol) prepared in a 1:4 ratio using room air (Tessari technique) is injected into the vein and dispersed throughout the network of target varices using the ultrasound probes. Immediately a compression bandage is applied up to the level of upper thigh. The patient is asked to walk for 3 mins. The patient is then observed for one day and discharged. Patient is asked for follow-up on day 3, day 7, day 14, 1 month & 6 months.

### Surgery Group

Patients in this group are taken up for Surgery after detailed physical examination, regular investigations & Duplex scan. Under SAB/GA patient undergoes Trendelenburg procedure, stripping of GSV up to a level below the knee, subfascial ligation of prior marked in competent perforators, multiple phlebectomies. Incisions

are closed and compression bandage applied. Patient will be observed for 2 or 3 days and then discharged. Patient is asked to follow-up on day 7, day 14, 1 month, 6 months.

**Results**

Table 1: Duration of operation.

Duration of operation	Surgery	Percent	Sclerotherapy	Percent	p-value
30-45 mins	12	25	22	45.8	<b>0.002</b>
45-60 mins	3	6.2	11	22.9	
60-75 mins	11	22.9	7	14.5	
75-90 mins	17	35.4	6	12.5	
90-105 mins	5	10.4	2	4.1	
Mean	68.33±22.22		54.58±19.51		

Chi Square Test, Independent t test, Sig. 2 tailed, p<0.05.

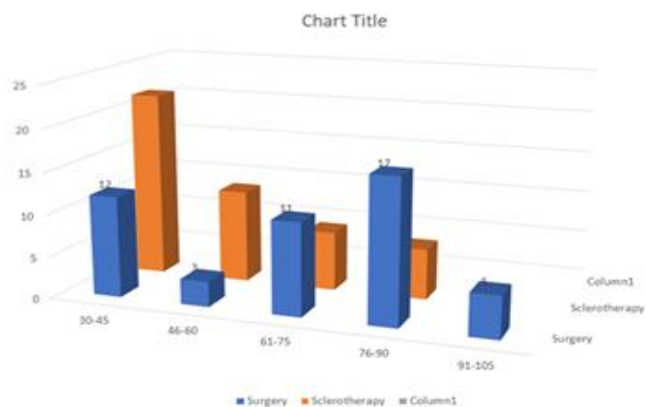


Figure 1: Duration of operation.

Table 2: Length of Hospital stay

Length of Hospital stay	Surgery	Sclerotherapy	P value
1	0	42	
2	24	6	
3	24	0	
Mean	2.5± .505	1.12±.33	.001

Figure 2: Length of hospital stay.

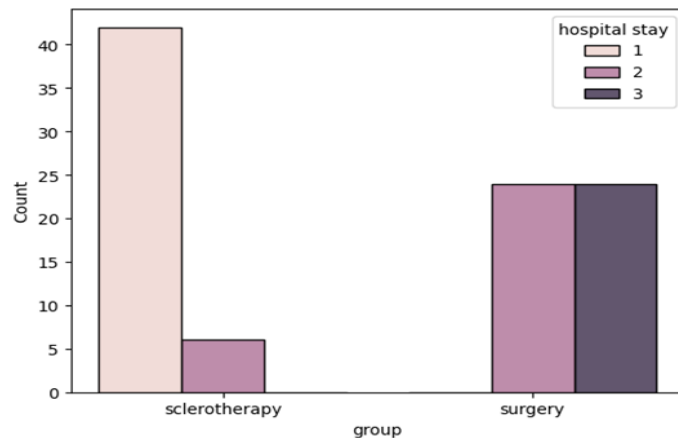


Table 3: Return to normal activity

Return to normal activity	Surgery	Sclerotherapy	P value
0-5 days	10	25	0.01
6-10 days	15	15	
11-15 days	22	8	
Mean	9.47±3.47	6.83±3.49	

Figure 3: Return to normal activity.

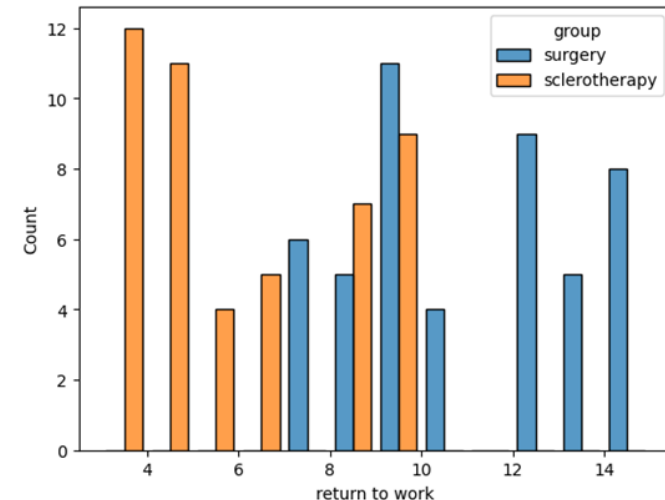


Table 4: Post operative complications.

Post-procedure Complication	Surgery	Sclerotherapy	p-value
Hyperpigmentation	0	5	0.08
Telangectatic matting	1	1	
Urticaria	0	5	
Pain	0	4	
Chest tightness	0	0	
Superficial thrombophlebitis	0	0	

Hematoma	1	0
Seroma	3	0
Wound Infections	3	0
Ecchymosis	2	0
DVT	0	0
Enlarged veins	0	0

Chi Square Test, Sig. 2 tailed,  $p < 0.05$ .

Figure 4: Postoperative complications.

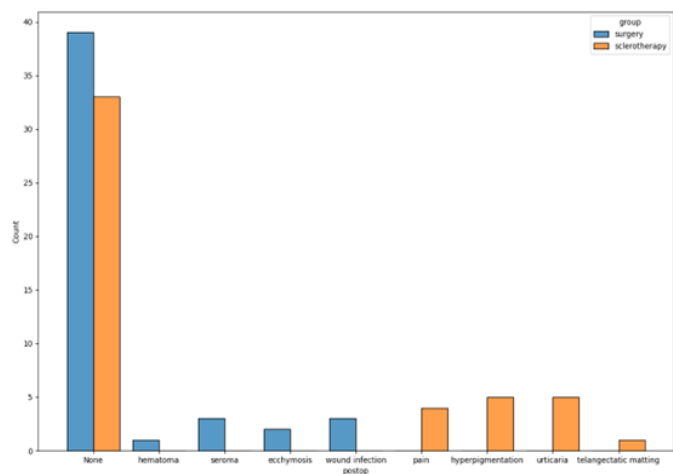
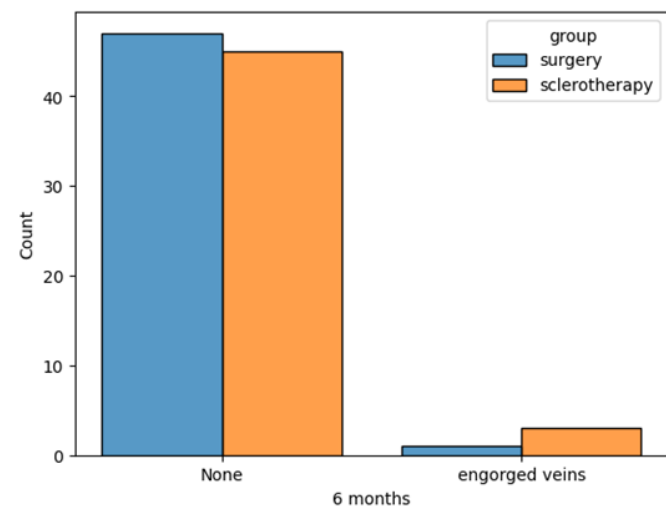


Table 5: Recurrence at 6 months

Recurrence	Surgery	Sclerotherapy	p value
Yes	1	2	0.117
No	47	46	

Figure 5: Recurrence at 6 months



**Discussion**

Mean age of patients presented in our study were in the range of 44.81 years with 52% males and 48% females

included in our study. Majority of patients in our study are in the age group of 40 to 50 years which is 41%. A study published in 2016 in Indian journal of surgery also observed more frequent age group of 40-50yrs with a mean of 44 years, which was similar to our study.

The male to female is close to 1 which is similar to the Edinberg venous study. Our study also showed that majority of our patient were in the age group of <50 years (77%) and rest were above the age of 50years (23%).

Most of the patients in our study presented with CEAP grade C3(31.25%), followed by C4(29.16%) with 17% patients with healed ulcers. Time of operation for surgery group is more compared to sclerotherapy group with mean of surgery group 68.33 S. D 22.22 while in sclerotherapy group mean is 54.58 S. D 19.51 which is statistically significant ( $p < 0.002$ ). The finding is similar to a study conducted by DG Bountouroglou et.al.

In our study most patients had VCSS score in the range of 11 to 15(36.45%), followed by 16 to 20 (28.12%).

In our study mean hospital stay for surgery group was 2.5 while in sclerotherapy group is 1.12 which is statistically significant ( $p < 0.001$ ). Immediate Post procedural complications such as seroma, hematoma, wound infections, ecchymosis are 3%,1%,3%,2.8% respectively in surgery group while in sclerotherapy group, urticaria, hyperpigmentation are major complication with 5.2% each followed by post injection pain in 4.16%.

In our study number of days to resume normal activities in surgery group has a mean of 9.47 S. D 3.47 while in sclerotherapy group is 6.83 S. D 3.49 which is statistically significant ( $p < 0.01$ ).

In our study on 6-month follow-up 2 patients in sclerotherapy group had DVT (2.08%), 1 patient in

surgery group and 2 patients in sclerotherapy had dilated veins in the treated segment of veins. The complication rate and recurrence rate were similar to the literature published earlier. T, Yamaki, in 2011, conducted a prospective randomized controlled study of visual foam sclerotherapy alone or ultrasound guided foam sclerotherapy for treatment of superficial venous insufficiency. The study consists of 97 patients total of 51 limbs in 48 patients were treated with UGFS + VFS, and 52 limbs in 49 patients were treated with VFS alone. Finally, study indicate that UGFS + VFS and VFS alone have equivalent efficacy in the treatment of GSV reflux.<sup>4</sup> D.G. BONTOUROGLOU et al conducted a prospective randomised control trial on 60 patients with 30 patients in each study group comparing saphenofemoral junction ligation, great saphenous vein stripping and multiple avulsions with saphenofemoral junction ligation and ultrasound guided foam sclerotherapy to the saphenous vein with patient recovery period and quality of life as primary end point and complications of two techniques as secondary end point. Conclusion of the study is Ultrasound guided sclerotherapy combined with saphenofemoral junction ligation was less expensive, involved a shorter treatment time and resulted in more rapid recovery compared to saphenofemoral junction ligation, stripping of great saphenous vein and multiple avulsions.<sup>5</sup>

N SHAHID et al conducted a randomised control trial on 430 patients with 230 patients treated with Ultrasound guided foam sclerotherapy and 200 patients treated with surgery for incompetent great saphenous vein comparing 2-year probability of recurrence. The conclusion of the study is that at 2year follow up Ultrasound guided foam sclerotherapy was not inferior to surgery when the reflux associated with venous symptoms is considered.<sup>6</sup>

## Conclusion

According to this study Saphenofemoral junction ligation with Ultrasound guided foam sclerotherapy of saphenous vein, perforators, superficial veins is equally effective with less operative time, shorter hospital stay and less complications compared to saphenofemoral junction ligation, stripping, perforator ligation and phlebectomies in a patient with lower limb varicose veins.

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