

Comparative study of efficacy of treatment of varicose veins with Saphenofemoral ligation and Foam sclerotherapy compared to Saphenofemoral ligation and stripping

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Abstract

Background: Varicose veins affect 20–30% of adults. If symptoms persist, the main treatment options are sclerotherapy, surgery (usually stripping and ligation of the long or short saphenous veins and phlebectomies), and ablation (by laser or radiofrequency ablation). Present study was aimed to compare the efficacy of treatment of varicose veins with Saphenofemoral ligation and Foam sclerotherapy compared to Saphenofemoral ligation and stripping.

Material and Methods: Present study was single-center, prospective, comparative, study, conducted in patients of either gender with varicose veins of the lower limbs, including those with venous ulcers. Patients were randomly allocated to group 1(SF ligation with foam sclerotherapy) &group 2 (SF ligation and stripping).

Results: The demographic data of the patients included in this study showed no significant difference between both groups in terms of age and sex. The time taken to complete treatment was shorter in the foam sclerotherapy plus SFJ ligation group: 40 vs. 55 min. The rate of longer-term (>30 days) ulcer healing rate in the case series ranged from 75 to 85%. 6 (85.7%) of 7 ulcers healed in the foam sclerotherapy group compared with 6 (75%) of 8 in the SF ligation and stripping group. At 3 months, median CEAP class dropped from four preoperatively to one following treatment in both groups. 1 patient out of 25 treated by foam sclerotherapy reported venous recanalization at one year after treatment. Median time to return to normal activities was significantly reduced in the foam sclerotherapy group (4 days) compared to the surgical group (9 days). Rates of thrombophlebitis was 16%.skin staining/pigmentation at 8%, and pain at the site of injection ranged was 28%.

Conclusion: Treatment of varicose veins with Foam sclerotherapy instead of stripping and avulsions reduces the operative and post operative recovery time.

Keywords: varicose veins, foam sclerotherapy, saphenofemoral ligation, stripping, post operative recovery

Introduction

Varicose veins affect 20-30% of adults. People with venous insufficiency may suffer from

heaviness, aching, throbbing, itching and cramps or fatigue in the legs ^[1]. In some patients, chronic venous insufficiency can lead to skin discoloration, inflammatory dermatitis and skin ulceration. Conservative methods such as compression hosiery may improve symptomatic varicose veins. If symptoms persist, the main treatment options are sclerotherapy, surgery (usually stripping and ligation of the long or short saphenous veins and phlebectomies) and ablation (by laser or radiofrequency ablation).

Treatment of venous insufficiency with liquid sclerotherapy is considered by some to be an unfulfilled promise. Ultrasound-guided foam sclerotherapy for varicose veins is a variation of liquid sclerotherapy in which sclerosant foam is injected into the affected veins using ultrasound monitoring. The foam causes inflammation of the vein wall, leading to obliteration and occlusion of its lumen ^[2].

It is useful in all types of varices and it is proven to be safe, simple, cheap, reliable and repeatable. It is a potentially useful treatment for both main trunk and minor vein disease, and can be conducted as an outpatient procedure without the requirement for general or regional anaesthesia ^[3, 4]. This could have implications in terms of releasing theatre time and space for other surgical procedures. In addition, foam sclerotherapy can be delivered in an outpatient setting and possibly also a primary care setting, as long as the surgeon is appropriately trained and adequate diagnostic and monitoring facilities are available ^[5, 6, 7]. Present study was aimed to compare the efficacy of treatment of varicose veins with Saphenofemoral ligation and Foam sclerotherapy compared to Saphenofemoral ligation and stripping.

Material and Methods

Present study was single-center, prospective, comparative study, conducted in department of general surgery, at Govt. Rajaji Hospital, attached to Madurai Medical College, Madurai, India. Study duration was of 2 years (July 2006 to June 2007).

Inclusion criteria

- patients of either gender with varicose veins of the lower limbs, including those with venous ulcers

Exclusion criteria

- Patients with recurrent varicose veins.
- Patients with multiple perforator incompetence.
- Patients with allergy to sclerosant and history of deep vein thrombosis.

After obtaining approval by the ethics committee and informed consent, a total of 50 patients were enrolled for this study. The study protocol included history, physical examination, assignment of CEAP class and assessment venous clinical severity score (VCSS) and colour duplex ultrasound to identify sites of incompetent perforators and to rule out deep vein thrombosis.

All patients underwent Doppler scanning to identify Saphenofemoral incompetence, the sites of incompetent perforators and to rule out deep vein thrombosis. The patients were randomly allocated to one of the two groups.

Group 1: SF ligation with foam sclerotherapy-Patients underwent ultrasound-guided sclerotherapy with sapheno-femoral ligation under local anaesthesia (n=25). The Tessari technique was used to convert liquid sclerosant (3% sodium tetradecyl sulphate) to foam. Duplex ultrasound imaging was used to guide cannulation, monitor the injection and flow of

foam and to minimise the risk of foam diffusion to the deep venous system. Sapheno-femoral ligation was done under local anaesthesia after a period of 2 days.

Group 2: SF ligation and stripping-Patients underwent sapheno-femoral ligation, stripping and multiple avulsions under general or regional anaesthesia (N=25).

Patients in both groups were followed up for a period of 1 yr. and compared for the following parameters procedure time, perioperative complications, complete occlusion of treated veins (by Duplex scanning at 3 months), healing of venous ulceration, quality of life such as time to return to normal activity, symptom relief and change of disease severity measured by CEAP score & any recurrence of varicose veins.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Statistical analysis was done using descriptive statistics. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

The demographic data of the patients included in this study showed no significant difference between both groups in terms of age and sex.

Table 1: Age & gender

Characteristic	Group 1-SF ligation+ Foam sclerotherapy		Group 2-SF ligation + stripping	
	No	%	No	%
Age group (in years)				
31 - 40	4	16	6	24
41 – 50	10	23.3	8	23.3
51 – 60	8	16.7	8	23.3
61 – 70	3	10.0	3	10.0
Gender				
Males	27	90	28	93.3
Females	3	10	2	6.7

The time taken to complete treatment was shorter in the foam sclerotherapy plus SFJ ligation group: 40 vs. 55 min.

Table 2: Procedure time

Procedure time	Group 1-SF Ligation + foam sclerotherapy		Group 2-SF Ligation + stripping	
	No.	%	No	%
36- 45 min	19	76	3	12
46- 55 min	4	16	12	48
56- 65 min	2	8	9	36
66-75 min	-		1	4

The rate of longer-term (>30 days) ulcer healing rate in the case series ranged from 75 to 85%. 6 (85.7%) of 7 ulcers healed in the foam sclerotherapy group compared with 6 (75%) of 8 in the SF ligation and stripping group.

Table 3: Healing of ulcer

Ulcer healing	Group 1-SF ligation + foam sclerotherapy		Group 2-SF ligation + stripping	
	No.	%	No.	%
Healed	6	85.7	6	75
Residual ulcer	1	14.3	2	5

At 3 months, median CEAP class dropped from four preoperatively to one following treatment in both groups.

Table 4: Quality of life (CEAP score change)

C score improved by	Group 1-SF ligation + Foam sclerotherapy		Group 2-SF ligation +stripping	
	No.	%	No.	%
1	1	4	2	8
2	7	28	9	36
3	15	60	13	52
4	2	8	1	4

1 patient out of 25 treated by foam sclerotherapy reported venous recanalization at one year after treatment. There was no recurrence in the group that underwent stripping and multiple phlebectomies.

Table 5: Recurrence at 1 yr.

Recurrence	Group 1-SF ligation+ Foam sclerotherapy		Group 2-SF ligation + stripping	
	No.	%	No.	%
Present	1	4	-	0
Absent	24	96	25	100

Median time to return to normal activities was significantly reduced in the foam sclerotherapy group (4 days) compared to the surgical group (9 days).

Table 6: Time to return to normal activity

Time in days	Group 1-SF ligation+ Foam sclerotherapy		Group 2-SF ligation + stripping	
	No.	%	No.	%
2-3	1	4	-	0
4-5	12	48	2	8
6-7	8	32	3	12
8- 9	4	16	17	68
10-11	-	0	3	12

Local adverse events were relatively common. Rates of thrombophlebitis was 16%.skin staining/pigmentation at 8% and pain at the site of injection ranged was 28%. There were no systemic complications except for a patient with transient cough and chest tightness.

Table 7: Complications in Foam sclerotherapy

Complications in Foam sclerotherapy	No.	%
Pain at injection site	7	28
Thrombophlebitis	4	16
Skin ulceration	2	8
Pigmentation	2	8
Coughing &chest tightness	1	4

Discussion

Significant advances have occurred in the understanding, diagnosis, and management of venous insufficiency over the last decade or so, mostly owing to the use of duplex ultrasound (DUS) technology^[6, 7]. Stripping of the great saphenous vein (GSV) has been widely agreed upon as essential to minimizing recurrence due to redevelopment of incompetent communication with the sapheno femoral confluence and/or thigh perforator incompetence. Stripping of the vein requires additional incisions at the knee or below the knee and is associated with a high prevalence of minor surgical complications. Avulsion phlebectomy requires multiple 2-to 3-mm incisions along the course of the vein and can cause damage to adjacent nerves and lymphatic vessels.

Sclerotherapy with liquid sclerosant was introduced as an alternative to surgery but was soon abandoned as a result of high failure rates, frequent recurrence and unacceptably high rates of complications due to the large volume of sclerosant required^[8]. Foam sclerotherapy which has gained popularity in the last decade and has been evaluated in this study as an alternative to stripping of varicose veins. Converting the sclerosant to foam has served to reduce the dose of sclerosant and also increased its efficacy.

In this study there was no significant difference in the median age and sex ratio in the case and control groups. In the present series the time required for foam sclerotherapy and Sapheno femoral ligation was significantly less than that required for Sapheno femoral ligation, stripping and multiple phlebectomies^[9].

Bountouroglou DG *et al.*,^[10] reported data on operation time (foam sclerotherapy plus ligation was 45 minutes versus 85 minutes for ligation plus stripping plus avulsion). The foam sclerotherapy was combined with sapheno-femoral junction ligation. This goes well with the present series.

Three case series involving 216 patients and two case reports involving three patients reported data on healing of venous ulcers. All studies used polidocanol foam. The ulcer healing rate in the case series ranged from 76.4% to 100%^[11].

In this study Sodium Tetra decyl sulphate was the sclerosant used and showed healing rates of 85%. It is unclear if the better healing rate can be attributed to the sclerosant used. Majority of patients in both groups in our series showed improvement in the quality of life (measured by the CEAP score) compared to baseline, however there was no significant difference between the two groups, showing that both were equally efficacious.

In a randomised control trial^[12], involving 45 patients treated by foam sclerotherapy reported venous recanalization at one year after treatment, with a rate of 4.4%. This was lower than that in the liquid sclerotherapy group but not statistically significant (relative risk 0.5, 95% CI 0.1 to 2.5).

One non-randomized comparative study involving 37 patients treated by foam sclerotherapy reported venous disease recurrence also at one year after treatment, with a rate of 8.1%, which was also lower than that in the liquid sclerotherapy group.¹³ In the present series 1 out of 25 (4%) patients showed recurrence at 1 yr.

Bountouroglou DG *et al.*,^[10] in their study found that the median time required to return to normal activity following surgery (13 days) was significantly higher compared to those who underwent foam sclerotherapy (2days). This correlates well with our series in which most patients recovered in 8 days following surgery and in 2 days following foam sclerotherapy.

'Minor' vein thrombosis (rates ranged from 0 to 17.6%), thrombophlebitis (rates ranged from 0 to 45.8%), and skin matting/pigmentation/staining (rates ranged from 0 to 66.7%), were relatively common occurrences and their incidence was similar to those in comparator groups, other than in one RCT where the risk of skin matting/pigmentation/staining was significantly higher for foam sclerotherapy compared with surgery^[12]. Pain provoked by

injection or long-term pain localized at the area sclerosed was reported as ranging from 0.6 to 41.0%.

Arterial events, particularly stroke and myocardial infarction (MI), can be life threatening. One case of stroke was reported one possible explanation for arterial events is the existence of a Patent Foramen Ovale (PFO), especially with right-to-left shunt [14]. In our series the commonest complication encountered was pain at site of injection at 28% and thrombophlebitis (16%) followed by skin ulceration and pigmentation (8%).

The short period of follow up in this study is insufficient for observing longer term efficacy. Though this study has established the safety of Foam sclerotherapy further studies with a longer follow-up period, are required to determine the comparative effectiveness of foam sclerotherapy and its optimal place in clinical practice.

Conclusion

Treatment of varicose veins with Foam sclerotherapy and saphenofemoral ligation or Saphenofemoral ligation and stripping provide similar results, but use of Foam sclerotherapy instead of stripping and avulsions reduces the operative and post operative recovery time. Sclerotherapy obviates the need for general anaesthesia and hence can be used in patients who are poor candidates for surgery.

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