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Original research article

Comparative Study Of Efficacy Of Treatment Of Varicose Veins With Saphenofemoral Ligation And Foam Sclerotherapy Compared To Saphenofemoral Ligation And Stripping

[1]Dr. Hosni Mubarak Khan

[1]Associate Professor, Department of General Surgery, Ambedkar Medical College, Bangalore, Karnataka, India

Corresponding Author:
Dr. Hosni Mubarak Khan

Abstract

Background: Varicose veins are a common condition that affects 20–30% of adults. Sclerotherapy, surgery (often consisting of stripping and ligation of the long or short saphenous veins and phlebectomies), and ablation are the primary treatment options available in the event that symptoms continue to be present (by laser or radiofrequency ablation). The purpose of the present study was to evaluate the efficacy of treating varicose veins with saphenofemoral ligation and foam sclerotherapy in comparison to treating varicose veins with saphenofemoral ligation and stripping.

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

Introduction

Varicose veins are a common condition that affects 20–30% of adults. People who have venous insufficiency may have symptoms such as heaviness, hurting, throbbing, itching, and cramping in their legs in addition to weariness. 1 Skin ulceration, skin discolouration, and inflammatory dermatitis are among conditions that can be caused by chronic venous insufficiency in certain patients. Varicose veins that cause symptoms can sometimes be improved with conservative treatments like compression hosiery. Sclerotherapy, surgery (often consisting of stripping and ligation of the long or short saphenous veins and phlebectomies), and ablation are the primary treatment options available in the event that symptoms continue to be present (by laser or radiofrequency ablation).

Some people believe that the treatment of venous insufficiency with liquid sclerotherapy is a promise that has not yet been fully realised. Varicose veins can be treated with a modification of liquid sclerotherapy known as ultrasound-guided foam sclerotherapy. In this method, sclerosant foam is injected into the veins that are afflicted while ultrasound monitoring is performed. Inflammation of the vein wall is brought on by the foam, which then leads to the obliteration and blockage of the vein's lumen. 2

It has been demonstrated to be risk-free, straightforward, economical, dependable, and repeatable, making it an extremely versatile tool. It is a treatment that has the potential to be helpful for both major and minor vein problems, and it can be performed as an

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outpatient operation without the need for either general or regional anaesthesia. 3,4 This might have repercussions in terms of freeing up time and space in the operating theatre for other types of surgical procedures. In addition, foam sclerotherapy can be administered in an outpatient clinic, and possibly even in a primary care setting, so long as the surgeon doing the procedure has had the requisite level of training, and so long as proper diagnostic and monitoring facilities are available.,5,6,7 The purpose of the present study was to evaluate the efficacy of treating varicose veins with saphenofemoral ligation and foam sclerotherapy in comparison to treating varicose veins with saphenofemoral ligation and stripping.

Material and Methods

The present investigation was a prospective single-center study that was carried out in the department of general surgery.

Patients of either gender who have varicose veins in the lower limbs, including those who have venous ulcers, are considered to meet the inclusion criteria.

Exclusion conditions

Patients who have a history of DVT and an allergy to sclerosants Patients who have recurrent varicose veins Patients who have multiple perforator incompetence Patients who have an allergy to sclerosants and a history of DVT

A total of fifty patients agreed to take part in this research after it was granted clearance by the ethics committee and they were given the opportunity to provide their informed permission. The protocol for the study consisted of taking a history, performing a physical exam, determining the patient's CEAP class, determining the patient's venous clinical severity score (VCSS), and performing a colour duplex ultrasound in order to locate sites of incompetent perforators and exclude the possibility of deep vein thrombosis. Doppler scanning was performed on every patient in order to diagnose saphenofemoral incompetence, locate locations of incompetent perforators, and exclude the possibility of deep vein thrombosis. The patients were assigned to one of the two groups based on a random drawing.

1. Group 1: Sapheno-femoral ligation with foam sclerotherapy – Patients were given local anaesthesia and underwent ultrasound-guided sclerotherapy with sapheno-femoral ligation (n=25). Foam was produced by applying the Tessari method to liquid sclerosant, which consisted of 3% sodium tetradecyl sulphate. In order to guide cannulation, monitor the injection and flow of foam, and reduce the risk of foam diffusing into the deep venous system, duplex ultrasound imaging was utilised. After a delay of two days, a sapheno-femoral ligation was performed under the influence of local anaesthesia.
2. Patients in Group 2 had sapheno-femoral ligation, stripping, and several avulsions while under general or regional anaesthesia (n = 25). This procedure was known as SF ligation and stripping.

Patients in both groups were followed up for a period of one year and compared for the following parameters: procedure time, perioperative complications, complete occlusion of treated veins (as measured 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 in disease severity as measured by CEAP score, as well as any recurrence of varicose veins. Patients in the sclerotherapy

Microsoft Excel was used to collect and compile the data, and the SPSS 23.0 version was utilised for the analysis. Utilizing descriptive statistics, the statistical analysis was carried out. The chi-square test and the Fisher exact test, depending on the circumstances, were used to analyse the proportional differences between qualitative variables. A statistic was considered statistically significant if it had a P value of less

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than 0.5.

Image 1: Surgery of varicose veins.

Results

Table 1: Procedure time

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

Table 2: Healing of ulcer

Ulcer healing	Group 1- SF ligation + foam sclerotherapy	Group 2 - SF ligation + stripping
	%	%
Healed	85.7	75
Residual ulcer	14.3	5

Table 3: Quality of life

C score improved by	Group 1- SF ligation + Foam sclerotherapy	Group 2 – SF ligation + stripping
	No.	No.
1	1	2
2	7	9
3	15	13
4	2	1

Table 4: Recurrence at 1 yr.

Recurrence	Group 1 – SF ligation+ Foam	Group 2 – SF ligation +

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	sclerotherapy		stripping
	No.	%	
Present	1	4	Nil
Absent	24	96	

Table 5: 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	-
4-5	12	2
6-7	8	3
8- 9	4	17
10-11	-	3

Table 6: Complications in Foam sclerotherapy

Complications in Foam sclerotherapy	%
Pain at injection site	28
Thrombophlebitis	16
Skin ulceration	8
Pigmentation	8
Coughing &chest tightness	4

Discussion

The utilisation of duplex ultrasound (DUS) technology has been primarily responsible for the majority of the significant progress that has been made in the understanding, diagnosis, and management of venous insufficiency during the past decade or so. 6,7 It is generally accepted that stripping the great saphenous vein, also known as the GSV, is a critical step in the process of reducing the risk of recurrence brought on by the regrowth of incompetent connection with the sapheno femoral confluence and/or thigh perforator incompetence. It is necessary to make further incisions at the knee or below the knee in order to strip the vein, and there is a high risk of developing minor surgical complications as a result of the procedure. Avulsion phlebectomy needs many incisions ranging from 2 to 3 millimetres in length along the course of the vein, and it has the potential to inflict harm to the nerves and lymphatic veins that are located nearby.

Sclerotherapy with liquid sclerosant was introduced as an alternative to surgery; however, it was quickly abandoned due to high failure rates, frequent recurrence, and unacceptably high rates of complications due to the large volume of sclerosant that was required. Sclerotherapy with solid sclerosant was also introduced.

8 As an alternative to vein stripping, foam sclerotherapy, which has seen a rise in popularity over the past ten years, has been investigated in this study as a treatment option for varicose veins. By changing the sclerosant into a foam, we were able to decrease the amount of sclerosant used while simultaneously increasing its effectiveness.

In this particular investigation, there was not a discernible difference between the case group and the control group with regard to the median age or the ratio of males to females. In the current study, the amount of time needed for foam sclerotherapy and Sapheno femoral ligation was noticeably shorter than the amount of time needed for

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Sapheno femoral ligation, stripping, and several phlebectomies combined. 9
The researchers Bountouroglou DG et al.,10 published statistics on the amount of time a procedure takes (foam sclerotherapy plus ligation was 45 minutes versus 85 minutes for ligation plus stripping plus avulsion). The sapheno-femoral junction ligation was performed in conjunction with the foam sclerotherapy. This fits in nicely with the other episodes in the series.
Healing of venous ulcers was studied in three case series including 216 patients and in two case reports involving three patients. The total number of patients involved was 73. In each of the investigations, polidocanol foam was utilised. In the case series, the ulcer healing rate was anywhere from 76.4 percent to 100 percent. 11
In this particular trial, the sclerosant that was used was sodium tetra decyl sulphate, and it demonstrated healing rates of 85%. It is not apparent whether the sclerosant that was utilised contributed to the faster rate at which the wound healed. There was no significant difference between the two groups, indicating that both were equally effective. The majority of patients in both groups in our series showed an improvement in the quality of life (measured by the CEAP score) compared to baseline. However, there was no significant difference between the two groups.
In a randomised controlled trial12 comprising 45 patients treated by foam sclerotherapy, the rate of venous recanalization after one year following treatment was reported to be 4.4%. The trial was conducted in the United Kingdom. This was a lower rate than that seen in the group that had liquid sclerotherapy, but the difference did not reach statistical significance (relative risk: 0.5, 95% confidence interval: 0.1 to 2.5).
One non-randomized comparative study that had 37 patients treated by foam sclerotherapy found venous disease recurrence also at one year following treatment, with a rate of 8.1%. This rate was likewise lower than that in the group who received liquid sclerotherapy.
13 In the current series, there was a recurrence in one out of twenty-five individuals (four percent).
In their research, Bountouroglou DG DG and colleagues10 discovered that the median amount of time needed to return to regular activity after surgery was much longer than the amount of time required for individuals who received foam sclerotherapy. This amount of time was 13 days (2days). This is a strong correlation with the findings of our series, in which the majority of patients healed within 8 days after surgery and within 2 days after foam sclerotherapy.
'Minor' vein thrombosis had rates ranging from 0 to 17.6%, thrombophlebitis had rates ranging from 0 to 45.8%, and skin matting/pigmentation/staining had rates ranging from 0 to 66.7%. These were relatively common occurrences, and their incidence was similar to those in comparator groups, with the exception of one RCT, in which the risk of skin matting/pigmentation/staining was significantly
12 From 0.6 to 41.0% of patients reported experiencing discomfort either prompted by the injection itself or long-term pain that was localised in the sclerosed location.
Arterial events, in particular a stroke or myocardial infarction (MI), can pose a significant risk to one's life. There was one instance of stroke that was reported. The presence of a patent foramen ovale (PFO), particularly in the context of a right-to-left shunt, is one of the hypotheses that can help to explain arterial events. 14 Pain at the injection site was the most prevalent consequence in our study, occurring in 28% of patients. Thrombophlebitis was the second most common problem, occurring in 16% of patients, followed by skin ulceration and pigmentation (8%).
The limited amount of time spent following up with participants in this trial is insufficient for determining longer-term effectiveness. Even though the safety of foam sclerotherapy has been demonstrated in this study, additional research with a more extensive time of follow-up is necessary in order to evaluate the relative efficacy of

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foam sclerotherapy and determine where it should be used most effectively in clinical practise.

Conclusion

The treatment of varicose veins with foam sclerotherapy and saphenofemoral ligation or with saphenofemoral ligation and stripping provide similar results; however, the use of foam sclerotherapy rather than stripping and avulsions reduces the amount of time needed for recovery both during and after surgery. Sclerotherapy does not require the use of general anaesthesia, and as a result, it can be administered to individuals who are not good candidates for surgical treatment.

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