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Comparison of complications of varicose veins treatment 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.

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

Introduction

Varicose veins have an overall prevalence of between 20 and 60%, and approximately 25% of the adult population have at least one varicose vein [1]. This condition is often associated with great saphenous vein (GSV) reflux [2-4]. The disease has a substantial impact on quality of life, as well as on the resources and budgets of healthcare systems [5]. Treatment of varicose veins is considered appropriate by the majority of vascular surgeons if the veins are symptomatic [6]. Common symptoms attributable to varicose veins include poor cosmesis (cosmetic appearance), ache and itching. Less common problems include haemorrhage (bleeding) and thrombophlebitis (inflammation of the vein wall with associated blood clot) [7]. For many years, ligation of the saphenofemoral junction (SFJ), stripping of the great saphenous vein (GSV) and multiple avulsions is considered to be the standard treatment for varicose veins [8]. The rate of recurrence of varicose veins after 5 years has been reported to vary from 20% to 80% [9]. In the past decade, alternative treatments such as endovenous ablation of the GSV with laser (EVLA), radiofrequency ablation (RFA) and foam sclerotherapy have gained popularity [10]. Despite the prevalence of varicose veins and the vast numbers of people being treated, the criteria for each of the various treatments are not well defined. Furthermore, there is no general consensus over which intervention is the most effective [11-14].

The aim of this study was to compare the results of conventional surgery with high ligation and stripping of GSV trunk combined with foam sclerotherapy.

Material and methods

Present study was single-center, prospective, comparative study, conducted in department of general surgery, at Kanachur Institute of Medical Sciences, Mangalore, 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

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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

1. 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.

2. 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

Table 1: 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

Table 2: 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

Table 3: 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

Table 4: 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

‘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. 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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