

Comparing Foam Sclerotherapy Combined with Saphenofemoral / Saphenopopliteal Junction Ligation with Surgery Alone for Varicose Veins

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Abstract

Background: Among chronic venous insufficiency, varicose veins are the most common manifestation affecting upto 25% of women and 15% of men [1]. While conventional surgical treatment for varicose veins has proven effective, it has fallen out of favour due to time away from work, poor cosmesis and procedural complications. **Materials and Methods:** The present study was conducted in the Postgraduate Department of General Surgery, Government Medical College Srinagar from February 2013 to October 2014 in 100 patients randomly divided into two groups A and B, each group having 50 patients irrespective of age and sex. Patients in group A underwent Sapheno femoral Junction Ligation and Greater Saphenous Stripping/ Multiple Ligations or Saphenopopliteal Junction Ligation and Lesser Saphenous Stripping/Multiple Ligations. Patients entitled for study in Group B underwent Foam Sclerotherapy Combined with Saphenofemoral Junction / Saphenopopliteal Junction Ligation. **Results:** Most of our patients in our study belonged to working age group of 20- 49 years, showing female predominance of varicose veins in our study: In group A in 48 (96%) patients the procedure was successful whereas in group B 44 (88%) had successful outcome. In group A operative time ranged from 70 to 100 min with mean of 83.72 min , S.D of 9.15 and S.E of 1.83 whereas in group B the operative time ranged from 40 to 60 min with mean of 50.96min, S.D of 6.37 and S.E of 1.27. In group A time required to return to work ranged from 4-16 days with

mean time of 9.4 days and in group B it ranged from 1-8 days with mean time of 3.92 days ($p<0.001$). In group A 1 (2%) patient developed recurrence after procedure where as in group B 3 (6%). No major complications like pulmonary embolism, anaphylaxis, stroke occurred in our study except one case of DVT in foam group. Minor complications reported included skin pigmentation, superficial thrombophlebitis, wound infections. **Conclusion:** Ultrasound guided sclerotherapy combined with sapheno-femoral ligation was found to be safe, very effective, less expensive, involved a shorter treatment time and resulted in more rapid recovery compared to sapheno-femoral ligation, and was cosmetically better, with shorter duration of hospital stay compared to surgery alone. It has high patient satisfaction results and improvement in quality of life.

Keywords: Foam Sclerotherapy; SPJ /SFJ Ligation; Varicose Veins.

Introduction

Chronic venous insufficiency is a common and under recognized problem affecting greater than 20% of general population [1]. Among chronic venous insufficiency, varicose veins are the most common manifestation affecting upto 25% of women and 15% of men [1].

Treatment of varicose veins is done not only for cosmetic reasons in asymptomatic individuals, but becomes necessary in view of complications it can cause. While conventional surgical treatment for varicose veins has proven effective, it has fallen out of favour due to time away from work poor cosmesis and procedural complications. Current therapies are becoming less invasive with better cosmesis less complications and faster recovery.

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Materials and Methods

The present study entitled "Comparing Foam Sclerotherapy Combined With Saphenofemoral/ Saphenopopliteal Junction Ligation With Surgery Alone For Varicose Veins." was conducted in the Postgraduate Department of General Surgery, Government Medical College Srinagar from February 2013 to October 2014 in 100 patients randomly divided into two groups A and B, each group having 50 patients irrespective of age and sex. The study was comparative and prospective one.

The present study included patients of symptomatic varicose veins regardless of age and gender admitted for treatment for varicose veins in SMHS hospital Srinagar. The selection of patients was made on the basis of detailed history, thorough physical examination and clinical tests and Doppler study. After detailed history and thorough examination, all routine baseline investigations including [Haemogram (Hb, TLC, DLC, Platelet Count, BT, CT), urine examination, Serum urea, Serum creatinine, Blood sugar (Random/Fast), Serum Sodium and Potassium, Liver function tests, X-Ray Chest (P/A View), ECG-12 leads] were done.

Patients were subjected to duplex color Doppler ultrasonography which demonstrated both anatomical patterns of veins and abnormalities. The duplex USG findings were utilized to establish (a) Sapheno femoral junction incompetence (b) Main saphenous trunk incompetence (c) Saphenopopliteal junction incompetence (d) Deep perforators incompetence (e) Any other superficial vein incompetence (f) Deep vein incompetence.

Patients included in the study were

- Patients with primary symptomatic varicose veins of lower limbs.
- Patients with no previous treatment for varicose veins.
- Patients with varicose veins of both limbs, only one limb was considered for treatment randomly.

All patients with previous surgery for varicose veins; with congenital causes for varicose veins; Secondary cause of varicose veins; Known allergic to local anaesthetic or sclerosing agent; with any contraindication to general/spinal anaesthesia were excluded from the study.

All the patients included in the study were randomly divided into two groups, and were randomly subjected to two techniques. Patients in group A underwent Saphenofemoral Junction Ligation and Greater Saphenous Stripping/Multiple Ligations or Saphenopopliteal Junction Ligation and Lesser Saphenous Stripping/Multiple Ligations. Patients entitled for study in Group B underwent Foam

Sclerotherapy Combined with Saphenofemoral Junction / Saphenopopliteal Junction Ligation.

Preoperatively the patients after completing the baseline investigations were subjected to pre-anaesthetic check-up. On the day before surgery, an informed consent was taken for the procedure after explaining the patient the advantages and potential complications of the procedure. Soft diet was prescribed to patients on the evening before surgery. Patients were kept fasting at least for six hours before surgery.

Equipment

- Colour Dopplar USG.
- 3 way IV canula
- 10ml syringes
- Scalp vein set
- Intraluminal stripper
- Mosquito forceps
- BP knife with blade
- Normal saline
- Sodium Tetra Decyl Sulphate [STD]
- Hooks

Operative Technique

Surgery – A

- Saphenofemoral Junction Ligation and Greater Saphenous Stripping/ Multiple Ligations* The patients were positioned in supine position. The operation was performed under spinal anesthesia in all patients. An oblique incision was made in the groin centered 2.5cm below and lateral to the public tubercle. The long saphenous vein was not ligated until the T-junction was confirmed and the femoral vein was exposed for a centimeter in either direction. The sphenous trunk was then retrogradely stripped to the knee by intraluminal stripper which invaginates the vein and may cause less bruising. Stripping not only avulses the main vein trunk but also pulls out the termination of the tributaries.
- Saphenopopliteal Junction Ligation and Lesser Saphenous Stripping / Multiple Ligations:* Preoperative ultrasound localization of the junction carried out. A transverse skin incision was made in the popliteal fossa just below the termination of the vein. The vein was found and traced to the saphenopopliteal junction before it was divided. After the vein was divided, a stripper was passed upwards from the ankle, carefully dissecting off the sural nerve to ensure that the whole of the lesser saphenous vein was removed.

Surgery – B

Foam Sclerotherapy Combined with Saphenofemoral Junction / Saphenopopliteal Junction Ligation

In the foam sclerotherapy group, the procedure was performed under spinal anaesthesia. SFJ ligation was performed in the same way as in the surgery group. The patients were then subjected to foam sclerotherapy. The sclerosing foam was prepared using the Tessari method [2] with two disposable 10ml syringes and a three way stop cock. One part of 3% sodium tetradecyl sulphate (STD), and four parts of air were used to produce the sclerosing foam. A suitable varicose vein, connecting with the GSV trunk, preferably below the knee was selected, marked with the aid of ultrasound and with the patient in supine position, was subsequently canulated with a 21 gauge butterfly canula. The limb was then elevated to 45° and the sclerosing foam injected. Any perforating veins protected by applying digital pressure to prevent foam entering the deep venous system. The aim was first to treat and obliterate the segment of the GSV that otherwise would have been stripped. USG was performed immediately after the procedure to document presence of foam in superficial vein tributaries and exclude evidence of DVT.

Postoperative Care and Follow Up

Short stretch crepe bandages were applied in immediate postoperative period and later on elastic stockings worn in all patients. Postoperatively the legs were elevated, adequate analgesia was given and bandages were applied. All patients were reviewed and examined at 1 week, 3 weeks and 3 months postoperatively. The follow up evaluation included history, physical examination and colour duplex venous ultrasound.

Results

1. *Age Distribution:* Most of our patients in our study belonged to working age group of 20- 49 years with 40-49 years age group being most common followed closely by 30-39 and 20-29 years age groups. Least common age was below 20 years and above 70 years. Mean age of patients in our study was 42.6 years.
2. *Sex of the Patient:* In group A 27 (54%) were females and 23 (46%) patients were males where as in group B 29 (58%) patients were females and 21 (42%) patients males showing female predominance of varicose veins in our study (p=0.840).
3. *Limb Affected:* In group A Right limb was effected in 26 (52%) patients and left limb in 24(48%) patients where as in group B right limb was effected in 22(44%) and left limb in 28(56%) of patients (p=0.548).

4. *Success of the Procedure:* In group A in 48 (96%) patients the procedure was successful where as in 2 (4%) patient the procedure failed and required further treatment whereas in group B 44 (88%) had successful outcome and in 6 (12%) patients the procedure failed and required further treatment (p=0.269).
5. *Comparision of Operating Time:* In group A operative time ranged from 70 to 100 min with mean of 83.72 min, S.D of 9.15 and S.E of 1.83 whereas in group B the operative time ranged from 40 to 60 min with mean of 50.96min, S.D of 6.37 and S.E of 1.27 (p<0.001).

	Mean	S.D	S.E
Group A	83.72	9.15	1.83
Group B	50.96	6.37	1.27

6. *Complication Rate between Two Groups:* In group A 1(2%) patient developed groin infection whereas in group B 2 (4%) patients developed groin infection in postoperative period. 2 (4%) patients developed skin pigmentation in group A and 7 (14%) in group B, superficial thrombophelibits occurred in 1(2%) of patient in group A and in 7 (14%) patients in group B. Deep vein thrombosis didn't occur in any of patients in group A and in 1 (2%) patients in group B. Saphenous nerve injury occurred in 2 (4%) patients in group A and none in group B. Pulmonary embolism, anaphylaxis and stroke didn't occurred in any of the patients in either group.

	Group A	Group B	P valve
Groin infection	1 (2%)	2 (4%)	1.000
Skin pigmentation	2 (4%)	7 (14%)	.160
Superficial thrombophelibits	1 (2%)	4 (8%)	.362
Deep vein thrombosis	0	1 (2%)	1.000
Saphenous nerve injury	2 (4%)	0	.495
Pulmonary embolism	0	0	0
Anaphylaxis	0	0	0
Stroke	0	0	0

7. *Comparision of Median Time to Return to Work:* In group A time required to return to work ranged from 4-16 days with mean time of 9.4 days and in group B it ranged from 1-8 days with mean time of 3.92 days (p<0.001).
8. *Recurrence Rate:* In group A 1 (2%) patient developed recurrence after procedure where as in group B 3 (6%)

Discussion

Current therapies for varicose vein treatment are becoming less invasive cosmetically better ,with

minimal rate of complications and improved recovery. Therapies aim to remove the superficial venous system either through surgery, endovenous ablation, or sclerotherapy .

- Modern version of sclerotherapy as a treatment modality for varicose veins was developed by Cabrera et al. [3] and has since grown wide spread use. Foam sclerotherapy has become widely used in recent years and has been found that median term outcome is similar to that of surgery. Sclerotherapy has been found to be more effective in patients with dilated superficial or residual varicose veins or incompetent perforating veins of moderate size without the vein reflux. Foam sclerotherapy plays a crucial role in the management of recurrent varicose veins by replacing more traumatic part of operation.

The mean age of patients in our study was 42.6 years. In a study conducted by Colredge Smith P et al. [4,5,6] mean age for these patients was 44 years. This in accordance with Asma Naheed et al. [7] (mean age (44.7 years). Incidence of varicose veins increases with age as shown by Preziosi P et al. [8], and Abramson J et al. [9]. Majority of patients were in working age groups with preponderance in age group of 40-49 years followed by 30-39 years group and 20-29 years.

Our study showed female predominance of varicose veins in both groups. In group A 27 were females and 23 patients were males whereas in group B 29 pts were females and 21 patients were males. In a study conducted by DG Bontongo et al. [10] in Sixty patients, 32 were females and 28 males showing female predominance of varicose veins. Worldwide also varicose veins are more common in females as documented in various studies like Weddell J et al. [11], Preziosi P et al. [8] .

There were 52 limbs with left sided varicose veins and 48 limbs with right sided varicose veins, demonstrating left sided predominance. This is in accordance with studies by Safar et al. [12] where 57% cases had left lower limb involvement and 43% had right lower limb involvement as well as Aparna Irodi et al. [13] 59 left sided limbs affected and only 41 right, but in Edinburg vein study incidence was similar in right and left limbs.

The Mean time to return to work in our study in Group A was ranging from 4-16 days mean 9.40 days and in Group B was 1-8 days mean 3.92 days. In a study conducted by DG Bontongo et al. [10] time to return to work ranged from 0 to 6 days with mean 2 days in the foam sclerotherapy group, and from 5 to 20 days (median 8) in the surgery group. Colredge Smith P et al. [4,5,6] found that patients undergoing varicose vein surgery required on average 16 days off work compared to 6.5 days following Sclertherapy of the saphenous trunk.

The operating time in our study in group A ranged from 70-100 min with mean operating time of 83.72

min. and in group B ranged from 40-60 min with a mean of 50.96 min. The length of the procedure ranged from 45-60min (median 45) in the foam sclerotherapy group, and from 70-95 min (median 85) in the surgery group in a study conducted by DG Bontongo. As reported by Colredge Smith P et al. [4,5,6] .

Colredge Smith P et al. [4,5,6] foam sclerotherapy required 30 minutes per treatment session.

Complications

Endovenous foam sclerotherapy procedure is simple with minimum complications without need for general anaesthesia or hospital admission and more cost effective. Adverse effects reported with endovenous foam sclerotherapy include [11] hyperpigmentation, thrombophilabitis and deep vein thrombosis. No major systemic complications [anaphylaxis, stroke, transient ischemic attack] were seen in our study. Similar results were seen in a study conducted by K.A. Myers et al. [14] with no major complications reported. No clinical episodes of pulmonary embolism or other cardiovascular complications were observed in a study conducted by K Starvos et al. [15]. In our study in group A 1 (2%) patient developed groin infection whereas in group B 2 (4%) patients developed groin infection in postoperative period. Skin pigmentation was seen in 2 [4%] in group A and 7 (14%) in group B. DG Bontongo et al. [10] reported Groin infection in 2 patients following Foam sclerotherapy group. K.A. Myers et al. [14] reported Skin pigmentation in 115 of 459 limbs at 6 months and palpable lumps were present in 21 limbs. Superficial thrombophlebitis occurred in 1 (2%) of patient in group A and in 7 (14%) patients in group B. In a study conducted by K.A. Myers et al. [14], Thrombophlebitis occurred in a small number of patients (5%) and was managed by analgesia, compression and aspiration of thrombus. Superficial thrombophlebitis occurred in 6 (8.2%) of the 73 injection sessions in a study conducted by DG Bontongo et al. [10].

Deep vein thrombosis didn't occur in any of patients in group A and in 1 (2%) patients in group B. Patient with deep vein thrombosis in our study was managed conservatory with subcutaneous low molecular weight heparin and resolved uneventfully. In a study conducted by K Starvos et al [15]. Deep vein thrombosis was detected by the routine early postoperative scan after 16 procedures. There were 9 occlusive posterior tibial vein thromboses and 7 partially occlusive femoropopliteal thromboses which represented 1.8% and 1.4% of the 489 patients respectively. All were asymptomatic and resolved with a short period of treatment with subcutaneous low molecular weight heparin therapy. Saphenous nerve injury occurred in 2 (4%) patients in group A and none in group B. Saphenous nerve injury occurred in 2

patients [9%] surgery group in a study conducted by D G Bontongo et al. [10]. Skin ulceration was seen in none of patients in our study.

Pulmonary embolism, anaphylaxis and stroke didn't occurred in any of the patients in either group.

K.A. Myers et al. [14] reported no major systemic complication such as anaphylaxis, stroke or transient ischaemic attack, deep vein thrombosis occurred in this series. A number of patients (14, 2% of all patients treated) reported visual disturbance following treatment. Skin pigmentation was seen in 115 of 459 limbs at 6 months and palpable lumps were present in 21 limbs, superficial thrombophlebitis occurred in 6 (8.2%) of the 73 injection sessions.

K Starvos et al. [15] reported deep vein thrombosis detected by the routine early postoperative scan after 16 procedures. There were 9 occlusive posterior tibial vein thromboses and 7 partially occlusive femoropopliteal thromboses which represented 1.8% and 1.4% of the 489 patients respectively. Follow-up scans showed persisting reflux after recanalisation in the posterior tibial segment in 5 limbs. All deep vein thromboses followed use of foam and the volume infused ranged from 5-35 ml (median 14 ml). No clinical episodes of pulmonary embolism or other cardiovascular complications were observed. Three patients with a prior history of migraine headaches developed visual aura during mobilisation after injection, all typical of previous symptoms, and all settled within 20 minutes without headache or residual neurological deficit. No other neurological symptoms were observed. No other complications occurred.

Recurrence of varicose veins following surgery is a common event and is often attributable to neovascularisation [21,23,24].

In our study in group A 1 (2%) patient developed recurrence after procedure where as in group B 3 (6%) patients developed recurrence after the procedure. In the stripping group two patients (7%) needed a further sclerotherapy session for full obliteration of their residual veins.

Fischer et al. [16] reviewed 125 limbs in 77 patients after an average of 34 years following SFJ ligation and GSV stripping and found recurrence in 60%.

Surgical treatment which is widely regarded as the reference standard, carries the risk of significant post-operative complications, necessitates significant time off work and despite this does not prevent recurrence.

Conclusion

Modern evolution of varicose vein surgery has been towards less traumatic, minimally invasive percutaneous intervention therapies which include

foam sclerotherapy, Endovenous laser treatment, Radiofrequency ablation, Subfacial endoscopic perforator vein surgery, Obliteration of Saphenous trunks with hyperheated steam.

Endovenous foam sclerotherapy procedure is simple with minimum complications without need for general anaesthesia or hospital admission and more cost effective. Ultrasound guided sclerotherapy combined with sapheno-femoral ligation was found to be safe, very effective, less expensive, involved a shorter treatment time and resulted in more rapid recovery compared to sapheno-femoral ligation, and was cosmetically better, with shorter duration of hospital stay compared to surgery alone. It has high patient satisfaction results and improvement in quality of life.

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