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Efficacy of Foam Sclerotherapy in Treating Truncal and Perforator Reflex a Six Months Study: Hospital based Prospective Study

Rajesh K[1], Edwin Emperor C[2]

[1]Assistant Professor, Department of Vascular Surgery, [2]Associate Professor, Department of Plastic Surgery, Kanyakumari Government Medical College, Asaripallam, Kanyakumari, Tamil Nadu

ABSTRACT

Background: Veins varicose are the important disorder which affects the male adult population. Various factors cause veins varicose. The present studies aim is to see the efficacy of foam sclerotherapy in treating truncal and perforator reflex in varicose patients for the period of six months.

Materials and Method: This study was conducted in the Department of Vascular surgery, Kanyakumari Government Medical College for a period of 6 months. Patients came to the Vascular surgery OPD with varicose veins was selected for the study. Total of 38 patients selected for the study on the basis of inclusion and exclusion criteria. Demographic and clinical data were collected from the patients. All the patients were explained procedure and inform consent was obtained from each patient. The selected patients were subjected to the foam sclerotherapy and observed for 6 months.

Results: A total of 38 patients were included in the study. Males (n=32) was more than females (6). Maximum number of patients had SFJ incompetence (17), perforator (10), SFJ with perforator incompetence (9) and 2 had SFJ, SPJ with perforator incompetence. Out of 38 patients only 6 patients showed recurrent/residual varicose. Thrombophlebitis was the commonest complication compared to others.

Conclusion: From the study observations it can be concluded that foam sclerotherapy has its own advantages for patients with varicose veins. Patients who had undergone this procedure have less recurrence of varicose veins.

Keywords: *Foam sclerotherapy, truncal, incompetence, perforator reflex, Varicose vein, healing rate*

INTRODUCTION

Varicose veins mainly develop in the lower limbs affect the lower extremities Various methods are used in the treatment of varicose veins. Each method has its own advantages and complications. They are surgical treatment it is a old method to treat varicose veins. It is associated with less success rate and recurrence of varicosities[1,2]. Subfascial Endoscopic Perforator Surgery procedure must be performed under general anaesthesia. It has own limitations and complications. 20-28% recurrence was reported patients underwent this procedure. Another method is Radiofrequency ablation (RFA) involves the use of high frequency alternating current delivered via a bipolar catheter, placed intraluminally under duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating resulting in venous spasm and irreversible denaturation of collagen with intimal destruction. This produces a fibrotic luminal seal with minimal thrombus formation. The procedure is performed under general, regional or tumescent local anaesthesia.

Corresponding author :
Dr Rajesh K
Assistant Professor, Department of Vascular Surgery,
Kanyakumari Government Medical College,
Asaripallam, Kanyakumari
Tamil Nadu, Mobile no: +91-9442154779
Email id: rajesh.kanniah@gmail.com

Endovenous Laser Treatment (EVLASER) is the advanced method in the treatment of varicose veins. In EVLASER uses laser energy delivered through laser fibre to obliterate the vein. Steam bubbles generated from boiling blood in the lumen cause thermal injury to the vein wall. This procedure had more recurrent rate and associated with other complications. Liquid sclerosing agents have their greatest effect in the smallest incompetent veins, usually non truncal varicosities below the knee (macro sclerotherapy) and telangiectasias (microsclerotherapy). The technique is not useful however, if proximal venous hypertension exists and any proximal venous reflux should be corrected first. Foam sclerotherapy method injection of sclerosing agent such as sodium teradecyl sulphate, polidoconal in a foam vehicle, the sclerosing agent having been mixed forcibly with air. Several techniques have been proposed to produce sclerosant foam and Tessari and Frullini techniques appear to give the most favourable results. The foam replaces blood in the vein, which enhances the efficacy of the sclerosing agent by reducing the volume of sclerosant required for the treatment and increasing the effective surface area of the sclerosant in contact with the vein wall[11,12]. Duplex monitoring during the procedure is necessary to prevent spread of foam into femoral vein. The present study was conducted to evaluate the efficacy of foam sclerotherapy in treating truncal and perforator reflex in patients with varicose veins a 6 months study.

MATERIALS AND METHOD

Study settings and time period

The study is a prospective hospital based study conducted in the department of Vascular surgery, Kanyakumari Government Medical College, for the period from January 2017 to June 2017.

Inclusion criteria

- **Any age with varicose veins affecting long/ short saphenous system or isolated perforators or the combinations**
- **Truncal/perforator reflux proven by duplex**
- **Patients of C4, C5 and C6 involvement**
- **New or already underwent varicose surgery**

Exclusion criteria

- **Involvement of C1, C2 and C3 degree**
- **Congenital anomalies in venous**
- **Acute deep venous thrombosis**
- **Post phlebitis legs**
- **Any arterial disease**
- **Patients with cardiac disorders, neurological diseases**

Procedure

A total of 38 patients were enrolled as inpatients after clinical examination. A detailed procedure was explained to all the study population. The demographic and clinical data was recorded. The patients were observed at the time of inclusion of study and follow up for 6 months. In patients with C6 varicose veins, the size of ulcer was measured during the first clinical examination and followed up during subsequent reviews. They are subjected to duplex study. IVC, iliac veins, femoral veins, popliteal vein and tibial are examined to rule out venous thrombosis and any reflux in deep venous system. The superficial system is assessed for reflux in the SFJ, SPJ and all the perforators. In all the veins any reflux more than 0.5 sec inferred as positive. All the incompetent perforators are assessed and their levels from the heel given in cms, the amount of reflux, size of veins at the junction and at various levels are assessed.

Directional continuous wave–Doppler examination with proximal compression or Valsulva maneuver is a qualitative test for assessing reflux in both the superficial and deep venous systems. Duplex ultrasonography performed with the patient in upright position and with the limb examined in a non weight bearing position, in combination with Valsalva maneuver, is the best documented non invasive method of quantifying reflux, by measuring reflux duration in specific axial superficial and or deep venous segments. Although various methods of creating foam and various agents have been described the method we followed in our institute will be described.

Procedure of intervention

The sclerosant used was 3% polidoconol. Shown strength agent foamed as per Tessari double syringe

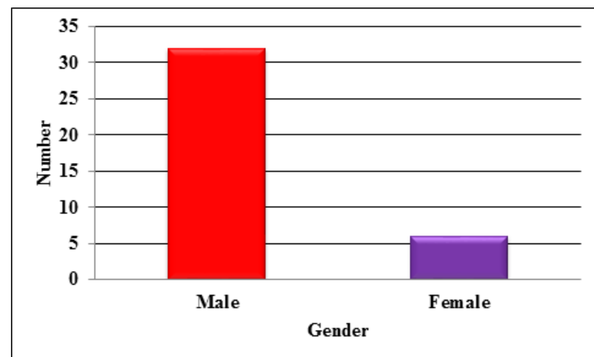
method using room air, the ratio of air to liquid are 4:1. The volume of foam injected depends on the diameter and length of the vein to be sclerosed. The maximum amount of foam used in this study is 20 ml in single sitting. Vascular access for foam injection is usually under duplex guidance with direct puncture of GSV/SSV/ Perforators. The foam is guided to SF junction where firm finger pressure or transducer pressure is applied to halt proximal passage or of the foam. After foam, the foot and legs are elevated 45 degrees. The deep veins are assessed for evidence of foam. If any present they are cleared by ankle flexion and extension maneuvers, follow up assessment was done to rule out DVT. Then compression bandage are applied with focal compression over larger veins and saphenous vein post treatment bandage are replaced with class 2 compression after 24 hrs for 14 days. If the patient was not fully relieved or any residual varicosities found during follow up further sitting of sclerotherapy was given. Surveillance was done by inspection, palpation and duplex study after 1 year. The primary outcome is gaining of reflex and the secondary outcomes are recurrence of canalization, neovascularisation and post procedure complications[13].

Statistical analysis

The data was expressed in number and percentage. Microsoft excel 2017 used to calculate the percentage.

RESULTS

The study had males were more compared to females. Out of 38 patients 32 was primary varicose and 6 showed recurrence. Maximum patients had SFJ incompetence (17), Perforate (10), SFJ+perforator incompetence (9) and 2 had SFJ+SPJ+perforator incompetence. C4 (6) and C5 (6) more in patients with SFJ incompetence, C5 (6) was more in perforator. C6 (6) in SFJ+perforator incompetence and 2 had C6 SFJ+SPJ+ perforator incompetence was observed. 3 patients showed thrombophlebitis and it is a major complication. In the recurrence perforator incompetence (3) was more compared to others.



Graph-1: Distribution of patients based on gender

Table-1: Number and percentage of patients based on primary treatment

Anatomical distribution of Reflux	**No of cases**
SFJ Incompetence	17
Perforator	10
SFJ +Perforator Incompetence	9
SFJ + SPJ + Perforator Incompetence	2
Total	**38**

Table-2: Distribution of patients based on category treated

Anatomical distribution of Reflux	**C6**	**C5**	**C4**	**Total**
SFJ Incompetence	5	6	6	17
Perforator	5	1	4	10
SFJ +Perforator Incompetence	6	3	0	9
SFJ + SPJ + Perforator Incompetence	2	0	0	2
Total	**18**	**10**	**10**	**38**

Table-3: Number and percentage of patients with complications

Type of complication	**Number**
Thrombophlebitis	3
Hyperpigmentation	1
Skin necrosis	1
Pain along injected site	3
Total	**8**

Table-4: Number and percentage of patients with recurrent/residual varicose in different category

Anatomical distribution of Reflux	C4	C5	C6	Total
SFJ + Perf Incompetence	1	0	1	2
SPJ Incompetence	0	0	1	1
Perf Incompetence	1	1	1	3
Total	**2**	**1**	**3**	**6**

DISCUSSION

The venous disease burden in our country is so voluminous in centres which are specialized in vascular work the case volume will be around 60 – 70 % of the outpatient set up. Many of these patients may need intervention for their symptoms as the critical limb ischemia patients were given priority , most of the venous cases could not be accomadated in the list for elective SFJ ligation / SPJ ligation as it requires operating table and anesthesia. As the foam sclerotheraphy can be given in the duplex scan room, early patient ambulation, return to work and the repeatability of the procedure makes it more applicable in our set up. We have treated 38 patients with foam sclerotherapy with six months follow up study[23].

Echogenic phenomena in the central venous circulation and specifically in the right heart appear to be a very common occurrence after foam sclerotherapy, even with modest quantities of foam injected. These signals are probably foam bubbles, but may represent particulate matter such as clumps of endothelial cells. These episodes occurred with both air- and CO_2- based foam when the limb was injected in a horizontal position and occlusion of the saphenofemoral junction was performed. Occlusion of the saphenofemoral junction tended to result in a bolus of foam being released into the central venous circulation when groin pressure was removed, even after 3 to 5 minutes of occlusion. It can be speculated that junctional compression may simply dam up foam particles, which are then released en mass when the pressure is removed.

Release of pressure may also create a suction that aspirates foam from the proximal great saphenous vein into the common femoral vein. Gas bubbles can persist in treated superficial veins for many minutes after injection, even when CO_2 is used. Techniques that occlude the saphenous junction with either manual compression or balloon dilatation in conjunction with foam injection may actually amplify the hazards they seek to prevent[23].

Leg elevation before injection has several advantages. Smaller volumes of foam are generally regarded as safer than large quantities. In many cases, leg elevation dramatically reduces the diameter of the target vein, thus permitting injection of significantly lower amounts of foam to achieve treatment of the same length of vein. Because foam is lighter than blood, leg elevation also facilitates the persistence of foam in the treated vein and reduces the degree of foam migration into the femoral vein through the saphenofemoral junction[10].

Although details were not included in the study[23], they have consistently observed significant amounts of foam in the central venous circulation and right heart if the saphenous vein is injected without compression at the junction when the leg is in a horizontal position. The advantages of reduced vein caliber and gravitational effects on foam movement are lost if foam is injected with the leg level and subsequently elevated. However, cannulation before leg elevation is advantageous because it is easier to obtain venous access with the leg horizontal. A catheter may be preferable to a needle to avoid loss of access during leg elevation and permit unhurried foam injection.

In most of the studies quoted in literature female patients occupy 60 -70 % of cases, but in our study female patients are only 8%. Although varicosities are more common in females most of them are in the category C1-C3. Why ulcerations are less common in females the cause has to elucidate. (76.2%) female and (23.8%) male patients J-**L Gillet, J M Guedes** et.al [24]. We have treated 28 cases of SFJ Incompetence in this group of these 24 cases the veins were occluded at the end of 6 month 24 /28 (85 %). The veins that are recanalised during follow up 3 had veins more than 7 mm out of 9 patients, occlusion rate 66 %. Only one patient in less than 7 mm group recanalised out of 19 occlusion rate 94 %. 2 cases of SFJ Reflux were treated in both these cases the vein diameter is 7 mm. The veins remained occluded at the end of 6 months. In this group 3 patients were treated for perforator incompetence for them the veins are occluded at the end of 6 months.

One case of SPJ Reflux treated in this group remained occluded at the end of 6 months Stavros

K. Kakkos reported 87 % occlusion rates in his study for recurrent varicose veins (Immediate results)[31]. The occlusion rate of 76 % in group 1 and 85% in group 3 are acceptable as it has been quoted in various literatures. The recanalisation rate of 24% in Group 1 is seen in veins more than 7 mm.. The occlusion rate of 100% in the recurrent group cannot be compared to other studies as the treated group consists of only 12 patients. Guex et al.[30] reported that in a registry of 12,173 sessions of sclerotherapy, the incidence of adverse events (principally visual disturbance) was 0.4%. In our series we encountered only one case (1/56) 0.01%.superficial thrombophlebitis (STP) (10.3%) was reported by P Chapman-Smith and A Browne in our series it was 5%. Allergy was reported in 0.01 to 0.1% (very rare) in series by Guex et al in our series it is 0.01% transient visual loss, breathlessness are self limiting. Thrombophelbitis settled with analgesics and antibiotics for a period of 2 weeks. skin allergy settled with 2 doses of anti-histaminics. In most of these cases we followed the technique of saphenofemoral junction Compression during foam injection.

CONCLUSION

Ultrasound guided foam sclerothreapy is effective in abolishing primary as well as recurrent varicosities for both truncal and perforator incompetence. High patient satisfaction due to immediate return to activity and avoiding cost of time off work. Repeatability of the procedure is also well accepted by the patients. The vein size determines the early recanalisation/recurrence in our study.

Ethical Committee clearance: The study protocol was approved by Institutional Human Ethics Committee, Government Medical College, Kanyakumari (Dist), Tmail Nadu.

Conflict of Interest: No conflict of interest.

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