

Foam Sclerotherapy in the Management of Venous Malformation in Day Care Surgery

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ABSTRACT

Background: Venous malformation and its complications are commonly seen these days. Surgery has been the most often used treatment for Venous malformation. Foam sclerotherapy refers to introduction of sclerosing foam into the varicose veins, which causes the blood to displace from the vessel, permitting homogenous contact between the sclerosant and the endothelium leading endothelial destruction. Foam sclerotherapy is being practised extensively now days. Hence, this study aims to evaluate the efficacy of foam sclerotherapy in managing venous malformation.

Aims: To study the safety and efficacy of foam sclerotherapy in the treatment of venous malformation

Methods: This is a prospective observational cohort study involving 36 patients with venous malformation attending the out-patient department. The study was conducted over a period of 12 months. After thorough clinical, laboratory, and radiological evaluation, the patients were treated with foam sclerotherapy using polydocanole. The patients were then followed up to look for disappearance of veins or any other complications.

Results: Patients showed a good response to treatment with foam sclerotherapy. 70-80% of patients showed symptomatic improvement along with disappearance of veins. Most of the complications were minor, which resolved over a period of few weeks.

Conclusion: Foam sclerotherapy is a simple, safe and effective procedure for the treatment of venous malformation. The procedure is particularly effective for smaller, early varicosities and also for residual veins after surgery. Hence, it is recommended to take up this procedure, which can be an efficient tool to manage patients with venous malformation.

Keywords: Foam sclerotherapy, venous malformation, congenital venous malformation.

INTRODUCTION

Venous malformation is the veins, which have permanently lost its valvular efficiency and as a product of resultant venous hypertension in the standing position become dilated, tortuous, and thickened¹. About 17-50% of patients with varicose veins may have cutaneous findings². Venous malformation may cause significant morbidity including stasis dermatitis, ankle oedema, spontaneous bleeding, superficial thrombophlebitis, recurrent cellulitis, lipodermatosclerosis and ulceration of the ankle and foot³. The various modalities to treat venous malformation include surgery, sclerotherapy and endo-venous occlusion by lasers or radiofrequency. The indications for any of the treatments of Venous malformation include:

- (a) prevention of complications;
- (b) relief of symptoms; and
- (c) improvement of cosmetic appearance⁴.

Foam sclerotherapy refers to the introduction of sclerosant agent which induces denaturation of tissue protein, precipitating protoplasm and subsequent permanent obliteration of the vessel lumen. It has been extensively used by surgeons in the management of superficial varicose veins and other venous abnormalities⁵. However, it has not been widely practiced in India. The search for more effective means of prevention and treating venous malformation continues and this study aims at establishing the role and efficacy of foam sclerotherapy in managing venous malformation.

METHODOLOGY

The study included 36 patients who presented in the OPD (Table 1). The study was conducted over a period of 12 months. All patients with VM were diagnosed with various noninvasive and less invasive diagnostic methods: Doppler arterial and venous blood flow study, including waveform analysis; duplex sonography to assess hemodynamic and anatomophysiological relationships among feeding arteries, the malformation lesion, and its draining vein; infrared optometric volumetry for the measurement of extremity volume; transarterial lung perfusion scintigraphy for ruling out any hidden microarteriovenous shunting malformation combined and magnetic resonance imaging (MRI) study. Invasive study with various forms of arteriography or venography was the ultimate gold standard for the differential diagnosis and was also necessary as a road map for the treatment. Follow-up assessment with clinical examinations was supplemented with ultrasonography and magnetic resonance imaging, according to protocol, once the multisession therapy was completed. The average follow-up period was 6 months after completion of a multisession treatment.

Table 1: Area affected in patients

Affected area	Total number of patients
Upper limb	8
Lower Limb	22
Other	6

Inclusion criteria

The inclusion criteria for the study were patients older than 18 years with varicose, reticular, telangiectatic leg veins or with any other venous malformation.

Exclusion criteria

The various exclusion criteria for the study were (a) deep venous thrombosis; (b) saphenofemoral junction/saphenopopliteal junction incompetence; (c) pregnancy; (d) myocardial decompensation; (e) hypercoagulable state; (f) dependency edema; (g) arterial disease; (h) diabetes mellitus; and (i) any other serious illness.

Laboratory and clinical assessment

The following investigations were carried out before the procedure: (a) Complete hemogram; (b) Random blood sugar; (c) Coagulation profile; (d) Urine-albumin, sugar and microscopy; and (e) Venous doppler of involved limb/ MR Angiography.

Each symptom and sign (eg, pain, discomfort, ache, stiffness, limited motion of joint or gait) the patient had before starting the treatment was thoroughly documented by the patient. Clinical criteria of the outcome assessment have been based on the improvement of clinical findings and the quality of life as previously described elsewhere⁶.

Thorough duplex scan assessment of the lesion and related vessels was done routinely per protocol on all patients treated on the first day after the sclerotherapy and subsequently in 1 week, 1 month. It was done more frequently when there was potential high risk of deep vein thrombosis (DVT) or developed DVT as a complication.

Clinical and laboratory evaluation of the 36 patients was made after each session of form sclerotherapy. Interim treatment results were evaluated periodically on the basis of clinical findings and also on the various tests mentioned previously.

DECISION TO TREATMENT

Most patients with indication for the form sclerotherapy had at least two if not three conditions to meet the following criteria: lesions with symptoms and signs (eg, pain, discomfort, heavy sensation, difficult mobility and difficult joint motion, swelling, limited range of motion, ulcer, hemorrhage, stasis dermatitis); lesions with significant functional impairment or cosmetically severe deformity; lesions located at trauma-prone region (knee, ankle, foot, elbow, wrist, and hand) with increased risk of complications (eg, hemarthrosis); lesions located at a potentially life-threatening vital area that compromised seeing, hearing, eating, or breathing (eg, proximity to airway, eyelid lesion to block eye sight, especially in infant); or combined abnormal long bone growth with limb length discrepancy from vascular bone syndrome^{7,8}.



Fig. 1 Pre operative picture of venous malformation

Procedure

Foam sclerotherapy involves injecting “foamed sclerosant drugs” within a blood vessel using a pair of syringes - one with sclerosant in it and one with gas (room air)⁹. The sclerosant drugs (sodium tetradecyl sulfate or polidocanol) are mixed with air or a physiological gas (carbon dioxide) in a syringe. This increases the surface area of the drug. The foam sclerosant drug is more efficacious than the liquid one in causing sclerosis¹⁰ (thickening of the vessel wall and sealing off the blood flow), for it does not mix with the blood in the vessel and in fact displaces it, thus avoiding dilution of the drug and causing maximal sclerosant action. It is therefore useful for longer and larger veins. Experts in foam sclerotherapy have created “tooth paste” like thick foam for their injections, which has revolutionized the non-surgical treatment of varicose veins¹¹ and venous malformations, including Klippel Trenaunay syndrome¹².

Fegan's technique was used for injecting the sclerosant². The patient was made to sit with the leg to be treated in the dependent position. The vein was cannulated with a needle and the leg was elevated and supported over the table to allow drainage of blood. With the help of 3 way valve polidocanol and air are mixed and foam is formed, this foam is then injected into affected vein with the help of feeding tube. Finger pressure was applied several centimeters above and below the injection point followed by immediate application of compression. The procedure was done in the surgery operation theatre or in OPD. The sclerosant foam amount was decided depending on the size of veins. Elastic compression bandage was applied after injecting the sclerosant foam. The patient was advised to use the compression bandage for the next 3 months.



Fig 2 Intra Operative Picture

Follow-up

All patients were observed for 1 h after the procedure to look for any evidence of allergic reactions (anaphylaxis) and sent home on the same day. They were asked to review after 3 days in case of any adverse events at the site of injecting the sclerosant foam. They were followed-up for 6 months after the procedure and the response was evaluated to look for: (a) relief (b) Recurrence (c) Healing of venous ulcers; (d) eczema; (e) Pigmentation; and (f) Reduction of edema.

RESULTS

The study included 36 patients venous malformation. In the study out of 36 patients, maximum number of patients ie. 17 (47%) were in the 20-40 years age group followed by 8 (22%) patients in the 40-60 years age group, next followed by 6 (17%) patient in 0-20 years age group and the least being in 60-80 years age group with 5 (14%) of patients (Table 2).



Fig 3 Post Operative picture

Table 2: Age distribution acc. to age group

S. No	Age Group	Total No Of Pt.	Percentage
1.	0-20 yrs	6	17%
2.	20-40 yrs	17	47%
3.	40-60 yrs	8	22%
4.	60-80 yrs	5	14%

Out of the 36 cases included in the study, 24 (66%) cases were male with only 12 (34%) female patients. In the present study, the commonest presentation was that of dilated and tortuous veins. The other symptoms were (a) pain in the affected limb - 32 patients (89%); (b) eczema - 17 patients (47%); (c) oedema - 24 patients (67%); (d) ulceration - 17 patients (47%); (e) lipodermatosclerosis - 3 cases (8%) [Table 3].

Table 3: Symptomatology of Venous Malformation

S.No	Symptoms	Number Of Pt.	Percentage
1.	Pain	32	89%
2.	Dilated veins	30	84%
3.	Eczema	17	47%
4.	Oedema	24	67%
5.	Ulceration	17	47%
6.	Lipodermatosclerosis	3	8%

Therapeutic results

As a result we considered disappearance of varices and eczema, reduction of edema, healed ulcers and relief of symptoms (pain, fatigue, tiredness). No concomitant local medications were used for venous ulcers. The response is based on the clinical findings of basic signs of venous malformation.

Pain improved in 29 patients out of 32 cases (91%), dilated veins reduced in 27 (90%) out of 30 cases, oedema reduced in 12 of 24 patients (50%), ulceration reduced in 10 (59%), eczema showed a good response with 15 (88%) out of 17 patients showing improvement and lipodermatosclerosis responded poorly with 1 out of 3(33%)patients showing improvement.

Complications

Most of the acute complications were minor, confined to skin and subcutaneous tissue injury, because of the proximity of lesions to the skin, and healed spontaneously with or without minimal wound disposition (eg, debridement). Pain and bruising at the site of injection was the most common complication seen in 14 (39%) patients followed by phlebitis in 6 (17%) cases, pigmentation was seen in 7 (19%) cases, and deep vein thrombosis (DVT) was noted in 1 patient (3%) [Table 4]. There were no episodes of skin necrosis and anaphylaxis. However, most of the complications resolved over a period of few weeks, with pigmentation taking a 2 to 3 weeks to resolve.

VM lesions complicated with DVT after the therapy were confirmed to be located near the normal deep vein system of the lower extremity, showing significant drainage of the VM lesion by the connecting vessels into the deep system on direct puncture phlebography or venous duplex scan before the sclerotherapy..

Table 4: Complications of sclerotherapy

S No.	Complications	Number of pt.	Percentage
1.	Pain & Bruising	14	39%
2.	Phlebitis	6	17%
3.	Pigmentation	7	19%
4.	DVT	1	3%

DISCUSSION

The etiology of venous malformation is multi-factorial and all treatments presently available including, surgery and sclerotherapy are palliative and not etiological¹³. Venous malformation are commonly seen in the surgery OPD (out patient department). Surgical procedures like ligation, compression and stripping are the preferred modalities of treatment. Foam Sclerotherapy is a valuable method of treatment for venous malformation including varicose veins of the lower limb and is one of the frequently used procedures by surgeons these days^{2,14}. The first reported attempt at sclerotherapy was by D Zollikofer in Switzerland, 1682 who injected an acid into a vein to induce thrombus formation¹⁵.

There is constant risk of recurrence through the potential evolutionary power of CVM (congenital venous malformation) when it is an embryonal remnant of extratruncular form, maintaining the original ability to grow when the condition should become optimum for the growth of mesenchymal cell-originated tissue. Therefore, the recurrence of the CVM lesion still remains a paramount issue within the clinical management of CVM.

However, not a single treatment method previously available was able to provide an acceptable rate of recurrence for the management of VM^{16,17,18}. Lately, polidocanol has been accepted as a new scleroagent with a substantial reduction of recurrence. Polidocanol induces denaturation of tissue protein, precipitating protoplasm and subsequent permanent obliteration of the vessel lumen, so that it is the only known and clinically tested effective scleroagent to be able to provide no chance of regeneration of endothelial cells, with the prospect of a “cure” in selected cases^{1,19,20,21,22,23,24}.

Casual use with inaccurate understanding should be the first and most important “contraindication” to polidocanol form sclerotherapy. Polidocanol should be used only by individuals and centers with professional expertise and experiences exercising extreme precaution to prevent or at least minimize various anticipated complications and morbidity. Sclerosing solutions are classified into three groups, based on the mechanism of action; detergent agents, osmotic agents and chemical irritants. The various sclerosants include STS, polidocanol, hypertonic saline, sodium morrhuate, etc. STS, a polidocanol sclerosant was used in our study.

According to a study by Leach and Goldman, bruising was seen in 54% of patients, pain in 15% of patients²⁵. Another study by Goldman has shown hyperpigmentation in 64%, vein thrombosis in 46%, local urticaria in 36%, telangiectatic matting in 11% and skin necrosis in 6% of patients²⁶. Most of the complications in our study are minor and gradually resolved. Other rare complications reported in the literature include anaphylaxis, extensive tissue necrosis and pulmonary embolism^{27,28}. However, the treating physician should be aware of the early signs of anaphylaxis and should have emergency equipment available

CONCLUSION

Sclerotherapy is a simple, safe, and effective procedure for the treatment of VM. The procedure is particularly effective for early smaller VM, which may help in preventing the development of skin changes and also for residual after surgery. Any treatment failures could be most often due to inappropriate technique rather than shortcoming of the procedure²⁹. However, ultrasound guided foam sclerotherapy can further enhances the efficacy and safety of the procedure. Hence we recommend more and more of our fellow surgeons to take up this procedure, which can be an efficient tool in management of venous malformation on opd basis.

Polidocanol form sclerotherapy can deliver excellent results as an independent therapy, especially to the infiltrating type of extratruncular form of VM, but with substantial risk of acute and chronic, major, and minor complications and accompanied morbidity This study intended to prove the clinical efficacy of form sclerotherapy, so that it may be fully integrated with other well-established treatment methods in the new concept of a multidisciplinary approach, thereby establishing an advanced management of VM.

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