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Review Article

Image-Guided Sclerotherapy with Sodium Tetradecyl Sulfate: Transforming the Management of Venous Malformations – A Tertiary Care Centre Experience

*Dr. Vivek Ukirde, Dr. Abhay Mustapure[1], Dr. Akshay More[2], Dr. Chaitanya Bendale[3]

*Dr. Vivek Ukirde, Additional Professor, Division of Interventional Radiology, LTMMC and LTMG, Sion, Mumbai,India.
[1]Dr. Abhay Mustapure, MBBS, MD, Fellow, Division of Interventional Radiology, LTMMC and LTMG, Sion, Mumbai,India.
[2]Dr. Akshay More, Assistant Professor, Division of Interventional Radiology, LTMMC and LTMG, Sion, Mumbai,India.
[3]Dr. Chaitanya Bendale, MBBS, MD, Fellow, Division of Interventional Radiology, LTMMC and LTMG, Sion, Mumbai, India.

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ABSTRACT

Background: Venous malformations (VMs) are congenital, low-flow vascular anomalies arising from developmental errors in vascular morphogenesis. They frequently present with pain, swelling, cosmetic deformity, or functional impairment. Image-guided percutaneous sclerotherapy has emerged as a minimally invasive, first-line therapeutic option for symptomatic VMs. Objective: To evaluate the therapeutic efficacy, safety, and clinical outcomes of image-guided percutaneous sclerotherapy using Sodium Tetradecyl Sulfate (STS) in patients with slow-flow venous malformations. Materials and Methods: A prospective study was conducted over two years (2018–2020) involving 50 consecutive patients (mean age 20.3 years; range 2–70 years) with clinically and radiologically confirmed VMs. Foam sclerotherapy using 1.5–3% STS (Tessari technique) was performed under ultrasound and/or DSA guidance at 4–6week intervals. Clinical improvement was assessed based on reduction in pain, lesion size, consistency, and vascularity on Doppler imaging. Results: The most commonly affected regions were the head/neck/face (38%), followed by the lower extremities (30%) and upper extremities (24%). Lesions were medium-sized (3–5 cm) in 48%, small (<3 cm) in 32%, and large (>5 cm) in 20% of patients. Following treatment, 68% demonstrated excellent improvement, 26% good improvement, and 6% minimal improvement. Minor complications such as pain and skin discoloration occurred in 22% of patients. No major adverse events were recorded. Conclusion: Image-guided STS sclerotherapy is a safe, effective, and minimally invasive treatment modality for venous malformations, offering significant symptomatic relief and favorable cosmetic outcomes with low complication rates.

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Introduction

Vascular malformations are congenital morphogenic anomalies of vessels that can present at any age.Vascular malformationsare the result of abnormal development of vascular elements during embryogenesis [1]. Venous malformations (VMs) are the most common type of congenital vascular malformations [2]. The diagnosis and management of venous malformations may be very challenging, as venous malformations may be located anywhere in the body and ranges from small and superficial to large and extensive lesions [3, 8, 35].

***Corresponding author:**

Dr. Vivek Ukirde
Additional Professor, Division of Interventional Radiology
LTMMC and LTMG Hospital, Sion, Mumbai, India
Email: abhaymustapure12@gmail.com
Phone: 9049412733

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VMs are readily diagnosed based on the clinico-radiologic profile and image guided percutaneous sclerotherapy has become the first choice of treatment [2]. The goal of sclerotherapy is to obliterate the vascular channels by causing damage to the endothelium with subsequent inflammation and fibrosis [5].

According to the International Society for the Study of Vascular Anomalies (ISSVA) in 2014, vascular anomalies are divided into two main groups: Proliferating vascular tumours (haemangiomas) and Vascular malformations. Vascular malformations are further subdivided into slow; high-flow groups and complex combined groups. Slow flow vascular malformations are subdivided into Capillary malformation (CM); Lymphatic malformation (LM); venous malformations (VMs) and Combined malformations [5, 6].

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Positive clinical findings are Bluish/purple superficial appearance, Well-defined or diffuse and infiltrative Soft and compressible non pulsatile mass may enlarge during Valsalva manoeuvre, puberty or pregnancy, occasionally palpable phleboliths, Swelling, Pain, inflicts cosmetic annoyance, and exposes the patient to infection [2, 6, 8, 12, 28].

Diagnosis of a vascular malformation is primarily clinical, but ultrasound and especially magnetic resonance imaging (MRI) has an important role in the diagnosis and characterization of the lesion. Prognosis and treatment of vascular malformations depend primarily on the velocity of flow within the lesion [3, 8, 9, 34, 35, 42]. Image guided percutaneous sclerotherapy has become first line treatment for venous malformations [2].

The purpose of this study is to clarify the therapeutic efficacy and tolerance of image guided sclerosis with SETROL (Sodium Tetradecyl Sulphate) in the treatment of low flow venous malformations.

Proposed or expected outcome of the Project-

- Improvements in patient care.
- Attainment of more knowledge regarding the subject.
- Bridging the lacuna in existing knowledge about the subject.

AIMS & OBJECTIVES

- Evaluate the slow flow venous malformation diagnosed clinically and with USG Doppler / MRI.
- Treatment of slow flow venous malformations with percutaneous sclerotherapy.
- Follow up outcome of the patients treated with percutaneous sclerotherapy within 1 year.
- To study complications related to the percutaneous sclerotherapy procedures.

Review Of Literature

Vascular malformations are the result of abnormal development of vascular elements during embryogenesis [1]. Venous malformations are the most common type of congenital vascular malformations. Venous malformations (VMs) are low-flow vascular anomalies composed of endothelial-lined venous channels that can arise in any part of the body, range in size from solitary lesions to diffuse masses and extend across multiple tissue planes. Although VMs are benign, treatment is often pursued after the lesions become symptomatic.

Common symptoms include pain, swelling, bleeding, infection, and cosmetic deformity. Among the various treatments for VMs, percutaneous sclerotherapy has emerged as a first-line therapy. This technique involves placing a needle into the lumen of the lesion and injecting an endothelial-damaging agent (sclerosant) under imaging guidance. This results in thrombosis, fibrosis, and ultimately regression of the lesion. Many VMs can be safely accessed and treated with sclerotherapy using a combination of ultrasonography and fluoroscopy for imaging guidance [11].

Incidence and burden:

Vascular malformations are present in approximately 1.5% of the population. Most often located superficially within the head and neck (40%), trunk (20%), or limbs (40%), Vascular malformations can also be found in the viscera. slow flow vascular malformations accounts for more than 90% of vascular lesions outside the central nervous system [3, 6, 7]. Capillary malformations (CM): CMs have an equal gender distribution; the birth prevalence is 0.3%. Facial CMs often occur in a dermatomal distribution; 45% are restricted to one of the three trigeminal dermatomes. Conversely, 55% of facial CMs overlap sensory dermatomes, crossing the midline or occurring bilaterally.

Lymphatic malformation (LM): LM is characterized by the size of the malformed channels: microcystic, macro-cystic, or combined. lymphatic-venous malformation (LVM) can also occur.

LM is usually noted at birth or within the first 2 years of life. On occasion, LM first becomes evident in later childhood, adolescence, or even adulthood LM is most commonly located on the head and neck; other common sites are the axilla, chest, and perineum.

Venous malformation (VM):

VM is typically sporadic and solitary in 90% of patients. Sporadic VM is usually greater than 5 cm (56%), single (99%), and located on the head/ neck (47%), extremities (40%), or trunk (13%). Almost all lesions involve the skin, mucosa, or subcutaneous tissue; 50% also affect deeper structures (i.e., muscle, bone, joints, viscera).

Classification:

In a 1982 landmark article, Mulliken and Glowacki [39] put forth a vascular anomaly classification scheme based on endothelial cell characteristics. Vascular anomalies were divided into vascular tumours or vascular malformations. Vascular malformations were further divided into capillary malformations (CMs), venous malformations (VMs), lymphatic malformations (LMs), arteriovenous malformations (AVMs), and combined lesions.

In 1993, a complementary classification scheme was developed by Jackson and colleagues8 based on flow characteristics, which has evolved to divide vascular malformations into high-flow lesions and low-flow lesions [3].

Slow-flow vascular malformations contain combinations of capillary, venous, and lymphatic components [4, 7, 33].

Classification of vascular anomalies (ISSVA 2014)

According to the International Society for the Study of Vascular Anomalies (ISSVA) in 2014, vascular anomalies are divided into two main groups:

1.Proliferating vascular tumors (haemangiomas)

2.Vascular malformations.

Vascular malformations are further subdivided into slow and high-flow groups and complex combined groups (Table 1) [5, 6, 7, 32].

Table 1.

TUMORS	MALFORMATIONS	
	SLOW FLOW	FAST FLOW
Infantile hemangioma (IH)	Capillary malformation (CM) Cutis marmorata telangiectatica congenita (CMTC) Telangiectasias	Arterial malformation (AM) Aneurysm Atresia Ectasia Stenosis
Congenital hemangioma (CH)	Lymphatic malformation (LM)	Arteriovenous malformation (AVM)
R Rapidly involuting congenital hemangioma (RICH) Noninvoluting congenital hemangioma (NICH)	Microcystic Macrocystic Primary lymphedema	Capillary malformation-arteriovenous malformation (CM-AVM) Hereditary haemorrhagic telangiectasia (HHT) PTEN-associated vascular anomaly
Hemangioendotheliomas Kaposiform hemangio-endothelioma (KHE) Other	Venous malformation (VM) Cerebral cavernous Malformation (CCM) Cutaneomucosal venous malformation (CMVM) Glomuvenous malformation (GVM) Verrucous hemangioma (VH)	Combined malformations Capillary-arteriovenous malformation (CAVM) Capillary-lymphatic arteriovenous malformation (CLAVM)

Pyogenic granuloma (PG)	Combined malformations Capillary-venous malformation (CVM) Capillary-lymphatic malformation (CLM) Capillary-lymphatic-venous malformation (CLVM) Lymphatic-venous malformation (LVM)	

High Flow Vascular Malformations

High flow vascular malformations exhibit variable presentation dependent on location. Superficial lesions may present as a warm painless mass with palpable bruit and associated dilated veins. Skin erosion and bleeding is possible.

Deeper lesions may present with steal phenomena as the malformation deprives blood flow from downstream structures [6].

Slow-Flow Vascular Malformations

Venous malformations result from abnormal sprouting or branching during embryonic development. Venous malformations may be focal, multifocal or diffuse and infiltrative [21].

Clinical Features Of Venous Malformations [6, 8, 34, 35]

- Non pulsatile, compressible area of soft-tissue prominence or a discrete soft-tissue mass associated with skin temperature, thrill, or bruit & blue in color.
- Swelling and pain, worse as the day progresses and exacerbated in the dependant position.
- Paediatric patients with altered limb growth and gait abnormalities.
- The lesions usually increase in size and coloration during a Valsalva manoeuvre, with dependent positioning, and sometimes with the application of a tourniquet. If the skin is involved, a blue-purple hue or superficial veins can be seen.
- Sudden enlargement of lesions may occur after trauma and with intralesional thrombosis. Enlargement can also occur during the hormonal changes of puberty, pregnancy, and oral contraceptive use.

Imaging in venous malformations (VMs) [3, 4, 9,10,26, 27, 30, 33, 39, 41]

Types of imaging modality used are

1. RADIOGRAPHS
2. ULTRASOUND
3. MRI
4. Digital subtraction angiography (DSA)

1. RADIOGRAPHS

Calcified phleboliths can be identified on plain Xray radiograph.

2. ULTRASOUND

Ultrasound with color Doppler evaluation for perceptible flow is the first line of imaging in the evaluation of suspected venous malformations.

Venous malformations can be seen as focal, well-defined, sponge like lobulated structures with varying echogenicity or as multiple tortuous and beaded varicosities arranged in a haphazard manner, violating multiple tissue planes.

Monophasic waveforms on Color Doppler examination reveals typical of venous malformations in most of cases. some venous malformations may have minimal or no flow, which may reflect very low flow below detectable limits or thrombosis.

Biphasic flow may be seen in few of lesions, possibly reflecting a mixed capillary component

3. MRI

An MRI protocol using T1 and T2-weighted imaging is currently the preferred method as it offers non-invasive imaging with high spatial resolution that is able to characterize the structure of the lesion and its involvement with the surrounding tissue.MRI has become the imaging modality of choice in the confirmation, characterization, and differentiation between vascular malformations and their subtypes and allows for treatment planning and objective imaging follow-up posttherapy.

MRI is currently the preferred complementary imaging modality to ultrasound and is particularly useful in evaluating the full extent of lesions and for planning and assessing response to therapy. MRI protocol is shown in table 2 [20, 43].

Table 2

Sequence	Feature Evaluated
Coronal (less frequently sagittal) STIR or T2-weighted fat-saturated	Extent of the lesion
Axial T1-weighted	Contents: blood, proteinaceous material, fat, and involvement of adjacent musculature
Axial STIR or T2-weighted fat-saturated	Relation between malformation and adjacent structures: skin, neurovascular bundle, bone
Axial gradient T1-weighted	Presence of phleboliths, recent bleeding, or flow voids in hypervascular lesions
Axial T1-weighted fat-saturated before gadolinium enhancement	Enhancement pattern (sequence required for this evaluation)
2D Time-of-flight MR angiography and MR venography*	Vascular supply, deep venous system, and flow characteristics
Multiple-phase gadolinium-enhanced MR angiography*	Flow dynamics
Axial T1-weighted fat-saturated after gadolinium enhancement	Enhancement pattern: dynamics and possible solid component
Second-plane T1-weighted fat-saturated after gadolinium enhancement	Delayed enhancement; very useful in venous malformations
* Optional sequence for evaluation of definite lymphatic malformation or for follow-up of venous malformation.	

4. Diagnostic Angiography

DSA provides high temporal (1s frame time) and high spatial resolution (1 mm) but is an invasive procedure that uses iodinated contrast material and ionizing radiation with images acquired as projections.

Angiography is only indicated for intravascular embolization and demonstrates a hyper vascular mass with a dense, prolonged capillary blush, and dilated feeding and draining vessels.

Treatment Of Venous Malformations

Treatment reserved for symptomatic or cosmetically disfiguring venous malformations [8, 11, 22, 25, 30, 31, 39, 40, 41].

It includes:

- o Observation
- o Custom-fitted compression garments
- o Sclerotherapy
- o Cryoablation
- o Laser photocoagulation therapy
- o Surgical resection

Custom-fitted compression garments reduce pain & blood stagnation and minimize expansion of lesions and phlebolith for¬mation in Patients with an extensive extremity venous malformation.

Intervention for venous malformations is reserved for symptomatic lesions that cause pain, deformity, obstruction (i.e., vision, airway), or gastrointestinal bleeding

Sclerotherapy[23, 24, 29, 36, 37, 38]

First-line treat¬ment in venous malformation is sclerotherapy, which is safer and more effective than resection. Good to excellent results are obtained in most of patients, including reducing the size of the malformation and alleviating symp¬toms. Sclerotherapy is repeated until symptoms are alleviated or when injectable vascular spaces are no longer present.

Sclerotherapy is targeted elimination of small vessels, varicose veins and vascular anomalies by the injection of a sclerosant.

The aim of sclerotherapy is to damage the vessel wall and transform it into a fibrous cord that cannot be recanalized.

It is a simple, cost-effective, efficacious and aesthetically acceptable modality for both therapeutic and aesthetic purposes.

Sclerotherapy is indicated in the treatment of low-flow vascular malformations and symptomatic haemangiomas.

Sclerosing agents most commonly used are polidocanol and sodium tetradecyl sulfate. More recently, these sclerosants have been used in microfoam form for increased efficacy [15, 18, 19, 37].

Sclerosing agents

•Detergents: Disrupt vein cellular membrane
- ○ Sodium tetradecyl sulfate (Sotradecol)
- ○ Polidocanol (Aethoxysklerol)
- ○ Sodium morrhuate (Scleromate)
- ○ Ethanolamine oleate (Ethamolin)

• Osmotic agents: Damage the cell by shifting the water balance
- ○ Hypertonic sodium chloride solution
- ○ Sodium chloride solution with dextrose (Sclerodex)

• Chemical irritants: Damage the cell wall
- ○ Chromated glycerin (Scleremo)
- ○ Polyiodinated iodine (Sclerodine)
- ○ Alcoholic solution of zein (Ethibloc)
- ○ OK 432 (Picibanil)
- ○ Bleomycin

Sodium Tetradecyl Sulphate(STS): Combined with non-ionic contrast for final concentration of 1.5%; foamed according to Tessari's method [13]

Doxycycline: 10 mg/mL, maximum dose 1000 mg

Ethanol: 95% concentration; Risk of systemic toxicity increases with doses > 1 mL/kg or total volume > 60 mL

Bleomycin:0.3-0.5 mg/kg

OK-432/Picibanil: 1-3 intralesional injections of 0.2 mL each dose at 0.01 mg/kg

Polidocanol: 0.5-1.0% concentration; Inject 0.1-0.3 mL for a total administered dose of 10 mL [17]

n-BCA glue: Combined with Ethiodol for polymerization

Onyx: Dissolved with DMSO and tantalum; three different concentrations (6%, 6.5%, 8%)

(STS: Sodium Tetradecyl Sulphate; n-BCA: n-butyl cyanoacrylate.)

The basic principle of a successful sclerotherapy technique is the use of an optimal volume and concentration of the sclerosant according to the size of the vessel. The quantity of the sclerosant and the number of sites injected depends on the size and location of the vascular malformation.

The maximum dosage of the sclerosant should not be exceeded. The maximum dosage for POL is 2 mg/kg and for STS is 10 ml of 3% solution. Initially, it is preferable to inject a lower concentration and a lower dose to avoid unexpected reactions.

Using real-time sonographic / DSA guidance, lesions are punctured percutaneously with a 20gauge needle, First begin injection into the largest vein and then into the small varicosities. After injection, the site is compressed with cotton balls and tape followed by compression garments. Patients should also be instructed to walk for 30 min after the procedure and daily for the next few days. Intensive workouts, heavy exercise, hot baths, strong UV radiation as well blood thinners like aspirin should be avoided for a few days.

The procedure may be performed in multiple sittings. Treatment intervals may vary, but allowing 6-8 weeks between treatments helps to minimize the number of necessary sessions. The number of sittings depends on the response, concentration of sclerosant, volume used and skill of the operator.

Advantage of sclerotherapy

- Minimally invasive procedure that can be performed in the outpatient clinic and there is no need for hospitalization or an aesthetic.
- There is no surgical scarring and virtually no downtime.

Limitations of sclerotherapy

Sclerotherapy is not effective for the treatment of
- Flat port wine stains,
- High-flow lesions like AV fistulas

Contraindications of sclerotherapy

Contraindications include:

- Allergic reactions to sclerosants.
- Immobile patient because ambulation is important to minimize the risks of thrombosis
- Hypercoagulable state
- Arterial disease
- Superficial and deep venous thrombosis
- Dependency edema & diabetes mellitus there is compromised circulation and prolonged healing.
- Pregnancy
- Myocardial decompensation
- Migraine
- Serious systemic illness

Complications of sclerotherapy [14, 24, 38]

While sclerotherapy is usually a safe procedure, complications may occur due to inappropriate patient selection or improper injection techniques. The complications may be acute or delayed.

Complications include

- Hyperpigmentation
- Matting
- Local urticarial cutaneous necrosis
- Atrophy and contracture due to extravasation of the sclerosant into muscle.

- Microthrombi
- Accidental intra-arterial injection
- Phlebitis
- Deep vein thrombosis &|thromboembolism
- Scintillating scotomas
- Nerve damage and allergic reactions.
- Compartment compression in extremity venous malformations.
- Systemic adverse events following sclerotherapy includes haemolysis, haemoglobinuria, and DIC.
- Ethanol associated additional systemic toxicity includes CNS depression, pulmonary hypertension, haemolysis, thromboembolism, and arrhythmias.

Although sclerotherapy effectively reduces the size of the lesion and improves symptoms, the malformation remains. Consequently, patients may have a mass or visible deformity after treatment that may be improved by resection.

Patients and families are counselled that venous malformations can expand following excision, and additional operative procedures may be required in the future.

MATERIALS AND METHODS

Method of Collection of Data / Study Description:

a. Design: Prospective.
b. Place of study: at tertiary hospital
c. Type of study: Image guidedEndovascular Interventional procedures
d. Duration of study: 2 years (2018-2020)
e. Sample size: 50 Patients.
f. Source of Data: Cases referred to intervention Radiology unit of Department of Radiology at tertiary hospital
g. Sampling Method: prospective study of 50 consecutive patients with venous malformations who have given valid consent and fulfilling the inclusion and exclusion criteriawere subjected for Percutaneous sclerotherapy study.
h. Inclusion and Exclusion criteria:

Inclusion Criteria: Case of venous malformation:

- Symptomatic patients diagnosed clinically and with USG Doppler / MRI consenting for the study.

Exclusion Criteria:

- Patients not consenting for the study
- Patients with known h/o contrast allergy
- Immobile patient
- Patient with Hypercoagulable state
- Patient having arterial disease
- Patient having Superficial and deep venous thrombosis
- Pregnant patient
- Patient with myocardial decompensation
- Patient having Migraine
- Patient having Serious systemic illness
- Patients with deranged renal function (Serum creatinine >1.4 mg/dl)
- Patients with end stage Renal failure

Study Description: All 50 Patients with venous malformations fulfilling inclusion criteria, diagnosed clinically and with USG Doppler / MRI was clinically evaluated prior to sclerotherapy. Size & consistency of swelling and vascularity within the swelling on USG Doppler was evaluated. Optimal volume and concentration of the sclerosant (Sodium Tetradecyl Sulphate) according to the size of vessel were injected percutaneously under image guidance. The procedure was performed in multiple sittings depending on outcome with a time interval of 4-6 weeks. On follow up, outcome of patient's improvement in the size & consistency of swelling and vascularity within the swelling on USG Doppler was graded with scores. Based on total improvement score outcome was classified as poor, minimal, good and excellent.

Name of the sclerosant:SETROL (Sodium Tetradecyl Sulphate)

Concentration of the sclerosant: 0.5 – 1.0 %

Dose of the sclerosant: 0.1 – 0.3 ml for a total administered dose of 10 ml.

Maximum dose of the sclerosant: 2mg/kg

Route of administration of the sclerosant: Percutaneous under image guidance

f) Machines used:

- Siemens Artis Zee biplanar DSA
- Samsung RS80A USG machine

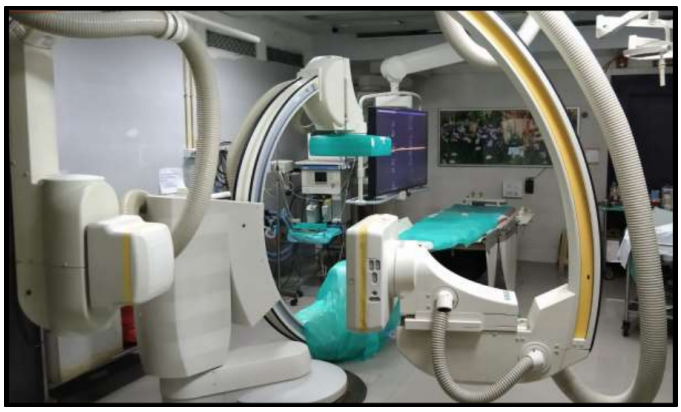


Fig.1.1 showing Siemens Artis Zee Biplanar DSA machine



Fig.1.2 showing Samsung RS80A USG machine

Technique

Well informed written consent was obtained in all cases after explaining the procedure, Its advantages and its complications in detail.

Routine Investigations

•Blood Investigations: CBC, KFT, LFT, PT/INR, HIV, HBSAG, HCV.
•Imaging Investigations: MRI

Ethical clearance was obtained from the research and dissertation committee/ ethical committee of the institution for this study.

A prospective study was conducted between January 2019 and September 2020 included total of 50 patients between 2 and 70 years of age (mean age 20.34 years) referred to the interventional radiology department in our tertiary care center.

These patients with symptomatic VMs, diagnosed on MRI have complaints of disabling pain not responding to conservative management, swelling with functional impairment affecting daily activity or quality of life/ excessive cosmetic implication/physiological disability and with recurrent infection. Treatment was mainly DSA and ultrasound guided percutaneous SETROL (3% Sodium Tetradecyl Sulphate)foam sclerosis using Tessari's technique in multiple sessions separated by 4-6weeks interval according to response of treatment done.

Procedure

The treatment was performed as OPD basis in an outpatient operating room. In all cases, the written informed consent was obtained from the patients or their parents before the procedure. At the beginning of each treatment session, a pre-treatment color-Doppler was carried out to verify the type, depth and accessibility of the malformation. Depending on the topography of the malformation and the patient's age, local anesthesia or mild sedation was given.

The sclerosing agent used was SETROL (Sodium Tetradecyl Sulphate) at concentrations ranging from 1.5% to 3%, according to the size and depth of the lesion and the response to previous treatment. Foam was produced by modified Tessari's method [13], the sclerosing liquid being diluted with air and water-soluble contrast (OMNIPAQUE 350) at a ratio of 1:1:2 (1 volume of liquid sclerosant, 1 volume of contrast and 2 volumes of air) using a three-way stopcock and pumping for foam sclerotherapy.

The patient was supine or prone, according to the topography of the lesion. First, a scalp vein (20 G/ 22 G butterfly needle 1.1 48 mm or 0.9 22 mm) was inserted under ultrasound / DSA-guided control in all aseptic precautions with sterile gel and gloves [14,15]. After confirming by aspiration that the needle was inside the venous lumen, the foam was injected [16]. The volume of foam injected was estimated by the amount necessary to obtain a venous spasm, but never exceeded 10 ml.

After the procedure the lesion was compressed with sterile cotton for 10 minutes. After one hour of observation the patient was released with prescription of some analgesics with instructions to rest and to avoid any sports activity for 10 days [17]. In those patients with malformation on a limb, an elastic compression stocking (20e36 mmHg) was worn during the day for 15 days.

Post procedure follow up

A clinical and ultrasound examination was performed on day 8. In cases of repeated procedures, an interval of at least 4-6 weeks between sessions was observed [18]. The decision to continue the treatment or not was made on the basis of the symptomatic improvement regarding the decrease in pain, size, change in consistency of lesion and obliteration of vascular channels on imaging. The end point was successful reduction in size or complete obliteration of vascular channels [19].The median follow-up of patients was 2months after the last treatment session. When a consultation was not possible, telephone contact was made with the patient.

Data Collection And Analysis

The study protocol was approved by the Institutional Ethics Committee. Data concerning image guided sclerotherapy procedures that were carried out in our institution were prospectively accumulated.

Patients were asked to follow up at 4-6 weeks intervaland 2 months after the last sclerotherapy session for clinical assessment,evaluation for adverse events and duplex ultrasoundexamination. The safety end point was a freedom from procedure-related death within 30 days after the procedure.

Statistical Methods

Collected data was entered into Microsoft excel spreadsheet. Continuous variable waspresented as mean ± SD. Categorical variables were expressed in frequency andpercentage.

VMs were categorised based on their

A. Age group
B. Sex group.
C. Site of malformations in head neck & face region, over lower extremity, over upper extremity and over trunk.
D. Size of malformations in small (<3cm),medium (3-5cm), and large (>5cm) sized VMs.
E. Mode of sclerosis: sclerotherapy done in under DSA+USG guidance, under DSA guidance and under USG guidance.
F. Total number of sclerotherapy sessions.
G. Total number of vials used according to the size of lesion and patient response to the treatment.
H. Complications.
I. Total score after each session based on size of swelling, consistency of swelling and vascularity within the swelling as given in table 3.

Table 3

Size of swelling (% of reduction)			
1 - (0 - 5%)	2 – (25 - 50%)	3 – (50 - 75%)	4 - (75 – 00%)
Change in consistency of swelling			
0 – (Soft)	1- (Semi-hard)	2 –(Hard)	
Vascularity within the swelling (% of decrease on USG)			
1- (0 - 25%)	2 – (25 - 50%)	3– (50 - 75%)	4 - (75 – 100%)

J. Total final outcome score based on size of swelling, consistency of swelling and vascularity within the swelling as given in table 3.

K. Grades of improvement based on total score of final outcomeas given in table 4.

Table 4

SCORE	**GRADE OF IMPROVEMENT**
< 3	Poor
3 - 5	Minimal
6 - 8	Good
9 - 10	Excellent

L. Current status of the VMs.

Comparisons were made between these groups by performing "Descriptive test", "One Way Repeated Measure ANOVA test", "Chi- square test" and "paired samples T-test".
For multiple comparisons "Post HOC test" was used.
For small sample size "Fischer exact test" was used whenever required.

p value<0.05 was considered as of statistical significance.
Statistical software STATAversion 14.0 was used for data analysis.

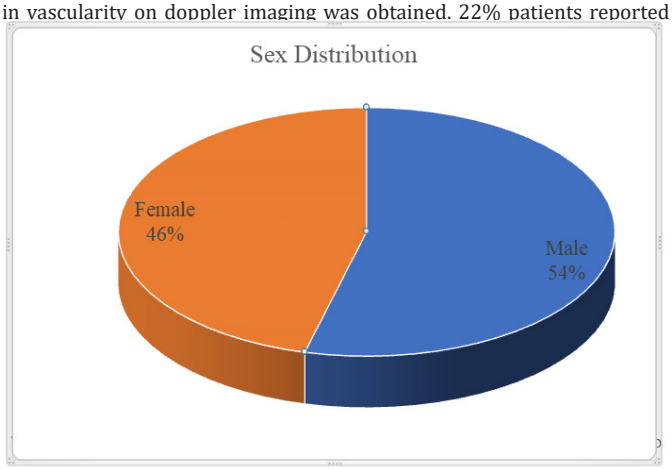
CONFLICT OF INTEREST - nil.

Observations And Results

Observation:Between January 2019 and September 2020, we analyzed the complete records of 50 patients with symptomatic venous malformation, diagnosed on MRI treated by SETROL (Sodium Tetradecyl Sulfate) foam sclerosis using Tessari's technique under guidance of DSA and ultrasound. multiple sclerotherapy sessions separated by 4-6week interval according to response of treatment done; during the follow-up, we evaluated symptomatic improvement regarding the decrease in pain, size, change in consistency of lesion and obliteration of vascular channels on imaging. The end point was successful reduction in size or complete obliteration of vascular channels.

Results

A total of 50 patients between 2 and 70 years were treated (38% had lesions on head neck & face, 30 % on lower extremity, 24% on upper extremity and 8% on trunk). The lesion was Small (<3 cm) in size in 32%, Medium (3-5 cm) in 48% and Large (>5 cm) in 20% of patients. The concentrations of SETROL (Sodium Tetradecyl Sulfate) used ranged from 1.5% to 3%. The maximum number of sessions was 5 (between January19 to September 20). After a median follow-up at 2 months after the last session, 68% patients reported excellent improvement, 26% good improvement and 6% minor improvement in decrease in pain; change in consistency; reduction in size compare to the original size and change in vascularity on doppler imaging was obtained. 22% patients reported minor complications.



Demographical Data

Table 2.1: Sex distribution.

sex	Frequency	Percent	Valid Percent	Cumulative Percent
Male	27	54.0	54.0	54.0
Female	23	46.0	46.0	100.0
Total	50	100.0	100.0	

females, n=23 (46%), out of total n=50, as shown in above table 2.1 and pie chart.

Table 2.2: Age distribution

Age in years	Frequency	Percent	Valid Percent	Cumulative Percent
2	2	4.0	4.0	4.0
6	1	2.0	2.0	6.0
7	4	8.0	8.0	14.0
8	4	8.0	8.0	22.0
10	4	8.0	8.0	30.0
11	2	4.0	4.0	34.0
12	2	4.0	4.0	38.0
13	2	4.0	4.0	42.0
14	2	4.0	4.0	46.0
15	2	4.0	4.0	50.0
16	3	6.0	6.0	56.0
17	2	4.0	4.0	60.0
18	2	4.0	4.0	64.0
20	3	6.0	6.0	70.0
23	1	2.0	2.0	72.0
24	2	4.0	4.0	76.0
25	1	2.0	2.0	78.0
30	3	6.0	6.0	84.0
32	1	2.0	2.0	86.0
35	1	2.0	2.0	88.0
42	1	2.0	2.0	90.0
50	1	2.0	2.0	92.0
55	1	2.0	2.0	94.0
60	1	2.0	2.0	96.0
69	1	2.0	2.0	98.0
70	1	2.0	2.0	100.0
Total	50	100.0	100.0	

Table 2.3: statistics of age distribution.

Age		
N	Valid	50
	Missing	0
Mean	20.34	
Std. Deviation	16.238	

Age ranges from 2 to 70 years (mean age is 20.34 years with standard deviation 16.238), as shown in above table 2.2 and table 2.3.

Table 2.4: Site of Malformations

	Site	Frequency	Percent
Valid	HNF	19	38.0
	LE	15	30.0
	T	4	8.0
	UE	12	24.0
	Total	50	100.0

(Abbreviations: HNF- HEAD NECK & FACE, LE- LOWER EXTRIMITY, T- TRUNK, UE- UPPER EXTRIMITY)

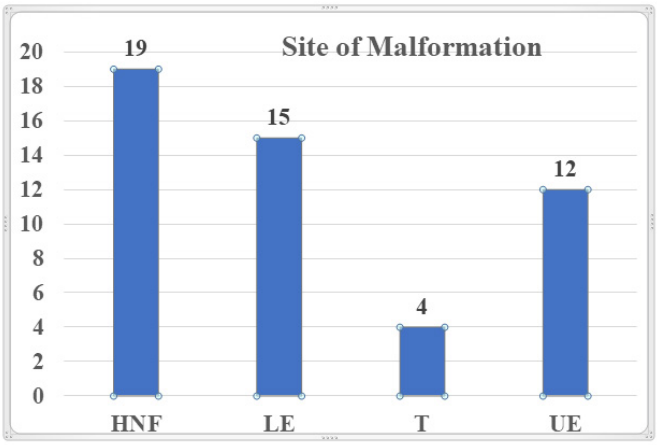


Figure 2.2: Column showing site of malformation

(Abbreviations: HNF- HEAD NECK & FACE, LE- LOWER EXTRIMITY, T- TRUNK, UE- UPPER EXTRIMITY)

In this study, 38% patients had VMs on head neck & face region, 30% over lower extremity, 24% over upper extremity and 8% over trunk, as shown in Table 2.4 and figure 2.2

Table 2.5: Lesions Size			
	Lesion size	**Frequency**	**Percent**
Valid	Small (<3 cm)	16	32.0
	Medium (3-5 cm)	24	48.0
	Large (>5 cm)	10	20.0
	Total	50	100.0

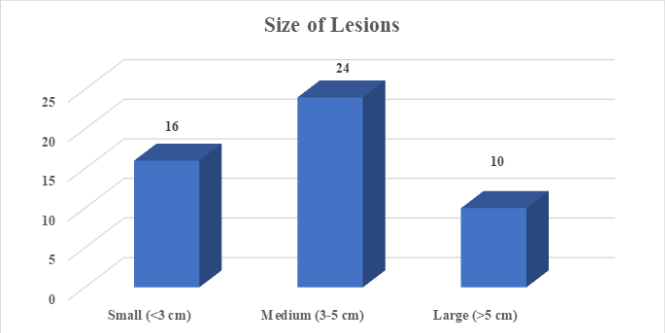


Figure 2.3: 3 D clustered Column showing lesions size

Table 2.6: Mode of sclerosis			
Valid	**Mode of Sclerosis**	**Frequency**	**Percent**
	DSA	19	38.0
	USG	10	20.0
	DSA + USG	21	42.0
	Total	50	100.0

The 48% patients had medium sized (3-5cm), 32% small sized (<3cm) and 20% large sized (>5cm) VMs, as shown in table 2.5 and figure 2.3.

Mode of sclerosis was under DSA+USG guidance in 42% patients, under DSA guidance in 38% patients and under USG guidance in 20% patients, as shown in table 2.6.

Multiple sessions of sclerosis and number of vials used according to the size of lesion and patient response to the treatment.

Total No. of Sclerotherapy Session
Table 2.7

	Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
1	19	38.0	38.0	38.0
2	13	26.0	26.0	64.0
3	9	18.0	18.0	82.0
4	1	2.0	2.0	84.0
5	8	16.0	16.0	100.0
Total	50	100.0	100.0	

Table 2.7 showing total number of sclerotherapy sessions received by the patients to achieve the expected outcome.

Total No. of Vialused

Table 2.8

	Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
1	6	12.0	12.0	12.0
2	13	26.0	26.0	38.0
3	7	14.0	14.0	52.0
4	13	26.0	26.0	78.0
5	3	6.0	6.0	84.0
6	1	2.0	2.0	86.0
7	1	2.0	2.0	88.0
8	3	6.0	6.0	94.0
10	2	4.0	4.0	98.0
11	1	2.0	2.0	100.0
Total	50	100.0	100.0	

Table 2.8 showing total number of vials used according to the size of lesions to achieve the expected outcome.

Descriptive study showing comparison between size of lesions and total number of vials used in table 2.9.

Table 2.9.

Total Vial Used

	N	**Mean**	**Std. Deviation**	**Minimum**	**Maximum**
Small (<3 cm)	16	2.25	1.125	1	4
Medium (3-5 cm)	24	3.58	1.998	1	10
Large (>5 cm)	10	6.60	2.716	4	11
Total	50	3.76	2.454	1	11

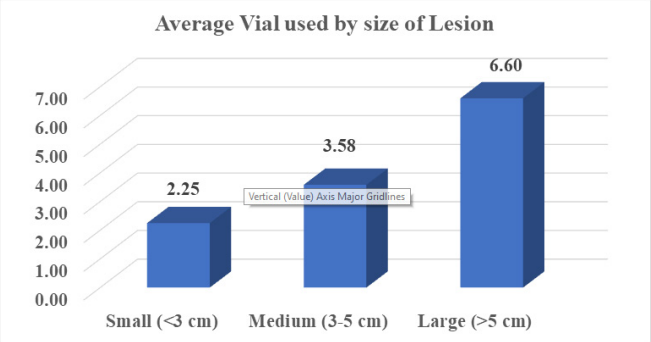


Figure 2.4: 3 D clustered Column showing average number of vials used based on lesions size.

One Way Repeated Measure ANOVA test showing comparisons between and within groups based on size of VMs with total number of vials usedas shown in table 3.

Table 3

ANOVA test

TOTAL VIAL USED

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	117.887	2	58.943	15.631	.000
Within Groups	177.233	47	3.771		
Total	295.120	49			

ANOVA test show there is significant difference in mean vial used for lesion size in between groups than within groups (p value is 0.000), as shown in table 3.

Post Hoc Tests

Table 3.1

Multiple Comparisons

Dependent Variable: Total Vial used

Bonfer-roni	(J) Size of Lesion	Mean Differ-ence (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound
Small (<3 cm)	Medium (3-5 cm)	-1.333	.627	.116	-2.89
	Large (>5 cm)	-4.350*	.783	.000	-6.29
Medium (3-5 cm)	Small (<3 cm)	1.333	.627	.116	-.22
	Large (>5 cm)	-3.017*	.731	.000	-4.83
Large (>5 cm)	Small (<3 cm)	4.350*	.783	.000	2.41
	Medium (3-5 cm)	3.017*	.731	.000	1.20

Post Hoc Testsshowing, the total sclerosant volume used in large group differ significant from small and medium size group but small and medium group has not significant p value, as shown in table 3.1.

Crosstables showing Case Processing Summary:

Table 3.2.

	Valid		Cases Missing		Total	
Session 1Size	31	62.0%	19	38.0%	50	100.0%
* Session FinalSize	50	100.0%	0	0.0%	50	100.0%

Session 1Size * Session 2Size

Table 3.3

Crosstab

			Sess2_ Size				Total
			1	2	3	4	
Sess1_ Size	1	Count	5	7	2	0	14
		% within Sess1_ Size	35.7%	50.0%	14.3%	0.0%	100.0%
	2	Count	0	1	8	3	12
		% within Sess1_ Size	0.0%	8.3%	66.7%	25.0%	100.0%
	3	Count	0	0	0	5	5
		% within Sess1_ Size	0.0%	0.0%	0.0%	100.0%	100.0%
		Count	5	8	10	8	31
		% within Sess1_ Size	16.1%	25.8%	32.3%	25.8%	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	33.657a	6	.000

a. 12 cells (100.0%) have expected count less than 5. The minimum expected count is .81.

Table 3.2 & 3.3 show there is significant decrease in lesion size after session 2 of sclerosis than session 1(Chi-square shows p value is 0.000)

Session 1Size * Session FinalSize:

Table 3.4.

Crosstab

Session Final Size

Session-1Size			2	3	4	Total
	1	Count	3	3	8	14
		% within Session 1Size	21.4%	21.4%	57.1%	100.0%
	2	Count	3	4	8	15
		% within Session 1Size	20.0%	26.7%	53.3%	100.0%
	3	Count	0	3	5	8
		% within Session 1Size	0.0%	37.5%	62.5%	100.0%
	4	Count	0	0	13	13
		% within Session 1Size	0.0%	0.0%	100.0%	100.0%
Total		Count	6	10	34	50
		% within Session 1Size	12.0%	20.0%	68.0%	100.0%

Table 3.5

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	11.240a	6	.081
Likelihood Ratio	15.544	6	.016
Linear-by-Linear Association	6.687	1	.010
N of Valid Cases	50		

a. 8 cells (66.7%) have expected count less than 5. The minimum expected count is .96.

Table 3.4& 3.5 show there is significant reduction in lesion size after final session of sclerosis than session 1(Chi-square shows p value is 0.081)

Frequencies

Table 3.6.

Session 1 Size

Size reduction after session 1 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(0 -25%)	14	28.0	28.0	28.0
	(25 - 50%)	15	30.0	30.0	58.0
	(50 - 75%)	8	16.0	16.0	74.0

Table 3.7.

Session 1Consistency

Change in consistency after session 1 of sclerosis	Frequency	Percent	Valid Percent	Cumulative Percent
Soft	34	68.0	68.0	68.0
Semi Hard	14	28.0	28.0	96.0
Hard	2	4.0	4.0	100.0
Total	50	100.0	100.0	

Following frequency Tables showing total numberof VMs after session 1 sclerosis based on size (Table3.6), consistency (Table3.7),vascularity (Table3.8) and total score (Table3.9)

Table 3.7 showstotal number of lesions with its consistency after session 1 of sclerosis.

Table 3.8.

Session 1Vascularity

Change in vascularity after session 1 of sclerosis	Frequency	Percent	Valid Percent	Cumulative Percent
(0 -25%)	9	18.0	18.0	18.0
(25 - 50%)	13	26.0	26.0	44.0
(50 - 75%)	11	22.0	22.0	66.0
(75 – 100%)	17	34.0	34.0	100.0
Total	50	100.0	100.0	

Table 3.8 showstotal number of lesionswith its vascularity after session 1 of sclerosis.

Table 3.9.

Session 1 Total score

Total score after session 1 of sclerosis	Frequency	Percent	Valid Percent	Cumulative Percent
2	9	18.0	18.0	18.0
3	5	10.0	10.0	28.0
4	8	16.0	16.0	44.0
5	3	6.0	6.0	50.0
6	7	14.0	14.0	64.0
7	4	8.0	8.0	72.0
8	4	8.0	8.0	80.0
9	8	16.0	16.0	96.0
10	2	4.0	4.0	100.0
Total	50	100.0	100.0	

Table 3.9 showstotal number of lesions with its totalscore after session 1 of sclerosis.

Table 4

Session 2 Size

Reduction in size after session 2 of sclerosis	Frequency	Percent	Valid Percent	Cumulative Percent
(0 -25%)	5	10.0	16.1	16.1
(25 - 50%)	8	16.0	25.8	41.9
(50 - 75%)	10	20.0	32.3	74.2
(75 – 100%)	8	16.0	25.8	100.0
Total	31	62.0	100.0	
Missing System	19	38.0		
Total	50	100.0		

Table 4 showing total number of VMs based on its size reduction after session 2 of sclerosis.

Table 4.1.

Session 2 Consistency

Change in consistency after session 2 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Soft	17	34.0	54.8	54.8
	Semi Hard	11	22.0	35.5	90.3
	Hard	3	6.0	9.7	100.0
	Total	31	62.0	100.0	
Missing	System	19	38.0		
Total		50	100.0		

Table 4.1 showing total number of VMs based on its change in consistency after session 2 of sclerosis.

Table 4.2.

Session 2 Vascularity

Change in vascularity after session 2 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(0 -25%)	1	2.0	3.2	3.2
	(25 - 50%)	7	14.0	22.6	25.8
	(50 - 75%)	11	22.0	35.5	61.3
	(75 – 100%)	12	24.0	38.7	100.0
	Total	31	62.0	100.0	
	System	19	38.0		
Missing	System	19	38.0		
Total	50	100.0			

Table 4.2 showing total number of VMs based on its change in vascularity after session 2 of sclerosis.

Table 4.3.

Session 2 Total score

Total score after session 2 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	2	1	2.0	3.2	3.2
	3	3	6.0	9.7	12.9
	4	3	6.0	9.7	22.6
	5	6	12.0	19.4	41.9
	6	5	10.0	16.1	58.1
	7	1	2.0	3.2	61.3
	8	5	10.0	16.1	77.4
	9	4	8.0	12.9	90.3
	10	3	6.0	9.7	100.0
	Total	31	62.0	100.0	
Missing System		19	38.0		
Total	50	100.0			

Table 4.3 showstotal number of lesions based on its totalscore after session 2 of sclerosis.

Table 4.4.

Session 3 Size

Reduction in size after session 3 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(25 - 50%)	7	14.0	38.9	38.9
	(50 - 75%)	6	12.0	33.3	72.2
	(75 – 100%)	5	10.0	27.8	100.0
	Total	18	36.0	100.0	
Missing	System	32	64.0		
Total		50	100.0		

Table 4.4 showing total number of VMs based on its size reduction after session 3 of sclerosis.

Table 4.5.

Session 3 Consistency

Change in consistency after session 3 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Soft	5	10.0	27.8	27.8
	Semi Hard	11	22.0	61.1	88.9
	Hard	2	4.0	11.1	100.0
	Total	18	36.0	100.0	
Missing	System	32	64.0		
	Total	50	100.0		

Table 4.5 showing total number of VMs based on its change in consistency after session 3 of sclerosis.

Table 4.6.

Session 3 Vascularity

Change in vascularity after session 3 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(50 - 75%)	10	20.0	55.6	55.6
	(75 – 100%)	8	16.0	44.4	100.0
	Total	18	36.0	100.0	
Missing	System	32	64.0		
Valid		50	100.0		

Table 4.6 showing total number of VMs based on its change in vascularity after session 3 of sclerosis.

Table 4.7.

Session 3 Total score

Total score after session 3 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	5	5	10.0	27.8	27.8
	6	2	4.0	11.1	38.9
	7	3	6.0	16.7	55.6
	8	2	4.0	11.1	66.7
	9	5	10.0	27.8	94.4
	10	1	2.0	5.6	100.0
	Total	18	36.0	100.0	
Missing	System	32	64.0		
	Total	50	100.0		

Table 4.3 showstotal number of lesions based on its totalscore after session 3 of sclerosis.

Table 4.8.

Session 4Size

Reduction in size after session 4 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(25 - 50%)	2	4.0	22.2	22.2
	(50 - 75%)	6	12.0	66.7	88.9
	(75 – 100%)	1	2.0	11.1	100.0
	Total	9	18.0	100.0	
Missing	System	41	82.0		
Total		50	100.0		

Table 4.8 showing total number of VMs based on its size reduction after session 4 of sclerosis.

Table 4.9.

Session 4 Consistency

Change in consistency after session 4 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Soft	1	2.0	11.1	11.1
	Semi Hard	8	16.0	88.9	100.0
	Total	9	18.0	100.0	
	System	41	82.0		
Missing	System	41	82.0		
Total		50	100.0		

Table 4.9 showing total number of VMs based on its change in consistency after session 4 of sclerosis.

Table 5

Session 4Vascularity

Change in vascularity after session 4 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(50 - 75%)	8	16.0	88.9	88.9
	(75 – 100%)	1	2.0	11.1	100.0
	Total	9	18.0	100.0	
Missing	System	41	82.0		
Total	50	100.0			

Table 5 showing total number of VMs based on its change in vascularity after session 4 of sclerosis.

Table 5.1.

Session 4 Total score

Total score after session 4 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
	5	1	2.0	11.1	11.1
	6	1	2.0	11.1	22.2
	7	6	12.0	66.7	88.9
	9	1	2.0	11.1	100.0
	Total	9	18.0	100.0	
Missing	System	41	82.0		
Total	50	100.0			

Table 5.1 shows total number of lesions based on its total score after session 4 of sclerosis.

Table 5.2.

Session 5 Size

Reduction in size after session 5 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(25 - 50%)	1	2.0	12.5	12.5
	(50 - 75%)	1	2.0	12.5	25.0
	(75 – 100%)	6	12.0	75.0	100.0
	Total	8	16.0	100.0	
Missing	System	42	84.0		
Total		50	100.0		

Table 5.2 showing total number of VMs based on its size reduction after session 5 of sclerosis.

Table 5.3.

Session 5Consistency

Change in consistency after session 5 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Semi Hard	4	8.0	50.0	50.0
	Hard	4	8.0	50.0	100.0
	Total	8	16.0	100.0	
Missing	System	42	84.0		
Total		50	100.0		

Table 5.3 showing total number of VMs based on its change in consistency after session 5 of sclerosis.

Table 5.4.

Session 5Vascularity

Change in vascularity after session 5 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(75 – 100%)	8	16.0	100.0	100.0
Missing	System	42	84.0		
Total		50	100.0		

Table 5.4 showing total number of VMs based on its change in vascularity after session 5 of sclerosis.

Table 5.5.

Session 5 Total Score

Total score after session 5 of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
	7	1	2.0	12.5	12.5
	9	4	8.0	50.0	62.5
	10	3	6.0	37.5	100.0
	Total	8	16.0	100.0	
Missing	System	42	84.0		
Total		50	100.0		

Table 5.5 showstotal number of lesions based on its totalscore after session 5 of sclerosis.

Table 5.6.

FINALSIZE

Reduction in size after final session of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(25 - 50%)	6	12.0	12.0	12.0
	(50 - 75%)	10	20.0	20.0	32.0
	(75 – 100%)	34	68.0	68.0	100.0
	Total	50	100.0	100.0	

Table 5.6 showing total number of VMs based on its size reduction after final session of sclerosis.

Table 5.7.

Final Consistency

Change in consistency after final session of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Soft	8	16.0	16.0	16.0
	Semi Hard	30	60.0	60.0	76.0
	Hard	12	24.0	24.0	100.0
	Total	50	100.0	100.0	

Table 5.7 showing total number of VMs based on its change in consistency after final session of sclerosis.

Table 5.8.

Final Vascularity

Change in vascularity after final session of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(50 - 75%)	6	12.0	12.0	12.0
	(75 – 100%)	44	88.0	88.0	100.0
	Total	50	100.0	100.0	

Table 5.8 showing total number of VMs based on its change in vascularity after final session of sclerosis.

Table 5.9.

TOTAL FINAL SCORE

Total score after final session of sclerosis		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	5	3	6.0	6.0	6.0
	6	3	6.0	6.0	12.0
	7	3	6.0	6.0	18.0
	8	7	14.0	14.0	32.0
	9	24	48.0	48.0	80.0
	10	10	20.0	20.0	100.0
	Total	50	100.0	100.0	

Table 5.9 showstotal number of lesions based on its totalscore after final session of sclerosis.

The final outcome is classified as grade of improvement is based on score as given in below Table A & B.

Table A

Size of swelling (% of reduction):			
1 - (0 - 5%)	2 – (25 - 50%)	3 – (50 - 75%)	4 - (75 – 00%)
Change in consistency of swelling:			
0 – (Soft)		1- (Semi-hard)	2 –(Hard)
Vascularity within the swelling (% of decrease on USG)			
1- (0 - 25%)	2 – (25 - 50%)	3– (50 - 75%)	4 - (75 – 100%)

Table B

SCORE	**GRADE OF IMPROVEMENT**
< 3	Poor
3 - 5	Minimal
6 - 8	Good
9 - 10	Excellent

Improvement Grade

Table 6.

Valid	**Minimal**	**3**	**6.0**
	Good	13	26.0
	Excellent	34	68.0
	Total	50	100.0

On follow-up, 2 months after the last session of sclerosis final result is illustrated in table 6.1.

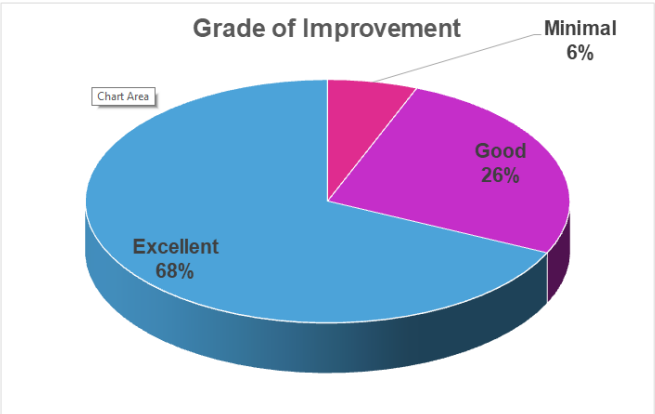


Figure 2.5: Pie chart showing grades of improvement.

Out of total 50 patients, 68% patients had excellent improvement, 26% patients had good improvement and 6% patients had minor improvement in the form of decrease in pain; change in consistency of VMs; reduction in size of VMs compare to the original size and change in vascularity on doppler imaging, as shown in table 6 and figure 2.5.

Table 6.1.

	Frequency	**Percent**
Operated	1	2.0
10% SWELLING PERSISTENT	3	6.0
20% SWELLING PERSISTENT	1	2.0
25% SWELLING PERSISTENT	9	18.0
50% SWELLING PERSISTENT	6	12.0
COMPLETELY RECOVERED	30	60.0
Total	50	100.0

60% patients were completely recovered from the swelling and 2 % patient had no improvement, as shown in table 6.1.

Table 6.2

Complications

		Frequency	**Percent**	**Valid Percent**	**Cumulative Percent**
Valid	B	2	4.0	4.0	4.0
	N	39	78.0	78.0	82.0
	P	8	16.0	16.0	98.0
	P + B	1	2.0	2.0	100.0
	Total	50	100.0	100.0	

(Abbreviations: B- Blackening, P- Pain, N- Normal)

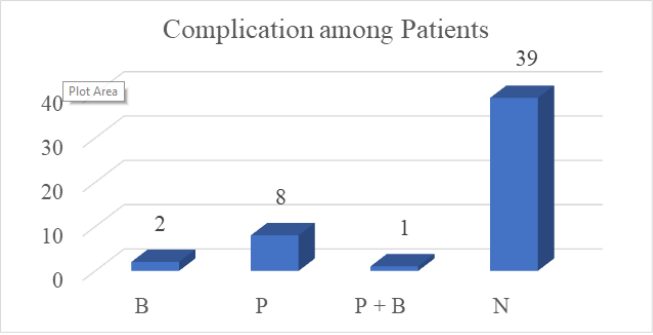


Figure 2.6: 3 D clustered column showing post sclerotherapy complication.

(Abbreviations: B- Blackening, P- Pain, N- Normal)

22% patients reported minor complications including pain and blackening as shown in table 6.2 and figure 2.6.

Crosstables

Multiple cross tables are made to compare in size, consistency and vascularity among session 1, session 2 and final session outcome.

COMPARISON IN SIZE

Case Processing Summary

Table 6.3. **Cases**

	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Session1_Size * Session 2_Size	31	62.0%	19	38.0%	50	100.0%
Session1_Size * Session FinalSize	50	100.0%	0	0.0%	50	100.0%

Session1_Size * Session2_Size

Crosstab

Table 6.4. **Session2_Size**

			(0 -25%)	(25 - 50%)	(50 - 75%)	(75 – 100%)
Session1_ Size	(0 -25%)	Count	5	7	2	0
		% within Sess1_Size	35.7%	50.0%	14.3%	0.0%
	(25-50%)	Count	0	1	8	3
		% within Sess1_Size	0.0%	8.3%	66.7%	25.0%
	(50-75%)	Count	0	0	0	5
		% within Sess1_Size	0.0%	0.0%	0.0%	100.0%
Total		Count	5	8	10	8
		% within Sess1_Size	16.1%	25.8%	32.3%	25.8%

Table 6.5.

Chi-Square Tests

	Value	df	Asymptotic Significance(2-sided)
Pearson Chi-Square	33.657a	6	.000
Likelihood Ratio	36.660	6	.000
Linear-by-Linear Association	20.371	1	.000
N of Valid Cases	31		

a. 12 cells (100.0%) have expected count less than 5. The minimum expected count is .81.

Session1_Size * Session Final _Size

Table 6.6.

Crosstab **Session FinalSize**

			(25 - 50%)	(50 - 75%)	(75 – 100%)	Total
Session1_ Size	(0 -25%)	Count	3	3	8	14
		% within Sess1_Size	21.4%	21.4%	57.1%	100.0%
	(25 - 50%)	Count	3	4	8	15
		% within Sess1_Size	20.0%	26.7%	53.3%	100.0%
	(50 - 75%)	Count	0	3	5	8
		% within Sess1_Size	0.0%	37.5%	62.5%	100.0%
	(75 – 100%)	Count	0	0	13	13
		% within Sess1_Size	0.0%	0.0%	100.0%	100.0%
	Total	Count	6	10	34	50
		% within Sess1_Size	12.0%	20.0%	68.0%	100.0%

Table 6.7.

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	11.240a	6	.081
Likelihood Ratio	15.544	6	.016
Linear-by-Linear Association	6.687	1	.010
N of Valid Cases	50		

a. 8 cells (66.7%) have expected count less than 5. The minimum expected count is .96.

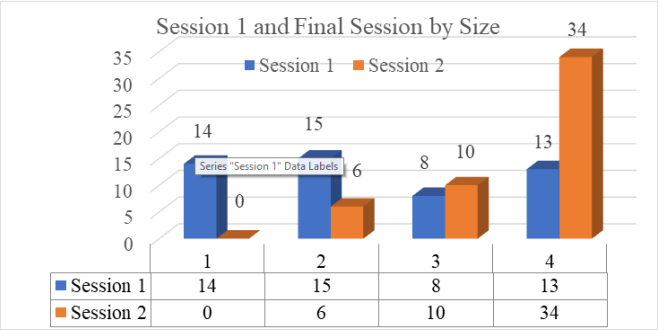


Figure 2.7: 3 D clustered column showing improvement of score in change in size after final session of sclerotherapy as compared to the session 1.

Table 6.8 **Comparison In Vascularity.**

Case Processing Summary

	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Session1_Consis-tency * Session2_ Consistency	31	62.0%	19	38.0%	50	100.0%
Session1_Consis-tency * Session FinalConsistency	50	100.0%	0	0.0%	50	100.0%

Session1_Consistency * Session2_Consistency

Table 6.9.

Crosstab

			Session2_Consistency		
			Soft	Semi Hard	Hard
Session1_ Consis-tency	Soft	Count	17	10	0
		% within Session1_ Consis-tency	63.0%	37.0%	0.0%
	Semi Hard	Count	0	1	3
		% within Session1_ Consis-tency	0.0%	25.0%	75.0%
Total		Count	17	11	3
		% within Session1_ Consis-tency	54.8%	35.5%	9.7%

Table 7.

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	22.911a	2	.000
Likelihood Ratio	17.140	2	.000
Linear-by-Linear Association	14.545	1	.000
N of Valid Cases	31		

a. 4 cells (66.7%) have expected count less than 5. The minimum expected count is .39.

Table 7.1.Session1_Consistency * Session FinalConsistency

			Session FinalConsistency		
			Soft	**Semi Hard**	**Hard**
Sess1_ Consistency	Soft	Count	8	20	6
		% within Sess1_ Consistency	23.5%	58.8%	17.6%
	Semi Hard	Count	0	10	4
		% within Sess1_ Consistency	0.0%	71.4%	28.6%
	Hard	Count	0	0	2
		% within Sess1_ Consistency	0.0%	0.0%	100.0%
Total		Count	8	30	12
		% within Sess1_Consis-tency	16.0%	60.0%	24.0%

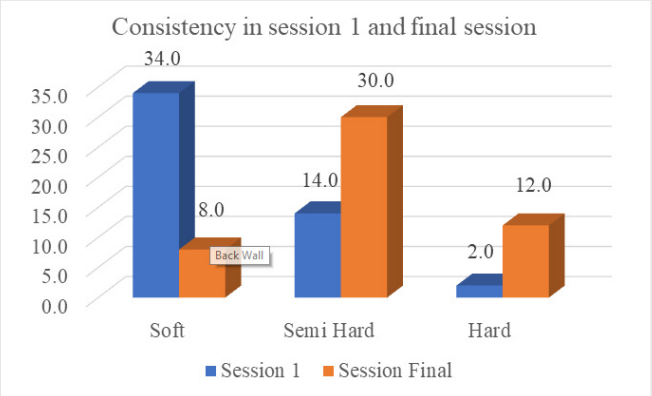


Figure 2.8: 3 D clustered column showing improvement of score in change in consistency after final session of sclerotherapy as compared to the session 1.

Table 7.2.

Chi-Square Tests

	Value	**df**	**Asymptotic Significance (2-sided)**
Pearson Chi-Square	10.784a	4	.029
Likelihood Ratio	12.279	4	.015
Linear-by-Linear Association	6.904	1	.009
N of Valid Cases	50		

a. 5 cells (55.6%) have expected count less than 5. The minimum expected count is .32.

Table 7.3. COMPARISON IN VASCULARITY

Session1_vascularity

Session 1_Vascularity					
		Frequency	**Percent**	**Valid Percent**	**Cumu-lative Percent**
Valid	(0 -25%)	9	18.0	18.0	18.0
	(25 - 50%)	13	26.0	26.0	44.0
	(50 - 75%)	11	22.0	22.0	66.0
	(75 – 100%)	17	34.0	34.0	100.0
	Total	50	100.0	100.0	

Table 7.4.

Session FinalVascularity

Session Final Vascularity					
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	(50 - 75%)	6	12.0	12.0	12.0
	(75 – 100%)	44	88.0	88.0	100.0
	Total	50	100.0	100.0	

Table 7.5. Session1_vascularity* Session final vascularity

Vascularity	Session 1	Session Final
(0 -25%)	9.0	0.0
(25 - 50%)	13.0	0.0
(50 - 75%)	11.0	6.0
(75 – 100%)	17.0	44.0

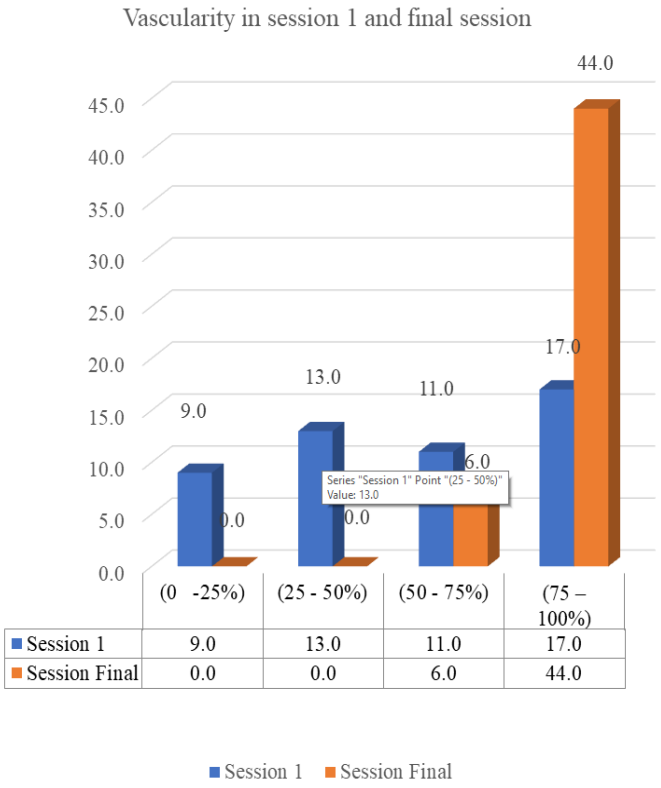


Figure 2.9: 3 D clustered column showing improvement of score in change in vascularity after final session of sclerotherapy as compared to the session 1

Table 7.6. Grade of improvement by site of malformation.

		Grade of Improvement			Total
Site of Malformation		Minimal	Good	Excellent	
	HNF	3	4	12	19
	LE	0	4	11	15
	T	0	0	4	4
	UE	0	5	7	12
Total		3	13	34	50

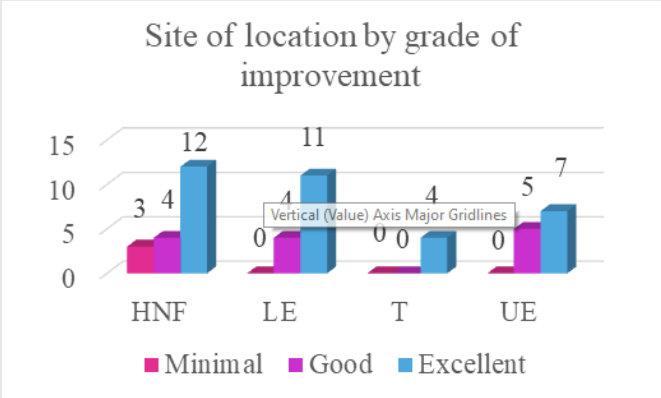


Figure 3: 3 D clustered column showingcomparison between grade of improvement with site of malformation,

(Abbreviations: HNF- Head neck & face, LE- Lower extremity, T- Trunk, UE- Upper extremity)

T-Test

Table 7.7.

Paired Samples Statistics

		Mean	N	Std. Deviation
Pair 1	Session 1_Total	3.84	31	1.635
	Session 2_Total	6.32	31	2.329
Pair 2	Session1_ Total	2.89	18	.900
	Session 3_Total	7.17	18	1.757
Pair 3	Session 1_Total	2.56	9	.882
	Session 4_Total	6.89	9	1.054
Pair 4	Session 1_Total	2.38	8	.744
	Session 5_Total	9.13	8	.991
Pair 5	Session 1_Total	5.48	50	2.613
		8.52	50	1.374

Table 7.8.

Paired Samples Test

		Paired Differences				
		Mean	Std. Deviation	t	df	Sig. 2-tailed)
Pair 1	Session1_ Total –	-2.484	1.151	-12.016	30	.000
	Session 2_Total					
Pair 2	Session1_ Total -	-4.278	1.274	-14.241	17	.000
	Session3_ Total					

Pair 3	Session1_ Total	-4.333	.866	-15.011	8	.000
	Session 4_Total					
Pair 4	Session1_ Total	-6.750	1.035	-18.445	7	.000
	Session 5_Total					
	Session1_ Total	-3.040	2.710	-7.931	49	.000
	Session FinalTotal					

Discussion

Venous malformations (VMs) are congenital endothelial malformations that result from errors in vascular morphogenesis. The estimated incidence of VMs is 1 in 10,000, and VMs are the low-flow vascular malformation [20]. Treatment of venous malformations is highly varied and includes conservative management with compression stockings or gloves, surgery, endovascular laser treatment, embolization, or sclerotherapy [21].

In our prospective study conducted between January 2019 and September 2020 included total 50 symptomatic patients (most common symptom was pain, swelling and cosmetic impairment) who were not responding to the conservative management. Contrast enhanced MRI was done in all patients prior to treatment.

Age group ranges between 2 to 70 years (mean age 20.34 years). Males are more commonly affected (54%) than females (46%).

The most common site is head neck and face (38%) followed by lower extremity (30%), upper extremity (24%) and trunk (8%). Based on size VMs are divided into three groups: small (<3 cm), medium (3-5 cm) and large (>5 cm) groups. Multiple sessions of sclerosis have given based on outcome in decrease in pain, size, vascularity and change in consistency.

Prior to each session colour doppler USG done. At Gray-scale sonographic evaluation, superficial VMs are compressible with heterogeneous echotexture (98%) and can be hypoechoic (82%), hyperechoic (10%), or isoechoic (8%) with respect to surrounding structures. Colour Doppler examination reveals waveforms with monophasic flow typical of venous structures in 78% of cases. Sixteen percent of VMs have minimal or no flow, which may reflect very low flow below detectable limits or thrombosis and a possible source of diagnostic confusion [20].

Treatment was mainly DSA and ultrasound guided percutaneous SETROL (1 - 3%Sodium Tetradecyl Sulfate) foam sclerosis using Tessari's technique in multiple sessions separated by 4-6weeks interval according to the response of treatment. Under real-time ultrasound guidance, the lesions were accessed with a 20-gauge puncture needle (scalp vein), once blood return was obtained, foam was inserted. Large size lesions required a greater number of sessions and vial compared to small and medium size lesions. Sclerotherapy was effective in all patients in their 1st session and effectiveness increases in subsequent sessions.

All patients were evaluated 7 days after each session to look any complication. Maximum 5 sessions of sclerotherapy had given to the patients in this study. Minor complications (including pain and blackening) seen in 22% of patients. A median follow-up at 2 months, after the last session, 68% patients reported excellent improvement, 26% good improvement and 6% minor improvement in decrease in pain; change in consistency; reduction in size of VMs compare to the original size and change in vascularity on doppler imaging was obtained.

Large size group of VMs required a greater number of vials (mean 6.6) compare to medium (mean 3.58) and small sized groups (mean 2.25). Total sclerosant volume used in large group differ significant from small and medium size group but small and medium group has not significant p value, as shown in table 3.1. ANOVA test show there is significant difference in mean vial used for three lesion size, as shown in table 3.

After each session of sclerosis there is significant reduction in size of VMs and its change in consistency and vascularity.

Size of VMs has gradually reduced after each session. Chi-square test shows significant reduction in size after final session as compared to first session of sclerosis (p value 0.081), as shown in table 3.5.

There is 75% to 100% reduction of VMs size in 68% patients, 50% to 75% reduction of VMs size in 20% patients and 25% to 50% reduction of VMs size in 12% patients after final session of the sclerotherapy, as shown in table 5.6.

The VMs become semi hard in 60% patients, hard in 24% patients and no change in consistency i.e. remain soft in 12% of patients 2 months after final session of the sclerotherapy, as shown in table 5.7.

There is 75% to 100% reduction of vascularity in VMs 2 months after final session of the sclerotherapy in 88% patients and 50% to 75% reduction in 12% patients, as shown in table 5.8.

On follow-up, 2 months after the last session of sclerosis, 60% patients were completely recovered from the swelling and 2 % patient had no improvement, as shown in table 6.1.

Comparisons between session 1, session 2 and 2 months after the last session of sclerosis was done to calculate the change in size, consistency and vascularity of VMs as shown in tables from 6.3 to 7.5.

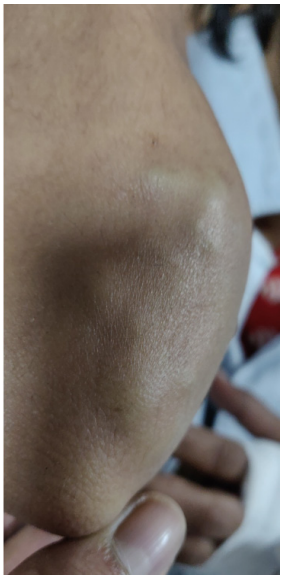
- Chi-Square test shows significant improvement in size score after session 1(p value 0.000) in comparison with 2 months after final session (p value .081), as shown in table 6.5 and 6.7.
- Final outcome of consistency is compared, with after session 1 consistency shows significant improvement (p value for consistency is 0.029 for final outcome, as shown in table 7.2). (p value 0.000 after session 1, as shown in table 7).
- There is significant improvement in grading of vascularity after final session of sclerotherapy as compared with session 1 as shown in table 7.5 and figure 2.9.

Paired samples T- test between session 1 and final outcome is satisfactory with mean -3.040, std deviation 2.710, t -7.931, df 49, p value 0.000 as shown in table 7.7 and table 7.8.

VMs located on head neck and face region shows better grade of improvement than VMs over lower extremity, trunk and upper extremity, as shown in table 7.6 and figure 3.

Pictorial Essay

Case 1. **CLINICAL IMAGES**



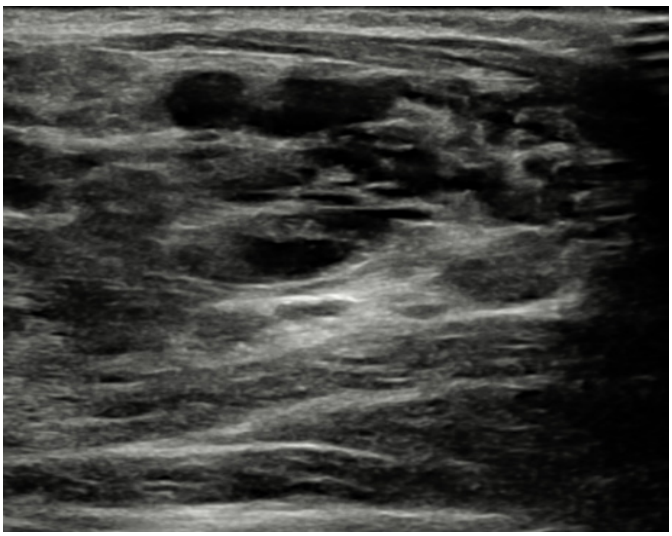
Before sclerotherapy

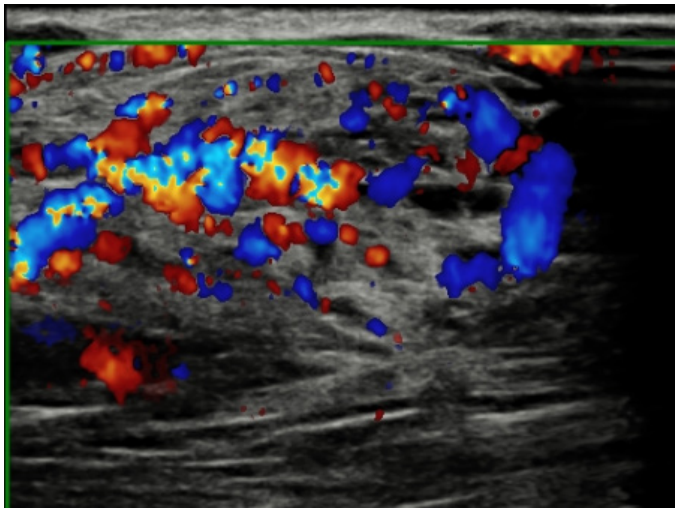


After sclerotherapy

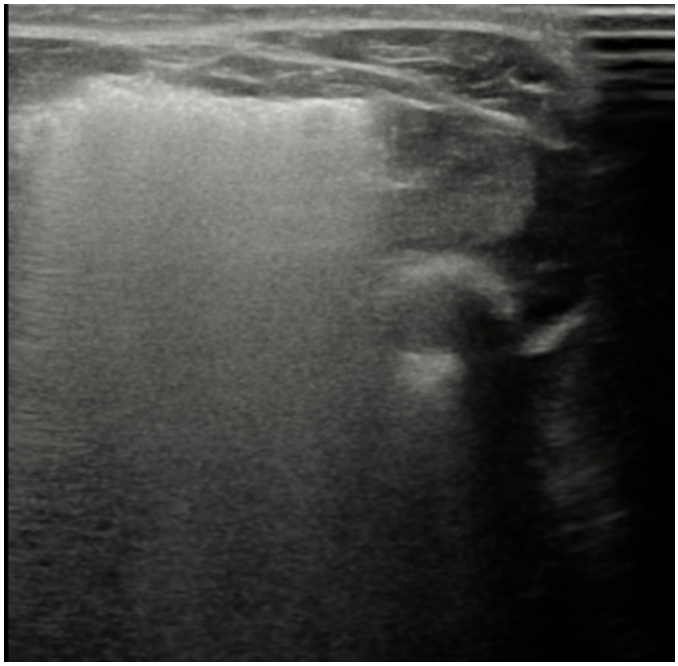


Negative subtraction technique to confirm the needle position.

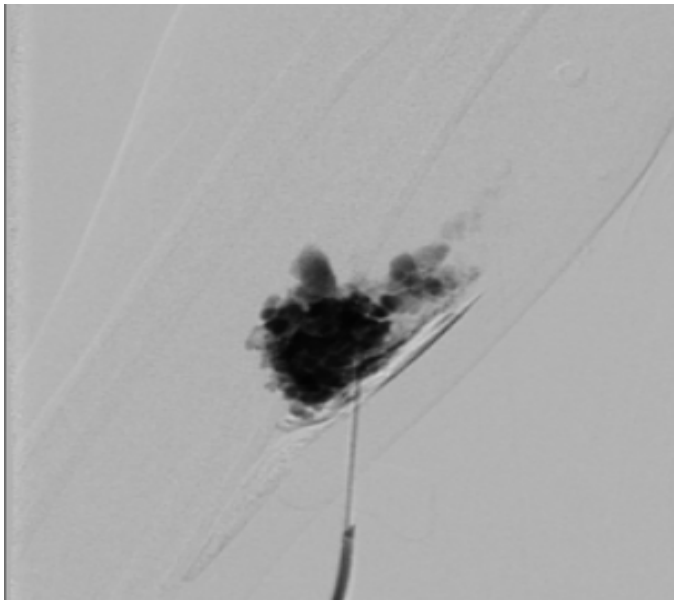




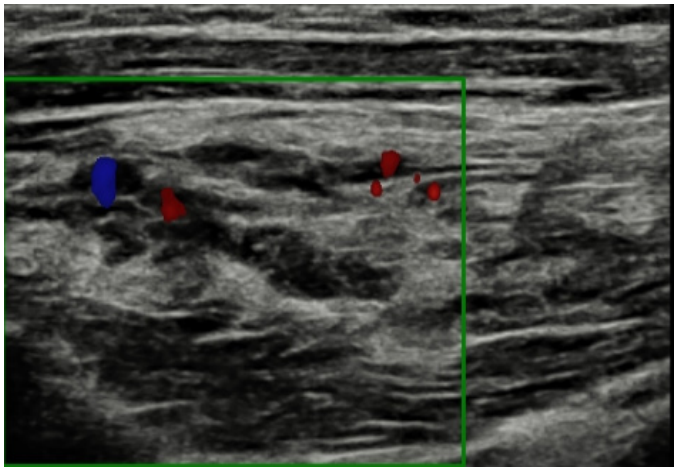
USG showing VMs in Grey scale and color doppler mode

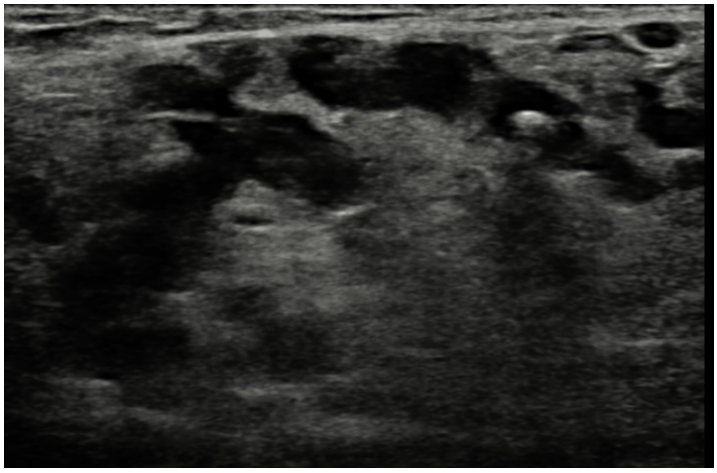


USG guided foam sclerotherapy



DSA guided foam sclerotherapy





Follow up USG showing resolution of hypoechoic vascular channels.

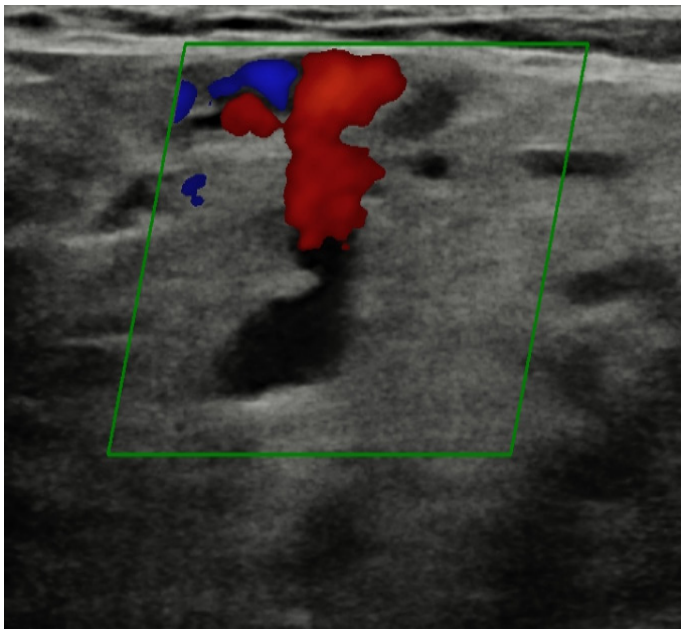
Case 2. **CLINICAL IMAGES**



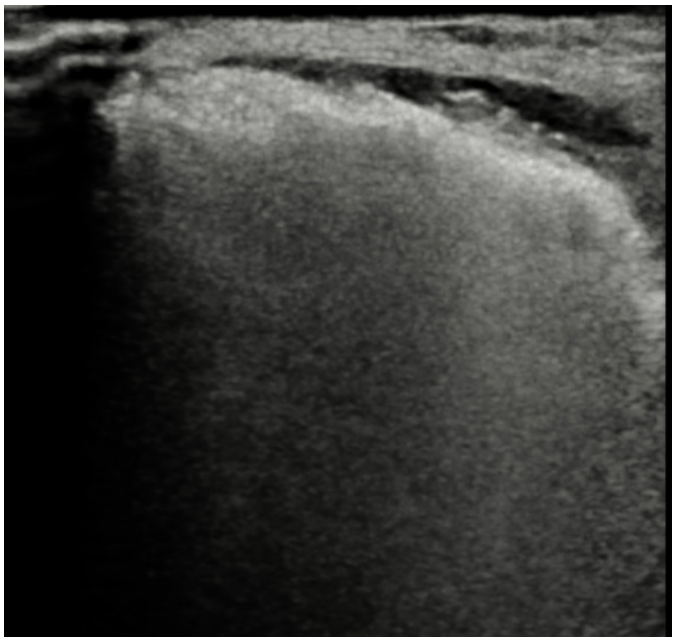
Before sclerotherapy



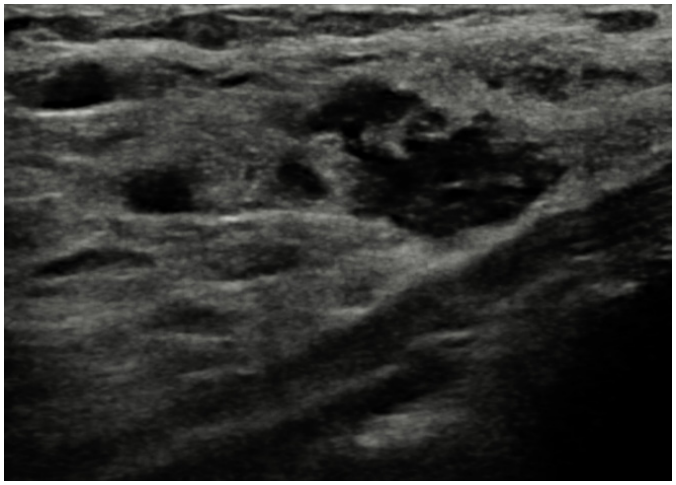
After sclerotherapy



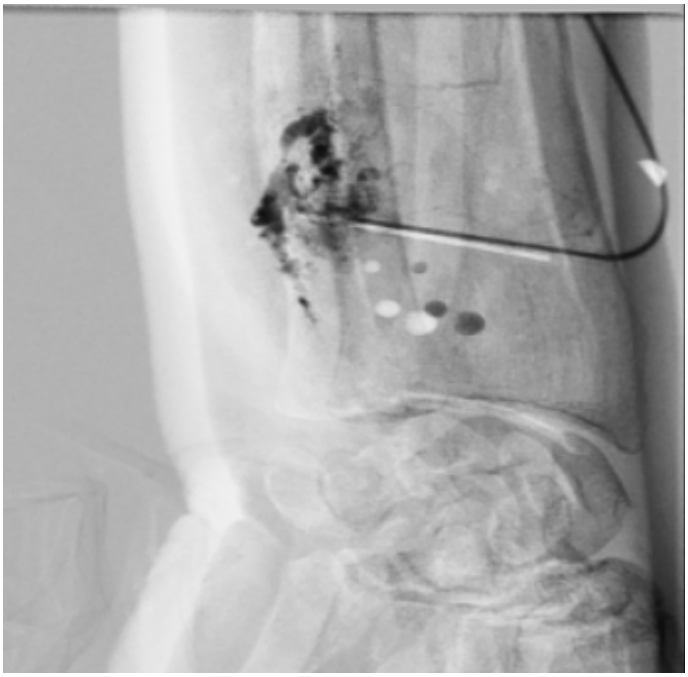
USG showing VMs in Grey scale and color doppler mode



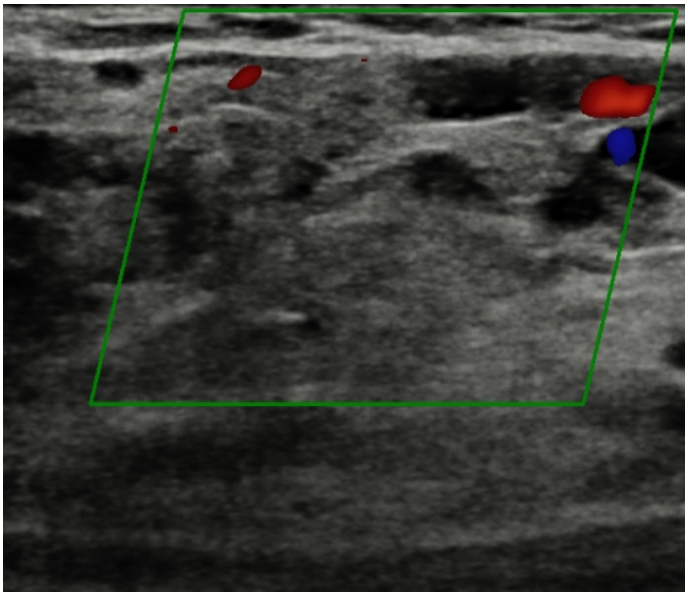
USG guided foam sclerotherapy



Follow up USG Grey scale image

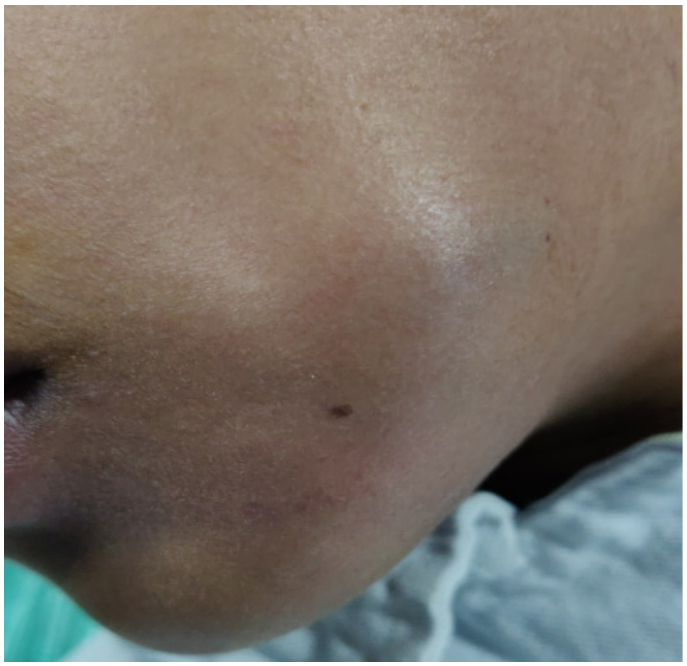


DSA guided foam sclerotherapy

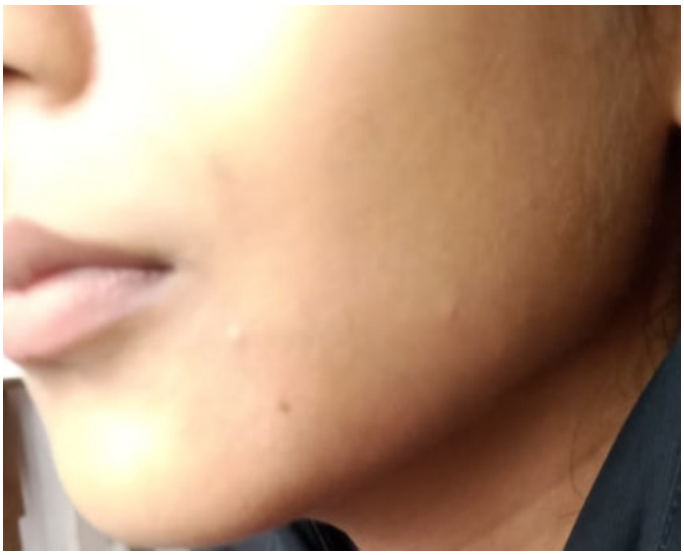


Follow up USG showing decrease hypoechoic vascular channels.

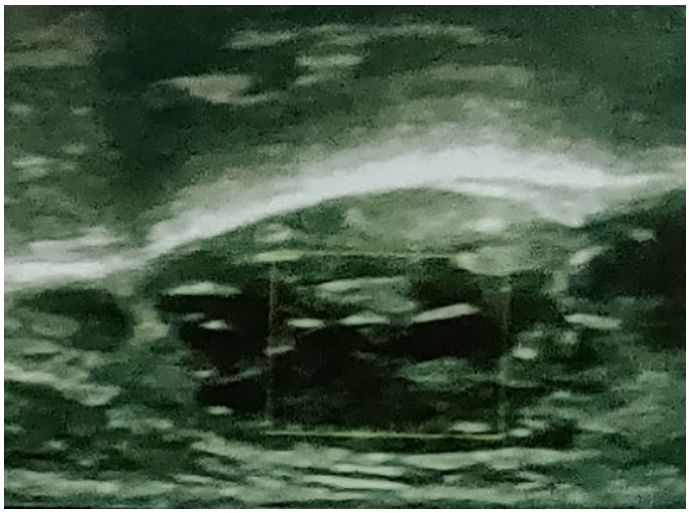
Case 3. **CLINICAL IMAGES**



Before sclerotherapy



After sclerotherapy



USG Grey scale image



DSA guided foam sclerotherapy

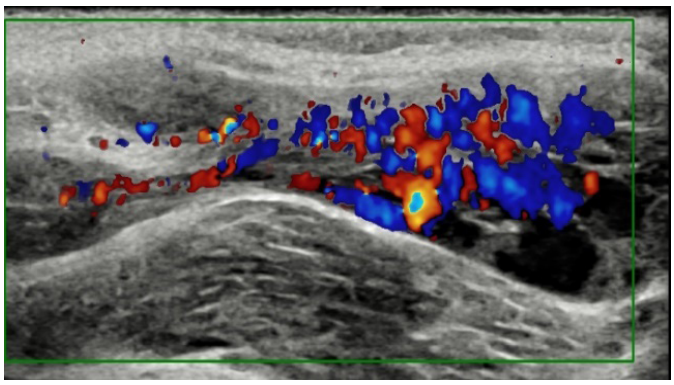
Case 4. **CLINICAL IMAGES**



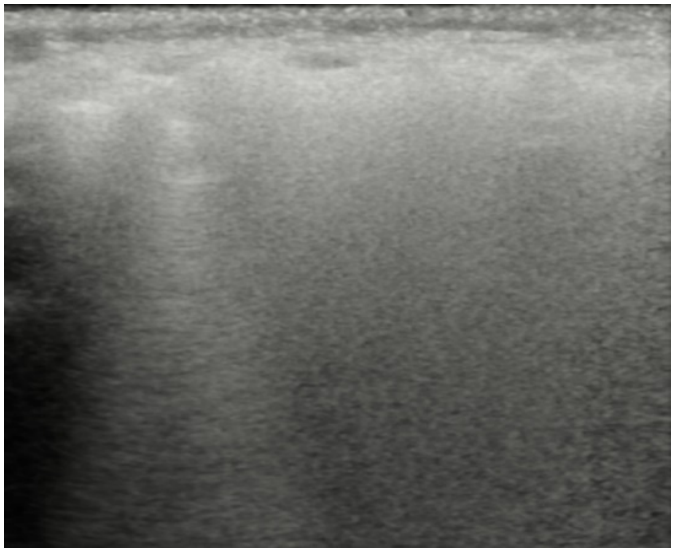
Before sclerotherapy



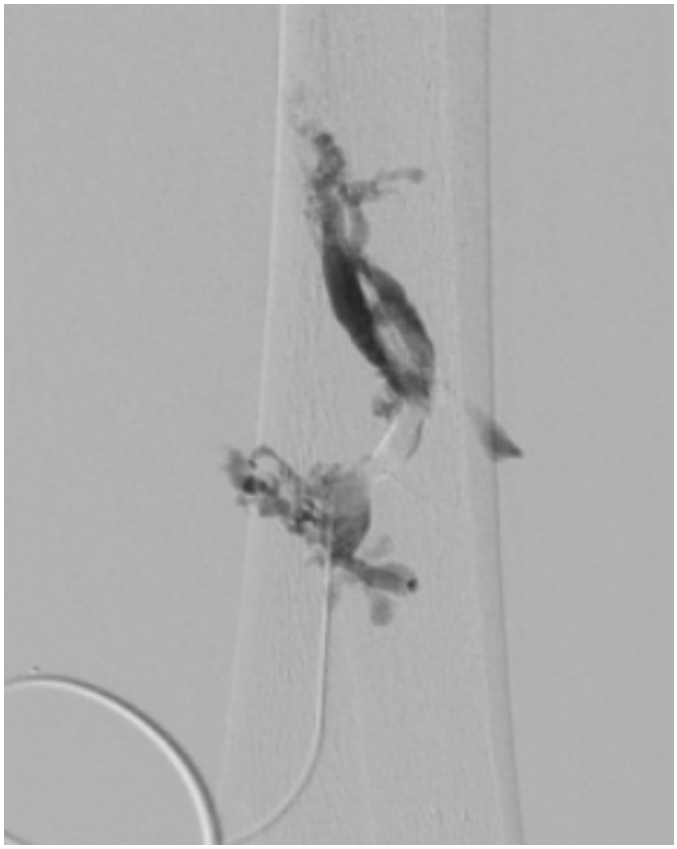
After sclerotherapy



USG color mode showing hypoechoic vascular channels

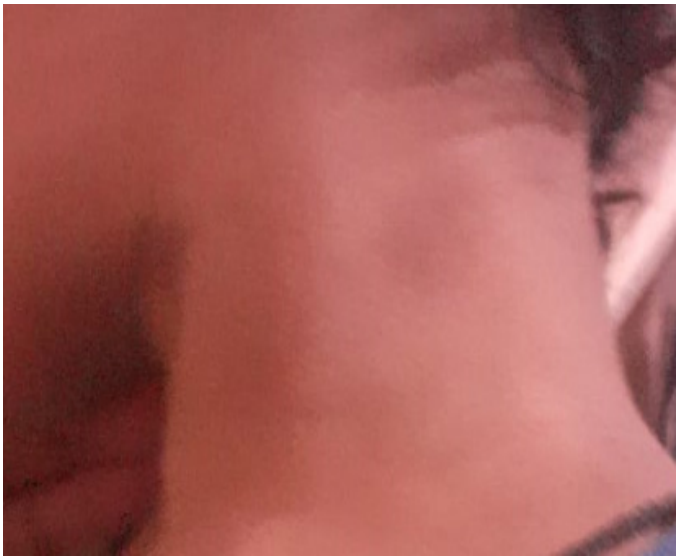


USG guided foam sclerotherapy

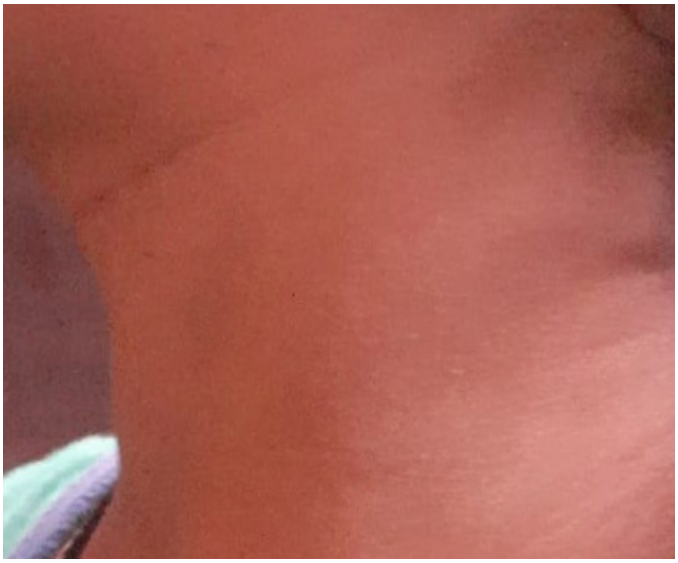


DSA guided foam sclerotherapy

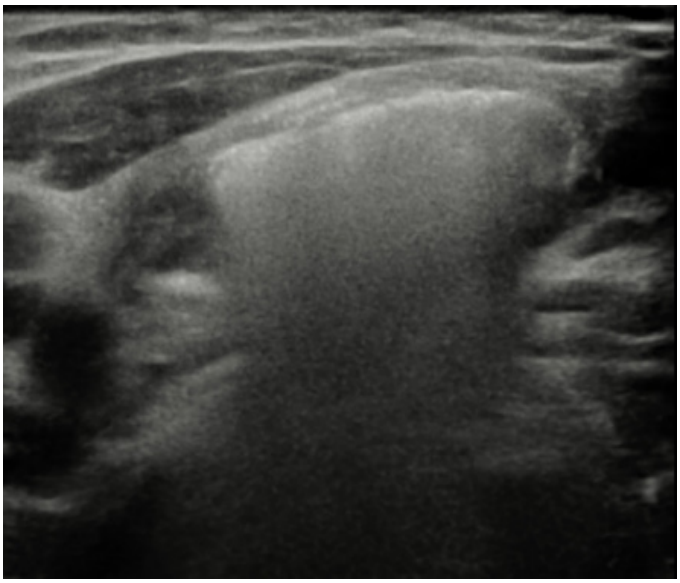
Case 5. **CLINICAL IMAGES**



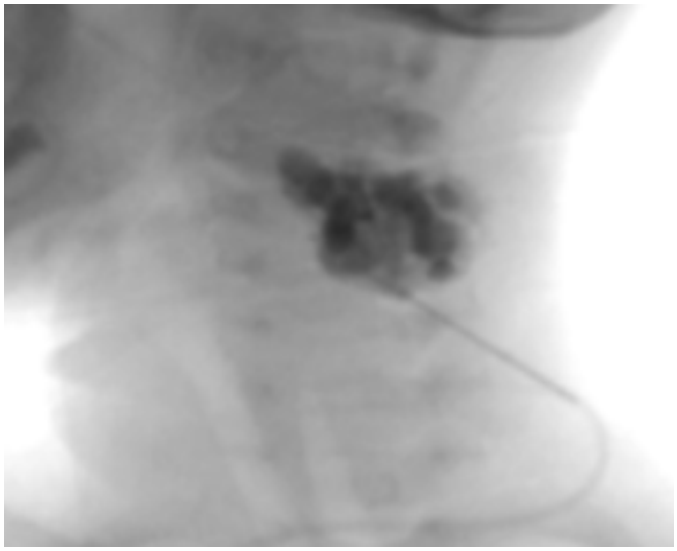
Before sclerotherapy



After sclerotherapy



USG guided foam sclerotherapy



DSA guided foam sclerotherapy

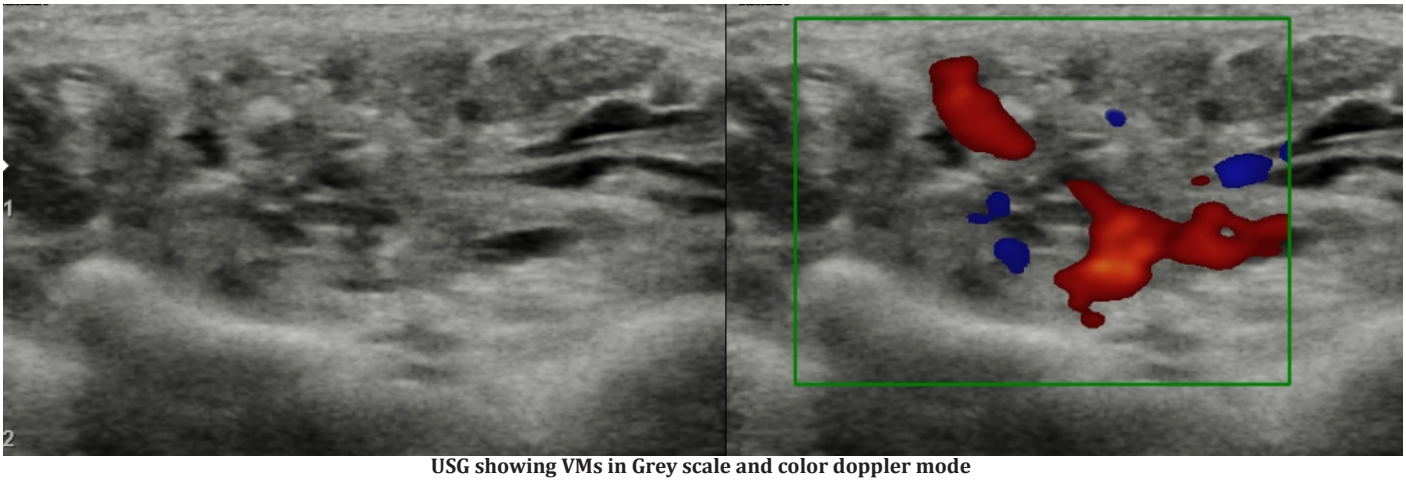
Case 6. **CLINICAL IMAGES**



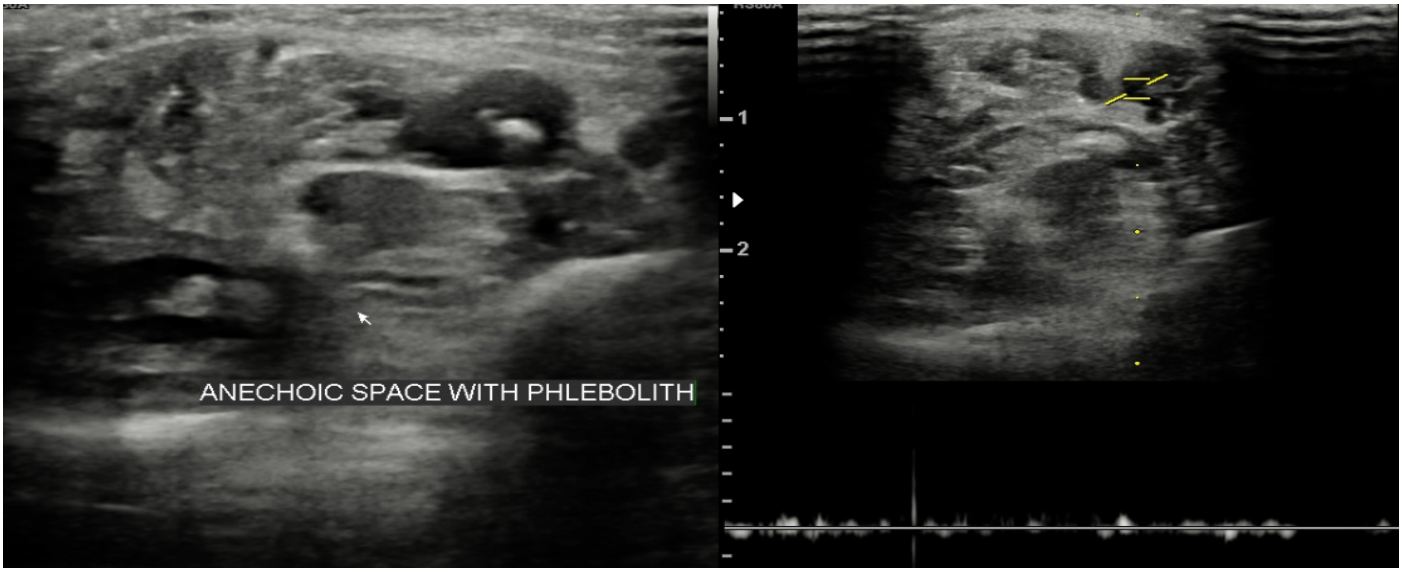
Before sclerotherapy



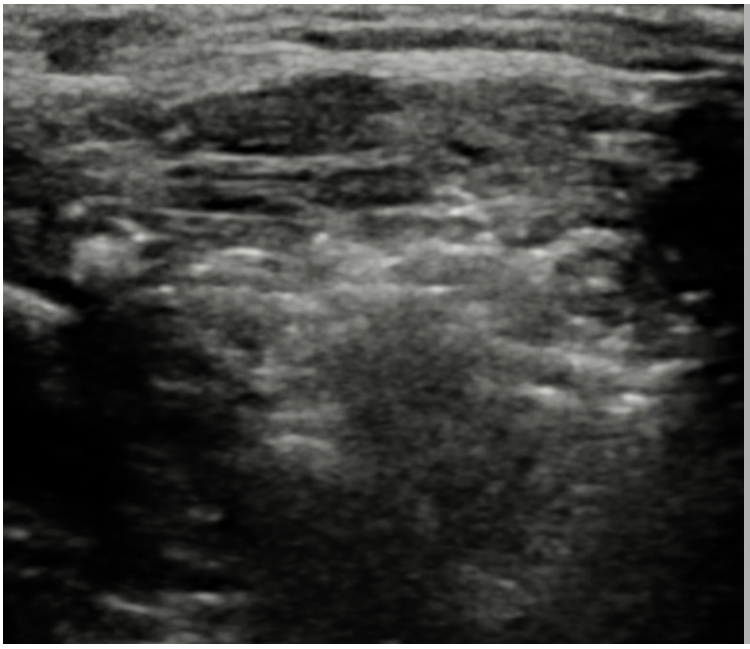
After sclerotherapy



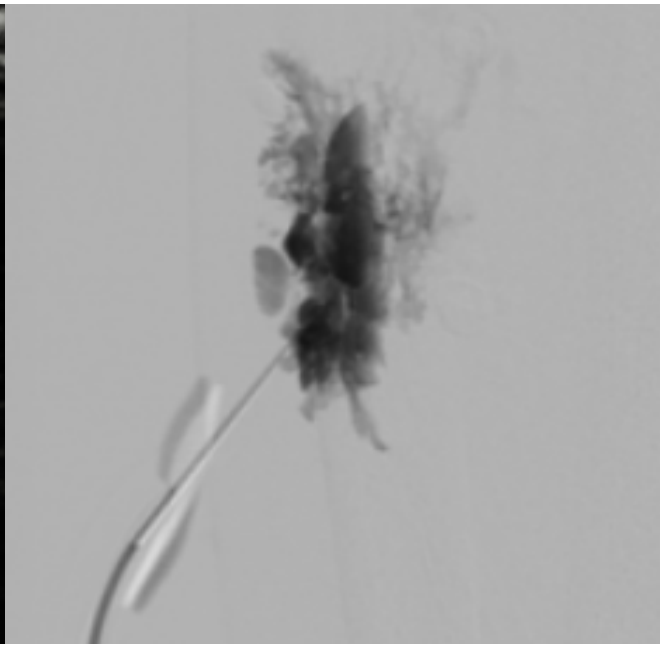
USG showing VMs in Grey scale and color doppler mode



USG Grey scale showing anechoic space and low vascularity on power doppler mode.

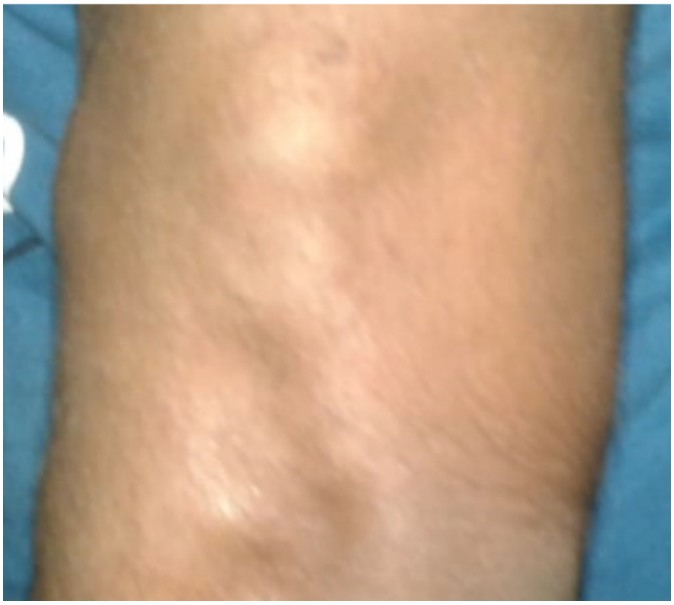


USG guided foam sclerotherapy



DSA guided foam sclerotherapy

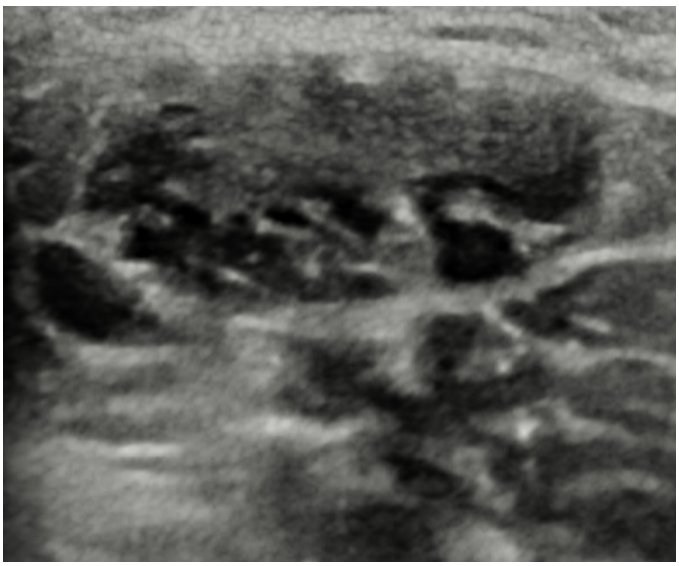
Case 7. **CLINICAL IMAGES**

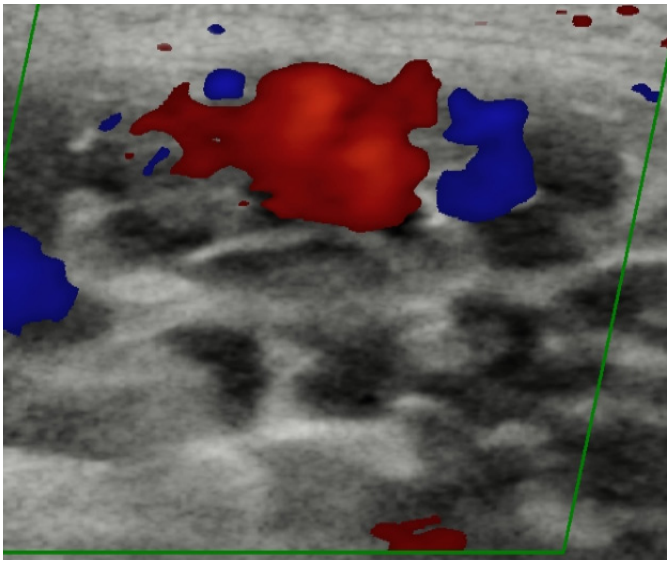


Before sclerotherapy

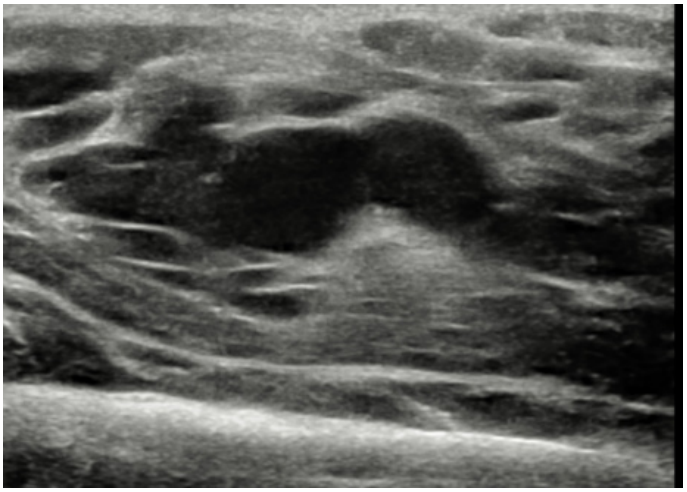


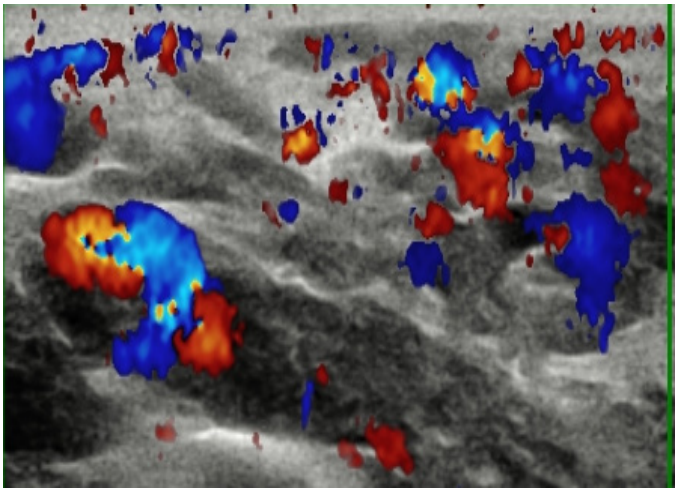
After sclerotherapy



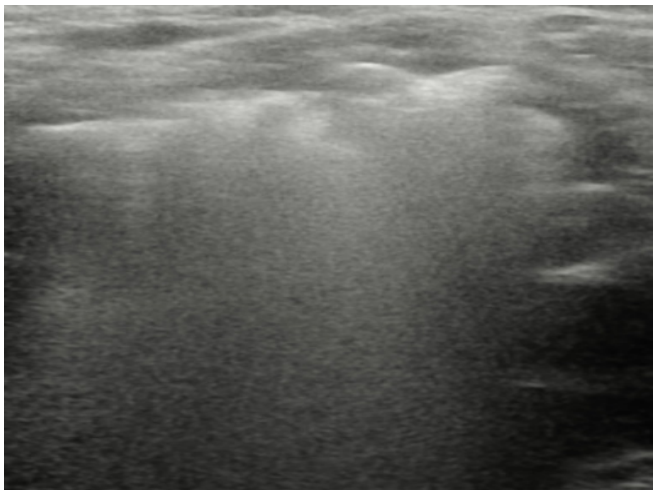


USG showing VMs in Grey scale and color doppler mode

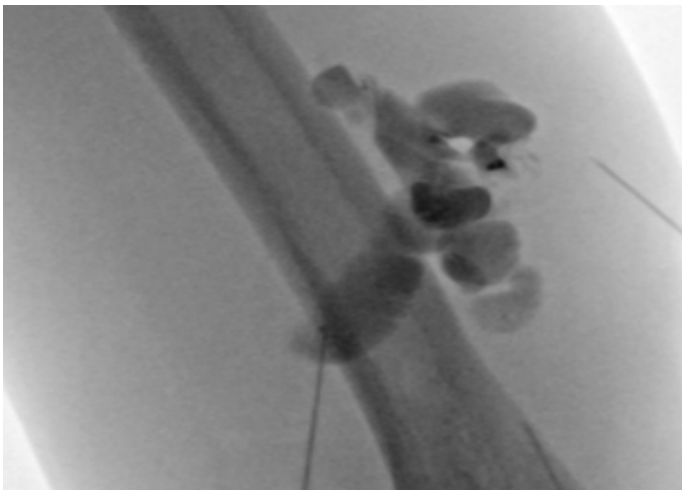




Follow up USG in Grey scale and color doppler modeshowing reduction in anechoic channels and vascularity in VMs



USG guided foam sclerotherapy



DSA guided foam sclerotherapy

Case 8. **CLINICAL IMAGES**



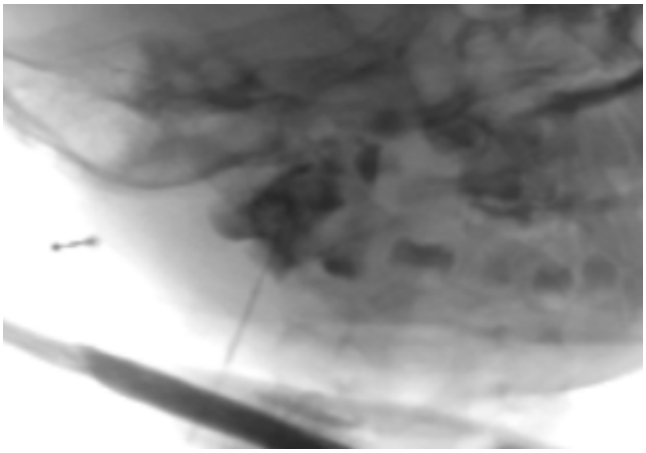
Before sclerotherapy



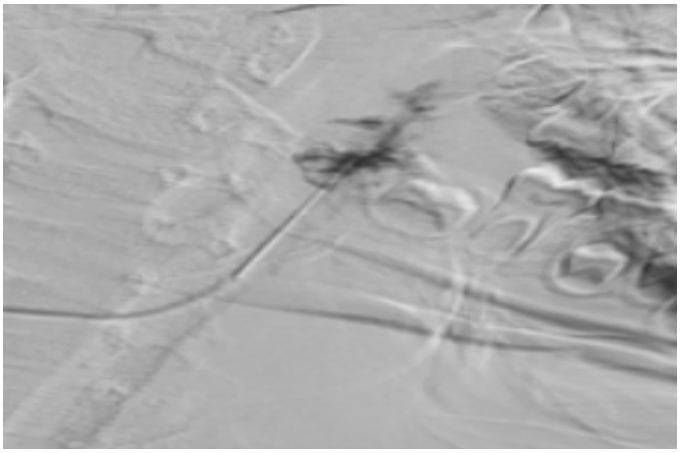
follow-up sclerotherapy



2 Months After sclerotherapy



DSA guided foam sclerotherapy



Follow up DSA guided foam sclerotherapy

Case 9.

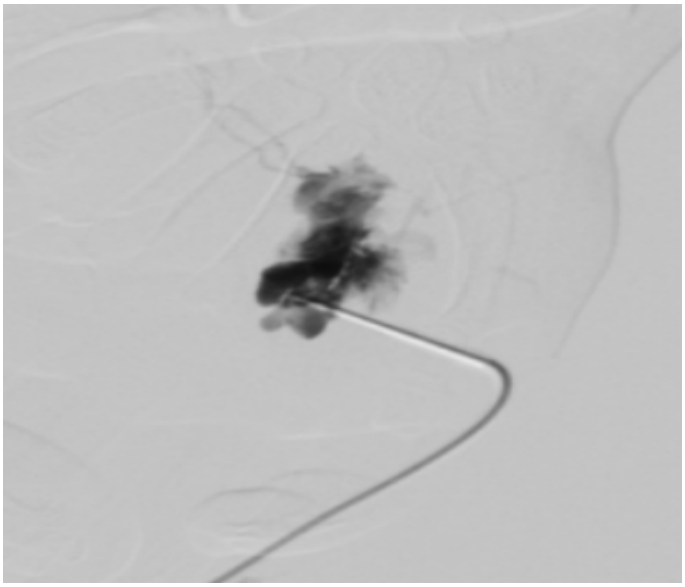
CLINICAL IMAGES



Before sclerotherapy



After sclerotherapy

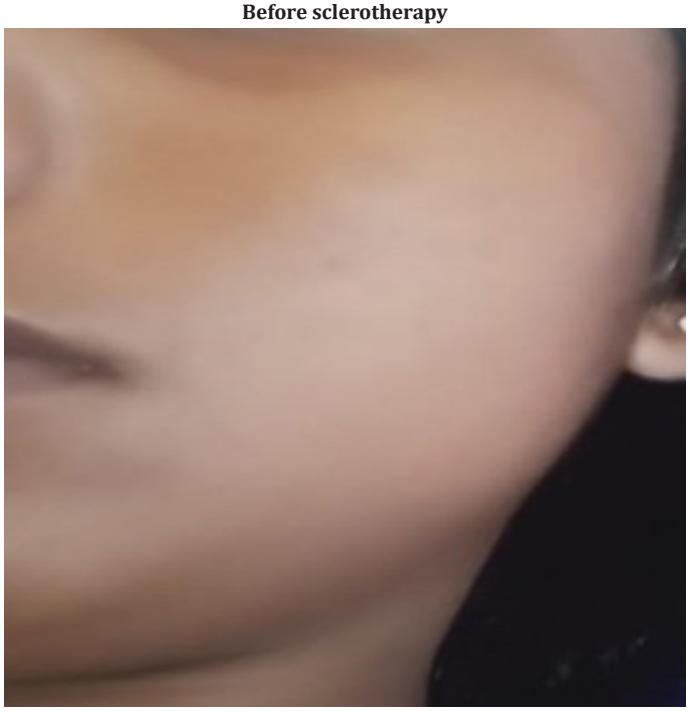


USG guided foam sclerotherapy

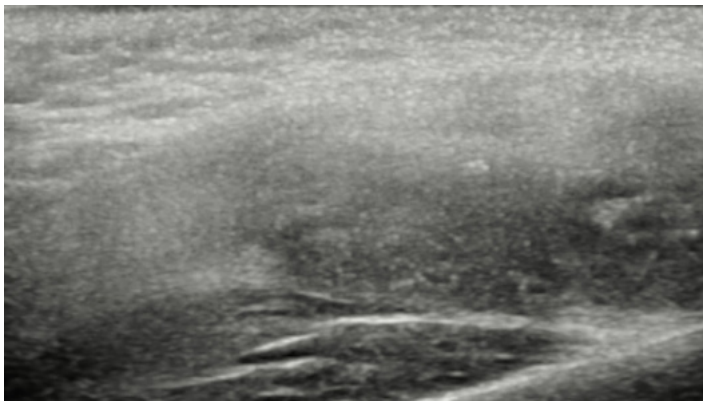
Case 10. **CLINICAL IMAGES**



Before sclerotherapy



After sclerotherapy



USG guided foam sclerotherapy

Summary

Image guided percutaneous sclerotherapy has become first line treatment for venous malformations. The main objective of this prospective study was to clarify the therapeutic efficacy and tolerance of image guided sclerosis with SETROL (Sodium Tetradecyl Sulfate) in the treatment of low flow venous malformations.

Design: Prospective single-center consecutive series.

Material and methods

From January 2019 to September 2020, we analyzed the complete records of 50 patients with symptomatic venous malformation, diagnosed on MRI treated by SETROL (Sodium Tetradecyl Sulfate) foam sclerosis using Tessari's technique under guidance of DSA and ultrasound. Multiple sclerotherapy sessions separated by 4-6week interval were done, according to response of treatment done. During the follow-up, we evaluated symptomatic improvement regarding the decrease in pain, size, change in consistency of lesion and obliteration of vascular channels on imaging. The end point was successful reduction in size or complete obliteration of vascular channels.

Results

A total of 50 patients between 2 and 70 years were treated. Males are more commonly affected (54%) than females (46%).38% had lesions on head neck & face, 30 % on lower extremity, 24% on upper extremity and 8% on trunk. The lesion was Small (<3 cm) in size in 32%, Medium (3-5 cm) in 48% and Large (>5 cm) in 20% of patients. The concentrations of SETROL (Sodium Tetradecyl Sulfate) used ranged from 1.5% to 3%. The maximum number of sessions was 5 (between January19 to September 20). Large size lesions required a greater number of sessions and vial compared to small and medium size lesions.

Sclerotherapy was effective in all patients in their 1st session and effectiveness increases in subsequent sessions. All patients were evaluated 7 days after each session to look any complication. A median follow-up of 2 months after the last session, 68% patients reported excellent improvement, 26% good improvement and 6% minor improvement of decrease in pain; change in consistency; reduction in size compared to the original size and change in vascularity on doppler imaging was obtained. Minor complications (including pain and blackening) seen in 22% of patients.

Large size group of VMs required a greater number of vials (mean 6.6) compare to medium (mean 3.58) and small sized groups (mean 2.25). Total sclerosant volume used in large group differ significantly from small and medium size group but small and medium group doesn't show significant difference. After each session of sclerosis there is significant reduction in size of VMs and its change in consistency and vascularity.

There is 75% to 100% reduction of VMs size in 68% patients, 50% to 75% reduction of VMs size in 20% patients and 25% to 50% reduction of VMs size in 12% patients after final session of the sclerotherapy.

The VMs become semi hard in 60% patients, hard in 24% patients and no change in consistency i.e. remain soft in 12% of patients 2 months after final session of the sclerotherapy.

There is 75% to 100% reduction of vascularity in VMs 2 months after final session of the sclerotherapy in 88% patients and 50% to 75% reduction in 12% patients,

On follow-up, 2 months after the last session of sclerosis, 60% patients were completely recovered from the swelling and 2 % patient had no improvement VMs located on head neck and face region shows better grade of improvement than VMs over lower extremity, trunk and upper extremity.

Conclusion

Treatment of VMs by DSA and ultrasound-guided sclerosis using SETROL (Sodium Tetradecyl Sulphate) is effective & well tolerated with a satisfactory clinical response in patients' symptoms in 94% of cases.

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