Journal of Cardiovascular Disease Research

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

Original research article

Therapeutic and cosmetic efficacy of foam sclerotherapy for percutaneous management of vascular malformations under imaging guidance

[1]Dr. Nikhil Bansal, [2]Tejas P Sadavarte, [3]Dr. Medha Gupta, [4]Dr. Neharika Kothari

[1]MD (Radiology), PGDHHM, FIPM, FVIR, Assistant Professor, Department of Interventional Radiology, Mahatma Gandhi Medical College, Jaipur, Rajasthan, India

[2]MD (Radiology), Associate Professor, Department of Radiology, Datta Meghe Medical College, Shalinitai Meghe Hospital and Research Centre, Hingna, Nagpur, Maharashtra, India

[3]MD (Medicine), DM (Neurology), Deep Hospital and Research Center, Jaipur, Rajasthan, India

[4]MD (Radiology), Assistant Professor, Department of Radiology, Mahatma Gandhi Medical College, Jaipur, Rajasthan, India

Corresponding Author:

Dr. Neharika Kothari

Abstract

This study exhibits our experience of performing percutaneous sclerotherapy (PS) coupled with imaging guidance with Setrol (sodium tetradecyl sulfate) and Polidocanol to treat slow-flow vascular malformations (SVMs) and to monitor its therapeutic outcomes and complications.

In our prospective observational study between August 2017 and January 2022 at our department, patient's demographic information, lesion characteristics, number of treatment sessions, therapeutic results, and complications were analyzed. One hundred eleven treatment sessions were performed for lesions in 45 patients, with the majority (77.8%) in pediatric population. The female to male ratio was almost 1.2:1 (female 25 male 20). The location of the SVMs included the head, neck, and face (57.7%) upper extremity (31.1%), and lower extremity (11.1%). The majority of the lesions were focal in 36 cases (76.6%), while 11 (23.4%) were diffuse. Nine patients (20%) underwent single PS session, 24 patients (53.33%) underwent 2 sessions, 6 patients (13.3%) underwent 3 sessions and 6 patients (13.3%) underwent ≧4 sessions. The mean PS session per patient was 2.2 ± 1. The mean follow-up duration was 10.2 ± 5 months. After the last PS session, 34 patients (75.6%) had excellent outcomes and 11 patients (24.4%) had satisfactory outcomes. After the PS procedure, temporary local swelling occurred in 92 sessions, local pain occurred in 42 sessions, fever occurred in none, and transient local numbness occurred in 8 sessions. Overall, satisfactory outcomes were obtained (34 patients benefited cosmetically and functionally and 11 patients were satisfied functionally).

Hence, we concluded that PS with sclerosant under the guidance of Ultrasound and DSA is proven to be a safe and effective therapy for the management of SVMs.

Keywords: Efficacy, sclerotherapy, percutaneous management, vascular malformation

Introduction

The prevalence of vascular malformations (VAMs) is 4.5% worldwide. VAMs are often complex in structure, and highly variable in size and location. They permeate and infiltrate the dermis, subcutaneous fibro fascial planes, muscle, bone, joint, nerve, mucous membrane, and viscera. Their location may be superficial or deep, localized or diffuse, solitary or multifocal. VMs originate from disruption of vascular morphogenesis in embryonic life with abnormal networks of venous channels, with thin channel walls and abnormal smooth muscles. Being slow-flow vascular malformations, they expand gradually and contiguously and are clinically asymptomatic until they are large enough to cosmetically or functionally compromise the region. However, dramatic enlargement can occur as a consequence of hormonal changes, inappropriate therapy, or post-traumatic. The symptoms depend on the location and depth of infiltration. Common symptoms of VMs include pain, dysfunction, swelling, bleeding, coagulopathy, disfigurement, nerve compression, and functional debility. The surgical resection of these is difficult and impossible in many cases as inadequacy of the overlying integument is seen. Our purpose to negate functional debility and cosmetic disfigurement as the possible side effects of surgical resection was fulfilled through the use of foam sclerotherapy with no or tolerable minimal side effects and desirable outcomes.

The effectiveness and success rate of sclerotherapies as monotherapy have been studied and our results reiterate its use. Other therapeutic options have been explored for VMs, including compressive wrapping, laser therapy, sclerotherapy, surgical excision etc. Percutaneous sclerotherapy (PS) [9, 10], as a minimally invasive therapy, is widely used to reduce the size of VMs and relieve the symptoms. Various sclerosing

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

agents e.g. ethanol, sodium tetradecyl sulfate (STS), polidocanol, and pingyangmycin are suggested. However, they may lead to complications, such as fever, anaphylactic reactions, tissue necrosis, and nerve injuries. The main objective of this study was to report therapeutic outcomes and complications of PS with polidocanol under imaging guidance to treat VMs.

Aims and Objectives

To evaluate the efficacy of percutaneous management of vascular malformation with setrol or polidocanol [10], assessing the lesion, creation of a treatment protocol, determining the number of sessions and sequential monitoring of its size and symptoms and success after treatment.

Material and Methods

This is an institution-based prospective observational study which was conducted in the TIFAC-CORE Interventional Radiology, AVBRH, Sawangi, Wardha, and Interventional Radiology Dept. at Mahatma Gandhi Hospital Jaipur from July 2017 to Feb 2022, after receiving ethics committee approval.

A total of 45 patients were included in the study. Age, number and anatomy of lesions, any prior treatment, nature of the malformation (venous, lymphatic, venolymphatic, capillary, or arteriovenous), number of treatment sessions, nature of the sclerosant used (Sodium tetradecyl sulfate), intraprocedural and post-procedural complications, and treatment duration (follow-up) were all taken into consideration. After counseling and obtaining written informed consent from patients/parents, a detailed clinical examination was conducted and customized protocol was explained to the patient.

- Treatment for SFMs was typically tailored to each lesion and to each patient; therefore a uniform treatment protocol is not applicable. SVMs were classified as focal or diffuse by anatomic distribution and morphologic characteristics [2]. The VMs were classified as small (max diameter <10 cm) or large (max diameter ≧10 cm) by maximum diameter.
- High-resolution USG with color Doppler was applied to each lesion to determine the extent of color flow, depth and, permeation extent and important regional anatomy, contrast study was done to gauge volume and dimensions through fluoroscopy and MRI in deep-seated lesions.
- Treatment of VMs was performed using a direct percutaneous injection of a mixture of sodium tetradecyl sulfate (setrol), Air and contrast (iohexol (3:2:1) in below Head & neck and sodium tetradecyl sulfate (setrol) and Iohexol (3:1) in above neck lesions.
- Direct puncture of the lesion was performed using a 23 or 24-gauge needle under ultrasound guidance and then confirmed by aspiration and DSA shoot. Patients with Contrast allergy and raised PT/INR were excluded.

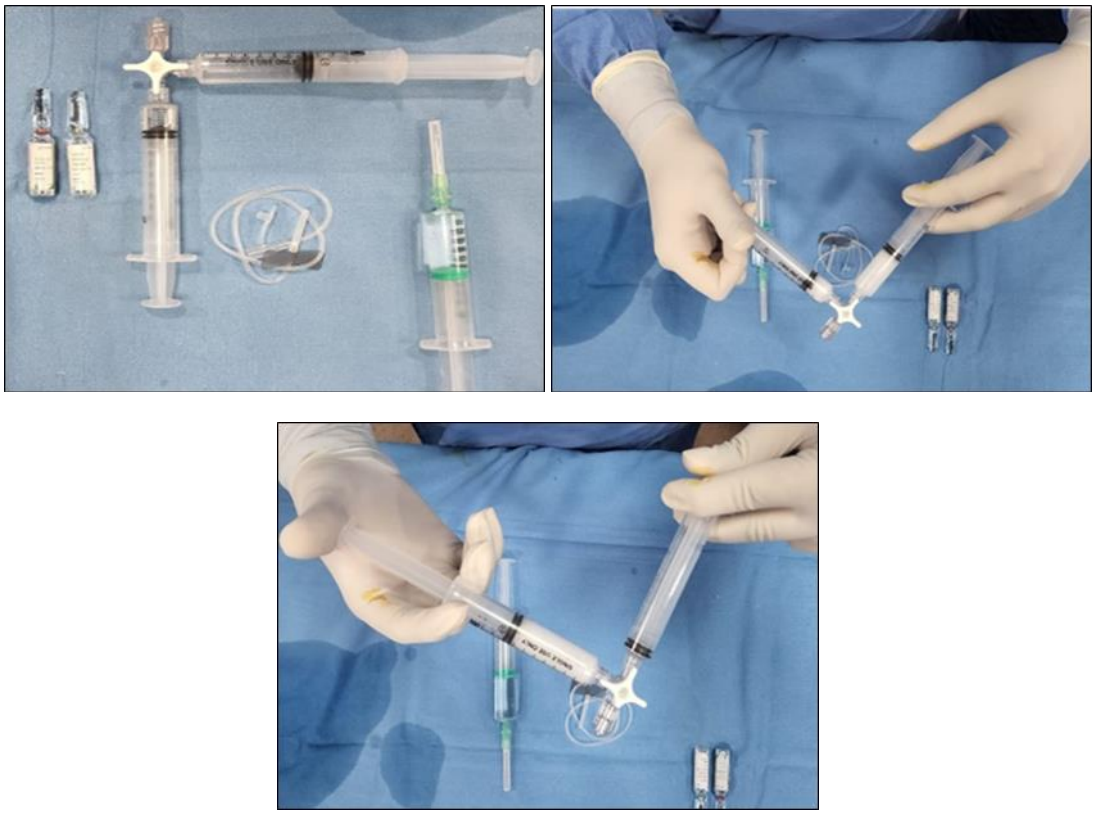
Equipment and Procedure

All the cases were clinically assessed and confirmed with ultrasonography & color Doppler using an Aloka Ultrasound machine. Conventional angiography and magnetic resonance imaging (MRI) were used in a few cases to classify vascular anomalies according to the International Society for the Study of Vascular Anomalies (ISSVA) classification [3]. Interventional Endovascular treatment was done by Digital Subtraction Angiography on Philips Allura FD20 Cath Lab System [5]. The aim of the treatment was not to eliminate the VMs, but to reduce their volume, alleviate the symptoms and improve functions. All patients were treated for pain, functional disorders, bleeding, and discomfort. Sclerosing agents produce endothelial injury and vascular damage and result in endofibrosis. To check for allergic reactions, a test dose of polidocanol is injected 1 week before the start of treatment.

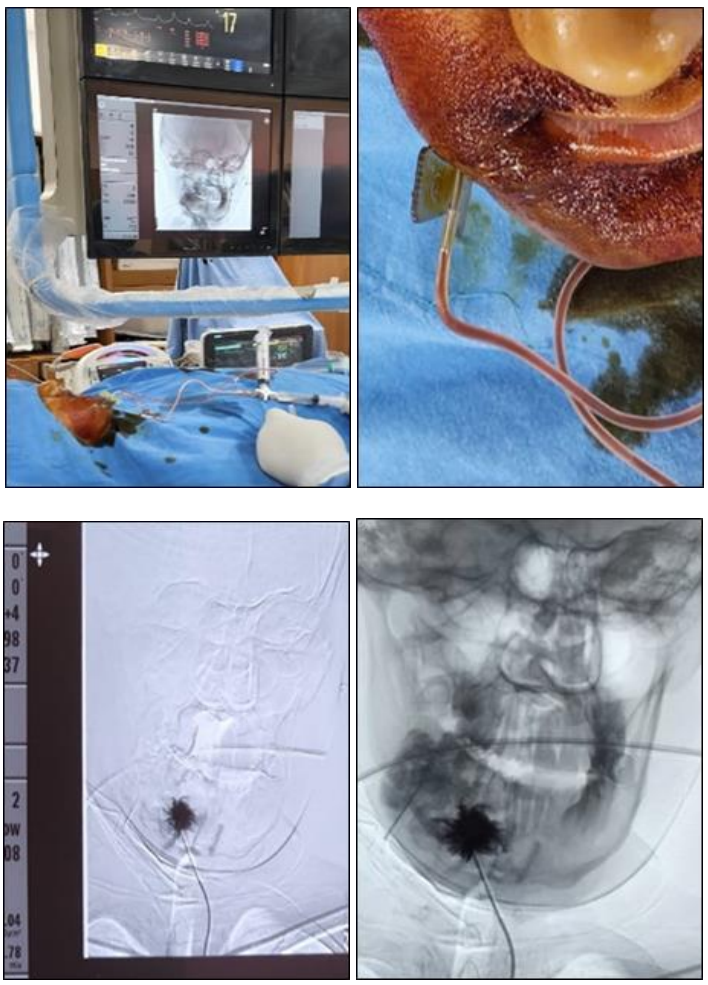
PS was performed under continuous US guidance with 22 to 27 gauge needles and blood is withdrawn to check needle position. Then, the polidocanol or setrol foam (0.5 to 1% polidocanol) was prepared according to the Tessari technique (2 disposable 20ml syringes, a three-way tap, reusable extender adapted to intravenous needle with a maximum dose of 2 mg/kg mixed with three times the volume of air) was gently injected [7].

Some patients experienced some degree of thrombus development and hyperpigmentation, which gradually resolves. There were no ulcerations, pulmonary emboli, or anaphylactic reactions [8]. One patient developed superficial chemical thrombophlebitis. From the first and last PS session to the present, there has been a record of follow-up. After the last PS, patients were clinically observed for the next three months. Repeat PS was based on the residual size and symptoms of the lesions, 4 weeks after PS. Any improvements and complications were noted.

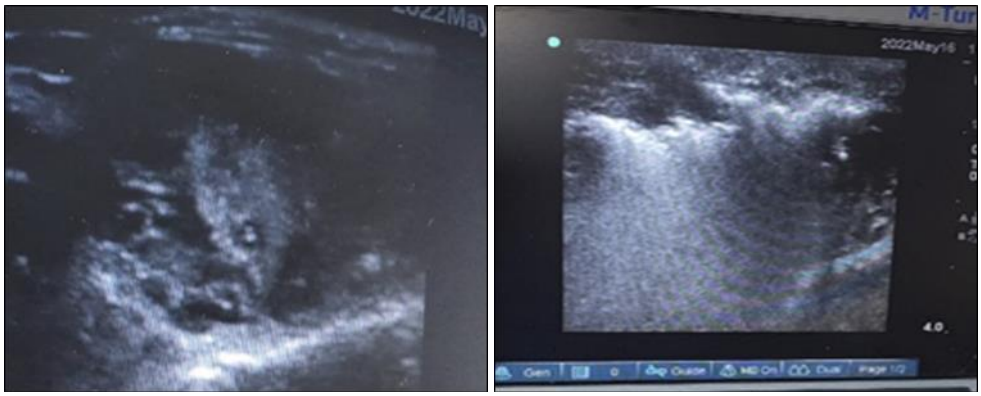
ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022



Polidocanol foam (0.5 to 1% polidocanol) is prepared using the Tessari technique (2 disposable 20ml syringe, a three-way tap, reusable extender adapted to intravenous needle. (3:1 air: drug ratio is taken and foam prepared). DSA Imaging and ultrasound guidance during cannulation coupled with vital parameter recording throughout the procedure.



ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022



(A) **(B)**

A & B): USG image of SVM and Polidocanol foam

(C) **(D)**

C & D): Pre and immediate post-procedural photograph

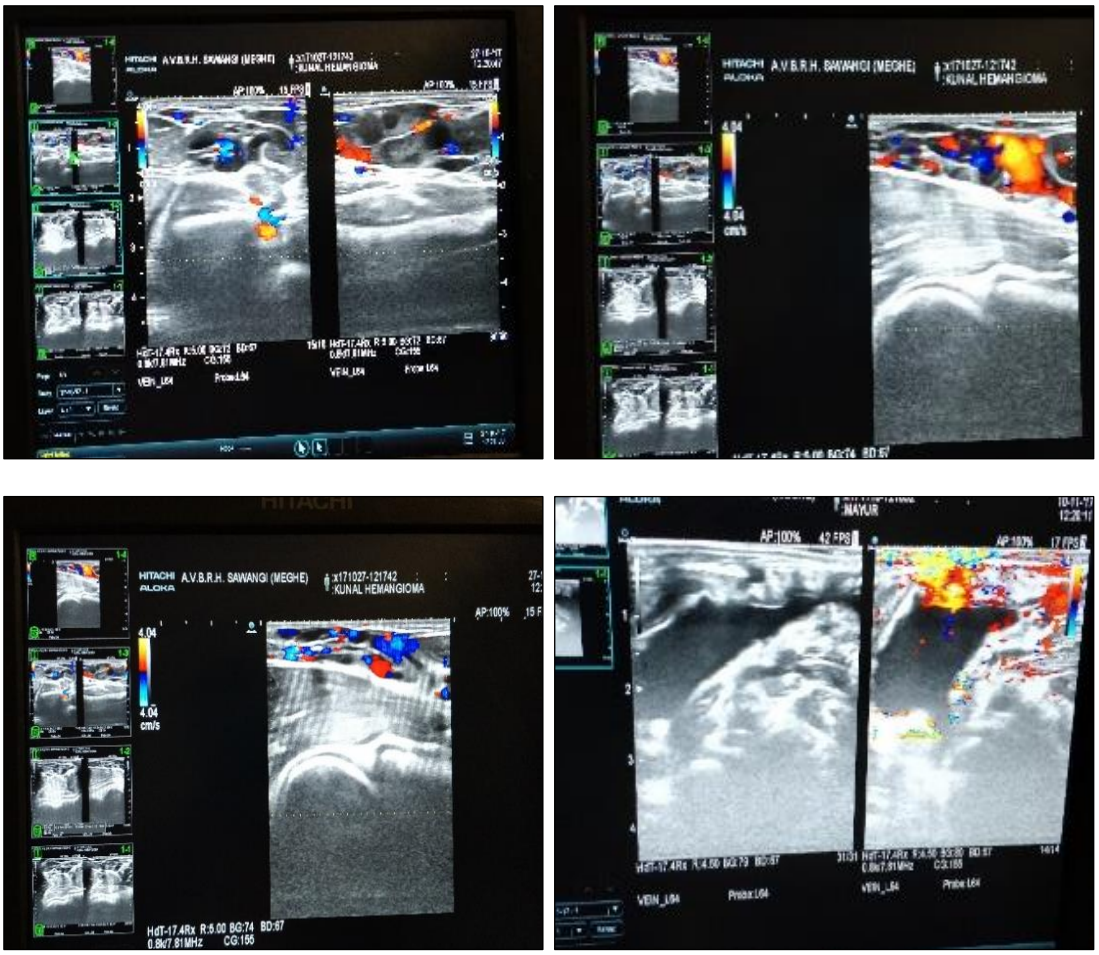
Observation and Results

Our 45 participants consisted of 20 males and 25 females ranging in age from 1 to 35 years old, with maximum under 5 years old, indicating a higher incidence in paediatric population [6]. The majority of vascular malformations is in the head and neck of which 57.7% were perioral and upper cervical lesions, with the cheek and lips being the most frequently involved (33.3 percent). The major complaint was regional VM swelling, congenital or progressive with much concern of cosmetic disfigurement than functional deficits. Iohexol, sodium tetradecyl sulphate and Air for Foam formation as sclerosant were used as it has lower complication rates and good final outcomes.

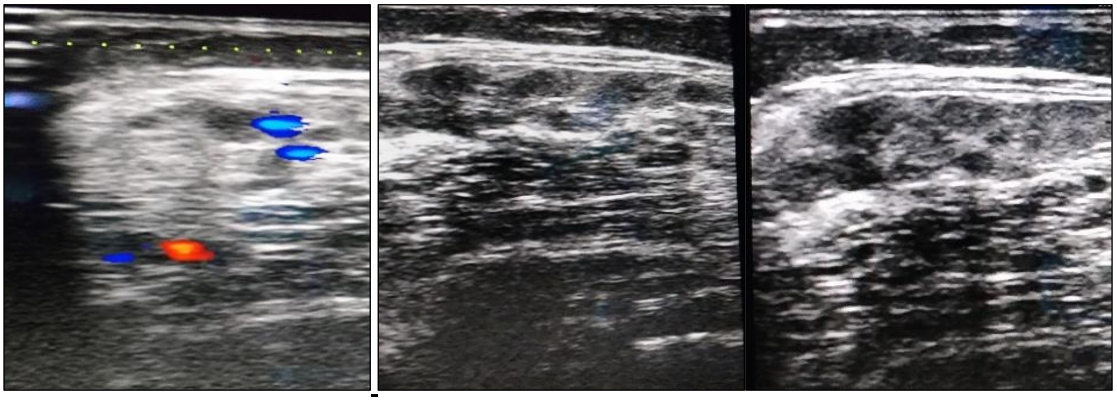
Few minor complications such as pain (4.4%), swelling (13.3%), infection (4.4%) were effectively managed. No major complications occurred. Average number of sclerotherapy sessions required were around 5.9. The post procedural results were remarkable in the majority and appreciable in rest. Hence a satisfactory outcome in all patients was observed.

Upon follow up, improvement in symptoms, decrease in size of malformation and decrease in number of vascular channels was noted with therapy with minor complications.

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022



Pre-Procedure Doppler Images



Post Procedure Doppler, Reduced Lesion Size and Vascularity Seen

Age Range	Number of Patients (%)
1-5YRS	21 (46.6%)
6-10 YRS	6 (13.33%)
11-15YRS	8 (17.7%)
16-20 YRS	5 (11.1%)
21-25 YRS	3 (6.6%)
26-30 YRS	1(2.2%)
31-35 YRS	1(2.2%)

Anatomic Location		Number of Patients
Head and Neck	Face Mandible	2
	Cheek	2
	Lips	7
	Cheek, Lips, Nose	4
	Cheek, Lips	C2
	Neck	7

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

	Occipital Region	2
Upper Extremity	Forearm	4
	Shoulder	3
	Wrist	3
	Back	4
Lower Extremity	Ankle	2
	Calf	3

Location of vascular malformation

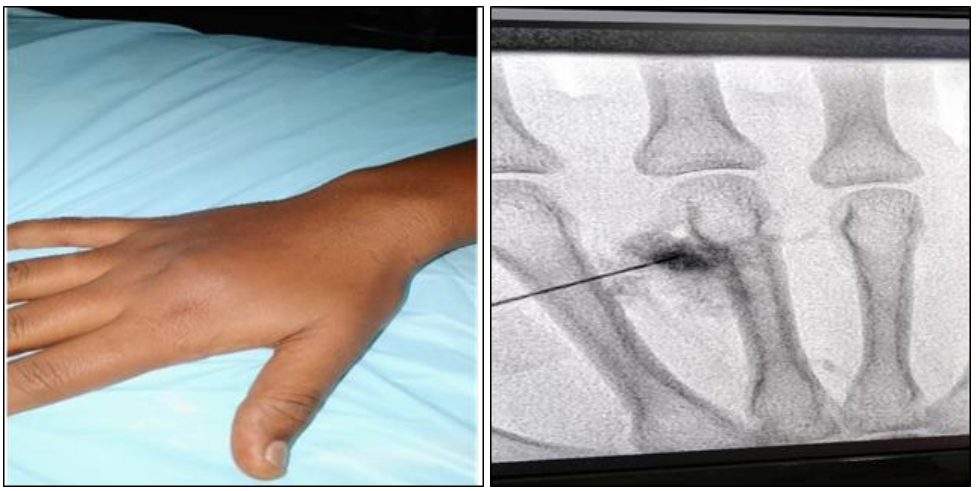
Symptoms	Number of patients
Swelling, functional limitation	4 (8.8%)
Swelling, pain, functional limitation	8 (17.7%)
Swelling, pain	5 (11.1%)
Swelling (only)	23 (51.1%)

Sclerosant	Number of Patients
Lipiodol + Setrol + Air	19
Lipiodol + Setrol	26

Complications	Number of Patients (%)
Pain	2 (4.4%)
Swelling	6 (13.3%)
Infection	2 (4.4%)

Imaging of the lesion and surgical outcomes

MRI of Slow Flow Vascular Malformation of Face



Angiogram of SVM dorsum of hand

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

Angioma upper lip, reduction post therapy

Reduction of SVM cubital region, contrast, DSA images and post procedural image

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

Post Treatment (Wall of smile☺)

A 2 month old female with a large diffuse VM involving the left face region. (A) The lesion was superficial, discoloured, compressible and soft on palpation. (B) 2 months after the first PS session, the volume of the lesion significantly changed. (C) 6 months later, the lesion was smaller and flat. Although partial VM remained, the desired purpose of treatment was achieved

Multifocal SVM treated in 5 sessions show significant reduction in size with functional restoration

Discussion

Liquid sclerosants are widely used in the treatment of SVMs, but due to immediate dilution and irregular distribution in the circulation, become less effective with risks of systemic side effects. Tessari *et al.* technique to create microfoam using a three-way tap approach. Foam displaces the blood with even distribution over the endothelium which is visualized with ultrasound. No serious adverse events were observed in our study, such as neurotoxicity or evidence of embolism. Minor problems of local bruising, swelling and lumpiness were reported in all patients, were chiefly procedural, and also as an inflammatory angiosclerosis response to the sclerosing agent.

Our successful

Case series has proven that foam sclerotherapy used under imaging guidance is effective in the management of SVM in the head and neck and extremities and also as an adjunctive to surgery of the lesion. However, this series was limited to a small number of patients who have been treated to date, and long-term follow-up of existing patients is needed to audit the outcomes of patients. Large and deep SVMs including bone was not included and the lesion size could only be reduced and not eliminated and we did not follow the reoccurrence.

Surgical options in cervico facial regions may pose a greater functional risk (Pappas *et al.*) [11] and the bigger scar would additionally disfigure the integument with the need for skin graft etc. A LASER workup would also end up in scarring.

Conclusion

The combined, minimally invasive, radio surgical approach to treating various SVMs replaces conventional phlebography, stripping and open surgery. Customizing the treatment plan and marking the course of the arteriovenous channel and/or direct puncture of the lesion under ultrasound or fluoroscopic guidance under anesthesia and asepsis, ensuring accurate placement of wire tip in varix, and administering closure agents with interval monitoring, lead to a satisfactory clinical outcome. Higher

ISSN:0975 -3583,0976-2833 VOL13, ISSUE 05, 2022

clinical grades of these malformations may require revision procedures. Thus, a cost-effective, fairly accurate, and result-oriented procedure is carried out worldwide successfully.

References

1. Lee BB, Laredo J, Lee TS, Huh S, Neville R. Terminology and classification of congenital vascular malformations, Phlebology. 2007;22(6):249-252.
2. Greene AK. Vascular anomalies: current overview of the field, Clinics in Plastic Surgery, View at Publisher, Google Scholar, Scopus. 2011;38(1):1-5.
3. Legiehn GM, Heran MKS. Classification, diagnosis, and interventional radiologic management of vascular malformations, Orthopedic Clinics of North America. 2006;37(3):435-474.
4. Azizkhan RG. Complex vascular anomalies, Pediatric Surgery International. 2013;29(10):1023-1038.
5. Image guided sclerotherapy for the treatment of venous malformations. Gorman J, Zbarsky SJ, Courtemanche RJM, Arneja JS, Heran MKS, Courtemanche DJ. CVIR Endovasc. 2018;1(1):2. Doi: 10.1186/s42155-018-0009-1. Epub 2018 Jun 28. PMID: 30652135
6. Mulliken JB, Glowacki J. Haemangioma and vascular malformations in infants and children: a classification based on endothelial characteristics. Plast Reconstr. Surg. 1982;69:412-7.
7. Tessari L, Cavezzi A, Frullini A. Preliminary experience with a new sclerosing foam in the treatment of varicose veins. Dermatol Surg. 2001;27:58-60.
8. Berenguer B, Burrows PE, Zurakowski D, Mulliken JB. Sclerotherapy of craniofacial venous malformations: complications and results. Plast Reconstr Surg. Discussion 1999;104:1-11, 12-5.
9. De Lorimer A. Sclerotherapy for venous malformations. J Pediatr Surg. 1995;30:188-94.
10. Siniluoto TM, Svendsen PA, Wikholm GM, Fogdestam I, Edström S. Percutaneous sclerotherapy of venous malformations of the head and neck using sodium tetradecyl sulphate (sotradecol) SCAND J Plast Reconstr Surg Hand Surg. 1997;31:145-50.
11. Pappas DC, Jr Persky MS, Berenstein A. Evaluation and treatment of head and neck venous vascular malformations. Ear Nose Throat J. 1998;77:914-6, 918-22.