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Role of sclerotherapy in low flow vascular malformations

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Abstract

Vascular malformations arise due to abnormalities of vessels which may comprise veins, arteries, lymphatics, or, even capillaries or a combination of these Venous mal formations (VMs) are one of the most common vascular malformations, with an estimated incidence of 1 per 5000 to 10,000 individuals, and equal gender distri bution. The aim of the study was to analyse the role of sclerotherapy in the treatment of low flow vascular malformations.

Material and Methods: This was an Hospital based observational study with due approval of the institutional ethical committee, SMS medical college Jaipur. Sample size of 36 patients were included in this study. The study population included patients which included children and adults who were diagnosed as having a low flow vascular malformation, which includes venous, venolymphatic, or lymphatic malformations, from the various departments within SMS Medical College and attached Hospitals and were being referred to the Department of Radiodiagnosis for sclerotherapy.

Results: In this study there was an unequal distribution of extremity and head & neck low-flow vascular mal formations which consists of 50% extremity cases, 36.1% head & neck cases and 13.9% trunk cases. Majority of the patients had the venous type of low flow vascular malformation (63.9%), while 11.1% had lym phatic malformation and 25% had the mixed type with both venous and lymphatic components. Out of the 36 patients, 31 (86%) did not have any significant compli cations and 5 patients (13.9%) had minor complications. Of these 5 patients, 3 had skin discoloration and 2 had small skin & mucosal ulcerations, which were managed conservatively.

Conclusion: This study demonstrates that sclerotherapy for low-flow vascular malformations is a safe and reliable way to alleviate the symptoms of the patients. Accurate delineation of the lesion before treatment facilitates the planning the appropriate therapy.

Keywords: Vascular malformations, sclerotherapy.

Introduction

Vascular malformations arise due to abnormalities of vessels which may comprise veins, arteries, lymphatics, or, even capillaries or a combination of these.[1] Vascular malformations have often been misdiagnosed in the past and continue to be even today. The classification of vas cular malformations has undergone tremendous Modi

fications in recent years. The most recent and widely accepted one being the ISSVA classification 2014 with the latest revision in 2018.

Venous malformations (VMs) are one of the most com mon vascular malformations, with an estimated incidence of 1 per 5000 to 10,000 individuals, and equal gender distribution.[2] Approximately 40% of VMs are located in the head and neck region, 40% in the extremities and 20% in the trunk, respectively.[3] Low flow vascular mal formations are one of the most common soft tissue lesions in children, adolescents, and young adults. They not only cause a cosmetic problem and functional im pairment but can also be a cause of mortality if these are located close to the vital structures.

VMs are usually clinically asymptomatic until they are large enough to cause a visible mass or symptoms. However, dramatic enlargement can occur as a result of hormonal changes, inappropriate therapy or trauma.[4] The symptoms depend on the location and infiltration depth of the VMs. Common symptoms of VMs include pain, dysfunction, swelling, bleeding, coagulopathy, disfigure ment, nerve compression and airway obstruction.[5,6]

Ultrasound and colour doppler is considered as the primary modality for assessment of vascular malforma tions because of its wide availability and ease of use and it helps in classifying lesions on flow characteristics that guide management plan. MRI examination along with gadolinium-enhanced scans which have become the investigation of choice for most of these malformations, has the advantages of imaging in three dimensions, which is useful in planning and also to know its relation to vital deeper structures.

Various sclerosing agents have been used to treat VMs, such as ethanol, sodium tetradecyl sulphate (STS), poli docanol and pingyangmycin. However, they may lead to complications, such as fever, anaphy lactic reactions, tissue necrosis, and nerve injuries.[7] In our study, poli docanol was used for the treatment of venous malforma tions and bleomycin for lymphatic malformations. Our end points included patient satisfaction and objective evaluation of the lesion's size.

Material and methods

This was an hospital based observational study with due approval of the institutional ethical committee, SMS medical college Jaipur. Sample size of 36 patients were included in this study. The study population included patients which included children and adults who were diagnosed as having a low flow vascular malformation, which includes venous, venolymphatic, or lymphatic malformations, from the various departments within SMS Medical College and attached Hospitals and were being referred to the Department of Radiodiagnosis for sclero therapy. Sclerotherapy was offered to them as a treatment option after explaining the possible risks and benefits. The patients in this study were included after they gave informed consent.

The risks of the invasive procedure have to be weighed against the potential benefits. The patient/ patient's attendees were informed about the procedure, other alter native methods available, and specific risks of the inter vention as well as the need for subsequent interventional procedures, as malformation treat ment is rarely comp leted within a single session. Basic blood investi gations were done such as hemo globin, viral markers, bleeding parameters such as pro thrombin time, INR, and platelet count. All the pro cedures were carried out under local anesthesia, or conscious sedation depending upon the patient's age, location of the malformation.

All procedures were carried out under USG and C-arm Philips Allura X-per FD10 guidance under strict aseptic precautions.

Inclusion Criteria

Patients who presented to SMS Medical College and Attached Hospitals for the first time and have been diag nosed with a low flow vascular malformation, and who have not undergone any prior surgical treatment or sclero therapy were included in the study. They also needed to give their consent to be treated by sclero therapy procedure and be available for follow up questions and clinical evaluation.

Exclusion Criteria

Patients who had received prior treatment either sclero therapy or surgery in any hospital or treatment centre were excluded from this study.

Observation and result

In the present study we included 36 patients. The range of ages of the patients in this study was 3-47 years with a mean of 19.8 years with a standard deviation of 11.5 years. In the present study unequal distribution of females and males was seen with slightly higher female pre ponderance (55%). In this study there was an unequal distribution of extremity and head & neck low-flow vascular malformations which consists of 50% extremity cases, 36.1% head & neck cases and 13.9% trunk cases. Lower extremity cases were more common than upper extremity cases.

Table 1: Type of low flow vascular malformations.

Types of Vascular Mal formation	No. of Patients	Percentage
Venous Malformations	23	63.88
Lymphatic Malformations	4	11.11
Venolymphatic Malformations	9	25

In the present study majority of the patients had the venous type of low flow vascular malformation (63.9%), while 11.1% had lymphatic malformation and 25% had the mixed type with both venous and lymphatic com ponents. Majority of the patients presented with swelling (55.5%) while 22.2% of patients complained of pain, 8.3% skin/ mucosal changes like ulceration and discolo luration as the predominant presenting complaint and 5.5% had restriction of movement as the predo minant presenting complaint at the initial visit.

Figure 1: Grade of response at the end of the procedure

As shown in figure 1, Majority of the patients in the study showed improvement after sclerotherapy. 27.8% of patients showed excellent response more than 60% size reduction and clinically asymptomatic at the end of treatment, while 55.6% showed good response with substantial improvement in size (30-60%) and symptoms. 16% of patients had a poor response with no significant (<30%) decrease in size and symptoms. None of the patients had unchanged or worsening at the end of the sclerotherapy.

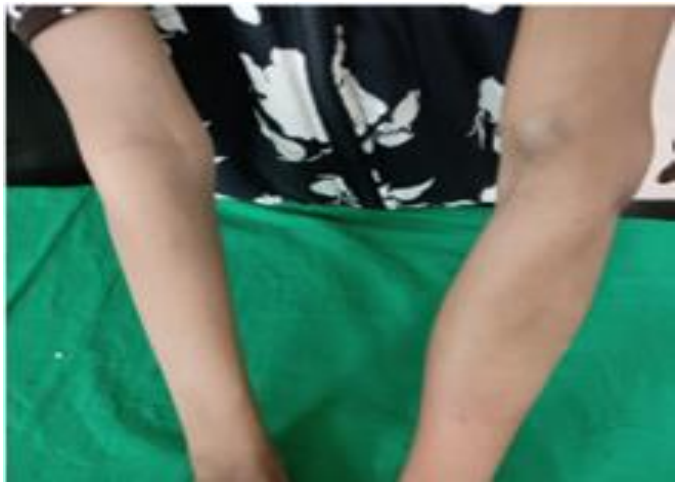

Figure 2: showing swelling around left elbow extending to forearm

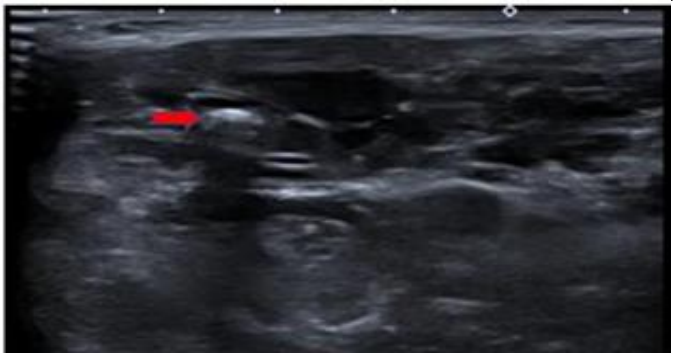

Figure 3: greyscale USG showing dilated vascular channels with a phlebolith (red arrow)

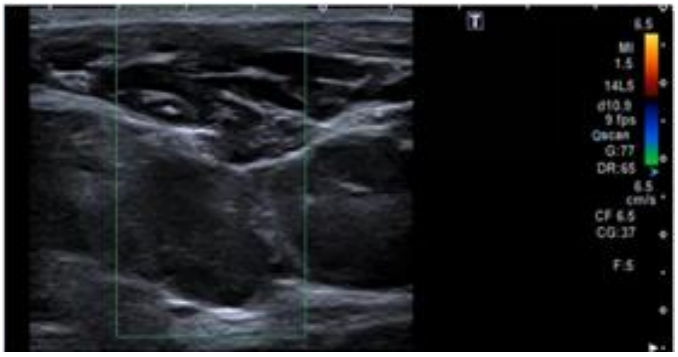

Figure 4: showing no blood flow on colour doppler

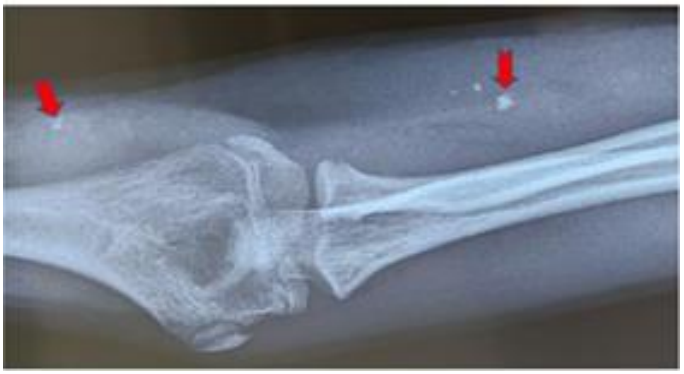

Figure 5: showing phleboliths on plain radiography

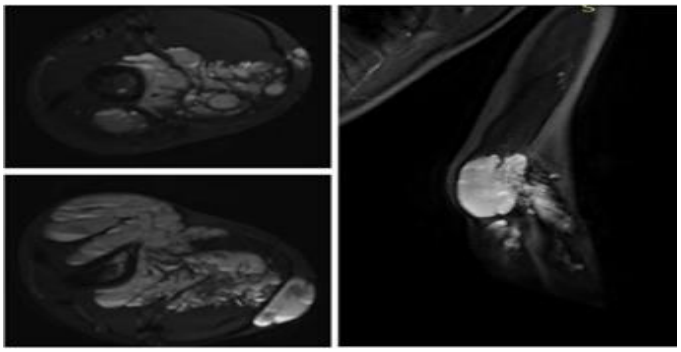

Figure 6: showing T2 hyper intense lesions in sub cuta neous and deep muscular plane on axial and coronal sections

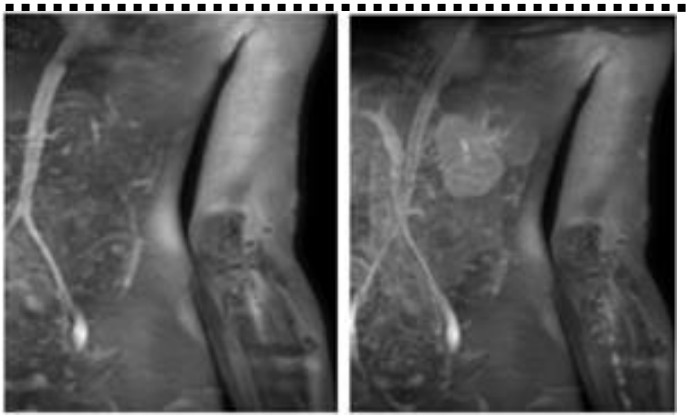

Figure 7: showing Dynamic contrast MRI: - No contrast filling in arterial phase (left). And Minimal contrast fill ing in venous phase (right)

Figure 8: showing catheterisation of vascular channer with butterfly cannula.

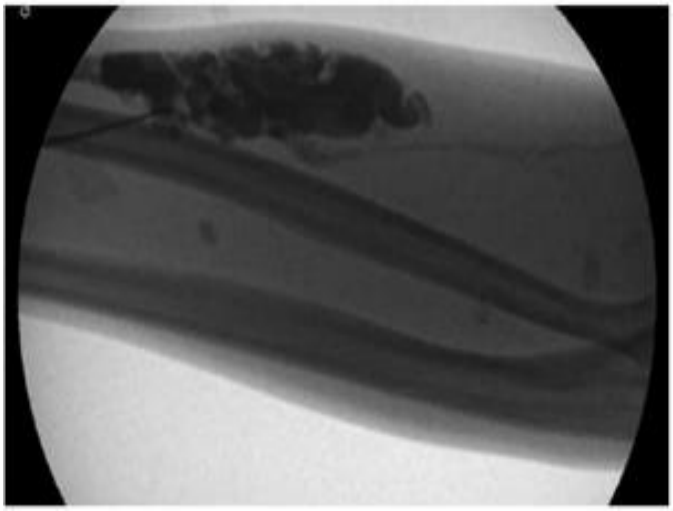

Figure 9: showing angiogram obtained under C-Arm guidance.

Figure 10: showing preparation of Gelfoam by Tessari technique

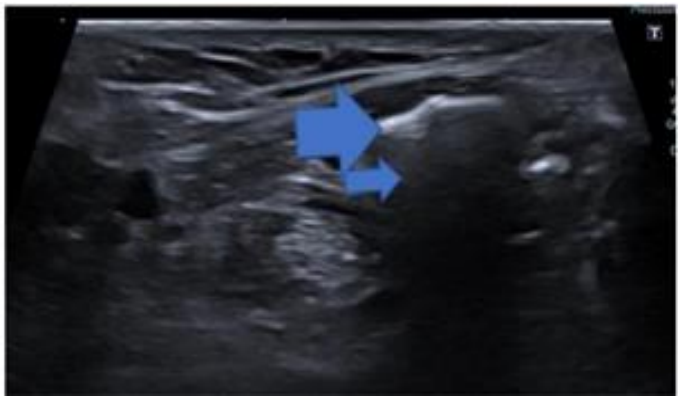

Figure 1:1 showing Gelfoam (bigger arrow) filling the lesion and its dirty shadow (smaller arrow).

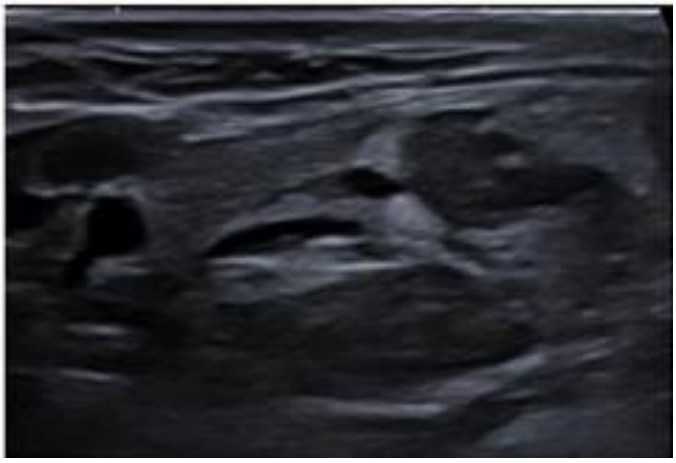

Figure 12: showing thrombosed vascular channels on follow-up.

Table 2: complications

Type of Complication	No. of Patients	Percentage
No Complication	31	86.1
Minor Complication	5	13.9
Major Complication	0	0

In table-2, Out of the 36 patients, 31(86%) did not have any significant complications and 5 patients (13.9%) had minor complications. Of these 5 patients, 3 had skin dis coloration and 2 had small skin & mucosal ulcer ations, which were managed conservatively. None of the patients had major complications in our study.

Table 3: Summary

Correlation between variables	Tests used	p-value	Statistical Correlation
Age and quality of life score	Spearman's rho correlation coefficient	0.1 0.69 0.14	Not Significant
Gender and quality of life score	Independent t-test	0.52 0.42	Not Significant
Means of QOL scores with time	Friedman's test	0.001	Significant
Location of lesion and QOL score	Kruskal-Wallis test	0.052 0.49 0.31 0.1	Not Significant
Type of malformation and QOL score	ANOVA (F-value) Kruskal-wallis test	0.09 0.27 0.63 0.62	Not Significant
Pre-treatment size and QOL score	Spearman's rho correlation coefficient	0.0001 0.0001 0.0002 0.0001	Significant

In table-3, we summarised statistical analysis. Here we used 2-tailed spearman correlation which did not reveal any statistically significant correlation between age and quality-of-life score at different time. We had used independent sample T-test and Mann-Whitney U test were used to assess if there was any statistical signifi cance between the gender and the outcome following sclerotherapy. There was no statistically significant difference between the 2 genders. The mean quality-of-life (QOL) scores was calculated before sclerotherapy and at 3 points of the follow-up, at day 1, 3, and day 7 post sclerotherapy. The Friedman test showed a statisti cally significant difference ($p<0.001$) between the means of the quality-of-life at pre-sclerotherapy, day 1, day 3 and day 7 of sclerotherapy.

Since the sample did not follow a normal distribution, non-parametric tests like the ANOVA test and Kruskal-Willis test were used to assess the relationship between the different types of low flow vascular malformations (VM, VLM, LM) & the quality of-life. There was no statistical difference ($p=0.09,0.27,0.68$ and 0.62) between the different types of low flow vascular malformations & quality-of-life scores at different times. Spearman's cor relation was used to assess if there was a relationship between the pre sclerotherapy size of the lesion and the quality-of-life scores. It revealed significant positive correlation (p-value = 0.001) between the pre-treatment size and QOL scores at pre-sclerotherapy, Day-1, Day-3 and Day-7.

Discussion

Out of the 36 patients, 10 (26.3%) patients showed excellent response and 20 (57.9%) patients showed good response while 6(15.8%) out of 36 patients showed poor response. Thus, the overall response was 83.4% in our study.

The age at which sclero therapy is done was not associated with a change in the quality-of-life score on day-7 post sclerotherapy ($P=1.43$). Both younger and older patients responded better to sclerotherapy proce dures under USG and fluoroscopy guidance.

In our study, 2 (5.5%) patients had complications of mucosal ulcers and 3(8.3%) patients had blackish skin dis cololur ation. These patients didn't require hospital admission and managed con servatively.

Both ulcers healed completely without any further com plication. There was no statistically significant difference between the location and the quality of-life ($p=0.10$).

Most patients in our study had minor pain and worsening of the swelling after the sclerosant injection which was managed conservatively with NSAIDs and local sym ptomatic measures. These immediate pain and swelling were not documented as they occurred universally in all patients and were transient and easily managed with NSAIDs and local symptomatic measures.

Conclusion

This study demonstrates that sclerotherapy for low-flow vascular malformations is a safe and reliable way to alleviate the symptoms of the patients. Accurate de lineation of the lesion before treatment facilitates the planning the appropriate therapy. Polidocanol is an effective sclerosant for therapy.

DSA guidance helps in treatment plans and deciding amount of sclerosant needed. This study demonstrated a few clinical and radiological factors of a favourable outcome.

Smaller pre -treatment size of the lesion was associated with a better outcome in terms of quality-of-life. A complete cure may never be possible in larger lesions, but sclerotherapy is an effective remedy for alleviating the patient's symptoms and makes further surgery easier by reducing size significantly.

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