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Original Article

Surgery Section

Therapeutic use of Sodium Tetradecyl Sulphate in Management of Cutaneous Vascular Malformations

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ABSTRACT

Introduction: Vascular malformations are congenital lesions. There are various kinds of treatment methods and sclerotherapy with Sodium Tetradecyl Sulphate (STDS) as a sclerosing agent is one of the effective method.

Aim: To assess therapeutic use of STDS in management of cutaneous vascular malformation.

Materials and Methods: This prospective study was conducted in Department of Surgery at Rohilkhand Medical College and Hospital, Bareilly, U.P (West), India. Total 50 cases of uncomplicated cutaneous vascular malformation were studied prospectively and results were followed. The findings were noted on a structured protocol and were subsequently entered into MS-Excel 2013 software and subjected to statistical analysis.

Results: The result showed the distribution of age most common in <10 years group, distribution of malformation site head and neck (38%) as most common site. Most of the patient responded in two sittings of sclerotherapy. Complete resolution was seen in 70% cases.

Conclusion: Sclerotherapy was observed to be a relatively cost effective procedure with low complications, high patient satisfaction, and a high success rate and can be considered as a treatment option in all cases of uncomplicated cutaneous vascular malformation.

Keywords: Sclerosing agent, Sclerotherapy, Uncomplicated

INTRODUCTION

Vascular malformations arise due to abnormalities of vessels which may comprise veins, arteries, lymphatics, or, even capillaries or a combination of these [1]. Such lesions usually don't manifest cell proliferation and usually do not regress by themselves [2].

Vascular anomalies are a result of abnormal vascular development [3]. These lesions almost invariably affect the skin and are evident from birth or in early neonatal life [4]. These lesions are produced due to abnormal vascular development and it includes vascular tumours as well [5]. A common childhood problem, these are mostly harmless and transient.

Various treatment methods for cutaneous vascular malformations, include surgery, sclerotherapy, laser therapy, cryotherapy, and electro coagulation treatment [6-8].

Sclerotherapy is one of the most popular treatment modality for management of cutaneous vascular malformations as it has relatively good success in almost all cases [9,10].This comprises injection of a sclerosing agent into the epicenter of the vascular lesion during occlusion of flow. This produces obliteration of the lesion and a satisfactory outcome [11].

STDS is a sclerosing agent that has been used for the treatment of hemangioma and other vascular conditions [12-14]. Like other sclerosants, STDS also induces extra vascular inflammatory reactions and causes vascular fibrosis and occlusion [15,16].

MATERIALS AND METHODS

This prospective study was conducted in the Department of Surgery at Rohilkhand Medical College and Hospital, Bareilly, U.P (West), India. After proper ethical clearance by the ethical committee, for one year from November 2015 to October 2016. Total 50 patients with uncomplicated cutaneous vascular malformation who attended the surgical OPD or were admitted in the Department of Surgery were considered for the study. Age, sex, demographic profile, site of lesion, duration of symptoms, amount and number of sittings of sclerotherapy required and outcome of the procedure were recorded.

All patients who presented in surgical outpatient department and admitted patient with uncomplicated cutaneous vascular malformation were included in the study.

Patients previously allergic to STDS drug, previously failed attempt of sclerotherapy, complicated cutaneous vascular malformation and patients who were not willing for sclerotherapy were excluded from the study.

Procedure

After painting and draping 3% STDS injection was given in the epicenter of lesion using insulin syringe. Free backflow of blood was confirmed by withdrawing plunger of syringe and after confirmation STDS was injected at multiple sites in lesions not exceeding 2 mL at single sitting.

Chemically 3% STDS solution contains 30 mg of sodium tetradecyl sulfate, 0.02 mL of benzyl alcohol, and 9.0 mg of dibasic sodium phosphate, anhydrous in water for injection at a pH of 7.9. All the patients received an oral analgesic in the post op phase. Follow-up of each patient was scheduled every 3 weeks, and therapy was repeated after 3 weeks if there was no response or only a partial response. A maximum of four sittings were given. Outcome was noted in terms of complete or partial recovery. Outcome was compared against number of sittings and per sitting dose used. Pressure bandage for 24 hours was done, analgesics were given for pain and swelling in post operative period.

STATISTICAL ANALYSIS

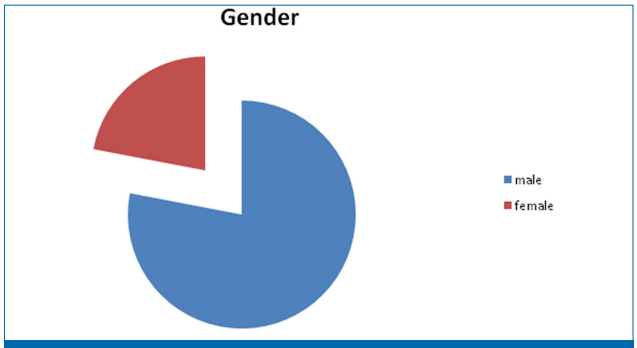
The findings were noted on a structured protocol and were subsequently entered into MS-Excel 2013 software and subjected to statistical analysis.

RESULTS

In present study out of 50 patients 11 (22%) patients were female and 39 (78%) were male [Table/Fig-1].

Age of patients ranged from 5 months to 40 years [Table/Fig-2]. Mean age of patients was 14.50±10.65 years. Majority of patients were males (n=39, 78%), below 20 years of age (n=36, 72%).Swelling was the universal presenting complaint with a mean presenting duration of 3.65±4.31 years. Pain (n=6, 12%), bleeding (n=4, 8%) and ulceration (n=1, 4%) were the other presenting complaints [Table/Fig-3].

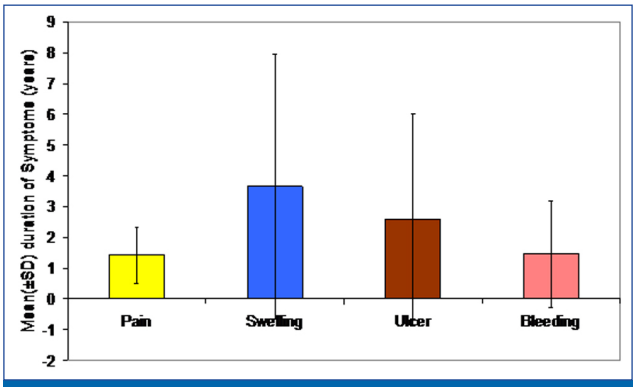
Head and neck (n=19,38%) were the most common affected locations followed by arm (n=11,22%) and leg (n=11,22%) while Upper back (n=2,4%), buttocks (n=2,4%) and shoulder (n=1,2%) were the least commonly affected locations [Table/Fig-4]. In maximum number of cases, malformations were irregular in shape (n=24, 48%) followed by circular (n=22, 44%) and oval (n=4, 8%) shapes. Pulsatility at affected site was observed in 1 (2%) case. There were 6 (12%) cases reporting dull aching pain at the malformation site (Fig 2). History of trauma (n=4, 8%), cyanosis (n=2, 4%), anaemia (n=2, 4%)



[Table/Fig-1]: Gender distribution of patients.

Age Group	No. of Cases	Percentage (%)
≤10 years	24	48
11-20 years	12	24
21-30 years	11	22
31-40 years	3	6
Total	50	100

[Table/Fig-2]: Distribution of patients according to age.



[Table/Fig-3]: presenting symptoms with their duration.

Site	No. of Cases	Percentage
Arm	11	22.0%
Back (Upper)	3	4.0%
Buttock	2	4.0%
Chest	3	8.0%
Head and neck	19	38.0%
Leg	11	18.0%
Shoulder	1	2.0%
Total	50	100.0%

[Table/Fig-4]: Distribution of patients according to site of malformation.

Number of Sittings	No. of Cases	Percentage (%)
One	9	18
Two	21	42
Three	16	32
Four	4	8
Total	50	100

[Table/Fig-5]: Distribution of patients according to STDS sittings.

and thin built (n=1, 2%) were the other additional findings.

Maximum number of cases required only two sittings (n=21, 42%) followed by those requiring three sitting (n=16, 32%). There were four (8%) cases requiring four sittings while 9 (18%) required only one sitting [Table/Fig-5]. Mean per sitting STDS dose ranged from 0.5 to 2 ml with a mean of 1.11±0.38 ml. No noticeable side effect except for transient pain and swelling that resolved within 24 hours, was noted in any case in either of two groups. Complete response rate was (n=35)70%. All the remaining patients (n=15,-30%) had a partial response [Table/Fig-6]. Significantly higher proportion of cases requiring only upto two sittings showed complete response as compared to those requiring more than two sittings [Table/Fig-7]. Survival function for 12 weeks follow-up was 0.254. Mean time taken for complete response was 7.726 weeks (median 6 weeks).

The findings of present study thus showed that STDS sclerotherapy is a useful modality for treatment of vascular malformations with promising response rate. In present study, the response rate was poor for those requiring larger dosages thus showing that large sized malformations failed to provide complete response.

Outcome	No. of Cases	Percentage (%)
Partial response	15	30
Complete response	35	70
Total	50	100

[Table/Fig-6]: Distribution of patients according to outcome.

Number of Sittings	Complete (n=35)		Partial (n=15)		Total (n=50)	
	n	%	n	%	n	%
One	7	20.00	2	13.33	9	18.00
Two	19	54.29	2	13.33	21	42.00
Three	9	25.71	7	46.67	16	32.00
Four	0	0.00	4	26.67	4	8.00

[Table/Fig-7]: Association of outcome with number of STDS sittings.
Note:- χ^2=15.226 (df=3); p=0.002 (Sig)

DISCUSSION

Vascular malformations are common disorders which are amenable to treatment in most of the cases and can be satisfactorily treated by sclerotherapy using STDS.

These anomalies are common and are present in about 1.5% of the population with no gender variation, having male to female ratio 1:1 [17]. Patients may present with cosmetic problems, tissue changes such as ulceration, swelling or, pain and sometimes with functional limitations. If mild, conservative treatments may suffice however severe symptoms mostly require more invasive treatment.

Cutaneous vascular malformations are often benign in nature and are rarely associated with life threatening complication [18] however, when falling in visible zone they often are of psychological concern affecting the quality of life of patient owing to esthetic concerns, [19]. Our study showed sclerotherapy to be a cheap and effective treatment for vascular malformations.

We enrolled 50 patients of uncomplicated cutaneous vascular malformation for sclerotherapy.

In present study, swelling was the universal presenting complaint with a mean presenting duration of 3.65±4.31 years. Pain (12%), bleeding (8%) and ulceration (4%) were the other presenting complaints, with mean duration ranging from 1.42±0.92 to 2.59±4.31 years.

In present study, arm (22%), head and neck (38%)and leg (22%) were the most common affected locations while upper back (6%), buttocks (4%) and shoulder (2%), chest (6%) were the least commonly affected locations.

In present study, maximum number of cases, malformations were irregular in shape (48%) followed by circular (44%) and oval (8%) shapes while size of malformation ranged from 0.25 to 35 cm^2. Mean area was 6.52+6.51 cm^2. Bajpai H et al., in their series reported the size of lesion to range from 0.48 cm^2 to 5 cm^2 in size [20]. Alakailly X et al., in their study reported the size range from 1 to 8 cm^2. However, in their study they reported multiple lesions at a site iin some cases thus indicating the average area to be larger [21]. Although, the maximum size of lesion in present study was much larger than that reported in various studies but given the fact that multiple lesions present at a single site contribute towards a larger area and moreover irregular shape of lesion in different cases bring about discrepancy in size in different studies. In present study size was calculated as multiplication of largest width and largest height of the lesion. However, the method of calculating the size has not been stated in various studies. The variability in size of lesion in different studies is also dependent on the method of measurement used.

In present study maximum number of cases required only two sittings (42%) followed by those requiring three sitting (32%). There were four (8%) cases requiring four sittings while 9 (18%) required only one sitting. As a result we obtained complete response rate in 70% cases while partial response was seen in remaining 30% cases.

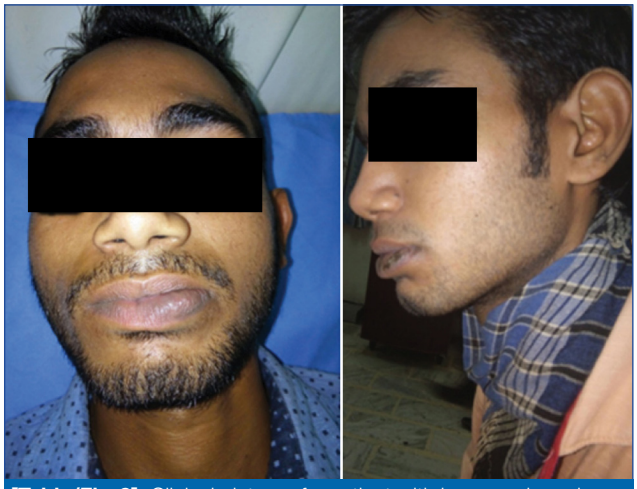
There are different perspectives and modalities of sclerosing agent delivery in different studies. Mostly, it is dependent on the size of the lesion and the maximum dose in a single sitting. Agarwal S et al., in their study used a protocol of 0.1 to 1 mL injection in a single sitting but had to have up to 10 sittings and showed regression of malformation in all the cases, and focused on the adequacy and appropriateness of the dose [22].

In present study mean area was 6.69 cm^2 and all the malformations were solitary in nature. In a previous study, a dose of 0.5 mL for each 2 cm size of lesion was suggested to be appropriate [21]. Taking this a reference in present study the average per sitting dose should have been above the maximum mark of 2 mL, thus indicating that in many cases the per sitting dose was inadequate and could have been the reason for failure to achieve complete response. Alaikally X et al., too in their study observed the lower efficacy of sclerotherapy in larger caliber or faster flow lesions could be a result of less sclerosant agent making contact with the endothelial cells of the lesion wall [21].

On evaluating the association of response pattern with different characteristics of sclerotherapy we observed that significantly higher proportion of cases requiring only up to two sittings showed complete response as compared to those requiring more than two sittings [Table/Fig-8,9]. We did not find any significant side effect of the drug which was limited only to mild pain and edema of transient nature. Other workers too at variable dosages have not reported any significant side effect of the drug apart from pain and swelling at the injection site which was emolliated by analgesics and anti inflammatory drugs [11, 21-24].

In present study, survival function for 12 weeks follow-up was 0.254. Mean time taken for complete response was 7.726 weeks (median 6 weeks). However, in view of a sizeable proportion of patients failing to achieve the complete response (n=15; 30%), the mean duration of treatment was even longer (8.5 weeks), thus indicating that despite a longer duration of treatment the treatment failed to yield the desirable results even on further sclerotherapy, and yielded only partial response.

The findings of the present study thus indicated that STDS sclerotherapy is a useful, convenient, cheap, safe, effective modality for treatment of uncomplicated vascular malformations. However, there is need to optimize the dose and number of sittings in order to achieve optimum response. Further studies in this direction are highly warranted.



[Table/Fig-8]: Clinical picture of a patient with haemangioma lower lip. **[Table/Fig-9]:** Clinical picture of a same patient after two sittings of sclerotherapy.

LIMITATION

This study was conducted among poor patients attending our institution. Although, resource rich centres are using LASER treatment as an option, however this was not done in our study.

CONCLUSION

Overall, sclerotherapy was observed to be a relatively cost effective procedure with low complications, high patient satisfaction, and a high success rate offering an effective and cheap treatment option to majority of patients suffering from cutaneous vascular malformations which can be done on OPD basis which further reduces the treatment cost and can be considered as a treatment option in all cases of uncomplicated cutaneous vascular malformation.

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