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# EFFECT OF SODIUM TETRADECYL SULPHATE INJECTION AS SCLEROSING AGENT IN VENOUS MALFORMATION OF ORAL CAVITY

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#### **ABSTRACT**

**Objectives:** To determine the effectiveness of using sodium tetradecyl sulphate foam sclerotherapy in the treatment of venous malformations of oral cavity.

Materials and Methods: In this quasi-experimental study 21 patients presenting with oral venous malformations at oral and maxillofacial OPD from 1-1-2017 till 31-12-2018 were included. After confirmation of the diagnosis with color Doppler ultrasonography and magnetic resonance imaging, we used direct injections of 3% STS foam using a 25G needle at a dose of 1ml per cm3. The injection was repeated up to a maximum of six times until a favorable response (50% reduction) was achieved. The results were recorded and analyzed by SPSS version 23.

**Results:** The mean age of patient was  $37.33\pm9.91$  years. There were 10 males (47.6%) and 11 females (52.4%) patients. Site of the lesion was buccal mucosa in 12(57.1%) patients and 9(42.9%) patients had lesion on tongue. Treatment response showed that only 23.8% patients had complete treatment response, 28.6% patients had good treatment outcome and 33.3% patients had moderate treatment outcome and 14.3% patients had no response. Side effects experienced by patients were edema (42.9%), pain (23.8%) and ulceration (19%).

Conclusion: STS is an effective treatment of VMs and can be used with minimal side effects and favorable results.

**Key words:** Magnetic resonance imaging; Sclerotherapy; Vascular malformations.

#### INTRODUCTION

Venous malformations (VMs) are the result of errors in the venous development and are most common vascular malformation. The VMs in head and neck region constitute above 40%. This close proximity with this anatomically delicate area makes their treatment complex.<sup>1-3</sup>

Clinical presentation of VMs varies significantly, ranging from complex lesions involving multiple tissue planes and viscera to a spongy mass or skin

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varicosity. They are compressible, non-pulsatile masses, soft in consistency, with rapid refilling. Their symptoms include a bluish discoloration of the skin or mucosa, swelling and pain, infectious purulent discharge, a bleeding ulcer or breathing, speech and swallowing difficulty, depending upon their size and location.<sup>3-5</sup>

The management protocol of VM has not been standardized yet. Multiple treatment options are available for low flow lesions like conservative management observation or minimally invasive interventions such as sclerotherapy, cryotherapy, embolization and laser ablation. If these procedures fail, then more aggressive surgical resection can also be considered<sup>1-3, 6-8</sup>. The patient's age, size, location

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and type of the lesion, and surgeon's experience significantly effects the choice of therapy. Cosmesis as well as function are the main concerns for the lesions in head and neck region except peri-oral lesions which can be associated with pain and bleeding during eating. 10-12

The sclerotherapy is an effective management option for VMs as it is safe, easy to administer, and has acceptable aesthetic and functional outcomes. An oreover, the surgical intervention can be completely avoided or significantly reduced by the use of sclerotherapy. Since 1946, the small varicosities of the legs, as well as lymphatic and venous malformations were widely treated with Sodium tetradecyl sulphate as sclerosing agent. The STS works by producing endothelial damage leading to fibrosis and subsequent shrinkage of the lesion without significant thrombus formation. The luminal obliteration of the vessels may or may not be permanent. 13-15

The efficacy of STS for VMs of oral cavity has not been assessed in our population and setup. The aim of our study was to assess its efficacy in the treatment of oral cavity venous malformations. The objective of this study was to observe the efficacy of sodium tetradecyl sulphate injection as sclerosing agent in venous malformation of oral cavity.

## **MATERIALS AND METHODS**

This was an qausi experimental study, which was conducted at the department of Oral and Maxillofacial Surgery, MTI, Lady Reading Hospital, Peshawar from 1st Jan 2017 to 31st Dec 2018. Ethical approval from Institutional review board was taken and informed consent from parents/guardians was obtained. Total 21 patients presenting with VM in oral cavity were recruited. The diagnosis of VMs was confirmed using color dopler ultrasonography and magnetic resonance imaging (MRI) when indicated. All previously treated patients of VMs were excluded. STS 3% foam was injected as a sclerosing agent with a 25G needle. The injection dose was calculated according to the size of the lesion as 1ml of the sclerosing agent per cm3 of the lesion. The total volume STS injected per patient was maximum 10 mL divided into multiple doses of 1 to 1.5 mL per injection, which was converted into foam by adding air in it using disposable syringes. For large lesions, multiple injections at different sites were used. The injections were repeated at 4 weekly intervals until 50% reduction in the size of the lesion was achieved. A maximum of 6 sessions of foam sclerotherapy were performed. However, those lesions which does not show any reduction in size after 2 sessions, no further injections were given. The location of VMs, number of treatment sessions, and the subsequent complications were recorded. Monthly follow-up assessments were continued for at least 1year post procedure (range, 12-24 months). A 50% lesion size reduction on clinical assessment was defined as favorable outcome. Data was entered into SPSS version 23 and analyzed. Mean  $\pm$  SD was presented for quantitative variables and frequency and percentages were presented for qualitative variables.

### **RESULT**

In this study mean age of patient was 37.33±9.91 years. There were 10 males (47.6%) and 11 females (52.4%) patients. Site of lesion was buccal mucosa in 57.1% patients (n=12) and 42.9% patients had lesion on tongue (n=9). Treatment response showed that only 23.8% patients had complete treatment response (100 % reduction in size), 28.6% patients had good treatment outcome (75% reduction in size) and 33.3% patients had moderate treatment outcome (more than 50 % reduction in size) while 14.3% patients had no response. Side effects experienced by patients were edema (42.9%), pain (23.8%) and ulceration (19%). The results are shown in Table 1, 2 and Table 3.

Table 1. Gender and site distribution of patients (n=21)

		Frequency	Percent
Gender	Male	10	47.6%
	Female	11	52.4%
Site	Buccal Mucosa	12	57.1%
	Tongue	9	42.9%

**Table-2: Treatment response and complications (n=21)** 

		Frequency	Percent
	No Response	3	14.3%
Treatment	Moderate	7	33.3%
Response	Good	6	28.6%
<b>F</b>	Complete Response	5	23.8%
	Pain	5	23.8%
Complications	Edema	9	42.9%
	Ulcer	4	19%

### **DISCUSSION**

One of the simplest effective treatment modalities to shrink the VM lesions is foam sclerotherapy. 1,10,16 The mechanism of action of STS is to induce temporary or permanent fibrosis of the vessels by endothelial damage with minimal thrombus formation which results in shrinkage of the lesion. 15

In this study, the outcomes of using STS 3% foam sclerotherapy as a treatment modality for VM lesions were reported. Currently, 3% STS is being used widely in the treatment of VMs and has the advantage of reduced side effects and fewer recurrences and complications.<sup>17</sup> In addition, in contrast to ethanol which can be injected in limited quantity especially in pediatric cases, STS can be recommended for the swelling and lesions which require a large volumes to be injected. STS has an additional advantage, being considered to produce less neurotoxicity after the procedure. In this study 23.8% patients had complete response, 28.6% had good and 33.3% patients had moderate treatment

Table no 3. Pre and post treatment details (n=21)

Initial Size	Final Size	Percentage Reduction	Response
(cm)	(cm)	in size	
3.4	0.72	78.82	Good Response
2.6	1.4	46.15	Moderate Response
4.2	3.5	16	No Response
3.1	0.2	93.5	Complete Response
3.9	1.59	61	Moderate Response
2.8	0.64	78	Good Response
1.7	0.1	94.2	Complete Response
3.5	1.26	64	Moderate Response
1.4	0.26	81	Good Response
1.1	0.1	90	Complete Response
4.1	3.9	4.9	No Response
3.2	1.55	51.5	Moderate Response
4.4	4.2	4.54	No Response
1.8	0.43	76	Good Response
3.5	1.13	77.6	Moderate Response
3.3	3.2	3.0	No Response
2.9	0.95	67	Moderate Response
1.4	0.2	86	Complete Response
2.7	1.5	44	Moderate Response
3.6	0.52	85.4	Good Response
1.2	0.1	92	Complete Response

response. Only 14.3% patients had not responded to the therapy.

Ebrahim Karimi with his team members reported that 95.6% of the patients showed 50% reduction in the size of the lesions. According to the imaging before and after the procedures, 67.3% of the patients displayed 50% reduction in the size. <sup>18</sup> Xena Alakailly in his study reported that a complete resolution occurred in (4/13) 28.57% of the patients treated, a good response in (5/13) 35.7%, a moderate response in (2/13) 14.28%, a mild response in (2/13) 14.28% patients and no response in (1/13) 7.14 % patients. The pain and edema after injection were the only side effects seen in all patients except two (11.76%), in which superficial ulceration was also seen. <sup>19</sup>

Stimpson et al in their study, treated 12 patients of VM in the head and neck region, with 3% STS foam sclerotherapy. They noted that a single session was not adequate for most of the lesions except those which were very small, and to obtain a satisfactory result in large lesions, multiple injections may be administered.<sup>20</sup> Khandpur et al reported a 90 – 100 % regression of venous and lymphatic malformations by a direct intra-lesional injection of 3 % STS without radiological guidance.<sup>21</sup>

The results of above mentioned studies are consistent with the results of this study up to a certain extent but every study has used a variable methodology regarding measurement of treatment response which makes it difficult to directly correlate the results of this study with other studies, however, overall treatment response can be matched.

This study showed that STS foam is extremely effective sclerosing agent which results in significant reduction in the size of VM lesions. Foam sclerotherapy with STS, with low rate of major complications, can replace the other treatment modalities of VM lesions because of its safety.

### **CONCLUSION**

Results of this study showed that new STS 3% sclerosing foam, produced in a disposable syringe, can be effectively used to treat Venous malformation of oral cavity.

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