Original Article Use of Sodium Tetradecyl Sulphate in the Treatment of Venous Malformation of Oral Cavity

Abubakar Saddique, Jehan Alam, Zubair Ahmed, Shoaib Mirza, Gobind Rai and Arsalan Tariq

ABSTRACT

Objective: To observe the efficacy of sodium tetradecyl sulphate as sclerosing agent in venous malformation of oral cavity.

Study Design: Cross sectional study

Place and Duration of Study: This study was conducted at the Department of Oral and Maxillofacial Surgery, Jinnah Postgraduate Medical Centre from September 2023 to March 2024 over six months.

Methods: The clinical efficacy of the treatment was evaluated based on the following grades: "No response," indicating no change in size post-injection; "Mild response labeled as 25% reduction in lesion size, moderate response labeled as 50% reduction in lesion size, good response 75% and 100% reduction considered as complete response.

Results: Regarding response of treatment in 8% of patients no response was observed, moderate response was observed in 36% of cases, 23% patients showed good response and in 33% complete response was observed. Edema was the most common complication among the study patients, in 50.8% patients.

Conclusion: Sclerotherapy with sodium tetradecyl sulfate (STS) is widely recognized as an effective treatment for venous malformations (VMs), boasting minimal side effects and yielding favorable results in many cases.

Key Words: Venous malformation, Sodium tetradecyl sulphate, Oral cavity, Sclerotherapy, Treatment response

Citation of article: Saddique A, Alam J, Ahmed Z, Mirza S, Rai G, Tariq A. Use of Sodium Tetradecyl Sulphate in the Treatment of Venous Malformation of Oral Cavity. Med Forum 2024;35(10):3-6. doi:10.60110/medforum.351001.

INTRODUCTION

Venous malformations (VM) are congenital lesions commonly found in the oral cavity, with prevalence rates ranging from 14% to 65% in the head and neck region, posing challenges for treatment due to the anatomical complexity of this area¹. These anomalies, which do not regress spontaneously but rather enlarge with body growth, can undergo rapid expansion triggered by factors such as puberty, pregnancy, infections, trauma, or hemorrhage². They manifest along a spectrum, from isolated skin varicosities to complex lesions infiltrating multiple tissue planes, typically presenting as soft, compressible, non-pulsatile masses with quick refilling³.

Department of Oral & Maxillofacial Surgery, Jinnah Postgraduate Medical Centre, Karachi.

Correspondence: Dr. Abubakar Saddique, Resident of Oral & Maxillofacial Surgery, Jinnah Postgraduate Medical Centre, Karachi. Contact No: 03469399810 Email: abubakar_pef@yahoo.com

Received:	April, 2024
Reviewed:	April-May, 2024
Accepted:	July, 2024

Symptoms vary based on location, size and may include pain, discoloration (blue skin), infection, swelling, bleeding, ulcers, difficulty in speech and breathing, as well as dysphagia^{4,5}.

Sodium tetradecyl sulfate (STS) was utilized in the treatment of vascular malformation in the soft palate region, aiming for maximal endothelial damage with minimal thrombus formation⁶, ultimately leading to fibrosis and shrinkage of the lesion, as per clinical experience described by previous reports. Patient satisfaction and objective evaluation of lesion size were the endpoints assessed in the study⁷.

STS utilized as a sclerosing agent since 1946, effectively treats small varicosities of the legs, lymphatic⁸, and venous malformations by inducing endothelial damage, resulting in fibrosis and shrinkage of the lesion without significant thrombus formation, offering a safe, minimally invasive alternative to surgical intervention with satisfactory aesthetic and functional outcomes, thus potentially reducing or obviating the need for surgery^{9,10}.

The efficacy of sodium tetradecyl sulfate for venous malformation of oral cavity has not been assessed in our local population and setting. The aim of our study was to assess its efficacy in the treatment of oral cavity venous malformations.

October, 2024 Efficacy of

Sodium

Tetradecyl Sulphate in

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Oral Cavity

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METHODS

A study conducted at the Department of Oral and Maxillofacial Surgery, Jinnah Postgraduate Medical Centre from September 2023 to March 2024 over six months included patients with venous malformation of the oral cavity. The sample size of 61 was determined using OpenEpi Online software, based on a prevalence of complete response of 23.8%, an 80% confidence level, and a 7% margin of error. Female and male gender both having age 18-60 years were enrolled in the research.

Venous malformation in the floor of the mouth, characterized by swelling and bluish discoloration, was diagnosed via clinical intraoral examination, and confirmed through either color Doppler ultrasonography or magnetic resonance imaging (MRI). Sclerotherapy treatment involved direct injections of 3% sodium tetradecyl sulfate, with the dosage tailored to the lesion size, administering 1 millimeter of the sclerosing substance per 1 centimeter of lesion. Injections were repeated at 4-week intervals until a 50% reduction in lesion size was achieved, with a maximum of 6 sessions performed. If no reduction was observed after 2 sessions, further injections were discontinued.

The clinical efficacy of the treatment was evaluated based on the following grades: "No response," indicating no change in size post-injection; "Mild response labeled as 25% reduction in lesion size. moderate response labeled as 50% reduction in lesion size, good response 75% and 100% reduction considered as complete response.

Patients who had previously received treatment and those with incomplete records due to loss of follow-up, as well as medically compromised individuals such as those with diabetes, hypertension, or end-stage renal disease, were excluded from the study. Prior to participation, eligible patients were informed about the study purpose, protocol, and the intended use of their data for research. Demographic information including age, gender, and residential status was collected using a validated questionnaire. Additionally, patients were queried about their medical history, any complications experienced post-treatment, and outcomes such as the site of venous malformation in the oral cavity, initial size, and presence of pain, edema, ulceration, and response to treatment, categorized as no response, mild response, moderate response, good response, or complete response according to predefined criteria.

Data entry and analysis were conducted using SPSS version 27. Descriptive statistics were computed for both quantitative and qualitative variables. A significance level of $p \le 0.05$ was employed, indicating statistical significance.

RESULTS

Overall, 61 patients were included in this study. The age of patients was 41.22±7.65 years. There were more males than females as 41 (67.2%) and 20 (32.8%),

respectively. According to area of residence, 31 (50.8%) patients lived in urban area whereas 30 (49.2%) lived in rural area. Buccal mucosa was the most common site among the study patients, as 39 (63.9%). (Table. I).

Table No. 1: Demographic and baseline characteristics of the study patients

Characteristic	Presence			
Age (years)	41.22±7.65			
Gender				
Male	41 (67.2)			
Female	20 (32.8)			
Area of residence				
Urban	31 (50.8)			
Rural	30 (49.2)			
Site				
Buccal	39 (63.9)			
mucosa				
Tongue	22 (36.1)			
Mean \pm SD. N ($\overline{\%}$)				

Table	No.2:	Complications	and	outcome	distribution
of the	study	patients			

	Ν		
	(%)		
Complication			
Pain	16 (26.2)		
Edema	31 (50.8)		
Ulcer	14 (23.0)		
Outcome			
No response	5 (8.1)		
Moderate	22 (36.1)		
Good	14 (23.0)		
Complete response	20 (32.8)		
N (%)			

■ Moderate ■ Good ■ Complete response No response



Figure No.1: Outcome

Edema was the most common complication among the study patients, in 31 (50.8%) patients. Regarding response of treatment in 8% of patients no response was observed, moderate response was observed in 36% of cases, 23% patients showed good response and in 33% complete response was observed (Figure. I). (Table. 2).

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Foam sclerotherapy effectively shrinks venous malformation lesions by inducing temporary or permanent fibrosis of the vessels through damage of endothelial, with little formation of thrombus, ultimately leading to the shrinkage of the lesion¹¹. In this study complete response was obtained in 33% of patients with use of STS. Kayalvizhi et al¹² successfully treated a vascular lesion located on tongue towards ventral surface by administering a single injection of STS 1 ml mixed with distilled water 4 ml, resulting in complete reduction of lesion size.

Remarkable response in terms of moderate results was observed in 33% in this study followed by 23% good outcomes. Min et al¹³ reported remarkable regression of lesions in two cases of venous malformation in the tongue and left buccal mucosa following treatment with 1% sodium tetradecyl sulfate (STS) injection. A lakailly et al¹⁴ conducted a study on thirteen vascular malformation patients, treating them with 3% STS intralesional injections. Results showed complete resolution in 28.57% patients, good response in 35.7%, moderate response in 14.28%, mild response in 14.28%, and no response in 7.14% patients.

In a case study conducted by Maharjan et al¹⁵ a pyogenic granuloma was successfully treated by administering intralesional injections of undiluted 0.2 ml of sodium tetradecyl sulfate (STS) at a concentration of 30mg/ml. The injections were precisely administered at the base of the pedunculated mass using an insulin syringe. Remarkably, the lesion completely regressed after three treatment sessions, demonstrating no recurrences thereafter. Khaitan et al¹⁶ conducted a study on clinically diagnosed patients with pyogenic granuloma, successfully treating them by administering 0.2-0.5ml of sodium tetradecyl sulfate.

Al-Ghamdi et al^{17} successfully treated a case of lymphangioma circumscriptum through intralesional injection of 2 ml of 1% STS, resulting in a remarkable 70% regression of the lesion following two treatment sessions. Shivhare et al^{18} have reported that sodium tetradecyl sulfate 3% sclerotherapy demonstrates efficacy in treating various oral lesions, including vascular malformations, pyogenic granuloma, lymphangioma, and mucocele.

Stimpson et al¹⁹ treated 12 patients with venous malformations (VM) in the head and neck region using 3% sodium tetradecyl sulfate (STS) foam sclerotherapy, noting that a single session was generally insufficient for larger lesions, necessitating multiple injections for satisfactory results, while Khandpur et al²⁰ reported 90-100% regression of venous and lymphatic malformations with direct injection of 3% STS intralesional without radiological guidance.

Limitations: The study might have a small sample size, which could limit the generalizability of the findings to

a broader population. Small sample sizes can also reduce the statistical power of the study, making it difficult to detect significant effects.

CONCLUSION

Sclerotherapy with sodium tetradecyl sulfate (STS) is widely recognized as an effective treatment for venous malformations (VMs), boasting minimal side effects and yielding favorable results in many cases.

Author's Contribution:

Concept & Design of Study:	Abubakar Saddique,
	Jehan Alam
Drafting:	Zubair Ahmed, Shoaib
	Mirza
Data Analysis:	Gobind Rai, Arsalan
	Tariq
Revisiting Critically:	Abubakar Saddique,
	Jehan Alam
Final Approval of version:	By all above authors

Conflict of Interest: The study has no conflict of interest to declare by any author.

Source of Funding: None

Ethical Approval: No.F.2-81/2023-GENL/188/JPMC Dated 23.09.2023.

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