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Original Article

Nonsurgical Management of Ranula with Intralesional Sclerotherapy with 3% Sodium Tetradecyl Sulfate in Pediatric Patients

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Abstract

Background: Ranula is a term for mucocele occurring on the floor of the mouth after trauma or obstruction to components of the salivary gland. Surgical method was the only choice of treatment for ranula. However, there are certain limitations of surgical approach. Alternatively, intralesional sclerotherapy with 3% sodium tetradecyl sulfate is newer, simpler and non-invasive treatment procedure.

Objective: The objective is to analyze the effect of 3% sodium tetradecyl sulfate (STS) on ranula and to evaluate whether sclerotherapy can be a potent alternative to other surgical treatment modalities.

Materials and Methods: This study was carried out among children aged between 7 and 14 years with the chief complaint of swelling in the floor of mouth causing functional impairment and pain in some cases. Surface local anesthesia was applied over the lesion. STS 3% was injected under aseptic conditions with an insulin syringe and this was subsequently repeated on weekly intervals till complete regression. Follow-up was done after every 1, 3, 6 months, and 1 year interval to check for any recurrence.

Results: After the first injection of 0.5–1 mL of 3% STS, we observed a complete clinical disappearance of lesion in 9 (31%) cases, a moderate response in 13 (44.9%), and no response in 7 (24.1%) children. Four weeks after the first injection, regression of lesion was observed in all the cases.

Conclusion: Sclerotherapy with 3% STS is minimally invasive, safe, and effective treatment of different oral lesions and may be the method of choice in pediatric populations.

Key words: 3% Sodium tetradecyl sulfate, Intralesional injection, Ranula, Sclerosing agents, Sclerotherapy

INTRODUCTION

Ranula is a clinical term for mucocele occurring on the floor of the mouth after trauma or obstruction to components of the salivary gland situated in the submandibular or sublingual space.[1]

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In general, they are slow growing, asymptomatic, well circumscribed, fluctuant, bluish-colored swelling present on one side of the midline of the floor of the mouth. Ranula is derived from the latin word "Rana" meaning frog and are so named because of their resemblance to the bloated underside of a frog's belly.[2,3]

Ranulas can be cystic (mucous retention cyst) and pseudo cystic (mucous retention phenomenon or mucocele). In the cystic type, there is partial obstruction of the distal end of a sublingual gland duct that results in a small epithelial-lined cyst usually <1 cm in diameter.[3] However, the most common variety of ranula (which is pseudo cystic) forms

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as a result of extravasation of mucus into the fibrous connective tissue (without a distinct membrane) after a tear in the sublingual gland duct and arises as a result of the escape of mucus into the adjacent connective tissue.[4]

Based on their location, ranulas are classified as follows:
- Sublingual
- Sublingual-submandibular
- Submandibular.

Sublingual group of ranula also known as simple ranula, are pseudocyst that occur due to extravasation or retention of mucous in the floor of the mouth.[5] On the other hand, the plunging ranula is represented by the sublingual-submandibular and submandibular ranula group. The term plunging ranula is used when extravasated mucous dissects through the mylohyoid muscle and along the facial planes of the neck, producing a swelling in the floor of the neck.[6]

Simple ranula is common during the first and second decade of life while plunging ranula occurs frequently during the third decade of life. Females are more commonly affected than males with a ratio of 1:1.4.[7,8]

Ranula if left untreated, can cause difficulty in speech and mastication. Furthermore, acute airway obstruction can also occur in rare cases.[9,10]

Earlier, surgical method was the only choice of treatment for ranula. However, there are certain limitations of surgical excision when considering surgery such as intraoperative bleeding, recurrence, incomplete resection, esthetic concern, and functional impairment.

Considering these drawbacks of surgery, alternative treatment methods are mentioned in the literature including curettage, cryosurgery, electro dissection, laser, steroid injections and sclerotherapy.[11]

Sclerotherapy is defined as the "targeted elimination of small vessels, varicose veins and vascular anomalies by the injection of a sclerosant." Sclerosing agents are known for marked tissue irritation, endothelial damage with minimal thrombosis and subsequent local inflammation and tissue necrosis. This inflammation and tissue necrosis within the lesion results in fibrosis with tissue contracture resulting in the disappearance of the lesion.[12,13]

The most commonly used sclerosing agents are sodium tetradecyl sulfate (STS), polidocanol, sodium morrhuate, ethanolamine oleate, sodium silicate, pingyangmycin, OK-432, and ethanol. This intralesional sclerotherapy is simple and non-invasive procedure that is economical and reduces complications associated with surgery of ranula, a common salivary gland lesion.[4,14]

Due to less literature available on the treatment of ranula using 3% STS and no consensus on the best approach, this study was conducted to analyse the effect of a 3% STS on ranula and to evaluate whether sclerotherapy can be a potent alternative to other surgical treatment modalities.

MATERIALS AND METHODS

The study was carried out among children aged between 7 and 14 years of age, visiting the Department of Pedodontics and Preventive Dentistry, Indira Gandhi Government Dental College and Hospital, Jammu, with the chief complaint of swelling in the floor of mouth causing functional impairment and pain in some cases [Figure 1]. Written informed consent was obtained from all patients. The study was conducted only after approval by the institutional ethical committee, IGGDC, Jammu.

All the cases treated by 3% STS in the mentioned study period were included while incomplete cases due to loss of patient follow-ups were excluded. After complete case history and diagnosis of lesions based on the following clinical findings, 29 patients out of 40 were short listed:
- Swelling in the floor of mouth, which may be painful
- Mostly unilateral, on one side of frenulum
- Spherical in shape with size varies from 1 to 5 cm in diameter
- Color is pale blue with characteristics semi-transparent appearance
- The surface is smooth and the mucous membrane is mobile over the swelling
- Tenderness is absent
- Fluctuation test is positive
- Transillumination test is positive

Figure 1: Pre-operative

- Cervical lymph nodes are not enlarged
- No extension into the neck.

Investigations including ultrasonography, computed tomography [Figure 2], magnetic resonance imaging, and sialochemistry were done.

Armamentarium

Armamentarium required for sclerotherapy were 3% of STS, 2% lignocaine with adrenaline, gel lignocaine 2%, insulin syringe, 3 ml syringe, povidine-iodine solution 5%, mouth mirror, gauze, and tweezer.

Methodology

Patients were subjected to a patch test to rule out any hypersensitivity reaction to the sclerosing agent 3% STS (60 mg/2 mL). Patients with any allergy to sclerosant were excluded from the study. In our study, no patient had an allergy to 3% STS.

First, surface local anesthesia was applied over the lesion. Aspiration was done before injecting the sclerosing agent (3% STS) [Figures 3 and 4]. STS, due to the side effects they produce, need to be diluted with distilled water, hypertonic saline, or local anesthetic agent in the ratio of 1:3 before injecting. 0.5–1 mL of 3% STS was slowly injected under aseptic conditions by insulin syringe in a circumferential manner around the lesion until the solution leaked out from the surface of the lesion [Figure 5]. The puncture site was gently compressed for about 3–5 min with a gauze.

Regular follow-up was done at weekly intervals to check the healing, if the lesion did not resolve, second and third injections were given consecutively at weekly intervals. After completion of treatment, follow-up was done after every 1, 3, 6 months, and 1 year to check for recurrence [Figure 6]. Patient's information such as age of the patient, site of the lesion, residual pigmentation, post-operative pain, swelling and ulceration, recurrence, functional impairment, and number of sessions for treatment were collected.

Based on data collected, the response to the treatment was graded as follows: no response (no change in size after injection), mild response (25% decrease in the size after injection), moderate response (50% decrease in size after injection), good response (75% decrease in size after injection), and complete response of the lesion (100% shrinkage of the lesion with normal-appearing skin and/or mucosa).

RESULTS

A total of 40 patients treated by 3% STS were arranged in Microsoft excel. Eleven patients were excluded due to unavailability of detailed information regarding dose of application or due to incomplete patient treatment. Thus, 29 patients with complete information were selected for the study between the age group of 7 and 14 years. Figure 7 shows the age of the patient in years.

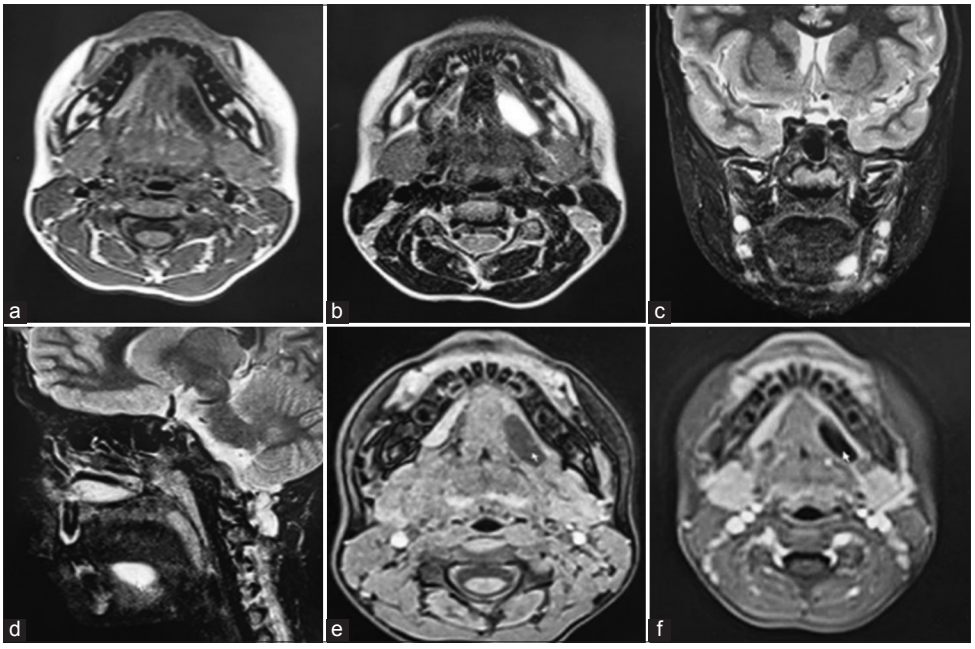

Figure 2: The findings of the magnetic resonance imaging showed unilocular homogenous well defined cystic mass (arrow) measuring (23 × 9 mm) with low signal on axial T1 weighted images (a) and high signal on axial (b), coronal (c) and sagittal (d) T2 weighted images. The lesion is in sublingual gland. Axial pre and post contrast T1 weighted FS images (e and f) shows absence of enhancement. The lesion shows high signal on diffusion weighted images

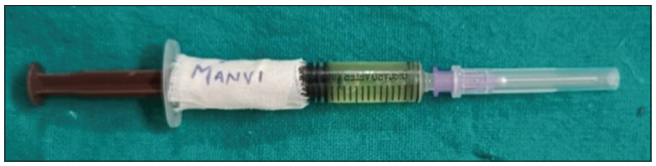

Figure 3: Aspiration fluid of the lesion

Figure 4: 3% STS

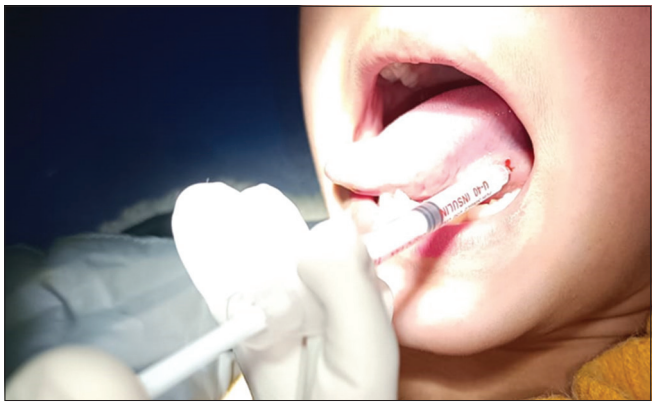

Figure 5: Intralesion sclerotherapy injection

Figure 6: Complete regression of the lesion

The following parameters were assessed: age at presentation, site of the lesion, chief complaint, recurrence, residual pigmentation, and functional impairment. All patients' swelling were treated by sclerotherapy with 3% STS solution. Number of sclerotherapy injections and post-operative responses such as pain, swelling, and ulceration assessed by clinical examination were also recorded and are depicted by Table 1.

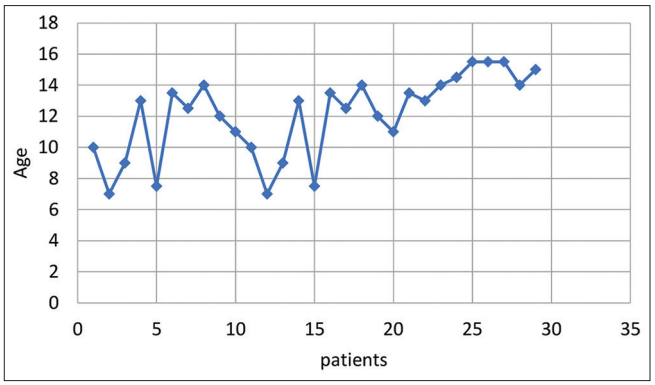

Figure 7: Age in years

The site of the lesion was right or left side of the floor of the mouth (right 41.4% and left 58.6%) and all the lesions had unilateral presentation. The patient's chief complaint was mostly centered on the disfigurement and functional impairment caused by the lesion. No prior therapeutic interventions were recorded in any of the patient except for the medications provided in some cases. The number of injections of STS per lesion ranged from one to three at different visits with a typical dose of 0.5–1 mL/injection, well under the maximum recommended dose of 0.5 mL/kg. Among the 29 patients, the responses to treatment were complete response in 9 patients (31%), good response in 13 patients (44.9%), moderate response in 7 patients (24.1%). No hypersensitivity reactions were observed. The side effects encountered in all patients were pain (31%) and edema (31%) after injection [Figures 8 and 9]. There was no residual pigmentation, post-operative ulceration, or functional impairment in any of the patients.

After the first injection of 0.5–1 mL of 3% STS, we observed a complete clinical disappearance of lesion in 9 (31%) cases, a moderate response in 13 (44.9%), and no response in 7 (24.1%) children.

Four weeks after the first injection, regression of lesion was observed in all the cases.

The recurrence rate after the treatment of 29 patients was 31% after 1 year of the treatment. Among the 9 patients who had a complete clinical response in 1 session only, 2 patients (22.9%) patient presented a recurrence 1 year after treatment. Among the 13 patients who showed completed resolution of the lesion in 2 sessions, 5 patients

Table 1: Parameters considered for study

Use of STS for the treatment of swelling at the floor of mouth		
Parameters	**Options**	**Percentage**
Age (years)	5–8	13.8
	9–12	34.5
	13–14	51.7
Site (floor of the mouth/unilateral)	Left	58.6
	Right	41.4
Recurrence	Yes	31
	No	69
Residual pigmentation	Yes	0
	No	100
Functional impairment	Yes	0
	No	100
Number of sessions for treatment (weeks)	1	31
	2	44.9
	3	24.1
Post-operative symptoms		
Post-operative pain	Absent	69
	Mild	31
Post-operative swelling	Absent	69
	Mild	31
Post-operative ulceration	Absent	100
	Present	0

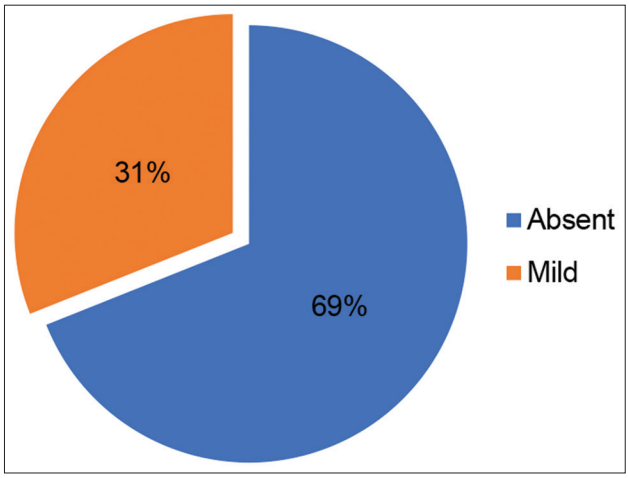

Figure 8: Post-operative swelling cases

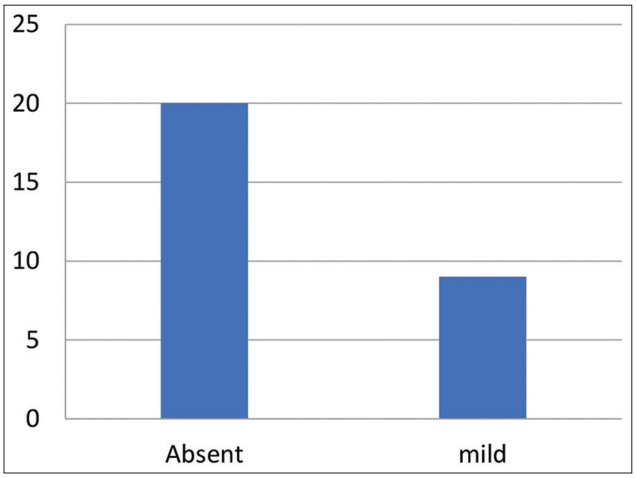

Figure 9: Count of post-operative pain cases

reported with recurrence after 1 year of treatment (38.4%) and among 7 patients that required 3 sessions for complete resolution, 2 patients showed recurrence after 1 year of treatment (28.5%). Regardless of the medical evaluation, all children's parents reported a satisfactory aesthetic result and an improvement of their kid's quality of life after the treatment.

As to postinjection complications, 3 children had fever (38.5–39°C), treated with paracetamol (10–15 mg/kg, 3–4 times/day) and resolved after 1–3 days. Five children presented signs of inflammation (pain, redness, and induration) in the site of injection, which were treated with nonsteroidal anti-inflammatory drug (ibuprofen 15 mg/kg 3 times/day) and resolved after 3–5 days.

No local scarring or deformity of the lower lip occurred in any patients. As side effects, local discomfort at the injection site was observed in four of the patients, but such problems resolved within a few days. We performed this treatment on an outpatient basis without hospitalization. Our results confirmed that 3% STS therapy is simple, easy, and relatively safe, and can be used as a substitute for surgery in the treatment of ranula.

DISCUSSION

There are three types of sclerosing agents namely: hyperosmolar, detergent, and chemical. STS is the most commonly used detergent type of surface active sclerosant which disrupt cellular membrane.[5,15] STS (sodium l-isobutyl-4-ethyl octyl sulfate) is a long-chain fatty acid manufactured synthetically. Sclerosing agents are irritants that act on the endothelial surfaces, resulting in the obliteration of space between the surfaces.[6] The resultant obliteration causes tissue fibrosis and further necrosis and sloughing of the tissue leads to total or partial regression of the lesion. Sclerotherapy is effective in the management of various lesions such as mucoceles, pyogenic granulomas, ranulas, vascular malformations, hemangiomas, and lymphatic malformations.[7,16]

Various treatments for ranulas have been suggested. These include sclerotherapy with OK-432, marsupialization, incision and drainage, aspiration of cystic fluid, ranula excision only, and excision of the sublingual gland with or without ranula excision. Surgery is the most commonly used modality in the treatment of oral ranulas.[17,18] Sclerotherapy has several advantages over surgery: It is an easily available, safe, reliable, simple, effective, and minimally invasive technique, with negligible complications. It causes negligible discomfort to patient with minimal loss of blood and no requirement for any particular

care. Moreover, the patient can resume his daily activities immediately.[9] Keeping all these advantages in mind, STS which is used in other oral lesions was used for treatment of ranula in our case. STS has been approved by the US Food and Drug Administration for sclerotherapy of varicose veins.[19]

Yoshimura *et al.* compared three different methods of ranula treatment. The recurrence rate was 25.0% for the excision of the ranula only, 36.4% for marsupialization, and 0% for excision of sublingual gland along with the ranula. Their study concluded that removal of the sublingual gland with the ranula was the most effective treatment modality.[6]

Zhao *et al.* compared the recurrence rates of 580 ranulas treated using different surgical methods. They showed that recurrence was not associated with the type of ranula, but was correlated with the surgical method; the recurrence rate was 66.7% for marsupialization, 57.69% for excision of the ranula, and 1.2% for excision of the sublingual gland either with or without the ranula. Their study stressed that transoral sublingual gland removal was a basic and essential measure required to reduce the recurrence of any type of ranula.[2]

Harrison surveyed the literature about the success rate of ranula treatments. In oral ranulas, the success rate was 100% for the removal of the sublingual gland, 55% for marsupialization only, 82% for marsupialization with packing, and 73% for injection of OK- 432.[6]

Complications may occur due to damage to the lingual nerve and submandibular duct during excision of the sublingual gland. Careless manipulation of the distal lingual nerve may lead to paresthesia of the tongue and stenosis of the submandibular duct due to extensive scarring, which may further lead to obstructive submandibular sialadenitis.[20,21] Baurmash insisted that to reduce the incidence of this complication, complete removal of the ranular component may not be necessary. In addition, ductal laceration may induce additional salivary leakage.[8,22,23]

In ranulas that originate from the submandibular gland, it is essential to excise the ranula along with the submandibular gland through a cervical approach. When the sublingual gland sticks to the ranula, it is wise to remove this sublingual gland along with the submandibular gland at the same time.[7,24,25] Kim and Simental also recommended that transoral removal of the sublingual gland with placement of a drain to the left of the residual ranula cavity for 2 weeks can avoid the morbidity associated with invasive therapy without requiring a transcervical approach.[10]

Injection of a sclerosing agent such as 3% STS into the cavity of the ranula has been shown to be a highly effective treatment method for cystic lesions, including ranulas.[11,16] The cytokines released after an injection STS induce inflammation in the cystic wall, fibrosis, and eventual shrinkage of the cyst.[4,12]

However, a 100% rate of recovery was not possible. The side effects were encountered in patients such as pain and edema ulceration which healed without scarring, after injection with 3% STS.[26,27] Because no patients reported damage to the facial nerve and there were few complications compared to surgery, no negative effects of the therapy, STS may be the method of choice for treatment of ranulas, especially in pediatric populations. For complete regression, however, multiple injections are sometimes required; if there is no response to 3% STS, surgery should be carried out.

In our study, our clinical experience with the use of STS 3% solution tends to validate STS as a minimally invasive, safe, and effective treatment of oral ranulas. The responses to therapy after first injection were very satisfactory in patients who showed complete clinical disappearance of lesion in 9 (31%) cases, a moderate response in 13 (44.9%), and no response in 7 (24.1%) children. Four weeks after the first injection, regression of lesion was observed in all the cases.

Limitations of the Study

The data were collected by the same author who administered the treatment in the same department.

CONCLUSION

Sclerotherapy with STS 3% is effective in the treatment of different oral lesions such as ranula, vascular malformations, pyogenic granuloma, lymphangioma, and mucocele. Ranulas are one of the most common of the oral cavity. Various treatment modalities are available for their treatment, but they have various disadvantages and can lead to frequent recurrence. Sclerotherapy is being performed for ages to treat vascular disorders which can be a very useful, safe, and cost-effective alternative in the treatment of oral ranulas with the advantages of less invasiveness and reduced chances of recurrence, especially in pediatric patients.

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