Foam Polidocanol Sclerotherapy for Low-Flow Vascular Malformations of Tongue

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Abstract

Introduction: Low-flow vascular malformations (LFVMs) of the tongue are one of the most common presentations among different vascular anomalies of oral and maxillofacial regions. The present study was conducted with the objective to assess the outcome of a simple, easily available, safe and cost-effective therapeutic measure using foamed polidocanol in patients with LFVMs of the tongue. **Materials and Methods:** Fifteen patients with LFVMs of tongue were randomly selected in the study from the pool of 32 individuals affected with vascular malformation of oral and maxillofacial region. The diagnosis was made by a combination of clinical presentation and Doppler ultrasound. Lesions on the tongue were measured along their longer axis using a calliper and assigned to one of the three groups according to size: small-sized (<1 cm; 3 patients), medium-sized (between 1 and 3 cm; Four patients), or large-sized (>3 cm; eight patients). Foam sclerotherapy was done by directly injecting the foam (polidocanol) into identified sinusoids, under real-time ultrasound guidance. Foam polidocanol was prepared using the Tessari method. **Results:** Fifteen patients (Nine males and Six females), aged 7–50 years, with an average age of 23.53 years were included in our study. Of these 15 vascular lesions, three were small (<1 cm), four were medium (1–3 cm) and eight were large (>3 cm) in size. Treatment results were evaluated based on a reduction in lesion size. Complete or partial regression of lesions was reported by 14 (93.33%) patients and remained unchanged in one (6.67%) patient. The number of sclerotherapy sessions performed in this study ranged from 1 to 6 and was directly related to lesion size. Small- and medium-sized lesions responded well and complete resolution was seen in 1–3 sessions. Of the eight large lesions, seven showed complete or partial resolution in 4–6 sessions except one lesion which did not show any responses in subsequent sessions. **Conclusion:** Foam polidocanol therapy for LFVM of tongue is cost-effective,

Keywords: Foam sclerotherapy, low-flow vascular malformation, polidocanol, vascular malformation of oral and maxillofacial region

INTRODUCTION

Vascular anomalies are a heterogeneous group of congenital lesions of abnormal vascular development and may occur anywhere on the body. International Society for the Study of Vascular Anomalies has provided guidelines to differentiate vascular anomalies, according to the novel classification first published by Mulliken et al., in 1982, which has been recently revised in 2018.^[1,2] Vascular anomalies are broadly classified into two groups: vascular tumors and vascular malformations. Vascular malformations can be subdivided anatomically by the vessels involved: capillary, venous, lymphatic, and arterial. These lesions may consist of a single type of vessel anomaly, but combinations of formations occur frequently. Arterial or arteriovenous malformations are high-flow lesions, whereas capillary, venous lymphatic malformations are low-flow lesions that have characteristic clinical behavior.^[3] Low-flow vascular malformations (LFVM) of tongue are one of the most

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common presentations among different vascular anomalies of oral and maxillofacial regions.^[4]

The surgical resection of large tongue lesions often produces hemorrhagic, muscular, and nervous complication and fail to conserve lingual tissue required for vital functionality of tongue.^[5] In recent time, sclerotherapy has become the widespread treatment approach with advent of many foam sclerosing agents under image-guided delivery.^[6]

Polidocanol is an alkyl polyglycol ether of lauryl alcohol. It is chemically defined as an alcohol ethoxylate having an average alkyl chain of 12–14 carbon atoms (C12–C14) and an ethylene

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oxide chain of nine ethylene oxide units.^[7] In recent years, the use of foam sclerosants has become increasingly popular, largely because foam instillation confers several specific advantages for clinical therapy. Foam displaces intravascular blood and is not diluted in it, such as occurs with liquid sclerosant injection, the concentration of the sclerosing agent in the vessel is known and controlled.^[8]

The present study was conducted with the objective to assess the outcome of a simple, easily available, safe, and cost-effective therapeutic measure using foamed polidocanol in patients with LFVMs of the tongue.

MATERIALS AND METHODS

Prior to the start of the study, ethical clearance of the protocol was obtained from the Institutional Ethical Committee. The study was conducted in the Department of Dentistry from the year 2014 to 2018. Fifteen patients with LFVMs of the tongue were randomly selected in the study from the pool of 32 individuals affected with vascular malformations of the oral and maxillofacial region. In all cases, the written informed consent was obtained from the patients or their parents before the procedure. The diagnosis was made by a combination of clinical presentation and Doppler ultrasound. Individuals with LFVM of tongue were included in the study; whereas individuals who were hypersensitive to polidocanol agent, pregnant women in the first trimester, cardiovascularly compromised conditions, having diabetes mellitus, bedridden individuals, individuals with high risk of thromboembolic events and with the previous history of visual or neurological disturbances following foam sclerotherapy were excluded from the study.

Lesions on the tongue were measured along their longer axis using a calliper and assigned to one of the three groups according to size: small-sized (<1 cm; 3 patients), medium-sized (between 1 and 3 cm; 4 patients) or large-sized (>3 cm; 8 patients). Twelve individuals with large- and medium-sized lesions had chewing discomfort, esthetic and difficulty in speaking as a chief complaint whereas three individuals with small lesions were apprehensive about the condition.

Foam sclerotherapy was done by directly injecting the foam (polidocanol) into identified sinusoids [Figure 1] under real-time ultrasound guidance [Figure 2]. Foam polidocanol was prepared using the Tessari method^[7] [Figure 3]. 0.5 ml liquid polidocanol was taken in a syringe which was connected to another syringe with air by a three-way stopcock valve. The stopcock valve was turned 30°–45° from its flat position to make the foamed bubbles as small as possible while allowing the two syringes to mix. The dilution ratio for sclerosant to air was 1:3. The syringes were mixed vigorously back and forth at least 20 times to obtain 2 ml of foam containing 0.5 ml of 3% polidocanol. Each 1 ml of foam would deliver 0.75% of polidocanol. The maximum recommended dose of polidocanol is 2 mg/kg of body weight.^[5] After the sclerosant was injected in the identified sinusoids, it was checked by the real-time

ultrasonography (USG) to prove that foam filled the vessels completely and afterward the pressure pack was given for 45 min. The subsequent session of sclerotherapy was given only after 3–4 weeks, and afterward patients were kept on the regular follow-up to assess the recurrence. The longest follow-up in our study was of 5 years.

RESULTS

Fifteen patients (9 males and 6 females), aged 7–50 years, with an average age of 23.53 years, were included in our study [Tables 1 and 2]. Of these 15 vascular lesions, 3 were small (<1 cm), 4 were medium (1-3 cm), and 8 were large (>3 cm) in size [Figure 4]. Treatment results were evaluated based on reduction in lesion size preoperatively and postoperatively. Complete or partial regression of lesions was reported by 14 (93.33%) patients and remained unchanged in one (6.67%) patient. Data on lesion size progression are displayed in Table 3. The number of sclerotherapy sessions performed in this study ranged from one to six and was directly related to lesion size [Table 4]. Small- and medium-sized lesions responded well, and complete resolution was seen in one to three sessions. Of the eight large lesions, seven showed complete or partial resolution in four to six sessions except 1 lesion which did not show any responses in subsequent sessions.

DISCUSSION

LFVM of tongue is the most common presentation among different vascular malformations of oral and maxillofacial regions. Vascular malformation management is based on flow characteristics, and it must be gauged. High-flow lesions require presurgical embolization followed by aggressive ablative therapy whereas low-flow lesions have numerous

Table 1: Age distribution of patients $(n=15)$	
Age (years)	n(%)
<20	8 (53.33)
20-30	3 (20)
>30	4 (26.67)

Table 2: Gender distribution of patients $(n=15)$		
Gender	n(%)	
Male	9 (60)	
Female	6 (40)	

Table 3: Lesion size reduction		
Group	Size reduction (partial or complete), n (%)	Unchanged, <i>n</i> (%)
Small(<i>n</i> =3)	3 (100)	0 (0)
Medium(n=4)	4 (100)	0 (0)
Large(n=8)	7 (87.5)	1 (12.5)



Figure 1: Foam polidocanol injected into identified sinusoids



Figure 3: Foam polidocanol prepared using Tessari technique



Figure 5: The large-sized lesion of tongue preoperatively

ways to be treated. Easily collapsible lesions that are accessible can be treated by sclerotherapy, laser therapy, and cryotherapy^[9] whereas nonaccessible, noncompressible and functionally compromising lesions require ablative surgery. The gold standard treatment that is surgical excision has



Figure 2: Sclerotherapy done under real-time ultrasound guidance

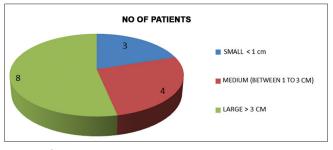


Figure 4: Size of vascular lesion of tongue categorized into three groups



Figure 6: Postoperatively lesion subsides after subsequent sessions of foam polidocanol

its own limitations like excessive tissue bleeding during surgery causing incomplete excision and increased chance of recurrence. Furthermore, vital functions of the tongue such as swallowing, speech, and airway maintenance are compromised due to loss of tongue muscle mass following excision of large vascular lesions. Laser therapy like Flashlamp pulsed-dye laser (FPDL) along with other multiple adjunctive procedures are promising in case of insufficiently ablated or sclerosed lesions.^[10] The common sclerosing agents

Table 4: Number of sessions		
Group	Sessions	
Small(n=3)	1-2	
Medium(<i>n</i> =4)	1-3	
Large (n=8)	4-6	

like hypertonic saline (osmotic agents) exert their effect by dehydrating endothelial cells through osmosis which results in endothelial destructions, whereas detergent solutions such as sodium morrhuate, ethanolamine oleate, sodium tetradecyl sulfate, and polidocanol damage the endothelium through interference with cell membrane lipids. Absolute ethanol has been used for over 100 years and has a direct toxic effect on vascular endothelium that activates the coagulation system on dehydrated endothelium.^[9,11,12]

Polidocanol was approved by the United States Food and Drug Administration in March 2010 for use as sclerosing agent which was originally developed as local anesthetic in France in 1950s.^[13] Polidocanol can be used as 1% or 3% in liquid as well as foam form. A study conducted by Alòs et al.[8] showed the efficacy of foam sclerotherapy to be higher than liquid form for a given concentration. The foam is highly echogenic and facilitates ultrasound-guided sclerotherapy but has the risk of minor and adverse effects such as pain, inflammation, and skin pigmentation. In this study, the complications which occurred were swelling which persists for 2-3 days and in one patient partial necrosis was seen in the lesion of tongue mucosa for which supportive medications like topical antibiotic was given. For small children and uncooperative patients, foam polidocanol injections were given under monitored anesthesia care/general anesthesia.

In this study, complete resolution was seen in small, medium, and larger lesions [Figure 5 and 6] whereas in some patients with larger lesions, only partial resolution was seen after multiple sessions. One lesion did not show any response even during subsequent sessions which might be due to the presence of hypertrophied endothelium which leads to reduced effect of sclerosing agent.^[14] Similar results were seen in the study conducted by Górriz-Gómez *et al.*^[6] Foam polidocanol therapy (Tessari technique) has the advantage of treating the LFVM lesion as an office daycare procedure at an affordable cost.

CONCLUSION

Foam polidocanol therapy for LFVM of maxillofacial region and particularly tongue is a promising application because it is cost-effective, less invasive and with added advantage of local anesthetic effect. Monitoring under real-time USG allows for controlled delivery of the sclerosing agent and prevention of unexpected complications.

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Conflicts of interest

There are no conflicts of interest.

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