Treatment of Oral and Perioral Benign Vascular Lesion with Ethanolamine Oleate: A Systematic Review

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ABSTRACT

Background: Benign oral vascular lesions are abnormalities defined by the proliferation or malformation of blood vessels. The appearance of vascular lesions varies according to age and anatomical location. There are no criteria to evaluate its therapeutic effectiveness. Treatment with the sclerosing drug ethanolamine oleate irrigates the vessel, causing a sterile inflammatory response.

Objectives: This article provides an overview of the effectiveness and complication of ethanolamine oleate in the management of oral and perioral benign vascular lesion.

Methods: This article is based on a comprehensive literature search, identifying relevant articles using Ovid, PubMed, and Google Scholar. The data mainly involve a critical review of various studies from sample groups of different ethnicities, age groups, and gender, were evaluated.

Findings: Hemangiomas and vascular malformations are among the many disorders that can cause vascular lesions of the head and neck. When vascular lesions are producing pain or symptoms, they need to be treated. Systemic and intralesional steroids, intralesional sclerosing drugs, interferon, laser therapy, embolization, cryotherapy, and radiation are some of the therapeutic approaches and techniques that have been suggested for the treatment of vascular lesions. As a primary amine and a primary alcohol, ethanolamine oleate is an organic chemical molecule that, when injected into tissues, can result in a dose-related inflammatory response that causes fibrosis and a reduction in the size of lesions. The most affected age group was between 41 and 70 years (mean age: 47 years, range: 4-87 years). The female gender was predominant (56%), and 86% of patients were Caucasian. Half of the patients reported the presence of a lesion (complaint period) lasting longer than 5 years. Regarding the location, there was a higher rate of occurrence on the lips (70%) followed by the tongue (16%) and buccal mucosa (14%). According to the clinical appearance of the lesions, approximately 90% were classified as nodules. A total of 41% of the lesions were between 0.5 cm and 1.0 cm in size (Table 1). Swelling was the most common type of complaint, reported by 28 patients (65%) followed by color alteration (7 patients, 16%). Most patients reported no pain (90%). Concerning the clinical diagnostic hypothesis, 40 lesions were defined as hemangiomas and vascular malformations (93%) and 3 as varices (7%). Only one session of one application of 5% EO was sufficient to obtain a satisfactory result in 58% of the patients. The regression of the lesions usually occurred in 2 to 3 weeks after the application. Regarding the lesions larger than 1.0 cm, 6 cases received a total dose of 0.4 to 0.7ml of EO, 9 cases received 0.8 to 2.0 ml, and 4 cases received more than 2.0 ml.

Conclusion: Ethanol Amine Oleate Sclerotherapy is a less intrusive and safe technique that is simple to repeat and poses little risk to the patient. Some individuals may experience procedure-related side effects, such as induration, edema, discomfort, and cutaneous or mucosal blisters at the injection site. These issues are mild, though, and should go away in three to four days.

Keywords: Ethanolamine Oleate, Benign vascular lesion, Hemangioma, Oral mucosa.

INTRODUCTION

Vascular malformations and hemangiomas are benign blood vessel lesions that are somewhat frequent in the ead and neck area. The lips, tongue, buccal mucosa, gums, and palate are the oral regions most afflicted, accounting

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for about 60% of all hemangiomas. The frequency is higher in twins, preterm newborns [1–3], and females (65%). Vascular lesions can result in facial asymmetries, range in size from a few millimeters to several centimeters, and are typically asymptomatic. Depending on the depth and location of tissue invasion as well as the level of vascular congestion in the afflicted area, the color might vary from red to purple [4]. Oral veins are more common in persons over 60 than hemangiomas and vascular abnormalities. Predisposing factors include age, tissue deterioration, and elevated venous pressure. The most prevalent kind of varices are sublingual ones, which manifest as one or more bluish-purple nodules along the tongue's ventral-lateral border. The varicose can also appear in the lips and other areas of the oral mucosa, although they are less common [5, 6].

One The International Society for the Study of Vascular Anomalies (ISSVA) has categorized these as vascular malformations and hemangiomas. Mulliken and Glowacki originally proposed this classification in 1982 based on endothelial cell properties and clinical behavior. Regarding the patient's care, it is very important that vascular lesions be divided into one of these two categories. Complex laboratory procedures are not required to classify a lesion into one of the two main categories vascular malformation or hemangioma. An accurate history and physical examination are typically sufficient to make a diagnosis [7].

If vascular malformations or even hemangiomas begin to create clinical symptoms or pain for the patient, therapeutic intervention is necessary [8]. For the management of benign vascular lesions, several treatment approaches have been put forth, including laser, embolization, cryotherapy, radiation therapy, systemic and intralesional corticosteroids, intralesional injection of sclerosing agents, and interferon [9]. The fact that there are so many different approaches to treating vascular lesions shows that no one approach is completely effective.

Benign vascular lesions can be effectively and conservatively treated with sclerosing, which carries no risk of bleeding [10]. Sodium Tetradecyl Sulfate, 1% Polidocal, 5% Ethanol Amine Oleate, 5% Sodium Morruhate, and Absolute Alcohol are the agents used in sclerotherapy [11].

There are no clinical studies that compare the efficacy of different sclerosing drugs. Nonetheless, ethanol amine oleate (EAO) is a recognized sclerosing agent for esophageal varices and cutaneous vascular lesions.

However, there aren't many studies on the effectiveness of ethanol amine oleate in vascular lesions of the head and neck, especially those that are oral and perioral [7]. Johann et al. carried out an open clinical investigation for the first time in 2005 to support the use of a safe and simple application of ethanol amine oleate in the treatment of 30 benign vascular lesions.

METHODOLOGY

This article is based on a comprehensive literature search, identifying relevant articles using Ovid, PubMed, and Google Scholar. We performed a thorough search using the following terms: “(1.25% Ethanolamine Oleate OR effectiveness of 1.25% Ethanolamine Oleate OR Complication of 1.25% Ethanolamine Oleate OR Sclerotherapy with Ethanol Amine Oleate OR ethanolamine oleate for oral vascular anomalies) AND (oral and perioral benign vascular lesion OR benign oral vascular lesions treated by ethanolamine oleate OR Management of oral benign vascular lesion OR Management of perioral benign vascular lesion)" Excluded were studies that did not specifically address the themes and other narrative review articles. In the end, the review contained 14 studies. Among them Brazil study- 9, American study- 1, Egypt study- 2, Iraq-1, and 1 Bangladeshi study.

FINDINGS

The initial searches generated a total of 29 peer-reviewed articles. Only 14 literatures were finally reviewed following exclusion of articles based on duplications, irrelevant titles and abstracts and quality assessment.

Table I: Distribution of the patients according to Demographic characteristics and clinical features

Age (years)	< 10	3	7
	11 – 20 years	3	7
	21 - 30 years	3	7

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	31 - 40 years	5	12
	41 - 50 years	6	14
	51 - 60 years	9	21
	61 – 70 years	10	23
	>70 years	4	9
Gender	Male	19	44
	Female	24	56
Skin Colour	Caucasian	37	86
	Others	6	14
Location	Lower lip	21	9
	Upper lip	9	21
	Tongue	7	16
	Buccal mucosa	6	14
Size	≤0.5	6	14
	>0.5 and ≤1.0	18	41
	>1.0 and ≤1.5	8	19
	>1.5 and ≤3.0	8	19
	>3.0	3	7

Oral and Perioral Benign Vascular Lesion

Non-cancerous growth affecting blood vessels in or near the mouth are known as oral and perioral benign vascular lesions. They fall into one of two categories: vascular malformations or hemangiomas. Vascular malformations are developmental abnormalities, while hemangiomas are actual neoplasms. Hemangiomas, vascular malformations (venous, capillary, lymphatic, or arterial), and pyogenic granulomas are common kinds. Observation, minimally invasive techniques, and occasionally surgery are used to treat benign vascular lesions of the mouth and perioral region, including hemangiomas and vascular malformations. The size, location, and nature of the lesion (venous or arterial), as well as the patient's symptoms and aesthetic concerns, all influence the therapeutic strategy. Since many hemangiomas gradually shrink over time, smaller, asymptomatic lesions may be seen as spontaneous regression, especially in youngsters. Sclerotherapy involves injecting the lesion with a sclerosing substance (such as ethanolamine oleate) to cause fibrosis and shrink it. This is a less intrusive choice that works well in a variety of settings.

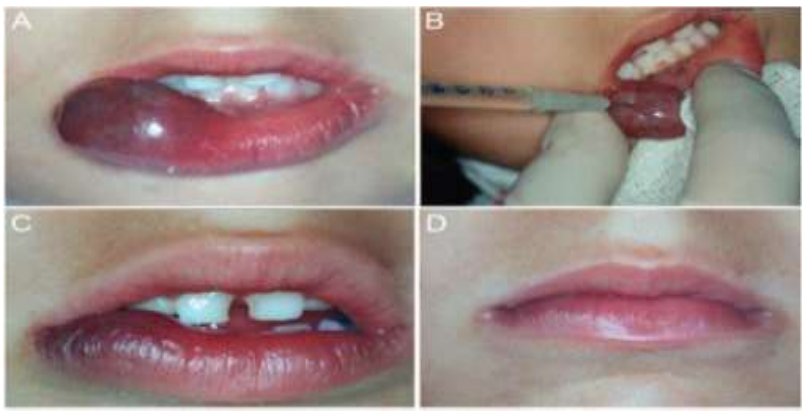

Fig. 1- Female patient, 5 years old, with a congenital lesion in the lower lip. A. Initial clinical aspect of the lesion. B. Intralesional application of EO. C. The result after two applications. D. Final clinical aspect showing a complete regression of the lesion after six applications of EO.

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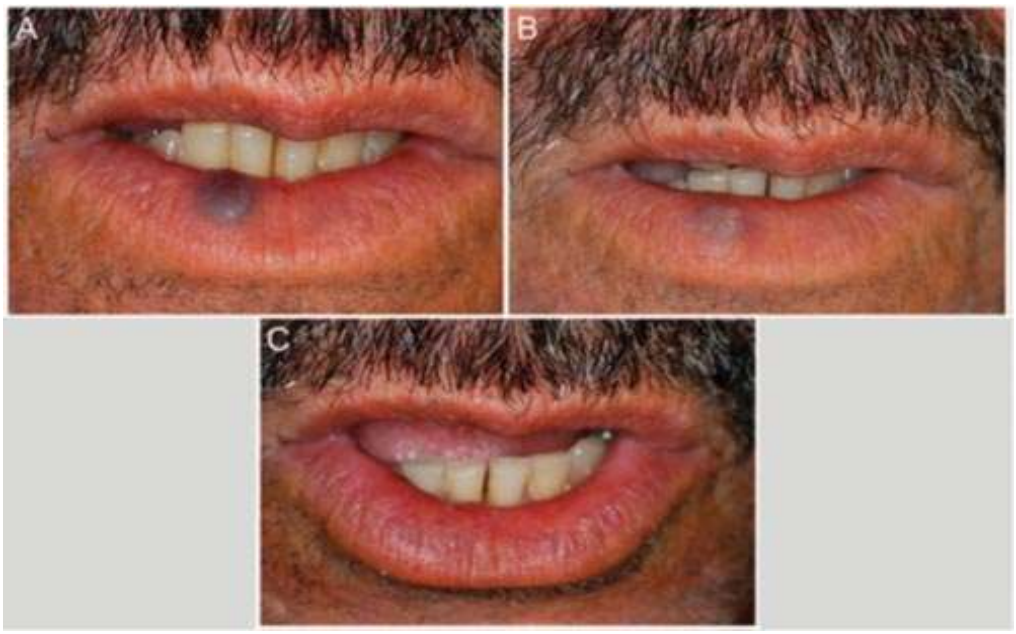

Fig. 2. Male patient, 56 years old with a congenital lesion in the lower lip. A. Clinical aspect in the first moment. B. After 1 application of EO. C. Complete regression of the lesion after 2 applications.

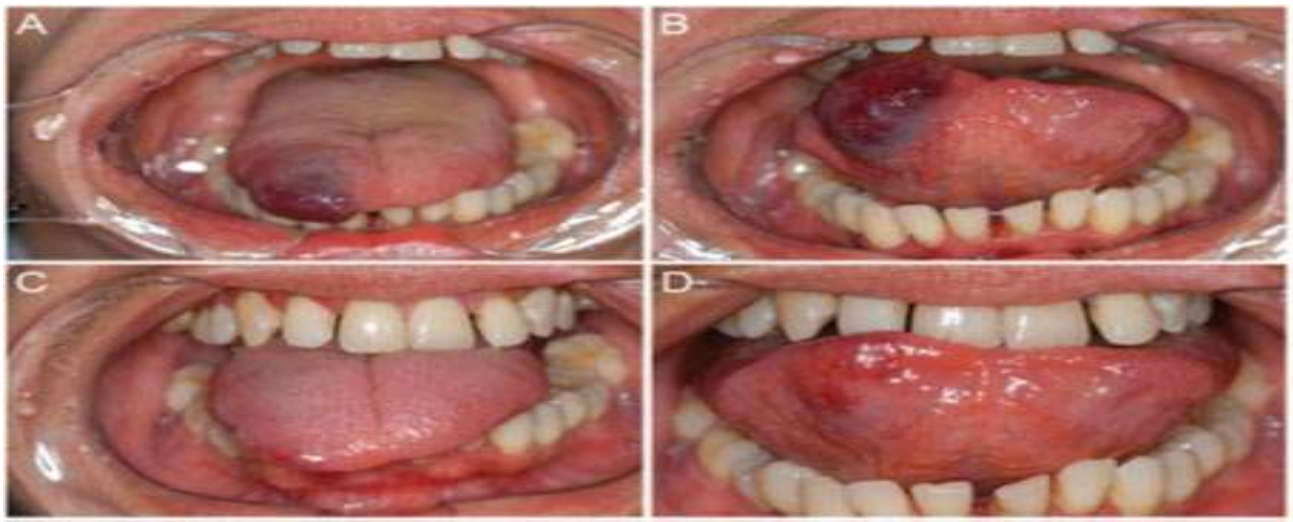

Fig. 3. Female patient, 39 years old, with tongue lesion present for 15 years. A/B. Initial clinical aspect. C/D. Partial and functional result after two applications of EO.

Effectiveness of Ethanolamine Oleate

For the treatment of benign oral vascular lesions such as varices and hemangiomas, 1.25% ethanolamine oleate works well as a sclerosing agent. According to studies, it can result in full clinical healing in as little as 28 days. The 1.25% concentration of EO is a good choice, especially for tiny lesions, even if 5% EO would work better for larger lesions. The size and kind of vascular malformation, as well as the reaction of each patient, can affect the ideal EO concentration and dosage. Studies on oral vascular malformations have shown minimal systemic negative effects, making ethanolamine oleate usually regarded as harmless. Local responses, such as discomfort, edema, and inflammation, may happen, though. Oral lesions and esophageal varices are among the vascular abnormalities that can be treated with 1.25% EO. It helps stop rebleeding and is especially helpful in treating freshly bled esophageal varices.

Evaluation of the effectiveness of treatment was based on three criteria: change in color, reduction in size of the lesion and evidence of fibrosis. The response to Sclerotherapy with Ethanol Amine Oleate was then evaluated in 4 patterns: Excellent: extinguished and symmetrical appearance obtained, Good: definitive reduction obtained, Fair: slight reduction obtained and Poor: lesion unchanged or worsened [12].

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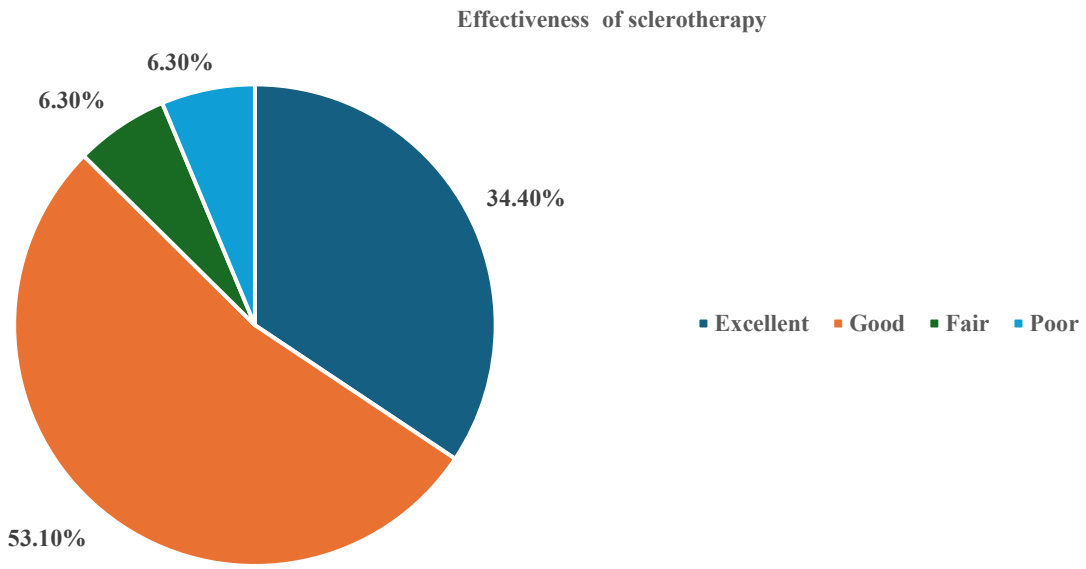

Figure I: Effectiveness of Sclerotherapy after 8 weeks of Sclerotherapeutic session

Complication of Ethanolamine Oleate

When used as a sclerosing agent, ethanolamine oleate can lead to several problems. Fever, chills, coughing, chest pain, and difficulty swallowing are typical adverse effects. Esophageal ulcers, pleural effusions, esophageal strictures, pneumonia, and in rare instances, anaphylactic shock or spinal cord paralysis, are examples of serious consequences.

DISCUSSION

Following Mulliken and Glowacki's groundbreaking work [1], the International Society for the Study of Vascular Anomalies (ISSVA) [13] proposed a classification that is based on the fundamental division of vascular anomalies into those lesions with a proliferative component (referred to as "vascular tumors") versus relatively static "vascular malformations." Consequently, there is still a notable discrepancy between the epidemiological data. Classification and clinical differential diagnosis of oral lesions may be challenging due to the clinical similarities between vascular malformations and hemangiomas. But in these situations, the differences between these lesions won't affect how the right treatment is administered [14]. 93% of the treated lesions in the current study were clinically identified as hemangiomas and vascular malformations based on clinical criteria, whereas 7% were categorized as varices. This study did not include ventral-lateral tongue varices, in contrast to Corrêa et al. (2007) [4].

Clinicians must be well-versed in the diagnosis and management of oral vascular lesions since many standard procedures, like surgery, have the potential to cause severe bleeding. Sclerotherapy is typically used when there is a risk of bleeding and when there is a compromise in physiological and/or aesthetic abilities (e.g., speech and chewing). Important factors to take into account in this situation include the patient's age, the lesion's size, location, and hemodynamics (high or low blood flow). These factors, together with the professional's experience, should be the primary considerations when choosing a treatment. Clinical follow-up may be the best course of action in asymptomatic instances and when no other illnesses are present.

Sclerotherapy can produce good outcomes for lesions of all sizes, particularly in areas (the lips and face) where alternative treatment methods, such surgery, might jeopardize the final aesthetics and physiology.

Patients with uncontrolled diabetes, expectant mothers, nursing mothers, and areas with secondary infections where therapy could result in oedema and bleeding in the injured area are among the contraindications for the procedure. A higher injection volume than advised was linked to complications such worsened tissue necrosis and the unintended induction of an allergic reaction to the medication [15, 16, 17].

Numerous drugs, such as ethanolamine oleate (EO), sodium morrhuate, sodium tetradecyl sulfate, sodium psylliate, hypertonic solution, 75% glucose, 100% alcohol, bleomycin, and others, have been utilized to treat vascular lesion sclerosis [17,18,19]. Although research has shown that these remedies are beneficial, each one has unique properties, indications, and adverse effects [12, 13].

According to scientific research, EO has been used for over 60 years and damages connective tissue less frequently. When used properly, EO's adverse effects are minimal and relatively preventable [18-20]. EO has been the preferred sclerosing agent in a variety of services because of these factors as well as the ease with which this medication may be obtained in Brazil. Endothelium fibrosis and an intra- and extravascular inflammatory response are key components of EO's mode of action.

While the ethanolamine component arranges the inhibition of the fibrin clot, the oleic acid component triggers an inflammatory response and may potentially initiate coagulation. Fibrosis thus takes the place of the vascular lesion [23]. Following administration to vascular lesions, these measures enable hemostatic equilibrium and stop bleeding [15,20,23].

Although the scientific literature identified rather various protocols, sclerosing may be regarded as a conventional treatment for oral vascular lesions. Notwithstanding the technique's ease of use and convenience, it is important to consider the potential for related issues. The method employed, the kind and concentration of the sclerosing agent, and the professional's experience all have a direct impact on the frequency and severity of these problems (20, 23–25).

Johan et al. [19] investigated two distinct EO concentrations (1.25% and 2.5%) and discovered no differences in the end outcomes or post-application symptoms. Similarly, dilution of EO in distilled water did not lessen symptoms, according to Bonan et al. [23]. Additionally, two of the six lesions treated by these authors showed a partial regression of lesions, which may have been caused by dilution decreasing the effect of the chemical agent in the artery wall.

CONCLUSION

Ethanolamine oleate serves as an effective outpatient option for addressing low flow vascular lesions found on the face and in the oral cavity, particularly for smaller lesions, with minimal complications and low morbidity rates. Larger lesions or those that penetrate deeper tissue require several treatment sessions and are associated with a higher risk of ulceration and scarring. Some research has indicated that using 5% EO for treating OVAs under 20 mm resulted in reduced final volume, lower total dosage, and a trend toward fewer treatment sessions compared to 1.25% and 2.5%, despite the limitations. Consequently, this concentration of EO is recommended for the treatment of OVAs measuring 20 mm or less. To establish a robust protocol for OVA sclerotherapy, further investigation is needed, particularly through randomized clinical trials. These early findings, however, could assist medical professionals in selecting the EO concentration for OVA treatment.

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