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# Effectiveness and safety of foam sclerotherapy with 5% ethanolamine oleate in the treatment of low-flow venous malformations in the head and neck region: a case series

**M. C. Ribeiro[1], S. de Mattos Camargo Grossmann[2], M. B. F. do Amaral[3], W. H. de Castro[1], T. P. Navarro[4], R. J. Procopio[4], T. A. da Silva[1], C. de Nazaré Alves de Oliveira Kato[1], R. A. Mesquita[1]**

[1]Department of the Oral Surgery and Pathology, School of Dentistry, Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil; [2]Department of Oral Surgery and Pathology, School of Dentistry, Universidade Vale do Rio Verde Unincor, Belo Horizonte, Minas Gerais, Brazil; [3]Department of Oral and Maxillofacial Surgery, Baleia Hospital/CENTRARE, Belo Horizonte, Minas Gerais, Brazil; [4]Hospital das Clínicas, Universidade Federal de Minas Gerais, Belo Horizonte, Minas Gerais, Brazil

*M. C. Ribeiro, S. de Mattos Camargo Grossmann, M. B. F. do Amaral, W. H. de Castro, T. P. Navarro, R. J. Procopio, T. A. da Silva, C. de Nazaré Alves de Oliveira Kato, R. A. Mesquita: Effectiveness and safety of foam sclerotherapy with 5% ethanolamine oleate in the treatment of low-flow venous malformations in the head and neck region: a case series. Int. J. Oral Maxillofac. Surg. 2018; xxx: xxx–xxx.* 

*Abstract.* The aim of this study was to evaluate the effectiveness and safety of 5% ethanolamine oleate (EO) foam in the treatment of low-flow venous malformations in the head and neck region. Seventeen consecutive patients (six male, 11 female) and 34 low-flow venous malformations were enrolled. The vascular anomalies ranged between 20 mm and 80 mm in size. The typical clinical indication was a swelling (88.2%) with a purple colour (85.3%); the most frequent location was the tongue (23.5%). Ethanolamine oleate foam was produced via the Tessari method and applied at 10 mg per 1 cm to the vascular anomalies. This process resulted in the highest clinical healing score in 64.7% of cases, and half of the patients reported a high level of satisfaction (score >9). In the majority of cases (88.2%), the patients reported that the pain immediately postoperative was mild or moderate. There were direct relationships between vascular anomaly size and the volume of EO applied, the number of sessions, and healing ($P < 0.05$). No recurrence was observed during 6 months of follow-up. This case series showed the effectiveness and safety of 5% EO foam for the treatment of venous malformations in the head and neck region.

Key words: foam sclerotherapy; vascular anomalies; vascular malformation; treatment.

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Vascular anomalies (VAs) are alterations in the endothelial architecture that affect various types of vessels: capillaries, arteries, veins, and lymphatics. The current classifications of the International Society for the Study of Vascular Anomalies (ISSVA) include two groups of disorders: vascular tumours and vascular malformations (VMs)[1,2]. Vascular tumours include haemangiomas and locally aggressive and malignant endothelial proliferations. VMs are classified according to the anomalous vessels involved, i.e., capillary malformations, venous malformations, lymphatic malformations, arteriovenous malformations, and arteriovenous fistulae, and also according to the type of flow, i.e., high-flow or low-flow[2–4].

VMs are present at birth and persist throughout life. Sixty percent of cases occur in the craniofacial region[5]. Clinically, VMs appear as soft masses or stains that are compressible and non-pulsatile (low-flow), with colouration varying from blue to bluish-red or purple, and palpation may elicit some tenderness, especially when acute clots or phleboliths are present[6]. A VM must be treated because it can disrupt the normal functioning of the stomatognathic system, create pressure in vital regions, and result in aesthetic defects, and also because of the risk of haemorrhage[4,7].

Several techniques can be used to treat VMs, such as surgery, laser therapy, bleomycin, and radiofrequency ablation[1,2,8], with sclerotherapy being an efficient, safe, and low-cost option in the treatment of low-flow VMs[9,10]. Currently, the sclerosing agents most commonly used are 1% and 3% polidocanol, hypertonic saline combined with dextrose, alcohol, sodium tetradecyl sulphate, hypertonic saline, and 5% ethanolamine oleate (EO)[11,12]. Among these agents, 5% EO is one of the most effective, safe, and readily available in Brazil[12,13].

The foam sclerotherapy technique was developed and published in 1944 by Egmont James Orbach. It improved the results of sclerotherapy because the injection of a small amount of air into the venous segment displaces the blood and intensifies the contact between the sclerosing agent and the endothelium[14]. The results of previous studies have demonstrated that foamed sclerosing substances are twice as effective as sclerosing liquid alone[15]. Over the years, the technique of producing foam has undergone changes. Specifically, the modification by Tessari et al. – the 'Tourbillon technique' – has shown success in clinical trials[16]. The most commonly used foam sclerosing agents are 1–3% sodium tetradecyl sulphate and 1–3% polidocanol[11,16,17].

Considering the importance of defining VM treatment protocols, the aim of this study was to evaluate the effectiveness and safety of 5% EO foam in the treatment of low-flow VMs in the head and neck region. The incidence of complications, healing scores, and satisfaction scores of patients who underwent this treatment are reported herein.

## Patients and methods

The study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional ethics committee.

### Research participants

Patients diagnosed with VMs in the head and neck region who were admitted and treated in the Ambulatory of Endovascular Surgery of Hospital das Clínicas and the Oral Pathology Clinic of the School of Dentistry (Universidade Federal Minas Gerais, Belo Horizonte, Minas Gerais, Brazil) during the period from January 2012 to December 2014 were eligible for inclusion in this study. All volunteers signed an informed consent agreement. Demographic and clinical data, such as sex, age, skin colour, comorbidities, clinical characteristics of the VM, and previous treatments, were obtained through anamnesis.

The diagnosis of VMs was performed according to the criteria of Mulliken and Glowacki[3]. All patients performed clinical manoeuvres in the form of a position-shifting test (placing the head between the knees for 3 min)[18]. Patients with low-flow VMs in the head and neck region with sizes $\geq$20 mm were included consecutively in this study. The indications for treatment included pain, growth, swelling, pressure, and aesthetic complaints.

Patients with high-flow VMs, uncontrolled systemic disease, or who were pregnant, as well as those who reported allergies to the anaesthetic lidocaine, EO, or antiseptic chlorhexidine, were excluded from this study. The eligibility criteria for inclusion were age $\geq$18 years, a diagnosis of VM in the head and neck region with size $\geq$20 mm, aesthetic or functional complaints, and having signed the informed consent agreement.

### Study drug

Ethanolamine oleate is a synthetic mixture of ethanolamine and oleic acid with the empirical formula $C_{20}H_{41}NO_3$. According to Hyodoh et al.[19] and Ozaki et al.[20], the most important side effect seen after extravascular administration is haemolysis with renal failure, and this requires the prophylactic administration of albumin (>3.0 g/dl) and treatment with haptoglobin (2000–4000 U/h). Exacerbation of heart failure, pleural effusions, and right-sided heart failure have also been reported and are likely related to the broad intravascular distribution of EO[19].

It is important to never exceed the safe dose of 20 ml or 0.3 ml/kg of EO[20]. To avoid ulceration, necrosis, and cosmetic problems, e.g., fibrosis, the EO in this study was applied in the deep portion of the VA under light pressure and inside the vessels[7].

### Protocol

A clinical manoeuvre called the position-shifting test (placing the head between the knees for 3 min) was performed in all patients to swell the injury further and facilitate hitting the lumen[18]. Following this, all VAs were measured with a flexible ruler before the start of treatment. A single operator conducted all treatments to prevent variations in technique.

To prepare the foam sclerosing agent, a 10-ml syringe with 2 ml of 5% EO and another similar syringe with 8 ml of air were used. The two syringes were interconnected via a three-way stopcock. To create the foam, 20 cycles of transferring the contents of one syringe to the other were performed, as described in the literature[16] (Fig. 1).

A proportion of 1 ml of foam (10 mg EO) per 1 cm of VA was determined to be ideal, with 8 ml of foam (80 mg of EO) being the maximum volume applied during each session[16]. The maximum dose did not exceed 20 ml for adult patients, or 0.3 ml/kg 5% EO foam per session[20].

Under strictly aseptic conditions, in an operating room set up, the skin and/or mucosa overlying the VA was scrubbed with surgical spirits containing 2% chlorhexidine. Infiltration anaesthesia with 2% lidocaine and without vasoconstrictors was performed using 1 ml of anaesthetic in the centre of the VA. The technician then waited for 2 min.

The foam sclerosant was applied intralesionally into the centre of the VA through a 25 G scalp vein set that was connected to the syringe containing the foam after holding aspiration to ensure the correct position. The foam was injected

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