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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Percutaneous sclerotherapy with gelified ethanol of low-flow vascular malformations of the head and neck region: preliminary results

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PURPOSE
We aimed to evaluate the safety and effectiveness of percutaneous sclerotherapy using gelified ethanol in patients with low-flow malformations (LFMs).

METHODS
A retrospective study was performed, analyzing treatment and outcome data of 6 patients that presented with 7 LFMs (3 lymphatic and 3 venous). Median diameter of LFMs was 6 cm (interquartile range [IQR], 4.5–8.5 cm). Data regarding pain, functional and/or cosmetic issues were assessed. Diagnosis was performed clinically and confirmed by Doppler ultrasound, while extension of disease was assessed by magnetic resonance imaging (MRI). Percutaneous puncture was performed with 23G needle directly or with ultrasound guidance. All the LFMs were treated with gelified ethanol injection. The median volume injected per treatment session was 4.4 mL.

RESULTS
Technical and clinical success were obtained in all cases. No recurrences were recorded during a median follow up of 17 months (IQR, 12–19 months). Among the 6 patients, 5 had complete relief (83%) and one showed improvement of symptoms. The median VAS score was 7 (IQR, 6–7.5) before and 0 (IQR, 0–0) after treatment. All patients had functional and esthetic improvement (100%). Four patients (66.7%) revealed very good acceptance and two patients (33.3%) good acceptance. No major complications or systemic side effects were observed.

CONCLUSION
Gelified ethanol percutaneous sclerotherapy was easy to handle, well-tolerated, safe and effective in the short-term follow-up. Longer follow-up of efficacy is mandatory for further conclusions.

Venous malformations (VMs), lymphatic malformations (LMs), cutaneous capillary malformations, together with their derived combined lesions, are currently considered low-flow vascular malformations (LFMs). They are congenital, hence already present at birth, and grow along with the growth of the individual. They can present focally, multifocally or diffusely, with possible infiltration of superficial and deep structures (1). The International Society for the Study of Vascular Anomalies (ISSVA) has published a classification system, based on biological features, which is a landmark for proper distinction between the various types of anomalies, and is currently the most widely used (2).

Dedicated categorizations for LMs have also been proposed, like the anatomy-based classification system for head and neck LMs by de Serres et al. (3), which made a grading/staging system possible, and the radiology-based distinction between macrocystic, microcystic, and mixed LMs, which has therapeutic implications (4).

It has been reported that unilateral lesions below the hyoid bone tend to be macrocystic and to have a better response to nonsurgical treatment, while lesions located above the hyoid tend to be frequently microcystic or mixed and to have worse results in terms of treatment efficacy (5, 6).

The diagnosis in the postnatal period is usually made clinically. Doppler ultrasonography (US) and magnetic resonance imaging (MRI) with and without contrast are required to con-

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firm the diagnosis and to better define each malformation (7).

In general, the absence of the flow-void effect differentiates LFMs from high-flow lesions. Macrocystic LMs, unlike VMs, have large vascular chambers with no contrast enhancing properties, and do not contain phleboliths. The differential diagnosis between microcystic LMs and VMs can be harder, but VMs have a detectable flow in the majority of cases, and their appearance changes with position (6).

Although LMs can be found in any anatomic region, their most frequent localizations are in areas with a naturally high content of lymphatic tissue, like head and neck (45%–52%), axillae, mediastinum, groin, and retroperitoneum (7, 8). VMs can manifest at any location of the body as a solid soft tissue mass consisting of multiple enlarged venous channels and lakes (9). The clinical presentations of both VMs and LMs are extremely variable, depending on the location and the dimension of the lesion.

Treatment is currently indicated in cases of pain, swelling of tissues, invasion of functionally and/or cosmetically relevant structures, as well as in cases of thromboembolic complications and sepsis. Surgical and non-surgical treatments have been described.

In many cases percutaneous sclerotherapy has been reported as first-line therapy. Various sclerosing agents have been reported; ethanol, bleomycin, doxycycline, and picibanil (OK-432) are the most commonly described, but also the use of acetic acid and fibrin glue can be found in literature (6, 10). Some sclerosing agents, in particular absolute ethanol, are at risk of adverse events related to the harmful effect that the agent can have on healthy tissues surrounding the malformations. Complications such as nerve damage, skin breakdown and swelling have been described. The latter may be managed with intubation and intensive care unit observation, but sometimes tracheotomy is required.

An ideal sclerosing product should be characterized by a high efficacy on the target malformation, like absolute alcohol, but should also have a low diffusibility to avoid harmful effects on the healthy surrounding tissues.

Recently, a new sclerosing agent has been developed. It was obtained by mixing pure alcohol with an absorbable gelling, cellulose derivative that is hydrophilic, non-toxic, and soluble in alcohol. This agent has already been used for embolization in the form of microspheres or associated with cisplatin, bismuth trioxide (11), and tantalum (12).

The benefits of this gelified ethanol, when compared with pure alcohol, seem to include better efficacy and, at the same time, a lower risk of damage to any surrounding healthy tissue, due to the fact that smaller quantities of ethanol are used, increasing safety (13).

We are presenting our preliminary results in terms of efficacy and safety in patients with LFMs treated with percutaneous sclerotherapy using gelified ethanol.

Main points

- Percutaneous sclerotherapy is currently the main therapeutic alternative to surgery in the treatment of low-flow vascular malformations, like venous and lymphatic malformations. It can be used alone, if surgery is contraindicated, or as a bridge to resection.
- Sclerogel consists of ethanol, confined by a gelous network, and combined with water-insoluble cellulose derivative. This composition has several advantages when compared to pure liquid alcohol, including longer contact to the vessel wall, more rapid dehydration of the vessel wall, lower content of ethanol needed per treatment, and better control of allocation.
- To date, efficacy of gelified ethanol in terms of therapeutic results, has been reported to be at least as good as absolute ethanol. However, there is still no evidence describing which agent is better in terms of outcome, time of action, and the number of complications. In this study, we report our preliminary experience in the treatment of venous and lymphatic malformations with Sclerogel. We achieved technical and clinical success in all patients, with good results in terms of functional and cosmetic outcomes and the overall satisfaction of patients. No major complications or recurrence were recorded. A longer follow-up and a higher number of patients are mandatory.

Methods

Patients

A retrospective study was performed after approval of our Internal Review Board. Between January 2017 and November 2017, 6 patients presented to the Department of Maxillo-Facial Surgery of our Institution with 7 LFMs that were treated percutaneously with injection of gelified ethanol. Sex and age of patients, together with type and size of lesions, were assessed (Table 1). Lesions were classified, according to their type, using the ISSVA classification (2). The diagnosis was made on the basis of clinical and ultrasound examination. The extension of the malformation and its anatomical relations with the surrounding tissues and organs were studied with MRI. Each case was discussed by a multidisciplinary team with involvement of maxillo-facial surgeons, plastic surgeons, radiologists and interventional radiologists. Indications, benefits and risks of each procedure were explained and discussed with the patients, and informed consent was obtained before treatment. This study was conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Procedure

Coagulation blood tests resulted within the reference values in all patients (14). Each patient was given a first-generation cephalosporin (cefazolin 2 g b.i.d., Pfizer Srl) at the beginning of the procedure as prophylaxis. Anesthesiologic specialized support was not needed for two patients, in whom only local anesthesia was performed. An anesthesiologist was present in the other cases. Moderate sedation was achieved in 3 patients through intravenous injection of propofol, fentanyl, and midazolam. General anesthesia was required for one patient in relation to the proximity with airways. Vital parameters, oxygen saturation, and electrocardiographic tracing were continuously monitored.

A 23G butterfly needle (Terumo) was positioned under US-guidance (Arietta V70, Hitachi Aloka Medical) in two cases. In the remaining cases, direct puncture of the malformation was performed and the correct position of the needle was verified with US. In all cases a lymph or blood back-flow was obtained. In LMs, complete aspiration of lymph was performed before injecting the gelified ethanol (Sclerogel, Ab Medica). In VMs, contrast agent was injected to define the anatomy of the malformation and visualize potential large draining veins, which should not be sclerosed.

More than one puncture was necessary in all cases because all malformations consisted of several chambers that were rarely communicating. In two patients, Sclerogel was used to embolize the deepest components, closer to vessels or trachea.

The amount of sclerosing agent used was equal to the volume of lymph aspirated in

Table 1. Patients, malformations characteristics, pre- and post-procedural aspects

Pt	Age (y)/ Sex	Type	Site	Dimensions (cm)	Treatment	Sclerogel dose (vl)	Anesthesia	Complications	VAS	Functional impairment	Esthetic prejudice	Pt satisfaction
1	37 M	LM	CF	10	For CF:	2	Sedation	No	Pre: 7	Pre: Yes	No	2
					Doxycycline, 7 y ago				Post: 0	Post: -2		
					Doxycycline, 6 y ago							
					Bleomycin, 2 y ago							
					STS 3%, 9 m ago							
			T	8	-	2	Sedation	Transient edema	Pre: 4	Pre: Yes	Pre: Yes	2
									Post: 0	Post: -2	Post: -2	
2	22 M	LM	CF	9	Surgery (10 y ago)	3	Sedation	Transient edema	Pre: 8	Pre: Yes	Pre: Yes	2
					STS 3% (6 m ago)				Post: 0	Post: -1.5	Post: -2	
3	38 M	VM	CF	6	Ethanol (18 m ago)	2	General anesthesia	Transient edema	Pre: 8	Pre: Yes	Pre: Yes	1.5
									Post: 0	Post: -2	Post: -1.5	
4	31 F	VM	CF	4	STS + Bleomycin (2y ago)	2	Local anesthesia	Pain (auto-solved)	Pre: 7	Pre: Yes	Pre: Yes	2
					Ethanol (20 m ago)				Post: 1	Post: -2	Post: -1.5	
5	34 F	VM	CF	2	Ethanol (20 m ago)	1	Local anesthesia	No	Pre: 7	Pre: Yes	Pre: Yes	2
									Post: 0	Post: -2	Post: -2	
6	75 F	VM	CF + basocellular Ca	5	Ethanol (18 m ago)	2	Sedation	No	Pre: 5	Pre: Yes	Pre: Yes	1.5
									Post: 0	Post: -1.5	Post: -1.5	

Pt, patient; y, years; vl: vials; VAS, visual analogue scale; M, male; LM, lymphatic malformation; CF, cervico-facial; STS, sodium tetradecyl sulphate; m, months; T, thoracic; VM, venous malformation; F, female; Ca, carcinoma.

LMs and to the volume of contrast media injected to opacify the malformation in VMs; all volumes were recorded (Fig. 1).

This procedure was repeated over time for every patient until the achievement of a clinically and subjectively satisfying result.

Outcomes

Technical success was defined as positioning the needle into the different compartments of the target lesions, as planned before treatment. Clinical success was defined as the improvement or disappearance of the symptoms. In particular, pain, functional impairment, cosmetic impairment were recorded before and 12 months after treatment. Overall patient satisfaction after treatment was also recorded.

Before and after treatment pain was classified by patients using the visual analogue scale (VAS), ranging from 1 to 10. For the evaluation of the other symptoms and aspects, the scoring method described by Dompmartin et al. (13) was adopted and modified, as shown in Table 2. Functional impairment, esthetic prejudice and overall patient satisfaction were all graded from 0 to 2, and results were reported for each patient (Table 1) (13).

Complications were classified according to Common Terminology Criteria for Adverse Events (15, 16). Safety was evaluated on the basis of the complications recorded. These were classified as "immediate" if occurring within 24 hours after procedure, "peri-procedural" if occurring within 30 days, and "delayed" if occurring more than 30 days after procedure (16). Major complications were defined as events that, if untreated, could be judged life threatening, or that could have led to significant morbidity or disability, or could have caused readmission to the hospital or prolonged hospital stay (16). This group includes systemic side effects like hemolysis, renal or cardiovascular failure. Minor complications included local side effects: edema, epidermolysis, hematoma, abscess, necrosis of the skin, paresthesia, and nerve palsy.

Results

Table 1 reports sex and age of the patients, size and localization of the malformations, treatment history including the quantity of gelified ethanol used, and anesthesia type. A total of 7 malformations were treated in 6 patients (median age, 35.5 years; interquartile range [IQR], 31–38

Table 2. Scoring system for the evaluation of sclerotherapy (13)

	Grades			
Evaluated features	2	1.5	1	0
Functional impairment	Very good	Significantly better	Few improvements	No change
Esthetic prejudice	Very good	Significantly better	Few improvements	No change
Patient satisfaction	Very good	Good	Quite good	Not satisfied

Figure 1. a, b. Percutaneous puncture of lymphatic malformation **(a)** and aspiration of lymphatic fluid **(b)**.

years), with one patient having two different malformations with different symptomatology and esthetic issues.

Median diameter of LFMs was 6 cm (IQR, 4.5–8.5 cm). Technical and clinical success were obtained in all cases. No recurrences were registered during the available follow-up (median 17 months; IQR, 12–19 months); in one patient a residual portion of a malformation remained stable during the available follow-up (18 months) (Fig. 2).

Of the 6 patients, 5 experienced complete relief of pain (83%) and one had pain improvement, with a residual pain of mild intensity that did not require therapy. The median VAS score of pain was 7 (IQR, 6–7.5) before and 0 (IQR, 0–0) after treatment.

All patients had functional improvement (100%). All patients (100%) had esthetic improvement. In terms of procedure tolerance, 4 patients (66.7%) showed very good acceptance and 2 patients (33.3%) good acceptance. Four patients who had been previously sclerosed with other sclerosing agents, noted less postprocedural swelling.

The median injected volume of gelified ethanol was 4.4 mL per treatment session. Three patients experienced post-sclerotherapy local edema (Table 1), but none required special medications; patient 3 was precautionarily intubated. No systemic ethanol contaminations were detected. No major complications neither systemic side effects, such as hemoglobinuria, hemolysis, renal failure, myocarditis, or collapse, were observed.

No particular pre-medications were used; when necessary, oral analgesia with paracetamol was prescribed to reduce pain secondary to the inflammatory reaction. The patient that underwent the procedure under general anesthesia was followed in the intensive care unit for 24 hours.

The data resulted insufficient for any statistical analysis.

Discussion

Surgical resection is the therapy of choice for LFM, but their frequent infiltrating nature has been associated with high rates of relapse and complications such as lymphatic effusions, infections, and local nervous lesions, so alternative treatments have also been looked for (17,1).

Percutaneous sclerotherapy is currently the main therapeutic alternative, either alone in cases where surgery is not possible, or as a bridge to surgical resection.

Several agents have been used for percutaneous treatment of vascular malformations such as Ethibloc, OK432, polydocanol, sodium tetradecyl sulphate (STS), doxycycline and bleomycin. In comparative analyses, no significant differences were determined between these agents in terms of success rates.

The number of treatment sessions required to achieve an adequate result varies widely between cases, and more than 20 sessions have been reported in some patients (1, 18, 19).

This study reports preliminary results on the safety and effectiveness of percutaneous sclerotherapy of LFMs using gelified ethanol. Sclerogel consists of ethanol, with its strong sclerosing power, confined by a gelous network that limits its effusion into the surrounding healthy tissues. In this way the high efficacy of alcohol can be preserved, allowing a smaller volume to be used, and a better control can be achieved. One vial of Sclerogel contains gelified ethyl alcohol attached to a cellulose derivative. When injected, the gelified alcohol comes into contact with the vascular epithelium, for a time that is longer than the one observed with pure liquid alcohol. The hydrophilic property of ethanol causes dehydration of the vascular wall, which is enhanced by the presence of a macromolecule (water-insoluble cellulose derivative) that induces an osmotic effect. The cellulose derivative in the presence of water allows the gelified alcohol of the emulsion to solidify and fill the vessel lumen. The ethanol remains *in situ*, with a better control of its final allocation. The final result is the narrowing of the caliber of the vessels or of the (cystic) space in which Sclerogel is injected.

In order to prolong the surface contact, Cabrera et al. (20) developed a foam made of polidocanol and carbon dioxide. The foam resulted more effective than other solutions for their original purpose, but the

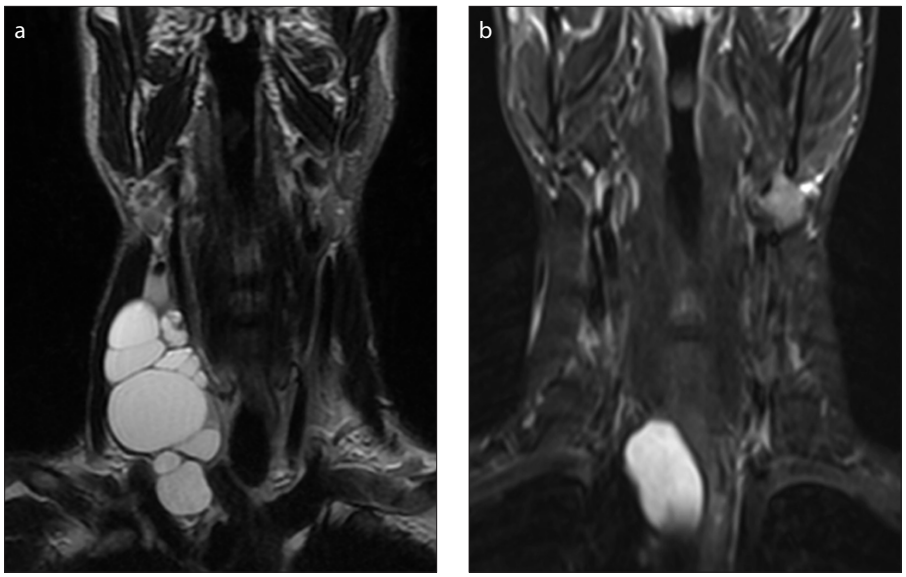

Figure 2. a, b. T2-weighted coronal image **(a)** demonstrates the malformation; T2-weighted coronal image **(b)** performed 18 months after treatment demonstrates disappearance of the treated malformation with stable residual lesion.

sclerosing efficacy of the detergent components resulted lower than ethanol, with gas bubbles disappearing more rapidly than ethylcellulose.

Currently, efficacy of gelified ethanol in terms of therapeutic results, has been reported to be at least as good as absolute ethanol (1, 21). However, there is still no evidence describing which agent is better in terms of outcome, time of action, and number of complications (13). Absolute pure liquid ethanol is generally used by experienced operators, but its use carries a risk of local and systemic complications, which have been reported between 7.5% and 28% (22). In our small series no major complications were noted; we attributed the high safety to the low amount of alcohol used, even though multiple injections were performed. Moreover, the rapid thickening of ethylcellulose in aqueous media makes its release and its cardiac toxicity less likely. The procedure resulted less painful and postprocedural swelling was less pronounced when compared with the use of other agents, as noted by the patients who had undergone previous sclerosing treatments. Ethylcellulose, which should give a palpable nodule in the site of injection, disappears spontaneously within 3–6 months.

All malformations were located in areas at high risk for local side effects, but in our series no side effects were noted except for swelling, which disappeared within a few days, depending on the dimension of the treated malformation. We treated small lesions under local anesthesia, with all the related benefits. This is not possible when using absolute ethanol as the sclerosing agent.

Some patients of our series presented with residual disease or recurrence after sclerotherapy performed with other agents, or after surgery. Although the follow-up was not long enough, our preliminary results in these patients are encouraging, because no residual disease nor recurrences were observed. Our clinical success is in agreement with the data published by Teusch et al. (23): their mean follow up of 103 days is shorter than ours but more cases of LFMs, localized in different areas (upper and lower extremities and face) were treated. Despite our positive preliminary results, we believe that a longer follow-up and larger series are surely needed. In the last 9 months Sclerogel was not available in our country so a slowdown in the collection of our data was inevitable.

Our study has limitations, such as its retrospective nature and the paucity of patients that has not allowed any statistical analysis. Furthermore, the indication to treatment was given by experienced interventional radiologists and surgeons, but no strict and specific protocol was used. Clinical outcomes were based primarily on subjective follow-up visits and less on postprocedural imaging; although imaging could be considered a good way to objectify results, we believe that relying on clinical assessments and subjective symptoms of patients is the best way to measure our treatments, since these are the true endpoints of the process.

In our opinion, sclerotherapy with Sclerogel can be indicated for areas at high risk for local side effects from the injection of absolute ethanol, such as perineural areas, the periocular region, the tongue, and areas close to airways (trachea). In these sites the lower diffusibility of gelified ethanol can in fact make a difference. An excessive amount of ethylcellulose can be harmful, so a careful injection is always recommended.

In conclusion, gelified ethanol may be considered easy to handle, well-tolerated, safe and effective according to a short-term follow-up. Further follow-up to evaluate long-term efficacy is mandatory.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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