Ethanol Sclerotherapy for the Management of Craniofacial Venous Malformations: the Interim Results

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Objective: We wanted to evaluate the safety and feasibility of ethanol sclerotherapy for treating craniofacial venous malformations (CVMs).

Materials and Methods: From May 1998 to April 2007, 87 patients (40 men and 47 women; age range, 2–68 years) with CVMs underwent staged ethanol sclerotherapy (range, 1–21 sessions; median number of sessions, 2) by the direct puncture technique. Clinical follow up (range, 0–120 months; mean follow up, 35 months; median follow up, 28 months) was performed for all the patients. Therapeutic outcomes were established by evaluating the clinical outcome of the signs and symptoms in all patients, as well as the degree of devascularization, which was determined on the follow-up imaging, in 71 patients.

Results: A total of 305 procedures with the use of ethanol were performed in 87 patients. Follow-up imaging studies were performed for 71 of 87 patients. Twenty-three (32%) of the 71 patients showed excellent outcomes, 37 patients (52%) showed good outcomes and 11 patients (16%) showed poor outcomes. Ethanol sclerotherapy was considered effective for 60 patients. All the minor complications such as bulla (n = 5) healed with only wound dressing and observation. Any major complication such as skin necrosis did not develop.

Conclusion: Percutaneous ethanol sclerotherapy is an effective, safe treatment for CVMs.

Index terms:
Ethanol
Head and Neck
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Venous malformations (VMs) are the most common vascular malformations and they consist of dysplastic venous channels. These lesions are present at birth and they grow proportionately with age (1–4). VMs also cause various clinical presentations from a simple birthmark to a life-threatening condition, including skeletal anomalies or an intravascular coagulopathy (5–7). VMs can involve any location, including the head and neck area. Craniofacial VMs (CVMs) involve multiple anatomical spaces and significant neuromuscular structures (8). Surgery in the head and neck area for CVMs is difficult to perform and it usually leads to nerve damage, massive bleeding and/or deformity, and it has a high recurrence rate and high morbidity (8). Therefore, CVMs have been treated with various treatment techniques as the primary or preoperative therapy. Sclerotherapy for CVMs has an advantage of producing no external scarring and it causes few complications compared with surgical treatment. Ethanol has been the most commonly used agent for percutaneous sclerotherapy for the treatment of congenital vascular lesions (5, 8–11). However, the previous studies have generally included only a small number of patients with CVMs (8, 12). The purpose of this study was to describe the safety and the feasibility of ethanol sclerotherapy for the treatment of a relatively large series of

CVMs and to assess the method's clinical efficacy.

MATERIALS AND METHODS

Patient Population and Evaluation

From May 1998 to April 2007, a series of 87 consecutive patients (40 men and 47 women, mean age, 17.5 years; age range, 2–68 years) at our hospital and who had CVMs were treated with percutaneous ethanol sclerotherapy. Approval from the institutional review board was not needed for reviewing their medical records and the radiological images for research purposes at our institute. We retrospectively reviewed the clinical and radiological findings. For all the cases, written informed consent was obtained from the patients or their parents before the procedures. Diagnosing the CVMs was based on the clinical and gross anatomic findings and the radiological examinations of all the patients. The clinical criterion for the diagnosis of CVMs was an early presentation, and especially at birth, of the presenting features of a lesion with slow and steady or progressive growth with age. A confirmed radiological diagnosis was made by regurgitation of blood on direct puncture venography in all the patients. We also examined the masses that had wide venous pools, as established on magnetic resonance imaging (MRI) (n = 85), computed tomography (CT) (n = 23) and whole body blood pool scintigram (WBBPS) (n = 45). We performed MRI for evaluating the extent of disease, and MRI was helpful for making the diagnosis of VM, especially when a phlebolith was present in the lesion. Physical examinations were also performed to evaluate the lesions. The imaging studies, which were mainly comprised of MR imaging and WBBPS, were used to obtain the baseline data. Seventy-one of 87 patients underwent MR imaging or WBBPS after sclerotherapy. MR imaging was performed with a 1.5-T unit (Signa; GE Medical Systems, Milwaukee, WI). The MR imaging protocol included the axial, sagittal and coronal imaging with the fat saturated T2-weighted sequences, the axial gradient echo and T1-weighted images and/or the contrast enhanced T1-weighted images.

Sclerotherapy Procedure

After reviewing the imaging studies, we performed direct puncture venography to evaluate the size, location and anatomy of the lesions and the hemodynamics, and we determined the possible sites of these lesions in all the patients. The lesions were directly punctured using 23-gauge needles with all the patients under general anesthesia. When venous reflux was established, contrast material was then injected manually to perform digital subtraction angiography for evaluating the extent and volume of the lesions and for draining the venous system. However, the extent and volume of the lesions were not evaluated sufficiently in several patients because the contrast material did not fill the large, nondependent areas of the VMs, which consisted of wide venous spaces or partially collapsed lesions. The ethanol used in sclerotherapy was usually kept in a refrigerator. After confirming the CVM via direct puncture venography, we used pure or diluted ethanol (i.e., 2 ml of 50% ethanol means 1 ml of ethanol mixed with 1 ml of contrast media). The ethanol was injected together with a simultaneous fluoroscopic "road map" to ensure intralesional administration and to prevent unwanted extravasation into the surrounding normal tissue or draining veins, or to prevent massive vascular penetra-

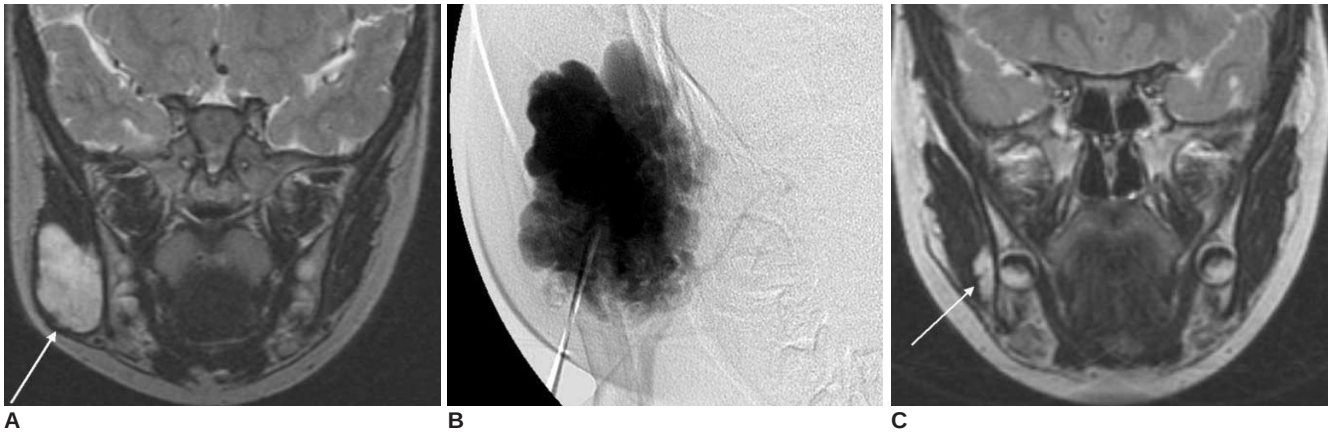


Fig. 1. 5-year-old-girl with venous malformation in right cheek.
A. Coronal T2 weighted image shows venous malformation (arrow) in right cheek.
B. Direct puncture venography shows opacification of venous malformation.
C. Coronal T2 weighted image obtained after two sessions of sclerotherapy with ethanol reveals significant shrinkage of venous malformation (arrow).

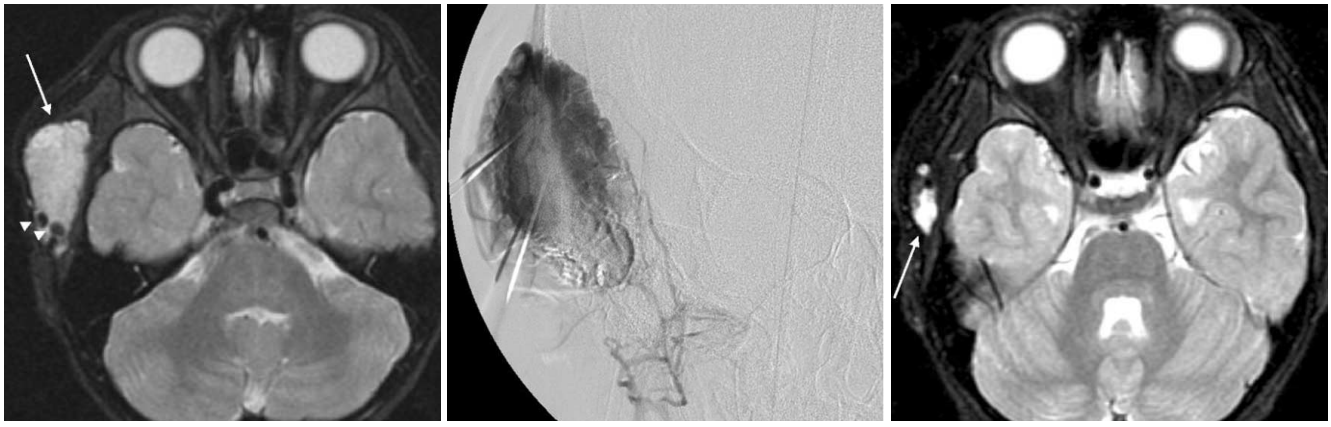
tion. In the cases of using pure ethanol, we performed the procedures by dividing the permitted ethanol dose into small amounts, which were less than the amount of contrast media used, for preventing extravasation. Ethanol injection was stopped when the venous pools were sufficiently filled according to the enlargement of the lesions or when resistance to the injection was encountered or opacification of the venous drainage was seen. The volume of ethanol injection was calculated based on the size and location of the VMs and the weight of the patient. We calculated the size of the VMs as based on the contrast media that was used for the direct puncture venography. A maximum ethanol volume of 1 ml/kg was injected in a single session. However, the actual amount of ethanol we used was less than half of the maximum amount permitted for most patients. Pure (99.9%) ethanol was used in 166 sessions of the total 305 sessions of ethanol sclerotherapy, and diluted ethanol (50–90%) with nonionic contrast medium (iobitridol, Xenetix 300; Guerbet, France) was used in 139 sessions of the total ethanol sclerotherapy sessions. We used pure ethanol as much as possible because pure ethanol is more effective than diluted ethanol, but diluted ethanol was used in the lesions adjacent to skin to prevent skin necrosis. The amount of injected alcohol ranged from 1 ml (pure ethanol) to 76 ml (58 ml of pure alcohol and 18 ml of 90% diluted alcohol). After the ethanol injections, we waited for 10 minutes and the stasis of ethanol in the lesions was reconfirmed at the end of the procedure by a further injection of contrast medium. If the lesions showed high flow or prominent venous drainage, then manual compression of the outflow was performed before injection of ethanol. The patients were carefully observed during these procedures and for at least 24 hours after the procedures to detect complications.

Evaluation and Follow up

Clinical follow up was possible for all 87 patients and the duration of the follow-up period ranged from 10 days to 120 months (mean: 35 months). The effectiveness of sclerotherapy was assessed based on the clinical findings and the radiological findings of the follow-up MR imaging or WBBPS. Two radiologists who worked in consensus analyzed the therapeutic responses to ethanol sclerotherapy by comparing the size of the VMs between the baseline MR imaging and the follow-up MR imaging. The effectiveness of percutaneous sclerotherapy was also assessed by quantitatively measuring the reduction of the radioisotope count over the designated lesion between the baseline WBBPS and the follow-up WBBPS. Excellent was defined as clinical obliteration of the signs and symptoms with over 75% reduction of uptake on the WBBPS or near complete obliteration of the VM on the MR imaging. Good was defined as complete or partial resolution of the signs and symptoms with a 25–75% reduction of uptake on the WBBPS or a 25–75% size decrement on the MR imaging. Poor was defined as partial resolution or no change of the signs or symptoms with less than a 25% reduction of uptake on the WBBPS or less than a 25% size decrement on MRI.

Periprocedural Complications

Complications were classified into major and minor complications according to the Society of Cardiovascular and Interventional Radiology (SCVIR) reporting standards.



A **B** **C**

Fig. 2. 5-year-old-boy with venous malformation in right temporalis muscle.
A. Fat suppression axial T2 weighted image demonstrates presence of venous malformation (arrow) with phlebolithes (arrowheads) in right temporalis muscle.
B. Direct puncture venography shows opacification of venous malformation.
C. Fat suppression axial T2 weighted image obtained after one session of sclerotherapy shows significant shrinkage of venous malformation (arrow) in right temporalis muscle.

The major complications included death, systemic embolization of the sclerosant, renal toxicity, hepatic toxicity, nerve damage, overlying skin injury and trismus. The minor complications included any nonpermanent adverse sequela such as indurations, swelling and pain that required nominal therapy or no therapy. Physical and neurological examinations were performed before and after sclerotherapy to assess the complications. Laboratory examinations were considered for the cases with signs or symptoms related to renal or hepatic toxicity.

RESULTS

Details of the Patients

All the patients reported cosmetic concerns at presentation. Before undergoing sclerotherapy in our hospital, 26 patients had undergone surgical excision or sclerotherapy at another hospital. One of them had also undergone previous partial excision at our hospital.

Therapeutic Outcomes

Among the total 87 patients, 45 patients had diffuse or multispace CVMs and the other 42 patients had localized CVMs. The number of required procedures varied from patient to patient, depending on the size and behavior of the lesions. The total number of procedures was 213 (range, 1–21; mean number of sessions, 4.7) for the patients with diffuse or multispace CVMs and 92 (range, 1–8; mean number of sessions, 2.2) for the patients with localized CVMs. A total of 305 ethanol sclerotherapy sessions (range, 1–21; mean number of sessions, 3.5) were performed for the 87 patients. Two or more procedures were performed for 67 patients. After or during a course of sclerotherapy, seven of 87 patients underwent plastic surgery for cosmetic deformity. Follow-up imaging studies were performed for 71 of 87 patients. Twenty three (32.4%) of the 71 patients showed an excellent outcome, 37 patients (52.1%) showed a good outcome (Figs. 1–4) and 11 patients (15.5%) showed a poor outcome (Fig. 5). Ethanol sclerotherapy was considered effective for 60 (84.5%) of the 71 patients. The responses after percutaneous ethanol sclerotherapy are summarized in Table 1.

Complications

There were no major complications such as skin necrosis. Two patients experienced transient oxygen desaturation, which was probably due to pulmonary hypertension, immediately after the injection of ethanol. However, the

Table 1. Responses after Percutaneous Ethanol Sclerotherapy

Response	Localized	Diffuse or Multispace	Number (%)
Excellent	19 (26.8%)	4 (5.6%)	23 (32.4%)
Good	12 (16.9%)	25 (35.2%)	37 (52.1%)
Poor	1 (1.4%)	10 (14.1%)	11 (15.5%)
Total	32	39	71

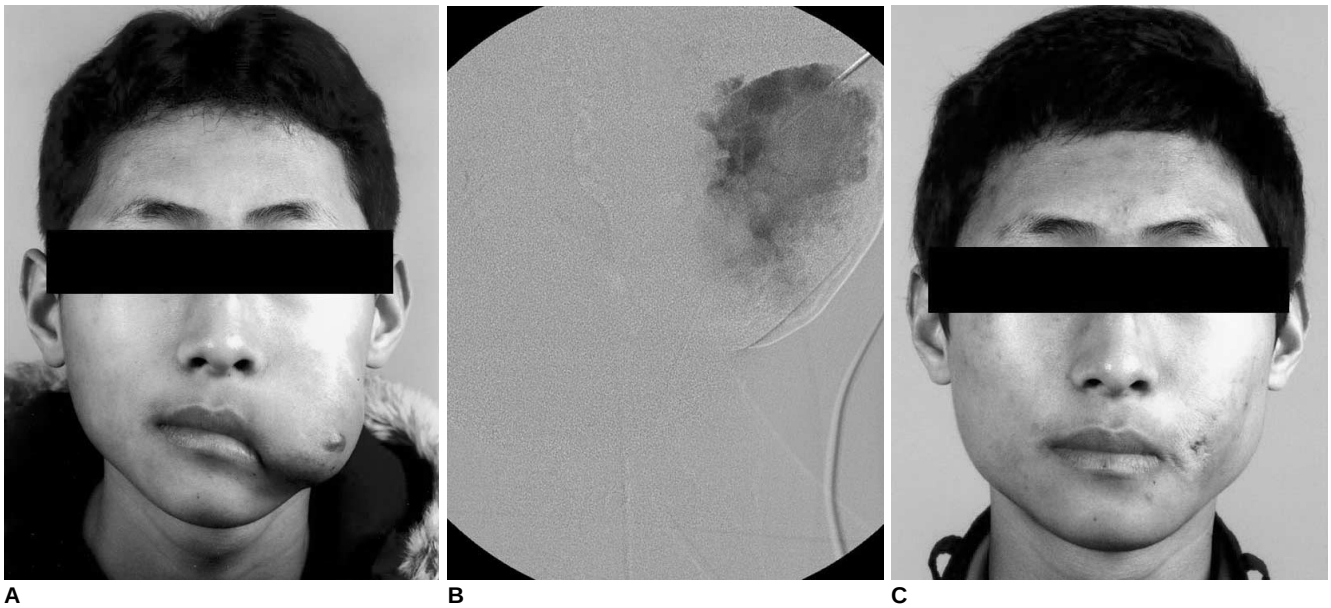


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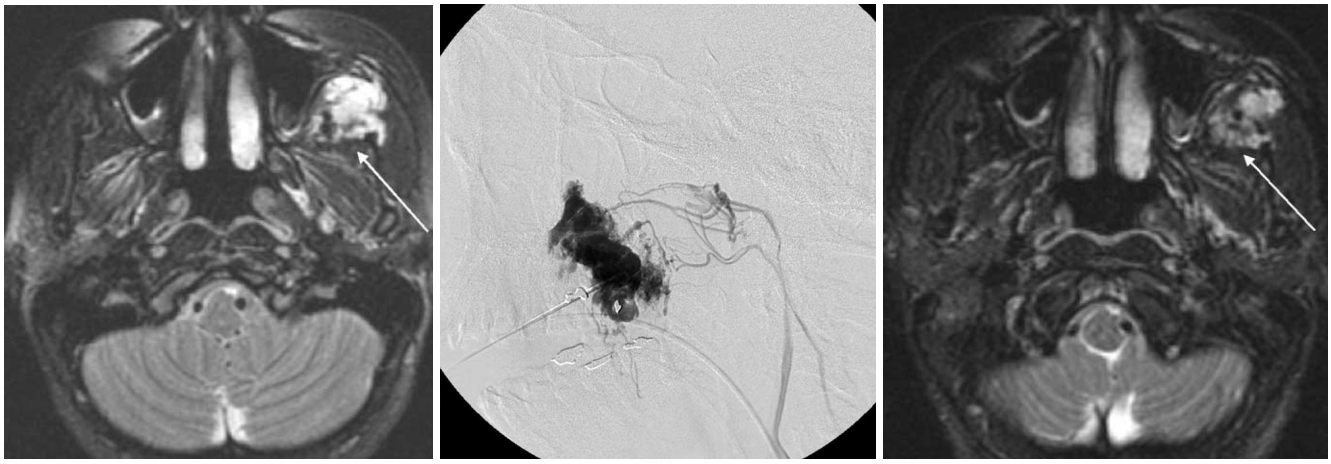
Fig. 3. 16-year-old-man with venous malformation involving tongue, lower face and left parapharyngeal space.
A. Clinical appearance of soft tissue mass that is located in patient's left cheek.
B. Direct puncture venography shows opacification of venous malformation.
C. Near-complete shrinkage of venous malformation was obtained with three sessions of sclerotherapy.

oxygen saturation immediately recovered. One patient with a tongue VM experienced transient reduction of the sensation of the tongue and the other patient with a cheek VM experienced transient facial nerve palsy (Table 2). For all the patients, there was induration and swelling of the lesions immediately after injection of the ethanol. Most patients reported pain at the areas of the lesions, which was effectively controlled by intravenous or intramuscular analgesics. There were no major complications related to the procedures, such as embolism of ethanol into the

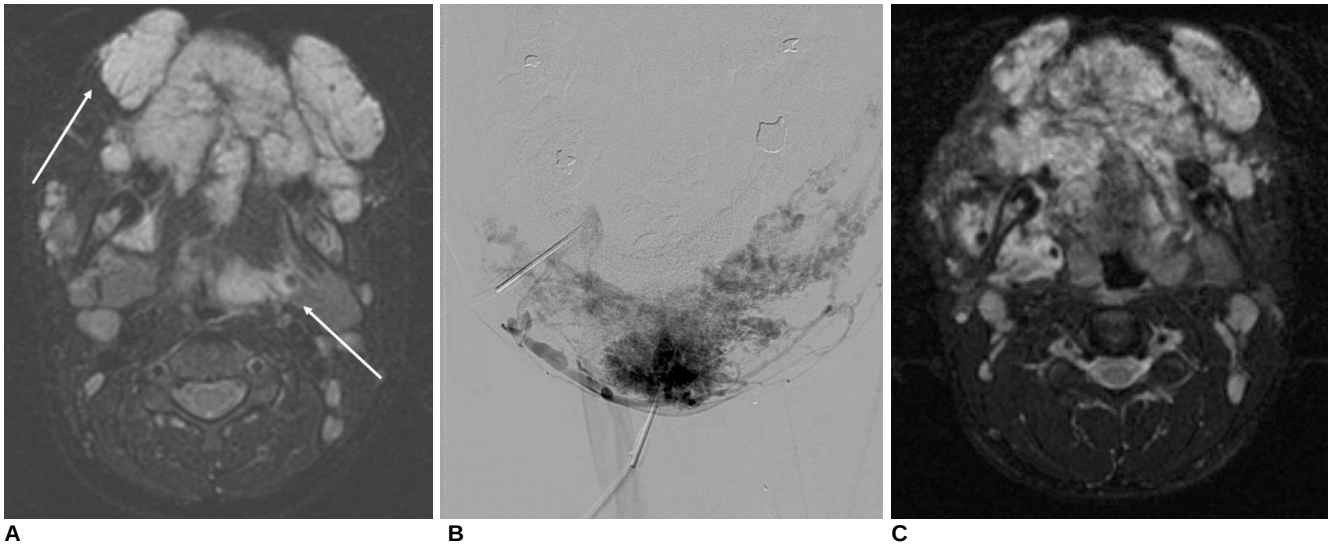
Table 2. Complications after Percutaneous Ethanol Sclerotherapy

Complication	Number (%)
Skin necrosis	0 (0)
Respiratory difficulty (Saturation decrement)	2/87 (2.3%)
Tongue dullness	1/87 (1.15%)
Transient facial nerve palsy	1/87 (1.15%)
Total	4/87 (4.6%)



A **B** **C**

Fig. 4. 36-year-old woman with venous malformation in left cheek.
A. Fat suppression axial T2 weighted image demonstrates presence of venous malformation (arrow) in left cheek.
B. Direct puncture venography shows opacification of venous malformation.
C. Fat suppression axial T2 weighted image obtained after two sessions of sclerotherapy shows 50% shrinkage of venous malformation (arrow) in left cheek.



A **B** **C**

Fig. 5. 15-year-old man with venous malformation involving tongue, lower face and left parapharyngeal space.
A. Fat suppression axial T2 weighted image demonstrates presence of venous malformation (arrows) involving tongue, lower face and left parapharyngeal space.
B. Direct puncture venography shows opacification of venous malformation.
C. Fat suppression axial T2 weighted image obtained after nine sessions of sclerotherapy shows no significant change of venous malformation involving tongue and lower face.

systemic circulation, injury of the skin overlying the lesion or nerve injury. No patients reported signs or symptoms related to renal or hepatic toxicity.

DISCUSSION

Depending on the predominantly involved vasculature, congenital vascular malformations are classified as arterial, capillary, lymphatic, venous or combined (1, 12–16). Histologically, VMs consist of thin-walled channels that are lined with a single layer of endothelium, which is deficient in smooth muscle (1, 4). VMs consist of dilated venous spaces with very slow blood flow histologically and these dilated venous spaces are uncommonly seen on arteriography, so conventional or direct puncture venography is necessary to visualize the lesions and define their extent (17, 18). The diagnosis of VMs is based on a careful history taking and the clinical examination. The lesions may be localized or they can involve extensive areas of the body. The symptoms vary depending on the location and size of the lesions and even small VMs can cause severe pain.

Craniofacial VMs may be become more engorged during the Valsalva maneuver or they are dependent on positioning (16). Most patients with craniofacial VMs have concerns for cosmetic considerations more than for functional difficulties. Besides sclerotherapy and surgery, VMs have been treated by a variety of techniques, including irradiation, electrocoagulation, cryotherapy, intravascular magnesium or the use of copper needles, lasers and compression. All these techniques have their particular indications and limitations. Surgical excision is useful only for the localized and limited lesions. Aggressive excision can lead to significant loss of motor function, cosmetic problems, nerve damage or massive bleeding in patients with extensive involvement because of the complicated anatomy of the face and neck.

Sclerotherapy has several advantages, including no external scarring, and it incurs few complications as compared with surgical treatment. There are various choices of agents to use for sclerotherapy: 5% sodium morrhuate, sodium tetradecyl sulphate (Sotadecol), ethanolamine oleate, OK432, bleomycin, ethanol and hypertonic saline, alone or in various combinations, have all been used (1, 12, 13, 18–25).

There is no ideal vaso-occlusive substance applicable to all VMs. Among the different sclerosing agents, ethanol is the most popular and potent and it shows the lowest rate of recurrent malformation. Ethanol is considered the most reliable of all of the sclerosing agents (5, 12, 16, 26). However, ethanol sclerotherapy requires general anesthesia because the procedure is very painful (21). Direct percutaneous puncture venography is required to measure the lesion volume and to confirm the involvement of multiple compartments.

In our study, we used 50–90% ethanol mixed with contrast media, as well as pure ethanol. The radiopacity of the contrast media mixed with ethanol for percutaneous sclerotherapy or direct puncture venography is beneficial for monitoring procedures and the contrast media shows the distribution of the ethanol injected into the lesions (18, 27). After injection, ethanol sclerotherapy requires extended contact with the endothelial lining to cause disruption of the endothelium, intense inflammatory reactions and blood coagulation (1, 4, 16, 21). Sclerotherapy is most successful when the vascular spaces are small or when the blood flow is slow, and the possibility of dilution must be considered in the large vascular spaces or that dispersion can happen due to fast blood flow. To achieve the necessary result and to minimize the flow of ethanol into the normal venous drainage structures, several techniques have been used, including manual compression, the use of rubber bands to compress the forehead and chin to occlude facial venous return or mechanical occlusion of the draining vein (8). In our study, manual compression was used for some of the patients. Because an excessively forceful injection into the lesion causes ethanol to flood into the systemic circulation and this can increase the development of complications, the injection rate and amount must be carefully controlled under fluoroscopic guidance. In most patients, swelling and hardness of the VMs were seen just after the injection of ethanol. After the procedure, the pain due to the expansion of blood pools was effectively treated with intravenous or intramuscular analgesics. The major complications of sclerotherapy include skin necrosis, peripheral nerve palsies and hypotensive crisis, as well as fatalities such as cardiac arrest and pulmonary emboli (22, 24, 28–33). In our study, none of the patients experienced skin necrosis or permanent facial nerve palsy, except for two cases with tongue dullness in one patient with a tongue VM and transient facial nerve palsy in one patient with a cheek VM. For prevention of complications such as skin necrosis, we used diluted ethanol in the lesion adjacent to skin. Two patients experienced transient pulmonary hypertension in our study. To avoid a catastrophic situation such as acute pulmonary hypertension with cardio-pulmonary collapse, it is suggested to inject the ethanol slowly and combine this with rubber band compression and not to exceed a level of 1 ml ethanol/kg of body weight, along with monitoring the pulmonary artery pressure (12, 21, 34, 35). For prevention of pulmonary hypertension during the procedures in our study, nitroglycerin (0.5–1 μg/kg/min) was administered

during the procedures with the patients under general anesthesia. The volume of ethanol to be injected is determined from the percutaneous study with injecting intralesional contrast medium. The reported complication rates for ethanol sclerotherapy have ranged from 7.5 to 26.7% (5, 13, 24, 34, 35), and the complication rate was 4.6% in our study (Table 2) and there were no major complications such as skin necrosis or permanent nerve injury. Although percutaneous ethanol sclerotherapy was considered effective in 60 of the 71 patients with follow-up images, all the patients experienced symptomatic or cosmetic improvement. This success rate (84.5%) is comparable to those (60–95%) described in the previous reports in which VMs were treated by percutaneous sclerotherapy with the same agent we used or with other liquid agents, but with the use of a similar technique (11, 18, 22–25).

The following feature was noted for those CVMs with a poor outcome. Ten (91%) of the 11 patients with a poor outcome had diffuse or multispace CVMs, the targeted lesions were limited to the site of percutaneous sclerotherapy and the targeted lesions were matched to the needs of the patient (Table 1). Most of all, we tried to reduce the cosmetic problems rather than to reduce the functional problems because almost all the patients had cosmetic problems and they wanted cosmetic improvement. Even though the degree of devascularization of CVMs in the patients with a poor outcome was less than 25%, the clinical satisfaction of the patients was more than a good outcome. Several sessions of ethanol sclerotherapy are necessary for very large VMs because recanalization can occur. Further, several sessions of ethanol sclerotherapy can help to reduce the risk of major morbidity due to the ethanol injection (1, 5), and so two or more procedures were performed in 67 patients in our study. However, the use of percutaneous ethanol sclerotherapy may be limited in inaccessible lesions due to the lack of a proper vein for direct puncture, in lesions with venous outflow connected to the deep vein system and in lesions surrounding a nerve (5, 11).

There are limitations in our study. As not all the patients with ethanol sclerotherapy underwent follow-up imaging, we did not evaluate the response after ethanol sclerotherapy in 16 of the 87 patients. Clinical follow up was performed for all the patients, and although the clinical outcome of those 16 patients was not used for objective analysis, we thought that the clinical outcome of these patients could replace the therapeutic outcome.

In conclusion, ethanol sclerotherapy is an effective treatment for CVMs, and it is wise to begin this treatment as early as possible once a diagnosis is made. Careful planning is essential to reduce the potential risks of this procedure, and long-term follow up of patients is required to detect any recurrence.

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