

*Original Article*

## Percutaneous Sclerotherapy for Venous Malformations Using Polidocanol under Fluoroscopy

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This retrospective study evaluated the safety and efficacy of using polidocanol with X-ray fluoroscopy for percutaneous sclerotherapy of venous malformations of the limbs, head, and neck. The subjects were 16 of 18 patients who presented to our department with venous malformations. Two patients were excluded because they were unlikely to benefit from the treatment. Of the 16 included in the study, 1 could not be treated because of inaccessibility, and another was lost to follow-up. Among the 14 cases that we were able to follow-up, 11 cases had had pain as their primary symptom. Following treatment, this symptom remained unchanged in 1 patient, was improved in 4, and had disappeared in 6; however, there was a recurrence of pain for 3 of these patients. Two patients had sought treatment for cosmetic purposes; following treatment, the lesion disappeared in one and showed a significant reduction in the other. The remaining patient presented with a primary symptom of mouth bleeding, which disappeared following treatment. There were no critical complications. Percutaneous sclerotherapy of venous malformations using polidocanol is safe and effective, and permits repeat treatments. The efficacy is especially good for resolving pain, and complications are minor. It is desirable to use fluoroscopy for these procedures.

**Key words:** venous malformation, sclerotherapy, polidocanol, fluoroscopy guidance

**T**raditionally, surgery has been the standard medical treatment for venous malformations. However, imperfect resections often occur, recurrences of venous malformations are not unusual, and there are occasional functional or cosmetic problems following surgery. Recently, however, good results from treatment by percutaneous sclerotherapy have been reported [1-14], although there has been significant variation among the techniques used and in selection of the scleros-

ing agent. Traditionally, ethanol has been the agent of choice for sclerotherapy [1-8]; however, we used polidocanol because its activity is more moderate with fewer complications, and there is less pain during the injection. In traditional sclerotherapy with polidocanol, direct observation or ultrasound (US) have been the methods usually selected to guide the needle, rather than guidance by fluoroscopy [9-11]. This study, the first series to report sclerotherapy with polidocanol using fluoroscopy for guidance, was carried out to evaluate the safety and efficacy of the treatment.

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## Materials and Methods

**Patients.** Of the 18 patients with venous malformations who visited our department from May 1998 to August 2002, 16 patients were treated. Two patients were excluded because they were considered unlikely to benefit from sclerotherapy because of their progressed thrombosis or fibrosis. The remaining patients included 6 males and 10 females, ages ranging from 3–48 years. The anatomical distribution was 13 with limb lesions, and 3 with head and neck lesions. For 12, the decision to seek treatment was based on pain; for 3, treatment was for cosmetic purposes to reduce swelling; and for 1 it was to treat mouth bleeding. Prior medical treatments consisted of surgical resection for 6 and laser surgery for 1. Prior to the procedure, all patients underwent an ultrasound and MRI, the size of the lesion was determined, progression of the disease was evaluated, the relationship to surrounding structures was assessed, and internal blood flow of the involved vessel was measured.

Diagnosis of venous malformations was made either by histopathology from an operative or biopsy specimen, or by a characteristic MRI image [17–19], based on the clinical appearance according to the classification of Mulliken and Glowacki [15] and Jackson [16].

**Procedures.** If possible, after the blood vessel was observed to be engorged at the proximal portion of the lesion by either a sphygmomanometer cuff or a tourniquet, puncture of the lesion was performed with a 23G butterfly needle, a 22G surflo needle, or a 21G spinal needle under US guidance or direct observation. Reflux of blood was checked, and then imaging under fluoroscopy was carried out. If the contrast media appeared in the lesion and an outflow vein was delineated, or if an image typical of a venous malformation such as a lobular or varicose shape was obtained, then it was judged that the needle was in the lumen of the venous malformation to be treated.

In the event that an image of an outflow vein appeared before the lumen of the venous malformation was filled with contrast media, and the outflow vein was superficial, the vein was pressed with a gauze-wrapped clamp and the lesion was imaged again. This procedure was carried out to create conditions where contrast media would stay within the venous malformation for as long as possible. The sclerosing agent, typically 5 mL of 3% polidocanol, was mixed with 1 or 2 mL of contrast media. If possible, the infusion volume was kept to less than 10 mL (the dose of polidocanol is 300 mg). If an increased volume was

required, 1% polidocanol was used. Further, in the early stages of 2 cases there were concerns about complications, so even though not much sclerosing agent was to be infused, we used just 1% polidocanol from the beginning. For larger lesions, several sites should be accessed if possible, thus enabling possible injection of the sclerosing agent into several parts of the lesion. After injection of the sclerosing agent, a cuff or a tourniquet remained applied to maintain pressure on the draining vein for approximately 10 min, primarily to contain the sclerosing agent, but also to prevent rapid outflow of the sclerosing agent to the systemic circulation, which could lead to complications. Usually, the sclerosing agent was not aspirated. However, aspiration was carried out using the puncture needle in 1 case where it was felt that on release of the tourniquet the sclerosing agent would flow out too rapidly, and in another case of a superficial lesion of a fingertip where it was felt that too much sclerosing agent would remain.

Local anesthesia for pain control during the procedure was chosen for 11 patients. General anesthesia was selected for the 3 juvenile patients and for 1 with mental retardation both to reduce pain and to maintain sedation to facilitate the procedure. For the 1 patient who had a lesion on the lips, the use of ethanol was also considered, and general anesthesia was used. Moreover, with 1 other patient, the use of ethanol was considered, and spinal anesthesia was used for the first of 2 sclerosing treatments.

**Evaluation Methods.** Follow-up measurements of the sizes of the lesions and changes in their characteristics were conducted at 1 and 3 months following sclerotherapy. If possible, patients were evaluated using MRI at these follow-ups. If an improvement in symptoms or reduction in the size of the lesion was not observed 3 months after treatment, additional medical treatment was usually performed. The results regarding symptoms of pain were judged as unchanged, improved, or disappeared. The results regarding changes in lesion size were judged as unchanged, reduced, or disappeared.

**Ethical Conduct of Research.** During the period of this study, since all medical fees were usually covered by national health insurance, we did not believe that our clinical study required approval of our Institutional Review Board. However, our study protocol is now under submission to our Institutional Review Board because we now consider it to be a clinical study involving technical innovation. All procedures were carried out with

the adequate understanding and written consent of each subject and/or guardian.

### Results

**Sclerotherapy and Evaluation before Treatment.** Sclerotherapy was performed on 16 patients with venous malformations. For 1 patient, the treatment was attempted but failed; although the needle entered the lesion, we were not able to inject the medication because the lumen of the blood vessel internal to the lesion could not be found. This lesion presented with a low signal on a T2-weighted MR image, and it was thought that the internal blood vessel lumen had contracted due to prior laser treatment or to surgery. One other patient was lost to follow-up. The final case series consisted of 14 patients who had sclerotherapy and who were subsequently followed-up.

A summary of the cases is shown in Table 1. The size of each lesion was measured by MRI before and after treatment. However, the lesion could not be measured in 1 case (case 9) because it spread diffusely from the chest to the hand, and in 3 cases (case 5, case 11, and case 12)

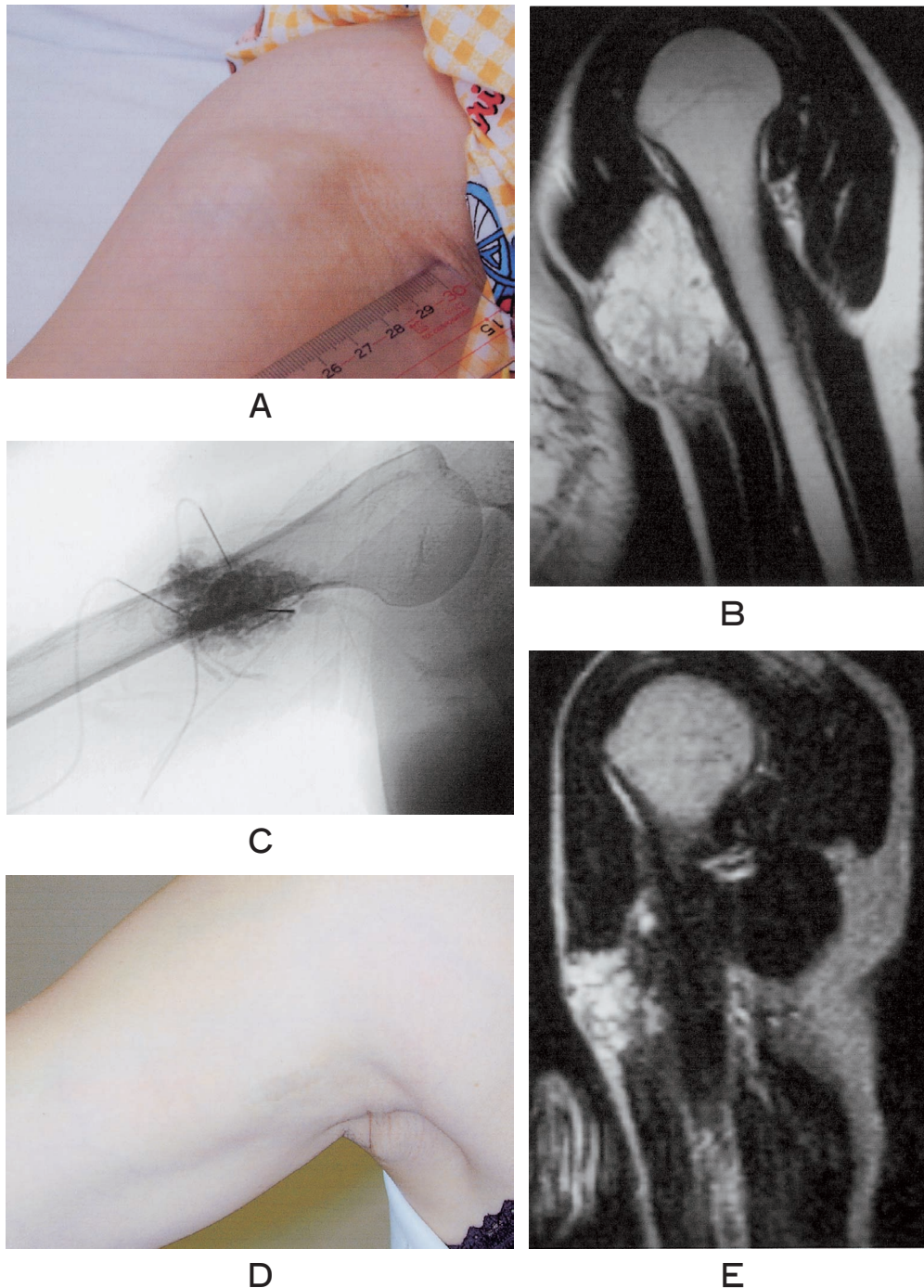
the lesions were plexiform in nature. The diameter range for the other lesions was 2.2–24.3 cm (average 9.2 cm). Patients were treated 1–3 times (average 1.4). The dose of polidocanol for each treatment ranged from 9–450 mg (average 156 mg). A total of 21 treatments were conducted in the study.

**Evaluation after Treatment.** For the 14 patients whose progress was followed after sclerotherapy, the observation periods were from 3–55 months (average 24) postprocedure. Among the 11 for whom the primary symptom was pain, disappearance occurred in 6 (55%) (Fig. 1), improvement occurred in 4 (36%), and one remained unchanged. For one of the 2 seeking treatment for cosmetic reasons (Fig. 2), the lesion completely disappeared. For one patient who had a diffuse lesion on the upper limbs, significant shrinkage of the lesion in the areas treated was observed. The patient with a bleeding mouth as the primary symptom achieved complete remission. The treatment was effective for 13 of the 14 patients (93%). We did not set disappearance of the lesion as a medically necessary goal, but rather set improvement in symptoms such as pain, or a degree of reduction of the lesion satisfactory to the patient as the objective. There-

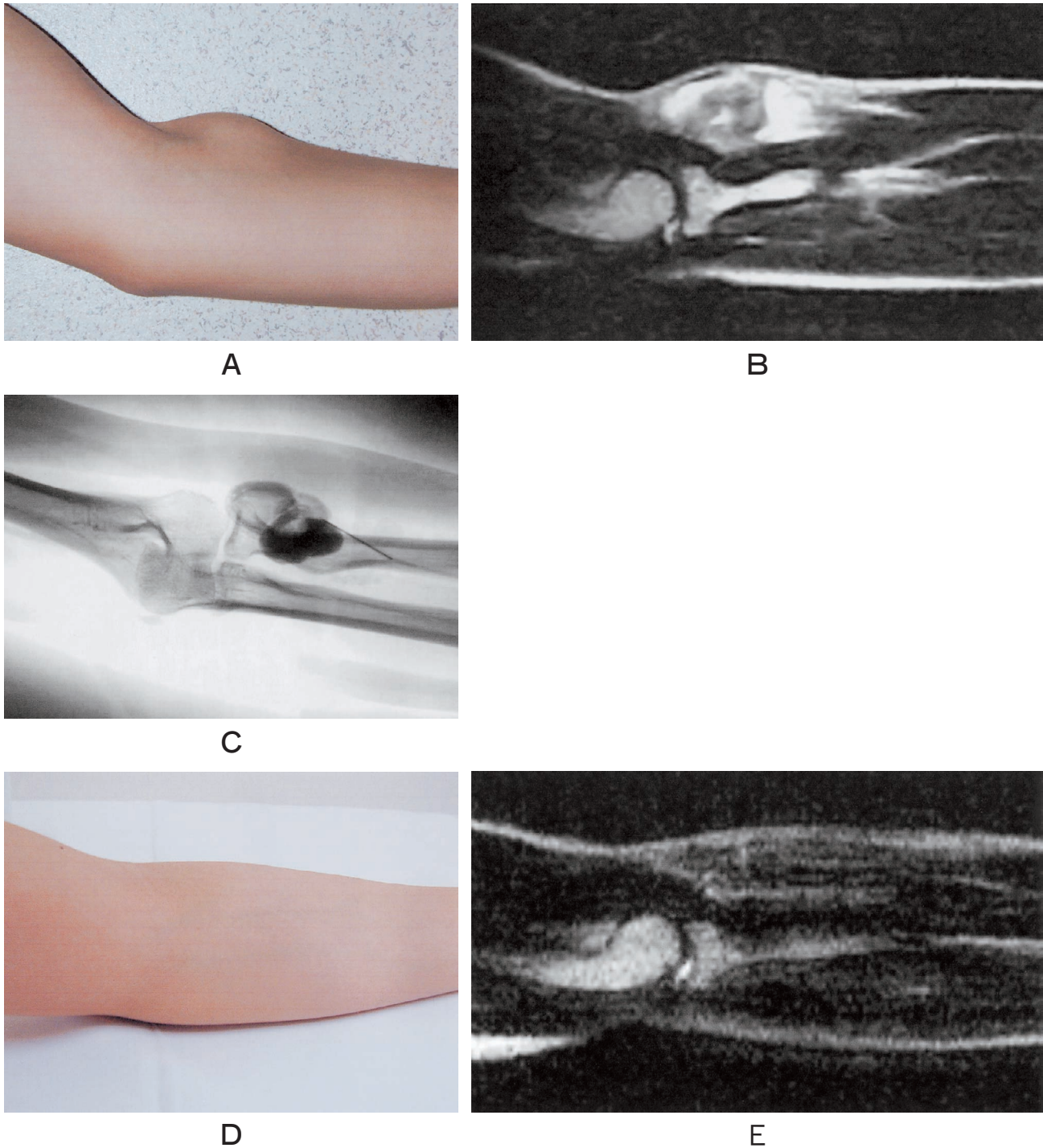
**Table 1** Summary of study patients

Patient No.	Age (Years)	Location	Chief complaint	Prior treatment	Size (cm)		Injection No.	Injection Amount (mg)	Follow up (months)	Clinical Outcomes
					before treatment	after treatment				
1	27F	Foot	Pain	None	3.8 × 2.8 × 2.5	3.8 × 2.5 × 2.2*	2	170	55	Pain disappeared, then recurred
2	23F	Thigh	Pain	None	15.7 × 5.0 × 4.4	15.7 × 5.0 × 3.9	1	40	49	Pain improved
3	18M	Leg	Pain	None	23.5 × 6.7 × 6.7	13.8 × 5.0 × 4.7	2	630	45	Pain improved
4	18M	Cheek	Pain	None	2.2 × 1.8 × 1.2	2.2 × 2.0 × 1.2*	2	99	28	Pain disappeared, then recurred-operation
5	15F	Forearm	Pain	None	-	-	1	81	40	Pain improved
6	48M	Cheek	Hemorrhage	Excision	6.8 × 4.3 × 1.9	6.8 × 3.8 × 1.4	1	108	36	Hemorrhage resolved
7	11F	Leg	Pain	None	12.3 × 4.4 × 2.1	12.4 × 4.7 × 2.2	1	300	3	Pain unchanged - operation
8	32F	Arm	Pain	Excision	5.6 × 3.9 × 3.8	4.0 × 2.9 × 2.0	1	225	30	Pain disappeared
9	16F	Arm-forearm	Pain	Excision	-	-	1	48	Lost	
10	25F	Forearm	Swelling	None	4.3 × 2.0 × 2.0	Disappeared	1	150	15	Swelling disappeared
11	16M	Chest-hand	Swelling	None	-	-	3	373	14	Swelling reduced
12	17F	Thigh	Pain	None	-	-	2	600	8	Pain improved
13	3F	Forearm	Pain	Excision	5.9 × 4.0 × 2.9	5.7 × 3.7 × 2.2	1	54	6	Pain disappeared
14	16F	Face	Swelling	Excision, Laser	3.2 × 1.7 × 1.2	-	-	-	-	Failure
15	23M	Arm-forearm	Pain	None	24.3 × 7.3 × 4.5	24.3 × 7.7 × 5.0	1	300	3	Pain disappeared, then recurred
16	7M	Thigh	Pain	Excision	3.2 × 2.5 × 1.7	2.5 × 2.2 × 1.4	1	105	3	Pain disappeared

\*The size of the lesion was measured by MRI after the first sclerotherapy.



**Fig. 1** A 32-year-old woman's venous malformation of the right upper arm had increased in size after surgery performed 12 years previously. (A) Photograph prior to sclerotherapy shows elevation of the lesion in the right anterior brachial region. The surgical scar can be observed on the elevated region of the skin. (B) In a T2-weighted sagittal MR image prior to sclerotherapy, the multilobular venous malformation is observed in the right anterior brachial region. (C) The x-ray image during sclerotherapy shows 3 butterfly needles inserted into the multilobular venous malformation. Contrast medium mixed with the sclerosing agent is administered and held in venous stasis. A tourniquet is wound around the lesion, and the outflow vein is compressed. (D) Approximately 6 months after treatment, it is not possible to identify the lesion near the surgical scar where it was previously observed. (E) In a T2-weighted sagittal MR image taken approximately 1 month after treatment, the lesion is significantly reduced.



**Fig. 2** A 25-year-old woman with a venous malformation in the left forearm region. (A) Photograph prior to sclerotherapy shows elevation of the lesion in the left ante-cubital region. (B) In a T2- weighted sagittal MR image prior to sclerotherapy, the venous malformation containing thrombi is observed on the left forearm. (C) Under x-ray fluoroscopy during sclerotherapy, a butterfly needle is inserted in the venous malformation; contrast medium mixed with the sclerosing agent has been injected and is being held in venous stasis. A filling defect caused by the thrombi can be observed. (D) Three months following treatment, no lesion can be seen. (E) In a T2- weighted sagittal MR image taken approximately 3 months following treatment, the lesion cannot be seen.

fore, even if the lesion remained, in whole or in part, we ended medical treatment when the original objective was achieved.

One patient who had had footdrop did not experience an improvement in pain or a reduction of the lesion. This patient was judged to require urgent treatment, so surgery was performed. It was considered that the volume of the sclerosing agent and the dwelling time in the lumen of the lesion was insufficient to be effective in this case.

Three patients experienced recurrence of pain following an initial disappearance. The duration of remission was 3 months (case 15), 10 months (case 4), and 3 years (case 1). A repeat sclerosing treatment was performed for case 1. However, pain recurred approximately 4 months later. This patient had a pregnancy after the first treatment and again after the second treatment, although any cause and effect relationship between the pregnancies and the recurrence of pain was not clear in this patient. Repeat sclerotherapy was performed for case 4, and pain recurred 17 months later. The lesion was isolated to the masseter, and after the second recurrence surgery was performed at the patient's request because it was painful to chew. Recurrent pain was slight and weaker than before sclerotherapy in case 15. For all 3 of these cases the size of the lesion was almost unchanged following sclerotherapy.

**Complications.** There was 1 case of a decrease in blood pressure and bradyarrhythmia during treatment, which was responded to by fluid replacement and intramuscular injection of atropine sulfate. Two patients experienced a numbness of limbs, but the numbness lessened during the procedure. As early side effects after treatment, there were 10 cases of swelling and 8 of increasing pain or signs of pain. Both symptoms showed improvement within 1 week. Blistering of the skin and erythema was observed in 1 case, but these effects improved conservatively. Neuropathy and skin necrosis, which have been reported following sclerotherapy with ethanol, were not observed in our study.

## Discussion

Percutaneous sclerotherapy is becoming the treatment of choice for venous malformations rather than surgery with ethanol as the sclerosing agent, as is generally used in Europe and America. Sodium tetradecyl sulfate and ethibloc have been mentioned as alternative agents [11-14]; however, these are not obtainable in Japan. A 64-

96% response rate, observed as an improvement in symptoms or a reduction of the lesion, has been reported for ethanol sclerotherapy of venous malformations [2-6]. Yakes *et al.* [2] have reported a complication rate of 10%, including minor skin blisters, skin necrosis, transient pain, muscle contractures, sensory nerve injury, motor nerve weakness, superficial cellulitis, deep vein thrombosis, pulmonary embolus, and cardiopulmonary collapse.

Polidocanol, used in this study, is a medicine generally used for sclerotherapy of esophageal varices and lower limb varices in Japan. Polidocanol consists of 95% hydroxypolyethoxydodecane and 5% ethyl alcohol. The former, a urethane local anesthetic that differs from the more classic ester and amide anesthetic agents by its lack of an aromatic ring, is the active component of the product. Its detergent action induces a rapid overhydration of endothelial cells, leading to vascular injury. The latter is added as a preservative [20]. The sclerosing action of polidocanol is weak compared with the absolute ethanol traditionally used to treat venous malformations. However, we believed that if the lumen of the lesion could be filled with polidocanol, sufficient effect would be obtained. It is of note that a desired treatment objective is the removal of pain, and this removal was observed here in 6 of the 11 cases where pain was the primary symptom. Of these cases, only in one did the lesion actually disappear. Even though the lesions remained in the other cases, there was a tendency for the pain to disappear. Further, as our aim was improvement of symptoms such as pain, oral bleeding, or swelling satisfactory to the patient, the treatments ended when the treatment objective was achieved, even if the lesion remained.

However, among the 5 cases whose volume-reduction rates were less than 30%, improvement of pain could not be achieved in 1 case, and a recurrence of pain was experienced in 3 cases. Pain, oral bleeding, or swelling was eliminated in 5 of 6 cases whose volume-reduction rates were greater than 30%. It thus appears that the removal of symptoms can depend on the decrease in the size of the lesion. It may therefore be necessary to reduce the lesion size to prevent the recurrence of symptoms.

We used polidocanol as our first-choice sclerosing agent rather than ethanol for 2 reasons. First, there have been reports of complications such as neuropathy and skin necrosis following sclerosing treatment with ethanol [1, 2, 4-7]. In contrast, there have been no reports of such complications following sclerotherapy with

polidocanol for venous malformations [9-11]. Venous malformations are benign lesions, and the predominant symptoms are pain, especially after exercise or on contact, or cosmetic concerns. Serious pain occurs less commonly. Many patients prefer to undergo several treatments of mild efficacy because complications are less likely to appear, rather than to have one treatment of strong efficacy where more severe complications such as neuropathy and skin necrosis are more likely to occur. Secondly, ethanol causes pain during its injection. Therefore, measures such as general anesthesia are more often required to control this pain [2, 4, 6-8]. In contrast, there is hardly any pain during the injection of polidocanol due to its anesthetic effect, and thus treatment is of low invasiveness because general anesthesia is not necessary [10-11]. This feature of using polidocanol is especially advantageous when the lesion is large and ongoing treatment is required. However, though in this respect polidocanol is superior to ethanol, if the effect of the sclerotherapy with polidocanol is inadequate, then we believe that ethanol should then be used.

Yamaki *et al.* [9], and Jain *et al.* [10] have reported sclerotherapy of venous malformations using polidocanol under sonographic guidance. Yamaki *et al.* have reported a disappearance or reduction of lesions in 82% of their cases treated only under sonographic guidance, not with fluoroscopy. Our report is the first of a series of sclerosing treatments for venous malformations using polidocanol under fluoroscopic guidance. It is our belief that if fluoroscopy is not used, some problems might occur. For example, it is difficult to check for leakage of the sclerosing agent to the outside of the lumen when using only a sonographic guide. Even if the needle tip is observed to be within the lumen of the blood vessel during puncture, if the sclerosing agent is injected too forcefully or if the amount of sclerosing agent injected exceeds the capacity of the venous malformation, leakage from the lumen might occur. Leakage outside of the lumen may cause skin necrosis. Yamaki *et al.* [9] have reported epidermal necrosis in 3 of 28 patients, speculating that this effect may have been due to the extravasation of polidocanol. We did not encounter either dermal or epidermal necrosis in our series.

Almost all venous malformations take the form of multiple loculi. It is therefore necessary to carry out several punctures at each treatment to fill all with sclerosing agent. It is difficult to monitor the distribution of sclerosing agent by US. The use of fluoroscopy is

therefore desirable for monitoring the distribution of sclerosing agent with contrast medium. Polidocanol is a mild sclerosing agent, so it is necessary to administer enough to fill the lumen of the lesion, and for this reason extravasation and venous outflow of the sclerosing agent should be minimized. Without fluoroscopy, it is difficult to check for the venous outflow of the sclerosing agent as well as for extravasation.

On the other hand, when considering side effects, if too much sclerosing agent passes into an outflow vein, venous thrombosis could occur [10]. If too much sclerosing agent enters the systemic circulation over a short period of time, it represents a risk for cardiac function. Marrocco-Trischitta *et al.* [20] have reported that the induction of reversible cardiac arrest when using 4 mL of 1% polidocanol to treat venous malformations in the legs of a 5-year-old child. Cardiac complications following polidocanol injections are extremely rare, and when they occur are due to the local anesthetic properties of polidocanol. Local anesthetics, proportionally to their blood levels, reduce the electrical excitability of and the conduction rate through the heart and depress spontaneous pacemaker activity in the sinus node, resulting in progressive sinus bradycardia and eventual sinus arrest [20]. Allergic and anaphylactic reactions are possible causes of cardiac complications, but they are infrequent, with a reported incidence that varies between 0 and 0.3% of cases [21]. We encountered one case of a decrease in blood pressure and bradyarrhythmia during treatment with rapid outflow of the sclerosing agent into the systemic circulation. This effect may have been due to the cardiac complications caused by polidocanol, although vasovagal reflex associated with anxiety or pain during puncture cannot be eliminated as a possibility. While it is not definite what amount of polidocanol will affect the heart, the amount of polidocanol and the rate at which it enters the systemic circulation should be kept as low as possible.

In conclusion, percutaneous sclerotherapy of venous malformations using polidocanol is safe, effective, and allows for repeat treatments. Although its power as a sclerosing agent is weaker than that of ethanol, sufficient efficacy was observed, especially for resolving pain. Further, complications were slight, and general anesthesia was usually unnecessary. It is important to keep the sclerosing agent within the lumen of the lesion and it is desirable to use fluoroscopy for these procedures.

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