Title: Effectiveness and safety of percutaneous sclerotherapy using absolute ethanol and/or polidocanol for maxillofacial venous malformations involving the masticatory muscles: a case series

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Abstract

Objective. This study evaluated the effectiveness and safety of percutaneous sclerotherapy for maxillofacial venous malformations.

Study Design. Patients with venous malformations involving the masticatory muscles who underwent sclerotherapy were enrolled in this retrospective study.

Results. Twenty-four patients (13 female, 11 male; mean age 21 years) were analyzed. Major clinical symptoms were swelling (100%) and intralesional pain (54%). Intramuscular lesions involved the masseter muscle only in 38% of cases, both the masseter and temporalis muscles in 33%, all masticatory muscles in 21%, and the temporalis muscle only in 8%. Extramuscular involvement was observed in 58% of patients. Absolute ethanol and polidocanol were used as sclerosants. The mean number of sclerotherapy sessions per patient was 6.6 (range, 1–32). The mean follow-up duration after the first sclerotherapy session was 64.8 months (range, 6–178). Complications included paralysis of the facial nerve (25%), intraoral ulceration (8%), and hemoglobinuria (8%). Effectiveness of treatment was rated as excellent in 33% of cases, good in 46%, and fair in 21%. Better results were obtained in patients without extramuscular involvement.

Conclusion. Percutaneous sclerotherapy can be effective and safe for maxillofacial intramuscular venous malformations, especially localized lesions of the masseter muscle.

Introduction

Venous malformations (VMs) are a subclass of congenital vascular malformations that develop in the maxillofacial region more often than in the trunk or extremities. VMs have a wide spectrum of presentations, from isolated cutaneous or intramuscular varicosities to more complex anomalies involving several tissue planes. [1] VMs that are symptomatic can be disfiguring, cause pain, induce neuropathy, ulcerate, and bleed. [2] Surgical excision is useful only for localized lesions. Sclerotherapy has become a useful alternative to surgical excision of maxillofacial VMs. [1] Although symptoms vary depending on the size and location of the lesion, there have been few reports on maxillofacial intramuscular VMs. [3-8] This study sought to evaluate the effectiveness and safety of percutaneous sclerotherapy for maxillofacial VMs involving the masticatory muscles, focusing on the distribution of the lesions.

Materials and Methods

Ethical approval

The study was approved by the institutional review boards of Hokkaido University Hospital (number 015-0340) and Tonan Hospital (number 15-1-1) and conducted in accordance with the Declaration of Helsinki. The requirement for informed patient consent was waived due to the retrospective nature of the study.

Patients

The medical charts of all patients with VMs treated between 1992 and 2013 at Hokkaido University Hospital (1992–2013) and between 2008 and 2013 at Tonan Hospital (2008–2013) were retrospectively reviewed. Patients with maxillofacial VMs

involving the masticatory muscles who underwent percutaneous sclerotherapy with a minimum follow-up duration of 6 months were enrolled in the study. Data were collected for sex, age at presentation, symptoms, findings in clinical photographs, presence of phleboliths on imaging, radiologic studies, and surgical procedures during the follow-up period.

Before the procedure, all patients underwent color duplex ultrasound and magnetic resonance imaging (MRI) to evaluate the extent, distribution, and characteristics of the lesions. Diagnosis of VM was based on clinical history and findings on physical examination, ultrasonography, and MRI. All lesions included in the study met the MRI criteria for VM.[9] The distribution of lesions was recorded in the masticatory muscles and at extramuscular sites.

Procedures

To visualize needle placement and facilitate direct cannulation of the vascular channels, the lesion was punctured directly using a 22-G angiocatheter with color duplex ultrasound (LOGIQ e; GE Yokogawa Medical Co., Ltd., Tokyo, Japan). For lesions in the temporal muscle and lesions involving the oral cavity and/or orbit, to confirm the absence of any life-threatening venous drainage, water-soluble contrast material was injected under fluoroscopic guidance. A sclerosing solution with contrast material at a ratio of 4:1 was subsequently injected into the lesion. The sclerosants used were absolute ethanol and polidocanol (Polidocasklerol 3% injection; Zeria Pharmaceutical Co., Ltd., Tokyo, Japan). We used polidocanol 1% until the end of 2007 and polidocanol 3% thereafter. Since publication of the report by Tessari et al.,[10] we have used polidocanol 3% foam, which is obtained by mixing 2 mL of polidocanol with

atmospheric air at a ratio of 1:4 in two syringes attached using a three-way stopcock. We stopped the sclerotherapy upon sufficient filling of the vascular lesion as seen on duplex sonography or upon reaching a maximum dose of the sclerosant (1 mL/kg). Patients were treated with absolute ethanol under general anesthesia and with polidocanol under general anesthesia or without anesthesia in the outpatient clinic. The interval between each treatment session was generally scheduled as 3–6 months to allow swelling and changes directly related to sclerotherapy to subside and for clinical status to be evaluated accurately. Some patients chose to have multiple sclerotherapy sessions using polidocanol without anesthesia in the outpatient clinic for social reasons. The number of sclerotherapy sessions, sclerosant doses, and post-treatment complications were recorded. Acute swelling of the treated lesions and a transient increase in pain after sclerotherapy were not considered to be complications. [2, 11] Transient trismus after sclerotherapy was also excluded as a complication.

Evaluation of outcomes

Photographs taken before and after treatments were used to evaluate improvement of appearance, which was graded as follows: excellent (complete reduction of swelling), good (more than 50% reduction of swelling), fair (less than 50% reduction of swelling), and poor (no change or worse). Improvement of intralesional pain was graded as excellent (complete relief), good (more than 50% reduction), fair (less than 50% reduction), and poor (no change or worse). The outcomes were retrospectively evaluated using photographs and documentation in the medical records at the last follow-up by two clinicians who had not performed the treatment. The grade for treatment effectiveness was defined as the lower of the grade for improvement of

appearance and the grade for improvement of pain.

Statistical analysis

Data are expressed as mean ± standard deviation or as number (percentage). The relationships of pain with sex or presence of phleboliths were assessed using Fisher's exact test. Two-tailed P-values < 0.05 were considered statistically significant.

Results

Twenty-four consecutive patients (13 female, 11 male) with VMs involving the masticatory muscles were identified. Mean patient age at presentation was 21 years (range, 1–58). Table 1 summarizes the clinical characteristics of the patients. Symptoms were swelling on the affected side in all patients, intralesional pain in 13 patients (10 female, 3 male), exophthalmos in 1 patient, and malocclusion in another patient. Intralesional pain was reported in 54% of cases and was significantly more common in female patients (77% vs 27%; P = 0.038). Ten of 17 patients with phleboliths reported pain (P = 0.659).

The intramuscular lesions were in the masseter muscle alone in 9 patients, in the masseter and temporalis muscles in 8, in all the masticatory muscles in 5, and in the temporalis muscle alone in 2. There were 14 extramuscular sites, namely, the subcutaneous tissue (n = 10), oral cavity (n = 9), and orbit (n = 6).

The mean number of sclerotherapy sessions was 6.6 ± 8.1 (range 1–32). In total, 159 sclerotherapy sessions were performed. The mean dose per session was 11.1 ± 9.2 mL for absolute ethanol and 8.2 ± 6.6 mL for polidocanol. The mean follow-up duration after the first sclerotherapy session was 64.8 ± 51.2 months (range, 6–178).

Improvement of appearance was excellent in 9 of 24 patients, good in 14, and fair in 1. Improvement of pain was excellent in 3 of 13 patients, good in 6, and fair in 4. Therefore, the effectiveness of treatment was rated as excellent in 8 patients, good in 11, and fair in 5. Representative cases of each treatment effectiveness grade are shown in Figs. 1-3 (Patients 1, 7, and 11). The complications were facial nerve paralysis in 6 patients (buccal branch, n = 3; temporal branch, n = 2; marginal mandibular branch, n = 1), intraoral ulceration in 2, and hemoglobinuria in 2. Facial nerve paralysis completely resolved in 5 of the 6 patients, but one (Patient 7, Fig. 2) had persistent facial nerve paralysis in the temporal branch that required a facelift. All complications occurred when absolute ethanol was used, whether or not in combination with polidocanol. Surgical procedures were conducted in 7 patients during the follow-up period, including facelift (n = 3) and resection (n = 5).

Better results were obtained in patients without extramuscular involvement (Table 2). Among the 7 patients with lesions in the masseter muscle alone, the effectiveness of treatment was rated as excellent in 5 patients and good in 2 after a mean 2.6 ± 1.4 sclerotherapy sessions without complications. Among the 13 patients with intralesional pain, improvement of pain was fair in 4 patients, including 3 with lesions including the temporalis muscle and 1 with lesions in the masseter muscle infiltrating into the subcutaneous tissue. Transient facial nerve paralysis was seen in 5 patients with extramuscular involvement in the subcutaneous tissue and in 1 patient with a lesion in the temporalis muscle only.

Discussion

VMs that affect the skeletal muscles are most common in the head and neck, followed

by the lower and upper extremities and thorax.[3] Treatment of VMs in the maxillofacial region remains a formidable challenge for surgeons.[7] Surgical excision is not usually possible without causing functional impairment and disfigurement.[12] Percutaneous sclerotherapy is an established minimally invasive treatment option for slow-flow vascular malformations.[3] The sclerosant damages the vascular endothelial cells, causing thrombosis and subsequent fibrosis.[3] Absolute ethanol, ethanolamine oleate, polidocanol, and bleomycin are frequently used as sclerosants.[13] Absolute ethanol is the most effective sclerosant with the lowest recurrence rate.[1] However, complications of ethanol sclerotherapy, such as tissue necrosis, peripheral nerve injury, cardiac arrhythmia, and pulmonary embolism, have been reported.[7] In patients with maxillofacial VMs, the most frequent of these complications is facial nerve injury.[1, 14, 15] The zygomatic, temporal, and buccal branches of the facial nerve are vulnerable to damage after ethanol sclerotherapy, with reported injury rates of 41.7%, 5.6%, and 3.5%, respectively.[15] We observed transient facial nerve paralysis after ethanol sclerotherapy in 25% of our patients. Because infiltrating VMs in the masseter muscle usually involve the parotid gland, it is important to puncture the ventral portion of a masseteric lesion. Facial nerve paralysis may be avoided by using polidocanol foam sclerotherapy, but several treatment sessions are required. Polidocanol is a nonionic detergent that causes lysis of the endothelial lining via absorption at the cell membrane. Compared with the liquid form, foamed polidocanol can cause more severe damage to the intima of the veins.[10]

Sclerotherapy is effective for well-defined VMs with large vascular channels.[3] More extensive lesions that involve more than one muscle often require multiple sessions.[3] In our experience, patients with extramuscular involvement need more sclerotherapy

sessions and are likely to have complications. Excellent results were relatively rare in patients with extensive lesions involving several tissue planes. Better results were obtained in patients without extramuscular involvement, especially those with an isolated masseteric lesion. Our findings in this regard are consistent with those of other studies of treatment for patients with maxillofacial VMs. [2, 7, 8]

Considering that the veins of the head and neck lack valves and the middle third of the face communicates with the cavernous sinus, [4] patients undergoing sclerotherapy for temporal lesions should be monitored carefully with radiographic visualization to avoid accidental thrombosis of the cavernous sinus. However, most of the venous flow from the lower third of the face is directed inferiorly toward the jugular venous system. [4] Therefore, sclerotherapy for lesions involving the cheek is considered safer and can be performed without radiographic visualization. We used absolute ethanol for large, deep cheek lesions under general anesthesia and polidocanol for smaller, superficial cheek lesions even in the outpatient setting. Patients with VMs involving the masticatory muscles usually develop transient trismus after sclerotherapy and require a mouth-opening training device designed for temporomandibular disorders.

VMs are painful occasionally when waking up in the morning, during or after exercise, and in cold weather. [16] Migraine is a common feature in patients with maxillofacial VM located in the temporalis muscle. [17] VMs differ from other types of vascular malformations in that they cause intralesional pain in the absence of ulceration, infection, or bleeding in up to 90% of patients. [16] In our study, intralesional pain was more common in female patients with VM than in male patients, as in a previous report. [16] Another report suggested that the discomfort might be due to formation of phleboliths inside VMs and the resulting release of stimuli in pain pathways. [18] In our study, there

was no significant association between presence of phleboliths and intralesional pain. Sclerotherapy does not remove phleboliths but can reduce venous spaces with potential for future formation of thrombi that will bind to calcium deposits and form phleboliths. Percutaneous sclerotherapy using absolute ethanol in combination with polidocanol is an effective and safe treatment for intramuscular maxillofacial VMs, especially lesions localized to the masseter muscle, without severe complications. In our study, patients with extramuscular involvement needed more sclerotherapy sessions and had some complications. Improvement of appearance was achieved in 96% of patients (excellent in 9 of 24 patients, good in 14 patients), but improvement of pain was obtained in 69% of patients (excellent in 3 of 13 patients, good in 6 patients). Patients with fair improvement of pain needed 7 or more sclerotherapy sessions. These data may be useful for determining appropriate candidates for sclerotherapy and when counseling patients and their families about the outcomes expected.

The limitations of this study were its small patient population, lack of radiological evaluation of lesion size, and limited duration of follow-up. We evaluated the effectiveness of treatment from the patient's perspective by evaluating improvements of appearance and pain. Maxillofacial intramuscular VMs involving multiple tissue planes changed and their images became blurred on MRI with sclerotherapy (Fig. 1), so it was difficult to compare the size of the lesion radiologically, especially in growing patients. Although constant evaluation of pain is difficult during long-term follow-up, a study that includes a prospective design and assessment of pain using a numeric rating scale or visual analog scale in an outpatient setting is needed in the future.

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Figure legends

Fig 1. Patient 1 showed good effectiveness of treatment. (A) Initial clinical photograph of a 1-year-old boy with venous malformation in the left cheek. Sclerotherapy was started at the age of 4 years and consisted of 5 sessions of ethanol sclerotherapy followed by 18 sessions of polidocanol 1% sclerotherapy. Transient facial nerve paralysis of the buccal branch occurred at the 24th session of sclerotherapy, at which time 28 mL of ethanol was used. Since then, he has undergone sclerotherapy using ethanol and polidocanol 3% without any complications. (B) Clinical photograph and (C) fat-suppressed T2-weighted magnetic resonance image obtained at the age of 14 years after 26 sessions of sclerotherapy. (D) Clinical photograph and (E) short tau inversion recovery T2-weighted magnetic resonance image obtained at the age of 19 years after 32 sessions of sclerotherapy and operations including a facelift and partial resection of the lip lesion.

Fig 2. Patient 7 showed fair effectiveness of treatment. (A) Initial clinical photograph and (B) fat-suppressed T2-weighted magnetic resonance image of a 26-year-old woman with venous malformation in the left cheek. Sclerotherapy was started at the age of 26 years and consisted of 1 session of ethanol sclerotherapy followed by 30 sessions of polidocanol 1%–3% sclerotherapy. Persistent facial nerve paralysis of the temporal branch occurred at the first session of sclerotherapy, at which time 20 mL of ethanol was used. Since then, she has undergone sclerotherapy using polidocanol 1%–3% without any complications. (C) Clinical photograph and (D) short tau inversion recovery T2-weighted magnetic resonance image obtained at the age of 39 years after 31 sessions of sclerotherapy and a facelift. Although improvement of appearance was

292 good, improvement of intralesional pain was fair.

293

294 **Fig 3.** Patient 11 showed excellent effectiveness of treatment. (A) Clinical photograph
295 and (B) fat-suppressed T2-weighted magnetic resonance image of a 23-year-old woman
296 with venous malformation in the left temple. One session of sclerotherapy using ethanol
297 was conducted at the age of 23 years. (C) Clinical photograph and (D) fat-suppressed
298 T2-weighted magnetic resonance image obtained 8 months after the sclerotherapy.
299 Complete relief of intralesional pain was obtained.

Tables

Table 1. Clinical characteristics of 24 patients with venous malformations involving the masticatory muscles

			Distribution of venous malformations				Sclerotherapy				Treatment outcomes			
Patient	Sex	Age, years	Intramuscular lesions	Extramuscular lesions	Symptoms	Presence of phleboliths	Agents	Numbers of sessions	Follow-up, months	Surgical procedures	Improvement of appearance	Improvement of pain	Effectiveness of treatment	Complications
1.	M	1	All masticatory muscles	Oral, subcutaneous	Swelling	Yes	Ethanol, polidocanol	32	178	Facelift Partial resection (lip)	Good	-	Good	Transient facial paralysis (buccal branch), hemoglobinuria
2.	F	22	Temporalis	-	Swelling, pain	Yes	Ethanol, polidocanol	14	158	Total resection (temporalis)	Good	Fair	Fair	Transient facial paralysis (temporal branch)
3.	F	0	Masseter, temporalis	Oral, orbital, subcutaneous	Swelling, pain, exophthalmos	Yes	Ethanol, polidocanol	8	18	Partial resection (temporalis)	Fair	Good	Fair	Hemoglobinuria
4.	F	16	Masseter, temporalis	Oral, pharyngeal, subcutaneous	Swelling, pain	Yes	Ethanol, polidocanol	10	136	Facelift	Good	Good	Good	Intraoral ulceration
5.	F	7	All masticatory muscles	Oral, pharyngeal	Swelling, pain	Yes	Ethanol	5	60	None	Good	Good	Good	-
6.	M	35	Masseter, temporalis	Glossal, oral, orbital	Swelling	Yes	Ethanol, polidocanol	2	34	Partial resection (tongue)	Excellent	-	Excellent	-
7.	F	9	Masseter	Subcutaneous	Swelling, pain, malocclusion	Yes	Ethanol, polidocanol	31	151	Facelift	Good	Fair	Fair	Persistent facial paralysis (temporal branch)
8.	F	11	Masseter	-	Swelling, pain	None	Ethanol, polidocanol	3	98	None	Excellent	Excellent	Excellent	-

9.	M	9	Masseter, temporalis	Subcutaneous	Swelling, pain	Yes	Ethanol, polidocanol	5	112	None	Good	Good	Good	Transient facial paralysis (buccal branch)
10.	F	36	All masticatory muscles	Parotid	Swelling, pain	None	Ethanol, polidocanol	7	124	None	Good	Fair	Fair	-
11.	F	23	Temporalis	-	Swelling, pain	Yes	Ethanol	1	8	None	Excellent	Excellent	Excellent	-
12.	F	29	Masseter	-	Swelling, pain	Yes	Ethanol	1	6	None	Excellent	Excellent	Excellent	-
13.	M	52	Masseter, temporalis	Orbital, Subcutaneous	Swelling	Yes	Ethanol, polidocanol	5	61	Partial resection (lower eyelid, lip)	Good	-	Good	-
14.	M	16	All masticatory muscles	Glossal, oral, subcutaneous	Swelling	Yes	Ethanol, polidocanol	4	44	None	Good	-	Good	Transient facial paralysis (marginal mandibular branch)
15.	F	6	Masseter	-	Swelling, pain	None	Ethanol, polidocanol	4	76	None	Excellent	Good	Good	-
16.	M	2	Masseter	-	Swelling	Yes	Ethanol, polidocanol	1	40	None	Excellent	-	Excellent	-
17.	M	8	Masseter, temporalis	Oral, orbital	Swelling, pain	Yes	Ethanol	7	46	None	Good	Fair	Fair	-
18.	M	1	Masseter	Oral, orbital, subcutaneous	Swelling, pain	Yes	Ethanol, polidocanol	5	56	None	Good	Good	Good	Transient facial paralysis (buccal branch), intraoral ulceration
19.	F	58	All masticatory muscles	Oral, parotid, subcutaneous	Swelling	None	Ethanol, polidocanol	2	38	None	Excellent	-	Excellent	-

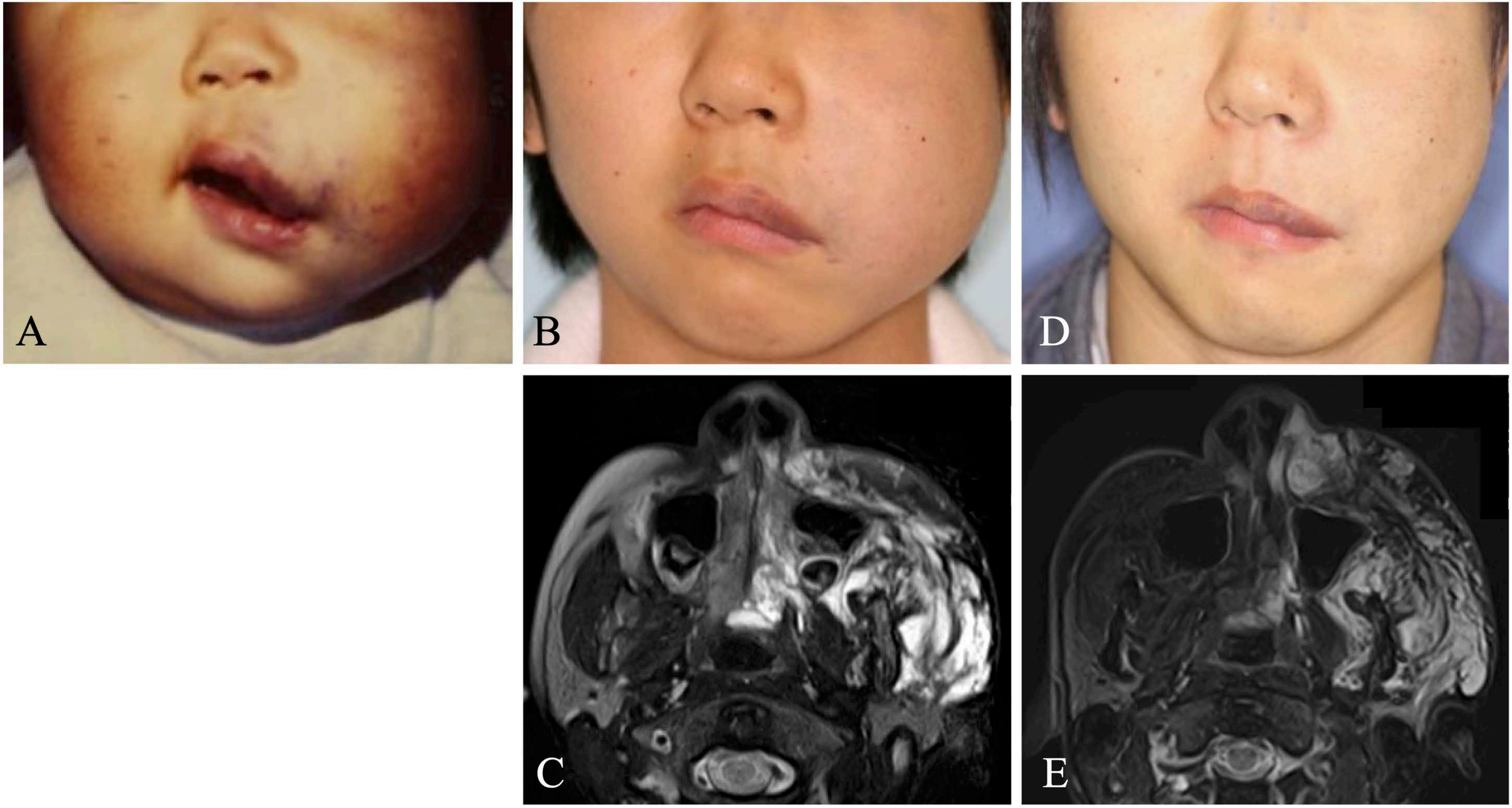
20.	F	8	Masseter	-	Swelling	Yes	Ethanol, polidocanol	4	32	None	Good	-	Good	-
21.	M	47	Masseter	-	Swelling	None	Polidocanol	4	27	None	Excellent	-	Excellent	-
22.	M	52	Masseter	-	Swelling	None	Ethanol	1	30	None	Excellent	-	Excellent	-
23.	F	16	Masseter, temporalis	Orbital, subcutaneous	Swelling	None	Ethanol, polidocanol	1	12	None	Good	-	Good	-
24.	M	43	Masseter, temporalis	-	Swelling	Yes	Ethanol, polidocanol	2	8	None	Good	-	Good	-

Improvement of pain was not recorded in patients without pain before treatment.

The grade for treatment effectiveness was defined as the lower of the grade for improvement of appearance and the grade for improvement of pain.

Table 2. Evaluation of treatment outcome

	Sclerotherapy	Effectiveness of treatment				
	Sessions, n	Excellent	Good	Fair	Poor	Complications, n
Extramuscular lesions						
Present (n=14)	8.6 ± 9.5	2 (14.3%)	8 (57.1%)	4 (28.6%)	0	7 (46.7%)
Absent (n=10)	3.5 ± 3.7	6 (60.0%)	3 (30.0%)	1 (10.0%)	0	1 (4.2%)
Masseter muscle only (n=7)	2.6 ± 1.4	5 (71.4%)	2 (28.6%)	0	0	0
Total	6.6 ± 8.1	8 (33.3%)	11 (45.8%)	5 (20.8%)	0	8 (33.3%)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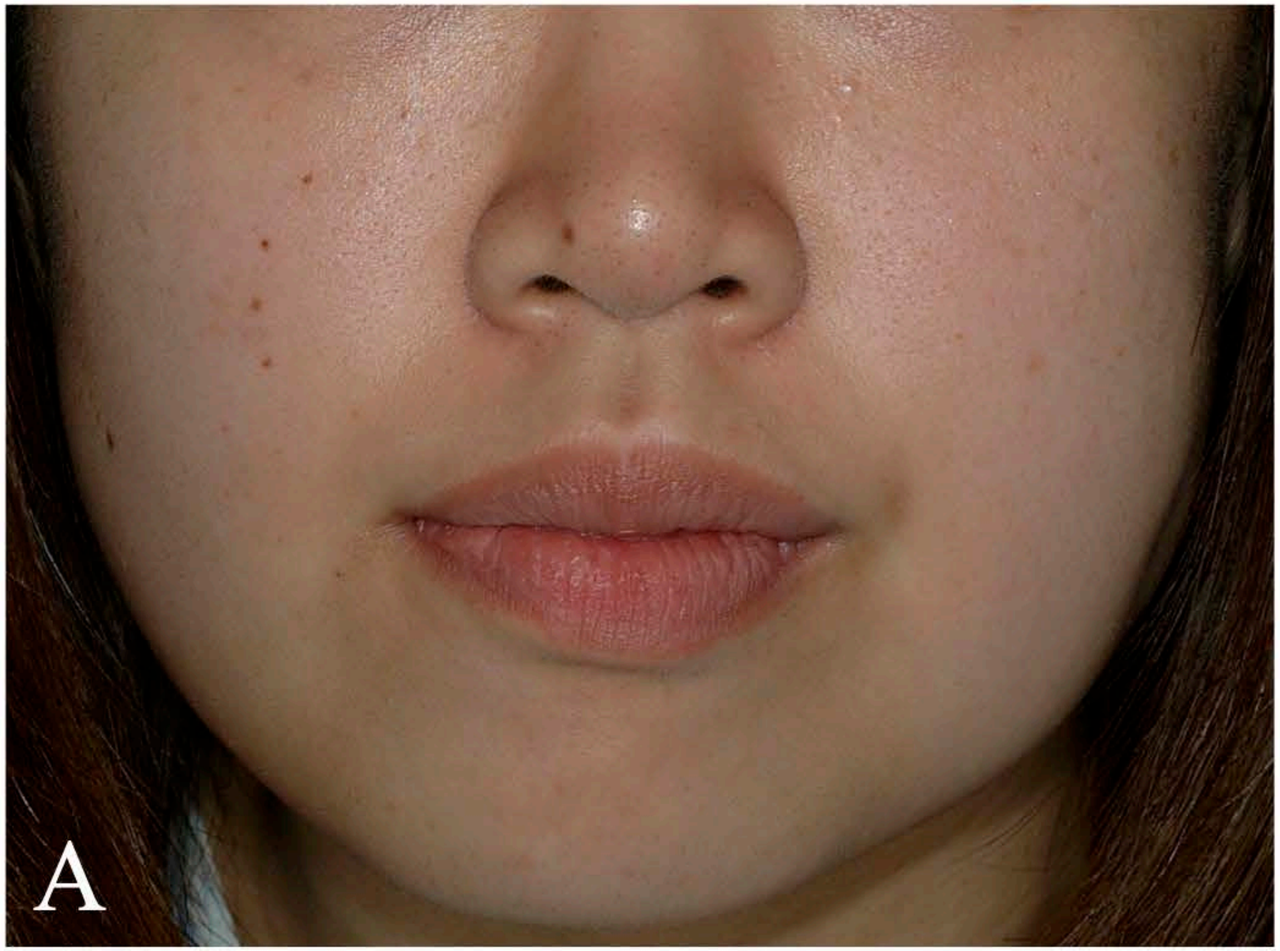
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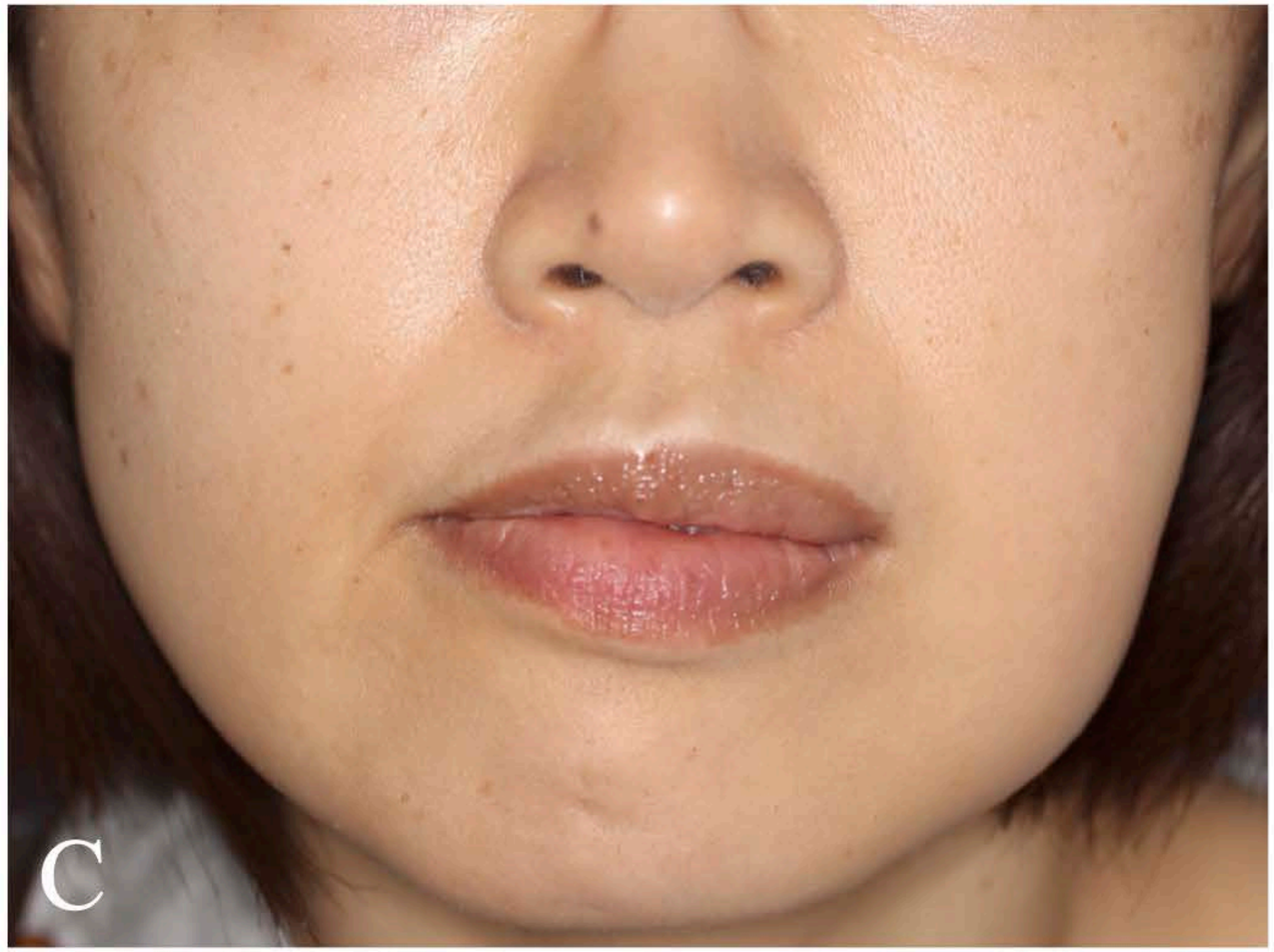
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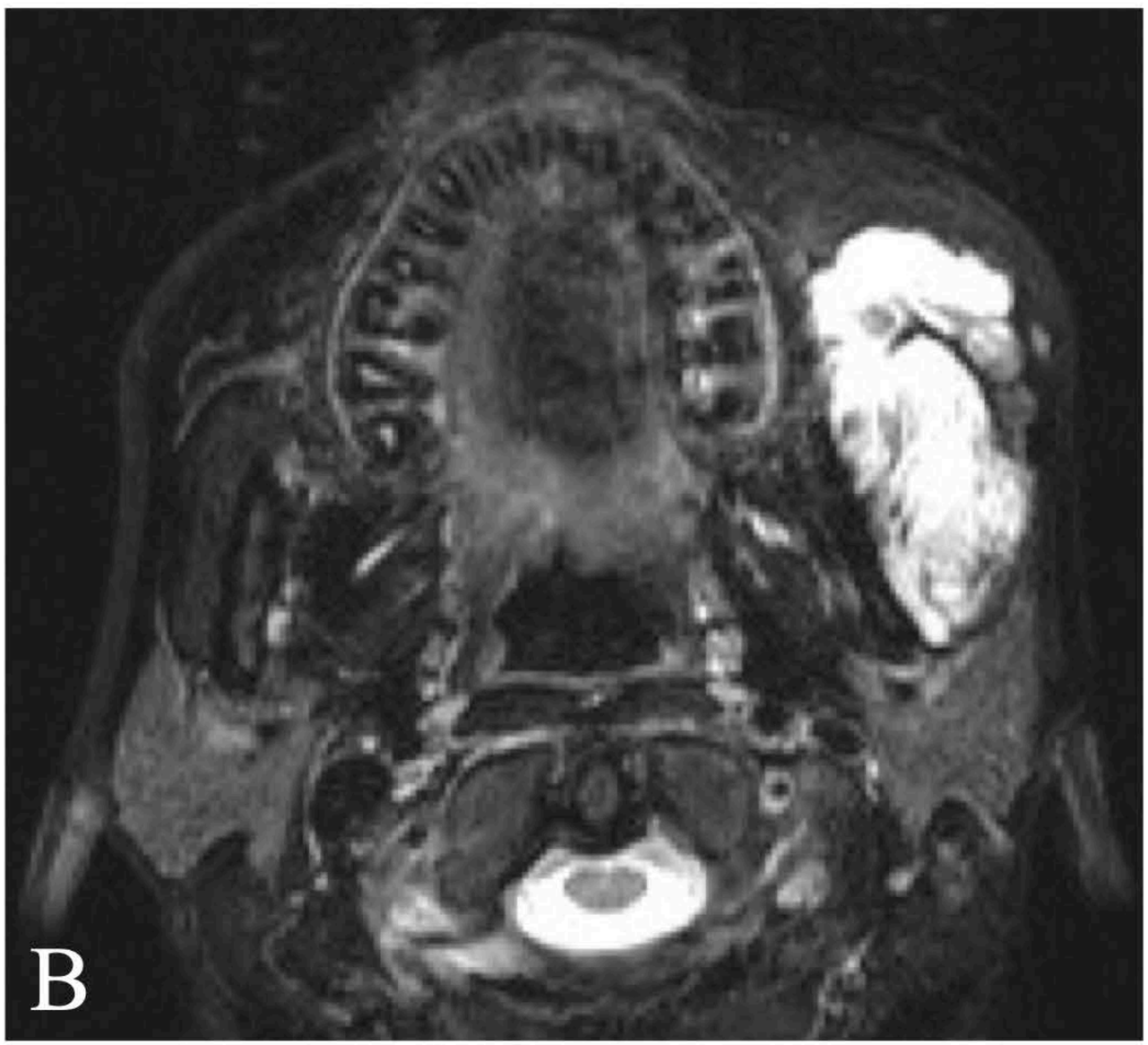
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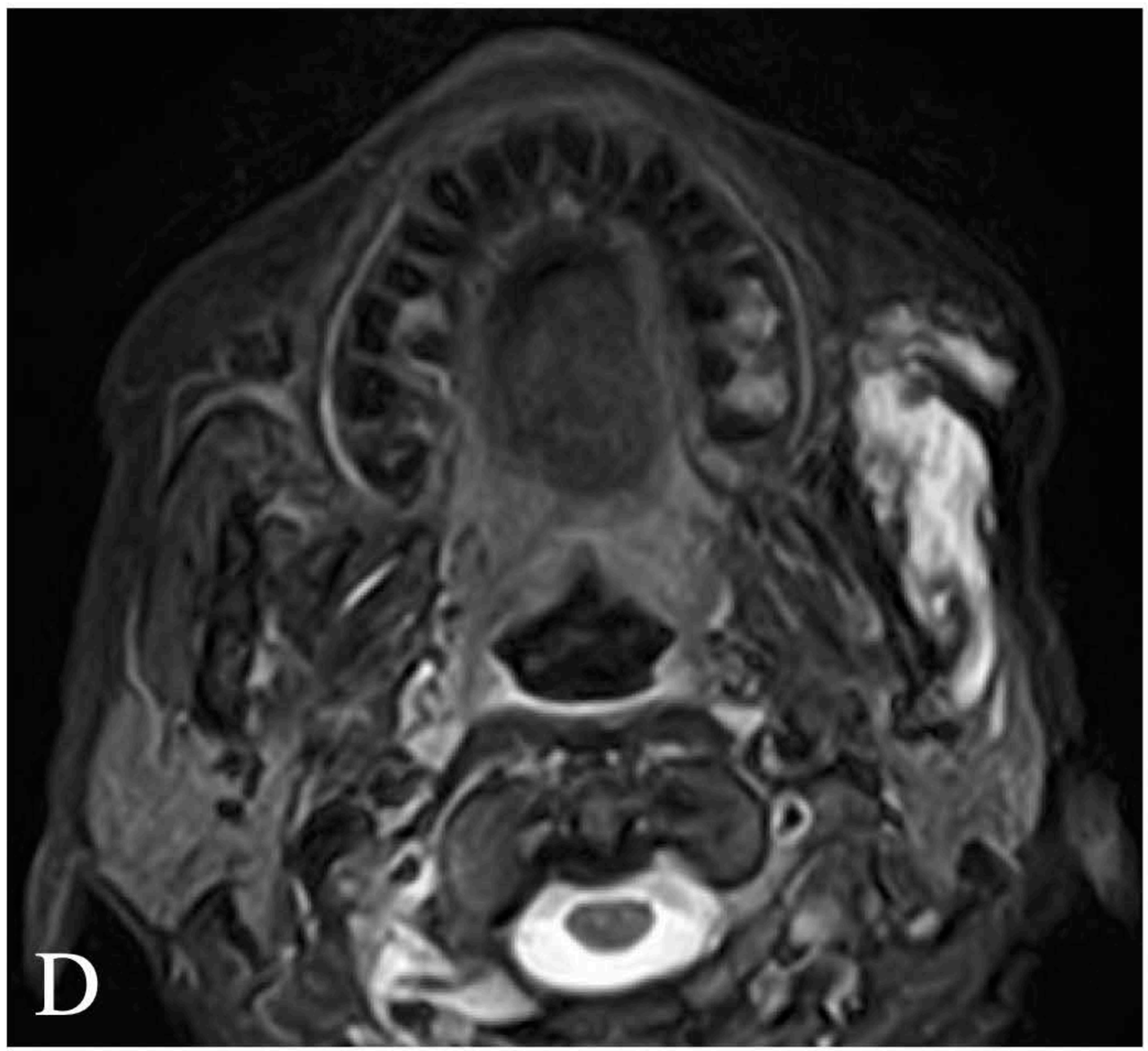
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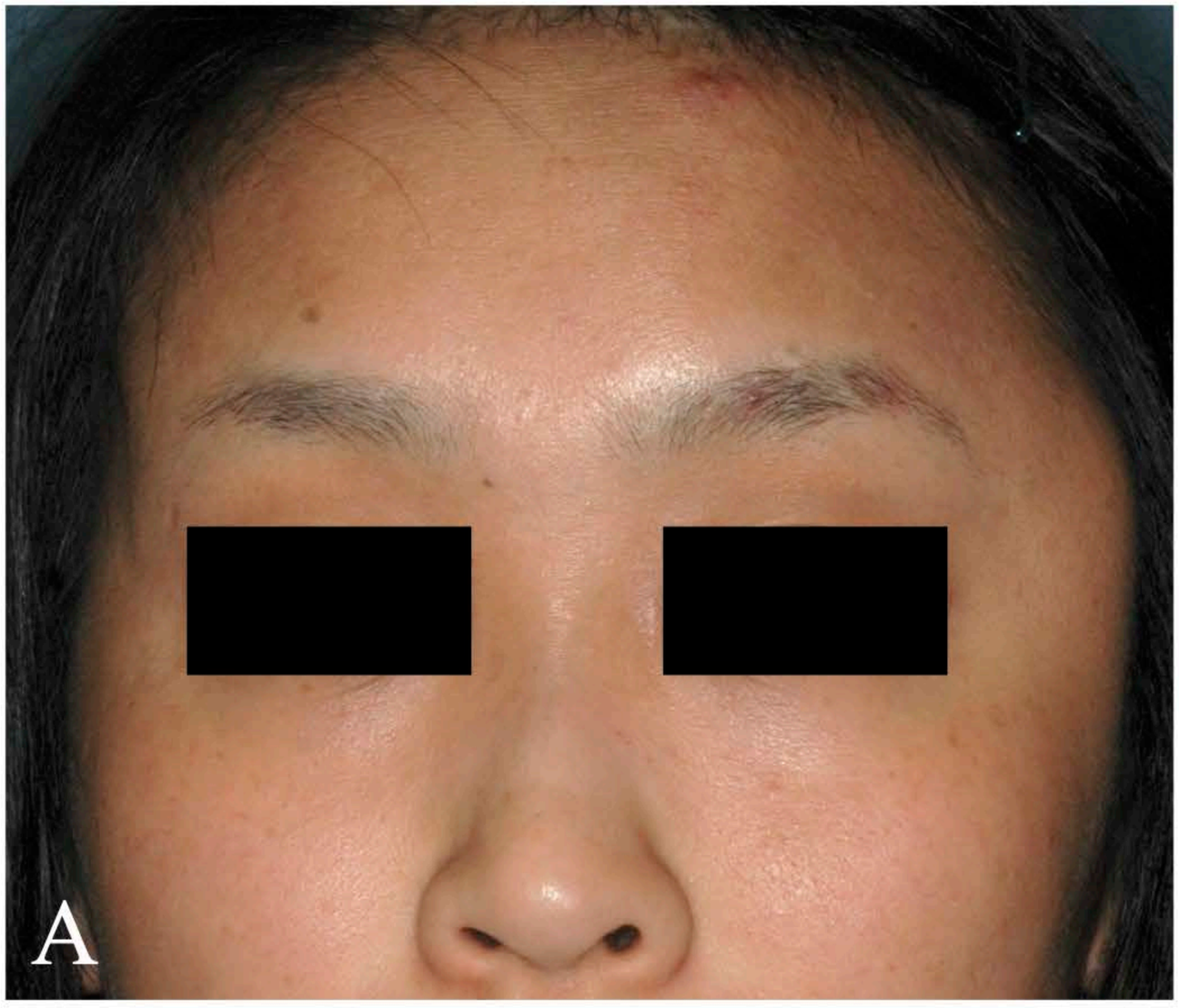
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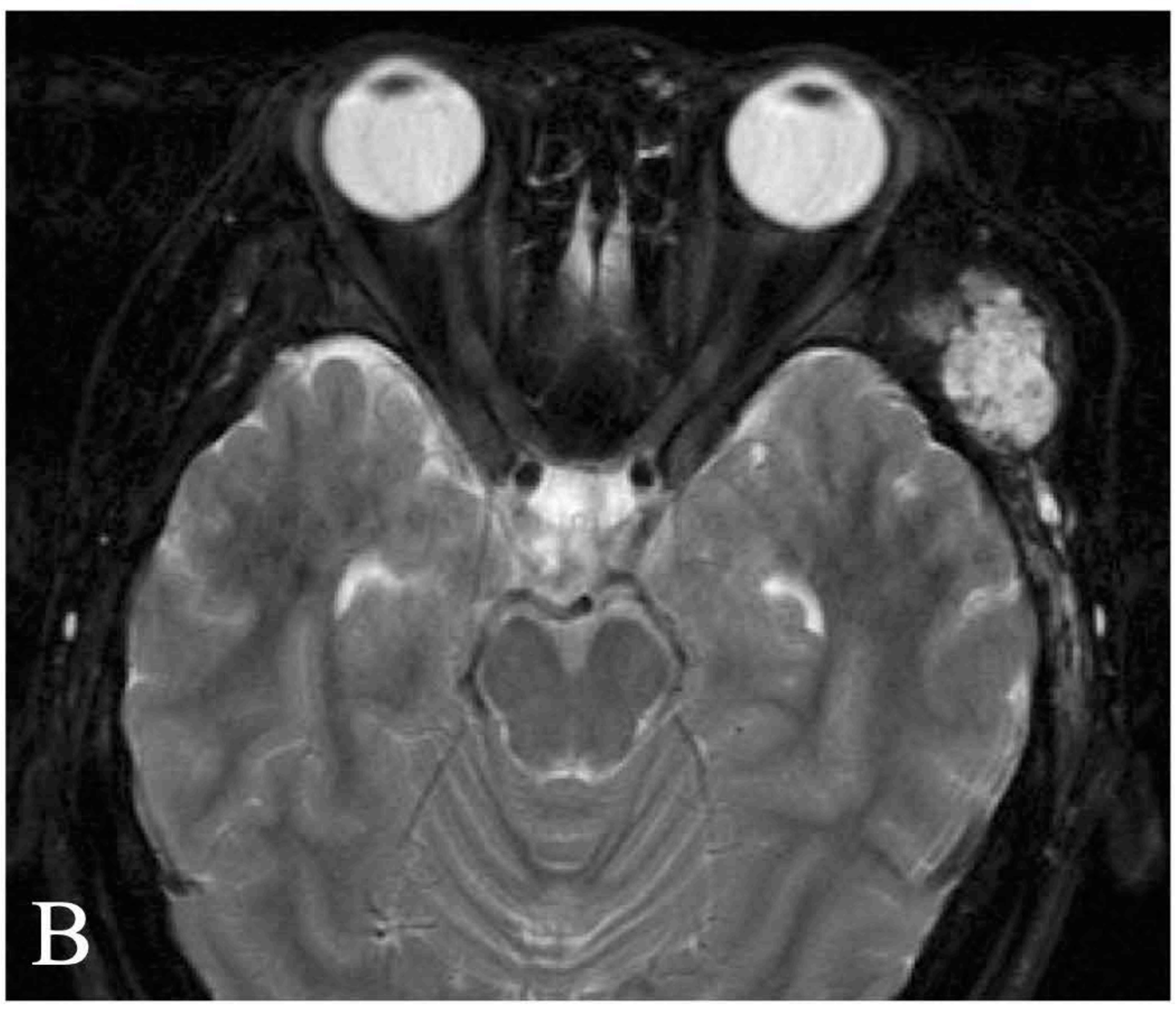
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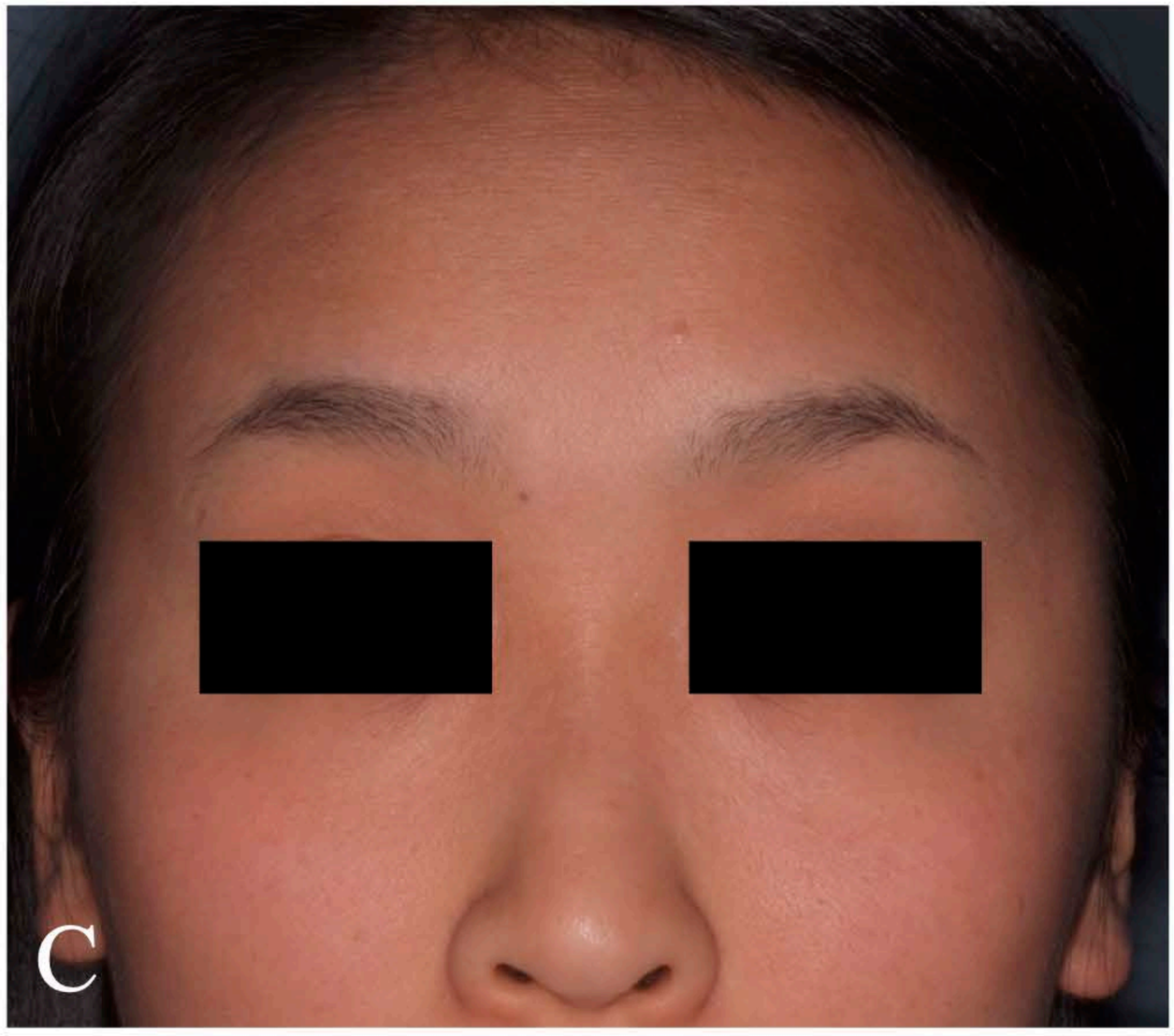
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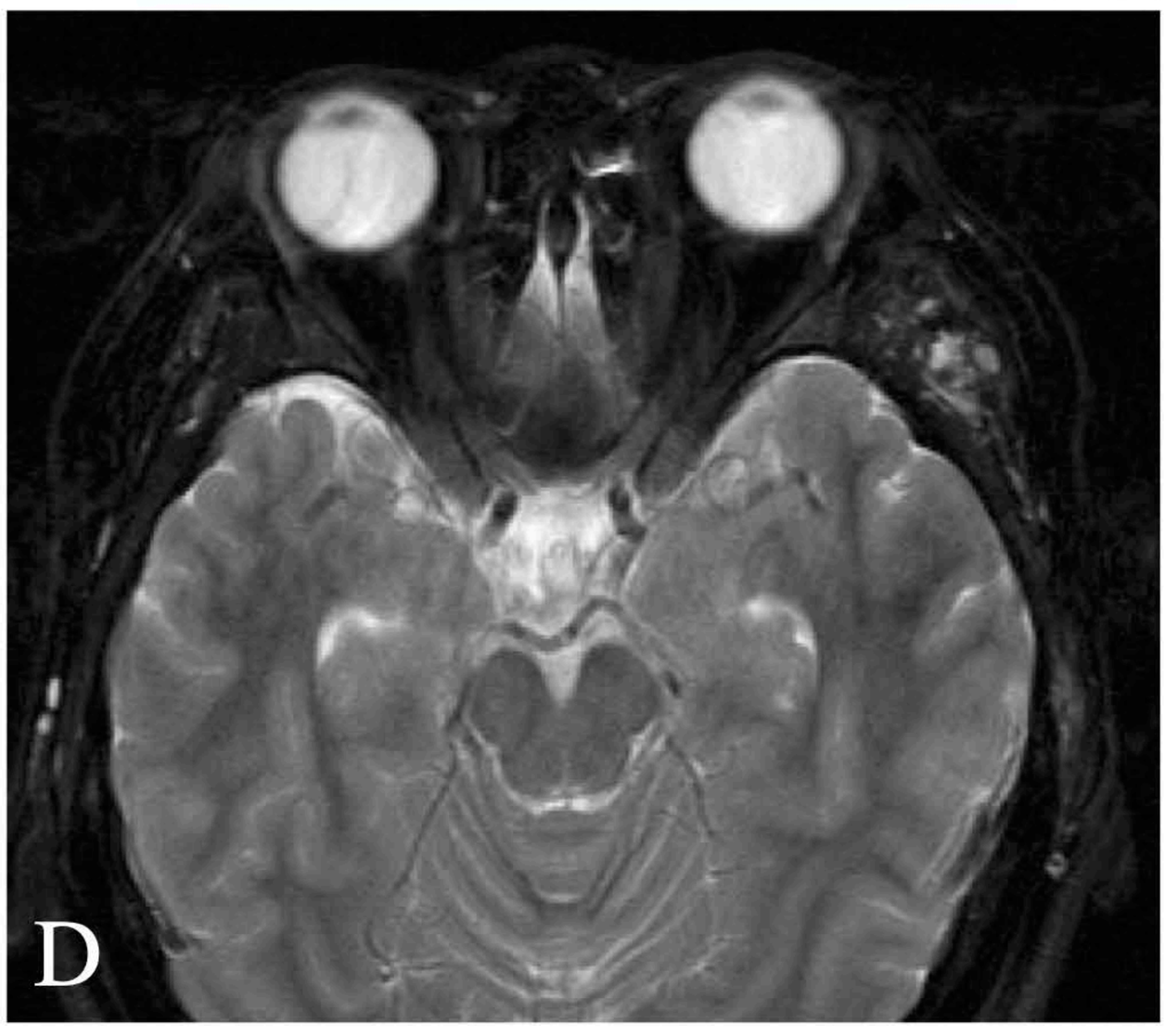
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