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Treatment of the Patulous Eustachian Tube with Soft-Tissue Bulking Agent Injections

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Objective: A patulous Eustachian tube ([ET] tuba aperta) may cause symptoms as autophony, breath synchronous tinnitus, pressure sensation, and conductive hearing loss and thus lead to an enormous cutback in quality of life. In combination with ''sniffing,'' it can trigger the development of cholesteatoma. Because of the ambiguous symptoms, the diagnosis can be challenging. A patulous ET can only be diagnosed through a well-structured examination, including patient history, physical examination with thorough observation of the movements of the tympanic membrane, and tympanometry with reflex-decay.
Study Design and Methods: Transnasal endoscopic injection of injectable soft-tissue bulking agent into the torus tubarius was performed in 20 patients as a new treatment option for patulous ET. All patients were followed up 6 weeks and 6 and 12 months after treatment. For each intervention, 0.8 to 2 mL of injectable soft-tissue bulking agent was used.
Results: In nine patients, more than one procedure was necessary. On follow-up, 10 out of 15 patients were satisfied with the result. Only three out of 15 patients reported no improvement of their symptoms. The procedure was minimally invasive, fast, and easy to perform.
Conclusion: There is no gold standard for the therapy of patulous ET. The injection of soft-tissue bulking agent in the torus tubarius is a new minimally invasive therapeutic approach, but much more clinical experience is needed.
Level of Evidence: IV.
Key Words: Eustachian tube dysfunction—Injectable soft-tissue bulking agent—Patulous Eustachian tube—Tuba aperta.
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Knowledge about the incidence and pathophysiology of the patulous Eustachian tube (ET) is sparse. Schwartze (1) and Jago (2) were the first to describe this condition. The incidence is estimated at about 6% of the population (3).

Patients with a patulous ET describe an aural pressure sensation and difficulties performing Valsalva's maneuver. In addition, it can cause symptoms like autophony, breath synchronous tinnitus, and hearing loss. In combination with ''sniffing,'' it can trigger the development of cholesteatoma (3). Exercise worsens the symptoms, and patients often mention an improvement in the supine position. However, there is a lack of diagnostic tools and effective therapies for ET dysfunction (4–6). A patulous ET can be diagnosed through a structured examination, including patient history and microscopic observation of movements of the tympanic membrane especially during forced nasal breathing. The compression of the jugular veins with temporary improvement of the symptoms might be helpful to confirm the suspected diagnosis. Endoscopy of the nasopharynx might reveal a longitudinal concavity in the anterolateral wall of the torus tubarius (4).

Effective causal therapies of patulous ET have not been described so far. Paracentesis and grommet insertion might reduce the symptoms. However, this therapy is only symptomatic. The treatment of the patulous ET with injection of soft-tissue bulking agent is a new and minimally invasive treatment approach.

MATERIALS AND METHODS

Between February 2011 and April 2014, we obtained prospective data from 20 patients with patulous ET. All patients were treated with the injection of the soft-tissue bulking agent (Vox-Implants, Uroplasty, Inc., Minnetonka, MN, USA) into the torus tubarius. Inclusion criteria were typical symptoms as previously described, immediate opening in the tubomanometry (7,8), saw-tooth pattern in reflex-decay tympanometry (Fig. 1), and visible breath synchronous movement of the tympanic membrane. Unsuccessful conservative treatment with saline nasal spray and estrogen nasal ointment three times a day for 6 weeks was required before surgical intervention. The injection of soft-tissue bulking agent into the torus tubarius was offered as a new

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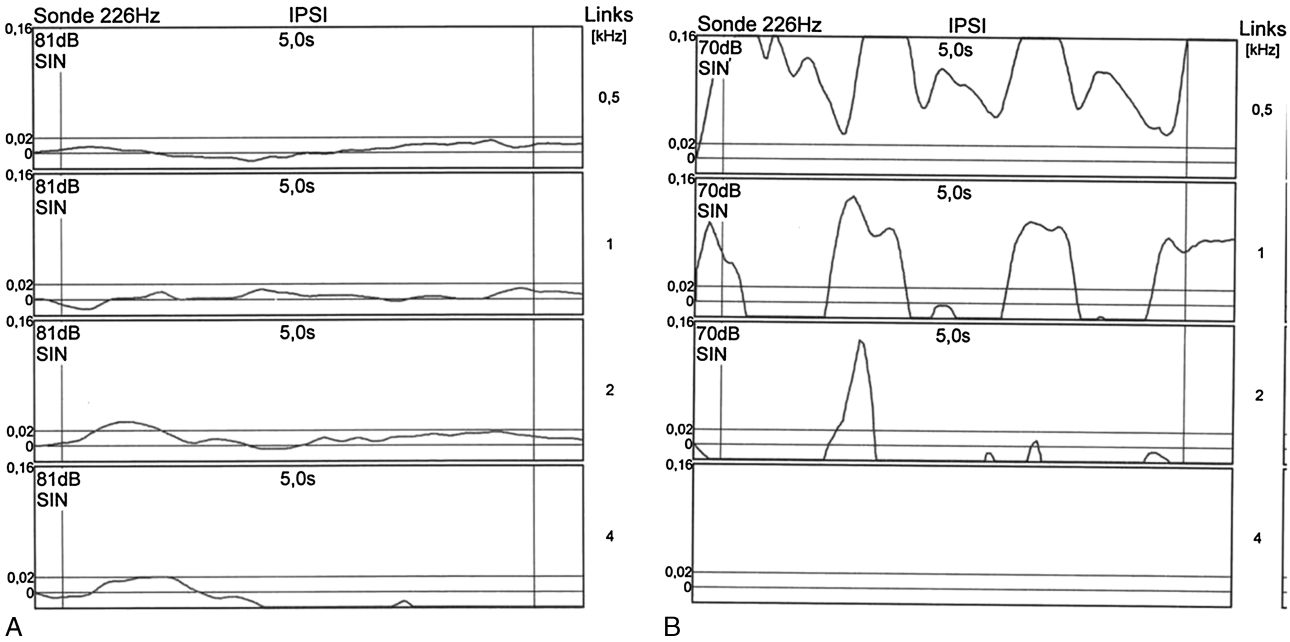

FIG. 1. Reflex-decay. *A*, Healthy subject. *B*, Saw-tooth pattern in patulous Eustachian tube.

second-line treatment option. All included patients had objected to grommet insertion as a treatment alternative. The minimum age to be included in the study was 18 years, and the patients had to be able to give informed consent to participate. All patients were informed about possible complications and the experimental character of this treatment.

Vox-Implants consists of a polydimethylsiloxan-elastomer implant suspended in a hydrogel of polyvinylpyrrolidone and was designed for vocal cord augmentation. Through integration into the local tissue, the agent remains at the injection site.

Augmentation of the torus tubarius was performed under general anesthesia by three different surgeons of our department, with the patient in a supine position. The applicator (Fig. 2) was transnasally positioned in front of the torus tubarius under endoscopic control, with a 45-degree Hopkins endoscope in the contralateral nostril. One milliliter of Vox-Implants was injected in two portions submucosally, posterior and superior-anterior, into the torus tubarius (Fig. 3). The procedure took on average about 20 to 30 minutes for both sides. Patients were discharged from the hospital on Postoperative Day 1. All included patients were reevaluated 6 weeks, 6 months, and 1 year postoperatively. A revision with a second injection was planned when there was no benefit at least 6 weeks after the initial treatment. That means that patients had no sufficient symptom improvement and still a visible movement of the tympanic membrane.

RESULTS

A total of 20 patients with patulous ET were treated: eight patients on the right side, six patients on the left, and six patients with bilateral disease. A total of 30 interventions with injection of Vox-Implants into the torus tubarius were performed. Eleven out of 20 patients were treated with a single injection. In nine patients, repeated injections were necessary (Table 1). So far, serious complications were not observed apart from occasional mild epistaxis. Signs of obstruction of the ET or granuloma formation were not observed in our patient collective.

After the first injection of Vox-Implants, six patients reported a mild improvement of their symptoms; seven patients, a significant improvement; and five patients, no improvement. Six patients were satisfied with the result after treatment and needed no further intervention. In nine patients, a second injection of Vox-Implants was performed at least 6 weeks after the first intervention. After the second injection, one patient reported a slight improvement; four patients, a significant improvement; and two patients, no improvement. Four patients were satisfied with the result and needed no further intervention. Of the patients with a complete follow-up after the first intervention, 33% had a mild, 39% a significant, and 28% no improvement. One-third was satisfied after the first intervention. After a second intervention, another 57% reported a significant improvement (Table 2).

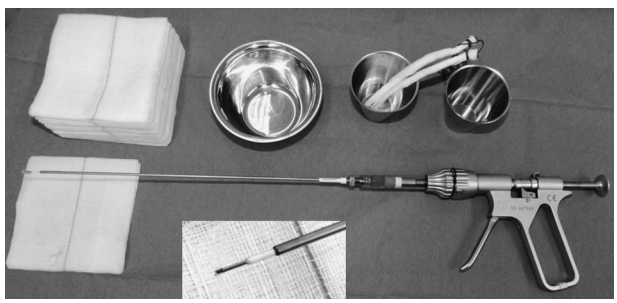

FIG. 2. Instruments for the application of the injectable soft-tissue bulking agent.

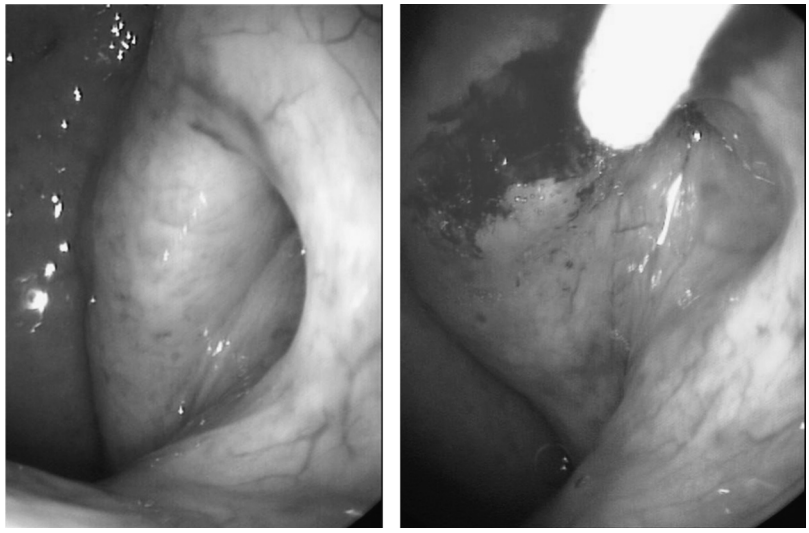

FIG. 3. Endoscopic view after injection of the soft-tissue bulking agent into the torus tubarius.

TABLE 1. *Overview of all treated patients*

Patient	Age (yr)	Sex	Main complaints	Side	No. interventions	Injected amount of Vox in milliliters per intervention
1	21	Female	Hyperacusis Autophonia	Right	2	1
2	27	Male	Autophonia	Left	3	1
3	43	Female	Autophonia	Right	1	1
4	68	Male	Pressure sensation Autophonia	Both sides	1	1
5	51	Female	Autophonia Hyperacusis	Left	2	1 In the revision 2
6	44	Female	Autophonia	Both sides	2	1
7	18	Female	Autophonia	Right	1	1
8	38	Male	Autophonia	Right	1	1
9	55	Male	Autophonia Hypacusis	Left	1	1
10	59	Female	Autophonia Pressure sensation	Right	2	1
11	30	Female	Autophonia Breath synchronous tinnitus	Right	2	1
12	58	Male	Autophonia Tinnitus	Left	2	1
13	53	Female	Autophonia Pressure sensation	Both sides	2	1
14	69	Male	Autophonia Breath synchronous tinnitus	Both sides	2	1
15	19	Female	Breath synchronous tinnitus Pressure sensation Autophonia	Right	1	1
16	41	Female	Autophonia	Both sides	1	1
17	28	Male	Autophonia Pressure sensation	Left	1	1
18	25	Female	Breath synchronous tinnitus Pressure sensation Autophonia	Both sides	1	1
19	37	Male	Pressure sensation Tinnitus	Right	1	1
20	42	Female	Pressure sensation Autophonia	Left	1	0.8

TABLE 2. *Subjective development of complaints after treatment*

Patient	Complaints after first intervention	Complaints after second intervention	Complaints after third intervention	Satisfaction
1	Mild improvement	Significant improvement	—	Yes
2	No improvement	Mild improvement	Unknown	Unknown
3	Unknown	—	—	Unknown
4	Significant improvement	—	—	Yes
5	No improvement	No improvement	—	No
6	No improvement	No improvement	—	No
7	Mild improvement	—	—	No
8	Significant improvement	—	—	Yes
9	Significant improvement	—	—	Yes
10	No improvement	Significant improvement	—	Yes
11	Mild improvement	Unknown	—	Unknown
12	Significant improvement	Significant improvement	—	Yes
13	Mild improvement	Significant improvement	—	Yes
14	Mild improvement	Unknown	—	Unknown
15	Significant improvement	—	—	Yes
16	Mild improvement	—	—	No
17	Significant improvement	—	—	Yes
18	Unknown	—	—	Unknown
19	Significant improvement	—	—	Yes
20	No improvement	—	—	No

In summary, 10 out of 15 patients with a complete follow-up were satisfied with the outcome and three patients reported no improvement of their symptoms. The procedure was fast and minimally invasive with low morbidity.

Eight patients (with 11 injected ETs) returned for a complete follow-up after the treatment. Audiometry and tympanometry were unaltered after treatment. The reflex-decay tympanogram revealed a clear reduction of the saw-tooth pattern in seven ears after the first injection, whereas four ears showed no effect, which was concordant with the persistent complaints of the patients. However, a second treatment reduced the saw-tooth pattern and subjective complaints in another two out of four ears.

DISCUSSION

There is no gold standard for the diagnosis and treatment of ET dysfunction. The most important differential diagnoses for patulous ET are obstructive ET dysfunction and superior semicircular canal dehiscence (4). Preoperative computed tomography scans of the temporal bone were performed in 10 of our 20 patients. In one out of these 10 patients, a dehiscence of the superior semicircular canal was suspected by radiology. However, the clinical symptoms with breath synchronous movements of the tympanic membrane and easing of the symptoms in supine position were very clear in this patient.

If conservative measures do not sufficiently improve the symptoms, there are several surgical treatment options for patients with patulous ET. Paracentesis and grommets have been demonstrated effective in reducing the symptoms but are no causal therapy (9,10). Causal therapy options include the injection of different substances, such as Teflon, Gelfoam, or paraffin into the pharyngeal ostium of the ET. These treatment options bear significant risks (4,11). The injection of autologous fat has also been described as safe and easy to perform. However, resorption of this material might compromise the long-term effect (12). A number of much more invasive techniques have been introduced in the past decades. The ''laser-assisted curvature inversion technique'' of the medial and lateral lamina of the ET was published by Yanez et al. (13) in 2011. A symptom relief and sufficient narrowing of the ET was reported in 82% of the 11 treated patients (13). Poe (14) reported the patulous ET reconstruction whose aim is to narrow the concave defect in the functional valve of the ET. Despite an initially complete relief of autophony, only 43% of the 14 patients were satisfied at the end of the average follow-up period of 15.8 months. Kobayashi described the patulous ET plug. The ''Kobayashi Plug'' is made of silicone and inserted into the bony part of the ET via paracentesis. The plug blocks the ET, but grommets are needed to prevent middle ear effusion. This treatment is claimed effective in about 71% (9,15). Major trials to prove the effects of these procedures are missing.

The injection of Vox into the torus tubarius is a new treatment option for patulous ET dysfunction. It is easy and fast to perform. Serious complications or side effects have not been observed in the presented series. The tissue compatibility is high; no dislocation or granuloma was observed. All patients were discharged from the hospital on Postoperative Day 1 at well-being. The normal ET function was not adversely affected. Patients have to be informed that one to three injections can be necessary to achieve the desired effect. Injection of more than 1 mL in one intervention should be avoided because of the risk of total occlusion of the ET with postoperative middle ear effusion. The advantage of this treatment is that it is minimally invasive and relatively easy to perform. Because this is a novel treatment option, only 20 patients were treated so far and long-term follow-up data are not yet available. In the absence of any reliable diagnostic tool for a patulous ET, we could only use the subjective improvement of the patient's complaints to judge if our therapy was successful. There is no evidence that any audiologic test or imaging can

reliably determine the improvement of this disease. Therefore, our data are not yet sufficient to prove the injection of Vox into the torus tubarius as a standard treatment for patulous ET. In the absence of any proven effective causal therapy for patulous ET dysfunction, further investigation of the different suggested therapeutic options seems desirable. We present our first data on this novel therapy approach for a very difficult-to-treat condition. It is obvious that there is still a need for more detailed investigations concerning the diagnosis and treatment of the patulous ET.

CONCLUSION

A gold standard for the causal therapy of patulous ET is missing. If therapy is requested, conservative treatment options should be exhausted first. Several new treatment options have recently been described, but data on complications, success rates, and long-term results are missing. The transnasal injection of soft-tissue bulking agent in the torus tubarius is a new minimally invasive therapeutic approach.

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