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A new device for delivering drugs into the inner ear: Otoendoscope with microcatheter

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Abstract

Objectives: Intratympanic injection (ITI) of drugs into the inner ear is an attractive way to deliver therapy. However, if the round window membrane (RWM) cannot be visualized, adhesions need to be removed first before ITI can be performed. We developed and tested a novel otoendoscopy device that allows visualization of the RWM for the purpose of ITI.

Methods: Our otoendoscope consists of a catheter channel for delivering drugs and a suction channel.

Results: The novel otoendoscope for inner ear drug delivery has a fine needle with catheter, which can be used to remove or perforate round window niche (RWN) mucosal adhesions. The elliptical shape of the otoendoscope effectively captures the field in the light-guided area, resulting in bright images.

Conclusions: Our otoendoscope can be used to apply drugs directly onto the surface of the RWM and to verify the correct placement of an inner ear drug delivery system, ensuring that it is safely in place.

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Keywords: Inner ear; Round window membrane; Otoendoscope; Catheter; Drug delivery system

1. Introduction

The intratympanic injection (ITI) of drugs into the inner ear is a very attractive way for delivering therapy in Meniere's disease and idiopathic sensorineural hearing loss [1]. Delivering steroids by ITI is more efficient than by systemic injections. Trials have demonstrated that ITI is effective and decreases chances of side effects related to systemic steroid injections [1,2]. ITI, however, is a blind procedure. When the round window niche (RWN) is covered with fibrous or connective tissue, which occurs in about 10–30% of cases [1,3,4], it is impossible for drugs injected by ITI to reach the perilymph of the scala tympani via the round window membrane (RWM).

Therefore, if the RWM cannot be visualized, adhesions covering the RWM should be removed first through

otoendoscopy before drugs are delivered [1]. Anatomic barriers to the RWM may be a significant cause of ITI failure [5]. Although drugs have been delivered successfully into the inner ear with the aid of microcatheters [6] or otoendoscopes [7] employing a working channel for drug injection, a separate instrument is needed to remove adhesions overlying the RWM. To address this issue, we developed a new otoendoscopy device that allows visualization of the RWM, removal of adhesions, and drug delivery.

2. Materials and methods

We developed an otoendoscope that consists of a fiber optic lens (0.6 mm) for viewing and two working channels (1.0 mm and 0.3 mm, respectively); a catheter channel for delivering drugs; and a suction channel for removing adhesions (Machida Corporation, Tokyo, Japan). The working length is 50 mm. The diameter of this device is

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only 2.4 mm \times 1.4 mm, which is small enough for use in the inner ear and for approaching the small space around the RWN. The small diameter of such devices, however, exposes them to four potential problems—(1) low-quality images, (2) increased chance of clogging the channel with drug solution, (3) increased effort required to clean the channel, and (4) increased fragility—all of which we took into account during the development of our improved otoendoscope.

The otoendoscope system for inner ear drug delivery has the following features:

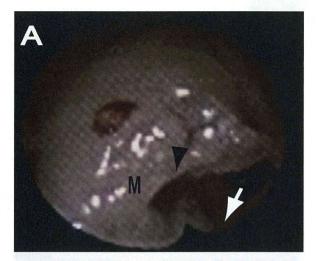
- 1. A 30-gauge needle attached to a catheter to remove or perforate RWN mucosal adhesions and to inject drugs (Fig. 1).
- 2. A catheter threaded inside the channel to deliver drug solutions so liquids never directly contact the working channel, preventing channel clogging.
- 3. An elliptical shape that enables our otoendoscopy device to more effectively capture the field in the light-guided area than prototype otoendoscopes, resulting in brighter and higher-quality images.

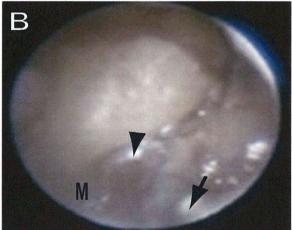
This modified otoendoscope has a similar bore as previous ones, but it is less fragile and less troublesome to use. We tested a conventional otoendoscope, a prototype otoendoscope, and the newly developed otoendoscope on cadaver temporal bones. Prior to using the drug delivery device, under otoendoscopy conventional myringotomy was performed with a small blade (2 mm) at the junction between the posteroinferior quadrants, and then the otoendoscope combined with a catheter was inserted into the inner ear.

All research was conducted with the approval of the Keio University Hospital Institutional Review Board and in accordance with the Helsinki Declaration. The novel otoendoscope inner ear drug delivery device is currently being developed for clinical use.

3. Results

We observed complete obstruction of the RWN in 2 of 5 cadaver temporal bones (Table 1). We also compared our otoendoscope with prototype (Machida Corporation, Tokyo Japan) or conventional otoendoscopes (Olympus Corporation Tokyo, Japan). After performing myringotomy, we used the three different types of otoendoscopes to view the RWM and found that our novel otoendoscope produced good-quality images of the RWM (Fig. 2A). However, because the lens contained within our otoendoscope is only 0.6 mm in diameter, image resolution was not as high-quality as that of the conventional otoendoscope we tested. Thus, the lens requires additional refinement. Although 30°-angled otoendoscopy is typically used to view the RWN, straight (0°) otoendoscopy





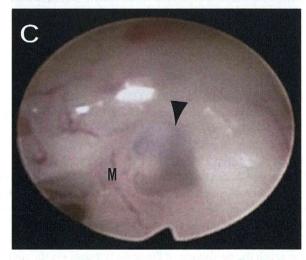
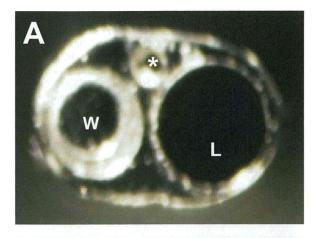
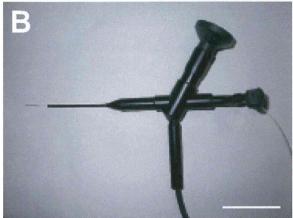


Fig. 1. Novel otoendoscope developed in our clinic. (A) Frontal view of the otoendoscope showing the lens (L) and two channels (W, working channel; *, suction channel). (B) Side view of the otoendoscope with catheter and needle. Scale bar: 5 cm. (C) High magnification view of the tip of the otoendoscope (E) showing the catheter (Ca) and needle (N). A catheter for angiography is also available for this scope. For inner ear procedures, a 30-gauge needle (*) is inserted into the tip of the catheter.





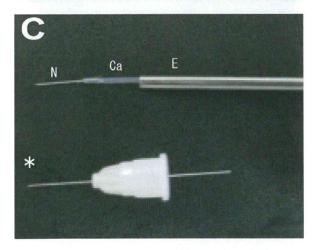


Fig. 2. Round window membrane (RWM indicated by "M" and arrowheads) images as visualized through different otoendoscopes. RWM images captured with the novel otoendoscope (A), a prototype otoendoscope (B), and a 30-angled (1.9 mm; Olympus) conventional otoendoscope (C). The image shown in panel C was especially of high quality. (A and B) Using a needle, we opened up the connective tissue overlying the RWN and injected a solution onto the RWM (M). The needles are indicated by arrows.

can also capture images of the RWM (Fig. 2). Because 0° -angled otoendoscopes are easier to handle, it may be easier to view RWM images through 0° -angled otoendoscopy than through 30° -angled otoendoscopy.

Table 1 RW obstruction of cadaver.

Case (age, sex)	Cadaver condition	RW obstruction
Unknown, F	Fixed	+
Unknown, F	Fixed	_
90 y/o, F	Unfixed	+
94 y/o, F	Unfixed	+/-
92 y/o, F	Unfixed	_

RWM obstruction +: present, +/-: partial present, -: not present.

Table 2 Comparison of different otoendoscopes.

	Results of comparison
Observation of RWM	C > N = P
Treatment of adhesions	N = C > P
Otoendoscope diameter (mm)	N(1.5) > C(1.9) > P(2.4)

C, conventional otoendoscope; N, novel otoendoscope with catheter; P, prototype otoendoscope with catheter.

4. Discussion

Our otoendoscope represents a new concept in treating and diagnosing inner ear-associated hearing loss. If ITI is unsuccessful, the RWM should be examined. This can be carried out conveniently with our otoendoscope. Additionally, our otoendoscope can be used also for diagnosing perilymphatic fistulas and for providing related therapy.

We compared the advantages and disadvantages of the novel otoendoscope, a prototype otoendoscope, and a conventional otoendoscope (Table 2). Although our otoendoscope is smaller than other types of otoendoscopes, it still captures an adequate image of the RWN. Moreover, our otoendoscope combined with a catheter can be used to evaluate the RWN before a local drug delivery system is put into place; to apply drugs directly onto the surface of the RWM; and to verify the correct placement of an inner ear drug delivery system, ensuring that it is safely in place.

Acknowledgements

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ORIGINAL ARTICLE

Pure tone auditory thresholds can change according to duration of interrupted tones in patients with psychogenic hearing loss

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Abstract

Conclusion: Pure tone auditory thresholds can change according to duration of interrupted tones in patients with mild to severe psychogenic hearing loss (PHL). Objectives: To examine how the duration of stimulus tones affects the hearing thresholds of patients with PHL. Methods: Twelve patients with PHL (21 ears) were enrolled in this study. We initially measured their hearing thresholds using interrupted tones with a duration of 2 s and equal length of on-time and off-time, 225 ± 35 ms, respectively. After a 10 min interval, we measured their hearing thresholds using the same interrupted tones conditions lasting 5 s. The average threshold gains (2 s thresholds minus 5 s thresholds) were compared to those of 15 control subjects with normal hearing (25 ears), 15 patients with cochlear hearing loss (23 ears), and 4 patients with retrocochlear lesions (4 ears). Patients with profound PHL (4 patients, 6 ears) were analyzed separately. Results: The average threshold gain of PHL patients (excluding profound PHL patients) at all frequencies was 18.3 dB, which was significantly larger than that of other groups: 0.3 dB (profound PHL patients), 3.8 dB (controls with normal hearing), 3.0 dB (patients with cochlear hearing loss), and 3.2 dB (patients with retrocochlear lesions).

Keywords: Attention, loudness, short-term memory, audiogram

Introduction

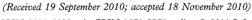
Psychogenic hearing loss (PHL) is defined as hearing loss that cannot be explained by anatomic or physiologic abnormalities and is differentiated from malingering and factitious disorder [1,2]. Many terms besides PHL have been used in the literature to describe the discrepancy between actual hearing thresholds and measured pure tone thresholds in the absence of organic disease: nonorganic hearing loss, pseudohypoacusis, conversion deafness, and functional hearing loss [3,4].

Many studies exist on the pure tone thresholds of PHL patients. The pure tone thresholds of PHL patients typically exhibit a 'saucer-shaped' audiometric configuration, which is considered to be a result of adherence to an equal-loudness standard [5]. The

test-retest reliability of the pure tone audiometry is sometimes poor in PHL patients, and audiometric fluctuations often reveal to clinicians that the hearing loss is PHL [3]. It is also known that the duration of the stimulus tones may affect the audiogram results of patients with PHL. When patients with PHL listen to a sound lasting several seconds, some begin to respond gradually to the sound a few seconds after the sound starts, even though the loudness of the sound does not change. They typically express their feelings as follows: 'At first, the sound felt like it was coming from a far place. Then I started to notice the sound.'

Although this phenomenon is accepted as one of the characteristics in patients with PHL, to the best of our knowledge, no studies have determined how much the pure tone thresholds of audiograms may

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change according to the duration of tones. We hypothesize that pure tone auditory thresholds can change according to the duration of the stimulus tones in patients with PHL, irrespective of the severity of the PHL.

Material and methods

Twelve patients with PHL (21 ears exhibiting PHL) were enrolled in this study. These patients were evaluated and treated at the Hearing and Tinnitus Clinic of the Keio University Hospital. Of the 12 patients, 2 were men and 10 were women; age ranged from 15 to 71 years (median age 27 years). Of the 21 ears, 11 had left-sided PHL and 10 had right-sided PHL. The average auditory threshold at all frequencies tested (125, 250, 500, 1000, 2000, 4000, and 8000 Hz) of all the ears was 67.7 (SD 29.5) dBHL, which included six ears in the range of 21–40 dBHL (mild PHL), four ears in the range of 41–70 dBHL (moderate PHL), five ears in the range of 71–90 dBHL (severe PHL), and six ears in the range of 91–110 dBHL (profound PHL).

First, we measured the hearing thresholds using interrupted tones with a duration of 2 s and equal length of on-time and off-time, 225 ± 35 ms, respectively (2 s thresholds). These are standard parameters for pure tone audiometry in Japan [6]. After a 10 min interval, we obtained the other hearing thresholds using the same interrupted tones conditions lasting 5 s (5 s thresholds), which are 3 s longer than those used in the standard method. The average threshold gains (2 s thresholds minus 5 s thresholds) at all frequencies tested of the patients with PHL were compared to those of 15 controls with normal hearing (25 ears), 15 patients with cochlear sensorineural hearing loss (23 ears), and 4 patients with retrocochlear lesions (4 ears). Of the 15 controls, 7 were men and 8 were women; age ranged from 17 to 58 years (median age 32 years); average auditory threshold at all frequencies tested was 11.4 (SD 4.1) dBHL. Of the 15 patients with cochlear sensorineural hearing loss, 10 were men and 5 were women; age ranged from 34 to 79 years old (median age 67 years); average auditory threshold at all frequencies tested was 43.1 (SD 22.3) dBHL. Of the four patients with retrocochlear lesions, all were men; age ranged from 29 to 78 years (median age 54 years); average auditory threshold at all frequencies tested was 49.8 (SD 28.7) dBHL. The lesions of all four of these patients were vestibular schwannomas.

Patients with profound PHL (four patients, six ears) were analyzed separately from patients with mild to severe PHL, because the former barely responded to any sounds. Consequently, the

remaining group of PHL patients comprised 8 patients (15 ears) with an average auditory threshold of 54.9 (SD 25.0) dBHL at all frequencies tested.

The diagnoses of PHL, cochlear hearing loss, or retrocochlear hearing loss depended on the following tests: pure tone audiometry, otoacoustic emissions (OAEs), auditory brain response (ABR), and magnetic resonance imaging (MRI) [7]. Normal hearing level in pure tone audiometry was defined as <30 dBHL at all frequencies measured. PHL patients frequently require a longer time to respond to the stimulus tones than subjects with normal hearing and patients with organic hearing loss, therefore it took a longer time to measure pure tone audiometry for PHL patients than for other subjects. All of the patients with PHL enrolled in this study had normal hearing function, indicated by OAE and ABR. Malingering and factitious disorder were carefully ruled out.

We obtained informed consent from all patients to have their hearing thresholds measured twice. However, considering possible increased attention to the stimuli that may be caused by explained instructions, especially in patients with PHL, the difference of the duration of interrupted tones between the two measurements was not referred to in the explanation of the test procedure.

The threshold gains between groups were statistically examined with analysis of variance (ANOVA) followed by the Bonferroni post hoc test. All significance tests were two-tailed and conducted at the 5% significance level. All statistics were calculated using JMP version 8.0.1 (SAS Institute Inc., Cary, NC, USA).

This study was approved by the Institutional Review Board at Keio University, School of Medicine.

Results

Representative case report

A 19-year-old woman came to our clinic because of bilateral hearing loss. Pure tone audiometry revealed bilateral sensorineural hearing loss (Figure 1); however, there was a discrepancy between the patient's ability to converse and her measured hearing level. We performed distortion-product and transient-evoked OAEs (DPOAEs and TEOAEs, respectively) and ABR tests on the patient, which revealed normal hearing function for both her ears (Figures 2 and 3). We noted that she experienced much daily stress from family problems. Her symptoms and test results led us to diagnose PHL. Next, we performed pure tone audiometry using different tone durations, as described above. The tests showed significant hearing



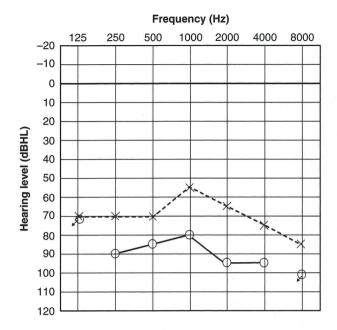


Figure 1. Pure tone audiometry results for a 19-year-old patient with psychogenic hearing loss. Hearing thresholds were measured by using the interrupted tones with a duration of 2 s and the equal length of on-time and off-time, 225 ± 35 ms, respectively.

gains for both of her ears when the tests were performed with interrupted tones lasting for 5 s versus those lasting for 2 s (Figure 4).

Results for all the cases

The average threshold gain of 8 patients with PHL (15 ears), excluding those with profound PHL, at all frequencies tested was 18.3 (SD 13.7) dB, which was significantly larger than that of other groups (p < 0.01,

ANOVA): 0.7 (SD 1.2) dB in patients with profound PHL; 4.6 (SD 2.4) dB in controls with normal hearing; 3.1 (SD 3.1) dB in patients with cochlear hearing loss; and 3.2 (SD 2.2) dB in patients with retrocochlear lesions (Figure 5). The average threshold gain of patients with PHL did not differ according to the measured frequencies. Patients with PHL presenting with profound hearing loss barely responded to any tone, regardless of the duration of interrupted tones. There were no differences between normal controls, patients with cochlear lesions, and patients with retrocochlear lesions.

Discussion

The results of this study indicate that pure tone auditory thresholds can change according to the duration of interrupted tones in patients with mild to severe PHL. Our study also suggests that patients presenting with profound PHL barely responded to any tone, regardless of the duration of interrupted tones.

The absolute thresholds of sounds depend on durations of the sounds [8]. For durations less than \sim 200 ms, the sound intensity necessary for detection increases as duration of the sound decreases; on the other hand, for durations exceeding \sim 500 ms, the sound intensity necessary for detection is independent of duration of the sound. This mechanism for sound detection cannot explain the hearing improvement observed in the patients with PHL in the present study. We consistently used the interrupted tones of which on-time was 225 ± 35 ms, and varied only the total length of the interrupted tones from 2 to 5 s, which resulted in improved response to tones in

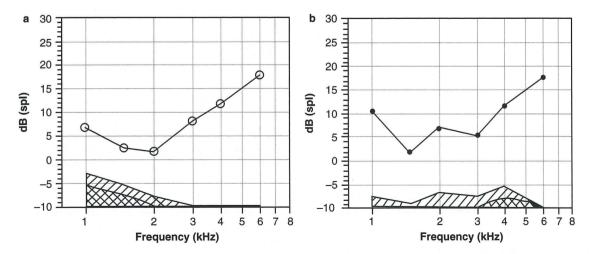


Figure 2. Distortion-product otoacoustic emission (DPOAE) results for a 19-year-old patient with psychogenic hearing loss. (a) Right ear, (b) left ear. Function of outer hair cells in both ears was normal.



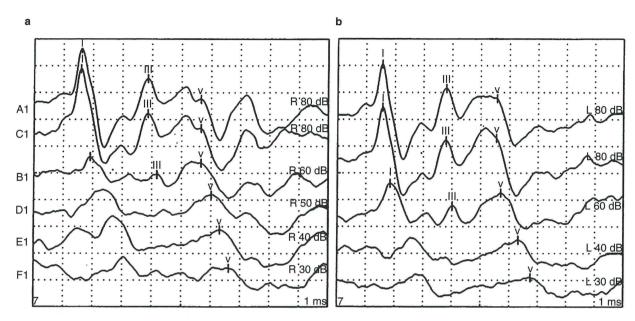


Figure 3. Auditory-brain response results for a 19-year-old patient with psychogenic hearing loss. (a) Right ear, (b) left ear. V waves were observed in both ears following 30 dB stimulation. This was not consistent with the patient's pure tone audiometry results (see Figure 1).

patients with PHL. Thus, we need to consider other mechanisms that may underlie the sound duration-related hearing improvement in patients with PHL.

In patients with PHL, hearing thresholds typically show a saucer-shaped audiometric configuration [5], and Bekesy audiograms are typically type V [9,10].

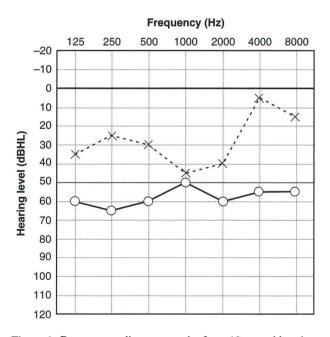


Figure 4. Pure tone audiometry results for a 19-year-old patient with psychogenic hearing loss. Hearing thresholds were measured by using interrupted tones with a duration of 5 s and equal length of on-time and off-time, 225 ± 35 ms, respectively. In comparison with the thresholds evoked by relatively shorter 2 s tones (see Figure 1), the thresholds evoked by longer 5 s tones showed significant improvement. These tests were performed at an interval of 10 min.

Both patterns are considered to be a result of adherence to an equal-loudness standard in the patients' memory [5,11]. Although it is not known why patients with PHL judge the loudness of sounds by tracing their memory, memory seems to play an important role in determining auditory thresholds in these patients.

Another characteristic audiometric phenomenon in patients with PHL is observed during 'suggestion audiometry,' a test procedure used to detect nonorganic hearing loss and to determine the actual healing levels of a patient [12]. In this test, a tester 'suggests' to a patient that wearing a hearing aid would improve his/her hearing. However, unbeknownst to the patient, the hearing aid is switched off during the pure tone audiometry. In children with PHL, this type of 'suggestion' protocol improved the auditory thresholds of the children [12]. These authors provided an explanation for this phenomenon, proposing that the 'suggestion' improves attention in children with attention deficits, which in turn improves the children's ability to detect sounds. Findings by Hosoi et al. [12] complement those of another study, which reported that attention deficit may affect the N100 m findings of auditory-evoked fields in patients with PHL [13]. They observed attenuation of the N100 m amplitude in 5 PHL patients but not in 10 control patients. Together, these findings indicate that attention may also play an important role in determining auditory thresholds in patients with PHL.

Models exist that describe the relationship between attention and awareness [14]. One model posits that



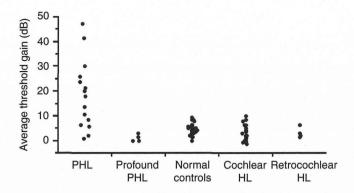


Figure 5. Distribution of average threshold gains at all frequencies tested of all the subjects. Threshold gains were calculated by subtracting 5 s threshold values from 2 s threshold values. The subjects were classified into 5 groups: PHL, PHL patients excluding profound PHL patients (8 cases, 15 ears); profound PHL (4 cases, 6 ears); normal control, controls with normal hearing (15 cases, 25 ears); cochlear HL, patients with cochlear sensorineural hearing loss (15 cases, 23 ears); and retrocochlear HL, patients with retrocochlear lesions (4 cases, 4 ears). The average threshold gain of the PHL group was significantly larger than that of other groups (p < 0.01, ANOVA). PHL, psychogenic hearing loss; HL, hearing loss.

sensory inputs are analyzed and gated by attention into awareness, which can prompt the subject to react to the sensory information. This model can be applied to our present results. The 5 s tones may attract more attention than the 2 s tones, which makes the patients more aware of the tones and thus improves the patients' reaction to the tones. Another model considers sensory input and memory [14], such that information about sensory inputs is moved into short-term memory via the attention process. Shortterm memory is one of the key steps in the neural mechanisms underlying auditory discrimination of long-duration tones [15]. This concept can also be applied to our results. The increased attention caused by the 5 s tones causes the 'sound' information to move into the patients' short-term memory; and when the loudness of the sound matches the loudness in the patients' long-term memory, the PHL patients can react to the sound.

In this study, we analyzed patients with mild to severe PHL separately from patients with profound PHL, because the latter patients barely responded to any sound, regardless of the duration of the interrupted tones. Although it is unclear whether a different mechanism underlies the hearing loss in patients with profound PHL, our results indicated that enhancing attention in patients with profound PHL does not improve their auditory thresholds. Considering the rare incidence of profound PHL [16], it may be necessary to consider that profound PHL may have a different etiology than mild to severe PHL.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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