

## Original Research Article

# Effect of transtympanic ventilation tube insertion for patients with intractable Meniere's disease

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## ABSTRACT

**Background:** This study aimed to clarify the effects of transtympanic tube insertion on patients with Meniere's disease refractory to conservative treatment.

**Methods:** Between January 2010 and December 2019, 40 patients with refractory Meniere's disease were assigned to group I, a group of 19 patients who underwent transtympanic tube insertion (13 males, 6 females; age range 15-79 years) and group II, a control group of 21 patients who did not undergo intratympanic tube insertion (10 males, 11 females; age range 26-81 years). Definitive vertigo spells, hearing level, tinnitus and aural fullness were assessed for 2 years after treatment. The effectiveness of treatment for vertigo attacks and hearing loss was assessed according to the 1995 American academy of otolaryngology-head and neck surgery criteria. The degree of disability due to vertiginous attacks was also assessed and compared between groups using the dizziness handicap inventory (DHI) before and 2 years after treatment.

**Results:** The frequency of vertigo attacks and the DHI score were significantly better in group I than in group II 2 years after treatment. Group I also showed significantly improved tinnitus and feelings of fullness. However, the hearing level remained unaffected in both groups.

**Conclusions:** This less invasive treatment might offer short term efficacy in reducing persistent vertigo, tinnitus and a feeling of aural fullness for some patients with Meniere's disease.

**Keywords:** Meniere's disease, Ventilation tube, Vertigo, Endolymphatic hydrops, Eustachian tube

## INTRODUCTION

Meniere's disease is the most common cause of spontaneous recurrent vertigo attacks associated with fluctuating hearing loss, tinnitus and a feeling of fullness in the ears. Repeated vertigo attacks over a long period of time can lead to chronic vestibular abolition and disequilibrium.

Many experts consider endolymphatic hydrops as the pathology underlying Meniere's disease but little evidence to fully support this hypothesis has been

accumulated. In a recent study, magnetic resonance imaging (MRI) was performed with gadolinium injected via the Eustachian tube before and after surgery for endolymphatic sac decompression (ESD). The ratio of perilymph to endolymph was found to have decreased after compared with before the procedure, providing support for the hydrops theory.<sup>1</sup>

In the early stages of Meniere's disease, a low salt diet and diuretics are used to reduce endolymphatic volume and control symptoms. In about 80-90% of patients with Meniere's disease, vertigo attacks decrease spontaneously

over time.<sup>2,3</sup> The remaining patients continue to experience refractory dizziness with conservative treatment. Patients with such refractory Meniere's disease may require other, more invasive surgical procedures, such as ESD or unilateral vestibular resection techniques (intratympanic gentamicin, vestibular nerve section or labyrinthectomy).

Tumarkin and Lall first reported transtympanic ventilation tube placement as a less invasive, non-destructive and relatively safe treatment for refractory Meniere's disease.<sup>4,5</sup> The effect of transtympanic ventilation tube placement for Meniere's disease remains controversial.<sup>6</sup> This study therefore analyzed the effects of transtympanic ventilation tube placement in patients with refractory Meniere's disease.

## METHODS

This study was a retrospective analysis. Among 560 patients with Meniere's disease who visited dizziness outpatient clinic of Aichi medical university, Aichi, Japan from January 2010 to December 2019, there were 102 cases of refractory Meniere's disease with frequent vertigo persisting for more than 6 months despite conservative treatment. Of these, 40 patients who had been able to follow up for more than 2 years were enrolled and assigned to two groups: group I comprising 19 patients who underwent intratympanic tube insertion and group II, a control group of 21 patients who did not undergo intratympanic tube insertion. Definitive vertigo spells, hearing level, tinnitus and aural fullness were assessed for 2 years after treatment and compared between groups. The compositions of the two groups are shown in Table 1.

All patients experienced typical attacks of Meniere's disease such as vertigo, hearing loss and tinnitus resistant to conventional medical treatment for  $\geq 6$  months. Meniere's disease was diagnosed according to the American academy of otolaryngology-head and neck surgery (AAO-HNS) foundation 1995 guidelines proposed by the commission on hearing and equilibrium.<sup>3</sup> All patients underwent otoneurological and audiological examinations including pure tone audiometry (PTA) and Eustachian tube function testing (sonotubometry) before insertion of the tympanostomy tube to exclude other inner ear and retro-labyrinthine disorders. This study was approved by the clinical research and ethics board of our tertiary medical center.

Each of the 19 patients in group I was informed that a ventilation tube would be inserted through the eardrum to evaluate the effects of the tympanostomy tube on inner ear function. All participants in group I provided their written, informed consent prior to registration. The tympanostomy tube was inserted in the antero-inferior part of the eardrum of the affected ear after local anesthesia by placing a cotton ball soaked with 4% lidocaine on the eardrum for a few minutes. Paparella-

type vent tubes (Medtronic, Minneapolis, Minnesota, USA) were used as tympanostomy tubes.

Treatment outcomes in terms of hearing and equilibrium were assessed according to the AAO-HNS (1995) criteria.<sup>3</sup> Outcomes were assessed at both 1 and 2 years after treatment in group I. Outcomes were also compared before and 2 years after treatment between group I and group II. The frequency of definitive vertiginous attacks occurring during the 6 months before treatment was compared with those occurring within 6-12 months (1 year) and within 18-24 months (2 years) after treatment.

To evaluate the effects of treatment on vertiginous attacks, a numeric value was calculated as the mean number of definitive attacks per month after tube insertion divided by the number occurring prior to tube insertion (as per AAO-HNS guidelines).<sup>3</sup> Control of vertigo as determined by the numeric value was categorized as: 0, complete control; 1-40, substantial control; 41-80, limited control; 81-120, insignificant control and  $\geq 121$ , worsened (poor) control. The degree of disability due to vertiginous attacks was assessed and compared using the DHI before and 2 years after treatment between groups I and II.

Hearing level change was also assessed using AAO-HNS (1995) criteria.<sup>3</sup> The poorest hearing level using the four-frequency (0.5, 1, 2 and 3 kHz) pure tone average was assessed and compared between groups before (6 months) and after (18-24 months) treatment. Hearing level change was defined as improved for a gain  $>10$  dB, unchanged for a change of  $\pm 10$  dB and deteriorated for a loss  $>10$  dB.

Tinnitus and feelings of aural fullness were assessed and compared as improved or unchanged before (6 months) and after (18-24 months) treatment for both groups.

## Statistical analysis

The Mann-Whitney U test was used to compare improvements in postoperative results such as vertiginous attacks, hearing level, ear fullness and tinnitus. The Wilcoxon signed-rank test was used to compare DHI scores before and after treatment and Welch's t test was used to compare degrees of improvement in DHI scores between groups I and II. Significance was defined as values of  $p < 0.05$ .

## RESULTS

Mean durations of postoperative follow up were 36.3 months (range, 24-96 months) for group I and 36.1 months (range, 24-98 months) for group II (Table 1). Long term assessment of each patient was done in the 24-month period after treatment. In 10 of the 19 patients, tubes were extruded spontaneously within 2 years after insertion. The tube was reinserted once in 2 patients, twice in 1 patient and 3 times in 3 patients. Permanent

eardrum perforation remained in 4 patients (Table 2). In 2 patients, vertiginous attacks recurred after the tube became obstructed or was extruded, in these patients, vertiginous attacks disappeared immediately after tube reinsertion.

### Vertigo

#### Control of vertigo in group I

In group I at 12 months post treatment, 3 of the 19 patients showed complete control of vertigo, 8 displayed substantial control, 5 had limited control and 3 had insignificant control. In the tube insertion group at 24 months post treatment, 7 of the 19 patients had achieved complete control of vertigo, 5 had substantial control, 2 showed limited control and 5 had insignificant control (Table 2-4). The number of patients who had complete control of vertigo was clearly increased after 2 years when compared with the treatment effects after 1 year. Of the 7 patients with complete control at the 2 year evaluation, 3 patients had shown complete control and 4 patients had shown substantial control at 1 year. Two of the 5 patients who had insignificant control of vertigo at 2 years required alternative treatment. Those two patients underwent transmastoid endolymphatic sac surgery at 30 months and 32 months, respectively, after tube placement, leading to control of vertigo (Table 5).

#### Comparison of control of vertigo between groups I and II

In group II at 24 months post treatment, none of the 21 patients showed complete control of vertigo, 2 had substantial control, 9 had limited control, 9 had insignificant control and 1 had worsened control (Table 2-4). A significant difference in the degree of improvement of vertigo attacks was evident between groups ( $p=0.0034$ , Mann-Whitney U test). Clearly, the improvement rate for vertigo was higher in group I than in group II.

### DHI score

DHI scores in both groups were significantly reduced after treatment compared to before treatment. Furthermore, the degree of DHI score improvement between pre and post treatment tended to be significantly higher in group I ( $p<0.001$ , Welch's t-test) (Table 6).

### Hearing level

In group I at 12 and 24 months after treatment, hearing had improved in 2 of 19 patients, was unchanged in 15, and was worse in 2 (Table 3 and 4). No differences in treatment effects were identified between 1 and 2 years. In group II at 24 months after treatment, hearing had improved in 4 of 21 patients, was unchanged in 15 and was worse in 2 (Table 3 and 4). No significant difference in the improvement of the hearing level after treatment was seen between groups ( $p=0.252$ , Mann-Whitney U test) (Table 4). No significant difference in mean hearing thresholds was identified in either group after treatment or between groups ( $p>0.05$ ) (Table 6).

### Tinnitus and feeling of aural fullness

In group I at 12 and 24 months of treatment, tinnitus had improved in 11 of 19 patients and was unchanged in 8 (Table 7 and 8). Feelings of aural fullness had improved in 12 patients and were unchanged in 7 (Table 7 and 8). No differences in treatment effects for tinnitus or aural fullness were seen between 1 and 2 years. In group II at 24 months of treatment, tinnitus had improved in 5 of 21 patients, was unchanged in 13 and was worse in 3 (Table 7 and 8). Feelings of aural fullness had improved in 12 patients and were unchanged in 7 (Table 7 and 8). At 24 months after treatment in the two groups, the improvement in tinnitus and aural fullness tended to be significantly higher in group I than in group II ( $p=0.0149$ ,  $p=0.0078$ , respectively, Mann-Whitney U test).

**Table 1: Demographic characteristics of the 40 patients with intractable Meniere's disease.**

| Variables                                | Control group (n=21) | Transtympanic tube insertion group (n=19) |
|--|----------------------|---|
| Male/ Female                             | 10/11 (21)           | 13/6 (19)                                 |
| Median age (years)                       | 53.2 (26-81)         | 57 (15-79)                                |
| Pre-operative duration (months) (range)  | 26.2 (6-120)         | 34.8 (9-120)                              |
| Post-operative duration (months) (range) | 36.1 (24-98)         | 36.3 (24-96)                              |

**Table 2: Condition of ventilating tubes and ear drums, hearing level and control of vertigo in the 19 patients of the tube insertion group at 24 months after treatment.**

| Patient No. | Ventilating tube | Chronic perforation of ear drum | Hearing level | Control of vertigo (12M) | Control of vertigo (24M) |
|-------------|------------------|---------------------------------|---------------|--------------------------|--------------------------|
| 1           | +                | (-)                             | Unchanged     | Substantial              | Complete ↑               |
| 2           | -                | (+)                             | Unchanged     | Substantial              | Substantial →            |
| 3           | +++              | (-)                             | Improved      | Limited                  | Substantial ↑            |
| 4           | -                | (+)                             | Unchanged     | Complete                 | Complete →               |

Continued.

| Patient No. | Ventilating tube | Chronic perforation of ear drum | Hearing level | Control of vertigo (12M) | Control of vertigo (24M) |
|-------------|------------------|---------------------------------|---------------|--------------------------|--------------------------|
| 5           |                  | (-)                             | Unchanged     | Insignificant            | Insignificant →          |
| 6           | -                | (+)                             | Unchanged     | Complete                 | Complete →               |
| 7           | +                | (-)                             | Unchanged     | Substantial              | Limited ↓                |
| 8           | +++              | (-)                             | Unchanged     | Limited                  | Limited →                |
| 9           | +                | (-)                             | Unchanged     | Complete                 | Complete →               |
| 10          |                  | (-)                             | Worse         | Limited                  | Insignificant ↓          |
| 11          | ++               | (-)                             | Unchanged     | Limited                  | Insignificant ↓          |
| 12          | -                | (+)                             | Unchanged     | Substantial              | Substantial →            |
| 13          |                  | (-)                             | Worse         | Substantial              | Complete ↑               |
| 14          |                  | (-)                             | Unchanged     | Substantial              | Complete ↑               |
| 15          |                  | (-)                             | Unchanged     | Limited                  | Substantial ↑            |
| 16          |                  | (-)                             | Unchanged     | Substantial              | Complete ↑               |
| 17          |                  | (-)                             | Unchanged     | Insignificant            | Insignificant →          |
| 18          |                  | (-)                             | Improved      | Insignificant            | Insignificant →          |
| 19          |                  |                                 | Unchanged     | Substantial              | Substantial →            |

Control of vertigo at 24 months as compared with 12 months is shown as improvement (↑); no change (→); or worse (↓); condition of ventilating tubes is shown as reinserted once, (+); reinserted twice, (++); reinserted 3 times, (+++) and extruded (-).

**Table 3: Changes in control of vertigo and hearing level at 12 and 24 months after treatment in the 19 patients of the tube insertion group.**

| Changes in control        | 12 months | 24 months |
|---------------------------|-----------|-----------|
| <b>Control of vertigo</b> |           |           |
| Complete                  | 3         | 7         |
| Substantial               | 8         | 5         |
| Limited                   | 5         | 2         |
| Insignificant             | 3         | 5         |
| Worse                     | 0         | 0         |
| <b>Hearing level</b>      |           |           |
| Improved                  | 2         | 2         |
| Unchanged                 | 15        | 15        |
| Worse                     | 2         | 2         |

**Table 4: Changes and comparisons of control of vertigo and hearing level at 24 months after treatment in the tube insertion and control groups.**

| Changes and comparisons of control | Control group (N=21) | Transtympanic tube insertion group (N=19) | P value Mann Whitney U test |
|------------------------------------|----------------------|---|-----------------------------|
| <b>Control of vertigo</b>          |                      |   |                             |
| Complete                           | 0                    | 7   | 0.0034                      |
| Substantial                        | 2                    | 5   |                             |
| Limited                            | 9                    | 2   |                             |
| Insignificant                      | 9                    | 5   |                             |
| Worse                              | 1                    | 0   |                             |
| <b>Hearing level</b>               |                      |   |                             |
| Improved                           | 4                    | 2   | 0.252                       |
| Unchanged                          | 15                   | 15  |                             |
| Worse                              | 2                    | 2   |                             |

**Table 5: Changes and comparisons of DHI scores and hearing thresholds at 24 months after treatment in the tube insertion and control groups.**

| Groups               | DHI score (pre-treatment) | DHI score (post-treatment) | P value Wilcoxon signed rank test | P value Welch's t test |
|----------------------|---------------------------|----------------------------|-----------------------------------|------------------------|
| <b>Control group</b> | 56.1±15.68                | 41.05±16.35                | 0.000953                          | 0.0000154              |

Continued.

| Groups                                | DHI score (pre-treatment) | DHI score (post-treatment) | P value Wilcoxon signed rank test | P value Welche's t test |
|---------------------------------------|---------------------------|----------------------------|-----------------------------------|-------------------------|
| <b>Trans tympanic insertion group</b> | 60.1±12.0                 | 15.58±11.76                | 0.000155                          |                         |
|                                       | Hearing level (dB)        | Hearing level (dB)         |                                   |                         |
| <b>Control group</b>                  | 34.37±19.30               | 34.19±24.21                | 0.289                             |                         |
| <b>Trans tympanic insertion group</b> | 41.59±19.34               | 41.85±21.38                | 0.308                             | 0.854                   |

**Table 6: Therapeutic effect of transtympanic tube insertion on vertigo attacks in refractory Meniere's disease: comparison with previous reports.**

| Control of vertigo determined by the numeric value | 0 complete (%) | 1-40 substantial (%) | 41-80 limited (%) | 81-120 insignificant (%) | >120 worse (%) | Change to another treatment (%) |
|--|----------------|----------------------|-------------------|--------------------------|----------------|---------------------------------|
| <b>Montandon et al<sup>20</sup></b>                | 28             | 20 (71)              | 1 (4)             | 2 (7)                    | 3 (11)         | 0                               |
| <b>Thomsen et al<sup>11</sup></b>                  | 14             | 5 (36)               | 4 (25)            | 3 (21)                   | 1 (7)          | 0                               |
| <b>Sugawara et al<sup>12</sup></b>                 | 7              | 0                    | 5 (71)            | 1 (14)                   | 1 (14)         | 0                               |
| <b>Park et al<sup>13</sup></b>                     | 22             |                      | 5 (23)            | 8 (36)                   | 7 (32)         | 0                               |
| <b>Ogawa et al<sup>14</sup></b>                    | 15             | 7 (47)               | 3 (20)            | 1 (7)                    | 0              | 4 (27)                          |
| <b>Present cases</b>                               | 19             | 7 (37)               | 5 (26)            | 2 (11)                   | 5 (26)         | 0                               |

**Table 7: Preoperative Eustachian tube functional type by sonotubometry, improvement of tinnitus and improvement of aural fullness in the 19 patients of the tube insertion group at 24 months after treatment.**

| Patient no. | Eustachian tube type by sonotubometry | Tinnitus  | Aural fullness |
|-------------|---------------------------------------|-----------|----------------|
| 1           | Stenosis                              | Improved  | Improved       |
| 2           | Normal                                | Improved  | Improved       |
| 3           | Patulous                              | Improved  | Improved       |
| 4           | Stenosis                              | Improved  | Improved       |
| 5           | Stenosis                              | Unchanged | Unchanged      |
| 6           | Stenosis                              | Unchanged | Unchanged      |
| 7           | Stenosis                              | Unchanged | Unchanged      |
| 8           | Stenosis                              | Improved  | Improved       |
| 9           | Patulous                              | Improved  | Improved       |
| 10          | Patulous                              | Improved  | Improved       |
| 11          | Patulous                              | Unchanged | Unchanged      |
| 12          | Stenosis                              | Improved  | Improved       |
| 13          | Patulous                              | Unchanged | Unchanged      |
| 14          | Stenosis                              | Improved  | Improved       |
| 15          | Patulous                              | Unchanged | Unchanged      |
| 16          | Normal                                | Unchanged | Improved       |
| 17          | Stenosis                              | Unchanged | Unchanged      |
| 18          | Stenosis                              | Improved  | Improved       |
| 19          | Stenosis                              | Improved  | Improved       |

**Table 8: Changes and comparison of control of vertigo and hearing level at 24 months after treatment in the tube insertion and control groups.**

| Variables             | Control group, (n=21) | Transtympanic tube insertion group, (n=19) | P value Mann Whitney U test |
|-----------------------|-----------------------|--|-----------------------------|
| <b>Tinnitus</b>       |                       |  |                             |
| Improved              | 5                     | 11   | 0.0149                      |
| Unchanged             | 13                    | 8  |                             |
| Worse                 | 3                     | 0  |                             |
| <b>Aural fullness</b> |                       |  |                             |
| Improved              | 4                     | 12   | 0.0078                      |
| Unchanged             | 15                    | 7  |                             |
| Worse                 | 2                     | 0  |                             |

### ***Eustachian tube function***

In line with a previous report, the normal duration from sonotubometry was defined as 66.1-778.9 ms and a peak >5 dB on sonotubometry was defined as a positive response.<sup>7</sup> Durations <66.1 ms or amplitudes <5 dB were consistent with a diagnosis of tubal stenosis, whereas durations >778.9 ms were consistent with a diagnosis of patulous Eustachian tube.

On the basis of these definitions, 17 of the 19 patients in group I were diagnosed with Eustachian tube dysfunction in the affected ear, comprising 11 patients with tubal stenosis and 6 patients with patulous Eustachian tubes (Table 7).

### **DISCUSSION**

The exact cause of Meniere's disease has yet to be clarified, but changes in atmospheric pressure have been reported to affect symptoms of Meniere's disease. Tumarkin hypothesized that the stage of underpressure in the middle ear was associated with continuous impairment of labyrinth function due to pressure transfer through the round window.<sup>4</sup> In 1975, Cinnamon rejected this concept, finding no association between Eustachian tube dysfunction and Meniere's disease, noting that the use of transtympanic tubes to relieve symptoms was ineffective.<sup>8</sup> This treatment was also rejected by Hall et al in 1977.<sup>9</sup> In 1988, Montandon et al reexamined the effects of transtympanic tubes in 28 patients with refractory Meniere's disease, showing improvement or complete relief of vertiginous attacks in most patients (82%, 23 patients).<sup>10</sup>

In 1998, Thomsen et al investigated differences between the effects of two surgical procedures in 29 patients with refractory Meniere's disease.<sup>11</sup> Fifteen patients underwent transmastoid sac surgery and the remaining 14 underwent transtympanic ventilation tube insertion. Postoperatively, no clear difference between groups was apparent in terms of the reduction of vertiginous attacks.

In the present study, inserting an intratympanic ventilation tube into the affected ear of patients with refractory Meniere's disease completely resolved vertiginous attacks in 37% of patients and reduced the frequency and severity of vertigo in 74%. These findings showed a lower rate of improvement than described by Montandon et al but similar to those reported by Sugawara et al and Park et al (Table 6).<sup>10,12,13</sup> Densert et al and Ingelstedt et al reported that acute cochlear and vestibular symptoms were relieved when changes in external pressure caused the middle ear of Meniere's disease patients to become pressure-positive.<sup>14,15</sup>

Kimura et al demonstrated experimentally that endolymphatic hydrops was reduced in animals with tympanic membrane ventilation tubes.<sup>16</sup> They noted that increased partial pressure of oxygen in the middle and

inner ear may reduce the inner ear symptoms seen in Meniere's disease. Lall and Hall et al investigated whether Eustachian tube function affects endolymphatic hydrops, but they failed to clarify the association between Meniere's disease and Eustachian tube function.<sup>5,9</sup>

In contrast, almost all cases of group 1 in the present study showed stenotic and patulous types of Eustachian tubes on sonotubometry. Eleven patients (58%) showed a stenotic-type Eustachian tube and 6 (32%) showed a patulous type. Ogi et al.<sup>17</sup> focused on the association between development of Meniere's disease and Eustachian tube dysfunction. They speculated that continuous negative pressure of the middle ear due to a stenotic Eustachian tube was the cause of the onset of Meniere's disease, but they also suggested that frequent fluctuations in middle ear pressure due to a patulous Eustachian tube may represent the trigger. Changes in middle ear pressure due to Eustachian tube dysfunction were considered to affect inner ear pressure and may cause secondary Meniere's disease and intractable dizziness. In previous studies, inner ear hypoxia caused by negative pressure in the middle ear was one of the most widely recognized theories regarding the cause of Meniere's disease. Obstruction of the Eustachian tube in patients with Meniere's disease is thought to cause negative pressure in the middle ear cavity. Under such conditions, oxygen tension in the middle ear (which is already lower than that in the atmosphere) would decrease further.<sup>18</sup> This hypoxic condition in the middle ear cavity causes a decrease in the endocochlear potential, as well as an increase in endolymphatic pressure and an increase in Ca<sup>2+</sup> concentration in the scala media.<sup>19,20</sup> The decrease in middle ear pressure reduces perilymph pressure through the round window, resulting in displacement of Reissner's membrane and the promotion of relative endolymphatic hydrops. In addition, endolymphatic secretion and/or absorption homeostasis is believed to be maintained by circulatory hormones, including mineralocorticoids, atrial natriuretic peptides, and vasopressin. In support of this controversy, the presence of receptors for these hormones in the cochlea was confirmed.<sup>21</sup> Therefore, persistent negative pressure in the middle ear affects the amount of endolymph through these hormones.

On the other hand, how a patulous Eustachian tube affects inner ear function remains unclear. Two major mechanisms have been considered. The first theory is that pressure changes through the Eustachian tube may move the eardrum and then the oval window, resulting in an effect on endolymph via the ossicular chain.<sup>22</sup> The second theory was that changes in sound pressure through the Eustachian tube can occur directly through the thin round window membrane and affect endolymph via the perilymph. One study suggested that non-physiological movements of the round and oval windows may act like the membrane of a gasoline pump, resulting in increased loss of perilymph by diuretic hormones (in response to pressure) or through the cochlear aqueduct.<sup>23,24</sup>

More loss of perilymph will result in dilation of the endolymphatic space. In patients with a patulous Eustachian tube, movements such as vocalization and swallowing in daily life cause fluctuations in the round window and oval window. These fluctuations associated with such frequent movements can lead to loss of perilymph and subsequent secondary Meniere's disease. Treatment in patients with a patulous eustachian tube had been reported to improve symptoms such as deafness and vestibular symptoms.<sup>22,25</sup> Both of these hypotheses appear to support the potential usefulness of placing tympanic tubes for patients with Meniere's disease.<sup>6</sup> The transtympanic tube was thought to indirectly suppress the pressure rise in the perilymph by reducing the pressure change in the middle ear. It seemed unlikely that the observed results may represent a placebo effect, due to the accumulated experience. The relapse of dizziness in patients with tympanic tube shedding or obstruction seems to support the physiological explanation for the usefulness of the tympanic tube.

The present results showed that tube insertion in the affected ear decreased vertigo spells in 16 of the 19 cases at 12 months after treatment. At the 24 month follow up, the effectiveness of tube insertion did not seem to have changed. However, the number of patients who showed complete control of vertigo rose from 3 to 7. Ogawa et al have published similar reports.<sup>14</sup> As they noted, the reason why the number of patients showing complete control of vertigo was increased after 2 years as compared to after 1 year may be due to natural healing rather than tube placement.<sup>14</sup> Furthermore, in the present study, it was possible to compare long term results between group I with tube insertion and group II controls who had similarly intractable Meniere's disease but without tube insertion. Group I showed outcomes clearly superior to those of group II controls in the degree of improvement in vertigo. To clarify not only the frequency of dizziness, but also the degree of the effect of dizziness in daily life, DHI scores were compared between groups, and it was found that the DHI score was decreased predominantly in Group I. Comparison with group II controls strongly suggests that tympanic tube placement can alleviate symptoms of dizziness in terms of frequency of dizziness and impacts on actual daily life. On the other hand, middle ear ventilation showed no benefits in terms of hearing loss during the observation period. However, tinnitus and feelings of aural fullness were significantly reduced with tube insertion 2 years after treatment compared to the controls. Leveo et al reported that 68% of patients with Meniere's disease had ear fullness and 37% had moderate or severe symptoms.<sup>27</sup> Aural fullness was rated as the worst problem by 4.4% of those subjects. Similarly, Yoshida et al reported that some patients with Meniere's disease consider tinnitus to be an important symptom, with 19% rating it as the most serious complaint.<sup>28</sup>

Tinnitus and aural fullness are associated with poor quality of life and complaints such as dizziness attacks,

imbalance and hearing loss. The treatment applied in the present study may be as effective for tinnitus and aural fullness as for dizziness in patients with Meniere's disease.

The number of cases in the present study was relatively small, so that the effectiveness of this treatment has not been fully demonstrated. In addition, the exact mechanism of the effect of inserting a ventilation tube was only speculative and unclear. However, at least in terms of results, tube insertion appeared to have some potential as a treatment for some Meniere's disease patients who were experiencing a persistent spell of dizziness. This was because the procedure was simple and less invasive than other surgical procedures such as intratympanic gentamicin administration and transmastoid endolymphatic sac surgery with the risk of sensorineural hearing loss.

Ventilation tube placement was often effective immediately after the procedure. In the present study, ventilation tube placement tended to be effective at an early stage. Moreover, ventilation tube placement can be performed even in small clinics where surgery is not possible. Placement of a ventilation tube should be considered when standard medical management fails and before planning ablative surgical methods. In selected patients with Meniere's disease, ventilation tube placement might delay more invasive treatment decisions. If tube placement remains inadequate, gentamicin and steroid treatment can be easily administered via the tube from the middle ear to the inner ear.

### **Limitation**

This treatment was not effective in all cases with refractory Meniere's disease. This study was a single-center report with a very small number of cases, which was insufficient to predict the efficacy of this treatment. Furthermore, there was no clear pathophysiological explanation for the suppression of vertigo by tympanostomy tube insertion.

### **CONCLUSION**

However, the present findings show that transtympanic tube placement might reduce persistent vertigo, tinnitus and the feeling of aural fullness in patients with refractory Meniere's disease. This treatment is considered to be a relatively minimally invasive and effective treatment for patients with Meniere's disease that has not responded to conservative treatment.

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