

# Transtympanic Tube Placement in Patients with Meniere's Disease: Two Year Follow Up Results of Ten Cases

## Meniere Hastalığında Transtimpanik Tüp Yerleştirilmesi: 10 Vakanın 2 Yıllık Takip Sonuçları

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### ABSTRACT

**Objective:** Our aim is to evaluate the efficacy of transtympanic tube placement on hearing thresholds, tinnitus, vertigo and aural fullness in patients with medically intractable Meniere's disease (MD).

**Material and Methods:** Ten MD patients were participated in our cross sectional prospective study. A ventilation tube was placed on the affected side. The efficacy of treatment for vertigo attacks (AA0-HNS, 1995), perception of tinnitus and aural pressure were evaluated before, and one month and two years after treatment.

**Results:** One month after the insertion of the ventilation tube three patients experienced complete and five had substantial control of the vertigo. After two years, two experienced complete, two experienced substantial, four had limited, one had insignificant and one worsened control of the vertigo respectively. There were no significant difference between preoperative and postoperative (1 month and 2 years) perception of tinnitus and aural fullness ( $p<0.05$ ). There was not any significant differences between preoperative and postoperative hearing levels ( $p>0.05$ ).

**Conclusion:** Transtympanic tube placement in MD is a simple, minimally invasive, safe and effective treatment for patients with uncontrolled symptoms after medical therapy, especially in the short term (1 month).

### Keywords

*Meniere disease; tympanostomy tube insertion; hearing loss; vertigo*

### ÖZET

**Amaç:** Medikal tedaviye dirençli Meniere hastalığı olan hastalarda transtimpanik tüp yerleştirilmesinin işitme eşiklerine, tinnitus, vertigo ve kulakta basınç hissine etkisini araştırmaktır.

**Gereç ve Yöntemler:** Prospektif, kesitsel çalışmamızda 10 Meniere hastası, çalışmamıza dahil edildi. Hastaların etkilenmiş kulağına ventilasyon tüpü yerleştirildi. Uygulanan tedavinin etkinliği için, vertigo ataklarının (AA0-HNS, 1995), tinnitusun ve hastanın aural dolgunluğunun değerlendirilmesi, tedavi öncesi ve tedaviden 1 ay sonra ve 2 yıl sonra yapıldı.

**Bulgular:** Tedaviden 1 ay sonra 10 hastanın üçünde vertigonun tam, beşinde ise tama yakın kontrolü sağlandı. İki yıllık takip sonucunda 10 hastanın ikisinde tam, ikisinde tama yakın, dördünde sınırlı, birinde çok az vertigo kontrolü sağlandı. Hastaların birinde vertigoda kötüleşme tespit edildi. Transtimpanik tüp yerleştirilmesi öncesi ve sonrası (1 ay ve 2 yıl) tinnitus ve aural dolgunluk VAS değerleri arasında anlamlı farklılık vardı ( $p<0.05$ ). Hastaların işitme seviyelerinde tedavi öncesi ve sonrasında anlamlı farklılık tespit edilmedi ( $p>0.05$ ).

**Sonuç:** Meniere hastalarında transtimpanik tüp yerleştirilmesi özellikle kısa dönemde (1 ay) basit, minimal invazif, güvenli ve efektif bir tedavi yöntemidir.

### Anahtar Sözcükler

*Meniere hastalığı; timpanostomi tüpü yerleştirilmesi; işitme kaybı; vertigo*

**This study was presented as a poster at 33<sup>rd</sup> Turkish National Congress of Otorhinolaryngology and Head & Neck Surgery (October 26-30, 2011, Antalya, Turkey).**

Çalışmanın Dergiye Ulaştığı Tarih: 22.06.2014

Çalışmanın Basıma Kabul Edildiği Tarih: 17.11.2014

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## INTRODUCTION

Meniere's disease probably appears due to labyrinthine endolymphatic hydrops with periodic rupturing of the membrane that separates the endolymphatic and perilymphatic spaces.<sup>1</sup> Since its first description, the pathophysiologic mechanism and etiology have been unknown, except for a strong correlation with endolymphatic hydrops.<sup>1</sup> A classic Meniere's attack consists of rotatory vertigo, tinnitus, hearing impairment, and pressure sensation in one ear.<sup>2</sup> The natural history of the disease is variable. The lifetime prevalence of this condition is 0.5%.<sup>1,3</sup> Vertigo attacks reduce with time for about 70% of Meniere's disease patients.<sup>1,2</sup> The aim of treatment is to improve the patient's well being and to control the disease. The standard initial medical therapy is a low sodium diet and diuretic use to reduce endolymphatic volume and to control symptoms. About 30% of Meniere's disease patients have intractable vertigo despite medical therapy and may require other surgical (endolymphatic sac decompression) and unilateral vestibular ablation techniques (intratympanic gentamycin, vestibular nerve section or labyrinthectomy), which are more predictable but are invasive methods.

The absence of specific, non-destructive and safe treatment to control vertigo has motivated research into Meniere's disease. Improvement of electrophysiologic parameters were demonstrated after application of low amplitude positive pressure pulses to the middle ear.<sup>4-6</sup> Kimura and Hutta observed endolymphatic hydrops reduction after the insertion of a ventilation tube in an experimental model.<sup>7</sup> However, today the relationship between inner ear function and the middle ear is still controversial.<sup>8-11</sup> Transtympanic ventilation tube placement in patients with Meniere's disease was firstly described by Tumarkin and Lal as a noninvasive, nondestructive and safe treatment method.<sup>12,13</sup> Montandon et al. stated that vertigo attacks may be prevented in patients with Meniere's disease after ventilation tube placement.<sup>8</sup> In this paper we present the effects on hearing thresholds, clinical parameters such as tinnitus, vertigo, and perception of aural pressure after transtympanic tube placement in patients with Meniere's disease who were refractory to medical treatment.

## MATERIAL AND METHODS

This study was approved by our tertiary medical center's Clinical Research and Ethics Board. Ten Me-

niere's disease patients who were resistant to other medical therapy were included in our study. Participants were given verbal and written information about the study, and signed an informed consent form before enrollment. All patients had a diagnosis of definite Meniere's disease according to American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 1995) criteria as follows: 2 attacks of rotatory vertigo lasting/20 min; documented fluctuating hearing loss; tinnitus and/or aural fullness; underlying otologic and systemic causes excluded using a diagnostic protocol, which included clinical, magnetic resonance imaging (MRI) and laboratory studies.<sup>2</sup> The staging was 2 to 3; hearing loss in the range of 26 to 68 dB HL pure-tone average in the frequencies 500 Hz, 1 kHz, 2 kHz, and 3 kHz. All patients were between 27 and 66 years of age (Table 1). All patients should have had a history of conservative management proven to be ineffective for at least 6 months. Baseline characteristics of the study population are summarized in Table 1. Patients were excluded if they had undergone previous surgery of the inner ear, had any systemic disease requiring steroid therapy, had used diuretics or vasodilators within 2 weeks before the transtympanic tube placement, or had active bilateral disease or had undergone any previous destructive procedure (e.g., injections with gentamycin). Cases with suspicion of perilymphatic fistula as well as patients with purely vestibular symptoms were excluded. Pregnancy was also an exclusion criteria. After two years of the treatment, all of the ten patients were called in for the clinical examinations. They all accepted to come in to our clinic for the control after two years.

A grommet tube was placed in the postero-inferior quadrant of the drum in the affected side of each patient. This procedure was carried out under topical anesthesia with lidocaine drops in the external auditory canal. Patients were followed up but after 2 years most of the pa-

**Table 1.** Descriptive findings of the patients.

Patient Number	Age	Sex	Ear
1	27	Female	Left
2	37	Male	Right
3	36	Female	Right
4	44	Female	Right
5	62	Female	Left
6	43	Female	Left
7	66	Female	Left
8	47	Female	Left
9	36	Male	Left
10	53	Female	Right

tients did not visit hospital and we called all patients for the clinical examinations and all of the ten patients accepted to come to our clinic for controls. Pure-tone audiometry (PTA) was performed in a sound-proof booth, hearing thresholds being determined in 5-dB steps at 250, 500, 1000, 2000 and 4000 Hz before tube placement and one month and two years after tube placement. Hearing thresholds were averaged over all frequencies. PTA was assessed before and after (1 month, 2 years) transtympanic tube placement. Hearing change was defined as improved ( $>10$  dB), unchanged ( $\leq 10$  dB) or worse (loss of more than 10dB). Vertigo was scored and evaluated pre- and postoperatively under the guidelines proposed by the Committee on Hearing and Equilibrium in the American Academy of Otolaryngology /Head and Neck Surgery (AAO-HNS, 1995). The efficacy of treatment for vertigo attacks was evaluated by a numeric value that was calculated as the ratio of the average number of definitive spells per month for the 6 months 18 to 24 months after therapy with the average number of definitive spells per month for the 6 months before therapy, multiplied by 100. If the numeric value was 0, it was complete, 1-40 substantial, 41-80 limited, 81-120 insignificant, and  $>120$  worse (poorer) vertigo control. Visual analogue scale (VAS) evaluations were made in the presence of the study audiology assistant. Perception of tinnitus (VAS scale) and patient perception of aural pressure (VAS scale) were also evaluated before treatment and one month and two years after treatment. Wilcoxon signed ranks non-parametric test was used to compare the preoperative and post-operative differences.

## RESULTS

One of the patients had a middle ear infection after 3 months of tube placement. In six out of ten patients, ventilating tubes were reinserted after the extrusions in other clinics and after two years these six patients' ventilation tubes remained in place. In the other four cases, tubes were extruded spontaneously within 10 months after insertion. After extrusion of the tube, the tympanic membrane was intact for all patients.

### Vertigo

One month after the insertion of the ventilation tube, three of ten patients experienced complete control of vertigo and five of the ten had substantial control of the disease, one had limited and the other one insignificant control (Table 2). At a 2 year follow-up, two of the ten patients experienced complete control of vertigo,

two had substantial control of vertigo, 4 limited, 1 insignificant and one worse control of the disease (Table 2). Four patients who had not any ventilation tube after two years were in worse, insignificant and limited vertigo control group.

### Hearing Thresholds

In the study group one month after transtympanic tube insertion, five of the ten patients' hearing thresholds were unchanged, the other five were improved (Table 3). At the two year follow-up, 9 of the 10 patients' hearing thresholds were unchanged.

### Tinnitus and Aural fullness

One month after transtympanic tube insertion, five of the ten patients' hearing thresholds were unchanged, the other five were improved. At the two year follow-

**Table 2.** Control of vertigo after transtympanic tube placement.

Patient Number	Post-1 month	Post-2 year
1	Complete	Complete
2	Complete	Complete
3	Substantial	Insignificant
4	Substantial	Substantial
5	Substantial	Limited
6	Substantial	Limited
7	Limited	Limited
8	Complete	Substantial
9	Substantial	Limited
10	Insignificant	Worse

**Table 3.** Hearing threshold levels before and after transtympanic tube placement treatment.

Patient Number	Pretreatment	Post-1 month	Post-2 year
1	30 dB	22 dB (unchanged)	25 dB (unchanged)
2	33 dB	13 dB (improved)	10 dB (improved)
3	35 dB	25 dB (unchanged)	25 dB (unchanged)
4	28 dB	25 dB (unchanged)	25 dB (unchanged)
5	68 dB	60 dB (unchanged)	78 dB (unchanged)
6	65 dB	55 dB (improved)	65 dB (unchanged)
7	46 dB	30 dB (improved)	33 dB (unchanged)
8	30 dB	20 dB (improved)	33 dB (unchanged)
9	55 dB	40 dB (improved)	55 dB (unchanged)
10	45 dB	50 dB (unchanged)	50 dB (unchanged)

up, 9 of the ten patients' hearing thresholds were unchanged. There was a significant difference between preoperative and postoperative VAS values of tinnitus (postoperative 1 month  $p=0.005$ , postoperative two year  $p=0.007$ ). Aural fullness was also significantly reduced one month ( $p=0.005$ ) and 2 years ( $p=0.007$ ) after transtympanic tube placement (Table 4).

## DISCUSSION

The initial step in the treatment of Meniere's disease consists of dietary advice and medical management to control the disease. However, in intractable cases more invasive and ablative treatment modalities that involve risks and complications are required. The insertion of transtympanic ventilation tubes in Meniere's disease patients who were resistant to medical therapy is non-destructive and has the least complications.

Pressure changes affect cochlear and vestibular functions. Knowledge of this fact led researchers to study the influence of external pressure changes on vestibulocochlear functions and endolymphatic hydrops. The clinical idea to place a ventilation tube in the endolymphatic hydrops emerged after electrophysiological experiments.<sup>4,7</sup> Densert et al. and Ingelstedt et al. demonstrated relief of acute cochlear and vestibular symptoms when patients were exposed to a relative over-pressure in the middle ear.<sup>4,7</sup> Animal studies first demonstrated a reduction in endolymphatic hydrops after ventilation tube placement.<sup>7</sup> Tumarkin first described inner ear pressure sensitivity to static pressure changes and placement of transtympanic tube applied with reduced middle-ear ventilation via the eustachian tube in patients with endolymphatic hydrops.<sup>1</sup> Then Lall, Hall and Brackmann studied the relationship between endolymphatic hydrops and eustachian tube function.<sup>13,14</sup> They did not observe any correlation between Meniere's disease and eustachian tube function. Montandon et al. observed a prevention of occurrence of vertiginous attacks in 82% of a series of 28 patients suffering typical Meniere's disease with incapacitating vertigo resistant to medical treatment.<sup>8</sup> Sugawara et al. mentioned the ventilation tube's therapeutic effect as limited.<sup>15</sup> Park et al. showed an improvement of disability from vertigo after transtympanic ventilation tube insertion, although an effect on vestibular function was not seen.<sup>16</sup> The reason for the discrepancies between the studies may arise from different study populations or from small sample sizes in general.

**Table 4.** Comparison of preoperative and postoperative VAS values of tinnitus and aural fullness.

	Pre-treatment	Post-one month	p value
Mean tinnitus VAS values	8.1±1.1	4.8±1.7	0.005
	Pre-treatment	Post-two year	p value
Mean tinnitus VAS values	8.1±1.1	4.4±2.4	0.007
	Pre-treatment	Post-one month	p value
Mean aural fullness VAS values	8.2±0.9	3.6±2.3	0.005
	Pre-treatment	Post-two year	p value
Mean aural fullness VAS values	8.2±0.9	3.7±2.9	0.007

There are several hypotheses that explain the effects of pressure variations on the ear with endolymphatic hydrops. Initially, it was thought that an increase in middle ear pressure may cause decongestion of the labyrinthine vascular bed so that drainage of the endolymph to the endolymphatic duct and sac is improved. Later studies of the intralabyrinthine pressure in animals showed the displacement of an excess of endolymph out of the labyrinth and finally an endolymphatic hydrops reduction.<sup>17</sup> Sakikawa investigated the possibility of other mechanisms being responsible for the reduction in endolymphatic hydrops using experimental animals and found the stria vascularis and surrounding tissues as the routes for the reduction of endolymph volume under an increase in perilymph pressure.<sup>18</sup> Kitahara et al. suggested short-term pressure changes may affect the inner ear fluid and change hearing in patients with Meniere's disease but not in normal subjects.<sup>19</sup> When the tympanic membrane is perforated, the middle ear pressure increases. After the pressures changes, we can postulate that as a consequence, middle ear and inner ear oxygen pressure increases, so ventilation of the middle ear could be helpful for preventing the development of hydrops. Although it is assumed that the control of vertigo by means of middle ear pressure application is obtained by reduction of the membranous labyrinth distention, the exact mechanism of influence of external pressure on the hydrodynamic conditions of the inner ear is not well known. Apart from ventilation tube placement, a new, non-invasive treatment for Meniere's disease has been proposed using the Meniett pressure generator, which applies pressure pulses of predetermined parameters through a ventilation tube to the middle ear.

The effectiveness of transtympanic tube placement and the Meniett pressure generator is controversial.<sup>20-24</sup> Strokkroos et al. studied the effect of the Meniett device

on caloric stimulation findings in Meniere's disease.<sup>20</sup> Thompson et al. found that the Meniett device significantly reduced vestibular symptoms in patients with Ménière's disease in a randomized, multicenter, double-blind, placebo-controlled study.<sup>21</sup> According to experimental studies, most of the authors hypothesize that ventilation of the middle ear can prevent endolymphatic hydrops. However, this hypothesis has some handicaps, such as the indistinctness of the time of endolymphatic hydrops findings in Meniere's disease, whether at an early or late stage of the disease, and the absence of a correlation between the presence and degree of hydrops and the duration and stage of the disease. According to these findings, one would expect that middle ear ventilation in longstanding Meniere's disease would rarely be successful. However, Barbara et al. demonstrated that middle ear ventilation alone improved symptoms in the majority of patients regardless of duration of the disease.<sup>23</sup> Sugawara et al. described the short-term effect of transtympanic tube placement for the reduction of persistent vertigo in some patients with Meniere's disease.<sup>15</sup> In our study, transtympanic tube placement is effective for reducing vertigo attacks in nine of the ten patients who were suffering typical Meniere's syndrome with vertigo resistant to medical treatment, after one month, but two years later only five of ten patients had substantial and complete vertigo control. Hearing loss was unchanged in most of the patients, as in the previous studies. However tinnitus and aural fullness were significantly decreased one month and 2 years after transtympanic tube placement.

In this study, we used Shepard Grommet ventilation tubes. However, these tubes are short term and are

expelled after 6-12 months. When the symptoms of the disease occur, the transtympanic tube has to be placed again. As an alternative, permanent ventilation tube placement can be considered, but the main risk of permanent tube placement is the possibility of tympanic membrane perforation. Another issue is the status of the symptoms after extrusion of the ventilation tubes. The response of patients after ventilation tube extrusion has to be observed in further studies. Ventilation tube placement should be considered upon failure of standard medical management, before planning ablative surgical treatment methods.

One limitation of our study was that the number of patients was small (ten). Also the main reason for the reduction of vertigo, tinnitus and aural fullness may have been due to oxygenation of the middle ear, since after two years some of the patients' ventilation tubes expelled and the symptoms improved. We do not know the actual reason and can only suggest this reason for the symptom changes. These results might also have been the natural course of the Meniere disease or a placebo effect.

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## CONCLUSION

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In conclusion, our results support that transtympanic tube placement reduces vertigo spells, tinnitus and aural fullness at one month and two year follow-ups. The transtympanic tube placement should be considered in patients with Meniere disease who are intractable to medical therapy.

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