

# Transtympanic Gentamicin Treatment in Meniere's Disease: A Preliminary Report

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**Objective:** To evaluate the effectiveness of transtympanic gentamicin treatment in Meniere's disease.

**Material and Method:** The present study is a prospective study of 8 patients in Ramathibodi Hospital who had transtympanic gentamicin treatment of Meniere's disease by fixed dose regimen of 12 injections during a period of 4 days. The committee on hearing and equilibrium guidelines for reporting treatment results in Meniere's disease of the American Academy of Otolaryngology and Head & Neck Surgery (1995) were used. Paired t-test or Wilcoxon Signed Ranks Test was used for statistical comparisons.

**Results:** Among 8 patients, there were 2 males and 6 females. All patients (100%) had either complete (37.5%) or substantial (62.5%) control of vertigo. Disability was also improved in all of the subjects (100%). Tinnitus was improved in 62.5%. Their tinnitus score and functional level scale were much improved with statistical significance ( $p = 0.001$ ,  $p < 0.005$ , respectively). Hearing was unchanged in 87.5% and slightly worse in 12.5%. This was not significant.

**Conclusion:** Transtympanic gentamicin treatment was found to be an effective treatment option for patients with disabling or intractable Meniere's disease, with a low incidence of hearing loss. The use of this method appears to be practical and may replace the vestibular surgery.

**Keywords:** Meniere's disease, Vertigo, Tinnitus, Pure tone average, functional level scale, Transtympanic gentamicin

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Meniere's disease or endolymphatic hydrops of the inner ear has an unknown etiology<sup>(1)</sup>. Most patients have symptoms of vertigo, sensorineural hearing loss, tinnitus and aural fullness. The course of the disease is progressive. A similar incidence is found in both sexes and it mostly occurs in the 4<sup>th</sup> to 6<sup>th</sup> decades. However, the most disrupted symptom to daily functional life is the vertigo that can last hours or days. For these reasons, the study according to the Meniere's treatment is widely performed in a search for a non-invasive way of treatment for vertigo control as well as hearing preservation.

Many theories have been proposed for the etiology of Meniere's. However, the pathophysiology continues to be idiopathic. The majority of patients

respond to medical treatments consisting of a salt restricted diet, coffee avoidance, alcohol and stress control, together with oral medications of antiemetic, antivertiginous, diuretics, antidepressants and vasodilators. The effectiveness of using diuretics in symptom control has been reported to be 58%<sup>(2)</sup>. Betahistine derivatives are widely used in Meniere's disease<sup>(3)</sup>. Other paramedical treatment reports include acupuncture, herbal medication and hyperbaric pressure chamber<sup>(4,5)</sup>. These methods are only supportive and not a cure treatment.

10-20% of Meniere's patients do not respond to the above management. Such failure of medical treatment has continued to be a challenge, since the surgical destruction of the inner ear is the definitive method<sup>(6,7)</sup>. This invasive method includes endolymphatic sac decompression and shunt, vestibular neurectomy, and labyrinthectomy. The chemical ablation

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is another alternative method standing between the oral medical and destructive surgical treatment. Shea and Ge<sup>(8)</sup> referred to the old literature of Joseph Hawkins in 1948 who was the first to use streptomycin intramuscular injection for treatment of Meniere's patients who did not respond to medical treatment. In 1957 Schuknecht<sup>(9)</sup> reported using streptomycin injected into the tympanum of eight cases and found that vertigo was controlled in five cases but all had profound hearing loss. This made the method unpopular, until Lang<sup>(10)</sup> in 1989 reported good control of vertigo by using gentamicin instead of streptomycin injected intratympanically. This was popularized by Nedzelsky et al<sup>(11)</sup> in 1992. This method of local instillation of gentamicin into the middle ear appears to be noninvasive and practical, with low morbidity. It soon became an alternative treatment for intractable Meniere's disease.

The aim of the present study was to report the preliminary result of transtympanic gentamicin treatment of disable Meniere's patients in Ramathibodi Hospital.

#### **Material and Method**

This prospective study was conducted from March 1999 to December 2000 at the Otolaryngology Department, Ramathibodi Hospital, Faculty of Medicine, Mahidol University.

#### **Patients**

Adult patients in whom intractable or disabling Meniere's disease had persisted for more than 6 months were selected. Inclusion criteria: A patient with the diagnosis of unilateral Meniere's disease by following the "Committee on Hearing and Equilibrium Guidelines for diagnosis and evaluation of therapy in Meniere's disease (1995)"<sup>(1)</sup>. All had active symptoms of vertigo, fluctuating sensorineural hearing loss by pure tone audiometry at 0.5, 1, 2, 3 kHz more than 40 decibels or speech discrimination score less than 50% and active tinnitus aurium. All had full medical treatment for at least 6 months without improvement and those symptoms had significantly affected their normal daily activities. Exclusion criteria: A patient who had otitis media, had allergy to aminoglycoside, had only one-hearing ear or other risk with the use of aminoglycosides.

#### **Method**

A detailed history with particular reference to the frequency and duration of vertigo was documented. Questionnaire tests of tinnitus and functional level scale

of vertigo according to "Committee on Hearing and Equilibrium Guidelines for Diagnosis and Evaluation of Therapy in Meniere's disease (1995)"<sup>(1)</sup> were individually evaluated pre- and 6-months post treatment. Routine physical examination, audiologic and neuro-otological examinations were carried out in each patient. Explanation related to the disease was given and this particular choice of treatment was then performed with the patient's informed consent.

The method of intratympanic gentamicin administration was done by performing a myringotomy at the postero-inferior part of tympanic membrane under local anesthesia. A self-prepared long tympanostomy tube was gently inserted into the fitted myringotomy hole. The outer part of the tube was connected to the butterfly intravenous fluid set. The needle end was cut and the tube was placed in circle and strapped to the pinna. The injection of gentamicin would be easily done through the injection site of the connected intravenous set. Gentamicin solution of 26.4 mg/ml at pH 6.4 was freshly prepared using gentamicin 40 mg/ml and 7.5% NaHCO<sub>3</sub>. The fixed dose regimen of 4-days' period was used in the present study by injecting gentamicin (26.4mg/ml), 0.65 ml per dose for 12 doses, making a total of 206 mg. The injection would be terminated if there was any inappropriate symptom of inner ear disease.

The statistical analysis of this prospective study (one-group, pre-test, post-test design) was done on demographic data, daily functional scale, average hearing threshold and speech discrimination score, tinnitus score before and 6-months after treatment by paired t-test or Wilcoxon Signed Ranks test with  $p < 0.05$  was of significant difference.

#### **Results**

The demographic data and results of eight patients treated with local gentamicin are summarized in Table 1. There were six males and two females, age ranging between 26 and 70 years (average 49.25 years). Both ears were equally involved. The average length of time before treatment was 10.8 months (range: 6 to 18 months). There were 75% of the patients who received treatment with more than three drugs. Two patients (number 3 and 6) received this treatment for the second time because they were diagnosed with recurrent and bilateral Meniere's disease, respectively. Table 2 shows the results of vertigo control, the functional level scale, the average hearing threshold, speech discrimination score and tinnitus score at the time of 6-month post treatment. The authors found that all

**Table 1.** Demographic data of patients

Patients	sex	age	site	Duration of disease	Tinnitus score before Rx	Tinnitus score after Rx	No. of vertigo before Rx	No. of vertigo after Rx	Medication and duration of Rx	Follow-up (month)
1	F	45	L	105	9	6	4	0	Oral med 105 months	18
2	F	43	R	53	8	5	5	0	Oral med 27 months	18
3	M	52	R	38	11	7	3	2	Previous transtympanic gentamicin left ear 24 months	11
4	F	26	R	32	8	8	2	0	Oral med 25 months	10
5	F	57	L	21	5	4	1	0	Oral med 13 months	7
6	F	52	L	41	8	4	6	0	Oral med 37 months	7
7	M	48	L	56	10	4	1	0	Previous transtympanic gentamicin left ear 18 months	7
8	F	70	R	12	11	9	15	2	Oral med 7 months	6

**Table 2.** Results of post treatment with gentamicin

	Vertigo (number of cases)	Daily functional life	Average hearing level	Speech discrimination score	Tinnitus
Improve	8/8 (100%)	8/8 (100%)	0	1/8 (12.5%)	7/8 (87.5%)
Same	0	0	7/8 (87.5%)	4/8 (50%)	1/8 (12.5%)
Deteriorate	0	0	1/8 (12.5%)	3/8 (37.5%)	0

patients had improvement in their vertigo control. The vertigo control after treatment using a numeric value showed that all were free of vertigo, absolutely in 37.5% and had occasional unsteadiness in 62.5% (Table 3).

For the results of the functional level scale, three cases were in level 3, four cases in level 4 and one case in level 6. After treatment, those three cases in level 3 and one case in level 4 changed into level 1. This meant that they enjoyed their functional life better. The other two from level 4 had changed to level 2. They had to stop when vertigo attacked but could continue their daily life. The most symptomatic patient from level 6 had improved to level 3 where he still had the vertigo and had to adapt his functional life. These results showed that all patients (100%) had improvement in

their daily functional activities (Table 2). The functional level scale was shown to be statistical significance between pre and post treatment ( $p = 0.001$ , Table 4).

The pure tone average (PTA) at 0.5, 1, 2 and 3 kHz at 6-month pre and post treatment were evaluated. The PTA was classified into 4 groups: group 1 had PTA 0-25 dB, group 2 had PTA 26-40dB, group 3 had PTA 41-70 dB, and group 4 had PTA more than 70 dB. Before the treatment, there was none in group 1 and only one case in group 2, five cases were in group 3 and two cases were in group 4. After treatment, seven cases (87.5%) were in the same group as before, showing that their PTA had changed less than 10 dB. The hearing had been worsened in one case (12.5%) and none had hearing improvement (Table 2). There was no statisti-

**Table 3.** Results of vertigo control (Numeric value )

Control of definite spells	Numeric value*	6-months post treatment	Percent
Complete	0	3	37.5
Substantial	1-40	5	62.5
Limited	41-80	0	0
Insignificant	81-120	0	0
Worse	>120	0	0

\* numeric value =  $\frac{\text{number of vertigo attacks per month (6 months after treatment)}}{\text{number of vertigo attacks per month (6 months before treatment)}} \times 100$

**Table 4.** Results of average parameters before and after treatment with gentamicin

Parameters	6 months before treatment	6 months after treatment	p-value
Functional level scale	3.88 ± 0.99	1.62 ± 0.74	0.001
PTA (decibels)	58.03 ± 15.7	61.06 ± 17.53	0.176
SDS	52.00 ± 31.57	48.50 ± 27.33	0.351
Tinnitus score	8.75 ± 1.98	5.88 ± 1.96	0.004

cal difference of PTA between pre and post treatment ( $p > 0.05$ , Table 4). Post treatment of the speech discrimination score showed improvement of more than 15% in one case, decreased for more than 15% in three cases, and four cases remained at the same level, having their scores change by less than 15% (Table 2). There was no statistical significance between pre and post treatment ( $p > 0.05$ , Table 4).

Every patient had tinnitus with various severities. The tinnitus score before and after treatment is shown in Table 1. Seven cases had decreased score, meaning improvement, whereas only one remained unchanged. Comparison before and after treatment showed a significant improvement ( $p < 0.005$ , Table 4).

### Discussion

Based on a retrospective review of the previous intratympanic injection studies<sup>(11-24)</sup>, both protocols of a daily fixed dose and titration technique yielded a similar success rate in controlling vertigo. However, the ideal, smallest dose that would eliminate vertigo, while sparing hearing, is still being sought. This review of 14 studies is shown in Table 5<sup>(11-24)</sup>. Patients ranged from 8 to 93 cases, using a dose from 10 to 320 mg. and the number of injections ranged from 1 to 12 times. Post treatment could control vertigo in 81 to 100%, while hearing deterioration occurred in 10 to 75%. Only 2 studies showed hearing reduction of more than 50%. The present study used fixed drug

regimen of 206 mg, divided in 12 doses, administered every 8 hours for 4 days. When compared to those studies<sup>(11,16-18,23)</sup> using the same method of drug administration, it shows similar results of vertigo control and hearing preserved. Kaplan, et al<sup>(23)</sup> recently reported 90 patients by using fixed dose regimen of gentamicin 26.7 mg/ml, 0.7 ml intratympanic injection of 12 doses every 8 hours in 4 days. They reported 84.4% were free of vertigo and 9% had minimal vertigo. Hearing was preserved at the same level in 48.2% but with a reduction in 25.6%. In Thailand, Saowaros and Karnjana<sup>(24)</sup> have reported using gentamicin 40 mg/ml, 0.4-0.6 ml intratympanic injection of 9 doses, every 8 hours for 3 days in 8 patients, and found that 7/8 (87.5%) were completely free from vertigo, the last patient had minimal vertigo at the 14<sup>th</sup> month. All could work and perform their daily functional activity, but the hearing was deteriorated in 50% of the cases, improved in 25% and remained as previous in 25%.

The suggested mechanism of ototoxicity is damage done to the endolymph secreting dark cells located in the crista ampullaris of the semicircular canals, the posterior wall of the utricle, and the lateral wall of the crus communes, resulting in reduction of endolymph production<sup>(25-28)</sup>.

The ototoxic activity has made aminoglycoside become a drug used in selective treatment in intractable Meniere's disease. However, controversies exist according to the dose, concentration, amount

**Table 5.** Results of treatment in other reports

Reports	Number of patients	Methods and dosage	Percent of vertigo improvement	Percent of hearing reduction
Schmidt, Beck and Lange (1980) <sup>(12)</sup>	40	Fixed dose 144 mg	93	15
Odkvist (1988) <sup>(13)</sup>	29	Fixed dose 130 mg	97	31
Moller and Odkvist (1988) <sup>(14)</sup>	15	Fixed dose 200 mg	93	33
Nedzelski et al. (1992) <sup>(11)</sup>	20	Fixed dose 208 mg	90	15
Youssef and Poe (1995) <sup>(15)</sup>	37	Titration dose 30 mg weekly, 1-8 wks	87	28
Corsten et al. (1997) <sup>(16)</sup>	21	Fixed dose 216 mg divided into 12 times	81	75
Pfleider (1998) <sup>(17)</sup>	25	Fixed dose 320 mg divided into 12 times	87	12
Mc Feely (1998) <sup>(18)</sup>	25	Fixed dose 320 mg once daily 12 times	88	20
Kaasinen et al. (1998) <sup>(19)</sup>	93	Fixed dose 160 mg once daily, 4 days	81	10
Minor (1999) <sup>(20)</sup>	34	Titration dose 26 mg weekly, 1-6 wks	91	32
Atlas and Parnes (1999) <sup>(21)</sup>	68	Titration dose 13-26 mg weekly, 1-8 wks	90	17
Hirsh and Kamerer (1999) <sup>(22)</sup>	28	Titration dose 15 mg weekly, 1-9 wks	91	31
Kaplan et al. (2000) <sup>(23)</sup>	90	Fixed dose 320 mg divided into 12 dose	90	25
Saowaros and Karnjana (1998) <sup>(24)</sup>	3	Fixed dose 216 mg divided into 9 dose	100	50
This study (2000)	8	Fixed dose 206 mg divided into 12 dose	100	12.5

and method of administration. This is still under investigation.

Although a variety of drug concentrations has been reported ranging from 26 to 40 mg/ml, successful control of vertigo has been achieved with each of the concentrations. The concentration might not be the important indicator of the treatment's success. The amount of drug injection has been reported ranging from 0.4 to 1 ml. This should depend on the size of the middle cavity and the function of eustachian tube. The authors have found that the dose of the drug is absolutely proper, painless, and without membrane distension. Different methods have been used to deliver gentamicin into the middle ear. The authors prefer using a long catheter tube retained at the tympanic membrane. This is more practical and easy to perform. The effectiveness of gentamicin therapy also depends on the successful absorption into the inner ear via the round window membrane. It is impor-

tant to warn the patient about the possible occurrence of vertigo during the second to fourth week post treatment, waiting for unilateral vestibular compensation. Most patients will compensate well and have a better daily functional life after receiving gentamicin transtympanic treatment.

In conclusion, transtympanic gentamicin treatment is an effective treatment option for patients with disabling or retractable Meniere's disease, with a low incidence of hearing loss. The use of this method appears to be practical and may replace the vestibular surgery.

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## การรักษาผู้ป่วยโรคมีเนียร์โดยวิธีการฉีดยาเจนตามัยซินเข้าหูชั้นกลาง: รายงานเบื้องต้น

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**วัตถุประสงค์:** เพื่อศึกษาผลของการรักษาโดยวิธีการฉีดยาเจนตามัยซินเข้าหูชั้นกลางผ่านทางแก้วหูในผู้ป่วยโรคมีเนียร์

**วัสดุและวิธีการ:** การศึกษานี้เป็นชนิดศึกษาไปข้างหน้า ทำการศึกษาในผู้ป่วยโรคมีเนียร์ที่ไม่สามารถควบคุมอาการได้ด้วยการรับประทานยาจำนวน 8 รายที่มารับการรักษาในโรงพยาบาลรามธิบดี โดยวิธีการฉีดยาเจนตามัยซินเข้าหูชั้นกลางผ่านทางแก้วหู ผู้ป่วยแต่ละรายได้รับปริมาณยาเท่ากัน 12 ครั้ง ในเวลา 4 วัน ประเมินผลการรักษาโดยใช้แนวทางตามคู่มือ American Academy of Otolaryngology and Head & Neck Surgery สถิติศึกษาใช้ Paired t-test

**ผลการศึกษา:** ผู้ป่วยทั้งหมด 8 รายเป็นชาย 2 ราย หญิง 6 ราย ทุกคนหายจากอาการเวียนศีรษะบ้านหมุน โดยร้อยละ 37.5 หายขาด และสามารถกลับไปทำงานได้ อาการเสียงรบกวนดังในหูลดลงร้อยละ 62.5 เมื่อวัดเป็นคะแนน พบว่าทั้งอาการเสียงดังรบกวนในหูที่ลดลงและระดับความสามารถในการดำรงชีวิตประจำวันที่ดีขึ้นมีการเปลี่ยนแปลงอย่างมีนัยสำคัญทางสถิติ ( $p=0.001$  และ  $p<0.005$  ตามลำดับ) ผู้ป่วยร้อยละ 87.5 มีระดับการได้ยินเท่าเดิม และร้อยละ 12.5 มีระดับการได้ยินแยลงเพียงเล็กน้อย

**สรุป:** วิธีการฉีดยาเจนตามัยซินเข้าหูชั้นกลางมีประสิทธิภาพในการควบคุมอาการเวียนศีรษะบ้านหมุนและเสียงดังรบกวนในหู ทำให้ผู้ป่วยสามารถดำรงชีวิตประจำวันได้ดีขึ้น โดยที่ระดับการได้ยินไม่ต่างไปจากเดิมมากนัก การรักษานี้เพื่อเป็นอีกทางเลือกสำหรับผู้ป่วยโรคมีเนียร์ที่มีอาการมาก ไม่สามารถควบคุมได้ด้วยยารับประทาน และยังไม่อยากเข้ารับการผ่าตัดทำลายระบบการทรงตัว

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