Low Dose Transtympanic Gentamicin Treatment for Intractable Meniere's Disease: A Prospective Study

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Objective: *To evaluate the effectiveness of low dose transtympanic gentamicin treatment in Meniere's disease.*
Material and Method: *Prospective study of 20 disable Meniere's patients in Ramathibodi Hospital who received transtympanic gentamicin treatment for Meniere's disease by fixed dose regimen of 12 injections during a period of 4 days. The study took place from March 1999 to December 2004. The 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. The outcomes of treatment were evaluated at the 6th month. The multivariate repeated measures ANOVA was used for statistical comparisons.*
Results: *During the 5-year period, there were 20 patients, 9 men, and 11 women. The six-month outcomes of vertigo control, the functional level scale and tinnitus score were significantly improved by the treatment. Whereas, the mid frequency pure tone threshold average and the speech discrimination score were not significantly affected.*
Conclusion: *Fixed low dose 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 deterioration. The use of this method appears to be practical and has been set as the standard protocol replacing the vestibular surgery in Ramathibodi Hospital.*

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

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Meniere's disease is one of the chronic miserable diseases. Although many theories have been proposed for its etiology, the pathophysiology has continued to be idiopathic[1]. Treatment for Meniere's disease is usually directed to control the vertigo, which is the most miserable symptom lasting hours or days, besides the hearing loss, tinnitus and aural fullness. The majority of cases respond to medical treatments which consist of salt restricted diet, coffee and alcohol avoidance, stress control, together with oral medications of antiemetic, anti-vertiginous, diuretics, antidepressants and vasodilators in which betahistine derivatives are widely used[2]. The invasive surgical method is reserved for individuals, the minority that fails medical treatment. Traditionally, they are endolymphatic sac decompression or shunt surgery, vestibular neurectomy, and labyrinthectomy. Recently, over the past decade, intratympanic gentamicin has become a new alternative treatment modality for intractable Meniere's disease[3,4]. It has gained widespread popularity standing between the oral medication and destructive surgical treatment.

A large number of reports and a few meta-analyses have been published in terms of the effective outcome of this treatment[3-17]. However, the appropriate dosage and delivery routes for the most effective outcome of vertigo control as well as hearing preservation are still being searched. This has encouraged an increasing number of otologists to approach studying this way of treatment. The objective of the present study was to report the outcome of the authors' 5-year

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study of treatment, introducing and discussing the regimen and a practical way of instilling gentamicin transtympanically.

Material and Method

This prospective study was conducted from March 1999 to December 2004 at the Otolaryngology Department, Ramathibodi Hospital, Faculty of Medicine, Mahidol University, Bangkok, Thailand.

Patients

From 200 patients of the neuro-otological clinic, 20 adult patients in whom intractable Meniere's disease had persisted for more than 6 months were selected. Inclusion criteria included a patient who was diagnosed with unilateral Meniere's disease by following the guidelines of the "Committee on Hearing and Equilibrium Guidelines for diagnosis and evaluation of therapy in Meniere's disease (1995)"[1]. All patients had active symptoms of vertigo, fluctuating sensorineural hearing loss by pure tone audiometry at 0.5, 1, 2, 3 kHz of more than 40 decibels, or speech discrimination score less than 50% and active tinnitus aurium. They must have full medical treatment at least 6 months without improvement and those symptoms had significantly affected their normal daily activities. Exclusion criteria included patients who had otitis media, were allergic to aminoglycoside, had only one-hearing ear, or had other risks with the use of aminoglycosides.

Method

A detailed history with particular reference to the frequency and duration of vertigo was documented. Questionnaire tests for functional level scale (Table 1) and tinnitus score (Table 2) adapted from the guidelines of the "Committee on Hearing and Equilibrium Guidelines for Diagnosis and Evaluation of Therapy in Meniere's disease (1995)"[1] were individually evaluated at pre and 6-month post treatment. According to the questionnaire tests. The patients were classified into different levels of daily functional activities and tinnitus scores were calculated. Routine physical examination, audiological and neuro-otological examinations were carried out in each patient. Explanation related to the disease and this particular choice of treatment was performed then with the patient's decision and informed consent.

After admission, intratympanic gentamicin administration would be done via a specially-designed tympanostomy tube, inserted at a myringotomy hole at the postero-inferior part of the tympanic membrane. A long tympanostomy tube was used and it was prepared by cutting a 5 cm long polyethylene tube from a polyethylene tubing package, I.D. 1.14 mm, O.D.1.57 mm. Heating one end and flattened to flare it out (Fig. 1) then sent for sterilization. The outer part of the tube was extendedly connected to the scalp vein intravenous fluid set in which the needle end was cut (Fig. 2). This long tube was gently inserted into the fitted my-

Table 1. Questionnaire test for functional level scale

Level 1	My dizziness has no effect on my activities at all
Level 2	When I am dizzy I have to stop what I am doing for a while, but it soon passes and I can resume activities, I continue to work, drive, and engage in any activity I choose without restriction, I have not changed any plans or activities to accommodate my dizziness
Level 3	When I am dizzy I have to stop what I am doing for a while, but it does pass and I can resume activities, I continue to work, drive, and engage in most activities I choose, but I have had to change some plans and make some allowances for my dizziness
Level 4	I am able to work, drive, travel, take care of a family, or engage in most essential activities, but I must exert a great deal of effort to do so, I must constantly make adjustments in my activities and budget my energies. I am barely making it
Level 5	I am unable to work, drive or take care of a family, I am unable to do most of the active things that I used to, even essential activities must be limited. I am disabled
Level 6	I have been disabled for 1 year or longer and/or I receive compensation (money) because of my dizziness or balance problem

Fig. 1 The polyethylene tube, prepared by heating one end and flattened to flare it out

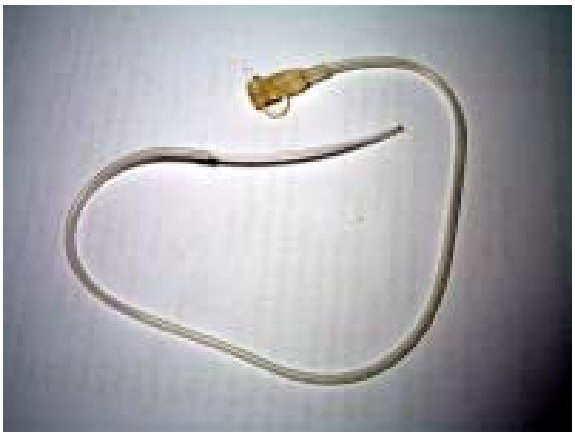

Fig. 2 The long polyethylene tube was connected to the scalp vein intravenous fluid set in which needle end was cut

ringotomy hole, outer part was strapped to the pinna (Fig. 3). The injection of gentamicin would be easily done through the injection site of the extension set. Gentamicin solution of 26.4 mg/ml at pH 6.4 was freshly prepared by the hospital pharmacy and the fixed dose regimen of 4-day period was used by injecting gentamicin (26.4mg/ml), 0.65 ml per dose for 12 doses, made total of 206 mg. The drug was extremely slowly pushed into the middle ear and that left in the extension tube was totally re-pushed by air. The injection would be terminated if there were any inappropriate symptoms especially of inner ear disease or patient's rejection.

The statistical analysis of this prospective study was done on demographic data, daily functional level scale, averaged hearing threshold, speech discrimination score, and tinnitus score at pre and 6-month post treatment by multivariate repeated measures ANOVA. Significance was defined as $p < 0.01$.

Results

The demographic data of 20 patients treated with local gentamicin included 9 men and 11 women, left and right sides were 11 and 9, respectively. Mean age was 48.50 $\pm$ 10.53 years (range: 26 to 70 years),

Table 2. Questionnaire test for tinnitus score

1 Loudness of tinnitus	
1 point	Tinnitus is not noticed
2 points	Tinnitus is mildly noticed
3 points	Tinnitus is moderately noticing
4 points	Tinnitus is noisy
5 points	Tinnitus is noisy and uncomfortable
2 Level of interference	
1 point	You need an intention to be aware of tinnitus
2 points	Tinnitus is seldom present and can be overlooked
3 points	Tinnitus is always present
4 points	Tinnitus annoys you and causes stress
5 points	Tinnitus bothers you all the time even when you relax
3 Level of activity disturbance	
1 point	Tinnitus does not cause trouble to your daily activity
2 points	Tinnitus causes some trouble but you can do your daily activities
3 points	Tinnitus moderately interferes with your daily activity
4 points	You are disturbed by tinnitus and can do only simple activities
5 points	You are disturbed by tinnitus and can not do any activity

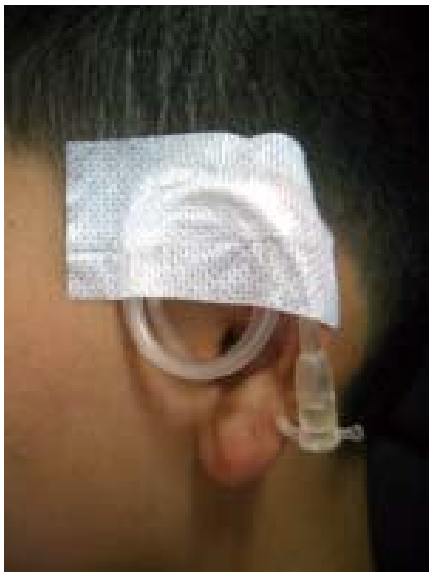

Fig. 3 The long tube was fitted into the myringotomy hole and the outer extension tube wasstrapped circularly at the pinna

length of time before treatment was 43.35 ± 24.78 months (range: 10 to 105 months). There were 75% of the patients who received previous oral treatment with more than three drugs. Two patients received this treatment for the second time because they were diagnosed of recurrent and bilateral Meniere's disease, respectively. The results are displayed in Table 3.

The result of vertigo control (VER) at the end of the 6-month post treatment showed that all patients had improvement in their vertigo control. Seventy-five percent of the patients were completely controlled and they were free of vertigo, the remaining 25% were satisfied with the treatment. The results are shown in Table 4.

From the classification of the functional level scale (FLS) (Table 1), the results prior to treatment showed that all patients were in level 3 and higher levels: 9 cases were in level 3, 7 cases were in level 4, each 2 cases were in level 5 and 6, respectively. Six-month post treatment, ninety-five percent of the patients (19 of 20) had changed to the lower (better) levels. Fifty percent of the patients (10 of 20) had changed to level 1 in which their daily functional life had become completely normal. Forty-five percent (9 of 20) had changed to level 2 and 3 in which they had to cease their activities sometimes when they had vertigo (level 2), and had to change some daily performance but still could drive and work (level 3). This showed that 95% of the patients had an improvement and had enjoyed their functional life better than before. Only one case (5%) had a worsened functional life changing from level 3 to 4. Interestingly, the two most disabled cases in level 6 had changed to level 1 and 3 respectively. The results are shown in Table 5.

The pure tone threshold 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 (normal) had PTA 0-25 dB, group 2 (mild) had PTA 26-50 dB, group 3 (moderate) had PTA 51-75 dB, and group 4 (severe) had PTA more than 76 dB. Before the treatment, there were none in the normal group, four

Table 3. Demographic data of patients (n = 20)

Categorical variables							
Demographic variables		Group		Frequency		Percentage	
1. Gender		1.1 men		9		45.00	
		1.2 women		11		55.00	
2. Ear side		2.1 left		11		55.00	
		2.1 right		9		45.00	
Continuous variables							
Demographic variables	Mean	SD	Max	Min	CV	Skewness	Kurtosis
1. Age (years)	48.50	10.53	70.00	26.00	0.22	-0.13^{ns}	0.14 ^{ns}
2. Length of time before treatment (months)	43.35	24.78	105.00	10.00	0.57	0.93^{ns}	0.68 ^{ns}

note: ^{ns} = non-significant; standard error for skewness = .512; standard error for kurtosis = .992

Table 4. Results of vertigo control (VER) 6 months after treatment

Level of control	Vertigo control (%)
Improved	20 (100)
Same	0 (0)
Deteriorated	0 (0)
Total	20 (100)
Level of definite spells/ Numeric value*	**6-month after treatment (%)**
Complete/0	15 (75)
Satisfied/1-80	5 (25)
Limited/81-120	0 (0)
Worse/> 120	0 (0)
Total	20 (100)

* Numeric value = number of vertigo attacks per month (6 months after treatment) 100/ number of vertigo attacks per month (6 months before treatment)

cases (20%) had mild hearing loss, 14 cases (70%) had moderate hearing loss, and two cases (10%) had severe hearing loss. After treatment, among those four cases of mild hearing loss, three cases had their hearing back to normal while the fourth case's hearing was unfortunately deteriorated to deaf. Among 16 patients who had moderate to severe hearing loss prior to treatment, all still had their hearing remained in the same level in which their PTA had changed less than 10 dB after treatment. In conclusion, fifteen percent of the patients had their hearing improvement, five percent had deteriorated, and eighty percent remained at the previous level. The results are shown in Table 5.

Post treatment of the speech discrimination score (SDS) showed improvement more than fifteen percent in four cases (20%), decreased for more than fifteen percent in six cases (30%), and 10 cases (50%) remained at the same level in which their scores had changed less than fifteen percent. The results are shown in Table 5.

Every patient had tinnitus with various severities. The results of the tinnitus score from the questionnaire test (Table 2) showed an improvement in 80% (16 of 20) by decreasing in scores at post treatment. Three cases (15%) remained unchanged and only one case (5%) had deteriorated. The results are shown in Table 5.

A multivariate repeated measures ANOVA was used for evaluating the effects of treatment. The sphericity assumption was met (epsilon = 1.00) and the multivariate analysis yield significance at the.01 level (Wilk's Lamda (5, 15) = 0.17, p =.000). Since these were significant, step-down univariate ANOVAs was followed to determine which physiologic parameters were significantly affected by treatment. Step-down univariate ANOVAs indicated that vertigo control (VER), the functional level scale (FLS), and tinnitus score (TINS) were significantly affected by treatment (VER: F (1,19) = 16.75, p =.001; FLS: F (1,19) = 58.95, p = .000; TINS: F (1,19) = 13.98, p = .001), whereas the pure tone threshold average (PTA) and the speech discrimination score (SDS) were not significantly affected by treatment (PTA: F (1,19) = 0.19, p = .668; SDS: F (1,19) = 1.98, p = .176). The results are displayed in Table 6.

Discussion

Based on a retrospective review of the previous intratympanic injection studies[3-17], both protocols of daily fixed dose and titration technique yield similar success rates in controlling vertigo. However, the ideal, most minimum dosage, which would eliminate vertigo while sparing hearing, is still being searched. From the review of 14 studies[3-17], patients ranged from 3 to 93 cases, using dosage 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 two studies showed hearing reduction more than 50%. The present study used a fixed drug regimen of 206 mg, divided in 12 doses, administered every 8 hours, totally 4 days, when compared to other studies[3,5,10,11,15],

Table 5. Results of daily functional level scale (FLS), pure tone threshold average (PTA), speech discrimination score (SDS), and tinnitus score (TINS) 6 months after treatment

Level	FLS (%)	PTA (%)	SDS (%)	TINS (%)
Improved	19/20 (95)	3/20 (15)	4/20 (20)	16/20 (80)
Same	0/20 (0)	16/20 (80)	10/20 (50)	3/20 (15)
Deteriorated	1/20 (5)	1/20 (5)	6/20 (30)	1/20 (5)
Total	20 (100)	20 (100)	20 (100)	20 (100)

Table 6. Multivariate analysis of physiologic parameters between pre and post treatment

Within subject effect		Value	Approximate F	Hypothesis df	Error df	p
Gentamicin	Pilai's Trace	0.84	15.20	5	15	.000
	Wilk's Lamda	0.17	15.20	5	15	.000
	Hotelling's Trace	5.07	15.20	5	15	.000
	Roy's Largest Root	5.07	15.20	5	15	.000

Tests of within-subjects contrasts

Source	Measure	Pre treatment Mean ± SD	Post treatment Mean ± SD	SS	df	MS	F	p
Gentamicin	VER	11.10 ± 11.67	0.50 ± 0.95	1123.60	1	1123.60	16.75**	.001
	FLS	3.85 ± 0.99	1.65 ± 0.93	48.40	1	48.40	58.95**	.000
	PTA	61.10 ± 16.89	62.85 ± 22.32	30.63	1	30.63	0.19	.668
	SDS	61.00 ± 27.09	52.20 ± 30.48	774.40	1	774.40	1.98	.176
	TINS	8.70 ± 3.10	5.65 ± 2.23	93.03	1	93.03	13.98**	.001

note: ** $p < .01$; Mauchly's Test of Sphericity: Epsilon = 1.00

using the same method of drug administration showing similar results of vertigo control and hearing preserved. Kaplan et al[15] reported 90 patients using a 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% 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, Asawavichianginda and Tirasut[16] reported using gentamicin 40 mg/ml, 0.4-0.6 ml intratympanic injection of 9 doses, every 8 hours for 3 days and found that 87.5% were completely free from vertigo. All could work and perform their daily functional activity but the hearing was deteriorated in 50%, improved in 25%, and resumed as previous in 25%. However, the authors' previous preliminary report of eight patients showed all patients had the statistical improvement in their daily functional life and vertigo control[17].

The drug's ototoxic activity has made aminoglycoside become a drug used in selective treatment in intractable Meniere's disease. 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[18-21]. However, controversies exist according to the dosage, concentration, amount, and method of administration, which are still under investigation.

Although a variety of drug concentrations have 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 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 ear cavity and the function of eustachian tube. The authors have found that the dose of the drug is absolutely proper, painless without membrane distension. The effectiveness of gentamicin therapy also depends on the successful absorption into the inner ear via the round window membrane. It is important 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. Upon review of the literature, different methods have been used to deliver gentamicin into the middle ear cavity. The best way to deliver the exact dosage of drug was in doubt and was not clearly expressed. The present study proposed the practical delivery method by using a self-prepared long catheter tube retained at the tympanic membrane connecting to the extension set easily for injection. This method is noninvasive for multiple injections, decreases the risk of large or permanent perforation of tympanic membrane, and is accurate for drug dosage.

Since the majority of Meniere's patients responded to oral medical treatment, it left only a few cases to be selected in which 20 patients were collected in the present five-year study. From the present study,

the authors found that this method is effective in controlling vertigo in which all had the improvement of vertigo and most had gained their daily functional life. Eighty percent had hearing level resumed at the same level although 15% had incredible improved hearing. Unfortunately, one had marked deterioration of hearing to deaf as mentioned before. This patient had been treated as sudden hearing loss with steroids therapy however, the hearing was not recovered. She also had decreased speech discrimination score and increased tinnitus score consequently from the hearing loss. Upon follow-up, 3 months later, she had another sudden deafness on the other side in which it fortunately recovered after steroids administration. The authors presumed that this case might have the underlying autoimmune inner ear disease but presented as Meniere's like syndrome. Another possible cause of sudden deafness in this patient was also investigated and she was found to carry a heterozygous gene of conexein 26. Any relationship to this method of treatment is in doubt. However, her vertigo was absolutely controlled finally and despite her hearing loss in one ear, she felt relieved and secure.

In conclusion, transtympanic gentamicin treatment is 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 has replaced the vestibular surgery in Ramathibodi Hospital.

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การฉีดยาเจนตามัยซินเข้าหูชั้นกลางในการรักษาผู้ป่วยโรคมีเนียร์ที่มีอาการอย่างรุนแรง: ประสบการณ์ 5 ปี

ลลิดา เกษมสุวรรณ, จันทร์ชัย เจรียงประเสริฐ, สุวิมล รื่นเจริญ, พิสมัย อรทัย

วัตถุประสงค์*: เพื่อศึกษาผลการรักษาโรคมีเนียร์ที่มีอาการอย่างรุนแรง โดยวิธีการฉีดยาเจนตามัยซินเข้าหูชั้นกลางด้วยปริมาณน้อยและคงที่*

วัสดุและวิธีการ*: เป็นการศึกษาไปข้างหน้าในผู้ป่วยโรคมีเนียร์ที่มารับการรักษา ณ ภาควิชาโสต ศอ นาสิก โรงพยาบาลรามาธิบดี เป็นผู้ป่วยที่มีอาการรุนแรง ไม่สามารถควบคุมอาการได้ด้วยการรับประทานยา ผู้ป่วยได้รับการรักษาด้วยยาเจนตามัยซินปริมาณน้อยฉีดเข้าหูชั้นกลางด้วยปริมาณยาคงที่ 12 ครั้ง รวม 4 วัน ประเมินผลโดยใช้แนวทางตามคู่มือ American Academy of Otolaryngology and Head & Neck Surgery เริ่มศึกษาเดือนมีนาคม พ.ศ. 2542 ถึงธันวาคม พ.ศ. 2547 โดยวัดผลการรักษาแต่ละรายที่เดือนที่หก ใช้สถิติการศึกษาด้วย Multivariate Repeated Measures ANOVA*

ผลการศึกษา*: มีผู้ป่วยทั้งหมด 20 ราย ในช่วง 5 ปี เป็นชาย 9 ราย หญิง 11 ราย พบว่าการควบคุมอาการเวียนศีรษะ ระดับการดำรงชีวิตประจำวัน และเสียงดังในหูหลังให้การรักษา 6 เดือน มีผลลัพธ์ที่ดีขึ้น อย่างมีนัยสำคัญทางสถิติ (p = .001, .000, .001 ตามลำดับ) โดยที่ระดับการได้ยินในชีวิตประจำวันไม่แตกต่างจากเดิมอย่างมีนัยสำคัญทางสถิติ (p = .668)*

สรุป*: การฉีดยาเจนตามัยซินเข้าหูชั้นกลางในปริมาณน้อยและคงที่ ได้ผลดีในผู้ป่วยโรคมีเนียร์ที่มีอาการรุนแรง และมีผลต่อการสูญเสียการได้ยินไม่มาก ในปัจจุบันนี้ที่ภาควิชาโสต ศอ นาสิก โรงพยาบาลรามาธิบดีได้ใช้วิธีนี้เป็นมาตรฐานการรักษาผู้ป่วยกลุ่มนี้*