

Vestibular Nerve Section Versus Intratympanic Gentamicin for Meniere's Disease

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Objectives/Hypothesis: Vestibular nerve section and transtympanic gentamicin administration are procedures with proven efficacy in the treatment of vertigo associated with Meniere's disease refractory to medical management. Hearing loss is a known complication of each of these procedures; however, there has not been a report of hearing results of both treatments from a single institution. **Study Design:** Retrospective review. **Methods:** Review was made of 25 patients undergoing gentamicin injection and 39 patients undergoing vestibular nerve section for Meniere's disease. Rate of vertigo control and pretreatment and post-treatment pure-tone average values and speech discrimination scores were reported. **Results:** The mean preoperative pure-tone average for patients having vestibular nerve section was 47.2 dB, with a speech discrimination score of 75.4%. In these patients, the postoperative pure-tone average was 49.1 dB and the speech discrimination score was 75%. Patients undergoing gentamicin injection had a mean pretreatment pure-tone average of 55.9 dB and a speech discrimination score of 62%. The post-treatment pure-tone average and speech discrimination score for the gentamicin group were 68.8 dB and 49.3%, respectively. Five of 25 patients (20%) in the gentamicin treatment group and 1 of 39 (3%) in the vestibular nerve section treatment group had an increase in bone-conduction threshold greater than 30 dB. The amount of postprocedure hearing loss was significantly greater in the gentamicin treatment group ($P = .006$). Control of vertigo was good to excellent in 95% of the patients treated with vestibular nerve section and in 80% of the patients treated with gentamicin. **Conclusion:** Although vestibular nerve section and transtympanic gentamicin are both acceptable treatment options for vertigo associated with Meniere's disease, gentamicin causes a higher level of hearing loss related to treatment and vestibular nerve section has higher vertigo control

rates. **Key Words:** Meniere's disease, intratympanic gentamicin, vestibular nerve section, vertigo.

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INTRODUCTION

Meniere's disease is an often-disabling disease characterized by episodic vertigo, fluctuating hearing loss, and aural fullness. The vertigo associated with this condition is by far the most debilitating symptom and the target of therapeutic intervention. In cases refractory to medical management, a vestibular ablation procedure is often required. When a patient has serviceable hearing in the affected ear, commonly used destructive procedures are the vestibular nerve section and intratympanic gentamicin injection.

Vestibular nerve section was first attempted for control of Meniere's disease by Fedor Krause, was repopularized by Walter Dandy, and was described using microscopic technique by William House.¹ Silverstein and Norrell² popularized the retrolabyrinthine vestibular nerve section, as described in 1980. This was followed by the description of the retrosigmoid-internal auditory canal approach that was designed to better identify the vestibulocochlear cleavage plane.³ These approaches have the advantage of a high rate of vertigo control and hearing preservation. Although risks are uncommon, there are risks associated with the surgery, including bleeding, meningitis, and cerebrospinal fluid (CSF) leak. Intratympanic gentamicin has been described as an alternative method for vestibular ablation. It is touted as highly effective and without the complications associated with surgery. Because of this, many otologists are using gentamicin injections as the first-line treatment for patients with Meniere's disease who fail medical treatment.

There are several studies that have reported the vertigo control and hearing loss rate for either gentamicin injection or vestibular nerve section independently. However, there are no reports that have compared both methods of treatment from the same institution. We report the acute hearing loss rates, vertigo control efficacy, and complications associated with both vestibular nerve section and gentamicin injection as performed at Pittsburgh Ear Associates.

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PATIENTS AND METHODS

We reviewed the charts of patients in our practice during the 12-year period from January 1990 to December 2002 with the diagnosis of "definite" Meniere's disease as defined by the 1995 American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) criteria¹ who required vestibular ablation. No other disease processes were studied for the present report. We evaluated only consecutive patients who either had undergone retrolabyrinthine or retrosigmoid vestibular nerve section or had received intratympanic gentamicin injection. All patients had pretreatment audiograms, and only those with measurable hearing in the affected ear were included. Patients must have had at least one post-treatment office visit with audiometric evaluation within 12 months after treatment. For the vertigo control analysis, patients must have had follow-up for at least 12 months.

Each patient was determined to be a candidate for vestibular ablation after failure of medical management to control the vertigo associated with Meniere's disease. The patients were informed about the risks and benefits of gentamicin injection, labyrinthectomy, endolymphatic duct shunt or decompression, and retrolabyrinthine vestibular nerve section. The patients then selected the specific procedure that was to be performed based on their individual concerns and desires. Only patients with measurable hearing were offered a retrolabyrinthine vestibular nerve section.

The vestibular nerve section was performed as described by Silverstein and Rosenberg.⁵ The patients underwent a mastoidectomy, bone was taken off the sigmoid sinus and posterior fossa dura, and the dura was incised. If needed, a retrosigmoid approach was used when a canal wall down mastoidectomy had been performed previously or when a contracted mastoid was found on preoperative imaging. Over the period of the study, our closure technique evolved from packing the mastoid defect with fat to provide a watertight seal to a combined fat-hydroxyapatite cranioplasty technique.⁶

Gentamicin injection was performed by first anesthetizing the posterosuperior quadrant of the tympanic membrane with topical phenol. A 25-gauge needle was used to inject approximately 0.5 mL of a buffered gentamicin solution into the middle ear. The gentamicin solution was made with stock 40-mg/mL solution mixed with 8.4% sodium bicarbonate and bacteriostatic water to create a solution with a concentration of 26.7 mg/mL gentamicin. The pH balancing helped with the patient's tolerance of the procedure. After injection the patient was kept supine for 10 minutes and told not to swallow. Saliva was collected in a basin or towel during this period. A series of three weekly injections was scheduled. However, the second or third treatment was given only for persistent vertigo. Repeat injections were deferred if hearing loss was noted after one injection or if there were clinically obvious signs of unilateral vestibular hypoactivity.

We used the first follow-up audiogram obtained at least 2 months after treatment to measure hearing change in both treatment groups. The audiogram was obtained within 3 months in the patients treated with gentamicin and in most of the patients treated with vestibular nerve section. All of the patients treated with vestibular nerve section had a follow-up audiogram within the first year after treatment. The pure-tone average (PTA) using 500, 1000, 2000, and 4000 Hz and the speech discrimination score (SDS) were used to monitor hearing change. Air and bone conduction was measured to determine the nature of the hearing change as well. Hearing change was defined as a shift in PTA of 10 dB or SDS of 15% as recommended by the AAO-HNS guidelines.

We also measured the efficacy of vertigo treatment. A questionnaire was developed using the AAO-HNS reporting guidelines as a template. The patients were asked to report the number of vertigo attacks in the 6-month period before treatment, the

time period from 18 to 24 months after treatment, and the 6-month period before the date when the questionnaire was completed. These data were used to determine the class of therapeutic effect (Table I). The questionnaire also contained a modified functional level scale used to classify the amount of disability caused by the disease process before and after treatment (Table II). Patients were asked to report any side effects including headache and persistent dysequilibrium. Patients were interviewed by telephone for clarification of any ambiguous responses and when a response from the first questionnaire was not received.

RESULTS

A review of our charts during the period from January 1990 to December 2002 produced 75 patients who had vestibular nerve section and 34 who had intratympanic gentamicin for treatment of vestibulopathy. Of these, 39 of the patients treated with vestibular nerve section and 25 of the patients treated with gentamicin injection qualified by the meeting the criteria listed earlier in the present report. Two patients were in both categories, initially undergoing a gentamicin injection that failed to control vertigo adequately and then having vestibular nerve section.

Seventy-five patients received vestibular nerve section from 1990 to 2002 at our institution. Of these patients, 39 met inclusion criteria. There were 13 male and 26 female patients with an average age of 48.9 years. Twenty right and 19 left ears were affected in this group. Five patients had undergone previous endolymphatic sac surgery. Two patients had received previous intratympanic gentamicin but had continued poor control of their vertigo.

The preoperative bone conduction PTA for the patients treated with vestibular nerve section was 47.2 dB. The preoperative SDS was 75.4%. The postoperative bone conduction PTA at first follow-up was 49.2 dB, representing an average decrease of only 1.9 dB. This change in PTA seen after treatment was not significant ($P = .36$). The average air-bone gap was 1.8 dB preoperatively and 2.8 dB postoperatively. The average postoperative SDS was 75%. A summary of hearing results is given in Table

TABLE I.
AAO-HNS Committee on Hearing and Equilibrium Summary of Reporting Guidelines.

Numerical Value	Class
0	A (complete control of definite spells)
1-40	B
41-80	C
81-120	D
>120	E
Secondary treatment initiated because of disability from vertigo	F

Numerical value = $(X/Y) \times 100$, rounded to the nearest whole number, where X is the average number of definitive spells per month for the 6-month period 18 to 24 months after therapy and Y is the average number of definitive spells per month for the 6-month period before therapy. In the present study, because of shorter follow-up time, the time period of 6 to 12 months after therapy for the gentamicin group was used in some patients.

AAO-HNS, American Academy of Otolaryngology—Head and Neck Surgery.

TABLE II.
Modified Functional Level Scale Based on AAO-HNS Committee on Hearing and Equilibrium Functional Scale.

Regarding my current state of overall function, not just during attacks (check one that best applies):

1. Dizziness has no effect on activities at all.
2. Dizziness does not necessitate change in plans or activities.
3. Dizziness necessitates some changes in plans.
4. Am able to engage in essential activities, but constant adjustments are needed.
5. Unable to work, drive, take care of a family member, or do most active things. Even essential activities are limited.
6. Disabled for 1 year or longer and receive compensation.

AAO-HNS, American Academy of Otolaryngology—Head and Neck Surgery.

III. The number of patients having improved, decreased, or unchanged hearing is shown in Figure 1. Of the patients with hearing loss after vestibular nerve section, five patients (13%) had a PTA threshold increase of 10 to 15 dB, three patients (8%) had an increase of 16 to 20 dB, one patient (3%) had increase of 21 to 25 dB, and one patient (3%) had an increase greater than 30 dB (38 dB). The final patient with hearing loss in this group had a stable PTA but a significant drop in the SDS.

There were no cases of meningitis, neurological deficit, wound infection, or death in the vestibular nerve section treatment group. There was a CSF leak rate of 12.8%. All of these cases resolved with either a pressure dressing and bed rest or a lumbar drain.

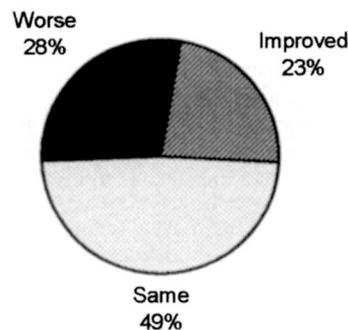
Thirty-four patients received intratympanic gentamicin injection from 1998 to 2002 at our institution. Twenty-five of these patients qualified for inclusion in the present study. There were 14 male and 11 female patients with an average age of 61.4 years. Eleven right ears and 14 left ears were treated. Five patients in this group had endolymphatic sac surgery before gentamicin treatment. Two of these patients later had vestibular nerve section for refractory vertigo. The average number of injections performed was 2.0. There were no complications resulting from treatment.

TABLE III.
Summary of Hearing Results in Both Groups.

Hearing Assessment	VNS	IT Gent	P Value (Difference: VNS vs. IT Gent)
Pretreatment PTA (dB)	47.2	55.9	.02
Post-treatment PTA (dB)	49.1	68.8	.0005
Difference in PTA before vs. after treatment (dB)	1.9	12.9	.01
P value (difference before vs. after treatment)	$P = .36$	$P = .006$	
Pretreatment SDS (%)	75.4	62	
Posttreatment SDS (%)	75	49.3	

VNS, vestibular nerve section group; IT Gent, intratympanic gentamicin group; PTA, pure-tone average; SDS, speech discrimination score.

Vestibular Nerve Section Postoperative Hearing
n=39



Intratympanic Gentamicin Post-procedure Hearing
n=25

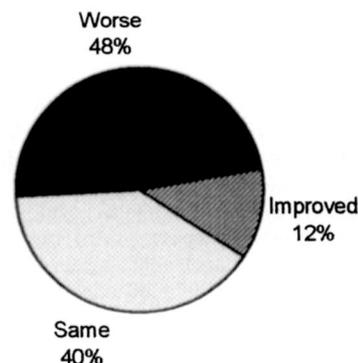


Fig. 1. Comparison of post-treatment hearing results. (A) Postoperative hearing after vestibular nerve section. (B) Hearing after treatment procedure with intratympanic gentamicin.

The preinjection bone-conduction PTA for the gentamicin treatment group was 55.9 dB. The preinjection SDS was 62%. The postinjection bone-conduction PTA was 68.8 dB, representing a threshold increase of 12.9 dB. This difference was significant ($P = .006$). The postinjection SDS was 49.3%. The average air-bone gap before injection was 2.8 dB and remained at 2.8 dB postinjection. Three patients (12%) had a PTA threshold increase of 10 to 15 dB, and one patient (4%) had a PTA increase of 21 dB. There were five other patients (20%) with losses greater than 30 dB (35-, 36-, 57-, 59-, and 60-dB losses). Threshold shift in patients with post-treatment hearing loss in both treatment groups is shown in Figure 2.

Analysis of vertigo control was a secondary goal of the present study. Chart review was performed, and patients were classified into one of three groups: excellent control, in which patients had minimal vertigo after treatment that did not have a significant effect on lifestyle; moderate

TABLE IV.
Vertigo Control Questionnaire Results by Control Class and Functional Level.

Control Class	VNS (n = 25) n (%)	IT Gent (n = 15) n (%)
A	14 (56)	8 (53)
B	9 (36)	2 (13)
C	1 (4)	1 (7)
D	1 (4)	1 (7)
E	0 (0)	3 (20)
F	0 (0)	0 (0)
*Level of function before treatment	4.4	4.2
*Level of function after treatment	1.5	1.9

*The functional level scale ranges between a best score of 1 and a worst score of 6.

VNS, vestibular nerve section group; IT Gent, intratympanic gentamicin group.

solving dysequilibrium, the median time to resolution was 4 months.

In the gentamicin group, 8 of the 15 patients reported some post-treatment dysequilibrium. Three of the eight patients had persistent dysequilibrium, which was not severe in any of these patients. Of patients who had resolution of their dysequilibrium, the median time to resolution was 4 months.

Headache is a reported complication of retrosigmoid operations. In the vestibular nerve section treatment group, 2 of the 25 (8%) respondents noted persistent postoperative headaches that were not present before the operation. These headaches were not severe and did not require further treatment. Interestingly, these two patients had a retrolabyrinthine approach without a retrosigmoid component, with all drilling completed before opening dura. None of the four patients undergoing a retrosigmoid approach noted postoperative headaches. In the gentamicin treatment group, only 1 patient of the 15 respondents noted post-treatment headaches. Again, these headaches were not reported as severe.

DISCUSSION

When medical treatment is inadequate to relieve the vertigo associated with Meniere's disease, vestibular ablative treatment is often required. When usable hearing in the affected ear remains, treatments that attempt to preserve hearing function are desirable. Two such treatments are vestibular nerve section and intratympanic gentamicin injection. There are multiple reports referring to the rate of hearing loss and vertigo control rates of either vestibular nerve section or intratympanic gentamicin injection separately. The present study is the first report comparing post-treatment hearing and vertigo control results of these two different treatments from a single institution.

Intratympanic aminoglycoside administration has been a treatment for Meniere's since Schuknecht⁷ first described his results with intratympanic streptomycin in 1956. Since then, approximately 90 reports referring to the use of intratympanic aminoglycoside injection for vestibular ablation therapy have been published. A smaller number of these have primarily discussed the rate of vertigo control and hearing loss following treatment of Meniere's disease with this therapy. It is generally accepted that intratympanic aminoglycoside administration has a high rate of success but can be complicated by sensorineural hearing loss. Recently reported vertigo control rates have ranged from 72% to 95% depending on the measurement criteria used.⁸⁻¹⁵ Hearing loss rates in these studies have varied from 19% to 95%. A summary of recent treatment results from a selection of these reports is given in Table V. The variability of the reported treatment results may in part be a result of measurement methods, which often vary from report to report. This reporting inconsistency also makes comparing these results with other treatment methods more difficult.

High rates of vertigo control can also be obtained by treatment with vestibular nerve section. Most reviews have reported "good" (85% to 100%) vertigo control rates with either retrosigmoid or retrolabyrinthine vestibular nerve section.¹⁶⁻²⁰ These reports noted a 27% to 50% incidence of hearing decrease defined as a shift of 10 dB in

TABLE V.
Recently Reported Intratympanic Gentamicin Results.

Study	Treatment Modality	N	Hearing Decrease Rate (%)	Vertigo Control (%)
Hirsch (1997)	IT gent	28	33	91
Driscoll et al. (1997)	IT gent	23	95	84
Youssef and Poe (1998)	IT gent	37	43	87
Abou-Halawa and Poe (2002)	IT gent (30 mg/mL)	44	30	81
	IT gent (40 mg/mL)	43	19	72
Kaplan et al. (2000)	IT gent	90	32	93
Rauch and Oas (1997)	IT gent	21	38	95
Minor (1999)	IT gent	34	32	91
McFeely et al. (1998)	IT gent	25	20	88

IT gent, intratympanic gentamicin.

PTA or decrease of 15% on SDS testing. Again, these reports use a variety of outcome measures taken at variable follow-up times, making comparison of these outcomes with other modalities impossible. In addition, the natural history of fluctuating hearing thresholds in Meniere's disease further confounds outcome measurement. It was our intent to compare our treatment results using a single patient population and uniform measurement techniques to more reliably compare gentamicin and vestibular nerve section treatments.

We found a significant difference in the incidence and magnitude of post-treatment hearing loss between vestibular nerve section and intratympanic gentamicin. Although patients treated with vestibular nerve section had a 28% rate of significant hearing loss, there was a similar rate of significant hearing improvement (23%), comparable to previous reports in the literature. However, the average PTA change (1.9 dB) was small, calling into question the clinical significance of the hearing loss seen. The small post-treatment change noted may be a reflection of the natural hearing fluctuations seen with Meniere's disease. There was a much higher rate of hearing loss (48%) in the patients treated with intratympanic gentamicin. The patients who had significant hearing loss in this group also had much larger threshold increases than were seen in the vestibular nerve section treatment group. Although only 1 patient of the 11 patients having post-treatment hearing loss in the vestibular nerve section treatment group had a bone-conduction threshold increase of greater than 30 dB, there were 5 of 12 patients in the gentamicin treatment group who had at least 30 dB of post-treatment bone-conduction threshold increase. All five of these patients started with hearing that was serviceable and were left with severe to profound losses.

Our protocol for intratympanic injection was chosen for patient comfort and convenience. The concentration we used was among the lowest of the concentrations that were used in recent studies. The average number of injections was small as well, with an average number of only two injections per patient. Of the five patients who had serious hearing loss (>30-dB shift in PTA), two patients had a single injection, two patients had two injections, and one patient had an initial series of three injections. In the latter patient, a delayed fourth injection was used after hearing loss was already realized, to help with residual vertigo spells. Therefore, it would be difficult to conclude that our protocol alone was responsible for the hearing loss rate that was seen. In an excellent review of recent literature on intratympanic gentamicin, Blakley²¹ concluded that there was no particular intratympanic gentamicin protocol that had an advantage with regard to hearing preservation. It is likely that there are numerous uncontrollable factors which contribute to gentamicin-induced hearing loss, including genetic predisposition, anatomical variability of the round window niche, the presence of adhesions over the round window, and pretreatment hearing levels. Therefore, it is impossible to come to a clear conclusion that our hearing results were a direct effect of the protocol we used. Nonetheless, our hearing loss rate was comparable to recently reported results.

Significant differences in vertigo control rates between the two groups were also found in the present study. Although both treatment modalities were effective, patients who underwent a vestibular nerve section had a higher rate of clinically assessed vertigo control. When AAO-HNS criteria were used for comparison, a 92% excellent control rate (classes A and B) in the vestibular nerve section treatment group and a 66% excellent control rate in the gentamicin treatment group were seen. The number of patients achieving excellent control (classes A and B) versus poor control (classes C-F) was statistically higher in the vestibular nerve section treatment group on χ^2 analysis ($P = .041$). However, although we used AAO-HNS Committee on Hearing and Equilibrium criteria, the follow-up period for the gentamicin treatment group was somewhat truncated because a large number of these patients had treatment less than 2 years before being included in the present study. Nonetheless, the average follow-up period was 22 months, and no patients were included unless they had at least 12 months of follow-up. It is possible that the patients in the gentamicin treatment group, had they been followed until the end of the 2-year follow-up period recommended by AAO-HNS, could have had an improved rate of vertigo control, making their control rate comparable to those receiving vestibular nerve section. However, based on the present study, it appears that vestibular nerve section has a higher rate of vertigo control.

One of the stated disadvantages of surgical intervention as compared with intratympanic ablation is the higher rate of complications related to wound infection, CSF leak, or meningitis. We did not see any patients in the present series with a wound infection or meningitis. However, we did have a CSF leak rate of 12.6% with vestibular nerve section. Although all of these leaks resolved with either a pressure dressing or lumbar drain, or both, they all caused an increase in the number of days in the hospital.

Another potentially life-altering complication related to vestibular ablation is the potential for development of post-treatment, persistent dysequilibrium. In the vestibular nerve section treatment group, 56% of the patients reported a period of significant dysequilibrium. Of these patients, six (24%) reported persistent dysequilibrium after a 2-year period, but all of them reported it to be mild, and only one of them reported that it affected her lifestyle. Of patients with transient dysequilibrium, the average time to resolution was 4 months.

We saw a similar rate of post-treatment dysequilibrium in the intratympanic gentamicin treatment group (53%). Again, the average time to resolution was 4 months. Of the three patients (20%) who reported continued dysequilibrium after the follow-up period, all stated that it was mild and none reported lifestyle change as a result. Therefore, it seems that the rate and severity of post-treatment dysequilibrium is similar in the two groups.

We maintain that intratympanic gentamicin plays an important role in the treatment of the vertigo associated with Meniere's disease. Although hearing is likely to be at

greater risk with this treatment than with vestibular nerve section, there are many situations in which this risk is acceptable. In patients who are at risk for operative complications because of concomitant medical problems, gentamicin treatment offers an alternative that eliminates anesthetic risk and potential risk associated with postoperative complications. In some patients the pre-treatment hearing in the affected ear may be so poor that aural rehabilitation is impossible and therefore damage to remaining hearing is inconsequential. Also, there is a group of patients who have serious apprehension about undergoing surgical intervention and are willing to accept the moderate increase in risk to remaining hearing to avoid an operative procedure.

CONCLUSION

Vestibular ablation remains an important therapeutic option in the treatment of Meniere's disease when medical management has failed. Vestibular nerve section and intratympanic gentamicin injection provide two different methods for vestibular ablation with different complication profiles and efficacy rates. In our practice, vestibular nerve section has a higher rate of vertigo control with less risk to remaining hearing. Intratympanic gentamicin remains our first choice for patients with poor hearing in the affected side or with medical conditions that preclude surgical intervention.

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