ORIGINAL ARTICLE

Evaluation of Treatment Options for Disabling Vertigo in Unilateral Ménière's Disease

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OBJECTIVES: We evaluated the effectiveness of diverse treatment options in patients with disabling vertigo due to unilateral Ménière's disease.

PATIENTS AND METHODS: This retrospective study included 169 patients (78 males, 91 females; mean age 50.1 years; range 23 to 80 years) who were treated for recurrent peripheral vertigo from January 1990 to January 2000. All the patients were classified in accordance with the AAO-HNS (American Academy of Otolaryngology-Head and Neck Surgery) 1995 criteria. Intratympanic application of gentamicin was used in 29 patients who refused surgery or where surgery was contraindicated. Endolymphatic sac surgery was performed in 20 patients with a disability defined in level 4 of the AAO-HNS Functional Level Scale. Labyrinthectomy, either transcanal or transmastoid, was performed in eight patients whose hearing function was absent or not useful in the affected ear. Vestibular nerve section (VNS) was performed in 112 patients who had a good general condition, a serviceable hearing in the diseased ear, and a real disability affecting social and professional activities. In the first years, it was performed through the retrolabyrinthine approach (18 patients) and in the latter years through the retrosigmoid approach (94 patients). Hearing levels were assessed before and 4 to 10 weeks after treatment and vertigo control rates were determined between 18 to 24 months after treatment. The overall follow-up period ranged from 24 to 93 months.

RESULTS: With gentamicin, vertigo improved significantly in 86.2% of the cases (class A 48.3, class B 37.9), but at the expense of impairment in hearing in 41.3%. With endolymphatic sac surgery, deterioration in hearing was 10%. Improvement in vertigo control was 65% at the end of a two-year follow-up period. Nine patients whose follow-up period was nine years showed a remarkable decrease in vertigo control. All the patients who underwent labyrinthectomy had vertigo control, with a complete hearing loss. The most beneficial treatment was VNS, in terms of both complete control of vertigo spells (98.3%; class A 92.9, class B 5.4%) and preservation of hearing (93.8%). None of the patients in this group required a revision procedure.

CONCLUSION: For disabling vertigo in Ménière's disease, VNS is of choice if hearing is worthy of preservation. In patients with unilateral non-useful hearing labyrinthectomy may be considered. In elderly patients and/or in those with a poor health condition, intratympanic gentamicin seems to be the most appropriate option.

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Patients with intractable vertigo in Ménière's disease (MD) are currently offered a variety of therapies, which may be surgical or non-surgical, destructive or conservative.

The aim of this study was to evaluate, through a retrospective review of our cases, the effectiveness of diverse treatment options in disabling vertigo in patients with unilateral MD.

MATERIALS AND METHODS

From January 1990 to January 2000, a total of 370 patients with unilateral MD were referred to our Department (a tertiary referral center) for recurrent peripheral vertigo spells. All patients were classified in accordance with the AAO-HNS (American Academy of Otolaryngology - Head and Neck Surgery) 1995 criteria.[1]

Of this patient group, vertigo was controlled with medical therapy (prednisone, diuretics, salt and dietary restrictions) or underwent spontaneous remission over time in 178 patients (48.1%). The remaining patients (n=192, 51.9%) required additional interventional treatments after medical therapy of at least six-month duration had been unsuccessful. Of these, four patients had previously undergone endolymphatic sac surgery, and seven patients had been treated with intratympanic gentamicin at other institutions.

Inclusion criteria were the presence of *(i)* "definitive" MD according to the AAO-HNS 1995 guidelines;[1] *(ii)* no symptoms suggestive of MD in the contralateral ear; *(iii)* useful hearing in the contralateral ear; *(iv)* subjective complaints suggesting real "disability" as defined in levels 4 to 6 of the AAO-HNS Functional Level Scale (Table 1); and *(v)* a follow-up period of at least 24 months. Twenty-three patients who did not satisfy these criteria were excluded; thus, 169 patients (78 males, 91 females; mean age 50.1 years; range 23 to 80 years) comprised the study group.

The pre-treatment hearing levels based on the four-tone average of pure-tone thresholds at 0.5, 1, 2, and 3 kHz are shown in Table 2. In all cases, magnetic resonance imaging was utilized to exclude cerebellopontine angle pathology.

The treatment modalities employed for intractable vertigo are shown in Table 3.

Intratympanic application of gentamicin was mainly applied in patients who refused surgery or where surgery was contraindicated. Before each injection, the patient was evaluated with a pure tone audiogram (PTA 0.5, 1, 2, 3 kHz) and speech discrimination score (SDS). Treatment was discontinued when one of the following was observed: significant persistent reduction in hearing (PTA ≥15 dB and/or impairment in SDS ≥15%), onset of persistent vestibular symptoms such as disequilibrium, and onset of spontaneous nystagmus and/or florid post head-shake nystagmus. Two injections (30 mg/ml gentamicin) were planned with a week interval. Preparation of the solution was made as described in the literature.[2] About 1 ml of the solution was injected with the use of a small syringe through the pos-

Table 2. Functional Level Scale according to the AAO-HNS (1995) regarding the current state of overall function, not just functioning during attacks

FLS-scale	Patient's subjective experience
1	My dizziness has no effects on my activities at all.
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.
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 allowance for my dizziness.
4	I am able to work, drive, travel, take care of my 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.
5	I am unable to work, drive or take care of my family. I am unable to do most of the active things that I used to do. Even essential activities must be limited. I am disabled.
6	I have been disabled for one year or longer and/or I receive compensation (money) because of my dizziness or balance problem.

Table 2. Pre-treatment hearing levels

Stage[*]	Pure-tone average (dB)	No. of patients
1	<25	30
2	26-40	56
3	41-70	59
4	>70	24

[*] Based on the four-tone average of pure-tone thresholds at 0.5, 1, 2, 3 kHz.

teroinferior aspect of the tympanic membrane of the affected side. After the injection, the patient was left supine for about 40 minutes with the head placed contralaterally. In case that vertigo spells continued, additional injections were administered with a maximum of four.

Endolymphatic sac surgery was recommended to patients who generally had a disability defined in level 4 of the AAO-HNS Functional Level Scale and who accepted surgery excluding an intracranial intervention. Endolymphatic mastoid shunt operations were performed mainly under general anesthesia and the patients were discharged the same day.

Labyrinthectomy, either transcanal or transmastoid, was performed in patients whose hearing function was absent or not useful in the affected ear. For transcanal operations, a less invasive approach was preferred.

Vestibular nerve section (VNS) was considered in patients with a good general condition, a serviceable hearing in the diseased ear, and a real disability affecting social and professional activities (mostly in level 5 and 6 of the AAO-HNS Functional Level Scale). Selective VNS was performed through retrolabyrinthine (18 patients) or retrosigmoid (94 patients) approaches. In the first years of patient enrollment, the retrolabyrinthine approach was employed, while in the latter years the retrosigmoid approach was of choice. Following unilateral ablation of the diseased vestibular periphery, all patients received vestibular rehabilitation to eliminate disequilibrium resulting from asymmetrical vestibular inputs between the two ears.

Table 3. Treatment modalities employed for intractable vertigo

Treatment	No. of patients	%
Intratympanic gentamicin	29	17.2
Endolymphatic sac surgery	20	11.8
Labyrinthectomy (transcanal, transmastoid)	8	4.7
Vestibular nerve section (retrolabyrinthine, retrosigmoid)	112	66.3

On follow-up visits, the patients were questioned with regard to the frequency and intensity of vertigo spells and their hearing levels were tested. A change in PTA of ≥10 dB was considered clinically significant.

The results on vertigo control were evaluated according to the classification system (A, B, C, D, E, F) of the AAO-HNS 1995,[1] comparing the number of vertigo spells in the six-month period before the treatment with those seen between the 18- to 24-month period after the treatment. The overall follow-up period ranged from 24 to 93 months.

RESULTS

The overall early posttreatment audiometric results obtained 4 to 10 weeks after treatment and vertigo control rates obtained from 18 to 24 months after the treatment are summarized in Table 4 and Table 5, respectively.

Intratympanic application of gentamicin

Vertigo improved significantly in 86.2% of the cases (class A 48.3, class B 37.9), but at the expense of impairment in hearing in 41.3%. Caloric responses at the end of the treatment showed a wide range of variations. Three patients (10.3%) had persistent tympanic membrane perforations, all of which were repaired with a simple outpatient myringoplasty.

Endolymphatic sac surgery

Deterioration in hearing was 10%. Vertigo control rate was 65%. In a group of nine patients who were

Table 4. Early audiometric results (4 to 10 weeks after treatment)

Treatment	Improvement or no change		Worsening in pure tone audiograms					
			10-25 dB		25-40 dB		>40 dB	
	No.	%	No.	%	No.	%	No.	%
Intratympanic gentamicin (n=29)	17	58.6	6	20.7	3	10.3	3	10.3
Endolymphatic sac surgery (n=20)	18	90.0	2	10.0	–		–	
Vestibular nerve section (n=112)	105	93.8	4	3.6	2	1.8	1	0.9

Table 5. Vertigo control rates in the treatment groups

Treatment	Class A		Class B		Class C or others	
	No.	%	No.	%	No.	%
Intratympanic gentamicin (n=29)	14	48.3	11	37.9	4	13.8
Endolymphatic sac surgery (n=20)	7	35.0	6	30.0	7	35.0
Labyrinthectomy (n=8)	7	87.5	1	12.5	–	
Vestibular nerve section (n=112)	104	92.9	6	5.4	2	1.8

Class A: complete vertigo control; class B: substantial control; class C and others: treatment failure.

followed-up for nine years, there was a remarkable decrease in vertigo control. No significant postoperative complications were encountered in this treatment group.

Labyrinthectomy

All the patients in this group had nonserviceable hearing in the diseased ear. After labyrinthectomy, all had vertigo control, with a complete hearing loss. No serious complications occurred postoperatively.

Vestibular nerve section

The most beneficial treatment was VNS, in terms of both complete control of vertigo spells (98.3%; class A 92.9, class B 5.4%) and preservation of hearing (93.8%). None of the patients required a revision procedure. A transient postoperative cerebrospinal fluid leak occurred in two (11.1%) and six (6.4%) patients who were operated on through retrolabyrinthine and retrosigmoid approaches, respectively. Headache occurred in one patient (5.6%) after the retrolabyrinthine approach and in 12 patients (12.8%) after the retrosigmoid approach. This symptom resolved spontaneously within a few weeks.

DISCUSSION

Both medical treatment, including psychological support, and the natural evolution of the disease are effective in the prognosis of vertigo spells. Interventional therapy is considered for patients with disabling vertigo nonresponsive to medical treatment. However, the ideal interventional therapy remains a matter of debate. A number of factors should be taken into consideration including the disease itself, the patient, and the study design. The behavior of the disease is variable with a capricious clinical course, making the frequency and severity of vertigo spells unpredictably increased or decreased. Vertigo may undergo spontaneous remission in some patients. Moreover, the disease may sometimes be bilateral. Factors related to the patient include age, general health condition, psychological status, hearing levels both in the affected ear and the contralateral ear, and occupation. Most patients tend to report subjective improvement with any therapy. Finally, the design of studies performed in vertigo patients may present some limitations and drawbacks. Although a two-year follow-up period is necessary to evaluate the results according to the AAO-HNS criteria, this may not be adequate to reliably assess the progress of symptoms and the development of contralateral disease. In some studies, the patients are not followed-up for at least two years. Moreover, the follow-up data may be confounded by the patient's ability to qualify his/her symptoms. Assessment of the results are not always made according to the AAO-HNS criteria. The effects of placebo and spontaneous improvement are not carefully evaluated. In addition, post-treatment hearing levels may be influenced by the fluctuating hearing in Ménière's disease.

In intractable cases, intratympanic aminoglycoside therapy is a nonsurgical procedure administered on an outpatient basis. Blakley[3] reviewed 18 studies with intratympanic gentamicin treatment for vertigo in MD and addressed the need for a better standardization because all the studies reported high success rates, but with considerable variations in technique, dose, duration, and treatment philosophy.

The ototoxic effects of gentamicin are unpredictable. The development of hearing loss following treatment is about 30%, presenting a wide variation in a range of 0% to 95%.[4,5]

Vertigo control rates range from 80% to 100%,[6-8] and, in a majority of studies, the overall improvement rate including total control (class A) and substantial control (class B) are reported, with class B varying from 5% to 25%.[3] However, the efficacy of intratympanic aminoglycoside therapy in the long-term remains unpredictable.[8]

Elderly patients or those who are at significant risk for surgery may be treated safely with intratym-

panic gentamicin and thus are primary candidates for this therapy. It can also be used in patients with recurrent vertigo after ineffective ablative vestibular surgery.

Endolymphatic sac surgery yields considerably lower rates of vertigo control ranging from 33% to 80%,[9-12] and its hearing benefits remain controversial. Long-term data show a steady decrease in the number of class A-B patients and an increase from 5% to 37% in the number of revision procedures.[13,14] It is associated with impaired hearing in about 18% of the patients.[10] Considering the literature data that cast doubt on the effectiveness of endolymphatic sac surgery in the long-term control of vertigo,[12,15] we no longer perform endolymphatic sac procedures.

Transcanal labyrinthectomy is a short, safe procedure and requires minimal hospitalization. It may be considered in patients with nonserviceable hearing in the affected ear. However, the possibility of hearing loss in the contralateral ear has to be taken into consideration.

Keeping the unpredictable effect of gentamicin injections on hearing in mind, our results demonstrated that the most beneficial treatment was VNS, in terms of both complete control of vertigo spells (class A) (92.9%) and preservation of hearing (93.8%) at the pre-treatment levels. Patients who suffer from a high level of disability (4-6 levels of the AAO-HNS Functional Level Scale) usually develop important emotional and psychological discomfort, especially if their occupation requires a good psychophysical performance. They seek a safe treatment that will provide an immediate, complete, and permanent relief of vertigo spells while preserving their hearing. Thus, in these patients, even a substantial control of vertigo (class B) may still be regarded as a high level of disability. In this respect, the best method to meet these expectancies seems to be VNS performed through an approach safe for the labyrinth, which offers the highest likelihood of complete control of vertigo spells and preservation of hearing from the first postoperative month. We do not perform VNS in patients older than 70 years or in those exhibiting a bad general condition, in order to avoid potential intracranial complications and a more difficult central vestibular compensation.

In conclusion, if hearing is to be preserved, VNS is the procedure of choice in patients with a high disability level due to unilateral vertigo spells in MD. Labyrinthectomy is a surgical option when there is no serviceable hearing in the damaged ear. Intratympanic gentamicin administration may be considered in patients who refuse surgery or present with surgical contraindications. For each individual patient, proper pretreatment counseling is of paramount importance regarding the natural history of the disease, the risk/benefit ratio, and real expectations from each treatment.

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