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Tenotomy of the tensor tympani and stapedius tendons in Ménière's disease

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Abstract. *Tenotomy of the tensor tympani and stapedius tendons in Ménière's disease. Objective*: In Ménière's disease (MD), when patients have incapacitating vertigo that is resistant to drug treatment, an intratympanic gentamicin application (ITG) is often proposed. Recently, some authors suggested that tenotomy, sectioning of the tensor tympani and stapedius tendons, could be a promising treatment. We examined whether tenotomy (ST) has additional benefit, compared to ITG alone, with respect to tinnitus, vertigo, and quality of life.
Methodology: We conducted a retrospective survey of the charts of 24 patients with MD who underwent ITG, or ITG plus ST. Baseline data and follow-up assessments were obtained, using the Ménière's Disease Outcomes Questionnaire (MDOQ), the Dizziness Handicap Inventory (DHI), vertigo frequency per month, tinnitus visual analogue scale, and functional level. Failure was determined by the need for an additional procedure.
Results: ITG was performed on 15 patients, and 9 patients underwent ITG plus ST. The procedure was sufficient in 53% of the ITG group and in 22% of the ITG plus ST group. No significant difference was found between the two groups concerning MDOQ scores, DHI, functional level, vertigo frequency, and tinnitus. In the ITG group, we found a significant improvement in number of vertigo attacks and the tinnitus visual analogue scale. In the ITG plus ST group, there was a significant reduction in vertigo attacks, but not in tinnitus.
Conclusion: This preliminary study suggests no additional benefit of stapedius and tensor tympani tenotomy in the treatment of Ménière's disease patients.

Abbreviations

AAO-HNS: American Academy of Otolaryngology – Head and Neck Surgery
DHI: Dizziness Handicap Inventory
ITG: Intratympanic Gentamicin Application
MD: Ménière's Disease
MDOQ: Ménière's Disease Outcomes Questionnaire
PTA: Pure-Tone Average
QoL: Quality of Life
ST: Stapedius and Tensor Tympani Tenotomy
SVN: Selective Vestibular Neurectomy
TQ: Tinnitus Questionnaire
VAS: Visual Analogue Scale

Introduction

Ménière's disease (MD) is a condition classically characterized by episodes of vertigo, sensorineural hearing loss, tinnitus, and aural fullness. The underlying pathologic lesion is generally assumed to be idiopathic endolymphatic hydrops. Diagnosis is based on a history of the classic clinical signs, hearing loss in the affected ear on pure-tone audiometry, electrocochleography and electronystagmography. Conditions that mimic MD have to be ruled out, (i.e. tumours of the central nervous system, aneurysms, Chiari malformations, multiple sclerosis, etc.). This can be done by magnetic resonance imaging (MRI).[1]

There is no definitive cure for MD, although medical management, including dietary restrictions and drug therapy with diuretics and/or betahistine,[2] can halt its progression. Hearing aids and vestibular rehabilitation can also improve the patient's quality of life. Some patients have intractable or progressive MD despite medical therapy. In this population, interventional (mainly destructive) treatment is indicated. This includes intratympanic gentamicin application (ITG), selective vestibular neurectomy (SVN), labyrinthectomy, or endolymphatic sac surgery, which

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is commonly performed in the USA.[3-6]

Intratympanic application of gentamicin (ITG) is the least surgically invasive method of partial ablation of the vestibular end organ. ITG takes advantage of the aminoglycoside antibiotic's toxicity to the inner ear. The mechanism of action consists of the passive diffusion of gentamicin through the round window membrane, and absorption into the inner ear structures, where it selectively destroys the vestibular apparatus, and generally leaves the cochlea intact. Overall, ITG is well tolerated by patients, and improves vestibular symptoms.[7-14]

Beside the surgical procedures, another procedure was described in the late 19th century by Weber,[15] and widely used up until 1920. This is tenotomy, the sectioning of the tensor tympani and stapedius tendons. This therapeutic approach was recently rediscovered and re-evaluated. Tenotomy seemed to significantly reduce the frequency and intensity of vertigo, and improved both the functional profile and tinnitus. Moreover, the authors suggested that tenotomy should be reconsidered as a promising treatment for MD.[16]

To examine whether stapedius and tensor tympani tenotomy has an additional benefit, compared to the ITG procedure alone, with respect to tinnitus, vertigo and quality of life, we conducted a chart review, and interviewed patients to learn their condition after treatment.

Materials and methods

Subjects

We conducted a retrospective survey on the follow-up charts of 24 consecutive patients with intractable MD, who underwent ITG or ITG combined with stapedius and tensor tympani tenotomy (ITG plus ST) from April 2001 until January 2005.
Only subjects with unilateral MD were included. Diagnosis of MD was based on the classic history, and findings of a fluctuating or progressive sensorineural hearing loss, recurrent episodes of vertigo, and associated tinnitus. MRI was used to rule out other conditions that mimic MD.

Ten women and 14 men were included. Their ages at the time of the procedure ranged from 17 yr to 71 yr (mean 50 yr). Eleven patients (46%) were older than 50 yr at that time. We could not follow up on two patients: one patient died and another was lost to follow-up (subjects 10 and 19 in Table 1).

This study was performed in accordance with the guidelines approved by the Committee for Medical Ethics of the Antwerp University Hospital. Informed consent was obtained from each patient.

We obtained baseline data before the procedure. Follow-up evaluation included a detailed clinical and audiometric assessment of patient symptoms.

Measures

To assess the effect of vertigo on daily activities, the Dizziness Handicap Inventory (DHI)[17,18] was used in combination with the patient's report of vertigo frequency per month. Pure-tone audiometry was performed before surgery, and periodically after treatment. Audiometric findings were used to calculate the pure-tone average (PTA, mean of the thresholds at 500, 1000, 2000 and 3000 Hz in decibels).

The situation of the patient after treatment was evaluated in an interview, in which the Ménière's Disease Outcomes Questionnaire (MDOQ), vertigo frequency, DHI and functional level according to the AAO-HNS criteria[19] were obtained. The functional level was determined using a 6-point scale, in which 1 = activities are unaffected by dizzy spells, 2 = activities are slightly affected by dizzy spells, 3 = activities are moderately affected by dizzy spells, 4 = major adjustments are necessary, 5 = the patient is limited to essential activities, and 6 = the patient is completely disabled. Functional level was not routinely tested and was therefore omitted from the retrospective data.

For the patient's assessment of tinnitus before and after treatment, a subjective scale from 1 to 10 was used, in which 1 = barely noticeable, and 10 = intolerable (tinnitus visual analogue scale or TVAS). The difference in the tinnitus visual analogue scale (TVAS difference) was defined as the difference between the patient's assessment before and after the procedure. A negative value denotes deterioration. A positive value denotes improvement.

The Dizziness Handicap Inventory (DHI) is a 25-item, validated, self-reported questionnaire designed to evaluate the precipitating physical factors associated with dizziness and unsteadiness, as well as the functional and emotional consequences of vestibular system disease.[17] Each item is answered 'No' (0 points), 'Sometimes' (2 points), or 'Yes' (4 points). Scores on the DHI range from 0 (indicating no problems) to 100 (maximum perceived

Table 1
Overview

Subject	Group	Age/sex	Duration MD (years)	Baseline FV/T	Baseline PTA (dB)	Failure	4-6 months PTA (dB/FV)	Functional level (AAO-HNS)	Now FV/T	TVAS difference	MDOQ	M-MDOQ	P-MDOQ	S-MDOQ	DHI
1	ITG + ST	67/M	5	8/5	105	No	86/1	2	0/5	0	13.2	18.8	11.1	15	44
2	ITG + ST	40/F	2	5/10	29	No	28/0	1	0/1	9	72.4	68.8	86.1	65	0
3	ITG + ST	55/F	15	4/9	48	Yes	54/0	3	0/9	0	27.6	12.5	33.3	35	46
4	ITG + ST	17/M	1	1/9	54	Yes	40/0	2	2/9	0	36.8	25	38.9	50	28
5	ITG + ST	43/M	8	5/9	39	Yes	40/1	6	5/9	0	0	0	0	0	82
6	ITG + ST	32/F	6	20/9	58	Yes	40/0	6	1.5/4	5	21.1	12.5	22.2	30	42
7	ITG + ST	47/M	1	2/6	44	Yes	43/0	1	0/6	0	44.7	43.8	47.2	50	2
8	ITG + ST	54/M	4	8/3	34	Yes	74/12	2	0.2/8	-5	-7.9	0	-13.9	-5	24
9	ITG + ST	61/M	4	4/7	70	Yes	64/0	3	2/2	5	5.3	6.3	2.8	10	66
10	ITG	45/F	1	4/-	34	Yes	55/28	-	-	-	-	-	-	-	-
11	ITG	38/F	3	16/8	56	No	24/0	1	0/1	7	52.6	50	58.3	55	28
12	ITG	71/F	11	9/9	89	Yes	87/13	4	0/4	5	21.1	12.5	25	25	66
13	ITG	59/M	3	0/9	66	Yes	59/0	1	0/2	7	34.2	31.3	36.1	40	8
14	ITG	43/M	24	28/8	80	No	75/0	3	0/3	5	36.8	43.8	33.3	45	30
15	ITG	67/F	18	1/6	74	No	71/0	1	0/8	-2	40.8	43.8	36.1	55	42
16	ITG	34/F	4	2/6	44	No	56/1	1	0/3	3	64.5	68.8	61.1	80	2
17	ITG	60/M	2	28/9	65	No	81/0	1	0/1	8	67.1	56.3	69.4	85	2
18	ITG	44/F	27	2/7	88	Yes	90/0	3	2/7	0	10.5	0	16.7	10	74
19	ITG	64/M	7	56/7	74	Yes	80/0	-	-	-	-	-	-	-	-
20	ITG	45/F	10	14/8	98	No	30 (CI)/0	2	0/8	0	2.6	0	2.8	5	46
21	ITG	59/M	4	8/3	88	No	69/0	3	2/0	3	39.5	25	50	40	28
22	ITG	47/M	2	28/8	70	Yes	53/2	2	2/8	0	31.6	18.8	38.9	35	26
23	ITG	55/M	26	14/8	36	Yes	34/2	3	0/4	4	40.8	37.5	50	35	80
24	ITG	48/M	34	3/10	60	No	23/0	1	0/0	10	57.9	37.5	69.4	65	16

Duration of MD: the interval between the onset of symptoms and the time of procedure, in years.
Failure: defined as the need for an additional procedure (i.e. ITG or selective vestibular neurectomy).
PTA: pure-tone average according to the AAO-HNS guidelines (i.e. the arithmetic mean of the pure-tone thresholds at 500, 1000, 2000 and 3000 Hz in decibels, rounded to the nearest whole number). If 3 kHz was not available, it was replaced by the mean of 2 and 4 kHz.
FV: vertigo frequency (i.e. the number of attacks of vertigo persisting >20 minutes, per month).
FL: functional level, according to the AAO-HNS guidelines.
T: tinnitus VAS: subjective scale from 1 to 10 where 1 = barely noticeable and 10 = intolerable.
TVAS difference: difference of tinnitus VAS between the situation before procedure and the current situation. A negative value denotes deterioration. A positive value denotes improvement.
MDOQ: Ménière's Disease Outcomes Questionnaire, M-MDOQ: mental subscore, P-MDOQ: physical subscore, S-MDOQ: social subscore. A positive value denotes improved QoL; a negative value, worsened QoL; and 0 denotes stable QoL.
DHI: dizziness handicap inventory, evaluates the effect of dizziness on QoL and daily functioning, scores range from 0 (indicating no problems) to 100 (maximum perceived handicap).

handicap), and can be further subdivided into physical, functional and emotional subscores. The Dutch version of the DHI was used. Recently, this version was shown to be a highly reliable instrument for assessing self-perceived handicap, with excellent test-retest reliability, with Intraclass Correlation Coefficients ranging from 0.94 to 0.99 for DHI subscores and DHI total scores (n = 106).[17,18]

The MDOQ is a disease-specific questionnaire to assess quality of life (QoL) in patients with MD before and after treatment.[20] The MDOQ addresses three domains that determine QoL in physical, mental, and social well being. The questionnaire consists of 19 multiple-choice questions, which are paired for pre- and postoperative conditions. The main outcome determinant is the change in the MDOQ QoL score, calculated as the difference between the preoperative and postoperative score. A change of '0' indicates no improvement. The higher the score, the greater the subjective benefit of the therapy.

Failure was described as the need for an additional procedure, another ITG or selective vestibular neurectomy (SVN).

Statistics

For the statistical analysis, we used Statistical Package for Social Sciences software (SPSS 14.0). Because of the small sample size, only non-parametric tests (Mann-Whitney U test and Wilcoxon signed rank test) were applied. Chi-square was used for categorical variables. Statistical difference was considered significant at the $p<0.05$ level.

Results

Patient characteristics of the two groups:

The mean duration of disease at the time of the procedure was 9 yr; with a range of 1 yr to 34 yr. ITG was performed on 15 patients (62.5%). ITG plus ST were performed on 9 patients (37.5%). Thirteen patients (54%) were treated on the left side, and 11 (46%) were treated on the right side. The mean time period between the first procedure and the final evaluation was 3.3 yr (SD 1.4), ranging from 2 yr to 7 yr.

Comparing the two groups, there was no significant difference in the age distributions (ITG mean age 52 yr, SD 10.9; ITG plus ST mean age 46 yr, SD 15; Mann-Whitney U test, $p = 0.41$), or in the gender ratio (Chi-Square test, $p = 0.52$). One patient in the ITG group (subject 20) received a cochlear implantation after the first procedure. For this reason, this patient was excluded in the analysis of hearing and tinnitus.

Before surgery, there was no significant difference between baseline parameters of the two groups with respect to hearing loss, vertigo frequency, and visual analogue scale of tinnitus (Mann-Whitney U test, respectively $p = 0.07$; $p = 0.34$; and $p = 0.80$). Table 1 gives an overview of the 24 patients.

Comparison between the two groups (See Table 2)

After treatment, in the ITG group, 77% of the patients were completely free of vertigo attacks, compared to 56% in the ITG plus ST group (difference not significant, $p = 0.29$).

There was no statistical difference in the percentage of failures between the two groups (Chi-square analysis, $p = 0.13$). In the ITG group, the procedure was sufficient in 8 patients (53%), and failed in 7 patients (47%). In this group, three patients had one additional ITG, and three had two additional ITGs. In the group that underwent ITG plus tenotomy, the procedure failed in 7 patients (78%), of which 6 had an additional ITG, and one patient had 5 additional ITGs, in order to have a good result. In each of the two groups, there was one patient who eventually underwent a SVN.

Although scores and subscores on the Ménière's Disease Outcome Questionnaire (MDOQ) seemed to be better in the group with ITG, this difference was not significant. Nor was there a significant difference with regard to the other parameters (DHI, functional level, vertigo frequency, and tinnitus VAS).

Analysis of the two groups separately (See Table 3)

Patients who underwent the ITG procedure alone had a significant reduction of vertigo attacks, with the mean number reduced from 12 to 1 per month, and experienced less tinnitus (Wilcoxon signed rank test; $p = 0.019$ and 0.007 respectively) after treatment. Hearing thresholds improved, but this improvement was not statistically significant (Wilcoxon signed rank test; $p = 0.33$).

In the ITG plus ST group, we also noticed a significant improvement in the number of vertigo attacks, with the mean number reduced from 6 to 1 per month (Wilcoxon signed rank test; $p = 0.037$). Tinnitus VAS and hearing

Table 2
Comparison between the two groups

	ITG	ITG plus tenotomy	p
No more vertigo	77%	56%	NS (0.29)**
Failure (%)	47 %	78 %	NS (0.13)**
MDOQ	39 (20)	24 (25)	NS (0.13)*
MDOQ-mental	33 (21)	21 (23)	NS (0.18)*
MDOQ-physical	42 (20)	25 (30)	NS (0.09)*
MDOQ-social	44 (24)	28 (24)	NS (0.15)*
DHI	35 (26)	37 (27)	NS (0.84)*
Functional level	2 (1)	3 (2)	NS (0.31)*
Vertigo frequency (per month)	1 (1)	1 (2)	NS (0.31)*
VAS tinnitus (0-10)	3.4 (2.9)	5.9 (3.1)	NS (0.058)*
Difference VAS tinnitus	4.2 (3.6)	1.6 (4.1)	NS (0.17)*

* Mann-Whitney U-test, ** Chi Square.

Table 3
Analysis of the two groups separately

ITG group	**baseline**	**Follow-up**	**p**
Number of vertigo attacks/month	12 (11)	1 (1)	0.019
Tinnitus VAS	7.6 (2)	3.4 (3)	0.007
Hearing PTA (dB)	68 (17)	60 (23)	NS (0.33)
ITG + ST group	**baseline**	**Follow-up**	**p**
Number of vertigo attacks/month	6 (6)	1 (2)	0.037
Tinnitus VAS	7 (2)	6 (3)	NS (0.26)
Hearing PTA (dB)	53 (23)	52 (19)	NS (0.41)

Legend: Wilcoxon signed rank test was used for statistical analysis.

thresholds did not improve significantly (Wilcoxon signed rank test; p = 0.26 and p = 0.41 respectively).

Discussion

In patients with intractable Ménière's disease, more invasive treatment such as intra-tympanic gentamicin application, labyrinthectomy, selective vestibular neurectomy, or endolymphatic sac surgery may be proposed. Of these surgical techniques, selective vestibular neurectomy is the most invasive, as it necessitates a craniotomy. Labyrinthectomy has disadvantages over selective vestibular neurectomy because of the complete loss of hearing, and the loss of the option to perform a cochlear implantation if profound bilateral sensorineural hearing loss evolves. Endolymphatic sac decompression is frequently performed in the United States, and consists of a mastoidectomy with wide decompression of the sigmoid sinus, localisation of the endolymphatic sac, and insertion of a custom made Silastic sheet in the sac. However, there are controversies about the effectiveness of endolymphatic sac surgery, since Thomsen *et al.* found no difference in results between this surgery and a sham procedure.[20,21]

The advantage of intratympanic gentamicin application (ITG) is its mildly invasive nature. This treatment has been intensively studied, and proved to be efficient in improving vertigo attacks.[7-14] In 2003, Franz *et al.*[16] concluded that another surgical approach in which the tensor tympani and stapedius muscles tendons are sectioned, called 'tenotomy,' could be a promising treatment for MD.

In our preliminary study, we compared a group of patients who had ITG treatment with patients who had ITG plus ST, in order to evaluate whether tenotomy would have an additional benefit. One of our main outcome parameters was the need for an additional intervention, called 'failure of procedure.' We found a relatively high percentage of failure in both groups, with an even higher percentage in the group with ITG plus ST (78%, compared to 44% in the ITG alone group), although this difference was not significant. When evaluating quality of life using MDOQ and functional level score, ITG alone patients seemed to perform better, but again this difference was not significant. The same can be said about tinnitus and vertigo (assessed by tinnitus VAS and vertigo frequency per month). When analyzing the two

groups separately, we found a significant improvement concerning vertigo frequency and tinnitus in the ITG alone group. Similarly, in the ITG plus ST group, we noticed an improvement. However this improvement in tinnitus was not significant, in contrast with the results of Franz *et al*.[16] His research group stated that, two years after tenotomy, 70% of the patients were completely free of vertigo attacks. All our patients had a minimum follow up of two years. In the ITG alone group, 80% of the patients had no more vertigo attacks, as did 44% of the patients in the ITG plus ST group. These results suggest that ST in combination with ITG has no additional benefit. Furthermore, some parameters suggest a negative effect of tenotomy. However, no statistically significance could be obtained. We are aware of the limitations in our study, the rather small sample size and the retrospective design. However, because of the doubtful results of this preliminary study, we did not perform a prospective survey with the tenotomy procedure.

Conclusion

Our results suggest that addition of tenotomy to the treatment of Ménière's disease with ITG doesn't have an additional value.

References

1. Saeed SR. Fortnightly review. Diagnosis and treatment of Ménière's disease. *BMJ*. 1998;316:368-372.
2. Claes J, Van de Heyning PH. Medical treatment of Meniere's disease: a review of literature. A*cta Otolaryngol Suppl*. 1997;526:37-42.
3. Van de Heyning P.H., De Valck C.F.J., Boudewyns A, *et al*. Ménière's disease. *B-ENT* 2007;3 Suppl 6:11-20.
4. Van de Heyning PH, Wuyts FL, Claes J, Koekelkoren E, Van Laer C, Valcke H. Definition, classification and reporting of Meniere's disease and its symptoms. *Acta Otolaryngol Suppl*. 1997;526:5-9.
5. Van de Heyning PH, Wuyts F, Boudewyns A. Surgical treatment of Meniere's disease. *Curr Opin Neurol*. 2005;18:23-28.
6. Kaylie DM, Jackson CG, Gardner EK. Surgical management of Meniere's disease in the era of gentamicin. *Otolaryngol Head Neck Surg*. 2005;132:443-450.
7. Assimakopoulos D, Patrikakos G. Treatment of Ménière's disease by intratympanic gentamicin application. *J Laryngol Otol*. 2003;117:10-16.
8. Bottrill I, Wills AD, Mitchell AL. Intratympanic gentamicin for unilateral Meniere's disease: results of therapy. *Clin Otolaryngol Allied Sci*. 2003;28:133-141.
9. Cohen-Kerem R, Kisilevsky V, Einarson TR, Kozer E, Koren G, Rutka JA. Intratympanic gentamicin for Menière's disease: a meta-analysis. *Laryngoscope*. 2004;114:2085-2091.
10. Kaasinen S, Pyykkö I, Ishizaki H, Aalto H. Intratympanic gentamicin in Meniere's disease. *Acta Otolaryngol.* 1998;118:294-298.
11. Pfleiderer AG. The current role of local intratympanic gentamicin therapy in the management of unilateral Menière's disease. *Clin Otolaryngol Allied Sci*. 1998;23:34-41.
12. Rauch SD, Oas JG. Intratympanic gentamicin for treatment of intractable Meniere's disease: a preliminary report. *Laryngoscope*. 1997; 107:49-55.
13. Stokroos R, Kingma H. Selective vestibular ablation by intratympanic gentamicin in patients with unilateral active Ménière's disease: a prospective, double-blind, placebo-controlled, randomized clinical trial. *Acta Otolaryngol*. 2004;124:172-175.
14. Suryanarayanan R, Cook JA. Long-term results of gentamicin inner ear perfusion in Ménière's disease. *J Laryngol Otol*. 2004;118:489-495.
15. Weber FE. Tenotomie des Tensor Tympani. *Monatsschr Ohrenheilkd*. 1870;10:120-126.
16. Franz P, Hamzavi JS, Schneider B, Ehrenberger K. Do middle ear muscles trigger attacks of Menière's disease? *Acta Otolaryngol*. 2003;123: 133-137.
17. Jacobson GP, Newman CW. The development of the Dizziness Handicap Inventory. *Arch Otolaryngol Head Neck Surg.* 1990;116:424-427.
18. Vereeck L, Truijen S, Wuyts F, Van de Heyning PH. Test-retest reliability of the Dutch version of the Dizziness Handicap Inventory. *B-ENT*. 2006;2: 75-80.
19. Committee on Hearing and Equilibrium guidelines for the diagnosis and evaluation of therapy in Menière's disease. American Academy of Otolaryngology-Head and Neck Foundation, Inc. *Otolaryngol Head Neck Surg.* 1995;113:181-185.
20. Kato BM, LaRouere MJ, Bojrab DI, Michaelides EM. Evaluating quality of life after endolymphatic sac surgery: The Ménière's Disease Outcomes Questionnaire. *Otol Neurotol.* 2004;25:339-344.
21. Thomsen J, Bretlau P, Tos M, Johnsen NJ. Ménière's disease: endolymphatic sac decompression compared with sham (placebo) decompression. *Ann N Y Acad Sci*. 1981;374:820-830.

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