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Intratympanic lidocaine instillation for Menière's disease

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Abstract. *Intratympanic lidocaine instillation for Menière's disease. Objectives*: We studied the role of intratympanic lidocaine instillation as part of the treatment for vertigo in Menière's disease.
Methodology: We retrospectively analyzed 40 patients who underwent 74 labyrinth anaesthesias in our center between 1996 and 2006. We studied the attack-free period after instillation, the effect of repetitive procedures and the efficacy according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (1995) criteria.
Results: Labyrinth anaesthesia was effective in 70% of the studied procedures. If effective, the mean duration of the attack-free period was 12.6 months. Repetition was effective in 80.7% of the procedures if the previous procedure was effective as well. Two years after treatment 21 patients had AAO-HNS functional levels of 1 or 2 and 23 patients were class A or B.
Conclusion: Labyrinth anaesthesia is an effective treatment for Menière's disease and a useful tool for the control of symptoms. Repetitive instillation is effective especially when the previous instillation was also effective.

Introduction

According to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (Tables 1 and 2) , Menière's disease is defined as the combination of three symptoms: recurrent, spontaneous episodic vertigo, sensorineuronal hearing loss and tinnitus and/or aural fullness on the affected side.[1] At onset, the disease has a serious impact on the patient's quality of life, especially given the unpredictable nature of the recurrent vertigo spells.[2] Therefore, treatment is primarily focused on reducing the frequency and intensity of vertigo attacks and preventing their recurrence. The ultimate goal of therapy is a non-destructive (if possible) improvement in patient quality of life with minimal side effects from the treatment.[2,3] In 85% of cases this aim is achieved through medical treatment and lifestyle changes alone.[3] When medical treatment fails, various treatment strategies are possible such as intratympanic gentamicin instillation or vestibular nerve section: however none of these treatments is 100% successful and until now there has been no consensus on preferred therapy.[2,3]

In our institution we perform an intratympanic instillation with lidocaine 2% if conservative measures with oral medication and lifestyle changes fail to control symptoms of vertigo. This technique is also known as labyrinth anaesthesia and to date only a few reports in English include this non-destructive therapy.[4-9] We wished to review the efficacy and role of labyrinth anaesthesia as part of the treatment for Menière's disease. Therefore, we studied the attack-free period after instillation, the effect of repetitive procedures and the efficacy according to the AAO-HNS criteria.

Materials and methods

We performed a retrospective analysis of labyrinth anaesthesias performed at the ENT-department of the University Hospitals Leuven between January 1996 and January 2006. During this period 40 patients (16 females and 24 males) with definite Menière's disease, according to the AAO-HNS criteria, underwent 74 labyrinth anaesthesias. Two patients had bilateral disease; all other patients were unilateral. All patients had been treated unsuccessfully with medication (betahistine, diuretics and sulpiride) and lifestyle changes

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Table 1

Functional level scale for Menière's disease according to the 1995, AAO-HNS classification

	Regarding my current state of *overall* function, *not just during attacks*:
1.	My dizziness has no effect 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 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.
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.
6.	I have been disabled for 1 year or longer and/or I receive compensation (money) because of my dizziness or balance problem.

Table 2

Vertigo classes and scoring according to the 1995 AAO-HNS classification

- A = frequency of attacks 18-24 months after treatment
- B = frequency of attacks 6 months before treatment
- score = A/B ×100
- each score obtained with this calculation corresponds to a specific class as shown below

score	class
0	A
1-40	B
41-80	C
81-120	D
>120	E
salvage	F

including salt, chocolate, alcohol and caffeine restriction. None of these patients had been previously treated for Menière's disease with otologic surgery. Persistent vertigo attacks at least three times per month served as the indication to perform a labyrinth anaesthesia.

Each labyrinth anaesthesia was performed in the day care hospital. Primary or single instillations were performed by CD or a senior resident. If the first instillation failed, one more repetitive instillation was performed by CD. Before instillation, each patient received an infusion with normal saline and 50 mg alizapride. The patient was placed in a supine position with the head turned 45° to the non-affected side. After local anaesthesia of the tympanic membrane with Bonain's solution (phenol 5 g + menthol 5 g + cocaine 5 g), the patient was asked to hold the injection tube for 15 minutes to heat it to body temperature and to prevent caloric nystagmus and vertigo during instillation. The cavity of the middle ear was filled with 1-1.5 cc of a 2% lidocaine solution, which was slowly injected into the inferior-posterior quadrant at the level of the round window. A 2% solution was chosen due to its routine availability at the day care hospital. The patient remained in this position for 30 minutes and was advised not to swallow in order to allow the lidocaine to pool in the round window niche and penetrate into the inner ear. Fifteen to thirty minutes after a well-performed labyrinth anaesthesia a mixed horizontal-rotatory nystagmus to the opposite side appeared that was associated with nausea and vertigo, and lasted up to three hours. Additional anti-emetic treatment was given if severe nausea and vomiting occurred. The patient remained in the day care hospital until these symptoms disappeared. No additional medication was prescribed at discharge, the current treatment was continued and the patient was advised not to work for three days (including the day of the injection). The first follow-up consultation was scheduled after one month. If the patient remained attack-free, the medical treatment (betahistine, sulpiride and/or diuretics) was slowly reduced depending on case evolution. A second labyrinth anaesthesia was performed in case of recurrence.

We reviewed the medical reports of the 40 patients included in this study. When the medical file contained insufficient data to obtain the functional level scale or the AAO-HNS classification two years post-treatment, the patients were contacted by phone in January 2008 (Table 3: patient 18; Table 4: patients 7 and 11). We

Table 3

Results from 20 patients who underwent only one labyrinth anaesthesia. M = male, F = female, R = right, L = left, FL = functional level, both = betahistine and diuretics. FL-scale pre = score on the functional level scale (Table 1) six months before treatment. FL-scale post = score on the functional level scale 18-24 months after treatment

Patient	Sex	Ear side	Total follow up (mth)	Age at first operation (years)	FL-scale pre	FL-scale post	Vertigo AAO-HNS classification	Post-operative time without vertigo attacks (mth)	Last therapy
1	F	R	57	39.4	4	1	B	7	None
2	M	R	117	37.2	5	5	D	0	Diuretics
3	M	R	46	39.6	5	2	A	3	Both
4	M	R	44	26.9	3	1	A	36	None
5	M	R	22	40.6	5		F	0	Vestibular neurectomy
6	F	R	34	73.0	4	1	A	11	None
7	M	R	4	45.8	5		F	1	Gentamicin
8	M	R	50	62.1	5	1	A	38	Both
9	M	R	31	51.5	5		F	0	Gentamicin
10	F	L	75	45.2	4		F	2	Labyrinthectomy
11	F	L	25	70.8	5	2	A	24	Both
12	M	L	35	38.3	5	5	D	0	Both
13	M	L	54	51.1	4	1	A	48	Both
14	F	L	42	51.4	4	1	A	9	None
15	F	L	65	56.4	5	1	A	24	Betahistine
16	F	L	62	52.3	5	2	B	0	Betahistine
17	M	L	45	62.4	4	2	A	26	Diuretics
18	F	L	36	35.1	5	3	B	10	Betahistine
19	M	L	48	46.1	5	2	A	0	Betahistine
20	M	L	44	68.8	4	1	A	24	None

studied the attack-free period (the time between instillation and the first vertigo attack), the functional level 6 months pre- and 18-24 months post-intervention (Table 1) and the frequency of vertigo attacks 6 months pre- and 18-24 months post-intervention to determine the classification according of each case to the AAO-HNS criteria (Table 2).[1] We also compared the group of primary procedures containing the single and first instillations with the group of repetitive procedures containing the procedures following one or more previous instillations by the Log-Rank Mantel Cox test (Table 5). Statistical analyses were carried out with the GraphPad Prism.

Results

The mean age in our group of 40 patients at the first operation was 51.3 years (range 26.9 80.6). Single labyrinth anaesthesias were performed in 20 of the 40 patients (Table 3). Thirteen patients underwent two procedures, four patients had three instillations, two patients underwent five procedures and one patient experienced up to six procedures (Table 4). No complications due to the surgical procedure were reported. The mean follow-up time was 54.5 months (range 4-123 months). Fourteen patients required salvage therapy: nine of these patients were additionally treated with intratympanic gentamicin, two patients were treated with saccus decompression and intratympanic gentamicin, one patient received saccus decompression alone, one patient received intratympanic gentamicin and vestibular neurectomy and one patient was treated with intratympanic gentamicin and labyrinthectomy.

Since the patients experienced more than three attacks per month prior to the labyrinth anaesthesia, this treatment was considered

Table 4

Results from 20 patients who underwent more than one procedure. M = male, F = female, R = right, L = left, FL = functional level, both = betahistine and diuretics. FL-scale pre = score on the functional level scale (Table 1) six months before treatment. FL-scale post = score on the functional level scale 18-24 months after treatment

Patient	Sex	Ear side	Total follow up (mth)	Age at First operation (years)	FL-scale pre	FL-scale post	Vertigo AAO-HNS classification	Post-operative time without vertigo attacks (mth)	Last therapy
1	M	R	47	51.5	5		F	4/4	Gentamicin
2	F	R	59	71.7	5		F	7/0/0	Saccus decompression
3	M	R	21	47.6	4		F	1/0	Gentamicin
4	F	R	72	57	5	1	A	2/41	Diuretics
5	M	R	38	53.7	4	1	A	3/21/5	None
6	M	R	69	49.3	4		F	3/0	Gentamicin
7	M	R	40	65.1	4	1	A	0/27	Betahistine
8	M	R	35	53.2	5	4	B	0/6/4/6/8	Diuretics
9	F	R	103	65.6	5	2	A	6/23	Betahistine
10	F	R	32	80.6	5		F	0/0	Gentamicin
11	M	L	110	53.0	5	1	A	2/22/1/2/48	Diuretics
12	M	L	85	39.2	5		F	16/1/4/6/19/1	Saccus decompression
13	F	L	123	69.0	5	1	A	3/17	None
14	M	L	53	45.6	5		F	7/0/0	Gentamicin
15	F	L	9	37.4	4		F	0/0	Gentamicin
16	F	L	96	38.9	4	2	A	2/32	Diuretics
17	M	L	65	50.9	5		F	0/6	Gentamicin
18	M	L	59	33.5	4	4	C	1/4/5	Both
19	F	L	86	45.9	4		F	0/0	Gentamicin
20	M	L	42	50.5	5	5	B	22/0	Both

effective if the patient experienced no vertigo attacks during the first month after the instillation. In 70% of all procedures (N = 74), patients were free of attacks for a period of at least one month (Table 5). For at least one month, primary instillation was effective in 62% of procedures and repetitive instillation was effective in 71% (Table 5). There was no significant difference between the effect of primary and repetitive procedures ($p \leq 0.82$).

The period without vertigo attacks ranged from 0 months to 48 months. If labyrinth anaesthesia was effective, in 58% of procedures the effect lasted for at least six months and the mean attack-free interval was 12.6 months.

Six months before instillation one patient was rated as functional level 3, fifteen patients had functional level 4 and twenty-four patients had functional level 5 (Tables 3 and 4). No patients were rated as functional level 1, 2 or 6. The patients who were treated with salvage therapy were not included in these results.

From 18-24 months after treatment, thirteen patients were free of vertigo (functional level 1) and eight patients still had a few complaints but no or very little effect on daily life (seven patients at functional level 2 and one patient at functional level 3). Two patients reported no effect of treatment (functional level 5). Three patients experienced vertigo attacks 18-24 months after the first instillation, therefore their daily comfort level was worse when the score was adjudged, resulting in a reduction of their functional level (two patients at functional level 4, one patient functional level 5). Comparing pre- and post-operative status, therefore, the functional level scores in these three patients did not improve, although a positive effect of treatment was experienced during the first 18 months after instillation. Overall, twenty-one patients experienced a

Table 5

Duration of the attack-free period following labyrinth anaesthesia, presented as percentages for four subgroups: all procedures, effective procedures that resulted in an attack-free interval of at least one month, primary procedures, and repetitive procedures including all procedures (except primary) performed in patients who underwent at least two labyrinth anaesthesias. There was no significant difference between the primary procedure group and the repetitive procedure group ($p \leq 0.83$)

	1 mth	3 mth	6 mth	12 mth	18 mth	24 mth
All procedures (n = 74)	70%	55%	41%	24%	22%	15%
Effective procedures (n = 52)	100%	79%	58%	35%	31%	21%
Primary procedures (n = 40)	6%	47%	36%	20%	18%	16%
Repetitive procedures (n = 34)	71%	59%	41% 26% 24% 12%			

reduced frequency of vertigo attacks 18-24 months after the first instillation. Seven of these patients stopped medical treatment. The other patients (N = 23) continued treatment with betahistine or diuretics or both.

According to the AAO-HNS classification (Table 2) 23 of the 40 patients were class A or B after two years (57.5% of the study population); only three patients were class C or D (7.5%). Because labyrinth anaesthesia has only a temporary effect (mean 12.6 months if effective), fourteen patients required salvage therapy as a definite solution; of these patients thirteen received salvage treatment within the first two years after labyrinth anaesthesia and one patient was treated by saccus decompression six years after the first instillation because of recurrent vertigo attacks (Table 4: patient 12).

If the first instillation procedure failed, only three labyrinth anaesthesias were effective out of eight repetitive procedures (37.5%). If the preceding procedure had been effective, 21 out of 26 repetitive labyrinth anaesthesias were also effective (80.1%). Although our study population was small, this intergroup difference was significant ($p \leq 0.026$).

Discussion

The effect of lidocaine on the inner ear and the vestibular system was first described by Barany in 1935 after intravenous lidocaine and by Ersner in 1951 after intratympanic application.[9] Lidocaine was initially basically used for the treatment of tinnitus, so basic research focused on its effect on the cochlea. In 1976 Englesson *et al*.[10] reported an affinity of lidocaine to inner-ear melanin; an accumulation of labeled lidocaine in the melanin of the modiolus of the cochlea was observed after an intravenous application.[11]

Due to its low molecular weight (MW 234,14) lidocaine effectively passes the round window and reduces the outer hair cell-dependent potential: with increasing concentration lidocaine even influences the inner hair cell-dependent potential and the whole nerve action potential.[12] These effects were explained by a dual mechanism: blocking the Ca^{2+} activated K^+-channels of the outer hair cells in a dose-dependent manner and inhibiting the neuronal Na^+-channels that are responsible for the initial phase of the action potential.[12]

More recent research[13] on the effect of lidocaine on the vestibular system revealed a transient vestibular nerve blockade in rats after administration of lidocaine into the middle ear cavity. The best nerve blockade was obtained with lidocaine 4%. Intratympanic instillation of lidocaine 4% resulted in all of the characteristic postural disturbances of a unilateral vestibular loss, as well as a typical spontaneous nystagmus towards the opposite side. The symptoms of postural imbalance that were observed in the rats following lidocaine instillation, were similar to those noted after a unilateral labyrinthectomy. In contrast to the unilateral labyrinthectomy, however, the lidocaine application did not cause structural damage to the vestibular system (only a temporary loss of function) and the procedure was repeatable.[13,14] Although these reports documented the affinity and effect of lidocaine on the cochlear and the vestibular systems, they did not explain the molecular mechanism of lidocaine action on the vestibular system.

While there is experimental evidence of the vestibular effect of intratympanic treatment with lidocaine, this procedure is not widely implemented by clinicians. The only controlled study revealed an immediate improvement in vertigo in 82% of 28 Menière-patients that lasted up to six months after intratympanic instillation of lidocaine 1%: an injection of a similar amount of normal saline in five control patients with Menière's disease had no effect on their complaints.[4] The largest published study [5] of Menière patients included the treatment of 75 patients with lidocaine 4%. Following performance of labyrinth anaesthesia 4-5 times at intervals of 3-4 days, beneficial effects and improvement of vestibular complaints were reported by 87% of the study population.[5]

In 2003 Adunka *et al*.[6] detected a noticeable decrease in vestibular symptoms in 87.5% of 24 patients with Menière's disease after intratympanic treatment with lidocaine 4% in combination with furfuryladenine to enhance the permeability of the round window. Of the treated patients 66.7% were free of recurrent vertigo attacks for at least one month. Thirteen of the patients were AAO-HNS class A, ten patients were class B and only one patient was class C. Functional levels of 1 or 2 were achieved by 16 patients, three patients had functional level 3 and five patients had functional levels 4 or 5. One patient required salvage therapy endolymphatic sac decompression. Although only one patient was class C, the functional levels of five patients were low (functional level 4-5). This study also reported an average of 0.2 dB hearing decrease at 500, 1000, 2000 and 3000 Hz 24 months after surgery, but failed to determine whether this hearing loss was due to the treatment or to progression of the underlying Menière's disease.[6] Laurikainen *et al*.[12] examined the effect of labyrinth anaesthesia on hearing by pure tone audiometry, auditory evoked brain stem responses and otoacoustic emissions suggesting that lidocaine has a temporary influence on the organ of Corti without any effect on the auditory nerve or central auditory pathways. Earlier reports did not include hearing loss due to the labyrinth anaesthesia.[4,5] None of our patients complained of noticeable hearing loss with the first follow-up one month after labyrinth anaesthesia.

Few side effects occur in addition to a small effect on hearing following labyrinth anaesthesia. The most important and expected treatment-related side effects are vertigo and nausea which occur approximately 30 minutes after an effective labyrinth anaesthesia and are associated with a mixed horizontal-rotatory nystagmus to the opposite side. Unsteadiness may occur during the subsequent 24 to 72. In general these side effects are well-tolerated and are less pronounced than a real vertigo spell. Moreover, if no nystagmus and vertigo occur, non-penetration of lidocaine into the labyrinth should be suspected. This scenario can be due to malpositioning of the patient, early swallowing without lidocaine accumulation into the round window niche, obstruction of the round window niche by connective tissue or insufficient penetration through the membrane. It is therefore worthwhile to repeat the procedure if the first one fails. The observation that repetitive procedures are less effective if the first one failed, however, suggests problems with penetration through the round window membrane. Conversely, once labyrinth anaesthesia had a beneficial effect, repetition yielded better results in our patient group (Table 4).

We detected a beneficial effect in 70% of the procedures included in this study (Table 5). With regard to primary procedures, labyrinth anaesthesia was effective in 62% of patients. A previous report,[6] that 66.7% of studied patients were free of attacks for at least one month, is comparable to our results. Other studies[4,5] reported success rates of 82-87% without referring to the AAO-HNS criteria. The major difference between this study and previous work, is that we considered the attack-free period to be the most objective measurable effect of the treatment, while previous work assessed improvement of vestibular symptoms, comfort and patient well-being, all of which can be influenced in ways not related to labyrinth anaesthesia.[4,5] Unlike Adunka *et al*.[6] we did not employ a questionnaire to evaluate the results after several years: this tool possesses an inherently subjective tone and the current state of the patient plays an important role in retrospective answers. As we based our results on a retrospective review of patient medical files, we considered the duration of the attack-free period as the most reliable measurement. On the other hand, patients who experienced fewer vertigo attacks after labyrinth anaesthesia or patients who had an attack within one month but did not experience any further attacks, were not included in these results because they were not attack-free, although they may

have achieved a better functional level due to the labyrinth anaesthesia.

When we looked at the long-term results according to the AAO-HNS criteria (1995), we detected a good effect after two years in 57.5% of the patients in classes A or B. This observation is not comparable to the effect of intratympanic gentamicin instillation or vestibular neurectomy, after which 66-97% and 92-100% of the patients, respectively, are in classes A or B.[15-18] However, gentamicin instillation carries a considerable risk of treatment-related hearing loss; a 30-dB hearing reduction has been reported in up to 20.8% of treated patients.[15,17] Moreover, as both treatments result in a definitive complete ablation of the vestibular system, they incorporate a noticeable risk for imbalance problems.[18]

Our observation that patients experience a mean attack-free period of 12.6 months after effective labyrinth anaesthesia indicates that patients who experienced more than three vertigo spells per month before treatment, are free of vertigo for a longer period. This scenario may also explain why some patients scored worse on the functional level scale after two years, although their AAO-HNS classifications were good. As recurrence of vertigo attacks influences social activities and comfort in daily life, the functional level is reduced when it is evaluated after a single recurrent attack. On the other hand, as the AAO-HNS classification compares the frequencies of attacks over a period of six months pre- and post-treatment, one recurrent attack has less impact on the score (Table 4: patients 8, 18 and 20) possibly explaining the varying results obtained by the AAO-HNS (1995) the evaluation methods. Labyrinth anaesthesia has only a temporary effect over a mean period of 12.6 months, suggesting that recurrence and reduced results are to be expected in a number of cases if evaluation takes place after 18-24 months. Nevertheless, in case of recurrence, repetition of labyrinth anaesthesia has a reproducible beneficial effect in 80.1% of cases indicating that more destructive procedures such as gentamicin instillation or vestibular neurectomy can be avoided or postponed. Labyrinth anaesthesia represents a non-destructive step between medication plus lifestyle changes and more destructive, ablative treatments.

Conclusion

Intratympanic instillation of lidocaine 2% is a useful treatment for medically intractable Menière's disease, providing an attack-free period of at least one month in 70% of the analyzed procedures. If effective, the attack-free period lasts on average 12.6 months and the effect is reproducible with repetitive instillations. This technique is worthwhile for Menière's disease after unsuccessful treatment with medication and changes in lifestyle and before intratympanic gentamicin ablation or other more invasive surgical techniques.

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