OTOLOGY



Endolymphatic duct blockage: quality of life assessment of a novel surgical technique for Ménière disease

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Abstract The aim of this study is to evaluate the quality of life (QOL) of patients treated by endolymphatic duct blockage (EDB) for Ménière's disease with a dedicated questionnaire. This is a retrospective cross-sectional study which included 54 patients diagnosed with severe, refractory Ménière's disease according to the AAO-HNS criteria and treated with EDB between 2010 and 2013. Answers to the first 38 questions have assigned scores from 0 to 4 (0 corresponding to the poorest QOL). A preoperative score called S1 was calculated as follows: S1 = sum of preoperative question scores/maximum possible preoperative score ×100. The same formula was used to calculate the postoperative score S2. The change in QOL score, S3, was then calculated (S3 = S2-S1). All answers were analyzed anonymously. Statistical analysis was done using Student t test and Chi square test. A response rate of 89 % was obtained with the Ménière's disease outcome questionnaire. The preoperative (S1) score was 21.4 (\pm 12.6) and the postoperative score (S2) was 64.6 (\pm 21.6) with a change in QOL (S3) of 43.3 (p < 0.001). Postoperatively, 89.9 % reported no Ménière's attacks (p < 0.001). Seventy-nine percent (15/19) of the questions showed a significant improvement after surgery. These results show that EDB is associated with a significant improvement of the QOL of patients suffering from severe Ménière's disease.

Keywords Quality of life · QOL · Ménière's disease · Endolymphatic duct · Endolymphatic sac · Decompression · Vertigo · Hearing loss · Ear fullness · Tinnitus

Introduction

Ménière's disease is an idiopathic condition characterized by vertigo attacks, fluctuating hearing loss, tinnitus and aural fullness. The exact underlying pathophysiological mechanism of this disease remains unknown. Therefore, its treatment remains controversial, empirical and mainly symptomatic against the vertigo attacks. Several medical and surgical therapies are used to control the symptoms of Ménière's disease.

Endolymphatic Sac Decompression (ESD) has been described by Portmann in 1927 [1]. It has always been considered a favorable option for Ménière's disease patients since it does not ablate hearing level and has low surgical morbidity. However, the results of this surgery are widely variable in the literature and there are several debates on its efficacy. In fact, a recent Cochrane analysis found no evidence basis to recommend ESD for this indication [2].

Aside from the sensorineural hearing loss, Ménière's disease is mainly characterized by subjective manifestations that can be very debilitating and patients experience deterioration in their physical, social and mental well-being. Therefore, the impact of Ménière's disease cannot be fully assessed using objective measurements such as the functional impairment scales and vertigo control classifications recommended by the AAO-HNS committee of hearing and



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equilibrium in 1995 [3]. In fact, using objective tools would limit our understanding of the true disability experienced by the patients and, therefore, it would also limit our understanding of the effectiveness of certain treatments.

In 2004, Kato et al. established the Ménière's disease outcome questionnaire (MDOQ), which is a validated questionnaire that was first used to study the efficacy of ESD in Ménière's disease patients [4].

We have reported a novel surgical technique for the treatment of Ménière's disease: Endolymphatic Duct Blockage (EDB) in January 2015 [5]. It is an effective surgical non-ablative technique: there is no clinically cochlear damage, and no more vestibular damage. There is a significantly better control of the vertigo attacks when compared to the traditional ESD. In addition, there were no significant complications or adverse events.

We aim in this study to evaluate the quality of life (QOL) of patients treated by EDB for Ménière's disease with a dedicated questionnaire.

Methods

Study design

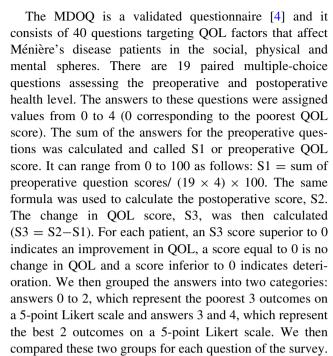
This is a retrospective cross-sectional study based on a survey sent to patients seen in our tertiary care center diagnosed with Ménière's disease and operated for EDB.

Our criteria of inclusion consisted of patients who underwent medical treatment of diuretics, vasodilators and symptomatic therapy for the nausea and vomiting accompanying the vertigo attacks in addition to restriction of CATS [Caffeine, Alcohol, Theophylline (exists in tea and chocolate) and Salt] for at least 6 months without improvement and who had more than six vertigo attacks for the last 6 months before the EDB surgery. Therefore, all patients must undergo EDB procedure to be eligible for this study. Generally, medical therapy and CATS restriction allow a control of the disease in almost two-thirds of the patients [6]. Our exclusion criteria included patients corresponding to the inclusion criteria but do not have at least one attack in the last month before the surgery and patients who have a bilateral Ménière's disease to avoid any confounding factor.

The study was approved by our institutional research ethics board and follows the standards of our institutional ethics committee. All survey answers were analyzed anonymously and confidentially.

Patients and outcome measures

Fifty-four patients met our study's inclusion criteria. They were sent electronically, via survey monkey, the MDOQ (see Appendix) between 12 and 18 months postoperatively.



Given the fact that our aim is to purely evaluate the subjective outcomes of this technique, demographic data including age and gender as well as objective data (hearing level and VNG) were not considered in this study as they were evaluated in our randomized controlled study [5]. However, this study was performed separately and was not correlated with the randomized controlled study previously published, hence the difference in the number of patients enrolled in both studies.

Surgical protocol of EDB

First, we performed a canal wall-up mastoidectomy: the tegmen mastoideum, sigmoid sinus, and sinodural angle are identified, and the posterior bony ear canal wall is thinned. We identified the posterior semicircular canal (PSCC) and the dura matter of the posterior fossa. Using the prominence of the horizontal semicircular canal, Donaldson line is identified to approximate the position of the endolymphatic sac. Bone over the sac and the dura are thinned with diamond burrs. The sac is completely skeletonized and decompressed. The infralabyrinthine dura is exposed because the main body of the sac and its lumen often lie within this area. The sac is neither incised nor dissected off the posterior fossa dura. We continue to dissect the bone of the vestibular aqueduct operculum and the posterior fossa dura from the retrolabyrinthine bone medial to the sac around the endolymphatic duct to identify the duct in its superior and inferior part in continuity from the endolymphatic sac and create a place to insert the tips of the instrument to clip the duct. At this level care must be taken not to traumatize the dura, which is often thin.



Finally we block the dissected endolymphatic duct with two small titanium clips. The titanium clips were applied using the ligating clip applier, similar to the one used in vascular surgery.

Statistical analysis

Statistical study was performed using SPSS (version 20) software (SPSS, Inc, an IBM Company, Chicago, IL). Student t test and Chi square test were used to compare means related to the MDOQ. p < 0.05 is considered statistically significant.

Results

Out of the 54 patients included in the study, 4 patients were unreachable by email and 2 patients received the email but did not complete the survey. The MDOQ was therefore completed by 48 patients (response rate of 89 %). The mean preoperative (S1) score was 21.4 ± 12.6 and the mean postoperative score (S2) was 64.6 ± 21.6 with a change in QOL (S3) of $+43.3 \pm 23.1$ (p < 0.0001). Table 1 demonstrates the comparison of the QOL outcome of the preoperative and postoperative groups for each question. Seventy-nine percent (15/19) of the questions showed a significant improvement after surgery. The four questions that did not show a significant difference concern the change in tinnitus, hearing, memory and the need to call the physician between the preoperative and the postoperative state.

QOL was improved in 89 % (n = 43) of respondents, unchanged in 6 % (n = 3) of patients, and poorer in 2 % (n = 1) of patients after EDB.

Discussion

Ménière's disease was described in 1861 by Prosper Ménière; however, its underlying pathophysiology remains unknown. The treatment is mainly symptomatic, against vertigo attacks. The treatment of patients unresponsive to medical therapy is a strong subject of debate. Usually, in patients with worsening or persistent symptoms after strict medical therapy and CATS restriction, surgical options are considered.

ESD has remained the surgery most commonly performed because of its conservative effect on hearing and low morbidity. However, its results are widely variable with a complete vertigo control rate ranging from 30 to 72 % [7–12].

In our institution, we have recently introduced a novel surgical technique for the treatment of unresponsive Ménière's disease: EDB. This technique is based on two facts: surgical approach and histopathologic studies. First, a section of the endolymphatic duct during the retrolabyrinthine approach for the surgical treatment of vestibular schwannomas would develop hydrops and creates symptoms of Ménière's disease. However, surprisingly, in the two largest studies reporting data of this technique, none of the patients developed Ménière's symptoms [13, 14]. Second, postmortem histopathologic studies of patients, who underwent ESD, did not show an improvement of their hydrops [15] and other study showed no development of cochlear hydrops after amputation of the endolymphatic duct and sac [16]. Moreover, as recently suggested by Linthicum Jr et al. [17], the periductal channels of the endolymphatic duct may be involved in the hydrodynamic of the endolymph and contribute to its absorption. Therefore our hypothesis supporting EDB is that in Ménière's disease the endolymphatic sac would have an increased secretion of endolymph outweighing the decreased absorption. Therefore, by blocking the endolymphatic duct distally near the sac, we are able to reduce the accumulation of endolymph in the inner ear without affecting the potential absorption, taking place at the endolymphatic duct.

In our previous randomized control study [5], in which we compared the outcomes of 35 patients who underwent EDB with 22 patients underwent ESD, we showed that EDB is associated with a rate of vertigo recurrence of 3.5 % at 24 months postoperatively against 62.5 % with ESD. There was also an improvement of tinnitus and aural fullness. 17 % of patients demonstrated an improvement of their hearing level. 14 % of the patients had minor CSF leak during the surgery due to the dissection of the very thin dura matter from the petrous bone around the duct; these were treated intra-operatively using the temporalis fascia and covered with BioGlue. EDB is safe and does not cause any cochlear or vestibular damage [6].

As previously discussed, an evaluation of Ménière's disease cannot be completed using objective measurements alone, other items are to be considered, such as apprehension of attacks, their unpredictability, financial stress, professional absenteeism, and limitations on free time. In fact, Ménière's disease affects the patients socially, physically and mentally and therefore, in order to measure the efficacy of a treatment, objective and subjective measure should be combined.

In comparison to other general QOL questionnaires such as the medical outcome study short form-36 (MOS SF-36) or the Glasgow benefit inventory questionnaire, the MDOQ is a more disease-specific questionnaire and therefore, it integrates questions assessing vertigo, tinnitus, fluctuating hearing loss and aural fullness. The Glasgow benefit inventory questionnaire was initially shown to measure the



Table 1 Difference in answers between the preoperative and the postoperative state for each question of the Ménière's disease outcome questionnaire

Questions	Preoperative answers		Postoperative answers		p-value
	0–2	3 and 4	0–2	3 and 4	
1. How much does your Ménière's disease affect your life, overall?	100 %	0 %	50 %	50 %	<0.0001
	48/48	0/48	24/48	24/48	
2. How much does your Ménière's disease prevent you from traveling, either for recreational or business purposes? (i.e., going on trips, going on vacation, going to the movies, etc.)?	96 %	4 %	35 %	65 %	< 0.0001
	46/48	2/48	17/48	31/48	
3. How much are you bothered by a loss of hearing?	87 %	13 %	77 %	23 %	0.180
	41/47	6/47	36/47	11/47	
4. How often are you either at the doctor's office or on the phone with the doctor's office?	98 %	2 %	87 %	13 %	0.05
	46/47	1/47	41/47	6/47	
5. I feel that my self-confidence is	91 %	9 %	25 %	75 %	<0.0001
	43/47	4/47	12/47	35/47	
6. My physical health is:	94 %	6 %	30 %	70 %	< 0.0001
	44/47	3/47	14/47	33/47	
$7. \ How much trouble do you have doing day-to-day tasks (bathing, doing household chores, etc.)?$	96 %	4 %	32 %	68 %	< 0.0001
	45/47	2/47	15/47	32/47	
8. Do you have spinning episodes (vertigo)? If so, how disabling are they?	98 %	2 %	34 %	66 %	< 0.0001
	46/47	1/47	16/47	31/47	
9. Do you have bothersome noise or tinnitus in the ear?	98 %	2 %	89 %	11 %	0.0915
	46/47	1/47	42/47	5/47	
10. Do you a problem remembering things?	55 %	45 %	42 %	58 %	0.216
	26/47	21/47	20/47	27/47	
11. Do you have difficulty walking in a straight line?	94 %	6 %	45 %	55 %	< 0.0001
	44/47	3/47	21/47	26/47	
12. Do you have a problem with your concentration? (e.g., reading, working on a computer, etc.)?	81 %	19 %	36 %	64 %	< 0.0001
	38/47	9/47	17/47	30/47	
13. Do you feel depressed?	93 %	7 %	30 %	70 %	< 0.0001
	44/47	3/47	14/47	33	
14. How much unsteadiness (imbalance) do you have in-between Ménière's attacks?		11 %	28 %	72 %	< 0.0001
	42/47	5/47	13/47	34/47	
15. How often are your activities (shopping, socializing, going to restaurants, exercising, etc.) impaired?	98 %	2 %	40 %	60 %	< 0.0001
	46/47	1/47	19/47	28/47	
16. How much unsteadiness did you have when you were having a Ménière's attack?		0 %	27 %	73 %	< 0.0001
	47/47	0/47	13/47	34/47	10.0001
17. Does your Ménière's disease affect your work?	89 %	11 %	30 %	70 %	< 0.0001
	42/47	5/47	14/47	33/47	.0.0001
18. Approximately how often do you have a Ménière's attack?	100 %	0 %	11 %	89 %	< 0.0001
	47/47	1/47	5/47	42/47	
19. How severe are your worst Ménière's attacks?	100 %	0 %	32 %	68 %	<0.0001
	47/47	1/47	15/47	32/47	

^{0-2:} corresponds to the sum of the patients who chose one of the first three answers on a given question (poorest 3 answers on a 5-point Likert scale)



³ and 4: corresponds to the sum of the patients who chose one of the two last answers on a given question (most favorable 2 answers on a 5-point Likert scale)

change in health status (benefit) from various otolaryngological interventions.

Using the MDOQ, we assessed the QOL of patients who underwent EDB. We showed that these patients have a significant improvement of their postoperative QOL scores in comparison to the preoperative scores. As a matter a fact, 89 % of the patients stated that they never have Ménière's attacks after EDB (see Table 1). 79 % of patients showed significant improvement after surgery; the remaining patient, while did not report Ménière attacks, continue to suffer from instability and dizziness after the surgery due to a preoperative vestibular paresis confirmed on caloric tests. These patients were referred for vestibular rehabilitation.

Two studies used the MDOQ to evaluate the effect of ESD on QOL and the mean change in QOL score obtained were +25.6 [4] and +28.3 [18]. These results are significantly lower than the change of QOL score we found in this study (+43.3).

Our study has several limitations. First, our questionnaire uses subject recall to achieve a preoperative QOL score, which is a potential recall bias. Second, although our results could be compared with other studies using the same questionnaire, we do not have a control population. A multicenter, prospective, study would be ideal to obtain results with higher level of evidence.

Conclusion

Despite the small number of recruited patients, this study supports our previous findings on EDB. It shows the efficacy of EDB to improve the QOL of Ménière's disease patients in all the physical, social and mental aspects. EDB is safe and a promising novel surgical technique for the treatment of Ménière's disease.

Compliance with ethical standards

Conflict of interest None.

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Appendix

The Ménière's disease outcome questionnaire

- 1. Overall, how much did your Ménière's disease affect your life before your surgery?
 - 0. Completely
 - 1. Quite a lot
 - 2. Moderately

- 3. Just a little
- 4. Not at all
- 2. After your surgery, how much does your Ménière's disease affect your life, overall?
 - 0. Completely
 - 1. Quite a lot
 - 2. Moderately
 - 3. Just a little
 - 4. Not at all
- 3. Before your ear surgery, how much did your Ménière's disease prevent you from traveling, either for recreational or business purposes? (i.e., going on trips, taking vacation, going to the movies, etc.)
 - 0. Always
 - 1. Quite a lot
 - 2. Moderately
 - 3. Just a little
 - 4. Never
- 4. After your ear surgery, how much does your Ménière's disease prevent you from traveling, either for recreational or business purposes? (i.e., going on trips, going on vacation, going to the movies, etc.)
 - 0. Always
 - 1. Quite a lot
 - 2. Moderately
 - 3. Just a little
 - 4. Never
- 5. Before your ear surgery, how much were you bothered by a loss of hearing?
 - 0. Completely
 - 1. Quite a lot
 - 2. Moderately
 - 3. Just a little
 - 4. Not at all
- 6. After your ear surgery, how much are you bothered by a loss of hearing?
 - 0. Completely
 - 1. Quite a lot
 - Moderately
 - 3. Just a little
 - 4. Not at all
- 7. Before your ear surgery, how often were you either at the doctor's office or on the phone with the doctor's office?
 - 0. Far too often
 - 1. More than most
 - 2. Routine visits



- 3. Hardly ever
- 4. Never
- 8. After your ear surgery, how often are you either at the doctor's office or on the phone with the doctor's office?
 - 0. Far too often
 - 1. More than most
 - 2. Routine visits
 - 3. Hardly ever
 - 4. Never
- 9. Before my ear surgery, I felt that my self-confidence was:
 - 0. Terrible
 - 1. Poor
 - 2. Average
 - 3. Above average
 - 4. Great
- 10. After my ear surgery, I feel that my self-confidence is:
 - 0. Terrible
 - 1. Poor
 - 2. Average
 - 3. Above average
 - 4. Great
- 11. Before my ear surgery, my physical health was:
 - 0. Terrible
 - 1. Poor
 - 2. Average
 - 3. Above average
 - 4. Great
- 12. After my ear surgery, my physical health is:
 - 0. Terrible
 - 1. Poor
 - 2. Average
 - 3. Above average
 - 4. Great
- 13. Before your surgery, how much trouble did you have doing day-to-day tasks (bathing, doing household chores, etc.)?
 - 0. Maximal
 - 1. A lot
 - 2. Some
 - 3. A little
 - 4. None

- 14. After your surgery, how much trouble do you have doing day-to-day tasks?
 - 0. Maximal
 - 1. A lot
 - 2. Some
 - 3. A little
 - 4. None
- 15. Before your surgery, did you have spinning episodes (vertigo)? If so, how disabling were they?
 - 0. Yes, totally incapacitating
 - 1. Yes, they interfered with my life
 - 2. Yes, but I could manage
 - 3. Yes, but they hardly affected me
 - 4. No, never
- 16. After your surgery, do you have spinning episodes (vertigo)? If so, how disabling are they?
 - 0. Yes, totally incapacitating
 - 1. Yes, they interfered with my life
 - 2. Yes, but I could manage
 - 3. Yes, but they hardly affected me
 - 4. No, never
- 17. Before your surgery, did you have bothersome noise or tinnitus in the ear?
 - 0. Yes, it drove me crazy
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. No, never
- 18. After your surgery, do you have bothersome noise or tinnitus in the ear?
 - 0. Yes, it drove me crazy
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. No, never
- 19. Before your surgery, did you have a problem remembering things?
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never



- 20. After your surgery, do you a problem remembering things?
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 21. Before your surgery, did you have difficulty walking in a straight line?
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 22. After your surgery, do you have difficulty walking in a straight line?
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 23. Before your surgery, did you have a problem with your concentration? (e.g., reading, working on a computer, etc.)
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 24. After your surgery, do you have a problem with your concentration? (e.g., reading, working on a computer, etc.)
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 25. Before your surgery, did you feel depressed?
 - 0. All the time
 - 1. Often
 - 2. Sometimes
 - 3. Rarely
 - 4. Never
- 26. After your surgery, do you feel depressed?
 - 0. All the time
 - 1. Often

- 2. Sometimes
- 3. Rarely
- 4. Never
- 27. Before your surgery, how much unsteadiness (imbalance) did you have in-between Ménière's attacks?
 - 0. Extremely poor balance
 - 1. Ouite a lot
 - 2. A moderate amount
 - 3. A little bit
 - 4. None
- 28. After your surgery, how much unsteadiness (imbalance) do you have in-between Ménière's attacks?
 - 0. Extremely poor balance
 - 1. Quite a lot
 - 2. A moderate amount
 - 3. A little bit
 - 4. None
- 29. Before your surgery, how often were your activities (shopping, socializing, going to restaurants, exercising, etc.) impaired?
 - 0. I could not do anything
 - 1. More often than not
 - 2. A moderate amount
 - 3. A little bit
 - 4. Never
- 30. After your surgery, how often are your activities (shopping, socializing, going to restaurants, exercising, etc.) impaired?
 - 0. I could not do anything
 - 1. More often than not
 - 2. A moderate amount
 - 3. A little bit
 - 4. Never
- 31. Before your surgery, how much unsteadiness did you have when you were having a Ménière's attack?
 - 0. Extremely poor balance
 - 1. Quite a lot
 - 2. A moderate amount
 - 3. A little bit
 - 4. None
- 32. After your surgery, how much unsteadiness do you have when you are having a Ménière's attack?
 - 0. Extremely poor balance
 - 1. Quite a lot
 - 2. A moderate amount



- 3. A little bit
- 4. None
- 33. Before your surgery, did your Ménière's disease affect your work (job performance, sick days, time off, job termination, etc.)?
 - 0. I was fired or had to quit
 - 1. Often
 - 2. Occasionally
 - 3. Rarely
 - 4. Never, or I do not work
- 34. After your surgery, does your Ménière's disease affect your work?
 - 0. I was fired or had to quit
 - 1. Often
 - 2. Occasionally
 - 3. Rarely
 - 4. Never, or I do not work
- 35. Before your surgery, approximately how often would you have a Ménière's attack?
 - 0. Daily
 - 1. Weekly
 - 2. Monthly
 - 3. Rarely
 - 4. Never
- 36. After your surgery, approximately how often do you have a Ménière's attack?
 - 0. Daily
 - 1. Weekly
 - 2. Monthly
 - 3. Rarely
 - 4. Never
- 37. Before your surgery, how severe were your worst Ménière's attacks?
 - 0. Totally incapacitating.
 - 1. Severe
 - 2. Bothersome
 - 3. Not bad
 - 4. Barely noticeable/none
- 38. After your surgery, how severe are your worst Ménière's attacks?
 - 0. Totally incapacitating
 - 1. Severe
 - 2. Bothersome
 - 3. Not bad

4. Barely noticeable/none

(OPTIONAL) You may use the space that follows to describe (in words, drawing, photograph, etc.) how you felt about your Ménière's disease before surgery:

(OPTIONAL) You may use the space that follows to describe how you feel about your Ménière's disease after having had surgery.

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