



Outcomes of Endolymphatic Duct Blockage for Ménière's Disease: An Observational Cohort Study

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Abstract

Purpose: The objective of this paper is to assess quality of life, subjective complaints and objective hearing after treatment with endolymphatic duct blockage in patients with intractable Ménière's disease.

Methods: This is a retrospective observational study using questionnaires (the MDOQ and a self-developed questionnaire) and hearing tests, carried out in a secondary referral center with expertise in Ménière's disease. Patients with definite Ménière's disease who underwent endolymphatic duct blockage were included. Questionnaire scores and bone conduction Pure Tone Average (PTA) before and after EDB surgery were calculated and compared.

Results: Twenty-six patients who had undergone EDB participated in this study; 23 (88%) experienced improvement in quality of life after surgery. The mean change in MDOQ score was +37.1 points (95% CI +28.5 to +46.5, $p < 0.05$); no one reported worse quality of life after surgery. Twenty-two patients (85%) experienced less complaints of vertigo after EDB, of whom 10 were completely free of vertigo directly after surgery. The mean difference in hearing pre- and post-operatively was less than a decibel. The majority of patients had less complaints of instability after EDB, and experienced no change in tinnitus.

Conclusion: EDB leads to significant improvement in quality of life of patients with Ménière's disease, even though some patients require additional treatment. The effect on hearing and subjective complaints varies. More research, especially prospective studies, on EDB should be performed.

Keywords: Ménière's disease; Endolymphatic duct blockage; Surgical intervention; Quality of life; Hearing

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Abbreviations

MD: Ménière's Disease; QoL: Quality of Life; MDOQ: Ménière's Disease Outcome Questionnaire; EDB: Endolymphatic Duct Blockage

Introduction

Ménière's Disease (MD) is a widely studied, but poorly understood disease characterized by spontaneous bouts of vertigo, fluctuating sensorineural hearing loss and other aural symptoms like tinnitus and aural fullness of the affected ear [1]. In patients with MD, quality of life is decreased due to the vertigo attacks, as well as the constant imminence of having another attack [2-4]. The psychological stress often leads to depression [4]. As the etiology of MD is unclear, treatment of the disease is mainly symptomatic and there is no consensus on the clinical management of patients. Treatment options can be roughly divided into two categories: non-ablative or ablative. Management of patients is stepwise, starting with the least invasive and non-ablative therapy.

The first treatment option that should be considered is letting the disease run its natural course with only antiemetic drugs. Most patients reach a steady-state phase in which they are free of vertigo attacks [5]. However, years may pass before symptoms decrease and MD may severely affect hearing and equilibrium. Options for first line active treatment are dietary restrictions, administration of diuretics, betahistine, other anti-vertiginous drugs or intratympanic injection with corticosteroids [6]. However, these treatments either lack the support of scientific evidence or reach only temporary relief of complaints [7-13]. In case of intractable disease, ablative surgery can be considered. This includes intratympanic injection with gentamycin, selective neurectomy and labyrinthectomy. These treatments help against the vertigo attacks but carry the risk of irreversible damage to the vestibular and possibly the cochlear system, leading to balance problems and hearing loss [14,15].

Surgery on the endolymphatic sac, aiming to prevent vertigo attacks while sparing cochlear and vestibular function, has been proposed as treatment modality since 1927 [16]. Decompression, shunting and drainage of the sac have been studied but outcomes have been controversial [15]. A new surgical technique, targeting the endolymphatic duct, was proposed by Saliba et al. in 2015 [17]. In this procedure, the endolymphatic duct is blocked, hindering endolymph flow from the endolymphatic sac, thereby preventing endolymph accumulation in the rest of the inner ear. The trial performed by Saliba yielded a success rate of complete vertigo control in over 95% of the patients. In 2016, the same research group published an article in which quality of life is assessed after EDB, concluding that EDB is associated with a significant improvement in quality of life [18]. If EDB proves to be an effective treatment, it would be a new treatment possibility when non-invasive treatment is not effective, but before ablative surgery.

The EDB procedure was introduced in our clinic in 2015. In this paper, we report the outcomes of EDB in terms of quality of life, hearing and several MD-related complaints. Moreover, additional treatment after EDB was assessed.

Material and Methods

Study design

This is a retrospective observational study. The local research committee approved of this study. The study was exempt from approval of a medical ethics committee (see statement under Ethics approval).

Patients

Patients diagnosed with Ménière’s disease in our outpatient clinic who had been treated with EDB were asked to participate through phone or email in January 2019. If they agreed to participate, they received an email with a link to the electronic questionnaires using ConsultAssistent. Classification according to the 2015 AAO-HNS criteria was double-checked to include only patients with definite MD [1]. In January 2021, records of all subjects were studied to assess evolution of complaints since January 2019.

Endolymphatic duct blockage

Surgery was considered in patients who suffered more than three vertigo attacks in 6 months. Most patients were treated with intratympanic injection of corticosteroids first. EDB was performed as described by Saliba [17], although a small change in procedure was made: instead of following the posterior canal towards the endolymphatic sac, the dura is followed, thereby minimizing the risk of a lesion to the posterior canal.

Outcome measures

The primary outcome of this study is Quality of Life (QoL). This primary outcome measure was chosen because patients do not only suffer from the bouts of vertigo, but also from the constant imminence of another attack. The unpredictable pattern of the disease disrupts everyday life and leads to severe loss of QoL [3]. Therefore, the cumulative number of vertigo attacks may not reflect the patient’s burden of disease and quality of life is a logical parameter to measure treatment outcome. The Ménière’s Disease Outcome Questionnaire (MDOQ) was used to measure QoL [19].

The MDOQ consists of 20 pairs of questions. Of each pair, one question assesses pre-treatment health, and the other the post-treatment health. Per question, the score ranges from 0 (worst) to 4

(best, no complaints). The last pair of questions is an optional field in which patients can write or draw. No points are given for this question. The maximal score of both the pre- and post-treatment domain is therefore 76 points (19 questions x maximum of 4 points per question). The MDOQ-scores for the pre- and postoperative questions are calculated by dividing the total score by 76 followed by multiplying with 100 [19].

For secondary outcome measures, a simple questionnaire was set up. Patients were asked about change in complaints of vertigo, tinnitus, hearing loss, instability and aural fullness after their surgery. Possible outcomes were improvement, no change or worsening of each of these symptoms. The questionnaire can be found in Supplementary Figure 1.

Lastly, hearing tests pre- and postoperatively were assessed to determine objective hearing outcomes. The last test before surgery was considered the pre-operative hearing, and most patients underwent a hearing test six weeks after surgery. The mean bone conduction threshold was calculated from pure-tone hearing thresholds at 250, 500, 1000, 2000 and 4000 Hz.

Results

Patient characteristics

Forty-two of our patients have undergone EDB between 2015 and 2019. All patients telephonically agreed to participate but only 28 patients returned the questionnaires. Two patients had probable MD according to the 2015 AAO-NHS criteria and were not included [1]. Therefore, 26 patients were included in the analysis. Demographic data of this group of patients can be found in Table 1. Duration of follow up was similar among different treatment strategies.

All patient records were checked for additional treatment after EDB. Duration of follow up ranged from 4 to 66 months. However, in patients who were not lost to follow up, follow up was at least 32 months. Ten patients were free of vertigo after EDB. Thirteen patients kept suffering attacks and sought additional treatment. Usually, a CT-scan was made to assess the clip; when in doubt whether the clip was correctly in place, revision surgery was performed. If the CT-

Table 1: Characteristics of respondents.

Age (mean ± SD)	51.1 ± 12.5 (range 27-75)
Sex	
Female	14 (54%)
Male	12 (46%)
Side of MD	
AD	8 (31%)
AS	13 (50%)
ADS	5 (19%)
Duration of MD (years) until EDB	9.5 ± 8.1 (range 1-33)
Duration of follow up (months)	30.0 ± 16.3 (range 4-66 months)
Side of treatment	
AD	11 (42%)
AS	14 (54%)
ADS	1 (4%)
Mean number of ITC before EDB (n=21*)	2.1 ± 1.1 (range 1-4)
Mean number of ITC after EDB (n=14*)	3.6 ± 4.8 (range 0-18)

*From some patients, the exact number of IT injections could not be determined from the patient records

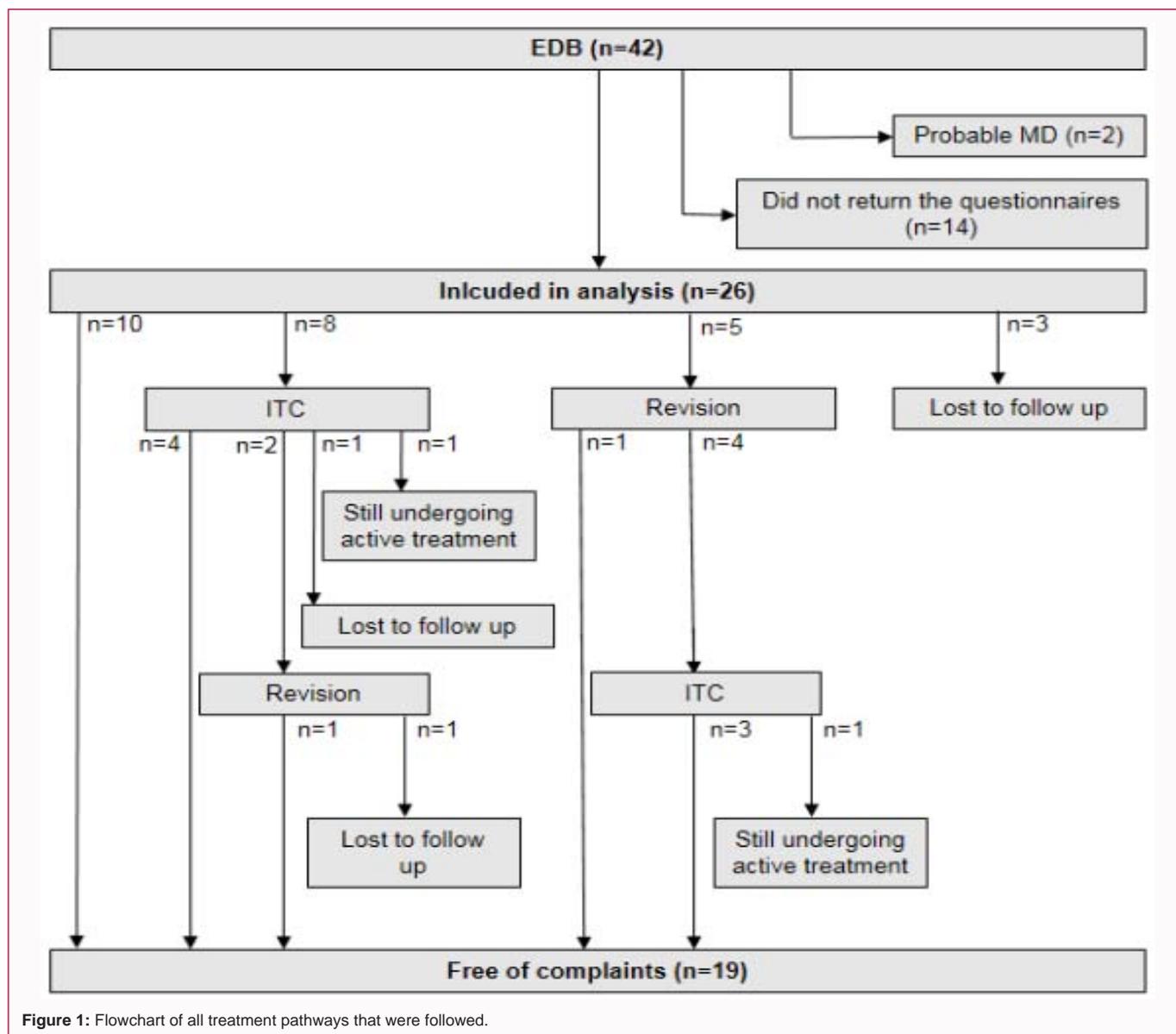


Table 2: Primary outcome: Quality of Life.

Higher QoL after EDB	23 (88%)
Same QoL after EDB	3 (12%)
Lower QoL after EDB	0
Mean MDOQ before EDB (mean ± SD)	24.2 ± 11.8
Mean MDOQ after EDB (mean ± SD)	61.3 ± 20.6
Difference	+37.1 points (95% CI 28.5 to 45.6) p<0.05

scan showed accurate clip position, treatment with intratympanic injection of corticosteroid was (re)started. The administered corticosteroids were triamcinolone acetonide (Kenacort 40 mg/ml, Bristol-Myers Squibb, New York City, USA) or dexamethasone (20 mg/ml, Centrafarm B.V., Etten-Leur, the Netherlands). Subsequent ITC was given on the patient’s request.

In January 2021, 19 patients (73%) were free of vertigo attacks. Five patients (19%) were lost to follow up after they had returned the questionnaire and 2 patients (8%) are still suffering vertigo attacks.

Quality of life

Twenty-three (88%) of the patients experienced an increase in quality of life. Three patients (12%) had the same quality of life pre- and post-treatment, and no patients had lower quality of life. The mean score pre-treatment was 24.2 ± 11.8 points, with a mean improvement of 37.1 points (95% CI 28.5 to 46.5) after surgery. This improvement is statistically significant.

Secondary outcomes-vertigo, hearing, tinnitus, instability, aural fullness

The perceived outcomes of vertigo, hearing loss, tinnitus, instability and aural fullness can be found in Figure 2. Improvement of vertigo and instability complaints was seen in the majority of the patients. In most patients, EDB had no effect on subjective hearing and tinnitus. However, some patients had more complaints after EDB. Instability was influenced positively in 17 (65%) of the patients, and most patients noticed improvement or no difference in aural fullness.

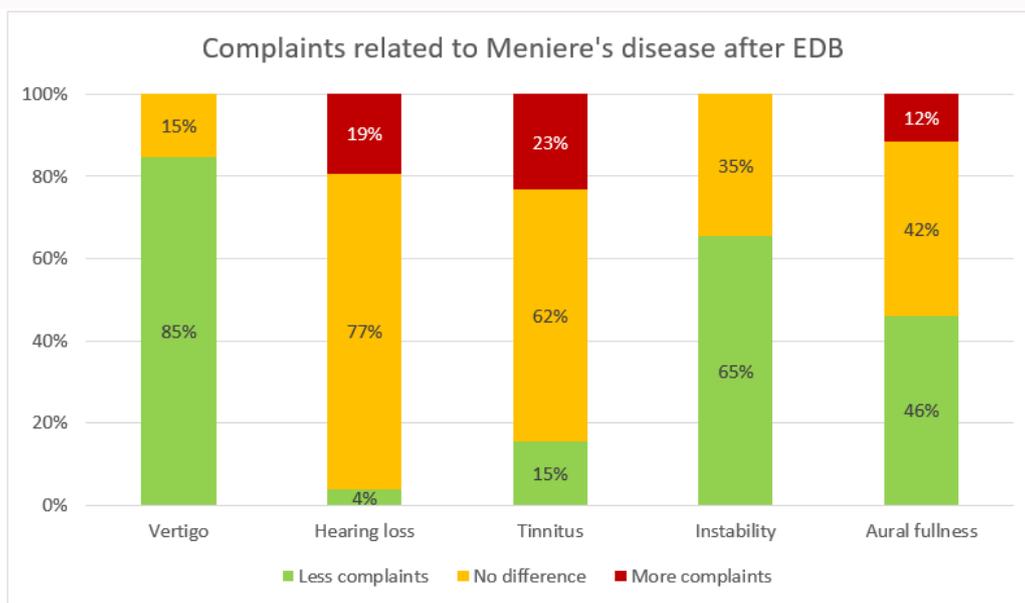


Figure 2: Secondary outcomes of complaints related to Meniere's disease.

Objective hearing

From 22 operated ears in 21 patients, both pre- and postoperative hearing tests were available. The hearing test after EDB was taken 15 weeks after EDB on average (range 5 to 69 weeks). There was a near-significant positive correlation between duration of disease and hearing loss (Pearson coefficient 0.43, $p=0.05$).

Eleven ears (50%) had lower hearing thresholds, i.e., better hearing after EDB. The mean decrease in threshold was 13.1 dB. Ten ears (45%) had worse hearing postoperatively, with a mean increase of thresholds of 12.4 dB. One patient (5%) had the exact same hearing postoperatively. Changes in hearing thresholds ranged from 44 dB decrease to 27 dB increase. The mean difference was less than a decibel in pre- and postoperative hearing (SD 17.0, 95% confidence interval -6.6 to 8.4). Results from all patients can be found in Figure 3.

Discussion

Despite decades of research, the pathophysiology of Ménière’s disease remains unclear. Hydrops of the endolymph in the inner ear seems to play a role: it is present in over 90% of the patients with definite MD [20]. Although the endolymphatic hydrops is constantly present in the inner ear, patients suffer from acute vertigo attacks. The unpredictable nature of the disease severely affects quality of life in most patients, especially in the emotional domain [4].

Endolymphatic duct blockage as treatment for MD was proposed recently, aiming to prevent vertigo attacks while preserving vestibular and cochlear function. If effective, it would add a new step in the step-up treatment for Ménière’s disease, after non-invasive therapy but before ablative surgery. However, little data on outcomes are published worldwide. The present study aims to add knowledge about this new surgical technique.

Quality of life

Among 26 patients with definite Ménière’s disease, we found that 23 patients (88%) experienced improved quality of life after a treatment strategy of which EDB is a part. However, only 10 patients (38%) were free of vertigo directly after surgery and 19 patients (73%)

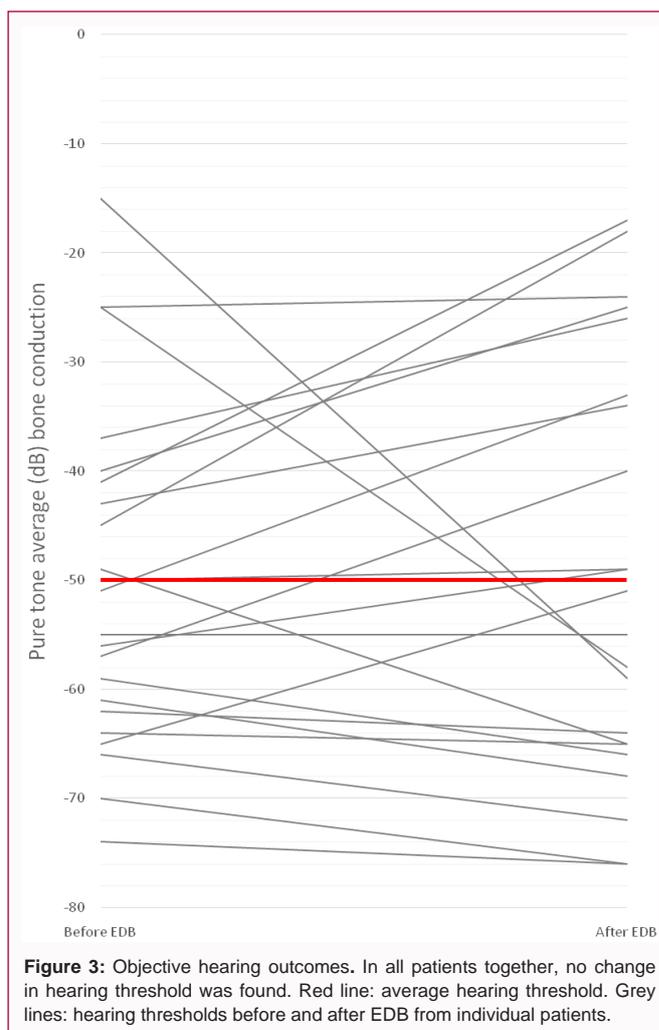


Figure 3: Objective hearing outcomes. In all patients together, no change in hearing threshold was found. Red line: average hearing threshold. Grey lines: hearing thresholds before and after EDB from individual patients.

after the total follow-up period. This indicates that some patients experienced improvement of quality of life despite still suffering vertigo attacks. Some patients described reduced frequency and

intensity of attacks after EDB, leading to less disruption of everyday life and reduction of fear for attacks. Therefore, even if complete vertigo control is not reached, a treatment strategy that involves EDB may improve QoL. This illustrates why quality of life is an important outcome measure, and why the cumulative number of vertigo attacks may not reflect burden of disease.

Gabra et al. also published results of quality of life after treatment with EDB, using the same MDOQ [18]. In 54 patients, a mean improvement of +43.3 points was found, which corresponds well to the mean increase of +37.1 points that we found.

Vertigo control

It is curious that only 10 patients (38%) were free of vertigo attacks directly after EDB. From our results, one can conclude that additional treatment may be necessary in some of the patients. This is in contrast with the scarce literature that is available, which yields much higher success rates of EDB. The only randomized controlled trial about this procedure reports a success rate of over 95% [17]. One other study of the same research group compared EDB to EDB combined with a decompression by means of biopsy of the endolymphatic sac. In both groups, significant reduction in vertigo attacks was found [21]. Unfortunately, only cumulative numbers of vertigo attacks per group were reported.

Success rates from He et al. are not as high as the previous numbers [22]. In 22 cases of patients who underwent EDB, complete vertigo control was achieved in 11 cases (50%), and substantial control in 9 cases [22]. Especially the rate of complete vertigo control is more similar to our result.

Based on the results we found, we assume that the endolymphatic sac is the site where most of the endolymph is produced. By clipping the endolymphatic duct, the bulk of endolymph is hindered from flowing to the rest of the inner ear. However, other production sites such as the vestibule and the stria vascularis still produce endolymph that may exceed the normal endolymph volume [23]. Therefore, patients may still suffer attacks after EDB, although less intense and less frequent than before EDB.

Subjective outcomes

Most patients experience relief of vertigo complaints and instability. The finding that 85% of the patients had less vertigo complaints after EDB is a crucial result, considering that vertigo is the most intrusive symptom of Ménière's disease [4]. In most patients, EDB does not influence subjective hearing loss or tinnitus, as 20 patients (77%) and 16 patients (62%) reported no difference, respectively. In both groups, there was a small proportion of patients who had more complaints of hearing loss and/or tinnitus. However, these outcomes suggest that this technique may indeed spare cochlear and vestibular function.

Objective hearing outcomes

The positive relation between hearing loss and duration of disease is a characteristic of MD that is widely endorsed [24]. It is interesting to note that 23 patients (50%) had objectively better hearing six weeks after surgery. This is in contrast to the one patient (4%) who subjectively experienced better hearing. Furthermore, there is a great variation in hearing outcome, ranging from 44 dB worsening to 27 dB improvements of hearing thresholds. However, the average thresholds differs less than a decibel in pre- and post-operative hearing, affirming that EDB does not inflict damage to the cochlear

function.

Alternative explanations

Although EDB yields positive results, alternative explanations for at least part of the outcome should be considered. First, the role of the effectiveness of placebo, as it plays an important role in all treatments for MD. Two trials compared endolymphatic sac surgery to placebo surgery in a blinded population to assess the placebo effect in MD [25,26]. In both studies, approximately 70% of the patients in both the active and the placebo group experienced relief of complaints. This indicates significant influence of the placebo effect. Moreover, the results of the trial of Saliba et al. [17] demonstrate the negative placebo effect, also known as the nocebo effect. Participants in his study were not blinded. In the control group (who underwent endolymphatic sac decompression), 34% of the patients remained free of vertigo, against 96.5% in the active treatment group (who underwent EDB). In other trials, where decompression is the active treatment, vertigo control rates of 80% to 95% were reported [27-29], which is much higher than the 36% reported by Saliba. The differences in outcome may be due to the unblinded character of the trial of Saliba: not being in the EDB-group may have caused disappointment and/or negative expectancies in the control patients, causing worse outcomes. This illustrates the susceptibility to the placebo effect of this population.

Second, research suggests that the more intensive the treatment is, the greater the placebo effect is [30]. As surgery is more invasive than first line treatment modalities for MD, it is likely that this factor too has influence on perceived outcomes.

Third, another factor to take into account is the natural course of the disease. Usually, vertigo attacks diminish within five to ten years and the majority of the patients reach remission [31]. It is hard, if not impossible, to distinguish between an asymptomatic episode, remission of disease or effect of the treatment. In this cohort too, it is possible that some patients would have reached relief of complaints without (any) active treatment.

Clinical recommendations

In clinical practice, several factors should be taken into account when discussing treatment options with patients. As mentioned, most patients eventually reach a vertigo-free steady state [31]. Therefore, waiting with active treatment is an option. However, as Ménière's disease severely affects quality of life, most patients opt for active treatment. Most conservative treatment modalities lack scientific proves of effectiveness, which should be discussed with the patient. Intratympanic injections with corticosteroids have proven to be effective, but seem to have a temporary effect only.

Before discussing ablative treatment, and especially in patients with good cochlear and vestibular function, EDB should be considered. Accumulating data on the effectiveness of EDB have been published in the past years. Although only one prospective trial was performed, it seems to be a safe and effective treatment. The patient should be counseled that EDB is a complex surgical procedure on the skull with risk of adverse events such as cerebrospinal fluid leakage, sensorineural hearing loss, vestibular dysfunction and damage to the facial nerve. However, EDB seems to be able to achieve improvement in quality of life in most patients. It is also important to discuss that current results on EDB are not conclusive, and that additional treatment after EDB may be necessary to reach complete vertigo control.

Limitations

This study is limited by several factors. We do believe the participants are representative for the MD population that seeks active treatment. Age and sex distribution are in line with previous scientific reports, with a slight female predominance and occurring between the age of 40 and 60 [3]. However, our center is acknowledged for its experience with Ménière's disease and part of our population is referred to us from second line treatment elsewhere. Therefore, there may be selection bias. Secondly, due to the retrospective nature of this study, there is a risk of recall bias. Thirdly, logistical factors should be taken into account. For example, another clip applier is now used. Moreover, later EDB procedures in our center are performed in a hybrid operating room, which is equipped with a CT-scan for perioperative assessment of clip position. Therefore, no revisions were necessary after these adjustments.

Conclusion

Despite the limitations, these results indicate that a treatment strategy that involves EDB has a beneficial effect on quality of life in patients with Ménière's disease. In case of intractable disease, EDB should therefore be considered. However, because of the paucity on data on EDB, more research on this surgical technique should be performed and the authors hope to encourage publication of these data. Moreover, a prospective, double blinded, multicenter trial will be executed by this research group, with start of inclusion planned in April 2021.

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