Endolymphatic Duct Blockage: A Randomized Controlled Trial of a Novel Surgical Technique for Ménière’s Disease Treatment

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Abstract
Objectives. To compare the effectiveness of the endolymphatic duct blockage (EDB) and the endolymphatic sac decompression (ESD) to control Ménière’s disease symptoms and to evaluate their effect on hearing level.

Study Design. Prospective nonblinded randomized study.

Setting. Tertiary medical center.

Subjects and Methods. Fifty-seven patients affected by a refractory Ménière’s disease were included out of which 22 underwent an ESD and 35 underwent an EDB. Five periods of follow-up were considered: 0 to 1 week, 1 week to 6 months, 6 to 12 months, 12 to 18 months, and 18 to 24 months. Mean outcome measurements consisted of vertigo control, tinnitus, aural fullness, instability, and hearing level. Hearing level was evaluated using pure-tone average (PTA) and speech discrimination score (SDS).

Results. There was no significant difference between the 2 groups in the number of vertigo spells per months preoperatively (P = .153). Twenty-four months postoperatively, 96.5% of the EDB group had achieved a complete control of vertigo spells against 37.5% of the ESD group with a statistically significant difference (P = .002). There was a better control of tinnitus and aural fullness with EDB (P = .021 and P = .014, respectively). There was no statistically significant difference in hearing level preoperatively (P = .976) and 24 months postoperatively (P = .287) between the 2 groups. Hearing level was preserved in each group with no significant difference between the preoperative and the postoperative levels (P > .05).

Conclusion. EDB is more effective than the traditional ESD in controlling the symptoms of Ménière’s disease. It is a novel surgical technique with promising results for a complete treatment of Ménière’s disease. There are no significant complications or adverse effect.

Keywords
Ménière’s disease, endolymphatic duct, endolymphatic sac, decompression, vertigo, hearing loss, ear fullness, tinnitus

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Introduction
Ménière’s disease is an idiopathic condition characterized by the presence of fluctuating hearing loss, episodic vertigo, tinnitus, and aural fullness due to an endolymphatic hydrops.

The treatment of Ménière’s disease remains controversial. It includes medical and surgical therapies to control the disabling vertigo attacks.

Medical treatment consists 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). It allows a control of the disease in almost two-thirds of the patients.1

When medical therapy fails, surgical options are explored. In 1927, Guild2 described the endolymphatic sac as the site of outflow of the endolymph. Later the same year, Portmann3 described the endolymphatic sac decompression (ESD) surgery for Ménière’s disease. Other surgical options include vestibular neurectomy that was described by Dandy4 in 1928 and labyrinthectomy, which is only performed in patients with an unserviceable hearing.

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Endolymphatic sac surgery has been a favorable option for patients as it is a hearing preservation surgery and has a low surgical morbidity. It has been performed with several variations: (1) sac shunting, (2) sac drainage, and (3) sac decompression with or without wide decompression of the posterior cranial fossa dura or sigmoid sinus decompression.

The effectiveness of these surgeries has been debated. However, ESD is, according to Paparella and Sajjadi, the most common surgical procedure for Ménière’s disease.

In our institution, we have, over the past few years, established a novel surgical technique for the treatment of Ménière’s disease: the endolymphatic duct blockage (EDB).

The aim of this study is first, to evaluate the effectiveness of EDB to control vertigo attacks, tinnitus, and aural fullness and to evaluate its effect on hearing level and second, to compare EDB results to the traditional ESD.

**Methods**

**Study Design**

This is a prospective study of patients conducted from November 2010 to January 2014 at our tertiary care center and diagnosed with Ménière’s disease according to AAO-HNS criteria. It is a simple nonblinded randomization using the coin toss method. A flow diagram showing the progress through the phases of the randomization is presented in Figure 1.

Our inclusion criteria consisted of: (1) only patients in the definite category of the Ménière’s disease, a diagnostic scale based on clinical criteria; (2) we have included patients who underwent medical therapy and CATS restriction for at least 6 months without improvement and who had more than 6 vertigo attacks for the last 6 months before the surgery. Our exclusion criteria included: (1) patients with refractory Ménière’s disease not responding to our inclusion criteria; (2) all patients must have had at least 1 attack in the last month before surgery.

Videonystagmography (VNG) was performed during the last month preoperatively and during the 6 months postoperatively. From the first day of the surgery all operated patients were asked to stop all kind of medication for Ménière’s disease and follow the CATS restriction.

The study was approved by the institutional research ethics board of the university of Montreal hospital center and follows the standards of our institutional ethics committee. Eligible patients were fully informed about the randomization of the 2 procedures and especially about the surgical techniques, risks, complications, and alternatives to the treatment. Patients gave their consent before the randomization. Therefore, the patient and the investigator are unaware of the group to which a participant will be allocated. Allocation concealment concentrates on preventing selection and confounding biases. However this study was unblinded; both the patient and the observer assessing the outcomes were aware of the treatment after the randomization.

**Patients and Outcome Measures**

Fifty-seven patients met our study’s inclusion criteria. Data gathering and hearing tests were made prospectively and was based on consultations and follow-ups per period: preoperative, then 1 week, 1 month, 6 months, 12 months, 18 months, and 24 months postoperative.

Vertigo was evaluated by the number of attacks the patient reported in the last 6 months preoperatively. Aural fullness and tinnitus were evaluated by their presence or absence at each control visit. Patients underwent a complete neurotologic physical exam.

Hearing was assessed according to the pure-tone average (PTA) at 0.25, 0.5, 1, 2, and 4 kHz frequencies and speech discrimination score (SDS). A change of 10 dB or more of the PTA or a change of 15% in SDS was considered clinically significant. In patients with bilateral Ménière’s disease, only data concerning the first affected ear were considered in the study to avoid any symptom confusion or biases. The affected side was determined upon the patients’ side complaint. Hearing test was performed a day before the surgery and at each visit postoperatively.

**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 identify 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 a 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 not incised neither dissected off the posterior fossa dura. These described parts of the surgery are performed for the 2 groups: ESD and EDB. For the ESD group, the sac is completely decompressed and the surgery is accomplished. However, for the EDB 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 in order 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 2 small titanium clips (Figure 2). The titanium clips were applied by using the ligating clip applier, similar to the 1 used in vascular surgery.

**Statistical Analysis**

Statistical study was performed using SPSS (version 20) software (IBM, Chicago, IL). The comparisons of the 2 groups were studied using the Student t test and chi-square test. The error bars represent the standard deviation (SD) of the mean. P < .05 is considered statistically significant.

**Results**

Patients were randomly distributed to 2 experimental groups. Thirty-five patients underwent EDB and 22 patients underwent ESD. All patients were operated as a 1-day surgery. Patients’ characteristics are given in Table 1; the 2 groups of patients were homogenous in age and gender (P = .13 and P = .950, respectively). The results were regrouped according to symptoms.

![Figure 2](image.png)

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**Vertigo Control**

The mean ± SD number of spells for the last 6 months before the surgery was 8.4 ± 5.8 (n = 35) in the EDB group and 9.6 ± 7.9 (n = 22) in the ESD group with no statistically significant difference (P = .150). From 0 to 24 months postoperatively the mean ± SD number of spells was 0.3 ± 0.7 (n = 35) in the EDB group and 4.5 ± 7.9 (n = 22) in the ESD group with a statistically significant difference (P = .0002) (Table 2).

Moreover, 6 months postoperatively, 3.5% of the EDB group (1 patient) had vertigo recurrence against 80% of the ESD patients with a statistically significant difference (P < .0001). Similar results are seen 24 months postoperative where 3.5% (the same patient) of the EDB group had vertigo recurrence against 66% of the ESD group (P = .001). The results are represented in Figure 3.

After EDB, 11 patients experienced a postoperative benign paroxysmal positional vertigo (BPPV) of the PSCC out of which 9 had it in the ipsilateral ear and 2 had it in the contralateral ear.

**Aural Fullness**

All the patients had aural fullness preoperatively. There was no difference in aural fullness control between the 2 groups at 1 week and 6 months postoperative (P = .586 and P = .095, respectively). However, 24 months postoperative, 25% of the EDB group had persistent aural fullness against 81% of the ESD group with a statistically significant difference (P = .014) (Table 2). Moreover, 42% of the EDB patients felt in the first 6 months postoperatively the aural fullness as a prodromal effect to a Ménière’s attack without any initiated attack thereafter.

**Tinnitus**

In total, there was no difference in tinnitus control between the 2 groups at 1 week and 6 months postoperative (P = .586 and P = .095, respectively). However, 24 months postoperative, 31% of the EDB group had persistent tinnitus against 80.1% of the ESD group with a statistically significant difference (P = .02) (Table 2).

**Pure-tone Average (air conduction threshold)**

Before the surgery, the mean PTA was 56 dB and 51 dB for the EDB and ESD groups, respectively (P = .981). There was a significant increase in both groups 1 week postoperative, however, 24 months postoperative they return to
baseline level with no statistically significant difference when compared to preoperative \( P = .932 \) for EDB and \( P = .864 \) for ESD). There was no significant difference between both groups at all periods (Figure 4A). Moreover, 4 out of 6 patients who improved clinically their hearing in the EDB group have showed an improvement of their PTA level at 12 months after surgery, as presented in Table 3.

### Bone Conduction

Concerning the bone conduction level at the 0.25, 0.5, 1, 2, and 4 kHz frequencies, there was no difference between both groups in the preoperative and 24 months postoperative levels. As shown in Table 3, 4 out of 6 patients who improved clinically their hearing in the EDB group have showed an improvement of their bone conduction level at 12 months after surgery, as presented in Table 3.

### Speech Discrimination Score

Before the surgery, the mean SDS was 70.8% and 65% for the EDB and ESD groups, respectively \( P = .447 \). There was a significant decrease in SDS 1 week postoperative with no difference between both groups \( P = .915 \). However, at 12 months postoperative they return to baseline level with no difference compared to preoperative \( P = .836 \) for EDB and \( P = .917 \) for ESD). There was no significant difference between both groups at all periods (Figure 4B). Moreover, it is important to note that 6 patients in the EDB group have showed a clinically improvement of their SDS at 12 months after surgery, as presented in Table 3.

### Videonystagmography

The caloric test done before EDB showed a nystagmus mean value of 14.4 deg/s in the operated ear and 24.2 deg/s in the contralateral ear with a total mean deficit of 47%. Postoperatively, the mean value was 12.4 deg/s in the operated ear and 28 deg/s in the contralateral ear with a mean deficit of 58%. There was no statistically significant difference in the vestibular deficit between preoperative and postoperative.

As well, no statistically difference was found between the preoperative and postoperative period in the ESD group (mean deficit 51% and 49%, respectively).

### Reoperated Patients

Five patients (out of 14) were reoperated for EDB after an ESD failure. They did not develop any improvement of their vertigo spells after the ESD and asked us to reoperate by blocking the endolymphatic duct. As shown in Table 4, these refractory patients had no episodes of vertigo and no fluctuating hearing loss at 24 months post EDB. Of course, these 5 patients at the moment of the reoperation were not randomized and their data were not included in the analysis of the EDB group.

### CSF Leak

Five patients of the EDB group (14%) had a minor CSF leak during the surgery by the dissection of the very thin dura mater from the petrous bone, around the endolymphatic duct. CSF leaks were treated by blocking the dura mater tear by a piece of temporalis fascia and covered by...
BioGlue (albumin/glutaraldehyde sealant) with no postoperative restriction.

Discussion

The underlying pathophysiology of Ménière’s disease is still not well defined, and the treatment of patients unresponsive to medical therapy remains controversial.

Ablative surgeries such as vestibular neurectomy and labyrinthectomy have been associated with 85% to 95% of vertigo control.\(^8,9\) These high control rates have been demonstrated to be superior to that found in ESD.\(^10\) However, these surgeries are associated with several comorbidities. They are destructive surgeries for the vestibular system in the operated side as well as intratympanic gentamicin injection findings.\(^11\)

An ideal treatment for Ménière’s disease would be nonablative for the vestibular system with a conservative effect on hearing. In the literature, the results regarding a complete vertigo control (Class A) with ESD largely vary (Sennaroglu 30%,\(^11\) Silverstein 40%,\(^12\) Jackson 46%,\(^13\) Smith 41%,\(^14\) Pensak 64%,\(^15\) Huang 72%).\(^16\) Our results of ESD are found in the lower limit of the reported data. However, it is difficult to analyze these results since the criteria used to diagnose Ménière’s disease are not the same, the technique of ESD is often modified, and the length of follow-up largely varies. Nevertheless, given this wide variety of results, it is acceptable to say that this technique is still a debate in the literature. This contradiction could be supported by 2 reported studies. A histopathologic study performed

Table 3. Six Patients with Hearing Level Improvement 12 Months Postoperatively.

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<th>Frequency (Hz)</th>
<th>250</th>
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<th>1000</th>
<th>2000</th>
<th>3000</th>
<th>4000</th>
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<th>SDS (%)</th>
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<td>20</td>
<td>60</td>
<td>60</td>
<td>40</td>
<td>30</td>
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<td>15</td>
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<td>96(^*)</td>
</tr>
<tr>
<td>2 Preoperative</td>
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<td>55</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>55</td>
<td>65</td>
<td>16</td>
</tr>
<tr>
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<td>40</td>
<td>50</td>
<td>65</td>
<td>60</td>
<td>55</td>
<td>60</td>
<td>44(^*)</td>
</tr>
<tr>
<td>3 Preoperative</td>
<td>45</td>
<td>65</td>
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</tr>
<tr>
<td>Postoperative</td>
<td>10</td>
<td>30</td>
<td>45</td>
<td>80</td>
<td>70</td>
<td>60</td>
<td>61.6(^*)</td>
<td>64(^*)</td>
</tr>
<tr>
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<td>55</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>18.33(^*)</td>
<td>96(^*)</td>
</tr>
<tr>
<td>5 Preoperative</td>
<td>10</td>
<td>30</td>
<td>40</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>69.1</td>
<td>36</td>
</tr>
<tr>
<td>Postoperative</td>
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<td>35</td>
<td>45</td>
<td>65</td>
<td>60</td>
<td>70</td>
<td>68.33</td>
<td>72(^*)</td>
</tr>
<tr>
<td>6 Preoperative</td>
<td>25</td>
<td>60</td>
<td>40</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>43.3</td>
<td>72</td>
</tr>
<tr>
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<td>5</td>
<td>5</td>
<td>10</td>
<td>10</td>
<td>16.66(^*)</td>
<td>100(^*)</td>
</tr>
</tbody>
</table>

Abbreviations: dB, decibels; Postoperative, audiogram performed 12 months postoperatively; Preoperative, audiogram performed 1 day preoperatively; PTA, pure-tone average based on air conduction at 250, 500, 1000, 2000, 3000-, and 4000 Hz; SDS, speech discrimination score (in %).

\(^*\)A change of the PTA of more than 10 dB or of the discrimination level of more than 15% was considered clinically significant.

Figure 4. (A) Pure-tone average evolution and (B) speech discrimination scores evolution. Abbreviations: EDB, endolymphatic duct blockage; ESD, endolymphatic sac decompression; PTA, pure-tone average; SDS, speech discrimination score; Wk, week; Mo, months; N, number of patients.
by Chung et al on 15 patients whom had an endolymphatic sac surgery showed a diffuse hydrops involving the cochlea, the saccule, the utricle, and the ampulla. The authors conclude that ESD does not relieve hydrops in patients with Ménière’s disease. In addition, Linthicum et al reported no increase of hydrops on temporal bone histopathology of a transected endolymphatic duct with a complete amputation of the endolymphatic sac. The Reissner membrane was attached on the normal expected portion of the spiral ligament without any evidence of hydrops in the cochlea.

The role of the endolymphatic sac in the development of Ménière’s disease remains unclear. It has been hypothesized that the endolymphatic hydrops causing Ménière’s disease is partially due to a decrease of the absorption of the endolymph at the level of the endolymphatic sac. Therefore, endolymphatic sac decompression would allow drainage of the accumulated fluid. This is not defended by the retrolabyrinthine approach. Prades et al and Darrouzet et al described modifications to the retrolabyrinthine approach for the surgical treatment of acoustic neuromas. These modifications included section of the endolymphatic duct and separation of the endolymphatic sac from the inner ear to permit a better access of the inner acoustic canal and a wide visualization of the tumor. Theoretically, a section of the endolymphatic duct would worsen the hydrops and creates symptoms of Ménière’s disease. However, surprisingly, in these 2 studies, none of the patients developed Ménière’s symptoms.

In front of the variability of ESD reported results and in the absence of Ménière’s disease developed after endolymphatic duct section, we compared the effectiveness of this new surgical technique (EDB) to the ESD traditionally used.

EDB showed a significantly better improvement of vertigo spells, a lower percentage of recurrence at 24 months postoperatively, a better improvement of tinnitus, and aural fullness than ESD with a statistically significant difference. Regarding hearing outcome, there was no difference in PTA and SDS between both groups preoperatively and at each period postoperatively. However, at 1 week postoperative both groups experienced a temporary drop in their hearing level. We attributed this temporary finding to a postsurgical inflammatory state.

We explained that the postoperative BPPV in the EDB group is due to the drilling right posteriorly to the PSCC, which can stimulate the displacement of otoliths in the inner ear. Moreover, 5 patients (14%) had a minor CSF leak due to the very thin and adherent dura mater to the bone of the PSSC medically. CSF leaks were managed intraoperatively with no postoperative restriction. None of the patients had a PSSC injury, facial nerve injury, sigmoid sinus injury with hemorrhage, or significantly increased hearing loss.

Furthermore, 5 patients had previously undergone ESD with no further improvement of their symptoms. However, no attacks were noted in these patients after the EDB at 24 months of follow-up.

No study showed a clear relationship between an endolymphatic duct injury and hearing loss. In the retrolabyrinthine approaches of Prades and Darrouzet the

<table>
<thead>
<tr>
<th>Patient/Time</th>
<th>Period</th>
<th>Number of Spells</th>
<th>Vertigo</th>
<th>Tinnitus</th>
<th>Aural Fullness</th>
<th>Fluctuating Hearing Loss</th>
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<tr>
<td></td>
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<td></td>
<td>1 mo pre-EDB</td>
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<td>– – – –</td>
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</table>

*Time represents the time elapsed between the endolymphatic sac decompression (ESD) and the endolymphatic duct blockage (EDB). Pre, preoperative; Post, postoperative; mo, month.
hearing level was preserved in patients who had small tumors and a functional hearing preoperatively.

Moreover, other studies suggest that the endolymphatic sac has secretory functions. In a study of the subcellular structure of the endolymphatic sac in guinea pigs done by Takumida et al, the presence of dark cells in the endolymphatic sac has been shown. These cells have a secretory role, which supports the possible role of the endolymphatic sac in the endolymph secretion. Finally a study performed by Friss et al on Lewis rats showed that auto-antigens or trophic factors could induce alterations in the endolymphatic sac cells causing their hyperactivity, which could explain the creation of a hydrops in Ménière’s disease.

Therefore, our hypothesis is that in Ménière’s disease there is imbalance of the homeostasis of the endolymph at the level of the endolymphatic sac with an increased secretion outweighing a decreased absorption giving an increased pressure in the inner ear. Thus, by blocking the endolymphatic duct we decrease the volume of endolymph in the inner ear, which helps alleviating the symptoms of Ménière’s disease.

The endolymphatic sac is located within the layers of dura in the posterior cranial fossa. These layers are innervated by cranial nerve X and cervical nerves C1, C2, and C3. Therefore, an irritation of these dura layers by an enlarging endolymphatic sac with a blocked outflow of the endolymph can be responsible of the aural fullness fluctuation without a Ménière attack described in 42% of our patients.

Finally, an important factor to take into consideration is the natural course of Ménière’s disease. Silverstein compared 50 patients who were surgical candidates but refused surgery with 83 patients who underwent sac surgery, nerve section, and labyrinthectomy. They found that within an average of 8.3 years, 70% of patients were free of vertigo in the nonsurgical group. However, it doesn’t mean that for some patients immediate improvement is not required. Therefore, when evaluating the effectiveness of a surgical treatment for Ménière’s disease, results over 1 or 2 years are more clinically relevant as it bypasses the bias of a natural course of Ménière’s disease.

Limitation of the Study

We used a basic method of simple randomization by flipping a coin. However, this randomization in relatively small sample size clinical trials (n < 100) results in an unequal number of participants among groups. This explains why our randomization method leads to the discrepancy between the numbers of patients in either group. This trial was not blinded; both the patient and the observer assessing the outcomes were aware of the treatment, which can increase the risk of substantial bias.

Conclusion

This study offers EDB as a novel surgical approach for the treatment of Ménière’s disease. It is the unique reported 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.

Author Contributions

Issam Saliba, substantial contributions to conception and design, analysis and interpretation of data, revising the article critically for important intellectual content, final approval of the version to be published; Nathalie Gabra, substantial contributions to conception and design; acquisition, analysis, and interpretation of data; drafting the article; final approval of the version to be published; Musaed Alzahrani, substantial contributions to conception and design; acquisition, analysis, and interpretation of data; revising the article critically for important intellectual content; final approval of the version to be published.

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