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International consensus

## International consensus (ICON) on treatment of Ménière's disease



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### ABSTRACT

**Objective:** To present the international consensus for recommendations for Ménière's disease (MD) treatment.

**Methods:** Based on a literature review and report of 4 experts from 4 continents, the recommendations have been presented during the 21st IFOS congress in Paris, in June 2017 and are presented in this work.

**Results:** The recommendation is to change the lifestyle, to use the vestibular rehabilitation in the inter-critic period and to propose psychotherapy. As a conservative medical treatment of first line, the authors recommend to use diuretics and Betahistine or local pressure therapy. When medical treatment fails, the recommendation is to use a second line treatment, which consists in the intratympanic injection of steroids. Then as a third line treatment, depending on the hearing function, could be either the endolymphatic sac surgery (when hearing is worth being preserved) or the intratympanic injection of gentamicin (with higher risks of hearing loss). The very last option is the destructive surgical treatment labyrinthectomy, associated or not to cochlear implantation or vestibular nerve section (when hearing is worth being preserved), which is the most frequent option.

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### 1. Introduction

Ménière's disease (MD) treatment must be first based on a trustable diagnosis. To be confident with the diagnosis, it is recommended to use the consensual guidelines and classification of the AAO-HNS published in 1995 [1] and recently reviewed by the Equilibrium Committee in 2015 [2]. Although the diagnosis is primarily based on the clinical history, clinicians also utilize various tests to confirm the diagnosis before introduction of any treatment. The next step is to tailor the treatment for each patient based on an algorithm that seems frequently different from one center to another in the same country, even in the same country. During the last IFOS Congress in Paris in June 2017, an international consensus (ICON) Round Table joining six experts of MD from different continents (Asia, America, Europe, and Australia) was designed in trying to draw a minimal consensus, which could be summarized in an

algorithm. But this synthesis revealed highly challenging, as among the countries and/or continents of the participants of this ICON, only two have drawn a consensus or recommendation applicable in their countries, Japan in 2011 and France in 2016 [3]. Scientific literature was assessed using the Level of Evidence classification (1 to 5) and recommendations were given following the grading of recommendations assessment, development and evaluation (GRADE) scoring system.

In MD, the aim of the treatment is first to reduce the frequency, and secondarily the severity, of the vertigo crises, with a minimal impairment of hearing function, hoping this favorable result is associated with a hearing and tinnitus improvement [4]. The treatment is symptomatic and should always be related to the main complain of the patient. It must be conservative in the first place. The conservative treatments are used whatever the hearing function, as destructive ones are preferentially used in patients with hearing loss. Concerning bilateral MD, the difficulty is the unilateral presentation at the beginning and the delay of the contralateral involvement. That is why the treatment should always be conservative. Caregivers must remember the natural evolution of MD, especially the resolution of vertigo,

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and the major implication of the placebo effect in any kind of treatment.

Finally, the discussion before and during the congress between participants of ICON Round Table has led to propose a minimal intercontinental consensus on MD treatment, reported here. It reviews the different therapeutic options for the unilateral form, makes a focus on the bilateral form, and proposes a treatment algorithm based on a review of the literature and the authors experience.

## 2. First step: medical treatment of Ménière's disease

The authors recommend (Grade C), as the first care given to the patient, the modification of the lifestyle including well sleeping [5] (Level of proof 4), and a research of an obstructive sleep apnea syndrome [6] (Level of proof 2), decreasing stress, avoiding caffeine, alcohol and tobacco [7] (Level of proof 4) and adopt a low salt diet. Two treatment options should be considered to help the patient: vestibular rehabilitation and psychotherapy [8–10] (Level of proof 2). The vestibular rehabilitation should be avoided during crises and preferentially used in intercritical period. The authors recommend this rehabilitation (Grade B) even if a recent Cochrane review of the literature, using the risk of bias tool, cannot conclude on a positive effect of vestibular rehabilitation on balance and dizziness-related quality of life [8]. But this review studied the effects of vestibular rehabilitation in all unilateral peripheral vestibular dysfunctions, including MD. In this context, it reported moderate to strong evidence that vestibular rehabilitation was a safe and effective management [9] (Level of proof 2). Considering psychotherapy, especially the cognitive behavior therapy intervention, it produces significant improvements in dizziness-related symptoms, disability, and functional impairment among patients with chronic subjective dizziness [10] (Level of proof 2).

Diuretics represent the most commonly used first-line medical treatment. The drug chosen differs from one author to another but, according to the literature, hydrochlorothiazide, acetazolamide and chlorthalidone are used in decreasing order [11,12] (Level of proof 4). The authors recommend their use that may decrease vertigo spell frequency (Grade C). A special attention must be paid to their respective contraindications and side-effects.

Betahistine is very popular in France, Europe, Japan and with many surgeons in Australia but not FDA-approved in USA. The dosage varies from one center to another but the literature reports a better effect with a minimal dosage of 48 mg/d. It could be used up to 288 to 480 mg/d for patient with severe MD who does not sufficiently respond to lower dosages [1–17] (Level of proof 1 and 3). The authors recommend, depending on their country, using betahistine at a dose of 48 to 96 mg/d (Grade C). Even if the side effects for higher dosage seem rare and the efficacy better in some reports, the authors do not give recommendation for these dosages for security reason.

Another non-invasive option is the Meniett® system (Medtronic Cie, the USA), producing sequences of micro-pressure pulses susceptible to act on the endolymphatic hydrops [18]. This device is included of the algorithm treatment in Italy and Australia, even if a recent Cochrane review concludes there is no evidence this therapy is effective [19] (Level of proof 2). Because of the very low rate of side effects reported in the five studies of the Cochrane review, the authors recommend using this device as a first line treatment (professional agreement).

## 3. Second step: intratympanic corticosteroids

At that point, after using one or all of these therapeutic options, the authors confirm that 80% of patients are in remission of MD

symptoms, especially vertigo [20]. To manage conservatively the rest of the patients, intratympanic injection of steroids (ITS) is proposed as a second-line treatment. It is more and more popular [21]. Dexamethasone [22] is more used than methylprednisolone [23] (Level of proof 2 for both). Patel et al. recently reported that two injections of methylprednisolone (62.5 mg/mL) given 2 weeks apart was safe and as efficient as gentamicin (40 mg/mL) used with the same protocol to treat refractory MD. Most authors use daily injections of dexamethasone solution (4 mg/mL) for five consecutive days. For the authors, the use of one injection per week for 1 to 4 consecutive weeks is also efficient [24]. ITS significantly improves both frequency and severity of vertigo spells compared to placebo at 24 months after treatment (Level of proof 2). The authors recommend the use of ITS, whatever the drug, preferably with the protocol previously described to treat patients with MD in a non ablative manner (Grade B) since these drugs are not ototoxic [25] (Level of proof 1).

## 4. Third step: surgical conservative treatment

A literature review considering the studies published during the last decade confirms a decline of surgical treatment of MD in favor of intratympanic injections [20]. The most favored surgical technique remains endolymphatic sac surgery (ELSS). It represents for the authors one of the third-line treatments of MD, even if it has long been criticized and considered as a placebo surgery. Most critics referred on two placebo-controlled Danish studies analyzed in the Cochrane review in 2010 and 2013. Both studies concluded that ELSS has no evidence-based effect on natural course and vertigo of MD [26,27] (Level of proof 2). But a more recent meta-analysis came to the conclusion there was a low level of evidence in favor of an effect [28] (Level of proof 2). This controversy is due to the great difficulty to evaluate in a blinded way surgical treatments in MD, since the choice of a placebo or control reveals rather impossible. For most authors today, grommet insertion or mastoidectomy, respectively chosen in the Danish studies, cannot be considered as placebo treatments. Therefore the conclusion of these studies is not relevant. This is underlined in the Cochrane review. Even if solid proofs are lacking in the literature, the authors agree that it should be the first option after failure of the medical conservative treatment, if hearing function useful and MD in young subjects (Grade B). All the authors favour ELSS but the evolution of the practice is toward an increase number of ITS, especially in USA and in France, and a decrease number of ELSS surgeries.

## 5. Fourth step: medical destructive treatment of Ménière's disease

Intratympanic injection of gentamicin (ITG) is probably the most effective non-surgical treatment to eradicate vertigo in MD. But it is also an ablative method that carries a non-negligible risk of hearing loss [29] (Level of proof 2). Currently, ITG is favored in USA and most European countries. But it is about to change, as in France, Japan and Australia, ITS is preferred to ITG as a second-line treatment. Concerning ITG, no consensus has been reached so far on the dosage and treatment duration as Syed et al. has reported recently in a review of the literature [24]. The authors recommend using ITG as a destructive method preferentially when hearing function is impaired for patients with good contralateral vestibular function (Grade A). Based on Syed et al. meta-analysis, is advocated a "titration" protocol, ITG injections (40 mg/mL) being repeated until disappearance of vertigo spells. This "tailored" protocol is about to prevent hearing loss more than systematic weekly or monthly injection [24,30] (Level of proof 2 and 4). As a systematic genetic screening of MD patients is not currently done, hypersensitivity

## ICON algorithm for treatment of Ménière's disease

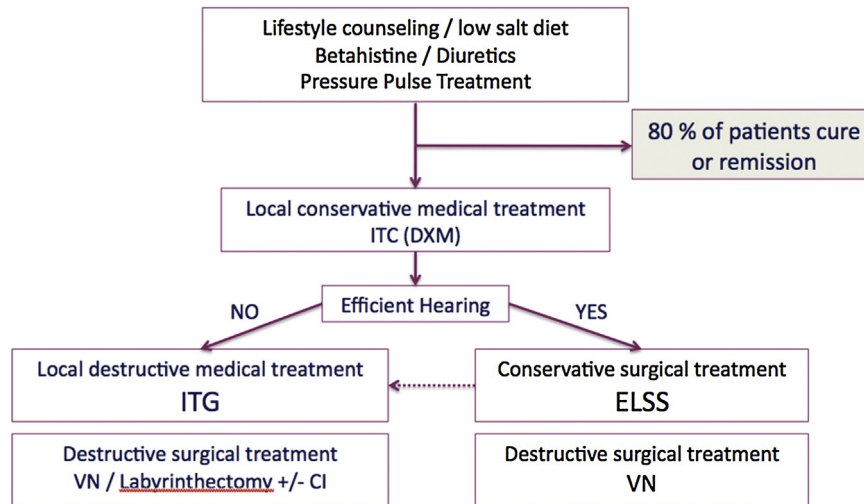


Fig. 1. Proposition of algorithm of treatment of Ménière's disease.

to the aminoglycosides in carriers of the mitochondrial mutation of the gene MTRNR1 is not screened. This mutation exposes to a complete and definitive deafness after a single injection of aminoglycosides [31]. ITG is now in transition between the third and the fourth line of treatment of the MD.

### 6. Fifth step: surgical destructive treatments

Evidence-based evaluations of totally ablative techniques, represented by surgical labyrinthectomy and vestibular neurectomy (VN) are scarce in the literature, compared to that of ELSS. No randomized controlled trials are available in the literature. Nevertheless, studies recommend their use after medical treatment failure and report a very good efficacy to control vertigo in MD patients. VN reveals more efficient than ITG [32,33]. The authors recommend indicating VN in patients suffering of intractable vertigo crises not influenced by medical treatment associated with poor but serviceable hearing function for patients with good contralateral vestibular function (Grade B). There is a trend to replace ELSS by VN in patients that do not respond to ITG or suffer of drop-attack crises. Surgical labyrinthectomy is less and less performed, even if the efficacy is close to the VN, since it totally destroys the remaining hearing function, at the difference with VN [34]. Most authors recommend to associate cochlear implantation to surgical labyrinthectomy in order to rehabilitate hearing in the same time. This practice is more common in Australia and USA than in Europe or Japan. It is not allowed in France.

### 7. Treatment of bilateral form of Ménière's disease

Specific data concerning occurrence of bilateral MD are not available and reports are from 2 to 47%. Bilateralization occurs secondarily after several years [35]. Obviously, bilateral MD should be treated in a conservative way to avoid bilateral deafferentation or ablative treatments. This occurrence has to be anticipated at the time of treating the first ear, especially when there are some arguments to forecast that the contralateral ear is not spared. This is the reason why the conservative treatment has always to be used for the first line, bringing more and more teams to switch from ITG to steroids ITS. Concerning the surgical treatment, the best option, even if controversial, is the ELSS in case of bilateral MD.

### 8. Proposition of algorithm of MD treatment

The Fig. 1 represents a proposal of an algorithm of MD treatment as an international consensus obtains for the IFOS meeting 2017. The first line of treatment includes the medical conservative treatment. After this line of treatment 80% of patients with MD are cured or in remission. Then the second line is the IT injections, mainly ITS as a conservative treatment and ITG in case of failure and preferentially in patients with hearing impairment. After this second line, 90 to 95% of the patients are cured or in remission [36]. The third line is the surgical, conservative or destructive, treatment. If indicated, ELSS must be indicated before ITG.

### Disclosure of interest

The authors declare that they have no competing interest.

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## Update

**European Annals of Otorhinolaryngology, Head and Neck diseases**

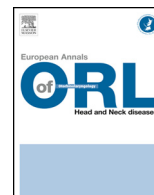
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## Erratum

# Erratum to “‘Algorithm’ for Meniere’s Disease” [Eur. Ann. Otorhinolaryngol. 1S (2018) S29–S32]



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In the 2018 special issue of the *European Annals of Otorhinolaryngology, Head and Neck Diseases*, Nevoux et al. [1] reported an algorithm for the treatment of Meniere’s disease, combining intratympanic steroids and gentamicin as well as surgical procedures such as endolymphatic sac surgery, labyrinthectomy and vestibular neurectomy, based on a consensus document by a group called ICON. A thorough literature review suggests that this algorithm was originally published by Sennaroglu [2], Gursel and Dini in a report in 2001 in the journal *Otolaryngology - Head and Neck Surgery*, a reference unfortunately not mentioned in the literature review performed by Nevoux et al. [1]. Our excuses for this omission.

## Disclosure of interest

The authors declare that they have no competing interest.

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