Clinical practice guideline: Ménière's disease.

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American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF)

Basura GJ, Adams ME, Monfared A, et al. Clinical practice guideline: Ménière's disease. Otolaryngol Head Neck Surg. 2020 Apr;162(2_suppl):S1-S55. [398 references] PubMed

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Overview

Guideline Objective

To improve the quality of the diagnostic workup and treatment outcomes of Ménière's disease (MD)

Note: This clinical practice guideline (CPG) focuses only on MD, recognizing that MD may arise in conjunction with or separate from other conditions presenting with vertigo, hearing loss, and/or tinnitus. This CPG does not discuss the specific management of those conditions that may mimic MD. This CPG is not intended for comprehensive management of MD.

Patient Population

Patients greater than or equal to 18 years old with suspected diagnosis of definite or probable MD

Notes:

- *Definite MD*:
    - Two or more spontaneous attacks of vertigo, each lasting 20 minutes to 12 hours
    - Audiometrically documented fluctuating low- to mid-frequency sensorineural hearing loss (SNHL) in the affected ear on at least 1 occasion before, during, or after 1 of the episodes of vertigo
    - Fluctuating aural symptoms (hearing loss, tinnitus, or fullness) in the affected ear
    - Other causes excluded by other tests

- *Probable MD*:
    - At least 2 episodes of vertigo or dizziness lasting 20 minutes to 24 hours
    - Fluctuating aural symptoms (hearing loss, tinnitus, or fullness) in the affected ear
    - Other causes excluded by other tests

Recommendations

Recommendation Statements

Statement 1. Diagnosis of Ménière's Disease (MD)

Clinicians should diagnose definite or probable MD in patients presenting with 2 or more episodes of vertigo lasting 20 minutes to 12 hours (definite) or up to 24 hours (probable) and fluctuating or nonfluctuating sensorineural hearing loss, tinnitus, or pressure in the affected ear, when these symptoms are not better accounted for by another disorder. (**Recommendation based on observational studies with consistently applied reference standard and a preponderance of benefit over harms**)

Action Statement Profile

- *Quality improvement opportunity*: Improving accuracy of diagnosis and increasing awareness of proper diagnosis for MD. (National Quality Strategy Domain: Effective Communication and Care Coordination)
- *Aggregate evidence quality*: Grade C, based on observational studies with consistently applied reference standard
- *Level of confidence in evidence*: High
- *Benefits*: Improved accuracy and efficiency of diagnosis, appropriately directed treatment, reduced misdiagnosis, appropriately directed diagnostic testing, educating clinicians about accurate diagnosis, appropriate referrals, reduced use of inappropriate testing, reduced cost, improved patient quality of life (QOL)
- *Risk, harm, cost*: Provider time for making diagnosis
- *Benefit-harm assessment*: Preponderance of benefit over harm

- *Value judgments*: The group preferred to be more inclusive in the initial clinical diagnosis to capture more patients who prove to have MD with the understanding that some patients with other diagnoses may initially be included.
- *Intentional vagueness*: Use of *definite* versus *probable*. Also, the presence of documented/audiometrically objectified hearing loss may not be present at the time of testing.
- *Role of patient preferences*: Small
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: There was disagreement among the panel regarding whether to include fluctuation as part of the criteria.

Statement 2. Assessing for Vestibular Migraine (VM)

Clinicians should determine if patients meet diagnostic criteria for VM when assessing for MD. (**Recommendation based on nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: VM is a common cause of dizziness that can closely mimic MD. Appropriate assessment for VM could lead to more appropriate treatment. (National Quality Strategy Domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality, Effective Communication and Care Coordination)
- *Aggregate evidence quality*: Grade C, based on case-control studies or studies with poor, nonindependent, or inconsistently applied reference standards
- *Level of confidence in evidence*: Low, studies were done in specialty populations and may not be generalizable to more primary care populations
- *Benefits*: Accuracy of diagnosis, avoid unnecessary treatments or testing, potential for more appropriate treatment, patient education, promotes multidisciplinary care
- *Risk, harm, cost*: Extra time for assessment. Referral to other specialists.
- *Benefit-harm assessment*: Preponderance of benefit over harm

- *Value judgments*: None
- *Intentional vagueness*: None
- *Role of patient preferences*: Small
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 3. Audiometric Testing

Clinicians should obtain an audiogram when assessing a patient for the diagnosis of MD. (**Strong recommendation based on systematic reviews [SRs] of cross-sectional studies with consistently applied reference standard and blinding for diagnostic testing with a preponderance of benefit over harms**)

Action Statement Profile

- *Quality improvement opportunity*: Determining both pure tone thresholds and measures of speech recognition will lead to more accurate diagnosis and appropriate and timely referrals for aural rehabilitation, hearing aids, and/or cochlear implants and may have significant implications for treatment options. (National Quality Strategy Domain: Effective Communication and Care Coordination)
- *Aggregate evidence quality*: Grade A, based on SRs of cross-sectional studies with consistently applied reference standard and blinding for diagnostic testing
- *Level of confidence in evidence*: High
- *Benefits*: Improving diagnostic accuracy, identifying deficits in contralateral ear (question of bilateral disease), improving treatment planning, establishing baseline of hearing prior to treatment, directing treatment options based on degree of residual hearing (ablative vs nonablative), and identifying opportunities for aural rehabilitation
- *Risk, harm, cost*: Cost of testing, time of testing, patient distress at unrecognized hearing loss, discrimination based on hearing impairment (vocation, access to disability benefits)
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: An audiogram is essential to make the diagnosis of definite MD.

- *Intentional vagueness*: None. Also, the presence of a documented/audiometrically objectified hearing loss may not be present at the time of testing.
- *Role of patient preferences*: Small. Some patients may elect not to get an audiogram for various reasons.
- *Exclusions*: None
- *Policy level*: Strong recommendation
- *Differences of opinion*: There was a minority of the group who felt that patients with probable MD can be treated without an audiogram, but the majority felt that the audiogram is key to confirming the diagnosis and all subsequent management. One committee member noted that there are no studies in MD that assess outcomes in those receiving an audiogram as compared with those who do not. The audiogram is required to move from a diagnosis of possible MD to definite MD. Some patients and providers may elect to proceed with noninvasive management without an audiogram.

Statement 4. Utility of Imaging

Clinicians may offer magnetic resonance imaging (MRI) of the internal auditory canal and posterior fossa in patients with possible MD and audiometrically verified asymmetric sensorineural hearing loss. (**Option based on observational and case studies with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: To reduce variations of care and unnecessary expense as well as potential adverse effects from radiation (if computed tomography [CT] is used) and/or contrast (CT/MRI) exposure. (National Quality Strategy Domain: Making Quality Care More Affordable)
- *Aggregate evidence quality*: Grade D, based on observational and case studies
- *Level of confidence in evidence*: Medium
- *Benefits*: Avoid unnecessary testing, minimize cost and adverse events, maximize the diagnostic yield of MRI when indicated, avoid radiation, patient reassurance
- *Risk, harm, cost*: Cost of the MRI scan, potential risks of contrast agents, potential for risk of injury in MRI scanner (e.g., heating of metallic wires and implants or subsequent malfunction of implants with magnetic components), physical discomfort of the imaging procedure (noise, claustrophobia), psychological distress of incidental

findings (and further workup necessitated by those findings), and potential for delayed/missed diagnosis

- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: None
- *Intentional vagueness*: None
- *Role of patient preferences*: Moderate
- *Exclusions*: Patients unable or unwilling to have MRI
- *Policy level*: Option
- *Differences of opinion*: The group was divided regarding the benefit of MRI. Specifically, many clinicians were uncomfortable treating MD without ruling out inner ear or retrocochlear lesions in either unilateral hearing loss or subsequent secondside loss in the setting of possible bilateral MD. Others felt comfortable using nonablative therapies without MRI.

Statement 5. Vestibular or Electrophysiologic Testing

Clinicians should not routinely order vestibular function testing or electrocochleography (ECochG) to establish the diagnosis of MD. (**Recommendation against based on systematic reviews of cross-sectional studies and observational ECochG studies**)

Action Statement Profile

- *Quality improvement opportunity*: Avoidance of unnecessary testing. (National Quality Strategy Domains: Patient Safety, Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- *Aggregate evidence quality*: Grade B, based on SRs of cross-sectional studies and observational ECochG studies
- *Level of confidence in evidence*: Medium, based on difficulty in assessing the quality of the SRs, the meta-analyses, and the subgroups within the cohort
- *Benefits*: Avoidance of unnecessary testing, decreased cost, improved efficiency of diagnosis, reduced patient burden of unpleasant testing
- *Risk, harm, cost*: Missed or delayed diagnosis of comorbid conditions

- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: While some of these tests may have a role in individualized patients, MD requires a clinical and audiometric diagnosis.
- *Intentional vagueness*: The word *routine* is used to allow for individualized use of these testing modalities in some of the settings specified in the supporting text.
- *Role of patient preferences*: Small
- *Exclusions*: None
- *Policy level*: Recommendation against
- *Differences of opinion*: None

Statement 6. Patient Education

Clinicians should educate patients with MD about the natural history, measures for symptom control, treatment options, and outcomes. (**Recommendation based on a randomized controlled trial [RCT] on patients educating themselves and shared decision-making literature and a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Informing patients about their disease to participate in shared decision making. (National Quality Strategy Domain: Effective Communication and Care Coordination)
- *Aggregate evidence quality*: Grade C, single RCT evaluating a patient education booklet and the considerable literature on shared decision making
- *Level of confidence in evidence*: High
- *Benefits*: Patient engagement, patient satisfaction, improved adherence to treatment, avoidance of unnecessary treatments, more optimal use of health care resources, improved symptom control, improved shared decision making
- *Risk, harm, cost*: Time for education, patient distress, diagnosis uncertainty
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: Education allows for improved shared decision making. This assumes that the patient is not already appropriately educated.

- *Intentional vagueness*: None
- *Role of patient preferences*: Small, but patients may express preference for optimal method of education
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 7. Symptomatic Management of Vertigo

Clinicians should offer a limited course of vestibular suppressants to patients with MD for management of vertigo only during MD attacks. (**Recommendation based on nonrandomized or historically controlled studies, including case-control and observational studies, and a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Communication with clinicians and their patients about how and when to use vestibular suppressants to control vertigo. (National Quality Strategy Domains: Effective Communication and Care Coordination, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade C, nonrandomized or historically controlled studies, including case-control and observational studies
- *Level of confidence in evidence*: Medium due to grade C evidence.
- *Benefits*: Better symptom control, improved QOL
- *Risk, harm, cost*: Cost, side effects—urinary retention, dry mouth, visual changes, sedation, addiction. Impaired vestibular compensation
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: Vertigo can have a detrimental impact on QOL, and patients tend to feel better when vertigo symptoms are alleviated.
- *Intentional vagueness*: None
- *Role of patient preferences*: Large depending on severity of symptoms

- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 8. Symptom Reduction and Prevention

Clinicians should educate patients with MD on dietary and lifestyle modifications that may reduce or prevent symptoms. (**Recommendation based on RCTs, observation studies, and cohort studies with indeterminate benefit, with preponderance of benefit over harms**)

Action Statement Profile

- *Quality improvement opportunity*: Identification of MD triggers may reduce symptoms in some patients. Allergies have been shown to contribute to symptoms of MD in up to 30% of the patients. (National Quality Strategy Domains: Effective Communication and Care Coordination, Person and Family Centered Care, Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- *Aggregate evidence quality*: Grade C, based on a dearth of RCTs regarding dietary modifications (1 small RCT on sodium restriction, negative for effectiveness but with study limitations; 1 relatively strong observational/survey study showing advantage to both low sodium and caffeine restriction), 1 RCT regarding decreasing stress hormone vasopressin and 1 RCT of booklet-based symptom control via relaxation and cognitive-behavior strategies to reduce anxiety, 1 RCT regarding an acupressure technique for treatment of dizziness and 2 SRs regarding acupuncture, 3 RCTs regarding antisecretory therapy (2 positive, 1 negative for effectiveness), and a number of observational studies and a strong literature review (human and animal) regarding the role of treatment of allergy symptoms in reducing symptoms of MD in allergic patients. There is a Cochrane SR currently underway for dietary modifications.
- *Level of confidence in evidence*: High
- *Benefits*: May improve symptom control, avoid unnecessary lifestyle modifications, improved QOL, patient empowerment, potential avoidance of more invasive/higher-risk therapy
- *Risk, harm, cost*: Time of counseling, burden of potentially ineffective lifestyle modifications on the patient/family, potential risk of hyponatremia, increased cost of Ménière's diet

- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: While the evidence of benefit of dietary and lifestyle modifications is limited, individual patients may have identifiable triggers, the identification of which may improve symptom control.
- *Intentional vagueness*: None
- *Role of patient preferences*: Small regarding the provision of education but large with regard to the choice to adopt lifestyle or dietary changes or not
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: A small group of panel members felt that there was a limited role and expressed concern regarding possible negative effects of sodium restriction, specifically hyponatremia, although this has not been reported in any of the studies and could be minimized as a risk with use of appropriate nutritional counseling.

Statement 9. Oral Pharmacotherapy for Maintenance

Clinicians may offer diuretics and/or betahistine for maintenance therapy to reduce symptoms or prevent MD attacks. (**Option based on observational studies and a Cochrane review on betahistine and oral diuretics with a balance of benefits and harms**)

Action Statement Profile

- *Quality improvement opportunity*: Improved symptom control. (National Quality Strategy Domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade B, based on observational studies and a Cochrane review on betahistine and oral diuretics
- *Level of confidence in evidence*: Medium. High risk of bias reported in most studies included in SR
- *Benefits*: Improved vertigo control, improved QOL
- *Risk, harm, cost*: Cost of therapy, side effects of medications, promotion of ineffective therapy
- *Benefit-harm assessment*: Balance of benefits and harm

- *Value judgments*: There are different practice patterns among treating physicians on the panel. There is no specific preference for one agent over another, and that is why they were grouped for this statement.
- *Intentional vagueness*: None
- *Role of patient preferences*: Large
- *Exclusions*: Patients with comorbid conditions making these medications contraindicated (i.e., renal or cardiac disease, asthma). Allergies or sensitivities to these medications
- *Policy level*: Option
- *Differences of opinion*: None

Statement 10. Positive Pressure Therapy

Clinicians should not prescribe positive pressure therapy to patients with MD. (**Recommendation against based on a SR and randomized trials showing ineffectiveness of devices like the Meniett device with a preponderance of benefit over harm for not using**)

Action Statement Profile

- *Quality improvement opportunity*: Avoidance of ineffective therapy. (National Quality Strategy Domain: Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- *Aggregate evidence quality*: Grade B, based on a Cochrane SR and 2 small RCTs on Meniett device showing no effect
- *Level of confidence in evidence*: High
- *Benefits*: Avoidance of ineffective therapy
- *Risk, harm, cost*: Patient or physician concerns at the lack of positive pressure therapy as an option if other noninvasive treatments have failed, with remaining options being destructive and/or invasive procedures.
- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: While this therapy is generally ineffective, there may be rare patients with limited other options.

- *Intentional vagueness*: None
- *Role of patient preferences*: Small
- *Exclusions*: None
- *Policy level*: Recommendation against
- *Differences of opinion*: A small group of panel members felt that some evidence supports the use of the Meniett device and that it could be used in symptomatic patients who have not obtained relief from other nonablative treatments.

Statement 11. Intratympanic (IT) Steroid Therapy

Clinicians may offer, or refer to a clinician who can offer, IT steroids to patients with active MD not responsive to noninvasive treatment. (**Option based on a systematic review and a RCT with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Improved vertigo control. (National Quality Strategy Domains: Effective Communication and Care Coordination, Prevention and Treatment of Leading Causes of Morbidity and Mortality, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade C, based on 1 Cochrane review that concluded limited efficacy for disability score and 1 small RCT looking at dexamethasone and gentamicin with 90% symptom reduction
- *Level of confidence in evidence*: High
- *Benefits*: Improved vertigo control, no risk of hearing loss, less risk of systemic side effects, improved QOL (dizziness handicap), no loss of vestibular function (nonablative therapy)
- *Risk, harm, cost*: Cost, perforation, possible need for multiple injections, infection, discomfort of the procedure, time for treatment
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: While this is less definitive than gentamicin therapy, the favorable risk-benefit profile makes this a good option for patients.
- *Intentional vagueness*: The term *noninvasive* refers to medical therapy and lifestyle modification.

- *Role of patient preferences*: Medium
- *Exclusions*: None
- *Policy level*: Option
- *Differences of opinion*: There was some controversy regarding whether the aggregate evidence strength in favor of this intervention is a grade B or a grade C. Given this, a few panel members felt that this statement should be a recommendation rather than an option.

Statement 12. IT Gentamicin Therapy

Clinicians should offer, or refer to a clinician who can offer, IT gentamicin to patients with active MD not responsive to nonablative therapy. (**Recommendation based on 2 randomized trials and several systematic reviews indicating efficacy in the treatment of vertigo with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Improved vertigo control. (National Quality Strategy Domains: Prevention and Treatment of Leading Causes of Morbidity and Mortality, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade B, based on 2 RCTs and several SRs indicating efficacy in the treatment of vertigo
- *Level of confidence in evidence*: High
- *Benefits*: Improved vertigo control, improved QOL, faster return to work, avoidance of general anesthetic, a risk of hearing loss (relative to surgical labyrinthectomy), improved safety
- *Risk, harm, cost*: Hearing loss, ear drum perforation, persistent imbalance, need for multiple treatments
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: None
- *Intentional vagueness*: The term *inadequate control* may vary for different patients.
- *Role of patient preferences*: Large regarding timing and when to initiate therapy

- *Exclusions*: Patients with contralateral disease or hypofunction. Patients with a known hypersensitivity to aminoglycosides
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 13. Surgical Ablative Therapy

Clinicians may offer, or refer to a clinician who may offer, labyrinthectomy in patients with active MD who have failed less definitive therapy and have nonusable hearing. (**Recommendation based on observation studies and case series with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Improve awareness of effective therapy. (National Quality Strategy Domains: Effective Communication and Care Coordination, Prevention and Treatment of Leading Causes of Morbidity and Mortality, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade C, based on observation studies and case series data that show efficacy
- *Level of confidence in evidence*: High
- *Benefits*: Definitive vertigo control, expedient treatment (single definitive treatment), ability to stop other less effective therapy (that may have side effects), control of drop attacks
- *Risk, harm, cost*: Risks of surgery, loss of residual hearing, need for general anesthetic, reduced therapy options in the event that the patient develops bilateral disease, poor compensation after surgery, active tinnitus
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: Labyrinthectomy represents a standard for control of active vertigo in MD
- *Intentional vagueness*: Nonusable hearing is not specifically defined and may be determined in conjunction with the patient. Less definitive therapy is also vague, as failed nerve section may be considered more invasive but may not have resolved symptoms.

- *Role of patient preferences*: Large opportunity for shared decision making
- *Exclusions*: Bilateral disease or vestibular hypofunction in the other ear
- *Policy level*: Recommendation
- *Differences of opinion*: A minority of panel members felt that *offer* was too strong a term but that a discussion about this intervention should be undertaken.

Statement 14a. Role of Vestibular Therapy for Chronic Imbalance

Interictal instability and following ablative therapy: Clinicians should offer vestibular rehabilitation/physical therapy for MD patients with chronic imbalance. (**Recommendation based on SRs and limited RCTs with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Offer therapy for patients who have chronic imbalance, bilateral MD, and/or following ablative therapy. Promoting effective therapy and increased patient safety. (National Quality Strategy Domains: Safety, Promoting Effective Prevention/Treatment)
- *Aggregate evidence quality*: Grade A, based on SRs and limited RCTs
- *Level of confidence in evidence*: High
- *Benefits*: Improved symptom control, safety, reduced risk of falls, improved confidence, improved QOL
- *Risk, harm, cost*: Cost of therapy, time for appointments, potential exacerbation of acute symptoms
- *Benefit-harm assessment*: Preponderance of benefit over harm
- *Value judgments*: While ineffective acutely, VR therapy has a significant role in the chronic management of MD patients.
- *Intentional vagueness*: Imbalance encompasses multiple varying scenarios, including vestibular dysfunction and chronic balance problems
- *Role of patient preferences*: Small; however, patients can have a larger role in deciding if they choose to do VR.

- *Exclusions*: Patients in the setting of an acute attack
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 14b. Role of Vestibular Therapy for Acute Vertigo

Clinicians should not recommend vestibular rehabilitation/physical therapy for managing acute vertigo attacks in patients with MD. (**Recommendation against based on RCTs studied that evaluated acute vertigo but were not specific to MD and a preponderance of benefit over harms**)

Action Statement Profile

- *Quality improvement opportunity*: Avoidance of inappropriate/ineffective therapy. (National Quality Strategy Domains: Patient Safety, Prevention and Treatment of Leading Causes of Morbidity and Mortality)
- *Aggregate evidence quality*: Grade B, based on subset analysis of RCTs that failed to identify any studies on the topic as well as expert opinion extrapolated from evidence from a CPG
- *Level of confidence in evidence*: Medium; the RCTs evaluated acute vertigo but were not specific to MD
- *Benefits*: Avoidance of noneffective therapy, preserving coverage for physical therapy at a later stage of disease, avoidance of potential exacerbation of symptoms
- *Risk, harm, cost*: Delay of treatment in patients with an underlying vestibular hypofunction
- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: Avoidance of inappropriate therapy
- *Intentional vagueness*: None
- *Role of patient preferences*: None
- *Exclusions*: None
- *Policy level*: Recommendation against

- *Differences of opinion*: None

Statement 15. Counseling for Amplification and Hearing Assistive Technology

Clinicians should counsel patients, or refer to a clinician who can counsel patients, with MD and hearing loss on the use of amplification and hearing assistive technology. (**Recommendation based on cohort studies of hearing outcomes in MD and benefits of amplification and cochlear implants with a preponderance of benefit over harms**)

Action Statement Profile

- *Quality improvement opportunity*: Shared decision-making opportunities between patients and clinicians regarding MD and hearing loss and the use of amplification and other hearing assistive technologies. (National Quality Strategy Domains: Effective Communication and Care Coordination, Person and Family Centered Care)
- *Aggregate evidence quality*: Grade C, based on cohort studies of hearing outcomes in MD and benefits of amplification and cochlear implants
- *Level of confidence in evidence*: High
- *Benefits*: Improved function, improved QOL, improved hearing, less missed work
- *Risk, harm, cost*: Clinicians and patients' time, creation of unrealistic expectations
- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: The handicap of associated hearing loss is underrecognized in MD patients
- *Intentional vagueness*: None
- *Role of patient preferences*: Small regarding counseling, large in terms of choice to use these technologies
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: None

Statement 16. Patient Outcomes

Clinicians should document resolution, improvement, or worsening of vertigo, tinnitus, and hearing loss and any change in quality of life in patients with MD after treatment. (**Recommendation based on the controlled arms of RCTs, outcomes from RCTs, cohort studies, and observational studies with a preponderance of benefit over harm**)

Action Statement Profile

- *Quality improvement opportunity*: Tracking outcomes of therapy provides an opportunity for modification of management to optimize outcomes. To ensure that patients have follow-up until symptoms are under adequate control. (National Quality Strategy Domain: Effective Communication and Care Coordination)
- *Aggregate evidence quality*: Grade C, based on the controlled arms of RCTs, outcomes from RCTs, cohort studies, and observational studies
- *Level of confidence in evidence*: Medium due to Grade C evidence
- *Benefits*: Opportunity to adjust for more effective therapy, possibility of more accurate diagnosis, opportunity for hearing rehabilitation, patient engagement
- *Risk, harm, cost*: Cost and time of visits
- *Benefit-harm assessment*: Preponderance of benefit over harms
- *Value judgments*: Not applicable
- *Intentional vagueness*: The word *symptoms* can refer to vertigo, hearing loss, tinnitus, or pressure depending on what is of most concern to the patient
- *Role of patient preferences*: Medium. Some patients with subjectively adequate disease control may choose not to follow up
- *Exclusions*: None
- *Policy level*: Recommendation
- *Differences of opinion*: Several group members wanted to document symptoms before, during, and after treatment, and others wanted to specifically document change in symptoms.

Evidence Rating Scheme

Aggregate Grades of Evidence by Question Type[a]

Grade	OCEBM* Level	Treatment	Harm	Diagnosis	Prognosis
A	1	Systematic review[b] of randomized trials	Systematic review[b] of randomized trials, nested case-control studies, or observational studies with dramatic effect[b]	Systematic review[b] of cross-sectional studies with consistently applied reference standard and blinding	Systematic review[b] of inception cohort studies[c]
B	2	Randomized trials or observational studies with dramatic effects or highly consistent evidence	Randomized trials, or observational studies with dramatic effects or highly consistent evidence	Cross-sectional studies with consistently applied reference standard and blinding	Inception cohort studies[c]

C	3-4	Nonrandomized or historically controlled studies, including case-control and observational studies	Nonrandomized controlled cohort or follow-up study (postmarketing surveillance) with sufficient numbers to rule out a common harm; case-series, case-control, or historically controlled studies	Nonconsecutive studies, case-control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Cohort study, control arm of a randomized trial, case series, or case-control studies; poor quality prognostic cohort study
D	5	Case reports, mechanism-based reasoning, or reasoning from first principles			
X	N/A	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm			

***** Oxford Centre for Evidence-Based Medicine.

a Adapted from Howick and colleagues (Oxford Center for Evidence-Based Medicine Work Group).

b A systematic review may be downgraded to level B because of study limitations, heterogeneity, or imprecision.

c A group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.

Recommendation Rating Scheme

Strength of Action Terms in Guideline Statements and Implied Levels of Obligation[a]

Strength	Definition	Implied Obligation
Strong recommendation	A strong recommendation means that the benefits of the recommended approach clearly exceed the harms (or,	Clinicians should follow a strong recommendation unless

	in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the supporting evidence is high (grade A or B).[b] In some clearly identified circumstances, strong recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits) but the quality of evidence is not as high (grade B or C).[b] In some clearly identified circumstances, recommendations may be based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and be sensitive to patient preferences.
Option	An option means that either the quality of evidence is suspect (grade D)[b] or well-done studies (grade A, B, or C)[b] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

a Adapted from the American Academy of Pediatrics classification scheme.

b Refer to the 'Evidence Rating Scheme' field.

Related Content

Supporting Documents

- Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action; 2013 Jan.

Implementation Tools

- Executive Summary; 2020 Apr 8.
- Podcast:
  - Part 1: Implications for Otolaryngologists; 2020 Apr.
  - Part 2: Implications for Non-otolaryngologists; 2020 Apr.
- Slide Set; 2020 Apr 8.
- The Original Guideline includes the following:
  - Ménière's Disease Algorithm (p. S41)

Patient Education

- Plain Language Summary; 2020 Apr 8.
- FAQs About Ménière's Disease. Also available in Spanish.
- FAQs About Ménière's Disease Triggers. Also available in Spanish.

Note: This patient information is intended to help patients better understand their health and their diagnosed disorders. Patients and their representatives should still consult with a licensed health care professional for evaluation of treatment options as well as answers to their personal medical questions.

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ECRI's Guideline Profiles are designed to provide information and assist decision-making. Variations in practice will inevitably, and appropriately, occur when clinicians take into account the needs and preferences of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional using these Guideline Profiles is responsible for evaluating the appropriateness of applying them in a clinical setting.

TRUST Scorecard

Composition of Guideline Development Group (GDG)

Multidisciplinary GDG Members	**Yes**
Methodologist Involvement	**Yes**
Incorporation of Patient and Public Perspective	★★★★★

Systematic Review of Evidence

Literature Search	★★★★★
Study Selection	★★★☆☆
Evidence Synthesis	★★★★☆

Foundations for Recommendations

Strength of Evidence Grade	★★★★☆
Description of Benefits and Harms of Recommendations	★★★★★
Summary of Evidence Supporting Recommendations	★★★★★
Strength of Recommendations Rating	★★★★★
Clear Articulation of Recommendations	★★★★★

Funding Source — **Yes**

Disclosure and Management of Financial Conflicts of Interests — ★★★★★

External Review — ★★★★☆

Updating — ★★★★★

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