NICE guidance

Micropressure therapy for refractory Ménière's disease

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety of micropressure therapy for refractory Ménière's disease is inadequate in quantity. There is some evidence of efficacy, but it is based on limited numbers of patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake micropressure therapy for refractory Ménière's disease should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having micropressure therapy for refractory Ménière's disease (see section 3.1).

1.3 NICE encourages further research into micropressure therapy for refractory Ménière's disease. Research studies should report long-term outcomes, in particular the need for subsequent surgical treatment.

2 The procedure

2.1 Indications and current treatments

2.1.1 Ménière's disease is characterised by symptoms of tinnitus, vertigo and deafness. Diagnosis of the disease is based on the American Academy of Otolaryngology–Head and Neck Surgery (AAO–HNS) Foundation's guidelines, based on the presence of recurrent, spontaneous episodic vertigo, hearing loss, aural fullness and tinnitus. It is thought to be caused by raised endolymph pressure in the inner ear (endolymphatic hydrops).

2.1.2 Surgery may be indicated for patients who are refractory to medical management and/or a low-salt diet. Surgical treatments include gentamicin vestibular ablation, labyrinthectomy, endolymphatic sac decompression and vestibular neurectomy.

2.2 Outline of the procedure

2.2.1 Micropressure therapy for refractory Ménière's disease aims to reduce endolymph pressure in the inner ear by administering low-pressure air pulses through the tympanic membrane onto the round window membrane, with the aim of stimulating the flow of endolymphatic fluid.

2.2.2 With the patient under local or general anaesthesia, a grommet (ventilation tube) is inserted into the tympanic membrane of the affected ear. A few weeks later, after checking for patency of the grommet by the Valsalva manoeuvre, a hand-held air pressure generator forms an airtight seal in the outer ear. The device administers computer-controlled micropressure pulses across the tympanic membrane.

2.2.3 Three 60-second pulses are administered per treatment, with rest periods (usually less than 1 minute) between each pulse. Micropressure therapy is administered by the patient at home, usually 3 times per day. Treatment is normally continued for 4 to 6 weeks, but it can be used for longer.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A randomised controlled trial of 40 patients (20 treated by micropressure therapy and 20 treated by a sham procedure) reported a mean number of vertigo attacks of 1.9 and 4 respectively during the last 4 weeks of treatment (p=0.09; maximum follow-up 8 weeks). The same study reported a significantly improved functional level (measured using AAO–HNS criteria on a scale of 1 to 6, lower score indicates better functional level) in the micropressure therapy group compared with the sham group (2.4 compared with 3.5, p=0.0014) during the last 4 weeks of treatment.

2.3.2 A case series of 36 patients reported a positive response (defined as a shift from Class D to Class A; AAO–HNS criteria) at 2-year follow-up after treatment in 69% (25 out of 36) of patients (that is, patients went from having 81 to 120 vertigo spells over 6 months to no vertigo after treatment). A study of 22 patients reported a significant reduction in the mean number of vertigo attacks after 20 days: from 9.22 to 1.28 (p=0.001) when the patients had grommet insertion only (n=20), and from 9.22 to 1.67 (p<0.001) when micropressure therapy was started (n=18). There was no significant difference in the number of vertigo attacks between the two groups at 40 days.

2.3.3 In a case series of 37 patients, 79% (27 out of 34) reported that the treatment had been helpful and had substantially improved their ability to perform daily tasks and work at 2-year follow-up.

2.3.4 The Specialist Advisers listed key efficacy outcomes as reduced frequency and severity of vertigo, improved hearing threshold, reduced tinnitus and reduced need for further therapy.

2.4 Safety

2.4.1 Middle ear infection was reported in 5 patients in the case series of 37 patients;

micropressure treatment was resumed after local antibiotics and grommet replacement.

2.4.2 Immediate postoperative ear discharge was reported in 6% (2 out of 36) of patients in the case series of 36 patients.

2.4.3 The Specialist Advisers listed adverse events reported in the literature or anecdotally as post-tympanostomy otorrhoea, repeated need for short-stay ventilation tube insertion and permanent ear drum perforation if a long-stay ventilation tube is used. The Specialist Advisers considered theoretical adverse events to include infection of the grommet, loss of the ventilation tube in the middle ear, scarring of the ear drum and hearing loss.

2.5 Other comments

2.5.1 The Committee noted that vertigo causes significant disability for some patients and that there is a lack of predictably efficacious conservative treatments for chronic vertigo in Ménière's disease. Therefore, if micropressure therapy were shown to be efficacious it could offer a useful option to improve quality of life in selected patients.

2.5.2 The Committee recognised the fluctuating course of Ménière's disease, which complicates the interpretation of evidence on its treatment.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.