Balloon dilatation of the Eustachian tube

Interventional procedures guidance
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nice.org.uk/guidance/ipg409

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. However, 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.

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.

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 efficacy and safety of balloon dilatation of the Eustachian tube is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research, which should address the efficacy of the procedure in the short and longer term, and also document safety outcomes. Research studies should clearly describe which parts of the Eustachian tube are being treated and report subjective measurements of
symptom improvement and objective measurements of Eustachian tube function.

2 The procedure

2.1 Indications and current treatments

2.1.1 The Eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked (does not open physiologically), symptoms such as muffled hearing, pain, a feeling of fullness in the ear, tinnitus or dizziness may occur. The Eustachian tube typically becomes blocked following the onset of an upper respiratory tract infection or allergic rhinitis. It is usually a temporary problem that resolves spontaneously, but sometimes symptoms persist and treatment is necessary. Long-term Eustachian tube dysfunction is associated with damage to the eardrum and middle-ear transformer mechanism.

2.1.2 Medical treatments include decongestants, oral and nasal steroids and antihistamines. Autoinflation is a technique whereby the Eustachian tube is reopened by raising the pressure in the nose. This can be achieved in several ways, including forced exhalation against a closed mouth and nose.

2.1.3 If troublesome Eustachian tube dysfunction persists, a tympanostomy tube (also known as a ventilation tube or grommet) may be inserted through a small incision: repeated tube insertions may be required. Special long-acting tubes are sometimes used but these are subject to crusting, infection, obstruction and permanent tympanic membrane perforation.

2.2 Outline of the procedure

2.2.1 Balloon dilatation of the Eustachian tube is used in adults with the aim of widening the Eustachian tube and improving its function.

2.2.2 Preoperative tubomanometry is initially used to quantify the degree of Eustachian tube dysfunction. Balloon dilatation of the Eustachian tube is usually performed with the patient under general anaesthesia. A balloon catheter is introduced into the Eustachian tube via the nose, under transnasal endoscopic vision. Once the balloon is correctly positioned within the Eustachian tube, it is
filled with saline up to a pressure of about 10 bars. Pressure is maintained for approximately 2 minutes. The balloon is then emptied and removed.

2.2.3 The aim is to dilate the Eustachian tube without structural damage.

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 Efficacy

2.3.1 A case series of 8 patients (a total of 13 treated Eustachian tubes) reported that the mean Eustachian tube score (range 0–10) improved from 1.08 at baseline to 4.15, 5.85 and 7.54 at follow-up of 1, 2 and 8 weeks postoperatively respectively (p < 0.05).

2.3.2 A case series of 30 patients (a total of 53 treated Eustachian tubes) reported that 60% of patients felt that their aural fullness had resolved (follow-up not stated).

2.3.3 The Specialist Advisers listed key efficacy outcomes as improvement of tubal function, resolution of symptoms, and fluid drainage from the middle ear.

2.4 Safety

2.4.1 The case series of 8 patients reported that there were no intraoperative or postoperative complications.

2.4.2 A case series of 30 patients reported that no patients had any postoperative pain, hearing loss or infection. A case series of 11 patients reported that the procedures were well tolerated, without pain or complications.

2.4.3 The Specialist Advisers listed adverse events reported in the literature as mucosal tears in the cartilaginous portion of the Eustachian tube. They considered theoretical adverse events to include rupture of the internal carotid artery, permanent conductive hearing loss, damage to the Eustachian tube, scarring, stenosis, ear infection and pain.
2.5 Other comments

2.5.1 The Committee noted that this procedure relates to a common condition and that it has the potential for significant impact, both for patients and the NHS, if shown to be efficacious.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ("Understanding NICE guidance"). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication

May 2012: minor maintenance

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responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation