



# Balloon dilation for chronic eustachian tube dysfunction

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www.nice.org.uk/guidance/ipg665

## 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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG409.

#### 1 Recommendations

1.1 Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out <a href="https://www.what.standard.org/">what standard arrangements mean on the NICE interventional procedures guidance page.</a>

# 2 The condition, current treatments and procedure

#### The condition

The eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked or does not open properly, there can be symptoms such as muffled hearing, pain, a feeling of fullness in the ear, tinnitus or dizziness. The eustachian tube typically becomes blocked after 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.

#### **Current treatments**

- 2.2 Medical treatments include oral and nasal corticosteroids, decongestants and antihistamines. Autoinflation is a technique that reopens the eustachian tube by raising pressure in the nose. This can be achieved in several ways, including forced exhalation against a closed mouth and nose.
- If eustachian tube dysfunction persists, a tympanostomy tube (also known as a ventilation tube or grommet) may be inserted through a small incision in the tympanic membrane. These typically fall out after several months, and repeated tube insertions may be needed. Some tubes are designed to stay in place for longer, but these can become crusted, infected or obstructed. Tympanostomy tubes may result in a small permanent hole in the tympanic membrane; this is more common with long-lasting tubes.

#### The procedure

- 2.4 Balloon dilation of the eustachian tube is done using local or general anaesthesia. A balloon catheter is introduced into the eustachian tube via the nose, under transnasal endoscopic vision. Once the balloon is correctly positioned in the eustachian tube, it is filled with saline up to a pressure of about 10 to 12 bars. Pressure is maintained for about 2 minutes. The balloon is then emptied and removed.
- 2.5 The aim of the procedure is to widen the eustachian tube and improve its function.

#### 3 Committee considerations

#### The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was

discussed by the committee. The evidence included 2 randomised controlled trials (both of which had longer follow up reported in separate papers), 2 systematic reviews and 4 case series (1 of which was also included in the systematic reviews). It is presented in <u>table 2 of the interventional procedures overview</u>. Other relevant literature is in the appendix of the overview.

- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: improvement in symptoms, disease-specific quality-of-life scores and physiological measures of eustachian tube function.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pain and patulous eustachian tube.
- 3.4 Patient commentary was sought but none was received.

#### Committee comments

- 3.5 The committee noted that the procedure was not effective in all patients, and that there was little evidence on the benefit of repeat procedures.
- The committee was informed that the procedure is only indicated for chronic eustachian tube dysfunction refractory to medical treatment.

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### **Endorsing organisation**

This guidance has been endorsed by Healthcare Improvement Scotland.