NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Balloon dilation for eustachian tube dysfunction

The eustachian tube connects the middle ear with the back of the nose. If the tube is blocked or does not open properly, there can be symptoms such as muffled hearing, pain, a feeling of fullness in the ear, ringing in the ear or dizziness. In this procedure, a thin flexible tube with a small balloon is inserted through the nose and into the eustachian tube. An endoscope (a thin tube with a camera on the end) is used to guide the process. Once in position, the balloon is filled with salt water. It is then left in place for around 2 minutes before being emptied and removed. The aim is to widen the eustachian tube and improve its function and relieve symptoms.

This is a review of NICE's interventional procedures guidance on <u>balloon</u> <u>dilatation of the Eustachian tube</u>.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for <u>consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

 meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

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 prepare a second draft, which will go through a <u>resolution</u> process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 20 September 2019

Target date for publication of guidance: December 2019

1 Draft 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 <u>standard arrangements</u> are in place for clinical governance, consent and audit.

2 The condition, current treatments and procedure

The condition

2.1 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.

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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.
- 2.3 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 and this is more common with long-lasting tubes.

The procedure

- 2.4 Balloon dilation of the eustachian tube is done under 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

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9 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials (1 of which had longer follow up reported in a separate paper), 2 systematic reviews and 4 case series (1 of which was also included in the systematic reviews). It is presented in table 2 of the interventional procedures overview. 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.

Committee comments

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

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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