NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon dilatation of the Eustachian tube

Treating a blocked Eustachian tube using a small inflatable balloon

The Eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked, symptoms such as muffled hearing, pain, a feeling of fullness in the ear, tinnitus or dizziness may occur. In balloon dilatation of the Eustachian tube, a flexible tube with a small balloon is inserted into the Eustachian tube through the nose. The balloon is filled with saline (salt water) and left in place for a short time, with the aim of widening the Eustachian tube.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in March 2011.

Procedure name

- Balloon dilatation of the Eustachian tube

Specialty societies

- ENT UK – The British Association of Otorhinolaryngologists, Head and Neck Surgeons.

Description

Indications and current treatment

Chronic Eustachian tube dysfunction

The Eustachian tube is a narrow tube that connects the middle ear with the back of the nose. If it is blocked, 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.

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

If Eustachian tube dysfunction persists, insertion of a tympanostomy tube (also known as a ventilation tube or grommet) through a small incision in the eardrum may be indicated. Repeated tube insertions may be required. Long-acting tubes are sometimes used but these are subject to crusting, infection, obstruction and permanent tympanic membrane perforation.

What the procedure involves

Preoperative tubomanometry is initially used to assess the level 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 in the cartilaginous and bony portion of 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.

The aim of the procedure is to widen the Eustachian tube and improve its function.

Assessing Eustachian tube dysfunction

In tubomanometry, the opening of the Eustachian tube and the transportation of gas into the middle ear is registered by a pressure sensor in the occluded outer ear after applying the stimulus of a controlled gas bolus into the nasopharynx during swallowing. If tube opening is registered, the time of opening in relation to pressure applied can be measured (opening latency index or index R). An R value of < 1 indicates early opening of the Eustachian tube, which is considered optimal.

The Eustachian Tube Score is a summation point score based on the patient's history and tubomanometry results. It ranges from 0 (worst value) to 10 (best value):

	2 points	**1 point**	**0 points**
Clicking noise during swallowing	Always	Infrequent	Never
Clicking noise during Valsalva manoeuvre	Always	Infrequent	Never
Tubomanometry 30 mbar	R < 1	R ≥ 1	No opening
Tubomanometry 40 mbar	R < 1	R ≥ 1	No opening
Tubomanometry 50 mbar	R < 1	R ≥ 1	No opening

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to balloon dilatation of the Eustachian tube. Searches were conducted of the following databases, covering the period from their commencement to 30 March 2011: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	**Criteria**
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.
Patient	Patients with Eustachian tube dysfunction.
Intervention/test	Balloon dilatation of the Eustachian tube.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 50 patients from 3 case series (2 of which were published only as conference abstracts) [1–3].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on balloon dilatation of the Eustachian tube

Abbreviations used: CT, computed tomography

Study details	Key efficacy findings	Key safety findings	Comments
Ockermann T (2010)[1] **Case series** Germany, UK Recruitment period: not reported Study population: adults with symptoms of chronic obstructive Eustachian tube dysfunction or adults who had undergone one or more recent tympanoplasties for relapsing acute or chronic persistent otitis media with effusion as a consequence of obstructive tube dysfunction. **n = 8 patients (13 Eustachian tubes)** Mean age: 44 years (range 21–81) Sex: 50% (4/8) female Patient selection criteria: patients were over 18 years old and not pregnant. Tubomanometry was used to quantify the degree of Eustachian tube dysfunction. All patients underwent a transnasal endoscopic examination of their Eustachian tubes and microscopic examination of their ears. Preoperative CT did not show any significant findings. Technique: A modified endoscope with suction and a working channel was used. The tip of the endoscope was placed adjacent to the pharyngeal ostium of the Eustachian tube and a balloon catheter (Spiggle & Theiss, Germany) was pushed through the working channel of the endoscope, under vision, 2 cm into the Eustachian tube. Pressure of 10 bars was applied for 2 minutes. **Follow-up: 2 months** Conflict of interest/source of funding: none	Number of patients analysed: **8 (13 Eustachian tubes)** Successful catheter placement = 100% (8/8) The Eustachian tube score relied on the patient's history (clicking noise during swallowing or Valsalva manoeuvre) and tubomanometry results. The score ranged from 0 (worst value) to 10 (best value). Mean Eustachian tube score: • Preoperative = 1.08 (± 0.61) • 1 week postoperative = 4.15 (± 3.02) • 2 weeks postoperative = 5.85 (± 2.61) • 8 weeks postoperative = 7.54 (± 1.39) $p < 0.05$ between preoperative and postoperative scores at all follow-up periods. At 1-week follow-up, Eustachian tube opening was found in all 3 tubomanometry measurements (30 mbar, 40 mbar and 50 mbar) in 7 cases. All patients answered positively to the question of whether they would undergo the procedure again.	There were no intraoperative or postoperative complications. Postoperative CT revealed no evidence of change in the bony lumen of the Eustachian tube.	**Follow-up issues**: • All patients underwent repeated computed tomography (CT) before and after the procedure. **Study design issues**: • CT scans were analysed for any abnormal findings by 2 independent staff radiologists.

Abbreviations used: CT, computed tomography			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Yu V (2010)[2] **Case series** Country: not reported Recruitment period: 2009 Study population: patients with persistent middle-ear effusions, aural fullness or other middle-ear disease. **n = 30 patients (53 Eustachian tubes)** Age: not reported Sex: not reported Patient selection criteria: not reported Technique: endoscopic placement of a 5 mm sinus balloon catheter into the proximal Eustachian tube. 75% of procedures were performed in the operating theatre at the same time as another procedure, 25% were performed under local anaesthesia in the office. **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **30** **(53 Eustachian tubes)** 60% of patients reported that their aural fullness had resolved.	No patients reported any pain, hearing loss or infection.	**Study design issues**: • Conference abstract – no details of study design are given.

Abbreviations used: CT, computed tomography			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Poe D (2010)[3] **Case series** Country: not reported Recruitment period: 2009 Study population: adults with longstanding otitis media with effusion or tympanic membrane atelectasis. **n = 12 patients** Age: not reported Sex: not reported Patient selection criteria: patients were unable to autoinsufflate their Eustachian tube by Valsalva, swallow or yawn. Technique: balloon dilatation of the cartilaginous Eustachian tube was performed under general anaesthetic in a day surgery setting. Inflation was to a maximum of 12 atm for 1 minute. **Follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **12** All Eustachian tubes were successfully dilated. Mucoid otorrhoea persisted in 1/8 patients. All patients could autoinsufflate after the procedure. All atelectases resolved.	The procedures were well tolerated, without pain or complications related to dilation.	**Study design issues**: • Conference abstract – no details of study design are given. **Study population issues**: • 11 patients had previously been treated with tympanoplasties. At the time of the procedure, 6 patients had a tube in place. 2 patients had a tympanic membrane perforation.

Efficacy

Eustachian tube function.

A case series of 8 patients with 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 1, 2 and 8 weeks postoperatively, respectively ($p < 0.05$)[1].

At 1-week follow-up, Eustachian tube opening was found in all 3 tubomanometry measurements (30 mbar, 40 mbar and 50 mbar) in 7 cases[1].

Safety

A case series of 8 patients with 53 treated Eustachian tubes reported that there were no intraoperative or postoperative complications[1].

A case series of 30 patients described in a conference abstract reported that no patients had any postoperative pain, hearing loss or infection[2]. Another case series of 12 patients described in a conference abstract reported that the procedures were well tolerated, without pain or complications[3].

Validity and generalisability of the studies

- Only 1 small case series published as a full article was identified[1]. Two further small case series were described in published conference abstracts; these provided limited information on the study methodology[2,3].
- There is a lack of long-term data.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. NICE interventional procedures guidance 273 (2008). Available from www.nice.org.uk/guidance/IPG273

Clinical guidelines

- Surgical management of children with otitis media with effusion in children. NICE clinical guideline 60 (2008) (Note: this only refers to children younger than 12 years). Available from www.nice.org.uk/guidance/CG60

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr A Banerjee, Mr R Irving, Mr C Raine (ENT UK - British Association of Otorhinolaryngologists, Head and Neck Surgeons).

- All 3 Specialist Advisers describe the procedure as definitely novel and of uncertain safety and efficacy.
- The comparator to the procedure would be insertion of ventilation tubes or laser tuboplasty.
- Theoretical adverse events include damage to the Eustachian tube(scarring, stenosis), ear infection, pain, bleeding (carotid rupture), and permanent conductive hearing loss.
- Adverse events reported in the literature include mucosal tears in the cartilaginous portion of the Eustachian tube.
- The key efficacy outcomes are improvement of tubal function, resolution of symptoms, and fluid drainage from the middle ears.
- There are uncertainties about the use of the procedure in children.
- There are no long-term follow-up data available.
- Two Advisers consider the potential impact on the NHS to be minor and 1 Specialist Adviser thought that the potential impact was major.

Patient Commentators' opinions

NICE's Patient and Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

To date, the procedure has only been used to treat adults.

References

1. Ockermann T, Reineke U, Upile T et al. (2010) Balloon dilatation Eustachian tuboplasty: a clinical study. Laryngoscope 120: 1411–6.

2. Yu V, Jonnalagadda S, Catalano P. (2010) Balloon catheter dilation of Eustachian tube: pilot study. Otolaryngology–Head and Neck Surgery 143: 86.

3. Poe D, Silvola J. (2010) Balloon dilation of the cartilaginous Eustachian tube. Otolaryngology–Head and Neck Surgery 143: 87.

Appendix A: Additional papers on balloon dilatation of the Eustachian tube

There were no additional papers identified.

Appendix B: Related NICE guidance for balloon dilatation of the Eustachian tube

Guidance	Recommendations
Interventional procedures	**Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis. NICE interventional procedures guidance 273 (2008).** 1.1 Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy. 1.3 Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence.
Clinical guidelines	**Surgical management of children with otitis media with effusion (OME). NICE clinical guideline 60 (2008)** 1.4.1 Children with persistent bilateral OME documented over a period of 3 months with a hearing level in the better ear of 25–30 dBHL or worse averaged at 0.5, 1, 2 and 4 kHz (or equivalent dBA where dBHL not available) should be considered for surgical intervention. 1.4.2 Exceptionally, healthcare professionals should consider surgical intervention in children with persistent bilateral OME with a hearing loss less than 25–30 dBHL where the impact of the hearing loss on a child's developmental, social or educational status is judged to be significant. ***1.5 Surgical interventions*** 1.5.1 Once a decision has been taken to offer surgical intervention for OME in children, the insertion of ventilation tubes is recommended. Adjuvant adenoidectomy is not recommended in the absence of persistent and/or frequent upper respiratory tract symptoms. 1.5.2 Children who have undergone insertion of ventilation tubes for OME should be followed up and their hearing should be re-assessed. ***1.6 Non-surgical interventions*** 1.6.2 Autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure. 1.6.3 Hearing aids should be offered to children with persistent bilateral OME and hearing loss as an alternative

	to surgical intervention where surgery is contraindicated or not acceptable. ***1.7 Management of OME in children with Down's syndrome*** 1.7.1 The care of children with Down's syndrome who are suspected of having OME should be undertaken by a multidisciplinary team with expertise in assessing and treating these children. 1.7.2 Hearing aids should normally be offered to children with Down's syndrome and OME with hearing loss. 1.7.3 Before ventilation tubes are offered as an alternative to hearing aids for treating OME in children with Down's syndrome, the following factors should be considered: • the severity of hearing loss • the age of the child • the practicality of ventilation tube insertion • the risks associated with ventilation tubes • the likelihood of early extrusion of ventilation tubes. ***1.8 Management of OME in children with cleft palate*** 1.8.1 The care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional multidisciplinary cleft lip and palate team. 1.8.2 Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment. 1.8.3 Insertion of ventilation tubes should be offered as an alternative to hearing aids in children with cleft palate who have OME and persistent hearing loss. ***1.9 Information for children, parents and carers*** 1.9.1 Parents/carers and children should be given information on the nature and effects of OME, including its usual natural resolution. 1.9.2 Parents/carers and children should be given the opportunity to discuss options for treatment of OME, including their benefits and risks. 1.9.3 Verbal information about OME should be supplemented by written information appropriate to the stage of the child's management.

Appendix C: Literature search for balloon dilatation of the Eustachian tube

Database	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	30/03/2011	Issue 3 of 12, Mar 2011
Database of Abstracts of Reviews of Effects – DARE (CRD website)	01/04/2011	-
HTA database (CRD website)	01/04/2011	-
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	30/03/2011	Issue 3 of 12, Mar 2011
MEDLINE (Ovid)	30/03/2011	1948 to March Week 3 2011
MEDLINE In-Process (Ovid)	30/03/2011	March 29, 2011
EMBASE (Ovid)	30/03/2011	1980 to 2011 Week 12
CINAHL (NLH Search 2.0/EBSCOhost)	30/03/2011	1981–present
BLIC (Dialog DataStar)	30/03/2011	-

Trial sources searched on 25/03/2011

- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov
- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database

Websites searched on 18/03/2011

- National Institute for Health and Clinical Excellence (NICE)
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference search
- General internet search

MEDLINE search strategy

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Balloon Dilation/
2	Dilatation/

3	Dilatation, Pathologic/
4	catheterization/ or catheterization, peripheral/
5	(Balloon* adj3 (dilat* or cathet*)).tw.
6	BET.tw.
7	(Cathet* adj3 peripher*).tw.
8	(Dilat* adj3 pathologic*).tw.
9	or/1-8
10	Eustachian tube/
11	exp Ear Diseases/
12	exp Otitis Media/
13	(Middle ear* adj3 (inflamm* or infect* or disease* or effus* or atelectas*)).tw.
14	((Eustach* or auditory or pharyngotympanic* or obstructive or chronic) adj3 tube adj3 (dysfunct* or obstruct* or block* or inflamm* or disorder*)).tw.
15	(otit* adj3 media*).tw.
16	or/10-15
17	9 and 16
18	Animals/ not humans/
19	17 not 18