Balloon dilatation of the Eustachian tube: an evidence-based review of case series for those considering its use

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Background: Eustachian tube dysfunction is common and implicated in persistent middle ear disease. Recent studies suggest the promise of balloon dilatation of the Eustachian tube to modify local anatomy and physiology, restoring normal function.

Objectives: A literature review of the outcomes of balloon dilatation of the Eustachian tube was conducted, assessing four criteria (tympanometry, otoscopy findings, Valsalva and subjective symptoms). Outcomes were divided into short term (≤6 months) and long term (>6 months). Rates and severity of complications were documented. We also assessed cost, learning curve and requisite training.

Search strategy: Medline via PubMed was consulted with the following search request: ‘eustachian tube’ OR ‘auditory tube’ AND ‘balloon’. No restrictions were placed on study date, type or language. Non-clinical studies, published abstracts and very small studies (<10 procedures) were excluded.

Results: Our search yielded 24 results and six case series, five of which met the inclusion criteria. Balloon dilatation has been performed on 375 Eustachian tubes (235 patients) and demonstrates clear short-term (<6 month) benefits across all recorded outcome measures in a majority of cases. 69 of 89 (78%) tympanogram profiles recorded preoperatively as abnormal (Type B/C/open) resolved to type A profiles postoperatively. 40 of 46 (87%) otoscopy findings preoperatively reported as abnormal (tympanic membrane retraction, perforation or otitis media with effusion) normalised postoperatively. The ability to perform a consistently positive Valsalva manoeuvre improved from 15 of 139 (11%) to 89 of 139 (64%) cases following dilatation. The two largest studies reported on 210 and 100 procedures and described symptom improvement in 67% of cases at 2 months and 71% at 26.3 weeks, respectively. An overall complication rate of ≥3% was observed, and no major adverse events are reported (0%). Cost and learning curve of the procedure were both deemed to be acceptable.

Conclusion: Balloon dilatation of the Eustachian tube appears to be safe, effective and affordable. Like many newly introduced techniques, the evidence remains limited to non-controlled case series, with heterogeneous data collection methods and lacking long-term outcomes. However, short-term data provides promising, consistent results based on objective measures, and when used selectively in patients refractive to maximal existing therapy, balloon dilatation presents a potentially significant advance.

Dear Editor

Articles in this series have addressed evidence for novel procedures in otolaryngology, offering practical advice regarding their safe and ethical introduction to practice. Topics have included minimally invasive thyroid surgery and sialendoscopy, techniques pioneered over the previous 10 and 20 years, respectively.1,2 In this article, we assess the evidence for balloon dilatation of the Eustachian tube, a procedure first described in 2010 that seeks to address the common and numerous symptoms arising from Eustachian tube dysfunction.

Eustachian tube dysfunction (ETD) is the failure of the Eustachian tube to adequately ventilate the middle ear. It is common, with an estimated incidence of 0.9%,3 and produces symptoms of aural fullness, otalgia, tinnitus and hearing loss, often exacerbated or precipitated by atmospheric pressure changes. It is commonly seen in individuals with persistent middle ear diseases such as otitis media with effusion (OME) and has been implicated in its pathogenesis.4,5 While tubal dysfunction commonly resolves in children with tubal maturation, its treatment in adults is often less satisfactory.6 Nasal steroid sprays appear to be no more effective than placebo.7 Ventilation tubes extrude, can result in persistent otorrhoea, and fail to treat underlying dysfunction, with recurrence rates of atelectasis and otitis media with effusion in between 30 and 50% of cases.8,9 The use of
long-term ventilation tubes carries the risk of permanent tympanic membrane perforation, estimated by one study to occur in 19% of cases.10

The cartilaginous portion of the Eustachian tube (Eustachian tube) is the most likely site of pathology,11,12 and the last decade has witnessed the emergence of endoscopic techniques to definitively address underlying Eustachian tube dysfunction. The most recent approach, balloon dilatation of the Eustachian tube (balloon dilatation of the Eustachian tube) is a minimally invasive technique, involving temporary inflation of a balloon catheter in the cartilaginous Eustachian tube. In 2011, a National Institute for Health and Clinical Excellence (National Institute for Health and Clinical Excellence) review of balloon dilatation of the Eustachian tube concluded that owing to inadequate evidence, the procedure should be used in a research-only capacity.13 Since then, considerable new clinical data has emerged, and we aim to provide an up-to-date review of the literature. Although primarily concerned with the efficacy and safety of balloon dilatation of the Eustachian tube, we also assess the cost, learning curve and requisite training.

**Technique**

The procedure described in the literature has been conducted under both general and local anaesthetic, with pre-procedural application of topical decongestant to the nasal mucosa and Eustachian tube orifice. Following examination of the Eustachian tube orifice with a rigid 0-degree nasal endoscope, an angled 70° guide catheter tip is positioned at Eustachian tube orifice entrance under 30 or 45° nasal endoscope visualisation. A 3–7 mm (diameter) balloon catheter is advanced along the guide catheter and through the Eustachian tube lumen until met with mild resistance (13–16 mm). The balloon is dilated with saline at 10–12 atm for 30–120 s, then deflated and removed. Notable variations are discussed in our results.

**Methods**

**Search strategy**

On February 15th 2013, we searched Medline via PubMed with the following terms:

‘eustachian tube’ OR ‘auditory tube’ AND ‘balloon’.

No restrictions were placed on study date, type or language. Due to the emerging nature of balloon dilatation of the Eustachian tube, case series constituted a baseline for acceptance. Non-clinical studies, published conference abstracts and very small studies (<10 balloon dilatation of the Eustachian tubes) were excluded. Appropriate citations were reviewed, and authors contacted to query the availability of unpublished data.

**Outcome measures**

As there is no accepted ‘gold standard’ for assessment of Eustachian tube function, benefits were observed across four commonly used outcome measures:

1. Tympanogram profiles: normal (Type A); abnormal (B; C; open)
2. Otoscopy findings: normal; abnormal (tympanic membrane retraction or perforation; otitis media with effusion)
3. Subjective symptoms: improved; not improved; worsened
4. Valsalva: always +ve; sometimes +ve; −ve

Outcome data were divided into short term (≤6 months postoperative) and long term (>6 months), and the nature, rates and outcomes of complications were also recorded. Where possible, outcome data were synthesised, facilitating overall estimations of benefits and safety. As many procedures were bilateral, each Eustachian tube constituted a single case.

**Results**

Our search strategy yielded 24 results and 6 case series, 5 of which met our study inclusion criteria (Table 1). One case series documented 4 procedures and was excluded.14 The remaining papers excluded were cadaveric, laboratory based or addressed topics other than balloon dilatation of the Eustachian tube. From the studies included, balloon dilatation of the Eustachian tube was carried out on a total of 375 Eustachian tubes (235 patients). Our review of the referenced literature revealed duplicates of published work in the form of preliminary conference abstracts, but no additional data.

**Patient selection**

The basic inclusion criteria for all studies were adults suffering from chronic symptoms of Eustachian tube dysfunction, diagnosed through history and examination (Table 2). One exception was Poe et al. who further specified a >5 year history of continuous chronic otitis media with effusion.17 McCoul et al. specified abnormal tympanogram and otoscopic findings as additional mandatory criteria.15 In numerous studies, subjects had unsuccessfully trialled medical treatment (oral antihistamine and nasal steroid spray),15 or relapsed following grommet placements.16,17 Cited exclusion criteria included craniofacial abnormalities, recent head and neck surgery, sinonasal malignancy, ongoing acute infection, evidence of internal carotid artery (internal carotid artery) dehiscence near the
Table 1. Case series of balloon dilatation of the Eustachian tube

<table>
<thead>
<tr>
<th>Study, location</th>
<th>No. of Eustachian tubes (pts)</th>
<th>Patient selection</th>
<th>Procedure information</th>
<th>Mean Follow up (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalano et al. (USA)</td>
<td>100 (70)</td>
<td>Adults with chronic symptoms of Eustachian tube dysfunction</td>
<td>Cartilaginous portion dilated 5 mm catheter for 5–30 s at 6–8 atm LA (41 cases) GA (59 cases)</td>
<td>30.3 weeks (up to 34 months)</td>
</tr>
<tr>
<td>McCouls et al. (USA)</td>
<td>35 (22)</td>
<td>Adults with symptoms of Eustachian tube dysfunction, abnormal tympanogram profile (non-A type curve), and abnormal otoscopy findings ( tympanic membrane retraction; otitis media with effusion). All subjects failed 2 month course of medical therapy including antihistamine, corticosteroids, and autoinsufflation</td>
<td>Cartilaginous portion dilated 5–7 mm catheter for 2 mins at 10 atm. GA</td>
<td>10 months (5–14)</td>
</tr>
<tr>
<td>Ockermann et al. (Germany)</td>
<td>13 (8)</td>
<td>Adults with chronic symptoms of Eustachian tube dysfunction, or adults who suffered from chronic otitis media with effusion and had undergone &gt;1 recent tympanoplasty</td>
<td>Cartilaginous and bony isthmus dilated 3 mm catheter for 2 minutes at 10 atm GA</td>
<td>8 weeks</td>
</tr>
<tr>
<td>Poe et al. (USA)</td>
<td>11 (11)</td>
<td>Adults with otitis media with effusion for ≥5 years broken only by tympanostomy tubes or tympanic membrane perforation.</td>
<td>Cartilaginous portion dilated 7 mm for 1 min at 12 atm GA</td>
<td>7 months (6–14)</td>
</tr>
<tr>
<td>Schroder et al. (Germany)</td>
<td>209 (120)</td>
<td>Adults with chronic symptoms of Eustachian tube dysfunction</td>
<td>Cartilaginous portion dilated 3 mm 9.9 atm for 2 minutes GA</td>
<td>(2 weeks–12 months)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Pre-operative</th>
<th>Post-operative ≤6 months</th>
<th>Post-operative &gt;6 months</th>
<th>Comments</th>
<th>Commercial support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalano</td>
<td>T - 72/100 type A 28/100 abnormal</td>
<td>T - 25/28 resolved S - 71/100 improved</td>
<td>S - 7/8 improved</td>
<td>GA cases included adjuvant sinonasal or otologic procedures 7 Eustachian tubes underwent revision balloon dilatation of the Eustachian tube to maintain benefit</td>
<td>No</td>
</tr>
<tr>
<td>McCouls</td>
<td>T - 0/35 type A O - 0/35 normal</td>
<td>T - 34/35 type A O -35/35 normal S - 23/29 improved</td>
<td></td>
<td>Adjuvant posterior inferior turbinectomy in all cases 2 Eustachian tubes underwent revision balloon dilatation of the Eustachian tube with success</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Eustachian tube or obvious extrinsic anomalies such as adenoid hypertrophy that may be primarily responsible for the condition.

In a majority of studies, preoperative assessment included tympanometry, otoscopy, Valsalva and computed tomography (CT) of paranasal sinuses. CT was also used to exclude the possibility of internal carotid artery dehiscence at the Eustachian tube in some studies. However, Tisch et al. in an evaluation of 1000 CT head scans identified no such dehiscence in 2000 carotid canals.

Variation in technique

Balloon dilatation of the Eustachian tube was carried out under general anaesthetic in most cases, although Catalano also performed the procedure under local anaesthetic with no demonstrable impact on outcome. One study advanced a guide wire with fibre optic light through the introducer catheter, visualization through the external auditory meatus of a red glow behind the tympanic membrane ensuring correct placement of the catheter. In the earliest published study of balloon dilatation of the Eustachian tube, a balloon catheter was inserted beyond the tubal isthmus, inflating both bony and cartilaginous portions of the Eustachian tube. This technique has lost favour, as it confers no additional benefits and runs an increased risk of bony fracture and injury to the internal carotid artery.

<table>
<thead>
<tr>
<th>Study</th>
<th>Key findings</th>
<th>Comments</th>
<th>Commercial support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ockermann16</td>
<td>V - 1/13 always +ve 2/13 sometimes +ve</td>
<td>Cartilaginous and bony portions of Eustachian tube dilated</td>
<td>No</td>
</tr>
<tr>
<td>Poe17</td>
<td>T - 0/11 type A O - 0/11 normal V - 0/11 always +ve</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Schröder19</td>
<td>T - 0/15 type A V - 14/115 always +ve</td>
<td></td>
<td>Yes</td>
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pts, patients; LA, local anaesthetic; GA, general anaesthetic; T, tympanometry; O, otoscopy; V, Valsalva test; S, reported symptoms.

Table 2. Commonly cited inclusion and exclusion criteria

Inclusion criteria

Clinically diagnosed chronic Eustachian tube dysfunction defined as one or more of the following symptoms in the absence of a clear extrinsic cause (i.e. adenoid hypertrophy):

- Sensation of aural fullness or pressure
- Otalgia
- Otic barotrauma
- Chronic otitis media with effusion
- Symptoms refractory to medical treatment and relapse following tympanostomy tubes
- Adults (>18 years)
- Evidence of internal carotid artery dehiscence near the Eustachian tube
- Partial or total bony portions of Eustachian tube

Exclusion criteria

- Craniofacial abnormalities
- Sinonasal malignancy
- Acute ongoing upper respiratory tract infection
- Recent head and neck surgery
- Recent head CT scan
- Clear extrinsic cause of Eustachian tube dysfunction (i.e. adenoid hypertrophy)
Outcomes and benefits

Balloon dilatation of the Eustachian tube demonstrated clear short-term (<6 month) benefits across all recorded outcome measures in a majority of cases (Table 1).

Tympanometry. Four of the five studies collected pre- and postoperative tympanometry data. 15,17,19,20 89 of 161 (55%) recorded preoperative tympanogram profiles were abnormal (Type B, C or open). Of the abnormal cases, 69 (78%) had resolved postoperatively to type A profiles at up to 6 months. In one study, postoperative data were limited to patients who had reported abnormal preoperative profiles.19

Otoscopy. Two studies reported pre- and postoperative otoscopy findings.15,17 Preoperatively, 46 of 46 (100%) documented examinations were reported as abnormal (tympanic membrane retraction, perforation or otitis media with effusion). Postoperatively, 40 (87%) of these cases were reported as normal at up to 6 months.

Valsalva. Three studies reported pre- and postoperative Valsalva ability. 16,17,20 124 of 139 (89%) recorded preoperative Valsalva assessments were abnormal (always −ve or sometimes +ve), with only 15 of 139 cases (11%) able to consistently perform the manoeuvre. Postoperatively, 89 of 139 (64%) cases reported normal (always +ve) findings at up to 6 months.

Symptoms. Four studies reported on subjective symptoms.15,17,19,20 The two largest studies reported on 210 and 100 procedures, describing symptom improvement in 67% of cases at 2 months and 71% at 26.3 weeks, respectively.18,19 Poe et al., whose 11 subjects had over 5 year histories of otitis media with effusion, reported symptom improvement in all cases (100%). McCoul et al. utilised a now validated 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7), to evaluate Eustachian tube dysfunction impact on quality of life,15,21 observing an average improvement in symptoms from ‘moderate-severe’ to ‘no problem-moderate’ (4.5/7 to 2.6/7 and 2.8/7) at 6 and 12 weeks, respectively. In no cases have authors reported postoperative worsening of symptoms. Longer term (1–3 year) follow-up was available in only 20 patients, of whom 17 of 20 (85%) reported sustained improvement of symptoms.19,20

Revision balloon dilatation of the Eustachian tube was performed in 7 years (2%) following relapse or persistence of symptoms.15,19 These initial failures were attributed to brief dilatation time (5 s) or small catheter diameter (5 mm), and addressing these matters with revision procedures resolved symptoms.

Drawbacks

Learning curve. There is no clinical data on the learning curve of balloon dilatation of the Eustachian tube. One cadaveric study of 24 balloon dilatation of the Eustachian tubes by three surgeons suggested shorter, easier procedures in the second half of the series, and a mean operative duration of 284 s.22 The longest procedural steps were placement and dilation of the balloon catheter (on average 100 and 142 s, respectively), and the step most likely to fail, requiring revision was placement of the balloon catheter in the lumen. In the outpatient context, there is the additional requirement of applying topical anaesthetic to the Eustachian tube lumen via a catheter. Catalano reported that refinement of this technique was necessary to allow for optimal dilatation duration and pressure to be well tolerated.19 This was achieved after 25 patients.

Complications. All reported complications of balloon dilatation of the Eustachian tube have been minor and transitory, with an overall rate of ≈ 3% (Table 3). A single potentially serious complication reported was pre-auricular emphysema, which occurred in one ear (<1%), and resolved

<table>
<thead>
<tr>
<th>Table 3. Reported complications of balloon dilatation of the Eustachian tube (/Eustachian tube case)</th>
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<tr>
<td>Pre-auricular emphysema (%)</td>
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<tr>
<td>Haemotympanum (%)</td>
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<tr>
<td>Minimal intra- or postoperative bleeding (%)</td>
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<tr>
<td>Mucosal laceration (%)</td>
</tr>
<tr>
<td>Worsening tinnitus (%)</td>
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<tr>
<td>C6-7 radiculopathy (%)</td>
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<tr>
<td>Overall complication rate (%)</td>
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spontaneously.19 One study reported small (<5 mm) mucosal lacerations of no clinical significance in 46% cases.17 It is feasible that similar rates occurred in all studies, but were neither considered nor documented as complications. Intra-operative bleeding occurred at unspecified rates, but was uniformly minimal. Significant intra- or postoperative bleeding has not been reported. A single instance of bilateral haemotympanum was attributed to adjuvant inferior turbinectomy, not balloon dilatation of the Eustachian tube itself.15 Aberrant carotid anatomy in relation to the Eustachian tube is well recognised,23 and although the overriding concern is the theoretical risk of damage to the internal carotid artery during balloon dilatation of the Eustachian tube, this was not reported in any of the literature.

Set up and costs
Rigid 0 and 30° nasal endoscopes and camera systems are widely and routinely used in ENT departments in the United Kingdom. We are aware of two systems in use for balloon dilatation of the Eustachian tube. The Bielefeld (Spiggle & Theiss, Overath, Germany) balloon catheters are designed for balloon dilatation of the Eustachian tube and consist of single-use balloon catheters costing £450–500, and a reusable catheter delivery handpiece. The Relieva Solo (Acclarent, Menlo Park, CA, USA) sinuplasty balloon, guidewire with fibreoptic light-source dilatation system, is used with similar results in balloon dilatation of the Eustachian tube. Both balloon and delivery system are single use and cost £700–950.

Discussion
Historically, the Eustachian tube has been an infrequent site of intervention owing to its location, uncertain function and anecdotal reports of catastrophic complications, such as internal carotid artery rupture following the inadvertent injection of Teflon.24,25 This largely remains the case, with only 73 Eustachian tube procedures reported by HESOnline (www.hesonline.nhs.uk) in the UK between 2010 and 2011. Research utilising video endoscopy has improved our understanding of Eustachian tube function and its role in middle ear disease, localising the common site of dysfunction to the cartilaginous lumen,11,12 and a number of techniques have been piloted to address this. These have included ablation of posterior Eustachian tube cushion mucosa with microdebriders26 or lasers,27 which are more invasive, and demonstrated modest benefits to patients. balloon dilatation of the Eustachian tube is the most recent and now most well-documented procedure.

In 2011, National Institute for Health and Clinical Excellence reviewed the literature on balloon dilatation of the Eustachian tube and concluded that the procedure is safe and effective when carried out by adequately trained otolaryngologists. The literature at this time consisted of three case series, two of which were conference abstracts, detailing 73 balloon dilatation of the Eustachian tubes performed on 50 patients. Our up-to-date literature review provides significant additional material detailing 375 balloon dilatation of the Eustachian tube procedures in 235 adults, and strengthens existing evidence that the procedure is safe and effective when carried out by adequately trained otolaryngologists.

Limitations
As with many novel surgical techniques, the evidence for balloon dilatation of the Eustachian tube remains limited to case series, with heterogeneous data collection methods and a lack of long-term outcomes. At present, long-term data are only available in 20 patients, and more will be necessary to assess the durability of the benefits.

Although many of the patients selected had proven refractory to conventional therapy, balloon dilatation of the Eustachian tube has yet to be compared directly against alternative treatment modalities. A case-controlled trial comparing the efficacy of balloon dilatation against ventilatory tubes and conservative management and to assess longer term outcomes is therefore warranted.

balloon dilatation of the Eustachian tube outcomes have yet to be reported in children (<18 years) and should not be utilised in this patient group outside of approved pilot studies. The authors are aware of one paediatric trial ongoing in Bristol, United Kingdom.28

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Diagnosis and indications

Consensus has yet to be reached on diagnostic criteria for Eustachian tube dysfunction and corresponding eligibility for undergoing balloon dilatation of the Eustachian tube, which has resulted in study cohorts with considerable differences in baseline pathology. A clear understanding of Eustachian tube dysfunction, and indications and contraindications for its treatment are essential, and in this regard, the inclusion and exclusion criteria of the papers discussed serves as a valuable framework (Table 2). One example of inclusion criteria for patient selection by a respected proponent of the technique requires the following:

1. Persistent otitis media with effusion or non-adherent atelectasis
2. Type B or C tympanogram
3. Symptoms of Eustachian tube dysfunction (pain, blockage, conductive hearing loss)
4. Symptoms improved with tympanostomy tubes

Balloon dilatation of the Eustachian tube outcome measures

Balloon dilatation of the Eustachian tube outcomes should be comprehensively documented pre- and postoperatively, and we recommend as a minimum tympanogram profiles, otoscopy findings, Valsalva and subjective symptoms. The validated, disease-specific ETDQ-7 developed by McCoul presents a valuable comparative instrument for symptom assessment.

Safety and training

The safety profile of balloon dilatation of the Eustachian tube appears to be good, and the procedure is not technically challenging in experienced hands, taking as little as 5 min to perform. Given the unfamiliarity of Eustachian tube surgery to most otolaryngologists, attendance at relevant expert-led courses should be undertaken prior to adoption of balloon dilatation of the Eustachian tube in clinical practice. Although we are aware of three courses that incorporate training in balloon dilatation of the Eustachian tube, only one course, ‘Hands-On Course: Endoscopic Dilatation of the Eustachian Tube’, in Hamburg, Germany, focuses solely on the procedure. The other courses, which take place in Boston, USA, and Cape Town, South Africa, incorporate balloon dilatation of the Eustachian tube training as part established sinus surgery courses. As these are new training opportunities, the authors are not aware of balloon dilatation of the Eustachian tube-specific feedback and unable to comment on the quality at present. Routine preoperative CT scanning has recently been questioned.

and as no obvious safety benefit has been conferred, the risks of radiation may soon outweigh its necessity.

Conclusion

The short-term results for balloon dilatation of the Eustachian tube are promising and consistent, based on objective and subjective measures. Postoperative symptom improvement at up to 6 months is reported in between 67 and 100% of cases, with similar rates of abnormal tympanogram profile resolution (78%). In adults with persistent Eustachian tube dysfunction, who meet the inclusion criteria and have failed to respond adequately to medical treatment and ventilation tubes, balloon dilatation of the Eustachian tube may offer a valuable treatment option.

Given the increasing but still limited evidence, an appropriate next step may be the prudent introduction of balloon dilatation of the Eustachian tube at a limited number of centres under expert supervision (Table 4). Careful monitoring of outcomes may contribute to a multicentre audit, the results of which may determine the viability of balloon dilatation of the Eustachian tube in mainstream practice.

Keypoints

- Balloon dilatation of the Eustachian tube is a new, minimally invasive, endoscopic approach in the treatment for Eustachian tube dysfunction, a common condition implicated in middle ear disease such as otitis media with effusion.
- A literature review of the outcomes of balloon dilatation of the Eustachian tube was conducted, using four criteria (tympanometry, otoscopy findings, Valsalva, subjective symptoms). Outcomes were divided into short term (≤6 months) and long term (>6 months). Rates and severity of complications, costs, learning curve and ease of implementation were all assessed.
- Balloon dilatation of the Eustachian tube has been performed on 375 Eustachian tubes (235 patients) and demonstrates clear short-term (<6 month) benefits across all recorded outcome measures in a majority of cases. A complication rate of approximately 3% has been observed, and these have been minor and transitory. We deem procedural costs and learning curve to be acceptable.
- Balloon dilatation of the Eustachian tube appears to be effective, safe, well tolerated and affordable. As an emerging surgical technology, the current evidence consists of non-controlled case series. Short-term data nonetheless provide promising, consistent results based on objective measures, and the authors offer recommendations regarding a safeguarded, limited introduction of the procedure.
Conflict of interest

None to declare.

References
