Eustachian tube dysfunction (ETD) is estimated to affect approximately 1% of the UK population.1 ETD and subsequent inadequate middle ear ventilation have been implicated in the pathogenesis of otological diseases including otitis media with effusion (OME), retraction pockets, tympanic membrane (TM) perforation and cholesteatoma.2 Patients may present with vague, non-specific symptoms including aural fullness, tinnitus, discomfort or pain, hearing loss, or sensations of ‘muffled hearing’, ‘cracking and popping’ in the ears, ‘clogged ears’ or ‘feeling under water’.3,4 Symptoms may occur as a result of, or be exacerbated by, changes in atmospheric pressure.3,4 The cartilaginous portion of the Eustachian tube (ET) is thought to be the primary site of pathology.3 Mucosal inflammation of this segment and of the nasopharynx can lead to symptoms of ETD and, while management of ETD, should first be directed at associated inflammatory pathologies, and effective treatments are lacking. The application of topical intranasal steroids has been shown to confer no additional benefits when compared to placebo.5 Tympanostomy tubes may result in persistent otorrhoea, crusting, obstruction, chronic perforation, infection and extrusion leading to recurrent disease and repeat surgery.3 Balloon eustachian tuboplasty (BET) is aimed at catheterisation and dilatation of the cartilaginous portion of the ET. It is a minimally invasive procedure performed under general anaesthetic where the ET is accessed endonasally via the nasopharyngeal Eustachian opening.3 As the technique was first reported in 2010,3 it has attracted growing interest from the international ENT community as an effective treatment for ETD. We report the early results from a UK centre.

Materials and methods

Ethical considerations

This study was registered with the hospital Clinical Governance department and approved locally (study no. 5392). All participants underwent informed consent in the outpatient setting 2 months prior to the procedure and were provided with patient information sheets. Informed consent was confirmed on the day of surgery.

Patient selection

BET was offered as a bilateral or unilateral intervention to patients with a clinical history of ETD confirmed by a positive Eustachian Tube Dysfunction Questionnaire (ETDQ-7) score (>14.5) despite at least 3 months of medical therapy with topical steroids, auto-inflation devices and regular Valsalva manoeuvres. All patients were assessed preoperatively with screening including otoscopy (presence of effusion or retraction), flexible nasendoscopy (assessment of endoscopic access to the nasopharynx, patency of the nasopharyngeal ostium and for the presence of obstructive pathology), audiometry and tympanometry. Patients were also asked to complete an ETDQ-7 questionnaire and to report subjectively regarding their ability to perform an effective Valsalva manoeuvre in one or both ears (recorded as +ve or –ve). In bilateral cases, patients completed separate pre- and post-procedure side-specific questionnaires (including ETDQ-7 scores) for each ear.

Intervention

All procedures were performed under a general anaesthetic, with topical application of nasal decongestant administered in the anaesthetic room. The balloon catheter (Acclarent Aera Eustachian Tube Balloon Catheter; length 16 mm, diameter 6 mm at 12 atm) was carefully advanced transnasally into the cartilaginous portion of the ET via the nasopharyngeal ostium under endoscopic visualisation with a 30-degree endoscope. Insertion of the balloon catheter to the level of the yellow safety proximal balloon marker (denoting canalisation of the cartilaginous segment of ET) was achieved without the use of force. The balloon was then inflated to a pressure of 12 atm using sterile normal saline solution with dilation maintained for a period of 2 min, before being deflated. After 1 min, with the catheter still in situ, the inflation of the balloon was repeated and...
maintained for a further 1 min, before being deflated, and the device removed under endoscopic observation. Double inflation of the balloon catheter was performed at the discretion of the operating surgeon after discussion with the manufacturer with the intention, based on clinical experience, of producing a better result than with single inflation.

**Outcome measures**

Patients were followed up in the outpatient setting at 6 weeks, 3 and 6 months post-procedure. The outcome measures were ETDQ-7 score, tympanometry and ability to perform an effective Valsalva manoeuvre.

**Results**

A total of 39 consecutive patients (16 bilateral, 55 ears) (age 19.4 – 74.3 years, mean 45.5 years) were included in the study with 100% follow-up at 6 months post-procedure. The mean preoperative ETDQ-7 score was 34.1 (SD ± 5.58), 17.82 (SD ± 8.26) at 6 weeks, 14.4 (SD ± 6.27) at 3 months and 13.88 (SD ± 5.57) at 6 months. Comparison of preoperative baseline and follow-up ETDQ-7 scores showed a statistically significant difference in patient scores at 6 weeks (P < 0.0001), 3 months (P < 0.0001) and 6 months (P < 0.0001) (Gaussian distribution, parametric analyses, two-tailed paired t-test) (Fig. 1). The proportion of ears in which patients reported being able to perform an effective Valsalva manoeuvre increased from 0% (n = 0) preoperatively, to 82% (n = 45) at 6 weeks and 96% (n = 53) at 3 and 6 months. Type ‘A’ tympanograms increased from 40% (n = 22) preoperatively to 80% (n = 44) at 6 weeks, 89% (n = 49) at 3 months and 95% (n = 52) at 6 months (Fig. 2). Subgroup analysis showed no statistically significant difference (P = 0.285) in the mean preoperative ETDQ-7 score in patients with ventilated (i.e. type A tympanogram) (n = 23, mean 35.7 (SD ± 5.84)) and non-ventilated (type B or C tympanogram) middle ears (n = 32, mean 33.0 (SD ± 4.89)). The mean ETDQ-7 scores in the non-ventilated group (n = 32) were 33.0 (SD ± 4.90) preoperatively, 15.9 (mean (SD ± 6.91) at 6 weeks post-procedure and 13.8 (SD ± 5.60) at 3 months post-procedure. The mean 6-month post-procedure ETDQ-7 scores were the same in the ventilated (13.9, SD ± 6) and non-ventilated middle ear groups (13.9, SD ± 5.14). No adverse events were recorded.

**Statistical analysis**

Statistical analysis was performed using GraphPad Prism version 6.00 for Mac OS, GraphPad Software, La Jolla California, www.graphpad.com.

Fig. 1. ETDQ-7 scores preoperatively, and at 6 weeks, 3 and 6 months post-procedure.

Fig. 2. Tympanography results in patients preoperatively and at 6 weeks, 3 and 6 months post-procedure.

**Discussion**

**Synopsis of key findings**

The results of our study show an improvement in all primary outcome measures. Pre- and postoperative ETDQ-7 scores showed a statistically significant improvement with a 48% reduction in mean post-procedure scores at 6 weeks, 58% reduction at 3 months and a 59% reduction at 6 months.
McCoul et al. reported ETDQ-7 as identifying ETD at a score of ≥14.5, equating to a mean score of 2.1 or above. The mean scores in our patient group were 4.9 preoperatively, 2.5 at 6 weeks post-procedure, 2.1 at 3 months and 2.0 at 6 months. All patients in the study reported an improvement in symptoms post-procedure with lower ETDQ-7 scores; 96% (n = 53) of patients reported being able to perform an effective Valsalva manoeuvre in a previously affected ear at 6 months postoperatively compared with 0% prior to the intervention. The percentage of normal type ‘A’ tympanograms increased from 40% pre-procedure to 96% at 6 months following intervention.

**Strengths and limitations**

This is a prospective study of a recent innovation in the management of a common and difficult-to-treat condition. While the authors deem it reasonable to use the ETDQ-7 as an ear-specific tool for the purposes of this study, we acknowledge that it has not been developed or validated to be ear specific. The study has no external control group.

**Classification of ETD**

Several classifications of ETD have been described. A 2015 expert panel consensus statement proposes acute ETD to refer to signs and symptoms of <3 months of duration and chronic ETD of more than 3 months. Three subtypes of ETD are described: dilatory, baro-challenge-induced and patulous ETD, with dilatory being subcategorised into functional obstruction, dynamic dysfunction and anatomical obstruction. By this classification, all patients in our cohort were treated for chronic dilatory ETD.

**Comparison with other studies**

Several other studies have also shown positive results of symptom improvement and resolution in ETD using balloon dilation of the cartilaginous ET. Schroder et al. report the long-term results in a cohort of 622 patients (1076 ears) describing an improvement in Eustachian Tube Score in 82% of patients at five-year follow-up. However, they note the reduced significance of the outcomes due to the low number of patients with complete follow-up (10% of cases at 2 years). Silvola et al. report the findings of BET in a patient group with OME (TM atelectasis, type B or C tympanograms and an inability to perform a Valsalva manoeuvre) relieved only by repeated tympanostomies. Of 41 consecutive BET procedures followed up over 2.5 years, they report that 80% (34/41) of patients post-procedure were able to perform a Valsalva manoeuvre and required no further tympanostomy tubes describing a subjective improvement in symptoms. In a cohort of 22 consecutive patients (35 ears), McCoul et al. report significant improvement in postoperative tympanometry and otoscopic appearance, as well as improved ETDQ-7 scores at 3, 6 and 12 weeks and 6 months. An evidence-based review by Miller at al. in 2013 reported that short-term results for BET appear promising and consistent based on objective and subjective measures.

**Use of BET in paediatric patients**

The number of studies reporting the use of BET in paediatric populations is limited. In a retrospective analysis of BET in 66 patients with ETD between the ages of 4–14 years, Maier et al. report clinical improvement in more than 80% of patients with a high degree of patient satisfaction and no complications. Schroder et al. report using BET in patients over the age of 7 years but consider it only as a second-line treatment in younger children. These results of BET in paediatric populations raise the possibility of an alternative treatment to tympanostomy tubes for the treatment of OME in children.

**Safety**

In the study we report, there were no complications associated with the procedure. A 2015 systematic review of literature (nine studies) found no reports of severe morbidity or mortality with only four reported cases of minor complications, all of which resolved spontaneously. In a report of over 1000 cases, Schroder et al. describe surgical emphysema in the parotid region due to mucosal tears in the ET in three patients, all of which resolved. They also observe minor bleeding and a case of transient increase in tinnitus. Subclinical mucosal lacerations and minimal bleeding of short duration have also been reported.

**Conclusion**

Early results analysis suggests that BET is a safe and effective treatment for symptoms of chronic ETD with improvement in all outcome measures at 6 weeks, 3 and 6 months. This has potential implications for the treatment of glue ear in children and improving the long-term outcomes of tympanomastoid surgery. Larger randomised studies with long-term follow-up are required with controls against existing treatments such as tympanostomy tubes.

**Keypoints**

- Eustachian tube dysfunction is a common and difficult-to-treat condition for which effective treatments are lacking.
• Our early results suggest that balloon dilatation of the Eustachian tube is a safe and effective treatment for symptoms of Eustachian tube dysfunction in adult patients.
• Balloon tuboplasty may represent an alternative treatment for glue ear in children.
• Larger randomised studies with long-term follow-up rates are required with controls against existing treatments such as tympanostomy tubes.

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Conflicts of interest

None declared.

References


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