The Journal of Laryngology & Otology

cambridge.org/jlo

Eustachian tube balloon dilatation: a cross-sectional, survey-based study of 137 UK consultants

F S Koumpa[1], I Moraitis[2], P Bowles[3] and N Saunders[3]

[1]Otolaryngology Department, Northwick Park Hospital, London, [2]Vascular Surgery Department, Milton Keynes University Hospital and [3]Otolaryngology Department, Brighton and Sussex University Hospital Trust, UK

Main Article

Mr S Koumpa takes responsibility for the integrity of the content of the paper

Presented at the Association of Otolaryngologists in Training meeting, 9–10 May 2019, London, UK.

Cite this article: Koumpa FS, Moraitis I, Bowles P, Saunders N. Eustachian tube balloon dilatation: a cross-sectional, survey-based study of 137 UK consultants. *J Laryngol Otol* 2020;**134**:41–45. https://doi.org/10.1017/S0022215119002561

Accepted: 1 October 2019
First published online: 23 December 2019

Key words:
Eustachian Tube; Dilatation; Ear Diseases; Surveys And Questionnaires; United Kingdom; Consultants

Author for correspondence:
Mr Stefania Koumpa,
Otolaryngology Department,
Northwick Park Hospital,
London, UK
E-mail: s.koumpas@doctors.org.uk

Abstract

Objective. To explore the opinions of the UK consultant body on endoscopic Eustachian tube balloon dilatation in the context of Eustachian tube dysfunction.
Method. A 10-question online survey was distributed to ENT consultants currently practising in the UK (July–September 2018).
Results. A total of 137 ENT consultants responded. Twenty-three per cent reported experience of Eustachian tube balloon dilatation, with a further 10 per cent planning to start performing the procedure. Of those performing the procedure, 16 per cent had more than two years' experience. Thirty-two per cent were performing zero to five procedures a year. Eustachian tube balloon dilatation was primarily conducted to treat Eustachian tube dysfunction symptoms, as well as retraction pockets, baro-challenge-induced Eustachian tube dysfunction and otitis media with effusion. The most common reason for not undertaking Eustachian tube balloon dilatation was insufficient evidence of efficacy (65 per cent). Seventy-two per cent of consultants thought that creating a national database for audit and monitoring purposes would benefit the specialty.
Conclusion. The majority of UK ENT consultants do not practise Eustachian tube balloon dilatation, citing a lack of high-level evidence to support its use. A national database for auditing and research could facilitate the creation of guidelines.

Introduction

The Eustachian tube connects the middle ear to the nasopharynx. Its functions include equalisation of middle-ear pressure, draining of mucus to the nasopharynx, and protection of the middle ear from acoustic trauma and pathogens.[1] Eustachian tube dysfunction describes a collection of symptoms including aural fullness, 'ear popping', ear discomfort and tinnitus.

Varying treatment modalities are applied to manage Eustachian tube dysfunction symptoms, including medical therapy such as steroids and/or nasal decongestants, autoinflation devices, and tympanostomy with or without ventilation tube insertion. However, these treatments have not been shown to consistently improve tubal function, and it remains unclear whether medical management provides significant symptomatic relief.[2] Eustachian tube balloon dilatation is a recent innovation aimed at treating Eustachian tube dysfunction symptoms, which involves inserting a balloon catheter to dilate the cartilaginous segment of the Eustachian tube.[3]

Eustachian tube balloon dilatation was approved by the Food and Drug Administration in the USA in 2016, but its application in the UK remains controversial. Results from early, largely uncontrolled, studies in small populations are encouraging.[4,5] However, the lack of 'gold standard' diagnostic criteria for Eustachian tube dysfunction with which to standardise patient selection and outcome measures has limited the development of high-quality randomised trials. In 2015, an expert panel proposed a classification system and diagnostic criteria for Eustachian tube dysfunction, but it remains to be seen whether these will be adopted by the broader ENT community.[1] This cross-sectional, survey-based study aimed to investigate the current opinions and practice of the UK ENT consultant body regarding Eustachian tube balloon dilatation.

Materials and methods

Ethical approval was not required as no direct patient information was acquired.

A 10-question online survey was designed by the authors and distributed via e-mail to 438 ENT consultants via ENT-UK (a UK professional body for ENT doctors). The survey was accessible via a third-party provider (www.surveymonkey.com) between July and September 2018 (Appendix 1). Survey questions enquired as to Eustachian tube balloon dilatation practice patterns, indications for use, experience in the field including National Health Service (NHS) and private practice experience, pre-operative investigations (symptom questionnaire, tympanometry, tubomanometry, computed tomography (CT)

scanning), intra-operative approach (intranasal *vs* intratympanic), and future perspectives. Responses were recorded and collated in Microsoft Office Excel® spreadsheet software.

Results

Demographics

A total of 137 ENT-UK consultants completed the survey. Regarding subspecialisation, 65 (47 per cent) categorised themselves as otologists, 33 (24 per cent) as rhinologists, 21 (15 per cent) as head and neck surgeons, 11 (8 per cent) as general ENT surgeons, and 7 (5 per cent) as paediatric ENT surgeons (Figure 1). Two otology consultants reported a dual interest in rhinology.

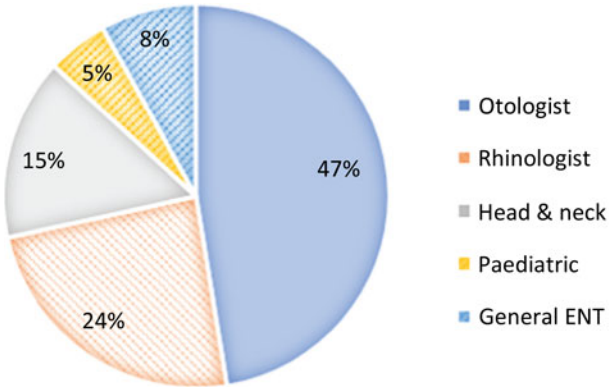

Fig. 1. ENT subspecialties of respondents.

Eustachian tube balloon dilatation experience

Thirty-one consultants (23 per cent) reported performing Eustachian tube balloon dilatation, with 106 (77 per cent) not performing the procedure. Of those who reported not undertaking Eustachian tube balloon dilatation, 69 (65 per cent) cited insufficient evidence of efficacy, 13 (12 per cent) reported an inability to obtain funding, 13 (12 per cent) perceived Eustachian tube balloon dilatation to be a high-risk procedure, 13 (12 per cent) said it was not in their field of interest and 2 (2 per cent) cited approval issues from their regulatory body. At the time of the survey, 14 respondents (10 per cent) were planning to undertake the procedure in the near future. Two respondents (2 per cent) had tried the procedure but since discontinued practice.

Among the respondents who had performed Eustachian tube balloon dilatation, 30 (83 per cent) had less than two years of experience, with 50 per cent of those having less than one year of experience. Five consultants (14 per cent) had been carrying out Eustachian tube balloon dilatation for three to five years, and one consultant (3 per cent) had been performing the procedure for six years or more. Twenty-four consultants (67 per cent) had performed 0–5 Eustachian tube balloon dilatation procedures, 8 (22 per cent) had undertaken 6–15 procedures, 4 (11 per cent) had performed 16–50 procedures and 0 had conducted over 50 procedures.

Thirteen consultants (36 per cent) reported performing 95–100 per cent of procedures in private practice. A further 13 consultants (36 per cent) reported performing 95–100 per cent of procedures in the NHS. The remaining survey respondents reported a reasonably even split between the numbers of procedures performed in the NHS and privately.

Indications for procedure

Multiple indications for Eustachian tube balloon dilatation were reported. Eustachian tube balloon dilatation was reported as being carried out to treat: Eustachian tube dysfunction symptoms (clicking, popping, sensation of aural fullness), by 29 consultants (78 per cent); otitis media with effusion or obstructive Eustachian tube dysfunction, by 24 (65 per cent); retraction pockets, by 9 (24 per cent); and barotrauma-related Eustachian tube dysfunction, by 8 (22 per cent) (Figure 2).

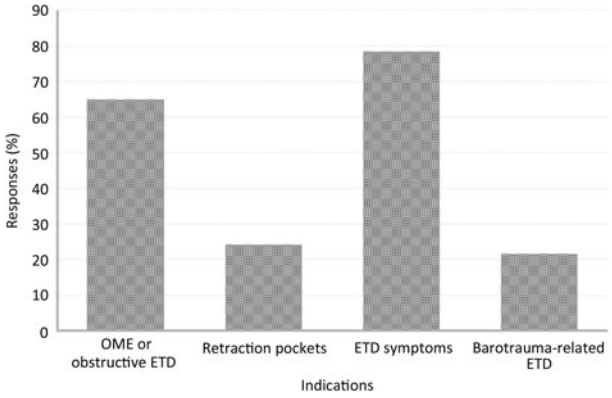

Fig. 2. Indications for which UK consultants perform Eustachian tube balloon dilatation. OME = otitis media with effusion; ETD = Eustachian tube dysfunction

Route and investigations performed

In terms of pre-operative investigations, 29 respondents (81 per cent) reported performing tympanometry, 23 (64 per cent) utilise a patient-reported symptom questionnaire, 10 (28 per cent) carry out a CT scan of the temporal bones, and 3 (8 per cent) perform tubomanometry. Intra-operatively, 100 per cent of consultants reported employing an endoscopic transnasal approach for the technique.

Future research

Thirty-nine consultants (28 per cent) responded to the question regarding the establishment of an Eustachian tube balloon dilatation national database to promote audit and research in the field, with 28 (72 per cent) being in favour.

Discussion

This is the first study to investigate the current practice and opinions of the UK ENT consultant body on Eustachian tube balloon dilatation. Current National Institute for Health and Care Excellence (NICE) UK guidelines regarding Eustachian tube balloon dilatation note a lack of existing high-quality evidence regarding the efficacy and safety of the procedure, and recommend its application for research purposes only.[6]

In our survey, insufficient evidence of efficacy was the most cited reason for not performing the procedure. Similarly, a US-based study by Micucci *et al.*[7] highlighted the need for higher level studies to ascertain the role of Eustachian tube balloon dilatation in the treatment of Eustachian tube dysfunction. Yet uptake of the procedure in the USA has been greater than in the UK, with 49.7 per cent ($n = 143$) of US consultants surveyed by Micucci *et al.* reported to be practising

https://doi.org/10.1017/S0022215119002561 Published online by Cambridge University Press

Eustachian tube balloon dilatation, compared to 23 per cent ($n = 31$) of UK consultants in our current study.[7] The approval of the procedure by the Food and Drug Administration for the treatment of persistent Eustachian tube dysfunction may explain the discrepancy in uptake and experience levels between US and UK ENT surgeons, with only 23 per cent ($n = 33$) of US consultants practising Eustachian tube balloon dilatation having performed less than five procedures, compared to 67 per cent ($n = 24$) in the UK.[7]

The majority (83 per cent) of respondents to our survey who currently practise Eustachian tube balloon dilatation had less than two years' experience. However, over 1 in 10 respondents (10 per cent) expressed an intention to start performing the procedure, suggesting that it is gaining interest in the UK. The survey found an even split of ENT surgeons performing Eustachian tube balloon dilatation almost exclusively (in more than 95 per cent of cases) in the private sector and those performing it almost exclusively in their NHS practice ($n = 13$, 36 per cent in each category), with the remainder of those performing the procedure in both the NHS and privately in equal proportion. This may be partly accounted for by each responding surgeon's experience of the procedure to date, and whether they are currently involved in Eustachian tube balloon dilatation research activity.

Pre-operative planning and investigation used in the context of Eustachian tube balloon dilatation has been a subject of debate. Abded-Aziz *et al.* showed that pre-operative high-resolution CT temporal bone scans were not able to predict intra-operative difficulties or post-operative complications of the procedure.[8] Most of the UK consultants surveyed request pre-operative symptom questionnaires and tympanometry (or tubomanometry), with only 28 per cent requesting a pre-operative CT scan. The most common pre-operative investigation performed in this cohort was tympanometry, followed by patient-reported questionnaires, in line with the 2015 consensus statement on Eustachian tube dysfunction diagnosis.[1] Additional investigations reported in the literature include pure tone audiometry[8] and 'successful Valsalva manoeuvre'.[9,10]

The effective management of Eustachian tube dysfunction symptoms poses a clinical challenge. Randomised, controlled trials investigating the effects of decongestants and intranasal steroids in the management of Eustachian tube dysfunction have shown no statistically significant difference when compared to placebo.[11,12] Randomised, controlled trials investigating the use of autoinflation devices in children have shown statistically significant improvements in tympanograms and ear-related symptoms compared to controls, yet evidence for their use in adult populations is lacking.[13]

Surgical treatment for Eustachian tube dysfunction includes the use of ventilation tubes, and methods of Eustachian tube dilatation such as balloon dilatation and laser. Early results from published studies have suggested that Eustachian tube balloon dilatation is effective in treating symptoms of Eustachian tube dysfunction.[4,14–16] However, these are mostly retrospective, single-centre case series in small sample populations, with limited long-term follow up. Randomised, controlled trials comparing Eustachian tube balloon dilatation to medical therapy[9,10] have also been encouraging, yet it is relevant to note that there is a lack of evidence to support the efficacy of medical management of Eustachian tube dysfunction. A meta-analysis of prospective and retrospective studies comparing Eustachian tube balloon dilatation and laser Eustachian tuboplasty in Taiwan showed no inferiority of Eustachian tube balloon dilatation results, but also noted the need for further studies to assess its efficacy.[17]

A recent retrospective study of 60 adults with chronic secretory otitis media showed that a combination of Eustachian tube balloon dilatation and ventilation tubes resulted in significantly better Eustachian tube function scores (based on a Eustachian tube dysfunction questionnaire, an effective Valsalva manoeuvre and tympanometry) compared to ventilation tubes alone.[18] Patient satisfaction ratings at 24 months following the procedure were 81 per cent, compared to 70 per cent in the ventilation tube group. Six patients in the combination group and 10 patients in the ventilation tube group reported no improvement.[18]

While results from the abovementioned studies are encouraging, high-level randomised, controlled studies comparing the efficacy of Eustachian tube balloon dilatation alone with established treatments such as ventilation tubes are lacking.[16] A systematic review by Huisman *et al.*, conducted in 2017, similarly concluded that Eustachian tube balloon dilatation may be a helpful treatment for Eustachian tube dysfunction, but stated that the literature is still heterogeneous with a lack of placebo-controlled trials, making it difficult to draw a conclusion for best practice.[19] Our survey findings showed that uptake of Eustachian tube balloon dilatation in the UK remains limited because of insufficient evidence of efficacy and long-term outcomes.

While Eustachian tube balloon dilatation has mainly been reported as a treatment for obstructive Eustachian tube dysfunction,[20] it has also been suggested as a potential treatment for adhesive otitis media with effusion, and as an adjunct to tympanomastoid surgery.[21] The indications reported for performing the procedure in UK practice were variable. Treatment of Eustachian tube dysfunction symptoms was the most common indication, followed by otitis media with effusion or obstructive Eustachian tube dysfunction, retraction pockets, and baro-challenge-induced Eustachian tube dysfunction symptoms (i.e. symptoms caused by changes in atmospheric pressure such as when flying or diving).

- Twenty-three per cent of ENT consultants surveyed (most with an interest in otology) perform Eustachian tube balloon dilatation
- The most common indication for Eustachian tube balloon dilatation was Eustachian tube dysfunction symptoms
- Over 1 in 10 respondents (10 per cent) intend to start performing Eustachian tube balloon dilatation
- Insufficient evidence of efficacy was the commonest reason cited among those not practising Eustachian tube balloon dilatation
- Respondents supported the proposal of a national database for Eustachian tube balloon dilatation to facilitate audit and research

Several databases exist in the US ENT community, notably those concerning cancer outcomes, as well as an international database of middle-ear operations (Common Otology Database), which facilitates participation in audit and research.[22] The variation in practice regarding indications for Eustachian tube balloon dilatation found in our survey is also reported in other studies. The application of Eustachian tube balloon dilatation to different pathologies, for which outcome measures may vary, suggests that a national or international database, to record and promote

https://doi.org/10.1017/S0022215119002561 Published online by Cambridge University Press

transparency and learning, may be beneficial in terms of developing evidence-based patient selection criteria and outcome measures. Consultants responding to our survey supported the proposal of a national database of Eustachian tube balloon dilatation procedures, through which to combine results, promote audit and research, and develop the evidence base.

The main limitation of this study is the low response rate of 31.3 per cent, although this does compare favourably with the response rate reported in a similar web-based questionnaire study, of 9.1 per cent.[7] A further limitation is that the survey is limited to the ENT-UK membership and does not include the practice of those UK ENT consultants who are not members. The retrospective nature of this survey-based study subjects it to recall bias.

Conclusion

Eustachian tube balloon dilatation is a recent surgical innovation for the management of Eustachian tube dysfunction symptoms, a common condition for which an effective treatment is lacking. The majority of UK consultants surveyed are not currently performing the procedure, with most citing a lack of existing evidence to support its efficacy. However, 23 per cent of UK consultants surveyed are currently practising the procedure, with more than 1 in 10 expressing an intention to commence performing Eustachian tube balloon dilatation.

A national database of Eustachian tube balloon dilatation procedures, including patient selection criteria and outcome measures used by those practising the procedure, may provide a basis for audit and research, and help develop the evidence base for the procedure, in line with current NICE recommendations. The majority of consultants surveyed supported the proposal of a national Eustachian tube balloon dilatation database through which to promote audit and research.

Acknowledgements. We would like to thank ENT-UK for distributing our questionnaire. Funding for questionnaire distribution by ENT-UK was obtained from the Royal Sussex County University Hospital ENT Department.

Competing interests. None declared

References

1 Schilder AGM, Bhutta MF, Butler CC, Holy C, Levine LH, Kvaerner KJ *et al.* Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. *Clin Otolaryngol* 2015;**40**:407–11
2 van Heerbeek N, Ingels KJAO, Rijkers GT, Zielhuis GA. Therapeutic improvement of Eustachian tube function: a review. *Clin Otolaryngol Allied Sci* 2002;**27**:50–6
3 Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. *Otol Neurotol* 2001;**22**:590–5
4 Tisch M, Maier H, Sudhoff H. Balloon dilation of the Eustachian tube: clinical experience in the management of 126 children. *Acta Otorhinolaryngol Ital* 2017;**37**:509–12
5 Tisch M, Störrle P, Danz B, Maier H. Eustachian tube dilation using the Bielefeld balloon catheter: clinical experience with 320 interventions [in German]. *HNO* 2013;**61**:488–91
6 NICE. Balloon dilatation of the Eustachian tube. In: https://www.nice.org.uk/guidance/IPG409 [17 November 2019]
7 Micucci S, Keschner DB, Liang J. Eustachian tube balloon dilation: emerging practice patterns for a novel procedure. *Ann Otol Rhinol Laryngol* 2018;**127**:848–55
8 Abdel-Aziz T, Schröder S, Lehmann M, Gehl H-B, Ebmeyer J, Sudhoff H. Computed tomography before balloon eustachian tuboplasty–a true necessity? *Otol Neurotol* 2014;**35**:635–8
9 Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP, Hoffmann K *et al.* Balloon dilation of the eustachian tube for dilatory dysfunction: a randomized controlled trial. *Laryngoscope* 2018;**128**:1200–6
10 Meyer TA, O'Malley EM, Schlosser RJ, Soler ZM, Cai J, Hoy MJ *et al.* A randomized controlled trial of balloon dilation as a treatment for persistent eustachian tube dysfunction with 1-year follow-up. *Otol Neurotol* 2018;**39**:894–902
11 Shapiro GG, Bierman CW, Furukawa CT, Pierson WE, Berman R, Donaldson J *et al.* Treatment of persistent eustachian tube dysfunction in children with aerosolized nasal dexamethasone phosphate versus placebo. *Ann Allergy* 1982;**49**:81–5
12 Gluth MB, McDonald DR, Weaver AL, Bauch CD, Beatty CW, Orvidas LJ. Management of Eustachian tube dysfunction with nasal steroid spray. *Arch Otolaryngol Head Neck Surg* 2011;**137**:449–55
13 Williamson I, Vennik J, Harnden A, Voysey M, Perera R, Kelly S *et al.* Effect of nasal balloon autoinflation in children with otitis media with effusion in primary care: an open randomized controlled trial. *Can Med Assoc J* 2015;**187**:961–9
14 Schmitt D, Akkari M, Mura T, Mondain M, Uziel A, Venail F. Medium-term assessment of Eustachian tube function after balloon dilation. *Eur Ann Otorhinolaryngol Head Neck Dis* 2018;**135**:105–10
15 Anand V, Poe D, Dean M, Roberts W, Stolovitzky P, Hoffmann K *et al.* Balloon dilation of the Eustachian tube: 12-month follow-up of the randomized controlled trial treatment group. *Otolaryngol Head Neck Surg* 2019;**160**:687–94
16 Schröder S, Lehmann M, Ebmeyer J, Upile T, Sudhoff H. Balloon Eustachian tuboplasty: a retrospective cohort study. *Clin Otolaryngol* 2015;**40**:629–38
17 Wang T-C, Lin C-D, Shih T-C, Chung H-K, Wang C-Y, Tsou Y-A *et al.* Comparison of balloon dilation and laser eustachian tuboplasty in patients with eustachian tube dysfunction: a meta-analysis. *Otolaryngol Neck Surg* 2018;**158**:617–26
18 Li Y, Chen Y, Yin G, Zeng X. Effect of balloon dilation eustachian tuboplasty combined with tympanic tube insertion in the treatment of chronic recurrent secretory otitis media. *Eur Arch Otorhinolaryngol* 2019;**276**:2715–20
19 Huisman JML, Verdam FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: a systematic review. *Laryngoscope* 2018;**128**:237–47
20 Dalchow CV, Loewenthal M, Kappo N, Jenckel F, Loerincz BB, Knecht R. First results of endonasal dilatation of the Eustachian tube (EET) in patients with chronic obstructive tube dysfunction. *Eur Arch Otorhinolaryngol* 2016;**273**:607–13
21 Bowles PF, Agrawal S, Salam MA. Balloon tuboplasty in patients with Eustachian tube dysfunction: a prospective study in 39 patients (55 ears). *Clin Otolaryngol* 2017;**42**:1057–60
22 Van Rompaey V, Yung M, Van de Heyning P. Auditing in middle ear surgery, feasibility of the common otology database. *B-ENT* 2010;**6**:189–94

https://doi.org/10.1017/S0022215119002561 Published online by Cambridge University Press

Appendix 1. Ten-question survey of UK balloon Eustachian tuboplasty practice in the UK

1. Please state your subspecialty – please select all relevant specialities

Otologist	Rhinologist	Head & neck
Paediatric	General	Other, please state_____

Comments_____

2. Do you undertake Eustachian tube balloon dilatation? Yes → Q3 No → Q10

Comments_____

3. What indications do you use it for? Please select all relevant conditions

OME	Retraction pockets	ETD symptoms	Barotrauma-related ETD	Obstructive ETD

Comments_____

4. Do you use any pre-operative tests? Please select all relevant answers

Symptom questionnaire	Tympanometry	Tubomanometry	CT scanning

Comments_____

5. How many years have you been carrying it out for?

<1 year	1–2 years	3–5 years	6+ years

Comments_____

6. How many balloon tuboplasty procedures do you undertake in a calendar year?

0–5	6–15	16–50	>50

Comments_____

7. What percentage of your cases are performed under the NHS?

0–5%	6–25%	26–50%	51–75%	76–100%

Comments_____

8. Which route do you use?

Intranasal	Intratympanic

Comments_____

9. There is currently no national database of surgeons undertaking this procedure. Would you like ENT-UK (or BSO) to establish a database of UK practising Eustachian tube otologists to promote future audit and research in this field?

Yes	No

Comments_____

10. Why do you not undertake it? Please select all relevant answers

Not in my field of interest in ENT	Insufficient evidence of efficacy	Not undertaking currently, but planning on doing so
Perceived high risk	Not aware of procedure	Have tried, but stopped
Unable to obtain funding	Unable to obtain ethical approval	Other reason, please state_____

Comments_____

https://doi.org/10.1017/S0022215119002561 Published online by Cambridge University Press