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The DILATE study: a prospective cohort study of balloon dilatation for Eustachian tube dysfunction in patients with no middle-ear disease

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Main Article

Aryan Kalra takes responsibility for the integrity of the content of the paper

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Abstract

Objective. This study evaluates the safety and utility of Eustachian tube balloon dilatation in treating Eustachian tube dysfunction symptoms in adults without middle-ear disease.
Methods. A prospective cohort study was performed. Adults with dilatory Eustachian tube dysfunction symptoms and no middle-ear disease underwent Eustachian tube balloon dilatation. A clinical assessment including tympanometry, pure tone audiometry, otoscopy, ability to Valsalva, and Eustachian Tube Dysfunction Questionnaire-7 was performed pre-operatively and repeated during a 12-month follow-up period.
Results. Fifteen participants were enrolled. The mean pre-operative Eustachian Tube Dysfunction Questionnaire-7 score of 4.6 reduced to 2.5 at six weeks ($P < 0.01$), 3.0 at six months ($P = 0.02$) and 2.6 at 12 months ($P < 0.01$) post-operatively. All patients without evidence of negative middle-ear pressure had Eustachian Tube Dysfunction Questionnaire-7 score improvements. There were no post-operative complications.
Conclusion. Eustachian tube balloon dilatation is safe and effective at treating Eustachian tube dysfunction in patients with no middle-ear disease or evidence of negative middle-ear pressure.

Introduction

Eustachian tube dysfunction is a disabling condition that is difficult to treat. It is estimated to have a prevalence of 1–5 per cent in the adult population and contributes to a significant healthcare visit burden.[1–3] Eustachian tube dysfunction occurs in the setting of inadequate middle-ear ventilation and it may contribute to diseases of the middle ear such as otitis media and cholesteatoma.[4,5] Patients typically present with symptoms such as otalgia, ear fullness, tinnitus, popping and muffled hearing.[4]

Several surgical and non-surgical treatments are available for Eustachian tube dysfunction. Evidence for the efficacy of non-surgical interventions such as intranasal corticosteroids, topical decongestants and mechanical pressure equalisation devices is scarce.[6,7] Surgical techniques such as myringotomy with tympanostomy tube insertion improve middle-ear ventilation, however, it may lead to complications such as tympanosclerosis and chronic perforation.[8]

Eustachian tube balloon dilatation is a novel endoscopic procedure that dilates the cartilaginous portion of the Eustachian tube. This technique improves middle-ear ventilation by increasing Eustachian tube compliance and inducing histopathological changes.[8,9] Several studies have demonstrated the efficacy of Eustachian tube balloon dilatation in treating Eustachian tube dysfunction.[8,10,11]

A recently published set of consensus statements by the American Academy of Otolaryngology–Head and Neck Surgery stated that "patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD [Eustachian tube dysfunction]."[12] Similarly, a European consensus statement concluded that the diagnosis of dilatory (obstructive) Eustachian tube dysfunction requires patient-reported symptoms in addition to tympanic membrane retraction or a tympanogram indicating negative middle-ear pressure.[4] However, it is possible for patients with normal tympanometry and otoscopy to experience Eustachian tube dysfunction symptoms, especially if their abnormal tympanometry may not be documented at the time of clinical assessment.[6,13–15]

Patients enrolled in studies evaluating Eustachian tube balloon dilatation often had concurrent middle-ear disease.[8,10,11] It is unclear what effect the pre-operative middle ear may have on the efficacy of Eustachian tube balloon dilatation in reducing Eustachian tube dysfunction symptoms. As a result, the patient population that may benefit from the procedure remains poorly defined. Furthermore, there has been no

prospective analysis of Eustachian tube balloon dilatation in an Australian population. This study was developed to better understand the utility of Eustachian tube balloon dilatation at treating dilatory Eustachian tube dysfunction symptoms in patients without middle-ear disease.

Materials and Methods

Patients

A prospective cohort study was conducted. It included patients undergoing Eustachian tube balloon dilatation at two centres over a two-year period. Patients were recruited at a pre-operative assessment and evaluated by two otolaryngologists (authors JK and SL). Patients were invited to participate based on a set of inclusion and exclusion criteria (Table 1). Informed consent was taken from all individual participants. Each patient was given study information and advised they could withdraw from the study at any time.

Ethics

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and approved by an institutional Human Research and Ethics Committee (HREC registration number 1805). Data were collected by a single investigator, stored on a secure network, and de-identified once entered into the study database.

Pre- and post-operative assessments

Participation involved a routine pre-operative assessment before Eustachian tube balloon dilatation. This included clinical history, examination (otoscopy and Valsalva test), tympanometry, pure tone audiometry, completion of Eustachian Tube Dysfunction Questionnaire-7 and computed tomography (CT) imaging of the temporal bones. The seven-item Eustachian Tube Dysfunction Questionnaire-7 was developed in 2012 as a tool for Eustachian tube dysfunction symptom assessment. It provides a valid and reliable technique by which symptom severity can be assessed and improvement post-treatment quantified.[16] Clinical history was used to categorise Eustachian tube dysfunction symptoms as acute (< 3 months) or chronic (> 3 months).[4]

Medical charts were reviewed to collect descriptive data of participants. Data were collected and analysed from routine follow-up at fixed intervals of six weeks, six months, and 12 months post-Eustachian tube balloon dilatation. This included the results of repeat assessments post-procedure with clinical history, examination (otoscopy and Valsalva test), tympanometry, pure tone audiometry and completion of Eustachian Tube Dysfunction Questionnaire-7. Statistical analyses were performed using R commander 4.2.3 and statistical significance was defined as $P < 0.05$. All reported P-values were calculated using a two-tailed independent sample t-test.

Table 1. Inclusion and exclusion criteria for enrolment of study participants

Inclusion Criteria
1 Age 18 years or older 2 Clinical diagnosis of dilatory Eustachian tube dysfunction, with at least one symptom on Eustachian Tube Dysfunction Questionnaire-7 3 Failed medical management of Eustachian tube dysfunction
Exclusion Criteria
1 Previous head and neck radiation treatment 2 Post-nasal space tumours 3 Ossicular erosion 4 Active paranasal sinus disease 5 Active middle-ear disease (tympanic membrane perforation, acute otitis media, chronic suppurative otitis media, cholesteatoma) 6 Carotid artery dehiscence on CT of the temporal bones imaging 7 Inner-ear hydrops or Ménière's disease on CT of the temporal bones imaging 8 Temporomandibular joint disorder on CT of the temporal bones imaging

Surgical technique

All Eustachian tube balloon dilatation procedures were performed by a single surgeon (SL) using a general anaesthetic. An endoscopic approach with a zero-degree rigid scope was used to introduce an XprESS ENT Dilation System (Entellus Medical, Plymouth, Minnesota USA) device. The 20-mm long dilatation device was inserted into the cartilaginous portion of the Eustachian tube at approximately a 45° angle (Figure 1). Using the Seldinger technique, a balloon was inserted over the device and inflated with sterile water to 12 atm for 2 minutes.

Aims

The primary aim of this study was to prospectively evaluate the effect of Eustachian tube balloon dilatation in patients without middle-ear disease, using clinical examination (status of tympanic membrane and ability to Valsalva), pure tone audiometry, tympanometry and Eustachian Tube Dysfunction Questionnaire-7 scores at six weeks, six months and 12 months post-procedure. The secondary aim was to investigate the presence of any post-operative complications following Eustachian tube balloon dilatation.

Results and analysis

Fifteen participants were included. All patients attended the post-operative six-week follow up, nine (60.0 per cent) attended the six-month follow up and fourteen (93.3 per cent) attended the 12-month follow up. Ten patients (66.7

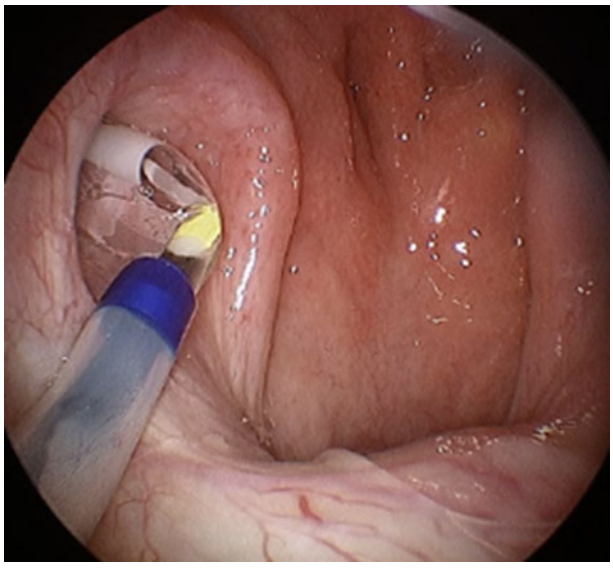

Figure 1. Endoscopic image of Eustachian tube dilatation. The Eustachian tube is ~35 mm long and 3 mm in diameter, with a 4:1 ratio of cartilaginous to bony length.

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per cent) were female, and the mean age was 56 years (range: 29–78 years).

The pre-operative characteristics of each study participant are described in Table 2. Thirteen (86.7 per cent) participants presented with symptoms of chronic Eustachian tube dysfunction, and two (13.3 per cent) with acute Eustachian tube dysfunction. All patients had a normal tympanic membrane and no middle-ear effusion. A pre-operative CT of the temporal bones confirmed the absence of middle-ear and mastoid pathology in each patient. Two participants had radiographic evidence of mild sinonasal disease in the absence of sinonasal symptoms. Both were deemed eligible for inclusion given a lack of clinical evidence for active sinonasal disease. Seven patients had left-ear Eustachian tube dysfunction, two had right-ear Eustachian tube dysfunction and six had bilateral Eustachian tube dysfunction. Of the 21 balloon dilatations performed, no intra-operative or immediate post-operative complications were noted. Pre-operatively, 14 (93.3 per cent) patients had type A tympanometry, and one (6.7 per cent) had type C. Four (26.7 per cent) participants were unable to Valsalva and four (26.7 per cent) had sensorineural hearing loss (SNHL) prior to surgery.

The mean pre-procedure Eustachian Tube Dysfunction Questionnaire-7 score was 4.6 (range: 3.4–6.3), indicative of patient-assigned moderate to severe symptoms. The mean post-procedure Eustachian Tube Dysfunction Questionnaire-7 scores were 2.5 (range: 1.1–4.3), 3.0 (range: 1–5.9) and 2.6 (range: 1.3–4.7) at six weeks, six months, and 12 months follow up, respectively (Figure 2). Improvements in mean post-operative Eustachian Tube Dysfunction Questionnaire-7 scores were statistically significant in comparison to pre-operative scores (Table 3). There was no significant difference between mean post-operative Eustachian Tube Dysfunction Questionnaire-7 scores. All fourteen patients presenting with type A tympanometry demonstrated statistically significant improvements in Eustachian Tube Dysfunction Questionnaire-7 scores six weeks ($P < 0.01$), six months ($P = 0.042$) and 12 months ($P < 0.01$) post-operatively, in comparison to pre-treatment scores.

Of the patients attending follow up, 14 (93.3 per cent) at six weeks, eight (88.9 per cent) at six months and 14 (100 per cent) at 12 months had improvements in total and mean Eustachian Tube Dysfunction Questionnaire-7 scores pre- and post-operatively (Figure 3). One patient did not attend the 12 month follow up. One third of participants sustained a 50 per cent improvement in Eustachian Tube Dysfunction Questionnaire-7 scores 12 months post-operatively. Patients with an Eustachian Tube Dysfunction Questionnaire-7 score improvement of at least 50 per cent at 12 months had higher mean pre-operative scores than cases with less than 50 per cent improvement (5.4 versus 4.3, $P = 0.03$, 95 per cent, confidence interval: 0.1–2.1).

No patient had an abnormal otoscopic examination post-operatively. All four (26.7 per cent) patients that failed to Valsalva pre-treatment were able to do so six weeks following Eustachian tube balloon dilatation. At the time of their last follow up, three of four patients maintained the ability to Valsalva (Table 4). Type C tympanometry of a single (6.7 per cent) patient remained unchanged pre- and post-operatively. Another patient, with pre-procedure type A tympanometry, developed concurrent cochlear hydrops and had type B tympanometry 12 months post-Eustachian tube balloon dilatation. All four patients with pre-operative SNHL had sustained SNHL at their last follow-up assessment. The pure tone audiometry results for two of these patients were likely confounded by other pathology present at follow up, including inner-ear hydrops and upper respiratory tract infection (Table 5). No post-operative complications were noted in the 12 months following Eustachian tube balloon dilatation.

Discussion

Over the last decade, balloon dilatation of the Eustachian tube has emerged as a promising treatment for Eustachian tube dysfunction. The safety and utility of the procedure continues to be an area of active research. Eustachian tube balloon dilatation devices were approved by the Australian Department of Health in 2016. To our knowledge, since approval, no prospective study has analysed the use of Eustachian tube balloon dilatation in an Australian population. This study's results demonstrate significant improvements in the Eustachian

Table 2. Pre-operative characteristics of study participants

Patients	Symptom Timeframe	Affected Ear	Otoscope Examination	Able to Valsalva	Tympanometry	Pure tone audiometry
Patient 1	Chronic	Right	Normal	Yes	Type A	Normal
Patient 2	Acute	Left	Normal	Yes	Type A	SNHL
Patient 3	Acute	Right	Normal	No	Type A	Normal
Patient 4	Chronic	Bilateral	Normal	Yes	Type A	SNHL
Patient 5	Chronic	Bilateral	Normal	Yes	Type A	SNHL
Patient 6	Chronic	Left	Normal	Yes	Type A	Normal
Patient 7	Chronic	Left	Normal	Yes	Type C	Normal
Patient 8	Chronic	Left	Normal	Yes	Type A	Normal
Patient 9	Chronic	Bilateral	Normal	No	Type A	SNHL
Patient 10	Chronic	Left	Normal	No	Type A	Normal
Patient 11	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 12	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 13	Chronic	Bilateral	Normal	Yes	Type A	Normal
Patient 14	Chronic	Left	Normal	No	Type A	Normal
Patient 15	Acute	Left	Normal	Yes	Type A	Normal

Abbreviations: SNHL = sensorineural hearing loss

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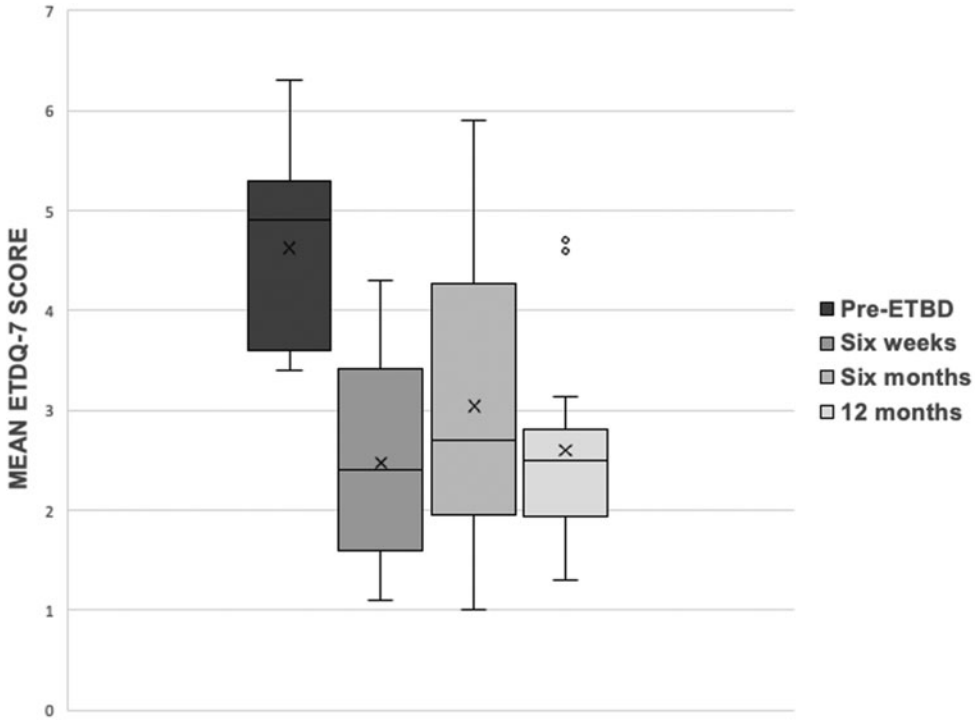

Figure 2. Patients' mean Eustachian Tube Dysfunction Questionnaire-7 scores pre-Eustachian tube balloon dilatation and six weeks, six months, and 12 months post procedure. The X within the box indicates mean. The horizontal line within the box indicates median. The bottom edge of the box indicates quartile 1; the top edge indicates quartile 3. The small horizontal lines extending outside the box with vertical lines represent the maximum (Q3 + 1.5*IQR) and minimum (Q1 − 1.5*IQR). The small open circles indicate observations above the maximum (i.e. outliers).

Tube Dysfunction Questionnaire-7 scores of patients with normal middle ears for at least 12 months following Eustachian tube balloon dilatation. The rate and extent of score improvement was similar to those reported in other publications.[8,10,11] Our results highlight the utility of Eustachian tube balloon dilatation in treating symptomatic patients that do not have objective evidence of negative middle-ear pressure, and therefore do not strictly meet dilatory Eustachian tube dysfunction diagnostic criteria.[4,12] This study also demonstrates the strong post-operative safety profile of Eustachian tube balloon dilatation, which is consistent with current literature.[8,10,14,15]

The pre-operative middle ear may influence Eustachian Tube Dysfunction Questionnaire-7 scores following Eustachian tube balloon dilatation. A retrospective review of 62 patients by Cheng *et al.* assessed Eustachian Tube Dysfunction Questionnaire-7 scores six months to two years following Eustachian tube balloon dilatation.[17] The authors demonstrated that 83.9–100 per cent of patients without middle-ear disease had improvements in scores pre- and post-Eustachian tube balloon dilatation. Our data are similar to these figures. Additionally, Cheng *et al.* found that a subgroup of patients with middle-ear pathology had inferior improvements in Eustachian Tube Dysfunction Questionnaire-7 scores.[17] These preliminary findings may suggest that middle-ear disease can reduce the extent of symptom improvement post-Eustachian tube balloon dilatation. However, other studies have demonstrated that the presence of middle-ear pathology, such as chronic otitis media, independently predicts a greater likelihood of Eustachian Tube Dysfunction Questionnaire-7 score normalisation (Eustachian Tube Dysfunction Questionnaire-7 score < 2.1) following Eustachian tube balloon dilatation.[18] Limited studies have compared outcomes of Eustachian tube balloon dilatation in those with and without middle-ear disease. Further research is warranted to better understand predictors of symptom improvement and the effect of middle-ear status on post-operative Eustachian Tube Dysfunction Questionnaire-7 scores.

Table 3. Statistical significance of mean Eustachian Tube Dysfunction Questionnaire-7 scores pre-operatively and six weeks, six months, and 12 months post-Eustachian tube balloon dilatation (ETBD); a two-tailed independent sample *t*-test was performed to calculate *p*-values and 95% confidence intervals

	Six weeks	Six months	12 months
Pre-ETBD	$P = 0.000003$ * (95% CI: 1.4–2.9)	$P = 0.02$ * (95% CI: 0.3–2.9)	$P = 0.000007$ * (95% CI: 1.3–2.8)
Six weeks		$P = 0.37$ (95% CI: −1.9 to +0.8)	$P = 0.76$ (95% CI: −0.9 to +0.7)
Six months			$P = 0.48$ (95% CI: −0.9 to +1.8)

*Statistically significant, $p < 0.05$

No patients in our study had tympanic membrane retraction. One patient (6.7 per cent) had a sustained type C tympanogram, pre- and post-Eustachian tube balloon dilatation. The remaining 93.3 per cent of participants, with no objective evidence of negative middle-ear pressure, all had statistically significant improvements in Eustachian Tube Dysfunction Questionnaire-7 scores post-operatively. These findings are consistent with current studies and underline the idea that symptomatic dilatory Eustachian tube dysfunction can be treated with balloon dilatation, regardless of normal tympanometry or otoscopic examination.[13]

Using conventional interpretation where type A tympanograms are −100 to +25 daPa, type B tympanograms have no peak pressure and type C tympanograms are less than −100 daPa, tympanometry may lead to underdiagnosis of Eustachian tube dysfunction.[19] Additionally, the test may be unreliable when used to monitor the efficacy of Eustachian

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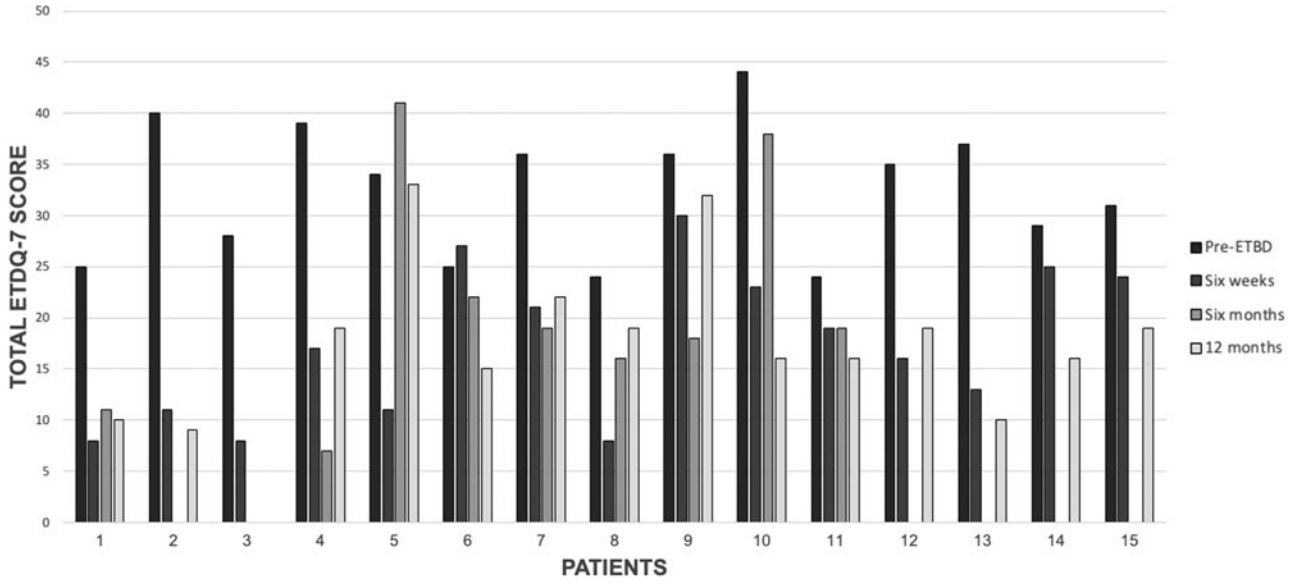

Figure 3. Patients' total Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7)scores pre-Eustachian tube balloon dilatation and six weeks, six months, and 12 months post procedure.

Table 4. Progression of patients unable to Valsalva pre-operatively at six weeks, six months, and 12 months post-Eustachian tube balloon dilatation; No = unable to Valsalva; Yes = able to Valsalva; DNA = did not attend follow up

Patients	Pre-operative	Six weeks	Six months	12 months
Patient 3	No	Yes	DNA	DNA
Patient 9	No	Yes	Yes	No
Patient 10	No	Yes	Yes	Yes
Patient 14	No	Yes	DNA	Yes

Table 5. Progression of abnormal pure tone audiometry results pre-operatively and six weeks, six months, and 12 months post-Eustachian tube balloon dilatation; CHL = conductive hearing loss, SNHL = sensorineural hearing loss, DNA = did not attend follow-up; †had upper respiratory tract infection at 12 months follow up; ‡developed inner-ear hydrops at six months follow up; *Patient 2 and Patient 9 did not complete pure tone audiometry at 12 months

Patients	Pre-operative	Six weeks	Six Months	12 months
Patient 2*	SNHL	SNHL	DNA	—
Patient 4†	SNHL	SNHL	SNHL	SNHL
Patient 5‡	SNHL	Normal	SNHL	SNHL
Patient 9*	SNHL	SNHL	SNHL	—

tube balloon dilatation or identify patients that may benefit from the procedure.[11,14,18–21] Although our data suggest Eustachian tube balloon dilatation may be performed on the sole basis of subjective measures, caution must be taken as this approach could greatly expand the number of surgical candidates. It is likely that a combination of subjective and objective measures is optimal to determine eligibility for Eustachian tube balloon dilatation and ongoing assessment of disease progression.

Several balloon catheter devices exist for dilatation of the Eustachian tube. These include the XprESS ENT Dilation System, the Bielefield system (Spiggle and Theis, Overath, Germany) and the Aera balloon catheter (Acclarent, Irvine, California USA). Variations exist amongst devices and surgical techniques, such as balloon sizes, inflation pressures, duration of inflation and the angle of catheter insertion.[8,11,22] For example, a prospective analysis of Eustachian tube balloon dilatation by Poe *et al.* used a shorter catheter (16 mm vs 18 mm) and inflated the device for less time (1 minute *vs* 2 minutes) in comparison to our approach.[23] The subtle differences in operative techniques and device characteristics may play a significant role when evaluating Eustachian tube balloon dilatation efficacy, however, this role is yet to be studied.

Current literature emphasises that care must be taken to avoid catheter advancement into the bony Eustachian tube, in order to minimise the risk of carotid artery injury on balloon inflation.[24] In our study, the dilation device was bent at the 20 mm mark for Eustachian tube access, preventing overly deep catheter insertion. Serious, albeit rare complications, such as carotid artery dissection and stroke, surgical emphysema, and the development of patulous Eustachian tube dysfunction, following Eustachian tube balloon dilatation have been reported in the literature.[25]

- Studies evaluating the efficacy of Eustachian tube balloon dilatation for treatment of Eustachian tube dysfunction often enrol patients with concurrent middle-ear disease
- Recently published consensus statements have concluded that the diagnosis of Eustachian tube dysfunction requires patient-reported symptoms along with objective evidence of negative middle-ear pressure
- Data from this prospective study, which enrolled patients with symptoms of dilatory Eustachian tube dysfunction in the absence of middle-ear disease, demonstrate the efficacy of Eustachian tube balloon dilatation in improving subjective Eustachian tube dysfunction symptoms in patients without middle-ear disease
- Findings demonstrate that patients who did not meet diagnostic criteria for Eustachian tube dysfunction, due to the lack of evidence for negative middle-ear pressures, still benefited from Eustachian tube balloon dilatation

There are some limitations to this study. Given our small sample size and short-term follow up, further research is warranted to investigate long-term Eustachian tube balloon dilatation outcomes in larger Australian cohorts. Our post-operative data must be interpreted with caution as the Eustachian Tube

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Dysfunction Questionnaire-7 solely relies on subjective measures, which are difficult to validate against objective post-Eustachian tube balloon dilatation tests. The development of inner-ear hydrops and upper respiratory tract infection in patients during the follow-up period likely confounded the interpretation of pure tone audiometry results. Additionally, patients were free to use medical interventions (such as intranasal corticosteroids) following Eustachian tube balloon dilatation. Although these interventions have a limited role in Eustachian tube dysfunction management, this may have confounded study data.[6,7] Nevertheless, this study's prospective design had the advantage of longitudinally tracking changes in each patient's subjective and objective measures post-operatively.

Conclusion

For the first year post-operatively, Eustachian tube balloon dilatation may be a safe and effective procedure to treat dilatory Eustachian tube dysfunction symptoms in patients without middle-ear disease. Although a strict diagnosis of dilatory Eustachian tube dysfunction requires objective evidence of negative middle-ear pressures, Eustachian tube balloon dilatation may improve subjective symptom control in patients with normal tympanometry and otoscopic examination.[4,12]

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Competing interests. The authors declare none.

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