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OTOLARYNGOLOGY HEAD AND NECK SURGERY

Royal Australasian College of Surgeons

Balloon dilation eustachian tuboplasty for dilatory dysfunction: Safety and efficacy analysis in an Australian cohort

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Key words

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Abstract

Background: Eustachian tube dysfunction (ETD) is a common clinical condition encountered by otolaryngologists. The severity and duration of symptoms range from the mild and transient to the chronic and severe along with secondary pathologies. Balloon dilation eustachian tuboplasty (BDET) as a treatment, was first described in 2010 and has been studied extensively. This study evaluates the efficacy and safety of BDET in an Australian cohort.

Methods: Retrospective chart review on all patients who underwent BDET from September 2016 to March 2020 was performed. The Eustachian Tube Dysfunction Patient Questionnaire (ETDQ-7) was chosen as the primary outcome measure. Secondary outcome measures included subjective global assessment of presenting symptoms, ability to perform Valsalva maneuver and tympanometry. Any complications related to the procedures were reported.

Results: One hundred and nineteen eustachian tube operations were included in this study. The patient cohort showed statistically significant improvement of mean EDTQ-7 score from 0.7 to 2.9. Improvement in EDTQ-7 was achieved in 83.9% of the cases. All patients in the baro-challenge-induced subgroup achieved improvement in ETDQ-7 score. Complete resolution of symptoms with an ETDQ <2.1 was achieved in 37.1% of the cohort. There were no adverse safety events associated with the procedures.

Conclusion: BDET resulted in improvement of the EDTQ-7 score in most of patients in this Australian cohort with no reported complications. BDET was most successful in baro-challenge-induced subgroup with universal improvement. Lower success rates were seen in patients with secondary pathology from their ETD.

Introduction

Eustachian tube dysfunction (ETD) is a common clinical condition encountered by otolaryngologists with an estimated 1% prevalence[1] and significant associated healthcare burden.[2] Patients present with a myriad of symptoms that may include aural fullness, discomfort, pain, pressure, underwater sensation, crackling, popping of the ear, autophony, and muffled hearing. Presenting symptoms also vary in severity and duration. A consensus statement has been established to provide a framework for the definition, clinical presentation, and diagnosis of ETD.[3]

The majority of patients suffer from dilatory ETD with impaired ability to ventilate the middle ear and mastoid. Otologic pathologies, including otitis media with effusion, tympanic membrane retraction, atelectasis, perforation, and cholesteatoma formation, are thought to be all associated with chronic ETD.[4] A smaller group of patients affected by baro-challenge-induced ETD suffer from transient symptoms related to the ETD under conditions with altered ambient pressure. Baro-challenged patients have symptoms that are mostly short-lived and associated with intense pain, rather than aural pressure. In contrast, patulous ETD is caused by abnormally patent eustachian tube. The pathophysiology and treatment of patulous ETD is distinct from dilatory ETD. For the purpose of this work, patients with patulous ETD were excluded and ETD henceforth only refers to those with dilatory dysfunction.

Numerous treatments are available for ETD.[5] Medical management with nasal decongestants, antihistamines, and nasal topical steroids[6] have not shown any conclusive treatment benefit. Myringotomy with and without insertion of ventilation tubes as well as adenoidectomy are commonly performed adjunctive surgeries.[7] Tuboplasties using laser[8] or microdebrider[9] have undergone preliminary investigative studies. Balloon dilatation eustachian tuboplasty (BDET) was first described in 2010,[10,11] and its use has been investigated by randomized control trials[12–15] and clinical studies.[10,11,16–19] In addition, a clinical consensus statement[20] and a National Institute for Health and Care Excellence guideline[21] have been published on this procedure. The efficacy and safety of this procedure continue to be vigorously studied and is an area of active research.

Eustachian balloon dilation systems have been approved by the Therapeutic Goods Administration under the Australian Department of Health since 2016. This study aims to assess the safety and efficacy profile of BDET in an Australian population.

Methods

Study design

Research board approval (2019/ETH12264) was obtained from the NSW Health Northern Sydney Area. A retrospective case note analysis from a prospectively gathered database was performed for all patients undergoing BDET from 2016 to March 2020. Only cases with follow-up period between 6 months and 2 years were included in this study. All operations were performed by four senior surgeons. Patients were subcategorised into three groups, based on their presentation: (1) Baro-challenge-induced ETD, with cardinal symptoms of pain and discomfort when flying or diving; (2) Chronic ETD, defined as a constant constellation of symptoms of ETD for more than 3 months, including isolated middle ear effusion or type C tympanogram; (3) Secondary pathology related to ETD, including tympanic membrane retraction pocket or perforation, chronic suppurative otitis media, and cholesteatoma.[4]

Balloon dilatation procedures

All patients underwent BDET using the Spiggle & Theiss (Overath, Germany) TubaVent Short balloons with 45 or 70° single-use TubaInsert introducers. All procedures were performed under general anesthesia. Rigid endoscopy was used for visualization of the nasal cavity, nasopharynx, and the eustachian tube orifices. In cases of bilateral dilatation, a single balloon catheter was used for both sides with more symptomatic side performed first.

Primary outcome measures

The primary outcome metric used to gauge the effectiveness of BDET was the Eustachian Tube Dysfunction Patient Questionnaire (ETDQ-7).[22] The ETDQ-7 is a validated quality of life instrument used in the study of ETD. It has become a common metric for ETD research due to its high sensitivity and specificity.[23] The ETDQ-7 score ranges from 1 to 7 with a score of greater than or equal to 2.1 as significant. In this study, complete success was defined as normalization of ETDQ-7 with a post-operative score of less than 2.1. Partial success was defined as the improvement of ETDQ-7 score after the intervention albeit with post-operative value greater than or equal to 2.1.

The primary safety endpoint was the complications related to the BDET operations in this clinical series.

Secondary outcome measures

Secondary outcomes included patient subjective global assessment of presenting symptoms, ability to perform Valsalva maneuver and tympanometry. The ability to perform Valsalva maneuver was assessed both pre- and post-operatively and quantified by otoscopic examinations. Improvement of tympanometry was characterized as either type C to A or type B to C/A configurations. The selection of the secondary outcome measures was supported by the published consensus statement on BDET and its research.[20]

Results

Patient population

There were a total of 62 patients with 96 eustachian tubes. The age of the patients ranged from 16 to 78 years, with mean and median age of 47.3 and 50 years respectively. The mean and median - follow-up durations were 10 and 7.2 months, respectively. The most common indication was chronic ETD (62.5%), followed by pathology secondary to ETD (20.3%) and baro-challenge-induced ETD (17.2%).

Primary outcome measures

Improvement of ETDQ-7 score after BDET was observed in 83.9% of the cases. This is illustrated in Figure 1. Complete success (improved post-operative ETDQ-7 < 2.1) and partial success (improved post-operative ETDQ-7 ≥ 2.1) were observed in 37.1% and 46.8% of the cohort, respectively. There were two cases (3.2%) with no change in ETDQ-7 score while eight cases (12.9%) resulted in worsening of the ETDQ-7 score. For the entire cohort, the mean ETDQ-7 score decreased from 4.7 to 2.9 after the BDET procedure ($p < 0.01$). All patients within the baro-challenge-induced ETD subgroup achieved improvement in their ETDQ-7 scores after surgeries, with 60.0% of patients in this subgroup achieving complete success. The chronic ETD subgroup achieved improvement in 85.0% of cases, with 30.0% complete success rate. The pathology secondary to ETD subgroup showed improvements in 71.4% of cases with a 35.7% complete success rate.

Safety outcome from all the 96 BDET procedures showed no major complications related to the surgeries. There was one case of dehiscent carotid artery identified on computed tomography (CT) and only unilateral BDET on the non-dehiscent side was performed. This illustrated the importance of pre-operative CT imaging to identify dehiscent carotid artery in preventing complication from the procedure.[20,24] One patient developed transient ischemic attack 5 days after the procedure. This was promptly and thoroughly investigated, and the event was deemed unrelated to the operation. The patient fully recovered with no sequelae.

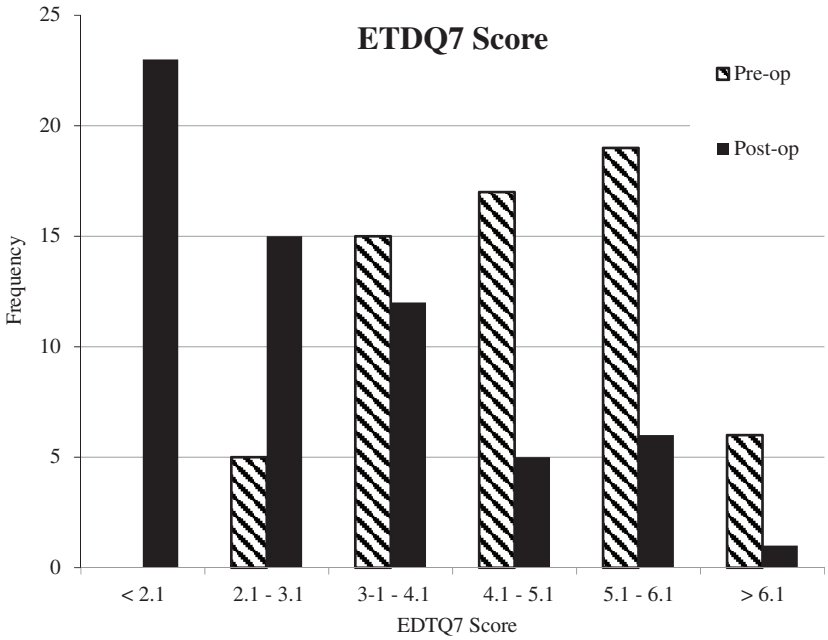

Fig. 1. Pre- and post-operative comparison of ETDQ-7 scores.

Table 1 Summary of outcomes: percentage of cases showing improvement in ETDQ-7, subjective symptom, positive Valsalva maneuver, and tympanometry

	Primary outcome	Secondary outcomes			
	Improvement of ETDQ-7 (%)	Improvement of subjective symptom (%)	Positive Valsalva maneuver (%)	Tympanometry (%)	
				Improvement	Unchanged type A
Overall cohort	83.9	70.5	70.7	47.6	12.2
Baro-challenge-induced ETD	100.0	100.0	100.0	12.5	87.5
Chronic ETD	85.0	70.0	66.7	48.4	8.1
Pathology secondary to ETD	71.4	53.8	61.5	52.9	0.0

Secondary outcome measures

Secondary outcomes included patient subjective overall symptom improvement, ability to perform Valsalva maneuver during physical examination and tympanometry measurements. The results are summarized in Table 1. Seventy percent of the 62 cases resulted in improvement of subjective overall symptom after the BDET procedure. Positive Valsalva maneuver was observed in 70.7% of the cases after surgery. Of note, only 19.0% of the patients was observed to have positive Valsalva maneuver pre-operative, including a few with sluggish response. Of the 82 tympanometry measurements, 47.6% noted improvement. Twelve percent of tympanometry measurements showed unchanged pre- and post-operative type A tympanometry.

The results were also analyzed based on the indication subgroups. Patients within the baro-challenge-induced ETD subgroup achieved the most benefit with 100% improvement of subjective sense of improvement, and ability to perform Valsalva maneuver. Among these patients, 87.5% maintained their type A while 12.5% showed improvement in tympanometry (from Type B to C or Type C to A) at follow-up. The results for the chronic ETD subgroup approximated the outcome of the overall patient population across secondary metrics. The pathology secondary to ETD subgroup showed inferior outcomes with only 53.8% reported improvement in subjective symptoms, 61.5% able to perform Valsalva maneuver, and 52.9% having improved tympanometry.

Discussion

Overall results

This retrospective study encompasses the surgical outcomes of multiple surgeons in an Australian cohort. The result of this study showed that BDET may be an effective treatment for patients presenting with symptoms associated with ETD, with over 83.9% of the patients achieved improvement of their ETDQ-7 scores. The mean ETDQ-7 score decreased from 4.7 to 2.9 after the BDET procedures, with statistical significance. Complete symptom resolution occurred in 37% of patients with a post-operative ETDQ-7 score of less than 2.1. The proportion of patients with improvement of ETDQ-7 score as well as the degree of ETDQ-7 improvement was consistent with published studies.[12,13,16–19,25]

Preoperative assessment

As for other surgical procedures, careful patient selection for surgery is paramount for BDET. In this study, all patients had undergone detailed clinical history and physical examination as well as other adjunctive investigative assessments prior to being deemed a surgical candidate. The physical examination included otoscopy/otomicroscopy/otoendoscopy with attempt at Valsalva maneuver, nasopharyngoscopy, and a complete ENT examination. In addition, pure tone audiometry and tympanometry were also used to objectively quantify the patient's pre-operative hearing and middle ear ventilation status. This battery of preoperative assessment is supported by the published consensus statement.[3] All patients also underwent pre-operative high-resolution CT imaging to investigate for possible contraindications to the procedure such as dehiscent carotid artery or space-occupying lesion in the skull base. High-resolution CT is also used to excluded differential diagnoses such as otic capsule dehiscence (third window phenomena) and temporomandibular joint pathologies.[26]

Safety of BDET

There were no complications related to the procedure in this study, in keeping with published series.[11–13,17,27] A recent systematic review of the safety profile of BDET comprising of the data from 1928 procedures spanning 14 studies estimated the major complication rate of 0.3% due to failure of the balloon. The minor complication rate was estimated to be 1.7%.[28]

In this study, there was one patient with unilateral dehiscent carotid artery identified in pre-operative high-resolution CT imaging. The side with the dehiscent carotid artery did not undergo BDET. As outlined in the clinical consensus statement on BDET, a dehiscent carotid artery is a relative contraindication to BDET procedure without a depth marker that demarcates insertion limited to the cartilaginous eustachian tube.[20,24]

Stratified success rates

Symptoms of ETD in this cohort were wide ranging and with varying degrees of severity, this is consistent with the published consensus statement guidelines.[3] The inclusion criteria for this study were intentionally broad in order to understand the efficacy of BDET in real-life clinical scenarios among this complex group of patients. By stratifying patients into different indication subgroups based on their relevant clinical history and physical exam findings, this study showed that BDET had varying level of success among these groups of patients. This is useful for providing patients with realistic expectation during informed consent discussion. This study suggests that patients with baro-challenged-induced ETD can achieve good results from the procedure. This finding is consistent with other published series involving the clinical results of BDET in SCUBA divers and military divers and aviators.[29,30]

The results from the subgroup of patients with prolonged ETD accompanied by secondary changes in the middle ear were less likely to exhibit improved ETDQ-7 scores. Biomechanical and histopathological studies have shown that mucosal tearing and cartilage cracking[31] along with reduction of inflammatory epithelial changes and submucosal inflammatory infiltrate[32] to be responsible for the improvement of eustachian tube function after BDET. While it is possible that prolonged or severe cases of ETD may not be as amenable to these therapeutic effects of BDET, study by Si et al. has shown that patients with adhesive otitis media that underwent BDET with or without cartilage tympanoplasty have improved eustachian tube score compared to those in the control group or cartilage tympanoplasty alone.[33] In addition, it is important to note that BDET has resulted in positive effect on the baro-challenge-induced group, whose perception of outcome was not confounded by any middle ear pathology. Therefore, it is reasonable to posit that some benefits were being imparted on the patients with middle ear pathology, but their ETDQ-7 scores were confounded by their concurrent otologic disease or interventions. This highlights the need for more vigorous study in this subgroup of patients with prolonged ETD accompanied by secondary changes in the middle ear.

Unchanged or worsening ETDQ-7

Further analysis of 11 cases that did not result in improvement of ETDQ-7 score was performed. Two cases (3.2%) resulted in no change in ETDQ-7 score while nine cases (12.9%) resulted in worsening of the ETDQ-7 score. However, the deterioration in EDTQ-7 score was minimal with the mean pre-operative ETDQ-7 score of 4.3 and mean post-operative score of 4.8. Six of the patients were in the chronic ETD group, with the remaining four patients in the pathology secondary to ETD group. One patient underwent further revision BDET and achieved improvement in ETDQ-7 score after the second surgery. The worsening of ETDQ7 scores may indicate that the ETDQ7 is not the correct instrument to evaluate patients with ETD and associated secondary pathology.

Weaknesses of the study

The retrospective nature of this study and lack of control group or blinding was suspectable to bias. The subjective nature of ETDQ-7 and voiced improvement by the patient is also susceptible to placebo bias. The inclusion of patients undergoing concurrent procedures introduced considerable potential source of confounder. However, the authors felt that the benefit of understanding the impact of concurrent surgeries on an Australian population justifies the broader inclusion criteria, which would more closely reflect real-life clinical scenarios.

Conclusion

In conclusion, BDET appears to have significant improvement on the quality of life of patients with ETD, with a low side-effect profile. Baro-challenge-induced and classic dilatory ETD patients demonstrate the most success. The role of BDET in patients with pathology secondary to ETD is less clear and is not well investigated by the ETDQ-7 score alone.

Conflict of interest

None declared.

Author contributions

Horace Cheng: Conceptualization; data curation; formal analysis; investigation; project administration; software; writing-original draft. **Alexander Saxby:** Conceptualization; data curation; methodology; supervision; writing-review & editing. **Nicholas Jufas:** Data curation; methodology; writing-review & editing. **Jonathan Kong:** Data curation; supervision; writing-review & editing. **Nirmal Patel:** Conceptualization; data curation; methodology; supervision; writing-review & editing.

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