Balloon Dilation of the Eustachian Tube

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DESCRIPTION

Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure is frequently due to inflammation and can cause symptoms such as muffled hearing, ear fullness, tinnitus, and vertigo. Chronic obstructive ETD can lead to hearing loss, otitis media, tympanic membrane perforation, and cholesteatomas. Balloon dilation of the eustachian tube (BDET) is a procedure intended to improve patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation.

The eustachian tube connects the middle ear space to the nasopharynx. It ventilates the middle ear space to equalize pressure across the tympanic membrane, clears mucociliary secretions, and protects the middle ear from infection and reflux of nasopharyngeal contents. Normally, the tube is closed or collapsed and opens during swallowing, sneezing or yawning. Eustachian tube dysfunction (ETD) occurs when the functional valve of the eustachian tube fails to open and/or close properly. This failure

may be due to inflammation or anatomic abnormalities. Symptoms of chronic obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia. In milder cases, ETD may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions.

Because the symptoms of ETD are nonspecific, clinical practice guidelines emphasize the importance of ruling out other causes of ETD with a comprehensive diagnostic assessment that includes patient-report questionnaires, history and physical exam, tympanometry, nasal endoscopy, and audiometry to establish a diagnosis.

Medical management of ETD is directed by the underlying etiology. Treatment of identified underlying conditions, such as systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; or treatment of mass lesions, may be useful in resolving ETD.

Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes or eustachian tuboplasty. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the eustachian tube. Surgery may be associated with adverse events such as infection, perforation, and otorrhea. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon dilation is a tuboplasty procedure intended to improve the patency of the cartilaginous eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less, after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Balloon dilation of the eustachian tube can be done as a standalone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g., septoplasty, turbinate procedures or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with or without tympanostomy tube placement. This evidence review addresses balloon dilation of the eustachian tube as a standalone procedure.

Balloon Dilation for Chronic Obstructive Eustachian Tube Dysfunction

Clinical Context and Therapy Purpose
The purpose of balloon dilation of the eustachian tube (BDET) is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with chronic obstructive eustachian tube dysfunction (ETD) despite medical management.

Populations
The relevant population of interest is individuals with chronic obstructive ETD despite medical management.

Eustachian tube dysfunction occurs when the functional valve of the eustachian tube fails to open and/or close properly, frequently due to inflammation. Symptoms may include ear fullness, recurrent barochallenge (difficulty clearing the ears with changes in ambient pressure), hearing loss, otalgia, and tinnitus.

Interventions
The therapy being considered is BDET.

Balloon dilation of the eustachian tube is a procedure intended to improve the patency by inflating a balloon in the cartilaginous part of the eustachian tube to cause local dilation. During the procedure, a saline-filled balloon catheter is introduced into the eustachian tube through the nose using a minimally invasive transnasal endoscopic method. Pressure is maintained for 2 minutes or less after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Comparators
Medical Management of ETD is directed by the underlying etiology: treatment of viral or bacterial rhinosinusitis; systemic decongestants, antihistamines, or nasal steroid sprays for allergic rhinitis; behavioral modifications and/or proton pump inhibitors for laryngopharyngeal reflux; and treatment of mass lesions. Treating underlying conditions, if identified, may be useful in resolving ETD. Patients who continue to have symptoms following medical management may be treated with surgery such as myringotomy with the placement of tympanostomy tubes, methods of eustachian tube dilation other than balloon dilation, or mechanical pressure equalization devices.

Outcomes
The general outcomes of interest are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. Specific outcome measures are described in the below table. Initial follow up examinations are typically done at 4 to 6 weeks to judge early efficacy. Follow-up should be at least 1 year to appropriately establish a clinically meaningful improvement.

Outcome Measure	Description	MCID, if Known
Eustachian Tube Dysfunction Questionnaire (ETDQ-7)	Validated, standardized, 7-item patient-reported questionnaire to assess symptom severity associated with ETD. Pressure, pain, feeling clogged, cold/sinusitis problems, crackling/popping, ringing, and muffled hearing. Patients rate the severity of 7 symptoms on a scale ranging from 1 (no problem) to 7 (severe problem). Dividing the total score by 7 yields the mean item score. A total score of ≥14.5 and mean item score of ≥2.1 indicate ETD Scores in the range of 1 to 2 indicate no to mild symptoms, 3 to 5 moderate symptoms, and 6 to 7 severe symptoms.	0.5 point improvement Normalization is defined as a mean item score <2.1 or a total score <14.5
Valsava maneuver	Patient breathes out while closing the nose and mouth to direct air to the eustachian tube and help them open. Modified: gentle nose blow with simultaneous swallow	Positive (ability to perform the maneuver when needed) Negative (unable to perform the maneuver)
Tympanometry	Measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak. Type A indicates normal middle ear and eustachian tube function; type B	Type A (normal)

	indicates poor tympanic membrane mobility (“flat” tympanogram), and type C indicates the presence of negative middle ear pressure.	
Otoscopy findings	Visual examination of the tympanic membrane using an otoscope. Classifies tympanic membrane as abnormal (retracted membrane, effusion, perforation, or any other abnormality identified on exam) or normal	Normal tympanic membrane

Review of Evidence

A 2022 annual review health technology assessment by Hayes was completed regarding eustachian tube balloon dilation (ETBD) for the treatment of chronic eustachian tube dysfunction in adults with a C rating (reflects an overall low-quality body of evidence that eustachian tube balloon dilation (ETBD) as a standalone procedure, or combined with medical management (MM), tympanoplasty (TP) or tympanic paracentesis (TPC)). While this technology assessment reported eustachian tube balloon dilation (ETBD) for the treatment of chronic eustachian tube dysfunction (ETD) in adults refractory to medical management (MM) may be relatively safe and associated with improvement in health outcomes from pretreatment to post-treatment intervals, these improvements persisted only in the short to intermediate term; and may suggest similar benefits compared with standard care including MM, TP, or TPC, however, additional studies are needed to refine patient selection and confirm study conclusions.

In 2020, Chen et. al. reported the results of a retrospective non-randomized controlled trial involving 50 subjects with otitis media with effusion who had received myringotomy and tympanostomy tube placement in conjunction with Eustachian tube dilation (n=25) vs. those who received myringotomy and tympanostomy tube placement only (n=25). The method of selecting which subjects to study was not explained. Adenoidectomy was conducted in subjects found to have adenoid hypertrophy (n=16 in the balloon group and n=17 in the control group). The authors reported a statistically significant difference in air-bone gap between the two groups at 18 months, with mean differences of the balloon group lower (about 4 dB HL) vs. the control group (p=0.05). At 18 months the cure rate was 76.1 % for the balloon group vs. 60.9% in the controls (p=0.116), and total effective rates were 93.5% and 89.1%, respectively (p=0.71). No serious adverse events or complications were reported. While significant improvements in air-bone gap measurements at 18 months were reported, differences in cure rate and total effective rates were not. While these results are not totally supportive of the use of Eustachian tube

dilation, the study methodology has serious flaws that weaken the strength of the findings, including its small size, potential selection bias, retrospective design, and lack of randomization and blinding.

In 2020, Froehlich et. al. examined the effectiveness of eustachian tube balloon dilation for the treatment of eustachian tube dysfunction. A systematic review of eustachian tube balloon dilation for the treatment of eustachian tube dysfunction was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines to identify randomized control trials and prospective and retrospective studies published prior to January 31, 2019. Meta-analysis of proportions evaluated 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ7) scores, tympanometry, otoscopy findings, and the ability to perform a Valsalva maneuver. The systematic review identified 35 studies. Twelve studies met inclusion for meta-analysis (448 patients). Mean ETDQ7 scores decreased by 2.13 from baseline to 6 weeks (95% CI, -3.02 to -1.24; $P < .001$). From baseline to 6 weeks, 53.0% of patients had improvement in tympanograms ($P < .001$). At the long-term point (3-12 months), 50.5% of patients had improved tympanograms from baseline ($P < .001$). There was no significant difference in the proportion of improved tympanograms at 6 weeks compared to long term ($P = .535$). Normal otoscopy exams at baseline increased by 30.0% at 6 weeks ($P < .001$) and 55.4% in the long term ($P < .001$). There was a 67.8% increase in proportion of patients able to perform a Valsalva maneuver in the long term compared to baseline ($P < .001$). The authors concluded eustachian tube balloon dilation appears to be associated with improvement in subjective and objective treatment outcome metrics. The improvement appears stable at 3 to 12 months after dilation. Patients with eustachian tube dysfunction are likely to benefit from balloon dilation, particularly those with medication-refractory disease.

In 2019, Anand et. al. published the results of a 52-week continuation of the Poe study detailed above. This trial involved 136 subjects in the balloon dilation of the eustachian tube (BDET) group, 73 control subjects, and 74 of the lead-in period subjects. At 52 weeks, the authors reported that the number of BDET-group subjects maintaining normalized tympanograms and normalized ETDQ-7 scores remained unchanged from the 6-week time point (tympanograms: 51.0% vs. 55.5%, ETDQ=7 scores: 57% vs. 63.6%). No device-related adverse events were reported.

In 2019, Cutler et.al. published the results of a follow-up study of the experimental arm of the trial reported by Meyer et. al. in 2019. Out of the 49 subjects completing the initial 12-month study, 47 were included in this follow-up study. Of the total study population, 93.6% were of Caucasian ethnicity. The mean follow-up for all participants was 29.4 months (range 18-42 months). Overall, ETDQ-7 scores were significantly reduced from a mean of 4.5 at baseline to 2.0 at last measured timepoint ($p<0.0001$). Additionally, each individual component of the ETDQ-7 tool was likewise significantly improved ($p<0.0001$ for all). Only 1 subject underwent repeat dilation procedure concurrently with FESS for rhinosinusitis. The ability to clear the ears with the Valsalva maneuver increased from 28.3% to 73.9% ($p<0.0001$). Type A tympanograms also increased from 70% to 86.3% ($p=0.005$). In subjects with abnormal middle ear assessments at baseline, tympanic

membrane position was normalized in 76% ($p<0.0001$), Valsalva maneuver response was positive ($p<0.0001$), and normalization of tympanograms occurred in 62.5% ($p<0.001$). These results, which equate to a long-term cohort study, indicate significant improvements with the use of Eustachian tube dilation. However, the small size of the study, limited diversity, lack of blinding, and other methodological flaws weaken the generalizability of these results

In 2019, Meyer et. al. reported the results of a prospective randomized controlled trial (RCT) involving 60 subjects with eustachian tube dysfunction undergoing treatment with either balloon dilation (n=31) or medical therapy (n=29). Subjects were followed for 1 year, but after 6 weeks, control participants had the option to undergo balloon dilation if symptoms persisted. Twenty-three control group subjects underwent balloon dilation treatment and continued through the remainder of the 12-month trial, resulting in 49 total subjects completing the trial. No adverse events were reported in either group. Among subjects with abnormal baseline assessments, improvements in tympanogram type ($p<0.006$) and tympanic membrane position ($p<0.001$) were significantly better for the balloon dilation group than for the control group. The authors reported that technical success was 100% (91 successful dilations/91 attempts) and most procedures (72%) were completed in the office under local anesthesia. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. This study included multiple methodological flaws, including no attempt to blind the participants as to which treatment they received, allowing crossover at 6 weeks, and including a small subject pool. Additional investigation is warranted with larger, more robust trials.

In 2019, Yin et.al. reported outcomes of balloon dilation Eustachian tuboplasty (BDET) combined with tympanostomy tube insertion and middle ear pressure equalization therapy in treatment of recurrent secretory otitis media. Methods Fifty-one patients with recurrent secretory otitis media (62 ears) underwent balloon dilation of Eustachian tube and tympanic tube insertion under general anesthesia, followed by long term middle ear pressure equalization therapies. The Eustachian tube score (ETS) and Eustachian tube function questionnaire (ETDQ-7) were used for pre- and postoperative (up to 12 months) evaluation of Eustachian tube functions. Results The mean ETS score was 2.34 ± 0.97 preoperatively, and 6.17 ± 1.54, 7.23 ± 1.62, 8.24 ± 1.97, and 7.63 ± 1.86 at 1, 3, 6 and 12 months postoperatively, respectively ($P < 0.05$). The ETDQ-7 score was 4.82 ± 1.07 preoperatively, and 2.20 ± 0.54, 2.32 ± 0.68, 2.53 ± 0.79, and 2.67 ± 0.76 at 1, 3, 6 and 12 months postoperatively, respectively ($P < 0.05$). The authors concluded although our study has shown that middle ear alternating pressure therapy following BDET and TTI is effective, because of the small sample size and short follow-up time, it is difficult to accurately explain the mechanisms. Long-term prospective studies with large sample sizes are needed to further evaluate the safety and efficacy of this treatment and determine whether other more effective treatment models exist.

In 2019 Yu et. al. investigated the simultaneous application of cartilage tympanoplasty combined with eustachian tube (ET) balloon dilatation in the treatment of adhesive otitis media (AdOM). The study design was a multicenter, prospective, double-blind, randomized, controlled clinical trial. Patients with AdOM were randomly divided into

four groups: control group (conservative treatment), ET balloon dilatation (ETBD) group, cartilage tympanoplasty (CT) group, and cartilage tympanoplasty combined with ET balloon dilatation (ETBD+CT) group. Patients were followed up at 3 months, 6 months, 1 year, and 2 years after treatment, receiving otoendoscopy and pure-tone audiometry, and were evaluated using the Tinnitus Handicap Inventory (THI), visual analogue scale (VAS) for the symptom of ear stuffiness, Chronic Otitis Media Outcome Test (COMOT-15), and eustachian tube scores (ETS). There was no improvement in tympanic membrane (TM) morphology and mean pure-tone air-bone gap (ABG) after treatment in the control and ETBD groups. The postoperative TM morphology was improved in the CT group and ETBD+CT group, although retraction pockets reoccurred in two cases of CT group. Reduced ABG and improvements in ETS, THI, VAS, and COMOT-15 were all achieved in these two groups, but the difference was not statistically significant.

UpToDate October 2019, discussed the pathophysiology, evaluation, and treatment of Eustachian tube dysfunction. The treatment of eustachian tube dysfunction should be directed at the underlying etiology, if known, and any associated complications. The choice of management strategies for isolated eustachian tube dysfunction remains controversial as randomized trial data are limited, study outcomes vary widely between studies, and much of what is known about the treatment of Eustachian tube dysfunction comes from animal rather than human studies. Surgery is generally indicated when medical management of obstructive Eustachian tube dysfunction fails. Balloon dilation of the Eustachian tube (BDET) is a newer tuboplasty technology used to increase the patency of the cartilaginous eustachian tube and reduce inflammation. A balloon catheter is used to dilate the cartilaginous portion through a minimally invasive transnasal endoscopic approach. In two systematic reviews, BDET was found to be safe with evidence of benefit, but all of the studies were retrospective case series with varied indications and outcome measures. Initial clinical trials were promising, and subsequent trials have demonstrated efficacy of BDET in adults. As an example, in a 2016 randomized trial of 323 adult patients with obstructive Eustachian tube dysfunction, more patients treated with BDET plus medical therapy demonstrated normal tympanograms than those treated with medical therapy alone (54 versus 14 percent); these results were sustained at 52 weeks [55,56]. In addition, BDET may also have a role in the management of children with Eustachian tube dysfunction who have failed previous tympanoplasty.

In 2018, Meyer et. al. compared eustachian tube balloon dilation versus continued medical therapy (control) for treating persistent eustachian tube dysfunction (ETD) in a prospective, multicenter, randomized controlled trial. Patients were diagnosed with medically refractory persistent eustachian tube dysfunction (ETD). 1:1 Randomization to balloon dilation or control. After 6 weeks, control participants had the option to undergo balloon dilation if symptoms persisted. Sixty participants were randomized (31 balloon dilation, 29 control). Mean (SD) change in overall ETDQ-7 score at 6 weeks was -2.9 (1.4) for balloon dilation compared with -0.6 (1.0) for control: balloon dilation was superior to control ($p < 0.0001$). No complications were reported in either study arm. Among participants with abnormal baseline assessments, improvements in tympanogram

type ($p < 0.006$) and tympanic membrane position ($p < 0.001$) were significantly better for balloon dilation than control. Technical success was 100% (91 successful dilations/91 attempts) and most procedures (72%) were completed in the office under local anesthesia. Improvements in the ETDQ-7 scores were maintained through 12 months after balloon dilation. The authors concluded balloon dilation is a safe and effective treatment for persistent ETD. Based on improved ETDQ-7 scores, balloon dilation is superior to continued medical management for persistent ETD. Symptom improvement is durable through a minimum of 12 months. Procedures are well tolerated in the office setting under local anesthesia. A limitation of this study was the inability to blind the participants to their treatment. This can lead to the placebo effect, especially with patient-reported outcomes. However, since we also observed significant improvements in objective findings such as tympanometry, otoscopy, and Valsalva maneuver in the balloon dilation arm and not in the control arm, we believe that any placebo effect is minimal and that the improvements observed in the ETDQ-7 scores are reliable and indicate true symptom improvement. The physicians were also not blinded to the participant's treatment assignment.

In 2018, Schmitt et. al. reported on a medium-term assessment of eustachian tube function after balloon dilation. There is at present no consensus on the treatment of obstructive eustachian tube dysfunction. In case of failure of well-conducted drug and pressure therapy, some authors recommend balloon dilation; the present study aimed to assess the efficacy and safety of eustachian tube balloon dilation. A single-center retrospective study assessed clinical and tubomanometric results of Eustachian tube balloon dilation, complications and satisfaction in a consecutive series managed between June 2012 and February 2015. Indications were based on clinical and paraclinical signs of obstructive tube dysfunction despite well-conducted medical treatment. Forty-five procedures were performed in 38 patients. Improvement in clinical symptoms was assessed as 88%, 80% and 80% at respectively 2 months, 6 months, and > 1 year. Improved function on tubomanometry was observed in 81% of cases. The procedure was well tolerated, with a minor complications rate of only 4%. The authors concluded the present study reports results for the first French series of eustachian tube balloon dilation for recalcitrant obstructive tube dysfunction. In our experience, the technique was effective, well tolerated, with few and only minor side effects. Good patient selection seems essential to minimize failure. Diagnosis is based on a set of clinical factors backed up by objective examination, tubomanometry being especially contributive. Special care should be taken of factors associated with the Eustachian tube dysfunction, so as to avoid early symptom recurrence. The present results need validating at a higher level of evidence before balloon dilation can be positioned with certainty in the otologic armamentarium.

In 2017, Poe et, al. reported the results of a study involving 323 subjects (462 ears) with persistent eustachian tube dilatory dysfunction, refractory to medical management with daily intranasal steroids or a single course of oral steroids. A pool of 81 subjects were involved in a lead-in population which were used to acclimate the investigators to the study procedure. The remaining subjects were randomized in a 2:1 manner to undergo treatment with balloon dilation of the eustachian tube (BDET) with concurrent medical

management (n=162, with 100 [61.7%] completing study) or continued medical management (n=80, with 71 [88.8%] completing the study). The condition was confirmed by tympanometry, the Eustachian Tube Dysfunction Questionnaire-7 symptom scoring tool (ETDQ-7) and nasal endoscopy. Subjects were allowed to continue concomitant use of other medications to treat sinus or nasal conditions as deemed medically necessary. Follow-up continued to 24 weeks. However, continuation of medical therapy was at the discretion of the investigator after 6 weeks and control subjects were permitted to cross over to the BDET group after 6 weeks and followed through 12 weeks. A majority of subjects in the control arm, while completing the 6-week follow-up, crossed over to the BDET group before the 12-week follow-up (82%, 59/71). At the 6-week follow-up, significantly more BDET group subjects had normal tympanograms (51.8% vs. 13.9%, $p<0.0001$). At 24 weeks, tympanogram normalization was 62.2% in the BDET group. No comparison to the controls was possible at this time point due to the high number of crossovers. Worsening of tympanograms was noted in 4% of BDET subjects and 5.7% of controls (no p-value provided). Improvement in the ETDQ-7 was significantly greater in the BDET group versus controls at 6 weeks (56.2% vs. 8.5%, $p<0.001$). The number of subjects with a positive modified Valsalva maneuver was better in the BDET group versus controls at 6 weeks (32.8% vs. 3.1%). No device- or procedure-related serious adverse events were reported. This study has several significant limitations, including lack of standardization of concomitant medications, significant loss to follow-up, and significant crossover before the 12-week mark. The results of this trial are questionable given these issues.

In 2017, Si et. al. conducted a double-blind randomized controlled trial (RCT) involving 120 subjects with adhesive otitis media (adOM) who were assigned to one of four groups: 1) conservative therapy, 2) balloon dilation of the eustachian tube (BDET), 3) cartilage tympanoplasty, or 4) combined BDET and cartilage tympanoplasty. There were 30 subjects in each group and the follow-up period was 2 years. No significant differences between the tympanoplasty alone and combined groups were noted. Both the tympanoplasty alone and combined groups had significant improvements in air-bone gap compared to controls ($p<0.1$), but no differences were found between these two groups. All three surgical groups had significant improvements in the Tinnitus Handicap Inventory vs. the control group ($p<0.05$). At both 1 and 2 years, the combined group had significant improvements vs. tympanoplasty alone ($p<0.05$). Results from the Chronic Otitis Media Outcome Score-15 (COMOT-15) indicated significant improvements in all surgical groups ($p<0.05$). The combined group had significantly higher scores vs. tympanoplasty alone ($p<0.05$). Eustachian tube scores (ETS) improved in both the BDET-only and combined groups vs. controls and vs. tympanoplasty alone ($p<0.05$ for both). No improvement in the tympanoplasty-alone group versus controls was reported.

In 2017, Skevas et. al. published the results of a meta-analysis assessing cervicofacial and mediastinal emphysema involving 3670 procedures in 2272 subjects treated with BDET at four centers across Europe. The ages ranged from 2 to 83 years. Postoperative emphysema developed in 7 subjects, limited to parotid region cheek and soft and hard palate. Another 3 developed emphysema of the soft tissues associated with

pneumomediastinum. The overall complication rate involving pneumomediastinum was reported as 0.27%.

Summary of Evidence
The current evidence has evaluated balloon dilation balloon dilation of the eustachian tube (BDET) as a standalone procedure, or combined with medical management (MM), tympanoplasty (TP) or tympanic paracentesis (TPC)).While the evidence may show some promise that the treatment of chronic eustachian tube dysfunction (ETD) refractory to medical management (MM) may be relatively safe and associated with improvement in health outcomes these improvements persisted only in the short to intermediate term. At this time there is insufficient evidence to support the safety and efficacy of balloon dilatation BDET for the treatment of conditions related to eustachian tube dysfunction (ETD). The available studies are either too small or have significant methodological flaws to provide reliable and generalizable results. Additional randomized controlled trials (RCTs) are needed to refine patient selection and confirm study conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Practice Guidelines and Position Statements

American Academy of Otolaryngology
In 2019, the American Academy of Otolaryngology published a clinical consensus statement on balloon dilation of the eustachian tube (BDET). The target population was defined as adults ages 18 years or older who are candidates for BDET because of obstructive eustachian tube dysfunction (ETD) in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded:

- BDET is an option for treatment of patients with obstructive ETD.
- The diagnosis of obstructive ETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy.
- BDET is contraindicated for patients diagnosed as having a patulous ETD
- Further study will be needed to refine patient selection and outcome assessment.

The authors emphasized the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux, and noted that medical management of these disorders is indicated prior to offering BDET. They also noted that potential risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD, and/or the need for additional procedures.

While this document may reflect the consensus opinion of medical experts, it is not annotated or supported by references to published evidence.

National Institute for Health and Clinical Excellence (NICE)
In 2019, the National Institute for Health and Clinical Excellence (NICE) issued a interventional procedure guidance that included the following:

- Evidence on the safety and efficacy of balloon dilation for eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

Committee Comments

- The committee noted that the procedure was not effective in all patients, and there was little evidence on the benefit of repeat procedures.
- The committee was informed that the procedure is only indicated for chronic eustachian tube dysfunction refractory to medical treatment.

Regulatory Status

Device	Manufacturer	Date Cleared	Indication
Acclarent Aera Eustachian Tube Balloon Dilation System	Acclarent, Inc.	01/16/2018	Eustachian tube dilation
Xpress ENT Dilation System	Entellus Medical, Inc.	04/05/2017	Eustachian tube dilation

In September 2016, the AERA® (Acclarent) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II, FDA product code: PNZ). The new classification applies to this device and substantially equivalent devices of this generic type. The AERA® is cleared for dilating the eustachian tube in patients ages 22 and older with persistent ETD.

In December 2016, the XprESS™ ENT Dilation System (Entellus Medical, Plymouth, MN) was cleared for marketing by the FDA through the 510(k) process (K163509). The FDA determined this device was substantially equivalent to existing devices for use in ETD. The predicate devices are XprESS™ Multi-Sinus Dilation System (K152434) and AERA® Eustachian Tube Balloon Dilation System.

PRIOR APPROVAL

Not applicable.

POLICY

The use of balloon dilation of the eustachian tube (BDET) including but not limited to the following is considered **investigational** for all indications, because the evidence is

insufficient to determine that the technology results in an improvement in the net health outcomes:

- Acclarent Aera Eustachian Tube Balloon Dilation System
- Xpress ENT Dilation System

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 69705 Nasopharyngoscopy, surgical, with dialation of eustachian tube (i.e., balloon dilation); unilateral
- 69706 Nasopharyngoscopy, surgical, with dialation of eustachian tube (i.e., balloon dilation); bilateral
- C1726 Catheter, balloon dilatation, nonvascular (may be utilized for balloon dilation of the eustachian tube [BDET]: Acclarent Aera Eustachian Tube Balloon Dilation System or Xpress ENT Dilation System)

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POLICY HISTORY

Date	Reason	Action
April 2022	Annual Review	Policy Revised
April 2021	Annual Review	Policy Revised
April 2020	Annual Review	Policy Revised
April 2019	Annual Review	Policy Revised
April 2018	Annual Review	Policy Revised
April 2017		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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