

Balloon Dilation of the Eustachian Tube

Policy MP-005

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.

Description:

Balloon dilation of the Eustachian tube is a tuboplasty procedure intended to improve the patency of the cartilaginous Eustachian tube. 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 approximately two minutes after which the balloon is emptied and removed. The procedure is usually performed under general anesthesia.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans does NOT cover balloon dilation of the eustachian tube as it is considered investigational/experimental for the treatment of any condition.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at

<http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)

3. Medicare Plans

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-

date Medicare policies and coverage, please visit their search website at:
<http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&> or [the manual website](#)

Clinical Rationale

Eustachian tube dysfunction (ETD) is a disorder for which symptoms are commonly treated with oral medications, nasal sprays, and placement of ear tubes. Recently, Eustachian tube balloon dilation has been proposed as a potential solution. Hwang et al, 2016 performed a systematic literature review. Abstracts were selected for relevance, and pooled data analysis and qualitative analysis was conducted. A total of 9 prospective studies, describing 713 Eustachian tube balloon dilations in 474 patients (aged 18 to 86 years), were identified. Follow-up duration ranged from 1.5 to 18 months. Ability to perform a Valsalva maneuver improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation and, where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 ears pre-operatively and in 86 out of 141 ears post-operatively. The authors concluded that prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are needed to establish a higher level of evidence of efficacy.

Additional studies have attempted to determine the safety and effectiveness of Eustachian tube balloon dilation for treatment of Eustachian tube dysfunction. Studies include a 2015 retrospective cohort study by Gurtler et al, a 2015 retrospective analysis by Maier et al, a 2015 meta-analysis and systematic review by Randrup, Ovesen et al. All studies concluded balloon tube dilation showed promise and appeared to have some level of efficacy but felt further study necessary to identify long term efficacy and define the definitive value of the procedure. Several of these studies concluded that additional randomized, controlled trials were necessary as much of the evidence is retrospective cohort reviews.

In 2015 publication, the Food and Drug Administration (FDA) summarizes more adverse events. Two-hundred ninety-nine patients who were treated with ETBC were included in the safety analysis (80 lead-in patients, 149 patients randomized ETBC, 70 patients randomized to medical management who received ETBC). There were 16 non-serious device or procedure-related adverse events in 13 patients most commonly, epistaxis and ETD. Two patients had 3 potentially device-related adverse events: mucosal tear worsened ETD, and conductive hearing loss. The potential device- or procedure-related adverse events were mild or moderate in severity and resolved without sequelae. Five serious adverse events were reported (4 events in the BDET group, 1 event in the medical management group); all were thought to be unrelated to device, procedure, or medications.

A 2017 UpToDate review on "Eustachian tube dysfunction" (Poe, Hanna et al) states that "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. Balloon dilation is a novel tuboplasty method to increase the patency of the cartilaginous Eustachian tube. Similar to the concept of balloon sinuplasty for the treatment of chronic sinusitis, a balloon catheter is used to dilate the cartilaginous portion through a minimally invasive transnasal endoscopic approach. Initial cadaveric studies and clinical trials are promising. A 2015 systematic review including 9 case series (443 patients) concluded that balloon tuboplasty is a safe procedure but is still lacking good evidence of benefit"

More recent reviews include a systematic literature search by Huisman, et al, 2018 and Hayes, 2017, systematic reviews on both the Bielefeld and the Acclarent Eustachian tube balloon dilation procedures. The Huisman review was based on title and abstracts, and resulted in 36 articles included in the review. These articles were screened as full text, 15 of them were eligible for critical appraisal. Data were extracted from selected studies and presented. A meta-analysis was conducted for four subgroups. A total of 1,155 patients were treated with balloon dilation of the tuba auditiva. Outcome parameters were relief of symptoms, otoscopy, Valsalva maneuver or Toynbee test, audiometry, tympanometry, Eustachian tube dysfunction classification, and Eustachian tube score. All articles showed short-term improvement of original symptoms; some showed further improvement over time. Follow-up ranged from just after therapy to 50 months. Relatively mild and self-limiting complications were described in 36 patients. All current studies suggest that balloon dilation of the Eustachian tube can be a helpful treatment in patients with Eustachian tube dysfunction. However, placebo controlled trials are still warranted.

The 2017 Hayes reviews similarly concluded there remained unanswered questions regarding the effectiveness of this therapy. In the case of the Bielefeld catheter system, the efficacy of ETBD does not allow for definitive conclusions due to a very-low-quality body of evidence provided by one randomized controlled trial and a number of single-arm observational studies with substantial limitations. Similarly the efficacy of ETBD in the Acclarent system, did not allow for definitive conclusions either by small single-arm observational studies.

According to a 2018 systematic review (Luukkainen et.al) Balloon Eustachian tube dilation is a promising and novel treatment for patients who have chronic Eustachian tube dysfunction resulting in chronic ear disease. The long-term follow-up studies were heterogeneous regarding the Eustachian tube dysfunction (ETD) definition, patient selection, follow-up duration, additional treatments, and outcome measures. The current, but limited, evidence suggests that BET is effective in the long-term. However, more long-term studies with uniform criteria and outcome measures as well as placebo-controlled studies are needed. At this time, the data is limited by small prospective studies and large retrospective studies. Large prospective trials with higher level of evidence are needed to show efficacy.

The 2019 clinical consensus statement on Balloon dilation of the eustachian tube stated, "Consequently, the panel ultimately could not reach consensus regarding the overall short-term or long-term effectiveness of BDET (balloon dilatation of eustachian tube)." Here is a summary of the literature included in the clinical consensus statement:

Thus far, there have been only 2 prospective, multicenter RCTs examining the efficacy of balloon dilation of the eustachian tube (BDET) for persistent obstructive eustachian tube dysfunction (OETD). The first was conducted by Poe et al who randomized 323 patients with medically refractory OETD to either undergo BDET plus medical therapy (n = 162) or medical therapy alone (n = 80). After 6 weeks, a significantly greater number of BDET patients demonstrated normalization of tympanograms and Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) scores (≤ 2.1) vs controls (51.8% vs 13.9%, $P < .001$; 56.2% vs 8.5%, $P < .001$). At 24 weeks, improvements in ETDQ-7 scores in the treatment arm were sustained but were no longer statistically significantly different from the control group (59.8% vs 22.2%, $P > .05$). This finding was attributed to the fact that 82% of patients in the control arm (59/72) crossed over to the BDET group prior to their 12-week follow-up. Consequently, only 13 patients were left in the control arm, which may have biased statistical comparisons.

In the second RCT, Cutler et al randomized 60 patients 18 years and older with medically refractory OETD greater than 12 months with 3 or more eustachian tube obstructive symptoms to undergo BDET (n = 30) or continued medical therapy (n = 29). After 6 weeks, greater reductions in overall ETDQ-7 scores

were observed in the BDET group relative to controls. In addition, symptom improvements in the treatment arm were sustained after a minimum follow-up of 1 year. However, it should be noted that similar to the Poe et al study, most of the patients in the control arm (23/29) crossed over to the BDET arm after 6 weeks. Consequently, no statistical comparisons were performed between the treatment and control arms at the 12-month follow-up. At this time, additional RCTs with longer follow-up are still necessary to establish a higher level of evidence for BDET efficacy. Consequently, the panel ultimately could not reach consensus regarding the overall short-term or long-term effectiveness of BDET."

Hayes (2021) recently released an article on Eustachian tube balloon dilation (ETBD) for treatment of adults with chronic Eustachian tube dysfunction (ETD) refractory to medical management (MM). A total of eleven studies met criteria, 4 RCTs, 5 pre/post studies, 1 case-control and 1 retrospective comparative study. No major safety concerns related to ETBD were found.

Applicable Coding

CPT Codes

No applicable codes

HCPCS Codes

C9745 Nasal endoscopy, surgical; balloon dilation of eustachian tube

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