

Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube

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Abstract

Objective. To develop a clinical consensus statement on the use of balloon dilation of the eustachian tube (BDET).

Methods. An expert panel of otolaryngologists was assembled with nominated representatives of general otolaryngology and relevant subspecialty societies. The target population was adults 18 years or older who are candidates for BDET because of obstructive eustachian tube dysfunction (OETD) in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. A modified Delphi method was used to distill expert opinion into clinical statements that met a standardized definition of consensus.

Results. After 3 iterative Delphi method surveys, 28 statements met the predefined criteria for consensus, while 28 statements did not. The clinical statements were grouped into 3 categories for the purposes of presentation and discussion: (1) patient criteria, (2) perioperative considerations, and (3) outcomes.

Conclusion. This panel reached consensus on several statements that clarify diagnosis and perioperative management of OETD. Lack of consensus on other statements likely reflects knowledge gaps regarding the role of BDET in managing OETD. Expert panel consensus may provide helpful information for the otolaryngologist considering the use of BDET for the management of patients with OETD.

Keywords

eustachian tube dysfunction, balloon dilation, otitis media, tympanometry, otoscopy, nasal endoscopy, consensus

Obstructive eustachian tube dysfunction (OETD) is a physiological disorder of the eustachian tube (ET) that results in the inability to appropriately equalize pressure between the middle ear and the environment. Pressure equalization and ventilation of the middle ear is a primary function of the ET; other functions include mucociliary clearance of secretions from the middle ear and protection of the middle ear from pathogens, material, and sounds from the nasopharynx.¹ Adult OETD has been reported to account for over 2 million health care visits annually.² OETD may be acute and short-lived, often

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associated with an upper respiratory tract infection (URI), or chronic, lasting months or years.³

Findings associated with short-term OETD may include otitis media with effusion (OME), tympanic membrane retraction, or perforation; longer term disorders that have been attributed to OETD include middle ear atelectasis, perforation, chronic otitis media (COM), and cholesteatoma. In milder cases, OETD may only be apparent in situations of barochallenge (inability to equalize with rapid barometric pressure changes), with otherwise normal function in stable ambient conditions. Symptoms of OETD may include aural fullness, otalgia, tinnitus, and hearing loss.⁴ OETD is distinct from the condition of patulous eustachian tube dysfunction (PETD), in which the functional valve of the ET is pathologically patent, creating an abnormally persistent state of pressure equalization between the middle ear and nasopharynx. Eustachian tube dysfunction (ETD) represents a spectrum of pathology affecting the lumen and functional valve within the ET, and although the conditions of OETD and PETD lie at opposite ends of that spectrum of disease, they may share associated comorbidities, such as chronic allergic rhinitis.⁵ Patients may alternate between OETD and PETD, depending on the manifestations of the pathology, making differential diagnosis imperative.

Despite the known consequences of OETD and impact on health and well-being, safe and effective treatments directed to the ET have not been previously established.⁶ Treatments such as placement of tympanostomy tubes (TTs) create an alternative route for ventilation of the middle ear space but do not primarily address the problem at the ET and may be associated with complications such as infection, persistent perforation, and tympanosclerosis.⁷ The literature is absent of any studies that show effectiveness of medical management using systemic decongestants, antihistamines, nasal topical decongestants, or corticosteroid sprays for the primary diagnosis of OETD in the absence of other defined treatable causes.⁸

In 2016, the US Food and Drug Administration (FDA) approved marketing of a device that uses an endoscopically directed balloon to treat persistent OETD.⁹ This approval followed a randomized, controlled, clinical trial that compared results at 6 weeks in patients who underwent balloon dilation of the ET (BDET) plus medical therapy (corticosteroid nasal spray) with those patients who had medical therapy only, with superior outcomes observed after BDET compared with medical management.⁶ The availability of a primary treatment intervention directed at the cause of OETD holds potential for effective management of this patient population. However, many questions remain unanswered, and there is no published or widely accepted guidance for assessment of OETD, safety parameters of BDET, established risks and complications, or outcome assessment.

Given the knowledge gap that exists regarding the role of BDET in managing OETD and the increasing rates of utilization, the American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) submitted this topic to the AAO-HNSF Guidelines Task Force (GTF) as a

potential topic for a clinical practice guideline. Due to limited evidence to support a clinical practice guideline, the topic of BDET was selected for clinical consensus statement (CCS) development. The objectives of the CCS are to identify areas of expert consensus regarding the selection of patients and criteria for the use of BDET, perioperative considerations, and optimal outcome measures.

Methods

This CCS was developed using an a priori protocol¹⁰ with the following steps: (1) define the subject of a clinical consensus statement as evaluation of the suitability of the BDET procedure, (2) recruit the expert panel, (3) vet potential conflicts of interest among proposed panel members, (4) perform a systematic literature review, (5) determine the scope and population of interest for the consensus statement, (6) develop and implement a modified Delphi survey, (7) revise the clinical statements in an iterative fashion based on survey results, and (8) aggregate the data for analysis and presentation. The pertinent details of each of these steps will be briefly described.

Determination of BDET as the Topic of a Consensus Statement, Panel Recruitment, and Vetting

BDET was first considered the subject of a clinical consensus statement based on a suggestion from the AAO-HNS Physician Payment Policy Workgroup (3P). After deliberation, the GTF supported the suggestion; consensus panel leadership was selected and administrative support was allocated. Panel membership was strategically developed to ensure appropriate representation of all relevant stakeholder groups and organizations within otolaryngology. The stakeholders were contacted regarding the consensus statement project and the requirements and desired qualifications for panel membership; each group then nominated its own representative content expert to participate.

Participating subgroups include the American Academy of Otolaryngic Allergy, the American Neurotology Society, the American Otological Society, the American Rhinologic Society, and the Triological Society, as well as appropriate committees within the AAO-HNS, including the Board of Governors, the Rhinology and Paranasal Sinus Committee, the Physician Payment Policy Work Group, the Hearing Committee, and the Medical Devices and Drugs Committee. The methodologists were nonvoting members of the development group. There were 2 nonvoting consultants to the group. One consultant, who represented the American Neurotology Society and the AAO-HNS Board of Directors, was determined to have potential conflicts of interest and for this reason was not included as voting committee member. A second consultant, an audiologist, represented the American Speech-Language-Hearing Association.

All panel members are in active clinical practice, and all were required to agree in advance of appointment to participate in all verbal discussions (performed via teleconference) and votes. Once the panel was assembled, complete disclosure of potential conflicts of interest was reported and

vetted within the group. Conflicts of interest were managed consistent with the Council of Medical Specialty Societies (CMSS) Code for Interactions with Companies,¹¹ which requires that the chair and a majority of the participants do not have a direct conflict with the deliberations. A panel vote was used to determine whether a disclosed conflict of interest necessitated disqualification from participating as a voting panel member or as nonvoting consultant. Panel members disclosed the nature of the relationship with each conflict to distinguish if the relationship was directly related to the balloon dilation. The process was facilitated by the chair and the methodologist, discussed by the panel members, and confirmed or refuted by the methodologist, chair, and AAO-HNSF staff. Given the nature of this consensus statement, it was necessary to include panel members who have direct experience performing the balloon dilation procedure; therefore, the performance of the procedure in medical practice itself did not prohibit a member from inclusion in the panel or voting on specific statements. The panel chair and panel assistant chair led the development of the clinical statements and the Delphi process with input from a senior consultant/methodologist from AAO-HNSF leadership and GTF, as well as with administrative support from an AAO-HNSF staff liaison.

Literature Review and Determination of the Scope of the Consensus Statement

A systematic literature review was performed by an information specialist to identify current evidence regarding the indications, perioperative considerations, and clinical outcomes for BDET in managing OETD.

The literature search was conducted in January 2018 and included all relevant publications in English from PubMed, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews, Web of Science, BIOSIS Citation Index, National Guideline Clearinghouse, Canadian Medical Association (CMA) Infobase, NHS Evidence ENT and Audiology, TRIP Database, Clinicaltrials.gov, Allied and Complementary Medicine Database (AMED), and SCOPUS:

(dilatation[mesh] OR dilation[tiab] OR dilations[tiab] OR dilatation[tiab] OR dilations[tiab] OR dilat*[tiab] OR balloon[tiab] OR balloons[tiab] OR tuboplasty[tiab] OR tuboplasties[tiab]) AND (auditory tube OR auditory tubes OR eustachian[tiab] OR pharyngotympanic tube OR pharyngotympanic tubes OR eustachian tube[mesh])

The literature search yielded 83 articles. After screening for relevancy, the total number of articles retained was 45. The 45 relevant articles were reviewed independently by the chair and assistant chair and classified based on the Oxford Centre for Evidence-Based Medicine (CEBM) 2011 Levels of Evidence.¹²

The panel made several decisions regarding the scope of this clinical consensus statement before formally beginning

the Delphi process. It was decided that the target audience of the statement would specifically be otolaryngologists considering or performing BDET in any clinical setting, including the operating room, ambulatory surgery center, physician office, and outpatient clinics. A working definition of BDET was determined to be “inserting a catheter with a balloon temporarily into the cartilaginous portion of the ET and then inflating the balloon to alleviate obstructive ETD.” The target population was defined as adults 18 years or older who are candidates for BDET because of OETD in 1 or both ears for 3 months or longer that significantly affects quality of life or functional health status. The following exclusions were determined: patients with PETD, extrinsic obstruction of the ET, or active primary inflammatory disorders. Once the target population and scope of practice were determined, the panel used the results of the literature review to identify and prioritize topics and questions for which knowledge gaps or uncertainty existed, which could most benefit from potential consensus from an expert panel. These areas were then used as the basis for the formulation of the initial statements that were then evaluated through the Delphi survey method.

Delphi Survey Method Process and Administration

A modified Delphi survey method was used to assess consensus for the proposed statements,¹⁰ with multiple anonymous surveys to minimize bias within the expert panel and facilitate consensus.¹³

Web-based software (www.surveymonkey.com) was used to administer confidential surveys to panel members. A potential topic list of 62 questions was developed by the panel during the first call, and each panel member was invited to provide 1 draft statement for each of his or her top 5 ranked topic list choices. The survey period was divided into 3 Delphi rounds. All answers were de-identified and remained confidential; however, names were collected to ensure proper follow-up, if needed.

Based on the outcomes of the top-ranked topic list choices and resulting discussion, the panel chair and assistant chair developed the first Delphi survey, which consisted of 62 statements. Prior to dissemination to the panel, the Delphi surveys were reviewed by the methodologist for content and clarity. Questions in the survey were answered using a 9-point Likert scale where 1 = *strongly disagree*, 3 = *disagree*, 5 = *neutral*, 7 = *agree*, and 9 = *strongly agree*. The surveys were distributed, and responses were aggregated, distributed back to the panel, discussed via teleconference, and revised, if warranted. The purpose of the teleconference was to provide an opportunity to clarify any ambiguity, propose revisions, or drop any statements recommended by the panel.

The criterion for consensus was established a priori and followed the criteria below¹⁰:

- **Consensus:** Statements achieving a mean score of 7.00 or higher and having no more than 1 outlier,

Table 1. Statements That Reached Consensus: Patient Criteria.^a

No.	Statement	Mean	Outliers
1	A comprehensive history and physical exam, including otoscopy, are essential parts of the diagnostic evaluation of a candidate for BDET.	8.89	0
2	Nasal endoscopy is an essential part of the diagnostic evaluation prior to BDET.	8.83	0
3	BDET is contraindicated for patients diagnosed as having a patulous ETD.	8.83	0
4	Nasal endoscopy in patients who are candidates for BDET is necessary for assessing the ET lumen and assessing the feasibility of transnasal access to the nasopharynx.	8.64	0
5	A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.	8.58	0
6	The benefit of repeat BDET after a prior ineffective BDET has not been determined.	8.55	0
7	Symptoms of obstructive ETD can include aural fullness, aural pressure, hearing loss, and otalgia.	8.50	0
8	Tympanometry is an essential part of the diagnostic evaluation prior to BDET.	8.50	0
9	Establishing a diagnosis of obstructive ETD requires ruling out other causes of aural fullness such as patulous ETD, temporomandibular joint disorders, extrinsic obstruction of the ET, superior semicircular canal dehiscence, and endolymphatic hydrops.	8.42	0
10	Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD.	8.36	1
11	Nasal endoscopy is necessary to rule out extrinsic causes of ETD.	8.18	1
12	Comprehensive audiometry is an essential part of the diagnostic evaluation prior to BDET.	8.17	1
13	BDET is appropriate in patients with obstructive ETD who have failed medical therapy for identified treatable causes.	8.09	1
14	Common causes of obstructive ETD that benefit from identification and management are allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.	8.08	1
15	Medical management of known pathology that could affect nasal or ET function is appropriate to perform prior to BDET.	8.00	0
16	Patients with a history of recurrent barochallenge, defined as uncomfortable pressure in the ear upon exposure to ambient pressure changes that cannot be easily relieved, may improve following BDET.	7.75	0
17	There is no scientifically proven or standard medical therapy for ETD.	7.25	0
18	Pneumatic otoscopy can identify negative pressure in the middle ear space and can differentiate between adhesive and nonadhesive retractions of the tympanic membrane.	7.08	1

Abbreviations: BDET, balloon dilation of the eustachian tube; ET, eustachian tube; ETD, eustachian tube dysfunction.

^aStatements are ordered according to mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

defined as any rating 2 or more Likert points from the mean in either direction

- **Near consensus:** Statements achieving a mean score of 6.50 or higher and having no more than 2 outliers
- **No consensus:** Statements that did not meet the criteria of consensus or near consensus

Three iterations of the Delphi survey were performed. The panel extensively discussed (via teleconference) the results of each item after the first Delphi survey. Items that reached consensus were accepted, and items that did not meet consensus were discussed to determine if wording or specific language was pivotal in the item not reaching consensus. The second iteration of the survey was used to reassess items for which there was near consensus or for items for which there were suggestions for significant alterations in wording that could have affected survey results. The entire panel also extensively discussed the results of the second Delphi survey. All items reaching consensus were accepted. The factors leading to the remaining items not reaching

consensus were not attributed to wording or other modifiable factors but rather a true lack of consensus.

The final version of the clinical consensus statements was grouped into 3 specific areas: (1) patient criteria, (2) perioperative considerations, and (3) outcomes. The final manuscript was drafted with participation and final review from each panel member.

Results

When revisions of the original 62 statements presented at the first Delphi round are included, a total of 70 clinical statements were developed for assessment through the Delphi survey method. After removal of duplicative statements and combining similar statements, 56 statements remained for assessment. All panelists completed all survey items. After 2 iterations of the Delphi survey, 28 statements (50%) met the standardized definition for consensus (**Tables 1-3**) and 28 (50%) did not (**Tables 4-6**). The clinical statements were organized into the 3 specific subject areas, and the results for each of the 3 areas are considered below.

Table 2. Statements That Reached Consensus: Perioperative Consideration.^a

No.	Statement	Mean	Outliers
19	Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone.	8.75	0
20	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.	8.64	0
21	Myringotomy with or without tympanostomy tube placement is not a mandatory prerequisite to BDET.	8.50	0
22	A dehiscent carotid artery identified on imaging is a contraindication to use of a device without a depth marker that demarcates insertion into the cartilaginous eustachian tube.	7.82	1
23	Patients with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube placement.	7.75	0
24	BDET is an alternative to tympanostomy tube placement for obstructive ETD.	7.33	1
25	Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD.	7.27	1

Abbreviations: BDET, balloon dilation of the eustachian tube; ETD, eustachian tube dysfunction.

^aStatements are ordered according to mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

Table 3. Statements That Reached Consensus: Outcomes.^a

No.	Statement	Mean	Outliers
26	Patient-reported symptom scores are useful in assessing baseline ETD symptoms and treatment outcomes.	7.73	0
27	The ability to perform a modified Valsalva maneuver is appropriate for assessing outcome after BDET.	7.09	1
28	Change in patient-reported symptom scores is appropriate for assessing outcome following BDET.	7.08	1

Abbreviations: BDET, balloon dilation of the eustachian tube; ETD, eustachian tube dysfunction.

^aStatements are ordered according to mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

Patient Criteria

Thirty-eight statements regarding patient criteria for BDET were polled at the Delphi rounds.

Eighteen statements regarding patient criteria met consensus (**Table 1**). These statements include the importance of using subjective complaints to distinguish OETD from PETD. Aural fullness and pressure, hearing loss, otalgia, and recurrent barochallenge imply OETD, while voice and breathing autophony, pulsatile tinnitus, and some forms of aural fullness imply PETD. BDET is contraindicated in cases of PETD. The symptoms listed above are nonspecific, and the panel emphasized that non-OETD causes of these symptoms, including PETD, temporomandibular disorders (TMDs, including dysfunction of the temporomandibular joint and muscles of mastication), extrinsic ET obstruction, superior semicircular canal dehiscence, and Ménière's disease must be ruled out. The importance of history and physical examination is highlighted in these statements. Pneumatic otoscopic examination can distinguish nonadhesive from adhesive retraction of the tympanic membrane. Nasal endoscopy will allow determination of the feasibility of the transnasal BDET procedure, as well as rule out extrinsic

causes of OETD. Audiometry and tympanometry are essential evaluations when considering patients for BDET.

The authors emphasize the importance of identifying other potentially treatable causes of ETD, including allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.¹⁴ Medical management of these disorders is indicated prior to offering BDET. There is no direct medical treatment for isolated OETD, and BDET is appropriate when OETD is present in isolation or remains following appropriate medical management of potential confounding/coexisting conditions as listed above. An important question is whether repeat BDET is indicated after initial BDET has been ineffective; no evidence currently supports performance of repeat BDET in this setting, as there is little in the literature that addresses this issue.

Seventeen statements in this category did not reach consensus (**Table 4**); of these, 6 met near consensus. While consensus was reached that nasal endoscopy is an essential component of the perioperative evaluation, providing assessment of the ET lumen as well as the feasibility of transnasal access to the nasopharynx, other statements on this topic only reached near consensus, as noted in **Table 4** (bolded

Table 4. Statements That Did Not Reach Consensus: Patient Criteria.^a

No.	Statement	Mean	Outliers
29	CT imaging is not necessary prior to BDET.	4.33	9
30	The concept of minimal or maximal medical treatment for ETD is not useful in preoperative management for BDET.	5.25	8
31	CT imaging to evaluate the integrity of the carotid canal is necessary prior to BDET.	5.92	7
32	A mandatory trial of nasal steroid spray prior to BDET is not beneficial in the absence of inflammation or other pathology that would indicate the use of the spray.	5.75	6
33	Nasal endoscopy is invaluable in the evaluation of ETD because it can identify physical obstruction of the ET lumen and dynamic dysfunction with direct observation.	6.83	4
34	Patient-reported symptom scores are insufficient as the sole indication for BDET.	7.17	3
35	A mandatory trial of oral steroids prior to BDET is not beneficial in the absence of inflammation or other pathology that would indicate the use of the medication.	6.42	3
36	A dehiscence carotid artery identified on imaging is a relative contraindication to BDET.	6.42	3
37	An appropriate medical therapy is mandatory before performing BDET.	5.83	3
38	Nasal endoscopy prior to performing BDET provides valuable information about extrinsic causes of ETD and the patency of the ET lumen.	7.75	2
39	Nasal endoscopy is valuable to rule out extrinsic causes of ETD.	7.67	2
40	Medical therapy directed at potential sources of nasopharyngeal mucosal inflammation, including allergy and reflux, is beneficial prior to offering BDET.	7.67	2
41	Nasal endoscopy is valuable for assessing feasibility of transnasal access to the nasopharynx in patients who are candidates for BDET.	7.50	2
42	Assessment of passive and active ET function using nasal endoscopy is important in candidates for BDET.	7.25	2
43	The benefit or harm of medical therapy prior to BDET is not established when the therapy is not directed at a specific underlying diagnosis.	7.08	2
44	Myringotomy with or without tympanostomy tube placement is a prerequisite to BDET.	2.50	2
45	Symptomatic relief with myringotomy or tympanostomy tube placement is predictive of benefit from BDET.	6.25	1

Abbreviations: BDET, balloon dilation of the eustachian tube; CT, computed tomography; ET, eustachian tube; ETD, eustachian tube dysfunction.

^aItems in boldface text reached “near consensus”; all other items reached “no consensus.” Statements are ordered according to the number of outliers with the statement obtaining the highest number of outliers listed first. When more than 1 statement had the same number of outliers, the statements were then ordered according to the mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

statements 38, 39, 41, and 42). Two other statements reaching near consensus considered the role of medical therapy prior to BDET (bolded statements 40 and 43).

Perioperative Considerations

A total of 7 statements met consensus regarding perioperative considerations (**Table 2**) while 4 did not reach consensus (**Table 5**). These statements address the risks, contraindications, concurrent procedures, and alternatives to BDET.

BDET *should not* be performed as part of a procedure to perform balloon dilatation of the paranasal sinus ostia in the absence of specific and distinct diagnostic criteria for the BDET procedure. Myringotomy with or without tympanostomy tube placement is not a mandatory prerequisite to BDET; rather, BDET may be an alternative to myringotomy, with or without tympanostomy tube displacement (M&T). However, the surgeon may choose to perform M&T at the time of BDET, dependent on clinical circumstances, including the presence of serous or mucoid fluid in the middle ear space. The reader is cautioned that failure of

myringotomy (\pm tube) to relieve symptoms while the tympanic membrane perforation is open suggests a diagnosis other than OETD.

Patient safety and patient counseling, along with shared decision making, are recognized as important aspects of patient care in this setting. ET balloons are designed for insertion depth limited to the cartilaginous (and not the osseous) portion of the ET. Accordingly, the panel agreed that preoperative temporal bone CT scan showing dehiscence of the carotid artery at the bony ET should prompt the surgeon to choose a device with a depth marker that demarcates insertion into the cartilaginous ET only. Potential risks associated with BDET include bleeding (including secondary to carotid artery injury), scarring, infection, development of PETD, and need for additional procedures.

Near consensus was reached on 2 statements regarding chronic ear surgery and BDET. The benefit of BDET performed concurrent with tympanoplasty or other middle ear surgery has not been determined. Similarly, the benefit of BDET in patients with prior tympanoplasty or other middle ear surgery has not been determined.

Table 5. Statements That Did Not Reach Consensus: Perioperative Considerations.^a

No.	Statement	Mean	Outliers
46	Off-label use of instruments for BDET may be associated with additional risks, including mucosal laceration, false passage and soft-tissue emphysema, and injury to the internal carotid artery.	6.83	6
47	Repeat BDET can benefit selected patients.	6.33	3
48	The benefit of BDET performed concurrent with tympanoplasty or other middle ear surgery has not been determined.	7.58	2
49	The benefit of BDET in patients with prior tympanoplasty or other middle ear surgery has not been determined.	7.42	2

Table 6. Statements That Did Not Reach Consensus: Outcomes.^a

No.	Statement	Mean	Outliers
50	The long-term effectiveness of BDET is uncertain.	6.42	5
51	Nasal endoscopy is useful for assessing outcome after BDET.	4.58	4
52	The short-term effectiveness of BDET is uncertain.	3.92	4
53	Pneumatic otoscopy is appropriate for assessing outcomes after BDET.	6.17	3
54	Patient-reported symptom scores provide a reliable measure of improvement after BDET.	6.08	3
55	Tympanometry is useful for assessing outcomes after BDET.	6.25	2
56	Tympanometry provides an objective measure of improvement after BDET.	6.25	2

Abbreviation: BDET, balloon dilation of the eustachian tube.

^aStatements are ordered according to the number of outliers with the statement obtaining the highest number of outliers listed first. When more than 1 statement had the same number of outliers, the statements were then ordered according to the mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

Outcomes

A total of 3 statements reached consensus regarding BDET outcomes (**Table 3**), while 7 did not reach consensus (**Table 6**); none of these 7 reached near consensus. These statements addressed the role of functional and patient-reported assessments in reporting treatment outcomes after BDET. Patient-reported symptom scores are useful in assessing baseline symptoms and treatment outcomes. The patient's ability to perform a modified Valsalva maneuver is an appropriate outcome assessment.

Consensus could not be reached for statements related to the utility of pneumatic otoscopy or nasal endoscopy in assessing outcomes following BDET, nor was the panel able to reach consensus regarding the overall short-term or long-term effectiveness of BDET, due to the lack of high-level evidence. Consensus was not reached on the utility of medical therapy prior to BDET. No consensus could be reached as to whether patient-reported symptom scores alone provide a reliable measure of improvement after BDET.

Discussion

Patient Criteria

The presentation of the patient with OETD can be variable and nonspecific; hence, the CCS panel felt it was important to emphasize the need to establish an accurate diagnosis,

prior to considering any therapeutic intervention, including BDET. Careful history taking, probing for symptoms that facilitate differential diagnoses or point toward an extrinsic cause, is a practice that enhance the specificity of diagnosis.¹⁵ Having established the diagnosis of OETD, use of a validated patient-reported symptom questionnaire is a sensitive means for measuring outcomes.

Symptoms of OETD may include aural fullness, aural pressure, hearing loss, and otalgia.^{1,15} These symptoms are nonspecific and can be observed in various other conditions, including, but not limited to, Ménière's disease (endolymphatic hydrops), superior semicircular canal dehiscence, temporomandibular disorders, PETD, and sporadic otitis media.^{1,15} A history of barochallenge may point to a diagnosis of OETD. If the patient has additional symptoms of autophony of voice, audible breathing, or pulsatile tinnitus, PETD is more likely.¹

The panel emphasized the need for identifying any underlying extrinsic cause of OETD, such as allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux.¹⁴ Targeted treatment for these conditions may result in symptomatic improvement of associated OETD. There is no "standard medical therapy" for primary OETD described in the literature.¹⁵ Intranasal corticosteroid sprays currently are not FDA approved for use in ETD, as there is no evidence that these medications can disperse transnasally to the ET orifice in

human subjects.¹⁶ Therefore, in the absence of extrinsic causes, there is no absolute role for a “treatment trial” of topical or systemic medical therapy in primary OETD.

A thorough otolaryngologic examination, with particular attention to the ears, temporomandibular joints and muscles, nose, and nasopharynx, is requisite in the assessment of the patient with suspected OETD.^{1,14} Movement of the tympanic membrane with nasal respiration suggests PETD. A retracted tympanic membrane (TM) that does not move with the Valsalva maneuver may be found in OETD. Pneumatic otoscopy will distinguish between a retraction that is adherent to the ossicles or promontory and one that is not. The more severe retractions are the ones that are adherent and irreversible, for which treatment must be directed to the tympanic membrane and middle ear as well as possibly to the ET.

Particular emphasis is placed on nasal endoscopy prior to considering BDET.¹⁴ Office-based nasal endoscopy is an essential part of the diagnostic assessment for OETD and provides the examiner with several pieces of information. First, nasal endoscopy assists in identifying extrinsic and therefore treatable causes of ETD as listed previously. Nasal endoscopy also allows the otolaryngologist to assess the feasibility of the transnasal approach for BDET, particularly in terms of access due to the size of the nasal airway and presence of septal deviation. If the nasal anatomy is challenging, and BDET is indicated, it may be addressed by using an angled endoscope in the contralateral nasal cavity and ipsilateral insertion of the balloon.^{6,17,18} Nasal endoscopy also permits the examiner to look into the ET lumen, which allows for more complete inspection of the cartilaginous ET. Given that the site of obstruction in OETD is typically not visible within the nasopharynx, as it resides up to a centimeter or more inside the isthmus of the cartilaginous ET, direct examination of the ET orifice via nasal endoscopy may confirm the presence of obstruction not visible on external inspection of the orifice. Alternatively, examination may show the added concavity that is often seen with the loss of Ostmann’s fat pad or lateral cartilaginous lamina in patients with PETD, thus contraindicating BDET. This is of particular benefit in the cases in which the history, questionnaire, and ear exam are not definitive.¹⁹ BDET is contraindicated in PETD as it may worsen the patient’s symptoms. Finally, nasal endoscopy permits the physician to determine the tolerance of the patient to nasal manipulation and can be helpful in determining candidacy for an office-based procedure vs use of monitored sedation or general anesthesia.^{6,17,18}

Comprehensive audiometry and tympanometry are essential in the diagnostic workup of OETD and prior to consideration of performing BDET.^{6,17,18} Audiometric findings that are consistent with endolymphatic hydrops or superior semicircular canal dehiscence should prompt reconsideration of the ETD diagnosis. Negative pressure (“type C”) tympanograms are typically seen in OETD. Some studies have shown that outcomes are equally good irrespective of the preprocedure tympanogram, but documentation of the status of the middle ear air space and TM mobility is necessary prior to performing BDET.^{6,17,18}

If the patient has had BDET previously but symptoms persist, the clinician is urged to consider a diagnosis other than OETD. There is inadequate literature to show if there is efficacy of repeat BDET if the first BDET has not been successful.

Proper patient selection may result in successful outcomes of BDET in patients with true primary OETD. A thorough assessment of the patient is mandatory; lack thereof may yield suboptimal results as a minimum and may even cause harm. Historical symptoms, patient-reported questionnaires, physical examination, nasal endoscopy, and audiometry and tympanometry are all inadequate to secure a diagnosis when relied upon in isolation. Patients must be assessed comprehensively so that only appropriate patients are offered BDET.

Perioperative Considerations

The panel reached consensus that if a tympanostomy tube does not alleviate symptoms, then diagnoses other than OETD should be considered. The panel felt it was important to consider other diagnoses that can cause the sensation of ear fullness when a tympanostomy tube fails to improve symptoms. OETD causes the sensation of ear fullness by producing negative pressure in the middle ear or an effusion. A tympanostomy tube (or myringotomy without tube placement) should relieve this condition. When there is no effusion seen on examination, or symptoms persist after myringotomy and tube placement, the sensation is likely caused by another condition. In these instances, the practitioner should consider other etiologies for the ear fullness such as temporomandibular disorders, patulous eustachian tube,²⁰ or superior semicircular canal dehiscence.²¹

The panel agreed that tympanostomy tube placement is not a requisite procedure prior to performing BDET. Patients who meet all of the diagnostic criteria for OETD and meet all surgical indications for BDET can undergo the procedure without prior tympanostomy tube placement. This includes the example of a patient with barochallenge. Such patients have difficulty with pain and hearing loss associated with rapid barometric pressure changes, such as while flying or scuba diving, or even with rapid ascent/descent in an elevator, and at times may even experience acute perforation of the tympanic membrane. Patients with this history are candidates for BDET without needing a prior tympanostomy tube to show relief of their symptoms while in inciting situations.

Some patients who meet criteria for BDET have concurrent middle ear effusion. Several studies have shown that concomitant placement of tympanostomy tubes at the time of BDET is beneficial.^{22,23} The panel concluded that placement of the tympanostomy tube may be beneficial in producing better hearing outcomes and normalization of the tympanogram but did not find evidence that it is mandatory.

Regarding adverse events, the complication rate of BDET has been reported to be 2%.³ Most complications have been minor and self-limiting, with local mucosal bleeding at the site of BDET being the most common.⁴

Acute otitis media,²⁴ transient increase in tinnitus,²⁵ preauricular emphysema,²⁵ rhinitis,²⁶ and hemotympanum due to reflux of blood into the middle ear space²⁷ and minor mucosal lacerations¹⁷ have also been reported. In the panel discussion, strong consensus was reached that the potential risks of BDET relevant to patient counseling include bleeding, scarring, infection, development of PETD, and/or the need for additional procedures (Statement 25). However, it should be noted that no incidents of PETD or carotid artery injury following BDET have yet been reported in the literature. In addition, neither of the 2 multicenter randomized controlled trials (RCTs) published thus far, which encompassed 356 patients, have reported any device- or procedure-related serious adverse events.^{17,28} The panel also determined that BDET performed using “off-label” instruments was associated with additional risks, and the importance of using devices FDA approved for BDET was emphasized.

Since the introduction of BDET, the necessity of a preoperative high-resolution computed tomography (HRCT) scan of the temporal bone has been a controversial topic. The HRCT scan of the temporal bone (or paranasal sinuses) may help to understand the relationship between internal carotid artery and the ET. It has been suggested in the literature that caution must be exercised during balloon catheter insertion into the ET, and use of a device that is designed with a built-in depth marker to prevent advancement into the bony ET has been recommended.²⁹ The panel concluded that a dehiscence carotid artery identified on imaging is a contraindication to use of a device without a depth marker that demarcates insertion limited to the cartilaginous ET.

There are reports of patients who have undergone repeat BDET on an ET that has been previously dilated.³⁰ The panel discussed that repeated BDET may benefit selected patients; however, the role for repeat BDET was unclear at this time, and a consensus was not reached.

Outcomes

Patient-reported symptoms have been used to assess the severity of ETD and outcomes of BDET. The Eustachian Tube Dysfunction Questionnaire–7 (ETDQ-7) is a validated, standardized patient-reported instrument that assesses the severity of symptoms commonly associated with ETD.²⁷ It comprises 7 items querying the following: ear pressure, ear pain, ear clogging, ear problems associated with cold/sinusitis, ear crackling/popping, ringing, and muffled hearing. The ETDQ-7 has been used in several trials to measure baseline ETD symptoms and response to treatment.^{6,27,28} Poe et al⁶ noted normalization of the ETDQ-7 score in 56.2% of patients in 1 study of outcomes after BDET. Overall, there was consensus by the panel that patient-reported symptom scores are useful in assessing baseline ETD symptoms as well as treatment outcomes and that change in patient-reported symptom scores is appropriate as 1 measure for assessing outcome following BDET (Statements 26 and 28). However, although beneficial in evaluating symptom severity, the ETDQ-7 does not have sufficient specificity to be used as the sole diagnostic criterion for OETD.

The panel reached consensus that the ability to perform a modified Valsalva maneuver is appropriate for assessing outcome after BDET (Statement 27). The modified Valsalva maneuver is performed by gently blowing the nose against a closed nose and mouth and simultaneously swallowing to allow the dilatory muscles of the ET to open the lumen against the increased intranasal pressure, equalizing pressure in the middle ear with ambient pressure. It is used in clinical practice to assess ET function and patency. Thirteen studies^{4,6,7,17,22,24,30-36} reported an increased ability to successfully perform the Valsalva or modified Valsalva maneuver as a positive outcome measure after BDET. Poe et al¹⁷ noted that all 11 patients in 1 study were able to perform a positive Valsalva maneuver. A significant increase was confirmed again by Poe et al⁶ in another study. In view of the number of studies reporting Valsalva outcomes as well as consistent improvement in that measure, the panel reached consensus on the value of the ability to perform a modified Valsalva maneuver as an outcome assessment after BDET.

The panel could not reach consensus as to whether tympanometry is useful for assessing outcomes after BDET (Statement 55) or whether tympanometry provides an objective measure of improvement after BDET (Statement 56). Thus far, 20 studies* have reported tympanometry results after BDET. Improvement in tympanometry is typically defined as conversion from type B to type C or type A, or conversion of type C to type A. Two studies^{41,42} focused on tympanometry as a primary outcome measure. Singh et al⁴¹ found significant improvement in tympanometry in all 11 patients, and Williams et al⁴² reported 36% improvement in tympanogram type with 32% normalization. Poe et al¹⁷ also reported significant improvement in both otoscopy and tympanometry, both of which are indicators of middle ear pathology. Panel members nevertheless found it difficult to suggest any one measure to assess outcomes after BDET. While the panel members agreed upon the usefulness of tympanometry for evaluation in many cases of OETD, the statements did not reach consensus due to concerns about overreliance on this measure, particularly as related to cases of barochallenge-associated ETD, which may be expected to have normal baseline tympanometry measures.

Likewise, the statement that pneumatic otoscopy is appropriate for assessing outcomes after BDET (Statement 53) did not reach panel consensus. The phrasing of the statement with “is appropriate” was felt to indicate that pneumatic otoscopy might be used as a stand-alone measure. While the panel considered that there may be a more limited role for pneumatic otoscopy, there is not enough evidence to support it as a primary measure for assessing outcome after BDET. Poe et al¹⁷ did find significant improvement in both otoscopy and tympanometry. Randrup et al³³ and Satmis et al³⁴ also reported significant improvement in tympanic membrane normalization. The panel, however, had concerns about the value of pneumatic otoscopy as an outcome measure similar to the concerns regarding tympanometry. That is, pneumatic

*References 4, 6, 7, 17, 22-24, 26, 27, 30, 31, 33, 35-42.

otoscopy would not be appropriate for assessing patients with barochallenge-associated ETD.

There was also no consensus reached that nasal endoscopy is useful for assessing outcome after BDET (Statement 51). While a role was determined for nasal endoscopy in patient selection, there is very limited evidence to support nasal endoscopy as an outcome measure after BDET.^{17,22,33,43} Scoring systems for findings on nasal endoscopy (mucosal inflammation) are not well established. Additional studies specifically addressing this outcome measure are required before consensus can be reached regarding the usefulness of nasal endoscopy after BDET as an outcome measure.

Multiple studies have investigated the short- and long-term efficacy of BDET. In a recent systematic review, Huisman et al⁴ evaluated the impact of BDET on reducing symptoms of OETD in adult patients. Fifteen studies were identified, all of which were case series, encompassing 1155 patients and 1881 procedures. Of the 8 studies that used patient-reported symptoms as an outcome measure, all showed significant short-term improvement after a mean follow-up of 6.9 months (range, 0-50 months). Meta-analysis of pooled data from 3 studies (670 procedures) also demonstrated significant improvement in multidimensional eustachian tube scores. However, no conclusions could be drawn regarding the long-term effectiveness of BDET. In addition, as none of the studies had a control group or were blinded, risk of selection bias was high.

Thus far, there have been only 2 prospective, multicenter RCTs examining the efficacy of BDET for persistent OETD. The first was conducted by Poe et al,⁶ 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 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, Meyer et al²⁸ randomized 60 patients 18 years and older with medically refractory OETD greater than 12 months with 3 or more ET 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 al⁶ 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 (Statements 52 and 50).

Conclusions

This clinical consensus statement was developed by otolaryngologists with the intention to promote appropriate, evidence-based care of patients with OETD for whom BDET is being considered. A series of clinical statements were developed by an expert panel using an objective survey method. Based on consensus reached by the panel, the diagnosis of OETD should not be made without a comprehensive and multifaceted assessment, including otoscopy, audiometry, and nasal endoscopy. This process demonstrated that BDET is an option for treatment of patients with OETD. Further study will be needed to refine patient selection and outcome assessment. The application of these statements is expected to result in decreased variations in the care of patients with OETD and an increase in the quality of care provided.

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