CEO Clinical and Experimental Otorhinolaryngology Vol. 17, No. 4: 273-281, November 2024 https://doi.org/10.21053/ceo.2024.00121
pISSN 1976-8710 eISSN 2005-0720

Original Article

Consensus Statement: Postoperative Management After Balloon Dilation of the Eustachian Tube

Min Young Kwak[1,*] · Ho Yun Lee[2,*] · Soo-Keun Kong[3] · In Seok Moon[4] · Bong Jik Kim[5]
Myung-Whan Suh[6] · Jae Yun Jung[7] · Hong Ju Park[8] · Kyu-Yup Lee[9] · Hyong-Ho Cho[10]
Ryoukichi Ikeda[11] · Jae-Jin Song[12] · Chi-Kyou Lee[13]

[1]*Department of Otorhinolaryngology-Head and Neck Surgery, Dongtan Sacred Heart Hospital, Hallym University College of Medicine, Hwaseong, Korea*
[2]*Department of Otorhinolaryngology-Head and Neck Surgery, Ewha Womans University College of Medicine, Seoul, Korea*
[3]*Department of Otorhinolaryngology-Head and Neck Surgery, Pusan National University College of Medicine, Busan, Korea*
[4]*Department of Otorhinolaryngology, Severance Hospital, Yonsei University College of Medicine, Seoul, Korea*
[5]*Department of Otorhinolaryngology-Head and Neck Surgery, Chungnam National University College of Medicine, Daejeon, Korea*
[6]*Department of Otorhinolaryngology-Head and Neck Surgery, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, Korea*
[7]*Department of Otorhinolaryngology-Head and Neck Surgery, Dankook University College of Medicine, Cheonan, Korea*
[8]*Department of Otorhinolaryngology-Head and Neck Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea*
[9]*Department of Otorhinolaryngology-Head and Neck Surgery, School of Medicine, Kyungpook National University, Daegu, Korea*
[10]*Department of Otolaryngology-Head and Neck Surgery, Chonnam National University Medical School and Chonnam National University Hospital, Gwangju, Korea*
[11]*Department of Otolaryngology-Head and Neck Surgery, Iwate Medical University, Morioka, Japan*
[12]*Department of Otorhinolaryngology-Head and Neck Surgery, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea*
[13]*Department of Otorhinolaryngology-Head and Neck Surgery, Soonchunhyang University College of Medicine, Seoul, Korea*

Objectives. Balloon dilation of the Eustachian tube (BDET) is widely recognized as a minimally invasive treatment for obstructive Eustachian tube dysfunction (ETD). We employed a Delphi consensus methodology to develop recommendations for the clinical management of BDET in cases of obstructive ETD.

Methods. A Delphi panel consisting of 26 expert physicians specializing in otology participated in two rounds of anonymous, iterative questionnaires. Consensus was defined as agreement from ≥70% of the panelists on a recommendation, while disagreement was defined as <70% agreement. The responses from the Delphi study were analyzed using both the content validity ratio and Kendall's coefficient of concordance.

Results. The panel finally evaluated 26 topics, reaching agreement on 9 and failing to reach consensus on 17 after two rounds. While consensus was not achieved regarding the postoperative follow-up period, a duration of 12 months was most commonly adopted. The Valsalva maneuver and questionnaire responses were identified as the most agreed-upon postoperative assessment tools following BDET.

Conclusion. Consensus was reached on several recommendations for managing BEDT in obstructive ETD. This agreement will guide future research aimed at defining standard postoperative management for BEDT.

Keywords. *Delphi; Eustachian Tube; Balloon Dilation; Obstructive*

• Received April 21, 2024
Revised September 15, 2024
Accepted October 3, 2024

• Corresponding author: **Chi-Kyou Lee**
Department of Otorhinolaryngology-Head and Neck Surgery, Soonchunhyang University College of Medicine, 59 Daesagwan-ro, Yongsan-gu, Seoul 04401, Korea
Tel: +82-2-709-9360, Email: drqlee@hanmail.net

*These authors contributed equally to this study.

INTRODUCTION

The word "Delphi" comes from ancient Greek mythology, related to Pythia, a powerful oracle whose prophecies influenced important decisions [1]. Delphi methods are essentially a structured approach designed to facilitate an efficient group communication process, enabling a collective of individuals to address complex problems [2]. The Delphi technique has been widely used in various medical fields to establish optimal clinical guidelines by prioritizing collective judgments over individual opinions.

The primary objective of this study was to synthesize expert opinions into clinical statements using the Delphi method, focusing on the balloon dilation of the Eustachian tube (BDET) procedure. The Eustachian tube (ET) plays a crucial role in maintaining the pressure balance between the middle ear and the external environment. When the ET is blocked, fluid accumulates in the middle ear, causing increased pressure, chronic otitis media, and potential hearing loss. The main purpose of the BDET procedure is to reshape the tubal cartilage and reduce inflammation by expanding the ET orifice. In recent years, surgeons have increasingly recognized this procedure as a safe and effective treatment for obstructive ET disease [3]. However, despite its expanding use, a significant gap remains in knowledge about preoperative and postoperative care, as well as surgical performance evaluation. Furthermore, there is a lack of diagnostic criteria or guidelines for managing and assessing patients after undergoing BDET for obstructive ET.

While the patient selection, operative techniques, and safety concerns associated with BDET are well-documented, there is less consensus regarding the perioperative instructions that follow the procedure. Preoperative and postoperative protocols can vary depending on surgeon preferences and may include medications such as antihistamines, antibiotics, nasal decongestants, and intranasal steroid sprays [4]. Additionally, uncertainty persists regarding the efficacy of performing repeated Valsalva maneuvers after BDET to maintain the dilation of the lumen, as well as the optimal timing for these exercises postoperatively. Furthermore, there are unresolved questions regarding the appropriate duration of follow-up, the tools used to assess surgical outcomes, and the need for repeated balloon dilations in cases where the initial BDET is unsuccessful.

Given the different methodologies used in patient management before and after BDET surgery, there is a pressing need for consensus to define the most effective practices in BDET. This will facilitate a clearer understanding of its efficacy and optimal outcomes. In this study, our objective was to explore the factors that surgeons must consider and make decisions about in BDET, with the aim of establishing standardized guidelines to improve patient care.

HIGHLIGHTS

- A Delphi survey on preoperative and postoperative care for patients undergoing balloon dilation of the Eustachian tube found agreement among respondents regarding the importance of education about disease progression and the post-surgical prognosis, as well as the implementation of the Valsalva maneuver after the procedure to improve symptoms.
- However, agreement was not reached on postoperative management strategies such as antibiotic use and treatments for allergic rhinitis.
- The evaluation of postoperative outcomes emphasized certain measurement tools but lacked consensus on others, with varied opinions on the optimal follow-up duration and the use of specific tests for assessing surgical outcomes.

MATERIALS AND METHODS

A two-round modified Delphi technique was used to reach agreement among members of the Korean Society of Otological Society with recognized experience in Eustachian tube dysfunction (ETD) throughout South Korea, about the perioperative management of Balloon dilation surgery of patients with obstructive ETD. Through iterative rounds of anonymous surveys, experts provide individual responses to written questions to identify, clarify, and ultimately establish a consensus. Evaluation involves analyzing responses for interquartile range (IQR), medians, variance, and means to determine areas of collective agreement or disagreement within the group. To prevent potential bias, a diverse multicenter research group, uninvolved in selecting the expert panel or interpreting results, oversaw the study using objective procedures in participant selection, statistical analysis, and result interpretation [5].

This consensus statement did not require Institutional Review

Board approval, as it was based on the synthesis of expert opinions with the aim of informing practice rather than conducting research. Additionally, it did not involve the collection of new data from human subjects.

Literature review and determination of the consensus statement

The panel chair and members from Korean Eustachian tube Research Group led the development of the clinical statements and Delphi process. The primary aim of our study was to identify clinical consensus on the management of patient with obstructive ETD after BDET. The experts conducted a systemic review of published studies to find recent evidence regarding the perioperative management and clinical considerations for BDET in managing obstructive ETD. The definition of BDET was established as "placing a balloon catheter into the cartilaginous ET portion and subsequently expanding the balloon to alleviate obstructed ET." The panel established various determinations concerning the range and specifics of this clinical consensus statement before initiating the Delphi process. An initial set of 40 questions was developed by two executives from the Korean Eustachian tube Research Group, and we discussed the clarity and conciseness of the questions in the initial group meeting. On the basis of this feedback, we revised set of final 30 questions.

Selection of the expert panel

The invitation letter was sent to 50 experts of the Otology Research Group members. The letter included a description of the study goals, the Delphi process, and the timeline. All expert members met the inclusion criteria: (1) an otological surgeon with at least 5 years of experience in prescribing medications and performing otologic surgery; (2) experience in BDET surgery and managing patients with obstructive ETD; and (3) willingness to share their opinions. Of the 50 invited experts, 26 (52.0%) agreed to participate. Table 1 showed the demographic characteristics of the included Delphi panel experts. The panel members did not receive any financial compensation for their participation.

Table 1. Demographic information of the Delphi expert panel

Demographic variable	Number (%)
Sex	
Male	22 (84.6)
Female	4 (15.4)
Age (yr)	
31–40	2 (7.7)
41–50	14 (53.8)
≥51	10 (38.5)
Work experience (yr)	
5–10	3 (11.5)
11–20	11 (42.3)
21–30	12 (46.2)
Education	
Master's degree	1 (3.8)
Master's degree, PhD degree	25 (96.2)
Eustachian tube surgical experience (number/year)	
5–10	12 (46.2)
11–20	10 (38.5)
21–30	4 (15.4)

Delphi survey method process and administration

The fieldwork was carried out over a 4-week period from August 22 to September 16, 2023. The information was sent electronically via SMS URLs to each member who agreed to participate in the study and a link with controlled access was available to fill out the questionnaire for each round. Responses collected through this link were anonymous.

Initially, we discussed 30 questions, which included 28 Likert scale questions, one multiple-choice question, and one single-choice question, resulting in 28 questions for the second round with the feedback demonstrating the results of initial round was included. For the first survey round, a series of 30 statements was provided to the panelists, and the level of agreement for each statement was ranked on a 0–9 scale with 0 being total disagreement and 9 total agreements. Scores between 1 and 3 were considered to represent disagreement with the question contained in the statement, scores between 4 and 6 were regarded as neither agreement nor disagreement, and scores between 7 and 9 were regarded as agreement with the question proposed. The second survey presented 28 questions, which included 26 Likert scale statement, one multiple-choice question, and one single-choice question to the panelists. Panel members were asked to re-evaluate their answers for which a consensus was not reached in the first round, considering this new information provided. A total of 26 individuals participated in the final round survey. However, two respondents submitted multiple responses, so we excluded their duplicate responses to ensure data integrity. Our analysis was based on the data from the remaining 24 participants in the last survey.

Analysis and interpretation of data

In this study, we aimed to reach a consensus among experts. To determine consensus, we looked for instances where over 70% of experts rated 7–9 points, and less than 15% rated 1–3 points. This level of agreement served as our benchmark for consensus and was also our convergence threshold. Consensus, in our context, means that a significant majority, at least 50%, of experts provided a similar response. We calculated this using the formula: Consensus=1–[(Q3–Q1)/median]. A strong consensus was considered when the consensus value exceeded 0.75. We assessed content validity using the content validity ratio (CVR). The CVR was calculated as CVR=[Ne–(N/2)]/(n/2), where Ne is the proportion of experts with positive responses, and N is the total number of experts. A CVR value exceeding 0.37 indicated a positive convergence of expert opinions. To understand the

Table 2. Statements that reached consensus for postoperative management after balloon dilatation

Statement	Convergence/ disagreement (%)	Consensus	CVR	IQR
Evaluation of the treatment results is necessary after BDET.	100/0	0.9	0.4	1.0
Depending on the results of BDET treatment, the insertion of a tympanostomy tube may be considered.	83.3/0	0.8	0.3	2.0
Patient education regarding the natural course of the disease before and after BDET is essential.	95.8/0	0.9	0.4	1.3
Patients suspected of having allergic rhinitis may require nasal steroid medication after BDET.	83.3/0	0.8	0.4	2.0
Education on the Valsalva maneuver is necessary for symptom improvement after BDET.	83.3/0	0.8	0.3	2.0
When performing BDET and middle ear surgery together, the Valsalva maneuver is prohibited for a specified period.	79.2/8.3	0.8	0.5	2.0
Depending on the treatment results of BDET, the option of repeating BDET can be considered.	79.2/12.5	0.8	0.7	1.2
Depending on the treatment results of BDET, the use of medication can be considered.	75.0/8.3	0.7	0.5	2.3
Required tests to evaluate the treatment results after BDET.	Otoendoscopy (95.8%), Valsalva (100%), PTA (83.3%), tympanometry (91.7%), ETDQ-7(100%), history-taking (83.3%)			

CVR, content validity ratio; IQR, interquartile range; BDET, balloon dilation of the Eustachian tube; PTA, pure-tone audiometry; ETDQ, Eustachian Tube Dysfunction Questionnaire.

variation in expert responses, we calculated the IQR as (Q3–Q1). Q3 represented the third quartile (75%), and Q1 represented the first quartile (25%), indicating alignment among the opinions of 50% of the experts. We used Fleiss Kappa to measure inter-rater agreement for items assessed with the Likert scale. All analyses were performed using R Statistical Software v4.3.0 (R Foundation for Statistical Computing).

RESULTS

When revisions of the original 30 questions presented at the first Delphi round were included, a total of 28 clinical questions —comprising 26 statements and two choice questions—were utilized in the second Delphi survey following discussion. After two iterations of the Delphi survey, nine statements achieved the standardized definition for consensus (Table 2), while the others did not reach consensus (Table 3). Regarding the Fleiss kappa, there was significant agreement among raters; however, the level of agreement remained quite low in the first Delphi round (kappa=0.024, $P<0.001$) and the second Delphi round (kappa=0.265), indicating only slight agreement among the raters. Statements that reached consensus and those that did not are listed in Tables 2 and 3.

Preoperative and postoperative care for patients undergoing BDET

Most respondents (95.8% agreement) rated the importance of patient education and counseling regarding the natural progression of the disease and post-surgical prognosis as a crucial aspect of perioperative care. The panel reached a consensus that patients should be educated about the Valsalva maneuver after BDET to improve their symptoms. However, they agreed that patients should avoid the Valsalva maneuver for a certain period when undergoing middle ear surgery in conjunction with balloon dilation.

The panel did not reach a consensus on the use of antibiotics postoperatively, reflecting the lack of compelling evidence to support their role in preventing postoperative infections following BDET. There was also no consensus on the postoperative use of systemic corticosteroids or nasal irrigation. However, the panel agreed that intranasal corticosteroids are preferable postoperatively for patients with allergic rhinitis. No consensus was achieved regarding other postoperative management strategies, including treatment for laryngopharyngeal reflux, the Buteyko maneuver—a breathing technique aimed at reducing hyperventilation and increasing respiratory efficiency—and other rhinitis treatments such as antihistamines and decongestants [6].

Evaluation of postoperative outcomes after BDET

All respondents (100% agreement) concurred on the necessity of assessing treatment outcomes following BDET. Among the 14 measurement tools evaluated, the panel identified four primary outcome measures: ETDQ-7, the Valsalva maneuver, otoendoscopy, and tympanometry (Fig. 1). Additionally, taking a patient's history and performing pure tone audiometry (PTA) were acknowledged as meaningful postoperative outcome measures. However, consensus was not reached regarding the use of ET function tests (nine-step method, sonotubometry, tubo-manometry) and imaging tests (Valsalva computed tomography [CT], magnetic resonance imaging [MRI]), as well as laryngoscopy, pneumatic endoscopy, allergy tests, and the Toynbee maneuver, in the evaluation of surgical outcomes.

Fig. 2 displays the survey responses regarding the required follow-up period after BDET, as indicated by a panel of experts. The follow-up periods selected by the panelists varied widely. Notably, 30.8% of the panelists recommended a follow-up period exceeding 12 months post-surgery. The average, median, and most frequently chosen durations for follow-up were 8.875 months, 12 months, and 12 months, respectively. However, the percent-

Table 3. Statements that did not reach consensus: postoperative management after balloon dilatation

Statement	Convergence/ disagreement (%)	Consensus	CVR	IQR
A prescription for anti-inflammatory pain medication may be necessary if the patient complains of pain or for pain prevention after BDET.[a)]	75.0/16.7	0.8	0.3	1.5
If the patient complains of pain after BDET, an anti-inflammatory analgesic prescription is required to prevent pain.[a)]	75.0/16.7	0.7	0.3	1.5
Drug treatment may be necessary after BDET.	66.7/16.7	0.8	0.4	1.5
Depending on the treatment results of BDET, a myringotomy procedure is considered.	66.7/8.3	0.5	0.3	4.0
The antihistamine may be necessary if there is a history of allergic rhinitis after BDET.	62.5/0	0.7	0.2	2.3
Rhinosinusitis treatment is necessary before and after BDET.	54.2/29.2	0.2	0.2	6.0
Allergic rhinitis treatment is necessary before and after BDET.	45.8/29.2	0.3	0.3	4.5
Nasal steroid treatment is necessary after BDET.	41.7/16.7	0.6	0.2	2.3
The recommended period for nasal irrigation after BDET is 2 weeks or less after surgery.	33.3/37.5	0.2	0.2	4.3
A prophylactic laryngopharyngeal reflux treatment is necessary before BDET because it is difficult to determine the degree of eustachian tube dysfunction.	29.2/45.8	–0.3	0.2	5.0
Oral nasal decongestants are necessary after BDET.	25.0/54.2	–0.2	0.2	3.5
Treatment of laryngopharyngeal reflux before and after BDET is necessary.	25.0/54.2	–0.4	0.3	4.3
Antibiotic treatment is necessary after BDET.	25.0/45.8	0.3	0.2	3.5
Antihistamines is necessary after BDET.	16.7/45.8	0.1	0.3	4.0
Nasal irrigation should be performed after BDET	16.7/37.5	0.4	0.2	3.0
A topical nasal decongestant is necessary after BDET.	12.5/45.8	0.4	0.4	3.0
The recommended period for nasal irrigation after BDET is at least 2 weeks after surgery.	8.3/66.7	–0.5	0.3	3.0
Buteyko breathing is necessary before and after BDET.	8.3/37.5	0.6	0.3	2.3
Required tests to evaluate the treatment results after BDET.	Nine-step method, sonotubometry, pneumatic otoscope, surgical microscope, Toynbee maneuver, tubomanometry, TTAG, inflation-deflation test, laryngoscopy, allergy test, CT, Valsalva CT, MRI			

CVR, content validity ratio; IQR, interquartile range; BDET, balloon dilation of the Eustachian tube; TTAG, tubo-tympano-aerodynamic graphy; CT, computed tomography; MRI, magnetic resonance imaging.
[a)]The items where consensus was reached, based on the criterion of 70% or higher agreement among the panelists, but not based on the CVR values.

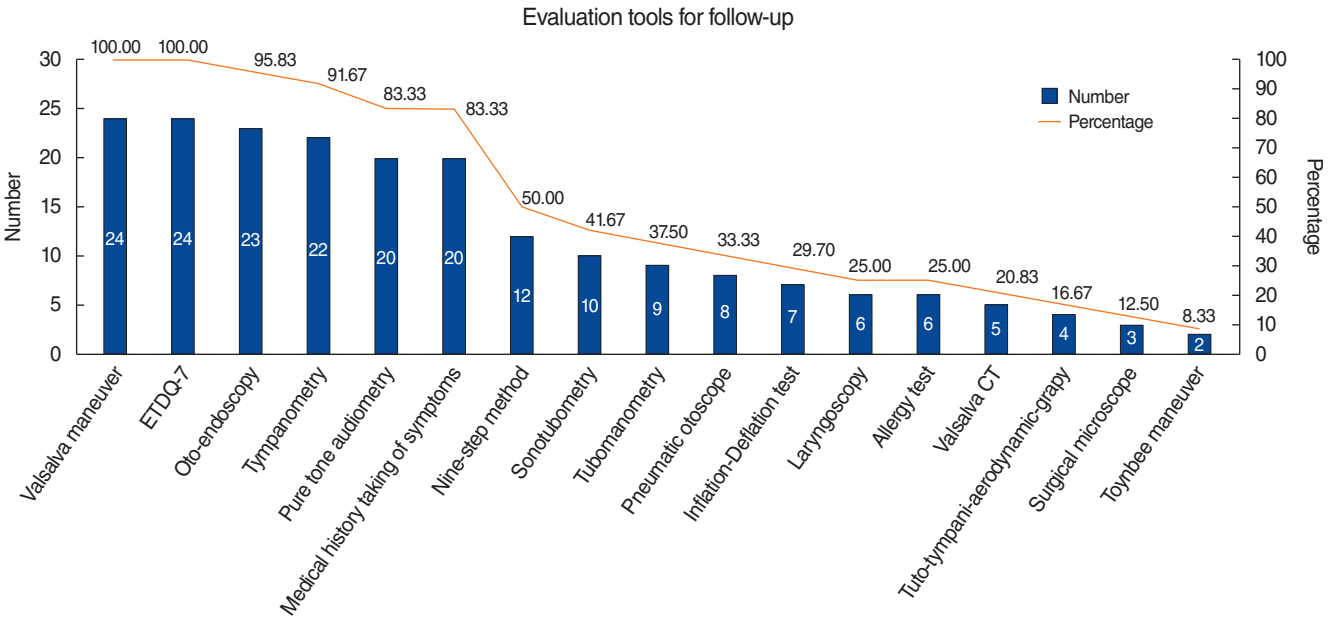

Fig. 1. Expert panel overview of evaluation tools for post-balloon dilation of the Eustachian tube follow-up. This figure presents a comprehensive list of tools and methods recommended for the follow-up evaluation of patients. The numbers below each tool indicate the frequency of their recommendation by experts in the field. ETDQ, Eustachian Tube Dysfunction Questionnaire; CT, computed tomography.

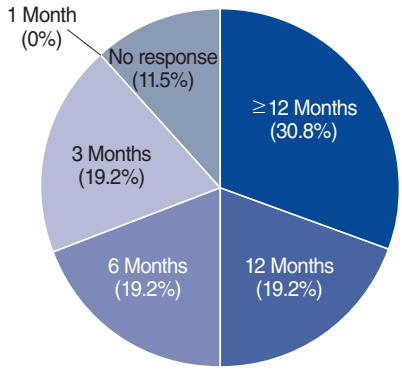

Fig. 2. Required period for follow-up after balloon dilation of the Eustachian tube (BDET). This pie chart represents the responses to a survey or study regarding the required period for follow-up after BDET. Follow-up recommendations for more than 12 months after BDET were made by 30.8% of the panel, while 19.2% recommended follow-up at 12 months, 6 months, and 3 months, respectively. None of the panel recommended a follow-up period of 1 month.

age of panelists who opted for a 12-month follow-up did not meet the 70% threshold necessary for consensus, highlighting variability in the recommended follow-up periods among the respondents. Although 12 months was the most commonly suggested duration and coincides with the median, the lack of a 70% consensus underscores the absence of strong agreement on this specific timeframe.

The members concurred that following an initial BDET failure, a decision regarding secondary surgery can be made. Additionally, depending on the outcomes of the BDET, the insertion of a ventilation tube or the initiation of medical treatment may be considered.

DISCUSSION

This Delphi study adhered to a stepwise quality assessment process that included: (1) identifying the topic or issue through an extensive literature search and group discussions; (2) choosing panel members based on specific, predefined criteria; (3) conducting survey rounds, providing controlled feedback, and engaging in iterative discussions; and (4) reaching consensus following a defined protocol. We included homogeneous group members, and criteria for panel selection were established to improve the qualitative strength of the consensus.

Adjuvant treatment after BDET

To date, there is a lack of medical evidence concerning the optimal perioperative management of BDET. Our survey indicates a strong consensus on the significance of the Valsalva maneuver in relation to ET function, even following ET dilation surgery. Traditionally, increasing nasopharyngeal pressure to open the ET has been a common practice in cases of ET dysfunction. This method may also act as an adjunct to aid in inflating the middle ear after the ET has been surgically dilated. However, evidence-based research is necessary to verify whether repeated Valsalva maneuvers post-balloon dilation positively affect postoperative outcomes, as is commonly believed. Additionally, there is a need to develop standardized protocols concerning the frequency, duration, and timing of the Valsalva maneuver following BDET.

The level of agreement on additional postoperative medical therapies, such as antihistamines, corticosteroids, nasal sprays, and other medications, was less comprehensive than anticipated. This variation in expert opinions likely arises from differences in experience and the interpretation of the limited data available. Although systemic corticosteroids are frequently used to reduce inflammation, their specific role in postoperative care after BDET remains ambiguous, necessitating further research to evaluate their effectiveness and safety. Systematic reviews conducted by Huisman et al. [7] and Luukkainen et al. [8] have identified topical corticosteroid nasal sprays as the most commonly used adjunctive treatment following BDET. However, our consensus recommends their use only for patients with confirmed allergic rhinitis.

Similarly, although nasal irrigation is believed to maintain nasal hygiene and reduce inflammation, its benefits following BDET are not well-supported by evidence, leading to a lack of consensus regarding its use. Considering that BDET is primarily indicated for patients with chronic, refractory cases of ETD who have not responded to previous medical interventions, it is crucial to critically evaluate the necessity of postoperative medications on a case-by-case basis. The panel was unable to reach a consensus regarding the administration of antibiotics before or after surgery. A prospective controlled study conducted in 2015 on perioperative antibiotic prophylaxis in BDET patients showed no signs of infection in either the group that received antibiotics or the group that did not. This led the authors to retract their earlier recommendation for routine antibiotic use in BDET [9].

Postoperative follow-up period

Reaching a consensus on the postoperative follow-up period was challenging; however, the recommendations based on survey responses suggest a follow-up duration of 12 months. Adopting an extensive follow-up period is believed to aid in assessing the recurrence of otitis media with effusion (OME) following the canal dilatation procedure. Additionally, it may help monitor the recurrence of ET obstruction, which can be triggered by upper respiratory infections, sinusitis, or allergic events. In a long-term evaluation study of BDET, researchers reported outcomes at both the 12-month follow-up and an average follow-up period of over 2 years post-BDET. Over an average follow-up of 29 months, individuals maintained the significant improvements observed at the 12-month mark in ETDQ-7 scores and standard middle ear examinations [10].

Postoperative outcome measurement after BDET

Diagnosing ETD remains challenging due to the limitations of current testing methodologies, and the evaluation of post-treatment outcomes for ET conditions continues to be a subject of debate. Although several case series suggest that BDET can effectively restore ET function, systematic reviews have yet to find high-quality evidence that supports its effectiveness based on "objective" measures [4,7]. Assessments of BDET outcomes largely depend on subjective measures, which include clinical outcome scoring both before and after the procedure using tools such as the ETDQ-7. In the most recent studies, these evaluations are enhanced by incorporating Valsalva maneuvers [11,12]. Similarly, the panelists in our survey unanimously selected the ETDQ-7 questionnaire and the Valsalva maneuver as the most essential tools for evaluating outcomes.

The next most frequently adopted evaluation methods by respondents were otoscopy, tympanometry, and PTA, following the ETDQ-7 and Valsalva maneuver. Otoscopy is utilized to check for an intact tympanic membrane in a neutral position, without middle ear effusion or a retraction pocket, which suggests that the ET is not obstructed. However, the presence of middle ear effusion does not necessarily indicate obstructive ETD. Otoscopy can also reveal tympanic detachment during the Valsalva maneuver, or the status of a tympanostomy tube. Given otoscopy's ability to provide a clear view of the tympanic membrane and middle ear cavity, the panel reached a consensus on its value as an outcome measure following BDET. More recently, slow-motion video otoendoscopy has been employed to enhance visualization of ET function. A correlation has been established between the appearance of the tube during swallowing and ET function via impedance audiometry (IA), prompting efforts to assess the dilatory movements at the ET orifice in both healthy individuals and those with ETD.

Tympanometry is widely described and one of the few tests of ETD in regular clinical use. This test is particularly effective in detecting middle ear effusions, boasting a sensitivity and specificity of 94% and 95%, respectively. However, the accuracy of IA as a diagnostic tool for ETD not associated with OME is limited. A single measurement of middle ear pressure does not yield information about ET function, and the pressures measured by IA can fluctuate significantly within a few hours. Despite these limitations, all panelists seem to support the use of tympanometry and PTA as traditional and fundamental diagnostic tools, providing objective assessments of the condition of both the middle ear cavity and inner ear status.

On the contrary, various ET function tests, such as tubomanometry (TMM; 37.5%), sonotubometry (41.6%), inflation-deflation test (29.1%), and the nine-step method (50.0%), have not reached a consensus as suitable methodologies for evaluating outcomes following BDET. These ET function tests involve specific technical considerations, including the selection criteria for suitable test ears (e.g., the nine-step inflation-deflation test is only possible in ears without tympanic membrane perforation). Additionally, the quantitative assessment of these tests is challenging due to the absence of a standardized method for each function test and a lack of standardized reference levels to identify openings. Each test also faces limitations in terms of accuracy, including issues with specificity or sensitivity, as well as concerns regarding test reproducibility. Despite the development of various ET function tests and their use in clinical practice, all continue to exhibit significant limitations.

When Sudhoff and Poe first introduced the feasibility and efficacy of BDET, they employed the Eustachian Tube Score-7 (ETS-7) as a quantitative measure of ET function. The ETS-7 score comprises subjective symptom questionnaires, the patient's ability to perform a positive Valsalva maneuver, and TMM. TMM measures the active and passive opening of the ET by applying pressure to the nasopharynx during swallowing. It tests three different pressure values (30–50 mbar) sequentially and calculates the opening latency index, or the R index. Although the presence of the R value indicates high sensitivity in detecting ET openings, it has low specificity for identifying ET non-openings [13]. The measurement of the R index may be influenced by individual variations in the temporal bone, such as mastoid volume and the amplitude of tympanic membrane movement. Additionally, a very weak correlation has been observed between the EAC pressure and the R value [14].

Using sonotubomanometry (STM), the rate of detectable ET opening with swallowing varies between studies, with reported rates ranging from 63% to 92%. Although STM is widely applicable, its efficacy is debated when a middle ear effusion is present. One study suggests that STM has an 85% predictive rate for OME in children. However, a persistent limitation of STM is that sound transmission, unlike pressure equalization, is not a normal function of the ET. Consequently, the frequency of tube opening can only provide a limited assessment of the ET's overall physiological function. In fact, the most consistent finding with STM is that 10%–20% of healthy individuals do not exhibit detectable opening during swallowing, which limits the utility of STM as a stand-alone test for ETD. STM may be more effective when used in conjunction with another test for ETD.

Visualization of the ET in imaging studies has always been challenging due to its typically closed state and its curved, narrow pathway [15]. MRI has been utilized less frequently, and the development of ET visualization techniques using this method remains limited. CT imaging of the ET is generally preferred only as part of the preoperative screening for BDET to assess the relationship between the internal carotid artery and the ET, aiming to prevent potentially lethal complications [16]. Various imaging techniques are being developed to assess the patency of the ET following dilation surgery. The Valsalva maneuver combined with CT imaging enables visualization of the lumen of the cartilaginous ET in patients with an obstructive tube. A recent study demonstrated the visualization of changes in the dilated

ET lumen following BDET using CT images in human cadavers [17]. Another study by Li et al. [18] highlighted changes in ET length post-BDET, utilizing iodine-based contrast mediums for ET visualization. However, the necessity of an imaging test for the ET remains a subject of debate, and there is still a need for an advanced imaging technique that offers both high accuracy and availability for effective visualization of the ET.

Consideration of secondary steps depending on treatment results

We may need to consider whether there is a measurable benefit in attempting the BDET procedure again for patients who do not show improvement after the initial surgery. A panel of experts has agreed on recommendations for secondary BDET in patients who did not show improvement. However, Keschner et al. [19] in 2022 reported the efficacy of repeat procedures for patients who showed no improvement even 3 months after the first procedure, as measured by ETDQ-7, but they did not show improvement even after the second procedure. Questions persist regarding the clinical management of patients who undergo BDET but do not report substantial improvement even after a recovery period. A comprehensive understanding of factors such as misdiagnosis, anatomic unfavorability, and high inflammation is necessary to demonstrate the necessity and benefits of a second operation.

This study has several limitations, notably the exclusive involvement of experts from the Korean Otological Society (KOS), which may restrict the broader applicability of the findings. Nonetheless, the composition of the panel, consisting solely of members from the Eustachian Tube Research Group of the KOS, provides a unique advantage. These experts possess an in-depth understanding of the local patient demographics and treatment practices, ensuring that the consensus statements are highly relevant and specifically tailored to the needs of the Korean population. To broaden the clinical relevance of this consensus statement internationally, we included a committee member from the Japanese Eustachian Tube Research Group during the revision phase of this study. This expert indicated that currently, in Japan, there are no definitive guidelines or consensus on BDET or the management of ETD. Regarding antibiotic use, some otolaryngologists in Japan employ low-dose macrolide therapy for ETD, similar to its use in chronic sinusitis [20]. The use of intranasal steroids has also been recognized as effective in managing OME, which supports our panel's findings on their benefits for patients with allergic rhinitis [21]. However, antibiotics and systemic corticosteroids are not typically recommended, which is consistent with the uncertainty in our panel's discussions. In addition, a larger sample size could enhance the robustness and representativeness of the consensus achieved. Furthermore, not all clinical statements reached consensus, indicating ongoing debates or insufficient evidence in certain areas. This underscores the complexities and nuances of managing obstructive ETD and highlights the need for further research.

To address these limitations, future research could involve larger, more diverse panels, incorporate a broader international perspective, and consider longitudinal studies to track evolving practices. Additionally, conducting randomized controlled trials to provide more robust evidence and updating guidelines in response to advancements in medical knowledge would contribute to refining perioperative management strategies for obstructive ETD.

Conclusion

In conclusion, this study employed a two-round modified Delphi technique to achieve consensus among KOS members on the perioperative management of BDET surgery in patients with obstructive ETD. The research covered a range of topics, including preoperative and postoperative care, adjuvant treatments, evaluation of postoperative outcomes, and considerations for subsequent interventions based on the results of the initial treatment. The findings indicated a consensus on several key issues, such as the critical role of patient education and counseling during perioperative care and the need to measure treatment outcomes using specific tools, including ETDQ-7, the Valsalva maneuver, otoendoscopy, and tympanometry. The study highlighted the necessity for ongoing research into postoperative management, the effectiveness of treatments, and evaluation techniques to improve the overall understanding of BDET outcomes and to establish standardized guidelines for patient care.

This Delphi study provides valuable insights into the varied perspectives of otological experts, facilitating future research and collaborative initiatives aimed at improving the management of patients with obstructive ETD who are undergoing BDET.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

ACKNOWLEDGMENTS

This work was supported by a National Research Foundation of Korea (NRF) grant funded by the Korean government (MSIT) (RS-2024-00352526 for HYL).

ORCID

Min Young Kwak https://orcid.org/0000-0003-1546-7861
Ho Yun Lee https://orcid.org/0000-0002-9590-3477
Soo-Keun Kong https://orcid.org/0000-0002-6783-3766
In Seok Moon https://orcid.org/0000-0002-3951-5074

Bong Jik Kim https://orcid.org/0000-0002-6384-2171
Myung-Whan Suh https://orcid.org/0000-0003-1301-2249
Jae Yun Jung https://orcid.org/0000-0002-1870-0748
Hong Ju Park https://orcid.org/0000-0002-6331-8556
Kyu-Yup Lee https://orcid.org/0000-0001-7170-4847
Hyong-Ho Cho https://orcid.org/0000-0002-1331-4039
Ryoukichi Ikeda https://orcid.org/0000-0003-0076-6092
Jae-Jin Song https://orcid.org/0000-0002-6631-3232
Chi-Kyou Lee https://orcid.org/0000-0001-5380-1651

AUTHOR CONTRIBUTIONS

Conceptualization: HYL, CKL. Methodology: HYL, MYK, JJS. Data curation: SKK, ISM, BJK, MWS, JYJ, HJP, KYL, HHC. Visualization: MYK. Funding acquisition: HYL. Writing–original draft: MYK. Writing–review & editing: HYL, CKL, RI. All authors read and agreed to the published version of the manuscript.

REFERENCES

1. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: how to decide its appropriateness. World J Methodol. 2021 Jul;11(4): 116-29.
2. Linstone HA, Turoff M. The Delphi method: techniques and applications. Addison Wesley; 1975.
3. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation eustachian tuboplasty: a clinical study. Laryngoscope. 2010 Jul;120(7):1411-6.
4. Hwang SY, Kok S, Walton J. Balloon dilation for eustachian tube dysfunction: systematic review. J Laryngol Otol. 2016 Jul;130 Suppl 4: S2-6.
5. Holey EA, Feeley JL, Dixon J, Whittaker VJ. An exploration of the use of simple statistics to measure consensus and stability in Delphi studies. BMC Med Res Methodol. 2007 Nov;7:52.
6. Zeng H, Chen X, Xu Y, Zheng Y, Xiong H. Buteyko breathing technique for obstructive Eustachian tube dysfunction: preliminary results from a randomized controlled trial. Am J Otolaryngol. 2019; 40(5):645-9.
7. Huisman JM, Verdam FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: a systematic review. Laryngoscope. 2018 Jan;128(1):237-47.
8. Luukkainen V, Kivekas I, Silvola J, Jero J, Sinkkonen ST. Balloon Eustachian tuboplasty: systematic review of long-term outcomes and proposed indications. J Int Adv Otol. 2018 Apr;14(1):112-26.
9. Schroder S, Abdel-Aziz T, Lehmann M, Ebmeyer J, Sudhoff H. Bacteriologic investigation of the Eustachian tube and the implications of perioperative antibiotics before balloon dilation. HNO. 2015 Sep; 63(9):629-33.
10. Cutler JL, Meyer TA, Nguyen SA, O'Malley EM, Thackeray L, Slater PW. Long-term outcomes of balloon dilation for persistent Eustachian tube dysfunction. Otol Neurotol. 2019 Dec;40(10):1322-5.
11. McCoul ED, Singh A, Anand VK, Tabaee A. Balloon dilation of the eustachian tube in a cadaver model: technical considerations, learning curve, and potential barriers. Laryngoscope. 2012 Apr;122(4): 718-23.
12. Schroder S, Lehmann M, Sauzet O, Ebmeyer J, Sudhoff H. A novel diagnostic tool for chronic obstructive eustachian tube dysfunction: the eustachian tube score. Laryngoscope. 2015 Mar;125(3):703-8.
13. Alper CM, Teixeira MS, Kim JH, Douglas Swarts J. Diagnostic accuracy of tubomanometry R value in detecting the Eustachian tube pressure equalizing function. Eur Arch Otorhinolaryngol. 2017 Apr; 274(4):1865-72.
14. Ruan K, Li J, Tan S, Liu L, Tang A. Comparison of sonotubometry, impedance, tubo-tympano-aerography, and tubomanometry to test eustachian tube function. Am J Otolaryngol. 2020;41(2):102384.
15. Niwa H, Takahashi M, Yanagita N, Naganawa S. Evaluation of clearance function of the Eustachian tube by sequential contrast CT. Acta Otolaryngol Suppl. 1990;471:43-50.
16. Abdel-Aziz T, Schroder S, Lehmann M, Gehl HB, Ebmeyer J, Sudhoff H. Computed tomography before balloon Eustachian tuboplasty: a true necessity? Otol Neurotol. 2014 Apr;35(4):635-8.
17. Cetin-Ferra S, Teixeira MS, Swarts JD, Rath TJ, Alper CM. CT imaging of Eustachian tube balloon dilation: method development on cadaver heads. Bioengineering (Basel). 2023 May;10(5):592.
18. Li L, Mao Y, Hu N, Yan W, Lu Y, Fan Z, et al. The effect of balloon dilatation eustachian tuboplasty combined with grommet insertion on the structure and function of the eustachian tube in patients with refractory otitis media with effusion. Ann Palliat Med. 2021 Jul;10(7): 7662-70.
19. Keschner D, Garg R, Loch R, Luk LJ. Repeat Eustachian tube balloon dilation outcomes in adults with chronic eustachian tube dysfunction. Otolaryngol Head Neck Surg. 2022 May;166(5):951-6.
20. Ikeda R, Hidaka H, Ito M, Kamide Y, Kuroki H, Nakano A, et al. Pharmacotherapy focusing on for the management of otitis media with effusion in children: systematic review and meta-analysis. Auris Nasus Larynx. 2022 Oct;49(5):748-54.
21. Hidaka H, Ito M, Ikeda R, Kamide Y, Kuroki H, Nakano A, et al. Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan: 2022 update. Auris Nasus Larynx. 2023 Oct;50(5):655-99.