Long-term Changes of Hearing Thresholds and Eustachian Tube Function after Balloon Dilation of the Eustachian Tube in Patients with Chronic Otitis Media

Yeonjoo Choi, Woo Seok Kang, Seung Cheol Ha, Sang Hun Lee, Joong Ho Ahn, Jong Woo Chung, Hong Ju Park

Department of Otorhinolaryngology-Head and Neck Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea

*Yeonjoo Choi and Woo Seok Kang contributed equally to this work and are co-first authors.

Yeonjoo Choi 0000-0002-6990-2454  Woo Seok Kang 0000-0003-1692-4155
Seung Cheol Ha 0000-0003-0949-0838  Sang Hun Lee 0000-0002-5481-8444
Joong Ho Ahn 0000-0001-6726-8894  Jong Woo Chung 0000-0003-0765-9134
Hong Ju Park 0000-0002-6331-8556

Corresponding author: Hong Ju Park, MD PhD

Department of Otorhinolaryngology-Head and Neck Surgery, Asan Medical Center, University of Ulsan, College of Medicine

88, Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Republic of Korea

E-mail: dzness@hotmail.com
Running title: Changes of hearing & ET function in patients with COM after BDET

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HIGHLIGHTS

- 21 of eustachian tube (ET) dysfunction ears were examined in changes of ability to perform Valsalva maneuver and audiologic improvements.

- None of the ears could perform a Valsalva maneuver before balloon dilation of eustachian tube (BDET), whereas 62% were able to perform a Valsalva maneuver after BDET.

- The successful Valsalva group after BDET showed hearing improvement and intact tympanic membrane more frequently than the unsuccessful Valsalva group.

- BDET can be a good treatment option for chronic otitis media patients with persistent ET dysfunction.
ABSTRACT

Objectives: To evaluate long-term changes after balloon dilation of eustachian tube (BDET) in chronic otitis media (COM) patients with ET dysfunction which was persistent after tympanomastoidectomy (TM op).

Methods: We retrospectively reviewed the medical records of consecutive patients who were diagnosed with COM and ET dysfunction and underwent TM op in our tertiary hospital from 2016 to 2017. The tympanic membrane status, the presence of ventilation tube, ability to perform a Valsalva maneuver, and audiologic changes by dilation of ET were observed.

Results: Twenty-one ears with 20 patients who had underwent TM op but could not perform a Valsalva maneuver with a persistent air-bone gap and eventually underwent BDET (M:F=8:13, right:left=11:10). Four ears showed perforation of the tympanic membrane after TM op. Among 17 ears, 15 ears underwent VT insertion before BDET, while 2 ears underwent VT insertion and BDET simultaneously. Although none of the patients were capable of the Valsalva maneuver before BDET, 13 ears (62%) were able to perform a Valsalva maneuver successfully after BDET. When evaluating the tympanic membrane status at the latest follow-up, ventilation tubes were still present in 8 cases. In the other 13 cases, intact tympanic membranes were present in 9 out of 11 in the successful Valsalva group, whereas none of them were intact in the unsuccessful Valsalva group (p=0.014). The successful Valsalva group after BDET showed improved air-bone gap of 8.9±12.4 dB, while the unsuccessful Valsalva group showed aggravated air-bone gap of 3.8±11.8 dB at 1 year after BDET with a significant difference (p=0.031).

Conclusion: A Valsalva maneuver could be performed successfully by 62% of patients after BDET in patients with COM and ET dysfunction. BDET is helpful for successful hearings improvement and improved tympanic aeration in COM patients with ET dysfunction.
Keywords: Chronic otitis media, Eustachian tube, Balloon dilation, Eustachian tube dysfunction, Tympanomastoidectomy
INTRODUCTION

Chronic otitis media (COM) refers to an inflammatory condition of the middle ear lasting for at least 3 months. Although some studies argue that eustachian tube (ET) dysfunction is not a leading cause of COM, many studies support the hypothesis that dysfunction of the ET plays an important role in the etiology of COM. Equalizing the pressure, mucociliary clearance of secretions, and protecting the middle ear are the major functions of the ET. When the ET does not work properly, negative pressure in the middle ear accumulates, and it can lead to the retraction of the tympanic membrane and fluid accumulation in the middle ear, resulting in COM.

Medical treatment including nasal steroids, decongestants, and antihistamines, was empirically tried to improve the mucosal conditions of the nasal cavity and ET. And more invasive treatments have been also tried, such as paracentesis and the insertion of ventilation tubes to equalize pressure via the tympanic membrane. However, these approaches could not solve the dysfunction of the ET in a direct way. Surgical widening of the cartilaginous ET by laser or microdebrider had been attempted for opening the ET with limited success. Thus, no definite treatment for ET dysfunction emerged until the balloon dilation of ET (BDET) was introduced in 2010. It directly places a balloon in the cartilaginous ET and mechanically dilates the cartilaginous part of the ET by inflation of the balloon. This procedure resulted in improved ET function in 66-100% and a reduction in symptoms. Despite these successful results of BDET, there exist still failure cases even with the repeated BDET techniques and stent insertion into the cartilaginous ET is being under development to treat these failure cases.

Although the dysfunction of the ET plays an important role in the etiology of COM, there have been few studies that evaluated the efficacy of BDET in patients with COM. As
summarized in a review article\cite{14}, most studies reported short-term changes after BDET and most of the studies regarding BDET focused on otitis media with effusion. Since some COM patients have underlying problems related to ET dysfunction, it is inevitable that COM patients with ET dysfunction will still need treatment for the ET dysfunction even after successful ear surgery. Therefore, this study aimed to identify the ability to do a Valsalva maneuver successfully, long-term changes of hearing thresholds and the status of the tympanic membrane in COM patients with the persistent ET dysfunction who underwent BDET after TM operation.

**MATERIALS AND METHODS**

**Study design and patients**

A retrospective analysis of the medical records was conducted for consecutive patients who underwent BDET after tympanomastoidectomy (TM op) from January 2016 to December 2017 at a single tertiary medical center. Any patients who underwent TM op were asked to perform a Valsalva maneuver, starting from three to four weeks after surgery. The entire packing in the external auditory canal was removed under the microscope at 2 weeks after TM op. Gelfoam pledgets filling the canal were removed by gentle aspiration using the smallest possible suction tubes. Otic drop was applied and the canal was cleaned regularly for 1-2 additional weeks. And then, the patient was instructed to perform a Valsalva maneuver when the fascia looked well attached under the endoscope. Thus, any patients who underwent TM op were asked to perform a Valsalva maneuver regularly (every hour, 10 times a day) at 3-4 weeks after the surgery. They were instructed to hold their breath by increasing the pressure for 5 seconds repeatedly until they felt any pressure change in the operated ear. They were instructed not to do a Valsalva maneuver further if they feel pressure changes in the ear, because too much inflation might rupture the tympanic membrane in the early postoperative stage. Successful
Valsalva maneuver was defined positive, when the bulging of the tympanic membrane could be observed by endoscopic examination or a patient felt the air passage when there was a perforation of the tympanic membrane (or ventilation tube was in place), while the patients were asked to do a Valsalva maneuver. When a patient could do a Valsalva maneuver successfully, he/she was followed up 6 months later, otherwise he/she was instructed to perform the Valsalva maneuver regularly (every hour, 10 times a day) and scheduled to visit an outpatient clinic 2-3 weeks later.

When patients could not perform a Valsalva maneuver even after 2-3 weeks of Valsalva trial period and there was also a persistent air-bone gap in pure-tone audiometry, they became a candidate for BDET. A ventilation tube was inserted to the tympanic membrane for immediate resolution of the middle ear effusion before BDET or simultaneously with BDET. When patients could not perform a Valsalva maneuver even after 2-3 weeks of Valsalva trial period and there was also a persistent air-bone gap in pure-tone audiometry, they became a candidate for BDET. A ventilation tube was inserted to the tympanic membrane for immediate resolution of the middle ear effusion before BDET or simultaneously with BDET. After BDET, the patients were asked to do a Valsalva maneuver more than ten times per day from the day after the procedure and were followed up at one week, 3 months, one year and as needed postoperatively. The study protocol of this study was approved by the Institutional Review Board of the institute and written informed consents were obtained from all patients.

**Measurement of hearing thresholds**

Hearing thresholds was determined by pure tone audiometry (PTA), and the mean hearing levels were expressed as the average of the hearing thresholds at 0.5, 1, 2, and 4 kHz.
(four-frequency average, 4FA). All patients were evaluated by PTA prior to BDET and at 3 months and at least yearly after dilation. The air-bone gap was measured before and after BDET.

The BDET procedure

All patients underwent topical anesthesia by placing surgical sponges soaked with normal saline containing 4% lidocaine and 1:1000 epinephrine to the nasal cavity and on the nasopharyngeal opening of ET for 5 minutes. A metallic guide sheath, a 0.035-inch flexible guidewire (Radiofocus M; Terumo, Tokyo, Japan) and a 6-mm wide, 20-mm long balloon catheter (Genoss Co Ltd, South Korea) were used. With endoscopic guidance, the guiding sheath was advanced through the nasal cavity to the orifice of the ET (Figure 1A). The guidewire was then introduced through the cartilaginous ET into the bony ET via fluoroscopic guidance (Figure 1B). And then the balloon catheter was passed through the inserted guidewire until it reached the first mild resistance approaching the narrowest diameter before the bony-cartilaginous isthmus. All procedures were performed in the Hirtz position for a submento-vertical view to identify both the location of the guidewire and the inflation of the balloon catheter under fluoroscopic guidance (Figure 1C). The balloon was then inflated with water-soluble contrast medium (Omnipaque 300; GE Healthcare, Cork, Ireland) to reach 10 atm for 1 minute and then deflated. And the balloon catheter was inserted deeper until it reached mild resistance and inflated again for another 1 minute.

Variables

Patient demographic and clinical data were collected, including age, sex, side, chief complaint, mean follow-up period, the status of the tympanic membrane, and the presence of a
ventilation tube. The ability to perform a Valsalva maneuver and any audiology changes were evaluated. The latest tympanic membrane status was also evaluated and compared between the successful and unsuccessful Valsalva groups.

**Statistical analysis**

Continuous variables are expressed as mean and standard deviation or median and range, while categorical variables are expressed as the number and percentage. Variables were compared using Mann-Whitney U test, chi-square test or Fisher’s exact test. A P-value of less than 0.05 was considered significant. Statistical analyses were performed using IBM SPSS software, version 24.0 (Chicago, IL, USA).

**RESULTS**

During the study period, a total of 21 ears (20 patients, 13 men and 8 women, aged from 31 to 71 years old), were enrolled in this study. The mean follow-up period was 69 months, range 9 to 238 months. The patient demographic data are summarized in Table 1. There was no difference between the left and right side. The most common chief complaints were hearing disturbance (57.1%), followed by ear fullness (28.6%), otorrhea (9.5%), and tinnitus (4.8%). Canal wall up mastoidectomy (CWUM) was performed in 13 ears (61.9%), while canal wall down mastoidectomy (CWDM) was performed in 8 ears (38.1%).

All patients could not perform a Valsalva maneuver successfully with a persistent air-bone gap after TM op, but could perform a Valsalva maneuver successfully on the non-operated ear except one patient who showed bilateral ET dysfunction. After BDET, 13 (61.9%) out of
21 ears were able to perform a Valsalva maneuver at the 1-year follow-up, and 10 (47.6%) out of 21 ears could perform a Valsalva maneuver at the latest follow up.

Among 21 ears, 17 ears needed ventilation tube insertion before or simultaneously with BDET. Four of these ears already had tympanic perforation, and therefore ventilation tube insertion was not required.

After BDET, the tympanic membrane was evaluated according to the ability to perform the Valsalva maneuver at the last follow-up (Table 2). Eight ears still had the ventilation tube inserted at the latest follow-up. Six of them were included in the unsuccessful Valsalva group and needed the VT for tympanic aeration. The ventilation tube was present in 2 of the successful Valsalva group because it was left in place until it spontaneously fell off in the successful Valsalva group. Among the successful Valsalva ears, 9 ears had an intact tympanic membrane, whereas 2 ears had an abnormal tympanic membrane; there was 1 case of retraction and 1 case of perforation. Among the unsuccessful Valsalva ears, 2 ears had an abnormal tympanic membrane, with 1 case of retraction and 1 case of perforation. In summary, successful Valsalva group showed normal tympanic membrane more frequently than the unsuccessful Valsalva group ($p=0.014$).

Figure 2 shows the individual hearing outcomes of the air-bone gap before and 1 year after BDET. Figure 3 shows the changes of air-bone gaps before and after DBET of the successful and unsuccessful Valsalva groups. The air-bone gap improved by 8.9±12.4 dB when comparing pre-BDET and 1 year in the successful Valsalva group, while the unsuccessful Valsalva group had a decreased air-bone gap of 3.8±11.8 dB, which was significantly different ($p=0.031$).

When comparing pre-BDET and the latest results, hearing improvement was observed
in the successful Valsalva group (5.4±9.3 dB), whereas a decrease was observed in the unsuccessful Valsalva group (0.8±11.6 dB), but the difference was not statistically significant (p=0.584).

**DISCUSSION**

Several plausible medical and surgical treatment options like ventilation tube for ET dysfunction have been introduced7-11, but they could not solve the ET dysfunction itself. After all of these efforts to manage ET dysfunction is inefficient, BDET was introduced9. Previous cadaver and numerous clinical studies proved the safety and effectiveness of BDET13,18-26. These successful results were also observed in children. A study reported that BDET effectively improved the audiologic outcomes by decreasing the air-bone gap compared to VT insertion alone for otitis media with effusion in children27. Another study also found that BDET is safe and effective for obstructive ET dysfunction in children28. Though most studies used endoscopy-guided BDET, endoscopy and fluoroscopy-guided balloon dilation of ET was also introduced with success without major complications29,30. There was also a study that demonstrated that a low pressure during balloon dilation is sufficient to inflate it via fluoroscopic guidance, suggesting that too high inflation pressure is not needed31. We used a 6-mm wide by 20-mm long balloon catheter and the balloon was inflated at 10 atm. Two balloon dilation systems are available widely and the Bielefeld system inflates the balloon at 10 atm for 2 minutes whereas the Acclarent system does so at 12 atm for between 30 seconds and 2 minutes31. For the Bielefeld system, the balloon is 20 mm long with a diameter of 3.28 mm, and thus has a smaller diameter than either the Acclarent system or the balloon we used here. The Acclarent balloon is 16 mm long with a diameter of 5 or 7 mm. Although it is challenging to compare the effectiveness of different systems, the reported efficacies of the
Bielefeld and Acclarent balloons seem to be comparable\textsuperscript{21,32,33}.

Our results showed that a Valsalva maneuver could be performed successfully after endoscopy and fluoroscopy-guided ET balloon dilation in 62\% of patients with COM who underwent TM op but still had ET dysfunction. Moreover, this technique allows for an intact tympanic membrane more frequently by making aeration of the tympanic cavity possible. An improved air-bone gap after BDET has also been observed at 1-year follow-up after BDET.

Most previous studies demonstrated the clinical outcomes of BDET with patients with middle ear effusion. Although the dysfunction of the ET plays an important role in the etiology of COM\textsuperscript{3,4}, there have been few studies that evaluated the efficacy of BDET in patients with COM. A recent study demonstrated the BDET with VT insertion effectively improved the symptoms and the ET score in adults with chronic recurrent otitis media\textsuperscript{34}. Since there is a lack of studies regarding the effects of BDET in patients with chronic otitis media, our study is meaningful in that it focuses on the effects of BDET on clinical features as well as the audiologic differences between the patients with chronic otitis media who could or could not perform a Valsalva maneuver.

The capability of a Valsalva maneuver represents adequate functioning of ET for middle ear ventilation by performing moderately forceful attempted exhalation against a closed airway. After mechanical dilation of the ET, airflow can be detected subjectively and objectively in the middle ear from the ET orifice opening in the nasopharynx when performing the Valsalva maneuver, which could not be observed before BDET. This can be an initial step to solve the middle ear problem. With aeration in the middle ear, this study has proven that the COM patients who could successfully perform a Valsalva maneuver after BDET can maintain a good tympanic aeration and an intact tympanic membrane, and eventually have better hearing compared to those who could not.
There are several limitations of this study. First, most COM patients could perform a Valsalva maneuver successfully, suggesting that the ET dysfunction might have been present only when it had caused COM. Therefore, this study does not generalize the idea that all COM patients have ET dysfunction, but BDET can be conducted for the COM patients with persistent ET dysfunction after TM op. Secondly, being unable to do a Valsalva maneuver does not always mean the presence of ET dysfunction, because even normal subjects can perform a Valsalva maneuver only 78-86% of the time\(^35\). That is why we performed BDET only for the COM patients who could not do a Valsalva maneuver with persistent ABG which might be another evidence of poor tympanic aeration. Third, it is possible that a few patients who could not perform a Valsalva maneuver shortly after TM op (upto 2 months in this study) might have been able to perform a Valsalva maneuver later even without BDET. Therefore, a randomized study with a larger study population is necessary to elucidate the advantages of BDET. Because there have been few studies focused on the results of BDET in COM patients with persistent ET dysfunction, this study suggests the possibility of treatment of ET dysfunction in COM patients with persistent ET dysfunction using BDET.

In summary, a Valsalva maneuver could be performed successfully after BDET in COM patients who underwent TM op but still had ET dysfunction. After BDET, the air-bone gap was significantly decreased, especially in patients who were capable of a Valsalva maneuver. Those patients could maintain an intact tympanic membrane. Therefore, BDET can be a good treatment for COM patients who cannot perform a Valsalva maneuver after TM op with ET dysfunction.
**Author contributions:** Dr Choi had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Choi, Kang, Park

Acquisition, analysis, or interpretation of data: Choi, Ha, Lee, Kang, Park

Drafting of the manuscript: Choi, Kang

intellectual content: Choi, Kang, Park

Statistical analysis: Choi, Ha, Lee

Administrative, technical, or material support: Ahn, Chung

Supervision: Ahn, Chung, Park

**Conflict of interest statement:** No potential conflict of interest relevant to this article was reported.

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TABLE LEGENDS

Table 1. Characteristics of the patients with COM and ET dysfunction after tympanomastoidectomies

Table 2. Status of tympanic membrane in successful and unsuccessful Valsalva groups after BDET

FIGURE LEGENDS

Figure 1. Technique of endoscope- and fluoroscopy-guided E-tube balloon dilation.

Figure 2. Air-bone gap before and 1-year after BDET in the successful Valsalva group (a) and the unsuccessful Valsalva group (b).

Figure 3. Changes of air-bone gaps before and 1 year after BDET. The air-bone gap improved by 8.9±12.4 dB in the successful Valsalva maneuver group, whereas the air-bone gap aggravated by 3.8±11.8 dB in the unsuccessful Valsalva maneuver group.
REFERENCES


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CWUM; canal wall up mastoidectomy, CWDM; canal wall down mastoidectomy

Note – Variables are expressed as number (percentage) unless indicated otherwise.
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Figure 1
Figure 2

(a) Successful Valsalva group

(b) Unsuccessful Valsalva group
Figure 3

The bar graph illustrates the changes in ABG (dB) for Valsalva (+) and Valsalva (-) conditions. The total change is also shown. The p-value for the difference between the two conditions is *p=0.031.

Changes of ABG (dB)

- Valsalva (+): 8.94 dB
- Valsalva (-): -3.75 dB
- Total: 4.11 dB

The term 'better' is indicated for the Valsalva (+) condition, while 'worse' is indicated for the Valsalva (-) condition.