

Original Article

# Balloon Dilation of the Eustachian Tube: A Randomized Controlled Trial with 6 Months Follow-Up

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**BACKGROUND:** Obstructive Eustachian tube dysfunction in adults is common. The purpose of this study was to examine whether balloon dilation of the Eustachian tube can improve ventilation of the middle ear among adult patients with mild chronic Eustachian tube dysfunction.

**METHODS:** This study included patients aged  $\geq 18$  years with unilateral chronic Eustachian tube dysfunction confirmed with an abnormal tympanometry and a retracted tympanic membrane. Patients were treated daily with nasal steroid spray and Valsalva maneuver for 2 months. If Eustachian tube dysfunction persisted, they were enrolled in the study and randomized to balloon dilation of the Eustachian tube or control. All patients underwent otomicroscopy, tympanometry, pure-tone audiometry and the Eustachian Tube Dysfunction Questionnaire-7. Follow-up visits were completed at 3 weeks, 3 months, and 6 months.

**RESULTS:** In total, 24 patients completed the study (13 balloon dilation of the Eustachian tube, 11 control). The balloon dilation of the Eustachian tube group showed normalization from retraction or serous otitis media in 9 out of 13 patients ( $P = .0006$ ) compared to 0 out of 11 patients in the control group. In the balloon dilation of the Eustachian tube group, 9 out of 13 patients showed an improvement in tympanometry from B to C/A or from C to A ( $P = .04$ ) compared to 3 out of 11 patients in the control group. The audiometric data showed no difference ( $P = .38$ ). There was no significant difference in mean Eustachian Tube Dysfunction Questionnaire-7 score between the two groups ( $P = .35$ ). In the balloon dilation of the Eustachian tube group, 69% answered that they had benefitted from the treatment.

**CONCLUSION:** The procedure is feasible and no complications were reported. The study indicates that balloon dilation of the Eustachian tube may be a beneficial treatment in a selected group of adult patients with mild chronic Eustachian tube dysfunction.

**KEYWORDS:** Eustachian tube dysfunction, balloon dilation, tympanogram, ETDQ-7

## INTRODUCTION

Obstructive Eustachian tube dysfunction (ETD) in adults is a common problem with a prevalence of 0.9%,<sup>1</sup> and there is no universal accepted and effective treatment strategy. One of the Eustachian tube's (ET) functions is pressure equalization and ventilation of the middle ear. Normally, a periodic opening of the ET equalizes the continually decreasing pressure in the middle ear with the surrounding atmospheric pressure. Patients with ETD experience symptoms of negative pressure in the middle ear, such as "aural fullness", "popping", or pain. If symptoms are present longer than 3 months, it is defined as chronic ETD. The symptoms should be followed by objective measures of negative middle ear pressure, either tympanometry or otomicroscopy, before diagnosis.<sup>2</sup>

There is currently no evidence that treatment with nasal steroid spray has higher efficacy than placebo treatment.<sup>3</sup> Insertion of tympanostomy tubes might only temporarily treat ETD and can cause complications such as persistent otorrhea, chronic perforation, and infection.<sup>4</sup> Recently, balloon dilation of the Eustachian tube (BDET) has emerged as a new treatment for ETD. This minimally invasive endoscopic procedure aims at catheterization and dilation of the cartilaginous portion of the ET.<sup>5</sup> In cadaver studies<sup>6-8</sup> and previous clinical studies,<sup>9-19</sup> BDET has been demonstrated to significantly increase the luminal volume of the Eustachian tube while being feasible and safe without evidence of any significant injury. However, only two of these previous clinical studies were randomized control trials and both presented a follow-up of the control group of only 6 weeks.<sup>11,12</sup>

The aim of the present randomized controlled trial was to investigate whether BDET is a procedure that can improve ventilation of the middle ear among adult patients with a mild chronic ETD and thereby possibly prevent complications to ETD.

## METHODS

### Study Design and Population

This was a prospective, randomized controlled trial carried out in two settings: The Departments of Otorhinolaryngology and Maxillofacial Surgery, Zealand University Hospital, Denmark and The Department of Otorhinolaryngology, North Zealand Hospital, Denmark.

Eligible patients were 18 years and older, capable of giving consent, and referred to one of the two participating departments due to a unilateral, persistent ETD. At the time of inclusion, the patients had completed 2 months of daily use of nasal steroid and Valsalva's maneuver (NSVM treatment). Only patients refractory to this NSVM treatment were enrolled in the study and randomized to either the BDET group or the control group. The ETD was considered refractory when (1) the tympanometry results remained abnormal, either a C- or B-curve and (2) the otomicroscopy revealed a tympanic membrane categorized as either retracted or with fluid. The time from referral to invitation was minimum of 1 month. Adding the 2 months NSVM treatment, all patients presented with chronic ETD having symptoms of negative pressure for more than 3 months before inclusion. The design was unpaired with an allocation ratio of 1 : 1.

Exclusion criteria were perforation or tympanostomy tube in the tympanic membrane, cholesteatoma, retraction pockets with suspicion of cholesteatoma, adhesive otitis media, visible damage to the auditory ossicles, lack of bone cover of the internal carotid artery documented by Computed tomography (CT) scan, cleft lip and palate, craniofacial syndrome including Downs syndrome, cystic fibrosis, primary ciliary dyskinesia, systemic immune deficiency, acute otitis media, sinonasal malignancy, prior radiation treatment in the head–neck region, and considerable heart–lung illness. Patients were excluded during the study if they received any steroid treatment aside from the study or had a tympanostomy tube inserted or perforated their tympanic membrane.

### Intervention

Eligible patients meeting the inclusion criteria at baseline were treated with the NSVM for 2 months prior to inclusion and randomization. This treatment consisted of Mometasonfuroat nasal spray

50 µg/dose, 2 sprays × 1 daily and performance of extended Valsalva maneuver at least 3 times a day using an Otovent® balloon (Abigo Medical AB, Ekonomivägen 5, SE-436 33 ASKIM, Sweden). Patients, who successfully could perform the Valsalva maneuver without the Otovent® Balloon, could do so.

Interventions limited to the patients randomized to the BDET group included a preoperative CT scan, general anesthesia, antibiotics, and a nasal fiber-endoscopy postoperative. CT scans were performed to rule out osseous malformation or dehiscence of the internal carotid artery. Intravenous cefuroxime of 1500 mg as single dose was administered preoperative as antibiotic prophylaxis to avoid acute otitis media. The day after BDET, the patients were prescribed V-penicillin 1 million International Unit (IU) ×3 daily for 7 days and Xylometazolin nasal spray, 1 spray ×3 daily for 7 days. Before discharge, a nasal fiber endoscopy was performed to objectify bleeding and assess the surroundings of the ET.

The surgical procedure for the patients in the BDET group was an endoscopic transnasal balloon dilation of the ET with general anesthesia. Phenylephrinhydrochlorid 50 mg/1 mg/mL gauzes were applied to the nasal cavity. An insertion instrument was placed near the opening of the ET and a Bielefeld balloon catheter (Spiggle & Theiss, Overath, Germany) was introduced 2 cm into the ET. An inflation pump dilated the balloon (3 × 20 mm) with sterile water to a diameter of 3.28 mm and a pressure of 10 bar for 2 minutes, after which the balloon was deflated and the catheter was removed.

Patients in both groups continued Mometasonfuroat nasal spray for 8 weeks and performed extended Valsalva maneuver throughout the study. Patients in the control group had the option to undergo BDET by the end of the study if the dysfunction persisted.

### Endpoints and Assessments

Patients in both groups underwent the same examination at baseline, inclusion, and follow-ups (3 weeks, 3 months, and 6 months). The examination included the primary outcomes: tympanometry and Eustachian Tube Dysfunction Questionnaire (ETDQ-7) and the secondary outcomes: otomicroscopy and pure-tone audiometry.

The ETDQ-7 is a 7-item patient-reported questionnaire assessing the severity of the patient's symptoms of ETD in the previous month.<sup>20</sup> A recently validated version of the questionnaire translated into Danish was used in this study. According to these validation studies, an EDTQ-7 score of ≥14.5 indicates ETD.<sup>21</sup>

The tympanometry was performed before and after extended Valsalva maneuver to assess the middle ear function. The tympanograms were classified into the following subtypes: A (100 to –99 daPa), C1 (–100 and –199 daPa), C2 peak (<–200 daPa), and B.<sup>22</sup> Type B is flat and was separated from the others by the gradient ratio; a measure of the relative sharpness of the tympanometric peak.<sup>23</sup> In this study, curves with a gradient ratio > 0.1 were considered subtypes A or C. Gradient ratios ≤0.1 were considered as type B. Type B with a normal volume suggested otitis media with effusion.<sup>24</sup> Since the study was not blinded, the gradient ratio was applied to objectify the evaluation and prevent observer bias. An improvement at follow-up was defined as a change from B to C/A or from C to A compared to assessment at inclusion.

## MAIN POINTS

- This randomized control trial is the first concerning study on balloon dilation of the eustachian tube (BDET), where the follow-up of the control group lasted longer than 6 weeks. The 6 months follow-up allows differentiation between natural improvement in the fluctuating symptoms and improvement due to BDET.
- The study indicates that BDET may be a beneficial treatment compared to control treatment in a selected group of adult patients with mild, chronic ETD. The BDET group reported high patient satisfaction with the BDET procedure.
- The BDET procedure is feasible and no complications were reported.

The otomicroscopy enabled the clinician to assess the tympanic membrane position and categorize it: retracted/visible fluid, bulging or normal. All patients were asked to perform Valsalva Maneuver during otomicroscopy to estimate if the Valsalva maneuver was positive. Improvement at follow-up was defined as a change from retracted/visible fluid to bulging or normal compared to assessment at inclusion.

The pure-tone audiometry was obtained at each examination at frequencies of 500, 1000, 2000, and 3000 Hz to allow calculation of air conduction (AC 4-pta) and air bone gap (ABG 4-pta). Further, the speech reception threshold (SRT) was assessed.

### Sample Size and Randomization

An a priori power calculation was performed by the co-authors at the Zealand University Hospital based on data from the McCoul et al<sup>20</sup> study validating the ETDQ-7. With an  $\alpha = 0.05$  and power = 0.8, the sample size estimation was  $n = 44$  (22 patients in each group). As there were no other studies on the subject at the time, the present study might be underpowered in regards to ETDQ-7 but might not be underpowered in regards to the results concerning tympanometry and otomicroscopy.

Eligible patients with unilateral, persistent ETD, refractory to the NSVM treatment were included and randomized 1 : 1 by envelope drawing to either the BDET group or the control group. In the BDET group, only the affected ear would undergo BDET. The study was not blinded to clinician or patient, since it would be unethical to expose the control group to CT scans, general anesthesia, and antibiotics.

### Statistical Methods

The results of tympanometry and otomicroscopy at every follow-up were categorized as either "improvement" or "no improvement", when compared to results at inclusion. These categorical data were then displayed in a  $2 \times 2$  table comparing "improvement" or "no improvement" between the BDET group and the control group. The chi-squared test and exact test with a level of significance ( $\alpha$ ) of 5% were used to test the null hypothesis: "balloon dilation does not have a greater positive effect than control treatment" for tympanometry and otomicroscopy.

The numerical data included ETDQ-7 scores, ABG 4-pta, AC 4-pta, and SRT. Differences in mean scores between groups from the time

**Table 1.** Patient Characteristics

	BDET Group (n = 13)	Control Group (n = 11)	All Patients	P*
Age, year, mean	49.07	53.27	51	
Sex, female (%)	5 (38.5)	6 (54.5)	11 (45.8)	.68
Indicated side, right (%)	10 (76.9)	7 (63.6)	17 (70.8)	.66

\*Fischer's exact test or chi-square test was used for categorical variables. *P*-value compares randomized BDET group and control group.  
BDET, balloon dilation of the eustachian tube.

of inclusion to every follow-up were compared using *t*-test under the assumption of normal distributed data. Bonferroni correction was applied on repeated tests for comparison between groups. Level of significance ( $\alpha$ ) was set to 5%. Any multiplied, observed *P*-values less than 4 times  $\alpha$  were determined to be statistically significant. The analysis for this article was generated using SAS software© (SAS Institute Inc., Cary, NC, USA).

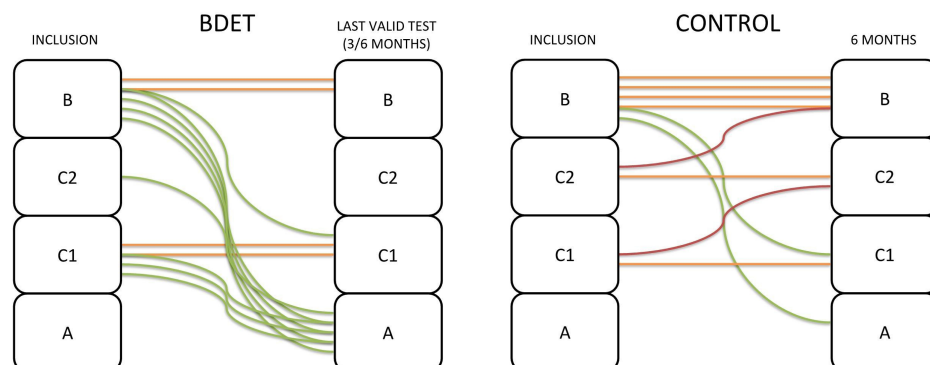
### Ethics

The study was approved by The Danish National Committee on Health Research Ethics and The Danish Data Protection Agency, protocol number: SJ-359. All participants signed informed consent before enrollment.

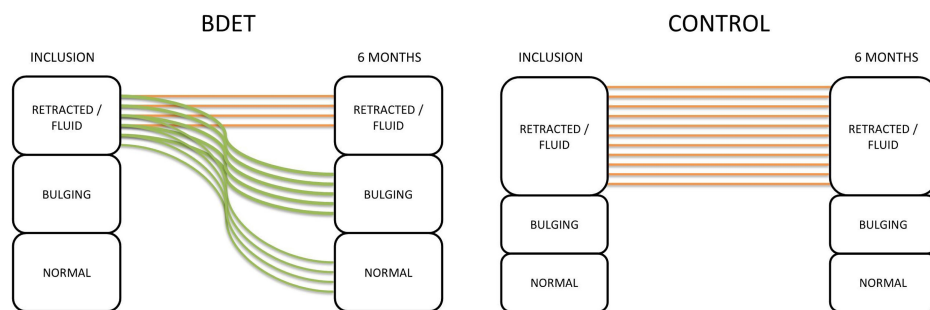
### RESULTS

In this study, 26 patients were included and randomized: 13 in the BDET group and 13 in the control group. The period of inclusion was December 2013 to February 2018. Follow-up was carried out until November 2018. The recruitment was stopped earlier than desired due to a lack of referred new patients to the two receiving departments. 37 patients were excluded before inclusion. Two patients in the control group left the study after randomization. One was lost to follow-up, one had a myringotomy performed elsewhere, and 24 patients completed the study (13 balloon dilation, 11 control). The patients' sex, age, and indicated sides for intervention were comparable between the BDET group and the control group (Table 1).

To eliminate any effect of the NSVM treatment prior to inclusion, the effect of the treatment in both groups was measured from the time of inclusion to 6 months. The results for both categorical and numerical data at every follow-up were therefore compared to the results at inclusion.



**Figure 1.** Tympanometry. The change in tympanometry type for each individual in the BDET group (left) and the control group (right) from inclusion to 6 months follow-up. BDET, balloon dilation of the eustachian tube.



**Figure 2.** Otomicroscopy. The change in otomicroscopic findings for each individual in the BDET group (left) and the control group (right) from inclusion to 6 months follow-up. BDET, balloon dilation of the eustachian tube.

Tympanometry results in the BDET group showed an improvement in 9 out of 13 patients at 6 months, while 4 out of 13 either maintained their tympanogram type or worsened. In the control group, 3 out of 11 showed improvement at 6 months, while 8 out of 11 either maintained their tympanogram type or worsened (Figure 1). One patient in the BDET group had an invalid tympanometry result but presented with a bulging tympanic membrane and a positive Valsalva maneuver during otomicroscopy at 6 months follow-up. Considering the otomicroscopy result, the patient should have presented a C or an A subtype had the tympanometry been done properly. The patient had a B-curve at the time of inclusion and a C1-curve at 3 months. Therefore, the patient's tympanometry result at 3 months follow-up was used. The result was significant when the BDET group was compared to the control group after 6 months ( $P = .041$ ). The difference between the effects in the groups was not significant at neither 3 weeks ( $P = .682$ ) nor at 3 months ( $P = .680$ ).

Within the BDET group, otomicroscopy showed an improvement to either bulging or normal in 9 out of 13 patients at 6 months compared to inclusion, while 4 out of 13 showed no improvement. In the control group, 0 out of 11 showed improvement at 6 months, while 11 out of 11 showed no improvement with a tympanic membrane still characterized as retracted or with visible fluid (Figure 2). The result was highly significant ( $P = .0006$ ). The difference between

the effects in the group was not significant at 3 weeks ( $P = .386$ ) but shows significance at 3 months ( $P = .0046$ ).

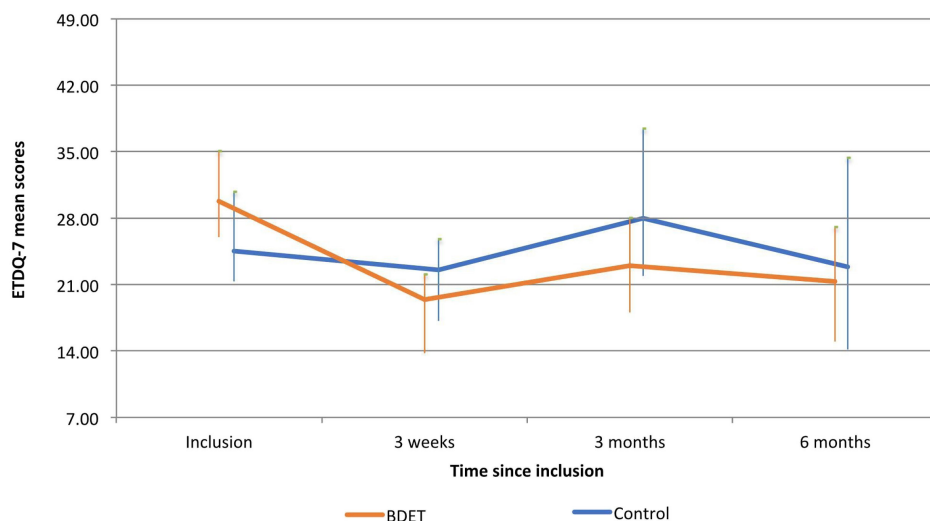
There was no significant difference in mean ETDQ-7 score between the 2 groups at follow-up. The corrected  $P$ -value for 6 months follow-up was 0.35 (Figure 3). The audiometric data, for example AC (4-pta), ABG (4-pta), and SRT scores, have proven no difference in hearing between the BDET group and the control group at any of the follow-ups. At 6 months, the corrected  $P$ -values for AC (4-pta), ABG (4-pta), and SRT were 0.38, 0.94, and 0.26, respectively.

Patients in the BDET group were asked three questions by the end of the study to estimate patient satisfaction with the treatment. In the BDET group, 69% of the patients reported "yes" to the question: "Did you benefit from the balloon dilation?," 85% reported "yes" to the question: "Would you do it again?," and 92% reported "yes" to the question: "Would you recommend it to others?."

No complications to BDET were reported from either of the two participating departments.

## DISCUSSION

This prospective randomized study shows significant improvement in the tympanometry and otomicroscopy results when comparing



**Figure 3.** ETDQ-7 mean scores. Horizontal lines: the change in mean scores in the BDET group (orange) and the control group (blue). Vertical lines: lower and upper quartile. There was no significant difference in mean ETDQ-7 score between the 2 groups at 6 months follow-up. BDET, balloon dilation of the eustachian tube; ETDQ-7, Eustachian Tube Dysfunction Questionnaire-7.



the BDET group and the control group. Considering the natural history of ETD with fluctuating symptoms, a long follow-up period for the control group is of crucial importance. The study design secured a follow-up period for the control group of 6 months. This resulted in difficulties with inclusion because an allocation to the control group resulted in at least 8 months of waiting period for treatment. Therefore, the recruitment was stopped earlier than desired, leading to a small study population.

Prior to inclusion, all patients underwent 2 months of NSVM treatment. Ten patients had an effect of the NSVM treatment and tympanometry was normalized. Thus, these patients were excluded. As pointed out in the introduction section, it has previously been questioned whether treatment with nasal steroid spray shows a difference in efficacy when compared to placebo. The current evidence on the subject is inadequate. The improvement experienced by the 10 patients in this study might be due to daily performance of the Valsalva maneuver.

To be enrolled in this study, the patients' ETD had to be persistent and refractory to the NSVM treatment. This was defined by abnormal tympanometry results and otomicroscopy revealing a tympanic membrane categorized as either retracted or with visible fluid in the middle ear. Previous studies used other definitions for ETD and other inclusion criteria, resulting in study populations with varying levels of symptom severity. In some studies, the inclusion criteria were based only on patient-reported symptoms,<sup>10,16,17,19</sup> while others were more extensive including a long duration of the ETD, symptoms refractory to medical treatment, and both abnormal tympanometry and otomicroscopy.<sup>11-14</sup> These independent study populations with varying levels of symptom severity were all treated with BDET. Their results vary as much as their study populations. As could be expected, their success rates depend on their inclusion criteria: the milder the ETD, the higher the success rate.

The ETDQ-7 detected ETD within the examined patient population. As described earlier, the power calculation was performed based on data from the McCoul et al<sup>20</sup> study validating the ETDQ-7. As estimated in these calculations, this study might be underpowered in regards to ETDQ-7 but might not be underpowered in regards to the results concerning tympanometry and otomicroscopy as no power calculations were made for these parameters. The ETDQ-7 results demonstrate a non-significant improvement in the BDET group compared to the control group. With the estimated sample, the results might have been significant.

The McCoul et al<sup>20</sup> study states: *The ETDQ-7 is a valid and reliable symptom score for use in adult patients with ETD that may facilitate clinical practice by highlighting the impact of ETD. Further testing is needed to determine its usefulness in assessing treatment response.* While the ETDQ-7 score is validated for detecting ETD, it has not been properly validated for assessing treatment response. The ETDQ-7 was able to detect ETD within this patient population but was unable to detect improvement in treatment response. Among the previous clinical studies, there are two randomized control trials, both presenting inclusion criteria fairly comparable to the present study. Poe et al<sup>11</sup> included patients from age  $\geq 22$  years with persistent ETD ( $>12$  weeks) and refractory to initial usage of intranasal steroid spray of minimum 4 weeks. Furthermore, the patients' dysfunction was

confirmed by both abnormal tympanometry and an ETDQ-7 score  $>14.5$ . Meyer et al<sup>12</sup> included patients from age  $\geq 18$  years with persistent ETD ( $>12$  months) and refractory to initial usage of intranasal steroid spray of minimum of 4 weeks. Furthermore, the patients' dysfunction was confirmed by an ETDQ-7 score of  $\geq 21$ , representing moderate to severe symptoms. Both studies allowed patients to cross over only after 6 weeks in the control group. A short follow-up for only 6 weeks weakens the results and makes it difficult to differentiate between natural improvement in the fluctuating symptoms and improvement due to BDET. In the BDET group, Poe et al<sup>11</sup> found that 62% improved their tympanometry at 24 weeks, while Meyer et al<sup>12</sup> found improvement in 55% at 12 months. These results are comparable to the improvement in the present study of 69% at 6 months. Unlike the present study, the two studies presented significant results only after 6 weeks. This should most likely be attributed to differences in study size.

This present study holds a potential selection bias. Only patients with mild ETD were selected for participation. In this study, mild ETD was defined as otomicroscopic evidence of a retracted tympanic membrane and a tympanogram indicating fluid or negative middle ear pressure. Otomicroscopy had to be without signs of cholesteatoma, adhesive otitis media, retraction pockets with suspicion of cholesteatoma, or visible damage to the auditory ossicles. The results support treating mild, chronic ETD, while more severe cases with adhesive otitis media or cholesteatoma were not investigated in this study. When adding up the success rates of the prior clinical studies and this study, it should be noted that BDET appears to be a beneficial treatment for patients with milder cases of ETD such as scuba, flight, or barotrauma<sup>19</sup> and fairly beneficial treatment for patients with severity of symptoms equivalent to our study. At the other end of the scale, there seems to be consensus that ears with cholesteatoma should not be treated with BDET, while there have been opposing findings regarding patients with atelectatic middle ears.<sup>15,19</sup> A clear, universal definition of ETD would ease the comparability of research on this topic and ease the selection of patients for treatment in clinical practice.

This study has three main limitations. As discussed earlier, there is a small study population and a potential selection bias. Because of the small study population, the study might be underpowered in regards to the results of ETDQ-7. Lastly, the study is not blinded due to ethical considerations, which might have had an effect on the subjective measures: otomicroscopy, ETDQ-7, and patient satisfaction.

## CONCLUSION

Results from this prospective, randomized control trial with 6 months follow-up show that BDET may be a beneficial treatment compared to control treatment in a selected group of adult patients with mild, chronic ETD. Balloon dilation of the Eustachian tube leads to a significant improvement in tympanometry type and otomicroscopic findings in the BDET group compared to the control group. Furthermore, the BDET group reported high patient satisfaction with the BDET procedure. These results are interpreted as an improvement in the ET function leading to an increase in the ventilation of the middle ear. Despite objective improvement in the BDET group, the patient-reported questionnaire, ETDQ-7, was underpowered and presented no significant difference in patient symptom improvement between the two groups. There was no impact on the audiometric data,

which prove no difference in hearing between the groups at any of the follow-ups. The procedure is feasible and no complications were reported. The study indicates that BDET may be a beneficial treatment and improves the ventilation of the middle ear among a selected group of adult patients with mild, chronic ETD.

**Ethics Committee Approval:** Ethical committee approval was received from the Danish National Committee on Health Research Ethics (approval No: SJ-359).

**Informed Consent:** Written informed consent was obtained from all participants who participated in this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – H.G.; Design – H.G.; Supervision – H.G.; Materials – M.K., A.J., H.G.; Data Collection and/or Processing – S.K., M.K., A.J., H.G.; Analysis and/or Interpretation – S.K., M.K., A.J., H.G.; Literature Review – S.K., H.G.; Writing Manuscript – S.K.; Critical Review – M.K., A.J., H.G.

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