

## Original Article

# Balloon Dilation of the Eustachian Tube in Chronic Eustachian Tube Dysfunction: A Retrospective Study of 107 Patients\*

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ORCID IDs of the authors: H.O. 0000-0003-2844-3711; J.P. 0000-0003-2116-9780; L.H. 0000-0003-0724-2187.

Cite this article as: Oehlandt H, Pulkkinen J, Haavisto L. Balloon dilatation of the eustachian tube in chronic eustachian tube dysfunction: A retrospective study of 107 patients. *J Int Adv Otol*. 2022;18(6):495-500.**BACKGROUND:** Eustachian tube dysfunction affects from 1% to 5% of adults. This study evaluates the effectiveness of balloon dilation of eustachian tube for treating nonselected patients with eustachian tube dysfunction in a long term.**METHODS:** We evaluated all balloon dilation of eustachian tube operations at Turku University Hospital from 2013 to 2016. The data from 107 patients and 167 ears were collected retrospectively and a questionnaire was sent to these patients regarding their symptoms.**RESULTS:** An evident reduction of the symptoms was noticed. Aural fullness, otalgia, recurrent acute otitis media, or otitis media with effusion as well as symptoms from changes to ambient pressure and the ability to do the Valsalva maneuver were significantly improved. The mean follow-up time with the questionnaire was 33 months. Of patients, 80% (36/45) reported long-term reduction of symptoms.**CONCLUSIONS:** In our study, balloon dilation of eustachian tube seems to have reduced symptoms of eustachian tube dysfunction and the results appear to be long lasting.**KEYWORDS:** Balloon dilation of eustachian tube, eustachian tube, eustachian tube dysfunction

## INTRODUCTION

The normal function of the eustachian tube (ET) allows for pressure equalization between the middle ear and the nasopharynx and the clearance of mucosal secretions from the middle ear.<sup>1,2</sup> In the case of dysfunction of the ET there is a risk of chronic middle-ear symptoms and causes complications such as aural fullness, otalgia, a feeling of pressure, a clogged sensation, recurrent otitis media, persistent otitis media with effusion, hearing loss, retraction of the tympanic membrane, and even cholesteatoma.<sup>1,3</sup> The incidence of eustachian tube dysfunction (ETD) in the adult population is estimated to be approximately between 1% and 5%<sup>4,5</sup> and in children as much as 40%.<sup>6</sup>

An international consensus statement on ETD pointed out that the reasons for dilatory dysfunction may be functional, dynamic (muscular), or anatomical (such as large adenoids).<sup>1</sup> To be diagnosed with ETD, a patient should have suitable symptoms together with evidence of negative pressure in the middle ear. Only in the baro-challenge-induced ETD are the clinical signs and symptoms perhaps absent at ground level.

A number of tests to evaluate ET function has been introduced, but most of them are either non-physiological (as with the Valsalva and Toynbee maneuver) or challenging to perform on a clinical basis (such as tubomanometry).<sup>1,3</sup> In addition, a few scoring systems for ETD symptoms and/or findings are available, like the Eustachian Tube Dysfunction Questionnaire (ETDQ-7) and the Eustachian Tube Score (ETS).<sup>7-9</sup> However, the role of these tests in clinical practice is still under research.<sup>1,2,10</sup>

Recurrent use of ventilation tubes at the tympanic membrane was previously the only surgical way to treat symptoms caused by ETD. Pharmacological treatment and mechanical devices lack evidence of effectiveness in treating adult ETD patients.<sup>11</sup> In 2010, a novel

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treatment with balloon dilation of the cartilaginous part of the ET was introduced (BET).<sup>12</sup> Since then, several studies on the results of BET have been published, but the indications of the operation are still controversial.<sup>3,6,13–16</sup> The complications reported are mostly minor and reversible<sup>14,17,18</sup> and their incidence in a meta-analysis was 2%.<sup>6</sup>

The aim of this study was to evaluate the outcome of the first series of BET performed in our tertiary referral hospital. The other aim was to evaluate the safety of the operation.

## METHODS

A retrospective evaluation of all consecutive BET operations performed between the years 2013 and 2016 was conducted. Balloon dilation of eustachian tube operation was performed as the only surgical intervention for patients with chronic symptoms of ETD. Concomitant BET was done in addition to other ear surgery if ET dysfunction was suspected. Reasons to suspect ETD were, for example, history of recurrent otitis media, poor performance in Valsalva or Toynbee maneuvers, revision myringoplasty, and underdeveloped mastoid air cells. There were 108 patients in the original data. One patient was excluded because the reason for the ear symptoms emerged to be a recurrence of a previous squamous cell carcinoma in the middle ear. Therefore, the results of 107 patients were used for further analysis. All operations were performed by the same ENT surgeon (JP) at the Department of Otorhinolaryngology – Head and Neck Surgery of Turku University Hospital, Finland.

The study design was approved by the Clinical Research Center of the Hospital District of Southwest Finland (TO6/055/17). Written consent was not deemed necessary.

## Surgical Technic

Dilation was performed under general anesthesia. Prior to the actual procedure, a nasal cotton package soaked in epinephrine solution (1%) was introduced in both nostrils to achieve decongestion of the mucosa. To visualize the ET ostium, a 45° Hopkins endoscope or Hopkins endoscope with an adjustable angle between 0° and 70° was used either on ipsilateral or contralateral side. The dilation was performed using Spiggle & Theis instrumentation with a balloon size of 3.3 × 20 mm (Medizintechnik GmbH, Overath, Germany). The balloon catheter was introduced into the cartilaginous part of the ET via an insertion tool with an angulation of 45° or 70° (Figure 1). The balloon was inflated with saline to achieve the pressure of 10 bars

for 2 minutes under visual control. The instrumentation was gently removed either before or after lowering the pressure. The procedure was repeated if there was any doubt about the correct position of the balloon.

## Data Collection

The data on preoperative and postoperative symptoms and findings were collected retrospectively. Special interest was focused on aural fullness, otalgia, hearing loss, recurrent acute otitis media, recurrent otitis media with effusion, symptoms from changes to ambient pressure, and on the patients' ability to do the Valsalva maneuver. Otomicroscopic findings were examined to record possible perforation, retraction, or ventilation tube in the tympanic membrane, and/or fluid, glue, or cholesteatoma in the middle ear.

Other operations than BET made in the same session were recorded, as well as possible perioperative or postoperative complications. Special interest was focused on patients who had no additional simultaneous operation (n = 31).

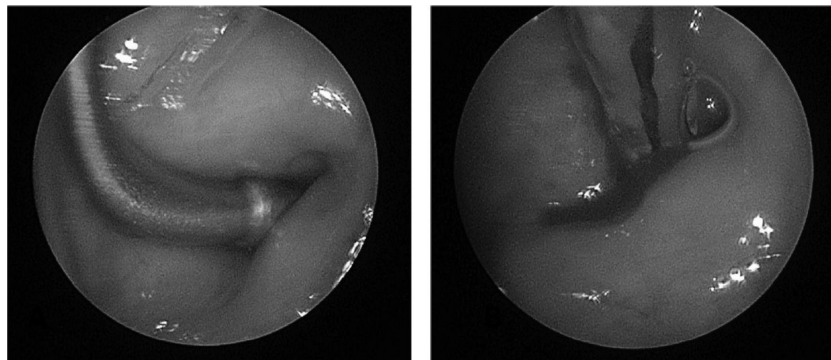
Postoperative care was mainly determined by the other operations performed. When only BET was done, patients were advised to perform the Valsalva maneuver 3 days after the operation and continue for 3 weeks.

## Questionnaire

A paper questionnaire was sent to all patients in March 2018. Patients were asked about their present symptoms (aural fullness, otalgia, hearing loss, recurrent acute otitis media, recurrent otitis media with effusion, symptoms from changes to ambient pressure, and ability to do the Valsalva maneuver) and how the operation had relieved their symptoms. In addition, patients were asked to complete an ETDQ-7 (unvalidated translation to Finnish) and to point out if they had had any side effects after the operation. Finally, the patients were asked retrospectively if they would have undertaken the operation.

## Statistical Analysis

Statistical analysis was conducted using an SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) in collaboration with a statistician. Data analysis comparing symptoms and clinical findings before and after surgery was done in two groups (all patients and only BET patients)



**Figure 1.** (A) A working channel at the orifice of the Eustachian tube (ET). The balloon catheter is introduced into the ET via the insertion tool. (B) The balloon catheter is removed after the dilation of 2 minutes duration and the pressure of 10 bars to 3.3 mm. Minor bleeding of the orifice is seen. Photo by J. Pulkkinen.

using McNemar's test. The *P* values lower than .05 were considered statistically significant.

## RESULTS

Balloon dilation of eustachian tube was performed on 107 patients (44 men, 63 women). In 60 patients, BET was performed bilaterally and altogether 167 ears were treated. The mean age of the patients was 34 years (SD 18.6, ranging from 9 to 77). There were 23 children (under 16 years). Patients reported that the symptoms of ETD had lasted for 12 years on average (SD 8.9). Baseline characteristics of the patients and findings are shown in Table 1.

In the subgroup of 31 patients, BET was the only intervention performed. Other operations made simultaneously included insertion of ventilation tubes (*n*=35), myringoplasty (*n*=28), attico/tympanotomy (*n*=15), mastoidectomy (*n*=4), adenoidectomy (*n*=6), sinus operation (*n*=3), and other miscellaneous procedures (*n*=5). Many of these operations were revisions: 50% of the myringoplasty operations were revisions, as were 60% of the attico/tympanotomies, and 75% of the mastoidectomies.

In the subgroup of children (*n*=23), BET as the only intervention was performed to 7 patients. Other operations in addition to BET were concomitant insertion of ventilation tubes (*n*=7), myringoplasty (*n*=7), attico/tympanotomy (*n*=1), adenoidectomy (*n*=4), sinus operation (*n*=2), and cleaning of the mastoid cavity (*n*=1).

## OUTCOME

The mean follow-up time from the operation to the last follow-up visit was 7.8 months (ranging from 1 to 12 months). Some of the patients had several follow-up visits. Altogether, 1 patient had follow-up visit at 1 month, 46 patients at 3 months, 59 patients at 6 months, and 35 patients at 12 months. Of the whole group, 19 patients did not have any follow-up visits. Instead, the surgeon made a phone call at 3 months and interviewed the patients to find out about any remaining symptoms and possible side effects and concluded that they had no need for a further follow-up.

A remarkable reduction in the symptoms was noticed during the follow-up visits or phone calls (Table 2 and Figure 2). Aural fullness,

otalgia, recurrent acute otitis media, or otitis media with effusion as well as symptoms from changes to ambient pressure and the ability to do the Valsalva maneuver were significantly improved in the whole group. In the group of BET only, aural fullness, recurrent acute otitis media or otitis media with effusion, and symptoms from changes to ambient pressure were significantly relieved. In the subgroup of children, recurrent acute otitis media and otitis media with effusion were significantly decreased. Change in subjective hearing loss was not significant in any of the groups.

Because part of the group did not have any follow-up visits to the outpatient clinic, the data on the postoperative status of the tympanic membrane was only available for 88 patients (82 %). Respectively, the postoperative data was only found for 21 patients (70 %) in the BET subgroup.

A significant change was only found in the middle-ear effusion and in the perforation of the tympanic membrane in the whole group. Otherwise, no significant change was found in the otomicroscopic findings (Table 3).

## Questionnaire

The questionnaire was returned by 45 patients (17 men, 28 women). The mean follow-up time from the operation to the questionnaire was 33 months (range from 16 to 58 months, SD 12). The preoperative symptoms had disappeared in 13 patients (29%), improved in 23 patients (51%), and remained unchanged in 7 patients (16%). Only 2 patients (4%) reported a worsening of the symptoms because of patulous ET. Eustachian Tube Dysfunction Questionnaire 7 was completely filled by 36 patients. The mean score was 17.4 (ranging from 7 to 33, SD 6.8).

Five out of the 45 (12%) patients related that considering the matter retrospectively they would not have had the operation, all of them still had some ear symptoms. Of the patients that only had BET and no concomitant operation 2 out of the 18 (11%) patients considered that in retrospect they would not have had the operation.

In the subgroup of children, 6 patients returned the questionnaire. The mean follow-up time was 32 months (range from 18 to

**Table 1.** Baseline Characteristics and Findings (N = 107)

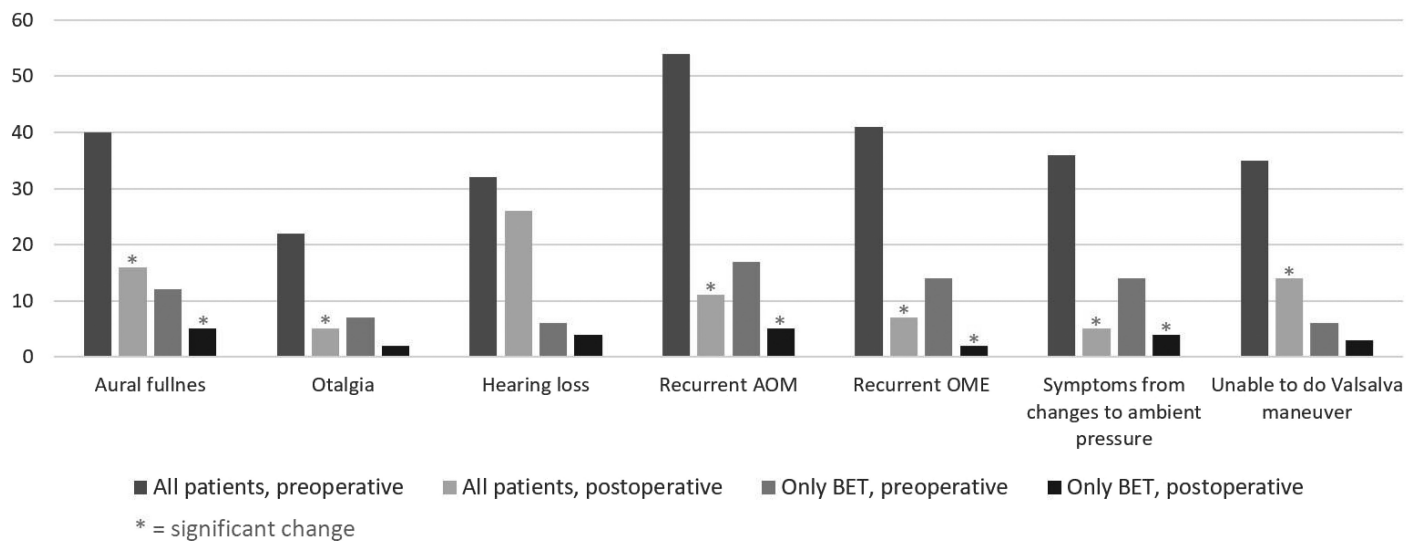
Reflux	19 (17%)	Preoperative findings	
Allergy	24 (22%)	Normal TM	12 (11%)
Smoking		Retraction of the TM	35 (33%)
		Fluid in the middle ear	25 (23%)
		Ventilation tube	24 (22%)
		Perforation of the TM	43(40%)
		Cholesteatoma	21 (20%)
Previous operations		Valsalva maneuver preoperatively	
Ventilation tubes	82 (77%)	Successful	15 (14%)
Vyringoplasty	19 (18%)	Unable to perform	43 (40%)
Atticotomy	24 (22%)	Missing data	49 (46%)
Mastoidectomy	24 (22%)		

TM, tympanic membrane.

**Table 2.** Pre- and Postoperative Symptoms

Symptom	All Patients (n = 102)			Only BET (n = 30)			Children (n = 23)		
	Preoperative	Postoperative	P	Preoperative	Postoperative	P	Preoperative	Postoperative	P
Aural fullness	40	16	<.001	12	5	<.05	3	2	NS
Otalgia	22	5	<.002	7	2	NS	2	1	NS
Hearing loss	32	26	NS	6	4	NS	9	8	NS
Recurrent acute otitis media	54	11	<.001	17	5	<.01	14	2	<.001
Recurrent otitis media with effusion	41	7	<.001	14	2	<.001	12	1	<.002
Symptoms from changes to ambient pressure	36	5	<.001	14	4	<.001	1	0	NS
Unable to do Valsalva maneuver	35*	14*	<.001	6**	3**	NS	7***	5***	NS

\*Pre- and postoperative data available from 47 patients.  
 \*\*Pre- and postoperative data available from 12 patients.  
 \*\*\*Pre- and postoperative data available from 9 patients.



**Figure 2.** Pre- and postoperative symptoms in all patients (n = 107) followed by pre- and postoperative symptoms only in the balloon dilation (BET) subgroup (n = 31).

**Table 3.** Pre- and Postoperative Findings. Mean Follow-up Time 7,8 Months (Range 1-12 Months)

Otomicroscopic Finding	All patients (n = 88)			Only BET (n = 21)			Children (n = 23)		
	Preoperative	Postoperative	P	Preoperative	Postoperative	P	Preoperative	Postoperative	P
Retraction of the tympanic membrane	20	20	NS	6	8	NS	9	10	NS
Fluid in the middle ear	20	8	<.005	2	2	NS	5	1	NS
Ventilation tube	18	13	NS	5	4	NS	3	1	NS
Perforation of the tympanic membrane	40	21	<.005	6	5	NS	8	5	NS

53 months, SD 12). The preoperative symptoms had disappeared in 3 patients (50%) and improved in 3 patients (50%). All children considered that in retrospect they would have had the operation.

### Complications

No serious perioperative or immediate postoperative complications occurred and 93 operations (86.9 %) were conducted without any problems. In 9 patients (8.4%), there were difficulties introducing the balloon catheter into the ET, and in 3 patients (2.8%) nose bleeding complicated either the insertion or the dilation. Consequently, balloon dilation was performed on 107 patients and 167 ears.

In the postoperative questionnaire, 4 of the 45 patients (9%) reported having late side effects (popping in the ears, lachrymation, hearing loss, or damage on the asymptomatic side).

### DISCUSSION

Eustachian tube dysfunction causes recurrent ear symptoms and is thought to be a risk factor for recurrent otitis media, persistent otitis media with effusion, hearing loss, retraction of the tympanic membrane, or even cholesteatoma.<sup>1,3</sup>

#### Symptoms

A retrospective study of 107 consecutive BET operations was made to evaluate the relief of ear symptoms and changes in tympanic findings. All of the patients were evaluated postoperatively by the surgeon during a follow-up visit (88%) or via phone call (12%). A remarkable reduction of the symptoms was noticed. In the whole group, aural fullness, otalgia, recurrent acute otitis media, or otitis media with effusion as well as symptoms from changes to ambient pressure and the ability to do the Valsalva maneuver were significantly improved. A significant change in the whole group was found in the perforation of the tympanic membrane; however, the success rate was only 53%. Eight of the 28 patients (29%) who underwent concomitant myringoplasty and BET had a postoperative perforation. This may be due to the challenges involved in this patient group as in the early-stages additional BET was only performed in complicated situations.

When considering the subgroup of patients who only had the BET and no concomitant operation ( $n = 31$ ), a significant relief was found in aural fullness, recurrent acute otitis media or otitis media with effusion, and symptoms from changes to ambient pressure.

These findings are in line with a meta-analysis of 15 studies and 1155 patients by Huisman et al (2018). They concluded that at least short-term improvement of ear symptoms can be achieved with BET.

In children, a significant decrease in recurrent acute otitis media or otitis media with effusion was found. In a recent review article, an improvement in symptoms was found in children with middle-ear effusion.<sup>19</sup>

#### Satisfaction

Satmis and van der Torn (2018) found a low subjective satisfaction of 48% in a short-term follow-up at 3 months. In our long-term follow-up at 16–58 months a much better result was found because the symptoms had disappeared or improved in 80% of patients.

Our 33 months follow-up time is noticeably long compared to the general consensus that 6–12 months is considered the normal time period for a long-term follow-up.<sup>1</sup> Two patients (4 %) reported worsening of the symptoms which are in line with previous studies.<sup>13</sup>

### Indications

The inclusion and exclusion criteria vary between studies<sup>3</sup> and only a few prospective studies have been published.<sup>15,16</sup> In one study, patients were randomized to either balloon dilation or control, but after 6 weeks, the control participants had the option to undergo balloon dilation if their symptoms persisted.<sup>20</sup>

The proposed indication for BET by the Finnish Otolaryngological Society is chronic bothersome symptoms referring to ETD, ETD-related symptoms following rapid pressure changes, or recurring serous otitis media.<sup>3</sup> Nordic consensus recommends BET mainly for adult patients and recommends tympanostomy tube treatment before BET.<sup>21</sup> In children, BET may be considered if standard treatment fails.<sup>19</sup> Further studies on the efficacy and safety of BET in children are needed.

### Complications

Complication rates vary between 0.3% and 21%.<sup>3</sup> Nonetheless, BET seems to be safe and the complications reported are mild and reversible; minor nasal bleeding, mucosal lacerations, local emphysema in the parotid region, hemotympanum, or temporary increase of tinnitus.<sup>14,17,18</sup> The usefulness of preoperative computer tomography (CT) to avoid critical carotid artery damage is limited.<sup>22</sup>

### Limitations

This study has some limitations. Because this study is retrospective, there is no control group. The comparison between preoperative and postoperative symptoms should be treated with caution. In addition, the preoperative evaluation and documentation were not complete, and for that reason, the comparison between preoperative and postoperative ETDQ-7 was not possible.

The study population was not homologous. In 76 of the 107 cases, this new technique was used in combination with conventional ventilation tubes or was introduced as a supporting procedure, for example, a re-myringoplasty. This is a common problem and the comparison between studies is difficult.<sup>6,23</sup> Confounding factors that are hard to control for and between different studies, the patient populations, follow-up times, and outcome measurements are not homogeneous.<sup>3,13</sup> Several subjective and objective criteria for the diagnosis of ETD have been introduced, but the indications for BET are still controversial.

### CONCLUSION

We conclude that BET is a safe operation and the side effects are mild. Balloon dilation of eustachian tube may be a useful treatment for specific symptoms of ETD, such as aural fullness, recurrent acute otitis media, or otitis media with effusion, and symptoms from changes to ambient pressure. It is notable that results seem to be long-lasting. However, more research with randomization and a control group is needed. Similarly, further studies on the beneficial effects of combining BET with other operations, for example, myringoplasty, are needed.



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**Informed Consent:** N/A.

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

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