

1 **Patient satisfaction in the long-term effects of Eustachian tube balloon**
2 **dilation is encouraging**

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1 **Patient satisfaction in the long-term effects of Eustachian tube balloon**
2 **dilation is encouraging**

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4 **Object:** Investigate the long-term effects of balloon Eustachian tuboplasty (BET)
5 from patient's perspective and to discover which symptoms of Eustachian tube
6 dysfunction (ETD) benefit the most from BET.

7 **Method:** We designed a retrospective postal questionnaire based on the seven-
8 item ETD questionnaire (ETDQ-7). Our questionnaire covered the severity of
9 present ETD symptoms in comparison with the preoperative situation, the
10 severity of current overall ear symptoms, and possible surgical interventions after
11 BET. Forty-six patients treated in our institution between 2011 and 2013 fulfilled
12 the inclusion criteria and 74% (34 patients; total 52 ears treated with BET)
13 returned the questionnaire with a mean follow-up time of 3.1 years (range 1.8-4.6
14 years).

15 **Results:** Pain in the ears, feeling of pressure in the ears, and feeling that ears are
16 clogged had reduced in 75% of the ears that suffered from these symptoms
17 preoperatively. Seventy-seven percent of all the responders felt that their overall
18 ear symptoms were reduced. Altogether, 79% of all the patients stated that they
19 would undergo BET again if their ear symptoms returned to the preoperative
20 level.

21 **Conclusion:** Patient satisfaction in the long-term effects of BET is encouraging.
22 These results may help clinicians in preoperative patient selection and
23 counselling.

24 **Keywords:** Eustachian tube dysfunction, balloon dilation, questionnaire, patient
25 satisfaction

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Introduction

3 The Eustachian tube (ET) has a central role in aeration of the middle ear. Therefore,
4 prolonged ET dysfunction (ETD) can lead to chronic ear diseases [1, 2]. One method
5 aiming to manage ETD and thereby prevent chronic ear diseases is ET balloon dilation
6 (balloon Eustachian tuboplasty, BET). How to most accurately evaluate the effect of BET
7 is still unclear. Clinical findings, tubomanometry, ET score (ETS), its extension ETS-7,
8 and the seven-item ETD questionnaire (ETDQ-7) are some examples of methods
9 available to help in the diagnostics of ETD and in assessing the effects of its treatment
10 [2-4].

11 Studies on the short-term effect of BET suggest that the procedure is effective and
12 safe [5-7]. Aural fullness, earache, pressure in the ear, hearing impairment, and vertigo
13 have been reported to improve in the short term. [5, 7]. Two long-term follow-up studies
14 showed significant improvement in ETS and overall ear symptoms at two years, and in
15 clinical findings and the ability to perform the Valsalva maneuver after follow-up of 2.5
16 years [1, 8]. Another study stated that 8 patients were followed for at least 34 months and
17 that seven of them reported persistent improvement [9]. The long-term studies left
18 specific symptoms that improved undefined. Therefore, we now concentrated on long-
19 term patient-reported outcome with a questionnaire covering symptoms of ETD.

20

Methods

Ethical approval

23 The study was approved by the Ethics Committee of Department of Surgery, Helsinki
24 University Hospital, Helsinki, Finland (reg. no. 60/13/03/02/2015). The patients gave

1 informed consent before enrolment in the study. The study was performed in accordance
2 with the Declaration of Helsinki.

3

4

5 *Patients*

6 We retrospectively identified 51 consecutive patients treated with BET in our department
7 from 2011 to 2013. Simultaneous ear operations, except tympanocentesis (2 patients) or
8 tympanostomy tube insertion (3 patients), lead to exclusion, as did previous Eustachian
9 tube operations. Forty-six patients met the inclusion criteria and received a postal
10 questionnaire, and 34 (74%) returned it. ET dysfunction type as defined in the consensus
11 statement [10] was of dilatory type in 31 of the responders and baro-challenge-induced
12 in three responders.

13 Preoperative studies included full otorhinolaryngological examination including
14 otomicroscopy and nasoendoscopy (or anterior and posterior rhinoscopy). Tympanic
15 membrane was retracted or tympanometry showed negative pressure in 76% of the
16 responders. The nasopharynx and ET openings were normal in 50%. In 35%, the mucosa
17 was swollen. In 6%, the Eustachian tube openings were especially narrow or scarred from
18 previous adenotomy. In 9%, the condition was undefined in the medical charts. Two
19 patients had small nasal polyps.

20 After BET, 25 patients required no further interventions whereas nine patients
21 underwent additional operations because their ear symptoms persisted. Six patients
22 required tympanostomy tubes once or repeatedly during the follow-up. One patient
23 received radical mastoidectomy because previously operated cholesteatoma recurred.
24 Other two patients previously operated for cholesteatoma experienced no recurrence

1 during the follow-up, and their ear symptoms required no further interventions after BET.
2 One patient, with history of recurring otitis media and myringostapedopexy, received
3 tympanoplasty. In one patient, scarred tubal opening on the left prevented BET to that
4 side but the operation was successful to the right. Later, he received bilateral BET but
5 required repeated bilateral tympanocenteses even after that. No symptom or diagnosis
6 clearly distinguished the patients who needed additional operations from those who
7 received only BET. Diagnoses were chronic secretory otitis media (64% of those that
8 received only BET and 78% of those that underwent additional interventions), Eustachian
9 tube dysfunction (28% and 8%), and chronic otitis media (8% and 0%).

10 Details on demography, preoperative clinical findings, treatment, and possible
11 further interventions were recorded from the medical charts.

12

13 *Questionnaire*

14 The postal questionnaire was modified from ETDQ-7, which covers the severity of
15 specific ear symptoms suggestive of ETD from the previous month [4, 9]. The ETDQ-7
16 is the only disease-specific questionnaire validated for diagnostics of ETD and for
17 evaluating the outcome of its treatment. First, the questions from the English version of
18 ETDQ-7 were translated to Finnish and Swedish (the official languages of Finland). As
19 detailed information of the symptoms was not gathered preoperatively, we modified the
20 questions so that we asked the patients if specific ear symptoms covered in the ETDQ-7
21 were currently clearly milder, somewhat milder, the same, somewhat worse, or clearly
22 worse compared to the preoperative situation. In addition to the symptom specific
23 questions based on ETDQ-7 we composed additional questions. We asked if the patients
24 could perform Valsalva maneuver better than before the operation. The maneuver was

1 explained to the patients in the questionnaire. We also asked if swallowing releases
2 pressure in the ears now better than preoperatively, how the patients would rate the
3 severity of their overall ear symptoms now, and how disturbing their current ear
4 symptoms are. The questionnaire also covered possible visits to a doctor and procedures
5 done after BET in order to treat ear symptoms. The questionnaire is provided in
6 Additional Files 1-3 (Finnish version in Additional File 1, Swedish version in Additional
7 File 2, and their translation to English in Additional File 3).

8

9 *Surgical procedure*

10 The patients were under general anesthesia, and cocaine-adrenaline solution in small
11 absorbent cotton pads provided nasal nerve block anesthesia. The balloon dilation was
12 carried out with sinus balloon dilation catheter, 7 mm x 16 mm Acclarent Relieva solo
13 (Acclarent, Inc., Menlo Park, CA, USA). Rigid nasoendoscopes with diameters of 3-4
14 mm and angles from 0⁰ to 45⁰ allowed visual control. The endoscope was inserted
15 through the ipsilateral nostril if the nasal anatomy allowed it. If not, it was inserted
16 through the contralateral nostril. When properly inserted to the Eustachian tube, the
17 balloon was inflated once to 10-12 atm for two minutes or twice to 10-12 atm for one
18 minute. Experienced ENT doctors performed the operations with the two-hands
19 technique. No immediate or late complications occurred.

20

21 *Statistics*

22 The differences in prevalences of the symptoms and in the effect of BET on different
23 symptoms in Table 2 were calculated using logistic regression and Fisher's exact test

1 (SAS software, SAS Institute Inc., Cary, NC, USA). Fischer's exact test was used with
2 Table 3.

3

4 **Results**

5 No differences existed in gender, age, or diagnosis between all the 46 patients meeting
6 the inclusion criteria and the 34 responders (Table 1). The follow-up time for the
7 responders was 3.1 ± 0.1 years (mean \pm SEM, range 1.8-4.6).

8 The most common preoperative symptoms among all the responders ($n = 34$, 52
9 ears, Table 2a), were feeling that ears are clogged (96% of treated ears) and muffled
10 hearing (92%). Other common symptoms were ear symptoms during a cold (77%),
11 crackling or popping sounds in the ears (77%), and pressure in the ears (73%). There was
12 no statistically significant difference ($p = 0.1584$) between the prevalences of feeling that
13 ears are clogged and muffled hearing. However, they both had significantly higher
14 prevalence than any other symptoms ($p \leq 0.0390$). Patients with pain in the ears seemed
15 to benefit the most from the procedure as pain reduced in 81% of preoperatively affected
16 ears. Pain in the ears as well as pressure in the ears (improvement in 79%), feeling that
17 ears are clogged (76%), and ear symptoms during a cold (66%) improved significantly
18 more ($p \leq 0.0346$) than ringing in the ears (improvement in 40%) and being able to release
19 pressure in the ears by swallowing (39%). Ability to perform Valsalva maneuver
20 improved in 50%, which was significantly less ($p \leq 0.0297$) than improvement of pain in
21 the ears, pressure in the ears, and clogged feeling in the ears.

22 Among those who underwent only BET ($n = 25$, 38 ears), the most common
23 symptoms were feeling that ears are clogged (95%) and muffled hearing (89%) (Table
24 2b). The prevalence of clogged feeling was significantly higher ($p \leq 0.0364$) than that of

1 any other symptom except muffled hearing. The difference between the prevalences of
2 muffled hearing and any other symptom than clogged feeling or ear symptoms during a
3 cold was also statistically significant ($p \leq 0.0493$). At least 70% of the ears improved
4 regarding feeling of pressure, ear symptoms during a cold, clogged feeling, pain, and
5 muffled hearing. Those who had trouble releasing pressure in the ears by swallowing
6 benefitted the least from BET in this group as only 48% were better at it at the end of the
7 follow-up than preoperatively. Valsalva maneuver improved only in 57% of the ears. Ear
8 symptoms during a cold improved significantly more than ringing in the ears and
9 swallowing releasing pressure in the ears (83%, 50% and 48%, respectively, $p \leq 0.0155$).
10 Feeling of pressure in the ears improved significantly more than swallowing releasing
11 pressure (87% and 48%, respectively, $p = 0.0101$). Other differences in improvement of
12 different symptoms were statistically insignificant in this group.

13 In the group that underwent additional procedures after BET ($n = 9$, 14 ears), every
14 ear had preoperatively suffered from feeling that ears are clogged, muffled hearing, and
15 pressure in the ears (Table 2c). However, the symptom that reduced the most in this group,
16 in 89% of the preoperatively symptomatic ears, was pain in the ears. This decrease and
17 the reduction of clogged feeling in the ears (71%) were significantly better results than
18 improvement in Valsalva maneuver (28%), releasing pressure in the ears by swallowing
19 (20%), ear symptoms during a cold (18%), or ringing in the ears (0%) ($p \leq 0.0423$).
20 Pressure in the ears improved in 64% which was significantly more than improvement of
21 Valsalva maneuver, ear symptoms during a cold, or ringing in the ears ($p \leq 0.0410$).

22 When asked about the change in overall ear symptoms, 77 % of all treated ears
23 had now less symptoms than preoperatively as 10% were asymptomatic, 42% had clearly
24 less and 25% somewhat less symptoms than preoperatively (Table 3). Those who felt

1 they benefitted from the procedure (symptoms less than preoperatively, 77%)
2 significantly outnumbered those whose overall symptoms showed no improvement (23%)
3 ($p = 0.0060$). Of those patients who only underwent BET, symptoms had disappeared or
4 reduced in 90% whereas of those who required additional interventions only 43% had
5 reduced symptoms and none was asymptomatic.

6 When asked how disturbing the current ear symptoms were, 67% of all the
7 responders reported that their current symptoms disturbed them not at all, very little, or
8 little (Table 4). Of those that underwent only BET, 8% were asymptomatic, 36%
9 experienced very little disturbance, and 32% little disturbance. This amounts to 76 % of
10 less disturbing ear symptoms in this group. However, in the group that had undergone
11 additional procedures, 55% experienced more than little disturbance from their ear
12 symptoms suggesting overall more treatment resistant symptoms in this group.

13 Finally, we asked the patients whether they, with their current knowledge of BET
14 and its effects on them personally, would be willing to undergo BET again if their
15 symptoms returned to the preoperative level. In that situation, 79% of all the responders
16 would choose BET again (Table 5). Of those who received only BET, 84% would
17 undergo BET again. Of those who required additional interventions, 67% would undergo
18 BET again.

19

20 **Discussion**

21 The long-term effect of BET seems satisfactory as 77% of the treated ears were less
22 symptomatic after the follow-up than preoperatively. Symptoms reduced in 90% of the
23 group that only underwent the initial BET. BET best alleviated pain in the ears, feeling
24 of pressure in the ears, and feeling that ears are clogged as each of these symptoms

1 improved in over 75% of all the affected ears. Ringing in the ears and the ability to release
2 pressure in the ears by swallowing responded the least to BET. The Valsalva maneuver
3 became easier in only 50% of all treated ears and only in 57% of those who required no
4 further interventions after BET. Of all the responders, 79% would undergo BET again, if
5 their symptoms returned to the preoperative level. Even though only 43% of those who
6 needed additional operations were less symptomatic at the end of the follow-up than
7 preoperatively, 67% of them would undergo BET again if their ear symptoms returned to
8 the preoperative level. That might suggest that the positive effect of BET might have been
9 stronger earlier and the symptoms might have been returning towards the end of the
10 follow-up. However, this might also reflect that the patients hope that reoperation would
11 have a better effect than the first operation.

12 Even though the postal survey return rate, 74%, is good, those who experienced
13 no benefit from the procedure might have failed to respond rendering our results as overly
14 optimistic. However, no differences existed in demographics between all the treated
15 patients and the responders (Table 1) suggesting that our sample population is
16 representative. As this was a retrospective questionnaire study, there was no baseline
17 assessment, and preoperative data in the medical charts was incomplete regarding the
18 symptoms listed in our questionnaire. Therefore, it was up to the patients to remember
19 the preoperative situation. There were no routine visits at the clinic at the time the patients
20 returned the questionnaire, and thus no objective information was obtained. Nonetheless,
21 in this particular setting we were interested in the patient's perspective on the long-term
22 effect of BET. It is noteworthy, that the ETDQ-7 is validated in English, and the Finnish
23 and Swedish modifications used in this study have not been validated. Also, the English
24 ETDQ-7 is validated for assessing ETD-related symptoms at a given time period and for

1 evaluating treatment outcome when the questionnaire is used both pre- and
2 postoperatively. In this study we used the modified questionnaire with no systematic pre-
3 treatment symptom assessment. For that reason, it is not certain that the questionnaire
4 used in this study has validity for the purpose.

5 Schröder and co-workers [1] reported that 73% of 89 patients were free of
6 symptoms or had less symptoms two years after BET. In our study, 77% of the 52 BET-
7 treated ears were asymptomatic or had reduced symptoms after mean follow-up of 3.1
8 years. Wanscher and Svane-Knudsen [7] found that, at two months, Valsalva maneuver
9 had improved in 66% and earache in 55%. In our study, the Valsalva maneuver improved
10 in 50% and earache in 81%. Silvola and colleagues [8] reported that after mean follow-
11 up of 2.5 years, the Valsalva maneuver had clearly improved in 80%. However, in their
12 study, the examiner evaluated the maneuver whereas in ours and one by Wanscher and
13 Svane-Knudsen the patients themselves evaluated it. Gürtler and colleagues [5] found
14 that, at three months, feeling of pressure had disappeared in 75% of preoperatively
15 symptomatic patients and hearing impairment in 44% but tinnitus in none. In our study,
16 pressure clearly improved in 42%, muffled hearing in 23%, and ringing in the ears in
17 20%. Catalano and co-workers treated 70 patients (100 ears) with BET [9]. Mean follow-
18 up time was 30.3 weeks, and eight patients were followed for at least 34 months. They
19 registered feeling of fullness in the ear, pressure, pain, tolerance to flying, and objective
20 findings in tympanic membrane at each visit. Of those eight patients that had the longest
21 follow-up, seven reported persistent improvement. However, it is unclear which
22 symptoms were relieved and if the report of persistent improvement was purely subjective
23 or if supporting objective findings were present. McCoul and Anand performed BET and
24 partial inferior turbinectomy on 22 patients (total 35 cases) with a 6-month follow-up

1 [9110]. They also performed simultaneous submucous resection of the nasal septum in
2 15 cases while 17 cases received simultaneous endoscopic sinus surgery. Retraction of
3 tympanic membrane was present in 33 cases (94%) preoperatively and healed in all of
4 them during the follow-up. Preoperatively, tympanogram was abnormal in all cases but
5 postoperatively only in one case with tympanic membrane perforation. In our study,
6 tympanic membrane retraction or negative pressure in the tympanogram was
7 preoperatively present in 76%. In addition to clinical findings, McCoul and Anand
8 evaluated the response to BET by ETDQ-7, which the patients completed preoperatively
9 and at every follow-up visit. In addition to ETDQ-7, patients were asked at every visit
10 whether their overall ETD symptoms had reduced since BET. ETDQ-7 improved
11 significantly at every follow-up point, and it had a significant association to patient's
12 evaluation of overall symptom reduction. Our study had a different questionnaire than the
13 original ETDQ-7 and it has no similar validity. However, based on the findings by
14 McCoul and Anand, it could be suggested that as 77% of patients evaluated improvement
15 in their overall ear symptoms since BET, they probably would have shown decrease in
16 ETDQ-7 after the follow-up if ETDQ-7 had been used in its original form pre- and
17 postoperatively.

18 The results of this study add to the evidence that BET is a simple and safe
19 procedure with significant subjective long-term benefits to the patients [1, 8-9]. We now
20 know which specific symptoms are most likely to improve in long term. These findings,
21 together with the results of other studies, help clinicians in preoperative patient selection
22 and counselling. However, more prospective studies on validated ETDQ-7 together with
23 objective outcome measures are needed to support the findings of this study.

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1 **Disclosure statement**

2 The authors report no conflicts of interest.

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- 1 Table 1. Demographics.
- 2 Table 2. Current ear symptoms compared to the preoperative situation.
- 3 Table 3. Current overall ear symptoms compared to the preoperative situation.
- 4 Table 4. Disturbance caused by current ear symptoms.
- 5 Table 5. Willingness to undergo BET again if ear symptoms returned to the
- 6 preoperative level.
- 7