

Promising results after balloon dilatation of the Eustachian tube for obstructive dysfunction

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ABSTRACT

INTRODUCTION: As the first ear, nose and throat department in Denmark, we introduced balloon dilatation of the Eustachian tube as a treatment of obstructive dysfunction in the summer of 2012. We present our preliminary experiences with this new treatment in adults.

MATERIAL AND METHODS: Preoperatively, several different tests were performed including otomicroscopy, audiometry, tympanometry and Toynbee's test. The patients were classified as Class 1 (if they could make a pressure equalisation of the middle ear by a normal Valsalva's test), Class 2 (if they needed an extended Valsalva's test), Class 3 (if only a test with the Otovent could make air flow to the middle ear), and Class 4 (if no passage of the Eustachian tube could be achieved). Furthermore, the patients filled out questionnaires using a visual analogue scale (VAS).

RESULTS: A total of 50 treatments were performed in 34 patients (16 patients had bilateral problems). Four patients (six Eustachian tubes) had intermittent problems, while 30 patients had chronic dysfunction. A significant effect of the treatment was documented when measuring both audiometry, tympanometry, Toynbee's test, classification of Eustachian tube dysfunction and VAS questionnaires. Some patients (e.g. patients with atelectatic ear drums) were not helped by the treatment. Among the first 40 treatments, 10% were observed to have acute otitis media post-operatively.

DISCUSSION: The majority of the patients experienced a positive effect of the treatment. Our results are comparable to those of other similar studies. We regard this new treatment as very promising, but look forward to more research.

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The Eustachian tube (ET) is localised between the epipharynx and the middle ear. It is divided into a lateral bony component (approximately 12 mm in length) and a medial cartilaginous component (approximately 24 mm in length).

The ET has various functions. By means of four associated muscles, the ET facilitates pressure equalisation of the middle ear when necessary by a brief opening. Another function of the ET is to facilitate the removal of fluids from the middle ear.

Symptoms of inadequate ability to pressure equal-

ise the middle ear are aural fullness, tinnitus and a sensation of being "under-water", among others. Over time, this inability can lead to middle ear effusion, atelectasis of the tympanic membrane, formation of retraction pockets, adhesive otitis media, and eventually to cholesteatoma. The majority of patients with inadequate ability to pressure equalise the middle ear have an obstructive dysfunction in the Eustachian tube (ETD).

The prevalence of chronic inability to pressure equalise the middle ear in the adult population is estimated to be about 0.9% [1].

Historically, many different treatments have been tried to solve ETD. Among these are systemic antihistamines and corticosteroids, intranasal corticosteroids and decongestants, non-invasive autoinflation manoeuvres, ET catheterisation, bougie dilatation, drilling of the bone and other invasive treatments. These treatments have not shown any evidence of success. In the past decade, laser-tuboplasty has been tried with some degree of effect in smaller series of patients [2]. The only effective treatment is ear drum tubulation, which potentially brings other problems such as chronic perforation of the tympanic membrane, infections and myringosclerosis.

Recently, balloon dilatation of the ET (**Figure 1**) has been introduced in Bielefeld, Germany, and the preliminary results of the treatment seem very promising [3].

As the first ear, nose and throat (ENT) department in Denmark, we introduced the treatment in the summer of 2012 at Odense University Hospital. The purpose of this article is to present our preliminary experiences with the treatment.

MATERIAL AND METHODS

The inclusion criteria were at least six months of ETD symptoms. To this we added patients with significant symptoms of ETD during flying, diving and/or secretory otitis media several times a year during even a mild upper respiratory infection as seen by an ENT doctor. Only adults were treated (> 18 years of age). The exclusion criteria were known pathology of the epipharynx such as prior malignancy in the area of the ET, anatomical abnormalities such as cleft palate and larger amounts of polyps in the epipharynx.

The patients underwent an examination by one of the two authors at least two weeks prior to the treat-

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FIGURE 1

Deflated (A) and inflated (B) balloon placed in the medial two thirds of the Eustachian tube.

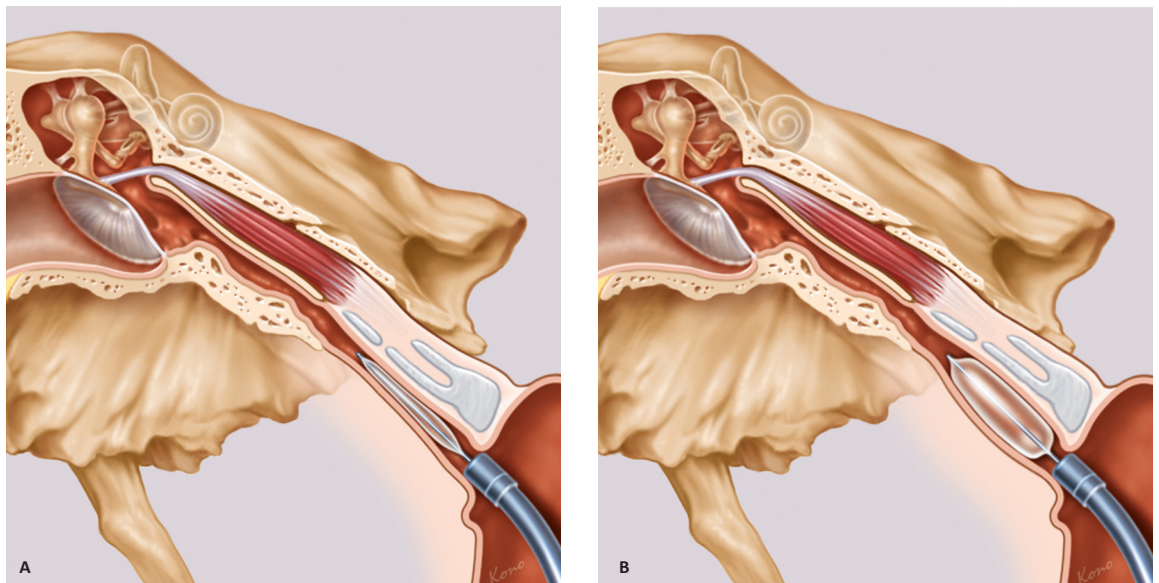
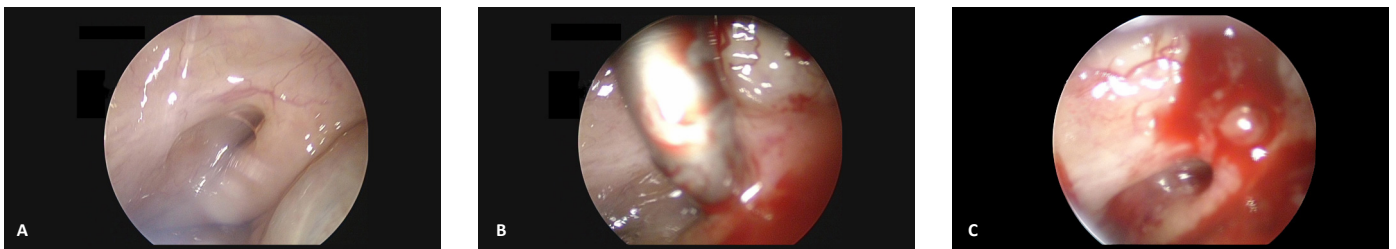


FIGURE 2

Orificium of the right Eustachian tube (seen from the nasal cavity) before (A), during (B) and after dilatation (C).



ment. The examination included a thorough interview focussing on the ETD symptoms and prior medical history, as well as otomicroscopy, rhinoscopy, audiometry, tympanometry and in selected cases a computerised tomography of the ET. The symptoms persisted at the time of surgery (except in case of intermittent problems with ETD).

To describe the tympanogrammes, we used the terms type A-curve (+50 to -99 daPa), type B-curve (flat), type C1-curve (-100 to -199 daPa) and type C2-curve (-200 daPa or less) [4].

The patients underwent two ETD tests. The first test was the Toynbee's test in which the patient swallows with and without pinching the nostrils. Between each swallowing, a tympanometry is made. A positive test (change of pressure in the middle ear of more than 10 daPa between the two tympanogrammes) indicates a

normal tuba function. The second test is an ETD classification [5]. In Class 1, the patient could perform a normal Valsalva's test. In Class 2, the patient could only equalise pressure in the middle ear by an extended Valsalva's test in which the patient did a maximal flexion and rotation of the cervical spine at the time the Valsalva's test was done (in this position, the patient tested the ear turning upwards). In Class 3, the patient could equalise pressure only by use of the autoinflation instrument Otovent [6]. In Class 4, the patient could not equalise pressure in the middle ear by any means at all. The middle ear pressure equalisation was noted by the patient's own subjective feeling and by objective assessment (otomicroscopy).

In addition, the ETD symptoms were examined with a visual analogue scale (VAS) questions focusing on aural fullness, earache and their ability to do Valsalva's test.

At the time of treatment, no patients had a change of symptoms compared with the primary examination. In most cases, the procedures were done in general anaesthesia combined with an extensive application of local anaesthesia and vasoconstrictor in the nasal cavity. The procedures were done in local anaesthesia alone only in three cases. We used the Bielefeld Balloon Catheter introduced into the ET at a fixed length of 20 mm through a special insertion instrument guided by a rigid scope (Figure 2). The balloon was inflated with sterile water to a pressure of ten bars for two minutes. Patients were admitted in the morning and discharged in the afternoon. The day after surgery, the patients were instructed to do Valsalva's test three times every day. Post-operatively, two types of nasal sprays were used, one containing decongestants (ten days) and one containing corticosteroids (14 days). Two months after the operation/treatment, the patients had consultations where the described preoperative tests were performed again.

Analysis

The results were analysed using SPSS (Statistical Package of Social Science). The data were tested with a Q-Q plot and hereby rendered to be normally distributed. Primarily, the paired-samples T-test was used, and a significance level of 0.05 was used when indicated.

Trial registration: not relevant.

RESULTS

A total of 34 patients (18 males and 16 females) had 50 procedures in the period from June 2012 to May 2013. In all, 16 patients had the procedure bilaterally. The mean age of the patients was 45 years and age ranged from 20 to 74 years.

Thirty patients (44 ears) had chronic ETD, whereas four patients (six ears) had intermittent ETD according to the inclusion criteria. The patients with chronic ETD all experienced aural fullness and a change in hearing (even though the audiometry could be normal), 60% had earache and 30% had tinnitus of different magnitudes.

The symptoms had persisted for an average of 19 years, ranging from two to 60 years. In all, 24 of the patients with chronic ETD had ear drum tube insertions done in the past (up to 22 times). In patients with chronic ETD, 30 tympanic membranes had pathology as seen by otomicroscopy. A total of 19 of those had a retraction of the tympanic membrane, five had atelectasis and six had a ventilation tube. Among those with post-operative retraction of the tympanic membrane, eight had normal findings post-operatively. In contrast, none of the atelectatic ears were resolved. Ear drum tubes seen post-operatively were left in the tympanic membrane.

Reviewing the audiometries in patients with intermittent ETD, we found no hearing losses either before or after treatment. In ears with chronic ETD, an air-bone gap (pure tone average with four tones 0.5-4 kHz) (conductive hearing loss) was seen in 82% of the ears. 42% of those had either no air-bone gap or a smaller air-bone gap in the audiometry post-operatively. The air-bone gap changed from an average of 28 dB to 18 dB ($p < 0.05$) with no change in bone conduction. The patients with atelectasis showed no hearing improvement post-operatively.

All of the cases with intermittent ETD showed an A-curve on the tympanometry both pre- and post-operatively, whereas an A-curve was not seen preoperatively in the cases with chronic ETD. A total of 23 ears with chronic ETD had a B-curve on the tympanometry (six due to a ventilation tube). Of the 17 ears with a B-curve but without a ventilation tube, four had a C2-curve, three had a C1-curve and three had an A-curve post-operatively, whereas seven did not change. Twelve ears had a C2-curve preoperatively, three of those had a C1-curve and five had an A-curve post-operatively, while four did not change. Five ears had a C1-curve preoperatively, four of those had an A-curve post-operatively, and one did not change. When excluding the ears with ventilation tubes, the remaining 38 ears with chronic ETD showed a positive change in the tympanometry in 22 cases (58%). See Table 1.

Among those with intermittent ETD, the Toynbee's test was positive (normal) in all cases both pre- and post-operatively. The results of the Toynbee's test within the ears with chronic ETD are seen in Table 1.

Using our ETD classification system, all of the pa-

TABLE 1

Chronic Eustachian tube dysfunction (ETD).

Test	Pre-operatively, %	Post-operatively, %
<i>Tympanometry (n = 44)</i>		
A	0	28
C1	11	17
C2	31	19
B without ventilation tube	42	19
B with ventilation tube	17	17
<i>Toynbee's test^a (n = 38)</i>		
Positive	7	77
Negative	93	23
<i>ETD classification (n = 44)</i>		
Class 1	0	45
Class 2	5	18
Class 3	6	9
Class 4	89	27

a) Patients with ventilation tubes excluded.



TABLE 2

Overall results of visual analogue scale scores. The values are mean (\pm SD).

Question	Pre-operatively	Post-operatively	p-value
To do Valsalva's, how easy ^a	85.8 (\pm 24.2)	43.6 (\pm 38.6)	< 0.05
Aural fullness, how often ^b	68.6 (\pm 26.8)	42.0 (\pm 31.8)	< 0.05
Earache, how often ^b	29.8 (\pm 25.8)	14.5 (\pm 18.3)	< 0.05

SD = standard deviation.

a) 0 = no problems; 100 = impossible; b) 0 = never; 100 = always.

tients with intermittent ETD were in Class 1 both pre- and post-operatively. The results of the group of ears with chronic ETD are presented in Table 1.

Summarising our ETD classification system in cases with chronic ETD, 75% moved to a lower class (positive effect) post-operatively, whereas 25% did not shift to another class. The patients with ear drum tubes were all in Class 4 preoperatively. Two patients changed to Class 1, one patient to Class 2, two patients to Class 3, whereas one patient did not change class post-operatively.

The results of the VAS questionnaire are shown in **Table 2**. Reviewing these results, 66% of the patients indicated a positive effect on doing Valsalva's test, 55% indicated a positive effect on earache, and 48% indicated a positive effect on aural fullness.

Among the 42 procedures, we saw only few problems. In all of the cases, the patients were discharged on the day of surgery. In four cases (8%), we saw an acute otitis media few days post-operatively. The first three cases of acute otitis media were seen among the first 20 treatments. After this experience, we introduced five days of antibiotics by oral therapy resulting in only one incident of acute otitis media in the following 30 treatments.

The patients filled in a questionnaire two months post-operatively focusing on their overall experience with the procedure. In one item, we asked about the overall discomfort experienced during and after the procedure. The average score was 11, range 0 to 65 (where 0 was no discomfort and 100 was extreme discomfort). In another item, the patients were asked if they would recommend the procedure to a friend with equivalent symptoms. The average score was 35, range 0 to 100 (where 0 indicated that they would recommend the procedure, and 100 indicated that they would not recommend the procedure).

DISCUSSION

As presented, the data can be divided into a group of subjective measures (questionnaires), objective meas-

ures (different types of examinations) and the ETD classification system, where the ability to equalise middle ear pressure is both evaluated by the patient and the examiner.

We chose to test the patients two months post-operatively by inspiration of Schröder et al [7], who described an improvement of the ET function within two months after the treatment. No further improvement seems to appear more than two months after the treatment. In our treatment, we employed two types of nasal medications; however, only for 10 and 14 days post-operatively. We do not believe that these treatments are the main reasons for the success observed in this study. It could be speculated that the balloon dilatation with the mentioned post-operative nasal medications and Valsalva's test should be compared with the same treatment, but without dilatation. However, we do not believe that this treatment alone would result in a difference. This has been examined in the past [8].

Overall, the analysis of the questionnaires showed a significant change in aural fullness, the ability to do Valsalva's test and an earache reduction. Furthermore, none of the patients indicated substantial discomfort due to the treatment. The patients would recommend the treatment to friends or family with equivalent problems with ETD.

The subjective measures were supported by the results of the objective measures, where we saw improvement of audiometry, tympanometry and Toynbee's test. The effect shown by Toynbee's test is, in our opinion, important because this test shows the physiological function of the ET. The ETD classification system showed an improvement within a considerable number of patients.

However, a group of patients showed no improvement of ET function after the treatment. It seemed as if patients with atelectatic ears did not achieve the ability to introduce a high enough pressure in the middle ear as to lift the tympanic membrane away from the medially placed structures of the tympanic cavity. In these patients, the treatment probably cannot stand alone, but could be followed, for example by regular middle ear surgery. This finding is in contrast to Poe et al [9] who presented two patients with apparent atelectasis, which was solved by balloon dilatation of the ET with a sinoplasty balloon catheter.

We also observed that the treatment did not have effect in other patients. Perhaps microfractures of the stenotic ET cartilage did not arise in contrast to what was proposed by cadaver studies [10]. Another reason could be that the stenosis was placed in the lateral bony portion of the ET where the balloon was not applied.

Our results regarding the subjective measures (VAS) are comparable to other larger studies of ET balloon

dilatation such as Tisch et al [11] who reported a positive subjective effect among 71.4% of the patients (320 treatments in 210 patients) in achieving ET passage.

In other studies, such as Schröder et al [7], a special type of instrument termed a tubomanometer was used to show how high the intranasal pressure had to be to open the ET. This measurement was combined with questions about the ability to do the Valsalva's test, and if the patients experienced an opening of the ET by swallowing. The combination of objective and subjective measures resulted in a single number describing the ET function. Of 209 treatments in 120 patients, 79% showed a positive effect of the treatments regarding the combined score.

We observed 10% of cases who experienced an acute otitis media post-operatively. Because of this, we chose to prescribe antibiotics the first five days post-operatively to patients who underwent the treatment of ETD after this study ended. We saw no other complications, such as major bleeding or emphysema. The patients indicated only a small amount of discomfort due to the treatment, and the majority would recommend the treatment to family members and friends with similar problems.

We look forward to more research in the area of ET dysfunction treatment. The following issues are of particular interest: How to select patients who will have an effect of the treatment, how to quantify the amount of dysfunction, long-term results of the treatment, and results of repeated treatments in case of no effect after the first treatment and in case of recurrence of symptoms. We also need more investigation into how long the effect of treatment lasts. Preferably, we would like to see randomised trials and trials where the balloon dilatation is compared to other treatments such as longer use of autoinflation devices like the Otovent. Furthermore, we speculate as to how the treatment would be tolerated by children, and how the treatment is tolerated when performed concurrently with middle ear surgery.

In conclusion, we find this new treatment very promising.

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