Balloon Eustachian Tube Dilatation as the Standard Causal Intervention for Eustachian Tube Dysfunction?!

A summary of published clinical research

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Objective

This white paper is intended to help the clinician in making their decision whether to recommend Balloon Eustachian tube dilatation to a patient suffering from Eustachian tube dysfunction, and in managing expectations regarding outcomes and success rates. The paper summarizes the relevant scientific literature, it does not attempt to provide a statistical meta-meta-analysis of existing systematic reviews and original papers. Also, this paper does not replace the official product documentation.

Context

Anatomy

The Eustachian tube connects the middle ear with the nasopharyngeal space **(Figure 1)**. It consists of a bony part facing the middle ear, and a cartilaginous part facing the nasopharynx. In normal function, this medial part can be opened and closed through attached muscles.

The purpose of the Eustachian tube is (a) to ventilate the middle ear and provide pressure equalization between middle ear and ambient air when necessary, (b) to drain secretions from the middle ear, and (c) to protect the middle ear from sounds, pathogens and nasopharyngeal secretions[1].

Eustachian Tube Dysfunction

> *"Chronic Eustachian tube dysfunction has multiple causes and is a difficult condition to treat."*[2]

Eustachian tube dysfunction (ETD) is the general term for any condition where the opening and closing of the tube is impeded, this includes patulous ETD (PETD), where the valve remains permanently open, and obstructive ETD (OETD), where the tube does not open. This latter condition and its treatment are the focus of this white paper. OETD may occur as persistent, complete blockage, or as a baro-challenge-induced temporary blockage.

Incidence

The prevalence of ETD has been estimated at 0.9% of adults in the UK[3] and 4.6% of adults[4] and 6.1% of children[5] in the US; the difference between countries may be due to somewhat different definitions of ETD. ETD accounts for over half a million patient visits to primary care providers per year, in the US alone[6].

Relevance

ETD causes significant discomfort and suffering in patients affected by it, and can trigger additional pathologies.

The inability to equalize pressure between middle ear and

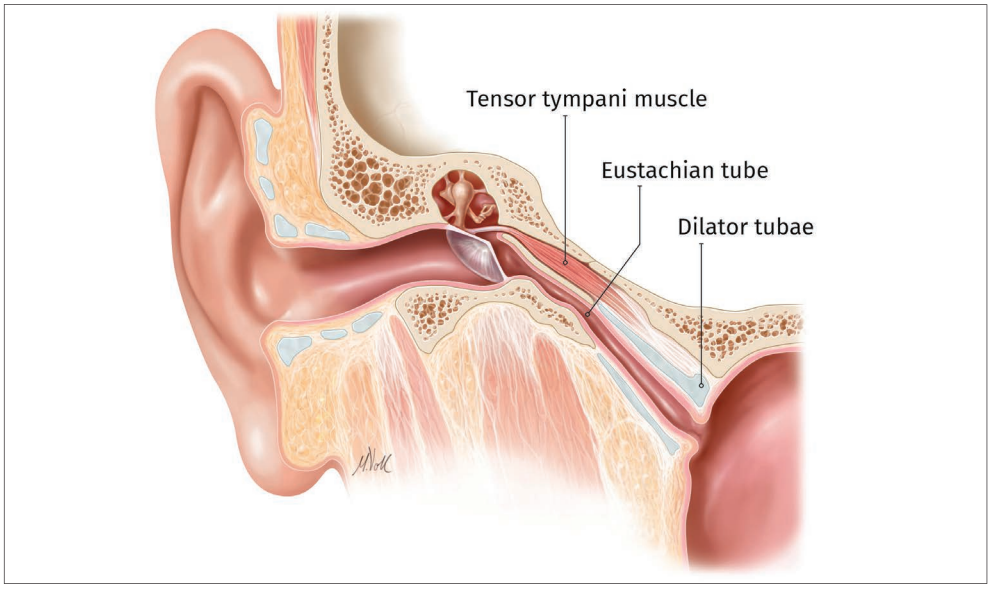

Figure 1:
Eustachian Tube

ambient air may result in rupture of the tympanic membrane (TM) under baro-challenge, or a retraction pocket of the TM[7].

The lack of ventilation of the middle ear space may contribute to otitis media with effusion (OME)[8,9] - 46% of OME cases are caused by Eustachian tube dysfunction[8] – and may eventually lead to chronic otitis media[7,9].

Either of those conditions can lead to hearing loss[9], and even cholesteatoma[7,9,10].

In some patients, ETD will also create functional impairments, such as the inability to fly or dive.

Symptoms

Symptoms of OETD include aural fullness, popping, discomfort or pain, feeling of pressure, clogged or 'under water' sensation, crackling, ringing, autophony, and muffled hearing[11]. These symptoms may also occur as a result of, or be exacerbated by, changes in atmospheric pressure[12], e.g. during flying or diving, or when passing through a train tunnel[13].

Differential Diagnosis

A comprehensive history and physical exam, including otoscopy, are essential parts of the diagnostic evaluation of a candidate for BET. Patient-reported symptom scores alone are insufficient to establish a diagnosis of obstructive ETD.[14]

The clinician's objective in determining the optimal treatment recommendation is to distinguish OETD from other pathologies with similar symptoms, such as endolymphatic hydrops, superior semicircular canal dehiscence, or patulous ETD.

One indicator for OETD is that myringotomy or the placement of a tympanostomy tube should relieve the symptoms, except in patients with baro-challenge induced OETD[14].

Before recommending the BET procedure, clinicians will commonly try to identify and treat, if applicable, other potential causes of ETD, including adenoids[1,10], nasal polyposis[1], allergic rhinitis[1,14], rhinosinusitis[1,14], or laryngopharyngeal reflux[1,14].

Consensus Statements

Recommendations for the diagnosis and treatment of OETD and for outcomes assessment have been made in the form of published consensus statements, by expert panels and professional societies in Finland[1], Spain[15], the United States[14], and by an international expert panel[11].

Treatment

"BET is a surgical, minimally invasive treatment that has shown its effectiveness and safety in obstructive Eustachian tube dysfunction in adults and children."[15]

Treatment options can be classified as conservative (e.g. nasal sprays, see section *"Alternative Treatments"* below), or interventional-symptomatic (e.g. tympanic paracentesis or ventilation tubes, see section *"Alternative Treatments"* below), or interventional-causal, the latter includes Balloon Eustachian tube dilatation, which is the focus of this publication.

Balloon Eustachian Tube Dilatation

Transnasal balloon dilatation of the cartilaginous part of the ET, called *"Balloon Eustachian Tuboplasty (BET)"*[16], or *"endonasal dilatation of the Eustachian tube (EET)"*[17], or *"balloon dilation of the eustachian tube (BDET)"*[18], is being used to treat OETD. It was first introduced in 2009 simultaneously in Finland[19] and in Germany[20].

In BET, an inflatable balloon catheter is inserted in the cartilaginous part of the ET, under endoscopic control. Once in position, the balloon is inflated by applying a pressure of typically 10 atm for 2 min **(Figure 2)**.

One manufacturer reports that their device has been used more than 100,000 times since its introduction in 2010[21].

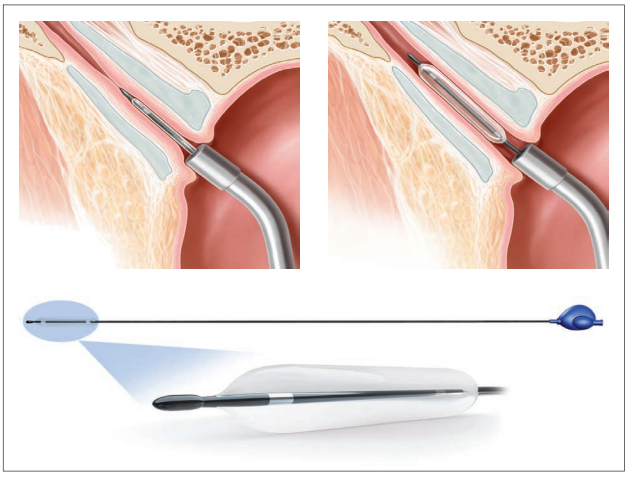

Figure 2:
Balloon Eustachian Tuboplasty procedure and device.
***Left:** uninflated; **right:** inflated*

Indication Criteria

For patients with: "(i) chronic bothersome symptoms referring to ETD, (ii) ETD-related symptoms in conjunction with rapid pressure changes, or (iii) recurring serous otitis media" BET is recommended e.g. by the Finnish Otosurgical Society[1].

Other studies recommend more generally that candidates should have a *"demonstrable burden of inflammatory disease visible within the lumen of the ET on preoperative endoscopic examination"*[18].

Exclusion Criteria

Clinicians choose not to perform BET in cases of patulous ETD, extrinsic obstruction of the ET, active primary inflammatory disorders[14] or poor access to the torus tubarius[15].
Additional contraindication criteria are listed in one consensus statement[15].

Adjunctive Treatments

Tympanic paracentesis performed in conjunction with BET appeared to accelerate improvement in one randomized controlled study with 90 adult patients (better results at 3 months postop, no added benefit at 6 months)[8], but showed no benefit in another randomized clinical trial with 25 adult patients[22].
Another retrospective study with 200 adult patients[23] found added benefit with a combination of BET with tympanic paracentesis and methylprednisolone irrigation, in terms of decreased intraepithelial inflammation, at 3 months and 6 months post intervention, but no added benefit at 12 months, compared to BET without adjunctive treatments.
One consensus statement[15] specifically recommends not placing a tympanic ventilation tube during the BET procedure, except in children with adhesive otitis.

Outcomes

Studies investigating the treatment of OETD and the efficacy of the BET procedure use a variety of objective and subjective outcome measures, and a variety of ways of reporting outcomes for one particular method; a fact that the authors of systematic reviews have struggled with and often commented on. This paper will simply describe what is available at this time, in decreasing order of popularity of the metric.

Valsalva

"The ability to perform a modified Valsalva maneuver is appropriate for assessing outcome after BET"[14]

The ability to perform a Valsalva maneuver successfully (referred to as *"Valsalva positive"*) indicates whether pressure equalization with the middle ear can be achieved.
Most clinical studies and systematic reviews include an assessment of the ability to perform the Valsalva maneuver successfully, either via subjective reporting by the patient, or by observing TM movement otoscopically.
For reference, in healthy subjects, Valsalva was found to be always positive in 89%, and always negative in 3.6% of 430 ears[7].

After BET patient´s ability to perform Valsalva improved up to 96 %[12].

All studies considered here report an improvement in patients' ability to successfully equalize pressure in the middle ear with a Valsalva maneuver after the BET procedure, in adults:

- from 0% positive Valsalva pre-op to 82% at 6 weeks post-op and 96% at 3 and 6 months, in a case series of 55 ears in 39 adult patients[12],
- from 8% pre-op to 72% post-op, in a systematic review of 9 studies with 713 ears[25],
- from 0% pre-op to 78% at 3 months post-op, 84% at 6 months, in a retrospective review of 332 ears[26].

In children, results are similar, e.g.

- from 28% pre-op to 65-80% at 3-6 months post-op, in a retrospective evaluation of 52 children[27],
- from 7% pre-op to 82% post-op, in 90 ears in 60 children[28]

The similar Toynbee maneuver (swallowing while pinching the nose) is used less often clinically. In healthy ears, it was found to be always positive in only 14%, and always negative in 31% of 430 ears[7].

Tympanometry

One success indicator for any treatment of OETD is the ability to revert from a tympanogram indicating a fluid-filled middle ear (type B) or negative pressure in the middle ear (type C) back to a normal status (type A).

Post-op 95 % of the treated ears showed a type A tympanogram[12].

Studies generally report an improvement in terms of tympanogram type, after the BET procedure.
Restoration of normal function (type A):

- from pre-op 40% with type A to 80% at 5 weeks post-op, 89% at 3 months, 95% at 6 months, in a prospective study with 55 adult ears[12]
- from pre-op 5% with type A to 61% post-op, in a systematic review of 9 studies with 713 adult ears[25]
- from pre-op 25% with type A to post-op 58%, in 128 ears in children treated only with BET, without adjuvant procedures such as paracentesis, VT placement, etc., and from 4% pre-op to 54% post-op in 171 ears treated with BET and adjuvant procedures, according to a retrospective multicenter analysis[10]
- from pre-op 1% with type A to 60% at 6 weeks post-op[9], and 54% at 52 weeks[18], in 234 ears in 162 adult patients, in a randomized controlled trial

ETD Questionnaire (ETDQ-7)

"Patient-reported symptom scores are useful in assessing baseline ETD symptoms and treatment outcomes."[14]

This questionnaire, first described and validated in 2012[29] is now available in many languages. It is very popular in studies on OETD and BET, and is mostly used in adults[24]. It measures seven symptoms commonly reported by patients (pressure, pain, clogged ears, sinusitis, crackling, ringing, muffled hearing) on a Likert scale, combined into a total score (range 7-49, normal <14.5) or an average score (range 1.0-7.0, normal <2.1).
There is consensus that the instrument is *"an important patient-reported outcome measure"*[30] and its use is considered best clinical practice[15].
Unfortunately, published studies report outcomes in a variety of formats: total score pre- and post-op, mean score pre- and post-op, change by score points, or percentage of patients pre/post with normal score.

ETDQ-7 scores showed a statistically significant difference in patient scores at 6 weeks, 3 months and 6 months[12].

All studies considered here report an improvement after the BET procedure, as seen by the ETDQ-7 instrument:

- From pre-op average score 4.9 to 2.6 at 6 weeks post-op, 2.0 at 6 months, in a prospective study with 39 adults[12]
- From pre-op average score 4.5 to 2.8 post-op, in a systematic review of 9 studies with 474 adults[25]
- From pre-op average score 4.3 to 2.4 post-op, in a retrospective review of 86 adults[31]

Tubomanometry

Tubomanometry is currently not considered an essential part of best clinical practice[15]*, and "should not be used as the only instrument for diagnosing diseases of the ET"*[7].

The objective and subjective metrics mentioned above provide indirect evidence for successful opening of the ET. The goal of tubomanometry is to make a more direct observation of ET opening possible. This is a *"clinical test measuring the active transport of gas from the nasopharynx to the tympanic cavity, based on simultaneously applied pressure in the external auditory canal as well as in the nasopharynx"*[17].
However, the method has only been used in a few studies[2,7,17,27]. Its correlation with perceived symptoms has not been established; one study noted that *"most patients noticed a relief of their complaints. In the same time, tubomanometry was not able to show improved tube function"*[17].

Eustachian Tube Score (ETS and ETS-7)

The ETS is a diagnostic tool first described in 2015[32], it combines subjective reports of clicking sounds when swallowing and the ability to perform a Valsalva maneuver with the outcome of objective tubomanometry at 3 pressure levels. The extended ETS-7 additionally includes tympanometry and objective Valsalva results in the calculation of the score.
Although it has good testretest reliability, and good sensitivity and specificity when compared against a combination of ETDQ-7, tympanometry and expert judgment[32], the instrument has only been used in a limited number of publications[2,20,33].

Audiometry

While audiometric assessment will certainly be part of the standard clinical routine, very few studies on BET outcomes provide an analysis of the effect on hearing loss, in particular a reduction of air-bone-gap. One study[34] reports a reduction of average air-bone-gap from a pre-op 17.5 dB to 10.8 dB at 6 months post-op, and 5.7 dB at 36 months post-op, in a cohort of 26 pediatric patients (46 ears).

Coping with Baro-Challenge

In addition to tests performed in a clinical setting, it is also important how the procedure affects patients' daily lives and their ability to engage again in activities that were precluded because of their OETD, such as flying or diving. This is particularly important for patients who need to engage in these activities for professional reasons, e.g. commercial or military pilots, flight attendants, or professional divers. After the procedure,

- most of the patients (79%) were able to fly normally[16]
- almost all of the patients (93%, 14/15) were able to continue working in an occupation that requires flying, including 75% (3/4) return to military aviator duty[16]
- most of the patients (75%, 9/12) were able to resume scuba diving[16]

Patient Satisfaction

As an indicator of satisfaction with the outcomes of the procedure, 86% (24/28) of the patients in one study would undergo the operation again if their symptoms returned to the same level[16]. In the same study, 93% of patients who completed a questionnaire, on average 4 years 8 months after surgery, found the operation beneficial.

Complications

Complications are reported to be mostly minor and self-limiting[16,35].

Minor Complications

One large retrospective multicenter analysis comprising 2272 patients[36] reported 3 cases of temporary tinnitus intensification and 1 case of acute otitis media.

One systematic review[35] comprising 15 studies with a total of 1830 procedures in 1155 patients found 36 cases of various mild and selflimiting complications.

One study reported, in a cohort of 39 adult patients, one case with persistent symptoms of patulous ET after BET, which resolved in a year[16].

In addition, one consensus statement[15] mentions the possibility of mild or moderate pain, mild bleeding, and changes to taste sensation.

Serious Complications

Postoperative cervicofacial emphysema was reported in 10 out of 3670 procedures by a systematic review specifically intended to find emphysematous complications[36]; out of those 10 cases, 3 extended to the mediastinum.

Another systematic review of 9 studies comprising 713 procedures[25] reports 2 cases of selfresolving subcutaneous emphysema.

A systematic review comprising 15 publications with a total of 1830 procedures[35] mentions one case of hematotympanum, where myringotomy was necessary to relieve symptoms.

Sensorineural hearing loss after a BET procedure was described in 7 out of 2614 ears in a systematic review specifically designed to look at this possible complication[37]; the hearing loss was permanent in 2 out of those 7 cases, on average 17.5 dB PTA.

Serious Adverse Events

While retrospective case series and systematic reviews may not capture all complications, the rigorous reporting required in randomized clinical trials should capture all serious adverse events (SAE). The randomized clinical trials published so far reported zero SAE in 91 ears[38] and zero SAE in 234 ears[9].

Alternative Treatments

There are a number of alternative procedures in clinical use which are also applied with the intention of treating OETD.

Tympanic Paracentesis or Ventilation Tubes

Traditional methods like tympanic paracentesis or ventilation tubes cannot directly improve ET function [8].

In the past, this has been the standard surgical treatment for OETD[16]. However, it does not treat the underlying pathology[14,16] of OETD, and it is not a viable treatment choice for divers[16].

Also, there is the risk for complications like infection[12], tympanosclerosis[14], recurrent and chronic otorrhea[12] and permanent perforations of the tympanic membrane[10–12,14], possibly associated with persistent conductive hearing impairment.

Tympanic paracentesis in adults has been shown to be far less effective than BET in a randomized controlled study with 90 patients[8].

The situation in children must be assessed separately, due to the differences in etiology, prevalence of middle ear diseases and maturation of ET (see the section on pediatric use below).

Intranasal Corticosteroids

One recent editorial commenting on the state of management of ETD[6] states that *"It is common practice to prescribe nasal steroids as firstline treatment for ETD [...] otolaryngologists continue to prescribe nasal steroids for the treatment of otitis media with effusion, despite evidence that they are no more effective than placebo in the treatment of ETD"*, referring to a randomized, placebo-controlled, double-blind prospective clinical trial[39] with 91 patients.
BET has been shown to be more effective than treatment with corticosteroids[40].

Other Pharmaceutical Treatments

In a recent consensus statement[14], the expert panel agreed that there is no published evidence of effectiveness of either systemic decongestants or antihistamines.

Laser Eustachian Tuboplasty

This procedure aims to treat OETD by vaporizing an appropriate amount of mucosa and cartilage on the posterior wall of the tubal lumen, through a combined endoscopic nasal and transoral approach to the Eustachian tube nasopharyngeal orifice. It is a complex surgery requiring use of an endoscopic CO_2 laser[2].
The procedure has been used since 1999 and has been shown to be effective[47]. However, a meta-analysis[41] of 13 publications comprising 1063 patients (including 121 treated with laser tuboplasty) found no evidence for higher effectiveness of laser tuboplasty compared to BET.

Practical questions

Use in Children?

> *"[BET] was feasible, safe, and an effective second-line treatment in children 4 years and older"[10].*

Dilatory ETD is very common in infants and usually ends by maturation of the ET[42]. There is evidence that exposure to high concentrations of environmental tobacco smoke increases the prevalence of ETD in children and adolescents[5].
For decades, adenoidectomy, myringotomy, and ventilation tube (VT) insertion have been the gold standard in the treatment for ETD[27]. An estimated 5% of all children in Central Europe have received paracentesis and VTs at least once[10]. These procedures are expected to *"stay the first line treatment in children presenting recurrent/persistent middle ear infections with or without effusion"[27].*
BET in children was first described in 2013[43]. BET has been used successfully in children as young as 28 months, with outcomes similar to what has been reported in adults[10,27,34].
Generally, BET is selected in therapy resistant children after trying other treatments such as adenoidectomy and VTs[27].

Anesthesia: General or Local?

> *"BET is a safe and feasible procedure under monitored anesthesia care, including local anesthesia along with sedation and analgesia."[44]*

Preferences among clinicians are not uniform, and are also influenced by health economics considerations. The majority of studies report the use of general anesthesia[35].
Outcomes from BET under local vs. general anesthesia are similar[26]. The Spanish consensus statement[15] recommends general anesthesia or deep sedation, not local anesthesia.
One study reported that 77% of the patients treated under local anesthesia considered the anesthesia and pain relief to be sufficient, and 12/13 patients would choose local anesthesia with sedation and analgesia if they needed to undergo the same procedure again[44].
The choice of local vs. general anesthesia is not identical to the choice of inpatient vs. ambulatory procedure. One review states that BET can be performed in an office setting under local anesthesia with the right patient selection, operative technique, and anesthesia protocol. This results in significantly reduced costs and minimizes the risk of general anesthesia[46].

Repeated Balloon Dilatation?

There is very limited public information about revision BET in cases where the first procedure did not have the desired outcome. Some studies[17,27,36,45] report having performed a very small number of revisions without providing details of the success of the second procedure.
One retrospective study specifically looked at outcomes of repeated BET procedures[31] in a cohort of 86 patients (145 procedures), including 10 patients who underwent repeat BET. The study results suggest that patients who fail to improve meaningfully on ETDQ-7 scores after the initial procedure are unlikely to show substantial improvements after a repeated procedure.

Imaging?

> *"In the light of current literature, our data suggest that fear of internal carotid injury during balloon dilation is disproportionate. … From March 2013, we no longer perform routine CT scans prior to BET."*[2]

Early on in clinical use of BET there was concern about possible damage to the carotid in cases of carotid canal dehiscence (CCD), implying the need for pre-op imaging to identify this condition and then exclude those patients. Injury to a dehiscent carotid artery in conjunction with BET has never been reported in the literature[25].

Carotid canal dehiscence (CCD) is rare: one study[2] found 18 cases in 284 patients. CCD is not a suitable predictor of the ability to insert the balloon catheter: the same study reported 3 patients (4 ears) where BET could not be performed, 2 of which had unremarkable CT scans. CCD is also not a suitable predictor of intra- or postoperative complications: the same study reported minor complications in 3 patients, none of whom had CCD.

CCD is not considered a reason not to perform BET: according to one consensus[14], if preoperative temporal bone CT scan shows CCD at the bony ET, then this should simply prompt the surgeon to choose a device with a depth marker that demarcates insertion into the cartilaginous ET only.

One consensus expert panel[14] could not agree on whether CT imaging was necessary.

The literature still recommends imaging under the following circumstances

- from inexperienced surgeons[2]
- patients with failed previous BET attempts[2]
- patients with lesions in the epipharynx, in the context of impaired middle ear ventilation in the absence of hypertrophic adenoid tissue[2]
- suspicion of an acute or previous disease of the temporal bone[15]

Conclusion

Obstructive Eustachian tube dysfunction (OETD) is an often chronic functional disorder in which the regulation of middle ear pressure and clearance of middle ear secretions is restricted. The consequences of this disorder include the development of chronic otitis media, which can lead to destruction of the middle ear structures and thus to hearing loss. Therefore, OETD is a relevant pathology, frequently seen by the ENT practitioner. The prevalent interventional-causal treatment, Balloon Eustachian Tuboplasty, was introduced to clinical practice already in 2009. Although it is not yet the standard treatment of ETD, the current body of knowledge of this surgical, minimally invasive procedure proves it as a safe and effective intervention. This knowledge enables clinicians to make confident decisions regarding patient selection, and manage expectations regarding expected outcomes.

Outlook

Future clinical research needs to unify the way outcomes are measured and reported, and maybe introduce or optimize means for objective characterization of the obstructive Eustachian tube disfunction that can be broadly accepted in many clinical settings.

Future clinical experience will likely also influence early pediatric use of the procedure, and broadening the use in an office setting, mainly driven by patient benefits and health economics considerations.

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