Balloon Eustachian Tube Dilation in Children

A summary of published clinical research

Dr. Jennifer Knuth, Dr. Kathrin Warnking, Clinical Affairs SPIGGLE & THEIS Medizintechnik GmbH

Objectives

This white paper is intended to help the ENT practitioner or pediatrician decide whether to recommend Balloon Eustachian tube dilation for a pediatric patient suffering from Eustachian tube dysfunction and manage 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.

This paper is not intended as a general overview of Eustachian tube dysfunction and treatment options in adults (on that topic, see our previous white paper[2]).

Of course, this paper also cannot replace a comprehensive textbook on the management of otitis media with effusion in children.

This paper does not replace the official product documentation for the TubaVent® product family.

Figure 1:
Eustachian Tube

The Eustachian Tube

> *"Knowledge of the structure and function of the Eustachian tube system is necessary to understand the pathogenesis of otitis media, which will result in rational management decisions"*[3]

Anatomy

The Eustachian tube (ET) connects the middle ear space to the nasopharyngeal space. 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 the middle ear and ambient air when necessary,
b. to drain secretions from the middle ear,
c. and to protect the middle ear from sounds, pathogens and nasopharyngeal secretions.[4]

Eustachian Tube Dysfunction

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 in children are the focus of this white paper. OETD may range from *baro-challenge-induced* temporary blockage to persistent complete blockage.

Pediatric Anatomy

> *"Even in apparently otologically normal children, Eustachian tube function is not as good as in adults, which could explain the higher incidence of middle ear disease in children"*[1]

Some anatomical differences between children and adults are relevant for ET-related pathologies.

The **ET is shorter** in young children than in older children or adults.[1,5] This may adversely affect the protective function

of the ET; free flow of nasopharyngeal secretions can result in reflux otitis media.[1]

The **cartilaginous ET is shorter** in young children. One imaging study on 193 neck CT scans reports an average cartilaginous ET length of 20 mm (range 13-26 mm) for children <2 years old, vs. 24 mm (range 18-30 mm) in the age group 2-5 years, and 25 mm (range 21-32 mm) in the age group 6-10 years.[6]

Another imaging study on 78 neck CT scans has similar results: an average cartilaginous ET length of 20 mm (range 19-21 mm) in <4-year-olds vs. 25 mm (range 24-25 mm) in 5 to 7-year-olds, and 28 mm (range 27-29 mm) in 8 to 18-year-olds and 28 mm (range 27-28 mm) in >18-year-olds.[5]

Yet another study of 150 Eustachian tubes (75 children) aged 5.6 months to 16.8 years also reported an increase in the length of the cartilaginous ET with age, with a length below 20 mm seen only in children younger than two years.[7]

The **ET is more horizontal** in young children (angle in relation to the horizontal plane 10° vs. 45° in adults),[3,5] which may decrease the ability of the tensor veli palatini muscle to open the ET, and it may affect the ability to drain fluid from the middle ear space.[3]

The **ET is narrower** in children; the area of the lumen increases almost fivefold from the newborn to age 20 years,[3] increasing the likelihood of obstruction in young children.

The fat tissue located in the inferolateral portion of the Eustachian tube, termed **Ostmann's fat pad**, is relatively wider in children than in adults, i.e., has relatively greater mass,[3] which could contribute to a less effective opening of the lumen of the tube[3] when the tensor veli palatini muscle contracts.[8]

The **ET is floppier** in children, and tubal cartilage increases in mass from birth to puberty.[3]

In addition, infants are frequently in a **supine position**, which enhances the flow of liquid into the middle ear, putting them at particular risk for reflux otitis media.[1]

Causes of ETD

As explained above, the anatomical differences in children make it more likely that the attached muscles cannot open the ET effectively. In addition, ETD in children can result from adenoid hypertrophy with associated mucosal swelling and pathological nasopharyngeal secretions leading to middle ear effusion or infection.[7]

There is also evidence that children exposed to high concentrations of tobacco smoke may have a higher prevalence of ETD.[9]

Effects of OETD When Not Treated

> *"The Eustachian tube in the child [...] hinders the ventilation of the middle ear contributing to the high incidence and prevalence of OME in the early years"*[10]

OETD causes significant discomfort and suffering in affected patients and can trigger additional pathologies.

The inability to equalize pressure between the middle ear and ambient air may result in **rupture of the tympanic membrane** (TM) under baro-challenge or a retraction pocket of the TM.[11]

The lack of ventilation of the middle ear space may contribute to otitis media with effusion (OME)[12,13] (see chapter on OME below for more details).

ETD is one of the main underlying causes of **chronic otitis media** (COM) development.[14]

OME or COM can lead to **hearing loss**[13] (see section on hearing health below for more details) and even **cholesteatoma**.[11,13,15]

Prevalence of OETD

OETD is most commonly seen in children. It is currently assumed that at least 80% of all preschool children are affected at least temporarily by this condition.[8]

Otitis Media with Effusion (OME)

> *"Acute otitis media and otitis media with effusion are the most common diseases that result in visits to the primary care physician by young children"*[16]

Otitis media with effusion (OME) is defined as "the presence of fluid in the middle ear without signs or symptoms of acute ear infection."[17] It is also referred to as serous, secretory, or nonsuppurative otitis media,[17] or serous tympanum.

Etiology

Risk factors for OME include cleft palate,[18,19] craniofacial abnormalities,[16] trisomy 21,[19] asthma,[19] and genetic predisposition.[16,20]

OME may occur during an upper respiratory infection, spontaneously because of poor Eustachian tube function, or as an inflammatory response following acute otitis media.[17]

Because of the anatomical differences in children (see section on pediatric anatomy above), the ET may not be fully effective in draining secretions from the middle ear and protecting the middle ear from nasopharyngeal secretions.[4]

46% of OME cases in the general population are caused by Eustachian tube dysfunction.[12]

Prevalence

Many affected children have repeated OME episodes, and 10% of episodes last ≥1 year.[22]

In the first year of life, >50% of children will experience OME, increasing to >60% by age two.[17] About 90% of children have OME before school age,[22] and they develop, on average, four episodes of OME every year.[17]

The recurrence rate is high: in a review of >50,000 pediatric records of paracentesis procedures,[23] 19.6% of children were found to have the procedure done twice, and 10% were found to have the procedure done three or more times.

Health Economic Impact

About 2.2 million diagnosed episodes of OME occur annually in the United States at the cost of $4.0 billion. The indirect costs are likely much higher since OME is largely asymptomatic, and many episodes go undetected, including those in children with hearing difficulties or school performance issues.[17]

Effects on Hearing Health

"OME [...] may be associated with hearing loss, balance [...] problems, poor school performance [and] behavioral problems"[17]

Persistent middle ear fluid results in decreased mobility of the tympanic membrane[17] and therefore causes conductive hearing loss. The international consensus reports that about 50% of OME patients have a hearing loss of 20 dB, 20% have a hearing loss greater than 35 dB, and 5-10% have a hearing loss of up to 50 dB.[10]

OME will occur most often between the ages of 6 months and 4 years[17] – i.e., during a period in a child's life that is highly relevant for speech and language development.

A child with persistent OME, especially bilateral OME, may be at increased risk for speech, language, or learning problems. As stated in the OME clinical practice guideline,[17] *"at least 25% of OME episodes persist for >3 months and may be associated with hearing loss, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, recurrent AOM, or reduced QoL."*

In general, hearing health is important for speech and language development. Hearing loss <30 dB HL is *"most closely related to speech perception in noise, and to cognitive abilities underpinning language and reading."*[24] Professional societies recommend early treatments of hearing loss, e.g., treatment of sensorineural hearing loss with hearing aids and cochlear implants.[25,26]

Treatment of OME

"The need for surgery in children with recurrent AOM or chronic OME should be balanced against the likelihood of timely spontaneous resolution and the potential risk of learning, language, or other adverse sequelae from persistent middle ear effusion"[27]

Current guidelines for managing chronic OME recommend ventilation tubes (VT) and, if the child is ≥4 years old, adenoidectomy.[10,17] These methods aim to improve aeration of the middle ear until the child reaches an age where the ET functions optimally.

Non-Surgical Treatment

"Use of topical intranasal corticosteroids is very unlikely to be a clinically effective treatment for OME"[28]

Non-surgical treatments do not effectively address the underlying problem of an age-dependent dysfunctional Eustachian tube.[10,21]

The international consensus statement on OME management strongly recommends *"against treating OME with steroids (oral or intranasal), antibiotics, decongestants, or antihistamines, all of which have not convincingly demonstrated effect on OME resolution, but have side effects and may be costly."*[10]

Tympanic Paracentesis and Ventilation Tubes

Prevalent treatment[10,21,29] for acute otitis media and OME in children, often caused by ETD, is a surgical incision of the tympanic membrane[14] to equalize pressure and allow fluid to drain from the middle ear cavity into the external ear canal. This is variously referred to as tympanic paracentesis, tympanotomy, or myringotomy. We will use the term *paracentesis* throughout this paper.

The effect of this intervention is typically prolonged by inserting a tube into the incision, variously referred to as a tympanotomy tube, ventilation tube (VT), pressure equalization tube (PET), or grommet. We will use the term VT throughout

this paper.

5% of all children in central Europe have received paracentesis and VTs at least once.[15] Insertion of VTs is the most common ambulatory surgery performed on children in the United States.[29]

Draining the middle ear does not treat the underlying pathology,[30] and the effect diminishes after the tube is dropped or extruded.[31,32] VTs typically remain functional for 6 to 24 months.[16] 20% of children that receive VTs bilaterally will subsequently have a second set of tubes placed.[16]

Success rate: Placement of a VT does not always work as desired. Undesired events include obstruction of the VT lumen (7%), premature extrusion of the VT (4%), and tube displacement into the middle ear (0.5%), according to the US clinical practice guideline.[17]

Outcomes: A review of 147 studies concludes that VTs improve hearing at 1 to 3 months compared with watchful waiting, with no evidence of benefit by 12 to 24 months.[33]

Complications: In addition to the risks associated with general anesthesia, there is the risk of complications including infection,[34] tympanosclerosis,[30] possibly associated with persistent conductive hearing impairment, recurrent and chronic otorrhea,[34] and permanent perforations of the tympanic membrane.[15,17,30,34,35] One study including 429 children reports that *"in otherwise healthy children who have persistent middle ear effusion during their first 3 years of life, ready resort to [paracentesis and VT placement] results in far more TM abnormalities at age 5 than does selective management in which most children do not receive the procedure."*[36]

Adenoidectomy

Several studies in children have confirmed the existence of an association between OME and adenoid hypertrophy.[23] Adenoid hypertrophy creates an obstruction of the ET orifice at the torus tubarius level.[37]

Repeated infections of the adenoids could cause inflammation of the ET, resulting in functional impairment.[21,37,38] One study reports a high incidence of ETD in pediatric patients with adenoid hypertrophy with a choanal obstruction ratio >75%.[37] They found that adenoidectomy was also effective in improving ETD (increasing ETS-7 score from 6.62 preop to 9.60 at six months post-surgery).

Outcomes: Adjuvant adenoidectomy, in addition to VT insertion, can increase the efficacy of OME surgery;[10] clinicians recommend adenoidectomy in children four years or older or children with a distinct indication (e.g., nasal obstruction, chronic adenoiditis).[17] The probability of having a second tympanostomy procedure is reduced if adenoidectomy was performed at the first tympanostomy procedure.[16]

Complications: In addition to the risks associated with general anesthesia, specific complications can occur. A study reviewing records of >50,000 children found the most common complication for adenoidectomy combined with VT insertion to be hemorrhage in 31 of 7,507 cases.[23] The same study found no recorded cases of hemorrhage associated with VT insertion alone (>36,000 cases).

Balloon Eustachian Tube Dilation

Transnasal balloon dilation of the cartilaginous part of the ET, called "Balloon Eustachian Tuboplasty (BET),"[39] or "endonasal dilatation of the Eustachian tube (EET),"[40] or "balloon dilation of the eustachian tube (BDET),"[41] is being used to treat OETD.

It was first introduced in 2009 simultaneously in Finland[42] and Germany[43] in adult patients.

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 minutes.

One manufacturer reports that their device has been used (mostly in adults) more than 100,000 times since its introduction in 2010.[44]

Pediatric Use of BET

BET was first used to treat pediatric patients in 2013.[45] From a regulatory perspective, pediatric use of BET is at the treating clinician's discretion in Europe. The US Food and Drug Administration has approved two BET devices for adults only (18 years and older). A recent publication by US authors concluded *"it should be safe to use adult FDA-approved devices in children with mature ET. Therefore, children 7 years of age and above could be potential candidates to safely undergo BET with dilation of the cartilaginous ET."*[14]

When the BET procedure is performed in children, it is often combined with VT placement.[15]

Minimum Age for BET

When considering BET for young children, two questions have to be addressed:

1. How does the risk of complications from general anesthesia compare to the expected benefit of the procedure?
2. Is the cartilaginous part of the ET long enough to insert the balloon catheter without the risk of moving into the bony part of the ET? (See section on pediatric anatomy above for more details.)

Sequence of Treatments for OME

1. Clinicians should first identify and treat potential causes of ETD like adenoids,[4,15] nasal polyposis,[4] allergic rhinitis,[4,30] rhinosinusitis,[4,30] or laryngopharyngeal reflux,[4,30] if applicable.
2. The recommended first action in asymptomatic OME, i.e., without hearing loss, is "watchful waiting": wait up to three months for spontaneous resolution of the condition.[17] The clinical practice guideline explains that *"about 75% of children with OME resolve by 3 months when it follows an episode of AOM. If the OME is spontaneous and the date of onset is unknown, the 3-month resolution rate is lower, at 56%. When the date of onset is known, however, this rate increases to 90%."*[17] The delayed insertion of VTs in children ≤3 years did not have a significant effect on developmental outcomes in those children tested at 9-11 years of age, in a study observing 391 children randomly assigned to prompt or delayed (up to 9 months) treatment.[32]
3. If the fluid persists for 3 months or more, or if there is hearing impairment,[10] or with recurring AOM,[10] the next step is commonly **tympanic paracentesis** and VT placement,[10,17] often combined with adenoidectomy if the child is ≥4 years of age.[10,17]
4. **Balloon dilation** has been typically reserved for persistent cases and as a secondary intervention[14,46] given that the majority of OME resolve spontaneously or with conventional treatment as described above.[47] It is considered a *"safe and effective alternative treatment option, when conventional therapy of chronic ETD does not succeed in children."*[47]

There is a tradeoff to be made here: perform the more common procedure of tympanic paracentesis and VT placement multiple times, exposing the child to prolonged hearing loss with possibly irreversible impact on speech and language development, or proceed to BET sooner, which can affect a significantly larger reduction of hearing impairment long-term.[31]

One study even recommends BET as the first-line treatment for OME.[48]

Clinical Guidance Statements

Panels of clinical experts have issued recommendations for the diagnosis and treatment of OETD in adults and outcome assessment in multiple countries: the USA,[30,35] Spain,[49] and Finland.[4]

For pediatric cases, there are three clinical references for the management of OME: 1. a clinical guideline developed by the American Academy of Otolaryngology—Head and Neck Surgery Foundation, the American Academy of Pediatrics, and the American Academy of Family Physicians,[17] 2. an international consensus statement,[10] and 3. a German clinical practice guideline,[21] which mentions BET.

Outcomes with BET

> *"Significant treatment effects could be observed by microscopic otoscopy, in hearing threshold assessment and tympanometry"*[15]

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. Outcomes measurements in children are mostly based on tympanometry or audiometry (airbone gap (ABG)). Additional measures commonly used in adults, such as questionnaires, are difficult to administer, especially with younger children, and have not been reported in studies.

Clinical Symptoms

> *Compared with simple [VT insertion], application of BET can effectively extend the improvement period and increase the cured rate, especially after the ventilation tube is removed.*[31]

76% of patients were **completely cured** after 18 months, in the group treated with BET with paracentesis and VTs, compared to **61%** of patients treated only with paracentesis and VT placement in a retrospective case study with 49 children aged 4-14 years.[31] Here, "cured" was defined as the complete disappearance of clinical symptoms, no OME, tympanogram type A, and ABG ≤10 dB.

62% of patients (21/34) with COME with TM retraction and **66%** of patients (21/32) with advanced ear disease (CSOM or cholesteatoma) were converted to a normal middle ear status after BET in a retrospective multicenter case study with 282 ears in 158 children aged 4-12 years.[15]

Pressure Equalization

The ability to successfully perform the Valsalva maneuver increased **from 28% to 60-85%**, preop vs. 6 and 12 months after BET, in a retrospective case study with 52 children

aged 3-15 years.[46]

The ability to equalize middle ear pressure (based on Valsalva or tympanogram) improved **from 8% to 82%**, preop vs. 6-8 weeks after BET, in a retrospective case study with 90 ears in 60 children aged 28 months to 12 years.[8]

The ability to successfully perform the Valsalva maneuver increased **from 12% to 65%** of reports, preop vs. postop after BET (combined with paracentesis and VT placement in about half of the cases) in a retrospective multicenter case study with 282 ears in 158 children aged 4-12 years.[15]

Tympanometry

The percentage of ears with **type A tympanogram** increased from **15%** (20/132) preoperatively to **58%** (76/132) at 6 months after BET in a retrospective case study with 132 ears in 66 children aged 4-14 years.[50]

The percentage of ears with **type A tympanogram** increased from **25%** preoperatively to **58%** after BET (median follow-up period 2.6 months) in a retrospective multicenter case study with 282 ears in 158 children aged 4-12 years.[15]

The percentage of ears with **type A tympanogram** reached **93%** (28/30) in the group with BET as a first-line treatment, versus **66%** (21/32) in the group treated conventionally with paracentesis and VT placement, at 12 months postop, in a retrospective case study on 55 ears in 30 children aged 3-12 years.[48]

Audiometry

In one retrospective case study with 49 patients aged 4-14 years, comparing combined treatment with BET, paracentesis, and VT placement versus paracentesis and VT placement alone, ABG was equally reduced in both groups at 6 months but significantly lower for the BET group at 18 months.[31]

ABG significantly decreased from **17.5 dB** preoperatively to **10.8 dB** at 6 months and **5.7 dB** at 36 months postop in a retrospective case study with 46 ears in 23 patients aged 7-17 years.[47]

ABG decreased from **27.6 dB** preop to **9.6 dB** postop (mean follow-up 14.4 months) with BET as a first-line treatment versus **25.6 dB** preop to **17.6 dB** postop treated conventionally with paracentesis and VT placement, at 12 months postop in a retrospective case study on 55 ears in 30 children aged 3-12 years.[48]

Complications with BET

> *"The procedure was safe with no major adverse events with the most common complication being epistaxis"*[51]

Minor Complications

In the eight original case studies analyzed here[8,14,15,31,40,46–48] comprising 461 children, 17 minor complaints were reported and resolved quickly, most of which were epistaxis[8,14,15] or hematotympanum.[46,48] Two patients reported symptoms of patulous ET that resolved over months.[47]

In many studies, the BET procedure is combined with concomitant surgical procedures such as paracentesis, VT placement, tympanoplasty, or adenoidectomy, so it is sometimes difficult to establish a causal relationship between the BET procedure alone and the minor complication.

Serious Complications

In the eight original case studies analyzed here[8,14,15,31,40,46–48] comprising 461 children, no serious complications or adverse events were reported.

Theoretical Complications

The internal carotid artery can reside within 2 mm to 10 mm of the osseous portion of the ET. Initial adopters of BET were concerned that this would make dilation of the osseous ET potentially hazardous.[14] However, Poe et al. showed no injury to the osseous portion upon dilation of the cartilaginous portion in cadaver models.[52]

BET could theoretically cause carotid artery rupture, which may be more likely if there is carotid canal dehiscence adjacent to the bony Eustachian tube.[7] To the best of our knowledge, no such case has ever been reported in the literature, in children or adults.

Revision Surgeries

In the eight original case studies analyzed here[8,14,15,31,40,46–48] comprising 461 children, a total of 18 repeated BET procedures were reported, without providing details of the success of the second procedure.

Special Risk Groups

When considering BET in children with suspected anatomical variations or evidence for insufficient maturation of the ET, clinicians strongly recommend preintervention tomographic imaging to evaluate the length of the cartilaginous portion of the ET, and the course of the internal carotid artery in relation to the cartilaginous portion of the ET, to

prevent any risk for injury.[15] In a radiological study of 75 scans (150 ears), 8% of carotid canals showed radiologically detectable dehiscence.[7]

Conclusion

OME, often caused by OETD, affects the majority of children before they reach school age. 30% of children experience two or more episodes of OME, with extended periods of impaired hearing.[23] If treatment of the hearing loss caused by OME is ineffective or slow, there is a risk of impeding speech and language development.

In common clinical practice, the first-line treatment of OME is tympanic paracentesis, placement of ventilation tubes, and optionally adenoidectomy, which is effective in many cases, but also comes with the risk of complications, especially if applied multiple times.

BET is mostly used as a second-line treatment in cases where the more common therapies have not been effective. After treatment with BET combined with VT, the complete absence of clinical symptoms is more likely than after VT alone,[31] as is the ability to equalize middle ear pressure, resulting in a normal tympanogram. Reduction of hearing impairment as seen in an air-bone gap is more effective and more prolonged after BET with VT than after VT alone.[1,48,53]

In summary, BET has been shown to be safe and effective in published clinical research, mostly involving children three years and older.[21]

List of Abbreviations

Abbreviation	Explanation
ABG	Air-bone gap
AOM	Acute otitis media
BET	Balloon Eustachian tuboplasty
COM	Chronic otitis media
COME	Chronic otitis media with effusion
CSOM	Chronic suppurative otitis media
CT	Computed tomography
ENT	Ear, nose and throat
ET	Eustachian tube
ETD	Eustachian tube dysfunction
HL	Hearing level
OETD	Obstructive Eustachian tube dysfunction
OME	Otitis media with effusion
PET	Pressure equalization tube
PETD	Patulous Eustachian tube dysfunction
QoL	Quality of life
TM	Tympanic membrane
VT	Ventilation tube

References

1. Bluestone CD, Doyle WJ. Anatomy and physiology of eustachian tube and middle ear related to otitis media. J Allergy Clin Immunol. 1988;81(5 PART 2):997-1003. doi:10.1016/0091-6749(88)90168-6
2. Knuth J, Warnking K. Balloon Eustachian Tube Dilatation as the Standard Causal Intervention for Eustachian Tube Dysfunction ?!; 2022. https://www.spiggle-theis.com/images/Instrumente/BET_WhitePaper.pdf
3. Bluestone CD. Eustachian Tube: Structure, Function, Role in Otitis Media.; 2005.
4. Luukkainen V, Kivekäs I, Silvola J, Jero J, Sinkkonen ST. Balloon eustachian tuboplasty: Systematic review of long-term outcomes and proposed indications. J Int Adv Otol. 2018;14(1):112-126. doi:10.5152/iao.2018.4769
5. Magro I, Pastel D, Hilton J, Miller M, Saunders J, Noonan K. Developmental Anatomy of the Eustachian Tube: Implications for Balloon Dilation. Otolaryngol - Head Neck Surg (United States). 2021;165(6):862-867. doi:10.1177/0194599821994817
6. Yu Y, Geffen B, McCrary H, et al. Measurements of The Pediatric Cartilaginous Eustachian Tube: Implications for Balloon Dilation. Laryngoscope. 2023;133(2):396-402. doi:10.1002/lary.30113
7. Toll EC, Browning M, Shukla R, Rainsbury JW. Cartilaginous Eustachian tube length and carotid canal dehiscence in children: a radiological study. Eur Arch Oto-Rhino-Laryngology. 2018;275(11):2675-2682. doi:10.1007/s00405-018-5128-8
8. Tisch M, Maier H, Sudhoff H. Dilatazione tubarica con balloon: Nostra esperienza nella gestione di 126 bambini. Acta Otorhinolaryngol Ital. 2017;37(6):509-512. doi:10.14639/0392-100X-1690
9. Patel MA, Mener DJ, Garcia-Esquinas E, Navas-Acien A, Agrawal Y, Lin SY. Tobacco smoke exposure and eustachian tube disorders in US children and adolescents. PLoS One. 2016;11(10):1-9. doi:10.1371/journal.pone.0163926
10. Simon F, Haggard M, Rosenfeld RM, et al. International consensus (ICON) on management of otitis media with effusion in children. Eur Ann Otorhinolaryngol Head Neck Dis. 2018;135(1):S33-S39. doi:10.1016/j.anorl.2017.11.009
11. Schröder S, Lehmann M, Korbmacher D, Sauzet O, Sudhoff H, Ebmeyer J. Evaluation of tubomanometry as a routine diagnostic tool for chronic obstructive Eustachian tube dysfunction. Clin Otolaryngol. 2015;40(6):691-697. doi:10.1111/coa.12451

12. Liang M, Xiong H, Cai Y, et al. Effect of the combination of balloon Eustachian tuboplasty and tympanic paracentesis on intractable chronic otitis media with effusion. Am J Otolaryngol - Head Neck Med Surg. 2016;37(5):442-446. doi:10.1016/j.amjoto.2016.03.006

13. Poe DS, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. Laryngoscope. 2018;128(5):1200-1206. doi:10.1002/lary.26827

14. Howard A, Babu S, Haupert M, Thottam PJ. Balloon Eustachian Tuboplasty in Pediatric Patients: Is it Safe? Laryngoscope. 2021;131(7):1657-1662. doi:10.1002/lary.29241

15. Tisch M, Maier S, Preyer S, et al. Balloon Eustachian Tuboplasty (BET) in Children: A Retrospective Multicenter Analysis. Otol Neurotol. 2020;41(7):e921-e933. doi:10.1097/MAO.0000000000002789

16. Boston M, McCook J, Burke B, Derkay C. Incidence of and risk factors for additional tympanostomy tube insertion in children. Arch Otolaryngol - Head Neck Surg. 2003;129(3):293-296. doi:10.1001/archotol.129.3.293

17. Rosenfeld RM, Shin JJ, Schwartz SR, et al. Clinical Practice Guideline: Otitis Media with Effusion (Update). Vol 154.; 2016. doi:10.1177/0194599815623467

18. Flynn T, Möller C, Jönsson R, Lohmander A. The high prevalence of otitis media with effusion in children with cleft lip and palate as compared to children without clefts. Int J Pediatr Otorhinolaryngol. 2009;73(10):1441-1446. doi:10.1016/J.IJPORL.2009.07.015

19. Marchica CL, Pitaro J, Daniel SJ. Recurrent tube insertion for chronic otitis media with effusion in children over 6 years. Int J Pediatr Otorhinolaryngol. 2013;77(2):252-255. doi:10.1016/J.IJPORL.2012.11.010

20. Allen EK, Chen W-M, Weeks DE, et al. A Genome-Wide Association Study of Chronic Otitis Media with Effusion and Recurrent Otitis Media Identifies a Novel Susceptibility Locus on Chromosome 2. J Assoc Res Otolaryngol. 2013;14(6):791-800. doi:10.1007/s10162-013-0411-2

21. Lautermann J, Begall K, Hilger G, et al. S2k Guidance Statement 017-004: Seromukotympanon (in German).; 2018. https://register.awmf.org/de/leitlinien/detail/017-004

22. Tos M. Epidemiology and natural history of secretory otitis. Am J Otol. 1984;5(6):459-462. http://www.ncbi.nlm.nih.gov/pubmed/6542752

23. Kadhim AL, Spilsbury K, Semmens JB, Coates HL, Lannigan FJ. Adenoidectomy for middle ear effusion: A study of 50,000 children over 24 years. Laryngoscope. 2007;117(3):427-433. doi:10.1097/MLG.0b013e31802c938b

24. Moore DR, Zobay O, Ferguson MA. Minimal and Mild Hearing Loss in Children: Association with Auditory Perception, Cognition, and Communication Problems. Ear Hear. 2020;41(4):720-732. doi:10.1097/AUD.0000000000000802

25. American Academy of Audiology. American Academy of Audiology Clinical Practice Guidelines: Pediatric Amplification. Am Acad Audiol. 2013;(June):5-60. http://audiology-web.s3.amazonaws.com/migrated/PediatricAmplificationGuidelines.pdf_539975b3e7e9f1.74471798.pdf

26. Ching TYC, Dillon H, Leigh G, Cupples L. Learning from the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study: summary of 5-year findings and implications. Int J Audiol. 2018;57(sup2):S105-S111. doi:10.1080/14992027.2017.1385865

27. Rosenfeld RM, Kay D. Natural history of untreated otitis media. Laryngoscope. 2003;113(10):1645-1657. doi:10.1097/00005537-200310000-00004

28. Williamson I, Benge S, Barton S, et al. A double-blind randomised placebo-controlled trial of topical intranasal corticosteroids in 4- to 11-year-old children with persistent bilateral otitis media with effusion in primary care. Health Technol Assess (Rockv). 2009;13(37). doi:10.3310/hta13370

29. Rosenfeld RM, Tunkel DE, Schwartz SR, et al. Clinical Practice Guideline: Tympanostomy Tubes in Children (Update). Otolaryngol Neck Surg. 2022;166(S1):S1-S55. doi:10.1177/01945998211065662

30. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical Consensus Statement: Balloon Dilation of the Eustachian Tube. Otolaryngol - Head Neck Surg (United States). 2019;161(1):6-17. doi:10.1177/0194599819848423

31. Chen S, Zhao M, Zheng W, et al. Myringotomy and tube insertion combined with balloon eustachian tuboplasty for the treatment of otitis media with effusion in children. Eur Arch Oto-Rhino-Laryngology. 2020;277(5):1281-1287. doi:10.1007/s00405-020-05828-9

32. Paradise JL, Feldman HM, Campbell TF, et al. Tympanostomy Tubes and Developmental Outcomes at 9 to 11 Years of Age. N Engl J Med. 2007;356(3):248-261. doi:10.1056/nejmoa062980

33. Steele DW, Adam GP, Di M, Halladay CH, Balk EM, Trikalinos TA. Effectiveness of tympanostomy tubes for otitis media: A meta-analysis. Pediatrics. 2017;139(6). doi:10.1542/peds.2017-0125

34. Bowles PF, Agrawal S, Salam MA. Balloon tuboplasty in patients with Eustachian tube dysfunction: a prospective study in 39 patients (55 ears). Clin Otolaryngol. 2017;42(5):1057-1060. doi:10.1111/coa.12812

35. Schilder AGM, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: Consensus statement on definition, types, clinical presentation and diagnosis. Clin Otolaryngol. 2015;40(5):407-411. doi:10.1111/coa.12475

36. Johnston LC, Feldman HM, Paradise JL, et al. Tympanic Membrane Abnormalities and Hearing Levels at the Ages of 5 and 6 Years in Relation to Persistent Otitis Media and Tympanostomy Tube Insertion in the First 3 Years of Life: A Prospective Study Incorporating a Randomized Clinical Trial. Pediatrics. 2004;114(1):e58-e67. doi:10.1542/peds.114.1.e58

37. Manno A, Iannella G, Savastano V, et al. Eustachian Tube Dysfunction in Children With Adenoid Hypertrophy: The Role of Adenoidectomy for Improving Ear Ventilation. Ear, Nose Throat J. Published online 2021. doi:10.1177/0145561321989455

38. Tisch M, Ahmad Z, Krüger K, et al. S2k Guidance Statement 017-021: Adenoid Growths (in German).; 2022. doi:10.1016/b978-3-437-24661-6.00039-8

39. Oehlandt H, Laakso J, Lindfors O, Toivonen J, Poe D, Sinkkonen ST. Efficacy of Balloon Tuboplasty for Baro-Challenge-Induced Eustachian Tube Dysfunction : A Systematic Review and a Retrospective Cohort Study of 39 Patients. Otol Neurotol. 2022;43(1):611–618. doi:10.1097/MAO.0000000000003558

40. Jenckel F, Kappo N, Gliese A, et al. Endonasal dilatation of the Eustachian tube (EET) in children: feasibility and the role of tubomanometry (Estève) in outcomes measurement. Eur Arch Oto-Rhino-Laryngology. 2014;272(12):3677-3683. doi:10.1007/s00405-014-3443-2

41. Anand V, Poe D, Dean M, et al. Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group. Otolaryngol - Head Neck Surg (United States). 2019;160(4):687-694. doi:10.1177/0194599818821938

42. Poe DS, Silvola J, Pyykkö I. Balloon dilation of the cartilaginous eustachian tube. Otolaryngol - Head Neck Surg. 2011;144(4):563-569. doi:10.1177/0194599811399866

43. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation Eustachian Tuboplasty: A clinical study. Laryngoscope. 2010;120(7):1411-1416. doi:10.1002/lary.20950

44. Spiggle & Theis. TubaVent ® Family Causal Therapy for Tube Dysfunction.; 2021.

45. Tisch M, Maier S, Hecht P, Maier H. Beidseitige Tubendilatation beim Kleinkind. HNO. 2013;61:492-493.

46. Leichtle A, Hollfelder D, Wollenberg B, Bruchhage KL. Balloon Eustachian Tuboplasty in children. Eur Arch Oto-Rhino-Laryngology. 2017;274(6):2411-2419. doi:10.1007/s00405-017-4517-8

47. Toivonen J, Kawai K, Gurberg J, Poe D. Balloon Dilation for Obstructive Eustachian Tube Dysfunction in Children. Otol Neurotol. 2021;42(4):566-572. doi:10.1097/MAO.0000000000003009

48. Demir B, Batman C. Efficacy of balloon Eustachian tuboplasty as a first line treatment for otitis media with effusion in children. J Laryngol Otol. 2020;134(11):1018-1021. doi:10.1017/S0022215120002340

49. Plaza G, Navarro JJ, Alfaro J, Sandoval M, Marco J. Consensus on Treatment of Obstructive Eustachian Tube Dysfunction With Balloon Eustachian Tuboplasty. Acta Otorrinolaringol Esp (English Ed. 2020;71(3):181-189. doi:10.1016/j.otoeng.2019.01.005

50. Maier S, Tisch M, Maier H. Einsatz der Ballondilatation der Eustachischen Röhre bei chronisch obstruktiven Tubenventilationsstörungen im Kindesalter. HNO. 2015;63(10):686-697. doi:10.1007/s00106-015-0050-5

51. Aboueisha MA, Attia AS, McCoul ED, Carter J. Efficacy and safety of balloon dilation of eustachian tube in children: Systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. 2022;154(January):111048. doi:10.1016/j.ijporl.2022.111048

52. Poe DS, Hanna BMN. Balloon dilation of the cartilaginous portion of the eustachian tube: initial safety and feasibility analysis in a cadaver model. Am J Otolaryngol. 2011;32(2):115-123. doi:10.1016/j.amjoto.2009.11.008

53. Toivonen J, Dean M, Kawai K, Poe D. Comparison of outcomes for balloon dilation of the Eustachian tube under local vs general anesthesia. Laryngoscope Investig Otolaryngol. 2022;(April):1-9. doi:10.1002/lio2.842