Eustachian tube dilation as a first line tool in the treatment of chronic otitis media in children.

A clinically controlled, randomized, patient blinded, prospective trial.

Eustachian Tube Dilation overview

Eustachian tube dysfunction has a prevalence of 5%[1] in the world adult population. However, if baro-challenged patients are included, the number rises to 14% of the population[2], but can be as high as 25% in children[3].

The procedure of balloon dilating the Eustachian tube, was first described in 2010 by Ökermann and Sudhoff[4,5], followed by a study group at Harvard, led by Prof. Dennis Poe in 2011[6,7]. The procedure was first customized from the well-established Sinus balloon procedure but using a balloon and technique from the cardiovascular scene. Spiggle & Theis provided the first balloon catheter specifically for Eustachian Tube dilation in 2010 in Germany and the procedure swiftly showed promise which was supported from key opinion leaders such as German prof. Holger Sudhoff and Matthias Tisch. The procedure has since then gained significant popularity among doctors and patients around the world by and has gained scientific validation with level 1B evidence in 2018 and 2019[8,9,10]. More than 400.000 procedures have been conducted since 2010, with no severe adverse events. The concern was a carotic dehiscence, which was dismissed in 2013 by Tisch, in a study of 2000 bony carotic canals[11]. Another concern was the occurrence of a patulous eustachian tube following a balloon dilation. Most recent studies, using a 5mm balloon has up to 7%[12] but in the 5000-patient strong material from Holger Sudhoff since 2010, less than 1% presented with a patulous tube following dilation using a smaller balloon size of 3mm diameter.

First clinical, randomized, controlled study was published in 2018 by D. Poe proving the procedure effective in the treatment of Chronic Otitis Media with Effusion (COME)[8]. In fact, the study was cut short due to the overwhelming evidence of the positive effect of the procedure during the study period. The study has since been followed up by another study as well as long term studies[9,10].

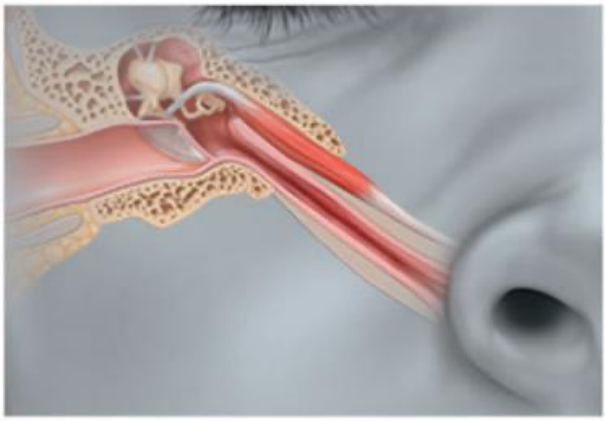
For children, there are yet to be conducted randomized studies. However, multiple retrospective studies have been published suggesting a positive effect on COME in children. The preceding country is Germany, where the clinic in Bundeswehr Hospital Ulm, led by prof. Tisch was the first to describe the procedure and outcomes in children[13,14,15] and the clinic has since performed thousands of procedures on children older than 2 years.

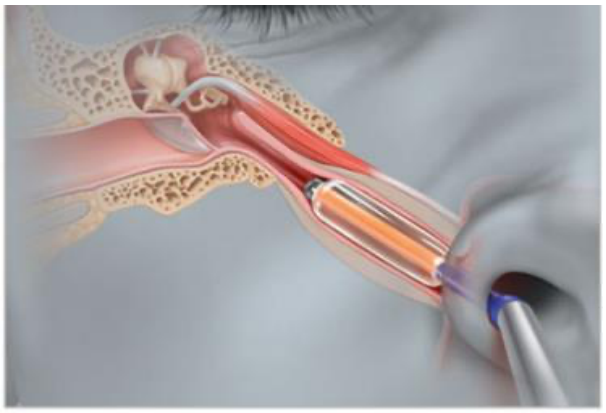
It is currently not recommended to perform dilation in children younger than 2 years due to the anatomy and available balloon size.

The procedure in short

1. An endoscope is inserted into nostril for visual guidance.
2. A steel guiding tube is inserted approximately 100 mm into same nostril and placed at Eustachian Tube opening.
3. A balloon is advanced out of the guiding tube and into the eustachian tube.

4. The balloon is inflated inside the Eustachian Tube for 2 min. at 10 bar creating a lasting dilation effect of the Eustachian Tube.
5. The balloon is deflated and retracted.





Background COME in children[16] – short

The cumulative incidence of otitis media (OM, COME) in Denmark for children younger than 7 years is 61%, making the disease one of the most common occurring among children in Denmark. Denmark also has one of the highest prevalence's of ventilation tube treatment, which is as high as 26% of COME patients, meaning that almost 16% (some materials up to 25%) of all children in Denmark under the age of 7 are treated with ventilation tubes at least once. Moreover, up to 50% of children treated with ventilation tubes fail to recover from COME and are treated with a second ventilation tube within the first 2 years of treatment.

Eustachian tube dilation is currently not included in any part of the treatment of COME in Denmark. Standard otomicroscopy, tympanogram and otoacoustic emissions are performed routinely along with standard audiometry for children older than 6 years.

A mandatory 3-months observation time comprising 2 times measurements of Tympanogram type B or C2 and Oto Acoustic Emissions (OAE) with REFER (as well as standard ENT examination) is included before ventilation tubes are indicated.

Purpose

To evaluate the effectiveness of eustachian tube dilation in children older than 2 years of age in the treatment of Chronic Otitis Media with Effusion (COME).

Hypothesis

Children treated with both VT and ETD will be less likely to fail treatment at follow-up 1 year post op.

Treatment success: Type A or C1 tympanogram or AOE pass.

Treatment failure: Type B or C2 tympanogram or AOE refer.

Study setup

Clinical, prospective, and randomized intervention study, comparing classic ventilation tube treatment with ventilation tube treatment AND eustachian tube dilation. Patient own control, only one ear receives randomized treatment.

1 year follow up for first part of study.

2 year follow up for second part of study (potential).

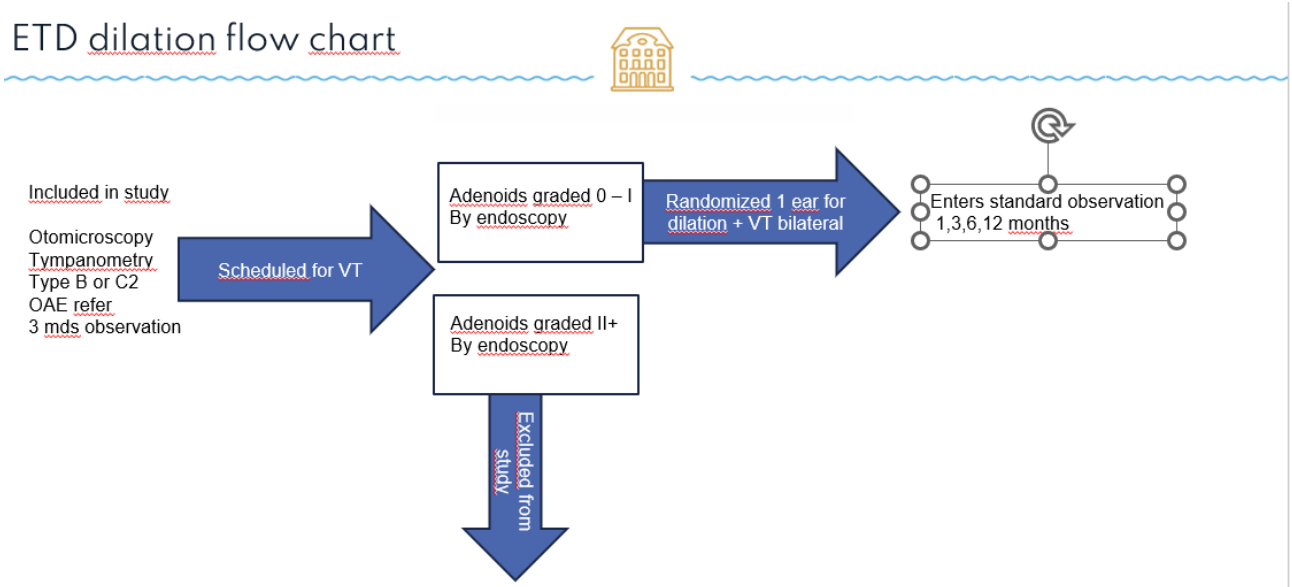
No additional surgery to be performed during first part of study period. If VT are extruded, no additional tubes are inserted.

Power calculations – how many do we need to treat?

It's difficult to obtain knowledge about the efficacy of ETD in the treatment of COME in children with VT tubes. A single study found the effect to be 30-60% with many variables. In adults, the efficacy is typically reported 60-80% comparing tympanometry B to A.

A conservative efficacy of 40% in children, with an overall 50% treatment efficacy off ventilation tubes, means we need 100 children in total and 50 balloons for the ear randomized to ETD to obtain a P value < 0.05.

Flow chart



Inclusion criteria

1. Children 2-17 years old
2. Eligible for ventilation tubes, using standard DK criteria.
3. Bilateral disease
4. Adenoids Grade 0 (none) or Grade I – Fossa Rosenmüller is free.

Exclusion criteria

1. Adenoids Grade II or higher – Fossa Rosenmüller is not free.

2. Cleft palate/lip.
3. Unable complete observation period.

Randomization

Patients are randomized to one ear – left or right. Simple coin flip is utilized on OP day. Coinflip is done by physician (sponsor). Parents and patients are blinded. Serial numbers are utilized and noted in patient journal. Randomization key is held secure by sponsor.

Standard operating procedure – Eustachian tube dilation

Patients are anesthetized for VT by standard means of inhalation. Following endoscopy of the nasal cavity and rhinopharynx by a standard 2.7mm digital fiberoptic or 2.7mm digital rigid optic, the patient is graded Adenoids 0 – IV, using the Cassano scale. Tetracainphenylephrine 2% soaked pledgets are used as decongestant. If patient is included in study, randomization occurs and the patient receives Donaldson silicone ventilation tubes bilaterally. Immediately after, a TubaVent (Spiggle & Theis, Germany) standard balloon 3x20mm is inserted into the Eustachian Tube, using the Combined Insertion Set, childrens edition, under visual guidance by the endoscope and subsequently pressurized to 10 bar for 2 min. The balloon is depressurized and retracted under visual guidance. Procedure ends.

Patients are observed by standard means after VT surgery, and discharged from the clinic after checkup by physician. Cilodex, Komb. 4 drops x 2 daily in each ear is prescribed for 7 days.

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