



SUBURBAN
Ear, Nose & Throat
Associates, Ltd.

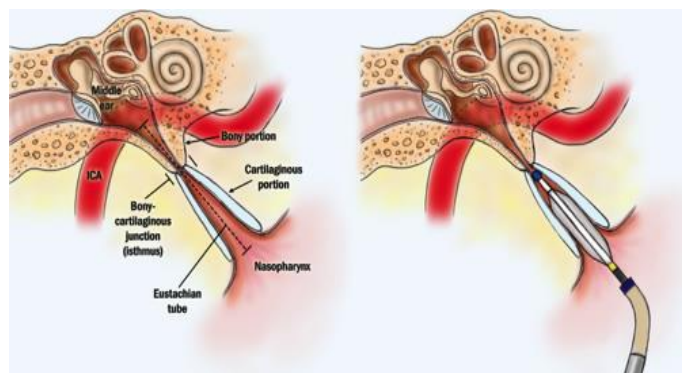
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- Adults and Children
- Head and Neck Surgery
- Facial Cosmetic and Reconstructive Surgery

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EUSTACHIAN TUBE BALLOON DILATION Patient Information and Informed Surgical Consent

The eustachian tube (ET) connects the middle to the back of the nose and throat, in the nasopharynx. About 1/3 of its length is bony (this portion enters into the middle ear), and about 2/3 cartilaginous (this portion enters back of the nose and throat). The cartilaginous portion periodically opens and closes to allow air to flow into the middle ear from the nasopharynx or vice-versa, air flows from the middle ear back into the nasopharynx to equilibrate the pressure



ear
the

between the middle ear and the outside environment. Eustachian tube dysfunction (ETD) causes many types of ear problems including frequent infections in the middle ear (otitis media), persistent fluid in the middle ear (otitis media with effusion), negative pressure or a relative vacuum in the middle ear that can pull the eardrum (tympanic membrane) inwards and can often weaken or thin the eardrum (atelectasis) and others. Eardrum skin may become trapped into a retracted pocket and develop into an expanding skin cyst in the middle ear and beyond (cholesteatoma). ETD that doesn't respond to medical management is currently treated by placement of a ventilating tube through the eardrum. Ventilation tubes allow air pressure to passively equalize between the middle ear space and the outside environment to try to limit further middle ear problems. Ventilation tubes are usually effective if/when they remain open, but most tubes will eventually fall out of the eardrum or become clogged. Ventilation tubes may need to be replaced multiple times over one's lifetime. Potential complications of ventilation tubes include further weakening of the eardrum and persistent hole in the eardrum which may need additional surgery to close. Ventilation tubes however do not address the root of the problem, the ETD.

Balloon dilation of the ET attempts to restore normal function of the ET, with the goal of no longer needing ventilation tubes. The procedure is FDA approved for use in adults 18 years of age and older. It is typically performed under general anesthesia, and is often performed in conjunction with other procedures. It has been determined that the cause of ETD is in the cartilaginous portion of the ET. This is the site of dilation with the instrument. The procedure is performed by visualizing the opening of the ET using endoscopes (surgical telescopes) and then the balloon dilation catheter under endoscopic visualization is inserted into the ET opening and the balloon is dilated for 2 minutes. The balloon is then deflated and removed. If needed the procedure is then performed on the other ET.

Outcomes: ET dilation in the properly selected patient is an effective option in management of ETD, but does not work for everyone. Medical management alone only helps about 8% of patients with chronic ETD after a year, whereas ET balloon dilation helps about 50% of patients, with results that so far are sustained for at least a year, more than 4 times the chance of improvement as compared to medical management.

Instructions: It is very important that you do not try to pop your ears for 1 week following the ET balloon dilation. Discomfort is typically minimal after the procedure, so if you experience excessive pain please contact

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us. A small amount of nose or throat bleeding, along with a sore throat might be expected for a few days. Excessive bleeding is not typical and we should be notified.

Risks: As with any surgical procedure risks exist.

- Scarring and further obstruction of the ET. This is rare, and if was to occur would likely need continued ventilation tube placement.
- Overcorrection of the ETD. This could lead to a chronically open ET (patulous ET) which could cause a troublesome sound in the ear with breathing and possibly and echoing of one's voice.
- Failure to achieve the objectives of the surgery, with the need for possible revision surgery.
- Injury to the carotid artery. This is exceedingly rare, but would be a very serious and potentially fatal complication.

Alternatives: Eustachian tube balloon dilation is an elective procedure. Your alternative is not to have the procedure performed. You can continue medical management and/or ventilation tubes for your ETD. You can also opt for no intervention.

At Suburban ear, Nose and Throat Associates Ltd., we go to great lengths to try to help you understand your plan of care. If at any time you have questions or concerns please call us at (847) 259-2530.

I have been given an opportunity to ask questions about my condition, alternative forms of therapy, risks of non-treatment, the procedure and risks and hazards involved. I have sufficient information to give this informed consent. I understand every effort will be made to provide a positive outcome, but there are no guarantees.

Patient PRINTED Name: _____

Patient SIGNATURE: _____

Date: _____ Time: _____

Witness: _____ Date: _____