Eustachian Tube Dilation via a Transtympanic Approach in 6 Cadaver Heads: A Feasibility Study

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Abstract
The goal of this study was to evaluate the feasibility of endoscopic transtympanic balloon dilation of the cartilaginous eustachian tube. To accomplish this, transtympanic balloon dilation of the cartilaginous eustachian tube was performed on 11 eustachian tubes (6 cadaver heads). The balloon catheter was introduced and passed through the protympanic orifice of the eustachian tube transtympanically under endoscopic view and cannulated without incident in all cadavers. Computed tomography was then performed postprocedure to evaluate for inadvertent dilation of the bony eustachian tube, adverse placement of the balloon, or any bony fractures. The balloon was seen to be successfully inflated in the cartilaginous portion without damage to surrounding structures in all cases. This demonstrates that under endoscopic guidance, the protympanic orifice of the eustachian tube can be feasibly cannulated and reliably traversed, allowing for targeted dilation of the cartilaginous eustachian tube from a transtympanic approach.

Keywords
eustachian tube, auditory tube, dilation, dilatation, balloon, transtympanic, otologic endoscopy

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Dilatory dysfunction of the eustachian tube continues to affect approximately 0.9% of the adult population.1 Traditionally, surgical therapy for refractory dilatory dysfunction has been limited to treatment of the associated conditions; however, there has been recent growing interest in surgical management of eustachian tube pathology directly.

Kepchar et al performed transtympanic eustachian tube dilation in 6 cadavers and reported serious safety concerns, fracturing the bone around the internal carotid canal in 3 cases. Their study utilized a rigid catheter system and microscopic technique.2 The purpose of our work was to determine whether an endoscopic transtympanic approach with a flexible balloon catheter may feasibly allow access to the cartilaginous eustachian tube from within the middle ear.

Materials and Methods
Approval was obtained from the Boston Children’s Hospital institutional review board, and 6 fresh-frozen whole cadaver heads were purchased from Innoved Institute LLC (Rosemont, Illinois).

An endoscope (45 degrees, 3-mm outer diameter; Karl Storz, Corp, Tuttingen, Germany) was passed transtympanically through an anterior myringotomy where the semilunar canal was identified and followed to the bony eustachian tube orifice (Figure 1). A 1.3- × 24-mm flexible balloon catheter (Prototype Model; Acclarant, Palo Alto, California) was passed 40 mm through the bony eustachian tube orifice under endoscopic view. The balloon catheter was then inflated to 2 atm and retracted superiorly until meeting resistance. The balloon was then inflated with Omnipaque contrast solution (300 mg/mL; GE Healthcare, Princeton, New Jersey) to a pressure of 10 atm and a maximum diameter of 3.6 mm (Figure 2). The catheter was secured to the head, with resistance maintained to avoid changes in position while being scanned.
The heads underwent computed tomography (CT; CereTom OTOscan; NeuroLogica Corporation, Danvers, Massachusetts) and were evaluated in a blinded fashion by the second author for catheter position, integrity of the carotid canal, and abnormalities of the surrounding bony structures. The length from the promontory of the bony isthmus to the nasopharyngeal orifice was measured from the axial images with 3-dimensional multiplanar reconstructions in Synapse software (Fujifilm Corp, Tokyo, Japan).

Results and Analysis

All 11 attempts to view the bony eustachian tube orifice endoscopically were successful, and the bony isthmus was seen to be intact and easily distinguished from air cells inferior to the true orifice. Cannulation of the eustachian tube was achieved in every case with a single insertion. All catheters remained anterior to the malleus, never contacting the ossicular chain.

Successful passage into the nasopharynx was confirmed by nasal endoscopy and postprocedure CT scan in all cases. The balloon was dilated to 2 atm once the 40-mm distance marker reached the bony orifice. The balloon was withdrawn until resistance was met as it engaged the isthmus and was then inflated to 10 atm.

Pre- and postprocedure CT scans were evaluated by an otologist blinded to the procedures (Table 1). The eustachian tube mean lengths were as follows: total, 37.8 mm; cartilaginous, 27.3 mm; bony, 10.6 mm. Bony isthmus diameter was unchanged at 2.6 mm. No evidence of ossicular discontinuity, bony fractures, or damage to neurovascular structures was demonstrated.

Discussion

One disadvantage of transnasal techniques for eustachian tube dilation is that it addresses pathology within only the cartilaginous eustachian tube, which could leave up to 10% of patients inadequately treated. The transtympanic approach described above addresses the cartilaginous and bony eustachian tube within a single procedure. It has the advantage of being used as an adjunct procedure during more traditional otologic procedures designed to correct the sequelae of long-term chronic eustachian tube dysfunction. Inflation of the balloon within the bony portion is not recommended, due to the risk of injury to the adjacent carotid artery.

The challenges for a transtympanic approach include the bony-cartilaginous isthmus, which limits the outside diameter of a balloon catheter and the proximity of neurovascular structures. The study by Kepchar et al utilized a microscopic technique and rigid balloon catheter, sometimes requiring removal of overlying bone to access the bony orifice. Three of the 10 procedures failed to cannulate the eustachian tube, and complications included 1 catheter becoming lodged in the carotid canal and 2 extending into the vidian canal.

We investigated the possibility of an endoscopic transtympanic approach with a prototype flexible catheter for dilation of the cartilaginous eustachian tube. Utilizing the lessons learned from the Kepchar study, we modified their approach by utilizing a 45-degree endoscope and flexible catheter. By following the semilunar canal into the lumen, we were able to cannulate the full length of all 11 eustachian tubes without difficulty. The absence of any difficulties with insertion or adverse effects provides some evidence that such a procedure is feasible in the future.

The limitations of this study include the small number of cases performed and the use of CT and endoscopy to inspect for adverse effects. No histology was performed, so it is possible that microfractures of bone or cartilage could be missed; however, this study demonstrated that our transtympanic approach to the eustachian tube is feasible. It offers (1)
the advantages of dilating the cartilaginous eustachian tube from a transtympanic approach and (2) a theoretical therapeutic benefit for pathology within the bony portion by the action of passing the catheter through the lumen.

Conclusion
This study provides evidence to support the feasibility of performing balloon dilation of the cartilaginous eustachian tube by utilizing a flexible balloon catheter via an endoscopic transtympanic approach. The procedure offers the possibility for being combined with traditional otologic surgical techniques.

Author Contributions
Marc Dean, design and acquisition, drafting, final approval, accountability for all aspects of the work; Wei-Chieh Chao, data analysis, drafting, final approval, accountability for all aspects of the work; Dennis Poe, design and acquisition, revising, final approval, accountability for all aspects of the work.

Disclosures
Competing interests: Marc Dean—consultant for Acclarent. Dennis Poe—consultant for Acclarent.

References

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