Caution in Transnasal Balloon Dilation of the Eustachian Tube: Middle Ear Penetration of Catheter Tip in a Cadaveric Model

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Objective: To investigate the degree to which transnasal eustachian tube (ET) dilation balloon catheters are able to be passed through the ET in a cadaver model.
Patients and Interventions: A cadaveric study of 8 cadaver heads (16 ears), which underwent transnasal ET insertion with a 3 × 20-mm balloon catheter with transtympanic endoscopic visualization and grading.
Results: Catheter tip incursion into the protympanum or mesotympanum occurred in all ears. Radiological validation was obtained with correlation to published ET length data.
Conclusion: Middle ear incursion of balloon catheter tips can be demonstrated in a cadaver model and highlights the ongoing need for both caution in novel surgical techniques and evolution in device design.
Key Words: Balloon dilation—Balloon eustachian tuboplasty—Cadaver dissection—Computed tomography—Eustachian tube.

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INTRODUCTION

Balloon dilation of the eustachian tube (BDET) is a novel surgical technique first described in the literature in 2010 (1), the original objective of which was to dilate the cartilaginous component of the ET (2). The length of the cartilaginous ET and total ET can vary significantly, averaging 22.13 mm (19.92–24.34 mm) and 35.01 mm (27.8–42.21 mm), respectively (3), with the isthmus being reported as being 17.57 to 29.36 mm (4) from the pharyngeal orifice in adults. There is a paucity of evidence in the literature examining the exact tip position of the BDET device once placed. The balloon catheter tips are reportedly designed to prevent placement into the bony ET (5), but there seem to be no proven safeguards against this. This study therefore investigated the degree to which BDET balloon catheter tips are able to be passed through the ET using a cadaver model with dual transtympanic and transnasal endoscopic visualization.

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METHODS

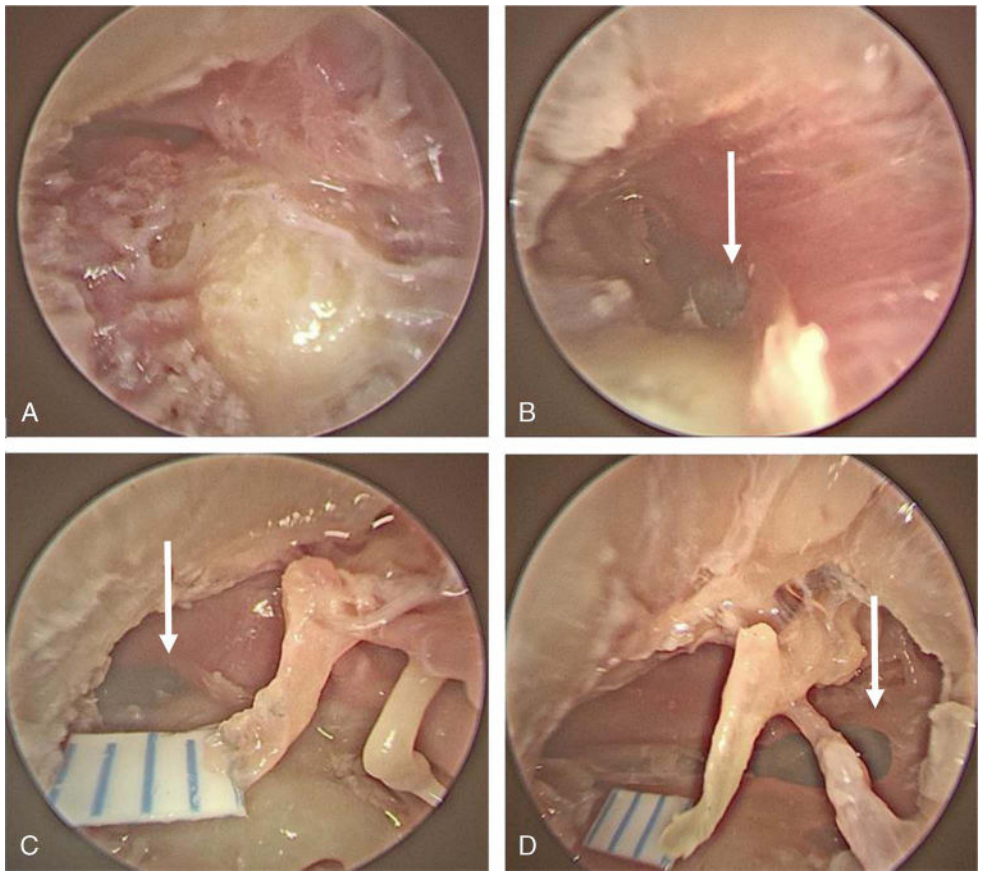
Cadaveric Dissection

Eight cadaver heads were sourced for the primary purpose of use in the Sydney Endoscopic Ear Dissection Course and subsequently used at the conclusion of the course for this anatomical research. The cadaver heads were obtained from ScienceCare Anatomical (Phoenix, AZ) with ethics preapproval under institutional anatomical license (University of Sydney, Royal North Shore Hospital, Australia). The cadavers were kept in a fresh-frozen state and thawed before dissection, as previous research by our group had shown this to be superior for investigation (6).

Bilateral endoscopic ear dissection was performed during the Sydney Endoscopic Ear Course as per the *Sydney Endoscopic Ear Surgery Dissection Manual* (7). BDET procedure was performed in the postdissection cadavers using the TubaInsert and Tubavent system (Spiggle and Theis Medizintechnik GmbH, Overath, Germany) in accordance with the device instructions (5). Postinsertion transtympanic endoscopic images were taken of the middle ear. A grading system of potential balloon catheter incursion was defined with grading from "1" to "4" (Fig. 1).

Radiographic Study

High-resolution computed tomography (CT) was acquired before the investigation and reformatted to the plane of the ET. Landmarks for the cranial and caudal ends of the cartilaginous and bony ET were defined (Fig. 2) as described in previous anatomical studies (8,9). The measurements were then compared with previously



Grade	Description
1	No balloon incursion: no part of balloon tip visible
2	Balloon in ET: tip visualized in ET but not reaching protympanum
3	Balloon in protympanum: tip not reaching malleus handle
4	Balloon in mesotympanum: tip extends past malleus handle

FIG. 1. Observational grading of middle ear incursion by BDET catheters (tip indicated by white arrow). *A*, Grade 1. *B*, Grade 2. *C*, Grade 3. *D*, Grade 4. BDET indicates balloon dilation of the eustachian tube.

published radiological data from live patients (8), and statistical analysis was performed.

RESULTS

All 16 ETs were able to be successfully catheterized with the BDET balloon catheter. No abnormal nasopharyngeal or tubal cartilaginous anatomy was noted during the procedures.

Comparison of the two independently graded incursion scores showed 100% concordance. No ears were graded as 1 or 2, 3 ears (19%) were graded as 3, and 13 ears (81%) were graded as 4 (Table 1).

The means of the radiologically measured total ET lengths were 36.89 and 37.81 mm with standard deviations of 1.18 and 1.87 by each independent radiologist, respectively, and two-sample paired *t* test showed no significant inter-rater difference between the measurements ($p = 0.108$). Measurements of the cartilaginous ET lengths were 25.66 and 25.75 mm with standard deviations of 0.66 and 1.24, respectively ($p = 0.804$). Comparison to published data on live adult cartilaginous ET lengths (8) showed a mean difference of 0.99 mm, which did not reach statistical significance ($p = 0.071$). Comparison to total live adult ET lengths in another study (9) showed a mean difference of −1.85 mm, which was statistically significant ($p < 0.05$).

DISCUSSION

There is a growing body of evidence to support the safe use of BDET in primary otolaryngology practice (10–14), with the indications for surgery continuing to evolve through the use of consensus guidelines (15). The balloon tested in

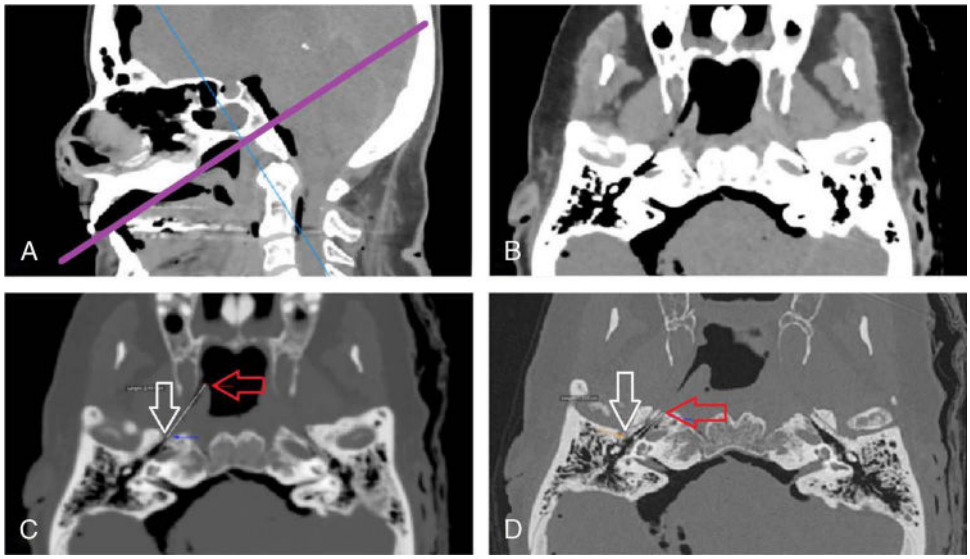


FIG. 2. Technique for measuring ET lengths. *A*, Angle for reformatting (purple line). *B*, Axial slice with entire ET in plane. *C*, Cranial end of the cartilaginous ET (white down arrow) and caudal end of the cartilaginous ET (red left arrow). *D*, Tympanic end of bony ET (white down arrow) and caudal end of bony ET (red left arrow). ET indicates eustachian tube.

this study was at the time the only device currently approved specifically for BDET in Australia by the Therapeutic Goods Administration, although others are now available.

The main concern resides in the use of a single balloon length, which does not account for anatomical variation in ET length. Although the balloon used in this study has a length of 20 mm, the maximum potential distance when fully inserted into the introducer from the distal tip of the insertion device to the distal catheter tip is up to 38.8 mm (Fig. 3). When compared with our radiologically measured range of total ET length (34.4–41 mm), it is feasible that the tip of this catheter could penetrate further into the middle ear than intended (Fig. 4).

The results of our study demonstrated middle ear incursion in all 16 cases, with intrusion beyond the malleus handle in over 80% of insertions and injury to the tensor fold in one specimen (Fig. 4B). This finding poses a potential safety concern with potential for injury to middle ear structures. To our knowledge, this is the first study in the literature reporting these novel findings.

The results of this study are clearly at odds with the clinical experience of these devices, as the feasibility and safety of BDET have been previously well documented (2,13–19). We would expect reports of iatrogenic trauma to middle structures if such high rates of grade 4 penetration were occurring in live patients undergoing BDET, which has clearly

TABLE 1. *Grade of middle ear incursion, radiological computed tomography measurements of cartilaginous, bony and total eustachian tube lengths, and dissection comments*

Specimen	Side	Introducer Angle (degree)	Middle Ear Incursion Grading	Average Measured CT Cartilaginous ET Length (mm)	Average Measured CT Bony ET Length (mm)	Average Measured CT Total ET Length (mm)	Dissection Comments
1	Right	30	4	26.5	12.5	39	
1	Left	30	4	26.8	12.9	39.7	
2	Right	70	4	25.2	11.3	36.5	
2	Left	70	4	26.3	11.9	38.2	Tip punctured tensor fold
3	Right	30	4	26.1	11.2	37.3	
3	Left	30	3	25.7	11.7	37.4	
4	Right	30	4	25.6	12.3	37.9	
4	Left	30	4	25.7	12.9	38.6	
5	Right	70	4	25.2	10.7	35.9	Slightly stiff ET
5	Left	45	4	25	11.4	36.4	Slightly stiff ET
6	Right	70	3	26	9.8	35.8	
6	Left	70	3	25.3	10.1	35.4	
7	Right	30	4	24.8	11.7	36.5	
7	Left	30	4	24.8	12.8	37.6	
8	Right	70	4	26.8	11.8	38.6	More vertical ET angle
8	Left	70	4	26.1	11.7	37.8	More vertical ET angle

CT indicates computed tomography; ET, eustachian tube.

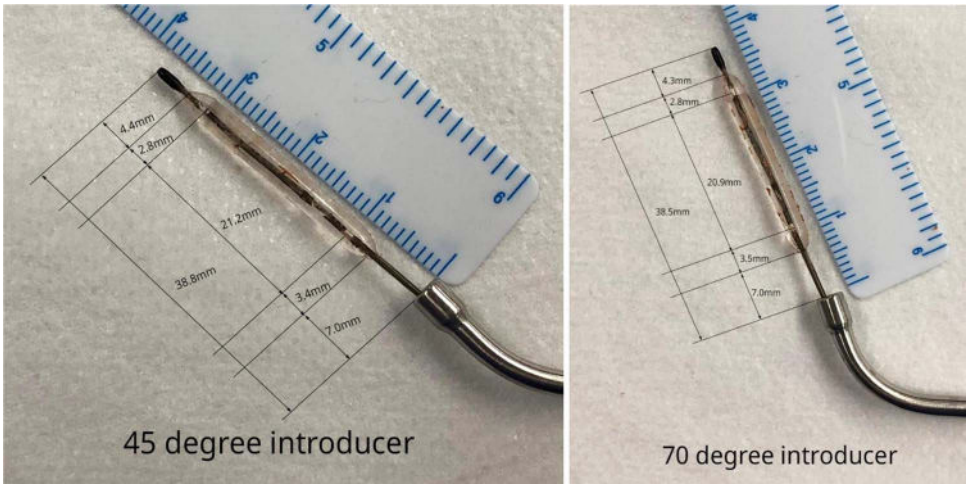


FIG. 3. Measured lengths of fully inserted balloon catheters through 45- and 70-degree introducers.

not been borne out in the literature. In our recent publication of our clinical outcomes of BDET in live patients (14), no such complications were evident.

One limitation of this study that may explain the results is the use of cadaveric specimens. Physiological engorgement of soft tissues in a live patient may pose a greater barrier to inadvertent catheter advancement. Conversely shrinkage of the tissues in the freezing process might, despite adequate thawing, permit deeper catheter insertion. However, the similarity between our radiological measurements to previously published data counters this argument. The cadaveric specimens had been fully dissected in a clinical training course before this study was performed, which, although not having changed the anatomy of the ET, did preclude more accurate measurements of incursion from being obtained. A further limitation is that other BDET systems approved internationally, and that have since become available in Australia also, have not been tested in this particular study.

Despite the identified study limitations, the authors believe that the results do warrant publication as both a cautionary note to surgeons performing BDET and to act as a pilot study to encourage further research into device design. We propose the following considerations as a result:

1) Preoperative CT scanning and measurements of ET length for patients undergoing BDET could have additional utility in the future including the use of different balloon catheter lengths. A recent consensus statement on BDET (13) found that preoperative imaging with CT was controversial and a consensus was not reached. Initial feasibility studies involving CT imaging predominantly focused on the potential risk for carotid artery or canal injury, particularly in the setting of a dehiscent carotid canal (6,15), and even suggested that it was a potentially unnecessary investigation (20).As for many otologic prostheses benefiting from a range of sizes, a range of balloon catheter lengths could allow for better matching to a patient's regional anatomy. Preoperative CT imaging and analysis could allow individualized ET measurements to be obtained, allowing for future directed therapy with appropriate catheter lengths and avoiding potential complications.
2) Future BDET clinical outcome studies should include preoperative and postoperative audiograms.The majority of studies reporting on safety of BDET do not report on postprocedure audiological results. Two studies that did performed post-BDET audiology actually did

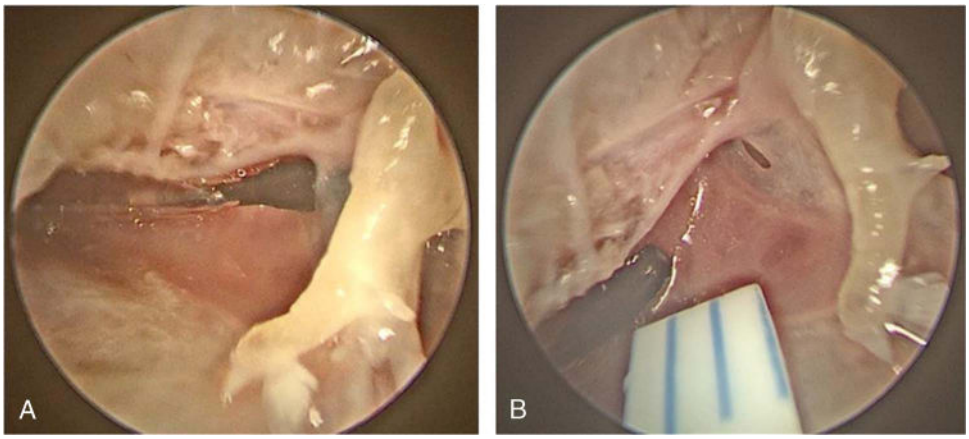


FIG. 4. *A*, Full insertion of balloon catheter. *B*, Injury to tensor fold seen after partial retraction of balloon catheter.

report low rates of hearing deterioration, one noting conductive loss (21) and noting a very low rate of sensorineural loss (22). Tinnitus is a recognized uncommon complication of BDET (13), but the mechanism behind this is not fully understood. Possible minor trauma from BDET catheter insertion to the ossicular chain could explain subclinical hearing loss or associated tinnitus, and further investigation is warranted including reporting of postoperative audiogram results.

3) Balloon catheter design and procedure refinement is crucial.

Despite the catheter in this study having an olive-shaped tip designed to prevent penetration beyond the isthmus (Fig. 3), previous studies have shown that insertion past this point is possible (6,23) and this is reinforced by our findings. With the increasingly widespread uptake of BDET, there will be a natural evolution in device design including tip shapes, sizes, and materials to optimize accurate placement and patient safety. Some studies have investigated novel methods of confirming tip placement using fluoroscopic (24) and navigation-assisted (25) methods to facilitate accurate catheter positioning. Another balloon catheter system has an integrated LED light fiber that could be used to check catheter tip. Another option would be to mark insertion depth measurements on the balloon catheter to guide the surgeon intraoperatively.

4) Tactile feedback is paramount to avoiding complication.

The blind nature of balloon catheter advancement is perhaps the main threat to iatrogenic injury. Tactile feedback is therefore crucial to avoiding false passage and potentially could alert the surgeon to over insertion and pressure on middle ear structures, and surgeons should pay particular attention to this during the insertion process.

CONCLUSION

Eustachian tube balloon dilation catheters, in this cadaver model, have been shown to unintentionally violate the protympanum and mesotympanum and thus could conceivably cause middle ear injury in patients. Further studies are required to establish more robust means of ascertaining individualized catheter length to prevent inadvertent injury and provide surgeons with an objective means of predicting tip position. Surgeons should be particularly aware when the catheter is at the limits of insertion and considering offsetting the catheter from its normal stopping position as clinically appropriate.

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