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Endoscopically Guided Transtympanic Balloon Catheter Dilatation of the Eustachian Tube: A Cadaveric Pilot Study

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Objective: To assess the feasibility, safety, and efficacy of transtympanic balloon catheter dilatation of the Eustachian tube (ET) in a cadaver model.
Patients and Interventions: A cadaveric study of 10 cadaver heads, which underwent unilateral transtympanic dilatation of the ET with a 3 × 20 mm balloon catheter with full endoscopic guidance and visualization.
Results: Procedural safety was demonstrated, with no damage to any essential structures found. Feasibility of the procedure was demonstrated in all cadavers with 100% success rate, despite a small number of encountered difficulties. Statistically significant efficacy was also demonstrated in both radiologic and manometric data.
Conclusion: With full endoscopic visualization, the transtympanic approach to balloon catheter dilatation of the ET seems to be a feasible and safe procedure in the cadaver model. **Key Words:** Balloon dilatation—Balloon eustachian tuboplasty—Cadaver dissection—Computed tomography—Eustachian tube—Transtympanic.

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The Eustachian tube (ET) is a unifying passageway between the nose and ear and its function remains incompletely understood. ET dysfunction is the most commonly implicated cause in a number of middle ear pathologies. The dysfunction most commonly relates to obstruction of the ET and may be because of a wide array of causes, more commonly physiological rather than anatomical (1).

Transnasal balloon dilatation of the ET (BET) was first described in the literature 5 years ago by the Bielefeld group in Germany (2), and shortly thereafter by two other U.S.A.-based groups in Boston (3) and New York (4). These three initial studies reviewed the method in cadaver models and all concluded that the procedure was both feasible and safe.

A recent systematic review examined the evidence for BET. Although no published randomized controlled trials or case-control studies were identified, existing case series did suggest a benefit with safety and feasibility reaffirmed (5). Across the studies analyzed by this systematic review, efficacy of BET was demonstrated in up to 70% of patients. A subsequently published large study of 622 patients demonstrated similar efficacy (6).

Although the literature points to the cartilaginous portion of the ET being the most likely site of pathology (7), increasing the minimal cross sectional area is the key philosophy of almost all other clinical applications of balloon dilation catheters. Data from three-dimensional computer-aided reconstructions of histological slides show that the minimum cross-sectional area lies in the lateral aspect of the cartilaginous ET consistently within 5 mm of the junctional portion (8,9). Given the length of the ET and commonly used balloon catheters, it is likely this minimum area is missed in a significant proportion of transnasal balloon dilation, which may afford the transtympanic technique a unique advantage.

Transtympanic BET may warrant consideration in patients undergoing simultaneous middle ear surgery, as they often have coincident ET dysfunction. Additionally, a potential indication for the transtympanic approach may be in patients in whom the transnasal approach has failed. However, these are theoretical indications and direct comparison of the respective indications and merits of the two approaches is beyond the scope of the present study.

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Two studies to date have specifically looked at transtympanic BET, one in a cadaver model (10) and the other in human subjects (11).

The aim of this work is to evaluate the safety and short-term efficacy of transtympanic balloon dilatation in the cadaveric model. The study is unique in design using full endoscopic visualization of insertion and dual endoscopic confirmation of correct balloon position. Efficacy will be tested with manometry and blinded radiologist review.

Objectives

To perform unilateral, transtympanic, and endoscopically guided BET using radiographic and manometric studies to assess the safety and efficacy of the procedure in a cadaver model:

1) Radiographic Study
   a. Assessment of safety by pre- and postdilatation high-resolution computed tomographic (CT) analysis of the carotid canals and surrounding bony anatomy for the presence of any fractures;
   b. Assessment of efficacy by pre- and postdilatation high-resolution CT analysis for any radiographic evidence of difference in sides with blinding of the radiologist to the side of intervention;
2) Manometric Study
   a. Assessment of efficacy by pre- and postdilatation manometry to determine the opening pressure of the ET.

MATERIALS AND METHODS

Experimental Design

Approval was obtained under institutional anatomical licencing for cadaveric research for medical and scientific purposes. Ten human fresh-frozen cadaveric heads (ScienceCare Anatomical, Inc., Phoenix, AZ, U.S.A.) were thawed in a licenced anatomical laboratory with an ambient temperature of 16°C for 72 hours to ensure the deep tissues around the ET were fully thawed, and would not hinder balloon catheter insertion. The cadavers had no history of ear surgery, ear disease, or trauma.

Both ear canals of each head were cleaned of wax and debris and external canal hair trimmed before the procedure. The 10 specimens were block randomized into two groups of five, either undergoing left-sided or right-sided balloon dilatation. The principal investigators raised a wide, anteriorly based tympanomeatal flap, which was carefully detached from the malleus. The method used for this approach has been previously described in detail with respect to performing an over-under tympanoplasty (12).

The flap was easily laid back into anatomical position before tomographic scanning to ensure sides were indistinguishable with respect to flap elevation. Flaps were raised using a 0 degree, 3-mm diameter, 14-cm endoscope, with a SPIES H3-Z three-chip full HD camera, Image1 Connect Processing Module and full HD monitor (Karl Storz Gmbh & Co., Tüttlingen, Germany).

Tympanomeatal flap elevation was completed before predilatation scanning of the heads to ensure minimal elapsed time between pre- and postdilatation scans, decreasing the chances of tissue degradation between scans which may have affected interpretation of results.

The protympanum was completely visualized using a 30-degree endoscope with the tip carefully inserted anteroinferior to the umbo and angled anteriorly and slightly superiorly. The endoscope was withdrawn to the external canal. A 3-mm diameter, 20-mm length Sterling Monorail Balloon Dilatation Catheter with attached Encore 26 Inflator (Boston Scientific Corp., Marlborough, MA, U.S.A.) was then inserted into the gap between the handle of the malleus and the anterior annulus under direct and continual endoscopic visualization.

Simultaneously, a second endoscope connected to an independent camera system was inserted via the ipsilateral nostril by a second investigator to visualize the ET opening in the nasopharynx. Confirmation of successful ET catheterization was through visualization of the tip of the balloon catheter exiting the ET into the nasopharynx. After this, the catheter was withdrawn so that the proximal end of the balloon was beyond the curvature of the carotid and just visible with the endoscope in the protympanum. The balloon was inflated by a second investigator to the nominal pressure of 6 atmospheres to dilate the balloon to 3 mm and held for 2 minutes. After this, the balloon was deflated and the catheter withdrawn under endoscopic visualization.

Correct insertion of the catheter was confirmed using three sequential criteria:

1) transtympanic endoscopic visualization of the shaft of the catheter following a reasonable trajectory without kinking;
2) lack of resistance to progressive gentle insertion of the shaft;
3) transnasal endoscopic visualization of the tip of the catheter shaft exiting the ET orifice in the nasopharynx on over-insertion.

If these criteria were compromised at any point, the catheter was withdrawn, the guidewire adjusted if needed, and reinsertion attempted. Otherwise, the catheter was withdrawn to the optimal position and inflation proceeded as previously described. Endoscopic photographs of the steps described above are shown in Figure 1.

Radiographic Study

All cadaver heads were transported by the investigators to the radiology suite, located in the same building complex as the dissection laboratory. They sequentially underwent CT scanning on bone and soft tissue windows in a GE Lightspeed 64 slice VCT scanner (slice thickness 625 μm, slice spacing 300 μm, peak kilovoltage 120 kVp, tube current 200 mA; GE Healthcare, Waukesha, WI, U.S.A.) before and after undergoing balloon dilatation. Source DICOM data were reviewed on a TeraRecon 3D platform (TeraRecon, Foster City, CA, U.S.A.). The scans were analyzed by a college certified neuroradiologist, who was blinded to the side of balloon dilatation.

Manometric Study

After raising the tympanomeatal flap, the opening pressure of the ET was measured immediately before and after balloon dilatation. This was performed using an endotracheal tube cuff pressure manometer (Mallinckrodt, Athlone, Ireland) connected via a short sealed semirigid circuit to an appropriately

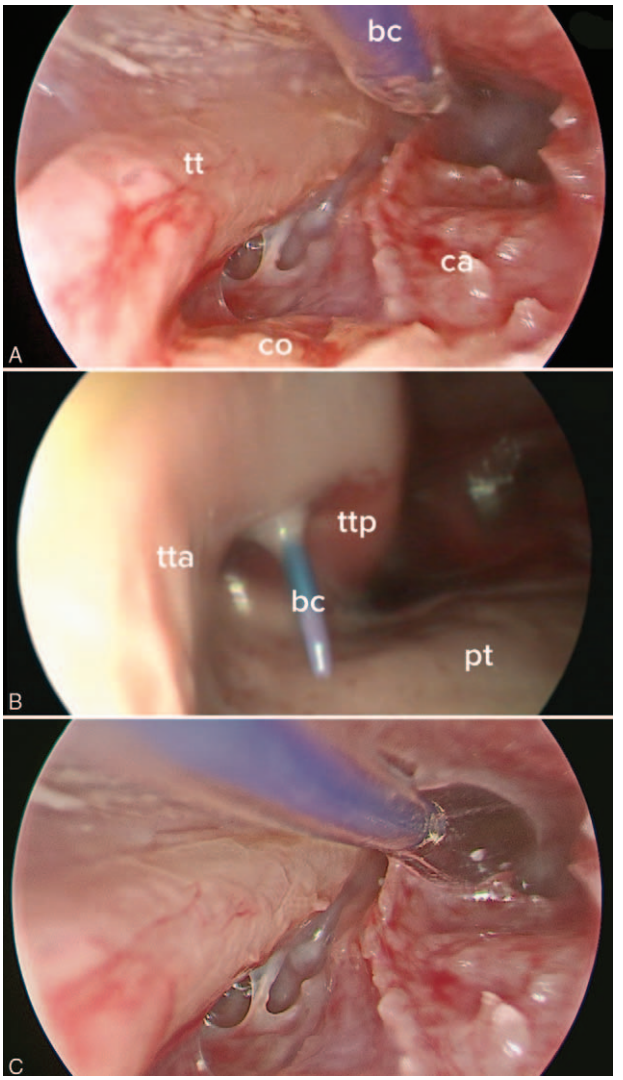

FIG. 1. *A*, Transtympanic view of the protympanum in a right ear (cadaver 9) with a 30-degree 3-mm endoscope, after balloon catheter insertion. *B*, Transnasal endoscopic view of balloon catheter tip exiting Eustachian tube in nasopharynx with 0-degree 3-mm endoscope. *C*, Transtympanic view of the protympanum with a 30-degree 3-mm endoscope, after balloon catheter inflation. bc indicates balloon catheter shaft; ca, carotid artery prominence; co, cochlear; pt, palate; tt, tensor tympani canal; tta, torus tubaris (anterior cushion); ttp, torus tubaris (posterior cushion).

sized ''mushroom''-type ear tip (Interacoustics, Middelfart, Denmark).

Pressure was applied via the manometer at a rate of approximately 5 cm of H_2O per second, until a ''wash off'' of pressure was observed. This was repeated a total of three times pre- and postdilatation, with two investigators observing to ensure consistency of the results. If the results differed, the least recorded value was chosen. Values were rounded to the nearest 5 cm of H_2O.

RESULTS

All 10 cadaver heads successfully underwent unilateral BET (five left and five right). Visual confirmation of successful ET catheter insertion was appreciated in all cadaveric specimens (Fig. 2). No obvious complications occurred during the procedure, such as damage to the ossicles, or overt bony fracture.

The following challenges were encountered in conducting this aspect of the experiment.

In one cadaver (cadaver 3), a balloon puncture was detected at the point of inflation. The puncture had occurred at a point before or during insertion of the balloon and was noticed when the balloon was not able to hold pressure at any point. This necessitated removal and successful reinsertion of a new balloon.

In one cadaver (cadaver 4), a mild degree of resistance was encountered during insertion through the medial aspect of the ET. This was secondarily confirmed by failure of transnasal endoscopy to visualize the balloon tip. The balloon was not inflated, but rather withdrawn and reinserted. On the second attempt, no resistance was encountered and the balloon tip was visualized transnasally.

In one cadaver (cadaver 8), a dehiscent carotid canal was suspected and then confirmed with gentle palpation. The area of dehiscence was within the posterior protympanic segment, over an area of 1 to 2 mm. Despite this, balloon insertion and dilatation was successfully performed in this cadaver, bypassing this dehiscence with care.

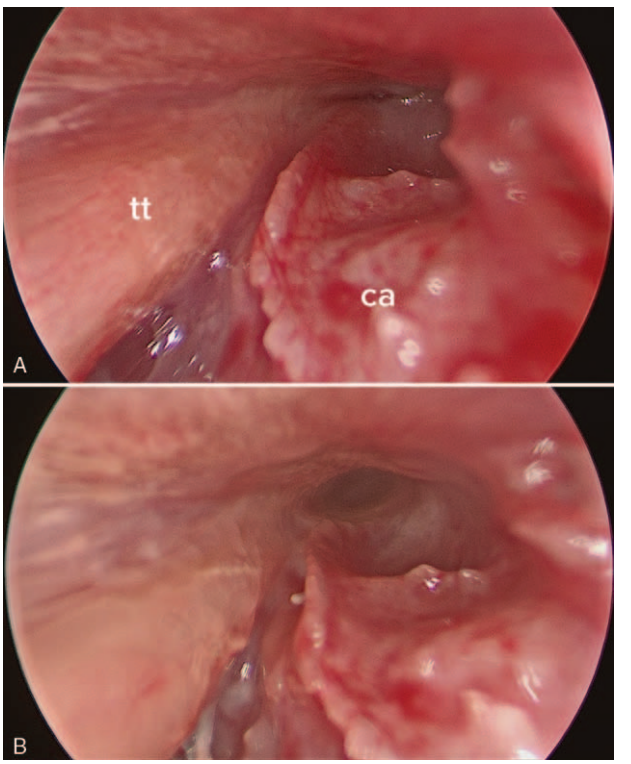

FIG. 2. Transtympanic view of the protympanum in a right ear (cadaver 9) with a 30-degree 3-mm endoscope. *A*, Before balloon insertion/inflation. *B*, Subsequent to balloon deflation/withdrawal. ca indicates carotid artery prominence; tt, tensor tympani canal.

Radiographic Study

On review of all pre- and postdilatation CT imaging, there were no carotid canal or bony fractures around the ET in any cadavers.

Pre- and postdilatation images were also directly compared to ascertain which side had undergone the intervention. The main data point measured was the change in the width of air-filled space within the lumen of the ET. Occasionally, dilatation at the tympanic or pharyngeal end was also noted. In all 10 cadaver heads, the correct side that underwent intervention was identified. A comparison of pre- and postdilatation CT imaging is shown in Figure 3.

Manometric Study

The opening pressures of the ET predilatation had a mean of 55.5 cm H_2O (range, 35–75; SD 13.0). The opening pressures postdilatation had a mean of 20.5 cm H_2O (range, 5–35; SD 8.6). A paired sample *t* test was used to analyze the differences between these values, and it was found to be statistically significant with a *p* value of 0.000014. Graphical representation of these results is shown in Figure 4.

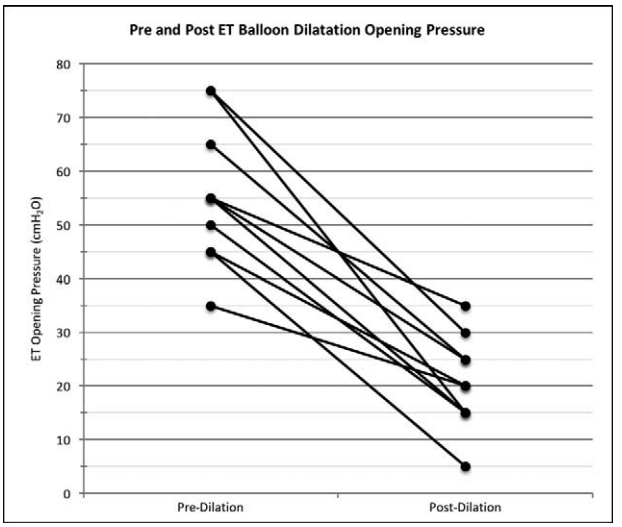

FIG. 4. Graphical representation of Eustachian tube opening pressure (cm H_2O) as measured by a closed circuit on an endotracheal tube manometer. Lines are drawn to connect samples in the same cadaver. Mean of predilatation opening pressures is 55.5 cmH_2O and of postdilatation opening pressures in 20.5 cmH_2O (*p* value of 0.000014).

DISCUSSION

This study is the second to investigate the transtympanic BET on cadaver models. The first study by Kepchar et al. (10) found serious safety concerns with the technique, which is in direct opposition to the findings of this work. There are numerous points of difference in methodology between the two studies.

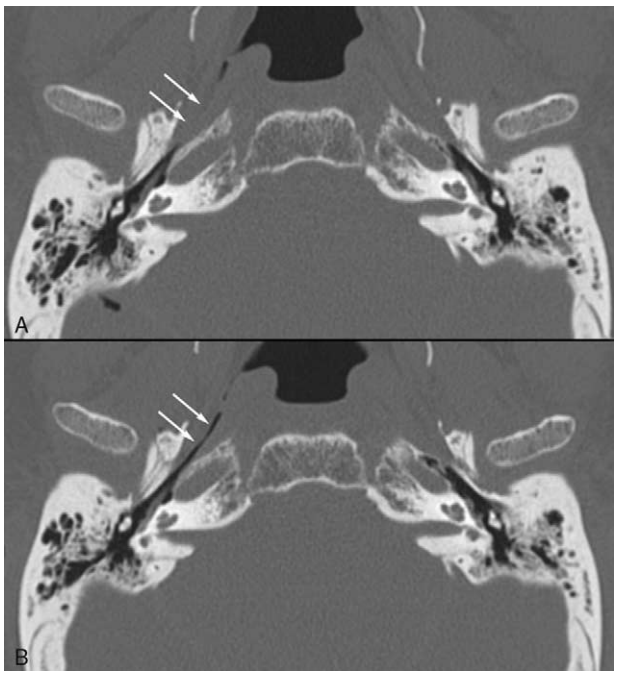

FIG. 3. Computer tomographic scans of the temporal bone (cadaver 9) reformatted in an arbitrary para-axial plane to view the length of the Eustachian tube in its entirety: *A*, before balloon insertion/inflation; *B*, subsequent to balloon deflation/withdrawal.

The study performed by Kepchar et al. (10) used a total of six cadavers, performing balloon dilatation bilaterally using a 2 × 13-mm Lacricath balloon dilatation catheter. In two of the cadavers, pre-existing trauma prevented insertion of the catheter on one side, resulting in a total of 10 catheterization attempts. In one of these, catheterization was attempted, but unable to be completed. Three of the remainder resulted in creation of false passages into the carotid canal and vidian canal. It should be noted that the cadaver heads where this occurred had all sustained significant skull base fractures. In contrast to this, there was no pre-existing trauma in the cadavers used in the present study.

Furthermore, in the Kepchar et al. (10) series, pre- and postdilatation CT scans were performed with balloon catheters in situ. This may have allowed artifact to obscure bony injuries, which could have potentially masked subtle detail and left doubt as to whether any injuries observed were pre-existing or occurred as a result of catheter insertion. To improve this situation in the present study, balloons were removed during both scans, to prevent artifact masking any injuries.

In the six catheterization attempts that were successful, Kepchar et al. (10) stated it was difficult to visualize the ET orifice well enough to ensure successful catheterization. This necessitated drilling away of the posterior external auditory canal bone until there was a more favorable angle, even if it meant exposing mastoid air cells. Despite this, it is possible the authors were unable to microscopically visualize the entire protympanum with a similar view that the present study obtained with an angled endoscope (13). In the present study, dual

endoscopic visualization confirmed correct insertion and placement of the balloon catheter. The endoscopic visualization and lack of pre-existing trauma in the cadavers may have led to the improved feasibility and safety identified in these results.

The only other study that has investigated transtympanic BET was by Tarabichi and Najmi (11). They performed unilateral dilatation in eight patients undergoing surgery for either closure of a perforation or removal of cholesteatoma using a 3 × 20-mm catheter. In all eight patients the procedure was safely performed with no intra- or postoperative complications reported. Seven patients reported no pressure symptoms in their ear on follow-up, with one patient lost to follow-up. Six of seven had good objective medium term postoperative results. Five of these six thought that they were able to perform a Valsalva manoeuvre, with three demonstrating evidence of insufflation. This approach may offer benefits to patients on the basis of this limited case series.

The feasibility of this technique has been demonstrated in the present study, despite the procedural challenges encountered. In one cadaver, a balloon puncture occurred before inflation, caused by either a pre-existing balloon defect or puncture on bony spicules present in the protympanum. The second insertion with a new balloon proceeded uneventfully. Resistance was also encountered in one of the balloon catheter insertions along with failure of the catheter tip to be visualized exiting into the nasopharynx. This may have been because of the creation of a false passage, and if so, likely occurred in the cartilaginous portion of the ET, as the tip was fully visualized passing through the bony portion. This was confirmed before deployment and successful reinsertion occurred. A contributing factor may have been postmortem mucosal layer separation because of production of hydrolytic enzymes from junctional interlayer cells, altering characteristics to applied forces in a cadaver model (2,14). It is encouraging that the small series performed transtympanically in human subjects to date has not reported any false passages (11).

Carotid artery injury remains the primary safety concern with ET manipulation (15). A small pre-existing carotid canal dehiscence was noted on one of the cadavers in this study. If such a dehiscence was observed in a human subject, it would certainly be a contraindication to dilatation. Future work in the area in human subjects should be performed with caution. The carotid artery lies in close proximity to the protympanum and indeed forms part of its medial wall in the usual anatomical configuration. It is of critical importance to keep the balloon catheter fully visualized with the endoscope as it passes beyond the carotid prominence, and also to ensure that when the balloon is deployed, it is done so beyond the bony ET and is situated in the junctional and cartilaginous portions of the ET. Also of concern is the possibility of plaque dislodgement and intimal tears, which can result from manipulation around the carotid. Although these were not identified in this study, they can theoretically occur.

Ossicular trauma is another potential concern with this approach. This could occur at three points: 1) during separation of the TM from the malleus; and 2) during insertion of the endoscope; or 3) insertion and deployment of the balloon catheter. This trauma could result in either sensorineural or conductive hearing loss. Care must obviously be taken to reduce ossicular manipulation and prevent trauma during these key manoeuvres.

There are no available data that specifically address the effect of tympanic membrane flap elevation on sensorineural thresholds. Despite this lack of data, there is an encouraging trend evident in a review of the literature. In a retrospective review of 141 ears that underwent over-under tympanoplasty, a less than 2-dB threshold change in the average postoperative bone conduction pure-tone average and 4-kHz bone conduction thresholds occurred (16). Additionally, a recent series of 51 ears that underwent over-under tympanoplasty reviewed change in sensorineural thresholds in those who also had mastoidectomy compared with those who did not, finding that all sensorineural hearing loss that had occurred 24 hours postoperatively had resolved by 6 months (17).

With respect to the transnasal approach, a systematic review and large case series reported complications of surgical emphysema subsequent to mucosal tear, minor bleeding, and worsening of pre-existing tinnitus, but the rate and severity of these was low (5,6). If the transtympanic approach is to be considered, it must be done so carefully given the added risks over transnasal. Complications of middle ear surgery such as perforation, dysgeusia, disequilibrium, vertigo, tinnitus, hearing loss, and facial nerve injury are all theoretically possible in addition to those reported in the transnasal approach.

The balloon catheter device used was one not previously reported in dilatation of the ET and not FDA approved for this indication, but rather indicated for use in percutaneous transluminal angioplasty in peripheral vasculature. Nonetheless, the design and dimensions of the balloon match the most commonly used balloon in the wider literature on the transnasal approach to the technique. It is possible that the type of balloon catheter used in this and the previous cadaveric study may have contributed to the conflicting results as the balloons were of sufficiently different length and diameter. If future cadaveric studies demonstrate safety and efficacy with different balloon catheter types, it would add to the robustness of the technique. It would be interesting to ascertain the ideal range for balloon catheter design, specifically the minimum diameter necessary for efficacy to be achieved and the maximum diameter possible before safety is compromised. Consideration may even be given to simple catheterization, which, if efficacious, may afford increased safety. An insertion device similar to that devised previously for the transnasal approach (6) may also be useful in improving the transtympanic approach.

Dual endoscopic visualization used to confirm the placement of the balloon catheter constitutes an

important safety measure that should be used in any future studies of this technique. In particular, in the cadaver where resistance of catheter insertion may have led to the creation of a false passage in the cartilaginous ET, this allowed for easy detection and correction without compromising safety.

A limitation of dual endoscopic visualization in a human subject is the need for an assistant to perform endoscopy of the nose, given the clean and contaminated nature of the respective operative fields. Draping of the patient in an appropriate manner and decongestion of the nose at an appropriate time point would certainly facilitate this in the real world. Given most anesthetists' present-day familiarity with flexible fiberoptic endoscopes inserted transnasally, this could provide a viable alternative to a formal surgical assistant in the procedure.

The statistically significant results from the present study demonstrate efficacy of the transtympanic technique in the cadaver model; however, true efficacy remains to be demonstrated by human trials. Although a comprehensive set of reporting outcomes have been recommended in BET (5), the present study used radiologic and manometric data as those reporting outcomes are difficult to assess in a cadaver model. Future studies using human subjects should include comprehensive reporting outcomes as efficacy measures. Studies might also be considered directly comparing the efficacy and applicability of transnasal and transtympanic approaches.

Further cadaveric research would also be needed to ensure correlation with our findings. The overall safety and benefit of the transtympanic approach versus the more commonly performed transnasal remains questionable. To date, there have only been two cadaveric studies including this one looking at the safety and efficacy of the transtympanic approach, with conflicting results. This obliges further cadaveric study, ideally maintaining the principles of constant endoscopic visualization and using cadavers free of pre-existing major head trauma. Certainly, the primary objective of any future studies of this technique must be safety, with a secondary aim of demonstrating efficacy.

CONCLUSION

This study has demonstrated the feasibility and efficacy of transtympanic approach to BET in a cadaver model. No radiological evidence of trauma to the carotid canal was identified and therefore the approach was found to be safe in all cadavers in this study. The use of a dual endoscopic visualization technique provides a foundation for further study.

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