Balloon Dilation of the Eustachian Tube in a Cadaver Model: Technical Considerations, Learning Curve, and Potential Barriers

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Objectives/Hypothesis: The surgical management options for eustachian tube dysfunction have historically been limited. The goal of the current study was to evaluate the technical considerations, learning curve, and potential barriers for balloon dilation of the eustachian tube (BDET) as an alternative treatment modality.

Study Design: Prospective preclinical trial of BDET in a cadaver model.

Methods: A novel balloon catheter device was used for eustachian tube dilation. Twenty-four BDET procedures were performed by three independent rhinologists with no prior experience with the procedure (eight procedures per surgeon). The duration and number of attempts of the individual steps and overall procedure were recorded. Endoscopic examination of the eustachian tube was performed after each procedure, and the surgeon was asked to rate the subjective difficulty on a five-point scale.

Results: Successful completion of the procedure occurred in each case. The overall mean duration of the procedure was 284 seconds, and a mean number of 1.15 attempts were necessary to perform the individual steps. The mean subjective procedure difficulty was noted as somewhat easy. Statistically shorter duration and subjectively easier procedure were noted in the second compared to the first half of the series, indicating a favorable learning curve. Linear fissuring within the eustachian tube lumen without submucosal disruption (nine procedures, 37%) and with submucosal disruption (five procedures, 21%) were noted. The significance of these physical findings is unclear.

Conclusions: Preclinical testing of BDET is associated with favorable duration, learning curve, and overall ease of completion. Clinical trials are necessary to evaluate safety and efficacy.

Key Words: Eustachian tube, balloon, dilation, endoscopic, otitis media, learning curve, cadaver, surgical skills.

INTRODUCTION

Balloon dilation of the eustachian tube (BDET) has been recently introduced as an alternative treatment for eustachian tube dysfunction.1,2 Observational studies have shown that the procedure is effective in selected patients.1,3 However, the procedure has not yet been standardized. Prior cadaveric studies have shown that BDET produces significant increases in luminal volume of the eustachian tube.4 Histological examination has shown that injury to surrounding structures is not observed, a finding that is supported by radiological evaluation.4,5 However, although the feasibility of single-operator BDET has been previously explored, no studies have sought to critically evaluate the steps of the operation or the operator experience with this procedure.

The implementation of new technology often poses a challenge in moving from concept to practice. This transition requires not only the demonstration of technical effectiveness but acceptance by the intended practitioners. A major impediment to this acceptance is the perception that a procedure may be too difficult to perform or unlikely to be performed successfully.6 Therefore, the aim of the present study was to assess the ease of skill acquisition by first-time surgeons. To accomplish this goal, the procedure was analyzed as a series of sequential technical steps, which has not been previously described. Secondary aims of the study were to identify potential barriers to successful completion and to verify the mucosal changes that have been previously reported after BDET.

MATERIALS AND METHODS

This study is a prospective preclinical evaluation of the technical steps, learning curve, and potential barriers for performing BDET in a cadaver model. The procedure was performed by three independent otolaryngologists, each performing dilatation on four separate nonembalmed cadaver heads (eight total sides per surgeon). This yielded a total of 24 separate procedures. The surgeons were all right handed, were fellowship trained in rhinology, and had no significant past experience in performing the procedure.

At the onset of the study, the procedure was demonstrated to the surgeons. The nasal cavities of the specimens were cleaned prior to the study; and no prior eustachian tube
procedures had been performed on the specimens. Visualization during the procedure was performed with a 0° rigid endoscope, high-definition camera, and a monitor. Following the conclusion of the procedure, the area of the surgical site was examined with a combination of 0°, 30°, and 70° endoscopes (Fig. 1). Digital video recordings of the entire procedure and the postprocedure examinations were performed.

**Eustachian Tube Balloon Dilation Procedure**

A standardized protocol for performing the procedure was used throughout this study. The dilation was performed using the Relieva Solo Pro Balloon Catheter (7 × 16 mm), Relieva Flex Guide Catheter (F-70C), and Acclarent Inflation Device (all from Acclarent, Inc., Menlo Park, CA). Following adequate visualization, the introducer catheter is positioned immediately proximal to the eustachian tube orifice. The deflated balloon is then passed through the catheter into the eustachian tube lumen. This is done with minimal pressure and may require redirection for smooth passage. If the balloon does not pass easily, a guidewire is placed into the eustachian tube, and the balloon is passed over the guidewire. The balloon is inflated with normal saline to a pressure of 10 atmospheres for 2 minutes using the inflation device under endoscopic visualization. The balloon is then deflated, and the entire system is gently removed.

**Data Collection and Statistics**

For the purposes of the study, the procedure was divided into multiple individual steps (Table I). Independent members of the study team performed data collection including the duration of time for each step, the overall procedure time, and the number of attempts necessary to perform each step. Following completion of each procedure, the operating surgeon was asked to report any perceived barriers to performing successful completion of each step. The overall subjective difficulty of the procedure was queried based on a five-point Likert scale: 1 = easy, 2 = somewhat easy, 3 = moderate, 4 = somewhat difficult, 5 = difficult. Nasal endoscopy findings were assessed both during the procedure and on review of the procedure video by the operating surgeon. Potential barriers and complications are defined in Table I.

The data were entered onto database software (Excel 2007; Microsoft Inc., Redmond, WA). Descriptive statistics including mean, range, and standard deviation (SD) were calculated for the procedure times and the number of attempts for each step. Comparison between the first and second half of the series was made with regard to the procedure times, number of attempts, and incidence of potential complications to evaluate for possible learning-curve effect. Comparison for these measures was also made between procedures performed on the left versus right sides. The Student *t* test was used for these comparisons. Subjective procedure difficulty was reported as median, range, and SD. Comparison of the difficulty scores between the first and second half of the series and left versus right sides was performed using the Mann-Whitney *U* test.

**RESULTS**

The procedure was successfully completed in all 24 attempted trials. Endoscopic evidence of visible dilation of the eustachian tube orifice was noted following all procedures. The duration and number of necessary attempts for the different aspects of the procedure are reported in Table II. The overall mean procedure time was 284 seconds. The overall mean number of attempts to complete the individual steps was 1.15 attempts. Thirteen (54%) procedures required no repeat attempts at any step. Statistical comparison among the different steps of the procedure with regard to the number of necessary attempts revealed a statistically significant greater number of attempts necessary for step 3 (cannulation of the eustachian tube) versus each of the other individual steps (*P* = .01 for step 1 vs. 3 and step 5 vs. 3; *P* = .03 for step 2 vs. 3 and step 4 vs. 3). The rate of completion of each individual step on the first attempt was >90% for every step except step 3 (Table II). The median subjective difficulty score for the procedure was 2, somewhat easy (range, 1–5; SD, 1.3). Comparison between the first and second halves of the series revealed a statistically significant shorter duration of the procedure in the second half (337 vs. 291 seconds,
<table>
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<th>Step</th>
<th>Definition</th>
<th>Potential Barrier to Performance</th>
<th>Potential Complication</th>
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<tr>
<td>1.</td>
<td>Endoscopic visualization of eustachian tube orifice. The duration of time from the placement of the endoscope into the nasal cavity until the eustachian tube is well visualized. If the endoscope needs to be removed from the nasal cavity, then that is counted as an unsuccessful attempt. The total time of step 1 encompasses all of the attempts, not just the successful attempt.</td>
<td>Deviated nasal septum, exudates/debris, adenoid hypertrophy, obstruction from inferior turbinate, hypertrophy/position/ pathology.</td>
<td>Significant mucosal lacerations and trauma, damage to sinonasal structures.</td>
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<td>2.</td>
<td>Positioning of introducer catheter proximal to eustachian tube orifice. The duration of time from the placement of the endoscope and introducer catheter into the nasal cavity until the catheter is well positioned proximal to the eustachian tube orifice. If either the endoscope or catheter is removed from the nasal cavity, then that is counted as an unsuccessful attempt. The total time of step 2 encompasses all of the attempts, not just the successful attempt.</td>
<td>Deviated nasal septum, obstruction from torus tubarius, inferior turbinate, hypertrophy/position/ pathology, soft palate position.</td>
<td>Significant mucosal lacerations and trauma, damage to sinonasal structures, misplacement in fossa of Rosenmüller or nasopharynx.</td>
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<td>3.</td>
<td>Successful cannulation of eustachian tube. The duration of time from the placement of the introducer catheter in good position until successful cannulation of the eustachian tube by the balloon. If the catheter/balloon is misdirected or requires removal/repositioning, then that is counted as an unsuccessful attempt. The total time of step 3 encompasses all of the attempts, not just the successful attempt.</td>
<td>Unfavorable sinonasal and eustachian tube/ orifice anatomy, incorrect assessment of when to stop advancing.</td>
<td>Significant mucosal lacerations and trauma, damage to sinonasal structures, creation of false passage, inadvertent distal insertion of the balloon.</td>
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<td>4.</td>
<td>Inflation time. The duration of time from successful placement of the balloon until termination of inflation. If the balloon does not inflate or requires removal/repositioning, then that is counted as an unsuccessful attempt. This step encompasses 2 minutes of dilation time. The total time of step 4 encompasses all of the attempts, not just the successful attempt.</td>
<td>Unfavorable sinonasal and eustachian tube/orifice anatomy, over- or underinflation, displacement of the balloon at the time of inflation.</td>
<td>Significant mucosal lacerations and trauma, damage to sinonasal structures, creation of false passage, bony fracture, balloon rupture, inadequate inflation, displacement of the balloon from the eustachian tube.</td>
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<td>5.</td>
<td>Removal of balloon system. The duration of time from completion of successful inflation until removal of the entire balloon system, including the balloon, catheter and endoscope. The total time of step 5 encompasses all of the attempts, not just the successful attempt.</td>
<td>Unfavorable sinonasal and eustachian tube/orifice anatomy.</td>
<td>Significant mucosal lacerations and trauma, damage to sinonasal structures, retained balloon and introducer catheter.</td>
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The subjective barriers reported during the procedure included the position of the soft palate (three procedures), presence of obstructive nasal septal deviation (two procedures), difficulty in performing step 3 secondary to the angulation and position of the eustachian tube (seven procedures), difficulty in performing step 3 secondary to resistance within the eustachian tube (seven procedures), and kinking of the balloon during step 4 (one procedure). The use of a guidewire and a second balloon was necessary in one procedure, secondary to inability to cannulate the eustachian tube on four consecutive attempts with the balloon catheter alone.

Close endoscopic inspection of the nasopharynx, eustachian tube orifice, and eustachian tube lumen following the procedures revealed no evidence of mucosal findings in 10 procedures (42%), linear fissuring within the eustachian tube lumen without submucosal disruption in nine procedures (37%), and linear fissuring within the eustachian tube lumen with submucosal disruption in five procedures (21%) (Fig. 2). There was no statistically significant difference between the procedures where mucosal findings were noted versus those without mucosal findings with regard to procedure time, number of procedure attempts, first versus second half of the series, and subjective procedure difficulty. There were no statistically significant differences in left-versus right-sided procedures with respect to procedure time, number of attempts, subjective procedure difficulty, and mucosal findings.

### DISCUSSION

The introduction of BDET holds potential as a new treatment for eustachian tube dysfunction. At the time of this study, BDET is considered an off-label use of an existing US Food and Drug Administration-approved medical device; a standardized surgical procedure remains to be established. Because of the investigational nature of the procedure, efforts to clarify the associated technical aspects, ease of use, and potential barriers are important to better defining the procedure. We have reported the first study of the technical steps of BDET and the process that contributes to the operator experience. The findings of this study indicate that skills are readily acquired by first-time surgeons, and that a favorable learning curve is present. These findings complement previously published work that has demonstrated the feasibility and safety of BDET. Moreover, the results of this study may promote understanding of this new surgical procedure and facilitate acceptance for use in the clinical setting.

A strength of this study is the application of BDET to preclinical testing using a systematic protocol. Study data were recorded by staff independent of the three participating surgeons, and responses were recorded prospectively throughout the course of study. All work was performed in a single day in a predetermined sequence. Similar to results of previously published studies describing the learning curve for other rhinologic procedures, the acquisition of BDET appeared to be enhanced by the performance a small number of initial procedures in a systematized controlled environment with detailed analysis.

The performance of BDET was associated with a high rate of success on the initial attempt. Fifty-four percent of cases required no second attempt at any...
stage. Additionally, four of the five steps had high rates of completion on the first attempt. The third step, cannulation of the eustachian tube, was associated with a significantly greater likelihood of requiring more than one attempt for successful completions. Similarly, the third step was the most time-consuming part of the procedure, whereas the preparatory and concluding steps were relatively rapid. These findings indicate that cannulation of the eustachian tube is the most technically challenging maneuver in this procedure. Future training programs for BDET may focus on this portion of the procedure as a potential challenge to the operator. Future device and technique modifications may additionally improve the ease of this step.

Operator-perceived difficulty was generally favorable for this procedure. Each participant in this study had been exposed to a limited number of BDET procedures as an observer but had never participated as a surgeon. Despite this, favorable learning-curve findings and overall subjective ease of the procedure were noted. The aggregate results of the last four procedures performed by each surgeon showed significant improvement from the first four procedures performed by each surgeon. This included significant improvements in operative time and operator-perceived difficulty. This suggests that familiarity with other rhinologic procedures and performance of a small number of cases in a supervised training environment may be sufficient preparation for learning BDET.

The mean overall time of all attempts of the procedure was 284 seconds, or just under 5 minutes. This is comparable to other common procedures in otolaryngology practice, such as tonsillectomy and myringotomy with tympanostomy. This brief operative duration can minimize exposure to general anesthetic. Moreover, it falls well within the effective duration of common local anesthetics, which may be important if BDET is eventu-

Several barriers were identified that may contribute to the technical challenges of the procedure. These can be categorized into anatomic barriers and operational barriers. Anatomic barriers such as septal deviation, turbinate hypertrophy, and adenoid hypertrophy may require additional surgical procedures to correct, either as separate surgery or concurrent with BDET. Operational barriers such as resistance within the eustachian tube, difficulty with angulation, and catheter kinking are specific problems that may each be addressed with improved instrument design. Other operational barriers including balloon displacement, underinflation, or overinflation may be remedied through training and practice.

Endoscopic examination after BDET revealed three patterns of mucosal findings of the eustachian tube lumen. Approximately 42% of cases had no abnormal findings. Another 37% demonstrated superficial mucosal fissuring without submucosal disruption. The remaining 21% were found to have discrete fissuring with submucosal disruption. A similar observation has been previously reported after BDET in a cadaver model. The significance of these endoscopic findings is unclear, but may represent mucosal stretching, direct trauma, or an artifact specific to the cadaver model. These findings were not associated with differences in operative time, laterality, position in the learning curve, number of attempts, or operator-perceived difficulty. There were no abnormal mucosal findings noted at the torus tubarius, nasopharynx, or nasal cavity structures, suggesting that collateral injury to adjacent structures during BDET is minimal.

The use of a guidewire as a routine component of BDET is the subject of potential debate. Although it has been an essential part of the balloon dilation system for paranasal sinus procedures, its applicability to eustachian tube dilation remains to be decided. A guidewire was not routinely used in this study and was required in only one procedure. The main reasons for not using the wire routinely included the ease of performing the procedure without the wire and the absence of a reliable system for gauging the depth of wire insertion, because the wire does not possess any calibration marks. Because the inadvertent insertion of any object into the middle ear space was deemed a significant hazard, we opted instead to use the balloon catheter without any guidewire. The theoretical risk of excessive penetration by the balloon catheter is minimal given its limited length and the presence of marked calibrations. The limitation of this approach is the risk of creation of a false passage by the leading edge of the balloon catheter. Malpositioning of the introducer catheter may potentially create a trajectory that is not parallel with the eustachian tube lumen and might lead to undue mucosal trauma. However, these events are hypothetical and were not positively identified in this study. Development of a device with a calibrated or premeasured guidewire may be a useful refinement for the application of BDET, especially in cases where other operational barriers may be present.

Although the mechanism of action of BDET at the tissue level remains a matter of speculation, the present study provides a possible insight. The observation of mucosal fissuring in a majority of post-BDET specimens may support the notion that balloon dilation produces a focal fissuring of the mucosa and/or submucosa. Subsequent fibrosis and contraction during tissue healing may then lead to improved patency of the eustachian tube lumen. Additional preclinical study is needed to advance this theory beyond the realm of speculation.

The novel aspect of BDET, in contrast to historical attempts at eustachian tube catheterization or dilation,

9 is that BDET is a hybrid procedure that combines controlled catheterization with the principles of focal expansion of a stenotic lumen that have been previously applied elsewhere in the body. In contrast to traditional bougie dilation, which creates shearing forces that promote mucosal trauma, balloon dilation produces a radial force that is distributed evenly and simultaneously. For this reason, BDET may provide a safe alternative treatment modality for eustachian tube dysfunction. Clinical correlation of mucosal changes after BDET is necessary to determine the safety of this procedure.

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The present study has several limitations. Although each of the participating surgeons had not previously performed BDET, all were otolaryngologists with specialized training in advanced rhinologic techniques, which may have introduced selection bias. Additionally, the endoscopic inspection of the eustachian tube lumen was limited to postoperative examination. By definition, this could only be performed atraumatically once the eustachian tube had been visibly dilated, which occurred after all 24 BDET procedures. Attempts to manipulate the eustachian tube orifice prior to BDET, such as by retracting the torus tubarius with an instrument, would have posed the risk of producing trauma unrelated to the BDET, which may be interpreted incorrectly. Therefore, the possibility that postprocedure mucosal fissuring was present prior to BDET cannot be excluded. Similarly, the creation of a false passage by the dilation catheter was not definitely ruled out in this study, which would have required sectioning of each specimen through the entire distance of the dilated lumen after BDET. Furthermore, the assessment of operator-perceived difficulty was limited by subjectivity bias and did not use a validated instrument. Finally, the use of cadaver heads implies that certain tissue properties, such as distensibility and compliance, may differ from those observed in vivo and may limit the applicability of the physical findings from this study.

CONCLUSION

Preclinical testing demonstrates that BDET is associated with a favorable technical process, duration, and overall ease of completion. A limited learning curve is present during the initial cases, indicating that hands-on training may be important for skill acquisition prior to clinical application. Definite conclusions about the significance of postprocedure physical findings cannot be drawn at this time. Clinical testing of BDET in a controlled setting is warranted to establish safety and efficacy as a surgical procedure.

BIBLIOGRAPHY