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Balloon Catheter Dilatation of Eustachian Tube: A Preliminary Study

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Objective: Eustachian tube dysfunction is a common problem and transnasal endoscopic balloon dilation of the Eustachian tube (ET) is a new surgical technique. The goal of this study is to review the evolution of this novel technique and study the preliminary outcomes.
Subjects and Methods: Balloon catheter dilation of the 100 Eustachian tubes in 70 adults was performed at a tertiary medical center from January 2009 to January 2011. A 5-mm sinus balloon catheter was endoscopically placed transnasally into the proximal ET to dilate the cartilaginous ET. Cases were reviewed with respect to indications, outcomes, and complications.
Results: Of the 100 ETs, ear fullness and pressure were improved in 71% of patients studied for 26.3 weeks (±3.6). Of 8 patients followed for a minimum of 34 months, 87% reported persistent improvement. One complication is reported.
Conclusion: Endoscopic transnasal ET balloon dilation is a novel approach to treating ET dysfunction. Benefits can be durable up to 3 years. This technique holds much promise and merits further investigation. **Key Words:** Balloon dilatation—Eustachian tube dysfunction—Technique.

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The incidence of ET dysfunction in adults is approximately 0.9% (1); however, most otolaryngologists report a much higher prevalence in their practices. The cause of ET dysfunction includes chronic sinus infection, nasal allergy, laryngopharyngeal reflux, developmental abnormalities, enlarged adenoids, and anatomic considerations. Eustachian tube dysfunction, although not fatal, can nevertheless cause considerable and chronic discomfort, middle ear and mastoid infections, hearing loss, and possibly cholesteatoma. Conventional treatment of the middle ear does not address the underlying cause of ET dysfunction. Repeated placement of pressure equalization tubes increase risks of complications such as tympanosclerosis (2), perforation, otorrhea, retraction, and even cholesteatoma. Pressure equalization tubes are also susceptible to extrusion, crusting, and obstruction, and myringotomy alone is transient. To address the ET directly, other techniques to widen the osseous portion have been described (3–5).

Others have recently attempted dilating the ET with a specially designed balloon catheter within a modified microendoscope (6) or performing laser resection of the proximal ET tissue (7).The transnasal approach to the ET requires the ability to visualize the ET orifice well, anesthetize the nasal mucosa, and if being done in the office setting, to anesthetize the mucosa within the lumen of the ET itself. Our study reported herein describes the evolution of a technique for balloon catheter dilation of the ET in the operating room and the first to do so in the office settings using commercially available instruments with the goal of examining the technique, indications, and outcomes in a symptomatic and refractory adult population.

METHODS

Patient Selection

During the period from January 2009 to October 2011, balloon catheter dilation of the ET was offered as a unilateral or bilateral procedure to 70 adults older than 18 years who reported a chronic sensation of ear fullness, pressure, pain, and otitic barotrauma (None of our study patients had a history of ET dysfunction since childhood but rather developed this condition during their adult years. All patients were screened for temporomandibular joint disease and early hydrops before being enrolled, as it is possible for either of these conditions to present with otologic complaints similar to pure ET dysfunction. Forty unilateral and 30 bilateral procedures were performed, for a total of 100 cases of ET dilation. For data analysis, each case of ET dilation was treated as a single data point. Concurrent otologic or sinonasal procedures were performed if indicated. If ET dilation was the only procedure being performed, the clinic setting was

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most appropriate using localized topical anesthesia. General anesthesia was used when concurrent nasal or otologic procedures were also performed. Approval for this study was obtained from the institutional review board.

Technique

Figure 1 shows the instruments used in this procedure. A rigid 0-degree nasal endoscope was used to examine the nasal cavity to evaluate for a septal deviation. If present, this would require the procedure be done in the operating theater, possibly with a concurrent septoplasty. If performed in the clinic, a series of 3 sprays each of topical 0.05% oxymetazoline followed by 1% lidocaine was used to anesthetize the nasal mucosa and reduce inferior turbinate tissue bulk to improve access to the posterior nares. Anesthesia of the ET lumen was found to be crucial to patient tolerance and was achieved by endoscopically passing an F-70 guide catheter (Acclarent, Menlo Park, CA, USA) transnasally into the posterior nares. Visualizing the ET orifice with a 30-degree endoscope, a soft, flexible Relieva Vortex (Acclarent) sinus irrigation catheter was inserted through the guide catheter into the pharyngeal orifice of the ET for a distance of 15 mm. An assistant then injected 1.5 ml of 2% lidocaine gel through the Vortex catheter as it was simultaneously withdrawn from the ET to topically apply the gel along the proximal length of the ET lumen. A minimum of 5 minutes was required for the ET mucosa to be adequately anesthetized before the ET dilation was performed. Patients undergoing concomitant procedures underwent general anesthesia and did not receive topical lidocaine gel.

After local or general anesthesia, the F-70 guide catheter tip was then placed transnasally with a 30-degree endoscope into the posterior nares and rotated so that the catheter tip was flush with the ET's pharyngeal orifice and angled parallel to the long axis of the ET (Fig. 2). This angle was typically between 45 and 60 degrees from horizontal and toward the target ear. The same guide catheter was then used to place a 5-mm wide and 16-mm long balloon catheter (Acclarent) through the pharyngeal orifice into the cartilaginous portion of the ET. It is critical that this be done gently and under direct vision to avoid injury to the ET mucosa. If the balloon catheter does not pass easily, it is recommended that the angle of insertion be changed accordingly and the endoscope be used to look into the ET orifice as the balloon is being passed to determine the best angle for insertion.

The balloon catheter was initially dilated to only 6 atm of pressure in 5 ears because of patient tolerance. Once the anesthetic technique for the ET mucosa was improved, 20 ears tolerated dilation to 8 atm for 10 seconds (Fig. 3) and the remainder for 30 seconds. All instruments were then removed from the patient, and the ET was reexamined for signs of trauma. In our opinion, there should be no blood on the balloon catheter or at the ET orifice if the procedure is being carried out properly. The presence of blood suggests disruption of the ET mucosa, which was seen in only the one reported complication in this series.

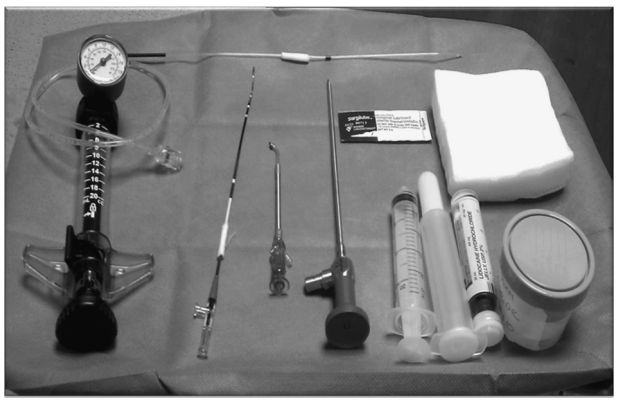

FIG. 1. Instruments used in balloon catheter dilation of ET.

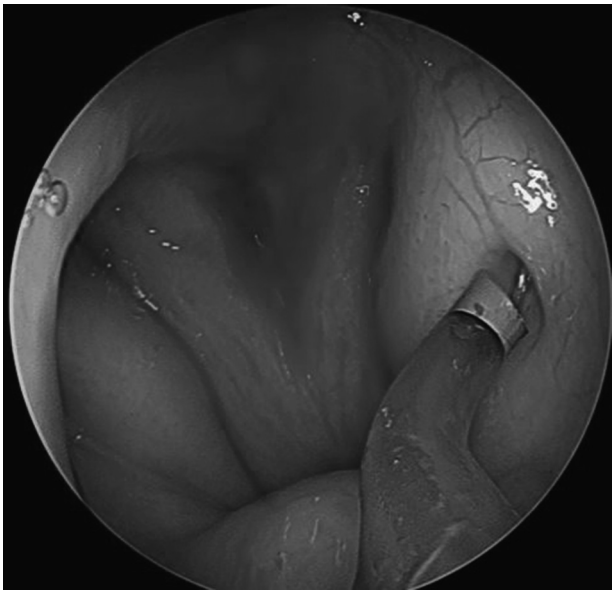

FIG. 2. The guide catheter is positioned at the ET pharyngeal orifice.

Study Design

Patients were seen initially at 4 weeks after the procedure and then at 3-month intervals for as long as possible. Changes in their sensation of ear fullness, pressure, pain, and tolerance to air

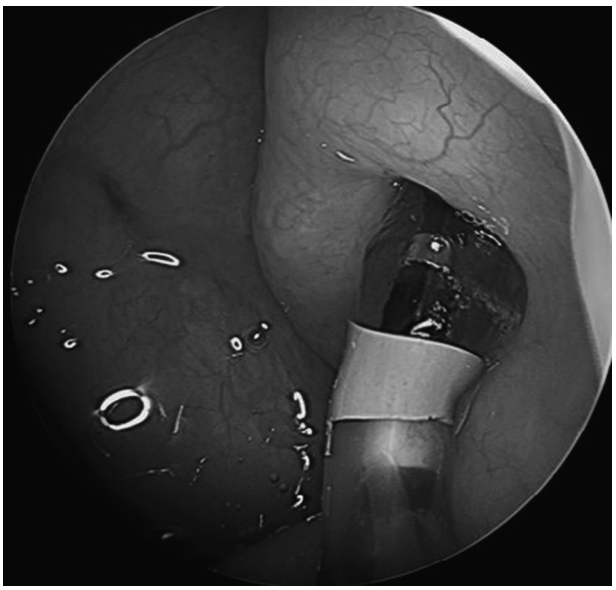

FIG. 3. The balloon catheter is dilated in the ET pharyngeal orifice.

travel, as well as any visible alteration in the appearance of the TM, was recorded at each clinic visit. Preoperative tympanograms were obtained in every patient and only repeated postprocedure if they were abnormal preprocedure or there was a new clinical reason to do so.

RESULTS

The average age of the study group was 45 years with the ages ranging from 18 to 73 years. Forty-seven percent procedures were on the left; 53% of procedures were on the right. Sixty-two percent of patients were female subjects, and 38% were male subjects. Sixty-three percent underwent general anesthesia for concomitant procedures, and 37% received only topical anesthesia in the office setting.

Five patients underwent concomitant otologic procedures, and 3 (60%) of 5 ears showed improvement. Thirty-nine patients underwent concomitant sinonasal procedures, which represented 54 ears; of these, 36 (67%) of 54 showed improvement. Twenty-six patients underwent ET dilation alone, which represented 41 ears; of these, 30 (73%) of 41 patients showed improvement. Thus, overall, 71 (71%) of 100 ears showed notable improvement or reduction in symptoms. Patients were followed for an average of 30.3 weeks (±3.6), with some as long as 34 months. Of the 8 patients followed for a minimum of 34 months, 7 of 8 reported persistent improvement. Sex and anesthetic technique were not significant factors in outcomes of ET dilation. Tympanograms were abnormal (type B or C) in 28 ears and improved to type A in 25 (90%) of 28 ears.

Four of the original 5 ears treated had good results after only a short dilation (5 s); however, the results were not durable, and the procedure was eventually repeated in the office setting using the newer protocol, which included a 30-second dilation. Overall, 7 ears (10%) that initially improved required a second dilation to maintain clinical benefit; 4 of 7 were in our early experience using a shorter dilation time. In this study, once an ear responded to dilation, it also responded to any subsequent dilation with increased durability. However, if an ear failed to respond to an initial dilation, it also failed to respond to any subsequent dilation using the same-sized balloon catheter.

One patient undergoing bilateral ET dilation concurrent with endoscopic sinus surgery had a difficult balloon insertion on the left side. She had no immediate postoperative complaints, no otalgia, and normal ear examination in the recovery area. On post-op day 2, she noted preauricular emphysema that was limited to the ipsilateral parotid region and still without any otalgia or other symptoms. She was instructed to discontinue nasal saline irrigations and nose blowing for the next 4 days. The subcutaneous emphysema resolved spontaneously within 48 hours, and she remains free of ET symptoms after 9 months.

DISCUSSION

The development of nasal endoscopes has introduced transnasal approaches to examining and potentially treating ET dysfunction. A flexible endoscope has been used to insufflate air into the pharyngeal lumen in an attempt to insufflate the ET and middle ear (8,9). Various methods of laser Eustachian tuboplasty have also been described. Poe et al. (7) followed patients the longest, with 8 patients at 2 years and reported 38% of middle effusions resolved. In Yanez's (10) technique of laser-assisted cross-hatching, 92% of 25 patients reported improvement in ear blockage at 15 months. Sedlmaier et al. (11) reported that 68% of 38 patients demonstrated positive effects 8 weeks after a laser ET procedure. However, laser technology is not readily available to ENT surgeons and increases the risk of injuring critical structures such as the internal carotid artery and ET mucosa resulting in synechiae and/or functional ET compromise. Catastrophic internal carotid injury has been described in patulous ET procedures (12). The advent of sinus balloon catheters has introduced a novel minimally invasive approach and has been shown not to cause carotid injury in cadaveric and human studies (6,8).

It is our hypothesis that the mechanism of effect of ET dilation involves causing multiple microfractures of the cartilaginous ET and altering/loosening of the corresponding connective tissue architecture, thus decreasing the ET's minimal opening pressure and allowing pharyngeal muscles to more easily open the ET. Accidental creation of a patulous ET has not been reported nor would it be expected. Other mechanisms not addressed by ET dilation, such as a proliferation of soft tissue around the pharyngeal ET orifice, may also play a role and explain why some patients do not benefit from this technique. Another mechanism includes a dysfunctional neuromuscular mechanism of the tensor veli palatini and levator veli palatini muscles, as is seen in childhood. Of note is that none of our study patients had a prolonged childhood history of ET dysfunction. Thus, the various possible mechanisms of ET dysfunction suggest that careful patient selection may improve success rates for ET dilation, an interesting and important area for further exploration.

The proper balance or best combination between dilation pressure, balloon diameter, and dilation time has yet to be determined for each potential indication or subpopulation for this procedure. Anecdotal reports from other physicians cite the 6- and 7-mm diameter balloons as being effective (6,8). Our concern has always been patient safety, and in our experience, the balloon used for dilation should not have any blood on it when it is extracted from the ET after the procedure. This ensures an atraumatic procedure and would help avoid the one reported complication in our series of subcutaneous emphysema of the ipsilateral cheek. Although this complication was self-limited, it highlights the possible risks of the procedure and why, in our opinion, use of larger balloons may pose an increased risk to the patient.

Further studies may determine if longer inflation times and larger balloon sizes may be of benefit in ears not improving after initial dilation. Ockermann et al. (6), using custom instrumentation, demonstrated significant improvement of ET scores after ET dilation following 13 cases over 8 weeks. In comparison, our study used instruments

commercially available to otolaryngologists and followed a larger sample of 70 patients over an average of 30 weeks with initial patients reporting benefits even after 34 months. The technique described herein is minimally invasive, generally well tolerated, and resulted in only 1 self-limited but potentially serious complication. Limitations of this study, which may be addressed in the future, include the lack of conclusive objective data and control groups, a validated instrument to better measure subjective outcomes, and impact of concomitant procedures. With respect to the latter, our results show no statistical difference between those patients undergoing ETD alone versus when combined with nasal and sinus surgery. ETD seems best for those who complain of ear pressure and fullness, especially if exacerbated by changes in atmospheric pressure such as with weather change, elevation change, or air travel, even if the tympanogram is normal.

Because this was a preliminary study, patient enrollment was initially quite liberal as different cohorts were included to help refine the eventual indications and develop the technique. In addition, evaluation of ET dysfunction is currently poorly developed and not standardized. Possible explanations for aural symptoms with normal tympanograms include temporomandibular joint dysfunction, early hydrops, and a new condition termed *ET squeeze*. Patients in this study were screened for TMJ disorders and hydrops by history and examination but, depending upon several factors, could have been misdiagnosed. Eustachian tube squeeze refers to a concept based on principles of referred pain whereby sensory feedback is presented to the brain from 2 distinct anatomic areas along the same sensory network. In this case, it would involve sensory nerves within the middle ear and along the length of the ET lumen. Increased muscle tone or mucosal contact within the ET might be perceived by the brain as uncomfortable pressure or fullness in the middle ear despite normal tympanograms. If correct, this phenomenon is responsible for many unnecessary myringotomies and PE tube insertions in adults who have these very complaints and are refractory to medical management. In our study, this group of patients faired best from ETD, lending further credance to this clinical entity. The study limitations include liberal inclusion criteria, absence of a separate control group, and the possibility for placebo effect. The authors felt that patients would be able to serve as their own controls in this preliminary study. The possibility of placebo effect is always important to consider, and although it may have occurred in this study, the length of follow-up would minimize its potential as it is unlikely for placebo effect to last 30 weeks, which is the average follow-up of the study cohort.

This study also established the feasibility of performing this technique using topical anesthesia in the outpatient clinic setting. This allows for efficient use of health-care resources, patient convenience, and the possibility of repeated dilations without the risks and costs of a general anesthetic. This technique holds promise for improving outcomes of ET dysfunction with minimal risk in both the operating theater and outpatient clinic.

CONCLUSION

Balloon catheter dilation of the ET as described herein is a safe procedure that offers relief of middle ear pressure, aural fullness, and otalgia in 71% of ears treated. The procedure can be performed in both the clinic and operating room using either local or general anesthesia. Durability of results was exceptional and equals or exceeds those reported after myringotomy and PE tube placement minus the associated risks of the latter. Our study shows that Eustachian tube dilation can be safely performed with the current commercially available sinus balloon dilation systems, but further refinements in the technique and corresponding tools are anticipated and warranted.

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