Balloon Dilation of the Cartilaginous Portion of the Eustachian Tube
Juha Silvola, Ilkka Kivekäs and Dennis S. Poe
Otolaryngology -- Head and Neck Surgery 2014 151: 125 originally published online 4 April 2014
DOI: 10.1177/0194599814529538

The online version of this article can be found at:
http://oto.sagepub.com/content/151/1/125

Published by:
SAGE
http://www.sagepublications.com

On behalf of:
AMERICAN ACADEMY OF
OTOLARYNGOLOGY--
HEAD AND NECK SURGERY

American Academy of Otolaryngology- Head and Neck Surgery

Additional services and information for Otolaryngology -- Head and Neck Surgery can be found at:

Email Alerts: http://oto.sagepub.com/cgi/alerts
Subscriptions: http://oto.sagepub.com/subscriptions
Reprints: http://www.sagepub.com/journalsReprints.nav
Permissions: http://www.sagepub.com/journalsPermissions.nav
Balloon Dilation of the Cartilaginous Portion of the Eustachian Tube

Juha Silvola, MD, PhD1,2, Ilkka Kivekas, MD, PhD3,4, and Dennis S. Poe, MD, PhD3

Abstract

Objective. Studies of balloon Eustachian tuboplasty (BET) have shown encouraging results in small series with short follow-ups. Our pilot study suggested that patients with protracted otitis media with effusion (OME) or atelectasis of the tympanic membrane (TM) could benefit from BET.

Study Design. A prospective study where subjects act as their own controls. Patients from the pilot study and additional cases were enrolled in this cohort with long-term follow-up.

Setting. Regional Academic Center.

Subjects and Methods. Out of 80 patients who underwent BET, 41 consecutive Eustachian tube (ET) operations were included. Subjects’ inclusion criteria were OME and/or TM atelectasis, type B or C tympanograms, and inability to inflate their middle ears by Valsalva maneuver. All patients had longstanding ET dysfunction relieved only by repeated tympanostomies. Outcomes included ability to perform a Valsalva maneuver, audiometry, tympanometry, videoendoscopy of the ET with mucosal inflammation rating scores, and otomicroscopy.

Results. All cases were dilated successfully, without significant complications. Mean follow-up was 2.5 years (range, 1.5-4.2 years). Eighty percent (33/41) could do a Valsalva maneuver postoperatively; none of these ears required new tympanostomy tubes and subjective symptoms were relieved. Tympanometry results showed overall improvement. Nine patients had persistent perforations and 3 declined removal of the tube. Subjective symptoms were not relieved for 10% (4/41).

Conclusion. The results show that BET can effectively improve ET function in ears with OME or atelectasis. The procedure is well tolerated and without significant complications. The follow-up continues and we are investigating possible reasons for failures.

Keywords

Eustachian tube, balloon dilation, secretory otitis media

Received October 7, 2013; revised February 27, 2014; accepted March 7, 2014.

Introduction

Chronic dilatory dysfunction of the Eustachian tube (ET) may lead to significant problems within the middle ear.1 The prevalence of ET dysfunction is estimated to be roughly 1% of the adult population.2 Optimal conservative treatment of potential underlying disease should be done. In a recent randomized, placebo-controlled trial, steroid nose spray failed to show improvement in ET dilatory dysfunction symptoms versus placebo.3 Myringotomy and tympanostomy tubes have been for decades the only treatment for persistent ET dysfunction.

At the end of the 1990s, Kujawski4 described a laser Eustachian tuboplasty, where inflamed ET mucosa was removed with a laser, and later, Metson et al5 described a microdebrider-assisted tuboplasty. Long-term follow-up results have shown that 65% to 70% of patients were symptom-free after 1 year.5,6 Recently, balloon dilation of the cartilaginous ET has shown encouraging results. Ockermann et al7 described improvement in tubomanometer scores in all 8 patients with 2-month follow-up. Poe et al8 described improvement in Valsalva maneuver in all 11 patients with 6-month follow-up. Schroeder et al9 described improvement in tympanometer scores in all 20 patients with 12-month follow-up. McCool and Anand10 described 35 cases with 6-week follow-up data including tympanometry and clinical outcomes.
with 3-month follow-up data for 26 cases including a new symptom-specific instrument for ET dysfunction (ETDQ-7). In these studies, the preoperative middle ear status, balloon diameter, follow-up time, and follow-up outcome measures have been variable.

The purpose of this study is to present longer term follow-up data from pilot study and subsequent patients with long-standing otitis media with effusion (OME) or atelectasis and previous tympanostomy tubes.

**Materials and Methods**

This prospective study of 42 consecutive balloon Eustachian tuboplasties (BETs) (37 patients) was conducted in the ENT outpatient department at the Päijät-Häme Central Hospital, Lahti, Finland, between 2009 and 2012. The mean age for the patients was 48 (range, 15-38) years with even sex distribution. The mean follow-up was 2.5 (range, 1.5-4.2) years. The study design was approved by the ethical review board of the Pirkanmaa hospital district (Tampere University Hospital), and informed consent was obtained from all participants. All patients were operated on by the first author. Inclusion criteria were unilateral or bilateral persistent OME or significant nonadherent tympanic membrane atelectasis for at least 5 years and postoperative follow-up of at least 1.5 years. Patients for 42 of 80 consecutive operations fulfilled all the criteria. One case was lost to follow-up. Most of the patients had undergone several tympanostomy tubes. Conservative treatment was administered in every case before surgery was offered and all patients had a trial of intranasal corticosteroid spray administered from the date of enrollment, which was on average 1 month preoperatively. Patients who failed to improve were candidates for surgery and steroid spray was continued postoperatively for 1 month. Sixteen cases (16/41, 39%) had associated chronic rhinitis and/or sinusitis (with or without nasal polyps) that were treated with longer courses of nasal steroids as indicated. Patients with reflux symptoms were referred for gastroenterological consultation.

None of the patients could perform a Valsalva maneuver despite an attempted dilation with a Politzer insufflation and careful coaching in the technique. Antonio Valsalva originally described his maneuver as a self-induced effort to insufflate air into the middle ear through the Eustachian canal. The Politzer maneuver was initiated the ability to perform a Valsalva maneuver even with complete failure of tubal opening), as previously described rating scale (1 = normal, 2 = mild inflammation, 3 = moderate with compromise of tubal opening, 4 = severe with complete failure of tubal opening), as previously described.

Temporal bone high resolution computed tomography (CT) scans with axial and multi-planer reconstructions were obtained for all patients to measure the dimensions of the bony and cartilaginous ET. The CT scans were also used to evaluate anatomical anomalies of the ET or cranial base.
dehiscence of the internal carotid artery into the tubal lumen, and possible sinonasal disease.

Statistical analyses were calculated using SPSS for Windows (SPSS, Inc, Chicago, Illinois, USA). McNemar test with matched pairs of cases was performed using a \( P < .05 \) as the significance limit for effusion, tympanometry, and Valsalva maneuver results. Two-tailed paired \( t \) test was performed using a \( P < .05 \) as the significance limit for Eustachian tube inflammation scores.

Results

The results are summarized in Table 1 (see also Supplemental Table S1, available at www.otojournal.org). The overall success rate for all patients was 80% (33/41 ears), which was defined by the positive ability to perform a Valsalva maneuver. This was a highly significant difference from the preoperative measure of inability to perform a Valsalva in all cases (\( P < .0001 \), McNemar test).

Type A tympanogram was present in 79% of cases (23/29 ears, \( P < .0001 \), McNemar test). No patients had type B tympanograms and 21% (6/29) had type C tympanograms. Tympanometry results B and C were considered as negative and A as positive in Table 1. If there was a tympanic membrane perforation or tympanostomy tube still present at the last office visit, the case was excluded from tympanometry analysis. There were 12 such cases, leaving 29 ears with closed tympanic membranes.

Nine ears (9/41, 22%) had a persistent perforation for more than a year postoperatively. Two of these had positive Valsalva and are awaiting myringoplasty. Three ears (3/41, 7%) still had a tympanostomy tube, of which 1 patient was able to perform a Valsalva. Tympanometry in cases with an open tympanic membrane showed a type B tympanogram with a large volume (open) result. These 3 patients declined removal of the tube and are awaiting possible spontaneous extrusion. Inability to do a Valsalva 1 month postoperatively correlated with negative Valsalva during follow-up.

One patient with a relatively short cartilaginous ET (26 mm) failed to gain the ability to do a Valsalva. Computed tomography scan showed a patent bony ET, and the patient accepted a second operation with a thinner 3.5 \( \times \) 10 mm balloon followed by successful Valsalva ability. Three patients had bilateral sequential BETs with several months’ interval between their procedures.

Eight patients failed to perform a Valsalva at any time postoperatively. Four of these 8 (4/41, 10%) included the patients who failed to have any subjective relief in their symptoms. These 4 patients were additionally investigated with Technetium scintigraphy, with the same procedure as used for mucociliary flow studies in maxillary sinuses.13 These patients received Technetium combined with Trypan blue through the perforation or the tube, into the middle ear, and the patients were monitored with scintigraphy and live videoendoscopy of the ET orifice in the nasopharynx. None of the patients had any passage of the Technetium or Trypan blue from the middle ear during the 30-minute procedure. These patients were then informed that it is possible to evaluate the ET and middle ear under anesthesia. All consented to the procedure. The CT scan of 1 patient showed a dehiscent internal carotid artery in the middle ear and he was excluded from further procedures. The 3 remaining patients underwent a new procedure with an exploratory tympanotomy and endoscopy of the middle ear using a 1.9-mm, 30-degree endoscope (Karl Storz, Tutlingen, Germany). The bony ET was found to be narrow. A guide wire (tip diameter 0.9 mm) was introduced from the middle ear into the ET, and in each case,
it was met with obstruction to passage at a distance corresponding to the bony isthmus or bony-cartilaginous junction of the ET. The wire was also introduced from the cartilaginous ET but it again stopped in the bony isthmus or junction. All of these patients had a short cartilaginous ET (22-25 mm).

In 16 cases, the ear symptoms were associated with nasal pathology. Three of the patients with negative Valsalva ability had chronic sinusitis and/or nasal polyps (3/8, 38%). Thus, nasal pathology had a nonsignificant effect on BET results ($P = 1.00$, Fisher’s test).

There was significant ($P < .0001$, 2-tailed paired $t$ test) improvement in the mucosal inflammatory rating scores with preoperative values of 23 out of 41 patients having grade 3 or 4 (moderate or severe) inflammation preoperatively, compared with postoperative results of 5 out of 41. This improvement is illustrated in Figures 2A and 2B.

The length of the cartilaginous part of the ET showed significant variation. The maximum length was 32 mm and the minimum length was only 20 mm, as measured both by CT and by the depth of balloon insertion. The length of the cartilaginous part of the ET appeared to correlate with the rate of surgical success. Seven of the 8 patients with negative Valsalva had a short cartilaginous ET ($< 26$ mm, $P < .003$, 2-tailed $t$ test). The procedure was noted to be technically more difficult if the cartilaginous ET were short in that the balloon had an increased tendency to extrude out of the short ET and had to be manually maintained in position by propping the guide catheter against the nasal floor to prevent extrusion.

**Discussion**

There is no generally accepted hypothesis to explain the benefits for BET. We have formulated hypotheses based on our experiences and observations. Postoperatively, the lumen of the ET appeared wider and with reduced inflammation. The larger lumen can facilitate improving the function of the tensor veli palatini (TVP) muscle. The reduction in inflammation may be due to crushing of irreversibly injured mucosa and submucosa, allowing for healthy regrowth of tissue if the underlying etiological conditions have been controlled. The significant improvement in the ET mucosal inflammation score supports the hypothesis that inflammation within the cartilaginous ET plays an important role in ET dysfunction. Some adhesions within the lumen were observed and the balloon appeared to lyse these adhesions.

The Valsalva maneuver served as more than a test of ET function. It played an important role in initiating dilation of the ET in many cases. Most patients were initially either

**Table 1. Preoperative Findings and Postoperative Results.**

<table>
<thead>
<tr>
<th>Clinical findings</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal, No. (%)</td>
<td>0 (0)</td>
<td>37 (90)</td>
<td>&lt; .0001(^a)</td>
</tr>
<tr>
<td>Effusion, No. (%)</td>
<td>38 (93)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Retraction/atelectasis, No. (%)</td>
<td>3 (7)</td>
<td>3 (7)</td>
<td></td>
</tr>
<tr>
<td>Eustachian tube inflammation scale (1-4)</td>
<td>2.8 (1.2)</td>
<td>1.4 (0.8)</td>
<td>&lt; .0001(^b)</td>
</tr>
</tbody>
</table>

**Tymanometry**

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A, No. (%)</td>
<td>1 (2)</td>
<td>23 (56)</td>
<td>&lt; .0001(^a)</td>
</tr>
<tr>
<td>B, No. (%)</td>
<td>6 (15)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>C, No. (%)</td>
<td>10 (24)</td>
<td>6 (15)</td>
<td></td>
</tr>
<tr>
<td>B/open (tympanic membrane perforation or tympanostomy tube), No. (%)</td>
<td>24 (59)</td>
<td>12 (29)</td>
<td>&lt; .0001(^a)</td>
</tr>
</tbody>
</table>

**Valsalva maneuver**

<table>
<thead>
<tr>
<th></th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive, No. (%)</td>
<td>0 (0)</td>
<td>33 (80)</td>
<td>&lt; .0001(^a)</td>
</tr>
<tr>
<td>Negative, No. (%)</td>
<td>41 (100)</td>
<td>8 (20)</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)McNemar test.

\(^b\)2-tailed, paired $t$ test.

**Figure 2.** (A) Left Eustachian tube nasopharyngeal orifice, 45-degree 4-mm endoscope view. Pre-balloon dilation, resting position. Mucosa is moderately inflamed on the posterior cushion with some edematous redundant mucosal folds protruding into the lumen at its midpoint. There is mild “cobblestoning” of the mucosa over the posterior cushion. The mucosa of the lumen appears otherwise normal. (B) Two months post-balloon dilation, resting position. Mucosa within the lumen is thinner, and the bulk of the mucosal folds on the luminal side of the posterior cushion is significantly reduced. There is a much deeper view into the valve region of the lumen compared to pre-dilation.
afraid to attempt the Valsalva or lacked an understanding of how to perform it. It was important to train the patients preoperatively in how to perform the maneuver. Postoperatively, the Politzer maneuver appeared to help patients understand what they should gain from the Valsalva, and they were subsequently more likely to perform the maneuver successfully. A tympanostomy tube for the first postoperative month facilitated the patients to start Valsalva training without fear of pain.

There was a lack of correlation between treatment results and presence or severity of nasal pathology despite such a correlation having been previously observed. All patients received nasal corticosteroids 1 month pre/postoperatively, which could be expected to have only a short-term effect on results. It is possible that the effects of the balloon dilation were sufficiently efficacious that they remained protective despite ongoing sinonasal disease.

The balloon should slide easily and unimpeded into the tubal lumen, but during the introduction of the balloon into the ET, it was sometimes met with earlier-than-expected resistance. It is important to assess such a situation carefully, never forcing the catheter against resistance. The catheter can easily become impacted against the mucosa, risking penetration and creation of a false passage with undue force. In such cases, the angle of introduction can be adjusted and careful reintroduction of the balloon catheter attempted. In its final position of insertion, the balloon was usually allowed to slightly extrude during inflation. Safety with this new procedure remains an important consideration. Surgeons should become thoroughly familiar with the surgical anatomy of the ET and be aware of the location of the internal carotid artery (ICA).

The preoperative CT scans were important for determining the expected length of the cartilaginous ET and to rule out aberrancies or bony dehiscence of the ICA. It was important to know in advance the length of the cartilaginous part of the ET, in order to know whether the balloon had reached the expected depth of the isthmus. Dilation should not be performed in the bony portion, as it would risk injury to the ICA.

There was a correlation between a short cartilaginous ET and failed balloon dilation results. One hypothesis, consistent with that proposed by Bluestone, could be that a short tube may be more prone to reflux of pathogens or other material from the nasopharynx that could induce inflammation within the ET or middle ear. In addition, a short tube might be associated with weaker TVP muscular function. Without a CT scan, it is difficult to know if meeting early resistance comes from contact with the isthmus or some other reason. The balloon tended to extrude more easily from a short cartilaginous ET. Further studies are needed to show if a short cartilaginous ET is simply more difficult to dilate with this balloon or if there are other reasons for poorer results.

High resolution CT may not adequately reveal an obstruction within the lumen of the bony portion of the ET. There was a 10% prevalence of obstruction within the bony portion in this small series. Bony obstructive lesions should be excluded from the balloon treatment. Further study is indicated to better identify this situation preoperatively.

There were several limitations to this study. It is a relatively small series without external control cases. However, these patients had particularly long-lasting ET dysfunction that strongly supported the use of their historical performance as a control. The duration of inflation and the inflation pressure were selected based on an estimate and without any comparative data, and the parameters were borrowed from sinuplasty studies. The mucosal inflammation rating scale has been used in previous reports and appears to be reasonably reproducible. We are currently working on validating the scale. Although the scores were obtained by a blinded reviewer for the pilot study, the subsequent scores were obtained by the operating surgeon, introducing some potential for bias. However, the scale is simple and the significant difference noted in the results appears to exceed the potential for influence by bias. Valsalva is known to be an inconsistent measure of ET function, but it appeared to closely correlate with patients’ estimation of their success, and we have continued to find it useful to follow this outcome. Twelve ears persisted with a perforation or tube at the time of the last follow-up, so the objective results could not be judged in these cases. However, there were significant improvements in the most objective measurement, tympanometry, which supported the evidence for benefit of this procedure.

Conclusion

These results support the findings from our pilot study, with an overall success rate of 80%, and the benefits appeared durable over time.

Balloon Eustachian tuboplasty was found to demonstrate efficacy, in a prospective study with moderately long-term follow-up, in improving aeration of the middle ear and ability to perform a Valsalva maneuver. Patients with presumably irreversible disease, but having had their underlying etiology adequately managed, appear to be candidates for the procedure. There were no significant complications, suggesting an encouraging promise for establishing a reasonable safety record with the procedure. Studies with controls and studies of the mechanisms of effects of balloon dilation are needed.

Acknowledgments

The Päijät-Häme Hospital District, Central Hospital, made this study possible with a positive attitude and support toward new surgical treatments. The authors would like to extend their sincere appreciation to Tali Rasooly, MS, for her contributions in reviewing and editing the manuscript.

Author Contributions

Juha Silvola, study design, data collection, primary surgeon for all cases, data review; Ilkka Kivekäs, study design, data review and analysis, review of manuscript; Dennis S. Poe, study design, data review and analysis, review of manuscript.
Disclosures

Competing interests: Dennis S. Poe is a consultant for Acclarent, but compensation for time has been donated to departmental research, exclusive of Dr Poe’s research activities. Dr Poe receives no direct benefit or compensation from any proceeds from Acclarent.

Sponsorships: None.

Funding source: None.

Supplemental Material

Additional supporting information may be found at www.otojournal.org/supplemental

References