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What is This?
Balloon Dilation of the Cartilaginous Eustachian Tube

Dennis S. Poe, MD1,2, Juha Silvola, MD, PhD3, and Ilmari Pyykkö, MD, PhD1

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

Objectives. (1) To translate techniques developed in a previous cadaver study of balloon dilation of the cartilaginous eustachian tube (ET) into clinical treatment for refractory dilatory dysfunction and (2) to study the safety/efficacy of the technique in a pilot clinical trial.

Study Design. Prospective with subjects as their own historical controls since June 2009.

Setting. Regional academic center.

Subjects and Methods. Eleven consecutive adult patients with longstanding otitis media with effusion (OME) who were unable to autoinsufflate their ET by Valsalva, swallow, or yawn and who had previous tympanostomies (average, 4.7). At the time of intervention, 5 of 11 had a tube; 2 of 11 had a tympanic membrane (TM) perforation. Four of 11 had intact TMs, 2 with OME and tympanogram type B and 2 with TM retraction and tympanogram types B and C. Balloon dilation of the cartilaginous ET was performed with sinus dilation instruments via transnasal endoscopic approach under general anesthesia in a day surgery setting. Inflation was to a maximum of 12 atm for 1 minute. Outcome measures: ability to Valsalva, rating of ET mucosal inflammation, tympanogram, and otomicroscopy findings.

Results. All cases successfully dilated. Eleven of 11 could self-insufflate by Valsalva (P < .001); tympanograms were A (4/11), C (1/11), or open (6/11). All atelectases resolved. Procedures were well tolerated, without pain or complications related to dilation.

Conclusion. Dilation of the cartilaginous ET appeared to be beneficial and without significant adverse effects in the treatment of ET dilatory dysfunction. Larger controlled trials with long-term results are now justified and needed.

Keywords

otitis media, OME, eustachian tube dysfunction, balloon dilation

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Methods

Hypothesis

Sinus balloon dilation catheters could be adapted to safely and effectively dilate the cartilaginous portion of the ET in patients with chronic OME.

Aims/End Points

1. To evaluate the effectiveness of using a balloon for dilation of the cartilaginous portion of the ET in patients with chronic OME.
2. To evaluate the safety of the dilation procedure with an analysis of any potential adverse effects.

Outcomes included the ability to self-insufflate air through the ET with a Valsalva maneuver, rating of mucosal inflammation at the tubal orifice as seen by endoscopy, otomicroscopic findings of OME/TM retraction/normal, and tympanogram curve types A/B/C.

Patient Selection

Patients with unilateral or bilateral persistent OME for ≥5 consecutive years, broken only by tympanostomy tubes or tympanic membrane (TM) perforation, were evaluated as candidates for ET surgery. None of the subjects could insufflate their ears with a Valsalva maneuver. Otomicroscopy and tympanometry were done bilaterally. Video rigid or fiberoptic endoscopy of the eustachian tube with slow-motion review demonstrated mucosal inflammation as the predominant finding, indicating dilatory dysfunction of the ET as opposed to dynamic (muscular) dysfunction. The techniques for endoscopic examination and a scoring system for rating mucosal inflammation have been previously reported.9 The mucosal inflammation score was modified to separate mild and moderate disease. The score consisted of 1 = normal mucosa; 2 = mild edema and/or erythema, with or without increased mucus; 3 = moderate edema and erythema with significant compromise of dilation of the lumen during swallows and yawns; and 4 = severe edema and erythema with inability to dilate the lumen open. Preoperative high-resolution computed tomography (CT) scans were obtained to rule out anatomical anomalies of the ET or cranial base and dehiscence of the internal carotid artery into the tubal lumen.

Candidates for surgery were offered the option of continuing their current management or undergoing a procedure consisting of unilateral balloon dilation of the cartilaginous ET. In the case of bilateral disease, the side with the worst ear pathology was selected.

Informed consent was obtained, and the protocol was approved by the Ethical Committee (equivalent to a US institutional review board) for the Päijät-Häme Central Hospital, Lahti, Finland (Balloon Dilation of the ET R09054). All cases were performed by the second author at that teaching hospital.

Surgical Technique

Patients were induced and maintained under general anesthesia with endotracheal intubation in the supine position.

Topical oxymetazoline hydrochloride decongestant was applied to the nasal cavities. A 30-degree Hopkins rod endoscope (Karl Storz, Culver City, California) was introduced through the ipsilateral or contralateral nasal cavity (Figure 1). Video images were displayed on a monitor (Karl Storz, Tuttingen, Germany).

The sinus balloon dilation system (Acclarent, Inc, Menlo Park, California) was employed to dilate the cartilaginous portion of the ET. A curved guiding catheter with a tip angle of 70 degrees was passed through the nasal cavity with the tip placed just into the ET nasopharyngeal orifice (Figure 2). A 7 mm (diameter) × 16 mm (length) Relieva Solo (Acclarent) sinus balloon catheter was passed through the guiding catheter andatraumatically into the ET orifice until reaching the first mild resistance as it approached the narrowest diameter at the bony-cartilaginous isthmus (Figure 3). The balloon typically protruded from the tubal orifice about 2 to 3 mm.

The balloon catheter lumen was left open to allow for air escape from the proximal (toward the middle ear) ET during inflation. The balloon was inflated with sterile water according to the manufacturer’s recommendations to a target pressure of up to 12 atm for 1 minute (Figure 4), after which it was deflated and removed (Figure 5). In the event that a balloon began to slip out of the ET orifice into the nasopharynx during inflation, it was either maintained at the maximum pressure attained before beginning to slip or reinserted and the inflation repeated. Careful endoscopic inspection was made of the postdilation tubal lumen to assess the effects and to note whether there was any evidence of an adverse effect (Figure 6). The posterior cushion was manipulated and rotated medially, before the dilation and afterward, looking for any change in the flexibility or increase in angle of rotation.
The immediate effect on widening of the lumen of the ET was judged qualitatively from intraoperative videos reviewed following the surgery. The degree to which the functional valve was opened by the dilation and remained open was estimated by the increase in apparent depth of view into the lumen of the ET. As the mucosal surfaces are normally in apposition in the valve, the length of persistent opening of the valve could reflect the immediate result of the dilation. The effectiveness of the dilation was rated as none if there was no visible change, small if the apparent increase in distance seen was estimated at <4 mm, medium for ≥4 mm without seeing the isthmus, and patent if the valve was dilated open and the isthmus was visible.

All patients were treated on an outpatient basis. Follow-up exams were scheduled for 1 and 6 months postoperatively and were planned to include otomicroscopy, tympanogram, endoscopy of the ET, demonstration of an attempt to do a Valsalva maneuver, and a repeat rating of the mucosa of the ET lumen.

Statistical analysis was done using SPSS 17.0 statistical software package (SPSS, Inc, an IBM Company, Chicago, Illinois) with 2-tailed paired samples t tests performed using $P < .05$ for significance. The patients were used as their own historical controls, given their longstanding disease.

**Results**

Eleven patients (5 men, 6 women) aged 33 to 76 years (average, 51.8) having had previous tympanostomy tubes...
(average, 4.7) underwent unilateral balloon dilation of the cartilaginous portion of their ET since June 2009. Preoperative findings are summarized in Table 1.

Two patients had OME with type B tympanograms, 2 had generally retracted TMIs with type B or C tympanograms, 5 had tympanostomy tubes in place, and 2 had TM perforations. ET mucosal inflammation scores were 2 in 4 of 11 (36.4%), 3 in 4 of 11 (36.4%), and 4 in 3 of 11 (27.2%), with a mean (SD) of 2.91 (0.83). None of the patients could insufflate air into their ears with a Valsalva maneuver. Middle ear mucosa seen through tympanostomy tubes was mildly inflamed with some mucus in 1 case, moderately inflamed (significant hypertrophy reducing the middle ear space) in 2, and severely inflamed (hypertrophy nearly filling the middle ear space) in 2 cases, including a small polyp in one of those. In the 2 cases with perforations, mucosal inflammation was mild in one and moderate in the other.

**Adjunctive Procedures**

At the time of surgery, tympanostomy tubes were placed in the 2 patients with OME, and tubes were removed from 3 patients with moderate to severe middle ear mucosal inflammation. Balloon dilation results are summarized in Table 2.

Dilation was done at 12 atm in 7 cases and 8 to 10 atm in the remainder. Reinsertion and repeat dilation due to slippage were done in 1 case. The balloon typically protruded out of the orifice by 25% to 30%. It was monitored during inflation and the guide catheter adjusted to hold it in position if it began to slip out more than 30%. The balloon began protruding in 1 case as the pressure reached 8 atm, and this pressure was maintained for the 1-minute duration, but the catheter slipped out at the end of the minute. Repeat dilation was not deemed to be necessary in this case.

Dilation of the ET occurred successfully in all cases. The dilation effectiveness was small in the 2 cases inflated to 8 atm, medium in the 2 cases dilated to 10 atm, and dilated to fully open in 5 of 6 (83.33%) cases inflated to 12 atm. The full dilation associated with 12 atm was significant ($P = .004$). The position of the posterior cushion was not altered, and there was no increase in flexibility to suggest cartilaginous fractures. There was no persistent bleeding.

**Adverse Effects**

A mucosal laceration within the lumen of the ET occurred in 5 of 11 (45.5%), and 4 of the 5 had been inflated to 12 atm. The lacerations were limited to the mucosa, were under 5 mm in length, and were considered clinically acceptable (minor adverse effect). Bleeding from the lacerations was very limited and of brief duration. All of the patients had a mild sore throat after surgery that resolved within 2 days. There were no major adverse effects.

Postoperative results are summarized in Table 3. Follow-up duration ranged from 6 to 14 months (median 7.0). All patients could perform a Valsalva maneuver postoperatively ($P < .001$). At the time of the last follow-up visit, 7 of 11 (63.6%) could still consistently perform the maneuver, and 4 of 11 (36.4%) could perform it but inconsistently. Otomicroscopy demonstrated that 5 of 11 (45.4%) tympanic membranes now appeared normal, although 1 of these cases had a type C tympanogram but normal hearing. Mucosal inflammation scores of the ET lumen were 1 in 4 of 11 (36.4%), 2 in 4 of 11 (36.4%), and 3 in 2 of 11 (18.2%) with a mean (SD) of 1.73 (0.79). Improvement in mucosal inflammation scores was statistically significant ($P = .003$). All mucosal lacerations had healed without scarring. There was no evidence of injuries, synechial bands, narrowing of the lumen, or patulous ETs. There was no postoperative epistaxis.

**Complications**

A C6-7 contralateral radiculopathy occurred in 1 patient thought to be due to the neck extension required for endotracheal intubation. It fully recovered. There were no complications related to the balloon dilation. No patients developed patulous ET symptoms (including autophony), even transiently. There were no cases of reflux otitis.

**Discussion**

This study demonstrated that balloon dilation of the ET is technically feasible and can be performed without significant adverse effects. The 7-mm sinuplasty balloon fit reasonably well into the tubal lumen and dilated the functional valve effectively, tending to slip out in a minority of cases. In the majority, the balloon actually “locked” into position, fitting to the inside curvature of the medial cartilaginous lamina that is contained within the posterior cushion. Protrusion of the balloon up to 30% was common and of no concern. Slippage of the balloon out of the ET could be
### Table 1. Preoperative Findings

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age, y</th>
<th>Sex</th>
<th>No. of Tubes</th>
<th>Type of Effusion</th>
<th>Associated Diagnosis</th>
<th>Previous Adenoidectomy</th>
<th>TM Status&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Tympanogram</th>
<th>Mucosal Inflammation</th>
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<tbody>
<tr>
<td>1</td>
<td>55</td>
<td>M</td>
<td>5</td>
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<td>36</td>
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<td>Mucoid</td>
<td>Atelectasis, OME</td>
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<td>3</td>
<td>76</td>
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<td>Open</td>
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<td>Retracted</td>
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<td>3</td>
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<td>48</td>
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<td>Perforated</td>
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<td>7</td>
<td>48</td>
<td>M</td>
<td>5</td>
<td>Mucoid</td>
<td>Chronic rhinitis</td>
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<td>Tube</td>
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<tr>
<td>8</td>
<td>49</td>
<td>M</td>
<td>6</td>
<td>Mucoid</td>
<td>Chronic rhinitis, polyps</td>
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<td>OME</td>
<td>B</td>
<td>4</td>
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<td>9</td>
<td>49</td>
<td>F</td>
<td>6</td>
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<td>10</td>
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<td>35</td>
<td>F</td>
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<td>Mucoid</td>
<td>Isolated OME</td>
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<td>OME</td>
<td>B</td>
<td>2</td>
</tr>
</tbody>
</table>

Abbreviations: F, female; M, male; OME, otitis media with effusion; TM, tympanic membrane.

<sup>a</sup>No. of tubes = number of previous tympanostomy tubes.

<sup>b</sup>TM status = otomicroscopic exam of the tympanic membrane.

### Table 2. Balloon Dilation Results

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Side</th>
<th>atm</th>
<th>Dilation Effectiveness</th>
<th>Mucosal Tear</th>
<th>Adjunctive Procedure</th>
<th>Comment</th>
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<td>1</td>
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<td>12</td>
<td>Medium</td>
<td>Yes</td>
<td>Remove tube</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>L</td>
<td>12</td>
<td>Patent</td>
<td>Yes</td>
<td>Remove tube</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>L</td>
<td>10</td>
<td>Medium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>L</td>
<td>8</td>
<td>Small</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5</td>
<td>L</td>
<td>8</td>
<td>Small</td>
<td>Remove tube</td>
<td>Balloon protruded 30%</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>L</td>
<td>12</td>
<td>Patent</td>
<td></td>
<td>Balloon protruded 30%</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>L</td>
<td>12</td>
<td>Patent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>L</td>
<td>12</td>
<td>Medium</td>
<td>Insert tube</td>
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<td></td>
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<tr>
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<td>10</td>
<td>Medium</td>
<td>Yes</td>
<td>Dilation repeated 1×</td>
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<tr>
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<td>L</td>
<td>12</td>
<td>Patent</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>L</td>
<td>12</td>
<td>Patent</td>
<td>Yes</td>
<td>Insert tube</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: atm, atmosphere; L, left; R, right.

### Table 3. Postoperative Findings

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Follow-up, mo</th>
<th>Valsalva</th>
<th>TM Status</th>
<th>Tympanogram</th>
<th>ET Mucosal Inflammation</th>
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</thead>
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<td>14</td>
<td>Yes, inconsistent</td>
<td>Normal</td>
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<td>3</td>
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<td>A</td>
<td>1</td>
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<tr>
<td>3</td>
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<td>Perforated</td>
<td>Open</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>10</td>
<td>Yes</td>
<td>Normal</td>
<td>A</td>
<td>3</td>
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<td>5</td>
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<td>Yes</td>
<td>Normal</td>
<td>A</td>
<td>1</td>
</tr>
<tr>
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<td>6</td>
<td>Yes, inconsistent</td>
<td>Perforated</td>
<td>Open</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>7</td>
<td>Yes</td>
<td>Tube</td>
<td>Open</td>
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<tr>
<td>8</td>
<td>7</td>
<td>Yes</td>
<td>Tube</td>
<td>Open</td>
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</tr>
<tr>
<td>9</td>
<td>7</td>
<td>Yes, inconsistent</td>
<td>Tube</td>
<td>Open</td>
<td>2</td>
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<tr>
<td>10</td>
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<td>Normal</td>
<td>A</td>
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<td>7</td>
<td>Yes</td>
<td>Tube</td>
<td>Open</td>
<td>1</td>
</tr>
</tbody>
</table>

Abbreviations: ET, eustachian tube; TM, tympanic membrane.
limited by bracing the shaft of the guiding catheter against the floor of the nose for stability.

Balloon dilation in this pilot study demonstrated evidence for effectiveness intraoperatively, with an immediate widening of the functional valve, and postoperatively, with persisting benefits that included improvement in the ability to insufflate the ET and ear with a Valsalva maneuver in 11 of 11 patients with an intact TM, and a reduction in inflammation of the mucosa of the ET from a mean of 2.91 to 1.73.

Dilation of the cartilaginous ET could widen the lumen, thereby reducing the work required for the muscles, especially the TVP muscle, to fully open the lumen on demand. It is known that balloon dilation of vascular stenoses creates tearing of the intima and sometimes the media, with healing occurring by scar filling in the gaps, thus maintaining the widened lumen. Compression of irreversibly injured hypertrophic mucosa and submucosa may permit healing with thinner and healthier layers. Histology following laser eustachian tuboplasty showed return of normal ciliated epithelium and thinner submucosa.

Balloon dilation appeared to most effectively dilate the mid-portion of the cartilaginous ET, which corresponds to the functional valve, and this is likely because of the combination of the tapered shape of the balloon at each end, the flexibility of the loose cartilage at the orifice, and the rigid circumferential cartilage at the isthmus. These results correlated well with a cadaver study.

The targets of 12 atm inflation pressure for 1 minute duration were taken from previous sinus experience and from the preclinical cadaver trial because, to our knowledge, this was the first clinical trial of balloon dilation of the ET. There was a greater tendency for mucosal laceration with this was the first clinical trial of balloon dilation of the cartilaginous ET.
in the rate of OME and improvement in the ability to consistently perform a Valsalva maneuver (100% postoperatively, 63.6% at 6 months). Intraluminal mucosal inflammation was reduced. A controlled clinical trial study to determine the efficacy of balloon dilation of the ET in patients with medically refractory dilatory dysfunction of the ET is now indicated.

Author Contributions

Dennis S. Poe, principal author, study design, assisted in surgical cases and data review; Juha Silvola, study design, primary surgeon for all cases, assisted in data review; Ilmari Pyykö, study design, review of manuscript.

Disclosures

Competing interests: Dennis Poe received a speaker honorarium from Acclarent Corp, July 2010, for Sinus Forum, Waldorf Astoria, New York.

Sponsorships: None.

Funding source: Balloon catheters were supplied free of charge from Acclarent Corp.

Disclaimer

Sinuplasty balloons are not approved by the Food and Drug Administration for off-label use in the eustachian tube.

References