Nonsurgical Placement of a Balloon-expandable Metallic Stent: Human Cadaver Study of the Eustachian tube

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Introduction

Interventions for non-vascular luminal organs

- Balloon dilation & stent placement for benign and/or malignant strictures
- Alternative therapeutic options for surgical procedures
  
  Shorter hospital stay, decreased cost, and faster symptom relief

Balloon dilation for ET dysfunction

- Minimally invasive treatment strategy in selected patients
- No standardization: procedural technique, diagnosis, and indications

Temporary stent placement
- Accepted therapeutic option for refractory benign strictures
- No consensus on techniques for Eustachian tube stent placement

Purpose
- To investigate the technical feasibility and safety of placement of a balloon expandable metallic stent in the cartilaginous portion of the ET.
- To evaluate the optimal size of Eustachian tube stent for patients with ET dysfunction in a cadaver model before consideration of a human trial.
Materials and Methods

Study design
- Twelve ETs of six fresh-frozen adult human cadavers
- No history of ear surgery, ear disease, or trauma

Safety and feasibility of ET stent placement
- Subtraction Eustachian tubography
- Pre- and post- CT
- Endoscopic and fluoroscopic images
Materials and Methods

Stents
- Two different size of balloon expandable stent
  - Right-side: 2.5-mm diameter, 28-mm length
  - Left-side: 3.5-mm diameter, 28-mm length
- Cobalt-chrome alloy, strut thickness: 85 um

Metallic guiding sheath
- 2.5-mm and 3.45-mm in its inner and outer diameters, 190 mm long
- Distal 10 mm: J shape (65°)
- Stainless steel
Materials and Methods

Technical steps of stent placement

Metallic guiding sheath with micro guidewire

Distal end of stent
Materials and Methods

Study definition and data analysis

- Technical success
  - Successful stent placement into the cartilaginous portion of the ET
  - Successful passage of contrast medium through the stent
- Procedure time, Radiation dose, and fluoroscopy time
- Location of the stent
- Inner luminal diameter
Results

Procedural outcomes

- Technical success: 91.7% (11 of 12)
  Bony canal of ET without any resistance (bony isthmus: > 3 mm)
  Distal end of the stent was located in the middle ear cavity
- Procedure time: 128 ± 37 sec
- Radiation dose for both ETs: mean, 3235.4 cGy/cm²
- Fluoroscopy time for both ETs: 139 ± 35 sec
# Results

## Results of stent location

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Technical success</th>
<th>Locations of the stent</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1R (2.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Orifice</td>
</tr>
<tr>
<td>1L (3.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Orifice</td>
</tr>
<tr>
<td>2R (2.5)</td>
<td>N</td>
<td>Middle ear cavity</td>
<td>-</td>
</tr>
<tr>
<td>2L (3.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Orifice</td>
</tr>
<tr>
<td>3R (2.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Cartilaginous</td>
</tr>
<tr>
<td>3L (3.5)</td>
<td>Y</td>
<td>Cartilaginous</td>
<td>Nasal cavity</td>
</tr>
<tr>
<td>4R (2.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Orifice</td>
</tr>
<tr>
<td>4L (3.5)</td>
<td>Y</td>
<td>Cartilaginous</td>
<td>Nasal cavity</td>
</tr>
<tr>
<td>5R (2.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Nasal cavity</td>
</tr>
<tr>
<td>5L (3.5)</td>
<td>Y</td>
<td>Cartilaginous</td>
<td>Nasal cavity</td>
</tr>
<tr>
<td>6R (2.5)</td>
<td>Y</td>
<td>Isthmus</td>
<td>Orifice</td>
</tr>
<tr>
<td>6L (3.5)</td>
<td>Y</td>
<td>Cartilaginous</td>
<td>Nasal cavity</td>
</tr>
</tbody>
</table>
## Results

### Results of inner luminal diameter

<table>
<thead>
<tr>
<th>Side</th>
<th>Location</th>
<th>Luminal diameter (mm)</th>
<th>*All</th>
<th>$^$P vs. M</th>
<th>$^$P vs. D</th>
<th>$^$M vs. D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right (2.5)</td>
<td>Proximal</td>
<td>2.49 ± 0.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Middle</td>
<td>2.46 ± 0.39</td>
<td>&lt; 0.001</td>
<td>0.181</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Distal</td>
<td>1.67 ± 0.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left (3.5)</td>
<td>Proximal</td>
<td>3.47 ± 0.21</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Middle</td>
<td>3.45 ± 0.47</td>
<td>&lt; 0.001</td>
<td>0.647</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>Distal</td>
<td>1.59 ± 0.41</td>
<td></td>
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</tr>
</tbody>
</table>

Note. Data are mean ± standard deviation.

* Kruskal-Wallis test

$^\$ Mann–Whitney U test
Conclusion

- Stent placement in the cartilaginous portion of the ET under combined endoscopic and fluoroscopic technique seems to be technically feasible and safe.

- A 2.5 mm in diameter and 28 mm long stent seems to be appropriate for patients with Eustachian tube dysfunction.

- Accurate placement of the stent remains technically challenging and further studies are needed to determine the optimal length and diameter of the stent for the ET.