The Use of Balloon-Expandable Metallic Stents in the Treatment of Pediatric Tracheomalacia and Bronchomalacia

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Objective: To evaluate the use of balloon-expandable metallic stents in the treatment of children with tracheomalacia and bronchomalacia in whom conventional therapy has failed.

Design: Retrospective case series.

Setting: Tertiary pediatric otolaryngology and cardiothoracic surgery referral center.

Patients: Six patients were identified as having undergone bronchoscopic placement of metallic balloon-expandable stents between 1994 and 1997. The age at stent placement, prior surgical interventions, and indications for and sites of stent placement were noted. Also, the complications related to stent placement and the current airway status of the patients were reviewed.

Interventions: Twelve balloon-expandable metallic angioplasty stents (Palmaz; Johnson & Johnson Interventional Systems Co, Warren, NJ) were placed bronchoscopically in 6 patients. Six stents were placed in the lower trachea, and 6 were placed in the main bronchi. The stents were balloon expanded under fluoroscopic guidance.

Main Outcome Measure: Discontinuation of mechanical ventilation.

Results: The age at stent placement ranged from 1.5 to 38 months (mean age at placement, 10 months). The indications for stent placement were (1) tracheomalacia or bronchomalacia, (2) pericardial patch or slide tracheoplasty failure, and (3) bronchomalacia caused by tetralogy of Fallot and large pulmonary arteries. The primary complication of stent placement was postoperative granulation tissue formation. One patient required the removal of 2 tracheal stents because of granulation tissue formation. There were 2 deaths in the series, 1 possibly related to stent placement. Four of the 6 patients were weaned from mechanical ventilation, and 3 experienced prolonged relief of airway obstruction.

Conclusions: Metallic balloon-expandable stents are effective in relieving lower tracheomalacia and bronchomalacia in select patients. Only patients in whom conventional therapy has failed should be considered for stent placement.


TRACHEOMALACIA IS the most common congenital anomaly of the trachea. No intervention is required in the majority of cases. Most often, children with this anomaly are minimally symptomatic, presenting with chronic cough or expiratory stridor on exertion. The majority gradually improve, with symptoms usually resolving by the age of 3 years. A few present with more severe symptoms of airway obstruction and increased work of breathing: respiratory distress, severe stridor, and apparent life-threatening events. Severe primary tracheomalacia is usually amenable to management with standard or custom tracheostomy tubes. Tracheomalacia may be due to vascular anomalies, tracheoesophageal fistula, or foregut cysts. Tracheomalacia caused by innominate artery compression may be treated by anterior suspension to the sternum.

Over the past 3 years, we have encountered a group of patients with severe tracheomalacia or bronchomalacia in whom all conventional therapy failed. Four of these patients underwent prior surgical intervention for long-segment congenital tracheal stenosis with complete tracheal rings. Two patients had bronchomalacia due to large pulmonary arteries resulting from tetralogy of Fallot with absent pulmonary valve. Stent placement with custom tracheostomy tubes was either ineffective or put the tip of the tube in close proximity to the carina, resulting in obstruction from granulation tissue or from intermittent contact with the carina. All patients had required long-term...
PATIENTS AND METHODS

A retrospective review of 6 cases of stent placement over a 3-year period was undertaken at Children's Memorial Hospital. The balloon-expandable metallic angioplasty stents (PalmaZ; Johnson & Johnson Interventional Systems Co, Warren, NJ) are constructed of stainless steel mesh and are available in a variety of lengths and diameters. At bronchoscopy, selection of the stent length was based on the measured length of the abnormal tracheal or bronchial segment. The correct diameter was estimated by comparison with the age-appropriate endotracheal tube size, as well as with the estimated diameter of the adjacent unaffected trachea or bronchus. All stents were placed through a 3.0 or 3.5 rigid bronchoscope, positioned, and expanded under fluoroscopic control. The bronchoscope tip was placed at the upper and lower margins of the lesion, and metallic markers were placed on the skin. The stents were then placed and expanded under fluoroscopic guidance (Figure 1). Balloon expansion was achieved with a standard angioplasty syringe equipped with a pressure gauge. Pressures of 12 to 17 atm were used to inflate the balloon and stent until the waist at the narrowing was obliterated (Figure 2 and Figure 3). Balloon diameter was selected to correspond to the estimated diameter of the trachea or bronchus. If further dilation was required at the initial stent placement or later, a larger-diameter balloon was used. The findings of bronchoscopic examination, performed immediately after stent placement, confirmed the proper location (Figure 4). A postoperative chest x-ray film provided radiographic documentation (Figure 5).

RESULTS

The initial presentation in each of the 6 cases is summarized in Table 1. Five of the 6 patients had concurrent congenital heart disease. Four patients underwent periatrial patch or slide tracheoplasty for correction of long-segment tracheal stenosis, 3 at the time of surgical correction of their congenital heart disease. The remaining 2 patients had bronchomalacia due to enlarged pulmonary arteries as a result of tetralogy of Fallot with absent pulmonary valve.

The age of the children at the time of stent placement ranged from 1.5 to 38 months. (Table 2) Five of the 6 children required more than 1 stent, 3 at the time of initial stenting (Table 2). One child required 3 stents, each placed at a separate occasion. The sites of stent placement are listed in Table 2. A total of 12 stents were placed: 6 in the lower trachea and 6 in the bronchi.

The stents had mucosalized by 20 to 90 days (average, 44 days). In 5 of the 12 stent procedures, some degree of preoperative inflammation and/or granulation tissue was present in the trachea or bronchus. Six of the 12 stent applications required postoperative bronchoscopic removal of granulation tissue. There was no association between preoperative airway inflammation and poststent granulation tissue formation. One child required removal of the stents because of recurrent granulation tissue and the need for a tracheostomy.

There were 2 deaths in this series. One child died of aortic valve endocarditis 2 months after tracheal stent placement. The patient was weaned from mechanical ventilation within 6 days after the stent placement. At postmortem examination, the trachea was healed and patent. The stent was in place, partially mucosalized, without excessive granulation or erosion through the tracheal wall. The stent was difficult to remove at autopsy because it had been incorporated into the tracheal wall.

A second child died of systemic sepsis 4 months after placement of bilateral bronchial stents. After the stent placement, her hospital course was complicated by a second cardiac surgical procedure and progressive neurological deterioration. She could not be weaned.
from mechanical ventilation. At postmortem examination, the left bronchus was patent and the stent was mucosalized. The right bronchus was nearly occluded with granulation tissue. The source of sepsis was not identified.

Four of 6 children were weaned from mechanical ventilation, and 3 had long-term relief of airway obstruction. Our longest follow-up period has been 38 months. The patient involved recently required a third stent in the right main bronchus inferior to her existing tracheal stents. The lower trachea was patent, with complete mucosalization of the stents. Over the course of 3 years, the child has required 2 progressive dilations of the stents. There have been no complications associated with dilation of the stents.

Balloon-expandable metallic angioplasty stents have become available for use in the treatment of pediatric tracheomalacia and bronchomalacia.\textsuperscript{17-19} The first application of an airway stent in the pediatric population was reported by Loeff et al\textsuperscript{20} in 1988. Although silicone rubber–coated steel springs were well tolerated in the animals in Loeff and colleagues’ study, clinical application was hindered by stent migration and retained tracheal secretions. Several authors have reported limited use of self-expanding metallic stents in children.\textsuperscript{13-16}

Metallic balloon-expandable angioplasty stents have the advantages of small size, accurate placement, and precise luminal diameter.\textsuperscript{17-19} In this series, the stents were particularly applicable in the treatment of tracheomalacia, which may occur after tracheoplasty. The severity of airway obstruction in our patients and the absence of a reasonable alternative led us to consider endobronchial stenting. Similar to the self-expanding metallic stents, the wire mesh design of the metallic balloon-expandable angioplasty stents was found to preserve mucociliary clearance and hinder migration of the stent.\textsuperscript{17-19} Also, the metallic balloon-expandable stents can be placed over a bronchial orifice (such as a right upper lobe bronchus), with no apparent untoward effects. No children in our series

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{image1}
\caption{Balloon-expandable metallic angioplasty stent loaded on angioplasty catheter for insertion.}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{image2}
\caption{Balloon-expanded metallic angioplasty stent.}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{image3}
\caption{Bronchoscopic view of tracheal stent.}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{image4}
\caption{Postoperative posteroanterior chest radiograph of stents in each main bronchus.}
\end{figure}
have experienced pneumonia or bronchiectasis after stent placement.

The main complication associated with the use of the balloon-expandable stents was granulation tissue formation, as has also been observed with the use of self-expanding stents in the adult population.9-11 All stents demonstrated some degree of granulation formation; 6 of the 12 stents required multiple bronchoscopies for removal of granulation tissue (Table 2). One patient required removal of the stents because of recurrent granulation formation. The literature suggests a correlation between preoperative tracheal inflammation and postoperative granulation in adults.9-11 Limited data in the pediatric population support this contention,18 although we identified no clear correlation (Table 2). Tracheal inflammation was not regarded as a contraindication to stent placement in this series.

The indications for stent placement included lower tracheomalacia, bronchomalacia, the combination of tracheobronchomalacia, and midtracheal stenosis. Our limited experience with stents for midtracheal stenosis suggests that they may not be the best option for this problem. As noted, the child with the midtracheal stenosis required removal of the 2 stents because of persistent obstruction from granulation tissue. In retrospect, a tracheostomy tube alone would have been satisfactory. We conclude that balloon-expandable metallic angioplasty stents are indicated only in cases of lower tracheomalacia and bronchomalacia that are not amenable to conventional therapy.

Mucosalization of the stents was found to be highly variable. It occurred between 20 and 90 (mean, 45 days). This period was determined by the findings of frequent bronchoscopic evaluations that were performed after stent placement. Since not all patients required frequent bronchoscopic evaluation, the precise time for mucosalization is unknown. In one patient, mucosalization proved to be transient. As this child’s overall condition worsened, the fully mucosalized stent became reexposed. Animal studies with self-expanding metallic stents have noted mucosalization in 4 to 6 weeks.21

Table 1. Presentation

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Cardiac Diagnosis</th>
<th>Airway Diagnosis</th>
<th>Cardiac Surgery</th>
<th>Airway Surgery</th>
<th>Age at Surgery, d</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pulmonary artery sling</td>
<td>Long-segment tracheal stenosis</td>
<td>Reimplantation of pulmonary artery</td>
<td>Pericardial patch tracheoplasty</td>
<td>9</td>
</tr>
<tr>
<td>2</td>
<td>None</td>
<td>Subglottic stenosis</td>
<td>None</td>
<td>Cricoid split</td>
<td>60</td>
</tr>
<tr>
<td>3</td>
<td>Tetralogy of Fallot</td>
<td>Long-segment tracheal stenosis</td>
<td>Blalock-Taussig shunt</td>
<td>Pericardial patch tracheoplasty</td>
<td>60</td>
</tr>
<tr>
<td>4</td>
<td>Tetralogy of Fallot,</td>
<td>Bronchomalacia</td>
<td>Tetralogy repair</td>
<td>Slide tracheoplasty</td>
<td>210</td>
</tr>
<tr>
<td>5</td>
<td>Pulmonary artery sling</td>
<td>Long-segment tracheal stenosis</td>
<td>Reimplantation of pulmonary artery</td>
<td>Pericardial patch tracheoplasty</td>
<td>32</td>
</tr>
<tr>
<td>6</td>
<td>DiGeorge syndrome,</td>
<td>Bronchomalacia</td>
<td>Tetralogy repair</td>
<td>None</td>
<td>58</td>
</tr>
</tbody>
</table>

Table 2. Stent Data*

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age at Stent Placement, mo</th>
<th>Indication for Stent Placement</th>
<th>Stent Site</th>
<th>Preexistent Airway Inflammation</th>
<th>No. of Poststen Bronchoscopies</th>
<th>Mucosalization, d</th>
<th>No. of Months in Place</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.5</td>
<td>Tracheomalacia</td>
<td>Lower trachea</td>
<td>Yes</td>
<td>10</td>
<td>60</td>
<td>38</td>
<td>Well</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>Tracheomalacia</td>
<td>Lower trachea, proximal to previous stent</td>
<td>No</td>
<td>0</td>
<td>60</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>38</td>
<td>Bronchial stenosis</td>
<td>Right main bronchus, lower trachea</td>
<td>No</td>
<td>. . .</td>
<td>. . .</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7.5</td>
<td>Tracheobronchomalacia</td>
<td>Left main bronchus, lower trachea</td>
<td>Yes</td>
<td>2</td>
<td>90</td>
<td>25</td>
<td>Well</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Tracheomalacia</td>
<td>Lower trachea</td>
<td>Yes</td>
<td>1</td>
<td>27</td>
<td>2</td>
<td>Died of endocarditis</td>
</tr>
<tr>
<td>4</td>
<td>1.5</td>
<td>Bronchomalacia</td>
<td>Left and right main bronchi</td>
<td>Yes</td>
<td>0</td>
<td>20</td>
<td>17</td>
<td>Well</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>Tracheal stenosis</td>
<td>Midtrachea</td>
<td>No</td>
<td>1</td>
<td>25</td>
<td>4</td>
<td>Stents removed, tracheotomy</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>Tracheal stenosis, proximal to stent</td>
<td>Midtrachea, proximal to previous stent</td>
<td>Yes</td>
<td>2</td>
<td>?</td>
<td>4</td>
<td>Died of sepsis</td>
</tr>
</tbody>
</table>

* Ellipses indicate too early for follow-up data; question mark, too few postoperative bronchoscopies to determine.
Mucosalization of the stents has advantages and disadvantages. It allows the restoration of mucociliary flow and prevents migration of the stent. However, it also complicates removal of the stents. The 2 stents that had to be removed in our series had not mucosalized. In a recent series, 17 11 of 30 stents were removed, with no recurrence of airway obstruction. Six of the 11 stents were removed because of recurrent granulation formation. The others were removed routinely after 1 year. One child died of airway obstruction at the time of stent extraction. This stent was believed to be “welded” to the tracheal wall as a result of laser resection of granulation. The report does not state whether these stents were mucosalized.

In our preliminary work in rabbits, attempts to remove the mucosalized stents were unsuccessful. Based on our experience, mucosalized stents should be regarded as permanent. Vinograd et al 22 recently tested temperature-sensitive coiled ribbon nitinol stents, which, when cooled, assume their unexpanded shape, perhaps facilitating removal.

The long-term outcome of metallic endobronchial stents in young children is unknown. Our longest follow-up has been 3 years. The child involved has required dilation of stents twice and, recently, placement of a third stent for recurrent bronchomalacia requiring mechanical ventilation. Dilations will probably be required as the children grow. The maximal internal diameter that can be achieved varies with the size of each stent. They can be “overdilated,” although they then may lose the structural integrity required to support the lumen. If necessary, another larger stent may be placed within and expanded to provide needed support.

In conclusion, balloon-expandable metallic angioplasty stents play a significant adjunctive role in the treatment of select cases of severe pediatric tracheomalacia and bronchomalacia. Their use should be restricted to the very limited situations in which conventional therapy has failed. In the future, absorbable, polytef-coated, or temperature-sensitive stents may have advantages over the currently available metallic stents.

Accepted for publication August 25, 1998.

Presented in part at the annual meeting of the American Society of Pediatric Otolaryngology, Palm Beach, Fla, May 14, 1998.

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REFERENCES