BALLOON-EXPANDABLE METALLIC STENTS IN THE MANAGEMENT OF TRACHEOMALACIA IN NEONATES

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Tracheomalacia is a challenging problem after operations for certain congenital heart malformations in neonates and infants. It may often prevent the patients from being weaned from mechanical ventilation. Management of this condition remains difficult. Many surgical approaches have been suggested, although none of them is universally accepted. Conversely, a major role could be played by stent implantation at the level of the malacic segment. However, both silicone stents and self-expanding metallic stents present major technical or physiologic problems in pediatric patients. This article reports on our preliminary experience with the use of endovascular balloon-expandable metallic stents in the treatment of neonatal tracheomalacia after surgical repair of congenital heart malformations.

Patient population. During 1993, three patients (Table I) were subjected to implantation of a balloon-expandable metallic stent at the airway level. The stent was used to treat tracheobronchial malacia that caused failure to wean from assisted ventilation after operations for congenital cardiovascular malformations. In each case, informed parental consent was obtained before stent implantation.

Technique. The morphologic features of the malacic segment were evaluated by tracheography during spontaneous respiration. Peak respiratory pressure and pulmonary compliance were measured before and after stent implantation by a Capnomac Ultima monitor (Datex Medical Instrumentation, Tewksbury, Mass.). Endovascular balloon-expandable Palmaz-Schatz stents (Johnson & Johnson, New Brunswick, N.J.), 128 mm long, were used to support the tracheomalacic segment. The stent was mounted on the Lo-Bow (Mallinckrodt Medical, Inc., St. Louis, Mo.) 6 mm balloon guidewire (0.035 inch) and positioned, under fluoroscopic guidance, at the level of the malacic segment through the endotracheal tube used for mechanical ventilation. After the endotracheal tube had been withdrawn as far as possible, mechanical ventilation was briefly suspended and the balloon rapidly inflated to expand the stent.

Statistical analysis. Morphologic and functional data were expressed as mean values ±1 standard deviation. Statistical analysis was performed by the paired Student’s t test.

Results. Balloon-expandable stent implantation was simply, quickly, and successfully performed in all cases. On the whole, assisted ventilation was stopped for about 30 to 45 seconds, and the mean time for the entire procedure was about 5 minutes. No significant adverse side-effects were recorded. Two patients were extubated soon after the procedure and the third after 1 week of assisted ventilation. After stent implantation, the diameter of the tracheomalacic segment increased from 4.8 ± 0.2 to 6.0 ± 0.3 mm (+32.4%, p < 0.05) (Figs. 1 and 2); peak respiratory pressure decreased from 41 ± 3.6 to 13.7 ± 9.3 cm H2O (-66.6%, p < 0.01); and pulmonary compliance increased from 7 ± 1 to 12.3 ± 2.5 ml/cm H2O (+44.1%, p < 0.05). The first two patients died, 2 and 3 weeks, respectively, after stent implantation, because of intractable sepsis from gram-negative bacteria.

Discussion. Tracheobronchial malacia is an infrequent but potentially life-threatening clinical problem in the postoperative course of neonates and infants undergoing operations for congenital cardiovascular malformations. Vascular rings or slings are the most frequently diagnosed lesions causing compression and hence malacic degeneration of the tracheobronchial tree; this degeneration results in inspiratory collapse of the airway tree and leads to postoperative inability to wean the patient from mechanical ventilation. To date, many therapeutic approaches have been suggested, none of which has been accepted with confidence in pediatric patients. In fact, the surgical approach of patching, resecting, or suspending the tracheomalacic segment has not been widely embraced. Conversely, implantation of endoluminal stents that give rigid support to the malacic segment and thereby prevent inspiratory collapse seems to be a useful option.

Silicone stents and self-expanding metallic stents have been proposed for use in children. Silicone stents have the major advantages of being easy to implant, amenable to fine adjustment after insertion, well tolerated, and possibly retrievable. However, bronchoscopic guidance is frequently necessary for implantation, and the stents tend to migrate distally over time. Furthermore, because the prosthesis does not become epithelialized, the area covered by the silicone stent is devoid of the normal mucociliary clearance mechanism and becomes prone to mucus accumulation and secondary infections.

Self-expanding metallic stents seem more useful for the treatment of tracheomalacia in children: they are easily implanted, well tolerated, and do not affect the mucociliary function of the site of implantation, because they are eventually covered by ciliated columnar epithelium. However, bronchoscopic guidance is needed to implant them, and their diameter may not be suited to the size of the patient’s trachea, so that they cannot be easily used in neonates and infants. Conversely, endovascular balloon-
expandable stents\textsuperscript{6} are easily implanted with merely fluoroscopic guidance, and they do not interfere with the epithelial mucociliary function; thus the risk of mucus accumulation and possible subsequent infections is lessened. Again, it might be possible to suit their diameter to the size of the child’s trachea by using adequate-sized expanding balloons and by redilating the stent over the time, to progressively suit its diameter to the tracheal size during the patient's growth. However, like other metallic stents, the balloon-expandable stent, once placed, cannot be adjusted or moved easily, if at all.

Table 1. Clinical data of the patients submitted to endoluminal stent implantation

<table>
<thead>
<tr>
<th>Age</th>
<th>Cardiac anomaly</th>
<th>Site of stent implantation</th>
<th>Period of mechanical ventilation</th>
<th>Time to extubation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 mo</td>
<td>Scimitar syndrome</td>
<td>Left bronchus</td>
<td>8 wk</td>
</tr>
<tr>
<td>2</td>
<td>2 mo</td>
<td>Left PA sling</td>
<td>Trachea</td>
<td>6 wk</td>
</tr>
<tr>
<td>3</td>
<td>2 mo</td>
<td>Double aortic arch</td>
<td>Trachea</td>
<td>6 wk</td>
</tr>
</tbody>
</table>

PA, Pulmonary artery.
In our study, the clinical condition and respiratory functional parameters of the patients significantly improved early after stent implantation. All patients whose tubes had previously been considered unremovable because failure of several methods, including synchronized intermittent mandatory ventilation, with or without either pressure support or continuous positive airway pressure, were easily weaned from mechanical ventilation early after the procedure. Unfortunately, after this dramatic improvement, two of the patients died of intractable sepsis 2 and 3 weeks later. However, at the time of stent implantation, they were already critically ill, having clinical and laboratory evidence of sepsis and several blood cultures positive for gram-negative organisms (*Klebsiella* spp.). Furthermore, in the second patient, a large endocardial septic vegetation at the cavoatrial junction had been visualized by echocardiography long before stent implantation.

In conclusion, we think that the infective problems recorded in our series cannot be related in any way to stent implantation. In fact, more aggressive management of tracheomalacia by earlier stent implantation might have avoided prolonged assisted ventilation and lessened the likelihood of secondary infections. This approach may have lowered the morbidity and mortality in our series.

**Conclusions.** Our preliminary results with implantation of an endovascular balloon-expandable metallic stent at the airway level of critically ill infants are promising. Our experience is limited, and a longer follow-up period is needed to confirm our preliminary data. However, we suggest that this safe and effective procedure should be
strongly considered as an alternative treatment for children with tracheomalacia.

REFERENCES

TRUNCUS REPAIR WITH A VALVELESS CONDUIT IN NEONATES

Douglas M. Behrendt, MD, and Macdonald Dick III, MD, Iowa City, Iowa, and Ann Arbor, Mich.

In 1984, we reported the successful use of 8 and 10 mm polytetrafluoroethylene (PTFE) tubes to connect the right ventricle to the pulmonary arteries in the repair of truncus arteriosus types I and II in the neonate (Fig. 1).1 These infants were operated on at the ages of 1 to 9 days because of severe heart failure. At that time, the smallest commercially available conduit was a 12 mm Dacron polyester tube containing a porcine heterograft valve. Although this device was used successfully by Ebert and coworkers2 in a large series of infant truncus repairs, it was too cumbersome for insertion into the neonates in our series, who ranged in weight from 2.1 to 3.3 kg. Allografts were not in general use at that time.

These PTFE tubes were technically relatively easy to insert, yet we were concerned that neonates would not be able to tolerate the pulmonary insufficiency created by unvalved conduits. Although the first successful repairs of right ventricle–pulmonary artery discontinuity had used nonvalved tubes, these operations were performed on older children, who had anatomy that restricted pulmonary blood flow and therefore had a low pulmonary resistance.3 Our fears proved unfounded. Five of the seven infants survived the operation, and the two who died did so of unrelated conditions.

Our second major concern was that these small tubes would require replacement at an early age, committing these infants to multiple revisionary operations. This also has not proved to be the case. As outlined in Table I, PTFE tubes in the four long-term survivors lasted for 3 to 11 years, when it was possible to insert allografts of 19 to 25 mm diameter. Each patient was found to have stenosis at the origin of one or both pulmonary artery

Fig. 1. Repair of truncus arteriosus with a PTFE conduit.