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French Experience of Silicone Tracheobronchial Stenting in Children

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Summary. Silicone stents were inserted into the trachea or left main-stem bronchus in 14 children aged 2–69 months (median, 7 months). Indications were as follows: tracheomalacia or airway kinking (7 cases), vascular compression (5 cases), and surgically corrected congenital tracheal stenoses (2 cases). The best results were obtained in tracheomalacia. Overall, 6 cases out of 14 (43%) were considered successful, with a stent placement duration of 3–15 months (median, 7 months). Two cases were considered a technical success, although they were clinical failures. Five cases were considered failures primarily due to stent migration. A retrospective analysis of failures suggests that most of these could have been avoided by the use of larger stents. One patient died of stent obstruction. No wall erosion was observed, and the development of granulation tissue was infrequent. Endoscopic removal of the prostheses was uneventful. The biocompatibility of silicone stents appears to be better than what is reported for metal ones, although the stability of the former is less satisfactory. The present study shows the feasibility of silicone stent placement in infants. These stents should be considered as a possible therapeutic option in certain types of childhood airway disorders, although further studies are required. **Pediatr Pulmonol. 2005; 00:1–8.** © 2005 Wiley-Liss, Inc.

Key words: child; stents; silicones; respiratory tract diseases; airway obstruction; tracheomalacia.

INTRODUCTION

Experience with airway stenting in infants and children remains limited. The first publications regarding the use of tracheobronchial stents in young children date back to the late 1980s. Such procedures were performed in combination with surgery for the treatment of severe bronchomalacia or for the prevention of posttracheoplasty restenosis.[1–3] In 1995, Zinman showed that tracheal stenting improved ventilatory mechanics in cases of major tracheobronchial dyskinesia.[4] Filler et al. developed a stenting technique using a vascular mesh metal prosthesis (Palmaz®) inserted via rigid tube bronchoscopy and calibrated with a balloon catheter.[5] They published their results with a series of 16 children aged 1 week to 26 months and made the following points: several prostheses may be successively required in the same patient; stents can be placed in the main-stem bronchi (in particular, on the left side); several prostheses can simultaneously be inserted in the same patient (trachea and main-stem bronchi); and tracheobronchial stenting may be useful irrespective of any kind of surgery of the respiratory tract (e.g., tracheobronchomalacia, extrinsic compression).[6]

However, despite reports of excellent tolerance for up to 6 years,[7] one major complication arising from the use of metallic stents is mucolization, which complicates stent removal. Furman et al. suggested that mucolized stents should be regarded as permanent.[8] This may be dangerous, since several observations of complete erosion of the tracheobronchial wall, eventually causing aortic perforation, were reported.[6,9–11] Such widely reported complications in adult series have led some teams to totally discontinue placing metal prostheses.[12]

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In 1987, Dumon devised a silicone molded prosthesis with a soft surface and tips in order to prevent the formation of granulation tissue, combined with a knobbly outer surface so as to facilitate its adhesion to the mucosa.[13] A multicenter study encompassing over 1,000 adults presenting with malignant or benign tracheobronchial stenosis demonstrated its efficacy and good tolerance in this population.[14] The most frequent complication was migration (9.5% of cases), linked to the very nature of the prosthesis, which did not become integrated into the wall, in contrast to metal stents[Q2].[15] In children, tracheal stenting with silicone tubes was previously described, either through attachment to tracheostomy devices (e.g., Montgomery's T-tubes, long tracheostomy tubes) or direct suturing to the tracheal wall in order to prevent migration.[16]

We report on the placement and withdrawal of 26 silicone airway stents in 14 children between 1994–2000 in five French centers specializing in pediatric bronchoscopy.

METHODS

In all cases, clear information was given to the parents, and their consent was obtained prior to any attempt at stenting. For each patient, the lack of clinical studies validating this therapeutic approach was explained to the parents.

The following assessments were first made by rigid tube bronchoscopy: length of stenosis, distance from dental arches, and diameter of largest tube passing through the stenosis. The prosthesis was then custom-manufactured using molded polysiloxane, which could be made radiopaque as required (Tracheobronxane® BB series, Novatech SA, http://www.novatech.fr). Stent length was the sum of the height of the stenosis and 5–10 mm; its external diameter corresponded to that of the largest bronchoscopy tube passed through the stenosis. In case of airway malacia, which is often significantly expandable, a second stent of the next higher caliber was also manufactured. Subsequent to the molding of the prosthesis, its surface was coated so as to ensure proper biocompatibility. Consequently, it was never cut prior to insertion. The silicone leaf being 0.5 mm thick, the difference between inner/outer diameters was 1 mm. Available stents had diameters of 4/5, 5/6, 6/7, and 7/8 mm (Fig. 1).

No specific insertion device is currently available for such small calibers. Before being placed, stents were lubricated with silicone spray, folded along their longitudinal axis, and inserted at the distal end of the bronchoscopy tube. The lateral channels of the rigid tubes were obturated using a thin plastic film in order to avoid damaging the stent. The rigid bronchoscopy tube was then inserted within the airways and positioned at the level corresponding to the previously measured distance from the dental arches. The stent was maintained in position by a rigid instrument (rigid optical device, soft-tip forceps), and the rigid tube was withdrawn. In small infants, the stent was inserted using foreign-body forceps under direct laryngoscopic vision.

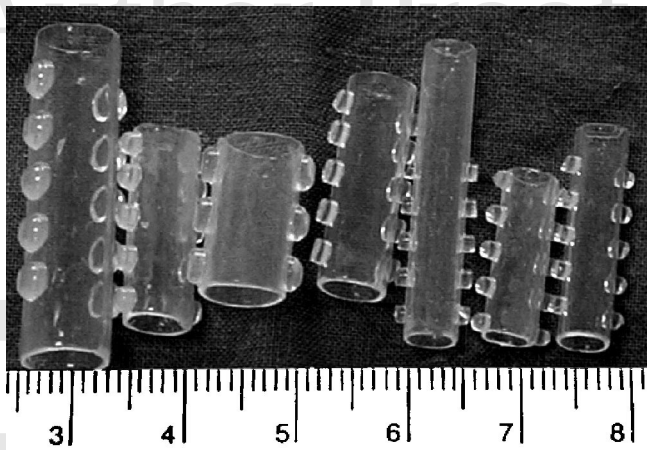

Fig. 1. Tracheobronxane® BB series silicone stents (Novatech SA, France[Q3]).

The deployed prosthesis unfolded within the stenosis, and its placement was visually checked using a flexible or rigid optical device (Figs. 2 and 3). Another fiberoscopic examination was systematically performed 24 hr later in order to ensure that the stent was correctly positioned. Moreover, the absence of atelectasis and the prosthesis position were verified by chest X-ray. Twice-daily nebulizations of normal saline and chest physiotherapy were administered in order to prevent mucus impaction within the prosthetic lumen. Subsequent fiberoscopic examinations were regularly performed. When dislodged, the prosthesis was removed by a rigid bronchoscopy tube and forceps, similar to foreign-body removal. This was replaced by a prosthesis of a greater caliber. If laser therapy was required, the prosthesis was removed, since it is flammable.

The results shown below are mainly descriptive, based on a global assessment using an arbitrary grading (1, clinical efficacy; 2, properly placed stent but clinical failure; and 3, stent failure).

RESULTS

Study Population

Sixteen tracheal prostheses were placed in 8 children, and 10 were inserted into the left main-stem bronchus in 6 other patients. All children benefited from multidisciplinary management in tertiary care pediatric centers. Twelve had previously undergone one or several surgical procedures. Inclusion data are summarized in Table 1. Median age at first prosthetic placement was 7 months (range, 2–69 months).

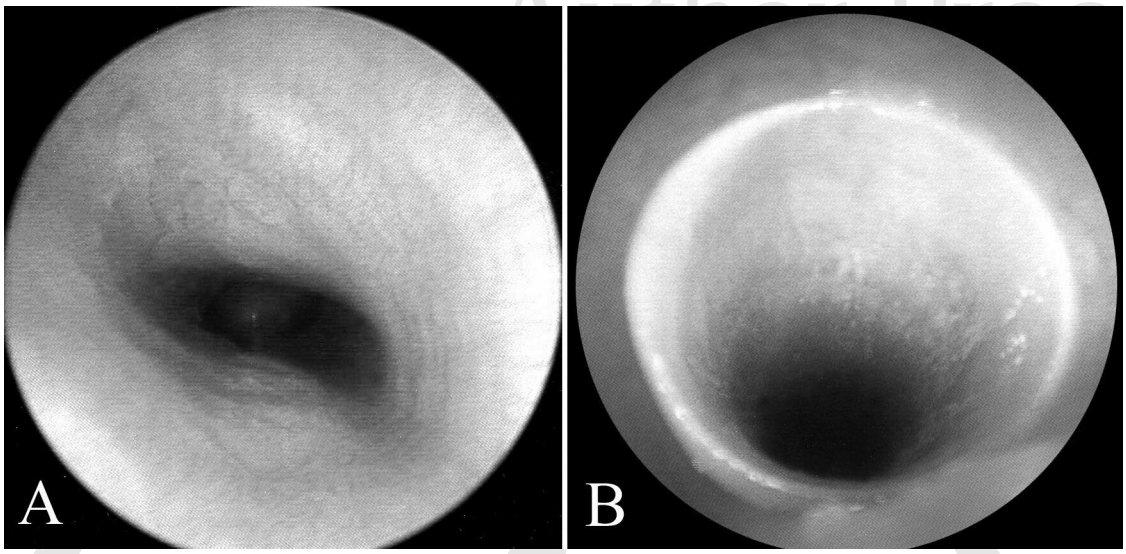

Fig. 2. A: Postoperative tracheal kinking in child with omphalocele (case 1). B: Same view as in A (case 1) of 5/6 mm (ID/OD) silicone tracheal stent.

Efficacy

Table 2 indicates the results regarding the tracheal and left main-stem bronchi stents, respectively. The prostheses were considered clinically efficient in 43% (6/14) of cases. Median duration of stent placement was 7 months (range, 3–15 months). In all cases, ventilatory improvement was obvious and immediate. Five children were discharged home for several weeks with their stent, which remained virtually undisplaced. Technically efficient prostheses (stable and properly calibrated for the stenosis) contrasted with clinical failure in 14% (2/14) of cases. The clinical symptoms or signs were obstruction (see case 1, below) or major dyspnea (case 4) due to inspiratory collapse of the larynx. In the latter, a pantracheal stent had been inserted within the context of a generalized cartilaginous malformation. A tracheostomy was immediately performed following stent removal. Stent failure was noted in 43% (6/14) cases. This was due to stent migration (5 cases) or obstruction caused by a plicature (case 2). Migration, observed in 4 cases of stenosis, resulted from high-pressure vascular compression (the aorta or its branches),

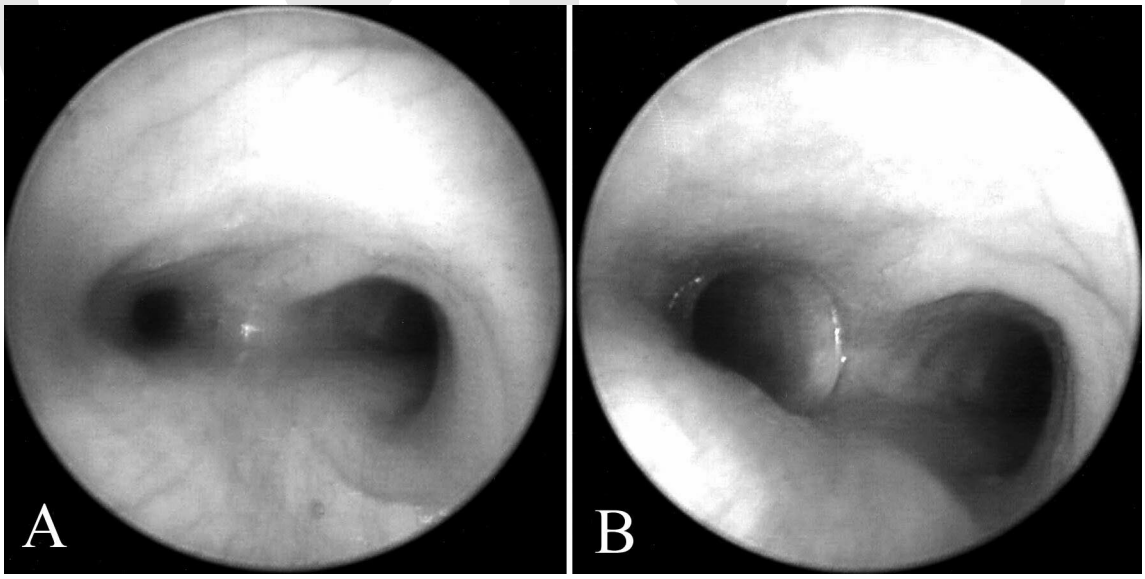

Fig. 3. A: Postoperative left-stem bronchus compression by left pulmonary artery in child with tetralogy of Fallot (case 12). B: Same view as in Figure 2A (case 12) of 5/6 mm (ID/OD) silicone left main-stem bronchus stent.

TABLE 1— Clinical Data at Time of Initial Stenting[1]

Patient	Diagnosis	Previous interventions	Clinical status	Age at stent insertion
Type 1 tracheo-bronchomalacia				
1	Omphalocele Tracheal kinking	Abdominal surgery (Schuster)[Q4]	Severe anoxic spells Intubated since birth	6 mo
2	Right lung malformation LMB[Q5]kinking	Right pneumonectomy Intrathoracic expander	Severe hypoventilation Ventilated since birth	14 mo
3	Tracheomalacia		Severe anoxic spells	7 mo
4	Laryngeal diastema VACTERL-type syndrome Severe tracheobronchomalacia	Esophageal surgery Laryngoplasty Gastrostomy	Severe anoxic spells Intubated since birth	9 mo 24 mo
5	Tracheomalacia		Severe anoxic spells	7 mo
6	Aortic coarctation Tracheomalacia	Aortic surgery	Severe anoxic spells Stridor-dyspnea Left vocal-cord palsy	3 mo
7	Congenital tracheal stenosis	Tracheoplasty Balloon dilatation	Recurrent stenosis	8 mo 21 mo
8	Congenital tracheal stenosis	Tracheoplasty Balloon dilatation	Recurrent stenosis	8 years
Type 2 tracheo-bronchomalacia				
9	Double aortic arch Tracheoesophageal fistula Tracheomalacia	Aortic surgery Esophageal surgery	Severe anoxic spells	3 mo
10	Aortic arch hypoplasia Vascular compression of LMB	Aortic surgery	Left lung emphysema Chronic hypoxemia	4 years
11	Aortic arch hypoplasia Vascular[Q6]compression of LMB	Aortic surgery	Left lung emphysema Chronic hypoxemia	23 mo
12	Tetralogy of Fallot Catch-22 (22q11 microdeletion) Vascular compression of LMB	Cardiac surgery LPA coil	Left lung emphysema Chronic hypoxemia Worsening PAHT Left vocal cord palsy	4 mo
13	Aortic arch hypoplasia LMB vascular compression	Aortic surgery	Left lung emphysema Chronic hypoxemia Left vocal-cord palsy	27 mo
14	Transposition of great arteries LMB vascular compression	Cardiac surgery	Left lung emphysema Chronic hypoxemia	2 mo

[1]**Type 1** tracheomalacia, congenital or intrinsic tracheal abnormalities of cartilaginous portion with or without tracheooesophageal fistula; **Type 2** tracheomalacia, extrinsic compression by cardiovascular structures, tumors, lymph nodes, or other masses. LMB, left main-stem bronchus; LPA, left pulmonary artery; PAHT, pulmonary arterial hypertension; MO, months.

which induced mechanical mobilization of the stent (cases 9, 10, 13, and 14). It was also related to the use of small-caliber prostheses, since all except one of the 4/5 mm stents resulted in technical failure (cases 7, 9, 10, 13, and 14) or required a change of caliber (cases 3, 6, and 12). Interestingly, one 4/5 mm stent remained stable for 3 months in the left main-stem bronchus of an infant, before migrating (case 11). Substituting for a greater-caliber stent was not always successful, as shown by case 14, in whom the 5/6 mm prosthesis replacement of a migrated 4/5 mm stent did not unfold.

Tolerance

In the present cohort, 3 children died, 2 of them from the severe initial disease. Only one death could be attributed to stent use (case 1). The prosthestic dysfunction appeared to be due to inadequate secondary management. The child's condition had initially significantly improved after tracheal stent insertion. He was thus transferred 4 months later to a secondary hospital where nebulizations and chest physiotherapy were inadvertently discontinued as a result of his improved medical condition, leading to the formation of mucus plugs. This unfortunate outcome was considered avoidable. In our series, no cases of bleeding or wall erosion were observed. Stent withdrawal or replacement did not present any particular technical difficulties. Low-grade granulation tissue, localized to the tips of the stent, was noted in 5 cases. Such tissue did not induce obstruction or require resection. It was usually observed when the stent was too mobile. The stent's tips could have exerted a traumatic effect on the mucosal wall upon coughing. Patient 12 is a case in point. After the insertion of a stent of insufficient diameter, a fiberoscopic examination 24 hr later showed that it was too mobile, and that granulation tissue was already developing at its proximal

TABLE 2—Tracheal and Left Main-Stem Bronchus Stent Characteristics and Overall Results[1Q11]

Patient	Stent characteristics (*ID/OD, length*)	Overall stenting duration	Complications	Overall result
Tracheal				
1	5/6, 28 mm	4 mo	Death by stent obstruction	2
3	4/5, 25 mm			
	5/6, 30 mm	7 mo	Minor granulation	1
4	7/8, 31 mm		Laryngeal dyspnea due to severe laryngomalacia	
	9/10, 36 mm			2
	9/10, 61 mm	48 hr		Tracheostomy[Q7]
5	5/6, 32 mm	4 mo		1
6	4/5, 25 mm			
	5/6, 30 mm	8 mo		1
7	4/5, 22 mm			
	4/5, 30 mm			
	5/6, 40 mm	3 weeks	Granulation at tip of stent	3
		4 weeks	Stent migration	
			Relapse of stenosis	
8	7/8, 45 mm			
	7/8, 50 mm			
	8/9, 50 mm	7 mo	Minor granulation	1
			Relapse of stenosis after stent removal	
9	4/5, 20 mm	Immediate withdrawal	Unsteady stent	3
			Cerebral anoxia	
Bronchial				
2	4/5, 8 mm			
	5/6, 8 mm	4 days	Stent plicature	3
			Death by sepsis	
10	4/5, 25 mm			
	5/6, 25 mm	1 mo	Granulation at tip of stent	3
			Stent migration	
11	4/5, 25 mm	3 mo	Granulation at tip of stent	1
			Stent migration	
12	4/5, 15 mm			
	5/6, 15 mm	15 mo	Bronchial infection	1
13	4/5, 18 mm	48 hr	Stent migration	3
14	4/5, 20 mm			
	5/6, 20 mm	2 days	Stent migration	3

[1]MO, months; ID, inner diameter; OD, outer diameter (mm). Overall results: 1, clinical and technical success; 2, technical success but clinical failure; 3, technical failure.

end. A larger stent remained in optimal position during the 15 subsequent months without any granulomatous relapse (Fig. 3).

DISCUSSION

In the present report, we illustrated the feasibility of silicone airway stenting in infants as young as 2 months old with benign conditions. The longest duration of stent placement was 15 months. The overall clinical and/or technical success rate was 57% (8/14 cases). Tracheal stents achieved a success rate of 75% (6/8 cases). Tolerance appeared to be good, and no technical difficulties were encountered with respect to stent removal. Silicone stents can thus be inserted and maintained in children without suturing to the tracheal wall. However, a lethal but avoidable case of stent obstruction was observed. Moreover, stent performance was unsatisfactory in the presence of high-pressure vascular compression.

In most cases of tracheobronchomalacia, a conservative approach is adequate, since even very severe endoscopic obstruction may be well-tolerated clinically. When patent clinical symptoms are present and do not resolve rapidly, a more aggressive approach is required. In the absence of randomized clinical trials, there are no firm recommendations regarding the indications of stenting vs. aortopexy, tracheostomy, or other surgical approaches. Traditionally, in most institutions in France, CPAP (with or without tracheostomy) is the usual therapeutic option in the presence of proximal or diffuse malacia. Tracheobronchopexy and tracheoplasty are therapeutic options in children with type 1 tracheomalacia (congenital or intrinsic tracheal abnormalities of the cartilaginous portion, with or without tracheoesophageal fistula). Aortopexy and specific treatments may be proposed in some cases of type 2 tracheomalacia (extrinsic compression by cardiovascular structures, tumors, lymph nodes, or other

masses).[16] In the present study, the limited number of patients with tracheomalacia associated with tracheoesophageal fistula was due to the fact that such conditions were managed by with aortopexy in some centers. The use of stents is considered in certain cases of localized proximal type 1 malacia.

In the same vein, in the absence of randomized clinical trials, it is impossible to compare the efficacy and tolerance of metal vs. silicone airway stents in children. Several teams are currently placing metal stents in young children with similar indications, e.g., tracheomalacia, posttracheoplasty stenosis, or vascular compression of the lower airway tract. Most authors published their results as a limited series or selective cases.[6,7,9,10,16–23] The mortality rate was high, but indications for stenting were mostly last-option rescue procedures. In one study, the overall complication rate in adults and children was 32% (9/28 stents in 23 patients).[22] The stability of metal prostheses was generally satisfactory, and displacement was infrequently observed. However, the conformation of such a device can be altered by violent coughing.[7] Its local tolerance was poor, with a tendency to incorporate itself into the airway wall. This can represent a problem at time of removal, or even cause a perforation of the aortic wall.[6,9,10] Development of granulation tissue was frequent at the stent tips. Such a situation was sometimes responsible for major obstruction and residual stenosis after stent removal. We also personally experienced severe complications with prostheses of this type (unpublished data). Biocompatibility is reportedly better with soft metal prostheses (e.g., titanium, nitinol) that have tips which are less damaging or are covered by a silicone film.[7] However, the literature on the use of such stents in children remains scanty. Notably, about 50% of patients still had their stent in place when data pertaining to them were published. Indeed, stenting duration was substantially longer than in our study.

The biocompatibility of silicone stents appears better than what was reported for metal ones.[22] Granulomatous reactions were infrequent and moderate, and usually pointed to abnormal prosthetic mobility. No complications such as mucosal erosion or wall inclusion were observed in our series. When a problem occurred, prosthesis withdrawal could easily be performed by bronchoscopy, as it would be for foreign-body removal. This is in contrast with metal stent removal, which requires experience and caution. In adult series, stent placement is usually indicated as a palliative procedure (malignant tumors of the respiratory tract) or for benign but fixed stenoses. Conversely, indications in children pertain to abnormalities which in the majority of cases will improve with both the radial growth of the respiratory tract and the shift of mediastinal vessels. Therefore, silicone stenting appears to be a very interesting solution whenever temporary airway patency is sought. Tracheostomy, chronic ventilation, and hospital observation may be avoided in certain cases. Notably, and in contrast with what is currently believed, in our series the best results were obtained in tracheomalacia.[21]

Despite the good overall results in our case series of silicone airway stenting in children, a few obstacles need to be overcome. First, such stents can be difficult to insert in small infants. The small caliber of rigid bronchoscopy tubes may be a problem for stent placement. In a 3-month-old child, we inserted a tracheal stent using foreign-body/Magill's forceps and then positionned it using a rigid tube (case 6). Such a procedure was also used for placing a pantracheal stent (case 4). Second, the degree of stability of silicone stents has to be improved. In our series, migration was the most frequent complication. Fortunately, since silicone stents remained in the axis of the aerial tract, their migration did not cause suffocation. Cough and dysphagia were early sentinel symptoms which called for emergency endoscopic verification. The prosthesis was designed to remain in position as a result of its knobs and radial expansion force. Care should therefore be taken to select the largest possible diameter which allows for unfolding within the stenosis. The size of the latter should be determined via the bronchoscopy tube. Nevertheless, this may not be adequate in case of airway malacia, which can expand to significant proportions. We recommend that several prostheses with incremental calibers be available at the time of insertion, and that the smallest size be inserted first. A retrospective analysis of failures due to migration indicated that the insertion of a greater-caliber stent (which repeatedly proved to be more efficacious) could have been attempted in 3 of the earliest cases. Failures were most frequently observed when small-caliber stents were compressed by high-pressure vessels (4 cases). The high pressure of the latter modified the stent conformation and ultimately ejected it. Most likely, this represented a wrong indication for this type of stent. Metal stents are probably more suitable in such situations, although the risk of vascular erosion appears to be greater.[11] In case 12, in whom the compression was caused by a low-pressure vessel (left pulmonary artery), the stent remained fully stable for 15 months[Q8]. The child returned home with daily chest physiotherapy and thoracic compression maneuvers never led to stent mobilization. Third, the enhanced biocompatibility of silicone did not eliminate the risk of obstruction, which was responsible for one death in our series (case 1). Obstruction was caused by an interruption of the mucociliary escalator, but not by granuloma proliferation as described with metal stents. Such a risk of occlusion should always be kept in mind especially regarding tracheal prostheses, irrespective of their type. Stent humidification via nebulizations several times daily is suggested, as well as evacuation of secretions by chest physiotherapy, which is technically possible if the stent is stable. As much as possible, the

child should be in the vicinity of a specialized center where rapid bronchoscopy can be performed. Emergency intubation should also be performed with caution. Fourth, the optimal in situ longevity of pediatric stents needs to be determined. The decision to remove a stent in a stable patient is difficult. With respect to stenting in airway malacia, the most logical approach is to await spontaneous prosthesis mobilization, which indicates radial growth of the stenotic area. In the case of a rigid stenosis, the question of whether it is appropriate to change the prosthesis caliber should be reassessed on a regular basis. An endoscopic reexamination should be performed at least every 3 months, or more often if necessary.

CONCLUSIONS

This short series offers some evidence that silicone tracheobronchial stents may be a feasible therapeutic option in short- and medium-term obstruction of the lower respiratory tract in infants and children. Compared to what has been published on metal stents, silicone prostheses appear to improve airway wall tolerance, but this is counterbalanced by a loss of stability. We speculate that the results presented here may be improved as experience in stenting is accumulated. The role of airway stents remains unclear, and at the present time the aim of the present paper is not to sway clinical management of airway diseases in children. However, pediatric pulmonologists should be aware of the existence of such stents. Further studies are required in order to compare the use of stents (and their type) vs. tracheostomy in the following indications: tracheomalacia, tracheobronchial surgery, and large-airway vascular compression.

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