The Journal of THORACIC AND CARDIOVASCULAR SURGERY

GENERAL THORACIC SURGERY

EMERGENCY STENTING OF MALIGNANT OBSTRUCTION OF THE UPPER AIRWAYS: LONG-TERM FOLLOW-UP WITH TWO TYPES OF SILICONE PROSTHESES*

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Objective: We evaluated the long-term prognosis of stents placed on an emergency basis in the trachea and its bifurcation for malignant stenosis. **Methods:** We retrospectively analyzed all bronchologic treatments of obstructing airway lesions from January 1993 to December 1995. **Results:** We report on 10 patients with severe malignant "mixed-type" obstruction of the proximal trachea or distal trachea plus both main-stem bronchi. They had far-advanced inoperable tumor (esophageal cancer: $n = 4$; lung cancer: $n = 3$; recurrent laryngeal, uvula, and thyroid cancer: $n = 1$ each). Emergency treatment consisted of a dilating bougie maneuver followed by the insertion of a large one-way ($n = 4$) or Y-shaped silicone prosthesis ($n = 6$). After the intervention, there was a long-lasting clinical improvement. Median survival from stent insertion was 8 months for all patients irrespective of tumor type; it was 5 months for patients with lung carcinoma and 8 months for those with esophageal cancer. The results are in accordance with other studies using different therapeutic modalities. Stent exchange was necessary in five patients. Main reasons were continuing tumor growth beyond the proximal and distal boundaries and recurrent productive bronchial infection. Patients died of pneumonia ($n = 4$), pulmonary lymphatic spread ($n = 1$), cardiac failure ($n = 2$), and fatal hemorrhage ($n = 1$). As of December 1995, three patients were still alive 2, 5, and 8 months after implantation. **Conclusions:** As evidenced by clinical efficiency and length of palliation, endoscopic placement of silicone-based one-way and bifurcational prostheses in far-advanced tumor of the central airways is technically feasible and ethically justifiable. (J Thorac Cardiovasc Surg 1996;112:859-66)

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Received for publication Feb. 5, 1996; revisions requested March 12, 1996; revisions received April 9, 1996; accepted for publication April 11, 1996.

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*Dynamic Stent, produced by Willy Rüsch AG, 71385 Kernen, Germany. Dumon Stent Endoxane, distributed by Bess Medizintechnik GmbH 14169 Berlin, Germany.

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0022-5223/96 \$5.00 + 0 12/1/74184

Until recently, obstructive lesions of the central airways caused by extrinsic tumor growth necessitated open surgical procedures to restore the lumen. A tracheostomy was the therapy of choice whenever the subglottic area was involved. However, processes located both in the distal trachea and in the bifurcation were extremely difficult to address: Mechanical debulking of the infiltrated mucosa was short-lived. Extrinsic compression, on the other hand, precluded endoscopic resection. With the advent of cylindrical and bifurcated silicone prostheses, longstanding patency can be achieved by means of bronchoscopic techniques alone. These new devices may provide valuable palliation for patients with inoperable malignant disease of the central airways.

Patients and methods

In a retrospective analysis of bronchoscopic interventions from January 1993 to December 1995, only patients with malignant obstruction of the trachea or tracheobronchial bifurcation, or both, were considered. They were selected from 53 patients who had endoscopic treatment of malignant obstructing airway lesions during that period. As we focused on the "natural history" of stents in the upper airways, we excluded patients who underwent airway recanalization without insertion of stents or with stents placed at more distal sites. In addition, we excluded those who needed only transient support by a prosthesis to bridge the delay until decompression was achieved by other well-established techniques.

When the patients arrived at the bronchology unit, 14.6 ± 19 months (mean $\pm$ standard deviation; median 8 months; range 0 to 60 months) had passed since the initial diagnostic workup (Table I). As first-line therapy three patients had undergone surgical resection with intention for cure. Seven patients had been pretreated with standard radiotherapy or chemotherapy, or both. The presenting sign was respiratory distress. Complaints of gradually worsening stridor over the previous weeks or months had been attributed to symptoms of acute upper airway infection.

Bronchoscopic examination revealed local tumor invasion along with considerable stenosis of the trachea alone ($n = 4$) or of both the trachea and carina involving the ostium of the main-stem bronchi ($n = 6$). In every single case the obstructive lesion was of the mixed type, that is, composed of extrinsic compression and mucosal infiltration and congestion.

Biopsy sampling yielded esophageal cancer in four patients, small-cell and non-small-cell bronchogenic carcinoma in three, thyroid carcinoma and uvula carcinoma in one patient each, and recurrent laryngeal carcinoma in one patient who had a tracheostomy after complete laryngectomy. All tumors were inoperable at presentation.

Short-term management. The patients needed urgent dilation and stenting of the central airways to avoid imminent asphyxia.

With the patient under general anesthesia orolaryngeal intubation was performed with an operating laryngoscope attached to a chest support (Karl Storz, Tuttlingen, Germany). The tip of the laryngoscope had an internal diameter of 20 mm. It was positioned to expose the entire circumference of the vocal cords. Ventilation was sustained by a low-frequency oxygen jet through a nozzle fixed to the proximal orifice of the instrument. The laryngoscope thus served as an access for manipulations necessary within the trachea. At the same time, it allowed continuous administration of oxygen.

Emergency treatment consisted of a bougie maneuver in which a series of rigid bronchoscopes of increasing diameters were used. In all patients, placement of the appropriate stents (Fig. 1) was facilitated by use of the end of the bronchoscope to peel off the congested mucosa. For the insertion of the cylindrical Dumon stents ($n = 4$; 16 mm outer diameter; Dumon Stent Endoxane, distributed by Bess Medizintechnik GmbH, Berlin, Germany),¹ a metal or plastic tube was used with a pusher inside. After the stent was folded into the tip of the tube, the applicator was introduced into the trachea and passed just beyond the previously dilated stenosis. Then the tube was drawn back over the pusher so that the stent was released into the obstructed segment (Fig. 2, A). Whenever subsequent fiberoptic bronchoscopic examination indicated the need to move the prosthesis, it was moved into the correct location with the help of a rigid forceps.

Atraumatic placement of a bifurcated Dynamic stent ($n = 6$; 13 or 15 mm outer diameter at the distal tracheal portion; Dynamic Stent, produced by Willy Rsch AG, Kernen, Germany)² necessitated that its divergent main-stem limbs be held together from the inside by the branches of a foreign body forceps. Passage through the vocal cords was eased by turning the stent on its long axis so that the two limbs were in line with the glottis. The prosthesis could then be advanced without difficulty. Once within the trachea, the stent was turned back to its normal position and was pushed further down to be firmly anchored on the carina. Usually, the limbs readily entered their respective main-stem bronchi themselves (Fig. 2, B). In case of kinking or infolding, a flexible bronchoscope inserted into the limbs helped to deploy them and served as a "guidewire."

Results

Preimplantation versus postimplantation lung function values were available for comparison in five patients (Table II). Before intervention, peak expiratory flow and forced expiratory volume in 1 second (FEV_1) were clearly reduced and body plethysmographic airway resistance, which showed a typical S-shaped flow-pressure loop, was elevated.³ Vital capacity was in the low normal range. Stent placement resulted in a median increase of peak expiratory flow and FEV_1 by 92% and 54%, respectively, airway resistance fell by a median of 48% from the preimplantation value, and vital capacity remained essentially unchanged.

Table I. Patient characteristics

Patient (sex, age)	Diagnosis and management	N	L	Tumor site, growth characteristics, and complications	Follow-up (mo); ID to BU*; BU to death or 12/95†
1 (F, 51)	Esophageal Ca, T4 N1 M1 (pul). After radiotherapy; mechanical dilation, Dumon (16), RT	1	+	Subtotal proximal tracheal stenosis due to extrinsic compression and mucosal congestion.	5 mo;* 2 mo.† Died of resp. failure, Ca lymphangitic.
2 (M, 58)	Esophageal Ca, T4 N1 M0; mechanical dilation, Dumon (16), RT, chemotherapy	1	+	Subglottic tracheal obstruction due to extrinsic compression and mucosal infiltration. Later subglottic fistula.	1 mo*; 12 mo.† Tumor progression. Died of pneumonia.
3 (M, 66)	Esophageal Ca, T4 N1 M0; RT; mechanical dilation, Dumon (16)	1	NA	Subglottic tracheal stenosis due to extrinsic compression and infiltration.	4 mo*; 8 mo.† Died of cardiac failure and pneumonia.
4 (F, 69)	SCLC, T4 N3 M0, extensive disease; mechanical dilation, Dumon (16), chemotherapy	1	+	Mid-to-lower tracheal compression and infiltration, esophageal infiltration, middle lobe bronchial obstruction. Tracheoesoph fistula subsequent to chemotherapy.	0 mo*; >2 mo.†
5 (F, 58)	Tracheal recurrence of papillar thyroid Ca. After total thyroidectomy and radiotherapy; laser resection, mechanical dilation, Dynamic stent (15)	3	NA	Distal one third of trachea, bifurcation; wall destruction, intraluminal growth, carinal compression.	33 mo*; 12 mo.† Stent exchange due to kinking. Died of cardiac failure.
6 (M, 66)	Tracheal and carinal recurrence of uvula Ca. After resection and radiotherapy; laser resection, mechanical dilation, brachytherapy, Dynamic stent (13)	2	NA	Distal trachea, bifurcation, RMB/LMB swollen and distorted by infiltrating tumor.	60 mo*; 8 mo.† Stent exchange due to tumor overgrowth. Died of recurrent pneumonia.
7 (M, 62)	NSCLC, T4 N3 M0. Local recurrence after combined radio/chemotherapy, mechanical dilation, Dynamic stent (15) + Dumon (13), brachytherapy	4	+	Distal trachea, bifurcation, RMB/LMB infiltrated; <i>Proteus vulgaris</i> .	17 mo*; 8 mo.† Stent exchanges due to dislodgment and restenosis by tumor overgrowth. Died of fatal hemorrhage.
8 (M, 61)	NSCLC, T4 N3 M1 (hep); superior vena cava syndrome. First presentation; mechanical dilation, Dynamic stent (13), RT	1	NA	Distal trachea, bifurcation, RMB/LMB infiltrated.	0 mo*; >5 mo.† Clinical improvement.
9 (M, 45)	Esoph. Ca, T4 N2 M1 (cer, oss). Esoph. tubing, chemotherapy, RT, mechanical dilation, recanalization, Dynamic stent (15), Dumon (13), brachytherapy and Dumon (16)	5	+	Tumor infiltrating distal trachea and LMB, fistula, tumor infiltration of RMB and LMB; <i>Pseudomonas aeruginosa</i> .	11 mo*; >8 mo.† Stent placement at restenosis and tumor overgrowth.
10 (M, 53)	Tracheal recurrence of pharynx Ca. After resection and radiotherapy; T3 N2 M0; Dynamic stent (13)	2	NA	Tumor compression of whole trachea distal to tracheostomy; <i>Staphylococcus aureus</i> .	15 mo*; 3 mo.† Stent exchange due to multiresistant <i>Staph</i> . Died of pneumonia

Ca, Carcinoma; RT, radiotherapy; SCLC, small-cell lung carcinoma; NSCLC, non-small-cell lung carcinoma; pul, pulmonary metastases; hep, hepatic metastases; cer, cerebral metastases; oss, osseous metastases; N, number of stents implanted consecutively or simultaneously; L, lung function before and after implantation; +, available; NA, not available; RMB/LMB, right/left main-stem bronchus; ID, time of initial diagnosis; BU, first appearance in bronchology unit; 13, 15, 16, outer diameter in millimeters (only most recent stents are given). Data as of December 31, 1995.

After a successful primary endoscopic treatment, five of 10 patients needed replacement of stents, such that a total of 21 devices were implanted consecutively or simultaneously (Table III). The first exchange was 3.8 ± 1.8 months (mean $\pm$ standard deviation) from the initial bronchoscopic treatment ($n = 5$), the second occurred 2.0 ± 0.9

months later ($n = 3$), and one patient had a third exchange after another 2.5 months. The need for restenting seemed to depend on the presence or absence of subsequent radiotherapy and chemotherapy (see Table I). In case these options had already been exhausted before the first stent placement and continuing tumor growth beyond the boundaries of

Fig. 1. The two types of silicone stents described in the current study. *Top*, A full-length Dynamic bifurcated prosthesis. Both the tracheal portion (horseshoe stainless steel inlays) and either main stem limb can be shortened to the appropriate length. *Bottom*, A Dumon radiopaque tracheal prosthesis.

the prosthesis led to restenosis, the lesions were then bridged by longer and more appropriate devices. Because in two patients the limbs of a Dynamic stent could not be introduced through a complex conical stenosis of the main-stem bronchi, these obstructions were bridged by short Dumon tubes before the remainder of the bifurcational narrowing was stented with a Dynamic prosthesis. Thus two serial stents were necessary (Fig. 3). A course of brachytherapy was added to improve sustained airway patency at the distal edges.

A further important reason for stent exchange was recurrent bronchial infection ($n = 3$). The patients complained of purulent secretions and bad breath. One of them had a tracheostomy after a laryngectomy. Bacterial bronchitis developed as a result of multiresistant *Staphylococcus aureus* organisms colonizing on the silicone material. Lavage in two more patients yielded *Proteus mirabilis* and *Pseudomonas aeruginosa* bacteria on several occasions. From the explanted stent material, *Candida albicans*, *Staphylococcus aureus*, and *Proteus mirabilis* could be cultured. Despite effective antibiotic therapy, the infection recurred after short disease-free intervals.

In one patient a tracheoesophageal fistula developed underneath the stent after completion of the first chemotherapy course directed against extrinsic invading small-cell lung carcinoma. The stent re-

mained in place and the fistula was sealed with an additional esophageal prosthesis. Significant restenosis from mucus impaction or granulation tissue was not encountered. Nonproductive cough caused by foreign body irritation was rare.

As of December 31, 1995, all patients had survived for a mean of 6.8 ± 3.7 months (median 8 months) after their first arrival in the bronchology unit. The replacement group had an entire follow-up of 7.8 ± 3.2 months, whereas the remaining five patients with one stent only survived for 5.8 ± 4.3 months. The difference was not significant.

No deaths occurred within 30 days of intervention. Causes of death were cardiac ($n = 2$) and respiratory failure ($n = 5$); the latter was due to carcinomatous lymphangitis and pneumonia. One patient died of acute hemorrhage during stent replacement. The fatal event occurred during endoscopic manipulation of a tumor-infiltrated bronchial wall adjacent to the pulmonary artery.

Three patients were still alive at the time of this writing 2, 5, and 8 months after implantation.

Discussion

Among the different techniques to restore patency in malignant obstructive lesions of the upper airways, stents are the mainstay. They establish immediate luminal patency and thus have a significant role in respiratory emergencies. Furthermore, they are thought to prevent long-term restenosis. In our opinion, therefore, placement of expandable metallic prostheses⁴ is obsolete, because they allow continuous tumor growth through the wires of the stent and secondary obstruction within.

The decision to introduce a tracheobronchial stent depends on (1) the type of growth of the malignant process, (2) the site of the stenosis, and (3) the severity of dyspnea, generally reflecting the amount of reduced luminal diameter.

High-grade extrinsic compression of the trachea or carina by mediastinal malignant tissue with or rarely without additional wall infiltration requires prompt prosthetic placement. The same applies to tumor-induced tracheomalacia because the wall is liable to collapse with every expired breath. Under these circumstances, no other therapy but stent repair provides immediate relief and permanent airway patency, if chemotherapy and radiotherapy options have been exhausted during previous trials.

Both slight to moderate stenosis of the central airways and any variant of malignant obstruction at

Fig. 2. Drawing of stenting techniques. **A**, Dumon stent implantation via operating laryngoscope. *Top*, Applicator pushed beyond tracheal stenosis. *Inset and bottom*, Stent release by drawing the tube against the pusher. For details see text. **B**, Dynamic stent placement via operating laryngoscope. *Top*, Stent inserted with a rigid foreign body forceps whose branches put the divergent limbs together (*bottom right*). *Bottom left*, Stent anchored on the carina with the limbs in place. For details see text.

Table II. Lung function results before and after emergency stenting in five patients

Patient	PEF	Raw	FEV ₁	VC
1				
Before	0.56 (8.5%)	1.56 (519%)	0.72 (26%)	2.48 (75%)
After	4.05 (+623%)	0.81 (-48%)	2.52 (+250%)	2.63 (+6%)
2				
Before	4.30 (49%)	0.47 (160%)	2.69 (75%)	5.07 (108%)
After	6.37 (+48%)	0.15 (-68%)	4.00 (+48%)	4.99 (-1.6%)
4				
Before	1.28 (25%)	1.35 (449%)	0.96 (60%)	2.09 (102%)
After	2.99 (+133%)	0.34 (-75%)	1.48 (+54%)	2.04 (-2.4%)
7				
Before	2.33 (30%)*	0.56 (187%)	1.48 (50%)	2.88 (74%)
After	4.48 (+92%)†	0.40 (-29%)	2.12 (+43%)	3.15 (+9%)
9				
Before	4.58 (48%)	0.42 (141%)	2.56 (61%)	4.15 (76%)
After	6.03 (+31%)	0.31 (-26%)	4.00 (+56%)	5.32 (+28%)
Median*	30	187	60	76
Delta median†	+92	-48	+54	+6

PEF, Peak expiratory flow (L/sec); Raw, body plethysmographic airway resistance (kPa × sec/L); FEV₁, forced expiratory volume in 1 second (L); VC, vital capacity (L).

*Percent predicted normal.

†Percent deviation from preimplantation value (=100%).

more distal sites can await gradual reopening achieved by chemotherapy, external-beam radiotherapy, or bronchoscope-guided brachytherapy. In addition, mere intraluminal tumor growth does not necessitate stents in any location. Tumor debulking with a rigid forceps or coring with a rigid bronchoscope⁵ will suffice as a first-line measure. Some authors prefer laser resection,^{6,7} the use of a diathermy loop,⁸ or electrocautery⁹ to remove neoplastic tissue of this type.

In our series, after the intervention all patients had dramatic clinical improvement, best reflected by the relative change of peak expiratory flow. Peak expiratory flow is the most sensitive parameter for upper airway disease in model experiments.³ Median survival was 8 months from the time of stent placement irrespective of histologic tumor type. Therefore long-standing local tumor control can be obtained with the help of stents in malignant lesions of the upper airways. However, a clear-cut survival

Table III. *Reasons for stent exchange*

Insufficient closure of fistula	1
Tracheal kinking	1
Stent dislodgment	1
Tumor overgrowth at proximal or distal ends	5
Growth and adherence of (multiresistant) bacteria	3

benefit does not seem to be derived from placement of a permanent prosthesis alone. All patients had had additional treatments with radiotherapy or chemotherapy, or both, before or after stenting. Median overall survival (i.e., from initial diagnosis to death) for those who had esophageal cancer ($n = 4$) was 12.5 months. This survival time is not different from that in a recently published study of radiotherapy and chemotherapy of inoperable esophageal cancer.¹⁰ Median survival was 12.5 months for the combination protocol and 8.9 months for radiotherapy only. In contrast to our patients, a great majority of the study participants were recruited at earlier (i.e., T2) tumor stages. Moreover, a survival analysis of the subgroup of patients who had complicating metastatic obstruction of the upper airways is missing.

Patients with lung cancer ($n = 3$) survived a median of 5 months from the time of stent placement. This survival time compares favorably with other recently published data on brachytherapy (median survival 4.5 months)¹¹ and endobronchial laser resection (median survival 6 months)⁶ of far-advanced inoperable obstructive bronchogenic carcinomas. Again, patients with tumor involvement of the trachea, who made up only 10% and 25% of the respective total study populations, were not considered as subgroups of their own. A most recent article on permanent tracheobronchial silicone stents (Dumon) inserted for palliation of obstructing cancer of various histologic types¹² found median survivals of 6 and 4 months for the stage IIIB lung cancer groups with or without additional radiotherapy. The difference between these two samples was not significant. Although only 43% of tumors involved the trachea, the survival results agree with our findings. The issue of location and survival is still unresolved. However, one could speculate that tumor growth involving the trachea or carina is associated with less serious complications and longer survival than more distally located airway lesions, once satisfactory patency can be obtained. Malignant stenosis of main-stem, intermediate, or lobar bronchi may produce lung compromise such as

Fig. 3. Chest x-ray film of patient 9 with three serial tracheobronchial stents (Dumon 16 mm, Dynamic 15 mm, Dumon 13 mm). An esophageal tube had been inserted before.

atelectasis, secondary pneumonia, and abscess formation before patients are referred to the bronchologist. Recanalization will then often be unrewarding. Interestingly enough, for our experience, patients with stents inserted into these distal sites had a 30-day mortality of about 25% (unpublished data), as compared with no early deaths in those undergoing stent placement in the obstructed upper airways.

Bacterial adherence to intravascular or intracavitary plastic devices such as catheters, biliary stents, and drainage tubes poses a major problem because it occasionally causes infections and septic complications.^{13, 14} The chemical composition of the material may determine the amount of adherence: Polyurethane pieces coated with synthetic hydrophilic monomers seem less likely to attract and deposit bacteria than are uncoated tubes made of polyethylene or silicone rubber.¹³⁻¹⁵ It is also conceivable that the number of colonizing strains per surface area should increase as indwelling time increases. In addition, we postulate that both silicone biodeterioration¹⁶ and limited clearance of secretions from within the tubes may contribute to the high affinity of microbes to the foreign material. In our patients either cultures of bacteria and yeasts from the explanted stents or recurrent bronchitis with the same gram-negative strain argue strongly in favor of adherence to and colonization on plastic. Fatal pneumonias in some patients may thus have been induced. Even in the

absence of overt pneumonia, however, relapsing purulent sputum production indeed is a serious side effect of stents that necessitates removal. Because of the focus on acute effects of airway stents, this issue is clearly underreported in the current literature.¹⁷ In any case, this complication should stimulate research into less adherent or more bactericidal materials designated for long-term use.

Minor stent-related complications like kinking, dislodgment, and even dried secretions are foreseeable and can be handled with ease.¹⁷ However, like Bolliger and coworkers,¹² we were concerned about one case of acute fatal hemorrhage occurring during stent extraction. After the end of the study period we saw another similar case. The underlying cause was presumably not stent-related, although pressure-induced necrosis of the bronchial wall and neighboring vascular structures cannot be entirely precluded. It is rather suggested that previous brachytherapy at this particular site may have contributed significantly to the fatal event. The prevalence of spontaneous late massive hemoptysis in patients undergoing endobronchial brachytherapy ranges from 20% to 50%.¹¹ The reason is thought to be radiation-induced tumor necrosis involving the large pulmonary vessels in proximity to a friable main-stem bronchus.¹⁸ In our patient, endobronchial irradiation had been instituted because of recurrent malignant stenosis at the very distal edge of the right limb of a Dynamic stent. Information regarding changes in stent material (flexibility, brittleness) caused by brachytherapy are sparse. But the issue is rather speculative, because at a usual after-loading course, with the radiation source inside the stent, the interior surface will receive a total amount of four times 15 to 30 Gy, which is but a small fraction of the 5 to 10 kGy that the material is exposed to during the production process (Rüsch, personal communication, March 1996). On the other hand, because of the distancing effect of the prosthesis itself, the tissue underneath the stent will absorb less energy than the adjacent stent-free bronchial segment. Thus, in combination with brachytherapy, it is not stents that make the bronchial wall more vulnerable, it is brachytherapy alone. However, a single delicate touch on the damaged bronchus during stent exchange sufficed to precipitate rupture and fatal hemorrhage. Therefore manipulating stents within a region of previous brachytherapy is strongly discouraged.

In conclusion, Dumon and Dynamic silicone stents are most valuable tools to promptly restore

sustained patency in tumor-obstructed upper airways. The effect on survival equals that of other antineoplastic modalities in patients in whom the trachea or bifurcation is not involved in the malignant process. Quite a few stents were exchanged every 2 to 4 months from the preceding treatment. The main reasons for replacement were tumor overgrowth and purulent bronchitis.

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