

## **DUMON-NOVATECH Y-STENTS: A FOUR-YEAR EXPERIENCE WITH 50 TRACHEOBRONCHIAL TUMORS INVOLVING THE CARINA**

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### **SUMMARY**

This article reports a 4-year experience using a new silicone Y-stent characterized by highly elastic construction material, optimal inner diameter, and non-stick surface quality. Fifty patients with advanced malignant disease involving the carina were treated by rigid bronchoscopy including dilatation using laser therapy and/or mechanical dilatation followed by Y-stent insertion using a dedicated stent applicator. Mean survival was only 109 days due to the severity of illness but quality of life was good. Particularly good results with prolonged survival were achieved in 19 patients with esophageal cancer. For the 8 patients with esophageal carcinoma with invasion or compression of the airway without fistula, mean duration of survival was 138 days. In the 11 patients presenting tracheo-esophageal fistulas in the vicinity of the carina, survival was only 71 days. Good life quality was directly related to good tolerance and complete re-establishment of respiratory function.

Dumon-Novatech Y-Stents: A four-year experience with 50 tracheobronchial tumors involving the carina

### **INTRODUCTION**

Since the end of the 1980s, endobronchial stents have allowed palliative treatment of patients with extrinsic airway compression formerly beyond the reach of any other therapeutic modality [1]. The silicone stent that we designed in cooperation with the Novatech Company in France (Dumon-Novatech stent) features a patented studded outer surface. These studs hold the stent in place by fitting between the cartilaginous rings and limit contact between the silicone tube and tracheobronchial mucosa. A major advantage of silicone stents is easy removal regardless of duration

of implantation.

Since Dumon-Novatech stents were first introduced, many improvements have been made to reduce complications observed in early experience. Rims have been beveled limit irritation of the mucosa. As a result of this change, the problem of granuloma formation has been practically eliminated. Silicone quality has been upgraded to enhance elasticity and the range of standard sizes has been broadened. These changes have reduced events involving migration. The surface of the stent has been treated to reduce adherence of secretions. This improvement greatly lowers the risk of obstruction which was once a major drawback.

Straight stents have been shown to be highly effective for indications in midsections of the trachea and main stem bronchi [2, 3, 4, 5, 6, 7]. However they were not well suited to lesions located on or near the carina. In view of this problem, we designed and produced a Y-stent specifically for these lesions. The purpose of this report is to describe our initial experience in a series of 50 patients treated using the Dumon-Novatech Y-stent for tumors involving the carina.

### **MATERIAL AND METHODS**

#### **Stent design**

Design of the Dumon-Novatech Y-stent was based on over 10 years of experience with the straight stent. This experience showed that tolerance depends mainly on elasticity of construction material, inner diameter, and surface quality. Other important factors in stent design include overall length, rim design, and wall thickness.

Adjusting elasticity is a major problem in stent design. The stent must be strong enough to withstand extrinsic compressive forces without excessive rigidity. By trial and error, we determined that a wall thickness of 1.3 mm was sufficient to maintain the normal diameter of the carina by the vault effect. In this regard it should be underlined that we have never observed stent compression in our experience of over 1000 cases. Slight compression may be observed immediately after insertion but stents always reopen fully within three days.

Inner stent diameter should be as close as possible to that of the normal airway lumen, i.e. 15 to 16 mm for the trachea and 12 to 13 mm for the main stem bronchi. This size requirement further underlines the importance of elasticity which must be great enough to allow insertion into the airways. This is also the

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reason why it is important to re-establish original airway diameter by laser resection and/or mechanical dilatation using either the scope or balloon catheters prior to insertion.

Surface quality is an essential factor for long-term placement. Stent obstruction due to accumulation of secretions has been a major problem in the past. This problem has now been almost completely eliminated by polishing and treating the surface of the stent.

Several features of the Y-stent have been studied to facilitate placement. Rims have been beveled to the inside and finely polished to allow smooth sliding over mucosa. The range of sizes has been broadened so that the lesion can be completely covered without excessive projection onto healthy mucosa. The stent has been designed to permit identification of the front and back before deployment.

Figure 1A shows the most commonly used 16x13x13 size Y-stent. These numbers indicate that the diameter of the tracheal leg is 16 mm while those of the right and left legs are both 13 mm. Only the front and sides of the tracheal leg of the stent are studded. Studs were left off the bronchial legs to facilitate insertion. Thus the back of the prosthesis can be identified by the absence of studs. A Y-stent with a short slant-cut right leg can be used to preserve ventilation of the right upper lobe bronchus. Models are available with longer branches and slightly smaller diameters (15x12x12) (Figure 1B).

**Figure 1B:**

Figure 1 Tuesday, November 09, 1999A : short Y-stent, 16/13/13. (These numbers indicate that the diameter of the tracheal leg is 16 mm while those of both the right and left legs are 13 mm). Only the front and sides of the tracheal leg of the stent are studded. B: Long Y-stent, 15/12/12. The legs of this stent can be trimmed if necessary.

**Placement**

Y-stent placement must be performed using a rigid therapeutic bronchoscope under general anesthesia. The first step in placement is to re-establish normal airway diameter by means of mechanical dilatation with or without laser-assisted resection. To get a tactile feedback and preserve ventilation, we prefer to use the barrel of the rigid scope rather than the balloon catheters for mechanical dilatation. Reopening of the airway is a prerequisite for placement of any type of stent.

Placement is performed using a large diameter tracheal

rigid tube (12 mm). The stent is lubricated with silicone and loaded into a 16 mm stent applicator. The applicator is then inserted through the bronchoscope and the stent is pushed out into the trachea just above the carina. After grasping the upper rim of the prosthesis with foreign body forceps, it is turned so that the unstudded side faces the back. Finally the stent is seated on the carina. Beginners sometimes have trouble deploying of the legs especially into the left main stem, but this problem is quickly overcome with experience.

**Stent removal**

Stent removal is always possible regardless of the duration of placement. The upper rim is seized using foreign body forceps and the prosthesis is twisted so that the walls collapse. The collapsed stent is then jammed against the tip of the bronchoscope and withdrawn. It is usually not possible to pull the stent into the bronchoscope.

**RESULTS**

**Patients**

Between July 1, 1994 and December 31, 1998, a total of 50 patients with malignant lesions involving the carina were treated by insertion of a Y-stent. There were 7 women and 43 men with a mean age of 60.3 years (range, 20-91 years). The histological diagnosis was squamous cell carcinoma in 32 cases, adenocarcinoma in 7, cylindroma in 3, undifferentiated carcinoma in 2, small cell carcinoma in 2, embryonal carcinoma in 1, lymphoma in 1, melanoma in 1, and sarcoma in 1. Airway obstruction or compression was the indication for Y-stent placement in 44 cases. The remaining 6 cases involved tracheo-esophageal fistula with no obstruction or compression of the airway. A total of 19 patients had esophageal cancer including 11 with tracheo-esophageal fistula.

**Table I:** Mean survival in 50 patients treated with Dumon-Novatech Y-stents for tumors involving the carina.

Indications	N° of patients	Survival duration (days)
Isolated tracheal tumor	31	118
Esophageal cancer without fistula	8	138
Esophageal cancer with fistula	11	71
Overall	50	109

### Type of stent

The following Y-stent models were used: Y 16x13x13 short in 40 patients, Y 15x12x12 long in 9, and Y 18x13x13 in 1. In 23 patients with extensive tumors, a short-legged Y 16x13x13 stent was used in combination with a straight tracheal (17 cases) or bronchial (6 cases) stent. Straight stents were attached by telescoping into the Y-stent. Short-legged Y-stents were used alone in only 17 cases.

### Removal

Removal was performed in 6 cases. In one case immediate removal was necessary because tumor compression resulted in such extensive deformation of tracheobronchial geometry that the Y stent was almost completely flattened into a T-shape. In the remaining cases, removal was carried out 43, 55, 78, 222, and 1259 days after placement. Two Y-stents are still in place at 108 and 304 days after insertion.

### Survival

Forty-two patients died during follow-up. This high mortality rate attests to the advanced stage of disease in patients indicated for palliative stenting. Survival data are given in Table I. Mean survival was 139 days for the 40 patients still alive more than one month after placement. Three patients survived between 12 and 18 months. Survival in the 8 patients with esophageal cancer without fistula was longer than for patients with isolated tracheobronchial tumors. In the 11 patients presenting tracheo-esophageal fistulas in the vicinity of the carina, survival was only 71 days. However it should be pointed out that one of these patients survived more than one year after placement and another was still alive at 3 months after placement.

## CASE REPORTS

### Case 1

In 1998, a 64-year-old woman undergoing treatment for melanoma developed severe dyspnea. Endoscopic examination revealed a tumor involving the carina. Therapeutic endoscopy using a rigid bronchoscope under general anesthesia was performed on March 2, 1998. A large tumor was found on the carina with complete obstruction of the right main stem bronchus and 90% obstruction of the left main stem bronchus. Histological study confirmed metastasis of melanoma. Laser-assisted resection was performed and airways were re-established. To maintain patency,

a Y-stent (16x13x13) was inserted. Full examination of the tracheobronchial tree revealed black metastatic lesions in most segmental bronchi with obstruction of the left upper division bronchus. Dyspnea improved dramatically, but the patient complained of chronic coughing which she attributed to the stent. At her request, the stent was removed on April 26, 1998. However immediate replacement was required due to collapse of the carina after removal. Coughing was controlled by medical treatment using antitussive and sedative drugs. The cause of this complication is unclear but was probably related to extensive metastatic involvement of peripheral airways. Subsequent follow-up was uneventful. The patient returned to a practically normal life-style and was still alive eight months after stent placement (Figure II).

### Figure II: Metastasis of melanoma.

- A: Large tumor astride the carina
- B: Result after endoscopic YAP laser resection and dilatation
- C: Dumon-Novatech Y-stent in the trachea
- D: Close up showing the carina covered by the Y stent

### Case 2

In November 1994, a 48-year-old man was sent to our department from Toulon, France, for emergency treatment of acute respiratory distress due to extrinsic compression of the anterior wall of the airway by a mediastinal tumor. The tumor caused 75% narrowing of the distal end of the trachea and 80% narrowing of the right main stem bronchus. Therapeutic bronchoscopy with mechanical dilatation under general anesthesia allowed re-establishment of the airway lumen. To prevent recurrence, a Dumon-Novatech Y-stent (16x13x13) was inserted. Respiratory function immediately improved and the patient was sent back to the referring physician 24 hours later. Histological study of biopsy specimens obtained during therapeutic endoscopy demonstrated adenocarcinoma. The patient underwent high-dose radiation therapy in Toulon and was not re-examined in our department. In April 1998, the patient returned complaining of slight dyspnea. Thoracic CT-scan showed that the stent was still in place and that the mediastinal tumor had disappeared. The patient reported that he had never used the aerosol sprays advised to reduce accumulation of secretions and that he had lived a practically normal life. On May 5, 1998, (Figure III) i.e. 41 months after placement, the stent was removed. Removal was easy. The stent was clean. Inspection of the airway showed that the mucosa was almost normal

with only the presence of a small benign granuloma at the upper rim of the stent on the left side of the prosthesis. The patient was re-examined three months after removal and was then lost from follow-up.

**Figure III:** Long-term follow-up of a Y-stent

CT scan 41 months after Y-stent placement for adenocarcinoma treated by radiation therapy and chemotherapy. The stent is visible at the level of:

- A: the trachea;
- B: the carina;
- C: the two main stem bronchi;
- D: the right upper lobe bronchus. The short slant-cut right leg preserves ventilation of the right upper lobe bronchus.

**Case 3**

A 69-year-old male patient with cancer in the middle third of the esophagus with tracheo-esophageal fistula was sent to our department for emergency treatment. Five days earlier, he had undergone placement of a partially covered Ultraflex esophageal stent. Endoscopic examination revealed the presence of two fistulas. The first was located in the middle third of the trachea over the uncovered segment of the stent. More distally another fistula extending 3 cm down to the carina was found over the covered segment of the stent. Insertion of two stents was required to cover and seal the fistulas. A Y-stent (16x13x13) was inserted into the carina and a straight stent (18/60) was then telescoped into the tracheal leg of the Y-stent. The patient was able to eat the next day but died suddenly 11 days later (Fig IV).

**Figure IV:** Iatrogenic tracheo-esophageal fistula

- A: Upper tracheo-esophageal fistula revealing uncovered segment of an Ultraflex esophageal stent;
- B: Lower fistula extending 3 cm down to the carina and revealing the covered segment of the same stent;
- C: Straight stent (18/60) covering the upper fistula;
- D: Y-stent (16x13x13) covering the lower fistula at the level of the carina. The 2 stents have been telescoped together.

**Case 4**

A 53-year-old patient presenting an obstructive tumor in the middle third of the esophagus underwent placement of an uncovered Ultraflex stent. Ten days after placement, erosion of the mucosa led to fistula with exposure of the stent through the posterior wall of the trachea. The patient was referred to our department for treatment. Endoscopic examination revealed a fistula located 1 cm above the carina with no extrinsic compression. Because of the proximity of the fistula to the carina, a straight stent could

not be used. Instead a Dumon-Novatech Y-stent (16x13x13) was inserted. Coverage and sealing was satisfactory. The patient was able to eat again the next day. Survival with almost normal life-style lasted for 2 months (Figure V).

**Figure V:** Iatrogenic tracheo-esophageal fistula.

- A: Large fistula located 1 cm above the carina with no extrinsic compression;
- B: Close-up showing the carina;
- C: Y-stent covering the fistula;
- D: The fistula is visible through the stent.

**Case 5**

A 66-year-old patient was referred to our department for treatment of tracheo-esophageal fistula following radiation therapy. Tracheobronchial endoscopy revealed a fistula located 1 cm above the carina in association with extrinsic compression of the lower third of the trachea and high-grade stenosis of the left main stem bronchus. After therapeutic endoscopy to re-establish the airway lumen, a Y-stent (16x13x13) was inserted. Inspection of the esophagus revealed a tumor starting 20 cm below the dental arches and extending 10 cm. An Atkinson prosthesis was inserted into the esophagus. The two stents achieved effective sealing of the fistula and the patient was able to eat normally for three months. He was still alive 108 days later.

**DISCUSSION**

Several points deserve further discussion. The first is the short mean survival which was only slightly over 3 months, i.e. 109 days. This finding must be correlated with the poor prognosis of patients indicated for palliative Y-stent placement. Survival without stenting would probably have been much shorter and the quality of life dramatically lower. Most patients with tracheo-esophageal fistula, survival die within one week after occurrence under extremely difficult circumstances. Mean survival after placement of a Y-stent in these patients was 71 days with good quality of life. Stenting was successful without migration in all but one case in which placement failed due to compressive deformation of tracheobronchial geometry. Insertion was easy provided that the lumen of two main stem bronchi was re-established to a diameter greater than 13 mm prior to placement. Removal was always easy even after almost three and a half years in one case.

An interesting finding in our experience was the remarkably good tolerance of these stents. One patient complained of persistent coughing following placement but this symptom was controlled by medication and tolerance has been good for 8 months. Obstruction due to accumulation

of secretions was not observed. Granulomas were uncommon and always of small size. High-dose radiation therapy did not affect the integrity of the stent.

The large Y-stent (16x13x13) was used most frequently. The length of this stent is 4 cm which is excellent in terms of ease of insertion and coverage of the carina. However in 23 of the 40 cases, this model had to be used in combination with placement of a straight stent proximally in the trachea (17 cases) or distally in the main stem bronchi (6 cases). Based on this initial experience, we asked the manufacturer (Novatech) to include models with longer legs.

### CONCLUSION

Over a period of 54 months, we placed a total of 50 Dumon-Novatech stents in patients with tracheobronchial or mediastinal tumors. The inner diameter of the bronchial legs of all stents used was greater than 12 mm. This feature probably accounted for the remarkably good tolerance. In all cases therapeutic bronchoscopy was performed to re-establish normal tracheobronchial diameter before placement and allow full deployment of the stent. Mean survival was relatively short due to the severity of illnesses but quality of life was good. Good life quality was directly related to good tolerance and complete re-establishment of respiratory function.

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