The Use of the Covered Wallstent for the Palliative Treatment of Inoperable Tracheobronchial Cancers*

A Prospective, Multicenter Study

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Study objective: To investigate the safety, efficacy, and tolerance of the covered Wallstent for the palliative treatment of inoperable tracheobronchial cancer.

Design: An 8-month prospective study employing either a rigid bronchoscope or a flexible delivery system for prosthesis insertion.

Setting: Multicentric setting involving four teaching hospitals in Switzerland and Germany.

Patients: Forty patients (29 men, 11 women), average age of 62 years, presenting with an inoperable tracheobronchial cancer.

Interventions: After partial airway recanalization with an Nd-YAG laser, the covered Wallstent was inserted 23 times using a rigid bronchoscope (Rigidstep device), and 27 times using a flexible delivery system (Telesstep device) under fluoroscopic and endoscopic visualization.

Results: Clinical and endoscopic examination at 1, 30, and 90 days showed improvement in the bronchial lumen and in the dyspnea index. No serious complication (death, perforation, hemorrhage, inability to remove an improperly placed prosthesis) was observed during surgery. Late complications included migration (12%), inflammatory granulations or tumor regrowth at the tip of the prosthesis (36%), and symptomatic retention of secretion (38%).

Conclusions: Compared with other tracheobronchial prostheses, notably the Dumon stent, the covered Wallstent presents the following advantages: insertion with visual guidance, treatment of extrinsic compressions and esophagobronchial fistulas, and little chance of migration when the prosthesis diameter is chosen correctly. The following disadvantages can be noted: high price; both repositioning and extraction of the released stent are more difficult, though certainly possible; and risk of granulations at the tips of the prosthesis and retention of secretions. Suggestions are made for potential improvements to the stent and insertion system that may result in a significant decrease in early and late complications.

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Key words: covered Wallstent; palliative treatment; tracheobronchial cancer; tracheobronchial prosthesis

Since the advent of the Nd-YAG laser in interventional bronchoscopy, the palliative treatment of inoperable tracheobronchial cancer has become widely used.1-4 The technique of airway recanalization with a rigid bronchoscope is currently well documented, safe, and effective.5 However, the duration of the functional advantage of the airway reopening is limited, even after adjuvant brachytherapy.6-9 The tumoral regrowth inevitably leads to the recurrence of the tracheal or bronchial stenosis. Moreover, laser treatment is ineffective and contraindicated in cases of pure extrinsic compression without intraluminal tumor growth.

These factors stimulated the development of endobronchial prostheses in oncology. The idea of stenting the airway is not new and, indeed, it dates back to the past century (Trendelenburg10 1872, Bond11 1891). It was revived in the 1960s by Montgomery,12 whose T-shaped siliconized tracheal prosthesis was widely used, notably in the United States.13 Later, Westaby et al14 modified the purely tracheal prosthesis into a tracheobronchial one. Even though these early prostheses played a major role in the treatment of tumoral and

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one most frequently used is that developed by Dumon,\textsuperscript{15} which is a radio-opaque silicon cylinder covered with studs that facilitate the anchorage of the stent in the tumor and thus decrease the risk of migration. The diameter of the prosthesis is predetermined without radial expansion forces; the wall is relatively thick, which decreases the diameter of the reopened bronchus. The Dumon stent (Bryan Corp; Woburn, Mass) is inserted in a blind procedure using a rigid bronchoscope especially designed for this purpose. A wide range of prostheses of different diameters and lengths exists, enabling most conditions, with the exception of tumoral stenoses at the tracheal bifurcation, to be handled effectively. For the latter, the Y prostheses by Freitag et al (Dynamic stent; Rüsch AG; Kernen, FRG)\textsuperscript{23} and Hood (Hood Laboratories; Pembroke, Mass)\textsuperscript{17} are especially designed for that purpose. They completely cover the tracheobronchial bifurcation without risk of migration.

As with the other models,\textsuperscript{12,14,17,18} the Dumon prosthesis is not exempt from complications, the most important of which are the risk of migration, inflammatory granulation formation at the ends, and retention of secretion. Finally, if an extrinsic stenosis is very indurated, then the prosthesis may not expand completely and the lumen may remain partially obstructed, especially if dilatation or laser treatment was not carried out beforehand. Based on experience acquired in angiology, new auto-expandable metallic prostheses have made their appearance on the market during the past years. These include the Gianturco Z-stent (Cook Inc; Bloomington, Ind), the Strecker Stent (Medi-Tech; Boston Scientific Corp; Natick, Mass), the Palmaz Stent (Cordis Corp; Miami, Fla), and the Wallstent (Schneider [Europe] AG; Bülach, Switzerland).\textsuperscript{24-32} Initially made without a covering, the limitation of these prostheses became quickly evident, as tumoral regrowth occurred rapidly through the metallic meshes. Moreover, some of them, such as the Gianturco Z-stent,\textsuperscript{24,25} had a metallic structure that was rather loose and increased the pressure per unit surface area, leading to possible penetration into the mediastinum with the risk of fatal hemorrhagic complications. To reduce these disadvantages, it seemed necessary to cover these prostheses with a silicone or polyurethane sheath. Of all the auto-expandable metallic prostheses currently on the market, the Wallstent appeared to be the best conceived and most elaborate, and thus, was used for the prospective multicenter study presented in this article.

Materials and Methods

Prosthesis and Insertion Devices

The covered Wallstent (Schneider [Europe] AG, CH 8180 Bülach/Switzerland) is a woven metallic prosthesis surrounded by a layer of polyurethane, which prevents tumoral regrowth through the metallic meshes. Thus, this prosthesis can be used to treat...
esophagobronchial, bronchomediastinal, and bronchopleural fistulas. Due to its thin wall, auto-expandability, and flexibility, it adapts easily to the local anatomic conditions and is effective in treating pure extrinsic compressions. Radiologically visible, but not interfering with MRI, it is easily positioned under fluoroscopic control. It is available in diameters of 10, 12, 14, and 16 mm, and lengths ranging from 2.5 to 7 cm (Fig 1). Two prosthesis delivery systems have been developed.

The Rigidstep device (Schneider AG; Bülach, Switzerland) (Fig 2) consists of a rigid bronchoscope whose internal tube is attached to a handle. It is equipped with a channel for jet ventilation and is used with a telescope (Hopkins), offering a perfect view during endoscopy. After reopening the airway with the laser, the distal end of the bronchoscope (Rigidstep device) is passed through the stenosis, and the prosthesis is progressively inserted under optical control by precisely (to the millimeter) fitting its distal end to the inferior extremity of the stenosis or to a bronchial bifurcation. The Wallstent is easily inserted in the external bronchoscopy tube with a special applicator.

With the Telestep device (Schneider AG) (Fig 3), positioning of the Wallstent is performed under fluoroscopic control in cases of distal bronchial stenosis, or with extrinsic compression that cannot be handled by the rigid bronchoscope. This system, whose external diameter is 5 mm, is formed by 3 semiflexible sheaths; the Wallstent is constrained by the 2 outer structures.

Using the integrated mandrel or a guidewire for appropriate positioning in the bronchus, and by means of two radio-opaque reference marks, the Wallstent is accurately delivered through the open tube of the rigid bronchoscope under fluoroscopic control. A half deployed stent can be repositioned distally or proximally. This is a disposable system.

Patients

Between December 1993 and July 1994, we carried out a prospective multicenter study to test the security, the reliability, and the efficacy of the covered Wallstent in the palliative treatment of inoperable tracheobronchial cancer. Four teaching centers in Switzerland and Germany participated in this study, which was approved by the Committee on Human Research of each hospital. An informed consent was obtained from all patients.

Forty patients presenting with inoperable tracheobronchial cancer were included in the study. There were 29 men and 11 women whose average age was 62 years (range, 36 to 83 years). All patients were at the end stage of the disease and were severely debilitated, presenting with dyspnea and/or pulmonary or lobar atelectasis. Most of them had already undergone 1 or more treatments: 15 courses of radiotherapy, 11 pulmonary resections, 10 palliative laser dilatations, 7 rounds of chemotherapy, and 4 insertions of another stent.

Except in cases of pure extrinsic compression, the tracheal or bronchial lumen was initially reopened using an Nd-YAG laser.

The histologic features of the lesion revealed a primary tracheal or bronchial squamous cell carcinoma in 25 cases; in 3 cases there was tumor recurrence of anaplastic small cell carcinoma after chemotherapy; 3 cases presented with esophageal squamous cell carcinoma and a tracheobronchial fistula, and other histologic features were present in 9 cases. The tumor was situated in the trachea only in 11 patients, and at the level of the carina in 6 cases (left-sided prevalence in 4 and right-sided in 2). The tumoral stenosis involved the left main bronchus only in 11 cases, the right main or intermediate bronchus in 10 cases, and finally, 1 case each where only the right main or intermediate bronchus was implicated.
The severity of the stenosis ranged from total obstruction to a residual lumen of approximately 6 mm (median diameter, 3.8 mm). Expressed as percentages, the residual lumina represented an average obstruction of 75% (±25%). The length of the stenosis was estimated to be, on average, 34 mm, with extremes ranging from 20 to 50 mm. In addition to the characteristics of the tumoral stenosis, the following parameters were analyzed: ease of prosthesis insertion; late migration of the prosthesis; change in the dyspnea index based on a scale ranging from 1 to 5 (Table 1); changes in coughing pattern; and finally, the Karnofsky Performance Index. This index only imperfectly reflects the clinical improvement of patients with end-stage cancer who are often debilitated by metastatic cancer.

In the postoperative phase, a chest radiograph was systematically taken on the day following the deployment of the prosthesis to judge the position of the stent and the improvement of a lobar or pulmonary atelectasis. Finally, within the framework of this prospective study, an endoscopic examination was systematically performed at 1 and 3 months, specifically to evaluate the rate of delayed prosthetic migration, minor retention of secretions, and the development of inflammatory granulations at the superior and inferior ends of the Wallstent.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>Asymptomatic while climbing stairs</td>
</tr>
<tr>
<td>1</td>
<td>Symptomatic climbing stairs</td>
</tr>
<tr>
<td>2</td>
<td>Symptomatic after walking 100 m on flat ground</td>
</tr>
<tr>
<td>3</td>
<td>Symptomatic with the least effort (talking, getting dressed)</td>
</tr>
<tr>
<td>4</td>
<td>Symptomatic in bed, at rest</td>
</tr>
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</table>

**Results**

**Technical Aspects**

Fifty Wallstents were inserted initially in 40 patients presenting with a tracheal or bronchial tumor. In six cases, the prostheses were not optimally inserted due to the following reasons: poor placement in two cases when the stent was inserted under fluoroscopic guidance; immediate migration in another two cases, because the prosthesis diameter was too small; and anesthesiologic complications in two additional cases (severe bronchospasm leading to the patient’s death and downward displacement of the ST segment on the ECG, respectively).

Thus, a total of 44 prostheses were eventually left in situ; in 4 cases, the extensive length of the tumor necessitated the immediate insertion of 2 prostheses.

For prosthesis insertion, the rigid bronchoscope (Rigidstep) was used 23 times and the flexible device (Telestep) was used 27 times. Immediately following prosthesis deployment, the lumen was restored to an average diameter of 92% (±6.3%) of the normal lumen.

In 30 cases (77%), the prosthesis completely covered the tumoral stenosis, in 9 cases (23%) there was incomplete coverage, and in 1 case, the attending physician provided no accurate information on this subject.
Follow-up

Thirty-nine patients could be examined on the first postoperative day. One patient died during implantation of the prosthesis. Concurrent to the relief of tumoral obstruction (Table 2), dyspnea clearly improved immediately after prosthesis insertion in 25 of 29 (86%) patients who initially presented with grade 3 or 4 dyspnea (Table 3).

Of the remaining four patients, one died during the endoscopic procedure, the conditions of two with a superior vena cava syndrome remained unchanged, and the condition of one improved only after several days because of postoperative laryngeal edema. Paradoxically, the conditions of only 6 of 10 patients initially presenting with grade 1 or 2 dyspnea improved to a lesser grade. In four patients, the dyspnea index remained unchanged. This may be due to the peripheral site of the obstruction in one case, and to the partial obstruction of the prosthesis with retained secretions after the relief of atelectasis in three cases. In the nine patients in whom the prosthesis did not cover the tumoral stenosis completely, the dyspnea index improved in all patients but one, by one grade in three patients, by two grades in two patients, and by three grades in three patients. One patient remained in stable condition. The improvement in percentage of the lumen size was greater than 80% in 7 cases and 50% in the remaining 2 cases. This means that the incomplete coverage of the stenosis left almost nonobstructive tumor tissue beyond the extremities of the prosthesis.

The average Karnofsky Performance Index also improved from 40 to 70 after prosthesis deployment, which denotes a change from dependence needing assistance to a subnormal/normal activity. Coughing disappeared in 14 patients (approximately 30%).

On the 30th postoperative day, 22 patients could be evaluated. Nine patients who were free of dyspnea had died of their disease by this date. Eight additional euoneic patients did not attend the scheduled visit because of their poor general condition due to metastatic disease.

In all 22 patients who were examined, the dyspnea index remained good (Table 3). Nineteen of these 22 patients underwent fibroscopic examination; 3 refused the endoscopy. In three asymptomatic cases, a minor dislocation of the prosthesis was noted.

In 11 cases, the prosthesis was partially obstructed, but without aggravation of the dyspnea index in 6 cases. The remaining five patients had a worsening of their dyspnea by one grade only.

When analyzing cases with initial incomplete coverage of the tumor by the prosthesis, only two of seven showed no tumor regrowth at endoscopy. This figure is only slightly better for the patients in whom the prosthesis fully covered the tumor initially, since only

| Patients, n |
|---|---|---|---|
| 0-25 | 0 | 39 (100%) | 10 (83%) | 7 (90%) |
| 25-50 | 3 | 0 | 2 (90%) | 0 (90%) |
| 50-75 | 14 | 5 (92%) | 0 | 2 |
| 75-90 | 10 | 2 | 1 |
| 90-100 | 13 | 0 | 0 |

*Immediately after the endoscopic Wallstent insertion, the tracheal or bronchial lumen is reopened to more than 90% of the normal luminal diameter. After 1 month, a certain degree of relapse of the stenosis is noted, most of the time by tumoral regrowths at the extremities of the stent. At 3 months, more than 60% of patients examined endoscopically maintain a permeable lumen whose diameter is greater than 50% of the normal lumen.

Table 2—Degree of Bronchial Obstruction Before and After Insertion of the Covered Wallstent (Endoscopic Evaluation)*

<table>
<thead>
<tr>
<th>Dyspnea Grade</th>
<th>Preoperative (n=40)</th>
<th>Day 1 (n=39)</th>
<th>Day 30 (n=22)</th>
<th>Day 90 (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>7 (87%)</td>
<td>2 (81%)</td>
<td>4 (85%)</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>14 (97%)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>13 (92%)</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>13</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

*From the first day after stent deployment, dyspnea is eased. This improvement is maintained at the same level at 1 month and at 3 months postoperatively since more than 80% of patients have a dyspnea level less than or equal to 2.

Table 3—Evaluation of Dyspnea After Wallstent Insertion*
6 of 12 control subjects who underwent endoscopy showed no tumor or granulation tissue formation at the extremities of the prostheses. Nine of these 11 partial reobstructions had confirmed tumoral recurrence at the extremities, necessitating laser reopening and the insertion of additional stents in 4 cases. In two cases, the obstruction was secondary to secretions that could be removed by bronchofibroscopy. The stent covering of polyurethane was intact in all 19 patients who underwent endoscopy.

After 3 months, 13 patients could be examined. All other patients had died of their disease by this time. The dyspnea index remained stable (Table 3). Ten of the 13 patients were reexamined with bronchofibroscopy; 3 refused further endoscopic examination. In seven cases, a partial obstruction at the ends of the prosthesis was noted, essentially due to tumoral growth leading to additional stent placements in four cases. All patients who had incomplete coverage of their tumor by the prosthesis at the onset had tumor recurrence at the extremities of the stent. In all patients who were examined endoscopically, the polyurethane coating was intact. No delayed migration was observed at 3 months.

No death was attributed to a complication related to the Wallstent. Among the 44 stents initially inserted, 6 eventually had to be removed or changed for the following reasons: incorrect size in 3 cases, twice after chemotherapy and radiotherapy; and in another 3 cases because of migration (1 case after chemotherapy). Over the 3-month period of follow-up, a total of 15 cases of retention of secretion were observed inside the stent, of which 13 were associated with the above-mentioned complications.

In four cases, the inflammatory granulations that occurred were probably caused by the sharp extremities of the stent, although these are useful for anchoring the prosthesis. All other cases of obstruction of the prosthesis were due to regrowth of the tumor.

**Discussion**

To our knowledge, this clinical trial is the first prospective multicenter study in stenting of the airway that has been published. This may explain in part the somewhat high rate of complications reported, such as the immediate removal of several prostheses incorrectly placed on the first trial, and the presence of secretions, granulations, or tumor regrowths detected during the systematic follow-up endoscopies at 1 and 3 months, although half of the patients remained asymptomatic. In nonprospective studies, these cases would not have been considered as complications.

As the initial goal was to investigate the safety, efficacy, and tolerance of the covered Wallstent, several patients with advanced local or metastatic disease were also included in this series. This explains the high mortality rate at 3 months (27 of 40 patients, approximately 68%). To be cost-effective, such a palliative treatment of inoperable bronchogenic carcinomas should probably last for at least 3 months. This implies stricter inclusion criteria. In situations where the estimated survival seems limited to less than 3 months, the use of this expensive Wallstent is questionable. However, in extrinsic compressions of the airway or in esophagobronchial fistulas, the auto-expandability of the stent opens the stenosis effectively and seals the fistula tightly. Although our data are insufficient to prove the superiority of this stent in bronchoesophageal fistulas, its effectiveness in three cases was impressive in comparison with the Dumon stent.

A severe inflammation of the bronchial mucosa proximally or distally to the Wallstent represents a relative contraindication to its use, since the uncovered extremities designed to anchor the prosthesis may precipitate the development of granulation tissue. Finally, the role of this stent in the treatment of benign stenosis remains to be demonstrated.

Although the covered Wallstent has interesting characteristics that place it among the first choice of auto-expandable stents for treating inoperable obstructive bronchial cancers, this study has also revealed several other problems. Prosthesis insertion, under visual control because of the Rigidstep device, enables the exact fitting (to the millimeter) of the stent’s distal extremity to the tumor or to a bronchial bifurcation. However, the different rate of expansion of the prosthesis as a function of the degree of stenosis is associated with length changes that do not allow such an exact fitting of the stent’s proximal end (Fig 4). For some locations (eg, trachea), this disadvantage is negligible, but it may become significant when it is important to preserve the ventilation of certain bronchi adjacent to the tumoral stenosis. The external diameter of the Rigidstep device (12 mm) is relatively large for prostheses insertion in the right intermediate and basal bronchi, but it proves effective in the trachea and main bronchi.

Although the Telestep device (flexible delivery system) rates well in its ease of use, it has the disadvantage of requiring fluoroscopic control. The accuracy of this method is clearly inferior to endoscopy, especially for visualizing a nonstenotic extension of the tumor at the extremities of the stent. In our opinion, the Telestep device should never be employed without rigid bronchoscopy control using radiographic techniques only. Once the prosthesis has been inserted, only the gripping forceps of a rigid endoscope enable it to be adjusted or removed if it is not optimally placed on the first try.

It is interesting to note that the rate of improper
placement of the prosthesis varied greatly from 1 center (0%) to another (45%). This was mainly due to the more frequent use of the flexible device for delivering the prosthesis in the series with the greatest rate of incomplete coverage of the tumor by the prosthesis. The consequences of this are not to be minimized, as all patients with incomplete coverage at the onset eventually showed tumor recurrence at the extremities of the prosthesis after 1 or 3 months.

The stent itself is flexible and easily compressible; however, the occurrence of retention of secretions revealed that its internal surface covering should be smoother. Moreover, the extremities of the prosthesis proved to be too sharp, which encouraged the formation of inflammatory granulations even though these extremities may prevent migration.

Although the Wallstent is very effective for the treatment of extrinsic compressions and esophagobronchial tumoral fistulas, it does not solve the problem of tumoral stenosis at the carina, where the Y-shaped prostheses (Hood, Freitag, and recently Dumon) are clearly superior. The Wallstent can be inserted easily and removed due to its polyurethane covering as long as a rigid bronchoscope is used. With a gripping forceps, it is always possible to adapt the exact position of the stent after its delivery.

When comparing with the Dumon stent, that though still imperfect is regarded as the standard stent in bronchology, the Wallstent presents the following advantages and disadvantages: advantages—easy and precise insertion using visual control; possibility of treating extrinsic compressions and esophagobronchial fistulas; low migration rates with proper prosthesis diameter; and thin wall giving a large lumen; disadvantages—high price; relatively high risk of inflammatory granulations at the extremities of the stent; difficult repositioning and removal; and frequent retention of secretions.

**Conclusions**

The covered Wallstent may be considered as the most elaborate of the auto-expandable tracheobronchial prostheses. We believe that its Rigidstep device for insertion still requires improvement before this stent becomes one of the standard prosthesis for treating tumoral stenoses of the tracheobronchial tree. However, the possibility of inserting the prosthesis under constant visual control represents a decisive improvement in comparison with other prostheses.

This prospective multicenter study carried out on 40 patients has revealed the following points. The superiority of the covered Wallstent seems indisputable for pure extrinsic stenoses and in esophagobronchial fistulas; although our data are quantitatively insufficient to support this statement. The migration risk is low when the diameter is correctly chosen at insertion. The rate of minor complications (immediate improper placement of the prosthesis, granulation formation at the extremities, retention of secretions) is relatively high. This may be related in part to the prospective aspect of this study, in which documentation of minor complications is more accurate than in retrospective studies. Some modifications of the prosthesis, notably of its internal covering (smoother) and of its extremi-
ties (less sharp and more regular), might solve most of the disadvantages encountered with this type of prosthesis.

Considering its high price, the covered Wallstent might be used only in cases in which the estimated survival of the patient is longer than 3 months or in extrinsic compressions and esophagobronchial fistulas. Its role in the treatment of benign stenosis still remains to be demonstrated.

REFERENCES