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Study on the Treatment of Tracheobronchial Stenosis using Expandable Metallic Stents

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Abstract

The purpose of this study is to clarify the clinical usefulness of Gianturco-Z stent (G-Z stent) for the management of malignant and benign tracheobronchial stenosis.

Seventy-three stents were used in 30 patients. In 20 cases, we used the so-called “stent-in-stent” method. Twenty-four patients were grade 5, and 6 were grade 4 according to the Hugh-Jones classification of respiratory status. The technical success rates, clinical condition, respiratory status, blood gas analysis, survival rate, and complications were reviewed on the basis of the patients’ medical records and radiographs.

All stents were successfully placed in the appropriate position. After the procedure, respiratory status improved in 97% (29/30) of the patients. PaO₂ increased statistically ($p < 0.05$), and PaCO₂ decreased one week after the treatment. Mean survival of 30 patients after stent placement was 123 days. Mean survival in 9 malignant patients treated in combination with radiotherapy (182 days) was statistically longer ($p < 0.01$) than in those treated without radiotherapy (65 days, $n = 20$). The tracheobronchial burn patient who received a combination of stent placement and post operative radiotherapy survived 540 days. No major complications were encountered during or after the procedure. Only 3 minor complications were observed: 1 stent migration, 1 partial rupture of the stent, and 1 stent deformation.

G-Z stent treatment with the “stent-in-stent” technique is useful for palliation of malignant and benign tracheobronchial stenosis, and should contribute to improving the quality of life in patients with advanced cancer. (J Nippon Med Sch 2001; 68: 318—327)

Key words: stent and prostheses, lung neoplasms, tracheal stenosis or obstruction, bronchial stenosis or obstruction, complications

Introduction

The expandable metallic stent (EMS) is a therapeutic implement that has drawn much attention for its application in the treatment of tracheobronchial,

esophageal, biliary, and vascular lesions. The Gianturco Z-stent (G-Z stent) has been widely used for palliative treatment of airway stenosis in advanced malignant lung cancer and benign diseases¹⁻³. Our research group started EMS placement for airway stenosis due to malignant tumors six years ago. We

designed and made covered stents intended to cover malignant broncho-esophageal fistula and to prevent tumor ingrowth into the stent. Furthermore, in order to prevent stent migration and breakage, we tried to place the stents using the "stent-in-stent" technique. We report our results in a large number of patients treated with G-Z stents and discuss the best therapeutic means and techniques. Indications, complications and outcome are also to be analyzed.

Materials and Methods

From May 1994 to Sep. 1999, 30 patients (24 males and 6 females, mean age 62 years, range 30~87 years) were studied. The causes of the tracheobronchial stenosis were primary lung cancer in 20 patients (13 squamous cell carcinoma, 6 adenocarcinoma and 1 large cell carcinoma, including 3 post operation cases), esophageal cancer in 4 patients (including 3 post operation cases), mediastinal lymph node metastasis with unknown origin in 2 patients, thyroid cancer in 1 patient, malignant lymphoma in 1 patient, recurrent hypopharynx cancer in 1 patient, and severe respiratory tract burn in 1 patient.

The location of the strictures was the trachea in 6 patients, trachea and left and right bronchi in 7, left and right bronchi in 3, trachea and right bronchus in 4, left main bronchus in 8, and right main bronchus in 2 cases.

In addition, 7 lung cancer, 2 esophageal cancer, and 1 respiratory tract burn were received a combination therapy of stent placement with conventional radiotherapy (RT). The total radiation dose was 24~55 (mean 45.5 Gy). We also used the remote after loading system (RALS) in 1 lung cancer patient (17.5 Gy).

The G-Z stent is made of a 0.018-inch (tracheal stent) or 0.016-inch (main bronchial stent) stainless steel monofilament bent into a zig-zag configuration and formed into a cylinder 25 mm long. Two cylinders are sutured so that the complete stent is 50 mm long. Each stent was 20 mm (tracheal stent) or 15 mm (main bronchial stent) in diameter. We used 1 to 4 stents depending on the length of the lesion. We also used 9 home-made covered stents, sewn to the struts of the stent.

Each procedure took place in the angiography labo-

ratory under general anesthesia. First, flexible bronchoscopy was performed, and stenosis was delineated. Under fluoroscope guidance, a metallic marker was placed on the patient's chest wall in a position corresponding to the stenosis. Under the guidance of bronchoscopy and fluoscopy, a 180 cm long, 0.038 inch wide guide wire (Amplatz extra stiff wire, Cook) was advanced into the bronchus across the stenosis. A 14~16 Fr. delivery sheath was advanced over the guide wire, and the G-Z stent was deployed into the stenosed region through the delivery sheath using a pusher. When the stent was in a suitable position, the sheath was retracted, so that the self expandable stent spring could open within the airway. In total, 73 G-Z stents were deployed in 30 patients. We used the so called "stent in stent" methods in 20 cases.

Three patients were also treated with a combination of superior vena cava stents because of superior vena cava syndrome (SVCS). In 3 cases with recurrence of esophageal cancer and lung cancer invasion into the esophagus, esophageal stents were also used.

The improvement in the respiratory status of all patients was evaluated according to the Hugh-Jones classification (H-J scale, **Table 1**). Twenty-four patients were categorized as grade 5, and 6 as grade 4 before treatment. Follow up chest X-rays were taken on days 1 and 7 after stenting.

We analyzed the patients' general condition, H-J scales, blood gas analysis, discharge rate and survival rate in order to check the medical results after stent treatment. With follow-up chest X-ray examinations, the presentation of disruption and/or migration of the stents were also evaluated.

Results

The initial success rate was 100% in 30 cases. All of the stents were placed in the appropriate position. The average time was 20 minutes from the insertion of the bronchoscope to the end of the procedure.

Among the 30 cases, 29 (97%) showed improved clinical symptoms and H-J scores. The details were: improvement of two grades was seen in 8 patients, and at one grade in 21 cases (**Fig. 1**). In 2 cases where percutaneous cardio-pulmonary support (PCPS) was given, stent treatment made the PCPS unnecessary

Table 1 Hugh-Jones classification for breathlessness on the basis of daily activities affected

Grade	Description
1	The patient's breathing is as good as that of others of the same sex, age, and build while at work, on walking, or on climbing hills or stairs
2	The patient is able to walk with healthy persons of the same sex, age, and build on the level but is unable to keep up on hills or stairs
3	The patient is unable to keep up with healthy persons on the level but is able to walk a mile or more at a slower speed
4	The patient is unable to walk more than about 100 yards on the level without a rest
5	The patient is breathless on talking or undressing or is unable to leave the house because of breathlessness

on the second day after the G-Z stent placement (**Fig. 2, Case 1**).

Comparisons of blood gas analyses (room air) before and after treatment were carried out in 18 cases with detailed records. PaO₂ improved from 65.3 ± 19.2 mmHg before treatment to 79.9 ± 18.9 mmHg after one week (p<0.05), PaCO₂ declined from 42.1 ± 9.2 mmHg before treatment to 38.2 ± 6.7 mmHg after one week (**Fig. 3**).

Forty percents of the patients were able to be discharged mean 40 (3~160) days after treatment.

One patient with lung cancer who received a combination of G-Z stent placement and post operative RT was still alive more than 675 days after treatment. Twenty-nine patients died of primary disease. The average survival period of the 30 patients after the stent placement was mean 123 (5~675) days. Survival period in 9 malignant patients treated in combination with radiotherapy {mean 182 (30~675) days} was statistically longer than in those treated without radiotherapy {mean 65 (5~206) days, n=20} (p<0.01) (**Fig. 4**). The tracheobronchial burn patient who received a combination of stent placement and post operative radiotherapy survival 540 days.

No severe complications were observed during or after the procedure. The minor complications were: one covered stent coughed out (**Fig. 5, Case 2**), one upper tracheal stent broke partially (**Fig. 6, Case 3**), and one upper trachea stent migrated and deformed during a further bronchoscopy (**Fig. 7, Case 4**).

Discussion

In 1986, 2 cases of successful EMS placement were first reported by Wallace et al¹. Sawada et al² evalu-

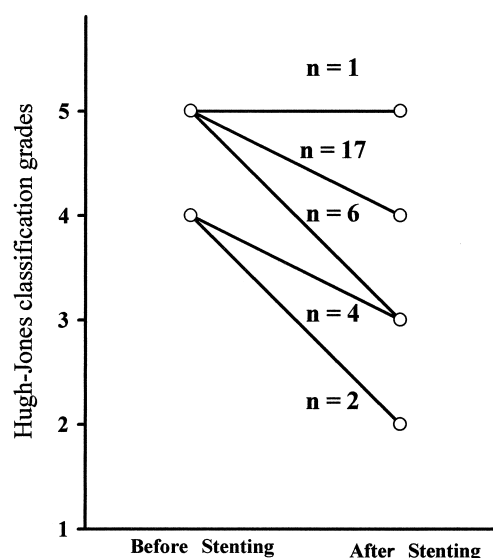


Fig. 1 Comparison of Hugh-Jones Classification Grade before and after Stent Placement.

ated the usefulness of stent treatment in a large number of patients. Afterwards, G-Z stents have been widely used in clinical applications. Some reports³⁻⁵ were documented on the therapy of airway narrowing in the terminal stage of lung cancer, bronchomalacia, tuberculous stenosis, post surgical stenosis and many other related diseases.

The common clinical indications are airway stenosis or obstruction resulting from primary lung cancer, metastatic lung cancer, metastasis of the mediastinal lymph node and dyspnea above grade 3 on the H-J scale. In the present study, all cases were higher than grade 4 on the H-J scale. Tracheo-esophageal fistula cases are also an indication for covered stent treatment, even if there are no symptoms of airway stenosis. However, in benign diseases, the long-term safety of this method has not yet been established. Until now, only our groupe have reported a case of G-Z

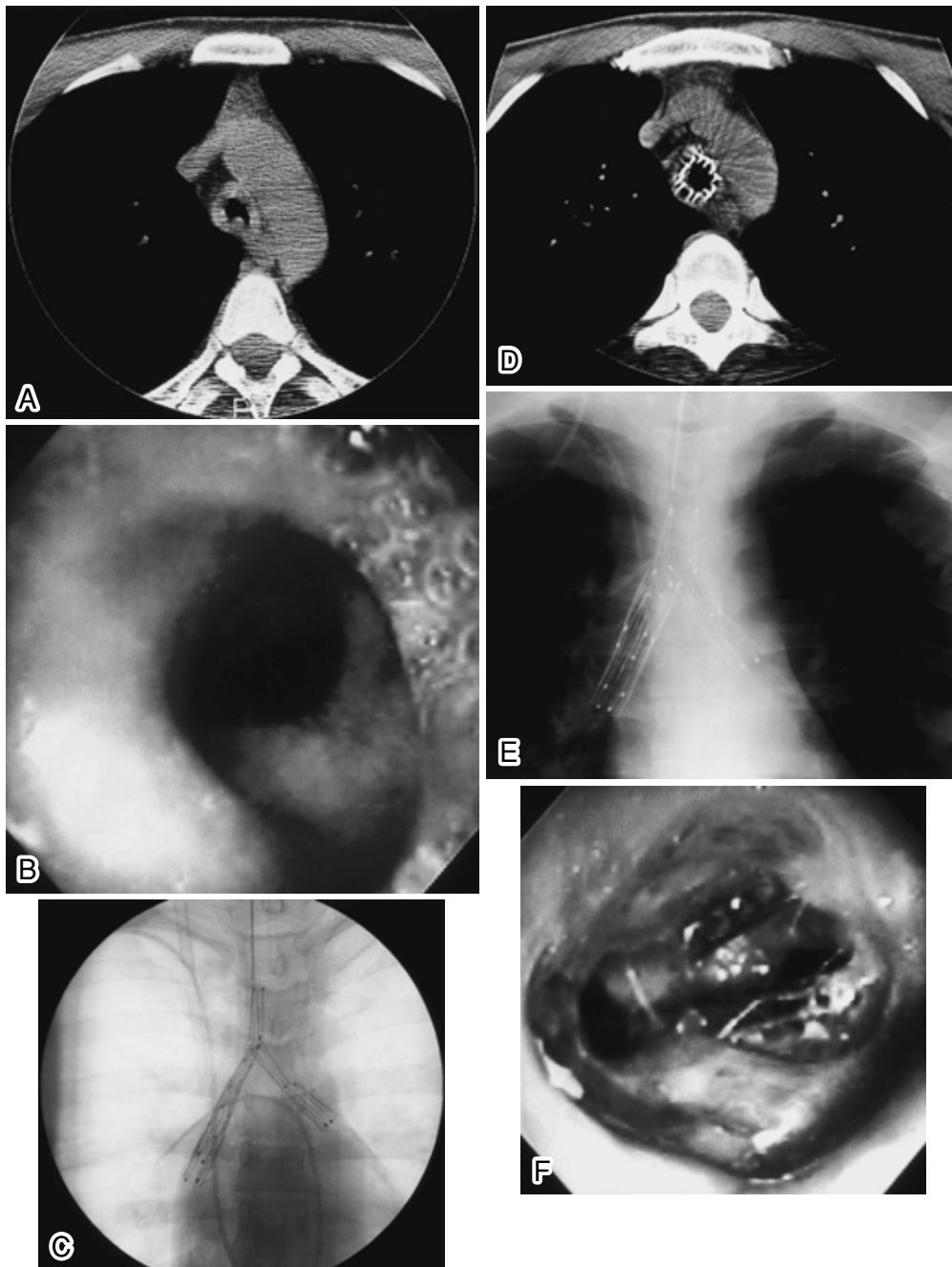


Fig. 2 Case 1. 32-year-old, male. Tracheobronchial burn.⁶

A. Ten days after a respiratory tract burn, an obvious hypertrophic stenosis of the trachea as a result of granulation invasion is observed on CT.

B. Bronchoscopy shows an edematous membranous state of the tracheal mucosa.

C. The whole procedure was performed under the guidance of PCPS. Before the stent placement, a bronchoscope is inserted through the tracheotomy fistula. An obvious stenosis from the tracheal bifurcation to the left and right main bronchi caused by granulation tissue hyperplasia is observed. Two 15 mm in diameter, 50-mm-long stents are positioned from the right intermediate bronchus to the right main bronchus by means of "stent-in-stent" technique, one 15 mm in diameter, 50 mm long stent is placed in the left bronchus and one 20 mm in diameter, 50 mm long stent is placed in the right main bronchus up to the trachea using the "stent-in-stent" technique. A 10 mm balloon is used to expand the stents. After that, RT 24 Gy is applied. Respiratory status improved from grade 5 to 3 on H-J scale.

D. CT shows that the stents are well expanded one month later.

E. F. All stents are fully expanded on chest radiography and in the bronchoscopy view after 3 months.

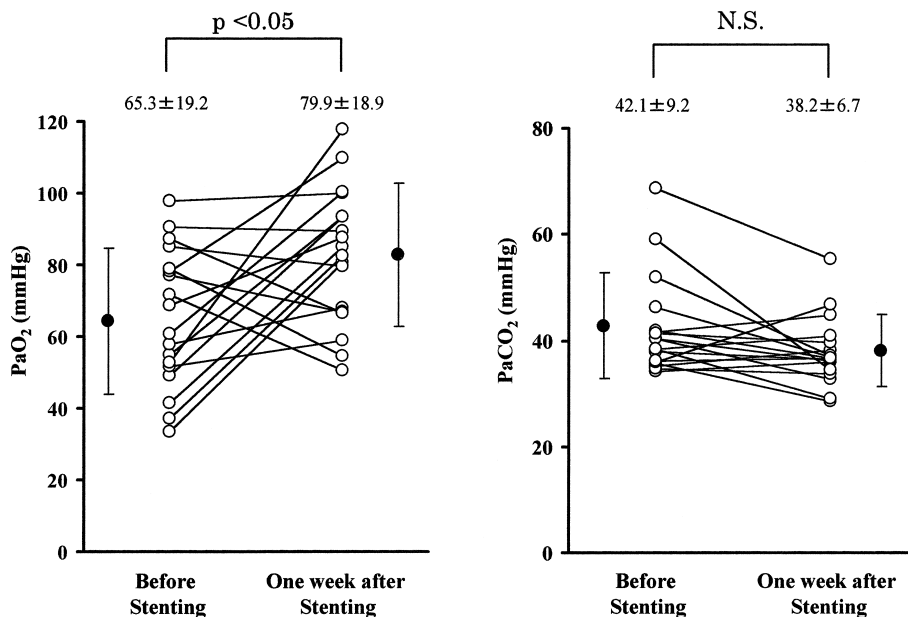


Fig. 3 Comparison of Blood Gas Analyses before and after Stent Placement.

stent placement in a patient with severe respiratory tract burns⁶.

The major advantages of G-Z stent treatment include: (1) because of the self-expandable property of the stent, it can immediately dilate the narrowing site after placement. Furthermore, with covered stents, the tracheo-esophageal fistula may be covered, too; (2) there is enough space between the stents to ensure that no side branches of the trachea are obstructed. (3) since the stent placement is performed under clean manipulation, there is a low risk of infection.

We report our results in 30 patients treated with G-Z stents and discuss the best therapeutic means and techniques. Indications, complications and outcome are also to be analyzed.

1. G-Z stent placement technique

Once a stent is placed, it is caught in the surrounding granulation tissue and is difficult to readjust or to pull out^{3,4}. Thus, the precise positioning of a stent is of the utmost importance. This requires confirmation of the stricture's status by means of diagnostic imaging e.g. CT. Furthermore combining bronchoscopy with fluoroscopy during the procedure increases the success rate.

In order to make sure that no stent migration takes

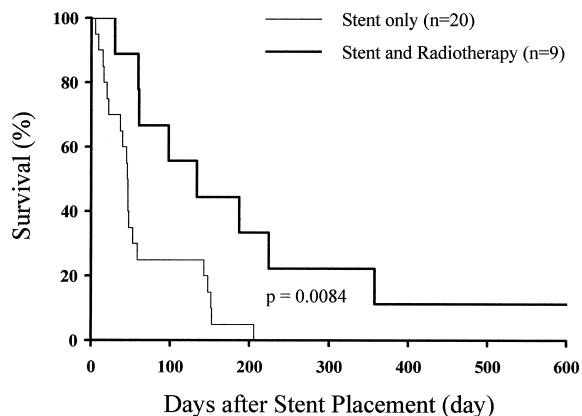


Fig. 4 Survival Time after Stent Placement With and Without Radiotherapy.

place after the procedure, a stent with a little larger than the desired diameter should be chosen. We used stents of 20 mm in diameter, 50-mm-long stents for strictures in the trachea and 15 mm in diameter and 50-mm-long stents for the bronchus. The locations of stent placement are usually the central airways such as the trachea, bronchus and intermediate bronchus.

All stents were placed under general anesthesia, since none of the patients were in good physical condition. All the procedures in 30 cases were successful and all of the stents were positioned in the appropriate places. Five to seven days were needed for full

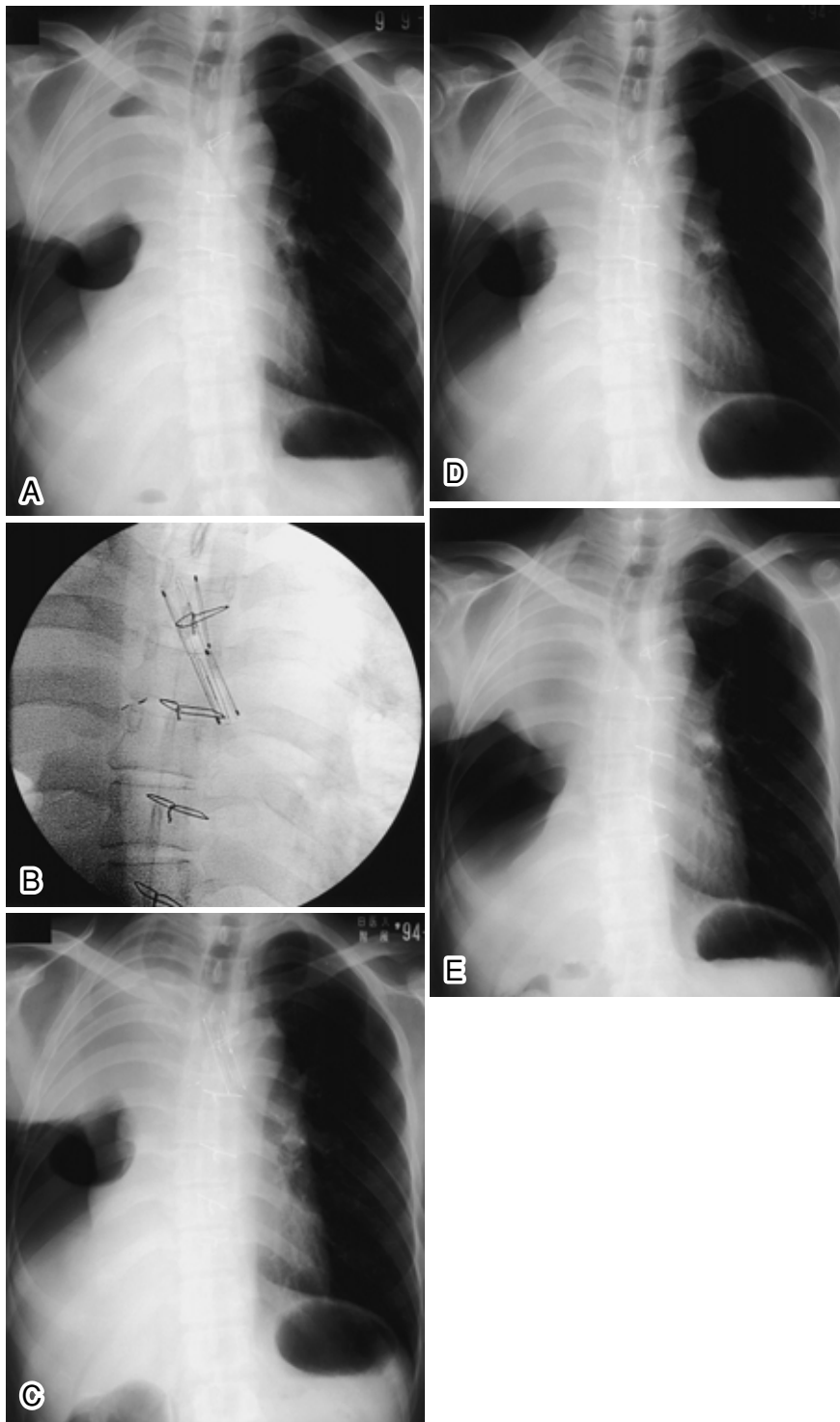


Fig. 5 Case 2. 47-year-old, male. Right middle bronchus squamous cell carcinoma (Stage IIIb). Three months post pneumonectomy of the right lung.
 A. The local recurrence and stenosis of the left main bronchus is shown.
 B. A Gore-Tex covered stent (15 mm in diameter, 50 mm in length) is placed in the left main bronchus.
 C. The stent is well expanded on the 20th day after stent placement. Meanwhile, RT 48 Gy has been applied.
 D. On the 21st day after stent placement, the stent has been coughed out, but the X-ray picture shows an open airway.
 E. On the 132nd day after the stent was coughed out, the left main bronchus shows minimal re-stenosis. The patient died on the 224th day after stent placement.

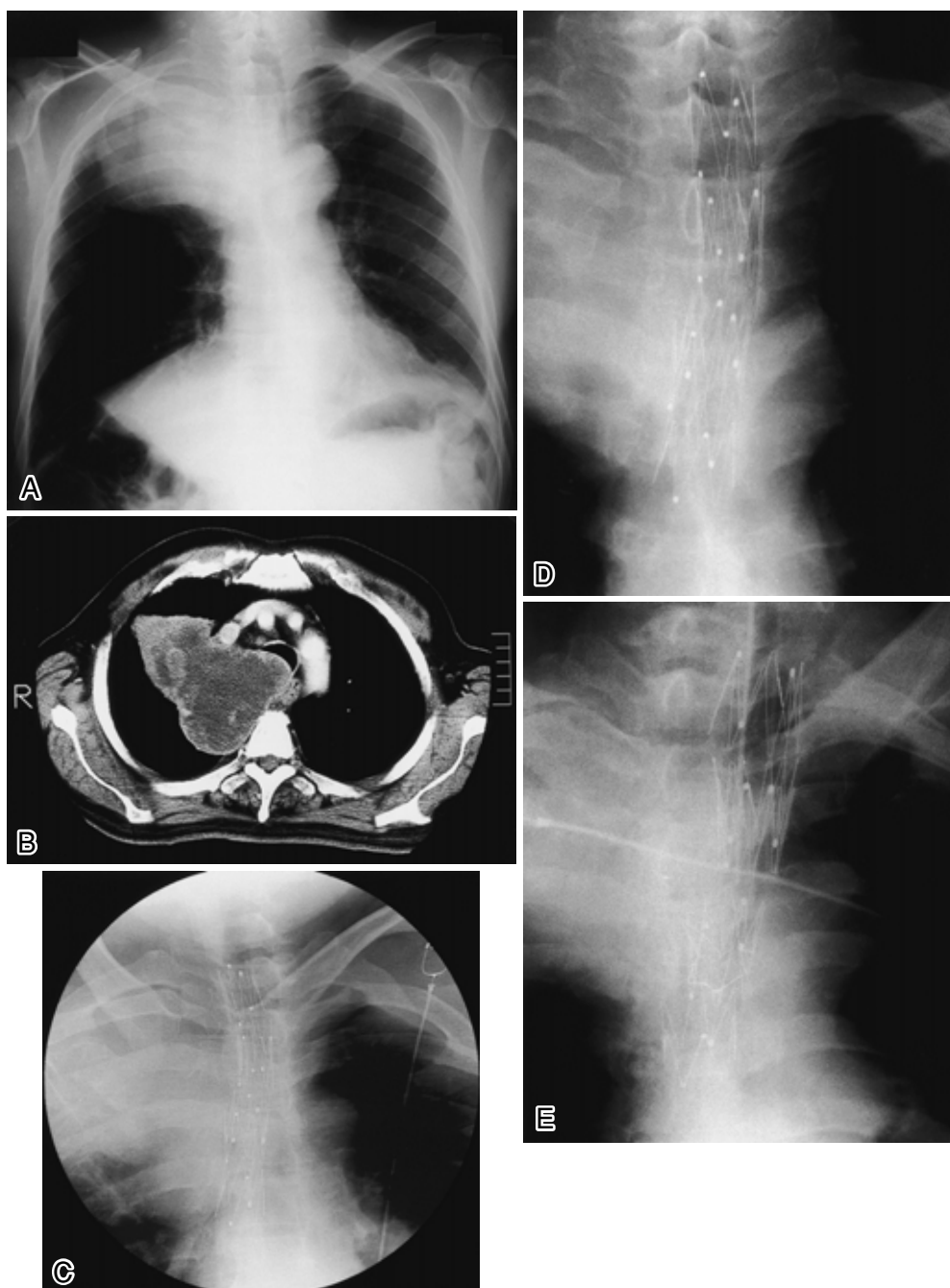


Fig. 6 Case 3. 72-year-old, male. Right upper lobe large cell carcinoma with Superior Vena Cava Syndrome (Stage IIIb).

A. B. Chest X-ray and CT show an extrinsic stenosis (75 mm long) of the trachea caused by a right upper lobe large tumor.

C. Three stents (20 mm in diameter and 50 mm in length) are placed in the trachea by the "stent-in-stent" method. Respiratory status improved from grade 5 to 4 on the H-J scale.

D. The stents are well expanded after one week. No complications were observed.

E. The patients' status deteriorate due to primary disease. Three stents show a fully expanded state, with a partial breakage of the distal stent on the day of death.

expansion of the stents after placement.

The aim of stent treatment is to dilate non-organic tracheo-bronchial stenosis and to maintain the dilated

state. It is not a therapy directly aimed at the tumor control. The ingrowth of carcinoma through the struts of the stents, and the embedding of the stents

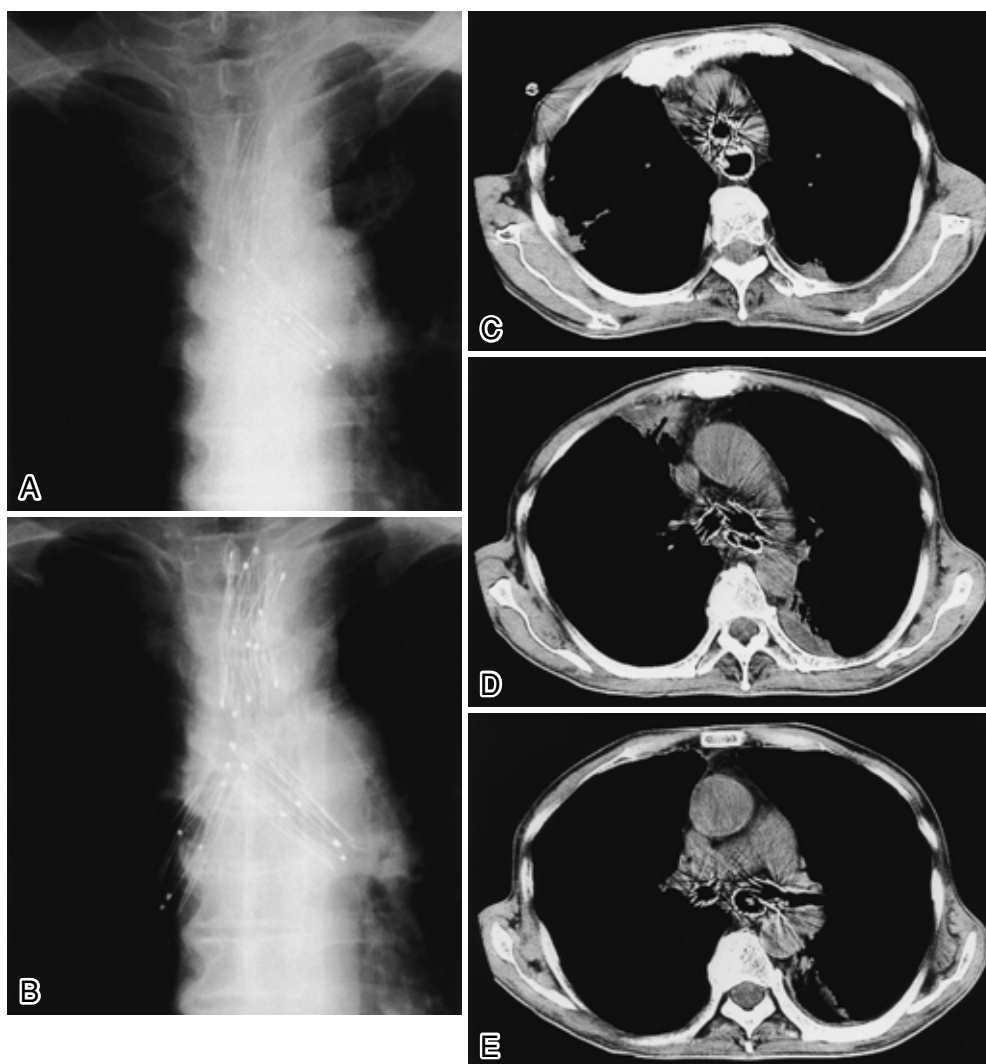


Fig. 7 Case 4. 52-year-old, male. Esophageal cancer. Because of an inoperable state, treatment by ultraflex esophageal stent placement. At bronchoscopy, one fistula of the tracheal membranous part at the level of the sternoclavicular joint and another at the region of the tracheal bifurcation at the origin of the left main bronchus are observed.

A. Two Tegaderm covered stents (20 mm in diameter, 50 mm in length) are positioned in the upper part of trachea and the left main bronchus. Chest radiography shows that both of them are well expanded.

B. After that, a stent (20 mm in diameter, 50 mm in length) is placed in the right main bronchus. During the procedure, the bronchoscope causes the migration and deformation of the covered stent in the trachea. We treated this by placing another stent (20 mm in diameter, 50 mm in length) into the former covered one using the "stent-in-stent" technique.

C. D. E. CT after three months shows the esophageal and tracheobronchial stents well expanded.

in granulation tissue may result in a secondary tracheobronchial stenosis. In these cases, the covered stent therapy is considered to be an effective treatment⁷. We placed 9 hand-made covered stents, in one case to block a fistula, and in 5 cases to prevent the tumor ingrowing into the stent. The cover is tube-shaped Polyurethane, Gore-Tex, or Tegaderm sewn

to the struts of the stent. It was suspected that this type of stent may interfere with airway secretion and the resistance of the mucosa, leading to infections⁵.

2. Therapeutic effects

As an objective evaluating standard, the H-J scale² was adopted to assess the improvement of patients' respiratory status before and after the stent

treatment. Of the 30 cases in total, 29 cases had a greater than one grade improvement (97%) (Fig. 1). This result is superior to other previous reports of 86%², 95%⁸ and 38%⁹.

Analyses of blood gas before and after stent treatment have been reported by Sawada² et al. Their five cases showed no statistical improvement. Our 18 cases demonstrated that PaO₂ was increased significantly ($p < 0.05$), while PaCO₂ decreased one week after stent placement.

Another report⁵ comparing the improvement rate of tracheo-bronchial stenosis caused by malignant tumors between RT and stent placement demonstrated a primary success rate of 46.2% in the RT group and a 100% success rate in the stent group. Ventilation was improved in 46.2% in the RT group compared to 76.4% in the stent group. It has been shown that RT alone or combined with other therapies can improve the quality of life (QOL) and life span in patients with terminal malignant diseases. None of the 10 patients treated with a combination of RT and stent placement in our group had complications from the RT. The average survival rate of 182 days of 9 malignant patients was significantly longer than the average survival of the patients who received stent placement alone (65 days). The anti-tumor effect of RT was believed to be well acceptable. According to our results, patients in an acceptable physical state should benefit from additional RT.

Stenosis caused by intrinsic airway diseases can be effectively treated by laser coagulation⁸. However it is impossible to improve ventilation when the lesion is large and the stenosis is caused by extrinsic pressure or a feeble chondral ring. One report⁵ even speculated that laser treatment was a cause of stent ruptures. For these reasons we did not administer a combined laser treatment.

3. Complications

According to recent reports, the common complications are expectoration failure, infection, swallowing difficulty, faulty placement, migration and breakage of the stent, perforation and lethal hemoptysis^{3,5,8,9}. A 41.2% complication occurrence rate has been reported, 90% of which was related to expansion and mechanical stimulation⁵.

(1) Migration

Loose contact of the stents with the narrowing position or the second insertion of a bronchoscope or sheath may cause the migration of the stent. Two cases of stent migration in the upper part of the bronchus were reported by Kitano¹⁰. They thought that migrations were common if stents were placed in the upper part of the bronchus, within a short, extrinsic stenosis with a smooth surface. The trachea itself and the surrounding organs play an important role in stent migration. Although the stent itself has hooks to prevent migration, they are not enough. We placed stents by the "stent-in-stent" method in 20 cases (66.7%) to prevent faulty placement and migration. More than 2 stents together enhance the stability of the stents. With this method, no migration was observed, while migration was observed in 2 cases treated with a single stent.

The second insertion of a sheath should be avoided if possible in order to prevent stent deformation and migration. In our group, one case was observed.

(2) Breakage

The reasons for stent breakage are the force of expectoration and long-term deterioration. The breakage rate of stents in benign disease was 31% in a report by Rousseau et al⁴, while a breakage rate of 27% (6/22), including 18% (4/22) with lethal hemoptysis was reported by Nakajima et al⁸. In our group, only one stent breakage (3.3%) occurred in the upper trachea as diagnosed by X-ray examination. In Nakajima's group, an average of 1.6 stents were used per patient, while an average of 2.4 stents per patient were used in the present group. We believe that the "stent-in-stent" method will guarantee the stability and integrity of stents, and improve the therapeutic effects of stent placement compared with the conventional stent method.

(3) Others

Impediment of expectoration after placement sometimes makes tracheotomy necessary to ensure smooth ventilation. Complicating infections can commonly be controlled by symptomatic treatment. But in a case report¹¹ of transient airway edema caused by dilatational stimulation of the sheath and balloon catheters leading to possible atelectasis, steroids should be administered. After the procedure, most patients show

irritating coughs, expectoration and local inflammation, which can be cured by antiseptic treatment.

If stents large in diameters are positioned in the trachea and left bronchus, sometimes swallowing difficulty may be observed resulting from compression on the esophagus³. We think it is suitable to use stents with a diameter 1.2 times larger than those used in a normal bronchus. If swallowing impediment is caused by an intraluminal tumor, esophageal stenting, combined RT or chemotherapy should also be considered.

To prevent perforation, a stent conformable to the narrowed bronchus or trachea should be chosen. If hemorrhage occurs, hemostatic drugs may be injected directly into the bleeding site. Paying attention to the details of placement can never be overemphasized. No perforation, lethal hemorrhage or other severe complications were encountered in the present study.

In conclusion, G-Z stent placement with the "stent-in-stent" technique is an excellent palliative therapeutic method of improving symptoms of airway stenosis and QOL in patients with advanced malignancies.

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