Application of self-expandable metallic stents for treating malignant tracheal stenosis under general anesthesia and fluoroscopic guidance

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【Abstract】

Objective — To evaluate the safety and effectiveness of the self-expandable metallic stents used in treating malignant tracheal stenosis under general anesthesia and fluoroscopic guidance.

Methods — 10 patients with malignant tracheal stenosis were treated with a self-expandable metallic stents under fluoroscopic guidance and general anesthesia.

Results — 10 patients were successfully placed with the self-expandable metallic airway stents, one of them with the lesion involving the swelling of trachea was placed the Y-shaped stent. The symptoms of dyspnea and asthma were totally improved in all cases after the placement of the tracheal stent.

Conclusion — Under general anesthesia and fluoroscopic guidance, the treatment of malignant airway stenosis with placing self-expandable metallic stents is safe, rapid and effective method. It can rapidly relieve a series of symptoms of malignant airway stenosis, and significantly improve the quality of life. Thus, it has a high clinical application value.

【Key words】 General anesthesia; Malignant airway stenosis; Stents

The tracheal stenosis caused by the malignant tumors can lead to progressive dyspnea, asthma and chest pain. Respiratory failure or even death may be resulted in the worst situation. Tracheal metal stent placement can immediately alleviate the breathing difficulties caused by tracheal stenosis and improve the quality of life. However, the tracheal metal stent placement has a certain degree of risk. It has been reported in the literature that the mortality rate related to the procedures in stent placement was about 3% [1]. Currently, the majority of domestic tracheal metal stent placement was conducted under local anesthesia. However, it was a painful procedure if the patient was only under local anesthesia and the stent migration was easily occurred. In contrast, less pain would be found if the patient was under general anesthesia, which facilitated the procedure with high accuracy in stent positioning. Here is a report regarding the treatment of malignant tracheal stenosis by placing metal stents in ten patients under general anesthesia and X-ray guidance.

1 Material and Method

1.1 Materials

.1.1 Background: From January 2006 to December 2008, 10 patients with malignant tracheal stenosis, including 5 males and 5 females, aged 44 to 71 years old, an average of 57.5, were admitted. 5 cases of esophageal cancer, 3 cases of lung cancer, 2 cases of thyroid cancer, including one case of esophageal cancer patients associated with metastasis of lung cancer. 10 patients were confirmed by clinical pathology, with the main clinical manifestations such as dyspnea, asthma and chest distress and other symptoms.

1.1.2 Devices: 5 FR H1 Headhunter catheter (COOK, USA), 0.035" guide wire (TERUM, Japan), 0.035" Amplatz guide wire (CORDIS, USA), Datex-Ohmeda anesthesia machine

(GE, USA), Axiom Artis FA digital subtraction angiography (SIEMENS, German), Self-expandable metal stent and delivery system (Micro-tech, Nanjing).

1.2 Operational procedures

1.2.1 Preoperative preparation: Preoperative fasting should be conducted for patients 12 hours before surgery. Drinking was prohibited 4 hours before surgery. Atropine was given by intramuscular injection half an hour before surgery (Make sure that the patient had no allergy to medication, such as atropine). Electrocardiographic monitoring, anesthesia machine, suction apparatus and other equipments were connected before endotracheal intubation and intravenous infusion started.

1.2.2 Anesthesia: Anesthetists were necessary for monitoring the patients throughout the operation. After the consciousness of patients disappeared, the muscle relaxants were injected. Patients experienced the progressive relaxation of systemic skeletal muscle and submaxilla, with breathing from shallow to completely stop. The anesthesia mask should be applied for artificial respiration and endotracheal intubation should be conducted. To reduce cardiovascular response caused by endotracheal intubation, 3-5g/kg of fentanyl should be given by intravenous injection before intubation. The oral intubation of distinct vision was applied to 10 patients. After the glottis was exposed under direct vision with laryngoscope, the endotracheal tube was inserted into the trachea. The T-shaped endotracheal connected to the anesthesia machine. The tail hole of T-shaped endotracheal connecting tube was closed. The mechanical ventilation was carried out. The main task during maintenance of general anesthesia was to maintain adequate anesthesia in order to meet the surgical needs.

1.2.3 Stent Placement: Based on the results of imaging data, under the fluoroscopic monitoring, the position and dimension of lesions were determined by making metal markers on the body surface. Patients should lie on the back on DSA examination bed, 0.035" Amplatz super-hard guide wire was directly inserted into trachea through the tail hole of endotracheal T-shaped connecting tube under fluoroscopic monitoring and introduced into left or right bronchus through the sites of tracheal stenosis (if the passage was narrow with difficulties, 0.035" super-smooth guide wire with 5FR H1 catheter can be used to go through the segment of tracheal stenosis and then exchanged by 0.035" Amplatz super-hard guide wire instead.). After the super-hard guide wire was fixed in place, the endotracheal tube was removed (It is because the stent delivery system could not pass the endotracheal tube, the mechanical ventilation at this time was required to be disconnected). The stent delivery system was inserted along the Amplatz super-hard guide wire until the stenosis site. The stent deployed once the position was confirmed under fluoroscopy. The whole process of the inserting the stent delivery system and the stent deployment should be quick and consistent. After the deployment of stent, the stent delivery system and the Amplatz super-hard guide wire should be quickly removed under fluoroscopy. Attention should be paid during the removal of stent delivery system as the distal end of the stent delivery system may cause the migration. After the stent delivery system was removed, the re-intubation should be conducted by the anesthesiologist to maintain ventilation. After the withdrawal of narcotics control, the intubation should be removed. If the stent's location was closed to glottis, intubation may cause the stent migration. Intubations were recommended to be carried out under fluoroscopic monitoring. Shallow anesthesia was found in 2 patients, no re-intubation was carried out after removal of stent delivery systems, and only the mask ventilation was given.

Y-shaped stent with a special Y-shaped stent delivery system, manufactured by Nanjing Micro-tech, was introduced for delivering an integrated Y-shaped metal stent under fluoroscopy. The deployment process was similar with the straight cylinder-shaped stent. The difference was that it needed to use two guide wires, which inserted into the left and right main bronchus respectively at the same time. The detail deployment process was described in literature [2].

1.3 Postoperative management

The consciousness was recovered after the general anesthesia was gone. The mechanical ventilation could be disconnected once the patient could spontaneously breathe. Patients should return recovery department accompanied by the professional anesthetist. ECG, blood pressure monitoring was connected. Antibiotics IV and related symptomatic medications were followed. Based on the condition of patients, the following treatment should be given. Regularly CT reviews were recommended.

2 Results

A total of 11 tracheal stents were placed in 10 patients. All

stents were successfully placed, and the stent deploying process was 2 minutes. The ventilation break duration should not more than 1 minute. The chest CT scanning was taken 3 days after the surgery. All stents were opened properly without any migration. All preoperative symptoms such as dyspnea, asthma, chest distress and other symptoms before surgery had witnessed remarkable improvement. The average postoperative hospital stay was 3.5 days. All patients had a different degree of chronic irritant cough, phlegm and other symptoms.

Date to the follow-up of January 2009, 6 cases of death were in this group, with a survival time of 3 to 6 months (an average survival time was 4.5 months), and all died of tumor progression. The remaining 4 patients were alive, of whom the longest survival time was 16 months and the patient with thyroid cancer. The lung and mediastinal lymphatic node metastases were found in this patient about 10 months after the stent placement at the CT review. However, no recurrence of dyspnea and asthma symptoms was scored. CT review showed that granulation tissues had migrated into the stents 14 months after the surgery, resulting in stent intracavity restenosis. The asthma and dyspnea symptoms could be found in the patient if they had physical activities. After re-placement of a tracheal coated stent under general anesthesia, the asthma and dyspnea symptoms in this patient had been improved again (Figure 1). No recurrence of significant dyspnea, asthma symptoms occurred during the survival of the remaining 9 patients, and no serious tracheal stenosis affecting the ventilatory function occurred (Table 1).

3 Discussions

3.1 The endotracheal stent placement is applicable for treating inoperable malignant airway stenosis [3]. 10 patients with tracheal stenosis caused by advanced malignant tumors were treated. 7 patients caused by the compression by tracheal extraluminal tumor and metastatic lymph nodes, 3 patients caused by the tumor infiltration of tracheal wall. In addition, the indications of tracheal stent placement include tracheobronchial malacosis by supporting at the weakness site of cartilage, closure for the tracheobronchial fistula or cleft, tracheobronchial benign stenosis and tracheal stenosis after postoperational anastomosis.

3.2 The bare stents were used for the first line treatment for 10 patients in this group, and the coated stent was used for one patient with recurrence of tracheal stenosis caused by granulation ingrowth. No severe stent restenosis or blockage occurred during the postoperational survival of 6 patients who had died. The author believed that the stenosis was caused by malignant tumor. As a result, the bare stent could not be migrated. Since the survival time of patients with advanced malignant tumors was really limited, the probability of stent restenosis was not high. So the bare stent may be an option to use. However, some literatures mentioned that the complications of the bare stent were more serious than those of the coated stent [4]. Currently, the membrane-coated stent were more commonly used than that of the bare stent had reduced [5].

When the lesion was found at the carina region of trachea or the region of bronchus, Y-shaped stent was appropriately used, especially in patients combined with multiple stenosis. One patient associated with multiple stenosis of left and right principal bronchus on the carina region had chosen the Y-shaped stent, the treatment of this case was fully embodied the advantages of Y-shaped stent [2]: ① For multiple tracheal and bronchial stenosis near the carina region, the problem could be resolved by placing one stent. The operational procedures of intervention were simplified. Both the X-ray radiation dose and the medical costs were reduced. ② The stent was composed of two connected branches, stent migration was less possible to be occurred. It facilitated breathing and sputum discharge; ③ The operating techniques were similar to those of the general endotracheal stent placement. The procedures were simple and convenient to handle with accurate positioning.

Since the patient with benign stenosis had a longer survival time and many complications may be occurred after the stent placement. Using stent as a transitional purpose was advocated in the recent years internationally. The main advantage was less complication. [6]

3.3 Currently, the domestic tracheal metal stent placement was conducted using a local anesthesia. It was because most of the interventional catheterization laboratories were not equipped with the necessary equipment and professional anesthetist for general anesthesia. Relatively, local anesthesia was a simple with low operating cost. It could be finished by a surgeon alone. However, tracheal stent placement under local anesthesia had the following disadvantages: Patients would suffer from a painful procedures during the surgery and affect the stent

deployment. As a result, the inaccurate stent deployment and placement may be occurred. The glottal closure may be occurred when spraying anesthesia. As a result, the anesthesia drug could be reached the trachea and bronchus properly, leading to an inadequate anesthesia. Intraoperative coughing with plenty of secretions occurred. The pharyngeal anesthesia by injecting at the cricothyroid membrane was too difficult to be acceptable since the patient would so scare on such painful injection. In addition, suffocation was very dangerous and may occur during operation. Professional intubation with well-trained anesthetist was strongly recommended.

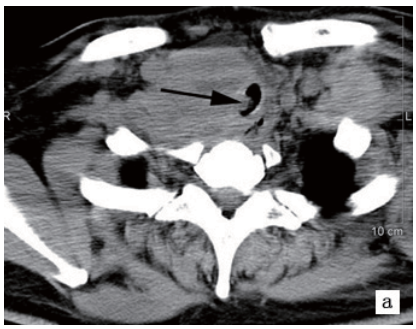
10 patients were under general anesthesia for 11 times of the stent placement. Previously, we applied the local anesthesia method to conduct the tracheal stent placement for patients with malignant tracheal stenosis. By contrast, it was found that for the tracheal stent placement under radiography, the general anesthesia was more reliable than that of local anesthesia. The general anesthesia of tracheal intubation had the following advantages: ① The guide wire may be directly inserted into the trachea and the bronchus through the tracheal ventilation tube. ② The unobstructed respiratory tract could be maintained in any body position of the surgery. Intubation could prevent foreign matter from entering into the respiratory tract. It was an effective way to remove the endotracheal and endobronchial secretion; ③ Intubation facilitated the respiratory management and ensured the appropriate oxygen supply; ④ As adequate pre-ventilation allowed a longer ventilation interruption time, the safety margin could be ensured within 2 to 3 minutes. ⑤ Preventing patient from body movement was a key factor of the accuracy of stent deployment and placement. It was especially important for the beginners; ⑥ Patients feel less painful during stent placement if he/she was under general anesthesia. Although there was some risk for general anesthesia in itself, such as reflux, aspiration, lack of ventilation, etc. The incidence rate under the operation of the professional anesthesiologist was very low after fully preoperative preparation and pre-anesthesia evaluation were performed.

3.4 The symptoms of early complications may be occurred within 2 weeks after stent placement, such as irritating cough, chest pain, a small amount of hemoptysis, expectoration difficulties, which were correlated to the effects of the stent on the stimulation to the tracheal mucosa, the expansion of the tracheal cavity, the damage to the diseased tissues and the emission the sputum. 10 patients in this group, after 11 times of the stent placement, all had the above mentioned symptoms, and most of the symptoms disappeared within 1 week after symptomatic treatment. However, the follow-up showed that most patients were with different degree of chronic irritation cough, increased sputum and other phenomena. If the symptoms were severe, the symptomatic treatment should be given. Early complications of stent placement also included the stent migration. Within 48h of the placement, the stent was not fully expanded. Coughing should be treated in order to prevent stent migration. No stent migration was found in 10 patients of this group after stent placement. If stent migration occurred, injecting icy saline water was applied under bronchoscopy and the stent could be taken out easily [7].

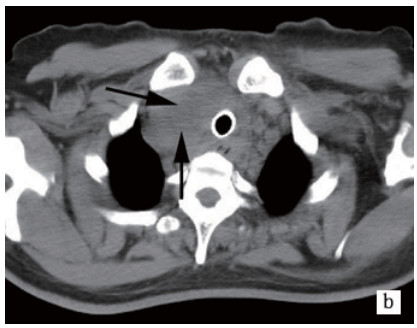
The most common long-term complications were the stent lumen re-stenosis caused by the ingrowth of granulation tissues. If necessary, the intra-cavitary brachytherapy, high electrocautery, or cryotherapy and other methods could be taken [6]. Some literature indicated that the hyperplasia of granulation tissues occurred at 1~6 months after stent placement and would be stabilized after 6 months [8]. The different levels of granulation hyperplasia were found in the stent of 10 patients in this group after a CT review. The ventilatory function was affected in one case of patients 14 months after the surgery due to the tracheal re-stenosis induced by the granulation ingrowth. After re-placing an additional membrane-coated tracheal stent, the symptoms were relieved again. No significant airway stenosis symptoms were, such as dyspnea, asthma, occurred during the survival of the remaining 9 patients, and no local intracavitary burning, freezing and other means for the treatment of the proliferative tissues, probably due to fewer cases in this group and the short survival time. In addition, there were some uncommon complications such as stent fatigue, fracture and the perforation of tracheal wall. Once the metal stent fracture and disintegration was occurred, the stent should be taken out as soon as possible in order to avoid further damage of surrounding tissues. The stent embedding and penetration through tracheal wall were the most dangerous complications, although the incidence was not high, but often resulted in the trachea, bronchial fistula, which could induce a massive fatal hemoptysis, suffocation and death when the invasion involved in the surrounding large blood vessels around trachea [9]. No

stent damage or embedding or penetration through the tracheal wall and other phenomena occurred in all 10 patients in the group.

Lung cancer, esophageal cancer, thyroid cancer and other malignant tumors at middle and advanced stage were often accompanied by mediastinal lymphatic node metastasis. As a result, compression of trachea by the tumor tissues, enlarged lymphatic nodes and/or the infiltration of trachea by the tumor tissues, leading to tracheal stenosis, with the dyspnea, asthma and other symptoms. Tracheal stent placement was a safe and rapid, reliable method for removing tracheal stenosis, relieving the symptoms of dyspnea, asthma in patients and improve quality of life. It was an effective palliative treatment. The use of chemotherapy, radiotherapy and other means after stent placement to treat the primary disease could prolong the survival time of patients and improve the patient's quality of life to a certain extent.

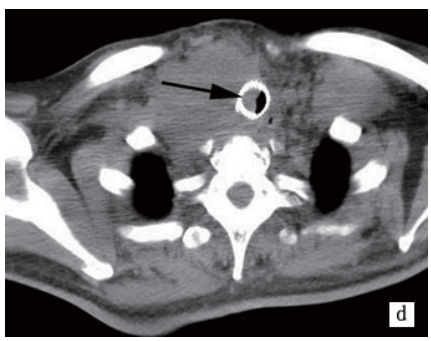


a The chest CT scan was made 3 days before the surgery showed that tracheal stenosis was found at middle and superior segment, with the endotracheal invasion of the tumor tissues (as shown by the arrow).

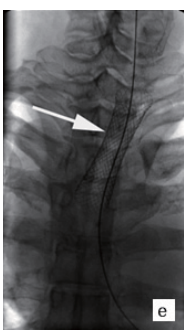


b The throat scan was made one day after stent implantation showed the tumor tissues around the stent (as shown by the arrow).

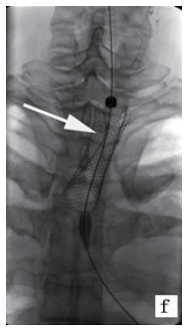
c The chest CT scan was made 10 months after the surgery. It showed the tumor tissues had grown into the stent (as shown by the arrow). However, no significant dyspnea was found in this patient.



d The chest CT scan made 14 months after the surgery, showed the tumor tissues had grown further into the stent (as shown by the arrow). The symptoms of tachypnea after activities were found in this patient.



e For the first stent placement surgery, under fluoroscopy, a well opened stent could be observed after the stent placement, without significant pressure trace of tumor tissue pressure trace at the border (as shown by the arrow).



f One coated stent was placed into the bare stent 14 months after the surgery, stent was oppressed by tumor tissues (as shown by the arrow), the extent of opening is acceptable.

Table 1 Basic information of patients

No. / Sex / Age	Diagnosis	Sites of airway stenosis	Preoperative symptoms	Postoperative symptoms	Survival time
1/F/60	EC	middle segment	D, O, T	(P, He)C	7 months L
2/M/50	EC	middle segment	C, D, O, T	(P, He)C	3 months
3/M/54	EC	middle segment	D, O, T	(P, He)C	4 months
4/F/71	EC	middle segment	D, O, T	(P, He)C	4 months L
5/M/67	EC, LC	middle segment	C, D, O, T	(P, He)C	6 months
6/M/54/Y	LC	Multiple left and right bronchial stenosis of inferior segment	C, D, O, T	(P, He)C	3 months L
7/F/57	LC	middle segment	Ho, D, O, T	(P, He)C	5 months
8/F/61	LC	middle segment	C, D, O, T	(P, He)C	4 months
9/F/44	ThC	middle and superior segment	Ho, D, O, T	(P, He)C	16 months L
10/M/57	ThC	middle and superior segment	Ho, D, O, T	(P, He)C	5 months

Note: EC: esophageal cancer, LC: lung cancer, ThC: thyroid carcinoma, C: cough, D: dyspnea, O: orthopnea, He: hemoptysis, Ho: hoarseness, T: three concave sign, P: retrosternal pain, L: is still alive, Y: Y-shaped stent, (): This indicated the symptoms would exist for a short period and disappear after a period of time

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