An application of a membrane-covered stents in treating esophageal strictures and fistula after esophagectomy

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(Abstract)	
Objective	To evaluate the efficacy of metallic stent placement in patients with strictures and fistula after esophagectomy.
Methods	Metallic stents were placed in 18 patients, 5 cases were complicated with anastomotic leakage and strictures. The diameters of the strictures was between 3 to 5 mm, with an average was 2.5±1.2 cm. The stents were placed under radiography after the lesion was confirmed and dilated by the balloon dilation. Balloon dilation was performed after the stent placed.
Results	The technical success rate was 100%. The complication was preventable. A supporting treatment after the placement may reduce or prevent restenosis.
【Key words】	Esophagus neoplasms; Anastomotic strictures; Stent treatment

Background:

Recently, an esophageal balloon dilation and South strip dilation were the first choice for treating strictures of anastomotic stoma after esophagectomy and esophageal reconstruction. The dilation treatment was almost no help and induced many complications for patients, such as co-existence of fistula and anastomotic strictures and sinus. Many reports [1-5] mentioned that metal stents were being used for treating strictures due to esophageal stenosis in China and overseas. In China, Professor Han, Xinwei from First Affiliated Hospital of Zhengzhou University, Professor Mao, Aiwu from Shanghai Tongyan Hospital and Professor Yang Renjie from Beijing Cancer Hospital contributed their outstanding achievements in this field. Since 2007, our department had been worked on the study by using titanium-nickel alloy membrane-covered stents (manufactured by Nanjing Micro-tech) for treating pleural fistula and strictures of

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anastomotic stoma after esophageatomy, and the following results have been obtained.

Data and method

1 Clinical data

Among 18 patients, 13 were male and 5 were female in the gender proportion of 1.6:1, and age was ranging from 38~78 years old with the average value of 54.3. All had an esophageatomy, thus their stomachs were acting as the esophagus. After operations, a barium meal, esophageal iodine imaging examination and ultrasonic gastroscopy were followed. It was found that they all suffered from fistula between esophagus and pleura or strictures of anastomotic stoma between esophagus and stomach. 3 of them suffered from the complication of anastomotic stoma leakages. The examination carried out 1-24 months after the operation. 3-5 mm strictures of anastomotic stoma and the complication of fistula of anastomotic stoma were found in 5 patients. Clinical symptoms mainly included swallowing difficulties of different degrees (Based on the swallowing functions are divided into: Grade 0: common diet; Grade 1: soft diet; Grade 2: semi-liquid diet; Grade 3: liquid diet; Grade 4: no diet at all). 8 persons were Grade 2, 6 were Grade 3 and 4 were Grade 4.

2 Selection and placement method of stents

2.1 Selection of stents

All patients adopted the titanium-nickel alloy membranecovered stents manufactured by Nanjing Micro-tech, the length varied between 3-12cm and width between varied 12-25mm.

2.2 Placement method of stents

The stent was inserted from the mouth into position of esophagus fistula and strictures under the monitoring of X-ray (Apelem Digital Gastrointestinal Machine/ France). Before operation, the patients were injected 0.1g atropine, 2% lidocaine was sprayed on the throat as a local anesthesia and in the supine and lateral position. Patients took the ultrasonic gastroscopy to determine the thickness of esophagus wall and location of esophagus stricture. In order to select a proper stent, the position and length of fistula and stricture were confirmed by barium meal imaging examination. The stent was deployed under the monitoring of X-ray. After the positions were confirmed, the lead-out wires were kept. Follow-up examinations with esophageal barium meal were carried two days after operation in order to confirm the positioning of stent. It was found that all the stents were deployed totally after operation. Warm water was taken for every two hours regularly. Treatments of antacids, inflammation, homeostasis, analgesia were provided if necessary. Their diets were guided gradually from fluid to regular one.



Esophageal iodine imaging showed that fistula and stricture of anastomotic stoma occurred between esophagus and stomach before the stent placement.



After stent placement, fistula was fully healed and stricture was totally dilated.

1 Result

The success rate of stent placement was 100%. After stent placement, the patients' swallowing functions were greatly improved. Based on the swallowing function range, 8 patients scored Grade 0 and 10 patients scored Grade 1. Fistula and anastomotic stoma were both blocked and healed.

2 Complication

One patient reported stent migration. 3 patients reported restenosis. A mild bleeding occurred in all patients after endoscopy. 5 patients scored chest pain during and after operation, i.e. 5/18 (27.7%) felt transitional pain and analgesics were provided one to two weeks' time. 3 patients scored gastric reflux, i.e. 3 (16.6%). 2 patients scored perforation, i.e. 2/18 (27.7%). 1 patient got pneumonia.

3 Follow-up results

Esophageal or gastric barium meal imaging examinations were carried out to determine the positioning of stents. The surveillance was followed from 4.0-24.0 months, averagely 13.48±8.55 months. Most patients could bear the stent placement. Only one patient could not bear the stent as the stent was placed closely to pharynx. The strong irritation sensation was reported. The patient required to take out the stent finally.

Discussion

1 Indication

The incidence rate of esophageal cancer is relatively high in China, especially in Henan Province. Anastomotic strictures or fistula is the common complication of esophagectomy, with its 2.5%-6.4% incidence rate and mortality rate as high as 38.1%-53.6%. Balloon dilation are commonly used on the strictures of anastomotic stoma after esophagectomy. Metallic stent placement is indicated for combined fistula of anastomotic stoma. In general, dilation treatment is operated at beginning, and then placement of metallic stent is considered if no improvement scores.

Recently, researches show that the lifespan of the patients after esophagectomy is approximately the same as that of patients after the stent placement combined with radiotherapy. In order to reduce the pains of repeated esophageal dilation, the metallic stent placement is applies to patients, who received no effect or poor effect after more than 4 times of dilation treatments within 2 months. A good result has been obtained. Stent placement is simple and safe. The stent staying at the anastomotic stoma is similar to the mechanism of continuously dilation. The fistula heals after the stent places. We believe that stent placement not only promotes the healing of fistula but also dilates the anastomotic stoma, which can greatly improve the ingestion function of the patients.

2 Selections of Stent

There are varies kinds of esophagus stents in the market. Basically, they are classified as Chinese local-made ones and imported ones. There is no standardized guiding on the usage or selection. We use the Chinese localmade stents with membrane-covered. We completely adopted the stents, which are manufactured by Nanjing Micro-Tech, for clinical cases of this test. Their stents have the following characteristics: 1) The stents have a strong bearing force with two round blunt taps, and the double trumpet stents for better stability. 2) Stents without membrane-covered can cause re-strictures as the cancer cells easily migrate into the stent lumen. We advocate the usage of stents with membrane-covered which protect wall of esophagus and greatly lower incidence of restenosis. These stents have good flexibility with smooth edges and strong bearing force. 3) The required lengths of stents should be calculated after the accurate location of the lesion is determined. The top end of the stent should be 1-2 cm longer than the lesion and the lower end should be located at 1/5-1/4 of the cardia in order to make foods entering stomach easily. In addition, the stents have a function of anti-reflux for preventing reflux of the foods from the stomach to the esophagus (anti-reflux valves are adopted for the stents used in clinical cases of this test for further prevention of reflux).

3 Discussion of several problems about stent placement

Only accurate positioning could improve treatment effectiveness and reduce possible complications. Thus, endoscopy, barium meal (or radiography) and/or ultrasonic gastroscope are necessary before the stent placement. 2) The stricture part should be located at the center of the stent. However, attention should be paid if the strictures are close to pharynx. A heavy irritation sensation would be noted if the stent placed closed to the pharynx, such as coughing. As a result, patient would refuse the placement. It occurred in our test. 3) If the strictures or occlusion are so serious, inserting a smooth guide wire followed by a non-bendable guide

wire is recommended. Then, the delivery system of stent placement could be inserted along the guide wire until passed through the strictured part. Once the location is being confirmed, the stent could be deployed totally.

4 Evaluation

The surveillance of clinical cases show that the placement of membrane-covered metallic stent into esophagus areatly improved the indestion function of patients and the result was satisfactory. For a long-term result, some complications occurred in several clinical cases, such as restenosis and esophageal reflux. Preventive medications were necessary. Multiple stent placements were possible in some cases. The method of placing stent in treating esophageal strictures of anastomotic stoma or fistula of esophageal pleura after esophagectomy is simple, safe with significant clinical improvements, and it is worthy to be advocated and maybe the only way to resolve the dysphagia problem for some relapsing patients.

5 Treatment of Complications

1) Esophageal reflux: According to the literature, it happened almost 100%, even if the stent wasn't remained in anastomotic stoma between esophagus and stomach. The compelling dilating action of stent reduced peristalsis. The retention of esophagus secretion and mechanical stimuli of the stent to esophageal wall would result in insufficient blood circulation, which would make esophagus worse, reduce the pH value, and result in reflux esophagitis finally. Obviously, gastroesophageal reflux in this test accounts for only 16.6%, lower than in literature, which maybe the stent we placed capable of the function of anti-reflux. Moreover, the patients of this test take hydrochloric acid esomeprazole routinely after operation in order to release reflux esophagitis symptom.

2) Ulceration: The incidence of ulceration in this test was 11.1%. The compelling dilating action of stent may result in esophagus wall blood supply failure, and would cause ischemia, putrescence and even perforation in severe cases. In addition, mechanical stimulation of the both ends of the stent would also promote the ulceration in mucous membrane of esophagus. A 67-years-old female patient was died of massive hemorrhage and broad putrescence on anastomotic part two months after operation.

3) 27.7% of patients scored transitional retrosternal pain and recovered one week after taking analgesics. Such symptoms were commonly found in those patients, who were extremely thin and thus his esophagus stent is too

close to vertebral column.

4) Stent migration.

Possible reasons: (1). Inaccurate estimation of stricture before operation. (2). The incorrect selection of the stent. (3). The disappearance of partial scar and granulation due to some patients' postoperative radiotherapy. (Barium meal and esophagus ultrasound gastroscopy were offered to the patients of this test before operation. With a complete evaluation on their fistula and stricture of anastomotic stoma, no patients suffered from stent migration.)

5) Esophageal perforation:

It mainly caused by postoperative fistula and stricture

of anastomotic stoma, combined with relapse of anastomotic stoma tumor or increased fragility of tumor tissue after radiation treatment, the worn-off of necrotic tissue, esophagus wall attenuation. Also, the insertion of guide wire may damage esophageal wall.

6) Esophageal stent placement could only improve patients' food intake without any therapeutic action for tumor. In order to expand patients' lifespan, continuous treatment to tumor is necessary, including comprehensive treatment measures such as radiotherapy, chemotherapy and immuno-therapy. Recently, stents with 1251 particles have started to be applied in major hospitals, but the therapeutic effect needs further evaluation.

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