Selection and evaluation of three interventional procedures for achalasia based on long-term follow-up

Ying-Sheng Cheng, Ming-Hua Li, Wei-Xiong Chen, Ni-Wei Chen, Qi-Xin Zhuang, Ke-Zhong Shang

INTRODUCTION
Achalasia is the most common primary motility disorder of the esophagus. Three interventional procedures are used clinically for achalasia, namely pneumatic dilation, permanent metal stent dilation, and temporary metal stent dilation. These methods provide excellent immediate therapeutic efficacy, but their long-term results are unknown. Therefore, we formulated several treatment plans for patients with achalasia from July 1994 to May 2002 and evaluated them in terms of long-term follow-up.

MATERIALS AND METHODS
Materials
The subjects were 133 patients (77 males, 56 females; aged 12-84 years, mean 48.3 years) with symptoms of dysphagia. A dysphagia score was assessed by the quality of swallowing: grade 0 for normal swallowing, grade 1 for swallowing most solid food, grade 2 for swallowing semisolids, grade 3 for swallowing liquid food, and grade 4 for complete dysphagia. Based on different methods of interventional procedure, the patients were divided into three groups as follows. In 60 patients with pneumatic dilation (group A), the mean dysphagia score was 2.7±1.4, and the mean diameter of the narrowest region of the cardia was 3.3±2.1 mm. In 55 patients with permanent uncovered or antireflux covered metal stent dilation (group B), the mean dysphagia score was 2.6±1.3, and the mean diameter of the narrowest region of the cardia was 3.4±1.9 mm. In 65 patients with temporary partially covered metal stent dilation (group C), the mean dysphagia score was 2.4±1.3, and the mean diameter of the narrowest region of the cardia was 3.1±2.3 mm. The course of disease in all the patients was 1-10 years (mean 5.4±4.4 years). All the patients were examined by barium-meal radiography of the upper digestive tract and gastroscopy or esophageal intracavity manometric method.

Methods
Preoperative preparation involved an empty stomach for at least 4 hours and examination of the bleeding and clotting times. The device used was an SY dumbbell-like catheter (manufactured in Jinan, Shandong, China). The metal stent during a 12-month follow-up, and 8 patients (14.5 %) out of 55 exhibited dysphagia relapse during a 36-month follow-up. All the stents were inserted and withdrawn successfully. The follow-up in groups A-C lasted 12-96 months.

CONCLUSION: Temporary partially covered metal stent dilation is one of the best methods with interventional procedure for achalasia in terms of long-term follow-up.
for achalasia was a nitinol stent (developed by Zhiye Medical Equipment Research Institute, Changzhou, China, and Youyan Yijin Advanced Materials Co.Ltd, Beijing, China). Uncovered and antireflux covered metal stents were used in group B. Partially covered metal stents were used in group C. The body of partially covered stents was covered with intracavity silica gel. The areas within 2 cm of both ends of partially covered stents were not covered. Stents were 6-10 cm in length and 16-30 mm in diameter.

The patients in which pneumatic dilation was used were placed in lying on the side or sitting position. Topical anesthesia of the pharynx was administered before the procedure. A guidewire was inserted through the mouth and passed through the stricture section under fluoroscopy. A catheter with a diameter of 28 mm was passed through the region of achalasia of the esophagus via the guidewire, which aligned the center of the saccule with the most strictured point. The saccule was injected using an injector with diluted contrast medium or gas. Under fluoroscopy, and according to the pain reaction of the patient, pressurization was applied to gradually dilation of the saccule. The back of saccule was dumbbell-shaped. When further pressurization flattened the surface of saccule or when the pressure did not change as pressurization was applied, pressurization was suspended and the piston was closed off. The pressure of saccule was maintained for 5-30 min, after which the piston was released. After the pressure of saccule had been reduced for 5 min, pressurization was again applied. Typically each treatment involved 3-5 dilations, after which the catheter was withdrawn. The second and third treatments with graded pneumatic dilation were carried out using dilators with diameters of 30 mm and 32 mm, respectively, in some of the patients every 2 weeks until clinical symptoms disappeared and the patients returned to a normal diet.

When stents were placed in groups B and C, the sites of thoracic vertebra and spine were determined by barium-meal radiography to facilitate the stent placement. Patients were placed in a sitting position or lying on the side, and false teeth were removed and a teeth bracket was mounted. A 260-cm-long exchange guidewire was firstly led into the stomach. The second and third treatments with graded pneumatic dilation were carried out using dilators with diameters of 30 mm and 32 mm, respectively, in some of the patients every 2 weeks until clinical symptoms disappeared and the patients returned to a normal diet.

During the procedure, barium-meal radiography was performed immediately after intervention to check the esophageal patency and the dysphagia scores (Table 1) were statistically significant (P<0.01). The incidence of complications in the three interventional procedures is presented in Table 2 and the rate of dysphagia recurrence during follow-up is shown in Table 3. The follow-up period for the three interventional procedures was 12-96 months.

### RESULTS

The 60 patients in group A involved 130 dilations (mean 2.2 times per case), of which 29 patients had three graded dilations of increasing diameter, 12 patients had two graded dilations of increasing diameter, and 19 patients had one dilation. In 3 patients of group A, 5 uncovered and 3 antireflux covered stents were successfully placed. In group C, 65 partially covered stents were placed and removed under gastroscopy guidance 3-7 days after interventional procedure. The success rate of stent placement and removal was 100 %. The differences in the cardiade diameter before and after the three methods of interventional procedure and the dysphagia scores (Table 1) were statistically significant (P<0.01). The incidence of complications in the three interventional procedures is presented in Table 2 and the rate of dysphagia recurrence during follow-up is shown in Table 3. The follow-up period for the three interventional procedures was 12-96 months.

### Table 1 Diameter of the narrowest cardia region before and after treatment with three interventional procedures, and dysphagia score

| Group | Diameter of cardia before and after treatment (mm) | Dysphagia score before and after treatment (grade) |
|-------|--------------------------------------------------|--------------------------------------------------|
| A     | 3.2±2.1                                          | 10.6±3.8                                         |
| B     | 3.4±1.9                                          | 19.5±1.1                                         |
| C     | 3.1±2.3                                          | 18.9±3.9                                         |

### Table 2 Incidence of complications following treatment with three interventional procedures (％)

| Group | Pain (n) | Reflux (n) | Bleeding (n) | Hyperplasia of granulation tissue (n) |
|-------|----------|------------|--------------|--------------------------------------|
| A     | 50.0％(30/60) | 26.7％(16/60) | 10.0％(6/60)  | -                                    |
| B     | 62.5％(3/8)  | 62.5％(5/8)  | 37.5％(3/8)   | 37.5％(3/8)                          |
| C     | 40.0％(26/65)| 20.0％(13/65)| 12.3％(8/65)  | -                                    |

### Table 3 Relapse rate of dysphagia during follow-up

| Group | Follow-up >12 months | Follow-up >36 months |
|-------|-----------------------|----------------------|
|       | Relapse of dysphagia (n) | Relapse rate (%) | Relapse of dysphagia (n) | Relapse rate (%) |
| A     | 60 | 36 | 60% | 50 | 45 | 90% |
| B     | 8  | 4  | 50% | 3  | 2  | 66.7% |
| C     | 65 | 6  | 9.2%| 55 | 8  | 14.5% |


DISCUSSION

Techniques of interventional procedures

The techniques used to treat achalasia, such as surgery, bougienage, pneumatic dilation, botulinum toxin injection, permanently uncovered or antireflux covered metal stent dilation and temporary partially covered metal stent dilation, had advantages and drawbacks [1-5]. Bougienage is now uncommon since it has poor therapeutic efficacy and many complications. The use of surgery is declining due to the associated large lesion, a high risk, and high recurrence rate. Pneumatic dilation was first introduced in the plasty of hematostenosis, as its reliable therapeutic efficacy led to its gradual application to other plasty operations. Remarkable results were achieved when it was used in benign gastrointestinal strictures, and later it was widely used in the nonsurgical treatment of achalasia, exhibiting remarkable therapeutic efficacy. Many authors [6-15] have reported that graded dilation is better than single dilation in therapeutic efficacy, and our experience has confirmed this. Botulinum toxin injection in achalasia had a short term therapeutic efficacy, dysphagia was relapsed within 6 months.

Permanent metal stent dilation is primarily used in the treatment of malignant gastrointestinal stricture and obstruction, and exhibits remarkable palliative therapeutic efficacy. Cwikiel et al [16] reported an experimental and clinical study of the treatment of benign esophageal stricture with expandable metal stents. We used uncovered stents in five patients with achalasia in order to reduce the occurrence rate of stent migration. After stent placement, dilation was excellent and dysphagia disappeared, thus achieving the goal of treatment. However, it was accompanied by new problems such as gastroesophageal reflux, recurrence of stricture (hyperplasia of granulation tissue). The reflux could be treated with drugs, but this took a long time. Recurrence of stricture could be reduced by heat cauterization under gastroscope, but it could easily recur. So we used antireflux covered stent, compaction of gastroesophageal reflux and hyperplasia of granulation tissue were not found, but many unexpected results occurred. These difficulties led to the use of a temporary partially covered metal stent dilation. Clinicians and patients have gradually accepted and now prefer to use temporary partially covered metal stent dilation due to its fewer complications and excellent therapeutic efficacy [16-22].

Long-term follow-up

Dysphagia recurred in 60 % of the patients at a 12-month follow-up, and in 90 % of the patients at a 36-months follow-up, demonstrating that pneumatic dilation of achalasia has excellent immediate therapeutic efficacy but its long-term therapeutic efficacy was poor. This was mainly due to the frequent occurrence of serious gastroesophageal reflux and hyperplasia of granulation tissue. After a 12-month follow-up the stent could not be removed in three patients, and hence we had to resect and reconstruct the esophageal cardia. Therefore, permanently uncovered metal stent dilation was unsuitable for patients with achalasia [23-44]. Temporary partially covered metal stent dilation had excellent immediate and long-term therapeutic efficacy. First, the design of the stent coincided with the specific physiological structure of the cardia and the specific pathological manifestations of achalasia. The epicardia is a part of the expanded esophagus and the lower cardiac part is a very large gastric cavity. If a stent is not well designed, it will lose its therapeutic efficacy, and moreover, the rate of stent migrations will increase. To avoid these problems, we designed a special stent for achalasia. The stent was partially covered with a membrane covering the inner wall of the stent but not covering the area within 2 cm of the stent outlet. The upper outlet of the stent was a large horn, which increased the stability of the stent but made it difficult to extract. Second, the diameter of the stents used in this group was 20-30 mm. By expanding the stent, the cardia could be returned nearly to the maximum diameter of the normally dilated esophageal lumen. The most appropriate stent diameter was that which could expand the cardia stricture while not cause gastroesophageal reflux. This needs to be investigated further. Thirdly, the internal metal stent expansion procedure took a long time, and the stent was placed for 3-7 days. Why the therapeutic efficacy of temporary partially covered stent dilation was better than that of pneumatic dilation? We considered that this was mainly due to the stent expansion which caused chronic tearing of the cardia muscularis. The stent gradually expanded with body temperature, taking 12-24 h to reach 36 °C, for it to reach the expected diameter. Therefore, the cardia muscularis was torn regularly with relatively few scars formed and a very low incidence of restenosis when it was repaired. In pneumatic dilation the tearing of cardia muscularis was acute and irregular with many scars formed when it was repaired. Therefore, restenosis was common and the long-term therapeutic efficacy was poor. This might explain why the therapeutic efficacy of temporary partially covered metal stent dilation was better in the treatment of achalasia than that of pneumatic dilation.

Developments in biologically degradable stents for the esophagus which are degraded within 2 months, would provide the advantages of a long retention time without the need for stent removal. This would provide another interventional procedure for patients with achalasia. We compared three methods of interventional procedure for patients with achalasia and took the following factors into consideration such as extent of lesion, incidence of complications, therapeutic efficacy, and degree of patient acceptance. We found that in the treatment of benign gastrointestinal stricture, the use of temporary partially covered metal internal stent dilation was preferred due to its superior long-term therapeutic efficacy.

REFERENCES

1. Cwikiel W, Willen R, Stridebeck H, Libol-Gil R, Von Holstein CS. Self-expanding stent in the treatment of benign esophageal strictures: Experimental study in pigs and presentation of clinical cases. Radiology 1993; 187: 667-671
2. Song HY, Park SI, Do YS, Yoon HK, Sung KB, Sohn KH, Min YJ. Expandable metallic stent placement in patients with benign esophageal strictures: results of long-term follow-up. Radiology 1997; 203: 131-136
3. Kadakia SC, Wong RK. Graded pneumatic dilation using Rigiflex achalasia dilators in patients with primary esophageal achalasia.
Cheng YS et al. Interventional procedures for achalasia.