P.O.Box 2345, Beijing 100023,China
Fax: +86-10-85381893
E-mail: wjg@wjgnet.com www.wjgnet.com

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• BRIEF REPORTS •

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

Ying-Sheng Cheng, Ming-Hua Li, Qi-Xin Zhuang, Ke-Zhong Shang, Department of Radiology, Sixth People' s Hospital, Shanghai Jiaotong University, Shanghai 200233, China
Wei-Xiong Chen, Ni-Wei Chen, Department of Gastroenterology, Sixth People' s Hospital, Shanghai Jiaotong University, Shanghai 200233, China
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Correspondence to: Dr. Ying-Sheng Cheng, Department of Radiology, Sixth People' s Hospital, Shanghai Jiaotong University, Shanghai 200233, China. chengys@sh163.net
Telephone: +86-21-64368920 **Fax:** +86-21-64701361
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Abstract

AIM: To determine the best method out of the three types of interventional procedure for achalasia based on a long-term follow-up.

METHODS: The study cohort was comprised of 133 patients of achalasia. Among them, 60 patients were treated under fluoroscopy with pneumatic dilation (group A), 8 patients with permanent uncovered or antireflux covered metal stent dilation (group B), and 65 patients with temporary partially covered metal stent dilation (group C).

RESULTS: One hundred and thirty dilations were performed on the 60 patients of group A (mean 2.2 times per case). The mean diameter of the strictured cardia was 3.3±2.1 mm before dilation and 10.6±3.8 mm after dilation. The mean dysphagia score was 2.7±1.4 before dilation and 0.9±0.3 after dilation. Complications in group A were chest pain (n=30), reflux (n=16), and bleeding (n=6). Thirty-six patients (60 %) in group A exhibited dysphagia relapse during a 12-month follow-up, and 45 patients (90 %) out of 50 exhibited dysphagia relapse during a 36-month follow-up. Five uncovered and 3 antireflux covered expandable metal stents were permanently placed in the 8 patients of group B. The mean diameter of the strictured cardia was 3.4±1.9 mm before dilation and 19.5±1.1 mm after dilation. The mean dysphagia score was 2.6±1.3 before dilation and 0.4±0.1 after dilation. Complications in group B were chest pain (n=6), reflux (n=5), bleeding (n=3), and hyperplasia of granulation tissue (n=3). Four patients (50 %) in group B exhibited dysphagia relapse during a 12-month follow-up, and 2 case (66.7 %) out of 3 patients exhibited dysphagia relapse during a 36-month follow-up. Sixty-five partially covered expandable metal stents were temporarily placed in the 65 patients of group C and withdrawn after 3-7 days via gastroscopy. The mean diameter of the strictured cardia was 3.3±2.3 mm before dilation and 18.9±3.5 mm after dilation. The mean dysphagia score was 2.4±1.3 before dilation and 0.5±0.2 after dilation. Complications in group C were chest pain (n=26), reflux (n=13), and bleeding (n=8). 6 patients (9.2 %) out of 65 exhibited dysphagia relapse 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.

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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 unknow[1,2]. 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[1,2]: 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 8 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 internal 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 gastroscope 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

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 saccule with the most strictured point. The saccule was injected using an injector with dilated 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 nomal 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 stent was installed on the propeller whose front end was covered with sterilized liquid paraffin. Guided by the guidewire, the propeller on which the stent was mounted was moved through the segment with lesions. Under fluoroscopic control, the outer sheath was slowly withdrawn and the stent expanded under its own tension. After a stent was placed, esophageal radiography was performed to observe the patency of the esophagus. In group C, 500-1 000 ml of ice-cold water was injected 3-7 days after stent placement via a bioptic hole under gastroscope, which caused the stent to retract and reduce its diameter. Bioptic pliers were then used to withdraw the stent with the help of a gastroscope. Gastroscopy was performed again to detect complications, such as bleeding, mucosa tearing, and esophageal perforation. The patients returned to the ward and consumed cold drinks and snacks for 2 days before returning to a normal diet. It was preferable for patients to eat solid food since the natural expansion of food reduced retraction of the esophagus.

The criteria for therapeutic efficacy were as follows: the diameter of the narrowest region of the esophagus before and after dilation, and the dysphagia score before and after dilation. Postoperative treatment of pneumatic dilation, barium-meal radiography of the esophagus was performed immediately after interventional procedure to check the esophagus patency and perforation and submucous hematomas. Patients drank fluids for 2 h after interventional procedure and were treated with antibiotics, antacid drugs, and analgesics. In groups B and C, after stent placement, barium-meal radiography was used to observe the patency of the esophagus. Patients ate semisolid food on the day after interventional procedure and were treated with antibiotics and antacid drugs. In group C, esophageal radiography was performed within 1 week after stent removal to observe the patency of the esophagus. The follow-up time was 1 month, 6 months, 1 year and 3 years by telephone or clinic visit.

All the data were expressed as the mean±SD, and the paired *t*-test was used for statistical comparisons before and after interventional procedure within a group.

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 8 patients of group B, 5 uncovered and 3 antireflux covered stents were successfully placed. In group C, 65 partially covered stents were placed and removed under gastroscope guidance 3-7 days after intervertional procedure. The success rate of stent placement and removal was 100 %. The differences in the cardia 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]	2.7±1.4	0.9±0.3[b]
B	3.4±1.9	19.5±1.1[b]	2.6±1.3	0.4±0.1[b]
C	3.1±2.3	18.9±3.5[b]	2.4±1.3	0.5±0.2[b]

[b]$P<0.01$ *vs* before and after treatment.

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 %(5/8)	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		
	Follow-up (*n*)	Relapse of dysphagia (*n*)	Relapse rate (%)	Follow-up (*n*)	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 therapentic efficacy, dysphagia was relapsed witnin 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*[1] 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 reccur. So we used antireflux covered stent, compication 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 is poor[23-44]. Firstly, this was associated with the diameter of the saccule. Kadakia *et al*[10] suggested that the saccule diameter in pneumatic dilation should be 35-45 mm, but the incidence of complications was very high (e.g., 15 % had esophageal perforation). We used saccules with diameters of 28-32 mm in order to reduce the incidence of serious complications, but their long-term therapeutic efficacy was not satisfactory. Secondly, the therapeutic efficacy was associated with the frequency of dilation. One dilation did not produce excellent therapeutic efficacy, since it was affected by various factors. For example, whether the saccule was correctly located, whether pressure applied to the saccule reached the stipulated index, and variations in the anatomy of the cardia. It was suggested that three graded dilations should be used to achieve the treatment goal. Thirdly, the therapeutic efficacy was associated with the course of the disease. If this was very short, the cardiac muscularis was not fleshy and elastic. If this was very long, the cardiac muscularis was fleshy and not elastic. We used permanently uncovered stent dilation in five patients with achalasia and achieved 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[45-48]. 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 ℃, 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.

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