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## Long-term follow-up of two interventional procedures for achalasia

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**【Abstract】 Objective** To observed the long-term follow-up of the two types of interventional procedure for achalasia. **Methods** The study cohort was comprised of 140 patients of achalasia including 70 patients treated under fluoroscopy with pneumatic dilation (group A) and 70 with temporary partially covered metal stent dilation (group B). **Results** One hundred and forty dilations were performed on the 70 patients of group A with complications of chest pain ( $n = 35$ ), reflux ( $n = 18$ ), and bleeding ( $n = 8$ ); 38 patients of relapsing dysphagia during a 12-month follow-up, and 50 patients out of 60 of recurrent dysphagia during a 36-month follow-up. Seventy partially covered expandable metal stents were temporarily placed in the 70 patients of group B and withdrawn after 3-7 days via gastroscopy with complications of chest pain ( $n = 28$ ), reflux ( $n = 15$ ), and bleeding ( $n = 9$ ); 7 patients out of 70 exhibited dysphagia relapse during a 12-month follow-up, and 9 out of 58 patients exhibited dysphagia relapse during a 36-month follow-up. All the stents were inserted and withdrawn successfully. The follow-up in groups A-B lasted for 12-96 months. **Conclusion** Temporary partially covered metal stent dilation is one of the best methods of interventional procedure for achalasia in long-term follow-up. (J Intervent Radiol 2005, 14: 171-174)

**【Key words】** Achalasia; Long-term follow-up; Interventional therapy

## INTRODUCTION

Achalasia is the most common primary motility disorder of the esophagus. Two interventional procedures are used clinically for achalasia, namely pneumatic dilation and temporary metal stent dilation. These methods provide excellent immediate therapeutic efficacy, but their long-term results are not well known<sup>[1]</sup>. Therefore, we formulated treatment plans for patients with achalasia from July 1994 and evaluated them in terms of long-term follow-up.

## MATERIALS AND METHODS

## Materials

One hundreds and forty patients (83 males, 57 females; aged 11-84 years, mean 47.8 years) with symptoms of dysphagia were assessed by the quality of swallowing<sup>[1]</sup>: 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. The patients were divided into two groups as 70 patients with pneumatic dilation (group A) with mean dysphagia score of  $2.6 \pm 1.3$ , and the

mean diameter of the narrowest region of the cardia ( $3.4 \pm 1.9$ ) mm; the other 70 patients with temporary partially covered metal internal stent dilation (group B) with mean dysphagia score  $2.5 \pm 1.4$ , and the mean diameter of the narrowest region of the cardia ( $3.2 \pm 2.2$ ) mm. The course of disease in all the patients covered 12-120 months. All the patients were examined by barium-meal radiography of the upper gastrointestinal tract and gastroscopy or intraluminal esophageal manometric method.

## Methods

Preoperative preparations involved an empty stomach for at least 4 hours, and examination of the bleeding and clotting times. The SY dumbbell-like catheter (manufactured in Jinan, Shandong, China) for application in group A, and partially covered metal stents (developed by Zhiye Medical Equipment Research Institute, Changzhou, China, and Youyan Yijin Advanced Materials Co. Ltd, Beijing, China) with intraluminal silica gel lining for group B. The areas within 2 cm of both ends of partially covered stents were not covered with total length of 6-10 cm and 18-30 mm in diameter.

Patients of group A were placed in lateral prone or sitting position. Topic anesthesia of the pharynx was undertaken before the procedure and followed by inserting guide wire from the mouth down through narrowing

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segment under fluoroscopy. A saccular catheter of a diameter of 28 mm was then passed through the region of achalasia over the guidewire filling with contrast medium or gas. Under fluoroscopy and according to the pain sensation of the patient , pressure was applied with gradually dilation of the sacculle until the pressure inside reached the stable line and then the piston was closed off , maintaining for 5-30 min ; finally the piston was released. After 5 min , pressure was again applied. For a typical treatment , 3-5 dilations were performed before the withdrawn of the catheter. The second and third treatments with graded pneumatic dilation were carried out using dilators with diameters of 30 mm and 32 mm , respectively. Some of the patients needed the treatment every other weeks until clinical symptoms disappeared and the patients returned to a normal diet.

Patients in groups B , after taken barium-meal localization radiography were placed in a sitting position or lying on the side with removal of prosthetic and replacement of a teeth bracket , a 260-cm-long exchange guidewire was firstly inserted into the stomach. The stent was installed on the propeller whose tip was covered with sterilized liquid paraffin. Passing through the guidewire , the stent was moved down into the diseased segment. Under fluoroscopic control , the outer sheath of the stent was slowly withdrawn and followed by self expansion of the stent. After the stent was placed , esophageal radiography was performed to observe the patency of the esophagus. 500-1 000 ml of ice-cold water was injected in 3-7 days afterwards via a bioptic hole under gastroscopy , making the stent to retract and reduce its diameter. Bioptic pliers were then used to withdraw the stent under help of gastroscopy , simultaneously 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 resuming normal diet. It was preferable for patients to take solid food after the natural reexpansion of esophagus.

The criteria for therapeutic efficacy were as follows : In group A ,the diameters of the narrowest region of the esophagus , and the dysphagia scores before and after the dilation. Postoperative treatment of pneumatic dilation , barium-meal radiography of the esophagus was performed immediately to check over the esophagus patency ,

perforation and submucous hematomas ; followed by treatment with antibiotics , antacid drugs , and analgesics. In groups B , after stent placement , barium-meal radiography was taken to observe the patency of the esophagus. Patients were allowed to take semisolid diet together with antibiotics and antacid drugs. Esophageal radiography was performed within 1 week after stent removal to observe the patency of the esophagus and then follow-up at 1 month , 6 months , 1 year and 3 years by telephone or clinic visit.

All the data were expressed as the mean  $\pm$  SD , and the paired t-test was used for statistical comparisons before and after the interventional procedure.

### RESULTS

One hundred and forty dilations were performed on the 70 patients of group A. Complications in group A were chest pain (  $n = 35$  ) , reflux (  $n = 18$  ) , and bleeding (  $n = 8$  ) ; 38 patients exhibited dysphagia relapse during a 12-month follow-up , and 50 patients out of 60 exhibited dysphagia relapse during a 36-month follow-up. 70 partially covered expandable metal stents were temporarily placed in the 70 patients of group B and withdrawn after 3-7 days via gastroscopy. Complications in group B were chest pain (  $n = 28$  ) , reflux (  $n = 15$  ) , and bleeding (  $n = 9$  ) ; 7 patients out of 70 exhibited dysphagia relapse during a 12-month follow-up , and 9 patients out of 58 exhibited dysphagia relapse during a 36-month follow-up. All the stents were inserted and withdrawn successfully. The differences in the cardia diameter before and after the two methods of interventional procedure and the dysphagia scores ( Table 1 ) were statistically significant (  $P < 0.01$  ). The incidences of complications in the two groups were presented in Table 2 and the rates of dysphagia recurrence during follow-up were shown in Table 3. The follow-up for groups A-B lasted 12-96 months.

**Table 1** Diameters of the narrowest cardia region before and after treatment with two kinds of interventional procedure , and dysphagia scores

Group	Diameters of cardia before and after treatment ( mm )		Dysphagia scores before and after treatment ( grade )	
A	3.4 $\pm$ 1.9	10.3 $\pm$ 3.9 <sup>b</sup>	2.6 $\pm$ 1.3	0.8 $\pm$ 0.4 <sup>b</sup>
B	3.2 $\pm$ 2.2	19.1 $\pm$ 3.6 <sup>b</sup>	2.5 $\pm$ 1.4	0.6 $\pm$ 0.3 <sup>b</sup>

<sup>b</sup>  $P < 0.01$  vs before and after treatment

**Table 2** Incidence of complications following treatment with two kinds of interventional procedure( % )

Group	Pair( <i>n</i> )	Reflux( <i>n</i> )	Bleeding( <i>n</i> )
A	50.0%( 35/70 )	25.7%( 18/70 )	11.4%( 8/70 )
B	40.0%( 28/70 )	21.4%( 15/70 )	12.9%( 9/70 )

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

Group	Follow-up > 12 months			Follow-up > 36 months		
	Follow-up( <i>n</i> )	Relapse of dysphagia( <i>n</i> )	Relapse rate( % )	Follow-up( <i>n</i> )	Relapse of dysphagia( <i>n</i> )	Relapse rate( % )
A	70	38	54.3 %	60	50	83.3%
B	70	7	10.0%	58	9	15.5%

DISCUSSION

Techniques of interventional procedure

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<sup>[ 1 2 ]</sup>. Bougienage is now uncommon since it has poor therapeutic efficacy and many complications. The use of surgery is declining due to the associated large area of tissue damage , high risk , and high recurrence rate. Pneumatic dilation was first introduced in hematosenotic plasty. Its reliable therapeutic efficacy led to the gradual application in other plastic operations. Remarkable results were achieved in benign esophageal strictures , and later in the nonsurgical treatment of achalasia. Many authors<sup>[ 3-6 ]</sup> have reported that graded dilation is better than single dilation confirming our experience. Botulinum toxin injection possessed only a short term therapeutic efficacy , dysphagia was relapsed witnin 6 months.

Permanent metal stent dilation was primarily used in the treatment of malignant esophageal stricture and obstruction , and exhibits remarkable palliative therapeutic efficacy. Cwikiel et al<sup>[ 1 ]</sup> reported an experimental and clinical study of the treatment for 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 achieving the goal of the 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 , requiring a long time while recurrence

of stricture by heat cauterization under gastroscopy with high recurrency. These could be overcome by using antireflux covered stent , but still many unexpected results occurred. These difficulties led to the use of a temporary partially covered metal stent dilation , gradually accepted by clinicians and patients due to lesser complications and excellent therapeutic efficacy<sup>[ 7-10 ]</sup>.

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 poor for long-term therapeutic efficacy<sup>[ 11-14 ]</sup>. The successful rate correlated closely with the follows , firstly , this was associated with the diameter of the saccule. Kadakia et al<sup>[ 5 ]</sup> suggesting the saccule diameter should be 35-45 mm , but with the high incidence of complications ( e. g. 15% esophageal perforation ). The diameters 28-32 mm of ours were used in order to reduce the serious complications , but less satisfactory for long-term efficacy. Secondly , the therapeutic efficacy was associated with the frequency of dilation. Once dilation often showed not enough efficacy , because various factors involved such as the correct localization , appropriate pressure applied , and variations in the anatomy of the cardia. It would be more complimented through three graded dilations. Thirdly , it was related to the course of the disease , because the cardiac muscularis was not fleshy and elastic in short duration and was fleshy and not elastic in long duration. Permanently uncovered stent dilation were performed in five patients with achalasia and achieved excellent immediate therapeutic efficacy , but with poor long-term therapeutic efficacy. 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 resulting as to reset and reconstruct the esophageal cardia. Therefore, permanently uncovered metal stent dilation was unsuitable for patients with achalasia<sup>[15,16]</sup>. Temporary partially covered metal stent dilation possessed excellent immediate and long-term therapeutic efficacies. Firstly, the design of the stent coincided with the specific physiological structure of the cardia and the specific pathological manifestations of achalasia. The superior cardia is a part of the expanded esophagus and the inferior cardia is the very large gastric cavity. To avoid the migration and increase the effectiveness of the stent placement, we designed a special stent for achalasia with partially covered with a membrane lining closely to the inner wall of the stent but leaving a naked area within 2 cm of the stent outlet. The upper outlet of the stent was a large horn increasing the stability of the stent with prevention to be extracted. Secondly, the diameter of the stents used in this group was 20-30 mm, making the cardia to return nearly to the maximum normal diameter. The most appropriate stent diameter needs to be investigated further. Thirdly, the internal metal stent expansion procedure took a long time for 3-7 days. The better result of temporary partially covered stent dilation was mainly due to the stent expansion causing chronic tearing of the cardia muscularis by gradually expanded with body temperature, taking 12-24 h to reach 36 °C outcoming with regularly torn cardia muscularis, less scar formation and a very low incidence of restenosis. Concersely, the pneumatic dilation often outcame with acute and irregular cardia muscularis torn and scar formation, therefore with poor long term efficacy.

Developments of biologically degradable stents for the esophagus which would be degraded within 2 months, could provide the advantages of a long retention time without the need for stent removal. It could be a new horizons for interventional procedure to patients with achalasia. We compared the two methods of interventional procedure for patients with achalasia and obtained the following factors including extent of lesion, incidence of complications, therapeutic efficacy, and degree of patient acceptance as major important criteria. We found that in the treatment of benign gastrointestinal stricture, the use

of temporary partially covered metal internal stent dilation was the preferred choice due to its superior long-term therapeutic efficacy.

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