

# Comparative observation on different intervention procedures in benign stricture of gastrointestinal tract

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## Abstract

**AIM:** To determine the most effective intervention procedure by evaluation of mid and long-term therapeutic efficacy in patients of stricture of the gastrointestinal tract (GIT).

**METHODS:** Different intervention procedures were used to treat benign stricture of GIT in 180 patients including pneumatic dilation (group A,  $n=80$ ), permanent (group B,  $n=25$ ) and temporary (group C,  $n=75$ ) placement of expandable metallic stents.

**RESULTS:** The diameters of the strictured GIT were significantly greater after the treatment of all procedures employed ( $P<0.01$ ). For the 80 patients in group A, 160 dilations were performed (mean, 2.0 times per patient). Complications in group A included chest pain ( $n=20$ ), reflux ( $n=16$ ), and bleeding ( $n=6$ ). Dysphagia relapse occurred in 24 (30%) and 48 (60%) patients respectively during 6-and-12 month follow-up periods in group A. In group B, 25 uncovered or partially covered or antireflux covered expandable metallic stents were placed permanently, complications included chest pain ( $n=10$ ), reflux ( $n=15$ ), bleeding ( $n=3$ ), and stent migration ( $n=4$ ), and dysphagia relapse occurred in 5 (20%) and 3 patients (25%) during the 6-and-12 month follow-up periods, respectively. In group C, the partially covered expandable metallic stents were temporarily placed in 75 patients and removed after 3 to 7 days via gastroscope, complications including chest pain ( $n=30$ ), reflux ( $n=9$ ), and bleeding ( $n=12$ ), and dysphagia relapse occurred in 9 (12%) and 8 patients (16%) during the 6-and-12 month follow-up periods, respectively. The placement and withdrawal of stents were all successfully performed. The follow-up of all patients lasted for 6 to 96 months (mean  $45.3\pm 18.6$  months).

**CONCLUSION:** The effective procedures for benign GIT stricture are pneumatic dilation and temporary placement of partially-covered expandable metallic stents. Temporary placement of partially-covered expandable metallic stents is one of the best methods for benign GIT strictures in mid and long-term therapeutic efficacy.

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## INTRODUCTION

Benign stricture of gastrointestinal tract (GIT) is caused by postsurgical anastomoses, ingestion of corrosive agents, simple sclerosis after radiation therapy for tumors, digestive ulcer and functional disturbances, which involve different sites including esophagus, stomach, duodenum, colon and rectum. From July 1994, 180 patients with benign GIT stricture were treated with intervention procedures. Our experiences and follow-up data are reported herein.

## MATERIALS AND METHODS

### Materials

Our cohort comprised 180 patients with benign GIT stricture (101 males, 79 females; age, 12 to 78 years, mean 48.7 years). The subjects were divided into three groups according to the intervention procedures used: 80 patients with pneumatic dilation (group A), 25 with permanent uncovered or partially covered or antireflux covered metallic stent dilation (group B), and 75 with temporary partially covered metallic stent dilation (group C). Among the 180 patients, 8 had simple sclerosis stricture after radiation therapy for esophageal carcinoma, 132 had achalasia, 32 had esophageal and esophagogastric anastomosis stricture (complicated with anastomosis fistula in two patients), 4 had gastroduodenal anastomosis stricture, and 4 had esophageal chemical corrosive stricture. All patients were examined by barium radiography of GIT and gastroscopy before the intervention procedures.

### Methods

The GIT was emptied for at least 4 h before intervention procedures. Bleeding and clotting times were examined. The devices used were as follows. The catheter was an SY dumbbell-like catheter (Sanyuan Medical Instrument Research Institute, Jinan, Shandong, China) with a length of 75 cm. The diameters upon saccule dilation were 28 mm, 30 mm, and 32 mm, and length of the saccule was 8 cm. There were two types of metallic stents, one was an imported covered Z-stent made from stainless steel wire (Wilson-Cook Medical Inc, NC, USA), the other made domestically from nitinol and uncovered or partially covered or antireflux covered (Zhiye Medical Instrument Research Institute, Changzhou, Jiangsu, China; Youyi Yijin Advanced Materials Co. Ltd, Beijing, China). The body of the partially covered metallic stents was coated with intracavity silica gel. The areas within 2 cm of both ends of the stent were not membrane covered. The stents were 4 to 14 cm in length and 16 to 30 mm in diameter, with one or two horns (diameter, 20 to 35 mm).

Patients for pneumatic dilation were placed in a supine or

**Table 1** Incidence of complications following treatment with different intervention procedures (%)

Groups	Patient numbers ( <i>n</i> )	Number (%) with pain ( <i>n</i> )	Number (%) with reflux ( <i>n</i> )	Number (%) with bleeding ( <i>n</i> )	Number (%) with stent migration ( <i>n</i> )
A	80	20 (25.0%)	16 (20.0%)	6 (7.5%)	-
B	25	10 (40.0%)	15 (60.0%)	3 (12.0%)	4 (16.0%)
C	75	30 (40.0%)	9 (12.0%)	12 (16.0%)	-

**Table 2** Dysphagia relapse rate during follow-up

Group	6 months follow-up		12 months follow-up	
	Number tested ( <i>n</i> )	Number (%) with DR ( <i>n</i> )	Number tested ( <i>n</i> )	Number (%) with DR( <i>n</i> )
A	80	24(30%)	80	48(60%)
B	25	5(20%)	12	3(25%)
C	75	9(12%)	50	8(16%)

DR: dysphagia relapse.

sitting position. Surface anesthesia was first applied to the pharynx. The guidewire was inserted through the mouth and passed through the stricture section as demonstrated by X-ray examination. The catheter with a diameter of 28 mm was introduced through the region of benign esophageal stricture via the guidewire, with the center of sacculi at the most-strictered section. The sacculi was injected using an injector with the diluted contrast medium or gas. Under fluoroscopy and according to the pain reaction of the patient, pressurization was applied to gradually dilate the sacculi. The central portion of the sacculi was dumbbell-shaped. When further pressurization flattened the surface of the sacculi or when the pressure did not further change, the piston was turned off. The pressure of the sacculi was maintained for 5 to 30 min. After the sacculi pressure had reduced for 5 min, pressurization was again applied. Typically each treatment involved 3 to 5 dilations, and then 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 patients, the treatment was conducted every 2 weeks until clinical symptoms disappeared.

The placement of metallic stents was performed as follows. In upper GIT, lidocaine (1%) was first sprayed (as a mist) for anaesthesia on the pharynx. Patients were placed in a sitting position or lying on the side. Applicable false tooth were removed and a tooth bracket was mounted. A 260 cm long exchange guidewire was inserted into the stomach. The stent was mounted on the propeller whose front end was coated with sterilized liquid paraffin. Guided by the wire, the propeller on which the stent was mounted was moved through the section of pathological change. Under fluoroscopic control, the outer sheath was slowly withdrawn and the stent was expanded under its own tension. After placing a stent, GIT radiography was performed to observe the patency of the GIT. In group C, 500 to 1 000 ml ice-cold water was injected via a bioptic hole under gastroscopy for 3 to 7 days after stent placement, which resulted in retraction of the stent and reduced its diameter. Bioptic pliers were then used to withdraw the stent using a gastroscopy. Gastroscopy was performed again to detect complications, such as bleeding, mucosa tearing, or perforation. Patients returned to the ward and consumed cold drinks and liquid food for 2 days before resuming a normal diet. It was preferable for patients to eat solid food since the natural expansion of the food reduced the retraction of the GIT. The criterion for therapeutic efficacy was the diameter of the most-strictered gastrointestinal segment before and after dilation.

For postoperative treatment of pneumatic dilation, barium radiography of the GIT was performed immediately after

intervention procedure to observe the patency of the GIT and check the presence of perforations and submucous hematoma. Patients drank fluids 2 h after intervention procedure and were treated with antibiotics, antacids, antireflux drugs, and analgesics. For postoperative treatment of stent placement, barium radiography was used to observe the patency of the GIT. Patients ate semisolid food on the day following intervention procedure. Within one week after stent removal, barium radiography of the GIT was again used to observe the patency of the GIT. Patients were followed-up by telephone and out-patients after 1 month, 6 months, 1 year.

## RESULTS

The diameters of the strictured GIT were significantly greater after the treatment of all procedures employed ( $P < 0.01$ ). The 80 patients in group A involved 160 dilations (mean 2.0 times per patient). Among them, five graded dilations of increasing diameters were performed in 1 patient, three in 29 patients, two in 18 patients and a single dilation in 32 patients. In the 25 patients of group B, uncovered or partially covered or antireflux covered stents were placed. Stent placement was successful in 100% of the patients. In the 75 patients of group C, 75 partially covered stents were placed and removed under gastroscopy guidance 3 to 7 days after intervention procedure. The success rate of stent placement and extraction was 100%. The complications of the treatment are listed in Table 1, and the relapse rates of dysphagia are listed in Table 2.

## DISCUSSION

Benign stricture of the GIT is a common complication of gastrointestinal diseases. Its causes are diverse, its treatment is usually difficult. The procedures used included surgery, bougienage, pneumatic dilation, permanent metallic and temporary metallic stent dilation, each having their own advantages and drawbacks<sup>[1-7]</sup>. Bougienage is now uncommon since it has a poor therapeutic efficacy and many complications. The use of surgery is declining due to the associated large lesion, high risk, and high relapse rate, but it is still one of the most common methods of treatment. Pneumatic dilation was primarily used in the plasty of angiodysplasia, and then applied gradually to other organs for its reliable therapeutic efficacy. It exhibits a remarkable therapeutic efficacy when used in benign esophageal stricture. Currently, it has been widely used in the nonsurgical treatment of benign GIT stricture. According to most authors<sup>[8-31]</sup>, the graded dilation is more effective than single dilation.

Permanent metallic stent dilation was primarily used in the treatment of malignant obstruction of the GIT, and exhibited a remarkable palliative therapeutic efficacy<sup>[32-40]</sup>. Cwikiel *et al*<sup>[2]</sup> reported an experimental and clinical study of the treatment of benign esophageal stricture with expandable metallic stents. We used uncovered or partially covered or antireflux covered stents in 25 patients of benign GIT stricture in order to reduce the possibility of stent migration. After placement of the uncovered stent, dilation of the stricture was excellent and dysphagia disappeared. Thus we achieved the treatment goal. However, the patients were accompanied by new problems including gastroesophageal reflux or biliary regurgitation, followed by occurrence of restenosis (hyperplasia of granulation tissue). Reflux could be treated with drugs, but this took a long time. Restenosis was reduced after cauterization using hot-point therapy under gastroscope guidance, but it was easy to relapse. Even though an antireflux stent was used, many unexpected results appeared. These difficulties led to dilation using temporary partially covered metallic stents. After their clinical trials, they not only produced fewer complications, but also exhibited excellent therapeutic efficacy. Now their use has been gradually accepted by clinicians.

For the temporary metallic stents, optimal placement time remains to be determined. If the therapeutic efficacy is poor, stents cannot be easily removed after a long-time placement. Usually, the stents are placed within 1 week. Cwikiel *et al*<sup>[2]</sup> placed a covered metallic stent in the esophagus of the pigs in an experimental study. One week later, granulation tissue grew and merged with the noncovered area of the stent, resulting in difficulties for removing the stent. The stent could not be removed following the placement for 10 to 14 days or longer. By our experience, stent migration occurred mostly within 1 week. Therefore, after the placement of a partially covered metallic stent, it should be extracted within 1 week. In our series, the stent was easily removed on the third to fourth day, but this became quite difficult on the fifth day, and extremely difficult after 6 to 7 days. Song *et al*<sup>[3]</sup> reported the removal of a stent 2 months after its placement. In such patients the stent should be completely coated (including its outer layer) so that granulation tissue cannot grow into the lumen. However, the use of this type of stent should be limited to patients with tumor, since in patients of benign GIT stricture, it migrates easily. In terms of the degree of acceptance of patients, therapeutic efficacy, extent of tissue lesion, and incidence of complications, the best method for malignant stricture or obstruction of the GIT is the partially covered metallic stent, and for benign stricture of the GIT, graded pneumatic dilation or temporary partially covered metallic stent dilation should be recommended<sup>[41-45]</sup>.

Sixty percent of patients with the follow-up of 1 year or longer had dysphagia relapse, demonstrating that pneumatic dilation of benign stricture of the GIT had an excellently immediate therapeutic efficacy but a poor mid and long-term therapeutic efficacy. First, this was associated with the diameter of sacculae. Kadakia *et al*<sup>[4]</sup> suggested that the diameter of the sacculae in pneumatic dilation should be 35 to 45 mm, but the incidence of complications was very high (*e.g.*, 15% presented esophageal perforation). We used sacculae with a diameter of 28 to 32 mm in order to reduce the incidence of serious complications, but the mid and long-term therapeutic efficacy was not satisfactory. Second, 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 such as the correct location of the sacculae pressure applied to the sacculae, and variations in the anatomy of GIT. The graded dilation was suggested by most authors. Third, the therapeutic efficacy was associated to the course of the disease. When the course was long, the GIT muscularis would

become fleshy and lose elasticity.

Permanent uncovered or partially covered metallic stents were used in the treatment of malignant stricture or obstruction of the GIT with excellently immediate therapeutic efficacy and poor mid and long-term therapeutic efficacy. This was mainly due to tumor growth. Since uncovered or partially covered metallic stents could only provide palliative treatment for the obstruction, only by adopting a combined therapy for the tumor, can mid and long-term therapeutic efficacy be achieved. In our series, permanent uncovered or partially covered or antireflux covered metallic stent dilations were used in 25 patients of benign GIT stricture, their immediate therapeutic efficacy was excellent and the mid and long-term efficacies were unsatisfactory. The poor mid and long-term outcome for permanent uncovered metallic stent dilation was mainly due to frequent gastroesophageal reflux or biliary regurgitation and restenosis. Three uncovered stents could not be extracted after a 12-month follow-up period, and hence the cardia had to be excised with the stent and surgically reconstructed. Therefore, permanent uncovered metallic stent dilation was not suitable for patients with functional GIT stricture<sup>[46-49]</sup>. Permanent partially covered metallic stent dilation had poor mid and long-term therapeutic effects. This was mainly due to reflux and stent migration. Temporary partially covered metallic stent dilation used for benign GIT stricture resulted in excellent immediate effect, thus becoming the best method for mid and long-term therapeutic efficiencies. First, design of the stent coincided with the physiological structure of the gastrointestinal tract and the specific pathological manifestations of the benign stricture. The upper outlet of the stent was a large horn without cover, increasing stability of the stent. However, this made removal of the stent more difficult. Second, the diameter of the stents used in this group was 16 to 30 mm. Upon stent dilation, the stricture returned almost to the maximum normal diameter of gastrointestinal dilation. Third, the duration of dilation was very long, with a typical period of stent placement for 3 to 7 days. Why was the therapeutic efficacy of temporary partially covered metallic stent dilation better than that of pneumatic dilation? We thought that this was mainly due to the stent expanding the strictured gastrointestinal region, causing chronic tearing of the strictured wall muscularis. As a stent gradually expanded with the body temperature of the patient, it took 12 to 24 h for a stent to reach 36 °C. The stent thus expanded completely to reach the expected diameter. In our consideration, the wall muscularis was torn regularly by the metallic stent, and scars were relatively few when repaired. This resulted in a markedly lower incidence of restenosis compared to that for pneumatic dilation.

**Table 3** Strategies of intervention procedure for different benign strictures in upper gastrointestinal tract

Types of GIT stricture	Strategies
AS	TCSD > PD > PCSD > PUCSD
AS with fistula	PCSD > TCSD
New scar stricture	TCSD > PD > PCSD
Scar stricture	PCSD > TCSD > PD
Functional stricture (achalasia)	TCSD > PD > PCSD with antireflux

AS: anastomosis stricture, TCSD: temporary covered stent dilation, PD: pneumatic dilation, PCSD: permanent covered stent dilation, PUCSD: permanent uncovered stent dilation.

With different intervention procedures compared in consideration of the extents of lesion, incidences of complication, therapeutic efficacies, and degrees of acceptance of patients,

we found that partially covered metallic stents could provide excellent therapeutic effect. However, different strategies should be adopted to different types of lesion (Table 3). Development of biologically removable stents, which can be catabolized in 2 months after their placement, may provide a much longer retention time with no necessity for extraction<sup>[50-56]</sup>.

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