Malignant Esophagogastric Junction Obstruction:
Palliative Treatment with an Antireflux Valve Stent

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The authors assessed the efficacy of an antireflux valve stent in the palliation of malignant esophagogastric junction (EGG) obstruction after in vitro testing of the stent. Seventeen patients with inoperable malignant EGJ obstruction were treated. Antireflux valves, made of three polyurethane leaflets, were attached to the distal part of the stent to prevent reflux. When the flow rate of normal saline was 100 mL/sec in the forward direction, the valve fully opened at a pressure of 10 mm Hg. When the flow rate of normal saline was 0.35 mL/sec in the backward direction, the valve nearly completely closed at a pressure of 10 mm Hg. Stent placement was successful in all patients without complications. The median dysphagia score decreased significantly, from 3.0 (dysphagia to liquids) to 1.0 (dysphagia to normal solid food) (P < .0005). No patients experienced reflux symptoms. There was one case of stent migration. A valve stent that can prevent major reflux is an effective device for the palliation of malignant EGJ obstruction.

Index terms: Esophagus, grafts and prostheses. Esophagus, stenosis or obstruction

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Abbreviation: EGI = esophagogastric junction

COVERED or uncovered self-expanding metallic stents have proven to be easy and safe devices for palliation of malignant esophageal and esophagogastric junction (EGJ) obstruction. The satisfactory relief of dysphagia by stent placement has been well documented (1-5). However, when the stent traverses the EGJ for palliation of malignant EGJ obstruction, high-grade gastroesophageal reflux has been reported as a complication (1-3,6). In such cases symptoms of reflux have been treated with antacids, proton pump inhibitors, changes in posture (sleeping with the

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MATERIALS AND METHODS

From October 1996 to June 1999, we treated 17 consecutive patients with inoperable malignant esophagogastric junction obstruction by placing an antireflux valve stent. There were 14 men and three women, aged years 45-83 years (mean age, 65 y). Of the 17 patients, 11 had advanced gastric carcinoma with distal esophageal invasion and six had squamous cell carcinoma of the distal esophagus. The diagnosis was established by means of endoscopic biopsy and computed tomography. Diseases were inoperable because of distant metastasis in 16 patients and tumor invasion of the aorta in one patient. The strictures were located in the lower esophagus involving the EGJ. The valve stent was placed as a palliative treatment of dysphagia. Patient dysphagia was graded on a scale of 0-4 before and after stent placement: 0 = no dysphagia; 1 = dysphagia to normal solid food; 2 = dysphagia to soft food; 3 = dysphagia to liquids; and 4 = inability to swallow saliva. The median grade of dysphagia was 3 in these patients. The Wilcoxon signed rank test was used to determine significant differences of dysphagia grade before and after stent placement.

The valve stent consisted of three parts: body (middle portion of the stent), proximal part, and 11 part. The body of the valve stent was 18 mm in diameter. The proximal and distal parts were 8 mm and 12 mm larger in diameter than the body. The valve stent was covered with polyurethane with 3-mm gaps between each metallic stent body part to provide longitudinal flexibility. The method of making and covering of the stent was described in detail previously (10). The antireflux valves consisted of three leaflets, like a tricuspid valve of the heart. They were made of polyurethane and attached to the inner portion of the distal part of the valve stent to prevent reflux (Fig 1). The valve stent was made by hand in our research laboratory. We used...
an introducing tube made of polytetrafluoroethylene, with an outer diameter of 10 mm, and a pusher catheter made of polyurethane. Figure 2 illustrates the delivery system. The valve stent was deployed by the same method described previously (10). This study was approved by our institutional review board and informed consent was obtained from each patient before the valve stent placement.

**Figure 1.** The antireflux valve stent. Note three antireflux valves (arrow) at the distal part of the stent. The ruler indicates centimeters.

**Figure 2.** Diagram illustrating the delivery system, which consists of a guiding tube (a), pusher catheter (b), introducing tube (c), compressed stent (d), and guiding tip (e).
Funotional Test of the Valve Stent

The function of the valve stent was tested five times with a simple system in our research laboratory (Fig 3). The valve stent was fitted between two chambers containing saline solution and the flow rate and the pressure of normal saline solution through the valve stent were measured in both directions. Pressure was needed to measure the flow rate in a backward direction.

Patient Follow-up

Patients ingested fluids immediately after the procedure and were restricted to a soft diet for 2 days and then advanced to a solid diet. We recommended that patients drink water after eating to prevent obstruction of the valve stent. Status of oral food ingestion and symptoms of reflux (offordless regurgitation, heartburn) were sequentially monitored over a 1-month interval on an outpatient basis or by telephone. Barium study was performed 3 days after the procedure to evaluate patency and reflux of the valve stent. After filling of the stomach with 200-400 mL of barium, reflux was evaluated while the patient rolled from the prone position to the supine position or from the supine position to the right lateral position and during stress maneuvers such as Trendelenburg and Valsalva performed with the patient in the supine position fourth of the volume of the stent was filled by refluxed barium, we regarded it as a minimal reflux. We recommended patients undergo this barium study at monthly intervals if possible. Simple chest and abdominal radiographs were also checked to monitor stent morphology and migration.
Figure 4. These figures show the relationship between the flow rate and the pressure of normal saline solution through the stent in the forward (a) and backward (b) directions.

Figure 5. Images from an 80-year-old man with inoperable carcinoma of the distal esophagus. His grade 4 dysphagia resolved after stent placement. (a) Esophagogram showing distal esophageal carcinoma (arrows). (b) A stent with an 18-mm diameter and a 21-cm length was inserted. (c) Three-week follow-up esophagogram with stress maneuver shows a minimal degree of barium reflux (arrow).
RESULTS

The relationship between the flow rate and the pressure through the valve stent in both directions are shown in figure 4. In the forward direction, when the flow rate of normal saline solution was 100 mL/sec, the valve fully operated at a pressure of 10 mm Hg. In the backward direction, when the flow rate of normal saline was 0.35 mL/sec, the valve nearly completely closed at a pressure of 10 mm Hg. Stent placement was successful in all patients without any complications.

The procedure was well tolerated by all patients. One week after stent placement, 16 of 17 patients (94%) showed an improvement of dysphagia and could eat soft food or normal solid food. The median dysphagia score decreased significantly from 3.0 to 1.0 within 1 week (P < .0005). One patient could not swallow any liquid after stent placement because of proximal jejunal obstruction caused by peritoneal seeding of the tumor. Barium study performed 3 days after stent placement demonstrated good flow of barium with no reflux in seven patient flux in 10 patients (59%) (Figs 5,6).

Figure 6. Images from a 75-year-old man with inoperable carcinoma of the distal esophagus. His grade 2 dysphagia resolved after stent placement. (a) Esophagogram showing distal esophageal carcinoma with ulcer. (b) Three-day follow-up esophagogram after stent placement shows good passage of barium. (c) Esophagogram with stress maneuver shows no barium reflux.
Because the valve stent needs a small amount of pressure to prevent reflux completely (Fig 4b), a minimal degree of reflux was observed on barium study in 10 patients. Follow-up examination was performed with simple radiography in three patients and with barium study in 10 patients. There was minimal or no barium reflux at follow-up. No patients reported involuntary regurgitation of food and heartburn as symptoms of reflux during follow-up.

Downward migration of the valve stent was observed as a complication in one patient 2 weeks after stent placement. The stent remained in the stomach for 3 weeks and was spontaneously passed with stool. The patient did not want to have another stent placed. Four patients did not undergo follow-up studies or visit the hospital after stent placement because stent placement was performed during the terminal phase of illness. We could contact them or their family only by telephone.

Fifteen patients died (13 of diffuse metastasis, one of tumor bleeding, one of biliary sepsis) 3-36 weeks (median 8.0 wk) after stent placement. One patient was lost to follow-up. One patient was alive with a patent stent in place for 16 weeks at the end of the study.

**DISCUSSION**

Malignant EGJ stenosis or obstruction usually occurs in lower esophageal carcinoma or advanced gastric carcinoma with invasion of the lower esophagus. Because the resectability rate for cancers of the esophagus or cardia is approximately 40%, a palliative procedure for relief of dysphagia is usually indicated for most patients with inoperable malignant EGJ obstruction (11). The major goal of palliative treatment is to relieve dysphagia with minimal invasiveness and low rates of morbidity and mortality. In this respect, covered or uncovered self-expanding metallic stents have great advantages, and different kinds of covered and uncovered self-expanding metallic stents have been used for palliation of dysphagia of EGJ neoplasms. Stent insertion leads to prompt relief of dysphagia in 83%-97% of patients (2,5,6). The dual-sphincter mechanism at the EGJ is composed of the intrinsic smooth muscles of the lower esophageal sphincter and extrinsic skeletal muscles of the diaphragmatic hiatus. It prevents gastroesophageal reflux (12). However, when the stent transverses the EGJ for palliation of malignant EGJ obstruction, high-rate gastroesophageal reflux has been reported as a complication (1-3,6). In such case, patients have been instructed to elevate the head of the bed and avoid being recumbent after meals to reduce the risk of reflux and aspiration. Symptoms of reflux have been treated with a combination of proton pump inhibitors and motility agents (1,2,5). Antireflux prostheses with flat rubber or polyurethane valves at the distal portion of the esophageal tube or stent have been developed to treat these patients (7-9). The prevention of gastroesophageal reflux has been documented, but possible acute kinking of the long intragastric portion of the valve against gastric wall and obstruction of the tube has been
Our valve stent was designed to overcome this problem. Because antireflux valves are attached to the inner portion of the distal part of the valve stent, there is no risk of kinking of the valves.

The esophageal peristaltic wave associated with swallowing is called primary peristalsis. The peristaltic wave is produced by a segmental contraction of the esophageal muscle. Recording peak pressure of the peristaltic wave with an intraesophageal transducer system reveals values of 53.4 mm Hg ± 9.0 in the upper esophagus, 35.0 mm Hg ± 6.4 in the middle portion, and 69.5 mm Hg ± 12.1 in the lower esophagus (13). In this respect, the valve should be open at the lowest possible pressure for comfortable swallowing. Our valve sten opened widely at the pressure of 10 mm Hg in the forward direction so that all patients except one (16 of 17; 94%) could eat more than soft food after stent placement. We made the diameter of the distal part of the valve stent 12 mm larger than that of the body part for improving the flow rate through the attached valve. In our study, because the amount of reflux through the valve was small (<0.35 mL/sec), no patients reported involuntary regurgitation of food and heartburn as symptoms of reflux during follow-up. Placement of a covered stent may prevent tumor ingrowth, but migration of these stents, particularly from strictures at the EGJ, is a disadvantage. In our study, although only 13 of 17 patients underwent follow-up study the rate of stent migration was relatively low compared with those reported elsewhere (1,2,4,14). Only on stent migrated into toe stomach and the migrated stunt did not cause any problems. The low rate of migration may be explained by the 3-mm gap between each metallic stent body part made of polyurethane membrane without metallic mesh. It makes the valve stent flexible and makes each metallic part act as a separate unit during peristaltic wave. The valve stent showed flexion, elongation, constriction, and expansion along the esophageal peristaltic wave on fluoroscopy (10). But, in a study of conventional covered stents connected by metallic struts, the stents acted as a single tube during peristaltic waves and may have caused higher rates of migration (1,4).

If a migrated valve stent rotates in the stomach and then moves to the small intestine, obstruction of the small bowel by the rotated valve stent may be possible. To investigate this, we inserted valve stents in the stomachs of four dogs and follow-up simple abdominal radiographs were checked for possible obstruction. All four stents passed per rectum within 3 days without any problems. Objective assessment of gastroesophageal reflux requires radiologic, scintigraphic, manometric, or pH monitoring techniques. At present, 24-hour pH monitoring is the most reliable means of diagnosing gastroesophageal reflux disease (15). But, because it was difficult to perform 24-hour pH monitoring for the patients with terminal disease, barium study and clinical symptoms of the patients were used for evaluating the reflux of the valve stent. Although further clinical trial and follow-up studies are needed, our study suggests that placement of the antireflux valve stent is effective in the relief of dysphagia caused by
malignant EGJ neoplasm and it can prevent major gastroesophageal reflux.

References


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