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Malignant Gastroduodenal Obstructions: Treatment by Means of a Covered Expandable Metallic Stent—Initial Experience[1]

PURPOSE: To investigate the technical feasibility and clinical effectiveness of a polyurethane-covered expandable nitinol stent in the treatment of malignant gastroduodenal obstructions.

MATERIALS AND METHODS: The stent was constructed in-house by weaving a single thread of 0.2-mm nitinol wire in a tubular configuration and was covered with polyurethane solution by means of a dipping method. With fluoroscopic guidance, the stent was placed in 19 consecutive patients with malignant gastric outlet obstruction ($n = 15$) or duodenal obstruction ($n = 4$). All patients had severe nausea and recurrent vomiting, and their obstructions were inoperable.

RESULTS: Stent placement was technically successful in all but one patient. After stent placement, symptoms improved in all but one patient, who had another stenosis at the proximal jejunum. One patient with stent placement in the second portion of the duodenum became jaundiced. During the mean follow-up of 11 weeks, stent migration occurred in five patients 1–4 days after the procedure. All patients with stent migration were treated by means of placing a second, uncovered nitinol stent. Two of these five patients showed recurrence of stricture because of tumor ingrowth; they underwent coaxial placement of a third, covered nitinol stent with good results.

CONCLUSION: Placement of a polyurethane-covered expandable nitinol stent seems to be technically feasible and effective for palliative treatment of inoperable malignant gastroduodenal obstructions. Stent migration, however, is problematic and requires further investigation.

Malignant obstruction of the stomach or duodenum is a preterminal event that causes nausea, vomiting, dysphagia, and then nutritional deficiencies that lead to progressive deterioration in a patient's quality of life. Although surgical palliation is an available option in such patients, the morbidity and mortality are high, and good control of symptoms is achieved in about only half of the patients treated (1–3). Self-expandable metallic stents recently have been used for palliative treatment of malignant gastric and duodenal obstructions. Although no large, controlled trials have been performed, published data suggest that the procedure is a safe and effective nonsurgical treatment for cases of inoperable gastric and duodenal obstructions (4–15). However, recurrent stenosis of the stent because of progressive tumor ingrowth has been a problem because most of the stents used were uncovered (7,9,11–14). Overall recurrent stenosis rates of 8%–46% at an interval of 2–21 weeks (mean, 7.5 weeks) have been reported in studies (7,9,11–14) that have included more than six but fewer than 12 patients.

Covered stents have been used in the esophagus to prevent tumor ingrowth (16) and most likely will contribute to the solution of this problem. However, the delivery systems used in the esophagus are too large and rigid to be used in the gastric outlet or in the duodenum. Song et al (17) successfully implanted a covered stent in a patient with obstructing cancer of the gastric antrum; however, the stent was placed through a surgical

Data in 19 Patients with Gastroduodenal Stent Placement

Patient No./Age (y)/Sex	Stenosis		Stent		Symptoms*		Food Intake Capacity		Compli-cation†	Patient Outcome	Follow-up (wk)
	Cause	Site	No.	Diameter/Length (mm)	Before	After	Before	After			
1/62/M	Klatskin tumor	Antrum, plyorus	1	16/80	V	None	Liquid	Soft	None	Dead	7
2/74/F	Gastric carcinoma	Antrum, pylorus	2	16/80, 18/80‡	V, D	None	None	Liquid	M	Dead	5
3/33/M	Gastric carcinoma	Body, antrum	2	16/80, 18/80‡	V, D	ON	None	Liquid	M	Dead	6
4/70/M	Gastric carcinoma	Antrum	1	16/80	V	None	Liquid	Soft	None	Dead	13
5/69/M	Gastric carcinoma	Antrum, pylorus	1	16/80	V	None	Liquid	Solid	None	Dead	11
6/56/F	Common bile duct carcinoma	Duodenum, part 2	3	16/60, 18/60‡, 16/60	V	None	Liquid	Soft	J, M, SS§	Alive	22
7/76/M	Gastric carcinoma	Antrum, pylorus	1	16/70	V	None	Liquid	Solid	None	Alive	20
8/67/F	Gastric carcinoma	Antrum	1	16/80	V	None	Liquid	Soft	None	Dead	15
9/67/M	Gastric carcinoma	Pylorus	1	16/50	V	None	Liquid	Solid	None	Alive	20
10/77/F	Gastric carcinoma	Antrum, pylorus	1	16/80	V	None	Liquid	Soft	None	Dead	7
11/47/M	Gastric carcinoma	Antrum, pylorus	1	16/80	V, D	V	None	Liquid	None	Dead	3
12/75/M	Gastric carcinoma	Antrum, pylorus	1	16/70	V	None	Liquid	Soft	None	Alive	15
13/80/M	Gastric carcinoma	Body, antrum	3	16/80, 18/80‡, 16/80	V	ON	Liquid	Soft	M, SS§	Alive	15
14/68/M	Gastric carcinoma	Antrum, pylorus	1	16/90	V, D	None	None	Soft	None	Alive	14
15/75/M	Gastric carcinoma	Antrum, pylorus	2	16/90, 18/90‡	V	None	Liquid	Soft	M	Dead	5
16/65/F	Gastric carcinoma	Antrum	1	16/40	V	ON	Liquid	Soft	None	Alive	11
17/58/M	Pancreatic carcinoma	Duodenum, part 2	1	16/80	V	None	Liquid	Soft	None	Dead	4
18/38/M	Pancreatic carcinoma	Duodenum, part 2	1	16/80	V, D	None	None	Soft	None	Alive	8
19/72/M‖	Pancreatic carcinoma	Duodenum, part 3	NA	NA	NA	NA	NA	NA	NA	NA	NA

* D = dysphagia, ON = occasional nausea, V = vomiting.
† J = jaundice, M = migration, SS = stent stenosis.
‡ Uncovered stent.
§ Recurrent stent stenosis after placement of a second, uncovered stent.
‖ Patient with technical failure. NA = not applicable.

gastrostomy. Therefore, better-designed stents and delivery systems are needed for peroral placement of a covered stent in gastroduodenal obstructions.

To solve these problems, we designed a polyurethane-covered expandable nitinol stent and a delivery system for peroral placement in patients with inoperable gastric or duodenal obstructions. The purpose of this study was to describe the technique of making and implanting this stent, as well as early clinical outcomes.

MATERIALS AND METHODS

From September 1998 to April 1999, 19 consecutive patients (14 men, five women; age range, 33–80 years; mean age, 65 years) with severe nausea and vomiting caused by a gastric outlet obstruction ($n = 15$) or a duodenal obstruction ($n = 4$) were treated by means of peroral fluoroscopic placement of a covered expandable nitinol stent. The underlying causes of gastric outlet obstructions were gastric carcinoma in 14 patients and Klatskin tumor in one patient. The causes of duodenal obstructions were pancreatic carcinoma in three patients and distal common bile duct carcinoma in one patient (Table).

The diagnosis was established by means of endoscopic biopsy ($n = 14$), percutaneous needle aspiration biopsy ($n = 3$), or imaging technique and forceps biopsy during percutaneous transhepatic biliary drainage and stent placement ($n = 2$). In all patients, the tumors were considered inoperable because of extensive tumor growth and the presence of distant metastases. Patients 1 and 6 underwent biliary stent placement 284 and 402 days before gastroduodenal stent placement, respectively. Patient 17 underwent percutaneous transhepatic biliary drainage 98 days before stent placement. Patient 18 underwent choledochojejunostomy 72 days before stent placement. Informed consent was obtained from each patient, and this pilot study was approved by our institutional review board.

Stent Construction and Stent Introducer Set

The stent was woven 16 times from a single thread of 0.2-mm nitinol wire in a tubular configuration. To prevent tumor growth or mucosal hyperplasia through the stent wires, the stent was covered with 12% polyurethane solution (Chronoflex; Cardiotech International, Woburn, Mass) by means of a dipping method. To provide a firmer covering to the most proximal and distal parts of the stent to prevent detachment of the polyurethane covering from the nitinol wire, those areas were covered with 100% nylon mesh and then coated by dipping in polyurethane. The stent was 16 mm in diameter when fully expanded and 40–90 mm long, and both ends of the stent were flared up to 26 mm (Fig 1). A radiopaque mark made of gold was attached at both ends of the stent. The stent was constructed in our research laboratory. A stent at least 20 mm longer than the stricture was selected for placement so that its proximal and distal parts would rest above and below the stricture, respectively.

The stent introducer set consisted of a Teflon sheath with a 6-mm outer diameter and a 5-mm inner diameter, a pusher catheter, and a guiding balloon catheter 6 mm in diameter and 4 cm long (Boston Scientific, Natick, Mass) (Fig 1). We used the guiding balloon catheter instead of a long tapered dilator to increase the longitudinal flexibility of the introducer set.

The sheath and pusher catheter were constructed by a local manufacturer (Stentech, Seoul, South Korea) to our specifications.

Stent Placement and Removal Techniques

The site, severity, and length of the stricture were evaluated by means of a barium study before stent placement by either one of two authors (G.S.J. or H.Y.S.) who then placed the stent. Topical anesthesia of the pharynx and larynx was achieved routinely before the procedure by using an aerosol spray (Atomizer; Devilbiss, Somerset, Pa). Sedatives were used routinely in all patients. A nasogastric tube was placed before the procedure to empty the stomach in patients with severe gastric distention.

A 100-cm-long, 5-F angled vascular catheter (HI Headhunter Cerebral; Cook, Bloomington, Ind) with a 260-cm-long, 0.035-inch-diameter exchange guide wire (Radiofocus M; Terumo, Tokyo, Japan) was inserted through the mouth and down the esophagus into the stomach. After injection of iopromide (Ultravist 300; Schering-Korea, Ansung, South Korea) to demonstrate the proximal extension of the stenosis, the catheter was advanced across the stenosis to the distal portion of the stenosis with fluoroscopic guidance and the help of the guide wire. In four patients with substantial gastric distention despite decompression of the stomach by means of nasogastric tube insertion, the exchange guide wire was placed endoscopically through the stenosis.

After removal of the endoscope (Olympus GIF-P30; Olympus, Tokyo, Japan), the vascular catheter was advanced over the guide wire to the distal portion of the stenosis. After placement of the vascular catheter distal to the stenosis with fluoroscopic or endoscopic guidance, water-soluble iodinated contrast medium was injected to demonstrate the distal extension of the stenosis, and the vascular catheter was replaced with a 5-F, graduated sizing catheter (Cook) to measure the length of the stenosis. The 0.035-inch exchange guide wire was then exchanged for a 260-cm-long, 0.035-inch extra stiff guide wire (Lunderquist Extra Stiff Wire Guide; Cook-Europe, Bjaeverskov, Denmark), and the catheter was removed with the guide wire left in place.

Subsequently, a deflated guiding balloon catheter was passed through the 6-mm sheath of the stent introducer set with half of the balloon lying out of the sheath; it was inflated with diluted, water-soluble iodinated contrast medium to guide the sheath. This sheath balloon catheter assembly was passed over the guide wire into the stomach and advanced until the distal end of the sheath reached approximately 1 cm beyond the stenosis. After the guiding balloon catheter was removed, a covered nitinol stent was compressed into the sheath and advanced by using a pusher catheter until the distal part of the stent reached the distal end of the sheath. After that, the pusher catheter was held in place with one hand while the sheath was slowly withdrawn in a continuous motion with the other hand. This freed the stent and allowed it to lie within the stenosis and to expand. All stents demonstrated adequate, immediate self-expansion without postdeployment balloon dilation.

In patients with upward migration of the stent, the migrated stent was removed by using a loop-snare technique. To remove the stent, a 0.035-inch exchange guide wire was introduced through the mouth into the stomach. A 13-F sheath with a dilator (Stentech) was passed down over the guide wire into the stomach. After the dilator was removed from the sheath, the loop snare was introduced through the sheath by using a 0.032-inch guide wire, thereby forming a wide loop inside the stomach lumen. After the migrated stent was snared with fluoroscopic guidance and endoscopic monitoring, the loop was tightened around the stent and was pulled out without complication.

Follow-up

All patients underwent barium study 1 day after stent placement to verify the position and patency of the stent. Endoscopy was performed before the patient was discharged. Further follow-up in each patient was based on monthly clinical examinations in the outpatient clinic. Follow-up barium study or endoscopy was performed only in patients with recurrent symptoms. When the performance of clinical examinations was not practical, the patients or their families were contacted by telephone every month, while the patients were alive, for information concerning nausea, vomiting, and dysphagia.

RESULTS

Stent placement was technically successful (Fig 2) and well-tolerated in all patients except patient 19, and no procedural complications occurred. Once the vascular catheter was placed beyond the stenosis and an extra stiff guide wire was inserted, there were no patients in whom the introducing sheath with a guiding balloon catheter was not able to be placed and no patients in whom the covered stent was not able to be placed through the introducing sheath. In patient 19, with a complete obstruction in the third portion of the duodenum, the procedure failed because the vascular catheter was not able to be placed beyond the obstruction owing to failure in negotiation of the guide wire through the obstruction.

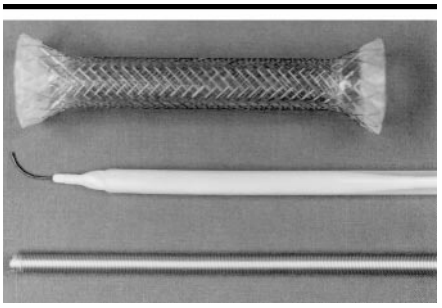
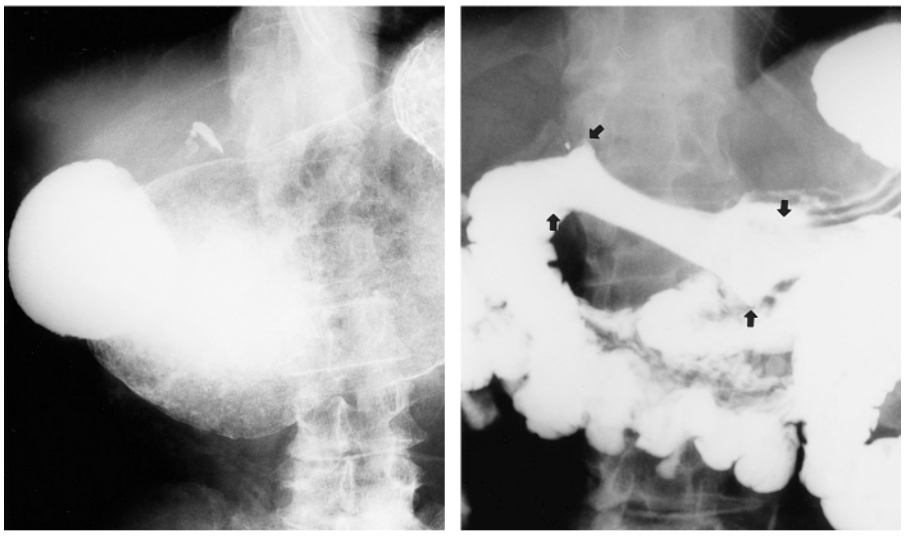


Figure 1. Photograph of (top) a polyurethane-covered nitinol stent, (middle) a sheath with inflated balloon catheter for guiding, and (bottom) a pusher catheter.

Stent migration occurred in patients 2, 3, 6, 13, and 15 1–4 days after the procedure; the stent migrated upward completely in two patients and migrated downward completely in three. Two stents with upward migration were removed by using a loop-snare technique. Two of the three stents with downward migration came out of the anus uneventfully 10 and 12 days after placement. The remaining stent with downward migration remained in the second portion of the duodenum until the patient's death. All patients with stent migration were treated by means of placing a second, uncovered nitinol stent 18 mm in diameter.

Symptoms improved after placement of initial or second stents in all patients except patient 11. Patient 11 had another stenosis at the proximal jejunum that had been overlooked prior to stent placement. This patient required intravenous nutrition until death 22 days later because of no symptomatic improvement even after stent placement. The other 17 patients were able to take liquids or solid foods after stent placement, and three of them subsequently were able to eat almost any type of food. Endoscopy performed before the patient was discharged showed the widely opened lumen containing the stent in all 18 patients. Three



a. b.

Figure 2. Patient 9. Gastric carcinoma in a 67-year-old man. **(a)** Anteroposterior upper gastrointestinal radiograph obtained before stent placement shows a dilated stomach because of nearly total obstruction of the pyloric portion of the stomach. **(b)** Anteroposterior upper gastrointestinal radiograph obtained 1 day after placement of a covered stent (arrows) shows barium passage.

patients who had massive gastric involvement of cancer had occasional nausea or vomiting during the follow-up period, although follow-up endoscopic or barium study results showed the patent lumen containing the stent.

Patient 6, one of the three patients with stent placement in the second portion of the duodenum, developed jaundice after stent placement in the duodenum; however, the stent migrated 4 days after placement, and the jaundice was relieved. A second, uncovered stent was then placed (Fig 3), and the patient was asymptomatic for 9 weeks with soft food intake. No jaundice developed thereafter. The other two patients, patients 17 and 18, underwent percutaneous transhepatic biliary drainage or choledochojejunostomy before stent placement and did not develop jaundice after the procedure.

Among the five patients in whom a second, uncovered stent was placed because of migration of the first, covered stent, tumor ingrowth, which was confirmed at endoscopy with biopsy, occurred in patients 6 and 13 64 and 11 days after stent placement, respectively. In these two patients, we placed a third, covered nitinol stent 16 mm in diameter coaxially in the uncovered one (Fig 3). They were able to take soft food, and no stent stenosis or delayed stent migration has occurred as of the writing of this article. No other complications, particularly no bleeding or perforation, were noted.

During the mean follow-up of 11 weeks, 10 of 18 patients died 3–15 weeks (mean, 7.6 weeks) after stent placement owing to sepsis or diffuse metastasis of the underlying cancer, and the remaining eight patients were without symptoms 8–22 weeks (mean, 15.6 weeks) after stent placement.

DISCUSSION

A simple, nonsurgical method to palliate intractable vomiting and the inability to eat would be an important advance in the management of inoperable malignant gastroduodenal obstructions. Different types of uncovered expandable metallic stents have been reported to provide effective treatment alternatives with minimal morbidity in patients with benign or malignant gastroduodenal obstruction (4–15). However, peroral placement of covered stents in gastroduodenal obstructions by using the currently available introducer was considered extremely difficult because of the acute angulation of the gastric antrum to the esophageal axis (17).

In our study, peroral placement of a polyurethane-covered expandable nitinol stent was technically feasible. With our method of stent construction, it was possible to reduce the introducing sheath down to 6 mm in outer diameter and 5 mm in inner diameter. We used an afterloading technique to place the stent because it was difficult to pass the delivery system mounted with the stent through the stenosis, as reported by Binkert et al (4) and Strecker et al (5). Concerning an extra stiff guide wire inserted beyond the stenosis, the introducing sheath with a guiding balloon catheter could be passed over the guide wire through the stenosis without difficulty even in an extremely dilated stomach, because of the relatively small diameter and sufficient flexibility of the sheath. Once the introducing sheath was advanced beyond the stenosis, the covered stent was placed successfully by using the pusher catheter through the sheath. With this method, placement of the covered stent was successful in 18 of 19 patients without procedure-related complications. One technical failure in our study was due to failure of negotiation of the guide wire through the stenosis.

Despite their ability to prevent tumor ingrowth, covered stents have been reported to migrate more often than uncovered stents in the esophagus (18), as was true in our study. Various methods of preventing stent migration in the esophagus have been described already (19–22). We agree with the opinion that stent migration could be minimized by using a stent with proximal and distal shoulder formation (22). However, the diameter of the introducing sheath must be increased if the stent is constructed with a shoulder formation rather than flaring, because a shoulder formation makes it difficult to compress the stent into the sheath. Further investigations are necessary to modify the stent design and reduce the diameter of the introducing sheath by using a different material to prevent stent migration.

Two of five patients with a second, uncovered stent due to stent migration showed recurrence of the stricture because of tumor ingrowth. These two patients underwent coaxial placement of a covered stent in the uncovered one. Interestingly, no immediate or delayed stent migration occurred thereafter in these patients.

In most previous articles (4–15), the diameter of the uncovered stent used for gastroduodenal obstructions was 16–22 mm. In uncovered stents, the ex vivo stent caliber is not correlated with the final, fully expanded luminal diameter after stent insertion (13,23). When the stents are placed in the stenotic lumen, they are incorporated gradually into the tumor tissue and at the same time expand the stenosis (23). Thus, the final, fully expanded luminal diameter after

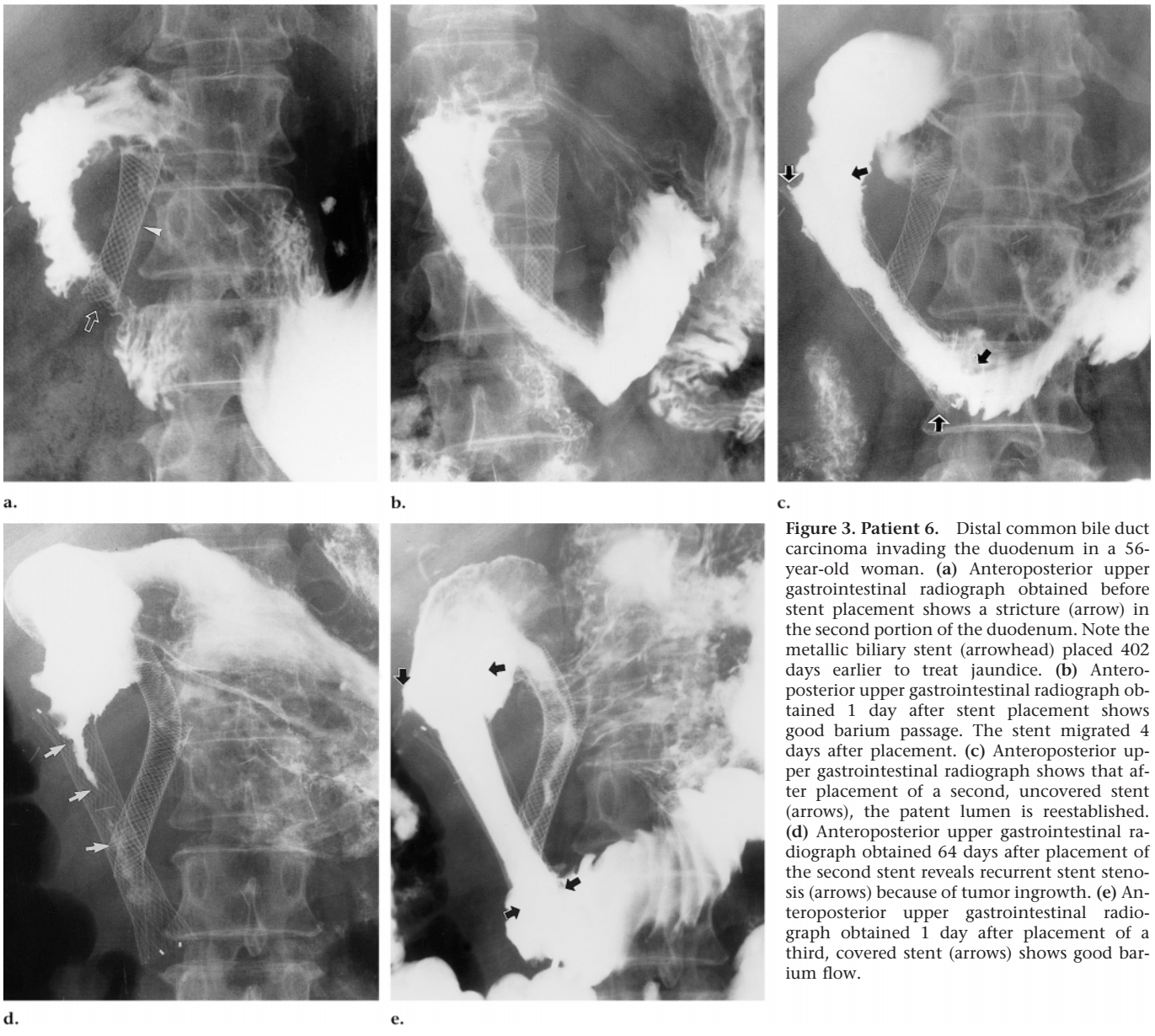


Figure 3. Patient 6. Distal common bile duct carcinoma invading the duodenum in a 56-year-old woman. **(a)** Anteroposterior upper gastrointestinal radiograph obtained before stent placement shows a stricture (arrow) in the second portion of the duodenum. Note the metallic biliary stent (arrowhead) placed 402 days earlier to treat jaundice. **(b)** Anteroposterior upper gastrointestinal radiograph obtained 1 day after stent placement shows good barium passage. The stent migrated 4 days after placement. **(c)** Anteroposterior upper gastrointestinal radiograph shows that after placement of a second, uncovered stent (arrows), the patent lumen is reestablished. **(d)** Anteroposterior upper gastrointestinal radiograph obtained 64 days after placement of the second stent reveals recurrent stent stenosis (arrows) because of tumor ingrowth. **(e)** Anteroposterior upper gastrointestinal radiograph obtained 1 day after placement of a third, covered stent (arrows) shows good barium flow.

stent insertion is always smaller than the original stent diameter. On the other hand, the covered stents could have nearly the same luminal diameter as the original stent diameter after full expansion of the stents. Therefore, we thought that the use of a 16-mm, covered nitinol stent would create a wide enough luminal diameter to enable free passage of food, although we are not sure of the ideal stent diameter for use in gastroduodenal obstruction. In our study, 17 of the 18 patients with successful stent placement experienced relief of their obstructive symptoms and improved oral intake. Three of these patients subsequently were able to eat almost any type of food.

Yates et al (13) suggested a possible limitation of using covered stents in duodenal obstruction because of the possibility of creating a biliary obstruction at the level of the papilla of Vater. In our study, one of the three patients with stent placement in the second portion of the duodenum developed jaundice. The other two patients underwent percutaneous transhepatic biliary drainage or choledochojejunostomy before stent placement and did not develop jaundice. We therefore recommend that either an uncovered stent should be used or biliary decompression should be mandatory prior to placement of a covered stent in the second portion of the duodenum. However, malignant duodenal obstruction due to pancreatic or bile duct carcinoma often is preceded by biliary stenosis (24,25). Therefore, biliary decompression commonly is required before palliation of a duodenal obstruction even with the use of uncovered stents (24,25).

In conclusion, despite the short follow-up period and several limitations, our preliminary results indicate that use of a polyurethane-covered expandable nitinol stent is a feasible and effective method of treating inoperable malignant gastroduodenal obstructions. Use of a covered stent can prevent tumor ingrowth and thereby decrease the rate of recurrent obstruction. However, one should take precautions to use a covered stent in treating a duodenal obstruction

because of the potential for biliary obstruction. Moreover, further investigations will be necessary to prevent stent migration.

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