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Dual-Design Expandable Colorectal Stent for a Malignant Colorectal Obstruction: Preliminary Prospective Study Using New 20-mm Diameter Stents

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Objective: To evaluate the safety and effectiveness of a 20-mm diameter dual-design expandable colorectal stent for malignant colorectal obstruction.

Materials and Methods: The study series included 34 patients with malignant colorectal obstruction who underwent implantation of a 20-mm dual-design expandable colorectal stent in our department between March 2009 and June 2010. The 20-mm dual-design expandable colorectal stent was placed by using a 3.8-mm delivery system that had 28-mm diameter proximal and distal ends. Among the 34 patients, stent placement for palliation was performed in 20 patients, while stent placement for bridge to surgery was performed in 14 patients.

Results: A 97% (33 of 34) success rate was achieved for the stent placement. The perforation rate in the bridge to surgery group was 7% (1 of 14), compared to 0% (0 of 19) in palliative group. Migration occurred in one of 33 patients (3%) at 30 days after stent placement.

Conclusion: The placement of a 20-mm diameter dual-design stent appears to be clinically safe and effective for the management of colorectal obstruction, with low perforation and migration rates.

Index terms: *Colorectal cancer; Stent; Dual-design; Expandable*

INTRODUCTION

Colorectal stenting is well known to be effective and safe in relieving obstructions, either palliatively or as a bridge to surgery in patients with primary colorectal cancer (1-6). The overall success rate is very high, ranging from 80% to 100% (7-12). Even though there is a high success rate for the stent placement, complications are still encountered. In bare stent placement, recurrent obstruction rates of 3-46% due to tumor ingrowth have been reported (7, 12, 13). Reported recurrent obstruction rates due to tumor ingrowth have been reduced to 0-7% with the use of covered expandable metal stents (14, 15). Although covered stents have proven to be effective for the occlusion of fistulas or ruptures in the gastrointestinal tract (14, 16), their use has been plagued by stent migration problems. While the migration rates associated with bare stent placement have ranged from 3% to 12% (11, 13, 17), the overall migration rates of covered stents have been reported to be as high as 30% to 50% (14, 15, 18).

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To overcome migration of the stent and tumor ingrowth, a dual-design expandable colorectal stent has been devised (1). Even though the dual design stent has a low tumor ingrowth rate (3%) and migration rate (3%), the perforation rate is still reported to be 11%, mainly due to upper flared ends of the stent (1). In order to decrease the perforation rate of dual-design stents, Kim et al. (19) designed a study to test the hypothesis that a dual-design colorectal stent with bent ends had lower risk of causing colonic perforations than a dual-design stent with flared ends. However, the rates of colonic perforation did not differ significantly between stent types, nor did the rate of stent-related mortality. In addition, the two stent types had similar technical and clinical success as well as stent migration rates (19).

We hypothesized that a dual stent with a smaller diameter could decrease the rate of perforation due to the low expansion force and better conformability; therefore, placing a smaller diameter stent may be a safe and effective strategy in treating a colorectal obstruction. The aim of this prospective study was to report the clinical results of a 20-mm diameter stent placement in 34 patients with a malignant colorectal obstruction.

MATERIALS AND METHODS

Patients

Informed consent for placement of 20-mm dual-design expandable colorectal stents was obtained for each patient, and our Institutional Review Board approved this prospective study.

Demographic details of all 34 patients are summarized in Table 1. This prospective non-randomized study involved 34 patients with a malignant colorectal obstruction and who were implantated with a 20-mm dual-design expandable colorectal stent in our department between March 2009 and June 2010. The 34 patients consisted of 19 male and 15 female patients ranging in age from 37 to 86 (mean, 59.7) years. Among the 34 patients, stent placement for palliation was performed in 20 patients, while stent placement for bridge to surgery was performed in 14 patients. The indication of palliative stent placement in patents was to relieve bowel obstruction. Inclusion criteria for stent placement were as follows: 1) documented malignancy and 2) bowel obstruction as defined by symptoms resulting in defecation difficulty. Exclusion criteria included asymptomatic patients with malignant colorectal obstruction and who showed clinical evidence of perforation or colorectal obstruction combined with small bowel obstructions. Data collected included demographic information, causes of malignancy, sites and length of obstruction, indications for stent placement, symptom improvement after stent placement, procedure or stent-related complications, management of complications, and expansion of stents.

The underlying causes of obstruction were colorectal carcinoma in 32 patients, ovarian carcinoma in one patient, and metastatic carcinoma of the stomach in one patient. The sites of obstruction included the rectum in five patients, rectosigmoid in three patients, sigmoid in 20 patients, descending colon in three patients, transverse colon in one patient, and ascending colon in two patients. The lengths of stricture ranged from 3 cm to 10 cm (mean, 5.0 cm).

Stents and Stent Introducer Sets

The 20-mm dual stent (S&G Biotech, Seongnam, Korea) consisted of an outer stent and an inner bare nitinol stent (Fig. 1). The outer stent consisted of three parts: a proximal bare nitinol stent (diameter, 28 mm; length, 25 mm), a nylon mesh (diameter, 20 mm), and a distal bare nitinol stent (diameter, 28 mm; length, 25 mm). The inner bare nitinol stent was 20 mm in diameter. The total length of the inner stent was the same as that of the outer stent. The expansion force of the stent was 2.42-N (Newton) in the middle and 1.92-N at both ends. For the previously used 24-mm dual stent, the expansion force was 2.96-N in the middle and 3.60-N at both ends. The expansion force was measured by LR5K PLUS testing machine (AMETEK LLOYD, England). The new inner bare stent could easily be bent without a decrease in the luminal diameter (Fig. 1). The conformability of the inner stent is attributed to the thinner wire used. Previously, the 24-mm inner stent was made of a 0.254-mm wire, but now the new 20-mm inner stent is made of 0.203-mm wire. The delivery system is also smaller for the new stent compared with the 24-mm inner stent, which now is only 3.8 mm, while it was previously 4.5 mm. With the smaller delivery system and more conformable stent, the new stent could be delivered even in the most adverse situations.

The S&G Biotech stent introducer system consisted of a Teflon sheath, 3.8 mm in outer diameter and 80-150 cm in length, a pusher coil catheter, and a guiding olive tip. The outer and inner stents were loaded in their own separate delivery systems.

Table 1. Demographic Details of All Patients

Patient	Sex	Age	Site of Obstruction	Diagnosis	Indication	Complication	Immediate Remedy
1	F	52	Rectum	Ovarian cancer	Palliation	None	
2	M	81	Ascending colon	Colorectal cancer	Palliation	None	
3	M	49	Descending colon	Colorectal cancer	Palliation	None	
4	M	54	Sigmoid colon	Colorectal cancer	Palliation	Incomplete expansion	Balloon dilatation
5	F	37	Sigmoid colon	Colorectal cancer	Palliation	None	
6	M	51	Sigmoid colon	Colorectal cancer	Palliation	None	
7	M	63	Sigmoid colon	Colorectal cancer	Palliation	None	
8	F	47	Sigmoid colon	Colorectal cancer	Bridge to surgery	Incomplete expansion	Balloon dilatation
9	M	51	Sigmoid colon	Colorectal cancer	Bridge to surgery	Incomplete expansion	Balloon dilatation
10	M	70	Sigmoid colon	Colorectal cancer	Palliation	Incomplete expansion	Balloon dilatation
11	F	60	Sigmoid colon	Colorectal cancer	Palliation	None	
12	M	65	Rectum	Colorectal cancer	Bridge to surgery	None	
13	M	37	Rectum	Colorectal cancer	Palliation	Incomplete expansion	Balloon dilatation
14	M	61	Transverse colon	Colorectal cancer	Palliation	Incomplete expansion	Balloon dilatation
15	M	68	Recto-sigmoid	Colorectal cancer	Palliation	None	
16	M	67	Descending colon	Colorectal cancer	Bridge to surgery	None	
17	F	68	Recto-sigmoid	Colorectal cancer	Bridge to surgery	None	
18	M	73	Sigmoid colon	Colorectal cancer	Bridge to surgery	None	
19	M	64	Rectum	Colorectal cancer	Bridge to surgery	None	
20	F	55	Sigmoid colon	Colorectal cancer	Bridge to surgery	Perforation	Operation
21	F	55	Sigmoid colon	Colorectal cancer	Bridge to surgery	None	
22	F	38	Sigmoid colon	Colorectal cancer	Palliation	None	
23	M	69	Sigmoid colon	Colorectal cancer	Palliation	None	
24	F	46	Recto-sigmoid	Colorectal cancer	Bridge to surgery	None	
25	F	62	Sigmoid colon	Colorectal cancer	Bridge to surgery	None	
26	F	49	Sigmoid colon	Colorectal cancer	Palliation	Fail	Operation
27	F	86	Ascending colon	Colorectal cancer	Palliation	None	
28	F	68	Sigmoid colon	Colorectal cancer	Bridge to surgery	None	
29	M	61	Descending colon	Colorectal cancer	Bridge to surgery	None	
30	F	58	Sigmoid colon	Colorectal cancer	Bridge to surgery	None	
31	M	67	Rectum	Stomach cancer	Palliation	None	
32	M	54	Sigmoid colon	Colorectal cancer	Palliation	None	
33	M	65	Sigmoid colon	Colorectal cancer	Palliation	None	
34	F	78	Sigmoid colon	Colorectal cancer	Palliation	None	

Note.— F = female, M = male

Stent Placement Technique

The details of dual stent placement have been described previously (1). Briefly, with the patient in the left lateral decubitus position, a 0.035-inch guidewire (Radiofocus M, Terumo, Tokyo, Japan) was inserted under fluoroscopic guidance through the anus, across the obstruction, and into the proximal region of the obstruction. After the guidewire was exchanged for a superstiff, 260-cm-long Amplatz guidewire (Medi-tech, Boston Scientific, Boston, MA), the stent delivery system containing the outer component of the stent was passed over the superstiff guidewire, through the obstruction, until the proximal stent had passed through the obstruction. The pusher catheter was held in place, while the sheath was slowly withdrawn, and deployed across the stent stricture. The stent delivery system was removed with the superstiff guidewire left in place. A stent delivery system containing the inner bare component of the stent was then advanced over the superstiff guidewire to

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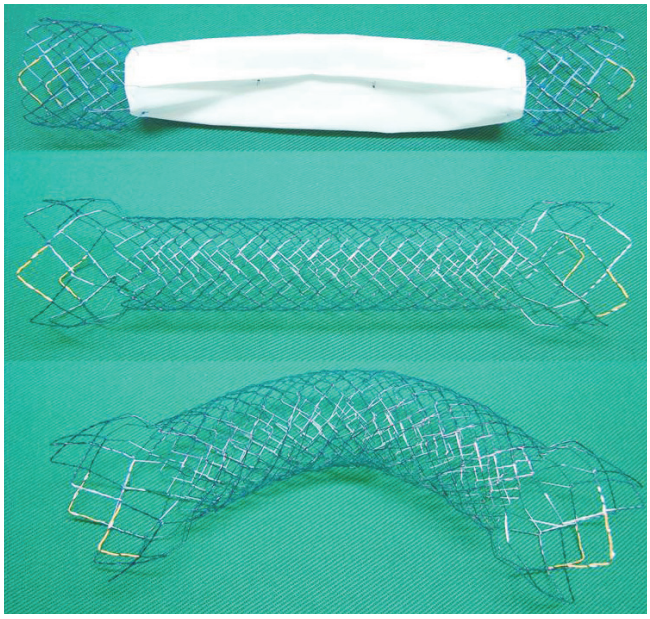

Fig. 1. Photograph showing, from top to bottom, outer stent of dual stent, inner bare nitinol stent of dual stent, and bended inner bare nitinol stent.

place the inner bare component coaxially into the outer stent.

Follow Up

Patients underwent a plain abdominal radiographic examination and a barium study 1 to 3 days after stent placement to assess the expansion and patency of the stent as well as possible complications. Patients for palliation also underwent a barium study one month after stent placement to verify delayed complications, such as stent migration or obstruction. Further follow-up in each patient was based on monthly plain radiography and clinical examinations in the outpatient clinic. A 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 until their death. Information was obtained concerning defecation difficulty.

Interpretation of the Results

Clinical success was defined as relief of bowel obstruction. Tumor overgrowth was defined as symptomatic narrowing of the stent lumen above or below the covered portion of the stents as a result of tumor growth. Tumor ingrowth was defined as symptomatic narrowing of the stent lumen within the covered portion of the dual stent. Complications including bleeding, pain, tumor overgrowth or ingrowth, perforation, migration, and symptom recurrence were evaluated.

RESULTS

The collective technical and clinical success rate of stent placement was 97% (33 of 34). The only failure case was a 49-year-old lady suffering from a sigmoid colon obstruction due to underlying colorectal carcinoma. The colonic carcinoma caused by complete obstruction of the sigmoid colon, with failure to cross the obstruction with the guide wire. She proceeded to operation right after stent placement failure.

A total of 33 stents were placed at the time of the initial stent placement in the 33 patients with successful stent placement (Fig. 2): all patients required only one stent to traverse the site of the obstruction. In six of 33 patients (18%), dilatation of the dual stent using a 14-mm balloon catheter was performed after insertion of the inner bare stent because the diameter of the both placed stent was less than a third of the preset expanded diameter (20 mm).

In all the successful stent placement patients, there was no symptom recurrence until the date of this article was revised (July 2011). The follow-up period ranged from 12 days to 760 days (mean, 335.7 days; median, 297.5 days; standard deviation, 259.1 days). Perforation occurred in one patient two days after stent placement. The perforation rate for the bridge to surgery group was 7% (1 of 14), compared to 0% (0 of 19) for the palliative group. The patient with a perforation suffered from obstructive sigmoid carcinoma and a stent was placed as a bridge to surgery. An emergency colectomy was performed for this patient. The perforation site was at the proximal end of the stent. After nine months of follow up, the patient still performed well without any complication or sign of recurrence.

Migration occurred in one of 33 patients (3%) at 30 days after stent placement. The patient with stent migration was a 37-year-old female suffering from obstructive sigmoid carcinoma. The stent was placed for palliation and subsequently underwent chemotherapy and radiotherapy. The stent was expelled spontaneously one month after chemoradiation.

We did not encounter any tumor ingrowth or overgrowth in this study.

DISCUSSION

Recently, colorectal metallic stenting has been performed in lieu of a colostomy for patients that are good candidates for curative surgery to allow time for preoperative bowel

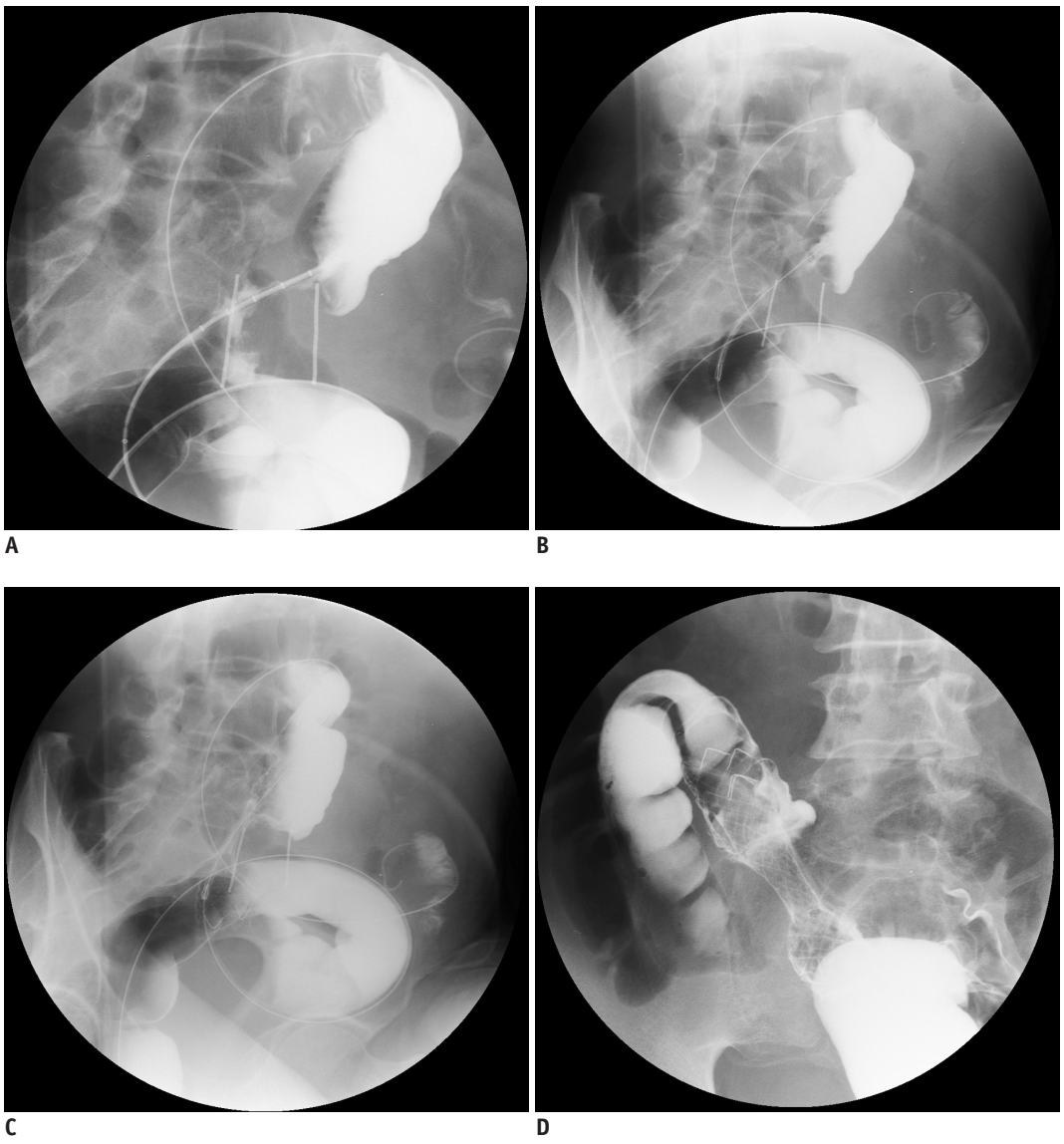

Fig. 2. Illustration of patient with sigmoid colon cancer (patient 11).
A. Water-soluble contrast study with sizing coil catheter during stent placement showing incomplete colonic obstruction. **B.** Plain radiograph obtained during placement of dual stent showing loaded distal stent. **C.** Plain radiograph obtained immediately after outer stent placement with loaded inner stent. **D.** Plain radiograph obtained immediately after stent placement of dual stent showing good flow of contrast medium through stent.

preparation (13, 20-22). Placement of an expandable metallic stent has also been used as a logical method for palliation in patients unsuitable for curative surgery, not only because it avoids a palliative colostomy but also because it reduces hospital stays (17, 23, 24). In previous studies (7-12), there was high success rate in treating colorectal obstructions using metallic stents. However, problems such as migration and perforation were still experienced.

In our study, our success rate in placing the stent was 97%. Among all the successful stent placements, one case of perforation and one case migration were experienced. The perforation rate in the bridge to surgery group was 7% (1 of 14), compared to 0% (0 of 19) for the palliative group. The migration rate was 3% (1 of 33).

The perforation rate was reported to be around 4% of patients who are implantated with colorectal self-expandable metallic stents (8-11), though higher perforation rates (16-83%) have also been reported (25-27). For dual-design expandable metallic stents, the perforation rate was reported to be 22% in the bridge to surgery group, and 5% in the palliative group (1). Kim et al. (19) tried to use a dual-design colorectal stent with bent ends but there was no significant difference noted.

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Given that a small-diameter stent has a lesser expansion force (28), the risk of perforation may theoretically be reduced. Our study was designed to test the hypothesis that a dual-design colorectal stent with smaller a diameter had a lower risk of causing colonic perforation. As expected, our results indicated that the perforation rate of the new stent measuring 20 mm in the middle and 28 mm at both ends was lower when compared with the larger diameter dual-design stent (24 mm in the middle and 32 mm at both ends). For this new 20-mm dual-design stent, the perforation rate for the bridge to surgery group was only 7%, which was much lower than the 22% previously reported using the larger diameter dual-design stent (1). Even more, the perforation rate for the palliative group attained 0% (0 of 19). The lower perforation rate decreased patient mortality and morbidity.

Migration is another problem for colorectal stenting. The reported migration rates range from 3-12% for the bare metallic stent (11, 13, 17) and 30-50% for the covered stent (14, 16). After employing the newly invented dual-design expandable metallic stent, a significant drop in migration rate was observed. The recent reported migration rate for the 24-mm diameter stent was 3% (1). In our study, even though we used a 20-mm diameter stent, which was expected to have less expansion force (28), we encountered only one case of migration among the 33 stent placements (3%). For this migration case, it was a case of 37-year-old suffering from obstructive sigmoid carcinoma. The stent was put in for palliative purposes. After placement of the stent, the patient underwent through chemotherapy and radiotherapy. We believed that the stent migration was due to the shrinkage of tumor caused by the chemoradiation.

Our study has several limitations. First, the study was not performed in a randomized manner. Second, the study included a small number of patients. Third, the follow-up duration for some of the patients was relatively short due to the death of terminal cases.

In conclusion, 20-mm diameter stent placement seems to be clinically safe and effective in patients with a colorectal obstruction, with low perforation and migration rates.

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