A dual-design expandable colorectal stent for malignant colorectal obstruction: results of a multicenter study

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submitted 4 July 2006
accepted after revision 10 November 2006

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DOI 10.1055/s-2007-966270
Endoscopy 2007; 39: 448–454 © Georg Thieme Verlag KG Stuttgart · New York
ISSN 0013-726X

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Background and study aims: It is known that metal stent placement is safe, easy, and effective for the treatment of malignant colorectal obstruction, but these stents are associated with delayed complications of tumor ingrowth and stent migration. The aim of this study was to prospectively investigate the technical feasibility, clinical effectiveness, and safety of a dual-design colorectal stent (consisting of an outer stent and an inner bare nitinol stent) in patients with malignant colorectal obstruction.

Patients and methods: Placement of the dual stent using a 4.5-mm stent delivery system was attempted in 151 patients with malignant colorectal obstruction, either before surgery (n = 50) or for palliation (n = 101). Multivariate logistic regression analysis was used to identify risk factors associated with complications.

Results: Stent placement was technically successful in 145/151 patients (96%). Of the patients who had a technically successful placement, bowel obstruction resolved within 2 days after stent placement in 48/50 (96%) of the patients in the bridge-to-surgery group and in 87/95 (92%) of the patients in the palliative group. Perforation occurred in 16 patients, incomplete stent expansion in eight patients, stent migration in four patients, tumor overgrowth in five patients, severe rectal pain in five patients, and bleeding in eight patients. Complete obstruction was the only significant risk factor for perforation (odds ratio 6.88, 95% CI 2.04 – 23.17, $P = 0.002$). In the palliative group, the median survival was 152.0 days and the mean survival was 263.8 days.

Conclusions: The dual stent with a 4.5-mm stent delivery system is easy to insert, safe, and reasonably effective for the palliative treatment of malignant colorectal obstruction. However, a great deal of care is needed in its deployment because of the high rate of perforation.

Introduction

It has been estimated that 7% – 29% of patients with colorectal cancer present with bowel obstruction requiring emergency surgery [1]. Curative surgery is not feasible in up to 30% of these patients due to extensive local tumor infiltration, distant metastasis, and severe co-morbidities [2]. The mortality and morbidity of emergency surgery is 15% – 20% and 45% – 50% respectively, compared with a mortality of 0.9% – 6% for elective surgery [3,4]. To take advantage of the improved outcome of elective surgery, a two-stage surgical procedure that includes a temporary colostomy has been used. However, colostomy is also associated with high morbidity and reversal of the stoma is not performed in up to 50% of cases [5].

In recent years, placement of bare or covered metal stents has been performed in lieu of a colostomy for patients suitable for curative surgery, to allow time for bowel preparation and correction of dehydration and electrolyte imbalances [6]. Furthermore, metal stent placement has been used as a palliative option in patients who are unsuitable for curative surgery because it avoids a palliative colostomy and reduces hospital stay [7 – 10]. However, metal stent placement has been plagued by delayed complications of tumor ingrowth and stent migration [11 – 14]. To overcome the problems associated with conventional bare and covered stents, a dual colorectal stent was designed to take advantage of the strengths of both stents. The purpose of this study was to assess the technical feasibility, clinical effectiveness, and safety of the dual colorectal stent in 151 patients with malignant colorectal obstruction.

Patients and methods

Patients

Between September 2001 and January 2006, patients with symptomatic malignant colorectal obstruction who were referred for fluoroscopic dual stent placement were enrolled in this prospective study. The study was conducted in nine university hospitals and one public general hospital. Inclusion criteria were as follows: (a) documented malignancy; (b) colorectal obstruction as defined by symptoms resulting in difficulty in defecation; and (c) expandable metallic stent placement. Exclusion criteria were: (a) nonsymptomatic patients with malignant colorectal obstruction; (b) clinical evidence of perforation or peritonitis combined with multiple small-bowel obstructions; (c) cecal or ascending-colon obstruction (due to the shortness of the length of the stent delivery system); and (d) extension of rectal cancer to the anal sphincter.

Data were collected regarding demographic information, the type of malignancy, the site and length of the obstruction, the indications for stent placement, the use of balloon dilation during and/or after stent placement, the use of a guiding sheath or endoscope for negotiation of a guide wire or stent delivery system through the obstruction, the number of stents required, symptom improvement after stent placement, procedure- or stent-related complications, the management of complications, the need for re-intervention, the full expansion time of the stent after placement, and survival.

Informed consent was obtained from all patients, and the study was approved by all institutional review boards.

The stent and stent-introducer set

The dual stent (S&G Biotech, Seongnam, Korea) consisted of an outer stent and an inner, bare nitinol stent (**Figure 1**). The outer stent consisted of three parts: a proximal bare nitinol stent (32 mm in diameter and 25 mm in length), a nylon mesh (24 mm in diameter), and a distal bare nitinol stent (32 mm in diameter and 25 mm in length). The inner bare nitinol stent was 24 mm in diameter; both ends of the stent were flared up to 38 mm. The total length of the inner stent was 2 cm shorter than that of the outer stent. The S&G Biotech stent introducer system consisted of a Teflon sheath, 4.5 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.

Stent placement technique

With the patient in the left-lateral decubitus position, a 0.035-inch guide wire (Radiofocus M; Terumo, Tokyo, Japan) was inserted under fluoroscopic guidance through the anus, across the obstruction, into the proximal part of the obstruction. A S&G Biotech sizing coil catheter was passed over the exchange guide wire, across the obstruction, to measure the length of the obstruction as previously described [15]. The guide wire was replaced with a super-stiff, 260-cm-long Amplatz guide wire (Medi-tech/Boston Scientific, Watertown, Massachusetts, USA), and the coil catheter was removed with the super-stiff guide wire left in place.

An outer stent that was approximately 50 mm longer than the obstruction was selected for placement so that the proximal and distal bare stent parts of the outer stent would extend sufficiently above and below the obstruction. Under fluoroscopic guidance, a stent delivery system containing the outer stent was passed over the super-stiff guide wire through the obstruction until the proximal stent passed through the obstruction. The pusher catheter was then held in place while the sheath was slowly withdrawn, deploying the stent across the stricture. The stent delivery system was removed with the super-stiff J-tip guide wire left in place. A stent delivery system containing the inner bare stent was then advanced over the guide wire to place the inner bare stent coaxially into the outer stent.

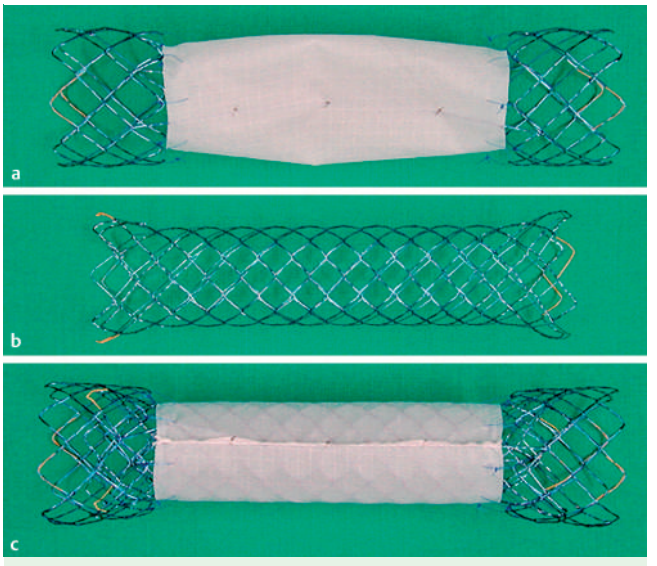

Figure 1 The dual-design expandable colorectal stent, showing the outer stent (**a**), the inner stent (**b**), and the assembled dual stent (**c**).

Where it was not possible to place the guide wire fluoroscopically, a combined attempt using endoscopy was made at the same session. In patients with a tight obstruction, in whom negotiation of the 4.5-mm introducing assembly through the stricture was difficult, dilation of the stricture was performed using an 8-mm or 10-mm balloon catheter, before or after the outer stent placement. When the fluoroscopic views obtained immediately after inner bare stent placement showed the placed stent expanded to less than a third of the preset expanded diameter of the stent, dilation of the placed stent was performed using a 15-mm or 20-mm balloon catheter.

Follow-up

Patients underwent a plain abdominal radiographic examination and a barium enema study 1 – 3 days after stent placement to assess the expansion and patency of the stent and possible complications. In patients with partial or no decompression of the colon due to incomplete stent expansion, an 18-mm PTFE-covered esophageal stent (Tae-woong, Ilsan, Korea) with greater expansile capability was placed into the dual stent. Patients being treated for palliation also underwent a barium study 1 month after stent placement to identify or 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 barium enema was performed in patients with recurrent symptoms.

Data interpretation

We considered a procedure to be a “fluoroscopic technical failure” when we were unable to advance a guide wire through the obstruction under fluoroscopic guidance and a “technical fail-

ure" when we were unable to negotiate a guide wire or the stent delivery systems through the obstruction under combined fluoroscopic and endoscopic guidance.

Overall fluoroscopic technical failure rates and technical failure rates were analyzed and compared according to the site and severity of the obstruction using the chi-squared test or Fisher's exact test. Complications were evaluated and compared in the preoperative and palliative groups using Fisher's exact test. To find the predictive factors for colon perforation after stent placement, a multivariate logistic regression analysis was performed and the following potential predictive factors were evaluated: age; sex; the site, severity, and length of the obstruction; the source of the malignancy; and balloon dilation before and after stent placement. The method of variable selection was performed in a forward "stepwise" fashion. Model fit was evaluated by means of the Hosmer–Lemeshow goodness-of-fit test.

In the palliative treatment group, the cumulative patient survival rate was calculated using the Kaplan–Meier method. A two-sided *P* value of less than 0.05 was considered to indicate statistical significance. All statistical analyses were performed using the SPSS package, version 11.5 (SPSS, Chicago, Illinois, USA).

Results

A total of 151 consecutive patients were included in this study (87 men, 64 women; mean age 62.8 years, range 17 – 89 years). Dual stent placement was attempted as a bridge to surgery in 50 patients and as palliative treatment in 101 patients. The underlying causes of the malignant obstruction were colorectal cancer (n = 115), gastric cancer (n = 25), cervix cancer (n = 3), pancreatic cancer (n = 2), ovarian cancer (n = 2), gallbladder cancer (n = 1), cholangiocarcinoma (n = 1), urinary bladder cancer (n = 1), and renal transitional-cell cancer (n = 1).

The obstruction sites were the rectum (n = 34), the rectosigmoid junction (n = 35), the sigmoid colon (n = 56), the descending colon (n = 10), and the transverse colon (n = 16). The obstructions were complete (with no passage of contrast medium during contrast medium studies before or during stent placement) in 59 patients and incomplete in the remaining 92 patients. The mean length of the stricture was 58 mm (range 25 – 200 mm). Three of the 101 patients in the palliative group also had profuse watery diarrhea, caused by a fistula between the rectum and the urinary bladder (n = 1), the rectum and the ileum (n = 1), or the transverse colon and the jejunum (n = 1).

Procedural results

Fluoroscopic negotiation of a guide wire was considered a technical failure in 13/151 patients (8.6%): in nine of the 59 patients with complete obstruction (15.2%) and in four of the 92 patients with partial obstruction (4.3%). In seven of the 13 patients with fluoroscopic technical failure, it was possible to negotiate the guide wire under combined endoscopic and fluoroscopic guidance, but this was not possible in the other six patients (five complete obstructions and one partial obstruction). The fluoroscopic technical failure rate was significantly higher in cases of complete obstruction than in partial obstruction ($P = 0.034$); similarly, the technical failure rate was also significantly higher in cases of complete obstruction in comparison with partial obstruction ($P = 0.034$). However, there was no statistically significant difference between the sites ($P = 0.106$ for the fluoroscopic technical failure rate; $P = 0.244$ for the technical failure rate).

A total of 147 stents were placed at the time of initial stent placement in the 145 patients with successful stent placement: 145 patients required only one stent to traverse the site of the obstruction; the other two patients required two stents because of the length of the obstruction. In 12/145 patients (8.2%), dilation of the nylon mesh of the outer stent using a balloon catheter was performed before insertion of the inner bare stent delivery system due to the tightness of the obstruction. No patients needed balloon dilation in the negotiation of the stent delivery system for the outer stent through the obstruction. In 39/145 patients (26.9%), including all 15 patients who had balloon dilation before stent placement, dilation of the dual stent using a 15-mm balloon catheter (n = 20) or a 20-mm balloon catheter (n = 19) was performed after insertion of the inner bare stent because the diameter of the placed stent was less than a third of the preset expanded diameter.

Functional results

In 48 of the 50 patients (96.0%) in the bridge-to-surgery group with technical success, complete expansion of the placed stent occurred and bowel obstruction was resolved within 2 days after stent placement. In the other two patients, partial or no decompression was achieved because of incomplete expansion of the stent. For these patients, an 18-mm PTFE-covered esophageal stent was placed into the dual stent 2 days after placement, with good results. The mean interval between stent placement and surgery was 7 days (range 1 – 30 days).

Of the 95 patients in the palliative group with technical success, 87 patients (91.6%) showed complete decompression, and the three patients with a fistula showed occlusion of the fistula (**Figure 2**), with improvement of defecation difficulty and watery diarrhea. Six of the remaining eight patients (6.3%) showed partial decompression (n = 5) or no decompression (n = 1) even after successful stent placement because of incomplete expansion of the stent. For these patients, an 18-mm PTFE-covered esophageal stent was placed into the dual stent. In the other two patients (2.1%), complete expansion of the placed stent occurred and large bowel decompression was achieved, but they still had obstructive symptoms because of extension of the tumor to the adjacent small bowel.

Complications

Perforation. Colon perforation occurred in 11/50 patients (22%) in the bridge-to-surgery group and in 5/95 patients (5%) in the palliative group 1 – 30 days (mean 6.5 days) after stent placement (**Table 1**). Fifteen of the 16 patients with colon perforation were successfully treated by surgery and antibiotics, but one died of sepsis 26 days after surgery. The perforation rate in the bridge-to-surgery group was significantly higher than that in the palliative group ($P = 0.004$). Perforation was detected before surgery in 10 patients (five in the bridge-to-surgery group and five in the palliative group) and during surgery in six patients (all in the bridge-to-surgery group). The perforation site was either in the tumor bed (n = 8) or in the normal colon proximal to the tumor bed (n = 8) (**Figure 3**). The cause of perforation of the normal colon proximal to the tumor bed was pressure necrosis from the proximal ends of bare stents. The median survival period in the 16 patients with colon perforation was 173 days (range 31 – 913 days).

In our multivariate logistic analysis with forward stepwise selection, complete obstruction was the only significant independent factor for perforation (odds ratio 6.88, 95% CI 2.04 – 23.17,

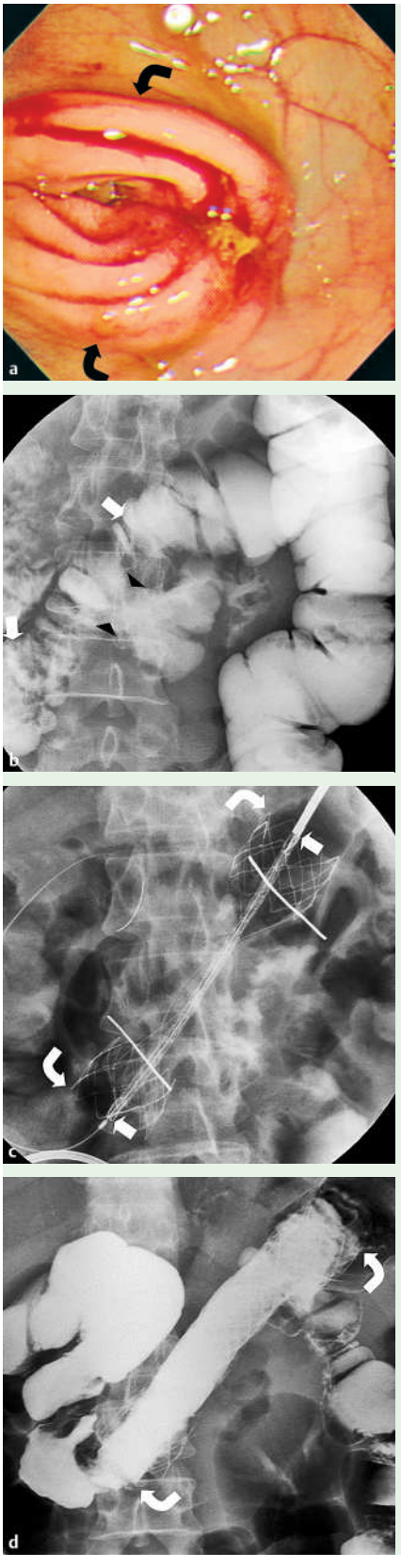

Figure 2 A patient with recurrent gastric cancer extending to the transverse colon, creating a fistula. **a** Endoscopic view showing the fistula (arrows). **b** A colon contrast study 2 days before stent placement showed a mild stricture at the level of the transverse colon (arrows) and a fistula between the transverse colon and the small bowel (arrowheads). **c** The stent delivery system containing the inner bare stent (straight arrows) is positioned within the outer covered stent (curved arrows). **d** A colon contrast study 1 day after stent placement showed a good flow of contrast medium through the dual stent (arrows), with occlusion of the fistula.

$P = 0.002$). Age, sex, site and length of the obstruction, the source of the malignancy, and balloon dilation before and after stent placement were not related to the likelihood of perforation. The Hosmer–Lemeshow goodness-of-fit test showed a nonsignificant P value (0.814) for the model, which indicated good fitness of the model.

Stent migration. Stent migration occurred in none of the bridge-to-surgery group and in four patients in the palliative group 32–636 days (mean 273 days) after stent placement. These patients underwent chemotherapy (n = 3) or chemoradiation therapy (n = 1) after stent placement. The sites of obstruction were the rectosigmoid colon (n = 2), the rectum (n = 1), and the sigmoid colon (n = 1). After migration of the stent, two patients needed a second stent placement, 64 days and 103 days after stent migration because of recurrent obstruction. The remaining two patients did not need further intervention for 68 days and 235 days until their death, because of improvement of the obstruction.

Bleeding. Bleeding occurred after stent placement in two patients in the bridge-to-surgery group and in six patients in the palliative group. In all cases this resolved spontaneously.

Pain. Five of the 34 patients who had had a stent placed in the rectum (but none of the 111 patients with stents placed in other parts of the colon) complained of severe rectal pain 2–22 hours after stent placement that required analgesics.

Tumor overgrowth. Tumor overgrowth occurred in none of the bridge-to-surgery group patients and in five patients in the palliative group, 61–393 days after stent placement (mean 195 days). These patients were treated by means of coaxial placement of a second stent into the first stent with overlap at the ends.

Follow-up

Nine of the 50 patients in the bridge-to-surgery group died 40–378 days (mean 171.2 days) after stent placement because of colon perforation (n = 1), myocardial infarction (n = 3), or recurrence of cancer (n = 5). The other patients were still alive 15–1608 days (mean 434.2 days) after stent placement.

In the palliative group, 62/95 patients died 5–706 days (mean 109.3 days) after stent placement due to progression of their disease, myocardial infarction, bleeding, or sepsis. The remaining 33 patients were still alive 21–683 days (mean 210.5 days) after stent placement. The median survival period was 152.0 days (95% CI 107.8 days to 196.2 days) and the mean survival period was 263.8 days (95% CI 96.4 days to 331.3 days) (**Figure 4**). The 30-day, 60-day, 90-day, and 180-day survival rates were 87%, 78%, 62%, and 42%, respectively.

Discussion

It is well known that placement of bare or covered expandable metal stents is safe and effective for the palliative treatment of malignant gastroduodenal obstruction [16] or colorectal obstruction [6,12]. However, recurrent obstruction rates of 3%–46% due to tumor ingrowth have been reported with the placement of bare stents [6,11,13]. Reported recurrent obstruction rates due to tumor ingrowth have been reduced to 0%–7% with the use of covered expandable metal stents [12,16]. However, although covered stents have proved effective for the occlusion of fistulas or ruptures in the gastrointestinal tract [12,17], their use has been plagued by stent migration problems. While the migra-

Table 1 Demographic, clinical, and follow-up data of the 16 patients who developed colon perforation after dual stent placement

Patient	Sex	Age, years	Indication	Site of obstruction	Balloon dilation (diameter of balloon used)	Site of perforation	Treatment of perforation (day*)	Outcome (days of follow-up)
1	M	76	B to S	Sigmoid	Yes (15 mm)	Tumor bed	Emergency surgery (1)	Dead (223)
2	M	85	B to S	Sigmoid	Yes (20 mm)	Tumor bed	Emergency surgery (3)	Alive (459)
3	M	59	B to S	Sigmoid	Yes (15 mm)	Proximal	Elective surgery (30)	Alive (147)
4	M	40	B to S	Sigmoid	No	Proximal	Emergency surgery (1)	Alive (682)
5	M	29	Palliation	Transverse	No	Tumor bed	Emergency surgery (1)	Dead (43)
6	M	84	Palliation	Rectosigmoid	No	Proximal	Emergency surgery (1)	Dead (31)
7	M	77	B to S	Rectosigmoid	No	Tumor bed	Emergency surgery (3)	Alive (77)
8	M	65	B to S	Sigmoid	No	Proximal	Elective surgery (3)	Alive (56)
9	M	69	Palliation	Sigmoid	No	Tumor bed	Emergency surgery (1)	Alive (439)
10	M	64	B to S	Sigmoid	No	Tumor bed	Elective surgery (5)	Alive (913)
11	M	66	B to S	Rectosigmoid	No	Tumor bed	Elective surgery (29)	Dead (211)
12	M	42	Palliation	Rectosigmoid	No	Tumor bed	Emergency surgery (1)	Dead (74)
13	F	85	B to S	Sigmoid	No	Tumor bed	Elective surgery (14)	Dead (40)
14	F	66	B to S	Rectosigmoid	Yes (20 mm)	Proximal	Elective surgery (7)	Alive (199)
15	M	49	B to S	Rectosigmoid	Yes (20 mm)	Proximal	Emergency surgery(1)	Alive (379)
16	F	42	Palliation	Transverse	No	Tumor bed	Emergency surgery (3)	Alive (94)

B to S, bridge to surgery; Proximal, proximal to the tumor bed.
* The number of days after stent placement when the operation took place.

tion rates associated with bare stent placement have ranged from 3% to 12% [6,10,14], the overall migration rates of covered stents have been reported to be as high as 30%–50% [12,16,18]. In our study, the dual stent occluded a fistula in three patients, and there was no tumor ingrowth in any of the study patients. The 2.7% migration rate of the dual stent placed in our study was much lower than that of covered stents and slightly lower than that of bare stents placed in previous studies. The low migration rate of the dual stent in our series is to be expected, not only because of the incorporation of the bare parts of the stent into the colorectal wall, but also because of the fixation of the stent above and below the obstruction by means of the large (34 mm) proximal and distal bare rims of the outer stent, as well as the flared ends (38 mm) of the inner bare stent.

Sebastian et al. [14] reported a perforation rate of 3.7% (45/1198 patients): the perforation was related to the stent wiring or balloon dilation in 33 patients and to the guide wire in the remaining 12 patients. In our study, the perforation rate was 11% (16/145). The perforation occurred in 11/50 patients in the bridge-to-surgery group (22%) and in 5/95 patients in the palliative group (5%). The perforation rate in the bridge-to-surgery group was significantly higher than that in the palliative group ($P = 0.004$). The perforation was detected before surgery in 10 patients (five in the bridge-to-surgery group and five in the palliative group) and during surgery in six patients (all in the bridge-to-surgery group). Because patients with microperforations can be asymptomatic [6,8,9], we surmise that there might have been patients who had an asymptomatic colon perforation in the palliative group in our series. The higher perforation rate in our study compared with the rates reported by previous studies can be attributed to the use of stents of larger diameter, particularly the 38-mm flared ends of the inner bare stent. The higher perforation rate can also be attributed to a high rate of complete bowel obstruction in our series.

Reports of an association between colonic perforation and balloon dilation performed prior to stent placement [6,13,14] have led some authors to believe that balloon dilation prior to colorectal stent placement is a contraindication to stent placement [13,14]. In patients with a tight stricture, especially in the tortuous sigmoid colon, however, it was very difficult to advance the 4.5-mm inner bare stent delivery system through the outer stent because the nylon mesh of the outer stent tended to collapse in the tight stricture. We therefore found it helpful (and at times mandatory) to dilate the tight stricture or collapsed nylon mesh with the use of an 8-mm or 10-mm balloon catheter. When the fluoroscopic views obtained immediately after stent placement

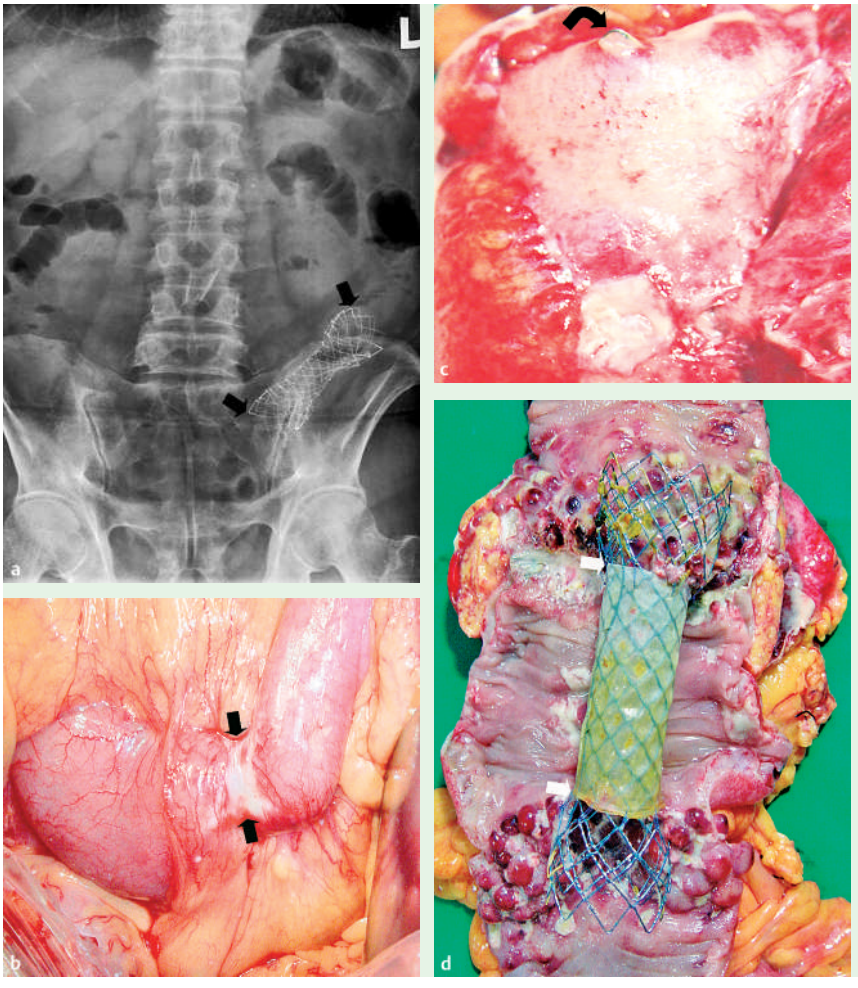

Figure 3 A patient with a colon perforation that developed after stent placement. **a** A plain radiograph taken 2 days after stent placement showed the stent in the left lower abdomen (arrows). **b** At operation, the colon was found to be perforated (arrows) in a section of normal colon proximal to the tumor bed. **c** The gross speciman showed that the cause of the perforation was pressure necrosis from the proximal ends of the bare stents (arrow). **d** A longitudinal section of the specimen showing the nylon mesh of the outer stent (arrows).

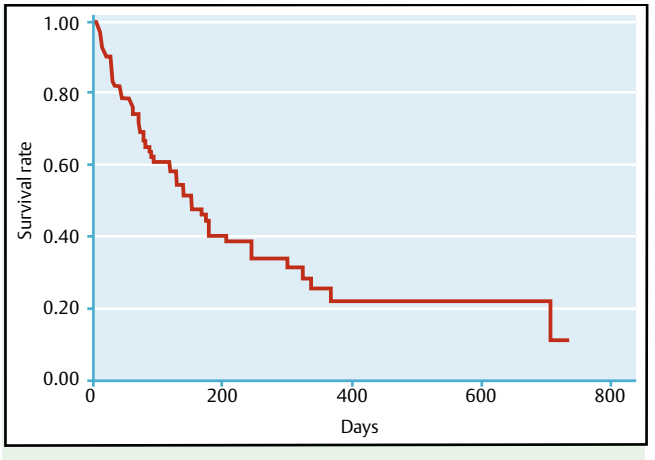

Figure 4 Graph showing the overall cumulative survival in the palliative group after stent placement.

showed that the placed stent had expanded less than a third of the preset expanded stent diameter, we dilated the placed stent using a 15-mm or 20-mm balloon catheter to enable passage of stool through the stent. It also helped patients in the passage of their stool, especially when the hard stool occluded the incompletely expanded stent. In our multivariate logistic analysis, balloon dilation before or after stent placement was not a significant factor with regard to perforation.

As for the dual stent, there were two problems that need to be addressed. First, the diameter of the flared ends of the inner bare stent should be reduced because these can cause perforation. We are testing new stent designs with 34-mm flared ends on the inner bare stent. Secondly, the stent placement technique is slightly more complicated than that of bare stent placement because of the need to introduce the stent delivery system twice. Nevertheless, the dual stent has two distinct advantages over the conventional stents in the treatment of obstructing colorectal strictures: there is no tumor ingrowth and the stent migration rate is lower than that of conventional covered stents.

In conclusion, the dual stent with its 4.5-mm stent delivery system is easy to insert, safe, and reasonably effective for the treatment of malignant colorectal obstruction. However, the diameter of the flared ends of the bare stents should be reduced because they can cause perforation.

Competing interests: None

Institutions

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