The Feasibility of 18-mm-Diameter Colonic Stents for Obstructive Colorectal Cancers

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Keywords

Colonic neoplasms · Self-expanding metal stents · Stent diameter · Bridge to surgery · Perforation

Abstract

Objectives: This study aimed to evaluate the characteristics and the feasibility of 18-mm-diameter stents for obstructive colorectal cancer, comparing the clinical courses with 22-mm-diameter stents. **Methods:** We retrospectively compared 33 consecutive cases treated with 18-mm-diameter stents (bridge to surgery [BTS] in 25, palliative therapy [PAL] in 8) with 27 consecutive cases treated with 22-mm-diameter stents (BTS in 21, PAL in 6) for obstructive colorectal cancer between May 2013 and November 2015 in our institution. **Results:** There were no significant differences between the 18-mm and 22-mm groups in technical success rates (97 and 96%, respectively) and clinical success rates (100 and 100%, respectively). As a BTS, the rates of complications and stoma formation were not significantly different between groups. For PAL, although the rates of complications and stent patency were similar, stent occlusion occurred in 1 pa-

tient (12.5%) in the 18-mm group. **Conclusions:** The 18-mm-diameter stents were similarly effective when compared with 22-mm-diameter stents. Because 18-mm-diameter stents are easy to handle and produce less mechanical stress, they have the potential to decrease the perforation rate and mitigate the stent's impact on the tumors. 18-mm-diameter stents can be useful and safe, especially as a BTS.

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Introduction

Colorectal cancer is one of the most common cancers, and 8–29% of patients with colorectal cancer have obstruction-related symptoms [1, 2]. Because obstructive colorectal cancer can be fatal, emergent management is needed. It was reported that the morbidity and mortality rates associated with emergent surgery were high [1, 3, 4]. In the last few decades, there have been many reports about the usefulness of self-expanding metal stents (SEMS) for obstructive colorectal cancer. SEMS are used as a bridge to surgery (BTS) and for palliative therapy

(PAL). A systematic review revealed SEMS placement as a BTS has a lower stoma formation rate and complication rate than emergent surgery [5]. A meta-analysis showed that SEMS placement for PAL is associated with a shorter time to chemotherapy and lower 30-day mortality [6].

Recently, concerns have been raised regarding the possibility for exacerbation of the oncological prognosis. A few randomized controlled trials and a cohort study have shown a significantly higher local disease recurrence rate with SEMS use than emergent surgery [7–10]. According to the European Society of Gastrointestinal Endoscopy (ESGE) guidelines, SEMS placement as a BTS is not recommended as a standard treatment for potentially curable patients with obstructive colorectal cancer [11]. However, one meta-analysis suggests that SEMS as a BTS have no adverse effects in terms of patients' oncological outcomes [12]. The cancer recurrence rate has been shown to be higher in the subgroup of patients with stent-related perforations [9]; thus, it is suggested that a lower perforation rate may improve the prognosis. Small-diameter stents mitigate the mechanical impact of the stents on the tumor and the colonic wall, and can reduce the perforation rate.

To date, few reports examine stent diameter, and the optimal stent diameter has not been determined. In our hospital, we have inserted the Niti-S enteral colonic uncovered stent D-type (Taewoong Medical Inc., Gimpo, Korea) in cases with obstructive colorectal cancer since May 2013. We used 22-mm-diameter stents until May 2014 but now use 18-mm-diameter stents. Then, our study aimed to evaluate the characteristics and the feasibility of 18-mm-diameter stents, comparing them with 22-mm-diameter stents.

Methods

Patients

We retrospectively reviewed the endoscopy database and clinical records on all patients who underwent Niti-S enteral colonic uncovered stent placement for obstructive colorectal cancer at the Japanese Red Cross Society Wakayama Medical Center between May 2013 and November 2015. Bowel obstructions were diagnosed through clinical symptoms, CT, and endoscopy.

We analyzed consecutive cases utilizing 18-mm-diameter Niti-S stents from June 2014 to November 2015 and compared them with consecutive cases utilizing 22-mm-diameter stents from May 2013 to May 2014.

Patients who had been followed up at our institution for at least 4 weeks were eligible to be enrolled in this study. Relevant data were retrieved from the medical records of our institution. This study was approved by the Institutional Review Board of our institution. We excluded patients who underwent chemotherapy with the stents inserted, considering the possibility that chemotherapy affects stent patency rate. We followed patients' clinical courses until December 2015.

Table 1. Patient characteristics

	18 mm (33 cases)	22 mm (27 cases)	<i>p</i>
Median age (range), years	77 (49–91)	78 (31–97)	0.22
Sex (male/female)	17/16	13/14	0.98
Performance status (0–1/2–4)	27/6	24/3	0.45
Stage (II/IIIA/IIIB/IV)	11/8/3/11	7/7/5/8	0.75
Tumor location (right/left)	12/21	11/16	0.73
Median length of stenosis $\pm$ SD, cm	2.8 $\pm$ 1.2	3.3 $\pm$ 1.4	0.07
Complete/incomplete obstruction	32/1	25/2	0.58
Length of stent (6 cm/8 cm)	31/1	25/2	0.59
Purpose (BTS/PAL)	25/8	21/6	0.85

BTS, bridge to surgery; PAL, palliative therapy.

Endoscopic Procedure

Before colonic stent placement, all patients underwent abdominal CT scans to evaluate the clinical stage of the tumor and to assess the location and length of the obstruction. Generally, patients underwent enemas for preparation and were maintained under conscious sedation with 0.05 mg/kg intravenous midazolam. Patients were continuously monitored during the procedure with an automated noninvasive blood pressure device, electrocardiogram tracing, and pulse oximetry.

We used Niti-S enteral colonic uncovered D-type stents (Taewoong Medical Inc., Gimpo, South Korea), 18 or 22 mm in diameter and 60 or 80 mm in length.

All procedures were performed under endoscopic and fluoroscopic guidance. We used conventional endoscopes (CF-H260, CF-HQ290, Olympus Medical Systems, Tokyo, Japan) in cases utilizing 22-mm-diameter stents. We also used slim-diameter endoscopes (PCF-Q260AI or GIF-Q260J, Olympus) in cases utilizing 18-mm-diameter stents. We used a guidewire (0.025-inch Visi-Glide, Olympus, or 0.035-inch Jagwire, Boston Scientific Corporation, Natick, MA, USA) and an ERCP catheter (ERCP catheter filiform, MTW Endoscopie W. Haag KG, Wesel, Germany, or Swing Tip Cannula, Olympus) to pass the stricture and select the oral intestinal tract. Thereafter, contrast medium was injected to confirm the position and the length of the stricture. We did not attempt dilation of strictures due to risk of perforation. Stent length was selected to cover the entire stricture adequately.

Abdominal radiographs were obtained 1 day after stent placement to evaluate the degree of stent expansion. To prevent stool impaction, a low residual diet with laxatives, such as magnesium formulations, was recommended.

Study Design

Patients were divided into two groups according to stent diameters. We retrospectively compared the two groups for patient characteristics, technical success rate, clinical success rate, procedure time, and the time until resumption of diet.

Patients receiving stents as a BTS were followed perioperatively and assessed for complications related to stents, the time interval to operation, laparoscopic resection rate, stoma formation rate, and perioperative complications.

Table 2. Results of the procedures

	18 mm (33 cases)	22 mm (27 cases)	<i>p</i>
Median procedure time (range), min	20 (8–65)	25 (11–60)	0.08
Technical success rate, %	97 (32/33)	96 (26/27)	0.86
Clinical success rate, %	100 (32/32)	100 (26/26)	1.00
Mean CROSS before procedure $\pm$ SD	1.2 $\pm$ 1.2	1.3 $\pm$ 1.4	0.70
Mean CROSS after procedure $\pm$ SD	4.0 $\pm$ 0.1	4.0 $\pm$ 0.2	0.44
Mean period of restarting meal $\pm$ SD	1.4 $\pm$ 0.6	2.1 $\pm$ 1.8	0.19
CROSS, ColoRectal Obstruction Scoring System.			

Patients with stents inserted for PAL were followed until their last clinical follow-up, telephone interview, death, or the study endpoint and assessed for complications related to stents, the period of stent patency, and the patency rate during the follow-up period. Stent patency was determined as patients without stent occlusion and still alive.

Statistical Analysis

Student *t* test was used for continuous data comparison. Fisher exact probability test and χ^2 test were used for comparison of categorical data. A *p* value of <0.05 was considered to be significant. All statistical analyses were performed using JMP 12.2 (SAS Institute Inc., Cary, NC, USA).

Definitions

We defined the patients receiving stents prior to elective surgery as the BTS group and the patients receiving stents for relief of symptoms as the PAL group.

Technical success was defined as successful stent placement in an appropriate site without complications. Clinical success was defined as effective decompression of the colon with resolution of obstructive symptoms within 72 h of stent placement [5]. The clinical success rate was calculated as the percentage of clinically successful cases relative to the technically successful cases. In cases where the patients underwent multiple stenting procedures, analysis was applied to the initial procedure.

The degree of obstruction was divided into two groups, complete and incomplete. Incomplete obstruction was defined as a narrow stool caliber or the ability to pass only small amounts of liquid stool or gas, and complete obstruction was defined as a lack of an endoscopically visible lumen or the inability to pass stool or gas [13, 14].

Performance status was recorded to determine the clinical condition according to the Eastern Cooperative Oncology Group performance status.

To evaluate the level of oral intake, we used the ColoRectal Obstruction Scoring System (CROSS), which assigns a point score based on the patient's oral intake level: CROSS 0, requiring continuous decompression; CROSS 1, no oral intake; CROSS 2, liquid or enteral nutrient intake; CROSS 3, soft solids, low residue, and full diet with symptoms of stricture; and CROSS 4, soft solids, low residue, and full diet without symptoms of stricture [15, 16].

Results

Patient Characteristics

Insertion of 18-mm-diameter stents was attempted in 33 cases (BTS in 25, PAL in 8), and insertion of 22-mm-diameter stents in 27 cases (BTS in 21, PAL in 6). Baseline patient characteristics are summarized in Table 1. Demographic features of both groups were not significantly different.

Clinical Outcomes and Complications of SEMS Placement

Median procedure time was not significantly different between groups. Technical success rates of the 18- and 22-mm groups were 97% (32/33) and 96% (26/27), respectively. We were unable to pass the guidewire in a patient with ileocecal cancer in the 18-mm group, requiring urgent surgery. Additionally, a perforation related to stent insertion occurred in 1 patient with sigmoid colon cancer in the 22-mm group, and emergent surgery was performed. The perforation occurred at the anal side of the tumor and was caused by the delivery system. The clinical success rates were 100% (32/32) and 100% (26/26), respectively. Procedure time and the time to resumption of an oral diet are shown in Table 2.

The results of patients who underwent stent placement as a BTS are shown in Table 3. Abscess formation around the tumor occurred in 2 cases (one in the 18-mm group and the other in the 22-mm group). Both cases were treated with antibiotics and elective surgery was performed. The median time to surgery was significantly longer in the 18-mm group. The laparoscopic resection rate was high in both groups, and all indications for open surgery were related to tumor infiltration into the surrounding organs. There were no cases of inadequate colonic decompression. Perioperative complications occurred in

Table 3. Complications and clinical courses of the bridge-to-surgery cases

	18 mm (25 cases)	22 mm (21 cases)	<i>p</i>
Complication	1/25	2/21	
Perforation	0	1	
Migration	0	0	
Bleeding	0	0	
Occlusion	0	0	
Abscess	1	1	
Median time interval to operation (range), days	26 (18–41)	22 (10–30)	0.003 ^a
Laparoscopic resection rate, %	84 (21/25)	81 (17/21)	0.79
Stoma formation rate, %	0 (0/25)	4.8 (1/21)	0.46

^a Statistically significant.

only 1 case. In this case, minor leakage occurred and was treated conservatively.

The results of the patients who underwent stent placement for PAL are shown in Table 4. Stent occlusion occurred in 1 patient in the 18-mm group at 73 days postoperatively due to tumor ingrowth and was treated with re-insertion of an additional 18-mm-diameter stent. Bleeding occurred in 1 case in the 22-mm group at 132 days postoperatively and was treated with surgical resection. Among patients in the 18-mm group, 87.5% maintained stent patency until death or the end of follow-up.

Discussion

This is a single-center retrospective study comprising 60 patients with obstructive colorectal cancer who underwent SEMS placement as a BTS or for PAL. The technical and clinical success rates in our hospital were in line with a previous systematic review with medians of 96.2% (66–100%) and 92% (42–100%), respectively [5]. As the result of this study, 18-mm-diameter stents were feasible, compared with 22-mm-diameter stents.

Characteristics of 18-mm-Diameter Stents

Advantages of the 18-mm-diameter stents include the decrease in mechanical stress and high versatility. Small-diameter stents exert less stress against the tumor and colonic wall. The small outer diameter of the 18-mm stent delivery system (9 Fr) allows easy insertion through the working channel (>3.0 mm) of the endoscope and allows for use of various endoscopes (PCF-Q260AI or GIF-

Table 4. Complications and clinical courses of the palliative-therapy cases

	18 mm (8 cases)	22 mm (6 cases)	<i>p</i>
Complication	1/8	1/6	
Perforation	0	0	
Migration	0	0	
Bleeding	0	1	
Occlusion	1	0	
Median period of stent patency (range), days	107.5 (26–194)	182 (13–481)	0.27
Stent patency rate, %	87.5 (7/8)	100 (6/6)	0.37

Q260J, Olympus). In contrast, when inserting 22-mm stents, we have to use conventional endoscopes (CF-H260 or CF-HQ290, Olympus) because the outer diameter of the delivery system is 10 Fr.

Disadvantages of the 18-mm-diameter stent include the risks of occlusion, migration, and inadequate decompression.

To Decrease Perforation Rate

Stent-related perforation may result from 4 causes: (1) guidewire or catheter malpositioning, (2) dilation of the stricture before or after stent placement, (3) stent-induced perforation (tumor and non-tumor local perforation), and (4) proximal colonic distension because of inadequate colonic decompression or excessive air insufflation [17]. A meta-analysis revealed that the overall perforation rate with SEMS is 7.4% [18], but the prevalence of stent-related complications is likely to be underestimated because of subclinical perforations [9].

When using 18-mm-diameter stents, we can use slim scopes, which are flexible and easy to handle. It then becomes easier to maintain a good view of the tumor, especially in the bent positions such as in the sigmoid colon. It is also easier to determine the oral side and pass the guidewire and the catheter safely and precisely. Although there was no significant difference in procedure times, the procedure time of the 18-mm group was shorter than that of the 22-mm group. The reason is possibly that the procedures become easier with a greater choice of scopes.

Next, the strong stent radial force, which is the radially directed expanding force that maintains the luminal patency at the stricture once the stent is deployed, can cause perforation, and the large-diameter stent is associated with late perforations [19]. One meta-analysis reported that procedure-induced perforations accounted

for 19.4% of early perforations and that the remaining early perforation could be caused by failure of the colonic wall to adapt to the expanding forces of the stent [18]. In other words, perforation occurs due to the stent itself; thus, small stents may be advantageous as they create less disruption of the preexisting structure.

Finally, although there was concern regarding the potential for inadequate colonic decompression in the 18-mm group, 18-mm stents improved the CROSS score to the same degree as 22-mm stents in this study.

Therefore, 18-mm stents have the potential to decrease the perforation rate.

BTS

Although smaller-diameter stents may theoretically increase the migration and occlusion rates, there were no complications noted in the 18-mm group. Lee et al. [20] used the 18-mm-diameter Niti-S uncovered stent in 20 cases as a BTS. They reported no occlusions; migration occurred in 3 cases (15%) before surgery, although elective surgery was performed without additional treatment in all cases [20]. The reason why migration did not occur in our study may be that almost all our cases were complete obstructions. We recognize that it is undesirable to insert stents for incomplete obstruction prophylactically.

As 18-mm stents obtained enough decompression, laparoscopic resections were performed safely, and no cases required stoma formation because of inadequate decompression in either group. In our institution, the interval from SEMS insertion to surgery is longer than in a previous report [21]. The anastomotic leakage rate is higher when the interval is 1–9 days than 10 days or longer [22], although longer intervals may increase the stent-related complication rate. A certain period may allow for better recovery and optimal nutrition [15], and this optimal interval should be established in future studies. Though the interval of the 18-mm group was significantly longer, it is because the waiting time of the surgery has become longer in our hospital nowadays.

We conclude that 18-mm stents as a BTS can decrease the perforation rate without exacerbation of the oncological disease process, because they provide easy handling and lower mechanical stress. Therefore, the 18-mm-diameter stent is feasible and can be useful as a BTS. Larger and longer examinations are needed in the future to evaluate the impact on prognosis.

PAL

There were no complications, except for 1 case of occlusion in the 18-mm group. According to a previous report,

complications of SEMS placement for PAL happen more often in small-diameter stents [23]. In contrast, a prospective study showed complications and long-term patency were not significantly different in varying stent diameters [24]. Our median patency periods are in line with those of previous reports (90–204 days) [23, 24]. Although there were no significant differences in the patency periods between the 18-mm- and 22-mm-diameter groups in our study, the number of cases is small and follow-up period is short. Then, larger and longer studies are necessary.

Optimal Diameter of SEMS

Our obstruction and migration rate of the 18-mm group were totally 4.8 and 0%, which is in line with a previous report [25]. In addition, 18-mm stents could get adequate decompression. Actually, no perforations occurred with the Niti-S uncovered 18-mm-diameter stents in our study (33 cases) and Lee et al.'s study (39 cases) [20]. Therefore, we see that 18-mm-diameter stents can be optimal, especially as a BTS.

Limitation

Our study has several limitations. First, these study outcomes were examined in a single institution retrospectively, and the number of subjects was small. Second, it is necessary to consider the possibility that there is improvement of the operator's technique because the periods of the 18-mm group and 22-mm group are different. A prospective large study is expected to exclude these biases. More than anything, it is necessary to examine the long-term oncological prognosis in 18-mm-diameter stent cases.

Conclusion

As a BTS, 18-mm-diameter stents are feasible because the effectiveness is not inferior to that of 22-mm-diameter stents in clinical practice. Furthermore, 18-mm-diameter stents may be safer to place, because they are easy to handle and their mechanical stress is small. Moreover, they have the potential to decrease perforation rates and improve long-term prognoses.

For PAL, there was no significant difference in the stent patency period between the stent types. Therefore, 18-mm-diameter stents are feasible. However, the number of cases is small, and follow-up periods were very short. Further study is necessary to confirm the feasibility of 18-mm-diameter stents.

Acknowledgement

Ishii et al. [26] have already previously reported the data regarding BTS cases in this article in Japanese. Some data are based on Ishii et al.'s data. We added additional cases and investigated further. In addition, because this article was to be written in English, we authored the manuscript.

Disclosure Statement

The authors have no conflicts of interest to declare.

Author Contributions

S.O., T.I., K.M., and Y.Y. designed the study. S.O. wrote the initial draft of the manuscript. T.I. and K.M. contributed to analysis and interpretation of data, and assisted in the preparation of the manuscript. Y.N., K.H., T.A., T.S., S.U., Y.U., Y.Y., and M.K. contributed to data collection and interpretation, and critically reviewed the manuscript. The final version of the manuscript was approved by all authors.

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