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ORIGINAL ARTICLE

Utility and safety of the self-expandable metallic colonic stent in Japanese patients who received systemic chemotherapy or palliative treatment for obstructive primary advanced colorectal cancer: A retrospective single-center medical chart evaluation

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Abstract

Background and Aim: The present study aimed to compare the utility and safety of the colonic self-expandable metallic stent between patients with obstructive primary colorectal cancer who underwent chemotherapy or palliative treatment care and patients bridging for surgery.
Methods: The cases of 71 patients with colonic obstructive stenosis and in-dwelling stents who were hospitalized between May 2012 and April 2020 at Karatsu Red Cross Hospital were retrospectively analyzed. The patients were classified into three groups: bridging for curative surgery (group I), receiving systemic chemotherapy (group II-A), and receiving only palliative treatment (group II-B). Technical and clinical success rates and complication rates after stenting were evaluated.
Results: No significant differences were observed in the technical (procedure) success rates (group I: 100%; group II, 97.6% [II-A: 100%; II-B: 95.8%]). The total clinical success rate was 85.9% (61/71) and did not vary significantly among the groups (group I: 82.8%; group II 88.0% [II-A: 83.3%; II-B: 91.6%]). No significant differences were observed in the early complication rates between groups I and II and in the late complication rates between groups II-A and II-B. Nutrition status, general condition, tumor staging, and 1-year survival were poorer in group II than in group I.
Conclusion: The findings show that colonic stenting for malignant obstruction was performed successfully and safely both in patients who received systemic chemotherapy or palliative therapy and in patients bridging for curative surgery, regardless of risk status for malnutrition, poor general condition, cancer stage progression, and short survival.

Introduction

Advanced colorectal cancer is one of the most common cancers leading to death worldwide, and several therapeutic approaches are implemented for medical treatments.[1–3] Obstructive stenosis of the ileus or sub-ileus is a serious complication of advanced colorectal cancer.[2,3] Colonic stenting is globally the preferred method of releasing the obstruction.[4] The method has been widely applied in Japan since 2012 for relieving obstruction caused by colorectal cancer after health insurance approval.[2,3] Decompression by colonic stenting for stenosis in advanced colorectal cancer has been used during bridging before curative surgery and systemic chemotherapy.[3,5–11] The technical- and patient-related risk factors for colonic stenting have been identified in several Japanese studies in the last 3 years.[12–17] Regarding surgical outcomes, the advantages and disadvantages of colonic stenting for bridging for surgery were compared with those for emergency surgery and the trans-anal decompression tube in Japanese studies and were found to be controversial.[18–22] Several studies that focused on the clinical safety

and effectiveness of the self-expandable colonic stent have been conducted in the last 3 years in Japan, most of which were limited to advanced colon cancer patients who were bridged before surgical curative therapy.[1–3,5–11] The present study aimed to compare the utility (technical and clinical success rates) and the safety (rate of early and late complications after stent placement) of the colonic stent between patients who received systemic chemotherapy or palliative treatment and the best supportive care and patients who were bridged for surgery.

Methods

Patient characteristics. The retrospective medical chart review included 73 patients who received treatment using the self-expandable metallic colonic stent (SEMS) for colonic obstructive stenosis caused by malignant tumors at Karatsu Red Cross Hospital (Karatsu City, Saga Prefecture, Japan) between May 2012 and April 2020. Two cases of colonic stenosis due to metastatic cancer were excluded, and a final total of 71 patients with in-dwelling stents for colonic stenosis caused by primary colorectal cancer were analyzed. The patients were divided into two groups: stented patients undergoing bridging for surgery (group I), and stented patients undergoing chemotherapy and palliative treatment (group II). Group II was further divided into two subgroups: patients receiving chemotherapy (group II-A), and patients receiving palliative treatment with the best supportive care (group II-B). Patient characteristics, including age, gender, body mass index (BMI), blood examination, site of stenosis, cancer staging, and stent diameter, and length, were collected from medical charts.

Physical status assessment. The general condition of the patient was evaluated by performance status[23] and the American Society of Anesthesiologists physical status classification (ASA-PS).[24]

The performance status evaluation is as follows: status 0: fully active, able to carry on all pre-disease performance without restriction; status 1, restricted in physically strenuous activity but ambulatory and able to perform work of a light sedentary nature such as light housework and office work; status 2: ambulatory and capable of all self-care but unable to perform any work activities for more than 50% of waking hours; status 3: capable of only limited self-care and confined to bed or chair for more than 50% of waking hours; and status 4: completely disabled, unable to perform any self-care, and totally confined to bed and/or chair.[23]

The ASA-PS is as follows: ASA I: a normal healthy patient; ASA II: a patient with mild systemic disease; ASA III: a patient with severe systemic disease; and ASA IV: a patient with severe systemic disease that is a constant threat to life.[24]

Colonic stenting. Three types of SEMS were used: the Niti-S colonic stent (Taewoong Medical, Gimpo, Korea), the WallFlex colonic stent (Boston Scientific, Marlborough, MA, USA), and the HANAROSTENT (Boston Scientific). The metallic colonic stent is indicated for patients with obstructive symptoms who had colonic ileus on imaging (computed tomography and plain X-ray) and/or non-passable stenosis. Colonic stenting was performed via colonoscopy with fluoroscopy by expert endoscopists with ≥10 years of experience. To pass through the stricture, a guidewire was inserted through the cannula, and the position and length of the stricture were assessed radiographically. After removing the cannula, the metallic stent was deployed through the guidewire as described in previous studies.[2,4]

Table 1 Characteristics of patients with an in-dwelling colonic stent for stenosis followed by surgical treatment (group I) or by chemotherapy and/or palliative treatment with best supportive care (group II)

	Group I ($n = 29$)	Group II ($n = 42$)	*P*-value
Age	73.0 ± 2.2	76.0 ± 1.8	0.34
Gender (male/female)	16/13	26/16	0.57
BMI (kg/m^2)	21.2 ± 0.7	19.6 ± 0.6	<0.01
Total protein (g/dL)	6.8 ± 0.1	6.7 ± 0.1	0.66
Albumin (g/dL)	3.6 ± 0.1	3.3 ± 0.1	0.04
Hemoglobin (g/dL)	12.4 ± 0.4	11.6 ± 0.3	0.05
Stenosis site of the colon			0.12
Cecum or ascending	6 (20.7%)	6 (14.3%)	
Transverse	4 (13.8%)	4 (9.5%)	
Descending	6 (20.7%)	6 (14.3%)	
Sigmoid	5 (17.2%)	20 (47.6%)	
Rectum	8 (27.6%)	6 (14.3%)	
Performance status			0.42
0	8 (27.6%)	13 (31.0%)	
1	8 (27.6%)	6 (14.3%)	
2	10 (34.5%)	14 (33.3%)	
3	3 (10.3%)	6 (14.3%)	
4	0	3 (7.1%)	
American Society of Anesthesiologists (ASA) physical status			<0.01
I/II	26 (89.7%)	25 (59.5%)	
III/IV	3 (10.3%)	17 (40.5%)	
Cancer stage			<0.01
II	7 (24.1%)	7 (16.7%)	
III	16 (55.2%)	6 (14.3%)	
IV	6 (20.7%)	29 (69.0%)	

Values are means ± standard error.
BMI, body mass index.

Technically, successful stent placement was confirmed radiologically and endoscopically. Clinical success was defined as the successful decompression of the colon within 72 h after the first stent placement with +2 or more colorectal obstruction scoring system (CROSS) score improvement.[2]

The CROSS score is defined as follows: 0: requiring continuous decompressive procedure; 1: no oral intake; 2: liquid or enteral nutrition; 3: soft solids, low residue; and 4: full diet, without symptoms of stricture.

An early complication was defined as symptoms that develop within 1 week of stent placement, whereas a late complication was defined as symptoms that develop more than 1 week after stent placement. Survival periods were retrieved from medical records, including information from previous hospitals.

All procedures were conducted according to the ethical standards of the committee on human studies (institutional and national) and with the Helsinki Declaration of 1964 and later versions. All patients gave their informed consent, and the research protocol was approved by the ethics committee and the institutional review board of Karatsu Red Cross Hospital (KRCH 5-1).

Table 2 Therapeutic outcomes of surgical treatment (group I) and chemotherapy and/or palliative treatment (group II) after colonic stenting for stenosis caused by advanced colon cancer

	Group I ($n = 29$)	Group II ($n = 42$)	*P*-value
Technical success	29 (100%)	41 (97.6%)	0.40
Clinical success	24 (82.8%)	37 (88.0%)	0.53
Improved CROSS score			0.19
0–1	5 (17.2%)	3 (7.1%)	
2–3	24 (82.8%)	39 (92.9%)	
Stent length (mm)			0.15
<80	26 (89.7%)	32 (76.2%)	
>90	3 (10.3%)	10 (23.8%)	
Stent diameter (mm)			0.11
18	19 (65.5%)	17 (40.5%)	
22	10 (34.5%)	25 (59.5%)	
Early complications after the stent placement within 1 week			
Total	3 (10.3%)	6 (14.2%)	0.62
Stent dilation failure	0	1 (2.3%)	
Perforation	0	0	
Abdominal pain	1 (3.4%)	2 (4.7%)	
Fever	1 (3.4%)	2 (4.7%)	
Sepsis	1 (3.4%)	0	
Bloody stool	0	1 (2.3%)	
Migration	0	0	
Obstruction	0	0	
Survival period			<0.01
<1 year	2 (6.9%)	29 (69.0%)	
≧1 year	27 (93.1%)	13 (31.0%)	

Group I: surgical treatment. Group II: chemotherapy and/or palliative treatment. Technical success: successful stent placement in the first procedure, confirmed radiologically and endoscopically; clinical success: decompression of the colon within 72 h after the first stent placement with +2 or more CROSS score improvement.
CROSS score, colorectal obstruction scoring system score.

Table 3 Characteristics of patients with in-dwelling colonic stent for stenosis followed by chemotherapy (group II-A) or palliative treatment with the best supportive care (group II-B)

	Group II-A ($n = 18$)	Group II-B ($n = 24$)	*P*-value
Age	66.8 ± 2.3	82.9 ± 2.0	<0.01
Gender (male/female)	14/4	12/12	0.07
BMI (kg/m^2)	19.6 ± 0.9	19.6 ± 0.8	0.99
Total protein (g/dL)	6.6 ± 0.2	6.7 ± 0.2	0.35
Albumin (g/dL)	3.6 ± 0.2	3.1 ± 0.1	0.03
Hemoglobin (g/dL)	12.2 ± 0.5	11.1 ± 0.4	0.11
Stenosis site of the colon			0.44
Cecum or ascending	1 (5.6%)	5 (20.8%)	
Transverse	3 (16.8%)	1 (4.2%)	
Descending	2 (11.1%)	4 (16.7%)	
Sigmoid	9 (50.0%)	11 (45.8%)	
Rectum	3 (16.7%)	3 (12.5%)	
Performance status			<0.01
0	10 (55.5%)	3 (12.5%)	
1	5 (27.8%)	1 (4.2%)	
2	2 (11.1%)	12 (50.0%)	
3	1 (5.6%)	5 (20.8%)	
4	0	3 (12.5%)	
American Society of Anesthesiologists (ASA) physical status			0.34
I/II	13 (72.2%)	12 (50.0%)	
III/IV	5 (27.8%)	12 (50.0%)	
Cancer staging			<0.01
II	1 (5.6%)	6 (25.0%)	
III	0	6 (25.0%)	
IV	17 (94.4%)	12 (50.0%)	

Values are means ± standard error.
BMI, body mass index.

Data analysis. Categorical data are expressed as numbers and percentages, and the χ^2 test was used to identify differences between the two groups. Numerical data with a normal distribution are expressed as mean ± standard error (SE), and Student's *t*-test was used to determine differences between the two groups. Statistical significance was defined as $P < 0.05$. All the analyses were conducted using JMP version 13.2.1 (SAS Institute Inc., Cary, NC, USA).

Results

Table 1 presents basic patient characteristics. The general condition of patients in group I was significantly better than of those in group II, including BMI ($P < 0.01$), serum albumin ($P = 0.04$), hemoglobin ($P = 0.05$), and ASA-PS ($P < 0.01$). No significant differences were found between the two groups in age, gender, total serum protein, performance status, and stenotic site of the colon. Cancer stage was more advanced in group II ($P < 0.01$).

Table 2 presents the clinical outcomes of the colonic stent placements in the two groups. The overall technical (procedural) success rate was 98.6% (70/71) and did not vary statistically significantly between the two groups (group I: 100%; group II: 97.6%). The overall clinical success rate was 85.9% (61/71) and was almost the same between the two groups (group I: 82.8%; group II: 88.0%). The CROSS score was improved in the majority of patients in both groups with an overall outcome of CROSS scores 2–3 (group I: 82.8%; group II: 92.9%). The length and diameter of the stent did not vary significantly between the two groups. The overall early complication rate was relatively low (12.7%: 9/71) and did not vary significantly between the two groups (group I: 10.3%; group II: 14.2%). The percentage of patients who survived more than 1 year in group I was 93.1% (27/29), which was significantly higher ($P < 0.01$) than that in group II (31.0%; 13/42).

Table 3 presents the patient characteristics in group II. The mean age of the patients of group II-B (82.9 ± 2.0 years) was significantly higher ($P < 0.01$) compared with that of group II-A (66.8 ± 2.3 years). No significant differences were observed between the two groups in gender, BMI, total serum protein, and hemoglobin. However, serum albumin was significantly lower in group II-B ($P = 0.03$). In physical ability measurements, performance status was better in group II-A ($P < 0.02$), but the ASA-PS did not differ significantly between the two groups. Cancer stage was more advanced in group II-A ($P < 0.01$), and the stenosis site of the colon did not differ in the two groups.

Table 4 Therapeutic outcomes of chemotherapy (group II-A) and palliative treatment with best supportive care (group II-B) after colonic stenting for stenosis caused by advanced colon cancer

	Group II-A ($n = 18$)	Group II-B ($n = 24$)	*P*-value
Technical success	18 (100%)	23 (95.8%)	0.38
Clinical success	15 (83.3%)	22 (91.6%)	0.41
Improved CROSS score			0.73
+0–1	3 (16.7%)	2 (8.3%)	
+2–3	15 (83.3%)	22 (91.7%)	
Stent length (mm)			0.83
<80	14 (77.8%)	18 (78.2%)	
>90	4 (22.2%)	6 (21.8%)	
Stent diameter (mm)			0.15
18	5 (27.8%)	12 (50.0%)	
22	13 (72.2%)	12 (50.0%)	
Early complications after stent placement			
Total	3 (16.6%)	3 (12.5%)	0.70
Stent dilation failure	0	1 (4.2%)	
Perforation	0	0	
Abdominal pains	1 (5.6%)	1 (4.2%)	
Fever	1 (5.6%)	1 (4.2%)	
Sepsis	0	0	
Bloody stool	1 (5.6%)	0	
Migration	0	0	
Obstruction	0	0	
Late complications			
Total	5 (27.8%)	11 (45.8%)	0.23
Obstruction	3 (16.6%)	10 (41.6%)	
Bleeding	0	0	
Perforation	2 (11.1%)	1 (4.2%)	
Migration	0	0	
Survival period			0.02
<1 year	9 (50%)	20 (83.3%)	
≧1 year	9 (50%)	4 (16.7%)	

Technical success: successful stent placement in the first procedure, confirmed radiologically and endoscopically; clinical success: decompression of the colon within 72 h after the first stent placement with +2 or more CROSS score improvement.
CROSS score, colorectal obstruction scoring system score.

Table 4 shows the clinical outcomes of the stenting in groups II-A and II-B. The technical success rate did not differ significantly between the two groups (group II-A: 100%; group II-B: 95.8%), resulting in equivalent clinical success rates: 83.3% in group II-A and 91.6% in group II-B. The clinical success improved the CROSS scores to 2 or higher in both groups, and no difference was found in the CROSS scores between the two groups: 83.3% in group II-A and 91.7% in group II-B. The length and diameter of the stent did not differ significantly between the two groups.

In complications, the early complication rate did not differ significantly between the two groups. The main late complications observed were re-obstruction caused by the tumor and perforation (Table 4). The number of patients who suffered from obstruction was higher in group II-B, but not significantly. The percentage of patients who survived more than 1 year in group II-A was 50% (9/18), which was significantly higher ($P < 0.01$) than that in group II-B (16.7%; 4/24).

Discussion

The present study examined the efficacy and safety of metallic colonic stent insertion for obstructive stenosis due to primary colorectal cancer and compared the findings between patients who received systemic chemotherapy (group II-A) and palliative treatment with the best supportive care (group II-B) and patients who underwent bridging for curative surgery (group I).

The main findings were as follows: (i) The utility of the colonic stent as evaluated by the technical and clinical success and CROSS scores did not differ significantly between groups I and II, although the risks of malnutrition, low ASA-PS, advanced cancer stage progression, and low 1-year survival rate were higher in group II. (ii) The overall safety of colonic stenting was high, as indicated by a low rate of early complications within 1 week of 10% in both groups with no significant difference between the groups. (iii) Except for re-obstruction due to tumors, late complications were low in both groups II-A and II-B with no significant difference between the two groups.

The utility of colonic stenting has mainly been evaluated on the basis of the surgical outcomes, including long-term survival and postoperative complications, of Japanese patients who were bridged for curative surgery.[2–6,9] The present study suggests that colonic stenting for decompression for obstructive colorectal cancer is as valuable and effective in patients who undergo systemic chemotherapy and palliative therapy as it is in patients who are bridged for curative surgery, which are partly supported by the findings of previous studies.[7,12]

Previous studies have demonstrated the safety of colonic stent insertion and have identified the risk factors for stenting in patients who received curative surgery, which include tumor length and staging, the stenosis site of colorectal cancer, the interval to the surgery, and the general condition of the patient, including nutrition status.[6,8,10,16] The present study indicates that colonic stenting for patients who received chemotherapy and palliative therapy was performed safely without serious early complications compared with that for patients who received curative surgery, regardless of risk status for tumor length and staging, stenosis site, survival prognosis, and general condition.

The late complications after stenting did not differ significantly between the systemic chemotherapy patients (group II-A) and supportive care patients (group II-B). The complication rate of obstructive stenosis caused by colorectal cancer was higher in group II-B, but not significantly. The results suggest that colonic stenting for obstructive advanced colorectal cancer was equally applicable to both patients receiving systemic chemotherapy and supportive care, despite the increased risk posed by age, poor general condition, and poor 1-year survival.

In addition, there were two cases of perforation as a late complication of stenting in patients who received systemic chemotherapy. Both these cases were treated with anti-VEGF antibody. Perforation is a serious complication that is difficult to manage with conservative treatment and requires urgent surgical management. Lee *et al.* analyzed 21 cases of perforation after SEMS implantation and reported that 14 (66.7%) patients required emergency surgery and 5 (23.8%) patients died within 30 days.[25] The updated European Society of Gastrointestinal Endoscopy (ESGE) guideline states that antiangiogenic therapy may be considered for patients after colon stenting and that colon

stenting is not recommended while patients are receiving antiangiogenic therapy.[26] The World Society of Emergency Surgery (WSES) guidelines also state that "alternatives to SEMS should be considered for patients who are eligible for bevacizumab-based therapy" and that "involvement of an oncologist in the decision is strongly recommended."[27] On the other hand, Japanese Society for Cancer of the Colon and Rectum (JSCCR) guidelines 2019 do not recommend stent treatment for patients who are indicated for systemic chemotherapy, not just antiangiogenic agent.[28] Our findings reveal that systemic chemotherapy without antiangiogenic agent after SEMS implantation did not increase the rate of perforation in Japanese patients with malignant colorectal obstruction.

This study has several limitations. Because this is a single-center retrospective study, the grouping of the patients by therapeutic approach was decided by different physicians using different criteria. Specifically, aging may be one of the main factors for classification into chemotherapy or supportive care because of the serious side effects of chemotherapy for elderly patients.[3] The number of patients in each group was small, which thus warrants further exploration involving large datasets obtained from multiple institutions.

In conclusion, the present study suggests that the insertion of SEMS for obstruction caused by advanced primary colorectal cancer can be useful and safe even for patients treated by systemic chemotherapy or palliative therapy. These findings may lead to revisions of the Japanese guidelines, which do not recommend stent treatment for patients who are indicated for systemic therapy, and chemotherapy will be recommended as a safe treatment in patients who have undergone palliative colonic stenting in Japan.

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