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Outcomes of self-expandable metal stent as bridge to surgery versus emergency surgery for left-sided obstructing colon cancer: A retrospective cohort study

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Background: Long-term outcomes of self-expandable metal stents (SEMSs) as bridges to surgery versus emergency surgery in the treatment of left-sided obstructing colon cancer remain unclear.
Methods: Using a nationwide inpatient database in Japan, we performed one-to-one propensity score matching to compare overall survival, the stoma requirement, postoperative complications, and the length of stay between the SEMS and emergency surgery groups.
Results: Compared with the emergency surgery group, the SEMS group showed worse survival (hazard ratio, 1.80; 95% confidence interval, 1.07–3.01), a higher incidence of postoperative ileus (8% vs. 4%, $P = 0.010$), a longer postoperative length of stay (14 vs. 12 days, $P < 0.001$), and a lower stoma requirement (10% vs. 29%, $P < 0.001$).
Conclusions: SEMSs as bridges to surgery are associated with significantly poorer overall survival, a higher incidence of postoperative ileus, a longer length of stay, and a lower stoma requirement than is emergency surgery.

Introduction

Placement of self-expandable metal stents (SEMSs) has become a popular alternative to emergency surgery in the management of acute left-sided obstructing colon cancer. Although it has been established that SEMSs as bridges to surgery (BTSs) have short-term benefits, the prognostic impacts of their use as BTSs remain controversial.[1,2]

The use of a SEMS as a BTS was first reported by Tejero et al.[3] in 1994. Placement of SEMSs for malignant stenosis of the colon has been covered by Japanese public health insurance since 2012 and has become widespread practice throughout Japan. SEMSs are used in two settings: (1) as palliative care in patients with metastatic colorectal cancer or those for whom surgery is otherwise contraindicated and (2) to enable restoration of patients' general condition before curative surgery. A systematic review of randomized controlled trials showed that the use of a SEMS as a BTS is associated with good technical and clinical success, with a smaller proportion of permanent stoma than with emergency surgery.[4] A meta-analysis showed that the use of a SEMS as a BTS has advantages over emergency surgery regarding reducing postoperative complications (such as wound infection) and permanent stomas.[5] Another meta-analysis showed that the use of a SEMS as a BTS has long-term oncological outcomes such as recurrence, 3-year survival, and 5-year survival similar to those of emergency surgery.[6] A one-to-two propensity score-matched analysis of 222 patients undergoing the use of a SEMS as a BTS showed that it has equivalent oncological outcomes to emergency surgery with fewer permanent stomas.[7]

While these studies support the use of a SEMS as a BTS, several studies have reported worse oncological outcomes after SEMS placement for various pathophysiological and iatrogenic reasons; for example, dissemination of cancer cells into the peripheral circulation may result in distant metastases, and SEMS-related

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perforation may increase the incidence of locoregional recurrence.[1,8–10] Because of these concerns, the current European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline does not recommend the use of a SEMS as a BTS as a standard treatment for symptomatic left-sided malignant colonic obstruction.[11] To date, whether a SEMS as a BTS has long-term advantages over emergency surgery remains unclear.

Understanding the real-world impacts of a SEMS as a BTS for left-sided obstructing colon cancer on long-term outcomes is important in establishing treatment principles. In this study, we compared long-term and postoperative outcomes between patients who underwent curative resection after placement of a SEMS as a BTS and those who underwent emergency surgery. The aim of this study was to determine the real-world impacts of a SEMS as a BTS for left-sided obstructing colon cancer using a nationwide inpatient database in Japan.

Materials and methods

For this retrospective cohort study, we used the Japanese Diagnosis Procedure Combination database to search for patients with left-sided obstructing colon cancer (located in splenic flexure, descending colon, and sigmoid colon) who had undergone placement of a SEMS or emergency surgery between April 2012 and March 2018. The database includes outpatient data, discharge abstracts, and administrative claims data from around 300 acute-care hospitals in Japan. The database includes the following data: unique identifiers for hospitals; patients' age, sex, height, body weight, and smoking index on admission; diagnoses, comorbidities on admission, and complications during hospitalization (recorded with text data in Japanese and the International Classification of Disease, Tenth Revision [ICD-10] codes[12]); clinical cancer stage and Tumor, Node, Metastasis classification of malignant tumors (according to the seventh edition of the Union for International Cancer Control); procedures (coded with Japanese original codes); discharge status; medications and treatment in both inpatient and outpatient settings; and dates of admission and discharge. The sensitivity and specificity of primary diagnoses of malignancy are 83.5% and 97.7%, respectively. Other details of this database have been described elsewhere.[13] Body mass index was classified into four categories (<18.5, 18.5–24.9, 25.0–29.9, and ≥30 kg/m^2). Patients were categorized into three groups according to their smoking index (0, 1–49, and ≥50 pack years) and Barthel Index (<20, 20–60, and >60). The Charlson comorbidity index was calculated based on Quan's protocol. Each ICD-10 code for 17 comorbidities was converted into a score and the scores totaled for each patient.[14] Patients' level of consciousness was classified according to the Japan Coma Scale score as follows: 0, alert consciousness; 1–3, drowsy but awake without any stimuli; 10–30, somnolence but aroused by some stimuli; and 100–300, coma.[15] Diabetes mellitus was defined as prescription of diabetic medications during hospitalization. Hospital volume was defined as the average annual number of SEMS placements performed in a given hospital, and the patients were divided into two groups of equal size (low- and high-volume).[16]

Clinical cancer stage was divided into II and III according to the Japanese Classification of Colorectal Carcinoma (eighth edition): tumors that invade the muscularis propria without regional lymph node metastases are Stage II, whereas tumors with regional lymph node metastases are Stage III.[17] The Japanese Colorectal Cancer Guideline recommends adjuvant chemotherapy for patients with Stage III disease and advises that adjuvant chemotherapy can be administered to patients with high-risk Stage II cancer (T4, fewer than 12 lymph nodes harvested, presentation with obstruction or perforation, vascular invasion, lymph node invasion, and poorly differentiated or undifferentiated tumor).[18] Recommended adjuvant chemotherapy in the Japanese universal healthcare coverage system includes the following regimens: 5-fluorouracil plus leucovorin, UFT plus leucovorin, capecitabine alone, FOLFOX (oxaliplatin, leucovorin, and 5-fluorouracil), and CapeOX (capecitabine and oxaliplatin) for 6 months. Chemotherapy administered within 12 weeks after surgery was regarded as adjuvant chemotherapy.

The exclusion criteria were as follows: Stage 0, I, or IV disease; no surgery performed; bowel perforation present on admission; insertion of transanal drainage tube before surgery; and history of colectomy.

The patient outcomes were overall survival, proportion of patients requiring stomas, postoperative complications, and length of hospital stay.

All analyses and data reporting in this study complied with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.[19] This study was approved by the International Review Board of The University of Tokyo. The requirement for informed consent was waived because of the anonymous nature of the data.

Statistical analyses

One-to-one propensity score matching was performed without replacement. Propensity scores were estimated using a generalized linear model based on sex, age, body mass index, smoking index, Charlson comorbidity index, Barthel Index, preoperative pneumonia, Japan Coma Scale score, diabetes mellitus, use of steroids, admission to the intensive care unit, tumor location, clinical cancer stage, TNM classification, type of hospital, hospital volume, and fiscal year. The C-statistic for evaluating concordance was calculated. Nearest-neighbor matching was performed with a caliper width equal to 0.2 of the standard deviation of the logit of the propensity scores. Standardized differences were used to compare baseline patient characteristics between the SEMS and emergency surgery groups. An absolute standardized difference of >10% was considered to indicate significant imbalance.[20]

Kaplan–Meier curves were drawn and the log-rank test used to compare the survival curves of the two groups. Cox proportional hazards regression analysis was used to estimate the hazard ratio of survival. The proportional hazard assumption was tested using analysis of Schoenfeld residuals. Patients who neither had cancer relapses nor died during the observation period were censored at the date of the last visit to each hospital. Patients who were alive on 31 March 2018 were censored for overall survival analysis. Overall survival was calculated from the date of curative resection to the date of death of any cause.

Student's *t*-tests were used to compare the averages of continuous variables and χ^2 tests to compare the proportions of categorical variables between the groups. Continuous variables are presented as median and interquartile range, whereas categorical variables are presented as absolute numbers with percentages. The threshold for significance was $P < 0.05$, and all reported P values are two-sided. All statistical analyses were conducted using Stata/MP 16.0 (Stata Corp, College Station, TX, USA).

Results

After application of the inclusion and exclusion criteria, 2651 patients were included in the present study, 538 of whom were assigned to the SEMS group and 2113 to the emergency surgery group (Fig. 1).

Table 1 shows the baseline characteristics of the patients in the two groups before and after propensity score matching. One-to-one propensity score matching resulted in creation of 498 matched

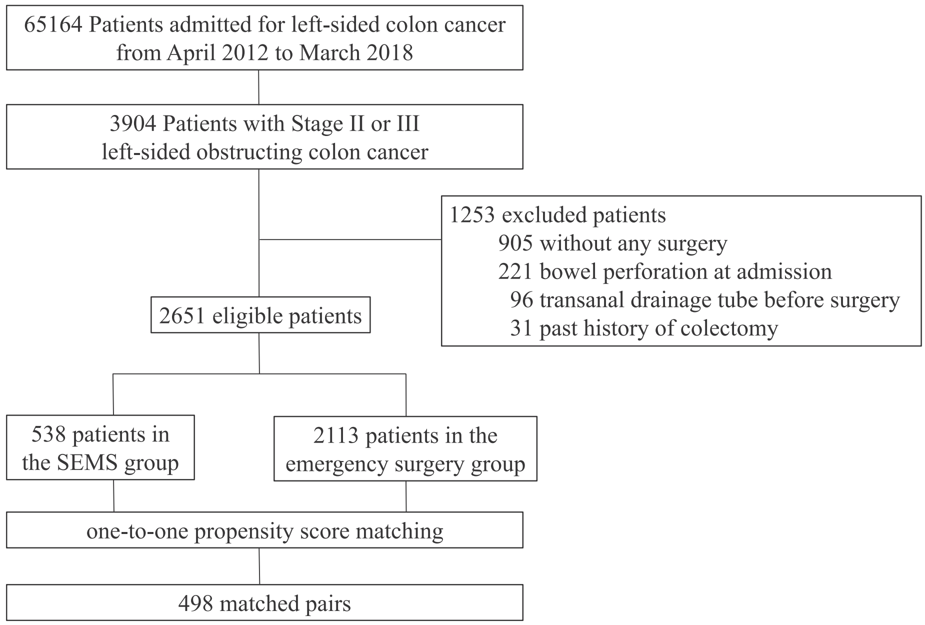

Fig. 1. Flowchart of patient selection. SEMS, self-expandable metal stent.

pairs. The C-statistic was 0.74 (95% confidence interval, 0.72–0.76). The patient characteristics were well balanced between the two groups after propensity score matching.

Table 2 shows the treatment characteristics of the two groups. There was no significant difference in operative type between the two groups. The proportion of postoperative ileus was significantly higher in the SEMS group than in the emergency surgery group ($P = 0.010$). The median postoperative length of stay was 12 (8–22) days in the emergency surgery group and 14 (11–21) days in the SEMS group ($P < 0.001$). There were no significant differences in the incidence of postoperative complications (including both surgical and non-surgical complications) between the two groups, except for postoperative ileus. The patients in the emergency surgery group were more likely to require creation of stomas (including colostomies and ileostomies, temporary and permanent) than those in the SEMS group. The proportion of overall SEMS-related complications for which emergency surgery was required was 2.6% (13/498). Additionally, in patients who did not undergo stoma creation, the proportion of ileus was significantly higher in the SEMS group than in the emergency surgery group (8.5% vs. 3.4%, $P = 0.003$).

The Kaplan–Meier curves showed that the SEMS group had significantly worse overall survival than the emergency surgery group ($P = 0.024$) (Fig. 2). The median length of follow-up for all propensity score-matched patients was 14.9 months (interquartile range, 5.4–21.3 months) in the SEMS group and 14.7 months (interquartile range, 5.3–20.6 months) in the emergency surgery group. Proportional hazards was verified by analysis of Schoenfeld residuals ($P = 0.15$). Cox proportional hazards regression analysis showed that the SEMS group had worse overall survival than the emergency surgery group (hazard ratio, 1.80; 95% confidence interval, 1.07–3.01; $P = 0.024$).

Discussion

In this study, we used a nationwide large database to investigate long-term and postoperative outcomes of a SEMS as a BTS. We adjusted for patient and hospital characteristics by propensity score matching. We found that the use of a SEMS as a BTS was associated with poorer overall survival, less frequent stoma creation, a higher incidence of postoperative ileus, and a longer length of stay.

Prior studies have shown that a SEMS offers better short-term morbidity and mortality than emergency surgery; accordingly, a SEMS is considered a good alternative to emergency surgery. However, some studies have found that the use of a SEMS as a BTS has long-term oncologic disadvantages: more frequent locoregional recurrence, more frequent peritoneal metastases, and impaired overall survival.[2,5,21–24] In the present study, the SEMS group showed poorer overall survival than the emergency surgery group. It remains controversial whether SEMS-related perforation is associated with these disadvantages.[11,25] A randomized clinical trial found that the SEMS group showed better overall postoperative survival than the emergency surgery group in the short term; however, Kaplan–Meier survival curves reversed during the study period.[10] Other mechanisms besides SEMS-related perforation, such as dissemination of tumor cells into the peripheral circulation as a result of manipulation in SEMS placement, may be associated with this reversal and poorer long-term outcomes.[8,9]

Postoperative ileus occurred more frequently in the SEMS group than in the emergency surgery group in the present study. In patients without stoma creation, the incidence of ileus was also higher in the SEMS group. The operative type did not vary between the groups. A time interval to surgery of approximately 2 weeks is suggested by the ESGE Clinical Guideline, and that in the present study was 15 days. Two other Japanese studies reported an interval to surgery of 21.5 days and 16 days.[11,23,26] A longer interval may result in local tumor infiltration and fibrosis, making the procedure more difficult and thus contributing to development of postoperative ileus. Because the impact of the time interval to surgery on long-term outcomes remains unclear, surgeons may be eager to reduce postoperative complications. A retrospective study showed that a ≥10-day interval to surgery was associated with a reduction in the risk of anastomotic leakage.[27] Two Japanese studies showed that most SEMS-related complications occurred within 7 days.[23,28] These results imply that a reduction in the interval to surgery might not lead to a reduction in SEMS-related complications. However, there are concerns that a prolonged interval to surgery might result

Table 1
Baseline characteristics before and after propensity score matching.

	Before PS matching					After PS matching				
	Emergency surgery (n = 2113)		SEMS (n = 538)		ASD	Emergency surgery (n = 498)		SEMS (n = 498)		ASD
Sex										
Male	1195	(57)	294	(55)	4.5	271	(54)	272	(55)	0.4
Age, years	70	[62–77]	74	[66–81]	29.5	72	[65–79]	73	[66–81]	2.5
Body mass index, kg/m^2										
<18.5	281	(14)	102	(20)	15.5	93	(19)	93	(19)	0.0
18.5–24.9	1298	(63)	347	(66)	8.1	336	(68)	334	(67)	0.9
25.0–29.9	415	(20)	70	(13)	18.5	67	(14)	68	(14)	0.6
≥30	67	(3)	5	(1)	19.6	2	(0)	3	(1)	2.8
Smoking index, pack-years										
0	1140	(54)	313	(58)	9.7	281	(56)	291	(59)	4.1
1–49	590	(28)	120	(22)	14.4	114	(23)	112	(23)	1.0
≥50	383	(18)	105	(20)	3.7	103	(21)	95	(19)	4.0
Barthel Index										
<20	240	(12)	58	(11)	0.9	60	(12)	54	(11)	3.8
20–60	129	(6)	63	(12)	21	55	(11)	55	(11)	0.0
>60	1713	(82)	410	(77)	15.8	383	(77)	389	(78)	2.9
Charlson comorbidity index										
≤2	1505	(71)	373	(69)	4.2	364	(73)	350	(70)	6.2
3	461	(22)	130	(24)	6.1	108	(22)	118	(24)	4.8
≥4	147	(7)	35	(7)	2.6	26	(5)	30	(6)	3.5
Japan Coma Scale										
0, alert	2026	(96)	509	(95)	8.5	470	(94)	475	(95)	4.6
1–3, drowsy	79	(4)	27	(5)	8.1	26	(5)	21	(4)	4.7
10–30, somnolence	8	(0)	2	(0)	2.5	2	(0)	2	(0)	0.0
100–300, coma	0	(0)	0	(0)						
Diabetes	377	(18)	129	(24)	13.5	112	(23)	111	(22)	0.5
Steroid use	300	(14)	71	(13)	2.5	66	(13)	69	(14)	1.8
Pneumonia on admission	30	(1)	13	(2)	8.4	12	(2)	10	(2)	2.7
ICU admission	273	(13)	18	(3)	33	18	(4)	16	(3)	2.2
Tumor location										
Splenic flexure	12	(1)	13	(2)	14.6	9	(2)	9	(2)	0.0
Descending colon	360	(17)	160	(30)	30.6	150	(30)	145	(29)	2.2
Sigmoid colon	1741	(82)	365	(68)	34.2	339	(68)	344	(69)	2.2
Clinical cancer stage										
II	1091	(52)	269	(50)	2.0	248	(50)	256	(51)	2.0
III	1022	(48)	269	(50)	2.0	250	(50)	245	(49)	2.0
TNM classification										
T category										
1–2	328	(16)	37	(7)	29.6	25	(5)	34	(7)	7.7
3	1267	(61)	372	(61)	0.1	316	(64)	307	(62)	3.7
4	488	(23)	170	(32)	20.8	157	(32)	157	(32)	0.0
N category										
0	1111	(54)	278	(52)	2.4	247	(50)	262	(53)	6.0
1	751	(36)	190	(36)	2.4	195	(39)	177	(36)	7.5
2	187	(9)	62	(12)	8.2	52	(10)	55	(11)	1.9
3	19	(1)	4	(1)	1.3	4	(1)	4	(1)	0.0
Type of hospital										
Teaching	1934	(92)	473	(88)	10.7	438	(88)	439	(88)	0.6
Nonteaching	179	(9)	65	(12)	10.7	60	(12)	59	(12)	0.6
Hospital volume, per year										
High	453	(21)	180	(34)	26	158	(32)	165	(33)	3.0
Low	1660	(79)	358	(67)	26	340	(68)	333	(67)	3.0
Fiscal year										
2012	307	(15)	37	(7)	23.9	39	(8)	34	(7)	3.9
2013	331	(16)	64	(12)	12.9	51	(10)	54	(11)	2.0
2014	363	(17)	105	(20)	7.4	97	(20)	101	(20)	2.0
2015	344	(16)	109	(20)	9.1	101	(20)	103	(21)	1.0
2016	388	(18)	104	(19)	2.5	101	(20)	93	(19)	4.1
2017	380	(18)	119	(22)	10.2	109	(22)	113	(23)	1.9[a]

[a] Continuous variables are expressed as median [interquartile range]. Categorical variables are expressed as *n* (%). ASD, absolute standardized difference; SEMS, self-expandable metal stent; ICU, intensive care unit

in worse oncological outcomes.[29] As a result, our 15-day interval to surgery was comparable with the recommendation in the ESGE Clinical Guideline.

The overall proportion of patients requiring stomas was higher in the emergency surgery group than in the SEMS group in the present study. This result is consistent with that of a previous study.[30] Creation of stomas may enable patients to start oral intake earlier, thereby enabling earlier discharge. This possibility and the smaller proportion of patients with postoperative ileus may at least in part account for the shorter length of stay observed in the emergency surgery group. The difference in the postoperative length of stay was statistically significant but clinically insignificant.

To some extent, SEMS placement may involve a trade-off

Table 2
Treatment characteristics in matched cohort.

Operative type	Emergency surgery (n = 498)		SEMS (n = 498)		p-value
Open	241	(48)	246	(49)	0.75
Laparoscopic	257	(52)	252	(51)	
Overall stoma creation	145	(29)	52	(10)	<0.001
Time interval from SEMS to operation, days			15	[10–19]	
Postoperative length of stay, days	12	[8-22]	14	[11–21]	<0.001
Adjuvant chemotherapy	184	(37)	193	(39)	0.56
Death from any cause	24	(5)	38	(8)	0.066
Postoperative complications	107	(22)	116	(23)	0.49
Surgical site infection	22	(4)	13	(3)	0.12
Anastomotic leakage	20	(4)	19	(4)	0.19
Ileus	22	(4)	42	(8)	0.010
Respiratory failure	17	(4)	24	(5)	0.41
Pulmonary embolism	1	(0)	3	(1)	0.36
Acute coronary syndrome	1	(0)	1	(0)	0.95
Heart failure	6	(1)	6	(1)	0.88
Stroke	0	(0)	4	(1)	0.055
Acute renal failure	1	(0)	0	(0)	0.30
Urinary tract infection	3	(1)	6	(1)	0.38
Sepsis	2	(0)	7	(1)	0.12

Continuous variables are expressed as median [interquartile range]. Categorical variables are expressed as *n* (%).SEMS, self-expandable metal stent.

between having a stoma and having better long-term survival. The treatment preference may be influenced by the individual patients' choice of particular outcomes. Patients of advanced age may place high importance on short-term outcomes and thus prefer SEMS placement to avoid having a stoma, while young patients may regard long-term survival as their first priority and accept emergency surgery with stoma creation. For achievement of personalized medicine, appropriate and sufficient explanations and discussions are essential in the individual decision-making process.

The present study had several limitations. First, the following data were not available: extent of bowel stenosis, type of device, and oral intake and nutritional status before surgery. These factors could have led to unmeasured confounding. Because we used propensity score matching with measured variables to reduce bias in the estimated causal effects due to observed differences between the study groups, the present study is still subject to unmeasured confounding. Additionally, the results of the present study are generalizable among patients within the range of the propensity scores, but they may not be applicable to those who are out of this range. Second, we could only follow up patients who continued to attend the same hospital. Patients who changed hospitals were regarded as censored for survival analysis. Third, because we used real-world data, assignment of treatment was not random; randomized controlled trials with rigid protocols are preferable. However, there are practical difficulties in designing randomized controlled trials for emergency situations.

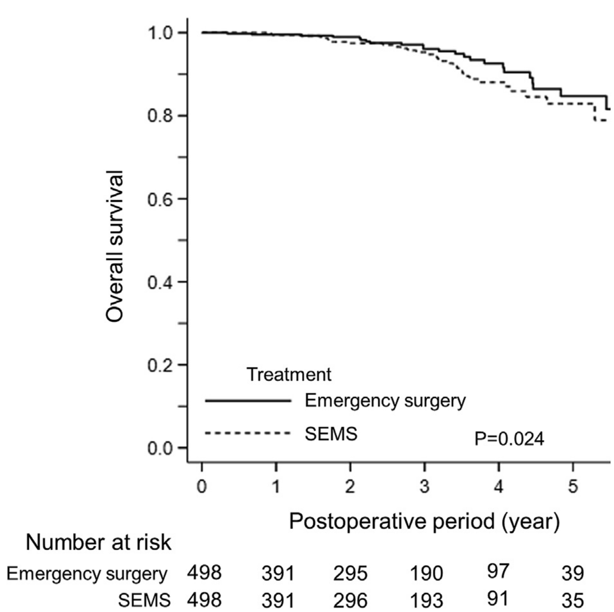

Fig. 2. Kaplan–Meier survival curves. SEMS, self-expandable metal stent.

Conclusions

In conclusion, we performed a propensity score-matched analysis using a large nationwide cohort to investigate prognostic impacts of using a SEMS as a BTS for left-sided obstructing colon cancer. Our findings suggest that although a SEMS as a BTS is associated with a reduction in the overall proportion of stomas required, it also has several disadvantages such as poorer overall survival, a greater incidence of postoperative ileus, and a longer length of stay than emergency surgery. Therefore, further studies are needed to verify the results of the present study. Careful explanations and discussions of the short- and long-term outcomes may be essential in the individual decision-making process.

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Declaration of competing interest

The authors declare they have no conflicts of interest.

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