

Long-term outcomes of self-expandable metallic stents as a bridge to surgery for obstructive and symptomatic primary tumors of stage IV colorectal cancer: A propensity- score analysis

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Abstract

[Purpose]

Self-expandable metallic stent (SEMS) was introduced for the treatment of obstructive colorectal cancer (CRC) a few decades ago. However, its long-term outcomes remain controversial, especially for stage IV CRC. The aim of this study was to clarify the outcomes of SEMS as a “bridge to surgery” (BTS) for obstructive and symptomatic primary tumors in stage IV CRC by one-to-one propensity-score matching.

[Methods]

This retrospective cohort study was conducted at a single center from January 2007 to December 2017. Patients with obstructive and symptomatic primary tumors of stage IV CRC underwent primary resection (PR) or placement of a SEMS as a BTS. They were divided into SEMS and PR groups, and their short- and long-term outcomes were compared.

[Results]

In total, 52 patients were reviewed (SEMS group, 21; PR group, 31). Thirteen patients in both groups were matched using propensity scores. Patients in the SEMS group more frequently underwent laparoscopic surgery than those in the PR group (77% vs. 8%, $p = 0.001$) and fewer of them underwent stoma creation (8% vs. 38%, $p = 0.16$). The two groups showed no significant differences in perioperative and pathological outcomes. The 3-year overall survival was not significantly different between groups (41% vs. 31%, $p = 0.19$).

[Conclusion]

As a BTS, the use of SEMS for obstructive and symptomatic primary tumors in CRC stage IV can be a comparable option to PR in terms of short- and long-term outcomes, and would be less invasive with respect to surgical procedures or stoma creation rate.

Introduction

Colorectal cancer (CRC) is one of the most common malignant tumors worldwide, especially in economically developed countries [1]. Approximately 20% of CRCs present with distant metastasis, while approximately 10% of CRC tumors are obstructive [2-4]. Although several treatments for CRCs have been identified with advancements in surgical approaches or chemotherapy, treatment of stage IV CRC remains challenging. Furthermore, obstructive and symptomatic stage IV CRCs pose an extremely difficult challenge for clinicians.

For obstructive CRC, self-expandable metallic stents (SEMSs) have been used for palliation or as a bridge to surgery (BTS) since the 1990s [5]. Previous reports have presented contrasting findings for the short-term and long-term effects of SEMS [6-11]. As a palliative measure for incurable stage IV CRC, the effects

of SEMS have been reported in comparison to surgical decompression [12, 13]. The European Society of Gastrointestinal Endoscopy (ESGE) guidelines in 2020 describe that SEMS can be used for palliation of malignant colonic obstruction [14]. However, the safety of systemic chemotherapy after SEMS insertion, especially with targeted agents such as bevacizumab, is not fully assured [15-17].

The aim of this study was to clarify the effectiveness of SEMS as a BTS for obstructive and symptomatic stage IV CRC, in comparison with primary surgical resection.

Material And Methods

This study was approved by the institutional review board of Saiseikai Noe Hospital (IRB #2020226) and complied with the Declaration of Helsinki, 1964 (revised in 2013). Considering the anonymized nature of the data, informed consent was not required.

Patients

Hospital records of patients from January 2007 to December 2017 were retrospectively reviewed, and the patients with obstructive and symptomatic stage IV CRC were included in the present study. The baseline characteristics (age, sex, body mass index [BMI], colorectal obstruction scoring system [CROSS] classification [18], tumor location, site of metastasis, carcinoembryonic antigen [CEA] level, and American Society of Anesthesiologists [ASA] physical status), perioperative status (interval to surgery, surgical approach, stoma creation, operative time, blood loss, postoperative complications, chemotherapy, and interval to next therapy), and 3-year survival were determined. The method of intervention depended on the mutual decision among surgeons, physicians, and patients. The exclusion criteria were as follows: intestinal or bowel perforation at the first visit, unresectable main tumor severely invading the adjacent organs, or rectal cancer within 10 cm from the anus.

Definition

Colorectal obstruction was defined on the basis of symptoms, physical findings, and radiological findings. All patients underwent contrast-enhanced computed tomography (CT) to diagnose large bowel dilation and rule out perforation or abscess formation around the primary tumor. The severity of obstruction was classified using the CROSS classification. All tumors were proven to be stage IV by radiological assessments, in accordance with the UICC TNM staging (8th edition) classification for colon and rectal cancer. Patients were separated into two groups depending on the intervention. The SEMS group underwent SEMS placement and subsequent surgery to resect the original tumor, while the primary resection (PR) group was treated by emergent or urgent surgery to remove the obstructive site.

SEMS strategy

SEMS placement was performed by gastroenterologists using colonoscopy under fluoroscopic guidance. After confirming stricture of the colon, the guidewire was passed through the site, and the SEMS was set on the targeted site through the guidewire. Then, contrast enema was injected through the SEMS to check

the opening of the narrow segment and perforation. After the procedure, symptoms, stool conditions, and physical examination findings were monitored, and oral intake was gradually initiated. Migration of the SEMS was examined by abdominal radiography on the subsequent days.

Surgical procedure

Primary resection of the obstructive colon was performed emergently or urgently, depending on several factors, such as the severity of bowel dilation or general condition. As for BTS, elective surgery for resecting CRC was scheduled within approximately 2 weeks after SEMS placement. To clear fecal material from the bowel lumen, we induced mechanical bowel preparation with magnesium citrate and sodium phosphate, and performed a laparoscopic procedure for subsequent surgery, aiming at primary anastomosis without a permanent stoma. In both procedures, stoma creation was added depending on the intraoperative findings.

Subsequent treatment

Systemic chemotherapy was initiated after recovery of the patient's physical condition. The main regimen was a combination of folinic acid, fluorouracil, and oxaliplatin (FOLFOX) plus bevacizumab or panitumumab. For resectable metastases, a surgical approach was performed approximately one month after resection of the primary tumor.

Statistical analysis

All data are presented as median (interquartile range [IQR]). The mean for continuous variables (such as age) was compared using t-tests (or Wilcoxon rank-sum tests), while proportions for categorical variables (such as sex) were compared using chi-squared tests (or Fisher's exact tests). Propensity scores were calculated using multivariable logistic regression. The variables in propensity-score matching (PSM) analysis included age, sex, BMI, ASA status, CROSS classification, tumor location, and TNM stage. One-to-one matching was performed with a caliper width of 0.2 of the standard deviation of the logit of the propensity scores. Kaplan–Meier curves were drawn, and the log-rank test was used to compare the survival curves of the two groups. All statistical analyses were conducted using JMP ver. 12.0.2 (SAS Institute Inc., Cary, NC, USA), with $p < 0.05$ set as the threshold for significance.

Results

In total, 52 patients underwent treatment for stage IV obstructive and symptomatic CRC, with 21 and 31 patients in the SEMS and PR groups, respectively. Under one-to-one propensity-score matching, 13 patients in the SEMS group were matched with the same number of patients in the PR group. Baseline data are presented in Table 1. Before PSM, the SEMS and PR groups showed significant differences in age and tumor location (age: 69 years vs. 75 years, $p = 0.04$; rate of ascending CRC: 5% vs. 29%, $p = 0.04$). No significant differences were observed in other baseline characteristics.

Perioperative outcomes are presented in Table 2. No complications were associated with SEMS placement. The interval from the first visit to surgery was significantly longer in the SEMS group than in the PR group (17 days vs. 3 days, $p < 0.0001$). In terms of surgical approach, the rate of laparoscopic resection was significantly higher in the SEMS group than in the PR group (81% vs. 26%, $p < 0.0001$). The SEMS group showed a lower rate of stoma creation, although the difference was not statistically significant (10% vs. 32%, $p = 0.09$). The amount of blood loss during surgery was significantly lower in the SEMS group (69 mL vs. 326 mL, $p = 0.01$). The two groups showed no significant difference in the open conversion rate, operative time, postoperative complications, and postoperative hospital stay. In addition, the pathological outcomes were not significantly different between the SEMS and PR groups in terms of stage, T factor, N factor, differentiation, vascular invasion, and lymphatic invasion, except for the number of resected lymph nodes (20 vs. 12, $p = 0.01$). The interval from the first visit or surgery to the next therapy, which was systemic chemotherapy or resection of metastatic regions, was not significantly different. The rate of adjuvant chemotherapy as well as the use of targeted agents, such as bevacizumab or panitumumab, also did not significantly differ between the two groups. There was no significant difference in the duration of observation period (2.0 years vs 1.4 years, $p = 0.12$). Figure 1 shows the Kaplan–Meier estimates of overall survival.

After PSM, baseline characteristics showed no significant differences. Perioperative data presented the same trend before PSM, with a significantly higher rate of laparoscopic surgery in the SEMS group (77% vs. 8%, $p = 0.001$). The SEMS group was less likely to need stoma creation, but the difference was not significant (8% vs. 38%, $p = 0.16$). The three-year survival rate was not significantly different between the SEMS and PR groups (41% vs. 31%, $p = 0.19$). Figure 2 shows the Kaplan-Meier estimates of overall survival after PSM.

Discussion

SEMS has been used to treat obstructive colonic cancer since the 1990s [5]. Although the efficacy of SEMS placement for obstructive CRC is still debatable, some previous studies have shown improvements in short- and long-term outcomes [7, 19, 20]. To the best of our knowledge, this is the first report to discuss the short- and long-term outcomes of SEMS as a BTS for obstructive and symptomatic CRC in stage IV, compared to emergent or urgent resection of primary tumor. The results of this study can show the efficacy of SEMS in this setting with less invasive treatment, regarding surgical procedures or stoma creation rate.

Particularly for obstructive stage IV CRC, ESGE guidelines recommend SEMS for palliative aims since it may improve short-term outcomes in comparison with emergency surgery, which is potentially related to higher rates of mortality or morbidity [14]. However, since the treatment strategies for stage IV CRC have advanced in the last decades, a certain proportion of patients in that setting can now survive longer, receiving palliation with a combination of surgery, systemic chemotherapy, or radiotherapy [21, 22]. In this regard, the aim of SEMS placement for obstructive stage IV CRC needs to be discussed further.

Resection of primary tumors in stage IV CRC has been topic of debate. Some previous reports showed some benefits of primary tumor resection, such as reduction of late complications or improvement of overall survival (OS), even in asymptomatic cases [23-25]. However, a recent RCT proved that asymptomatic primary tumor resection does not contribute to an improvement in OS in comparison with chemotherapy alone [26]. In the RCT, some patients in the chemotherapy arm had to receive a surgical approach due to subsequent primary tumor symptoms. In this context, primary tumor resection of stage IV CRC would be less beneficial for prolonging OS, as long as the disease is not symptomatic.

On the other hand, the treatment for symptomatic primary tumors is more complicated, and patients may require interventions in order to proceed to the next treatment or palliation. The most effective option for obstructive and symptomatic stage IV CRC is still a topic of debate. Emergent surgical approaches have been reported to present a high risk for morbidity and mortality, mainly because patients are often already in a challenging physical condition [27-29]. In comparison with emergent surgery, SEMS is considered to be a useful method to overcome the symptoms of obstructive CRC [12, 13]. The advantages of SEMS over emergent operations include an improved 30-day mortality, lower morbidity and stoma creation rates, shorter duration of hospitalization, and earlier initiation of chemotherapy, while the negative aspects include the possibility of perforation related to the procedure or a slightly lower success rate.

After SEMS placement for stage IV CRC, some previous reports described that subsequent chemotherapy without resection of primary tumor could be introduced as long as the patient's physical status was tolerable [15-17, 30, 31]. However, aggressive chemotherapy, including treatment with targeted agents such as bevacizumab, can cause late complications related to primary tumor with SEMS, such as perforation, stent migration, or re-obstruction, which appear in approximately 20% of the cases. Since a certain number of patients eventually need to undergo surgical intervention or, in the worst-case scenario, experience a life-threatening condition, the long-term use of SEMS under systemic chemotherapy would not be completely safe.

Quality of life (QOL) should also be focused on in the treatment of stage IV CRC. Laparoscopic surgery for colon cancer has been shown as a better option than open surgery with regard to the short- and long-term QOL, because of a quicker recovery, less pain, or better cosmesis [32, 33]. As for decompression stoma, it is a useful option to relieve the symptoms of obstructive CRC, however the deterioration of QOL associated with this stoma has been problematic, especially among older populations [34, 35]. From these points of view, SEMS as a BTS for stage IV CRC would be superior to primary resection in QOL, due to higher frequency of laparoscopic surgery, and lower rate of stoma creation.

Considering these concerning aspects, SEMS has been used as a bridge to elective surgery for the treatment of obstructive and symptomatic stage IV CRC in our department. This strategy would prevent the late complications of SEMS placement, potentially precluding the patients' ability to receive or continue systemic chemotherapy; therefore, subsequent chemotherapy with targeted agents could be safely introduced. In the present study, no patients experienced later complications associated with

primary tumors, which may have caused critical problems. Consequently, the 3-year overall survival in the SEMS group was comparable to that in the PR group.

The present study had several limitations. First, this was a single-institutional, retrospective study. Therefore, the development of chemotherapy possibly affected the outcome of the patients. However, in the present study, there was no significant difference between the two groups in the parameters related to chemotherapy. Second, both groups included a few cases with resectable metastatic sites, such as liver or lung metastases, which may have influenced the long-term outcomes. Third, this strategy may delay the initiation of systemic chemotherapy in comparison with emergent or urgent surgery or SEMS placement alone. At this moment, it is still unclear whether a delay in chemotherapy can influence long-term outcomes. In addition, it is possible that a small percentage of patients with stage IV obstructive CRC are unresectable. Three cases of unresectable CRCs were treated in our institution during the study period, and these patients underwent only decompression stoma. These cases would require different treatment strategies. Finally, since there is a major limitation that the small number of patients did not allow sufficient statistical power, further study is warranted.

Conclusion

This is the first report to compare SEMS as a BTS with PR for obstructive and symptomatic primary tumors in CRC IV. The short- and long-term outcomes were almost equal between the two groups, and the SEMS group was able to receive less invasive surgical treatment with laparoscopic surgery and a lower frequency of decompression stoma.

Declarations

Authors' Contributions:

Study conception and design: A.S, S.O, T.I, Y.M, K.T, M.O, Y.A. Acquisition of data: A.S, Y.L, S.I, Y.S, R.T, Y.S. Analysis and interpretation of data: A.S, S.O. Drafting of manuscript: A.S. Critical revision of manuscript: A.S, S.O, T.I, Y.M, K.T, M.O, Y.L, S.I, Y.S, R.T, Y.S, Y.A.

Compliance with ethical standards

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none

Conflict of interest:

The authors declare that they have no conflicts of interest.

Ethics approval:

This study was approved by the institutional review board of Saiseikai Noe Hospital (IRB #2020226). Since this was a retrospective study, formal consent for the study was not required.

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The authors have no conflicts of interest or financial ties to disclose.

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Tables

Table 1. Baseline characteristics. SEMS, self-expandable metallic stent; PR, primary resection; BMI, body mass index; CROSS, colorectal obstruction scoring system; CEA, carcinoembryonic antigen; ASA, American society of anesthesiologists.

	before matching			after matching		
	SEMS (n=21)	PR (n=31)	p	SEMS (n=13)	PR (n=13)	p
Age (year)	69 (63-75)	75 (67-79)	0.04	68 (63-76)	68 (64-79)	0.68
Male (%)	15 (71%)	21(68%)	0.78	11 (85%)	9 (69%)	0.64
BMI (kg/m ²)	21.9 (19.9-25)	20.8 (19.5-22.1)	0.18	23.1 (20.4-24.2)	18.9 (18.5-23.9)	0.28
Location						
rectosigmoid	2 (10%)	3 (6%)	1	2 (15%)	1 (8%)	1
sigmoid	13 (62%)	13 (42%)	0.26	6 (46%)	9 (69%)	0.43
descending	3 (14%)	2 (6%)	0.38	3 (23%)	2 (15%)	1
transverse	2 (10%)	1 (3%)	1	1 (8%)	0	1
ascending	1 (5%)	9 (29%)	0.04	1 (8%)	1 (8%)	1
cecum	0	3 (6%)	0.26	0	0	1
CROSS classification			0.20			0.95
0	4 (19%)	14 (45%)		4 (31%)	3 (23%)	
1	2 (10%)	4 (13%)		2 (15%)	2 (15%)	
2	4 (19%)	4 (13%)		2 (15%)	3 (23%)	
3	11 (52%)	9 (29%)		5 (38%)	5 (38%)	
Site of metastases						
Liver	13 (62%)	17 (55%)	0.61	6 (46%)	7 (54%)	0.69
Lung	5 (24%)	10 (32%)	0.55	3 (23%)	2 (15%)	1
Carcinomatosis	5 (24%)	12 (39%)	0.37	5 (38%)	3 (23%)	0.67
Distant metastatic node	1 (5%)	4 (13%)	0.64	0	4 (31%)	0.10
Other (bone, ovary, adrenal)	2 (10%)	1 (3%)	0.56	1 (8%)	0	1
Preoperative CEA (ng/ml)	47 (14-118)	24 (5.7-66)	0.13	35 (12-83)	12 (3.3-196)	0.23
ASA			0.34			0.88
1	3 (14%)	1 (3%)		1 (8%)	1 (8%)	
2	13 (62%)	22 (71%)		10 (77%)	9 (69%)	

3	5 (24%)	8 (26%)	2 (15%)	3 (23%)
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Table 2. Short and long-term outcomes. SEMS, self-expandable metallic stent; PR, primary resection; CD, Clavien-Dindo; ARDS, acute respiratory distress syndrome.

	before matching			after matching		
	SEMS (n=21)	PR (n=31)	p	SEMS (n=13)	PR (n=13)	p
Interval from first visit to surgery (day)	17 (15-19)	3 (0-8)	<0.0001	18 (15-19)	5 (0-8)	<0.0001
Surgical procedure			<0.0001			0.001
open	5 (19%)	25 (74%)		3 (23%)	12 (92%)	
laparoscopy	17 (81%)	6 (26%)		10 (77%)	1 (8%)	
conversion	2	2		1	1	
Stoma creation	2 (10%)	10 (32%)	0.09	1 (8%)	5 (38%)	0.16
Operative time (min)	214 (164-259)	193 (148-228)	0.22	220 (164-274)	197 (168-261)	0.50
Blood loss (ml)	69 (19-571)	326 (151-592)	0.01	167 (19-728)	534 (301-817)	0.08
Postoperative complication						
minor (CD I-II)	2 (9%)	4 (13%)	1	1 (8%)	1 (8%)	1
ileus	1	1			1	
superficial surgical site infection	1	1		1		
pneumonia		1				
skin-bladder fistula		1				
major (CD III-IV)	4 (19%)	3 (10%)	0.42	2 (15%)	1 (8%)	1
anastomotic leakage	2			1		
intestinal obstruction	2	2		1		
ARDS		1			1	
Postoperative hospital stay (day)	18 (11-35)	19 (13-27)	0.69	18 (12-35)	22 (15-28)	0.66
Mortality within 30 days	0	1 (3%)	0.41	0	0	
TNM Stage						
IVA	12 (57%)	14 (45%)	0.40	7 (54%)	9 (69%)	0.69

IVB	4 (19%)	5 (16%)	1	1 (8%)	1 (8%)	1
IVC	5 (24%)	12 (39%)	0.37	5 (38%)	3 (23%)	0.67
T factor						
3	2 (10%)	4 (13%)	1	0	0	1
4a	17 (81%)	19 (61%)	0.13	11 (85%)	9 (69%)	0.64
4b	2 (10%)	8 (26%)	0.17	2 (15%)	4 (31%)	0.64
N factor						
0	2 (10%)	9 (29%)	0.17	0	3 (23%)	0.22
1a	6 (29%)	3 (10%)	0.13	4 (31%)	3 (23%)	1
1b	3 (14%)	5 (16%)	1	2 (15%)	2 (15%)	1
2a	4 (19%)	5 (16%)	1	4 (31%)	2 (15%)	0.64
2b	5 (24%)	7 (26%)	1	2 (15%)	3 (23%)	1
lymph node metastasis (n)	2.5 (1-7)	3 (0-6.5)	0.70	3 (1-5.5)	3 (0.5-6.5)	0.62
lymph node dissection (n)	20 (12-31)	12 (6-18)	0.01	20 (14-31.3)	11 (6-14.5)	0.004
Differentiation						
well	6 (29%)	4 (13%)	0.28	2 (15%)	2 (15%)	1
moderate	12 (57%)	25 (81%)	0.07	8 (62%)	11 (85%)	0.38
poorly	3 (14%)	0	0.06	3 (23%)	0	0.22
papillary	0	1 (3%)	1	0	0	1
signet	0	1 (3%)	1	0	0	1
Vascular invasion			0.98			0.77
0	2 (10%)	2 (6%)		1 (8%)	0	
1	6 (29%)	9 (29%)		4 (31%)	5 (38%)	
2	7 (33%)	10 (32%)		3 (23%)	3 (23%)	
3	6 (29%)	10 (32%)		5 (38%)	5 (38%)	
Lymphatic invasion			0.42			0.35
0	10 (48%)	13 (42%)		5 (38%)	4 (31%)	

1	5 (24%)	11 (35%)		2 (15%)	6 (46%)	
2	3 (14%)	6 (19%)		3 (23%)	2 (15%)	
3	3 (14%)	1 (3%)		3 (23%)	1 (8%)	
Adjuvant chemotherapy	19 (90%)	22 (71%)	0.17	12 (92%)	9 (69%)	0.32
targeted agent	15 (71%)	18 (58%)	0.33	10 (77%)	8 (62%)	0.67
bevacizumab	13 (62%)	17 (55%)	0.61	10 (77%)	7 (54%)	0.41
panitumumab	10 (48%)	7 (23%)	0.06	7 (54%)	5 (38%)	0.70
Interval from surgery to next therapy (day)	35 (14-57)	32 (23-49)	0.53	34 (24-55)	26 (18-51)	0.55
Interval from first visit to next therapy (day)	50 (37-71)	40 (27-56)	0.07	50 (37-70)	35 (25-54)	0.14
Resecting synchronous metastasis	3 (14%)	2 (6%)	0.35	3 (23%)	2 (15%)	0.62
Observation period (year)	2.0 (1.3-3.9)	1.4 (0.6-3.2)	0.12	1.8 (1.3-5.0)	1.5 (0.6-3.8)	0.19
3 years survival	44%	30%	0.07	41%	31%	0.19

Figures

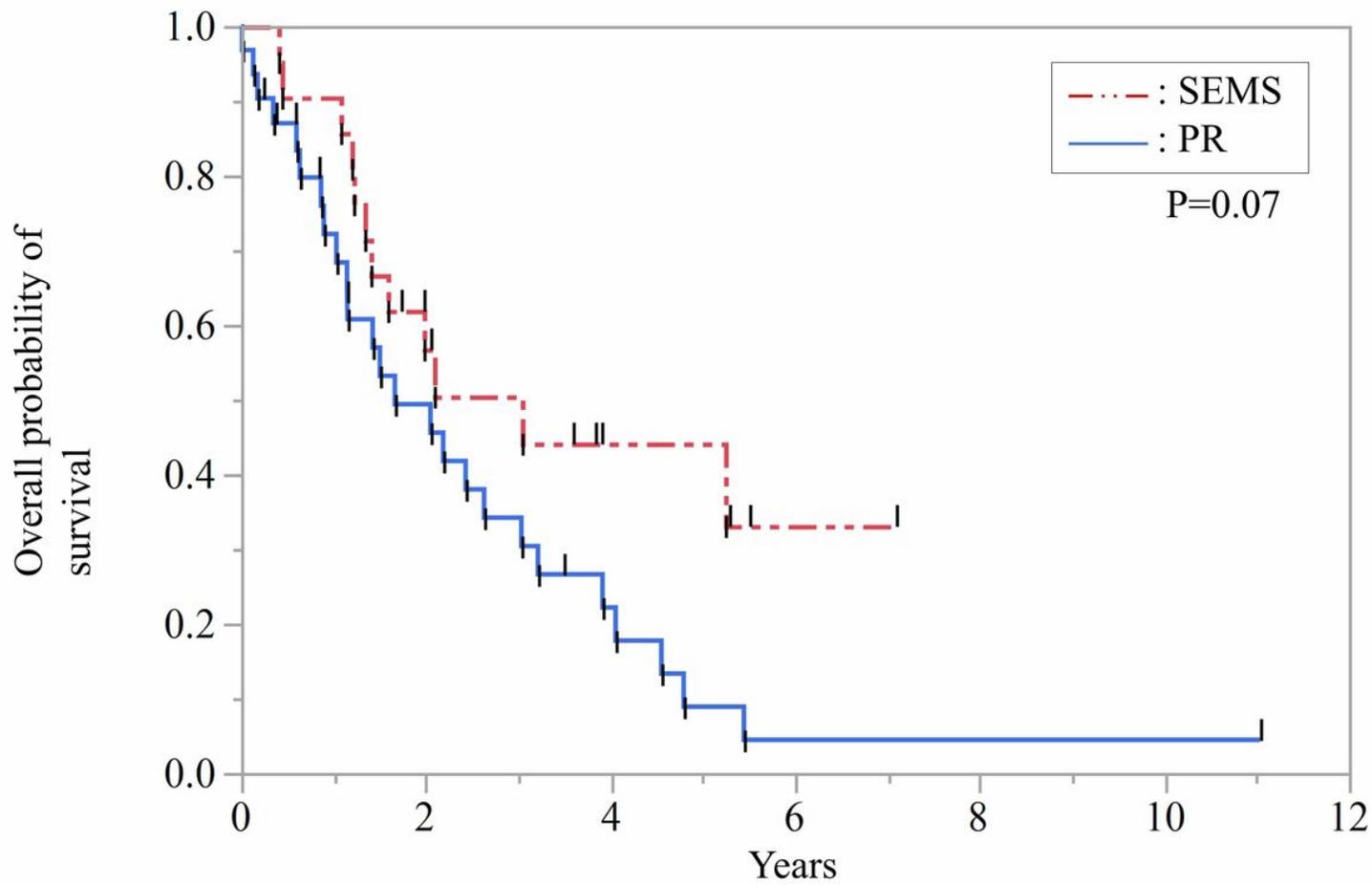


Figure 1

Kaplan-Meier Estimate of survival. SEMS, self-expandable metallic stent; PR, primary resection.

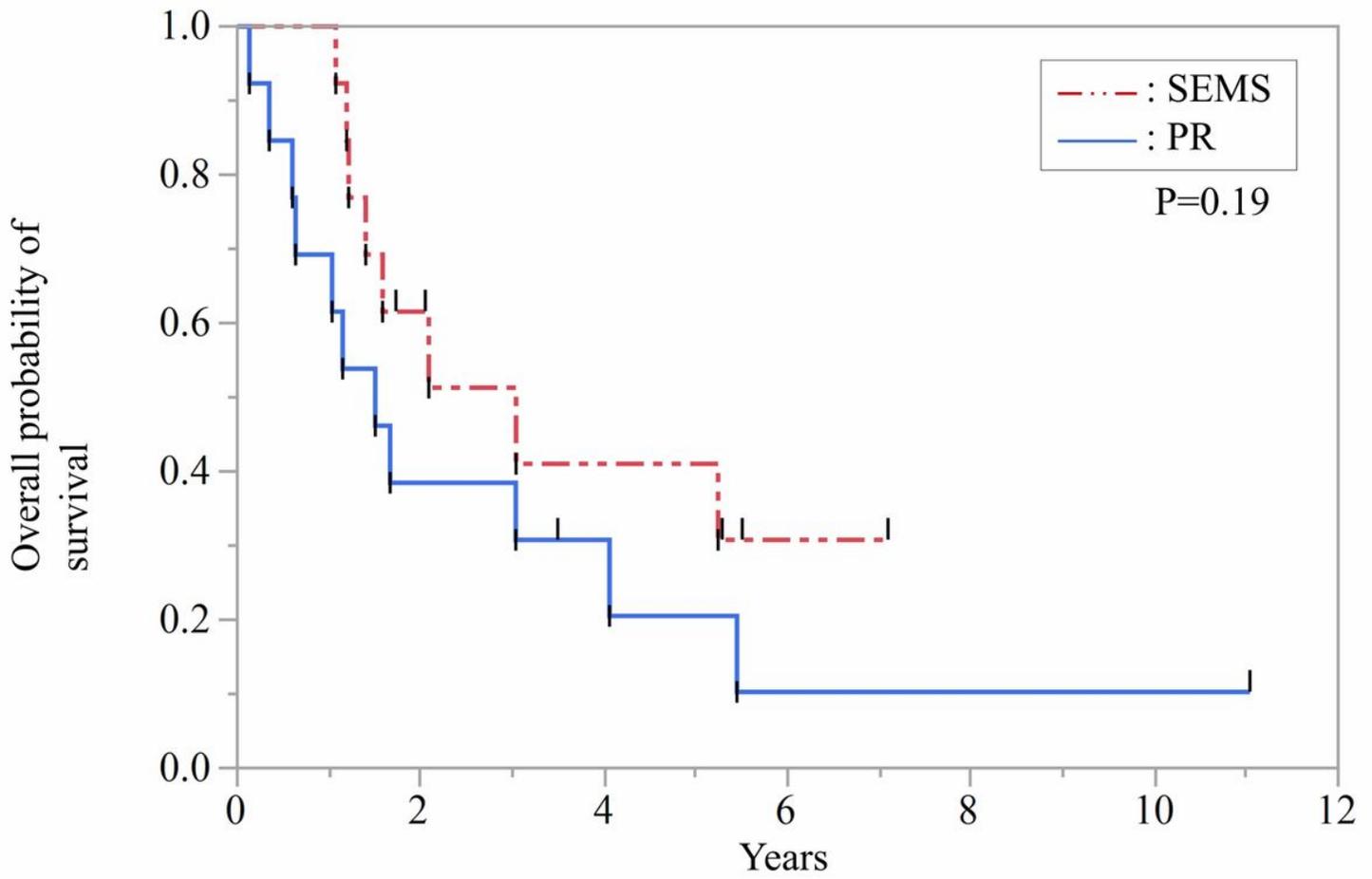


Figure 2

Kaplan-Meier Estimate of survival after propensity score matching. SEMS, self-expandable metallic stent; PR, primary resection.