

## ORIGINAL ARTICLE - ENDOSCOPY

# Optimal Timing of Surgery After Insertion of Self-Expandable Metallic Stent to Obstructive Colorectal Neoplasm as a Bridge to Surgery

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**Received:** 27 February 2025 | **Revised:** 28 March 2025 | **Accepted:** 10 April 2025

**Funding:** This work was supported by Chonnam National University, BCRI-23090 and BCRI-23026.

**Keywords:** colorectal neoplasms | colorectal surgery | intestinal obstruction | self-expandable metallic stents | survival analysis

## ABSTRACT

**Background and Aims:** Colonic stenting using self-expandable metallic stents (SEMS) as a bridge to surgery offers an effective alternative to emergency surgery for the management of malignant colorectal obstruction. However, the optimal timing of elective surgery after stenting remains controversial.

**Methods:** This retrospective multicenter cohort study analyzed 380 patients with obstructive colorectal cancer who were treated with SEMS as a bridge to surgery. Patients were categorized into four groups based on the time from stent insertion to surgery: within 7 days, 8–14 days, 15–21 days, and 22 days or more.

**Results:** The study cohort had a slight male predominance (55.8%), with an average age of 65.8 years. Most surgeries (74.2%) were laparoscopically performed. No significant differences were observed in stoma formation rates or postoperative complications between the different timing groups. Similarly, recurrence-free survival, overall survival, locoregional recurrence, and distant metastasis rates showed no significant variations with the timing of post-stenting surgery. A restricted cubic spline curve indicated that surgery within the 15–21-day period post-SEMS insertion resulted in the lowest incidence of stoma formation.

**Conclusions:** Delaying elective surgery for up to 3 weeks post-SEMS placement for obstructive colorectal cancer is recommended, particularly within the 15–21-day period, to minimize stoma formation rates without compromising on long-term outcomes.

## 1 | Introduction

Malignant colonic obstruction can arise from advanced colorectal cancer (CRC), affecting approximately 8–13% of patients [1–3]. This emergent condition necessitates immediate intervention to alleviate the obstruction. Emergency surgery has traditionally been the cornerstone of treatment. Colonic

stenting using self-expandable metallic stents (SEMS) has emerged as an effective alternative to emergency surgery for the management of malignant obstructions [4]. This minimally invasive procedure can significantly reduce the morbidity and mortality associated with emergency surgery [5, 6]. In cases of curable advanced CRC, colonic stenting serves as a “bridge,” enabling patients to prepare for elective surgery for curative

intent. It allows for medical resuscitation, bowel preparation, optimization of comorbidities, and staging workup for CRC [7, 8]. These advantages are driving the increasing use of colonic stenting.

Elective surgery following colonic stenting requires a careful balance between potential stent-related adverse events and surgical outcomes. Theoretically, a shorter interval between the surgery and stent placement may reduce the incidence of stent-related adverse events. However, a longer interval could potentially optimize nutritional status, manage comorbidities, and improve surgical outcomes. Additionally, delaying surgery may affect tumor recurrence rates, necessitating consideration of this factor in decision-making.

The optimal timing for elective surgery after colonic stenting remains debatable. Some studies advocate earlier surgery, suggesting that delaying surgery increases the risk of metastasis, stent restenosis, and emergency interventions, while performing surgery within 7 days yields superior disease-free and overall survival [9–12]. Conversely, other reports have suggested that delayed surgery leads to fewer surgical complications, better recurrence-free and overall survival rates, increased laparoscopic surgery rates, and reduced stoma formation [13–16]. The 2020 ESGE guidelines suggest a 2-week interval between stent placement and surgery for patients with curable left-sided colon cancer to optimize clinical outcomes, although evidence supporting this recommendation is limited [17].

Therefore, this study aimed to determine the optimal timing of surgery by evaluating both short-term complications and long-term oncological outcomes using long-term follow-up data from a large cohort of patients who underwent colonic stenting as a bridge to surgery.

## 2 | Materials and Methods

### 2.1 | Study Design and Population

This retrospective multi-center cohort study was conducted between January 2009 and February 2018 across six tertiary medical centers (Cheonan Soonchunhyang University Hospital, Chonnam National University Hospital, Chonnam National University Hwasun Hospital, Hallym University Sacred Heart Hospital, Kyung Hee University Hospital, and Seoul St. Mary's Hospital). All participating hospitals were high-volume centers with experienced endoscopists who had performed at least 50 SEMS procedures. The study cohort included patients with curable obstructive colorectal cancer who underwent SEMS placement as a bridging method to relieve obstruction. Exclusion criteria included cases involving SEMS placement for palliation, stage IV cancer, loss to follow-up within 30 days after SEMS placement, SEMS-related perforation, emergency surgery due to SEMS-related complications including stent migration or restenosis, and instances with missing data. The study was approved by the Institutional Review Board of each hospital and was conducted in accordance with the principles outlined in the Declaration of Helsinki. The requirement for informed consent was waived due to the retrospective nature of the study.

The study cohort was categorized into four groups based on the time from SEMS insertion to surgery: within 7 days, 8–14 days, 15–21 days, and 22 days or above.

### 2.2 | SEMS Placement

The SEMS placement adhered to standard procedures [17]. After confirming the malignant stricture endoscopically, a guidewire was passed through it under fluoroscopic guidance, and a contrast tube was introduced into the proximal lumen, followed by the injection of water-soluble contrast medium. The length of the SEMS was determined based on the stricture length and tumor location, with the stent ideally extending beyond the stricture by 1.5–2 cm at each end. Stricture dilatation by ballooning was not performed before or after SEMS placement.

Technical success was defined as SEMS placement at the intended site. Clinical success was defined as bowel lumen decompression. This is indicated by the immediate escape of liquid feces or air through the stent, followed by the subsequent resolution of occlusive symptoms.

### 2.3 | Outcomes Following SEMS Insertion

Outcomes after SEMS insertion were categorized into short- and long-term oncological outcomes. Short-term surgical outcomes included stoma formation, leakage, wound abscesses, and intra-abdominal abscesses. The long-term oncological outcomes included recurrence-free survival, overall survival, locoregional recurrence, and distant metastasis. The recurrence analysis focused on patients who underwent curative surgical resection, with recurrence categorized as either locoregional recurrence or distant metastasis. Although detailed pathological confirmation of R0 versus R1 resection was not consistently available due to the retrospective nature of the study, patients classified as having undergone curative resection were considered to have had R0 resection for the purposes of survival and recurrence analyses.

### 2.4 | Statistical Analysis

Continuous data are presented as the mean  $\pm$  standard deviation or median (range). Categorical data were expressed as absolute and relative frequencies. These data were compared among the four groups, which were categorized based on the interval from SEMS insertion to surgery: within 7 days, 8–14 days, 15–21 days, and 22 days or above. Continuous variables were evaluated using Student's *t* test, while categorical data were analyzed using Fisher's exact test or the chi-squared test. Statistical significance was set at  $p < 0.05$ .

Kaplan–Meier curves were used to evaluate overall survival and recurrence-free survival as well as locoregional and distant recurrences. A predictive model using a restricted cubic spline curve was used to analyze the relationship between the interval from SEMS insertion to surgery and stoma formation. The restricted cubic spline curve illustrates the predicted probability (solid line) and 95% confidence interval (CI; faded line) of stoma formation relative to the time interval between SEMS insertion

and surgery. All statistical analyses were performed using Stata/SE 16.1 software (StataCorp LLC, College Station, Texas, United States) and R software version R3.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

### 3 | Results

#### 3.1 | Patient Demographics and Baseline Characteristics

Among the 1592 patients who underwent SEMs placement for malignant colorectal obstruction, a total of 380 patients were included in the study after excluding the followings cases: SEMs placement for palliation ( $n=405$ ), stage IV cancer ( $n=689$ ), loss to follow-up within 30 days after SEMs placement ( $n=62$ ), SEMs-related perforation ( $n=25$ ), emergency surgery due to SEMs-related complications ( $n=7$ ), and missing data ( $n=24$ ) (Figure 1). The included patients who underwent colonic stenting as a bridge to surgery, divided into four groups based on the time from stent insertion to surgery: within 7 days ( $n=105$ ), 8–14 days ( $n=132$ ), 15–21 days ( $n=74$ ), and 22 days or more ( $n=69$ ). The mean follow-up period was 3.67 years. The interval from SEMs insertion to surgery in the  $\geq 22$ -day group ranged from 22 to 96 days. The average age at the time of SEMs insertion was 65.8 years, with a slight male predominance (55.8%). Significant differences were noted in the Charlson comorbidity index across the groups, with later surgery associated with higher comorbidity scores ( $p < 0.01$ ) (Table 1).

Most patients (74.2%) underwent laparoscopic surgery, whereas 25.8% underwent open surgery, with no significant difference in the surgical approach between the groups (Table 2). Tumor size varied significantly among the groups, with larger tumors observed in patients who underwent surgery at later intervals ( $p < 0.01$ ). In terms of TNM staging, T3 was the most common

tumor type (70.3%). N stage 0 was the most common at 40.3%, followed by N stage 1 at 37.4%, and N stage 2 at 22.4%. There were no cases of TNM stage IV, with stage III being the most prevalent (59.7%), followed by stages II (39.5%) and I (0.8%). Pathological examination revealed moderately differentiated adenocarcinomas (76.8%), followed by well-differentiated adenocarcinomas (16.3%). Curative resection was performed in 98.2% of the patients.

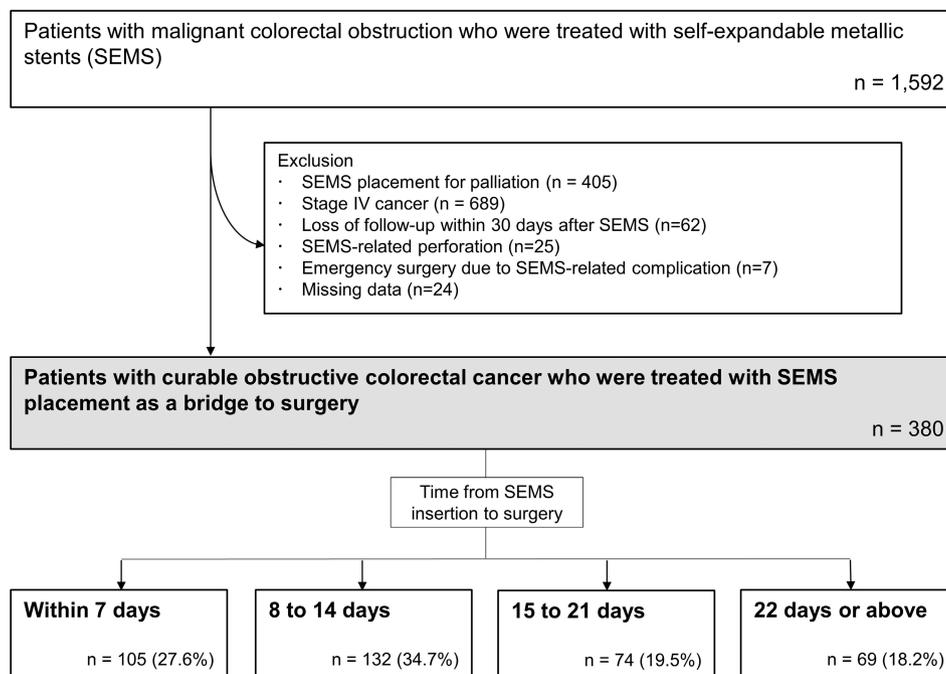
#### 3.2 | Short-Term Surgical Outcomes Following SEMs Insertion

The overall stoma formation was 12.1% (Table 3). Temporary stoma formation occurred in approximately 9.2% of the cases, whereas permanent stoma formation was observed in 2.9% of the cases, with no significant differences across the surgical interval groups. Complication rates, including anastomotic leaks, intra-abdominal abscesses, wound abscesses, peritonitis, renal failure, and pneumonia, were similarly distributed across the groups, with 9.5% of patients experiencing some form of postoperative complication.

Using a restricted cubic spline curve to model the prediction of stoma formation rates based on the time interval between stent insertion and surgery, the rate was found to be approximately 20% when the interval was approximately 0. The rate decreased to below 10% between days 15 and 21 and then increased again after 21 days (Figure 2).

#### 3.3 | Long-Term Oncological Outcomes Following SEMs Insertion

The 3-year and 5-year recurrence-free survival rates of the entire cohort were 77.1% (95% CI, 0.725–0.820) and 73.4% (95% CI, 0.684–0.789), respectively. There was no significant difference



**FIGURE 1** | Flowchart of this study.

**TABLE 1** | Demographics of the included patients.

	Total	-7d	8–14	15–21	22d-
Time to surgery group	(N = 380)	(n = 105)	(n = 132)	(n = 74)	(n = 69)
Age at SEMS insertion (years)	65.8 ± 13.2	63.7 ± 13.9	66.4 ± 13.7	65.5 ± 12.4	68.3 ± 11.9
Male	212 (55.8%)	50 (47.6%)	74 (56.1%)	52 (70.3%)*	36 (52.2%)
Charlson comorbidity index	3.8 ± 1.9	3.0 ± 1.7	3.7 ± 1.8*	4.1 ± 1.8**	4.8 ± 1.7**
Tumor location					
Ascending colon	12 (3.2%)	8 (7.6%)	4 (3.0%)	0 (0.0%)	0 (0.0%)
Hepatic flexure	6 (1.6%)	2 (1.9%)	3 (2.3%)	1 (1.4%)	0 (0.0%)
Transverse colon	20 (5.3%)	8 (7.6%)	7 (5.3%)	5 (6.8%)	0 (0.0%)
Splenic flexure	19 (5.0%)	7 (6.7%)	7 (5.3%)	1 (1.4%)	4 (5.8%)
Descending colon	52 (13.7%)	16 (15.2%)	14 (10.6%)	11 (14.9%)	11 (15.9%)
Sigmoid colon	211 (55.5%)	51 (48.6%)	81 (61.4%)	45 (60.8%)	34 (49.3%)
Rectum	60 (15.8%)	13 (12.4%)	16 (12.1%)	11 (14.9%)	20 (29.0%)
Technical success of SEMS insertion	380 (100%)	105 (100.0%)	132 (100%)	74 (100.0%)	69 (100.0%)
Clinical success of SEMS insertion	375 (98.7%)	105 (100.0%)	127 (96.2%)	74 (100.0%)	69 (100.0%)

Abbreviation: SEMS, self-expandable metal stent.

\* $p < 0.05$ , compared to the within 7-day group. \*\* $p$  value  $< 0.01$  compared to the within 7-day group.

in recurrence-free survival among the different time points ( $p = 0.33$ ) (Figure 3A). The 3-year and 5-year overall survival rates of the entire cohort were 83.0% (95% CI, 0.788–0.873) and 71.8% (95% CI, 0.663–0.778), respectively. There was no significant difference in overall survival across different time points ( $p = 0.55$ ) (Figure 3B).

There was no significant difference in the location of recurrence between the groups for locoregional recurrence ( $p = 0.88$ ) or distant metastases ( $p = 0.22$ ) (Figure 4A,B).

#### 4 | Discussion

This study analyzed the short- and long-term outcomes related to the interval between SEMS insertion and curative resection for colorectal malignant neoplasms, focusing on colostomy rates, surgical complications, recurrence, and survival. In the baseline characteristics of each group, an increase in the interval from SEMS insertion to surgery was significantly associated with a higher Charlson comorbidity index but showed no significant relationship with age. Additionally, there was no significant correlation between the interval and tumor location or with the technical and clinical success rates of SEMS insertion.

The overall stoma formation rate was 12.1%, with the 15–21-day interval group experiencing a notably lower rate of 5.4% than the other groups, although this difference was not statistically significant. To further analyze the relationship between stoma formation and the interval from SEMS insertion to surgery, we developed a predictive model using a restricted cubic spline curve. This curve provides a linear prediction model that provides an intuitive understanding of this relationship. According

to the model, the predicted stoma formation rate was approximately 20% when the surgical interval was close to 0 day. In contrast, performing surgery 15–21 days after SEMS insertion resulted in the lowest stoma formation rate ( $< 10\%$ ). However, as the interval extended beyond this period, the stoma formation rate increased.

The optimal timing of surgery after colonic stent insertion remains under discussion, with no definitive consensus on the ideal interval between stent placement and surgical intervention. Over time, the guidelines have been updated to provide new insights. The 2014 ESGE guidelines recommend elective surgery within 5–10 days of SEMS insertion [18]. However, the 2020 ESGE guidelines revised this recommendation to approximately 2 weeks post-SEMS insertion [17]. These guideline changes reflect ongoing evaluations of the optimal surgical timing and are based on retrospective research findings published since 2014. These changes underscore the continuous reassessment of the balance between surgery-related adverse events and the risks of systemic and local tumor recurrence associated with different surgical timings.

Studies have indicated that a shorter interval between SEMS insertion and surgery can decrease the risk of metastasis and improve disease-free and overall survival. Broholm et al. reported that delaying elective surgery for 18 days or more after SEMS insertion may increase the risk of metastasis [10]. Kye et al. conducted a study dividing the interval between stenting and surgery into three groups: within 7 days, 8–14 days, and 15 days or more. Their findings showed that the group that underwent surgery within 7 days had superior disease-free and overall survival rates, with similar rates of short-term postoperative complications across all groups [11].

**TABLE 2** | Surgical characteristics and pathology-related variables.

	Total (N = 380)	-7d (n = 105)	8-14 (n = 132)	15-22 (n = 74)	22- (n = 69)
<b>Time to surgery group</b>					
Time from SEMS insertion to surgery (days)	14.9 ± 13.0	5.1 ± 1.6	10.6 ± 2.1**	17.9 ± 1.9**	34.8 ± 18.0**
<b>Surgical approach</b>					
Open	98 (25.8%)	24 (22.9%)	40 (30.3%)	20 (27.0%)	14 (20.3%)
Laparoscopic	282 (74.2%)	81 (77.1%)	92 (69.7%)	54 (73.0%)	55 (79.7%)
Tumor size (cm)	6.0 ± 2.0	5.5 ± 2.0	5.6 ± 1.8	6.3 ± 1.9*	6.9 ± 1.9**
<b>pT</b>					
1	2 (0.5%)	1 (1.0%)	1 (0.8%)	0 (0.0%)	0 (0.0%)
2	2 (0.5%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
3	267 (70.3%)	75 (71.4%)	94 (71.2%)	51 (68.9%)	47 (68.1%)
4	109 (28.7%)	28 (26.7%)	37 (28.0%)	23 (31.1%)	21 (30.4%)
<b>pN</b>			**		
0	153 (40.3%)	28 (26.7%)	60 (45.5%)	35 (47.3%)	30 (43.5%)
1	142 (37.4%)	45 (42.9%)	49 (37.1%)	21 (28.4%)	27 (39.1%)
2	85 (22.4%)	32 (30.5%)	23 (17.4%)	18 (24.3%)	12 (17.4%)
<b>pStage</b>			*	*	
I	3 (0.8%)	2 (1.9%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
II	150 (39.5%)	26 (24.8%)	60 (45.5%)	35 (47.3%)	29 (42.0%)
III	227 (59.7%)	77 (73.3%)	72 (54.5%)	39 (52.7%)	39 (56.5%)
<b>Histology</b>				*	**
Adenocarcinoma, WD	62 (16.3%)	9 (8.6%)	13 (9.8%)	20 (27.0%)	20 (29.0%)
Adenocarcinoma, MD	292 (76.8%)	84 (80.0%)	113 (85.6%)	48 (64.9%)	47 (68.1%)
Adenocarcinoma, PD	12 (3.2%)	5 (4.8%)	4 (3.0%)	2 (2.7%)	1 (1.4%)
Others	14 (3.7%)	7 (6.7%)	2 (1.5%)	4 (5.4%)	1 (1.4%)
<b>Curative resection</b>					
Yes	373 (98.2%)	101 (96.2%)	131 (99.2%)	73 (98.6%)	68 (98.6%)

Abbreviations: MD, moderately differentiated; PD, poorly differentiated; WD, well differentiated.

\* $p < 0.05$ , compared to the within 7-day group; \*\* $p$  value  $< 0.01$  compared to the within 7-day group.

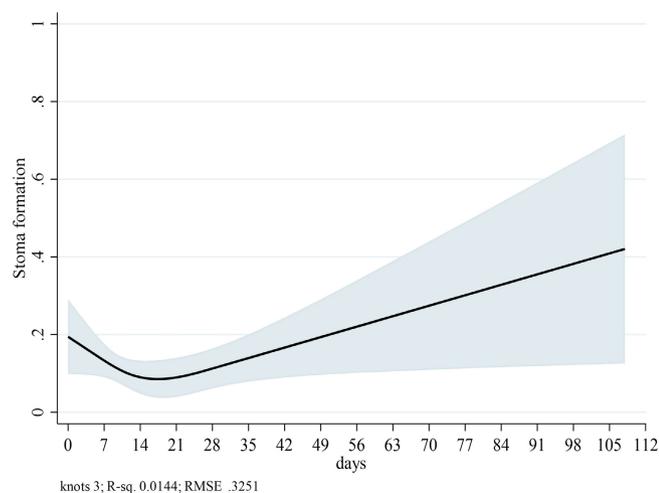
Conversely, some studies have suggested that a slight delay in surgery may be beneficial. Matsuda et al. reported that an operation interval of  $> 15$  days reduced operation-related complications, such as anastomotic site leakage [14]. Lee et al. reported that the risk of anastomotic leakage significantly decreased when surgery was delayed by at least 10 days [13]. De Roos et al. found that patients who had surgery 4 weeks or more after SEMS insertion had significantly better 5-year recurrence-free survival (82.1% vs. 63.2%) and overall survival (75% vs. 51.4%) than those who had surgery within 4 weeks [15]. Additionally, Oh et al. found that while the interval between SEMS insertion and surgery did not affect complications, mortality, or survival outcomes, the immediate stoma formation rates were significantly higher in the  $\leq 2$  weeks group (21.3%) than those in the 2–3 weeks and  $> 3$  weeks groups (2.3% and 6.9%, respectively) [16].

The results of previous studies vary widely, making it difficult to determine the appropriate interval between SEMS insertion and surgery. Additionally, the relatively small number of patients enrolled in these studies (ranging from 47 to 174) was insufficient for proper evaluation of the interval. In contrast, our study analyzed data from over 10 years across six large-volume centers involving a total of 380 patients. This sample size was more than twice that of the largest previously reported cohort of 174 patients, providing a relatively reliable dataset for analysis. In this study, although no significant differences were observed in the long-term outcomes, such as recurrence-free survival, overall survival, local recurrence, and distant metastasis, based on the interval between SEMS insertion and surgery, surgeries performed between 15 and 21 days after SEMS insertion were associated with a relatively lower rate of stoma formation.

**TABLE 3** | Short-term outcomes of surgery.

Time to surgery group	Total (N = 380)	-7d (n = 105)	8-14 (n = 132)	15-22 (n = 74)	22- (n = 69)
Stoma formation					
No	334 (87.9%)	91 (86.7%)	115 (87.1%)	70 (94.6%)	58 (84.1%)
Temporary	35 (9.2%)	11 (10.5%)	14 (10.6%)	3 (4.1%)	7 (10.1%)
Permanent	11 (2.9%)	3 (2.9%)	3 (2.3%)	1 (1.4%)	4 (5.8%)
Stoma formation_any					
No	334 (87.9%)	91 (86.7%)	115 (87.1%)	70 (94.6%)	58 (84.1%)
Yes	46 (12.1%)	14 (13.3%)	17 (12.9%)	4 (5.4%)	11 (15.9%)
Complication					
Anastomosis leak	4 (1.1%)	1 (1.0%)	0 (0.0%)	1 (1.4%)	2 (2.9%)
Intra-abdominal abscess	1 (0.3%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)
Wound abscess	15 (3.9%)	3 (2.9%)	6 (4.5%)	4 (5.4%)	2 (2.9%)
Peritonitis	5 (1.3%)	1 (1.0%)	0 (0.0%)	3 (4.1%)	1 (1.4%)
Renal failure	1 (0.3%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Pneumonia	6 (1.6%)	1 (1.0%)	2 (1.5%)	0 (0.0%)	3 (4.3%)
Others	4 (1.1%)	1 (1.0%)	2 (1.5%)	0 (0.0%)	1 (1.4%)
Complication_any					
No	344 (90.5%)	97 (92.4%)	122 (92.4%)	65 (87.8%)	60 (87.0%)
Yes	36 (9.5%)	8 (7.6%)	10 (7.6%)	9 (12.2%)	9 (13.0%)

\* $p < 0.05$ , compared to the within 7-day group; \*\* $p$  value  $< 0.01$  compared to the within 7-day group.

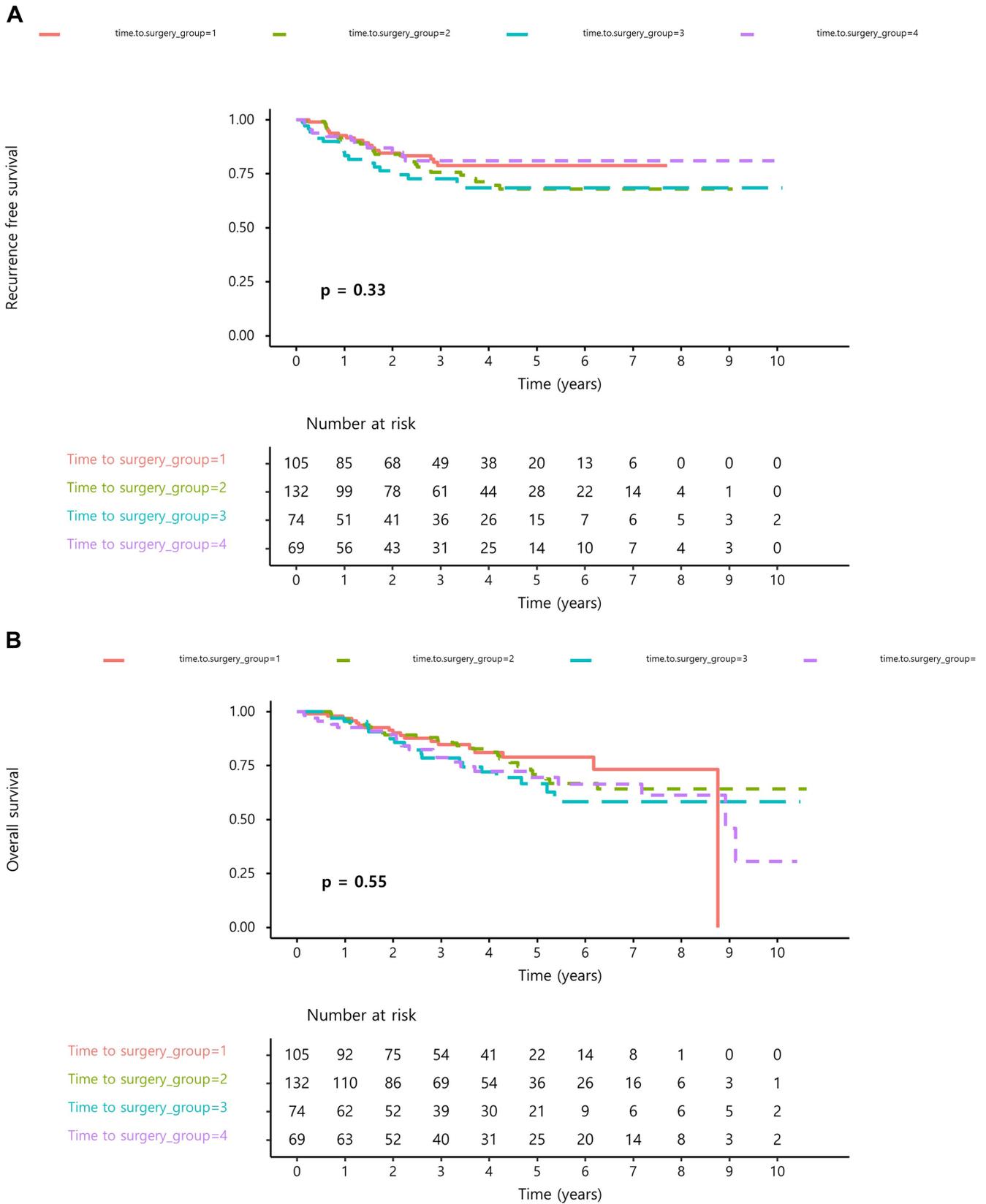


**FIGURE 2** | Spline cubic curve of colostomy formation based on the interval between stent insertion and surgery.

The lower stoma formation rate observed in the 15–21-day SEMS to surgery interval may be attributed to several factors. This period likely provides sufficient time for the bowel to recover from the initial obstruction and stent placement, reduces inflammation, and allows better healing, thereby lowering the risk of complications that necessitate a stoma. Additionally, this window allows for adequate preoperative optimization of the patient,

including nutritional support and management of comorbidities, which can improve the overall surgical outcomes and reduce the need for a stoma. Moreover, patients with an SEMS-to-surgery interval  $> 21$  days had a significantly higher Charlson comorbidity index score, indicating that delayed surgery might have occurred in patients with more comorbidities. This may reflect a selection bias in which patients with greater comorbidity burden and older age were more likely to undergo delayed surgery due to higher perceived surgical risk. Such delays could have contributed to an increased rate of stoma formation in this group, independent of the optimal surgical interval. These patients may have impaired wound healing, leading to a high rate of stoma formation. Although the 15–21-day interval group showed the lowest stoma formation rate, this may in part reflect the relatively favorable general condition of patients in this group. If patients with poor nutritional or functional status had been more prevalent in this group, the outcomes may have differed. However, due to the retrospective design of the study, comprehensive data on nutritional status or frailty were not available.

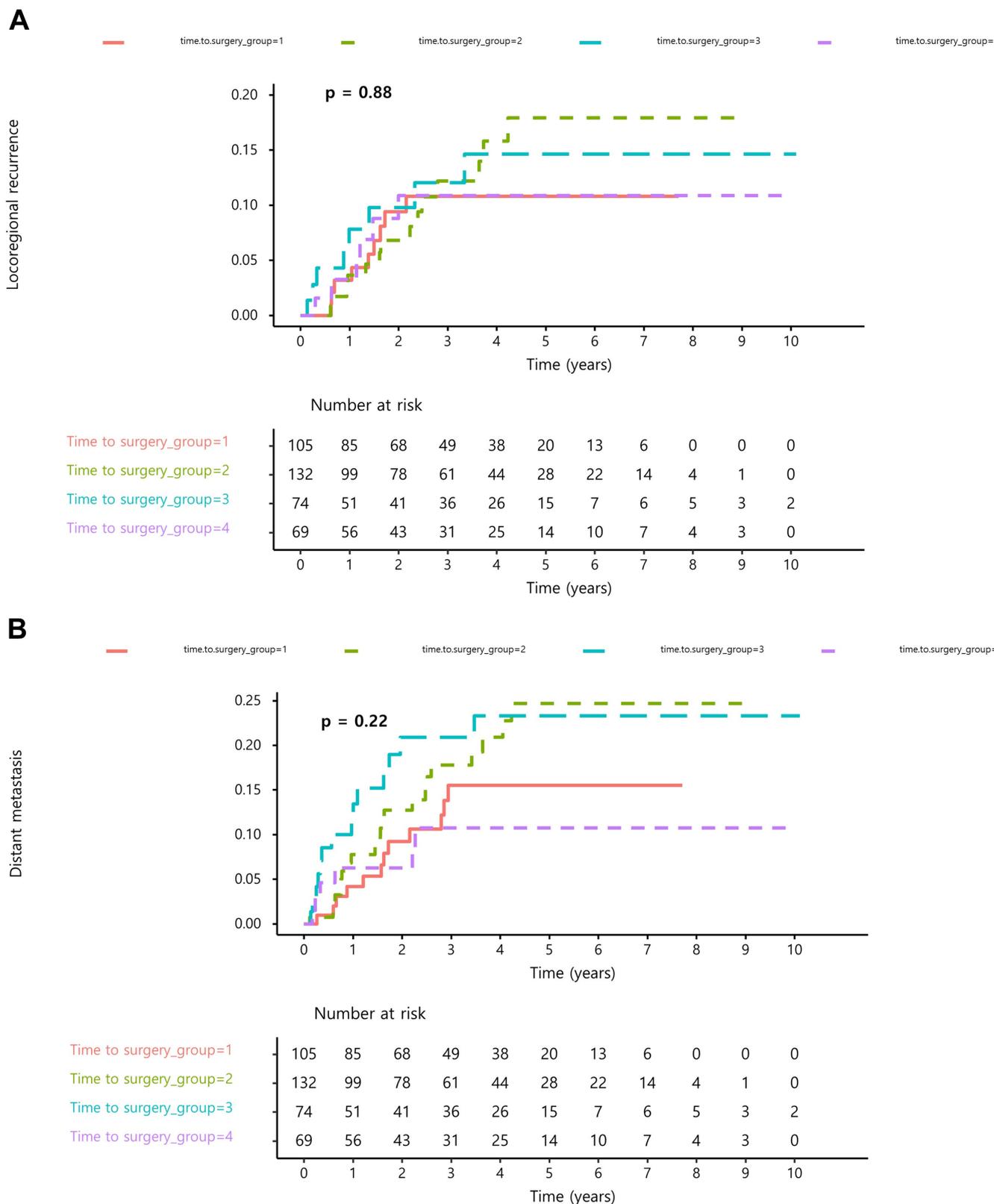
The strengths of our study include its large sample size and multicenter design, which enhanced the generalizability and reliability of the findings. By analyzing data from over 10 years across six high-volume centers, our study provides a robust dataset that surpasses the number of patients reported in previous studies. However, the retrospective nature of this study introduced potential biases related to data collection and patient



**FIGURE 3** | (A) Recurrence-free survival based on the four interval groups. (B) Overall survival based on the four interval groups. Both graphs were created using Kaplan–Meier analysis.

selection, and the lack of randomization may have affected the comparability of baseline characteristics across groups. Additionally, the higher Charlson comorbidity index in patients with longer intervals suggests a possible bias towards delayed

surgery, which could influence outcomes. Future prospective studies with randomized designs are required to provide more definitive evidence regarding the optimal timing of surgery after SEMs placement.



**FIGURE 4** | (A) Locoregional recurrence rate based on the four interval groups. (B) Distant metastasis rate based on the four interval groups. Both graphs were created using Kaplan–Meier analysis.

## 5 | Conclusion

In conclusion, delaying elective surgery to 15–21 days after post-SEMS placement for obstructive colorectal cancer is associated

with a lower rate of stoma formation and does not compromise surgical safety or oncological outcomes. This timing allows for optimal bowel recovery and patient preparation, suggesting a tailored approach for scheduling surgery.

## Author Contribution

D. H. K.: study conceptualization, design, data analysis, and drafting of the manuscript. H.L., J.-W.K., Y.J., K.H.-K., and J.W.K.: data collection. H.-S.K.: revision of the manuscript. Y.-E. J and B.-I.L.: review and editing of the manuscript. H.H.L: study supervision; editing, review, and finalization of the manuscript. All the authors have full access to all of the data and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors have read and approved this.

## Acknowledgments

Nothing to declare.

## Conflicts of Interest

The authors declare no conflicts of interest.

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