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SYSTEMATIC REVIEW

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Long-term outcomes between self-expandable metallic stent and transanal decompression tube for malignant large bowel obstruction: A multicenter retrospective study and meta-analysis

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Abstract

Aim: To compare the oncological outcomes between self-expandable metallic stent (SEMS) as a bridge to surgery and transanal decompression tube (TDT) placement for malignant large bowel obstruction (MLBO).

Methods: A total of 287 MLBO patients who underwent SEMS (n = 137) or TDT placement (n = 150) were enrolled in this multicenter retrospective study. Overall survival (OS) and disease-free survival (DFS) between the two groups were compared. A meta-analysis was performed using random-effects models to calculate odd ratios (OR) with 95% confidence intervals (CIs).

Results: Postoperative complications of Clavien–Dindo grade ≥II and ≥III occurred frequently in the TDT group compared with the SEMS group (P = 0.002 and 0.005, respectively). The 3-y OS in the overall cohort and 3-y DFS in the pathological stage II/III cohort in the SEMS and TDT groups were 68.6% and 71.4%, and 71.0% and 72.6%, respectively. The survival differences were not significantly different in the OS and DFS analyses (P = 0.819 and P = 0.892, respectively). A meta-analysis of nine studies (including our cohort data) demonstrated no significant difference between the SEMS and TDT groups for 3-y OS and DFS (OR = 0.96, 95% CI = 0.57–1.62, P = 0.89 and OR = 0.69, 95% CI = 0.46–1.04, P = 0.07, respectively).

Conclusion: Our study demonstrated that SEMS placement had no inferiority regarding long-term outcomes, including OS and DFS, compared with TDT placement. Considering the short-term benefits of SEMS placement, this could be a preferable preoperative decompression method for MLBO.

KEYWORDS
bridge to surgery, long-term outcome, malignant large bowel obstruction, self-expandable metallic stents, transanal decompression tube

1 | INTRODUCTION

Malignant large bowel obstruction (MLBO), which is one of the main causes of oncological emergencies among gastroenterological cancers, occurs in 10% of patients with primary colorectal cancer (CRC).[1] Conventional emergency surgery for MLBO is associated with unacceptably high morbidity, mortality, and deterioration of patients' quality of life because of the high stoma creation rate.[2] To improve the surgical outcomes, various preoperative intestinal decompression devices, including self-expandable metallic stent (SEMS) and transanal decompression tubes (TDT), were developed. SEMS placement followed by elective surgery (ie, bridge to surgery [BTS]) has been introduced and has spread rapidly worldwide. The BTS strategy using SEMS prevents high-risk emergency surgery and may allow full preoperative staging, screening for synchronous proximal lesions, and appropriate bowel preparation. The authoritative guidelines from the European Society of Gastrointestinal Endoscopy (ESGE) recommend BTS using SEMS for MLBO through shared-decision making.[3] Although the influence on long-term outcomes is undetermined, two recent randomized controlled trials (ie, ESCO[4] and CReST[5] trials) comparing BTS using SEMS with emergency surgery demonstrated equivalent oncological outcomes for disease-free survival (DFS), overall survival (OS), and recurrence.

TDT also avoids two-stage surgery for MLBO, and has short-term postoperative advantages and noninferior long-term outcomes compared with emergency surgery.[6,7] However, TDT use has been limited to predominantly south-east Asian countries, such as Japan and China. Furthermore, some institutes stubbornly continue to use TDT because of concerns about the long-term prognosis with SEMS placement. Recently, a meta-analysis of short-term outcomes between BTS using SEMS and TDT clarified the benefits of SEMS regarding laparoscopic one-stage surgery without stoma creation, and equivalent morbidity and mortality. However, the long-term outcomes have not been evaluated.[8]

The aim of this multicenter retrospective cohort study and comprehensive meta-analysis, including this cohort study data, was to compare oncological outcomes between SEMS and TDT in MLBO patients and to draw a definitive conclusion.

2 | MATERIALS AND METHODS

2.1 | Patients and eligibility

The medical records of MLBO patients who had undergone SEMS or TDT placement followed by surgery from January 2005 to December 2019 in the three Departments of Surgery of the Nippon Medical School Hospitals (Main Hospital, Chiba Hokusoh Hospital, and Musashikosugi Hospital) were reviewed. When the national insurance in Japan began to cover SEMS placement for MLBO in January 2012, a rough transition in our choice of decompression device from a TDT to a SEMS was observed. The choice of either decompression device was basically dependent on the physicians' decisions. MLBO was diagnosed on the basis of the following symptoms and findings: (1) symptoms of abdominal pain, fullness, vomiting, and constipation; (2) contrast-enhanced computed tomography findings of colonic dilatation caused by obstructive primary colorectal cancer; and (3) endoscopic findings of an obstructive primary colorectal tumor. Left-sided lesions were defined as CRC located distal to the splenic flexure. Patients who underwent initial emergency surgery and temporary stoma creation were excluded. The patients' demographic baseline and surgical data were collected retrospectively. This study was performed in accordance with the Helsinki Declaration. The requirement for written informed consent for inclusion in the study was waived because the study was retrospective in design. The study protocol was approved by the three Ethics Committees of Nippon Medical School.

2.2 | Endoscopic procedures and preoperative management

Under fluoroscopic and endoscopic guidance, a guidewire (0.052 inches in diameter for TDT; 0.035 inches in diameter for SEMS) was introduced through the tumor beyond the point of the obstruction and proximally to the distended colon. For TDT placement, we used a Dennis Colorectal Tube (22-Fr outer diameter and 120-cm length; Nippon Sherwood, Tokyo, Japan). For SEMS placement, all SEMS were uncovered and comprised WallFlex (Boston Scientific, Marlborough, MA, USA), Niti-S (Taewoong Medical, Gimpo, South Korea), HANAROSTENT Naturfit (Boston Scientific), or JENTLLY (Japan Lifeline, Chiba, Japan). The particular SEMS product, size, and diameter were determined by the endoscopist performing the procedure. Clinical success with TDT or SEMS placement, which was defined as radiological resolution of the obstruction with no TDT or SEMS-related complications or need for endoscopic reintervention or emergency surgery, was assessed until definitive surgery was performed. All surgery-related complications were recorded daily by attending physicians during the patients' hospital stays and from the first visit to the outpatient clinic until 30 d after surgery. Surgery-related complications were classified in accordance with the Clavien–Dindo (CD) grading system.[9] The postoperative surveillance program adhered to the Japanese guidelines available at the time of the study.

2.3 | Statistical analysis

Continuous data are expressed as median with interquartile range (IQR). A two-tailed Student's *t*-test or the Mann–Whitney *U* test was used to compare continuous variables, whereas the χ^2 and Fisher's exact tests were used to compare discrete variables. DFS and OS were calculated using the Kaplan–Meier method, and the results were compared statistically using the log-rank test. A P value of <0.05 was considered to denote statistical significance.

2.4 | Systematic review and meta-analysis

The meta-analysis was designed in accordance with the 2020 Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[10] A comprehensive electronic literature search was performed to October 2022 using MEDLINE (PubMed), the Cochrane Central Register of Controlled Trials (CENTRAL), Google Scholar, and Ichushi (database of Japanese articles). The search was performed by independent investigators (A.M. and G.T.) using the keyword terms "colorectal neoplasms" AND ("colonic stent" OR "self-expandable metallic stent" OR "transanal tube") AND "surgery" AND "survival." Studies that compared long-term outcomes between SEMS or TDT placement followed by primary tumor resection were included in this meta-analysis. The quality of each included study was assessed using the Methodological Index for Non-Randomized Studies (MINORS) score.[11] Pooled odds ratios (ORs), representing the odds of an adverse event occurring with SEMS placement compared with TDT placement, were calculated using the DerSimonian–Laird random-effects model along with 95% confidence intervals (95% CIs). An OR of <1 favored the SEMS group, and the point estimate of the OR was considered statistically significant at $P<0.05$ if the 95% CI did not include the value 1. Cochran's chi square-based Q test and the I^2 statistic were used to test interstudy heterogeneity; χ^2 $P<0.05$ and $I^2 \geq 50\%$ indicated heterogeneity. Publication bias was assessed by visual analysis of funnel plot symmetry. The meta-analysis was performed using Review Manager v. 5.4 for Windows (Nordic Cochrane Center, Cochrane Collaboration; Copenhagen, Denmark; http://www.ccims.net/RevMan).

3 | RESULTS

3.1 | Characteristics of the study cohort

A total of 287 patients with MLBO who underwent SEMS ($n = 137$) or TDT ($n = 150$) placement followed by primary tumor resection were retrospectively included in this study. The patients' characteristics are shown in Table 1. Comparing the tumor location, the SEMS group had more right-sided tumors compared with the TDT group ($P = 0.001$). The SEMS group had significantly higher preoperative albumin levels than the TDT group (median; 3.4 vs 3.2 g/dL, respectively) ($P = 0.004$). The interval between decompression and surgery in the SEMS group was significantly longer than that in the TDT group (median; 20 vs 8 d, respectively) ($P<0.001$). The SEMS group had a significantly higher proportion of patients who underwent laparoscopic surgery and, consequently, a longer operation time and less intraoperative blood loss compared with the TDT group ($P<0.001$, <0.001, and 0.003, respectively). Significantly higher rates for primary tumor resection and anastomosis, and lower stoma creation were observed in the SEMS group compared with the TDT group (both, $P<0.001$). Pathological stage and curability rates were not significantly different between the groups.

3.2 | Decompression and surgery-related short-term outcomes

The details of decompression- and surgery-related complications are shown in Table 2. Regarding the decompression-related complications, the clinical success rate was significantly higher in the SEMS group than that in the TDT group ($P<0.001$). The TDT group experienced significantly more frequent perforation compared with the SEMS group (8 (5.3%) and 1 (0.7%) patients, respectively; $P = 0.038$). Regarding the surgery-related complications, surgical site infection and complications of CD grade ≥II and ≥III occurred more often in the TDT group compared with the SEMS group ($P = 0.003$, 0.002, and 0.005, respectively); however, the anastomotic leakage rate did not differ significantly between the groups ($P = 0.262$). Deaths occurred in only the TDT group (two patients). The length of postoperative hospital stay was significantly shorter in the SEMS group than that in the TDT group ($P<0.001$).

3.3 | Long-term outcomes in the SEMS and TDT groups

The median follow-up period for the included patients was 36.7 (11.8–61.2) mo. The Kaplan–Meier curves for OS and DFS in the SEMS and TDT groups are shown in Figure 1A,B. DFS analysis was performed using data for patients with pathological stage II and III MLBO (SEMS: $n = 100$ and TDT: $n = 106$). The 3-y OS rates in the SEMS and TDT groups were 68.6% and 71.0%, respectively, and the 3-y DFS rates were 71.4% and 72.6%, respectively. Survival did not differ significantly different between the groups in the OS and DFS analyses ($P = 0.819$ and $P = 0.892$, respectively). In the subgroup analyses of left- and right-sided MLBO, no significant differences were observed for OS ($P = 0.774$ and $P = 0.516$, respectively) (Figure 2A,B). To assess the impact of postoperative complications on long-term outcomes, the SEMS and TDT groups were divided into patients with and without CD grade ≥II postoperative complications. Postoperative complications had a statistically significant negative impact on OS in patients with SEMS placement; the impact was not statistically significant with TDT placement ($P = 0.004$ and $P = 0.444$, respectively) (Figure 3A,B). Details of recurrence patterns in patients with pathological stage II and III MLBO were shown in Table 3. The recurrence pattern including peritoneal dissemination was similar in the two groups.

3.4 | Literature review and included studies in the meta-analysis

The initial screening using the search terms listed earlier identified 134 citations. After reviewing article titles and abstracts, and following full-text evaluation, we extracted eight studies for a total of nine studies (including our study data) included in the meta-analysis

TABLE 1 The patients' characteristics in the TDT and SEMS groups

Variables	TDT group (*n* = 150)	SEMS group (*n* = 137)	*P* value
Age (ys)[a]	71.0 (60.3–78.0)	71.0 (65.0–80.0)	0.155
Sex (male: female) (%)	90 (60.0):60 (40.0)	78 (56.9):59 (43.1)	0.632
Body mass index (kg/m^2)[a]	20.5 (18.4–22.8)	20.9 (19.2–23.0)	0.598
Location (right:left-sided) (%)	20 (13.3):130 (86.7)	40 (29.2):97 (70.8)	0.001
Cecum (%)	0 (0)	0 (0)	
Ascending (%)	2 (1.3)	18 (13.1)	
Transverse (%)	19 (12.7)	22 (16.1)	
Descending (%)	14 (9.3)	17 (12.4)	
Sigmoid (%)	76 (50.7)	44 (32.1)	
Rectum (%)	39 (26.0)	36 (26.3)	
ASA score (I/II/III) (%)	19 (12.7)/96 (64.0)/33 (22.0)	13 (9.5)/105 (76.6)/19 (13.9)	0.090
Preoperative albumin (g/dL)[a]	3.2 (2.9–3.6)	3.4 (3.1–3.8)	0.004
Interval between decompression and surgery (d)[a]	8 (4.0–13.0)	20 (13.0–29.0)	<0.001
Surgical approach (open:lap) (%)	122 (81.3):28 (18.7)	33 (24.1):104 (75.9)	<0.001
Operation time (min)[a]	200 (151–253)	241 (180–306)	<0.001
Blood loss (ml)[a]	100 (40–354)	30 (30–130)	0.003
Primary tumor resection and anastomosis (%)	105 (70.0)/45 (30.0)	127 (92.7)/10 (7.3)	<0.001
Stoma creation (including temporary creation) (yes:no) (%)	50 (33.3):100 (66.7)	18 (13.1):119 (86.9)	<0.001
Pathological stage (II/III/IV)[b] (%)	50 (33.3)/56 (37.3)/44 (29.3)	43 (31.4)/57 (41.6) /37 (27.0)	0.756
Surgical curability (Cur A, B/C)[b]	102 (68.0)/6 (4.0)/42 (28.0)	96 (70.1)/10 (7.3)/31 (22.6)	0.321

Abbreviations: ASA, American Society of Anesthesiologists; SEMS, self-expandable metallic stent; TDT, transanal decompression tube.
[a]Median (interquartile range).
[b]Japanese Classification of Colorectal, Appendiceal, and Anal Carcinoma, 9th edition.

TABLE 2 Details of decompression- and surgery-related complications

Variables	TDT group (*n* = 150)	SEMS group (*n* = 137)	*P* value
Decompression-related			
Clinical success (%)	112 (74.7)	128 (93.4)	<0.001
Bleeding (%)	0 (0)	1 (0.7)	0.477
Perforation (%)	8 (5.3%)	1 (0.7)	0.038
Migration (%)	1 (0.7%)	5 (3.6)	0.107
Surgery-related			
Anastomotic leakage (%)	9 (6.0)	4 (4.5)	0.262
SSI (%)	31 (20.7)	11 (9.0)	0.003
Ileus (%)	16 (10.7)	9 (6.6)	0.295
Clavien–Dindo grading			
≥ II (%)	49 (32.7)	22 (16.1)	0.002
≥ III (%)	31 (20.7)	12 (8.8)	0.005
V (%)	4 (2.7)	0 (0)	0.124
Postoperative hospital stay (d)[a]	17 (12–30)	12 (10–16)	<0.001

Abbreviations: SEMS, self-expandable metallic stent; SSI, Surgical site infection; TDT, transanal decompression tube.
[a]Median (interquartile range).

(date of publication from 2018). The detailed characteristics of the included studies are shown in Table 4. All included studies originated from Japan and all had a retrospective study design. Among the eight[12–19] extracted published studies, seven[12–15,17–19] studies were published in English and one[16] in Japanese. One extracted study[12] and our study were multicenter, and the remaining[13–19] were single-institution studies. A comprehensive list of the MINORS scores for the included studies is shown in Table S1. The mean MINORS score was 11.2, which indicates a fair quality of evidence for non-randomized studies. Among the 885 patients included in the meta-analysis, 482 (54.5%) underwent SEMS placement and 403 (45.5%) underwent TDT placement. The number of patients included in each study ranged from 42 to 287.

3.5 | Long-term outcomes by meta-analysis

Six extracted studies[14–19] and our study, yielding 645 MLBO patients (SEMS: n = 349, TDT: n = 296), were included in the meta-analysis of 3-y OS. The 3-y OS rates of the SEMS and TDT groups were 79.1% and 76.4%, respectively. The meta-analysis demonstrated no significant difference between the SEMS and TDT groups (OR = 0.96, 95% CI = 0.57–1.62; P = 0.89), with no between-study heterogeneity (I^2 = 30%, χ^2 = 8.59; P = 0.20)

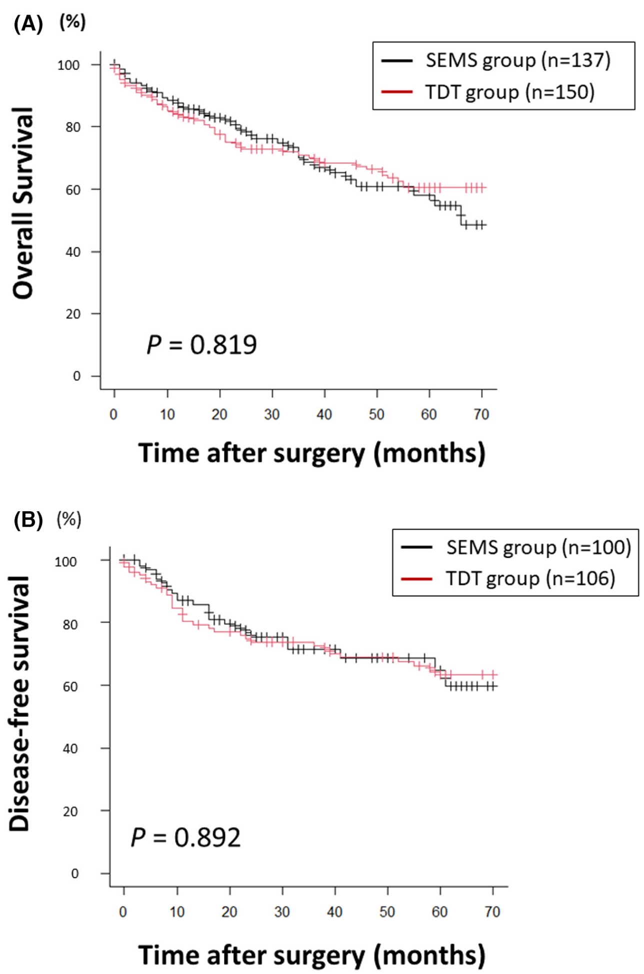

FIGURE 1 Kaplan–Meier curves for (A) overall survival in overall cohort and (B) disease-free survival in pathological stage II and III cohort according to intestinal decompression devices. SEMS, self-expandable metallic stent; TDT, transanal decompression tube

(Figure 4A). Eight extracted studies[12–19] and our study, yielding 750 pathological stage II/III MLBO patients (SEMS: n = 423, TDT: n = 327), were included in the meta-analysis of 3-y DFS. The 3-y DFS rates of the SEMS and TDT groups were 69.7% and 61.8%, respectively. The meta-analysis demonstrated no significant difference between the SEMS and TDT groups (OR = 0.69, 95% CI = 0.46–1.04; P = 0.07), with no between-study heterogeneity (I^2 = 32%, χ^2 = 11.70; P = 0.17) (Figure 4B). Five extracted studies[12,15–18] and our study were included in the meta-analysis of overall recurrence. The overall recurrence rates in the SEMS and TDT groups were 25.9% and 34.3%, respectively. The meta-analysis demonstrated a significant difference between the SEMS and TDT groups (OR = 0.64, 95% CI = 0.45–0.90; P = 0.01), with no between-study heterogeneity (I^2 = 0%, χ^2 = 3.19; P = 0.67) (Figure 4C). Funnel plots of OS, DFS, and recurrence showed symmetrical distributions, which indicated no publication bias (Figure S1A,B,C, respectively).

4 | DISCUSSION

This multicenter retrospective study and meta-analysis compared the long-term outcomes of preoperative SEMS versus TDT placement for MLBO. To the best of our knowledge, this is the first meta-analysis to investigate the oncological impact of these two preoperative intestinal decompression devices. The results demonstrated that SEMS placement did not worsen the long-term outcomes, including DFS and OS, compared with TDT placement. Rather, SEMS placement had a significantly lower overall recurrence rate compared with TDT placement. Furthermore, in our multicenter study, the oncological inferiority of SEMS placement compared with TDT placement was consistent in both left- and right-sided MLBO, and postoperative complications had a significant negative impact on OS in patients with SEMS placement; the impact was not statistically significant with TDT placement.

Preoperative intestinal decompression using specific devices, such as SEMS and TDT, has recently provided an alternative to emergency surgery for MLBO management. Preoperative transanal intestinal decompression using a general catheter, which enables safe one-stage surgery, was first introduced by Lelcuk et al[20] in 1986. Previous studies demonstrated higher primary tumor resection and anastomosis rates, and lower morbidity rates with this approach compared with emergency surgery.[21,22] In Japan, dedicated devices such as TDTs have been commercially available since the 1990s. These devices have been used frequently since then, and they are still a principal strategy for MLBO management. However, the use of TDT placement is mostly limited to south-east Asian countries; therefore, evidence related to clinical efficacy is limited. Regarding short-term outcomes in the comparison between SEMS and TDT, we recently published a meta-analysis demonstrating that SEMS had better technical and clinical success rates, maintenance of preoperative patients' quality of life, such as solid food oral intake and temporary discharge from the hospital, and promotion of laparoscopic one-stage surgery without stoma creation. However, we found no superiority with SEMS regarding anastomotic leakage and postoperative complications compared with TDT.[8] Judging from the limited use and results from the meta-analysis, the ESGE guidelines do not recommend TDT placement over SEMS placement.[3] The results of our multicenter study also showed a higher clinical success rate and equivalent anastomotic leakage rates, with significantly fewer perforations, surgical site infections, and overall postoperative complications in the SEMS group compared with the TDT group.

Studies evaluating the long-term outcomes in patients with TDT placement compared with standard emergency surgery are rare and are based on limited evidence. Only two previous studies of the comparison of TDT with emergency surgery have been reported. Shigeta et al[6] reported better OS in patients with one-stage surgery after TDT placement compared with nondecompression patients. Shingu et al[7] reported that TDT placement had equivalent DFS, OS, and recurrence rates compared with those of a matched cohort of patients

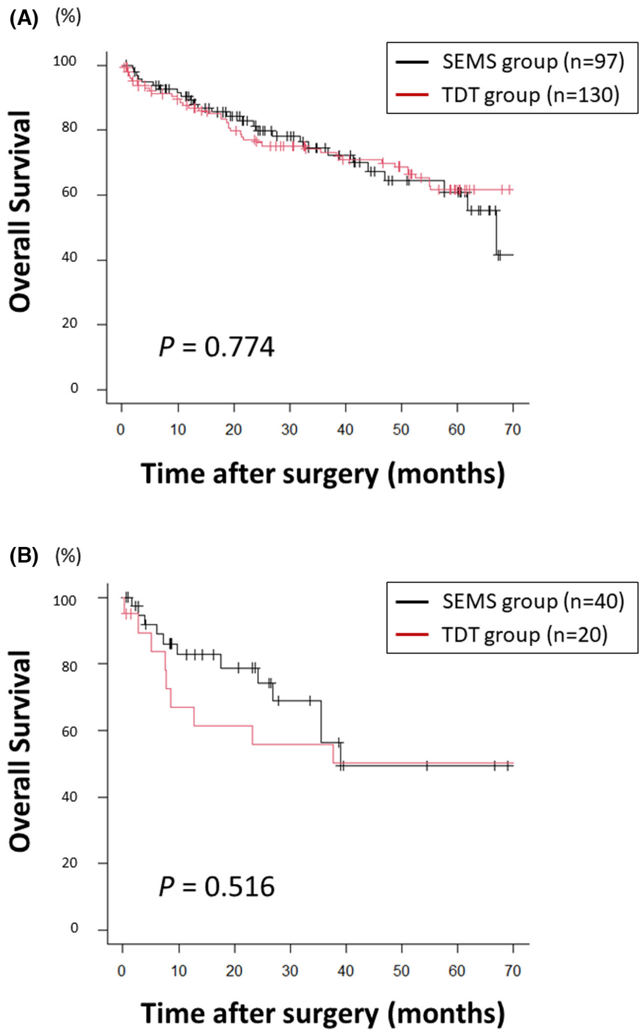

FIGURE 2 Kaplan–Meier curves for overall survival in (A) left- and (B) right-sided tumor according to intestinal decompression devices. SEMS, self-expandable metallic stent; TDT, transanal decompression tube

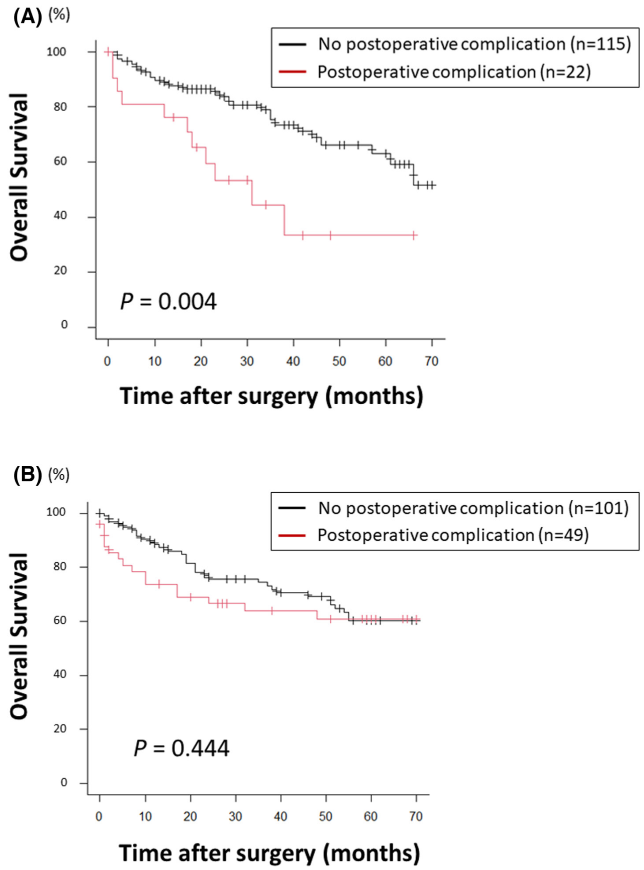

FIGURE 3 Kaplan–Meier curves for overall survival in patients with (A) SEMS and (B) TDT placement according to the presence or absence of postoperative complication. SEMS, self-expandable metallic stent; TDT, transanal decompression tube

TABLE 3 Details of recurrence pattern in stage II/III patients

Recurrence site	TDT group (n = 106)	SEMS group (n = 100)	P value
Liver	8 (7.5)	12 (12.0)	0.349
Lung	3 (2.8)	6 (6.0)	0.321
Locoregional	6 (5.7)	3 (3.0)	0.500
Peritoneal dissemination	6 (5.7)	7 (7.0)	0.779
Lymph node	1 (0.9)	4 (4.0)	0.201
Bone	3 (2.8)	0 (0)	0.247
Spleen	2 (1.9)	0 (0)	0.498
Brain	1 (0.9)	0 (0)	1.000

Note: The values are presented as *n* (%).

with nonobstructive CRC. Since the national insurance coverage of SEMS in 2012, Japanese researchers have become interested in comparisons of other approaches with SEMS. This process has led to scattered reports on long-term outcomes since 2018; however, all studies included in our meta-analysis were retrospective. While previous studies were single-institution studies, Endo et al[12] recently published a multicenter study with a relatively large sample size comprising 103 emergency surgery, 113 SEMS, and 85 TDT patients. The 3-y relapse-free survival rates in these groups were 74.8%, 69.0%, and 55.3%, respectively. Although a direct statistical comparison was not performed, relapse-fee survival between SEMS and TDT appeared to be at least equivalent.

This multicenter cohort study and meta-analysis evaluated both left- and right-sided MLBO patients. Endoscopic intestinal decompression for right-sided MLBO is technically challenging. However, recent studies have demonstrated significantly higher operative risks for emergency resection compared with decompression, even though emergency surgery is the standard therapy in right-sided MLBO.[23,24] Studies reporting the short-term safety of BTS using SEMS have emerged for right-sided MLBO, and we recently published a meta-analysis demonstrating that SEMS as BTS contributed to a significant reduction in postoperative complications and mortality compared with emergency surgery (OR = 0.78, 95% CI = 0.66–0.92 and OR = 0.51, 95% CI = 0.28–0.92, respectively).[25] Additionally, the recent ESGE guidelines suggest consideration of SEMS placement for right-sided MLBO. In

TABLE 4 Characteristics of included studies in the meta-analysis

Reference	Year	Country	Study design	Study period	Institutions	Total cases (SEMS/TDT)	Tumor site	SEMS type	TDT type	pStage	Age (mean) (range)	Follow-up period (mo) (range)
Hosono M[13]	2018	Japan	RS	2010–2017	Single	42 (20/22)	Rt and Lt-sided	Niti-S	CLINY	II/III/IV	74 (42–96)	21.0
Kagami S[15]	2018	Japan	RS	2003–2015	Single	59 (26/33)	Rt and Lt-sided	WallFlex/Niti-S	DENNIS	II/III/IV	69 (46–90)	NA (0.6–159.1)
Motegi D[16]	2018	Japan	RS	2011–2016	Single	53 (31/22)	Rt and Lt-sided	WallFlex/Niti-S	NA	I/II/III/IV	76 (28–96)	SEMS:19/TDT:41
Sato R[18]	2019	Japan	RS	2009–2018	Single	76 (53/23)	Rt and Lt-sided	Niti-S	DENNIS	II/III	NA (37–93)	30 (0.6–93)
Suzuki Y[19]	2019	Japan	RS	2007–2017	Single	40 (19/21)	Rt-sided	NA	NA	II/III/IV	67.5 (59–78)	36.2 (18.1–60.0)
Endo S[12]	2021	Japan	RS	2010–2014	Multicenter	198 (113/85)	Lt-sided	NA	NA	II/III	69 (48–80)	NA (0.2–93.2)
Inoue H[14]	2021	Japan	RS	2007–2019	Single	48 (23/25)	Rt and Lt-sided	WallFlex//HANARO/ Niti-S	DENNIS	≤III/IV	72 (47–91)	35.5 (1.3–112)
Sato K[17]	2022	Japan	RS	2005–2019	Single	82 (60/22)	Lt-sided	WallFlex//HANARO/ Niti-S	DENNIS	II/III	68 (48–88)	40.8 (13.2–98.4)
Our study	2022	Japan	RS	2005–2019	Multicenter	287 (137/150)	Rt and Lt-sided	WallFlex//HANARO/ Niti-S/JENTTLY	DENNIS	II/III/IV	70 (23–98)	36.7 (0.1–155.0)

Abbreviations: RS: retrospective study, SEMS: self-expandable metallic stent, TDT: transanal decompression tube, NA: not applicable.

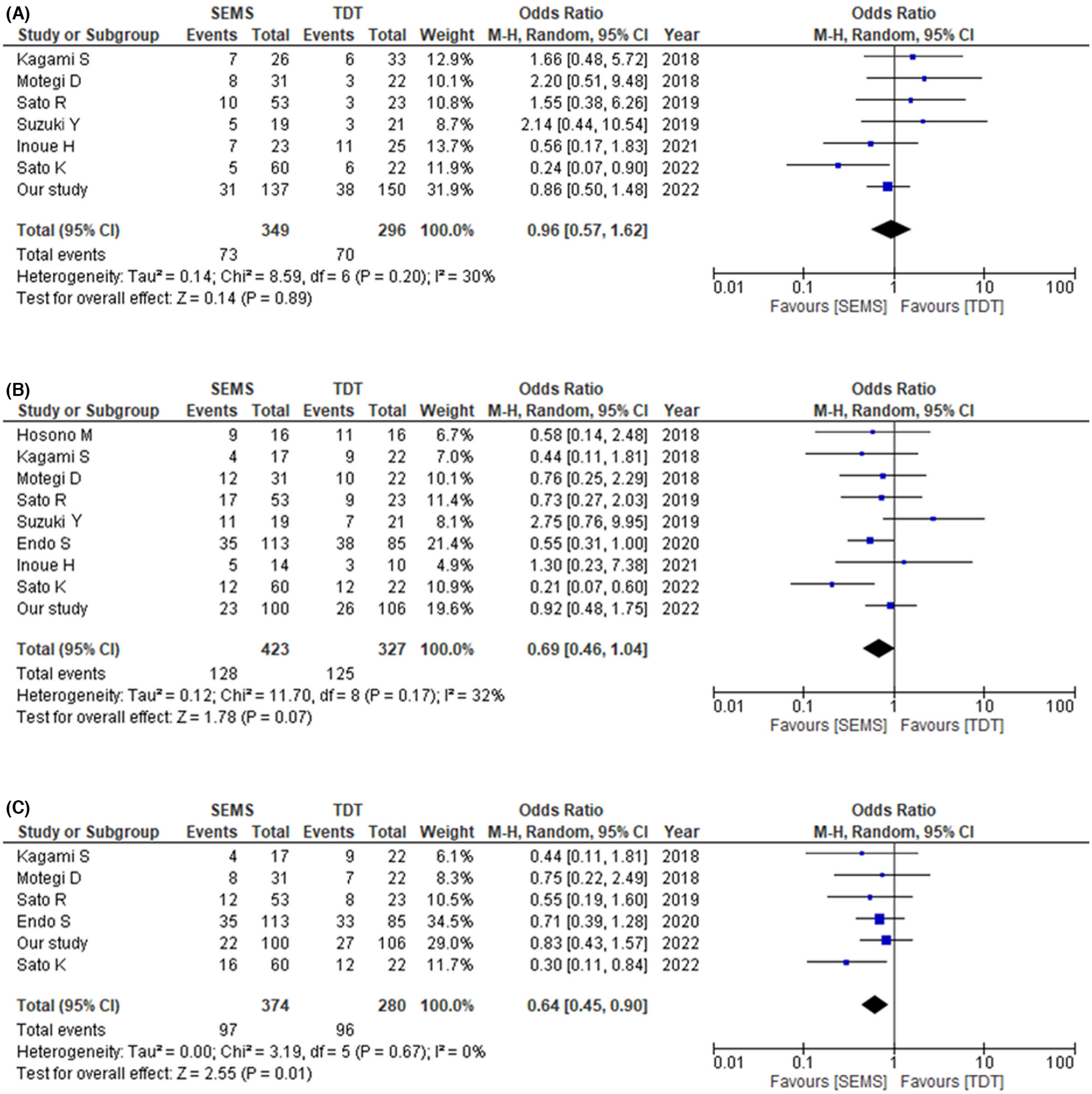

FIGURE 4 Meta-analysis of (A) overall survival in overall cohort, (B) disease-free survival, and (C) overall recurrence in pathological stage II and III cohort according to intestinal decompression devices. SEMS, self-expandable metallic stent; TDT, transanal decompression tube

a comparison with TDT placement for right-sided MLBO,[3] Moroi et al[26] reported that SEMS placement had equivalent technical success and morbidity rates, and a better clinical success rate, which is consistent with the findings in our multicenter study. Although the sample size was small (ie, SEMS: $n = 40$; TDT: $n = 20$), our multicenter study demonstrated similar OS between SEMS and TDT placement. Considering these findings, SEMS placement is recommended over TDT placement for right-sided MLBO, if preoperative intestinal decompression is being considered because of concerns about short-term outcomes.

Postoperative complications are a well-documented negative prognostic factor in CRC surgery.[27,28] We recently performed a multicenter retrospective cohort study with a relatively large sample size of 1817 curative CRC surgical patients. We reported that both Cox proportional hazards models and propensity score matching demonstrated significantly worse cancer-specific survival in patients with vs without postoperative infectious complications (hazard ratio = 1.60, 95% CI = 1.10–2.34).[29] The plausible underlying mechanisms are as follows: abdominal implantation of intraluminal cancer cells in the case of anastomotic leakage, and overproduction and activation of proinflammatory cytokines and mediators both locally and systemically, which promotes micrometastasis.[30] Our multicenter retrospective study demonstrated that the prevalence of postoperative complications (ie, CD grade ≥II and ≥III) was significantly lower in the SEMS group compared with the TDT group. However, the negative survival impact on OS was greater in the SEMS group than that in the TDT group. Although the reason for the difference in the oncological impact was uncertain, this finding suggests that more sophisticated perioperative management for BTS using SEMS placement is needed to reduce postoperative complications and to avoid worse survival. One of the concerns related to postoperative complications is the appropriate interval from SEMS placement to elective surgery. We previously reported that a shorter interval (ie, cutoff of 15 d) was associated with higher postoperative complication rates compared with a longer interval.[31] In our multicenter cohort study, the median value (ie, 20 d) for the interval appeared appropriate for the patients' stabilization. In terms of long-term survivals, several retrospective studies have reported that a longer interval between SEMS placement and elective surgery is associated with a worse prognosis.[32,33] However, the difference of the interval in our multicenter cohort study did not affect either 3-y DFS or OS (data not shown).

Even without perforation, which is a major contributor to poor oncological outcomes,[34] the major concern with SEMS placement is the negative influence on long-term outcomes induced by mechanical manipulation of the tumor. Theoretically, TDT-induced mechanical manipulation of the tumor could be negligible owing to the tubular structure. Takahashi et al[35] demonstrated a significant increase in cell-free DNA and circulating tumor DNA after SEMS placement compared with TDT placement. These increases were considered to be caused by mechanical compression damage to the tumor tissue created by radial pressure induced by the SEMS. In contrast, we previously reported that epithelial exfoliation, tumor necrosis, infiltration of inflammatory cells, and fibrosis were observed in SEMS-inserted surgically-resected specimens. However, the expression of vascular endothelial growth factor and epidermal growth factor receptor, which are related to tumor progression, were not significantly upregulated. Additionally, Ki-67, which is a marker of cell proliferation, was downregulated.[36] Moreover, adverse histopathological changes after SEMS placement (especially perineural invasion, which has a strong negative prognostic impact) have been observed in several studies,[37,38] but the positive rates of perineural invasion in our multicenter cohort study did not differ significantly between the TDT and SEMS groups (data not shown). These controversial findings imply that further basic research focusing on SEMS placement-induced alterations of the tumor microenvironment and systemic conditions and their interactions is warranted.

The endoscopic procedure-related total medical expenses of TDT and SEMS are US $482 and $2627 in Japan, respectively. Although medical cost of SEMS is relatively higher than that of TDT, benefits of using SEMS, including patients' comfort (tube free), decompression efficacy, tolerance of free food intake, temporary preoperative discharge, and reducing the surgical treatment period due to the allowance of minimally less invasive surgery and less postoperative complications may compensate for the increased expense.

This study has several limitations. First, our multicenter study and the studies included in the meta-analysis were nonrandomized and, therefore, there might have been considerable selection bias in the choice of decompression devices. Second, as this was a retrospective observational study, the details of the patients' perioperative management, such as selection of the type of SEMS and the interval from decompression to surgery, were not available. Third, all studies were performed in Japan, which potentially hampers global application of the results.

In conclusion, our multicenter cohort study and the meta-analysis demonstrated that SEMS placement had no inferiority regarding long-term outcomes, including OS and DFS, compared with TDT placement. Considering the limited use and the inferior short-term outcomes associated with TDT, especially regarding higher postoperative complication rates, SEMS placement could be a preferable preoperative decompression method for MLBO patients.

AUTHOR CONTRIBUTIONS

Conception/design (Matsuda A, Yamada T); data acquisition (Matsuda A, Yokoyama Y, Takahashi G); data interpretation and writing (Matsuda A); critical revision (Yoshida H); final approval (all authors).

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CONFLICT OF INTEREST

All authors have no conflicts of interest to disclose.

DATA AVAILABILITY

The raw data supporting the conclusions of this article will be made available by the authors without undue reservation.

ETHICS STATEMENTS

Approval of the research protocol: The protocol for this study was approved by the Ethics Committee of Nippon Medical School (Approval No. R1-07-1170).

Informed Consent: Not applicable (the need to obtain written informed consent from the included patients was waived because of the retrospective nature of the study).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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