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REVIEW ARTICLE

Short-term outcomes of a self-expandable metallic stent as a bridge to surgery vs. a transanal decompression tube for malignant large-bowel obstruction: a meta-analysis

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Abstract

Purpose Preoperative intestinal decompression, using either a self-expandable metallic stent (SEMS) as a bridge to surgery (BTS) or a transanal decompression tube (TDT), provides an alternative to emergency surgery for malignant large-bowel obstruction (MLBO). We conducted this meta-analysis to compare the short-term outcomes of SEMS placement as a BTS vs. TDT placement for MLBO.

Methods We conducted a comprehensive electronic search of literature published up to March, 2018, to identify studies comparing the short-term outcomes of BTS vs. TDT. Decompression device-related and surgery-related variables were evaluated and a meta-analysis was performed using random-effects models to calculate odd ratios with 95% confidence intervals.

Results We analyzed 14 nonrandomized studies with a collective total of 581 patients: 307 (52.8%) who underwent SEMS placement as a BTS and 274 (47.2%) who underwent TDT placement. The meta-analyses showed that the BTS strategy conferred significantly better technical and clinical success, helped to maintain quality of life by allowing free food intake and temporal discharge, promoted laparoscopic one-stage surgery without stoma creation, and had equivalent morbidity and mortality to TDT placement.

Conclusions Although the long-term outcomes are as yet undetermined, the BTS strategy using SEMS placement could be a new standard of care for preoperative decompression to manage MLBO.

Keywords Bridge to surgery · Malignant large-bowel obstruction · Self-expandable metallic stent · Short-term outcome · Transanal decompression tube

Introduction

Colorectal cancer (CRC) is one of the most common cancers worldwide and approximately 10% of these patients will suffer malignant large-bowel obstruction (MLBO) [1, 2]. MLBO is a life-threatening oncologic emergency. Emergency surgery frequently requires stoma creation and is performed as a standard treatment for MLBO; however, the morbidity and mortality rates associated with emergency surgery for MLBO are high because of the poor general and intestinal condition of these patients, as well as insufficient preoperative assessment and preparation [1, 3, 4]. Furthermore, one study showed that colostomies created with

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temporary intention were closed in only 60% of patients who underwent Hartmann's procedure [5].

Preoperative intestinal decompression using specific devices, such as a self-expandable metallic stent (SEMS) or a transanal decompression tube (TDT), have provided an alternative to emergency surgery to manage MLBO. SEMS placement is performed worldwide in both the preoperative setting, as a bridge to surgery (BTS), and with palliative intent [6]. In contrast, TDT placement is applicable only in the preoperative setting and its use is limited to predominantly Eastern countries, including Japan and China [7, 8]. TDT insertion followed by one-stage surgery is still a principal strategy for MLBO management in Japan. Satisfactory short- and long-term outcomes have been achieved using either of these two decompression devices, providing one-stage surgery instead of emergency surgery for prepared MLBO patients [8–11]. However, because of the limited use of TDT placement, few studies have compared SEMS placement as a BTS with TDT placement; thus, no high-quality evidence is available. We conducted a meta-analysis to compare the short-term outcomes of SEMS vs. TDT placement for MLBO, including decompression device- and surgery-related outcomes, with a relatively large sample size ($n = 581$).

Materials and methods

Literature search strategy and data collection

A comprehensive electronic search of literature published up to March, 2018, was conducted 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 K.S.) using the keyword terms "colorectal neoplasms" AND ("colonic stent" OR "self-expandable metallic stent" OR "transanal tube") AND "surgery." Reference lists of all relevant publications were searched manually for additional studies that had been initially overlooked using this search strategy. This method of cross-referencing was continued until no further relevant publications were identified. The quality of the included studies was assessed according to the Newcastle–Ottawa Quality Assessment Scale [12], which includes three aspects of evaluation: selection, comparability, and outcome in the case and control groups. Studies with scores of ≥ 6 were defined as being of high-quality. This systematic review and meta-analyses were performed under the recommendations of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2015 [13].

Eligibility and exclusion criteria

We defined the inclusion and exclusion criteria *a priori*. Only the following published studies were included: (1) if they included patients with histopathologically diagnosed CRC; (2) if they were randomized controlled trials or other comparative studies evaluating predefined outcomes of patients who underwent surgery after placement of a SEMS (BTS) or TDT; and (3) if they analyzed predefined short-term device-related and surgery-related outcomes. Articles written in any language were considered eligible. The following studies were excluded: (1) if predefined outcomes were not reported for the two techniques or it was impossible to extract the number of outcome events from the published results; and (2) if SEMS insertion was performed only with the intent of palliation, without subsequent surgery.

Data extraction

Data were extracted from each study by two independent authors (A.M. and K.S.). The following information was recorded for each eligible trial: the authors' names, the year of publication, the country in which the study was performed, the design and duration of the study, and the number of included patients and their characteristics. The patient characteristics included age, sex, tumor-related variables, device-related variables (technical success, clinical success, overall complications, perforation, solid food intake, and temporal discharge), and surgery-related variables (laparoscopic surgery, emergency surgery, primary resection and anastomosis, stoma creation, overall postoperative complications, anastomotic leakage, surgical site infection, ileus, postoperative hospital stay, and mortality). The technical success and clinical success of device placement were defined as the ability to deploy the device adequately across the obstructive tumor and as radiologic evidence of resolution of the obstruction followed by the introduction of an oral liquid diet.

Data synthesis and statistical analysis

Pooled odds ratios (ORs), representing the odds of an adverse event occurring with BTS vs. surgery after TDT insertion, were calculated using the DerSimonian–Laird random-effects model, with 95% confidence intervals (95% CIs) [14]. Considering the between-study heterogeneity, a "random-effects" meta-analytical technique was applied, resulting in a more conservatively calculated OR than that

obtained with a fixed-effects model. An OR of < 1 favored the BTS group, and the point estimate of the OR was considered significant at $P < 0.05$ if the 95% CI did not include the value 1. All data in the meta-analysis were analyzed using Review Manager Version 5.3 (Cochrane Collaboration, Copenhagen, Denmark). I^2 was used to test the heterogeneity between the included studies. Study heterogeneity was measured using the χ^2 and I^2 statistics, with χ^2 $P < 0.05$ and $I^2 \geq 50\%$ indicating heterogeneity [15].

Publication bias was assessed by the visual examination of a funnel plot, with asymmetry formally assessed using Egger's linear regression test and Begg's rank correlation test [16, 17]. Publication bias was analyzed using WINPEPI software [18].

Results

Literature review and included studies

In total, 147 citations were matched in the initial screening. After the titles and abstracts were reviewed, 105 studies were excluded. Twenty-eight studies were also excluded after full-article evaluation. The 14 remaining studies, published between 2013 and 2018 [19–32] were included in the meta-analysis (Supplementary Fig. 1). Table 1 summarizes the basic characteristics of the included studies. Six studies [21, 23, 25, 30, 31, 33] were published in English and eight [19, 20, 22, 26–29, 32] were published in Japanese. Thirteen studies [19–22, 24–32] originated from Japan and one [23] from China. These 14 studies included 13 [19–22, 24–32] retrospective observational studies, 1 [23] prospective study, and no randomized controlled trials. Of the 581 patients included in the meta-analysis, 307 (52.8%) underwent BTS, as SEMS placement followed by surgery, and 274 (47.2%) underwent TDT placement followed by surgery. Table 1 details the characteristics of the 14 included studies [19–32]. The number of patients included in each study ranged from 21 to 79.

Decompression device-related variables

The technical success rates of device placement in the SEMS and TDT groups were 97.7% (300/307) and 90.9% (249/274), respectively. The meta-analysis of the 14 studies demonstrated a significantly higher technical success rate in the SEMS group than in the TDT group, with an OR of 0.29 (95% CI 0.12–0.70, $P = 0.006$) (Fig. 1a). No significant between-study heterogeneity was observed ($I^2 = 0\%$, $P = 0.62$) and we found no significant publication bias by visual inspection of the funnel plot (Supplementary Fig. 2A), Egger's test ($P = 0.887$), or Begg's test ($P = 0.956$). The clinical success rate was evaluated as an outcome in 13 studies. The clinical success rates of device placement in the SEMS and TDT groups were 93.2% (248/266) and 77.3% (260/201), respectively. The meta-analysis of the studies demonstrated a significantly higher clinical success rate in the SEMS group than in the TDT group, with an OR of 0.25 (95% CI 0.13–0.50, $P < 0.001$) (Fig. 1b) without significant between-study heterogeneity ($I^2 = 15\%$, $P = 0.29$). No significant publication bias was detected by visual inspection of the funnel plot (Supplementary Fig. 2B), Egger's test ($P = 0.753$), or Begg's test ($P = 0.807$).

The overall device-related complications were investigated in 12 studies. The rates of these complications in the SEMS and TDT groups were 5.5% (13/235) and 11.7% (26/222), respectively. The meta-analysis showed a trend toward a better result in the SEMS group than in the TDT group, but the difference did not reach significance (OR 0.46, 95% CI 0.21–1.02, $P = 0.06$). The rate of perforation, which is the most important and critical device-related complication, was 3.0% (7/235) in the SEMS group and 6.3% (14/222) in the TDT group, with no significant difference (OR 0.59, 95% CI 0.23–1.50, $P = 0.27$; Table 2).

Preoperative maintenance of quality of life was evaluated by the solid food intake and temporal discharge rates. Five studies included each of these parameters as a measured outcome. The meta-analysis showed significant superiority in the SEMS group (OR < 0.01, 95% CI 0.00–0.02, $P < 0.001$ for solid food intake; OR 0.04, 95% CI 0.00–0.39, $P < 0.001$ for temporal discharge; Table 2).

Surgery-related variables

The rates of primary tumor resection and anastomosis favored the SEMS group over the TDT group (90.1% and 67.8%, respectively), and the rates of stoma creation were

Table 1 Characteristics of the 14 studies included in the meta-analysis

Reference	Year	Country	Study design	Study period	Institutions	Total cases (SEMS/TDT)	Tumor site	SEMS type	TDT type	Age (mean) (SEMS/TDT)	Male sex (%) (SEMS/TDT)	Study quality (rating) (max 9)
Li CY	2013	China	PS	2005–2010	Single	29 (26/13)	Lt-sided	Niti-S™	CLINY™	73.1 (72.6/73.3)	62.1 (62.5/61.5)	7
Narahashi K	2013	Japan	RS	2012	Single	36 (10/26)	Rt and Lt-sided	WallFlex™	DENNIS™	NA	NA	6
Moroi R	2014	Japan	RS	2007–2014	Single	28 (21/7)	Rt and Lt-sided	WallFlex™ Niti-S™	NA	73.2 (73.5/72.4)	50.0 (42.9/71.4)	4
Nakano Y	2014	Japan	RS	2012–2013	Single	27 (13/14)	Rt and Lt-sided	WallFlex™	NA	NA (69.3/74.4)	63.0 (57.1/64.3)	4
Shimizu Y	2015	Japan	RS	2007–2014	Single	43 (28/15)	Rt and Lt-sided	WallFlex™ Niti-S™	NA	NA (72.8/67.5)	41.9 (39.3/46.7)	6
Fukami Y	2015	Japan	RS	2011–2014	Single	21 (10/11)	Rt and Lt-sided	WallFlex™ Niti-S™	NA	NA (75.4/66.1)	57.1 (50.0/63.6)	5
Yamana D	2015	Japan	RS	2005–2013	Single	59 (32/27)	Rt and Lt-sided	WallFlex™	NA	NA (72/68)	NA	5
Takeyama H	2016	Japan	RS	2010–2015	Single	41 (22/19)	Rt and Lt-sided	WallFlex™ Niti-S™	DENNIS™	NA (71.3/68.5)	47.0 (36.4/66.7)	5
Nakano Y	2016	Japan	RS	2010–2015	Single	36 (24/12)	Rt and Lt-sided	WallFlex™ Niti-S™	CLINY™	NA (75/61)	63.9 (66.7/58.3)	5
Matsuda A	2016	Japan	RS	2005–2014	Single	79 (29/50)	Rt and Lt-sided	WallFlex™ Niti-S™	DENNIS™	NA (66/70)	63.0 (60.7/64.4)	5
Kiriyama S	2016	Japan	RS	2010–2015	Single	47 (32/15)	Rt and Lt-sided	WallFlex™	CLINY™	NA (82/70)	51.6 (50.0/53.8)	6
Ishigouoka S	2017	Japan	RS	2006–2016	Single	69 (26/43)	Rt and Lt-sided	WallFlex™ Niti-S™	DENNIS™	NA (68.0/67.0)	59.4 (65.9/53.8)	5
Kawachi J	2017	Japan	RS	2006–2016	Single	31 (19/12)	Lt-sided	Niti-S™	DENNIS™	NA (69.4/74.1)	41.9 (42.1/41.7)	5
Takahashi G	2018	Japan	RS	2014–2017	Single	35 (25/10)	Rt and Lt-sided	Niti-S™	DENNIS™	NA (72/77)	62.9 (68.0/50.0)	5

PS prospective study, *RS* retrospective study, *SEMS* self-expandable metallic stent, *TDT* transanal decompression tube, *NA* not applicable

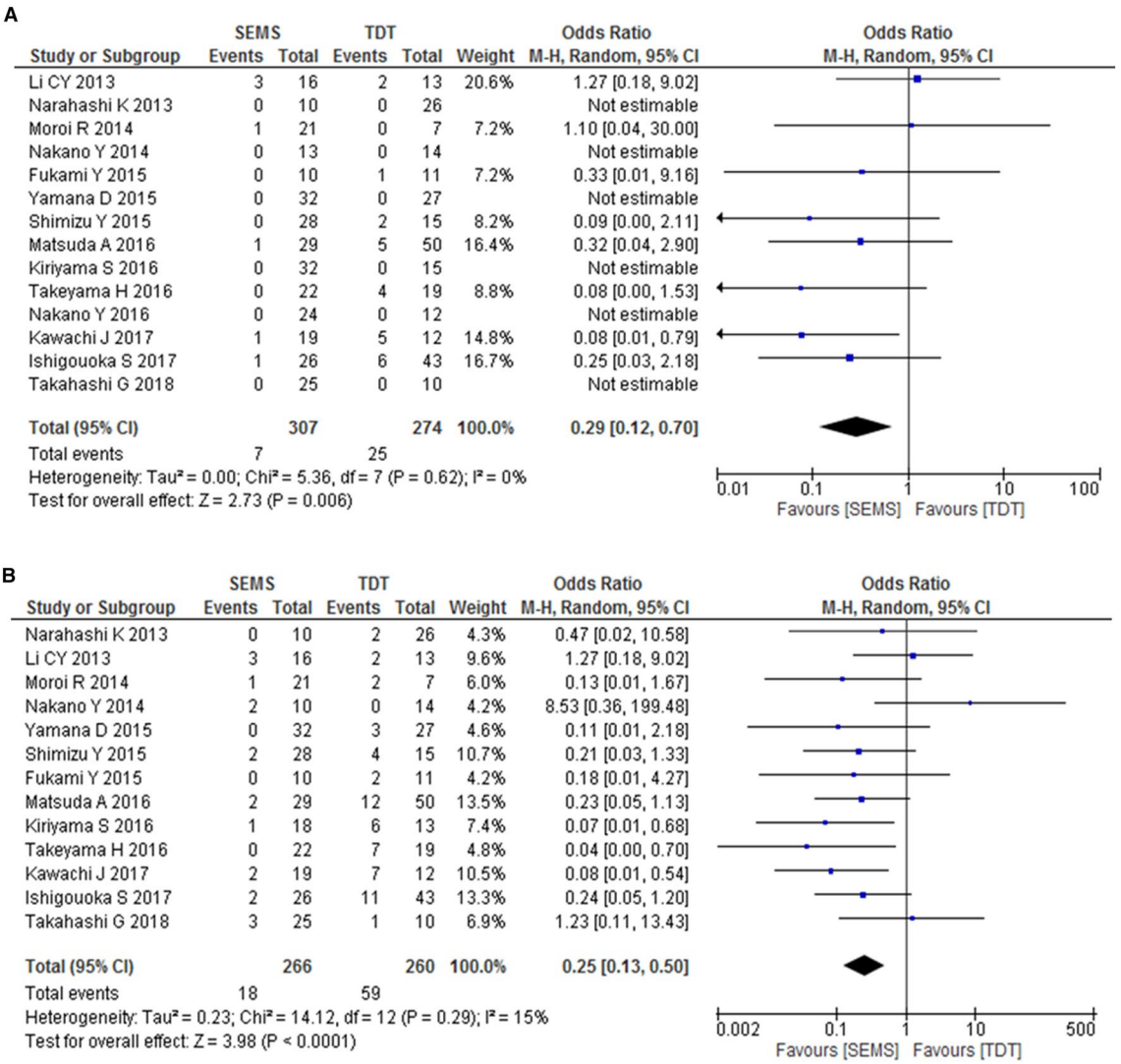

Fig. 1 Meta-analysis of technical success (**a**) and clinical success (**b**) of bridge to surgery vs. transanal decompression tube placement for malignant large-bowel obstruction. *SEMS* self-expandable metallic stent, *TDT* transanal decompression tube, *CI* confidence interval

consistent (7.7% and 31.9%, respectively). Both meta-analyses showed significant differences between the groups (OR 0.25, 95% CI 0.08–0.78, $P=0.02$ for the primary tumor resection and anastomosis rate; OR 0.17, 95% CI 0.08–0.39, $P<0.001$ for the stoma creation rate) without between-study heterogeneity ($I^2=53\%$, $P=0.08$ and $I^2=13\%$, $P=0.33$, respectively; Fig. 2a, b).

SEMS placement allowed laparoscopic surgery to be performed and emergency surgery to be avoided more; the laparoscopic surgery and emergency surgery rates being 81.0% vs. 21.5% and 5.3% vs. 16.6% in the SEMS and TDT groups, respectively. The pooled OR was significantly better in the SEMS group than in the TDT group (OR 0.06, 95% CI 0.01–0.31, $P<0.001$ for the laparoscopic surgery rate; OR 0.28, 95% CI 0.13–0.59, $P=0.001$ for the emergency surgery rate). Although the between-study heterogeneity in the analysis of the emergency surgery rate did not reach significance ($I^2=0\%$, $P=0.49$), the analysis of the laparoscopic surgery rate showed significant heterogeneity ($I^2=75\%$, $P=0.001$; Table 2).

The overall postoperative complications and mortality were evaluated in eight studies. The rates of postoperative complications in the SEMS and TDT groups were 21.1% (37/175) and 24.8% (36/145), respectively. The mortality rates were 1.2% (2/165) and 2.7% (5/185), respectively. Both meta-analyses demonstrated no significant differences between the groups (OR 0.68, 95% CI 0.38–1.22, $P=0.20$ for postoperative complications; OR 0.52, 95% CI 0.12–2.31, $P=0.39$ for mortality) without between-study heterogeneity ($I^2=0\%$, $P=0.99$ for postoperative complications; $I^2=0\%$, $P=0.83$ for mortality). Figure 3a shows

Table 2 Meta-analyses of short-term outcomes of bridge to surgery vs. transanal decompression tube placement for malignant large-bowel obstruction

Outcome	No. of studies	Total cases (SEMS/TDT)	OR	95% CI	*P* value	Heterogeneity		
						χ^2	I^2 (%)	*P* value
Decompression device-related								
Device-related complications	12	457 (235/222)	0.46	0.21–1.02	0.06	7.26	0	0.61
Perforation	12	457 (235/222)	0.59	0.23–1.50	0.27	4.01	0	0.91
Solid food intake	5	221 (105/116)	0.00	0.00–0.02	< 0.001	5.21	23	0.27
Temporal discharge	5	226 (114/112)	0.04	0.00–0.39	< 0.01	15.77	75	0.003
Surgery-related								
Laparoscopic surgery	6	263 (142/121)	0.06	0.01–0.31	< 0.001	19.82	75	0.001
Emergency surgery	11	395 (190/205)	0.28	0.13–0.59	0.001	8.41	0	0.49
Surgical site infection	9	358 (186/172)	0.57	0.29–1.12	0.10	6.48	0	0.48
Ileus	8	221 (160/161)	1.09	0.45–2.63	0.85	5.53	0	0.48
Postoperative hospital stay	2	93 (54/39)	− 7.12[a]	− 14.42–0.17	0.06	0.10	0	0.76
Mortality	8	350 (165/185)	0.52	0.12–2.31	0.39	0.87	0	0.83

SEMS self-expandable metallic stent, *TDT* transanal decompression tube, *OR* odds ratio, *CI* confidence interval

[a]Mean difference

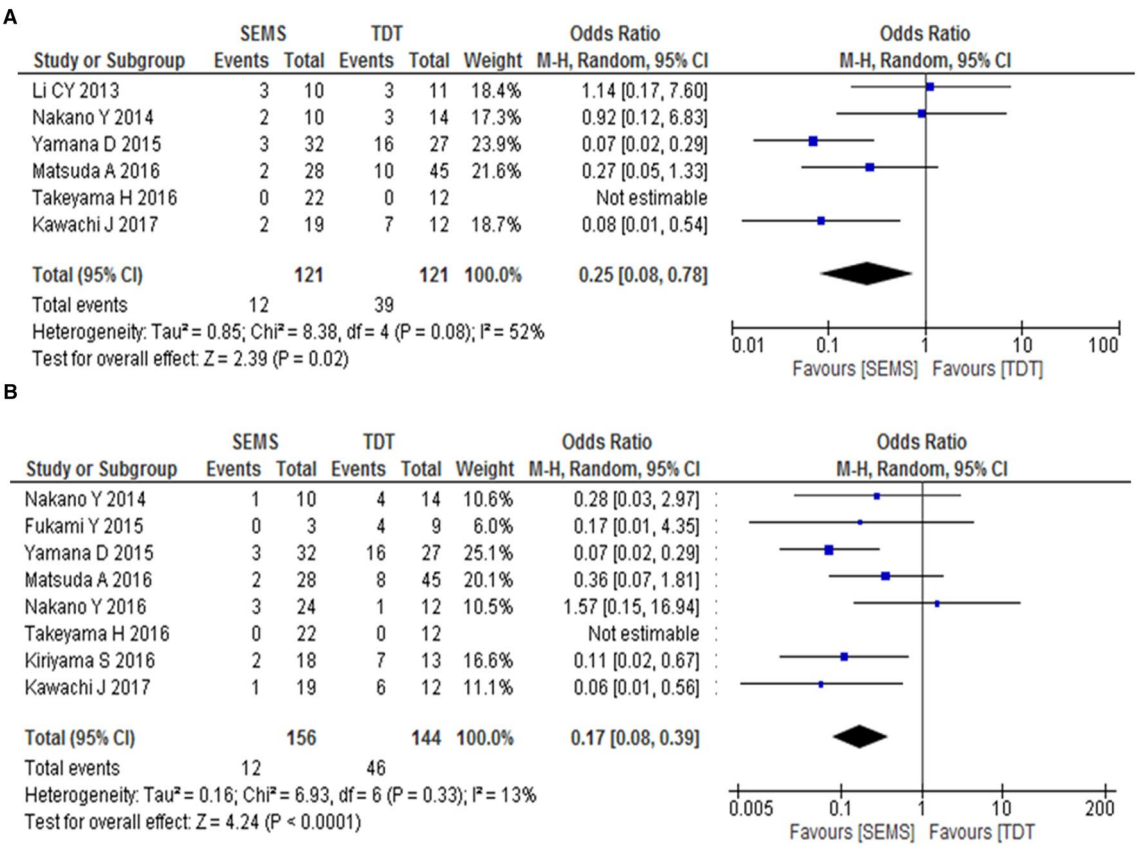

Fig. 2 Meta-analysis of primary tumor resection and anastomosis (**a**) and stoma creation (**b**) between bridge to surgery vs. transanal decompression tube placement for malignant large-bowel obstruction. *SEMS* self-expandable metallic stent, *TDT* transanal decompression tube, *CI* confidence interval

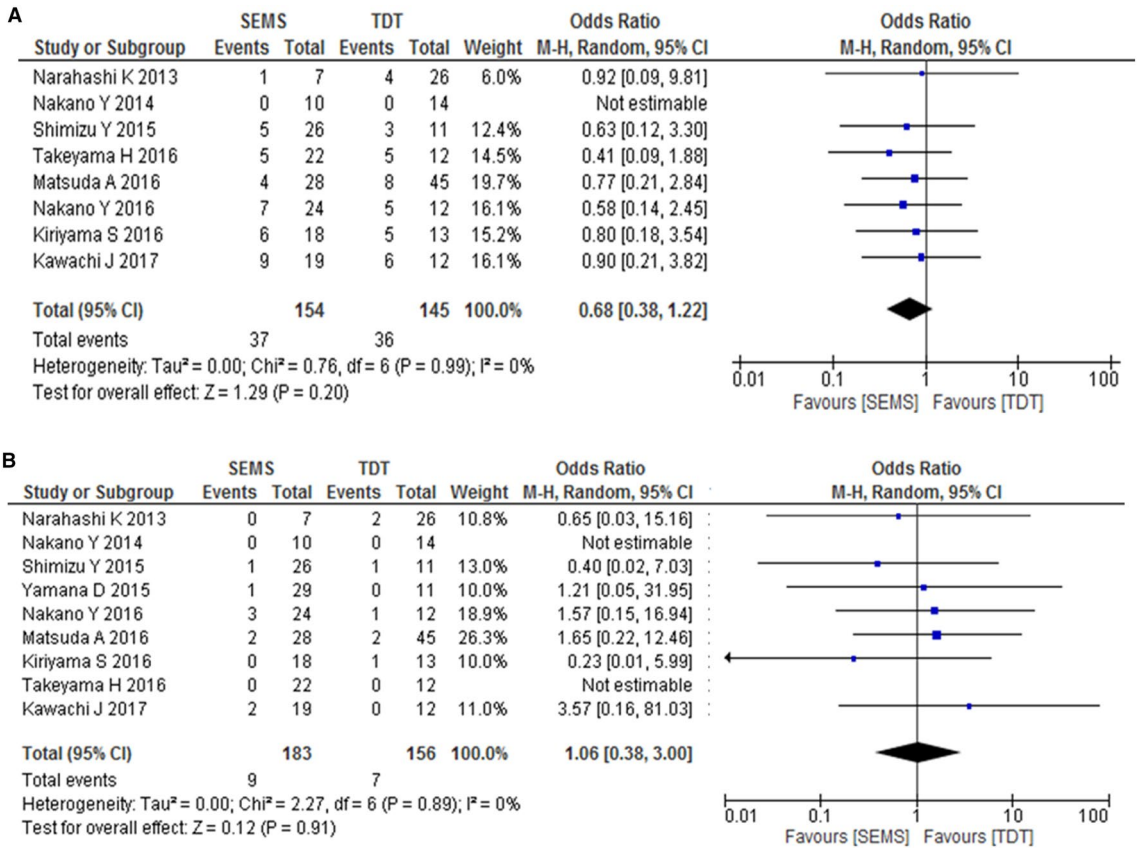

Fig. 3 Meta-analysis of overall postoperative complications (**a**) and anastomotic leakage (**b**) between bridge to surgery vs. transanal decompression tube placement for malignant large-bowel obstruction. *SEMS* self-expandable metallic stent, *TDT* transanal decompression tube, *CI* confidence interval

data on postoperative complications and Table 2 summarizes data on mortality.

The meta-analyses of individual postoperative complications, including anastomotic leakage, surgical site infection, and ileus, are shown in Fig. 3b (anastomotic leakage) and Table 2 (others). No significant differences were observed in these analyses. The length of postoperative stay was evaluated in only two studies. The meta-analysis showed a trend toward a shorter stay in the SEMS group, but the difference did not reach significance (mean difference = −7.12, 95% CI −14.42–0.17, $P = 0.06$) (Table 2).

Discussion

This systematic review and meta-analysis of 14 studies involving 581 patients compared the short-term outcomes of BTS (SEMS placement followed by surgery) vs. TDT placement for MLBO. To our knowledge, this is the first meta-analysis to compare these two established preoperative intestinal decompression devices. The results demonstrated that SEMS placement provided significantly better decompression device-related variables, including the technical and clinical success rates, and a trend toward fewer overall device-related complications, including perforation. Furthermore, SEMS placement maintained quality of life more effectively during the interval from device placement to surgery, as assessed by tolerance of solid food intake and temporal discharge. In terms of surgery-related variables, although the morbidity and mortality rates were equivalent, SEMS promoted elective and laparoscopic one-stage surgery without the need for a stoma.

The placement techniques of both the SEMS and TDT share general procedures in common. A guidewire is introduced endoscopically through the obstructive tumor and proximally to the distended oral-side colon. Each device is then placed in the appropriate position through the guidewire. Considering this, the technical success rates of both devices should be equivalent; however, our meta-analysis showed a significantly better success rate for SEMS than for TDT placement (97.7% vs. 90.9%, respectively). This is because SEMS placement has major technical advantages over TDT placement; namely, both fluoroscopic and endoscopic guidance are available during SEMS placement,

through the scope technique; a thinner guidewire is used for SEMS placement than for TDT (0.035-inch diameter vs. 0.052-inch diameter, respectively), which makes it easier to pass through the obstructive tumor; and the hand-produced insertion force can be transmitted to the tip of the SEMS delivery device through the scope, maintaining a straight and rigid colonic axis. Hence, SEMS placement can be performed relatively easily for both left- and right-sided MLBO.

Perforation is the most feared device-related complication: it usually requires emergency surgery and is the main cause of mortality. Moreover, perforation presumably results in the spread of intra-abdominal cancer cells, which ultimately affects long-term outcomes. Previous studies have shown that SEMS-associated perforation has a strong negative impact on long-term survival [34, 35]. Kim et al. reported that the odds of perforation resulting in peritoneal dissemination was 46.0 [34]. Our meta-analysis showed a lower perforation rate in association with SEMS than with TDT (3.0% vs. 6.3%, respectively), but the difference was not significant. Along with improvements in endoscopic techniques and the properties of SEMS, including lower radial and axial forces, the perforation rate is decreasing dramatically. In fact, recent prospective large cohort studies conducted in Japan showed a perforation rate of 0% [36, 37].

The most distinguished benefits of SEMS over TDT are its higher intestinal decompression efficacy and maintenance of quality of life as indicated by tolerance of free food intake and temporal preoperative discharge. Because of the narrow internal diameter of the TDT (7.3-mm outer diameter), the tube can easily become clogged with solid stool; hence, colonic wash-out through the TDT to dissolve the stool should be performed frequently. The continuous contact between the tip of the tube and the colonic mucosa is another known cause of perforation; hence, frequent changes in the tip position are recommended. This management requires tremendous effort by the medical staff. Additionally, the fecal odor released from the tube and storage bag and the protrusion of the tube from the anus are distressing for these patients. Conversely, because of its wide internal diameter of 18–20 mm and tube-free structure, the SEMS can completely resolve these disadvantages of the TDT.

The better decompression efficacy of the SEMS is considered to be strongly influenced by several surgical variables, including laparoscopic surgery and primary tumor resection and anastomosis, the avoidance of emergency surgery and stoma creation. The results of the present study indicate that a BTS strategy allows for minimally invasive one-stage surgery with sufficient preparation, which can reduce the surgical treatment period. Although the expense of the SEMS is higher than that of the TDT, the endoscopic procedure-related total costs being US $3120 vs. $570, respectively, the ability of SEMS placement to prevent extension of the surgical treatment period may adequately compensate for the higher cost of the device itself.

The overall postoperative complication rate (21.1% vs. 24.8%) and the rate of specific complications, including anastomotic leakage (4.4% vs. 4.1%), surgical site infection, ileus, and mortality, were not significantly different between the groups. This suggests that the postoperative short-term outcomes of both devices are equivalent; however, the higher rate of avoidance of one-stage surgery in the TDT group, which resulted in an abundance of high-risk patients undergoing curative resection and anastomosis due to insufficient intestinal decompression, could have introduced strong selection bias into the results. Therefore, the BTS strategy has potential for better postoperative short-term outcomes than TDT placement.

The oncological effect of the BTS strategy remains unclear. The negative long-term survival after SEMS placement compared with emergency surgery is a concern [38, 39]. Takahashi *et al*. [30] reported very recently a negative oncological effect of SEMS placement vs. TDT as assessed by the significant increase in cell-free DNA and circulating tumor DNA, which are potential cancer biomarkers. These increases are considered caused by mechanical compression damage to the tumor tissue created by radial pressure of the SEMS. In contrast, our recent meta-analysis of 1136 patients demonstrated equivalent long-term survival between the BTS strategy and emergency surgery [33]. Although a direct comparison of oncological outcomes between the BTS strategy and TDT placement has not been reported, a recent first report by Kagami *et al*. demonstrated that the 5-year overall survival rates of patients, including those with stage IV disease, in the SEMS ($n=26$) and TDT ($n=33$) groups were not significantly different (73.0% and 67.1%, respectively; $P=0.423$). The 5-year disease-free survival rates of patients with stage II and III disease in the SEMS and TDT groups also did not differ significantly (72.2% and 52.0%, respectively; $P=0789$) [40].

This study has several limitations. First, all included studies with a small sample size were nonrandomized and so there may have been considerable selection bias in the choice of devices. Second, the detection of statistical heterogeneity was limited by the small sample size of each included study, so a potential heterogeneity was undeniable. Third, most of the studies were conducted in Japan and published in the Japanese literature, potentially hampering global application of the results. Fourth, the included retrospective historical studies involved some degree of time bias with the complete switch from TDT to SEMS, which could have contributed to the better outcomes of the SEMS group.

In conclusion, a BTS strategy using a SEMS for MLBO confers better technical and clinical success, helps to maintain quality of life, promotes laparoscopic one-stage surgery without stoma creation, and is associated with equivalent

morbidity and mortality to TDT placement. Although the results may have been limited by the small sample size and the long-term outcomes are as yet undetermined, the BTS strategy could be a new standard of care for preoperative decompression for MLBO.

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Author contributions All authors are in agreement with the content of the manuscript. The authors' contributions are as follows: study concept and design, AM and TY; acquisition of data, AM, YK, KS, and NS; analysis and interpretation of data, AM, SM, and TM; drafting of the manuscript, AM; study supervision, MM and HY.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

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