



Is self-expandable metallic stents superior to transanal decompression tubes for the treatment of malignant large-bowel obstruction: a meta-analysis

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Background: Preoperative intestinal decompression, such as self-expandable metallic stents (SEMS) and transanal decompression tubes (TDT), has been widely used for patients with malignant large-bowel obstruction (MLBO). The aim of this study is to evaluate the clinical outcomes of SEMS for MLBO as a bridge to surgery compared to TDT.

Methods: We searched three databases, including PubMed, Embase, and Web of Science from inception until June 12, 2019. Risk ratio (RR) or weight mean difference (WMD) with 95% CIs was used to calculate the data extracted from included studies.

Results: Five studies with 226 participants were included in this review. SEMS insertion showed significantly higher clinical success rate (RR =1.30, 95% CI: 1.06, 1.60; P=0.012) and technical success rate (RR =1.33, 95% CI: 1.07, 1.65; P=0.011), as well as higher rates of solid food intake (RR =27.15, 95% CI: 8.73, 84.45; P<0.001) and temporal discharge (RR =64.47, 95% CI: 9.10, 456.57; P<0.001), as compared with TDT insertion. Moreover, SEMS insertion significantly reduced the blood loss (WMD =-69.73 mL, 95% CI: -81.61, -57.85; P<0.001), and prolonged the operative time (WMD =93.49 minutes, 95% CI: 14.24, 172.75; P=0.021) in the treatment of MLBO. Duration of hospital stay, complication rate and mortality rate were comparable between the two treatments.

Discussion: Preoperative SEMS insertion offered better effects for MLBO, including higher success rate, and higher rates of solid food intake and temporary discharge, compared with TDT.

Keywords: Self-expandable metallic stents (SEMS); transanal decompression tubes (TDT); malignant large-bowel obstruction (MLBO); meta-analysis

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Introduction

Colorectal cancer (CRC) ranks one of the most common cancers around the world (1), and 7–29% of CRC patients will suffer emergent malignant large-bowel obstruction (MLBO) at the time of diagnosis (1,2). As a life-threatening oncologic emergency, MLBO has relatively higher

morbidity and mortality rates, which ranges from 30–60% and 7–22%, respectively (3,4). The high rates are caused by the poor general and intestinal condition of the patients, as well as the inadequate preoperative assessment and preparation (3–5). Two-stage surgery strategy is traditionally recommended in these patients, who underwent

decompressive colostomy with or without tumor resection followed by delayed anastomosis (6). However, this method has been shown to reduce the quality of life (QoL) (7,8), and 57% of patients would develop parastomal hernias and some other complications, such as foul smell and stool leakage (9,10).

Recently, in order to improve the QoL and prognosis in patients with acute left-sided MLBO, many nonsurgical approaches have been developed, including placement of a self-expandable metallic stent (SEMS) (11-13) and transanal decompression tube (TDT) (14,15). SEMS is considered as a preferable alternative intervention for decompression of MLBO. Previous meta-analysis (16-18) have shown that, SEMS insertion after surgery is more effective than emergency surgery alone, with lower rates of morbidity and stoma creation, as well as shorter duration of hospital stay (16-18). In 2020, SEMS has been recommended by the European Society of Gastrointestinal Endoscopy (ESGE) guidelines as bridge to surgery for MLBO (19). TDT insertion can also avoid the two-stage surgery for MLBO, however, its application is only limited to Eastern countries, including Japan and China (20,21).

SEMS insertion is currently regarded as an effective and safe option for MLBO as bridge to surgery in terms of shorter hospital stay, lower mortality and morbidity rates than emergency surgery, especially in Western countries. Whereas, TDT placement is used as a bridge to an elective surgery without stoma in limited areas, including Asia. Recently, several comparative studies have been reported regarding the clinical outcomes of SEMS and TDT for MLBO (22-26), however, the benefits and safety of the two techniques were not inconsistent among them. In order to address the issue, we performed this meta-analysis of eligible studies that compared the short-outcomes of these two decompression devices.

We present the following article in accordance with the PRISMA reporting checklist (available at <https://dx.doi.org/10.21037/apm-20-2600>).

Methods

Search strategy

This meta-analysis was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (27). Relevant articles were identified using electronic databases (PubMed, Embase, and Web of Science) from their inception to

June 12, 2019. The search was not limited to language or publication status. The search terms we used were the followings: (metallic[All Fields] AND (“stents”[MeSH Terms] OR “stents”[All Fields] OR “stent”[All Fields])) AND (transanal[All Fields] AND (“drainage”[MeSH Terms] OR “drainage”[All Fields]) AND tube[All Fields]) AND (metallic[All Fields] AND (“stents”[MeSH Terms] OR “stents”[All Fields] OR “stent”[All Fields])). A manual literature search for potential studies using reference lists of included articles was also performed.

Selection criteria

Eligible studies must be: (I) randomized controlled trial (RCT), case-control study, cohort study, or comparative study; (II) adult patients who had been diagnosed with MLBO; (III) patients underwent SEMS or TDT; (IV) they must provide the following outcome measures: success rate, solid food intake, temporal discharge, surgery time, duration of hospital stay, and complications.

Data extraction and quality assessment

Two independent reviewers evaluated the eligibility of all identified publications from selected articles. The following information were extracted: study characteristics (study design, first author’s name, year of publication, country), patient characteristics (mean age, gender, sample size in each group, clinical stage, tumor location), and the outcome data of comparison between intervention and control. In order to minimize data entry error, all data were entered by two independent reviewers and checked by a third review, and disagreement between them was resolved by discussion.

Study quality was evaluated by two independent reviewers using the modified Newcastle-Ottawa (NOS) scale (28). This method used 3 items to assess the methodological quality of a non-randomized trial (28). The total score was 9 points, and high score indicated high quality. A study was classified as high quality if the total score was more than 5 points (28).

Statistical analysis

Risk ratio (RR) with 95% confidence intervals (95% CIs) was calculated as effect size for the meta-analysis of dichotomous data, weight mean difference (WMD) with 95% CIs for continuous data. Heterogeneity among the included studies was assessed using Q chi-square

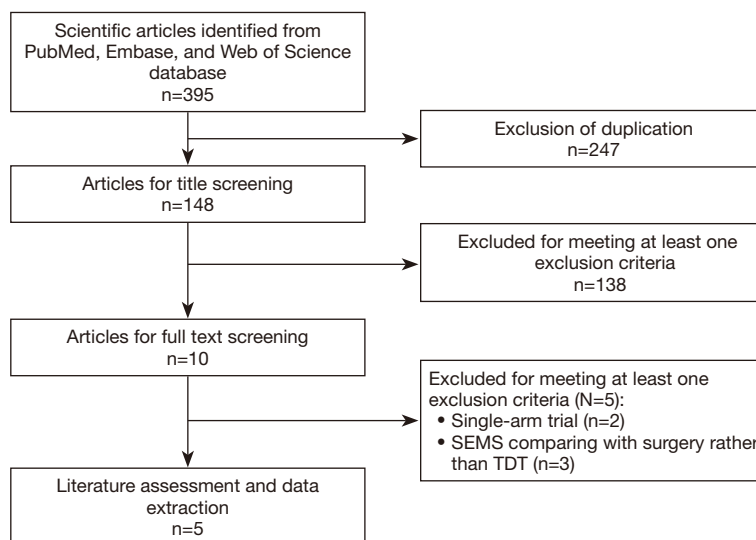


Figure 1 Eligibility of studies for inclusion in meta-analysis. SEMS, self-expandable metallic stents; TDT, transanal decompression tubes.

test, in which A P value less than 0.1, or I^2 greater than 50% represent significant heterogeneity (29). A random-effects model (30) or a fixed-effects model (31) was used to pool the data according to the presence or absence of heterogeneity. For clinical heterogeneity, sensitivity analysis was performed to explore the potential sources of heterogeneity. The publication bias was not assessed since the number of included studies was less than 10. A P value less than 0.05 was judged as statistically significant, except where otherwise specified.

Results

Search results

The initial screening retrieved 395 publications from the databases, of which 247 were removed because of duplicates. Then the review for title or abstract excluded 138 studies. In the next phase, 10 studies were screened for full-text information, in which 5 were excluded for a variety of reasons (single-arm study design, non-comparison between SEMS and TDT). Then the remaining 5 studies (22-26) were identified for data extraction and meta-analysis. The detailed flow diagram is shown in *Figure 1*.

Study characteristics

Table 1 describes the detailed characteristics of the five included studies. Among these studies, four were performed

in Japan (22,24-26) and one in China (23). The sample size in SEMS group ranged from 16 to 28, whereas that of TDT group ranged from 12 to 45. All these studies were retrospective or prospective comparative studies, and no randomized controlled trials. Among the patients, 27.92% of them were classified as pathological stage II, 41.12% as stage III, and 30.96% as stage IV. The NOS score of all the studies were greater than 5 points, which indicated that these studies were of high quality.

Success rate (technical success, clinical success)

All the articles provided the data of success rate (22-26). The overall success rate was 92.1% in SEMS group compared to 71.9% in TDT group. The pooled estimate showed that SEMS had better effects than TDT in terms of clinical success rate (RR =1.30, 95% CI: 1.06, 1.60; P=0.012) and technical success rate (RR =1.33, 95% CI: 1.07, 1.65; P=0.011) (*Figure 2*).

Operative time

Three studies presented the data of operative time (24-26). Significant heterogeneity ($I^2=92.4%$, $P<0.001$) was observed across these studies that enrolled 76 patients in SEMS group and 90 patients in TDT group. SEMS significantly prolonged the operative time within the random-effects model (WMD =93.49 minutes, 95% CI: 14.24, 172.75; P=0.021) (*Figure 3*).

Table 1 Baseline characteristics of patients in the trials included in the meta-analysis

Study	Country	Treatment regimen	No. of patients	Male/female	Age (mean \pm SD, y)	TNM stage (II/III/IV)	NOS score
Kawachi J (22)	Japan	SEMS	19	8/11	69.4 \pm 12.3	8/7/4	6
		TDT	12	5/7	74.1 \pm 10.5	7/2/3	
Li CY (23)	China	SEMS	16	10/6	73.3 \pm 8.5	NR	6
		TDT	13	8/5	72.6 \pm 4.7	NR	
Matsuda A (24)	Japan	SEMS	28	17/11	66 [60–73]	3/17/8	7
		TDT	45	29/16	70 [56–77]	4/22/19	
Takeyama H (25)	Japan	SEMS	22	8/14	71.3 \pm 10.3	6/11/5	6
		TDT	12	8/4	68.5 \pm 10	5/5/2	
Kagami S (26)	Japan	SEMS	26	17/9	70 [50–85]	11/6/9	7
		TDT	33	23/10	68 [46–90]	11/11/11	

SD, standard deviation; NOS, Newcastle-Ottawa; SEMS, self-expandable metallic stent; TDT, transanal decompression tube.

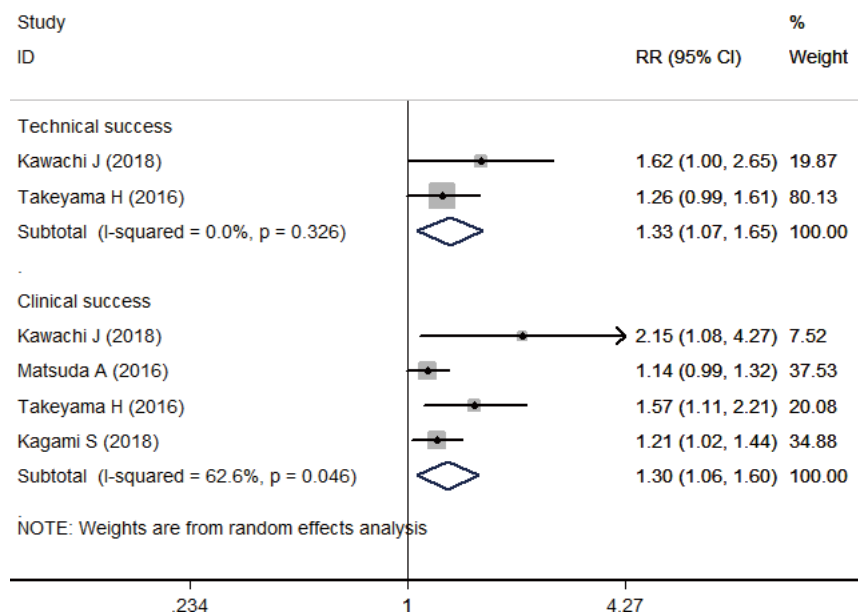


Figure 2 Forest plot showing the comparison between SEMS and TDT in clinical success rate and technical success rate. SEMS, self-expandable metallic stents; TDT, transanal decompression tubes.

Hospital stay

All the articles provided the data of hospital stay (22–26), in which 111 patients participated in SEMS group and 115 in TDT group. The test for heterogeneity across the articles was found to be significant ($I^2=96.6\%$, $P<0.001$), thus a random-effects model was applied to summarize the data. Results demonstrated that, SEMS-treated patients had

similar duration of hospital stay than TDT-treated patients (WMD =1.58 days, 95% CI: –15.90, 19.06; $P=0.860$) (Figure 4). Sensitivity analysis was conducted by excluding the trial with outlier (24) showed that, the summarized data (WMD =6.95 days, 95% CI: –4.27, 18.18; $P=0.225$) changed a lot but the heterogeneity was still present ($I^2=79.6\%$, $P=0.002$).

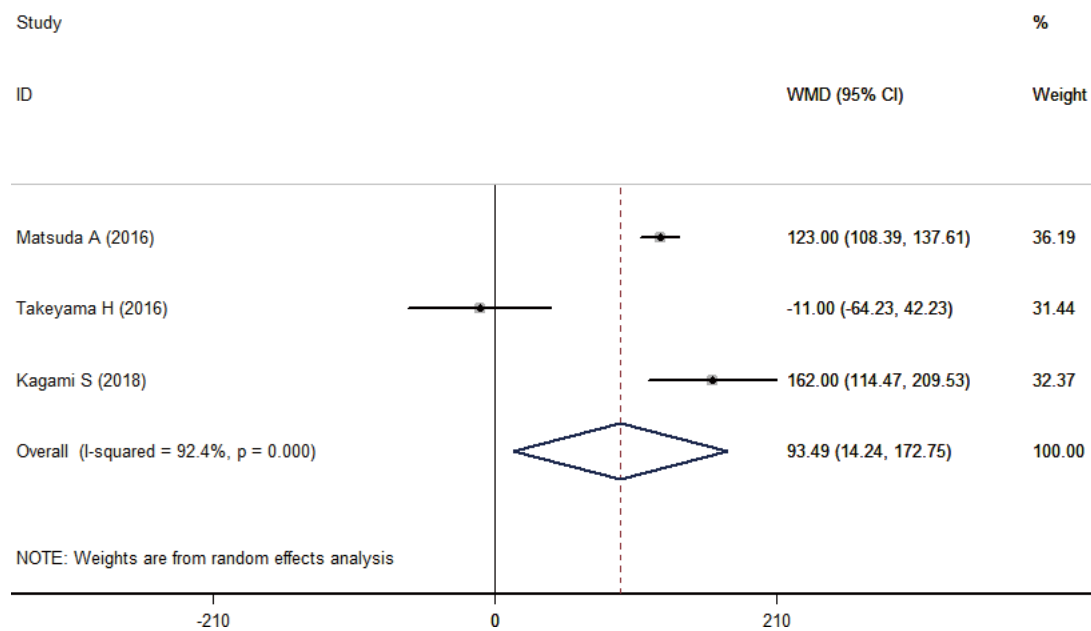


Figure 3 Forest plot showing the comparison between SEMS and TDT in operative time. SEMS, self-expandable metallic stents; TDT, transanal decompression tubes.

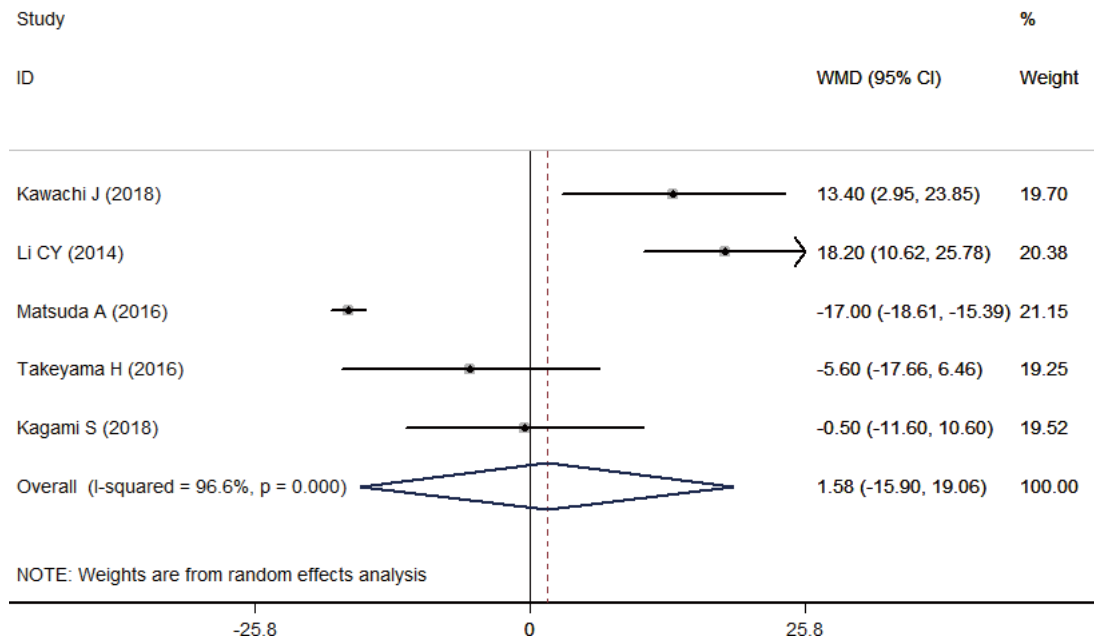


Figure 4 Forest plot showing the comparison between SEMS and TDT in hospital stay. SEMS, self-expandable metallic stents; TDT, transanal decompression tubes.

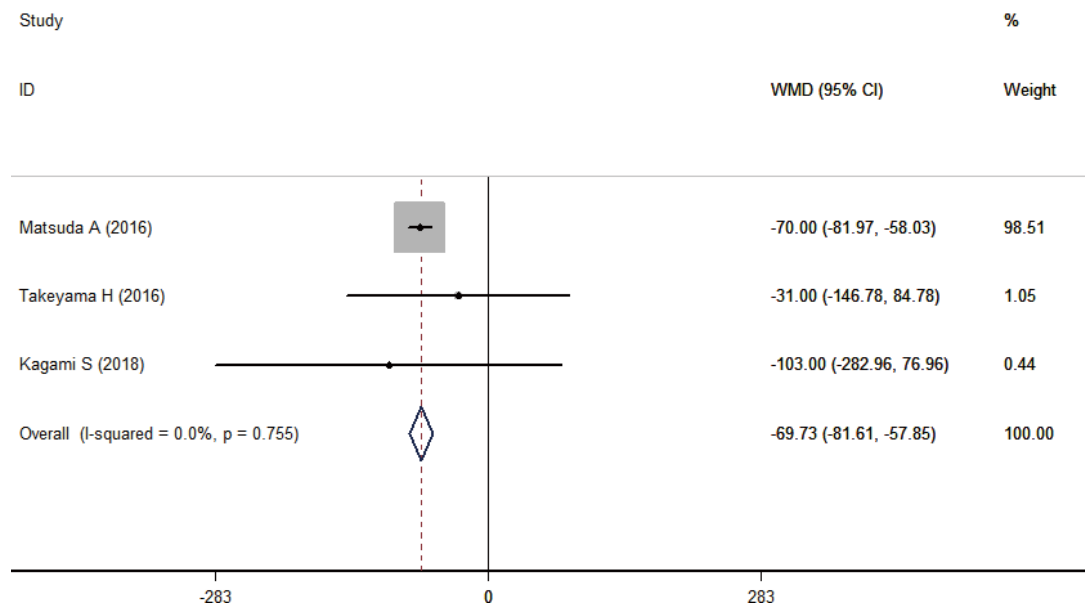


Figure 5 Forest plot showing the comparison between SEMS and TDT in blood loss. SEMS, self-expandable metallic stents; TDT, transanal decompression tubes.

Blood loss

The data of blood loss was reported in three studies (24–26). These studies involved 166 patients with 76 in SEMS group and 90 in TDT group. The heterogeneity across studies was not significant ($I^2=0.0\%$, $P=0.755$). Results using a fixed-effects model suggested that, the blood loss was significantly lower in SEMS group compared to that in TDT group (WMD = -69.73 mL, 95% CI: -81.61 , -57.85 ; $P<0.001$) (Figure 5).

Solid food intake and temporal discharge

Three studies reported these data, however, only two of them (24,26) provided available data. The rates of solid food intake and temporal discharge prior to surgery were 100% and 83.33% in SEMS group, and 2.56% and 0% in TDT group, respectively. Meta-analysis of these data revealed significantly better QoL in SEMS group than in TDT group, including solid food intake (RR =27.15, 95% CI: 8.73, 84.45; $P<0.001$) and temporal discharge (RR =64.47, 95% CI: 9.10, 456.57; $P<0.001$). There was no significant heterogeneity across the articles.

Mortality

Two studies reported the data of mortality (22,24). The

mortality rate in SEMS and TDT group was 4.44% and 5.26%, respectively. Pooled data indicated that the mortality rate in the two groups was comparable (RR =0.78, 95% CI: 0.12, 4.69; $P=0.767$).

Complications

All the included articles provided the complications (22–26). Pooled the results suggested that, there was no significant difference between the SEMS and TDT groups regarding the complications, including surgical site infection (RR =0.72, 95% CI: 0.23, 2.28; $P=0.574$), anastomotic leakage (RR =1.98, 95% CI: 0.40, 9.78; $P=0.404$), bowel obstruction (RR =0.89, 95% CI: 0.27, 2.96; $P=0.842$), pneumonia (RR =0.22, 95% CI: 0.03, 1.88; $P=0.167$), stoma creation (RR =2.12, 95% CI: 0.36, 12.63; $P=0.408$), and perforation (RR =0.18, 95% CI: 0.02, 1.39; $P=0.099$).

Discussion

The present meta-analysis included five studies and evaluated the clinical outcomes of SEMS for MLBO as a bridge to surgery compared to TDT. Data-analysis showed that, SEMS had significantly longer operative time, less blood loss, and higher success rate as compared with TDT. Patients' QoL as shown by solid food intake and

temporal discharge was also better in SEMS group than in TDT group. However, the hospital stay and mortality rate were comparable between the two groups. Postoperative complications, including surgical site infection, anastomotic leakage, bowel obstruction, pneumonia, stoma creation and perforation, were also equivalent between the two treatment strategies. These results indicated the preoperative SEMS insertion was comparable with decompression with TDT regarding hospital stay, mortality and complications. However, SEMS provided better outcomes in terms of success rate and QoL compared with TDT.

In the present study, a significantly greater percentage of patients in SEMS group achieved success than in TDT group. The clinical and technical success rates of SEMS were 96.84% and 97.56%, as compared with 75.23% and 70.97% for TDT, respectively. Our findings were consistent with the success rates of SEMS and TDT reported in the previous studies, which ranged from 83% to 100% for SEMS, and 60-90% for TDT (20,23,32-34). Kagami *et al.* retrospectively collected data from 56 patients with malignant left-sided colon obstruction (26). They found that patients in SEMS group obtained significantly higher success rate than TDT (technical success rate: 94.7% *vs.* 58.3%, clinical success rate: 89.4% *vs.* 41.7%) (26). Previous study has reported that SEMS has a significantly higher clinical success rate than TDT, which might be due to its relatively larger internal diameter (35). Kawachi *et al.* (22) found that although the tumor size in TDT group was smaller than that in SEMS group, the clinical success rate for TDT was lower than SEMS (41.7% *vs.* 89.4%), which might be the result of the endoscopists' skill. The better effect of SEMS than TDT in success rate might be explained by the following reasons: (I) the guidewire is thinner for SEMS placement than for TDT, which makes it easier to pass through the tumor; (II) the hand-produced insertion force can be efficiently transmitted to the tip of SEMS device through the scope, maintaining a straight and rigid colonic axis (24). Therefore, SEMS placement could be relatively easily performed for both left-and right-sided MLBO.

In the present meta-analysis, SEMS increased the operative time and reduced blood loss in the treatment of MLBO when compared with TDT. Matsuda *et al.* (24) retrospectively reviewed 101 patients with MLBO (24), and showed that the surgery duration in SEMS group [258 [162-313] minutes], was significantly longer than in TDT group [135 [162-313] minutes]; however, the blood loss was less in SEMS group than in TDT group, although the

difference between them was not significant ($P=0.360$) (24). Similarly, Kagami *et al.* (26) also reported longer operative time and less blood loss in SEMS group than in TDT group.

The most advantaged benefit of SEMS for MLBO than TDT was the maintenance of patients' preoperative QoL. SEMS-treated patients were able to initiate solid food intake and underwent preoperative temporary discharge when compared to TDT-treated patients. In the present study, SEMS had higher rates of solid food intake and temporal discharge than TDT. Matsuda *et al.* (24) reported that solid food intake after decompression and preoperative temporary discharge only occurred in SEMS group but not in TDT group (24). Kagami *et al.* (26) reported similar results in their retrospective study, which showed that all patients in SEMS group could initiate solid food intake and underwent preoperative temporary discharge from hospital (26).

Intestinal perforation was more frequently occurred in TDT group than in SEMS group, however, this difference was not significant. Previous studies revealed that the perforation rate of SEMS was generally comparable with that of TDT, with the corresponding values of ranging from 3% to 10%, and 4% and 12%, respectively (23,36-38). However, in some other recent studies, they have suggested that the perforation rate of SEMS could be reduced to be 0% because of the technical improvement (39,40). This was confirmed in the study of Matsuda *et al.* (24), in which no perforation occurred in SEMS group. The authors reported that this might be explained by the following possible reasons: (I) the guide wire was handled gently; (II) the SEMS was performed with low axial force in majority of patients (25 of 28, 89%); (III) they chose a SEMS with appropriate length in order to avoid the contact with normal colonic mucosa (24).

There were several potential limitations. First, the sample size in some studies was relatively small. This would downgrade the overall quality of evidence about the effective comparison the two decompression advices for MLBO. Second, statistical analysis to assess publication bias was not assessed due to the limited number of included studies. Third, although no language restriction was imposed in the literature search, all the studies were published in English, which might result in language bias. Fourth, four of the five included studies were conducted in Japan, which potentially prevented the global application of these results. At last, due to the limited data, we did not perform meta-analysis to investigate survival-related outcomes (overall survival, progression free survival and

local recurrence), as well as to explore whether some of the outcomes were influenced by potential factors (type of patients, tumor stage, and tumor location). Further studies focused on these issues are needed.

In conclusion, the present study suggested that, treatment with SEMS for MLBO had better effects than TDT, including higher success rate, less operative time and blood loss, as well as tolerance with higher rates of solid food intake and temporary discharge. Regarding the safety file, the two treatments were equivalent. However, the present meta-analysis is limited by small sample size and potential publication bias. Thus, more large-scale trials were needed to verify our findings.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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