



Is bridge to surgery stenting a safe alternative to emergency surgery in malignant colonic obstruction: a meta-analysis of randomized control trials

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Abstract

Background Despite studies showing superior results in terms of reduced stoma rate and higher primary anastomosis rate, the safety of bridge to surgery stenting (BTS stent) for left-sided malignant colonic obstruction, especially in oncological terms, remains a concern.

Aim The aim of this meta-analysis was to evaluate whether BTS stent is a safe alternative to emergency surgery (EmS).

Methods Randomized control trials (RCTs) comparing BTS stent and EmS for left-sided colonic obstruction caused by primary cancer of the colon, up to Sep 2018, were retrieved from the Pubmed, Embase database, clinical trials registry of U. S. National Library of Medicine and BMJ and Google Search.

Results There were seven eligible RCTs, involving a total of 448 patients. Compared to EmS, BTS stent had a significantly lower risk of overall complications (RR = 0.605; 95% CI 0.382–0.958; $p = 0.032$). However, the overall recurrence rate was higher in the BTS stent group (37.0% vs. 25.9%; RR = 1.425; 95% CI 1.002–2.028; $p = 0.049$). BTS stent significantly increased the risk of systemic recurrence (RR = 1.627; 95% CI 1.009–2.621; $p = 0.046$). This did not translate into a significant difference in terms of 3-year disease-free survival or 3-year overall survival.

Conclusion BTS stent is associated with a lower rate of overall morbidities than EmS. However, BTS stent was associated with a greater chance of recurrence, especially systemic recurrence. Clinicians ought to be aware of the pros and cons of different interventions and tailor treatments for patients suffering from left-sided obstructing cancer of the colon.

Keywords Colon obstruction · Bridge to surgery · Stent · Colorectal cancer · SEMS

Up to 30% of patients suffering from colorectal cancer present with acute large bowel obstruction [1–3]. Emergency surgery (EmS) for acute obstruction at the left colon is associated with significant morbidity and mortality [4–7]. Self-expanding metallic stent (SEMS) can be used to relieve malignant colonic obstruction in patients with resectable disease, acting as a “bridge to surgery” [8]. Despite reports quoting high technical and clinical success rates, up to over

90% [9], there is a concern that the use of SEMS as a bridge to surgery might jeopardize oncological outcomes in patients with potentially curable disease [10]. A non-randomized comparative study demonstrated poorer survival in patients with SEMS compared to those with EmS [11]. The European Society of Gastrointestinal Endoscopy guideline stated that SEMS as a bridge to surgery is not recommended for left-sided malignant colonic obstruction, except in those with increased perioperative risks [12]. Nonetheless, the opposite view was proposed by a different consensus group, supporting the use of SEMS in such circumstances [13]. At present, the benefit of SEMS as a bridge to surgery remains unclear.

As new evidence has emerged [14], there is renewed interest in the above topic. Here, we aim to evaluate the updated evidence and attempted to answer the following question: is bridge to surgery stenting (BTS stent) a safe alternative to EmS in malignant left-sided colon obstruction? The primary

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objective was to compare the safety parameters between the two interventions: overall complications rates, mortality rates, locoregional recurrence, and systemic recurrence rates. The secondary objective was to compare the long-term outcomes, including the overall survival and disease-free survival rates.

Methods

Studies screening and selection

The methodology was adapted from the standard guidelines from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [15]. The search was carried out by Poon and Cheung, and included articles were reviewed by Poon, Cheung, and Chiu. All studies that compared the clinical outcomes of BTS stent with EmS in managing malignant colon obstruction were retrieved from Medline (PubMed), Embase (1980–), the clinical trials registry of U.S. National Library of Medicine and BMJ and Google Search. The search was carried out in September 2018. The MeSH terms “colon obstruction,” “stent,” “surgery,” and “malignant” were used as search terms. Only these four terms were used with the intention to include more literature for preliminary screening. In addition, “left sided,” “colonic stent,” and “malignant obstruction” was used for Google Search. Only randomized control trials (RCTs) with full articles in English and those that involved patients with potential curable disease were included. Editorials, case reports, expert opinions, letters to the editor, reviews without original data, conference abstract, and studies solely on the right-sided colon obstruction were excluded.

Data extractions and quality assessments

Data extractions and quality assessments were performed by Poon, which was then confirmed by Chiu. All data were captured from published literature except the locoregional and systemic recurrence rate of the study by Tung et al., for which the data were sought directly from the author [16].

Definitions of long-term outcomes

The measurement of long-term outcomes was made with reference to the time that the patients were enrolled in the trials. The local recurrence rate was known to be affected by its definition [17]. The definition of locoregional recurrence for colon cancer used in this review was adopted from Bowne et al., which included perianastomotic, mesenteric/nodal, retroperitoneal, and peritoneal [18].

Statistical analysis

Comprehensive meta-analysis (version 3, Biostat Inc, USA) was used for analyzing the results and constructing the forest and funnel plots. The risk ratio (RR) of adverse events occurring in patients treated with BTS stent compared to the EmS group was employed to evaluate the outcomes of the two interventions, except for survival outcomes, which odds ratio (OR) was used. 95% confidence intervals (95% CI) were used to evaluate the statistical significance of the RR and OR. An RR or OR value less than 1 indicates a superior outcome for BTS stent compared to EmS, and the value was considered statistically significant when $p \leq 0.05$. Assessment of heterogeneity was done by the χ^2 test and represented by the inconsistency index, I^2 . A fixed-effect model was used when $I^2 \leq 50\%$. A random-effect model was used when $I^2 > 50\%$. The χ^2 test was not employed to determine the heterogeneities of various analyses owing to its low power in detecting heterogeneity in a small-sample-sized analysis. Publication bias was evaluated by visual evaluation of the funnel plots. Results with asymmetrical funnel plots were further analyzed by Egger's linear regression.

Results

Search result

A total of 276 studies were identified. After removing duplicates, there were 274 studies remaining. After going through the titles and abstracts, 143 studies were excluded because of irrelevance or because the full articles were not available in English. A full review was performed for 131 full-text articles. A further 104 studies were excluded, and 27 studies were included for qualitative analysis. Seven trials were included for quantitative analysis (Fig. 1) [14, 16, 19–25].

Study characteristics

There were seven RCTs identified with a total of 448 patients (Table 1) [14, 19–21, 23–25]. There were 222 patients in the BTS stent group and 226 patients in the EmS group. The time from BTS stent to curative surgery ranged from 5 to 14 days. Two more publications reported the long-term follow-up results of previously published RCTs [16, 22]. There were four single-center trials [19, 23–25] and three multicenter trials [14, 20, 21]. Short-term outcomes were reported in seven publications [14, 19–21, 23–25]. Long-term outcomes were reported in five publications (Table 2) [14, 16, 22, 24, 25]. Three out of the seven RCTs were prematurely terminated. Two RCTs were stopped because of a

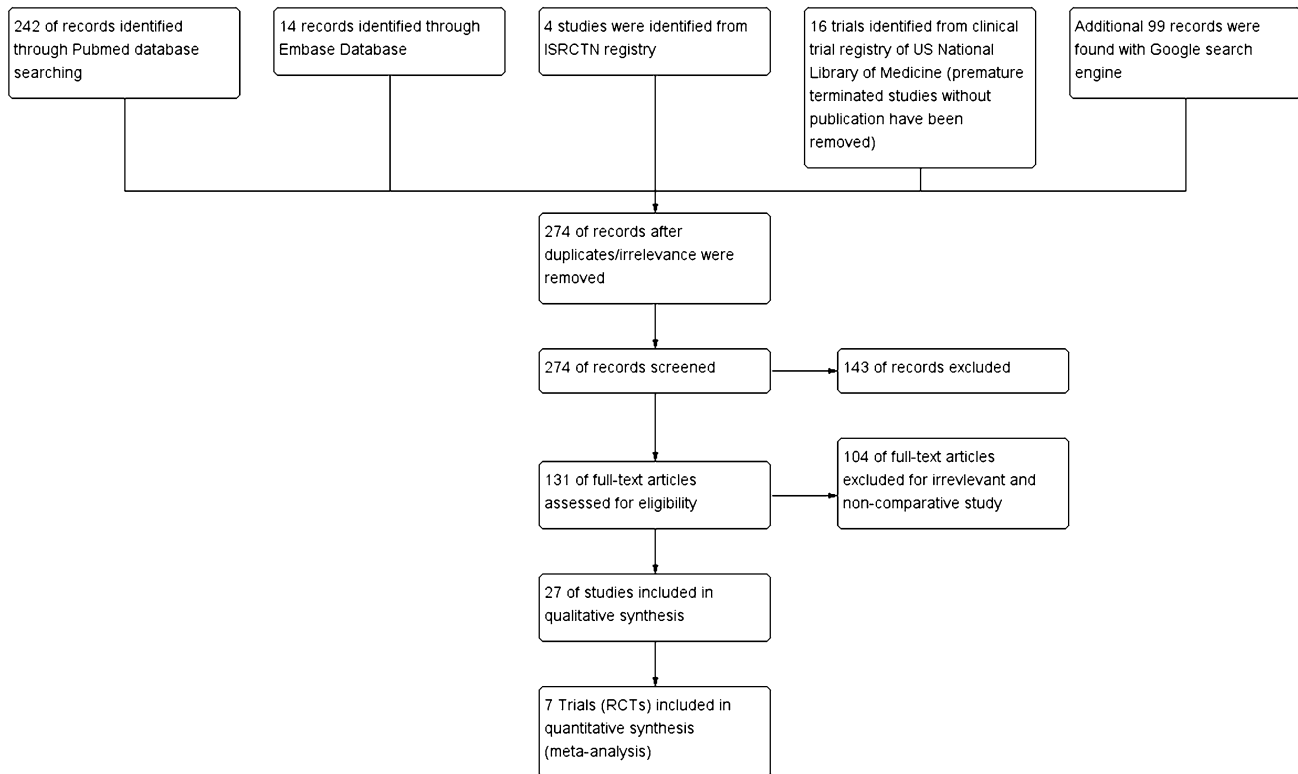


Fig. 1 PRISMA flow diagram

Table 1 Studies included in the analysis of overall complications rate and 30-day mortality rate of BTS stent versus EmS in malignant left-sided colonic obstruction

Authors	Stent type	Sample size	Year of publication	Study origin	Parameters included in this analysis
Cheung et al. [23]	Wallstent colonic stent	BTS stent: 24 EmS: 24 <i>T</i> =48	2009	Hong Kong, China	1
Pirlet et al. [20]	Bard Nitinol uncovered self-expanding stent	BTS stent : 30 EmS: 30 <i>T</i> =60	2011	France	1, 2
van Hooft et al. [21]	Wallstent & Wallflex colonic stent	BTS stent : 47 EmS: 51 <i>T</i> =98	2011	Netherlands	1, 2
Alcantara et al. [25]	Wallflex colonic stent	BTS stent : 15 EmS: 13 <i>T</i> =28	2011	Spain	1, 2
Ho et al. [19]	Wallflex colonic stent	BTS stent : 20 EmS: 19 <i>T</i> =39	2012	Singapore	1, 2
Ghazal et al. [24]	Not specified	BTS stent : 30 EmS: 30 <i>T</i> =60	2013	Egypt	1
Arezzo et al. [14]	Not specified	BTS stent : 56 EmS: 59 <i>T</i> =105	2016	Spain and Italy	1, 2

BTS stent bridge to surgery stenting, *EmS* emergency surgery, *T* total no. of patient

1—included for overall complications; 2—included for 30-day mortality risk assessment

Table 2 Studies included in the meta-analysis of overall, locoregional and systemic recurrence rates, 3-year disease-free survival and 3-year overall survival rates of BTS stent versus EmS in malignant left-sided colonic obstruction

Authors	Year	Sample size	Location of tumors (BTS stent/EmS)	Interval between stenting and surgery	Median follow up
Alcantara et al. [25]	2011	BTS stent = 15 EmS = 13 T = 28	Splenic flexure (2/4) Descending colon (1/2) Sigmoid colon (11/4) Rectosigmoid (0/3) Upper rectum (1/0)	5–7 days	38 months for BTS stent 38 months for EmS
Ghazal et al. [24]	2013	BTS stent = 29 EmS = 30 T = 59	Descending colon (4/3) Sigmoid colon (14/17) Rectosigmoid (12/10) Synchronous (0/1)	7–10 days	18 months for BTS stent 18 months for EmS
Tung et al. [16]	2013	BTS stent = 24 EmS = 24 T = 48	Not specified	Within 14 days	65 months for BTS stent 32 months for EmS
Sloothaak et al. [22]	2014	BTS stent = 26 EmS = 32 T = 58	Not specified	5–14 days	41 months for BTS stent 45 months for EmS
Arezzo et al. [14]	2017	BTS stent : 56 EmS: 59 T = 105	Splenic flexure (5/13 ^a) Descending colon (43/34 ^a) Sigmoid colon (8/12 ^a)	3–8 days	36 months for BTS stent 36 months for EmS

BTS stent bridge to surgery stenting, EmS emergency surgery, T total no. of patient

^aTen patients in the BTS stenting group of Arezzo's study were excluded from analysis after randomization (eight developed complications following stent placement and two refused surgery after obstruction relieved by stent) and this constitutes to T = 105 in the study

high perforation rate in the BTS stent arm [20, 21] and one was stopped because of a high anastomotic leakage rate in the EmS arm [25].

Critical appraisal

All included studies reported random sequence generation and allocation concealment, resulting in a low risk of selection bias. The blinding of patients and personnel was considered impractical and was not assessed. The blinding of the assessor was unclear in two studies [19, 24] and not done in four trials [14, 16, 20, 23, 25]. There were four studies with high risk of performance bias due to variations in practices (e.g., choice of EmS, among different surgeons and different centers, some explained by their multi-center nature) [19–22]. Two trials were regarded as having high attrition bias due to a high dropout rate [21] and premature closure [25]. One study was considered at high risk of reporting bias as only the overall survival, without the disease-free survival, was reported [25]. The risk of bias assessment is summarized in Fig. 2. As the number of included studies was small, the funnel plots and Egger's test did not show useful information.

Overall complications rate

The morbidities associated with the two interventions were reported in seven publications [14, 19–21, 23–25], with a

total sample size of 447. Regarding the overall complications rate, the risk was significantly reduced by the BTS stent with a RR of 0.605 ($p = 0.032$; 95% CI 0.382–0.958). However, the results of individual studies on the occurrence of adverse events were quite heterogeneous with an I^2 value of 72.8% (Fig. 3A).

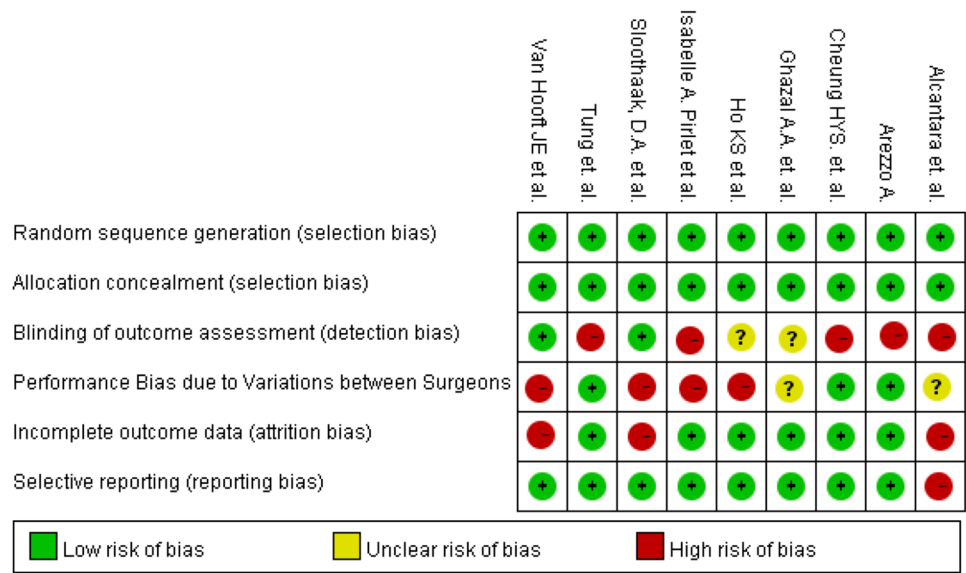
The 30-day mortality rate

In total, five studies with 338 patients were included in the 30-day mortality rate analysis [14, 19–21, 25]. There were 166 and 172 patients in the BTS stent group and EmS group, respectively. The overall RR was 0.963 (95% CI 0.468–1.982; $p = 0.918$) (Fig. 3B). No significant difference was noted between the two interventions. The included studies were homogeneous ($I^2 = 0.0\%$), and the funnel plot was symmetrical.

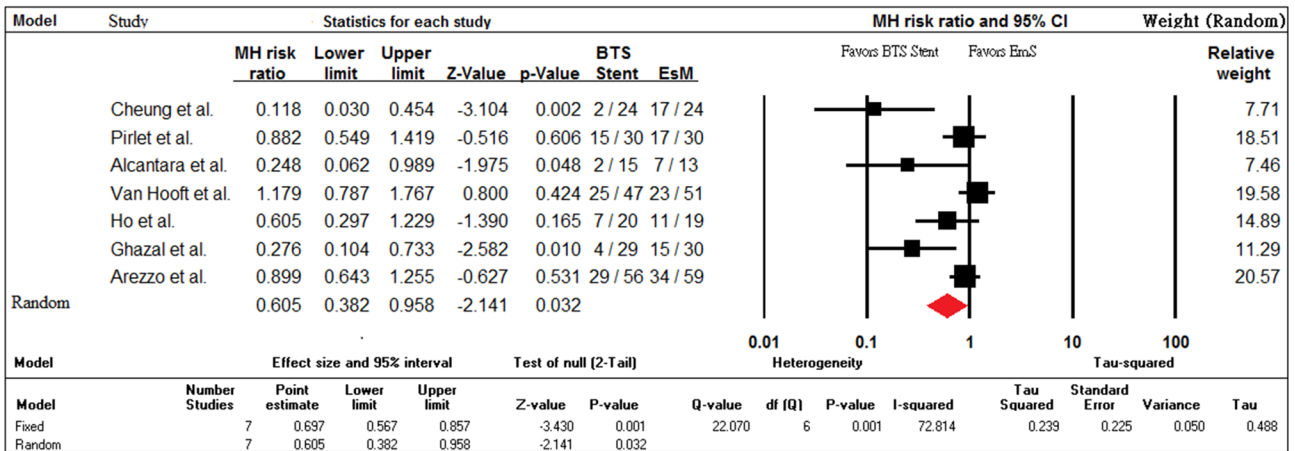
Locoregional and systemic recurrences

Five studies with a total of 293 patients reported on the recurrence rate. The median follow-ups in the BTS stent and EmS groups were compared using a two-tailed Mann Whitney U test, and no significant difference was detected. The overall recurrence rates were 37.0% and 25.9% for BTS stent and EmS, respectively. A statistically significant RR of 1.425 (95% CI 1.002–2.028; $p = 0.049$) was detected,

Fig. 2 Risk of bias analysis



A



B

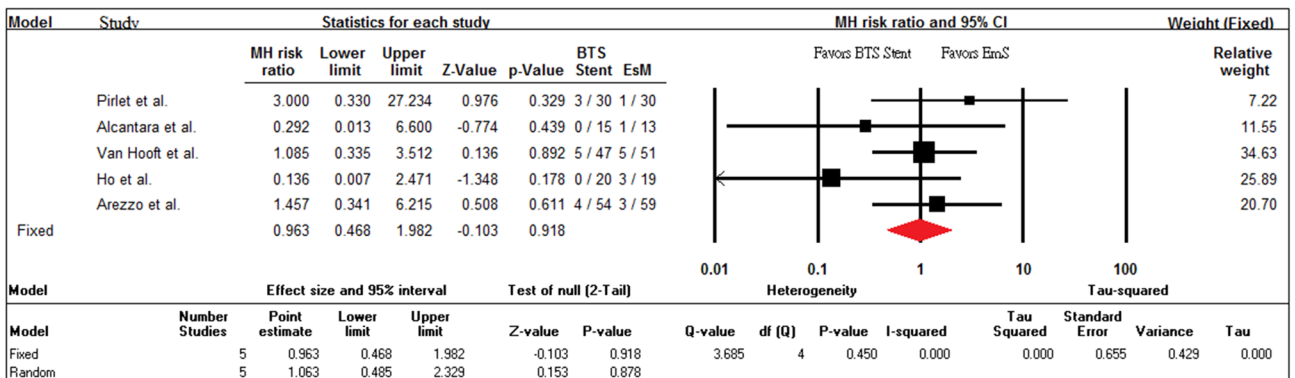
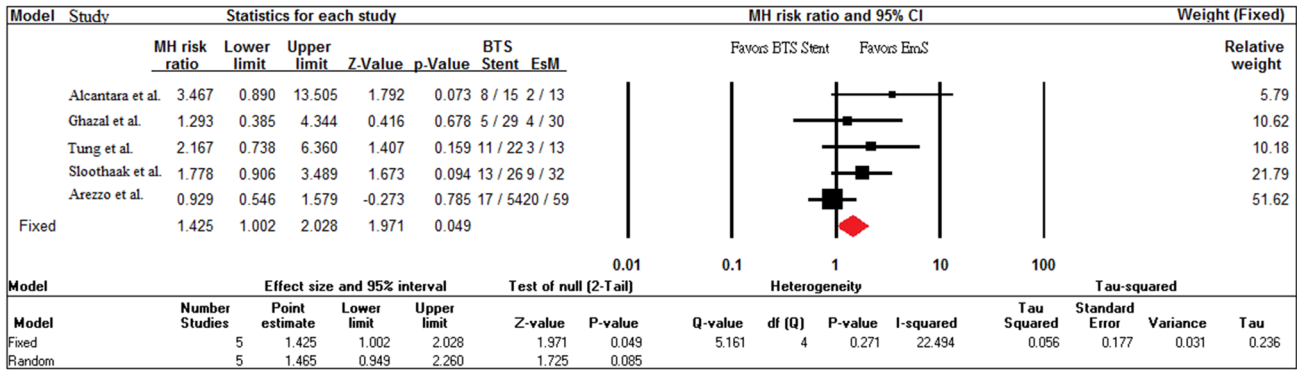
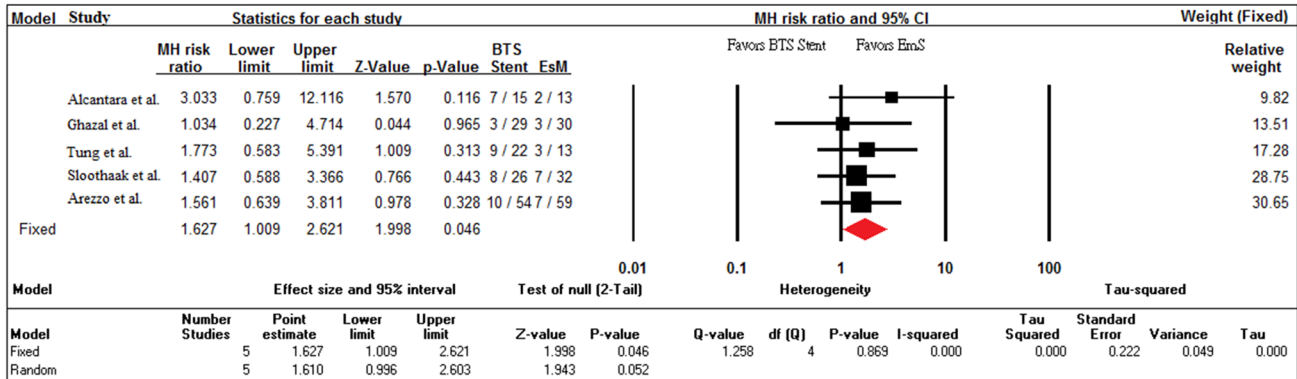


Fig. 3 Forest plot of A overall complications and B 30-day mortality of BTS stent versus EmS for malignant left-sided colonic obstruction

A



B



C

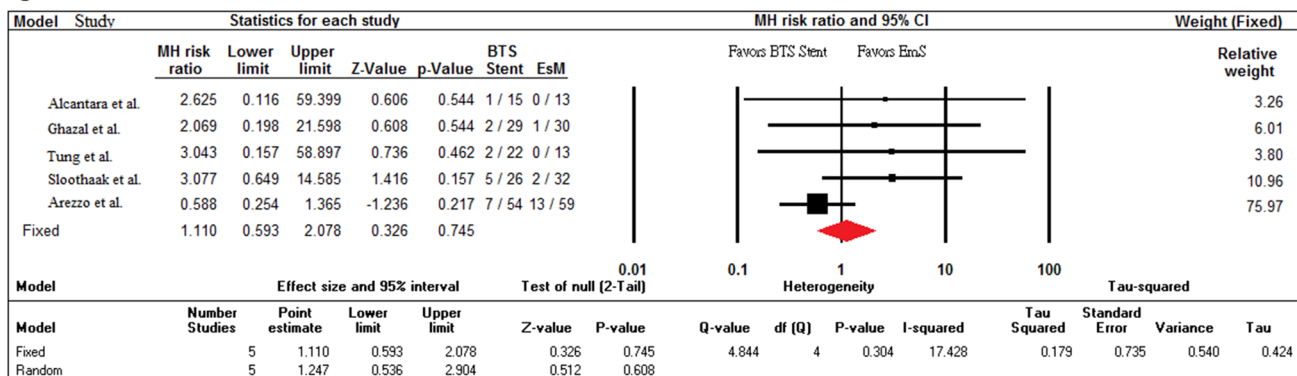


Fig. 4 Forest plot of **A** overall recurrence, **B** systemic recurrence, and **C** locoregional recurrence of BTS stent versus EmS for malignant left-sided colonic obstruction

suggesting a higher risk of overall recurrence in the BTS stent group (Fig. 4A).

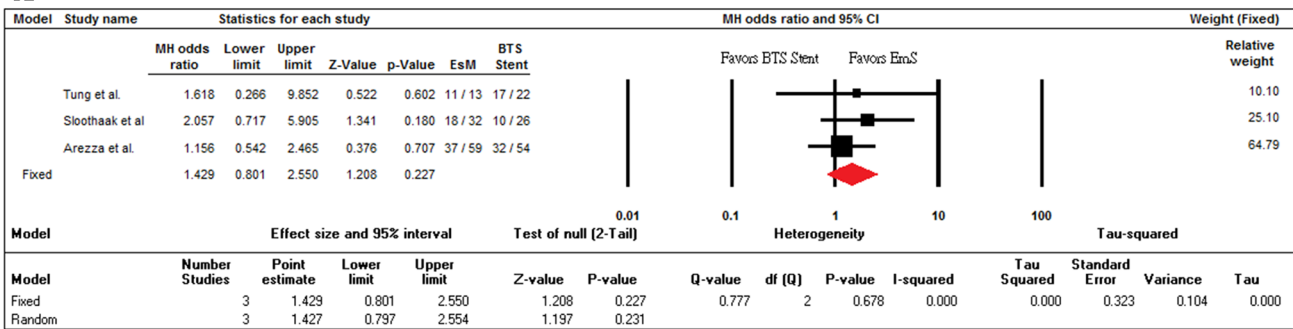
The analysis on the pattern of recurrence revealed a significantly greater chance of systemic recurrence with an RR of 1.627 (95% CI 1.009–2.621; $p=0.046$) in the BTS stent group (Fig. 4B). 37 of 146 (25.3%) patients from the BTS stent group developed systemic recurrence, whereas 22 of 147 (15.0%) patients in the EmS group developed systemic recurrence. All RRs from individual RCTs (i.e., $RR > 1$) favored EmS, despite their lack of statistical significance

individually, and the result was homogenous with $I^2=0.0\%$. The loco-regional recurrence rates were 11.60% and 10.9% for BTS stent and EmS, respectively. The RR was 1.110 (95% CI 0.593–2.078; $p=0.745$), and the risk was not statistically significant (Fig. 4C).

Three-year disease-free survival and overall survival

There were three studies including a total of 206 patients that reported 3-year disease-free survival [14, 16, 22].

A



B

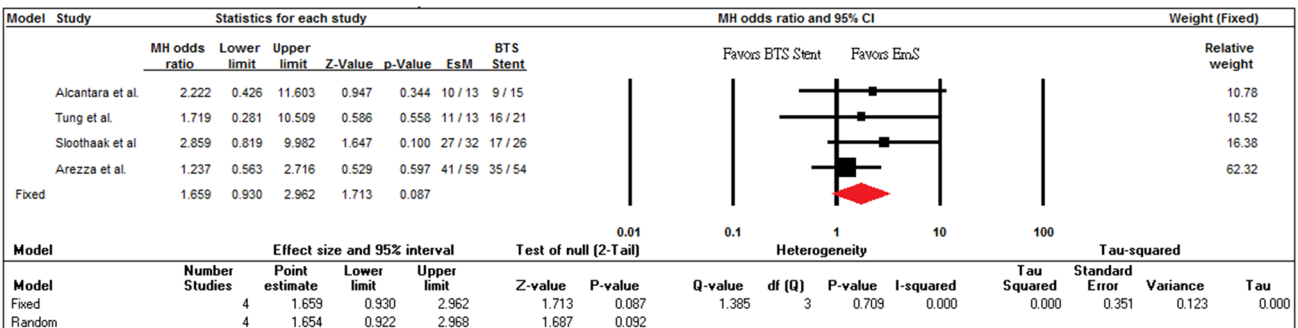


Fig. 5 Forest plot of **A** 3-year disease-free survival, and **B** 3-year overall survival of BTS stent versus EmS for malignant left-sided colonic obstruction

Pooled analysis showed comparable results between the two interventions (OR = 1.429; 95% CI 0.801–2.550; $p = 0.227$) (Fig. 5A). Four studies with a total of 233 patients reported on the 3-year overall survival [14, 16, 22, 25]. Pooled analysis showed no significant difference between the two interventions (OR = 1.659; 95% CI 0.930–2.962; $p = 0.087$) (Fig. 5B).

Sensitivity test

Sensitivity tests were performed on the 30-day mortality and overall complications. By alternatively removing individual studies, the 30-day mortality remained comparable between the BTS stent and EmS group. The RR was 0.834 (95% CI 0.360–1.932; $p = 0.672$) and 1.051 (95% CI 0.496–2.227; $p = 0.897$) after removing the largest and smallest study, respectively. The risk of overall complications remained significant after excluding the largest study (RR = 0.505; 95% CI 0.269–0.948; $p = 0.034$) but became insignificant after removing the smallest study (RR = 0.659, 95% CI 0.417–1.042; $p = 0.074$). The result also becomes insignificant when the study by Cheung et al. [23] was excluded. A sensitivity test was not performed for survival and recurrence rates due to the scarcity of studies included.

Discussion

The advantage of using SEMS to relieve obstruction in left-sided colon cancer is that it converts an emergency operation into a semi-elective one, with patients spared from the high operative risks and potential morbidities associated with emergency colorectal resections. A meta-analysis found that 78% of patients who underwent BTS stent were able to undergo a single-stage surgery with primary anastomosis [26]. Although not all studies favored BTS stent [27], multiple meta-analyses showed that BTS stent was associated with lower complication rates, higher primary anastomosis rate, and lower permanent stoma rate compared to EmS [28–32]. However, the majority of these meta-analyses focused only on the short-term outcomes. The concern that, despite having a superior short-term outcome, BTS stent may jeopardize the long-term oncological outcome of patients with potentially curable cancers was not addressed.

Part of the reason why earlier meta-analyses did not focus on long-term outcomes was because of a scarcity of data. In fact, few comparative studies reported long-term outcomes. Of those that did, many were retrospective non-randomized studies [33, 34]. The results from the ESCO trial, a multi-center randomized controlled trial published recently, provided more data in this regard and allowed better analysis of the long-term outcomes from BTS stent [14].

This meta-analysis shows lower complication for BTS stent than EmS. The overall and disease-free survival rates were comparable. These findings were in line with previous meta-analyses [29, 31, 32, 35, 36]. However, those with BTS stent were more prone to overall and systemic recurrences. Locoregional recurrence is primarily related to the failure of local control, which, in the case of cancer of the colon, is surgical resection. Systemic recurrence is, however, more related to the dissemination of cancer cells from the primary tumor before resection. The systemic recurrence rate is more relevant in the evaluation of whether BTS stent has an adverse impact on oncological outcomes. To date, this is the first meta-analysis that analyzed systemic and locoregional recurrence rates following BTS stents and EmS and showing an inferior oncological outcome in BTS stent from data derived from RCTs.

Sloothaak et al. performed a subgroup analysis for the Dutch Stent-in 2 trial and demonstrated that those who had perforation after BTS stent were at increased risk of recurrence, compared to those without perforation [22]. Three European multicenter trials were prematurely terminated due to a high perforation rate, 6.6%, 12.77%, and 54.44% [20, 21, 37]. It was noted that a high percentage of patients in these trials suffered from complete obstruction [20, 21]. It is reassuring to see that these high perforation rates were not seen in later studies [38]. But apart from clinical perforation, silent perforation could occur. Sloothaak et al. also reported that microperforation was noted in 10% of the resected specimens from patients who had prior stent insertion. Unlike clinical perforation, which is usually procedure- and technique-related, silent perforation is related to stent expansion and is highly unpredictable and, therefore, difficult to prevent.

However, perhaps stent-related perforation is not the only explanation of poorer oncological outcome in patients with BTS stent. Some postulated that forceful expansion of the gut lumen and tumor by SEMs, even in the absence of perforation, could introduce cancer cells into surrounding vessels and facilitate hematological tumor dissemination. Maruthachalam et al. detected an increase in the expression of CK20 micro RNA in the peripheral blood samples of patients after SEMs insertion [39]. Malgras et al. demonstrated a higher incidence of peritoneal carcinomatosis and poorer survival after colonic stenting in a mouse model [40]. Stenting itself might also have an impact on tumor biology. Two studies reported a higher incidence of perineural invasion in resected specimens after BTS stent, albeit not translating into poor survival in one of them [41, 42].

The overall survival and disease-free survival of BTS stent and EmS were comparable in this meta-analysis, despite a higher risk of systematic recurrence in the BTS stent group. The available data from the RCTs only allowed pooled analysis for 3-year survival outcomes. Therefore, it

remains a possibility that the effect of systematic recurrence was not reflected in a relatively short period. Also, only three RCTs reported disease-free survival.

There are limitations to this meta-analysis. One of the major limitations of this analysis was that there are a limited number of long-term results from RCTs in the literature, and hence the sample size was somewhat inadequate to answer the question of whether BTS stent hurts long-term outcomes. It is unlikely that eligible studies were missed in this review. However, given the skepticism about BTS stent, conducting large-scale RCTs in the future would be extremely difficult [10]. Hopefully, the long-term follow-up results of some of the RCTs will be available in the future and help to address this issue. Another limitation was that EmS encompasses a wide variety of surgical procedures, each with a different clinical impact. Analyzing them as a single entity is far from ideal but often unavoidable.

Conclusion

BTS stent provided a favorable short-term outcome by reducing the overall complications in the treatment of malignant left-sided colonic obstruction. The 30-day mortality rate of BTS stent was comparable to EmS. In terms of long-term outcomes, both interventions have a similar 3-year disease-free survival and overall survival rate. However, BTS stent was associated with a higher incidence of systemic and overall recurrence. Therefore, this meta-analysis could not demonstrate that BTS stent is an oncologically safe alternative to EmS. Physicians should be aware of the pros and cons of BTS stent. The short-term advantages of BTS stent should be weighed against the potential long-term oncological hazards.

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Compliance with ethical standards

Disclosures Drs. Chi Chung Foo, Samuel Ho Ting Poon, Rosemaire Hon Yiu Chiu, Wai Yiu Lam, and Lam Chi Cheung and Professor Wai Lun Law have no conflicts of interest or financial ties to disclose.

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