

# Colonic stent versus emergency surgery as treatment of malignant colonic obstruction in the palliative setting: a systematic review and meta-analysis



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## Bibliography

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## ABSTRACT

**Background and study aims** Colorectal cancer (CRC) is the third most common malignancy and the third leading cause of cancer death worldwide. Malignant colonic obstruction (MCO) due to CRC occurs in 8% to 29% of patients. The aim of this study was to perform a systematic review and meta-analysis of RCTs comparing colonic SEMS versus emergency surgery (ES) for MCO in palliative patients. This was the first systematic review that included only randomized controlled trials in the palliative setting.

**Methods** A literature search was performed according to the PRISMA method using online databases with no restriction regarding idiom or year of publication. Data were extracted by two authors according to a predefined data extraction form. Primary outcomes were: mean survival, 30-day adverse events, 30-day mortality and length of hospital stay. Stoma formation, length of stay on intensive care unit (ICU), technical success and clinical success were recorded for secondary outcomes. Technical success (TS) was defined as successful stent placement across the stricture and its deployment. Clinical success (CS) was defined as adequate bowel decompression within 48 h of stent insertion without need for re-intervention.

**Results** We analyzed data from four RCT studies totaling 125 patients. The 30-day mortality was 6.3% for SEMS-treated patients and 6.4% for ES-treated patients, with no difference between groups (RD: -0.00, 95% CI [-0.10, 0.10], I<sup>2</sup>: 0%). Mean survival was 279 days for SEMS and 244 days for ES, with no significant difference between groups (RD: 20.14, 95% CI: [-42.92, 83.21], I<sup>2</sup>: 44%). Clinical success was 96% in the ES group and 86.1% in the SEMS group (RD: -0.13, 95% CI [-0.23, -0.02], I<sup>2</sup>: 51%). Permanent stoma rate was 84% in the ES group and 14.3% in the SEMS group (RR: 0.19, 95% CI: [0.11, 0.33], I<sup>2</sup>: 28%). Length of hospital stay was shorter in SEMS group (RD: -5.16, 95% CI: [-6.71, -3.61], I<sup>2</sup>: 56%). There was no significant difference between groups regarding adverse events (RD 0.18, 95% CI: [-0.19, 0.54;]) neither regarding ICU stay. (RD: -0.01, 95% CI: [-0.08, 0.05], I<sup>2</sup>: 7%). The most common stent-related complication was perforation (42.8% of all AE).

**Conclusion** Mortality, mean survival, length of stay in the ICU and early complications of both methods were similar. SEMS may be an alternative to surgery with the advantage of early hospital discharge and lower risk of permanent stoma.

## Introduction

Colorectal cancer (CRC) is the third most common malignancy and the third leading cause of cancer death worldwide. Malignant colonic obstruction (MCO) due to CRC occurs in 8% to 29% of patients, which is a gastrointestinal emergency requiring urgent decompression. If not adequately treated, MCO can lead to electrolytic fluid imbalance, bacterial translocation, colonic necrosis, and death [1–3].

Surgery has been the primary treatment of MCO for decades although surgical morbidity and mortality are higher in emergency scenarios than in elective procedures [4–6]. In the mid-1990s, endoscopic self-expanding metal stents (SEMS) emerged as a treatment for gastrointestinal surgical emergencies [7–9], including MCO, and the first studies raised high expectations because use of stents could avoid surgical intervention such as colostomy, leading to reduced morbidity and mortality, possibly resulting in higher quality of life (QOL) [10–11].

Many studies, including 13 randomized controlled trials (RCTs) [12–24] and 20 meta-analyses, have reported results of colonic SEMS as a bridge to surgery. However, SEMS use with palliative intent is not well studied.

The aim of this study was to perform a systematic review and meta-analysis of RCTs comparing colonic SEMS versus emergency surgery (ES) for MCO in palliative patients. This was the first systematic review that included only RCTs in the palliative setting.

## Methods

### Protocol and registration

A protocol was established and documented prior to initiating the study to specify eligibility criteria and analytical methods for the studies included in this systematic review and meta-analysis. This protocol can be accessed at [http://www.crd.york.ac.uk/PROSPERO/display\\_record.php?ID=CRD42017082304](http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017082304)

### Study selection

A literature search was performed using MEDLINE, EMBASE, the Cochrane Library, Scopus, LILACS, BVS, Cochrane Central Register of Controlled Trials (CENTRAL), and The Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases from March 2017 to November 2017, with no restriction regarding the idiom or the year of publication. The search results are shown in the supplementary material.

Complete manuscripts of all relevant studies published were retrieved, and reference lists were searched to identify any additional relevant papers. When more than one publication by the same group of investigators was available, the latest and most complete study was included in the analysis.

Reviews, meta-analysis, letters, editorials, abstracts, unpublished studies, case reports, and small case series were excluded.

### Inclusion criteria

RCTs comparing colonic SEMS versus surgery for malignant large bowel obstruction in palliative patients were included.

### Exclusion criteria

Studies reporting the following were excluded: stenting for benign stenosis; stents as a bridge to surgery; stents placed under fluoroscopic guidance alone by an interventional radiologist; inadequate data on outcome variables for the two techniques; and reports wherein the data were impossible to calculate from the published results.

### Data extraction

Data were extracted by two authors (IB and BM) according to a predefined data extraction form. Disagreements were resolved by consulting with a third investigator.

Data regarding study characteristics, total number of patients included, characteristics of the study population, and the number of subjects in each group were collected. Clinical variables included the American Society of Anesthesiologists classification (ASA), tumor site, metastasis, the type of stent used, and technical and clinical success after stent placement.

Technical success (TS) was defined as successful stent placement across the stricture and its deployment. Clinical success (CS) was defined as adequate bowel decompression within 48 hours of stent insertion without the need for reintervention.

Primary outcomes included 30-day mortality, survival, CS, and early adverse events (from 0 to 30 days). Secondary outcomes included TS, stoma formation, intensive care unit (ICU) stay, and length of hospital stay.

### Assessment of study quality

Four RCTs were included in the analysis. The quality of these studies was assessed by applying the Jadad score and the Cochrane Collaboration's tool for assessing risk of bias (► **Table 1**).

### Statistical analysis

Regarding meta-analysis, the difference was calculated as the risk difference (RD) for the Cochran-Mantel-Haenszel test with a 95% confidence interval (CI) dichotomous variables and as the mean difference (MD) with fixed effect using inverse variance with a 95% CI for continuous variables. Semi-quantitative measures were described as arithmetic mean, standard deviation (SD), and results of Student's *t*-test analysis. All data were addressed in an intention-to-treat (ITT) analysis.

The RevMan 5 software (Review Manager Version 5.3.5: Cochrane Collaboration, Copyright © 2014) was used for the meta-analysis of primary and secondary outcomes. Student's *t*-test was used to compare the weighted arithmetic means survival, time stay on the ICU and hospital stay because the standard deviation of these data could not be extracted from most of the included studies. Heterogeneity was tested with the Q test for significance and with the inconsistency index ( $I^2$ ), where a value >50% was considered as substantial heterogeneity between studies. A funnel plot was generated and linear regression tests were performed excluding the studies that were loca-

► **Table 1** Methods used in therapeutic studies.

Study	Clinical question	Adequacy randomization	Allocation concealment	Double-blinding	Dropouts (<20%)	Characteristics, prognostics or demographic	Outcomes	Intent-to-treat	Sample size	Jadad
Young, 2015 [10]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	4
Fiori, 2012 [25]	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No	3
Van Hooft, 2008 [26]	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes	3
Xinopoulos, 2004 [28]	Yes	Nr	Nr	Yes	Yes	No	Yes	Yes	No	3

ted outside the funnel plot (outliers). Next, another meta-analysis was performed without the outliers. True heterogeneity was presumed and the random effects model was applied in case of persistent high heterogeneity or if outliers could not be detected.

## Results

A search of the literature yielded 32,048 records from all databases. In total, 27 trials were included in the initial selection of articles on surgery and stents; four studies were duplicates. Therefore, full texts of 23 studies were reviewed and 19 were excluded for one or more of the following reasons: the study was not a controlled clinical trial; SEMs was used as a bridge to elective surgery; or the study was irrelevant to this topic.

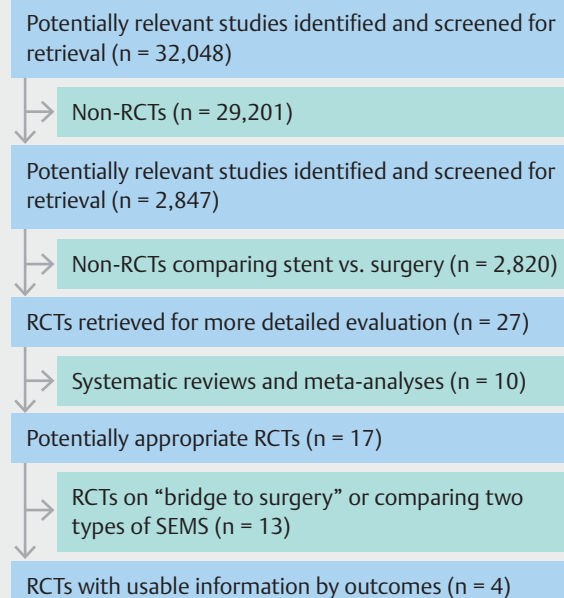
Finally, four RCTs were selected for this study including 125 patients (► **Fig. 1**).

### Results of individual studies

Characteristics and available data on the number of patients in each group, their ages, the location of neoplasia (i. e., colonic or rectal), metastasis, and ASA status for all included studies are summarized in ► **Table 2**.

### Primary outcomes

Mortality rate was assessed in all of the included studies. Thirty-day mortality was 6.3% in the SEMs group and 6.4% in the ES group, but mortality rate did not statistically differ between the groups (RD: 0.00, 95% CI: -0.10 to +0.10  $I^2$ : 0%). Egger's linear regression test did not reveal any publication bias (bias = 0.03;  $P$  = 0.98) (► **Fig. 2**). In three studies assessing survival, mean survival was 279 days in the SEMs group and 244 days in the ES group, with no statistically significant difference between groups (MD: 20.14, 95% CI: -42.92 to +83.21,  $I^2$ : 44%) (► **Fig. 3**). CS was higher in the ES group (96%) than in the SEMs group (84%) (RD: -0.13, 95% CI: -0.23 to -0.02,  $I^2$ : 51%) (► **Fig. 4**). Data regarding 30-day adverse events (AEs) were available for all four studies, with no statistically significant difference between the groups regarding AEs (RD: 0.18, 95% CI: -0.19 to +0.54,  $I^2$ : 87%) (► **Fig. 5**).

► **Fig. 1** Search strategy [36].

### Secondary outcomes

TS was compared using ITT analysis, slightly favoring the ES group (RD: -0.13, 95% CI: -0.23 to -0.02  $I^2$ : 51%) (► **Fig. 6**).

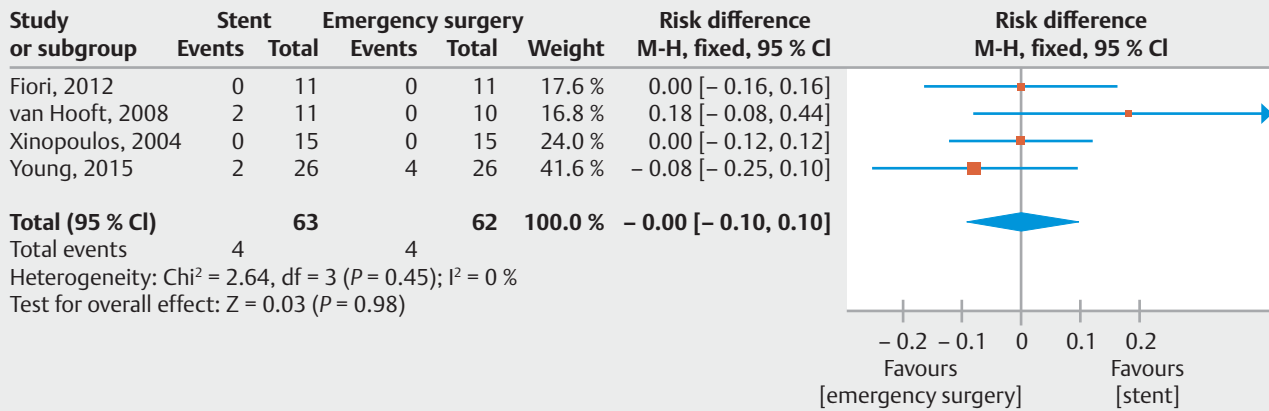
Stoma formation was higher in the ES group, in which 86.1% of the patients underwent a definitive colostomy compared to 14.3% of patients in the SEMs group (RR: 0.19, 95% CI: 0.11 – 0.33,  $I^2$ : 28%) (► **Fig. 7**). Three studies reported ICU admission after treatment and corresponding information from the fourth article was acquired from the author [25]. Meta-analysis revealed no statistically significant difference between the groups (MD: -0.01, 95% CI: -0.08 to +0.05,  $I^2$ : 7%) (► **Fig. 8**). All studies reported the length of hospital stay (► **Fig. 9**). In case of high heterogeneity ( $I^2$ : 74%), funnel plot (► **Fig. 10**) analysis was performed to detect an outlier study [26], and heterogeneity decreased after removal of that study ( $I^2$ : 56%) (► **Fig. 11**). Mean hospital stay was 17.5 days in the SEMs group

► **Table 2** Population characteristics.

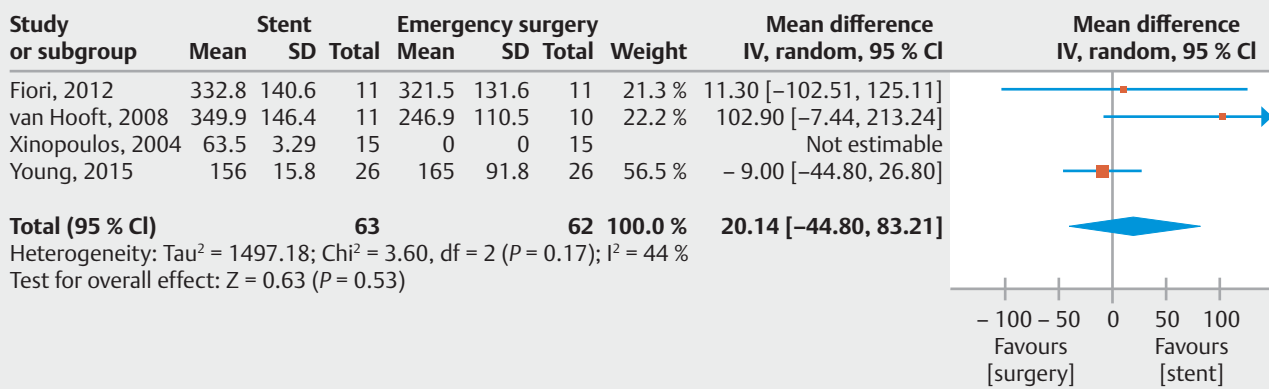
Author	Year	Total n	Tumor site	N site tumor (sems)	N site tumor (es)	Metastasis		Age		Sex ratio (m/f)		ASA		Follow-up		
						SEMS	ES	SEMS	ES	SEMS	ES	SEMS	ES			
Fiori [25]	2012	22	Sigmoid Rectal	7	7	Liver	9	77.2 <sup>1</sup>	76 <sup>1</sup>	6/5	7/4	ASA I/II	10	12 months		
				4	4	Lung Peritoneal	2 3						1		ASA III	1
Van Hooff [26]	2008	21	Rectosigmoid Descending colon	7	9	Lung	6	61.5±12.9 (42±88)	67.8±12.3 (46±81)	4/7	7/3	NR	NR	12 months		
				4	1	Liver Bone Lymphatic Others	11 1 3 1									
Young [10]	2015	52	Rectum Rectosigmoid Sigmoid Descending Splenic flexure Transverse colon Hepatic flexure Ascending colon	5	6	Liver	19	66	67	17/9	18/8	ASA I/II	17	12 months		
				9	5	Lung	7	(41–83)	(35–86)				ASA III		7	
				8	12	Peritoneal	8									
				2	1	Retropertitoneal	1									
				1	1	Bone	0									
				0	0	Brain	1									
Xinopoulos [28]	2004	30	Rectosigmoid Sigmoid	NR	NR	NR	NR	NR	NR	9/6	7/8	NR	NR	NR		
				NR	NR	NR	NR	NR	NR	NR	NR	NR	NR		NR	

NR: Not reported.

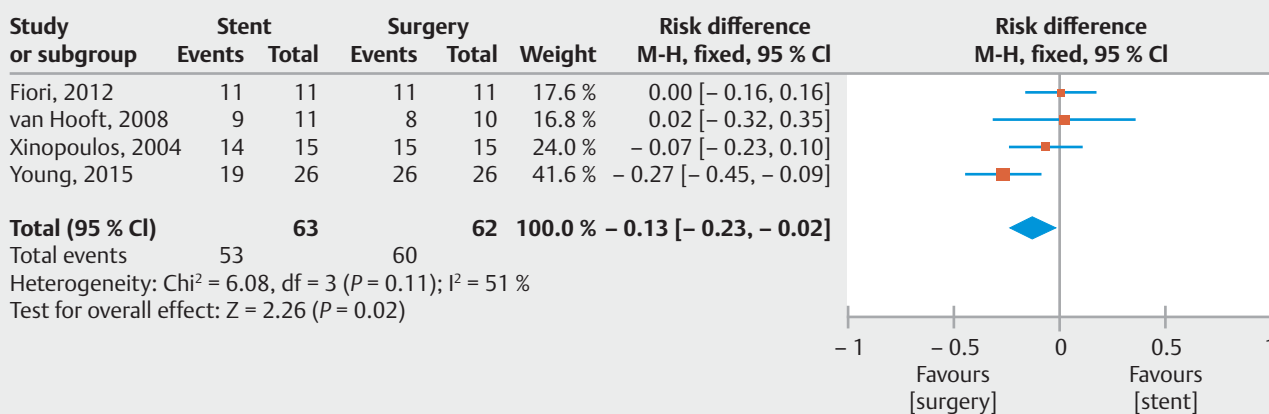
<sup>1</sup> Mean age.



► Fig. 2 Mortality in 30 days.

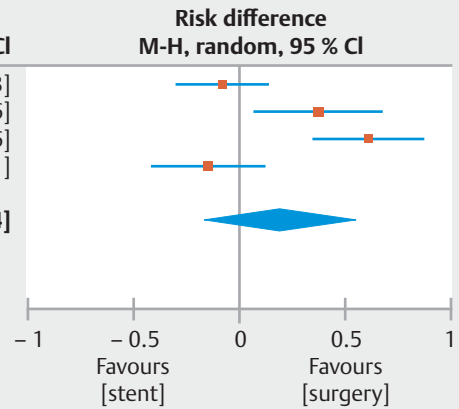


► Fig. 3 Survival.



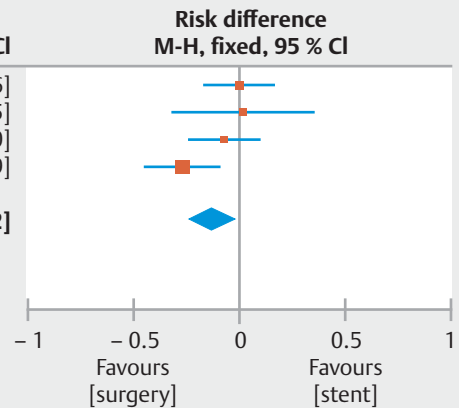
► Fig. 4 Clinical success.

Study or subgroup	Stent		Surgery		Weight	Risk difference
	Events	Total	Events	Total		M-H, random, 95 % CI
Fiori, 2012	0	11	1	11	26.0 %	-0.09 [-0.31, 0.13]
van Hooft, 2008	4	11	0	10	24.0 %	0.36 [0.06, 0.66]
Xinopoulos, 2004	9	15	0	15	25.1 %	0.60 [0.34, 0.86]
Young, 2015	10	26	14	26	24.8 %	-0.15 [-0.42, 0.11]
<b>Total (95 % CI)</b>		<b>63</b>		<b>62</b>	<b>100.0 %</b>	<b>0.18 [-0.19, 0.54]</b>
Total events	23		15			
Heterogeneity: Tau <sup>2</sup> = 0.12; Chi <sup>2</sup> = 23.64, df = 3 (P < 0.0001); I <sup>2</sup> = 87 %						
Test for overall effect: Z = 0.95 (P = 0.34)						



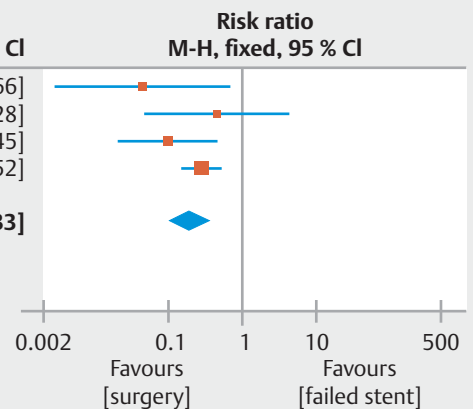
► Fig. 5 Early adverse events (30 days).

Study or subgroup	Stent		Emergency surgery		Weight	Risk difference
	Events	Total	Events	Total		M-H, fixed, 95 % CI
Fiori, 2012	11	11	11	11	17.6 %	0.00 [-0.16, 0.16]
van Hooft, 2008	9	11	8	10	16.8 %	0.02 [-0.32, 0.35]
Xinopoulos, 2004	14	15	15	15	24.0 %	-0.07 [-0.23, 0.10]
Young, 2015	19	26	26	26	41.6 %	-0.27 [-0.45, -0.09]
<b>Total (95 % CI)</b>		<b>63</b>		<b>62</b>	<b>100.0 %</b>	<b>-0.13 [-0.23, -0.02]</b>
Total events	53		60			
Heterogeneity: Chi <sup>2</sup> = 6.08, df = 3 (P = 0.11); I <sup>2</sup> = 51 %						
Test for overall effect: Z = 2.26 (P = 0.02)						

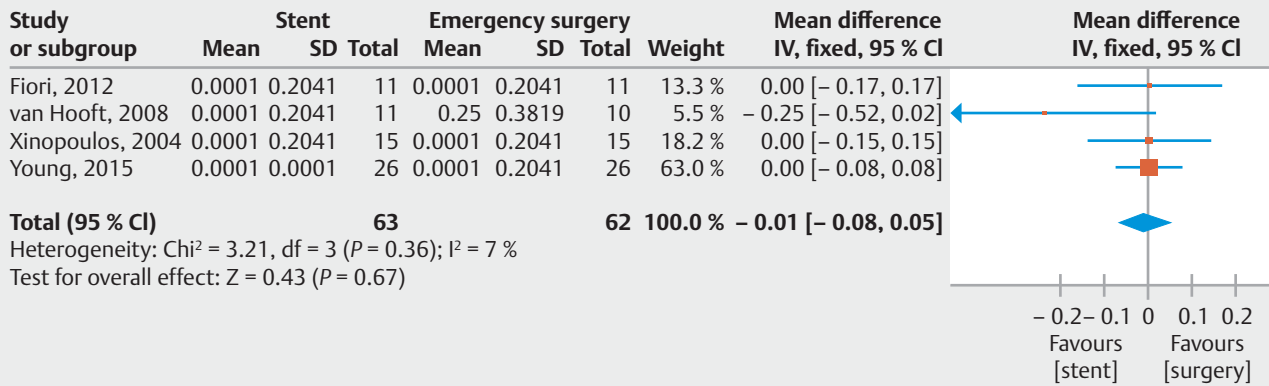


► Fig. 6 Technical success: intent-to-treat.

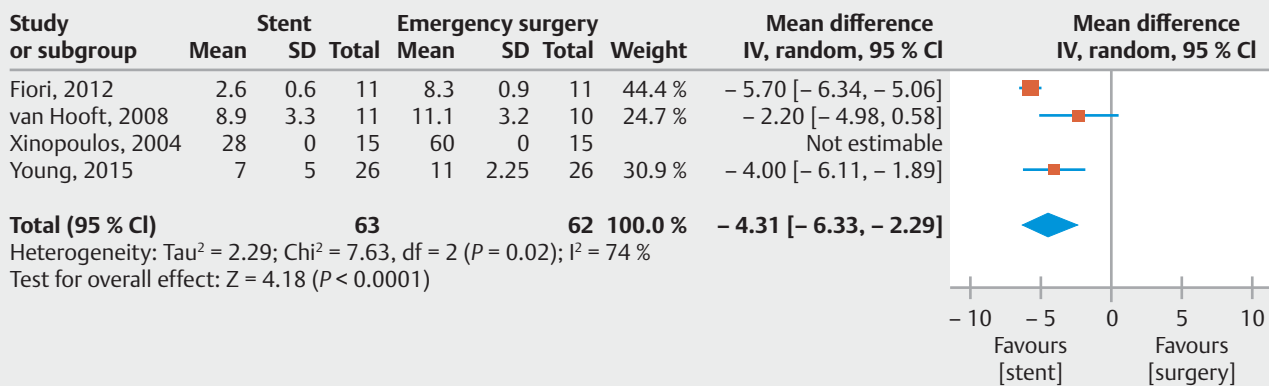
Study or subgroup	Failed stent		Emergency surgery		Weight	Risk ratio
	Events	Total	Events	Total		M-H, fixed, 95 % CI
Fiori, 2012	0	11	11	11	20.7 %	0.04 [0.00, 0.66]
van Hooft, 2008	1	11	2	10	3.8 %	0.45 [0.05, 4.28]
Xinopoulos, 2004	1	15	15	15	27.9 %	0.10 [0.02, 0.45]
Young, 2015	7	26	26	26	47.7 %	0.28 [0.15, 0.52]
<b>Total (95 % CI)</b>		<b>63</b>		<b>62</b>	<b>100.0 %</b>	<b>0.19 [0.11, 0.33]</b>
Total events	9		54			
Heterogeneity: Chi <sup>2</sup> = 4.16, df = 3 (P = 0.24); I <sup>2</sup> = 28 %						
Test for overall effect: Z = 5.87 (P < 0.00001)						



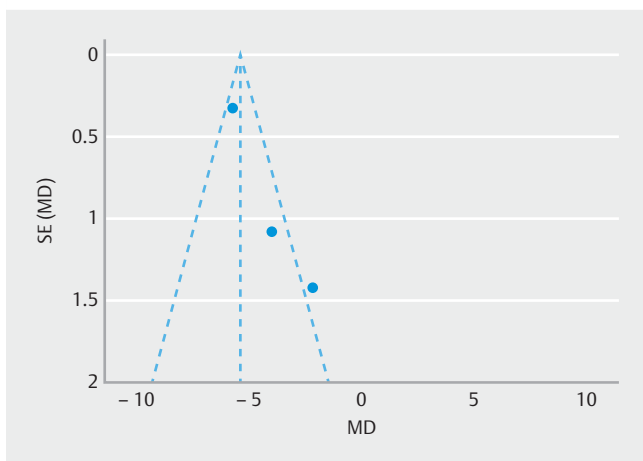
► Fig. 7 Stoma formation.



► Fig. 8 Time stay on the intensive care unit.



► Fig. 9 Hospital stay with outlier.



► Fig. 10 Hospital stay: funnel plot.

and 35.5 days in the ES group, with an overall MD of  $-5.16$  (95 % CI:  $-6.71$  to  $-3.61$ ,  $I^2 = 56\%$ ).

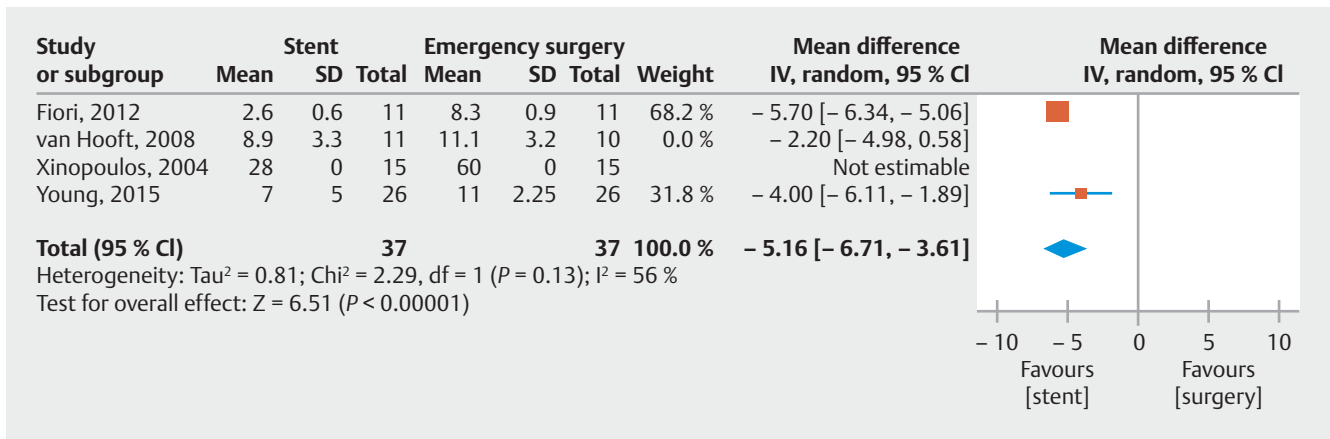
Perforation was the most commonly reported complication in SEMS patients, accounting for 42.8 % of all AEs (► Fig. 12).

## Discussion

For approximately three decades, colonic stents have been used to treat colonic malignancies either as a bridge to surgery or as a palliative measure [27]. The majority of RCTs that focused upon use of SEMS as a bridge to definitive surgery were published in the last decade; however, these studies reported conflicting results, triggering a large debate on the true efficacy of colonic SEMS.

The first RCT that included only palliative patients was published in 2004 [28] and showed promising results for use of SEMS compared to ES as definitive treatment for MCO. In that study, a TS of 93.3 % was reported in the SEMS group, with all patients remaining free of colonic obstruction until their death, which occurred at 6 to 18 weeks of SEMS placement. Stoma was performed in all patients undergoing ES, and there was no significant difference between the groups in terms of survival.

The most recent systematic review using RCTs of palliative patients also included data from those in whom SEMS was placed as a bridge to surgery and final treatment [3]; thus these results should be interpreted with caution. The last systematic review regarding SEMS focused on its placement as a bridge to surgery and not as a definitive treatment for palliative patients



► Fig. 11 Hospital stay without outlier.

	Perforation	Migration	Obstruction
Fiori <sup>[25]</sup>	0	0	3
van Hoot <sup>[26]</sup>	6	1	2
Young <sup>[10]</sup>	0	0	1
Xinopoulos <sup>[28]</sup>	0	0	1

► Fig. 12 Stent-related complications.

[29]. The current study is the first systematic review that used only RCT (evidence 1A) including palliative patients with CRC.

ES may cause morbidity and may be related to worse health-related QOL because an ostomy is the most likely treatment for relieving an obstruction. Conversely, colonic stenting can result in perforation, obstruction and other fatal complications [10, 25, 26, 30].

Because one of the goals for treating patients with advanced neoplasia is to prolong survival and maintain the best QOL possible, SEMS placement may enable patients to maintain a high QOL by avoiding colostomy or other surgical interventions [10].

In 2014, the European Society of Gastrointestinal Endoscopy recommended use of SEMS as the method of choice in patients receiving palliative care on the basis of results of retrospective, case series, and non-comparative studies [2].

Until the emergence of the first RCTs, use of SEMS for treating MCO was thought to reduce morbidity and mortality [31] and to induce less trauma compared with ES. However, this concept was not supported by the RCTs reporting use of SEMS as a bridge to surgery or by their respective meta-analyses.

In this study, we detected no statistical significance between the groups in terms of 30-day mortality (6.4% for the SEMS group and 6.3% for the ES group). Another meta-analysis [32] demonstrated a significant reduction in mortality in the SEMS group compared with the surgical intervention group. However, in that study, the authors included retrospective studies and non-RCTs, which could have led to selection bias (patients with better prognosis were selected for surgery, whereas those with worse clinical status were selected for stent placement).

Our study showed no significant statistical difference in terms of survival time between the groups, which is in agreement with results of previous meta-analyses [33]. Early complications of stents included perforation, migration, and obstruction, which were observed in 36.5% of patients. Surgical complications included non-functioning ostomy, suture dehiscence, intestinal volvulus, which were observed in 24.1% of patients. Contrary to the findings of Takahashi et al., [32] SEMS placement did not reduce risk of early complications as demonstrated by Liang et al. [11].

As expected, the ES group showed favorable results regarding CS but at the cost of a higher risk of colostomy (86.1% vs 14.3%). Despite lower CS rates in the SEMS group, there was no significant increase in the number of early AEs in these patients.

The reported difficulty in the SEMS group was related to performance of the guidewire technique, and the procedure was suspended if there was no success [10, 25, 26, 28].

Although the ES group showed a 13% superior technique and CS, patients in the SEMS group still had the possibility of surgical intervention if there was a therapeutic failure of both emergency surgery and follow-up [25, 28, 34]. Overall, in 9 of the 63 patients randomized to the SEMS group, the technique used had failed; thus, these patients were allocated to the ES group.

Long-term patency of colorectal stents is a matter of concern because obstruction or dislodgment can occur. Late stent dysfunction is reported in up to 19% of patients undergoing stent placement. However, stent dysfunction is typically treated by tunneling with argon plasma coagulation, laser, or further stenting [10, 25, 26, 28, 34, 35].

The main limitation of this study was the paucity of data regarding use of SEMS in palliative settings. Only four RCTs on use of SEMS in the palliative scenario were included in this analysis, from which the data were derived. Lack of standardization, such as post-procedure QOL analysis, could not be meta-analyzed owing to the unavailability of a dedicated evaluation questionnaire.



## Conclusion

Results of this meta-analysis indicate that mortality, mean survival, length of ICU stay, and early complications were similar for both SEMS use and ES. Surgery was associated with higher CS, whereas SEMS corresponded with shorter hospital stay and less permanent stoma. Further studies are required to address whether QOL is affected by any of these treatments.

SEMS may be an alternative for managing patients with unresectable obstructive CRC, with the advantage of early hospital discharge and shortened hospitalization time in relation to patients undergoing surgery as well as the main objective in patients receiving palliative care: survival with QOL being able to avoid a colostomy.

## Competing interests

None

## References

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#### CORRECTION

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In the above mentioned article was a misspelling in three author names. Correct is: Diogo Turiani Hourneaux de Moura, Nelson Tomio Miyajima, Eduardo Guimarães Hourneaux de Moura