Systematic Review/Meta-Analysis

Short-Term outcomes of stents in obstructive rectal cancer: A systematic review and meta-analysis

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Abstract

Background: With acute obstruction due to rectal or recto-sigmoid cancer, the safety and success of deploying self-expandable metal stents has been controversial. The aim of this systematic review was to synthesize the existing evidence on the outcomes and complication rates of stent placement in these patients.

Methods: We performed a literature search of PubMed by using appropriate keywords, and manual reference screening of included articles was done. The article screening, data extraction, and quality assessment was done by four independent reviewers. A meta analyses was performed for the main outcome measures: technical and clinical success and complication rates.

Results: We identified 962 articles in the search. After applying inclusion and exclusion criteria, we included 32 articles in the meta-analysis. The pooled technical success rate across 26 studies that reported it was 97% [95% confidence interval (CI): 95%-99%] without evidence of significant heterogeneity ($I^2 = 0.0\%$, $P = 0.84$), and the clinical success rate across 26 studies that reported it was 69% (95% CI: 58%-79%) with evidence of significant heterogeneity ($I^2 = 81.7\%$, $P < 0.001$). The pooled overall complication rate across the 32 studies was 28% (95% CI: 20%-37%) with evidence of significant heterogeneity ($I^2 = 79.3\%$, $P < 0.001$).

Conclusion: The use of rectal stents in obstructing rectal or recto-sigmoid tumors seems to be technically feasible. A high rate of technical success, however, does not always translate into clinical success. A considerable complication rate is associated with this approach. Randomized controlled trials are needed to compare the outcomes of rectal stent placement with those of surgery.

Keywords: Complication, obstruction, rectal cancer, stent

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INTRODUCTION

Colorectal cancer (CRC) has a heterogenous presentation as a result of the anatomical and functional differences between the right colon, the left colon, and the rectum. Because of these differences, the management approaches and outcomes vary.[1] Intestinal obstruction in CRC commonly presents with lesions on the left side and in the rectosigmoid junction because of the smaller lumen size compared with the right colon[2] and the fact that stool is well formed at this level.[3]

Emergency surgery on obstructed colon cancer can be challenging, with significant morbidity of up to 49% and mortality rates of up to 16%.[4-7] Moreover, surgery mostly involves creating a stoma, which has a negative impact on the patient's quality of life and can delay further oncological management.[8] The introduction of self-expandable metallic stents (SEMS) has emerged as a bridge to surgery or palliative treatment for malignant colorectal obstruction. This approach has several advantages over emergency surgery.[9,10] When used as a bridge to surgery, stenting allows the surgeon to operate on the patient in an elective setting after maximal optimization. It also allows the bowel to decompress and, on relief of the obstruction, to be prepared preoperatively. SEMS increases the chances of the procedure being performed laparoscopically instead of as an open surgery, after the obstruction resolves and the bowel has returned to its normal diameter.[11] Stenting thus allows full preoperative staging and treatment with neoadjuvant therapy if indicated.

The insertion of SEMS to treat obstructing rectal cancers is nonetheless problematic because of rectal irritation, which may lead to anal pain, tenesmus, incontinence, and stent migration and perforation.[9,10] Available guidelines for stents focus mainly on colonic obstruction and lack specific recommendations on SEMS for the rectum.[11,12] This absence of information can be attributed to the sparse data on rectal stents compared to that for colonic stents.[13]

We aimed in this review to synthesize the existing evidence on the outcomes and complication rates of stent placement in patients who present with rectal or recto-sigmoid obstruction due to primary malignant tumors.

METHODS

The PRISMA guideline was followed in conducting this systematic review.[14] The objectives, methods of analysis, inclusion criteria, and outcomes of primary interest were specified in advance and documented in a protocol (HA-02-J-008) registered at the National Committee of Biomedical Ethics (Reference No. 21-18). The protocol was registered and is available for review at http://www.crd.york.ac.uk/PROSPERO/. The registration code is Crd42017069731.

Literature search strategy

We identified studies by searching the electronic database PubMed and by screening reference lists of the included articles, from January 2000 to July 2018. The database was searched by using Medical Subject Headings (MeSH) or their equivalent key words. We performed the search strategy by applying Boolean operators as follows: "rectal cancer" AND "colorectal obstruction" AND "stent." Synonyms for each search aspect were also used. Study selection was initially based on the title and/or abstract, from which the full texts of relevant articles were further assessed. All potentially relevant studies were retrieved for review, and the references of the included studies were further screened to identify any additional potentially relevant studies.

Studies were included if they reported the rates of (1) technical success, defined as accurate SEMS placement with adequate stricture coverage; (2) clinical success, defined as decompression and relief of obstructive symptoms without further intervention during the hospital stay; and (3) complications, including perforation, tumor overgrowth, migration, severe pain, bleeding, and other complications that were reported to be caused by SEMS placement in the included studies, or relevant raw data that would allow the calculation of these outcomes of SEMS placement in patients who presented with rectal and/or recto-sigmoid obstruction due to a primary malignant tumor.

Four reviewers (HH, RA, SJ, and EA) performed the eligibility assessment for the records in an independent standardized manner. The retrieved articles were divided between two groups, and each article group was screened independently by two of the reviewers. Disparities between reviewers were resolved by discussion with a fifth reviewer (NT). Conference proceedings, reviews, case reports, and non-English articles were excluded.

Data extraction

We developed a data extraction form, pilot tested it on 47 randomly selected studies, and refined it accordingly. Four authors (HH, RA, SJ, and EA) independently extracted the data from the included studies. Two authors independently extracted the data from each half of the articles. Discrepancies between reviewers were discussed,

documented, and resolved by consensus. A fifth author (NT) arbitrated if no resolution was reached.

Information extracted from each study included the following: (1) first author name and year of publication; (2) study design; (3) characteristics of participants (including diagnosis, number of participants, age, gender, and site of obstruction); (4) intention of procedure (palliative or bridge to surgery); (5) study outcomes: technical success rate, clinical success rate, and any recorded complications; (6) need for reoperation and reintervention; (7) length of follow-up; and (8) overall disease-free survival.

Some of the potentially eligible articles had insufficient data, in which case their authors were contacted (291 authors in total); only 5.49% responded by providing sufficient data.

Assessment of study quality

Four reviewers (HH, RA, SJ, and EA) independently assessed the risk of bias in the included studies by using the methodological index for non-randomized studies (MINORS) criteria. Two reviewers independently assessed each half of the studies. Disparities between reviewers were resolved by discussion with a fifth reviewer (NT). MINORS is a validated 12-item instrument designed to assess the methodological quality of non-randomized studies, whether comparative or non-comparative. The 12 items include: the stated aim of the study, inclusion of consecutive patients, prospective collection of data, appropriateness of the end point to the study aim, unbiased evaluation of endpoints, appropriateness of the follow up period to the major end point, loss to follow-up not exceeding 5%, prospective calculation of the sample size, and four more items specifically for comparative studies (the latter four items were not applicable to our included studies). The MINORS score ranges from 0 to 16.[15]

Statistical analyses

Three outcomes were assessed: (i) technical success rate; (ii) clinical success rate; and (iii) complications rate, which included perforation, tumor overgrowth, migration, severe pain, bleeding, and other complications reported to be caused by SEMS placement in the included studies. The three outcomes were expressed as percentages. In the presence of heterogeneity, random effects models were used, whereas fixed effects were used in its absence.[16] Forest plots were constructed for each outcome. For clinical success rate, summary estimates were presented for all studies combined and then stratified by study size. Studies comprising of a least 50 participants were considered large.

Heterogeneity was assessed with the index of heterogeneity, I^2,[17,18] which is expressed as a percentage and quantifies the proportion of variation among the studies that is attributed to heterogeneity.[17] The lower the number, the less the heterogeneity. All statistically significance tests were two sided, and analyses were conducted by using Stata 12.1 (StataCorp LP, College Station, Texas, USA).

RESULTS

Literature search and study selection

The initial search identified 962 publications, of which 404 studies were excluded based on the title and/or abstract, and 526 more were excluded based on a full-text review. Reasons for exclusion are shown in the flow chart in Figure 1. Thus, 32 studies matched our inclusion criteria and were included in the final analysis. Three studies were published in the United States,[19-21] four in Italy,[22-25] four in the United Kingdom,[26-29] seven in Korea,[13,30-35] one in Spain,[36] three in China,[37-39] two in Finland,[40,41] one in Canada,[42] one in Australia,[43] one in Portugal,[44] one in South Africa,[45] one in Pakistan,[46] one in Turkey,[47] one in Norway[48] and one in Denmark.[49]

Characteristics of included studies

Descriptive statistics – including number of patients per study, population age, duration of follow-up, and quality assessment score – are reported in Table 1. The original articles included 2487 patients, who had a stent placed for either colonic or rectal obstruction. This systematic review included 811 patients of those 2487 stented patients who had a rectosigmoid or rectal obstruction. Eighteen of the studies were retrospective, as indicated by medical records,[13,19,20,25,26,31,34,37-39,41-44,46-49] and 14 were prospective.[21-24,27-30,32,33,35,36,40,45] Twenty-six studies reported technical and clinical success rates,[20-24,27-38,40-46,48,49] and 32 reported the complication rate.[13,19-49] All included studies were non-comparative. The studies were published between 2000 and 2018. The age of the patients included in the studies ranged from 18 to 97 years.

Quality of the included studies

The quality score of the included studies ranged from 7 to 14, of which 15 studies had a score of 75% or above.[21-24,26,27,30,32,33,35,40,41,43-45] Two studies did not mention an adequate follow-up period to the major endpoint,[37,38] and six studies did not report a loss to follow-up item.[28,31,38,43,48,49] Quality assessment scores are reported in Table 1.

Meta-analyses

The summary estimate of the technical success rate among the 26 studies[20-24,27-38,40-46,48,49] that reported this outcome was 97% [95% confidence interval (CI): 95%-99%] without evidence of significant heterogeneity. Six studies did not report the technical success rate[13,19,25,26,39,47] for patients

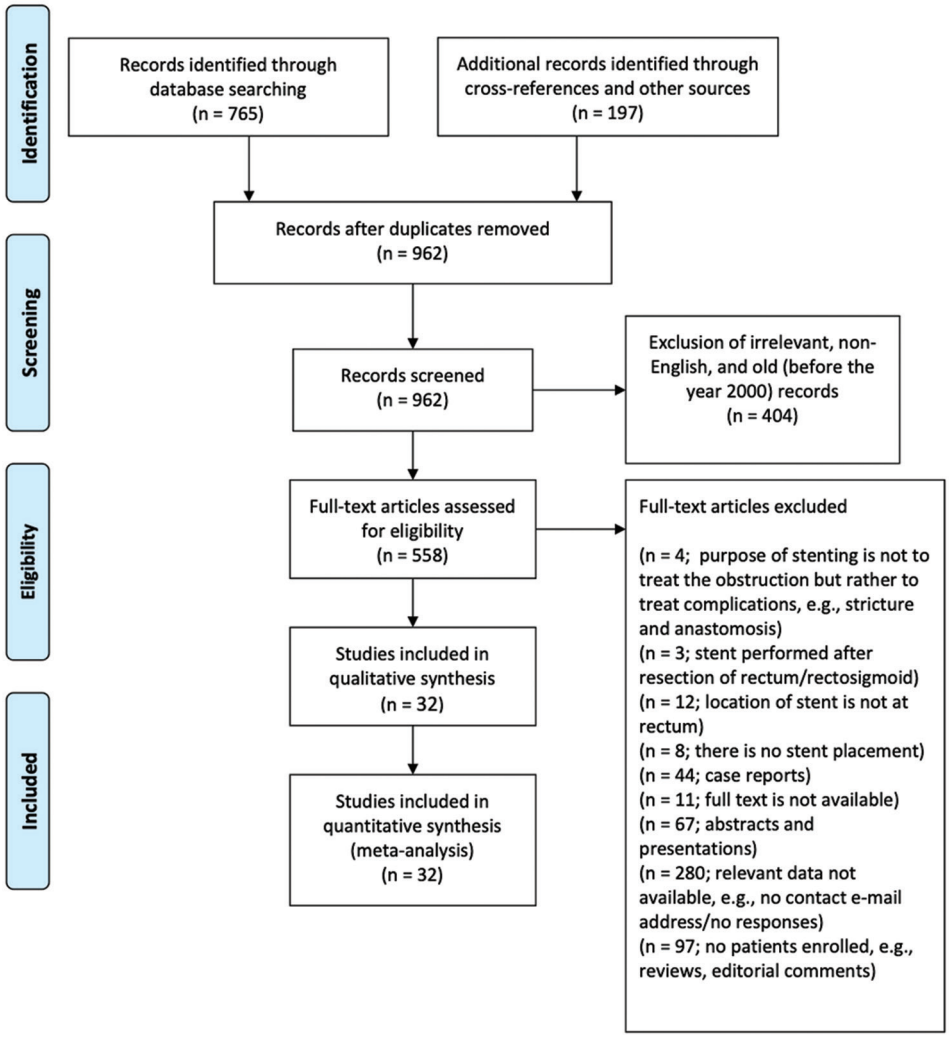

Figure 1: Flow chart of the selection process of the included articles

with rectal cancer separately [Figure 2]. Subgroup analysis by study quality and sample size did not reveal different results (data not shown).

The clinical success rate among the 26 studies[20-24,27-38,40-46,48,49] that reported this outcome was 69% (95% CI: 58%-79%) with evidence of considerable heterogeneity (I^2 = 82.0%, P < 0.001). Six studies did not report the clinical success rate[13,19,25,26,39,47] separately for patients with rectal and with rectosigmoid cancer. Heterogeneity remained after stratifying the studies by methodological quality. Studies with a score of 75% (12 out of 16) and higher were considered good quality and lower scores indicated poorer quality. The pooled estimate for the low-quality studies was 79% (95% CI: 70%-87%), I^2 = 42.8%, P = 0.06, whereas for high-quality studies, it was 59% (95% CI: 40%-78%), I^2 = 88.2%, P < 0.001 (data not shown). Subgroup analysis by sample size reduced heterogeneity. For large sample size studies (>50 patients), the summary estimate was 84% (95% CI: 79%-89%).[23,44,46] For small sample size studies (<50 patients), the summary estimate was 66% (95% CI: 53%-78%) [Figure 3]. The median clinical success rate was 84.3% (13%-100%).

The summary of the overall complication rate among the 32 studies[13,19-49] was 28% (95% CI: 20%-37%), with evidence of considerable heterogeneity [Figure 4]. The results remained heterogenous despite stratifying the studies by methodological quality and sample size. The median complication rate was 27% (0%-100%).

Among 811 patients who underwent stenting for primary rectal cancer obstruction, stent reobstruction was the most common reason for clinical failure, occurring in 75 patients (10.50%) and reported in 18 studies,[13,19,21-24,26-30,39,41-44,46,47] followed by stent migration in 67 patients (9.38%) reported in 20 studies,[13,19,21,23,24,26-30,33,34,36,39,43,44,46-49] severe persistent pain due to stent placement in 29 patients (4.06%) reported

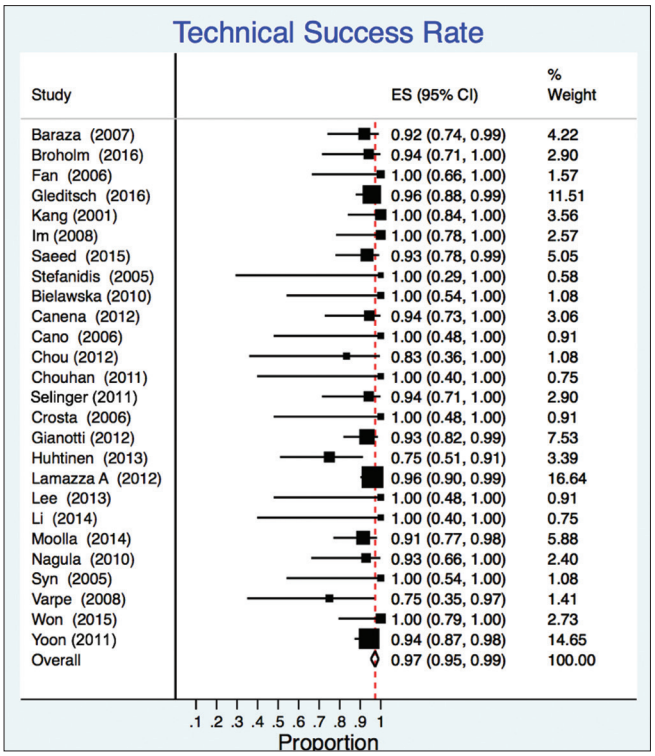

Figure 2: Forest plot of the technical success rates in the included studies

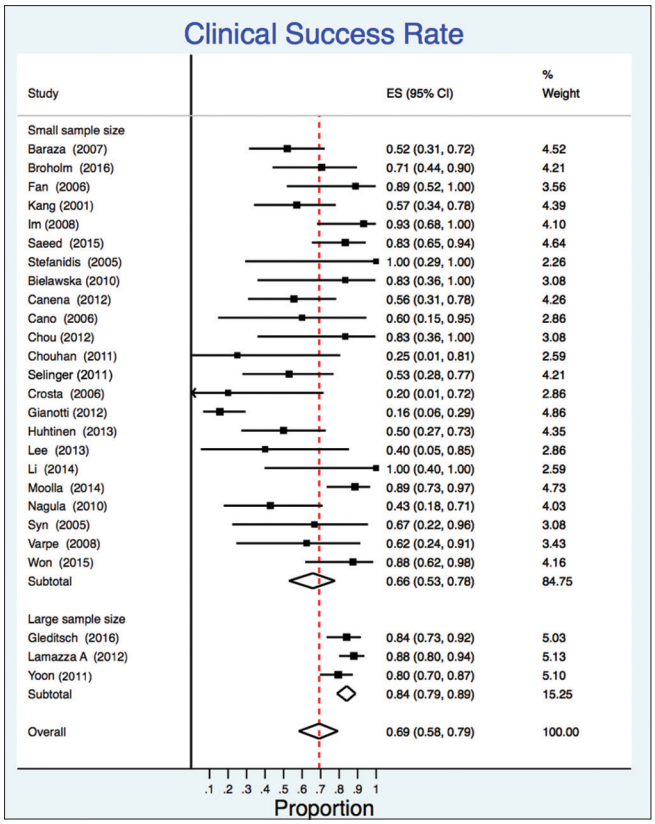

Figure 3: Forest plot of the clinical success rates in the included studies

in 9 studies,[13,22,23,26,35,40,41,46,47] and perforation after stent placement in 21 patients (2.94%) reported in 10 studies.[13,23,25,32,33,39,45,46,48,49] Thirty-one patients (14.69%) needed endoscopic reintervention as reported in 11 studies,[21,22,26-28,30,35,36,39,44,48] and 33 patients (8.31%) needed surgery after stent failure, reported in 17 studies.[13,21,22,25-27,30,32,33,35,39-44,48] There were 83 (53.20%) stent placements for palliation among 11 studies that reported this outcome,[20,27,30,33-38,40,48] and 113 (43.29%) stent replacements were intended as a bridge to surgery among 14 studies that reported this outcome.[19,20,23,27,28,30,33,34,36-38,44,46,48]

DISCUSSION

SEMS has been used as a bridge to surgery or for palliation in patients with malignant colorectal obstruction. In this review, we synthesized the evidence on the outcomes and complications of stent placement in patients who presented with rectal or recto-sigmoid obstruction due to primary malignant tumors. Despite the reported advantages of SEMS, such as shorter length of hospital stay, fewer postoperative complications, and lower stoma rates, controversy remains regarding its role in rectal and rectosigmoid obstruction.[50-52] Use of SEMS seems technically less effective for palliative purposes because of the risk of severe complications such as perforation, migration, and post-stent bacteremia associated with SEMS use in the long term.[11] The pooled estimate of the clinical success rate of SEMS in previous studies was significantly lower than that for surgery (93.1% vs. 99.8%, $P = 0.0009$), although the rate of total complications was similar between the two groups (34.0% vs. 38.1%, $P = 0.60$).[9,53]

Our systematic review and meta-analysis demonstrated that stents in rectal and recto-sigmoid primary tumors have a high technical success rate that does not always translate into clinical success. These findings are in accordance with a previous systematic review by Sebastian *et al*.[9] that examined the efficacy and safety of SEMS in the setting of obstructed CRC in 1198 patients. These authors reported a median technical success rate for obstructed CRC of 94% and a median clinical success rate of 91%.[9] Rectal and rectosigmoid stenting in our study thus compares unfavorably with these numbers; although the technical success rate in our review was very high at 97%, the clinical success rate was only 69%. The complication rates were similar for both Sebastian *et al*.'s population and ours, with reobstruction rates of 7.3% vs. 10.50%, migration rates of 11.9% vs. 9.38%, and perforation rates of 3.7% vs. 2.94%, respectively. Among reported perforations in their study, 98% occurred in stenting at the rectosigmoid junction, most likely related to its tortuosity.

Table 1: Details of population and quality assessment in the included studies

Author	Year	Total number of patients in the study	Mean age of all patients in the study	Number of rectal patients	Mean age for rectal patients	Mean follow-up in months	Quality assessment score of the study out of 16
Liberman *et al*.[19]	2000	12	67	4	48	7.88	11
Aviv *et al*.[26]	2002	15		7	79.86		12
Kang *et al*.[30]	2002	26	60.69	21	61.3	1.6	13
Stefanidis *et al*.[20]	2005	21	62.2	3	59.3		10
Syn *et al*.[27]	2005	17	75.2	6	79		12
García-Cano[36]	2006	12	73.9	5	73.2		11
Fan *et al*.[37]	2006	26	63.2	9	58.4		9
Crosta *et al*.[22]	2006	24	67	5			12
Baraza *et al*.[28]	2008	63		25			10
Varpe *et al*.[40]	2008	26	69	8	69	5.9	12
Im *et al*.[32]	2008	49		15		11	14
Bielawska *et al*.[42]	2010	30	67	6		15.2	9
Nagula *et al*.[21]	2010	44	57	14		6	13
Yoon *et al*.[31]	2011	256	60	88			8
Selinger *et al*.[29]	2011	96	72.3	17		15	11
Chouhan *et al*.[43]	2012	35	69	4		28.5	12
Canena *et al*.[44]	2012	89	74	18	77.1		14
Chou *et al*.[33]	2012	34	59.7	6	58	11.1	12
Lamazza *et al*.[24]	2012	100	77	100	77	4.1	12
Gianotti *et al*.[23]	2013	132	70	45			13
Lee *et al*.[35]	2013	6	67	5	65.6		12
Huhtinen *et al*.[41]	2013	56	70	20			13
Moolla and Madiba[45]	2014	203	59	35			12
Li *et al*.[38]	2014	29	73	4	74.7		7
Xu *et al*.[39]	2015	45	60.7	23		6.9	11
Bayraktar *et al*.[47]	2015	49		23			11
Won *et al*.[34]	2015	49	66	16	66.3		10
Saeed *et al*.[46]	2016	49	50	30		16.6	10
Zanghì *et al*.[25]	2016	26		9			10
Gleditsch *et al*.[48]	2016	183		69		69	9
Broholm *et al*.[49]	2017	112	71	17			9
Lee *et al*.[13]	2018	573	62.2	154			11

A previous systematic review and meta-analysis compared the outcomes of stenting to treat obstruction of the left colon and rectum with the outcomes of emergent surgery. It showed significantly lower clinical success rate among the stenting group (52.5%) than that for the emergency surgery group (99%).[52] However, the stenting group had a significantly higher primary anastomosis rate compared to that in the emergency surgery group (64.9% vs. 55%, respectively). In addition, the stenting group had a significantly lower stoma rate (45.3% vs. 62%). However, the rate of permanent stoma and anastomotic leakage was similar for both groups.

In addition to the technical and clinical success rates in SEMS, peri-procedure complications are an important aspect to consider. Our pooled overall complication rate was 28%. Complications included reobstruction, migration, pain, and perforation. It is important to recognize that this high complication rate may have been the result of bias against SEMS because patients who were not candidates for surgery due to malnutrition, poor overall condition, or the presence of contraindications to surgery would not be offered this procedure. They would have done poorly regardless of the type of intervention. A previously reported randomized control trial by Van Hooft *et al*.[54] randomized patients with left-sided CRC obstruction into surgery and endoscopic treatment groups. In the endoscopic stent group, 8 of 10 patients had one or more stent-related complications vs. 1 of 8 who had postoperative complications in the surgical arm. A high rate of perforations (6 of 10) was noted after endoscopic stent placement that resulted in reoperation and/or mortality in three patients. Perforations are an especially important complication to assess, as they result in both septic complications and oncological outcomes by upstaging the tumor. Other reported adverse effects were stent migration, obstruction, pain, and diarrhea. This trial was prematurely closed, given these results.

To the best of our knowledge, this is the first systematic review and meta-analysis to specifically analyze the short-term outcomes of stenting for obstructive rectal and recto-sigmoid cancers and to summarize the evidence for technical and clinical success and complications. The

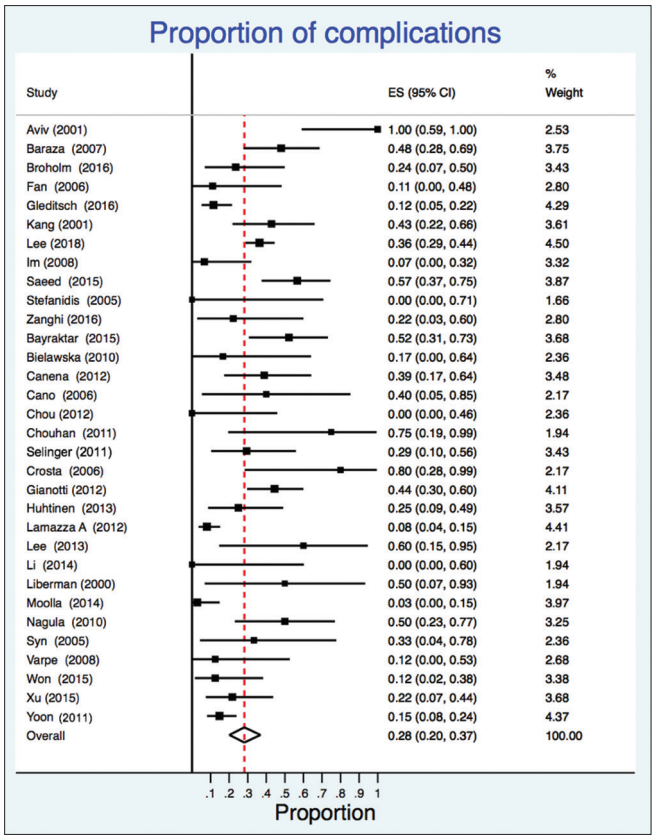

Figure 4: Forest plot of the complications rates in the included studies

results of this study will help clinicians and patients with decision making when managing large bowel obstruction in the setting of rectal and rectosigmoid cancer.

This study has several limitations. Our search could have been limited as we only searched PubMed and performed manual reference screening. We reviewed articles in English only. The low response rate from authors contacted to obtain detailed outcomes for rectal and rectosigmoid cancers was another limitation to our study, since some articles could not be included due to insufficient information. Lastly, our results showed high heterogeneity among the pooled estimates of clinical success and complication rates. Subgroup analysis by quality and size of study did not decrease the heterogeneity of the complication rates. Factors that could explain the significant heterogeneity are inclusion of studies that had very high or very low complication rates; variability of defining and reporting of complications; variation in the length of follow-up (maximum success will be achieved 48 hours after stent placement when it is fully deployed); variation of periprocedural adjuvant therapy such as the use of bevacizumab, as it was found to be associated with gastrointestinal perforation[54,55]; variation in the level of experience of the endoscopists and the volume and expertise of the center; and variation in treatment intent (palliative vs. curative). Some of these variables are difficult to control or define. We did not have access to the type of stents placed, which may have contributed to the heterogenous clinical outcomes (covered, not covered, or partially covered). Concerning the quality of the studies themselves, only 15 of the 32 had an acceptable score of 75% or higher per the MINORS criteria. Our systematic review is thus limited by the poor quality of some of the included studies.

CONCLUSION

SEMS as treatment for obstructive rectal and rectosigmoid tumors is technically feasible but does not always translate into clinical success. In addition, complication risks associated with this approach are considerable. Because the data are significantly heterogeneous, definitive conclusions cannot be made. Obstructing rectal tumors are a different entity from obstructing colonic tumors; thus, future prospective studies are needed to assess the efficacy and safety of SEMS in the setting of malignant rectal obstruction.

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Conflicts of interest
There are no conflicts of interest.

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