



Uncovered versus covered stent in management of large bowel obstruction due to colorectal malignancy: a systematic review and meta-analysis

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Abstract

Purpose To compare outcomes of uncovered stent and covered stent in management of large bowel obstruction secondary to colorectal malignancy.

Methods We conducted a search of electronic databases identifying studies comparing outcomes of uncovered and covered stents in management of large bowel obstruction secondary to colorectal malignancy. The Cochrane risk-of-bias tool and the Newcastle–Ottawa scale were used to assess the included studies. Random or fixed effects modelling were applied as appropriate to calculate pooled outcome data.

Results One randomised controlled trial (RCT) and nine observational studies, enrolling 753 patients, were identified. Uncovered stent was associated with lower risks of complications (RR 0.57 95% CI 0.44–0.74, $P < 0.0001$), tumour overgrowth (RR 0.29 95% CI 0.09–0.93, $P = 0.04$), and stent migration (RR 0.29 95% CI 0.17–0.48, $P < 0.00001$); longer duration of patency (MD 18.47 95% CI 10.46–26.48, $P < 0.00001$); lower need for stent reinsertion (RR 0.38 95% CI 0.17–0.86, $P = 0.02$); and higher risk of tumour ingrowth (RR 4.53 95% CI 1.92–10.69, $P = 0.0008$). Rates of technical success (RR 1.02 95% CI 0.99–1.04, $P = 0.21$), clinical success (RR 1.03 95% CI 0.98–1.08, $P = 0.32$), perforation (RD 0.01 95% CI –0.03–0.02, $P = 0.65$), bleeding (RD 0.00 95% CI –0.03–0.03, $P = 0.98$), stool impaction (RR 0.56 95% CI 0.12–2.04, $P = 0.38$) and stent obstruction (RR 2.23 95% CI 0.94–5.34, $P = 0.97$) were similar.

Conclusions Our results suggest that uncovered stents are superior as indicated by fewer complications, lower rates of stent migration, longer duration of patency and a reduced need for stent reinsertion. The best available evidence is mainly derived from non-randomised studies; there is a need for more RCTs.

Keywords Intestinal obstruction · Colorectal cancer · Stent

Introduction

Large bowel obstruction is the presenting feature in 24% [1, 2] of colorectal carcinoma. Malignant obstruction was conventionally treated by surgical diversion and stoma formation, associated with higher morbidity and mortality as compared

to elective treatment [3]. Insertion of self-expanding metal stents (SEMS) can be used as a bridge to surgery for subsequent one-stage resection as well as for palliative purposes in those with irresectable tumours. Insertion is associated with equivalent clinical outcomes, decreased hospital stay, fewer complications and lower mortality [4].

Available stents are uncovered and covered, the latter can vary as fully covered and partially covered. Uncovered stents were traditionally associated with increased rates of stent occlusion, and increased tumour ingrowth and overgrowth [5, 6]. Covered stents were designed to hypothetically reduce the rate of tumour ingrowth. However, this is associated with decreased stent patency as the coating decreases the ability of the stent to anchor to the intestinal wall [7].

Little conclusive clinical evidence exists for whether the hypothetical benefits translate clinically. Hence, we aimed to

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perform a comprehensive systematic review and conduct a meta-analysis of outcomes comparing uncovered stent and covered stent in management of large bowel obstruction secondary to colorectal malignancy.

Methods

This systematic review was performed according to an agreed predefined protocol and was conducted and presented according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement standards.

Eligibility criteria

Observational studies and RCTs investigating outcomes of uncovered versus covered SEMs in management of large bowel obstruction secondary to colorectal malignancy were included. The population of interest comprised adults over the age of 18 undergoing SEMs insertion for relief of large bowel obstruction secondary to primary colorectal malignancy or colorectal metastases from other malignancies. The intervention of interest was uncovered SEMs insertion and the comparator, covered SEMs insertion. Studies including cases with large bowel obstruction secondary to extrinsic compression and studies investigating stents for gastric outlet, biliary or small bowel obstruction were excluded.

Outcomes

The following outcome measures were considered: technical success, clinical success, total complications (early and late), perforation, bleeding, stent migration (total, early and late), tumour ingrowth, tumour overgrowth, stool impaction, stent obstruction, duration of stent patency, and need for stent reinsertion.

Literature search strategy

Two authors (MM, RM) independently conducted a literature search on the following databases: MEDLINE, EMBASE and CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL). The final search was conducted on 17 June 2018. Search operators, thesaurus headings and limits in each database were adjusted as necessary; this strategy is outlined in Fig. 1. ClinicalTrials.gov, the World Health Organisation International Clinical Trials Registry and ISRCTN Register were searched for ongoing trials or unpublished studies. References of related reviews were searched for any other relevant studies. Language restrictions were not applied during the literature search.

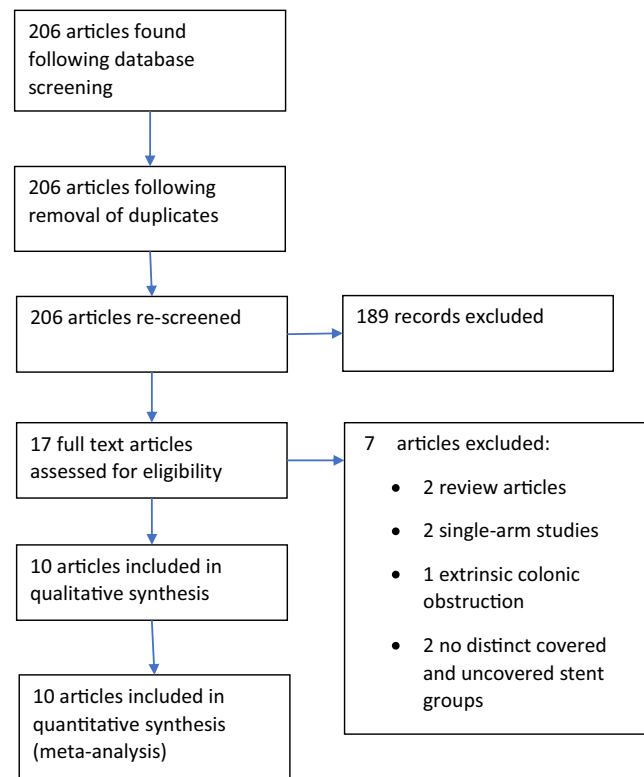


Fig. 1 Study flow diagram

Study selection

Two authors (MM, RM) independently reviewed titles and abstracts. Subsequently, full texts were retrieved for relevant articles. Eligible studies were selected. In the event of discrepancy, the two authors discussed and a third (SH) was consulted if they could not agree.

Data collection

An electronic data collection spreadsheet was created, which was piloted and adjusted using random articles. Data collection included study-related information (first author, year of publication, country of origin of the corresponding author, publishing journal, study design, number of participants and their clinical condition), baseline characteristics of the included population (age, gender, purpose for stenting, site of obstruction), characteristics of the SEMs (shape, cover), primary, and secondary outcome data. Two authors independently collected the data (MM, RM). Disagreements were initially discussed. If no resolution could be reached, a third author (SH) was consulted.

Methodological quality and risk of bias assessment

Two authors independently assessed methodological quality and risk of bias of the articles using the Cochrane tool and

the Newcastle–Ottawa scale (NOS) for assessing the risk of bias of randomised trials and observational studies, respectively. The Cochrane tool assesses domains including selection bias, performance bias, detection bias, attrition bias, reporting bias and other sources of bias and, for each individual domain, classifies studies into low, unclear and high risk of bias. The NOS uses a star system with a maximum of nine stars to evaluate a study in three domains (eight items): the selection of the study groups, the comparability of the groups and the ascertainment of outcome of interest. For each item of the scale, we judged each study as low risk (one star awarded) or high risk (no star awarded). We determined studies that received a score of nine stars to be of low risk of bias, studies that scored seven or eight stars to be of moderate risk, and those that scored six or less to be of high risk of bias. Disagreements were resolved by discussion between the reviewers. If no agreement could be reached, a third author was consulted. A risk of bias graph was constructed to present the results.

Data synthesis and statistical analyses

For dichotomous outcome variables, risk ratios (RR) were calculated as the summary measure for uncovered vs covered stents. We planned to calculate the risk difference (RD) when more than a third of the studies had zero events in both groups. For continuous parameters, the mean difference between the covered and uncovered stent groups was calculated. The unit of analysis was individual patient. Any information regarding withdrawals, dropouts and other missing data were recorded. We based our analysis on intention-to-treat data from individual clinical studies. Review Manager 5.3 software was used for data synthesis. Random or fixed effects modelling were applied as appropriate for analyses; random-effect models were used if considerable heterogeneity was found amongst studies. Forest plots with 95% confidence intervals (CIs) were used to present the results. Cochran's Q test was used to assess inter-study heterogeneity. We calculated I^2 to quantify inconsistency, and it was interpreted according to the following guide: 0–50% indicated low heterogeneity, 50–75% indicated moderate heterogeneity and 75–100% indicated high heterogeneity. We intended to construct funnel plots and visually assess their symmetry to evaluate publication bias for outcomes reported by at least ten studies.

Sensitivity and subgroup analyses

To explore potential sources of heterogeneity and assess the robustness of our results, additional analyses were conducted for outcomes reported by at least four studies. We repeated the primary analysis using the random effects and fixed effect model. In addition, we calculated the RR, odds ratio (OR) and RD separately for dichotomous outcomes. We assessed

the effect of each study on the overall effect size and heterogeneity by repeating the analysis after removing one study at a time. We planned to perform separate analyses for RCTs with low risk of selection bias in terms of randomisation and allocation concealment to assess the change in direction of the effect size. Moreover, where possible, we aimed to perform subgroup analysis based on shape and type of covered stent (cylindrical shape vs dumbbell shape, fully covered vs partially covered), or purpose for stenting (preoperative decompression vs palliative).

Results

Results of search

Literature searching gave rise to 207 studies, of which 10 were eligible [5, 8–16]. These included seven prospective cohort studies, two retrospective cohort studies and one RCT, in total 753 patients. The indication for stenting was preoperative decompression or palliative management in six studies, palliative management only in three studies, preoperative decompression only in one study. Overall, 301 patients underwent covered stent insertion and 452 patients underwent uncovered stent insertion. In terms of the shape of covered stent, three studies used cylindrical-shaped or dumbbell-shaped stents; four studies used cylindrical-shaped stents only; two studies used dumbbell-shaped stents only; one study used dumbbell-shaped or bamboo-shaped stents. Length of follow-up period ranged from 2 to 20 months. Nine studies defined technical success as accurate stent placement, and nine defined clinical success as relief of obstruction clinically. The literature search flow chart, baseline characteristics of included studies and baseline characteristics of the included populations are demonstrated in Fig. 1 and Tables 1, 2, respectively.

Methodological quality

The summary and results of methodological quality assessment of the one RCT [8] and nine observational studies [5, 9–16] are demonstrated graphically in Fig. 2.

Outcome synthesis

Technical success Technical success of stent insertion was reported in 8 studies [5, 8–11, 14–16], enrolling 644 patients. There was no significant difference in technical success of stent insertion (RR 1.02 95% CI 0.99–1.04, $P = 0.21$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.79$) (Fig. 3).

Clinical success Clinical success of stent insertion was reported in 5 studies [5, 8–10, 15], enrolling 422 patients. There was no

Table 1 Baseline characteristics of included studies

First author	Country	Journal	Study design	Clinical presentation	Purpose of stent insertion	Groups	Stent properties	Technical success	Clinical success	Sample size
Choo (1998) [5]	Korea	RSNA	Prospective observational cohort study	Colorectal obstruction	Preoperative decompression or palliative management	Covered Uncovered	Cylindrical fully covered with polyurethane Cylindrical uncovered	Not defined	Relief of obstruction clinically	20 8 12
Lee (2007) [9]	Korea	Gastrointestinal endoscopy	Prospective observational cohort study	Colorectal obstruction	Preoperative decompression or palliative management	Covered Uncovered	Dumbbell shape partially covered with polyurethane Cylindrical uncovered	Accurate stent insertion across lesion, patency of the stent, and radiological relief of obstruction	Relief of obstruction clinically	80 41 39
Park (2010) [8]	Korea	Gastrointestinal endoscopy	RCT	Colorectal Obstruction	Preoperative decompression or palliative management	Covered Uncovered	Cylindrical shape partially covered with polytetrafluoroethylene Cylindrical uncovered	Accurate stent insertion across lesion	Relief of obstruction clinically without immediate stent-related complications within 96 h	151 75 76
Moon (2010) [10]	Korea	ASCRS	Prospective observational cohort study	Colorectal obstruction	Preoperative decompression or palliative management	Covered Uncovered	Cylindrical shape partially covered with Polytetrafluoroethylene Cylindrical uncovered	Accurate stent insertion across lesion and proper stent expansion	Relief of obstruction clinically without need for reintervention within 48 h	68 31 37
Lim (2013) [11]	Korea	Gut and Liver	Prospective observational cohort study	Colorectal Obstruction	Preoperative decompression	Covered Uncovered	Cylindrical or dumbbell shape covered Cylindrical uncovered	Accurate stent insertion across lesion and proven patency by fluoroscopy or endoscopy	Not defined	45 20 25
Han (2014) [12]	Korea	Scandinavian Journal of Gastroenterology	Prospective observational cohort study	Colorectal obstruction	Palliative management	Covered Uncovered	Cylindrical or dumbbell shape covered Cylindrical or dumbbell uncovered	Accurate stent insertion across lesion	Relief of obstruction clinically within 72 h	72 14 58
Choi (2013) [14]	Korea	Surgical Endoscopy	Prospective observational cohort study	Colorectal obstruction	Preoperative decompression or palliative management	Covered Uncovered	Cylindrical or dumbbell shape covered Cylindrical or dumbbell uncovered	Accurate stent insertion across lesion and proven patency by fluoroscopy	Relief of obstruction clinically and radiologically without reintervention within 48 h	152 111 37
Choi (2007) [13]	Korea	Korean Journal of Radiology	Retrospective observational cohort study	Colorectal obstruction	Palliative management	Covered Uncovered	Cylindrical shape fully covered with Polyurethane Dumbbell shape partially covered with polyurethane or silicon Cylindrical or dumbbell uncovered	Accurate stent insertion across lesion without immediate complications	Relief of obstruction clinically within 24 h	37 23 14 30
Park (2011) [15]	Korea	Surgical Endoscopy	Retrospective observational cohort study	Colorectal obstruction	Palliative management	Covered Uncovered	Dumbbell shape partially covered with polyurethane or silicon Cylindrical or dumbbell uncovered	Accurate stent insertion across lesion	Relief of obstruction clinically	103 73 18
Kang (2002) [16]	Korea	Korean Journal of Radiology	Prospective observational cohort study	Colorectal obstruction	Preoperative decompression or palliative management	Covered Uncovered	Dumbbell shape or bamboo shape fully covered with polyurethane Cylindrical uncovered	Accurate stent insertion across lesion	Relief of obstruction clinically	25 7

Table 2 Baseline characteristics of included population

First author	Groups	Number	Age	Male gender	Site of obstruction					Hepatic flexure	Recurrence at colostomy site	
					Rectum	Sigmoid colon	Rectosigmoid	Descending colon	Transverse colon			Splenic flexure
Choo (1998) [5]	Covered	8	64.3 ± 14.6	5/8	1/8	2/8	5/8	0/8	NR	NR	NR	0/8
	Uncovered	12	63.0 ± 11.2	4/12	2/12	3/12	5/12	1/12	NR	NR	NR	1/12
Lee (2007) [9]	Covered	41	63.6	23/41	19/41	13/41	6/41	2/41	NR	NR	NR	NR
	Uncovered	39	63.4	22/39	19/39	15/39	4/39	1/39	NR	NR	NR	NR
Park (2010) [8]	Covered	75	62.1 ± 13.1	39/75	14/75	40/75	NR	7/75	2/75	6/75	5/75	1/75
	Uncovered	76	60.8 ± 12.8	47/76	13/76	38/76	NR	7/76	5/76	7/76	4/76	2/76
Moon (2010) [10]	Covered	31	66.3 ± 15.4	18/31	6/31	11/31	NR	7/31	4/31	1/31	2/31	NR
	Uncovered	37	65.5 ± 14.5	21/37	8/37	16/37	NR	4/37	5/37	4/37	0/37	NR
Lim (2013) [11]	Covered	20	63.4 ± 13.98	11/20	5/20	12/20	2/20	1/20	NR	NR	NR	NR
	Uncovered	25	63.4 ± 14.64	15/25	6/25	16/25	2/25	1/25	NR	NR	NR	NR
Han (2014) [12]	Covered	14	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Uncovered	58	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Choi (2013) [14]	Covered	41	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Uncovered	111	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Choi (2007) [13]	Covered	23	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Uncovered	14	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Park (2011) [15]	Covered	30	70.9 ± 12.4	17/30	7/30	12/30	NR	6/30	2/30	NR	2/30	NR
	Uncovered	73	65.8 ± 13.9	37/73	18/73	27/73	NR	16/73	6/73	NR	6/73	NR
Kang (2002) [16]	Covered	18	61.9	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Uncovered	7	58	NR	NR	NR	NR	NR	NR	NR	NR	NR

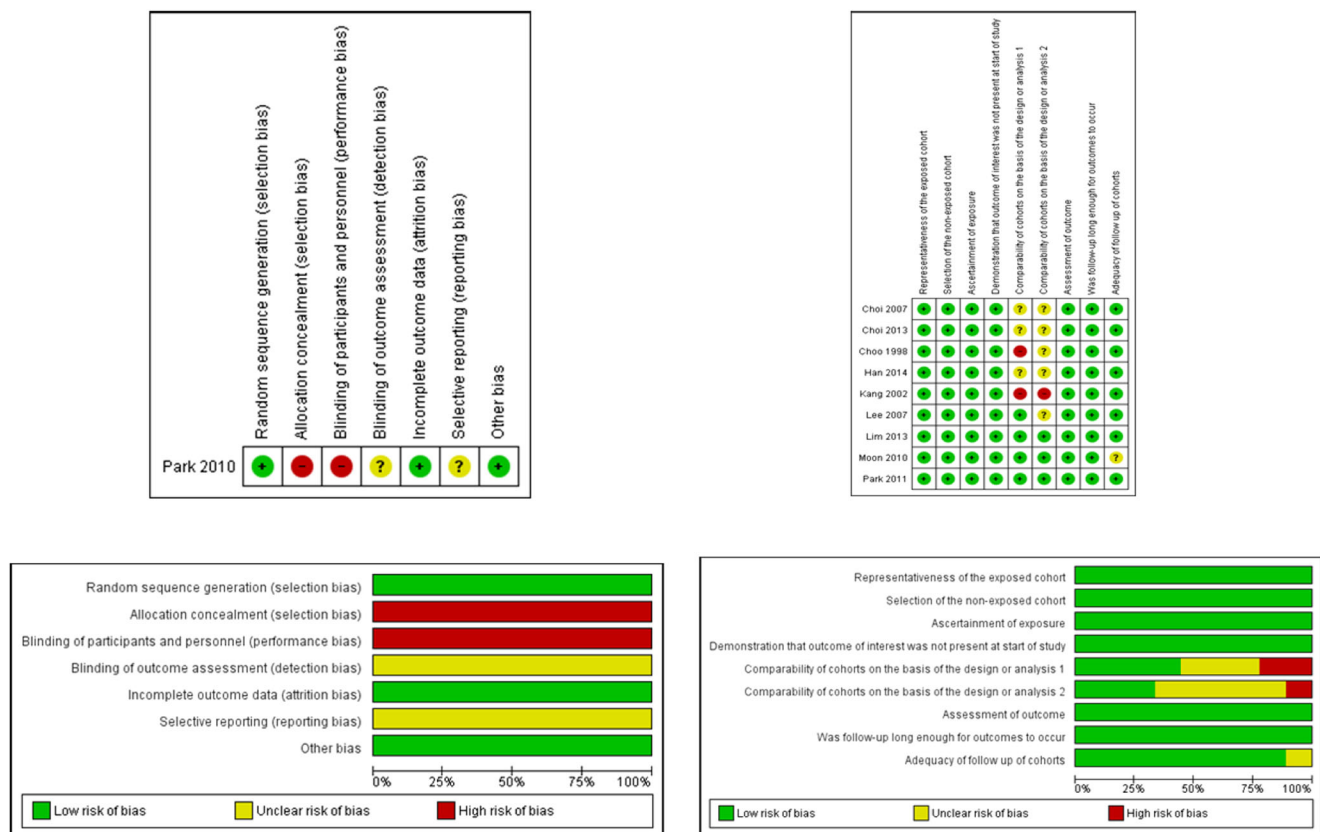


Fig. 2 Risk of bias summary and graph showing authors' judgements about each risk of bias item. **a** Randomised trial. **b** Observational studies

significant difference in clinical success of stent insertion (RR 1.03 95% CI 0.98–1.08, $P = 0.32$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.41$) (Fig. 3).

Complications Total complications were reported in 9 studies [5, 8–11, 13–16], enrolling 681 patients. Risk of complications was lower in the uncovered stent group (RR 0.57 95% CI 0.44–0.74, $P < 0.0001$). A moderate level of inter-study heterogeneity existed ($I^2 = 50\%$, $P = 0.04$) (Fig. 3).

Early complications Early complications were reported in 4 studies [5, 8–10], enrolling 319 patients. There was no significant difference in the risk of early complications (RR 0.54 95% CI 0.25–1.16, $P = 0.11$). A moderate level of inter-study heterogeneity existed ($I^2 = 51\%$, $P = 0.11$) (Fig. 3).

Late complications Late complications were reported in 3 studies [8–10], enrolling 299 patients. Risk of late complications was lower in the uncovered stent group (RR 0.58 95% CI 0.34–0.99, $P = 0.05$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.65$) (Fig. 3).

Perforation Perforation was reported in 7 studies [8–11, 13, 15, 16], enrolling 509 patients. There was no significant difference in the risk of perforation (RD 0.01 95% CI –0.03 to

0.02, $P = 0.65$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.94$) (Fig. 3).

Bleeding Bleeding was reported in 4 studies [8–11], enrolling 344 patients. There was no significant difference in the risk of bleeding (RD 0.00 95% CI –0.03 to 0.03, $P = 0.98$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.80$) (Fig. 3).

Stent migration Stent migration was reported in 9 studies [5, 8–13, 15, 16], enrolling 601 patients. The risk of stent migration was lower in the uncovered stent group (RR 0.29 95% CI 0.17–0.48, $P < 0.00001$). A low level of inter-study heterogeneity existed ($I^2 = 33\%$, $P = 0.15$) (Fig. 3).

Early stent migration Early stent migration was reported in 6 studies [5, 8–10, 13, 16], enrolling 381 patients. There was no significant difference in the risk of early stent migration between the two groups (RR 0.47 95% CI 0.21–1.06, $P = 0.07$). A low level of inter-study heterogeneity existed ($I^2 = 33\%$, $P = 0.019$) (Fig. 3).

Late stent migration Late stent migration was reported in 5 studies [8–10, 13, 16], enrolling 361 patients. Risk of late stent migration was lower in the uncovered stent group (RR

0.12 95% CI 0.04–0.37, $P = 0.0002$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.90$) (Fig. 3).

Tumour ingrowth Tumour ingrowth was reported in 7 studies [5, 8–10, 13, 15, 16], enrolling 484 patients. Risk of tumour ingrowth was higher in the uncovered stent group (RR 4.53 95% CI 1.92–10.69, $P = 0.0008$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.62$) (Fig. 3).

Tumour overgrowth Tumour overgrowth was reported in 6 studies [5, 8–10, 15, 16], enrolling 447 patients. The risk of tumour overgrowth was lower in the uncovered stent group (RR 0.29 95% CI 0.09–0.93, $P = 0.04$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.99$) (Fig. 3).

Stool impaction Stool impaction was reported in 4 studies [8–10, 13], enrolling 336 patients. There was no significant difference in the risk of stool impaction (RR 0.56 95% CI 0.12–2.04, $P = 0.38$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.47$) (Fig. 3).

Stent obstruction Stent obstruction was reported in 4 studies [8, 10, 12, 15], enrolling 334 patients. There was no significant difference in the risk of stent obstruction (RR 2.23 95% CI 0.94–5.34, $P = 0.97$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.58$) (Fig. 3).

Duration of stent patency Duration of stent patency was reported in 5 studies [8, 9, 13, 15, 16], enrolling 396 patients. Stents were patent for a significantly longer in the uncovered stent group (MD 18.47 95% CI 10.46–26.48, $P < 0.00001$). A low level of inter-study heterogeneity existed ($I^2 = 24\%$, $P = 0.28$) (Fig. 3).

Need for stent reinsertion Need for stent reinsertion was reported in 5 studies [5, 8–10, 13], enrolling 356 patients. There was a significantly lower need for stent reinsertion in the uncovered stent group (RR 0.38 95% CI 0.17–0.86, $P = 0.02$). A low level of inter-study heterogeneity existed ($I^2 = 0\%$, $P = 0.74$) (Fig. 3).

Additional analyses

Sensitivity analyses

We performed sensitivity analyses for outcomes that were reported by at least four studies (all outcomes except late complications). The use of random-effects or fixed-effect models did not affect the direction of the effect sizes in any outcome measures. When ORs, RRs or RDs were calculated separately, the direction of the effect sizes remained unchanged for all the outcomes. Removing one study at a time changed the direction of the effect size in favour of uncovered stent for early

Fig. 3 Forest plots of the comparisons of outcomes between the uncovered and covered stent groups. **a** Technical success. **b** Clinical success. **c** Total complications. **d** Early complications. **e** Late complications. **f** Perforation. **g** Bleeding. **h** Stent migration (total). **i** Early stent migration. **j** Late stent migration. **k** Tumour ingrowth. **l** Tumour overgrowth. **m** Stool impaction. **n** Stent obstruction. **o** Stent patency duration. **p** Need for stent reinsertion

stent migration and early complications and changed it towards non-significance for tumour overgrowth and need for stent reinsertion; the direction of the effect sizes for other outcomes remained unchanged. The separate analyses for studies with low or moderate risk of bias did not affect the direction of the effect sizes.

Subgroup analysis

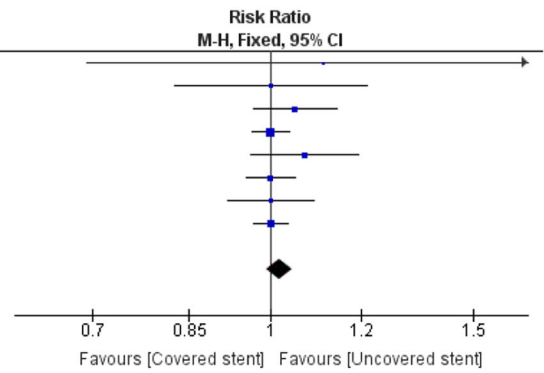
Data from the included studies was not adequate to perform subgroup analysis according to purpose for stenting (preoperative decompression vs palliative) or type of covered stent in terms (fully or partially covered). Hence, subgroup analysis was performed on shape of the stent.

Cylindrical-shaped stent Subgroup analysis of data from 276 patients showed that uncovered stents were associated with lower risks of total complications (RR 0.48 95% CI 0.30–0.75, $P = 0.002$), stent migration (RR 0.10 95% CI 0.03–1.30, $P < 0.0001$), and need for stent reinsertion (RR 0.28 95% CI 0.10–0.75, $P = 0.01$) but higher risk of tumour ingrowth (RR 3.56 95% CI 1.33–9.49, $P = 0.01$) compared to cylindrical-shaped covered stents. There was no difference between the two groups in terms of technical success (RR 1.02 95% CI 0.98–1.06, $P = 0.37$), clinical success (RR 1.00 95% CI 0.93–1.08, $P = 0.96$), perforation (RD 0.01 95% CI –0.02–0.04, $P = 0.64$), bleeding (RD 0.01 95% CI –0.02–0.04, $P = 0.58$), tumour overgrowth (RR 0.28 95% CI 0.06–1.36, $P = 0.12$), stool impaction (RR 0.79 95% CI 0.18–3.54, $P = 0.76$), stent obstruction (RR 1.81 95% CI 0.60–5.43, $P = 0.29$), and duration of stent patency (MD 6.21 95% CI –12.23–24.65, $P = 0.51$).

Dumbbell-shaped stent Subgroup analysis of data from 208 patients showed that uncovered stents were associated with longer duration of stent patency (MD 21.32 95% CI –12.43 to 30.22, $P < 0.00001$) and higher risk of tumour ingrowth (RR 7.59 95% CI 1.30–44.25, $P = 0.02$) compared to dumbbell-shaped covered stents. There was no difference between the two groups in terms of technical success (RR 1.02 95% CI 0.97–1.07, $P = 0.39$), clinical success (RR 1.06 95% CI 0.99–1.13, $P = 0.07$), total complications (RR 0.95 95% CI 0.62–1.46, $P = 0.81$), perforation (RD –0.03 95% CI –0.08 to 0.03, $P = 0.33$), bleeding (RD –0.02 95% CI –0.10 to 0.05, $P = 0.53$), stent migration (RR 0.62 95% CI 0.31–1.24, $P = 0.18$),

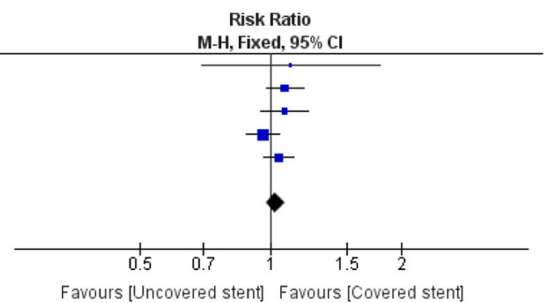
a) Technical success

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio M-H, Fixed, 95% CI	Year
	Events	Total	Events	Total			
Choo 1998	10	12	6	8	2.5%	1.11 [0.69, 1.78]	1998
Kang 2002	7	7	18	18	3.8%	1.00 [0.82, 1.21]	2002
Lee 2007	39	39	39	41	13.3%	1.05 [0.97, 1.14]	2007
Park 2010	75	76	74	75	25.8%	1.00 [0.96, 1.04]	2010
Moon 2010	37	37	29	31	11.1%	1.07 [0.96, 1.19]	2010
Park 2011	73	73	30	30	14.9%	1.00 [0.95, 1.05]	2011
Lim 2013	25	25	20	20	7.8%	1.00 [0.92, 1.09]	2013
Choi 2013	111	111	41	41	20.9%	1.00 [0.97, 1.04]	2013
Total (95% CI)		380		264	100.0%	1.02 [0.99, 1.04]	
Total events	377		257				
Heterogeneity: Chi ² = 3.91, df = 7 (P = 0.79); I ² = 0%							
Test for overall effect: Z = 1.25 (P = 0.21)							



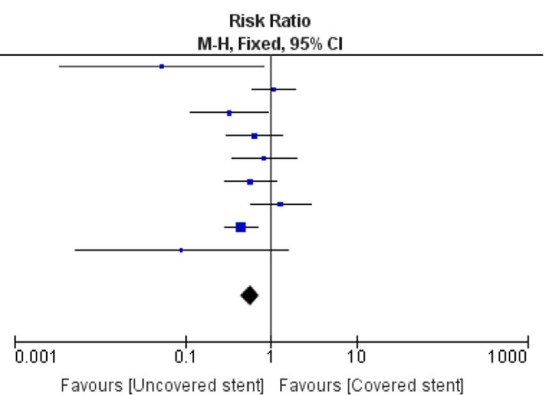
b) Clinical success

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio M-H, Fixed, 95% CI	Year
	Events	Total	Events	Total			
Choo 1998	10	12	6	8	3.8%	1.11 [0.69, 1.78]	1998
Lee 2007	39	39	38	41	19.9%	1.08 [0.98, 1.19]	2007
Moon 2010	36	37	28	31	16.2%	1.08 [0.95, 1.22]	2010
Park 2010	69	76	71	75	38.0%	0.96 [0.88, 1.05]	2010
Park 2011	73	73	29	30	22.1%	1.04 [0.96, 1.13]	2011
Total (95% CI)		237		185	100.0%	1.03 [0.98, 1.08]	
Total events	227		172				
Heterogeneity: Chi ² = 3.98, df = 4 (P = 0.41); I ² = 0%							
Test for overall effect: Z = 1.00 (P = 0.32)							



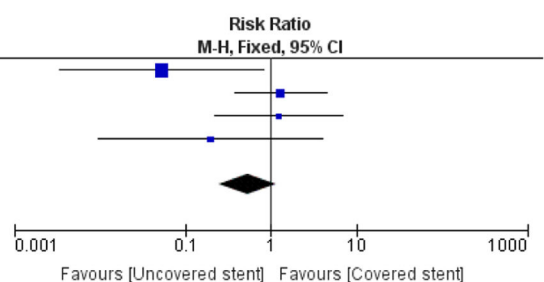
c) Total complications

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio M-H, Fixed, 95% CI	Year
	Events	Total	Events	Total			
Choo 1998	0	12	6	8	7.0%	0.05 [0.00, 0.83]	1998
Kang 2002	5	7	12	18	6.1%	1.07 [0.61, 1.90]	2002
Choi 2007	3	14	15	23	10.3%	0.33 [0.12, 0.94]	2007
Lee 2007	8	39	13	41	11.5%	0.65 [0.30, 1.39]	2007
Moon 2010	8	37	8	31	7.9%	0.84 [0.36, 1.97]	2010
Park 2010	10	76	17	75	15.6%	0.58 [0.28, 1.18]	2010
Park 2011	19	73	6	30	7.7%	1.30 [0.58, 2.94]	2011
Choi 2013	27	111	22	41	29.2%	0.45 [0.29, 0.70]	2013
Lim 2013	0	25	4	20	4.5%	0.09 [0.01, 1.57]	2013
Total (95% CI)		394		287	100.0%	0.57 [0.44, 0.74]	
Total events	80		103				
Heterogeneity: Chi ² = 16.08, df = 8 (P = 0.04); I ² = 50%							
Test for overall effect: Z = 4.30 (P < 0.0001)							



d) Early complications

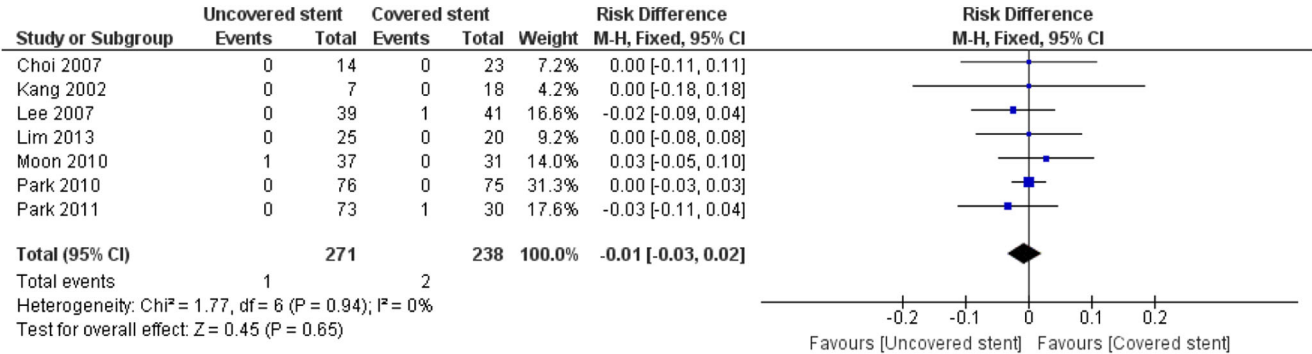
Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio M-H, Fixed, 95% CI	Year
	Events	Total	Events	Total			
Choo 1998	0	12	6	8	47.2%	0.05 [0.00, 0.83]	1998
Lee 2007	5	39	4	41	24.0%	1.31 [0.38, 4.54]	2007
Moon 2010	3	37	2	31	13.4%	1.26 [0.22, 7.05]	2010
Park 2010	0	76	2	75	15.5%	0.20 [0.01, 4.04]	2010
Total (95% CI)		164		155	100.0%	0.54 [0.25, 1.16]	
Total events	8		14				
Heterogeneity: Chi ² = 6.06, df = 3 (P = 0.11); I ² = 51%							
Test for overall effect: Z = 1.58 (P = 0.11)							



e) Late complications



f) Perforation



g) Bleeding



h) Stent migration (total)

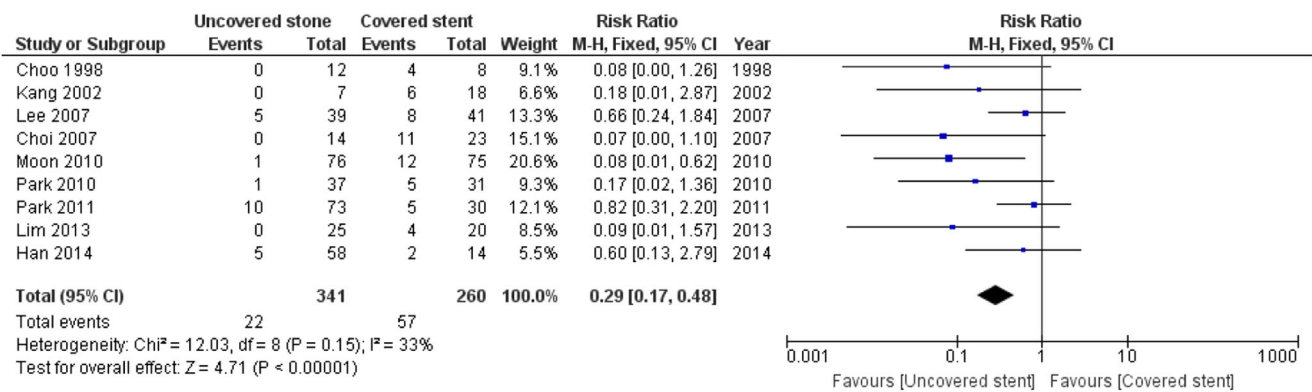


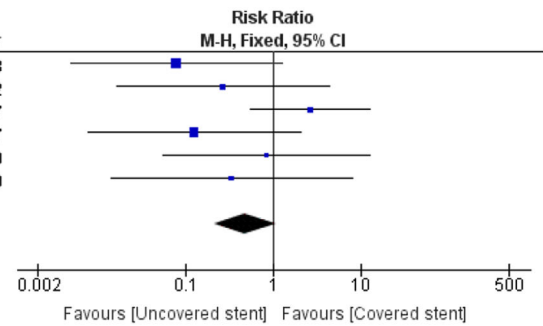
Fig. 3 continued.

tumour overgrowth (RR 0.30 95% CI 0.05–1.67, *P* = 0.17), stool impaction (RR 0.21 95% CI 0.01–4.24, *P* = 0.31), stent

obstruction (RR 3.70 95% CI 0.49–27.93, *P* = 0.20), and need for stent reinsertion (RR 1.05 95% CI 0.14–7.87, *P* = 0.96).

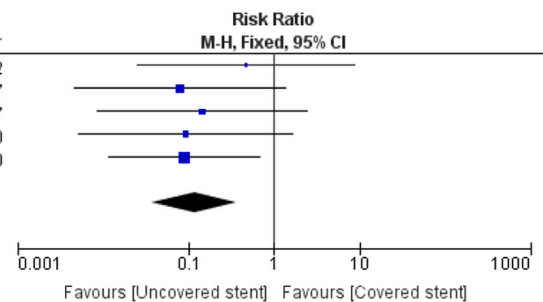
i) Early stent migration

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Choo 1998	0	12	4	8	30.3%	0.08 [0.00, 1.26]	1998	
Kang 2002	0	7	4	18	15.2%	0.26 [0.02, 4.35]	2002	
Lee 2007	5	39	2	41	11.1%	2.63 [0.54, 12.76]	2007	
Choi 2007	0	14	6	23	28.5%	0.12 [0.01, 2.03]	2007	
Moon 2010	1	37	1	31	6.2%	0.84 [0.05, 12.85]	2010	
Park 2010	0	76	1	75	8.6%	0.33 [0.01, 7.95]	2010	
Total (95% CI)		185		196	100.0%	0.47 [0.21, 1.06]		
Total events	6		18					
Heterogeneity: Chi ² = 7.43, df = 5 (P = 0.19); I ² = 33%								
Test for overall effect: Z = 1.81 (P = 0.07)								



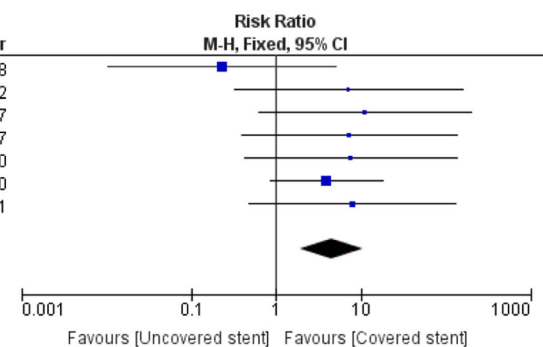
j) Late stent migration

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Kang 2002	0	7	2	18	5.3%	0.47 [0.03, 8.82]	2002	
Lee 2007	0	39	6	41	22.6%	0.08 [0.00, 1.39]	2007	
Choi 2007	0	14	5	23	15.1%	0.15 [0.01, 2.45]	2007	
Moon 2010	0	37	4	31	17.4%	0.09 [0.01, 1.67]	2010	
Park 2010	1	76	11	75	39.5%	0.09 [0.01, 0.68]	2010	
Total (95% CI)		173		188	100.0%	0.12 [0.04, 0.37]		
Total events	1		28					
Heterogeneity: Chi ² = 1.06, df = 4 (P = 0.90); I ² = 0%								
Test for overall effect: Z = 3.69 (P = 0.0002)								



k) Tumour ingrowth

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Choo 1998	0	12	1	8	28.6%	0.23 [0.01, 5.05]	1998	
Kang 2002	1	7	0	18	4.8%	7.13 [0.32, 156.93]	2002	
Choi 2007	3	14	0	23	6.2%	11.20 [0.62, 201.95]	2007	
Lee 2007	3	39	0	41	7.9%	7.35 [0.39, 137.84]	2007	
Moon 2010	4	37	0	31	8.8%	7.58 [0.42, 135.51]	2010	
Park 2010	8	76	2	75	32.5%	3.95 [0.87, 17.98]	2010	
Park 2011	9	73	0	30	11.4%	7.96 [0.48, 132.57]	2011	
Total (95% CI)		258		226	100.0%	4.53 [1.92, 10.69]		
Total events	28		3					
Heterogeneity: Chi ² = 4.45, df = 6 (P = 0.62); I ² = 0%								
Test for overall effect: Z = 3.45 (P = 0.0006)								



l) Tumour overgrowth

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Choo 1998	0	12	1	8	15.4%	0.23 [0.01, 5.05]	1998	
Kang 2002	0	7	2	18	12.9%	0.47 [0.03, 8.82]	2002	
Lee 2007	0	39	1	41	12.7%	0.35 [0.01, 8.34]	2007	
Park 2010	0	76	2	75	21.8%	0.20 [0.01, 4.04]	2010	
Moon 2010	1	37	2	31	18.9%	0.42 [0.04, 4.40]	2010	
Park 2011	0	73	1	30	18.3%	0.14 [0.01, 3.33]	2011	
Total (95% CI)		244		203	100.0%	0.29 [0.09, 0.93]		
Total events	1		9					
Heterogeneity: Chi ² = 0.50, df = 5 (P = 0.99); I ² = 0%								
Test for overall effect: Z = 2.09 (P = 0.04)								

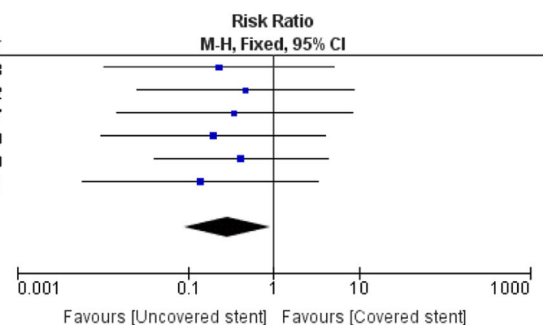
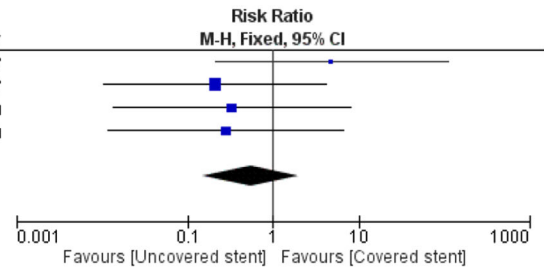


Fig. 3 continued.

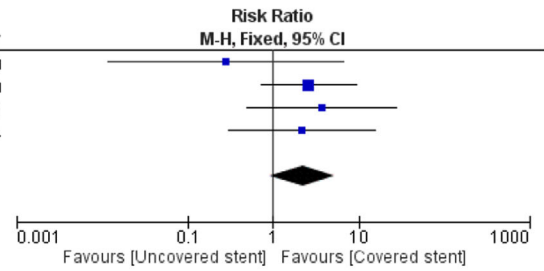
m) Stool impaction

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Choi 2007	1	14	0	23	6.5%	4.80 [0.21, 110.34]	2007	
Lee 2007	0	39	2	41	40.9%	0.21 [0.01, 4.24]	2007	
Park 2010	0	76	1	75	25.3%	0.33 [0.01, 7.95]	2010	
Moon 2010	0	37	1	31	27.3%	0.28 [0.01, 6.66]	2010	
Total (95% CI)		166		170	100.0%	0.56 [0.15, 2.04]		
Total events	1		4					
Heterogeneity: Chi ² = 2.50, df = 3 (P = 0.47); I ² = 0%								
Test for overall effect: Z = 0.89 (P = 0.38)								



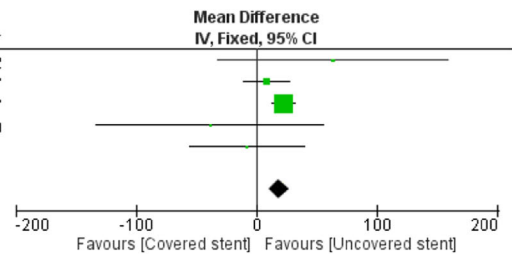
n) Stent obstruction

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Moon 2010	0	37	1	31	21.2%	0.28 [0.01, 6.66]	2010	
Park 2010	8	76	3	75	39.3%	2.63 [0.73, 9.54]	2010	
Park 2011	9	73	1	30	18.5%	3.70 [0.49, 27.93]	2011	
Han 2014	9	58	1	14	21.0%	2.17 [0.30, 15.76]	2014	
Total (95% CI)		244		150	100.0%	2.23 [0.94, 5.34]		
Total events	26		6					
Heterogeneity: Chi ² = 1.95, df = 3 (P = 0.58); I ² = 0%								
Test for overall effect: Z = 1.81 (P = 0.07)								



o) Stent patency duration

Study or Subgroup	Uncovered stent			Covered stent			Weight	Mean Difference		Year
	Mean	SD	Total	Mean	SD	Total		IV, Fixed, 95% CI		
Kang 2002	146.25	112	7	82.93	102	18	0.7%	63.32 [-32.10, 158.74]	2002	
Choi 2007	165	25	14	157	33	23	18.2%	8.00 [-10.80, 26.80]	2007	
Lee 2007	89	25	39	67	15	41	77.6%	22.00 [12.91, 31.09]	2007	
Park 2010	180	266	76	219	323	75	0.7%	-39.00 [-133.45, 55.45]	2010	
Park 2011	88.5	84.9	73	96.8	123	30	2.8%	-8.30 [-56.43, 39.83]	2011	
Total (95% CI)			209			187	100.0%	18.47 [10.46, 26.48]		
Heterogeneity: Chi ² = 5.23, df = 4 (P = 0.26); I ² = 24%										
Test for overall effect: Z = 4.52 (P < 0.00001)										



p) Need for stent reinsertion

Study or Subgroup	Uncovered stent		Covered stent		Weight	Risk Ratio		Year
	Events	Total	Events	Total		M-H, Fixed, 95% CI		
Choo 1998	0	12	1	8	9.0%	0.23 [0.01, 5.05]	1998	
Choi 2007	0	14	5	23	21.4%	0.15 [0.01, 2.45]	2007	
Lee 2007	2	39	2	41	9.9%	1.05 [0.16, 7.10]	2007	
Moon 2010	0	37	2	31	13.8%	0.17 [0.01, 3.38]	2010	
Park 2010	4	76	9	75	45.9%	0.44 [0.14, 1.36]	2010	
Total (95% CI)		178		178	100.0%	0.38 [0.17, 0.86]		
Total events	6		19					
Heterogeneity: Chi ² = 1.98, df = 4 (P = 0.74); I ² = 0%								
Test for overall effect: Z = 2.31 (P = 0.02)								

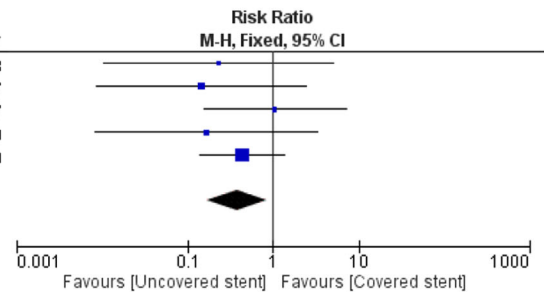


Fig. 3 continued.

Discussion

We performed a systematic review and meta-analysis comparing outcomes of covered versus uncovered stents in management of large bowel obstruction secondary to colonic malignancy, either primary or due to metastasis. Nine observational studies and one randomised controlled trial were included, totalling 753 patients. Analysis indicated insertion of uncovered

stents was associated with lower risks of complications, tumour overgrowth, and stent migration: a lower need for stent reinsertion and a longer duration of patency. Covered stents were associated with a lower risk of tumour ingrowth. We found no significant difference in terms of technical success, clinical success, perforation, bleeding, stool impaction and stent obstruction. Between-study heterogeneity was low for all the outcomes except complications where the level of heterogeneity was

moderate. The results remained consistent through sensitivity analyses. The quality of the evidence was moderate.

Our results indicate covered and uncovered stent insertion are equally feasible, indicated by comparable technical or clinical success rates. Presence of a stent covering should not significantly affect procedure of stent insertion. Whether the stent is covered or uncovered, it should not affect the procedure of stent insertion significantly. Difficulties in stent insertion are largely due to the characteristics of the lesion, such as a high-grade obstruction or the anatomy of the colon, such as tortuosity [17]. The sites of obstruction by tumour were comparable between the uncovered and covered stent groups in included studies. All of these may explain the comparable technical or clinical success rates in the uncovered stent and covered stent groups in our study.

Safety of stent insertion [18] was supported by early complication data; perforation was only seen in three cases and bleeding in two. Stent obstruction is the most common complication, mostly due to tumour ingrowth. Tumour ingrowth is narrowing of the stent lumen within interstices whilst tumour overgrowth is narrowing of the lumen at both ends of the stent by tumour growth [19]. The covering on an enteral stent is hypothetically supposed to decrease the risk of tumour ingrowth, given the mesh acts as a physical barrier in addition to the wire mesh. This largely explains the decreased rates of tumour ingrowth in the covered stent group found in this review. However, the presence of the mesh additionally impedes strong anchoring of the covered stent, as it cannot embed as firmly into the intestinal wall as compared to the wire mesh [20]. Hence, there is an increased risk of stent migration. New designs of covered stents such as partial covering, interior membranes, flanged ends or different shaped have been created to decrease stent migration [9, 21]. Our pooled analysis demonstrated increased rates of overall and late stent migration in the covered stent group. Rates of early stent migration did not vary and perhaps this reflects insufficient time for the uncovered stent to embed in the intestinal wall. Further study could evaluate whether variation in stent design could contribute to decreasing the rates of stent migration.

Stent reinsertion [17] appears to be more effective than other techniques to relieve obstruction from stent migration, such as dilation, argon beamer or laser. Hence, rates of stent reinsertion were raised in the covered stent group, likely secondary to the increased rate of stent migration.

Risk of tumour overgrowth was significantly lower in the uncovered stent group. However, through sensitivity analyses, the direction of the effect size for tumour overgrowth moved towards non-significant; therefore, results for this outcome are not statistically robust. No included studies give details regarding patients who developed tumour overgrowth. The higher tumour overgrowth in the covered stent group may simply reflect the extent of disease in those individual patients.

Drug eluting, stents have been popularised in coronary intervention for their anti-tumour effects and are being investigated for enteral stent insertion [22]. Their potential for obstruction in colorectal malignancy has not been investigated, but perhaps this may further alleviate the problem of tumour ingrowth.

Our results indicated uncovered stents lasted 18 days longer despite the increased rate of tumour ingrowth, which may be due to the higher rate of stent migration in the covered group. Some argue covered stents are poorer when used for palliative purposes given the necessity for long-term patency, indicating a need for treatment stratification based on the purpose for stenting [20]. Unfortunately, data from the included studies did not allow subgroup analysis on this indication.

Our review and reported outcomes have limitations. We identified only 10 eligible studies of which 9 were non-randomised observational studies that are inevitably subject to selection bias. Hence data does not provide robust basis for conclusions. The data from the included studies was not adequate to perform subgroup analysis based on the purpose for stenting (preoperative decompression vs palliative) or type of covered stent in terms of being fully or partially covered. Less than ten studies were eligible for this review, preventing formal assessment of publication bias as planned in our protocol; therefore, reporting bias cannot be excluded in this study.

Conclusions

The best available evidence suggests that uncovered stents are superior to covered stents in the management of large bowel obstruction due to colorectal malignancy as indicated by fewer complications, lower rates of stent migration, longer duration of patency and a reduced need for stent reinsertion. However, conclusions are largely from non-randomised studies. More randomised controlled trials are needed, especially stratifying by patient population (palliative vs bridge to surgery) and stent design (covered vs partially covered).

Author contributions Project lead: SH

Conception and design: SH

Data collection: All authors

Analysis and interpretation: All authors

Writing the article: All authors

Critical revision of the article: All authors

Final approval of the article: All authors

Statistical analysis: SH

Compliance with ethical standards

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

Ethical approval Not required.

Appendix

Search no.	Search strategy [†]
#1	large bowel obstruction: TI, AB, KW
#2	MeSH descriptor: [intestinal obstruction] explode all trees
#3	MeSH descriptor: [colorectal cancer] explode all trees
#4	#1 OR #2 OR #3
#5	MeSH descriptor: [stent] explode all trees
#6	cover* near2 stent*: TI,AB,KW
#7	uncover* near2 stent*: TI,AB,KW
#8	Metal near 2 stent: TI,AB,KW
#9	#5 OR #6 OR #7 OR #8
#10	#4 AND #9

[†]This search strategy was adopted for following databases: MEDLINE, EMBASE, CINAHL and the Cochrane Central Register of Controlled Trials (CENTRAL)

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