Common format for Evidence Table – Treatment Primary studies

Headings	Description
I Study ID	
1. Reference	First author; Journal name; Publication Date;
II Method	
1. Study design	Specify the type of study: RCT, CCT, case control, case series
2. Source of funding/conflicts of interest	Specify the source of funding: public research funds, government, not governmental organization, healthcare industry or other (give name of organization or corporation) presence of declaration of interest.
3. Setting	Numbers of centers, countries involved, healthcare setting, urban/rural/mixed.
4. Sample size	Give the calculated number in each group and the actual number of patients in each group.
5. Duration of the Study	Duration in months or years.
III Patient characteristics	
1. Eligibility criteria	State the most relevant inclusion and exclusion criteria for population (patients and pathology).
2. Patient characteristics	Specify a priori characteristics (age, tumor, stage).
3. Group comparability	p for group comparability.
IV Intervention(s)	
1. Intervention(s)	Precise details of the interventions for each group (including dose, length, regimen and timing if relevant).
2. Comparator(s)	Placebo, other treatment (including dose, length, regimen and timing if relevant).
V Results primary outcome	
1. Effect size primary outcome	Summary of the primary outcome in each and between groups: effect size and its precision (p value, CI) Including efficacy: Absolute risk reduction, relative risk (reduction), odds ratios, confidence intervals.
VI Results secondary and all other outcomes	
1. Effect size secondary outcome(s)	Brief description of secondary outcome(s) and p values.
2. Effect size all other outcomes, endpoints	All other outcomes, endpoints, including adverse effects, toxicity, quality of life
VII Critical appraisal of study quality	
1.Level of evidence	Classification of intervention studies.
2. Dropouts	Number of dropouts/withdrawals in each group
3. Results critical appraisal	Summarize internal validity: sample size, randomization and blinding, use of inappropriate statistical analysis, etc

KEY QUESTION 5

Assessment table relative importance patient important outcomes

Patient-important outcomes	Mean rating	Relative importance
Morbidity	7	Crucial
Mortality	7	Crucial

As rated by 4 guideline panel members, none of whom were patients

1.1.1.1 Evidence table systematic reviews

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results primary outcome	VI Results secondary and other outcome(s)	VII Critical appraisal of study quality
De Salvo 2008	• SR • Support: Centro Oncologico Regionale di Padova, Italy; CoI: none • Databases searched: Medline, Embase, Central, Cancerlit • Search date: January 2004 • Languages: no restriction • Included studies: none	• Inclusion: patients with intestinal obstruction from left primary colorectal carcinoma • Exclusion: • Patient characteristics:	Primary resection vs. staged resection	One RCT was identified that was excluded by the authors as: ´it contained no prior sample size estimation or description of the standard treatment. The type of random procedure used was not specified and the accrual period (15 yrs) was very long. Moreover, no information was given regarding the number of excluded patients or the reason for their exclusion and, although one of the most important inclusion criteria was the presence of colorectal carcinoma, 14% of randomised patients were later considered ineligible because during or after surgery they were found to have no malignant tumour. Furthermore, since the long-term outcome of patients was not adequately recorded, a comparison between the two groups was unreliable´	-	• Authors searched for RCTs and controlled clinical trials

Abbreviations: CoI: conflict of interest; SR: systematic review

1.1.1.2 Evidence table randomised controlled trials

I Study ID	II Method	III Patient characteristics	IV Intervention(s)	V Results primary outcome	VI Results secondary and other outcome(s)	VII Critical appraisal of study quality
Alcantara 2011	• RCT • Support: Parc Taulí Foundation; CoI: not reported • Setting: single centre, Spain • Sample size: N= 28 • Duration: February 2004-December 2006 • Follow-up: mean 37.6 months (SD: 16.1)	• Inclusion: obstructive left-sided colonic cancer; age ≥18 years • Exclusion: unresectable lesion (intraoperative); severe ischemia or cecal perforation; fecal or advanced purulent peritonitis; hemodynamic instability during surgery; immunodepressed state; septic shock • Patient characteristics: ○ 43% male ○ Mean age ±71 years ○ 14% stage IV, with resectable hepatic metastases which were operated on as scheduled surgery during follow-up	Stent placement before surgery vs. emergency surgery with primary anastomosis with intraoperative colonic lavage	In-hospital mortality: 0 vs. 1 (p=0.464) Overall in-hospital morbidity: 2/15 (13.3%) vs. 7/13 (53.8%) (p=0.042) Anastomotic dehiscence: 0 vs. 4/13 (30.7%) (p=0.035) Surgical site infection: 2 (13.3%) vs. 6 (46.1%) (p=0.096) Stent related complications: 0% No differences were found with respect to long term survival or disease-free period. There were more relapses in the stent group, although the number was not significant (p=0.055) (actual data not reported, survival depicted in a figure)	-	• Likely that patients were treated with curative intent as unresectable lesions were excluded and the stage IV patients had resectable hepatic metastases which were operated on as scheduled surgery during follow-up • Small study • Suspended early because of excess mortality in the emergency surgery group • Sequence generation not reported on • Allocation concealment through sealed envelopes • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analyses
Cheung 2007	• RCT • Support: ; CoI: none • Setting: single centre, Hong Kong • Sample size: N= 48 • Duration: January 2002-May 2005 • Follow-up: not reported	• Inclusion: Adult patients with an obstructing tumour between the splenic flexure and recto sigmoid junction • Exclusion: peritonitis, right lower quadrant tenderness, or a grossly distended cecum (>10 cm in maximal dimension) on plain abdominal radiography; patients who were	Self-expanding metal stent followed by laparoscopic resection vs. emergency open surgery	Successful 1-stage operations: 67% vs. 38% (0.04) Permanent colostomy: 0 vs. 25% (p=0.03) Stent related complications:	Four patients had failed endoluminal stenting owing to failed cannulation	• Not reported whether patients were treated with curative or palliative intent. Likely a mixed group as 25% of patients were stage IV • Small study

		considered unfit for operative treatment; patients with a previous laparotomy; and patients with a clinically palpable tumour on abdominal examination • Patient characteristics: ○ 54% male ○ 25% stage IV		0% Anastomotic leakage: 0 vs. 2 (p=0.45) Wound infection: 2 vs. 8 (p=0.04) Chest infection: 0 vs. 1 (p=0.99) Intra-abdominal sepsis: 0 vs. 1 (p=0.99) Other morbidities: 0 vs. 5 (p=0.02) Peri-procedural mortality: 0 vs. 0		• Time of follow-up not reported, likely <1 year • 3/24 vs. 9/24 patients had stage IV (p=0.02 using STATA´s prtesti command) • Originally 50 patients were randomised; 1 patient from each group was excluded from analysis because of withdrawal and because of ascites • Computer-generated randomisation • Allocation concealment not reported • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analyses
Fiori 2004, Fiori 2012	• RCT • Support: not reported ; CoI: not reported • Setting: single centre, Italy • Sample size: N= 22 • Duration: January 2001-May 2003 • Follow-up: 4 to 6 years, until death of all patients	• Inclusion: malignant sub acute obstruction of the recto sigmoid region presenting an advanced unresectable stage • Exclusion: not reported • Patient characteristics: ○ 59% male ○ Mean age: ±76 years ○ Site of obstruction: 8 sigmoid; 14 rectum ○ 100% stage IV	Stenting vs. elective colostomy	Stent related complications: 0% Peri-procedural mortality: 0 vs. 0% 1 patient had colostomy prolapse There were no statistically significant differences between the 2 groups concerning peri-procedural morbidity Long-term mortality: 297 days (range: 125–612 days) vs. 280 days (range: 135–591 days) (not significant) No case of mortality during long-term follow-up was related to the procedures	Three patients complained of abdominal pain during the follow-up period: 2 patients had fecal impaction at the stent site, which was resolved by removing mechanically the stool; in the 3rd patient, there was an almost complete obstruction at the stent site by a tumor in-growth, which was resolved with laser treatment and the insertion of a new stent. One patient	• Patients were treated with palliative intent • Small trial • Suspended early because no stent-related complications were found (which was considered to occur à priori) • Randomisation with random-number tables • Allocation concealment procedure not reported on • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analyses, no loss to follow-up

					had chronic anemia requiring blood transfusion In 1 patient the stoma prolapsed 9 months after the operation, which was well tolerated by the patient without the need for surgical revision. One patient had evidence of significant skin inflammation and irritation around the stoma. Two patients had chronic anemia requiring blood transfusion	
Ho 2012	• RCT • Support: not reported; CoI: not reported • Setting: single centre, Singapore • Sample size: N= 39 • Duration: October 2004-February 2008 • Follow-up: 60 days	• Inclusion: acute left-sided malignant colonic obstruction with no evidence of peritonitis • Exclusion: obstruction due to non-colonic malignancy • Patient characteristics: ○ 56% male ○ Median age: ±68 years ○ 26% stage IV	Stenting + elective surgery vs. emergency surgery	Complication rate: 35% vs. 58% (p=0.152) Mortality: 0% vs. 16% (p=0.106) Defunctioning stomas: 2 vs. 6 (p=0.127) Permanent stoma 1 year post-surgery: 1 vs. 2	Technical stent failure occurred in five patients (25%)	• Small trial • Computer-generated randomisation • Allocation concealment: sequentially numbered, opaque, sealed envelopes • 1 patient developed peritonitis before stenting and was excluded • 10/20 vs. 5/19 patients were stage III (p=0.13 with Stata´s prtesti command); 3/20 vs. 7/19 patients were stage IV (p=0.12) • Blinding of patients and personnel not possible • Blinded outcome assessment not reported

						• ITT analyses
Kronborg 1995	• RCT • Support: not reported; CoI: not reported • Setting: single centre, Denmark • Sample size: N= 121 • Duration: 1978-1993 • Follow-up: 4 months to 15 years	• Inclusion: patients presenting with signs of left-sided obstructive colorectal tumours; no synchronous tumour in the right colon; complete resection of tumour possible • Exclusion: distant spread; low rectal tumours; intestinal gangrene; inflammatory bowel disease • Patient characteristics: o 42% male o Mean age: ±71 years o 22% Dukes C	Transverse colostomy + resection with anastomosis vs. resection without immediate anastomosis, and anastomosis in a later stage	≥1 postoperative complication: 31 vs. 42 (p=0.19) Post-operative mortality: 11 vs. 8 Patients surviving curative resection for cancer without permanent colostomy: 32/35 vs. 36/50 (p=0.05) (and excluding the protocol violations: 32/35 vs. 30/44, p=0.01) Local recurrence: 9/34 vs. 5/50 (p=0.09) Overall recurrence: 16/34 vs. 22/50 Median disease-free interval: 18 vs. 12 months (p=0.02) Cancer-specific survival: no significant difference	-	• Sequence-generation not described • Allocation concealment not described • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analyses • 7/63 patients in the immediate resection without anastomosis group had an anastomosis at the time of resection (protocol violation • 11 vs. 6 patients were wrongly diagnosed as having cancer, mainly due to diverticular strictures • 3 vs. 0 patients had unexpected distant spread
Pirlet 2011	• RCT • Support: metallic stent devices were provided free of charge by BARD France SAS; hospital clinical research program, Montpellier University Hospital, Agence Française de Sécurité sanitaire des produits de santé.; CoI: none • Setting: multicentre, France • Sample size: N= 60 • Duration: December 2002-October 2006 • Follow-up: not reported	• Inclusion: acute left-sided malignant large bowel obstruction; age ≥ 18 years, fit for both emergency surgery and colonic stenting • Exclusion: symptoms suggesting bowel perforation; stage IV carcinoma • Patient characteristics: o 48% male o Mean age: ±73 years o 0% stage IV	Stent + surgery vs. emergency surgery	Two colonic perforations directly related to the stent placement procedure occurred (7%) Stoma placement: 43 vs. 57% (p=0.30) Permanent stoma: 9 vs. 8 Overall primary anastomosis rate without leakage: 53 vs. 43% (p=0.45) In-hospital mortality: 3 vs. 1 In-hospital morbidity: - Abdominal complications: 7 vs. 7 (p=1.00)	-	• Prematurely closed trial (intended to randomise 80 patients) because of 2 colonic perforations during stent placement • 10/70 randomized patients were excluded from analysis because of protocol violations (treatment before randomisation, no surgery after stent placement, benign lesions) • Randomisation sequence generation through computer-generated lists • Allocation concealment

				- Extra abdominal complications: 8 vs. 10 (p=0.57)		procedure: secured web site • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analyses
Sankararajah 2005	• RCT • Support: not reported; CoI: not reported • Setting: not reported, United Kingdom • Sample size: N= 19 • Duration: 2000-2004 • Follow-up: median 12 months	• Inclusion: patients with a large bowel obstruction • Exclusion: not reported • Patient characteristics: ○ 58% male ○ Median age: 79 years ○ 58% of the lesions were Dukes B or C; 32% had liver metastases	Stent with or without elective surgery vs. emergency surgery	Post-procedural (≤30 days) mortality: 1 vs. 1 Post-procedural morbidity: 24% post-stenting + 14% post-elective surgery vs. 66% (numbers not reported) Estimated 1-year survival: 54 vs. 57% (numbers not reported) Median survival: 23 months vs. 19 months	-	• Interim analysis in abstract form • 1 patient randomised to emergency surgery refused treatment • 57% of stented patients underwent elective surgery • Randomisation sequence generation not reported • Allocation concealment procedure not reported • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • unclear whether ITT analysis was performed
Xinopoulos 2004	• RCT • Support: not reported; CoI: not reported • Setting: single centre, Greece • Sample size: N= 30 • Duration: March 1998-April 2002 • Follow-up: not reported but up until all patients died	• Inclusion: inoperable malignant partial colon obstruction, from colon (n=24) or ovarian cancer (n=6) • Exclusion: • Patient characteristics: ○ 53% male ○ Mean age: 72 years ○ Stage not reported	Stent vs. colostomy	Stent-related complications: 0% Peri-procedural morbidity: 0 vs. 0% Median survival: 21.4 vs. 20.9 weeks Endoscopic inspections were carried out every 8 weeks. A moderate occlusive in growth of tumor into the stent lumen was documented in 6 patients and was treated with internal laser application for a total of 16 sessions, with an interval of 8 weeks between each	-	• Small trial • 1 patient in whom stent placing was not possible was excluded from the trial • Randomisation sequence generation not reported • Allocation concealment procedure not reported • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • no ITT analysis

				session. After 44 weeks of follow-up and internal application of a laser, 1 stent was expelled to the anal side of the lesion without complication Surgery was performed without serious complications		
Van Hooft 2008	• RCT • Support: ZonMw; CoI: none • Setting: multicentre, the Netherlands • Sample size: N= 21 • Duration: December 2004-January 2006 • Follow-up: until death or at least 1 year	• Inclusion: stage IV left−sided colorectal cancer and imminent obstruction; age ≥18 years • Exclusion: ileus; Karnofsky performance status <50% or an American Society of Anaesthesiologists class of IV or V • Patient characteristics: ○ 52% male ○ Mean age: ±65 years ○ 100% stage IV	Stent vs. palliative surgery (resection or fecal diversion)	Median survival in good health out of hospital during the first year: 38 days (interquartile range: 5.25±288.75 days) vs. 56 days (interquartile range: 7.5±338.5 days) (p=0.68) Adverse events including long-term follow-up: 11 vs. 1 (p<0.001) Stent-related complications within 30 days: 2 perforations, 1 hospital admission for diarrhea and 1 hospital admission for severe pain that spontaneously resolved Peri-procedural mortality: 2 vs. 0 Colostomy: 0 vs. 2	-	• A high number of serious adverse events in the nonsurgical arm led to premature closure of the trial • Computerised, central randomisation • Blinding of patients and personnel not possible • Blinded outcome assessment not reported • ITT analysis
Van Hooft 2011	• RCT • Support: none; CoI: reported in detail • Setting: multiple centres, the Netherlands • Sample size: N= 98 • Duration: March 2007-August 2009 • Follow-up: 6 months	• Inclusion: acute obstructive left-sided colorectal cancer; age ≥18 years • Exclusion: signs of peritonitis, perforation, fever, sepsis, or other serious complications demanding urgent surgery; physical status of class 4 or 5 according to the American Society of Anaesthesiologists; obstruction caused by a non-colonic malignancy or a benign disease; distal tumour margin of less than 10 cm from the anal verge; inability to complete self-report quality-of-life questionnaires • Patient characteristics:	Stenting + surgery vs. emergency surgery	30-day mortality - 5 vs. 5 - Absolute risk difference: 0.01 (95%CI: -0.12 to 0.14) (p=0.89) Overall mortality: - 9 vs. 9 - Absolute risk difference 0.02 (95%CI: –0.14 to 0.17) (p=0.84) Morbidity:	No significant differences according to EORTC-QLQ-C30, including subscales, based on available data and corrected for differences at baseline No significant differences according to	• A higher morbidity in the stent arm led to premature stopping of the trial • Computer-generated randomisation • Web-based allocation • Blinding of patients and personnel not possible • Blinded outcome assessment: blinded assessors evaluated outcomes • ITT analysis

		○ 52% male ○ Mean age: ±71 years		- 25 vs. 23 - Absolute risk difference: 0.08 (95%CI: –0.11 to 0.27) (p=0.43) Stoma rates post-surgery: - 24 vs. 38 - Absolute risk difference: -0.23 (95%CI: –0.40 to 0.04) (p=0.02) Stoma rates at latest follow-up: - 27 vs. 34 - Absolute risk difference: -0.09 (95%CI: –0.27 to 0.10) (p=0.35) Six stent perforations at 6 months; 3 silent stent perforations detected in the operative specimen	EORTC-QLQ-CR38, based on available data and corrected for differences at baseline, except for the stoma-related problems subscale were the emergency surgery group scored better (–12.0 (–23.7 to –0.2) (p=0.046)	

Abbreviations: CI: confidence interval; CoI: conflict of interest; ITT: intention to treat; RCT: randomised controlled trial; SD: standard deviation

1.1.1.3 Grade table KQ5: staged vs. acute resection

Quality assessment							No of patients		Effect (95%CI)			
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Staged resection**	**Acute resection**	**Relative**	**Absolute**	**Quality**	**Importance**
No permanent colostoma at the longest available follow-up in surviving patients with cancer												
1	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [1]	No other considerations	35	50	-	32/35 vs. 36/50 (p=0.05)	Moderate ⊕⊕⊕O	Critical
Peri-procedural mortality												
1	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [1]	No other considerations	58	63	-	11 vs. 8	Moderate ⊕⊕⊕O	Critical

Long-term cancer-specific mortality (follow-up 4 months to 15 years)												
1	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	Serious other considerations [2]	58	63	-	No significant difference [3]	Moderate ⊕⊕⊕O	Critical
≥ periprocedural complication												
1	RCT	Serious risk of bias[4]	No serious inconsistency	No serious indirectness	No serious imprecision	No serious other considerations	58	63	-	31 vs. 42 (p=0.19)	Moderate ⊕⊕⊕O	Critical
Overall quality of evidence: moderate												

Abbreviations: CI: confidence interval

[1] Few events lead to fragility of results

[2,3] Actual data not reported

[4] Blinding of patients and personnel not possible; blinded outcome assessment not reported on but unlikely

Figure 1 Peri-procedural morbidity in trials comparing stents vs. surgery (fixed effects analysis, I2=29.6)

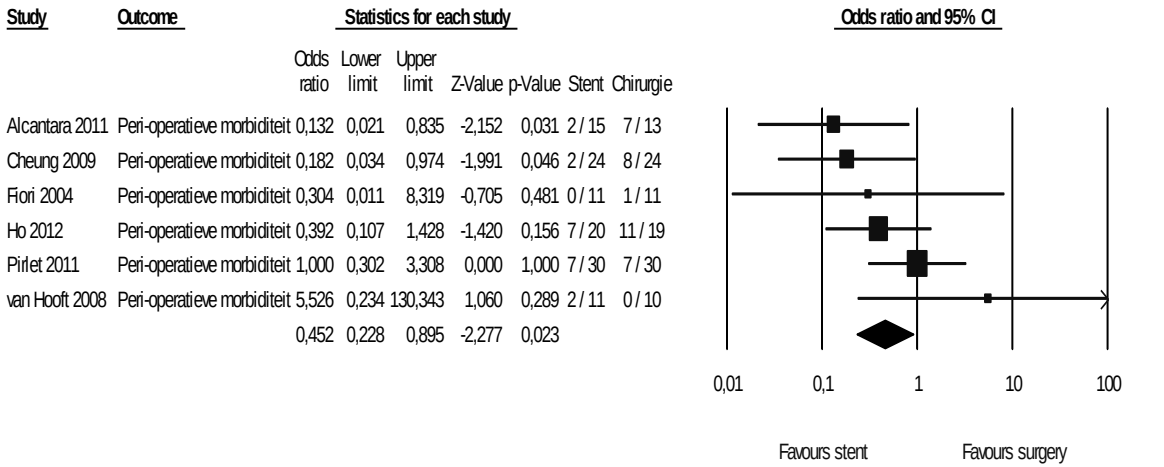


Figure 2 Overall morbidity in trials comparing stents vs. surgery (random effects analysis, I2=69.7)

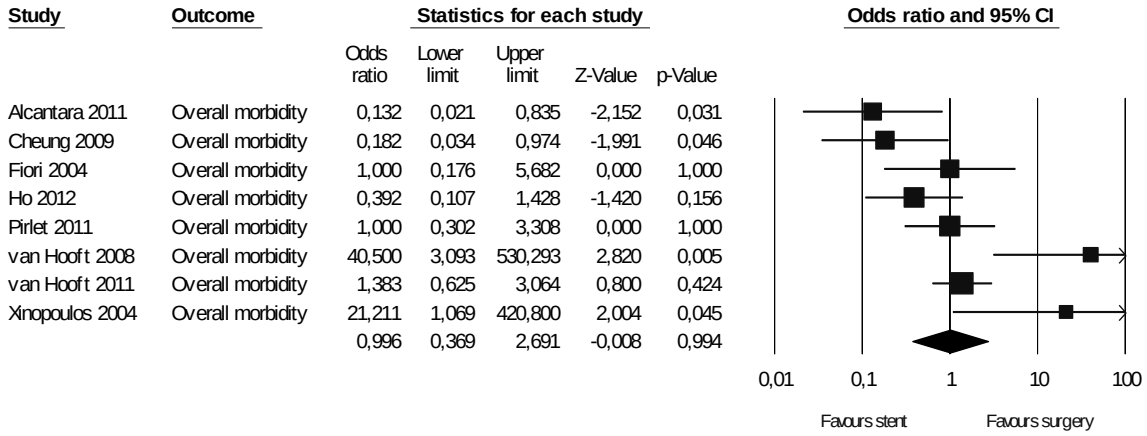


Figure 3 Peri-procedural mortality in trials comparing stents vs. surgery (fixed effects analysis, I2=0.0)

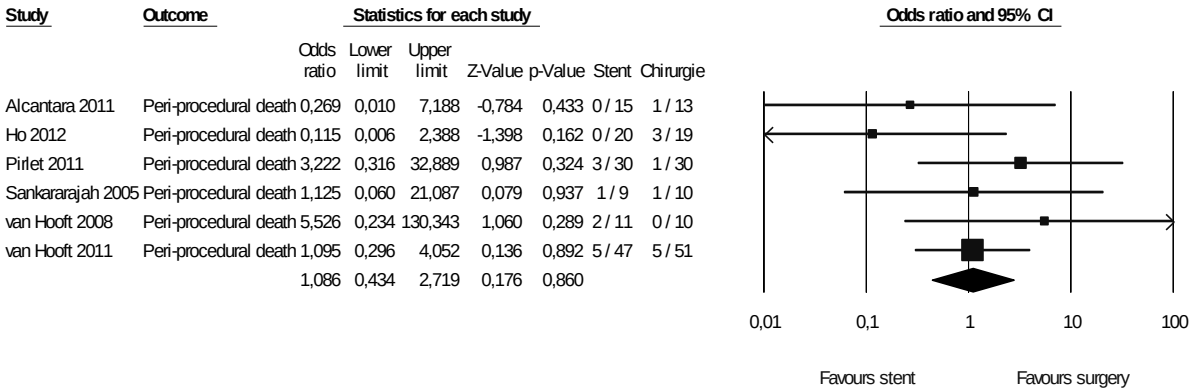
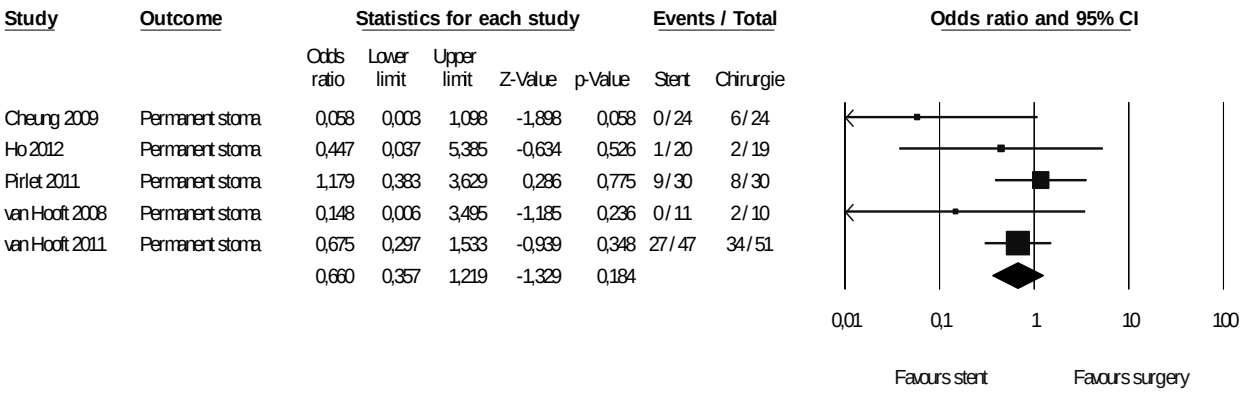


Figure 4 Definitive colostoma at the longest available follow-up (excluding trials of stent vs. colostoma) (fixed effects analysis, I2=13.2)



1.1.1.4 Grade table KQ5: stent vs. acute resection

Quality assessment							No of patients		Effect (95%CI)			
No. of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Stent**	**No stent**	**Relative**	**Absolute**	**Quality**	**Importance**
Definitive colostoma at the longest available follow-up (excluding trials of stent vs. colostoma)												
5	RCT	Serious risk of bias[$]	No serious inconsistency	No serious indirectness	No serious imprecision	Serious other considerations [§]	132	134	OR 0.66 (95%CI: 0.36 to 1.22)	RD -11% (95%CI: -20 to -2%)	Low ⊕⊕OO	Critical
Peri-procedural mortality												
9 [1]	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [2]	Serious other considerations [§]	173	173	OR 1.09 (95%CI: 0.43 to 2.72)	RD 0% (95%CI: -7 to 7%)	Low ⊕⊕OO	Critical
Long-term mortality												
6	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision [2]	Serious other considerations [§]	108	110	-	No significant difference [3]	Low ⊕⊕OO	Critical
Peri-procedural morbidity												
8 [1]	RCT	Serious risk of bias[$]	No serious inconsistency	No serious indirectness	No serious imprecision	Serious other considerations [§]	173	173	OR 0.45 (95%CI: 0.23 to 0.90)	RD -11% (95%CI: -21 to -1%)	Low ⊕⊕OO	Critical
Overall morbidity												
8	RCT	Serious risk of bias[$]	No serious inconsistency	No serious indirectness	No serious imprecision	Serious other considerations [§]	173	173	OR 0.99 (95%CI: 0.37 to 2.69)	RD: -4% (95%CI: -5% to 13%)	Low ⊕⊕OO	Critical
Peri-procedural stent perforation												
7 [4]	RCT, observational outcome	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious other considerations	126	-	-	4 (3.2%)	Low ⊕⊕OO	Critical
Stent perforation at long term follow-up												
4 [4]	RCT, observational outcome	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	No serious other considerations	84	-	-	12 (14.3%)	Low ⊕⊕OO	Critical
Overall quality of evidence: Low												

Abbreviations: CI: confidence interval; OR: odds ratio; RD: risk difference
[1] Including 2 or 3 trials with zero events in both treatment groups
[$] Blinding of patients and personnel not possible; blinded outcome assessment not reported on but unlikely
[§] Four trial were stopped early for conflicting reasons
[2] Small trials and few events/zero events lead to fragility of results
[3] Meta-analysis not performed as results were presented differently e.g. as median survival in days or deaths at follow up

[4] Including 5 trials with zero events