

Systematic reviews, meta-analyses De Salvo 2008 ¹

Internal validity

- The study addresses an appropriate and clearly focused question
Yes
- A description of the methodology used is included
Yes
- The literature search is sufficiently rigorous to identify all the relevant studies
Yes
- Study quality is assessed
Not applicable: no studies included
- Data extraction is clearly described
Not applicable: no studies included
- The most important characteristics from the original research are described
Not applicable: no studies included
- There are enough similarities between the selected studies to make combining them reasonable
Not applicable: no studies included
- Statistical pooling is correctly performed
Not applicable: no studies included
- Statistical heterogeneity is adequately taken into account
Not applicable: no studies included
- Study quality is taken into account
Not applicable: no studies included
- Overall assessment of the study**
- Are the results of the systematic review:
 - valid? Not applicable: no studies included
 - applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Alcantara 2011 ²

Internal validity

- The study addresses an appropriate and clearly focused question
Yes
- The assignment of subjects to treatment groups is randomized
Yes – sequence generation not reported
- An adequate concealment method is used
Sealed envelopes were used. Not reported whether these were opaque
- Subjects are kept blind about treatment allocation
No
- Outcome assessors are kept blind about treatment allocation
Not reported
- The treatment and control groups are similar at the start of the trial
Yes
- The only difference between groups is the treatment under investigation
Yes
- All relevant outcomes are measured in a standard, valid and reliable way
Not reported
- All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)
Yes
- Overall assessment of the study**
- Are the results of the study:
 - valid? Yes
 - applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Cheung 2009 ³

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes

An adequate concealment method is used

Not reported

Subjects are kept blind about treatment allocation

Not possible

Outcome assessors are kept blind about treatment allocation

Not reported

The treatment and control groups are similar at the start of the trial

No: more stage IV patients in the open surgery group (9 vs. 3, $p=0.02$)

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

Yes – though time of follow-up was not specified for the outcome permanent stoma. All other outcomes seem perioperative outcomes

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Fiori 2004 ⁴, Fiori 2012 ⁵

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes

An adequate concealment method is used

Not reported on

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation

Not reported

The treatment and control groups are similar at the start of the trial

Yes

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

Not reported

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Ho 2012

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes – computer-generated randomisation

An adequate concealment method is used

Yes – sequentially numbered, opaque sealed envelopes

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation

Not reported

The treatment and control groups are similar at the start of the trial

No – better stage patients in the stent group

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

No

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Kronborg 1995⁶

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes – sequence generation not reported on

An adequate concealment method is used

Unclear – not reported on

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation

Not reported

The treatment and control groups are similar at the start of the trial

No: 11 vs. 6 patients were wrongly diagnosed as having cancer; 3 vs. 0 patients had distant spread

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

Yes

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Pirlet 2011⁷

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes – computer-generated lists

An adequate concealment method is used

Yes – central secured website

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation
Not reported
The treatment and control groups are similar at the start of the trial
Yes
The only difference between groups is the treatment under investigation
Yes
All relevant outcomes are measured in a standard, valid and reliable way
Yes
All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)
Yes

Overall assessment of the study

Are the results of the study:
- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Sankararajah 2005

Internal validity

The study addresses an appropriate and clearly focused question
Yes
The assignment of subjects to treatment groups is randomized
Yes – sequence generation not described
An adequate concealment method is used
Not described
Subjects are kept blind about treatment allocation
No
Outcome assessors are kept blind about treatment allocation
Not described
The treatment and control groups are similar at the start of the trial
Not described
The only difference between groups is the treatment under investigation
Yes
All relevant outcomes are measured in a standard, valid and reliable way
Not reported
All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)
Not reported

Overall assessment of the study

Are the results of the study:
- valid? yes
- applicable to the patient group targeted in the search question? yes

Checklist Randomised Controlled Trials Xinopoulos 2004⁸

Internal validity

The study addresses an appropriate and clearly focused question
Yes
The assignment of subjects to treatment groups is randomized
Yes –sequence generation not reported on
An adequate concealment method is used
Not reported on
Subjects are kept blind about treatment allocation
No
Outcome assessors are kept blind about treatment allocation
Not reported
The treatment and control groups are similar at the start of the trial
Not reported on
The only difference between groups is the treatment under investigation
Yes
All relevant outcomes are measured in a standard, valid and reliable way

Not reported

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

No – 1 patient with unsuccessful stent placement was excluded from analysis

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials Van Hooft 2008⁹

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes – computer generated randomisation sequence

An adequate concealment method is used

Yes – central randomisation

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation

Not reported

The treatment and control groups are similar at the start of the trial

Yes

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

Not reported

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

Checklist Randomised Controlled Trials van Hooft 2011¹⁰

Internal validity

The study addresses an appropriate and clearly focused question

Yes

The assignment of subjects to treatment groups is randomized

Yes – computer-generated randomisation

An adequate concealment method is used

Yes – web-based allocation

Subjects are kept blind about treatment allocation

No

Outcome assessors are kept blind about treatment allocation

No – though a blinded panel was used to evaluate outcomes

The treatment and control groups are similar at the start of the trial

Yes

The only difference between groups is the treatment under investigation

Yes

All relevant outcomes are measured in a standard, valid and reliable way

Yes

All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

Yes

Overall assessment of the study

Are the results of the study:

- valid? Yes
- applicable to the patient group targeted in the search question? Yes

1. De Salvo GL, Gava C, Pucciarelli S, Lise M. Curative surgery for obstruction from primary left colorectal carcinoma: primary or staged resection? Cochrane database of systematic reviews. 2004(2):CD002101.
2. Alcantara M, Serra-Aracil X, Falco J, Mora L, Bombardo J, Navarro S. Prospective, controlled, randomized study of intraoperative colonic lavage versus stent placement in obstructive left-sided colonic cancer. *World journal of surgery*. 2011;35(8):1904-10.
3. Cheung HY, Chung CC, Tsang WW, Wong JC, Yau KK, Li MK. Endolaparoscopic approach vs conventional open surgery in the treatment of obstructing left-sided colon cancer: a randomized controlled trial. *Archives of surgery*. 2009;144(12):1127-32.
4. Fiori E, Lamazza A, De Cesare A, Bononi M, Volpino P, Schillaci A, et al. Palliative management of malignant rectosigmoidal obstruction. Colostomy vs. endoscopic stenting. A randomized prospective trial. *Anticancer research*. 2004;24(1):265-8.
5. Fiori E, Lamazza A, Schillaci A, Femia S, Demasi E, Decesare A, et al. Palliative management for patients with subacute obstruction and stage IV unresectable rectosigmoid cancer: colostomy versus endoscopic stenting: final results of a prospective randomized trial. *Am J Surg*. 2012;204(3):321-6.
6. Kronborg O. Acute obstruction from tumour in the left colon without spread. A randomized trial of emergency colostomy versus resection. *International journal of colorectal disease*. 1995;10(1):1-5.
7. Pirlet IA, Slim K, Kwiatkowski F, Michot F, Millat BL. Emergency preoperative stenting versus surgery for acute left-sided malignant colonic obstruction: a multicenter randomized controlled trial. *Surgical endoscopy*. 2011;25(6):1814-21.
8. Xinopoulos D, Dimitroulopoulos D, Theodosopoulos T, Tsamakidis K, Bitsakou G, Plataniotis G, et al. Stenting or stoma creation for patients with inoperable malignant colonic obstructions? Results of a study and cost-effectiveness analysis. *Surgical endoscopy*. 2004;18(3):421-6.
9. van Hooft JE, Fockens P, Marinelli AW, Timmer R, van Berkel AM, Bossuyt PM, et al. Early closure of a multicenter randomized clinical trial of endoscopic stenting versus surgery for stage IV left-sided colorectal cancer. *Endoscopy*. 2008;40(3):184-91.
10. van Hooft JE, Bemelman WA, Oldenburg B, Marinelli AW, Holzik MF, Grubben MJ, et al. Colonic stenting versus emergency surgery for acute left-sided malignant colonic obstruction: a multicentre randomised trial. *The lancet oncology*. 2011;12(4):344-52.