# Systematic reviews, meta-analyses De Salvo 2008

**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

**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

**Internal validity**

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<thead>
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**Overall assessment of the study**

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

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### Checklist Randomised Controlled Trials Fiori 2004 *, Fiori 2012 *

**Internal validity**

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**Overall assessment of the study**

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

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### 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

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**Checklist Randomised Controlled Trials Kronborg 1995**

**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

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**Checklist Randomised Controlled Trials Pirlet 2011**

**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 2004

**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 2008

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 2011

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 – tough 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
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