## Systematic reviews, meta-analyses

**Internal validity**

- The study addresses an appropriate and clearly focused question
- A description of the methodology used is included
- The literature search is sufficiently rigorous to identify all the relevant studies
- Study quality is assessed
- Data extraction is clearly described
- The most important characteristics from the original research are described
- There are enough similarities between the selected studies to make combining them reasonable
- Statistical pooling is correctly performed
- Statistical heterogeneity is adequately taken into account
- Study quality is taken into account

**Overall assessment of the study**

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

## Checklist Randomised Controlled Trials

**Internal validity**

- The study addresses an appropriate and clearly focused question
- The assignment of subjects to treatment groups is randomized
- An adequate concealment method is used
- Subjects are kept blind about treatment allocation
- Outcome assessors are kept blind about treatment allocation
- The treatment and control groups are similar at the start of the trial
- The only difference between groups is the treatment under investigation
- All relevant outcomes are measured in a standard, valid and reliable way
- All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)

**Overall assessment of the study**

Are the results of the study:
- valid?
- applicable to the patient group targeted in the search question?
### Checklist Randomised Controlled Trials (Park, Kang et al. 2007)

#### Internal validity

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Yes</td>
</tr>
<tr>
<td>The assignment of subjects to treatment groups is randomized</td>
<td>Yes</td>
</tr>
<tr>
<td>An adequate concealment method is used</td>
<td>Yes</td>
</tr>
<tr>
<td>Subjects are kept blind about treatment allocation</td>
<td>Yes</td>
</tr>
<tr>
<td>Outcome assessors are kept blind about treatment allocation</td>
<td>Yes</td>
</tr>
<tr>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Yes</td>
</tr>
<tr>
<td>The only difference between groups is the treatment under investigation</td>
<td>Yes</td>
</tr>
<tr>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Yes</td>
</tr>
<tr>
<td>All the subjects are analyzed in the groups to which they were randomly allocated (intention to treat)</td>
<td>No: although this is stated in the article, 2 vs. 4 patients were excluded from analyses because of poor compliance</td>
</tr>
</tbody>
</table>

#### 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 COHORT studies (Allgayer, Dietrich et al. 2005)

#### Internal validity

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Yes</td>
</tr>
<tr>
<td>The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation</td>
<td>Unclear – patients were referred, likely that the more severe cases were referred and less severe cases not</td>
</tr>
<tr>
<td>The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Comparison by exposure status is made between full participants and those lost to follow up</td>
<td>No – 24/95 patients lost to follow-up. Unclear why</td>
</tr>
<tr>
<td>The outcomes are clearly defined</td>
<td>Yes</td>
</tr>
<tr>
<td>The assessment of outcome is made blind to exposure status</td>
<td>No</td>
</tr>
<tr>
<td>The measure of assessment of exposure is reliable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>The main potential confounders are identified and taken into account in the design and analysis</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

#### 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 COHORT studies (Bartlett, Sloots et al. 2011)

#### Internal validity

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Met</th>
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</thead>
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<tr>
<td>The study addresses an appropriate and clearly focused question</td>
<td>Yes</td>
</tr>
</tbody>
</table>
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear – patients were referred, likely that the more severe cases were referred and less severe cases not
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No – 7/19 patients were not reported on at 2.4 years of follow-up. Unclear why
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (de Miguel, Oteiza et al. 2011)

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable: no loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No-non-blinded study
The measure of assessment of exposure is reliable
Yes
The main potential confounders are identified and taken into account in the design and analysis
No

### Checklist COHORT studies (Gillespie, Barbaric et al. 1985)

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
This is a single case study form a larger series, unclear why not more cases/complete series was reported on
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
No

**Overall assessment of the study**

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

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**Checklist COHORT studies (Ho and Tan 1997)**

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear what the source population was. 1/11 patients had had cervical cancer; 10/11 patients had had rectal cancer
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up reported
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Ho 2001)**

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear what the source population was
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**Overall assessment of the study**

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

Checklist COHORT studies (Holzer, Rosen et al. 2008)

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
Unclear what the source population was, in addition, 1/7 patients had Crohn’s disease
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
No

**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 COHORT studies (Jarrett, Matzel et al. 2005)

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Yes – though actual figures FIQL not reported
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Kim, Yu et al. 2011)

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Yes
The main potential confounders are identified and taken into account in the design and analysis
Not applicable
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 Case Control studies (Koch, Rietveld et al. 2009)

Internal validity
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Yes
The main potential confounders are identified and taken into account in the design and analysis
Not applicable
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 Case Control studies (Laforest, Bretagnol et al. 2012)

Internal validity
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
The likelihood that some subjects might not be incontinent is not described and unlikely to have been taken into account
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Yes
The main potential confounders are identified and taken into account in the design and analysis
No: pre-intervention scores were not identified

**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**

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The assignment of subjects to treatment groups is randomized
Yes – computer generated sequence
An adequate concealment method is used
Yes – central allocation
Subjects are kept blind about treatment allocation
Yes – though might have been able to guess allocation because of side effects
Outcome assessors are kept blind about treatment allocation
Not applicable
The treatment and control groups are similar at the start of the trial
Yes, with regard to erectile function scores – other characteristics 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
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? in part, 20/32 patients did not have rectal cancer

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**Checklist COHORT studies (Maeda, Maruta et al. 2002)**

**Internal validity**

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear – the source population is not described
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Matzel, Stadelmaier et al. 2002)

#### Internal validity

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear what the source population was
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
Not applicable
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Yes
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Moya, Arroyo et al. 2012)

#### Internal validity

The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear: source population not reported on
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up described
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Ortega, Ortega et al. 2012)
Internal validity
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up described
No
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable
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 COHORT studies (Pucciani, Ringressi et al. 2008)

Internal validity
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up described
No
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable
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 COHORT studies (Ratto, Grillo et al. 2005)

Internal validity
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear what the source population was
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis

Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Ratto, Parello et al. 2009)**

**Internal validity**
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Unclear what the source population was
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis
Not applicable

**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 COHORT studies (Sterk, Shekarriz et al. 2005)**

**Internal validity**
The study addresses an appropriate and clearly focused question
Yes
The cohort being studied is selected from source populations that are comparable in all respects other than the factor under investigation
Yes
The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis
Not applicable
Comparison by exposure status is made between full participants and those lost to follow up
No loss to follow-up
The outcomes are clearly defined
Yes
The assessment of outcome is made blind to exposure status
No
The measure of assessment of exposure is reliable
Not applicable
The main potential confounders are identified and taken into account in the design and analysis of the study.

Overall assessment of the study

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


