

# 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

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

Yes

Subjects are kept blind about treatment allocation

Yes

Outcome assessors are kept blind about treatment allocation

Yes

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) No: although this is stated in the article, 2 vs. 4 patients were excluded from analyses because of poor compliance

## 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

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 – 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 – 24/95 patients lost to 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 (Bartlett, Sloots 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 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 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 (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 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

#### No

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

# 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

# **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

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

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

# 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

# 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

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 (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

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 c

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

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

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 (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 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

- Allgayer, H., C. F. Dietrich, et al. (2005). "Prospective comparison of short- and long-term effects of pelvic floor exercise/biofeedback training in patients with fecal incontinence after surgery plus irradiation versus surgery alone for colorectal cancer: clinical, functional and endoscopic/endosonographic findings." <u>Scand J Gastroenterol</u> **40**(10): 1168-1175.
- Bartlett, L., K. Sloots, et al. (2011). "Biofeedback therapy for symptoms of bowel dysfunction following surgery for colorectal cancer." <u>Tech Coloproctol</u> **15**(3): 319-326.
- de Miguel, M., F. Oteiza, et al. (2011). "Sacral nerve stimulation for the treatment of faecal incontinence following low anterior resection for rectal cancer." <u>Colorectal Dis</u> **13**(1): 72-77.
- Gillespie, L., Z. Barbaric, et al. (1985). "Effect of abdominal perineal resection on genitourinary tract." <u>Urology</u> **25**(3): 259-263.
- Ho, Y. H. (2001). "Postanal sphincter repair for anterior resection anal sphincter injuries: report of three cases." <u>Dis Colon Rectum</u> **44**(8): 1218-1220.
- Ho, Y. H. and M. Tan (1997). "Biofeedback therapy for bowel dysfunction following low anterior resection." <u>Annals of the Academy of Medicine Singapore</u> **26**(3): 299-302.
- Holzer, B., H. R. Rosen, et al. (2008). "Sacral nerve stimulation in patients after rectal resection--preliminary report." J Gastrointest Surg **12**(5): 921-925.
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- Kim, K. H., C. S. Yu, et al. (2011). "Effectiveness of biofeedback therapy in the treatment of anterior resection syndrome after rectal cancer surgery." <u>Dis Colon Rectum</u> 54(9): 1107-1113.
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- Maeda, K., M. Maruta, et al. (2002). "Effect of oral diazepam on anal continence after low anterior resection: a preliminary study." <u>Tech Coloproctol</u> **6**(1): 15-18.
- Matzel, K. E., U. Stadelmaier, et al. (2002). "Bilateral sacral spinal nerve stimulation for fecal incontinence after low anterior rectum resection." Int J Colorectal Dis **17**(6): 430-434.
- Moya, P., A. Arroyo, et al. (2012). "Sacral nerve stimulation in patients with severe fecal incontinence after rectal resection." <u>Techniques in Coloproctology</u> **16**(3): 263-264.
- Ortega, M., G. S. Ortega, et al. (2012). "Sacral nerve stimulation for the treatment of faecal incontinence after anterior resection." <u>Colorectal Disease</u> 14: 29.
- Park, J. S., S. B. Kang, et al. (2007). "The efficacy and adverse effects of topical phenylephrine for anal incontinence after low anterior resection in patients with rectal cancer." <u>Int J Colorectal Dis</u> 22(11): 1319-1324.

- Pucciani, F., M. N. Ringressi, et al. (2008). "Rehabilitation of fecal incontinence after sphincter-saving surgery for rectal cancer: encouraging results." <u>Dis Colon Rectum</u> 51(10): 1552-1558.
- Ratto, C., E. Grillo, et al. (2005). "Sacral neuromodulation in treatment of fecal incontinence following anterior resection and chemoradiation for rectal cancer." <u>Dis Colon Rectum</u> 48(5): 1027-1036.
- Ratto, C., A. Parello, et al. (2009). "Sacral nerve stimulation as therapeutic option in patients with faecal incontinence following rectal cancer treatment." <u>Colorectal Disease</u> **11**: 22.
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