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## Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)

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[Intervention Review]

# Quality of life after rectal resection for cancer, with or without permanent colostomy.

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## ABSTRACT

### Background

For almost one hundred years abdominoperineal excision has been the standard treatment of choice for rectal cancer. With advances in the techniques for rectal resection and anastomosis, anterior resection with preservation of the sphincter function has become the preferred treatment for rectal cancers, except for those cancers very close to the anal sphincter. The main reason for this has been the conviction that the quality of life for patients with a colostomy after abdominoperineal excision was poorer than for patients undergoing an operation with a sphincter-preserving technique.

However, patients having sphincter-preserving operations may experience symptoms affecting their quality of life that are different from stoma-patients.

### Objectives

To compare the quality of life in rectal cancer patients with or without permanent colostomy.

### Search methods

We searched PUBMED, EMBASE, LILACS, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Colorectal Cancer Group's specialised register. Abstract books from major gastroenterological and colorectal congresses were searched. Reference lists of the selected articles were scrutinized.

### Selection criteria

All controlled clinical trials and observational studies in which quality of life was measured in patients with rectal cancer having either abdominoperineal excision/Hartmann's operation or low anterior resection, using a validated quality of life instrument, were considered.

### Data collection and analysis

One reviewer (JP) checked the titles and abstracts identified from the databases and hand search. Full text copies of all studies of possible relevance were obtained. The reviewer decided which studies met the inclusion criteria.

Both reviewers independently extracted data. If information was insufficient the original author was contacted to obtain missing data. Extracted data were cross-checked and discrepancies resolved by consensus.

### Main results

Sixty-nine potential studies were identified. Thirty-five of these, all non-randomised and representing 5127 participants met the inclusion criteria. Fourteen trials found that people undergoing abdominoperineal excision/Hartmann's operation did not have poorer quality of

life measures than patients undergoing anterior resection. The rest of the studies found some difference, but not always in favour of non-stoma patients.

Due to clinical heterogeneity and the fact that all studies were observational trials, meta-analysis of the included studies was not possible.

### **Authors' conclusions**

The studies included in this review do not allow firm conclusions as to the question of whether the quality of life of people after anterior resection is superior to that of people after abdominoperineal excision/Hartmann's operation. The included studies challenges the assumption that anterior resection patients fare better.

Larger, better designed and executed prospective studies are needed to answer this question.

### **PLAIN LANGUAGE SUMMARY**

#### **No apparent differences in quality of life are found in rectal cancer patients with a permanent stoma when compared to non-stoma patients.**

For patients diagnosed with rectal cancer, surgery is the definite treatment. The surgical outcome is either restored bowel continuity, or the formation of a stoma. Traditionally the formation of a colostomy has been regarded as an unfavourable outcome, as the quality of life of stoma patients is believed to be inferior compared to that in non-stoma patients. The included studies in this review do not support this assumption, although firm conclusions cannot be drawn.

## BACKGROUND

### Description of the condition

Since the beginning of the last century when Miles (Miles 1908) described abdominoperineal excision (APE), this operation has been the standard treatment of choice for rectal cancer (Enker 1997; Koller 1998; Zaheer 1998; Lange 2009). With advances in the technique of rectal anastomosis, anterior resection with preservation of the sphincter function (AR) has become the usual treatment for cancers of the upper and mid rectum. Furthermore, the advent of mechanical stapling devices has made it possible to perform anastomosis at the distal rectum and anal canal.

As the oncological results after APE/Hartmann's operation and AR are considered comparable, in recent years it has become the state of the art, that whenever feasible, rectal cancer should be treated by a sphincter-preserving technique (Williams 1984; Wolmark 1986; Lange 2009;).

The main reason for this change has been the conviction, that the quality of life (QoL) for people with a colostomy after APE/Hartmann's operation was poorer, than for patients operated upon with a sphincter-preserving technique.

### How the intervention might work

However, functional results after low and ultra-low resections and anastomosis may indeed be so poor, that this technique also compromises the patient's QoL (Lewis 1995; Ortiz 1996; Wexner 1998). There are reports indicating that the QoL after AR might even be poorer than after APE (Camilleri-Brennan 1998; Camilleri-Brennan 2002; Ortiz 1996; Sprangers 1995).

### Why it is important to do this review

QoL is being increasingly recognised as an important outcome measure in comparing different treatment modalities for the same disease. In the future it could probably be one of the determinants in advising patients whether to undergo APE/Hartmann's operation or AR (Anthony 2003; Langenhoff 2001).

## OBJECTIVES

The objective was to evaluate the QoL in patients treated for rectal cancer with either APE/Hartmann's operation (both with a permanent stoma) or AR.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All controlled clinical trials and observational controlled studies in which QoL in patients with rectal cancer, having either APE/Hartmann's operation or AR, were studied using a multidimensional QoL instrument. Additionally, the questionnaires used had to be validated in terms of reliability (the extent to which a test effectively measures anything at all), validity (the extent to which a test measures that which it is supposed to measure), and sensitivity to change.

In addition, the following minimum standards for rating scales were set: the rating scale should either be

(a) a self-report or (b) completed by an independent rater or relative.

Studies using questionnaires designed for a specific study without validation were not included. Likewise studies using originally validated questionnaires, but with ad hoc changes potentially altering the original psychometric properties of the questionnaire, were not included in the study.

#### Types of participants

Individuals with verified cancer of the rectum, which had been treated with either APE/Hartmann's operation or AR. There were no discriminatory criteria concerning age, gender, race or social status.

#### Types of interventions

Abdominoperineal excision/Hartmann's operation (APE/Hartmann's operation) or anterior resection (AR) for rectal cancer. Quality of life assessments using validated multidimensional questionnaires. Self-reported questionnaires filled by the patient, a relative or independent rater will be considered eligible for inclusion.

#### Types of outcome measures

##### Primary outcomes

QoL using validated multidimensional questionnaires. Self-reported questionnaires filled by the individual, a relative or independent rater was considered eligible for inclusion. Assessments of functional results or one-dimensional aspects of QoL (e.g. sexual function, urinary function, pain) were not included in the review.

#### Search methods for identification of studies

See: Colorectal Cancer Group methods used in reviews.

The literature searches were made without language restrictions from December 2002 to January 2003 with updates October 2004, December 2006 October 2009 and March 2012. The following electronic databases were searched: PUBMED, EMBASE, LILACS, Cochrane Central Register of Controlled Trials (CENTRAL), and the Cochrane Colorectal Cancer Group's specialised register. A hand search in relevant literature was carried out. Abstracts books from major Gastroenterological and Colorectal congresses were searched. Additional searches were made via the reference lists of the selected articles. The electronic searches were made using:

##### PUBMED:

Due to changes in the PubMed database two different search strategies have been used.

Initially the search was as follows:

(colorectal neoplasms OR colorect\* neoplasms OR colorectal neoplasm\* OR colorect\* neoplasm\* OR colorectal cancer OR colorect\* cancer OR colorectal Canc\* OR colorect\* canc\* OR colorectal carcinoma OR colorect\* carcinoma OR colorectal carcinom\* OR colorect\* carcinom\* OR rectal neoplasms OR rect\* neoplasms OR rectal neoplasm\* OR rect\* neoplasm\* OR rectal cancer OR rect\* cancer OR rectal canc\* OR rect\* canc\* OR rectal carcinoma OR rect\* carcinoma OR rectal carcinom\* OR rect\* carcinom\*) AND (quality of life OR qualit\* of life OR quality adjusted life years OR qualit\* adjusted life years OR quality adjusted life year\* OR qualit\* adjusted life year\* OR health status OR mental health OR well-being OR quality adjusted survival OR qualit\* adjusted survival)

The following search was used at the updates:

(colorectal neoplasm\* OR colorectal cancer OR rectal cancer OR rectal neoplasm\*) AND (quality of life OR quality adjusted life year\* OR health status OR mental health OR well-being OR quality adjusted survival).

A test was run of the original search and yielded the same amount of hits.

#### CENTRAL:

#1 COLONIC-NEOPLASMS\*:ME #2 RECTAL-NEOPLASMS\*:ME #3 (#1 or #2) #4 (((COLORECT\* near CANCER) or NEOPLASM\*) OR CARCINOM\*) OR ADENOM\*) #5 (((COLO\* near CANCER) or NEOPLASM\*) OR CARCINOM\*) OR ADENOM\*) #6 (((RECT\* near CANCER) or NEOPLASM\*) OR CARCINOM\*) OR ADENOM\*) #7 ((#4 or #5) or #6) #8 (#3 or #7) #9 QUALITY-OF-LIFE\*:ME #10 (HEALTH and STATUS) #11 (MENTAL and HEALTH) #12 WELL-BEING #13 ((QUALITY and ADJUSTED) and SURVIVAL) #14 (((QUALITY and ADJUSTED) and LIFE) and YEARS) #15 (((((#9 or #10) or #11) or #12) or #13) or #14) #16 (#8 and #15)

The Cochrane Colorectal Cancer Group's specialised register:

#1well-being OR "quality of life" OR "mental health" OR "health status" OR "quality adjusted survival" OR "quality adjusted life years"#2"colorectal neoplasms" OR "colorectal cancer" OR "colorectal carcinoma" OR "rectal cancer" OR "rectal carcinoma"#1 AND #2

#### EMBASE:

#1 colorectal,#2 neoplasms,#3 colorectal neoplasms,#4 colorect\*,#5 neoplasms, #6colorect\* neoplasms,#7 colorectal,#8 neoplasm\*, #9colorectal neoplasm\*,#10colorect\*, #11neoplasm\*, #12colorect\* neoplasm\*,#13colorectal,#14cancer#15colorectal cancer, #16colorect\*, #17cancer,#18colorect\* cancer,#19colorectal,#20canc\*,#21colorectal canc\*,#22colorect\*,#23canc\*,#24colorect\* canc\*, #25colorectal,#26tumour,#27colorectal tumour, #28colorect\*, #29tumour,#30colorect\* tumour,#31rectal,#32neoplasms,#33rectal neoplasms,#34rect\*,#35neoplasms,#36rect\* neoplasms, #37rectal, #38neoplasm\*,#39rectal neoplasm\*,#40rect\*,#41neoplasm\*,#42rect\* neoplasm\*,#43rectal,#44cancer,#45rectal cancer,#46rect\*,#47cancer, #48rect\* cancer,#49rectal,#50canc\*,#51rectal canc\*,#52rect\*, #53canc\*,#54rect\* canc\*,#55rectal,#56tumour,#57rectal tumour, #58rect\*,#59tumour,#60rect\* tumour,#61quality, #62of, #63life, #64quality of life,#65qualit\*,#66of,#67life,#68qualit\* of life, #69quality,#70adjusted,#71life,#72years,#73quality adjusted life years,#74qualit\*,#75adjusted,#76life,#77years, #78qualit\* adjusted life years, #79quality, #80adjusted, #81life, #82year\*, #83quality adjusted life year\*, #84health, #85status, #86health status, #87mental, #88health, #89mental health, #90wellbeing, #91quality, #92adjusted, #93survival, #94quality adjusted survival. (#3 or #6 or #9 or #12 or #15 or #18 or #21 or #24 or #27 or #30 or #33 or #36 or #39 or #42 or #45 or #48 or #51 or #54 or #57 or #60) and (#64 or #68 or #73 or #78 or #83 or #86 or #89 or #90 or #94)

#### LILACS:

Quality of life combined with colorectal cancer/colorectal neoplasms/rectal cancer/rectal neoplasms.

## Data collection and analysis

One of the reviewers (JP) checked the titles and abstracts identified from the databases and hand search. Full text copies of all studies of possible relevance were obtained. The reviewer decided which studies meet the inclusion criteria.

Both reviewers independently extracted data, using a data collecting form. If information was insufficient the author was being contacted by e-mail to obtain further data.

Extracted data were cross-checked and discrepancies resolved by consensus.

The following data were extracted: quality of life measures, study design, level of evidence, methods of HRQoL analysis and results, inclusion criteria, questionnaire used, number of patients, age, gender, tumour grade (Dukes and/or TNM staging criteria), tumour distance from anal verge, level of anastomosis, formation of pouch, preservation of autonomic nerves, time since surgery, adjuvant treatment (chemo and/or radiotherapy).

Pooling of data, i.e. meta-analysis, was considered only to be appropriate for subjective outcomes, if there were sufficient studies that used comparable outcomes measures, i.e. questionnaires, and the studies were considered homogeneous. Comparisons between generic and disease-specific questionnaires and between different generic or disease-specific questionnaires were not performed.

Subgroup analysis (straight coloanal anastomosis/pouch anal anastomosis versus APE/Hartmann's operation) or level of anastomosis (upper/middle/lower third of rectum versus APE/Hartmann's operation) was only performed if sufficient data were available.

## RESULTS

### Description of studies

#### Results of the search

The search identified sixty-nine potential studies.

#### Included studies

Thirty-five of these, including 5127 participants (range 23 to 491) meet the inclusion criteria (Allal 2000;Allal 2005; Arndt 2006; Bloemen 2009;Camilleri-Brennan 2002;Celasin 2011; Campos-Lobato 2011; Engel 2003; Fischer 2011; Fucini 2008; Gosselink 2005; Grumann 2001; Grundmann 1989; Guren 2005; Hamashima 2002; Harisi 2004; Jess 2002; Kasperek 2011; Krouse 2009; Kuzu 2002; Marquis 1992; Peng 2011; Perez Lara 2004; Pucciarelli 2008; Rauch 2004; Ross 2007;Schmidt 2005; Schmidt 2010; Sideris 2005; Smith-Gagen 2009;Thong 2010; Varpe 2011; Vironen 2006; Yau 2009; Yoo 2005).

None of the studies were randomised; twenty were retrospective (Allal 2000; Bloemen 2009; Camilleri-Brennan 2002; Fischer 2011 Fucini 2008; Gosselink 2005; Grundmann 1989; Guren 2005; Hamashima 2002; Harisi 2004; Jess 2002; Kasperek 2011; Krouse 2009; Kuzu 2002; Marquis 1992; Pucciarelli 2008; Rauch 2004; Sideris 2005; Thong 2010 Vironen 2006), and fifteen prospective (Allal 2005; Arndt 2006; Campos-Lobato 2011; Celasin 2011; Engel 2003; Grumann 2001; Peng 2011; Perez Lara 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Smith-Gagen 2009; Varpe 2011; Yau 2009; Yoo 2005). Thirty-two of the studies were cohort studies (Allal 2000; Allal 2005; Arndt 2006; Bloemen 2009; Campos-Lobato 2011; Celasin 2011; Engel 2003; Fischer 2011; Fucini 2008; Gosselink 2005; Grumann 2001; Grundmann 1989; Guren 2005; Hamashima 2002;

Harisi 2004; Jess 2002; Kasperek 2011; Kuzu 2002; Marquis 1992; Perez Lara 2004; Pucciarelli 2008; Rauch 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Sideris 2005; Smith-Gagen 2009; Thong 2010; Varpe 2011; Vironen 2006; Yau 2009; Yoo 2005), eleven of these longitudinal (Allal 2005; Arndt 2006; Campos-Lobato 2011; Celasin 2011; Grumann 2001; Ross 2007; Schmidt 2005; Smith-Gagen 2009; Varpe 2011; Yau 2009; Yoo 2005), and the rest cross-sectional. Two studies were cross-sectional case-control studies (Camilleri-Brennan 2002; Krouse 2009).

Twenty-four studies identified their patients through hospital records (Allal 2000; Arndt 2006; Bloemen 2009; Camilleri-Brennan 2002; Campos-Lobato 2011; Celasin 2011; Fischer 2011; Gosselink 2005; Grumann 2001; Jess 2002; Kasperek 2011; Kuzu 2002; Marquis 1992; Peng 2011; Perez Lara 2004; Pucciarelli 2008; Rauch 2004; Schmidt 2005; Schmidt 2010; Sideris 2005; Varpe 2011; Vironen 2006; Yau 2009; Yoo 2005), four recruited patients from the outpatient clinic (Fucini 2008; Grundmann 1989; Harisi 2004; Krouse 2009), five identified the patients through the regional Cancer Registry (Engel 2003; Guren 2005; Hamashima 2002; Smith-Gagen 2009; Thong 2010), one study recruited patients from another Phase I-II trial (Allal 2005), one study recruited from a randomised psychosocial intervention study on cancer patients (Ross 2007).

twenty-three studies assessed the quality of life using disease specific questionnaires ("European Organization for the Research and Treatment of cancer (EORTC) QLQ-C 30, QLQ-CR 38, FACT-C, QLI-CP or CRC\_QoL (Allal 2000; Allal 2005; Arndt 2006; Bloemen 2009; Engel 2003; Fischer 2011; Fucini 2008; Gosselink 2005; Grumann 2001; Guren 2005; Harisi 2004; Kasperek 2011; Marquis 1992; Peng 2011; Pucciarelli 2008; Rauch 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Sideris 2005; Smith-Gagen 2009; Yau 2009; Yoo 2005)). Seven studies used generic questionnaires (SF-36 (Campos-Lobato 2011; Celasin 2011; Kuzu 2002; Varpe 2011; Vironen 2006), EuroQol (Hamashima 2002), Grogogno Health Index, QLI (Spitzer's) (Grundmann 1989)). Five studies used generic as well as disease-specific questionnaires (EORTC QLQ-C 30/CR 38 and Medical Outcomes Study Short-Form 36 (SF-36) version 2 (Camilleri-Brennan 2002), SF-36 and Fecal Incontinence Quality of Life Scale (FIQL) (Jess 2002), modified City of Hope Quality of Life-Ostomy questionnaire (mCOH-QoL-Ostomy) and SF-36v2 (Krouse 2009), EORTC QLQ-CR38 and Nottingham Health Profile (Perez Lara 2004), EORTC QLQ-CR38 and SF 36 (Thong 2010)).

Two studies did not report the age of the patients (Allal 2000; Thong 2010), but one of the studies stated it to be similar in the two groups (.Allal 2000). One study did not report the specific age, but reported that significantly more APE patients were more than 70 years of age (Engel 2003). Nine studies did not report the grade of the rectal tumour (neither Dukes nor TNM) (Allal 2000; Arndt 2006; Camilleri-Brennan 2002; Krouse 2009; Marquis 1992; Pucciarelli 2008; Sideris 2005; Thong 2010; Varpe 2011); twenty-three studies did not report the distance from the anal verge to the tumour (Allal 2005; Arndt 2006; Bloemen 2009; Camilleri-Brennan 2002; Celasin 2011; Engel 2003; Gosselink 2005; Grumann 2001; Grundmann 1989; Guren 2005; Harisi 2004; Kasperek 2011; Krouse 2009; Kuzu 2002; Marquis 1992; Perez Lara 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Sideris 2005; Thong 2010; Yau 2009; Yoo 2005), twenty-nine studies did not report the exact height of the anastomosis in AR patients (Allal 2000; Allal 2005; Arndt 2006; Bloemen 2009; Camilleri-Brennan 2002; Campos-Lobato 2011; Engel 2003; Fucini 2008; Gosselink 2005; Grundmann 1989; Hamashima 2002; Harisi 2004; Jess 2002; Krouse 2009; Marquis 1992; Peng 2011; Perez

Lara 2004; Pucciarelli 2008; Rauch 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Sideris 2005; Smith-Gagen 2009; Thong 2010; Varpe 2011; Vironen 2006; Yau 2009; Yoo 2005); three studies did not report the time from surgery to quality of life assessment (Allal 2000; Perez Lara 2004; Schmidt 2005). Eleven studies reported whether a pouch was created after AR (Allal 2005; Bloemen 2009; Fischer 2011; Fucini 2008; Gosselink 2005; Guren 2005; Harisi 2004; Jess 2002; Schmidt 2005; Schmidt 2010; Vironen 2006). Six studies did not report the frequency of radiotherapy (Camilleri-Brennan 2002; Grundmann 1989; Hamashima 2002; Kuzu 2002; Marquis 1992; Varpe 2011) and seven did not report the frequency of chemotherapy (Allal 2000; Camilleri-Brennan 2002; Grundmann 1989; Guren 2005; Kuzu 2002; Marquis 1992; Varpe 2011).

### Excluded studies

Forty-three studies were excluded for various reasons.

Twelve studies were excluded for using questionnaires that were not validated (Bossema 2011; Del Frari 2002; Küchenhoff 1981; La Monica 1985; MacDonald 1984; MacDonald 1985; Pählman 1987; Rudinskaitė 2003; Schaub 1996; Schwemmler 1989; Williams 1983; Wirsching 1975). Eight studies yielded insufficient information to be included in the review (Bruheim 2010; Koller 1994; Kopp 2000; Schmidt 1999; Schmidt 2002; Sentovic 1997; Szczepkowski 2002; Zieren 1996). One study was excluded for using a questionnaire that was not validated and for being a duplicate publication (Frigell 1990). Four studies for being duplicate publications (Arndt 2004; Hoppe de Mamani 2004; Schmidt 2005a; Schmidt 2005b)); five for comparing patients with rectal respectively colonic cancer (Hornbrook 2011; Michelone 2004; Rinaldis 2012; Wilson 2006; Wilson 2006a). One study was excluded because comparison was made between AR and stoma patients with either ileostomy or colostomy (Hoerske 2010). One study was excluded because some of the non-stoma patients were not operated (Gray 2011) One study was excluded because stoma was created as a consequence of anastomotic leakage, and not at the primary operation (Hassan 2006). Finally one was excluded for comparing with perineal colostomy (Pocard 2006).

### Risk of bias in included studies

As non-randomised studies were included in the review the usual criteria for assessing the quality of the included studies could not be used.

Instead the studies were assessed according to the guidelines for "Levels of Evidence and Grades of Recommendation" supplied by the "Oxford-Centre for Evidence-based Medicine" ([www.cebm.net/index.aspx?o=1025](http://www.cebm.net/index.aspx?o=1025)) The reviewers assessed each study independently. Discrepancies were resolved by consensus.

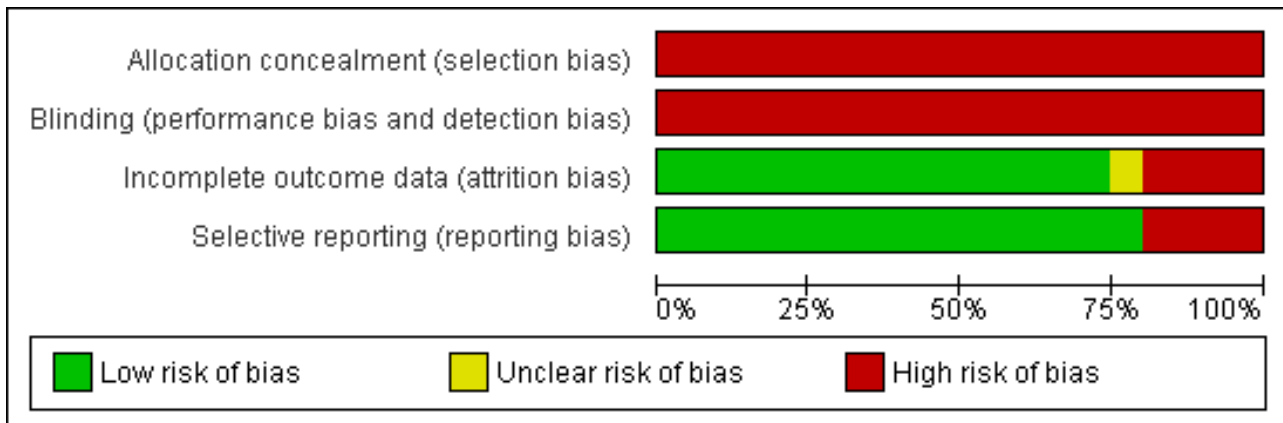
Methods of HRQoL analysis and results are reported according to the suggestions by Efficace et al (Efficace 2004).

Further we have assessed bias for the individual studies according to the guidelines given in the Handbook (see risk of bias tables, figure 1 and below).

### Allocation

All studies possess high risk of selection bias. As mentioned earlier randomisation between APE and AR is not possible, and as a consequence most of the studies included are cohort studies. Figure 1

**Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**



**Blinding**

Blinding as to which kind of surgery the patient had is not possible. [Figure 1](#)

**Incomplete outcome data**

In most studies risk of bias due to incomplete outcome data was deemed low. However seven studies ([Arndt 2006](#); [Campos-Lobato 2011](#); [Engel 2003](#); [Grumann 2001](#); [Ross 2007](#); [Schmidt 2010](#); [Smith-Gagen 2009](#)) did not supply data for all included patients for various reasons. In two studies ([Schmidt 2005](#); [Yoo 2005](#)) it was not possible to assess the issue ([Figure 1](#)).

**Selective reporting**

Six studies did not present all data ([Arndt 2006](#); [Pucciarelli 2008](#); [Ross 2007](#); [Schmidt 2005](#); [Schmidt 2010](#); [Yoo 2005](#)). Instead data were presented in the text and mostly if significant difference was found. One study only presented overall QoL scores ([Campos-Lobato 2011](#)). [Figure 1](#)

**Other potential sources of bias**

A further source of bias is the fact that patients having a stoma may need medical support due to the stoma. In general one could argue that this support may enhance the QoL in stoma patients compared to non-stoma patients not having the same amount of care. On the other hand, depending on the medical system and the public culture in the patients environment, having a stoma may possess financial and social problems not seen in non-stoma patients.

**Effects of interventions**

**Methodological quality.**

According to the chosen method of assessing the quality of the studies, thirty-three of the studies were grade 2b (cohort studies) ([Allal 2000](#); [Allal 2005](#); [Arndt 2006](#); [Bloemen 2009](#); [Campos-Lobato 2011](#); [Celasin 2011](#); [Engel 2003](#); [Fischer 2011](#); [Fucini 2008](#); [Gosselink 2005](#); [Grumann 2001](#); [Grundmann 1989](#); [Guren 2005](#); [Hamashima 2002](#); [Harisi 2004](#); [Jess 2002](#); [Kasperek 2011](#); [Kuzu 2002](#); [Marquis 1992](#); [Peng 2011](#); [Perez Lara 2004](#); [Pucciarelli 2008](#); [Rauch 2004](#); [Ross 2007](#); [Schmidt 2005](#); [Schmidt 2010](#); [Sideris 2005](#); [Smith-Gagen 2009](#); [Thong 2010](#); [Varpe 2011](#); [Vironen 2006](#); [Yau 2009](#); [Yoo 2005](#)) and two were 3b (case-control study) ([Camilleri-Brennan 2002](#); [Krouse 2009](#)).

**Methods of HRQoL analysis and results:**

All studies applied test of statistical significance and presented the results. Three of the studies partly explored missing data ([Arndt 2006](#); [Guren 2005](#); [Kasperek 2011](#)), none of the other studies explored missing data; six studies to some degree documented missing data ([Allal 2005](#); [Arndt 2006](#); [Engel 2003](#); [Guren 2005](#); [Kasperek 2011](#); [Rauch 2004](#)); Seven of the studies addressed whether the observed difference was expected to be clinically significant whether statistically so or not ([Arndt 2006](#); [Campos-Lobato 2011](#); [Guren 2005](#); [Kasperek 2011](#); [Krouse 2009](#); [Smith-Gagen 2009](#); [Thong 2010](#)). Twenty-two studies reported some difference between treatment arms ([Bloemen 2009](#); [Camilleri-Brennan 2002](#); [Engel 2003](#); [Fischer 2011](#); [Fucini 2008](#); [Gosselink 2005](#); [Grundmann 1989](#); [Guren 2005](#); [Kasperek 2011](#); [Krouse 2009](#); [Kuzu 2002](#); [Marquis 1992](#); [Peng 2011](#); [Perez Lara 2004](#); [Pucciarelli 2008](#); [Ross 2007](#); [Schmidt 2005](#); [Schmidt 2010](#); [Sideris 2005](#); [Thong 2010](#); [Varpe 2011](#); [Yau 2009](#)) and thirteen did not ([Allal 2000](#); [Allal 2005](#); [Arndt 2006](#); [Campos-Lobato 2011](#); [Celasin 2011](#); [Grumann 2001](#); [Hamashima 2002](#); [Harisi 2004](#); [Jess 2002](#); [Rauch 2004](#); [Smith-Gagen 2009](#); [Yoo 2005](#)). [Table 1](#)

**Quality of life.**

Overall fourteen studies found that patients undergoing APE/Hartmann's operation did not have poorer QoL than patients undergoing AR ([Allal 2000](#); [Allal 2005](#); [Arndt 2006](#); [Camilleri-Brennan 2002](#); [Campos-Lobato 2011](#); [Celasin 2011](#); [Grumann 2001](#); [Hamashima 2002](#); [Harisi 2004](#); [Rauch 2004](#); [Smith-Gagen 2009](#); [Varpe 2011](#); [Vironen 2006](#); [Yoo 2005](#)). Three studies found that a stoma only to some extent affected the patients QoL ([Jess 2002](#); [Pucciarelli 2008](#); [Yau 2009](#)). Twelve studies found that patients after APE/Hartmann's operation had significantly poorer QoL than after AR in one or more sub-scales ([Engel 2003](#); [Fucini 2008](#); [Gosselink 2005](#); [Grundmann 1989](#); [Krouse 2009](#); [Kuzu 2002](#); [Marquis 1992](#); [Peng 2011](#); [Ross 2007](#); [Schmidt 2005](#); [Sideris 2005](#); [Thong 2010](#); ), while five studies found that AR patients scored significantly better in some sub-scales, APE/Hartmann's operation in others ([Bloemen 2009](#); [Guren 2005](#); [Kasperek 2011](#); [Perez Lara 2004](#); [Schmidt 2010](#)). One study found that patients undergoing APE/Hartmann's operation had better QoL ([Fischer 2011](#)).

Allal et al ([Allal 2000](#)) used a disease specific questionnaire (EORTC QLQ-C 30/CR 38) and found no significant difference between APE and AR in any sub-scale. AR patients tended to score



poorer in constipation, physical function, global QoL and future perspective; and better in sleep disturbances, body image and sexual dysfunction of males; although none of the differences were significant.

Symptom scores related to anorectal function in AR patients were comparable to symptom score in stoma-related problems. None of the females responded to the items concerning sexual dysfunction.

Another study from Allal et al (Allal 2005) using EORTC QLQ-C 30/CR 38 in a group of patients recruited from a Phase I-II trial studying preoperative radiotherapy, failed to show statistically significant differences between AR and APE. Comparing colorectal with coloanal anastomosis they found significant better results for role and emotional function, fatigue and sleep disturbance for patients with colorectal anastomosis.

Arndt et al (Arndt 2006) used EORTC QLQ-C 30/CR 38 and found that after twelve month AR scored better on role function, but the difference disappeared after 36 month as the scores in the APE group improved, whereas the AR group remained stable throughout the study.

Bloemen et al. (Bloemen 2009) explored the influence of severe postoperative complications and/or stoma formation on patients QoL using EORTC QLQ-C 30/CR 38. In patients having stoma, they found that AR scored better on global health status, future perspective and weight loss, while APE/Hartman scored better on diarrhoea and gastrointestinal problems. The stoma group however included as well patients whose stoma initially was intended as being temporary as APE/Hartman.

In evaluating QoL in patients with severe postoperative complications they found that patients who suffered high-grade complications scored significantly poorer in social functioning, fatigue, pain and weight loss.

Camilleri-Brennan et al (Camilleri-Brennan 2002) used a generic (SF-36) as well as a disease-specific questionnaire (EORTC QLQ-C 30/CR 38), and found no significant difference except for two dimensions. AR patients had significantly more problems with constipation but better perception of body image than APE patients.

Using SF-36 there was a slight tendency toward better scores for AR in physical functioning, role limitations because of physical problems, energy and vitality, body pain and general health perception although not statistically significant.

Using EORTC QLQ-C 30/CR 38 AR patients tended to score better in role and emotional function, pain and male sexual problems; APE patients tended to score better in cognitive function, none of the differences were statistically significant different.

Campos-Lobato et al (Campos-Lobato 2011) compared low rectal cancer patients (tumour located < 6 cm from anal verge) using a generic (SF-36) questionnaire and found no difference between treatment arms. Patients were assessed pre- and postoperatively. Unfortunately not all patients attended all follow-up. The study addressed clinically as well as statistically relevant difference, and found no difference doing so.

Celasin et al (Celasin 2011) used a generic (SF-36) as well as a modified version of ASCRS Fecal Incontinence Questionnaire (A-FIQ), in a group of Muslim rectal cancer patients receiving surgical treatment combined with ostomy education and religious

education and counselling. No difference was found using SF-36 whereas AR patients scored better in the domain "Embarrassment" in A-FIQ. The study also compared low vs. high AR resection and found similar results.

Engel et al (Engel 2003) used a disease specific questionnaire (EORTC QLQ-C 30/CR 38). They recruited the patients via the Munich Cancer Registry. All patients so identified were invited to participate and the data were collected prospectively. Initially 1038 patients were identified, informed consent to participate was received from 443 patients and 329 patients were included. However only 48 patients completed all questionnaires. Data analysis was made on cross-sectional cohorts. No preoperative data were available. Over the 4 years the stoma patients (APE and AR patients with stoma) scored significantly worse on role-physical-social-cognitive-sexual function as well as micturition and male sexual problems, body image and global QoL. They scored better on constipation.

Fischer et al (Fischer 2011) used a disease specific questionnaire (EORTC QLQ-C 30/CR 38) in their comparison of ultra low AR and APE/Hartman. Except the item diarrhoea where APE/Hartman scores significantly better, no difference was found between groups. They further investigated patients having secondary permanent stoma, and found that this group of patients had significantly poorer QoL in several domains.

Fucini et al. (Fucini 2008) studied a group of patients all having low rectal cancers (tumour located less than 5 cm from anal verge) using EORTC QLQ-C 30/CR 38. Patients in the non-stoma group all had some or their entire anal sphincter excised. In the latter cases dynamic graciloplasty was performed. Despite the extensive operations the AR group after 5 years scored significantly better in sexual, physical and role functioning, global QoL, fatigue, dyspnoea, appetite loss and body image perception.

Gosselink et al (Gosselink 2005) used EORTC QLQ-C 30/CR 38 and the EuroQol EQ-5D and compared stoma patients with AR patients having either colorectal/anal (LRA) or J-pouch anal anastomosis. The pouch group was significantly younger than the other groups, and consistently scored better than the general population in EQ-VAS and EQ-5D index score. APE patients scored poorer on body image perception than both LRA and pouch patients; both APE and LRA patients scored poorer on global QoL score and sexual dysfunction male.

Grumann et al (Grumann 2001) using a disease specific questionnaire (EORTC QLQ-C 30/CR 38), found that on most scales APE patients had superior, although not significantly better, scores than the AR patients. Exceptions were for constipation and diarrhoea where APE patients had significantly better scores than AR patients.

Several sub-scales had more than 50% missing items and were therefore excluded from the analysis (nausea/vomiting, pain, dyspnoea, appetite loss, financial problems, sexual functioning, sexual enjoyment, sexual dysfunction in male and female, weight loss).

Over time both groups showed a decrease in scores in role function and body image, whereas there was an increase in scores in emotional well-being and future perspective across time.

In a subgroup analysis Grumann et al (Grumann 2001) evaluated whether the level of anastomosis affected the AR patients' assessment of their postoperative QoL. The AR group was divided

into those with anastomosis up to 5 cm from the ano-cutaneous line and those with higher levels of anastomosis. The analysis involved 15 patients with low (LAR) and 35 patients with high AR (HAR). Multiple analyses showed a main effect of the factor group for the variables role function, social function, global QoL, body image, future perspective, gastrointestinal symptoms and defecation-related symptoms, as LAR scored significantly poorer than HAR patients. No comparison was made between HAR/LAR and APE.

Grundmann et al (Grundmann 1989) used two different generic questionnaires (QLI (Spitzer's) and Grogono Health Index). Using QLI and Grogono Health Index they found that AR patients had significantly better QoL than APE patients; however no significant difference was found in QLI in women, indicating that the QoL in men was more affected than in women when using these questionnaires.

Guren et al (Guren 2005) used EORTC QLQ-C 30/CR 38 in multicenter study and found that APE scored poorer on sexual dysfunction male and body image perception. AR scored poorer on constipation and diarrhoea. Patients in the APE group were older, and more of them received preoperative radiotherapy. Comparing the QoL in patients with anastomosis at different levels, they found no difference. Comparing patients to the general population clinically relevant difference (> 10) was found only considering constipation and diarrhoea in APE patients.

Hamashima (Hamashima 2002) used a generic questionnaire (EuroQol) and found that although APE patients tended to have a higher prevalence of moderate and severe problems and prevalence of any problem in all of the five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression) and overall, this difference was not statistically significant.

Harisi et al (Harisi 2004) used CRC\_QoL, a questionnaire developed and validated by the authors. They found statistically significant differences at several sub-scales (activity around the house, activity resting hour, fatigable, concentration, meteorismus, nervousness, future fear, death fear and supporting environment) as the AR patients scored poorer than the APE patients. In the overall cumulative scorer statistical significant difference was only found in the functional status.

Jess et al (Jess 2002) used a generic questionnaire (SF-36) and found that APE patients tended to score poorer than AR patients in all aspects except mental health; however the difference was not statistically significant.

An additional comparison was made to the SF-36 score of the Danish normal population (DNP). Interestingly, the APE patients tended to score better than DNP in the scales for role physical, general health, social function, role emotional and mental health. The AR patients scored better than DNP in all scales.

Using a disease-specific questionnaire (FIQL) they found that APE patients tended to score poorer than AR patients except for the sub-scale of coping. Statistically significant difference was found in the total score of FIQL.

Kasperek et al (Kasperek 2011) used a disease specific questionnaire (EORTC QLQ-C 30/CR 38) in their cohort study of rectal cancer patients comparing AR in the form of coloanal anastomosis and APE/Hartman. They found significant differences in several items, as AR patients scorer better in physical functioning, fatigue, pain, financial problems, weight loss, chemotherapy

side effects, and body image men. On the other hand patients after APE/Hartman scored significantly better in constipation, gastrointestinal symptoms and sexual functioning. Applying clinically significant difference most of the differences would disappear.

Krouse et al (Krouse 2009) in their case control study examined rectal cancer survivors with 5 year follow-up using a disease specific (modified City of Hope Quality of Life Ostomyspecific questionnaire (mCOP-QoL-Ostomy)) and a generic (SF-36v2) questionnaire. They hypothesized that there would be differences between sexes, and analysis was therefore made for males and females separately. Further in advance they defined minimally important difference (MID) for both questionnaires.

In men no difference was found, neither statistically nor in MID, using SF-36v2; using mCOP-QoL-Ostomy difference in favour of AR was found only in the social domain, whether comparing statistically or MID.

In women using SF-36v2 AR scored better as well judged statistically as in MID on the domains role physical and emotional, general and mental health and on the summary mental dimension. Not statistically significant but exceeding MID were the domains energy and vitality, physical and social function and the summary physical dimension.

In mCOP-QoL-Ostomy AR scored significantly better and exceeded MID in the domains psychological and social.

Kuzu et al (Kuzu 2002) used the same generic questionnaire as Jess et al (Jess 2002) and Camilleri-Brennan (Camilleri-Brennan 2002) (SF-36). They found that APE patients scored significantly poorer in all aspects than as well patients who had LAR (anastomosis within 8 cm of the anal verge) or HAR (anastomosis higher than 8 cm from the anal verge including the sigmoid colon). Additionally, they found that people with LAR tended to score poorer than those with HAR in all aspects; this was statistically significant only in mental health and vitality.

Marquis et al. (Marquis 1992) found overall that AR participants had better QoL, except for the sub-scales for psychological well-being and social function. This, however, was only found in women as no statistically significant difference was found in men for the overall QoL or sub-scales for physical well-being and surgical response. For the sub-scales body image and nutritional response statistically significant differences was found in men as well as women favouring AR.

Peng et al (Peng 2011) used EORTC QLQ-C 30/CR 29 in their study of Chinese rectal cancer patients comparing QoL among different treatment modalities and between AR-APE/Hartman. They found that AR scored significantly better in body image and embarrassment by bowel movements, while APE/Hartman patients had fewer defecation problems. Additionally the study found that the frequency of diarrhoea and incontinence was significantly higher after radiation therapy.

Perez Lara et al (Perez Lara 2004) used the generic questionnaire Nottingham Health Profile and the disease specific EORTC QLQ CR-38. In both questionnaires women scored poorer than men, although not statistically significant. The AR group scored poorer in the dimensions energy, pain, emotional response and over-all score in the Nottingham Health Profile, while APE patients scored poorer in male sexual problems in EORTC QLQ CR-38 only.

Pucciarelli et al (Pucciarelli 2008) used EORTC QLQ-C 30/CR 38 to assess QoL in an Italian population. Their stoma group was small (10 patients) compared to the AR (107). Statistical analysis must therefore be regarded with caution. The only statistical difference in favour of AR was in body image. They also compared patient QoL scores with general population data (German) finding no statistical difference. Defining a difference of 10 points as clinically relevant, a difference in favour of rectal cancer patients (stoma and non-stoma) was found in the domains global QoL and pain.

Rauch et al (Rauch 2004) used a disease specific questionnaire (EORTC QLQ-C 30/CR 38). They found statistically significant differences in the sub-scales constipation and gastrointestinal tract problems, as AR patients scored poorer on both sub-scales.

The study also compared scores of EORTC QLQ-30 between patients and two samples of general populations from Norway and Germany. Surprisingly the patients had QoL scores similar or better than the general population samples.

Proportion of missing data were EORTC QLQ-30: 2,3% EORTC QLQ-38: 9,1%. Most missing information concerned very old patients and sexuality items.

Ross et al (Ross 2007) recruited patients from a randomised psychosocial intervention study of the effects of home visits by a healthcare professional on the QoL of colorectal cancer patients. Assessment was made using EORTC QLQ-C 30/CR 38 and the Hospital anxiety and Depression Scale (HADS). Their entire population consisted of patients treated for as well colonic as rectal cancer and in this population stoma patients scored poorer on HADS as well as the sub-scales social function, body image perception, future perspective, micturition problems and male sexual problems. If rectal cancer patients alone was evaluated no difference was found in HADS, AR scored poorer on constipation and APE on body image perception.

In their ten year historic cohort comparing rectal cancer patients having either APE or AR with or without pouch, Schmidt et al (Schmidt 2005) using EORTC QLQ-C 30/CR 38 found that AR patients scored significantly better on sexual sub-scales, whereas pouch patients had significantly more problems with diarrhoea. Overall rectal cancer patients having adjuvant treatment had more impaired QoL than patients not having adjuvant treatment.

In an other study from 2010 Schmidt et al (Schmidt 2010) using EORTC QLQ-C 30 and a supplementary colorectal module similar results were found, as AR scored better in sexual function whereas they had poorer outcome in diarrhoea.

Sideris et al (Sideris 2005) used EORTC QLQ-C 30/CR 38 to assess QoL and supplemented it with the short version of Beck's depression Inventory and the State-Trait Anxiety Inventory (STAI) to perform a psychological evaluation of the patients. The psychological evaluation yielded no difference between APE and AR patients. On EORTC QLQ-C 30/CR 38 APE patients scored better on gastrointestinal symptoms and poorer on body image perception and financial problems.

Smith-Gagen et al (Smith-Gagen 2009) used FACT-T to assess whether QoL differed by tumour location, type of surgery (AR vs. APE) and receipt of adjuvant therapy. They found no significant effect of surgery type or location on any sub-scale. Nor did they find clinically relevant difference in scores in any dimension.

Patients receiving adjuvant therapy had statistically lower scores in physical well-being.

Thong et al (Thong 2010) conducted a population-based study aimed to assess the impact of preoperative radiotherapy (pRT) on general and disease-specific health status of rectal cancer survivors up to 10 years post diagnosis. In a subgroup analysis they compared AR vs. APE (both having pRT) using a generic (SF-36) and a disease specific (EORTC QLQ-CR 38) questionnaire. They found that AR scored statistically significant better in the SF-36 domains general health, physical function and physical component summary (PCS) and EORTC QLQ-CR 38 domain sexual function. P-values were adjusted for variety of factors. None of the statistically significant differences were clinically relevant.

Comparing the entire group with stoma (primary as well as secondary) they found that AR scored statistically better in physical function, role limitation physical, role limitation emotional and PCS using SF-36. In EORTC QLQ-CR 38 APE had poorer scores in future perspective, sexual function and sexual enjoyment. However only in the domain sexual enjoyment the difference in scores were clinically relevant.

Varpe et al (Varpe 2011) conducted a prospective study using RAND (SF) 36 to assess the influence of rectal cancer surgery regarding general QoL. In general they found that QoL after 1 year was comparable to preoperative values except for mental function, which had improved. Comparing AR and APE no statistically significant difference was found. No influence of pRT was found.

Vironen et al (Vironen 2006) used the generic questionnaire SF-36v2 and found no difference between APE/Hartman and AR.

They further compared the study group with data from the general Finnish population. Overall they found that the QoL of rectal cancer patients did not differ greatly from that of the same aged general population, though older patients (65-79 years) scored significantly better than the general population on several domains (general health perception, physical functioning, mental health, energy and vitality, pain).

Yau et al (Yau 2009) assessed a group of rectal cancer patients receiving adjuvant chemotherapy using EORTC QLQ-C 30. Patients were assessed at baseline before start of chemotherapy (but after surgery), during chemotherapy and 1 and 3 years after completing chemotherapy.

At baseline no difference between the two groups were found except for constipation where stoma patients score significantly better than AR. One and 3 years after chemotherapy AR scored significantly better in social functioning, but no other differences were found.

Interestingly on subgroup analysis comparing patients after AR, patients with permanent stoma and patients with temporary stoma that had been reversed Yau et al (Yau 2009) found that patients who have had their stoma reversed, after 3 years scored as poor as APE/Hartman in social functioning and complained of more appetite loss.

Yoo et al (Yoo 2005) evaluated a cohort of Korean patients using FACT-C. Patients were evaluated 1 and 6 month post-surgery. One month after surgery stoma patients scored significantly poorer on several sub-scales of FACT-C; this difference disappeared 6 month post-surgery in all areas.

### Level of anastomosis.

Seven of the studies made distinctions between patients in respect to the height of the anastomosis or tumour (Celasin 2011; Engel 2003; Grumann 2001; Guren 2005; Kuzu 2002; Perez Lara 2004; Vironen 2006). Grumann et al (Grumann 2001) defined LAR as patients with an anastomosis within 5 cm from the anal verge. Kuzu et al (Kuzu 2002) defined LAR as patients with an anastomosis within 8 cm from the anal verge; HAR was for patients with an anastomosis above 8 cm from the anal verge, including the sigmoid colon. Celasin et al (Celasin 2011) in their study from the same department as Kuzu et al (Kuzu 2002) defined LAR as patients with anastomosis > 6 cm from the anal verge; AR was for patients with an anastomosis above 7 cm from the anal verge, including the sigmoid colon. Engel defined LAR as tumour location below 8 cm and HAR at 8 cm or above (Engel 2003). Perez Lara et al (Perez Lara 2004) compared QoL according to tumour site dividing rectum into the upper-middle- and lower third. Guren et al (Guren 2005) made distinctions according to the level of the anastomosis (<3, 4-6, 7-8cm from anal verge). Vironen et al (Vironen 2006) termed resection for tumours located >12 cm from the anal margin as HAR. Three studies differentiated between AR with and without pouch (Gosselink 2005; Schmidt 2005; Sideris 2005). In the statistical comparison, Grumann et al (Grumann 2001) and Guren et al (Guren 2005) compared APE to AR for patients without subgroup analysis while Kuzu et al (Kuzu 2002) and Celasin et al (Celasin 2011) made comparison between APE and LAR as well as HAR. Engel et al (Engel 2003) compared stoma patients (APE and AR patients with stoma) with AR. Perez Lara (Perez Lara 2004) compared APE, anterior resection and lower anterior resection. All six studies made subgroup analysis comparing different levels of anastomosis.

Eight studies reported the distance from the anal verge to the rectal tumour (Allal 2000; Camilleri-Brennan 2002; Campos-Lobato 2011; Jess 2002; Peng 2011; Smith-Gagen 2009; Varpe 2011; Vironen 2006). According to this information's the operation in the study by Jess et al (Jess 2002) could be classified as HAR, the operation by Allal et al (Allal 2000), Camilleri-Brennan et al (Camilleri-Brennan 2002), Fischer et al (Fischer 2011) and Kasparek et al (Kasparek 2011) as LAR.

The patients in the studies by Allal (Allal 2005), Arndt (Arndt 2006), Bloemen et al (Bloemen 2009), Campos-Lobato et al (Campos-Lobato 2011) Fucini et al (Fucini 2008), Grundmann et al (Grundmann 1989), Hamashima (Hamashima 2002), Krouse et al (Krouse 2009), Marquis et al. (Marquis 1992), Peng et al (Peng 2011), Pucciarelli et al (Pucciarelli 2008), Ross et al (Ross 2007), Schmidt et al (Schmidt 2005; Schmidt 2010), Smidt-Gagen et al (Smith-Gagen 2009), Thong et al (Thong 2010), Varpe et al (Varpe 2011), Yau et al (Yau 2009) and Yoo et al (Yoo 2005) could not be classified according to the height of the anastomosis.

Eight studies gave information on whether an autonomic nerve-sparing technique was used as they stated that the total mesorectal excision (TME) technique was used (Allal 2000; Allal 2005; Gosselink 2005; Guren 2005; Sideris 2005; Thong 2010; Varpe 2011; Vironen 2006). None of the remaining studies revealed this information. One must however assume that studies including patients operated within recent years have been operated using the TME technique.

## DISCUSSION

### Summary of main results

Traditionally, patient outcomes measures after cancer surgery have been for overall or cancer specific survival, complications, clinical health status, functional results and biochemical indices.

Throughout the past decades there has been increasing research in the field of quality of life, and many researchers now regard it as a key measurement in clinical trials (Anthony 2003; Koller 2002).

Surprisingly, there is no consensus as to the definition of this measure. WHO defines QoL as: "An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment". (<http://www.who.int/msa/qol/ql1.htm>).

Koller et al (Koller 1996) define QoL as: "an individuals sense of well being in the somatic, emotional and social domains".

An other description is found on Wikipedia: "Quality of life (QOL) is used in healthcare to refer to an individual's emotional, social and physical well being, including their ability to function in the ordinary tasks of living"

([www.en.wikipedia.org/wiki/Quality\\_of\\_life\\_\(healthcare\)](http://www.en.wikipedia.org/wiki/Quality_of_life_(healthcare))).

The results of this review challenge the assumption, that APE/Hartmann's operation with its subsequent formation of a permanent colostomy severely impairs patients QoL.

Fourteen of the included studies found no significant difference between APE and AR (Allal 2000; Allal 2005; Arndt 2006; Camilleri-Brennan 2002; Campos-Lobato 2011; Celasin 2011; Grumann 2001; Hamashima 2002; Harisi 2004; Rauch 2004; Smith-Gagen 2009; Varpe 2011; Vironen 2006; Yoo 2005). Two studies found that a stoma only slightly affected the patients QoL (Jess 2002; Pucciarelli 2008). In four of the studies using generic questionnaires AR patients tended to score better in more aspects than APE/Hartmann's operation patients (Camilleri-Brennan 2002; Hamashima 2002; Jess 2002; Thong 2010), in one study (Perez Lara 2004) AR patients scored poorer in several sub-scales, in three studies no difference was found (Campos-Lobato 2011; Celasin 2011; Varpe 2011) while in one study (Krouse 2009) no difference was found in men while women scored poorer after APE/Hartmann's operation in almost all aspects when analysing either statistically or considering MID. The tendencies in studies failing to show significant differences and using disease-specific questionnaires were more heterogeneous. The fact that the patients receiving APE in the study by Jess et al (Jess 2002) actually tended to score better than the Danish normal population and that no difference was found between the study group and Finnish general population in the study by Vironen et al (Vironen 2006) indicates that when using a generic questionnaire one may not capture relevant differences between AR and APE for patients related to the different operations. On the other hand, Arndt et al (Arndt 2006), Guren et al (Guren 2005), Pucciarelli et al (Pucciarelli 2008) and Rauch et al (Rauch 2004) using a disease specific questionnaire likewise found that patients scored similar or better than general population samples. All studies lack preoperative values for QoL.

These results as well as the fact that several studies surprisingly found that there were no statistically significant difference between the two groups, could be due to the so-called response shift,

meaning that "the experience of cancer" may induce a conscious awareness that leads to a positive appreciation of everyday life (Anthony 2003; Carr 2001; Padilla 1992; Rauch 2004).

Eighteen studies found that the formation of a stoma significantly affected the patients QoL in one or more sub-scales (Bloemen 2009; Engel 2003; Fucini 2008; Gosselink 2005; Grundmann 1989; Guren 2005; Kasperek 2011; Krouse 2009; Kuzu 2002; Marquis 1992; Peng 2011; Perez Lara 2004; Ross 2007; Schmidt 2005; Schmidt 2010; Sideris 2005; Yau 2009).

Interestingly, one of these studies (Kuzu 2002) used the same questionnaire, as was used in four of the studies where no differences between patients were found (Camilleri-Brennan 2002; Celasin 2011; Jess 2002; Vironen 2006). There are several possible reasons for this difference. The study by Kuzu et al (Kuzu 2002) contained many patients from a low social class, with low income level and poor education, and it is argued that patients in poor areas may have problems managing their stoma due to a lack of proper supportive care. Even in well-developed countries studies indicate that low income and problems paying for stoma supplies affect patients QoL (Coons 2007)

Secondly, one of the inclusion criteria in the study by Kuzu et al (Kuzu 2002) was Muslim faith. As pointed out by the authors, the presence of a stoma may influence the patients' worship, which may socially stigmatise them, impair their social life and cause psychological distress. Thirdly it is possible that cultural differences may also contribute to the differences as shown by Tchen et al (Tchen 2003) and Holzer et al (Holzer 2005).

The study by Celasin et al (Celasin 2011) is therefore very interesting. The inclusion criteria were the same as in the study by Kuzu et al (Kuzu 2002). Patients in the study by Celasin et al (Celasin 2011) however received stoma-education given by a stoma-therapist and religious education and counselling with the aid of an imam. As the QoL did not differ between stoma and non-stoma patients, these counselling's apparently helped the patients cope with the problems they encountered having a stoma.

The eight longitudinal studies by Arndt et al (Arndt 2006), Campos-Lobato et al (Campos-Lobato 2011), Celasin et al (Celasin 2011), Engel et al (Engel 2003), Ross et al (Ross 2007), Smidt-Gagen et al (Smith-Gagen 2009), Varpe et al (Varpe 2011) and Yau et al (Yau 2009) could have been key studies on the matter of QoL in rectal cancer patients. However only three of the studies had preoperative QoL data (Campos-Lobato 2011; Celasin 2011; Varpe 2011), and not all patients filled out all questionnaires except in the study by Celasin et al (Celasin 2011). Further Engel et al (Engel 2003) failed to have sufficient numbers of patients completing all questionnaires to be able to conduct a longitudinal study; instead the result are presented as cross-sectional study. Differences between the two groups were found in several areas and were not consistent throughout the study periods.

The study by Grundman et al (Grundmann 1989) is the oldest study included, and it used two different generic indices to assess a patient's QoL. No data were given about the height of the anastomosis in the AR group, but as the patients were assessed an average of 3,8 to 4,3 years after operation and the study was published in 1989, one might assume, that the resected patients had tumours located in the upper half of the rectum. As indicated by other studies in this review (Celasin 2011; Engel 2003; Grumann 2001; Kuzu 2002; Perez Lara 2004; Vironen 2006) this may affect the resulting QoL, as HAR patients tend to score better than LAR.

Grundman et al. (Grundmann 1989) found that women with a colostomy tended to score better than men. On the other hand, Marquis et al (Marquis 1992) found that men after APE revealed no significant difference in several sub-scales (overall QoL, physical well-being and surgical response). Marquis et al. (Marquis 1992) explained this by the fact that most men in the APE group were older and had retired from work; they did not have to consider being disabled by handling the colostomy at work or working at home. Furthermore, several of the men complaining of sexual dysfunction had done so preoperatively. Perez Lara et al (Perez Lara 2004) found that women treated for rectal cancer scored poorer than men in several aspects of the Nottingham Health profile; possible explanations according to the authors are that women have more health-related problems than men, that women have greater life expectancy and more physical problems than men. Sideris et al (Sideris 2005) found that women complained more of fatigue and appetite loss. Krouse et al (Krouse 2009) found significant differences between men and women whether using a generic or a disease-specific questionnaire. Using SF-36v2 and mCOH-QoL-Ostomy in men, no difference between stoma and non-stoma patients was found except for the social domain in mCOH-QoL-Ostomy. In the contrary women showed differences (statistically and MID) in most domains and sub-scales. According to the authors one possible explanation could be that "women engage in more coping behaviours and seek more social support than men, including emotional and spiritual activities". No gender difference was found by Schmidt et al (Schmidt 2005), although in an other study on rectal cancer patients without stoma Schmidt et al (Schmidt 2005d) found that women appear to be affected by impaired physical functioning and global health. Further in the latest study by Schmidt et al (Schmidt 2010) found that women rated their pre-and postoperative functional status significantly worse than men did. On the symptom scale women complained of fatigue and sleep disturbance.

Adjuvant treatment has become increasingly frequent using radio and/or chemotherapy. Six studies addressed this subject (Guren 2005; Peng 2011; Schmidt 2005; Smith-Gagen 2009; Thong 2010; Varpe 2011) and all found that adjuvant treatment affected the patients QoL negatively.

In the study by Yau et al (Yau 2009) a trend towards better QoL after completion of chemotherapy was seen, but the study was not designed in order to examine this issue. Bruheim et al (Bruheim 2010) in their study on radiotherapy found that RT+ patients had significantly poorer scores than RT- in a population with at least 2 years of follow-up. These findings may have impact on the results of the included studies, as the proportions of patients receiving adjuvant treatment differ between groups.

### Overall completeness and applicability of evidence

There are several problems when comparing the results of the different studies.

As expected, no randomised studies were identified. In order to randomise between two different treatments, the treatments have to be considered equal in terms of outcomes. However, APE/Hartmann's operation means, that the patient will have a colostomy for a lifetime, which generally will be considered as an unfavourable outcome, if it can be avoided. Most Ethics Committees will, therefore, consider it unethical to randomise patients between APE/Hartmann's operation and AR. Therefore, we decided to include cohort and case-control studies.

When comparing APE/Hartmann's operation and AR it would be desirable that the tumours were located in the same part of the rectum, e.g. the lower third of the rectum. Studies have shown that the functional results after HAR are better than after LAR (Camilleri-Brennan 2002; Wheeler 1999). This is paralleled by the results of Engel et al (Engel 2003), Grumann et al (Grumann 2001) and Perez Lara (Perez Lara 2004) who found that QoL was significantly better after HAR than after LAR.

Kuzu et al (Kuzu 2002) found that patients after HAR had significantly better scores in mental health and vitality compared with LAR.

Furthermore, the risks of complications after surgery are greater the more distally the tumour is situated (Camilleri-Brennan 1998; Wheeler 1999). And QoL could be affected by postoperative complications as shown by Bloemen et al (Bloemen 2009). As the tumours in patients having APE/Hartmann's operation are normally situated in the distal third of rectum, one would expect that their QoL would be lower than for patients having AR due to tumours located in the upper third of the rectum.

The studies included in this review have several shortcomings.

All studies except six (Allal 2005; Campos-Lobato 2011; Celasin 2011; Grumann 2001; Varpe 2011; Yau 2009) lack a baseline assessment of the patients' QoL; it is therefore not possible to determine whether the lacks of difference between the two groups were due to an apparently better QoL in the APE patients or a poorer QoL in the AR patients than expected. Furthermore, it was not possible to capture preoperative differences between the groups. In some of the studies participants in the APE/Hartmann's operation group tended to be older (Camilleri-Brennan 2002; Campos-Lobato 2011; Engel 2003; Gosselink 2005; Guren 2005; Jess 2002; Kuzu 2002) than in the AR group. One cannot rule out that the APE/Hartmann's operation group already had an impaired QoL preoperatively, especially for the functional sub-scales due to older age (Schmidt 2005c). Or that differences found throughout the study period may be subscribed to higher age.

Missing data may be a problem especially when dealing with cancer patients, as some may not survive long enough to be assessed. Furthermore, some patients may not answer all the questions. Some scoring manuals have therefore decided that if more than a certain number of the items are not answered, then that specific sub-scale is excluded. However, both the missing persons and the missing items may be some of the most informative data in a study. Consequently the lack of correction for missing data may cause an erroneous estimation of QoL (Anthony 2003; Efficace 2004; Kopp 2003; Moinpour 2000; Staquet 1996). Most of the studies in this review did not supply sufficient information on the missing data (Arndt 2006; Bloemen 2009; Camilleri-Brennan 2002; Campos-Lobato 2011; Celasin 2011; Fischer 2011; Fucini 2008; Grumann 2001; Gosselink 2005; Grundmann 1989; Harisi 2004; Krouse 2009; Kuzu 2002; Marquis 1992; Peng 2011; Perez Lara 2004; Pucciarelli 2008; Ross 2007; Schmidt 2005; Sideris 2005; Smith-Gagen 2009; Thong 2010; Varpe 2011; Vironen 2006; Yau 2009).

As pointed out by Carr et al (Carr 2001) "patients' perception of QoL varies between individuals making it a dynamic outcome when viewed over time". The results may therefore depend on the time elapsed since surgery. The cross-sectional studies have tried to overcome this problem by evaluating the patients at least one year after surgery. This time period is generally adopted due to the assumption, that QoL at that point of time is stable, a

statement supported by the findings by Camilleri-Brennan and Steele (Camilleri-Brennan 2001), Ramsey et al (Ramsey 2000) and Sailor et al (Sailor 2000). On the other hand the study by Engel et al (Engel 2003) found considerable differences at different time points. It does not change the overall results of the study, but it emphasizes the need for comparable time since surgery as well in groups as between studies.

In the included studies the median follow-up period varied considerably between the studies and between the groups (14 to 214 months), which may have influenced the results.

None of the studies reported on the social class of the patients. As pointed out by Burström et al (Burström 2000) Dapuetto et al (Dapuetto 2005) and Devlin et al (Devlin 1971) social class is an important variable to take into account, as lower social class may negatively affect a patients' QoL. None of the studies made an attempt to analyse for this factor, although Krouse et al (Krouse 2009) Kuzu et al. (Kuzu 2002) commented on this matter.

QoL instruments are developed as an instrument under specific cultural circumstances. In general there are rules for translation to other languages and how to validate the instruments after translation. However as shown by Holzer et al (Holzer 2005) and de Haes et al (de Haes 1998) there may even so be differences across geographic regions that are normally considered relatively homogenous. One must therefore be cautious when comparing studies across countries and regions.

It may well be, that on analysing the results one may find a statistical significant difference between two groups. But that does not necessarily mean, that the results are clinically significant (Anthony 2003; Osoba 2002). Two of the studies have speculated on this matter (Krouse 2009; Pucciarelli 2008) in the statistical section. However only Krouse et al (Krouse 2009) commented on the issue in the result and discussion section.

It may therefore be that the differences found in some of the studies were statistically significant in favour of AR, but it does not necessarily mean that the difference was clinically significant. Likewise one may not detect a statistically significant difference, the observed difference may even so be clinically important.

## Quality of the evidence

The study samples included in this review are in general relatively small ranging from 23 to 491 participants, and none of these comparative trials have made an estimate of what sample sizes were needed to be in order to detect differences between groups. Small sample size precludes meaningful statistical analysis. One potential way of overcoming this problem could be to pool data and perform a meta-analysis.

However, we consider the studies included in this review of being too heterogeneous to allow this. The studies used different questionnaires, and the study populations were not homogeneous enough to allow a meta-analysis. Furthermore, we do not consider it advisable to perform meta-analysis on observational data.

## Agreements and disagreements with other studies or reviews

Despite the above concerns with conducting meta-analysis, Cornish et al (Cornish 2007), including many of the same studies as in this review, did not identify differences in general QoL following rectal resection with or without stoma formation. In general they

found, "that patients undergoing APE had improved psychological and emotional scores, with superior "future perspective" than those undergoing AR, while those outcomes focusing on physical symptoms and pain tended to be more positive following AR" (Cornish 2007).

## **AUTHORS' CONCLUSIONS**

### **Implications for practice**

It is not possible to draw conclusions whether the QoL measures of stoma patients are poorer than for non-stoma patients. However, the results challenge the assumption, that people with stoma generally fare less well than non-stoma patients.

### **Implications for research**

As stated in this review one cannot expect that randomised trials will be performed in this field. Therefore we need large prospective cohort studies in which patients' QoL measurements are recorded both pre- and post-operatively.

Some countries have national or regional societies and databases for colorectal cancer. It would be desirable if these organisations could take up this challenge.

There is an additional need for exploring the influence of a wide variety of co-variables and their influence on patients QoL.

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**CHARACTERISTICS OF STUDIES**
**Characteristics of included studies** [ordered by study ID]

**Allal 2000**

Methods	Cohort Retrospective Cross-sectional.
Participants	23 patients(17 men, 6 women)with primary rectal cancer up to 6 cm from the anal verge. 11 APE, 12 AR. Patients were selected if they had minimum 1 year follow-up, did not present uncontrolled locoregional failure or were under treatment for distant metastases and accepted participation. Switzerland.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Age, tumour stage, time since surgery, level of anastomosis in AR group,pouch in AR group, chemotherapy.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients included consecutively.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Allal 2005**

Methods	Cohort Prospective Longitudinal.
Participants	53 patients (36 men, 17 women) with rectal cancer; included from a Phase I-II trial. Assessment made pre-RT and 12-16 month post-RT. No sign of disease progression at follow-up. Treated between 1997-2001. Switzerland

**Allal 2005** (Continued)

Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Dukes grade; level of anastomosis; pouch

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Patients included from a Phase I-II oncologic trial.  Criteria for selection of patients not stated.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Arndt 2006**

Methods	Cohort Prospective Longitudinal.
Participants	87 patients ( 45 men, 32 women) rectal cancer patients; 70 AR, 17 APE; treated between 1996-1998. Germany
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Tumour grade; tumour and anastomotic distance from anal verge; pouch

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Patients recruited from a population-based study of cancer patients. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias)	High risk	Blinding not possible due to surgical therapy.

**Arndt 2006** (Continued)

Anterior resection or abdominoperineal resection

Incomplete outcome data (attrition bias) Quality of life	High risk	Not all patients completed the questionnaire at all times.
Selective reporting (reporting bias)	High risk	All data not presented. Only significant results commented.

**Bloemen 2009**

Methods	Cohort Retrospective Cross-sectional.
Participants	121 patients (51 men, 70 women) with proven adenocarcinoma of the rectum. 51 stoma-patients. Treated between Jan. 2003 and Dec. 2005. QoL assessment made median 36(range 16-51) month after surgery. Patients with recurrent tumours or need for intraoperative brachytherapy were excluded. Netherlands.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Dukes grade; level of anastomosis; exact tumour distance from anal verge.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	Blinding not possible due to surgical therapy.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Camilleri-Brennan 2002**

Methods	Case-control Retrospective Cross-sectional.
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**Camilleri-Brennan 2002** (Continued)

Participants	106 patients (54 men, 52 women), 53 APE, 53 AR. Fifty-three patients who had elective primary curative AR for low rectal cancer (distal two-thirds) from 1992 to 1997 at four hospitals in Scotland, and in whom there was no evidence of local or distant tumour recurrence. They were individually matched for gender, age and socioeconomic status with 53 tumour-free patients who had undergone elective APE for low rectal cancer during the same period of time. United Kingdom
Interventions	Quality of life assessment with EORTC-C30/CR38 and SF-36.
Outcomes	Quality of life.
Notes	Evidence level: 3B. Not stated: tumour stage, level of anastomosis in AR group, pouch in AR group, radio/chemotherapy.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Campos-Lobato 2011**

Methods	Cohort  Prospective  Cross-sectional
Participants	153 patients (104 men, 49 women)  APE 68, AR 85  USA
Interventions	Quality of life assessment with SF-36
Outcomes	Quality of life
Notes	Evidence level: 2B.  Not stated: Dukes grade, level of anastomosis in AR group, pouch in AR group



**Campos-Lobato 2011** (Continued)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, cross-sectional cohort study. Rectal cancer patients identified through local database. Only patients with documented preoperative overall QoL assessment included
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	High risk	Not all patients completed the questionnaire at all times.
Selective reporting (reporting bias)	High risk	Only overall QoL were reported in the publication

**Celasin 2011**

Methods	Cohort  Prospective  Longitudinal
Participants	72 patients (33 men, 39 women)  APE 50, AR 22  Turkey
Interventions	Quality of life assessment with SF-36 and ASCRS Faecal Incontinence Scale
Outcomes	Quality of life
Notes	Evidence level: 2B.  Not stated: Dukes grade, level of anastomosis in AR group, pouch in AR group

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias)	Low risk	All included patients completed the study.

**Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)**

**Celasin 2011** (Continued)

Quality of life

Selective reporting (reporting bias)	Low risk	All QoL data reported.
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**Engel 2003**

Methods	Cohort Prospective Cross-sectional
Participants	299 patients(192 men, 97 women) APE 54, AR 245. Patients with primary rectal cancer identified in The Munich Cancer Registry between 1996-1998. Patients with metastatic disease excluded. Patients responding to postal questionnaire. Assessment annually for 4 years. Germany.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Age, Dukes grade, tumour distance from anal verge, level of anastomosis, formation of pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective cross-sectional cohort study. Patients identified through Munich Cancer Registry.  Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	High risk	Out of 329 included patients only 48 completed all questionnaires.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Fischer 2011**

Methods	Cohort  Retrospective  Cross-sectional
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**Fischer 2011** (Continued)

Participants	48 patients (29 men, 18 women)  APE: 15, ULAR 33.  Identified through database. Patients with ultra-low AR (ULAR) and APE were selected.  Switzerland
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Interventions	Quality of life assessment with EORTC-C30/CR38.
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Outcomes	Quality of life
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Notes	Evidence level: 2B.  Not stated: Dukes grade, level of anastomosis.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Fucini 2008**

Methods	Cohort Retrospective Cross-sectional.
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Participants	62 patients (24 men, 38 women) with primary cancer located less than 5 cm from the anal verge, without relevant comorbidity at operation, and who, after rectal operation, had not suffered from any other major illness and had never been affected by either local or distant recurrences, or new cancers were included. Italy
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Interventions	Quality of life assessment with EORTC-C30/CR38.
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Outcomes	Quality of life
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Notes	Evidence level: 2B. Not stated: Nihil.
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**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)**

**Fucini 2008** (Continued)

Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery, attended follow-up after five years and meet predefined inclusion criteria were invited to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Gosselink 2005**

Methods	Cohort Retrospective Cross-sectional.
Participants	137 patients, 51 APE, 116 AR (45 of which had pouch); Recruited from hospital records; treated between 1997-2001. Netherlands
Interventions	Quality of life assessment with EORTC-C30/CR38, EuroQol
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Tumour and anastomotic distance from anal verge;

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients identified through hospital records. Patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Grumann 2001**

Methods	Cohort Prospective Longitudinal.
Participants	73 patients (45 men, 28 women), 23 APE, 50 AR. Patients were selected from a convenience sample and meet the following inclusion criteria: Surgery with curative attempt (R0 resection), free of recurrence throughout the study period, both clinical and QoL data had to be available at each point of assessment. Germany.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour distance from anal verge, pouch in AR group.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Patients were selected for investigation from a convenience sample.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	High risk	Only patients for whom data for each point of assessment were available are reported in the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Grundmann 1989**

Methods	Cohort Retrospective Cross-sectional.
Participants	82 patients (37 men, 45 women). 41 APE patients and 41 AR patients who attended follow-up in out-patient clinic were included. Germany.
Interventions	Quality of life assessment with Grogono Health Index, QLI (Spitzer's) and Karnofsky Performance Status.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour distance from anal verge, level of anastomosis in AR group, pouch AR group, radio/chemotherapy.

**Grundmann 1989** (Continued)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients attending follow-up in out-patient clinic were included.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Guren 2005**

Methods	Cohort Retrospective Cross-sectional.
Participants	319 patients ( 179 men, 140 women), 90 APE, 229 AR. Patients having Ro resection between 1993-2001 identified through Norwegian Cancer Registry. Norway
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour distance from anal verge.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients identified through national rectal cancer registry. Patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.

**Guren 2005** (Continued)

Selective reporting (reporting bias)	Low risk	All QoL data reported.
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**Hamashima 2002**

Methods	Cohort Retrospective Cross-sectional.
Participants	110 patients (65 men, 45 women), 38 APE, 72 AR. Postal survey of surviving patients who had received surgery for rectal cancer between 1978 and 1997. Response rate 67.1%. Japan.
Interventions	Quality of life assessment with EuroQoL.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour distance from anal verge, level of anastomosis in AR group, pouch AR group, radio/chemotherapy.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients identified from Kananga Cancer Registry were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Harisi 2004**

Methods	Cohort Retrospective Cross-sectional.
Participants	372 patients (240 male, 132 women), 132 APE, 240 AR. Patients with primary rectal cancer operated between 1993 and 1999, still alive after one year. Questionnaire completed at follow-up. Hungary.
Interventions	Quality of life assessment with CRC_QoL

**Harisi 2004** (Continued)

Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated:Dukes grade, tumour distance from anal verge, level of anastomosis.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients attending 12 month follow-up visit in out-patient clinic were included.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Jess 2002**

Methods	Cohort Retrospective Cross-sectional.
Participants	40 patients (22 men, 18 women), 14 APE, 26 AR. Consecutive sample operated on for rectal cancer 1998-1999. Inclusion criteria: operated primarily with curative intent, free of recurrence when QoL was assessed not less than 1 year after primary operation or closure of temporary stoma. Denmark.
Interventions	Quality of life assessment with SF-36 and FIQL.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Level of anastomosis in AR group.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. A group of patients were selected from a consecutive sample of patients operated for rectal cancer.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.



**Jess 2002** (Continued)

Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Kasperek 2011**

Methods	Cohort Retrospective Cross-sectional
Participants	155 patients (112 men, 42 women) APE 83, AR 72. Patients identified through institutional database. USA
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Dukes grade, tumour distance from anal verge, level of anastomosis, pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Krouse 2009**

Methods	Case-control Retrospective
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**Krouse 2009** (Continued)

Cross-sectional.

Participants	491 patients (304 men, 187 women). Patients included rectal cancer survivors with permanent ostomies (termed "cases", 246 patients) and those who had similar rectal cancer treatment-related procedures but who had an anastomosis (termed "controls", 245 patients). Presurvey matching was conducted by age (within 5 years), sex, and time interval since diagnosis (5-year intervals). Patients who had their ostomy reversed were excluded from this study. USA.
Interventions	Quality of life assessment with SF-36v2 and mCOH-QoL-Ostomy
Outcomes	Quality of life
Notes	Evidence level: 3B. Not stated: Tumour grade; Tumour and anastomotic distance from anal verge; pouch

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional case-control study. APE patients surviving five years after their diagnosis and meeting inclusion criteria, were matched with patients, who had similar rectal cancer related treatment but with anastomosis.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Kuzu 2002**

Methods	Cohort Retrospective Cross-sectional.
Participants	126 patients (77 men, 49 women), 75 APE, 51 AR. Cohort of patients treated for rectal cancer between 1987 and 1999. Inclusion criteria: Curative surgery for colorectal adenocarcinoma, no other primary malignant tumour, no additional complicating or disabling disease necessitating nursing help, minimum 1 year since surgery, no chemoradiotherapy within the previous four month, no admittance to hospital during study period, no clinical evidence of tumour recurrence. Turkey.
Interventions	Quality of life assessment with SF-36.
Outcomes	Quality of life.

**Kuzu 2002** (Continued)

Notes Evidence level 2B.  
 Not stated: Tumour distance from anal verge (APE), pouch AR group, radio/chemotherapy.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Marquis 1992**

Methods	Cohort Retrospective Cross-sectional.
Participants	60 patients ( 37 men, 23 women) 32 APE, 28 AR. Cohort of patients treated in two university hospitals between 1980-1990. Inclusion criteria: Tumour less than 12 cm from anal verge, time since surgery more than 1 year, free of recurrence. Montréal, Canada.
Interventions	Quality of life assessment with QLI-CP
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Level of anastomosis in AR group, tumour distance from anal verge, pouch in AR group, Dukes grade, TNM stage, adjuvant treatment.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.

**Marquis 1992** (Continued)

Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Peng 2011**

Methods	Cohort  Prospective  Cross-sectional
Participants	154 patients (88 men, 66 women)  APE 75, AR 79.  Rectal cancer patients treated with curative intent in single centre and meeting predefined inclusion criteria.  China
Interventions	Quality of life assessment with EORTC-C30/CR29
Outcomes	Quality of life
Notes	Evidence level: 2B.  Not stated: Dukes grade, level of anastomosis in AR group, pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Perez Lara 2004**

Methods	Cohort
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**Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)**

**Perez Lara 2004** (Continued)

Prospective

Participants	116 patients identified through hospital records, 48 APE, 68 AR ( 78 men, 38 women) having Ro resection between 1994-1999. Spain
Interventions	EORTC-CR38 Nottingham Health Profile.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Tumour and anastomotic distance fro anal verge; pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective cohort study. Patients receiving intention-to-cure surgical treatment for rectal cancer were included.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported, though in figures.

**Pucciarelli 2008**

Methods	Cohort Retrospective Cross-sectional.
Participants	117 patients (74 men, 43 women) with histologically confirmed primary rectal adenocarcinoma located up to 11 cm from the anal verge (mid-low rectal cancer), alive without recurrence or a second primary tumour, who had received a radical (R0) resection and who had a minimum follow-up of 2 years from the date of surgery were included. 10 stoma-patients, 107 AR. Italy.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Tumour grade; Tumour and anastomotic distance from anal verge; pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
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**Pucciarelli 2008** (Continued)

Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients identified through institutional cancer database and meeting predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	High risk	Not all data reported in publication.

**Rauch 2004**

Methods	Cohort Retrospective Cross-sectional.
Participants	121 patients (78 men, 43 women) Cohort of patients having curative surgery for rectal cancer between 1990-1996, at least 2 years of follow-up, no sign of recurrence, no other malignancy. Postal questionnaire. France.
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Dukes grade, formation of pouch, level of anastomosis.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Ross 2007**

Methods	Cohort Prospective Longitudinal.
Participants	104 patients recruited patients from a randomised psychosocial intervention study of the effects of home visits by a healthcare professional on the QoL of colorectal cancer patients. 40 APE, 64 AR. Patients followed for 2 years. Denmark
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour and anastomotic distance fro anal verge; pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Longitudinal, prospective cohort study. Patient recruited from a randomised psychosocial intervention study. Patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients accepted to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	High risk	Not all patients completed the questionnaire at all times.
Selective reporting (reporting bias)	High risk	Data not presented. Data commented in paper.

**Schmidt 2005**

Methods	Cohort Prospective Cross-sectional.
Participants	261 rectal cancer patients treated with Ro resection between 1992-2002 identified through hospital records. 41 APE, 219 AR ( 24 pouch), 146 men 115 women). Germany
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour and anastomotic distance fro anal verge.

**Schmidt 2005** (Continued)

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, cross-sectional cohort study. Consecutive series, patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients accepted to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Unclear risk	Paper does not yield sufficient data, whether all included patients supplied data.
Selective reporting (reporting bias)	High risk	Data not presented in paper.

**Schmidt 2010**

Methods	Cohort  Prospective  Cross-sectional
Participants	368 patients (185 men, 183 women)  APE 38, AR 330. Consecutive cohort from single centre having Ro resection.  Germany
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B.  Not stated: Dukes grade, tumour and anastomotic distance from anal verge.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, cross-sectional cohort study. Consecutive series, patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients accepted to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias)	High risk	Not all patients completed questionnaire at all times.



**Schmidt 2010** (Continued)

Quality of life

Selective reporting (reporting bias)	High risk	All data not presented in paper.
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**Sideris 2005**

Methods	Cohort Retrospective Cross-sectional.
Participants	132 rectal cancer patients with Ro resection between 1986- 2002, identified through hospital records. France
Interventions	Quality of life assessment with EORTC-C30/CR38.
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Tumour and anastomotic distance from anal verge; pouch. Tumour grade.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients identified through electronic hospital records. Patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients accepted to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Smith-Gagen 2009**

Methods	Cohort  Prospective  Longitudinal
Participants	97 patients (46 men, 43 women)  APE 27, AR 62.

**Smith-Gagen 2009** *(Continued)*

Patients aged 40-84 identified through cancer database.

Interventions	Quality of life assessment with FACT-C
Outcomes	Quality of life
Notes	Evidence level: 2B.  Not stated: Dukes stage, tumour and anastomotic distance from anal verge; pouch

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Patients identified through cancer database.  Not all eligible patients responded.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	High risk	Not all patients completed all questionnaires
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Thong 2010**

Methods	Cohort  Retrospective  Cross-sectional
Participants	340 patients  APE 79, AR 149  Patients selected through a weighted random selection among survivors. Weights derived from distribution of rectal cancer survivors in the general population.  Netherlands
Interventions	Quality of life assessment with SF-36 and QLQ-CR38
Outcomes	Quality of life
Notes	Evidence level: 2B.  Not stated: Age, gender, tumour stage, tumour and anastomotic distance from anal verge; pouch

**Risk of bias**

**Thong 2010** (Continued)

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Patients selected through a weighted random selection among survivors. Weights derived from distribution of rectal cancer survivors in the general population.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Varpe 2011**

Methods	Cohort Prospective Longitudinal
Participants	65 patients, APE 21, AR 44. Patients with histologically proven rectal cancer invited to participate.
Interventions	Quality of life assessment with RAND-36
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Gender, tumour grade, tumour and anastomotic distance from anal verge; pouch, adjuvant treatment.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Not all eligible patients accepted to participate.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.

**Varpe 2011** (Continued)

Selective reporting (reporting bias)	Low risk	All QoL data reported.
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**Vironen 2006**

Methods	Cohort Retrospective Cross-sectional.
Participants	67 patients (44 men, 23 women) with Ro resection and a minimum follow-up of one year; patients who were alive without a sign of recurrence and who accepted the study were included. 28 APR, 39 AR. Finland.
Interventions	Quality of life assessment with SF-36v2
Outcomes	Quality of life
Notes	Evidence level: 2B. Not stated: Level of anastomosis; time since surgery.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Retrospective, cross-sectional cohort study. Rectal cancer patients who had undergone surgery and meet predefined inclusion criteria were invited to participate. Not all eligible patients responded to questionnaire.
Blinding (performance bias and detection bias) Anterior resection or abdominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (reporting bias)	Low risk	All QoL data reported.

**Yau 2009**

Methods	Cohort Prospective Longitudinal.
Participants	135 rectal cancer patients (64 AR) recruited from a multicenter chemotherapy study after initial Ro resection. United Kingdom.
Interventions	Quality of life assessment with EORTC-C30
Outcomes	Quality of life

**Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)**

**Yau 2009** (Continued)

Notes Evidence level: 2B.  
 Not stated: TNM grade; tumour and anastomotic distance fro anal verge; pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Prospective, longitudinal cohort study. Patients were initially part of a RCT comparing different chemotherapy regiments for colorectal cancer patients. Patients with rectal cancer were enrolled in this study. Not all eligible patients entered the study.
Blinding (performance bias and detection bias) Anterior resection or ab- dominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Low risk	All included patients completed the study.
Selective reporting (re- porting bias)	Low risk	All QoL data reported. Though some data only presented in figures.

**Yoo 2005**

Methods	Cohort Prospective Longitudinal.
Participants	98 rectal cancer patients. Follow-up 6 month. USA
Interventions	FACT-C
Outcomes	Quality of life.
Notes	Evidence level: 2B. Not stated: Age, men/ women ratio; Tumour and anastomotic distance fro anal verge; pouch.

**Risk of bias**

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	High risk	Longitudinal, prospective cohort study. Patients having surgery for rectal cancer were enrolled by random sampling.
Blinding (performance bias and detection bias) Anterior resection or ab- dominoperineal resection	High risk	Blinding not possible due to surgical therapy.
Incomplete outcome data (attrition bias) Quality of life	Unclear risk	Paper does not yield sufficient data, whether all included patients supplied data.

**Yoo 2005** (Continued)

Selective reporting (reporting bias)      High risk      Data not presented. Data commented in paper.

Evidence level according to Oxford-Centre of Evidence-based Medicine.

**Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion
<a href="#">Arndt 2004</a>	Duplicate publication.
<a href="#">Bossema 2011</a>	QoL assessed using only certain sub-scales of EORTC-C30½
<a href="#">Bruheim 2010</a>	Study comparing effect of radiotherapy on long-term QoL. Insufficient data in comparison between stoma and non-stoma patients.
<a href="#">Del Frari 2002</a>	Additional data requested from author. None supplied.
<a href="#">Frigell 1990</a>	Questionnaire not validated. Duplicate publication.
<a href="#">Gray 2011</a>	Non-stoma group contains patients not operated
<a href="#">Hassan 2006</a>	No primary stoma patients. Stoma only created as consequence of complications.
<a href="#">Hoerske 2010</a>	Stoma-group contains patients with ileostomy as well as colostomy
<a href="#">Hoppe de Mamani 2004</a>	Duplicate publication.
<a href="#">Hornbrook 2011</a>	Study group contains colon as well as rectal cancer patients
<a href="#">Koller 1994</a>	Additional data requested from author. No reply.
<a href="#">Kopp 2000</a>	Additional data requested from author. No reply.
<a href="#">Küchenhoff 1981</a>	Questionnaire not validated.
<a href="#">La Monica 1985</a>	Questionnaire not validated.
<a href="#">MacDonald 1984</a>	Not all questionnaires validated.
<a href="#">MacDonald 1985</a>	Not all questionnaires validated.
<a href="#">Michelone 2004</a>	Comparisons made between colon and rectal cancer patients
<a href="#">Pocard 2006</a>	Comparisons made between APE and perineal colostomy with colonic muscular graft
<a href="#">Pählman 1987</a>	Questionnaire not validated.
<a href="#">Rinaldis 2012</a>	Study group contains colon as well as rectal cancer patients
<a href="#">Rudinskaitė 2003</a>	Abstract from the European Association of Coloproctology Annual Meeting, Erlangen, Germany 12-14 September 2002. Questionnaire not validated. The authors used a non-validated modification of EORTC-C30/CR38, SF-26 and FACT.

Study	Reason for exclusion
Schaube 1996	Not all questionnaires validated.
Schmidt 1999	Abstract from the 6th Annual Conference of the International Society for Quality of Life Research; 3-6 November 1999 Barcelona, Spain. Additional data requested from author. No reply.
Schmidt 2002	Abstract from the 9th Annual Conference of the International Society for Quality of Life Research (ISOQOL) October 30 - November 2 2002, Orlando, Florida, USA . Additional data requested from author. No reply.
Schmidt 2005a	Duplicate publication.
Schmidt 2005b	Duplicate publication.
Schwemmler 1989	Questionnaire not validated.
Sentovic 1997	Abstract from ASCRS 1997. Additional data requested from author, none supplied.
Szczepkowski 2002	Additional data requested from author. None supplied.
Williams 1983	Questionnaire not validated.
Wilson 2006	Comparison made between stoma (ileostomy and colostomy) and non-stoma for as well colonic and rectal cancer patients without distinction between groups .
Wilson 2006a	Study compares QoL in colorectal cancer patients, irrespective of tumour localisation.
Wirsching 1975	Questionnaire not validated.
Zieren 1996	Additional data requested from author. No reply.

## ADDITIONAL TABLES

**Table 1. Methods of HRQoL analysis and results**

Author	Test of statistical significance applied	Difference between treatment arms	Clinical difference addressed	Presentation of results	Missing data documented	Exploration of missing data
Allal 2000	YES	NO	NO	YES	NO	NO
Allal 2005	YES	NO	NO	YES	YES	NO
Arndt 2006	YES	NO	YES	YES	NO	NO
Bloemen 2009	YES	YES	NO	YES	NO	NO
CamilleriBrennan2002	YES	YES	NO	YES	NO	NO

**Table 1. Methods of HRQoL analysis and results** (Continued)

Campos-Lobato 2011	YES	NO	YES	YES, SUMMARY	NO	NO
Celasin 2011	YES	NO	NO	YES	NO	NO
Engel 2003	YES	YES	NO	YES	YES	NO
Fischer 2011	YES	YES	NO	YES	NO	NO
Fucini 2008	YES	YES	NO	YES	NO	NO
Gosselink 2005	YES	YES	NO	YES	NO	NO
Grumann 2001	YES	NO	NO	YES	NO	NO
Grundmann 1989	YES	YES	NO	YES	NO	NO
Guren 2005	YES	YES	YES	YES	YES	(YES)
Hamashima 2002	YES	NO	NO	YES	NO	NO
Harisi 2004	YES	NO	NO	YES	NO	NO
Jess 2002	YES	NO	NO	YES	NO	NO
Kasperek 2011	YES	YES	YES	YES	YES	(YES)
Krouse 2009	YES	YES	YES	YES	NO	NO
Kuzu 2002	YES	YES	NO	YES	NO	NO
Marquis 1992	YES	YES	NO	YES	NO	NO
Peng 2011	YES	YES	NO	YES	NO	NO
Perez Lara 2004	YES	YES	NO	YES	NO	NO
Pucciarelli 2008	YES	YES	NO	YES	NO	NO
Rauch 2004	YES	NO	NO	YES	YES	NO
Ross 2006	YES	YES	NO	YES	NO	NO
Schmidt 2005	YES	YES	NO	YES	NO	NO
Schmidt 2010	YES	YES	NO	YES	NO	NO
Sideris 2005	YES	YES	NO	YES	NO	NO
Smidt-Gagen 2010	YES	NO	YES	YES	NO	NO
Thong 2010	YES	YES	YES	YES	NO	NO
Varpe 2011	YES	NO	NO	YES	NO	NO
Vironen 2006	YES	NO	NO	YES	NO	NO



**Table 1. Methods of HRQoL analysis and results** (Continued)

Yau 2009	YES	YES	NO	YES	NO	NO
Yoo 2005	YES	NO	NO	YES	YES	NO

## WHAT'S NEW

Date	Event	Description
30 April 2012	New citation required but conclusions have not changed	New studies included. Conclusion not changed.
24 April 2012	New search has been performed	New update - new studies added

## HISTORY

Protocol first published: Issue 3, 2003

Review first published: Issue 3, 2004

Date	Event	Description
23 February 2010	New citation required and conclusions have changed	Substantive amendment

## CONTRIBUTIONS OF AUTHORS

First author (JP) checked the titles and abstracts identified from the databases and hand search.

Both reviewers (JP; PWJ) independently extracted the data, using a data extraction sheet. Disagreements solved in consensus.

JP compiled a first draft of the review. Both reviewers confirmed and commented on the review content.

## DECLARATIONS OF INTEREST

"AAGE og JOHANNE LOUIS-HANSENS FOND" (a private foundation) has in part founded the review.

## SOURCES OF SUPPORT

### Internal sources

- No sources of support supplied

### External sources

- Aage og Johanne Louis-Hansens Fond, Denmark.

## NOTES

This updated version has included nine additional studies, that were identified during the updated search.

Six additional studies were added in the 2010 update

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Colostomy; \*Quality of Life; Anal Canal; Controlled Clinical Trials as Topic; Organ Sparing Treatments [\*methods]; Rectal Neoplasms [\*surgery]; Rectum [\*surgery]

**Quality of life after rectal resection for cancer, with or without permanent colostomy. (Review)**

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**MeSH check words**

Humans