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CHAPTER 5

Quality of life after laparoscopic and open colorectal surgery: A systematic review

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Abstract

Aim
This study was a systematic review of the available evidence on quality of life in patients after laparoscopic or open colorectal surgery.

Methods
A systematic review was performed of all randomized clinical trials (RCTs) comparing laparoscopic with open colorectal surgery. Study selection, quality assessment and data extraction was independently done by two reviewers. Primary endpoint was quality of life after laparoscopic and open colorectal surgery, as assessed by validated questionnaires.

Results
The search resulted in nine RCTs that included 2263 patients. Short- and long-term results of these RCTs were described in 13 articles. Postoperative follow-up ranged from 2 days to 6.7 years. Due to clinical heterogeneity, no meta-analysis could be conducted. Four RCTs, did not show any difference in quality of life between laparoscopic or open colorectal surgery. The remaining five studies reported a better quality of life in favor of the laparoscopic group on a few quality of life scales at time points ranging from 1 week to 2 years after surgery.

Conclusion
Based on presently available high-level evidence, this systematic review showed no clinically relevant differences in postoperative quality of life between laparoscopic and open colorectal surgery.

Introduction

Since the introduction of laparoscopic surgery in the early 90s, several multicenter randomized clinical trials (RCTs) have established that laparoscopy is a safe and feasible approach in colorectal surgery. These studies have focused on benign diseases such as diverticulitis, ulcerative colitis (UC), pre-malignant diseases like familial adenomatous polyposis (FAP)[1;2] and malignant diseases, mostly colorectal carcinoma.[3-5] Advantages of laparoscopic surgery include shorter postoperative hospital stay, less perioperative blood loss, less postoperative pain and cosmetic advantages. Long-term follow-up will most probably show less incisional hernias and adhesions. However, no sufficient data are available yet. Morbidity and oncologic follow-up have been reported to be similar for open and laparoscopic colorectal surgery.[4-6] Disadvantages are the prolonged operating time, the higher costs and the need for an experienced surgeon, since it takes at least 20 procedures to get through the learning curve.[7;8]

After colorectal surgery for malignancy, many patients experience a combination of physical and emotional problems for a longer period of time. Symptoms such as fatigue, pain and disturbed bowel function, as well as problems in social and role functioning, inevitably affect the patients' wellbeing. Assessment of self-reported quality of life is therefore increasingly important in clinical trials, and also when considering the higher costs for laparoscopy and its cost-effectiveness. In addition, in cancer trials, it has been shown that assessing quality of life could contribute to an improved treatment.[9] In 2008, Dowson et al.[10] performed a systematic review included studies published up to March 2007 on quality of life following laparoscopic and open surgery. The authors however concluded that there was a lack of data and a need for further research.[10] Over the last three years, more trials on quality of life after open or laparoscopic colorectal surgery have been published, therefore, an update of this systematic review was required.

The aim of this systematic review was to examine the latest evidence of quality of life in patients after laparoscopic or open colorectal surgery.

Materials and methods

Search Strategy

A literature search of the following electronic databases was conducted: PubMed, Cochrane Central Register of Controlled Trials, and EMBASE (all from January 1980 to April 2010). The key words used were: (colon [MeSH] OR colon OR colonic OR colorectal OR rectal OR mesorectal OR rectoanal OR anorectal OR rectum [MeSH] OR rectum OR colectomy [MeSH] OR colectomy) AND (minimal* AND invasive OR laparoscopy [MeSH] OR laparoscop* OR laparotomy [MeSH] OR laparotom*) AND (quality of life [Mesh] OR quality of life).

No limits as to language were applied. Additionally, a hand-search was performed of the references of relevant studies. Two reviewers (SB and MV) independently selected studies on the basis of their titles and abstracts. Studies were included if they were a RCT that compared laparoscopic and open colorectal surgery for malignant or benign disease, and contained comparative data on quality of life, either as primary or secondary endpoints. If studies reported on similar patient data, the study with the largest sample size was included. Exclusion criteria were: clinical comparative studies, case series, case reports, reviews, letters, or abstracts. In case of disagreement between the two reviewers, a third reviewer (WB) was involved.

Data extraction

The results of each included trial were extracted onto a form that contained the following items: methodological aspects of the trial (i.e. randomization, concealment of allocation, blinding, follow-up, intention to treat, possible selective reporting, other possible bias), inclusion and exclusion criteria, patient characteristics, details on the surgical procedures, primary and secondary endpoints, instruments, timing, and results of the quality of life measurements. All quality of life results were extracted at any time interval, as well as preoperative baseline characteristics and short- and long-term postoperative follow-up data.

Assessment of methodological quality

The methodological quality of the RCTs was assessed using 'The Cochrane Collaboration's Tool for Assessing Risk of Bias'.[11] This tool assesses the quality of RCTs by addressing items such as: the methods of randomization, concealment of allocation, blinding, drop-out rate, intention to treat, and other forms of potential bias. Again, this assessment was made by two reviewers independently (SB and MV).

Outcome Measure: quality of life instruments

Studies were included if at least one of the following validated quality of life instruments was used: European Organization for Research and Treatment of Cancer (EORTC)-QLQ-C30; EORTC-QLQ-C38; Short Form-36 (SF-36); Gastro Intestinal Quality of Life Index (GIQLI); Quality of Life Index (QLI); EuroQoL-5D (EQ-5D); Symptom Distress Scale (SDS) and Global QoL. A summary of the four most commonly used questionnaires is given below.

The EORTC-QLQ-C30 questionnaire has been developed by the quality of life department of the EORTC. This is a self-reported patient questionnaire that included: five functional scales (physical, role, emotional, social, and cognitive); three symptom scales (fatigue, nausea

and vomiting and pain); a global health status/QoL scale; and six single items (dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties).[12] The EORTC-QLQ-C38 is an extra module used specifically for colorectal cancer. This questionnaire consists of 38 items covering symptoms and side-effects related to different treatment modalities, body image, sexuality and future perspective.[13] The SF-36 consists of 36 items within eight dimensions: psychological functioning; role limitations due to physical problems; pain; general health perceptions; energy/vitality; social functioning; role limitations due to emotional problems and mental health.[14] Lastly, the GIQLI assesses bowel related quality of life. It contains 36 items and covers symptoms, physical, emotional and social functioning.[15]

Results

Literature search

A total of 594 potentially relevant titles were identified from the initial literature search in aforementioned electronic databases. After scanning of all titles by both reviewers independently, 117 abstracts were selected to be reviewed for inclusion criteria and of methodological quality. Hereafter, 25 full-text articles remained for assessment of inclusion criteria and of methodological quality. After this assessment 12 articles were excluded for the following reasons: four articles for being non-randomized studies[16-19]; three for presenting data on similar patients[20-22]; three for reporting on ongoing trials, i.e. not presenting data[23-25]; one for not presenting quality of life data[26]; and one could not be translated from Russian.[27] A total of 13 full-text articles remained for final analysis and data extraction. These articles reported on the results of nine different RCTs.[1;2;4;25-33] The long-term results of four of the nine included RCTs were presented in separate papers; therefore, 13 articles were included.[34-37] Details of the search are shown in Figure 1.

Risk of bias in included trials

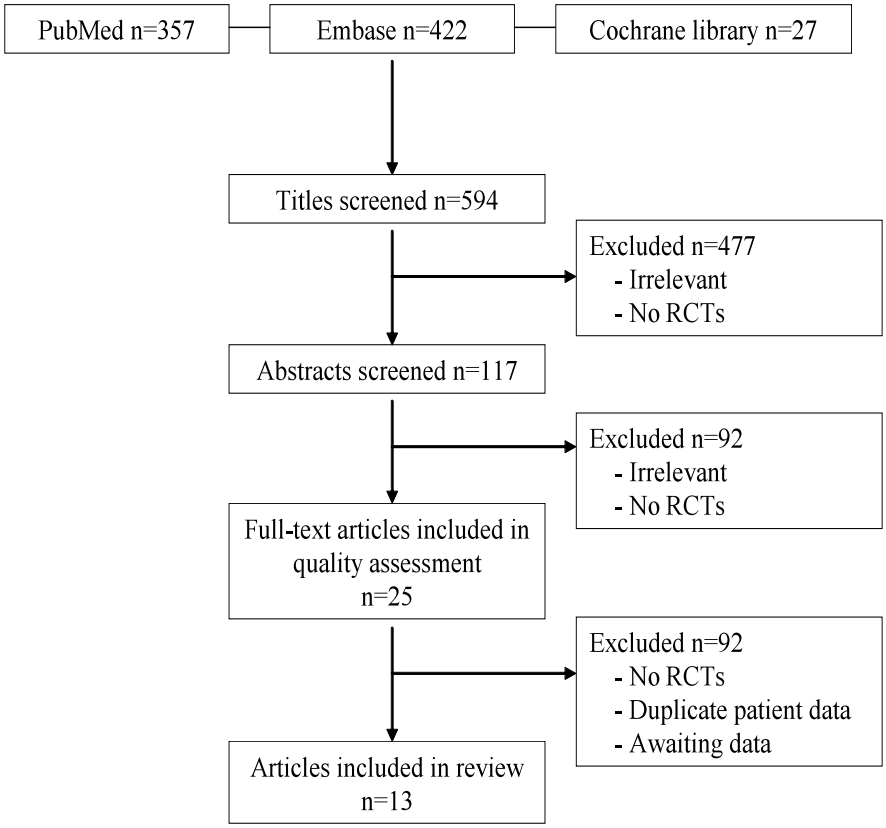
The methodological quality of the nine included trials is summarized in Figure 2. In general, overall study quality was good. All studies were properly randomized and in one[31], concealment of allocation was unclear. Patients were blinded for the approach in one out of nine studies, and in none of the studies the personnel (i.e. the surgeons) were blinded. In most studies, it was unclear if the outcome assessor was blinded; only one study stated adequate blinding of the outcome assessor. Eight out of nine studies were analyzed according to the intention to treat principle; in one study this was unclear. All predefined outcome parameters were reported in eight trials, and thus, free of selective reporting. Seven studies were free of other bias: baseline characteristics of the patients were comparable and treatment was similar apart from the intervention.

Description of trials

An overview of the included trials is given in Table 1. A total of 2263 patients (laparoscopic surgery n=1257, open surgery n=1006) were included in nine trials. Six trials reported on patients with colon or colorectal cancer and three reported on patients with diverticulitis, Crohn's disease and UC or FAP. Quality of life was a primary outcome measure in five of

the trials. The following validated questionnaires were used for measuring quality of life: EORTC-C30 (4 times), SF-36 (4 times), EORTC-C38 (2 times), GIQLI (2 times) and EQ-5D, QLI, SDS and Global Quality of Life, which were all used once.

Figure 1 Flow chart of article inclusion



RCTs=randomized controlled trials

Figure 2 Assessment of risk of bias of the nine included randomized clinical trials

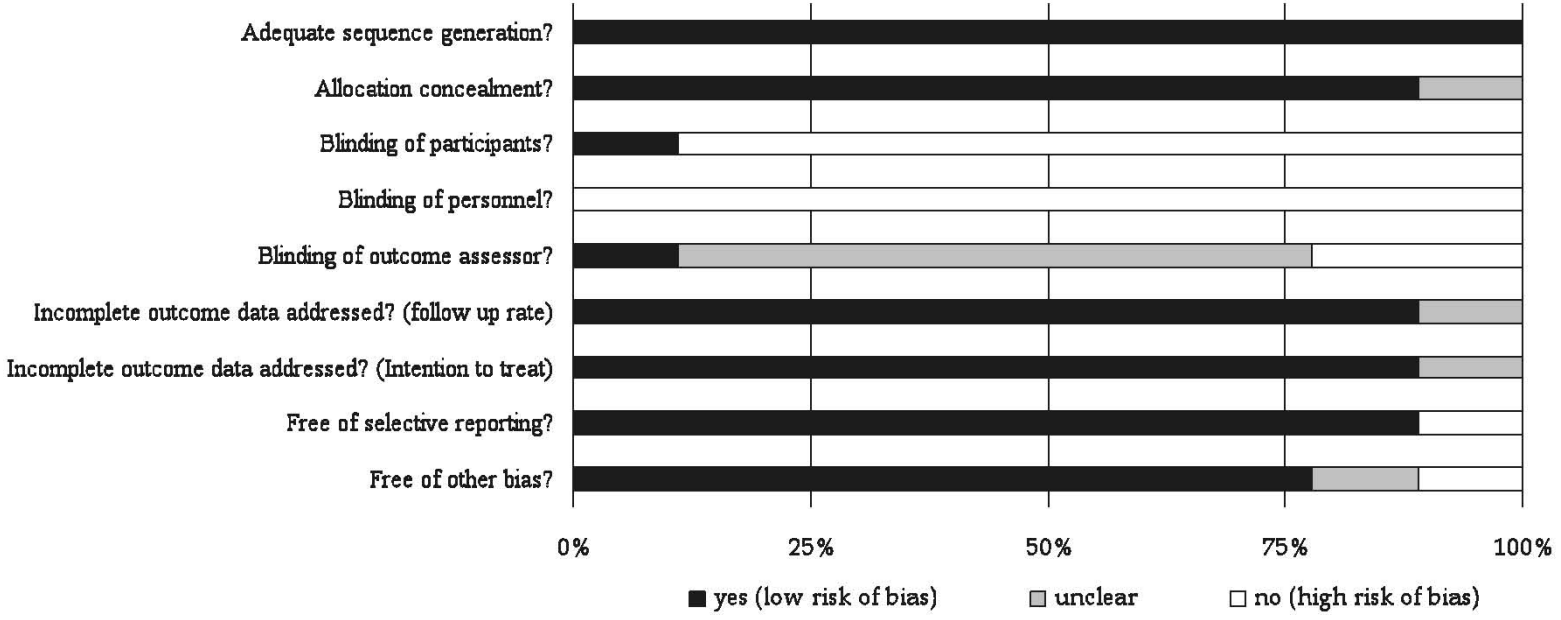


Table 1 Overview of included trials

Author	Trial	Year	QoL 1° or 2° endpoint	No of patients		Conversion rate (%)	Patients	Surgery	QoL Measures	Timing of measures	
				Lap	*Open*					*Pre*	*Postoperative*
Janson[28]	Color	2007	primary	130	155	17.7	Colon cancer	Colon resection	EORTC – C30, EQ-5D	yes	2, 4 and 12 weeks
King[33]		2006	secondary	41	19	0.0	Colorectal cancer	Colorectal resection	EORTC – C30 and C38	yes	2 and 6 weeks
King[34]		2008	secondary	41[1]	19[1]						3, 6 and 12 months
Guillou[4]	Clasicc	2005	secondary	526	268	29	Colorectal cancer	Colorectal resection	EORTC – C30 and C38	yes	2 and 12 weeks
Jayne[35]		2007	secondary	696[2]							6, 18 and 36 months
Braga[29]	Consort	2005	secondary	190	201	4.2	Colorectal cancer	Colorectal resection	SF-36	no	1, 2 and 4 years
Weeks[30]	Cost	2002	primary	228	221	25.7	Colon cancer	Colon resection	QLI, SDS, Global QOL	yes	2 days, 2 and 8 weeks
Schwenk[31]		1998	primary	30	30	-	Colorectal cancer	Colorectal resection	EORTC – C30	yes	1, 4 and 12 weeks
Klarenbeek[1]	Sigma	2009	secondary	52	52	19.2	Diverticulitis	Sigmoid resection	SF-36	yes	6 weeks
Maartense[32]		2006	primary	30	30	10.0	Crohn's Disease	Ileocolic resection	SF-36, GIQLI	yes	1, 2, 4, and 12 weeks
Eshuis[36]		2010	secondary	29[1]	26[1]						6.7 years[3]
Maartense[2]		2004	primary	30	30	0.0	UC and FAP	RP & IPAA	SF-36, GIQLI	yes	1, 2, 4 and 12 weeks
Polle[37]		2007	secondary	26[1]	27[1]						1 year[3]

[1]Long term follow-up of same study population / [2]Number of patients included in long term follow-up, data not specified for laparoscopic or open surgery / [3]median / - = no data available / UC = ulcerative colitis / FAP = familial adenomatous poliposis / RP & IPAA = restorative proctocolectomy with ileo pouch anal anastomosis / QoL = Quality of Life / EORTC = European Organization for Research and Treatment of Cancer / SDS = Symptom Distress Scale / QLI = Quality of Life Index / GIQLI = Gastro Intestinal Quality of Life Index / SF-36 = Short-Form 36

Quality of life

An outline of the results is shown in Table 2. The studies were heterogeneous in terms of variation in diseases treated, outcome measures, and timing of measurements. Hence, meta-analysis was not feasible. Preoperative quality of life was measured in eight out of the nine studies. In all but one of these, preoperative quality of life was similar between the groups. The study of Janson et al.[28] reported a significantly better quality of life in 1 out of the 5 scales of the EQ-5D ('usual activities') for the group which was about to undergo open surgery (P=0.006). Postoperative follow-up in the different studies ranged from 2 days to 6.7 years. Except for Weeks et al.[30], all studies started measuring quality of life at least 1 week after surgery.

King et al.[33,34], Guillou et al.[4], Jayne et al.[35], Maartense et al.[32], Eshuis et al.[36] , Maartense et al.[2], and Polle et al.[37] showed no significant differences in postoperative quality of life following open or laparoscopic colorectal surgery on short-term (1 to 12 weeks) or long-term (3 months to 6.7 year) follow-up.

Five studies, Janson et al.[28], Braga et al.[29], Weeks et al.[30], Schwenk et al.[31] and Klarenbeek et al.[1], did find a significant difference in postoperative quality of life in favor of laparoscopic surgery. Janson et al.[28] showed a significant difference in favor of laparoscopic surgery in two ('social function' and 'role function') and one ('social function') of 15 subscales of the EORTC-C30 questionnaire at 2 and 4 weeks, respectively, following surgery. The authors also calculated the effect size (Cohen's) of these subscales; the effect size of 'role function' was 0.51 (moderate) and the effect sizes of social function were 0.42 (low) and 0.38 (low) at 2 and 4 weeks, respectively. In the same study, there was no difference between the open and laparoscopic group as measured with EQ-5D.

Braga et al.[29] measured quality of life at 1, 2 and 4 years postoperatively. Only three subscales ('general health', 'physical functioning' and 'social functioning') of the SF-36 were used for analysis. Two of three subscales ('physical functioning' and 'social functioning') scored significantly better in the laparoscopic group at 1 year after surgery; scores on one subscale ('social functioning') were still significantly better at 2 years postoperative, and no significant difference was found at 4 years following surgery.

Weeks et al.[30] reported no difference between the groups measured with the SDS at 2 days postoperatively. At 2 weeks after surgery the authors reported a significantly better outcome for the laparoscopic group on the Global QoL questionnaire; at the same time point scores on the QLI and SDS were similar for both groups. At 8 weeks postoperatively no significant differences were found.

After 1 week Schwenk et al.[31] found a significant difference in favor of laparoscopy as measured with the EORTC-C30 questionnaire. These differences were shown on four out of five functional scales ('physical', 'emotional', 'social', and 'cognitive function'), on 'global quality of life' and on four of nine symptom- or single item scales ('fatigue', 'pain', 'dyspnoea' or 'appetite loss'). After 4 weeks, two out of the five functional scales ('social' and 'cognitive function') and 'global quality of life' remained significantly better in the laparoscopic group. After 12 weeks, quality of life scores were similar.

Klarenbeek et al.[1] performed one quality of life measurement after 6 weeks and reported a difference in four ('pain', 'social functioning', 'role limitations due to physical health' and 'role limitations due to emotional problems') of eight dimensions of the SF-36.

Discussion

This systematic review showed no substantial differences in quality of life, as measured two days to several years postoperatively, between laparoscopic and open surgical procedures for colorectal disorders. In only five out of the nine trials found, quality of life after laparoscopic colorectal surgery appeared slightly but significantly better during short-term follow-up compared to that with open colorectal surgery. However, this was not considered clinically relevant, because the observed differences were merely found in certain subscales at few and differing time intervals.

The clinical relevance of significant differences in quality of life is debatable. Osoba et al.[38] have studied the outcomes of the EORTC-C30 by comparing changes in C-30 scores to a subjective significance questionnaire (SSQ). The SSQ asked patients to rate their own changes in physical, emotional and social functioning. These results were compared to the outcomes of the C-30, which resulted in a small change (5-10 points), moderate change (10-20 points) and large change (> 20 points). These results imply that statistical significance does not necessarily correlate with clinical relevance, which was illustrated in the trial of Janson et al.[28] In that study, a low and moderate effect size was calculated for significant differences in quality of life outcomes in the EORTC-C30. They also stated that, due to the large number of subscales analyzed in multiple tests at different assessment points in time, the finding of false-positive results is likely to occur. Hence, the relatively small differences found in this review on sets of subscales were not considered to be clinically relevant findings.

Several studies have shown that laparoscopic surgery results in less perioperative blood loss, less inflammatory response[36], and smaller incisions. Obviously, laparoscopic surgery is associated with less perioperative trauma to the abdominal wall compared to open surgery. Therefore, differences in quality of life are expected to be more prominent in the first week after surgery. Unfortunately, in this review no conclusions could be drawn about that period, because almost all included studies started measuring quality of life after a minimum of 1 week. This is a possible explanation for the rare differences we found in quality of life, which is corroborated by the fact that nearly all of the reported differences in quality of life disappeared over time. If quality of life was indeed influenced by the surgical technique, another explanation for the marginal differences we found could be that in four out of the nine trials included, quality of life was not a primary outcome measure, which possibly lead to an underpowered quality of life analysis. Finally, quality of life is determined by many other postoperative factors, even if baseline characteristics are similar at the time of preoperative assessment. For example, the course of the disease differs per patient and may subsequently affect quality of life.

Results from this systematic review are in accordance with recent literature. Dowson et al.[10] have shown no significant quality of life advantages after a laparoscopic approach com-

pared to open surgery, but also stated that there was a lack of good quality data. The authors did state that there was a possible trend of an improved quality of life after laparoscopic surgery. In a Cochrane systematic review on short-term benefits for laparoscopic colorectal surgery, Schwenk et al.[40] found that quality of life might be improved in the early postoperative course. The authors, however, were not able to present a clear conclusion due to the low methodological quality of the studies that they included. In addition to the earlier review, the present systematic review included sufficient high-level evidence to state that there was no clinical relevant difference in quality of life on short- or long-term follow-up, measured 1 week to 6.7 years postoperatively.

A limitation of this review is the clinical heterogeneity among the included studies. Virtually every study used different quality of life instruments and did not present exact data. Furthermore, the recruited patients were treated for a range of different disorders. Therefore, it was impossible to recalculate the statistical analyses or to perform a meaningful meta-analysis. Future randomized trials comparing open with laparoscopic surgery are needed[41], and should be well-designed, sufficiently powered, and focus on quality of life; in particular shortly after the operation, i.e. within 1 week, in which period, most of the differences are likely to occur.

In conclusion, based on presently available high-level evidence, this systematic review showed no clinically relevant differences in postoperative quality of life between laparoscopic and open colorectal surgery.

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