Laparoscopic colorectal surgery is associated with a higher intraoperative complication rate than open surgery
Sammour T, Kahokehr A, Srinivasa S, Bissett IP, Hill AG

CRD summary
The review concluded that laparoscopic colorectal resection was associated with a significantly higher total intraoperative complication rate (and intraoperative bowel injury rate) than equivalent open surgery with no significant differences for intraoperative haemorrhage and intraoperative solid organ injury. The authors’ conclusions did not allow for biases seen in many of the studies and do not appear likely to be reliable.

Authors’ objectives
To compare intraoperative complication rates for laparoscopic and open colorectal surgery.

Searching
MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials (CENTRAL) (from January 1966) and EMBASE (from 1947) were searched to August 2009 for publications in any language; search terms were reported. The search was performed using the Cochrane Highly Sensitive Search Strategy for randomised controlled trials (RCTs). Bibliographies of retrieved articles and the abstracts of relevant scientific meetings were handsearched. Published and unpublished trials were included.

Study selection
RCTs that evaluated laparoscopic versus open surgery for any colonic or rectal indication were eligible for inclusion. Trials with different surgeons for each intervention group, trials of hand-assisted laparoscopic resection and trials that excluded conversions to open surgery were excluded. There were no restrictions on outcomes, but the primary outcomes were intraoperative complications. Complications were: haemorrhage defined as a bleeding event requiring transfusion or conversion to open surgery; bowel injury defined as any hollow viscus injury requiring repair; and solid organ injury defined as any solid organ injury that required intervention.

Study details were provided only for the included studies that provided data for the meta-analysis. These RCTs were published between 2001 and 2009. Sixty per cent were multicentre trials and the rest were single centre trials. The indications for surgery were colonic cancer (40% of studies), both colonic and rectal cancer (30% of studies) and rectal cancer, sigmoid diverticulitis and ileocaecal Crohn's disease (individual studies). Half of the studies excluded patients aged less than 17 or 18 years. Patients were excluded from studies for many other reasons; the most common were surgery related issues/problems (80% of studies), pregnancy (60% of studies), previous malignancy (50% of studies), metastatic disease (40% of studies), previous colorectal or locally relevant surgery (30% of studies) and emergency operations (30% of studies). Most studies (70%) used credentialed trial surgeons.

Two independent reviewers performed study selection. Disagreements were resolved by consensus or consultation with a third senior reviewer.

Assessment of study quality
Study quality was assessed by two reviewers. Risk of bias was assessed using the Cochrane Collaboration tool with criteria for adequate sequence generation, allocation concealment, blinding, incomplete outcome data addressed, free of selective reporting and free of other bias.

Data extraction
Intention-to-treat data on intraoperative complications were extracted on an intention-to-treat basis using specifically designed tables. Complications were counted per event and categorised into total complications, haemorrhage, bowel injury and solid organ injury. The number of events was used to calculate Peto odds ratios (OR) with 95% confidence intervals (CI). For published articles the authors’ definitions of complications were used. Corresponding authors were contacted for missing or unclear information. Studies were excluded from the analysis if no data were obtained after a second contact.
The authors did not report how many reviewers performed data extraction.

**Methods of synthesis**
Odds ratios were pooled using a fixed-effect model (Peto) as significant heterogeneity was not expected; a random-effects model was also used to test the robustness of effects. Between-study heterogeneity was determined with $\chi^2$ and $I^2$ statistics. Publication bias was assessed visually using funnel plots. A per patient meta-analysis and subgroup analyses for cancer resections and colonic cancer resections were performed.

**Results of the review**
Thirty RCTs were identified but only 10 provided complete intraoperative complication data (4,055 participants, range 60 to 1,082). Relevant data were published in only four studies; data for the other six studies were obtained by contacting the authors. Studies were of moderate quality. There was minimal apparent publication bias. From the study quality table it appeared that all studies except two had adequate sequence generation. Two studies had adequate allocation concealment this was unclear for the other studies. Two studies had adequate blinding. Four studies addressed incomplete outcome data and seven studies were free of selective reporting; the other studies did not address these criteria. All the studies were at risk of other bias. The results reported here were for the fixed-effect model.

There was a significantly higher total intraoperative complication rate (OR 1.37, 95% CI 1.06 to 1.76; $I^2=17\%$, nine studies) and intraoperative bowel injury rate (OR 1.88, 95% CI 1.10 to 3.21; $I^2=36\%$, seven studies) for laparoscopic versus open surgery. There was no significant difference for intraoperative haemorrhage ($I^2=47\%$, nine studies) and intraoperative solid organ injury ($I^2=0\%$, eight studies). Per patient analysis also found a significantly higher total intraoperative complication rate (OR 1.54, 95% CI 1.09 to 2.17; $I^2=49\%$, seven studies).

Results were similar in subgroup analyses for all cancer resections (eight studies) with a significantly higher total intraoperative complication rate (OR 1.42; $I^2=16\%$) and intraoperative bowel injury rate (OR 1.93; $I^2=46\%$) for laparoscopic versus open surgery and no significant difference for intraoperative haemorrhage or intraoperative solid organ injury.

Results were similar in subgroup analyses for colon cancer resections (five studies) with a significantly higher total intraoperative complication rate (OR 1.55, 95% CI 1.12 to 2.15; $I^2=43\%$) and intraoperative bowel injury rate (OR 2.28, 95% CI 1.27 to 4.10; $I^2=42\%$) for laparoscopic versus open surgery and no significant difference for intraoperative haemorrhage ($I^2=71\%$) and intraoperative solid organ injury ($I^2=0\%$).

**Authors’ conclusions**
Laparoscopic colorectal resection was associated with a significantly higher intraoperative complication rate than equivalent open surgery.

**CRD commentary**
The review addressed a well-defined question in terms of participants, interventions, study design and relevant outcomes. Relevant databases were searched in any language and unpublished studies were considered. There was minimal evidence of publication bias but most of the studies identified did not report data for the primary outcomes. Study quality was assessed using suitable criteria. More than half of the studies were at a high risk of bias for three or more of the assessment criteria. Validity assessment and study selection were carried out with efforts to reduce error and bias; whether this also applied to data extraction was not clear.

Relevant study details were reported but there were no details of gender and minimal details of patient age. Statistical heterogeneity was assessed and a large majority of the meta-analyses showed minimal or moderate heterogeneity. The statistical method used for the meta-analysis of the RCTs seemed appropriate. Relevant subgroup analyses were performed. There was no sensitivity analysis to examine the impact of risk of bias on the results.

In reaching their conclusions the authors did not allow for the biases that may have affected many of the studies; their conclusions appear unlikely to be reliable.

**Implications of the review for practice and research**
Practice: The authors recommended that surgeons who performed laparoscopic colorectal surgery should inform patients of the potential increased risk of complications, prospectively audit rates of intraoperative complications for their individual practice and reconcile these with any short-term postoperative benefits gained.

Research: The authors identified a need for future RCTs to record and report rates of intraoperative complications.

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