Laparoscopic-assisted resection of colorectal malignancies

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Authors' objectives
To assess the safety and efficacy of laparoscopic-assisted resection of colorectal malignancies compared with traditional open surgical procedures.

Searching
Current Contents, MEDLINE (from 1984 to July 1999), EMBASE (from 1974 to July 1999) and the Cochrane Library (Issue 2, 1999) were searched. The search terms included combinations of 'colectomy', 'resection', 'hemicolectom*', 'laparoscop*', 'neoplasm', 'endoscp*', 'colorectal' and 'cancer'. A full list of terms was provided in the report. Following the initial search, which considered studies reported in any language, the search was restricted to English language papers if articles in other languages were not considered to be superior. Given the large volume of studies identified, this effectively meant that only randomised controlled trials were considered in non-English language literature.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials, controlled clinical trials, case series and case reports in humans were eligible. In vivo and in vitro studies of tumour cell spread in animals were also included. Additional published letters, conference material, commentaries and discussions were included as background information. While a variety of study designs were eligible, the authors state that many of the lower quality papers included data for patients that were excluded by the review protocol, for instance, people who underwent abdominoperineal resections.

Specific interventions included in the review
Studies assessing laparoscopic (total) or laparoscopic-assisted resection of the colon, including right hemicolecotomy and/or sigmoid/left hemicolecotomy, with or without colostomy, were eligible. The comparative intervention was open colorectal resection. While the authors stated that studies of interventions with abdominoperineal resection, transverse colectomy or total colectomy were excluded, it was also stated that three papers did include these invalid procedures (papers shown in Table 2 of the report).

Participants included in the review
Studies of people with adenocarcinoma of the colon were eligible. In vivo or in vitro studies of tumour cell spread in animals were also eligible. The authors did not provide details about the total number of participants or their disease or demographic characteristics.

Outcomes assessed in the review
To be eligible for inclusion, the studies had to include at least one of the following outcomes: 3- and 5-year disease-free survival rates; post-operative mortality; post-operative complications; oncological factors; post-operative pain; operative time; start of oral food intake; length of hospital stay; total hospital costs; time to resumption of normal activities; conversion rate; and immunological response. Animal studies had to include data on the number of tumour sites and/or tumour volume.

How were decisions on the relevance of primary studies made?
Two reviewers were involved in selecting the studies for the review. The selections were made by one reviewer and checked by a surgeon. The authors did not state whether the reviewers were independent or blinded when selecting the papers for inclusion.

Assessment of study quality
The authors do not report a method for assessing the quality of the individual studies. However, the included studies were rated using criteria developed by the Medical Services Advisory Committee. This hierarchy of evidence graded...
the studies according to six levels of evidence, based on the study design and randomisation method. The authors
reported in the text whether the studies within each grade were considered to be of good or poor quality overall, along
with information on blinding. The authors also examined the appropriateness of study exclusion criteria, the quality of
reporting, blinding, and possible confounding variables. The authors do not state how validity was assessed, or how
many of the reviewers performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data
extraction. Data were extracted on study design, location, year of publication, level of evidence, study population,
exclusion criteria and outcomes.

For studies that compared safety outcomes for patients undergoing laparoscopic colectomies with those undergoing
open procedures, measures of relative risk or relative risk reduction were calculated where possible.

Papers were only included in the analyses if they specifically reported on an item of interest and did not make
assumptions from the presence of missing data. For example, papers that did not report a complication rate were not
assumed to have zero complications. They were treated as if the data were missing and excluded from that particular
analysis.

Methods of synthesis
How were the studies combined?
The authors provided a narrative synthesis of the findings, and summary tables listing statistics from individual studies
where relevant.

How were differences between studies investigated?
The authors discussed differences between the studies in a narrative.

Results of the review
One hundred and sixty studies were included in the review. Eighty were review papers, 51 were human studies and 29
were animal studies. The authors did not provide a further breakdown of the study designs, although they provided
'levels of evidence' based on study design.

Mortality: data on peri-operative mortality were generally of a poor quality. Two randomised trials reported zero
mortality, while others did not report mortality data or did not state whether deaths resulted from treatment. Only two
non-randomised trials reported peri-operative mortality data. These found no significant differences between the
groups.

Data about long-term survival was also poor. Only one randomised controlled trial reported long-term survival data,
finding a non significant increase in the risk of death in the laparoscopically- assisted group, compared with open
surgery, after a minimum of 12 months' follow-up (relative risk 1.61, 95% confidence interval, CI: 0.47, 5.51). One non-
randomised controlled trial, one study with historical controls and five case series found no statistically- significant
difference between groups.

Disease-free survival: data on disease-free survival rates were also poor. None of the randomised trials reported data on
disease-free survival. Two non-randomised trials and two case series reported disease-free survival, for time periods
ranging from 2 to 5 years. There was no significant difference between the treatment groups.

Cancer recurrence: one randomised trial, one non-randomised trial, one non-randomised trial with historical controls
and three case series reported recurrence rates. There was no significant difference in recurrence rates between the
laparoscopic and the open surgery groups.

Port site recurrence: four randomised controlled trials found no port site recurrence. Out of 1,114 cases, including case
series but excluding case reports, there were 14 instances of port site recurrence.
Morbidity: there were insufficient data to draw conclusions about morbidity. Overall, it appears that laparoscopic and open procedures have similar morbidity rates.

Efficacy: the authors found evidence that laparoscopic colectomy, in comparison with open surgery, may be associated with quicker hospital discharge, less narcotic use, less pain at rest (at least for patients who have unconverted procedures) and earlier return of bowel function and resumption of normal diet. Potential disadvantages of laparoscopic-assisted surgery were longer operating times, cost, worse short-term immune effects, and an increased rate of serious cardiac complications.

Cost information
The authors reported data from one non-randomised trial with contemporary controls, which compared the hospital costs associated with laparoscopically-assisted and open colectomies. The laparoscopically-assisted group incurred significantly more total hospital costs than the open colectomy group; the overall mean cost was Aus$9,064 vs Aus$7,881. The authors noted several problems with the methods of this cost analysis.

Authors' conclusions
The safety and efficacy of laparoscopic-assisted resection of colorectal malignancies cannot be determined at present due to incomplete and poor-quality evidence. The procedure should be used with caution. It is recommended that further research be conducted to establish its safety and efficacy. While patients undergoing laparoscopic colectomy may be at greater risk of short-term suppression of the immune system, there is little evidence to suggest an increased risk of port site recurrence.

CRD commentary
This review is of a reasonable quality. The authors addressed a clearly defined research question and listed the inclusion and exclusion criteria. A number of databases were searched with, initially, no language restrictions. It is unclear whether the authors searched for unpublished material, but they do not specify having done so. A large number of studies were identified, although all were published.

Two reviewers extracted the data, although the procedures used to select the studies and extract the data were not described in full. The total number of different study designs and participants from which the data were drawn is unclear. It is therefore not possible to make complete assessments of the quality of the studies included in the review. It appears that many of the studies included were of a limited quality. The authors did not report a method of weighting the findings to account for variations in study quality when synthesising the results narratively.

The authors did not examine the possibility of publication bias, or other problems which could impact on their findings. Although an appropriate narrative synthesis was used to collate the findings, it was difficult to synthesise the findings given the large variations in study design, sample size, follow-up periods and outcomes assessed in the different studies. This made it difficult for the authors to draw firm conclusions.

Overall, the data support the authors' conclusions, although the limited quality of the studies included and the wide variations between the studies make it difficult to assess the generalisability of the findings. As the authors suggest, further high-quality research is needed before firmer conclusions can be drawn.

Implications of the review for practice and research
Practice: The authors suggest that laparoscopic colectomy appears to be more expensive and to take longer than traditional open surgery. The safety and efficacy of laparoscopic-assisted resection of colorectal malignancies cannot be determined at present due to incomplete and poor-quality evidence.

Research: The authors suggest a controlled clinical trial, ideally with random allocation, is required because of the lack of evidence detailing the circumferential marginal clearance of tumours in the rectum, ascending and descending colon, and the need to determine a precise incidence of cardiac and other major morbidity.
Bibliographic details

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.