Randomized clinical trial comparing laparoscopic and open surgery for colorectal cancer within an enhanced recovery programme


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined laparoscopic and open resection for colorectal cancer (CRC).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised those patients under the care of one surgeon, in a single institution, who had been diagnosed with adenocarcinoma of the colon or rectum. Patients were excluded on the basis of any non-elective admission, preoperative evidence of distant metastases, aged less than 18 years, pregnancy, or refusal to consent to randomisation. A protocol amendment to exclude patients who were identified before surgery as unsuitable for epidural anaesthesia was made after one year.

Setting
The setting was secondary care. The economic study was undertaken in Yeovil, Somerset, UK.

Dates to which data relate
The effectiveness data and resource use data were gathered between January 2002 and March 2004. Year 2002 prices were used.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were used to determine the sample size. During the study period, 94 consecutive patients were assessed for entry into the trial. Twenty-one patients did not meet the inclusion criteria. Five patients were excluded because they were not suitable for laparoscopic surgery, while six were excluded for other reasons. Thus, 62 patients were randomised. After randomisation 2 patients were excluded, one because the histological finding was of a benign tumour and one was found to be unsuitable for epidural anaesthesia. Two patients who died were excluded from the
primary end point analysis of hospital stay. In summary, 41 patients received laparoscopic surgery and 19 received open surgery. The groups had similar baseline characteristics and tumour stages. The mean age of the participants was 72.3 years in the laparoscopic group and 70.4 years in the open group. Fifty-six per cent of the laparoscopic patients were male, compared with 42% of the open surgery patients.

Study design
The study was a randomised controlled trial that was carried out in a single centre (East Somerset NHS Trust, Yeovil, UK). Eligible patients were randomised on a 2:1 basis to laparoscopically assisted surgery or open surgery, stratified for colon or rectum. Randomisation was made by telephone call to a computer-generated randomisation programme. The duration of follow-up was 3 months, and there was no loss of patients during this time. Neither the patients nor the researchers were blinded.

Analysis of effectiveness
The analysis of effectiveness was conducted on an intention to treat basis. The primary outcome measure was hospital stay, calculated as the period from the date of operation to the date of discharge. Hospital stay, including convalescent stay and readmission stay, was a secondary outcome. Other clinical end points included morbidity, requirement for opioid analgesia, and anti-emetic administration. The patients were assessed for complications at the time of discharge and at 2 and 6 weeks after surgery. Quality of life was assessed using the validated cancer questions, the European Organization for Research and Treatment of Cancer QLQ-C30 and the CRC-specific QLQ-CR38 module11,12. Quality of life was assessed at baseline, and follow-up assessments were performed by post at 2 and 6 weeks after surgery. Comparisons between the laparoscopic and open groups were made using analysis of variance or logistic regression, as appropriate, adjusting for cancer site. Repeated measures analyses were conducted for quality of life data, correcting for cancer site and chemotherapy as potential confounders.

Effectiveness results
Patients who underwent laparoscopic surgery had a 32% shorter hospital stay than those undergoing open surgery (95% confidence interval, CI: 7 to 51; p=0.018).

The lengths of hospital plus convalescent stay and of hospital plus convalescent plus readmission stay were also significantly shorter after laparoscopic surgery. The combined hospital, convalescent and readmission stay was 37% shorter (95% CI: 10 to 56; p=0.012).

Major morbidity occurred in 11 patients, six after laparoscopic surgery and five after open surgery (odds ratio 0.40, 95 CI: 0.10 to 1.66; p=0.208).

In both groups, most aspects of quality of life deteriorated 2 weeks after surgery, but had improved by 6 weeks.

Repeated-measures analyses showed that scores in the two groups were similar.

Clinical conclusions
The study has shown improved short-term outcomes with laparoscopically assisted surgery for CRC compared with open surgery, when both were performed within an enhanced recovery programme. Both groups of patients had a shorter postoperative hospital stay than that reported with standard care for CRC, but after laparoscopically assisted surgery, the hospital stay was 32% lower than after open surgery. This difference remained significant when convalescent and readmission stay were included. Other short-term outcomes were significantly in favour of laparoscopic surgery.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.
**Direct costs**
Resource use and quantities were not reported separately. Information on resource usage was provided at the individual patient level, using hospital records and questionnaires sent to patients about their use of health resources at both 2 weeks and 3 months after the operation. The unit costs were calculated on the basis of local and national figures, and health resource unit costs after discharge were estimated from published national figures. The resource use data were collected during the study period (January 2002 to March 2004) and 2002 prices were used. However, there appears to have been no adjustment for inflation. Discounting was not required. The total costs of care included theatre costs, hospital (hotel) costs, postoperative costs, chemotherapy and radiotherapy, and follow-up costs.

**Statistical analysis of costs**
The mean cost estimates were derived from bootstrap estimations (10,000 iterations). The mean difference and 95% CI around this difference were reported.

**Indirect Costs**
The indirect costs were assessed by determining the number of days that patients in paid work (full or part time) took off for their condition. The resource quantities and the unit costs were not reported separately. There were no details of how these indirect costs were valued.

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
A univariate sensitivity analysis was undertaken. The duration of inpatient stay and use of community resources after hospital discharge were increased and decreased by 20%.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The average total cost was 6,433.40 for laparoscopic surgery and 6,786.90 for open surgery. This included the productivity loss, which was greater for the open surgery group.

The mean difference in costs between the two procedures was 353.50 (95% CI: -2,167.10 to 2,991.50).

The sensitivity analysis showed minimal effect on this overall mean difference, with variations in perioperative and inpatient costs affecting the difference by less than 100 in either direction.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
Despite perioperative optimisation of open surgery for colorectal cancer (CRC), short-term outcomes were better following laparoscopic surgery. There was no deterioration in quality of life or increased cost associated with the laparoscopic approach.
CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparator used, but it would appear to have been appropriate as open surgery generally represents current practice. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial which was appropriate for the study question. The study sample was representative of the study population. The patient groups were shown to have been comparable at baseline. Appropriate statistical analyses were undertaken to take potential biases and confounding factors into account.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences analysis.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted (i.e. that of the health sector) were included in the analysis. The authors also included indirect costs and, as such, the analysis was actually undertaken from a societal perspective. The costs were not reported separately from resource use, and there was no statistical analysis of the quantities. The unit costs were estimated using local and national sources. There was no statistical analysis of the prices, but the price year was reported. Discounting was not necessary given the short time horizon of the study.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and the scope of the analysis was clearly reflected in their conclusions.

Implications of the study
The authors suggested that laparoscopic resection of CRC within an enhanced recovery programme may provide the best short-term clinical outcomes for patients with resectable CRC.

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