Laparoscopic versus open colorectal surgery: cost-benefit analysis in a single-center randomized trial

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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 compared colorectal resection by laparoscopic surgery (LPS) with open colorectal surgery in patients with colorectal disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with colorectal disease. Inclusion criteria were age 18 years or older, and suitable for elective surgery. Exclusion criteria were cancer infiltrating adjacent organs, organ dysfunctions, ongoing infection and neutropenia.

Setting
The setting was inpatient tertiary care. The economic study was carried out at the San Raffaele University Hospital, Milan, Italy.

Dates to which data relate
The effectiveness and resource use data were collected between February 2000 and December 2003. The price year was not reported.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
No sample size appears to have been determined in the planning phase of the study to assure a certain power. Patients admitted to the authors' hospital for colorectal disease were assessed for study eligibility. Of the 588 patients assessed, 71 were excluded (14 refused to participate, 24 for infiltrating organ, 14 for cardiovascular problems, 8 for infection, 8 for respiratory problems, 2 for hepatic problems and 1 for neutropenia). Of the remaining 517 patients, 258 were allocated to LPS and 259 to open surgery.

Study design
The study was a randomised controlled trial (RCT) undertaken at a single centre. The patients were randomly allocated.
to LPS or open surgery using computer-generated randomisation lists according to the site of lesion. Four trained members of the surgical staff, who were not involved in the study, registered postoperative complications using an a priori definition. The patients were followed up for 30 days after hospital discharge. No patient was lost to follow-up.

**Analysis of effectiveness**

The primary health outcomes used were:

- infectious complications (i.e. wound, abdominal abscess, respiratory tract, urinary tract and sepsis);
- non-infectious complications (i.e. cardiovascular, bleeding, intestinal obstruction and ileus); and
- anastomotic leak.

The analysis of effectiveness was conducted on an intention to treat basis. At analysis, the patients groups were comparable in terms of their demographic characteristics (including age and gender) and clinical characteristics (e.g. Dukes’ stage and distribution of benign diseases).

**Effectiveness results**

The overall morbidity rate was 18.2% (n=42) in the LPS group versus 34.7% (n=90) in the open surgery group, (95% confidence interval, CI: 9.1 to 24; p=0.0005).

Twenty-four (9.3%) patients in the LPS group had an infectious complication compared with 53 (20.5%) patients in the open surgery group, (95% CI: 5.1 to 17.3; p=0.006).

Thirty patients in the LPS group had an infectious postoperative complication compared with 60 in the open surgery group, (p=0.0008).

The LPS group also had a lower wound infection rate than the open surgery group (6.2% versus 13.5%; 95% CI: 2.2 to 12.4; p=0.009).

There were no statistically significant differences between the two groups in terms of postoperative non-infectious complications and anastomotic leakage.

**Clinical conclusions**

The study showed that patients allocated to laparoscopic colorectal surgery had a significantly lower postoperative complication rate than patients allocated to open surgery.

**Measure of benefits used in the economic analysis**

In their objectives the authors reported that a cost-benefit analysis had been undertaken. However, as the outcomes were not converted into monetary benefits and no summary measure of benefit was derived, in effect, a cost-consequences analysis was performed.

**Direct costs**

The direct costs included in the economic analysis were those of the hospital. These included the costs of surgery, the mean in-hospital-related costs of routine surgical care, and the costs of treating postoperative infectious and non-infectious complications. Resource use was collected from the effectiveness study. The resources used in the treatment of complications were those documented in the patient records. They were recorded on a specific electronic record form, with the following items being assessed:

- complication type and duration;
laboratory and microbiology analysis;
medical, technical and diagnostic services;
surgical and therapeutic interventions;
medications; and
ambulatory follow-up consultations.

The unit costs were derived from the National List of Sanitary Costs. Discounting was not relevant, as the costs were incurred during a short time, and was appropriately not performed. The price year was not reported. The study reported the incremental costs. The costs and the quantities were not reported separately, although the authors reported the costs by category of resource use (i.e. operative room, length of stay, complications).

**Statistical analysis of costs**
Since the costs were not normally distributed, a bootstrap technique with 30,000 replicates was used to analyse the difference in costs between the two groups.

**Indirect Costs**
Productivity costs were not considered.

**Currency**
Euros (EUR).

**Sensitivity analysis**
A sensitivity analysis was used to evaluate the effect on the results of variations in certain underlying parameters. In this case, the authors analysed whether the exclusion of non-surviving patients had a major impact on the results.

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

**Cost results**
Compared with open surgery, the additional operative room charge in the LPS group was EUR 1,171 per patient randomised (EUR 864 due to surgical instruments and EUR 307 due to longer time).

The saving in the LPS group was EUR 1,046 per patient randomised (EUR 401 due to shorter length of stay and EUR 645 due to the lower cost of postoperative complications).

The net balance resulted in an extra cost of EUR 125 per patient randomised to the LPS group.

The results of the sensitivity analysis showed that censoring for death had no impact on the results.

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

**Authors' conclusions**
The results of the study showed a slight additional cost in the laparoscopic surgery (LPS) group in comparison with the
open surgery group. The better postoperative short-term outcome in patients receiving LPS had a key role in nearly balancing the operative room charges due to laparoscopy.

CRD COMMENTARY - Selection of comparators
Although no explicit justification was given for using open surgery for colorectal dissection as the comparator, it appears to have represented current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The study design was that of an RCT. This was appropriate for the study question since well-conducted RCTs are considered the 'gold' standard study design when comparing health interventions. The study sample was representative of the study population and the patient groups were shown to have been comparable at analysis. The method of randomisation, blinding, length of study and follow-up, and loss to follow-up were all appropriately reported. Further, the authors also reported the study design according to the CONSORT statement. These factors suggest that the internal validity of the study is likely to be good. Appropriate statistical analyses were undertaken to test for statistically significant differences between the two groups, but power calculations do not appear to have been undertaken. Nonetheless, the study sample was large (n=517) and the study appears to have had sufficient power to detect significant differences.

Validity of estimate of measure of benefit
In their objectives the authors reported that a cost-benefit analysis had been undertaken. However, as the outcomes were not converted into monetary benefits and no summary measure of benefit was derived, in effect, a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of the health care provider (i.e. the hospital). All the relevant categories of costs, and all relevant costs, appear to have been included in the analysis. Therefore, it is unlikely that any omissions would have affected the authors' conclusions. Resource use and costs were not reported separately, which will reduce the generalisability of the authors' results. The authors appear to have used charges to proxy prices. This might have affected the results as charges may not reflect the true cost to the hospital of providing a particular service. Discounting was not relevant, as the costs were incurred during a short time, and was appropriately not performed. The authors reported that non-parametric bootstrapping was performed to analyse differences in the costs. However, they only reported 95% CIs for the costs of complications, and did not report any intervals alongside the total costs, length of stay costs or costs of the operative room. The price year was not reported, which will hinder future inflation exercises.

Other issues
The authors reported that other studies had also found LPS to be associated with better outcomes and shorter hospital stay than open surgery. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. However, it would have been appropriate had the authors reported 95% CIs around the total per patient costs. The authors reported a number of further limitations to their study. These were associated with the issue of generalisability and transferability of their results. For example, they reported that the economic parameters used will differ between countries according to the type of health care and reimbursement system employed.

Implications of the study
Although the authors did not make any explicit recommendations, they would appear to suggest that LPS should be undertaken since it is associated with better outcomes and only a small incremental cost in comparison with open surgery.
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None stated.

Bibliographic details

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Other publications of related interest
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Indexing Status
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