Advantages of laparoscopic resection for ileocecal Crohn's disease
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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 use of laparoscopic surgery (LAP) for surgical resection was studied in patients with ileocecal Crohn's disease. The comparator treatment was the same surgery carried out by laparotomy (OPEN).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The population comprised patients undergoing elective initial resection for ileocecal Crohn's disease. Patients had to have no sign of enterocutaneous fistula or prior bowel resections.

Setting
The setting was secondary care. The economic study was carried out in Ohio, USA.

Dates to which data relate
The effectiveness evidence and resource evidence related to 1999 to 2000. The price year was 2000.

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

Link between effectiveness and cost data
The costing was carried out on the same patient sample as that used in the effectiveness analysis. It appears that the costing has been carried out retrospectively.

Study sample
No power calculations were reported. There was no sample selection, as all patients meeting the inclusion criteria were included. Forty-five patients were included in the study, of which 21 were in the LAP group and 24 in the OPEN group.

Study design
This was a single-centred, non-randomised controlled study in which the operating surgeon decided what type of surgery the patient should undergo. The patients were followed up until they left hospital.
Analysis of effectiveness
The analysis was conducted on an intention to treat basis. The health outcomes used to evaluate the two types of surgery were:

- the rate of conversion,
- the operating time,
- the intraoperative blood loss,
- the postoperative recovery times,
- the intraoperative and postoperative complication rates, and
- the time taken to return to work.

The two patient groups were found not to be comparable in certain respects. The median age in the OPEN group was slightly older (39 years, range: 19 - 63) than in the LAP group (31 years, range: 19 - 54), (p<0.05). There was a higher ratio of females to males in the OPEN group (15:9) than in the LAP group (9:12), (p<0.05). The body mass index was higher in the OPEN group (26, interquartile range, IQR: 23 - 30) than in the LAP group (21, IQR: 20 - 25), (p<0.05).

Effectiveness results
In the LAP group, conversion to formal laparotomy was necessary in one patient (conversion rate 4.8%).

The operating time in the LAP group was significantly shorter (median 75 minutes, IQR: 60 - 90) than in the OPEN group (median 98 minutes, IQR: 70 - 130), (p<0.05).

The intraoperative blood loss was statistically significantly less in the LAP group (50 mL, IQR: 25 - 100) than in the OPEN group (100 mL, IQR: 50 - 265), (p<0.05).

Postoperative recovery was significantly faster in the LAP group. For example, a nasogastric tube was used for 0 versus 1 day, (p<0.05) and there was earlier resumption of full liquids (0 versus 2 days; p<0.05). Patients in the LAP group also experienced earlier passage of flatus (2 versus 3 days; p<0.05) and an earlier time to first bowel movement (2 versus 4 days; p<0.05).

There were no intraoperative complications in either group.

The overall postoperative complication rate was not significantly different, 14.3% of LAP patients and 16.7% of OPEN patients.

The time before returning to work was shorter in the LAP group (4 weeks, IQR: 3 - 6) than in the OPEN group (6 weeks, IQR: 4 - 8), (p<0.05).

Clinical conclusions
The authors concluded that, in their hospital with surgeons experienced in LAP, patients did not suffer any harm undergoing LAP for ileocecal Crohn's disease and were able to resume normal activities earlier than if they had undergone surgery with OPEN.

Measure of benefits used in the economic analysis
No summary measure of benefits was produced. The study was, in effect, a cost-consequences analysis.

Direct costs
It would appear that the perspective adopted was that of the hospital. No discounting was carried out since the costs were incurred during less than a year. The costs included were those for laboratory services, pharmacy, radiology, anaesthesia, operating room and hospitalisation, and disposable operative equipment. The patient costs were not broken down into quantities and costs. Hospital costs per patient were calculated using actual data provided by the hospital. The price year was 2000.

Statistical analysis of costs
No statistical analysis was carried out.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
The cost per patient was $2,547 in the LAP group and $2,985 in the OPEN group, (p<0.05).

The costs until discharge were included.

The costs of adverse effects were dealt with in the costing.

It was unclear whether the 2 patients in the LAP group who were readmitted had the costs of their readmission included.

Synthesis of costs and benefits
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Laparoscopic surgery (LAP) was cheaper than laparotomy (OPEN) for patients with ileocecal Crohn's disease. It also brought with it the advantages of quicker recovery time and an earlier return to work.

CRD COMMENTARY - Selection of comparators
The choice of the comparator (conventional surgery via OPEN) was justified by it being the surgical alternative to LAP in many settings. You should decide if it represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The analysis was based on a non-randomised trial with concurrent controls. A randomised controlled trial (RCT) would have provided a more robust estimate of effectiveness,
as well-conducted RCTs are considered the 'gold' standard when comparing different health interventions. The fact that the patients were non-randomly allocated to the type of surgery means that the conclusions cannot be extrapolated to all patients needing resection. The study sample was representative of the study population since all patients meeting the inclusion criteria were included in the study. The patients groups were shown not to be comparable at analysis and adjustments for confounding factors were not performed. This is another drawback to the study. The analysis of effectiveness was handled credibly in that the authors acknowledged the disadvantages of a non-randomised trial. They also realised that the study was short term only, and that a full evaluation of the two types of surgery would require a longer follow-up. There were no other sources for the effectiveness data.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The health benefits were therefore those associated with the effectiveness outcomes.

**Validity of estimate of costs**
Given the cost perspective adopted, which appears to have been that of the hospital, it was unclear whether all the relevant costs were included in the study. For example, it was unclear whether staff physician costs and costs of hospital readmissions were included. If the costs of hospital readmissions were not, this would have biased the results towards underestimating the cost of LAP. The authors reported that some costs were not included, these being described as "indirect fixed and variable indirect costs", but these were not defined. It was not clear whether these cost omissions could have biased the authors' results. The health care costs were not calculated after hospital discharge, and it was unclear whether this would have biased the cost results in a particular direction.

The costs were not reported separately from the quantities. There was also very little cost information provided, which would make it difficult for decision-makers in other settings to assess the cost results. The resource use quantities were taken from a single study alone, while the prices were taken from the authors' setting only. No analyses were carried out on either the quantities or the prices. The price year used was 2000, which will facilitate any future reflation exercises.

**Other issues**
The authors made appropriate comparisons of their results with the findings from other studies. The issue of the generalisability to other settings was not addressed, although the authors pointed out that the surgeons in the study were all experienced in performing this kind of LAP. The authors did not present their results selectively, but their conclusions did not reflect the disadvantage of the non-randomised nature of the study and the lack of comparability of the patient groups. Also, the authors did not seem to be aware of the limited usefulness of the cost data that they provided.

**Implications of the study**
The authors concluded that LAP for patients with ileocecal Crohn's disease should become much more widely accepted as it leads to quicker recovery time and is less expensive. However, the comments made about the lack of randomisation, lack of long-term follow-up and lack of detailed cost data mean that more research is needed to confirm the authors' conclusions.

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