Laparoscopic-assisted versus open ileocolic resection for Crohn's disease: a randomized trial

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-assisted ileocolic resection for the treatment of Crohn's disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients requiring ileocolic resection for Crohn's disease.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The clinical effectiveness and resource use data were collected between 2000 and 2003. No price year was reported.

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

Link between effectiveness and cost data
The cost data were collected from the same patient sample that provided the clinical effectiveness evidence.

Study sample
Sample size calculations were reported. These indicated that the study had the power to detect a 20% difference between the two patient groups. Patients were recruited to the trial in the outpatient department. The study comprised 60 patients, of which 30 were in the laparoscopic resection group and 30 in the open resection group. Two patients were excluded from the study as they refused to be randomised to treatment.

Study design
The study was a multi-centre randomised controlled trial that involved three hospitals. The patients were randomised using sealed envelopes. There was no blinding of the patients or professionals to the treatment given. The patients were followed up for 3 months after surgery. Eight patients did not provide any postoperative quality of life data. This loss to follow-up was equal in both patient groups.
**Analysis of effectiveness**
The analysis of the study data was conducted on an intention to treat basis. The primary health outcome was quality of life, as measured by the SF-36 and Gastro-Intestinal Quality of Life Index (GIQLI). Other outcomes were operating times, length of hospital stay, morphine requirements, time to returning to normal diet, and complications and readmissions 30 days post surgery. The two patient groups were shown to be comparable at baseline.

**Effectiveness results**
There were no statistically significant differences in postoperative SF-36 and GIQLI scores between the two patient groups.

The mean operating time was 115 minutes (range: 70 to 255) in the laparoscopic group compared with 90 minutes (range: 30 to 160) in the open surgery group, (p=0.003).

The mean hospital stay was 5 days (range: 3 to 13) in the laparoscopic group compared with 7 days (range: 4 to 12) in the open surgery group, (p=0.008).

Three patients in the laparoscopic group and eight in the open surgery group had minor complications in the 30 days post surgery.

One patient in the laparoscopic group and four in the open surgery group had major complications in the 30 days post surgery.

No patients in the laparoscopic group but four in the open surgery group were readmitted within 30 days.

The morphine requirement was lower in the laparoscopic group than in the open surgery group (mean 29 mg versus 62 mg; p=0.27).

The mean time to return to normal diet was 4 days (range: 2 to 7) in the laparoscopic group compared with 4 days (range: 3 to 10) in the open surgery group, (p=0.003).

**Clinical conclusions**
The authors concluded that, compared with open surgery, laparoscopic ileocolic resection for Crohn's disease results in reduced morbidity and hospital stay.

**Measure of benefits used in the economic analysis**
No measure of health benefit was combined with the cost data. Therefore, a cost-consequences study was performed.

**Direct costs**
The direct costs of the hospital were included in this study. The resource use data were taken from the same patient sample that provided the clinical effectiveness data. The unit costs were taken from one of the hospitals participating in the study. Details of resource use, but not unit costs, were provided in the paper. No price year was reported.

**Statistical analysis of costs**
The differences in costs between the two patient groups were tested using Mann-Whitney tests.

**Indirect Costs**
No indirect costs were included in the study.
Currency
Euros (EUR).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The median total cost was EUR 6,412 (range: 4,195 to 35,569) in the laparoscopic resection group compared with EUR 8,196 (range: 4,964 to 19,018) in the open surgery group, (p=0.042).

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
There was no clear difference in clinical outcomes between laparoscopic and open resection, but laparoscopic resection had lower costs.

CRDCOMMENTARY - Selection of comparators
The authors compared laparoscopic ileocolic resection with open ileocolic resection for Crohn's disease. No explicit rationale for this choice was reported in the paper, but it would appear that open surgery was usual practice in the authors' setting. You should consider how this relates to usual practice in your own setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The measure of clinical effectiveness was taken from a randomised controlled trial, which is appropriate for the study question. Although it was not practical to blind the patients or health care professionals to the type of surgery, it is possible that this might have introduced some bias into the trial. The two patient groups were shown to be comparable at baseline. However, the authors did not compare their sample with the wider patient population, so it is not clear whether the sample was representative. An appropriate statistical analysis was undertaken on an intention to treat basis.

Validity of estimate of measure of benefit
No measure of health benefit was combined with the cost data. Therefore, a cost-consequences study was performed.

Validity of estimate of costs
The hospital costs were identified in this study. The paper did not provide a breakdown of the individual costs included in the study, so it was not clear whether all the appropriate costs were included. No statistical or sensitivity analysis was undertaken, which means that the extent of uncertainty around the cost data was not taken into consideration. A breakdown of resource use and unit costs was not provided, and the source of the unit costs was not reported. These factors reduce the generalisability of the study findings. No price year was reported, which will prevent any future reflation exercises.

Other issues
The authors do not appear to have presented their results selectively and their conclusions reflected their analysis. They did not consider how their findings could be generalised to other settings. However, they compared their results with other relevant studies and discussed the differences between them.

Implications of the study
The authors did not make any recommendations for further research or changes to practice. However, the findings support the use of laparoscopic-assisted ileocolic resection from both effectiveness and economic perspectives.

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