Randomised controlled trial of laparoscopic versus open repair of inguinal hernia: early results


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
Transabdominal laparoscopic repair of inguinal hernia performed as day surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with primary, unilateral inguinal hernia, less than 70 year old, who did not undergo previous major abdominal surgery or needed overnight admission.

Setting
Teaching hospital and district general hospital. The economic study was conducted in Oxford, UK.

Dates to which data relate
Effectiveness data were collected between December 1992 and December 1993. Costs related to 1992/93. 1992/93 market prices were used for costing consumables.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations were reported. 124 men randomised to laparoscopic or open repair of inguinal hernia. 66 were randomised to open surgery and 58 to laparoscopic repair. Initially, 130 patients were randomised of whom 129 underwent surgery. Four of these were female and were excluded from analysis. One patient was found to have a femoral hernia at the time of the surgery and was also excluded from the analysis.

Study design
Randomised controlled trial, multicentre study (2 centres). Follow-up at the onset for ten days, at six weeks and at three
months. Investigator at six weeks was not present at the operation. There was loss to follow-up (2-6%).

**Analysis of effectiveness**
The analysis was based on treatment completers. The health outcomes assessed in the analysis were: morbidity, postoperative pain and quality of life. Outcomes were assessed by questionnaires administered to patients postoperatively and by outpatient review. Linear analogue pain scores (on a 0-100 scale) were used. Quality of life was assessed using a multidimensional profile measure of health status (short form 36). The patients' self reported health state was assessed using the linear analogue section of Euroqol.

**Effectiveness results**
One vascular complication (2%) occurred in the group that had open repair. Seven complications (12%) arose in the group that had laparoscopic repair (difference in complication rate 10%, 95% confidence interval: 4% to 18%; P=0.02). Pain scores and quality of life showed a significant benefit to the laparoscopic group in the early postoperative period. Return to normal activity was not significantly different between the two groups.

**Clinical conclusions**
Laparoscopic repair was associated with a higher risk of complication than open repair of inguinal hernia.

**Measure of benefits used in the economic analysis**
The health outcomes assessed in the analysis were: morbidity (complication rate), postoperative pain and quality of life. Outcomes were assessed by questionnaires administered to patients and by outpatient review. Return to normal activity was assessed by questionnaire. Linear analogue pain scores (on a 0-100 scale) were used. Quality of life was assessed using a multidimensional profile measure of health status (short form 36). The patients' self reported health state was assessed using the linear analogue section of Euroqol.

**Direct costs**
Costs and quantities were reported separately. Direct health service costs were considered: consumables, staffing, theatre, equipment. 1992/93 market prices were used for consumables, including VAT. Estimates of costs were based on actual data (units of analysis plus DHA's data). Learning effects for the laparoscopic procedure were discussed.

**Statistical analysis of costs**
Differences in use of analgesics were assessed performing a X2 test to compare laparoscopic and open procedures. Operating time was compared in the two groups using Student's t test. An unpaired t test was used to compare theatre costs in the two groups, and the mean difference in costs was calculated.

**Indirect Costs**
Lost working days were reported for the intervention and comparator groups. Estimates were based on actual data.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
One vascular complication (2%) occurred in the group that had open repair. Seven complications (12%) arose in the group that had laparoscopic repair (difference in complication rate 10%, 95% confidence interval: 4% to 18%; P=0.02). Pain scores and quality of life showed a significant benefit to the laparoscopic group in the early postoperative period. Return to normal activity was not significantly different between the two groups.

**Cost results**
Total theatre costs were higher in the group that had laparoscopic repair- mean cost 850 compared with mean cost for open repair 268 (p < 0.001). Only 15% of the costs were explained by the surgeons' learning curve.

**Synthesis of costs and benefits**
Laparoscopic repair of inguinal hernia generated higher theatre costs and greater complication rates.

**Authors' conclusions**
Because of greater complication rate and higher theatre costs for laparoscopic repair the results of larger trials of clinical and cost-effectiveness using recurrence as the primary outcome measure should be known before laparoscopic hernia repair is widely adopted.

**CRD Commentary**
One of the best studies reviewed so far. The study is methodologically sound and its methods and results are presented in a clear and detailed way. A sensitivity analysis would have been useful to test the robustness of the results, given that the economic analysis was conducted in the 'constrained' setting of a RCT.

**Implications of the study**
The results of larger trials of clinical and cost-effectiveness of laparoscopic hernia repair using recurrence as the primary outcome measure are needed before laparoscopic hernia repair is widely adopted.

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