Cost-utility analysis of open versus laparoscopic groin hernia repair: results from a multicentre randomized clinical 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
Laparoscopic and open repair for groin hernia were examined. Laparoscopic repair was performed using either a transabdominal preperitoneal or a totally extraperitoneal approach. Open repair was mainly performed using tension-free mesh repair.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis; cost-utility analysis.

Study population
The study population comprised patients with an inguinal or femoral hernia. The patients were excluded if they were medically unfit for anaesthesia. They were also excluded if they had a prior midline or paramedian incision, an incarcerated or inguinoscrotal hernia, an uncorrected coagulation disorder, or were pregnant.

Setting
The setting was a hospital. The economic study was carried out in 26 hospitals in the UK and Ireland.

Dates to which data relate
The effectiveness and resource use data were gathered from January 1994 to March 1997. The price year was 1998.

Source of effectiveness data
The effectiveness evidence was 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 analysis.

Study sample
Power calculations to determine the sample size were not reported. A total sample of 928 eligible patients was recruited at the 26 hospitals during the study period. Of these, 468 patients underwent laparoscopic hernia repair and 460 patients underwent open surgery. It was not reported whether some of the patients were excluded from the sample.

Study design
This was a multi-centre randomised controlled trial. The method of randomisation was not reported. The patients were followed for one year. No blinding method for the assessment of the outcomes was used.

**Analysis of effectiveness**

The basis of the analysis of the clinical study (intention to treat or treatment completers only) was unclear. The primary health outcome was the quality-adjusted life-year (QALY). This was measured through the EQ-5D questionnaire, which defines the health status in terms of five dimensions (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression). In order to obtain the QALY value, the scores obtained from each questionnaire for each health state were multiplied by the length of time spent in that specific state. The data were measured at three time points, i.e. 1 week, 1 month and 3 months after the operation. The EQ-5D profiles were modelled over the period from baseline to 3 months by fitting power curves.

The secondary outcome measures were complications, return to usual social life, usual interests or hobbies or to paid employment, the recurrence of hernia, and groin pain persisting at 1 year. The comparability of the groups was not reported.

**Effectiveness results**

The mean utility scores at 1 week were 0.74 (standard deviation, SD=0.24) in the laparoscopic group and 0.68 (SD=0.24) in the open group, (p=0.003). The corresponding values at 1 month were 0.82 (SD=0.23) in the laparoscopic group and 0.79 (SD=0.22) in the open group, (p=0.12). At 3 months, the corresponding values were 0.85 (SD=0.22) in the laparoscopic group and 0.86 (SD=0.20) in the open group, (p=0.80).

The power curves showed that the overall mean gain in the laparoscopic group over the open group was 0.00583 QALYs.

The results for the secondary outcomes were as follows.

Laparoscopic group: the mean time to return to usual social life was 10 days (range: 7 - 21) days; the mean time to return to usual interests or hobbies was 14 days (range: 10 - 30); and the mean time to return to paid employment was 28 days (range: 14 - 42).

Open group: the mean time to return to usual social life was 14 days (range: 7 - 28); the mean time to return to usual interests or hobbies was 21 days (range: 10 - 42); and the mean time to return to paid employment was 42 days (range: 21 - 61). All of the differences were statistically significant.

One year after the operation, groin pain occurred in 28.7% of patients in the laparoscopic group and in 36.7% of those in the open group, (p=0.005). The recurrence of hernia was reported in 1.9% of the patients in the laparoscopic group and did not occur in the open group, (p=0.001).

The complications were not reported.

**Clinical conclusions**

Overall, a small improvement in terms of the QALYs was observed in the laparoscopic group when compared with the open group. In terms of the clinical outcomes, the laparoscopic approach was generally more effective than the open surgery approach.

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

The main benefit measure used in the economic analysis was the QALY. The secondary benefit measures were the times to return to usual activities (social life) and to usual interests or hobbies. All the benefit measures were derived from the effectiveness analysis. See the 'Effectiveness Results' section.
Direct costs
Although the time horizon of the study was one year, a 6% discount rate was used for potential future costs, such as those associated with recurrent hernias. The cost/resource boundary was that of the health service. The unit costs were reported, but the quantities of resources were not. The cost analysis included staff, theatre time, pharmacological agents, anaesthetic equipment, operating equipment, sterilisation, inpatient day, and follow-up appointments. The data on the quantities of resources used were obtained from the trial. The cost data were estimated using actual data derived from the centres involved in the study. The resources used were gathered between January 1994 and March 1997. The price year was 1998.

Statistical analysis of costs
Statistical analyses of the total cost data were conducted to test for statistical significance of the results.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling (£).

Sensitivity analysis
Sensitivity analyses were conducted to assess the robustness of the cost-utility ratio to variations in the cost of the laparoscopic equipment (reusable versus disposable) and in the length of stay. The analyses were presumably one-way. A threshold analysis was also carried out, to calculate the reduction in operating time required for the laparoscopic procedure to break even with the costs of the open repair.

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

Cost results
The operative costs were 998.15 in the laparoscopic group and 689.79 in the open group. The difference was 308.36 (95% confidence interval, CI: 259.18 - 357.53).

The postoperative and appointment costs were 114.49 in the laparoscopic group and 99.00 in the open group. The difference was 15.49.

The overall costs were 1,112.64 in the laparoscopic group and 788.79 in the open group. The difference was 323.85 (95% CI: 275.27 - 372.45).

Synthesis of costs and benefits
The costs and the benefits were combined using incremental cost-utility and cost-effectiveness analyses. The incremental cost per QALY of the laparoscopic approach over the open repair approach was 55,548.00 (95% CI: 47,216.00 - 63,885.00). In terms of return to usual activities (social life), the cost of an extra day's gain in usual activities for the laparoscopic procedure over the open repair was 80.97. In terms of return to usual interests or hobbies, the cost of an extra day's gain in usual interests or hobbies was 46.26.

The sensitivity analyses indicated that when reusable equipment was employed, the incremental cost per QALY gained with the laparoscopic procedure over the open repair was 24,612.00. When disposable equipment was used, the incremental cost per QALY gained was 102,439.00. Finally, the threshold analysis showed that the operating time at which the laparoscopic approach was equivalent in cost to open repair was 34 minutes.
Authors' conclusions
The laparoscopic approach led to significantly greater short-term benefits in terms of the quality of life when compared with the open repair approach. However, this difference was not statistically significant after 3 months. In addition, the costs of the laparoscopic procedure were quite high. Therefore, the laparoscopic intervention was not particularly cost-effective in comparison with traditional open repair.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. The laparoscopic and open repair approaches represented the new and traditional techniques, respectively, for the treatment of patients with groin hernia. You should assess whether they represent widely used health interventions in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a randomised clinical trial and a very large sample size. Thus, the internal validity of the study is likely to be high. However, it was not reported whether the patient groups were comparable at baseline. In addition, the basis for the analysis of the clinical study was unclear. The main outcome measure was represented by the QALYs, which were estimated on the basis of the patients' preferences. In the long run, these estimated QALYs were similar in both study groups. The authors stated that generic QALYs might not be appropriate to identify relevant differences in the surgical outcomes. These issues must to be taken into account when interpreting the study's results.

Validity of estimate of measure of benefit
The main benefit measure was the QALY gained using the laparoscopic approach over the open repair. It was derived directly from the effectiveness analysis.

Validity of estimate of costs
The perspective of the study was that of the health service system. It appears that all the relevant categories of costs have been included in the analysis. The unit costs and the price year were reported separately. Statistical analyses of the cost results were carried out. Sensitivity analyses were conducted to take into account the high variability of the costs among the different study centres. These features of the cost results strengthen their internal and external validity.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of the generalisability of the study to other settings was not explicitly addressed. Few sensitivity analyses were conducted.

Implications of the study
The authors suggested that future research should be carried out in order to provide a better assessment of the patients' preferences for different outcomes, especially in the case of specific surgical procedures.

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Bibliographic details

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