Randomised controlled trial of laparoscopic versus open mesh repair for inguinal hernia: outcome and cost


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 versus open mesh repair for inguinal hernia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with inguinal hernia.

Setting
The setting was two acute general hospitals in the UK.

Dates to which data relate
The cost data were from the years 1996/97. Drug prices and the cost of community based health services were based on costs published in 1996. The effectiveness data were based on the patients enrolled in the trial between May 1995 and December 1996.

Source of effectiveness data
The evidence for effectiveness was based on a single randomised controlled trial.

Link between effectiveness and cost data
The costing conducted for the study was undertaken on the same patient sample as that used in the effectiveness study, and was conducted prospectively alongside the effectiveness study.

Study sample
The study sample consisted of all patients who presented with inguinal hernia at one of two acute general hospitals in the UK. Patients were excluded from the study if they were considered to be unfit for general anaesthesia, had psychological complaints, were pregnant, were under 18 years of age, or had a poor understanding of English. Power calculation based on a previous study estimated that 340 patients would be required to provide 80% power at the two-sided 5% significance level, in order to detect a 26% change in analgesic use and a 19% change in days until normal activity. A total of 551 patients were screened for entry into the trial, 403 of whom were recruited into the trial. Of the remaining 148, 59 refused to take part and 89 were considered to be ineligible. Three patients were excluded from the
final analysis (one did not have a hernia, one had a femoral hernia, and one withdrew following randomisation), although it was not reported which intervention group they belonged to. 200 patients underwent laparoscopic hernia repair and 200 underwent open mesh repair. The two groups were reported to be comparable, with the exception that more patients undergoing laparoscopy had hypertension compared to the open mesh group (32 versus 16).

**Study design**
The study was a randomised controlled trial which took place in two acute general hospitals. Patients were followed-up for a total of 3 months. Patients were randomly allocated to the two treatment groups in balanced blocks randomly chosen to be of length 4 or 6. Allocations were placed in consecutive sealed opaque envelopes, and the seal broken in the anaesthetic room immediately before surgery. The analysis was conducted on the 400 patients who received the operations to which they had been allocated (3 patients were excluded from the analysis following randomisation). No blinding of patients, clinicians or outcome assessors was attempted, in common with most surgical trials.

**Analysis of effectiveness**
The analysis was stated to be based on intention to treat, however 3 patients who were included in the randomisation process were in fact excluded from the analysis. Outcomes were assessed by using a patient diary card filled in for the first 7 days after surgery and at the end of the 2nd, 3rd and 4th weeks. Further data were collected by a research nurse at outpatient visits at 1 week, 1 month and 3 months after surgery. The primary health outcomes assessed were: intraoperative and anaesthetic complications; length of stay; pain scores at various time points using a visual analogue scale; function and well-being (measured using the SF-36); the duration of convalescence (assessed from patient diary cards); return to employment at 3 months; and patients’ level of satisfaction.

**Effectiveness results**
Few intraoperative complications were seen in either group. In terms of length of stay, significantly more patients in the open repair group went home on the day of the operation than those patients in the laparoscopy group (191 versus 177, P<0.01). Nausea, dizziness and headache at 0.5, 1 and 2 hours following surgery were more common following laparoscopy, due to the use of a general anaesthetic in this group. Laparoscopic patients also experienced significantly more pain at these time points and at 4 hours after surgery than the open repair group (P<0.01). No analgesia was required on the day unit in 167 open repair patients compared to 132 laparoscopic repair patients (P<0.01). The visual pain scores recorded in patients’ diary cards revealed significantly less pain in the laparoscopy group on each of the first 7 days (P<0.01) and for the second week (P=0.03) following surgery. No significant differences in pain scores were seen between groups at weeks 3 or 4.

During the first 3 months after surgery, there was a significantly higher rate of wound infection, persisting groin or thigh pain, genital swelling, local numbness and constipation in the open repair group (P<0.01). At 1 month after surgery there was greater improvement (or less deterioration) in mean scores on the SF-36 compared to baseline in the laparoscopic group compared with the open group for each of the 8 dimensions of the instrument except general health. This difference was significant (P<0.05) for five dimensions. At three months after surgery there were no significant differences between the two groups. The median time at which patients returned to activity was shorter for the laparoscopy group (significant to P<0.05 for 9/11 activities). Patients having laparoscopic surgery were more satisfied with surgery at both 1 month and 3 months follow-up (P<0.01).

**Clinical conclusions**
In terms of effectiveness all the patient-based outcomes and pain after the day of operation favoured laparoscopic repair or were equivalent.

**Measure of benefits used in the economic analysis**
No single measure of benefit was produced from the effectiveness results. Instead, costs were considered as a trial outcome, and a mean cost per patient undergoing each type of surgery was produced.
Direct costs
Direct costs included operating theatre resources, operative drugs (antibiotics and anaesthetic), consumables used during surgery, equipment, the cost of treating operative complications, and the cost of hospital stay. Costs were valued at 1996/97 prices. Staff costs were based on midpoint salaries and include employers' costs. Drug and equipment costs included VAT and were in accordance with manufacturers' list prices. Equipment costs were translated into an equivalent annual cost using a 6% discount rate and estimates of each item's useful life expectancy. No further discounting was undertaken.

Statistical analysis of costs
Kaplan-Meier estimation was used to estimate the mean (SE) cost.

Indirect Costs
Indirect costs were based on costs to the health service incurred following surgery, including visits to a GP, home visits from a nurse, outpatient visits, and hospital readmissions.

Currency
UK pounds sterling (€).

Sensitivity analysis
Sensitivity analysis was carried out to assess the effect on differential cost of a "mainly disposable consumables" policy and a "mainly reusable equipment" policy, and to assess the importance of variation in the unit cost of stay on the day case unit and on a surgical ward.

Estimated benefits used in the economic analysis
No estimated benefits were used in the economic analysis. As such, the effectiveness results are assumed to be the benefits of the intervention compared with the comparator.

Cost results
The mean costs at 3 months follow-up were 746.87 per patient for laparoscopic repair (SE 35.19) and 412.27 per patient for open repair (SE 41.14), giving a mean cost difference of 335 per patient (95% CI: 228 to 441). This cost difference was driven by the higher cost of theatre consumables (mean difference 281, 95% CI: 271 to 291) and equipment (mean difference 31, 95% CI: 30 to 31) incurred by the laparoscopic approach. Sensitivity analysis showed that if, as part of the laparoscopic procedure, reusable scissors were used and instead of stapling the mesh into place it was stitched, the mean difference in cost would fall to 75, (95% CI: -31 to 181). If a "largely disposable" policy was followed, the mean cost difference would increase to 523 (95% CI: 419 to 626). Plausible changes in the cost of an hour on the day case unit, and the cost of a day on the ward had a very small effect on the differential cost of the two procedures.

Synthesis of costs and benefits
No synthesis of costs and benefits was undertaken. An incremental cost analysis was undertaken.

Authors' conclusions
Laparoscopic hernia repair is more effective than open repair in terms of patient-based outcomes and pain after the day of the operation, but at a higher cost.

CRD COMMENTARY - Selection of comparators
The selection of comparators for this study was adequate, and the trial was well conducted in terms of study design (sample size, power calculations, randomisation procedure, outcome measures) and analysis. The only flaw in the study is the statement of the use of intention to treat analysis when in fact 3 patients who were included in the randomisation process were excluded from the analysis. However this is not likely to have a large effect on the results of the study.

Validity of estimate of benefits:

No specific measure of benefit was used in the analysis. Costs were considered as an outcome of the trial, and a resulting mean cost per patient from each procedure was estimated. Costs and benefits were not directly synthesised in any form of cost-effectiveness analysis.

Validity of estimate of costs
The estimation of costs was conducted in a valid and appropriate way. The analysis was conducted from the perspective of the health service and all apparently relevant costs were considered.

Other issues
As an economic evaluation this study has limitations as no synthesis of cost and benefit was undertaken. The authors’ conclusion that laparoscopic hernia repair is more effective than open repair but not necessarily more cost-effective may be valid, however a full economic evaluation synthesising both costs and benefits is required.

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