Efficacy and safety of elective laparoscopic cholecystectomy in elderly: a case-controlled comparison with the open approach

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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
Elective laparoscopic cholecystectomy was compared with the open cholecystectomy approach in the treatment of elderly people with symptomatic, uncomplicated, gall bladder disease. Laparoscopic cholecystectomy was performed with 4 trocars and the patient placed supine with lower legs wide, inclined to 45 degrees, and placed on stirrups. The first trocar was always introduced bluntly after the pneumoperitoneum was established, with the Verres needle introduced through the umbilicus. Open cholecystectomy was performed by a right subcostal incision with a classic autograde or retrograde cholecystectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised elderly male and female patients aged over 70 years with symptomatic, uncomplicated gallbladder disease. Patients with complications such as diffuse or localised peritonitis, septic shock, or gallbladder malignancy were excluded from the study.

Setting
The study setting was secondary care. The economic analysis was carried out in Italy.

Dates to which data relate
The effectiveness data were retrospectively collected for patients seen from June 1995 to October 1998. The resource utilisation data were collected during the same period. The date of the prices used was not stated.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively from the records of the same sample of patients as that used in the effectiveness study.

Study sample
There was no mention of whether power calculations were used to determine the sample size. The records of
consecutive patients who underwent the procedures were reviewed. The sample appears to have been appropriate for the clinical question. It took over 3 years at one institution to produce this number of patients. Twenty-four patients (age 74 +/- 4.1 years) underwent elective laparoscopic cholecystectomy and 11 patients (age 74 +/- 2.4 years) underwent open cholecystectomy.

Study design
The study used a retrospective, cohort study that was carried out in a single centre. The diagnostic evaluation of all patients included laboratory exams and abdominal ultrasound. The patients were submitted to laparoscopic or open surgery on the basis of the surgeons’ skills and attitude to laparoscopic surgery. In the postoperative period, analgesics (for pain relief) and antibiotics (for infectious prophylaxis) were administered to all patients in both groups. All of the patients were followed up weekly for a mean duration of 2 weeks (range: 1 - 4). There was no loss to follow-up.

Analysis of effectiveness
The primary health outcomes were complication rates, the length of hospital stay and the quantities of antibiotics consumed. The groups were comparable in terms of their age, gender, severity of disease and prevalence of major underlying comorbid diseases. Differences between the groups were not statistically significant.

Effectiveness results
Postoperative complication were 75% lower in the laparoscopic group than in the open group, 12.5% versus 54.5%, (95% confidence interval, CI, for the difference: -0.73 to -0.11; p=0.026).

The lower incidence of postoperative complications was reflected in the shorter hospital stay. The laparoscopic group had 50% shorter stay, 3.5 (+/- 2.1) days versus 7.6 (+/- 3.1) days, (95% CI for the difference: -5.3 to -2.9; p<0.001).

Analgesic consumption was 40% lower in the laparoscopic group than in the open group, 4.3 (+/- 2.5) mL versus 7.5 (+/- 3.1) mL, (95% CI for the difference: -4.6 to -1.9; p<0.001).

Antibiotic consumption was 50% lower in the laparoscopic group than in the open group, 5.8 (+/- 3.2) mL versus 12.1 (+/- 4.9) mL, (95% CI for the difference: -8.2 to -4.4; p<0.001).

Clinical conclusions
The authors concluded that elective laparoscopic cholecystectomy is a safe and effective procedure, especially when performed by an experienced surgeon.

Measure of benefits used in the economic analysis
No summary measure of benefit was used in the economic analysis. A cost-consequences analysis was therefore conducted.

Direct costs
The costs of the hospital were measured, which included hospital stay, analgesics and antibiotics consumed. The surgeons’ anaesthesiologists’ and nurses’ fees were excluded from the final analysis, as their fees were identical for both treatment options. Discounting was not carried out since the study period was less than one year. The quantities were reported, but the unit costs were not. The quantities and costs were estimated on the basis of patient records and charges of the institution. The quantities of resources were measured between June 1995 and October 1998. The price year was not stated.

Statistical analysis of costs
The costs were treated in a stochastic way. The data were summarised as the mean plus or minus the standard deviation.
The 95% CIs for the difference were also calculated to assess the size of the difference in comparison with the variability in the data sample. To determine the differences in the mean estimates, Students t-tests were performed on parametric data, while a chi-squared test was performed to compare proportions. Differences were considered to be statistically significant at p<0.05.

**Indirect Costs**
The indirect costs were not considered.

**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 analysis revealed a 25% cost-savings in the laparoscopic group, as deducted from the total hospital charges, $2,565 (+/- $805) versus $3,578 (+/- $1,199), (95% CI for the difference: -1,486 to -540.7; p<0.01).

**Synthesis of costs and benefits**
The estimated costs and benefits were not combined. However, the evidence implies that elective laparoscopic cholecystectomy dominated open cholecystectomy since both the complications and the costs were lower for the laparoscopic approach.

**Authors’ conclusions**
The findings indicated that an elective laparoscopic approach is well tolerated, cost-effective and allows curative treatment with low morbidity.

**CRD COMMENTARY - Selection of comparators**
There was no explicit justification given for the comparator used, although it would appear to represent current practice in the authors' setting. You should decide if the comparator represents current practice in our own setting.

**Validity of estimate of measure of effectiveness**
The analysis used a retrospective cohort study, which may have introduced biases and confounding. The results may also have been biased since the patients were allocated to a treatment according to the doctors’ skills and attitudes towards the treatment options. The authors acknowledged that the fact that the study was neither randomised nor prospective was a limitation. The study sample was very small, albeit constrained by the circumstances. This raises doubts about the reliability of the results. The patients were shown to be comparable at analysis.

**Validity of estimate of measure of benefit**
No summary measure of benefit was used.
Validity of estimate of costs
Some relevant costs were omitted from the analysis. The surgeons’, anaesthesiologists’ and nurses’ fees were excluded as they were considered to be identical for both surgical procedures. Although these costs were omitted, they are unlikely to have affected the authors’ conclusions. The quantities were reported, but the unit costs were not. A statistical analysis of the quantities and costs was performed. However, the sample size was low, thus introducing uncertainty in the results. No details were given on whether charges were used to proxy prices, and the date to which the prices related was not reported. This hinders generalisability of the results to other settings.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The results of this study were broadly consistent with the studies quoted. The issue of generalisability to other settings was not addressed. The authors discussed the limitations of their study design, as already mentioned. The results were reported in full.

Implications of the study
The authors suggest that the elective laparoscopic approach can become the procedure of choice, even for elderly patients, as it is well tolerated, cost-effective and most importantly, permits curative treatment with low morbidity.

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Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
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