A population-based cohort study comparing laparoscopic cholecystectomy and open cholecystectomy

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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
The use of laparoscopic cholecystectomy (LapC) and open cholecystectomy (OpenC) in patients with gallbladder and biliary conditions needing cholecystectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing OpenC and LapC.

Setting
The setting was secondary care. The economic study was carried out in North Carolina, USA.

Dates to which data relate
The effectiveness evidence and resource use data related to 1991 to 1994. No price year was given.

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

Link between effectiveness and cost data
The same patients provided both the cost and effectiveness data. The costing appears to have been carried out prospectively.

Study sample
No power calculations were reported. There was no sample selection. All patients from the North Carolina Hospital Discharge Abstract Database undergoing OpenC and LapC between 1991 and 1994, and who met the inclusion criteria, were included in the study. Patients with gallbladder and biliary conditions needing cholecystectomy were included. Patients who had an endoscopic retrograde cholangiopancreatography, intraoperative cholangiogram, or percutaneous transhepatic cholangiogram were identified. There were 43,433 patients overall, 19,662 in the LapC group and 23,771 in the OpenC group.
Study design
This was a retrospective, multi-centred study (covering all hospitals in North Carolina). The patients were followed up until hospital discharge. The fact that the data were taken retrospectively from a clinical database means that there was no loss to follow-up.

Analysis of effectiveness
The analysis was conducted on an intention to treat basis. The health outcomes used to assess the patients were:

the prevalence of biliary tract diseases;
the mortality rate;
the percentage needing home care at discharge; and
the complication rate.

The patients were not comparable at baseline. The LapC patients were younger (mean age 51.3 years, standard deviation, SD=18.6) than the OpenC patients (55.5 years, SD=18.8), (p<0.05). There was a higher percentage of females in the LapC group (74.3%) than in the OpenC group (67.4%), (p<0.05). The age-adjusted Charlson comorbidity index showed that OpenC patients were in slightly worse health than LapC patients, 4.3 (SD=1.9) versus 4.1 (SD=1.6), (p<0.05). When determining the effect of surgery on mortality, the authors took the differences between the patient groups into consideration.

Effectiveness results
The prevalence of patients with acute cholecystitis who underwent LapC increased, while the prevalence of patients with acute cholecystitis who underwent OpenC increased slightly and then started to decline.

Mortality was higher in the OpenC group (1.8%) than in the LapC group (0.4%), (p<0.05).

The percentage of patients needing home care after discharge was also higher in the OpenC group (2.5% versus 1.2%; p<0.05).

The complication rate was given for each year and was higher in the OpenC than in the LapC group. The incidence was 6.01% for OpenC and 3.84% for LapC in 1991, (p<0.001), and 10.15% (OpenC) and 4.67% (LapC), respectively, in 1994, (p<0.001).

When an adjustment was made for age, co-morbidities, gender and type of admission, OpenC was associated with a higher risk of mortality than LapC (odds ratio 3.0, 95% confidence interval: 1.4 - 6.5; p=0.01).

Clinical conclusions
The authors concluded that, despite a higher proportion of patients with acute cholecystitis, LapC was associated with a lower risk of mortality than OpenC, even when accounting for the different patient characteristics in the two patient groups.

Modelling
A regression model was used to assess the effect of LapC when allowing for age and co-morbidity.

Measure of benefits used in the economic analysis
No summary measure of benefits was used. As such, the authors carried out a cost-consequences analysis.
Direct costs
This study considered only the hospital costs. No discounting was carried out since the costs were incurred during less than 2 years. The quantities and the costs were not analysed separately. The costs were derived using data on charges from the hospitals. The hospital costs were measured, but no information was given on the composition of those costs. The unit costs were taken from the authors’ setting. The costs were calculated during the hospital stay. No price year was given.

Statistical analysis of costs
Simple descriptive statistics were given for the costs.

Indirect Costs
No indirect costs were estimated.

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 mean costs were $9,139 for the LapC patients and $12,125 for the OpenC patients, (p<0.05).

The mean total charges were consistently lower for LapC than for OpenC between 1991 ad 1994.

When an adjustment was made for age, co-morbidities, gender and type of admission, the type of surgery had the second strongest association with charges (regression coefficient $3,868.9, 95% confidence interval: 2,435.8 - 5,302.0; p<0.01).

Synthesis of costs and benefits
The costs and benefits were not combined as the study was, in effect, a cost-consequences analysis.

Authors' conclusions
Laparoscopic cholecystectomy (LapC) cost less and had better outcomes for patients than open cholecystectomy (OpenC).

CRD COMMENTARY - Selection of comparators
The choice of the comparator (OpenC) was justified by it representing current practice in many settings. You should decide if it represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study. The analysis was based on a retrospective examination of patient records. A randomised controlled trial (RCT) would have provided a more robust estimate of effectiveness, as
well-conducted RCTs are considered the 'gold' standard when comparing different health interventions. For example, the assessment of complications associated with the interventions would come from the RCT and would not be based on a retrospective list of complications reported in the literature, as was the case in this study. Although the authors tried to account for the differences in patient characteristics at baseline, they did not address the question of how the patients had been selected for the different types of surgery. The study sample was representative of the study population, as all patients undergoing the two kinds of surgery in the region were included. The two groups were not comparable at baseline, but adjustments for confounding factors were appropriately performed and an appropriate statistical analysis was undertaken. There were no other sources for the effectiveness data.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The health benefits were therefore those associated with the effectiveness outcomes.

Validity of estimate of costs
The cost perspective adopted was that of the hospital. The study assessed resource use in terms of length of stay in the hospital, and laboratory tests, physician and pharmacy costs were not included. It was unclear how those omissions would have affected the authors' conclusions. The costs and the quantities were not reported separately, thus limiting the generalisability of the authors' results to other settings. The resource use quantities were taken from the discharge records of patients leaving hospital. No sensitivity or any other kind of analysis was carried out on the quantities to identify the degree of certainty around the differences in costs between the two groups. The authors derived unit costs from their own setting. No statistical or any other kind of analysis of the prices was carried out. The effect of prices changing over the 4-year period was not considered and no constant price year was used, which will hinder future reflation exercises. Charges were used to proxy prices. Discounting was unnecessary since all the costs were incurred during less than 2 years.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies, but did not address the issue of generalisability. They cited the fact that their data came from several hospitals and a large geographical region as a strength of their study, but they did not test for variability of their results from the different centres. There were several drawbacks of the cost data. Physician fees were not included, charges were used as a proxy for costs, no adjustments were made for changing price levels, and there was no breakdown of prices and quantities and of different cost components. These make it difficult to generalise the results to other settings difficult. The authors did not present their results selectively, but their conclusions do not reflect the scope of the analysis.

The authors were aware of some of the limitations of their study. First, they realised that ideally a RCT would be best and accepted that it is not possible to account for the reasons why a surgeon decides to use LapC or OpenC, although they did not think this affected their main conclusions. Second, a retrospective examination of patient records may be subject to errors in classification of diagnoses and procedures. Third, the lack of data after hospital discharge may have given a misleading picture of patient outcomes, although the authors pointed to evidence on the need for home care which showed an advantage to LapC over OpenC.

Implications of the study
The authors considered that their study showed morbidity and mortality to be better with LapC than with OpenC, and that the costs were also lower. However the drawbacks of the study design and the inadequate cost data mean that their results are not as solid as presented.

Source of funding
Supported in part by grants from the National Institutes of Health (T32 DK07634, P30 DK34987), an award from the American Digestive Health Foundation, and a Glaxo Wellcome Institute for Digestive Health Healthcare Advancement Award.