Bile duct stones and laparoscopic cholecystectomy: a decision analysis to assess the roles of intraoperative cholangiography, EUS, and ERCP

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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
Management strategies for patients undergoing laparoscopic cholecystectomy (LC).

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
An individual patient awaiting LC.

Setting
Hospital. This study was carried out in Charleston, South Carolina, USA.

Dates to which data relate
Effectiveness data were collected from studies previously published between 1974 and 1998. Resource use and cost data were collected from the Digestive Disease Centre, Medical University of South Carolina sources. The price year was not stated.

Source of effectiveness data
Effectiveness data were derived from a literature review and estimates of effectiveness.

Modelling
A decision model was used to determine the cost-effectiveness of the four clinical scenarios for patients undergoing LC.

Outcomes assessed in the review
The review assessed the following outcomes: the sensitivity and specificity of the 4 peri-LC management strategies, complication rates, hospitalisation rates, and rates of indeterminate procedures.

Study designs and other criteria for inclusion in the review
Prospective studies of IOCG and EUS accuracy.
Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Summary statistics from each study.

Number of primary studies included
Approximately 25 studies were included in the review.

Methods of combining primary studies
Summary statistics from each study were used to calculate weighted averages (based on the number of patients in each study).

Investigation of differences between primary studies
Not stated.

Results of the review
The sensitivity and specificity were 92% and 97% for EUS, 90% and 95% for IOCG, and 95% and 98% for ERCP. EUS and IOCG were assumed to have no associated complications. The risk of complications with ERCP was set at 3% (range: 0 - 6%) for mild and 0.1% (range: 0 - 1%) for severe pancreatitis. Cases of mild pancreatitis called for 3 days (range: 0 - 5 days) of hospitalisation in a regular hospital ward, and severe pancreatitis called for 3 days (range: 0 - 10 days) in an intensive care unit, plus 7 days (range: 0 - 20 days) in a regular ward. The risk of indeterminate ERCP procedures was set at 5% (range: 0 - 25%). The rates of indeterminate EUS and IOCG were set at 3% and 9%, respectively (range: 0 - 25%).

Methods used to derive estimates of effectiveness
A panel of 10 experts in the fields of laparoscopic biliary surgery and biliary endoscopy were surveyed.

Estimates of effectiveness and key assumptions
For stones less than 5mm in diameter, the risk of any symptoms occurring in a 10-year period was 27% (range: 1 - 60%) and the proportion of recurrent symptoms presenting as a severe or life-threatening complication was 8% (range: 1 - 30%). For stones 5mm in diameter or larger, the risk for any symptoms occurring in a 10-year period was 62% (range: 25 - 97%) and the proportion of complicated symptoms was 23% (range: 5 - 90%). The risk of any symptoms due to missed stones was 100% and missed stones had a 50% risk of presenting as a severe complication.

Measure of benefits used in the economic analysis
The costs of the 4 peri-LC management strategies in function of the risk of bile duct stones were used as the measure of benefits.

Direct costs
Costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were reported separately. Direct costs included costs of patient monitoring, intravenous kits and drugs, recovery time,
physician time, operating room time, anaesthesia, fluoroscopy, and all nonreusable endoscopic and operating room equipment. Direct costs were incorporated in the model in the form of relative cost ratios. The quantity/cost boundary of the hospital was adopted. The estimation of quantities and costs was based on actual data. Cost estimates were derived from the Digestive Disease Centre, Medical University of South Carolina sources. The price year was not reported.

**Statistical analysis of costs**
Not reported.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
For each scenario, one-way sensitivity analysis was performed, plotting costs against the estimated risk of bile duct stones. Two-way sensitivity analyses were then performed, plotting the risk of bile duct stones versus changes in each of all the other variables.

**Estimated benefits used in the economic analysis**
Not relevant.

**Cost results**
Not relevant.

**Synthesis of costs and benefits**
From 0% to 10%, expectant management, with no bile duct imaging before or during surgery, is least costly; from 11% to 55% EUS is least costly; and for all levels of risk greater than 55%, preoperative ERCP is least costly. These results are most sensitive to changes in the following variables: the risk of any symptoms, the proportion of recurrent symptoms presenting as complications, the intensive care unit and ward length of stay and cost for complications due to retained stones, the sensitivity of EUS and IOCG, the risk of indeterminate EUS and IOCG, and the EUS and IOCG cost ratios.

**Authors' conclusions**
The least costly strategy for laparoscopic cholecystectomy patients depends primarily on the risk of stones and stone-related symptoms, but procedural costs and operator expertise are also critical.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear. You, as a user of this database, should verify whether these health technologies are relevant to your setting.

**Validity of estimate of measure of benefit**
Costs were used as one possible measure of benefit (cost-minimization). Alternatively, the detection rate of bile duct stones, patient preferences, and quality-of-life measures could have been considered. The results do not appear to have
been presented selectively. Estimates of effectiveness variables were derived from the literature, or from expert opinion where data from the literature were not available. Given the uncertainty surrounding these estimates, an extensive sensitivity analysis was conducted. The value of IOCG in preventing bile duct injuries by delineating aberrant biliary anatomy was not incorporated in the model. The results were based on the assumption of adequate operator expertise, a level that relatively few physicians achieve at the present time.

Validity of estimate of costs
Costs, as opposed to charges, were used. Cost ratios were used to permit generalisation across centres. The actual costs are likely to vary across settings and countries. No indirect costs were considered.

Other issues
Given that an optimal management strategy is unlikely to be determined through a prospective trial, evaluation needs to be based on a literature review and decision analysis. The generalisability of the results to other settings or countries was discussed. Adequate comparisons with other relevant studies were not made.

Implications of the study
In terms of cost-minimization the strategy for laparoscopic cholecystectomy patients depends primarily on the risk of stones and stone-related symptoms, but procedural costs and operator expertise are also critical.

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