Choledocholithiasis: endoscopic versus laparoscopic management
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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
Use of laparoscopic common bile duct exploration (LSCBDE) in the treatment of choledocholithiasis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing laparoscopic cholecystectomy who had choledocholithiasis in addition to gallbladder disease.

Setting
Hospital. The economic study was conducted in the USA.

Dates to which data relate
Effectiveness and resource use data were collected between 1 January 1990 and 1 January 1996. The price year was not explicitly stated.

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

Link between effectiveness and cost data
Costing was undertaken retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used in determining the sample size. Out of 913 patients who underwent LC, 62 had choledocholithiasis in addition to gallbladder disease. All but one of these 62 patients had successful clearance of their common duct stones by either LSCBDE or ERCP/ERS. These 61 patients form the sample of this study. LSCBDE was attempted in 45 patients while ERCP/ERS was attempted in 28 patients. The mean age for 35 patients cleared by LSCBDE was 47.7 (range: 21 - 85) years. Patients undergoing successful ERCP/ERS (n=26) had a mean age of 56.5 years (range: 20 - 90).

Study design
This was a retrospective cohort study, carried out in a single centre. The mean-follow-up was 38.9 months (range: 15 -
68). Loss to follow-up was not reported.

**Analysis of effectiveness**
The analysis was based on treatment completers only. The main health outcomes used in the analysis were the number of successfully completed procedures (resulting in clearance of common duct stones), perioperative mortality rate and complication rate. Length of stay (LOS) was also reported.

**Effectiveness results**
LSCBDE was attempted in 45 patients and successfully completed in 35, while ERCP/ERS was attempted in 28 patients and successfully completed in 26. There were no perioperative deaths in either treatment group. There was one minor complication in the LSCBDE group (minor bile leak resolved without intervention) and all patients were asymptomatic at the last visit, with no late complications identified. Six patients (23.1%) developed early or late complications in the ERCP/ERS group. 4 (15.4%) developed early complications (3 with pancreatitis and 1 with microperforation) and 2 (7.7%) developed late complications (ampullary stenosis). Statistical analysis showed a significant difference between the groups in terms of the complication rate (2.9% in the LSCBDE group versus 23.1% in the ERCP/ERS, p=0.034). LOS was 3.4 days in the LSCBDE group versus 5 days in the ERCP/ERS, (p=0.028).

**Clinical conclusions**
In most of the 10 patients in whom LSCBDE failed, the surgeon did not have sufficient experience to perform this procedure.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**
Costs were not discounted since the cost analysis only covered the hospital charges. Some quantities (mean LOS and mean operative time) were reported separately from the costs. Cost items were not reported separately. Mean hospital charges were used as proxy for costs. The medical consumer price index was used to adjust costs for inflation. The price year was not stated. The cost analysis did not cover professional fees.

**Statistical analysis of costs**
Costs were statistically analysed using a t test.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was performed.

**Estimated benefits used in the economic analysis**
Not applicable (the reader is referred to the effectiveness section).
Cost results
LOS was 3.4 days for LSCBDE and 5 days for ERCP/ERS, (p=0.028). The mean hospital charges were $9,100 for LSCBDE and $11,823 for ERCP/ERS (p=0.066, not statistically significant).

Synthesis of costs and benefits
A synthesis of costs and benefits was not performed.

Authors' conclusions
LSCBDE results in a significantly shorter LOS and significantly fewer complications, and is less costly than ERCP/ERS. LSCBDE, where feasible, should be considered the gold standard for the management of choledocholithiasis.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (ERCP/ERS). It was considered the commonly used heath technology and procedure of choice for the management of choledocholithiasis in the era of LC. You, as a database user, should consider if this is applies in your own setting.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results can not be guaranteed because of the retrospective nature of the study design. The study may be regarded as a cost-consequences analysis.

Validity of estimate of costs
Some quantities were reported separately from the costs. Hospital charges were used as proxy for costs. More details about cost analysis would have been helpful. It is not clear what price year was used when estimating costs. Charge results may not be generalisable to other settings or countries.

Other issues
Given the retrospective nature of the study design and the lack of sensitivity analysis, the study results should be treated with some degree of caution. Costs and effects could have been synthesised by selecting an appropriate cost-effectiveness measure. The issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with studies.

Implications of the study
The authors currently use this treatment plan (LSCBDE) for unsuspected CBD stones and suspected CBD stones in patients without significant comorbid illness, cholangitis, or severe biliary pancreatitis. However if the patient has suspected CBD stones and severe comorbid illness, ascending cholangitis, or unresolving pancreatitis, they should undergo preoperative ERCP/ERS. The authors believed that, for the contemporary laparoscopic biliary surgeon, it is no longer reasonable to perform routine preoperative ERCP or rely on a successful postoperative endoscopic papillotomy until the single-stage management approaches have been exhausted.

Source of funding
None stated.

Bibliographic details