Management of choledocholithiasis: comparison between laparoscopic common bile duct exploration and intraoperative endoscopic sphincterotomy

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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 common bile duct exploration (LCBDE) and intraoperative endoscopic sphincterotomy (IOES), both performed during laparoscopic cholecystectomy, for the treatment of choledocholithiasis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with choledocholithiasis. Specific inclusion or exclusion criteria were not reported.

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

Dates to which data relate
The effectiveness and resource use data were gathered from November 1999 to October 2002. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The use of power calculations was not reported. A sample of 102 eligible patients was identified at one centre. There were 45 patients in the LCBDE group and 57 in the IOES group. The patients were aged from 29 to 79 years in the LCBDE group and 18 to 75 years in the IOES group. Seventeen patients in the LCBDE group and 20 in the IOES group were male. It was not stated whether some patients were excluded from the initial study sample for any reason.

Study design
This was a retrospective cohort study that was conducted in a single centre. The patients were identified from those who had undergone either LCBDE or IOES. The data were then retrospectively compared. No follow-up was performed.

**Analysis of effectiveness**
All of the patients included in the initial study sample were considered in the effectiveness analysis. The health outcomes used were:
- the rate of ductal stone clearance,
- the rate of conversion to open surgery (which was considered as a failure),
- the rate of morbidity associated with the procedure,
- operative time,
- hospital stay, and
- postoperative stay.

The study groups were comparable at baseline in terms of their demographic and clinical characteristics.

**Effectiveness results**
The rates of ductal stone clearance were equivalent in the two groups, 88% in the LCBDE group and 89% in the IOES group, (p=0.436).

The rate of conversion to open surgery was 4.4% in the LCBDE group versus 8.8% in the IOES group, (p=0.381).

The rates of morbidity associated with the procedure were 6.7% (LCBDE group) and 12.3% (IOES group), respectively, (p=0.336).

The median operative time was 180 minutes (25 - 75% quartile range: 130 - 220) in the LCBDE group versus 155 minutes (25 - 75% quartile range: 130 - 210) in the IOES group, (p=0.661).

The median length of hospital stay was longer in the LCBDE group (7 days, 25 - 75% quartile range: 6 - 9) than in the IOES group (6 days, 25 - 75% quartile range: 4.5 - 8), (p=0.041).

The median postoperative stay was longer in the LCBDE group (4 days, 25 - 75% quartile range: 3 - 6) than in the IOES group (3 days, 25 - 75% quartile range: 2 - 5), (p=0.024).

**Clinical conclusions**
The effectiveness study showed that LCBDE and IOES were similarly effective, but that hospital stay was significantly shorter in IOES patients.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

**Direct costs**
Discounting was not relevant because the costs were incurred during a short time and, appropriately, it was not carried out. The unit costs and the quantities of resources used were not presented separately. The health services included in the economic evaluation were hospital admission, procedures, treatment of complications, additional anaesthesia or
intraoperative cholangiography, and additional stay or procedures. The cost/resource boundary of the study was not reported. Resource consumption was estimated from actual data that referred to the patients involved in the effectiveness study from November 1999 to October 2000. The costs were estimated from the hospital admissions department. The price year was not reported.

**Statistical analysis of costs**
The Mann-Whitney test and chi-squared test were used to test the statistical significance of differences in the estimated costs.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
Chinese yuan (Yuan).

**Sensitivity analysis**
No sensitivity analyses were performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The median cost per patient was Yuan 11,362 (25 - 75% quartile range: 10,196 - 14,822) in the LCBDE group and Yuan 15,466 (25 - 75% quartile range: 13,555 - 17,689) in the IOES group. The difference was statistically significant, (p=0.000).

Among patients with complications, the median cost per patient was Yuan 15,121 (25 - 75% quartile range: 11,706 - 19,895) in the LCBDE group and Yuan 23,910 (25 - 75% quartile range: 20,746 - 111,289) in the IOES group. The difference was statistically significant, (p=0.000).

Among patients without complications, the median cost per patient was Yuan 11,210 (25 - 75% quartile range: 10,119 - 14,380) in the LCBDE group and Yuan 14,955 (25 - 75% quartile range: 12,650 - 16,793) in the IOES group. The difference was statistically significant, (p=0.000).

The differences between LCBDE and IOES patients reached statistical significance in patients with or without complications. However, within the LCBDE group, there was no statistically significant difference in costs between patients with and without complications, while within the IOES group, the median cost per patient with complications was significantly higher than the median cost per patient without complications.

**Synthesis of costs and benefits**
Not relevant as a cost-consequences analysis was carried out.

**Authors' conclusions**
The rates of ductal stone clearance were comparable between the two groups. Compared with intraoperative endoscopic sphincterotomy (IOES), laparoscopic common bile duct exploration (LCBDE) appears safer, has no life-threatening complications, and can significantly decrease the hospital cost in the treatment of patients with choledocholithiasis.
CRD COMMENTARY - Selection of comparators

The authors stated that both IOES and LCBDE represented two widely used approaches for the treatment of patients with choledocholithiasis in their own setting. You should decide whether they are currently used in your own setting.

Validity of estimate of measure of effectiveness

The basis of the analysis of effectiveness was a retrospective cohort study. A trial with a prospective design would have been more appropriate for the study question. The main limitations to the internal validity of the analysis were the small group of patients and the lack of power calculations to justify the sample size used in the study. In a larger group of patients, some of the differences in the clinical outcomes could have achieved statistical significance. Further, statistical tests to assess the impact of potential confounding factors were not performed. The investigators were not blinded to the patients' allocation to the study groups. Therefore, assessment bias might have had some impact on the results of the analysis. Finally, the data came from a single centre and the method used to select the sample was unclear (e.g. patients who refused to participate or who were excluded from the initial study sample). Thus, it was unclear whether the study sample was representative of the study population. The study groups were comparable at baseline.

Validity of estimate of measure of benefit

No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.

Validity of estimate of costs

The authors did not explicitly report which perspective was adopted in the study. In addition, few details of the economic analysis were provided. For instance, a breakdown of the cost items, the price year, and information on the unit costs were not given. This would make it difficult to replicate the study in other settings. Discounting was not relevant since the costs were incurred during a short time. The cost estimates were derived from a single centre and were specific to the study setting. Sensitivity analyses were not carried out. Statistical tests of the costs were performed when the cost estimates were compared.

Other issues

The authors compared their findings with those from other studies, showing consistent results. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. The external validity of the study was low. Caution should therefore be exercised when extrapolating the study results to different contexts. The authors did not discuss any limitations of their analysis. The study considered patients with choledocholithiasis and this was reflected in the authors' conclusions.

Implications of the study

The study results suggested that LCBDE could be a better option for treating choledocholithiasis than IOES, owing to the lower costs and fewer complications. However, given the methodological limitations mentioned, some caution is required when interpreting the authors' conclusions.

Source of funding

None stated.

Bibliographic details


PubMedID

14669352
Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Bile Ducts /surgery; China; Choledocholithiasis /surgery; Costs and Cost Analysis; Female; Humans; Intraoperative Care /economics; Laparoscopy /economics /methods; Male; Middle Aged; Retrospective Studies; Treatment Outcome

AccessionNumber
22004000122

Date bibliographic record published
30/11/2004

Date abstract record published
30/11/2004