A cost-effectiveness analysis of intraoperative cholangiography in the prevention of bile duct injury during laparoscopic cholecystectomy

Flum D R, Flowers C, Veenstra D L

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 study examined the effect of routine use of intraoperative cholangiography (IOC) during laparoscopic cholecystectomy (LC) in preventing common bile duct (CBD) injuries.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of a hypothetical cohort of 10,000 patients undergoing LC. Life expectancy for patients surviving LC was based on the proportion of women (74.4%) and men who underwent LC in the state of Washington, and their average ages at the time of LC (48.7 and 57.7 years, respectively).

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

Dates to which data relate
Effectiveness data were taken from studies published between 1994 and 2001. Resource use data were derived from studies published between 1992 and 1997. The price year was 2000.

Source of effectiveness data
Effectiveness data were derived from a review or synthesis of previously completed studies.

Modelling
Two decision models were developed to calculate cost per life year saved and cost per injury avoided using routine IOC during LC, compared to LC performed without IOC. Since CBD injuries during LC occur infrequently, the performance of a prospective randomised controlled trial was not a practical option. Primary data, available from different published studies, were used to construct and value the models in order to perform the evaluation.

Outcomes assessed in the review
The outcomes that were taken from the studies consisted of the CBD injury rates during LC, with and without routine use of IOC; the re-operation rate of patients with CBD injuries; the death rate associated with CBD; and the rate of death after CBD repair. The CBD injury rates were defined as injuries requiring operative repair of the CBD.
Study designs and other criteria for inclusion in the review
Not stated.

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
Not stated.

Number of primary studies included
Data from eight studies were included.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
The authors presented the differences that were found between the primary studies and provided explanations for these differences as appropriate. Extreme values were adopted as alternative values and used in the sensitivity analyses.

Results of the review
Base case values and alternative values (in brackets) taken from the studies were:

- rate of CBD injury with IOC: 19 per 10,000 cases (21-22/10,000);
- rate of CBD injury without IOC: 33 per 10,000 cases (42-43/10,000; 169/10,000);
- rate of re-operation after CBD injuries: 0.33 (0.122);
- rate of death associated with CBD injury: 0.11;
- rate of death after CBD repair: 0.06 (0.187).

Measure of benefits used in the economic analysis
The benefits used in the economic analysis were the number of lives saved and the number of CBD injuries avoided.

Direct costs
In the base-case analysis direct costs consisted of the medical cost of intraoperative cholangiography, and the cost of repair of CBD. Additionally, the cost of in-hospital death after repair and alternative values for the cost of cholangiography and CBD repair were reported and used in the sensitivity analyses. Separate components of cost were not further specified. Unit costs were taken from previously published studies. The cost of intraoperative cholangiography was based on claims data. The cost of injury repair was estimated from several repair procedures presented in a case control study. The authors presented a crude estimate of cost of in-hospital death after CBD based
on assumption. Quantities were derived using modelling and were not reported separately. Discounting was not carried out. All cost estimates were adjusted for inflation to the year 2000. The inflation rate used was not reported.

**Statistical analysis of costs**
Cost data were treated as point estimates.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were performed using the alternative values of effectiveness and cost data.

**Estimated benefits used in the economic analysis**
LC performed with IOC resulted in 2.5 deaths avoided and 14 CBD injuries prevented per 10,000 LCs. The time horizon used was the period from LC to hospital discharge, successful CBD injury repair, or death.

**Cost results**
Total costs were not reported. Accounting for all medical care after injury resulted in an increased cost of IOC per patient undergoing LC of $100.

**Synthesis of costs and benefits**
In the base-case analysis, cost per life saved was approximately $139,000 ($13,900 per life year saved) and cost per injury avoided was $87,100.

The most influential parameters were cost of IOC and the attributable risk reduction in CBD injury using IOC. Using a range of cost of IOC from $77 to $738 resulted in cost per injury avoided ranging from $57,846 to $554,417.

Varying the reduction of CBD injuries using IOC from 0 to 150 per 10,000 patients resulted in cost per injury avoided varying from $8,185 to $150,000.

Based on effectiveness figures from the literature, the cost per injury avoided was $60,983 for surgeons who had performed fewer than 36 earlier LCs (risk reduction of 0.2%).

The routine use of IOC during LC in a population with complex cases resulted in a cost of approximately $8,000 per avoided injury.

**Authors’ conclusions**
Routine use of IOC during LC among less experienced surgeons and in high-risk operations is a cost-effective strategy. Given the cost implications of IOC in the context of other interventions, routine use of IOC for the general population undergoing LC is considered a cost-favourable intervention.

**CRD COMMENTARY - Selection of comparators**
An implicit justification for the comparator was given. LC without the routine use of IOC was considered to be the
usual care in the United States. You should decide whether this is current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The authors did not state that a systematic review of the literature had been undertaken to identify and select data to populate the decision analysis models. Effectiveness estimates were derived credibly from the primary studies. However, given the study designs and the limited number of studies providing CBD rates, the internal validity of the results is likely to be low. Appropriate sensitivity analyses were performed to assess the impact of varying the effectiveness estimates on the final results.

**Validity of estimate of measure of benefit**
The estimation of benefits (lives saved and CBD injury avoided) was modelled. The instrument used to derive the health benefits, a decision model, was appropriate.

**Validity of estimate of costs**
All costs relevant to the perspective adopted in the study were included in the analysis. The cost of LC was excluded, because it was common to both therapies. Unit costs were reported separately and were taken from published sources. The cost of IOC was based on charges. The cost of CBD injury repair was taken from a study evaluating different repair procedures. The authors acknowledged that the value adopted for the cost of repair in the base case analysis may have resulted in an underestimation of the total cost of repair. The cost of in-hospital death after injury repair was based on an author's assumption. Since different methods were used to estimate cost, the generalisability of the cost results may be limited. Sensitivity analyses were performed using cost ranges taken from the literature to estimate the impact on the results. Since it is likely that costs were incurred over one year, discounting was appropriately not performed. The price year was reported.

**Other issues**
The authors made an appropriate comparison of their findings with the results found in a recent study and the generalisability of the result to (other) practice settings was addressed. In addition, the results were not presented selectively and the authors pointed out the importance of comparing local practice information with the values taken for the parameters in the model. Several limitations of the study were reported, namely the modelling approach and the variability of data presented in the literature. The results reported were within the scope of the study. Moreover, the authors reported the importance of examining the actual prevention of CBD injuries after broadening the use of IOC.

**Implications of the study**
A causal relationship between IOC and the prevention of CBD injuries still remains to be determined. The authors state that, considering the context of the cost associated with injury, IOC appears to be cost effective. The analytical framework and the information from this study are considered useful for individual surgeons and institutions to determine if IOC use is cost effective in their particular practice environments.

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Other publications of related interest


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