Economical and clinical outcomes of alternative treatment strategies in the management of common bile duct stones in the elderly: wait and see or surgery?

Drake B B, Arguedas M R, Kilgore M L, Hawn M T, Wilcox C M

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 compared two strategies for the treatment of common bile duct stones in the elderly. The treatment strategies were endoscopic retrograde cholangiography with sphincterotomy (ERC-S) followed by either elective laparoscopic cholecystectomy (ERC-S/LC) or observation (ERC-S/O).

In the latter strategy (ERC-S/O), cholecystectomy is only performed in those patients with recurrent symptoms (biliary colic or cholecystitis). In patients who developed biliary complications of gallstone disease, repeat ERC-S was performed and was followed by cholecystectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of elderly patients with common bile duct stones.

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

Dates to which data relate
The effectiveness data were derived from studies published between 1989 and 2003. The price year was 2003.

Source of effectiveness data
The effectiveness data were derived from a review and synthesis of published studies.

Modelling
A decision tree model was constructed, using DATA 3.5 software (Williamstown, MA), to estimate the costs and outcomes associated with the two treatment strategies for patients with common bile duct stones.

Outcomes assessed in the review
The outcomes assessed included:
the probability of recurrent biliary colic;
the probability of complications (cholecystitis, pancreatitis, choledocholithiasis and cholangitis) associated with conservative management;

the incidence of complications of elective and emergent LC;

the probability of conversion to open cholecystectomy, and complications of repeat ERC-S;

the probability of death associated with LC, open cholecystectomy and ERC-S.

**Study designs and other criteria for inclusion in the review**

Not reported.

**Sources searched to identify primary studies**

MEDLINE was searched using the keywords "cholelithiasis", "biliary colic", "complicated gallstone disease", "elderly", "cholecystectomy", "endoscopic retrograde cholangiopancreatography" and "sphincterotomy". References from relevant literature were then manually reviewed.

**Criteria used to ensure the validity of primary studies**

Not reported.

**Methods used to judge relevance and validity, and for extracting data**

Not reported.

**Number of primary studies included**

Approximately 18 studies were included in the review of the literature.

**Methods of combining primary studies**

Not reported.

**Investigation of differences between primary studies**

It was unclear if the authors investigated any differences between the primary studies.

**Results of the review**

The probability of complications was:

- 0.026 (range: 0.01 to 0.16) after ERC-S;
- 0.10 (range: 0.04 to 0.20) after elective LC;
- 0.25 (range: 0.05 to 0.50) after elective open cholecystectomy;
- 0.13 (range: 0 to 0.33) after emergent LC; and
- 0.45 (range: 0.10 to 0.75) after emergent open cholecystectomy.

The probability of death from complications was:

- 0.33 (range: 0 to 0.38) after ERC-S;
0.05 (range: 0 to 0.25) after LC; and
0.20 (range: 0 to 0.25) after open cholecystectomy.

The probability (per 2 years) of recurrent symptoms in the ERC-S/O strategy was 0.15 (range: 0.08 to 0.47).
The probability (per 2 years) of biliary complications in the ERC-S/O strategy was 0.08 (range: 0.04 to 0.16).
The conversion to open cholecystectomy after elective LC was 0.06 (range: 0.05 to 0.23).
The conversion to open cholecystectomy after emergent LC was 0.16 (range: 0.16 to 0.55).
The probability of death from unrelated causes (per 2 year) was 0.05 (range: 0 to 0.10).

**Measure of benefits used in the economic analysis**
The measure of benefits used was the life-years gained.

**Direct costs**
The direct costs included in the analysis were those to the third-party payer. These included the costs of both open and laparoscopic cholecystectomy, the cost of ERC, and the cost of complications post-ERC and cholecystectomy. The costs were derived from average Medicare reimbursement rates at the authors’ institution according to diagnosis-related groups and Current Procedural Terminology (CPT) codes. Discounting was not necessary, as the costs were incurred during 2 years, and was therefore not performed. The study reported the average costs. The price year was 2003.

**Statistical analysis of costs**
The costs were treated as point estimates.

**Indirect Costs**
The indirect costs were not included as the authors felt that the difference between the two groups would be insignificant.

**Currency**
US dollars ($).

**Sensitivity analysis**
One-way sensitivity analyses were performed on all clinical and cost variables. Two-way sensitivity analyses were then performed to examine the results of simultaneously varying select pairs of variables that were found to be influential in the one-way sensitivity analyses. The authors also performed Monte Carlo simulations to evaluate the robustness of their results.

**Estimated benefits used in the economic analysis**
The life-years gained were 1.894 with the ERC-S/O strategy and 1.886 with the ERC-S/LC strategy.

**Cost results**
The mean costs were $1,173 for the ERC-S/O strategy and $5,259 for the ERC-S/LC strategy.

**Synthesis of costs and benefits**
The costs and benefits were not combined as the ERC-S/O strategy was found to be both more effective and less costly than the ERC-S/LC strategy (dominant).

The results from the one-way sensitivity analyses showed that the probability of developing recurrent symptoms or biliary complications was the most sensitive parameter in the model. The results of the Monte Carlo simulation showed that ERC-S/O remained less costly and more effective than ERC-S/LC in 75% and 60% of the trials, respectively.

**Authors' conclusions**

In patients aged over 60 years, expectant management after endoscopic retrograde cholangiography with sphincterotomy (ERC-S) for common bile duct stones was a reasonable approach. However, its economic attractiveness depended on the probability of recurrent symptoms.

**CRD COMMENTARY - Selection of comparators**

A justification was given for using ERC-S followed by cholecystectomy as the comparator. It represented the current standard of care for common bile duct stones. You should decide if this intervention is widely used in your own setting.

**Validity of estimate of measure of effectiveness**

The authors did not undertake a systematic review of the literature to identify all relevant research and minimise biases. However, they reported the sources searched for relevant research and the search strategy used, and they also handsearched references identified from relevant literature. It is therefore possible that they believed that all the major relevant literature on the subject was identified. The authors did not report how the data from relevant studies were combined, nor if there were any differences between these studies. The poor reporting of these issues makes it difficult to ascertain whether the best available evidence has been found and used in an appropriate manner to populate the model.

**Validity of estimate of measure of benefit**

The estimation of benefits was modelled appropriately using a decision tree model. However, the authors reported that the use of quality-adjusted life-years would have provided better outcome measures to aid the decision-making process.

**Validity of estimate of costs**

All the categories of cost relevant to the third-party payer perspective were included in the analysis. No major relevant costs appear to have been omitted from the analysis. The authors did not report resource use and prices separately, which will limit the generalisability of their conclusions. The costs were derived from Medicare charges, which were used to proxy prices. In this case, the use of charges (which normally do not reflect the true cost of the services being provided) was appropriate, as these are the costs paid by the third-party payer to the health care providers. Appropriate sensitivity analyses of the costs were performed. Discounting was not performed. However, as the costs were incurred during 2 years, it is likely that discounting would not have greatly impacted on the results obtained. The price year was reported, which will aid any possible inflation exercises.

**Other issues**

The authors reported that other studies had also found expectant management observation to be associated with reduced, or at least comparable, morbidity in comparison with cholecystectomy. The issue of generalisability to other settings was partly addressed in the sensitivity analysis. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported further limitations to their study. First, some of the studies included in the review measured outcomes in both younger and older patients. Second, the use of a limited time horizon of only 2 years means that the economic and clinical benefits of the two strategies might not have been fully captured. Finally, quality of life estimates were not included in the outcome measure.
Implications of the study
The authors highlighted the need for long-term, randomised, prospective studies comparing observation versus cholecystectomy in elderly patients.

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Other publications of related interest


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