Intra-operative vs pre-operative endoscopic sphincterotomy in patients with gallbladder and common bile duct stones: cost-utility and value-of-information analysis
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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.

CRD summary
The study assessed the cost-effectiveness of conventional pre-operative endoscopic sphincterotomy followed by laparoscopic cholecystectomy (gall bladder removal through keyhole surgery) versus intra-operative endoscopic sphincterotomy during laparoscopic cholecystectomy for patients with gallbladder and common bile duct stones. The authors concluded that intra-operative endoscopic sphincterotomy should be implemented based on cost effectiveness. The study used valid methodology and was presented in detail. The authors’ conclusions appear robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study assessed the cost-effectiveness of preoperative endoscopic sphincterotomy followed by laparoscopic cholecystectomy versus intra-operative endoscopic sphincterotomy during laparoscopic cholecystectomy for patients with gallbladder and common bile duct stones.

Interventions
Preoperative endoscopic sphincterotomy followed by laparoscopic cholecystectomy (two separate operations) was compared with intra-operative endoscopic sphincterotomy during laparoscopic cholecystectomy (one combined operation).

Location/setting
UK/hospital.

Methods
Analytical approach:
The analysis was based on a decision-tree with a three-year time horizon. The authors stated that the analysis was carried out from the perspective of the UK NHS.

Effectiveness data:
Most clinical inputs were from a recently published systematic review with a meta-analysis that compared the two procedures. This meta-analysis included only randomised clinical trials. Additional data were based on other published sources. For some parameters, a ‘non-informative’ prior probability (equal probability of all events happening) was used; this was based on experts’ opinions that were revised with data from published sources to obtain a posterior probability (to account for rare events). The probability of successful extraction of stones was a key input of the model.

Monetary benefit and utility valuations:
Utility valuations were derived from two studies that were identified through a search of the Harvard Cost-Effectiveness Analysis Registry. One study used the time trade-off approach in a sample of 79 Australian patients. A second study used the standard gamble questionnaire in 20 healthy individuals from the USA.

Measure of benefit:
Quality-adjusted life-years (QALYs) were used as the summary benefit measure and were discounted at a rate of 3.5% per annum.
Cost data:
Costs included were laparoscopic cholecystectomy, conversion to open cholecystectomy (when required), endoscopic sphincterotomy, post-endoscopic sphincterotomy complications (perforation, pancreatitis, cholangitis, cholecystitis, bleeding, and gastric ulcer), additional hospital stay for preoperative endoscopic sphincterotomy, guidewire in intra-operative endoscopic sphincterotomy, annual additional costs for acute pancreatitis in the long term, and cost difference between operating theatre and Endoscopy unit. Costs were calculated from several sources including official tariffs set by the NHS, published studies, local estimates and authors’ assumptions for long-term expenses. Costs were in UK pounds sterling (£) and were discounted at an annual rate of 3.5%. The price year was 2008. A budget impact analysis was performed.

Analysis of uncertainty:
Uncertainty was investigated with a probabilistic sensitivity analysis that used 5,000 replications and assigned distributions to model inputs. Details of the types of distributions used were reported for each set of inputs. Cost-effectiveness acceptability curves were plotted. One-way sensitivity analyses were conducted on all input parameters. Confidence intervals (CIs) were calculated for the budget-impact analysis. Value-of-information analysis was carried out to calculate the population-expected value of perfect information and the expected value of partial-perfect information based on 5,000 procedures a year.

Results
In a hypothetical cohort of 1,000 patients, intra-operative endoscopic sphincterotomy during laparoscopic cholecystectomy expected costs were £3,509,402 and QALYs were 2,589.26; for preoperative endoscopic sphincterotomy followed by laparoscopic cholecystectomy the expected costs were £4,132,695 and QALYs were 2,581.36. Intra-operative endoscopic sphincterotomy resulted in substantial cost-savings (£623 per patient) and a slight improvement in QALYs (0.008 per patient), so it was the dominant strategy.

At a willingness-to-pay threshold of £20,000 per QALY, intra-operative endoscopic sphincterotomy was likely to be preferred in 92.9% of the simulations. Intra-operative endoscopic sphincterotomy remained the cost effective option in all deterministic sensitivity analyses except for assumptions not generally encountered in clinical practice.

The budget impact analysis suggested that NHS could save £2.8 million per annum (95% CI 0.2 to 6.9).

At a willingness-to-pay threshold of £20,000 per QALY, the population-expected value of perfect information was £0.6 million. Two groups of parameters were found to have positive expected value of partial perfect information. The population expected value of partial perfect information for the complication and conversion rates was £0.2 million, and that for costs was £0.03 million.

Authors' conclusions
The authors concluded that intra-operative endoscopic sphincterotomy during laparoscopic cholecystectomy should be implemented instead of the conventional preoperative endoscopic sphincterotomy followed by laparoscopic cholecystectomy based on cost effectiveness.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear, as the proposed intervention (intra-operative endoscopic sphincterotomy) was compared with the traditional approach to surgery (preoperative endoscopic sphincterotomy).

Effectiveness/benefits:
The clinical data were based on a systematic review that included a meta-analysis of randomised clinical trials. This should have ensured high internal validity. The authors stated that there were some differences in the selected trials that might have biased the results, but findings were very stable to variation in model parameters. Other sources of clinical data were only partially described. The clinical analysis was conducted satisfactorily. The benefit measure was appropriately QALYs, as gallstones have an impact on mortality and morbidity. Sources of utility weights were reported and valid instruments were used to elicit preferences.

Costs:
The methods and reporting of the cost analysis were conducted satisfactorily. An extensive description of costs and resource quantities was given for most items. These cost categories appeared relevant to the stated perspective. Sources of cost data were clearly reported and reflected the NHS setting. Reflation exercises in other time periods would be possible as the price year was explicitly stated. The impact of variations in cost estimates was investigated in the sensitivity analyses.

Analysis and results:
A description of the decision tree and key pathways was given. Uncertainty was well considered and represented a strong point of the analysis, as the study focused on the assessment of the value of information analysis. The methods and results were clearly presented and discussed. The results were combined using an incremental approach. The authors acknowledged some limitations of the analysis, mainly the need for some simplifying assumptions, but these were tested in the sensitivity analysis. The model and sources used were described clearly. The authors stated that results were likely to be specific to the UK and might be transferable only to settings with similar costs and clinical practices.

Concluding remarks:
The study used valid methodology and was presented in detail. The authors’ conclusions appear robust.

Funding
No funding received.

Bibliographic details

PubMedID
22077427

DOI
10.2165/11594950-000000000-00000

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Biliary Tract /physiopathology; Biliary Tract Surgical Procedures /economics; Cost-Benefit Analysis; Gallstones /surgery; Great Britain; Humans; Intraoperative Care; Preoperative Care; Quality of Life; Sphincterotomy, Endoscopic /economics; State Medicine

AccessionNumber
22012000118

Date bibliographic record published
22/02/2012

Date abstract record published
29/03/2012