Prospective randomized trial using cost-utility analysis of early versus delayed laparoscopic cholecystectomy for acute gallbladder disease

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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 objective was to examine the cost-effectiveness of early laparoscopic cholecystectomy versus conventional management with elective cholecystectomy for patients newly diagnosed with acute gallbladder disease. The authors concluded that the costs and clinical outcomes were similar for both strategies, but the cost-utility analysis slightly favoured conventional management. The study was well conducted and satisfactorily presented and the authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of early laparoscopic cholecystectomy versus conventional management for newly diagnosed acute gallbladder disease, in patients with a first episode of biliary colic or acute cholecystitis.

Interventions
Early laparoscopic cholecystectomy was performed within 72 hours of hospital admission, while elective cholecystectomy with conventional management was undertaken three months after the first hospital admission. Patients receiving conventional management were initially managed with analgesia, intravenous fluids, and antibiotics.

Location/setting
UK/hospital.

Methods
Analytical approach:
The analysis was based on data from a single study with a one-month time horizon. The authors stated that the perspectives of both the National Health Service (NHS) and society were considered.

Effectiveness data:
The clinical data came from a prospective randomised controlled trial (RCT), carried out at a single hospital between September 2004 and February 2007. The inclusion and exclusion criteria were reported. The sample included 72 patients, with 36 in the early laparoscopic cholecystectomy group and 36 in the conventional group. The median age was 52 years in the early group and 53 years in the conventional group. The number of women was 26 in the early group and 21 in the conventional group. The length of follow-up was one month after surgery. The key clinical endpoint was the change in health status.

Monetary benefit and utility valuations:
The utility valuations were derived using the European Quality of life (EQ-5D) questionnaire for all patients in the RCT at 30 to 35 days after surgery.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure.
Cost data:
The economic analysis considered the costs of in-patient, out-patient, and community services, including hospital stay, surgery, diagnostic and laboratory tests, prescriptions, out-patient visits, and general practitioner and district nurse visits. The resource use data were collected alongside the RCT. The unit costs were derived from official NHS sources, such as NHS Reference Costs, Unit Costs of Health and Social Care, the Hospital Finance Department, and the British National Formulary. Overhead and capital charges were included. All costs were in UK pounds sterling (£) and the price year was 2007. A non-parametric bootstrapping approach was used to deal with the skewed distribution of costs. In a supplementary analysis, the societal costs related to time off work, travel to and from hospital, visits to primary care facilities related to gallbladder disease, and over-the-counter or prescription drugs were also included.

Analysis of uncertainty:
A nonparametric percentile bootstrap method with 2,000 replications was used to generate confidence intervals (CIs) around the incremental cost-utility ratios. The impact of using an imputation method for the QALYs was also investigated.

Results
The mean QALY gain was 0.85 (SD 0.26) in the early group and 0.93 (SD 0.13) in the conventional group. This difference was not statistically significant (p=0.262).

From the perspective of the NHS, the mean costs were £4,589 (SD 1,715) in the early group and £4,671 (SD 2,243) in the conventional group. From the societal perspective, the mean total costs were £5,911 (SD 2,445) in the early group and £6,132 (SD 3,244) in the conventional group. Neither of these differences in costs was statistically significant.

The mean incremental cost per QALY gained with the conventional group over the early group was £3,810 (95% CI -34,761 to 75,771). Imputation of missing data did not alter the conclusions.

In all scenarios considered, all cost-utility CIs included zero, suggesting that both approaches can be considered equally cost-effective.

Authors’ conclusions
The authors concluded that the costs and clinical outcomes were similar for both strategies, but the cost-utility analysis slightly favoured conventional management.

CRD commentary
Interventions:
The selection of the comparators was appropriate as the conventional approach was compared against an alternative timing for the procedure.

Effectiveness/benefits:
The clinical analysis was based on a well conducted and well reported RCT, which is a valid source of evidence. Details of the inclusion and exclusion criteria and the randomisation procedure were reported. Blinding was not performed because it was not possible to mask the timing of the surgical procedure. Strengths of the study were the use of the intention-to-treat principle, the baseline comparability of the study groups, and the use of power calculations to justify the sample size. A possible drawback of the analysis was the ability of the patient sample to be representative, as all the participants were from a single medical institution, and they may not have had the same characteristics as patients at other institutions. QALYs are a valid benefit measure and they not only capture the impact of the intervention on patients’ quality of life, but also permit cross-disease comparisons to be made. A validated instrument was used to elicit the patient preferences.

Costs:
The analysis of costs was carried out in a satisfactory fashion. A broad range of cost categories was considered, and the authors reported the price year, details of the key resources consumed, the sources of data, and the use of statistical tests. The use of both a third-party payer and a societal perspective was another strength of the analysis. The authors took account of the skew in the cost data by means of non-parametric bootstrapping.
Analysis and results:
The analytic approach used to synthesise the costs and benefits was appropriate. The issue of uncertainty was addressed using a stochastic approach. In general, the findings were clearly presented and discussed, but the issue of the generalisability of the results was not investigated and caution may be needed if extrapolating the findings to other settings or patient populations. The authors acknowledged some potential limitations of their study, such as the small sample size.

Concluding remarks:
The study was well conducted and was satisfactorily presented. The authors' conclusions appear to be valid.

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