Laparoscopic cholecystectomy: day-care versus clinical observation
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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 health technology studied was laparoscopic cholecystectomy (LC) as an outpatient procedure. The comparator was LC with clinical observation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with symptomatic cholelithiasis (gallstones) confirmed by ultrasound. The study sample comprised patients living within 50 km of the hospital, who had an adult willing to accompany them home and to stay with them for at least 24 hours. Patients were excluded if they met the following criteria:

- they had an American Society of Anesthesiology (ASA) physical fitness classification of III or IV;
- they were aged over 70 years;
- they had received extensive abdominal surgery;
- there was a clinical suspicion of common bile duct stones, acute cholecystitis, or calcified gallbladder.

Setting
The setting was secondary care. The study was conducted in the Netherlands.

Dates to which data relate
The effectiveness data were gathered from patients recruited between February 1996 and December 1997. The data on the resources used were also collected during this period. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken on the same patient sample as that used in the effectiveness study. The authors did not report whether the costing was undertaken prospectively or retrospectively.
Study sample
Power calculations were used to determine the sample size. These were performed during the planning stage of the study.

The sample size was calculated on the basis of two questions.

1. Was the QOL of patients treated in day-care reasonably equivalent to that in the clinical observation group, after 1 and 6 weeks?

2. Was the absolute prevalence of readmission after day-care LC less than 25% (expected to be 5 to 10%)?

The sample size required to achieve a 5% level of significance with 80% power was 80 patients (40 per treatment group). One hundred and seventy-nine consecutive patients were assessed for inclusion in the study. Of these, 80 (44%) fulfilled the inclusion criteria and were recruited into the trial. The patients recruited had uncomplicated symptomatic cholelithiasis. Of those who did not enter the trial, 32% did not fulfil the inclusion criteria. The authors did not report the characteristics of the patients that were excluded, or the details of those who refused to participate. These factors suggest that the study sample may not be representative of all patients with symptomatic cholelithiasis.

The authors reported that 42 other patients could have been included in the study, if they had been identified in time. It was noted that the characteristics of these patients were similar to those in the trial. A total of 80 patients were recruited in the study: 40 patients were randomised to day-care and 40 to clinical observation.

Study design
The study was a randomised controlled trial carried out in a single centre. The patients were randomly allocated to either day-care or clinical observation using the sealed envelope method. The patients were followed for 6 weeks. Six patients were lost to follow-up. Three patients (1 in the day-care group and 2 in the clinical observation group) were admitted to hospital before the scheduled LC because of acute cholecystitis. These patients underwent urgent LCs, which were converted to open cholecystectomies. Three patients (2 in the day-care group and 1 in the clinical observation group) decided to delay surgery.

Analysis of effectiveness
The authors reported an analysis of treatment completers. The data were reported separately for those patients who did not undergo the scheduled surgery. The primary health outcomes included:

- surgical time and findings;
- pain, as assessed using a visual analogue scale, and the use of pain medication;
- post-surgical complications, including contact with general practitioners and the day-care centre within 4 days of surgery;
- QOL during follow-up, as assessed using the EuroQol questionnaire;
- the resumption of normal activities, as assessed by interview; and
- the treatment preference, as assessed by interview.

The two study groups were comparable at baseline in terms of the following:

- gender;
- ASA score;
- body mass index;
the percentage of patients with professional activities outside of the home;

the duration and frequency of biliary pain;

previous removal of common bile duct stones by endoscopic retrograde cholangiopancreaticography; and

increased levels of serum liver enzymes.

**Effectiveness results**

A total of 37 patients in each group underwent surgery.

There was no difference in mean surgical time between the day-care (76 +/-5 minutes) and clinical observation patients (81 +/-5 minutes), (p=0.32). The surgical findings were evenly distributed.

Pain medication intake was stopped 24 hours after surgery in 51% of the day-care group and 53% of the clinical observation group, (non significant). The pain scores decreased in both groups during the first 48 hours after surgery, (non significant).

Three patients in the day-care group and 1 patient in the clinical observation group had complications after surgery. None of the patients in either group consulted a general practitioner during the first week after surgery.

At 1 and 6 weeks after surgery, the two groups were comparable in terms of pain, mobility, self-care, usual activity, pain or discomfort, and anxiety or depression. Mood, QOL and the overall health status score were not significantly different for the two groups at 1 and 6 weeks of follow-up.

There was no difference between the groups in the length of disruption of usual activities. For the day-care group, 63% of patients had resumed their usual activities after 2 weeks, 81% had resumed them after 4 weeks, and 88% had resumed them after 6 weeks. The corresponding figures for the clinical observation group were 65% (2 weeks), 83% (4 weeks) and 89% (6 weeks).

At 1 and 6 weeks after surgery, 92% of the day-care patients and 8% of the clinical observation patients preferred day-care. The proportion of patients who preferred admission for 24 hours was 8% in the day-care group, and 80% in the clinical observation group. The proportion of patients who preferred admission for more than 24 hours was 0% in the day-care group, and 12% in the clinical observation group.

**Clinical conclusions**

The authors concluded that LC performed on a day-care basis and LC performed with clinical observation were equally effective. Both groups of patients appeared to be satisfied with their treatment.

**Measure of benefits used in the economic analysis**

No summary measure of benefit was assessed in this study. The study was therefore categorised as a cost-consequences analysis.

**Direct costs**

The resource use quantities and costs were reported separately. The analysis included the direct costs to the health service, i.e. the costs for the stay in the hospital or day-care centre. The costs of investigations, interventions, readmissions, and consultations with general practitioners or the hospital or outpatient clinic, were only determined if the number differed for the two treatment groups. The price estimates were derived from standard prices or tariffs. The cost of staying at the hospital or day-care centre was obtained from the rates given by the Centraal Orgaan Tarieven Gezondheidszorg. The price year was not reported. The study reported average costs. Discounting was irrelevant as the costs were incurred over a time period of less than 2 years.
Statistical analysis of costs
The authors did not perform a statistical analysis of costs.

Indirect Costs
Indirect costs were not included in the analysis as they were not appropriate to the perspective of the study.

Currency
US dollars ($). The exchange rate used to convert the costs into US$ was not reported. The year of conversion was not reported.

Sensitivity analysis
The authors did not carry out a sensitivity analysis.

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

Cost results
For LC performed on a day-care basis, the hospital costs were $212 (+/-14) per patient. For LC performed with clinical observation, the hospital stay alone cost $1,002 (+/-76) per patient.

Synthesis of costs and benefits
The authors did not report a synthesis of costs and benefits.

Authors' conclusions
The effectiveness of laparoscopic cholecystectomy (LC) performed in day-care was equal to LC performed with clinical observation. Both groups of patients appeared to be satisfied with their treatment. Since no differences were found with respect to the other outcomes, day-care was the preferred treatment in most patients with an ASA classification of I or II, because it was less expensive.

CRD COMMENTARY - Selection of comparators
The same procedure was compared in two settings, day-care (the study setting) and clinical observation within a hospital (the comparator). Since clinical observation within a hospital represented the standard setting, the selection of the comparator would appear to have been appropriate.

Validity of estimate of measure of effectiveness
The study used a randomised controlled trial design. However, the sealed envelope method of randomisation used may be less effective in minimising selection bias than centralised telephone randomisation. The authors did not report any measures used to ensure that the health care professionals responsible for treatment, the patients, or the study investigators were masked to treatment allocation. This may have biased the assessment of outcomes.

The authors did not report whether the study sample was representative of the study population. The exclusion criteria and sample of people with uncomplicated gallstones suggest that the sample may not have been representative. The groups of patients were shown to be comparable at analysis in terms of their baseline characteristics and the loss to follow-up. The study required 40 patients per group to detect statistically significant differences with 80% power. The power calculations were designed to test for statistically significant differences in the outcomes, rather than equivalence. The analysis was based on treatment completers, of which there were 37 per group. In view of these
factors, the sample size used for the analysis may have been insufficient to demonstrate whether the two interventions were equivalent.

Validity of estimate of measure of benefit
No summary measure of benefit was assessed in this study. The authors reported that there was no difference between the interventions, and subsequently used the framework of a cost-minimisation analysis. However, the authors did not demonstrate that the two interventions were equivalent for the majority of outcomes measured. In addition, the patients indicated a preference for day-care surgery, suggesting differences between the benefits of the two interventions. The analysis was, therefore, a cost-consequences analysis.

Validity of estimate of costs
The authors derived the cost estimates from data collected on the patients recruited into the clinical trial. Only the costs of the hospital stay were included in the analysis. The authors reported that other costs were not included because they were the same in both groups. However, they provided only limited details of these costs. Differences between the two interventions in the use of hospital care and services may result in differences in the use of other formal and informal care services outside the hospital, which were not investigated. The authors did not consider the cost to the patients of different lengths of hospitalisation. The method used to perform the currency conversion was unclear.

Other issues
The authors compared the effectiveness results with other published studies, and reported that they were comparable. The authors noted that the results might not be generalisable to populations with complications, and did not assess the generalisability of the results to other settings. The authors did not appear to present their results selectively. However, it was unclear whether the study had a large enough sample size to demonstrate equivalence. The conclusions drawn by the authors may not be supported by the results of the trial.

Implications of the study
The results of this study suggested that LC in day-care was the preferred procedure for most ASA I and II classified patients. Annual savings of $6 million would be achieved if the day-care LC procedure could be performed in 70% of the patients.

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