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 use of open versus laparoscopic cholecystectomy in the treatment of acute cholecystitis was examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing surgical treatment of acute cholecystitis.

Setting
The setting was a hospital. The economic study was carried out in Croatia.

Dates to which data relate
The effectiveness and resource use data were gathered from 1994 to 1998. The price year was not explicitly reported, but it could have been 1998.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed on the same sample of patients as that used in the effectiveness study, but it was not stated whether it was carried out prospectively or retrospectively.

Study sample
Power calculations were not reported. Of the 894 cholecystectomies performed at the study institution, clinical symptoms of acute cholecystitis were verified in 221 patients. However, in 12 patients the surgical procedure was extended to revision of the common bile duct. Therefore, the final study sample comprised 209 patients. The mean age was 57.18 years (range: 18 - 89). There were 69 (33.01%) men and 140 (66.99%) women. The sample included 115 patients in the open group and 94 patients in the laparoscopic group. The number of employed patients was 31 in both groups (26.96% of all open group patients and 32.98% of all laparoscopic group patients).

Study design
This was a cohort study that was carried out at a single institution, the Department of Surgery of the County General Hospital in Pozega. It was unclear whether the study was prospective or retrospective. The patients were presumably followed for 30 days postoperatively. No patient was lost to the follow-up assessment.

**Analysis of effectiveness**
All patients included in the initial study sample were accounted in the effectiveness analysis. The outcome measures used in the clinical study were:

- the mean time elapsed from the onset of clinical symptoms to operation;
- the use of antibiotics and analgesics;
- the duration of the operation and duration of operating room occupancy;
- complications and deaths;
- the number and size of stones;
- wound infection,
- the length of postoperative stay; and
- the duration of sick leave.

The authors stated that the two groups were closely matched at baseline in terms of demographic and clinical characteristics, but no other details were given.

**Effectiveness results**
The mean time elapsed from the onset of clinical symptoms to operation was 3.79 days in the open group and 3.25 days in the laparoscopic group.

The number of patients receiving antibiotics was 106 (mean 4.4 days, range: 1 - 23) in the open group and 43 (mean 2.3 days, range: 1 - 12) in the laparoscopic group.

The mean use of analgesia was 5.09 ampoules and 3.2 tablets or suppositories (open group) versus 3.13 ampoules and 2.1 tablets or suppositories (laparoscopic group).

The mean duration of the operation was 89 minutes in the open group (range: 49 - 133) versus 115 minutes in the laparoscopic group (range: 44 - 169). The mean duration of operating room occupancy was 119 minutes versus 145 minutes.

There were no intraoperative complications, but 2 patients died within 30 days in the open group. In the laparoscopic group, no deaths were recorded, but conversion was carried out in 9 patients (9.57%) and reoperation was required for 4 patients.

In the open group, multiple stones were found in 79 patients (very small stones with a diameter smaller than the cystic duct lumen were found in 41 patients), 4 patients had no stones, and 32 patients had solitary cystic calculi. In the laparoscopic group, multiple calculi were found in 74 cases and small stones in 29 patients, 2 patients were free of stones, and 18 patients had a solitary cystic calculus.

In the open group, wound infection developed in 10 (8.7%) patients and the mean number of dressings was 2.98 per patient. Prolonged biliary secretion was recorded in 2 (1.74%) patients and one patient had to be reoperated on for adhesive ileus. In the laparoscopic group, wound infection at the site of the supraumbilical incision developed in 2 (2.13%) patients and the mean number of dressings was 1.74 per patient. Herniation at the site of the supraumbilical
incision developed in 3 (3.19%) patients.

The mean length of postoperative stay was 8.4 days (range: 6 - 27) in the open group and 4.38 days (range: 2 - 19) in the laparoscopic group. The mean sick leave was 42 days versus 17 days.

Differences in postoperative hospital stay, use of antibiotics and analgesics, use of dressings, and duration of sick leave reached statistical significance (p<0.001) in favour of laparoscopic cholecystectomy.

**Clinical conclusions**
The effectiveness analysis showed that laparoscopic cholecystectomy was more effective than open cholecystectomy in reducing hospital stay, sick leave, and the use of both antibiotics and dressings.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

**Direct costs**
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were presented separately from the quantities of resources used for almost all cost items. The economic evaluation considered all relevant hospital costs, including preoperative hospital stay (accommodation and medical work), operation (operating room, supplies and medical work), anaesthesia (supplies and medical work), postoperative stay (accommodation and medical work), analgesics, antibiotics and dressings. In the case of conversion from laparoscopic to open cholecystectomy, the cost of conversion was added to the cost of the operation. The cost/resource boundary of the hospital was adopted in the analysis of direct costs. The source of the data was unclear. The resource use data were estimated using the same sample of patients as that used in the clinical study. The price year was not explicitly reported, but it could have been 1998.

**Statistical analysis of costs**
Statistical analyses were carried out to test the statistical significance of differences in the total costs.

**Indirect Costs**
Indirect costs (i.e. sick leave) were added to hospital costs since a societal perspective was adopted in the study. Resource use was estimated using data derived from the sample of patients included in the clinical study. The source of the costs was unclear. As in the analysis of the direct costs, discounting was not relevant and the price year was not explicitly reported. The unit costs were presented separately from the quantities of resources used.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

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

**Cost results**
The hospital costs were $873 in the open group and $1,181 in the laparoscopic group, (p<0.001). Sick leave costs were $1,119 in the open group and $486 in the laparoscopic group, (p<0.001).

The total treatment costs were $1,316 in the open group and $1,430 in the laparoscopic group, (p<0.001). However, in the category of employed patients, the total treatment costs were $2,167 in the open group and $1,750 in the laparoscopic group, (p=0.0065).

**Synthesis of costs and benefits**

A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was carried out.

**Authors' conclusions**

Laparoscopic cholecystectomy had some advantages over open surgery, including better clinical outcomes and a more rapid resumption of daily activities, for patients requiring surgical treatment of acute cholecystitis. Although the laparoscopic approach was more expensive, cost-savings could be achieved among the category of employed patients because of shorter sick leave in comparison with open surgery.

**CRD COMMENTARY - Selection of comparators**

The selection of the comparators was appropriate because open surgery represented the conventional cholecystectomy, while the laparoscopic procedure was the innovative surgical approach. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The effectiveness evidence came from a cohort study. It was not stated whether the study was carried out prospectively or retrospectively. This represents a crucial issue since the retrospective nature of the design would reduce the robustness of the analysis. The lack of random allocation of the patients to the study groups could have introduced some selection bias. Further, the impact of confounding factors could not be excluded. However, the two groups were comparable at baseline. The evidence came from a single institution, thus caution is required when extrapolating the results of the analysis to other centres. It was unclear whether the study sample was representative of the patient population. The authors stated that the high rate of conversion to open surgery could have reflected a learning curve for laparoscopy. Moreover, no evidence about the appropriateness of the sample size was provided. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**

No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments above in the 'Validity of estimate of measure of effectiveness' field.

**Validity of estimate of costs**

The authors adopted a societal perspective, which was the most appropriate one due to the impact of indirect costs on the total costs associated with the two surgical procedures. Therefore, all relevant categories of costs were considered. The unit costs were presented separately from the quantities of resources used, which enhances the possibility of replicating the study. The source of the costs was not clearly reported, while resource use data was derived from the sample of patients included in the clinical study. Statistical analyses of the costs were performed, but the cost estimates were specific to the study setting. The price year was not explicitly reported, which makes reflation exercises in other settings difficult. However, the authors reported the gross domestic product in Croatia for 1998, which could have been the price year.

**Other issues**

The authors compared their findings with those from other studies, but only for some clinical and economic end points.
The current results were generally consistent with those from other reports. The issue of the generalisability of the study results to other settings was not explicitly addressed and the authors did not perform any sensitivity analysis. All data were specific to the authors' setting, which reduces the external validity of the study.

Implications of the study
The study results suggested that laparoscopic cholecystectomy could be a cost-effective strategy for employed patients requiring surgical treatment of acute cholecystitis. The authors pointed out that both employers and health insurance companies should consider the impact of the interventions on the length of sick leave for employed patients.

Source of funding
None stated.

Bibliographic details

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Acute Disease; Adolescent; Adult; Aged; Aged, 80 and over; Cholecystectomy /economics /methods /statistics & numerical data; Cholecystectomy, Laparoscopic /economics /methods /statistics & numerical data; Cholecystitis /economics /surgery; Comparative Study; Cost-Benefit Analysis; Female; Health Care Costs; Hospital Costs; Humans; Male; Middle Aged; Reoperation; Sick Leave /economics /statistics & numerical data; Time Factors; Treatment Outcome

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