Mini-laparotomy cholecystectomy in the era of laparoscopic cholecystectomy: a community-based hospital perspective

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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 use of mini-laparotomy cholecystectomy (minicholecystectomy) and laparoscopic cholecystectomy was assessed. Minicholecystectomy was performed through a short incision, with the length of incision kept smaller than 6 cm (the authors reported that this technique was modified from that described in the literature). Laparoscopic cholecystectomy was performed using an open Hassan method.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were undergoing a cholecystectomy for non-acute symptomatic cholelithiasis. Patients who had preoperative endoscopic retrograde cholangiopancreatography, sphincterotomy before the laparoscopic cholecystectomy, and common bile duct explorations were excluded from the study.

Setting
The setting was secondary care. The economic study was carried out in Brooklyn, New York, USA.

Dates to which data relate
The dates to which the effectiveness evidence and resource use data related were not reported. The price year was also not reported.

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

Link between effectiveness and cost data
The costing was carried out retrospectively on the same patient sample that provided the clinical data.

Study sample
The patient sample was identified through a retrospective audit of hospital records. Over a 2-year period, the authors reviewed the charts of 108 patients. Eight patients in the control group and 12 patients in the intervention groups did not meet the inclusion criteria. Further, 14 patients (5 in the intervention group and 9 in the control group) were excluded because their operation was converted to an open procedure. Of the patients included in the study, 33 met the criteria...
for minicholecystectomy. These were matched with 33 patients from a pool of 62 potential control group patients on the basis of age, gender, body surface area, and Acute Physiological and Chronic Health Evaluation (APACHE II) score. No power calculations were reported.

**Study design**
This was a retrospective case-control study that was conducted in a single centre. The patients were followed up until discharge from the hospital. Due to the study design, there was no loss to follow-up and no blinding to treatment.

**Analysis of effectiveness**
Since patients in whom the operation was converted to an open procedure were excluded, the analysis of the data were conducted on the basis of treatment completers. The primary health outcomes assessed were:

- the duration of the operation,
- intramuscular analgesia required postoperatively,
- the incidence of postoperative complications,
- patient satisfaction, and
- the length of hospital stay.

The two patient groups were shown to be comparable in terms of age, gender, body mass index, and APACHE II scores.

**Effectiveness results**
For minicholecystectomy, the mean operation time was 93.0 minutes (range: 65 - 130) for male patients and 95.7 minutes (range: 55 to 140) for female patients. The corresponding values for patients undergoing laparoscopic cholecystectomy were 119.0 minutes (range: 80 - 190) for males and 116.3 minutes (range: 65 - 195) for females. The difference in the length of time taken for the two operations was not significant, (p=0.79).

For minicholecystectomy, the mean length of hospital stay was 1.2 days (range: 1 - 2) for male patients and 1.29 days (range: 0 - 5) for female patients. The corresponding values for patients undergoing laparoscopic cholecystectomy were 1.0 days (range: 0 - 2) for males and 2.21 days (range: 0 - 15) for females. The difference in hospital stay for the two operations was not significant, (p=0.68).

The mean amount of postoperative intramuscular analgesia for male patients having either operation was 30 mg meperidine (range: 0 - 50). Female patients received a mean of 108.0 mg meperidine (range: 0 - 650) if they had undergone a minicholecystectomy and 141.0 mg meperidine (range: 0 - 1,350) if they had undergone a laparoscopic cholecystectomy. This difference was not statistically significant, (p=0.35).

The patients in both groups were equally satisfied with their residual scars.

There were two postoperative complications (bile leak and post operative myocardial infarction) in the laparoscopic cholecystectomy group, but no complications in the minicholecystectomy group within 6 months postoperatively.

**Clinical conclusions**
The authors concluded that minicholecystectomies were as safe and effective as laparoscopic cholecystectomies.

**Measure of benefits used in the economic analysis**
No measure of benefits was included in the economic analysis. The study was, in effect, a cost-consequences analysis.
Direct costs
The authors did not report the perspective adopted, but it appears that the direct costs of the hospital were considered. The only costs included in this analysis were the standard average costs of the procedure and operating room instrumentation. The authors did not report how the data on resource use were collected, or the source of the unit costs. Resource use and the unit costs were not reported separately. No price year was reported. Discounting was not appropriate and was not undertaken.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect costs were included in the paper.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The average operating room expense for both groups was $1,318 for a 60-minute operation and $250 for each additional 30 minutes.

The cost of the instruments required for operation was $489 for minicholecystectomy and $1,279 for laparoscopic cholecystectomy.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
Mini-laparotomy cholecystectomy (minicholecystectomy) is a safe, clinically effective and cost-effective alternative to laparoscopic cholecystectomy.

CRD COMMENTARY - Selection of comparators
The comparator used in the study was chosen because it represented the 'gold' standard in the authors' setting. You should consider how this relates to your setting before applying the results of this study.

Validity of estimate of measure of effectiveness
The clinical effectiveness data were taken from a retrospective case-control study. This assessment has a number of inherent biases. A randomised controlled trial would have provided a more robust estimate of the effectiveness of the two operations. The two patient groups were shown to be comparable in terms of age, gender, body mass index, and
APACHE II scores. The authors did not compare their patient sample with the study population. Sample size or power calculations were not reported. The fact that the study failed to show any statistically significant differences might be attributable to the small sample size. The retrospective nature of the study means that the data were analysed on the basis of treatment completers, which potentially overestimates the effectiveness of the operations.

**Validity of estimate of measure of benefit**
No measure of benefit was used in the economic analysis. Therefore, the study was classified as a cost-consequences study.

**Validity of estimate of costs**
The economic perspective of the study was not explicitly reported, although a hospital view appears to have been adopted. The only costs included in the analysis were those of the procedure and operating room instruments required by each operation. This was due to the fact that there were no statistically significant differences in operation time or length of hospital stay between the two patient groups. It is unclear how the limited assessment of costs impacts on the economic analysis. However, the small sample size is likely to mean that the study did not have sufficient power to identify any potential difference in the costs. The paper did not report a price year, which will seriously impede any future reflation exercises. No statistical or sensitivity analyses were conducted, therefore the extent of uncertainty in the findings was not explored. These factors also limit the generalisability of the study results.

**Other issues**
The authors presented their data comprehensively and their conclusions accurately reflected the data presented in the paper. However, given the small sample size, their conclusions should be more tentative. The issue of generalisability to other settings was not addressed and sensitivity analyses were not performed, thus the external validity of the analysis is low. Caution is therefore required when extrapolating the results of the analysis to other settings. The authors made some limited comparisons with other studies. They did not report any further limitations of their study.

**Implications of the study**
The authors recommended that training in minicholecystectomy should routinely be provided to surgeons. They also suggested that minicholecystectomy should be used, in particular, in patients who cannot tolerate laparoscopic procedures and in areas where cost containment is critical.

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