Cost-effectiveness analysis of laparoscopic versus minilaparotomy cholecystectomy for gallstone disease: a randomized trial
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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 either laparoscopic cholecystectomy (LC) or minilaparotomy cholecystectomy (MC) for patients with gallstone disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with right upper abdominal pain without any history suggestive of obstructive jaundice, and ultrasonic demonstration of gallstones with normal common bile duct, pancreas and liver. Patients with a history of obstructive jaundice and with stones in the common bile duct were excluded.

Setting
The setting was a hospital. The study was carried out in India.

Dates to which data relate
The effectiveness and cost data were collected between July 1995 and April 1997. 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 performed prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations, to assure a certain power, were not reported in the planning phase of the study. Patients who met the inclusion criteria during the study period were considered for the effectiveness analysis. A total of 100 patients were recruited and randomised to either the LC arm (n=59) or the MC arm (n=41). In the MC group, one patient was found to have adenocarcinoma gall bladder postoperatively and was excluded from the initial MC group. Therefore, the final MC group comprised 40 patients. The method used to select the sample was not reported. The authors did not provide any evidence that the study sample was representative of the study population.
Study design
This was a randomised controlled trial (RCT) that was performed at a single centre. It seems that blinding of the patients was not possible, as both surgical procedures produced different number of cutting incisions, in different locations. The patients were followed up for 4 weeks. No losses to follow-up were reported, but the authors stated that one patient allocated to the MC group decided finally to undergo LC.

Analysis of effectiveness
The basis for the effectiveness analysis was intention to treat. The main health outcomes considered for each of the treatment arms were:

the number of successful cases; and

the pain scores at 24 hours after operation and at the first, second and fourth week of follow-up, as measured on a visual analogue scale from 0 to 10.

Other clinical outcomes included:

the number of conversions to open cholecystectomy;

the mean day of drain removal;

the mean postoperative hospital stay;

the number of patients with bile leak;

the number of patients with wound infection, and the number of these that had pus discharge from the wound.

The patient groups were similar in terms of age, education status and mean monthly income, although there was a higher percentage of women in the LC group than in the MC group.

Effectiveness results
There were 50 successful cases (out of 59) in the LC group versus 15 (out of 40) in the MC group.

The pain scores were significantly higher for patients in the MC group at all evaluated times, (p=0.0000).

There was one conversion to open cholecystectomy in the MC group versus none in the LC group.

Although patients in the MC group presented slightly higher mean values for the days of drain removal and the postoperative hospital stay, the differences were not significant in comparison with the LC patients, (p=0.06).

There were 5 patients (12.5%) with bile leak in the MC group versus one (1.7%) in the LC group.

There were 11 MC patients with wound infection, of which four had pus discharge. It was not stated whether any LC patient experienced wound infection.

Clinical conclusions
When compared with MC, LC was more effective for all the parameters considered in the clinical analysis. LC achieved more successful cases, lower pain scores, and shorter times of drain removal and hospital stay.

Measure of benefits used in the economic analysis
The summary measure of benefit used was the number of successful cases. This measure of benefit was obtained directly from the effectiveness analysis.
Direct costs
The direct costs considered in the study were related to the hospital and travel. The hospital costs included the costs of the operation (disposable materials, equipment, operation theatre, and others), hospital stay, drugs and investigation. The source used for the cost estimation was the hospital where the study was performed. Therefore, the costs appear to have been estimated from actual data. Some charges, instead of costs, were used in the estimation of the costs. No adjustments, to reflect the opportunity costs of the interventions, were made. Moreover, some but not all of the resources used were reported separately from the costs. The price year was not given. No discounting was performed, although it was not required since the period considered at analysis was only 4 weeks. The total costs and the average cost per patient were reported.

Statistical analysis of costs
The authors reported the mean costs per patient with 95% confidence intervals (CIs). No other statistical analyses of the costs were reported.

Indirect Costs
No indirect costs were included in the economic analysis. The authors justified the exclusion of such costs on the grounds that most of the patients were housewives, and assumed that the exclusion of loss of wages in both groups did not affect the overall cost-effectiveness of the interventions.

Currency
Indian rupees (Rs).

Sensitivity analysis
Sensitivity analyses were not reported.

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

Cost results
The total costs were Rs 386,769 for the LC group versus Rs 205,041 for the MC group.

The average cost per patient was Rs 6,555.407 (95% CI: 5,754.5 - 7,356.27) in the LC group and Rs 5,126.025 (95% CI: 4,543 - 5,708) in the MC group.

The incremental cost incurred per additional successful case attained when LC was performed, compared with MC, was Rs 1,429.37.

Synthesis of costs and benefits
The estimated benefits and costs were combined by calculating cost-effectiveness ratios (CERs) as the cost per successful case for each study group. Moreover, an incremental CER was estimated as the incremental cost per additional successful case obtained with LC when compared with MC.

The CERs obtained were Rs 7,735.38 per successful LC case versus Rs 13,669.40 per successful MC case. The incremental CER obtained when LC was performed, compared with MC, was Rs 3,028.33 per additional successful case.
Authors' conclusions
Laparoscopic cholecystectomy (LC) was more cost-effective than minilaparotomy cholecystectomy (MC) for the treatment of patients with gallstone disease.

CRD COMMENTARY - Selection of comparators
LC was implicitly chosen as the comparator, as it is the health technology currently used in the authors' setting for the treatment of patients with gallstone disease. You must decide which health technology is most widely used in your own setting for this type of patient.

Validity of estimate of measure of effectiveness
Although an RCT was performed, the use of blinding did not appear possible, which may have introduced bias in the clinical results obtained. The authors did not provide any evidence that the study sample was representative of the study population. The study groups were shown to be similar in terms of age, education status and mean monthly income, but the LC arm contained a higher percentage of women than the MC arm. Statistical analyses were not reported for the comparisons of some of the relevant health outcomes (e.g. for the number of successful cases, which was the primary health outcome used).

Validity of estimate of measure of benefit
The estimation of benefits was obtained directly from the effectiveness analysis. Whilst it may have been a relevant choice, other summary measures of benefit could have been used. For example, as quality-adjusted life years, which would have allowed the results to be compared with those from other interventions.

Validity of estimate of costs
The perspective adopted appears to have been societal since the authors aimed to include the indirect costs in the economic analysis, although they did not finally estimate them. The costs associated with lost work were not included because most of the patients were housewives. It can be argued that this is not a justified reason for leaving out this category of costs, in case a societal perspective were to be adopted. Further, it seems that the follow-up costs incurred after the surgical procedure have not been considered in the economic evaluation. Consequently, the estimation of the costs might have been biased. Some charges, instead of costs, were used for the cost estimation, which might not have reflected the true opportunity costs of the interventions. No adjustments to correct for this were made. Since not all the resource quantities were reported separately from the costs, and the price year was not given, there may be problems in performing reflation exercises to other settings.

Other issues
The authors made appropriate comparisons of the study findings with those reported by other studies. Several studies showed similar findings for some of the estimate results, although others were in disagreement. Therefore, the medical literature related to the health technologies under evaluation is controversial. The issue of the generalisability of the results was not addressed.

Implications of the study
The authors recommended the use of LC by most public hospitals in their setting. They pointed out that the surgical team must be appropriately trained to perform this surgical procedure.

Source of funding
None given.

Bibliographic details
NHS Economic Evaluation Database (NHS EED)
Produced by the Centre for Reviews and Dissemination
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PubMedID
11758294

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Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Cholecystectomy /adverse effects /economics /methods; Cholecystectomy, Laparoscopic /adverse effects /economics; Cholelithiasis /surgery; Cost-Benefit Analysis; Female; Humans; India; Male; Pain Measurement; Pain, Postoperative /classification; Technology Assessment, Biomedical /economics /methods

AccessionNumber
22001008290

Date bibliographic record published
28/02/2005

Date abstract record published
28/02/2005