Video-colecistectomia versus mini-colecistectomia: analisi dei costi ospedalieri e dei costi sociali in uno studio prospettico randomizzato [Laparoscopic versus mini-cholecystectomy: analysis of hospital costs and social costs in a prospective randomized study]


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 interventions under study were laparoscopic video cholecystectomy (VC) and mini-cholecystectomy (MC) for patients with gallstone disease.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis; Cost-utility analysis.

Study population
The study population consisted of patients with simple, symptomatic, gallstone disease.

Setting
The setting was a university hospital. The economic study was carried out in Genoa, Italy.

Dates to which data relate
Data on effectiveness and resource use were gathered between January 1994 and December 1999. No price year was reported.

Source of effectiveness data
A single study was used as the source of effectiveness data.

Link between effectiveness and cost data
The costing was conducted retrospectively on the same sample of patients as that used in the effectiveness study.

Study sample
The method of sample selection was not reported. Power calculations were not performed. A sample of 181 patients was enrolled in the study: 91 cases in the VC group and 90 in the MC group. However, 5 patients in the former group, and 4 patients in the latter, were converted to conventional cholecystectomy and were not considered for the final analysis. Thus the actual sample evaluated in the effectiveness study comprised 86 patients in each study group. The median age was 54 years (range: 23 - 83 years) in the VC group and 52 years (range: 19 - 76 years) in the MC group. The proportion of male patients was 39.5% and 36%, respectively. The authors stated that a substantial number of patients refused to participate in the study.
Study design
This was a prospective randomised controlled trial, carried out in a single centre, the University Hospital of Genoa. The method of randomisation was not reported. The same surgeon performed all interventions. The length of follow-up was six months and no loss to follow-up was observed in the actual sample of 86 patients in each group. Patients were visited after 8-10 days postoperatively and contacted by telephone at 30 days and 6 months after the intervention.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The health outcomes used in the effectiveness study were the proportion of patients receiving hepatic drainage, median operating time, median anaesthetic time, median hospital stay, median number of days off work, new admissions, postoperative complications, proportion of symptomatic patients after 30 days, use of domiciliary analgesic therapy, satisfaction with the intervention after 6 months. Study groups were well balanced with respect to age and gender at baseline. Further discussion on the comparison of clinical characteristics was not carried out.

Effectiveness results
The effectiveness results were as follows:

In the VC and MC groups, the proportion of patients receiving hepatic drainage was 38.4% and 74.7%, respectively, (p=0.0001);

the median operating time was 35 (range: 20 - 120) minutes in the VC group and 35 (range: 20 - 50) minutes in the MC group;

the median anaesthetic time was 50 (range: 35 - 140) minutes in the VC group and 50 (range: 30 - 70) minutes in the MC group;

the median hospital stay was 3 (range: 2 - 8) days in the VC group and 3 (range: 2 - 5) days in the MC group;

the median number of days off work was 10 (range: 2 - 45) days in the VC group and 20 (range: 7 - 30) days in the MC group, (p=0.007);

the number of new admissions was 4 in the VC group and 1 in the MC group;

among the postoperative complications, the most notable factor was that 10 patients in the MC group complained about unaesthetic wound compared to no patient in the VC group, (p=0.002).

With respect to occurrence of symptoms after 30 days, in the VC group 80.2% of patients were asymptomatic, 16.3% presented moderate symptoms, and 3.5% presented severe symptoms;

in the MC group 81.4% of patients were asymptomatic and 18.6% presented moderate symptoms.

In terms of use of domiciliary analgesic therapy, it was considered as adequate in 82.5% of patients and insufficient in 17.5% of patients in the VC group, while the corresponding figures in the MC group were 75.6% and 24.4% of patients.

At six months, full satisfaction with the intervention was observed in 95% of patients in the VC group and 78% of those in the MC group, (p=0.001).

Clinical conclusions
The effectiveness study showed that there were significantly more satisfied patients in the VC group than in the MC group. The number of days off work was statistically significantly greater and there was a higher occurrence of complications, such as unaesthetic wound, in the MC group than in the VC group.
Measure of benefits used in the economic analysis
The benefit measures used in the economic analysis were days off work and quality-adjusted life-years (QALYs). QALYs were calculated by multiplying the value of patient satisfaction (which was considered as a proxy for quality of life) by the duration of days off work. Both were evaluated in the effectiveness study.

Direct costs
Discounting was not relevant because costs were incurred over a period of six months. Unit costs were reported separately from quantities of resources only for a few items. The health service costs included in the economic evaluation of direct costs were surgical operation (operating room, equipment, drugs, and personnel) and hospital stay. The cost/resource boundary adopted in the study was that of the hospital. The estimation of unit costs was based on data coming from the Finance Department of the study hospital. Resource use was evaluated alongside the clinical trial over the period 1995-1999. No price year was reported.

Statistical analysis of costs
Statistical analyses of costs were not conducted.

Indirect Costs
Indirect costs were included in the economic evaluation as the cost of days off work, which were paid by the social insurance system (INPS). The unit cost of one day off work was reported separately from the number of days off work. Resource use was based on data derived from the same patients included in the effectiveness study. The price year was not reported.

Currency
Euros (Euro).

Sensitivity analysis
No sensitivity analyses were performed.

Estimated benefits used in the economic analysis
As evaluated in the effectiveness study, the median number of days off work was 10 (range: 2 - 45) in the VC group and 20 (range: 7 - 30) in the MC group. Thus in percentage terms, the benefit of the two interventions was 10% in the VC group and 5% in the MC group. The number of QALYs was 9.5 in the VC group and 3.9 in the MC group.

Cost results
Total costs were Euro 3,389.73 in the VC group and Euro 3,158.03 in the MC group.

Synthesis of costs and benefits
The authors calculated the incremental cost-effectiveness and cost-utility ratios in order to combine the costs and benefits of the two alternative treatments. However, the indirect costs were not included in the total costs included in the analysis. The incremental cost per day off work with VC over MC was Euro 164.96 and the incremental cost per QALY was Euro 146.51.

Authors' conclusions
The authors concluded that VC was more effective than MC with respect to days off work and quality of life, but the cost-effectiveness and cost-utility ratios showed that MC was efficient from the perspectives of both the hospital and
the society for patients with gallstone disease in Italy. Indeed, although the number of days off work was significantly higher after MC, the overall costs were higher with VC due to the expenses associated with the procedure itself. Thus MC should be implemented, above all for those patients who do not need to return to work early, for whom the greatest cost-savings may be realised.

CRD COMMENTARY - Selection of comparators
The authors stated that VC represented the standard approach for patients with gallstone disease since it replaced completely conventional cholecystectomy due to higher effectiveness and lower associated costs as reported in a substantial number of previous studies. VC represented a more innovative procedure, whose cost-effectiveness had not yet been evaluated. You, as a user of this database, should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on a randomised controlled trial, which was appropriate for the study question. However, the authors acknowledged that a high number of patients who were invited to participate refused to participate in the study. The methods of sample selection and randomisation were not described. Power calculations appear not to have been performed and no evidence concerning the appropriate sample size was provided. The analysis of the clinical study was limited to patients who completed the treatment. The length of follow-up was reported.

Validity of estimate of measure of benefit
QALYs were used as the main benefit measure and appear appropriate to enhance the comparability of the benefit of the present study with the outcomes of other interventions funded by the NHS in Italy. The method used to calculate QALYs was reported. The authors also used the number of days off work as a further benefit measure to evaluate the impact of the interventions from a societal perspective.

Validity of estimate of costs
The perspective adopted in the study was reported and it appears that all relevant categories of costs were included in the economic analysis. The source of cost data was reported and details on resource use and unit costs were mentioned. However, no price year was reported. Resource use was evaluated alongside the clinical study. No statistical analyses of costs were carried out.

Other issues
The authors compared their findings with those from previously published studies and their results were not similar to those reported in the literature. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not conducted, thus the external validity of the analysis was limited. The study referred to patients with gallstone disease and this was reflected in the conclusions of the analysis. The authors noted that MC may not represent a feasible approach for obese patients.

Implications of the study
The study results suggest that MC offers a more efficient cost-effectiveness ratio than VC for the management of patients with gallstone disease. The intervention produces the greatest benefits for those patients who do not need to return to work early.

Source of funding
None stated.

Bibliographic details

PubMedID
12469466

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Aged; Aged, 80 and over; Cholangiography; Cholecystectomy /economics; Cholecystectomy, Laparoscopic /economics; Cholelithiasis /surgery; Convalescence; Cost-Benefit Analysis; Costs and Cost Analysis; Data Interpretation, Statistical; Female; Humans; Length of Stay; Male; Middle Aged; Patient Compliance; Postoperative Complications; Prospective Studies; Retrospective Studies; Socioeconomic Factors; Time Factors; Work

AccessionNumber
22003006032

Date bibliographic record published
31/10/2003

Date abstract record published
31/10/2003