Hernioplasty and simultaneous laparoscopic cholecystectomy: a prospective randomized study of open tension-free versus laparoscopic inguinal hernia repair

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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 simultaneous laparoscopic cholecystectomy (LC) and laparoscopic transabdominal preperitoneal (TAPP) hernia repair for the treatment of patients suffering from both cholelithiasis and hernia.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients suffering gallbladder disease and abdominal hernia, for which a LC had been scheduled.

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

Dates to which data relate
The effectiveness and resource use data were gathered between January 1994 and April 1997. The price year was not reported.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
A specific sample size was preliminarily determined to assure a certain power. All adult low-risk patients requiring elective surgical treatment for both symptomatic chronic calculous cholecystitis and synchronous unilateral primary inguinal hernia, who were hospitalised at the authors’ institution between January 1994 and February 1997 were included in the sample.

The exclusion criteria were pregnancy, high risk for anaesthesia, coagulation disorders, prior complicated operations, irreducible or congenital hernia, and massive scrotal or sliding hernia. Only those patients who allowed the surgeon to...
select the type of procedure for the hernia treatment were included in the trial. Sixty patients were included, and were equally divided into the two groups.

**Study design**

This was a randomised clinical trial carried out in a single centre, a general surgery university practice. Patients were randomised using a blind envelope system whereby the seal was only broken the day before the operation. Patients were first examined 7 days after the intervention, following which short-term and long-term follow-ups were scheduled. The short-term follow-up consisted of post-operative examinations at 1 and 3 months. The long-term follow-up, post-operative examinations were carried out at 6, 12, 24 and 36 months. Two personnel performed the follow-up examinations, blinded to the nature of the surgical procedure used. Only one patient in the LC and open group was unavailable for the final follow-up examination, although he was interviewed by telephone.

**Analysis of effectiveness**

The clinical study was analysed on an intention to treat basis; all the participants included in the analysis completed the study. The primary health outcomes were:

- the duration of the operation;
- the nature of intra-operative complications;
- the number of patients converting to open surgery;
- the presence and intensity of post-operative pain;
- shoulder tip pain;
- the number of intramuscular analgesics;
- the number of oral analgesics after discharge;
- the duration of hospital stay;
- post-operative course, i.e. complications and recurrence of hernia;
- the time taken to resume physical activity; and
- the presence of discomforting pain in the inguinal region.

The intensity of post-operative pain was assessed using a visual analogue scale, which ranged from a value of 1 for the absence of pain to 10 for the worst possible pain. The evaluation was performed once immediately before surgery, and then at predetermined time intervals of 6, 12, 24, 48 hours and 7 days after operation. No statistical difference was found between the two groups in terms of age, gender, mean age, mean weight, mean height, physical status (ASA I and II), and distribution of hernia (Nyhus class II, IIIa, IIIc).

**Effectiveness results**

The mean (+/- standard deviation) operating time was 121 (+/-32) minutes in the LC and TAPP group, compared with 95 (+/-27) minutes in the LC and open group.

No intra-operative complications were observed and no patient required conversion to open surgery.

The proportion of patients reporting post-operative pain at any time during the first seven days after operation was 83% (25 patients) in the LC and TAPP group, and 90% (27 patients) in the LC and open group.
The median visual scores for pain revealed a greater intensity of post-operative pain in the LC and open group at 24 and 48 hours after the operation. No significant difference was found at any of the remaining control times.

Shoulder tip pain was significantly more frequent in the LC and TAPP group (40%), compared with the LC and open group (17%).

The number of intramuscular analgesics required was significantly higher in those who underwent the LC and open treatment (mean 3.3 injections), compared with those who underwent the LC and TAPP technique (mean 1.6 injections).

No significant difference was found between the number of oral analgesics required.

No differences were found in the duration of hospital stay, post-operative complications, hernia recurrence, and the time taken to resume physical activity.

Discomforting pain in the inguinal region was significantly more frequent in the LC and open group (30%), compared with the LC and TAPP group (7%).

Clinical conclusions
The study revealed that neither of the two interventions could be considered more effective. The LC and TAPP yielded better results in terms of post-operative pain and the use of pain medication. However, the operating time was shorter for the LC and open strategy, and shoulder tip pain was less frequent.

Measure of benefits used in the economic analysis
Since no summary health benefit was used, and the clinical effectiveness results were not shown to be equivalent, a cost-consequences analysis was performed.

Direct costs
The costs were not discounted. The operating costs were evaluated by listing the disposable instruments and materials, such as sutures. The anaesthetic costs were not included as they were assumed to be equal for both the interventions. The quantities and costs were not analysed separately and the estimation was based on the actual data. The quantities of resources were measured between January 1994 and February 1997. The price year was not reported.

Statistical analysis of costs
A statistical analysis of costs was undertaken in order to test for significant differences between the two groups of patients.

Indirect Costs
Indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Cost results
The mean total operating cost was $1,235 in the LC and TAPP group and $1,080 in the LC and open group. The difference was statistically significant.

Synthesis of costs and benefits
Not applicable.

Authors’ conclusions
The authors concluded that the study has demonstrated the safety of both procedures. The simultaneous laparoscopic cholecystectomy (LC) and laparoscopic transabdominal preperitoneal (TAPP) intervention produced no benefit other than improved comfort in the first 2 post-operative days. In addition, it was more expensive and more difficult to perform (longer operating time) than the LC and open tension-free procedure.

CRD COMMENTARY - Selection of comparators
The comparator was selected on the basis that it represented current practice: LC and open repair were the current technologies employed for gallbladder disease and inguinal hernia, respectively. You should consider whether these technologies are widely used in your own setting.

Validity of estimate of measure of effectiveness
The study design seemed appropriate for the study hypothesis. Patient groups were shown to be comparable, and an extensive statistical analysis was undertaken to take potential biases and confounding factors into account.

Validity of estimate of costs
Only direct operating costs were considered. The costs of anaesthesia were not included in the analysis, as these were assumed to be equal for both interventions. This variable could have been included since the operating times were longer for the LC and TAPP approach. However, as the authors noted, this would have only increased the cost differential between the two strategies: the average cost of LC and TAPP was already greater than for LC and open. The costs and quantities were not reported separately, and the price year was not reported.

Other issues
The authors compared their findings with those from other studies. The generalisability of the results to other settings could be limited because no sensitivity analysis was performed.

Implications of the study
The authors recommended that open preperitoneal mesh repair should be adopted, even for patients undergoing LC. The total laparoscopic approach is advisable only if performed by an experienced laparoscopic surgeon with special expertise in hernia surgery.

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