Laparoscopic versus open appendectomy: a prospective randomized trial

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
Laparoscopic appendectomy (LA) and open appendectomy (OA).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients older than 12 with a preoperative diagnosis of acute appendicitis.

Setting
Hospital. The study was carried out in Barcelona, Spain

Dates to which data relate
Effectiveness and resource data related to the period January 1992 to December 1994. The price year was not stated.

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

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

Study sample
The sample comprised 210 patients who were divided into two groups by means of a randomisation process (envelope method). 106 patients were allocated to the LA group and 104 to the OA group. The groups were comparable in terms of age, gender distribution and numbers of perforated appendicitis. The average age was 26.52 (+/- 13.23) years for the LA group and 28.74 (+/- 15.29) years for the OA group. The composition by gender was 42 male/64 female for the LA group and 48 male/56 female for the OA group. 5 patients had perforated appendicitis in the LA group (5 abscess, 0 diffuse, 5.5%) and 6 in the OA group (5 abscess, 1 diffuse, 6.6%). No patient refused to participate or wanted to change group. Power calculations were not performed to determine the sample size.

Study design
The study was a randomised controlled trial conducted in a single centre. The follow-up was until hospital discharge.
The experiment was conducted by randomly allocating the patients to the two groups. No loss to follow up was reported. No blinding was undertaken.

**Analysis of effectiveness**
The basis for the analysis was not explicitly stated but is likely to have been intention to treat. The main health outcome is understood to be the success rate which was implicitly considered to be equal between the two groups. In addition, the primary health outcomes used in the analysis were: operation room time (ORT), regular diet resumption (RDR), postoperative analgesia (PA), length of postoperative hospitalisation (LPH) and postoperative morbidity. The groups were comparable in terms of age, gender and other possible confounding variable.

**Effectiveness results**
The effectiveness results were as follows (standard deviation in brackets):

(a) ORT: LA=55.20 (26.14), OA=44.68 (16.63); p value <0.05.

(b) RDR: LA=1.60 (1.41), OA=2.31 (1.61); p value <0.05.

(c) PA: Parenteral: LA 2.80 (1.20), OA=4.10 (0.70); p value <0.05.

(d) PA: Oral: LA=3.91 (1.31), OA=6.90 (1.21); p value <0.05.

(e) LPH (days): LA=3.42 (1.86), OA=4.75 (2.65); p value <0.05.

(f) Postoperative morbidity: LA total=6 (1 abscess, 2 seromas, 2 urinary infections, 1 hemoperitoneum, 1 intraabdominal abscess); OA total=8 (5 abscess, 1 seroma, 1 small bowel occlusion, 1 bleeding gastric ulcer); difference not significant.

No confidence intervals were computed.

**Clinical conclusions**
The authors stated that the efficacy of the two techniques, as well as the postoperative morbidity, was the same, but the laparoscopic procedure offers a better postoperative course without adding morbidity.

**Measure of benefits used in the economic analysis**
No single unit of benefit was developed by the authors and, as such, the clinical outcomes are assumed to be the benefits.

**Direct costs**
No discounting was undertaken. Costs and quantities were not reported separately. Direct costs included operating room costs and postoperative costs. Reusable materials used in the laparoscopic procedure were essential to the cost outcomes. The perspective adopted was that of the hospital from which the costs were derived. The price year was not stated.

**Statistical analysis of costs**
No statistical analysis of costs was carried out. Costs were not regarded as stochastic.

**Indirect Costs**
No indirect costs were considered.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
The benefits were those reported in the effectiveness results.

Cost results
The total costs (standard deviation) per patient were as follows: LA = $394.19 (SD 194.52); OA = $508.32 (SD 266.56). Indirect costs were not considered. As individual cost items were not reported it is not possible to state if important cost items have been omitted.

Synthesis of costs and benefits
No synthesis of costs and benefits was undertaken.

Authors’ conclusions
The authors concluded that LA showed a more comfortable postoperative course (in terms of oral resumption, postoperative stay, and analgesia) over OA with similar morbidity. The LA procedure was associated with more operative but less global cost. The cost of the LA procedure was mainly influenced by the learning curve and the length of postoperative hospital stay.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of comparator is clear. The two procedures were well accepted alternatives in the treatment of the study population considered.

Validity of estimate of measure of benefit
As the study confined itself to a cost and outcomes analysis there was no summary measure of benefit, which introduced some limitations in terms of the strength of the study as an economic evaluation. This could be remedied by research using a utility measure such as the QALY or by a full cost-benefit analysis. In the current analysis, each outcome has to be taken on its own merit. The authors did not report success rate, although the outcomes assessed did implicitly reflect this.

Validity of estimate of costs
Cost data were not presented in sufficient detail thus creating limitations in terms of the generalisability of the results.

Other issues
The authors make good reference to other studies although their conclusions would have been stronger had appropriate cost-benefit measures been derived. An important feature highlighted by the authors is that the cost of the LA is crucially dependent on the learning curve of the technique. In their study the experience of the staff was similar for the two procedures. All conversion cases from LA to OA occurred in the first 50 cases, suggesting that, after a learning period, it is likely that the laparoscopic procedure becomes more efficient. The main variable of interest seems to be the length of hospitalisation and the authors clearly state that this is dependent on the environment, making the generalisability of the results problematic. Nevertheless, in a setting in which the length of hospitalisation is comparable to that in this study, and the time spent in the operating room is not a key feature, the LA procedure could be
considered as a dominant strategy with respect to the OA due to the better postoperative course found for patients treated with the laparoscopic procedure.

**Implications of the study**
No clear cut evidence is found for the choice between laparoscopic or open appendectomy and further studies should focus on developing the economic analysis of the two procedures.

**Source of funding**
None stated.

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