Bare bones laparoscopy: a randomized prospective trial of cost savings in laparoscopic cholecystectomy

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 technology considered was a reduced cost laparoscopic cholecystectomy (LC) protocol for gallbladder removal.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who had been referred for an elective LC. The study population included females and males aged between 21 and 80 who had had prior abdominal surgery. A health index was calculated for each patient and an average of this index was provided for both the control group and the study group. A statistical test was not conducted on the difference between averages of the two groups.

Setting
The setting was secondary care. The LC’s were all performed in the Washington Hospital Centre in Washington, D.C.

Dates to which data relate
The effectiveness data were collected between October 2000 and March 2001. Resource data were collected over the same period. The price year was 2000.

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

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

Study sample
The analysis was performed on 50 patients who were consecutively referred for an LC. No details were provided as to the basis on which patients were referred. No sample size calculations were performed. There were 25 patients in each treatment group.
Study design
The study was a prospective randomised trial conducted in a single centre. Patients were randomised to groups by a computer-generated randomisation scheme. The six physicians involved were also randomised to operations. Patients were blinded to the treatment technique they would receive and the physicians were also blinded to the treatment technique until the operation was due to start. Patients were telephoned 30 days after they were discharged to enable a questionnaire concerning postoperative pain, return to work or normal activity, and satisfaction to be completed.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat. The primary health outcomes considered in the study were complication rates and the results from the postoperative patient assessment (which looked at postoperative pain, return to work or normal activity, and patient satisfaction). The two groups were shown to be comparable in terms of age, sex and prognostic features.

Effectiveness results
The study did not find any significant differences between the two groups with regard to complication rates and the postoperative variables. There were, however, differences with regard to the length of the operation.

The LC took 75.21 +/- 22 minutes in the bare bones group and 90.12 +/- 49 minutes in the control group.

These operation times were reduced to 67.26 +/- 15 minutes in the bare bones group and 70.60 +/- 19 minutes in the control group, when cases converted to open cholecystectomy or when cases in which intraoperative cholangiography was used were excluded.

There were a number of adverse effects in both groups, 28% of the cases in the bare bones group needed suction/irrigation, 1 patient in the bare bones group had bile leak, 1 patient in the control group had a common bile duct (CBD) injury, 20% of gallbladders were perforated in the bare bones group, with 35% of gallbladders perforated in the control group.

In the control group 1 patient had a urinary tract infection, 1 had a flare up of gouty arthritis and 1 patient had urinary retention. Overall 4 cases had to be converted to open cholecystectomy.

Clinical conclusions
The use of a bare bones LC does not have any adverse affects on patients' outcomes when compared to standard LC protocols.

Measure of benefits used in the economic analysis
The effectiveness outcomes were demonstrated to be equal, so, in effect, a cost-minimisation analysis was carried out.

Direct costs
The only costs considered in the study were equipment costs. Other costs, such as hospital costs, could not be obtained but the authors did not explain why. The authors assumed that, as the equivalent length of hospital stay was the same for both groups, total hospital costs would also be the same. The total hospital costs did not include the operative equipment for operating room time or personnel, anaesthesia, postoperative stay in the recovery room or hospital ward. The price year was 1996.

Statistical analysis of costs
Costs were treated deterministically.
Indirect Costs
No indirect costs were recorded.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
The mean disposable equipment costs were $173.00 +/- $43.45 in the bare bones group and $434.42 +/- $50.54, (p<0.0001), in the control group.

Synthesis of costs and benefits
Not relevant as a cost-minimisation was carried out.

Authors' conclusions
The authors concluded that the bare bones LC procedure resulted in cost savings compared to the usual LC procedure. The authors conclude that there are two pieces of equipment that can be safely removed from the usual procedure. These pieces of equipment are the 5-mm trocars that are used in the right flank and the use of suction/irrigation. Removing these pieces of equipment does not lead to any adverse consequences in terms of the effectiveness of the LC procedure. The effectiveness and benefits of the two procedures are the same in both groups.

CRD COMMENTARY - Selection of comparators
The bare bones LC procedure was compared to the usual LC procedure. Usual LC was used as the comparator so that the authors could determine whether the costs of performing an LC could be reduced without sacrificing its effectiveness. Although no explicit justification was given for the comparator used, it would appear to represent current practice in the authors' setting. As a user of this database, you should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective randomised trial, which was appropriate for the study question and which appeared to have been well conducted. It is unclear as to whether the study sample was representative of the study population. Patient groups were shown to be comparable at analysis. Complication rates and postoperative patient assessment were used as measures of effectiveness. However, the authors' did not provide details of how these were calculated or what the results were for each group.

Validity of estimate of measure of benefit
The authors’ did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-minimisation study.

Validity of estimate of costs
The authors stated that some hospital costs could not be obtained. Presumably, these were relevant, however, the major cost comparison was between the equipment costs. The total hospital costs were assumed to be the same for both groups due to the fact that lengths of hospital stay were the same for both groups. Single duct leak was assumed to cost the same as the CBD leak. The authors commented that this latter cost assumption favoured the control group. This could mean that the bare bones protocol has an even greater cost saving. Costs and quantities were not reported separately. The price year was stated. No statistical analyses of quantities or prices were performed.

Other issues
The authors made appropriate comparisons of their findings with those of other studies. Other studies support the finding that a LC can be performed safely without the use of suction/irrigation. The issue of generalisability to other settings was not addressed. The study considered patients who had been referred for an LC and this was reflected in the authors' conclusions. In terms of limitations, the authors noted that the power (sample size) of the sample was too small; although the groups appear similar in terms of safety, the low power meant that the study was too small to detect significant differences in complications that occur at low rate. These complications could be costly.

Implications of the study
LC can be performed at a cost saving without reducing effectiveness.

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