Costs and effectiveness of extracorporeal gallbladder stone shock wave lithotripsy versus 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
Extracorporeal gallbladder stone shock wave lithotripsy (ESWL) and laparoscopic cholecystectomy (LC) for the treatment of symptomatic patients with cholelithiasis.

Type of intervention
Treatment; secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Symptomatic patients, with at least an episode of right upper quadrant or epigastric pain experienced within the last six months (clinically assessed as biliary colic), lasting at least 30 minutes, with ultrasound proven cholelithiasis.

Setting
Hospital. The economic study was carried out in Montreal, Canada.

Dates to which data relate
Cost and effectiveness data were retrieved during an unspecified two-year period. 1993 prices were used.

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

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

Study sample
Sixty patients, aged 16 to 85 were suitable to be enrolled in the study. Following randomisation, 3 (5%) of the 32 patients assigned to ESWL were not treated, the reasons being refusal to be treated, late diagnosis of Takayasu's arteritis and loss to follow-up prior to treatment. There were 25 patients in the LC group. There was no evidence of the use of power calculations in determining the sample size.

Study design
The study was a multi-centre Randomized controlled trial with a median follow-up period of 15 months. Patients were
stratified by age and randomly assigned to either treatment ESWL or LC. No further information about randomisation methods was provided. All symptomatic patients aged 16 to 85, who had experienced, within the last 6 months, at least one episode of right upper quadrant or epigastric pain lasting at least 30 minutes (clinically assessed as biliary colic), with ultrasound proven cholelithiasis, who were judged fit for elective cholecystectomy, were eligible for entry into the trial. Because of the requirements for ESWL, all patients included needed to have three or less non-calcified gallbladder stones, each measuring from 6 to 30mm within a gallbladder which opacified on oral cholecystography. Because of the requirements for LC, patients who were unfit for general anaesthesia, or who had previously undergone upper abdominal surgery were excluded. Other reasons for exclusion were pregnancy, advanced liver disease, acute cholecystitis, coagulation abnormalities, the presence of a pacemaker or abnormal atrioventricular conduction, an abdominal vascular aneurysm, a pneumonic consolidation on chest x-ray, or not wishing to accept random allocation to either treatment group. An additional reason for exclusion was the pre-operative suspicion of a common bile duct stone, based on historical, biochemical, or ultrasonographic abnormalities (3).

Analysis of effectiveness
Effectiveness data were analysed according to the intention to treat principle. The primary outcome of the study was duration of disability which mainly accounted for duration of convalescence, time away from usual activities attributable to follow-up and time away from usual activities due to recurrent biliary colic. Secondary outcomes included quality of life, assessed by administering three quality of life instruments: Nottingham Health Profile Questionnaire (NHPQ), the Visual Analogue Scale (VAS) and the German Quality of Life Questionnaire (GGQLQS). Additionally, post-operative pain was measured with the McGill Pain questionnaire. Groups were shown comparable in terms of their pre-treatment characteristics.

Effectiveness results
The mean total disability duration was 6.8 (+/- 8.5) days for ESWL and 22.7 (+/- 16.6) days for LC patients at a median of 15 and 18 months follow-up, respectively. Significant improvements in quality of life were identified in both the ESWL and LC group after the first month of the treatment. In each successive follow-up improvements in quality of life were identified but occurred at a slower rate. There were no significant differences in immediate post-treatment McGill Pain Questionnaire scores between the two groups.

Clinical conclusions
The authors concluded that there was "an immediate significant post-treatment improvement in the quality of life in both groups, followed by a rapid continued bettering in the LC group, which was not as marked as in the ESWL group at 6 and 12 months".

Measure of benefits used in the economic analysis
Benefits were measured in terms of the reduction in days of disability.

Direct costs
Detailed accounting of costs related to ESWL and LC was retrieved from an analysis prepared for the Conseil D'Evaluation des Technologies de la Sante du Quebec. No further information about costing was provided in the study.

Statistical analysis of costs
Not stated.

Indirect Costs
Not stated.
Currency
Canadian dollars (Can$) (1993).

Sensitivity analysis
One-way sensitivity analysis was performed on the cost and effectiveness estimators.

Estimated benefits used in the economic analysis
The marginal decrease in duration of disability over the first 15 months following treatment was estimated to be 16.2 days.

Cost results
On average the total cost of laparoscopic cholecystectomy for the management of symptomatic gallstones was estimated to be Can$2,889. Similarly the total average cost of evaluation, intervention, follow-up and UDCA for patients treated with lithotripsy was Can$3,825.

Synthesis of costs and benefits
Estimated total costs and benefits were combined to calculate the incremental cost of additional days of disability. Using baseline estimators an extra cost of $58 per additional day of disability was estimated. Sensitivity analysis revealed the ratio to be quite sensitive to variations in the duration of disability. Conversely, cost-effectiveness ratios were less sensitive to changes in actual total costs.

Authors' conclusions
The authors concluded that gallbladder stone ESWL is of limited applicability with the available generator technologies.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
Quality of life and pain were mentioned in the analysis as secondary outcomes. Nevertheless authors did not attempt to combine these results to produce alternative cost-effectiveness ratios.

Validity of estimate of costs
No details about cost estimation were provided. The authors referred to another source of information.

Other issues
The actual dates of the study were not reported. As the authors acknowledged, some of the limitations of the study were the small sample size and the short follow-up period, which affect the generalisability of the results. Appropriate comparisons were made with other studies. The issue of generalisability to other settings and countries was addressed by the authors.

Implications of the study
Further research is needed on the cost-effectiveness of treatments of cholelithiasis.

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