Outpatient laparoscopic cholecystectomy: patient outcomes after implementation of a clinical pathway


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 implementation of a clinical pathway to guide outpatient laparoscopic cholecystectomy (LC) was compared with inpatient LC. Before the implementation of the pathway, the staff involved were educated about the pathway itself, its structure and its goals.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with gallbladder disease who were eligible for elective LC. Pathway eligibility was based on the surgeon's judgement (no further details were reported).

Setting
The setting was secondary care. The economic study was set in an academic health centre.

Dates to which data relate
The pathways were introduced on 1 April 1999. The pathway patients were assessed for a 12-month period ending on 30 April 2000. The comparator patients were assessed for the 15 months immediately before pathway implementation. Resource use was measured during the same time. The prices were measured and adjusted to pre-pathway amounts, 1999.

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

Link between effectiveness and cost data
The costing was carried out retrospectively using the same sample of patients as that included in the effectiveness study.

Study sample
The authors did not report that power calculations were carried out to estimate the influence of chance on the results, although there was a brief discussion of the small sample size. The initial study sample was selected by including all patients eligible for elective LC in the study setting. It was therefore appropriate for the clinical study question. Eligibility for the pathway was based on the surgeon's judgement. The patients also had to have a responsible adult to
escort them home and be present on the night of surgery, access to medical care within 30 minutes, and the use of a telephone. Hotel accommodation adjacent to the hospital was offered where necessary.

Patients were excluded if they underwent conversion to an open procedure or underwent an urgent or emergency LC. Of the 180 eligible pathway patients, 3 were excluded due to failed (open) LC. Therefore, 177 patients participated in the study. There were 43 patients in the transition group (mean age 39.6 years; 79.1% female) and 137 in the post-pathway group, three of whom were later excluded due to co-morbidities (mean age 44.2 years; 79.1% female). Of the 212 eligible comparator patients (pre-pathway), 4 were excluded due to failed (open) LC. Therefore, 208 patients participated in the study (mean age 44.3 years; 80.3% female).

**Study design**
The basis of the analysis was a cohort study with the groups defined by their exposure to treatment at different times, relative to the introduction of outpatient treatment pathways. The study took place at a single centre, the University of Virginia Health System, Charlottesville (VA). The patients’ charts were reviewed by a trained independent observer and verified by a physician. Data were also collected from the Clinical Data Repository, an electronic database. The reliability of these records was tested with a random sample of patients being surveyed by telephone. The length of follow-up was not reported and the authors did not suggest that there was any loss to follow-up. The initial follow-up of satisfaction outcomes was conducted by telephone. No attempts to blind either the patients or the reviewers were reported.

**Analysis of effectiveness**
The analysis was conducted on the basis of the actual treatment received by the patient. The primary health outcomes were successful same day discharge, reasons for postoperative admission, readmission rates, complications, deaths and patient satisfaction. Patient satisfaction was assessed using the 5-point Likert scale. This scale considers satisfaction, time to return to daily living, adequacy of the length of stay, and specific problems encountered.

The authors initially compared the patient groups using 95% confidence intervals and conducted analyses to adjust for potential confounding factors (gender, age, race and indication for surgery). However, the authors also reported that the patients’ characteristics did not differ between the groups for any category, suggesting that no confounding factors were observed.

**Effectiveness results**
The average length of stay was 0.92 for pre-pathway, 0.63 for transitional and 0.34 for post-pathway patients.

The same day discharge rate increased from 21 to 72% for the entire post-pathway period, and to 88% in the final 3 months. The proportion of patients staying two or more days fell from 9 to 5%.

Of the pathway patients, 23% had unplanned admissions and, of these, 82% were discharged home the next day without complications.

Readmission was 4.3% for pre-pathway, 4.7% for transitional and 1.5% for post-pathway patients. It was not statistically different among the study periods.

There were no procedure-related deaths.

There were no significant differences in the responses of pre- and post-pathway patients to the satisfaction questionnaire, time out of work, or time required for return to normal activities. The authors did, however, acknowledge the small sample sizes and resultant difficulty in detecting significant differences.

The authors reported that adjustments for confounders did not generate any “meaningful” differences from the unadjusted analyses.
Clinical conclusions
The authors concluded that clinical pathway implementation for outpatient LC was "feasible, safe...and not associated with sacrifices in patient satisfaction".

Measure of benefits used in the economic analysis
The authors did not estimate a summary measure of health benefit. In effect, a cost-consequences analysis was conducted.

Direct costs
A perspective for the costing analysis was not reported, although the costs detailed appear to represent the hospital perspective. Discounting was not reported to have been carried out despite the costs being estimated over a prolonged time. The total and per-patient costs were calculated by summing service-specific costs. The quantities were obtained from patient charts, but the source of the unit costs was unclear. The authors focused on room, postanaesthesia unit, operating room, anaesthesia, central services, ambulatory services and pharmacy costs. The costs were measured during the same time as the clinical study (1998 to 2000) and were adjusted to 1999 prices.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
The authors acknowledged that the patients lost time from work but did not include indirect costs, such as those to the wider economy in terms of lost productivity, in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average institutional costs for LC were $3,504 between 1998 and 1999, and $3,684 between 1999 and 2000.

The projected post-pathway costs were $3,718 while the actual post-pathway costs were $3,362.

The authors also stated that the total inflation-adjusted cost-savings per case were $356, giving annualised savings of $62,300. Eligible pathway patients actually receiving treatment on an outpatient basis saved $651 over eligible patients who stayed overnight.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The implementation of a clinical pathway for outpatient laparoscopic cholecystectomy (LC) was "feasible, safe, cost effective and not associated with sacrifices in patient satisfaction".

**CRD COMMENTARY - Selection of comparators**
The authors compared outpatient pathways for LC with inpatient treatment because of increased evidence suggesting that outpatient LC may well be a safe and effective form of treatment that also saves resources. Inpatient LC was standard practice prior to the implementation of the outpatient pathways. The comparators were well explained and justified.

**Validity of estimate of measure of effectiveness**
The basis of the analysis was a cohort study with the cohorts determined by the date each patient was treated, relative to the implementation of the new pathway. This was appropriate for the study objectives and was a logical choice given the nature of the pathway implementation. However, although the authors discussed differences in accounting methods during the study period, they did not discuss whether other time-related confounding factors may have influenced the results. Nevertheless, appropriate comparisons were drawn between the patients groups at analysis demonstrating no significant differences, and suggesting the absence of other time-related factors. The random allocation of the patients to pathway or no pathway over the transition period may have improved the internal validity of the results, and might be considered in similar future work.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. In effect, a cost-consequences analysis was conducted.

**Validity of estimate of costs**
A perspective was not reported for the cost analysis. Therefore, it was not possible to assess whether all the relevant costs were included. The estimates included appear to have covered a broad range of costs from the hospital perspective. The savings per person represented approximately 10% of the total costs per person, suggesting that omissions in cost may not greatly affect the principle results or conclusions.

The authors reported that the unit costs increased during the study period due to a change in accounting methods. Informed adjustments were made, based on the consumer price index, to ensure the costs were comparable with pre-pathway costs. The study would have been greatly improved if further details of the cost analysis had been reported. However, the authors acknowledged that the costing element was not the main focus of their research. Further work might explore this issue in more depth. The indirect costs, which were not included, may well have been relevant to an analysis carried out from a societal perspective, and might be considered in further work.

**Other issues**
The authors made appropriate comparison of their findings with those from other studies, in particular highlighting the consistency between the results obtained. The issue of the generalisability to other studies was not explicitly addressed, but it was clear that this study was very specific to the changing practices within the authors' study. The results were not presented selectively. Several limitations of the study were highlighted, for example, the small sample size. The authors also discussed the learning effects that were noted during this study. This discussion may encourage readers to attempt similar studies in their own setting.

**Implications of the study**
The authors accurately stated that their work calls into question "the need for an explicit pathway that dictates all aspects of the patient's care". Further work is apparent from the study in term of randomisation to improve internal validity. In addition, the authors also explicitly discussed the benefits of studying specific interventions to combat the postoperative pain, nausea and vomiting associated with LC.
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Other publications of related interest

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