Laparoscopische cholecystectomie in dagbehandeling even effectief als tijdens klinische opname en vanuit maatschappelijk perspectief goedkoper: een gerandomiseerd onderzoek

[Ambulatory laparoscopic cholecystectomy is as effective as hospitalization and from a social perspective less expensive: a randomized study]

Dirksen C D, Schmitz R F, Hans K M, Nieman F H, Hoogenboom L J, Go P M

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 technology examined was ambulatory treatment versus overnight stay for laparoscopic cholecystectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients (age: 18-80 years) with symptomatic cholelithiasis (gallstones). The study sample comprised patients living within 30 minutes travel time of the hospital, who had an adult willing to stay with them at home for at least 24 hours after the operation. Patients were excluded if they met the following criteria:

- were suffering from complicated gallbladder;
- were in American Society of Anesthesiology (ASA) physical fitness classification of III or IV;
- underwent other interventions during surgery;
- were unable to communicate in Dutch; or
- did not give informed consent.

Setting
The setting was secondary care. The economic study was conducted in the Netherlands.

Dates to which data relate
The effectiveness data were gathered from patients recruited between 1 November 1997 and 30 September 1999. The data on the resources used were also collected during this period. The price year was not reported (1998 was mentioned for the hourly costs of LC surgery, for day-time hospital care and the care of an overnight stay).

Source of effectiveness data
The effectiveness data were derived from a single study.
**Link between effectiveness and cost data**
The costing was undertaken on the same patient sample as that used in the effectiveness study. The authors did not report whether the costing was undertaken prospectively or retrospectively.

**Study sample**
Power calculations were used at the planning stage of the study to determine the sample size. In the power calculations it was assumed that results for clinical effectiveness and quality of life would be comparable for both groups. It was also assumed that day care was only a sensible alternative if the average length of care was at least one day less in comparison with hospital admission. For hospital admission a 3-day average length of care was assumed.

The sample size required to achieve a 5% level of significance (in a 2-sided test) with 80% power was 128 patients (64 per treatment group). Ninety-four patients were randomised. Of these, 8 did not participate for the following reasons: 3 moved to a different hospital; 2 had an acute surgery; and 3 were not included for unknown reasons.

A total of 86 patients were recruited to the study: 42 patients were randomised to day-care and 44 to clinical observation. Two patients in the clinical-observation group received day-care in error. In the analyses both patients were included in the clinical-observation group according to the intention to treat principle.

The authors stated that the necessary numbers were not reached within the inclusion period; it was nevertheless decided to stop inclusion, the two main reasons being reported as:

one of the two surgeons selecting patients accepted a position elsewhere during the study; and

during the study a noticeable shift towards day care took place, which was, based on the favourable results, necessary because of the scarcity of hospital beds.

**Study design**
The study was a randomised controlled trial carried out in a single centre. The patients were randomly allocated to either day-care or clinical observation using the sealed envelope method. The patients were followed for 6 weeks.

**Analysis of effectiveness**
The authors stated that: analyses were performed according to the intention to treat principle; but went on to state that: only those patients for whom complete data were available were included in the analyses. It is not clear how these two statements can be reconciled as the description is more appropriately classified as treatment completers.

The primary health outcomes included:

- surgical time and post-surgical complications;
- length of hospital care and re-admissions;
- pain and nausea, as assessed using a visual analogue scale (VAS);
- QOL, as assessed using the EuroQol-VAS and a transformation of the SF-36;
- the resumption of normal activities, as assessed by VAS;
- satisfaction with the whole treatment; and
- the treatment preference, as assessed by interview.

The authors did not report whether study groups were comparable at baseline in terms of the main effect variables. However, they did test whether post-treatment differences were associated with pre-treatment scores, using analyses of
Effectiveness results
A total of 86 patients underwent surgery: 44 in the clinical observation group and 42 in the day-care group.

There was no difference in mean surgical time between the day-care (76.3 +/- 24.7 minutes) and clinical observation patients (74.6 +/- 19.2 minutes), (p=0.73).

The numbers of complications were evenly distributed (2 each), although more serious complications occurred in the clinical observation group (1 pancreatitis and 1 retained bile duct stone versus 2 (pain) complaints).

The average length of hospital care was significantly less in the day-care group (1.7 +/- 2.4 days), compared with the clinical observation group (3.1 +/- 2.1 days), (p<0.001). Both groups had 2 re-admissions.

There were no statistically significant differences between groups at 6-weeks follow-up for scores on pain, nausea, and QOL.

There was no statistically significant difference between the groups in the length of disruption of usual activities.

In the day-care group the average satisfaction-score was 8.3 (+/- 1.4), compared with 8.2 (+/- 1.3) in the clinical observation group, the difference was not statistically significant.

At 6 weeks after surgery, 69% (18/26) of the day-care patients and 59% (16/27) of the clinical observation patients would advise future patients to have the same type of care (p=0.051).

Clinical conclusions
The authors concluded that LC performed on a day-care basis and LC performed with clinical observation were equally effective.

Measure of benefits used in the economic analysis
No summary measure of benefit was assessed in this study, which is therefore categorised as a cost-consequences analysis. Moreover, as the effectiveness results were not statistically different, the economic analysis was, in effect, cost minimisation.

Direct costs
The resource use quantities and costs were not reported separately. The analysis included the direct costs to the health service and individual patients, i.e. the costs for the stay in the hospital or day-care centre, as well as medical costs outside the hospital or day-care centre. The price estimates were derived from standard prices or tariffs. The cost of staying at the hospital or day-care centre was obtained from the calculations by the Economisch-Administratieve Dienst of the Sint Antonius Hospital. Medical costs outside the hospital were recorded by patients using a costs-diary. The cost of GP-visits, and home-care was obtained from a publication from the 'College voor Zorgverzekeringen'. The price year was not reported. The study reported average costs. Discounting was irrelevant as the costs were incurred over a time period of less than 2 years.

Statistical analysis of costs
The authors did not perform a statistical analysis of costs.

Indirect Costs
The resource use quantities and costs were not reported separately. The analysis included the indirect costs for individual patients and society, i.e. the costs associated with delayed resumption of paid activities, and informal care.
Costs associated with delayed resumption of paid activities were based on recording by patients using a costs-diary and using the friction cost method. The price year was not reported. The study reported average costs. Discounting was irrelevant as the costs were incurred over a time period of less than 2 years.

**Currency**

Dutch guilders (Dfl).

**Sensitivity analysis**

The authors carried out a separate cost-analysis in which patients with complications were excluded from both groups. This was done because the seriousness of complications differed between groups, and this difference was not related to the type of treatment received (day-care versus clinical observation), but rather due to surgery.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

**Cost results**

For LC performed on a day-care basis (n=42), the average hospital costs were Dfl 2,312.36 (SD: 1,480.07) per patient. For LC performed with clinical observation (n=44), the average hospital costs were Dfl 3,700.09 (SD: 3,338.09) per patient. The difference was Dfl 1,387.73 favouring the day-care group, (p<0.001).

Medical costs outside the hospital averaged Dfl 299.54 for the day-care group versus Dfl 536.52 for the clinical observation group. This was based on data from 14 patients in the day-care group, and 16 in the clinical observation group.

Friction costs averaged Dfl 2,742.11 for the day-care group versus Dfl 2,701.79 for the clinical observation group. This was based on data from 14 patients in the day-care group, and 13 in the clinical observation group.

The sensitivity analysis, excluding patients with complications from both groups, yielded the following results:

For LC performed on a day-care basis (n=35), the average hospital costs were Dfl 1,941.00 (SD: 321.48) per patient.

For LC performed with clinical observation (n=36), the average hospital costs were Dfl 2,498.15 (SD: 378.12) per patient.

The difference was Dfl 557.15 favouring the day-care group, (p<0.001).

**Synthesis of costs and benefits**

Due to the cost-consequences approach adopted in the study, the authors did not report a synthesis of costs and benefits. From a cost-minimisation viewpoint the intervention was (weakly) dominant.

**Authors' conclusions**

LC was successfully performed as an ambulatory surgery procedure in 69% of the patients. The QOL, patient satisfaction, and resumption of activities in both groups were comparable. The ambulatory treatment was less expensive.

**CRD COMMENTARY - Selection of comparators**

The same procedure was compared in two settings, day-care (the study setting) and clinical observation within a hospital (the comparator). Since clinical observation within a hospital represented the standard setting, the selection of the comparator would appear to have been appropriate.
Validity of estimate of measure of effectiveness
The study used a randomised controlled trial design, which was appropriate for the study question. However, the sealed envelope method of randomisation used may be less effective in minimising selection bias than centralised telephone randomisation. The authors did not report any measures used to ensure that the health care professionals responsible for treatment, the patients, or the study investigators were masked to treatment allocation. This may have biased the assessment of outcomes.

The authors did not report whether the study sample was representative of the study population and did not report whether the study groups were comparable at baseline. However, analyses were corrected for baseline differences. The study required 68 patients per group to detect statistically significant differences with 80% power. These numbers were not met in the analysis. However, even when they were met, the power calculations were designed to test for statistically significant differences in the outcomes, rather than equivalence.

Validity of estimate of measure of benefit
No summary measure of benefit was assessed in this study. The authors reported that there was no difference between the interventions, and subsequently used the framework of a cost-minimisation analysis. However, the authors did not demonstrate that the two interventions were equivalent for the majority of outcomes measured. A cost-consequences classification is therefore the most appropriate.

Validity of estimate of costs
The authors derived the cost estimates from hospital data and data collected on the patients recruited into the clinical trial. Costs included were: hospital costs, and costs outside the hospital such as, GP-visits, home care and informal care, as well as productivity losses due to sick-leave. The use of friction cost analysis enhanced the validity of the indirect cost findings. Therefore most relevant costs were included in the analysis. The authors noted that the cost calculations outside the hospital were based on a small number of patients (30 patients in total), and that therefore the conclusions need to be treated with some caution.

Other issues
Although the findings support the strategy of ambulatory care, the authors did not appear to present their results selectively. However, the sample size was not large enough to demonstrate equivalence. The conclusions drawn by the authors may not be supported by the results of the trial.

Implications of the study
The authors did not report any recommendations regarding changes in policy or practice and/or need for further research.

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None stated.

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