Loop ileostomy closure at an ambulatory surgery facility: a safe and cost-effective alternative to routine hospitalization


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
A protocol for 23-hour observation after loop ileostomy closure (LIC) was examined. The patients were immediately released after overnight observation.

Type of intervention
Treatment and rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients deemed medically fit to undergo surgical LIC. The exclusion criteria included unstable angina, active congestive heart failure, recent (within 6 months) cerebral vascular accident or myocardial infarction, hypoxemia, and liver failure with coagulopathy and/or encephalopathy. Other exclusion criteria were sleep apnoea with cor pulmonale, body mass index greater than 50, end-stage renal disease on haemodialysis requiring general anaesthesia, and current infection other than any localised to the operative site.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered from April 2000 to November 2001. The price year was not reported.

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

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

Study sample
Power calculations were not reported. Eligible patients were retrospectively identified at the authors’ institution and were included in the study. Twenty-eight patients (14 men and 14 women) with a mean age of 46 years were included in the new protocol (intervention group). Thirty consecutive patients (17 men and 13 women) with a mean age of 51 years, who underwent LIC as hospital inpatients before implementation of the protocol, were considered in the control group.
No patient was excluded for any clinical reason from the initial study sample.

**Study design**
This was a retrospective comparative study with historical controls. The study was carried out at a single centre, the Duke University Medical Center, Ambulatory Surgical Center in Durham, North Carolina. After the intervention, the patients were discharged home and were followed for 6 to 8 weeks. No patient was lost to the follow-up assessment.

**Analysis of effectiveness**
All of the patients included in the initial study sample were accounted for in the analysis of effectiveness. The outcomes used were the mean length of stay (LOS) and the rate of readmission and/or prolonged hospitalisation. The study groups were comparable at baseline in terms of age, gender, diseases, and duration after the original operation.

**Effectiveness results**
The mean LOS was less than one day (23 hours) in the intervention group and 2.9 days (median 2.5; range: 2 - 8) in the control group. The rate of readmission and/or prolonged hospitalisation was 10.7% (3 of 28 patients) in the intervention group and 13.3% (4 of 30 patients) in the control group.

**Clinical conclusions**
The effectiveness analysis showed that the new protocol was effective in reducing hospital stay without worsening clinical end points.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

**Direct costs**
Discounting was not relevant since the costs were incurred during a short timeframe. The unit costs were not presented separately from the quantities of resources used. The health services included in the economic evaluation were operating room, anaesthesia, post-anaesthesia care unit, observation unit and pharmacy. The cost/resource boundary of the study was not reported. Resource use was estimated using individual-level data that were retrospectively derived from the sample of patients included in the effectiveness study. The source of the costs was not reported, but it could have been the hospital. The price year was not reported.

**Statistical analysis of costs**
The costs were presented as mean and median values (ranges of values were also reported). Statistical tests were conducted to test the statistical significance of differences in the estimated costs.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were carried out.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean cost per patient was $2,665 (+/- 253) (range: 1,907 - 3,010) in the intervention group and $3,811 (+/- 624) (range: 2,864 - 5,241) in the control group. The difference was 30%, (p<0.001).

When including the costs of treating complications, the corresponding costs were $3,137 (+/- 1,787) (range: 1,907 - 10,868) in the intervention group and $4,098 (range: 2,864 - 8,680) in the control group. The difference was 23%.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant because, in effect, a cost-consequences analysis was conducted.

Authors' conclusions
The protocol for early discharge of patients after loop ileostomy closure (LIC) was as safe as the traditional hospital-based approach. However, substantial reductions in costs were observed with the new protocol.

CRD COMMENTARY - Selection of comparators
The choice of the comparator was appropriate as it reflected the traditional procedure used in the postoperative management of patients who underwent LIC. You should decide whether this is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on a retrospective comparative study and patients in both groups were identified retrospectively. The use of a prospective randomised trial would have been more appropriate. In effect, the use of a retrospective design could have introduced some selection and assessment bias. The study groups were relatively comparable at baseline, but the potential impact of confounding factors was not investigated. Since the authors did not justify their choice of sample size, it was unclear whether the study had sufficient power to detect statistically significant differences in the outcome measures. The study sample was recruited from consecutively treated patients, thus it appears to have been representative of the study population. The method used to select the sample was reported. The use of more appropriate outcome measures to assess the impact of the intervention on the patients' health would have been helpful. These issues tend to limit the internal validity of the study.

Validity of estimate of measure of benefit
No summary benefit measure was used because, in effect, a cost-consequences analysis was conducted.

Validity of estimate of costs
The perspective adopted in the study was not explicitly stated. It appears that only those costs strictly related to the intervention and the discharge procedure have been considered in the analysis. Hospital charges were used in the analysis, which might not have reflected appropriately the true costs of the services. A detailed breakdown of the costs was not provided and only macro-categories of the costs were presented. Statistical analyses of the costs were carried out, but all the estimates were specific to the study setting. No sensitivity analyses were performed. The price year was not reported, which will hinder reflation exercises in other settings.

Other issues
The authors stated that their results compared favourably with those published in the literature. However, extensive comparisons were not made. The issue of the generalisability of the study results to other settings was not addressed and
no sensitivity analyses were carried out. This affected the external validity of the analysis. The study referred to patients who had undergone LIC and this was reflected in the authors’ conclusions.

Implications of the study
The authors stated that the 23-hour protocol for the postoperative management of LIC patients was actually implemented as routine at their medical centre after the favourable results obtained in the study.

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