Economic impact of laparoscopic versus open abdominal rectopexy

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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
This study compared laparoscopic rectopexy (LR) with open abdominal rectopexy (OAR) for full-thickness rectal prolapse.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a full-thickness rectal prolapse. Patients were excluded if concomitant gynaecological procedures were planned, rectopexy had been performed before, or a large irreducible prolapse was present which would be better repaired by perineal proctosigmoidectomy. Constipation developing in conjunction with the rectal prolapse was not an exclusion criterion, nor was prior lower abdominal surgery.

Setting
The setting was secondary care (a publicly funded hospital). The economic study was carried out in New South Wales, Australia (Royal Prince Alfred Hospital).

Dates to which data relate
The parent clinical study was published in 2002. The effectiveness data and resource use were collected between December 1996 and December 1999. The price year was 2002.

Source of effectiveness data
The effectiveness data were derived from a single study. The effectiveness analysis was published elsewhere (Solomon et al. 2002, see ‘Other Publications of Related Interest’ below for bibliographic details).

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the parent effectiveness study.

Study sample
Since the present paper briefly reported the outcome results, detailed information was derived from the parent study (Solomon et al. 2002).

Power calculations were not used to determine the sample size. Of 101 patients with a full-thickness prolapse, 40 were
included in the trial. One of these patients refused surgery after randomisation to open rectopexy and was excluded from the analysis. Another patient refused the open operation to which he was randomised and had a laparoscopic procedure after management committee review. There were 20 patients in the LR group and 19 in the OAR group. The characteristics of the patients were not reported (neither in the present study nor in the parent study).

**Study design**
This was a randomised controlled trial (RCT) that was conducted in a single centre. The method of randomisation was not reported. A blinded assessor documented the clinical outcomes. It would appear that the duration of follow-up was no longer than hospital discharge in the present study. No loss to follow-up was reported.

**Analysis of effectiveness**
Of the 40 patients randomised to the trial, 39 completed the study. The data were analysed on an intention to treat basis. The following outcomes were used to evaluate patient health:

- ingestion of clear fluids on day one (clinical pathway 1 - CP1);
- full mobility on day one (CP2);
- solid diet on day two (CP3); and
- discharge by day five (CP4).

The authors reported that there were no significant differences between the groups in terms of duration of prolapse, prior abdominal surgery, age, gender ratio, duration of severity of incontinence, or preoperative constipation scores. However, such results were not reported.

**Effectiveness results**
The outcomes from the parent clinical study were summarised as follows.

Seventeen patients in the LR group and 12 in the OAR group tolerated clear fluids on day 1, (p=0.118).

Eight patients in the LR group and 4 in the OAR group were fully mobile on day 1, (p=0.200).

Sixteen patients in the LR group and 3 in the OAR group tolerated solid diet by day 2, (p<0.0001).

Nineteen patients in the LR group and 9 in the OAR group were discharged by day 5, (p=0.010).

Seventy-five per cent of the clinical objectives of early recovery (CP1-4) were fulfilled in the LR group, compared with only 37% in the OAR group (60 of 80 versus 28 of 76; p<0.01).

The long-term outcomes were not reported in the present study, although they were assessed in the parent study.

**Clinical conclusions**
The authors reported that significant clinical differences were found in favour of the laparoscopic approach compared with the open operation.

**Measure of benefits used in the economic analysis**
No summary measure of benefits was used. The costs and effects were left disaggregated and the study was, in effect, a cost-consequences analysis.
Direct costs
The direct costs included in the cost analysis were hospital stay, operating time, surgical consumables and laparoscopic equipment. Hospital bed costs per day were evaluated using the direct and overhead component teaching hospital costs for a major bowel procedure, contained in the Australian National Diagnosis Related Groups, version 4.1. Operating time was evaluated using the fixed cost and variable cost (such as medical and nursing time, estimated as a cost per minute of operating theatre time) components from the same Australian National Diagnosis Related Groups. Disposable laparoscopic consumables were valued at the current market price. An equivalent annual annuity was estimated for laparoscopic equipment. This was based on current purchase price, a working life of 5 years, use of the equipment at Royal Prince Alfred Hospital, and an opportunity cost of funds tied up in the equipment of 5% per annum. Discounting was not necessary since the study had a short time horizon. The quantities and the costs were analysed separately, and were estimated from actual data. The price year was 2002.

Statistical analysis of costs
The direct costs were measured prospectively for each patient enrolled in the RCT. Stochastic hospital cost data were analysed using the 95% confidence interval (CI) around the mean length of hospital stay and mean operating time for each group, and the mean difference in total costs between the two groups.

Indirect Costs
The indirect costs were not reported.

Currency
Australian dollars (Aus$). These were converted to UK pounds sterling () using Organisation for Economic Cooperation and Development purchasing power parities.

Sensitivity analysis
A sensitivity analysis of the length of hospital stay was conducted to assess the level of savings. Scenarios with variable cost-savings of a shorter hospital stay (that according to published medical literature might represent between 30 and 50% of the mean hospital bed daily cost) were performed.

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

Cost results
The mean total operating room time was 51 minutes longer for LR than for OAR, (p<0.0001).

The duration of hospital stay was shorter in the LR group (mean 3.9 versus 6.6 days; p=0.001).

The mean total cost of LR was 2,812 (95% CI: 2,591 - 3,033) and the mean total cost of OAR was 3,169 (95% CI: 2,602 - 3,727).

The mean total cost of LR was 357 (95% CI: 164 - 592; p=0.042) per patient less than that of OAR.

The sensitivity analysis showed that using the range of marginal saving estimates, the total cost of LR remained less than that of OAR, with a cost-saving of between 154 and 235 per patient.

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was performed.
Authors' conclusions
Laparoscopic rectopexy (LR) was both clinically superior to and cheaper than the open procedure.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It reflected standard practice in the authors' setting. You should judge whether these procedures are relevant in your setting, or whether other comparators from other techniques and surgical procedures could also have been relevant.

Validity of estimate of measure of effectiveness
The analysis was based on an RCT. This was adequate for the study question as well-conducted RCTs are considered the 'gold' standard study design when comparing health interventions. As the authors did not report full details of the effectiveness evidence in the present study, information was derived from the parent clinical trial (Solomon et al. 2002).

The main drawbacks of the study were as follows. First, as the sample size was not determined in the planning phase, and no power calculations were conducted to assure a certain power of the results, it is possible that some of the results obtained were due to chance. Second, the method of randomisation was not stated. Third, the outcome measures chosen by the authors in the present study appear limited in that measurement was only concerned with short-term subjective clinical outcomes, whereas long-term outcomes were assessed in the parent study. In addition, the technique was performed by one specialised surgical unit and largely by one surgeon, and this may hinder the generalisability of the results to other setting.

The main strengths of the study were as follows. First, the assessors were blinded to the allocation of patients to the study groups, thus no assessment biases should have occurred. Second, the study sample appears to have been representative of the study population, as few eligibility criteria for entry into the study were reported. Finally, similar clinical characteristics between patient groups were reported at analysis, although the results and statistical tests were not shown, hence confounding factors may be low.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefits. The reader is therefore referred to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The cost analysis was performed from the perspective of a single provider. All the relevant cost categories were reported. The costs and the quantities were reported separately, thus enabling the analysis to be easily extrapolated to other settings. A statistical analysis of the costs was reported and 95% CIs were calculated. The costs were treated stochastically and sensitivity analyses were conducted with ranges selected from the medical literature. The price year was reported, which will aid future reflation exercises. Discounting was not relevant, as the costs were incurred during less than one year, and hence was not performed.

Other issues
The authors compared their findings with those from other studies and observed similar results. The issue of generalisability to other settings was addressed (see 'Implications of the Study' section below). The conclusions reflected the scope of the analysis. The authors recognised some limitations of the study. In particular, that the parent clinical study was a small RCT that was not powered primarily to consider cost efficiency. In that context, the significant reduction in hospital stay more than offset the increased costs of the surgery itself. In addition, certain aspects of the original design of the RCT might have minimised the cost-reduction associated with LR.

Implications of the study
In relation to changes in clinical practice and further research, the authors stated that, in hospitals in which the daily costs of a hospital bed were similar to or greater than those applied in this study, it is likely that LR would be cheaper than OAR. This issue could only be answered within the context of larger studies in other centres, especially those incorporating a specific cost-effectiveness analysis.

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None stated.

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**Other publications of related interest**


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