Cost effectiveness analysis of laparoscopic hysterectomy compared with standard hysterectomy: results from a randomised trial

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
Women underwent laparoscopic hysterectomy for reasons other than malignancy. The comparator was either an abdominal or vaginal hysterectomy.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women requiring a hysterectomy for non-malignant conditions. Women with a second- or third-degree uterine prolapse were excluded, as were those with a uterine mass greater than the size of a 12-week pregnancy. Also excluded were women with a medical illness that precluded laparoscopic surgery, and those who required bladder or other pelvic support surgery. Further details were provided elsewhere (Garry et al., see Other Publications of Related Interest).

Setting
The setting was secondary care. The economic study was carried out in the UK and South Africa.

Dates to which data relate
The dates relating to the effectiveness evidence were not given. The resource evidence related to 1999 to 2000. The prices used were from 1999 to 2000.

Source of effectiveness data
The effectiveness data were derived from a single study, full details of which were provided elsewhere (Garry et al., see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that which provided the effectiveness data.

Study sample
The authors reported limited information for this field, referring instead to the clinical paper (Garry et al., see Other Publications of Related Interest). The use of power calculations was not mentioned, nor was the sample selection method. A total of 1,380 patients were initially recruited into the whole trial, 876 in the abdominal trial and 504 in the
vaginal trial. Of the 876 patients recruited for the abdominal trial, 573 were allocated to receive laparoscopic hysterectomy and 286 to have abdominal hysterectomy. Of the 504 patients recruited for the vaginal trial, 324 were allocated to receive laparoscopic hysterectomy and 163 to receive vaginal hysterectomy.

**Study design**
The authors reported limited information for this field, referring instead to the clinical paper (Garry et al., see Other Publications of Related Interest). This was a multi-centre (30 centres), randomised controlled trial. There was a median follow-up of 52 weeks.

**Analysis of effectiveness**
The authors reported limited information for this field, referring instead to the clinical paper (Garry et al., see Other Publications of Related Interest). The basis of the analysis was per protocol. Only mean and median EQ-5D scores were recorded in the current paper. They were measured as described in the "Measure of Benefits Used in the Economic Analysis" section. The baseline clinical characteristics of the patient groups in this paper were not compared.

**Effectiveness results**
The authors reported no information for this field, referring instead to the clinical paper (Garry et al., see Other Publications of Related Interest).

**Clinical conclusions**
The authors reported no information for this field, referring instead to the clinical paper (Garry et al., see Other Publications of Related Interest).

**Measure of benefits used in the economic analysis**
The measure of benefits used was the quality-adjusted life-years (QALYs). A health utility score was derived from the EQ-5D at up to four time points. The women's responses to the EQ-5D questionnaire were taken at baseline and up to three points after hospital discharge (6 weeks, 4 months and 1 year).

**Direct costs**
Health service costs were included in the costing. These were for theatre, main admission to the hospital, and clinic follow-up visits. Theatre resources included time in the theatre and recovery room, equipment, antibiotics, anaesthetics and consumables. The resources during a woman's main admission included length of stay, use of urinary catheterisation and postoperative complications. The resource use data came from the hospital and patient questionnaires. The price information came from UK unit costs at 1999 to 2000 prices (Sculpher et al., see Other Publications of Related interest). The quantities and the prices were analysed separately, but the information was not given in the paper. Discounting was not carried out since the costs were incurred during less than 2 years.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
No indirect costs were calculated.

**Currency**
UK pounds sterling (£).
Sensitivity analysis
A sensitivity analysis was carried out to establish the difference caused by assuming that laparoscopic hysterectomies were carried out with reusable equipment.

Estimated benefits used in the economic analysis
The difference in QALYs per person over 1 year for laparoscopic hysterectomy over abdominal hysterectomy was 0.007 (95% non-parametric confidence interval, CI based on 1,000 bootstrap replications: -0.008 - 0.023). The difference over vaginal hysterectomy was 0.0015 (95% non-parametric CI: -0.015 - 0.018).

The side effects of treatment were accounted for when measuring the QALYs.

Cost results
In the abdominal trial, the mean cost of laparoscopy was 1,706 and that of abdominal hysterectomy 1,520. The difference in costs was 186 (95% non-parametric CI: -26 - 375).

In the vaginal trial, the mean cost of laparoscopy was 1,654 and that of vaginal hysterectomy 1,253. The difference in costs was 401 (95% non-parametric CI: 271 - 542).

The costs were calculated for 12 months after the operation and the costs of adverse effects were included.

Synthesis of costs and benefits
The cost per QALY gained was 267,333 for laparoscopic hysterectomy compared with vaginal hysterectomy, and 26,571 for laparoscopic hysterectomy compared with abdominal hysterectomy.

The cost-effectiveness acceptability curve for laparoscopic versus abdominal hysterectomy showed that, as the willingness to pay for an extra QALY increases, so does the probability that laparoscopic hysterectomy is more cost-effective. If the willingness to pay for a QALY is 30,000 then the probability is 56%. When accounting for sampling uncertainty to calculate the cost-effectiveness acceptability curves, the probability that laparoscopic hysterectomy is more cost-effective than vaginal surgery was never more than 50%.

When it was assumed that reusable equipment was used in laparoscopic hysterectomy, the mean difference in cost between laparoscopic and abdominal hysterectomy fell to 74 with a cost per QALY gained of 10,571. The mean difference between laparoscopic and vaginal hysterectomy fell to 260 and the cost per QALY gained was 173,334.

Authors’ conclusions
Any gains in terms of quality-adjusted life-years (QALYs) from laparoscopic hysterectomy in comparison with vaginal hysterectomy were too expensive when considering how much the National Health Service is willing to pay at the moment for gains in QALYs. The authors concluded that the gains in QALYs from laparoscopic as compared with abdominal hysterectomy were on the borderline as to whether they could be justified by the expense.

CRD COMMENTARY - Selection of comparators
The selection of the comparators (abdominal and vaginal hysterectomy) was justified on the grounds that they had been current practice in the past and were still current practice in many settings. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a multi-centre, randomised controlled trial. The study design was appropriate for the study question, although the authors did not discuss whether the distribution of the trial centres (28 UK centres and 2 South African centres) might have had a bearing on the results. It is not possible to comment on the internal
validity of the effectiveness results since the authors referred to a clinical paper for details of the clinical study.

**Validity of estimate of measure of benefit**
The measure of benefit used (QALYs) was taken from the EQ-5D questionnaire results. This was appropriate in many respects but, as the authors pointed out, it ignores data for the first 6 weeks after the operation. Thus, the higher pain levels that were recorded for the nonlaparoscopic procedures immediately after the operation would not have been considered and the relative advantage of laparoscopy may have been underestimated.

**Validity of estimate of costs**
The authors adopted the perspective of the health system and, as such, all the relevant categories of cost were included. The omission of the indirect costs will have overestimated the relative costs of laparoscopic surgery, as it was associated with less time off work. The costs and the quantities were reported in the full version of this paper (see Other Publications of Related Interest), but not in the current paper. The resource use quantities were taken from the current paper. A statistical analysis of the quantities was not carried out. A sensitivity analysis of the quantities, examining the use of disposable or non-disposable equipment in laparoscopy, appears to have been conducted properly. The prices were taken from published sources. Statistical and sensitivity analyses of the prices were not performed. The price year was 1999 to 2000

**Other issues**
The authors compared their findings with those from other studies. The issue of generalisability to other settings was not addressed and the authors did not state whether the South African and UK results had been similar. The authors did not present their results selectively. However, they did not discuss the difference in their conclusions with those of the earlier effectiveness study, which had focused on the higher rate of major complications observed with laparoscopic hysterectomy than with abdominal hysterectomy. The authors’ conclusions did not consider that the data seemed to show that, for the majority of women, laparoscopic surgery may well produce better outcomes but, for a minority, the outcomes might be much worse. The data used to produce the QALY information did not cover all women due to a loss of follow-up. It would be interesting to know if the data were subject to selection bias.

**Implications of the study**
The authors concluded that, in a UK context, the cost of a QALY gained by laparoscopy is too high to be recommended when the alternative is vaginal hysterectomy. When the alternative is abdominal hysterectomy, the cost of a QALY is on the borderline of acceptability. Further research using data from surgery to 6 weeks, and with a smaller loss to follow-up, would be useful in estimating the QALYs.

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**Other publications of related interest**
Garry R, Fountain J, Mason S, et al. The eVALuate study: two parallel randomised trials, one comparing laparoscopic
with abdominal hysterectomy, the second comparing laparoscopic with vaginal hysterectomy. BMJ 2004

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
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