Laparoscopy as the primary modality for the treatment of women with endometrial carcinoma

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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
The intervention studied was laparoscopically assisted vaginal hysterectomy (LAVH), bilateral salpingo-oophorectomy and (in most cases) lymphadenectomy, for the treatment of women with early stage endometrial carcinoma.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was women with stage 1 endometrial carcinoma or uterine sarcoma.

Setting
This study was set in secondary care in a Vermont university hospital.

Dates to which data relate
The effectiveness data for the cases were collected in a prospective study in 1998 and 1999. Data on the controls were collected in the previous two years (1996 and 1997). Resource use data were collected during the prospective study. The price year was not given.

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. Although the control group was treated prior to the commencement of the economic study, the authors did not say whether the resource use data were collected before or after the effectiveness results were known.

Study sample
The authors reported that the study had 85% power to detect a 20% difference in tumour recurrence at a two-tailed p-value of less than 0.05 provided that the incidence rate in the lower group was 10%. It was not stated whether this was a prospective or retrospective power calculation.

There were 86 patients in the intervention group excluding the four who were judged, for clinical reasons, not to be
candidates for LAVH. The number of patients in the control group was not reported but is deduced to have been 57.

The intervention group was comprised of women with clinical stage 1 endometrial carcinoma or uterine sarcoma who presented to this particular clinical unit during the study period (1998 and 1999), and who could tolerate laparoscopic surgery. The investigators excluded from the study patients who refused laparoscopy or who had one of a series of clinical conditions (including macroscopic cervical involvement by tumour, severe cardiopulmonary disease, severe hip disease or a body mass index (BMI) greater than 60). It would appear that only 4 of the 90 women presenting with early endometrial cancer were excluded for medical reasons, and that none refused to participate, although this was not stated.

The control group comprised all surviving women with the same diagnosis who had been treated with TAH in the same unit in the two years before the study period, and who continued to be followed by the unit.

The intervention group were representative of the majority of patients who presented to the hospital with early stage endometrial cancer. The control group was a non-random subset of patients (i.e., those patients who were alive and who continued to be followed-up).

Study design
This was a single-centre, unblinded study with historical controls. The median duration of follow-up was 17 months for the intervention (LAVH) group and 40 months for the control (TAH) group. No loss to follow-up was reported.

Analysis of effectiveness
Patients in the LAVH group were analysed on an intention to treat basis. The two groups were compared on characteristics including age, height, weight, BMI, menopause status and number of existing medical problems. The TAH group had significantly higher BMIs than those who underwent LAVH, but no adjustment was made to the analysis. The following health outcomes were analysed:

surgical procedures and their outcome (including type of procedures, adhesions score, number of complications, and postoperative change in haematocrit);

postoperative course (including length of stay, intravenous pain medications dose, number of postoperative complications); and

quality-of-life measures (including recall of postoperative pain, days to return to full activity, days to return to work and satisfaction with treatment, all measured by an in-person or telephone interview).

Effectiveness results
The significant results for the LAVH group versus the TAH group are summarised as follows:

the mean postoperative change in haematocrit was 4.6 versus 5.4, (p<0.001);

the mean operative time was 190.5 minutes versus 132.8 minutes, (p<0.001);

the mean number of pelvic lymph nodes harvested was 10.8 versus 4.9, (p<0.001);

the mean length of hospital stay was 2.5 days versus 5.2 days, (p<0.001);

the mean total dose of postoperative intravenous pain medication was 28.1 mg versus 103.4 mg, (p<0.001);

the mean number of days to return to full activity was 22.0 versus 40.8, (P=0.002), and to return to work, 34.4 versus 62.6, (p<0.001);

the mean satisfaction score (on a scale of 0 to 3) was 2.8 versus 2.6, (p=0.039).
Clinical conclusions
The majority of women with early stage endometrial carcinoma can be treated with laparoscopy with an excellent surgical outcome, shorter hospitalisation, earlier recovery and improved quality of life.

Measure of benefits used in the economic analysis
This was a cost-consequences study as no summary health benefit was used and clinical outcomes were left disaggregated. Please see the effectiveness results reported earlier.

Direct costs
The direct costs were measured as the hospital costs, including the surgeon's fees, anaesthesiologist's fees, operating room charge and inpatient stay charge. The prices were based on the amount billed to the payer. For some resources (such as length of stay), the quantities were reported but the unit cost was not. The costs related to the treatment only and therefore discounting was not relevant. The authors stated that the cost was adjusted to the date of surgery, which could refer to an inflation adjustment to account for the fact that the surgical procedures were conducted up to 4 years apart. However, no details were given. The price year was not given.

Statistical analysis of costs
The authors provided means and standard deviations for the surgeon's fee, anaesthesiologist's fee, hospital cost, operating room cost and total cost. The mean costs in the two groups were compared (apparently using a student t-test) and p-values were reported. The differences in all but the hospital costs were statistically significant. No justification was given for the choice of test.

Indirect Costs
Indirect costs were excluded from this study.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
See effectiveness results above.

Cost results
The average total costs (presumably per patient) were $13,051.30 for LAVH and $11,027.60 for TAH. The difference of approximately $2,000 was statistically significant, (p=0.004) and was, for the most part, due to the difference in surgeon's fees. The authors stated that these costs reflect the impact of operative or postoperative complications but do not appear to include any longer term follow-up.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The majority of women can be treated with laparoscopy with a superior outcome but with a higher financial cost.

**CRD COMMENTARY - Selection of comparators**
The authors explained that the comparator (TAH) has been current practice in their setting. TAH is also current practice in the NHS for this patient population.

**Validity of estimate of measure of effectiveness**
The women included in intervention group were a high proportion (96%) of the women who presented to this hospital and thus appear to have been appropriate for the clinical study question. As acknowledged by the authors, the control group included only those women who had survived and were not lost to follow-up, and therefore bias may have been introduced. They conjectured that, if any bias were introduced, it would have been in favour of TAH because the patients who died or who were lost to follow-up were more likely to have had a less favourable outcome. Despite this, the two groups were shown to be similar at baseline in most respects. The 'quality of life' assessment was made by asking general questions and cannot be converted to QALY-type utility weights. The authors noted that this assessment was performed at different time periods from the original surgery but did not speculate as to the effect of any possible bias.

**Validity of estimate of measure of benefit**
As this was a cost-consequences analysis, no summary measure of benefit was used. The authors noted that a longer follow-up period is needed to determine whether there is a survival difference between the two treatments.

**Validity of estimate of costs**
The quantities of some resources (in-patient days, theatre time) were reported separately from total costs. Hospital and physician charges were used to approximate unit costs. The authors mentioned that the difference in the total costs of the two treatments was mostly due to the difference in surgeon’s fees. They explained this finding by the fact that different billing codes exist for LAVH and laparoscopic pelvic lymphadenectomy (which was performed on 84% of LAVH patients) whereas TAH and pelvic lymphadenectomy are included in one code. Thus, it is possible that the difference in the total charges reflects this feature of the billing system, which may not be a fair reflection of the actual cost of the procedures.

**Other issues**
On the effectiveness side, this study demonstrates that the LAVH can be performed successfully for the majority of early state endometrial cancer patients and, in this respect, adds to the literature of more selective studies. The cost results are not easily generalisable to other settings such as the NHS, with the possible exception of the resources for which quantities were reported. The authors highlighted the superiority of LAVH on quality of life measures. At the same time, they acknowledged the methodological problems with their quality of life analysis.

**Implications of the study**
This study finds that LAVH produces better short-term outcomes than TAH but at a higher cost in the setting of a Vermont teaching hospital. It suggests that the best comparison between these two interventions would be provided by a randomised trial such as that being conducted by the Gynecologic Oncology Group (GOG).

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