A randomised comparison and economic evaluation of laparoscopic-assisted hysterectomy and abdominal hysterectomy

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 use of laparoscopic-assisted hysterectomy in the management of benign gynaecological disease.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised women scheduled for an abdominal hysterectomy for benign gynaecological disease. The women were unsuitable for vaginal hysterectomy because of a uterine size in excess of 14 weeks or a requirement for oophorectomy. Those women for whom hormone therapy was inappropriate were excluded.

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

Dates to which data relate
The dates during which the effectiveness, resource use, and cost data were obtained were not stated. The price year was 1997 to 1998.

Source of effectiveness data
The effectiveness data were derived from a single study.

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

Study sample
Two hundred patients were recruited over 2 years, 100 in each of the TAH and LAVH groups. It was stated that 120 patients per arm would allow an 80% chance of detecting a 15% difference in the complication rates at a 5% level. In addition, 25 patients per arm were required to detect a difference of 2 days in the hospital stay.

Seven women did not attend for the operation, and the case records were not available for a further 3 patients. The resultant sample size was 190 patients. There were 95 patients in the TAH group and 95 in the LAVH group. The baseline characteristics and indications for surgery were reported, thus enabling the study sample to be compared with
the study population.

Study design
The study was a prospective randomised controlled trial carried out at three centres. Patients were followed-up for one year. Eight of the women randomised to the LAVH group did not undergo LAVH. This was because of "peri-operative difficulty" or complications (3 patients), patient preference (2 patients), and a very difficult LAVH was anticipated at endoscopy (3 patients).

The response rate for the patient questionnaire was 81 for TAH and 85 for LAVH. The response rates for the EuroQol instrument were: 76 for TAH and 74 for LAVH, 1 month after surgery; 61 for TAH and 62 for LAVH, 6 months after surgery; and 47 for TAH and 43 for LAVH, 1 year after surgery.

Analysis of effectiveness
The analysis of the clinical study was stated to have been on an intention to treat basis. However, there were losses to follow-up with the questionnaire and EuroQol instrument, which were not accounted for. The primary health outcomes were the complication rates, self-reported problems and milestones, and the quality of life (EuroQol 5D visual analogue scale). There were no significant differences between the groups in terms of their demographic characteristics, or the presence of pelvic pathology at the start of the trial.

Effectiveness results
The duration of the operation was 45 minutes for TAH and 80 minutes for LAVH.

The overall complication rate was 14% for TAH and 8% for LAVH.

Major complications occurred in 6 women undergoing LAVH and one woman undergoing TAH.

Two women (one in each group) experienced ureteric damage.

The other major complications were haemorrhage requiring transfusion (n=2), pulmonary embolism (n=1), severe infection requiring intensive care unit (ITU) admission (n=1), and bladder damage (n=1).

With the exception of pyrexia, the TAH group experienced more minor complications.

Fourteen patients, 8 in the LAVH group and 6 in the TAH group, were readmitted. Of these, 5 required further treatment due to a vault haematoma (2 TAH; 1 LAVH) and for reimplantation of the ureter (1 TAH; 1 LAVH).

There were no significant differences in the self-reported post-operative problems, except for the category of "other problems". This included tiredness and constipation, which were higher for the women undergoing LAVH, (p=0.02).

There was reported to have been no difference in the time taken to achieve the post-operative milestones, but the data were not shown.

The mean changes in the EuroQol score (+/- standard deviation) were:

at 1 month, TAH 6.8 (+/-19.2) and LAVH 7 (+/-24.1);

at 6 months, TAH 14.9 (+/-16.7) and LAVH 11.3 (+/-23.9); and

at 1 year, TAH 15.9 (+/-21) and LAVH 12.6 (+/-2.5).

There was stated to have been no significant differences.

Overall, LAVH produced more complications and a statistically-significant number of more problems falling into the
"other problems" category. At 1 year, LAVH had produced a larger mean change in the EuroQol score, which did not reach statistical significance. In addition, there was a considerable loss to follow-up.

**Clinical conclusions**
LAVH was associated with a reduction in the length of hospital stay. Both the recovery following operation and patient satisfaction were not affected by the route chosen.

**Measure of benefits used in the economic analysis**
No summary measure was used. The study should therefore be considered as a cost-consequences analysis.

**Direct costs**
The direct costs were not discounted since the timeframe of the study was less than one year. The direct costs included the costs of pre-operative stay, blood tests, operation details, pain relief, post-operative stay, complications, additional surgery, and readmissions. The quantities were only given for length of stay, rates of admission to ITU, the number of women requiring additional surgery, the number of readmissions, and the number of blood transfusions. The unit costs were not given. The quantity/cost boundary adopted was that of the hospital. The quantities and costs were estimated from actual data. The costs and quantities were obtained from National Health Service sources. The price year was 1997 to 1998.

**Statistical analysis of costs**
Appropriate non-parametric tests were performed on the cost estimates. The authors reported the mean total costs.

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

**Currency**
UK pounds sterling ( £).

**Sensitivity analysis**
Sensitivity analyses were conducted on the cost estimates, doubling or halving the cost per inpatient day or per minute in the theatre.

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

**Cost results**
The total costs amounted to £1,832 for TAH and £2,479 for LAVH. The sensitivity analysis revealed that LAVH was associated with higher mean costs than TAH assuming the following: cost per minute in theatre halved, cost per inpatient day doubled and no disposable costs. The mean difference in total cost (£) between TAH and LAVH was -£647, (95% confidence interval: -£1,181, -£113)

**Synthesis of costs and benefits**
Not applicable.
Authors' conclusions
Despite the reduction in the length of hospital stay, laparoscopic-assisted vaginal hysterectomy (LAVH) was more expensive than total abdominal hysterectomy (TAH). Both the recovery following operation and patient satisfaction were not affected by the route chosen.

CRD COMMENTARY - Selection of comparators
The comparator used was justified on the grounds that it was a current treatment alternative. You should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was appropriate for the study question, although details of the randomisation were not given. Evidence was presented to show whether the study sample was representative of the study population. The groups of patients were shown to be comparable at analysis. However, there was significant loss to follow-up. This was not accounted for in the analysis.

The power calculation recommended 120 patients per arm, which is considerably more than were actually recruited and many more than were followed-up. The calculation was based on detecting a difference in the complication rates, which did not seem to have been analysed statistically. In addition, it did not account for the only longer-term measure, the EuroQol instrument, which showed LAVH was better than TAH on average. The lack of statistical significance could therefore have been due to a low sample size coupled with a high drop-out rate.

Validity of estimate of measure of benefit
Not applicable given that a cost-consequences analysis was conducted.

Validity of estimate of costs
A good feature of the cost analysis was that all relevant direct cost categories appear to have been included. The generalisability to other settings was hampered by the fact that a complete breakdown of resource quantities and unit costs was not given. Also, the sensitivity analysis was conducted for the cost input or cost output only, with the ranges chosen arbitrarily (halving or doubling).

The authors appear to have assumed that their effectiveness evidence revealed no difference, and so it only remained to show if the costs were statistically different. The power calculation was carried out only in terms of hospital stay, yet it was the operation cost that contributed the most to the difference. The price year was reported, which made reflation exercises in other settings possible. The indirect costs incurred by the patients and their families were not considered.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. They also, to some extent, addressed the issue of generalisability to other settings using a sensitivity analysis. It was unfortunate that some effectiveness results were missing. The study considered women scheduled for an abdominal hysterectomy for benign gynaecological disease, and this was reflected in the authors' conclusions.

Implications of the study
The authors stated "It is unlikely that LAVH represents an efficient use of NHS resources". In fact, the study was unable to clarify which technique was more effective, particularly in terms of the quality of life. Even if LAVH was more expensive in terms of resource use, it might be worth paying for if there was, on average, a marginal benefit.

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