Clinical and financial analyses of laparoscopically assisted vaginal hysterectomy versus abdominal hysterectomy

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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
Performing laparoscopically assisted vaginal hysterectomy (LAVH) in patients with pelvic pathology which traditionally required the abdominal approach to hysterectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with gynecologic conditions traditionally requiring the abdominal approach to hysterectomy.

Setting
Hospital. The economic study was carried out in Massachusetts, USA.

Dates to which data relate
The effectiveness and resource use data for LAVH were collected between August 1991 and December 1992, while the corresponding date for TAH was 1990. The price year was not explicitly specified.

Source of effectiveness data
The evidence for final outcomes was based on a single study.

Link between effectiveness and cost data
The costing for the intervention group (LAVH) appears to have been undertaken prospectively while the costing for the control group (those who underwent TAH) was performed retrospectively.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 34 women (with a mean age of 44-45 years and a range of 27 to 74) in the intervention group (LAVH) and 60 women (with a mean age of 45 years and a range of 28 to 81) in the control group (TAH for benign conditions).

Study design
This was a non-randomised study with historical controls (retrospectively collected), carried out in a single centre. The
duration of the follow-up was 30 days post-surgery. One patient from the TAH group with a final diagnosis of malignancy was excluded from data analysis in order to decrease bias in the control group toward longer hospitalisation and high complication rates. Important elements included in preoperative preparation for LAVH were patient education stressing decreased morbidity and early ambulation and recovery while for TAH, standard surgical procedures, and perioperative and postoperative care were used. Prophylactic antibiotics were administered to all patients in both groups.

Analysis of effectiveness
The principle used in the analysis of effectiveness was not explicitly specified. The clinical outcomes were surgical outcomes (duration of surgery, blood loss and transfusion rates, length of stay, time to return to work), complications, and readmission rate within 30 days. Telephone interviews were used to determine the interval between the operation and the week in which the patients returned to work. The two study groups were comparable in terms of patient demographics. Fibroids were the most common primary indication in both groups. There were some notable differences between the groups in terms of other surgical indications.

Effectiveness results
The mean (SD) duration of surgery was 139 (37) minutes in the LAVH group versus 118 (41) minutes in the TAH group, (p=0.019). Estimated blood losses (ml) were 314 (189) for LAVH and 488 (368) for TAH, (p=0.003). The transfusion rate was greater for TAH than LAVH. The LAVH group had a mean (SD) length of stay of 1.5 days (0.7) compared to 4.7 (1.6) days in the TAH group, (p<0.001). The mean time to return to work was 3.6 weeks (2.6) for LAVH and 5.8 weeks (2.3) for TAH, (p=0.001). The postoperative complication rate was 9% in the LAVH group versus 45% in the TAH group, (significant difference). The intraoperative complication rate was 3.03% for LAVH and 5.01% for TAH. Only one case of LAVH failed and was converted to TAH due to bleeding from the uterine artery. Readmission rates within 30 days were 9% (LAVH) and 3% (TAH).

Clinical conclusions
Laparoscopically-assisted vaginal hysterectomy is associated with significantly fewer minor complications and shorter length of hospital stay than TAH.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs in terms of length of stay and surgery time. Charge components were reported separately in general categories. The cost analysis covered the charges for operating room, recovery room, ancillary, and hospital room. The finance department of the study institution provided the charge data. The perspective adopted in the cost analysis was not explicitly specified. The price date was not explicitly specified. The cost analysis did not cover the costs of physician fees and readmission.

Statistical analysis of costs
Student’s t test was used to compare the study groups in terms of total charge and charge components.

Indirect Costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs in terms of time to return to work. The calculations related to indirect cost analysis were not performed on the study sample, instead, the cost saving to an employer from the use of LAVH as opposed to TAH was computed based
on a hypothetical case with an annual salary of $30,000. Other cost items discussed (but not calculated) were the costs of hiring replacement workers and disability insurance. The perspective adopted in the cost analysis appears to have been that of the employer or insurer. The date to which the price data referred was not explicitly specified.

**Currency**
US dollars ($).

**Sensitivity analysis**
Not conducted.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The LAVH group had a mean (SD) total charge of $7,623 (1,731) compared to $4,550 (1,118) in the TAH group, (p=0.001). The distribution of hospital charges for LAVH was as follows: operating room (OR), 72%; recovery room, 4%; ancillary, 17%; and hospital room, 7%. The corresponding values for TAH were: operating room, 32%; recovery room, 5%; ancillary, 31%; and hospital room, 32%. It was estimated that LAVH would save employers approximately $1,200 compared to TAH.

**Synthesis of costs and benefits**
Costs and benefits were not combined.

**Authors’ conclusions**
Although LAVH has a significantly lower complication rate than TAH, it is more costly to perform. This higher cost, despite a shorter hospital stay, is attributed to high operating room charges. Employers and patients benefit from early return to work with LAVH.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator (the use of TAH). It was regarded as the traditional approach in the context in question at the time of the study.

**Validity of estimate of measure of effectiveness**
The internal validity of the effectiveness results can not be guaranteed in view of the non-randomised nature of the study design and the retrospective control group which did not allow a preoperative counselling session to be provided. The latter, as the authors acknowledged, may have biased return to work expectations. It was deemed that the choosing time periods for the two study groups which did not overlap would decrease selection bias. The study groups were found to be comparable only in terms of patient demographics. Statistical analysis was not performed to adjust for the effects of the confounding variables. The degree to which the study sample was representative of the study population can not be objectively assessed due to lack of adequate information regarding the study inclusion criteria.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The analysis used a cost-consequences design.

**Validity of estimate of costs**
Some quantities were reported separately from the costs. Adequate details of the methods of cost estimation were given. The exclusion of some cost items such as professional fees and readmission costs casts some doubt on the internal validity of the cost analysis. Using charge data as opposed to true costs may have adversely affected the external validity of the cost results. The price year was not specified and it is not clear whether the valuation of resources used in different financial years was based on charge data from a unique base year. In the case of charge data coming from different years, the comparability of charge data was not ensured by adjusting for inflation using an appropriate price index. Cost analysis related to indirect costs (lost productivity) was not systematically performed by comparing the two study groups in terms of the valuation of lost productivity using the distribution of employment status and wage rates. Instead, it was performed only on a general case. If the indirect costs had been considered systematically it would have been possible to compare the two health modalities in terms of total costs (direct and indirect). This may possibly yield different conclusions with respect to cost results.

**Other issues**
In view of the non-randomised nature of the study design, the absence of sensitivity analysis, and the use of charges rather than true costs, some degree of caution may need to be exercised in the interpretation of the study results. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies. With regard to the involvement of patients' preferences (pertaining to qualities such as invasiveness, as mentioned by the authors), it may have been more appropriate to conduct the economic analysis in the framework of a cost-utility approach. Incremental cost-effectiveness analysis would have been appropriate, although this would have required the use of a single benefit measure.

**Implications of the study**
It was reported that at the time of the study, the complication rate for LAVH had not been defined by any large multicentre study. It was also acknowledged that the surgeons' learning phase in performing the operation could affect the complication rate. It was reported that, in 1990, the surgeons in the authors' group performed 89 hysterectomies for benign conditions, 69% by TAH. Since then, because the authors gained experience with LAVH, at least 75% of the authors' patients had this surgery or vaginal hysterectomy.

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