Prospective randomized clinical trial of laparoscopically assisted vaginal hysterectomy versus total 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
Laparoscopically assisted vaginal hysterectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Women scheduled for abdominal hysterectomy for benign disease. If a pelvic mass was present, the maximal size allowed was 2 cm below the umbilicus. Patients were not eligible if a concomitant incontinence procedure or pelvic reconstructive procedure was planned.

Setting
Department of Gynecology and Obstetrics, Cleveland Clinic Foundation (tertiary care academic centre), USA.

Dates to which data relate
1995 to 1997 effectiveness and resource use data were used. The date of the cost data was not stated. The price year was not stated.

Source of effectiveness data
The estimates of the effectiveness and resources used were derived from a single study.

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

Study sample
Power calculations showed that 22 patients per group were necessary to detect a difference of 30 minutes or more in surgical time between the two groups with 90% power and a significance level of 0.05. An assumption was made of a standard deviation of 30 minutes for surgery time based on observations in previous studies. This sample provided a power of 85% to 90% to detect a difference of 10 days or more in the median days for return to work (assuming a standard deviation of 12 days) and power of 80% to 90% to detect only large differences (30% to 40%) between groups on binary outcomes (yes/no) such as complications.
Study subjects were recruited between September 1995 and February 1997. During the study period 218 hysterectomies that were not eligible were performed for benign disease in the department and vaginal hysterectomy was performed in 66.5% of cases. Of the 55 patients meeting the inclusion criteria, 48 patients were assigned to one of the interventions. The other 7 patients declined to participate in the study. Of the 48 patients assigned, 4 withdrew before surgery (3 from the abdominal hysterectomy and 1 from the laparoscopically assisted vaginal hysterectomy group). One of the patients assigned to abdominal hysterectomy went on to have the scheduled surgery but declined to complete the follow-up portion of the study. The other 3 did not undergo a hysterectomy within the time period of the study. These 4 patients were included in the demographic and preoperative comparison and in the intention to treat analyses. Hospital data were available on all the abdominal hysterectomy patients (n=21) and all laparoscopically assisted vaginal hysterectomy patients (n=23). One patient in each group refused to complete the visual analogue scales and daily calendar. One patient in the laparoscopically assisted vaginal hysterectomy group was converted to an abdominal procedure because of difficulty in obtaining proper haemostasis. This patient was kept in the laparoscopically assisted vaginal hysterectomy group for the purpose of analysis. There were no bladder or ureteral injuries in this trial. There was 1 small bowel laceration in the laparoscopically assisted vaginal hysterectomy group, which did not require a laparotomy for repair.

Study design
The study was a single centre randomised controlled trial. Of the 48 patients who agreed to participate, 24 were assigned each group according to a computer-generated randomisation schedule with random block sizes. All patients were assigned and told of their assignment before surgery (the median time from assignment to operation was 28.5 days for the abdominal hysterectomy group and 30 days for the laparoscopically assisted vaginal hysterectomy group). All of the laparoscopically assisted vaginal hysterectomies were performed by one surgeon (the senior author) with the assistance of a pelvic surgery fellow or resident.

All patients followed a standardised postoperative protocol of intravenous and oral pain medication, diet progression, and ambulation regardless of surgical access. Each patient received a patient-controlled analgesia pump dispensing morphine sulfate unless the patient was allergic to morphine. The intravenous patient-controlled analgesia pump was discontinued when the patient tolerated oral fluids without nausea and reported a pain score of 4 or less on a scale of 0 to 10. The acute pain management team and the nurse asked the patients to rate their pain every 4 hours. There was only one oral medication protocol. The narcotic analgesic was oxycodone 5 to 10 mg every 4 to 6 hours as needed for pain. The non-narcotic analgesic was acetaminophen 325 to 650 mg every 4 to 6 hours as needed. The patient was eligible for discharge from the hospital when her pain was controlled with oral medication, she tolerated a clear liquid diet, could walk on her own, and voided without difficulty. All patients were afebrile (temperature below 38 degrees C) with stable vital signs and haematocrit to meet discharge criteria. Length of hospital stay was recorded in half days. All patients were discharged with the same protocol of oral medication and ambulation. Patients completed weekly visual analogue scales for pain and activity for 6 weeks, and a daily diary for 6 weeks with data on symptoms, lifestyle impact, life events, and medication.

Analysis of effectiveness
The analysis of the clinical study was based on intention to treat at the point of surgery. The primary health outcomes analysed were the duration of surgery, the length of stay, time to return to normal activity, postoperative morbidity and intraoperative variables (blood loss, postoperative haematocrit, postoperative complications, transfusion rate). The baseline characteristics of the patients in the two groups were comparable in age, occupation and main preoperative characteristics.

Effectiveness results
The median operative time was 130 minutes (quartiles, 97, 155) for the abdominal hysterectomy group and 180 minutes (139, 225) for the laparoscopically assisted vaginal hysterectomy group, (p<.001). The median blood loss was 250 ml (quartiles, 150, 300) for the abdominal hysterectomy group and 450 ml (250, 700) for the laparoscopically assisted vaginal hysterectomy group, (p=0.003). The median uterine weight was 309 g (quartiles, 178, 639) for abdominal hysterectomy group and 370 g (195, 561) for the laparoscopically assisted vaginal hysterectomy group, (p=0.78). The postoperative haematocrit measured on postoperative day 1 was not significantly different between the two groups: total
abdominal hysterectomy, 31.2 (+/- 3.2, range: 23 - 36), and laparoscopically assisted vaginal hysterectomy, 29.2 (+/- 4.5, range: 21 - 37), (p=0.1). There was no significant difference in postoperative complications between groups. There was no significant difference in the transfusion rate between the two groups with 14% (3/21) in the laparoscopically assisted vaginal hysterectomy and 17% (4/23) in the total abdominal hysterectomy, (p=0.99).

Patients in the laparoscopically assisted vaginal hysterectomy group required less patient controlled analgesia time with a median time of 22.1 hours (quartiles, 15.9, 23.5) versus 36.7 hours (26.2, 45.0) for the abdominal hysterectomy group, (p=0.001). They met the discharge criteria earlier at a median time of 1.0 day (quartiles, 1.0, 1.5) compared to 1.5 days (1.5, 2.0) for the abdominal hysterectomy group, (p=0.004). The median length of hospital stay was 2.5 days (quartiles, 1.5, 2.5) for the abdominal hysterectomy group versus 1.5 days (1.0, 2.3) for the laparoscopically assisted vaginal hysterectomy group, (p=0.038).

The weekly visual analogue scale results for return to normal activity and pain suggested that the mean percent return to normal activity was consistently higher for the laparoscopically assisted vaginal hysterectomy group, (p=0.06 with use of arcsin transformation), but the groups did not differ on mean pain scores over postoperative interval, (p=0.38).

Patients who had laparoscopically assisted vaginal hysterectomy returned to work sooner than patients who had a total abdominal hysterectomy, (p=0.03). There were no significant differences in the resolution of symptoms (including fatigue, depression, nausea, bloating, bowel irregularity, or appetite changes) or return to activities such as climbing stairs, housework, or exercise. A secondary analysis showed that the laparoscopically assisted vaginal hysterectomy group scored better on the days to last fatigue, (p=0.02) and the days to first climbing stairs, (p=0.036).

No patient required readmission after discharge. There were no deaths.

**Clinical conclusions**

Laparoscopically assisted vaginal hysterectomy has some advantages over a total abdominal hysterectomy. Patients who undergo a laparoscopically assisted vaginal hysterectomy can be discharged from the hospital sooner and return to work earlier than patients treated with a total abdominal hysterectomy, with no increase in morbidity.

**Modelling**

A time-to-event analysis was performed using Kaplan-Meier failure curves. The groups were compared on time-to-event with log rank tests. Random intercept and slope models (random coefficient regression models) were used to compare groups on the change-over time in pain score and return to normal activities reported on the weekly visual analogue questionnaires. No modelling was used to estimate costs. Differences and 95% confidence intervals between groups in terms of median costs were estimated by a nonparametric method considering all possible pairwise differences between subjects in the two groups.

**Measure of benefits used in the economic analysis**

No summary measure of benefits was used in the economic analysis. The benefits are therefore associated with the effectiveness results reported above. The costs were analysed separately for the two study groups and thus the economic analysis has a cost-consequences design.

**Direct costs**

Discounting was not conducted but may be relevant for some costs, which were incurred over a 3 year period. The hospital costs of the procedures were assessed through the hospital accounting system. The hospital costs included 3 components: the operating room costs, the anaesthesia costs, and the ward costs. Costs and quantities were not reported separately. The price years was not stated.

**Statistical analysis of costs**

The Wilcoxon rank-sum test was used to analyse statistical significance of the difference in medians, determined by
pairwise comparisons of the two groups.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

**Estimated benefits used in the economic analysis**
This was not applicable. See the Effectiveness Results section above.

**Cost results**
The difference in medians of total hospital costs between laparoscopically assisted vaginal hysterectomy and total abdominal hysterectomy was $277 (95% CI: -163 to 1097), \( p=0.21 \).

The difference in medians of operating room costs between laparoscopically assisted vaginal hysterectomy and total abdominal hysterectomy was $757 (95% CI: 440 - 1090), \( p<0.001 \).

The difference in medians of anaesthesia costs between laparoscopically assisted vaginal hysterectomy and total abdominal hysterectomy was $197 (95% CI: 100 - 337), \( p<0.001 \).

The difference in medians of postoperative costs between laparoscopically assisted vaginal hysterectomy and total abdominal hysterectomy was $417 (95% CI: -711 to -127), \( p=0.014 \).

**Synthesis of costs and benefits**
No synthesis of costs and benefits was performed.

**Authors’ conclusions**
Total hospital costs were not significantly higher in the laparoscopically assisted vaginal hysterectomy group than in the total abdominal hysterectomy group. A more rapid post-operative recovery and earlier return to work can also be anticipated for this procedure.

**CRD COMMENTARY - Selection of comparators**
The author explicitly justified the use of total abdominal hysterectomy as comparator treatment to laparoscopically assisted vaginal hysterectomy. Although total abdominal hysterectomy is the most frequently used method for hysterectomies, the evidence suggested that laparoscopically assisted vaginal hysterectomy was a safe alternative when a vaginal hysterectomy was contraindicated.

**Validity of estimate of measure of effectiveness**
The validity of the effectiveness results should be high as a randomised prospective design was used and the analysis was based on intention to treat at the point of surgery (subjects who withdrew before surgery were excluded from analysis) which was appropriate for the study design. The study sample appears to have been representative of the study population. The patient groups were shown to be comparable at analysis and appropriate statistical analysis was undertaken for the median estimates. The lack of mean estimates prevents the analysis of the overall results for the study population.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore a cost-consequences design.

Validity of estimate of costs
Only direct treatment costs were included in the analysis. All categories of costs relevant to the perspective adopted were included. Only median costs differences were reported which prevents the analysis of potential financial impact. Median quantities of resource use were also reported. Statistical analyses of median prices and median resource quantities were appropriately performed. Although the costs were incurred over 3 years, discounting was not reported. The price date was not reported. The users of this database are advised to consider the cost in their settings.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was addressed by discussing the differences in the mean length of stay in European countries compared with USA. The authors’ conclusions reflect the study scope.

Implications of the study
The study results suggest that laparoscopically assisted vaginal hysterectomy is potentially more beneficial and an equally costly alternative to total abdominal hysterectomy. The reporting of median estimates makes generalisability of the results difficult. The unavailability of a benefit measure makes it difficult to determine the overall benefit from the viewpoint of patients. Additional research around the postoperative recovery parameters and the indirect medical costs will be beneficial in informing the cost-effectiveness and cost-utility of both interventions and confirming the conclusions of this study.

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