Hysterectomy for obese women with endometrial cancer: laparoscopy or laparotomy?

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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 use of laparoscopy versus laparotomy for vaginal hysterectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised obese women with clinical stage I endometrial cancer or uterine sarcoma, and body mass indices (BMIs) between 28.0 and 60.0.

Setting
The setting was secondary care (gynaecologic oncology unit). The economic analysis was carried out in the USA.

Dates to which data relate
The effectiveness and resources data related to 1997 to 1999. The price year was not reported.

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

Link between effectiveness and cost data
The costing was carried out retrospectively using the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were reported. A power of 64.2% was needed to detect a 20% difference between the intervention and the control groups. All women with clinical stage I endometrial cancer or uterine sarcoma who presented to the authors’ division between 1998 and 1999, and who could tolerate laparoscopy, were offered laparoscopically-assisted vaginal hysterectomy (LAVH group; n=40). Patients who refused laparoscopic treatment, or had one or more contraindications to laparoscopy, were not included in the study. The control group included similar numbers of women (n=40) with clinical stage I endometrial cancer or uterine sarcoma, and similar BMIs, who underwent laparotomy and total abdominal hysterectomy (TAH group) at the authors’ division in the 2 years before the study period. A total of 80 women were included in the study.
**Study design**
This was a comparative study with historical controls that was conducted in a single centre. The duration of follow-up was not stated.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on the basis of treatment completers. The primary health outcomes used in the analysis were:

conversion to laparotomy,

the presence and degree of adhesions,

estimated blood loss,

preoperative and postoperative haematocrit,

operative time,

the incidence of operative and postoperative complications,

the length of hospital stay, and

tumour stage and grade.

The patient's satisfaction, in addition to postoperative pain, resumption of full activity and return to work, were compared between the two groups through interviews with the patients or nurses. The patients' characteristics were similar among the two groups (LAVH and TAH).

**Effectiveness results**
Laparoscopy was converted to laparotomy in 3 (7.5%) patients (the patients were kept in the LAVH group). Thus, laparoscopy was feasible in 88.1% of obese women with clinical stage I endometrial cancer.

There was no significant difference between the LAVH and TAH groups in the proportion of women who underwent lymphadenectomy. The two groups also showed no significant differences in the incidence of operative and postoperative complications, in the presence and degree of adhesions, in estimated blood loss, and in the preoperative and postoperative haematocrits.

There was no significant difference between the LAVH and TAH groups in the patients' recollection of postoperative pain and the patients' satisfaction with treatment.

Women who underwent LAVH had a significant longer operative time (194.8 minutes) than those who underwent TAH (137.7 minute), (p<0.001). They also had more pelvic lymph nodes removed (11.3 versus 5.3; p<0.001), a smaller drop in postoperative haematocrits (3.9 versus 5.4; p=0.029), less pain medication (32.3 versus 124.1 mg; p<0.001), and shorter hospital stay (2.5 versus 5.6 days; p<0.001).

Women who underwent laparoscopy showed a trend towards earlier resumption of full activity (23.2 versus 45.0 days; p=0.073) and return to work (35.3 versus 67.0 days; p=0.055).

**Clinical conclusions**
Compared with laparotomy, laparoscopy was a safe procedure with excellent surgical outcomes and less postoperative pain.
Measure of benefits used in the economic analysis
The authors did not develop a summary benefit measure. A cost-consequences analysis was therefore performed.

Direct costs
The direct costs were for the surgeon, anaesthesiologist, operating room and hospital costs. The cost was adjusted to the date of the surgery and any additional procedures performed. The source of the quantity and cost data was not reported. The unit costs/charges were estimated. Discounting was unnecessary since the costs occurred in less than one year. The price year was not given.

Statistical analysis of costs
Statistical analyses of the costs were performed using a two-sample t-test and Fisher's exact test. Descriptive statistics were presented (mean values and standard deviations).

Indirect Costs
No indirect costs were included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was carried out.

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

Cost results
Surgeon's fees, anaesthesiologist's fees, and operating room costs were significantly higher among the LAVH group than the TAH group, (p<0.001). The surgeon's fees were $4,629.7 (LAVH) versus $2,458.0 (TAH), the anaesthesiologist's fees were $1,442.5 (LAVH) versus $1,144.2 (TAH), and the operating room costs were $3,474.9 (LAVH) versus $2,018.9 (TAH).

There was no statistically significant difference in the total hospital cost between the LAVH ($8,373.7) and TAH ($9,415.4) groups, (p=0.323).

The difference in the total cost between the LAVH group ($13,003.1) and the TAH group ($11,878.9) was not statistically significant, (p=0.295).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Most obese women with clinical stage I endometrial cancer can be safely treated by laparoscopy with similar surgical outcomes, shorter hospitalisation and less postoperative pain than those treated by laparotomy.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator, laparotomy surgery, was clear. The comparator was chosen because it represented the traditional procedure for hysterectomy in the authors' setting. You should consider whether this is a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
A non-randomised study was conducted. A randomised trial dividing obese women with endometrial cancer into laparoscopy and laparotomy would have been a more reliable design in terms of eliminating potential bias and confounding factors. The small sample size and the low power may also limit the generalisability of the findings. The patients were shown to be comparable at analysis, so confounding should be low. However, the authors acknowledged that a significant proportion of obese women with endometrial cancer have BMIs exceeding 60.0. Thus, the findings may not be generalisable to this population.

Validity of estimate of measure of benefit
The authors did not develop a summary benefit measure. A cost-consequences analysis was performed.

Validity of estimate of costs
The perspective adopted was not reported, so the appropriateness of the cost analysis to a particular perspective was unclear. The duration of the follow-up was not clearly stated, but it is likely to be the time between initiating the intervention and hospital discharge. As such, the cost analysis did not include the resource used after discharge. The costs and the quantities were not reported separately. Finally, there were few details on how the costs were estimated. Statistical analyses, however, were performed. Discounting was not conducted, but this was appropriate given the short follow-up period.

Other issues
The limitation of the low generalisability of the results to other settings or countries was addressed. Adequate comparisons were made with studies dealing with the same topic. The authors enrolled obese women with clinical stage I endometrial cancer and this was reflected in the authors' conclusions. The authors highlighted the limitations of their study and do not appear to have reported their results selectively.

Implications of the study
The authors did not think that laparoscopy could completely replace laparotomy in the treatment of obese women with endometrial cancer and BMIs exceeding 60.0. The authors mentioned that morbid obesity could be a limiting factor in the laparoscopic treatment of women with endometrial cancer. A longer follow-up is needed before one can decide whether laparoscopy offers similar survival to laparotomy.

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