Laparoscopic-assisted vaginal hysterectomy with bilateral oophorectomy versus total abdominal hysterectomy and bilateral salpingo-oophorectomy: implications for gynecologic practice in the United Kingdom

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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 and bilateral salpingo-oophorectomy (LAVH-BSO) in patients with gynaecologic conditions requiring hysterectomy and bilateral oophorectomy.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study included patients who had been on the study institution waiting list with gynaecologic conditions requiring hysterectomy and bilateral oophorectomy. Patients who were morbidly obese, or whose uterus was larger than 14 weeks' gestation on clinical examination, were excluded from the laparoscopic procedure.

Setting
Hospital. The economic analysis was carried out in London, UK.

Dates to which data relate
Effectiveness and resource use data corresponded to operations performed between January 1992 and August 1992. The price year was not explicitly specified.

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

Link between effectiveness and cost data
Costing was conducted on the same patient sample as that used in the effectiveness analysis and appears to have been performed prospectively.

Study sample
Power calculations were not used to determine the sample size. A total of 40 patients constituted the study sample, 20 patients in each study group. The LAVH-BSO group had a mean age of 46.7 (range: 32-67) years versus 43.7 (range: 36-52) years in the TAH-BSO group.
Study design
This was a prospective, randomised study, carried out in a single centre. The duration of the follow-up appears to have been until discharge. The study appears to have had no loss to follow-up. The form of hysterectomy was determined on an alternate basis; it was deemed that in this way no selection bias would be introduced in performing a laparoscopic procedure. It was the study institution's practice at the time of the study to offer prophylactic oophorectomy to any woman, regardless of age, with significant pelvic pain or severe premenstrual syndrome. The same surgeon performed all LAVH-BSO operations. All patients were counselled by one of the authors and were prepared preoperatively in a similar fashion. Antibiotic therapy started while a patient was under general anaesthesia and continued postoperatively for 7 days.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been intention to treat. The health outcomes were length of operating time; estimated blood loss (ml); fall in haemoglobin postoperative day 2 (g/dl); maximum fever (degrees Centigrade); postoperative analgesic requirement (number of doses) in terms of opiates, rectal non-steroidal anti-inflammatory drugs (NSAIDs), and oral NSAIDs; postoperative stay; and major complications. The treatment groups were found to be comparable in terms of age and pelvic pathology.

Effectiveness results
There were no major complications in either group of patients. One woman who had LAVH required conversion to laparotomy. The rest of the mean (SD) outcomes were as follows:

- length of operating time (minutes), LAVH 9.75 (6.1) and TAH 54 (4), (p<0.001);
- estimated blood loss (ml), LAVH 226.5 (26.5) and TAH 215 (27.2), (non significant);
- fall in haemoglobin postoperative day 2 (g/dl), LAVH 1.6 (0.2) and TAH 1.6 (0.2), (non significant);
- maximum fever (degrees Centigrade), LAVH 37.2 (0.1) and TAH 37.5 (0.1), (p<0.001);
- postoperative analgesic requirement (number of doses) in terms of opiates, LAVH 1.4 (0.2) and TAH 2.2 (0.4), (non significant); in terms of Rectal NSAIDs, LAVH 2.1 (0.2) and TAH 2.5 (0.3), (non significant); and in terms of Oral NSAIDs, LAVH 4.1 (0.6) and TAH 11.7 (1.6), (p<0.0002); and
- postoperative stay (days), LAVH 3.8 (0.3) and TAH 6.0 (0.4), (p<0.0001).

Clinical conclusions
This early experience with LAVH-BSO shows it to be a safe alternative to TAH-BSO. Moreover, it is associated with reduced postoperative morbidity, particularly in terms of pain.

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 (cost-consequences).

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were not reported separately. Cost analysis covered the costs of disposable instruments and postoperative hospital stay; as the major points of differences between the operations. The perspective adopted in the cost analysis was not explicitly specified, but appears to have been that of the hospital. The price year was not explicitly specified. The cost analysis did not cover the costs of preoperative stay and work-up as these were reported to be identical for all patients and therefore did not contribute to cost differences.
Statistical analysis of costs
Statistical analysis was only performed on postoperative stay and not on the cost data.

Indirect Costs
Indirect costs were not included.

Currency
Not reported but the currency is presumed to have been UK pounds sterling (§).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The potential cost savings was 17.9% per case for LAVH-BSO compared with TAH-BSO.

Synthesis of costs and benefits
The strategy of performing LAVH-BSO was, in fact, the dominant alternative.

Authors’ conclusions
LAVH-BSO was a safe alternative to TAH-BSO, with less morbidity and earlier hospital discharge. Possible cost savings suggests the need for change to current (at the time of the study) operating and in-patient hospital resources.

CRD COMMENTARY - Selection of comparators
The strategy of performing TAH-BSO, as the routine procedure in the context in question at the time of the study, was regarded as the comparator. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results cannot be guaranteed as no power calculations were performed and the sample size was relatively small. However, the randomised nature of the study design will clearly have enhanced its internal validity. The treatment groups were found to be comparable in terms of age and pelvic pathology. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit and the analysis was therefore of cost-consequences design.

Validity of estimate of costs
The following features enhanced the validity of the cost results: some quantities were reported separately from the costs; the perspective adopted in the cost analysis appears to have been that of the hospital; statistical analysis was performed on some resource use. However, the analysis had some limitations in that: the price year was not reported; the cost breakdown was not reported; statistical analysis was not performed on cost data; and the effects of alternative...
procedures on indirect costs were not addressed. As a consequence, the cost results may not be generalisable outside the study setting.

Other issues
The study produced a clear finding in favour of the intervention but, due to the above-described limitations, the results may need to be treated with a degree of caution. In general terms, the issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was partially addressed in the authors' comments where it was noted that the study exclusion criteria for a laparoscopic operation did not include lack of uterovaginal prolapse; a logical extrapolation of the idea of laparoscopic oophorectomy was shown by the two patients who underwent the procedure at the time of vaginal hysterectomy for second-degree uterine prolapse.

Implications of the study
The authors argue that, if the intervention is to become accepted, it will require not only the development of laparoscopic surgery but also a reappraisal of practice of vaginal surgery. The implications for gynaecologic practice and hospital services are less well defined and will probably become more so only when the operation becomes widely performed.

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