Comparison of the harmonic scissors and endostapler in laparoscopic supracervical 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
Using harmonic scissors as the method of pedicle development in patients undergoing laparoscopic supracervical hysterectomy (LSH).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing LSH. Patients were excluded if they had a uterine size greater than 14 weeks' gestation.

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

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated between March 1993 and August 1994. 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 was undertaken retrospectively, based on assumptions made regarding the resources used.

Study sample
Power calculations were not used to determine the sample size. A retrospective power calculation showed that the sample size was sufficient to detect a 50% difference among the three variables of estimated blood loss, operative time, and uterine weight at the 5% level of significance with 95% certainty. There were 15 patients in the staple group with a mean age of 41 (range: 31 - 50) years versus 14 patients in the scissors group with a mean age of 38 (range: 30 - 48) years.

Study design
This was a retrospective cohort study, carried out in a single centre. The duration of follow-up appears to have been until discharge from hospital. The loss to follow-up was not reported. One surgeon performed all the operations. The reviewing hospital and office records were the basis for the retrospective comparisons of outcomes.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness (intention to treat or treatment completers) was not explicitly specified. The treatment outcomes were estimated blood loss, operative time, hospital stay, surgical indications, and complications. The groups were found to be comparable in terms of age and weight.

**Effectiveness results**
The mean treatment outcomes for the staple and scissors groups, respectively, were as follows:

- Operating room time, 127 (range: 65 - 210 mins.) and 135 minutes (range: 85 - 180 mins.);
- Estimated blood loss, 173 (range: 75 - 600 ml) and 244 ml (range: 75 - 500 ml);
- Hospital stay, 1.3 and 1.4.

It was reported that the differences between the groups in terms of the outcomes were not statistically significant. The groups were comparable in terms of surgical indications. There were four complications in the staple group and 2 cases in the scissors group. The overall immediate complication rate was 14%, but all of the events were minor. The late complication rate of cervical stump bleeding was 7%.

**Clinical conclusions**
The study groups were comparable in terms of the main clinical outcomes.

**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. Since the alternative instruments were comparable in terms of the main treatment outcomes, the economic study proceeded as a cost-minimisation analysis.

**Direct costs**
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs. Cost items were reported separately. The cost analysis covered the costs of substituting the scissors for staples (the cost of an Endo GIA device with load and per reload, the cost of harmonic scissors, the handpiece costs, and generator) based on the assumption of no other changes in the resource use structure. The perspective adopted in the cost analysis was not explicitly specified. Hospital mark-ups were not included in the cost analysis. The price date was not explicitly specified.

**Indirect Costs**
Not included.

**Currency**
US dollars ($).

**Estimated benefits used in the economic analysis**
Not applicable.
Cost results
The total cost of stapling was $900 versus $315 per procedure using the scissors, not including the generator. This leads to cost savings of $585 per case. The total saving in the study series was $8,775. The cost of the generator, a durable item, was about $13,000.

Synthesis of costs and benefits
Costs and benefits were not combined since the economic study was reduced to a cost-minimisation analysis in design after establishing the equivalence of the alternative instruments in terms of the treatment outcomes.

Authors’ conclusions
Both instruments resulted in similar outcomes with regard to operating time, blood loss, and hospital stay. The harmonic scissors have the advantage of decreasing patient cost compared with the stapler.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (the use of stapler). It was the preferred method used by many surgeons in the context in question.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results can not be guaranteed due to the retrospective nature of the study design and the small sample size. It is not possible to assess to what degree the study sample was representative of the study population due to lack of information on the study inclusion criteria. Patient groups were comparable in terms of age and weight at baseline. Historical bias might have affected the study results, as acknowledged by the authors, since almost all cases in the staple group were performed before those in the scissors group.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of treatment alternatives. The economic analysis therefore included only costs.

Validity of estimate of costs
Quantities were reported separately from the costs. Adequate details of methods of cost estimation were given. Excluding the hospital mark-up may have had a positive impact on the external validity of the cost results. The price date was not given. The perspective adopted in the cost analysis was not explicitly specified. Statistical analysis was performed on some components of the resource use data. The possible impact of alternative health technologies on indirect costs (productivity loss or gain) was not measured.

Other issues
Given the retrospective nature of the study design and lack of sensitivity analysis, the study results may need to be interpreted with some degree of caution. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons do not appear to have been made with other studies.

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