Cost-utility of levonorgestrel intrauterine system compared with hysterectomy and second generation endometrial ablative techniques in managing patients with menorrhagia in the UK

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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.

CRD summary
The objective was to examine the cost-utility of levonorgestrel intra-uterine system (LNG-IUS) in comparison with hysterectomy and second-generation endometrial ablation techniques (microwave and thermal balloon) in women with menorrhagia. On the basis of the model assumptions, LNG-IUS followed by endometrial ablation when required appears to have been the most cost-effective treatment from the perspective of the National Health Service. The study was based on valid methodology and was satisfactorily reported. The authors' conclusions appear to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to examine the cost-utility of the levonorgestrel intra-uterine system (LNG-IUS) in comparison with hysterectomy and second-generation endometrial ablation techniques, such as microwave endometrial ablation (MEA) and thermal balloon endometrial ablation (TBEA), in women with menorrhagia.

Interventions
The five strategies were LNG-IUS followed by endometrial ablation when required (L-A), LNG-IUS followed by hysterectomy when required (L-H), immediate MEA, immediate TBEA, and immediate hysterectomy. The LNG-IUS released 20μg of levonorgestrel every 24 hours.

Location/setting
UK/hospital.

Methods
Analytical approach:
This economic evaluation was based on a Markov model with a five-year time horizon. The authors stated that the analysis was carried out from the perspective of the National Health Service (NHS).

Effectiveness data:
The clinical data came from a selection of known, relevant studies. The treatment effectiveness for LNG-IUS and hysterectomy came from a large scale randomised controlled trial (RCT) which enrolled 236 women in Finland and had a five-year follow-up. The treatment effect for the ablation techniques came from a published Markov model. Other clinical inputs were derived from other published studies or UK life tables. The key clinical outcome was the ability of the surgical and non-surgical options to reduce bleeding.

Monetary benefit and utility valuations:
The utility valuations were derived from the Finnish RCT in which patients completed the European Quality of life (EQ-5D) questionnaire. Some assumptions were also made.

Measure of benefit:
Quality-adjusted life-years (QALYs) were used as the summary benefit measure and they were discounted at an annual rate of 3.5%.
Cost data:
The health service costs were those of LNG-IUS (acquisition, insertion, replacement and removal), general practitioner (GP) consultation, gynaecologist out-patient visit, hysterectomy, TBEA, MEA, and procedure-related complications. The macro-costs for each category were reported. These costs came from a published model as well as NHS official prices (Reference Costs, Personal Social Services Research Unit, and the British National Formulary). All costs were in UK pounds sterling (£) and referred to 2004 to 2005 prices. Those incurred after the first year were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
A deterministic sensitivity analysis was carried out on most of the model inputs to determine the threshold value that altered the decision on the most cost-effective strategy. The alternative values appear to have been defined by the authors. One alternative set of assumptions was based on an on-line survey of UK-based GPs and gynaecologists, conducted in December 2005. In addition, a probabilistic sensitivity analysis was undertaken, using a Monte Carlo simulation. The probability distributions assigned to the input parameters were reported.

Results
Over five years, the expected costs per patient were £828 with L-A, £1,355 with L-H, £1,679 with TBEA, £1,812 with MEA, and £2,983 with hysterectomy. The QALYs were 4.14 with L-A, 4.12 with L-H, 4.13 with TBEA, 4.13 with MEA, and 4.01 with hysterectomy.

The incremental analysis showed that L-A dominated L-H, the ablation techniques and hysterectomy. Similarly, the ablation strategies dominated hysterectomy. The incremental cost per QALY gained using MEA over L-H was £66,800 and using TBEA over L-H was £47,500. Treatment with TBEA instead of MEA reduced the health care costs by about £130, but did not change the QALY gain.

The deterministic sensitivity analysis indicated that L-A remained the preferred strategy, in several scenarios.

The probabilistic analysis showed that, at low levels of willingness to pay for a QALY (under £10,000), LNG-IUS was likely to be the preferred strategy, while at higher levels, TBEA and MEA became more preferable compared with L-H.

Authors' conclusions
The authors concluded that, on the basis of model assumptions, LNG-IUS followed by ablation appeared to be the most cost-effective treatment from the perspective of the NHS.

CRD commentary
Interventions:
The selection of the comparators appears to have been appropriate and reflected the strategies in the primary RCT. Furthermore, the authors pointed out that three of these options (MEA, TBEA, and L-A) corresponded to current recommendations by the National Institute for Clinical Excellence (NICE), while the L-H and hysterectomy strategies reflected the Finnish setting.

Effectiveness/benefits:
This analysis stemmed from the Finnish RCT, which was the main source for the clinical data. In general, a RCT is considered to be a robust source of evidence, given the strengths of its design. Additional data for the model came from other studies, which were selected. The level of reporting of inputs, their sources, and assumptions was satisfactory. The derivation of the utility valuations was clearly reported. QALYs are a validated benefit measure and appear to have been relevant, given the impact of the disease on the quality of life.

Costs:
The economic analysis reflected the perspective and the sources used were consistent with the NHS viewpoint. A breakdown of cost items was not provided, with costs being presented as macro-categories. Nevertheless, the economic analysis appears to have been presented in detail with respect to the cost categories, their sources, price year, use of discounting, and statistical analyses.
Analysis and results:
The use of an incremental analysis to combine the costs and benefits was appropriate. The issue of uncertainty was extensively addressed. The findings were clearly presented and discussed. The authors compared their findings with those from other studies. Some limitations of the analysis were also pointed out, including the use of utility values from the Finnish population, which might not have been applicable to the UK. Furthermore, the authors noted that the use of data from multiple sources rather than from real observation might have affected the validity of their conclusions.

Concluding remarks:
The study was based on valid methodology and was satisfactorily reported. The authors' conclusions appear to be robust.

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