Economic evaluation of the levonorgestrel-releasing intrauterine system for the treatment of dysfunctional uterine bleeding in Spain
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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
This study assessed the cost-effectiveness of the levonorgestrel-releasing intra-uterine system (LNG-IUS) versus the combined oral contraceptive or progestogens as first-line treatment for dysfunctional uterine bleeding. The authors concluded that the LNG-IUS was more effective and less expensive than either the combined oral contraceptive or progestogens from the perspective of the Spanish health system. The methods were appropriate and well-reported, which should ensure the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study assessed the cost-effectiveness of the levonorgestrel-releasing intra-uterine system (LNG-IUS) versus the combined oral contraceptive or progestogens as first-line treatment for women with dysfunctional uterine bleeding.

Interventions
Three interventions were considered: the LNG-IUS, the combined oral contraceptive, and progestogens. Patients could switch from one treatment to another if treatment failed. A surgical procedure (hysterectomy or resection) could be undertaken in the case of repeated failure.

Location/settings
Spain/hospital and secondary care.

Methods
Analytical approach:
The analysis was based on a Markov model, with a hypothetical cohort of women with a previous diagnosis of idiopathic heavy menstrual bleeding. Two scenarios were considered: a contraception scenario, where patients do not wish to have children and contraception was included, and a dysfunctional uterine bleeding scenario, which focused on the control of bleeding only. A five-year time horizon was considered. The authors stated that the analysis was conducted from the perspective of the Spanish National Health System.

Effectiveness data:
The clinical sources of evidence were identified by a review of the literature in commonly used electronic databases. These inputs were validated by Spanish clinical experts. The key model input was the treatment success, which was defined as the proportion of patients responding to treatment and not becoming pregnant.

Monetary benefit and utility valuations:
The utility values were from published studies that used the European Quality of life (EQ-5D) scale. UK tariffs were used, as there were no Spanish values.

Measure of benefit:
Three benefit measures were considered: symptom-free months, surgery-free months, and quality-adjusted life-months (QALMs). A 3% annual discount rate was applied.
Cost data:
The economic analysis included the costs of the LNG-IUS (device and gynaecology visit), the combined oral contraceptive (only gynaecology visit), progestogens (gynaecology visit and medications), resection, hysterectomy, abortion, and pregnancy and birth. The cost of the combined oral contraceptive medication was zero to the health system because it was paid by patients. The resource use was from a panel of Spanish experts with experience in the management of dysfunctional uterine bleeding. The costs were estimated using the eSalud database, which collected costs from the literature, and using tariffs from national and regional health services. They were in Euros (EUR) and were discounted at an annual rate of 3%. The price year was 2008.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken, using a second-order Monte Carlo simulation with 10,000 iterations. Log-normal distributions were selected for costs, normal distributions for resource use, and beta-distributions for probabilities. A one-way sensitivity analysis was carried out, by varying the model inputs one at a time. The ranges of values were based on authors’ opinions or published sources.

Results
Over five years and in the contraception scenario, the costs were EUR 3,099.37 with LNG-IUS, EUR 3,409.32 with the combined oral contraceptive, and EUR 3,676.98 with progestogens. The symptom-free months were 50.53 with LNG-IUS, 47.86 with the combined contraceptive, and 45.59 with progestogens. The surgery-free months were 34.79 with LNG-IUS, 30.31 with the combined contraceptive, and 28.05 with progestogens. The QALMs were 50.89 with LNG-IUS, 49.82 with the combined contraceptive, and 48.91 with progestogens.

LNG-IUS was the dominant treatment as it was more effective and less expensive than the other interventions. The same conclusion was reached in the dysfunctional uterine bleeding scenario; LNG-IUS was dominant.

The base-case findings were robust to the variations considered in the sensitivity analyses. The probability of LNG-IUS being dominant was 99.8% versus the combined oral contraceptive and 99.9% versus progestogens.

Authors' conclusions
The authors concluded that the LNG-IUS was more effective and less expensive than either the combined oral contraceptive or progestogens from the perspective of the Spanish health system.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the authors’ aim was to compare the most commonly used medical (non-surgical) interventions for the first-line treatment of dysfunctional uterine bleeding in women who wished to preserve future reproductive ability. The authors pointed out that tranexamic acid was a potential comparator, but was excluded because it was an acute treatment for the condition.

Effectiveness/benefits:
The clinical data were retrieved by a review of the literature that aimed to identify the most relevant studies of the three strategies compared. No information on the design and other characteristics of the studies selected was provided, and it is not possible to judge the validity of the clinical data. Extensive sensitivity analysis was conducted on all the clinical inputs. Disease-specific and generic benefit measures were reported, making the results relevant to clinicians and payers. Quality of life is a relevant dimension of health for patients with dysfunctional uterine bleeding. A validated instrument was used to elicit the preferences for health conditions, but the methods were not reported. The authors acknowledged that the use of values from UK patients could limit their analysis, but Spanish values were not available and changes in the utility weights did not affect the cost-effectiveness results.

Costs:
The cost categories were consistent with the stated perspective. The unit costs were reported for most items, but some were presented as category totals. The price year and discounting were clearly reported. The data sources reflected the Spanish accounting system and included a commonly used database and official tariffs reimbursed by the health system. The authors justified their exclusion of the costs of adverse events, which were considered to be negligible. The
inclusion of these costs was appropriately considered in the sensitivity analyses.

Analysis and results:
The results were extensively reported and an appropriate incremental approach was used to synthesise the costs and benefits of the strategies. The time horizon was chosen to reflect the duration of the LNG-IUS. The uncertainty was satisfactorily investigated, using appropriate approaches, and the findings were clearly reported and confirmed that the results were robust despite the need for some assumptions. The authors compared their results with those of other published studies that had similar findings. The results appear to be transferable to settings with similar cost structures.

Concluding remarks:
The methods were appropriate and well-reported, which should ensure the validity of the authors' conclusions.

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