COST-EFFECTIVENESS ANALYSIS OF ULIPRISTAL ACETATE 5MG FOR THE TREATMENT OF MILD TO SEVERE SYMPTOMS OF UTERINE FIBROIDS FOR PATIENTS SEEKING AN ALTERNATIVE TO SURGERY IN ENGLAND

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Context
- Symptomatic uterine fibroids (UF) affect 10-20% of women of reproductive age, and non-surgical treatment options are limited.
- Although repeated 12-week courses of daily oral ulipristal acetate 5mg (UPA) has been shown to effectively control bleeding and pain, reduce fibroid volume, and restore QoL in patients with symptomatic fibroids, the cost-effectiveness of such a strategy has not been assessed.

Objective
- Determine the cost-effectiveness of repeated intermittent use of UPA compared to non-surgical best supportive care (BSC) in an English setting.

Intervention
- Oral UPA indicated for adult women to treat moderate to severe symptoms of UF.

Main outcome measures
- Survival adjusted for quality of life expressed as quality-adjusted life-years (QALYs) and costs per treatment arm.
- Costs and QALYs combined into an incremental cost-effectiveness ratio (ICER).

Methods
- Based on the UPA Phase III clinical trial program (PEARL), a Markov model was developed to estimate the main outcomes for each treatment strategy over a lifetime time horizon. Trial data was supplemented and validated with inputs from clinical experts in the UK.
- Treatment-specific bleeding and pain symptoms were included in the analysis, modelled using trial-based levels of the pictorial bleeding assessment chart (PBAC) and visual analogue scale (VAS), respectively. Costs were based on medicine, surgery, complications, monitoring, and follow-up resource use associated with each strategy. Both costs and quality adjusted life years were discounted at 5.5% per year.
- The average patient age at treatment start is 41.5 years and the average patient reaches menopause at age 51.4 (Fig. 1).
- Except for long term complications, patients are assumed to be symptom free following enrolment.
- Based on clinical practice, patients could withdraw to surgery from both strategies, and UPA patients could also withdraw to BSC (Fig. 2).
- Mortality (from surgery and all-causes) were incorporated into the model and long term complications arising from surgery were included in the model according to rates published in the literature.

Womens with moderate to severe symptoms of UF

Fig. 1: Decision problem and time horizon

- The results of the cost-effectiveness analysis indicate that the cost per QALY gained with UPA is below the generally acceptable ICER threshold between £25,000 and £30,000 in England, implying that UPA is cost-effective (Table 1).
- The increase in costs related to treatment with UPA is mostly due to higher pharmaceutical costs and additional follow-up whereas the BSC strategy requires more surgery, a closer monitoring and additional management of adverse events.
- The clinical efficacy of UPA on bleeding and pain symptoms allows an improvement in QoL. In favor of UPA compared to the BSC strategy where patients will keep suffering until there is no other solution than to perform a surgery.

Table 1: Deterministic model results

<table>
<thead>
<tr>
<th>Strategy</th>
<th>QALYs</th>
<th>Cost (£)</th>
<th>Cost (£) + QALYs + ICER</th>
<th>BSC</th>
<th>UPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>median</td>
<td>17.22</td>
<td>6,674</td>
<td>11,533</td>
<td>17.4</td>
<td>17.2</td>
</tr>
</tbody>
</table>

- Sensitivity of the model’s results to input parameters were assessed through a sensitivity analyses where each input parameter was varied by 10%, individually (Fig. 3).

Results
- A probabilistic sensitivity analysis was conducted by taking the joint statistical uncertainty of all relevant parameters into account in order to estimate the uncertainty in the model’s outcomes (Fig. 4).
- The associated cost-effectiveness acceptability curve shows the probability that a treatment strategy is cost-effective at different cost-effectiveness thresholds (Fig. 5).
- Given a willingness to pay per QALY of £20,000, there is a 94% probability that UPA is cost-effective.

Conclusions
- Over a lifetime horizon, UPA is associated with a cost per QALY gained below cited ICER for England (£11,533).
- For patients with moderate to severe symptoms of UF seeking an alternative to surgery, repeated intermittent use of UPA has proved to be cost-effective thanks to increased control of UF symptoms resulting in a quality of life improvement compared with a BSC strategy.

Fig. 2: Model structure depicting health states and transitions between health states

Fig. 3: Sensitivity analyses varying each parameter individually

Fig. 4: Probabilistic sensitivity analysis

References
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