A cost-utility analysis of pregabalin in the management of peripheral neuropathic pain

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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 pregabalin added to usual care, compared with usual care alone, for the treatment of peripheral neuropathic pain. The authors concluded that pregabalin led to a small, but significant, improvement in patient health without increasing costs from the perspective of the Belgian health care payer. In general, the quality of the study methodology was good and the authors’ conclusions appear valid despite limited reporting of the economic side of the analysis.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of pregabalin added to usual care, compared with usual care alone, for the treatment of adult patients with peripheral neuropathic pain.

Interventions
Pregabalin was compared with usual care, which consisted of a mix of drug therapies excluding anti-epileptic drugs. Pregabalin was administered at 150, 300 or 600mg/day, depending on patient creatinine levels. A mixed dosage pregabalin strategy was evaluated based on the proportion of patients receiving each dosage. Each dosage was also evaluated separately.

Location/setting
Belgium/secondary care.

Methods
Analytical approach:
A Markov model was developed to simulate the treatment of disease under the two options based on different pain levels. The time horizon of the analysis was 1 year. The authors stated that the perspective of the health care payer was adopted in the study.

Effectiveness data:
The clinical data were derived from a large, randomised double-blind clinical trial that enrolled 368 patients. This study compared usual care (placebo) against three different dosages of pregabalin (150, 300 and 600 mg/day). The duration of follow-up was 13 weeks. The four different patient groups were similar at baseline. Assumptions were necessary to extrapolate 12-week results to a 1-year time horizon. The key clinical estimates were pain scores, which were transformed in transition probabilities to be fitted in the model.

Monetary benefit and utility valuations:
Utility valuations were derived from a Belgian prospective observational study of 88 patients who completed the Short-Form 36 (SF-36). The results of the SF-36 were converted to utility weights using the SF-6 algorithm.

Measure of benefit:
The summary benefit measure was the quality-adjusted life-years (QALYs). These were estimated using the decision model.

Cost data:
A breakdown of the cost items was not provided. Thus, it was not clear which cost categories, other than drug costs, were included. In general, costs were associated with each health state of the Markov model. The cost data were derived from a Belgian observational study of 88 patients, whose medical charts were prospectively reviewed over a 1-month period. Drug dosages were based on the data from the RCT. The costs were in euros (EUR). The price year was 2003.

*Note: since this abstract was written the author has confirmed that the cost data included all costs (drugs, tests, consults, hospital stay) from the perspective of the payer.*

**Analysis of uncertainty:**
A probabilistic sensitivity analysis was undertaken to address the issue of variability in the cost estimates, the range of which was very wide because of a small proportion of patients requiring hospitalisation. The sensitivity analysis focused also on variability in utility valuations. Both the costs and utilities were assigned probabilistic distributions (beta and normal, respectively).

**Results**
The total costs per patient were EUR 6,200 with usual care and EUR 5,984 with the mixed pregabalin strategy (difference EUR 216). The expected QALYs were 0.510 with usual care and 0.520 with mixed pregabalin (difference 0.01). Thus, under base-case assumptions, pregabalin was a dominant strategy (i.e. both more effective and less expensive) than usual care. This result held not only for the mixed pregabalin strategy but also for all dosages evaluated separately.

The probabilistic analysis indicated that pregabalin was cost-neutral in most scenarios but was significantly more effective.

**Authors' conclusions**
The authors concluded that, from the perspective of the Belgian health care payer, the addition of pregabalin to usual care for the treatment of peripheral neuropathic pain led to a small, but significant, improvement in patient health without increasing the costs.

**CRD commentary**
**Interventions:**
The choice of comparing a new drug with usual care was appropriate as this comparison had been previously performed in the RCT. The use of different dosages of pregabalin was appropriate in terms of reflecting real-world patterns of care.

**Effectiveness/benefits:**
The clinical data were derived from a single study. The use of an RCT ensures the high quality of the clinical estimates, given the robustness of the study design. Moreover, the study was blinded and the analysis was conducted on an intention to treat basis, which further enhances the internal validity of the effectiveness data. The authors provided their reasons for selecting this specific study, which was chosen to reflect the type of interventions under examination in their decision model. The use of utility weights obtained from Belgian patients represents a further strength of the effectiveness analysis. The use of QALYs as the summary benefit measure was appropriate as the impact of the interventions on quality of life is a relevant aspect of health in patients suffering from pain.

**Costs:**
The analysis of the costs was not extensively reported. There was no breakdown of the cost items and the costs were presented as macro-categories related to disease severity. This reduces the transparency of the whole economic analysis. However, the cost data were appropriately taken from an observational study conducted in Belgium. Other aspects of the analysis, such as the price year and the use of statistical analyses, were reported.

**Analysis and results:**
The costs and benefits were not combined as the intervention under examination was dominant. The issue of uncertainty was extensively addressed in the probabilistic sensitivity analysis. Nevertheless, the sensitivity analysis did not investigate the robustness of the clinical inputs, which were considered valid. On the whole, the study findings were
clearly presented and discussed.

**Concluding remarks:**
Overall, the study was well conducted, although more details of the main cost items would have been useful. In general, the authors’ conclusions appear valid, as confirmed in the sensitivity analysis.

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**Bibliographic details**

**Other publications of related interest**


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