Cost-effectiveness of licensed treatment options for restless legs syndrome in the UK and Sweden

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 study assessed the cost-effectiveness of non-ergot-derived dopamine antagonists (pramipexole and ropinirole) for the treatment of patients with restless legs syndrome in the UK and Sweden. The authors concluded that pramipexole was cost-effective compared with no treatment or ropinirole for patients with restless legs syndrome. The quality of the study was satisfactory. However, some aspects of the methods were not reported in detail, which makes it hard to assess the validity of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
The cost-effectiveness of non-ergot-derived dopamine antagonists (pramipexole and ropinirole) was assessed for the treatment of patients with moderate to severe idiopathic restless legs syndrome in the UK and Sweden.

Interventions
Pramipexole was compared with ropinirole (dosages based on clinical trial data) and no treatment. Both drugs were licensed in the UK and Sweden

Location/setting
UK and Sweden/primary care

Methods
Analytical approach:
A Markov model was used that allowed for the movement between severity of restless legs syndrome to be captured. The model was populated using data from the published literature, supplemented by expert opinion where necessary. The time horizon of the base-case analysis was one year (three-year and five-year time horizons were used in sensitivity analysis). The authors stated that the study perspective was the healthcare sector for the UK-based analysis and societal for the Swedish-based analysis.

Effectiveness data:
The clinical evidence came from a selection of known recent relevant published studies, primarily phase II and III randomised controlled trials (RCTs). Where trial evidence was lacking, expert opinion and authors experience were used to inform estimates. The follow-up periods of the trials ranged from three to 52 weeks, the methodology of the trials used was reported in a table. These trial data were used to obtain transition probabilities between the severity health states of the model. To allow the model states to map to the trial evidence, the authors used a different definition of severity levels to those published by the International restless legs syndrome Study Group Rating Scale. Due to a lack of head-to-head data, equal effectiveness was assumed for the two drugs (pramipexole/ropinirole). The effectiveness was discounted at a rate of 3.5% per year in the UK analysis and 3% per year in the Swedish analysis.

Monetary benefit and utility valuations:
The source of utility values was a patient survey, which collected EQ-5D scores from 250 people with restless legs syndrome. These values were supplemented with values from the literature in sensitivity analyses.
Measure of benefit:
The summary measure of benefit was quality-adjusted life-years (QALYs).

Cost data:
The cost categories included medication costs (obtained from the British and Swedish National Formularies) and the cost of general practitioner visits for adverse events. Drug usage was based on trial data. The estimates of other resource use were based on expert opinion. The Swedish analysis also included indirect costs. Estimates of time lost from work were based on two of the clinical trials used for effectiveness estimates. Lost productivity was calculated using the human capital approach, based on Swedish national wage statistics. Costs were in UK £ and Swedish kronor. The costs were discounted at a rate of 3.5% per year in the UK analysis and 3% per year in the Swedish analysis.

Analysis of uncertainty:
The authors conducted one-way sensitivity analyses and a probabilistic sensitivity analysis. The results of the sensitivity analyses were presented using cost-effectiveness planes and cost-effectiveness acceptability curves.

Results
For the UK base-case scenario, pramipexole was associated with a mean QALY gain of 0.764, ropinirole was associated with a mean QALY gain of 0.757, and no treatment was associated with a mean QALY gain of 0.669. The mean cost of pramipexole was £608, ropinirole £700, and no treatment £289. The incremental cost-effectiveness ratio of pramipexole was £3349 per QALY compared with no treatment. Pramipexole dominated ropinirole, as it was less costly and more effective.

In the Swedish base-case scenario, pramipexole dominated ropinirole and no treatment.

Authors' conclusions
The authors concluded that, at UK and Swedish acceptable thresholds, pramipexole was cost-effective compared with no treatment and ropinirole for patients with restless legs syndrome.

CRD commentary
Interventions:
The level of reporting of the interventions was good and was based on trials of licensed drugs for the UK and Sweden. The interventions included appeared relevant.

Effectiveness/benefits:
The details of the clinical effectiveness data were generally well reported. Full details of the RCTs used to derive data were reported, but no details were provided of the methods used to elicit expert opinion. The methods used to identify and select relevant studies were not provided, which made it difficult to assess if all relevant data were identified and included. It was not clear whether the assumption of equal efficacy of the two drugs was warranted or what impact this assumption had on the results obtained. The measurement of utilities was well described and the methods used to estimate QALYs appeared to be appropriate.

Costs:
The reporting of the cost data was mixed. Some aspects were reported in detail, but the authors did not explicitly state the price year or whether cost adjustment techniques had been performed. The methods used to elicit expert opinion were not described, which made the assessment and validation of quality of estimation of resource use difficult. The costs included appeared relevant to the perspectives health states.

Analysis and results:
Details of the model were well presented. An appropriate incremental analysis was undertaken to assess the relative cost-effectiveness of the different treatment options. Adequate methods to assess uncertainty on the results were performed. In general the results were described in full. The authors discussed some key limitations to their study. Despite comprehensive sensitivity analyses, some uncertainty remained due to a lack of evidence. Discontinuation rates needed to be better informed and the use of indirect meta-analysis may have allowed the assumption of equal effectiveness to be evaluated. The conclusions appeared robust to the assumptions tested, but the robustness of the assumptions may require additional evidence.
Concluding remarks:
The quality of the study was satisfactory. However, some aspects of the study were not reported in sufficient detail, so it is hard to assess the validity authors’ conclusions.

Funding
The study was sponsored by Boehringer Ingelheim GmH, Germany (manufacturers of pramipexole).

Bibliographic details

PubMedID
18796188

DOI
10.1185/03007990802344594

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Benzothiazoles /administration & dosage /economics; Costs and Cost Analysis; Dopamine Agonists /administration & dosage /economics; Female; Great Britain; Humans; Indoles /administration & dosage /economics; Male; Markov Chains; Models, Theoretical; Restless Legs Syndrome /drug therapy /economics; Sweden

AccessionNumber
22009100089

Date bibliographic record published
05/07/2012

Date abstract record published
29/08/2012