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Title **The Effectiveness and Cost Effectiveness of Cinacalcet for Secondary Hyperparathyroidism in End-Stage Renal Disease Patients on Dialysis: A Systematic Review and Economic Evaluation**

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Aim

To establish the effectiveness and cost effectiveness of cinacalcet in treating secondary hyperparathyroidism (SHPT) for people on dialysis due to end-stage renal disease (ESRD).

Conclusions and results

The systematic review included 7 trials comparing cinacalcet plus standard treatment with placebo plus standard treatment (846 people were randomized to receive cinacalcet). Cinacalcet was more effective at meeting parathyroid hormone (PTH) target levels (40% vs 5% in placebo, p<0.001). In those patients meeting PTH targets, 90% also experienced a reduction in calcium–phosphate product levels, compared to 1% in placebo. Significantly fewer people treated with cinacalcet were hospitalized for cardiovascular events, but no difference was seen in all-cause hospitalization or mortality. Significantly fewer fractures and parathyroidectomies were also seen with cinacalcet. Findings on all patient-based clinical outcomes were based on small numbers. The authors' economic model estimated that, compared to standard treatment alone, cinacalcet in addition to standard care costs an additional GBP 21 167 and confers 0.34 QALYs (or 18 quality-adjusted weeks) per person. The incremental cost-effectiveness ratio (ICER) was GBP 61 890/QALY. In most cases, even extreme adjustments to individual parameters did not result in an ICER below a willingness-to-pay threshold of GBP 30 000/QALY with probabilistic analysis showing only 0.5% of simulations to be cost effective at this threshold. Altering the assumptions in the model by changing the input data sources yielded an ICER range from GBP 39 000 to GBP 92 000/QALY.

Recommendations

Cinacalcet plus standard care is more effective than placebo plus standard care at reducing PTH levels without compromising calcium levels. However, information is limited about the impact of this reduction on patient-relevant clinical outcomes. It is unclear how data should be extrapolated to the long term. This, plus the high drug cost, means that cinacalcet is unlikely to be considered cost effective.

Methods

Electronic databases were searched for relevant literature on the clinical effectiveness of cinacalcet for SHPT in ESRD. Searches were updated in February 2006. Randomized controlled trials were critically appraised for internal and external validity. Relevant data were extracted and a narrative synthesis was carried out.

Electronic databases were searched for relevant literature on the cost effectiveness of cinacalcet for SHPT in ESRD. No studies were identified. Amgen (manufacturer of cinacalcet) submitted an economic evaluation to the National Institute for Health and Clinical Excellence. This was critically appraised and compared with the authors' economic evaluation.

The authors developed a Markov model to compare cinacalcet plus standard treatment with phosphate binders and vitamin D versus standard treatment alone. Incremental costs and quality-adjusted life-years (QALYs) were calculated. Extensive one-way sensitivity analysis and probabilistic sensitivity analysis were undertaken.

Further research/reviews required

Accurate estimates of the multivariate relationship between biochemical disruption in SHPT and long-term clinical outcomes are of paramount importance to model the effectiveness of cinacalcet, or other similar agents. Longer term studies of the maintenance of PTH control in SHPT and of the clinical impact with cinacalcet should examine its impact in subgroups based on age and diabetes. A better understanding of the epidemiology of fractures in SHPT is needed. The impact of fracture, cardiovascular events and uncontrolled PTH levels on quality of life in people with SHPT should be investigated.

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