Cost effectiveness of zoledronic acid in the management of skeletal metastases in hormone-refractory prostate cancer patients in France, Germany, Portugal, and the Netherlands

Carter JA, Joshi A, Kaura S, Botteman MF

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 objective was to assess the cost-effectiveness of zoledronic acid, compared with placebo, for skeletal metastases in patients with hormone-refractory prostate cancer, in four European countries. The authors suggested that zoledronic acid was highly cost-effective, compared with placebo, in France, Germany, Portugal, and the Netherlands. There was insufficient information on the estimation of the quality-adjusted life-years gained for an evaluation of the validity of the results.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of zoledronic acid, compared with placebo, for skeletal metastases in patients with hormone-refractory prostate cancer, in four European countries.

Interventions
Patients in the intervention group received 4mg zoledronic acid administered by intravenous infusion every three weeks.

Location/setting
France, Germany, Portugal, and the Netherlands/secondary care.

Methods
Analytical approach:
The benefit estimates were from a published economic evaluation (Reed, et al. 2004, see 'Other Publications of Related Interest' below for bibliographic details) and these were combined with the costs for each of the four European countries. The clinical evidence for the original economic evaluation came from a clinical trial, reported in 2002. The time horizon was 15 months and the authors stated that the study was conducted from a payer's perspective.

Effectiveness data:
The effectiveness data for the original economic evaluation came from a randomised, double-blind, placebo-controlled, multicentre, phase III trial of 214 patients treated with zoledronic acid and 208 patients given placebo. The main clinical estimates were the survival rate and the incidence of skeletal events, such as bone pain and spinal cord compression.

Monetary benefit and utility valuations:
The utilities were from the original economic evaluation and were valued by the cohort of patients in the randomised controlled trial, using the European Quality of life (EQ-5D) questionnaire.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs). A secondary measure was the incidence of skeletal events.

Cost data:
The cost categories were the costs of treating skeletal events and the drug costs, including administration, supplies, and laboratory tests. The cost data came from country-specific sources, including literature, official reimbursement tariffs, and the drug manufacturer. They were reported in Euros (EUR) at 2008 prices.

Analysis of uncertainty:
A one-way sensitivity analysis was conducted to assess the impact of the uncertainty, in the model parameters, on the results.

Results
Patients treated with zoledronic acid experienced 0.759 fewer skeletal events and received 0.03566 more QALYs than those given placebo.

Zoledronic acid was associated with an incremental total cost of EUR 1,284 in France, EUR 841 in Germany, EUR 309 in Portugal, and EUR 87 in the Netherlands.

The incremental cost per QALY gained for zoledronic acid over placebo was EUR 36,007 in France, EUR 23,582 in Germany, EUR 8,655 in Portugal, and EUR 2,430 in the Netherlands.

Authors' conclusions
The authors suggested that zoledronic acid was highly cost-effective, compared with placebo, for the management of skeletal metastases in hormone-refractory prostate cancer patients in France, Germany, Portugal, and the Netherlands.

CRD commentary

Interventions:
Zoledronic acid was compared with placebo, but the authors stated that there were other bisphosphonates that were used in clinical practice. Zoledronic acid should be compared with these to determine its cost-effectiveness.

Effectiveness/benefits:
The clinical data came from a large phase III randomised controlled trial. The authors did not report if this was the only trial with clinical evidence for zoledronic acid. The incremental benefit was from an economic evaluation of this trial and it was not clear how it was calculated. It was not clear how often the utilities were measured and how the survival curves were weighted by these utilities. The authors stated that adverse events, as well as skeletal events, were recorded every three weeks in the trial, but it was not clear what these were, if they had a significant impact on utility, and if any such impact was captured in the analysis.

Costs:
The economic analysis was consistent with the stated perspective and it included relevant categories of costs. The unit costs were from country-specific official sources, which reflected the economic viewpoint of the payer, in each country. Reflation exercises, for other time periods, will be possible as the price year was reported.

Analysis and results:
The results were clearly reported and the costs and benefits of the two alternatives were appropriately synthesised in an incremental analysis. The uncertainty was analysed in univariate sensitivity analyses, and the findings were clearly reported and discussed. The authors highlighted the limitations of their study.

Concluding remarks:
There was insufficient information on the estimation of the QALYs gained for an evaluation of the validity of the results.

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