The cost-effectiveness of risedronate in the UK for the management of osteoporosis using the FRAX

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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 examined the cost-effectiveness of risedronate, compared with no intervention, for the prevention and treatment of osteoporosis in post-menopausal women, aged 50 years or older, who had various absolute risks of fracture, assessed using the World Health Organization's FRAX tool. From the perspective of the health care system, risedronate provided good value for money. The methods appear to have been valid and the conclusions appear to be valid too, despite the limited reporting of some data sources.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of risedronate, compared with no intervention, for the prevention and treatment of osteoporosis in post-menopausal women aged 50 years or older, who had various absolute risks of fracture that were assessed by the World Health Organization (WHO)'s fracture risk assessment tool; FRAX.

Interventions
Five years of risedronate was compared with no treatment, in cohorts of women with different risks of fracture.

Location/setting
UK/primary care.

Methods
Analytical approach:
: A published decision model, the FRAX model, was used for a Markov cohort analysis, with a lifetime horizon (Kanis, et al. 2008, see ‘Other Publications of Related Interest’ below for bibliographic details). Two scenarios were considered; one with self-identified patients and the other with opportunistic assessment of women with a parental history of hip fracture. The authors stated that the study was carried out from the perspective of the health care system.

Effectiveness data:
The treatment efficacy was the key clinical input and was estimated by a meta-analysis of three pivotal randomised controlled trials (RCTs) that compared risedronate with placebo. The clinical risk factors were identified through several meta-analyses that were reported elsewhere, with the FRAX model. Some assumptions were also needed and these were generally conservative towards risedronate. A key assumption was the rate of reduction in fracture risk after stopping treatment and this was estimated by the authors. The FRAX tool was clearly described.

Monetary benefit and utility valuations:
The utility values were from published sources and expert opinion, and UK tariffs were used.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 3.5%.

Cost data:
The analysis included the costs of fractures, medications, and case finding, which included the general practitioner’s time and a bone mineral density (BMD) test. The fracture costs were from a published study, which included in-patient and out-patient costs. The cost of risedronate was from the British National Formulary. The price year was 2006. All costs were in UK pounds sterling (£) and they were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken and the results were presented as cost-effectiveness acceptability curves. Changes in the key model inputs were investigated in a deterministic analysis.

Results
At a threshold of £30,000 per QALY, in the self-identified scenario, risedronate treatment was generally cost-effective in women of 65 years and older. It was also cost-effective in younger women, with a previous fracture. In the opportunistic scenario, risedronate was cost-effective for osteoporotic women, with a parental history, in all age groups and it was cost-saving from the age of 75 years. It was also cost-effective in women over 65 years of age, without a BMD test. Risedronate was always cost-effective in women with any single clinical risk factor, which were a prior fracture, a family history of fracture, the use of glucocorticoids, rheumatoid arthritis, more than three units of alcohol daily, and a current smoker.

In a 70-year-old woman, risedronate had a 98% probability of being cost-effective at the threshold of £30,000 per QALY.

In a subgroup of osteopenic women, treatment with risedronate was cost-effective if they had any single clinical risk factor, except current smoking. The sensitivity analysis showed that the time horizon was the parameter with the strongest influence on the cost-effectiveness results, while other parameters, such as the efficacy, adverse events, and utility weights, had less impact.

Authors’ conclusions
The authors concluded that from the perspective of the health care system, risedronate provided good value for money.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the proposed prophylaxis and treatment with risedronate was compared against the usual pattern of care, which was no intervention. The authors stated that other potential comparators, such as alendronate, were not considered due to a lack of head-to-head clinical studies. However, alendronate is commonly considered as first-line therapy for women with osteoporosis.

Effectiveness/benefits:
No systematic review was reported, to identify the data sources. A meta-analysis of RCTs is generally considered to be a valid source for treatment efficacy, due to the methodological strengths of both the sources (clinical trials) and the pooling tool (meta-analysis). More details on the other sources of data would have been useful in judging the validity of the clinical inputs, but these were already incorporated in the FRAX model. Limited information on the derivation of utility values was provided, but QALYs were a valid benefit measure and they allow cross-disease comparisons to be made.

Costs:
The economic analysis was consistent with the perspective of the study. The unit costs and resource quantities were not explicitly reported as the costs were presented as total categories. This approach is common in the assessment of fracture costs, but reduces the transparency of the analysis. The data sources were not fully described, but it appears that typical UK sources were used and most of the data were from a published Health Technology Assessment submitted to the National Institute for Health and Clinical Excellence.

Analysis and results:
The expected costs and QALYs were not reported, but they were appropriately synthesised, in an incremental analysis. The results were selectively presented, but this might have been due to limited space. The issue of uncertainty was
appropriately investigated, in a probabilistic analysis, which was valid given the uncertainty underlying the model assumptions. Some key areas of uncertainty were further analysed deterministically. Limited details of the decision model were reported. The main strengths of the analysis were the use of a model that allowed the identification of several risk factors for fractures and the analysis of several subgroups of patients based on their age and T-scores.

Concluding remarks:
The study appears to have used valid methods and the authors’ conclusions appear to be valid, despite the limited reporting of some data sources.

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Other publications of related interest

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MeSH
Age Factors; Aged; Aged, 80 and over; Algorithms; Bone Density Conservation Agents /economics /therapeutic use; Cost-Benefit Analysis; Drug Costs /statistics & numerical data; Epidemiologic Methods; Etidronic Acid /analsogs & derivatives /economics /therapeutic use; Female; Great Britain; Health Care Costs /statistics & numerical data; Humans; Middle Aged; Osteoporosis, Postmenopausal /drug therapy /economics; Osteoporotic Fractures /economics /prevention & control; Quality of Life; Risedronate Sodium

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