A comparison of the effectiveness and cost of treatment for vertebral fractures in women
Francis R M, Anderson F H, Torgerson D J

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.

Health technology
Hormone replacement therapy (HRT), intermittent cyclical disodium etidronate (ICDT), and salmon calcitonin (CT) in the prevention of vertebral fractures in patients with established osteoporosis. The reason for the choice of comparators was not clearly stated.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Caucasian women with osteoporosis, from 6 randomised controlled trials (RCTs).

Setting
The practice setting for the RCTs used was not stated. The economic analysis was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were obtained from studies published in 1990 and 1992. The price year was not clearly stated.

Source of effectiveness data
Effectiveness data was based on a review of previously completed studies.

Outcomes assessed in the review
The outcome assessed in the review was the reduction in the incidence of vertebral fracture.

Study designs and other criteria for inclusion in the review
RCTs for the treatment of osteoporosis in Caucasian women were included in the review. Only studies with details of entry criteria, definition of vertebral deformation, and vertebral fracture rate were included. Only studies showing a statistically significant reduction in vertebral fractures were included in the economic analysis.

Sources searched to identify primary studies
Personal knowledge, two review articles (referenced), and a Medline search up to the end of 1994.
Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
Six studies were used for control group data, four of which were used for effectiveness estimates.

Methods of combining primary studies
For each primary study, the number of patient-years of observation was used to weight the corresponding incidence of further vertebral deformation in both control and treatment groups.

Investigation of differences between primary studies
One study investigated the development of vertebral deformation in previously normal and deformed vertebrae, whilst three others investigated only previously normal vertebrae. The studies had varying follow up periods accounted for in the weighting scheme used in the analysis, and different criteria for fracture (ranging from a 15% reduction in vertebral weight in one study to 20 - 25 for another two studies).

Results of the review
The incidence of further vertebral deformation in women with vertebral fractures (untreated) was 33.7/100 patient years (range: 6.3/100 - 72.3/100). The reduction in incidence was comparable for each treatment group with a reduction of 60% with HRT and salmon calcitonin, and of 53% (20% chance of fracture) and 58% (20-25% chance of fracture) with intermittent cyclical etidronate therapy.

Measure of benefits used in the economic analysis
The measure of benefits used in the economic analysis was further vertebral fractures avoided at one year.

Direct costs
Quantities of resource use were analysed separately from the costs, based on the drug regimens only. Drug costs were taken from the British National Formulary and were discounted at 6% per annum. It was stated that monitoring costs were not assessed, nor was the reduction in fracture risk at other sites, or the benefits of HRT on cardiovascular disease. The date for costing was not stated.

Currency
UK pounds Sterling (£).

Sensitivity analysis
No sensitivity analysis was carried out. However, the uncertainty surrounding the incidence of further fractures was discussed and reference was made to the fact that the relative cost-effectiveness of the three treatments would not be affected.

Estimated benefits used in the economic analysis
The estimated benefits were the number of vertebral fractures averted per 100 patient years, discounted at 6% per annum. The annual predicted percentage reduction in fractures (discounted) for HRT and salmon calcitonin was 56.6%.
and for etidronate was 47.2%.

**Cost results**
Annual drug costs (discounted at 6%) were given for eight different drug regimens. The costs of the regimens used for each of the treatment strategies were 26.38 - 129.71 for HRT, 163.03 (299) for ICDT and 943.75 (1,731) - 2,602.45 (4,471) for CT (2 year discounted costs in brackets).

**Synthesis of costs and benefits**
The discounted cost per fracture averted was calculated for each of the eight drug treatments as follows: total discounted cost of treatment times 100 divided by the discounted (at 5%) number of vertebral fractures averted per 100 patient years. The results ranged from 138 for a form of HRT (Premarin), to 25,013 for salmon calcitonin (HRT, 138 - 680 per fracture averted, cyclical etidronate, 1,880 per fracture averted, and salmon calcitonin, 9,075 - 25,013 per fracture averted).

**Authors’ conclusions**
The study demonstrated that further vertebral fractures may be averted at relatively low costs by the use of HRT or intermittent cyclical etidronate therapy in women with established osteoporosis. Salmon calcitonin is equally effective but much more expensive to use and should be reserved for use where the alternative drugs are inappropriate. HRT is the treatment of choice for post-menopausal women with osteoporosis.

**CRD Commentary**
While the effectiveness study was well conducted using scant information, it omitted studies showing no significant effects from treatment. It would have been useful to have carried out a sensitivity analysis testing the results by varying assumptions regarding compliance, and effectiveness. As the authors noted, other costs should ideally be included and further work could be carried out in this area. The period of follow up is only 1 to 2 years and may be too short to observe the long term effects of the drugs under investigation.

**Implications of the study**
The cost-effectiveness of the different drug treatments for this condition should be considered as they vary widely

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