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Title **The Clinical Effectiveness and Cost Effectiveness of Strontium Ranelate for the Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women**

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Aim

To estimate the clinical and cost effectiveness of strontium ranelate in preventing osteoporotic fractures in postmenopausal women at different levels of absolute fracture risk. This considers secondary prevention in women with previous fracture and primary prevention in women without previous fracture, as women with osteoporosis are asymptomatic prior to fracture.

Conclusions and results

Three trials were identified. Pooled data from 2 studies indicate that strontium ranelate therapy (SRT) reduces the risk of vertebral fracture and nonvertebral fracture. In general, SRT did not seem to increase the risk of adverse events. However, the risk of one rare but serious adverse event, venous thromboembolism (including pulmonary embolism), was found to be significantly higher in patients receiving strontium ranelate compared to placebo. Some nervous system disorders, eg, mental impairment, memory loss, and seizures, were more common in patients randomized to strontium ranelate. SRT provided gains in QALYs compared with no treatment in women with sufficient calcium and vitamin D intakes. The QALY gain for each intervention was strongly related to the absolute risk of fracture. In the algorithm used, SRT appears to be cost effective in women at relatively high risk of osteoporotic fracture. Probabilistic sensitivity analysis, using efficacy data from randomized controlled trials, suggests that it is not as cost effective as alendronate, a comparator intervention from the bisphosphonate class.

Recommendations

Strontium ranelate was shown to be clinically effective in preventing osteoporotic fractures. Scenarios have been found where SRT can be used cost effectively, but in the probabilistic sensitivity analyses conducted, this intervention appears to be less cost effective than the bisphosphonate alendronate.

Methods

A systematic review was used to determine clinical effectiveness. Major bibliographic databases were searched in September 2004 and updated in March 2005, and reference lists of relevant articles and sponsor submissions were handsearched. Data from selected studies were assessed and included in the meta-analyses. An updated Sheffield Health Economic Model for Osteoporosis was used to calculate cost effectiveness ratios. The model calculated the number of fractures that occur and provided as output data the costs associated with osteoporotic fractures, and the quality-adjusted life-years (QALYs) accrued by 100 osteoporotic women. When the intervention costs were included, the incremental cost compared to no treatment was calculated and divided by the gain in QALYs to calculate cost-effectiveness measures. SRT was calculated against a no-treatment option to evaluate whether it could be given cost effectively. An incremental analysis against alendronate estimated the cost effectiveness of SRT relative to a current standard treatment.

Further research/reviews required

Evidence needs to be strengthened on the efficacy of strontium ranelate in fracture prevention; on the T-score by age of the general female population; and on the prevalence of risk factors associated with fracture rates. Until head-to-head comparisons of strontium ranelate and bisphosphonates are undertaken, and decision-maker choices will be based on indirect evidence. Such trials are unlikely given the large number of patients needed to show statistical difference in efficacy between patients, but high-quality observational databases may provide further insight into relative efficacies.

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