

[2005] [FRI0341] STRONTIUM RANELATE REDUCES THE RISK OF VERTEBRAL FRACTURES IN OSTEOPOROTIC POSTMENOPAUSAL WOMEN WHATEVER THE BASELINE VERTEBRAL FRACTURES STATUS

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Background: The anti-fracture efficacy of strontium ranelate 2g/day, a new orally active anti-osteoporotic agent with an innovative mode of action both increasing bone formation and decreasing bone resorption, has been recently reported. The SOTI study (1649 patients) demonstrated a significant decrease in the reduction of vertebral fracture risk in postmenopausal osteoporotic women by 41% over 3 years ($p < 0.001$). The TROPOS study (5091 patients) demonstrated the efficacy in reducing nonvertebral and hip fractures: in the intent-to-treat population over 3 years, a significant reduction of 36% in the relative risk of hip fracture was shown in high risk osteoporotic postmenopausal women ($p = 0.046$). A pre-determined analysis of pooled data of SOTI and TROPOS was performed (the study designs, centers, BMD and X-ray central reading centers were common to both studies). Among the whole pooled population, vertebral X-rays were performed yearly (semi-quantitative assessment) in 5082 women receiving strontium ranelate 2g/day orally or placebo plus calcium/vitaminD in both groups during 3 years. There was no difference between groups for baseline characteristics of age 74 ± 6.2 years; lumbar BMD T-score -3.0 ± 1.6 ; femoral neck BMD T-score -3.0 ± 0.7 (mean \pm SD). Among those 5082 women, 2605 had no prevalent vertebral fracture (1320 in strontium ranelate group versus 1285 in placebo), 1110 had one prevalent vertebral fracture (533 versus 577) and 1365 had at least 2 prevalent vertebral fractures (682 versus 683). Whatever the baseline vertebral fracture status, a significant reduction in the incidence of patients experiencing a vertebral fracture was demonstrated in the intent-to-treat population over 3 years with a reduction of the relative risk by: 1) 48% in 2605 women without prevalent vertebral fracture (RR=0.52, 95%CI[0.40;0.67], $p < 0.001$). 87 patients in strontium ranelate group and 161 in placebo had a vertebral fracture during the study, 2) 45% in 1110 women with one only prevalent vertebral fracture (RR=0.55, 95%CI[0.41;0.74], $p < 0.001$), 70 patients in strontium ranelate group and 130 in placebo, 3) 33% in 1365 women with at least 2 prevalent vertebral fractures (RR=0.67, 95%CI[0.55;0.81], $p < 0.001$), 184 patients in strontium ranelate group and 252 in placebo. In conclusion, strontium ranelate 2g/day orally is a new anti-osteoporotic treatment effective in reducing the risk of vertebral fracture in osteoporotic postmenopausal women whatever the prevalent vertebral fracture status.

Osteoporosis Clinical aspects and treatment

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