

[2002] [OP0056] REDUCTION IN VERTEBRAL FRACTURE RATES BY A COMBINATION OF MONOFLUOROPHOSPHATE AND RALOXIFENE IN POSTMENOPAUSAL OSTEOPOROSIS

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Objectives: The aim of this study was to determine whether combining the antiresorptive agent (raloxifene) with an osteoanabolic agent (fluoride) as compared to fluoride treatment alone influences BMD response, fracture risk, and bone turnover.
Methods: Postmenopausal women with low bone mass (average age of 61.9 and baseline femoral neck T-score of -2.87, 25% of patients had preexisting vertebral fractures) were randomized to 20 mg/day fluoride (MFP) and 60 mg/day RLX (MFP+RLX arm, N=300) or 20 mg/day fluoride and placebo (MFP arm, N=296) for 18 months. All patients received calcium (1000 mg/day) and vitamin D (500 IU/day) supplements. BMD (primary endpoint: femoral neck), nonvertebral and morphometric vertebral fractures, biochemical markers of bone turnover (bone specific alkaline phosphatase [BALP] and urinary type I collagen fragment/creatinine ratio[uCTX/Cr]), were assessed at baseline and after 18 months.

Results: BMD increases at endpoint were significantly greater at all measurement sites in the MFP+RLX group. In the MFP group, treatment was associated with no significant change in BMD at the femoral neck (+0.33%; p=0.558) and a decrease at the total hip (-0.42%; p=0.023). In contrast, the MFP+RLX group resulted in mean BMD increases of 1.37% (p<0.001) at the femoral neck and of 0.89% (p=0.001) at the total hip. The BMD changes at the lumbar spine were 5.47% and 8.80% (p<0.001 for each), respectively. In the MFP group, 22 patients sustained 33 incident osteoporotic fractures (vertebral and non-vertebral combined), as compared with 16 fractures in 15 patients in the combination group (p=0.056); the numbers of patients with multiple fractures was significantly reduced in the MFP+RLX arm (8 vs 1; p=0.020). In the MFP group both bone formation (BALP, mean increase from 13.9 to 18.8 mg/L, p<0.001) and bone resorption (uCTX/Cr, mean increase from 289 to 398 mg/mol, p<0.001) increased at study endpoint. In the MFP+RLX group BALP increase was blunted: 14.2 to 16.2 mg/L, (p<0.001) and no change in bone resorption was observed (uCTX/Cr decrease from 305 to 295 mg/mol, n.s.). Differences in change from baseline between the groups were significant for both markers (p<0.001).

Conclusion: We conclude that adding RLX 60 mg/day to fluoride therapy for 18 months in postmenopausal women with low bone mass results in a favourable effect on BMD and osteoporotic fractures and this combination has a positive influence on bone turnover.

Osteoporosis

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