Conclusions: In this study, arzoxifene treatment increased BMD and suppressed bone turnover to a greater extent than raloxifene, and resulted in a lower incidence of new/worsening hot flushes.

OC31 - STRONTIUM RANELATE HAS A MORE POSITIVE INFLUENCE THAN ALENDRONATE ON DISTAL Tibia Cortical And Trabecular Bone Microstructure in Women With Postmenopausal Osteoporosis

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Strontium ranelate (SR) and alendronate (ALN) are anti-osteoporotic agents with antifracture efficacy against vertebral and non-vertebral fractures. Whereas ALN is a pure bone resorption inhibitor, SR, in vitro, increases bone formation and decreases bone resorption. For the first time, we non-invasively evaluated and compared the effects of SR and ALN on bone microstructure, a component of bone quality, hence of bone strength, in osteoporotic women.

Eighty-eight women ≥50 years with postmenopausal osteoporosis were randomised to SR 2g/day or ALN 70mg/week for 2 years. Microstructure of weight-bearing bone distal tibia was assessed by high-resolution computerised tomography (HR-pQCT) after 3, 6, 12, 18 and 24 months of treatment. A planned interim statistical analysis was performed after 1 year in the intention-to-treat population (patients with a baseline and post-baseline HR-pQCT value, n=85). Primary endpoint was HR-pQCT variables relative changes from baseline, secondary endpoints included lumbar spine hip areal BMD and bone turnover markers.

Baseline characteristics were similar in both groups: age 63.7±7.4 years; lumbar and hip T-Score -2.7±0.9 g/cm² and -2.0±0.8 g/cm², respectively. After 1 year of treatment, aBMD increases were similar to results from pivotal trials (L1-L4: ±5.7% and ±5.1%; total hip: ±3.3% and ±2.2%, in SR and ALN groups, respectively). For bone microstructure, mean increases of ±5.3% (p=0.001) for C.Th, ±2.0% (p=0.002) for BV/TV and +2.1% (p=0.002) for trabecular density were found in SR group, compared to no change in ALN group (1.3% p=0.130; 0.6% p=0.725 and 0.6% p=0.645, for corresponding variables, respectively), with thus a significant between-group difference in favour of SR (p=0.045, p=0.048 and p=0.034, C.Th, BV/TV and trabecular density, respectively). Improvement in microstructure was associated in SR group with significant decrease in heterogeneity of trabecular network (-3.6±8.6%, p=0.007). No between-group difference was observed in cortical density. For bone turnover markers, between-group differences were statistically significant at all time-points, with a +5% increase in bALP and a -7% decrease in sCTX in the SR group, compared to decreases of -35% and -58% in the ALN group.

In conclusion, strontium ranelate had significantly higher effects than alendronate on distal tibia microstructure including cortical and trabecular variables, in women with postmenopausal osteoporosis after one year of treatment.

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OC32 - EFFICACY OF MONTHLY ORAL IBANDRONATE IS MAINTAINED OVER 5 YEARS: THE MOBILE LTE STUDY

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Objectives: In the 2-year MOBILE (Monthly Oral ibandronate In LadiEs) study, significantly superior increases in lumbar spine and proximal femur bone mineral density (BMD) were shown for 150mg monthly ibandronate compared with 2.5mg daily (p<0.05) in women with postmenopausal osteoporosis (1,2). Patients continued to receive monthly ibandronate for an additional 3 years by entering the MOBILE long-term extension (LTE) study. First-year analysis from MOBILE LTE reported sustained efficacy (3). A post-hoc, pooled analysis of 3 years’ continuous 150mg monthly ibandronate, (2-year MOBILE plus 1-year MOBILE LTE), showed continued increases in lumbar spine and total hip BMD, as well as sustained serum CTX reductions, versus MOBILE baseline (p<0.001 all comparisons) (4). Here we present the 5-year efficacy and safety of monthly ibandronate (2-years in MOBILE plus 3-years in MOBILE LTE).

Materials and Methods: Patients (n=719) previously receiving monthly oral ibandronate 100mg or 150mg in the MOBILE study for 2 years continued to receive the same treatment in the LTE for an additional 3 years. Efficacy analyses were based on the ITT population.

Results: In patients receiving 5 years’ continuous monthly ibandronate 100mg or 150mg, lumbar spine (L2–L4) BMD increased by 8.2% and 8.4%, respectively, compared with MOBILE baseline (pooled analysis). BMD increases at the total hip (3.0%, 100mg; 3.5%, 150mg), femoral neck (2.4%, 100mg; 3.2%, 150mg) and trochanter (5.6%, 100mg; 6.0%, 150mg) were also reported after 5 years’ continuous monthly ibandronate treatment compared with MOBILE baseline. The overall proportion of patients with at least one adverse event in 5 years was similar between the 100mg and 150mg regimens. The most common adverse events were not different from those identified in previous clinical trials, including hypertension, nasopharyngitis and back pain.

Conclusion: In women with postmenopausal osteoporosis, 5 years’ treatment with 150mg once-monthly oral ibandronate was generally well tolerated and continuously improved lumbar spine BMD while maintaining the improvements in total hip, femoral neck and trochanter BMD achieved after 2 years of initial treatment.