endoscopic studies differed in regard to blinding, duration, and control. Endoscopy trials that were appropriately blinded and of longer duration (4–10 wks) found no difference between ALN and RIS or placebo, even at the higher doses used for once-weekly dosing⁴ or to treat Paget's disease.³ Randomised, blinded, controlled trials (RCTs) with clinically relevant GI endpoints represent the highest level of evidence, and tens of thousands of patients have participated in RCTs of ALN and RIS for up to 7 years. UGI complaints were common in these studies (~30% in the first year), and were comparable to placebo. In particular, the incidence of more worrisome UGI events (including esophageal events, and gastroduodenal perforations, ulcers, and bleeds) was low and comparable to the placebo group, even in high risk subgroups, among 6459 women randomised to ALN or placebo for up to 4.5 years in the Fracture Intervention Trial.⁵ Furthermore, two independent RCTs of patients who had previously reported intolerance to bisphosphonate reported that the large majority (~85%) were able to continue ALN or RIS when treatment was resumed, and the permanent discontinuation rates were no different from the placebo group.^{6,7}

Conclusion Based on extensive data from large RCTs, we conclude that any increase above placebo in clinically relevant UGI problems related to bisphosphonate use is very low – too low to detect in trials involving thousands of participants during several years of follow-up.

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SAT0155 PREVALENT VERTEBRAL FRACTURES ARE ASSOCIATED WITH PHYSICAL IMPAIRMENT

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Background Vertebral fractures are a hallmark of postmenopausal osteoporosis and an important end point in trials of osteoporosis treatment, but the clinical significance of prevalent fractures remains uncertain.

Objectives To examine the associations of prevalent vertebral fractures and other characteristics with physical functioning among 589 Japanese women ages 40 to 90 years.

Methods Lateral spine radiographs were obtained and radiographic vertebral fractures were assessed by quantitative morphometry, defined as vertebral heights more than 3 SD below the normal mean. A self-administered questionnaire was used to survey participants about difficulty in performing selected basic and instrumental activities of daily living (ADL).

Results The prevalence of vertebral fractures increased significantly with age. Half of women ages 80 and over had vertebral fractures. Impaired function was defined as difficulty performing 3 or more ADLs. Each vertebral fracture increased the odds of impaired function by 1.4 times (95% CI: 1.1, 1.8) in an age-adjusted logistic regression model. The number of vertebral

fractures remained a significant predictor independent of age, number of painful joints, and BMI in multiple variable logistic regression models; the odds ratio of impairment for number of vertebral fractures was 1.5 (CI: 1.2, 2.0). Additional adjustment for back pain did not alter these findings.

Conclusion The number of prevalent vertebral fractures contributed significantly to impaired function. The association was independent of age, back pain and the number of painful joints. The results also suggest that vertebral fractures may impair physical function even when back pain is not present.

SAT0156 PREDICTORS OF BONE MINERAL DENSITY IN HEALTHY MALES

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Background Osteoporosis (OP) is a growing health problem not only in women but also in men. It is well known that men lose bone during ageing and are at risk for OP, but the risk factors for OP in men remains controversial.

Objectives The aim of this study was to assess determinants of bone mineral density (BMD) at the lumbar spine and femoral neck in healthy males.

Methods Thirty-seven healthy men aged 43–73 years were included in this study. BMD was measured using dual photon absorptiometry. Predictors of lumbar spine and femoral neck BMD were determined using multiple linear regression analysis. Backward elimination procedure was used to identify variables significantly related to BMD. The independent variables entered the regression model included age, body mass index (BMI), smoking history, alcohol intake, urinary calcium and hydroxyproline, and serum concentrations of osteocalcin, parathyroid hormone, testosterone, growth hormone, and cortisol.

Results The mean age of the men was 59.8 ± 6.8 years. Mean BMD at the lumbar spine was 0.97 ± 0.10 gr/cm² and that of the femoral neck was 0.76 ± 0.06 gr/cm². Backward elimination procedure was used to identify variables significantly related to BMD. The independent variables entered the regression model included age, body mass index (BMI), smoking history, alcohol intake, urinary calcium and hydroxyproline, and serum concentrations of osteocalcin, parathyroid hormone, testosterone, growth hormone, and cortisol. Backward regression analysis indicated that testosterone, cortisol and BMI were significant predictors of BMD at the lumbar spine ($R = 0.44$, $p < 0.05$) while testosterone, hydroxyproline and osteocalcin were significant predictors of BMD at the femoral neck ($R = 0.20$, $p < 0.05$). Testosterone, cortisol and BMI accounted for 44% of the total variance in lumbar spine BMD, and testosterone, hydroxyproline and osteocalcin accounted for 20% of the total variance in femoral neck BMD. Men with lower BMI had significantly lower bone mass at the lumbar spine ($r = 0.43$, $p < 0.05$). In addition, men with lower bone mass at the lumbar spine had significantly higher serum cortisol levels ($r = -0.33$, $p < 0.05$).

Conclusion These observations suggest that testosterone, cortisol and BMI are main determinants of lumbar spine BMD, while testosterone, urinary hydroxyproline and osteocalcin are main determinants of femoral BMD in our group of healthy men.