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Bone And Mineral Metabolism

6733

Bone Turnover Markers Predict Bone Mineral Density Increases With Abaloparatide In Men Similarly To Women: Results From ATOM

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Disclosure: J.P. Brown: Advisory Board Member; Self; Amgen Inc. Consulting Fee; Self; Amgen Inc, Gilead, Paladin, Pfizer, Inc., Servier. Research Investigator; Self; Mereo BioPharma, Radius Health, Inc, Servier. Speaker; Self; Amgen Inc. Other; Self; Ultragenyx. **R.A. Adler:** Grant Recipient; Self; Radius Health, Inc. **E.M. Lewiecki:** Consulting Fee; Self; Amgen Inc, Radius Health, Inc, Kyowa Kirin, Angitia, Ascendis. Research Investigator; Self; Amgen Inc, Radius Health, Inc, Ultragenyx. Speaker; Self; Amgen Inc, Kyowa Kirin. **N. Binkley:** Consulting Fee; Self; Amgen Inc, Radius Health, Inc. Research Investigator; Self; Amgen Inc, Radius Health, Inc. **E.S. Orwoll:** Consulting Fee; Self; Amgen Inc, Angitia, Biocon, Radius Health, Inc, Ultragenyx. **Y. Wang:** Employee; Self; Radius Health, Inc. **D.L. Kendler:** Consulting Fee; Self; Amgen Inc, Radius Health, Inc. Grant Recipient; Self; Amgen Inc, Radius Health, Inc. Speaker; Self; Amgen Inc, Radius Health, Inc. **B.H. Mitlak:** Employee; Self; Radius Health, Inc. **R. Eastell:** Consulting Fee; Self; Immunodiagnostic Systems, Sandoz, Samsung, CL Bio, Biocon, Takeda, UCB. Grant Recipient; Self; Alexion Pharmaceuticals, Inc.. Speaker; Self; Pharmacosmos, Alexion Pharmaceuticals, Inc., UCB, Amgen Inc.

Background: Early serum procollagen type I N-terminal propeptide (PINP) increases correlate with 18-month lumbar spine (LS) bone mineral density (BMD) increases in postmenopausal women; however, this relationship has not been assessed in men. The Abaloparatide for the Treatment of Men with Osteoporosis (ATOM; NCT03512262) study demonstrated that abaloparatide (ABL) treatment in men with osteoporosis rapidly increased BMD at the LS, total hip (TH), and femoral neck (FN) compared with placebo (PBO). Bone turnover markers (BTMs), PINP and serum carboxy-terminal cross-linked telopeptide of type I collagen (CTX), were measured during the study. In this analysis, the correlation of early increases in BTMs and increases in BMD at 12 months between the ABL and PBO groups were determined and the results in men were compared to 12-month results in women from the ACTIVE study. **Methods:** ATOM was a randomized, double-blind, placebo-controlled, multicenter phase 3 study. A total of 228 men aged 40 to 85 years with osteoporosis or osteoporosis associated with hypogonadism were randomized 2:1 to receive 80 μg subcutaneous daily ABL or PBO for 12 months (ABL, n=149; PBO, n=79). Blood samples were collected under fasting conditions at baseline and post-dose at 1, 3, 6, and 12 months, and PINP and CTX measured. The correlation of increase from baseline in PINP and CTX concentrations, measured by log ratio over baseline, was compared with percentage increase from baseline BMD at 12 months using Spearman's rank correlation. To compare between men and women, Pearson correlation coefficients were assessed using the z score test after Fischer's Z transformation. **Results:** In the ABL group, median PINP level was 48.2 ng/mL at baseline, peaked at month 1 (109.0 ng/mL) and was 85.7 ng/mL at month 12. Median CTX level was 0.327 ng/mL at baseline, peaked at month 6 (0.476 ng/mL) and was 0.448 ng/mL at

month 12. The increase in BTMs relative to baseline were significantly greater at all time points compared to PBO ($P<0.0001$). Median levels of PINP and CTX in men and women were similar over 12 months. Early PINP increases and subsequent LS BMD increases were significantly correlated for ABL in men starting at month 1, with the strongest correlations observed between 3 and 6 months. The correlation at 3 months was considered more clinically relevant, and the correlation coefficient in men receiving ABL (r=0.6138; $P<0.0001$) and women receiving ABL (r=0.561; $P<0.0001$) at 3 months are similar. Additionally, there was a significant correlation between the 1-month log ratio of PINP and TH BMD in men receiving ABL (r=0.1903; $P<0.05$). **Conclusion:** In the ATOM study, there was a significant correlation between early increases of BTMs (1 and 3 months) and BMD increases at 12 months. The correlation between early increases in PINP and percentage increase in LS BMD after 12 months of treatment with ABL in men is similar to that reported in women.

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