Greater Increase in Bone Strength With Romosozumab vs Teriparatide or Denosumab in Women With Postmenopausal Osteoporosis in Real-world Clinical Setting

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INTRODUCTION:

In clinical practice, denosumab (DMAb) is commonly used as an initial therapy and is sometimes prescribed as an alternative to bone-forming agents for the treatment of women with postmenopausal osteoporosis (PMO) at very high risk of fracture. Bone strength reflects the ability of bone to resist fracture and is a crucial surrogate marker for predicting fracture risk. The objective of this study was to evaluate the real-world effectiveness of romosozumab (Romo), teriparatide (TPTD), or DMAb on bone strength in Japanese women with PMO using biomechanical computed tomography (BCT; VirtuOst®), an FDA-cleared diagnostic test.

METHODS:

Clinical CT scans of 141 Japanese women with PMO (age ≥55 years) were evaluated by BCT in this real-world BCT study. Of them, 57, 34, and 50 women received Romo, TPTD, or DMAb for 12 months, respectively, based on medical history, clinical assessment, and patient preference. None of them received osteoporosis treatment within 3 years before the respective treatment initiation. Bone strength and volumetric bone mineral density (vBMD) at vertebral body and proximal femur were assessed before and after treatment using BCT in a manner blinded to treatment status. The primary endpoint was least squares mean (LSM) percent change in vertebral strength from baseline at 12 months. Secondary endpoints included LSM percent change from baseline in vertebral vBMD, proximal femoral strength and proximal femoral vBMD at 12 months.

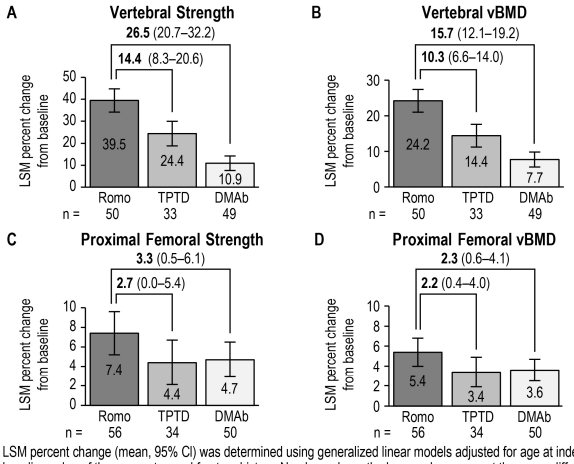
RESULTS:

At baseline, bone strength and vBMD at spine were comparable among Romo, TPTD, and DMAb groups. Bone strength and vBMD at proximal femur were similar between the Romo and TPTD groups and were slightly lower in the DMAb group. After 12 months of treatment, percent increase from baseline in vertebral strength was 39.5% with Romo, 24.4% with TPTD, and 10.9% with DMAb (Fig. A). The difference in percent increase in vertebral strength was 14.4% between the Romo and TPTD groups and 26.5% between the Romo and DMAb groups (Fig. A). Similar changes were observed for vertebral vBMD (Fig. B). Percent increase in proximal femoral strength was 7.4% with Romo, 4.4% with TPTD, and 4.7% with DMAb (Fig. C). A similar trend was observed for vBMD at proximal femur (Fig. D).

DISCUSSION AND CONCLUSION:

In this real-world BCT study, Romo, TPTD, or DMAb increased vertebral and proximal femoral strength and vBMD in women with PMO. However, the magnitude of improvement varied, with Romo showing greater increase in bone strength and vBMD than TPTD and DMAb.

Figure: LSM Percent Change From Baseline at Month 12



LSM percent change (mean, 95% CI) was determined using generalized linear models adjusted for age at index date, baseline value of the parameter, and fracture history. Numbers above the bar graphs represent the group difference of LSM percent change from baseline with 95% CI in parenthesis. CI, confidence interval; LSM, least squares mean; Romo, romosozumab; TPTD, teriparatide; DMAb, denosumab; vBMD, volumetric bone mineral density.