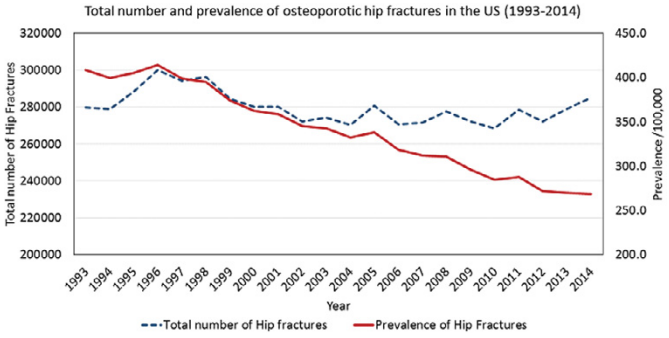

older declined since 1996, bottomed out in 2010 but has started increasing again. It is critical to evaluate risks and benefits of preventive treatments for optimal management of this potentially serious problem.

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OP0048 ROMOSOZUMAB RAPIDLY REDUCES CLINICAL VERTEBRAL FRACTURE INCIDENCE: RESULTS FROM THE FRAME STUDY

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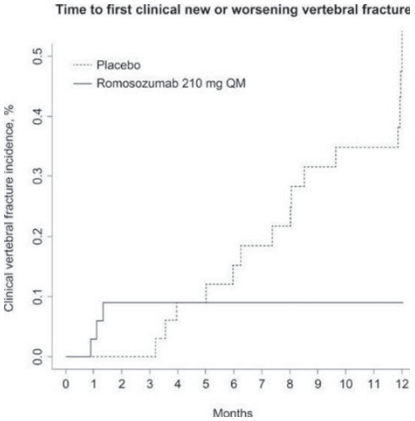
Background: Romosozumab (ROMO) inhibits sclerostin and has a dual effect on bone, increasing formation while decreasing resorption, resulting in significant increases in bone mineral density (BMD) at 6 months (m), which at 12m reach 13.3% vs placebo (PBO) at the spine.[1] Using high resolution quantitative computed tomography, BMD increases were observed at both trabecular and cortical compartments of the spine, explaining the significant reductions in radiographic vertebral fracture (VFx) risk in women with osteoporosis (OP) enrolled in the FRAME trial (NCT01575834).

Objectives: Here, we report the effect of ROMO on clinical (clin) VFx incidence over 12m in women in FRAME with back pain.

Methods: FRAME enrolled 7180 postmenopausal women with OP, mean age 70.9 yrs (total hip T-score –2.5 to –3.5) and no severe VFx. Patients received monthly ROMO (n=3589; 210mg) or PBO (n=3591) for 12m. At monthly visits, women with back pain consistent with a clin VFx had a confirmatory spinal X-ray. Clin VFx risk (ROMO vs PBO) was calculated by Cox-proportional hazards model.

Results: Of 119 women reporting back pain over 12m, 20 women were diagnosed with a new or worsening VFx. With ROMO, 3 clin VFx (<0.1%; all at <2m) were identified vs 17 (0.5% at 12m) with PBO (Figure). Clin VFx risk was 83% lower in the ROMO group vs PBO at 12m (hazard ratio 0.17; 95% CI, 0.05–0.58; p=0.001). In women with clin VFx vs no clin VFx, the lumbar spine T-score was numerically lower and the FRAX score higher at baseline; other baseline characteristics were comparable among all women who reported back pain.



Conclusions: ROMO treatment for 12m was associated with rapid and large reductions in clin VFx risk vs PBO. In the ROMO group, all clin VFx occurred <2m; clin VFx risk was ≥5 times higher with PBO vs ROMO. Monthly study visits in FRAME allowed for timely radiologic confirmation of a suspected clin VFx.

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OP0049 SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS EVALUATING BISPHOSPHONATES FOR THE PREVENTION AND TREATMENT OF GLUCOCORTICOID-INDUCED OSTEOPOROSIS

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Background: Glucocorticoid therapy is a major risk factor for osteoporosis related fractures. A previous meta-analysis conducted by Homik et al reported that bisphosphonates therapy increased BMD in glucocorticoid- induced osteoporosis (GIO) when compared to placebo, whereas results for incident vertebral fracture did not reach statistical significance

Objectives: To evaluate the efficacy of bisphosphonates in GIO based on randomized controlled trials (RCTs). Both placebo controlled and active comparator trials were analyzed.

Methods: Two authors screened citations from the following electronic databases: Medline (1998–2015), EMBASE (1998–2015), Cochrane Library (1998–2015). A manual search was completed for conference proceedings from the ACR (2010–2015), CRA (2009–2015), and ASBMR (2009–2014). We used the study by Homik et al to identify RCTs published prior to 1998. Only RCTs that had a minimum prednisone dosage of 5 mg/day or equivalent and treatment duration of at least 3 months were included. Primary outcomes were changes in BMD and incident fractures. Two authors abstracted data using a standardized data abstraction form. We used the Cochrane Risk of Bias Tool to evaluate the quality of the selected RCTs and devised a quality score ranging from 0 to 6, where 6 represents the highest quality.

Results: A total of 466 citations were identified (239 Medline, 217 EMBASE, and 10 Cochrane Library). Fourteen RCTs met the inclusion criteria. An additional two RCTs were identified from conference proceedings. Eleven RCTs compared bisphosphonates to a placebo, three RCTs compared bisphosphonates to a vitamin D derivative, one RCT compared alendronate to teriparatide, and one RCT compared zoledronic acid to risedronate. The RCTs were of reasonably good quality with a mean quality score of 4.

Overall, of the 11 RCTs that compared bisphosphonates to a placebo, all found that the bisphosphonates were superior. Nine RCTs were pooled for mean percentage change in lumbar spine BMD (bisphosphonates n=667, placebo n=654). The pooled mean percentage change was in favor of bisphosphonates compared to placebo [weighted mean difference (WMD) of 4.03%, 95% CI (1.59–6.47), p=0.001]. Six RCTs were pooled for mean percentage change in femoral neck BMD (bisphosphonates n=486, placebo n=481) and the results favored bisphosphonates compared to placebo [WMD of 2.95%, 95% CI (0.09 -5.82), P=0.04]. Seven RCTs were pooled for outcome of incident fractures (bisphosphonates n=613, placebo n=469) and the results favored bisphosphonates compared to placebo [RR of 0.65, 95% CI (0.48–0.88), P=0.006] (Figure 1). Results were pooled using RevMan (version 5.3).

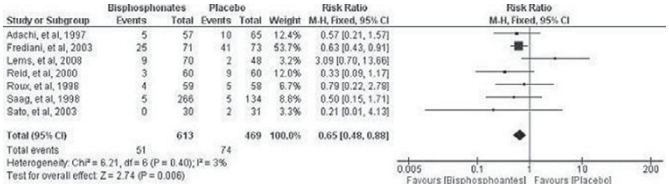

Figure 1

Conclusions: Bisphosphonates mitigate adverse changes in BMD and lower fracture risk in patients treated with glucocorticoids.