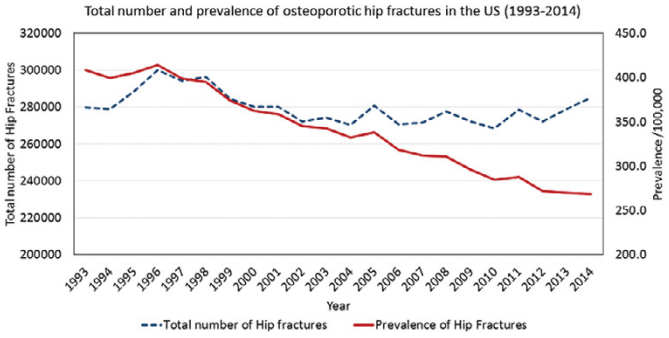

older declined since 1996, bottomed out in 2010 but has started increasing again. It is critical to evaluate risks and benefits of preventive treatments for optimal management of this potentially serious problem.

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[1] Sehgal, A., et al., A victory in the war on osteoporosis? Declining prevalence of hospitalizations for non-traumatic hip fractures in the US. Ann Rheum Dis 2008;67(Suppl II):55.

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

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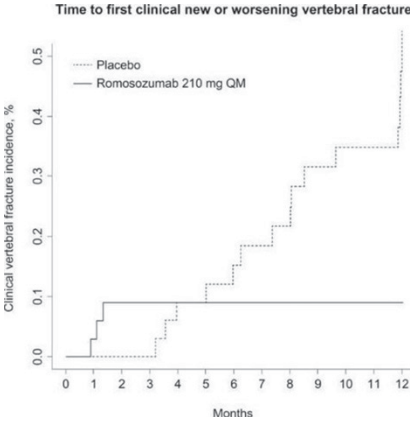
Background: Romosozumab (ROMO) inhibits sclerostin and has a dual effect on bone, increasing formation while decreasing resorption, resulting in significant increases in bone mineral density (BMD) at 6 months (m), which at 12m reach 13.3% vs placebo (PBO) at the spine.[1] Using high resolution quantitative 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.

References:

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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).

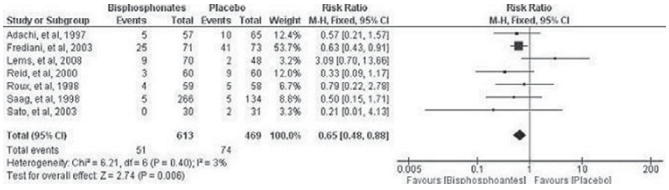

Figure 1

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

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Disclosure of Interest: None declared
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OP0050 THE TREATMENT GAP AFTER FRACTURE IN OSTEOPOROSIS PATIENTS IN SWEDEN

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Background: In Sweden, ~50% of women and ~25% of men are expected to suffer an osteoporosis (OP)-related fracture (Fx) during their lifetime, and hip Fx incidence in Sweden is one of the highest worldwide. Despite this, nationally only 12% of patients with Fx are prescribed an OP treatment following Fx.[1] Understanding the reasons for the marked under-treatment of patients with Fx may provide insights into how to improve deficiencies in the management of OP.
Objectives: To assess rates of OP treatment initiation within 1 year (<1 yr) following first Fx in treatment-naïve patients with fracture in Sweden and to evaluate the determinants of treatment initiation.
Methods: Patients aged ≥50 yrs with any type of Fx were identified from Swedish national registers between 2006–2012 and followed from time of first Fx. Patients who were treatment-naïve at the time of first Fx were included in the analysis. Here, we report OP treatment initiation <1 yr after Fx in the different baseline subgroups considering gender, age, Fx type, steroid use and comorbidities.
Results: 258,827 treatment-naïve patients with a first Fx (68% female; mean age 72.7 [SD 12.9] yrs) were included. Overall, 6.6% of patients initiated OP treatment <1 yr; the proportion was higher in females (8.5%) than in males (2.3%), and was highest in patients aged 70–80 yrs (10.7%) vs other ten-year age groups (mean 5.5%). Patients with a diagnosed vertebral Fx were more likely to start OP treatment (21.2%) compared with non-vertebral Fx (5.6%). The proportion of patients starting OP treatment was higher in patients receiving glucocorticoid (GC) treatment (17%) compared with those not treated with glucocorticoids (6.1%). In general, comorbidities were not positively associated with treatment initiation, except for those indirectly connected to known contributors of Fx risk, i.e. chronic pulmonary disease (GC use) and rheumatoid arthritis (FRAX-algorithm risk factor), which were associated with increased treatment initiation. Although both dementia and dependency are known to be associated with increased risk of Fx, the tendency to initiate treatment was lower in patients with these conditions compared with those without (1.5% vs 6.9% and 2.3% vs 7.4%, respectively).
Conclusions: This study confirms the large treatment gap in OP treatment initiation following a first Fx in Sweden; rate of OP treatment initiation was below the post-Fx treatment initiation rate goal of 30% and also lower than the 12% published national indicator for treatment exposure (2015).[1] The proportion of patients initiating OP treatment appears to be somewhat influenced by gender, age, Fx type, GC use, rheumatic disease, dependency and dementia; nevertheless, treatment initiation rates were low. These data highlight the need for significant efforts to improve OP management post Fx in Sweden.
References:
[1] Swedish Association of Local Authorities and Regions (SKL) and The National Board of Health and Welfare (2015) Öppna Jämförelser 2015, Hälso- och sjukvård vid kroniska sjukdomar.
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Disclosure of Interest: A. Spångéus Consultant for: Amgen, Speakers bureau: Amgen; Eli Lilly, K. Åkesson Grant/research support from: Amgen, Eli Lilly, Ö. Ljunggren Grant/research support from: Amgen, Eli Lilly, J. Banefelt Consultant for: Quantify Research, funded by UCB to conduct this study, Employee of: Quantify Research, funded by UCB to conduct this study, L. Karlsson Consultant for: Quantify Research, funded by UCB to conduct this study, Employee of: Quantify Research, funded by UCB to conduct this study, G. Ortsäter Consultant for: Quantify Research, funded by UCB to conduct this study, Employee of: Quantify Research, funded by UCB to conduct this study, C. Libanati Shareholder of: UCB Pharma, Employee of: UCB Pharma, E. Toth Shareholder of: UCB Pharma, Employee of: UCB Pharma, O. Ström Grant/research support from: Quantify Research, funded by UCB to conduct this study, Consultant for: Quantify Research, funded by UCB to conduct this study
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OP0051 THE ACTIVATING PATIENTS AT RISK FOR OSTEOPOROSIS STUDY: A RANDOMIZED TRIAL WITHIN THE GLOBAL LONGITUDINAL STUDY OF OSTEOPOROSIS IN WOMEN COHORT

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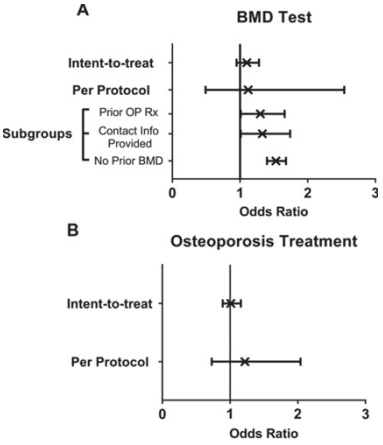
Background: Osteoporosis treatment rates are declining, even among those with past fractures. Novel, low cost approaches engaging and activating patients are needed to improve care.
Objectives: To test a multi-modal, tailored, direct-to-patient, behavioral, video intervention aimed at improving rates of osteoporosis medication use.
Methods: We conducted a controlled, randomized clinical trial of our novel intervention among US women in the Global Longitudinal Study of Osteoporosis in Women cohort with self-reported fracture history who were not currently using osteoporosis therapy. The primary outcome at 6-months was self-report of osteoporosis medication use. Secondary and exploratory outcomes included starting calcium and vitamin D, bone mineral density (BMD) testing, readiness for behavioral change, and barriers to treatment.
Results: We randomized 2684 women to receive the intervention materials or usual care. Study participants were 92.6% Caucasian, with a mean (SD) age 74.9 (8.0) years, and a self-reported lower than average risk for osteoporosis (40.0%). In the 12 months prior to randomization, 1390 women reported talking with their doctor regarding osteoporosis, 7.4% reported a fracture, vitamin D or calcium supplementation were reported as 83.5% and 68.6%, respectively. We observed no differences in sociodemographic characteristics and no significant differences in the primary (11.7% vs 11.4%) and secondary (calcium, 31.8% vs 32.6%; vitamin D, 41.3% vs 41.9%; bone density, 61.8% vs 57.1%) end points between the intervention and usual care groups. Exploratory post-hoc analyses demonstrated that women in the intervention arm had more favorable views towards osteoporosis medications compared with the usual care arm and a lower proportion were in the unaware and uninvolved stages of behavior change regarding osteoporosis medications (OR=1.57, CI[1.11, 2.23]). We found that barriers to treatment were higher in the intervention, as compared to usual care arm at 6 months: concerns regarding osteonecrosis of the jaw (OR=1.58[1.14, 2.18]). We found significant differences in self-report BMD testing among the subgroup of women with no history of osteoporosis medication use (OR=1.30 [1.01, 1.66]), among those who provided a contact phone number or email address (OR=1.33 [1.01, 1.74]), and among those who did not report past BMD testing on the baseline survey (OR=1.53 [1.40, 1.68]) (Figure A). The proportion of self-reported osteoporosis treatment was similar between those with appreciable exposure to the online intervention compared with the control group (adjusted OR=1.22 [0.73, 2.04]) (Figure B).



Conclusions: This randomized study testing a novel, personalized educational intervention, did not increase the use of osteoporosis therapy at 6 months. The intervention appeared to have influenced participants' readiness for behavior change.
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