Conclusion: Women with scoliosis showed significantly higher fracture risk for major osteoporotic fractures and for hip fractures compared to those without scoliosis.

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SAT0474

WHAT DETERMINES THE EFFECT OF THERAPY WITH DENOSUMAB ON BONE IN WOMEN WITH RHEUMATOID ARTHRITIS AND OSTEOPOROSIS

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Background: RANK-ligand is essential for osteoclast development, activation, and survival and it is a key mediator of increased osteoclast activity in rheumatoid arthritis (RA). Denosumab is a monoclonal antibody that binds RANK-ligand.

Objectives: The aim of this study was to evaluate the effects of denosumab on bone mineral density (BMD) and to define a contribution of factors: anamnesis, clinical/laboratory markers, glucocorticoids (GC) intake, etc. on the response to therapy with denosumab in women with RA and osteoporosis (OP).

Methods: 66 postmenopausal women (mean age 59.6±7.4) with RA (mean duration 17.7±10.4 years) and OP received s/c denosumab 60mg every 6 months pro 12 months. RF-positive were 72%, ACCP – 74% of patients. 34 (49%) patients continued GC. At baseline and after 12 months it was carried out the dual energy x-ray absorptiometry at 3 sites: lumbar spine (L1-L4), hip neck (HN) and distal forearm (DF) and x-ray of hands and feet (Sharp/van der Heijde (SVH) score). The Statistica 6.0 was used.

Results: After therapy it was noted the increase ($p < 0,05$) of BMD in L1-L4 and HN, a tendency to increase ($p = 0,0529$) in DF. Mean BMD (L1-L4) before/after the treatment was $0,821 \pm 0,104 \text{ g/cm}^2$ vs $0,864 \pm 0,110 \text{ g/cm}^2$, at HN was $0,625 \pm 0,089 \text{ g/cm}^2$ vs $0,639 \pm 0,088 \text{ g/cm}^2$, at DF was $0,498 \pm 0,090 \text{ g/cm}^2$ vs $0,503 \pm 0,089 \text{ g/cm}^2$. The mean change of BMD (%) after 12 months at L1-L4 was +4,6%, at HN +2,8%, at DF +0,7%. Positive response (increase or stabilization of BMD) was noted in 89% patients at L1-L4, 67% - at HN and 60% - at DF. Analysis of influence of various factors (statistically significant) on the response to therapy is presented in the Table.

Conclusion: After 12 months of therapy with denosumab in postmenopausal women with RA and OP it was shown the significant increase of BMD in L1-L4

Table. Influence of various factors on the response to therapy with denosumab after 12 months of treatment (n=66)

DXA site	Positive response on therapy is associated with	Negative response on therapy is associated with
L1-L4	–	– GC intake (> 3 months in anamnesis) ($p = 0,034$); – the beginning of GC intake after menopause ($p = 0,023$)
Hip neck	– higher concentration of the RF (initially and in dynamics) ($p < 0,05$); – the beginning of menopause later than RA onset ($p = 0,024$)	– GC intake (> 3 months in anamnesis) ($p = 0,024$)
Forearm (distal 1/3)	– RF-positivity ($p = 0,02$)	– back correlates with increase in erosion score and total SVH score: $r = -0,360$ ($p < 0,05$)

and HN, a tendency to increase in DF. The mean change of BMD (%) after 12 months was +4,6% at L1-L4, at HN +2,8%, at DF +0,7%. Positive response on denosumab (BMD) was noted in 89% patients at L1-L4, 67% - at HN and 60% - at DF. Analysis of influence of factors on the response to therapy showed that positive response on therapy in HN and DF was associated with RF-positivity. The distinct contribution to the negative response in L1-L4 and HN was associated with GC intake (previous intake more than 3 months in the anamnesis) and purpose of the GC after menopause onset. Also, negative response in DF back correlated with increase in erosion score and total SVH score.

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SAT0475

DENOSUMAB VERSUS ORAL BISPHOSPHONATE FOR OSTEOPOROSIS IN LONG-TERM GLUCOCORTICOID USERS: A 12-MONTH RANDOMIZED CONTROLLED TRIAL

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Background:

Objectives: To compare the efficacy of denosumab (DEN) and oral alendronate (ALN) on spinal bone mineral density (BMD) in long-term glucocorticoid users.

Methods: Patients receiving long-term prednisolone treatment for medical illnesses were recruited. Inclusion criteria: (1) adult patients ≥ 18 years of age; (2) prednisolone $\geq 2.5\text{mg/day}$ for ≥ 1 year. Exclusion criteria: (1) previous use of DEN, teriparatide; (2) plan for pregnancy; (3) metabolic bone disease or unexplained hypocalcemia; (4) renal insufficiency. Participants were randomized to receive either: (1) DEN (60mg subcutaneously every 6 months); or (2) ALN (70mg/week). Calcium (Caltrate 3000mg/day) and vitamin D3 (cholecalciferol 1000IU/day) was given. BMD (femoral neck, total hip, lumbar spine) at month 0, 6 and 12 months were performed. Markers of bone turnover (serum P1NP and CTX) were also assayed at the same time points. The primary outcome was the difference of lumbar spine BMD change at month 12 between the two groups.

Results: 139 subjects were recruited (age 50.0 ± 12.7 years): 69 assigned DEN and 70 assigned ALN. Underlying medical diseases: SLE (81%), RA (9.4%) and myositis (5%). Prednisolone dose at entry was $5.7 \pm 2.1\text{mg/day}$. 56% of female patients were postmenopausal. 73(53%) of patients were osteoporotic (T score < -2.5) at the hip, femoral neck or lumbar spine. The mean body mass index (BMI) was $23.1 \pm 4.1\text{kg/m}^2$ (11% patients had $\text{BMI} < 18\text{kg/m}^2$). 82(59%) patients were naive to bisphosphonates. Pre-existing fragility or vertebral fracture was present in 19 (14%) patients and 18 patients (13%) had a family history of fractures. Baseline demographic data, osteoporotic risk factors, and BMD at various sites were not significantly different between the two groups at entry. At month 12, a significant gain in BMD at the lumbar spine ($+3.5 \pm 2.5\%$; $p < 0.001$) and the hip ($+0.9 \pm 2.8\%$; $p = 0.01$) was observed in DEN-treated patients, whereas the corresponding change was $+2.5 \pm 2.9\%$ ($p < 0.001$) and $+1.6 \pm 2.7\%$ ($p < 0.001$) in the ALN group. The spinal BMD at month 12 was significantly higher in the DEN than ALN group after adjustment for BMD values at baseline, age, sex and other osteoporosis risk factors that included smoking, drinking, cumulative steroid doses in one year, BMI, menopausal status and personal history of fracture ($p = 0.045$). The differences in hip and femoral neck BMD were not significantly different between the two groups after adjustment for the same confounding factors. No new symptomatic fractures occurred in any participants at month 12. Adverse events were similar in frequency between the two treatment arms. Major infective episodes were uncommon (0.06/patient/year) and similar in the two groups. Minor upper gastrointestinal symptoms and non-specific dizziness were numerically more common in the ALN but arthralgia, minor infections (eg. upper respiratory tract) and new hypertension was more commonly reported in the DEN group. Three patients from ALN and 2 patients from DEN group were withdrawn from the study because of non-compliance but none withdrew because of adverse events.

Conclusion: In patients receiving long-term glucocorticoids, DEN is superior to ALN in raising the spinal BMD after 12 months' treatment. Both DEN and ALN were well tolerated.

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SAT0476

COMPLIANCE AND PERSISTENCE OF ANTI-OSTEOPOROTIC TREATMENTS IN PATIENTS WITH HIP FRACTURE

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