Conclusion: One year tofacitinib treatment effectively stabilized bone density in patients with rheumatoid arthritis, and led to the increase of bone turnover markers, which is beneficial for ossification in long term.

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SAT0472

GOAL-DIRECTED TREATMENT OF OSTEOPOROSIS IN PATIENTS WITH RHEUMATOID ARTHRITIS USING DENOSUMAB FOR FIVE YEARS

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Background: Osteoporosis (OP) is frequent complication identified in patients with rheumatoid arthritis (RA). Effective treatment must be provided to treat OP in RA (RAOP). Denosumab (DMB) is one of the promising drugs that are currently being used for the treatment of RAOP. We reported the results of 12-month DMB treatment for RAOP as part of Japanese multicenter registry study (TBCR-BONE) in EULAR2016 [1]. Recently, a treatment goal of OP was reported by the American Society for Bone and Mineral Research and the National Osteoporosis Foundation (ASBMR-NOF) working group [2]. This report advocated that the goal of treatment is a T-score of >-2.5 at the femoral neck, total hip (TH) or lumbar spine (LS) on DXA if the primary reason for starting treatment was a T-score of ≤ -2.5 at the abovementioned skeletal sites. The working group noted that it was reasonable to expect that initial treatment should offer at least a 50% chance of achieving the treatment goal within 3 to 5 years of initiating therapy. We have reported the achievement rates of treatment goal in RAOP with 3-year DMB treatment on RAOP in EULAR2019 [3].

Objectives: The aim of this retrospective study was to evaluate whether 5-year DMB treatment can achieve treatment goal of OP using data from TBCR-BONE.

Methods: The study included 46 female patients who had completed 5-year DMB treatment. The LS-BMD analysis included 22 patients with a baseline (BL) LS-BMD T-score of ≤ -2.5 . The TH-BMD analysis included 29 patients with a BL TH-BMD T-score of ≤ -2.5 . Similar to clinical setting in Japan, 60mg of DMB was administered once every 6 months with a vitamin D3 supplement. BL characteristics, change in T-score over time, and achievement of the treatment goal (T-score >-2.5) were evaluated.

Results: BL characteristics of the 46 female patients included: mean age of 69.1 years and RA duration of 16 years. Prednisolone was administered to 37% of the patients. In the LS-BMD analysis, T-scores improved significantly; the mean value at BL was -3.4 , which increased to -3.0 at 1 year, -2.6 at 3 years, and ultimately to -2.5 at 5 years. The fraction of patients who achieved the treatment goal was as follows: 36.4% at 1 year, 40.9% at 2 years, 45.5% at 3 years, 50.0% at 4 years, and 54.5% at 5 years (Fig. 1A). The patients who achieved this treatment goal were those who had a significantly lower risk of fracture at BL as determined by FRAX (17.9% vs. 32.2%, $p = 0.044$), who had significantly higher BL serum TRACP-5b level (572.8 vs. 401.0; $p = 0.03$), and who had significantly better BL LS-BMD T-scores (-3.0 vs. -3.9 , $p < 0.01$) than the nonachievers. In the TH-BMD analysis, T-scores improved significantly; the mean value at BL was -3.0 , and it increased to -3.0 at 1 year, -2.7 at 3 years, and reached -2.7 at 5 years. The fraction of patients who achieved the treatment goal was as follows: 20.7% at 1 year, 31.0% at 2 years, 34.5% at 3 years, 31.0% at 4 years, and 37.9% at 5 years (Fig. 1B). The patients who achieved this treatment goal were those who had significantly better BL TH-BMD T-scores (-2.7 vs. -3.2 ; $p < 0.01$) than the nonachievers. Cut-off values at BL for achievement of the treatment goal determined using ROC analysis were -3.1 for the LS-BMD (sensitivity 83.3%, specificity 90.0%) and -2.85 for the TH-BMD (sensitivity 100.0%, specificity 81.0%).

Fig1. Change of percentage of patients with T-score >-2.5

A: results of lumbar spine bone mineral density (n=22)
B: results of total hip bone mineral density (n=29)

Conclusion: The results of this study suggested that achievement of the treatment goal was comparatively easy for those with LS-BMD loss; however, it was comparatively difficult for those with TH-BMD loss. Early initiation or longer duration of DMB therapy may be necessary to improve achievement rates. Likewise, other agents, such as romosozumab, may be considered for those with significant TH-BMD loss.

References:

- [1] Hirano *et al.* Ann Rheum Dis 2016; 75 (Suppl 2): 94
- [2] Cummings *et al.* J Bone Miner Res 2017; 32: 3-10
- [3] Hirano *et al.* Ann Rheum Dis 2019; 78 (Suppl 2): A940

Disclosure of Interests: Yuji Hirano Speakers bureau: Tanabe-Mitsubishi, Pfizer, Eisai, Abbvie, Chugai, Bristol-Myers, Jansen, Astellas, UCB, Eli-Lilly, Asahikasei, Daiichi-Sankyo, Amgen, Yasuhide Kanayama: None declared, Hironobu Kosugiyama: None declared, Naoki Ishiguro Grant/research support from: AbbVie, Asahi Kasei, Astellas, Chugai, Daiichi-Sankyo, Eisai, Kaken, Mitsubishi Tanabe, Otsuka, Pfizer, Takeda, and Zimmer Biomet, Consultant of: Ono, Speakers bureau: Astellas, Bristol-Myers Squibb, Daiichi-Sankyo, Eli Lilly, Pfizer, and Taisho Toyama, Toshihisa Kojima Grant/research support from: Chugai, Eli Lilly, Astellas, Abbvie, and Novartis, Consultant of: AbbVie, Speakers bureau: AbbVie, Astellas, Bristol-Myers Squibb, Chugai, Daiichi-Sankyo, Eli Lilly, Janssen, Mitsubishi Tanabe, Pfizer, and Takeda

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SAT0473

COMPARISON OF THE FRACTURE RISK IN WOMEN WITH AND WITHOUT SCOLIOSIS THROUGH DUAL-ENERGY X-RAY ABSORPTIOMETRY

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Background: Osteoporosis is known to be a risk factor for fragility fractures [4, 5]. On one hand, vertebral body fragility fractures often lead to additional spine deformity [2]. On the other hand, it was found that with the progression of the spinal curvature in osteoporotic patients, the fragility fractures develop more frequently. The increased incidence of these fractures could be explained with a predominance of the mechanical forces on the one side of the already weakened osteoporotic vertebrae [3].

Objectives: The aim of this study is to compare the fracture risk (FRAX) for major osteoporotic fractures (MOF) and for hip fractures (HF) in women with and without scoliosis through dual-energy X-ray absorptiometry (DXA)

Methods: In the current study, 59 women underwent DXA scans. Scoliosis was defined as Cobb's angle $\geq 5^\circ$ according to the Chaklin's classification [6, 7]. Cobb's angle was measured from DXA images with DICOM software. We evaluated the following risk factors: previous fractures, parental hip fractures, secondary osteoporosis, rheumatoid arthritis, use of corticosteroids, current smoking and alcohol consumption more than 3 units daily. We estimated FRAX MOF and FRAX HF on the basis of these risk factors and on the basis of the femoral neck bone mineral density (BMD). The calculations were done through FRAX tool published on the website of the University of Sheffield [1].

Results: The mean age of the women was 63 years (yrs.) $\pm$ 10 yrs. (range 43 yrs. – 89 yrs.). Subjects with scoliosis were significantly older (67 yrs.) than those without scoliosis (59 yrs.), ($p = 0.004$). Mean weight and height didn't differ between the groups with- and without scoliosis. Mean lumbar spine BMD and T-score differed significantly between the groups, ($p = 0.02$). Women with scoliosis had lower mean BMD (0.786/g/cm²) and lower mean T-score (-2.1 standard deviations (SDs)) compared to those without scoliosis (mean BMD: 0.912/g/cm² and mean T-score: 0.9 SDs). The mean FRAX MOF (19.3%) and FRAX HF (5.9%) of the subjects with scoliosis were significantly higher than those of the women without scoliosis (FRAX MOF: 14.9% and FRAX HF: 3.1%), ($p = 0.004$ for FRAX MOF and $p = 0.010$ for FRAX HF).

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

References:

- [1] <https://www.sheffield.ac.uk/FRAX/index.aspx>
- [2] Mao YF, Zhang Y, Li K, et al. Discrimination of vertebral fragility fracture with lumbar spine bone mineral density measured by quantitative computed tomography. *J Orthop Translat.* 2018;16:33–39. Published 2018 Oct 10. doi:10.1016/j.jot.2018.08.007.
- [3] Sabo A, Hatgis J, Granville M, Jacobson RE. Multilevel Contiguous Osteoporotic Lumbar Compression Fractures: The Relationship of Scoliosis to the Development of Cascading Fractures. *Cureus.* 2017;9(12):e1962. Published 2017 Dec 19. doi:10.7759/cureus.1962.
- [4] Kirilova E, Cherkezov D, Gonchev B, Zheleva Z. OSIRIS Index for the assessment of the risk for osteoporosis in menopausal women, National conference with international participation, 6-7 october 2019, Kardzhali "Science and society 2019", RKR print OOD ISSN 1314-3425
- [5] Madzharova R, Kirilova E, Petranova T, Nikolova M. Assessment of the activity for self care in women with osteoporosis, Science and Technology Volume VIII, 2018, Number 1: MEDICAL BIOLOGY STUDIES, CLINICAL STUDIES, SOCIAL MEDICINE AND HEALTH CARE, 1-6.
- [6] Chaklin VD, Orthopedy - Moscow: Medgiz – 1965 – C. 209
- [7] Chaklin VD. Pathology, clinical manifestation and treatment of the scoliosis, 1st congress of the union of the orthopedists and traumatologists, Moscow: Medgiz, 1957 – T.2. – p 798

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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 60 mg 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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