Prior anabolic treatment reduces lumbar spine BMD response to romosozumab in Caucasian postmenopausal women with severe osteoporosis

**Keywords:** Osteoporosis, Real-world evidence, Bone diseases

P. Ravji1, M. McRorie2, K. Berg3, S.Ralston1,2, B. Hauser1,2. 1NHS Lothian, Rheumatology Department, Edinburgh, United Kingdom; 2Centre for Genomic and Experimental Medicine, Institute of Genetics and Cancer, University of Edinburgh, Edinburgh, United Kingdom

**Background:** Romosozumab, a monoclonal antibody against sclerostin, is a newly licensed dual-acting osteoporosis (OP) treatment for patients at very high fracture risk. Most patients included in the pivotal trials (ARCH[1] and FRAME [2]) were treatment naïve. However, many patients in day-to-day clinical practice who are eligible for anabolic therapy have been pre-treated with antiresorptive medications. Objective: Our aim was to analyse bone mineral density (BMD) treatment response to Romosozumab in patients with severe osteoporosis who are attending the osteoporosis clinic. A further objective was to analyse whether pre-treatment with antiresorptive osteoporosis medication (OPTx) influences the BMD treatment response at any BMD site.

**Methods:** Retrospective single-centre analysis of patients who have completed a 12-month course of monthly sc Romosozumab treatment (210mg) between February 2021 and November 2022. Local guidance recommends the use of Romosozumab in patients with severe spinal OP with at least two moderate vertebrae fractures and OP at the hip as defined by DXA. BMD assessment was usually performed with DXA at baseline and after treatment completion.

**Results:** Out of 56 patients offered Romosozumab, 52 agreed to start treatment and 47 patients completed the full course of therapy. All patients were postmenopausal women with an average age of 73.1 ± 9.7 years and BMI of 24.4 ± 7.1 kg/m². The baseline 10% major osteoporotic fracture risk as calculated by FRAX was 32.2 ± 13.5. Mean baseline BMD lumbar spine (LS) T-score was -3.8 ± 1.0 and total hip (TH) T-score was -3.0 ± 0.7. The vast majority (95%) of patients had a history of vertebral fractures and half of the patients (50%) had a history of an additional non-vertebral fracture. 31 (66%) patients were treatment naïve or had recent anitresorative treatment for less than 6 months, the remaining patients received recently oral or parenteral bisphosphonate treatment. After 12 months the overall mean % change BMD at the LS was 14.1 ± 9.4 and 5.7 ± 5.6 at the TH site. Spine BMD increase was significantly higher in treatment naïve patients than in patients who had previous OPTx over 6 months (17.3 ± 9.0 vs 7.8 ± 6.8; p<0.01). Prior OPTx however did not seem to influence TH BMD response to Romosozumab (5.1 ± 6.3 vs 6.1 ± 5.1 in OPTx naïve patients) as shown in Figure 1. 

**Figure 1.** Bone mineral density (BMD) change (%) after 1 year treatment with Romosozumab; OPTx naïve p<0.01 compared to OPTx naïve

**Disclosure of Interests:** Pollie Ravji: None declared, Morven McRorie: None declared, Kathryn Berg: None declared, Stuart Raistin Grant/research support from: UCB, Kyowa Kirin, AstraZeneca, Eli Lilly and Novartis, Barbara Hauser: Speakers bureau: UCB, Chugai-Roche, Astellas, Efrin, Consultant of: Fresenius-Kabi, Celltrion Healthcare, Gedeon-Richter, UCB.

**Acknowledgements:** NIL.

**References:**


Increased risk of osteoporosis and head of femur fractures in patients with familial Mediterranean fever - a large retrospective cohort study

**Keywords:** Epidemiology, Osteoporosis

Y. S. Pat1, N. Ben-Shabat1, L. Fishe1, K. Sharit1, S. Lasman1, A. Watad1, H. Amital1, 1Sheba Medical Center, Tel-Hashomer, Department of Internal Medicine B & Zabludowicz Center for Autoimmune Diseases, Ramat Gan, Israel; 2Sheba Medical Center, Tel-Hashomer, Department of Gastroenterology, Ramat Gan, Israel; 3Leeds Institute of Molecular Medicine, University of Leeds, Chapel Allerton Hospital, Leeds, UK, Section of Musculoskeletal Disease, NHRR Leeds Musculoskeletal Biomedical Research Unit; Leeds, United Kingdom

**Background:** Chronic inflammatory conditions are characterized by an inflammatory milieu and increased exposure to glucocorticoids both resulting in increased risk of osteoporosis and subsequently bone fractures. Familial Mediterranean Fever (FMF) is a prototypical autoinflammatory disorder not treated with steroids. FMF association with osteoporosis and risk for femur fractures is not well evaluated.

**Objectives:** To evaluate the incidence of osteoporosis and head of femur fractures in FMF patients compared to the general population.

**Methods:** A retrospective cohort study using the electronic database of Clalit Health Services (CHS), the largest health organization in Israel. All FMF patients diagnosed between 2000-2016 were included with age-, sex- matched controls in a 1:1 ratio. Follow-up continued until the first diagnosis of osteoporosis or femur fracture. The incidence of these conditions was compared between the groups using univariate and multivariate models adjusting for cardiovascular risk-factors.

**Results:** 9,769 FMF patients were followed for a median period of 12.5 years. 304 FMF patients were diagnosed with osteoporosis compared to 191 controls, resulting in an incidence rate (per 10,000 persons-years) of 28.8 (95%CI 15.7-32.5), and 17.8 (95%CI 15.4-20.6) respectively, and a crude HR of 1.62 (95% CI 1.35-1.93; p<0.001). Patients were diagnosed with osteoporosis at a considerably younger age than controls (60.1±12.4 vs 62.5±11.0 years; p=0.028).

**Table 1.** Incidence of osteoporosis and head of femur fracture in FMF patients compared to controls, time to event analysis

<table>
<thead>
<tr>
<th>Group</th>
<th>Variables</th>
<th>FMF</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Osteoporosis</strong></td>
<td>Events, n</td>
<td>304</td>
<td>191</td>
</tr>
<tr>
<td>Age at osteoporosis, mean ±SD</td>
<td>60.1 ± 12.4</td>
<td>62.5 ±11.0</td>
<td></td>
</tr>
<tr>
<td>Follow-up time, person-years</td>
<td>105,480</td>
<td>107,068</td>
<td></td>
</tr>
<tr>
<td>Follow-up time, median (IQR)</td>
<td>12.5 (6.8-14.6)</td>
<td>12.6 (7.1-14.7)</td>
<td></td>
</tr>
<tr>
<td>Incidence per 10,000 person-years, (95%CI)</td>
<td>28.8 (25.7 to 32.9)</td>
<td>17.8 (15.4 to 20.6)</td>
<td></td>
</tr>
<tr>
<td>Unadjusted HR (95%CI)</td>
<td>1.62 (1.35 to 1.93)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
<tr>
<td>Age-and-sex adjusted HR (95%CI)</td>
<td>1.80 (1.50 to 2.16)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
<tr>
<td>Multivariate4 HR (95%CI)</td>
<td>1.73 (1.43 to 2.10)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Head of Femur Fracture</strong></td>
<td>Events, n</td>
<td>56</td>
<td>35</td>
</tr>
<tr>
<td>Age at femur fractures, mean ±SD</td>
<td>69.8 ± 13.1</td>
<td>65.1 ±19.9</td>
<td></td>
</tr>
<tr>
<td>Follow-up time, person-years</td>
<td>105,718</td>
<td>108,813</td>
<td></td>
</tr>
<tr>
<td>Follow-up time, median (IQR)</td>
<td>12.5 (7.2-14.4)</td>
<td>12.5 (7.2-14.4)</td>
<td></td>
</tr>
<tr>
<td>Incidence per 10,000 person-years, (95%CI)</td>
<td>5.3 (4.0 to 6.9)</td>
<td>3.3 (2.3 to 4.6)</td>
<td></td>
</tr>
<tr>
<td>Unadjusted HR (95%CI)</td>
<td>1.60 (1.05 to 2.44)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
<tr>
<td>Age-and-sex adjusted HR (95%CI)</td>
<td>1.61 (1.06 to 2.48)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
<tr>
<td>Multivariate5 HR (95%CI)</td>
<td>1.58 (1.02 to 2.44)</td>
<td><strong>reference</strong></td>
<td></td>
</tr>
</tbody>
</table>

1 Adjusted for age, sex, ethnicity, socioeconomic status, obesity, smoking, diabetes, alcohol abuse, lupus, rheumatoid arthritis, sarcoidosis, thyroid dysfunction, parathyroid dysfunction, chronic renal failure, and amyloidosis. 2 P-value<0.05. 3 P-value<0.001. 4 Abbreviations: CI, confidence interval, HR, hazard ratio, IQR, interquartile-range; FMF, familial Mediterranean fever.
Regarding femur fractures, 56 FMF patients were diagnosed with the condi-
tion compared to 35 controls, resulting in an incidence rate (per 10,000 per-
sons-years) of 5.3 (95%CI 4.0-6.9), and 3.3 (95%CI 2.3-4.6) respectively, and
a crude HR of 1.60 (95% CI 1.05 to 2.44 p<0.05). Predictors of osteoporosis or
femur fractures among FMF patients included older age, Arab ethnicity, as
well as North African origin. In contrast, obesity was considered a protective
factor, while colchicine treatment did not significantly affect the risk of these
outcomes.

Conclusion: FMF patients are at increased risk for osteoporosis and conse-
quently femur fractures.

REFERENCES:
[1] Rachner TD, Khosla S, Hofbauer LC. Osteoporosis: now and the future. Lan-
cet. 2011 Apr 9;377(9773):1276-87.
BMJ. 1993;307(6941):948-60.
2019 Mar 3;4[1].

Objectives: To test the effectiveness of the co-created ActiveHip+ mHealth sys-
tem on the recovery of the functional status and the decrease of the pain and fear
of falling in older adults with hip fracture.

Methods: A total of 110 older adults with hip fracture and their family caregiv-
ers were recruited from hospitals in southern Spain. Participants were randomly
assigned to an intervention group (n = 55), in which rehabilitation was performed
through ActiveHip+, or to a control group (n = 55), in which they received stand-
ard rehabilitation for a hip fracture from the Andalusian Public Health System.
Participants were assessed during the hospital stay and 3 months after surgery.
Feasibility assessment was done through adoption (participation proportion
usage (access to the app), satisfaction with the app (Net Promoter Score) and
user perception of the quality of the app (Mobile App Rating Scale). Clinical
assessment was conducted through patient-reported outcomes, such as the
Functional Independence Measure and the New Mobility Score Spanish version
for functional status, the Numerical Rating Scale for pain and the Short Falls
Efficacy Scale-International for fear of falling.

Results: We obtained positive results in terms of feasibility as we observed 88% adoption,
82% usage, 8.3/10 in satisfaction with the app and 4.3/5 in perceived
quality of the app. The functional status of patients allocated to the intervention
group (those using ActiveHip+) had a statistically significant greater recovery
than participants of the control group at 3-months (medium effect size: 0.70
Cohen’s d; p = 0.02) and (medium effect size: 0.62 Cohen’s d; p = 0.03) respec-
tively. In addition, the level of pain was statistically significant lower in participants
of the intervention group than those in the control group (medium effect size:
0.45; Cohen’s d = 0.03). Regarding the fear of falling, there was no statistically
significant difference (medium effect size: 0.32 Cohen’s d; p = 0.17).

Conclusion: The ActiveHip+ mHealth system is effective in the recovery of
the functional status and the decrease of pain in older adults with hip fracture. How-
ever, it was not effective on the decrease of the fear of falling.

Table 1. Baseline characteristics and pre-interventions raw of sample
divided by groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention group</th>
<th>Control group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), Mean (SD)</td>
<td>79.70 (72)</td>
<td>79.94 (78)</td>
<td>0.73</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>33 (72)</td>
<td>37 (70)</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>13 (28)</td>
<td>16 (30)</td>
<td>0.58</td>
</tr>
<tr>
<td>Type of injury, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fracture Cervical Femoral (Intracapsular)</td>
<td>21 (46)</td>
<td>22 (42)</td>
<td>0.46</td>
</tr>
<tr>
<td>Fracture Trochanteric (Extracapsular)</td>
<td>20 (43)</td>
<td>23 (49)</td>
<td>0.18</td>
</tr>
<tr>
<td>No fracture, but degeneration</td>
<td>5 (11)</td>
<td>8 (15)</td>
<td>0.94</td>
</tr>
<tr>
<td>Type of surgery, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prosthesis</td>
<td>14 (65)</td>
<td>13 (25)</td>
<td>0.09</td>
</tr>
<tr>
<td>Screw Plate</td>
<td>30 (31)</td>
<td>35 (69)</td>
<td>0.09</td>
</tr>
<tr>
<td>PFNA-A Nail</td>
<td>1 (2)</td>
<td>5 (9)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Hospital stay (days), Mean (SD)</td>
<td>6.83 (4.2)</td>
<td>5.64 (3.3)</td>
<td>0.08</td>
</tr>
<tr>
<td>Functional status at hospital discharge</td>
<td>78.13 (19.23)</td>
<td>75.26 (13.39)</td>
<td>0.36</td>
</tr>
<tr>
<td>FIM (Total score 18-126) Mean (SD)</td>
<td>5.89 (2.31)</td>
<td>5.68 (1.73)</td>
<td>0.29</td>
</tr>
<tr>
<td>Fear of falling at hospital discharge</td>
<td>19.37 (72)</td>
<td>20.08 (5.18)</td>
<td>0.58</td>
</tr>
<tr>
<td>SFES-I (Total score 7-28) Mean (SD)</td>
<td>5.89 (2.31)</td>
<td>5.68 (1.73)</td>
<td>0.91</td>
</tr>
</tbody>
</table>

POS0392 EFFECTIVENESS OF THE ACTIVEHIP+ MHEALTH SYSTEM ON THE FUNCTIONAL STATUS, PAIN AND FEAR OF FALLING IN OLDER ADULTS WITH HIP FRACTURE: A RANDOMISED CLINICAL TRIAL

Keywords: Telemedicine, Clinical Trials, Osteoporosis

R. Prieto-Moreno1,2, P. Molina-Garcia1,4, M. Mora-Traverso2,4, M. Ortiz-Piña1, S. Salazar-Gravaní1, V. Cruz Guisado1, R. Del Pino Agarada1, M. Martín-
Mattila1, F. Estevéz Lopez2, P. Ariza-Vega2,3. PA-HELP “Physical Activity for HEaLth Promotion” research group, Department of Physical Education and
Sports, Faculty of Sports Science, University of Granada, Granada, Spain;
Granada, Spain; Instituto de investigación biosanitaria ibs.Granada, Granada,
Spain; PROFITH “PROmoting FITness and Health through physical activity”
research group, Physical Education and Sports, Faculty of Sports Science,
University of Granada, Granada, Spain; University Hospital Virgen de las
Nieves, Department of Physical Medicine and Rehabilitation, Granada, Spain;
University Hospital Jerez de la Frontera, Department of Physical Medicine and
Rehabilitation, Jerez, Spain; University Hospital Puerto Real, Department of
Physical Medicine and Rehabilitation, Puerto Real, Spain; Harvard University,
Harvard T.H. Chan School of Public Health, Cambridge, United States of America

Background: Osteoporotic hip fracture causes a high level of dependency in
older adults, as their functional status suddenly decreases greatly. In addition,
the high level of pain and the fear of falling that they frequently experience
maintain this decrease in functional status for a longer period. Digital health,
the promotion of health through the use of Information and Communication
Technologies, emerges as an option for the rehabilitation of older adults with
hip fracture.

Acknowledgements: NIL.

Disclosure of Interests: None Declared.

DOI: 10.1136/annrheumdis-2023-eular.4919