Merck, Roche, Pfizer, and UCB Pharma, Frank Buttgerit Grant/research support from: Amgen, BMS, Celgene, Generic Assays, GSK, Hexal, Horizon, Lilly, medac, Mundipharma, Novartis, Pfizer, Roche, and Sanofi.

DOI: 10.1136/annrheumdis-2020-eular.4391

OP0301

PREDICTION OF LOW BONE MINERAL DENSITY AND FRAX SCORE BY ASSESSING HIP BONE TEXTURE WITH DEEP LEARNING

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Background: Osteoporosis is a widespread health concern associated with an increased risk of fractures in individuals with low bone mineral density (BMD). Dual-energy x-ray absorptiometry (DXA) is the gold standard to measure BMD, but methods based on the assessment of plain films, such as the digital radiogrammetry,¹ are also available. We describe a novel approach based on the assessment of hip texture with deep learning to estimate BMD.

Objectives: To compare the BMD estimated by assessing hip texture using a deep learning model and that measured by DXA.

Methods: In this study, we identified 1,203 patients who underwent DXA of left hip and hip plain film within six months. The dataset was split into a training set with 1,024 patients and a testing set with 179 patients. Hip images were obtained and regions of interest (ROI) around left hips were segmented using a tool based on the curve Graph Convolutional Network. The ROIs are processed using a Deep Texture Encoding Network (Deep-TEN) model,² which comprises the first 3 blocks of Residual Network with 18 layers (ResNet-18) model followed by a dictionary encoding operator (Figure 1). The encoded features are processed using a fully connected layer to estimate BMD. Five-fold cross-validation was conducted. Pearson's correlation coefficient was used to assess the correlation between predicted and reference BMD. We also test the performance of the model to identify osteoporosis (T-score ≤ -2.5)

Figure 1. Schematic representation of deep learning models to extract and encode texture features for estimation of hip bone density.

Results: We included 151 women and 18 men in the testing dataset (mean age, 66.1 ± 1.7 years). The mean predicted BMD was 0.724 g/cm^2 compared with the mean BMD measured by DXA of 0.725 g/cm^2 ($p = 0.51$). Pearson's correlation coefficient between predicted and true BMD was 0.88. The performance of the model to detect osteoporosis/osteopenia was shown in Table 1. The positive predictive value was 87.46% for a T-score ≤ -1 and 83.3% for a T-score ≤ -2.5 . Furthermore, the mean FRAX® 10-year major fracture risk did not differ significantly between scores based on predicted (6.86%) and measured BMD (7.67%, $p=0.52$). The 10-year probability of hip fracture was lower in the predicted score (1.79%) than the measured score (2.43%, $p = 0.01$).

Table 1. Performance matrices of the deep texture model to detect osteoporosis/osteopenia

	T-score ≤ -1	T-score ≤ -2.5
Sensitivity	91.11% (95% CI, 83.23% to 96.08%)	33.33% (95% CI, 17.29% to 52.81%)
Specificity	86.08% (95% CI, 76.45% to 92.84%)	98.56% (95% CI, 94.90% to 99.83%)
Positive predictive value	88.17% (95% CI, 81.10% to 92.83%)	83.33% (95% CI, 53.58% to 95.59%)
Negative predictive value	49.47% (95% CI, 81.35% to 94.31%)	87.26% (95% CI, 84.16% to 89.83%)

Conclusion: This study demonstrates the potential of the bone texture model to detect osteoporosis and to predict the FRAX score using plain hip radiographs.

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Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2020-eular.5916

The new art of phenotyping and treating Sjögren's syndrome

OP0302

IANALUMAB (VAY736), A DUAL MODE OF ACTION BIOLOGIC COMBINING BAFF RECEPTOR INHIBITION WITH B CELL DEPLETION, REACHES PRIMARY ENDPOINT FOR TREATMENT OF PRIMARY SJOGREN'S SYNDROME

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Background: Primary Sjogren's syndrome (pSS) is a multi-organ autoimmune disease mainly affecting excretory glands and characterised by B-cell hyperactivity. No approved systemic treatment is available. Ianalumab (VAY736) is an anti-B-cell activating factor (BAFF) receptor fully human monoclonal antibody, engineered for direct ADCC-mediated B-cell depletion.

Objectives: This phase 2b study aimed at establishing a dose-response relationship over a range of VAY736 doses, using change from baseline (BL) in EULAR Sjogren's Syndrome Disease Activity index (ESSDAI) over 24 Weeks (Wks) as primary endpoint. The study is ongoing with a second blinded treatment period up to Wk52. Here we report efficacy and safety Wk24.

Methods: 190 patients (pts) were randomised 1:1:1:1 to receive monthly s.c. doses of VAY736 (5, 50, 300mg) or placebo (PBO). Prior to 1st-dose of study treatment, pts received methylprednisolone i.v. 250mg. Eligible pts fulfilled American European Consensus Group (AECG) criteria, were anti-Ro/SSA+, had ESS-DAI ≥ 6 and EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI) ≥ 5 . Statistical methods included MCP-Mod to assess dose-response on change of ESSDAI from BL and responder rate analysis to calculate the proportion of pts with ≥ 3 points improvement on ESSDAI. Secondary endpoints included ESSPRI, Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F), Physician's (PhGA) and Patient's Global Assessments (PaGA), SF-36, stimulated salivary flow (sSF), Schirmer's test.

Results: Primary endpoint was met with statistically significant dose-response for ESSDAI (Figure). The largest ESSDAI reduction was 1.92 points over PBO for VAY736 300mg at Wk24. Responder rate analysis on ESSDAI revealed for 300mg vs PBO responder rates of 42/47 (89.4%) vs 30/49 (61.2%), a difference of 28.1% ($p=0.0019$). No differences were seen for 5mg and 50mg vs PBO. PhGA change from BL was significantly different between 300mg and PBO ($p=0.022$). A numerical trend for sSF improvement for VAY736 300mg compared to PBO was notable at Wk24 ($p=0.092$). For secondary endpoints ESSPRI and FACIT-F, VAY736 treatment showed no benefits over PBO. PBO responses were generally high. Incidence of treatment emergent AEs was comparable across all studied groups, whereby site injection reactions were most frequent, mostly mild and showed a dose-response.

Conclusion: Primary endpoint assessing ESSDAI was met, showing statistically significant dose-response for iganalumab with clinically important improvement for 300mg vs PBO. Preliminary safety profile of iganalumab was good.