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**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 and that measured by DXA.

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, which comprises the first 3 blocks of Residual Network and that measured by DXA.

**Results:** We included 151 women and 18 men in the testing dataset (mean age, 66.1 ± 17 years). The mean predicted BMD was 0.724 g/cm² (p = 0.51). Pearson’s correlation coefficient between predicted and true BMD was 0.88. The performance of the model to detect osteoporosis (T-score ≤ -2.5) had a sensitivity of 91.11% (95% CI, 83.23% to 96.08%) and specificity of 96.08% (95% CI, 89.40% to 99.90%). The performance of the model to detect osteoporosis (T-score ≤ -2.5) had a sensitivity of 91.11% (95% CI, 83.23% to 96.08%) and specificity of 96.08% (95% CI, 89.40% to 99.90%). The performance of the model to detect osteoporosis 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 was not significantly different between the predicted values 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**

<table>
<thead>
<tr>
<th>T-score ≤ -1</th>
<th>T-score ≤ -2.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>91.11% (95% CI, 83.23% to 96.08%)</td>
</tr>
<tr>
<td>Specificity</td>
<td>96.08% (95% CI, 92.45% to 98.84%)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>88.17%</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>94.47% (95% CI, 81.10% to 92.83%)</td>
</tr>
</tbody>
</table>

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

**References:**


**Disclosure of Interests:** None declared

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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 SJÖGREN’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 methlyprednisolone i.v. 250mg. Eligible pts fulfilled American European Consensus Group (AECG) criteria, were anti-Ro/SSA+, had ESSDAI ≥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 Global Assessment (PGA), 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. Responder rate analysis on ESSDAI revealed for VAY736 300mg at Wk24. 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 Global Assessment (PGA), SF-36, stimulated salivary flow (sSF), Schirmer’s test.

**Conclusion:** Primary endpoint assessing ESSDAI was met, showing statistically significant dose-response for Ianalumab with clinically important improvement for 300mg vs PBO. Preliminary safety profile of Ianalumab was good.
Meniscus: an innocent bystander in osteoarthritis?

Objectives: This study explored the effects of IACI on the evolution of knee OA structural changes assessed by magnetic resonance imaging (MRI).

Methods: Participants were selected from the Osteoarthritis Initiative database. In this nested case-control design study, participants who received one treatment with IACI and had MRI exams available at the yearly follow-up visits before (pre-treatment), during (treatment), and after (post-treatment) were defined as ‘cases.’ Each case was matched with one control for age, gender, body mass index (BMI), height, joint space width (JSW), cartilage volume, bone marrow lesions (BML), meniscal extrusion, and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain at baseline. Ninety-three (93) participants fulfilling the inclusion criteria were selected and matched to controls (n=93). The study structural variables were MRI (cartilage volume, meniscal thickness, bone marrow lesion (BML), bone curvature), X-rays (JSW), and symptoms (WOMAC pain), assessed at the yearly consecutive visits and changes measured within the follow-up periods.

Results: At baseline, the control and treatment groups were balanced. In the pre-treatment period, the cartilage volume loss in the medial compartment was significantly greater in the IACI group (p=0.041). In the post-treatment period, there was no difference in the cartilage loss between the groups in both compartments. For the meniscal thickness loss in the pre-treatment period, no difference was found between groups; however, there was a significantly greater loss (p=0.007) during the treatment period in the IACI group. In the post-treatment period, the loss of the medial meniscus was similar in both groups. For the lateral meniscus, there was no significant difference at any time between the two groups. The loss in JSW in the pre- and post-treatment periods was not different between groups, but was significantly greater (p=0.011) in the IACI group in the treatment period. The changes in the BML sizes over time were small and similar between groups. For the bone curvature, IACI group showed a smaller change compared to the control (p=0.037) at the treatment period. The WOMAC pain changes in both groups were small and unlikely to be clinically relevant.

Conclusion: This study provides evidence that in knee OA, IACI were not associated with the occurrence of any deleterious effect on knee structures post-treatment, including cartilage volume and loss. The increase in the rate loss of medial meniscal thickness, which was associated with a loss of JSW, was a transient phenomenon and its clinical relevance unknown at that time.

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