Osteoporosis

Disclosure of Interests: Minalini Dey: None declared, Marwan Bukhari Speakers bureau: Bristol-Myers Squib, UCB celltech, Roche/Chugai, Pfizer, Abbvie, Merck, Menarini, Sanofi-aventis, Eli-Lilly, Janssen, Amgen and Novartis.

DOI: 10.1136/annrheumdis-2020-eular.855

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Background: Rheumatoid arthritis (RA) is a determinant risk factor of osteoporosis. BMD is clearly defined as diagnosis criteria of osteoporosis in Japan; that is less than -2.5 with T-score measured with dual-energy X-ray absorptiometry (DXA). The marker of T-score <-2.5 is widely used worldwide; however, the testing system is very expensive, preventing its extensive adoption.

Objectives: We tried to evaluate BMD not measuring with DXA, but the other method that substituting DXA with another X-ray picture of hand that is routinely taken for Sharp/van der Heijde score (SHS) calculation.

Methods: Patient with RA, who met the American College of Rheumatology/European League Against Rheumatism classification criteria, visited our institute has been routinely calculated SHS in taking X-ray pictures of bilateral hands and feet at first consultation. Cortical thickness was calculated from mid-portion of third metacarpal bone in X-ray picture that was taken for the calculation of SHS as taking cancellous bone diameter of the third metacarpal bone from transverse diameter at the same point. We set Cortical Thickness Ratio (CTR) as cortical thickness relative to transverse thickness (Figure 1). BMD measurements at the lumbar spine (LS) and femoral neck (FN) were obtained, and BMD values are presented as g/cm2 and T-score showing dissociation of the BMD compared with the mean BMD in healthy 30-year-old of the same sex with standard deviation was also presented. Patient with RA who underwent SHS calculation and BMD measurement at first consultation was picked up for the study. Relationship between BMD and the other parameters such as sex (male/ female), age, disease duration (years), ACPA titer, RF titer, body mass index (BMI), CTR, the HAQ score, DAS28-CRP, SHS, PS-VAS, tartrate-resistant acid phosphatase-5b value (TRACP-5b), previous treatment for osteoporosis and RA before initial consultation (pTx_OP and pTx_RA) (Yes/No) at initial consultation was evaluated with linear regression analysis.

T-score<-2.5 was statistically evaluated with binary regression analysis for the parameters that demonstrated significant correlation in multivariate linear regression analysis.

Then, Cut-off index (COI) of CTR for the BMD represented with T-score <-2.5 for both of LS and FN was evaluated with Receivers Operation Characteristics technique (ROC). Sensitivity, specificity, area under curve, odds ratio with 95% confidence interval (95%CI) for T-score <-2.5 was also calculated.

Results: A total of 300 patients were picked up for the study. BMDs were 0.867 and 0.682 with 0.203 and 0.143 for standard deviations, that means T-score was -1.93 and -1.86 with 1.64 and 1.15 for standard deviation in LS and FN, respectively. Mean transverse width of third metacarpal bone was 7.3 mm and thickness of the cortex was 2.0 mm, so CTR was 0.279 in average and 0.124 for standard deviation.

In linear regression analysis, BMD in LS demonstrated significant correlation with sex, CTR, and DAS28-CRP, while BMD in FN demonstrated significant correlation with sex, age, and CTR.

In binary regression analysis, CTR and DAS28-CRP demonstrated significant positive correlation with T-score <-2.5 in LS, while age and CTR demonstrated significant correlation in FN.

In ROC, cut-off index of CTR was 0.25 in both of LS and FN, and sensitivities demonstrated 67.9% and 76.1%, and specificity demonstrated 83.0% and 81.6% in LS and FN, respectively. Area under curve was 0.78 and 0.81 with 4.17 (95%CI: 2.51 – 6.92) and 4.90 (95%CI: 2.75 – 8.73) of odds ratios for LS and FN, respectively (Figure 2).

Conclusion: Results of this cross-sectional study encourages our hypothesis that thickness of cortical bone relative to full thickness in the cortex reflects BMD. CTR correlated with BMD in both of LS and FN. CTR of third metacarpal bone was suggested that has close correlation with BMD in both LS and FN. CTR could be strong candidate maker for screening of osteoporosis in patient with RA with the index less than 0.25.
Background: Vitamin D deficiency is a highly prevalent entity worldwide, with relevance in specific diseases and stages of life. Few guidelines assess the indications and optimal dosing in the general population, and although there is no international consensus, 800IU/day is associated with benefits in bone metabolism. Calcifediol, a vitamin D analog, is presented as a therapeutic alternative.

Objectives: To assess the efficacy of calcifediol in the treatment of vitamin D deficiency, compared with therapeutic guidelines recommendations for cholecalciferol in postmenopausal women.

Methods: Phase III-IV, double blind, randomised, controlled, multicentre superiority clinical trial. Postmenopausal women with baseline levels of 25(OH)D < 20 ng/mL were randomised to three arms: 266 mcg of calcifediol/month for 4 or 12 months (standard and test regime), or to cholecalciferol 25000 IU/month for 12 months (as per therapeutic guidelines).

Results from an interim analysis - performed upon completion of month 4 visit by 100% of evaluable patients - are presented and reported without unblinding the study treatments. Both calcifediol groups are summarised for analysis. The trial has been approved by the corresponding ethics committees and national competent authorities.

Results: 298 women were included in the ITT analysis. The average age was 63.4 ± 8.2 years, mean BMI was 29.3 ± 6 Kg/m², 10.7% had osteoporosis and received treatment. All demographic characteristics and risk factors for osteoporosis were balanced amongst groups.

When assessing per treatment group, 13.5% and 35% of women in the calcifediol group reached values of 25(OH)D > 30 ng/mL at 1 and 4 months when compared to 0% and 8.2% respectively in the cholecalciferol group (p<0.01), achieving target levels in a rapid manner (Figure 1).

Achieving both therapeutic levels in the calcifediol group (Table 1). No relevant safety issues were reported for the present analysis.

Table 1.

<table>
<thead>
<tr>
<th>Basal 25(OH)D levels</th>
<th>Calcifediol (n= 146)</th>
<th>Cholecalciferol (n= 78)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10ng/mL**</td>
<td>27 (50%)</td>
<td>135 (82.5%)</td>
</tr>
<tr>
<td>&gt;20ng/mL</td>
<td>8 (14.8%)</td>
<td>62 (42.5%)</td>
</tr>
<tr>
<td>Month 1</td>
<td>25 (17.1%)</td>
<td>7 (9%)</td>
</tr>
<tr>
<td>Month 4</td>
<td>106 (72.6%)</td>
<td>31 (39.7%)</td>
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</table>

p<0.05; **p<0.01

Conclusion: Calcifediol shows a greater efficacy than cholecalciferol regime (as recommended in therapeutic guidelines), for the treatment of vitamin D deficiency in postmenopausal women and in a timely manner, which could impact osteoporosis treatment. Cholecalciferol fails to achieve recommended levels in a significant proportion of this population. Baseline vitamin D levels are to be considered for the supplementation of vitamin D.

References:

Disclosure of Interests: None declared