Background: Tumor necrosis factor inhibitors (TNFi) have become a mainstay of management for axial spondyloarthritis (axSpA). However, it remains unclear whether patients with axSpA should continue the standard-dose TNFi after achieving stable disease activity. Although complete discontinuation of TNFi is followed by early relapse in most cases, several studies documented that reduced doses of TNFi in patients with prolonged low disease activity showed similar effects on disease control and drug survival compared to standard dose of TNFi. One of the main problems in the dose-tapering strategies for TNFi is a selection of the appropriate patient. However, there has been a lack of robust evidence regarding clinical factors predicting the flare after tapering of TNFi in patients with axSpA.

Objectives: This study aims to develop and validate the prediction model to select the patients in whom tapering of TNFi does not lead to flare.

Methods: We used the data from the Korean College of Rheumatology Biologics registry, which included a total of 1,730 patients receiving biologic DMARD from 2017 to 2019 in South Korea. In this study, a total of 526 patients who were initially treated with the standard-dose TNFi and tapered the dose after at least 1 year of the treatment were analyzed. Dose quotient (DQ, 0-1) was applied to quantified TNFi used during interval. The main outcome was an occurrence of flare defined as ASDAS-CRP score of ≥2.1 after 1 year of tapering TNFi. To develop the prediction model, clinical factors having relevant association (p < 0.1) with the outcome were first selected as candidate predictors. Logistic regression using a stepwise approach through backward elimination was used for the final model.

Results: Patients’ mean (SD) age was 37.5 (11.9) years, 418 (79.5%) were men, and 474 (90.1%) were HLA-B27 positive. Mean disease duration was 5.0 (6.1) years and 433 (82.3%) were TNF naïve. The mean BASFI and ASDAS-CRP at baseline were 3.4 (2.6) and 3.7 (1.0), respectively. Approximatively two-thirds of the patients (65.8%) were initiated TNFi tapering at the first 1 or 2 years from baseline. At the time of TNFi tapering, the mean DQ was 0.67 (0.15) and 381 (72.4%) were prescribed concurrently with NSAIDs, and the mean BASFI and ASDAS-CRP were 1.3 (1.8) and 1.6 (0.9), respectively. During 12 months of follow up starting from the TNFi tapering, 127 (24.1%) experienced the flare. The multivariable analysis revealed that HLA-B27 positivity (OR 3.375, 95% CI 1.161-10.075; p=0.004), inflammatory back pain (OR 2.920; 95% CI 1.283-6.648; p=0.011), ASDAS-CRP at tapering (OR 2.798; 95% CI 2.030-3.856; p<0.001), and BASFI at tapering (OR 1.214; 95% CI 1.051-1.402; p=0.008) were significantly associated with flare. Based on the results of the logistic regression analysis, the predicted probability was calculated by the following formula: P=1/[1+exp(-1.088 x HLA-B27 negativity + 1.072 x inflammatory back pain + 0.567 x psoriasis + 0.623 x family history of axSpA + 1.092 x diabetes mellitus + 0.435 x DQ at TNFI tapering + 1.029 x ASDAS-CRP at TNFI tapering + 0.194 x BASFI at TNFI tapering)]. The best cut-off value of the model to define the flare was 0.2416 (95% CI 0.176, 0.301) with sensitivity 74.0% and with specificity 81.0%, AUC = 0.828 (95% CI 0.786-0.869) indicating a good predictive performance (Figure 1). The internal validation with bootstrapping showed minimal overfitting (estimated AUC 0.794) and good calibration between observed and predicted values (calibration slope 1.110, 95% CI 0.903, 1.317; intercept 0.026, 95% CI -0.091, 0.039).

Conclusion: We developed the prediction model for the flare after 12 months of TNFI tapering in patients with axSpA. It might be applicable in real world setting, although external validation will be required in the future investigation.

REFERENCES:

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Background: Nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line treatment of axial Spondyloarthritis (axSpA) and biological disease-modifying antirheumatic drugs (bDMARDs) are effective in the management of patients refractory to NSAIDs. However, in some cases the introduction of bDMARDs is limited by absolute contraindications or patient opposition. Beyond the well-known anti-osteoclastic properties, bisphosphonates (BPs) can exert their benefits through other mechanisms, including reduction of proinflammatory cytokines (such as IL6 and TNFα), and modulation of macrophage and osteoblast activity.

Objectives: To examine the potential therapeutic properties of a BP, IV neridronate (IVNer), in patients with axSpA refractory to NSAIDs and not eligible for a second-line therapy with bDMARDs.

Methods: We retrospectively collected data of patients affected by axSpA according to ASAS classification criteria, treated with IVNer, referred to a tertiary Rheumatology Centre between Sept 2015 and Dec 2021. Patients with active disease, as defined by a BASDAI score ≥4, with active sacroilitis (SI) on MRI (according to ASAS MRI definition of active SI), who had failed/were intolerant to NSAIDs and not eligible for bDMARDs were recruited. IVNer (100mg) was given intravenously on Days 1, 4, 7, and 10, over 3h in 500ml of 0.9% saline. Response to IVNer was evaluated after 60 days from the last infusion as the mean change from baseline of BASDAI and visual analogue scale (VAS) pain score, and the improvement of MRI imaging.

Results: We included 30 patients (77% females, mean age±SD 39.0±16.8 yrs, and mean disease duration of 24±14.4 months (range 10-298). Fourteen had ankylosing spondylitis (AS), six had undifferentiated SpA, two had enteropathic arthritis, one had non-radiographic axSpA, and seven had axial spondritic arthritis. 50% had axial involvement, 30% axial and peripheral arthritis, and 20% had axial and enthesis involvement. Eleven were HLA-B27 positive. On MRI evaluation, 43% had...