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THU0376

THE EFFECT OF 8 YEARS OF TNF-A BLOCKING THERAPY ON BONE MINERAL DENSITY IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Ankylosing spondylitis (AS) is a chronic inflammatory disease that mainly affects the axial skeleton. Bone loss reflected by low bone mineral density (BMD) is a common feature of AS and can already be observed at early stages of the disease. A recent cohort study of 135 AS patients reported 7.2% improvement in lumbar spine BMD and 2.2% improvement in hip BMD after 4 years of tumor necrosis factor- α (TNF- α) blocking therapy.¹

Objectives: To assess the effect of 8 years of TNF- α blocking therapy on BMD of the lumbar spine and hip in AS patients.

Methods: Included in this study were consecutive AS outpatients from the Groningen-Leeuwarden Axial SpA (GLAS) cohort who received TNF- α blocking therapy for at least 8 years. A maximum of one switch to another TNF- α inhibitor was allowed. Patients were excluded when they used bisphosphonates at baseline or during follow-up. BMD of the lumbar spine (anterior-posterior projection L1-L4) (LS-BMD) and hip (total proximal femur) (hip-BMD) was measured at baseline, 1 year, 2 years and then bi-annually using dual-energy X-ray absorptiometry (Hologic QDR Discovery (UMCG) or Hologic QDR Delphi (MCL), Waltham, MA, USA). Z-scores, the number of SD from the normal mean corrected for age and gender, were calculated using the NHANES reference database. Low BMD was defined as lumbar spine and/or hip BMD Z-score ≤ 1 . Generalized estimating equations were used to analyze BMD over time within subjects. Pairwise contrast were used to compare baseline and follow-up visits. P values <0.05 were considered statistically significant.

Results: In total, 131 AS patients were included; 73% were male, 83% HLA-B27+, mean age was 41.3 ± 10.8 years, median symptom duration 14 years (IQR 7-24), median CRP levels 13 mg/L (IQR 6-22), and 28% had poor vitamin 25(OH)

D3 status (<50) at baseline. 27% of patients switched to a second TNF- α inhibitor during follow-up and disease activity improved significantly during treatment: mean ASDAS_{CRP} 3.8 ± 0.8 at baseline and 2.1 ± 0.9 after 8 years ($P<0.001$). At baseline, low BMD at the lumbar spine and hip was present in 34% and 19% patients, respectively. Both LS-BMD and hip BMD Z-scores were significantly improved during TNF- α blocking therapy at all follow-up visits compared to baseline. Significant improvement compared to the previous time point was found up to and including 4 years for the lumbar spine and up to and including 2 years for the hip. Thereafter, flattening of improvement was observed. Median percentage of improvement in absolute BMD after 8 years of TNF- α blocking therapy compared to baseline was 7.1% (IQR 0.8-13.5) for the lumbar spine and 1.6% (IQR -3.5-5.5) for the hip (Figure 1).

Conclusion: In AS patients with established disease, both lumbar spine and hip BMD improved significantly at group level during 8 years of TNF- α blocking therapy. This effect was most pronounced in the lumbar spine, which corresponds to the disease process in AS. Main improvements in lumbar spine BMD were observed during the first 4 years of treatment.

References:

- [1] Beek et al. J Bone Miner Res. 2019; jun;34(6):1041-8

Figure 1. Percentage improvement during 8 years of TNF- α blocking therapy on LS-BMD (A) and hip-BMD (B) in patients with AS (n=131). Box-and-whisker plots (Tukey): boxes indicate medians with interquartile ranges, + indicates mean; whiskers indicate 1.5 times interquartile distances; • indicate outliers.

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THU0377

IMPACT OF FILGOTINIB ON STRUCTURAL LESIONS IN THE SACROILIAC JOINTS AT 12 WEEKS IN PATIENTS WITH ACTIVE AXIAL SPONDYLOARTHRITIS: MAGNETIC RESONANCE IMAGING DATA FROM THE DOUBLE-BLIND, RANDOMIZED TORTUGA TRIAL

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Background: Filgotinib, an oral selective Janus kinase (JAK) 1 inhibitor, reduced disease activity and improved symptoms and inflammation of the sacroiliac joint (SIJ) and spine in patients with active axial ankylosing spondylitis (AxSpA) in the Phase 2 TORTUGA trial (NCT03117270).¹ The effects of JAK inhibitors on structural lesions in active AxSpA are unknown and optimal methods for image analysis of structural disease progression are not established.

Objectives: The aim of this post hoc analysis was to evaluate the effects of filgotinib on magnetic resonance imaging (MRI) measures of structural changes in the SIJ in patients from the TORTUGA trial, as assessed by Spondyloarthritis Research Consortium of Canada (SPARCC) SIJ Structural Scores (SSS).

Methods: TORTUGA was a multicenter, double-blind, randomized trial of 116 patients with active AxSpA treated with filgotinib 200 mg (n=58) or placebo (n=58) once daily for 12 weeks. MRI was conducted at baseline and Week 12 (or early discontinuation visit). MRIs were re-evaluated post hoc by two independent experts (blinded to time point and assigned treatment) to determine SPARCC SSS; inter-reader discrepancies were resolved by an independent adjudicator. Observed changes from baseline were evaluated using analysis of covariance

with factors for treatment, baseline value, and randomization stratification. Least-squares mean changes from baseline and between-group differences with 95% confidence intervals were calculated.

Results: MRI scans from 87 patients with an evaluable MRI at baseline and Week 12 (or early termination visit) were re-evaluated (48 filgotinib, 39 placebo). Erosion scores decreased in the filgotinib group and increased in the placebo group ($p=0.02$ for between-group difference; Table 1; Figure 1a). Backfill scores increased in the filgotinib group but not in the placebo group ($p=0.005$; Table 1; Figure 1b). There was no statistically significant between-group difference in SSS total ankylosis ($p=0.46$) or fat lesion ($p=0.17$) changes from baseline (Table 1).

Table 1. Summary of Spondyloarthritis Research Consortium of Canada Sacroiliac Joint Structural Scores.

Score	Mean (SD) BL score	LSM change from BL (95% CI) at Week 12	LSM group difference at Week 12 (95% CI)
Erosion			
FIL 200 mg	3.38 (5.34)	-0.46 (-1.31, 0.40)	-1.01 (-1.87, -0.16)
PBO	2.62 (3.76)	0.56 (-0.31, 1.42)	[$p=0.02$]
Backfill			
FIL 200 mg	1.02 (1.99)	0.76 (0.07, 1.45)	1.02 (0.32, 1.72)
PBO	1.35 (2.59)	-0.26 (-0.97, 0.45)	[$p=0.005$]
Fat metaplasia			
FIL 200 mg	4.19 (6.06)	0.37 (-0.23, 0.97)	0.43 (-0.18, 1.03)
PBO	4.35 (5.44)	-0.06 (-0.67, 0.56)	[$p=0.17$]
Ankylosis			
FIL 200 mg	9.58 (8.15)	0.14 (-0.02, 0.30)	0.06 (-0.10, 0.22)
PBO	9.83 (8.45)	0.08 (-0.08, 0.25)	[$p=0.46$]

BL, baseline; CI, confidence interval; FIL, filgotinib; LSM, least-squares mean; PBO, placebo; SD, standard deviation

Conclusion: In addition to previously reported decreases in SPARCC inflammation, filgotinib was associated with significant reduction in SIJ erosion scores and increase in backfill scores at Week 12 of the TORTUGA trial, versus placebo. Long-term effects are to be determined.

References:

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Figure 1. Cumulative probability of change from baseline to Week 12 in total erosion score (a) and total backfill score (b).

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THU0378

DO COMORBIDITIES DECREASE THE FIRST TNF-INHIBITOR RETENTION AND TREATMENT RESPONSE IN AXIAL SPONDYLOARTHRITIS PATIENTS? DATA FROM TURKBIO

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Background: The frequency of comorbidities has increased in spondyloarthritis patients compared to the general population. The effect of comorbidities on tumour necrosis factor alpha inhibitor (TNFi) drug retention and treatment response has not been well evaluated.

Objectives: The purpose of this study to assess the impact of comorbidities on the first TNFi drug survival and treatment response in patients with axial spondyloarthritis (axSpA) registered in the TURKBIO database.

Methods: In this study, the frequency of comorbidities, disease activity scores at baseline and month 6 and drug retention were recorded in AxSpA patients initiating first TNFi treatment between 2011 and 2019. Kaplan Meier plot and log rank tests were used for drug survival analysis. Cox regression analysis with HR was performed to evaluate the correlation between comorbidities and drug survival.

Results: There were 2428 patients with AxSpA (39.3% female) who used their first TNFi during the study period. Among them, a total of 770 (31%) had at least one comorbid disease. Hypertension was the most common comorbidity (9.7%), followed by the affective disorders (8%) and chronic lung disease (5.8%). The baseline characteristics of patients are shown in Table 1. The presence of any comorbidity did not impact the first TNFi retention (Figure 1). When comorbidities were analysed separately, we found that only history of cerebrovascular event was negatively associated with drug retention rate (HR: 6.9, $p=0.008$). There was no statistically significant difference in Bath AS Disease Activity Index 50% (BASDAI50) response between patients with and without comorbidity at 6 months. Less axSpA patients with comorbidity achieved a ASDAS score ≤ 2.1 compared to patients without comorbidity at 6 months.

Table 1. Baseline Characteristics of Patients

Radiographic Spondyloarthritis, n (%)	2318 (95.5)
Female, n(%)	954 (39.3)
Age, year	42.2±11.8
Age at diagnosis, years	32.5±11.3
Age at initial TNFi, years	39.4 ± 11.1
Symptom duration, years	9.7± 7.5
Time to initial TNFi, years	7±6.8
HLA-B27 positivity, n (%)	1144 (47.1)
Smokers, n (%)	1068 (44)
Baseline BASDAI	35.5±22.2
Baseline ASDAS-CRP	2.8±1.1
Baseline CRP (mg/L)	15.7±24.4
VAS global patient	46.6±28.7

-Quantitative variables are presented as mean ± SD, and qualitative variables are presented as frequency and percentage

-ASDAS-CRP, Ankylosing Spondylitis Disease Activity Score using C-reactive protein VAS, visual analogue scale

Conclusion: The results of this study demonstrated that the presence of previous cerebrovascular event decreased the first TNFi survival in patients with axSpA. It also suggested that comorbidities might decrease TNFi treatment response.