FRI0416

THE EFFICACY AND SAFETY OF ANTI-TNF A TREATMENT IN ANKYLOSING SPONDYLITIS PATIENTS WITH LATE ONSET COMPARED TO THOSE WITH ADULT ONSET; THE DATA FROM TURKBIO REGISTRY

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Background: The first symptoms of ankylosing spondylitis (AS) patients usually begin prior to 45 years, but can occur later in life.
Objectives: The purpose of this study is to evaluate the efficacy and safety of anti-TNFα treatment in late-onset AS (LoAS) patients in comparison to those with adult onset AS (AoAS).
Methods: We studied AS patients in TURKBIO registry between the dates of January 2011 and November 2018. All the patients fulfilled the modified New York criteria for AS [1] and were classified into 2 groups based on their age at symptom onset: AoAS (age>16 but ≤45 years); and LoAS (age>45 years). In both groups, the following data were compared: (1) epidemiological variables (2) clinical manifestations, including signs and symptoms at diagnosis; (3) laboratory results (4) disease activity markers and follow-up parameters (BASDAI, ASDAS-CRP and HAQ); (5) previous and current treatments (6) adverse events.
Results: A total of 2551 AS patients (91,1% with AoAS and 8.9% with LoAS) were included in the study. LoAS group had more female patients, older age, shorter disease duration and diagnostic delay, higher initial ESR and less HLA-B27 positivity compared to the AoAS (Table 1). Peripheral arthritis (not statistically significant) and dactylitis was seen more common in the LoAS. The frequency of other involvements was similar between the groups (Table1). The frequency of using drugs was similar between each groups although the use of glucocorticoids and sulphasalazine was more common in the LoAS. Switching from the first anti-TNFα treatment to the second one was more common in the AoAS. However, there was found no significant difference between the two groups in 2 or more switch ratios (Table 1). At the latest visit after the anti-TNFα therapy, the mean improvement in BASDAI was significantly higher in the AoAS (Table 2). A total of 10 (4.4%) serious adverse events were reported in LoAS and 39 (1.7%) in AoAS patients in the follow-up (HR: 2.62; 95% CI: 1.32–5.18). Severe infections were the most commonly seen serious adverse events (1.3% in LoAS and 0.8% in AoAS), followed by allergic reactions (0.9% in LoAS and 0.3% in AoAS). Tuberculosis was observed in 2 patients (0.9%) in LoAS and 9 (0.4%) in AoAS, malignancy in 3 patients (1.3%) in LoAS and 6 (0.3%) in AoAS.
Conclusion: Our data showed that almost 8.9% of the patients with AS had late-onset of symptoms. The results suggested that LoAS patients might have different demographic, clinical features, disease activity parameters at baseline. The frequency of anti-TNFα use and response rate to the treatment was also similar in LoAS to those in AoAS patients. The LoAS patients seem to have more common severe adverse events compared to the AOAS patients possibly related to their older age.

Table 1. Demographic and clinical characteristics of patients with AoAS and LoAS

	AoAS (≤45 yrs)	LoAS (>45 yrs)	p-value
N	2324	227	
Sex (male), n (%)	1411 (61)	109 (48)	0.000
Age, yrs	43.07 ± 10.26	62.10 ± 8.59	0.000
Duration of disease, yrs	14.50 ± 9.42	8.53 ± 6.27	0.000
Delay of diagnosis, yrs	6.12 ± 6.61	3.59 ± 4.37	0.000
HLA-B27 positivity, (%)	64	44	0.000
C-reactive protein (mg/L)	16.66 ± 24.32	19.20 ± 26.37	0.169
Erythrocyte sedimentation rate (mm/hr)	26.83 ± 21.56	34.47 ± 24.56	0.000
BASDAI	38.9±22.6	34.6±22.1	0.007
BASFI	29.3±22.7	30.4±23.8	0.535
ASDAS-CRP	2.70 ± 1.19	2.69 ± 1.21	0.454
HAQ	0.78±0.60	0.92±0.69	0.008
Uveitis, n (%)	192 (8)	14 (6)	0.328
Peripheral arthritis, n (%)	389 (17)	50 (22)	0.055
Enthesitis, n (%)	339 (15)	31 (14)	0.779
Dactylitis, n (%)	77 (3)	15 (7)	0.019
Inflammatory bowel disease, n (%)	41 (2)	7 (3)	0.254
Psoriasis, n (%)	30 (1)	0 (0)	0.162
Treatment, n (%)			
NSAIDs	762 (33)	70 (31)	0.600
Sulphasalazine	176 (8)	35 (15)	0.000
Methotrexate	111 (5)	16 (7)	0.179
Glucocorticoid	62 (3)	15 (7)	0.002
Anti-TNFα	1467 (63)	134 (59)	0.252
Secukinumab	31 (1)	2 (1)	0.788
Anti-TNFα switch, n (%)			
One switch	359 (15)	22 (10)	0.026
Two switch	113 (5)	7 (3)	0.297
Three switch	25 (1)	3 (1)	0.996
Four switch	8 (0.3)	0 (0)	0.792

AoAS: adult-onset ankylosing spondylitis, LoAS: late-onset ankylosing spondylitis
*Continuous variables were presented as mean ±SD for both tables

Table 2. Changes in follow-up parameters between the baseline and the latest visits in patients on biologicals

	AoAS (≤45 yrs)			LoAS (>45 yrs)		
	Baseline (mean±SD)	Latest follow-up (mean±SD)	Change (mean±SD)	Baseline (mean±SD)	Latest follow-up (mean±SD)	Change (mean±SD)
BASDAI	38.9±22.6	23.7±21.6*	15.2±23.6	34.6±22.1	23.4±21.1*	11.2±20.8**
BASFI	29.3±22.7	20.9±19.9*	8.3±20.2	30.4±23.8	24.1±23.4*	6.3±20.3
ASDAS-CRP	2.70 ± 1.19	1.98 ± 1.08*	0.72 ± 1.23	2.69 ± 1.21	2.03 ±1.08*	0.65 ± 1.17
CRP (mg/L)	16.66±24.32	11.33±18.87*	5.33±24.60	19.20±26.37	13.71±18.27*	5.49±25.25
HAQ	0.78±0.60	0.59±0.47*	0.19±0.52	0.92±0.69	0.71±0.58*	0.21±0.55

*Baseline vs the latest visits, **p<0.05**
Change between the baseline and the latest visits in AoAS vs LoAS groups, **p<0.05

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ETANERCEPT TREATMENT IN PATIENTS WITH NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS AND AN INADEQUATE RESPONSE TO NONSTEROIDAL ANTI-INFLAMMATORY DRUGS: PERIOD 1 RESULTS FROM THE RE-EMBARK TRIAL

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Background: Etanercept (ETN) is efficacious in patients with non-radiographic axial spondyloarthritis (nr-axSpA).[1] However, little is known[2] about the effect of ETN withdrawal in patients with nr-axSpA who achieved a significant clinical response.
Objectives: The primary objective of this ongoing, 3-period study is to estimate the proportion of patients with nr-axSpA who experienced a flare (Ankylosing Spondylitis Disease Activity Score with erythrocyte sedimentation rate [ASDAS-ESR] ≥2.1) within 40 weeks post-ETN withdrawal, after achieving inactive disease (ASDAS with C-reactive protein [ASDAS-CRP] <1.3). Here, we report results of the 24-week Period 1, whose goal was to generate a population of ETN-treated patients with inactive disease.
Methods: RE-EMBARK (NCT02509026) is a multicenter, open-label trial in 18-50-year-old patients with active nr-axSpA (defined as fulfillment of Assessment in Spondyloarthritis International Society [ASAS] criteria, but not modified New York criteria, plus ASDAS-CRP ≥2.1), with an inadequate response to ≥2 nonsteroidal anti-inflammatory drugs (NSAIDs),

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