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FRI0394

MAINTAINED CLINICAL REMISSION IN ANKYLOSING SPONDYLITIS PATIENTS SWITCHED FROM REFERENCE INFliximab TO ITS BIOSIMILAR. AN 18-MONTH COMPARATIVE OPEN-LABEL STUDY

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Background: switching from reference infliximab (RI) to biosimilar infliximab (BI) had no detrimental effects on efficacy and safety compared to continuous RI. However, long-term follow-up data is missing.

Objectives: the aim of this study was to evaluate if BI is equivalent to RI to maintain patients with Ankylosing Spondylitis (AS) in clinical remission, in a long-term fashion.

Methods: one hundred and nine consecutive unselected AS patients were investigated. All, followed-up at predefined times receiving RI (5mg/kg/8 weeks) and were naïve to other biologics. Patients who were in clinical remission were asked to switch from RI to BI using the same therapeutic dose. Patients switched to BI were compared with a match control group receiving continuous RI. During follow-up the demographic, clinical, laboratory parameters and comorbidities were all recorded for at least 18 months. Disease activity was measured using the Bath Ankylosing Spondylitis activity index (BASDAI), and the Ankylosing Spondylitis disease activity score (ASDAS), using the C-reactive protein. Remission was defined if patients achieved BASDAI <4 and ASDAS <1.3.

Results: twenty-one patients were excluded, nine because had no clinical remission and twelve because refused to switch. Thus, 88 were evaluated. From those, 45 switched to BI, while 43 continued receiving RI. There were no differences between groups regarding demographic, clinical and laboratory parameters. All patients were in clinical remission (BASDAI <4 and ASDAS <1.3). During follow-up, five patients from the switched group and three from the maintenance group discontinued the study. Four patients receiving BI presented nocebo effects and were switched back to the RI. Three responded well, while the fourth did not. After 18 months of treatment, all patients in both groups remained in clinical remission. No significant adverse events were noted between groups.

Conclusion: BI is equivalent to RI in maintaining AS in clinical remission for at least 18 months.

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FRI0395

SWITCHING RATE OF ANTI-TNF AGENTS IN SPONDYLOARTHRITIS PATIENTS: TREASURE – REAL LIFE DATA

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Background: In spondyloarthritis (SpA), biologic DMARDs are important treatment options in resistant patients. Inefficacy or side effects may cause switching between these drugs.

Objectives: This study aimed to determine features of patients switching from one biologic agent to another in SpA treatment and to investigate associated reasons.

Methods: This multicenter, prospective observational cohort study used the TReasure database in which web-based registration of rheumatoid arthritis and SpA patients are being performed in 15 centers across different regions of Turkey. In this study, data of SpA patients switching from one biologic agent to another were analyzed. Demographic and clinical data, follow-up duration, time to switch, and reasons for switching were retrieved from the database. Kaplan-Meier analysis was performed to show drug retention rates and Cox regression analysis was performed to investigate the factors affecting switching.

Results: Of the included 3138 SpA patients, 1165 (37.1%) switched to another biologic agent (switched group) and 1973 (62.9%) continued to receive their current therapies (continued group). The median follow-up duration of all patients was 3.8 years and the median time to switch was 1.0 years (0-13.4 years). According to the distribution of comorbidities, the rates of patients having diabetes mellitus, hyperlipidemia, asthma, gastrointestinal bleeding, and cancer were significantly higher in the switched group than those of in the continued group (8.4% vs. 5.8%, p=0.006; 14.5% vs. 9.2%, p<0.001; 15.6% vs. 6.2%, p<0.001; 3.2% vs. 1.8%, p=0.018; and 1.0% vs. 0.3%, p=0.019; respectively). Features of the patients are presented in Table 1. Cox regression analysis revealed that female gender HR 1.47 (95% CI 1.24-1.75), p<0.001, disease duration HR 1.016 (95%CI 1.00-1.03), p=0.009, and BASDAI score HR 1.095 (95%CI 1.05-1.14), p<0.001 were the significant increasing factors for switching from one biologic agent to another.

In the switched group (n=1165), the main reasons for switching were secondary inefficacy (n=351), primary inefficacy (n=328), and side effects (n=267) followed by primary or secondary unknown inefficacy (n=57), physician's request (n=45), patient's demand (n=36), willing to be pregnant (n=9), other (n=37), and unknown (n=70).

	Adalimumab	Etanercept	Golimumab	Infliximab
Etanercept	0,329			
Golimumab	0,016	0,004		
Infliximab	0,003	0,069	<0,001	
Certolizumab	0,002	<0,001	0,197	<0,001

Figure 1. Kaplan-Meier curve for drug retention rates in the switched group

Conclusion: In SpA patients, switching was frequent between anti-TNF agents and the median time to first switch was 1 year. Female gender, short disease duration, and lower BASDAI score were found to be the significant factors affecting switching from the anti-TNF agent used at first. The main reasons for this switching were primary (29.0%) and secondary (31.0%) inefficacy followed by side effects (23.6%). Switching between subcutaneous anti-TNF agents is generally less than switching from infliximab to another biologic agent.

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