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FRI0394 MAINTAINED CLINICAL REMISSION IN ANKYLOSING SPONDYLITIS PATIENTS SWITCHED FROM REFERENCE INFLIXIMABTO 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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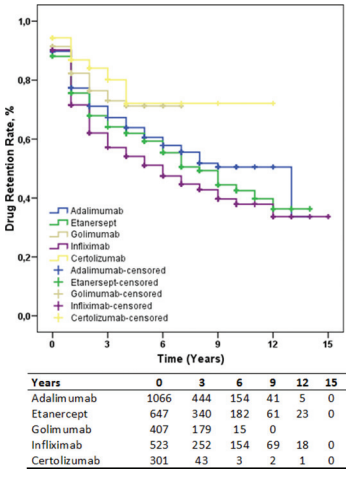
Background: In spondyloarthritis (SpA), biologic DMARDs are important treatment options in resistant patients. Inefficacy or side effects may cause switching between these drugs.
Objectives: This study aimed to determine features of patients switching from one biologic agent to another in SpA treatment 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	Etanersept	Golimumab	Infliximab
Etanersept	0,329			
Golimumab	**0,016**	**0,004**		
Infliximab	**0,003**	0,069	**<0,001**	
Certolizumab	**0,002**	**<0,001**	0,197	**<0,001**



Years	0	3	6	9	12	15
Adalimumab	1066	444	154	41	5	0
Etanercept	647	340	182	61	23	0
Golimumab	407	179	15	0		
Infliximab	523	252	154	69	18	0
Certolizumab	301	43	3	2	1	0

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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FRI0396 CHARACTERIZATION OF PATIENTS WITH INFLAMMATORY BOWEL DISEASE IN THE ANKYLOSING SPONDYLITIS COHORT PRIOR AND DURING ADALIMUMAB TREATMENT: DATA FROM A LARGE GERMAN NON-INTERVENTIONAL STUDY

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Background: Spondylarthritidies (SpA) are characterized by different disease manifestations such as arthritis, enthesitis, dactylitis and associated to concomitant diseases like Inflammatory bowel diseases (IBD) including ulcerative colitis (UC) and crohn's disease (CD). IBD might have a specific role to SpA due to common pathophysiological pathways. Characteristics of the rheumatic disease and response to treatment may differ within the phenotypic manifestation and with and without associated diseases. Adalimumab (ADA) is a monoclonal antibody inhibiting TNF alpha which has demonstrated efficacy in both, nraxSpA and ankylosing spondylitis (AS) as well as for UC and CD.

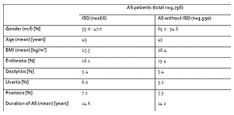
Objectives: To evaluate patient baseline characteristics prior to and treatment response on different disease manifestations in a cohort of AS patients with IBD compared to an AS without IBD during ADA treatment.

Methods: Data from a large German multicenter prospective observational non-interventional study (n=3.756) of patients with active AS who initiated ADA therapy during routine clinical care were analyzed with focus on specific patient groups: (1) patients with AS and IBD at baseline (n=166) and (2) patients with AS without IBD at baseline (n= 3.590). Patient characteristics and data of efficacy on different disease manifestations and prevalence of concomitant IBD over 24 months were analyzed.

Results: Of 3.756 patients in the main analysis set, 166 (4.4%) were identified to suffer from concomitant IBD at baseline. Baseline characteristics showed differences in gender distribution, proportion of patients with enthesitis, psoriasis and uveitis showing a higher proportion of each for the IBD group (Table). After 24 months of ADA treatment, both groups had similar decreases for BASDAI, BASMI, BASFI and dactylitis improvement. The IBD group had a fast decrease in BASDAI at M6 to its maximum improvement (delta of 1.9) which was kept stable until M24. For clearance of enthesitis, ADA had its largest therapeutic effect at M6 in the IBD group (clearance in 15.3% of the patients) while the AS without IBD group had the largest decrease of 10.2% at month 24. Resolving of uveitis with ADA therapy was more often seen in the IBD group compared to the AS without IBD (delta of 6% at M12 compared to delta of 2.6% at M12, respectively). The prevalence of IBD in AS in patients treated with ADA changed from 4.4% at baseline to 1.9% at M24.

Conclusion: Within the cohort of AS, patients' characteristics of manifestations are associated to different treatment responses: Patients identified to have IBD at baseline respond better for resolving of enthesitis and show a faster response in BASDAI compared to the group without IBD. Overall a significant reduction in the prevalence of clinically relevant IBD was seen earliest at month 3 after ADA initiation.

Table. Baseline characteristics of patients with IBD within the documented AS cohort treated with ADA



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FRI0397 EFFICACY AND SAFETY OUTCOMES IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS TREATED WITH CERTOLIZUMAB PEGOL: RESULTS FROM THE 48-WEEK RUN-IN PART OF C-OPTIMISE

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Background: C-OPTIMISE is the first trial to evaluate whether certolizumab pegol (CZP) can be reduced/discontinued in patients with radiographic(r)-axSpA/ankylosing spondylitis (AS) and non-radiographic(nr)-axSpA achieving sustained remission after 48 weeks' (wks') treatment.

Objectives: Here, we report interim efficacy and safety data for both subpopulations from the ongoing trial.

Methods: Up to Wk48**,** C-OPTIMISE (NCT02505542) was open-label (Part A), followed by 48-wk parallel-group, double-blind, placebo-controlled treatment (full dose and half dose) to Wk96 (Part B). Patients with adult-onset axSpA of <5 years' duration, fulfilling Assessment of SpondyloArthritis international Society (ASAS) classification criteria, were recruited. Part A: patients received CZP 400mg at Wks0/2/4, then 200mg every 2 weeks [Q2W]); patients achieving sustained remission (Ankylosing Spondylitis Disease Activity Score [ASDAS]<1.3 at Wk32 and <2.1 at Wk36 [or vice versa], and <1.3 at Wk48) were eligible for Part B (secondary outcome). Primary outcome (not reported): percentage of patients in Part B not experiencing a flare. Missing values were imputed using non-responder imputation (NRI) and last observation carried forward (LOCF).

Results: Part A: Of 736 patients (**Table A**), 43.9% achieved sustained remission (r-axSpA/AS: 42.8%; nr-axSpA: 45.3%; NRI). At baseline, 98.5% patients had high/very high disease activity (ASDAS≥2.1); at Wk48,

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