Table 1. Data on incident SpA patients between 2010-14, divided into two groups depending on whether bDMARDs were introduced (group B) or not (group A). Pain medication and DMARD use during the whole first year after the ID are shown.

	Group A N=2741	Group B N=836	p-value
Age, mean (SD)	39 (13)	38 (11)	0.16
Proportion of females,%	53	49	0.048
Pain medication,%			
Paracetamol	21.1	24.9	0.020
NSAID	71.9	78.5	<0.001
Opioid	18.2	33.0	<0.001
DMARDs			
None	3.6	0.2	
Methotrexate	29.9	53.8	<0.001
Sulphasalazine	84.5	78.6	<0.001
Prednisolone	33.8	47.0	<0.001
Other csDMARDs	6.5	9.8	<0.001
bDMARDs	0	58.0	..

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FRI0373 5-YEARS TREATMENT EFFECT OF TNF ALPHA INHIBITOR IN EARLY AXIAL SPONDYLOARTHRITIS AND ASSOCIATED FACTORS: AN INVERSE PROBABILITY WEIGHTING ANALYSIS OF THE DESIR COHORT

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Background: Only scarce data is available on the long-term treatment effect in a real-life setting (i.e. effectiveness) of TNFi in early axial SpA forms and its predisposing associated factors; furthermore, unbiased evaluation of treatment effect in non-randomized clinical trials is challenging, and new methods have been developed to overcome prescription bias.

Objectives: a) to estimate the probability to initiate a TNFi over 5 years of follow up in real life setting using novel statistical methods to overcome prescription bias; b) to determine the long-term effectiveness of first TNFi and its predictive factors.

Methods: Observational prospective French cohort (DESIR) with 5 years of follow-up, including 708 TNFi-naïve patients early axial spondyloarthritis. Study visits were scheduled every 6 months in the first two years of follow up then yearly up to 5 years. Treatment (TNFi or other) was at the discretion of the treating rheumatologist's. The probability to initiate a TNFi was estimated by the Kaplan Meier Method, assuming non informative dropouts. Effectiveness of the first TNFi was defined as the probability to reach an ASAS40 response in both groups (TNFi vs. any other treatment) after at least 10months of exposure. To evaluate treatment effect and overcome prescription bias repeatedly occurring over time, we have applied an iterative method based on inverse propensity score (PS) weighting using a marginal structural model, that allows the integration of the repeated weights derived from the propensity score at each visit (i.e. the probability to receive the treatment at each visit). The structural model used for this analysis was a PS-weighted cox regression, to estimate the probability to present an ASAS40 response after at least 10 months of treatment. Factors predicting first TNFi effectiveness, were explored by Cox (univariate and then multivariate) regression models.

Results: Of the 708 patients included in the analysis, 258 patients initiated a first TNFi during the first five years of follow up. The probability to initiate a TNFi treatment was 41.3% [95%CI 37.2-45.1]. Among the 258 patients who received a first TNFi, 163 (63.2%) were exposed for at least 10 months. On the original data, ASAS40 response was observed in 50/163(30.7%) vs. 58/450(12.9%) patients from the TNFi and usual care groups, respectively. The likelihood of an ASAS40 response was greater in the TNFi exposed group (HR= 3.3[95%CI 2.9-3.8], p <0.0001). Male gender (HR=1.5[95%CI 1.1-2.1]), HLAB27+ (HR= 1.4 [95%CI 1.1-2.0]) and the presence of at least one objective sign of inflammation

(MRI or CRP) or structural damage (radiographic sacroiliitis) (HR= 1.7 [95%CI 1.2-2.4]) were jointly predictive of an improved outcome.

Conclusion: Our study, applying novel statistical techniques to overcome prescription bias, confirms the 5-year effectiveness of TNF alpha inhibitors (TNFi) in patients with early axial Spondyloarthritis (axSpA), and we confirm that male gender, with HLAB7 positive and the presence of at least one objective sign of inflammation or structural damage are more frequently associated with such effectiveness.

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FRI0374 THE RISK OF INFECTION BY TUMOR NECROSIS FACTOR INHIBITORS AND ITS ASSOCIATED FACTORS IN PATIENTS WITH ANKYLOSING SPONDYLITIS: RESULT FROM KOREAN NATIONAL HEALTH INSURANCE DATA

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Background: Tumor necrosis factor inhibitors (TNFi) are effective in patients who do not respond to non-steroidal anti-inflammatory drugs, or disease modifying anti-rheumatic drugs, and have been widely used in patients with ankylosing spondylitis (AS). However, there is some evidence that treatment with TNFi can increase the risk of infection in patients with AS.

Objectives: The aim of this study was to investigate the risk of infection in patients with AS treated with TNFi.

Methods: Data was obtained from insurance claims database of the Health Insurance Review & Assessment Service (HIRA) in South Korea. Patients who have been prescribed a TNFi such as etanercept (ETN), adalimumab (ADA), golimumab (GLM), and infliximab (IFX) to treat AS from 1 July 2012 to 30 June 2017 were enrolled. We evaluated the incidence rate (IR) and hazard ratio (HR) of serious infections including pneumonia, tuberculosis, and herpes zoster in each TNFi treatment group by using cox proportional hazard model. We further analyzed the HR of infection by sex.

Results: A total of 2,515 patients were included in the study, and they were prescribed ETN (n=528), ADA (n=914), GLM (n=628), or IFX (n=445). The IRs of serious infection were 1668.63, 1489.88, 1457.58, and 1399.16 per 1,000 person years (pys) in ETN, ADA, GLM, and IFX treated groups, respectively. There was no significant difference in HR of serious infection between the TNFi groups. In the subgroup analysis of major infections, there was no difference in the HR of pneumonia between TNFi groups. However, the HR of tuberculosis with IFX group was significantly higher than that with ETN (adjusted HR 8.95, 95% CI: 1.12-71.4). In herpes zoster infection, there was no difference between TNFi groups in all patients, but the adjusted HRs significantly increased with GLM (adjusted HR 15.40, 95% CI: 1.64-144.34) and IFX (adjusted HR 10.02, 95% CI: 1.12-89.9) treatment as compared to ETN in female patients.

Conclusion: Patients receiving IFX had a higher risk of contracting tuberculosis than those receiving ETN. Moreover, the risk of herpes zoster was higher in female patients treated with GLM and IFX than in those treated with ETN in Korea.

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