

clinical trial were provided by AbbVie. AbbVie participated in the interpretation of data, drafting, review, and approval of the abstract.

Disclosure of Interest: D. Opris-Belinski Consultant for: Abbvie, BMS, Pfizer, Roche, Teva and consulting fees from Abbvie, BMS, Pfizer, Roche, Teva., S. Erdes Consultant for: Abbvie, MSD, Pfizer, USB, BIOCARD, Gedeon Richter, Dr. Reddy's, Novartis., S. Grazio Consultant for: Abbvie/Abbott Lab, Roche, MSD, Eli Lilly, Pfizer, Boehringer Ingelheim, Grünenthal, Stada, Sanofi-Aventis, PharmaSwiss, Berlin-Chemie, Pliva/Teva, Belupo, Krka, consulting fees from: Abbvie/Abbott Lab, Roche, MSD, Eli Lilly, Pfizer, Grünenthal, L. Šenolt Consultant for: AbbVie, Bristol-Myers Squibb, Celgene Corporation, Eli Lilly, Merck Sharp and Dohme, Novartis, Pfizer, Samsung, Takeda, UCB., M. Hojnik Employee of: AbbVie, O. Nagy Employee of: AbbVie, L. Iosub Employee of: AbbVie, S. Szántó Consultant for: Abbvie, Bristol Myers-Squibb, Novartis, Pfizer, Roche, Teva
DOI: 10.1136/annrheumdis-2017-eular.5244

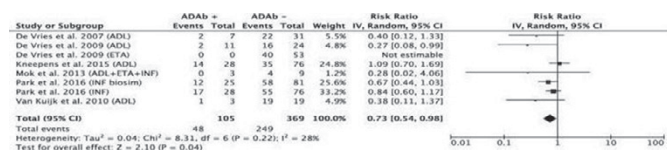
THU0364 IMMUNOGENICITY OF ANTI-TNF DRUGS AND CLINICAL RESPONSE IN PATIENTS WITH SPONDYLOARTHRITIS

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Background: Antidrug antibodies (ADAb) seem to be associated with a loss of response in immune-mediated inflammatory diseases (1) and in psoriatic arthritis (2). **Objectives:** To assess the effect of ADAb on clinical response in patients with spondyloarthritis (SpA) treated with anti-TNF drugs.

Methods: We conducted a systematic literature review of controlled trials and observational studies assessing the effect of ADAb on response to anti-TNF drugs (Adalimumab (ADL), Certolizumab (CTZ), Etanercept (ETA), Golimumab (GOL) and Infliximab (INF)) in patients with axial or peripheral SpA. Databases analysed were PubMed, the Cochrane library, and ACR/EULAR meeting abstracts, until January 2017. A meta-analysis was performed using the inverse variance approach and statistical heterogeneity was assessed with the Cochran Q-test and I² values. A statistical threshold of 5% was considered as significant.

Results: Over 1,387 publications screened, 7 studies were selected for meta-analysis (3–9). These studies were observational studies (n=6) or controlled trial (n=1); involved patients with axial or peripheral SpA (n=6) or psoriatic arthritis (n=1); included treatments with ADL (n=4), ETA (n=1), INF and INF biosimilar (n=2), or various anti-TNF drugs (n=1). ADAb rates varied between anti-TNF drugs: 0% for ETA, 13.6–31.4% for ADL, 0–28.9% for INF. Patients with ADAb were less often responders than patients without ADAb in 6 studies, more often responders in one study, while the risk ratio (RR) for response was not assessable in one study due to the absence of ADAb. The weighted pooled RR (95% CI) for response to anti-TNF drugs was 0.73 (0.54–0.98) in ADAb+ in comparison with ADAb- patients (p=0.04) (see figure). There were trends towards more infusion reactions and lower serum drug levels in patients with ADAb (data not shown).



Conclusions: According to the results of this meta-analysis, ADAb positivity is associated with a lower rate of response to anti-TNF agents in patients with SpA.

References:

- The immunogenicity of anti-TNF therapy in immune-mediated inflammatory diseases: a systematic review of the literature with a meta-analysis. *Garcés-S and al, ARD 2014; 72:1947–1955.*
- The comparative immunogenicity of biologic therapy and it's clinical relevance in psoriatic arthritis: a systematic review of the literature. *Balsa.A and al, ACR 2016, Abstract number 1691.*

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.5726

THU0365 DO EXTRA-ARTICULAR MANIFESTATIONS AFFECT THE CHOICE OF BIOLOGIC THERAPY IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS? A MULTICENTRE REAL-LIFE ANALYSIS

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Background: Extra-articular manifestations (EAMs), such as uveitis, inflammatory bowel diseases (IBD) and psoriasis (PsO), frequently complicate the disease

course of patients with axial spondyloarthritis (axSpA), although prevalence data on this regard are still controversial. The occurrence of EAMs might also contribute to the decision of introducing a biologic therapy and even influence the choice between the available TNF inhibitors (TNFi).

Objectives: The aim of this study is to retrospectively evaluate the prevalence of EAMs in a multicentre cohort of axSpA patients treated with TNFi, investigating how these influenced the choice of treatment.

Methods: Clinical data from axSpA patients treated with a TNFi between May 2003 and May 2016 were obtained from a multicentre registry. Prevalence of EAMs (uveitis, IBD and PsO) was calculated at the time of TNFi prescription, evaluating their distribution according to drug subgroup.

Results: The study included 503 patients with axSpA (172 [34.2%] women, mean age [±SD] 40.5 [±13.2] years, mean disease duration 9.7 [±14.7] years), receiving a total of 675 lines of treatment (I-line n=503, II-line n=118, ≥ III-line n=54) with a TNFi (272 infliximab [IFX], 173 adalimumab [ADA], 89 golimumab [GOL], 141 etanercept [ETN]). At the time of TNFi introduction, 28.6% patients claimed at least one EAM (IBD 11.3%, uveitis 10.9%, and PsO 8.8%). The baseline presence of at least one EAM was associated with a more frequent prescription of an anti-TNF monoclonal antibody rather than etanercept (34.1% versus 21.9%, respectively; p=0.005). In detail, EAMs were found in 41.6, 36.9, 29.8, and 21.9% patients treated with GOL, ADA, IFX, or ETN, respectively. The prevalence of IBD was significantly higher (p=0.004) in patients treated with ADA (12.7%), IFX (14.3%), or GOL (11.2%) compared with ETN (4.9%). Uveitis was numerically more frequent in GOL (20.2%) and ADA (13.3%) rather than IFX (9.5%) and ETN (9.9%) groups. Finally, PsO prevalence was similar in patients treated with ADA (10.9%) and GOL (10.1%), and numerically lower in the ETN (7.1%) and IFX (5.9%) groups.

Conclusions: In our cohort of axSpA patients treated with TNFi, EAMs were highly represented. The presence of extra-articular involvement has been carefully taken into account when a TNFi was required to better control the disease. In particular, IBD and uveitis drove more frequently the choice toward an anti-TNF monoclonal antibody instead of the receptor.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.3779

THU0366 GASTROINTESTINAL INFECTIONS IN PATIENTS WITH SPONDYLOARTHRITIS TREATED WITH ANTI-TNF DRUGS: RESULTS OF GISEA REGISTER

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Background: Tumour necrosis factor (TNF) plays a pivotal role in controlling intracellular of bacterial infection. The BSR Biologics Register (BSRBR) has reported an increase in the occurrence of listeria and salmonella infections in anti-TNF-treated rheumatoid arthritis patients in comparison with those patients treated with non-biological DMARDs.

Objectives: The aim of this study was to determine the incidence of gastrointestinal infection in the anti-TNF-treated spondyloarthritis (SpA) patients in the GISEA registry, and identify the factors associated with its development.

Methods: The prospective GISEA registry was designed to collect real-world clinical data concerning patients with RA or SpA treated with biological drugs. The baseline information includes demographics, disease duration, HAQ-DI, DAS-28, BASDAI, BASFI and BASMI scores, steroid use, smoking history and comorbidities.

Results: Of the 3321 anti-TNF-treated SpA patients in the registry (1731 males, 52.2%; mean age 47±13 years; median disease duration three years, interquartile range [IQR] 0–8), 1065 (32%) were treated with infliximab (IFN), 1052 (32%) with adalimumab (ADA), and 1204 (36%) with etanercept (ETN). Two thousand, one hundred and five patients (63.4%) had a median of one comorbidity (IQR 0–2), the most frequent being hypertension (701), thyroid diseases (281), diabetes mellitus (207), cardiopathy (189), and osteoporosis (145). In combination with the biological drug, 919 patients (27.7%) received steroids and 2451 (79.9%) at least one DMARD. The median follow-up was three months (IQR 1–2 years). Twenty-two patients 0.7% experienced bacterial gastrointestinal infections, the most frequent being due to listeria, klebsilla and salmonella. The crude incidence rate was 2.5 per 1000 patient-years (95% CI 1.6–3.7). Univariate analysis showed that female gender (OR 3.9, 95% CI 1.5–10.0; p=0.004) and comorbidities (OR 3.4, 95% CI 1.0–3.5; p=0.049) were associated with a high risk of gastrointestinal infections, and that the use of IFN rather than ETN and ADA (p=0.712 and p=0.238) was not associated with a higher risk of gastrointestinal infections.