Conclusion: This analysis of the results of treatment with anti-TNF drugs in the ATTRA Registry has shown that starting anti-TNF therapy in patients with RA and MDA leads more often to the target of remission or low activity, than in pts with HDA.

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Disclosure of Interests: Karel Pavelka Speakers bureau: Abbvie, Pfizer, Eli-Lilly, BMS, UCB, Sanofi, Novartis, Gilead, Paid instructor for: Abbvie, Consultant of: Abbvie, Pfizer, Eli-Lilly, BMS, UCB, Sanofi, Novartis, Gilead, Lucie Nekvindova: None declared, Jakub Zavada Speakers bureau: Abbvie, Eli-Lilly, UCB, Sanofi, Consultant of: Abbvie, UCB, Sanofi, Gilead

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POS0597 EFFECTS OF RITUXIMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS-RELATED INTERSTITIAL LUNG DISEASE: A SINGLE-CENTRE EXPERIENCE FROM TURKEY

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Background: Rheumatoid arthritis-related interstitial lung disease (RA-ILD) is the most common type of lung involvement in rheumatoid arthritis (RA). The existence of RA-ILD is associated with worse survival. There is no mainstay treatment for RA-ILD. However, in recent studies, rituximab (RTX) seems to be effective in RA-ILD.

Objectives: To determine the effects of RTX in patients with RA-ILD from a single-centre.

Methods: In our biological treatment outpatient clinic, a retrospective study was conducted in patients with RA who were treated with RTX. Among them, patients with RA-ILD were analysed. For lung response to RTX, progression was defined as a decline of 10% in forced vital capacity (FVC) and/or a decline of 15% in diffusion capacity of carbon monoxide (DLCO). Computed tomography of the chest (chest-CT) were integrated to lung response so as to constitute missing data of pulmonary function tests (PFTs).

Results: A total of 165 patients who are followed-up in our biological treatment outpatient clinic have been using RTX for their RA diagnosis. Among 165 patients, 26 (15.8%) patients with RA-ILD were initiated RTX. Five patients were started with RTX in LDA or HDA for other important predictive factors. The propensity score was used to match pts starting anti-TNF in MDA with HDA. The analysed population was divided into four subgroups with similar baseline characteristics (except for disease activity and quality of life). The differences between groups were significant in all evaluated intervals of 0, 3, 6, 12 months. Furthermore, a comparison of patients with MDA and HAD by propensity score matching, who no longer differ in the baseline characteristics (except for disease activity and quality of life) was performed. Patients with MDA were 2.4x more likely to achieve remission or low activity according to the Composite of Airways and Extra-ART (CAEXR) after 6 months and 1.7x more likely to achieve remission or low activity after 12 months of treatment compared to patients with HDA at the beginning of treatment.

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POS0596 THE THERAPEUTIC TARGET IS REACHED MORE OFTEN IN RA PATIENTS STARTING TNF INHIBITORS WITH MODERATE ACTIVITY THAN WITH HIGH DISEASE ACTIVITY – AN ANALYSIS FROM THE ATTRA REGISTRY

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Background: Treat to target guidelines recommend achieving remission or low disease activity in rheumatoid arthritis (RA). In the Czech Republic, anti-TNF therapy has been reimbursed only for patients with highly active RA until 2019, when pts with LDA have been also included in the reimbursement policy.

Objectives: The aim of the study was to compare the results of treatment in patients with rheumatoid arthritis and moderate disease activity (MDA) or high disease activity (HDA) starting the therapy with the first anti-TNF drug in routine clinical practice.

Methods: This was a retrospective cohort study of patients treated with the first anti-TNF drug in the Czech Republic. Propensity score was used to match pts starting anti-TNF in MDA or HDA for other important predictive factors. The propensity score was obtained by logistic regression with 10 covariates (gender, age, disease duration, seropositivity, comorbidity with MTX, comorbidity with other csDMARDs, number of previous csDMARDs, anti-TNF drug). Within the paired groups, one-dimensional logistic models were then calculated to estimate the odds of remission/low activity after 6 and 12 months of treatment.

Results: A total of 2416 patients were analyzed in the study. 2221 patients had high activity (DAS 28≥5.1) and 185 patients had moderate activity (3.2<DAS28<5.1) at baseline. After 12 months, the low activity state (DAS28<3.2) was achieved by patients with MDA in 74.0% and patients with HDA in 52.2% (p<0.001) (Fig 1). The differences between groups were significant in all evaluated intervals of 0, 3, 6, 12 months. Furthermore, a comparison of patients with MDA and HDA by propensity score matching, who no longer differ in the baseline characteristics (except for disease activity and quality of life) was performed. Patients with MDA were 2.4x more likely to achieve remission or low activity according to the Composite of Airways and Extra-ART (CAEXR) after 6 months and 1.7x more likely to achieve remission or low activity after 12 months of treatment compared to patients with HDA at the beginning of treatment.

Disclosure of Interests: The authors have declared no conflicts of interest.
Subjects with RA were treated with 50 mg of YLB113 once a week for 24 weeks. No differences in the incidence of ISRs and ISE during the 24 week treatment when the CI, WALD was -14.81%, -5.15%. For ISEs, the CI, WALD was -7.94% (-11.96%, -3.92%), Table 1. This could be explained by the absence of latex in the syringe needle cap of YLB113.

Table 1. Differences in ISRs and ISEs between YLB113 and Reference Product (RP)

<table>
<thead>
<tr>
<th>Event</th>
<th>YLB113</th>
<th>RP</th>
<th>Risk Diff (95% CI, WALD)</th>
<th>P-value (Chi-Square)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection-site erythema</td>
<td>10 (3.4%)</td>
<td>25 (9.8%)</td>
<td>-9.9% (-14.81%, -5.15%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Injection-site reactions</td>
<td>10 (3.4%)</td>
<td>25 (9.8%)</td>
<td>-9.9% (-14.81%, -5.15%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Conclusion: YLB113 has shown statistically significant lower incidences of ISRs (P-value <0.0001) and ISEs (P-value 0.0001) compared to RP. This property may translate to a better acceptability by patients.

References:


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POS0598

COMPARISON OF INJECTION SITE REACTIONS AND INJECTION SITE ERYTHEMA BETWEEN YLB113 AND ETAPLACE REFERENCE PRODUCT FROM PHASE 3 ACTIVE COMPARATOR STUDY (STUDY NO. YLB113-002)

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Background: YLB113 is an etanercept biosimilar approved in all indications of its etanercept Reference Product (RP). Therapeutic equivalence in terms of clinical efficacy, safety and immunogenicity was previously demonstrated in a pivotal multicenter, double-blind, randomized, parallel-group, active-control, comparative study (YLB113-002) in rheumatoid arthritis (RA) subjects. Similar incidence of treatment emergent adverse events (TEAEs) was seen in both treatment arms except for injection site reactions (ISRs) and injection site erythema (ISE), both of which were less frequent in subjects treated with YLB113.

Objectives: This post-hoc analysis was performed to further evaluate the differences in the incidence of ISRs and ISE during the 24 week treatment when the subjects with RA were treated with 50mg of YLB113 or RP given once a week as a SC injection along with methotrexate.

Methods: Safety analysis set (253 in YLB113 arm and 254 in RP arm) was considered for this analysis. Local reactions at the site of injection were assessed at each of eight study visits. The number of subjects who experienced ISRs and ISE were statistically compared for YLB113 and RP. The risk difference and 95% confidence interval (CI) were computed between arms to understand the magnitude of difference in the incidence of events. The statistical significance of difference between group difference was tested using chi-square test.

Results: The result of this analysis showed a statistically significant difference in the incidences of ISRs and ISE between subjects who received YLB113 and RP. The risk difference between YLB113 and RP arms for ISR was -9.9% (95% CI, WALD = 9.81% - 5.15%) and, for ISE it was -7.94% (95% CI, WALD = 11.86%, -3.92%); Table 1. This could be possibly explained by the absence of latex in the syringe needle cap of YLB113.

Disclosure of Interests: None declared
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