EPIDEMIOLOGICAL PROFILE AND CHANNELING TO TREATMENT IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH ABATACEPT OVER THE LAST 5 YEARS: DATA FROM THE SPANISH REGISTER BIOBADASER 3.0

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Background: Abatacept (ABA) is a selective T-cell co-stimulatory modulator. After its approval, changes in therapeutic recommendations, the arrival of new drugs (e.g., biosimilars or Janus kinase inhibitors) and growing focus on comprehensive patient care may have changed prescription patterns, channeling ABA use towards specific patient subtypes. To date, studies analyzing these aspects in clinical practice settings are scarce.

Objectives: We aimed to evaluate the epidemiological profile of ABA users and compare it to other DMARD groups included in the register.

Methods: We performed an observational study based on the nationwide Spanish register BIOBADASER, which includes patients with rheumatic diseases receiving biologic disease-modifying antirheumatic drugs (bDMARDs) or tumor necrosis factor inhibitors (TNFi). We analyzed biweekly groupings of all bDMARDs, by mode of action. Clinical effectiveness was assessed through drug survival obtained by the Kaplan-Meier method. Patients were right-censored if data were not available if they were still on treatment at the time of data analysis. The safety profile was assessed by the adverse events (AE) and serious AE incidence rates (IR) expressed as events per 1000 patient-years.

Results: There were 628 ABA-treated patients (71% (75%) using the subcutaneous presentation. Only 142 (23%) were on first-line while 381 (61%) were on continuous presentation. Only 142 (23%) were on first-line while 381 (61%) were on previous treatment; 186 (29%) were switched from bDMARDs to ABA. The biggest relative differences were seen for interstitial lung disease (ILD), chronic obstructive pulmonary disease (COPD), chronic obstructive pulmonary disease (COPD), diabetes and ischemic heart disease. (Table 1)

Table 1.

<table>
<thead>
<tr>
<th>N</th>
<th>ABA</th>
<th>IL-6</th>
<th>CD20</th>
<th>JAK1</th>
<th>TNFi</th>
</tr>
</thead>
<tbody>
<tr>
<td>628</td>
<td>786</td>
<td>181</td>
<td>669</td>
<td>1787</td>
<td></td>
</tr>
</tbody>
</table>

Mean age, years (SD): 64.1 (12.0) 50.7 (12.7) 63.2 (12.3) 59.6 (12.3) 60.7 (13.1)

Female sex, n (%): 482 (76) 652 (83) 135 (75) 537 (80) 1418 (79)

Median disease duration: 10.1 (2.4) 24 (9) 74

(p25-p75): (5.1-16.5) (4.6-15.9) (8.3-20.6) 15.7 (12.2) (2.1-27.3)

ACPA, n (%): 352 (76) 425 (75) 113 (79) 407 (70) 915 (72)

RF, n (%): 380 (77) 454 (77) 124 (86) 411 (70) 915 (72)

Current smokers, n (%): 98 (16) 137 (17) 338 (19) 90 (20) 259 (18)

ILD, n (%): 64 (13) 21 (3) 25 (2) 8 (2) 19 (2)

COPD, n (%): 38 (6) 23 (3) 58 (4) 14 (3) 48 (3)

Ischemic Heart Disease, n (%): 36 (6) 23 (3) 0 12 (3) 30 (2)

Diabetes, n (%): 73 (12) 66 (8) 13 (7) 46 (10) 100 (7)

Hypertension, n (%): 197 (31) 198 (25) 416 (23) 131 (30) 338 (23)

Osteoporosis, n (%): 133 (21) 141 (18) 26 (14) 72 (16) 215 (15)

IL-6: Tocilizumab and Sandumab; CD20: Rituximab and biosimilars; JAK1: Janus kinase inhibitors (Tofacitinib and Baricitinib); TNFi: TNF inhibitors and biosimilars; ACPA: anti-citrullinated peptide antibodies; RF: rheumatoid factor; ILD: interstitial lung disease; COPD: chronic obstructive pulmonary disease.

Overall, 63% of patients remained on ABA at 1 year, 48% at 2 and 31% at 5 years after drug initiation. The corresponding proportions were 79%, 65% and 52% for bionalveolar and 59%, 43% and 30% for those in third or later-line therapy. From 394 total discontinuations, loss of efficacy in 225 (57%) and AE in 98 (25%) were the main reasons. This trend was consistent among all therapy lines. The total IR of AE was 886.5 (837.3-958.5) and 156.4 (136.5-179.2) for SAE. Infections were the most frequent AE overall, IR 44.4 (34.4-57.3), and the highest IR was seen among bionaïve patients (69.4 (44.9-107.9)).

Conclusion: ABA-treated RA patients in Spain are older and have more comorbidities (vs other bDMARDs), especially ILD, COPD, ischemic heart disease and diabetes and receive ABA as third or later-line therapy. Although these factors are associated with worse response to treatment and a higher risk of infection, ABA presents a good drug survival and infectious AE are not the main cause of discontinuation.

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THE EFFECT OF RITUXIMAB BIOSIMILAR THERAPY ON THE EXPRESSION OF INTERFERON-STIMULATED GENES ("INTERFERON SIGNATURE") IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Type I interferons (IFN-αs) are a group of molecules with pleiotropic effects on the immune system forming a crucial link between innate and adaptive immune responses. The type I interferon pathway has been implicated in the pathogenesis of a number of rheumatic diseases, including rheumatoid arthritis. IFN-α activity is usually quantified using expression of interferon-stimulated genes (ISGs) referred to as an IFN signature. Acelibla (BIOCAD) is the first Russian rituximab (RTX) biosimilar which was approved for medical use in rheumatoid arthritis (RA) patients in Russia and some CIS countries.

Objectives: To evaluate the changes in expression of ISGs in patients (pts) with RA during RTX biosimilar therapy.

Methods: 20 RA pts (18 woman; MeIQ age 61.5 (54.66.5) years, disease duration 39.5 (20.84) months, mean DAS 28 5.6 (4.9-6.5).) received two intravenous RTX biosimilar infusions (600 mg Noz) in combination with DMARDs and glucocorticoids. Laboratory biomarkers were assessed at baseline and 24 weeks after the first infusion of RTX. 5 genes (IFI44L, MX1, IFIT 1, RSD2, EPST1) were selected for evaluation of the "interferon signature" (Type I IFN gene signature – IFNGS). IFI44L and IFIT1 expression was undetectable, therefore the remaining three genes (MX1, EPST1, RSD2) were included into further analysis. IFNGS was calculated as the average expression values of the three selected genes.

The control group included 20 age and gender matching healthy donors.

Results: The baseline expression levels of MX1-11.48 (5.45-19.38), EPST1-12.83 (5.62-19.64), RSD2-5.16 (2.73-10.4) and IFNGS-10.3 (5.18-17.12) in RA patients were significantly higher compared to healthy donors – 1.26 (0.73-1.6), 1.06 (0.81-1.48), 0.93 (0.72-1.19), 1.09 (0.92-1.42) (p<0.05, respectively). IFNGS was detected in 15 (75%) patients, and was not found in 5 (15%) patients. RTX induced reduction in disease activity, and the level of acute phase reactants (ESR, CRP) after 12 and 24 weeks of therapy, p<0.05 (fig.1). Increased RSAD2 expression was documented in the whole group, and also in patients with moderate therapeutic effects by week 24. Among patients with good EULAR response to therapy, changes in expression were not significant (p>0.05) (fig.1).

Disclosure of Interests: None declared

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