low rate of adverse transfusion reactions during the 18 months analyzed. The most frequent adverse reaction was shortness of breath.
Disclosure of Interest: None declared
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FRI0238 EFFECT OF BASELINE ANTI-CYCLIC CITRULLINATED PEPTIDE 3 ANTIBODY TITRE ON LONG-TERM DRUG SURVIVAL OF SUBCUTANEOUS ABATACEPT IN RHEUMATOID ARTHRITIS: A PROSPECTIVE COHORT STUDY

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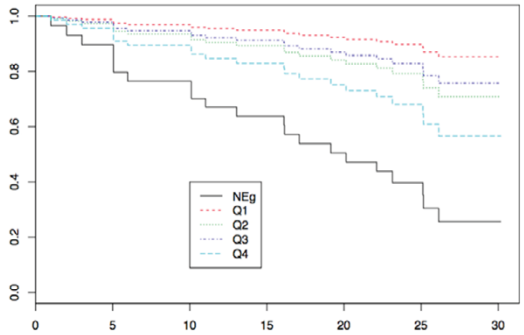
Background: Clinical response to biologics varies widely between individuals with rheumatoid arthritis (RA). To date, there are few, and in some cases, conflicting results in the personalized approach of patients with RA treated with abatacept. Only the seropositive subphenotype (anti-cyclic citrullinated peptide, CCP) was validated in several populations, including a real-life registry (ORA) [1], and non-inferiority trial (AMPLE) [2].
Objectives: To assess whether baseline anti-CCP3 antibody status and concentration correlated with drug survival of subcutaneous (SC) abatacept among patients with RA in a real-world setting.
Methods: This was a prospective study in which well-characterized patients with RA (by 1987 ACR criteria) were included from April 2014 to December 2016. Patients were evaluated at a single rheumatology outpatient center in Bogotá, Colombia. Baseline anti-CCP3 antibody status (positive/negative) and concentration were determined using an anti-CCP3 IgG ELISA (INOVA Diagnostics). Patients with a baseline anti-CCP3 IgG concentration of ≥20 U were considered to be positive and were further divided into equal quartiles according to concentration [Q1–Q4 (highest concentration)]. The Cox proportional hazards regression model was used to test if there were any differences in drug survival curves according to baseline anti-CCP3 antibody status and concentration. The test was performed by the coxph function of the "survival" R package [3].
Results: A total of 129 patients were included. Baseline characteristics: female gender 86%, mean age 52±13 years, median disease duration 10 (IQR 11) years, and erosions 35%. Treatment background was as follows: biologic-naïve (n=54), switched from IV to SC abatacept administration (n=24), and inadequate response to at least 1 biologic disease-modifying antirheumatic drug (n=51). Forty-three patients (33%) discontinued treatment. The most frequent reasons for drug suspension were loss of efficacy. Rheumatoid Factor and anti-CCP3 was positive in 94%, and 89%, respectively. Median titre of anti-CCP3 was 248 U (IQR 352), and number of patients in each quartile group were Q1 (22–122)=21; Q2 (123–248)=20; Q3 (249–475)=19; Q4 (476–1544)=19. According to Cox proportional hazards regression model (Fig.1), there were significant differences between survival curves for Q1 (HR 0.1; 0.02–0.60 95% IC; p=0.011), Q2 (HR 0.2; 0.06–0.94 95% IC; p=0.041), and Q3 (HR 0.2; 0.04–0.85 95% IC; p=0.030), compared to negative group at month 32.

Figure 1. Subcutaneous abatacept survival by anti-CCP3 antibody status.



Antibody-positive patients were divided into equal quartiles (Q1-Q4), representing increasing antibody concentrations. The duration of follow-up was 32 months.

Conclusions: Baseline anti-CCP3 positivity was associated with a better response for SC abatacept in a real-world setting. Patients with lowest baseline anti-CCP3 antibody concentrations had better drug survival than patients with higher concentrations. Our results highlight the importance of identification of factors associated with response to biologics in order to optimize treatment and reduce costs.
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FRI0239 RESULTS OF A PHASE 2B STUDY OF VOBARILIZUMAB, AN ANTI-INTERLEUKIN-6 RECEPTOR NANOBODY, AS MONOTHERAPY IN PATIENTS WITH MODERATE TO SEVERE RHEUMATOID ARTHRITIS

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Background: Vobarilizumab is a Nanobody® consisting of an anti-IL6 receptor domain and an anti-human serum albumin domain in development for treatment of RA.
Objectives: To assess the efficacy and safety of several dose regimens of vobarilizumab monotherapy administered subcutaneously to patients with active RA.
Methods: Patients with active RA who were intolerant to methotrexate (MTX) or for whom continued MTX treatment was inappropriate were randomized in a 1:1:1:1 ratio to 1 of the 3 blinded dose groups of vobarilizumab or to open-label tocilizumab (TCZ), all of which were given subcutaneously. Efficacy was evaluated descriptively at Week 12 using a number of widely accepted clinical endpoints. Adverse events and routine safety parameters including laboratory assessments were recorded. TCZ administered weekly or biweekly according to local labeling was included to obtain parallel descriptive information.
Results: The study enrolled 251 patients in Europe, Latin America and the United States. Baseline demographics and disease characteristics were well balanced across groups with mean $DAS28_{CRP}$ between 5.9 and 6.2.

Week 12 (% of patients)	Vobarilizumab 150mg q4w (N=62)	Vobarilizumab 150mg q2w (N=62)	Vobarilizumab (N=63) 225mg q2w (N=63)	Tocilizumab 162mg q1w (N=60) q2w (N=4)
ACR20	73	77	81	78
ACR50	44	37	49	45
ACR70	16	24	21	23
HAQ-DI score decrease ≥0.25	65	68	71	72
$DAS28_{ESR}$ <2.6	34	21	40	25
$DAS28_{CRP}$ <2.6	26	27	41	27
SDAI remission	8	5	8	11
CDAI remission	10	5	6	9

At Week 12, 73% to 81% of the patients assigned to one of the vobarilizumab groups achieved an ACR20 response, while ACR50 and ACR70 response rates between 37 - 49% and 16 - 24%, respectively, were observed (see table). At the end of the 12-week treatment period, clinically meaningful improvement in HAQ-DI scores and remission based on $DAS28_{CRP}$ and $DAS28_{ESR}$ was observed in a substantial number of patients treated with vobarilizumab, either q4w or biweekly. Between 5% and 10% of the patients achieved remission defined by the more stringent CDAI or SDAI criteria. In total, 94% of patients randomized to open-label TCZ received drug weekly. In spite of this disparity in dosing frequency similar efficacy results were obtained in the vobarilizumab and TCZ groups.
One vobarilizumab treated patient (225mg q2w treatment group, 1.6%) experienced a SAE during the treatment period as did 2 patients in the TCZ group (3.1%). Frequencies of treatment-emergent adverse events were similar across the groups. Of the vobarilizumab treated patients, 2.1% discontinued study drug due to TEAEs compared with 6% in the TCZ group. One case of severe hypersensitivity, not considered serious, was reported in the 225mg q2w treatment group. Liver function abnormalities were infrequent across all study groups. Grade 3 neutrophil toxicities were less commonly observed with vobarilizumab (1.1%) than with TCZ (4.3%).
Conclusions: In patients with active RA, treatment with vobarilizumab monotherapy had a positive impact on disease activity with no unexpected safety findings.
Disclosure of Interest: T. Dörner Consultant for: Ablynx, M. Weinblatt Consultant for: Ablynx, K. Van Beneden Employee of: Ablynx, E. Dombrecht Employee of: Ablynx, K. De Beuf Employee of: Ablynx, P. Schoen Employee of: Ablynx, R. Zeldin Employee of: Ablynx
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FRI0240 RHEUMATOID ARTHRITIS (RA) IMPACT FOLLOWING TREATMENT WITH SARILUMAB: PATIENT REPORTED OUTCOMES USING THE RAID SCALE FROM TWO RANDOMIZED PHASE III TRIALS

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Background: Patients with RA experience a variety of signs and symptoms and report significant physical and psychological impairment. The RA Impact of Disease (RAID) scale is a disease-specific measure of the impact of RA on patients' lives. RAID was assessed in two Phase 3 randomized trials of sarilumab,