number of previous anti-TNF, use of concomitant DMARDs and prednisone, drug retention rate at 1 year was significantly better for ABA compared to anti-TNF ($p=0.02$) and for TCZ compared to anti-TNF ($p=0.04$), but no difference was found between TCZ and ABA ($p=0.62$) (Figure).

Conclusions: Patients who received ABA following failure of RTX, seem to be older and with more comorbidities. Similar rate of good-or-moderate EULAR response was observed between patients receiving TCZ, ABA or anti-TNF. However, drug retention rate was better with TCZ and ABA compared to anti-TNF after RTX discontinuation.

Disclosure of Interest: None declared

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FRI0235 **CNCOMITANT USE OF INTRAVENOUS METHYLPREDNISOLONE TO OBTAIN HIGHER RETENTION RATE OF ABATACEPT IN RHEUMATOID ARTHRITIS**

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Background: Abatacept (ABT) is a widely used biologic for treating rheumatoid arthritis (RA).

Objectives: Concomitant use of intravenous corticosteroids with ABT infusion may contribute to achieve earlier remission and higher retention rates.

Methods: We conducted a retrospective cohort study at St. Luke's International Hospital, Tokyo, Japan, from January 2010 to June 2016. Patients who met the 2010 ACR/EULAR classification criteria for RA and treated with ABT were included in the study. We excluded patients who use two or more biologics prior to initiation of ABT. Our primary outcome was treatment retention rates of ABT at week 24. Secondary outcomes were changes in C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) during follow-up (week 0 vs. week 8). We compared these outcomes between the patients receiving concomitant intravenous methylprednisolone (mPSL) with first 3 consecutive doses of ABT and those not receiving it. Log-rank analysis and Fisher's exact test were applied for statistical analysis.

Results: 64 RA patients were included in the study. Mean age was 67.3 (± 14.2) and 55 (85.9%) were female. Among them, 13 (20.3%) received concomitant ABT with mPSL. The dosage of mPSL ranged from 30mg to 250mg (median dosage was 40mg). At week 24, the cumulative retention rates of the patients receiving mPSL (mPSL group) and those not receiving it (non-mPSL group) were 92.3% and 76.5%, respectively. There was no significant difference in the retention rates between the two groups (log-rank test, $p=0.21$) (figure). Changes in CRP between week 0 vs. week 8 were -1.56 mg/dl (± 2.92) in mPSL group and -1.08 mg/dl (± 2.17) in non-mPSL group ($p=0.22$), and those in ESR were -8.23 mm/h (± 18.40) in mPSL group and -6.61 mm/h (± 17.93) in non-mPSL group ($p=0.75$), respectively.

Kaplan-Meier curve of the cumulative retention rate of abatacept

Conclusions: This is the first real world study to investigate whether ABT administrated with intravenous mPSL maintain higher retention rates in rheumatoid arthritis. Though there was no statistically significant difference, the retention rates of ABT at 24 weeks were higher among patients receiving ABT and mPSL concomitantly, compared with ABT mono-therapy group. It may reflect rapid improvement of the disease activity.

Disclosure of Interest: None declared

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FRI0236 **AFTER DISCONTINUATION OF THE 1ST TUMOR NECROSIS FACTOR INHIBITOR (TNFI), NON-TNFI BIOLOGIC AGENTS HAVE SIMILAR RESPONSES BUT HIGHER SURVIVAL COMPARED TO A 2ND COURSE OF A DIFFERENT TNFI: LONG-TERM PROSPECTIVE OBSERVATIONAL STUDY OF PATIENTS WITH RHEUMATOID ARTHRITIS IN A TERTIARY HOSPITAL OF GREECE**

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Background: For rheumatoid arthritis (RA) patients who discontinue the first biologic agent (bDMARD), most commonly being a TNF inhibitor (TNFi), there is little evidence supporting the next best choice between a second TNFi course or a non-TNFi bDMARD in clinical practice.

Objectives: To compare the effectiveness and the adherence to therapy with non-TNFi versus TNFi administered as the second-line bDMARD in RA patients with one prior TNFi use.

Methods: All patients starting a bDMARD in the Rheumatology Department of the University Hospital of Heraklion, Crete, are included in a prospective observational study after their written informed consent. Data concerning disease activity at pre-specified time-points, drugs, comorbidities and any adverse events are recorded. For the present study we analyzed patients with RA starting their second course of a bDMARD after discontinuation of a TNFi. We compared DAS28 difference at 6 and 12 months using linear regression analysis and treatment retention using Kaplan-Meier survival curves with log-rank test.

Results: A total of 384 patients started a 2nd (different) TNFi [N=213 (Infliximab: 26, Adalimumab: 77, Etanercept: 89, Golimumab: 13 and Certolizumab: 8)] or a non-TNFi [N=171 (Rituximab:71, Abatacept:66, Tocilizumab:34)]. Patients' characteristics at baseline are described in the Table.

Two-year drug survival was higher for non-TNFi (64% vs. 39%, log rank $p<0.001$) due to lower frequency of discontinuations for primary failure ($p<0.001$) and adverse events ($p=0.019$).

δ DAS28 was comparable between non-TNFi and TNFi patient groups both at 6 [mean (SD): -1.16 (1.29) and -1.07 (1.55) respectively, $p=0.296$] and at 12 months [-1.41 (1.29) and -1.39 (1.26) respectively, $p=0.670$]. In patients who did not receive co-therapy with methotrexate, significantly greater δ DAS28 was observed with a non-TNFi (-1.25 (1.29) vs. -0.68 (1.61), $p=0.006$). When the first TNFi was discontinued due to primary failure, we observed a trend for greater δ DAS28 in the non-TNFi patient group compared to the 2nd TNFi group (-1.4 vs. -1.0, $p=0.12$) while the opposite was observed in patients who have experienced secondary failure to the 1st TNFi (-0.81 vs -1.48, $p=0.18$), but this did not reach statistical significance, probably due to the low number of available patients.

Conclusions: In RA patients who need a 2nd bDMARD after discontinuation of a TNFi, administration of a non-TNFi results in similar clinical responses but higher treatment adherence compared to a second TNFi agent. In patients who do not receive methotrexate, responses are better with a non-TNFi bDMARD.

Disclosure of Interest: None declared

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FRI0237 **SAFETY OF BIOSIMILAR INFlixIMAB USE IN A MEDICAL DAY HOSPITAL: A CASE-SERIES**

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Background: The first biosimilar anti-TNF (infliximab) approved by the EMA (European Medicines Agency) began to be used throughout Europe in 2015. Since then, it has been widely used throughout the world, even replacing the original treatment approved in 1999 Remicade® with Remsima®, a biosimilar drug. This medicine is currently approved to treat people who have been diagnosed with rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis in the field of rheumatology, in addition to ulcerative colitis (UC) or Crohn's disease (EC) in gastroenterology. However, safety data of the use of Remsima® infliximab in a medical day hospital (MDH) are lacking.

Objectives: To report intravenous and postinfusion adverse events related to intravenous Remsima® use in a medical day hospital. Besides, we will describe the rehospitalizations and continuity of treatment in the follow up.

Methods: We designed a prospective uncontrolled case-series study. Patients referred from March 2015 to October 2016 to our MDH to receive intravenous Remsima® were consecutively enrolled. Demographic data were collected, and a harmonised active monitoring strategy was applied. We recorded the indication for treatment, the doses administered and the number and symptoms of acute transfusion reactions (ATR) occurring both in the infusion period and during the 3 hour postinfusion observation interval.

Results: 2828 doses were administered, 0.67% presented ATR, all of them during the infusion and reported to the Regional Pharmacovigilance Center. 53% of those ATR were women and they were on average 35.78 years (SD 14.71). The mean dose used was 4,809 mg/kg (SD 0.47). The indications for treatment in patients suffering ATR were: EC (47%), CU (26%), Spondylitis (21%) and Psoriasis (5%). As a predominant symptom during ATR we found: shortness of breath (36.89%), pruritus (15.75%), flushing sensation (15.75%), urticaria (10.4%), alopecia (5.2%), chest pain (5.2%), paresthesia (5.2%) and nausea (5.2%). 95% of ATR showed complete recovery of the symptoms, 47% disappeared with the pause of infusion. However, they had prolonged in MDH stay, the infusion was stopped for 30 minutes and restarted at a lower rate according to the protocol. 21% of patients presenting ATR dropped out because of the symptomatology, which represents 0.14% of the total infusions.

Conclusions: Biosimilar Infliximab seems to be safe in a MDH setting, given the

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: Abylnx, M. Weinblatt Consultant for: Abylnx, K. Van Beneden Employee of: Abylnx, E. Dombrecht Employee of: Abylnx, K. De Beuf Employee of: Abylnx, P. Schoen Employee of: Abylnx, R. Zeldin Employee of: Abylnx

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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,