2019. The selected patients had initiated therapy with either TOFA or OMA (either without or in combination with MTX). The collected data include baseline characteristics (socio-demographic variables, concomitant and past medication, comorbidities and the Charlson comorbidity index (CCI)), variables measured over time (laboratory test results, patient and physician-reported outcomes, and disease activity measures such as CDAI and DAS28(4)-ESR) and persistence data (treatment duration, reason for cessation). The groups were compared to identify potential confounder, and persistence data were analyzed using Kaplan-Meier and proportional hazard methods.

Results: A total of 483 patients were initiated on TOFA (n=162) or an OMA (n=321) since January 1, 2014. Of those, 57% (n=92) and 59% (n=191) were treated with MTX in the TOFA and OMA group respectively. These represent the first treatment following csDMARD inadequate response for 33%(TOFA) and 29%(OMA) of these patients. These patients had a mean disease duration of 12.1 (standard deviation=11.0) and 11.1 (10.3) years. In the TOFA group, 84% were women, 15% were smokers, and the mean age at treatment initiation was 57.7 (11.5). In the OMA group, 75% were women, 18% were smokers, and the mean age at treatment initiation was 57.3 (12.0) years. Patient global, pain and fatigue assessments, made on a visual analogue scale ranging from 1 to 10, were 5.6 (2.5), 5.9 (2.7) and 5.7 (2.9) in the TOFA group and 5.7 (2.5), 6.1 (2.7) and 6.0 (2.8) in the OMA group. Disease activity was assessed as moderate or high/severe in 85.9% and 88.3% of patients (DAS28(4)-ESR criteria). Among the 56 (35%) TOFA and 149 (46%) OMA patients ceasing therapy, reasons for cessation were "inefficacy" (TOFA: 64% vs OMA: 59%) and "adverse events" (TOFA: 16% vs TNFi: 17%). Patients remaining on TOFA and OMA therapy at last follow-up had an average treatment duration of 1.7 (1.1) and 2.6 (1.4) years. No difference in retention was observed between TOFA and OMA treated patients (log-rank p=0.6138). Patients treated with an OMA+/-MTX had similar retention (log-rank p=0.2640) as did patients treated with TOFA+/-MTX (log-rank p=0.9553). These results remain unchanged when we adjust for age at treatment initiation, gender, disease duration, and comorbidities (CCI) using Cox models.

Conclusion: OMA and TOFA have similar retention as do subjects treated with OMA or TOFA with or without MTX.

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SAT0141

FREQUENCY AND REASONS FOR SWITCHING BACK TO BIOLOGIC ORIGINATOR FOLLOWING INITIAL SWITCH TO BIOLOGIC BIOSIMILAR

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Background: Since February 2015, a number of biosimilar drugs have been introduced for treatment of rheumatoid arthritis (RA) in the UK. Biosimilars are required to have no clinically meaningful differences in efficacy or safety from the originator product. There are clear cost-saving implications when switching patients to a biosimilar; however, the longer term implications of switching have yet to be studied.

Objectives: To describe the frequency of switching back to biologic-originator (BIO-O) in patients who initially switch from BIO-O to biologic biosimilar (BIO-B), focussing on etanercept (ETA) and infliximab (INF).

Methods: The study population comprised RA subjects recruited to BSRBR-RA to 30/11/2018 who had switched from BIO-O to BIO-B (INF and ETA) and had completed at least one further study follow-up following switch. Baseline characteristics at point of switch and the proportion of patients who were recorded as switching back to BIO-O or discontinuing BIO completely following switch with reasons are described.

Results: Nine hundred and sixty six patients were included (760 switching from ETA-O; 206 switching from INF-O). After a median follow-up of 22.5 months post-switch, the majority of patients remained on BIO-B (ETA-B = 619 (81%), INF-B =166 (81%)). Seven percent of patients switched back to originator, with a majority following reports of ineffectiveness or feeling generally unwell (Table). Eleven percent stopped BIO completely, with a majority stopping for serious adverse events such as malignancy or infection. Similar results were seen for both ETA and INF. Six ETA and 3 INF reported injection or infusion related reactions following switch (0.9% overall) leading to switch back (4 ETA) or biologic discontinuation (2 ETA/3 INF).

Conclusion: Data from this study show that the majority of patients who switched from BIO-O to BIO-B remain on the biosimilar over the short term. A small proportion of patients have switched back to the originator drug with the majority doing so for reports of ineffectiveness rather than safety concerns. Hypersensitivity reactions, such as infusion reactions were rare reasons to stop either drug completely or switch back to originator.

Table 1

Patients Switching from O to B		
N	966	
Etanercept	760 (79)	
Infliximab	206 (21)	
Age, years	66 (56-72)	
% Female	75	
Disease duration, years	20 (13-28)	
DAS28 score	3.2 (2.2-4.2)	
Time on BIO-O before switch years	11 (3-13)	
Follow-up time after switch, months	22.5 (16-25)	
Patients switching back or stopping biologic	BIO-B to BIO-O Switch back	Stop all BIO
N	71	104
Time to switch back or stop, months	5 (3-8)	7 (4-12)
Ineffectiveness	38	24
Adverse event	18	56
Drug hypersensitivity/infusion reaction	4	5
Infection	0	12
Malignancy	0	14
Generally unwell	8	2
Other AE*	2	20
AE unknown	4	3
Patient decision	2	1
Remission	0	4
Unknown	13	19

All values are median (IQR) or n(%). *Other adverse events include those that are unique events per patient

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SAT0142

DIFFERENCES IN PATIENT CHARACTERISTICS AND PATTERNS OF TREATMENT BY DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (DMARD) IN BDMA NAIVE VERSUS EXPERIENCED PATIENTS

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Background: For RA patients (pts), EULAR and ACR recommend various DMARDs. Available treatments have short durability and low persistency. Understanding differences between patients who initiate DMARDs as

biologic naïve vs experienced may help clinicians tailor treatment decisions to pts needs.

Objectives: This study aimed to compare DMARD initiation events in biologic naïve vs experienced pts.

Methods: In the Corrona registry (as of 2/28/2018), we selected DMARD initiation events (with at least one 6-month follow up) and stratified them on whether the initiator was biologic naïve or experienced. We compared pts baseline characteristics (demographic, clinical, treatment) between strata. We used Kaplan-Meier curves to describe time to discontinuation and log rank test to assess differences in persistence.

Results: For 48,246 RA pts, 10,347 DMARD initiations (index date, baseline; on 11/2012 or thereafter) in 6,858 adults were identified. Within initiations, 38% (n=3,931) occurred in bDMARD naïve pts. Females comprised 76% (naïve) vs 80% (experienced). Despite comparable age and retirement status (Table), the bDMARD experienced initiators had RA for longer (mean: 12.6 vs 5.4), were more likely to be disabled (19.6% vs 11.0%), had marginally higher CDAI scores (mean: 19.1 vs 17.6), were more likely to discontinue index treatment due to elevated CDAI (15.5% vs 10.9%), and had a shorter treatment duration (mean: 13.8 vs 15.1 months) than bDMARD naïve initiators. Persistence was higher in the bDMARD naïve than in experienced initiators (Figure)

Conclusion: The marked difference in RA duration and pts disability status, despite comparable age, confirms prior reports that bDMARD experienced pts do not respond as well to therapy as bDMARD naïve pts. The increased CDAI scores and shortened durability of response suggests that there is still a need for new efficacious and well-tolerated RA therapy.

Table. Patient and treatment characteristics

Characteristics	All initiations		bDMARD Naïve		bDMARD Experienced		p-value
	N=10,347	100%	N=3931	38%	N=6416	62%	
Demographics							
Female	8154	78.8	2992	76.1	5162	80.5	<0.0001
Age (years), mean (SD)	58.9	12.7	58.9	13.3	58.9	12.4	0.8
Disabled	1688	16.3	433	11.0	1255	19.6	<0.0001
Retired	3012	29.1	1220	31.0	1792	27.9	
RA Duration (years), mean (SD)	9.9	9.9	5.4	7.9	12.6	10.1	<0.0001
CDAI, mean (SD)	18.5	13.8	17.6	14.1	19.1	13.7	<0.0001
Therapy allocation (n, %)							
Monotherapy	3366	32.5	1496	38.1	1870	29.1	<0.0001
Combination therapy	6981	67.5	2435	61.9	4546	70.9	
Index treatment duration (months), mean (SD)	14.3	13.4	15.1	13.8	13.8	13.1	<0.0001
Reasons for discontinuation of index therapy (n, %)							
One or more reasons	4916		1624		3292		
Safety ^a	925	15.4	376	18.5	549	13.8	<0.0001
Efficacy ^b	1446	24.1	383	18.8	1063	26.8	<0.0001
CDAI>10 ^c	1421	25.8	427	10.9	994	15.5	<0.0001

a Safety: serious side effect, minor side effect, fear of future side effect, toxicity, lymphoma/malignancy, and infection.

b Efficacy: inadequate initial response, failure to maintain initial response, and lack of efficacy.

c Patients are counted as discontinuing due to high disease activity (CDAI>10) if no discontinuation reason is reported and CDAI>10 at time of discontinuation.

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SAT0143 SAFETY AND EFFECTIVENESS OF BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS IN ELDERLY PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Elderly population with rheumatoid arthritis (RA) is increasing. However, these patients are frequently excluded from clinical trials and data on effectiveness and safety of biologic Disease-Modifying Antirheumatic Drug (bDMARD) is scarce.

Objectives: To assess the persistence of 1st bDMARD and the effectiveness and safety of bDMARD among elderly (≥65 years).

Methods: Prospective multicenter cohort-study of RA patients starting a 1st bDMARD registered at Reuma.pt. Demographic and disease characteristics, comorbidities, medications, disease activity at baseline and follow up (3, 6 and 12 months) and adverse events (AE) were compared between elderly and adult (<65 years) patients. Treatment persistence was estimated using Kaplan-Meier analysis. Effectiveness was measured as EULAR crude response rates, LUNDEX corrected, and adjusted for baseline characteristics.

Results: 2400 patients were included, of which 486 aged ≥65 years (table 1). Crude median persistence in bDMARD was 19.7 months (95% CI 14-25) in adults and 14.5 (95%CI 3-26) in elderly patients (log rank test, p=0.46) (figure 1). EULAR response (crude and LUNDEX corrected) was similar in the two groups at 3 and 6 months (figure 2). After adjustment for baseline characteristics, response rate was inferior in elderly at 12 months (p=0.01). There were 697 AE reported. Except for infections, more common in elderly patients (p=0.03), the rates of severe AE, opportunistic infection, allergic reactions, cancer or hospitalizations were similar in the two groups, as well as the time to 1st AE occurrence (figure 2).

Conclusion: Our findings showed that persistence of 1st bDMARD was similar in adults and elderly RA patients. Though elderly had more severe disease and comorbidities at baseline, bDMARD treatment was equally effective and safe in the short term. However, it is necessary to consider the greater risk of infection in elderly when prescribing a biologic.

	Total	Adults	Elderly	P value
Female - N (%) N=2400	2038 (85)	1630 (85.2)	408 (84)	
Disease duration till 1st bDMARD in years - N (%) N=2074	10.3 (3.7-14.5)	7.4 (4-14)	9.6 (4-18)	<0.01
RF and/or anti-CCP positive - N (%) N=2400	1693 (70.5)	1350 (70.5)	343 (71)	
Erosive disease - N (%) N= 1639	1213 (74)	947 (73)	266 (79)	
Extraarticular manifestations - N (%) N=2400	482 (20)	383 (20)	99 (20.4)	
Hypertension - N (%) N=1769	530 (30)	381 (27)	149 (43)	<0.01
Dyslipidemia - N (%) N= 1769	141 (8)	107 (7.5)	34 (10)	
BMI - median ± IQR N=1210	27 (24-30)	26 (24-30)	27 (23-30)	
Diabetes - N (%) N= 1769	148 (8.4)	98 (7)	50 (14.3)	<0.01
Cardiovascular disease - N (%) N=1769	134 (8)	107 (7.5)	24 (10)	<0.01
DAS 28-ESR - mean ± SD N=1295	5.6 ± 1.3	5.5 ± 1.3	5.7 ± 1.3	0.02
CDAI - mean ± SD N=1069	29 ± 13	28 ± 13	31 ± 15	0.03
SDAI - mean ± SD N=1023	31 ± 14	30 ± 13	33 ± 16	0.01
HAQ-DI - mean ± SD N=1090	1.5 ± 0.6	1.4 ± 0.6	1 ± 0.7	<0.01

Table 1 - Baseline characteristics. N: number; IQR: interquartile range; SD: standard deviation; RF: Rheumatoid factor; CCP: Cyclic Citrullinated Peptide; BMI: Body Mass Index DAS: disease activity score, CDAI - clinical disease activity index, SDAI - simple disease activity index, HAQ-DI health assessment questionnaire-disability index. When p value>0,05 no value is presented.

Table 1. Baseline characteristics. N: number; IQR: interquartile range; SD: standard deviation; RF: Rheumatoid factor; CCP: Cyclic Citrullinated Peptide; BMI: Body Mass Index DAS: disease activity score, CDAI - clinical disease activity index, SDAI - simple disease activity index, HAQ-DI health assessment questionnaire-disability index. When p value>0,05 no value is presented.