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 1 st 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.

Figure 1 – Persistence in 1st bDMARD (months) for elderly and adults

Efficacy and safety	Total	Adults	Elderly	P value
EULAR response at 3 month (Lundex corrected) %	77.8 (51)	78.4 (51)	75 (51)	
EULAR response at 6 month (Lundex corrected) %	80.6 (50)	81.7 (52)	76 (45.2)	
EULAR response at 12 month (Lundex corrected) %	81.5 (35.6)	83.8 (37)	71.5 (29.3)	0.01
N patients with AE during 1st bDMARD	409	319	90	
AE infection – N (%) N=407	237 (58.2)	176 (55.3)	61 (68.5)	0.03
AE opportunistic infection – N (%) N=408	30 (7.4)	21 (6.6)	9 (10)	
AE allergic reaction – N (%) N=407	71 (17.4)	59 (18.6)	12 (13.5)	
Severe AEs – N (%) N=391	82 (21)	64 (21)	18 (20.9)	
Hospitalization – N (%) N=407	56 (13.8)	42 (13.2)	14 (15.7)	
bDMARD suspension due to AE – N (%) N=407	171 (42)	130 (40.9)	41 (46.1)	
bDMARD reintroduction after AE – N (%) N=211	61 (28.8)	48 (30)	13 (25.5)	

Figure 2 – Efficacy and safety. AE: adverse event. When p value>0.05 no value is presented.

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SAT0144

UNDERSTANDING THE LONG-TERM OUTCOME OF RITUXIMAB – IMPLICATIONS FOR MANAGEMENT

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Background: In patients with rheumatoid arthritis (RA), rituximab (RTX) is often prescribed after loss of response to TNF inhibitors; however, little is known about the long-term outcome of patients receiving treatment with RTX. Previous work [1,2] has shown that aiming for “complete B-cell depletion with clinical response” (CD-R) leads to an optimal management of the disease but unfortunately not all patients maintain this status. Whether CD-R can be regained with RTX retreatment remains unclear.

Objectives: To assess the outcome of RA patients treated with consecutive cycles of RTX, focusing on those who achieved complete B-cell depletion with clinical response.

Methods: A prospective 12 year observational study was conducted in RA patients who were treated with RTX in Leeds. Consecutive cycles of RTX consisting of 2 infusions of 1000mg were administered either on clinical relapse or a 6-monthly basis. B-cells were measured using highly sensitivity flow cytometry at 0 and 2 weeks post-RTX. Complete depletion (CD) was defined by total B-cell count $<0.0001 \times 10^9/L$ at week 2. Clinical response was defined by EULAR response criteria and CD-R was seen as the optimal outcome.

Results: 755 patients participated in the study of which 723 had complete data (see fig.1). The mean (range) number of RTX cycles administered was 3.8 (1-14). 76% (549/723) of patients reached CD-R at some stage during therapy while 24% (174/723) never did. The latter patients had a shorter period of RTX treatment vs CD-R with an OR of 7.98 after adjusting for age, gender, prior therapy with TNF-I and concomitant DMARDs (95% CI 5.86-10.86); $p<0.001$ (see fig.2). 84% of those who were retreated with RTX recovered CD-R (77% of them did it in the following cycle). Half of the patients that reached CD-R maintained it in prospective cycles but 47% lost it subsequently. A third of the patients that lost either clinical response or B-cell depletion were switched to other medication without receiving further cycles. Overall, at the end of the study, 55% of all patients treated with RTX (400/723) remained in CD-R.

Conclusion: Most patients treated with RTX will achieve CD-R, but approximately half of them will lose this optimal status at some point. In patients who achieve CD-R but subsequently lose it, retreatment with

RTX appears to be an effective strategy since 80% of them will regain it and will maintain long-term treatment with therapy

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Figure 1

Figure 2

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SAT0145

ON TAPERING THERAPY FOR RA PATIENTS IN CLINICAL REMISSION; FLARE ON CS-DMARDS IS PREDICTED BY CLINICAL PARAMETERS AND ULTRASOUND, WHEREAS T-CELL ABNORMALITIES ARE PREDICTIVE FOR B-DMARD TAPERING

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Background: Tapering of disease-modifying therapy (DMARDs) is recommended by EULAR/ACR for rheumatoid arthritis (RA) patients who achieve sustained remission on stable therapy(1,2). However, there is no guidance on how to manage this in clinical practice.

Objectives: We aimed to assess flare over 12 months in RA patients in sustained remission who were offered structured tapering of either conventional synthetic (cs) or biologic (b) DMARDs.

Methods: RA patients (ACR/EULAR 2010) prospectively attending a remission clinic were recruited when fulfilling the criteria of stable remission as defined by 3-variable DAS28CRP<2.6 for ≥ 6 months (stable therapy & no corticosteroids). Patients were offered tapering according to a structured protocol (Figure 1). For patients receiving combination cs/b-DMARDs, only the b-DMARD was tapered. Clinical, ultrasound (US) + immunological (T-cell subsets: naïve, Treg (both age-corrected) and