Table 2.

Disease-modifying drug	<70 years old	≥70 years old	p
Methotrexate	72 (53.73%)	9 (40.91%)	0.667
Leflunomide	22 (16.42%)	5 (22.73%)	
Sulfasalazine	2 (1.49%)	1 (4.55%)	
Hydroxychloroquine	6 (4.48%)	0 (0%)	
At least two of the above	7 (5.22%)	1 (4.55%)	

Conclusion: DMARD concomitant treatment has been related to a higher second biological treatment survival. This beneficial effect was not observed in RA patients ≥70 years of age whose second biological agent withdrawal cause was failure. In this age group, withdrawal related to adverse events was more frequent.

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AB0280

SURVIVAL ANALYSIS ON SECOND BIOLOGIC THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS OLDER THAN 65 YEARS

A. Briones-Figueroa¹, M. Tortosa-Cabañas¹, B. A. Blanco Cáceres¹, J. L. Morell Hita¹, J. Bachiller-Corral¹, M. Vázquez Díaz¹. ¹Ramón y Cajal University Hospital, Department of Rheumatology, Madrid, Spain

Background: Patients with Rheumatoid Arthritis (RA) ≥65 years old constitute an important and not very well studied group. Even though the course of the disease may be similar to that of younger patients, treatment is usually less aggressive given the limited information on efficacy, especially of biological treatments, in this age group.

Objectives: To describe the characteristics of patients with RA ≥65 years old who started a second biological agent. To compare the survival of this second-line treatment between patients ≥65 and <65 years old.

Methods: Retrospective, observational and longitudinal study. Patients diagnosed of RA, who started a second biological agent between 2000 and 2019, who discontinued a first-line TNF inhibitor, were included. Demographic, clinical and analytical data were obtained. The sample was divided in 2 groups: <65 and ≥65 years old. Kaplan Meier and Log-rank survival analysis were performed, as well as Cox regression to identify related factors.

Results: 157 patients were identified, 42 (26.8%) were ≥65 years old. In this group, 73.8% were women, with a mean age at the beginning of second biological treatment of 71.43±4.76 years. Demographic and clinical data of ≥65 years old patients are shown in the table. The most frequent second biological agent was Rituximab (23.8%), followed by Adalimumab (21.4%) and Tocilizumab (19%). 76.2% of patients had a disease-modifying drug associated, being Methotrexate the most frequent (45.2%). Discontinuation of second biological agent occurred in 30 patients (71.42%) ≥65 years old, which is similar to the percentage found in patients <65 years old (66.96%; p=0.70). The main causes of withdrawal of second-line agent in patients ≥65 years were adverse effects (23.8%) and secondary failure (23.8%), whereas in <65 years were primary and secondary failure (18.3% in both). Infections were more frequent in patients ≥65 years (14.3%) in comparison with patients <65 years (6.1%). In the survival analysis of the second biological agent, patients ≥65 years presented a median survival of 45 months (IC-95%=14.10-75.90); while patients <65 years had a median survival of 47 months (IC-95%=29.55-64.46), without statistically significant differences (p=0.803) (See Figure). Among elderly patients no statistically significant differences were found after comparison of survival curves in the subgroups: 65-69, 70-74 and ≥75 years. Rituximab presented a higher survival rate in patients ≥65 years (84.3 months; p<0.001), followed by Abatacept (58.5 months). Smoking (HR=13.96; IC-95%=2.12-91.93), erosions (HR=7.04; IC-95%=1.05-47.31) and diabetes mellitus (HR=13.37; IC-95%=1.25-143.46) were identified as risk factors for discontinuation of second biologic agent.

Conclusion: The survival of second biological agent after the failure of a first TNF inhibitor in patients ≥65 years is similar to the survival in younger patients, although there was a higher percentage of adverse effects in the first group. Rituximab and Abatacept showed a higher survival in patients ≥65 years. Smoking, erosions and diabetes mellitus were associated with an increased risk for the withdrawal of the second-line biological therapy.

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Variables	n= 42 (mean ± SD or %)
Age at diagnosis (years)	56.48 ± 9.94
Age at the beginning of the treatment (years)	71.43 ± 4.76
Women	31 (73.8%)
Smokers	11 (26.2%)
RF (+)	35 (83.3%)
ACPA (+)	30 (71.4%)
Erosions	29 (69%)
Arterial hypertension	21 (50%)
Diabetes mellitus	4 (9.5%)
Dyslipidemia	11 (26.2%)
Disease-modifying drug	
Methotrexate	19 (45.2%)
Leflunomide	10 (23.8%)
Sulfasalazine	1 (2.4%)
Hydroxychloroquine	0 (0%)
Infections	
Respiratory infection	3 (7.1%)
Skin/Soft tissues infections	2 (4.8%)
Herpes zoster	1 (2.4%)

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AB0281

SAFETY AND RETENTION RATE AFTER SWITCHING FROM ETANERCEPT ORIGINATOR (ETN) TO ETANERCEPT BIOSIMILAR (SB4) IN INFLAMMATORY JOINT DISEASES: DATA FROM REAL LIFE.

C. Bruni¹, S. Gentileschi², M. Capassoni¹, G. Pacini¹, M. Bardelli², C. Baldi², L. Tofani¹, L. Cometi¹, F. Nacci¹, F. Bartoli³, G. Fiori³, L. Cantarini², S. Guiducci^{1,3}, B. Frediani², M. Matucci-Cerinic^{1,3}. ¹University of Florence, Faculty of Medicine, Experimental and Clinical Medicine, Division of Rheumatology, Firenze, Italy; ²University of Siena, Medical Sciences, Surgery and Neurosciences, Rheumatology Unit, Siena, Italy; ³Careggi University Hospital, Rheumatology, Firenze, Italy

Background: SB4 is now commonly used in the treatment of inflammatory joint diseases, with evidence of efficacy and persistence up to 12 months from switching in both randomized controlled trials in Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) and Ankylosing Spondylitis (AS).

Objectives: we investigated the safety and retention rate of SB4 at 6, 12 and 18 months after switching from ETN in two rheumatology departments in our region.

Methods: adult patients with RA, PsA, AS, Juvenile Idiopathic Arthritis (JIA) and other rheumatic diseases treated with ETN for at least 6 months, switched to SB4 in stable clinical conditions, were eligible for this retrospective evaluation. Data on adverse events (in particular infectious events), loss of efficacy (articular, cutaneous, ocular or intestinal disease re-activation) and persistence on treatment were collected since latest available follow-up. Retention rate, reason for discontinuation and subsequent management data were collected at 6, 12, 18 months.

Results: 220 patients (142 females, mean age 58±7 years, disease duration 12±4 years, ETN duration 7±4 years) were enrolled, with median follow up of 12.1 (9.7-15.8) months duration; ETN was used in different biologic DMARDs treatment lines (first 76.8%, second 17.7%, third 3.2 %, fourth 2.3%). Study

population was composed of 85 RA, 81 PsA, 33 AS, 14 JIA and 7 other conditions (mostly scleroderma). In the follow-up, 50 patients (22.7%) presented with at least one non-serious adverse event, with 36 (16.4%) disease re-activation (mostly articular) and 30 (13.6% - 11 for safety and 19 loss of efficacy) SB4 interruptions. Retention rates were 99.1 (210/212) at 6, 90.9% (150/165) at 12 and 81.5% (53/65) at 18 months respectively. Back-switch to ETN was performed in 17/30 cases, the remaining cases were managed with change of bDMARD or csDMARD). Age was the only significant predictor of SB4 interruption at 6 months (OR 1.058, 95%CI 1.007-1.112, $p=0.026$), while disease, bDMARD line, csDMARD combination, gender, disease duration or ETN duration did not influence retention rates at 6, 12 or 18 months.

Conclusion: Our real-life data confirm the safety profile of switching from ETN to SB4. In our patients, the data show a higher retention rate, when compared to other-real life registries data (1,2)

References:

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AB0282

CLINICAL EFFECTIVENESS OF ABACEPT MONOTHERAPY OR ABACEPT CONCOMITANT METHOTREXATE THERAPY IN RHEUMATOID ARTHRITIS PATIENTS PREVIOUSLY TREATED WITH BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (bDMARDs)

N. Márquez Pete^{1,2}, M. D. M. Maldonado Montoro³, C. Pérez Ramírez⁴, R. Cáliz Cáliz⁵, A. Jiménez Morales⁶. ¹Virgen de las Nieves University Hospital, Pharmacy Service, Pharmacogenetics Unit, Granada, Spain; ²Universidad de Granada, Granada, Spain; ³Clínico San Cecilio University Hospital, Clinical Analysis Service, Granada, Spain; ⁴Virgen de la Macarena University Hospital, Pharmacy Service, Pharmacogenetics Unit, Sevilla, Spain; ⁵Virgen de las Nieves University Hospital, Rheumatology Service, Granada, Spain; ⁶Virgen de las Nieves University Hospital, Pharmacy Service, Granada, Spain

Background: Concomitant use of methotrexate (MTX) in abatacept (ABA) therapy is associated with good clinical response in patients with rheumatoid arthritis (RA) who are naïve to biological disease-modifying antirheumatic drugs (bDMARDs)^{1,2}. However, it is unclear when abatacept is used in patients with prior bDMARDs use³.

Objectives: We compared the effectiveness of abatacept monotherapy versus abatacept combined with methotrexate therapy in rheumatoid arthritis patients with prior bDMARDs use.

Methods: Retrospective cohorts study. Rheumatoid arthritis patients treated with abatacept between 2009 and 2019 (n=86). Socio-demographic, clinical and pharmacological characteristics of patients were collected. We compared clinical effectiveness between ABA monotherapy patients (n=49) and abatacept concomitant methotrexate therapy patients (n=37), prior treated with bDMARDs. The effectiveness was measured according to *The European League Against Rheumatism* (EULAR) response with *Disease Activity Score* (DAS28) like satisfactory (DAS28<3.2) or unsatisfactory (DAS28≥3.2), after 12 months of ABA therapy in RA patients.

Results: 49 RA patients have been evaluated in ABA monotherapy group; 83.67% (41/49) were women, disease duration was 16 (10-22) years and age of RA diagnosis was 48 (38.25-57.00). Concomitants glucocorticoids were administered in 81.63% (40/49). Rheumatoid factor (RF) was positive in 75.51% (37/49) patients and cyclic citrullinated peptide antibodies (ACPA) in 71.43% (35/49). At 12 months, 40.82% (20/49) of patients had satisfactory EULAR response.

In the combination therapy group, the age of RA diagnosis was 42.5 (35.75-53.50), 75.68% (28/37) were women and the disease duration was 12 (7-21) years. 89.19% (33/37) had concomitants glucocorticoids and the RF was positive in 72.97% (27/37) of patients. EULAR response was satisfactory at 12 months in 43.24% (16/37) of patients. No difference in treatment effectiveness was found in patients receiving abatacept in combination therapy with MTX compared with ABA monotherapy ($p=0.829$; $IC_{95}=0.35-2.35$).

Conclusion: Abatacept plus methotrexate therapy did not improve the effectiveness in rheumatoid arthritis patients with prior bDMARDs use, compared with abatacept monotherapy.

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AB0283

REDUCED HOSPITAL ADMISSION IN RA PATIENTS TAPERING BIOLOGIC DMARDs: PRELIMINARY ANALYSIS OF A RETROSPECTIVE STUDY

D. Camellino¹, A. Giusti¹, G. Girasole¹, C. Craviotto¹, P. Diana¹, A. Locaputo¹, T. Caviglia¹, L. Luca¹, G. Bianchi¹. ¹Azienda Sanitaria Locale ³, Division of Rheumatology, La Colletta Hospital, Arenzano, Italy

Background: bDMARDs are among the most effective therapies in the management of inflammatory arthritides, but they are associated with potentially severe adverse events (AEs), particularly infection. Tapering strategies of bDMARDs for patients in remission/low disease activity (R/LDA) have demonstrated comparable efficacy to standard-dose treatments, but their safety profile has not been studied yet.

Objectives: To compare the number and the causes of hospital admissions in RA patients in R/LDA continuing or tapering bDMARDs.

Methods: Consecutive patients with rheumatoid arthritis (RA) evaluated between 2011 and 2017, were assigned, based on treating physician's discretion, to continue the standard dose (STD) of bDMARDs or to undergo a predetermined tapering strategy (TAP), after being in R/LDA for two consecutive visits at least 3 months apart. Down-titration of bDMARDs was obtained by a stepwise increase of the dosing interval to achieve a reduction of about 30% (e.g. administration of etanercept every 10 days instead of weekly). Demographic, clinical data and concomitant treatments were retrospectively retrieved from the electronic charts of the outpatient clinics. Information about hospital admissions, including main diagnosis, period and duration of hospitalization, and death were retrieved from the Regional Healthcare System Database.

For the STD group, the observation period started with the occurrence of remission and finished with one of these events: loss of remission, switch to another bDMARD, withdrawal of the bDMARD, severe AE, death, end of the study period in (December 2017). For the TAP group, the observation period started with tapering onset and finished with one of these events: reduction of the dosing interval due to either a relapse (according to a DAS28 increase) or to a subjective, symptomatic relapse (according to the patient's definition), switch to another bDMARD, withdrawal of the bDMARD, severe AE, death, end of the study period in (December 2017).

Results: 81 patients were included, of whom 40 underwent TAP. Demographic, clinical and treatment data are shown in table 1. Baseline characteristics were comparable between the two groups, except for the number of previous bDMARDs before observational period entry that was slightly higher in the STD group (STD 1.0±0.9 versus TAP 0.5±0.8, $P=0.11$).

Table 1. Baseline demographic and clinical characteristics of the patients in remission or low disease activity.

	NO TAPERING (n=41)	TAPERING (n=40)	p value
Mean age (yrs)	57±11	58±13	0.563
Mean disease duration (yrs)	12±9	12±7	0.897
Starting bDMARD to tapering/monitoring (months)	52±45	67±41	0.128
Mean monitoring period (months)	22±24	19±23	0.632
Taking sDMARD at any time ((n (%))	40 (98%)	37 (92%)	0.359
Taking glucocorticoids	29 (71%)	28 (70%)	0.999
Mean prednisone dose (mg/day)	2.5±2.9	2.1±2.7	0.527
DAS28 at the time of tapering or first LDA/REM	2.3±0.8	2.3±0.9	0.863
Previous bDMARDs >1 (n (%))	10 (24.4%)	4 (10%)	0.140