diagnosed with RA and 41.3% were diagnosed with SpA. The mean disease duration was 6.7 ± 3.5 years [1-12] in patients with RA and 6.5 ± 3 [1-12] in patients with SpA. The mean Disease Activity Score (DAS28) and Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) were respectively of 4.9 ± 1.5 [1-8] and 4.1 ± 1.8 [0-9].

Therapeutically, 167 patients (56%) were on Prednisone at a mean daily posology of 8.2 ± 5.4 mg [4-60] and 70.3% on conventional synthetic disease modifying antirheumatic drug (csDMARD) in association with bDMARDs. It was about Tumor Necrosis Factor alpha antibodies (anti TNF α) in 87.9% of cases, Tocilizumab in 10.4% of cases and Rituximab in 5% of cases.

A screening of HBV was performed in 286 patients (96%). Ag HBs was positive in two cases (0.7%), and anti-HBc was positive in 16 cases (6.4%) which indicate a prior HBV infection. Fifteen patients (6%) were immunized with positive anti HBs. HBV-DNA was measured in 177 cases (66.8%) and was positive in 15 patients (6%). HCV infection was searched in 282 patients (94.6%) and anti-HCV was negative in all cases.

AST and ALT mean rates were respectively of 18.3 [2-108] and 17.9 UI/l [2-74]. A perturbation of these liver function tests was observed in 13 patients (4.4%).

Conclusion: Screening for hepatitis B and C were performed respectively in 96% and 94% of our Tunisian patients before receiving any bDMARDs. This should be systematic to avoid HBV reactivation which can lead to fulminant hepatic failure with a severe prognosis.

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AB0278

REAL LIFE EXPERIENCE OF DISEASE ACTIVITY AND QUALITY OF LIFE IN PATIENTS TREATED WITH BIOLOGICAL DMARDS VERSUS TOFACITINIB.

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Background: Assessment of disease activity and quality of life are one of the main indicators for determining the effectiveness of treatment with disease-modifying antirheumatic drugs. In recent years, a new group has entered the market - target synthetic DMARDS, which prove their effectiveness in treating RA comparable to that of biological products.

Objectives: The aim of this study is to evaluate the disease activity and quality of life of patients with rheumatoid arthritis (RA) treated with biological agents in comparison with Tofacitinib (real life data from Bulgarian population) and determine whether or not the benefits of different therapies were sustained over a follow up period of 1 year.

Methods: 164 patients were selected with a mean age 55.34 ± 16 SD years, meeting the 1987 ACR and /or ACR/ EULAR (2010) classification criteria for Rheumatoid arthritis (RA). Patients were arranged according to treatment regimens: Tocilizumab (TCL) 30 patients, Certolizumab (CZP) 16, Golimumab (GOL) 22, Etanercept (ETN) 20, Adalimumab (ADA) 20, Rituximab (RTX) 16, Infliximab (INF) 20, Tofacitinib (TOF) 20. Disease activity and quality of life was the primary concern. Independent joint assessor evaluated 28 joints on baseline, 6th and 12th month's thereafter. CRP was used to measure the inflammatory process.

DAS28-CRP, clinical disease activity index (CDAI) and simplified disease activity index (SDAI) were calculated. On baseline all of the patients' groups had severe disease activity (mean DAS28-CRP > 5.2, mean CDAI > 22, mean SDAI > 26. The quality of life was evaluated via EQ-5D.

All of the patients were on stable therapy according to the inclusion criteria, and didn't interrupt any of the medications including biological or target synthetic treatment.

Results: Significant clinical improvement and statistically significant reduction in disease activity were observed in patients treated with bDMARDS and tsDMARDS within 6 months ($p < 0.005$) of treatment and after 12 months of follow-up ($p = 0.039$). The mean value of DAS28-CRP after one year follow up showed a non-inferior effect of Tofacitinib (3.04 ± 0.81) in comparison to biological treatment (TCL: 3.07 ± 0.73 ; CZP: 3.06 ± 0.65 ; GOL: 2.49 ± 0.76 ; ETN: 2.85 ± 0.55 ; ADA: 3.15 ± 0.82 ; RTX: 2.90 ± 0.70 ; INF: 3.14 ± 0.61 ; TOF: 3.04 ± 0.81). An improvement was also observed for the 6 to 12 months of follow-up as we did not detect a significant difference in the activity of the disease assessed by CDAI among the different drug groups.

The mean values showing the change of the SDAI over the study period also outline comparable profiles. All of the treatment groups achieved a rapid reduction in disease activity that continued to decrease through the 6 and 12 months period, respectively, as supported by changes in SDAI. The quality of life evaluated with EQ-5D revealed significant improvement on the 6-th month of follow up

as well as after 12th month ($p < 0.005$) without significant difference between the observed groups.

Conclusion: Real-life data show that patients on biological treatment as well as those on Tofacitinib therapy achieve a significant decrease in disease activity after one year of follow-up. This gives us reason to accept the importance of non-inferior effect of jak-inhibitors and their place in treatment of Rheumatoid arthritis.

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AB0279

IMPACT OF DISEASE-MODIFYING DRUGS IN SECOND BIOLOGICAL TREATMENT SURVIVAL IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Several studies have proposed that the immunosenescence of elderly patients with Rheumatoid Arthritis (RA) in treatment with biological therapies could eliminate the need for concomitant immunosuppression with disease-modifying drugs (DMARDs), due to a probable lower production of anti-drug antibodies; however, the evidence is limited.

Objectives: To compare the characteristics of patients with RA who started a second biological agent, according to age groups. To analyse second biological agent survival and its relationship with DMARDs.

Methods: Retrospective, observational and longitudinal study. Patients with RA who started a second biologic 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: <70 and ≥ 70 years old. A comparative analysis was performed. Kaplan-Meier curves and Log-rank were used to conduct the survival analysis.

Results: 156 patients were included. 83.3% were women, with a mean age at the beginning of second biological treatment of 54.64 ± 13.54 years. 22 patients (14.1%) were ≥ 70 years. Comparative analysis is detailed in table 1: patients ≥ 70 years presented a longer time from diagnosis to the start of biological treatment, and a higher prevalence of hypertension and diabetes mellitus. The main cause of withdrawal in this group was adverse events (46.67%) while in younger patients was treatment failure (25.27% primary failure, 29.66% secondary failure). The most frequent biological agent in ≥ 70 years was Rituximab (27.26%) while in <70 years was Etanercept (26.12%). 126 patients (80.8%) had a DMARD associated. In both groups, Methotrexate was the most frequent (table 2). The second biological agent survival analysis showed that patients who received a DMARD presented a higher survival [77 months (55.50-98.55) vs. 51.53 months (41.67-61.40); $p = 0.023$]. After conducting a survival analysis in patients whose withdrawal cause was treatment failure, DMARDs use was associated with an increased biological agent survival in patients <70 years [103.48 months (82.28-124.68) vs. 81.95 months (66.05-97.86); $p = 0.037$]; but statistical differences were not found in patients ≥ 70 years [117.33 months (82.15-152.52) vs. 65.07 months (40.72-89.42); $p = 0.291$].

Table 1.

Variable	<70 years = 134 (mean $\pm$ SD or %)	≥ 70 years = 22 (mean $\pm$ SD or %)	p
Age at diagnosis (years)	40.5 $\pm$ 12.3	58.8 $\pm$ 8.9	<0.001
Age at the beginning of the treatment (years)	51.28 $\pm$ 11.44	75.14 $\pm$ 3.5	<0.001
Time since diagnosis (years)	10.65 $\pm$ 8.20	16.27 $\pm$ 9.09	0.003
Women	113 (84.33%)	17 (77.27%)	0.373
Smokers	29 (21.64%)	2 (9.09%)	0.320
Rheumatoid factor positive	109 (81.34%)	17 (77.27%)	0.770
Anti-CCP positive	114 (90.48%)	14 (63.64%)	0.390
Erosions	92 (70.23%)	16 (72.73%)	0.576
Arterial hypertension	28 (21.37%)	14 (63.64%)	<0.001
Diabetes mellitus	3 (2.24%)	4 (18.18%)	<0.001
Retirement	91 (67.91%)	15 (68.18%)	0.980
Infections	10 (7.46%)	3 (13.64%)	0.397
Second biological agent withdrawal cause			
Primary failure	23 (25.27%)	3 (20%)	0.242
Secondary failure	27 (29.66%)	3 (20%)	
Adverse events	25 (27.47%)	7 (46.67%)	
Remission	2 (2.20%)	0 (0%)	
Exitus	3 (3.30%)	0 (0%)	
Neoplasia	3 (3.30%)	0 (0%)	

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

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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.

References:

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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.

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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