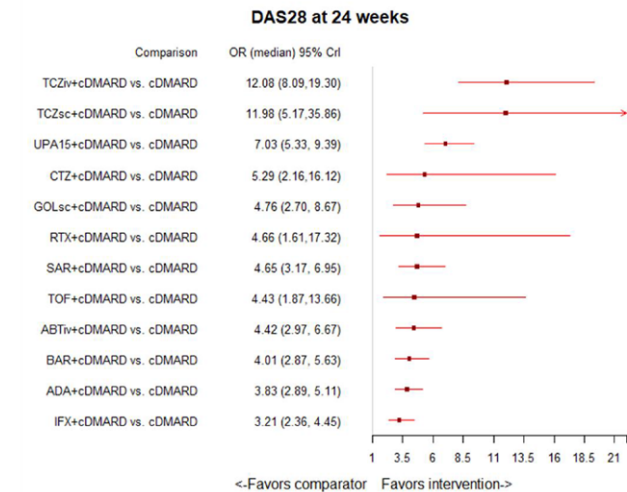


Figure 2. DAS28 at 24 weeks—All TIMs were more likely to achieve remission compared to cDMARD, but tocilizumab IV and SC had a greater magnitude of effect*



Abbreviations- ABT: Abatacept, ADA: Adalimumab, cDMARD: BAR: Baricitinib, Conventional Disease-modifying Antirheumatic Drugs, CTZ: Certolizumab pegol, CrI: credible interval, GOL: Golimumab, IFX: Infliximab, iv: intravenous, RTX: Rituximab, SAR: Sarilumab, sc: subcutaneous, TOF: Tofacitinib, TCZ: Tocilizumab, UPA: Upanaditinib (15 mg)
 * 95% CrIs that do not overlap with 1 are statistically significant
 cDMARDs are defined as systemic agents with broad immunomodulatory effects like methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine.

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AB0276 DIFFERENCES BETWEEN IMPACT OF BIOLOGICAL THERAPY AND IMPACT OF CONVENTIONAL TREATMENT ON PRODUCTIVITY AND QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Number of patients with rheumatoid arthritis in Montenegro amounts around 3,000, while 8% of them are on biological therapy. This percent is similar, or even higher in comparison to countries that are highly comparable to Montenegro. However, the percentage is still lower than in European countries.

Objectives: Objective of the study was to identify the differences between impact of biological and conventional therapy on quality of life of RA patients, their work ability and productivity, mental health, emotional state and social inclusion.

Methods: The analysis was based on data gathered from the questionnaires filled by RA patients in Montenegro: 92 patients treated with biological therapy and 78 treated with conventional therapy. More insights and information from examined patients were gathered on two focus groups. Following indicators were used in the study: two indicators that measure work ability and productivity: one monetized – Work Productivity and Activity Impairment Questionnaire General Health V2.0 (WPAI-GH) and one non-monetized – RA Work Instability Scale (RA WIS), and two indicators that measure quality of life – Health Assessment Questionnaire (HAQ-DI) and RAND 36-Item Health Survey (SF-36).

Results: WPAI-GH results are used in evaluation of absenteeism and presentism costs per RA patient per annum, which are caused exclusively by rheumatoid arthritis. WPAI-GH results are presented in the following figure. Total cost of absenteeism and presentism of RA patients in Montenegro amounts to 3.8 million EUR per annum. Results of RA WIS indicator suggest that patients treated with biological therapy are characterized by low to moderate level of work instability, and patients treated with conventional therapy by moderate level. Patients treated with biological therapy have shown 25% lower level of work instability. HAQ-DI indicator shows that both groups of patients are characterized by mild

difficulties to moderate disability in performing everyday activities. However, patients treated with conventional therapy deal with higher level of difficulties, even though their level of RA progression is lower, on average. SF-36 indicator shows that patients treated with conventional therapy have lower level of physical functioning, followed by 26% higher pain intensity. They are 25% more exposed to limitations due to physical health problems caused by RA, and 20% more to limitations due to emotional problems. Patients treated with biological therapy, on average, rate their health with 50% higher rank in comparison to subjective health rate of patients treated with conventional therapy. They also feel that their health has improved during the past year, or stayed approximately the same, while patients treated with conventional therapy feel that their health condition has aggravated, or stayed unchanged.

Conclusion: Results show that health condition, emotional state and life quality are better among the patients treated with biological therapy. Also, their productivity is higher compared to patients treated with conventional therapy. This conclusion is additionally supported by the fact that there is more progression of disease among RA patients treated with biological therapy, as well as by the fact that the average duration of RA is almost two times longer among examinees who are on biological therapy than among examinees who are on conventional therapy. Accordingly, access to biological therapy for greater number of patients in earlier stage of disease would result in reduction costs of lost productivity and work disability connected to RA, as well as in mitigation of RA impact on lives and functionality of patients.

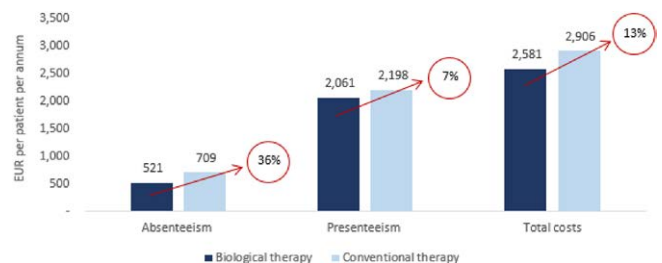


Figure 1. WPAI-GH

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AB0277 PREVALENCE OF HEPATITIS MARKERS IN PATIENTS TREATED WITH BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUGS: RESULTS OF THE TUNISIAN REGISTRY BINAR

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Background: In the recent decades, biological disease-modifying antirheumatic drugs (bDMARDs) have significantly improved management and quality of life in patients with rheumatoid arthritis (RA) and spondyloarthritis (SpA). However, bDMARDs have also a strong influence on the immune system, leading to a risk of serious infection. Reactivation of hepatitis B (HBV) and C (HCV) virus is one of the most redoubtable complications of these immunosuppressive agents.

Objectives: The aims of this study were to determine the screening rate for hepatitis B and C before starting a biological treatment and to examine the prevalence of their markers in patients with RA or SpA.

Methods: Our study evaluated all patients included in the Tunisian registry BINAR (Biologic National Registry) since 2018 who had RA (ACR/EULAR 2010) or SpA (ASAS criteria) aged with more than eighteen years old and receiving their first bDMARDs during the two past years.

The following information were retrieved from the registry: demographic data on the patients, disease parameters, medication, HBV surface antigen (HBs Ag), antibody to HBs Ag (Anti HBs), antibody to HBV core antigen (Anti HBC), HBV-DNA, antibody to HCV (anti HCV) status and liver function tests (AST: aspartate aminotransferase; ALT:alanine aminotransferase).

Results: A total of 298 patients was included, 111 men and 178 women, with a mean age of 49.2 ± 14.1 years old [18-79]. Among them, 58.7% were

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 a) 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.

Disclosure of Interests: None declared

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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 ± 16SD 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 ± SD or %)	≥70 years = 22 (mean ± SD or %)	p
Age at diagnosis (years)	40.5 ± 12.3	58.8 ± 8.9	<0.001
Age at the beginning of the treatment (years)	51.28 ± 11.44	75.14 ± 3.5	<0.001
Time since diagnosis (years)	10.65 ± 8.20	16.27 ± 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 (82.35%)	0.390
Erosions	92 (70.23%)	16 (76.19%)	0.576
Arterial hypertension	28 (21.37%)	14 (66.67%)	<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%)	