Table 1. Patient baseline characteristics

	RA (N=43)		axSpA (N=42)		PsA (N=38)	
	Mean (SD)	Q1, Q3	Mean (SD)	Q1, Q3	Mean (SD)	Q1, Q3
Age (years)	58.7 (11.3)	53, 64	52.3 (13.3)	41, 63	53.7 (14.1)	48, 63
Duration of disease (years)	6.8 (9.5)	1, 6	22.0 (14.4)	12.5, 32.5	13.8 (9.4)	5.5, 22
Women	n	%	n	%	n	%
Dosing regimen ADA to SB5:	31	72.1	16	38.1	16	42.1
40mg Q2W: 40mg Q2W	34	85.0	36	85.7	34	89.5
Other*	6	15.0	6	14.3	4	10.5
Stable disease (physician opinion)	34	91.9	27	65.9	30	85.7
Disease Activity Score:	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
DAS28 (n = 26)	2.71 (0.88)	2.36, 3.06	-	-	-	-
BASDAI (n = 31)	-	-	3.71 (2.89)	2.65, 4.77	-	-
PsA scores (n = 23)	-	-	-	-	0.3 (0.9)	-
Swollen joint	-	-	-	-	2.9 (5.7)	-0.1, 0.8
Tender joint	-	-	-	-	-	0.4, 5.4
Patient Awareness:	n	%	n	%	n	%
Instructed in self-administration	43	100.0	37	90.2	35	94.6
Know to remove SB5 from fridge 30 minutes pre-injection	43	100.0	38	95.0	36	97.3
Know SB5 can be stored out of fridge <25°C for 28 days	42	97.7	33	82.5	28	75.7

DAS-28 Disease Activity Score 28; BASDAI Bath Ankylosing Spondylitis Disease Activity Index; SD standard deviation; Q1 1st quartile, Q3 3rd quartile; CI Confidence Interval
 *Other includes all other reported doses and/or dosing intervals: 40mg QW, 80mg Q2W, and unspecified frequency

Conclusion: This interim analysis provides a first insight into a contemporary cohort of EU patients with established RA, axSpA and PsA, switched from reference to biosimilar ADA in clinical practice. The majority of patients have stable disease at transition, 85% or more of each cohort transitioned to the same dose regimen of biosimilar as received for the reference prior to transition, and most are aware of correct storage and self-administration of their biosimilar medication. With ongoing enrolment and longer follow-up, the study will provide pertinent information about clinical outcomes of transition from reference to biosimilar adalimumab in real-world practice and in indications not investigated in controlled studies.

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AB0312

REAL-LIFE DATA ON THE USE OF BIOLOGICAL DMARDS IN RHEUMATOID ARTHRITIS IN AUSTRIA WITH SPECIAL ATTENTION TO SWITCHING AFTER FIRST bDMARD FAILURE

V. Nell-Duxneuner^{1,2,3}, B. Reichardt⁴, T. Stamm^{3,5}. ¹Austrian Social Health Insurance Fund (österreichische Gesundheitskasse), Baden, Austria; ²Institute of Rheumatologie (IFR), Baden, Austria; ³Ludwig Boltzmann Institute Arthritis and Rehabilitation, Epidemiology, Vienna, Austria; ⁴Austrian Social Health Insurance Fund (österreichische Gesundheitskasse), Eisenstadt, Austria; ⁵Institute of Outcomes Research, Medical University of Vienna, Vienna, Austria

Background: The introduction of biological disease modifying anti-rheumatic drugs (bDMARDs) offered new dimensions in controlling disease progress for patients with Rheumatoid Arthritis (RA). According to the recommendations by EULAR, treatment should be commenced with a conventional synthetic DMARD as soon as diagnosis is made, followed by a bDMARD after treatment failure. The choice of drug is done in respect to comorbidities, preference of the patient and to costs.

Objectives: Drug expenditure data of 2012-2016 were retrieved to evaluate frequency of prescription and drug survival with special focus on switching habits after first bDMARD failure.

Methods: Data were extracted from 11 Austrian social health insurance funds covering 86% of the Austrian population. Only patients with first prescriptions

of bDMARDs were included. Absolute and relative frequencies of first bDMARD prescriptions, second and third courses of bDMARDs (switches) and probabilities of drug survival of first line bDMARDs were calculated. Baselines were set individually at the beginning of the first bDMARD course. A Sankey diagram was used to illustrate the relationships between first, second and third courses of bDMARDs (Figure). The first left column represents the first bDMARDs, the second and third columns the second and third switched bDMARDs, respectively. The quantity of the bDMARDs is reflected in the width of the lines.

Results: 7637 RA patients on bDMARD therapy were retrieved in total. With a presumed prevalence of 0.5% (Ref) this would account for 27% of RA patients being treated with a bDMARD. Of these, 3813 were first time prescriptions. The most commonly prescribed drug in bDMARD naïve patients was Etanercept with 26%, followed by Adalimumab with 25%. Third was Tocilizumab followed by Golimumab (16% and 15%), Abatacept with 9% and Certolizumab and Infliximab with both 4%. Tocilizumab showed the longest drug survival with 80% after one and 61% of patients still on the drug after 3 years. Golimumab was clearly favorable among TNF inhibitors with a drug survival of 71% after one and 50% after 3 years compared to Certolizumab showing the lowest with 63% after one year and only 38% after three years. Tocilizumab was the drug most often switched to after first course failure, followed by Adalimumab. The choice of second bDMARD was different: After Adalimumab failure more patients were switched to another mode of action (almost 50%), predominately Tocilizumab. This is also seen after Golimumab failure and is less pronounced in the other TNF inhibitors: they were mostly switched to second TNF inhibitor, mainly Adalimumab. The majority of patients started on Tocilizumab and Abatacept were switched to a TNF inhibitor (74% and 58%, respectively). In third DMARD choice again Tocilizumab is mostly chosen followed by Abatacept, leaving 42% to a TNF inhibitor, mostly Golimumab.

Conclusion: Patients were most often started on a TNF inhibitor as first bDMARD, namely Etanercept and Adalimumab. Golimumab was prescribed less often but showed the longest drug survival among TNF inhibitors. Tocilizumab showed the longest drug survival overall and was the bDMARD most often switched to as second bDMARD. When starting with Adalimumab or Golimumab there was a tendency towards change of mode of action, which was not as pronounced for the other three TNF inhibitors. After failing twice Tocilizumab and Abatacept were the most often prescribed drugs.

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AB0313

CLINICAL PREDICTORS OF MULTIPLE FAILURES TO BIOLOGICAL THERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS.

M. Novella-Navarro¹, C. Plasencia¹, C. Tornero¹, K. N. Franco Gomez¹, I. Monjo¹, V. Navarro-Compán¹, D. Peiteado¹, A. Balsa¹. ¹Hospital Universitario La Paz, Rheumatology, Madrid, Spain

Background: Biological therapies have improved the clinical course and quality of life of Rheumatoid Arthritis (RA) patients. Despite the availability and effectiveness of these treatments, some patients present multiple failures to biologic disease-modifying anti-rheumatic drugs (bDMARDs), constituting a challenge to clinicians.

Objectives: To determine the frequency of multiple failure to bDMARDs in RA patients and to identify baseline/early features as possible predictors of multiple failure.

Methods: This case-control study involved subjects with RA^{1,2} treated with bDMARDs from the RA-Registry at La Paz Hospital between 2000 and 2019. Patients who presented insufficient response to >3 different bDMARDs or >2 bDMARDs with different mechanism of action were considered Multi-refractory (MR-patients). Patients who achieved low disease activity or remission (by DAS-28) with the first bDMARD and maintained it in a follow-up period of at least 5 years were considered non-refractory (NR-patients). For all patients, demographic, clinical characteristics and laboratory parameters were assessed in the database at baseline visit, just prior to start bDMARD for first time and at 6-months visit. Descriptive analysis was performed, and using the "refractory status" as the dependent variable, multiple bivariate logistic regression models were performed to identify which variables should be considered in the multivariate analyses. P<0.05 was considered statistically significant. Odds Ratio (OR) and Confidence Intervals (CI) were calculated. IBM SPSS 21.0

Results: In total, 402 RA patients who had ever received bDMARD treatment were identified. According to pre-established inclusion criteria, 112 patients were included: 41 MR-patients (10%) and 71 NR-patients (18%). No differences in gender, age or age at RA diagnosis were found between both groups. Global time on bDMARD treatment was longer in MR-patients (11.7 vs 9.7 years, p=0.01) and survival on first bDMARD was 4.1±3.4 years, which was decreasing with the successive treatments. In MR-patients, shorter disease duration between RA diagnosis and starting bDMARD (6.9 vs 10.0; p=0.04) and higher number of previous cDMARDs were observed. Also presence of erosions and extra-articular manifestations were more frequent in MR-patients (58.5% vs 25.4%, p=0.03 and 29.3% vs 12.7%, p<0.001).

Results of variables included in bivariate and multivariate analyses are shown in Table 1. Finally, factors associated with multi-bDMARDs refractoriness in the multivariate analysis were presence of erosions, earlier age at bDMARD start, higher baseline DAS-28 and especially ΔDAS< 1.2 in the first 6 months of treatment (OR 11.12; 95% CI 3.34-26.82).

Table 1.

VARIABLE	Bivariate OR (95%CI)	Multivariate OR (95%CI)
Age at diagnosis	0.99 (0.96-1.0)	-
Sex (Female)	1.67 (0.58-4.73)	5.94 (0.92-38.20)
Age at bDMARD treatment	0.97 (0.93-1.00)	0.95 (0.90-0.99)
Time between diagnosis and bDMARD	0.94 (0.89-1.00)	-
Body mass index	1.01 (0.94-1.09)	-
Erosions (ref yes)	4.07 (1.79-9.26)	3.26 (1.18-9.00)
Extraarticular manifestations (ref yes)	2.81 (1.0-7.52)	2.14 (0.59-7.78)
Methotrexate (ref yes)	1.83 (0.66-5.10)	-
Previous cDMARDs	3.54 (2.05-6.1)	-
CRP baseline	1.02 (0.99-1.05)	-
DAS28 baseline	1.77 (1.2-2.6)	2.29 (1.39-3.76)
ΔDAS-28 (ref <1.2)	0.22 (0.09-0.52)	11.12 (3.34-26.82)
HAQ baseline	1.13 (1.03-1.23)	1.09 (0.92-1.29)

Conclusion: In our cohort, 10% of patients with RA were observed to have multi-refractoriness to bDMARDs. This study also identified baseline and early clinical characteristics of patients as predictors of multi-refractoriness, especially absence of clinical response during the first 6 months on a first bDMARD.

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AB0314

VIRAL HEPATITIS B REACTIVATION UNDER BIOLOGICAL THERAPY: SCREENING AND PREVENTION MODALITIES IN RHEUMATIC AND INFLAMMATORY BOWEL DISEASE PATIENTS

S. Nsibi¹, R. Ennaifer¹, B. Bouchabou¹, K. Ben Abdelghani², A. Fazaa², H. Ben Nejma¹, A. Laatar². ¹Mongi Slim Hospital, Hepatology and Gastro-Enterology, La Marsa, Tunisia; ²Mongi Slim Hospital, Rheumatology, La Marsa, Tunisia

Background: Viral hepatitis B reactivation (VHBr) is a serious complication of immunomodulatory therapy and in particular biological therapy (BT), which can be life-threatening, whence the adoption by societies of screening and prevention strategies based on the risk of VHBr which depends on serological status and the treatment used.

Objectives: The objective of our study was to determine the modalities of HBV screening, to describe the prevalence of HBV infection in this group of patients, and to evaluate the VHBr prevention strategies adopted in our country.

Methods: This was a retrospective, 8-year [2011-2018], single-centre, descriptive, retrospective study conducted in two departments: Rheumatology and Hepato-Gastroenterology. Patients under BT were included. Records with missing data were excluded. The modalities of screening and prevention of VHBr were determined and the prevalence of HBV markers was investigated.

Results: One hundred patients were included: 85 followed up for chronic inflammatory rheumatic disease: rheumatoid arthritis (n=40), ankylosing spondylitis (n=41), juvenile idiopathic arthritis (n=4) and 15 patients followed up for inflammatory bowel disease (11 Crohn's disease and 4 ulcerative colitis). The mean age was 44 years with a predominance of females (59%). The BTs prescribed were: anti-TNFα, anti-IL6 and antiCD20 in 83%, 11% and 7% respectively.

HBV screening was done in 89% of cases: HBsAg was tested in 89%, anti-HBc in 64% and anti-HBs in 43%. Complete B serology (HBsAg, anti-HBc and anti-HBs) was performed in 40%.

One patient had chronic hepatitis B on Entecavir for 3 years before starting anti-CD20 (HBsAg(+), anti-HBc(+)). A previous contact with HBV as evidenced by isolated anti-HBs(+) positivity was noted in 13 patients (20%).

A negative B serology was noted in 30 patients (30%). The vaccination rate was 10%.

Prophylaxis with Entecavir was indicated in 2 patients at high risk of viral B reactivation (candidates for anti-CD20 therapy and having anti-HBc(+) with undetectable viral load). One patient at moderate risk of reactivation (candidate for anti-TNF therapy and having anti-HBc(+)) was placed on Lamivudine for prophylaxis. Pre-emptive therapy based on monitoring of alanine aminotransferase (ALT) and HBV DNA levels every 1 to 3 months was indicated in 10 patients (with anti-HBc (+) and candidates for BT other than anti-CD20) but correctly applied in only 2 patients (20%). The remaining eight patients were monitored only for ALT levels. No cases of viral reactivation B were objectified.

Conclusion: In our study, viral hepatitis B screening was done correctly in 40% of the cases. The rate of VHBr vaccination was low (10%) despite the low cost of the vaccine. Prophylactic and pre-emptive treatment for viral reactivation were correctly applied in 100 and 20% of cases respectively. This underlines the difficulties encountered in applying pre-emptive treatment when access to HBV DNA level determination is limited and warrants more vigilance prior to the prescription of BT.

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AB0315

RETENTION RATE OF ABATACEPT MONOTHERAPY IN AN ITALIAN MULTICENTRIC RHEUMATOID ARTHRITIS COHORT

D. Iacono¹, L. Pantano², D. Birra³, G. Scalise¹, M. A. Coscia², V. Messiniti², G. Loi³, A. Merchionda³, P. Moscato³, F. Ciccio². ¹University of Campania Luigi Vanvitelli, Naples, Italy; ²University of Campania Luigi Vanvitelli, Naples, Italy; ³University of Salerno, Salerno, Italy

Background: EULAR recommendations focus the importance of Methotrexate (MTX) therapy as a key element in the treatment of patients with Rheumatoid Arthritis (RA), alone as first line therapy and in combination with biological Disease Modifying Anti-rheumatic Drug (bDMARDs). Abatacept (CTLA4-Ig) in Europe is approved for the treatment of moderate to severe active RA in combination with MTX. Several patients, however, discontinue MTX for intolerance, side effects or contraindications, and real-life data demonstrate how, even in patients receiving therapy with MTX, compliance could be suboptimal. The only data on the use of abatacept in monotherapy come from the ORA-Registry, where a worse performance is observed in monotherapy patients.

Objectives: To evaluate a multicenter cohort of RA patients treated with Abatacept in patients underwent combined MTX therapy vs monotherapy.

Methods: We retrospectively evaluated RA patients, referring to 2 Italian rheumatology centers, treated with Abatacept monotherapy or in combination with MTX. We compared both persistence in therapy and the rate of remission/low disease activity according to Clinical Disease Activity Index (CDAI) between the 2 groups.