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:

[1] Ebbers HC et al. Real-World evidence on Etanercept Biosimilar SB4 in Etanercept-Naïve or Switching Patients: A Systematic Review. Rheumatol Ther. 2019 Sep;6(3):317-338.

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AB0282 CLINICAL EFFECTIVENESS OF ABATACEPT MONOTHERAPY OR ABATACEPT CONCOMITANT METHOTREXATE THERAPY IN RHEUMATOID ARTHRITIS PATIENTS PREVIOUSLY TREATED WITH BIOLOGICAL DISEASE-MODIFYING ANTIRHEUMATIC DRUGS (BDMARDS)

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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 use[3].

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 administrated 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.

References:

[1] Genovese M, Schiff M, Luggen M, Becker J, Aranda R, Teng J, et al. Efficacy and safety of the selective co-stimulation modulator abatacept following 2 years of treatment in patients with rheumatoid arthritis and an inadequate response to anti-tumour necrosis factor therapy. Annals of the rheumatic diseases. 2008;67(4):547-54.

[2] Smolen JS, Landewe RBM, Bijlsma JWJ, Burmester GR, Dougados M, Kerschbaumer A, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2019 update. Ann Rheum Dis. 2020.

[3] Walker UA, Jaeger VK, Chatzidionysiou K, Hetland ML, Hauge E-M, Pavelka K, et al. Rituximab done: what's next in rheumatoid arthritis? A European observational longitudinal study assessing the effectiveness of biologics after rituximab treatment in rheumatoid arthritis. Rheumatology. 2016;55(2):230-6

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AB0283 REDUCED HOSPITAL ADMISSION IN RA PATIENTS TAPERING BIOLOGIC DMARDS: PRELIMINARY ANALYSIS OF A RETROSPECTIVE STUDY

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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

In the STD group, 14 hospital admissions occurred, while in the TAP group there were 7 admissions (p=0.128). The corresponding figures for hospital admission due to infectious diseases were 6 in the STD group and 0 in the TAP group (p=0.026).

Conclusion: Tapering bDMARDs in RA patients in R/LDA is associated with fewer hospital admissions, with a possible protective effect especially toward infections.

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AB0284 RHEUMATOID ARTHRITIS REFRACTORY TO BIOLOGICAL TREATMENT

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Background: In Rheumatoid arthritis (RA), between 20% and 40% of patients do not achieve a 20% improvement in American College of Rheumatology (ACR) criteria, another similar percentage loses response over time or experience adverse events that forces them to the suspension of treatment. Those patients who have failed one or more therapeutic strategies, are more refractory patients and the response to successive targets is usually lower than naive patients, with 50% ACR20 response percentages.

Objectives: To describe the clinical-analytical characteristics and response to the last treatment, in rheumatoid arthritis (RA) refractory to biological disease modifying anti-rheumatic drugs (bDMARDs) and targeted synthetic DMARDs (tsDMARDs). To identify possible factors related to refractoriness to bDMARDs and tsDMARDs.

Methods: Retrospective multicentre, controlled study of patients with RA refractory to bDMARDs and tsDMARDs. Control group was formed by patients with non-refractory RA; matched by gender, age and diseaseduration. Refractoriness was defined as failure to more than 2 different targets of bDMARDs or tsDMARDs. Demographic, clinical-analytical data and rates of disease activity and physical function were collected. A descriptive analysis, a bivariate analysis and a binary logistic regression were performed to see the variables associated with refractoriness.

Results: A total of 94 patients were selected from HRUM and HCUVV: 47 with refractory RA and 47 with non-refractory RA. The clinical-epidemiological characteristics of both groups are classified in Table 1. The majority were women with a mean age of 57 years. There was a greater proportion of patients with multimorbidity and cardiovascular risk factors among the refractory to FAMEb. All patients affected a significant improvement with the new treatment in activity and physical function at 6 months compared to baseline. Refractoriness is associated with a higher body mass index [OR(IC95%), 7.73 (1.56-8.42); p=0.012], and depression [OR(IC95%), 1.11 (1.24-1.83); p=0.035].

Table 1. Clinical-epidemiological characteristics of patients.

Variable	Refractory RA (N=47)	Non-refractory RA (N=47)	p-value
Sex (female), n (%)	38 (80,9)	38 (80,9)	1,000
Age, means (SD)	57,1 (10,8)	57,4 (10,8)	0,896
Caucasian race, n (%)	45 (95,7)	44 (93,6)	0,646
Body mass index, means (SD)	30,4 (6,8)	26,5 (3,8)	0,002
Non-smoker, n (%)	26 (55,3)	28 (59,6)	
Former smoker>6 months, n (%)	16 (34,0)	7 (14,9)	
Smoker, n (%)	5 (10,6)	12 (25,5)	
Rheumatoid Factor, n (%)	40 (85,1)	42 (89,4)	0,536
Anti-cyclic citrullinated peptide, n (%)	37 (78,7)	38 (80,9)	0,797
Erosions, n (%)	33 (70,2)	28 (59,6)	0,280
Hypertension, n (%)	24 (51,1)	20 (42,6)	0,408
Obesity, n (%)	19 (40,4)	9 (19,1)	0,024
Diabetes Mellitus, n (%)	10 (21,3)	6 (12,8)	0,272
Dyslipidemia, n (%)	20 (42,6)	15 (31,9)	0,286
Neoplasia, n (%)	2 (4,3)	0 (0,0)	0,153
Fibromyalgia, n (%)	4 (8,5)	1 (2,1)	0,168
Depression, n (%)	18 (38,3)	4 /8,5)	0,001
Multicomorbidity, n (%)	17 (36,2)	6 (12,8)	0,008
Comorbidities number, median (IQR)	2,0 (1,0-3,0)	1,0 (0,0-2,0)	0,002

Conclusion: Patients with refractory RA have an adequate response to subsequent treatment lines. These patients have a remarkable percentage of associated comorbidities.

Disclosure of Interests: None declared

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AB0285 RANDOMIZED, OPEN-LABEL, SINGLE-DOSE, PARALLEL-GROUP PHARMACOKINETIC STUDY OF PF-06410293, AN ADALIMUMAB BIOSIMILAR, BY SUBCUTANEOUS DOSING USING A PREFILLED SYRINGE OR A PREFILLED PEN IN HEALTHY SUBJECTS

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Background: Similarity in efficacy, safety, and immunogenicity (IMG) of PF-06410293 (ADL-PF), an adalimumab (ADL) biosimilar, and reference ADL sourced from the European Union (ADL-EU), by subcutaneous (SC) injection using a prefilled syringe (PFS), have been demonstrated in a randomised controlled trial in patients with rheumatoid arthritis (RA) (NCT02480153).

Objectives: To determine if the pharmacokinetics (PK), safety and tolerability of ADL-PF were similar following a single SC dose by prefilled pen (PFP) or PFS in healthy subjects (NCT02572245).

Methods: In this phase 1, 2-arm study, healthy subjects, aged 18–55 years, were randomised (1:1) to receive ADL-PF (40 mg, SC) in the lower abdomen or upper anterior thigh by PFS or PFP. Primary endpoints were maximum observed serum concentration (C_{max}) and area under the serum concentration–time profile from time 0–2 weeks after dosing ($AUC_{0\text{-}2wk}$). Safety, including injection-site reactions (ISRs), and secondary PK endpoints, were also assessed. Bioequivalence between ADL-PF administered by PFS or PFP device was demonstrated if the 90% confidence intervals (CIs) for the test/reference ratios of $AUC_{0\text{-}2wk}$ and C_{max} fell within the 80.00–125.00% pre-specified margin.

Results: A total of 164 subjects, stratified by body weight were randomised and assigned to treatment; ADL-PF PFS (n=81) and PFP (n=83). Baseline characteristics were comparable between treatment arms. 163 subjects were included in the primary PK analysis. The concentration–time profiles were comparable between the ADL-PF PFS and PFP treatment arms, and were characterized by an increase in serum drug concentrations, with the C_{max} achieved at approximately 6-7 days, followed by a multi-phasic decline in drug concentrations. The 90% CIs for test/reference ratios of the geometric means for the primary PK parameters fell within the pre-specified margin (**Table**). In total, 50 and 51 treatment-emergent adverse events (AEs) were reported in 31 (38.3%) and 29 subjects (34.9%), respectively, in the ADL-PF PFS and PFP groups. One subject experienced an unrelated serious AE in the ADL-PF PFS group. Injection-site pain was similar between treatment arms at all time points, and for the 2 injection-site locations. IMG testing was limited to subjects experiencing an ISR and/or rash AE, and a matched control group, with 11 (11/15; 73.3%) and 7 (7/15; 46.7%) subjects, respectively, testing anti-drug