Results: We enrolled 147 patients, out of them 66 patients were on monotherapy with Abatacept due to intolerance or contraindications and 81 in therapy with Abatacept plus MTX. The two cohorts appeared homogeneous in age, gender, disease duration and baseline activity indexes, with the only difference being higher baseline Physician Global assessment (PhGA) values in monotherapy patients. During the follow-up (median duration 24±14 months), the retention rate of Abatacept treatment was 71.2% in MTX patients (median duration 27–15.6 months) and 62.1% in monotherapy patients (median duration 25.2–17.5; p=ns). No differences between the two groups in terms of retention rate, low-disease activity and CDAI remission (log rank p=ns), Breslow p=ns) were detected.

Conclusion: In patients with RA with intolerance or contraindication to MTX use, Abatacept monotherapy could be an efficient and safe option even in the long term follow-up.

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AB0316 MULTIPLE SWITCH BETWEEN BIOSIMILARS DMARDS (BSDMARDS) IN PATIENTS WITH INFLAMMATORY ARTHRITIDES: EXPERIENCE OF A SINGLE ITALIAN CENTRE

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Background: The availability of bsDMARDs since some years represents an opportunity to improve patient access to effective biologic therapy, to better accommodate restraints within healthcare budgets and to improve overall patient outcomes. Different policies are followed in different countries to implement the use of bsDMARDs. Although the latest position paper of AIFA (Agenzia Italiana del Farmaco) envisions the automatic substitution between the originator and biosimilar, until now the prescriber decision and the patient consent are strongly advised. The question around biosimilar to biosimilar switching is overlooked. Nevertheless different rules are established at regional level and in our Hospital automatic switching between originator/biosimilar and biosimilar/biosimilar was applied.

Objectives: To analyze the efficacy and safety of switch from originator to biosimilar (O/B) and/or biosimilar to biosimilar (B/B) in patients with RA, PsA and SpA.

Methods: We retrospectively analyzed in 63 patients (30 F, mean age 58.3 yr, 21 RA, 26 PsA, 16 SpA), treated with Infliximab, Etanercept and Adalimumab, disease activity (DAS28 CRP for RA, Tender/Swollen joint count for PsA, BASDAI for SpA, CRP for all) and adverse events/infections (AE). The time points considered were 3rd month before the switch and 3rd and 6th month after.

Results: 45 patients underwent single switch (35 O/B, 9 B/B) and 18 (28.5%) double switch (O/B/B). 27 B/B switch were done. No differences in disease activity were observed before and after switch (8 RA patients: mDAS28 CRP 2.86>3.23, 11 PsA patients: mTJ count 2.5 > 3.43, 8 SpA patients: BASDAI 2.88 > 2.84). The mean number of swollen joints was very low in PsA group and we decided to exclude this variable. The CRP level was low and stable along all period examined in the three groups. No increase in steroid daily dose, nor in concomitant DMARDs therapy was reported. In the Etanercept B/B switch (14 pts) the number of infections was the same before (3) and after (3). In Infliximab B/B switch (13 pts) 3 infections were reported only before the switch. The severity was mild/moderate with prevalence of respiratory infections (57%). No remarkable variation of transaminases and blood counts were observed.

Conclusion: Although the population we examined was heterogeneous and quite small, we observed that the efficacy and safety of Infliximab and Etanercept are maintained with biosimilar to biosimilar switch, also after double switch (originator>biosimilar>biosimilar). We also can confirm that the switch from originator to biosimilar Infliximab, Etanercept and Adalimumab is safe in our experience.

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AB0317 BIOLOGIC THERAPY OPTIMIZATION IN RHEUMATOID ARTHRITIS PATIENTS IN COLOMBIA

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Background: The optimization of biological agents (bDMARD), is a strategy that has proven to be cost effective and its use can reduce the risk related to drug exposure (1–3). It is included in the EULAR management guidelines and in the consensus of the Colombian Rheumatology Association.

Objectives: To analyze optimization success of bDMARD therapies in patients with RA.

Methods: Cohort study of RA patients in a specialized multicenter institution in Colombia, followed from January 2015 to December 2019. Patients in remission or low activity for at least 6 months with bDMARD, and with at least two consecutive medical visits, were included. Optimization types were dose decrease, application interval increments, or both. Patients who had disease reactivation (DAS28- CPR >3.2) and returned to standard dose, were considered a failure. By Kaplan-Meier analysis, the optimization failure was estimated according to bDMARD type

Results: 92 patients were included, 78.26% were women, with a median age of 57 years (IQR 50–64), a disease evolution time of 15 years (IQR 10–21), a treatment of 5.6 years (IQR 2.7–8.0), and optimization of 7.75 months (IQR 3.25–15.75). The most commonly used bDMARD therapies were etanercept 36.96%, tocilizumab 30.43% and adalimumab 16.30%. 69.39% (34) were naive for biological treatment. The 53.26% (49) of patients had a follow-up time greater than 6 months.

95.92% remained under optimization scheme without disease activity changes, and 4.08% of patients underwent definitive discontinuation of bDMARD, for sustained therapeutic objective. 8.16% (4) had relapses in the first 6 months after onset, of which 2 patients returned to standard doses. In survival analysis it was observed that patients who were optimized for antiTNF failed faster than the non-antiTNF, although this difference was not statistically significant (Log Rank test 0.003 p value = 0.959). Of the total patients, 28 have been optimized for 12 months or more, of these, 96.43% (27) continue in sustained remission, and 55.56% (15) received combined therapy with s synthetic DMARD (sDMARD).

Figure 1. Kaplan Meier

Conclusion: During follow-up, most patients remain in optimization strategy. In those who continued in sustained remission, more than half received sDMARD, this suggests that their use may be a determining factor in preventing disease relapses. More studies are required to evaluate this hypothesis.

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AB0318

CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS WHO HAVE WITHDRAWN THE LAST BIOLOGICAL DRUG: REAL-LIFE RESULTS FROM A LOCAL REGISTRY

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Objectives: To assess the characteristics of patients with rheumatoid arthritis (RA), who have withdrawn the last biological drug (bDMARD), and to know the reasons for withdrawal of treatment.

Methods: Retrospective and cross-sectional study on December 31, 2019, of patients with RA, treated with any of the bDMARDs, including JAK (JAKi) inhibitor drugs, commonly used, from 1/1/2000 to 12/31/2019. General data were collected from patients, and RA: time of evolution, presence of rheumatoid factor (RF) and anti-citrullinated peptide antibodies (ACPA), type of bDMARD, time in bDMARD, and cause of withdrawal.

Results: Of 252 patients, who have received some bDMARD, 81 (32%) patients had withdrawn on 12/31/2019. 62 (77%) patients were women, with a mean age at diagnosis of RA of 48 years (SD: 16.5 years) and 59.5 (15) years at the beginning of the first bDMARD (F1), with an average evolution of RA 10.2 (2.5) years. 68% and 74% of patients were positive for RF and ACPA, respectively.

In 64 (79%) patients, bDMARD was withdrawn as second to fifth bDMARD received (F2 to F5): as F2: 37/81 (46%) patients, F3: 14 (18%), F4: 8 (10%) and as F5: (6%) patients.

When comparing the last bDMARD received, before the suspension as F1 vs F2-F5, 95% vs. 61% of patients ($p < 0.0001$), the drug was an anti-TNF (TNFi); Abatacept: 1 (1%) vs 9 (14%); Tocilizumab: 0% vs 8 (12%); Rituximab: 1 (1%) vs 5 (8%) and JAKi: 4 (5%) vs 3 (5%). The mean time in treatment with some bDMARD was 2.6 (SD: 3) years in the F1 group vs 1.7 (2) years in the F2-F5 group ($p = 0.034$). Among the F3-F5 patients, 9 (14%) patients had failed at 2 different previous therapeutic targets and 6 (9%) at 3 targets.

No differences were detected between the F1 group vs F2-F5, regarding the causes of withdrawal of bDMARD: whether it had occurred due to 1) loss of efficacy (25/31% patients vs 19/30%); 2) adverse events (31/38% vs. 29/45%): infection: 18/81 (22%) patients, malignancy: 5 (6%), malaise/pain: 11 (14%), laboratory parameters alteration: 7 (9%), death: 5 (6%), others: 14 (17%); 3) change of address/loss of follow-up (20/25% vs. 7/11%) or by 4) voluntary abandonment of treatment by the patient (5/6% vs. 9/14%).

Conclusion: 1. 32% of patients with RA withdraw the bDMARD. 2. The group treated with TNFi withdraws it significantly higher among the F1 group. 3. Survival of bDMARD is significantly higher in group F1 compared to F2-F5. 4. No differences were detected between the groups regarding the cause of withdrawal of bDMARD. 25% -30% of patients withdraw it due to loss of follow-up or voluntary abandonment of bDMARD.

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AB0319

DRUG SURVIVAL OF BIOLOGICS IN RHEUMATOID ARTHRITIS: PRELIMINARY DATA FROM THE TUNISIAN BINAR REGISTRY

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Background: The arrival of Biotherapy has changed the management and prognosis of rheumatoid arthritis (RA). However, drug survival of the first biotherapy is changing according to the studies.

Objectives: We aimed to report the data on the drug survival of biotherapies in RA, collected from the Tunisian Biologics National Registry (BINAR)

Methods: BINAR is a multicenter non-interventional and prospective study, conducted in Tunisia with 80 rheumatologists over a period of three years. It included patients with RA (ACR / EULAR 2010 criteria) and refractory to conventional background treatments (csDMARDs), who required the use of biological treatment of anti TNF, anti IL6 or Rituximab type. Data were collected and analyzed through an electronic platform managed by DACIMA. Sociodemographic data (age, gender, body mass index (BMI), smoking) and characteristics of RA (duration of evolution, erosive character) were collected. RA activity was studied by the DAS28-VS score and drug survival was evaluated by the duration of the biologics.

Results: We included 175 patients with a sex ratio of 5.7 and a mean age of 54.1 ± 12.6 years [19-79]. Patients were smoking in 6.7% of cases and mean BMI was $27.9 \pm 5.2 \text{ kg/m}^2$ [15.1-45.2]. RA was erosive in 73.1% of cases and the mean disease duration was 6.7 ± 3.5 years. Disease activity was moderate (mean DAS28vs: 4.9 ± 1.5). Concerning the treatments, 139 (79.4%) of the patients received TNF α inhibitor, 31 (17.7%) of the patients were on IL6 inhibitor and 15 (8.6%) were on Rituximab.

The mean duration of drug survival for TNF α inhibitor agents was 15.2 months, 18 months for anti IL6 and 16.3 months for Rituximab. The drug was discontinued by 19 patients (10.8%). The causes of discontinuation were primary failure in 31.8% (7 subjects), secondary escape in 9.1% (4 subjects), the occurrence of adverse effects in 31.8% (7 subjects), intolerance to drug in 9.1% (2 subjects), non-compliance for one patient and for other reasons in one case.

The drug survival of TNF inhibitor was not associated with socio-demographic data (gender ($p=0.9$), age ($p=0.4$), smoking ($p=0.9$), BMI ($p=0.9$)), nor with the characteristics of the disease duration ($p=0.5$), DAS28 vs ($p=0.9$), association with a csDMARDs ($p=0.2$) except the presence of erosion ($p=0.013$).

Also, drug survival of IL6 inhibitor drugs was not associated with socio-demographic parameters (gender ($p=0.1$), age ($p=0.6$), smoking ($p=0.6$), BMI ($p=0.4$)) and the characteristics of the disease (duration ($p=0.9$), erosive character ($p=0.6$), DASvs ($p=0.1$), association with a csDMARDs ($p=0.2$)).

Similarly, drug survival of Rituximab was not associated with socio-demographic data (gender ($p=0.6$), age ($p=0.7$), BMI ($p=0.7$)) or with the characteristics of RA (duration of evolution ($p=0.5$), erosive character ($p=0.6$), DASvs ($p=0.08$), association with a csDMARDs ($p=0.5$)).

Conclusion: Our study demonstrated that IL6 inhibitor had the longest duration of drug survival (18 months). The major causes of cessation were dominated by primary failure and the occurrence of an adverse event. Finally, the drug survival of TNF inhibitor agents was associated with the erosive character.

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AB0320

BDMARDS SURVIVAL: THE TUNISIAN DATA

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Background: The advent of biotherapies in the late 90s radically changed the face of inflammatory diseases including rheumatoid arthritis. The survival of these innovative therapies is an indicator, in clinical practice, of their long-term efficacy and safety.

Objectives: The objective of this study was to assess their use in Tunisia through their survival during rheumatoid arthritis as well as to determine the factors that may influence their therapeutic maintenance in real life.

Methods: This is a retrospective study including RA patients (ACR/EULAR 2010 criteria) and put on biotrapy between 01-01-2014 and 12-31-2016. They were followed until 12-31-2018. The therapeutic maintenance rate at 12, 24, 36 and 48 months as well as the survival curves of biotherapies were analyzed using the Kaplan-Meier survival curves and compared by the Log-rank test. Reasons for interruption and patterns of biological change have been reported. Finally, an analysis of factors influencing survival was performed using Cox regression. A $p < 0.05$ was considered statistically significant.

Results: Three hundred seventy-four patients were included in the study; sex ratio was 0,147. The baseline age was 55 ± 12.5 years [20 – 90] and the average disease duration was 11.7 ± 6.7 years [2 – 41]. Rheumatoid factor and ACPA were positive respectively in 79% and 71% cases. After failure of cDMARD, the first biotherapy prescribed was etanercept in 54%