Conclusion: In RA, biological agents have a positive benefit/risk ratio. However, non-infectious side effects are not rare, they are multifactorial and can be potentially serious.

Table I non-infectious adverse events in the RBSMR

Type of adverse events	Incidence per 100 patient-years	Number of adverse events	Biological agents
Infusion reactions	1,19	8	RTX (n=6) TCZ (n=2)
Paradoxical reactions	0,29	2	Uveitis under TCZ (n=1) Paradoxical arthritis under Golimumab (n=1)
Drug-induced lupus	0,14	1	RTX
Cancers	0,44	3	Urothelial carcinoma under TCZ having already received RTX (n=1) Breast carcinoma under TCZ having already received RTX (n=1) Non-Hodgkin's lymphoma under TCZ (n=1)
Liver toxicities	1,79	12	TCZ (n=7) RTX (n=5)
Hematological disorders	3,13	21	TCZ (n=14) RTX (n=5) Anti-TNFα (n=2)
Dyslipidemias	1,94	13	TCZ (n=8) RTX (n=4) Golimumab (n=1)
Severe heart rhythm disorder	0,14	1	TCZ
Phlebitis	0,14	1	Etanercept
Other AEs (injection site reactions, myalgia, depression…)	2,69	16	RTX (n=7) Anti-TNFα (n=5) TCZ (n=4)

REFERENCES: NIL.
Acknowledgements: NIL.
Disclosure of Interests: None Declared.
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AB0445 CHARACTERISTICS OF FIRST-LINE UPADACITINIB INITIATORS AND FACTORS CONTRIBUTING TO PRESCRIBING UPADACITINIB AS FIRST-LINE B/TSDMARD

Keywords: Disease-modifying Drugs (DMARDs), Real-world evidence, Rheumatoid arthritis

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Background: EULAR guidelines recommend switching to or adding a b/tsDMARD in patients with rheumatoid arthritis (RA) who do not respond or have an inadequate response to csDMARDs. Traditionally, TNF inhibitors (TNFi) are prescribed as the first b/tsDMARD. In Dec 2021, the upadacitinib (UPA) label in the US was updated to restrict use to those who have had an inadequate response or intolerance to one or more TNFi.
Objectives: In the period prior to the UPA label change in the US (through Jan 2022), to (1) compare characteristics of patients with RA receiving UPA as first b/tsDMARD with those who initiated TNFi as their first b/tsDMARD, and (2) explore the reasons why UPA was chosen as first-line advanced therapy.
Methods: Using CorEvitas RA registry data from Aug 2019 to Jan 2022, patients who initiated UPA or TNFi at or after enrollment in the registry with no history of prior b/tsDMARD use were evaluated. The patients' providers indicated which factors (they could choose more than one) contributed to prescribing UPA as first-line advanced therapy based on medical record chart review.
Results: Few differences in demographics, comorbidities, and disease activity at initiation were observed between the 815 TNFi initiators and 142 UPA initiators identified. UPA initiators were older (mean [SD] age 58.9 [12.8] vs 56.7 [13.9] yrs), had a higher proportion of White patients (87% vs 83%), and were less likely to be working (44% vs. 53%), and have private insurance (73% vs. 68%). UPA initiators had more frequent history of cardiovascular disease (16% vs 10%), joint deformity (17% vs 12%), and subcutaneous nodules (13% vs 10%), but less frequent history of anxiety/depression (29% vs 34%) than TNFi initiators. UPA initiators had greater disease severity, including mean CDAI (23.7 [14.9] vs 19.0 [13.0]), and tender (8.4 [7.7] vs 6.6 [6.7]) and swollen (6.1 [5.1] vs 4.3 [5.1]) joint counts, self-reported pain (54.5 [28.7] vs 50.3 [28.3]), and proportion with morning stiffness (89% vs 85%). UPA initiators were more likely to have a history of multiple csDMARDs (43% vs 35%), monotherapy b/tsDMARD initiation (32% vs 22%) and use of NSAIDs (53% vs 48%). For 142 patients initiating UPA as first-line, 34 providers (87% response rate) indicated major factors in the choice of prescribing UPA as first-line advanced therapy were the patient's level of disease activity (75%), patient's disease progression (61%), patient preference (51%), and patient's disease profile (43%). These reasons contributed to any part of the prescription decision in 99%, 96%, 77%, and 79% of patients, respectively. Oral delivery was indicated as a contributing factor by almost all (91%) of the 109 patients that were prescribed UPA as first-line therapy and indicated patient preference was a factor in prescribing UPA. Side effects were not a concern when deciding to prescribe UPA in at least 50% of the patients included in this study.
Conclusion: In a real-world cohort of patients with RA initiating a first-line b/tsDMARD, those who received UPA were more likely to have previously failed multiple csDMARDs, to initiate as monotherapy, and to have had greater disease activity based on both physician and patient measures compared to patients who received TNFi. Clinical factors including disease activity, disease progression, and disease profile influenced the prescribing decision by providers as well as patient preference.
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AB0446 SAFETY OF BIOLOGICAL THERAPIES: DATA FROM THE BIOBADAGUAY REGISTRY

Keywords: Registries, Safety, bDMARD

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Background: BIOBADAGUAY is the Paraguayan/Uruguayan registry of adverse events (AE) in patients with inflammatory rheumatic conditions under biologic therapy (BT).
Objectives: Determine the frequency and severity of AE of patients under BT in the BIOBADAGUAY registry.
Methods: Prospective, observational study of undetermined length to verify the efficacy, safety, and survival of the BT. The methodology applied is available at https://biobadaguay.ser.es. For the present study epidemiological and clinical variables, BT, type, and severity of AE were analyzed. The incidence rate (IR) was calculated as the total number of adverse events per 1000 patients/year and the incidence rate ratio (IRR) was analyzed using the Poisson regression model. (Significance value 0,05)

Results: 1104 patients with TB were analyzed, between 2016 and 2022. 73.28% were women, mean age at treatment initiation was 42±17.1 years. The most frequent diagnosis was rheumatoid arthritis (RA): 686 patients (62.4%). There were 1375 treatment cycles. 1365 AE were observed, 1191 (87.2%) were non-severe, 161 (11.8%) severe and 13 (0.95%) mortal. The IR of AE was 251.75 (238.6-265.8), for severe AE 32.1 (27.5-37.2). Infection was the most frequent AE in 731/1365 (55% of total AA): non-severe 661 (88%), 86 (11.5%) severe and 4 (0.5%) mortal. The IR of infections was 138.4 (126.69-265.47), 32.1 (27.48-37.2%) for severe infections. When analyzing the IR of AE according to diagnosis, it was observed that RA is associated with a higher IR of global AE when compared to other diagnoses (IRR=1.35 [95% CI,1.1-1.7] p=0.0088), and severe AE (IRR=1.72 [95% CI,1.2-2.5] p=0.006). Psoriatic arthritis (PsA) and ankylosing spondylitis (AS) were associated with lower overall IR of global AE: IRR=0.57 [95% CI,0.4-0.9] (p=0.007) and IRR=0.66 [95% CI,0.5-1] (p=0.04), respectively. corticosteroid use was associated with a higher global AE IR (IRR=1.46 [95% CI,1.2-1.8] p=0.0009). When IR was analyzed according to severity, it was observed that the second and subsequent cycles of BT were significantly associated with a higher IR of global and non-severe AE compared to the first cycle of BT (Table 1). Treatment with anti-TNF was significantly associated with lower IR of global and mortal AE compared to non-anti-TNF (Table 1).

INCIDENCE RATE OF ADVERSE EVENTS ACCORDING TO SEVERITY

First Cycle		Follow Cycles		
Adverse Event	Incidence Rate	Incidence Rate	Incidence Rate Ratio	P
Global	233.22 (219.28, 247.80)	339.2 (303.1, 378.3)	1.45 (1.14, 1.85)	**0.0024**
Not Serious	201.27 (188.34, 214.85)	306.50 (272.29, 343,82)	1.52 (1.18, 1.197)	**0.0014**
Serious	30.16 (25.26, 35.69)	27.39 (17.89, 40.13)	0.91 (0.55, 1.51)	0.7101
Mortal	1.79 (0,77, 3.52)	5.27 (1.71, 12,29)	2.95 (0.96-9.56)	0,0588
Non-antiTNF		AntiTNF		
Adverse Event	Incidence Rate	Incidence Rate	IRR	P
Global	306.31 (276.92, 337.98)	234.63 (220.09, 249.88)	0,77 (0.61, 0.97)	0,**0262**
Not Serious	261.56 (234.46, 290.94)	206.54 (192.91, 220.88)	0.79 (0.61, 1.02)	0.0695
Serious	38.58 (28.63, 50.86)	26.88 (22.11, 32.37)	0,70 (0.47, 1.04)	0,0758
Mortal	6.17 (2.66, 12.16)	1.21 (0.39, 2.83)	0.20 (0.06, 2.83)	**0.0043**

Conclusion: AE were in general non-severe, and infections were the most frequent. RA and concomitant treatment corticosteroid presented a higher IRR of global AE, whereas PsA and AS a lower IRR of AE. Second and Subsequent cycles of BT presented a higher IRR of global an AE. The RA diagnosis presented a higher rate of severe AE.

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AB0447 MEDICATION BELIEFS DURING THE PRECONCEPTION PERIOD AMONG PATIENTS WITH RHEUMATOID ARTHRITIS

Keywords: Safety, Disease-modifying Drugs (DMARDs), Rheumatoid arthritis

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Background: Treatment maintenance in young women with rheumatoid arthritis (RA) may be influenced by factors such as fears of side effects on fertility and conception.

Objectives: We aimed to assess the therapeutic beliefs of patients with RA during the preconception period and to investigate associated factors.

Methods: We conducted a cross-sectional study including patients diagnosed with RA before menopause. We assessed beliefs about treatment during the preconception period using the French version of Beliefs about Medicines Questionnaire (BMQ). The questionnaire assessing specific beliefs is composed of 10 items: 5 items to assess beliefs regarding the necessity for treatment and 5 items to assess concerns.

Results: We included 31 females (mean age: 49.7±10.4 years). RA was erosive in 93% of cases. Coxitis was noted in 6 patients (19%) and atloido-axial dislocation in 2 patients (6%). The average number of gestation and parity was, respectively, 3 [0-9] and 2 [0-7]. Contraception was used by 20 patients (64%). The contraceptive method was progestin-only pill (10 patients), intrauterine device (6 patients), condoms (2 patients), and calendar method (2 patients). The mean beliefs' score regarding treatment necessity and concerns were 18.8±3.3 [10-23] and 12.3±5.9 [5-23], respectively. The score of therapeutic necessity was higher in patients without desire to conceive, but the difference was not significant (19.1±3.1 vs 17.2±4.8, p=0.246). The presence of erosions had an influence on therapeutic necessity (19±3 vs 16.5±7.7, p=0.03). The therapeutic necessity score was statistically higher in patients with coxitis (20.1±1.6 vs 18.5±3.6, p=0.05). The conception desire had no influence on concerns. The disease duration had a statistically negative correlation with concern score (r=-0.480, p=0.006). Contraception use was not influenced by either therapeutic necessity or concerns (p=0.129 and p=0.140, respectively).

Conclusion: This study showed that beliefs about therapeutic necessity during the preconception period were more important than concerns. We emphasize the importance of therapeutic patient education to fight against negative beliefs.

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Disclosure of Interests: None Declared.

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AB0448 THE IMPACT OF ACPAS ON THE RESPONSE TO BIOLOGICAL THERAPY IN RHEUMATOID ARTHRITIS

Keywords: bDMARD

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Background: Rheumatoid arthritis (RA) is a chronic, debilitating disease associated with reduced quality of life. It is characterized by the positivity of various antibodies, the most specific being autoantibodies against citrullinated antigens (ACPA). Those antibodies are associated with severe erosive phenotype and higher mortality rate comparisons to seronegative RA. Moreover, ACPA status is known to be associated with a favorable response to biologics drugs.

Objectives: Our objective in this study was to investigate whether ACPA positivity in RA can predict treatment responses to biologic therapies in Tunisian patients with rheumatoid arthritis.

Methods: We conducted a cross-sectional and observational study. Files of patients with RA on biologics drugs (archived from the files of patients on the National Health Insurance Fund of Tunis) were studied. ACPA and rheumatoid factor assays were performed. RA activity was assessed by the composite score 'Disease Activity Score 28' (DAS28). Patient follow-up was done with the DAS28 disease activity score. The therapeutic maintenance rate as well as the biologics survival was analyzed using Kaplan-Meier survival curves and compared using the Log-Rank test.

Results: Three hundred and seventy-four files were selected. Their average age was 55±12.54 years [20-90]. A female predominance was noted with a sex ratio M/F=0.147. The average duration of RA was 11.7±6.76 years [2-41]. Rheumatoid serology specified in 324 patients (86%), was positive in 79% of cases. Anti-citrullinated protein antibodies (ACPA) data were available in the records for 267 patients (71%). These were positive in 72% of patients. Anti-nuclear antibodies (ANA) were only positive in 12% of our population. Native anti DNA and anti Sm were respectively positive in one patient. First biogics prescription was: etanercept 54%, adalimumab 14%, certolizumab pegol 13%, infliximab 6%, tocilizumab 6% and rituximab 7%. In patients with positive rheumatoid factors, survival after 4 years of the first biological treatment was 58.8% versus 35.5% in FR negative patients. Mean therapeutic maintenance was 42.15 months and 34.97 months respectively for the two groups. For ACPA negatives, the 4-year survival was 52.05% versus 49.2% for ACPA positives. These antibodies did not influence the survival of the biotherapy with an HR = 1.004 (p=0.987).

Conclusion: Our study did not reveal any impact of ACPA positivity on the therapeutic response to biologics. These results are inconsistent with most of those in the literature. A larger-scale study is needed to confirm our results.

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