RESPONSE TO BARICITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS WITH FAILURE TO CONVENTIONAL SYNTHETIC DMARD AND/OR BIOLOGICAL DMARD: DATA FROM A LOCAL REGISTRY

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Objectives: To know the characteristics of patients with rheumatoid arthritis (RA), in treatment with baricitinib (BARI), who have failed to conventional synthetic DMARD (DMARDcs) and/or biological DMARDs (DMARD).

Methods: Prospective observational study, in real life, of patients with RA, under treatment with BARI. General data of the patients, (age, gender, comorbidity), RA and treatment were collected (time of evolution, presence of RF and ACPA, efficacy indexes at the beginning of BARI and the last visit: DAS28-VSG and CDAI, previous or concomitant treatment with DMARDcs and/or DMARDb, end of treatment and cause, time in BARI, serious adverse effects during treatment with BARI.

Results: Of 529 patients in follow-up, who have received at least one dose of DMARDb, 224 (42%) are diagnosed with RA, and 58 (26%) of them receive some drug inhibitor of the JAK pathway; 40/224 (18%) of them BARI.

The patients treated with BARI, 77% were women, mean age of 58.95 ± 10.8 years and mean evolution of RA of 9.8 ± 8.8 years. The mean BMI is 28.8 ± 1.8. The FR and ACPA are positive at 86% and 89%, respectively. 94% of patients continued concomitant treatment with some DMARDcs.

BARI is the first drug after failure of DMARDcs (F1) in 24/40 (60%) patients, and in 16/40 (40%), after failure to some DMARDb; second drug after failure to DMARDb (F2) in 2 (6%), third (F3) in 5 (13%) patients, fourth (F4) in 6 patients (17%) and fifth (F5) in 3 (9%) patients.

The patients treated with BARI, F1 versus F2-F5, presented significantly higher BMI (29.9 ± 2.6 vs. 26.95 ± 4.4, p <0.001), higher percentage of ACPA (100% vs. 74%, P = 0.026), and lower mean time of evolution of RA (5.3 years, range: 0.7-25 vs 14.75 years, range: 2-36 years, p <0.001). 94% of patients continued concomitant treatment with some DMARDcs.

BARI F1: Baseline Last visit: DAS28-VSG 26.0 ± 5.0, CDAI 2.6 ± 5.0, p <0.001.
BARI F2-F5: Baseline Last visit: DAS28-VSG 27.8 ± 5.8, CDAI 2.6 ± 5.0, p <0.001.

Conclusion: 1. Baricitinib is effective and safe in real clinical practice.
2. It is competent of achieving clinical remission or low activity, in a high percentage of patients, even in those who have failed several biological drugs or several therapeutic targets previously.

Disclosure of Interests: None declared

RISK FACTORS OF JOINT SURGERY IN RHEUMATOID ARTHRITIS TUNISIAN PATIENTS

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Background: Rheumatoid arthritis (RA) is a chronic inflammatory disease characterized by poviarticular synovial inflammation and progressive joint destruction. Orthopedic surgery is an integral part of the treatment of RA and it is mainly reserved for severe and advanced forms where there is a failure of medical treatment.

Objectives: To assess the rate of joint surgery in rheumatoid arthritis (RA) Tunisian patients and to determine the risk factors of surgical treatment.

Methods: A retrospective cross sectional study over a period of 15 years including 500 Tunisian patients with RA was conducted. The prevalence of joint surgery indication has been evaluated. Clinical, paraclinical and therapeutic characteristics of RA were compared according to the need of surgical treatment.

Results: Mean age was 53.4 years. Female to male ratio was 5. The indication of joint surgery was noted in 59 patients (12%). Factors associated with joint surgery were delayed diagnosis (p = 0.037), long RA duration (p = 0.017), young onset of RA (p <0.001), presence of joint deformities (p = 0.034), presence of osteoporosis (p = 0.029), presence of joint surgery indication and failure of medical treatment (p <0.001).

Disclosure of Interests: None declared
of antinuclear antibodies<0.001), combination therapy of methotrexate with other conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) (p = 0.01), a short period of first medical treatment (p = 0.012) and high erythrocyte sedimentation rate (ESR) (p = 0.027). In multivariate analysis, three factors were independently related to the need of joint surgery: age at disease onset (OR 2.799 95%CI: 1.49-5.22 p=0.01), high ESR level (OR 2.807 95%CI: 1.5-5.24 p=0.01), and association of Methotrexate with other csDMARDs (OR 3.500 95%CI: 1.61-7.56 p=0.01).

**Conclusion:** Twelve percent of RA patients needed joint surgery treatment. Predictive factors of surgical treatment were young age at disease onset, high ESR level and association of methotrexate with other csDMARDs.

**REFERENCES**

**ABSTRACTS**

**REALISTIC OUTCOMES IN PATIENTS WITH RA USING CONVENTIONAL DMARDS UNDER A T2T STRATEGY AND A DISEASE MANAGEMENT MODEL – RESULTS FROM A FIVE YEAR REAL-WORLD REGISTRY**

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**Background:** Rheumatoid arthritis (RA) is a common chronic inflammatory disease. Treat-to-target (T2T) is a management strategy for RA that proposes as the therapeutic target a state of remission or low disease activity, additionally a multidisciplinary management of patients with RA has demonstrated to be an additional aid to achieve remission or low disease activity levels. Real-world evidence (RWE) refers to information coming from electronic health records, billing data, registries among others. RWE shows results that are difficult for clinical trials to demonstrate due to ideal conditions.(1, 2)

**Objectives:** The aim of this study was to describe global change in Disease Activity Score 28 (DAS28) using T2T strategy during 5 years in a cohort of patients receiving conventional DMARDs that attend to a specialized RA center.

**Methods:** A descriptive cohort study was conducted. Medical records of patients from specialized in RA center were reviewed during 2015-2017; those patients were followed under T2T standards and a multidisciplinary approach. Clinical follow-up was designed by the authors according to DAS28 as follows: every 3-5 weeks (DAS28 > 5.1), every 7-9 weeks (DAS28 > 3.1 and ≤ 5.1), and every 11-13 weeks (DAS28 < 3.1). Tendinosis joint count (TJC), swollen joint count (SJC) and DAS28 were measured on each visit. Therapy had to be adjusted with DAS28 > 3.2 unless patient's conditions don’t permit it; we considered this follow-up type as implementation of a T2T strategy in patients with RA. Patients entered into a multidisciplinary program of care with periodic consultation with a rheumatologist, psychologist, physiotherapist, occupational therapy nutrition, and a patient focused program. With a multidisciplinary model of care the patient is seen as a whole, and the expectation is to achieve the best results in the management of RA. We divided patients in four groups: remission (REM), low disease activity (LDA), moderate disease activity (MDA) and high disease activity (HDA). Patients and the aim of the study was to look at what percentage of patients who were in moderate or severe disease activity reached a low disease activity or remission. Descriptive epidemiology was done, we calculated means, and standard deviations for continuous variables and categorical variables were presented as rates. We compared disease activity at base line and at the end of follow-up.

**Results:** During 5 years we included 2,128 patients. 83% were female and 17% were male, mean age was 57 years ±14. At baseline median DAS28 4.34 RIQ (3.76-5.06) and at 5 years 2.02 RIQ (1.46-2.38). At the end of our follow-up 81% were remission and 7% in LDA. See table 1.

For our study DAS28 was not normally distributed, thus we performed a Wilcoxon test in order to compare the mean DAS28 at baseline/5-year showing statistical significance (P=0.05).

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<tr>
<th>ACTIVITY LEVEL</th>
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**Conclusion:** In our patients T2T strategy improved disease activity in patients with RA. This evidence from a real-life setting that shows the advantages of treating RA patients with a multidisciplinary team under a T2T model with a low-cost treatment. It is important to explore other predictors that can improve disease activity.

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**REAL-LIFE USE OF BARICITINIB IN RHEUMATOID ARTHRITIS: A MULTICENTER OBSERVATIONAL STUDY OF 150 PATIENTS**

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**Background:** Baricitinib is an oral selective JAK1/2 inhibitor recently approved in the EU for the treatment of rheumatoid arthritis (RA). No real-life data are available about its efficacy and safety.

**Objectives:** To investigate the efficacy and safety profiles of baricitinib in a real-life setting.

**Methods:** We performed a multicenter prospective observational study on adult RA patients starting JAK inhibitors between 12/2017 and 12/2018. Demographic and clinical data as well as laboratory values and adverse events were collected at baseline and after 12 and 24 weeks. Disease activity was measured by DAS28-CRP at baseline, after 12 and 24 weeks.

**Results:** We obtained data from 150 patients with RA (women 116 – 77.3%; median age 60 years, inter-quartile range IQR 54-68; median disease duration 10 years, IQR 4-18) treated with baricitinib 2 or 4 mg OD, however only 2/150 (1.3%) at the reduced dosage. At the time of database lock 95/150 (63%) patients have completed the 12 weeks follow-up, 38/150 (25%) patients have completed the 24 weeks follow-up. Baricitinib was started after at least one conventional synthetic DmARD in all 148/150 cases (99%), being in all of cases methotrexate, while was started prior to a biologic DmARD in 57/150 (38%) patients. It was prescribed as a second line in 17/93 (18%) patients, third in 27 (29%), fourth or higher in 49 (53%). Baricitinib was prescribed as monotherapy in 57/150 (38%) patients, while combined with methotrexate in 65/150 (43%), at a median dosage of 15 mg/week. Oral corticosteroids were used by 105/150 (70%) patients, at a median dosage of 5 mg/day. Mean DAS28-CRP at baseline was 4.92 (standard deviation 1.22), with 65 (43.3%) patients having a DAS28-CRP<5.1. At both 12 and 24 weeks, a significant reduction of disease activity scores was observed (DAS28-CRP mean 3.07, SD 1.36, and 2.85, SD 1.35, respectively; p-values<0.001). Eleven (11%) patients discontinued the treatment, with 8 (50%) due to primary ineflicity, mainly in the first 3 months of therapy (5/8– 63%). Adverse events were observed in 19/150 (13%) patients, 7 being non-serious infections (4