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AB0418 INTERSTITIAL LUNG DISEASE IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH TOFACITINIB

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Background: The presence of interstitial lung disease (ILD) is a common extra-articular manifestation in patients diagnosed with Rheumatoid Arthritis (RA), dyspnea being its cardinal symptom. Several of the drugs commonly used to treat this condition, such as TNF inhibitors (anti-TNF) and Disease Modifying Antirheumatic Drugs (DMARDs), have been implicated in the development or exacerbation of ILD. In regard to Tofacitinib, results of post hoc analysis of its pivotal and extension studies report a numerically lower ILD incidence rate in the group that received this drug compared with placebo.

Objectives: To describe the evolution of dyspnea, spirometric parameters, DLCO and high resolution computed tomography (HRCT) findings in patients with RA diagnosis with associated PID who received Tofacitinib for a period of 12 months.

Methods: Patients with a diagnosis of RA who fulfilled criteria ACR 1987/ACR-EULAR 2010, with interstitial lung disease previously diagnosed from clinical findings, spirometry and/or HRCT were included. Tofacitinib was used in dose of 10 mg/day orally. Design: Descriptive, retrospective, multicentric study. The following variables were analyzed: change at 12 months from baseline in the degree of dyspnea (according to the modified scale of dyspnea MMRC), forced vital capacity (FVC), DLCO and findings in HRCT. Continuous variables were reported as mean and standard deviation or median and interquartile range as appropriate. The categorical variables were reported as percentages.

Results: Fifteen patients were included. 60% (n: 9) were women. The mean age was 64.4 years ($\pm$ 10.92). The median time of evolution of RA was 9 years (IQR: 4-40). The median time of evolution of interstitial lung disease was 4 years (IQR: 1-24). 13% (n: 2) of the patients were receiving methotrexate (MTX) at the time of evaluation, 60% (n: 9) of the patients had previously received it. 80% (n: 12) had previously received DMARD different from MTX. 33% of the patients (n: 5) had received previous biological treatment. All patients received tofacitinib at a dose of 10mg/day. 47% of patients (n = 7) received tofacitinib monotherapy and 53% (n = 8) received it combined with DMARDs. 27% (n: 4) of the patients had grade 3-4 dyspnea at baseline. Improvement in the dyspnea scale was observed in 8 patients, while in the rest, it remained stable. The forced vital capacity (FVC) at baseline was <80% in 5 patients and > 80% in 2 patients. At 12 months, 4 patients achieved a FVC > 80%. The average of DLCO at baseline was 45.6 ($\pm$ 18.84), with an improvement of 30% at 12 months in 4 patients. No progression of the disease was observed in the HRCT at 12 months in any of the patients evaluated.

Conclusion: The present preliminary study was performed with patients of daily practice, not being available in all cases, the corresponding respiratory functional examinations. However, despite these limitations, none of the patients showed worsening of dyspnea, with improvement in some patients. Regarding respiratory functional examinations and DLCO, not only they remained stable after treatment in the majority of patients evaluated, but 4 patients presented improvement with respect to baseline parameters. It is necessary to perform more studies, with systematized controls of the pulmonary function and images, to corroborate this hypothesis.

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AB0419 FRACTURE RISK IN PATIENTS ON LONG TERM GLUCOCORTICOIDS WITH INFLAMMATORY ARTHRITIS

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Background: A main stay treatment of inflammatory arthritis is glucocorticoids (GCs)^[1]. However, long term use of GCs has been associated with an increased risk of fracture, with studies estimating up to 12% of patients having sustained a fracture whilst on GC treatment^{[1][2]}.

Objectives: The aim of this study was to determine the prevalence of fractures in a cohort of patients on long term GCs with a diagnosis of inflammatory arthritis.

Methods: A database of patients with inflammatory arthritis attending the rheumatology department at the Midlands Regional Hospital Tullamore, since 2009, was reviewed. Patients on long term GCs were identified and outpatient summaries were analysed. Data collection included age, sex, diagnosis, vertebral fracture, other fracture sites and osteoporosis treatment.

Results: As of September 2018, out of the 2118 patients with a diagnosis of inflammatory arthritis 364 were on long term GCs. 10% of patients had reported vertebral fractures on imaging. 36.4% of patients had other types of fractures reported on imaging; 20%, and the most common site of fracture, were wrist fractures. 83.7% of those who suffered from a vertebral fracture were female. 18.2% of those who sustained fractures were not on any osteoporosis treatment.

Conclusion: The incidence of fracture in our cohort of patients was higher than suggested in previous studies. Furthermore, it highlights the need for patients on long term GCs to be given osteoporosis prevention therapy.

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AB0420 A PROSPECTIVE, OBSERVATIONAL STUDY ON THE CLINICAL EFFICACY AND SAFETY OF LEFLUNOMIDE IN EGYPTIAN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS: CLEAR STUDY

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Background: Due to its anti-inflammatory and immunomodulatory properties, leflunomide can be used as a monotherapy or in combination with other conventional synthetic DMARDs (csDMARDs) in treating active RA.¹

Objectives: The aim of this observational study was to assess efficacy and safety of leflunomide in Egyptian patients with active RA, whether used as first-line and/or add-on therapy to other csDMARDs, with or without steroids.

Methods: Adult Egyptian patients with active RA, fulfilling the ACR/EULAR 2010 classification criteria, for whom leflunomide was prescribed, were included and followed up for 9 months. Leflunomide was prescribed at the physicians' sole discretion for patients who have previously experienced resistance, inadequate response or intolerance to other csDMARDs. Data about CDAI score and HAQ-DI score were acquired from patients who fulfilled the eligibility criteria, along with patients' demographics, medical history, physical examination, concomitant medications, and RA history including disease duration, previous RA medications and treatment response. This study was registered on clinicaltrials.gov (NCT03599986) and the preliminary results were previously published in 2018.²

Results: A total of 398 patients were enrolled in this study. Three hundred sixty-six patients with a mean age of 43.7 (SD 10.2) years and median disease duration of 2 (IQR 5.5) years were eligible for efficacy evaluation; 309 (84.4%) were female. We found that 86.1% of patients were leflunomide naïve. Patients who previously received leflunomide (13.9%) had a wash out period of at least 6 months prior to study enrolment. Patients were either prescribed leflunomide 20 mg/day (37.7%) or were prescribed a loading dose of 100 mg/day for the first 3 days of treatment then maintained with 20 mg/day (62.3%). Leflunomide was prescribed as first-line therapy in 21.1% of patients, as add-on therapy to other csDMARDs without steroids in 34%, and as add-on therapy to other csDMARDs with steroids in 44.9%. The mean total CDAI score

was significantly decreased ($p<0.001$) from 36.8 (14.9) at baseline, to reach 12.5 (10.3) after 9 months of treatment, with a reduction of 64%. In a similar pattern, the mean HAQ-DI score was significantly decreased ($p<0.001$) from 1.5 (0.7) at baseline to reach 0.6 (0.6) after 9 months of treatment, with a reduction of 57%. Figures 1 and 2 show changes in both CDAI and HAQ-DI scores throughout the study.

Figure 1: CDAI Score at Baseline, Month 3 and Month 9

Figure 2: HAQ-DI at Baseline, Month 3 and Month 9

Figure 3: Disease severity at Baseline, Month 3 and Month 9

Abstract Figure 3. shows that disease severity was significantly improved ($p<0.001$) throughout the study, and 19.1% of patients were at remission after 9 months of treatment.

Twenty-three adverse events (AEs) were reported in 20 patients (5%) throughout the study period; most frequently, increased hepatic enzymes (6 cases, 1.5%), increased swollen/tender joint count (2 cases, 0.5%), decreased white blood cell count (2 cases, 0.5%), and abdominal discomfort (2 cases, 0.5%). None of the reported AEs were related to treatment with leflunomide.

Conclusion: Results from this study demonstrate that leflunomide may offer an effective, tolerable and safe treatment –whether used as a monotherapy or in combination with other csDMARDs– in Egyptian patients with active RA.

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AB0421

METHOTREXATE COMPLIANCE AMONG PATIENTS WITH CHRONIC INFLAMMATORY DISEASE OR CONNECTIVE TISSUE DISEASE

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Background: Methotrexate (MTX) is widely used in rheumatology. About 30% of patients receiving MTX do not respond. One of the explanations could be poor adherence.

Objectives: The purpose of this study was to assess adherence and to identify predictive factors influencing it.

Methods: 188 patients with MTX for at least 3 months (rheumatoid arthritis (RA), peripheral spondyloarthritis (PS), psoriatic arthritis (PA), lupus, Sjögren's Syndrome (SS)) were enrolled between May 2017 and May 2018. Each patient completed a questionnaire including socio-demographic data, disease and MTX characteristics, 4-question Morisky, rheumatism activity scores including DAS 28, quality of life (EQ-5D), fibromyalgia (FIRST), anxiety and depression (HADS), catastrophism (PCS-CF), coping (WCC-R) and whether or not to participate in a therapeutic education program.

Results: 188 were recruited, of which 75% were women, with a mean age of 61.4 +/- 13.24 years: RA (77.12%), PS (7.98%), PA (10.11%), lupus (2.66%) and SS (2.13%). 68.6% were observant, versus 31.4% unobservant minor (28.2%) or major (3.2%) patients. In multivariate analysis, two models were performed and found a poor adherence in case of depression OR: 3.120 [1.051; 9.354], catastrophism OR: 3.974 [1.119; 14.108], anti-CCP antibodies OR: 4.019 [1.277; 12.653] in RA patients and depression OR: 2.715 [1.237; 5.963], absence of comorbidities OR: 2.309 [1.085; 4.915] with all rheumatism.

Conclusion: Some modifiable factors such as depression and catastrophism were associated with the risk of non-adherence with MTX. It is important to consider depression and catastrophism when taking care of our patients to improve adherence and avoid therapeutic escalations.

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AB0422

ACHIEVEMENT OF PATIENT ACCEPTABLE SYMPTOM STATE (PASS) IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH BARICITINIB

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Background: Baricitinib, a newly approved drug for the treatment of patients with moderate to severe rheumatoid arthritis (RA), is a selective inhibitor of Janus kinase 1 and 2. In a patient-centered care, patient-reported outcomes (PROs) are really helpful to better evaluate the disease activity and the response to therapy. Between them, Patient Acceptable Symptom State (PASS) is defined as the highest level of symptoms beyond which patients consider themselves well [1], and consists of a single question with dichotomized answer (yes or no): "Considering all the different ways your disease is affecting you, if you would stay in this state for the next months, do you consider that your current state is satisfactory?". In randomized controlled trials baricitinib showed significant improvement of pain, fatigue, tiredness and assessment of disease [2].

Objectives: The aim of the present study was to investigate the effect of baricitinib on PASS one month from the beginning of therapy. Further aim was to quantify the time patients needed to reach an acceptable state of health and determine the clinical variables associated with PASS.

Methods: Patients affected by RA according to 2010 ACR criteria, starting treatment with baricitinib as clinically indicated, were consecutively enrolled; PASS was determined after 1 month of treatment (T1); days to