Background: Baricitinib, an oral Janus kinase (JAK) 1-2 inhibitor, is currently used among biologic DMARDs (bDMARDs) after the failure of methotrexate (MTX) in rheumatoid arthritis (RA). Power Doppler ultrasound (PDUS) is a promising, non-invasive imaging method to assess synovitis in RA: results from numerous studies suggest that it provides additional information to clinical and conventional radiographic examinations.

Objectives: The main objective of our study was to evaluate short-term efficacy of Baricitinib in reducing synovitis, using the composite semi-quantitative score (0–3 grades) PDUS Synovitis score, developed by the Outcome Measures in Rheumatology–European League Against Rheumatism (OMERACT–EULAR)-Ultrasound Task Force. Moreover both synovial hyperplasia and intrasynovial power Doppler (PD) signal were also scored as single components/parameters on 0-3 scales. Secondary objective was to assess the concordance between patient reported outcomes (PROs), markers of inflammation, physical examination and US.

Methods: We enrolled 30 patients fulfilling 2010 ACR and EULAR criteria for RA. All patients had failed at least one anti-TNF. Each patient was prescribed Baricitinib 4 mg/daily at T0, in addition to MTX and/or oral steroids at a dosage ≤ 7.5 mg/day of Prednisone or equivalent, at T1. All patients were evaluated at baseline (T0) and then after one month (T1), 3 months (T2) and 6 months (T3) of treatment. Swollen and tender joints (out of 28) were evaluated and recorded, as well as patient (PGA) and physician global assessment (PGA) and pain, expressed in a visual analog scale (VAS). Disease activity was evaluated at each visit using DAS28 (Disease activity score 28), CDAI (Clinical disease activity index) and SDAI (Modified disease activity index), accompanied by a complete blood count, Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) collection. Statistical analysis was performed using GraphPad version 9.0.0. PDUS examination, was carried out by two rheumatologists (PF and CB) blinded to clinical conditions of the patients, using an Esaote Mylab Twice (Genoa, Italy), equipped with a high-frequency (6-18 MHz) linear probe. With standardised Doppler parameters (pulse repetition frequency between 500-750 Hz; Doppler frequency between 7-11 MHz), PDUS was performed at each visit bilaterally for 22 joint sites [MCPs 1–5, proximal interphalangeal joints (PIPs) 1–5, wrist, elbow, glenohumeral, knee, tibiotalar, talonavicular and calcaneocuboid and metatarsophalangeal joints (MTPs) 1–5] for a total of 44 joints for each patient.

Results: we obtained a reduction of VAS pain (T0 vs. T6=0.0001) PDUS composite score (T0 vs. T6 p=0.0001), Power Doppler (T0 vs. T6 p<0.0001) synovial hyperplasia (T0 vs. T6 p=0.0002), CRP (T0 vs. T6 p=0.0001) and ESR (T0 vs. T6 p<0.0001) was observed in our patients. Accordingly, DAS-28, CDAI and SDAI displayed a significant reduction too (DAS-28: T0 vs. T6 p<0.0001; CDAI: T0 vs. T6 p<0.0001; SDAI: T0 vs. T6 p=0.0003).

Conclusion: We investigated the efficacy of Baricitinib in real life, evaluating both from a clinimetric and ultrasound point of view. Baricitinib, demonstrated a significant parallel and fast improvement in VAS, PDUS and CRP was found at follow up assessment as early as one month of therapy. In conclusion, these results demonstrated the short term efficacy of Baricitinib 4mg for up to 6 months and providing a prompt improvement of PROs within the first weeks of treatment.
Objectives: The combination use due to potential risk of hepatotoxicity. LEF is very well established, but there have been lot of concern as regards their provides a potent and valuable low-cost treatment option. Efficacy of MTX and (RA) and seronegative inflammatory arthropathies refractory to other csDMARD combination therapy could be an effective initial evidence that MTX and LEF combination therapy could be an effective outcomes significantly influence decision making process, and our data provides conclusions significantly influence decision making process, and our data provides

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SAFETY AND EFFICACY OF COMBINING METHOTREXATE AND LEFLUNOMIDE AMONG PATIENTS WITH INFLAMMATORY ARTHROPATHIES: FINDINGS FROM THE PRIME REGISTRY

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Background: Currently, conventional synthetic DMDARs (csDMARDs) are the most commonly prescribed drugs as first-line treatment for peripheral arthritis. In resource-constrained settings where biologic agents are not widely available, there are limited therapeutic options for patients with rheumatoid arthritis (RA) and seronegative inflammatory arthropathies refractory to other csDMARD therapies. Hence, in our practice, we are inclined to use combination of potent DMARDs after MTX failure, prior to considering biologic therapies. We believe that combination of DMARDs, especially combining MTX and Leflunomide (LEF) provides a potent and valuable low-cost treatment option. Efficacy of MTX and LEF is very well established, but there have been lot of concern as regards their combination use due to potential risk of hepatotoxicity.

Objectives: We aimed to review our inflammatory arthropathies cohort data especially examining the safety, efficacy and drug retention of the combination usage of MTX and Leflunomide. We addressed this question using real-world data from the PRIME registry.

Methods: This was a cross-sectional study conducted using data collected at the time of patient enrolment in the PRIME registry. The PRIME Registry is a large, independent, prospective, observational cohort initiated in October 2019 that comprises patients diagnosed with RA. SLE, PsA or AS by a rheumatologist, and is being actively followed up. IRB approval and informed consent was obtained. A number of clinical variables were recorded. Detailed history was gathered from every patient regarding their present and past medications usage. Questions were asked directly about the usage or otherwise of all available DMARDs and biologics. The duration of usage, any adverse events, or the reasons for discontinuation were recorded. Evaluation of disease activity and severity was made as per internationally agreed definitions.

Results: The data of 766 inflammatory arthritis patients (RA=663, PsA=103) was reviewed. Among them, 241 patients (RA=196, PsA=45) were using combination therapy of MTX and LEF (combo MTX+LEF) with mean age 42.3±6 years; 42% females, 58% males. 14% (33.5%) patients had to discontinue this combo MTX+LEF therapy due to adverse events. Disease activity among combo MTX+LEF users was as follows: 64% (n=29) of PsA patients had achieved MDA; 42% (n=83) of RA cohort were in DAS28 remission, 46% (n=91) of RA patients were having DAS low disease activity.

Conclusion: Combination of MTX and LEF was well tolerated and had good drug retention time, with 94.6% of patients having ongoing treatment to date. In our practice, combination therapy of MTX+LEF is the first-line therapy of choice due to safety and efficacy concerns. LEF is very well established, but there have been concerns as regards their combination use due to potential risk of hepatotoxicity. The combination therapy could be an effective treatment option. Efficacy of MTX and LEF combination therapy could be an effective treatment option.

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A MULTICENTER RANDOMIZED STUDY IN RHEUMATOID ARTHRITIS TO COMPARE IGU RATIMOD, METHOTREXATE, OR COMBINATION: 52 WEEK EFFICACY AND SAFETY RESULTS OF THE SMILE TRIAL

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Background: Icutavigomod (IGU) has demonstrated efficacy and safety for active rheumatoid arthritis (RA) patients in double-blind clinical trials in China and Japan as a new disease-modifying antirheumatic drug (DMARD). There are no studies evaluating the radiographic progression of structural joint damage of IGU for the treatment of RA using the mTSS as the primary endpoint.

Objectives: Our study was to evaluate the efficacy and safety of IGU monotherapy and IGU combined methotrexate (MTX) compared with MTX monotherapy, including the inhibitory effects of joint destruction.

Methods: This randomized, double-blind, placebo-controlled, multicenter study in patients with active RA who have not previously used MTX and biological DMARDs (bDMARDs) (ClinicalTrials.gov Identifier NCT01548001) was carried out in China. Patients were randomized 1:1:1 to receive IGU 25 mg twice a day (bid), MTX 10mg once a week(qw) for the first 4 weeks and 15 mg/qw for week 5 to 52, or IGU combined MTX (IGU+MTX) for 52 weeks. The primary endpoints were to assess and compare American College of Rheumatology 20% (ACR20) response rate ( Sharp score of mTSS) score over 52 weeks (Intention-to-treat, ITT analysis). The non-inferiority test was used to analyze the difference of ACR20 response at 52 weeks between the IGU monotherapy and the MTX monotherapy arms, and the non-inferiority