keratopathy (2 studies) and tamoxifen use (2 studies). Sex (2 studies) and history of cataract surgery (2 studies) were not found to be predictors of toxicity. Only few studies performed regression analysis presenting odds and/or hazard ratios with confidence intervals.

Conclusion: The most recognised predictor of cardiac toxicity was co-administration with azithromycin. In ocular toxicity, commonly cited predictors included those already recognised by the RCOPhth¹, as well as cumulative dose, increased age, weight considerations, HCQ blood levels and keratopathy. Further research is warranted on better characterising predictors of cardiac and ocular toxicity in patients on HCQ and CQ therapy.

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POS0663

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 DMARDs (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, and 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% male]. These patients had failed MTX or LEF monotherapy. Among these 241 patients, 49 patients were also on concomitant hydroxychloroquine therapy. It was noted that median drug retention of combo MTX+LEF therapy has been 9.5 months (IQR 6-16). Regarding any adverse events of combo MTX+LEF therapy, hepatotoxicity (ALT ≤3 times the upper limit of normal) was noted among 15 (6.2%) patients, hepatotoxicity (ALT ≥3 times the upper limit of normal) was noted among 8 (3.3%) patients, and troublesome gastrointestinal upset (nausea, or vomiting, or diarrhoea) in 3 (1.2%). Overall, only 13 (5.4%) 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 low-income countries, where bDMARD availability is limited, financial arguments significantly influence decision making process, and our data provides initial evidence that MTX and LEF combination therapy could be an effective treatment option.

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POS0664

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

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Background: Igaratimod (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 anti-rheumatic 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, parallel-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 25mg twice a day (bid), MTX 10mg once a week(qw) for the first 4 weeks and 15mg once a week(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 and the change of modified total Sharp scoring (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