

uncontrolled RA activity, and rifampin had been administered concomitantly in four of these seven patients. Of the four patients, three stopped taking tofacitinib in the middle of LTBI treatment, and the DAS28-ESR scores of these patients were higher at discontinuation than at baseline.
Conclusion: Discontinuation rates were higher in RA patients who started tofacitinib during chemoprophylaxis involving rifampin than in those who did not receive rifampin. Physicians should be aware that the efficacy of tofacitinib could be decreased by the chemoprophylactic regimen for tuberculosis.

Figure 1. Discontinuation rates of tofacitinib owing to lack of efficacy within 6 months

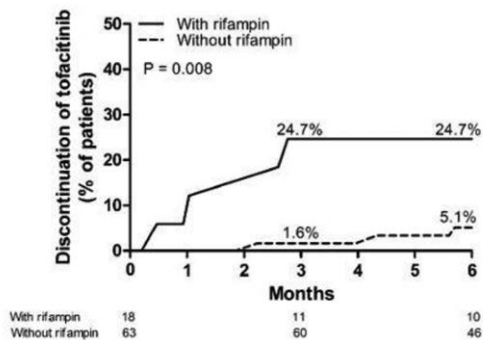
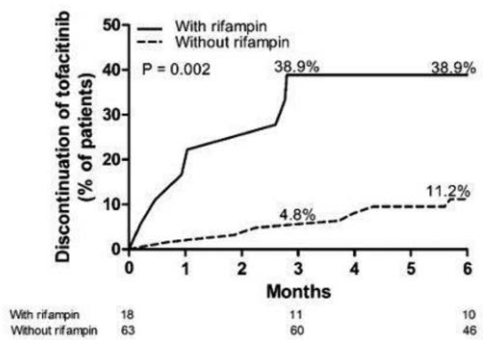


Figure 2. Discontinuation rates of tofacitinib owing to all causes within 6 months



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THU0211 RADIOGRAPHIC OUTCOMES IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING UPADACITINIB AS MONOTHERAPY OR IN COMBINATION WITH METHOTREXATE: RESULTS AT 2 YEARS FROM THE SELECT-COMPARE AND SELECT-EARLY STUDIES

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Background: For patients with rheumatoid arthritis (RA), long-term prevention of structural joint damage is a key treatment goal.¹ In the SELECT-EARLY and SELECT-COMPARE trials, upadacitinib (UPA), an oral JAK inhibitor, inhibited the progression of structural joint damage at 6 months and 1 year when used either as monotherapy or in combination with methotrexate (MTX) in patients (pts) with active RA.²

Objectives: To describe the radiographic progression up to 2 years (96 wks) among pts with RA receiving UPA either as monotherapy or in combination with MTX.

Methods: Both the SELECT-EARLY and SELECT-COMPARE phase 3, randomized controlled trials enrolled pts at high risk for progressive structural damage with baseline (BL) erosive joint damage and/or seropositivity.^{3,4} In SELECT-EARLY, MTX-naïve pts (N=945) were randomized to UPA 15 mg or 30 mg once

daily (QD) or MTX monotherapy. In SELECT-COMPARE, pts with an inadequate response to MTX (N=1629) were randomized to UPA 15mg, placebo (PBO), or adalimumab (ADA) 40mg every other wk, with all pts continuing background MTX; at wk 26, all pts receiving PBO were switched to UPA 15mg, regardless of response. In both trials, mean changes from BL in modified Total Sharp Score (mTSS), joint space narrowing, and joint erosion as well as the proportion of pts with no radiographic progression (change in mTSS ≤0) were evaluated based on X-rays taken at wks 24/26, 48, and 96 for those patients in whom wk 96 X-rays were available. Data are reported as observed (AO).

Results: BL demographics have been reported previously.^{3,4} In the SELECT-EARLY study, at wk 96 UPA monotherapy (15 mg and 30 mg doses) significantly inhibited radiographic progression compared with MTX as measured by mean change in mTSS and by the proportion of patients with no radiographic progression (Figures 1 and 2). When patients who were rescued (MTX added to UPA or UPA added to MTX) were removed from the analysis, changes in mTSS from baseline remained similar. By the same measures, in SELECT-COMPARE, the degree of inhibition of structural progression observed was comparable between UPA and ADA. Following the switch of all PBO patients to UPA, the rate of progression slowed and was comparable to that observed in pts receiving UPA from BL. Among pts from both studies that had no radiographic progression at wk 24/26, >90% remained without radiographic progression at wk 48 and 96.

Conclusion: UPA was effective in inhibiting the progression of structural joint damage through 2 years both in MTX-naïve patients receiving UPA monotherapy and MTX-inadequate responder patients receiving UPA in combination with MTX.

References:

- [1] Smolen, et al. *Ann Rheum Dis* 2017;76(6):960-77.
- [2] Peterfy, et al. *Ann Rheum Dis* 2019;78(suppl 2):369-370.
- [3] Fleischmann, et al. *Arthritis Rheumatol* 2019;71(11):1788-1800.
- [4] Van Vollenhoven, et al. *Arthritis Rheumatol* 2018;70(suppl 10).

Figure 1. Mean Change in mTSS from Baseline in SELECT-COMPARE (A) and SELECT-EARLY (B)

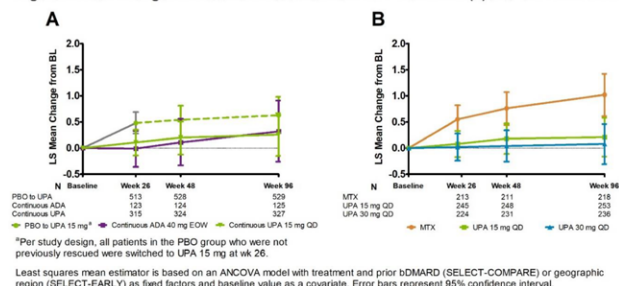
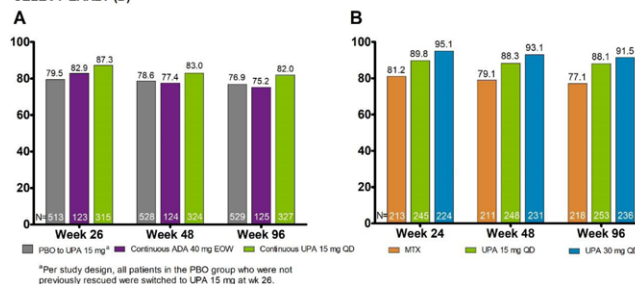


Figure 2. Proportion of Patients with No Radiographic Progression in SELECT-COMPARE (A) and SELECT-EARLY (B)



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THU0212

FIRST LINE TREATMENT WITH CONVENTIONAL SYNTHETIC DISEASE MODIFYING ANTIRHEUMATIC DRUGS IN RHEUMATOID ARTHRITIS: A MULTINATIONAL POPULATION-BASED COHORT FROM 14 REAL WORLD HEALTHCARE DATABASES AND 9 COUNTRIES - REALITY VERSUS GUIDELINES

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Background: Treatment guidelines recommend early initiation of csDMARDs following diagnosis of rheumatoid arthritis (RA), with methotrexate (MTX) as first-line therapy. Scarce evidence exists on adherence to this guidance

Objectives: To characterize first-line csDMARD treatment during the first year following an RA diagnosis.

Methods: 14 real world databases (3 Primary care, 6 primary/secondary care records, 5 claims) from 9 countries were included, all mapped to the OMOP common data model.

Patients were included on the earliest event of: 1st diagnosis of RA or 1st DMARD prescription with an RA diagnosis within 30 days. Patients were >18 years-old, required 1+ year pre-index data, and at least 1-year follow-up. Study period covered 2000-2018. Previous users of DMARDs or non-RA inflammatory arthritis history were excluded. Only MTX, Hydroxychloroquine (HCQ), Sulfasalazine (SSZ) and Leflunomide (LEF) were available in all databases.

Results: We identified 323,547 eligible participants. Large variation was observed internationally (Figure 1). MTX as first-line monotherapy ranged from 33.3% to 74.5%, and in combination with HCQ from 2.1% to 6.7%. Three

additional csDMARDs were used as first-line: HCQ in 10.1% to 30.2%, SSZ in 0.9% to 28.7%, and LEF in 1.8% to 15.2%.

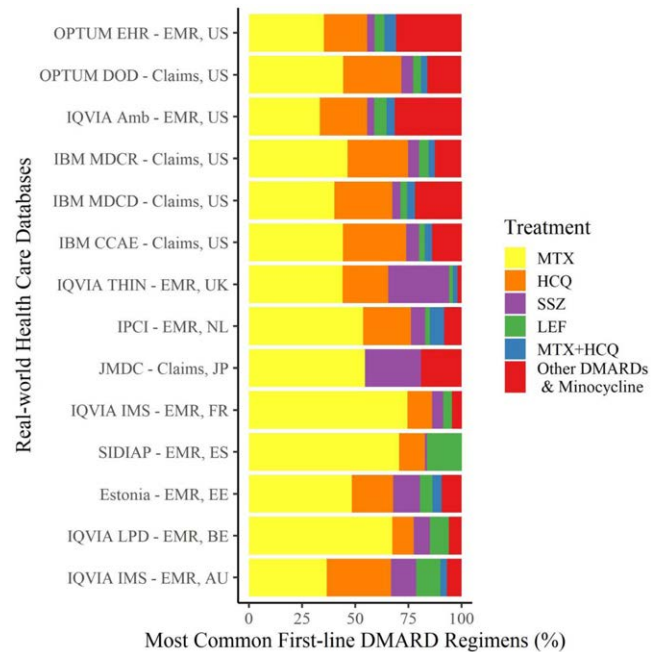


Figure 1. First line csDMARD treatment during 1yr from first observed RA diagnosis

Conclusion: We report wide heterogeneity of first-line csDMARDs regimens internationally. Despite recommendations for MTX to be first line therapy, data suggest that a large proportion of patients receive alternative csDMARD.

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THU0213

UPADACITINIB AS MONOTHERAPY IN PATIENTS WITH RHEUMATOID ARTHRITIS AND PRIOR INADEQUATE RESPONSE TO METHOTREXATE: RESULTS AT 84 WEEKS FROM THE SELECT-MONOTHERAPY STUDY

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