indirect, yet powerful indicator of the impact of MTX therapy on patients' quality of life.

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AB0337

TOFACITINIB MONOTHERAPY OR COMBINED WITH METHOTREXATE IN PATIENTS WITH RHEUMATOID ARTHRITIS SHOW SIMILAR RETENTION OVER FOUR YEARS. REPORT FROM RHUMADATA ®

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Background: Since the introduction of biologic agents around the turn of the century, the scientific evidence shows that the majority of agents, independent of the therapeutic target, have a better outcome when used in combination with methotrexate (MTX). In 2014, tofacitinib (TOFA), an agent targeting Janus kinase 1 and 3, has reached the Canadian market with data showing that the combination with MTX may not be necessary [1,2].

Objectives: To evaluate the efficacy and retention rate of TOFA in real-world patients with rheumatoid arthritis (RA).

Methods: Two cohorts of patients prescribed TOFA was created. The first cohort was formed of patients who were receiving MTX concomitantly with TOFA (COMBO) and the other of patients using TOFA in monotherapy (MONO). MONO patients either never use MTX or were prescribed MTX post-TOFA initiation for at most 20% of the time they were on TOFA. COMBO patients received MTX at the time of TOFA initiation or were prescribed MTX post-TOFA initiation for at least 80% of the time. For all those patients, baseline demographic data definitions. Disease activity score and HAQ-DI were compared from the initiation of TOFA to the last visit. Time to medication discontinuation was extracted, and survival was estimated using Kaplan-Meier calculation for MONO and COMBO cohorts.

Results: Overall, 194 patients were selected. Most were women (83%) on average younger than the men (men: 62.6 ± 11.0 years vs. women: 56.9 ± 12.1 years, p-value=0.0130). The patient's assessments of global disease activity, pain and fatigue were respectively 5.0 ± 2.7, 5.2 ± 2.9, 5.1 ± 3.1 in the COMBO group and 6.2 ± 2.5, 6.5 ± 2.6, 6.3 ± 2.8 in the MONO group all differences being significant across groups. HAQ-DI at treatment initiation was 1.3 ± 0.7 and 1.5 ± 0.7 in the COMBO and MONO groups, respectively, p-value=0.0858. Similarly, the SDAI score at treatment initiation was 23.9 ± 9.4 and 25.2 ± 11.5, p-value=0.5546. Average changes in SDAI were -13.4 ± 15.5 (COMBO) and -8.9 ± 13.5 (MONO), p-value=0.1515, and changes in HAQ -0.21 ± 0.63 and -0.26 ± 0.74, p-value 0.6112. At treatment initiation, DAS28(4)ESR were 4.4 ± 1.4 (COMBO) and 4.6 ± 1.3 (MONO), p-value 0.5815, with respective average changes of -1.06 ± 2.07 and -0.70 ± 1.96, p-value=0.2852. The Kaplan-Meier analysis demonstrated that the COMBO and MONO retention curves were not statistically different (log-rank p-value=0.9318).

Conclusion: Sustainability of TOFA in MONO or COMBO are not statistically different as are the changes in DAS28(4)ESR and SDAI. Despite this result, some patients may still benefit from combination with MTX.

References:

- Product Monograph - XELJANZ® (tofacitinib) tablets for oral administration Initial U.S. Approval: 2012.
- Reed GW, Gerber RA, Shan Y, et al. Real-World Comparative Effectiveness of Tofacitinib and Tumor Necrosis Factor Inhibitors as Monotherapy and Combination Therapy for Treatment of Rheumatoid Arthritis [published online ahead of print, 2019 Nov 9]. *Rheumatol Ther.* 2019;6(4):573–586. doi:10.1007/s40744-019-00177-4.

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AB0338

EVALUATION OF THE ASSOCIATION OF ALLELES OF INTOLERANCE RISK TO METOTREXATE IN RHEUMATOID ARTHRITIS PATIENTS UNDER TREATMENT WITH BIOLOGIC THERAPIES

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Background: Metotrexate (MTX) is the first-line treatment for rheumatoid arthritis (RA) both in monotherapy and in combination with biologic disease-modifying antirheumatic drugs (bDMARDs), it usually well tolerated but AEs may appear that causing toxicity that requires suspension of the treatment

Objectives: Determine the prevalence of certain polymorphisms among patients that receive bDMARD in monotherapy or in combination with MTX to confirm its relevance as biomarkers of intolerance. Evaluate the influence of certain polymorphisms in the effectiveness of monotherapy or combined treatment in patients, through "Disease Activity Score 28" (DAS28), SDAI Simple disease activity index (SDAI), Clinical disease activity index (CDAI) and each one of its components

Methods: Retrospective observational multicentric study (University Hospital Complex, Granada, Carlos de Haya Hospital, Málaga and University Hospital Reina Sofía, Córdoba), of cases-control of 227 patients with RA (criteria ACR/ EULAR), of which 120 received MTX and bDMARD combined therapy (cases) and other with only bDMARD (controls). All of them had been or were currently treated with MTX, remained with stable doses of bDMARD, and had a DNA sample stored before the inclusion in the study

DNA was isolated from total peripheral blood and by fluorescent probe Hyb-Probe and/ or Taqman, 10 polymorphisms of 10 protein coding genes were determined involved in the metabolism and toxicity of MTX according to current evidence

Besides the type of polymorphism, data on the activity of the disease were analysed (DAS28VSG, DAS28PCR, SDAI, CDAI, at the start of the MTX income, of the BT, and in the inclusion visit

A descriptive and comparative study was carried out on all that and afterwards an assessment was made through a multiple logistic regression analysis (MLR) on the risk of intolerance to MTX

Results: An analysis was carried out on 227 patients (120 cases and 107 controls) with an average age of 60 (12,1) being women 78,4%, with a time of evolution since diagnosis of 14,84 (7,78) years

48,9% registered adverse events (AE) MTX related, mainly gastrointestinal, hepatobiliary and skin-subcutaneous tissue. The percentage of AE appearance was superior in the monotherapy group than in the group with combined therapy