cross-over group, sustained inhibition of mTSS and erosion score (ES) progression was observed during long-term treatment phase (table 1). No effect on joint space narrowing (JSN) was observed (table 1). Overall proportions of patients with no progression (ie, mTSS change ≤ 0.5) at 36 months were 56.8% in P/Q6M, 53.3% in P/Q3M, 66.3% in Q6M group, and 65.7% in Q3M group. Incidence of adverse events (AEs), serious AEs and AEs leading to discontinuation of study drug were similar across treatment groups. No events of atypical femoral fracture were observed.

Conclusions: Denosumab treatment was associated with sustained inhibition of progression of joint destruction for up to 36 months and was generally well tolerated in Japanese patients with RA on csDMARDs. Denosumab has the potential to be a new therapeutic option to inhibit the progression of structural damage for patients with RA.

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SAT0174

DOES ABATACEPT INCREASE PERIOPERATIVE ADVERSE EVENTS IN PATIENTS WITH RHEUMATOID ARTHRITIS COMPARED WITH CONVENTIONAL SYNTHETIC DISEASE MODIFYING DRUGS? - A RETROSPECTIVE MULTICENTER NESTED CASE-CONTROL STUDY

H. Ito¹, S. Tsuji², M. Nakayama³, Y. Mochida⁴, K. Nishida⁵, H. Ishikawa⁶, T. Kojima⁷, T. Matsumoto⁸, A. Kubota⁹, T. Mochizuki¹⁰, K. Sakuraba¹¹, I. Matsushita¹², A. Nakajima⁹, R. Hara¹³, A. Haraguchi¹⁴, T. Matsubara¹⁵, K. Kanbe³, N. Nakagawa¹⁶, M. Haraguchi¹⁷, S. Momohara¹⁸ on behalf of JOSRA consortium. ¹Kyoto University Graduate School of Medicine, Kyoto, ²Osaka-Minami Medical Center, Sakai, ³Tokyo Women's Medical University, Tokyo, ⁴Yokohama City Hospital Medical Center, Yokohama, ⁵Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama, ⁶Niigata Rheumatic Center, Shibata, ⁷Nagoya University Graduate School of Medicine, Nagoya, ⁸The University of Tokyo Graduate School of Medicine, ⁹Toho University School of Medicine, ¹⁰Kamagaya General Hospital, Tokyo, ¹¹Kyushu Medical Center, Fukuoka, ¹²University of Toyama, Toyama, ¹³Nara Medical University, Nara, ¹⁴Kyushu University Graduate School of Medicine, Fukuoka, ¹⁵Matsubara Mayflower Hospital, Kato, ¹⁶Hyogo Prefectural Kakogawa Medical Center, Kakogawa, ¹⁷Kameoka Municipal Hospital, Kameoka, ¹⁸Keio University Graduate School of Medicine, Tokyo, Japan

Background: Abatacept (ABT) is clinically used as the only T-cell modifier available for rheumatoid arthritis treatment and has shown similar efficacy as tumour necrosis factor inhibitors and a safer profile, especially a lower infection ratio in registry data. Latourte et al. recently published the results of perioperative complications of orthopaedic and other types of surgery in patients using ABT. However, they did not compare the complication rates with those in patients who received

csDMARDs. It remains unknown whether ABT is associated with more postoperative complications than conventional synthetic DMARDs (csDMARDs).

Objectives: The aims of this study were to investigate whether ABT is associated with more adverse events after orthopaedic surgery compared with csDMARDs and, if so, to identify significant risk factors for those events.

Methods: A retrospective multicenter nested case-control study was performed in 18 institutions. Patients receiving ABT were matched individually with patients receiving csDMARDs and/or steroid. Serious adverse events were defined as surgical site infection, delayed wound healing, deep vein thrombosis or pulmonary embolism, flare-up, serious infection in other organs. The incidence rates of serious adverse events in both groups were compared with Mantel-Haenszel test. Risk factors for serious adverse events in the ABT group were analyzed by logistic regression model.

Results: A total of 3358 cases were collected. After inclusion and exclusion, 2651 patients were selected for matching, and 194 patients in 97 pairs were chosen for subsequent comparative analyses between the ABT and control groups. No between-group differences were detected in the incidence rates of each adverse event or in the combined incidence rate of adverse events. The odds ratio of the history of serious infection for serious adverse events was 12.6 (95%CI 1.12–141, P=0.04) in patients who received ABT and underwent orthopaedic surgery.

Conclusions: Compared with csDMARDs and/or steroid without ABT, adding ABT to the treatment does not appear to increase the incidence rates of postoperative adverse events in rheumatoid arthritis patients undergoing orthopaedic surgery. A history of serious infection is a significant risk factor for both infection and other serious adverse events, and such patients should be treated with particular caution.

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SAT0175

RESPONSE TO BIOLOGIC TREATMENT IMPROVES SEXUAL HEALTH ASSESSED BY THE QUALISEX SCORE IN RA

A. Perdriger¹, C. Lucas¹, J. Sibilia², J.-E. Gotteberg². ¹rheumatology, rheumatology Department, Rennes university, Rennes Cedex 2, ²rheumatology, strasbourg University, strasbourg, France

Background: Sexual health of RA patients is an aspect of the care often neglected and about which little is known. Qualisex is a simple (10 questions) and valid tool investigating impact of RA on sexuality. This tool can be useful to assess this important aspect of quality of life. (Gossec and al, Clin Exp Rheum, 2012).

Objectives: Qualisex questionnaire was used in active RA patients of the ROC (Rotation or change) study (Gotteberg et al, JAMA 2016) in order to investigate the association between disease activity and response to a biologic treatment and sexual health.

Methods: Among 153 patients of the randomized controlled trial "ROC", which compared a second anti-TNF to a non-TNF biologic in RA patients with inadequate response to a first anti-TNF. Qualisex questionnaire was proposed to 83 RA patients, and 57 of them filled the questionnaire before and after 6 months of their allocated biologic. Changes in the qualisex score was analyzed according to the variation of the clinical and biological parameters.

Results: The mean age of the 57 RA patients studied was 50.2 (9.6) years. The mean duration of disease was 11.2 (9.5) years, and 43 (75.4%) were female. After 6 months of treatments, 19 were considered with a good response to the treatment according to EULAR response (DAS 28 VS ≤ 3.2 and a variation of 0.6 of the DAS from the base line).

The mean value of qualisex score was 4.05 (+/- 2.53) at V0 and 3.91 (+/- 2.45) after 6 months of treatment. The variation of the qualisex score was more important among the 19 responder patients than among the 43 patients with a persistently active disease. Changes in the qualisex score was significantly correlated to the changes in DAS28, in asthenia, and in SF36 mental score, but not with changes in pain, or in SF36 physical score.

Variables correlation with qualissex score P value

Variation of DAS 28 CRP 0.33 0.01

Variation of DAS 28 VS 0.27 0.04

Variations of asthenia 0.31 0.03

Variation of pain 0.13 NS

Variations of SF 36 physical score -0.21 NS

Variation of SF36 mental score -0.3 0.03

Conclusions: This first study of sexual health of RA patients in a randomized trial demonstrates an improvement in sexual health in patients responders to a biologic treatment. Improvement of sexual health was associated with a decrease in disease activity and asthenia.

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SAT0176 CONTRIBUTION OF CD4+ T CELLS DECREASE ON CLINICAL RESPONSE TO RITUXIMAB IN RHEUMATOID ARTHRITIS

A. Bensalem¹, D. Mulleman^{1,2}, G. Thibault^{1,3,4}, N. Azzopardi³, G. Paintaud^{1,5}, P. Goupille^{1,2}, D. Ternant^{1,5}. ¹EA GICC, University of Tours, ²Rheumatology, CHRU de Tours, ³CNRS ERL 7001, University of Tours, ⁴Immunology, ⁵Pharmacology-Toxicology, CHRU de Tours, Tours, France

Background: Rituximab (RTX) is approved for the treatment of rheumatoid arthritis (RA), but there is a large inter-individual variability in clinical response. A better response was previously associated with a decrease in CD4+ T cell counts [1, 2].

Objectives: This study aimed at analyzing the contribution of CD4+ T cell decrease in the clinical response in RA patients treated with RTX.

Methods: In this retrospective monocentric observational study, 52 patients were assessed. All patients had received 2 infusions of 1000 mg of RTX 2 weeks apart. Disease activity score in 28 joints (DAS28) was used as clinical endpoint. RTX serum concentrations, peripheral blood CD4+ counts, and DAS28 were measured before and after each RTX infusion and at 3, 6 and 9 months after last infusion. A population PK-PD model, including a physiological turnover and direct response model, was developed to estimate the probability of CD4+ counts decrease. The turnover model was used to describe the effect of RTX on CD4+ T-cell counts, and the direct model was used to describe both RTX and CD4+ T cell count effect on DAS28.

Results: The probability of CD4+ counts decrease was estimated at 0.75. Patients with a CD4+ decrease had a higher Δ DAS28 than the patients without CD4+ decrease, with a maximal Δ DAS28 of -1.34 and -0.64 in patients with and without CD4+ cell decrease, respectively. Moreover, at M6, patients with CD4+

cell decrease had a median DAS28 of 3.5 (IQR: 2.7 – 4.4), among them 39.5 % with low disease activity (DAS28 $\leq$ 3.2) and 22.3 % in remission (DAS28<2.6). At the same time point, median DAS28 of patients without CD4+ cell decrease was 4.3 (IQR: 3.5 – 5.1), among them 17.7 % with low disease activity, and 8.6 % in remission (see Figure 1 Box plot of DAS28 in patients with and patients without CD4+ decrease.).

Conclusions: This is the first study to quantify the contribution of CD4+ T cell decrease to the clinical response in RA patients treated with RTX.

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SAT0177 REAL-WORLD INTERRUPTIONS IN JANUS KINASE INHIBITOR THERAPY OBSERVED AMONG BIOLOGIC-NAÏVE AND BIOLOGIC-EXPERIENCED RHEUMATOID ARTHRITIS PATIENTS

B. Chastek¹, E. Koep¹, U. G. Mallya², A. Cockerham², J. Choi², S. Boklage³, D. E. Furst^{4,5,6}. ¹Optum, Eden Prairie, ²Sanofi, Bridgewater, ³Regeneron Pharmaceuticals, Inc., Tarrytown, ⁴University of California Los Angeles, Los Angeles, ⁵University of Washington, Seattle, United States, ⁶University of Florence, Florence, Italy

Background: Orally administered janus kinase inhibitors (JAKi) can be used to treat moderate-to-severe rheumatoid arthritis (RA).

Objectives: Examine real-world patterns of use, including interruptions in therapy and switching, in biologic-naïve and biologic-experienced patients with RA newly prescribed a JAKi.

Methods: A retrospective analysis was performed using healthcare claims data from the Optum Research Database. Commercial and Medicare Advantage patients aged $\geq$ 18 years were included with: $\geq$ 1 pharmacy claim for a JAKi 01 January 2012–29 February 2016 (index date = date of first claim); continuous enrollment in health plan for $\geq$ 12 months before and 13 months post-index; and $\geq$ 1 claim with a RA diagnosis (ICD-9 = 714.0x; ICD-10 = M05* or M06*) during baseline or on the index date. A variable length pre-index period to 01 January 2006 was implemented to capture certain measures. Persistence was defined as the time from index prescription fill to earliest gap in fills $\geq$ 30 days (interruption) or switching to a biologic disease-modifying antirheumatic drug (bDMARD). Patients were classified as being: persistent with the index therapy for the full year, switching before interruption, switching after interruption, interruption with restart, and interruption without restart (discontinuation). Patients were assigned to two groups: those with and without $\geq$ 1 claim for bDMARD treatment during the variable length pre-index period (biologic-experienced and biologic-naïve). Data were expressed as % or mean (SD). Sensitivity analyses assessed prescription fill gaps $\geq$ 90 days.

Results: Of 1059 patients who met the inclusion criteria, 80.2% were biologic-experienced, 81.8% female, mean age 56.2 (11.8) years. More biologic-naïve patients (48.6%) had Medicare Advantage coverage than biologic-experienced (22.3%). For the primary analysis, 72.4% of patients were not persistent for the 1-year following initiation of a JAKi, with 39.1% not persistent beyond 90 days (figure 1). Among non-persistent patients, 42.4% interrupted and restarted a JAKi (time from index to restart, 168.9 [83.8] days), 16.8% switched to a bDMARD before interruption, 13.3% switched after interruption and 27.5% discontinued bDMARD and JAKi therapy (time to discontinuation, 148.4 [117.6] days). More biologic-naïve than biologic-experienced patients neither initiated a bDMARD nor restarted a JAKi after interruption (44.2% vs 23.3%, respectively; $P<0.001$). For the sensitivity analysis, 52.6% were non-persistent for the full year.