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

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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

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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.

Figure 1 Kaplan-Meier curve of persistence with JAKi therapy

Conclusions: Most patients (80.2%) newly initiating JAKi therapy had prior bDMARD experience. Over 70% were non-persistent with JAKi treatment for 1 year, with 39% non-persistent beyond 90 days. For non-persistent patients, the pattern of JAKi use was characterized most as interrupting with restart (42%), followed by switching (30%), and then discontinuation (28%). Reasons for the high non-persistence rate are unknown but may include suboptimal efficacy or intolerance. Further research is needed to elucidate these points.

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SAT0178 PREDICTORS OF DRUG SURVIVAL OF ABATACEPT IN RHEUMATOID ARTHRITIS – RESULTS FROM A LARGE NATIONAL QUALITY REGISTER COHORT STUDY

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Background: Abatacept is a biologic disease modifying anti-rheumatic drug (bDMARD) used to treat rheumatoid arthritis (RA). There is growing experience with abatacept in many countries. National registers are useful resources for investigation of long term real world outcomes.

Objectives: To compare the effectiveness of abatacept in the treatment of RA between bionative patients and patients with previous bDMARD treatment, and to investigate predictors of remaining on treatment with abatacept.

Methods: This was an observational cohort study, based on a national quality register database. Patients with a diagnosis of RA who initiated treatment with abatacept between April 1, 2006 and November 20, 2017, were included. Patients were censored at abatacept discontinuation, death, migration, or the end of the study period. Analyses were stratified by previous exposure to bDMARDs. Survival on drug was estimated using the Kaplan-Meier method. Predictors of discontinuation of abatacept were investigated in Cox Proportional Hazards analyses, with significance-based backwards stepwise selection of variables for the final multivariate model.

Results: A total of 2716 patients with RA (80 % females, mean age 59 years, mean duration of RA 14 years) started abatacept during the study period. Of these, 17 % had no previous bDMARD treatment (bionative patients), 27 % had received 1bDMARD previously, and 56 % had been treated with ≥ 2 bDMARDs.

Fifty percent each of the patients received intravenous and subcutaneous therapy. At the time of abatacept initiation, 57 % were on methotrexate (MTX), and 48 % were treated with glucocorticosteroids. There were significant differences in drug survival across categories of previous bDMARD exposure ($p=0.002$). The median survival time on treatment was 2.23 years for bionative patients (95 % confidence interval (CI) 1.69–2.79), 1.68 years for those with 1 previous bDMARD (95 % CI 1.34–2.01) and 1.56 years for those with ≥ 2 previous bDMARDs (95 % CI 1.35–1.76). At 6 months, 88 % of bionative patients remained on abatacept, compared to 74 % at 12 months. The corresponding figures for those with 1 or ≥ 2 previous bDMARDs were 78 % and 61 %, and 76 % and 59 %, respectively. In bivariate analyses, bionative patients were less likely to discontinue treatment compared to those treated with ≥ 2 previous bDMARDs previously (Table). Bionative patients were more often male (28 % vs 18 %) and had lower pain scores (mean Visual analogue scale score 58 vs 62) compared to those previously exposed to ≥ 2 bDMARDs. Measures of disease severity were associated with reduced drug survival (Table), but age, RA duration and method of administration had no significant impact on discontinuation. In the final multivariate model, pain increased the risk of abatacept discontinuation, whereas male patients and those on concurrent MTX had a reduced risk of stopping abatacept (Table).

Significant predictors for abatacept discontinuation. Cox regression analysis

		Unadjusted analysis HR (95 % CI)	Multivariate analysis – final model HR (95 % CI)
Sex	Male	0.85 (0.75-0.96)	0.86 (0.74-0.98)
No of previous bDMARDs	≥ 2 bDMARDs	reference (1.0)	*
	Bionative	0.78 (0.68-0.90)	*
	1 bDMARD	0.94 (0.84-1.05)	*
Baseline clinical characteristics	DAS28-CRP (per SD)	1.11 (1.04-1.17)	*
	VAS pain (per SD)	1.14 (1.08-1.21)	1.14 (1.07-1.20)
	Current Methotrexate	0.86 (0.78-0.96)	0.85 (0.76-0.95)
	HAQ-DI (per SD)	1.10 (1.04-1.17)	*

*Not included in the final model

Figure 1. Significant predictors for abatacept discontinuation. Cox regression analysis*Not included in the final model

Conclusions: Survival on abatacept was significantly longer in bionative RA patients compared to those previously exposed to bDMARDs. In the bionative subset, 50 % of the patients remained on treatment after 2.2 years. Concomitant MTX therapy, male sex and low pain scores were associated with longer drug survival for abatacept.

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SAT0179 THE BLOOD B-CELL SUBSETS AND EFFECT OF TOCILIZUMAB THERAPY ON THEM IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: The use of the IL-6 receptor antagonist, tocilizumab (TCZ), in rheumatoid arthritis (RA) produce pleiotropic effects that also involve circulating B-cells. Preliminary reports have suggested that B cell function and humoral immune responses might be modulated by TCZ treatments in RA pts.

Objectives: To assess the effect of 12 months (mo) TCZ therapy on B-cell phenotype and gene expression in RA and to analyze the association between B-cell subsets and RA activity.

Methods: 24 active RA pts (20 F/4 M); median age 55[49; 64] years; disease duration 72[24; 108]m; DAS28 score 5,8[5,3;6,3]; RF+100%, ACCP+ 87% were treated in an open-label study with tocilizumab (8 mg/kg every 4 weeks). Immunophenotyping was performed at baseline and 12 mo. Pts were assessed for B-cell subpopulations and laboratory data: ESR, RF, ACCP, CRP. CD19+B cells, memory B cells (CD19+CD27+), non-switched memory B cells (CD19+CD27+ IgD+), switched memory B cells (CD19+ CD27+IgD-), naive (CD19+CD27-IgD+), double-negative (CD19+CD27-IgD-), transitional (CD19+CD38++CD10+IgD+CD27-) B cells, and plasmablasts (CD19+CD38+++CD27+IgD-CD20-) were analyzed using multicolor flow cytometry.

Results: At baseline, the absolute counts of memory B cells (CD19+CD27+) and switched memory B cells (CD19+CD27+IgD-) were lower in RA pts compared to