suggests that discontinuation of bDMARD should be considered in patients on cDMARD therapy, fulfilling the more stringent remission criteria by CDAI.
Disclosure of Interest: None declared
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THU0221 CLINICAL OUTCOMES OF ABATACEPT VERSUS TNF INHIBITORS IN ACPA-POSITIVE PATIENTS WITH RHEUMATOID ARTHRITIS: DATA FROM THE BIOLOGIC REGISTER KOBIO

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Background: Determining the optimal, patient-tailored biologic agent is a new challenge for future guidelines in rheumatoid arthritis (RA) management. Recent studies demonstrated that anti-citrullinated protein antibody (ACPA) -positive patients have better disease activity improvement with abatacept (ABA), yet validation studies are in need.

Objectives: To investigate disease activity changes after treatment with ABA versus TNF inhibitors (TNFi) in Korean ACPA-positive, RA patients.

Methods: Data of RA patients were obtained from the Korean College of Rheumatology Biologics Registry (KOBIO). ACPA-positive patients who were treated with ABA and TNFi were selected through propensity score matching (1:2, calliper=0.2*SD). Clinical outcomes including CDAI changes at the first year of therapy were evaluated, and adjusted drug survival in each group was analysed.

Results: The baseline characteristics of the ABA (n=97) and TNFi (n=194) groups were comparable. The CDAI reduction after 1 year treatment was significant in the ABA group compared with patients who received TNFi (-16.78 versus -13.61, p=0.0198) [figure 1]. This was confined when used as the first-line agent (p=0.0213). Proportion of remission and low disease activity in ABA was significant as well (p=0.041). Patients with the lower tertile of ACPA titers treated with ABA had the most significant CDAI reduction compared with the TNFi group (p=0.0201). Drug retention rate (median follow-up 48 months) of ACPA-positive ABA users was also notable compared with TNFi yet did not meet statistical significance (adjusted hazard ratio 0.774, p=0.086).

Conclusions: Our data further support that ACPA could also be an important marker to help determine first-line biologic agent of choice among the armamentarium of biologic therapy for RA patients.

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THU0222 MULTISWITCHING – FROM REFERENCE PRODUCT ETANERCEPT TO BIOSIMILAR AND BACK AGAIN – REAL-WORLD DATA FROM A CLINIC-WIDE MULTISWITCH EXPERIENCE

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Background: The etanercept (ETN) biosimilar SB4 was introduced in Sweden in 2016 at a lower price than the reference product etanercept (RPE). Now the reverse is true, as the price of RPE dropped. Switching ETN-treated patients to the lowest priced ETN available is economically favourable. The safety of multiple switches between RPE and biosimilar has been addressed in a psoriasis trial,¹ finding no indications of harm. No reports on outcomes of multiswitching in a rheumatology setting are available.

Objectives: To describe the impact of a clinic-wide switch from RPE to SB4 and then back to RPE on disease activity and drug-survival, relating outcomes to a historical cohort of RPE-treated patients.

Methods: Observational study of 145 patients switched from RPE to SB4 (day 0=20/4/2016) and back to RPE (day 544=16/10/2017) for economical reasons. Letters were mailed to patients on day 0 and 544, informing them that prescriptions had been changed from RPE to SB4 and from SB4 to RPE respectively. During days 1–543, clinicians were allowed to switch patients back to RPE if requested by the patient or if medically indicated. Disease activity data was entered into the Swedish Rheumatology Quality Register (SRQ) at visits. The SRQ was searched retrospectively for data from day –365 to 771 (May 31, 2018). Visits were categorised into visits occurring a) on days –365 to day 0, b) on days 1–543 and c) on days 544–771. A reference cohort of all RPE-treated patients on April 20, 2013 at the clinic was used for comparison.

Results: Numbers and proportions of patients discontinuing SB4 during days 1–543 in the switching cohort and RPE in the historical cohort are shown in the table 1. On day 544, the 97 patients still treated with SB4 were switched back to RPE. In the switching cohort, DAS28 and CRP did not change significantly when comparing data from visits occurring before the switch from RPE to SB4 to data from visits that occurred on days 1–543 and days 544–636 (figure 1). Data from 5 months of additional follow-up, up until day 771 will be presented at the congress. Among the 24 patients that discontinued SB4 during days 1–543 and went back to RPE, no worsening of disease activity parameters was seen during SB4 treatment.

	Switching cohort, n=145	Historical RPE-treated cohort, n=98	p
Discontinued SB4/RPE, total*	48 (33)	15 (15)	0.002
‡Back to RPE	24 (17)	Not applicable	N/A
‡No biologic	14 (10)	6 (6)	0.32
‡Non ETN biologic	10 (7)	9 (9)	0.52
On ETN (SB4 or RPE) at day 544	121 (83)	83 (85)	0.80

*During days 1–543 ‡ Treatment after discontinuation of SB4/RPE

Abstract THU0222 – Figure 1. Mean DAS28 and CRP with 95% CI for 145 patients in the switching cohort according to timepoint of visit..n:s refer to number of visits contributing to data during each period.

Conclusions: The strategy of multiswitching ETN-treated patients has thus far not impacted disease activity negatively in our population. An additional 5 months of follow-up data after the second switch will be presented at the congress. A high proportion of patients discontinued SB4 after the initial switch, as no worsening in disease activity measures was seen in the data we believe this to have been due to nocebo effects.

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THU0223

IMPACT OF TREATMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS AND DEPRESSIVE SYMPTOMS IN THE MONARCH PHASE 3 TRIAL OF SARILUMAB

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Background: In the MONARCH Phase 3 randomised controlled trial (RCT) [NCT02332590], sarilumab subcutaneous (SC) 200 mg every 2 weeks (q2w) improved clinical outcomes and multiple aspects of health status/health-related quality of life (HRQoL), as measured by the Medical Outcomes Survey Short Form (SF-36) questionnaire, to levels greater than adalimumab SC 40 mg q2w. Both treatments were administered as monotherapy in patients with active rheumatoid arthritis (RA) who had discontinued treatment with methotrexate. Depression/mood disorder is a common co-morbidity in people with RA.

Objectives: To explore whether observed differences in health status/HRQoL following treatment with sarilumab compared with adalimumab are also seen in the subgroup of patients in the MONARCH trial with probable depressive symptoms.

Methods: Post-hoc statistical analyses were performed. Patients were categorised as having probable major depressive disorder¹ (PMDD; SF-36 mental health (MH) domain score ≤ 56) or probable depressed mood and anhedonia² (PDMA; score ≤ 10 on both items of the MH domain: "Have You Felt Downhearted and Depressed" and "Have You Felt So down in the Dumps that nothing could cheer you up"). Least squares mean (LSM) differences in changes from baseline (CFB) in SF-36 domains at Week 24 were calculated for sarilumab PMDD/PDMA versus adalimumab PMDD/PDMA. Sensitivity analysis included adjustment for Disease Activity Score 28 C-reactive protein (DAS28-CRP) at baseline.

Results: Of the 369 patients from MONARCH, 250 (67.78%) were categorised with PMDD (mean age 52 years, 85% female) and 194 (52.6%) with PDMA (mean age 52 years, 87% female). Disease duration, DAS-28 CRP, tender and swollen joint counts (table 1) and SF-36 domain scores (figure 1) were similar between sarilumab and adalimumab within the PMDD and PDMA subpopulations at baseline. LSM differences in CFB in SF-36 domains were greater for sarilumab versus adalimumab at Week 24 in physical functioning (PF), bodily pain (BP), vitality (VT) and social functioning (SF) domains in both the PMDD and PDMA subgroups, and role-physical (RP) in the PMDD subgroup (nominal $p < 0.05$) (figure 1). Sensitivity analysis showed similar results.

Abstract THU0223 – Table 1

Table Baseline characteristics in MONARCH patients with PMDD or PDMA	PMDD: SF-36 MH domain score ≤ 56 (N=250)		PDMA: ≤ 10 on both items of SF-36 MH domain (N=194)	
	Sarilumab 200mg q2w (n=128)	Adalimumab 40mg q2w (n=132)	Sarilumab 200mg q2w (n=98)	Adalimumab 40mg q2w (n=96)
Duration of RA since diagnosis, years, mean (SD)	8.29 (8.13)	7.03 (8.53)	7.92 (7.30)	7.46 (8.49)
DAS28-CRP, mean (SD)	6.13 (0.85)	6.18 (0.88)	6.17 (0.96)	6.18 (0.83)
Tender joint count (0-68), mean (SD)	29.03 (14.05)	28.36 (14.21)	28.98 (14.34)	28.69 (14.46)
Swollen joint count (0-66), mean (SD)	19.20 (11.67)	18.69 (10.74)	19.68 (11.78)	19.53 (11.09)

Conclusions: Among patients with RA and probable depressive symptoms, sarilumab SC 200 mg q2w monotherapy was more effective than adalimumab SC 40 mg q2w monotherapy in demonstrating clinically meaningful improvements in some domains of health status/HRQoL. This may be a function of the different

target of sarilumab (soluble IL-6 receptor [sIL-6R]) and associated improvements in disease activity versus adalimumab (tumour necrosis factor [TNF α]).

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THU0224

RENACER STUDY: EFFICACY AND SAFETY ASSESSMENT OF CZP THERAPY IN THE TREATMENT OF 501 PATIENTS WITH RHEUMATOID ARTHRITIS(RA) AMONG SPANISH POPULATION IN CLINICAL PRACTICE

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Background: Certolizumab PEGol (CZP) differs from other anti-TNFs in that it is monovalent and it lacks the Fc region found in monoclonal antibodies. CZP is also PEGylated. Its efficacy in patients with rheumatoid arthritis (RA) has been evaluated in previous clinical trials.

Objectives: The purpose of the current study is to assess effectiveness, safety and survival rate in patients with RA after 12 months of treatment and also within specific subgroups, in clinical practice settings.

Methods: Observational longitudinal prospective study of RA patients from 40 sites in Spain. Variables (baseline, 3- and 12 month assessment): socio-demographics, smoking status, previous synthetic DMARD (sDMARD) and biological DMARD (bDMARD) use; TJC, SJC, ESR, CRP, DAS28. Response variables EULAR Moderate/Good Response and DAS28 remission and Safety were assessed. Descriptive, comparative and Logistic regression analyses were performed. Kaplan-Meier survival curve was performed.

Results: A total of 501 patients were included: 78.6% women, mean age 53.6 year (± 13.2 SD) and 77% were aged < 65 year Mean disease duration 7.5 year (± 7.3 SD) and 27.7% having early RA. Baseline features are shown in table 1. Mean number of prior sDMARD 1.5 (± 1.1 SD). Mean number of prior bDMARD was 0.8 (± 1.2 SD). Mean duration of exposure to CZP was 9.8 months (± 3.4 SD); Concomitant steroids intake 12.6%, sDMARD 24.2% and sDMARD plus steroids 54.9%; Smoking status: 69.8% never smoked, 12.9% former smoker and 17.3% current smoker.

Baseline predictors of response: lower prior number sDMARD; low number prior bDMARD; higher CRP, ESR, TJC, SJC and DAS28 ($p < 0.05$) scores.

Patients < 65 year had shown better DAS28 Remission rates as well as those who had previously received < 2 sDMARDs, those who were "bionative" at CZP initiation and those who used CZP in combination.

CZP survival rates are shown in Figures 1 and 2.

Adverse effects from treatment were reported in 65 patients (13%), mostly mild.

Conclusions: CZP showed benefit in active RA patients, with clear improvement in all clinical parameters, mostly in < 65 yo patients and those who had received low number of previous sDMARD and bDMARD. Survival rate at 12 month assessment was high, demonstrating a reasonable safety profile.

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