Figure 2 Percentages of sarilumab and adalimumab responders at Week 24 by baseline noninflammatory pain status

24 when treated with sarilumab versus placebo or adalimumab. Patients with and without BL NIP had greater improvements in pain when treated with sarilumab versus adalimumab. The difference in clinical improvement was greater among patients with BL NIP versus without BL NIP for most measures. These trends support the emerging concept that mechanisms other than direct inflammation may contribute to pain in RA, potentially mediated via IL-6 signaling.

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SAT0103

THE EFFECT OF BODYWEIGHT ON RESPONSE TO INTRAVENOUS OR SUBCUTANEOUS TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Tocilizumab is an IL-6 receptor humanised monoclonal antibody treatment option in rheumatoid arthritis (RA) who have not responded or are intolerant of disease modifying anti-rheumatic drugs (DMARDs) or other biologics. Tocilizumab was available initially as an intravenous (IV) preparation, dosed according to weight, and more recently as a subcutaneous (SC) preparation given at 162mg/weekly irrespective of bodyweight.

Obesity is highly prevalent in RA and there has been concern that starting or switching patients to SC tocilizumab could reduce its effectiveness in those patients with a higher body weight when compared to IV tocilizumab.

Objectives: To investigate the relationship between bodyweight and DAS28 response at 6 months in tocilizumab naïve RA patients starting IV or SC tocilizumab.

Methods: The study population comprised RA subjects recruited to the BSRBR-RA up to 30/11/2018 commencing IV or SC tocilizumab for the first time. Patients had

to be tocilizumab naïve and have at least one six monthly study follow-up recorded after starting tocilizumab. Baseline characteristics at point of starting tocilizumab are described. Linear regression, fully adjusted for relevant confounders, was used to investigate the relationship between change in DAS28 score from baseline to six months and body weight per ten kilograms (kg), and in a separate analysis, as BMI category. Multiple imputation was used to handle missing data.

Results: 1241 patients starting tocilizumab (902 IV, 339 SC) were eligible for analysis. The median age was 59 years, majority were female, and had median disease duration of 11 years at baseline. Over seventy percent had prior biologic exposure. Median weight was 77kg for IV and 76kg for SC starters, and the majority of patients were categorised as normal weight (30% IV, 37% SC) or pre-obesity (31% IV & SC) according to BMI. Median DAS28 score was 5.8 (IV) and 5.5 (SC) at start of treatment with median improvement after 6-months of 1.50 and 2.02 units respectively. The fully adjusted linear regression model showed no association between body weight or BMI and change in DAS28 score at six months for patients starting IV or SC tocilizumab. (Table).

Table

Baseline Variable	Intravenous TCZ patients (n=902)	Subcutaneous TCZ patients (n=339)
Age, median (IQR)	58 (50-67)	60 (51-70)
Gender, n (%) female	708 (78)	233 (74)
Disease duration, median (IQR) years	11 (4-21)	11 (4-21)
DAS28 score, median (IQR)	5.8 (5.1-6.6)	5.5 (4.7-6.5)
Change in DAS28 score, median (IQR)	-1.50 (-3.10 - -0.23)	-2.02 (-3.72 - -0.37)
Weight in KGs, median (IQR)	77 (64-91)	76 (64-88)
Body weight per 10kgs*	0.04 (-0.01-0.09)	-0.005 (-0.11-0.10)
BMI category*	ref	ref
Normal weight	ref	ref
Underweight	-0.41 (-1.27-0.46)	0.08 (-1.62-1.77)
Pre-obesity	-0.26 (-0.57-0.05)	0.02 (-0.44-0.48)
Obesity class I, II & III	-0.03 (-0.35-0.29)	0.08 (-0.40-0.55)

*Fully adjusted for age, gender, disease duration, baseline DAS28 score, baseline HAQ score, co-morbidities, and number of previous biologics

Conclusion: Data from this study show that body weight does not appear to affect initial response to IV or SC tocilizumab. This is reassuring given that patients are likely to be given SC tocilizumab due to ease of administration and reduced hospital costs.

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SAT0104

MAINTENANCE OF SDAI REMISSION AND PATIENT-REPORTED OUTCOMES (PROS) FOLLOWING DOSE DE-ESCALATION OF ABATACEPT IN MTX-NAÏVE, ANTI-CITRULLINATED PROTEIN ANTIBODY (ACPA)+ PATIENTS WITH EARLY RA: RESULTS FROM AVERT-2, A RANDOMISED PHASE IIIB STUDY

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Background: The Phase IIIB Assessing Very Early RA Treatment (AVERT)-2 trial (NCT02504268) evaluated SC abatacept (ABA) + MTX vs ABA placebo (PBO) + MTX in ACPA+ patients (pts) with early, active RA. ¹ Results from the 56-wk induction period (IP) showed a significantly greater proportion of pts treated with ABA + MTX (vs MTX alone) reported clinically meaningful improvements in HAQ-DI, global disease activity and pain, which were sustained at 52 wks. ²

Objectives: To report maintenance of SDAI remission and PROs from the AVERT-2 de-escalation (D-E) period.

Methods: Pts received blinded SC ABA (125mg once wky [QW]) + MTX or ABA PBO + MTX induction treatment for 56 wks. In this analysis, pts who completed induction with ABA + MTX and had sustained SDAI remission (≤ 3.3 at Wks 40 and 52) were re-randomised 1:1 to ABA QW + MTX, stepwise D-E (ABA every other wk + MTX for 24 wks then ABA PBO + MTX for 24 wks), or ABA QW + MTX PBO for 48 wks in the D-E period. PROs included physical function (HAQ-DI [0–3; decrease=improvement] and Short-Form 36 [SF-36] v2.0 Physical Functioning Scale [PFS]; 0–100; increase=improvement), and fatigue (Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-F] score; 0–52; decrease=improvement). Endpoints included: proportion of pts in SDAI remission and pts with HAQ-DI response (decrease from IP Day [D1] in HAQ-DI ≥ 0.30); adjusted mean change (adMC) from D-E D1 in HAQ-DI, SF-36 PFS or FACIT-F to D-E Wk 48. adMCs were estimated using a mixed effect model with repeated measures.

Results: 147 ABA + MTX-treated pts were re-randomised in the D-E period. Across re-randomised arms, the range of mean scores was 1.87–2.52 for SDAI and 0.18–0.30 for HAQ-DI at entry into D-E period (D-E D1). 74% of pts receiving ABA QW + MTX maintained SDAI remission at D-E Wk 48 (Fig 1); this proportion was higher than in the ABA withdrawal and ABA QW + MTX PBO arms. Pts continuing ABA QW + MTX maintained HAQ-DI response during D-E (Fig 1), but by D-E Wk 48 the proportion of pts with HAQ-DI response in the ABA withdrawal arm declined by 30%. At D-E Wk 48, a small numerical decrease (adMC –0.04) in HAQ-DI was observed in the ABA QW + MTX arm; increases were seen in the withdrawal (adMC 0.26) and ABA QW + MTX PBO arms (adMC 0.16). By D-E Wk 48, SF-36 PFS increased (adMC 1.68) in the ABA QW + MTX arm but decreased in the withdrawal (adMC –3.34) and ABA QW + MTX PBO (adMC –1.45) arms. FACIT-F score increased during D-E in all arms, but the increase at D-E Wk 48 was lower in the ABA QW + MTX arm (adMC 0.79) vs the withdrawal (adMC 4.12) and ABA QW + MTX PBO (adMC 2.41) arms. Similar trends were seen for other PROs including Work Productivity and Activity Impairment-RA; while activity impairment remained stable in the ABA QW + MTX arm, there was a trend for worsening in the withdrawal arm.

Conclusion: In the AVERT-2 D-E period, continued combination therapy (abatacept + MTX) resulted in maintenance of benefits on PROs, particularly physical functioning, in seropositive pts with early RA. D-E of abatacept followed by complete withdrawal was associated with the greatest loss of remission as well as worsening of PROs. The PRO results corresponded well to the maintenance of clinical (SDAI) remission.

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Figure 1. Proportion of Patients in SDAI Remission (≤ 3.3) or with HAQ-DI Response (≥ 0.30) Over Time in the D-E Period Among Re-randomised Patients

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SAT0105

INFLUENCE OF RITUXIMAB ON DIASTOLIC FUNCTION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: One of the drugs used in the treatment of rheumatoid arthritis (RA) is rituximab. Given the fact that the RA affects not only the joints, but, in addition to other organs, and the heart, our interest has caused the likelihood of the impact of rituximab on non-articular manifestations of rheumatoid arthritis, in particular, related to the cardiovascular system.

Objectives: to study the effect of rituximab on the development of diastolic dysfunction of the heart in patients with RA.

Methods: 98 patients with RA were examined, of which 28 patients took rituximab 1000mg according to the scheme for 6-12 months and methotrexate up to 25mg per week per os (1st group), and 70 patients – only methotrexate up to 25mg per week at least 12 months (2nd group). They were held echocardiography with calculation of the E/a of mitral valve, E/a of tricuspid valve, end-diastolic size of left ventricle, electrocardiography with calculation of the dispersion of QT interval and vectorcardiography with determination of the areas of the P loop, QRS loop, T loop, and the maximum vector (MV), MV-azimuth and MV-lift.

Results: the E/a of mitral and tricuspid valves in 1st group were higher than in 2nd group ($p < 0.05$). In 1st group, a correlation was found between the E/a of both valves and the MV-lift; and also between the dispersion of QT interval and the maximum vector ($p < 0.05$).

Conclusion: in patients taking rituximab, there is a relationship between diastolic dysfunction, electrical instability of the ventricles and signs of electrophysiological remodeling. In addition, the use of rituximab is associated with a lower severity of diastolic dysfunction of both ventricles and a lower risk of life-threatening arrhythmias compared to the group that did not take this drug.

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