Fig4. The proportion of CD4⁺CD25⁺Foxp3⁺ Treg cells in treated RA patients under different treatment regimes.

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SAT0092

LOW SERUM LEVEL OF VITAMIN D AT TIME OF DIAGNOSIS IS ASSOCIATED WITH HIGHER ONE-YEAR REMISSION RATE IN PATIENTS WITH NEWLY DIAGNOSED RA, TREATED AGGRESSIVELY DURING FOLLOW-UP: POST-HOC ANALYSES OF THE CIMESTRA TRIAL

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Background: Vitamin D is often low in Rheumatoid Arthritis(RA), and immunomodulatory properties of vitamin D might be associated with disease-course in RA.(1)

Objectives: To evaluate association between baseline vitamin D metabolites and one-year remission, in newly diagnosed, treatment-naïve RA patients, aggressively treated during follow-up.

Methods: The CIMESTRA-cohort comprises 160 newly diagnosed RA patients, treated aiming at remission with methotrexate and intraarticular steroid, further randomized 1:1 to ciclosporine or placebo-ciclosporine.(2) A total of 158 patients had vitamin D metabolites measured at time of diagnosis. Dietary vitamin D supplementation was recommended in accordance with the national guidelines. Serum vitamin D_{total} (sum of 25OHD₂ and 25OHD₃) and 1,25(OH)₂D at time of diagnoses were measured by LC-MS/MS or RIA. D_{total} were dichotomized at 50 nmol/l, and 1,25(OH)₂D categorized in tertiles. Primary outcome was remission (DAS28-CRP ≤ 2.6) after one year. Associations were calculated using logistic regression, presented as Odds Ratios with 95% Confidence Intervals (95%CI). Adjustment of analyses included sex, age, symptom duration prior to diagnosis, DAS28-CRP and season of diagnosis.

Results: In univariate analyses, neither D_{total} nor 1,25(OH)₂D at time of diagnosis predicted remission at year one. In adjusted analysis, D_{total} <

50 nmol/l at time of diagnosis showed better odds for achieving one-year remission, compared to sufficient D_{total}; OR 2.56, 95%CI (1.11; 5.90) p = 0.03. 1,25(OH)₂D was not associated to remission.

Conclusion: Low D_{total} at time of diagnosis is associated to increased odds for achieving remission at year one in early, treatment naïve RA patients, treated aggressively during follow-up.

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SAT0093

THE ASSESSMENT OF THE SYNOVIAL VASCULARIZATION WITH POWER DOPPLER ULTRASONOGRAPHY AND ITS CORRELATION WITH THE SYSTEMIC INDICATORS OF INFLAMMATION AND WITH THE DISEASE ACTIVITY

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Background: Rheumatoid arthritis (RA) is an autoimmune disease with the predominant synovial inflammation. The disease activity and inflammatory markers in the serum indicate an active stage of the disease with a risk of joint destruction. As the synovial hypervascularity is considered a proof of an active inflammation, its assessment with different scoring methods in Power Doppler ultrasonography (PDUS) is being discussed.

Objectives: We investigated correlation of synovial vascularization (assessed in PDUS) with inflammatory markers and disease activity. We compared two methods for the evaluation of synovial vascularization : quantitative and semi-quantitative.

Methods: We studied 50 RA patients, mean age of 58 years, predominantly female (F/M ratio 3:1), mean disease duration span of 9.5 years. Data on: age, sex, patient global assessment of pain measured by a 100-mm visual analog scale (VAS) were obtained. The disease activity state was defined by DAS28 score (score in 28 joints) and simplified disease activity index (SDAI). Of the laboratory tests: erythrocyte sedimentation rate (ESR), serum C-reactive protein level (CRP), the presence of rheumatoid factor(RF) and anti-cyclic citrullinated peptide antibodies (ACPA) were performed. In ultrasound, the examination of the synovial vascularity, as a symptom of inflammation, was scored in PDUS, utilizing the validated scoring system, grade 0 – lack of flow, 1 – one to two vessels visible within the synovium, 2 – numerous vessels occupying up to 50% of the thickened synovium, 3 – numerous vessels occupying over 50% of the synovium volume. The second quantitatively scale was also used, with the color fraction index (CFI), defined as the ratio of the

number of color pixels to all the pixels in a selected range of interest (ROI). The study was approved by the proper ethics committee. Statistical analysis: differences between groups were analyzed using U Mann-Whitney test (continuous variables). Correlations between quantitative variables were assessed with the Spearman correlation coefficient. Statistical significance was set at $p < 0.05$.

Results: DAS-28: mean 6.0 (SD=0.9); median 6.1 (IQR: 5.5 - 6.6); SDAI: mean 61.1 (SD=38.3); median 51.3 (36.8 - 76.4). No correlation was found between CFI and age, platelet count, CRP, RF, ACPA, DAS28 and SDAI as well as with the disease duration. But there was a strong positive correlation between CFI and PDUS results, $\rho = 0.71$; $p < 0.05$. As expected, DAS28 and SDAI strongly correlated with inflammatory markers (ESR, CRP). The results showed, that CFI between 2-8 % is an equivalent of PDUS grade 1, CFI 8-50% of PDUS grade 2 and CFI > 50% of PDUS grade 3.

Conclusion: i) although PDUS is a method used to assess synovial inflammation, through the determination of the synovial vascularization, its results, regardless of the scoring system employed, do not correlate with the systemic inflammation indicators, such as ESR and CRP or with the disease activity – which needs further explanation, ii) the approximate equivalence of CFI and of PDUS scoring system is as follows: CFI > 50% - PDUS grade 3, CFI 8-50% - PDUS grade 2, CFI < 8% - PDUS 1, which confirms previously published research.

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SAT0094

UNITED STATES RHEUMATOLOGY PRACTICE-BASED REAL-WORLD EVIDENCE OF METHOTREXATE UTILIZATION AND RESPONSE TO THERAPY IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH INTRAVENOUS GOLIMUMAB

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Background: AWARE (Comparative and Pragmatic Study of Golimumab IV Versus Infliximab in Rheumatoid Arthritis) is an ongoing Phase 4 comparator study designed to provide a real-world assessment of intravenous golimumab (GLM) and intravenous infliximab (IFX) in patients (pts) with rheumatoid arthritis (RA). The primary objective of AWARE is to assess the incidence of infusion reactions, the concomitant use of methotrexate (MTX) is also reported. The FDA approved label for GLM states that it is indicated for the treatment of patients with moderately to severely active RA in combination with MTX; however prospectively obtained real world evidence based data on the rate of GLM use without MTX has not been reported.

Objectives: Here we compare patient demographics, disease characteristics, response to therapy and discontinuation of GLM treated patients with and without concomitant MTX from an interim analysis (IA) of the AWARE study.

Methods: AWARE is a prospective, noninterventional, observational, multicenter 3-year study conducted in the US. RA pts (1,200 adults) were enrolled at the time of initiating treatment with GLM or IFX. All treatment decisions including MTX utilization are made at the discretion of the treating rheumatologist. Imputations of CDAI data were not performed at this IA. Data shown are mean $\pm$ standard deviation.

Results: 678 GLM pts were enrolled; of these 487 (71.8%) were GLM Plus-MTX and 191 (28.2%) were GLM No-MTX. Demographics are shown in the table. Response to therapy was assessed with CDAs and shown in the figure below. Overall, 92.6% of GLM Plus-MTX and 91.5% of GLM No-MTX pts had a baseline (BL) categorical CDAI disease activity

of moderate or high, and 7.4% of GLM Plus-MTX and 8.5% of GLM No-MTX pts had a BL categorical CDAI disease activity of low or remission. Discontinuation from the study during the period of this IA was similar between the GLM Plus-MTX (173/487; 35.5%) and GLM No-MTX (64/191; 33.5%). 7.9% of GLM No-MTX pts reported leflunomide use.

	GLM Plus-MTX	GLM No-MTX
Number of Patients	487	191
Age (years)	61.7 $\pm$ 12.85	58.7 $\pm$ 14.55
Sex (% Female)	87.1%	81.7%
Disease Duration (yr)	9.0 $\pm$ 9.67	9.6 $\pm$ 10.74
Baseline CDAI	30.9 $\pm$ 14.58	33.2 $\pm$ 16.61
Race		
White	86.2%	87.4%
African American	8.6%	8.4%
Other	5.1%	4.2%
Weight (kg)	83.6 $\pm$ 24.55	84.0 $\pm$ 22.21
BMI (kg/m ²)	31.0 $\pm$ 8.45	30.8 $\pm$ 7.89

Conclusion: At BL 28.2% of pts on GLM did not report concomitant MTX use. The demographics of the GLM Plus-MTX pts did not differ remarkably from GLM No-MTX pts. The reported early response to treatment, assessed by CDAI score after 3 months and 6 months was similar in the GLM Plus-MTX and GLM No-MTX groups. These preliminary IA data suggest that in a real-world rheumatology practice setting, use of GLM with or without concomitant MTX led to similar CDAI scores at 3 and 6 months in RA pts with predominantly moderate to high BL CDAI disease category.

CDAI Score Among Patients Treated with Golimumab IV: Plus-MTX or No-MTX

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SAT0095

MEDICATION NECESSITY AND CONCERN BELIEFS ARE DISTINCT, INTERACTIVE PREDICTORS OF TREATMENT ADHERENCE IN RHEUMATOID ARTHRITIS

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Background: Medication adherence is instrumental for the successful management of rheumatoid arthritis (RA) to a goal of remission. Awareness of medication necessity and concerns regarding its use influence adherence and respectively foster or undermine the achievement of treatment goals.

Objectives: We explored the unique and interactive roles of patient beliefs about the necessity of RA medications and concerns about them in predicting adherence to prescribed treatments.