Results: Sample: 2055 RA patients, female=85.1%, median disease duration=6.02 yrs; mean (SD) age=50.3 (12.1) yrs; mean (SD) DAS28=5.3 (3.1); seronegative RA=14.1%; median follow-up duration=3.9 yrs. In total, 565 patients received 664 courses of the MTX-LEF combination (median duration, 2.5 years/course; 2209 person-years). The incidence of SAE was 4.75/100 patient-years in the entire sample. There was no significant increase in the risk of any of the outcomes with the use of combined therapy (table 1) comparing with methotrexate (without leflunomide). The use of antimalarials was associated with reduced risk of SAE (adjusted HR=0.62, 95% CI 0.48 to 0.79, $P<0.001$), while sulfasalazine (adj. HR=1.78, 1.18 to 2.68, $P=0.006$) and biologic DMARDs/tofacitinib (adj. HR=1.67, 1.31 to 2.12, $P<0.001$) increased the risk of SAE.

Table 1

Outcome(number of SAE)	HR (95% CI), p Value	HR (95% CI), p Value
SAE (457)	1.00(0.78-1.26), p=0.970	1.06(0.83-1.35), p=0.629
SAE infections (228)	1.1(0.79-1.55),p=0.538	1.24(0.89-1.75), p=0.207
SAE non-mycobacterial lung infections (78)	0.90(0.50-1.62), p=0.733	0.97(0.53-1.74), p=0.908
SAE hepatic AE(14)	1.12(0.28-4.48), p=0.873	NA
SAE hematologic (10)	2.09(0.52-8.36), p=0.299	NA
SAE CV (61)	1.22(0.65-2.30), p=0.529	1.11(0.58-2.12), p=0.755

*Comparing with MTX (without leflunomide) and adjusted for the use of LEF (without MTX) and a category representing absence of MTX and LEF. †Adjusted also for time-fixed covariates (age, gender, smoking, history of malignancy, diabetes, hypertension, renal failure, ischemic cardiomyopathy, bronchopulmonary obstructive disease) and time-varying covariates (use of sulfasalazine, antimalarials, biologic DMARDs/tofacitinib, and corticosteroids). SAE: serious adverse events, MTX: methotrexate, LEF: leflunomide, NA: not applicable due to reduced number of events, CV: cardiovascular.

Conclusion: BIOBADABRASIL results suggest that the combination of methotrexate and leflunomide is safe in the treatment of RA.

REFERENCES:

- [1] Ann Intern Med 2002; 137: 726.
- [2] Ann Rheum Dis 2010; 69: 43.
- [3] Ann Pharma cother 2004; 38: 1206.
- [4] J Rheumatol 2013; 40: 228.
- [5] Rev Bras Reumatol 2011; 51: 141/51:152.

Acknowledgement: monitor P Cabral

Disclosure of Interests: Markus Bredemeier: None declared, M Pinheiro Consultant for: Janssen, Pfizer, Speakers bureau: Abbot,Janssen,Novartis, C Macieira: None declared, A Duarte: None declared, B Stadler: None declared, R Ranza: None declared, Ana Medeiros: None declared, V Valim: None declared, M Bertolo: None declared, J Miranda Speakers bureau: Pfizer, C Brenol Speakers bureau: Pfizer, Roche, Janssen, Bristol., G Castro: None declared, V Fernandes Speakers bureau: Janssen, D Titton: None declared, F Sauma: None declared, I Pereira: None declared, R Botelho: None declared, H Carvalho: None declared, A Hayata: None declared, P Louzada: None declared, A Ranzolin: None declared, I Silveira: None declared, S Schowalski: None declared, D Feldman: None declared, I Laurindo Consultant for: Abbvie, UCB, GSK, JANSSEN, LILLY, NOVARTIS, PFIZER, Paid instructor for: Abbvie, JANSSEN, Speakers bureau: Abbvie, UCB, GSK, JANSSEN, LILLY, NOVARTIS, PFIZER, ROCHE, J Provenza: None declared

DOI: 10.1136/annrheumdis-2019-eular.3867

FRI0143

IS PATIENT – PHYSICIAN DISCORDANCE IN ASSESSMENTS OF BURDEN OF RHEUMATOID ARTHRITIS A DETERMINANT OF METHOTREXATE ADHERENCE?

Ana Bulatovic¹, Natasa Miketic¹, Milan Bogojevic¹, Svetlana Aligrudic², Rifat Medjedovic¹, Darija Kisic Tepavcevic³. ¹Clinical center of Montenegro, Podgorica, Montenegro; ²Mercur Nera Polyclinic, Podgorica, Montenegro; ³Institute of public health, Belgrade, Serbia

Background: Accurate assessments of disease activity in rheumatoid arthritis (RA) have a crucial role in establishing disease severity and monitoring response to treatment. There is no objective, numerical

measures to estimate RA severity and treatment response. A frequently used means of quantifying the overall perception of disease activity is through an subjective assessment of global disease activity on a visual analogue scale (VAS), both by the patient, and by the physician, as well. The common direction of the discrepancy usually points toward better rating by the physicians than by the patients themselves, leading to potential medication adherence.

Objectives: The aims of the study were to explore the presence of disagreement between patients' and physicians' assessment of global disease severity, as well as to investigate the possible correlation between patient – physician discordance in assessments of RA burden and methotrexate adherence.

Methods: In the period between May 1 and September 15, 2019, 98 consecutive RA patients who were treated in Clinical center of Montenegro and private clinic "Merkur Nera" randomly chosen Montenegrin clinics were enrolled in this multi-centric cross-sectional study. The inclusion criteria were as follows: age ≥ 18 years, diagnosis of RA of at least 6 months, current methotrexate (MTX) use for at least 1 month (with or without concomitant usage of another RA drugs), and written informed consent. Non-adherence to MTX was defined as ≥ 1 dose missed against medical advice. The global disease activity is estimated by VAS (using a 0–10 ordinal scale), both by the patient, and by the physician. The differences between groups are assessed using the Mann-Whitney U-test. The correlation between the patient – physician discordance and MTX adherence is evaluated using the Spearman rank correlation.

Results: The most of the participants (87.8%) were female with median current age of 57.5 years (range 21-83 years). The median duration of RA was 8 years (range 0-34 years), while the median duration of MTX treatment was 6 years (range 0-26 years). The median value of VAS score estimated both, by the patients and their physician was 5, with no statistically significant difference between these two groups ($Z = 1.447$; $p = 0.748$). The analysis of patient – physician discordance in VAS assessment showed that full agreement is achieved in 76 (77.6%) cases, while in 21 (21.4%) RA patients their doctors underestimated their self-perception of disease burden. In only one participant, the physician overestimated patient's perception of RA severity. In total sample the self-estimated prevalence of MTX non-adherence was 32.7%. However, the analyses of the frequency of MTX non-adherence in sub-cohorts stratified by the presence of patient – physician discordance in VAS assessment showed that in "concordance group" the prevalence was 26.3% (20 out of 76 RA patients), while in "discordance group" the prevalence was 54.5% (12 out of 22 RA patients), with statistically significant difference between these two groups ($Z = -5.745$; $p < 0.001$). Statistically significant correlation has been observed between presence of patient – physician discordance in VAS assessment and MTX non-adherence ($\rho = 0.427$; $p < 0.001$).

Conclusion: The results of our study have shown that the presence of patient – physician discordance in assessment of global RA activity could deeply influence the MTX adherence in a Montenegrin sample of patients with RA. This finding emphasizes the need to focus on patients' preferences and values to deliver individualized patient-centered care that could potentially enhance adherence and consequently achieved optimally control of disease activity.

Disclosure of Interests: None declared

DOI: 10.1136/annrheumdis-2019-eular.8002

FRI0144

JOINT-SPECIFIC RESPONSES TO TOFACITINIB AND ADALIMUMAB IN RHEUMATOID ARTHRITIS: A POST HOC ANALYSIS OF DATA FROM ORAL STANDARD AND ORAL STRATEGY

Adrian Ciurea¹, Oliver Distler¹, Tim Killeen², Ermeg Akylbekova³, Kenneth Kwok⁴, Lisy Wang⁵, Caroline Ospelt¹, Mojca Frank-Bertoncelj¹. ¹University Hospital Zürich, Zürich, Switzerland; ²Pfizer AG, Zürich, Switzerland; ³IQVIA, Durham, NC, United States of America; ⁴Pfizer Inc, New York, NY, United States of America; ⁵Pfizer Inc, Groton, CT, United States of America

Background: Inflammatory arthritides affect joints variably despite systemic inflammatory cues. Anatomical site-specific differences have been seen in the transcriptome and function of synovial fibroblasts from different joints,¹ including evidence that some joints in rheumatoid arthritis (RA) show differential methylation of genes encoding biological pathways, such as interleukin 6 signalling via the JAK-STAT pathway.² Whether such site-specific JAK-STAT sensitivity translates into joint-specific responses to therapeutic JAK inhibition is unknown. Tofacitinib is an oral JAK inhibitor for the treatment of RA.

Objectives: To explore joint-specific responses to tofacitinib and adalimumab (ADA) in RA clinical trials.