Figure 1. Kaplan-Meier curves of MTX and HCQ monotherapies and MTX+HCQ combination therapy, with (a) survival to first ADR and (b) drug survival.

Conclusion: Patients using MTX+HCQ combination therapy are more likely to experience an ADR during the first time drug use compared to MTX and HCQ monotherapies. MTX+HCQ combination therapy also leads to experiencing an ADR sooner compared to both monotherapies. Drug survival of patients treated with HCQ monotherapy as well as MTX+HCQ combination therapy is shorter compared to MTX monotherapy.

Disclosure of Interests: Kimberly Velthuis: None declared, My Nguyen: None declared, Joep Scholl: None declared, Jurriaan Jansen: None declared, Jette van Lint: None declared, Peter ten Klooster: None declared, Harald Vonkeman Consultant of: BMS, Celgene, Celltrion, Galapagos, Gilead, Janssen-Cilag, Lilly, Novartis, Pfizer, Sanofi-Genzyme, Grant/research support from: Abbvie, Naomi Jessurun: None declared

DOI: 10.1136/annrheumdis-2021-eular.181

POS0649

BARICITINIB PROVIDES GREATER IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES ACROSS ALL DISEASE ACTIVITY LEVELS COMPARED TO PLACEBO AND ADALIMUMAB IN RHEUMATOID ARTHRITIS

P.C. Taylor¹, R. Blanco², K. Ikeda³, B. Jia⁴, Y.F. Chen⁴, C. Walls⁴, E. Haladyj⁴, B. Fautrel⁵. ¹University of Oxford, Botnar Research Centre, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom; ²Hospital Universitario Marqués de Valdecilla, Department of Rheumatology, Santander, Spain; ³Chiba University Hospital, Department of Allergy and Clinical Immunology, Chiba, Japan; ⁴Eli Lilly and Company, Lilly Research Laboratories, Indianapolis, United States of America; ⁵Sorbonne University – Assistance Publique Hôpitaux de Paris, Pitie Salpetriere Hospital, Rheumatology Department, Paris, France

Background: Baricitinib (BARI) is a JAK1/JAK2 inhibitor which provides improvements to clinical signs, symptoms, and patient-reported outcomes (PROs) in patients with rheumatoid arthritis [1, 2].

Objectives: The effect of BARI on the relationship between disease activity and pain has been explored previously [3]. The purpose of this post hoc analysis was to determine the association between additional PROs (physical function, fatigue, and duration of morning joint stiffness) and disease activity status after 12 weeks of treatment and to evaluate whether patients with an inadequate response to methotrexate treated with BARI 4mg experienced greater PRO improvement than patients treated with either placebo (PBO) or adalimumab (ADA) across all levels of disease activity.

Methods: Data for these analyses were derived from the Phase 3 study RA-BEAM (N=1305; NCT01710358). Pain was evaluated using a 0-100mm visual analog scale, physical function was assessed using the Health Assessment Questionnaire-Disability Index (HAQ-DI), fatigue was measured using the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scale, and

duration of morning joint stiffness (MJS, minutes) was reported by the patient. Disease activity was measured using the Clinical Disease Activity Index (CDAI) and categorized as remission (REM, ≤ 2.8), low disease activity (LDA, >2.8 to ≤ 10), moderate disease activity (MDA, >10 to ≤ 22), or high disease activity (HDA, >22). Linear regression was used to model the relationship between change in PROs at Week 12 (response) and CDAI values at Week 12 (primary explanatory variable) to evaluate the extent of improvement in PROs with BARI relative to PBO and ADA across a spectrum of disease activity levels. Last observation carried forward was used to impute missing values.

Results: At baseline, 91% of patients were classified as having HDA and 9% as having MDA by CDAI across all treatment groups. After 12 weeks of treatment, 2%, 7%, and 9% of patients achieved REM; 16%, 27%, and 33% of patients achieved LDA; and 33%, 40%, and 38% of patients achieved MDA with PBO, ADA, and BARI, respectively [3].

At Week 12, the estimated changes in measures of pain and physical function, as well as duration of MJS, for BARI 4mg were greater than both PBO and ADA at all disease activity level threshold values of CDAI (Table 1). The estimated change in fatigue for BARI 4mg was similar to that of ADA, and greater than PBO, at all disease activity level threshold values (Table 1).

Table 1. Estimate of PRO Improvement by Disease Activity Threshold Level (CDAI) at Week 12

PRO	CDAI=2.8			CDAI=10			CDAI=22		
	PBO	ADA	BARI 4 mg	PBO	ADA	BARI 4 mg	PBO	ADA	BARI 4 mg
Pain VAS ^a (mm)	-28.4	-37.9	-40.9	-24.5	-32.6	-36.1	-18.0	-23.7	-28.1
HAQ-DI ^b	-0.6	-0.7	-0.9	-0.5	-0.7	-0.7	-0.4	-0.5	-0.6
FACIT-F ^c	9.8	11.8	11.1	8.8	10.6	10.2	7.0	8.7	8.7
Duration of MJS (min)	-6.9	-37.8	-64.9	-6.3	-35.3	-55.7	-5.3	-31.3	-40.2

^aPain VAS scores range from 0 (no pain) to 100 (worst pain).

^bHAQ-DI scores range from 0 (no disability) to 3 (completely disabled).

^cFACIT-F scores range from 0 (worst fatigue) to 52 (no fatigue).

Abbreviations: ADA, adalimumab; BARI, baricitinib; CDAI, Clinical Disease Activity Index; FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI, Health Assessment Questionnaire-Disability Index; MJS, morning joint stiffness; PBO, placebo; PRO, patient-reported outcomes; VAS, visual analog scale.

Conclusion: Estimates of treatment differences suggest that patients treated with BARI 4mg may experience greater improvements in pain, physical function, and MJS duration than patients treated with PBO or ADA regardless of their disease activity status reached after 12 weeks of treatment. Using this approach, improvements in fatigue with BARI 4mg may be greater than with PBO and similar to ADA after 12 weeks.

REFERENCES:

- [1] Taylor, P.C., et al., *N Engl J Med*, 2017. 376(7): p. 652-662.
- [2] Keystone, E.C., et al., *Ann Rheum Dis*, 2017. 76(11): p. 1853-1861.
- [3] Taylor, P., et al., *Arthritis Rheumatol*, 2019. 71(S10): p. 2455-2457.

Acknowledgements: The authors would like to acknowledge Catherine Lynch, with Eli Lilly and Company, for medical writing and project management support.

Disclosure of Interests: Peter C. Taylor Consultant of: AbbVie, Biogen, Galapagos, Gilead, GlaxoSmithKline, Janssen, Eli Lilly, BMS, Pfizer, Roche, Celltrion, Sanofi, Nordic Pharma, Fresenius and UCB, Grant/research support from: Celgene, Galapagos, Gilead, Eli Lilly, Ricardo Blanco Speakers bureau: AbbVie, Pfizer, Roche, BMS, Janssen, Eli Lilly and MSD, Consultant of: AbbVie, Pfizer, Roche, BMS, Janssen, Eli Lilly and MSD, Grant/research support from: AbbVie, MSD, and Roche, Kei Ikeda Speakers bureau: Eli Lilly, AbbVie, Mitsubishi-Tanabe, Novartis, Paid instructor for: AbbVie, Grant/research support from: Mitsubishi-Tanabe, Bochoa Jia Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Yun-Fei Chen Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Chad Walls Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, Ewa Haladyj Employee of: Eli Lilly and Company, Bruno Fautrel Speakers bureau: Eli Lilly, Consultant of: AbbVie, Biogen, Bristol-Myers Squibb, Celgene, Janssen Pharmaceuticals, Eli Lilly and Company, Medac, MSD, NORDIC Pharma, Novartis, Pfizer Inc., Roche, Sanofi-Aventis, SOBI, UCB, Grant/research support from: AbbVie, Eli Lilly and Company, MSD, Pfizer Inc

DOI: 10.1136/annrheumdis-2021-eular.182

POS0650

PREDICTORS OF DURABLE CLINICAL RESPONSE TO TOFACITINIB 11 MG ONCE DAILY WITH OR WITHOUT METHOTREXATE IN PATIENTS WITH RHEUMATOID ARTHRITIS: POST HOC ANALYSIS OF DATA FROM A PHASE 3a/4 METHOTREXATE WITHDRAWAL STUDY

K. Yamaoka¹, S. B. Cohen², N. Sugiyama³, H. Shi⁴, J. L. Rivas⁵, A. Diehl⁴, J. S. Smolen⁶. ¹Kitasato University, Department of Rheumatology and Infectious Diseases, Sagami-hara, Japan; ²Metroplex Clinical Research Center, Dallas,