JAK/STAT signaling and inflammation genes. No significant changes in the expression of DAGs were observed in PBO-treated patients. FIL also broadly reversed DAGs and DAPs, and ongoing research is exploring the relationship between changes in gene and pathway modulation across a range of clinical endpoints.

REFERENCE:

[1] Genovese MC, et al. ACR 2018. Abstract L06.

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THU0195

ULTRASOUND EVALUATION FOR MONITORING RESPONSE TO BARICITINIB IN RHEUMATOID ARTHRITIS PATIENTS AT EARLY STAGE AFTER TREATMENT

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Background: Baricitinib (bari) is approved for treating moderate-severe RA in many countries including Japan. Bari, an oral Janus kinase (JAK1)/JAK2 selective inhibitor, has shown the efficacy in patients with rheumatoid arthritis (RA) and in adequate response to conventional synthetic DMARDs in some clinical trials. Thanks to technological improvement in Ultrasound (US) equipment and the use of internationally approved scanning techniques and definitions for normal findings and pathology, US monitoring are widely used to assess inflammatory and structural lesions in daily clinic.

Objectives: To monitor the short-term response to baricitinib therapy in bilateral wrist and finger joints of RA patients by US and to evaluate correlation between US findings and clinical assessments.

Methods: We included 23 Japanese patients with RA who have inadequate response to csDMARDs or bDMARDs (biologics-naïve 19 cases and biologics-experience 4 cases). Patients were scheduled to receive bari 4mg or 2mg once daily dose as monotherapy or in combination with other csDMARDs. They were allowed to be decreased prednisolone when their disease activity was improved. Clinical evaluation was performed blinded to the results of the US assessment that had been carried out on the same day. Swollen joint counts on 28 joints (SJC), tender joint counts on 28 joints (TJC) and Clinical Disease Activity Index (CDAI) were registered for each patient. Each parameter was evaluated at baseline, after 1 month and 3 months. Four sonographers, experiences in musculoskeletal US, who were blinded to the clinical and laboratory data, performed the US examination. The US assessment and scanning technique included evaluation of synovial sites in 26 joints (wrist- radiocarpal, midcarpal, radiocarpal joints, 1 - 5 MCP joints and 1 - 5 PIP joints). Gray scale (GS) and power doppler (PD) were graded according to a 0 - 3 semi-quantitative score depending on their severity [1]. We calculated total scores for each patient in GS (GS score) and PD (PD score) differently. We compared the change of GS score and PD score. In addition, we evaluated the correlation between the changes in GS score or PD score and the variations in clinical evaluation items.

Results: Patient's backgrounds were provided in Table 1. All clinical parameters were significantly improved at each follow-up periods after treatment. Mean SJC, TJC and CDAI decreased from 7.52 ± 3.89 , 8.26 ± 3.82 and 26.89 ± 9.48 at baseline to 1.52 ± 1.75 , 1.82 ± 1.89 and 6.40 ± 5.17 at 1 month and to 1.27 ± 1.39 , 1.27 ± 1.38 and 3.99 ± 3.49 at 3 months respectively (Table 2). GS and PD score at each follow-up periods after treatment were also significantly improved. Mean GS and PD decreased from 8.11 ± 3.41 and 12.42 ± 4.45 at baseline to 3.63 ± 2.45 and 7.73 ± 4.70 at 1 month and to 2.10 ± 1.49 and 4.21 ± 2.70 at 3 months respectively (Table 2). GS score significantly correlated with SJC ($r = 0.586$, $p < 0.01$), TJC ($r = 0.602$, $p < 0.01$) and CDAI ($r = 0.656$, $p < 0.01$). PD score significantly correlated with SJC ($r = 0.606$, $p < 0.01$), TJC ($r = 0.624$, $p < 0.01$) and CDAI ($r = 0.658$, $p < 0.01$).

Conclusion: Baricitinib therapy had significantly improved disease activity of RA patients at early stage after the treatment. GS and PD score were also significantly improved and correlated with clinical parameters.

These data confirm that the use of US evaluation is very useful method for evaluating the monitoring the response of treatment and feasible method complementary to clinical assessment for guiding the clinician in the appropriate therapeutic decision.

Abstract THU0195 –Table 1.

Table 1. Patients' background			(mean $\pm$ SD)
Age (years)	66.6 $\pm$ 9.4	RF positive (%)	73.9
Disease duration (years)	3.93 $\pm$ 5.07	ACRA positive (%)	78.2
MTX dose (mg/week)	7.65 $\pm$ 8.82	Stage (I/II/III/IV)	6/10/7/0
PSL dose (mg/day)	1.28 $\pm$ 1.80	Class (I/II/III/IV)	3/8/10/2

Table 2. Changes of clinical assessments and GS/PO scores				(mean $\pm$ SD)
	baseline	1 month	3 months	
SJC	7.52 $\pm$ 3.89	1.52 $\pm$ 1.75*	1.27 $\pm$ 1.39*	
TJC	8.26 $\pm$ 3.82	1.82 $\pm$ 1.89*	1.27 $\pm$ 1.38*	
CDAI	26.89 $\pm$ 9.48	6.40 $\pm$ 5.17*	3.99 $\pm$ 3.49*	
GS score	8.11 $\pm$ 3.41	3.63 $\pm$ 2.45*	2.10 $\pm$ 1.49*	
PD score	12.42 $\pm$ 4.45	7.73 $\pm$ 4.70*	4.21 $\pm$ 2.70*	

*p < 0.05 vs baseline

Disclosure of Interests: None declared

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THU0196

EFFICACY AND SAFETY UP TO 24 WEEKS OF BARICITINIB FOR JAPANESE PATIENTS WITH RHEUMATOID ARTHRITIS IN REAL WORLD MULTICENTER CLINICAL DATA

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Background: Baricitinib (bari) is approved for treating moderate-severe rheumatoid arthritis (RA) in many countries, including Japan. Bari is an oral Janus kinase (JAK1)/JAK2 selective inhibitor that has shown good efficacy in patients with RA and adequate response to conventional synthetic DMARDs in some clinical trials. However, there have been few reports about the efficacy and safety of bari in real-world clinical data.

Objectives: We evaluated the efficacy and safety of bari for Japanese RA patients who have an inadequate response to DMARDs in real-world multicenter clinical data.

Methods: We included 32 Japanese patients with RA who show an inadequate response to csDMARDs or bDMARDs (biologics-naïve (BN group): 19 cases and biologics-experience (BE group): 13 cases). Patients were scheduled to receive bari 4 or 2 mg once daily dose as a monotherapy or in combination with other csDMARDs. If the disease activity was not improved within 3 months in patients treated with bari 2 mg, the bari dose was increased to 4 mg. Patients were allowed to decrease their prednisolone treatment if their disease activity improved. First, we evaluated changes in the number of swollen joints and tender joints, CRP (mg/dL), visual analog scale of pain (0–100 mm), patient's global assessment (0–100 mm), Clinical Disease Activity Index, and HAQ-DI for 24 weeks. Second, we evaluated the proportion of patients with adverse events (AEs) and progress after these AEs.

Results: Patients' backgrounds are provided Table 1. Many patients felt the early effect of bari. At 1 month after treatment, ACR20/50/70 were 84.2%/63.2%/21.1% in the BN group and 53.8%/23.1%/7.7% in the BE group, respectively. All measurement items of disease activity and patient-reported outcomes were significantly improved after treatment. This tendency continued until the final evaluation (Table 2). At 24 weeks, remission and low disease activity rates were 47.4% and 78.9% in the BN group and 15.4% and 61.5% in the BE group, respectively. One case in the BE group discontinued bari treatment due to no response. These data were better than clinical trial data (Japanese subpopulation data from RA-BEAM and RA-BUILD studies^[1]). We determined that we could take an aggressive treatment course according to treat to target strategies in real-world clinics. Greater early improvements in HAQ-DI were seen. HAQ-DI was improved significantly at each evaluation time point after bari treatment (Table 2).

We had two cases of mild pneumonia and one case of herpes zoster. These cases were improved after 1–2 weeks of antibiotic therapy or antiviral drug therapy. One case discontinued bari. Although the other two cases withdrew from bari treatment, we could restart it. We think that the most important reason why they did not advance in severe because we were able to diagnose and treat these cases earlier. No patient showed malignancies, cardiovascular events, or deep vein thrombosis. No patient discontinued bari treatment due to AEs. Also, increases in blood pressure and d-dimer were not observed during the follow-up period. Other mild AEs, including upper respiratory tract infection, nasopharyngitis, and laboratory data abnormalities occurred in 62.5% of patients (Table 3). A small increase in lymphocyte count and small decrease in neutrophil count