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Results: At baseline, 84% of the patients were in remission according to the SDAI (<3,3) with 44% of the cases showing SDAI remission and absence of PD signal in hands and feet (SDAI<3,3 and PD=0). Despite stringent remission, 48% of the patients showed an episode of flare during follow-up with a peak incidence between 6 and 9 months after drug withdrawal. With the exception of a mild protective role of SDAI remission, none of the investigated clinical and ultrasound parameters (alone or in combination) showed a significant impact on clinical evolution across 24 months. ACPA IgG levels showed instead a strong, inflammation-independent predictive value for disease recurrence, an observation that was confirmed in the overall cohort (HR: 3.39 [1.7-6.64], p=0.0006, Cox regression) and, invariably, across progressive clinical and/or ultrasound remission thresholds (SDAI remission, SDAI remission-PD=0). Sub-analyses focused on short-term events (0-6 months after DMARDs withdrawal), identified the systemic level of CXCL13 at baseline as the strongest predictor of early disease recurrence in ACPA IgG positive individuals.

Conclusions: The systemic immuno-type of patients in remission is the major determinant of drug-free disease recurrence, over and above drug-induced achievement of stringent clinical and ultrasonographic control of the peripheral inflammatory process.

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#### SAT0054 RISK FACTORS FOR ACUTE EXACERBATION OF RHEUMATOID ARTHRITIS-ASSOCIATED INTERSTITIAL PNFLIMONIA

A. Yashima, H. Yamashita, R. Kamei, K. Suga, M. Nakano, S. Yamada, Y. Takahashi, H. Kaneko. Division of Rheumatic Diseases, National Center for Global Health and Medicine, Tokyo, Japan

Background: Acute exacerbation (AE) is recently recognized as deterioration of respiratory status in idiopathic pulmonary fibrosis. It is reported that AE also occurs in other interstitial lung diseases (ILD) such as collagen vascular diseases associated ILD (CVD-ILD). However, the characteristics and risk factors of AE in CVD-ILD are not clearly identified.

Objectives: To clarify the characteristics of patients with rheumatoid arthritisassociated interstitial pneumonia (RA-IP) and to investigate the risk factors associated with AE and its survival of RA-IP.

Methods: We examined the clinical features of 60 RA-IP patients admitted to our hospital between July 2010 and September 2016. We compared the characteristics between patients who developed AE (AE group) and those who didn't (non-AE group), and between patients who survived after AE (alive group) and those who died after AE (dead group), and identified variables significantly associated with AE occurrence and survival using Cox hazards analyses.

Results: Thirty-six (60%) were female. Twenty-two (36.7%) developed AE and seven of them (11.7%) died with the mean follow-up period of 2.7 years. The mean age at RA diagnosis was 61.1±16.3 years in AE group and 61.5±13.1 years in non-AE group. Sex, smoking habit and high-resolution computed tomography (HRCT) pattern were not significantly different between two groups. Although there was no significant difference, more patients in AE group received methotrexate (MTX) treatment than those in non-AE group (40.9% vs. 18.9%, p=0.08), and MTX use was significantly associated with occurrence of AE in a Cox hazard analysis (Hazard ratio [HR] 1.09, 95% confidence interval [CI] 1.01-1.18). Further, age (median 70 vs. 82 years, p=0.002) and matrix metalloproteinase-3 (MMP-3) level (median 84.8 vs. 205.6 ng/mL, p=0.03) on admission were significantly higher in dead group than in alive group. Univariate analyses revealed that age  $\geq$  75 years (HR 10.53, 95% CI 1.26-88.15), MMP-3  $\geq$  200 ng/mL (HR 15.58, 95%) CI 1.38-175.8), and 3L or more oxygen use (HR 8.46, 95% CI 1.02-70.49) on admission were associated with death (Table 1).

Table 1. Risk factors for AE mortality based on univariate Cox hazard analyses

	HR	95% CI	p value
Age ≥75 years	1.19	1.05 to 1.36	0.008
Sex, male	1.65	0.37 to 7.41	0.51
HRCT, UIP pattern	3.82	0.74 to 19.8	0.11
KL-6 ≥700 U.mL	1.32	0.24 to 7.22	0.75
LDH ≥400 IU/L	0.40	0.05 to 3.32	0.40
MMP-3 ≥200 ng/mL	15.58	1.38 to 175.80	0.03
$O_2 \ge 3 L$	9.46	1.02 to 70.49	0.05

UIP, usual interstitial pneumonia; KL-6, Krebs von den Lungen-6; LDH, lactate dehydrogenase.

Conclusions: Our data suggest that MTX use relates to the occurrence of AE, and age, MMP-3 level, and oxygen volume on admission relate to AE survival in patients with RA-IP.

## References:

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### SAT0055 BARICITINIB SHOWED RAPID AND GREATER REDUCTION IN PAIN COMPARED TO ADALIMUMAB OR PLACEBO IN PATIENTS WITH RHEUMATOID ARTHRITIS

P. Taylor<sup>1</sup>, B. Zhu<sup>2</sup>, C. Gaich<sup>2</sup>, X. Zhang<sup>2</sup>, A.M. DeLozier<sup>2</sup>, D. Schlichting<sup>2</sup>, H. Patel<sup>2</sup>, F. Durand<sup>2</sup>, B. Fautrel<sup>3</sup>. <sup>1</sup> University of Oxford, Oxford, United Kingdom; <sup>2</sup>Eli Lilly and Company, Indianapolis, United States; <sup>3</sup>University Pierre et Marie Curie, Paris, France

Background: A rapid and meaningful reduction in pain is important to quality of life in patients (pts) with rheumatoid arthritis (RA). Baricitinib (bari) is a selective inhibitor of Janus kinase (JAK)1/JAK 2 in development for pts with active RA.1 Objectives: To evaluate the effect of bari treatment on pain reduction compared to adalimumab (ADA) or placebo (PBO) in pts with inadequate response to methotrexate (MTX) or biologic disease-modifying antirheumatic drugs (bD-

Methods: In RA-BEAM (NCT01710358), 1305 patients with inadequate response to MTX were randomised 3:3:2 to PBO QD, bari 4 mg once daily (QD), or ADA 40 mg biweekly.<sup>2</sup> In RA-BEACON (NCT01721044), 527 pts with inadequate response or intolerance to bDMARDs were randomised 1:1:1 to PBO or bari (2 or 4 mg) QD.3 This post-hoc analysis reports the pts' assessment of pain using a visual analogue scale (VAS, range: 0 to 100 mm). The proportion of pts who achieved pain improvement of  $\geq 30\%, \geq 50\%,$  and  $\geq 70\%$  of their baseline pain at 1, 2, 4, 8, 12, 16, 20, and 24 weeks of treatment were compared between treatment groups using logistic models adjusted for geographic region, baseline pain score, baseline joint erosion status (RA-BEAM only), and history of bDMARD at screening (RA-BEACON only). Missing data were imputed using modified last observation carried forward

Results: Mean baseline pain scores were 60, 62, and 61 for PBO, bari 4 mg, and ADA, respectively, in RA-BEAM and 65, 62, and 66 for PBO, bari 2 mg, and bari 4 mg, respectively, in RA-BEACON. A significantly greater proportion of pts treated with bari 4 mg achieved ≥30% and ≥50% pain improvement as early as week 1 compared to PBO (both studies) and as early as week 4 compared to ADA (RA-BEAM) (Table). A significant pain improvement of ≥70% was achieved at week 12 for pts treated with bari 4 mg compared to PBO (both studies) and ADA (RA-BEAM). Pain improvement of  $\geq$ 30%,  $\geq$ 50%, and  $\geq$ 70% with bari 2 mg was significant compared to PBO by week 12 (RA-BEACON). Significant improvements in pain for bari vs PBO and bari vs ADA were sustained through week 24.

Table 1. Percent Pain Improvement in RA-BEAM and RA-BEACON

	RA-BEAM			RA-BEACON		
	PBO (N=488)	Bari 4 mg (N=487)	ADA (N=330)	PBO (N=176)	Bari 2 mg (N=174)	Bari 4 mg (N=177)
Pain Improven	nent ≥30%					
Week 1	27	48***	47***	20	25	32**
Week 4	37	67*** <sup>†</sup>	60***	29	38	50***
Week 12	47	73***†	64***	31	43*	58***
Week 24	49	74***	69***	34	44*	57***
Pain Improven	nent ≥50%					
Week 1	13	26***	28***	6	9	17**
Week 4	22	48***‡	37***	15	25*	30***
Week 12	31	57***†	49***	17	31**	35***
Week 24	32	61***†	52***	20	32**	45***
Pain Improven	nent ≥70%					
Week 1	4	12***	11***	2	3	6
Week 4	8	26***	21***	6	11	14*
Week 12	14	37***‡	28***	7	19***	18**
Week 24	16	41***‡	32***	9	22***	29***

\*p<0.05 vs PBO; \*\*p<0.01 vs PBO; \*\*\*p<0.001 vs PBO; †p<0.05 vs ADA; ‡p<0.01 vs ADA; pvalues based on logistic regression model. ADA = adalimumab; Bari = baricitinib; PBO = placebo.

Conclusions: Bari-treated pts reported significantly greater and more rapid reductions in pain severity as measured by the pain VAS compared to PBO or ADA; improvements were sustained through 24 weeks. The results were similar regardless of the pt population.

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