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Conclusions: Depression and anxiety may reduce likelihood of remission based on composite scores in RA and should be taken into account in individual patients when making a shared decision on a treatment target.

# References:

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# THU0081 DIFFERENCES IN PATIENT-REPORTED OUTCOMES BETWEEN BARICITINIB AND COMPARATORS AMONG PATIENTS WITH RHEUMATOID ARTHRITIS WHO ACHIEVED LOW DISEASE ACTIVITY OR REMISSION

B. Fautrel 1, M. van de Laar 2, B. Kirkham 3, R. Alten 4, R. Cseuz 5, S. Van der Geest<sup>6</sup>, B. Zhu<sup>7</sup>, F. De Leonardis<sup>8</sup>, P. Taylor<sup>9</sup>. <sup>1</sup>University Pierre et Marie Curie, Paris, France; <sup>2</sup> Arthritis Centre Twente, Medisch Spectrum Twente, Enschede, Netherlands; <sup>3</sup>Guys Hospital, London, United Kingdom; <sup>4</sup>Schlosspark Klinik, Berlin, Germany; 5 Revita Private Clinic for Rheumatology, Budapest, Hungary; <sup>6</sup>Eli Lilly & Company, Utrecht, Netherlands; <sup>7</sup>Eli Lilly and Company, Indianapolis, United States; <sup>8</sup> Eli Lilly & Company, Geneva, Switzerland; <sup>9</sup> University of Oxford, Headington, United Kingdom

Background: Achieving remission is the ideal goal in treating rheumatoid arthritis (RA). In a randomised phase 3 trial, high remission and low disease activity (LDA) rates were achieved with baricitinib (BARI). However, little is known about the differences in patient reported outcomes (PROs) among patients (pts) who have already achieved these targets.

Objectives: To compare PROs between BARI, adalimumab (ADA), and placebo (PBO) in pts with RA who achieved LDA or remission in the Phase 3 RA-BEAM study.

Methods: 1305 pts with RA and background treatment with methotrexate were randomised to receive PBO (n=488), ADA (n=330), or BARI 4 mg (n=487) for 52 wks (24 wks for PBO). In each treatment group, pts in remission (DAS28-ESR<2.6) and with LDA (DAS28-ESR<3.2) at wk 24 were assessed from baseline for the following PROs: Pain VAS, HAQ-DI, WPAI, Morning Joint Stiffness (MJS), and FACIT-F. Sensitivity analyses were conducted for pts in remission or LDA by DAS28-CRP, SDAI, or CDAI. The assessment of response at wk 24 was determined by using the observed data, and the missing values for PRO measures were imputed by using mLOCF.

Results: Among pts in LDA, significantly greater improvements in Pain VAS and HAQ-DI scores were observed with BARI than ADA and PBO, and significantly greater improvements in MJS were observed with BARI and ADA than PBO. Significantly greater residual pain and HAQ-DI scores were observed with PBO. Among pts in remission, significantly greater improvements in pain and HAQ-DI scores were also observed with BARI than PBO. Patients in remission or LDA showed greater numerical improvement and less residual impairment in other PROs with BARI and ADA than PBO (Table 1). Consistent results were observed using other composite measures to define LDA and remission.

PRO Measures	Baseline	Residual Mean Value at Wk 24	Observed Change at Wk 24	Baseline	Residual Mean Value at Wk 24	Observed Change at Wk 24	Baseline	Residual Mean Value at Wk 24	Observed Change at Wk 24
	For Patients in Remission from BARI 4 mg (n=87)			For Patients in Remission from ADA (n=57)			For Patients in Remission from PBO (n=24)		
Pain VAS (mm)	56.5	10.1	-46.4**	48.2	11.5	-36.7	43.8	16.5	-27.3
HAQ-DI	1.3	0.3†	-0.9**	1.1	0.3	-0.7*	1.1	0.5	-0.5
FACIT-F	32.5	43.3	10.9	35.7	44.6†	8.9	32.8	41.1	8.3
MJS Duration (min)	125.2	24.8	-100.4	118.0	18.3	-99.6	51.5	73.4	21.9
Activity Impairment (%)	52.1	14.4	-37.7	41.2	14.6	-26.7	37.5	17.5	-20.0
	For Patients in LDA from BARI 4 mg (n=154)			For Patients in LDA from ADA (n=110)			For Patients in LDA from PBO (n=46)		
Pain VAS	57.8	11.9†	-45.9***	52.5	14.3	-38.2	45.2	18.5	-26.8
HAQ-DI	1.4	0.4†	-1.0**	1.2	0.4	-0.8	1.1	0.5	-0.6
FACIT-F	30.3	43.1	12.8	33.3	43.7	10.4	33.6	42.6	9.0
MJS Duration (min)	116.9	25.4	-91.6*	116.0	20.9	-95.0*	77.1	53.7	-23.4
Activity Impairment (%)	52.7	15.9	-36.8*	47.3	17.0	-30.3	43.5	20.0	-23.5

†\* significant at 05 level vs PBO using stest. \*\*\*, \*\*, \*\* significant at .001, .01, .05 levels, respectively, vs PBO. †\* significant at .05 level vs ADA using ANCOVA model with change value as dependent variable and treatment region, baseline joint erosion status (1-2 erosions plus seropogiaisity); 2 erosions), a baseline value as factors. For MJS duration for remission, FBO, n=17; BARI 4 mg. n=57; ADA, n=57; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and for LDA, FBO, n=30; BARI 4 mg. n=96; ADA, n=50; and n=50;

Conclusions: The preliminary findings from this study suggest that BARI showed

greater improvements in pain and HAQ-DI compared to ADA for pts in LDA, and greater improvements in pain and HAQ-DI scores as well as less physical impairment compared to PBO for pts in LDA and remission.

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# THU0082 | LUNG INVOLVEMENT IN ACPA POSITIVE SUBJECTS: A PILOT STUDY ON THE ROLE OF LABORATORY, FUNCTIONAL AND **IMAGING MARKERS**

B. Lucchino<sup>1</sup>, M.C. Gerardi<sup>1</sup>, C. Iannuccelli<sup>1</sup>, M.P. Guzzo<sup>1</sup>, M. Di Paolo<sup>2</sup> M. Bonini<sup>2</sup>, F. Vaccaro<sup>2</sup>, P. Palange<sup>2</sup>, F. Vullo<sup>3</sup>, D. Diacinti<sup>3</sup>, G. Valesini<sup>1</sup>, M. Di Franco 1, 1 Department of Internal Medicine and Medical Specialities: <sup>2</sup>Department of Public Health and Infectious Diseases; <sup>3</sup>Department of Radiology, Sapienza university of Rome, Roma, Italy

**Background:** The ACPA-positive Rheumatoid Arthritis (RA) is a complex disease. Signs of immune activity against citrullinated proteins may be present years before the onset of clinical manifestations. Recent findings suggest that the lung may represent an early site of autoimmune-related injury in ACPA-positive patients

Objectives: The purpose of the present study was to evaluate the presence of subclinical pulmonary abnormalities in ACPA-positive subjects without arthritis and in RA-patients through laboratory, functional and imaging markers.

Methods: Eleven ACPA-positive subjects without arthritis, 10 patients naïve to therapy with early ACPA-positive RA (<6 months duration) and 9 with established ACPA-positive RA (<36 months duration) were consecutively enrolled. Subjects underwent baseline pulmonary function tests (PFTs), DLCO measurement and CPET. The evaluation of Surfactant protein D (SP-D) serum levels was performed in all the patients and in 9 healthy controls matched for age and sex with an ELISA test. Twenty-four subjects underwent chest high-resolution computer tomography (HRCT), in order to evaluate parenchymal or airways abnormalities.

Results: The cohort consisted of 7 men and 23 women, mean age 48,93 (DS+/-12.1). PFTs resulted abnormal only in 2 patients. A DLCO reduction was observed in 54.5% of ACPA-positive subjects without RA, in 60% and in 55.6% of patients with early and established RA, respectively. In RA patients, an inverse correlation between disease duration and DLCO/Va (r=-0.50; p=0.03) was observed. The exercise tolerance at CPET was reduced in 54.5% of ACPApositive subjects without RA, in 20% of patients with early RA and in 55.6% of those with established RA. Serum SP-D levels were higher in established RA (p=0.079), in ACPA-positive subjects and early RA than in healthy controls. ACPA levels positively correlated (r=0.45;p=0.01) with CPET parameters of ventilation inefficiency, suggesting a ventilation/perfusion mismatch. A negative correlation between ACPA and SP-D levels and CPET metabolic parameters was also observed. The presence of pulmonary nodules was the most common alteration founded at HRCT, equal to 28% in ACPA-positive subjects without arthritis, in 66% and 87% of patients with early and established RA, respectively. In the last group, all patients showed parenchymal abnormalities. There was also a significant (p=0.022) higher frequency of lung abnormalities in patients with established disease compared with the other two groups.

Conclusions: The early lung involvement in RA is often subclinical and baseline PFT's are scarcely informative. Although preliminary, these findings suggest that DLCO, CPET parameters and SP-D can represent early markers of the subclinical lung injury. Furthermore, lung abnormalities detectable at HRCT seem to develop early in the course of the disease. However, additional studies are needed to clarify lung abnormalities in RA.

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# THU0083 THE RELEVANCE OF ELEVATED CRP AS AN INCLUSION **CRITERION IN CLINICAL TRIALS IN PATIENTS WITH** RHEUMATOID ARTHRITIS

C. Scoville<sup>1</sup>, J. Suboticki<sup>2</sup>, S. Zhong<sup>2</sup>, E. Keystone<sup>3</sup>. <sup>1</sup> Idaho Falls Arthritis Clinic, Idaho Falls; <sup>2</sup>AbbVie, N Chicago, United States; <sup>3</sup>Mount Sinai Hospital, Univ of Toronto, Toronto, Canada

Background: Elevated C-reactive protein (CRP) is often used as an entry criterion in clinical trials (CT) of patients (pts) with rheumatoid arthritis (RA), resulting in the potential exclusion of pts with active disease and high screen failure rates Objectives: To assess the relevance of requiring an elevated CRP (≥1 mg/dL) as an inclusion criterion for clinical, functional, and radiographic outcomes.

Methods: This post hoc analysis used data from 2 randomized CTs in RA pts with an inadequate response to methotrexate (MTX). In DE019, pts on background MTX received adalimumab (ADA) or placebo (PBO)2; in MUSICA, pts received either 7.5 or 20 mg MTX, along with ADA3. Data from MUSICA were used