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.

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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

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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$<$2.6) and with LDA (DAS28-ESR$\leq$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 *t*-test. ***, **, * = 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 seropositivity; 3 erosions), and baseline value as factors. For MJS duration for remission, PBO, n=17; BARI 4 mg, n=57; ADA, n=37; and for LDA, PBO, n=30; BARI 4 mg, n=96; ADA, n=62.

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

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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 without signs of arthritis.

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 ACPA-positive 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

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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[1].

Objectives: To assess the relevance of requiring an elevated CRP ($\geq$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 ADA[3]. Data from MUSICA were used

to confirm observations from DE019. Pts were subgrouped by CRP level at entry (CRP <1 mg/dL, ≥1 mg/dL). Baseline (BL) demographics and disease characteristics were summarized for each group. Clinical efficacy was assessed through swollen/tender joint count (S/TJC) at 66/68 joints, pain, patient global assessment (PtGA), physician global assessment (PhGA), CRP, clinical disease activity index (CDAI), 28-joint disease activity score based on CRP (DAS28-CRP), and proportions of pts achieving ACR20/50/70. Functional outcomes were assessed by the disability index of the health assessment questionnaire (HAQ-DI), and radiographic outcomes by the modified total Sharp score (mTSS). Outcomes were assessed in pts with CRP <0.8 mg/dL in DE019, which included pts with CRP levels as low as 0.75 mg/dL Observed data are reported at week 24.

Results: In DE019, 183 pts (89 and 94 in the ADA and PBO arms, respectively) had CRP <1 mg/dL and 224 pts (118 and 106, respectively) had CRP ≥1mg/dL. Pts with elevated CRP had higher BL disease activity compared with those with CRP <1 mg/dL at entry (not shown). After 24 wks of treatment with ADA, pts in both CRP subgroups experienced significant improvements in most clinical and functional outcomes vs PBO (Table). In pts with CRP <0.8 mg/dL, the ACR20 response rate difference (30.4, p<.001) and the difference in ΔmTSS (-1.3, p<.05) for ADA vs PBO treatment were still significant. Compared to pts with CRP <1 mg/dL, pts with elevated CRP experienced greater clinical and functional improvements. However, within the ADA subgroups, pts with elevated CRP had smaller differences vs PBO in mTSS, perhaps reflecting higher joint damage at BL. In general, similar trends were observed in MUSICA (not shown).

Disease characteristics at Week 24 in patients with CRP <1 or ≥1 mg/dL at entry in DE019

	CRP <1			CRP ≥1		
	PBO n=79	ADA n=74	Difference	PBO n=75	ADA n=101	Difference
TJC68	-13.2	-17.2	-3.2	-11.7	-16.5[e]	-6.0***
SJC66	-7.1	-11.3	-4.3**	-6.7	-12.5[e]	-5.0***
Pain	-13.0	-24.5	-11.7***	-20.3[c]	-35.8	-14.4***
PtGA	-11.0	-24.2	-13.2***	-20.7[c]	-35.5	-16.1***
PhGA	-24.4	-35.0	-10.2**	-28.0[c]	-43.2	-14.2***
HAQ-DI	-0.26[f]	-0.49	-0.24**	-0.38	-0.68	-0.31***
CRP	0.1	0.02	-0.08[g]	-0.54	-2.05	-1.08**
DAS28-CRP	-1.19	-1.92	-0.75***	-1.26[c]	-2.33[e]	-1.10***
CDAI	-15.9	-22.7	-7.6***	-15.7[c]	-26.5[e]	-11.1***
ACR20, n/N (%)	32/79 (41)	50/74 (68)	27***	30/72 (42)	82/99 (83)	41***
ACR50, n/N (%)	9/79 (11)	34/74 (46)	35***	11/72 (15)	46/99 (46)	31***
ACR70, n/N (%)	6/79 (8)	19/74 (26)	18**	0/72 (0)	19/99 (19)	19***
mTSS	0.93[a]	-0.32[b]	-1.30**	1.63[g]	0.79[d]	-0.84

Change from baseline values and least square mean differences (using ANCOVA) are reported for continuous endpoints. p-values for binary endpoints are calculated based on chi-square test or Fisher's exact test. ***, **, *: p < .001, .01 and .05, respectively for differences between treatment groups for change from BL. Missing values are not imputed.
[a]n=82, [b]n=76, [c]n=72, [d]n=102, [e]n=99, [f]n=78, [g]n=84 .
TJC68, tender joint count at 68 joints; SJC66, swollen joint count at 66 joints; PtGA, patients global assessment of disease activity; PhGA, physician's global assessment of disease activity; HAQ-DI, disability index of health assessment questionnaire; CRP, C-reactive protein; DAS28-CRP, 28-joint disease activity score based on CRP; CDAI, clinical disease activity index; mTSS, modified total Sharp score; ACR20/50/70, 20, 50 and 70% improvement in the American College of Rheumatology criteria

Conclusions: While pts with elevated CRP at entry experienced larger improvements from BL in clinical and functional outcomes upon treatment, significant improvements in most outcomes were also observed in those without elevated CRP at entry (as low as 0.75 mg/dL), suggesting that an elevated CRP may not be required to see differences between active and inactive treatment.

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THU0084 AGREEMENT BETWEEN THE DAS28-ESR AND THE DAS28-CRP AND FACTORS RELATED TO THE DISCREPANCIES BETWEEN DISEASE ACTIVITY LEVELS ACCORDING TO THESE 2 SCORES IN PATIENTS WITH EARLY RHEUMATOID ARTHRITIS: RESULTS FROM THE ESPOIR COHORT

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Background: DAS28 is often used as a treatment decision tool in patients with rheumatoid arthritis (RA) in the daily clinic. Although different versions of DAS28 have previously been validated, and although disease activity thresholds are the same, it is not clear whether DAS28-ESR and DAS28-CRP can be used interchangeably in individual patients.

Objectives: The aims of our study were to examine the agreement between these two DAS28 versions in individual early RA patients in the daily clinic and to idenditify factors related to the discrepancies between disease activity levels according to these 2 scores.

Methods: Baseline and 6 months data from 677 patients with early RA (ACR EULAR 2010) were extracted from the French cohort of early arthritis ESPOIR (at least 2 swollen joints for less than 6 months, DMARD naïve) and were used to calculate DAS28-ESR and DAS28-CRP. Disease activity levels according to the DAS thresholds and EULAR responses were assessed. Intraclass correlation coefficient [ICC] and weighted kappa (k) were calculated. The Bland-Altman method was used to examine the bias between the DAS scores and the 95% limits of agreement (LoA). Multivariate logistic regression was used to determine the patient and RA features independently associated with discrepancies between disease activity levels according to DAS28-ESR and DAS28-CRP.

Results: The mean value of DAS28-CRP (5.04±1.16 at M0 and 3.38±1.33 at M6) was smaller than that of mean DAS28-ESR (5.33±1.24 at M0 and 3.51±1.42 at M6). Agreement between the scores was excellent: ICC=0.93 at M0 and M6. Agreement between disease activity levels according to the 2 scores was good: k=0.70 at M0 and 0.75 at M6. Agreement between EULAR responses at M6 according to the 2 scores was good: k=0.78. At M0, the bias of DAS28-CRP was -0.28 (LoA -1.16, 0.59) and -0.14 (LoA -1.17, 0.89) at M6.There were discrepancies between disease activity levels according to the 2 scores in 122 (18.6%) patients at M0 with clear difference in moderate (88 patients for DAS28-CRP vs 29 for DAS28-ESR) and high disease activity (18 patients for DAS28-CRP vs 80 for DAS28-ESR), and in 171 (28.1%) patients at M6 with clear difference in remission (42 patients for DAS28-CRP vs 29 for DAS28-ESR) and high disease activity (9 patients for DAS28-CRP vs 32 for DAS28-ESR). At M0, presence of erosion (OR 95% CI=1.76 [1.07–2.90]), better mental component of the SF36 (OR 95% CI=2.14 [1.38–3.31]), fewer tender joint counts (TJC) and better physical component of the SF36 (PCS) (with significant interaction between TJC and PCS) were associated with discrepancies between disease activity levels according to the 2 scores. At M6, only being male (OR 95% CI=1.62 [1.09–2.41]) was associated with discrepancies.

Conclusions: DAS28-CRP significantly underestimated disease activity compared to DAS28-ESR. Agreement was high between the 2 scores, good for disease activity levels and EULAR responses. In the individual patient, however, the two scores may differ considerably. The scores should not be used interchangeably in the daily clinic without caution.

Disclosure of Interest: None declared

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THU0085 TIME TO REMISSION AND THE ACHIEVEMENT OF SUSTAINED REMISSION IN PATIENTS WITH EARLY RHEUMATOID ARTHRITIS: SITE VARIATION ANALYSIS IN THERAPEUTIC STRATEGY FROM THE CANADIAN EARLY ARTHRITIS COHORT (CATCH)

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Background: Treatment response in ERA reflects individual prognostic factors and therapeutic selection which may be influenced by provider experience and beliefs. This may lead to variations in rates of and time to remission across centres involved in multi-site cohorts.

Objectives: We compared therapeutic strategies across Canadian ERA clinics in relation time to CDAI and DAS28 remission, and frequency of attaining sustained remission.

Methods: Data were analyzed for patients with >1 year of follow-up, enrolled at sites with >40 patients at baseline and >30 patients with 2 years of follow-up data. We determined time to remission and frequency of sustained remission (2 consecutive visits at least 6 months apart), using DAS28 and CDAI scores. Treatment strategy was determined as initial and ever use of oral methotrexate monotherapy, subcutaneous methotrexate monotherapy, methotrexate-based combinations, non-methotrexate DMARDs, triple therapy, or biologic therapy.

Results: 1,749 participants from 13 centers with mean age 54 years, 73% female, mean DAS28 4.9 (SD 1.4) and mean CDAI 25.6 (SD 14.6) were included. There were significant differences between centers in participant characteristics (gender, age, symptom duration, body mass index, comorbidities, smoking status, education, ethnicity, marital status, seropositive status, erosions). The