rates were 74%, 18%, and 6%, respectively. Oral corticosteroids were used in 56% of PBO and 55% of BARI pts at baseline; pts continued use throughout the studies. The differences in clinical efficacy between BARI 4 mg and PBO at 12 weeks was similar regardless of the number or type of csDMARDs concomitantly used (Table) or the concomitant use of corticosteroids (data not shown). The rates of serious adverse events and discontinuation due to adverse events were comparable regardless of the number or type of csDMARDs used (Table) or corticosteroid use.

ACR20/50/70=20%, 50%, and 70% improvement in American College of Rheumatology criteria; csDMARDs=conventional synthetic disease-modifying antirheumatic drugs; DAS28-ESR=Disease Activity Score 28-erythrocyte sedimentation rate; MTX=methotrexate; SDAI=Simple Disease Activity Index.

Conclusions: BARI has demonstrated clinical safety and efficacy in a wide range of pts, regardless of the number of concomitant csDMARDs or concomitant use of corticosteroids.

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THU0079 EVALUATION OF SYNOVITIS IN THE FOOT AND THE ANKLE NOT INCLUDED IN THE 28-JOINT DISEASE ACTIVITY SCORE USING ULTRASONOGRAPHY AND HISTOLOGICAL FINDINGS IN THE PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: In the treatment of rheumatoid arthritis (RA), the early diagnosis and early medical treatment via tight control have become increasingly important with the advent of biological therapy. Ultrasonography (US) for the affected joints enables the evaluation of synovial hypertrophy, effusion and bone erosion in real time. US is a reliable method that can detect more erosive sites than radiography. US is now utilized widely and is a reliable tool of rheumatologists for diagnosing RA and evaluating the disease activity.

Objectives: This study was conducted to clarify the relationship between the systemic disease activity, local disease activity using US and a synovial histopathological evaluation.

Methods: Between March 2011 and September 2015, 668 joints were surgically treated on the whole, and synovial biopsies were performed at the time of surgery. Among them, a total of 118 toes and 21 ankles, which are not included in the 28-joint disease activity score (DAS28), were investigated. Just before surgery, the US probe was placed on the dorsal aspect of the ankle and/or the toes to evaluate the activity of local synovitis. The maximum grade of power Doppler (PD) signal was determined, ranging from 0 to 3. The serum C reactive protein (CRP), matrix metalloproteinase-3 (MMP-3) and DAS28 values were also examined

Figure 1

Abstract THU0080 – Table 1. Odds ratio (95% CI) for remission in patients with versus without baseline depression/anxiety according to the SF36-MH ≤ 56 criterion

Months	DAS28 <2.6	SDAI ≤ 3.3	CDAI ≤ 2.8	ACR/EULAR Boolean
3	0.48 (0.32–0.73), p<0.001	0.43 (0.25–0.74), p=0.003	0.38 (0.22–0.65), p<0.001	0.27 (0.13–0.57), p=0.001
6	0.36 (0.24–0.56), p<0.001	0.35 (0.20–0.60), p<0.001	0.38 (0.23–0.63), p<0.001	0.31 (0.16–0.61), p=0.001

Abstract THU0080 – Table 2. Odds ratio (95% CI) for remission in patients with versus without baseline depression/anxiety according to the SF36MCS ≤ 38 criterion

Months	DAS28ESR <2.6	SDAI ≤ 3.3	CDAI ≤ 2.8	ACR/EULAR Boolean
3	0.67 (0.49–0.93), p=0.02	0.51 (0.34–0.78), p=0.002	0.47 (0.32–0.70), p<0.001	0.35 (0.21–0.59), p<0.001
6	0.45 (0.32–0.63), p<0.001	0.46 (0.31–0.69), p<0.001	0.48 (0.33–0.69), p<0.001	0.46 (0.29–0.72), p=0.001

just before surgery. A histopathological examination of the gathered synovium at the surgical site was performed using the Rooney score (RS). Biological disease-modifying antirheumatic drugs were used in 45 cases, namely infliximab in 7 cases, etanercept in 16, adalimumab in 7, tocilizumab in 6, abatacept in 4, certolizumab pegol in 1, and golimumab in 4.

Results: The PD score was grade 0 in 82 cases, 1 in 32 cases, 2 in 20 cases and 3 in 5 cases. The total RS and its item scores except for “proliferating blood vessels” correlated well with the PD signal intensity. The systemic disease activity, as indicated by DAS28, CRP and MMP-3, had no significant correlation with the local PD signal intensity. However, the DAS28, CRP and MMP-3 values and each RS item score, except for “proliferating blood vessels”, were significantly lower in the PD grade 0 group than in the PD grades 1, 2 and 3 groups.

Conclusions: No PD signal intensity in the ankle and foot indicates systemically well-controlled disease activity. US is an excellent tool for determining local synovitis as well as the systemic disease activity in patients with RA.

Disclosure of Interest: None declared

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THU0080 DEPRESSION AND ANXIETY REDUCE THE LIKELIHOOD OF ACHIEVING REMISSION IN PATIENTS WITH RHEUMATOID ARTHRITIS: REAL LIFE DATA FROM THE NOR-DMARD STUDY

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Background: Depression and anxiety are reported to predict poorer treatment outcomes in rheumatoid arthritis (RA).¹ Whether this can be confirmed in larger prospective observational studies using various remission criteria remains to be explored.

Objectives: To investigate the predictive value of baseline depression/anxiety on the likelihood of achieving remission in RA as well as the associations between baseline depression/anxiety and the components of the remission criteria at follow-up.

Methods: From the prospective, multi-center NOR-DMARD study we included RA patients starting first-time tumour necrosis factor inhibitors (TNFi) and DMARD naïve RA patients starting methotrexate (MTX) between year 2006 and 2012. The following two criteria for depression/anxiety were assessed: 1) the Medical Outcomes Survey Short Form-36 (SF-36) Mental Health subscale (MH) ≤ 56 and 2) the SF-36 Mental Component Summary score (MCS) ≤ 38 .² The predictive value of baseline depression/anxiety on remission after 3 and 6 months treatment was explored in prespecified logistic regression models adjusted for age, sex, disease duration and smoking and the associations between baseline depression/anxiety and the different components of the remission criteria at follow-up in prespecified multiple linear regression models adjusted for age, sex, disease duration and smoking.

Results: A total of 1450 RA patients were included (mean (SD) age 54.4 (13.5) years, median (25th–75th percentile) disease duration 0.4 (0.0–5.0) years, 68.7% females and 28.6% current smokers). According to the SF-36MH ≤ 56 /SF-36MCS ≤ 38 criteria 18.1/29.9% of the patients were depressed/anxious at baseline, respectively. Lower percentages of patients with versus without baseline depression/anxiety achieved remission at 3 and 6 months treatment (unadjusted analyses, figure). Baseline depression/anxiety negatively predicted remission after 3 and 6 months (adjusted analyses, table 1 and 2).

The findings were confirmed in separate subgroup analyses of TNFi/MTX treated patients. Baseline depression/anxiety were associated with increased patient's and evaluator's global assessment and 28 tender joint count at 3 and 6 months, but not with level of acute phase reactants or 28 swollen joint count.

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

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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≤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	For Patients in Remission from BARI 4 mg (n=57)			For Patients in Remission from ADA (n=57)			For Patients in Remission from PBO (n=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	Baseline	Residual Mean Value at Wk 24	Observed Change at Wk 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	0.31	-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
PRO Measures	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)		
	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
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 0.5 level vs PBO using t-test. ***, **, * = significant at 0.01, 0.1, 0.05 levels, respectively, vs PBO. † = significant at 0.5 level vs ADA using ANCOVA model with change value as dependent variable and treatment region, baseline joint erosion status (1-2 erosions plus sequestrations; 3 erosions), and baseline value as factors. For MJS duration for remission, PBO, n=17; BARI 4 mg, n=57; ADA, n=57; 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 PFTs 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 rates¹.

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