Table 1. Summary of temporary interruptions during completed bimec Phase 3 studies in RA**

	Study RA-BEAM (0-24/0-52, data up to rescue)			Study RA-BUILD (0-24, data up to rescue)		
	PBO (N=488)	BARI 4 mg (N=467)	ADA (N=330)	PBO (N=228)	BARI 2 mg (N=229)	BARI 4 mg (N=227)
Total number of dose interruptions, I	67	62/103	30 /48	32	24	40
Patients with ≥1 interruption, n (% of N)	54 (11.1)	50 (10.3)/75 (15.4)	28 (8.5)/40 (12.1)	29 (12.7)	21 (9.2)	34 (15.0)
Number of interruptions per interrupted patient, mean	1.2	1.2/1.4	1.1/1.2	1.1	1.1	1.2
Time from first dose to first interruption, mean, days	68.9	70.6/126.9	73.2/112.3	53.1	41.0	53.6
Duration of individual interruptions, mean (SD), days	11.7 (13.2)	11.4 (9.4)/15.1 (15.7)	19.4 (24.6)/23.1 (29.1)	11.6 (10.2)	12.3 (12.6)	10.7 (9.8)
Interruption duration categories, n (% of I)						
0-7 days	35 (52.2)	26 (41.9)/44 (42.7)	10 (33.3)/15 (32.6)	16 (50.0)	10 (41.7)	20 (50.0)
8-14 days	14 (20.9)	15 (24.2)/28 (25.2)	10 (33.3)/16 (34.8)	7 (21.9)	8 (33.3)	10 (25.0)
15-21 days	6 (9.0)	5 (8.1)/6 (5.8)	4 (13.3)/4 (8.7)	5 (15.6)	4 (16.7)	4 (10.0)
22-28 days	3 (4.5)	5 (8.1)/14 (13.6)	0/1 (2.2)	1 (3.1)	0 (0.0)	3 (7.5)
>28 days	5 (7.5)	4 (6.5)/13 (12.6)	5 (16.7)/10 (21.7)	3 (9.4)	2 (8.3)	3 (7.5)
Reason for interruptions, n (% of I)						
Adverse event	44 (9.0)	46 (9.4)/69 (14.0)	26 (7.9)/37 (11.2)	24 (10.5)	16 (7.0)	26 (11.5)
Abnormal lab result	10 (2.0)	3 (0.6)/6 (1.2)	0/0	4 (1.8)	5 (2.2)	6 (2.6)
Investigator decision	3 (0.6)	2 (0.4)/2 (0.4)	2 (0.6)/3 (0.9)	2 (0.9)	0	2 (0.9)

Abbreviations: ADA=adalimumab; BARI=bimec; n=number of interruptions in the specified category; N=number of patients in safety population; n=number of patients in the specified category; PBO=placebo.
*Interruptions are based on daily tablet study drug. **Temporary interruption is defined as a temporary withholding of study drug that is followed by resumption of study drug during the study.

Table 2. Summary of ePRO daily diary scores among patients retreated following study drug interruptions*

Mean (SD)	Placebo 25 (25)*			Bimec 54 (25)*		
	Study drug initiation†	Pre- interruption‡	Last during interruption‡	Study drug initiation†	Pre- interruption‡	Last during interruption‡
MJS Duration	106 (87)	118 (157)	128 (159)	160 (167)	137 (164)	135 (171)
MJS Severity	5.5 (2.1)	4.3 (2.0)	4.5 (2.0)	5.8 (2.0)	4.2 (2.2)	4.4 (2.1)
Worst Joint Pain	5.8 (1.7)	4.6 (2.0)	4.9 (2.0)	6.1 (2.0)	4.6 (2.2)	4.7 (2.1)
Worst Tiredness	5.5 (2.5)	4.7 (2.2)	4.7 (2.2)	5.5 (2.0)	4.7 (2.3)	4.9 (2.4)

Abbreviations: ePRO=electronic patient reported outcome; MJS=morning joint stiffness.
*Data presented are mean (SD). †Number of patients; ‡Number of patients without at least 3 diary entries during interruption. †For MJS severity, it is 26 (26). ‡Includes combined doses of bimec (2 mg and 4 mg). †Average of values obtained within the first 3 days following randomization. ‡Average of up to 3 most recent values obtained in the 7 days prior to interruption. †Average of 3 most recent values in the last 7 days of the interruption. ‡Average of last 3 available values obtained following interruption and prior to any subsequent interruption or Week 12 study visit.

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FRI0125 RHEUMATOID ARTHRITIS PATIENTS WITH ANTI-ACETYLATED PEPTIDE ANTIBODIES STARTING THEIR FIRST TUMOR-NECROSE-FACTOR-INHIBITOR TREATMENT SHOW GREATER RESPONSE

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Background: Anti-acetylated-peptide antibodies (AAPA) have recently been described in rheumatoid arthritis (RA) patients.[1] Patients that show multiple autoantibody positivity have a higher likelihood to flare when stopping biological treatment. The role of AAPA antibodies for response to Tumor-Necrose-Factor-inhibitor treatment (TNFi) has not been explored.

Objectives: To determine the prevalence and serological overlap of AAPA to rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPA) in a cohort of RA patients starting their TNFi-inhibitor, and to assess their relation of autoantibody status to response to therapy.

Methods: We measured AAPA by ELISA using 21 acetylated peptides derived from vimentin, as well as RF and ACPA. We evaluated the prevalence of autoantibodies, baseline characteristics of autoantibody positive and negative patients, and their association with a 50% response by the Simplified disease activity index (SDAI50), and with achieving of SDAI low disease activity or remission at 6 months after starting the first TNFi. Likelihood ratios were calculated from logistic regression analyses. To better determine differences in SDAI change over time General Estimated Equation analyses (GEE) was used.

Results: Among our 93 patients starting treatment on a TNFi (85% female, mean disease duration: 7.7±7 years mean SDAI20±13), 50% were positive for AAPA, 57% for ACPA and 61% for RF (for overlap of antibodies see figure). There were no significant differences in baseline characteristics found between AAPA positive and negative patients. 61% of patients reached LDA or REM and 33% achieved an SDAI50 response after 6 months of TNFi treatment. AAPA positive patients showed a likelihood ratio (LR+) of 5.3 (p=0.022) to achieve an SDAI50 response and 3.9 (p=0.048) to reach LDA/REM. In contrast, being RF or ACPA positive did not coincide with a higher likelihood of achieving SDAI50 (LR+ of 0.08; p=0.773 and 1.09; p=0.297, respectively) or LDA/REM (LR+ of 1.83; p=0.177 and 1.55; p=0.213). Relative changes upon treatment with TNFi in composite scores were neither different between RF+ vs. RF- patients, nor between ACPA+ vs ACPA-patients; however AAPA+ showed significantly higher relative changes in SDAI (p=0.021), CDAI (p=0.025) and DAS (p=0.022) compared to AAPA- patients. Of note, relative changes in CRP were similar between the groups.

GEE on up to 230 days of TNFi treatment or until change of treatment, showed no significant difference in SDAI courses comparing RF+ vs RF- or ACPA+ vs ACPA-

Figure 1. Overlap of RF, ACPA and AAPA positive patients.

patients; but for AAPA+ vs. AAPA- patients the difference in change in SDAI was significant (p=0.045) over time.

Conclusions: AAPA positivity, in contrast to RF and ACPA positivity, appears to have a tighter association with greater levels of response in patients who are initiating TNFi-treatment. Therefore, AAPA might add additional information to estimate the chances of RA patients for responding to TNF-inhibitors.

References:

[1] Juarez M, Bang H, Hammar F, et al. Identification of novel antiacetylated vimentin antibodies in patients with early inflammatory arthritis. Ann Rheum Dis 2016;75(6):1099–107.

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FRI0126 AIMING FOR REMISSION ACCORDING TO ANY OF THE RHEUMATOID ARTHRITIS DISEASE ACTIVITY INDICES IS MORE IMPORTANT FOR PHYSICAL FUNCTION THAN THE ACTUAL CHOICE OF INDEX: A LONGITUDINAL ANALYSIS IN A CLINICAL PRACTICE SETTING (METEOR COHORT)

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Background: The association between remission and disability in patients with rheumatoid arthritis (RA) has been established mainly in clinical trial cohorts and not in “real-life” patients. Moreover, only a limited number of remission definitions have been tested.

Objectives: To compare the association between different remission criteria and physical function in patients with RA followed in clinical practice.

Methods: Longitudinal data from the METEOR database were used. Fifteen definitions of remission were tested: ACR-EULAR boolean-based; Simplified Disease Activity Index (SDAI); Clinical Disease Activity Index (CDAI); Disease Activity Score (DAS) and 28-joint count DAS (DAS28), both with ESR/CRP, with 3/4 variables (3v/4v), and various cut-offs tested. Disability was measured by the Health Assessment Questionnaire (HAQ) and HAQ≤0.5 was defined as a good outcome. Associations were investigated using generalised estimating equations (GEE), using HAQ≤0.5 as dependent variable and the various remission criteria as independent variables. Potential confounding factors (age, body mass index, gender, rheumatoid factor positivity, erosions and biologic treatment) were also tested. Sensitivity analyses were performed using first visits only and using patients with no missing data for all definitions of remission.

Results: Data from 32,915 patients and 157,899 visits were available. The most stringent definition of remission (table 1) was the ACR-EULAR boolean definition (4.5%). The proportion of patients with HAQ≤0.5 among patients in remission

Table 1. Remission rates (%) and association with HAQ≤0.5

Remission definition	Remission rate	HAQ≤0.5 (%)		Adjusted OR (95%CI) for HAQ≤0.5 (GEE)
		Among patients in remission	Among patients in non-remission	
ACR-EULAR boolean	4.5	87.0	34.1	2.6 (2.3-2.9)
CDAI≤2.8	13.4	78.5	27.4	3.2 (2.9-3.5)
SDAI≤3.3	17.1	78.1	25.7	3.4 (3.0-3.7)
DAS-CRP<1.6	4v 38.6 3v 39.1	59.1 56.4	19.3 20.7	3.2 (2.9-3.5) 2.8 (2.6-3.0)
DAS-ESR<1.6	4v 31.7 3v 30.4	63.2 60.4	22.6 24.3	3.0 (2.7-3.2) 2.6 (2.4-2.8)
DAS28-CRP<2.6	4v 34.8 3v 37.5	62.8 57.7	20.2 21.3	3.3 (3.0-3.6) 2.8 (2.6-3.0)
DAS28-ESR<2.6	4v 25.2 3v 24.4	68.1 62.5	26.5 28.7	2.8 (2.6-3.1) 2.3 (2.2-2.5)
DAS28-CRP≤1.9*	4v 20.0 3v 21.7	72.8 64.5	26.1 27.4	2.9 (2.7-3.2) 2.3 (2.2-2.5)
DAS28-ESR≤2.2*	4v 18.4 3v 17.3	71.3 64.4	29.9 31.8	2.6 (2.4-2.8) 2.1 (1.9-2.2)

*Fleischmann 2015 (PMID: 25143522)