Results: Over a 2-month period (April-May 2014), there were 248 (25%) RA attendees of 1000 participants. Significant differences were observed between current, past and non-smokers in regard to age [mean (SD): 59.5 (10.0) vs. 65.2 (10.6) vs. 61.0 (18.2) years; p=0.034], gender (male: 23.9% vs. 30.3% vs. 14.6%; p=0.027), unemployment due to disability (13.3% vs. 3.1% vs. 4.9%; p=0.044), number of RA medications [mean (SD): 2.3 (1.1) vs. 2.1 (1.1) vs. 1.8 (1.1); p=0.019], DMARD use (78.3% vs. 82.8% vs. 64.1%; p=0.008), opioid use (19.6% vs. 10.1% vs. 3.9%; p=0.009), pain [mean (SD): 5.0 (3.3) vs. 4.0 (2.9) vs. 3.7 (2.6) cm; p=0.040] and PGA [mean (SD): 3.8 (2.8) vs. 3.1 (2.8) vs. 3.0 (2.4); p=0.039]. Recreational marijuana was used by 3 non cigarette smokers only, with 1 also reporting medicinal marijuana use. Ever smokers vs. non-smokers used a greater number of RA medications [mean (SD): 4.3 (3.0) vs. 3.7 (2.6); p=0.081], were more likely to use DMARDs (81.4% vs. 64.1%; p=0.003) and opioids (13.1% vs. 3.9%; p=0.014), and showed a trend towards more pain [mean (SD): 4.3 (3.0) vs. 3.7 (2.6); p=0.081]. In multivariate analysis, male gender (OR=2.193; p=0.025) and DMARD use (OR=2.376; p=0.010) were significantly associated with ever smoking while opioid use (OR=2.784, p=0.103 for ever smoking; OR=3.561, p=0.074 for current smoking) showed a statistical trend.
Conclusions: Current, but also ever cigarette use, was associated with worse RA disease as indicated by the use of more drug categories, and more likely use of DMARDs to treat RA, and a trend to more pain and opioids. The combination of opioids and cigarettes may be a manifestation of a patient "chemical coping" strategy in RA patients.
Disclosure of Interest: None declared
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FRI0116 A HIGH LEVEL OF CLINICAL RESPONSE BASED ON COMPOSITE INDICES IS ASSOCIATED WITH IMPROVED HEALTH-RELATED QUALITY OF LIFE: ANALYSES FROM A PHASE 3 CLINICAL TRIAL IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is a chronic disease associated with inflammatory activity and joint damage that result in disability, pain, and other impairments. The current recommendation is to assess disease activity based on composite indices with objective signs of inflammation (e.g. synovitis, acute phase reactants) and patient's assessment of disease activity. The patient's perception of disease impact and its treatment also facilitate shared decision-making about treatment.
Objectives: To compare patient-reported outcomes (PROs) for RA patients who achieved low disease activity (LDA) or remission based upon the DAS28-ESR compared to those with moderate and high disease activity (MDA and HDA) in this post-hoc analysis of a randomized, double-blind phase 3 clinical trial, RA-BEAM[1].
Methods: 1305 patients were randomized to placebo (N=488), adalimumab (N=330) or baricitinib 4 mg (N=487). Patients with observed DAS28-ESR values at Week 24 (N=1,010) were divided into 4 disease activity groups: HDA (DAS28-ESR>5.1), MDA (3.2<DAS28-ESR≤5.1), LDA (2.6≤DAS28-ESR≤3.2), or remission (DAS28-ESR<2.6). Change from baseline to Week 24 were assessed for the pain visual analogue scale (VAS, 0–100 mm), Health Assessment Questionnaire-Disability Index (HAQ-DI) and SF-36 physical and mental component score (PCS and MCS) for the intent-to-treat (ITT) patients.
Results: Patients with HDA and MDA at Week 24 had greater baseline pain and HAQ-DI scores and lower PCS and MCS scores than patients achieving LDA or remission at Week 24. Lower disease activity at Week 24 was associated with improvement in pain, HAQ-DI, SF-36 PCS and MCS at Week 24. Among patients who achieved remission, residual pain was observed, with close to 40% still experiencing some level of pain and 20% of patients in remission at Week 24 had a residual pain score>20. Sensitivity analyses using other clinical measures (DAS28-CRP, SDAI, CDAI) to define disease activity confirmed the findings.
Conclusions: Improving patient disease activity is associated with improved health-related quality of life. Patients who achieved remission had greater improvement in PROs but residual pain remained. Further research is needed to understand the treatment differences in the association between disease activity and PROs among different therapies.

Table 1. Improvement in disease activity is associated with improved PROs.

PRO Measures	Outcomes at Week 24	Disease Activity at Week 24			
		HDA DAS28-ESR>5.1 N=210	MDA 3.2<DAS28-ESR≤5.1 N=490	LDA 2.6≤DAS-28-ESR≤3.2 N=142	Remission DAS28-ESR<2.6 N=168
Pain VAS	Baseline	65.8	61.3	56.6	51.9
	LSM Change	-10.6	-31.0[a]	-43.2[ab]	-46.7[ab]
	Pain VAS≤10, %	1.4	19.0[a]	48.6[ab]	60.7[ab]
	Pain VAS≤20, %	7.6	37.1[a]	70.4[ab]	79.2[ab]
HAQ-DI	Baseline	1.8	1.6	1.4	1.2
	LSM Change	-0.3	-0.7[a]	-1.0[ab]	-1.0[ab]
SF-36 PCS	Baseline	29.7	32.1	34.3	37.2
	LSM Change	3.3	8.0[a]	12.9[ab]	13.6[ab]
SF-36 MCS	Baseline	44.3	46.2	46.7	49.8
	LSM Change	1.8	4.1[a]	5.6[a]	5.2[a]

[a]p≤0.05 compared to DAS28-ESR>5.1; [b]p≤0.05 compared to 3.2<DAS28-ESR≤5.1; LSM=least squares mean

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FRI0117 CHRONOLOGICAL CHANGES IN ACHIEVING J-HAQ REMISSION IN PATIENTS WITH EARLY-STAGE RHEUMATOID ARTHRITIS IN THE IORRA COHORT

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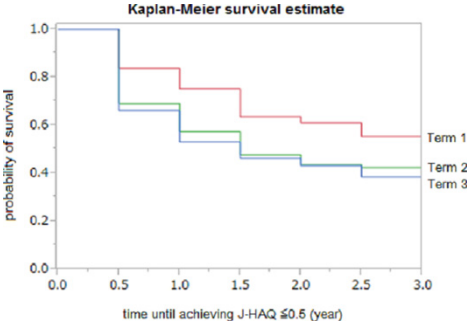
Background: With the introduction of biologic disease-modifying antirheumatic drugs (DMARDs) and the increase in the approved maximum dose of methotrexate in our country, the treatment of rheumatoid arthritis (RA) has advanced dramatically in the past 2 decades. Consequently, many patients were able to achieve clinical remission and low radiographic progression rates[1–3]. In view of these dramatic changes in RA treatment, we investigated whether the Japanese version of the Health Assessment Questionnaire (J-HAQ) improved chronologically due to improved treatment over time.
Objectives: To investigate chronological changes in achieving J-HAQ remission and the factors related to J-HAQ remission in Japanese patients with an early stage of RA.
Methods: RA patients who enrolled in the IORRA cohort for the first time between 2000–2002 (Term 1), 2005–2007 (Term 2), and 2010–2012 (Term 3) and were within 2 years of disease onset were examined. For each patient in Term 3, one patient was extracted from Term 1 and Term 2 by matching the sex, age, and J-HAQ score. Among them, patients with J-HAQ >0.5 at study entry (baseline) were selected; the time to achieve J-HAQ remission (J-HAQ ≦0.5) and the J-HAQ remission rate at 3 years were analyzed. Multivariate analysis was performed to assess factors related to achieving J-HAQ remission.
Results: In each term, 348 RA patients were extracted. At baseline, the average J-HAQ of all 1,044 patients was 0.52. Baseline characteristics of 408 patients with baseline J-HAQ >0.5 were as follows: female, 89.0%; mean age, 56.3 years; anti-cyclic citrullinated peptide (anti-CCP) antibody positivity, 78.0%; mean Disease Activity Score with 28-joint count (DAS28), 4.37; and mean J-HAQ, 1.11. The mean time from baseline to achieving J-HAQ remission became significantly shorter chronologically (Term 1: 2.2 years; Term 2: 1.8 years; Term 3: 1.7 years; p<0.005, Fig.1). J-HAQ remission rates significantly increased in both Term 2 (55.2%) and Term 3 (57.4%) compared with Term 1 (37.5%; p<0.005). The factors significantly related to achieving J-HAQ remission at 3 years were younger age (OR 1.02; 95% CI 1.00–1.04) and enrollment in Term 2 (OR 2.0; 95% CI 1.2–3.5) or Term 3 (OR 2.3; 95% CI 1.3–4.1) compared with enrollment in Term 1.



Conclusions: Along with the improvement in RA treatment, patients were able to achieve J-HAQ remission more frequently and more quickly.

[1] Mod Rheumatol. 2007;17:283–9.2) J Rheumatol. 2015; 42:2279–87.3) Rheumatology. 2016;55:1053–1065.

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FRI0118 CLINICAL UTILITY OF AREA-UNDER-CURVE (AUC) OF PATIENT-DERIVED DISEASE ACTIVITY SCORE (PDAS2) BETWEEN CLINIC VISITS ON REMISSION, FLARE UP AND RHEUMATOLOGIST'S DECISION TO ESCALATE ANTI-RHEUMATIC DRUGS

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Background: The standard of care in RA is treat-to-target of remission or low disease activity state (LDAS). Integral to this is the regular assessment of disease activity. Patient-derived Disease Activity Score 2 (PDAS2) was developed to allow RA patients to self-assess. Validation, corresponding disease activity statuses cut-points and response criteria had been published. PDAS2 scores <3.8, 3.8–4.5, 4.6–5.0, >5.0 correspond to remission, LDAS, moderate and high disease activities respectively. PDAS2 can be recorded by patients in-between clinic visits.
Objectives: To explore the clinical utility of PDAS2 on remission, flare and need of drug adjustment
Methods: A cohort of 100 consecutive RA patients was recruited to complete PDAS2 score at home fortnightly in between two consecutive rheumatology clinics. Patients would return the forms when they attended the second clinic. Rheumatologists adjusted treatment according to disease activity while blinded to the scores of PDAS2 recorded at home. AUC of PDAS2 was calculated from the mean of (PDAS2 score multiplied by the time interval between scores). They were compared with disease activity at the first and second visits. The change of PDAS2 score for those patients having SDAI flare-up (from remission/LDAS to moderate/high disease activity) was compared to those didn't flare-up using unpaired T-test. Receiver Operator Characteristic curve was used to determine the cut-point for AUC-PDAS2 increment to predict flare-up and the cut-point of PDAS2 score for rheumatologists to escalate anti-rheumatic drugs.
Results: Mean age of the cohort was 60 years, mean RA duration 14 years, 90% female, 71% sero-positive and 48% in remission/low disease activity. 89 patients (89%) returned written questionnaires which were done 7.8±3.5 times (mean±standard deviation) (range 1–16) for a follow-up interval of 17.5±9.4 weeks (range 3.9–60.3). Disease activities in first and second visits are shown in Table. *Remission:* For the 14 patients in SDAI remission in both visits, 13/14 were in AUC-PDAS2 remission, and 1/14 in LDAS. There were 47, 45 and 37 out of 89 patients in SDAI, CDAI and DAS28 remission/LDAS respectively – they were all in AUC-PDAS2 remission/LDAS. *Flare-up:* There were 10/89 patients in SDAI remission/LDAS in first visit and moderate/high activity in second visit. Their AUC-PDAS2 score rose by 0.33±0.35 points compared to 0.01±0.32 who had no flare-up (p=0.002). ROC curve AUC was 0.80 (95% CI: 0.64, 0.95) (p=0.002), with optimal cut-point at increment of AUC-PDAS2 score by 0.11 to predict flare, sensitivity and specificity both being 80%. Moreover, rheumatologists decided to *escalate anti-rheumatic drugs* in 15/89 patients. ROC curve AUC was 0.71 (95% CI: 0.56, 0.86) (p=0.01), with optimal cut-point at PDAS2 score 4.33 to predict the need of escalating anti-rheumatic drugs, sensitivity being 60% and specificity 77%.

		First visit		*Second visit*	
		N (%)	AUC-PDAS2 (SD)	N (%)	AUC-PDAS2 (SD)
SDAI	Remission	22 (24.7%)	3.23(0.40)	22 (24.7%)	3.22(0.43)
	LDAS	36 (40.4%)	3.72(0.52)	35 (39.5%)	3.80(0.55)
	Moderate	29 (32.6%)	4.50(0.60)	30 (33.7%)	4.40(0.66)
	High	2 (2.2%)	5.26(1.08)	2 (2.2%)	5.21(1.15)

Table. Simplified Disease Activity Index (SDAI) disease activities of RA patients (N=89) in first and second visits, and corresponding mean area-under-curve of Patient Disease Activity Score 2 (AUC-PDAS2)

Conclusions: PDAS2 scoring by patients in-between follow-up is feasible and useful in reassuring RA patients kept in remission/LDAS, informing a potential flare from previous remission/LDAS state, and predicting rheumatologists' decision to escalate anti-rheumatic drugs. AUC-PDAS2 concept is useful in development of smartphone application for patient use.
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FRI0119 A PROPOSAL FOR A SDAI, CDAI, AND RAPID3-BASED DEFINITION OF MINIMAL DISEASE ACTIVITY FOR USE IN ROUTINE CARE OF RHEUMATOID ARTHRITIS: RESULTS FROM A JAPANESE NATIONAL DATABASE

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Background: The OMERACT group proposed minimal disease activity (MDA) as a treatment target, given the current treatment possibilities and limitations. Whereas a Disease Activity Score 28 (DAS28)-based definition of MDA has been proposed[1], definitions based on the Simplified Disease Activity Index (SDAI), Clinical Disease Activity Index (CDAI), and Routine Assessment of Patient Index Data 3 (RAPID3) have not, despite the increasing use of these indices.
Objectives: To define SDAI, CDAI, and RAPID3-based definition of MDA for use in routine care.
Methods: We analyzed 15,101 patients registered in the Japanese National Database (NinJa 2015). As the OMERACT group proposed, patients with tender joint count (TJC) of 0, swollen joint count (SJC) of 0, and erythrocyte sedimentation rate (ESR) $\leq$10 mm/hour or patients with five of the following seven criteria, namely, pain $\leq$2, SJC $\leq$1, TJC $\leq$1, HAQ $\leq$0.5, physician's global $\leq$1.5, patient's global $\leq$2, and ESR $\leq$20, were considered to be in MDA.[1] The ROC curve was used to obtain the best cut-off points for the SDAI, CDAI, and RAPID3-based definitions of MDA, which emerged as good predictors of MDA as defined by the core dataset. To compare the usefulness of the indices, the interclass correlation of MDA in DAS28, SDAI/CDAI, and RAPID3 was compared to that of low disease activity (LDA).
Results: 57.6% of patients (5,629/9,767) were categorized as having MDA, and 29% of patients (4,003/13,781) were categorized as Boolean remissions. In the ROC analysis, the area under the curve for DAS28, SDAI, CDAI, and RAPID3 was 0.911, 0.955, 0.953, and 0.930, respectively. Based on the Youden index, SDAI $\leq$5.3, CDAI $\leq$4.8, and RAPID3 $\leq$5 were defined as SDAI, CDAI, and RAPID3-based MDA, respectively. The sensitivity and specificity of the DAS28, SDAI, CDAI, and RAPID3-based definitions were higher than those of the DAS28-based definition, with a sensitivity of 81.5%, 89.2%, 88.8%, and 90.0%, respectively, and a specificity of 83.5%, 89.4%, 89.9%, and 88.4%, respectively. Each index-based definition of MDA showed better interclass correlation than that of LDA; DAS28 vs CDAI/SDAI: MDA of 0.643/0.662 and LDA of 0.540/0.540; DAS28 vs RAPID3: MDA of 0.541 and LDA of 0.482; CDAI/SDAI vs RAPID3: MDA of 0.677/0.671 and LDA of 0.433/0.425.
Conclusions: SDAI $\leq$5.3, CDAI $\leq$4.8, and RAPID3 $\leq$5, values two points higher than each remission criterion, may provide a more stringent therapeutic goal than LDA in clinical practice.
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