was used in 57 (65%) of pts at (median) 3 [3;6] month [1]. Retrospectively, 45 out of 88 active eRA pts (35 woman, mean age 53.5; 46–59.5 years, mean disease duration 7.0; 4.0–11.5 months, mean DAS28 5.8; 4.9–6.4, mean hs-CRP 27.0; 9.7–61.0 mg/l) were selected to evaluate the changes in cytokine profile in MTX-naïve pts during SC MTX and SC MTX + adalimumab (SC MTX+ADA) therapy [2]. These 45 pts were genotyped for the following gene polymorphisms (SNPs): PTPN22 (+1858 C/T, rs2476601), CTLA4 (+49A/G, rs231775), TNFAIP3 (rs675520, rs6920220, rs10499194), IL6 (-174G/C, rs1800795), IL6R (+358A/C, rs8192284), TNFA (-308A/G, rs1800629), MCP1/ CCL2 (+2581A/G, rs1024611), IL10 (-592A/C, rs1800872, -1082 A/G, rs1800896), IL1A (-889C/T, rs1800587), IL1B (+3953C/T, rs1143634).

Results: By the end of 3 months of SC MTX therapy, 23 out of 45 eRA pts (51.1%) adequately responded to SC MTX (EULAR criteria) and continued on SC MTX monotherapy. In 22 pts (48.9%) SC MTX monotherapy failed, thus they were switched to SC MTX + ADA combination therapy. CTLA-4 gene polymorphism (+49A/G) was the only predictor for the administration of biological therapy in eRA pts, that was confirmed by a logistic regression analysis [OR=7.7 95% CI 1.4–40.9, p=0.017]. The carriers of at least one G allele (AG/GG genotypes) received the biological therapy more often than subjects with AA genotype (20/22, 90.9% and 13/23, 56.5% respectively). Moreover, the CTLA-4 (+49A/G) genotypes (AG/GG vs AA respectively) were associated with DAS28 (3.6±1.1 and 4.6±1.6, p=0.04), the number of tender joints (3.1±3.1 and 7.1±5.1, p=0.016), the number of swollen joints (2.7±2.5 and 5.3±4.9 p=0.024), SDAI (11.1±7.2 and 20.2±12.1, p=0.018), CDAI (10.6±7.1 and 18.6±10.6, p=0.025) and CRP (6.3±12.1 and 21.8±37.1 p=0.018) values after 3 months of SC MTX monotherapy.

Conclusions: Our data suggest that CTLA-4 (+49A/G) genetic polymorphism is associated with more severe rheumatoid arthritis and may predict the need for early administration of biological therapy.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.3023

AB0231 PHYSICIAN VISUAL ANALOG SCALE ESTIMATES FOR DAMAGE ARE HIGHER THAN FOR INFLAMMATION IN PATIENTS WITH OSTEOARTHRITIS AND ALSO IN PATIENTS WITH RHEUMATOID ARTHRITIS AT ALL LEVELS OF CLINICAL SEVERITY ACCORDING TO RAPID3

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Background: A visual analog scale (VAS) to estimate the patient's global status (DOGL) often is the most efficient of all 7 RA core data set measures to distinguish active from control treatments in clinical trials¹. DOGL is designed to assess inflammatory activity, but it may be influenced variably in different doctors by irreversible joint damage and/or distress. Therefore, 3 additional 0–10 VAS have been developed to estimate levels of inflammation, damage, and distress that may impact DOGL.

Objectives: To analyze 4 estimates for overall global, inflammation, damage and distress according to 4 RAPID3 (routine assessment of patient index data) severity categories in patients with RA or OA.

Methods: Patients seen at one academic clinical setting are assigned 4 0–10 VAS estimates: overall DOGL, inflammation (reversible), damage (irreversible), and distress (symptoms explained by neither inflammation nor damage, eg, fibromyalgia). All patients complete a self-reported MDHAQ questionnaire as part of routine care. The MDHAQ includes 0–10 scores for physical function (FN), pain (PN), patient global estimate (PATGL), compiled into a 0–30 RAPID3. Patients with a primary diagnosis of RA or OA according to their rheumatologists were included. The percentage of RA and OA patients in each RAPID3 severity category was compared according to mean DOGL and the 3 subscale estimates using chi-square and ANOVA.

Results: The study included 232 patients with RA and 274 with OA. Patients with OA were older than RA patients (66.5 versus 57.3, p<0.001) and had higher scores for RAPID3 (14.4 vs 11.7, p<0.001). A higher percentage of patients with OA had high RAPID3 severity compared with RA patients (66% vs 48%, p<0.001) (Table). DOGL and each subscale estimate were higher according to each of 4 RAPID3 categories from remission to high severity in RA and OA (Table). The level of inflammation was higher in RA than in OA, but estimates for damage higher in OA than RA. However, estimates for damage were higher than for inflammation in RA in each RAPID3 category.

Conclusions: Physician VAS for inflammation, damage, and distress may supplement the overall physician global estimate as quantitative physician

Table 1. Mean and SD for the four physician estimates according to RAPID3 categories in RA and OA patients

	RAPID3 Severity Categories				P
	Remission (<3)	Low (3–6)	Moderate (6–12)	High (>12)	
Rheumatoid Arthritis	N=45 (19%)	N=19 (8%)	N=57 (25%)	N=111 (48%)	
Overall DOGL (0–10 scale)	1.7 (1.4)	2.7 (1.5)	3.3 (1.4)	5.1 (1.9)	<0.001
Inflammation (0–10)	1.3 (1.9)	1.4 (1.8)	1.6 (1.3)	3.3 (2.5)	<0.001
Damage (0–10)	1.7 (1.5)	2.9 (2.0)	2.9 (2.0)	3.7 (2.2)	<0.001
Distress (0–10)	0.2 (0.7)	0.3 (0.8)	0.4 (0.9)	1.6 (2.4)	<0.001
Osteoarthritis	N=14 (5%)	N=18 (7%)	N=60 (22%)	N=182 (66%)	
Overall DOGL (0–10 scale)	1.3 (1.2)	2.5 (0.8)	3.2 (1.4)	4.7 (1.6)	<0.001
Inflammation (0–10)	0.4 (0.6)	0.7 (1.1)	0.8 (1.4)	1.0 (1.4)	0.25
Damage (0–10)	2.5 (1.5)	3.0 (0.9)	3.5 (1.5)	4.5 (1.8)	<0.001
Distress (0–10)	0.0 (0.0)	0.3 (0.6)	1.1 (2.1)	2.0 (2.8)	<0.001

estimates of reversible findings, irreversible findings, and distress to support clinical management decisions. Estimates of joint damage are higher in OA than in RA, although higher than estimates of inflammation in both RA and OA, in patients in all 4 RAPID3 severity categories.

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Disclosure of Interest: I. Castrejon: None declared, J. Chua: None declared, J. Block: None declared, T. Pincus Shareholder of: Health Report Services, Inc

DOI: 10.1136/annrheumdis-2017-eular.3556

AB0232 MINIMAL CLINICALLY IMPORTANT IMPROVEMENT (MCII) OF RAPID3 (ROUTINE ASSESSMENT OF PATIENT INDEX DATA 3), AN INDEX OF ONLY PATIENT SELF-REPORT SCORES, PERFORMS SIMILARLY TO TRADITIONAL RHEUMATOID ARTHRITIS (RA) INDICES, DAS28 AND CDAI

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Background: No single “gold standard” measure is available to assess patients with rheumatoid arthritis (RA) in clinical trials and routine care, as in hypertension, diabetes, and other diseases. Therefore, an index of several measures, such as a DAS28 (Disease Activity Score-28) and CDAI (Clinical Disease Activity Index), based on 7 RA core data set measures; is needed. However, the only quantitative data in many (most) patients in routine rheumatology care are laboratory test results. RAPID3 (routine assessment of patient index data), which includes only patient self-report scores, is considerably more feasible than DAS28 or CDAI for routine care, distinguishes active from control treatments in RA clinical trials similarly and is correlated significantly with these indices. A minimal clinically important improvement (MCII) to interpret changes in clinical trials and clinical care has not been established for RAPID3

Objectives: To estimate MCII of RAPID3, and compare results to MCII of DAS28 and CDAI.

Methods: Post hoc analyses were performed of a reported longitudinal study of 250 patients with active RA (1). All 7 RA core data set measures were collected at baseline and after treatment escalation with prednisone 1 month later or with disease modifying medications or biologic agents 4 months later (1). Patient judgment of improvement in arthritis status was obtained as “improved”, “the same” or “worsened”, and analyzed in relation to changes in RAPID3, DAS28 and CDAI. RAPID3 is the sum of 3 0–10 measures: physical function on a HAQ recalculated from 0–3 to 0–10, pain and patient global estimate on 0–10 VAS (visual analog scales), total=0–30. DAS28-ESR (erythrocyte sedimentation rate) and CDAI were computed as described in the literature. Changes in all indices, standardized response means (SRM), MCII as changes that had a specificity of 0.80 for improvement based on receiver-operating characteristic curves, and MCII as a proportion of the maximum score were computed.

Results: Among 250 patients, 167 (66.8%) reported improvement. RA activity and SRMs improved similarly per the 3 indices (Table). ROC curve areas were ≥0.77 (Table). MCII with specificity for improvement of 0.80 were -3.5 for RAPID3, -1.17 for DAS28-ESR, and -12.5 for CDAI. MCII were in a similar range of 11.6% to 16.8% of maximum score (Table).

Conclusions: MCII for RAPID3, DAS28, and CDAI were in a similar range. Knowledge concerning MCII thresholds can improve interpretation of data from clinical trials and routine clinical care.

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Disclosure of Interest: I. Castrejon: None declared, M. Ward: None declared, M.

Abstract AB0232 – Table 1. Changes in rheumatoid arthritis activity measures during the study

Measure (range)	Baseline	Follow-up	Mean (%) change	SRM (95% CI)	ROC Curve Area (95% CI)	MCII (95% CI)	% of Total
RAPID3 (0–30)	16.3±6.3	11.1±6.7	-5.2±6.5 (32%)	-0.79 (-0.71, -0.88)	0.80 (0.74, 0.86)	-3.5 (-2.9, -4.3)	11.6%
DAS28-ESR (0–9.4)	6.16±1.2	4.8±1.38	-1.31±1.34 (21%)	-0.98 (-0.90, -1.07)	0.77 (0.71, 0.82)	-1.17 (-1.36, -0.87)	12.4%
CDAI (0–76)	36.8±13.5	23.0±13.6	-13.7±14.1 (37%)	0.98 (-0.90, -1.08)	0.78 (0.73, 0.84)	-12.5 (-14.7, -10.5)	16.4%

*SRM = standardized response mean; CI = confidence interval.

Bergman: None declared, L. Guthrie: None declared, M. Alba: None declared, T. Pincus Shareholder of: Health Report Services, Inc
DOI: 10.1136/annrheumdis-2017-eular.3500

AB0233

REMISSION ACCORDING TO RAPID3 (ROUTINE ASSESSMENT OF PATIENT INDEX DATA 3) IN PATIENTS WITH RHEUMATOID ARTHRITIS: A CROSS-SECTIONAL STUDY FROM ROUTINE CARE AT 3 USA SITES

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Background: RAPID3 remission criteria provide similar results to DAS28 criteria, although less stringent compared to ACR/EULAR Boolean criteria. RAPID3 remission criteria are more feasible in routine care¹ and have been reported at 25% in patients from France¹ and 21% from Norway².
Objectives: We examined the proportion of patients in remission and 3 other severity categories according to RAPID3 at 3 sites at which MDHAQ is completed by all patients in routine care.
Methods: All patients seen at each rheumatology site complete an MDHAQ/RAPID3 at all visits in the waiting area as part of their routine care. The MDHAQ includes 0–10 scores for physical function, pain and patient global estimate, compiled into a 0–30 RAPID3, as well as scores for fatigue, RADAI self-report of painful joints, and demographic data. Physicians complete a global assessment (DOGCL) on a 0–10 visual analog scale (VAS). A random visit with complete questionnaire data for each RA patient from each site was included in the analyses. The proportion of patients in 4 RAPID3 categories, high severity (>12/30), moderate severity (6.1–12), low severity (3.1–6), and remission (≤3), was computed. MDHAQ demographic and clinical measures and DOGCL were compared in the 4 RAPID3 severity groups using chi-square and ANOVA tests.
Results: 420 RA patients from the 3 sites were analyzed. Remission rates according to RAPID3 severity ranged from 23% to 26%, similar to reported rates from France and Norway. Low severity ranged from 7–24%, moderate severity from 23–29% and high severity from 21–46%. Age and sex were similar in the disease severity categories at the 3 sites (Table). Patients in the moderate and high severity groups at each site had higher scores for fatigue, RADAI self-reported joint pain, and DOGCL.

Table 1. Mean (SD) for demographic and clinical characteristic of patients in remission versus other disease severity categories according to RAPID3 in each site. *p<0.001

	Remission (≤3)	Low (3.1–6)	Moderate (6.1–12)	High (>12)
Site 1 (N=137)	32 (23.4%)	11 (8%)	31 (22.6%)	63 (46%)
Female, n (%)	27 (84.4%)	9 (81.8%)	26 (83.9%)	59 (93.6%)
Age, yrs	58.5 (16.9)	57.9 (18.8)	56.8 (17.5)	55.6 (14.5)
Fatigue (0–10)	1.1 (1.5)	2.3 (2.0)	3.1 (2.1)	6.6 (2.3)*
Self-report RADAI (0–48)	1.9 (2.9)	5.0 (3.9)	7.5 (5.6)	17.0 (9.2)*
DOGCL (0–10)	1.6 (1.2)	3.7 (1.7)	3.2 (1.4)	5.3 (1.9)*
Site 2 (N=144)	37 (25.7%)	35 (24.3%)	42 (29.2%)	30 (20.8%)
Female, n (%)	28 (75.7%)	22 (62.9%)	34 (80.9%)	24 (80%)
Age, yrs	56.6 (16.9)	62.0 (14.6)	62.3 (14.7)	62.5 (15.9)
Fatigue (0–10)	0.9 (1.0)	2.7 (1.9)	4.1 (2.4)	5.6 (3.0)*
Self-report RADAI (0–48)	NA	NA	NA	NA
DOGCL (0–10)	0.9 (1.3)	1.0 (1.0)	1.7 (1.5)	3.4 (2.7)*
Site 3 (N=139)	32 (23%)	10 (7%)	33 (23.7%)	64 (46%)
Female, n (%)	23 (72%)	9 (90%)	20 (62%)	50 (79%)
Age, yrs	44.4 (13.8)	43.8 (17.0)	50.3 (17.8)	50.9 (15.0)
Fatigue (0–10)	0.4 (0.8)	2.6 (2.7)	4.1 (2.7)	6.9 (2.9)*
Self-report RADAI (0–48)	1.3 (1.9)	4.7 (4.2)	5.7 (5.1)	18.3 (12.2)*
DOGCL (0–10)	1.1 (1.1)	3.2 (1.9)	2.5 (1.2)	3.2 (1.5)*

Conclusions: Similar RAPID3 remission rates were seen at 3 USA sites (about 24%), comparable to results from France and Norway.

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Disclosure of Interest: I. Castrejon: None declared, M. Bergman: None declared, K. Gibson: None declared, Y. Yazici: None declared, J. Block: None declared, T. Pincus Shareholder of: Health Report Services, Inc
DOI: 10.1136/annrheumdis-2017-eular.2749

AB0234

ORAL CONTRACEPTIVES, MENOPAUSE AND RHEUMATOID ARTHRITIS IN KOREAN WOMEN: A NATIONWIDE STUDY

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Background: Rheumatoid arthritis (RA) is a chronic autoimmune inflammatory disease with a multifactorial etiology. Hormonal factors, ethnicity and their interaction may result in the development of RA.
Objectives: We investigated the effects of oral contraceptives (OCs) and menopause on RA in South Korea women using nationwide data.

Methods: Data were collected from the 2008–2012 Korea National Health and Nutrition Examination Surveys. A total of 17,890 eligible participants were included. As there were significant differences in baseline characteristics between the patients on OCs and those not taking OCs, we used propensity score-matching to adjust for such differences. We calculated the odds ratios (ORs) and 95% confidence intervals (95% CIs) of OCs leading to RA development.
Results: The peak incidence of RA was between 50–59 years old. The overall rate of OC usage was 16.5% and mean duration of OC using was 18.41±28.78 (ranged from 0 to 360) months. Before propensity score-matching, using multivariable logistic regression adjusted for traditional risk factors, taking OC was a significantly associated with RA development (OR 1.18, 95% CI 1.18–1.19, p <0.001). After propensity score-matching, taking OCs was not associated with RA (OR 1.05, 95% CI 0.83–1.34, p <0.001). Menopausal status showed strongly significant increase in the risk of RA.
Conclusions: There was an association between menopausal status and RA development in South Korean women. However, usage of OCs did not show significant effects on the development of RA.
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Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2017-eular.4769

AB0235

EFFECT OF BASELINE DISEASE ACTIVITY ON ACHIEVING SUSTAINED LOW DISEASE ACTIVITY IN BARICITINIB PHASE 3 STUDIES

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Background: In the Phase 3 studies RA-BUILD¹ and RA-BEAM², baricitinib (bari) has demonstrated clinical efficacy including reduced disease activity in RA patients (pts) with an inadequate response (IR) to conventional synthetic DMARDs (csDMARDs).
Objectives: To determine whether disease activity at baseline (BL) affects the achievement of sustained low disease activity (LDA) with bari treatment.
Methods: In this post hoc analysis, pts from the placebo (PBO) and bari 4 mg treatment arms of the RA-BUILD and RA-BEAM studies were categorised based on their level of disease activity at BL; either CDAI ≤median or CDAI >median, where median was 34.8 for RA-BUILD and 36.2 for RA-BEAM. Pts who achieved CDAI ≤10 at ≥2 consecutive visits (sustained LDA) within 12 and 24 weeks (wks) were considered as responders. The length of time required by pts to achieve sustained LDA was determined for each group using the incidence rate (percent pts responding per month). In addition, the association between response and dose of bari was explored in csDMARD-IR pts randomised to bari (2 mg or 4 mg) once daily from the RA-BUILD study.
Results: Within the bari 4 mg arm, a greater proportion of pts with CDAI ≤median at BL achieved sustained LDA and within a shorter treatment duration as indicated by higher incidence rates, compared to pts with CDAI >median at BL. In pts with CDAI ≤34.8 at BL, the 2 mg and 4 mg doses showed similar efficacy, but a larger proportion of pts with CDAI >34.8 reached sustained LDA at 24 wks with bari 4 mg than 2 mg (41.4% and 32.4%, respectively).

Table 1. Proportions and Rates of Sustained LDA Achievement with Baricitinib Treatment							
Pts achieving CDAI ≤10		BL CDAI ≤ median			BL CDAI > median		
		PBO	Bari 4 mg	Bari 2 mg	PBO	Bari 4 mg	Bari 2 mg
RA-BUILD	N	116	108	114	108	116	111
	Wk12	% 19.8	42.6	40.4	7.4	21.6	18.0
	i-rate	4.36	11.78	10.50	1.55	4.69	3.90
	Wk24	% 44.8	63.9	63.2	17.6	41.4	32.4
RA-BEAM	N	249	236	235	246		
	Wk12	% 23.7	39.8		4.3	18.7	
	i-rate	2.71	5.40		0.42	1.98	
	Wk24	% 34.5	69.1		14.0	41.9	
	i-rate	4.35	12.97		1.49	5.47	

Pts were defined as responders if they met the response criterion within the stated time frame, prior to any rescue or discontinuation. % = percent of pts meeting response criteria; CDAI median = 34.8 (RA-BUILD) or 36.2 (RA-BEAM); i-rate = exposure-adjusted incidence rate (% pts/month); N = number of randomised and treated pts.