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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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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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.

References:

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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.