RA patients with low MBDA scores (N=6 of 16; 37%) but high in those with moderate/high scores (N=10 of 13; 77%) (chi square p=0.015) (Figure; right graph).

Conclusions: These data show that the majority of RA patients in sustained clinical remission with low MBDA scores can successfully taper TNFi. In contrast tapering cannot be recommended in patients with moderate to high MBDA scores, as relapse rates are high in these patients.

References:
[1] Haschka J et al. Ann Rheum Dis 2016,75;45–51.
[2] Curtis JR et al. Arthritis Care Res 2012;64:1794–803.

Disclosure of Interest: None declared
DOI: 10.1136/annrheumdis-2017-eular.4787

FRI0099 PAIN REDUCTION IS ASSOCIATED WITH IMPROVED WORK PRODUCTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Patients with rheumatoid arthritis (RA) indicate pain is an important aspect of disease burden and may persist despite control of disease. In a randomized, double-blind phase 3 clinical trial of baricitinib (RA-BEAM),[1] baricitinib provided significant improvement in pain reduction. It is not clear, however, how much reductions in pain impacted other aspects of life, such as work productivity.

Objectives: To assess the relationship between pain reduction and improvements, regardless of treatment, in daily activity and work productivity in patients with RA.

Methods: In this post-hoc analysis of RA-BEAM[1], pain for the intention-to-treat patients was assessed using the patient's assessment of pain (0–100 mm visual analogue scale). The Work Productivity and Activity Impairment Questionnaire-RA (WPAI-RA) instrument was used to evaluate the percentage of activity impairment due to RA (impairment in regular daily activities, N=1302), percentage of work-time missed due to RA (absenteeism, N=521), percentage of impairment while working due to RA (presenteeism, N=490), and percentage of overall work impairment due to RA (impairment in work productivity, N=490). Pain was divided into pain reduction groups (<30%, 30% – <50%, ≥50% at Weeks 12 and 24; ≥30% [Y/N] and ≥50% [Y/N] at Weeks 1 and 2). Pairwise comparisons on improvement in WPAI-RA scores between pain reduction groups at Weeks 12 and 24 were assessed by ANCOVA adjusting for region, baseline joint erosion status, and baseline values of outcome variables. Missing values were imputed using the modified last-observation carried forward method.

Results: At baseline across treatment groups, the mean values ranged from 56–58 for daily activity impairment, 12–13 for absenteeism, 42–46 for presenteeism, and 45–49 for work productivity impairment. A ≥30% reduction in pain as early as Week 1 was associated with significantly greater (p<0.001) improvement than <30% pain reduction in regular daily activity (-22.8 vs -16.0), presenteeism (-17.5 vs. -12.1), and work productivity (-16.8 vs. -11.6) at Week 12. Greater improvement was observed in most WPAI-RA scores in patients who had more pain reduction at Weeks 12 and 24; with a reduction of ≥50% in pain from baseline, the WPAI-RA scores were substantially improved at Weeks 12 or 24 for daily activity, presenteeism, and work productivity (Table).

	Pain (VAS) % reduction from baseline at Week 12			Pain (VAS) % reduction from baseline at Week 24		
Mean (SD)%	**<30%**	**30% - <50%**	**≥50%**	**<30%**	**30% - <50%**	**≥50%**
Improvement in WPAI-RA	**WPAI-RA at Week 12**			**WPAI-RA at Week 24**		
Impairment in Regular Daily Activity	-5.6 (22.2)	-17.8 (21.8)[c]	-30.1 (25.4)[cd]	-3.5 (23.6)	-17.1 (22.4)[c]	-33.2 (25.3)[cd]
Absenteeism	0.7 (28.0)	-5.2 (29.7)[b]	-3.0 (18.2)[c]	-1.8 (28.5)	-2.1 (36.1)	-2.5 (21.8)
Presenteeism	-2.8 (24.6)	-12.9 (21.1)[c]	-23.4 (24.6)[cd]	-0.2 (25.1)	-7.7 (23.1)[a]	-26.0 (25.1)[cd]
Impairment in Work Productivity	-2.3 (24.4)	-11.3 (23.5)[c]	-23.1 (26.5)[cd]	0.5 (25.6)	-5.7 (26.2)	-25.2 (28.1)[cd]

[a]p≤0.05; [b]p≤0.01; [c]p≤0.001 vs. pain reduction <30%; [d]p<0.001 vs. pain reduction 30-<50%

Conclusions: Regardless of treatment, pain reduction was associated with improved regular daily activity and work productivity in patients with RA, with larger levels of reduction related to more improvement.

References:
[1] Taylor PC, Keystone E, van der Heijde D, et al. Baricitinib Versus Placebo or Adalimumab in Patients with Active Rheumatoid Arthritis (RA) and an Inadequate Response to Background Methotrexate Therapy: Results of a Phase 3 Study. Arthritis Rheum 2015;67(Suppl 10):3928.

Disclosure of Interest: K. Michaud Grant/research support from: Pfizer, B. Zhu Employee of: Eli Lilly and Company, C. Gaich Employee of: Eli Lilly and Company, A. DeLozier Employee of: Eli Lilly and Company, V. Arora Employee of: Eli Lilly and Company, C. Dickson Employee of: Eli Lilly and Company, J. Smolen Grant/research support from: Abbvie, Janssen, Lilly, MSD, Pfizer, Roche and has provided expert advice to and/or had speaking engagements for Abbvie, Amgen, Astra-Zeneca, Astro, BMS, Celgene, Celltrion, Chugai, Gilead, Glaxo, ILTOO, Janssen, Lilly, Medimmune, MSD, Novartis-Sandoz, Pfizer, Roche, Samsung, Sanofi, UCB
DOI: 10.1136/annrheumdis-2017-eular.1345

FRI0100 DETERMINING MINIMUM CLINICALLY IMPORTANT CHANGE IN MULTI BIOMARKER DISEASE ACTIVITY SCORE ASSOCIATED WITH CLINICAL IMPROVEMENT IN METHOTREXATE NAÏVE PATIENTS WITH EARLY RHEUMATOID ARTHRITIS

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Background: The Multi-Biomarker Disease Activity (MBDA) score is a validated tool that quantifies 12 biomarkers to assess disease activity in rheumatoid arthritis (RA) patients. Many studies have demonstrated usefulness of the score for assessing RA disease activity.

Objectives: To determine minimum clinically important change in MBDA score (ΔMBDA) from baseline (BL) to Month 3 (M3) associated with clinical improvement (decrease in DAS-ESR >1.2) in early RA patients after initiating methotrexate (MTX).

Methods: We evaluated the MBDA test in patients from one of the sites participating in the Solna Epidemiological Investigation of RA (EIRA) cohort. EIRA patients were eligible if they were ≥18 years; RA diagnosis within 12 months of symptom duration; had serum and clinical assessments at BL and M3; and clinical follow-up data in the Swedish Rheumatology Quality Register. Patients naïve to disease modifying anti-rheumatic drugs who received MTX were included. Kruskal-Wallis was used to test the null hypothesis that medians of ΔMBDA scores of 3 EULAR response groups are equal. Receiver operating characteristic (ROC) analysis was performed. The optimal threshold of ΔMBDA associated with DAS28-ESR improvement (decrease in DAS-ESR >1.2 at M3) was determined by Youden criterion maximizing sum of sensitivity and specificity.

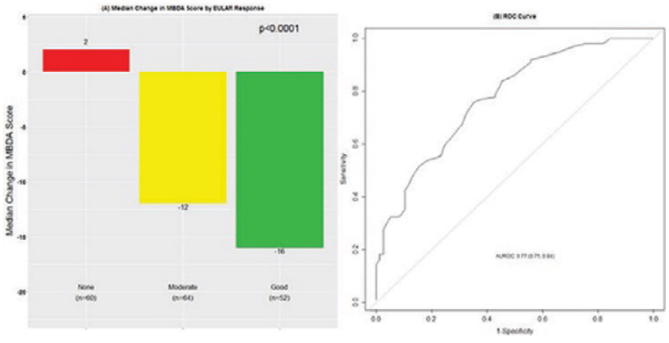
Results: 176 patients were included: 72% women, mean age 51 (SD: 11.7) years, mean DAS28-ESR score 5.6 (SD: 0.99); 51% had ESR <28 mm/hr, 66% were anti-CCP2+, and 22% received prednisone. Mean BL MBDA score was 56.8 (SD: 14.7) with 8 (5%) patients in low (<30), 29 (16%) patients in moderate (30–44) and 139 (79%) patients in high MBDA disease activity categories. Median MBDA scores for patients with no EULAR response worsened by 2 points and for patients with moderate and good response improved by 12 and 16 points, respectively (p<0.0001 across groups, Fig 1A). Median MBDA scores improved by 10 points for all patients and 15 points in patients with a DAS28-ESR decrease >1.2. The best combination of sensitivity and specificity to achieve a DAS28-ESR decrease >1.2 was provided by a ≥8 point MBDA score improvement (Fig 1B). A similar result was obtained using the bootstrap method. AUROC was 0.77 (95% CI: 0.71, 0.84). 125 patients (71%) had concordance between DAS28-ESR improvement and ΔMBDA improvement at the optimal threshold (Table 1).

Table 1. Performance Measures (95% CI) Based on Optimal Threshold of ΔMBDA Score from BL to M3 Associated with DAS28-ESR Improvement

Improvement		DAS28-ESR (decrease >1.2)		
		Yes	No	Total
MBDA (optimal threshold: improvement ≥8 points)	Yes	75	27	102
	No	24	50	74
	Total	99	77	176

Sensitivity: 0.76 (0.66, 0.83); Positive predictive value: 0.74 (0.64, 0.81); Specificity: 0.65 (0.54, 0.75); Negative predictive value: 0.68 (0.56, 0.77).r Concordance rate: 71%.

Figure A) Median Change in MBDA Score by EULAR Response; B) Receiver Operating Curve (ROC) to Determine the Optimal Threshold of Change in the MBDA Score Associated with Clinical Improvement (ΔDAS28-ESR Decrease >1.2)



Conclusions: The optimal threshold of ΔMBDA score associated with a clinically relevant decrease of DAS28 was 8 points. Using this threshold, the MBDA test is informative to detect clinical improvement. Thus, based on these results improvement in MBDA score ≥8 points at M3 after initiating MTX is indicative of meaningful clinical improvement.