changes using all diurnal and daily variation data. Bootstrapping was used to validate the result.
Results: Of patients included in the analysis, 13 had moderate MBDA scores and 9 had high MBDA scores at baseline. Baseline demographics were: 73% women, mean age 61.8 (SD: 12.1) years, mean MBDA score 43.9 (SD: 8.3), and mean CDAI 20.2 (SD: 17.1). No patients were on glucocorticoids. Based on the analysis of the absolute change of MBDA score in the data with daily and diurnal variation combined, the mean was 3.4 (SD: 3.8), the median (Q1, Q3) was 2 (1, 5), and the MID was calculated as 7. Similar results were obtained using a bootstrap method. Minimal variability in mean MBDA scores was observed over 4 days for patients with moderate and high baseline MBDA scores (Figure 1).
Conclusions: Based upon the short term biologic variability of moderate and high MBDA scores, the MID was 7 units. An absolute change exceeding this threshold is unlikely due to diurnal and daily biological variation of the MBDA scores.
Disclosure of Interest: D. Chernoff Shareholder of: Myriad Genetics, Inc., Employee of: Crescendo Bioscience Inc., R. Bolce Shareholder of: Myriad Genetics, Inc., Employee of: Crescendo Bioscience Inc., C. Hwang Shareholder of: Myriad Genetics, Inc., Employee of: Crescendo Bioscience Inc., X. Wang Shareholder of: Myriad Genetics, Inc., Employee of: Crescendo Bioscience Inc., A. Kivitz Consultant for: Genentech, Pfizer, UCB, Janssen, J. Curtis Grant/research support from: Crescendo Bioscience Inc., Consultant for: Crescendo Bioscience Inc.
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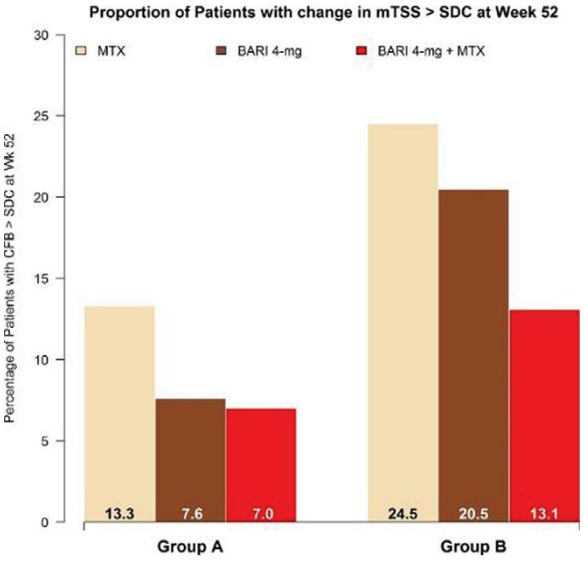
THU0088 STRUCTURAL DAMAGE PROGRESSION IN PATIENTS TREATED WITH METHOTREXATE, BARICITINIB MONOTHERAPY OR BARICITINIB + METHOTREXATE BASED ON THEIR LEVEL OF CLINICAL RESPONSE IN THE PHASE 3 RA-BEGIN STUDY

D. van der Heijde[1], P. Durez[2], G. Schett[3], E. Naredo[4], M. Østergaard[5], G. Meszaros[6], N. Bello[6], I. De la Torre[6], P. Lopez-Romero[6], D. Schlichting[7], E. Nantz[7], R. Fleischmann[8]. *[1]Leiden University Medical Centre, Leiden, Netherlands; [2]UCL-Saint Luc, Bruxelles, Belgium; [3]Universitätsklinikum Erlangen, Erlangen, Germany; [4]Hospital Universitario Fundación Jimenez Diaz, Madrid, Spain; [5]Copenhagen Centre for Arthritis Researc, Copenhagen, Denmark; [6]Eli Lilly & Company, Madrid, Spain; [7]Eli Lilly & Company, Indianapolis; [8]U Texas SW Medical Center, Dallas, United States*

Background: Baricitinib (BARI), an oral inhibitor of Janus kinase (JAK) 1 and JAK 2, is being developed for the treatment of rheumatoid arthritis (RA). RA-BEGIN was a phase 3 double-blind, three-arm multicentre study of BARI administered as monotherapy or in combination with methotrexate (MTX) to patients (pts) with early active RA who had no or limited treatment with DMARDs. Methotrexate (MTX) monotherapy was the active comparator.
Objectives: To evaluate the proportion of pts with structural damage progression, defined as change from baseline (CFB) greater than the smallest detectable change (SDC) in mTSS at week (wk) 52, depending on their disease state as measured by DAS28-CRP.
Methods: Pts were classified into two groups based on DAS28-CRP. Group A included pts who achieved sustained DAS28-CRP $\leq$3.2 at weeks 16, 20 and 24. Pts who did not achieve DAS28-CRP $\leq$3.2 consecutively at weeks 16, 20 and 24 and pts with missing DAS28-CRP at any of those 3 visits were included in Group B. The proportion of pts with CFB mTSS > SDC at wk 52 was estimated for each treatment arm for the two defined groups of response. The SDC in mTSS in the RA-BEGIN population at wk 52 was 1.4. Missing mTSS at wk 52 were imputed using linear extrapolation based on baseline data and the most recent radiographic data prior to the missed radiograph. No formal statistical tests were performed and comparisons are merely descriptive. All analyses were post-hoc.
Results: Out of the 584 pts of the modified-ITT population (all randomised pts who received at least 1 dose of study drug) in the RA-BEGIN study, 212 were classified in Group A: 21.4% (45/210), 42.1% (67/159), and 46.5% (100/215) for MTX, BARI and BARI+MTX, respectively. The odds ratios for sustained DAS28-CRP $\leq$3.2 response (weeks 16, 20 and 24) to BARI and BARI+MTX vs. MTX, were respectively 2.8 (95% CI 1.7–4.4) and 3.3 (95% CI 2.1–5.1). Pts classified in Group A maintained an adequate level of response up to wk 52. Further, pts in Group A (sustained DAS28-CRP $\leq$3.2) on either BARI + MTX or BARI, were less likely to show structural progression than patients who achieved sustained DAS28-CRP $\leq$3.2 on MTX. Pts in Group B on MTX or BARI monotherapy were more likely to show structural progression than patients who did not achieve a sustained DAS28-CRP $\leq$3.2 response on BARI + MTX (Figure 1).
Footnote: Group A: Patients who achieved sustained DAS28-CRP $\leq$3.2 (NRI) at weeks 16, 20 and 24 (N=212); Group B: Complement group
Conclusions: In patients who achieved sustained low DAS28-CRP scores, progression rates compared to MTX were reduced to a similar degree with BARI as monotherapy or in combination with MTX. Compared to MTX in patients who did not achieve sustained low DAS28-CRP scores, progression rates were reduced most markedly with combination therapy.
Disclosure of Interest: D. van der Heijde Consultant for: Abbvie, Amgen, Astellas, AstraZeneca, BMS, Boeringer Ingelheim, Celgene, Daiichi Sankyo, Eli Lilly and Company, Galapagos, Janssen, Merck, Novartis, Pfizer, Roche, Sanofi-Aventis, UCB, P. Durez: None declared, G. Schett: None declared, E. Naredo: None declared, M. Østergaard Consultant for: Abbvie, BMS, Boehringer-Ingelheim,



Celgene, Eli-Lilly, Centocor, GSK, Hospira, Janssen, Merck, Mundipharma, Novartis, Novo, Orion, Pfizer, Regeneron, Schering-Plough, Roche, Takeda, UCB, and Wyeth, G. Meszaros Employee of: Eli Lilly & Company, N. Bello Employee of: Eli Lilly & Company, I. De la Torre Employee of: Eli Lilly and Company, P. Lopez-Romero Employee of: Eli Lilly & Company, D. Schlichting Employee of: Eli Lilly and Company, E. Nantz Employee of: Eli Lilly and Company, R. Fleischmann Consultant for: Abbvie, Amgen, Astra Zeneca, BMS, Celgene, Janssen, Eli Lilly and Company, Novartis, Roche, Sanofi-Aventis, Pfizer, UCB
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THU0089 M-DAS28, DAS28 (CRP) AND RAPID3 SCORES AT BASELINE ARE GOOD PREDICTORS OF RADIOGRAPHIC DISEASE PROGRESSION AT 1 AND 2 YEARS: DATA FROM THE AMPLE TRIAL

E. Keystone[1], H. Ahmad[2], Y. Yazici[3], E. Muratti[4], J. Ye[2], M. Bergman[5]. *[1]University of Toronto, Toronto, Canada; [2]Bristol-Myers Squibb, Princeton; [3]New York University School of Medicine, New York, United States; [4]Bristol-Myers Squibb, Montreal, Canada; [5]Drexel University College of Medicine, Philadelphia, United States*

Background: Clinicians rely on time-efficient, validated disease activity assessments to help predict disease progression accurately in patients (pts) with RA. The utility in predicting structural damage progression for the Routine Assessment of Patient Index Data 3 (RAPID3)[1] is largely unknown, while that of DAS28 (CRP)[2] and modified (M-)DAS28 have been previously reported.[3]
Objectives: This *post hoc* analysis examined the relationship between baseline disease activity measures and their ability to predict structural damage progression in the Phase III AMPLE (NCT00929864) trial.[4]
Methods: AMPLE was a randomized, investigator-blinded study in which MTX-experienced pts with active RA $\leq$5 years received SC abatacept 125 mg weekly or adalimumab 40 mg every 2 weeks in combination with stable-dose MTX. Logistic regression analysis was used to correlate the effect of disease activity at baseline on radiographic (X-ray) progression at Months (M) 12 and 24. Disease activity was assessed using M-DAS28,[3] DAS28 (CRP), RAPID3, CDAI and SDAI. Radiographs were scored using the modified Sharp/van der Heijde scoring system; progression was defined as change from baseline in total score greater than the smallest detectable change, which was calculated as SD/square root (2) x 1.96 (where SD is standard deviation of paired differences of change from baseline in total score between two readers).
Results: Logistic regression analysis was carried out for all randomized and treated pts (abatacept, n=318; adalimumab, n=328). For these patients, M-DAS28, DAS28 (CRP) and RAPID3 at baseline were significant predictors of radiographic progression at M12 and M24, baseline SDAI was a significant predictor at M12 but not M24 and baseline CDAI was not a significant predictor at either time point

Logistic regression model and area under ROC curves for the impact of disease activity at baseline on radiographic progression at M12 and M24 (all randomized and treated patients)

Disease activity measure	M12			M24		
	OR (95% CI)	p value	AUC	OR (95% CI)	p value	AUC
CDAI	1.02 (1.00, 1.04)	NS	0.5762	1.01 (0.99, 1.03)	NS	0.5416
SDAI	1.02 (1.00, 1.04)	<0.05	0.5963	1.02 (1.00, 1.03)	NS	0.5634
DAS28 (CRP)	1.47 (1.15, 1.90)	<0.01	0.6271	1.31 (1.03, 1.67)	<0.05	0.5911
RAPID3	1.26 (1.08, 1.47)	<0.01	0.6270	1.16 (1.01, 1.34)	<0.05	0.5871
M-DAS28	1.51 (1.25, 1.83)	<0.001	0.6624	1.36 (1.13, 1.63)	<0.01	0.6208

AUC = area under the curve; M = month; NS = not statistically significant; OR = odds ratio; ROC = receiver operating characteristic.