Interference (PI). Comparisons to the general population can be made from PROMIS scores.¹⁻²

Objectives: To convert FACIT-F and SF-36 Bodily Pain (BP) scores to PROMIS Fatigue and PI scores to determine how PROMIS performs in 2 phase 3 baricitinib (bari) RA trials.

Methods: In RA-BEAM, pts with inadequate response (IR) to MTX were randomised 3:3:2 to placebo (PBO) once daily (QD), bari-4 mg QD, or adalimumab (ADA) 40 mg biweekly.³ In RA-BEACON, pts with IR to bDMARDs were randomised 1:1:1 to receive PBO or bari 2 mg or 4 mg QD.⁴ FACIT-F assessed fatigue and SF-36 BP, pain. Pt-level PROMIS scores were converted from FACIT-F/SF-36 BP using validated crosswalk tables.¹⁻² Analysis of covariance was conducted on PROMIS score conversions to compare bari to all treatment arms.

Results: Pts had considerable baseline fatigue/pain; mean scores approached or exceeded 1 SD (10 points on the metric) from population norms. Bari was associated with clinically relevant improvements (exceeding 0.5 SD/5 points on the T-score metric) vs PBO for PROMIS fatigue/PI scores (table 1). PROMIS fatigue/PI scores in RA-BEAM reached population norms (<55) by week 12 for bari and ADA (table 1). Bari remained associated with significant improvements in PROMIS fatigue/PI vs PBO through 24 weeks in both studies and vs ADA for PI in RA-BEAM (figure 1).

Data are mean (SD)

^aHigher PROMIS scores mean more fatigue/pain

^bBEACON was a 24 week study

ADA=adalimumab; bari=baricitinib; PBO=placebo

Abstract THU0106 – Figure 1. Change from baseline for PROMIS Fatigue and Pain Interference in RA-BEAM and RA-BEACON

Conclusions: While PROMIS was not used in the studies directly, pt-level cross-walk tables provide an estimate of effect that may be demonstrated when using PROMIS in clinical trials. These results provide preliminary evidence of the ability of PROMIS to demonstrate treatment benefit.

REFERENCES:

- [1] Lai et al. J Pain Symptom Manage 2014;48:639–48.
- [2] Cook et al. Qual Life Res 2015;24:2305–18.
- [3] Taylor, et al. NEJM 2017;376:652–62.
- [4] Genovese, et al. NEJM 2016;374:1243–52.

Disclosure of Interest: C. Bingham III Grant/research support from: BMS, Consultant for: Eli Lilly and Company, Janssen, Pfizer, UCB, BMS, Sanofi/Regeneron, C. Gaich Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, A. DeLozier Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, A. Quebe Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, L. Sun Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, S. Ottawa Shareholder of: Eli Lilly and Company, Employee of: Eli Lilly and Company, J. Pope Grant/research support from: Amgen, Bayer, BMS, GSK, Merck, Novartis, Pfizer, Roche, UCB, Consultant for: AbbVie, Amgen, Bayer, BMS, Celtrion, Lilly, Merck, Novartis, Pfizer, Roche, UCB

DOI: 10.1136/annrheumdis-2018-eular.1890

Abstract THU0106 – Table 1. PROMIS Patient-Reported Outcome scores^a in RA-BEAM and RA-BEACON

	PBO (n=488)	RA-BEAM Bari-4 mg (n=487)	ADA (n=330)	PBO (n=176)	RA-BEACON ^b Bari-2 mg (n=174)	Bari-4 mg (n=177)
PROMIS Fatigue converted from FACIT-F						
Baseline	58.1 (7.8)	58.6 (7.6)	59.0 (8.4)	62.8 (7.5)	62.4 (7.0)	61.9 (8.2)
Week 4	54.5 (7.6)	52.9 (7.5)	53.5 (7.9)	59.3 (8.0)	57.7 (8.5)	56.7 (8.5)
Week 12	53.2 (8.0)	51.4 (8.3)	51.7 (8.6)	58.7 (8.7)	56.0 (9.5)	55.3 (9.3)
Week 24	53.1 (8.5)	50.2 (8.7)	51.1 (9.0)	58.2 (8.7)	56.0 (9.4)	54.4 (10.3)
Week 52	–	50.1 (8.6)	51.0 (9.2)	–	–	–
PROMIS Pain Interference converted from SF-36 Bodily Pain score						
Baseline	61.3 (7.9)	61.9 (7.4)	61.9 (8.3)	65.2 (7.3)	63.7 (7.1)	64.8 (7.8)
Week 4	58.3 (7.8)	55.2 (7.4)	55.9 (7.9)	61.6 (7.1)	59.3 (8.3)	57.8 (7.9)
Week 12	57.5 (8.1)	53.7 (8.6)	54.8 (8.6)	60.2 (8.7)	57.6 (9.1)	57.2 (9.4)
Week 24	57.2 (8.4)	52.7 (8.9)	54.0 (8.8)	60.8 (8.3)	58.1 (8.8)	55.8 (9.8)
Week 52	–	52.0 (9.4)	53.1 (9.8)	–	–	–

THU0107

EVALUATION OF CARDIOVASCULAR RISK IN PATIENTS WITH RHEUMATOID ARTHRITIS AND ANTI-TNF-ALPHA THERAPY

D. Anghel¹, L. Panturu², V.C. Jurcut¹, M.M. Muresan³, E.L. Dilirici¹, M.M. Negru², R.A. Bursuc¹. ¹Dr. Carol Davila Central Military Emergency University Hospital; ²Sfanta Maria Hospital; ³Medlife Clinical Hospital, Bucharest, Romania

Background: Rheumatoid arthritis is a chronic inflammatory autoimmune disease that causes systemic inflammation associated with increased risk of coronary, cerebral and peripheral ischaemic accidents. Biological therapy, by decreasing systemic inflammation, implicitly reduces cardiovascular risk in patients with rheumatoid arthritis. The assessment of carotid atheromatosis in Doppler ultrasound examination can be a useful element in the diagnosis of patients with cardiovascular risk.

Objectives: We followed the cardiovascular risk as well as the development of the carotid artery plaque by carotid Doppler ultrasound, lipid profile and arterial hypertension in patients with rheumatoid arthritis who have undergone biological treatment with anti-TNF-alpha. We also studied the correlation of the intima-medium thickness index in the carotids with the activity of rheumatic disease (DAS28, CRP, VSH) and the evolution of these parameters under biological therapy.

Methods: Our study included 37 patients with rheumatoid arthritis in treatment with DMARD's (group 1) and 50 patients with rheumatoid arthritis in treatment with anti-TNF-alpha (etanercept, adalimumab, infliximab) biological therapy (group 2). The following parameters were assessed in all patients: DAS28, lipid profile (total cholesterol, LDL, HDL, triglycerides), which were followed at 0, 6, and 12 months. The Intima-Medium Thickness Index was measured by Mode B sonography at the level of the common carotid artery, bifurcation of both arteries and the external carotid artery. The value of the index above 0.7 mm was considered pathological.

Results: In lot 1, after the carotid Doppler ultrasound, of the 37 patients, 21 presented the carotid artery plaque, and in lot 2 of the 50 patients, 34 showed these changes. A full evaluation (DAS28, lipid profile, arterial tension, carotid ultrasound) of all patients was performed at the start of the study. At 6 months, inflammatory markers and DAS28 showed a decrease in baseline values in both groups, more significant in the biological therapy group. Reduction of the intima-medium thickness index and blood pressure was observed in both groups, with no significant differences. At 12 months, CRP and DAS28 in the DMARD-treated group corresponded to disease remission values in 33 patients (89%), and in the group treated with biological therapy, the same remission rates of the disease were recorded in 49 patients (97.7%). The intima-medium thickness index in the DMARD-treated group decreased from the 6 month values. In patients with biological therapy, the reduction in the mid-thickness index recorded a progressive decrease from the previous assessment.

Conclusions: There is a direct correlation between the markers of inflammation and the evolution of carotid atheromatosis in patients with rheumatoid arthritis. The intima-medium thickness index is a paraclinical feature useful in assessing cardiovascular risk in patients with rheumatoid arthritis.

Biological therapy, by controlling the underlying disease, also improves cardiovascular prognosis. Treatment with anti-TNF-alpha makes good control, together with lipid-lowering and antihypertensive medication of associated cardiovascular pathology, in patients with rheumatoid arthritis.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.5109

THU0108

PATIENT REPORTED OUTCOME MEASURES FOLLOWING KNEE AND HIP REPLACEMENT FOR INDIVIDUALS WITH RHEUMATOID ARTHRITIS: EVIDENCE FROM ROUTINELY-COLLECTED DATA

E. Burn¹, N.K. Arden¹, C.J. Edwards², C. Cooper¹, D. Murray¹, R. Pinedo-Villanueva¹, D. Prieto-Alhambra¹. ¹NDORMS, University of Oxford, Oxford; ²NIHR Clinical Research Facility, University Hospital Southampton, Southampton, UK

Background: Most estimates of patient-reported outcome measures (PROMs) following total knee replacement (TKR) and total hip replacement (THR) are from individuals with osteoarthritis (OA). It is not well-known whether individuals with rheumatoid arthritis (RA) achieve similar results.

Objectives: To assess the association between RA, relative to OA, with 1) post-operative PROMs and 2) the change between pre- and post-operative PROMs for TKR and THR.

Methods: PROMs for TKR and THR between 2009 and 2015 identified using Hospital Episode Statistics (HES), with diagnosis of RA or OA identified in the Clinical Practice Research Datalink (CPRD). The condition-specific Oxford Knee Score/Oxford Hip Score (OKS/OHS), with pain and function subscales, and Euro-Qol 5-dimension (EQ-5D) overall quality of life were collected prior to and six months following surgery. OKS/OHS ranges from 0 to 48, OKS/OHS function from 0 to 20, OKS/OHS pain from 0 to 28, and EQ-5D from -0.5 to 1, with higher scores being better for each. The effect of RA, relative to OA, on post-operative PROMs was estimated using multivariable linear regressions, which adjusted for age, gender, comorbidities (measured by the Charlson score) and socioeconomic status (measured by IMD Quintile). The effect of RA, relative to OA, on change in PROMs was assessed by adding pre-operative scores as an explanatory factor in the models.

Results: 2212 (2,070 OA and 142 RA) and 2128 (2,030 OA and 98 RA) individuals informed the analyses of TKR and THR, respectively. A diagnosis of RA, relative to OA, was associated with a one-point lower post-operative OKS and a 3-point lower OHS, although only the latter difference was significant. These lower estimates of post-operative OKS/OHS were primarily due to significantly lower scores on the function subscales. The estimated change in OKS/OHS, after accounting for pre-operative scores, was similar for those with RA and OA. RA was also associated with a 0.1 lower post-operative EQ-5D, which was significant for both TKR and THR. The expected change in EQ-5D remained significantly lower for those with RA. The effect of diagnosis from the models is summarised in table 1, with estimated change in OKS/OHS shown in figure 1.

Abstract THU0108 – Table 1. Effect of RA, relative to OA, on 1) total post-operative scores and 2) change in scores. Estimated coefficients with 95% confidence intervals. Significant differences in bold.

	TKR		THR	
	Total	Change	Total	Change
OKS/OHS (0 to 48)	-1.33 (-2.92 to 0.27)	-0.07 (-1.59 to 1.46)	-2.80 (-4.43 to -1.18)	-1.57 (-3.15 to 0.01)
OKS/OHS function (0 to 20)	-1.22 (-1.90 to -0.54)	-0.50 (-1.13 to 0.14)	-1.91 (-2.75 to -1.07)	-0.97 (-1.76 to -0.18)
OKS/OHS pain (0 to 28)	-0.13 (-1.12 to 0.87)	0.34 (-0.63 to 1.30)	-0.89 (-1.80 to 0.02)	-0.66 (-1.56 to 0.25)
EQ-5D (-0.5 to 1)	-0.12 (-0.16 to -0.08)	-0.09 (-0.13 to -0.06)	-0.12 (-0.17 to -0.08)	-0.08 (-0.13 to -0.04)

Abstract THU0108 – Figure 1. Estimated effect of diagnosis on expected change in OKS/OHS by pre-operative score

Conclusions: Individuals with RA undergoing TKR and THR appear to achieve similar improvements in condition-specific scores as those with OA, although the gain in function may be slightly less. The gain in overall quality of life is less for those with RA, however, which is likely due to the systemic nature of the disease.

Disclosure of Interest: E. Burn: None declared, N. Arden Consultant for: Freshfields Bruckhaus Deringer, Bioventus, Flexion, Merck, and Regeneron, C. Edwards: None declared, C. Cooper: None declared, D. Murray Grant/research support from: Zimmer Biomet, Consultant for: Zimmer Biomet, R. Pinedo-Villanueva: None declared, D. Prieto-Alhambra Grant/research support from: Amgen, Servier and UCB Biopharma, and non-financial support from Amgen

DOI: 10.1136/annrheumdis-2018-eular.3753

THU0109

AUTOANTIBODY PROFILING FOR RESPONSE TO BARICITINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS AND NO OR LIMITED EXPOSURE TO METHOTREXATE

L. Martinez Gamboa¹, H. Bang², M. Issa³, S. Zuckerman³, A. Cardoso³, T. Holzkaemper³, F. De Leonardis³, I. de la Torre³, Y. Tanaka⁴, E. Feist¹. ¹Charité-Universitätsmedizin Berlin, Berlin; ²Orgentec Diagnostika GmbH, Mainz, Germany; ³Eli Lilly and Company, Indianapolis, USA; ⁴University of Occupational and Environmental Health, Kitakyushu, Japan

Background: Posttranslational antigen modification plays a role in the pathogenesis of rheumatoid arthritis (RA). The associated autoantibodies are considered unfavourable prognostic factors with respect to disease severity and radiographic outcome. Limited information is available for different serotypes and prediction of treatment response to Janus kinase inhibitors including baricitinib (BARI).

Objectives: To clarify whether fine profiling of baseline autoantibodies against different modified isoforms of vimentin correlate with clinical or radiographic outcome in patients (pts) with active RA and no or limited prior DMARD treatment who initiate treatment with BARI.

Methods: Baseline sera samples from DMARD-naïve pts participating in the randomised, active comparator-controlled Ph3 trial RA-BEGIN¹ [methotrexate (MTX) n=210, BARI 4 mg (mono) n=159 and BARI 4-mg+MTX (combo) n=215] were investigated for autoantibody class (IgG, IgM and IgA) reactivity towards vimentin (V), modified by citrullination (MCV), carbamylation (Carb) or acetylation (Acct), using enzyme-linked immunosorbent assay. Pts were stratified according to negative (<20 U/ml), low-positive (20–60 U/ml) and high-positive (>60 U/ml, 3-fold above the ULN) antibody titre or with respect to the antibody titre tertiles. Change in clinical outcomes (DAS28-CRP, CDAI) and radiographic progression (modified Total Sharp Score) were analysed from baseline to Week 24 using modified last observation carried forward and linear extrapolation, respectively, by baseline autoantibody subclass and titre.