Supplemental material

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Supplemental Material

Impact of clinical domains other than arthritis on composite outcomes in psoriatic arthritis: comparison of treatment effects in the SEAM-PsA trial

Running title
Clinical domains and outcomes in psoriatic arthritis

Authors and Institutions
Philip S. Helliwell, MD, PhD;[1] Phillip J. Mease, MD;[2] Arthur Kavanaugh, MD;[3] Laura C. Coates, MD;[4] Alexis Ogdie, MD;[5] Atul Deodhar, MD;[6] Vibeke Strand, MD;[7] Greg Kricorian, MD;[8] Lyrica Liu, PhD;[9] David Collier, MD;[8] Dafna D. Gladman, MD[10]

[1]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK; [2]Rheumatology Research, Swedish Medical Center/Providence St. Joseph Health and University of Washington, Seattle, WA, USA; [3]Division of Rheumatology Allergy, and Immunology, University of California San Diego, La Jolla, CA, USA; [4]Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences, University of Oxford, Oxford, UK; [5]Department of Medicine, University of Pennsylvania, Philadelphia, PA, USA; [6]Division of Arthritis & Rheumatic Diseases, Oregon Health & Science University, Portland, OR, USA; [7]Division of Immunology/Rheumatology, Stanford University, Palo Alto, CA, USA; [8]Clinical Development, Amgen Inc., Thousand Oaks, CA, USA; [9]Global Biostatistics, Amgen Inc., Thousand Oaks, CA, USA; [10]Centre for Prognosis Studies in The Rheumatic Diseases, University of Toronto, Toronto, ON, Canada

Corresponding author
Philip S. Helliwell, MD, PhD; Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, 2nd Floor, Chapel Allerton Hospital, Harehills Lane, Leeds LS7 4SA, UK. Email: P.Helliwell@leeds.ac.uk; Phone: +44 113 392 3064

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Supplemental Table 1. Analysis of MDA, PASDAS LDA, and PASDAS Good Responses by baseline enthesitis (SPARCC EI and LEI), baseline LDI, baseline mNAPSI, and baseline psoriasis-affected BSA at Week 24

Clinical Domain	Odds Ratio (95% CI)	P-value[a]
MDA using SPARCC EI		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	0.5 (0.4, 0.7)	< 0.0001
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.1)	0.1000
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	< 0.0001
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	0.5 (0.4, 0.7)	< 0.0001
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.6 (0.4, 0.8)	0.0002
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.1)	0.1113
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	0.0001
Baseline LDI		
Baseline LDI (> 0 vs = 0)	1.4 (1.0, 2.0)	0.0457
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.1)	0.1301
Baseline 66-swollen joint count	0.9 (0.9, 1.0)	< 0.0001
Baseline mNAPSI		
Baseline mNAPSI (> 1 vs ≤ 1)	1.8 (1.1, 2.9)	0.0233
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.3, 0.7)	0.0002
Prior use of nonbiologic DMARD (yes vs no)	0.6 (0.4, 1.1)	0.1241
Baseline 66-swollen joint count	0.9 (0.9, 1.0)	< 0.0001
Baseline psoriasis-affected BSA		
Baseline BSA (≥ 10% vs < 10%)	0.9 (0.7, 1.3)	0.6733
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.1)	0.1614
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	< 0.0001
MDA using LEI		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	0.6 (0.4, 0.8)	0.0004
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.1)	0.1648
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	0.0003
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	0.5 (0.4, 0.7)	< 0.0001
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.2)	0.1771
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	0.0007
Baseline LDI		
Baseline LDI (> 0 vs = 0)	1.4 (1.0, 2.0)	0.0270
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.2)	0.1998
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	< 0.0001
Baseline mNAPSI		
Baseline mNAPSI (> 1 vs ≤ 1)	1.7 (1.1, 2.8)	0.0278
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.3, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.3)	0.2507

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Clinical Domain	Odds Ratio (95% CI)	P-value[a]
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	< 0.0001
Baseline psoriasis-affected BSA		
Baseline BSA ($\geq$ 10% vs < 10%)	0.9 (0.6, 1.2)	0.3991
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.8 (0.5, 1.2)	0.2566
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	< 0.0001
PASDAS LDA[a]		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	0.6 (0.4, 0.8)	0.0015
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.5 (0.4, 0.7)	0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.0)	0.0627
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0402
Baseline PASDAS score	0.8 (0.6, 0.9)	0.0008
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	0.6 (0.4, 0.8)	0.0008
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.6 (0.4, 0.8)	0.0002
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.0)	0.0749
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0503
Baseline PASDAS score	0.8 (0.6, 0.9)	0.0010
Baseline LDI		
Baseline LDI (> 0 vs = 0)	1.8 (1.3, 2.6)	0.0014
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.6 (0.4, 0.8)	0.0002
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.0)	0.0758
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0458
Baseline PASDAS score	0.6 (0.5, 0.7)	< 0.0001
Baseline mNAPSI		
Baseline mNAPSI (> 1 vs $\leq$ 1)	1.8 (1.1, 2.9)	0.0168
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.5 (0.4, 0.8)	0.0010
Prior use of nonbiologic DMARD (yes vs no)	0.8 (0.5, 1.4)	0.4655
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0388
Baseline PASDAS score	0.7 (0.6, 0.8)	< 0.0001
Baseline psoriasis-affected BSA		
Baseline BSA ($\geq$ 10% vs < 10%)	1.2 (0.9, 1.6)	0.3157
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.6 (0.4, 0.7)	0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.4, 1.1)	0.0823
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0637
Baseline PASDAS score	0.7 (0.6, 0.8)	< 0.0001
PASDAS Good Responses[b]		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	0.6 (0.4, 0.8)	0.0013
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.1)	0.1312
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0128
Baseline PASDAS score	0.9 (0.8, 1.1)	0.2405
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	0.5 (0.4, 0.7)	0.0001
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.1)	0.1508
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0165
Baseline PASDAS score	0.9 (0.8, 1.1)	0.3398

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Clinical Domain	Odds Ratio (95% CI)	P-value[a]
Baseline LDI		
Baseline LDI (> 0 vs = 0)	1.6 (1.1, 2.3)	0.0101
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.7)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.1)	0.1602
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0153
Baseline PASDAS score	0.8 (0.6, 0.9)	0.0014
Baseline mNAPSI		
Baseline mNAPSI status (> 1 vs ≤ 1)	1.6 (1.0, 2.5)	0.0592
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.8)	0.0006
Prior use of nonbiologic DMARD (yes vs no)	0.9 (0.6, 1.5)	0.7740
Baseline 66-swollen joint count	1.0 (0.9, 1.0)	0.0148
Baseline PASDAS score	0.8 (0.7, 1.0)	0.0303
Baseline psoriasis-affected BSA		
Baseline BSA (≥ 10% vs < 10%)	1.2 (0.9, 1.6)	0.2926
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.5 (0.4, 0.8)	< 0.0001
Prior use of nonbiologic DMARD (yes vs no)	0.7 (0.5, 1.1)	0.1646
Baseline 66-swollen joint count	1.0 (1.0, 1.0)	0.0226
Baseline PASDAS score	0.8 (0.7, 1.0)	0.0123

N = 851; number of subjects in the full analysis set. Based on logistic model adjusted for prior nonbiologic DMARD use, baseline BMI status (≤ 30 kg/m^2 or > 30kg/m^2), and baseline 66-swollen joint count and for each clinical domain status evaluated (baseline enthesitis, LDI, mNAPSI, or psoriasis-affected BSA); additionally adjusted for PASDAS for PASDAS LDA and PASDAS Good Responses. [a]PASDAS LDA status at a specified week defined as "Yes" if absolute PASDAS score ≤ 3.2, otherwise as "No," or as "missing" if PASDAS score is missing. [b]PASDAS Good Responses at a specified week defined as "Yes" if absolute PASDAS score ≤ 3.2 and PASDAS score change from baseline ≤ –1.6, otherwise as "No," or "missing" if PASDAS or PASDAS change from baseline is missing. BMI = body mass index; BSA = body surface area; CI = confidence interval; DMARD = disease-modifying antirheumatic drug; LDI = Leeds Dactylitis Index; LEI = Leeds Enthesitis Index; MDA = Minimal Disease Activity; PASDAS = Psoriatic Arthritis Disease Activity Score; PASDAS LDA = Psoriatic Arthritis Disease Activity Score Low Disease Activity; SPARCC EI = Spondyloarthritis Research Consortium of Canada Enthesitis Index.

Supplemental Table 2. Covariance analysis of PASDAS change and DAPSA score change from baseline to Week 24 by baseline enthesitis (SPARCC EI and LEI), baseline LDI, baseline mNAPSI, and baseline psoriasis-affected BSA at Week 24

Clinical Domain	Estimate (SE)	P-value[a]
PASDAS change from baseline to Week 24		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	0.0 (0.1)	0.7795
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.4 (0.1)	0.0007
Prior use of nonbiologic DMARD (yes vs no)	0.3 (0.2)	0.1441
Baseline 66-swollen joint count	0 (0)	0.0212
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	0.1 (0.1)	0.5314
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.4 (0.1)	0.0008
Prior use of nonbiologic DMARD (yes vs no)	0.3 (0.2)	0.1430
Baseline 66-swollen joint count	0 (0)	0.0177
Baseline LDI		
Baseline LDI (> 0 vs = 0)	–0.9 (0.1)	< 0.0001
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.4 (0.1)	0.0003
Prior use of nonbiologic DMARD (yes vs no)	0.3 (0.2)	0.0940
Baseline 66-swollen joint count	0 (0)	0.7405
Baseline mNAPSI		
Baseline mNAPSI (> 1 vs ≤ 1)	–0.7 (0.2)	0.0005
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.3 (0.2)	0.0286
Prior use of nonbiologic DMARD (yes vs no)	0.1 (0.2)	0.4878
Baseline 66-swollen joint count	0 (0)	0.2290
Baseline psoriasis-affected BSA		
Baseline BSA (≥ 10% vs < 10%)	–0.3 (0.1)	0.0098
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	0.4 (0.1)	0.0005
Prior use of nonbiologic DMARD (yes vs no)	0.3 (0.2)	0.1053
Baseline 66-swollen joint count	0 (0)	0.0168
DAPSA score change from baseline to Week 24		
Baseline enthesitis using SPARCC EI		
Baseline enthesitis (SPARCC EI > 0 vs = 0)	–1.5 (1.5)	0.3351
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	3.1 (1.4)	0.0318
Prior use of nonbiologic DMARD (yes vs no)	1.9 (2.1)	0.3520
Baseline 66-swollen joint count	–0.9 (0.1)	< 0.0001
Baseline enthesitis using LEI		
Baseline enthesitis (LEI > 0 vs = 0)	–0.5 (1.5)	0.7468
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	3.1 (1.4)	0.0344
Prior use of nonbiologic DMARD (yes vs no)	2.0 (2.1)	0.3339
Baseline 66-swollen joint count	–0.9 (0.1)	< 0.0001
Baseline LDI		
Baseline LDI (> 0 vs = 0)	–3.8 (1.6)	0.0155
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	3.1 (1.4)	0.0330
Prior use of non-biologic DMARD (yes vs no)	2.2 (2.1)	0.2904
Baseline 66-swollen joint count	–0.9 (0.1)	< 0.0001
Baseline mNAPSI		
Baseline mNAPSI (> 1 vs ≤ 1)	–3.6 (2.3)	0.1173
Baseline BMI (> 30 kg/m^2 vs ≤ 30 kg/m^2)	1.7 (1.8)	0.3504
Prior use of nonbiologic DMARD (yes vs no)	1.3 (2.6)	0.6216

Clinical Domain	Estimate (SE)	P-value[a]
Baseline 66-swollen joint count	–0.8 (0.1)	< 0.0001
Baseline psoriasis-affected BSA		
Baseline BSA ($\geq$ 10% vs < 10%)	–1.6 (1.5)	0.2745
Baseline BMI (> 30 kg/m^2 vs $\leq$ 30 kg/m^2)	3.1 (1.4)	0.0330
Prior use of nonbiologic DMARD (yes vs no)	2.2 (2.1)	0.2904
Baseline 66-swollen joint count	–0.9 (0.1)	< 0.0001

N = 851; number of subjects in the full analysis set. [a]Based on ANCOVA model adjusted for prior nonbiologic DMARD use, baseline BMI status ($\leq$ 30 kg/m^2 or > 30 kg/m^2), and baseline 66-swollen joint count, and for each clinical domain status evaluated (baseline enthesitis, LDI, mNAPSI, or psoriasis-affected BSA). BMI = body mass index; BSA = body surface area; DAPSA = Disease Activity Index for Psoriatic Arthritis; DMARD = disease-modifying antirheumatic drug; LDI = Leeds Dactylitis Index; LEI = Leeds Enthesitis Index; PASDAS = Psoriatic Arthritis Disease Activity Score; SPARCC EI = Spondyloarthritis Research Consortium of Canada Enthesitis Index.