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Validity and Psychometric Properties of 3 and 4 Visual Analog Scale in Participants With Psoriatic Arthritis Treated With Guselkumab

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ABSTRACT. ***Objective.*** To evaluate the validity of the 3-item visual analog scale (3VAS) and 4-item VAS (4VAS) and determine the minimal clinically important difference (MCID) and minimal detectable change (MDC) for each measure using data from 3 phase III randomized clinical trials of guselkumab in psoriatic arthritis (PsA).
Methods. Pooled data (1405 participants) from the DISCOVER-1, DISCOVER-2, and COSMOS studies were used. 3VAS/4VAS MCID and MDC were estimated using established formulas. Receiver-operating characteristic curve analysis was used to identify 3VAS/4VAS thresholds for low, moderate, and high disease activity. Criterion validity was assessed by correlating 3VAS/4VAS with other PsA measures. Mixed models evaluated the association between changes from baseline in 3VAS/4VAS at week 8 of guselkumab treatment with the total PsA-modified Sharp-van der Heijde (SvdH) score through week 100.
Results. 3VAS/4VAS showed moderate-to-strong correlation with all outcome measures assessed, with coefficients ranging from 0.56/0.62 for Health Assessment Questionnaire–Disability Index to 0.92/0.94 for patient global assessment. MCID was 0.9 for both 3VAS (range 0.7-1.3 depending on method used) and 4VAS (0.6-1.3); MDC was 3.1 and 3.0, respectively. 3VAS cutoffs for low, moderate, and high disease activity were 2.1, 3.3, and 4.8, respectively, and 2.1, 3.4, and 5.0 for 4VAS. Change in 4VAS at week 8 of guselkumab treatment significantly associated with change in SvdH score through week 100 ($P = 0.04$).
Conclusion. These analyses support the validity of 3VAS/4VAS as multidimensional measures of PsA disease activity. 4VAS may be preferred owing to its greater face validity and separate measurements of the 2 cardinal aspects of PsA (joint/skin disease) and pain.

PLAIN LANGUAGE SUMMARY.
Feasibility is a significant barrier to psoriatic arthritis (PsA) disease assessment and implementation of the treat-to-target strategy in clinical practice. The 3-item visual analog scale (3VAS) and the 4-item VAS (4VAS) are the first short multidimensional composite measures that can be completed rapidly within routine clinical care, with evidence supporting their superior performance in small datasets.
Using a large clinical trial dataset, this analysis assessed the criterion validity of the 3VAS and 4VAS and estimated thresholds of meaningful improvement in these measures.
Based on pooled results of 1405 participants with moderate-to-severe PsA treated with guselkumab in 3 phase III studies, 3VAS and 4VAS were highly correlated with other commonly used PsA measures, providing evidence for their criterion validity. The 3VAS and 4VAS thresholds for minimal clinically important difference and minimal detectable change, as well as estimated cutoffs for low, moderate, and severe disease activity were comparable with those reported previously. Early changes in 3VAS and 4VAS with guselkumab treatment were associated with long-term changes in radiographic progression.
These findings demonstrate that the 3VAS and 4VAS are feasible, patient-centered, multidimensional instruments for the assessment of PsA in routine care and the implementation of a treat-to-target strategy. The 4VAS may be the preferred measure owing to its greater face validity and clinical utility in daily practice. In addition to the physician global assessment, the 4VAS includes separate assessments for the two cardinal aspects of PsA, joint and skin disease, as well as pain, the outcome ranked as highest priority by patients with PsA.

Key Indexing Terms: 3VAS, 4VAS, composite outcome measure, minimal clinically important difference, minimal detectable change, psoriatic arthritis

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PsA is a heterogeneous disease with diverse manifestations, including peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis, and psoriatic nail disease.[1] Although continuous composite indexes have been validated for use in PsA, a comprehensive measure that accurately reflects disease burden and supports the treat-to-target (T2T) strategy[2] in clinical practice where feasibility is a priority, is needed.[3,4] Existing continuous measures for use in daily practice capture only a subset of PsA domains and may therefore miss important elements of disease activity.[5] Further, the barrier of feasibility has resulted in the majority of clinicians using either no measures at all in routine practice or the Disease Activity Score in 28 joints (DAS28) that does not adequately capture articular disease in PsA.[5] Other indexes, such as the Disease Activity in Psoriatic Arthritis (DAPSA), with a focus on joint disease,[6] and Routine Assessment of Patient Index Data 3 (RAPID3), developed for rheumatoid arthritis (RA),[7] do not consider measures of skin disease, enthesitis, dactylitis, or axial disease. Although the development of a single measure combining all PsA domains is of interest, it must be balanced against heterogeneity of treatment effects across component domains, as these do not always follow the same trajectory, to ensure sensitivity to change and responsiveness of the measure are maintained.[8]

The 3-item visual analog scale (3VAS) and 4-item VAS (4VAS) measures were developed by abridging the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) Composite Exercise (GRACE) measure, to be the first short multidimensional composite scores that can be completed rapidly, specifically for use in PsA routine clinical care.[9] The VAS instruments were developed with meaningful patient involvement in the study conduct and with an underpinning of understanding outcomes important to patients from treatments.[10,11] Both the 3VAS and 4VAS instruments have demonstrated similar performance when compared with several established composite measures using small datasets.[9,12] GRAPPA members recommended further testing of the 3VAS and 4VAS composite instruments in observational and trial datasets. Subsequently, the instruments were tested in the Dutch Southwest Early Psoriatic Arthritis (DEPAR) observational cohort of early PsA, with evidence supporting their construct validity and discrimination.[12] The authors reported a potential preference for the 4VAS with its separate measurements of joint, skin, and pain for greater utility in clinical practice, and therefore potentially superior face validity.[13] A training instrument has been developed to standardize the physician global assessment (PGA) VAS, a component of both the 3VAS and 4VAS in clinical practice.[14] Further testing of construct validity and discrimination of the 3VAS and 4VAS in clinical trial datasets is required to establish their utility and increase acceptance by physicians and researchers.

To facilitate a valid, reliable, and precise outcome measurement, thresholds defining objective assessment of treatment response enabling implementation of T2T are needed. The minimal clinically important difference (MCID) and minimal detectable change (MDC) aid in identifying changes beyond those expected from measurement error and individual variability. Estimates of the MCID and MDC for 3VAS and 4VAS have been derived from a multicenter observational study but have not yet been confirmed in larger clinical trial datasets.[15]

The efficacy of guselkumab, a fully human interleukin (IL)-23p19-subunit inhibitor, in the management of PsA has been demonstrated in several clinical trials of biologic-naïve participants, those with prior biologic treatment, as well as participants with an inadequate response to tumor necrosis factor inhibitors (TNFi).[1,16,17] Additionally, the DISCOVER-2 study of biologic-naïve participants with active PsA showed guselkumab was associated with less progression of structural damage at 6 months compared with placebo,[17] and low rates of radiographic progression were observed through 2 years of guselkumab treatment, regardless of dosing regimen.[18,19]

The aims of the current study were to assess the criterion validity of the 3VAS and 4VAS composite scores in a large clinical trial dataset of participants with PsA, and to estimate clinically meaningful change thresholds for 3VAS and 4VAS. As prediction of long-term radiographic changes in patients with PsA has important value for clinicians in their decisions regarding disease management, as well as to assess heterogeneity of patient populations with respect to disease activity and prognosis, this study also evaluated the association between early change in 3VAS and 4VAS with radiographic progression in participants with PsA treated with guselkumab in the DISCOVER-2 study.

METHODS

Participants and study design. These analyses included participants from the DISCOVER-1 (ClinicalTrials.gov: NCT03162796), DISCOVER-2 (NCT03158285), and COSMOS (NCT03796858) phase III studies evaluating the efficacy of guselkumab in participants with active PsA. Study design and results of these trials have been described previously.[16,17,20] In DISCOVER-1, eligibility criteria were swollen joint count (SJC; 0-66) and tender joint count (TJC; 0-68 joints) each ≥ 3, C-reactive protein (CRP) levels ≥ 0.3 mg/100 mL, and current or documented history of psoriasis; approximately 30% of participants could have previously received 1-2 TNFi.[16] DISCOVER-2 enrolled biologic-naïve adults with active PsA (SJC ≥ 5, TJC ≥ 5, and high-sensitivity CRP [hsCRP] ≥ 0.6 mg/100 mL) despite conventional PsA therapies.[17] In both studies, participants were randomized (1:1:1) to guselkumab 100 mg every 4 weeks

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(Q4W); guselkumab 100 mg at week 0, week 4, then Q8W; or placebo with crossover to guselkumab Q4W at week 24. Adults eligible for COSMOS had a diagnosis of PsA and had active disease (SJC ≥3; TJC ≥3) and active (≥1 psoriatic plaque of ≥ 2 cm) or documented history of plaque psoriasis or current nail psoriasis, and who also demonstrated a lack of benefit or an intolerance to 1-2 TNFi.[20] At week 0, participants were randomized (2:1) to receive either guselkumab 100 mg (week 0, week 4, then Q8W through week 44) or placebo (weeks 0, 4, 12, 20, followed by guselkumab 100 mg at weeks 24, 28, 36, 44).

Outcome measures and assessments. Overall PsA disease measures used were 3VAS and 4VAS, PGA, patient global assessment (PtGA), and the Psoriatic Arthritis Disease Activity Score (PASDAS). Joint involvement was measured with the DAPSA and RAPID3 instruments. Functional status was assessed with the Health Assessment Questionnaire–Disability Index (HAQ-DI; score range 0-3).[21]

The 3VAS comprises the PGA, PtGA, and the patient skin assessment, all measured on a 0- to 10-cm VAS. 4VAS is composed of the PGA, as well as patient pain, patient joint, and patient skin assessments, all evaluated using a 0- to 10-cm VAS. Each of the 3VAS and 4VAS scores are summed and divided by the denominator (3 for 3VAS and 4 for 4VAS), with scores ranging from 0 to 10, where 0 is indicative of inactive disease and 10 indicating highest disease activity possible.[9] PASDAS comprises SJC, TJC, hsCRP, Leeds Enthesitis Index, tender dactylitis count, PtGA, PGA, and the 36-item Short Form Health Survey physical component summary score with scores ranging from 0 to 10, where higher scores are indicative of worse disease activity.[22] The DAPSA is a validated composite measure primarily focused on joint disease and is calculated by summing TJC (0-68), SJC (0-66), PtGA, patient assessment of pain, and CRP, with scores ranging from 0 to 154.[6,23] RAPID3 is based on patient physical function/disability, patient pain, and PtGA, with each domain scored from 0 to 10, for a total score of 30.[7]

Radiographs of the hands and feet in DISCOVER-2 were obtained at weeks 0, 24, 52, and 100 or at early discontinuation, and scored in 3 separate reading sessions.[19] Data from reading session 3 that included radiographs from all timepoints were employed in the current analyses. Radiographs were evaluated using the total PsA-modified Sharp-van der Heijde (SvdH) score comprising the number and size of joint erosions and the degree of joint space narrowing in the hands, wrists, and feet, with a maximum score of 528, where a higher SvdH score indicates more radiographic damage.[24] Radiographic progression from baseline through week 100 was assessed with the change in the total PsA-modified SvdH score at these timepoints.

Statistical analysis.

Criterion validity. Data from the DISCOVER-1, DISCOVER-2 and COSMOS studies were pooled across treatment groups through week 24. Criterion-related validity was assessed by the Pearson correlation coefficient between 3VAS and 4VAS and each of RAPID3, PGA, PtGA, PASDAS, DAPSA, and HAQ-DI.

Estimates of MCID and MDC thresholds. MCID was estimated with 4 distribution-based methods[25-27] using the following formulas:

- Distribution method 1: baseline SD*√(1-Cronbach α)
- Distribution method 2: 0.5*baseline SD
- Distribution method 3: (last visit score-first visit score)/(baseline SD*√[1-Cronbach α]) averaged for each pair of visits from baseline through week 24
- Distribution method 4: (last visit score-first visit score)/(√[2]*baseline SD*√[1-Cronbach α]) averaged for each pair of visits from baseline through week 24.

Cronbach α was used as the reliability coefficient within participants across all visits.

MDC was estimated with the standard formula averaging the estimates from each pair of visits from baseline to week 24: 1.96*√(2)*standard error of measurement (SEM), where SEM = SD*√(1 – intraclass correlation coefficient).

MCID and MDC were determined by combining treatment (guselkumab Q4W and Q8W) and placebo groups across the pooled DISCOVER and COSMOS studies through week 24.

Derivation of disease activity state cutoffs. Clinically relevant thresholds for low, moderate, and high disease activity states of 3VAS and 4VAS were estimated with receiver-operating characteristic (ROC) curve analysis using established outcome measures as anchors (Supplementary Table S1, available with the online version of this article). Mean thresholds for 3VAS and 4VAS across all anchors were used to define the cutoffs for low, moderate, and high disease activity.

Association between change in 3VAS and 4VAS and long-term radiographic progression. As radiographic assessments were obtained only in DISCOVER-2, the following analyses were conducted only for participants in DISCOVER-2, with guselkumab Q4W and Q8W treatment groups combined. The association between changes in 3VAS, 4VAS, and the other PsA outcomes (DAPSA, PASDAS, RAPID3) at week 8 with the PsA-modified SvdH score at weeks 52 and 100 was assessed with mixed models for repeated measures (MMRM). The association between achieving therapeutic endpoints of low and very low (or remission depending on the outcome measure) disease activity states at week 8 in 3VAS and 4VAS and the other PsA outcomes with PsA-modified SvdH score at weeks 52 and 100 was also assessed with MMRM.

RESULTS

A total of 1405 participants were included in the analysis. In the overall population, the mean (SD) age was 47.1 (11.8) years, majority (76.37%) were White, with approximately equal distribution of male and female individuals (Supplementary Table S2, available with the online version of this article). Mean (SD) PsA duration since diagnosis was 6.4 (6.5) years and prior TNFi use was reported for 28.68% of participants, the majority of whom (354/403) had used 1 TNFi agent. The mean (SD) 3VAS and 4VAS scores at baseline were 6.4 (1.6) and 6.3 (1.6), respectively, consistent with active disease. Across all treatment groups, disease activity, as measured by the exam-

ined PsA outcomes, declined from baseline through week 24 (Supplementary Table S3).

Criterion validity. Correlation analysis demonstrated that 3VAS and 4VAS were very strongly correlated with RAPID3 ($r = 0.87$ and $r = 0.93$), PtGA ($r = 0.92$ and $r = 0.94$), and PASDAS ($r = 0.81$ and $r = 0.82$), and strongly with PGA ($r = 0.77$ and $r = 0.74$; Table 1). A strong correlation was observed between 4VAS and HAQ-DI ($r = 0.62$), as well as DAPSA ($r = 0.61$).

Clinically meaningful improvement thresholds for 3VAS and 4VAS. For 3VAS, the mean estimated MCID was 0.9, ranging from 0.7 to 1.3, depending on the method used (Table 2). Estimated 4VAS MCID was between 0.6 and 1.3 across methodologies, with a mean of 0.9 (Table 2). Similar method-dependent variation in the estimated MCIDs was observed for the other PsA outcomes examined (Supplementary Table S4, available with the online version of this article). When compared to the MCIDs for other PsA outcomes within the same method of calculation, the ratios of MCID to the maximum possible value for the 3VAS and 4VAS estimates were comparable with those for RAPID3, PGA and PtGA when using distribution methods 1 and 2.

The MDC for 3VAS and 4 VAS was 3.1 and 3.0, respectively (Table 2). The ratio of MDC to maximum score for both measures was comparable with those estimated for RAPID3, PGA, and PtGA (Supplementary Table S5, available with the online version of this article).

3VAS and 4VAS disease activity states. ROC analyses identified 3VAS cutoffs for low, moderate, and high disease activity as 2.1, 3.3, and 4.8, respectively (Figure 1A; Supplementary Table S6, available with the online version of this article). For 4VAS, these cutoffs were 2.1, 3.4, and 5.0, respectively (Figure 1B; Supplementary Table S6). Sensitivity of the 3VAS and 4VAS instruments was high, whereas specificity was lower across all PsA outcomes used as criteria (Figure 2). AUC values were all > 0.8, ranging from 0.83 to 0.98 (Figure 2; Supplementary Table S7).

Among participants in the guselkumab and placebo groups, majority (≥ 78% by 3VAS and 4VAS) had high disease activity (HDA) at baseline (Figure 3; Supplementary Table S8, available with the online version of this article). At week 8 of guselkumab treatment, the proportion of participants with HDA according to 3VAS and 4VAS declined to 35-41% in the guselkumab group compared with 59-62% in the placebo group. At week 24, 14-23% of guselkumab-treated vs 47-49% of placebo-treated

Table 1. Correlations between PsA outcome measures.

	3VAS	4VAS	RAPID3	PGA	PtGA	DAPSA	PASDAS	HAQ-DI
3VAS	1.00	0.98	0.87	0.77	0.92	0.59	0.81	0.56
4VAS		1.00	0.93	0.74	0.94	0.61	0.82	0.62
RAPID3			1.00	0.59	0.93	0.58	0.78	0.81
PGA				1.00	0.58	0.62	0.80	0.44
PtGA					1.00	0.53	0.74	0.59
DAPSA						1.00	0.80	0.49
PASDAS							1.00	0.61
HAQ-DI								1.00

Very strong correlation
Strong correlation
Moderate correlation

3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; DAPSA: Disease Activity index for Psoriatic Arthritis; HAQ-DI: Health Assessment Questionnaire–Disability Index; PASDAS: Psoriatic Arthritis Disease Activity Score; PGA: physician global assessment; PsA: psoriatic arthritis; PtGA: patient global assessment; RAPID3: Routine Assessment of Patient Index Data 3.

Table 2. Distribution-based estimates of MCID and MDC values for 3VAS and 4VAS.

	MCID					MDC[a]
	Distribution Method				Mean	
	1	2	3[a]	4[a]		
3VAS (0-10)	0.7 (7.0)	0.8 (8.0)	1.3 (13.0)	0.9 (9.0)	0.9 (9.0)	3.1 (31.3)
4VAS (0-10)	0.6 (6.0)	0.8 (8.0)	1.3 (13.0)	0.9 (9.0)	0.9 (9.0)	3.0 (29.5)

Numbers in parentheses represent the percent of the total for each estimated MCID value. [a] Triangulated from MCID values derived from each visit pair. 3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; MCID: minimal clinically important difference; MDC: minimal detectable change; PsA: psoriatic arthritis.

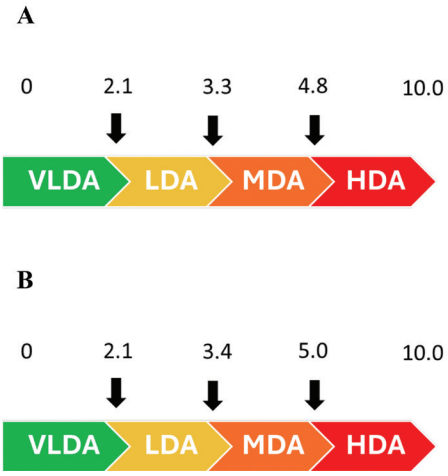

Figure 1. PsA disease activity thresholds for (A) 3VAS and (B) 4VAS. 3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; HDA: high disease activity; LDA: low disease activity; MDA: moderate disease activity; PsA: psoriatic arthritis; VLDA: very low disease activity.

participants had HDA as defined by 3VAS and 4VAS. 3VAS and 4VAS rates of very low disease activity (VLDA; ≤ 2.1) at week 24 reached 30-40% with guselkumab treatment compared with 10-12% with placebo. Low disease activity (LDA) or less at week 24, as per 3VAS (≤ 3.3) and 4VAS (≤ 3.4), was achieved by 48-60% of guselkumab-treated participants vs 25-26% of those treated with placebo.

Association between change in 3VAS and 4VAS and change in the total PsA-modified SvdH scores through week 100 among guselkumab-randomized participants. Using data from the DISCOVER-2 study for guselkumab-randomized participants with available radiographic assessments, change in 4VAS by week 8 was significantly associated with the change in total PsA-modified SvdH score through week 100 (P = 0.04). The association between changes in 3VAS at week 8 with the total PsA-modified SvdH score through week 100 approached but did not reach statistical significance (P = 0.08; Table 3) as did that of DAPSA (P = 0.08; Supplementary Table S9, available with the online version of this article); changes in PASDAS (P = 0.03) and RAPID3 (P = 0.006) were significantly associated with the total PsA-modified SvdH score through week 100 (Supplementary Table S9).

Similarly, week 8 attainment of 3VAS LDA was significantly associated with less radiographic progression through week 100 (least squares mean [LSM] difference between achievers vs nonachievers = −0.87, P = 0.01), with corresponding LSM changes in the total PsA-modified SvdH score of 0.78 vs 1.65 among those not achieving 3VAS LDA. Important statistical trends were seen for associations between radiographic progression through week 100 and attainment of week 8 4VAS LDA (P = 0.07) and 4VAS remission (P = 0.09; Supplementary Table S10, available with the online version of this article).

Table 3. Association of changes in 3VAS and 4VAS from baseline to week 8 with changes in total PsA-modified SvdH scores through week 100 in guselkumab-randomized participants in the DISCOVER-2 study.

	Estimate	SE	95% CI	*P*
3VAS	0.15	0.08	−0.02 to 0.31	0.08
4VAS	0.18	0.09	0.009 to 0.36	0.04

3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; PsA: psoriatic arthritis; SE: standard error; SvdH: Sharp-van der Heijde.

DISCUSSION

The primary aims of the current analyses were to evaluate the validity of the 3VAS and 4VAS composite scores as outcome measures in PsA, and to identify the associated MCID and MDC thresholds in the clinical trial setting. Although the 3VAS and 4VAS have been validated in other observational cohort studies and early PsA, the current analyses were based on pooled results of 1405 participants with moderate-to-severe PsA in the DISCOVER-1, DISCOVER-2, and COSMOS studies. Our findings showed that both the 3VAS and 4VAS had high correlation with other commonly used outcome measures in PsA, specifically PASDAS, DAPSA, RAPID3, and HAQ-DI, as well as PGA and PtGA. Correlation with PGA and PtGA is indicative of internal consistency between components of the 3VAS and 4VAS. The results confirm the concurrent criterion validity of the 3VAS and 4VAS and support the use of these instruments in clinical practice and research. MCID and MDC estimates for the 3VAS and 4VAS were comparable with those defined for other outcome measures assessed, as well as those reported previously in smaller datasets.[15] The MDC estimates for 3VAS and 4VAS, as well as for all other outcomes assessed (PASDAS, DAPSA, RAPID3, PGA, PtGA), were considerably higher than the corresponding MCIDs, most likely reflecting the method of estimation. Specifically, MDC accounts for measurement error across repeated measurements and a specified confidence interval around it to ensure that observed changes are not due to random error, whereas MCID calculation considered the baseline standard deviation and the internal consistency of the instruments.

Our study also identified 3VAS and 4VAS cutoffs for classification of low, moderate and high disease activity using other commonly employed PsA outcomes as external criteria. The estimates determined in the present study are generally similar to those reported previously, although cutoffs for LDA and VLDA were slightly higher in this analysis, possibly due to differences in the outcome measures used as anchors.[15] The change in the distribution of participants across disease activity states over 24 weeks of guselkumab treatment as classified by the 3VAS and 4VAS was comparable to that observed for other measures and was in line with the proven therapeutic effect of treatment. These findings further support the validity of the 3VAS and 4VAS as PsA outcome measures. Whereas AUC and sensitivity estimates for the 3VAS and 4VAS in detecting low, moderate, and high disease activity as measured by the other composite outcomes were high, specificity was lower. This is a usual observation of psychometric properties and may be a function of the distribution and the method of defining the thresholds.

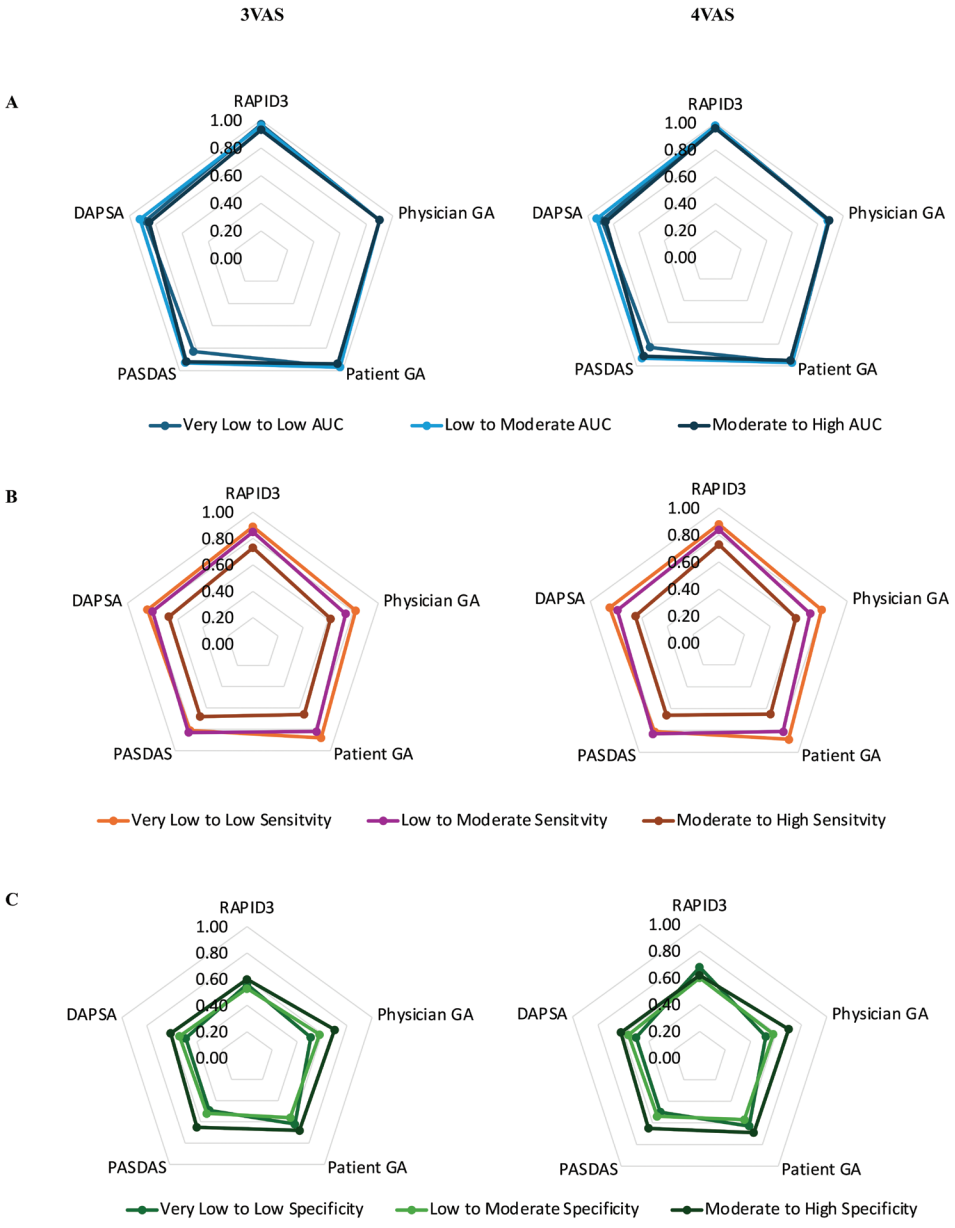

Figure 2. Psychometric properties of 3VAS and 4VAS cutoffs for PsA outcome measures: (A) AUC, (B) sensitivity, and (C) specificity. Values in outer perimeter of the radar plot are indicative of better predictive ability. 3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; AUC: area under the curve; DAPSA: Disease Activity Index for Psoriatic Arthritis; GA: global assessment; PASDAS: Psoriatic Arthritis Disease Activity Score; PsA: psoriatic arthritis; RAPID3: Routine Assessment of Patient Index Data 3.

Using the 2-year data from the DISCOVER-2 study that enrolled biologic-naïve participants, early improvements in both 3VAS and 4VAS with guselkumab were found to be associated with rates of radiographic progression. These associations were similar or marginally better than those observed for other PsA outcome measures and confirm the finding that early and sustained control of PsA disease activity may lessen future joint damage.[18,28] Achievement of LDA or less at 8 weeks as defined by 3VAS was significantly associated with lower rates of radiographic progression through 2 years, whereas statistical significance was approached for 4VAS; achievement of VLDA at 8 weeks defined by both 3VAS and 4VAS was associated with numerically but not statistically lower rates of radiographic progression. These results should be interpreted in light of the fact that the DISCOVER-2 study was not powered to detect associations of early response with radiographic progression; therefore, certain relationships may have been missed (ie, not detected as statistically significant).

Strengths of the study include the large sample size of the analysis population, the employment of a variety of established formulas for the estimation of MCID thresholds, and the use of validated PsA assessment instruments as anchors

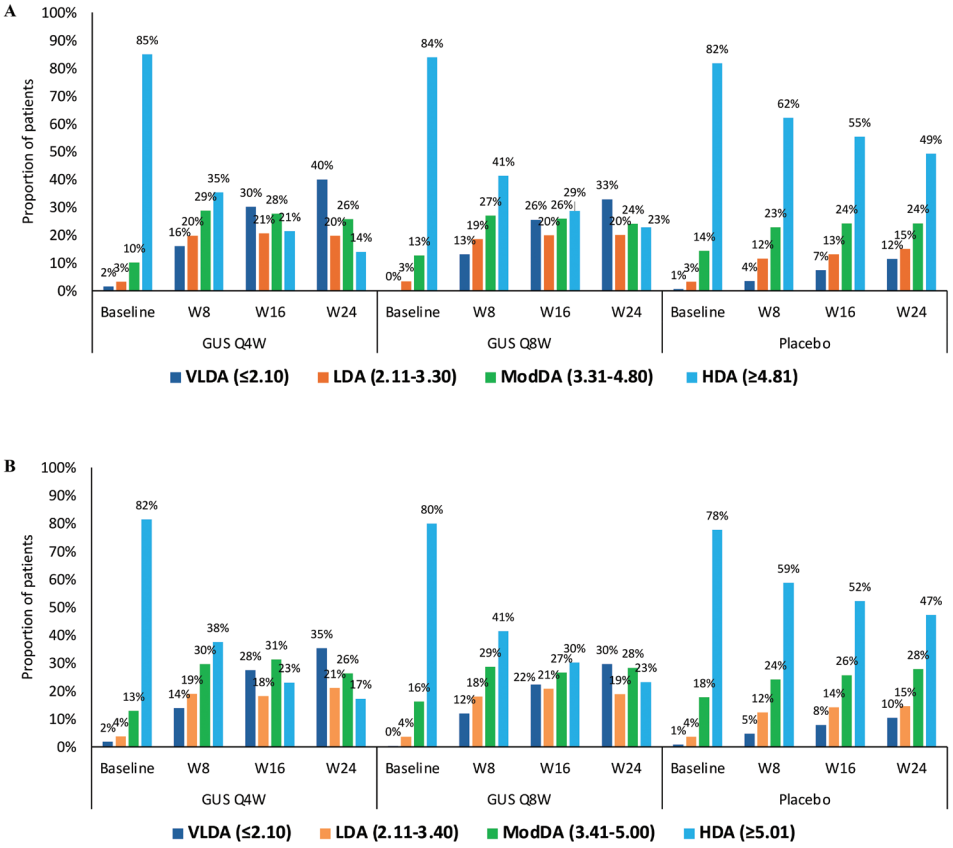

Figure 3. Disease states based on (A) 3VAS and (B) 4VAS through week 24. 3VAS: 3-item visual analog scale; 4VAS: 4-item visual analog scale; GUS: guselkumab; HDA: high disease activity; LDA: low disease activity; ModDA: moderate disease activity; Q4W: every 4 weeks; Q8W: every 8 weeks; VLDA: very low disease activity; W: week.

for determination of disease activity cutoffs. The fact that the analysis was conducted on a clinical trial population with restrictive enrollment criteria and the use of distribution-based methods for determining the MCID estimates (in the absence of prospectively determined patient-centered anchors) may limit the generalizability of the findings to the broader population of patients with PsA. Finally, the results involving the correlation of 3VAS and 4VAS with PtGA and PGA should be interpreted with caution due to inherent correlation.

In conclusion, the 3VAS and 4VAS are the first multidimensional composite measures developed with meaningful patient involvement specifically for feasible use in routine care of PsA, combining physician and patient assessment of disease. Taken together, data support the validity of 3VAS and 4VAS in observational cohort studies, early PsA, and now, in this present study, the clinical trial setting.[5,13] Given their practical administration, both instruments are suitable for monitoring disease activity in routine practice and in the implementation of T2T; although they are not meant to replace objective individual, domain specific measures of disease activity, such as the tender and swollen joint count, their use is preferable to measures such as DAS28 that do not adequately capture PsA disease activity or the nonuse of a comprehensive disease activity measure. Further, it is essential to emphasize that PGA is informed by patient history, physical examination, and tests, and is therefore a synthesis of a full clinical assessment. The question remains as to which instrument, the 3VAS or 4VAS, should be taken forward. Given the similar performance characteristics of both instruments in all studies to date, we suggest the 4VAS may be the preferred measure as, in addition to PGA, it has greater face validity and clinical utility of daily practice with the separate measurement of the 2 cardinal aspects of PsA, namely joint and skin disease, as well as pain, which is ranked top as an outcome of high priority for patients with PsA.[11,29]

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CONTRIBUTIONS

Study conception or design: WT, PSW, MZ, ER; data analysis, statistical analysis: ER; interpretation of data: WT, LCC, MV, MZ, KL, ER, ERS, JFM, MS, PN, PSH; drafting or revising the manuscript, final approval of the manuscript: all authors.

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COMPETING INTERESTS

WT received consultant fees from AbbVie, Amgen, Eli Lilly, J&J, MSD, Novartis, Ono, Pfizer, and UCB; grant/research support from AbbVie, Amgen, Eli Lilly, J&J, Pfizer, and UCB; and speaker fees from AbbVie, Amgen, Eli Lilly, J&J, MSD, Novartis, Pfizer, and UCB. LCC received consultant fees from AbbVie, Amgen, BMS, Celgene, Eli Lilly, Gilead, Galapagos, J&J, Moonlake, Novartis, Pfizer, and UCB; grant/research support from AbbVie, Amgen, Celgene, Eli Lilly, J&J, Novartis, Pfizer, and UCB; and speaker fees from AbbVie, Amgen, Biogen, Celgene, Eli Lilly, Galapagos, Gilead, GSK, J&J, Medac, Novartis, Pfizer, and UCB. The views expressed are those of LCC and not necessarily those of the NHS, the NIHR, or the Department of Health. MV received grant/research support, and consultant or speaker fees from AbbVie, Amgen, Dutch Arthritis Foundation, Eli Lilly, J&J, Novartis, Pfizer, and UCB. MZ and MS are employees of J&J, and own stocks or stock options in J&J. KL is an employee of J&J, and owns stock in J&J and BMS. ER is an employee of JSS Medical Research, and is a paid consultant of J&J. ERS received consultant fees from AbbVie, J&J, Novartis, and Roche; grant/research support from AbbVie, J&J, Novartis, Pfizer, Roche, and UCB; and is on the speakers' bureau from AbbVie, Amgen, BMS, Eli Lilly, J&J, Novartis, Pfizer, Roche, and UCB. JFM received consultant and/or investigator fees from AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, BMS, Dermavant, Eli Lilly, Incyte, J&J, Leo, Moonlake, Novartis, Pfizer, Sanofi-Regeneron, Sun Pharma, and UCB. PN received funding for research and clinical trials/honoraria for advice and lectures on behalf of AbbVie, Amgen, Boehringer Ingelheim, BMS, Celgene, Eli Lilly, Galapagos, GSK, J&J, Novartis, Pfizer, Sun Pharma, and UCB. PSH received consultant fees from Eli Lilly; and educational services fees from AbbVie, Amgen, Novartis, and J&J.

ETHICS AND PATIENT CONSENT

The DISCOVER and COSMOS studies were conducted in accordance with the principles of the Declaration of Helsinki and International Council for Harmonization Guidelines for Good Clinical Practice. Each participating site's governing ethical body approved study protocols, and all patients provided written informed consent.

PRIOR PRESENTATION

Limited data has been published previously in the following: (1) Tillett W, Coates L, Vis M, et al. P176 Minimal important difference, minimal detectable change and disease activity thresholds for two novel composite instruments, three visual analogue scale/VAS and four visual analogue scale/VAS, in patients with psoriatic arthritis: pooled analysis of three phase III studies [poster]. Rheumatology 2023;62(Suppl 2):kead104.217. (2) Tillett W, Coates L, Vis M, et al. Early improvement in 3 visual analogue scale (3VAS)/4VAS predicts reduced rates of radiographic change in bio-naive active psoriatic arthritis patients receiving guselkumab treatment [abstract]. Arthritis Rheumatol 2023;75(Suppl 9). Available from: https://acrabstracts.org/abstract/early-improvement-in-3-visual-analogue-scale-3vas-4vas-predicts-reduced-rates-of-radiographic-change-in-bio-naive-active-psoriatic-arthritis-patients-receiving-guselkumab-treatment/. (3) Tillett W, Coates L, Vis M, et al. POS0228 Minimal important difference (MID), minimal detectable change (MDC), and disease activity thresholds for two novel composite instruments (3VAS, 4VAS) in patients with psoriatic arthritis: pooled analysis of three phase 3 studies [poster]. Ann Rheum Dis 2023;82:343-4. (4) Tillett W, Coates L, Vis M, et al. POS1535 Early improvement in 3VAS/4VAS predicts reduced rates of radiographic change in bio-naive active psoriatic arthritis patients receiving guselkumab treatment [poster]. Ann Rheum Dis 2023;82:1131-2. (5) Tillett W, Coates L, Vis M, et al. Minimal important difference (MID), minimal detectable change (MDC), and disease activity thresholds for two novel composite instruments (3VAS, 4VAS) in patients with psoriatic arthritis: pooled analysis of three phase 3 studies [abstract]. Arthritis Rheumatol 2022;7(Suppl 9). Available from:https://acrabstracts.org/abstract/minimal-important-difference-mid-minimal-detectable-change-mdc-and-disease-activity-thresholds-for-two-novel-composite-instruments-3vas-4vas-in-patients-with-psoriatic-arthritis-pooled-analy/

DATA AVAILABILITY

Data are available upon reasonable request. The data sharing policy of Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA). Project site at yoda.yale.edu.

SUPPLEMENTARY DATA

Supplementary material accompanies the online version of this article.

REFERENCES

1. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. Nat Rev Rheumatol 2022;18:465-79.
2. Coates LC, Moverley AR, McParland L, et al. Effect of tight control of inflammation in early psoriatic arthritis (TICOPA): a UK multicentre, open-label, randomised controlled trial. Lancet 2015;386:2489-98.
3. Coates LC, FitzGerald O, Merola JF, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis/Outcome Measures in Rheumatology Consensus-based recommendations and research agenda for use of composite measures and treatment targets in psoriatic arthritis. Arthritis Rheumatol 2018;70:345-55.
4. Dures E, Taylor J, Shepperd S, et al. Mixed methods study of clinicians' perspectives on barriers to implementation of treat to target in psoriatic arthritis. Ann Rheum Dis 2020;79:1031-36.
5. Tillett W, McHugh N, Orbai AM, et al. Outcomes of the 2019 GRAPPA workshop on continuous composite indices for the assessment of psoriatic arthritis and membership-recommended next steps. J Rheumatol Suppl 2020;96:11-8.
6. Schoels M, Aletaha D, Funovits J, Kavanaugh A, Baker D, Smolen JS. Application of the DAREA/DAPSA score for assessment of disease activity in psoriatic arthritis. Ann Rheum Dis 2010;69:1441-7.
7. Pincus T, Yazici Y, Bergman MJ. RAPID3, an index to assess and monitor patients with rheumatoid arthritis, without formal joint counts: similar results to DAS28 and CDAI in clinical trials and clinical care. Rheum Dis Clin North Am 2009;35:773-8.
8. Wells GA, Tugwell P, Tomasson G, et al. Composite outcomes at OMERACT: multi-outcome domains and composite outcome domains. Semin Arthritis Rheum 2021;51:1370-77.
9. Tillett W, FitzGerald O, Coates LC, et al. Composite measures for routine clinical practice in psoriatic arthritis: testing of shortened versions in a UK multicenter study. J Rheumatol Suppl 2021;97:45-9.
10. Dures E, Hewlett S, Lord J, et al. Important treatment outcomes for patients with psoriatic arthritis: a multisite qualitative study. Patient 2017;10:455-62.
11. Tillett W, Dures E, Hewlett S, et al. A multicenter nominal group study to rank outcomes important to patients, and their representation in existing composite outcome measures for psoriatic arthritis. J Rheumatol 2017;44:1445-52.
12. Kasiem FR, Kok MR, Luime JJ, et al. Construct validity and responsiveness of feasible composite disease activity measures for use in daily clinical practice in patients with psoriatic arthritis. RMD Open 2023;9:e002972.
13. Leung YY, Gladman DD, Orbai AM, Tillett W. Composite outcome measures for psoriatic arthritis: OMERACT and 3 and 4 visual analog scale progress in 2023. J Rheumatol 2024;51 (Suppl 2):80-3.
14. Gunawardana S, Helliwell PS, Kok MR, et al. The development and validation of a novel training infographic for the physician global visual analog scale in psoriatic arthritis. J Rheumatol 2024;51:1084-91.
15. Tillett W, Day J, McHugh N, FitzGerald O, Coates LC, Helliwell P. OP0224 Continuous composite measures for routine care in

psoriatic arthritis: thresholds of meaning and clinically important difference estimates for the 3 and 4 VAS scales from a UK multicentre study [oral presentation]. Ann Rheum Dis 2021;80:135.
16. Deodhar A, Helliwell PS, Boehncke WH, et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naïve or had previously received TNFα inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial. Lancet 2020;395:1115-25.
17. Mease PJ, Rahman P, Gottlieb AB, et al. Guselkumab in biologic-naïve patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. Lancet 2020;395:1126-36.
18. Gottlieb AB, McInnes IB, Rahman P, et al. Low rates of radiographic progression associated with clinical efficacy following up to 2 years of treatment with guselkumab: results from a phase 3, randomised, double-blind, placebo-controlled study of biologic-naive patients with active psoriatic arthritis. RMD Open 2023;9:e002789.
19. McInnes IB, Rahman P, Gottlieb AB, et al. Long-term efficacy and safety of guselkumab, a monoclonal antibody specific to the p19 subunit of interleukin-23, through two years: results from a phase III, randomized, double-blind, placebo-controlled study conducted in biologic-naive patients with active psoriatic arthritis. Arthritis Rheumatol 2022;74:475-85.
20. Coates LC, Gossec L, Theander E, et al. Efficacy and safety of guselkumab in patients with active psoriatic arthritis who are inadequate responders to tumour necrosis factor inhibitors: results through one year of a phase IIIb, randomised, controlled study (COSMOS). Ann Rheum Dis 2022;81:359-69.
21. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: dimensions and practical applications. Health Qual Life Outcomes 2003;1:20.
22. Helliwell PS, Deodhar A, Gottlieb AB, et al. Composite measures of disease activity in psoriatic arthritis: comparative instrument performance based on the efficacy of guselkumab in an interventional phase II trial. Arthritis Care Res 2020;72:1579-88.
23. Ogdie A, Coates LC, Mease P. Measuring outcomes in psoriatic arthritis. Arthritis Care Res 2020;72 (Suppl 10):82-109.
24. van der Heijde D, Sharp J, Wassenberg S, Gladman DD. Psoriatic arthritis imaging: a review of scoring methods. Ann Rheum Dis 2005;64 Suppl 2:ii61-4.
25. Crosby RD, Kolotkin RL, Williams GR. Defining clinically meaningful change in health-related quality of life. J Clin Epidemiol 2003;56:395-407.
26. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008;9:105-21.
27. Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. Control Clin Trials 1989;10:407-15.
28. Mease PJ, Gottlieb AB, Ogdie A, et al. Earlier clinical response predicts low rates of radiographic progression in biologic-naive patients with active psoriatic arthritis receiving guselkumab treatment. Clin Rheumatol 2024;43:241-49.
29. Ogdie A, Myers K, Mansfield C, et al. Experiences and treatment preferences in patients with psoriatic arthritis: a cross-sectional study in the ArthritisPower Registry. Rheumatol Ther 2022;9:735-51.