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Composite Measures for Clinical Trials in Psoriatic Arthritis: Testing Pain and Fatigue Modifications in a UK Multicenter Study

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ABSTRACT. ***Objective***. To test the addition of pain and fatigue to the Composite Psoriatic Arthritis Disease Activity (CPDAI) and the Group for Research and Assessment of Psoriasis and PsA (GRAPPA) Composite Exercise (GRACE) composite measures of psoriatic arthritis (PsA).

Methods. Clinical and patient-reported outcome measures were assessed in patients with PsA at 3 consecutive follow-up visits over 6 months in a UK multicenter observational study. A pain visual analog scale and Functional Assessment of Chronic Illness Therapy Fatigue scale were added as modifications to the CPDAI and GRACE composite measures. Original and modified versions were tested against the PsA Disease Activity Score (PASDAS) and the Disease Activity Index for PsA (DAPSA). Discrimination between disease states and responsiveness were tested with *t*-scores, standardized response means (SRMs), and effect sizes. Data were presented to members at the 2020 annual meeting who then voted on the GRAPPA-recommended composite and treatment targets for clinical trials.

Results. One hundred forty-one patients were recruited with a mean PsA disease duration of 6.1 years (range 0–41 yrs). The SRMs for the GRACE and modified GRACE (mGRACE) were 0.67 and 0.64, respectively, and 0.54 and 0.46, respectively, for the CPDAI and modified CPDAI (mCPDAI). The *t*-scores for the GRACE and mGRACE were unchanged at 7.8 for both, and 6.8 and 7.0 for the CPDAI and mCPDAI, respectively. The PASDAS demonstrated the best responsiveness (SRM 0.84) and discrimination (*t*-scores 8.3). Most members (82%) agreed the composites should not be modified and 77% voted for the PASDAS as the GRAPPA-recommended composite for clinical trials, with 90% minimal disease activity (MDA) as the target.

Conclusion. Modifying the CPDAI and GRACE with the addition of pain and fatigue does not enhance responsiveness nor the measures' ability to detect disease status in terms of requiring treatment escalation. GRAPPA members voted for the PASDAS as the composite measure in clinical trials and MDA as the target.

Key Indexing Terms: GRAPPA, psoriasis, psoriatic arthritis

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Psoriatic arthritis (PsA) is an inflammatory arthritis occurring in up to 30% of patients with psoriasis (PsO).[1] Prospective studies of PsA have demonstrated progression of clinical joint destruction, deteriorating functional status, and a negative effect on quality of life (QOL) and ability to work.[2,3] PsA is a heterogeneous disease that can manifest in several ways including arthritis, spondylitis, enthesitis, dactylitis, iritis, and skin and nail disease. Historically, the primary outcome measures in PsA trials have been focused solely on the articular manifestations of disease, such as the Disease Activity Score in 28 joints or the American College of Rheumatology 20% improvement criteria.[4,5] There has been concern that applying a rheumatoid arthritis paradigm of assessment by focusing solely on articular disease may underestimate the burden of disease and response to treatment in PsA.

Continuous composite measures of disease activity that include more domains of disease have been developed.[6] Candidate continuous composite outcome measures include the PsA Disease Activity Score (PASDAS),[7] Composite PsA Disease Activity Index (CPDAI),[8] the Group for Research and Assessment of PsO and PsA (GRAPPA) Composite Exercise (GRACE),[7] and Disease Activity Index for PsA (DAPSA).[8] In addition to these continuous measures, the minimal disease activity (MDA) is proposed as a treatment target.[9] The MDA is a response criterion, a state representing low disease activity that is either achieved or not. The MDA was used as the target in the Tight Control of Psoriatic Arthritis trial.[10]

Continuous composite measures were the subject of a workshop at the GRAPPA annual meeting in 2019.[11] Members reviewed the existing continuous composite measures and outcomes important to patients,[12,13] discussed each composite in breakout groups, and reported the respective benefits, limitations, and barriers to their wider adoption.[11] Barriers included the poor representation of outcomes that are a high priority to patients, such as pain and fatigue, and members voted to test modifications.[14] We report the testing of modified versions of the CPDAI and GRACE (mCPDAI and mGRACE, respectively) to the original versions (PASDAS and DAPSA), followed by discussion and voting from the composites session at the GRAPPA 2020 annual meeting.

METHODS

ASSESS study design. Patients with PsA according to the ClASsification for Psoriatic ARthritis criteria[15] were sequentially recruited from the Royal National Hospital for Rheumatic Diseases in Bath, and 6 other centers across the UK. Participants received routine care from their rheumatologists based on current best practice. Study visits were scheduled at baseline, 3 months, and 6 months. A comprehensive clinical assessment was conducted at each clinical visit, including patient-reported outcome measures (PROMs), as shown in Supplementary Table 1 (available from the authors on request), and clinical assessments (tender and swollen joint count [TJC/SJC]; Leeds Enthesitis and Dactylitis Indices; body surface area of PsO [%]; PsO Area and Severity Index [PASI]), physician global assessment score (0–5), and C-reactive protein (CRP).

Based on the clinical assessment at each visit, the treating physician determined whether treatment change was required and if a treatment change was actually implemented. The decision to change treatment was used as a proxy for active disease regardless of whether the patient actually changed treatment (medication increase or addition of new medication; specified in Supplementary Table 2, available from the authors on request). If treatments were changed because of an adverse event, cases were excluded from the "changed medication" group. If no treatment change was required, this was regarded as a surrogate for stable disease. Participants were then asked to return 1 week later to repeat the assessments, thereby allowing assessment of test-retest reliability. Patients were therefore classified into 2 groups: those with active disease (requiring a change in treatment) and those with low disease activity/remission (not requiring treatment change).

Ethical approval for this study was given by the North East York Research Ethics Committee Ref: 17/NE/0084. All patients signed written consent in accordance with the Declaration of Helsinki.

Composite measures and modifications. The CPDAI measures disease activity in 5 domains: peripheral joints (68 tender and 66 swollen joints), Health Assessment Questionnaire (HAQ), skin (PASI and Dermatology Life Quality Index), enthesitis (Leeds Enthesitis Index and HAQ), dactylitis (number of tender dactylitic digits and HAQ), and spine (Bath Ankylosing Spondylitis Disease Activity Score and Ankylosing Spondylitis QOL index). Within each domain, activity is graded as 0 (none), 1 (mild), 2 (moderate), and 3 (severe), according to predefined cutoffs resulting in a score ranging from 0 to 15. For modification of the CPDAI, pain was incorporated using a pain visual analog scale (VAS), and fatigue using the Functional Assessment of Chronic Illness Therapy Fatigue scale (FACIT-F). Cutoffs between remission/low disease activity, low/moderate disease activity, and moderate/high disease activity for the pain VAS (10, 30, and 50 mm, respectively) were taken from the GRACE study,[16] and for the FACIT-F (15, 30, and 50 mm, respectively) from the Long-term Outcome in PsA (LOPAS II) study.[17] After the addition of pain and fatigue, the mCPDAI had a score range of 0–21.

The GRACE measure is derived from the TJC, SJC, HAQ, patient global assessment, skin and joint VAS scores, PASI, and PsA QOL. Scores are transformed into linear functions ranging from 0 (totally unacceptable state) to 1 (normal) based on established desirability functions. The 8 transformed variables are then combined using the following equation: the arithmetic mean GRACE = (1 − arithmetic mean of variables) × 8. The pain VAS and FACIT-F were also transformed into desirability functions and included in the arithmetic mean to find the mGRACE with the same 0–10 scale, where 0 is low and 10 is high disease activity.

The PASDAS is a weighted index comprising assessments of joints, function (physical component summary scale of the 36-item Short Form survey [SF-36] and the SF-36 physical functioning scale [SF-36-PF]), acute-phase response (CRP), QOL, and patient and physician by VAS.[14] The score range of the PASDAS is 0–10, with worse disease activity represented by higher scores.

DAPSA, developed from a measure of reactive arthritis, is a measure of articular disease comprising joint count, patient global and pain scores, and CRP.[18]

Sample size and statistical analysis. One hundred twenty-eight patients were required to demonstrate equivalence between the 2 versions of the GRACE instrument, with a 2-sided 95% CI excluding a difference in means of > 0.8 (the minimum clinically important difference [MCID] of the GRACE measure from the GRACE study[16]). Using the same calculation based on the CPDAI gave a sample size of 84. Recruitment of a total of 141 patients allowed for a 10% dropout rate. The ability of each measure to detect those patients requiring treatment change was calculated using the independent samples *t*-statistic. Responsiveness of each measure following a change in medication was calculated using the standardized response mean (SRM; the mean difference before and after treatment change divided by the SD of the difference) and magnitude of response using effect size (ES; the mean difference between scores divided by the pooled baseline SD). Test-retest reliability was assessed using ICC and Bland-Altman method. MCID was estimated using the anchor method.

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Table 1. Demographics of 136 patients with psoriatic arthritis recruited in the ASSESS study.

Outcome	All, n = 136	Mean (SD) Treatment Change, n = 63	No Treatment Change, n = 73
Age, yrs	52.5 (13.6)	50.2 (14.0)	54.3 (13.1)
Sex, M/F, n[a]	59/77	25/38	34/39
Disease duration, yrs	4.0 (6.2)	2.9 (4.8)	4.9 (7.0)
Tender joint count, 0–68	9.6 (11.8)	13.1 (11.6)	6.3 (11.1)
Swollen joint count, 0–66	3.0 (4.1)	4.2 (4.0)	1.9 (3.8)
PASI, 0–72	1.4 (2.0)	1.6 (2.2)	1.2 (1.9)
Enthesitis count, 0–6	0.9 (1.5)	1.3 (1.8)	0.5 (1.0)
Dactylitis count, 0–20	0.3 (0.9)	0.4 (1.1)	0.2 (0.7)
Global VAS, 0–100	48.0 (29.0)	64.8 (20.7)	35.6 (28.6)
HAQ, 0–3	0.8 (0.7)	1.0 (0.7)	0.7 (0.7)

Values are expressed as mean (SD) unless otherwise indicated. [a] Frequency. HAQ: Health Assessment Questionnaire; PASI: Psoriasis Area Severity Index; VAS: visual analog scale.

RESULTS

ASSESS results. Patient demographics are reported in Table 1. One hundred forty-one patients completed 414 of a potential 423 individual study visits, but valid data were only available for 136 patients. Data to calculate all composite measures were available for 28 patients. Twenty-nine patients with stable disease had repeat clinical assessments, allowing for test-retest reliability analysis.

In comparison with the CPDAI/mCPDAI, GRACE/mGRACE, and DAPSA, the PASDAS was the best-performing composite in all tests, including responsiveness (SRM 0.84), magnitude of response (ES 0.62), and ability to detect treatment change (*t*-score 8.3), as shown in Table 2.

The mGRACE showed very similar performance characteristics to the GRACE with an unchanged ability to detect treatment change (*t*-score 7.8), marginally reduced responsiveness (SRM 0.64 vs 0.67), and increased effect size (ES 0.44 vs 0.36).

Table 2. Composite score responsiveness, magnitude of response, and ability to detect treatment change.

Composite, n = 28	SRM	Effect Size	*t*-score	ICC (95% CI)
PASDAS	0.84	0.62	8.3	0.93 (0.78–0.98)
DAPSA	0.56	0.44	7.4	0.81 (0.44–0.94)
CPDAI	0.54	0.46	6.8	0.88 (0.65–0.96)
mCPDAI	0.46	0.36	7.0	0.92 (0.76–0.97)
GRACE	0.67	0.36	7.8	0.87 (0.62–0.96)
mGRACE	0.64	0.44	7.8	0.89 (0.68–0.96)

CPDAI: Composite Psoriatic Arthritis Disease Activity Index; DAPSA: Disease Activity Index for Psoriatic Arthritis; GRACE: GRAPPA Composite Exercise; GRAPPA: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; ICC: intraclass correlation coefficient; mCPDAI: modified CPDAI; mGRACE: modified GRACE; PASDAS: Psoriatic Arthritis Disease Activity Score; SRM: standardized response mean.

The mCPDAI also had very similar characteristic to the CPDAI (Table 2), with a slightly increased ability to detect treatment change (*t*-score 7.0 vs 6.8), marginally reduced responsiveness (SRM 0.46 vs 0.56), and reduced effect size (ES 0.36 vs 0.46).

The ICCs (95% CI) for TJCs and SJCs were 0.94 (0.87–0.97) and 0.91 (0.80–0.96), respectively. The ICC for PASI was 0.95 (0.90–0.98). All composite measures demonstrated high levels of test-retest reliability with ICC > 0.80 (Table 2). The Bland-Altman plots are shown in Figure 1.[19] The MCID for improvement was estimated based on 8 individuals who reported a "mild" improvement in the severity of their PsA, with complete datasets to calculate all composites. MCID estimates were 0.5 for the CPDAI, 1.2 for PASDAS, 0.3 for GRACE, and 7.2 for DAPSA.

GRAPPA discussion session. Dr. William Tillett introduced the session reviewing the need for a continuous composite measure as well as the existing candidate measures, including the CPDAI, PASDAS, DAPSA, and GRACE. The benefits and limitations of continuous composite measures, barriers to wider uptake, and proposed modifications from the GRAPPA 2019 Paris meeting were reviewed.[11] The historic lack of patient involvement in the development of composite measures and the relatively poor representation of outcomes important to patients, such as pain and fatigue, were also reviewed.[14,20] In addition, the role of the PsAID as an instrument to assess impact of disease in PsA and the rationale for separate measurement of disease activity and disease impact were discussed.[21,22] At the GRAPPA 2019 annual meeting in Paris, 76% of members supported the separate assessment of impact using the PsAID, but also supported testing the addition of pain and fatigue to the CPDAI and GRACE measure to determine the effect on the instruments' performance.[11]

Dr. Philip Helliwell reviewed the ASSESS study methods used to incorporate pain and fatigue, as well as the development of cutoff values for the pain VAS and FACIT-F, into the mCPDAI and mGRACE. He also reviewed the methods for assessing discrimination (SRM), decision to change treatment (*t*-score), and magnitude of response (ES). The results of the ASSESS study for the performance characteristics of the PASDAS, DAPSA, and MDA were presented. A recommendation not to include pain and fatigue in the GRACE/CPDAI and to support the PASDAS as the GRAPPA-recommended composite and MDA as the target for clinical trials was presented.

Comments from the discussion included the following:

- Why are we not including pain and fatigue in composites—is it because they are not important? The authors and other members discussed the importance of measuring pain and fatigue as a high priority; however, the data from the ASSESS study indicate that inclusion in the CPDAI and GRACE did not enhance their performance characteristics, and in some instances reduced them, leading to the view that pain and fatigue may be best measured in the PsAID (a measure of impact that can be affected by external nondisease factors) and not included in a composite measure of activity.
- Should PsA be treated to a dual-target biological remission measured by a composite measure of disease activity and remission for patient perspective (perhaps by the PsAID)? The

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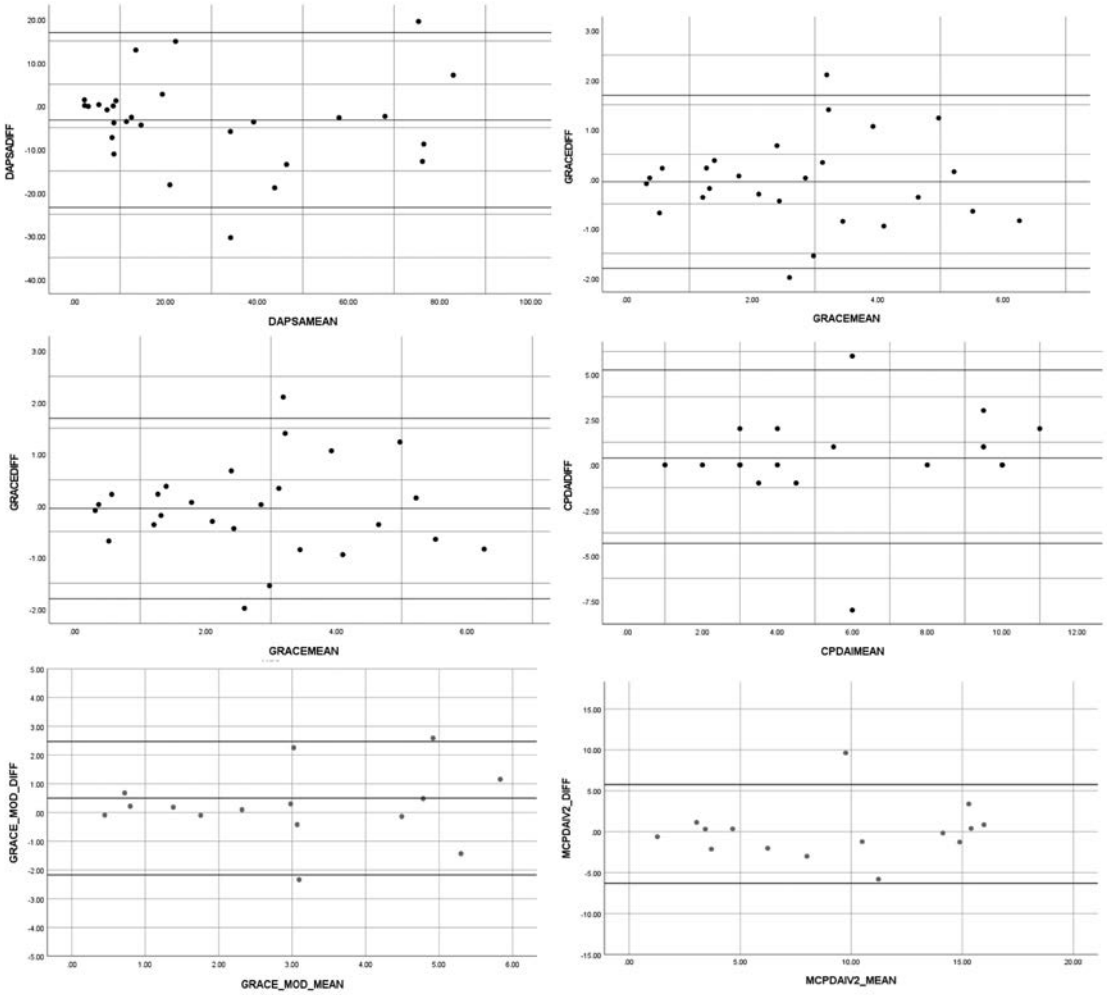

Figure 1. Bland-Altman plots for each composite measure in test-retest by Tillet, *et al*.[19] CPDAI: Composite Psoriatic Arthritis Disease Activity Index; DIFF: mean difference; GRACE: Group for Research and Assessment of Psoriasis and PsA (GRAPPA) Composite Exercise; GRACE_MOD: modified GRACE; mCPDAIv2: modified CPDAI; DAPSA: Disease Activity Index for Psoriatic Arthritis; PASDAS: Psoriatic Arthritis Disease Activity Score.

authors and other members agreed this could be a new approach, particularly allowing focus on fatigue with nonpharmacological interventions.

- Why are we not recommending the DAPSA for clinical trials? This is due to the superior performance of the PASDAS to discriminate between treatment groups, seen in the ASSESS study data as well at the Study of Etanercept and Methotrexate in Combination or as Monotherapy in Subjects with Psoriatic Arthritis trial[23] where the PASDAS but not DAPSA was able to discriminate between treatment arms.[24]
- What about a composite for clinical practice? The authors agreed that different, more feasible composites for clinical practice were required and these are addressed in a second set of analyses, discussions, and voting.
- What about axial disease in PsA? The authors highlighted that an improved definition of axial PsA was needed before outcomes can be tested.

Members went on to vote on modifications and targets for composite measures for clinical trials, and the results are summarized in Table 3. Video links to these sessions are in the Supplementary Material (available with the online version of this article.

DISCUSSION

We report the performance characteristics of mCPDAI and mGRACE, with the addition of pain and fatigue, and comparisons with the PASDAS, DAPSA, and original versions. Modifications did not enhance the ability of the GRACE or CPDAI to detect change and, in some instances, reduced it. The PASDAS was the best-performing continuous composite measure in terms of ability to detect treatment change, magnitude of response, and responsiveness. Members voted that the PASDAS should be the GRAPPA-recommended composite for clinical trials and MDA should be the treatment target.

Discussion during the composite session highlighted the importance of pain, fatigue, and patient-centered priority outcomes. There was recognition of the need to measure biological disease activity and the impact of disease on an individual (influenced by activity and external factors), and members voted that it is desirable to measure activity and impact separately.[22]

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Table 3. Voting results on composite measures for clinical trials.

Question	Yes	No	Undecided
Pain and Fatigue are represented in the impact measure of the PsAID. 76% GRAPPA members agree impact should be measured separately from disease activity. Data from the ASSESS study indicate incorporation of pain and fatigue to the CPDAI or GRACE does not enhance their ability to detect status (in terms of requiring treatment escalation), nor responsiveness.			
Do you agree that pain and fatigue should not be included in modified composite measure?	77%	6%	17%
The PASDAS received the most votes in the expert consensus exercise in 2018 ahead of the GRACE, CPDAI and DAPSA. The PASDAS has been shown to be the highest *t*-score, effect size and responsiveness in the ASSESS study and clinical trial datasets. Modifications to the CPDAI and GRACE do not improve performance.			
Do you agree that the PASDAS should be the GRAPPA recommended composite for use in clinical trials?	82%	9%	9%
The MDA was developed as a target for treatment, representing LDA. The MDA has been shown to discriminate between treatment arms in clinical trials and treatment strategy trials, correlate with LDA and remission states defined by continuous measures, and correlate with reduced radiographic progression in real-world cohorts.			
Do you agree that the MDA should be the GRAPPA-recommended target for use in clinical trials?	90%	6%	4%

CPDAI: Composite Psoriatic Arthritis Disease Activity Index; DAPSA: Disease Activity Index for Psoriatic Arthritis; GRACE: GRAPPA Composite Exercise; GRAPPA: Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; LDA: low disease activity; MDA: minimum disease activity; PASDAS: Psoriatic Arthritis Disease Activity Score; PsAID: Psoriatic Arthritis Impact of Disease.

Important considerations for continuous composite measures of disease activity are the philosophical advantages and disadvantages of combining different disease domains (joint/skin/entheses) in a single measure. In our view, there is a need to assess individual disease domains separately in clinical trials in order to detect differential responses to therapy on the individual domains of joint, skin and nail, entheses, axial disease, and dactylitis. However, a continuous composite provides additional information, giving an estimate of change in the overall disease burden in a single numeric value with contributions from both patient and physician. Such a global estimate of disease cannot be achieved with individual domain assessments or PROMs alone, and a composite measure of disease activity fills this need.

There are a number of strengths to this study design. We chose the modifications to have a foundation in qualitative work that identified, prioritized, and ranked outcomes, then mapped them to the existing composite measures.[12,13] The modifications to be tested were voted on by a global network of clinicians, patient research partners, and industry stakeholders.[11] The primary limitation to this study is missing data. While the proportion of missing data for any individual outcome was trivial, the total number of cases with complete data for all composites was small.

In summary, we reported on the performance characteristics of continuous composite measures of disease activity in PsA, including the PASDAS, DAPSA, CPDAI, GRACE, as well as the mCPDAI and mGRACE, modified with the addition of pain and fatigue. Modifications to the CPDAI and GRACE did not enhance their ability to detect change, and members voted for pain and fatigue to be measured separately in the PsAID. The PASDAS had the best performance characteristics and was voted by members to be the GRAPPA-recommended composite measure for clinical trials, with MDA as the treatment target.

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