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Composite Measures for Routine Clinical Practice in Psoriatic Arthritis: Testing of Shortened Versions in a U.K. Multicentre Study

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ABBREVIATIONS

CPDAI, Composite Psoriatic Arthritis Disease Activity Index; **DAS**, Disease Activity Score; **DAPSA**, Disease Activity in Psoriatic Arthritis; **GRACE**, GRAPPA Composite Exercise; HAQ, Health Assessment Questionnaire; LDI, Leeds Dacylitis Index; **LEI**, Leeds Enthesitis Index; **MDA**, Minimal Disease Activity; **PASDAS**, Psoriatic Arthritis Disease Activity Score; **PASI**, Psoriasis Areas Severity Index; **PROMS**, Patient Reported Outcome MeasureS; **PsA**, Psoriatic Arthritis;**SRM**, Standardized Response Mean; **VAS**, Visual Analogue Scale

ABSTRACT

Objective. To test shortened versions of PsA composite measures for use in routine clinical practice.

Methods. Clinical and patient reported outcome measures were assessed in patients with PsA at three consecutive follow up visits in a UK multicentre observational study. Shortened versions of the CPDAI and GRACE measures were developed using patient reported outcome measures and tested against the DAS 28, cDAPSA and RAPID3. Discrimination between disease states and responsiveness were tested with the t score, standardised response mean (SRM) and effect size (ES). Data were presented to members at the GRAPPA 2020 annual meeting and members voted on the recommended composite routine practice.

Results. The SRM for the GRACE, 3VAS and 4VAS was 0.67, 0.77 and 0.63, respectively and for CPDAI/ sCPDAI 0.54/ 0.55, respectively. Shortened versions of the GRACE increased the t-score from 7.8 to 8.7 (3VAS) and 9 (4VAS) but reduced the t-score in the CPDAI/ sCPDAI from 6.8 to 6.1. The 3VAS and 4 VAS had superior performance characteristics to the sCPDAI, DAS 28, DAPSA and RAPID3 in all tests. 60% members agreed that VAS scales contained enough information to assess disease and response to treatment. 53% recommended the 4VAS for use in routine care, 26% the 3VAS leaving 21% undecided.

Conclusion. Shortening the GRACE to VAS scores alone enhances the ability to detect status and responsiveness and has the best performance characteristics of the tested composite measures. GRAPPA members recommend further testing of the 3 and 4 VAS in observational and trial datasets.

INTRODUCTION

Observational studies have demonstrated that Psoriatic Arthritis (PsA) causes progressive clinical joint destruction, deteriorating functional status and has a negative impact on the quality of life and ability to work (1,2). Recent years have seen an increasing number of highly effective therapeutic drug options and a better understanding of how we should use them, including the clinical benefits of applying a treat-to-target strategy (3). Recently updated PsA treatment guidelines from the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) recommend a treat-to-target strategy in clinical practice (4,5). There is however no agreement on how to measure remission/low disease activity in routine practice and feasibility remains a major barrier to wider uptake. Instruments to measure disease need to be easy to perform and calculate in routine clinical practice and this is a particular challenge in PsA where disease manifestations are varied and assessment of multiple disease manifestations is required to adequately quantify disease. The benefits, limitations and barriers to wider uptake of composite measures of disease were the subject of a workshop at the 2019 Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) annual meeting (6). The majority (89%) of GRAPPA members agreed there was a need for a PsA-specific composite measure for routine practice however 62% were either using no measure at all in their practice or were using the DAS28, which was developed for use in rheumatoid arthritis. The members discussed each composite in breakout groups and reported the respective benefits, limitations and barriers to their wider adoption (6). The most significant barrier to wider adoption was feasibility. In particular the Psoriatic Arthritis Disease Activity Score (PASDAS) and Composite Psoriatic Arthritis Disease Activity Index (CPDAI) were not felt to be feasible in their current form and C-Reactive Protein (CRP) was identified as a barrier to use of the Disease Activity Score for Psoriatic Arthritis (DAPSA). The members voted to test shortened versions of the CPDAI and GRACE for use in routine care (7). We report the testing of shortened versions, comparison with the original versions and other more feasible composite measures such as the Disease Activity Score 28 (DAS28) (8) and routine assessment of patient index data RAPID3 (9,10) followed by discussion and voting from the composites session at the GRAPPA 2020 annual meeting.

MATERIALS AND METHODS

ASSESS Study design

Details of the ASSESS study design have been previously reported in another article in this supplement (11). In brief, patients with PsA diagnosed using the CASPAR criteria (12) were recruited across six hospitals in the United Kingdom (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) and clinical assessments [tender and swollen joint count (66/68), Leeds enthesitis and dactylitis count, Body Surface Area (BSA) of psoriasis (%), Psoriasis Areas and Severity Index (PASI), physician global score (0-5) and C-reactive protein] sufficient to calculate the composite measures. Patients were classified into 2 groups: those with active disease (requiring a change in treatment) and patients who have low disease activity /remission (who do not require treatment change).

Composite measures and modifications

The CPDAI measures disease activity in five domains using eight measures: peripheral joints (68 tender and 66 swollen joints, and Health Assessment Questionnaire (HAQ), skin [Psoriasis Areas and Severity Index- (PASI) and Dermatology Life Quality Index (DLQI)], enthesitis (Leeds Enthesitis Count and HAQ), dactylitis (number of tender dactylitic digits and HAQ), and spine (Bath Ankylosing Spondylitis Disease Activity Score (BASDAI) and Ankylosing Spondylitis QOL index (ASQoL). Within each domain, activity is graded as 0 (none), 1 (mild), 2 (moderate), and 3 (severe), according to predefined cut offs resulting in a score 0-15. The shortened CPDAI using five measures is reported in Table 1. In brief, the joint domain is assessed with the clinical DAPSA cut-offs, skin using a patient skin Visual Analogue Scale (VAS), enthesitis using the Leeds Enthesitis Index (LEI), dactylitis using the tender dactylitis count and Axial disease using a 0-10 numeric rating scale from question two of the Bath Ankylosing Spondylitis Activity Index (BASDAI), “How would you describe the overall level of AS neck, back or hip pain you have?”

The GRACE measure is derived from the tender and swollen joint count, HAQ, patient global, skin and joint VAS scores, PASI and Psoriatic Arthritis Quality of Life (PsAQoL). Scores are transformed into linear functions ranging from 0 (totally unacceptable state) to 1 (normal) based on established desirability functions. The eight transformed variables are then

combined using the arithmetic mean GRACE= (1-arithmetic mean of variables) x 10. Two shortened versions of the GRACE were derived. The physician assessments (joint count and PASI) were reduced to a physician VAS (informed by a full clinical assessment including history and examination) and patient VAS scores for skin, joints and pain;

- 3VAS; Physician global VAS, Patient global and skin VAS
- 4VAS: Physician global VAS, Patient pain, joint and skin VAS

Each score is added and divided by the relevant denominator to give a score range 0 – 10, where 0 is low and 10 is high disease activity.

The RAPID3 (range 0-30) is comprised of three 0-10 scores; the Health Assessment Questionnaire disability index (recalculated from 0-3), pain VAS and global VAS (9). The RAPID3 has been tested in PsA and was correlated significantly with PASDAS in TICOPA ($r=0.79$, $P < 0.01$) and with DAPSA in LOPAS II ($\rho= 0.59$, $P < 0.01$) and was able to discriminate between the treatment arms in the TICOPA study (10). The cDAPSA is calculated with the addition of the number of painful joints (68), swollen joints (66), patient global VAS, and patient pain VAS (13,14). The DAS28 is a weighted score comprising of the 28 tender and swollen joint count, patient global VAS and either CRP or erythrocyte sedimentation rate (8).

The statistical analysis plan for the ASSESS study has been previously reported (11). In brief, 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 standardised response mean (SRM, the mean difference before and after treatment change divided by the standard deviation of the difference) and magnitude of response using effect size (ES, the mean difference between scores divided by the pooled baseline standard deviation). Test re-test reliability was assessed using the Intra-Class Correlation method (ICC) and Bland Altman method (11).

RESULTS

ASSESS study results

One hundred and thirty-nine patients completed a total of 414 study visits. The mean age of participants was 52.7 $\pm$ 13.5 years and mean disease duration of 6.1 $\pm$ 6.2 years. The baseline

characteristics have been previously reported but, in brief the mean tender and swollen joint count was 9.6 ± 11.8 and 3.0 ± 4.1, mean Leeds enthesitis count was 0.9 ± 1.5, mean Leeds dactylitis count was 0.3 ± 0.9, mean Psoriasis Areas Severity Index (PASI) was 1.4 ± 2.0 and mean HAQ was 0.8 ± 0.7 (11).

A full comparison of all the composites and shortened versions are reported in Table 2. The shortening of the CPDAI had a minimal effect on responsiveness, SRM for CPDAI was 0.54 and for sCPDAI was 0.55, but shortening reduced the ability to detect treatment change (t-score fell from 6.8 to 6.1) and the ability to assess magnitude of response, reducing the Effect Size (ES) from 0.46 to 0.42, respectively. Shortening the GRACE to the 3VAS improved all the performance characteristics, including SRM (0.67 to 0.77, respectively), t-score (7.8 to 8.7, respectively) and ES (0.51 to 0.66, respectively). Shortening of the GRACE to the 4VAS reduced the SRM (0.67 to 0.63) and improved the t-score (7.8 to 9) and ES (0.51 to 0.55).

GRAPPA discussion session

William Tillett introduced the session reviewing the need for a continuous composite measure for use in routine clinical care and the existing candidate measures including the sCPDAI, 3VAS, 4VAS, DAPSA, RAPID3 and DAS28. He reviewed the discussions from the 2019 GRAPPA meeting where members voted on the need for a composite measure for routine practice, the feasibility barriers and voting to test modifications.

Philip Helliwell reviewed the ASSESS study the methods used to shorten the CPDAI and GRACE. He described the methods for assessing discrimination (SRM), decision to change treatment (t-score) and magnitude of response (Effect Size). He presented the results of the ASSESS study and trial data on the performance characteristics CPDAI, sCPDAI, GRACE, 3VAS and 4VAS, cDAPSA, DAS28 and RAPID3.

Comments from the discussion included:

- What is it about the construct of the VAS scores that drives the performance characteristics? It is felt likely that the physician VAS contributes significantly to the performance characteristics. Removal of the physician VAS is not reported but reduced the performance of all parameters.
- What was the correlation with the PSADAS/ GRACE and CPDAI? Although correlations have not been reported the correlations were all above 0.9 except for the

sCPDAI, This is possible because the CPDAI is the only measure that attempts to include assessment of axial symptoms.

- How do we persuade clinicians to do a full clinical assessment with only a Physician VAS, might clinicians not even perform a joint count, let alone other domain measures? There was recognition that this was a potential risk, though possibly no greater than other measures or response criteria (such as the DAS28 or states of LDA/ remission). There was discussion about the need to educate clinicians on how to assess all domains of disease formally in order to inform an accurate physician VAS.
- Patients commented that the VAS scores were patient-centered with a balance between patient and physician contributions and there was agreement with this approach.
- Could Numeric Rating Scales (NRS) be tested instead of VAS scores in other datasets? The advantages of NRS were recognised and there was agreement that this would be a good analysis to test as well as testing of the 3/4VAS in clinical trial and observational datasets.
- Could we look at the correlation between patient joint VAS and joint count? There was agreement this would be a valuable analysis.
- Should treatment acceptability be included in an assessment tool? This was felt to be important and a complimentary component of treatment assessment.

Members went on to vote on the modification of composites for clinical trials, the results are summarised in Table 3.

DISCUSSION

We report the performance characteristics of shortened versions of PsA-specific composite measures and comparison with feasible composites developed for the assessment of rheumatoid arthritis (DAS 28 and RAPID3). Modifications to shorten the CPDAI (sCPDAI) did not significantly alter its performance characteristics whilst shortening the GRACE to a 3 or 4 VAS either improved or made little change to its performance characteristics. The overall performance of the 3 and 4 VAS was superior to the DAS28, RAPID3, DAPSA, CPDAI/ sCPDAI and in some instances the best performing full composite, the PASDAS.

There are a number of strengths to the concept of a VAS scale for routine care. Condensing the physician assessment to a VAS frees the clinician to perform the joint count,

skin, enthesis, dactylitis, and axial assessment without the time consuming need to populate a formula or calculation on paper or computer. Furthermore, a physician VAS allows a clinician to include other less tangible aspects of disease that may not be represented in a joint count or skin assessment such as frequency, duration, intensity of flares, the impact of recent treatment (such as 'rescue' glucocorticoids) as well as the patient perspective from the patient reported outcome measures. It is likely that this increased depth of assessment that a physician VAS permits and its relative contribution to the total score in the VAS scales is responsible for its superior ability to detect treatment change and a magnitude of response comparable to that of the PSADAS.

The decision whether to choose a 3VAS or a 4VAS is challenging. The 4VAS has superior ability to detect treatment change (t score) and magnitude of response, but the 3VAS demonstrates better responsiveness using the SRM. From a routine practice perspective, there are advantages in using the 4VAS where patients have an opportunity to represent the two cardinal manifestations of PsA, being skin and joint disease, as well as pain, the top-priority outcome from the patent's perspective. Representation of core outcomes of skin, joints and pain can inform the emphasis of a consultation in a time limited consultation, yet still contribute to the composite score to act as a treatment target.

In general, there was support for the VAS measures but over 70% agreement was not reached in the voting. This was primarily due to the need for more data about cut-offs and comparison of use in clinical/RCT datasets. Some GRAPPA members also discussed the possibility that physicians may try to 'cut corners' should a VAS score alone be required instead of a formal assessment of all of the domains of involvement in PsA. It is our view that a physician VAS can only be correctly given following a full disease assessment. We need to make disease assessment as simple and as accessible as possible so as to facilitate the adequate assessment of disease in clinical practice. If a clinician is going to 'cut corners' with disease assessment when performing a VAS score, they are equally as likely to do this with a more complex score. Although the DAS28 has been included in the analysis reported in this study, it does not have face validity as a composite measure in PsA as it only reflects joint involvement and does not require an assessment of any joints below the knees. We would tentatively propose a tiered system of assessment for clinicians, whereby the 4 VAS would be the minimum requirement (informed by a full clinical assessment including history and examination) together with an impact of disease assessment (using the PSAID).

There are number of strengths to this study design. This is an observational study taken from routine care where composites for routine care would normally be used. We chose shortened measures based on a foundation of qualitative work identifying, prioritising and ranking outcomes. Shortened measures were then mapped to existing composite measures incorporating discussion and feedback from a global network of clinicians, patient research partners and industry stakeholders (6, 15,16).

CONCLUSION

In summary, we report the performance characteristics of shortened continuous composite measures for PsA for use in routine clinical practice. Whilst shortened versions of the CPDAI made little change or reduced its performance characteristics, the shortening of the GRACE measure to 3VAS or 4VAS scores resulted in superior performance characteristics in terms of ability to detect treatment change, magnitude of change and responsiveness. The majority of GRAPPA members (60%) voted in favour of the VAS scores, but feedback in the discussion supported the need for further data to support the case for a VAS score composite. This would also inform the decision as to whether to recommend 3VAS or 4VAS for use in routine clinical practice. Next steps will include the testing of both the 3VAS and 4 VAS scores in clinical trial and observational datasets.

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Supplementary file 1

Videos of the Composite sessions from the GRAPPA 2020 virtual annual meeting

Introduction: Why Shorten Composite Outcome Measures? W. Tillett, https://youtu.be/-OSl1tOw9GI

Shortening Existing Composite Measures using the ASSESS Data: P. Helliwell, https://youtu.be/MEv1eD5r0h4

Composite Session 2, Panel Discussion: O. FitzGerald, P. Helliwell, W. Tillett, https://youtu.be/iXj6HmLhHYw

Table 1. The shortened CPDAI- Score 0-15

Domain	Scored			
	0	1	2	3
Joints – cDAPSA	≤ 3	4 - 13	14 - 27	≥28
Skin – skin VAS	< 10	10 - 29	30 - 49	≥50
Enthesitis – LEI	0	1	2 - 4	5-6
Dactylitis – count	0	1	2 - 4	≥5
Axial – NRS Q2 BASDAI	0	1-2	3-4	≥5

Abbreviations: cDAPSA, composite Disease Activity in Psoriatic Arthritis; VAS, Visual Analogue Scale; LEI, Leeds Enthesitis Index; NRS Q2 BASDAI, Numeric Rating Scale, question 2 of the Bath Ankylosing Spondylitis Disease Activity Index.

Table 2: Composite score responsiveness, magnitude of response and ability to detect treatment change in 28 patients with psoriatic arthritis.

Composite	SRM	Effect Size	T-Score
PASDAS	0.84	0.62	8.3
CPDAI	0.54	0.46	6.8
sCPDAI	0.55	0.42	6.1
GRACE	0.67	0.51	7.8
3VAS	0.77	0.66	8.7
4 VAS	0.63	0.55	9
cDAPSA	0.59	0.44	5.9
RAPID3	0.5	0.32	7.0
DAS28	0.42	0.47	6.5

Abbreviations;, cDAPSA, composite Disease Activity in Psoriatic Arthritis; CPDAI, Composite Psoriatic Arthritis Disease Activity Index; DAS28, Disease Activity Score 28; GRACE, GRAPPA Composite Exercise; PASDAS, Psoriatic Arthritis Disease Activity Score; RAPID3, Routine Assessment of Patient Index Data;. sCPDAI, shortened CPDAI; SRM, Standardised Response Mean; VAS, Visual Analogue Scale.

Table 3. Voting results on composite measures for clinical trials in 55 GRAPPA members

Question	Yes	No	Undecided
Do you agree that VAS scores alone can give sufficient information to assess disease activity, and response to treatment?	60%	14%	26%
	4VAS	3VAS	Undecided
Based on the voting at the expert consensus statement and the ASSESS data, would you be happy to recommend one of the following VAS scores for use in routine care: 3VAS or 4VAS? (select any that apply)	53%	26%	21%