

Development of a Disease Severity and Responder Index for Psoriatic Arthritis (PsA) — Report of the OMERACT 10 PsA Special Interest Group

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ABSTRACT. Work within the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) to develop and validate composite disease activity measures in PsA has progressed. At the Outcome Measures in Rheumatology Clinical Trials (OMERACT) 8 meeting, a core set of domains to be assessed in randomized controlled trials (RCT) and longitudinal observational studies (LOS) of PsA was agreed upon. At OMERACT 10, work to date regarding proposed composite responder indices was presented. Five proposed composite responder definitions for PsA were reviewed and discussed including new data from the GRACE (GRAPPA Composite Exercise) study. There was agreement that the work to date was promising, and that developing composite outcome measures for use in RCT and LOS was important. Further work was required, including data on followup timepoints and less common phenotypes of PsA, to ensure that all subgroups were represented within GRACE. During discussion on the concept of composite measures for PsA, based on predominant/little/no involvement in several domains (such as skin versus joints, enthesitis, dactylitis, spondyloarthritis) it was acknowledged that a simple summative score encompassing all domains of PsA would be difficult to construct psychometrically and may not be appropriate. Ideally, any composite measure should retain the ability to differentiate between activity in individual domains, such as enthesitis or skin psoriasis, so that the influence of each can be assessed independently. Further work is required within the GRACE dataset to develop an optimal composite measure for PsA. Several proposals to date have shown preliminary validity according to the OMERACT filter. (J Rheumatol 2011;38:1496–501; doi:10.3899/jrheum.110278)

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Psoriatic arthritis (PsA) is a multifaceted disease with involvement in many areas, including peripheral joints, skin and nail disease, enthesal involvement, dactylitis, and axial disease. Outcomes research in PsA has always lagged behind that in rheumatoid arthritis (RA), with the lack of validated clinical outcome measures for all of the disease domains a particular difficulty. There are many different outcome measures available for each of these separate aspects of the disease, but most are borrowed from related diseases, and only some of these have been validated in PsA. Until recently, there were no composite outcome measures for PsA that take all of these disease aspects into account.

It is clear that composite measures used in RA to assess disease severity and employed in responder indices, such as the Disease Activity Score (DAS) and European League Against Rheumatism (EULAR) Response Criteria, or the American College of Rheumatology (ACR) Response Criteria, assess only joint activity and therefore do not fully represent all aspects of psoriatic disease. There is an absence of evaluation of the multiple clinical domains of PsA such as enthesitis, dactylitis, spine, and skin in these composite measures.

Recognition of this dearth of validated clinical outcome measures in PsA led to formation of a joint Outcome Measures in Rheumatology Clinical Trials (OMERACT)/Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) working group to develop the research agenda of outcome measurement in PsA. There are currently more than 300 members of GRAPPA, including rheumatologists, dermatologists, and industry and patient service league representatives, with international representation.

The first step was a workshop on outcome measures in PsA held at OMERACT 7 (Asilomar, USA, 2004). During this workshop, discussion on potential domains for inclusion in PsA clinical trials led to a research agenda to identify optimal measures for each aspect of psoriatic disease and to develop effective tools where none existed¹. Significant further progress was made at the OMERACT 8 conference (Malta, 2006) where a consensus was reached on the core domain set for PsA clinical trials², based on a series of projects conducted following OMERACT 7, including a clinician Delphi exercise and data-mining from clinical trials. Instruments to assess these domains in randomized controlled trials (RCT) have largely been derived from and validated in studies of RA and psoriasis. Although they have generally shown good reliability and discrimination capacity in PsA trials with highly effective drugs³, they have not been further validated in PsA. At OMERACT 8, no data were available on composite measures that attempted to assess multiple domains of PsA.

GRAPPA has been actively involved since OMERACT 8 in developing tools to reliably diagnose and assess PsA, including clinical, laboratory, imaging, and tissue analysis measures of disease activity. This work is pursued in individual clinical research centers, as well as collaboratively among members of the group.

At the GRAPPA Annual Meeting in 2008 (Leeds, UK) important ground work was achieved in the development of composite clinical outcome measures for PsA. Work on different proposed indices already developed was presented and this included many of the measures discussed below. Different potential approaches were also discussed using the examples of the RA and Ankylosing Spondylitis Disease Activity Score (ASDAS) and the methodology used to develop the British Isles Lupus Assessment Group (BILAG) score in systemic lupus erythematosus (SLE). Breakout groups discussed these different options, and a large collaborative exercise was proposed to start the process of development and validation of a GRAPPA/OMERACT composite disease activity measure⁴.

Proceedings During the Special Interest Group

At OMERACT 10 an historical overview of measures used in PsA RCT, proposed composite clinical outcome measures, was presented with a summary arguing for the development of a comprehensive composite outcome measure in PsA. This introduction was expected to provide a forum for discussion of these proposals and an opportunity for feedback and

debate, and to define issues that remain in the research agenda regarding domains and outcome measures in PsA.

Background and Aims of the Special Interest Group

Philip Mease provided an historical overview of the measures used in PsA clinical trials, composite outcome measures used to date, and summarized the argument for development of a more comprehensive composite outcome measure in PsA. He reviewed some of the recent work that had preceded the special interest group (SIG) and introduced the aims of the SIG at OMERACT 10, namely:

1. To present work to date on proposed responder indices for PsA assessment in clinical trials including preliminary validation data.
2. To provide a forum for discussion of these proposals and an opportunity for feedback and debate.
3. To define issues that remain in the research agenda regarding domains and measures in PsA.

Summary of Outcome Measures Used in PsA Clinical Trials

A number of outcome measures used in PsA clinical trials have been shown to be accurate, reliable, and discriminative^{2,5,6,7,8,9,10} (Table 1). These include measures that have been adopted from RA and psoriasis clinical trials, as well as generic measures such as the Medical Outcome Study Short-Form 36. Recognizing the importance of enthesitis and dactylitis as clinical domains, measures for these clinical features have evolved over the past several years and are now routinely performed. Several measures of enthesitis, which assess different groups of enthesal insertion sites, are being utilized, and it is anticipated that as these are evaluated, a single measure may emerge as standard. As part of this process, sites in the appendicular skeleton are being evaluated both clinically and with ultrasound to assess criterion validity of these clinical measures. These measures and their comparative performance characteristics are demonstrated in a small study of PsA patients by Gladman, *et al*¹¹. Because spine involvement is not universal and varies from one patient to another, axial physical examination measures have not been employed in PsA clinical trials; instead, results from ankylosing spondylitis (AS) trials, using Assessment in Spondyloarthropathies (ASAS)-developed measures, are used for evidence of effect of therapies in axial PsA. Physical examination measures of the spine are reliable in axial PsA¹². Several skin measures have been used, adopted from psoriasis RCT. Interestingly, patients enrolled in PsA clinical trials often have low body surface area (BSA) involvement and thus may not be reliably evaluated with the Psoriasis Area and Severity Index (PASI) score, one of the most quantitatively rigorous, because of its poorer performance in subjects with less than 3% BSA involvement. A “target lesion” score may be used, where one lesion is evaluated over the course of the study⁵. More recently, several PsA trials have incorporated a modified

Table 1. Key outcome measures used for all domains of psoriatic disease.

Domains	Abbreviations	Instruments
Composite measures	CPDAI	Composite Psoriatic Disease Activity Index
	PASDAS	Psoriatic Arthritis Disease Activity Score
Joint assessment	68/66 T/S	68/66 tender/swollen joint count
	ACR	American College of Rheumatology response criteria
	DAS	Disease Activity Score
	PsARC	Psoriatic Arthritis response criteria
	PsAJAI	Psoriatic Arthritis Joint Activity Index
Axial assessment	DAPSA	Disease Activity in Psoriatic Arthritis Score
	BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
	BASFI	Bath Ankylosing Spondylitis Functional Index
Skin assessment	BASMI	Bath Ankylosing Spondylitis Metrology Index
	PASI	Psoriasis Activity and Severity Index
Nail assessment	Target lesion	Target Lesion Score
	PGA	Physician's global assessment
Pain	mNAPSI	modified Nail Psoriasis Severity index
Patient global	VAS	Pain visual analog scale
	VAS	Visual analog scale (global, skin + joints)
Physician global	VAS	Visual analog scale (global, skin + joints)
	HAQ	Health Assessment Questionnaire
Function/QOL	SF-36	Short-Form 36
	PsAQoL	Psoriatic Arthritis Quality of Life Index
	DLQI	Dermatology Life Quality Index
	FACIT	Functional Assessment of Chronic Illness Therapy
Fatigue	KFSS	Krupp Fatigue Severity Inventory
	MFI	Multidimensional Fatigue Inventory
	VAS	Fatigue visual analog scale
	MEI	Mander Enthesitis Index
Enthesitis assessment	MASES	Maastricht Ankylosing Spondylitis Enthesitis Score
	LEI	Leeds Enthesitis Index
	Major	Major Enthesitis Index
	SPARCC	Spondyloarthritis Research Consortium of Canada Enthesitis Index
	4-point	Used in IMPACT studies (bilateral Achilles tendons and plantar fascia)
Dactylitis assessment	LDI	Leeds Dactylitis Instrument
	Present/absent	Simple count of dactylitic digits
Acute-phase reactant	ESR	Erythrocyte sedimentation rate
	CRP	C-reactive protein

Nail Psoriasis Severity Index (mNAPSI) score for evaluation of nail response¹³.

In an RCT of sulfasalazine in PsA, Clegg, *et al* utilized a composite measure of tender and swollen joint counts along with patient and physician global assessments of disease activity¹⁴. In the original etanercept trial, this composite measure was named the Psoriatic Arthritis Response Criteria (PsARC). It was not methodologically derived and does not incorporate other features of PsA such as enthesitis, dactylitis, or skin disease. The ACR response criteria and the DAS scoring system and its associated EULAR response criteria have been successfully adopted from RA for evaluation of joints in a composite fashion. Fransen, *et al*, analyzing two phase 2 PsA trials with anti-tumor necrosis factor (TNF) agents, demonstrated that these were reliable and discriminative measures and were slightly more so than the PsARC³.

Summary of Current Proposed Composite Outcome Measures

Gladman and colleagues have recently addressed the need for a composite outcome measure in PsA. This was done using a complex analysis of datasets from a number of RCT in PsA. Interestingly, the analysis showed that the addition of the PASI score reduced the effect of the joint count, supporting the argument that the skin should be treated as an independent domain when evaluating response to therapy in PsA. Therefore, the composite measure developed (the Psoriatic Arthritis Joint Activity Index — PsAJAI) assessed only joint disease activity¹⁵.

Recently, the Vienna group used a principal component analysis of key PsA outcomes in 105 patients to identify which outcome measures best reflected disease activity. They identified 3 principal components that reached significance: patient pain and global disease activity assessment, tender and

swollen joint counts, and C-reactive protein (CRP). A fourth component consisted of skin assessment, but this did not reach significance. After a review of existing measures, the Disease Activity in REactive Arthritis (DAREA) score was thought to be the most relevant composite outcome that encompassed all of these principal components^{16,17}. This group has now renamed the DAREA as the Disease Activity in Psoriatic Arthritis (DAPSA) score.

A composite measure of minimal disease activity in PsA has also been developed and validated since OMERACT 9. The result of expert consensus with input from the GRAPPA members¹⁸, the measure has since been validated using independent LOS¹⁹ and RCT datasets²⁰. However, this measure does not provide a disease activity score, but allows assessment only of whether patients achieve the minimal disease activity state.

Work developing 2 key composite measures has been initiated and led by members of GRAPPA. FitzGerald and colleagues developed a composite outcome measure based on the GRAPPA treatment grid published by Ritchlin, *et al*²¹. The Composite Psoriatic Disease Activity Index (CPDAI) assigns a score of 0–3 to each of the 5 domains of PsA based on disease activity and impact of disease for this domain (Table 2). The scores are added to give a total score of 0–15, thus providing an overall assessment of disease activity²². One concern raised during development of this measure was that patients with severe disease activity in only one domain may be disadvantaged by a relatively low total score. Two solutions have been proposed for this. The first is that anyone with a single domain scored as severe would also be classified as severe overall. The second solution was the proposal of a modified CPDAI, where the total score is divided by the number of domains involved, yielding a mean CPDAI score.

Aizad Mumtaz presented preliminary validation data for the CPDAI from LOS and from patients undergoing treatment change²². The CPDAI score showed an excellent correlation with both patient and physician global assessments. Further, in a tree analysis, total CPDAI scores > 6 were found to be

associated with treatment change. Further validation is under way and comparison with radiographic and ultrasound outcome is planned.

Comparison of CPDAI and DAPSA

A recent analysis using the Psoriasis Randomised Etanercept Study in Subjects with Psoriatic Arthritis (PRESTA) dataset compared the performance of the CPDAI and the DAPSA/DAREA. The PRESTA RCT compared 2 doses of etanercept in a large number of patients with active psoriasis and psoriatic arthritis (50 mg qiw and 50 mg biw)²³. Interestingly, while measures of joint disease, enthesitis, and dactylitis showed similar changes in the 2 treatment groups, a superior response was seen with the higher dose for skin disease. The PRESTA study therefore provides an ideal dataset with which to assess the sensitivity of composite disease activity measures. Analyses revealed that both the CPDAI and the DAPSA showed good responsiveness to change. CPDAI but not DAPSA identified a significant difference between treatment groups that was likely driven by the differential response in skin disease ($p = 0.049$). In stepwise regression analysis, enthesitis, Health Assessment Questionnaire (HAQ), dactylitis, and Dermatology Life Quality Index (DLQI) all contributed significantly to CPDAI values at baseline. Thus, while both the DAPSA and CPDAI show responsiveness in measures of arthritis, the CPDAI has a potential advantage in that it can also reflect changes in the other domains of PsA.

Preliminary Data from the GRACE Exercise

Following the GRAPPA annual meeting in 2008 and as part of the preparation for OMERACT 10, GRAPPA initiated a project that aims to develop an inclusive composite outcome measure based on real patient data, the GRAPPA Composite Exercise (GRACE). Longitudinal observational data are being collected on a large cohort of PsA patients internationally. Individual outcomes assessing disease activity in all of the domains of PsA, as well as patient-reported outcome measures, are being collected. Where no consensus has been

Table 2. Composite Psoriatic Disease Activity Index (CPDAI). Score total 0–15.

Condition	None (0)	Mild (1)	Moderate (2)	Severe (3)
Peripheral arthritis		≤ 4 joints (swollen or tender); normal function (HAQ ≤ 0.5)*	≤ 4 joints but function impaired; or > 4 joints, normal function	> 4 joints and function impaired
Skin disease		PASI ≤ 10 and DLQI ≤ 10	PASI ≤ 10 but DLQI > 10; or PASI > 10 but DLQI ≤ 10	PASI > 10 and DLQI > 10
Enthesitis		≤ 3 sites; normal function (HAQ ≤ 0.5)*	≤ 3 sites but function impaired; or > 3 sites but normal function	> 3 sites and function impaired
Dactylitis		≤ 3 digits; normal function (HAQ ≤ 0.5)*	≤ 3 digits but function impaired; or > 3 digits but normal function	> 3 digits and has function impaired
Spinal disease		BASDAI ≤ 4; normal function (ASQoL ≤ 6)	BASDAI > 4 but normal function; BASDAI ≤ 4 but function impaired	BASDAI > 4 and function impaired

* HAQ only counted if clinical involvement of domain (joint/enthesitis/dactylitis) present. HAQ: Health Assessment Questionnaire, PASI: Psoriasis Activity and Severity Index, DLQI: Dermatology Life Quality Index, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, ASQoL: Ankylosing Spondylitis Quality of Life Index.

reached regarding optimal outcome measures for each component of disease, e.g., enthesitis, multiple measures are being collected to allow comparison of different indices. Patients are classified by their treating physician into 2 groups: those with active disease requiring a treatment change and patients who in the opinion of their treating physician have a low disease activity or are in remission. The 2 groups can then be compared to see where significant differences exist between them and which individual outcome measures account for this difference.

To date, baseline information on 457 patients with PsA has been collected as part of the GRACE initiative, and followup data are available on 157 patients. Analysis of the many outcome measures included in the dataset has shown a difference in all key variables for those undergoing treatment change and those not, except for the mNAPSI, Maastricht Ankylosing Spondylitis Enthesitis Score, erythrocyte sedimentation rate, and Bath Ankylosing Spondylitis Metrology Index. A principal component analysis was performed for all variables included in disease activity measures with log transformation for PASI, Leeds Enthesitis Index, dactylitis, joint counts, and CRP. Factor analysis identified 5 components that were (1) patient and physician completed measures, (2) skin activity, (3) tender joint count and enthesitis, (4) swollen joint count and dactylitis, and (5) CRP. However, with regression analysis, nearly 80% of variability (adjusted R^2) was provided by patient global disease visual analog scale (VAS) and over 90% by just 3 VAS scores (patient global, patient skin, and physician global). Dr. Helliwell therefore proposed the Psoriatic Arthritis Disease Activity Score (PASDAS) as a composite of 3 VAS scales. This is similar to what was found in the development of the PsAJAI¹⁵.

The GRACE dataset further permitted a comparison of this proposed measure with the CPDAI, DAPSA, and DAS28: all 4 measures demonstrated adequate discrimination in terms of the construct of disease activity. Interestingly, this held true for the oligoarthritis and polyarthritis subgroups but not for those with severe skin disease (PASI > 10). In addition, all these measures showed good responsiveness in the GRACE data set. A preliminary analysis of a modular approach to disease assessment rating each domain (peripheral arthritis, skin, dactylitis, enthesitis, and spine) in terms of an intention to treat was also presented, whereby each domain would be rated from A to E on a 5-point scale, where E represents no involvement of that domain and A severe involvement requiring disease-modifying antirheumatic drug therapy.

The GRACE initiative has provided an excellent resource for both development and testing of PsA composite outcome measures. Evident by recent analyses, further testing, refinement, and validation are required to develop the optimal composite measure for PsA. More data from the GRACE dataset at followup timepoints will allow further assessment of responsiveness to change and aid in defining disease activity states. The dataset may also require further enriching to

ensure that a wide variety of disease phenotypes are included. Initial recruitment for GRACE resulted in a cohort with low mean/median skin disease activity, and later stages of GRACE recruitment have attempted to address this with recruitment of patients with significant skin involvement.

Discussion at OMERACT 10

All participants of the SIG agreed that the work to date was promising and that plans for development of a composite responder instrument for use in RCT and LOS was appropriate. It was also agreed that no decision on the optimal outcome measure could be made without further work. Concerns were raised about relatively small numbers of patients in various subgroups of PsA collected in the GRACE study, and it was agreed that additional recruitment for underrepresented populations, such as patients with more severe skin disease, should occur. It was also acknowledged that further data were required at followup to facilitate development and testing of measures.

Concerns were raised about a composite measure that included only VAS scales, which potentially may be very subjective — although many psychometric analyses have indicated VAS scales confer better sensitivity and equivalent reliability to categorical Likert scales. Further suggestions were made on approaches to analyzing the existing dataset.

A concern regarding the construct of the GRACE study was raised — that patients were divided into low and high disease activity groups based on the physicians' treatment decisions. Although similar methodology was used in the development of the DAS for RA and AS, such an approach presents a challenge when used in PsA. The majority of patients have been recruited by rheumatologists, and therefore the decision to change treatment is likely driven by articular disease, whereas treatment decisions in other cohorts may be based on skin and nonarticular manifestations. This remains a continuing discussion between rheumatologists and dermatologists in GRAPPA — hopefully future analyses within and outside the GRACE project will address this issue.

Finally, discussions concluded regarding the concept of composite measures for PsA. Concerns were raised that PsA is a highly heterogenous condition with disease activity manifested in many domains that may be unrelated. Should a composite disease score encompassing all domains of involvement be used in PsA, or would it be more appropriate to capture individual aspects of the disease? It was agreed that at this stage we did not have the ability to use a composite measure for all disease aspects and that individual outcome measures were currently the most validated measures available. However, progress has been made to define composite scores that may be useful in the future.

More discussion is required on the optimal design of such a measure. It was acknowledged that a simple summative score encompassing all domains of PsA may be difficult to construct psychometrically and may not be appropriate, as it

would not be able to differentiate between the magnitude of activity in the different domains. Ideally, any composite measure should retain the ability to be broken down into its disparate domains, as is the case with the CPDAI, so that the effects of each of these individual aspects of the disease, and their potential for differential treatment response, can be assessed. Composite measures may also need sophisticated weighting of the various components, which would be specific to psoriatic disease and should not be “borrowed” from composite measures in other diseases, such as the RA DAS.

The final comment was that a similar session with more time for discussion was required to advance the project. The chairs of the SIG commented that progress made in the next 2 years should mean that a module update can be planned for OMERACT 11 in 2012.

Conclusion

This special interest group provided a valuable opportunity to present work to date on composite measures in PsA and to provide a forum for discussion. Further work is required within the GRACE dataset to ensure that all phenotypes of PsA are included in data collection and to aid in further development of an optimal composite measure for PsA. Several proposals to date have shown good preliminary validity according to the OMERACT filter. It is intended to further develop this work within the GRAPPA organization and GRACE study, with regular teleconference discussions, meetings adjacent to rheumatology and dermatology conferences, and the annual GRAPPA meetings. We intend to present the results of these analyses at the next OMERACT meeting in 2012 within a module update, and to publish results contributed by GRAPPA and OMERACT in the field of outcome measures in psoriatic arthritis.

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