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# Patient Reported Outcomes in Psoriatic Arthritis

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## SYNOPSIS

Patient reported outcome (PRO) measures are an important component to assessing disease impact and therapy response in patients with psoriatic arthritis (PsA). Overall there are few PsA-specific PROs. Most PROs used in PsA are borrowed from other diseases (e.g. rheumatoid arthritis and ankylosing spondylitis) or general population PROs. PROs are used in PsA clinical trials and in the clinical management of PsA. In this review, we discuss the most commonly used PRO in PsA including their inclusion in composite measures. Future studies may be helpful to determine the best performing PROs in patients with PsA.

### Keywords

psoriatic arthritis; patient reported outcome; outcome measure; composite measures

## INTRODUCTION

Psoriatic arthritis (PsA) is a chronic inflammatory arthritis associated with psoriasis. It affects people heterogeneously with a range of clinical manifestations (e.g., inflammatory arthritis, dactylitis, enthesitis, spondylitis, skin psoriasis, nail disease). The disease has a significant impact on patients' physical function, energy level, social participation, mood, and quality of life (1). Physician-based outcome measures do not capture the patient's experience of the disease. Patient input in assessing disease status and the effectiveness of

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their treatments is an important aspect of the management of PsA. Patient reported outcomes (PROs) give us the ability to integrate patient input in a way that is complementary to physician assessments and laboratory measures. PROs are measures of self- reported health status used to evaluate the patient's perception of symptoms, function and other aspects of their life potentially impacted by disease.

In PsA, PROs are used in clinical trials and clinical practice. PROs are key components of efficacy end-points in clinical trials and are incorporated with physician-based measures in composite disease activity indices, including the primary outcome in PsA randomized controlled trials (RCTs), the American College of Rheumatology 20% improvement response criteria (ACR20). As a part of the OMERACT PsA Core Domain Set (2), PROs representing patient global assessment, pain, physical function, and health related quality of life are expected to be measured in all PsA RCTs in addition to physician assessments of joints and skin. Beyond these domains, PROs are used to capture work productivity, fatigue, psychological endpoints and other symptoms. A wide range of PROs exist and few have been developed specifically for PsA. Most measures used in PsA have been developed for other diseases (e.g. Health Assessment Questionnaire Disability index for rheumatoid arthritis, Functional Assessment of Chronic Illness Therapy-Fatigue for cancer-related anemia) or are generic and meant to assess population health (e.g., Medical Outcomes Study Short Form-36, European Quality of Life Index-5 Dimensions). Furthermore, even fewer PROs have been developed with input from patients with PsA. Patient input into PsA outcome measures has previously been reviewed and for a majority of measures there has been no patient input (3). For a few measures, patient input has been incorporated by developing items from qualitative research among patients with PsA (Psoriatic Arthritis Quality of Life index, Psoriasis Symptom Inventory, Worst Itch-Numerical Rating Scale) or using patient research partner opinions of the relative importance of domains (Psoriatic Arthritis Impact of Disease) (4). Measures of PsA have been reviewed previously (5).

In this review, we discuss PROs used in observational and interventional studies of psoriatic arthritis. We have organized the PROs into categories based on the domains they address.

## METHODS

We performed a systematic literature search on July 22, 2015 in PubMed. We included the following search terms for psoriatic arthritis: ("Arthritis, Psoriatic"[Mesh] OR "Psoriatic arthritis" OR "psoriatic arthropathy" OR "arthritis psoriatica" OR "arthropathic psoriasis" OR "psoriasis arthropathica" OR "psoriatic arthropathy" OR "psoriatic polyarthritis" OR "psoriatic rheumatism") and the Oxford Patient Reported Outcome Measurement filter (source: Oxford Department of Public Health PROM Group). We obtained 1422 entries which were reviewed by title and abstract for inclusion. We excluded duplicates and studies specifically for children. After this review, 247 articles were retained. We performed additional searches for individual outcome measures. For each measure we synthesized the available data on the use of the outcome measure in PsA.

## PATIENT REPORT OUTCOMES IN PSORIATIC ARTHRITIS STUDIES

PROs may be disease specific or generic and may address one or more health dimensions or domains. Domains assessed by PROs used in PsA are shown in Table 1 and studied measurement characteristics of PROs in PsA are abstracted in Table 2. The most frequently used PROs in PsA are discussed below.

### Pain

Pain is a prevalent and debilitating symptom in arthritis. Pain assessment is part of the Outcome Measures in Rheumatology Clinical Trials core domain set and one of the three PROs in the ACR response indices. It is an outcome measure that is uniformly collected in PsA RCTs and longitudinal studies. Pain is generally measured using a 100 mm visual analog scale (VAS) or an 11 point numerical rating scale (NRS) (range 0–10) with anchors “no pain” (left, 0) to “pain as bad as it could be” (right, 100 or 10 respectively) and a recall period of seven days.

### PsA Global Assessment Scales

As noted above, global assessment scales are a part of the 2006 OMERACT PsA Core Domain Set and are captured in most clinical trials and as part of many composite measures. Global assessment scales are meant to measure the impact of a patient’s disease on his/her life. These questions may be phrased in slightly different ways and generally specify a time period over which to rate the effect of their disease. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) has advocated for measuring three distinct global assessments which include separate skin and joint global assessments and a dual skin and joint global assessment (6). The skin and joint global item is formulated “In all the ways in which your PSORIASIS and ARTHRITIS, as a whole, affects you, how would you rate the way you felt over the past week?” and responses are recorded on a 100mm visual analog scale with anchors “Excellent” (left) and “Poor” (right). VAS are most often used in measuring a global assessment although some have used NRS or Likert-type scales, such as the MultiDimensional Health Assessment Questionnaire (MDHAQ) (7).

### Health Related Quality of Life (HRQL)

While the term “health-related quality of life” (HRQL) (8) has not been precisely defined, measures of HRQL are generally felt to measure the impact of chronic disease or therapeutic interventions on a patient’s quality of life. Self –rated health has long been shown to predict short and long-term mortality in the elderly after adjustment for physician assessment, co-morbidities, health-service utilization, demographics, income and life satisfaction (9). HRQL represents a broad concept and draws from different domains of health (such as fatigue, physical function, emotional function, etc.) to derive a final score. The most commonly used HRQL outcome measures are generic (e.g., SF36 and EQ5D) although some HRQL measures have been developed specifically for PsA (PsAQoL). HRQL measures are often secondary efficacy end points in RCTs and can be incorporated into composite measures assessing the cost effectiveness of interventions in PsA. Below we discuss those measures most frequently used in PsA. Other measures that less commonly used in PsA include the Arthritis Impact Measurement Scales (AIMS and AIMS2),

Ankylosing Spondylitis Quality of Life index (ASQoL), Routine Assessment of Patient Index Data (RAPID3), and the Rheumatoid Arthritis Disease Activity Index (RADAI).

*The Medical Outcomes Study Short Form-36 (SF-36)* was developed for use in the general population for clinical care, economic evaluations and health surveys (10, 11). It can be administered as a PRO but has also been administered by trained individuals via telephone. While a free version of the questionnaire (RAND-36) is available, (12) the SF36 is proprietary and the scoring is complex. The SF-36 questionnaire assesses the following eight health domains on a scale of 0–100, 100 being the best score: 1) limitations in physical activities (due to health problems); 2) limitations in social activities (due to physical or emotional problems); 3) limitations in usual role activities (due to physical health problems); 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities (due to emotional problems); 7) vitality (energy and fatigue); and 8) general health perceptions. Scores can also be summarized on 2 components using a population normed T score metric with a mean of 50 and standard deviation of 10. These sub-scores are termed the Physical Component Score (PCS) and Mental Component Score (MCS). Minimal important differences for improvement in PsA were examined using Rasch analysis in one (13) small study (20 patients with PsA starting biologic) and are estimated at 3.74 for PCS and 1.7 for MCS. Corresponding changes in an RA population are 4.4 for PCS and 3.1 for MCS (14). The SF-36 is widely used in PsA RCTs as the preferred measure for HRQL due to its responsiveness with treatment (13, 15, 16).

**The EuroQol 5-Dimensions (EQ-5D)—**The EQ-5D is a commonly used generic quality of life instrument developed in Europe. It assesses mobility, self-care, usual activities, pain and anxiety/depression. The final score is calculated using a derived formula. The score ranges from −0.594 to 1 where zero is equivalent to death (and therefore patients can rate their health status as being worse than death). EQ-5D has been measured in many PsA RCTs, particularly those conducted in Europe. However, it is widely used among many different diseases and has been validated in a variety of disease status. It is frequently used in economic analyses. An advantage and disadvantage of the EQ5D is it's brevity – it is easily and rapidly completed however, there are only three possible answers for each question which contributes to a ceiling effect (18, 19).

**Psoriatic Arthritis Quality of Life index (PsAQoL)—**PsAQoL is a PsA disease specific measure of quality of life composed of 20 yes/no questions, making this a relatively easy and rapid questionnaire for completion. The items address domains including social participation, fatigue, mood, and daily activities. This instrument was developed using results from focus groups conducted among patients with PsA and subsequent item surveys with patients. The PsAQoL had excellent test-retest reliability and two studies have demonstrated correlation of PsAQoL with other instruments, suggesting construct validity (27, 28). Additionally, the PsAQoL is sensitive to change. The PsAQoL has been adapted in additional languages for Sweden and Netherlands (29, 30). Similar to the SF-36, PsAQoL is proprietary. While not frequently used in clinical trials, the PsAQoL was used in the recent Tight Control in Psoriatic Arthritis (TiCOPA) trial and it is part of several candidate PsA disease activity indices (see Table 3) (24–26).

**Psoriatic Arthritis Impact of Disease (PsAID)—**The PsAID is a measure developed by the European League Against Rheumatism (EULAR) and is composed of domains selected by an international group of patients with PsA. The PSAID is not specifically a HRQL PRO. It is instead intended for use as a patient-reported measure of disease impact on life in general. The PSAID has two versions, one with nine domains for RCTs and one with 12 domains for clinical care. PSAID domains include: 1) pain (pain in joints, spine and skin), 2) skin problems (including itching), 3) fatigue (being physically tired, but also mental fatigue, lack of energy), 4) ability to work/leisure, 5) functional capacity, 6) feeling of discomfort, 7) sleep disturbance, 8) anxiety, fear and uncertainty (about the future, treatments, fear of loneliness), 9) coping (adjustment to the disease, managing, being in charge, making do with the disease), 10) embarrassment and/or shame due to appearance, 11) social participation, 12) depression. (Numbers 10–12 are added to the 9-item questionnaire). The questionnaire uses a weighted scoring system (weights were derived by patient impression of importance) and has a range of 0–10 (higher scores are worse) with 4 being considered a patient acceptable symptom state (4). The proposed Minimal Clinically Important Difference (MCID) is 3. Given that this is a relatively new measure, few studies have included the PSAID but studies are underway to determine sensitivity to change and convergent validity.

## Patient Reported Disease Activity, Disability and Physical Function

Patient reported disease activity measures have been developed for RA (e.g., RAPID3) and ankylosing spondylitis (AS) (e.g., BASDAI) and these measures have been extended to other rheumatologic diseases including PsA. One issue with patient reported disease activity measures is the lack of correlation between self-reported joint counts with physician assessments in PsA (33). In one study, there was weak correlation for tender joints; no correlation for swollen joints; and weak to moderate correlation for damaged joints. A study in the same cohort showed discrepancies between patient and physician global assessments (34); these patient-physician discrepancies were significantly associated in a multivariable regression model with scores for fatigue, pain, tender and swollen joints and HRQL. Nevertheless, these measures may provide different and complimentary information to physician-reported measures. Below we discuss the most commonly used patient-reported disease activity measures in PsA trials and in the clinical management of PsA. Additionally, we discuss PRO measures for disability and physical function, which have different meanings than disease activity. While physical function may correlate with disease activity, disability may not (35).

*Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)* has been developed in patients with ankylosing spondylitis and exclusively axial disease (43). BASDAI is a questionnaire consisting of six VAS items assessing fatigue, axial joint pain, peripheral joint pan, soft tissue tenderness to touch, severity and duration of morning stiffness consisting BASDAI. Responses are recorded on unlabeled 10 cm VAS with left and right anchor “None” and “Very severe” except for the morning stiffness duration item, from “0” to “2 or more hours” with additional labels for ½, 1 and 1½ hours. Score range is 0–10 calculated as the mean of the six items. BASDAI has been used in PsA with and without axial disease and scores were generally higher in the axial versus peripheral PsA phenotype (44, 45). In axial

PsA (grade 2 or more unilateral sacroiliitis, inflammatory back pain and stiffness) BASDAI did not differentiate between levels of disease activity defined by change in treatment in either axial or peripheral PsA (45). In the Toronto PsA cohort, BASDAI showed good discriminative ability for high and low disease activity in axial PsA (similarly defined as grade 2 or more sacroiliitis, inflammatory back pain or spinal mobility limitation). Three definitions were used for high disease activity: patient global>6; physician global>6; and change in treatment. BASDAI discriminative ability for high disease activity using the three definitions was calculated as Area Under the Curve (AUC) (95% CI): 0.92 (0.88–0.95); 0.78 (0.67–0.88); and 0.69 (0.63–0.76) respectively (46).

*Health Assessment Questionnaire Disability Index (HAQ-DI)* is a widely used outcome measurement instrument for disability, developed in patients with rheumatoid arthritis (47). HAQ-DI scores have been shown to predict future function, survival and resource utilization in RA (48), correlate with radiographic scores in RA.(49) Total HAQ-DI score range is 0–3 and normal scores are 0.5 or lower. Minimal clinically important improvement (MCII) in RA has been determined to be decrease of 0.375 in the total score (50) (equivalent to 3 points improvement in the raw score), and very similar, a decrease of 0.35 in PsA (51). The HAQ-DI has been measured in every PsA RCT as it is part of the ACR responder indices and is usually also reported as a separate endpoint. HAQ-DI has been shown to be limited by floor effect much more in PsA (30%) than RA (8%) (52, 53) a fact supported by a comparative review of RA versus PsA RCTs where mean HAQ-DI scores are systematically higher in RA vs PsA (17). While this may be interpreted as a lower level of disability, it may in fact be a reflection of common oligoarticular involvement with PsA.

*Disabilities of arm, shoulder and hand questionnaire (DASH)* was studied in one longitudinal PsA cohort. Correlations with clinical measures of disease/joint activity were lower for the total joint core compared to upper extremity score as expected since DASH measures upper limb function (55). Due to common lower extremity involvement in PsA the measure is not sufficient for assessing the construct of disability in a majority of PsA patients.

## Skin symptoms and related impact

While a complete review of the quality of life and disease activity indices for skin are beyond the scope of this review, we will briefly discuss those commonly included in clinical trials of PsA.

**Dermatology Life Quality Index (DLQI)—**The DLQI is a quality of life index designed for patients with skin disease. This 10-item questionnaire (with one additional item that branches) which ascertains the impact of skin disease on work and leisure activities, social participation/relationships, symptoms related to skin disease like itch and pain (56, 57). The DLQI is widely used in clinical trials for psoriasis and PsA and correlates well with the Psoriasis Area and Severity Index.(58). This questionnaire is easy to complete, sensitive to change and has been validated in multiple populations, in particular psoriasis (59).

**Psoriasis Symptom Inventory (PSI)—**The PSI is a recently developed PRO assessing psoriasis symptoms that can be administered on paper or electronically (60). Rather than a

HRQL index, this can be used more as a disease activity index. PSI was developed in people with psoriasis in the US who participated in focus groups and interviews to generate and subsequently clarify concepts and patient preferred terms. PSI has eight items assessing the severity of each of these symptoms: 1) itch; 2) redness; 3) scaling; 4) burning; 5) stinging; 6) cracking; 7) flaking; and 8) pain due to psoriasis (61). Item response options are a 5-point Likert type (score 0: not at all severe; 1: mild; 2: moderate; 3: severe; 4: very severe) and two versions exist, differing only in the recall period (24 hours and seven days). The PSI score range is 0–32 with higher score representing worse symptoms. PSI items test-retest reliability has been studies in 139 patients with psoriasis and it was good (individual items ICCs>0.7) as well as correlations with DLQI and SF-36 items. As expected, the highest correlations were observed with corresponding skin symptom items (62). PSI was tested in 154 people with PsA showing good test-retest reliability (total score ICC 0.7), moderate correlation with body surface area and patient global (−0.5 and 0.4 respectively) and low correlations with SF-36 concepts and physician global (63).

**Worst Itch Numerical Rating Scale (WI-NRS)—**The WI-NRS was developed in patients with psoriasis (n=22) and PsA (n=12) and consists of a single NRS (0–10, “no itch” to “worst imaginable itch”) for itch with an assessment over the past 24 hours. The item was developed using qualitative research with patients with psoriasis and psoriatic arthritis followed by item cognitive debriefing (64).

## Fatigue

**Functional Assessment Chronic Illness Therapy-Fatigue (FACIT-F)—**FACIT-F is a 13-item PRO initially developed in patients with cancer as the Functional Assessment of Cancer Therapy (65) and adapted for use in other chronic conditions. Score range is 0–52 with higher scores reflecting less fatigue. FACIT-F reliability and validity was examined in a longitudinal PsA study (66). Minimal important change in RA is 4 points (67) and it has not been specifically studied in PsA.

*Fatigue VAS* use is common especially in clinical care (including an 11-point NRS scale as a part of the MDHAQ) and longitudinal studies. Fatigue VAS have been criticized for lack of standardization because this causes great difficulty with comparisons across studies (68).

## Work Productivity

Work productivity and work disability are related concepts. PsA is associated with increased work disability (69) which can be reversed with treatment (70).

The arthritis-specific *Work Productivity Survey (WPS)* has been developed in rheumatoid arthritis on the basis of a literature review (71) and has data supporting its validity in PsA from one RCT (72). WPS is an interviewer-administered ten item questionnaire assessing employment status, missed workdays, productivity and arthritis interference both in the work place and at home, with a recall period of one month. Two of the items are visual analog scales with anchors “no interference” (left) and “complete interference” (right) and additional items are reports of numbers of days missed or not as productive.

### Sleep Disturbance

There is evidence that PsA is associated with sleep disturbance (73) and patients prioritized this impact in the EULAR PsAID measure, yet sleep is rarely assessed in PsA research or clinical care. The Medical Outcomes Study Sleep Scale has been used in a study of psoriasis and fibromyalgia but not specifically in PsA (74, 75). The PsAID questionnaire is the only PsA specific PRO assessing sleep disturbance as one of its domains. Further studies are needed to address optimal PROs for sleep in PsA.

## INCLUSION OF PATIENT REPORTED OUTCOMES IN COMPOSITE MEASURES FOR PSORIATIC ARTHRITIS

Composite outcome measures have been developed to attempt to integrate patient and clinician measures (Table 3) and to address several domains in a single measure. In composite indices, patient and physician measures are aggregated into a single score. There are two types of composite measures: those that are response indices and have a dichotomous cutoff (e.g. ACR20) and those that calculate a score for disease activity (e.g. DAPSA) that is sensitive to change and a cutoff is derived to serve as a threshold for "response." This second type of measure can be a static or dynamic measure of disease activity and often has defined categories of disease activity (e.g., remission, low, moderate and high disease activity). Patient measures most often included are the HAQ (or a functional assessment), pain and global assessments. A few of the composite measures include quality of life (via the SF36, PsAQoL, DLQI and/or ASQoL). Below we address the PROs in each composite index and how these were selected. The domains assessed by each composite measure are shown in Table 3. The Psoriatic Arthritis Joint Activity Index (PsAJAI) was previous developed but has not yet been used in additional studies since development and thus is not included below.(79)

**American College of Rheumatology 20%, 50%, and 70% Response Criteria (ACR20, ACR50 and ACR70)—**The ACR20 is the most commonly used response index and is the primary outcome for trials in PsA. The ACR criteria define response as a binary outcome. These criteria were initially developed for rheumatoid arthritis and utilize a 28 joint count. This has been modified in PsA to include a 66/68 joint count. The ACR criteria were developed using physician surveys and analysis of RA clinical trial data. These criteria define response at the 20%, 50%, and 70% thresholds based on the reduction in tender and swollen joint counts, physician's global assessment, acute phase reactant, and three PROs, HAQ-DI, patient pain assessment and patient global assessment (80).

**Disease Activity Score (DAS) of 28 or 66/68 joints, the Clinical Disease Activity Index (CDAI), and the Simplified Disease Activity Index (SDAI)—**Similar to the ACR outcomes, these measures were developed initially in RA. The DAS has been modified for PsA to include the 66/68 joint counts. These disease activity measures include only one PRO: the patient global assessment of health in the case of DAS, and the patient global assessment of arthritis for CDAI and SDAI. In addition, these measures include the swollen and tender joint counts and one or both of the C-reactive protein or sedimentation rate and physician (or evaluator) global assessment (81).

**Disease Activity index for Psoriatic Arthritis (DAPSA)—**Development of the DAPSA was based on a principal component analysis that revealed three significant components: two PROs (patient pain and global assessments), joint involvement (66/68 swollen joint counts), and acute phase response (C-Reactive Protein) (82) The Disease Activity Index for Reactive Arthritis (DAREA) had previously been derived for reactive arthritis and contained these same elements. It was thus tested in PsA and found to have good discrimination (AUC 0.74–0.80) (83). However, subsequent studies have suggested that other composite indices may have larger effect sizes (84). Recently DAPSA cutoffs for disease activity states and treatment response have been derived using patient level data from three PsA RCTs (85) therefore this index is now usable and interpretable.

**Composite Psoriatic Disease Activity Index (CPDAI)—**The domains of the CPDAI were derived from consensus among GRAPPA members and include joint disease, skin involvement, enthesitis, dactylitis and spinal disease. Instruments to measure each domain were similarly chosen by consensus. For each domain, activity is defined as none, mild, moderate or severe and these categories can be defined by more than one instrument. Each domain is assigned a point value depending on the severity (0–3 respectively) and these individual scores are then summed to a final score (range 0–15). PROs included in the CPDAI include the HAQ for peripheral arthritis, DLQI for skin disease, and BASDAI or ASQoL for spine disease (86).

**The Psoriatic Arthritis Disease Activity Score (PASDAS) and the Arithmetic Mean of Desirability Functions (AMDF)—**Both the PASDAS and AMDF were developed as a part of the GRACE project and were derived (although in different ways) from the same datasets. In this dataset (the GRAppa Composite Exercise or GRACE study), PROs included patient global assessments (overall global, skin, and joints), the DLQI, ASQoL index, PsAQoL index, SF36 and the individual components and the HAQ. PASDAS was derived using a principal component analysis and AMDF was derived using desirability functions (desirability was derived using physician surveys). Both have somewhat complex formulas. The PASDAS includes the physician and patient global assessments, the SF36 physical component scale, the tender and swollen joint counts, the Leeds enthesitis count, tender dactylitis count, and the C-reactive protein. The AMDF includes the same elements (different formula) but adds the mental component scale of the SF36 (87). These measures have not yet been used in PsA clinical trials but have shown large effect sizes in a clinical trial dataset.(88)

**Minimal Disease Activity (MDA)—**MDA are a set of criteria that define the “state of disease activity deemed a useful target of treatment by both the patient and physician, given current treatment possibilities and limitations.” Each domain is assessed as active or not active based on suggested thresholds. The OMERACT PsA Core Domains, agreed upon in 2006, were used to define MDA. However, HRQL was excluded because of lack of correlation between HRQL and other measures of disease activity to be included. Rheumatologists and dermatologists were then asked to decide whether patient profiles were in a state of MDA. Thresholds for each of the domains were maintained when >70% consensus was achieved. The final version of the MDA includes the following components

(threshold) patient pain and global VAS assessments (less than or equal to 15 and 20 respectively), the HAQ (less than or equal to 0.5), tender and swollen joint counts (less than or equal to 1), enthesitis count (less than or equal to 1), and psoriasis severity characterized by either Psoriasis Area and Severity Index (PASI) or Body Surface Area (BSA) (less than or equal to 1, and 3% respectively) (89). MDA state is defined as achieving the threshold for five out of the seven components.

**Psoriatic Arthritis Response Criteria (PsARC)—**The PsARC is a composite responder index that includes tender (68) and swollen (66) joint counts and physician and patient global assessments (measured on 5-point likert scales)(90). It was the first composite measure derived specifically for PsA. Similar to the ACR response criteria, this is a binary score where a patient can meet the definition of response if they have either a 30% reduction in tender joints or swollen joints or a 1-point improvement in either the physician or patient global assessment scale and the other items must not worsen (91). PsARC is generally not used as the primary outcome measure in RCTs but rather as a secondary outcome (92, 93).

## SUMMARY

Psoriatic arthritis is a complex disease. Patients with PsA have highly varied manifestations of PsA (e.g. peripheral arthritis, spondylitis, enthesitis, dactylitis) and are likewise varied in terms of how they experience their disease and the level of impact it has on their lives. From these perspectives, PsA can be difficult to measure. The patients' perspective of their illness and their response to therapy can be captured using PROs. While numerous PROs exist in general, only a few addressing each domain have been validated in PsA and even fewer have been developed specifically for PsA. However, some existing PROs do perform relatively well in PsA RCTs. Additional studies are needed to understand what patients think is important in defining the activity of their disease. With such knowledge we can more precisely define the unidimensional concepts that need to be assessed in PsA such that a set of PROs with optimized measurement properties for PsA can be selected and standardized for PsA assessment in clinical trials and clinical practice.

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**KEY POINTS**

- Psoriatic arthritis is a chronic and heterogeneous inflammatory arthritis associated with psoriasis.
- Patient reported outcomes are essential in assessing health status and treatment effects in psoriatic arthritis
- Additional studies are needed to understand what patients think is important in defining the activity of their disease.

**Table 1**

Domains and Patient Reported Outcomes in Psoriatic Arthritis Studies

| Domain | Patient Reported Outcome |
|---|---|
| Pain | Pain VAS |
| Patient Global | Patient global<br>Skin<br>Joints<br>Skin and Joints |
| Health Related Quality of Life | Medical Outcomes Study Short Form-36<br>Euro-Qol 5 Dimensions<br>PsA Quality of Life Index<br>Dermatologic Life Quality Index<br>Ankylosing Spondylitis Quality of Life Index |
| Impact of Disease | Arthritis Impact Measurement Scales<br>Psoriatic Arthritis Impact of Disease |
| Disease Activity | Routine Assessment of Patient Index Data<br>Rheumatoid Arthritis Disease Activity Index<br>Bath Ankylosing Spondylitis Disease Activity Index |
| Disability and Physical Function | Health Assessment Questionnaire Disability Index<br>Bath Ankylosing Spondylitis Functional Index<br>Disabilities of arm, shoulder and hand questionnaire |
| Skin | Psoriasis Symptom Inventory<br>Worst Itch Numerical Rating Scale |
| Fatigue | Functional Assessment Chronic Illness Therapy-Fatigue<br>Fatigue Visual Analog Scale/Numerical Rating Scale |
| Productivity | Work Productivity Survey (arthritis specific) |

**Table 2**

Studied Measurement Characteristics of Patient Reported Outcomes in Psoriatic Arthritis

| Patient Reported Outcome | Population | Reliability Internal consistency | Reliability e.g. test-retest | Measurement error | Content validity | Construct validity | Criterion validity | Responsiveness | Interpretability (existence of cutoffs) |
|---|---|---|---|---|---|---|---|---|---|
| Medical Outcomes Study Short Form-36 (SF-36) | general | Cronbach's alpha >0.8 for all 8 scales (25) | NR | NR | NR | Hypothesis testing based on convergent/divergent validity (25) Structural validity of PCS and MCS dimensions with confirmatory factor analysis (76) | NR | Area under Receiver Operator Curve (77) | PsA MID calculated (13) |
| Euro-Qol 5 Dimensions (EQ-5D) | general | NR | NR | NR | NR | NR | NR | NR | NR |
| PsA Quality of Life Index (PsAQoL) | psoriatic arthritis | Internal consistency 0.91 Rasch analysis: person separation index 0.93 (27) | Test retest reliability 0.89 (27) | NR | qualitative research | Hypothesis testing convergent validity (27) | NR | NR | NR |
| Dermatologic Life Quality Index (DLQI) | dermatological conditions | NR | NR | NR | NR | NR | NR | NR | NR |
| Psoriatic Arthritis Impact of Disease (9 and 12 item) | psoriatic arthritis | Cronbach's alpha=0.93–0.94 (4) | Test-retest reliability at 2–10 days ICC 0.95 and 0.94 (4) | NR | Patient prioritized domains (4) | Hypothesis testing convergent validity (4) | NR | Provided SRM (4) | Preliminary values PASS=4 MCII=3 (4) |
| Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) | ankylosing spondylitis | NR | NR | NR | NR | Hypothesis testing correlation w disease activity (45, 46) | NR | Area under Receiver Operator Curve calculated for predicting high disease activity/ change in treatment (46) | NR |
| Health Assessment Questionnaire Disability Index (HAQ-DI) | rheumatoid arthritis | NR | NR | NR | NR | NR | NR | Area under Receiver Operator Curve calculated (77) | PsA MID 0.131 (78) PsA MCII 0.35 (51) |
| Disabilities of arm, shoulder and hand questionnaire (DASH) | rheumatoid arthritis | NR | NR | NR | NR | Hypothesis testing, correlations with disease activity measures (55) | NR | NR | NR |
| Psoriasis Symptom Inventory (PSI) | psoriasis | Cronbach's alpha =0.95–0.97 (63) | Test re-test (0–2 week and 2–4 week) ICC=0.7 and 0.87 (63) | (psoriasis) Limits of agreement (62) | Qualitative research | Structural validity using confirmatory factor analysis and Rasch analysis: uni-dimensionality Hypothesis testing correlations w BSA, SF-36 (63) | NR | Comparison of PSI change scores w change in patient global (63) | NR |
| Functional Assessment Chronic Illness Therapy-Fatigue (FACIT-F) | cancer | Cronbach's alpha =0.96 (66) | Test – retest ICC=0.95 (66) | NR | NR | Hypothesis testing (66) | Correlation with Fatigue Severity Scale =−0.79 | NR | No PsA MID RA MID is 4 |

| Patient Reported Outcome | Population | Reliability Internal consistency | Reliability e.g. test-retest | Measurement error | Content validity | Construct validity | Criterion validity | Responsiveness | Interpretability (existence of cutoffs) |
|---|---|---|---|---|---|---|---|---|---|
| Work Productivity Survey (WPS) | rheumatoid arthritis | NR | NR | NR | Literature review | Hypothesis testing (72) | NR | Report SRM (72) | NR |

## Table 3

Composite Outcome Measures in Psoriatic Arthritis

| | ACR20* | DAS28* | CDAI | SDAI | PsARC | DAPSA | CPDAI | PASDAS | AMDF |
|---|---|---|---|---|---|---|---|---|---|
| Peripheral arthritis* | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| Psoriasis skin disease | | | | | | | ■ | | |
| Enthesitis | | | | | | | ■ | ■ | |
| Dactylitis | | | | | | | ■ | ■ | |
| Spinal disease | | | | | | | ■ | | |
| Health-related quality of life | | | | | | | ■ | ■ | ■ |
| Physical function assessment (HAQ) | ■ | | | | | | ■ | | ■ |
| Patient global: arthritis activity | | | | | | | | | ■ |
| Patient global: skin disease activity | | | | | | | | | ■ |
| Patient global: disease activity | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ |
| Patient pain assessment | ■ | | | | | ■ | | | ■ |
| Physician global assessment | ■ | | ■ | ■ | ■ | | | ■ | |
| Acute-phase response | ■ | ■ | | ■ | | ■ | | ■ | |

Patient reported outcomes are shown within the dark lines.

* Peripheral arthritis is captured through the number of swollen and tender joints. The ACR20 is defined as 20% improvement in tender and swollen joint counts as well as 20% improvement in 3 of the other 5 measures. The ACR20 and DAS28 assess the PIPs, MCPs, wrists, elbows, shoulders, and knees. DAPSA, CPDAI, PASDAS, and AMDF use the 66/68 joint counts. The DAS66/68 adds the hips, DIPs, sternoclavicular, temporomandibular, acromioclavicular, talotibial, midtarsal, metatarsophalangeal and interphalageal joints of the toes.

**Abbreviations**: ACR20 = American College of Rheumatology 20% Response; DAS28 = Disease Activity Score 28 Joints; PsAJAI = Psoriatic arthritis Joint Activity Index; DAPSA = Disease Activity in Psoriatic Arthritis; CDAI = Clinical Disease Activity Index; SDAI = Simplified Disease Activity Index; CPDAI= Composite Psoriatic Disease Activity Index; PASDAS= Psoriatic Arthritis Disease Activity Score; AMDF= Arithmetic Mean of Desirability Functions.

Adapted with permission from Coates LC, FitzGerald O, Mease PJ, DD. Gladman, et al. Development of a disease activity and responder index for psoriatic arthritis--report of the Psoriatic Arthritis Module at OMERACT 11. The Journal of rheumatology. 2014;41(4):782–91; with permission.