# Psoriatic Arthritis Quality of Life Instrument: An Assessment of Sensitivity and Response to Change

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*ABSTRACT.* ***Objective.*** To assess responsiveness of the Psoriatic Arthritis Quality of Life tool (PsAQoL) and add further data regarding the construct validity of PsAQoL.

***Methods.*** Twenty-eight patients with PsA underwent clinical assessment over a period of 6 months after change of disease modifying therapy, usually to methotrexate. Measures of outcome included PsAQoL, Health Assessment Questionnaire (HAQ), and assessment of disease activity.

***Results.*** PsAQoL revealed significant change at 3 and 6 months. Standardized response mean was large at 3 months and small at 6 months. There was strong correlation with other patient-derived measures such as the HAQ and Patient Global at all timepoints. Disease Activity Score-28 and Physician Global showed a relationship with PsAQoL at 3 and 6 months, while a tender joint count relationship was seen only at 6 months.

***Conclusion.*** The PsAQoL now has responsiveness data and a measure of construct validity to sit alongside previously demonstrated reliability data. Our study has compared the change characteristcs within a group of patients. The next step in the development will require a placebo controlled trial to test discrimination between patients undergoing active treatment or taking placebo. (First Release June 1 2008; J Rheumatol 2008;35:1359–61)

*Key Indexing Terms:*
PSORIATIC ARTHRITIS QUALITY OF LIFE RESPONSE TO CHANGE PsAQoL

The assessment of quality of life is increasingly important as an outcome in therapeutic trials. In psoriatic arthritis (PsA) there is the dual difficulty of considering both a dermatological and rheumatological disorder. At OMERACT 8, May 2006, health related quality of life (HRQoL) was included as one of the core set of outcomes for use in PsA[1]. A number of instruments have been developed to measure HRQoL in psoriasis (comprehensively reviewed recently[2]), and a specific instrument for PsA is available[3], although clinical trials in PsA to date have included other QoL measures such as the Short-Form 36 (SF-36)[4] and Disability Life Quality Index (DLQI)[5].

The Psoriatic Arthritis Quality of Life tool (PsAQoL)[3] was developed using qualitative methodology and is founded on a needs-based model of quality of life. This model reflects the effect of the disease on the ability of patients to meet their needs. This ability may or may not be related to the level of disease activity or impairment secondary to disease-related damage. It is increasingly recognized that these needs are not simply functional but include social, psychological, and vocational components. The PsAQoL contains 20 questions developed from patient interviews that explore these areas. Although developed with exemplary methodology (including robust selection of items that fit the Rasch psychometric model), as yet there are no data on the responsiveness of the PsAQoL and only limited data on construct validity. This study seeks to add to the evidence for these key properties.

## MATERIALS AND METHODS

The study took place in a secondary care setting in Bradford NHS Trust in West Yorkshire, UK. Approval was given by the local ethics committee. Patients over the age of 18 years fulfilling the criteria for PsA as described by the CASPAR study group[6] with active disease (≥ 3 tender and/or ≥ 3 swollen joints based on 78 tender and 76 swollen joint count) and who were intolerant or unresponsive to their current disease modifying therapies or had not yet begun disease modifying therapy, were invited to participate. Patients were enrolled as part of a longitudinal observational study of active PsA and dactylitis[7]. A full study information sheet and written consent form were provided. Those who provided written consent to participate underwent an initial assessment of joint and skin disease. Drug therapy was chosen by the managing clinician as considered appropriate. Patients underwent clinical assessments at baseline (start of new drug therapy), 2 weeks, 1 month, 3 months, and 6 months. Clinical assessment included the following instruments: a 78 joint count (78 tender and 76 swollen joints), a measure of acute-phase response [C-reactive protein (CRP)], the British version of the Health Assessment Questionnaire (HAQ)[8], Psoriasis Area and Severity Index (PASI)[9], the PsAQoL, and a patient and physician global assessment using both a 10-cm visual analog scale (VAS) score and a 5-point Likert scale. Together these measurements facilitate calculation of the

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disease activity scores Psoriatic Arthritis Response Criteria (PsARC)[10] and Disease Activity Score 28 joint (DAS28)[11]. Further validation of the DAS28 in PsA is required but preliminary data suggest that they may be useful in polyarticular PsA[12].

The Wilcoxon sign-rank test was used to show change and the standardized response mean (SRM) to evaluate the size of the change. SRM is calculated as mean change/standard deviation of change[13]. Accepted interpretation of the SRM is as follows: > 0.3 and < 0.5 small, between 0.5 and 0.7 moderate, and large if > 0.7. Spearman rho was used as the correlation statistic with 2-way significance tests.

## RESULTS

Twenty-eight patients were enrolled. Eight of these people had had symptoms suggestive of inflammatory back pain. The following drugs were initiated in this study: methotrexate in 19 patients, leflunomide in 4, etanercept in 4, and hydroxychloroquine in 1. Baseline patient characteristics are given in Table 1.

At 3 and 6 months, 54% and 61% of patients, respectively, had achieved a PsARC response; the corresponding figures for the American College of Rheumatology 20% response (ACR20) were 50% and 43%. The mean (SD) PsAQoL results were as follows: baseline 13.46 (5.15); 3 months 10.67 (6.32); and 6 months 10.5 (6.92). The PsAQoL showed a significant change from baseline at both 3 ($p < 0.01$) and 6 months ($p < 0.05$).

The SRM at 3 months was 0.71 (large) and at 6 months was 0.41 (small). SRM values for other variables are shown in Table 2. These broadly follow the pattern of PsAQoL, with the 3-month changes stronger than those at 6 months. Of note, the patient-derived data closely follow the change seen in PsAQoL. Table 3 shows the correlational analysis for some of the clinical and patient-derived variables. The important points to note are the relationship of the patient-derived Patient Global VAS and HAQ to PsAQoL at all timepoints.

*Table 1.* Baseline data.

| Characteristics | Result, mean (SD) | Range |
|---|---|---|
| M:F | 14:14 | |
| Age, yrs | 46.5 (10.5) | 24–70 |
| Disease duration, yrs | 10.5 (11.3) | 0.8–37 |
| CRP, mg/l (normal < 10) | 15.3 (13) | 5–51 |
| HAQ | 1.4 (0.8) | 0–2.9 |
| Tender joint count | 16.3 (12.5) | 1–47 |
| Swollen joint count | 8.9 (4.3) | 1–20 |
| Physician global VAS | 51.3 (21.1) | 15–89 |
| Patient global VAS | 56.2 (20.6) | 23–100 |
| DAS-28 | 4.3 (1.0) | 2.2–6.7 |
| PASI | 5.4 (4.9) | 0.6–18.6 |
| PsAQoL | 13.46 (5.15) | 0–20 |

HAQ: Health Assessment Questionnaire, VAS: visual analog scale, DAS-28: Disease Activity Score 28 joints, PASI: Psoriasis Area and Severity Index, PsAQoL: Psoriatic Arthritis Quality of Life tool.

## DISCUSSION

The PsAQoL was developed in a population of patients with psoriatic arthritis. It has established good test-retest reliability. This is the first study to show the response to change characteristics of the PsAQoL. It is encouraging to find a significant change using a mix of therapies dominated by methotrexate. The SRM suggests this effect is moderate at 3 months and small at 6 months. This result is likely to be more pronounced when using biological agents.

The magnitude of the changes (SRM) in the patient-derived measures (Patient Global VAS and HAQ) is similar to that of the PsAQoL changes. This similarity provides an element of construct validity for the PsAQoL as both these measures have been validated in PsA. Construct validity is often difficult to obtain for QOL measures as there is frequently no "gold standard," and this is particularly true in PsA[2]. While the DLQI and SF-36 have been used in previous studies of PsA they have not been formally validated and so cannot be considered the gold standard. Despite this, comparison of PsAQoL with DLQI or SF-36 is an important step for further validation. The DLQI and SF-36 were not included in this study as the cohort was gathered to assess responsiveness of a dactylitis instrument in active PsA. The PsAQoL was included to gain an understanding of its potential responsiveness in treated PsA. It should be noted that the SF-36 did not perform as well as a disease-specific measure in ankylosing spondylitis[14], and other studies comparing generic measures with disease-specific QOL measures generally demonstrate greater responsiveness for the disease-specific instrument[15].

The correlation with the disease outcome measures Patient Global VAS and HAQ also supports that these may be related to PsAQoL. The HAQ might be considered a disability index and it focuses mainly on the functional aspects of activities of daily life. The correlation suggests that these functional limitations may contribute to poor quality of life as assessed by the needs-based model. While this statement makes intuitive sense, it does not necessarily follow in a needs-based model, which neither necessitates nor precludes any impairment or activity having an effect on QOL. The relationship of tender joint count with PsAQoL at 6 months is harder to explain. Again, a contribution to QOL may be made by joint discomfort. However, given that there was no relationship at the earlier timepoints, it is most likely a problem generated by our small data set. Of note, however, the PsAQoL development report[3] also suggested these relationships, albeit with rather simpler and less formal measures of disease activity.

The lack of correlation with the PASI does not indicate that skin disease is an unimportant contributor to QOL. PASI is a cumbersome way of measuring skin disease, especially in patients who have a small disease burden, and there is debate regarding the level of improvement that indicates a response to treatment[16]. It should be noted that minimal skin

*Table 2.* Standardized response mean matrix: clinical variables.

| Timepoint | PsAQoL | Physician Global VAS | Patient Global VAS | Tender Joint Count | Swollen Joint Count | PASI | HAQ |
|---|---|---|---|---|---|---|---|
| 3 months | 0.71 | 1.67 | 0.99 | 0.85 | 1.23 | 0.16 | 0.97 |
| 6 months | 0.41 | 1.43 | 0.59 | 0.59 | 1.1 | 0.29 | 0.60 |

*Table 3.* Correlation matrix: PsAQoL versus other measures.

| Timepoint | Physician Global VAS | Patient Global VAS | Tender Joint Count | Swollen Joint Count | PASI | HAQ | DAS28 |
|---|---|---|---|---|---|---|---|
| Baseline | 0.271 | 0.442* | –0.070 | –0.259 | 0.076 | 0.690** | 0.132 |
| 3 months | 0.460* | 0.570* | 0.147 | –0.131 | 0.073 | 0.589** | 0.510* |
| 6 months | 0.582* | 0.582* | 0.560** | 0.286 | 0.379 | 0.569** | 0.515** |

* $p < 0.05$; ** $p < 0.01$

disease is the norm in patients with PsA[6]. As such, PASI is probably not an appropriate tool for skin outcomes in PsA trials. In this cohort the amount of change was significant, but the importance of that change is questioned by the low SRM. PASI is also a physician-determined outcome that may not represent the impact felt by a patient. In particular, it does not differentiate the effect from important areas such as the hands, face, and genitals from that of other body areas.

Quality of life is an important part of the core set of outcome domains for PsA being developed by the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), as recommended at OMERACT 8. The PsAQoL now has responsiveness data and a measure of construct validity to sit alongside the previously demonstrated reliability data. Our study compared the change characteristics within a group of patients. While it is important to know that a measure can change, only a placebo-controlled trial can show that the measure will discriminate between different groups. This will be the next step in the development of PsAQoL.

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