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## Title

PASDAS demonstrates excellent test-retest reliability in early, untreated PsA

## Authors

Gabriele De Marco, Dr. 1, 2,

Elizabeth MA Hensor, Dr. 1, 2

Dennis McGonagle, Prof. 1, 2

Ai Lyn Tan, Dr. 1, 2

Laura Coates, MBChB, PhD. 3

Paul Emery, Prof. 1, 2

Philip Helliwell, Prof. 1, 2

Helena Marzo-Ortega, Dr. 1, 2

## Institutions

1) NIHR-Leeds Biomedical Research Centre, Leeds Teaching Hospitals NHS Trust, Leeds, United Kingdom.

2) Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, United Kingdom.

3) Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford, United Kingdom.

## Abstract text

### Introduction

Psoriatic arthritis (PsA) is a chronic inflammatory arthritis characterised by heterogenous clinical features including peripheral arthritis, spondylitis, enthesitis, dactylitis, skin and nail disease. Historically, outcome measures in PsA trials focused on the articular manifestations of disease, with a recent emphasis in composite tools. The Psoriatic Arthritis Disease Activity Score (PASDAS) is a validated, composite measure with defined cut-off and excellent responsiveness when compared with other PsA-specific and non-specific composite measures. Although PASDAS is one of the recommended GRAPPA measures for research trials, data on its test-retest reliability are limited particularly in PsA of short disease duration.

### Aims and Objectives

To assess the test-retest reliability of the PASDAS composite index in a cohort of early, untreated PsA patients.

### Methods

Data were collected from a subset of participants recruited to the GOLMePsA clinical trial (EudraCT Number: 2013-004122-28), after a minor protocol amendment enabling additional data collection at the screening visit. The test-retest reliability of PASDAS was performed by calculating the intraclass correlation coefficient (ICC) between measurements collected at screening and baseline time-points (maximum 4 weeks apart, by protocol). Table 1 details the sample size calculation. Baseline variables collected in the GOLMePsA trial were described by absolute numbers, percentages, means, medians, absolute and inter-quartile ranges (IQR).

### Results

The PASDAS test-retest reliability was assessed in 37 consecutive participants. Average time between the two time-points was 1.9 weeks (range 0.4 to 4.0). Baseline characteristics of test-retest subset compared to all GOLMePsA participants were similar (table 1).

The ICC was 0.85 (95% confidence interval 0.73-0.92). The observed ICC was identical to the value assumed in the sample size calculation for this analysis, yielding an acceptably narrow confidence interval around the estimate. There was no substantial correlation between the means of the two measurements and the differences between them (Pearson's r=-0.26). The Bland-Altman limits of agreement were -0.11 ± 1.24 (-1.35 to 1.13).

### Conclusions

These results confirm the excellent test-retest reliability of PASDAS in early, untreated PsA, supporting its use as an outcome measure in interventional studies in newly diagnosed disease of short-duration.

## Table

**Table 1** – Demographic and clinical characteristics of the GOLMePsA participants at the baseline time-point

| Variable | All participants (n=84) | Test-retest subset (n=37)[A] |
|---|---|---|
| Age, in years (mean) | 42.5 (SD 12.4) | 39.9 (SD 12.7) |
| Gender – females/males (n) | 38/46 | 18/19 |
| Peripheral joints symptoms duration, in months (median) | 10.5 (IQR 5.4-21.6) | 10.5 (IQR 5.3-22.0) |
| PASDAS score (mean)[B] | 5.7 (SD 1.2) | 5.8 (SD 1.2) |
| Polyarticular phenotype (n) | 61 (72.6%) | 30 (81.1%) |
| Dactylitis present (n) | 42 (50%) | 22 (59.5%) |
| Leeds Enthesitis Index (median) | 1.0 (IQR 0.0-2.0) | 1.0 (IQR 0.0-2.0) |
| PASI score (median) | 2.7 (IQR 0.6-6.0) | 3.9 (IQR 0.6-6.7) |

SD = Standard Deviation; IQR = inter-quartile ranges; PASDAS = Psoriatic Arthritis Disease Activity Score; PASI = Psoriasis Area and Severity Index

A) To estimate the $ICC_{(3,1)}$ between two repeated readings of the PASDAS with a confidence interval of width 0.2, it was calculated that at least 31 participants would be needed (assuming an ICC of 0.85, based on a published estimate of ICC=0.87 for participant's global assessment of disease activity visual-analogue scale (VAS), which provides the greatest loading on the PASDAS score).

B) PASDAS mean scores reflected high disease activity levels.