Parkinson’s Disease Symptom Inventory (PDSI): a comprehensive and sensitive instrument to measure disease symptoms and treatment side-effects

Hogan T1, Grimaldi R2, Dingemanse J3, Martin M4, Lyons K5, Koller W5
1Health Economics Department, Novartis Pharma AG, Basel, Switzerland; 2Clinical Development Department, Novartis Pharma AG, Basel, Switzerland; 3Computer Consulting, Basel, Switzerland; 4Health Research Associates, Inc., Seattle, WA, USA; 5Kansas University Medical Center, Kansas City, Missouri, USA

Objectives:
To examine the psychometric performance of the PDSI in a small field test of 41 patients with Parkinson’s Disease.

Methods:
The Instrument
Items for inclusion in the PDSI were generated by expert opinion, reviews of the medical literature, and patient interviews. An instrument format suitable to the research objective was finalized after several layouts were designed and pilot-tested with patients. A validation study in a cross section of PD patients was then conducted to assess the psychometric performance characteristics of the instrument. Analysis for missing items, ceiling effects, low item-to-total correlations (suggesting irrelevant items), and high item-to-item correlations (suggesting redundancy) was used to reduce the 59-item PDSI to 51 items. The psychometric performance of this 51-item measure was then assessed.

Study Design
Forty-one clinic patients were enrolled in the study after being screened for the presence of fluctuating symptoms (by medical record review), and for mental sufficiency using Folstein’s Mini Mental State Exam (MMSE).

At the baseline clinic visit, a neurologist evaluated subjects using the Unified Parkinson’s Disease Rating Scale (UPDRS), a comprehensive assessment of the patient’s disease severity and functional status, yielding three domain scores (mentation, ADLs, and motor score) as well as a total score.

Participant’s impact of Parkinson’s Disease on their overall quality of life (QoL) was measured using the Parkinson’s Impact Scale (PIMS). The PIMS is a 10-item QoL measure specific to PD which elicits patient responses for, respectively, their ‘best’ and ‘worst’ periods for motor fluctuations. Scores for the PIMS were derived using published weights for both best and worst times. A higher score indicates lower QoL.

Subjects were also asked to self-report symptom frequency and associated levels of distress using this newly developed Parkinson’s Disease Symptom Inventory (PDSI). The PDSI yields two scores (symptom frequency and symptom distress) by summing all values and transforming them to a scale between 0 (no symptoms) and 100 (extremely severe).

Patients enrolled were also instructed to complete the PIMS approximately two weeks after the baseline visit.

This first analysis of the psychometric properties of the PDSI demonstrates a low patient burden, and relative ease of self-administration. Missing data was extremely low, and there were relatively few inappropriate responses. Psychometric evaluation of this 51-item measure demonstrated good internal consistency and acceptable reproducibility. Given both the strength and significance of the relationships demonstrated with convergent scales, the PDSI appears to be valid against other instruments that measure related domains. These results are from a pilot-study in a moderately severe and well functioning patient group. Additional research with the PDSI in a more severe population would be useful. It would also be informative to measure changes in symptoms and side-effects over time as treatment progresses. The PDSI might be a useful patient evaluation tool for helping to help clinicians assess and track the symptom-related disease status of patients.