

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

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Background:

Parkinson's Disease (PD) is a chronic, progressive neurological disorder associated with a selective degeneration of the dopaminergic pathway, resulting in reduced striatal dopamine. Clinical signs and symptoms include: tremor; rigidity; dyskinesias; and postural abnormalities. However, a variety of other motor and non-motor symptoms may also be present. No patient-based measure is available to assess the frequency and associated distress of a large array of PD symptoms and treatment side-effects. Accordingly, we designed, developed, and validated a comprehensive and sensitive instrument - the Parkinson's Disease Symptom Inventory (PDSI) - for use in drug evaluation studies.

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, 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 Parkinson's disease severity and functional status, yielding three domain scores (mentation, ADLs, and motor score) as well as a total score.

Measure:

Parkinson's Disease Symptom Inventory (PDSI)

Instructions

Please read the following list of symptoms that are commonly experienced by patients with Parkinson's Disease.

- Place a check mark [✓] in one of the boxes on the left to indicate how often you experience each symptom.
- After you indicate how often you experience each symptom, move to the boxes on the right and place a check mark [✓] in the box that best describes how much distress that symptom causes you.

How often do you experience each symptom?					Symptom	How much distress does this symptom cause you?				
None of the time	A little of the time	Some of the time	Most of the time	All of the time		Not at all distressing	A little distressing	Somewhat Distressing	Very Distressing	Extremely Distressing
					Difficulty starting movement					
					Reduced movement (less range of motion)					
					Hesitating or delayed movement					

The 51 items of the PDSI:

Difficulty starting movement	Decreased facial expression	Constipation
Reduced movement (less Range of Motion)	Slowness of speech	Stomach or abdominal pain
Hesitating or delayed movement	Soft or hoarse voice	Flatulence (gas)
Slow movement	Mumbling or slurred speech	Uncontrolled gestures
Sudden halting of movement	Difficulty swallowing	Hallucinations
Difficulty walking	Choking	Lack of concentration
Short quick steps	Excessive saliva (Drooling)	Forgetfulness
Shuffling when walking	Fatigue or tiredness	Confusion
Difficulty using arms or hands	Feeling drowsy or sleepy	Feeling angry or bitter
Difficulty writing	Difficulty falling asleep	Panic or anxiety
Difficulty with balance (falling)	Difficulty staying asleep	Feeling depressed, sad or blue
Stooping or slouched posture	Distressing dreams	Feeling tearful like crying
Tremors at rest	Pain or stiffness on awakening	Excessive sweating
Tremors with movement	Dizziness or light headedness	Difficulty to urinate
Rigidity or stiffness of muscles	Muscle cramps or spasms	Urgent need to urinate
Weakness of muscles or limbs	Heart palpitations	Vomiting
Aches or pains	Nausea	Diarrhea

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) derived by summing all values and transforming them to a scale between 0 (not at all) and 100 (most severe).

Patients enrolled in the study were re-evaluated using the PIMS approximately two weeks after the baseline visit.

Results:

Demographic Characteristics of the PDSI Sample (n=41)

Demographics	Mean (sd)
Age (years)	68 (10.8)
Diagnosed with PD (years)	11 (6.7)
	Percent
Gender	
Male	34
Female	66
Ethnicity	
White (non-Hispanic)	100
Marital Status	
Married or living as married	83
Widowed	12
Divorced	5
Income (annual)	
Under \$25,000	34
\$25,000 to \$49,000	12
\$50,000 and over	24
Missing	29
Education	
Elementary School	5
High School	51
College	27
Graduate and Professional School	17
Self Perceived Health	
Excellent	20
Very Good	39
Good	29
Fair	12

Internal Consistency and Test-Retest Reliability of the PDSI

Scale Identification	Alpha Coefficients (Cronbach's)
PDSI - Symptom Frequency	0.9229
PDSI - Symptom Distress	0.9348
	Intra-class Correlation Coefficient (ICC)
PDSI - Symptom Frequency	0.79
PDSI - Symptom Distress	0.72

Pearson's correlation coefficients (r values) of 51-item PDSI, the PIMS, and the UPDRS instrument components (baseline measures, n=41)

	PSI Distress	PIMS Best	PIMS Worst	UPDRS Mentation	UPDRS ADL	UPDRS Motor	UPDRS Total
PSI - Frequency	.83***	.69***	.67***	.65***	.60***	.29*	.56***
PSI - Distress		.73***	.72***	.54***	.44**	.28*	.46***
PIMS - Best Global			.92***	.51***	.59***	.29*	.53***
PIMS - Worst Global				.46***	.57***	.22	.47***
UPDRS - Mentation					.71***	.22	.63***
UPDRS - ADL						.47***	.86***
UPDRS - Motor							.85***

*** correlation is significant at the 0.001 level; ** correlation is significant at the 0.01 level; * correlation is significant at the 0.05 level

Discriminant validity of the 51-item PDSI, based on analysis of variance of groups with high and low instrument scores (baseline data; n=41)

Scale and ranges	PSI Frequency			PSI Distress		
	N	Mean (sd)	p-value	Mean (sd)	p-value	
UPDRS Mentation						
Score (0 - 1)	14	24.9 (12.3)*	P<0.000	20.9 (13.61)*	p=0.002	
Score (2 - 3)	19	32.0 (7.8)		30.9 (10.65)		
Score (4 - 10)	8	45.8 (11.4)		40.9 (12.52)		
UPDRS - ADL						
Score (0-11)	14	24.9 (10.8)*	P<0.000	23.0 (12.9)*	p=0.006	
Score (12-16)	15	30.4 (7.1)		27.6 (11.4)		
Score (17-27)	12	43.2 (12.6)		39.3 (13.0)		
UPDRS - Motor						
Score (0-22)	16	28.5 (12.3)	P=0.236	25.4 (12.5)	p=0.270	
Score (23-28)	12	33.0 (13.0)		30.2 (16.2)		
Score (29-42)	13	36.4 (11.5)		33.8 (12.6)		
TOTAL UPDRS SCORE						
Score (0-35)	14	25.4 (9.8)*	P=0.005	21.9 (12.7)*	p=0.012	
Score (36-48)	14	31.6 (10.0)		29.9 (12.1)		
Score (49-69)	13	40.4 (13.3)		37.1 (13.2)		
PIMS - Best Global Score						
Score (0 - 5.3)	14	20.7 (6.4)*	P=0.000	16.4 (6.1)*	p<0.000	
Score (5.4 - 13.2)	14	34.4 (7.1)		31.9 (9.7)		
Score (13.3 - 40)	13	41.5 (12.4)		39.7 (12.5)		
PIMS - Worst Global Score						
Score (0 - 6.5)	15	23.0 (8.2)*	P<0.000	17.8 (8.7)*	p<0.000	
Score (6.6-20.2)	13	32.4 (10.7)		32.2 (11.4)		
Score (20.3-40)	13	42.9 (9.7)		40.2 (10.7)		

* statistically significant difference in means versus the high score group, as per the F-statistic

Conclusion:

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.