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Validation of an Ambulatory Capacity Measure in Parkinson Disease: A Construct Derived from the Unified Parkinson's Disease Rating Scale

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Abstract

Background—A construct calculated as the sum of items 13, 14, 15, 29, 30 of the Unified Parkinson's Disease Rating Scale (UPDRS) has been used as an “Ambulatory Capacity Measure” (ACM in Parkinson disease (PD). Its construct validity has never been examined. A similar construct, consisting of the mean value of the same UPDRS items has been used under the acronym PIGD as a measure of postural instability and gait disorder in PD.

Objective—To examine the construct validity of the ACM and PIGD in PD.

Methods—We analyzed data in an existing database of 340 PD patients, Hoehn and Yahr stages (HYS) 1–5 who participated in a study of falls. Number of falls (NOF) was recorded over 4 weeks, and UPDRS (mental, ADL, and motor subscales), HYS, Activities Based Confidence Scale (ABC), Freezing of Gait Questionnaire (FOG), Five Times Sit-to-Stand (FTSS), Timed Up-and Go (TUG), Gait Velocity (GV), and Berg Balance Scale (BBS) evaluations were performed. Internal consistency was assessed by Cronbach's alpha. Construct validity was assessed through correlations of the ACM and PIGD to these measures and to their summed-ranks. A coefficient of determination was calculated through linear regression.

Results—Mean age was 71.4, mean age at diagnosis 61.4 years; 46% were women; mean UPDRS subscale scores were: mental 3.7; ADL 15.7; motor: 27.1; mean ACM was 6.51, and mean PIGD 1.30. Cronbach's alpha was 0.78 for both ACM and PIGD. Spearman correlation

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CONFLICTS OF INTEREST

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coefficients between the ACM/PIGD and ABC, FOG, TUG, GV and BBS were 0.69, 0.72, 0.67, 0.58, and 0.70 respectively. Correlation between the ACM/PIGD and summed-ranks of HYS, NOF, ABC, FOG, FTSS, TUG, GV and BBS was high (Spearman $r=0.823$, $p < 0.0001$); 68% of the variability in the summed-ranks was explained by ACM/PIGD.

Conclusion—The ACM and the PIGD are valid global measures and accurately reflect the combined effects of the various components of ambulatory capacity in PD patients with HY stages 1–4.

Keywords

Idiopathic Parkinson Disease; Ambulation; Scales; Balance; Falls; PIGD; Ambulatory Capacity

INTRODUCTION

Ambulatory capacity is impaired in Parkinson disease (PD) as a result of the progression of the motor symptoms, apprehension, and fear of falling. Severe restriction and eventual loss of ambulatory capacity constitutes a major source of disability for PD patients, affecting activities of daily living, and may lead to falls and injuries, medical complications, increased medical costs, and ultimately institutionalization and death [1–4]. Developing an accurate measure of ambulatory capacity in PD has been challenging, because of the heterogeneity of causes and symptoms that may lead to its decline: bradykinesia may impair the individual's ability to rise from the seated position, while freezing may interfere with effectiveness of ambulation and leads to falls. The loss of postural reflexes impairs the patient's ability to prevent a fall once their static or dynamic balance has been perturbed, while an increasing number of falls may undermine the patient's confidence in their own abilities. The combined effect of these processes is ultimately wheelchair-bound status [5].

The NIH Exploratory Trials in Parkinson Disease Long-Term Study 1 (LS-1) [6] was designed as a 5-year double blind, placebo controlled trial to examine the disease-modifying potential of creatine in PD. As a primary outcome measure it utilizes a composite measure that takes into account ambulatory capacity, activities of daily living, cognitive status, and global disability. Ambulatory capacity was measured in LS-1 using a construct (Ambulatory Capacity Measure – ACM) derived as the sum of the scores of the Unified Parkinson's Disease Rating Scale (UPDRS) items 13 (falling), 14 (freezing), 15 (walking), 29 (gait), and 30 (postural stability). A higher score reflects a greater impairment of ambulatory capacity. A similar construct has been extensively used in the literature under the acronym PIGD (for Postural Instability – Gait Disturbance) [7], which is the average value of the same items from the UPDRS. Although inter-rater and test-retest reliability can be established on the basis of such assessments of the entire UPDRS done in the past [8–10], the ACM/PIGD's construct validity and internal consistency has never been demonstrated.

In defining the concept of ambulatory capacity, and as a first step towards assessing the ACM's construct validity, we accepted that ambulatory capacity depends on the degree of gait impairment, the amount of freezing of gait experienced by the PD patient, the frequency of falling, the balance impairment, and the patient's self-confidence and fear of falling. Since the PIGD has been used extensively in the literature, we elected to examine the

validity of both constructs simultaneously. Because of the similarity of the two constructs, when reporting and discussing analyses that were parallel or results that were identical for the two constructs we will use the combined acronym ACM/PIGD. However, it should be understood that two sets of analyses were performed in parallel, one set for each construct.

MATERIALS AND METHODS

Participants

We utilized data from the Gait and Balance Initiative (GABI) cohort made available by the Struthers Parkinson's Center (a convenience sample). The database contains data from 340 participants in a research study of falling in PD [11]. Participants were recruited from the outpatient PD population at the Struthers Parkinson's Center in a sequential fashion, regardless of history of falling. The experimental protocol was approved by The Institutional Review Board of the Park Nicollet Institute. All participants fulfilled the United Kingdom PD Society brain bank clinical diagnostic criteria for PD [12]. Patients with HYS between 1 and 5 were included. After providing informed consent, participants completed falls diaries over a period of 4 weeks, at the end of which they underwent a battery of assessments, including objective and self-reported measures of both motor and non-motor impairment. Relevant to the present analysis, the following data on measures of PD severity, motor function and mobility were extracted from the GABI database, and utilized for the assessment of construct validity of the ACM/PIGD: items 13, 14, 15, 29, and 30 of the UPDRS [13] to calculate the ACM/PIGD; Hoehn and Yahr state while ON (HYS) as a measure of disease severity [14]; number of falls in the preceding 4 weeks (NOF); Activities Based Confidence Scale (ABC) [15] as a measure of the subjects' confidence in their own ability to ambulate safely; Freezing of Gait Questionnaire (FOG) [16] as a measure of freezing; Five Times Sit-to-Stand (FTSS) [17, 18], Timed Up-and Go (TUG) [19, 20], Gait Velocity (GV) [21], as global measures of bradykinesia and overall mobility; and, Berg Balance Scale (BBS) [22,23] as a measure of balance. Briefly, all objective assessments took place in the ON state, according to standardized protocols. Subjects were asked to perform the requested tasks at a comfortable speed. For each test a single trial was allowed. Subjects were allowed to use a gait assistive device, if they did so routinely during the performance of their daily activities. A 10-meter walk was used for GV testing. All objective testing was performed by trained staff. With regard to the definition of fall, this was defined as an instance of loss of balance that ended with the subject at a lower level than the one intended (e.g. from standing to sitting or to the floor, or from sitting to the floor).

Approach and hypotheses

There is currently no "gold standard" for measuring ambulatory capacity in PD. One might argue that the concept of ambulatory capacity is vague and ill-defined. As mentioned earlier, we proposed that ambulatory capacity would depend on the degree of gait impairment, the amount of freezing of gait experienced by the PD patient, the frequency of falling, the balance impairment, and the patient's self-confidence and fear of falling. We hypothesized that there would be strong correlations between the ACM/PIGD and the individual objective and self-reported measures of freezing, falling, gait, and postural stability contained in the

GABI assessment battery. Since the ACM/PIGD construct consists of items that address these related, yet not completely overlapping components of mobility in PD, we expected that correlation of ACM/PIGD with the individual measures would be moderately high (Spearman correlation coefficient $r > 0.50$), whereas, the correlation between ACM/PIGD and a composite of the mobility measures was expected to be higher ($r > 0.75$).

Statistical analysis

Internal consistency of the ACM/PIGD was assessed by Cronbach's coefficient alpha. The construct validity of the ACM/PIGD was assessed by estimating (r) between the ACM/PIGD and other measures of mobility (HYS, NOF, ABC, FOG, FTSS, TUG, GV and BBS). The null hypothesis $H_0: r = 0.50$ was tested at alpha of 0.05 (one-sided) using Fisher's Z transformation. The signs of ABC, TUG, and GV were reversed, so that for all measures, as well as for the ACM/PIGD, higher scores would reflect a greater impairment. In order to assess the correlation of ACM/PIGD with all the mobility measures jointly, HYS, NOF, ABC, FOG, FTSS, TUG, GV and BBS were combined into a summed rank score following the approach for O'Brien's nonparametric Global Statistic Test (GST) [24]. Specifically, after coding each outcome in the same direction, each participant was ranked on each outcome (HYS, NOF, ABC, FOG, FTSS, TUG, GV and BBS). Next, the ranks were summed for each participant, and the correlation between the summed-ranks and ACM/PIGD was estimated with Spearman correlation coefficient. A linear regression of the summed-ranks as the dependent variable with the ACM/PIGD as the regressor variable was utilized in order to obtain a coefficient of determination (R^2).

RESULTS

Descriptive Statistics

Demographics, disease characteristics, and measures are summarized in Table 1. A total of 46% of participants were women. Only 7 participants had HYS 5 during ON. ACM/PIGD results were received from 329 of the 340 patients, and the proportions of missing data from ACM/PIGD (3.2%) were lower than the missing data for HYS, ABC, FOG, FTSS, TUG, GV and BBS (5.3–10.3%) and were higher than NOF (0.9%). Figure 1 shows the distribution of ACM scores: less than 10% people had ACM over 12 and 59.3% of people had ACM greater than 3 and less than 10. Distribution is not shown for PIGD, but similarly, less than 10% people had PIGD over 2.4 and 59.3% of people had PIGD greater than 0.6 and less than 2. Table 2 shows ACM/PIGD by year since diagnosis; the average and median ACM/PIGD score increases as number of years since diagnosis increases. Likewise, the average ACM/PIGD scores increase with age category (Table 3). Although ACM/PIGD scores approached a normal distribution, few participants demonstrated ACM/PIGD scores at the high end of the range (Figure 1). There was no evidence of either a floor or a ceiling effect.

Internal Consistency

Cronbach's coefficient alphas are presented in Table 4. The full scales for both ACM and PIGD demonstrated good internal consistency with an overall Cronbach's coefficient alpha of 0.78. To determine how much each item affects the reliability of the constructs,

Cronbach's coefficient alpha was calculated after deleting each individual item (UPDRS question 13, 14, 15, 29, and 30). The coefficient alphas calculated without the deleted variable decreased slightly as compared to the overall coefficient alpha, which suggests each item is moderately positively correlated with the other items. The corrected-item total correlation coefficients of each item with the total of the remaining items ranged from 0.52–0.61.

Construct Validity

Spearman correlations between the scores of the ACM/PIGD and HY, NOF, ABC, FOG, FTSS, TUG, GV and BBS are presented in Table 5. The correlation coefficient for ACM/PIGD and the comparison measures ranged from 0.45–0.72. The null hypothesis of $H_0: r = 0.50$ was rejected for the Spearman correlation between ACM/PIGD and ABC, FOG, TUG, GV and BBS. A positive correlation (Spearman $r = 0.823$, $p\text{-value} < 0.0001$) was found between the ACM/PIGD and summed-ranks of HY, NOF, ABC, FOG, FTSS, TUG, GV and BBS. In a simple linear regression, 68% of the variability in the summed-ranks of HY, NOF, ABC, FOG, FTSS, TUG, GV and BBS is explained by ACM/PIGD ($R^2 = 0.68$).

DISCUSSION

In this analysis, we demonstrate the construct validity and internal consistency of the ACM and PIGD constructs as measures of ambulatory capacity in PD patients in Hoehn and Yahr stages 1–4. Currently there is no gold standard for ambulatory capacity in PD, therefore we adopted a hypothesis-driven approach to the validation process: we hypothesized that the ACM/PIGD would show good correlations with objective and self-reported measures of overlapping, but not identical determinants of ambulatory capacity, and an even stronger association to a combination of these measures. Our analysis confirmed our hypothesis: as expected, the ACM and PIGD were highly correlated with HY, NOF, ABC, FOG, FTSS, TUG, GV and BBS. The majority of the scales were statistically significantly correlated with ACM and PIGD, by a correlation of more than 0.50, the pre-specified hypothesis. More to the point, the ACM and PIGD were highly correlated with the summed-rank of these comparison measures.

The overall Cronbach's alpha of ACM/PIGD (0.78) was within the range that is recommended in order to demonstrate good internal consistency, 0.70–0.90. [25,26]. A low Cronbach's alpha indicates lack of correlation between items of the scale suggesting that they should not be combined, whereas a very high Cronbach's alpha indicates redundancy [26]. The range of the overall Cronbach's alpha and the similarity of Cronbach's alpha calculated for each deleted item with the overall Cronbach's alpha, suggested that the ACM/PIGD is measuring a uni-dimensional construct [27].

Very few patients scored in the upper range of the ACM/PIGD, and no patient had an ACM score of 20 (or 4 for the PIGD construct), the maximum possible score. This may be the result of inconsistencies in the scaling of the individual items of the UPDRS as has been discussed previously [28], or due to floor effects of the individual UPDRS items comprising the ACM/PIGD. It would be intriguing to assess the validity of similar constructs derived from the Movement Disorders Society optimized version of the UPDRS [29].

Our analysis has the strength of analyzing data from a well characterized cohort of PD patients who were evaluated with many bedside measures of various aspects of the disease. These patients, spanning from HYS 1 to 4 represent early, moderate, and advanced stages of the disease. The lack of a sufficient number of participants in HYS 5 constitutes a limitation of the applicability of our conclusions. HYS 5 represents mainly non-ambulatory or minimally ambulatory patients, and, conceivably, their inclusion would not be likely to alter the findings. The distribution of HYS in this cohort, may not be typical for a cross-sectional sample of PD. Based on previous studies there appears to be an over-representation of HYS 3, and an underrepresentation of HYS 2 in the GABI cohort [30]. It is unclear, however, how this skew in the data could have had an impact on our conclusions. A further limitation is that because we used a convenience sample, we were not able to evaluate the ACM/PIGD against a different, and, possibly, more comprehensive battery of instruments measuring aspects of ambulatory capacity. The GABI cohort has focused on bedside assessments of gait and balance. It will be interesting in the future to evaluate ACM/PIGD against instrumented measures of gait, balance, and ambulatory activity [31, 32]. For the same reasons, we had to include the available self-reported measures as comparators for validation, which may arguably compromise the objectivity of the assessments. Inter-rater and test-retest reliability could not be determined in this analysis as we utilized a convenience cohort. Although such reliability can be presumed on the basis of previous validations of the UPDRS as a whole, the inter-rater and test-retest reliability of the specific construct will need to be further assessed.

We conclude that the ACM, a score comprised of UPDRS items 13, 14, 15, 29, and 30, and the PIGD, consisting of the average score of the same UPDRS items, are valid measures of gait and ability to ambulate for PD patients with HY stages 1–4.

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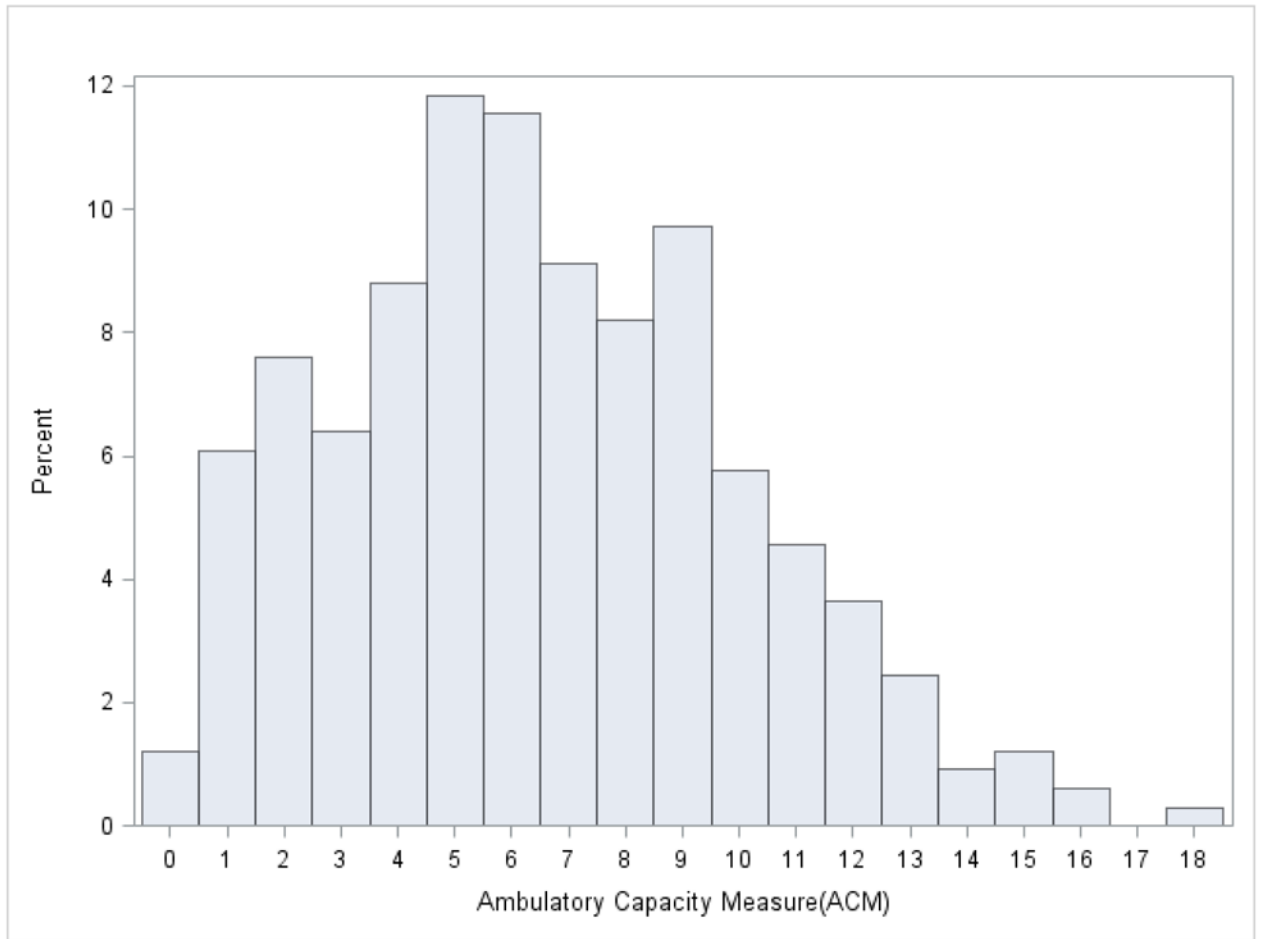


Figure 1.
Distribution of ACM scores in a sample of PD patients (N=329)

Table 1

Demographics and disease characteristics

Variable	N	Mean	Std Dev	25th Pctl	Median	75th Pctl
Age at diagnosis	340	61.40	11.50	54	61.5	70
Age at assessment	340	71.40	9.06	65.47	72.29	78.14
UPDRS mental	337	3.67	2.49	2	3	5
UPDRS ADL	338	15.73	6.65	11	15	20
UPDRS motor	328	27.07	11.12	19	27	35
HYS	320	2.63	0.98	2	3	3
NOF	337	2.13	4.90	0	1	2
ABC (%)	305	59.43	22.85	78.13	60.00	42.19
FOG	322	9.28	5.46	5	9	14
FTSS (sec)	313	19.47	12.27	13.1	16	22.4
TUG (sec)	313	16.53	11.19	10.31	12.5	18.83
GV (m/s)	314	0.99	0.31	1.24	1.00	0.76
BBS	316	43.38	11.78	53	48	37
ACM	329	6.51	3.53	4	6	9
PIGD	329	1.30	0.76	0.8	1.2	1.8

HYS	Frequency	Percent
1	65	20.31
2	34	10.63
3	183	57.19
4	31	9.69
5	7	2.19

Table 2

ACM and PIGD by year since diagnosis

Years since diagnosis	N	Mean	Std Dev	25th Pctl	Median	75th Pctl
ACM						
<5	86	5.24	3.36	2	5	7
5-9.9	112	6.39	3.32	4	6	9
10-14.9	63	6.92	3.63	4	7	9
15	68	7.91	3.48	6	8	10
PIGD						
<5	86	1.05	0.13	0.4	1	1.4
5-9.9	112	1.28	0.13	0.8	1.2	1.8
10-14.9	63	1.38	0.15	0.8	1.4	1.8
15	68	1.58	0.14	1.2	1.6	2

Table 3

ACM and PIGD by age at assessment

Age	N	Mean	Std Dev	25th Pctl	Median	75th Pctl
ACM						
<50	8	5.50	2.62	4	6	6.5
50-59	27	4.85	3.41	2	4	6
60-69	97	5.98	3.91	2	5	9
70-79	140	6.99	3.49	4	7	9
>=80	57	7.16	2.75	5	7	9
PIGD						
<50	8	1.10	0.10	0.8	1.2	1.3
50-59	27	0.97	0.14	0.4	0.8	1.2
60-69	97	1.20	0.16	0.4	1	1.8
70-79	140	1.40	0.14	0.8	1.4	1.8
>=80	57	1.43	0.11	1	1.4	1.8

Table 4

Cronbach's coefficient alphas for the ACM/PIGD

Overall Cronbach's Coefficient Alpha = 0.78	
Deleted Variable	Cronbach's Coefficient Alpha Without the Deleted Variable
UPDRS 13	0.75
UPDRS 14	0.75
UPDRS 15	0.74
UPDRS 29	0.72
UPDRS 30	0.75

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Table 5

Spearman correlations between the ACM/PIGD and other measures of ambulatory capacity

Variable	N	Correlation Estimate (<i>r</i>)	95% Confidence Limits on <i>r</i>	
FOG	314	0.72**	0.60	0.73
BBS	306	0.70**	0.67	0.77
ABC	298	0.69**	0.63	0.75
TUG	305	0.67**	0.64	0.76
GV	306	0.58*	0.50	0.65
HYS	312	0.50	0.35	0.53
NOF	327	0.48	0.39	0.56
FTSS	304	0.45	0.42	0.58

* The null hypothesis $H_0: r = 0.50$ was rejected at $p = .025$.

** The null hypothesis $H_0: r = 0.50$ was rejected at $p < .0001$.

The signs of ABC, TUG, and GV were reversed, so that for all measures, as well as for the ACM/PIGD, higher scores would reflect a greater impairment.