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TESTING BALANCE AND FALL RISK IN PERSONS WITH PARKINSON DISEASE, AN ARGUMENT FOR ECOLOGICALLY VALID TESTING

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Abstract

Introduction—Despite clear deficits in postural control, most clinical examination tools lack accuracy in identifying persons with Parkinson disease (PD) who have fallen or are at risk for falls. We assert that this is in part due to the lack of ecological validity of the testing.

Methods—To test this assertion, we examined the responsiveness and predictive validity of the Functional Gait Assessment (FGA), the Pull test, and the Timed up and Go (TUG) during clinically defined ON and OFF medication states. To address responsiveness, ON/OFF medication performance was compared. To address predictive validity, areas under the curve (AUC) of receiver operating characteristic (ROC) curves were compared. Comparisons were made using separate non-parametric tests.

Results—Thirty-six persons (24 male, 12 female) with PD (22 fallers, 14 non-fallers) participated. Only the FGA was able to detect differences between fallers and non-fallers for both ON/OFF medication testing. The predictive validity of the FGA and the TUG for fall identification was higher during OFF medication compared to ON medication testing. The predictive validity of the FGA was higher than the TUG and the Pull test during ON and OFF medication testing.

Discussion—In order to most accurately identify fallers, clinicians should test persons with PD in ecologically relevant conditions and tasks. In this study, interpretation of the OFF medication performance and use of the FGA provided more accurate prediction of those who would fall.

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Keywords

Balance; Falls; Parkinson Disease; Validity

Introduction

Persons with Parkinson disease (PD) demonstrate difficulty with multiple components of postural control when asked to self-impose or react to postural challenges in experimental paradigms.[1-3] These difficulties include, but are not limited to, delayed reaction time, hypometric preparatory adjustments, as well as bradykinesia and hypokinesia once movement begins. In addition, sensory integration in these patients may be impaired and may amplify postural control deficits.[3,4] These observed deficits in the laboratory form the foundation of the motor sign of postural instability in persons with PD.

The consequences of postural instability in PD are deficits in the ability to control the center of mass within the base of support during mobility in every day life. Such deficits often manifest themselves in near falls or falling episodes that result in at best, self imposed mobility restrictions, or at worst, fractures and mortality.[5,6] A challenge for clinicians is to accurately characterize the postural performance of persons with PD during their clinical encounters. Through the use of clinical balance tests, clinicians hope to identify those at risk for falls and direct preventative or rehabilitation services to decrease fall related injuries.

A variety of clinical examination tools are utilized for evaluating postural instability in PD. While the motor subsection of the Unified Parkinson Disease Rating Scale (UPDRS)[7] is used by clinicians to assess the motor signs and symptoms of PD, it has only one item that directly assesses postural responses (the Pull test). A strength of the overall UPDRS motor subsection is that it is utilized to contrast ON medication performance with OFF medication performance. The ON/OFF medication testing provides information regarding the variability of performance that persons with PD experience throughout their medication cycle. However, the Pull test only addresses one component of postural control by examining reactive balance responses. Neither the UPDRS motor subsection nor the Pull test consistently perform well in identifying fallers based on self reported fall history.[8-11]

Another clinical balance test that has not been validated in the PD population is the Functional Gait Assessment (FGA)[12]. The FGA is a revision of the Dynamic Gait Index (DGI)[13], which has been examined by several research groups in a PD specific sample and has been shown to have moderate levels of sensitivity and specificity that compare favorably with other clinical balance tests (Timed up and Go (TUG)[14] and Berg Balance Scale[15,16]).[17-19] An attractive feature of the FGA is the inclusion of items that require sensory integration during dynamic mobility tasks, such as head turns, walking with eyes closed, and walking backwards. The inclusion of such challenges may be discriminatory in terms of predicting falls in persons with PD by including sensory integration challenges, which may amplify their deficits.[3,4,20]

The FGA and other measures are typically used during medical or therapy appointments. Because of this, the majority of clinical balance examinations take place while persons are ON their dopamine replacement medications (Carbidopa / Levo-dopa, Trade names: Sinemet; Madopar). Given that persons with PD may encounter balance challenges in their everyday life during sub-optimal medication effects, an argument can be made for the potential of OFF medication testing being more accurate in terms of fall risk assessment. To our knowledge, there are no studies that have prospectively examined the responsiveness and predictive validity of clinical balance measures between ON and OFF medication

assessments as well as the validity of the FGA relative to other assessments of clinical balance performance of persons with PD.

In order to examine our research question that ecologically valid testing may be more valuable in examination of postural instability and fall risk in persons with PD, this study examined 3 specific objectives. These were: (1) to compare ON and OFF medication performance as well as the performance between those persons classified as fallers and non-fallers; (2) to examine the differences between ON and OFF medication balance performance testing to determine which condition had the most predictive validity in identifying fallers in a sample of persons with PD; (3) to examine the relative predictive validity of the FGA and other clinical balance tests in order to compare their performance in identifying fallers. Relative to objective 1, we hypothesized that clinical balance test performance when ON medication would exceed OFF medication performance and that non-fallers would perform better than fallers on each test. Relative to objective 2, we hypothesized that the fall prediction ability of OFF medication performance of clinical balance tests would exceed that of ON medication testing. Relative to objective 3, we hypothesized that because of its inclusion of dynamic tasks and environmental challenges, the FGA would have greater predictive validity for falls in persons with PD than other clinical balance tests.

Methods

Potential participants were a sample of convenience recruited through referral from local neurologists or through response to advertisement in a PD support group newsletter. Persons were considered for inclusion if they were over 40 years of age and had a neurologist confirmed diagnosis of idiopathic PD based on the United Kingdom Brain Bank criteria.[21] In addition, to be included potential participants had to be ambulatory, demonstrate clinical signs of gait hypokinesia, and have a mini-mental status exam score greater than 23 out of 30. Furthermore, potential participants had to be taking Carbidopa / Levo-dopa as an anti-Parkinson medication to provide a sample with significant clinical differences in the ON and OFF medication states. Potential participants were excluded if they had undergone surgical management of their PD, had uncontrolled motor fluctuations, or had any other medical conditions that affected their mobility and balance abilities. The inclusion / exclusion criteria as well as the sample size were determined in conjunction with a larger study of exercise effects on muscle and mobility function in persons with PD. The data presented here reflects data from participants that were being screened for participation in that larger study.

Procedures

Following recruitment, the purposes and procedures of the study were explained and all participants signed an institution approved informed consent form. After obtaining consent, demographics and disease specific variables were gathered from each participant. Testing of the motor subsection of the UPDRS and clinical balance tests were performed on one day. Participants were tested in a clinically defined OFF medication state after being off their anti-Parkinson medications for at least 12 hours. After completing OFF medication testing, participants took their medications and rested for 1 to 1.5 hours and were re-tested in a clinically defined ON medication state.

UPDRS and Clinical Balance Test Procedures

The motor subsection of the UPDRS and the clinical balance tests were conducted by one doctoral-trained physical therapist that had undergone standardized training in UPDRS and clinical balance testing. In conjunction with the UPDRS testing, a modified Hoehn and Yahr stage[22] was assigned.

Following completion of the UPDRS, participants performed the FGA and the TUG. For both the FGA and the TUG, participants performed the required tasks in an open, well-lit hallway without distractions. To perform the FGA, participants were tested in a standardized location as described in the original publication.[12] The FGA is comprised of 10 items each worth a maximum of 3 points for a total possible score of 30. Higher scores are indicative of more stability during specific balance tasks. Previous research has documented the validity of the FGA in people with vestibular disorders[12] as well as other neurologically impaired populations[23]. To perform the TUG, participants started sitting in a chair with a back. From this position, they were instructed on the word “Go” to stand up, walk out 3 meters from the chair, turn around, walk back to the chair and sit down as quickly as they could safely and without running. Performance was rated in seconds and participants were timed from the moment the rater said “Go” until they were seated again correctly in the chair with their back resting on the back of the chair. Previous research has established the reliability of this test as well as its sensitivity to medication states in persons with PD.[24]

Upon the completion of testing, contact information was confirmed with each participant. Participants were followed for at least 6 months following the initial testing. During the first 3 months participants were contacted on a weekly basis and for the second three months participants were contacted at the end of the study. Those participants that self-reported a ground-level fall 2 or more times within the 6 months following the initial testing were classified as fallers, while those participants who did not fall or only fell once were classified as non-fallers.

Data Analysis

All data was summarized and analyzed using SAS (SAS Institute Inc, Cary, NC) version 9.2 statistical analysis software and PASW Statistics (SPSS Inc, Chicago, IL) version 18. Demographic variables were summarized and represented as means, standard deviations, and 95% confidence intervals. In order to examine the responsiveness of clinical balance tests to medication condition, we compared ON and OFF medication performance using separate non-parametric tests for paired samples (Wilcoxon Matched Pairs tests). In order to examine the responsiveness of the clinical balance tests to fall status, performance differences between participants classified as fallers and those classified as non-fallers were compared using separate nonparametric tests for independent samples. Although the experiment wide level of significance was set at $p < 0.05$, to control for type I error risk, the overall alpha level for the tests for differences was adjusted using a Bonferroni correction ($0.05 / 9$ comparisons, therefore $p < 0.006$ was needed for significance on individual tests). In addition, measures of magnitude of effect (η^2) were reported.

In order to address the relative accuracy of ON medication versus OFF medication testing in terms of identifying fallers, we examined and compared receiver operating characteristic (ROC) curves of the clinical balance examinations in both medication conditions. Separate ROC curves were generated by plotting the sensitivity (true positive rate) along the Y-axis and 1- specificity (false positive rate) on the X-axis for all values of each clinical balance measure represented in the sample. The sensitivity and specificity values were calculated using the participants prospective fall history as the gold standard for diagnosis as a faller or non-faller. ROC curves can be thought of as a “signal to noise” comparison of a specific test. Tests that have ROC curves closer to the upper left corner of the plot maximize the signal to noise ratio and may have more clinical utility.[25] Lastly, the area under the curve (AUC) for the ROC curve was determined by calculating the Mann-Whitney two-sample rank measure of association statistic, as described previously.[26,27] Wald confidence intervals for the AUC were also calculated. The AUC was interpreted as the probability of correctly identifying the person with PD who was a faller from a randomly selected pair of patients and ranged from 0.50 (no identification ability) to 1.00 (perfect identification).

ability). To further understand these findings, we sought to find which medication condition and which test resulted in the largest AUC. The AUC values of each test were compared within each medication condition using non-parametric methods.[28] All tests of significance were two sided and the overall alpha level for the ROC comparisons was adjusted using a Bonferroni correction ($0.05 / 6$ comparisons, therefore $p < 0.008$ was needed for significance on individual tests).

Results

Thirty-six persons with PD were recruited and participated in this study without any loss of participants to follow-up. Modified Hoehn and Yahr ratings of the participants ranged from 1.5 to 4 when on their anti-Parkinson medications. Demographic characteristics of the sample are summarized in table 1. In confirmation of the overall positive effect of dopamine replacement medication on PD motor severity, the UPDRS motor subsection was significantly different between the ON and OFF medication conditions ($p < 0.006$).

Responsiveness of the tests to medication condition and faller/non faller classification

Without regard for fall classification, only the FGA and the Pull tests were significantly different between ON and OFF medication conditions (FGA ON mean (sd) 21.69 (7.61), FGA OFF mean (sd) 17.20 (7.25) $p < 0.006$; Pull test ON mean (sd) 0.94 (0.83), Pull test OFF mean (sd) 1.28 (0.74) $p < 0.006$). Upon dividing the overall sample into fall history categories, magnitude of effect size estimates indicated that the medication effect was stronger for the FGA than for the Pull test and the TUG.(Table 2)

When participants were segregated into medication condition, the FGA was significantly different between participants with a history of falls and those without a history of falls during ON and OFF medication testing ($p < 0.006$). TUG times were significantly different between fallers and non-fallers for only OFF medication testing ($p < 0.006$), while the Pull test results demonstrated no significant difference between fallers and non-fallers for both ON and OFF medication testing.(Table 2) Magnitude of effect size estimators indicated that the effect of fall history category was stronger for the FGA than the Pull test and the TUG. In addition, the fall history effect was larger for all tests in the OFF meds testing.

Relative accuracy of the clinical balance tests

In the OFF medication condition, the AUC for the FGA was significantly greater than the AUC for the Pull test ($p < 0.008$). Although the AUC of the FGA was greater than the TUG, these differences were not significant.

In the ON medication condition, while the AUC for the FGA was greater than the AUC of the TUG and the Pull test, these differences were not significant.

In both ON and OFF medication conditions, there was no difference between the AUC of the TUG and the Pull Test.(Table 3, Figure 1)

Discussion

This study sought to determine if ecologically valid testing may be more valuable in examination of postural instability and fall risk in persons with PD. This study examined 3 specific objectives. We hypothesized that OFF medication testing and a test which incorporated dynamic movement tasks and sensory integration challenges (the FGA) would be more robust relative to ON medication testing than other clinical balance tests. Our results suggest that the FGA was a more robust test in its ability to identify differences induced by medications or related to fall history and balance competence. In addition,

interpretation of the OFF medication performance appeared to provide a more accurate prediction of participants fall history than ON medication performance. Relative to which clinical balance test possessed the best relative predictive validity, our results suggest that the FGA and the TUG had higher predictive validity than the Pull test in terms of fall prediction accuracy especially during the OFF medication condition.

Responsiveness of the Clinical Tests to Inter and Intra-subject Variations

From a clinical perspective, clinical balance tests are needed that focus on the mechanisms of PD postural instability, are responsive to changes in performance within individuals (e.g., from medication status or disease progression), and are responsive to differences between individuals (e.g., fallers versus non-fallers). In our sample, only the FGA and the Pull test were responsive to medication-induced variations in performance. These results represent initial evidence for the responsiveness of the FGA in a PD specific sample. The Pull test results are consistent with a recent report examining the pull test and a potentially more accurate variant (the Push and Release Test)[11]. However, upon closer examination, this statistical significance of the Pull test may lack clinical relevance because there was no difference in the median scores for the ratings participants could receive on the Pull test. Also, the magnitude of within group medication effects was consistently smaller for the Pull test compared to the FGA. In addition, the tests were not equivalent in their ability to distinguish between those participants with a history of falls and those without a history of falls. The FGA was the only test that demonstrated the ability to determine between fallers and non-fallers regardless of medication status. The theoretical advantage of the FGA over the TUG and the Pull test is that it assesses performance during a spectrum of ecologically relevant tasks that a person with PD may encounter in their daily life[29,30].

Utility of OFF Medication Clinical Balance Examinations

Unless explicitly asked, most persons with PD will schedule office clinic visits at optimal medication periods and are tested in an environment where obstacles are minimized to decrease fall risk. Because of these intrinsic and extrinsic factors, persons with PD are generally examined in situations that lack ecological validity to the postural stresses, sensory integration, and variations in motor performance that they may experience in the community.

In the context of clinical balance examination, this lack of ecological validity may lead the clinician to a false sense of security. Based on the ROC analyses performed in this study, clinicians would be more accurate (meaning reduced false negatives and false positives) in their fall prediction decisions by examining clients during OFF medication periods. Theoretically, if 100 persons were tested ON and OFF medications with the FGA or TUG, 8-12 more persons would be accurately identified as fallers or non-fallers by testing in the OFF medication state. During this research, participants were tested in a functionally defined “OFF medication” state (after being OFF dopamine replacement medications for 12 hours). Such rigorous constraints may not be necessary in clinical practice if clients take multiple doses per day and examinations can be scheduled at the end of a given medication dosage window. These results are in agreement with Valkovic et al who demonstrated increased AUC values during OFF versus ON medication comparisons of the Pull test and the Push and Release test. [11]

Limitations and Directions for Future Research

Despite the findings supporting the advantage of OFF medication testing and the utility of the FGA, these results should be interpreted with caution. The burden of ON and OFF medication testing was high therefore we have a limited sample size. In addition, evaluators were not blinded and since ON and OFF medication testing were completed on the same day

a practice effect should be considered in interpreting the results. Future research with larger samples, testing order randomization, and blinded evaluators is needed to more strongly validate the utility of OFF medication testing and the FGA in terms of prospective documentation of fall risk.

While OFF medication testing and potentially ecologically valid tests like the FGA may have clinical utility, they represent a myopic view of what is needed for accurate fall prediction. Further studies that examine the individual and combined utility of demographic, disease specific, and clinical tests are needed.[8,9,31]

Unfortunately, all currently available tests do not account for the frequency of exposure to postural stability challenges. Treatment with dopamine replacement may improve gait and mobility and therefore may increase the exposure to postural stability challenges without improvements in postural responses.[32,33] Development of a test that was robust enough to withstand medication induced variations in performance as well as account for exposures would be an improvement over current testing tools and methods.

Lastly, this study included only those persons currently taking dopamine replacement medications. While such a cohort may reflect persons who have progressed to a moderate disease severity, persons with Hoehn and Yahr stage 1 and stage 5 were excluded for participation.

Summary and Conclusions

A constant challenge for clinicians is to accurately predict the fall risk of persons with PD during their clinical encounters. This study examined the FGA, TUG, and found that regardless of the test administered, interpretation of the OFF medication performance provided more accurate prediction of fallers than ON medication performance. As an isolated examination within the motor subsection of the UPDRS, the Pull test was less accurate as a predictor of falls compared to the FGA and the TUG. Additionally, the spectrum of postural tasks inherent to the FGA appeared to result in improved accuracy in fall prediction compared to the TUG. These results argue for the consideration of ecologically valid testing when examining persons with PD who may be at risk for falls.

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Figure 1.
ROC Curves for FGA, TUG, and Pull test for ON (A) and OFF (B) medication conditions.
Test curves above the reference line indicate a screening test that has better predictive ability
than a random choice.

Table 1

Participant Demographics

Variable	Fallers (n=22)	Non-Fallers (n=14)
Gender		
Male	14	10
Female	8	4
Age (years)		
Mean	70.95	66.64
SD	11.41	10.05
95% CI	65.89-76.01	60.84-72.45
Duration of PD (years)		
Mean	8.18	4.64
SD	4.58	3.25
95% CI	5.78-10.33	4.11-8.75
UPDRS Motor Subsection (ON/OFF)		
Mean	17.00 / 27.29	11.57 / 25.36
SD	8.07 / 7.96	6.43 / 9.99
95% CI	12.98-21.01 / 23.20-31.39	4.11-8.75 / 19.59-31.12
Modified Hoehn & Yahr Staging (ON / OFF)		
Median	2.5 / 3	2.25 / 2.5
Range	1.5-4 / 2.5-4	1.5-2.5 / 1.5-3

Table 2
Between Medication Condition and Between Group Comparisons of Individual Clinical Balance Tests

Variable	Fallers (n=22)		Non-Fallers (n=14)		Between Group ES
	Mean (SD)	95% CI	Mean (SD)	95% CI	
FGA (0-30)					
ON Meds	18.77 (8.38)*	15.06-22.49	26.29 (2.33)	24.94-27.63	0.24
OFF Meds	13.67 (6.93)*	10.51-16.82	22.50 (3.63)	20.40-24.60	0.38
Within Group ES	0.47		0.75		
TUG (sec)					
ON Meds	12.21 (7.42)	8.92-15.50	7.94 (2.15)	6.70-9.19	0.11
OFF Meds	15.5 (11.03)*	10.55-20.59	8.13 (2.34)	6.77-9.48	0.16
Within Group ES	0.15		0.03		
Pull Test (0-4)					
ON Meds	1.00 (0.91)	0-3	1.00 (0.51)	0-1	0.13
OFF Meds	1.00 (0.80)	1-3	1.00 (0.48)	0-2	0.15
Within Group ES	0.25		0.36		

Note: ES= Effect size, all ES expressed as η^2 .

* = significant difference between fallers and non-fallers within a medication condition ($p < 0.006$)

Table 3

Area Under the ROC curves for the Individual Clinical Tests

Variable	AUC	(95%CI)
Functional Gait Assessment		
ON Meds:	0.81	(0.66-0.95)
OFF Meds *:	0.89	(0.78-0.99)
Timed Up and Go		
ON Meds:	0.68	(0.51-0.86)
OFF Meds:	0.80	(0.65-0.95)
Pull Test		
ON Meds:	0.69	(0.54-0.84)
OFF Meds:	0.67	(0.54-0.79)

AUC = Area under the Receiver Operator Characteristic Curve

* = AUC of FGA OFF medications significantly greater than Pull test OFF medication (p<0.05)