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Functional capacity components do not predict fall risk in people with Parkinson's disease

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HIGHLIGHTS

- PwPD fallers and non-fallers have similar functional capacity performance.
- Functional capacity components (alone and combined) did not predict fall risk in PwPD.
- PwPD fallers of this study may be an unusual segment of this population.

ABBREVIATIONS

AUC	Area under the curve
BBS	Berg Balance Scale
BQHPA	Baecke Questionnaire of Habitual Physical Activity
CI	Confidence interval
H&Y	Hoehn & Yahr
LED	Levodopa equivalent daily dose
MMSE	Mini-Mental State Examination
PwPD	People with Parkinson's Disease
ROC	Receiver Operating Characteristic
STS	Sit-to-stand
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
TUG	Time Up and Go
UPDRS	Unified Parkinson's Disease Rating Scale
6-MWT	Six-Minute Walk Test

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BACKGROUND: Falls are an impactful problem for people with Parkinson's disease (PwPD), impairing the functional capacity and quality of life. Although some predictors of fall risk have been evidenced, the investigation of functional capacity components individual and combined is needed to a more detailed approach to identify fall risk prediction.
AIM: To verify the ability of individual and combined functional capacity components in predicting fall risk in PwPD.
METHOD: Ninety-six individuals participated in this cohort study. Functional capacity was assessed by Berg Balance Scale, Timed Up and Go, Six-Minute Walk, and Sit-to-Stand tests. The participants who fell at least once during the prospective follow-up of 12 months were considered fallers. A trained evaluator registered the fall's occurrence weekly. Mann-Whitney U, t-tests, and chi-square tests were used to compare fallers versus non-fallers. Receiver Operating Characteristics curves of functional capacity components (individual and combined) were performed to predict fall risk.
RESULTS: Thirty-six (37.5%) PwPD were classified as fallers, being recorded 56 falls, and 60 (62.5%) as non-fallers. There are no differences in functional capacity components between groups. The combined functional capacity components were not able to predict fall risk in PwPD (area under the curve = 0.52; p = 0.77). These components were also unable to predict fall risk when analyzed individually.
CONCLUSION: Our results indicated that functional capacity components, individual and combined, are not good predictors of fall risk in PwPD. The multifactorial characteristics of falls and the falls classification might affect the fall risk prediction and should be further investigated.

KEYWORDS: Neurodegenerative disease | Clinical tests | Falls prediction | Movement disorders

INTRODUCTION

Fall occurrence is a common problem for people with Parkinson's disease (PwPD) that can appear early after the disease diagnosis and becomes more common as the disease progresses [1]. Approximately 60% of PwPD fall at least once a year and 39% fall recurrently (>1 fall) [2]. Common consequences related to fall occurrence are the fear of falling and the loss of independence [3]. Indeed, evidence suggests that 22% of falls resulted

in physical injuries [4]. Additionally, a recent meta-analysis demonstrated that infections (e.g., urinary and pneumonia), worsening of disease motor impairments (e.g., rigidity and postural instability) and falls are the three main causes of hospitalization in PwPD [5]. Thus, identifying predictors of fall risk is one important step to avoid falls or minimize their consequences in PwPD.

A challenging aspect in the identification of fall-related factors is its multifactorial characteristic. Among the causes, deficits in functional capacity, such as in the level of strength [6], static and dynamic balance [7,8], functional mobility [9,10], and walking capacity [6,9] (assessed by maximum voluntary contraction, Berg Balance Scale (BBS), Timed Up and Go (TUG), Dynamic Gait Index and gait analysis by accelerometry, respectively) can reflect higher fall risks. Although individual functional capacity components can be related to falls, the fact that falls normally occur during complex motor tasks indicates that falls might emerge from the interaction in deficits in multiple components combined [2]. Therefore, it seems relevant that functional capacity components individual and combined can be used to predict fall risk. Indeed, evidence supports those functional capacity components as predictors of fall risk (e.g., functional mobility, static and dynamic balance, walking capacity, and functional lower limb strength) in prospective studies. For instance, as indicated by area under the curve (AUC), the TUG showed low to moderate accuracy (AUC ranged from 0.63[10] to 0.72[9]) in predicting fall risk. In the same way, the BBS showed low to moderate accuracy to predict fall risk in PwPD (AUC ranging from 0.60[10] to 0.87[7]). Previous studies that investigated the predictive accuracy of combined balance outcomes, such as BBS, Mini-BESTest, Functional Reach Test, and TUG (maximum of two outcomes per model) showed similar results [8,9]. Although investigated, the literature about combinations of functional capacity components as predictors of fall risk is scarce, making the integrative perspective of multifactorial involvement of several functional capacity components on falls difficult. Considering that such deficits in functional capacity components (alone and combined) in PwPD reflect impairments in postural and gait control tasks [3] and, probably, increases the fall risk, keeping such components well maintained might reduce the risk of falls.

Therefore, this study aimed to verify the ability of individual and combined functional capacity components in predicting fall risk in PwPD. We expected that both individual and combined functional capacity components can predict fall risk. However, since the combination of functional capacity components would integrate more elements potentially involved with falls, we hypothesize that combined vs. individual functional capacity components would have higher predictive accuracy.

METHODS

Participants

Analysis in Medcalc Statistical Software version 20.014 (Ostend, Belgium) indicated that at least 72 participants would be needed to obtain an AUC of 0.7 (minimum value for moderate prediction). The other input values were beta (0.2), alpha (0.5), and the ratio of sample in non-fallers and fallers (2). Thus, 108 PwPD from the community-dwelling were selected to participate in this study from the database at the Posture and Gait Studies Laboratory at Sao Paulo State University (UNESP), Institute of Biosciences, Rio Claro, Brazil. Participants were included if they had a Parkinson's disease diagnosis

confirmed by a neurologist according to UK Brain Bank Criteria [11], and were aged > 60 years. Participants were excluded if they presented impairments that impossibilities the performance of the test, scores on the modified Hoehn & Yahr scale (H&Y) [12] > 3, and indicative signs of dementia (score <20 points on the Mini-Mental State Examination - MMSE) [13]. The research ethics committee from UNESP approved the study (CAAE: 52534316.1.0000.5465). All participants were informed and gave their consent before participating in the experimental procedures.

Study design

The study was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [14] checklist (supplementary material). We used a cohort design with a prospective follow-up of 12 months. This follow-up period was performed to investigate the occurrence of falls in PwPD and started after clinical, cognitive, and functional capacity assessments (described below). After the follow-up period, participants who fell at least once were considered as fallers and individuals do not fall were classified as non-fallers. Falls were determined as any unintentional displacement of the body to the ground or to a lower level without the ability to correct it on time [15]. A trained evaluator registered any fall occurrence weekly through personal interviews or by telephone contact. This approach was established to reduce the participant's reporting bias as much as possible. The participants visited the laboratory on two different days, a maximum of two weeks apart. Clinical and cognitive assessments were performed on the first day. We assessed the functional capacity components on the second day, in random order during the "ON" state of Parkinson's disease medication (approximately 1 hour after medication intake, as the optimal medication phase occurs within this period [16]) at the Posture and Gait Studies Laboratory.

Clinical and cognitive assessment

The motor severity of Parkinson's disease, the stage of disease, and cognitive level were assessed by the Unified Parkinson's Disease Rating Scale motor part (UPDRS III) [17], the modified H&Y scale [12], and the MMSE [13], respectively. An experienced and trained evaluator performed these assessments. Levodopa equivalent daily dose was calculated according to the Tomlinson et al. (2010) [18] suggestion. The physical activity level was assessed through the Baecke Questionnaire of Habitual Physical Activity (BQHPA) [19].

Functional capacity assessments

The BBS was performed to assess static and dynamic balance [20]. This assessment consists of 5 balance static tasks and 9 balance dynamics tasks (14 tasks in general). Each item is ranked by the evaluator on an ordinal scale from 0 (unable to perform) to 4 (performed easily). Thus, high scores indicate good balance performance (maximum of 56 points).

The TUG was performed to evaluate functional mobility [21]. This test involves rising from a chair, walking 3 m, turning around a cone, walking back to the chair, and sitting down. The participants were instructed to complete the test as quickly and safely as possible without running. A stopwatch was started after the evaluator said "go" and was stopped at the end of the task (when the participant back to sit down on the chair). The

evaluator verbally encouraged the individuals during the test. The functional mobility performance was determined by the time to complete the task (in seconds). Thus, less time to perform the task represents great functional mobility. Three trials were performed, and the mean of the trials was considered for analysis.

The Sit-to-stand test (STS) was used to assess the functional lower limb strength[22]. Participants were instructed to completely stand up (knee and hip fully extended) from a standard chair and sit down back as quickly as possible during 30 s, keeping their arms crossed in front of their chests. Repetition was considered invalid if the participant did not stand up completely from the chair. The evaluator verbally encouraged participants during the test. The number of valid repetitions was registered. A higher number of repetitions indicates good functional lower limb strength.

The six-minute walk test (6-MWT) was used to evaluate the walking capacity [23]. Participants were instructed to walk over a 30-m pathway for 6 min. The distance was measured (in meters) in which great distances indicate good walking capacity. The individuals were verbally encouraged by the evaluator during the test and could stop walking if they needed. Marks every 3 m in the 30-m pathway were made to calculate the exact distance traveled.

Statistical analysis

The normality of quantitative variables was verified by Shapiro-Wilk tests. Student's t-tests for independent samples (normal data) and Mann-Whitney U tests (non-normal data) were performed to compare the clinical, cognitive, and functional capacity components between PwPD fallers and non-fallers. We conducted Pearson's Chi-Square tests to verify differences in sex between PwPD fallers and non-fallers. Receiver Operating Characteristic (ROC) curve analysis was used to test the performance of functional capacity components in predicting fall risk. The sensitivity, specificity, and AUC of each outcome (individual and combined) were calculated. The outcomes were combined with the method suggested by Vitório [24]. The TUG scores were multiplied by -1 to be in the same order of magnitude (higher values = better performance) as the other outcomes in the ROC analysis. AUC shows the overall accuracy of the test, and if the p-value of ROC curves were significant, the values of AUC were interpreted as a chance result (< 0.5), low (0.5 – 0.7), moderate (0.7 – 0.9), and high (> 0.9) [25]. Also, a 95% confidence interval (CI) around AUC was computed. The cutoff point was determined by choosing the minimal value of the following equation [25]: $(1 - \text{sensitivity})^2 + (1 - \text{specificity})^2$. We intended to compare AUC's differences among individual and combined functional capacity components using the method proposed by Delong and colleagues [26], only if such components were identified as predictors by the ROC ($p < 0.05$). The SPSS version 22.0 (IBM Corporation, Armonk, New York, USA) was used for the statistical analysis and the level of significance was set at $p < 0.05$.

RESULTS

The flowchart (Figure 1) shows the information regarding the prospective follow-up period of the study and the final sample size. Initially, four participants were excluded from the study due to the indicative of dementia (n = 2) and did not perform clinical and cognitive assessments (n = 2). After the eligible criteria, eight participants were excluded

due to did not complete the prospective follow-up (loss of contact = 4, dropped out = 2, died = 2). Therefore, the final sample consisted of 96 PwPD, which included 36 participants considered fallers (37.5%), being recorded 56 falls, and 60 participants considered non-fallers (62.5%).

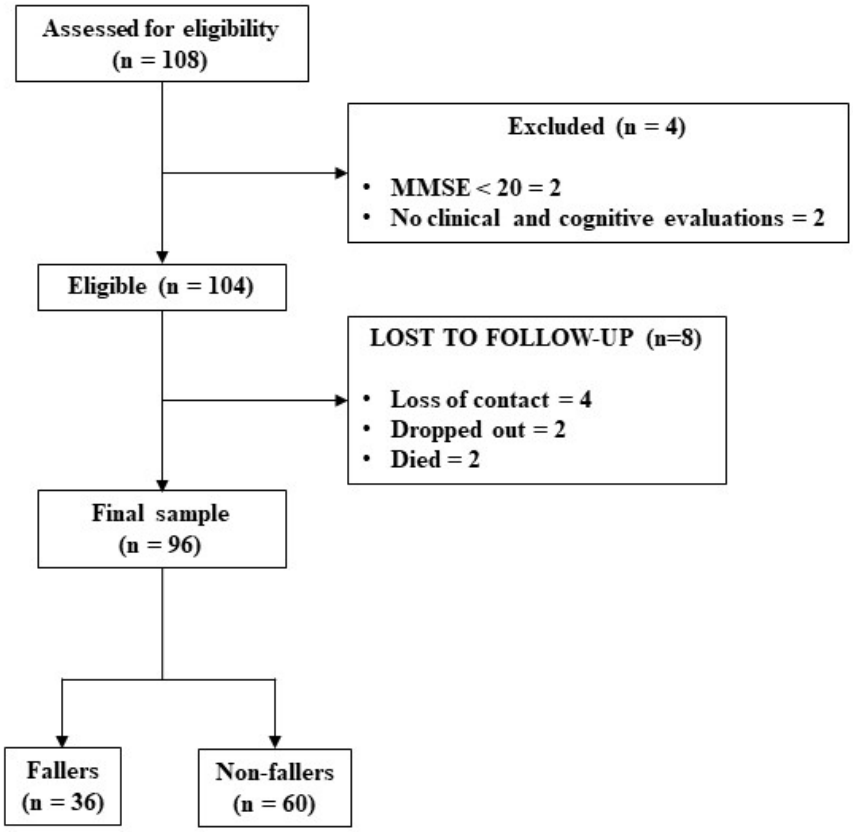

Figure 1. Flowchart of prospective 12-months follow-up of the sample.

Table 1 shows clinical, cognitive, demographic, and performance on functional capacity assessments for PwPD non-fallers and fallers. There are no differences in functional capacity components between fallers and non-fallers. In addition, the groups were similar in almost all characterization variables, except for the disease duration that was longer for fallers compared to non-fallers ($p = 0.02$).

Table 2 demonstrated the predictive ability of functional capacity components individually and combined. Analyzing individually, static and dynamic balance, functional mobility, functional lower limb strength, and walking capacity were not able to predict fall risk, with AUC values ranging from 0.50 to 0.53 (p-values from 0.58 to 0.96). Even after the combination of all outcomes, the functional capacity components were not able to predict fall risk in PwPD (AUC = 0.52 [95% CI = 0.38 – 0.66]; $p = 0.77$). Other combinations of the outcomes also did not improve the predictive accuracy (AUC range: 0.49 to 0.55, p range: 0.47 to 0.91). Figure 2 shows the ROC curves of individual functional capacity components. Figure 3 shows the ROC curves of a range of combinations of functional capacity outcomes. As individual and combined functional capacity components did not predict fall risk, we did not compare AUC's differences

between components.

Table 1. Characterization and performance in functional capacity assessments of people with Parkinson's disease non-fallers and fallers.

Variables	Non-fallers (n = 60)	Fallers (n = 36)	Significance
Sex			
Male	29 (48%)	17 (47%)	$x^2_{(1)}$ = 0.01; p = 0.92
Female	31 (52%)	19 (53%)	
Age (years)	70.52 ± 8.56	70.83 ± 7.44	$t_{(94)}$ = -0.18; p = 0.85
Body mass (kg)	66.95 (62.40 – 75.20)	67.90 (63.30 – 73.05)	U = 1076.50; p = 0.98
Body height (cm)	162.15 (154.40 – 168.00)	160.10 (156.75 – 166.50)	U = 1040.50; p = 0.76
MMSE (0-30)	27 (25 – 29)	27 (25 – 28)	U = 998.00; p = 0.53
UPDRS III (0-108)	30.33 ± 12.98	29.11 ± 11.34	$t_{(94)}$ = 0.468; p = 0.64
H&Y scale stages			
1	3 (5%)	0 (0%)	
1.5	4 (7%)	2 (6%)	
2	30 (50%)	25 (69%)	U = 1008.50; p = 0.54
2.5	18 (30%)	6 (17%)	
3	5 (8%)	3 (8%)	
Disease duration (years)[&]	4 (3 – 5)	6 (4 – 8)	**U = 610.00; p = 0.02**
Levodopa equivalent daily dose (mg/day)	525.00 (350.00 – 712.50)	593.75 (268.75 – 950.00)	U =819.50; p = 0.52
BQHPA[#]	3.70 (1.93 – 6.70)	4.29 (1.75 – 5.50)	U = 644.50; p = 0.81
BBS (0-56)	54 (51 – 56)	54 (51 – 55)	U = 781.50; p = 0.58
TUG (s)	7.33 (6.65 – 9.11)	7.31 (6.22 – 9.45)	U = 953.50; p = 0.87
STS (repetitions)	15.73 ± 5.51	15.62 ± 4.89	$t_{(88)}$ = 0.10; p = 0.92
6-MWT (m)	432.00 (368.55 – 495.00)	452.30 (372.00 – 486.00)	U = 1018; p = 0.91

Data are presented as mean ± standard deviation for parametric variables, median (25 – 75 quartiles) for non-parametric variables, or the number of individuals (%). Bold font indicates the difference between groups. Abbreviations: BBS, Berg Balance Scale; BQHPA, Baecke Questionnaire of Habitual Physical Activity; LED, Levodopa equivalent daily dose; MMSE, Mini-Mental State Examination; STS, Sit-to-stand test; TUG, Timed Up and Go test; UPDRS III, Unified Parkinson's Disease Rating Scale motor part; H&Y, Hoehn & Yahr; 6-MWT, Six-minute walk test.
Note: [&]sample size for this variable = 86; [#]sample size for this variable = 75. Data of these participants are missing due to a lack of registration during the clinical assessment.

Table 2. Predictive values of individual and combined functional capacity components.

Outcomes	Cutoff point	AUC (95% CI)	Sensitivity	Specificity	p-value
BBS (n = 84)	52.50	0.53 (0.41 – 0.66)	0.42	0.66	0.58
TUG (n = 92)	7.67	0.51 (0.39 – 0.64)	0.48	0.56	0.83
STS (n = 90)	15.50	0.50 (0.38 – 0.63)	0.56	0.41	0.96
6-MWT (n = 94)	402.11	0.51 (0.39 – 0.62)	0.37	0.68	0.91
TUG + BBS (n = 79)	1.50	0.53 (0.40 – 0.67)	0.65	0.40	0.61
TUG + 6-MWT (n = 90)	0.50	0.53 (0.40 – 0.66)	0.38	0.74	0.65
TUG + STS (n = 87)	2.50	0.52 (0.39 – 0.65)	0.68	0.38	0.76
BBS + 6-MWT (n = 82)	1.50	0.52 (0.39 – 0.67)	0.53	0.48	0.70
BBS + STS (n = 78)	1.50	0.52 (0.39 – 0.65)	0.68	0.32	0.75
STS + 6-MWT (n = 88)	0.50	0.49 (0.36 – 0.62)	0.30	0.74	0.91
TUG + BBS + 6-MWT (n = 78)	1.50	0.52 (0.39 – 0.65)	0.41	0.61	0.75
TUG + BBS + STS (n = 75)	1.50	0.55 (0.41 – 0.68)	0.54	0.58	0.47
TUG + 6-MWT + STS (n = 88)	2.50	0.52 (0.39 – 0.65)	0.67	0.36	0.77
BBS + 6-MWT + STS (n = 76)	1.50	0.49 (0.35 – 0.63)	0.37	0.65	0.91
BBS + 6-MWT + STS + TUG (n = 73)	2.50	0.52 (0.38 – 0.66)	0.52	0.52	0.77

Abbreviations: AUC, area under the curve; BBS, Berg Balance Scale; CI, confidence interval; SIT, Sit-to-stand test; TUG, Timed Up and Go test; 6-MWT, Six-minute walk test.
Note: Combined variable indicates the combination of the four functional capacity outcomes (e.g., BBS, TUG, STS, and 6-MWT).

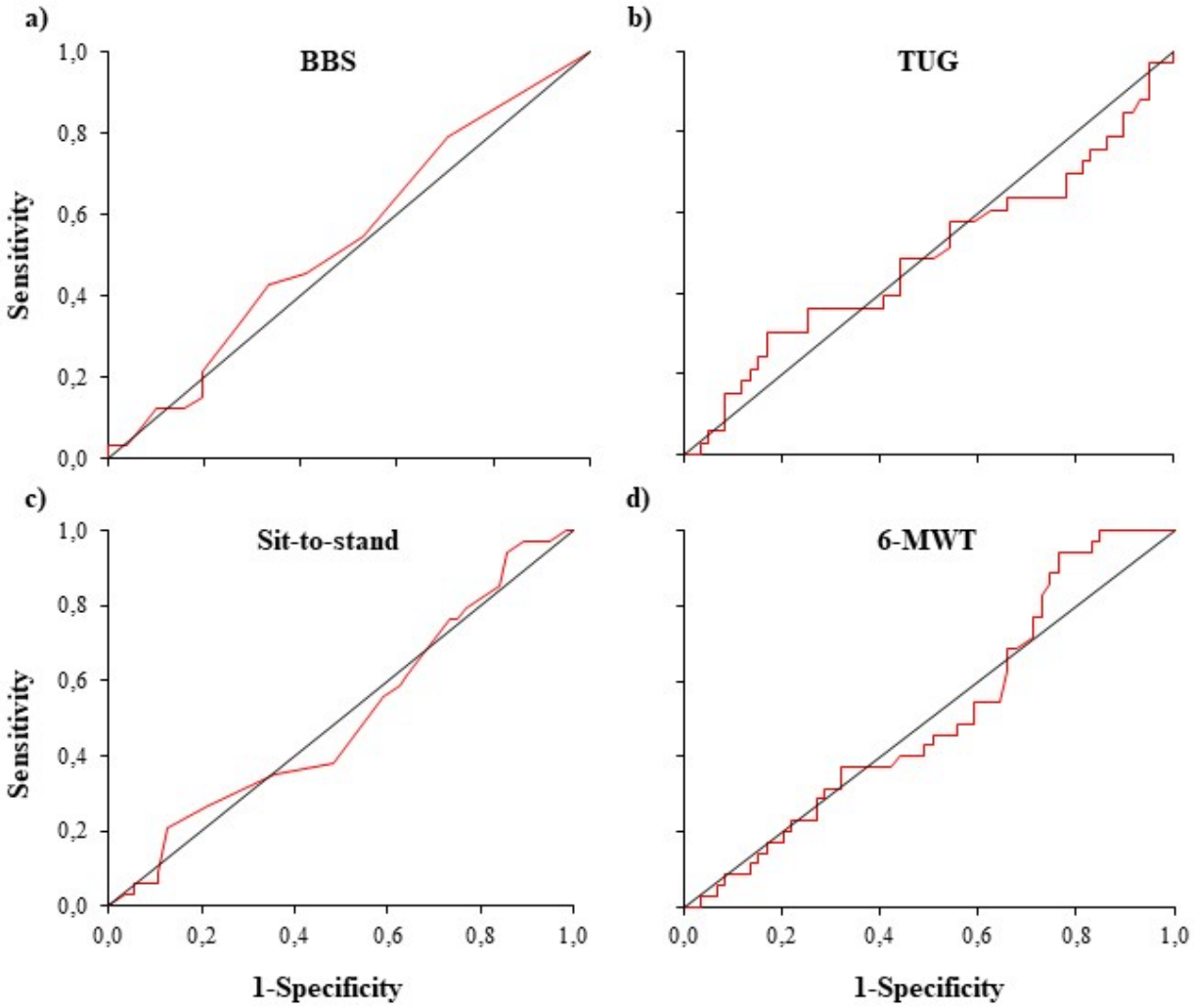

Figure 2. Receiver Operating Characteristic curves for individual functional capacity components (a-d).

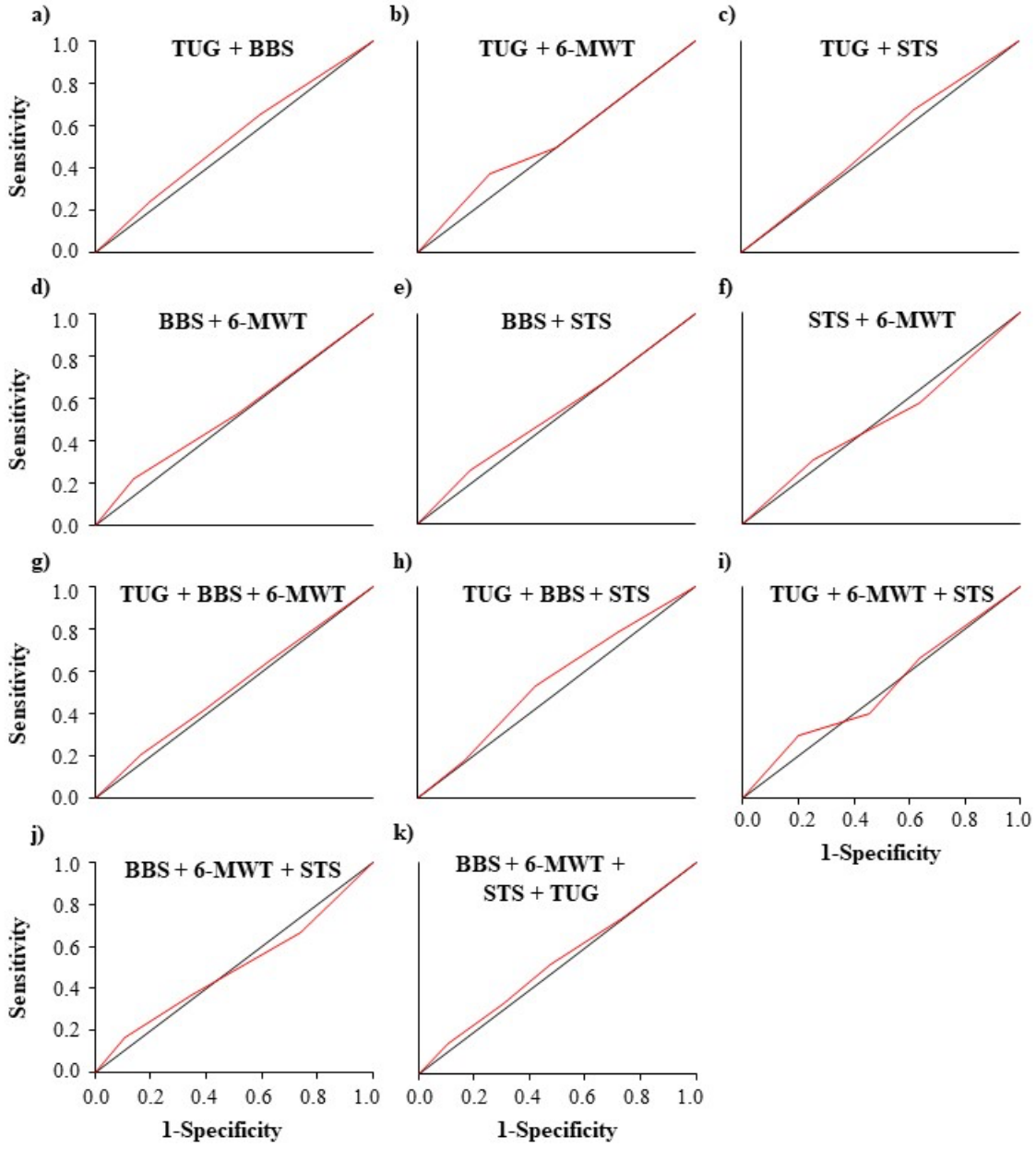

Figure 3. Receiver Operating Characteristic curves for different combinations of functional capacity outcomes (a-k).

DISCUSSION

The study aimed to verify the ability of individual and combined functional capacity components in predicting fall risk in PwPD. Individually, static and dynamic balance, functional mobility, functional lower limb strength, and walking capacity did not predict fall risk in a prospective follow-up of 12 months. When combined, these components were also not sensible to predict fall risk. In addition, the performance on functional capacity outcomes was similar between PwPD fallers and non-fallers. However, fallers demonstrate

a longer disease duration than non-fallers. Our results suggest that identifying PwPD at imminent risk of falls by functional capacity outcomes (individual or combined) may be difficult.

Contrary to our hypothesis, when analyzed individually, static and dynamic balance, functional mobility, walking capacity, and lower limb strength did not predict fall risk in PwPD. The results are somehow unexpected based on previous evidence showing that functional mobility [9,10], walking capacity [6,9] and balance [7,8] were able to predict fall risk in PwPD. Additional evidence also suggested that reduced lower limb strength is associated with a higher fall risk [6]. Therefore, it seems reasonable that the performance in BBS, TUG, 6-MWT, and STS would predict fall risk in PwPD. This observation is particularly supported by previous results indicating that fallers have more deficits in these components compared to non-fallers [6,8–10], which justifies the potential predictive accuracy of these components. Probably, the lack of consistency between our and previous studies is because that the performance of PwPD fallers in our vs. previous evidence. Specifically, while we observed that fallers scored 56 points in BBS and 7 seconds (approximately) in TUG, previous evidence indicated that fallers scored 47 points in BBS [8] and 12 seconds on TUG [6]. These inconsistencies between our findings and literature on functional capacity components, indicating a relatively well-maintained functionality in our fallers' population, may explain, at least partly, the lack of fall risk prediction. This idea is reinforced by our results indicating that PwPD fallers and non-fallers were similar in static and dynamic balance, functional mobility, walking capacity, and strength in this study (Table 1).

Reinforcing this argument, when combined, the functional capacity components were also not accurate in predicting fall risk (Table 2). The combination of different outcomes showed interesting results in fall risk prediction. For example, Schlenstedt and colleagues [8] demonstrated moderate accuracy in predicting falls risk in PwPD (AUC = 0.84) when combined specific BBS items with Mini-BESTest. Another recent study [9] combined many functional capacity outcomes, such as BBS and TUG, with self-report measures of fear of falling (e.g., Falls Efficacy Scale-International and Activities-specific Balance Confidence Scale) to verify fall risk prediction in PwPD. The authors suggested that the model composed with BBS and Falls Efficacy Scale-International were able to predict fall risk in PwPD (Akaike information criterion = 98) [9]. Thus, we attribute that perhaps combining functional capacity outcomes with other closely related fall measures (physical or cognitive) may be a more promising strategy to predict fall risk in PwPD.

The lack of fall risk prediction in our study, even when the functional capacity components were combined, sustain the need to consider recurrent instead of one fall on the classification of fallers. Our study classified as fallers the PwPD that fell at least only one time. However, the occurrence of only one fall may be an isolated event and not a signal of a significant impairment or disability in the daily life of participants. Thus, considering the occurrence of at least two falls to classify the PwPD as fallers, also called recurrent fallers, may be a good strategy as it represents more reliably the individual's current status than one fall. Another factor that should be highlighted is the low number of PwPD from our sample that fell after 12 months. A previous systematic review demonstrated that 60% of PwPD fell at least one time per year [2]. However, approximately only 38% of our sample presented at least one fall during the prospective follow-up. A possible explanation for this difference is the physical activity level of our sample since the fallers presented a higher physical activity level than non-fallers surprisingly. Besides, the

PwPD of our sample continuously participates in a physical exercise program (Physical Activity Program for Patients with Parkinson's Disease – PROPARKI/UNESP/Rio Claro) that also may have influenced the low number of fallers. This argument is reinforced by randomized clinical trials data showing positive effects of multidimensional exercise in falls reduction in PwPD [27]. The idea is that this modality of exercise by combining multi-factors that are impaired in PwPD would reflect in lower fall risk in this population. Also, the participation in the physical exercise program may explain the similar performance on functional capacity outcomes between PwPD fallers and non-fallers.

This study has some limitations. First, we did not use more objective posturography measures (e.g., center of pressure and center of mass outcomes), which can indicate a more sensible analysis of postural control and might predict fall risk. However, the outcomes used in this study are common and easy to apply in clinical practice in general populations, including PwPD. Second, the specific characteristics of our sample, such as the similarities of functional capacity components between PwPD fallers and non-fallers, prejudice the generalization of our findings. Thus, it is important to note that, considering the relatively preserved performance in functional capacity and the active involvement in a physical exercise program of our fallers participants, perhaps we assessed an unusual segment of PwPD fallers. We suggested that future studies should analyze the predictive accuracy of additional functional capacity outcomes, such as BESTest and Physical Profile Assessment, and combine these outcomes with objective measures of postural control (e.g., center of pressure outcomes), cognitive outcomes (e.g., executive function, attention), psychological state (e.g., fear of falling, depression) and/or with other aspects that might be related to the occurrence of falls. Future studies should also consider the population who experienced recurrent falls (2 or more), and from the overall community to have a more complete overview of functional capacity and falls risk.

CONCLUSION

Functional capacity components alone and combined did not predict fall risk in PwPD. Our conclusion should be carefully addressed since the participants that composed the PwPD fallers may not represent a usual, typical Parkinson's disease population of a faller, which is confirmed by lack of differences in functional capacity components when compared with non-fallers.

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