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ORIGINAL ARTICLE

Validation of the Freezing of Gait Questionnaire in patients with Parkinson's disease treated with deep brain stimulation

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Abstract

Background The Freezing of Gait Questionnaire (FoG-Q) is a fast and sensitive assessment tool for freezing (FoG).
Objective The objective of the study is for validation of a Czech version of FoG-Q. A further, explorative aim was to examine what FoG-Q indicates about the presence and severity of gait impairment in patients treated with DBS in their full OFF state.
Design The study was a cross-sectional validation study.
Methods We translated FoG-Q following standardized validation protocol. We assessed 35 patients with PD and STN DBS using history taking, UPDRS, Hoehn and Yahr staging, Mini Mental State Examination, Frontal Assessment Battery, FoG-Q, Short Falls Efficacy Scale International, and Beck Depression Inventory, Second Edition. UPDRS III, clinical and instrumental gait assessment, was repeated OFF MED/DBS OFF and OFF MED/DBS ON.
Results Internal consistency of FoG-Q was excellent ($\alpha = 0.91$) as well as convergent (significant correlations with UPDRS II item 14, UPDRS III item 29, several TUG parameters, and FoG Score) and divergent validity (no association with UPDRS I). OFF MED/DBS OFF, the total FoG-Q score correlated with UPDRS III items 29, 30, and PIGD subscore, step time variability, and negatively with step length and velocity.
Limitations Limitation of the study is a relatively small sample size.
Conclusions In conclusion, the Czech translation of FoG-Q is valid. With respect to gait and balance, FoG-Q does, to a certain extent, reflect the native state of the disease in patients treated with high frequency STN DBS.

Keywords Freezing · Gait · Parkinson's disease · Validation · Questionnaire

Introduction

Freezing of gait (FoG) is a paroxysmal gait disorder characterized by the inability to create effective stepping movements despite the intention to walk [1]. When FoG occurs, patients have physical impression that their feet are glued to the ground [2]. FoG accompanies a variety of diseases, including synucleinopathies like Parkinson's disease (PD) or multiple system atrophy, but also other conditions like progressive supranuclear palsy, normal pressure hydrocephalus, or vascular parkinsonism [3]. In PD, as the most common of these, FoG has been reported in up to 26% of the patients, even before the start of levodopa treatment [4], with its prevalence increasing up to 80% in advanced stages [3]. FoG is perceived by patients as a particularly disabling symptom that significantly affects their fall rates, levels of activity, and quality of life [5].

FoG is a precarious symptom for objective assessment, since even patients who subjectively report FoG often do not freeze when seen by their neurologist [6]. Therefore, subjective assessment methods such as the Freezing of Gait Questionnaire (FoG-Q) [7], the New Freezing of Gait Questionnaire (NFoG-Q) [8], or the self-administered version of the FoG-Q (FoG-Qsa) [9] still play a crucial role in establishing the occurrence of FoG. However, the current gold standard to definitely classify a patient as a "freezer" is the

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direct observation of FoG by an experienced examiner [10]. A more detailed objective analysis of FoG should be performed by 3 independent expert observers using a structured video assessment of complex gait tasks, including turns and walking in narrow space [11].

Since FoG-Q is well-validated [12], used worldwide [13–17], and recommended by the MDS Rating Scales Committee [18], it is a fast and sensitive tool for assessing FoG in clinical practice especially in combination with repeated full narrow turns. FoG-Q, originally developed by Giladi et al. [7], consists of six questions related to FoG and walking. The two questions that address gait difficulties in general (without specific regard to FoG) are in fact the most commonly reported weakness of this questionnaire, because they account for the possibility of false positivity in non-freezers [18].

FoG-Q has been shown to report about FoG as experienced by patients [12]. The most common is the OFF-related FOG [7, 11, 12]. However, not all patients with PD experience their full OFF state, i.e. those treated with deep brain stimulation (DBS) because their DBS is always ON. Therefore, one may wonder whether a low FoG-Q score necessarily indicates the absence of freezing in full OFF or not, and thus whether it distinguishes between freezers and non-freezers. Even though FoG-Q is commonly used in this population of patients, it has not, to our knowledge, been studied whether or what it indicates about the native state of the disease in advanced patients treated with DBS.

Therefore, the aim of the present study was to validate a Czech version of FoG-Q. A further, explorative aim was to examine what FoG-Q indicates about the presence and severity of gait impairment in case of patients treated with DBS in their full OFF state, i.e. medication (MED) OFF and DBS OFF.

Methods

Cross-cultural adaptation of the FoG-Q

We received authorization from N. Giladi to validate the scale and followed the standardized protocol by Beaton et al. [19]. The questionnaire was independently translated by two health professionals (OG and MH) native in Czech with good English language skills. Both versions were compared, and a consensus was reached with the help of other health professionals (HB and ER). The pre-final version was tested in 15 patients with PD for correct understanding by asking the patients how they understood each question. The pre-final version was translated back into English by a native English speaker with good Czech language skills who was not familiar with the original scale. The back-translation was then consulted with and authorized by N. Giladi. The final version (Appendix 1) was tested.

Patients

Thirty-five Czech-speaking patients with PD and implanted STN DBS were recruited from the Movement Disorders Centre of the university Department of Neurology. Inclusion criteria were a clinical diagnosis of PD according to UK Brain Bank diagnostic criteria [20], a Hoehn and Yahr stage of < 5 in the OFF state [21], variable severity of motor complications and/or gait disturbances as assessed by a movement disorders expert, and absence of severe cognitive impairment, i.e. a score above 24/30 on the Mini Mental State Examination (MMSE) [22]. Patients were excluded if they suffered from other serious neurologic or orthopaedic condition that could affect their gait, or severe sensory deficits such as blindness or peripheral neuropathy.

The study was approved by the Ethics Committee of General University Hospital in Prague (125/09). Written informed consent was obtained from all patients.

Clinical and instrumental assessment

The patients were first interviewed by a movement disorders specialist, and their demographic and clinical information was recorded using UPDRS I, II, and IV [23]; Hoehn and Yahr staging [21]; MMSE [22]; Frontal Assessment Battery (FAB) [24]; FoG-Q [7]; Short FES-I [25]; and Beck Depression Inventory, Second Edition (BDI-II) [26]. Afterwards, patients were examined OFF MED (withdrawal of dopamine agonist for 72 h, last dose of levodopa taken 12 h before the testing) with DBS ON and DBS OFF (90 min after turning STN-DBS OFF) by the same physician using UPDRS III [23] and clinical and instrumental gait assessment. These included Timed Up and Go test (TUG) [27], FoG Score [28], and walking 6 m on GAITRite carpet at normal speed. This examination was then repeated OFF MED with DBS ON. In the OFF MED and DBS OFF state, 11 patients were unable to complete the TUG test. The occurrence of FOG was directly observed by an experienced examiner.

Statistical analysis

Descriptive statistic methods were used to analyse the clinical and demographic characteristics of the participants.

Next, we verified whether the mean scores of individual items and their standard deviations were similar, and whether the item–total correlations were above 0.4. Floor and ceiling effects were set at 15% [29]. Internal consistency was analysed using Cronbach's alpha (α), and item analyses were conducted by examining α after excluding each the six FoG-Q items [30]. Values above 0.90 were considered to have a high internal consistency [31].

After visual inspection of the Q-Q plot, both convergent and divergent construct validity was tested using Pearson's

correlation coefficient (PCC). We calculated correlations between FoG-Q and UPDRS scores to assess the extent to which this replicated the pattern reported in the original FoG-Q study [7]. The strongest correlations were expected with UPDRS II (especially item 14 which specifically addresses FoG) and UPDRS III item 29 (gait), with several parameters of the TUG test (time, number of steps, and the occurrence of FoG), and with the FoG Score. Except for UPDRS II, values in two states were used: OFF MED + DBS ON and OFF MED + DBS OFF. The weakest correlation was expected for UPDRS I (mentation, behaviour, and mood).

Further correlations were expected with UPDRS II items 13 and 15 and in both states (OFF MED + DBS ON/OFF) with the total score of UPDRS III, UPDRS PIGD subscore [32], HY staging, Short FES-I, and with several spatiotemporal parameters of gait, i.e. with step length, double support time, velocity, and stride-to-stride variability [4, 33–36].

All analyses were performed using Statistical Package for the Social Sciences (SPSS, version 22.0, IBM Corp., Armonk, NY, USA). The level of statistical significance was set at $p < 0.05$. Because of the exploratory nature of the study, we did not correct for multiple testing.

Results

The 35 evaluated patients with PD had a median age of 61 years, disease duration median of 21 years, and a median HY stage of 2.7. Total FoG-Q scores ranged between 1 and 24 points with a mean of 11 (SD ± 5.547). Further clinical characteristics of the patients are presented in Table 1.

Item-total correlations of FoG-Q ranged between 0.75 and 0.90 (Appendix 2). Internal consistency as measured by Cronbach's α was 0.91 (excellent internal reliability). Based on our item analysis, all items contributed significantly to the total FoG-Q score. Reliabilities of FoG-Q after the exclusion of individual items are to be found in Appendix 3.

In the OFF MED state, statistical analysis further revealed significant correlations between FoG-Q and UPDRS II item 14 and with UPDRS III item 29, several TUG parameters (time, number of steps, and presence of FoG), and FoG Score. Details are provided in Table 2. These results show good convergent validity. By contrast, we found no association between FoG-Q and UPDRS I (mentation, behaviour, and mood), which can be interpreted as an indicator of good divergent validity.

Total FoG-Q score also correlated with age, HY staging, Short FES-I, UPDRS II item 13, UPDRS II item 15, UPDRS II, and UPDRS IV Dyskinesias (items 32–35), but not with UPDRS IV Motor fluctuations (items 36–39). OFF MED with DBS ON, the total FoG-Q score correlated positively with UPDRS III item 29, UPDRS III item 30, UPDRS PIGD subscore, the total UPDRS score, duration of the double support phase, and step length variability, and negatively with step length and speed. OFF MED with DBS OFF, the total FoG-Q score correlated with UPDRS III item 29, UPDRS III item 30, UPDRS PIGD subscore, and step time variability, but not with the total UPDRS score.

Furthermore, we observed negative correlations with step length, and velocity. Details are provided in Tables 3 and 4.

Table 1 Clinical and demographic characteristics of patients with PD. *PD*, Parkinson's disease; *TEED*, total electrical energy delivered; *J*, joule; *UPDRS*, Unified Parkinson's Disease Rating Scale; *DBS*, deep brain stimulation; *Short FES-I*, shortened version of the Falls Efficacy Scale-International; *MED*, medication; *MMSE*, Mini-Mental State Examination; *FAB*, Frontal Assessment Battery; *BDI-II*, Beck Depression Inventory, Second Edition

	Patients with PD ($n = 35$, 6 women, 29 men)	
	Mean (SD)	Median
Age (years)	61 (6)	63
Disease duration (years)	21 (5)	20
Time since DBS implantation (years)	5 (3)	5
TEED l.sin. (J)	103 (71)	89
TEED l.dx. (J)	103 (74)	76
Levodopa Equivalent (mg)	1110 (591)	900
Hoehn and Yahr stage	2.7 (0.7)	2.5
UPDRS III (OFF MED, DBS OFF)	47 (15)	48
UPDRS Total (OFF MED, DBS OFF)	68 (20)	65
UPDRS Total (OFF MED, DBS ON)	44 (18)	43
Short FES-I	14 (5)	13
MMSE	28 (2)	29
FAB	15 (2)	15
BDI-II	7 (5)	6

Discussion

This study validated the Czech translation of FoG-Q. We demonstrated excellent internal consistency ($\alpha = 0.91$), which is

Table 2 Convergent validity of the Freezing of Gait Questionnaire. *PCC*, Pearson correlation coefficient; *MED*, medication; *UPDRS*, Unified Parkinson's Disease Rating Scale; *TUG*, Timed Up and Go Test; *FoG*, freezing of gait

	PCC	*p* value
UPDRS II item 14	0.524	0.001
UPDRS III item 29 (OFF MED)	0.662	< 0.001
TUG time (OFF MED)	0.551	0.001
TUG steps (OFF MED)	0.586	< 0.001
TUG freezing (OFF MED)	0.548	0.001
FoG Score (OFF MED)	0.605	< 0.001

Table 3 Correlations of the Freezing of Gait Questionnaire. PCC, Pearson correlation coefficient; *UPDRS*, Unified Parkinson's Disease Rating Scale; *HY*, Hoehn and Yahr; *Short FES-I*, shortened version of the Falls Efficacy Scale-International

	PCC	*p* value
Age	0.516	0.002
Disease duration	0.030	0.864
UPDRS I Total	0.131	0.454
UPDRS II item 13 (falls)	0.626	< 0.001
UPDRS II item 15 (walking)	0.700	< 0.001
UPDRS II Total	0.583	< 0.001
UPDRS IV Dyskinesias (items 32–35)	0.486	0.003
UPDRS IV Motor fluctuations (items 36–39)	0.078	0.657
HY staging	0.724	< 0.001
Short FES-I	0.558	< 0.001

comparable with the results of previous studies [12–16]. The Czech version of FoG-Q shows good convergent construct validity as indicated by correlations with UPDRS II item 14, III item 29, TUG time, TUG steps, TUG FoG, and FoG Score. Divergent validity was also good, i.e. there was no correlation with UPDRS I subscore (mentation, behaviour, and mood). Both these results repeat the findings of previous validation studies [12–16]. Our item analysis and internal consistency results are congruent with the conclusions of Giladi et al. [7], who stated that none of the FoG-Q items can be excluded for the reason of high to excellent total-item correlation (the scale cannot be shortened without a sacrifice to the internal consistency of the items and homogeneity of the scale).

FoG-Q score correlated with age in our group, which is consistent with previous findings that FoG increases with age [4, 37]. Although both mean and median age of our patients were comparable to other validation studies [7, 12–16], they had much higher median disease duration (20 years), or at least a larger minimal range thereof (13–34 years). Their HY stage in the ON state was nevertheless similar to other studied populations [12–15], most likely due to DBS treatment. The aforementioned longer disease duration might explain the lack of correlation between the FoG-Q Total score and disease duration and caused stronger correlation with UPDRS II item 13 (falls) and 15 (gait) compared to other studies [7, 12–16]. Similarly to Nilsson et al. [15], who also had a larger median of disease duration (20.3 years), we found a stronger correlation of FoG-Q Total score with UPDRS II than other studies [7, 12, 16].

In the patients' full OFF (OFF MED, DBS OFF), FoG-Q Total score did not correlate with UPDRS III Total score (PCC = 0.302, $p = 0.08$) in comparison to the state OFF MED with DBS ON (PCC = 0.383, $p = 0.02$). This is probably given by the fact that since FoG-Q is a questionnaire, it only reflects the state known to the patients. However, patients treated with DBS do not experience their full OFF. In this sense, FoG-Q does not reflect the native state of the disease in this population. We found strong correlations with UPDRS III items that are related to gait (UPDRS III item 29), balance (UPDRS III item 30) or both (PIGD subscore) even in the patients' full OFF state (Table 4). This could be explained by the fact that our patients were treated with high-frequency STN DBS, which has smaller effect on gait, balance [38], and FoG severity [39]. Therefore, with respect to gait and balance, FoG-Q does, to a certain extent, reflect the native state of the disease in patients treated with high-frequency STN DBS.

Similarly, we observed several correlations with spatio-temporal gait parameters (velocity, step length, and its variability) both OFF MED with DBS ON and in full OFF. These findings are consistent with other studies which report decreased stride length, increased cadence preceding FoG, presence of a highly abnormal frequency of leg movements during FoG, marked stride-to-stride variability, and asymmetry and variability of swing time in patients with PD and FoG [4,

Table 4 Correlations of the Freezing of Gait Questionnaire with clinical gait parameters and gait-related UPDRS III items in OFF MED state with DBS ON and OFF. *PCC*, Pearson correlation coefficient. *MED*, medication; *DBS*, deep brain stimulation; *UPDRS*, Unified Parkinson's Disease Rating Scale

	OFF MED, DBS ON		OFF MED, DBS OFF	
	PCC	*p* value	PCC	*p* value
UPDRS III item 29 (gait)	0.662	< 0.001	0.686	< 0.001
UPDRS III item 30 (balance)	0.611	< 0.001	0.556	0.001
UPDRS III PIGD subscore	0.757	< 0.001	0.821	< 0.001
UPDRS III Total	0.383	0.02	0.302	0.08
Step length	− 0.616	< 0.001	− 0.505	0.01
Double support phase	0.524	0.002	0.311	0.12
Velocity	− 0.397	0.02	− 0.442	0.02
Cadence	0.070	0.70	− 0.016	0.94
Step length variability	0.652	< 0.001	0.472	0.02
Step time variability	0.346	0.08	0.449	0.02

33–36]. The correlations in full OFF state can be explained again by the relatively smaller efficacy of high-frequency STN DBS on gait, balance, and FoG severity (see above). We noted a lack of correlation with cadence in our study. This is most likely because, in comparison to TUG, walking on GaitRite does not involve initiation of gait and turning, which are two triggers of FoG. In addition, cadence increases shortly before the FoG episode [4]. To support this conclusion, our patients did not generally experience FoG when walking on GaitRite, and consequently did not increase cadence. Interestingly, FoG-Q lost its correlation with the duration of the double support phase in full OFF, but instead gained correlation with step time variability in this state. The former finding can most likely be explained by the fact that patients markedly slowed down in full OFF state, which may have caused an increase of the duration of the double support phase regardless of FoG severity [40]. Correlation with step time variability has already been noted by Hausdorff et al. [41] who proposed several explanations for this fact. Among other explanations, they discuss a "threshold" relationship in which increased stride-to-stride variability is a risk factor for FoG, which is consistent with the "threshold model" of FoG [3, 36]. A marked increase in step time variability in full OFF does likely reflect FoG severity.

In contrast to two previously published studies [15, 16], we found correlation only with UPDRS dyskinesia subscore (IV items 32–35), but not with motor fluctuations subscore (IV items 36–39). This may again be explained by the specifics of our study population, the fact that they were treated with DBS, which reduces motor fluctuations [38]. In fact, the range of the summary score of UPDRS IV items 36–39 was 0–4 with both a mean and median of 2.

One limitation of the current study is a relatively small sample size. This limitation, however, is comparable to other studies that validated FoG-Q including the original one [7, 13, 15]. A re-evaluation with a larger sample would nevertheless be advantageous. Also, 11 patients were unable to complete gait examination in the OFF MED state with DBS OFF.

Conclusions

In conclusion, we have shown that the Czech version of the FoG-Q is a valid tool for the assessment of FoG in patients with PD and DBS without severe cognitive impairment. With respect to our explorative aim, FoG-Q might be considered to reflect gait and balance impairment in native state of the disease (full OFF) in patients treated with high frequency STN DBS.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest.

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