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Validation of the Italian version of the Movement Disorder Society—Unified Parkinson's Disease Rating Scale

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The members of the MDS-UPDRS Italian Validation Study Group are given in the Appendix.
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Abstract

The Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) has been available in English since 2008. As part of this process, the MDS-UPDRS organizing team developed guidelines for development of official non-English translations. We present here the formal process for completing officially approved non-English versions of the MDS-UPDRS and specifically focus on the first of these versions in Italian. The MDS-UPDRS was translated into Italian and tested in 377 native-Italian speaking PD patients. Confirmatory and exploratory factor analyses determined whether the factor structure for the English-language MDS-UPDRS could be confirmed in data collected using the Italian translation. To be designated an 'Official MDS translation,' the Comparative Fit Index (CFI) had to be ≥0.90 relative to the English-language version. For all four parts of the Italian MDS-UPDRS, the CFI, in comparison with the English-language data, was ≥0.94. Exploratory factor analyses revealed some differences between the two datasets, however these differences were considered to be within an acceptable range. The Italian version of the MDS-UPDRS reaches the criterion to be designated as an Official Translation and is now available for use. This protocol will serve as outline for further validation of this in multiple languages.

Keywords: Parkinson's disease MDS-UPDRS Unified Parkinson's Disease Rating Scale Rating scales

Introduction

After its introduction in the 1980s, the Unified Parkinson's Disease Rating Scale (UPDRS) has become the gold standard clinical rating scale for Parkinson's disease (PD) [1, 2]. In 2008, a new Movement DisorderSociety (MDS)-sponsored revision of the UPDRS, known as the MDS UPDRS, successfully passed clinimetric testing with high internal consistency and reliable factor structures for each part of the scale [3].

The new MDS-UPDRS comprises four parts: Part I evaluates non-motor experiences of daily living (nM-EDL), Part II evaluates motor experiences of daily living (motor-EDL), Part III evaluates motor function, and Part IV evaluates motor fluctuations and dyskinesia. As with the previous version, scores are rated by a mix of both the physician and patient. Six of the 13 items in Part I (those dealing with complex behaviors) and all items in Part IV covering fluctuations and dyskinesia involve rater-led interviews of the patient or caregiver. The remaining questions in Part I and all items in Part II are answered with a patient/caregiver questionnaire without direct input from the rater, and Part III involves objective examination by the rater for all items [3]. The MDS-UPDRS was specifically designed to be less ambiguous than its predecessor and the significant patient/caregiver involvement means that it is vital that they understand the questions asked of them, preferably in their mother tongue. In order to establish a successful translation and designate non-English language versions as an 'Official MDS translation,' the MDS has set a strict protocol and criteria for testing. We present here the Italian version of the MDS-UPDRS.

Methods

Translation of the MDS-UPDRS

The MDS-UPDRS was translated into Italian by a team of PD expert investigators in Italy and was then back-translated by colleagues fluent in English and Italian and not involved in the original translation. This back-translation was then reviewed by a team of US experts (Glenn Stebbins, Christopher Goetz, Nancy LaPelle, and Barbara Tilley) who had been involved in the development of the original American version.

Cognitive pretesting

Cognitive pretesting using a structured interview format was performed to evaluate specific items of the MDS-UPDRS in terms of task difficulty for examiner and respondent, and respondent interest, attention span, discomfort, and comprehension. Items were selected for cognitive pretesting when the observed differences were between the back-translated Italian version and the English version. In addition, questions that were identified in cognitive testing of the American version were also tested [4]. Questions included in cognitive pretesting were MDS-UPDRS Parts 1.2 Hallucinations and Psychosis; 1.6 Features Of Dopamine Dysregulation Syndrome; 1.10 Urinary Problems; 2.13 Freezing; 3.12 Postural Stability; 3.17 Rest Tremor Amplitude; 4.1 Time Spent With Dyskinesias; and 4.2 Functional Impact Of Dyskinesias. Based on the results of the initial cognitive pretesting, other round(s) of translation and back translation and cognitive pretesting could be required. Once any issues identified during cognitive pretesting were addressed, the final translation was obtained.

Testing of the Italian version

A total of 17-experienced Italian movement disorder specialists were recruited to examine native-Italian speaking PD patients who had provided informed consent. Data without patient names or medical record numbers were transferred to the analytic team via a secure website. The patient sample size for the translation study was based on the statistical need for a minimum of five subjects per item of the questionnaire [5]. Thus, as there are 65 items on the MDS-UPDRS, a sample of at least 325 patients was required. Any participants with missing values within a part were deleted from analysis of that part only.

Factor analysis

Confirmatory and exploratory factor analyses were performed using M-plus, Version 6.1 (for categorical analyses). An unweighted least squares (ULS) approach to factor estimation that minimizes the sum of squared differences between observed and estimated correlation matrices not counting diagonal elements was used. In addition, an orthogonal VARIMAX rotation that constrains the factors to be uncorrelated was used to assist in interpretation of factors. For Part III, Factor 6, all factor loadings for the Italian data were negative (in the American data, Factor 2 had negative signs for all factor loadings). This is an artifact of the quadrant of the rotation. A factor analysis using a standardized CF-VARIMAX rotation, equivalent to the VARIMAX rotation, gave similar results but without the minus signs. Since the VARIMAX rotation is more widely used, we report the VARIMAX rotation without the (−) signs.

A confirmatory factor analysis (CFA) was used to determine if the factor structure for the English language MDS-UPDRS [3] could be confirmed in data collected using the Italian translation. The CFA was conducted separately for MDS-UPDRS Parts I–IV with the Italian data constrained to fall into the factors defined in the English language data and the CFA results were evaluated based on the Comparative Fit Index (CFI). To establish a successful translation and to designate that translation as an 'Official MDS translation' of the MDS-UPDRS, the CFI for each Part (I–IV) of the translated MDS-UPDRS had to be 0.90 or greater relative to the English language version. In the original factor structure report, three dopamine dysregulation syndromes (DDSs) had an item loading of 0.49 on Factor 1 of Part I. However, in the re-running of the analysis for the current program, the same item had an item factor loading of only 0.19, falling outside the acceptable range to be identified with any factor in the scale. Therefore, the CFIs for the Italian translation versus the English language version were calculated both with and without the DDS item.

An exploratory factor analysis (EFA) for the Italian version of MDS-UPDRS Parts I–IV using the same factor analytic approach as for the confirmatory factor analysis but without constraining the factors to follow a pre-specified factor structure was also performed. Separate SCREE plots were used in addition to the assessment of clinical interpretability of remaining factors to choose the cut-off for the number of factors to retain for each MDS-UPDRS part. The screen plot is a scatter plot of eigenvalues ranked against the amount of scale variance accounted for by each eigenvector. The number of factors can be defined by the number of eigenvectors that independently account of a significant amount of variance [6]. Once the factors were chosen, an item was retained in a factor if the factor loading for the item was ≥0.40.

Results

Cognitive pretesting

A total of 10 PD patients were interviewed as part of the cognitive pretesting step. One of the 10 patients interviewed had difficulty comprehending one item on Part 1 of the Italian MDS-UPDRS (question 1.2 "Hallucinations and psychosis"). Neither patients nor their examiners identified other difficulties. A second round of cognitive pre-testing was completed by three PD patients after a modification of the Italian version of the latter question. No difficulties were identified with question 1.2 (Hallucinations and psychosis) or any other item on this second round of testing. The modified version of the scale was approved as the Official Working Draft of the Italian MDS-UPDRS for testing in a larger group of patients with PD.

Testing of the Italian version of the MDS-UPDRS

In total, 377 native Italian-speaking PD patients were examined by 16-experienced movement disorder specialists using the Italian translation of the MDS-UPDRS. All patients fulfilled Brain Bank diagnostic criteria for probable PD. Patient demographic characteristics are given in Table 1.

For all four parts of the Italian MDS-UPDRS, the CFI, in comparison with the English-language version, was 0.94 or greater and thus the pre-specified factor structure was confirmed in the Italian data set (Table 2). Moreover, the overall CFIs for the English language version and the Italian version with or without the DDS item reached the criterion of CFI ≥0.90, showing that the Italian version of the MDS-UPDRS meets the requirements for designation as an Official Translation.

Exploratory factor analyses revealed some differences between the Italian and English language datasets. For Part I, in contrast to the English language version of the MDS-UPDRS, Cognitive impairment loaded on Factor 2 instead of Factor 1. In Part II, 3 of 13 items loaded differently in the Italian version in comparison to the English version. In Part III, 3 of 33 items loaded differently between the two versions. Given the variability of factor estimates and the smaller sample size used in the Italian version, the analytic team considered these differences within an acceptable range.

Table 1 Baseline characteristics

	Patients (n = 378)
Ethnicity (%)	
Non-hispanic white	100
Other	–
Gender (%)	
Male	59.8
Female	40.2
Age (years, mean ± SD)	64.5 ± 10.3
H&Y stage	2.1 ± 0.7
Years since PD diagnosis (mean ± SD)	7.1 ± 5.6
Years of education (mean ± SD)	9.6 ± 4.4

Table 2 Confirmatory factor analysis model fit

Part I: Non-motor aspects of experiences of daily living (a 2-factor model)	
Italian	CFI = 0.94, RMSEA = 0.07 (374 patients)
English language	CFI = 0.96, RMSEA = 0.06 (849 patients)
Part II: Motor aspects of experience of daily living (a 3-factor model)	
Italian	CFI = 0.98, RMSEA = 0.09 (369 patients)
English language	CFI = 0.97, RMSEA = 0.09 (851 patients)
Part III: Motor examination (a 7-factor model)	
Italian	CFI = 0.94, RMSEA = 0.08 (363 patients)
English language	CFI = 0.95, RMSEA = 0.07 (801 patients)
Part IV: Motor complications (a 2-factor model)	
Italian	CFI = 1.00, RMSEA = 0.06 (374 patients)
English language	CFI = 1.00, RMSEA = 0.04 (848 patients)

CFI comparative fit index, *RMSEA* root mean square error of approximation

Discussion

In order for the MDS-UPDRS to fully replace its predecessor, the UPDRS version 3, [2] as the international gold standard tool for the assessment of PD patients, it is vital that properly tested translations are made available for use in non-English speaking countries. The Italian version of the MDS-UPDRS presented here reaches the criterion to be designated as an Official translation of the MDS-UPDRS and as such is now available for use in clinical studies.

The Italian dataset shared a common factor structure with the English language dataset based on the high CFIs for all Parts of the MDS-UPDRS. Isolated item differences in factor loadings were identified, but the overall factor structure of the Italian version was consistent with that of the English language version confirming its suitability for use. Since this study was conducted, a DVD-based teaching program that covers the four parts of the scale has become available with visual and verbal (English language) instructions for the uniform application [7]. It is planned that this teaching program will also be translated into different languages and that this will further encourage international consistency of rating with this important new tool.

The Italian version of the MDS-UPDRS is the first officially approved non-English translation. The global program now includes two other completed translations (Spanish and Estonian) in statistical review and other language teams are organized for Chinese, Dutch, French, German, Hebrew, Japanese, Korean, Russian, Slovakian and Thai versions. Other language teams are encouraged to organize and participate (email contact: CG Goetz, cgoetz@rush.edu). Large-scale clinical trials using the MDS-UPDRS will necessarily recruit centers in countries where official translations are available, so this effort has very practical implications for future patient and research programs.

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Appendix

See Table 3

Table 3 MDS-UPDRS Italian Validation Study Group

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Francesca Del Sorbo	Fondazione IRCCS Istituto Neurologico Carlo Besta, Milano

References

1. Fahn S, Elton RL. Unified Parkinson's Disease Rating Scale. In: Recent developments in Parkinson's disease: MacMillan Healthcare Information, 1987:153–164
2. Movement Disorder Society Task Force on Rating Scales for Parkinson's Disease (2003) The Unified Parkinson's Disease Rating Scale (UPDRS): status and recommendations. Mov Disord 18:738–750CrossRef
3. Goetz CG, Tilley BC, Shaftman SR et al (2008) Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): scale presentation and clinimetric testing results. Mov Disord 23:2129–2170PubMedCrossRef
4. Goetz CG, Fahn S, Martinez-Martin P et al (2006) Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): Process, format, and clinimetric testing plan. Mov Disord 22(1):41–47CrossRef
5. Hatcher L (1994) A step-by-step approach to using the SAS system for factor analysis and structural equation modeling. SAS Institue, Cary
6. Gorsuch R (1983) Factor analysis, 2nd edn. Lawrence Erlbaum Associations, Hillsdale
7. Goetz CG, Stebbins GT, Chmura TA, Fahn S, Poewe W, Tanner CM (2010) Teaching program for the Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale: (MDS-UPDRS). Mov Disord 25:1190–1194PubMedCrossRef