Rasayely
Neurodegenerative Diseases International
https://rasayely-journals.com/index.php/ndi
Vol 2(1); 1–9, 2024

Original Article Open Access

The Italian Version of the Munich Dysphagia Test-Parkinson's Disease: Translation, Cultural Adaptation, and Clinical Validation

Fabio Viselli[1,*], Giulia Rossi[1], Ilenia Schettino[1], Jonathan Bemporad[1], Alessandra Monge[1], Michele Paradiso[1], Massimo Fiori[2], Chiara Piscitelli[2], Giovanni Galeoto[2], Irene Battel[3], and Janine Simons[4]

[1]*Department of Neurorehabilitation, San Giovanni Battista Hospital, Rome, Italy*

[2]*Department of Neurorehabilitation, Sapienza University of Rome, Rome, Italy*

[3]*Department of Biomedical Sciences, University of Milano, Italy*

[4]*National Centre of Excellence in Research on Parkinson's Disease (NCER-PD), Luxembourg Centre for Systems Biomedicine, University of Luxembourg, Luxemburg*

[*]Author to whom any correspondence should be addressed; email: f.viselli@acismom.it

Received: 08 November 2023; Revised: 23 February 2024; Accepted: 03 March 2024; Published: 16 April 2024

Academic Editor: Shaimaa I. El-Jaafary, Cairo University, Egypt

Abstract

Background: Intact swallowing functions are essential for nourishment and if impaired can seriously compromise the respiratory tract. Oropharyngeal Dysphagia (OD) can contribute to aspiration pneumonia, the leading cause of death in patients with Parkinson's Disease (PD). Heterogeneous screening instruments with low specificity/sensitivity impede early detection. The Munich Dysphagia Test-Parkinson's disease (MDT-PD), a patient-reporting questionnaire, is the first screening tool developed for the early detection of OD and the risk of aspiration. **Objective:** The objective of this study is the validation of an Italian-language version of the MDT-PD. **Design:** Blind Cross-Sectional study. **Methods:** translation/cultural adaptation of MDT-PD into Italian followed international guidelines. The validation of the Italian version involved 30 continuous PD patients. 119 patients were selected for diagnostic validation. **Inclusion Criteria:** males/females between 40–80 years of age, Hoehn & Yahr 2.5–4, stable therapeutical response for one month. Interclass coefficient correlation and Cronbach's Alpha Limit were evaluated. The repeatability of MDT-PD was assessed using Pearson r, and comprehension of each scale item was evaluated by an expert interviewer. **Results:** validation achieved highly significant scores for reliability and repeatability. The cut-off points obtained to discriminate the presence of dysphagia with aspiration risk were 1.15 and 2.4. **Conclusion:** the Italian version of MDT-PD is a viable, non-invasive, easy-to-administer screening tool for detecting subclinical or early stages of dysphagia and aspiration risk in Italian PD patients. **Clinical Rehabilitation Impact:** an early evaluation of PD inpatients, using the MDT-PD allows for a tailored and cost-effective speech pathology treatment and a significant reduction of respiratory complications.

Keywords

Parkinson's; validation; psychometric; dysphagia; swallowing; Fibrolaryngoscopy

1. Introduction

Dysphagia, the unsafe transfer of food, liquid, or saliva from the mouth into the stomach can contribute to aspiration pneumonia and other complications such as malnutrition, and dehydration [1]. It is often considered an inevitable consequence of Parkinson' Disease (PD) and negatively impacts the quality of life of these patients [2], affecting up to 100% of patients in advanced stages of the disease [3]. PD specialists have shown increasing attention to dysphagia because of its strong association with the development of aspiration pneumonia [4] the leading cause of death in PD patients [5]. Early detection of oropharyngeal dysphagia (OD) can improve the quality of life of individuals with PD. In addition, widespread screening might save a significant

number of lives as reported by Hinchey *et al.* [6] for individuals with dysphagia due to stroke.

Despite possible serious, dysphagia-related respiratory complications there are no standard screening protocols for PD patients. Patients usually get referred for evaluation only when there is suspicion of swallowing problems. This approach does not take into consideration the dangers of silent aspiration, which, as its name implies, occurs without noticeable signs of swallowing difficulty [7]. There is also an extremely low level of awareness of swallowing disturbances among Parkinson's patients and their caregivers, clinicians and healthcare professionals still rely largely on patient reporting [3]. Underreporting makes early detection and identification of patients at risk for serious complications difficult. Often, by the time dysphagia is diagnosed, it is too late: silent aspiration has already occurred [4].

Only two validated patient reporting instruments exist for swallowing difficulties specifically to be used in the PD population: these are the swallowing disturbance questionnaire (SDQ) [8] and the Munich Dysphagia Test – Parkinson's Disease (MDT-PD) [1]. The most common questionnaires focusing on several non-motor symptoms and activities of daily living, but including only a single question regarding swallowing problems, are the UPDRS [9] and the NMSQuest [10]. Clinical assessment of patients' swallowing functions can benefit from the use of diagnostic instrumental examinations that help explore and evaluate underlying physiology and the most widely used is Fiberoptic Endoscopic Evaluation (FEES) [11]. Results of the FEES are optimized if used in combination with either the Penetration Aspiration Scale (PAS) [3] that identifies the risk of penetration and/or aspiration or Video Fluoroscopy (VFSS) [12]. However, even though these diagnostic methods are clinically highly relevant, they are also invasive and their use to all patients is not feasible.

The MDT-PD questionnaire was the first self-report screening tool designed specifically for early detection of dysphagia as well as for identification of aspiration risk in patients with Parkinson's [1]. It was initially developed in German languages and subsequently underwent cross-national-translation into English adhering to international guidelines for cultural adaptations of patient questionnaires [13]. The purpose of this study was to perform the translation/cultural adaptation of the English version in Italian, to validate the new Italian language version (i.e., linguistic standpoint) and to evaluate the Italian version's diagnostic validity. International guidelines were used for the translation and cultural validation [13], and the clinical validation followed the original protocol of the German language questionnaire's diagnostic validation [1].

2. Materials and Methods

2.1. Population

Patients were recruited from both the rehabilitation and out-patient departments of our hospital, San Giovanni Battista ACISMOM in Rome.

2.2. Inclusion Criteria

1. Patients 40 - 80 years of age and native-speaking Italian.

2. The severity of Parkinson's is measured with a Hoehn & Yahr [14,15] score between 2.5 – 4.

3. Stable therapeutic response for at least one month.

2.3. Exclusion Criteria

1. Prior diagnosis of dysphagia.

2. Cognitive performance is less than 24 as measured by Mini-Mental State Examination [16].

3. The presence of other pathologies that might contribute to dysphagia.

4. Patients who might have the need to modify their pharmacological therapy during the recruitment phase and/or study period.

We have chosen to exclude patients over 80 years old to avoid the presence of dysphagia not related to Parkinson's disease, and those under 40 years old to keep away from the risk of statistical bias related to the small sample size of patients below this age limit. Moreover, we excluded patients with H&Y less than 2.5 because they rarely present dysphagia and patients with H&Y of 5 due to the presence of dysphagia in the majority of them.

All clinical and instrumental evaluations were performed with patients in the "ON" phase.

3. Translation

3.1. Ethical Considerations

The linguistic, cultural, and diagnostic validation study was conducted according to the Declaration of Helsinki, using the Good Clinical Practice criteria. All the patients were recruited after the study protocol had been approved by the Ethics Committee assigned to our hospital. All the participants read and signed the informed consent document. All patient data was protected according to current regulations. The study was

divided into two distinct phases, with the first phase being divided into two parts (A&B).

Phase One (A): Translation and cultural adaptation of the English-language MDT-PD into Italian.

Phase One (B): Validation of the Italian version (Pilot Study).

Phase Two: Diagnostic validation of the Italian version of the MDT-PD.

3.2. MDT-PD Questionnaire

The questionnaire **(Supplementary Materials)** consists of 4 parts, with a total of 26 items:

1. Food/liquid-related swallowing difficulties (10 items): to address the swallowing of foods of various consistencies during mealtimes.

2. Swallowing difficulties independent of food-intake (4 items): to address swallowing problems that are related to sialorrhea (drooling), drug-related xerostomia (dry mouth), saliva penetration/aspiration, taking pills, etc.

3. Additional swallowing-specific behaviors – assessment of additional burden (9 items): the focus is on motor fluctuation and identification of compensation strategies/avoidance behaviors during on or off phases due to the possible fears of patients of swallowing certain consistencies.

4. Swallowing-specific health questions (3 items): to address medically-relevant information useful for assessing risk – related to either the overall health or specifically to dysphagia: weight loss, lung infections having occurred in the previous year, and daily hydration issues.

3.3. Phase One (A): Translation/Cultural Adaptation into Italian

To assure the quality and validity of the translation/cultural adaptation of the English language MDT-PD into Italian, the authors followed the universally accepted steps outlined in the Principles of Good Practice guidelines (PGP) written by the Translation and Cultural Adaptation work group of the International Society for Pharmacoeconomics and Outcomes Research **[13]**.

1(a). Translation into Italian: forward translation of the English-language questionnaire (i.e., source document) into Italian was executed by two independent mother-tongue Italian experts in swallowing pathology to allow a translation and cultural and clinical adaptation.

1(b). A third mother-tongue Italian expert (i.e., in PD and in technical language/instruments), who is also fluent in English, collaborated with the two Italian translators from step 1(a) on each of the translations produced – and together they created a single document of the Italian language version.

2. Back translation into English: a mother-tongue English translator fluent in Italian, who was unfamiliar with the original source document (i.e., English-language MDT-PD), translated the Italian version of the questionnaire back into English.

3. Review/approval of the Italian version: three Italian-speaking physicians (mother-tongue Italian) from our institution, who are PD specialists, and familiar with English and Italian medical terms and screening instruments, reviewed the Italian translation to ensure that there were no differences between the source document (English) and the newly developed Italian translation. They had not participated in the earlier translation phases and after confirming no major discrepancies between the documents, they approved the definitive Italian version.

3.4. Phase One (B): Validation of the Italian Version

The definitive Italian version was administered to a sample of 30 representative PD patients diagnosed with Parkinson's Disease **[4]**, to evaluate the comprehension and acceptance of the items on the scale. These 30 individuals did not participate in the later diagnostic/clinical validation of the MDT-PD. The questionnaire was administered to the sample by an expert interviewer, a neuropsychologist. Recruitment of these patients was done according to the same inclusion/exclusion criteria used in the original validation of the MDT-PD **[1]**. The sample size was obtained using the sample size function included in "Medcalc."

3.5. Phase Two: Validation and Psychometric Properties of the Italian Version of the Munich Dysphagia Test Population

The validation of the Italian version of the MDT-PD followed the protocol used in the validation of the original questionnaire (source document) **[1]**. 119 patients, males and females, diagnosed with Parkinson's Disease **[4]**, excluding dropouts, were included in the study. Patients were recruited from the rehabilitation inpatient departments of our hospital, San Giovanni Battista ACISMOM in Rome.

3.6. Sum Score Clinical Evaluation

A clinical evaluation was carried out using the same criteria as the original study from which 3 evaluation criteria were identified: oropharyngeal dysphagia, any dysphagia, and dysphagia with risk of aspiration. The following criteria were evaluated: management of salivary secretions; oral facial praxia; oropharyngeal sensibility; oropharyngeal reflexes; delayed swallow reflex; laryngeal elevation; ventilatory functionality; the presence of cough reflex; voluntary cough; voice quality before and after swallowing thin fluid (by asking the patient to drink 90 ml of water quickly without pausing). Further swallowing tests include foods of various consistencies (half a slice of bread, cookies with a 5 cm diameter, cookies (novellini, brand "Gentilini"), and placebo pills of 8 mm diameter (standard "empty" capsules used as placebo). Swallowing rate and frequency were measured by palpation, counting, and the time required.

Participants underwent clinical evaluation of oropharyngeal reflexes and swallowing functions using fiberoptic endoscopic evaluation of swallowing (FEES) to determine that they were in a stable therapeutic regimen and having an optimal therapeutic response ("ON" phase). These elements were then compared with the responses to the Italian version of the MDT-PD. The Unified Parkinson's Disease Rating Scale Part III was used to evaluate patients' motor functions **[9]**.

3.7. Clinical Evaluation of the MDT-PD – Italian Version

Due to the invasive nature of the FEES, participants in the study were first administered the questionnaire (on the same day as admission to the study took place). In this way, answers could not be influenced by any discomfort from the FEES exam. Participants underwent FEES one hour after having responded to the MDT-PD. For re-test and repeatability evaluation, the MDT-PD was administered a second time, 4-5 days following the first administration.

Patients were asked to answer all of the items on the Italian-language MDT-PD questionnaire.

3.8. Fiberoptic Endoscopic Evaluation of Swallowing

FEES evaluation was performed according to the same procedures used in the original paper **[1]**. The evaluation was done with *fibrolaryngoscopy* (endoscopy PENTAX 0F-C5) with swallowing tests of boluses using various consistencies from pudding, to solid and liquid. The boluses administered during the test were, in sequence, semi-solid, soft-solid, chewable solid, and liquid. The test was interrupted in the presence of aspiration to ensure patient safety.

The swallowing tests used in both clinical evaluation and FEES include the same amount of water (90ml) and the same food samples.

3.9. Severity Classification of Dysphagia

Clinical evaluation together with FEES enabled the stratification of patients according to the severity of oropharyngeal symptoms by using an ordinal scale that describes the presence/absence of dysphagia and its severity: patients without presenting symptoms of dysphagia; patients with presenting symptoms of dysphagia; patients with dysphagia and at risk for penetration/aspiration.

3.10. Dysphagia Classification and Sum Score

The source document developed by Simons *et al.* (2014) (1) used 18 criteria to enable the identification of dysphagia severity by considering the range of oropharyngeal findings assessed by both clinical and FEES evaluation. We used the same 18 criteria, each one of which received a score between 0 and 2 (0 = 'not noticeable dysphagia', 1 = 'noticeable dysphagia', 2 = 'risk of aspiration'). The final scoring was obtained using the following system: patients received a classification of "no dysphagia" when they had less than 3 criteria with a score of 1, a classification of "oropharyngeal dysphagia" when they had at least 3 criteria with a score of 1, a classification of "dysphagia with penetration/aspiration" when they had at least 2 criteria with a score of 2 **(Table 1)**.

The Sum Score was computed using the web-based application program available on the MDT-PD website, witch actually provided the German and English language versions of the questionnaire **(www.mdt-parkinson.de)**. The menu section "questionnaire" contains the statistically determined coefficient estimates/item weights (revealed by linear regression analysis) that are required for MDT-PD test evaluation. (Underlying item weights have been earlier reported in Simons *et al.* **[1]**).

Table 1: Sum score.

	Diagnostic parameters clinical (CL)/ FEES (E)	Symptom scale range	Criterion classification (for each parameter)		
			Criterion value 0	Criterion value 1	Criterion value 2
1	CL/PILL or CL/TABLET	0-2	= 0	= 1	= 2
2	CL/water swallow and/or CL/pharyngealsensibility (PS)	0-4 0-2	water ≤ 1 and PS = 0 Or water = 0	water = 1 and PS ≥1 Or water = 2	water ≥3
3	CL/BREAD swallow	0-4	≤ 1	= 2	≥ 3
4	CL/COOKIE swallow	0-4	≤ 1	= 2	≥ 3
5	E/secretion management	0-4	= 0	= 2	≥ 3
6	E/bolus leakage water	0-4	≤ 1	= 2	≥ 3
7	E/bolus leakage BREAD	0-4	≤ 1	= 2	≥ 3
8	E/bolus leakage COOKIE	0-4	≤ 1	= 2	≥ 3
9	E/residues water (RES)	0-3	res = 0	res = 1 and CE = 2	res = 1 and CE = 3
10	E/residues BREAD (RES)	0-3	res = 0	res = 1 and CE = 2	res = 1 and CE = 3
11	E/residues COOKIE 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues COOKIE 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues COOKIE 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues COOKIE 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues COOKIE 0e3 RES. 0 RES. 1 and CE > 2 RES. 3
12	E/residues PILL (RES) and 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues PILL (RES) and 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues PILL (RES) and 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues PILL (RES) and 0e3 RES. 0 RES. 1 and CE > 2 RES. 3	E/residues PILL (RES) and 0e3 RES. 0 RES. 1 and CE > 2 RES. 3
13	E/leakage after WATER	0-4	≤ 1	= 2	≥ 3
14	E/leakage after BREAD	0-4	≤ 1	= 2	≥ 3
15	E/leakage after COOKIE	0-4	≤ 1	= 2	≥ 3
16	E/penetration aspiration scale water PAS	1-8	= 1	= 2	≥ 3
17	E/PAS BREAD	1-8	= 1	= 2	≥ 3
18	E/PAS COOKIE	1-8	= 1	= 2	≥ 3

0: Patients are assigned a classification of "no dysphagia" when they had less than 3 criteria with a score of 1

1: Patients are assigned a classification of "oropharyngeal dysphagia" when they had at least 3 criteria with a score of 1

2: Patients are assigned a classification of "dysphagia with penetration/aspiration" when they had at least 2 criteria with a score of 2

3.11. Comparison between MTD-PD and FEES/PAS

A comparison between MDT-PD and FEES/PAS was performed to identify the diagnostic sensitivity of the instrument. For the comparison with FEES, we considered a score PAS of 2 as an indicator of dysphagia and a score of over 2 as an indication of aspiration risk.

3.12. Statistical Analysis

Test validity (Pearson's r) and reliability (Cronbach's alpha) were computed using an ICC > 0.80. These analyses were done using the software SPSS 25.00 Italian version and Medcalc Italian version 28.10 for the item's correlation (correlogram).

Test stability was evaluated using Pearson r > 0.80.

An inferential analysis of MDT-PD results was performed using a linear regression which considered MDT-PD an independent variable for the identification of "absence of dysphagia"; "possible presence of oropharyngeal dysphagia without aspiration risk"; and "possible presence of oropharyngeal dysphagia with aspiration risk". The analysis was computed using the variation inflation factor (VIF) to value the collinearity of the items.

A bivariate correlation (Spearman's Rho) between the MDT-PD items and clinical plus the FEES exam was performed in order to correlate the results of the questionnaire with the international gold standard – FEES. A nonparametric bivariate correlation using Pearson's r was performed between the MDT-PD and the Hoehn & Yahr scale (H&Y) and between MDT-PD and the UPDRS III in order to determine the relation between the severity of swallowing problems with the disease stage/pathology or with the motility function, respectively. The cut-off was arrived at by using the weighted MDT-PD as status the variable and the 4 classifications of dysphagia as the dependent variables (not notifiable dysphagia, notifiable dysphagia, dysphagia with aspiration risk, and any dysphagia). The internal variation between the items was calculated using Kendell's Tau.

3.13. Population Cultural Adaptation

The definitive Italian version was administered to a sample of 30 representative PD patients diagnosed with Parkinson's Disease [4], to evaluate the comprehension and acceptance of the items on the scale. These 30 representative PD patients (Male 13; Female 17; Age 69.82±10.29; H&Y 2.9±0.42; disease duration 9.6±3.8; UPDRS III 19.55±4.38; MMSE 28.52±1.69) did not participate in the later diagnostic/clinical validation of the MDT-PD.

3.14. Validation and Psychometric Properties of the Italian-Version of the Munich Dysphagia Test Population

119 males and females diagnosed with Parkinson's Disease [4], excluding dropouts (Male 65; Female 54; Age 69.48±10.03; H&Y 2.7±0.65; disease duration 9.6±3.8; UPDRS III 19.76±4.38; MMSE 28.52±1.68), have been included in the study. Patients were recruited from both the rehabilitation and outpatient departments of our hospital, San Giovanni Battista ACISMOM in Rome.

4. Results

4.1. Reliability Internal Consistency

The Italian version of the MDT-PD demonstrated a high Internal Consistency (IC) ($\alpha = 0.898$ $p = 0.01$) and interclass consistency (ICC = 0.870-0.923), which had already been evident in the 30 patients included in Phase 1 of the study – the translation of the source document into Italian ($\alpha = 0.876$ $p = 0.01$ and ICC = 0794-0.929).

4.2. Stability

To see if the test itself would provide the same results after repeated assessments by the same operator, the test-retest reliability was conducted to estimate the stability of individual measures over time, after which we calculated the intraclass correlation coefficient (ICC) between the two assessments by Pearson's r performed 4-5 days after the first administration. The scale was stable from a statistical point of view regarding the ICC values (r = 0.966, $p = 0.01$). The test-retest reliability of the MDT-PD demonstrates optimal repeatability. These data are comparable to those obtained from the 30 patients included in the translation phase of the study (r = 0.969, $p = 0.01$).

4.3. Dysphagia Classification Sum Score

25 patients were classified as not having dysphagia (21%), 63 with notifiable dysphagia (52.9%), and 31 with dysphagia and aspiration risk (26.1%) **(Table 2)**. A mean criterion sum score of 1.06 was obtained (min/max 0-2). The average of the weighted MDT-PD sum score was 4.133 (interquartile range = 1.04 -16.87). The inverse non-parametric bivariate correlation between the group 'not notifiable dysphagia' vs. 'any dysphagia' was significant ($\tau = -0537$, $p = 0.01$).

The linear regression using MDT-PD as a dependent variable with 'possible presence of oropharyngeal dysphagia with aspiration risk' resulted as R = 0.996. The VIF (Variance Inflation Factor) obtained was > 4 for nearly all MDT-PD items and demonstrates a strong collinearity with some items in particular: start swallow (VIF 5.883), multiple swallowing (VIF 12.013), food residues (VIF 6.341), weight loss (VIF 8.830), and fluid intake (VIF 5.875), coughing while drinking (VIF 6.695), tiredness (VIF 7.076), duration meals (VIF 6.627) **(Table 3)**.

4.4. Bivariate Correlation

The bivariate correlation is significant for most of the items **(Table 4)**.

Table 2: Classification.

	Frequency	Valid %	Cumulative %
Not notifiable dysphagia	25	21	
Oropharyngeal dysphagia	63	52.9	73.9
Dysphagia with aspiration risk	31	26.1	26.1
Total	119	100	100

Table 3: Colinearity Statistics VIF.

Constant	Tolerance	VIF
Chewing swallowing	.265	3.780
Discharge	.232	4.316
Swallowing trigger	.170	5.883
Multiple swallowing	.083	12.013
Food remains	.158	6.341
Food gets stuck in my throat	.177	5.651
Coughing while eating	.213	4.688
Coughing while drinking	.149	6.695
Problems breathing	.180	5.550
Voice change	.203	4.924
Increase of saliva	.237	4.227
Dry mouth	.192	5.216
Choking on saliva	.283	3.528
Pills	.183	5.461
Off times	.177	5.661
Avoidance	.194	5.168
Clearing of throat	.185	5.397
Duration of meals	.151	6.627
Tiredness	.141	7.076
Rinsing afterwards	.248	4.034
Single swallowing	.197	5.064
Loss of appetite	.396	2.526
Heartburn	.173	5.770
Lung infection	.319	3.137
Weight loss	.113	8.830
Fluid intake	.170	5.875

4.5. Concurrent Validity

The evaluation of the correlation between FEES scores and the severity of dysphagia symptoms detected by the MDT-PD was significant ($r = 0.325$, $p = 0.01$; $\rho = 0.351$, $p = 0.01$).

The evaluation of the correlation between the H&Y score and the symptoms detected by the MDT-PD was not significant ($r = 0.010$, $p = 0.910$).

The correlation between the results of the UPDRS III and the score obtained by the MDT-PD was significant ($r = 0.254$, $p = 0.01$).

4.6. Diagnostic Validity and Cross Validity

The MDT-PD sum score of the Italian version is highly predictive. The discriminatory ability with regard to the three classifications is optimal **(Table 5)**. The results obtained are significant between MDT-PD and any dysphagia (cut-off 1.15), and between MDT-PD and notifiable dysphagia with aspiration risk (cut-off 2.4). No significant result was obtained between MTD-PD and notifiable dysphagia **(Table 5)**.

The comparison of MDT-PD with FEES shows excellent specificity scores, similar to those shown in **Table 5**, however, MDT-PD demonstrated a consistent increase in sensitivity (100%). These data confirm a good diagnostic quality of MDT-PD despite a lower ability to identify the risk of aspiration compared to FEES **(Table 6)**.

5. Discussion

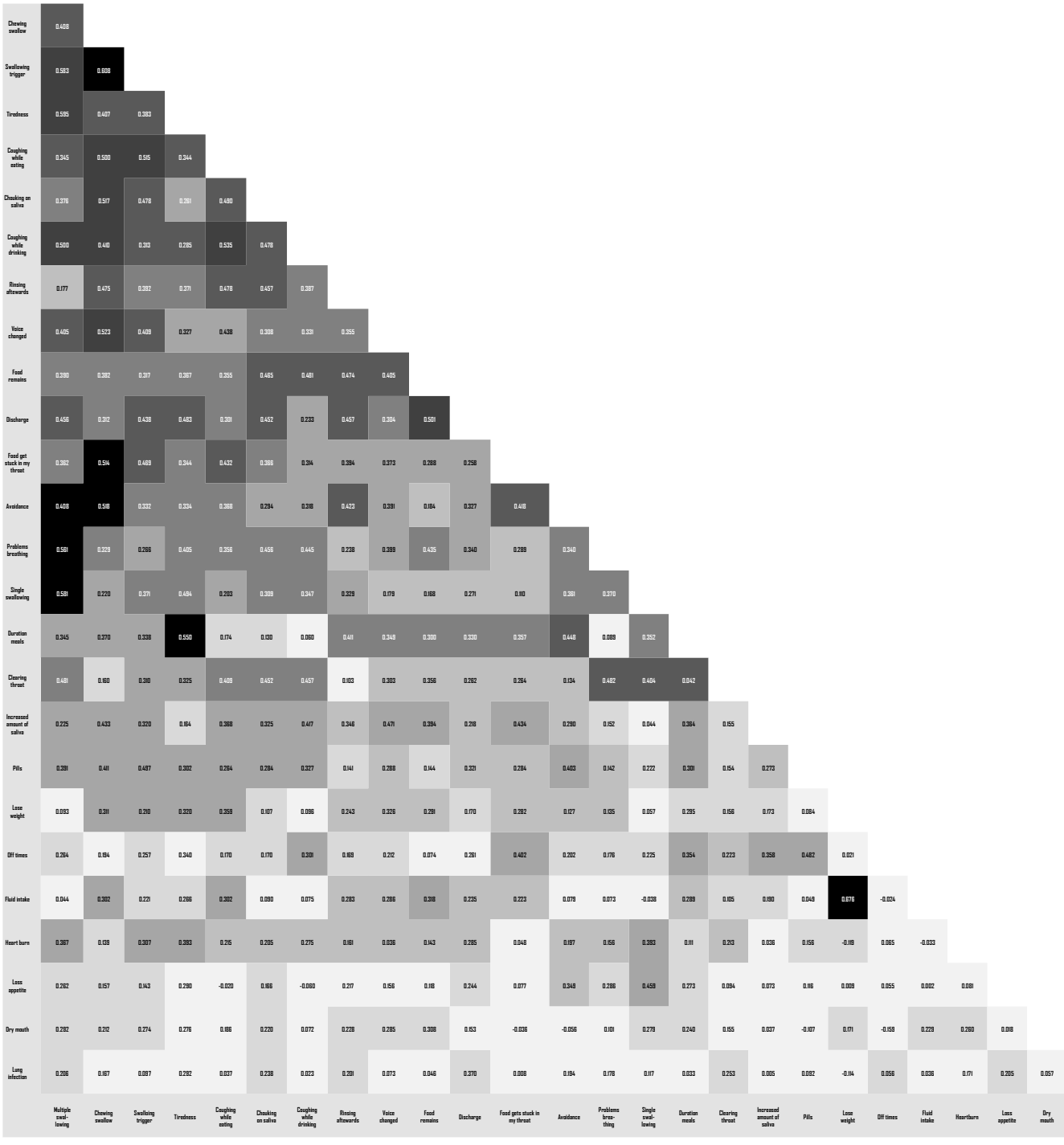
The Italian language version of the MDT-PD was easy to understand, and no item presented linguistic barriers or required additional instructions. Completing the questionnaire took approximately 15 minutes and its brevity is another strong factor in our decision to embark on the translation/validation project. The evaluation of the psychometric properties of the Italian version of the MDT-PD indicated optimal internal and intraclass consistency, for the most part in line with the original study. It means that the items of the MDT-PD scale correlate significantly with each other. Furthermore, it indicates that there is also a strong consistency between measurements made by different observers or on different occasions, thus ensuring the reliability of the scale.

The diagnostic power of most of the items in the Italian version exceeded the minimum acceptable values established in the original work and some were clinically relevant: swallowing trigger; multiple swallowing; food remains, weight loss, and hydration. The drooling item, which obtained less diagnostic power, did not prove to be a real predictive factor for early dysphagia, contrary to data in the literature **[17]**. The sample of patients analyzed in our study showed high scores on the items dedicated to identifying oropharyngeal sensitivity (food gets stuck in my throat; coughing while drinking; clearing of throat; multiple swallowing) with a lower value for the item dedicated to excess saliva (drooling). These data are compatible with an early stage of dysphagia. In fact, the accumulation of saliva in the oral cavity is linked to a deficit in oropharyngeal sensitivity which reduces the frequency of automatic swallowing acts and represents a later symptom of dysphagia **[18]**.

Our study included test-retest reliability and inter-rater reliability, two areas that were not validated in the original paper. Our Italian version of MDT-PD was administered the first day of inclusion in the study and again after 4-5 days and indicated optimal reliability and repeatability.

The comparisons obtained using the ROC curve between MDT-PD and FEES and water PAS confirm the good diagnostic capability of the test, in contrast with recent literature data, Buhmann *et al.* **[19]**. Buhmann, indeed, call into question the data obtained in the original study **[1]**, which are comparable to ours. In his study he analyzed a sample of patients with greater severity of dysphagia, as evidenced by PAS. We believe that this difference in the sample does not allow us to compare the two studies.

Table 4: Bivariate Correlation



Black = maximum correlation with two-tailed** $p = 0.001$

Lightest gray = low correlation with one-tailed* $p = 0.005$

Other grayscales indicate different levels of correlation with two-tailed** $p = 0.001$ (the darker the gray, the higher the correlation)

The underlying mechanisms of dysphagia progression are still not clear [4]. Taking this into consideration, the fact that our data indicated no correlation between the Hoehn & Yahr score and the MDT-PD results assumes a particular significance, suggesting that the presence of dysphagia is not associated with the severity of Parkinson's Disease, which contrasts with literature data [20]. The comparison between the MTD-PD, the severity of symptoms (UPDRS), and the severity of disease (H&Y) shows that the higher the motor function burden (as expressed on the UPDRS scale), the more dysphagia-positive test results occurred in the MDT-PD. It also confirmed that the severity of the disease, expressed by the H&Y scale, did not play a role in dysphagia's severity. The difference between the UPDRS scale and the H&Y scale may explain the variation in results. The H&Y scale measures the severity of Parkinson's disease by qualitatively evaluating the symptoms that describe the motor disorder. The UPDRS assesses a broader range of symptoms and clinical aspects (e.g. rigidity) which allowed

us to better identify the correlation of dysphagia between this scale and MDT-PD [21] compared to H&Y.

The correlation between FEES scores and the severity of dysphagia symptoms detected by the MTD-PD shows that the more severe patients were evaluated in the FEES examination (e.g., regarding penetration/aspiration, residues, or leakage), the more severe their results yielded in the MDT-PD. These results suggest that MDT-PD can effectively determine the severity of dysphagia in a manner consistent with the results obtained from FEES. The implication is that using a self-assessment scale prior to FEES could potentially provide valuable diagnostic information without the need for an invasive procedure.

Our study's data affirm the diagnostic reliability of the Italian version of the MTD-PD and, at the same time, highlight the urgent need for dysphagia screening even in the early stages of the disease, a phase in the disease course when clinicians do not tend to focus on swallowing difficulties. The strength of this questionnaire is its ability to indicate potentially serious respiratory complications that might go unnoticed by patients, caregivers, and clinicians. Early detection of dysphagia has positive effects on the quality of life for individuals affected by this condition. Swallowing difficulties can significantly impact a person's ability to enjoy meals, socialize, and maintain independence. By identifying dysphagia early and implementing appropriate management strategies, individuals can regain confidence in their ability to eat and drink without discomfort or fear. This can promote a sense of well-being, improve social interactions, and enhance overall quality of life.

Hopefully, with the development of this new patient reporting questionnaire, the MTD-PD, that focuses on early detection of dysphagia, data in the literature, indicating its onset 10-11 years following a PD diagnosis [2], would be re-evaluated. Further research concerning the dysphagia and disease stage is necessary to confirm our data.

5.1. Limitations

The cut-off points obtained for discriminating the presence of dysphagia were lower utilizing stratification of the three patient groups as in the original study. This value represents the best compromise between the test sensitivity and specificity. This cut-off also enables an optimal diagnostic level.

Table 5: MDT-PD diagnostic quality (Italian version)

MTD-PD VS.	AUC	Cut-off	Sensibility (%)	Specificity (%)	ICC
Notifiable Dysphagia	0.482	1.5	98	94	0.376-0.588
Any Dysphagia	0.578	1.15	87	84	0.464-0.693
Dysphagia with Aspiration Risk	0.655	2.4	84	62	0.547-0.770

Table 6: MDT-PD diagnostic quality Italian version

MTD-PD VS. FEES	AUC	Cut-off	Sensibility (%)	Specificity (%)	ICC
Notifiable Dysphagia -FEES (4-15)	0.728	1.3	100	80	0.545-0.907
Dysphagia with Aspiration Risk-FEES (15-40)	0.889	2.7	100	63	0.832-0.946
MDT-PD VS. water PAS	**AUC**	**Cut-off**	**Sensibility (%)**	**Specificity (%)**	**ICC**
Notifiable Dysphagia - water PAS (2)	0.583	1.3	100	80	0.450-0.716
Dysphagia with Aspiration Risk- water PAS (3-4)	0.907	2.4	100	64	0.853-0.961

6. Conclusion

Our data confirm that the MDT-PD is a reliable and valid dysphagia screening tool for PD. The questionnaire could easily be used during routine clinical activity to facilitate the identification of a greater number of patients with symptoms of dysphagia and those at higher risk of serious aspiration pneumonia. Considering our data of 26.1% of participants classified as at risk for aspiration, the questionnaire appears to be effective in the prevention of life-threatening complications, and thus, its use could contribute to saving lives. We hope that our results will encourage other PD specialists in non-English (or non-German) speaking countries to translate the MTD-PD into their languages as well. Additional validation of the MTD-PD by other research teams is necessary to confirm our data. If rigorous translation guidelines and diagnostic validation protocols such as those offered by Simons *et al.* (2014) are followed, perhaps this questionnaire will be included in routine care practices on an international scale.

Acknowledgments

The authors thank Lesley Pritikin for her collaboration and assistance with the preparation of the manuscript.

Authors' Contributions

All authors contributed to the reported work, whether in conception, study design, execution, data acquisition, analysis, and interpretation, or in all of these areas. G.R. and G.G. played a significant role in the statistical analysis. I.S. carried out all FEES assessments.

Supplementary Materials

The Italian version of the questionnaire consists of 4 parts, with a total of 26 items and is reported in **supplementary materials**.

Conflicts of Interest

The authors and all the co-authors have no conflicts of interest to declare. All co-authors have seen and agreed with the contents of the manuscript.

Data Availability

All data are available on reasonable request from the corresponding author.

Funding

We declare that we have not received any grant or funding for this study.

Ethical Approval

We received the approval of the ethical committee "LAZIO 2" Protocol N. 0068451/2016 dated 07/07/2016.

References

[1] Simons JA, Fietzek UM, Waldmann A, Warnecke T, Schuster T, Ceballos-Baumann AO. Development and validation of a new screening questionnaire for dysphagia in early stages of Parkinson's disease. Parkinsonism & Related Disorders 2014;20:992–8. https://doi.org/10.1016/j.parkreldis.2014.06.008.

[2] Kalf JG, de Swart BJM, Bloem BR, Munneke M. Prevalence of oropharyngeal dysphagia in Parkinson's disease: A meta-analysis. Parkinsonism & Related Disorders 2012;18:311–5. https://doi.org/10.1016/j.parkreldis.2011.11.006.

[3] Logemann JA, Gensler G, Robbins J, Lindblad AS, Brandt D, Hind JA, *et al.* A randomized study of three interventions for aspiration of thin liquids in patients with dementia or Parkinson's disease. Journal of Speech, Language, and Hearing Research 2008;51:173–83. https://doi.org/10.1044/1092-4388(2008/013).

[4] Gelb DJ, Oliver E, Gilman S. Diagnostic criteria for Parkinson disease. Archives of Neurology 1999;56:33–9. https://doi.org/10.1001/archneur.56.1.33.

[5] Bird MR, Woodward MC, Gibson EM, Phyland DJ, Fonda D. Asymptomatic swallowing disorders in elderly patients with Parkinson's disease: a description of findings on clinical examination and videofluoroscopy in sixteen patients. Age and Ageing 1994;23:251–4. https://doi.org/10.1093/ageing/23.3.251.

[6] Hinchey JA, Shephard T, Furie K, Smith D, Wang D, Tonn S. Formal dysphagia screening protocols prevent pneumonia. Stroke 2005;36:1972–6. https://doi.org/10.1161/01.str.0000177529.86868.8d.

[7] Rosenbek JC, Robbins JA, Roecker EB, Coyle JL, Wood JL. A penetration-aspiration scale. Dysphagia 1996;11:93–8. https://doi.org/10.1007/bf00417897.

[8] Cohen JT, Manor Y. Swallowing disturbance questionnaire for detecting dysphagia. The Laryngoscope 2011;121:1383–7. https://doi.org/10.1002/lary.21839.

[9] Goetz CG, Fahn S, Martinez-Martin P, Poewe W, Sampaio C, Stebbins GT, *et al.* Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): process, format, and Clinimetric testing plan. Movement Disorders 2007;22:41–7. https://doi.org/10.1002/mds.21198.

[10] Ray Chaudhuri K, Schapira A, Martinez-Martin P. Can we improve the holistic assessment of Parkinson's disease? Advances in Clinical Neuroscience and Rehabilitation 2004;4:20–4.

[11] Colodny N. Interjudge and intrajudge reliabilities in fiberoptic endoscopic evaluation of swallowing (FEES) using the penetration-aspiration scale: a replication study. Dysphagia 2002;17:308–15. https://doi.org/10.1007/s00455-002-0073-4.

[12] Rugiu MG. Role of videofluoroscopy in evaluation of neurologic dysphagia. Acta Otorhinolaryngologica Italica 2007;27:306–16.

[13] Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, *et al.* Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for translation and cultural adaptation. Value in Health 2005;8:94–104. https://doi.org/10.1111/j.1524-4733.2005.04054.x.

[14] Hoehn MM, Yahr MD. Parkinsonism. Neurology 1967;17:427–427. https://doi.org/10.1212/wnl.17.5.427.

[15] Goetz CG, Poewe W, Rascol O, Sampaio C, Stebbins GT, Counsell C, *et al.* Movement Disorder Society Task Force report on the Hoehn and Yahr staging scale: status and recommendations the Movement Disorder Society Task Force on rating scales for Parkinson's disease. Movement Disorders 2004;19:1020–8. https://doi.org/10.1002/mds.20213.

[16] Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. Journal of Psychiatric Research 1975;12:189–98. https://doi.org/10.1016/0022-3956(75)90026-6.

[17] Rodrigues B, Nóbrega AC, Sampaio M, Argolo N, Melo A. Silent saliva aspiration in Parkinson's disease. Movement Disorders 2010;26:138–41. https://doi.org/10.1002/mds.23301.

[18] Nienstedt JC, Buhmann C, Bihler M, Niessen A, Plaetke R, Gerloff C, *et al.* Drooling is no early sign of dysphagia in Parkinson's disease. Neurogastroenterology & Motility 2017;30. https://doi.org/10.1111/nmo.13259.

[19] Buhmann C, Flügel T, Bihler M, Gerloff C, Niessen A, Hidding U, *et al.* Is the Munich dysphagia Test–Parkinson's disease (MDT-PD) a valid screening tool for patients at risk for aspiration? Parkinsonism & Related Disorders 2019;61:138–43. https://doi.org/10.1016/j.parkreldis.2018.10.031.

[20] Ding X, Gao J, Xie C, Xiong B, Wu S, Cen Z, *et al.* Prevalence and clinical correlation of dysphagia in Parkinson disease: a study on Chinese patients. European Journal of Clinical Nutrition 2017;72:82–6. https://doi.org/10.1038/ejcn.2017.100.

[21] Mohamed A-AB, Mohamed GF, Elnady HM, Sayed MA, Imam AM, Hassan MM, *et al.* Evaluation of dysphagia in different phenotypes of early and idiopathic Parkinsonism. The Egyptian Journal of Neurology, Psychiatry and Neurosurgery 2018;54:28–28. https://doi.org/10.1186/s41983-018-0031-1.

How to Cite

Viselli F, Rossi G, Schettino I, Bemporad J, Monge A, Paradiso M, Fiori M, Piscitelli C, Galeoto G, Battel I, Simons J. The Italian Version of the Munich Dysphagia Test-Parkinson's Disease: Translation, Cultural Adaptation, and Clinical Validation. Neurodegener Dis Int 2024;2(1):1–9.