Reviews

Dysautonomia Rating Scales in Parkinson's Disease: Sialorrhea, Dysphagia, and Constipation—Critique and Recommendations by Movement Disorders Task Force on Rating Scales for Parkinson's Disease

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Abstract: Upper and lower gastrointestinal dysautonomia symptoms (GIDS)—sialorrhea, dysphagia, and constipation are common in Parkinson's disease (PD) and often socially as well as physically disabling for patients. Available invasive quantitative measures for assessing these symptoms and their response to therapy are time-consuming, require specialized equipment, can cause patient discomfort and present patients with risk. The Movement Disorders Society commissioned a task force to assess available clinical rating scales, critique their clinimetric properties, and make recommendations regarding their clinical utility. Six clinical researchers and a biostatistician systematically searched the literature for scales of sialorrhea, dysphagia, and constipation, evaluated the scales' previous use, performance parameters, and quality of validation data (if available). A scale was designated "Recommended" if the scale was used in clinical studies beyond the group that developed it, has been specifically used in PD reports, and clinimetric studies have established that it is a valid, reliable, and sensitive. "Suggested" scales met at least part of the above criteria, but fell short of meeting all. Based on the systematic review, scales for individual symptoms of sialorrhea, dysphagia, and constipation were identified along with three global scales that include these symptoms in the context of assessing dysautonomia or nonmotor symptoms. Three sialorrhea scales met criteria for Suggested: Drooling Severity and Frequency Scale (DSFS), Drooling Rating Scale,

and Sialorrhea Clinical Scale for PD (SCS-PD). Two dysphagia scales, the Swallowing Disturbance Questionnaire (SDQ) and Dysphagia-Specific Quality of Life (SWAL-QOL), met criteria for Suggested. Although Rome III constipation module is widely accepted in the gastroenterology community, and the earlier version from the Rome II criteria has been used in a single study of PD patients, neither met criteria for Suggested or Recommended. Among the global scales, the Scales for Outcomes in PD-Autonomic (SCOPA-AUT) and Nonmotor Symptoms Questionnaire for PD (NMSQuest) both met criteria for Recommended, and the Nonmotor Symptoms Scale (NMSS) met criteria for Suggested; however, none specifically focuses on the target gastrointestinal symptoms (sialorrhea, dysphagia, and constipation) of this report. A very small number of rating scales have been applied to studies of gastrointestinal-related dysautonomia in PD. Only two scales met "Recommended" criteria and neither focuses specifically on the symptoms of sialorrhea, dysphagia, and constipation. Further scale testing in PD among the scales that focus on these symptoms is warranted, and no new scales are needed until the available scales are fully tested clinimetrically. © 2009 Movement Disorder Society

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Dysautonomia-related gastrointestinal symptoms, including sialorrhea, dysphagia, and constipation are common in Parkinson's disease (PD)[1–4] and negatively impact on patient' safety and quality of life, yet may not directly correlate with other parkinsonian motor signs.[3,5–7] Although there are "gold standard" techniques for assessing dysphagia (e.g., VFSS or videofluoroscopic swallowing study) and constipation (colonic motility studies), these measures require specialized equipment and trained personnel, can be expensive, and may not be readily available to clinicians and/or researchers. Easily administered, validated rating scales that correlate well with the degree of symptom-related severity and impairment would be useful for clinicians and researchers. However, much of the literature evaluating epidemiology of and interventions for sialorrhea, dysphagia, and constipation have relied on rating scales with limited validation in PD.

METHODS

Administrative Organization and Critique Process

The MDS Task Force on Rating Scales for PD Steering Committee under its director (C.G.G.) invited the chairperson (M.L.E.) to form a Writing Committee and critique rating scales for gastrointestinal-related autonomic symptoms in PD—specifically, sialorrhea, dysphagia, and constipation. The committee included seven movement disorders neurologists and statisticians with clinimetric expertise from North America and Europe. Committee members assessed the scales' previous use, critiqued clinimetric properties, and made recommendations regarding their clinical utility. This report was reviewed by one member of the Steering Committee (CGG), and after the report was revised, it was circulated to the full Steering Committee. Once approved by this group, it was submitted to the Scientific Issues Committee of the MDS and once approved, submitted for peer-review publication.

Literature Search Strategy

A systematic search was conducted by PUBMED and Medline (1950–2007) using the combined MeSH search terms "SIALORRHEA" and "PARKINSON'S DISEASE" in the English language literature. The references of the papers retrieved were also systematically searched for rating scales of sialorrhea. Similarly, for dysphagia and constipation, the MeSH search terms "DYSPHAGIA" and "CONSTIPATION" were combined with "PARKINSON'S DISEASE," papers retrieved, examined, and references searched for rating scales.

Selection of Scales

Scales previously used as outcome measures in studies of patients with PD were selected for evaluation. If no such scales were identified, scales used in other populations were selected for evaluation. In the event, no scales specifically focusing on the symptoms of interest (sialorrhea, dysphagia, or constipation) were identified, general scales that included these symptoms were considered for evaluation (See Flow Diagram, Supplementary Material A).

Evaluation of Clinimetric Properties

The following criteria were used to evaluate the clinimetric properties of the selected scales. (See Supplemental Material B for further details): (1) Content validity; (2) Readability and comprehension; (3) Internal consistency; (4) Construct validity; (5) Acceptability/floor and ceiling effects; (6) Test-retest reliability; (7) Agreement; (8) Responsiveness; (9) Interpretability; (10) Minimal clinically important difference (MCID); (11) Time to administer; and (12) Administration burden. It should be noted that many validation studies referenced below employ the Hoehn and Yahr (H&Y) scale, which is anchored on motor symptoms as a com-

parator for establishing construct validity. This assumes that motor symptoms are an anchor for dysautonomia symptoms in PD, and this assumption may not be valid. Each selected scale's performance in these areas was critiqued and consolidated into a summary of *Advantages and Limitations*.

With regard to readability and comprehension, it should also be noted that validation studies on the feasibility of translation into a particular language and clinimetric properties of a scale once translated might be published in that particular language rather in the English literature. Our selection method of using English language literature search may therefore have introduced a selection bias and excluded such studies.

Finally, with regard to responsiveness, none of the scales specifically addressed the potential variability introduced by several factors, namely: timing of scale administration in relation to medication dosing, "*on*" versus "*off*" states,[8] presence/absence of deep brain stimulation, patient motivation, presence/absence of dementia, caregiver input, and circadian factors. Few interventional studies have been conducted clearly delineating the sensitivity of scales to these patient state changes. As these topics were not specifically addressed in validation studies, we do not address them below, but would expect investigators to consider such factors in study designs.

Conclusions

After the evaluation, a scale was rated "Recommended" if it is considered valid, reliable, and sensitive, and is reported in clinical studies beyond the group that developed it, and if it was applied to PD populations. Scales rated as "Suggested" met at least part of the above criteria, but fell short of meeting all.[9]

RESULTS—EVALUATION AND CRITIQUE OF SCALES BY SYMPTOM

The reported clinimetric properties for each scale are summarized in Table 1.

Sialorrhea

Results—Assessment of Sialorrhea in PD

Objective methods for evaluating salivary flow and volume include saliva collection,[24,25] suctioning,[26] using a Lashley disk over the parotid (Stenson's) duct,[12,13] patient based swallowing counts,[12,13] or most commonly, by placing dental cotton pads in the mouth.[26,27–33] These objective tests are too time-con-

suming and impracticable for routine use in the neurology clinic and do not quantify the discomfort or social embarrassment related to sialorrhea.

Many studies on sialorrhea treatment have used Item no. 6 of the UPDRS to evaluate sialorrhea treatment responses.[29,30,34] Visual Analog Scales (VAS) for sialorrhea frequency and familial and social impact have been included as outcome measures, but they have not undergone validity testing (see Supplemental Material C for details).[29,35,36] Three sialorrhea-specific rating scales were identified for review, but are insufficiently validated in the PD population:

Drooling Severity and Frequency Scale (See Table 1 for Clinimetric Summary and Supplemental Material D for Scale Details). *Concept Model*: The Drooling Severity and Frequency Scale (DSFS) is a semiquantitative assessment of the amount of drooling, has been used in studies of drooling in both cerebral palsy (CP)[10,11] and PD patients.[27,34,36] There are two questions: severity is rated on a five-point scale (never drools, dry to profuse-drooling off the body, and onto objects (furniture, books), whereas frequency is rated on a four-point scale (no drooling to constant drooling).

DSFS Advantages/Limitations: Despite its easy administration and widespread use, this scale has not been validated in either CP or PD populations. Furthermore, the DSFS does not address psychosocial impact, and it is also unclear how well this scale correlates with objective measures of salivary secretion.

Drooling Rating Scale (See Supplemental Material E for Scale Details). *Concept Model*: The Drooling Rating Scale[12,13] was developed in 2001 to evaluate sialorrhea in PD patients. Patients are given a score from 0 to 3 ("excessive dryness or no excess of saliva" to "continuous drooling, wet clothes, or constant use of handkerchief or tissue") for severity of drooling over the preceding week in the following situations: sitting, standing, in bed, talking, and while eating or drinking.

Drooling Rating Scale Advantages/Limitations: Although this scale was developed for use in PD patients, it has not undergone clinimetric evaluation. It is similar to the DSFS, but evaluates drooling severity in multiple situations.

Sialorrhea Clinical Scale for PD (See Supplemental Material F for Scale Details). *Concept Model*: The Sialorrhea Clinical Scale for PD (SCS-PD) was recently developed to address the lack of validated tools for the evaluation of drooling in PD.[14] The SCS-PD consists of seven questions assessing drooling severity and frequency as well as social and functional impairment.

TABLE 1. *References, study characteristics, and clinimetric properties of scales discussed in text*

Scale	Reference	Number of subjects	Comparison to objective measures?	CV[1]	R&C[2]	Int. consist.[3]	Const. val.[4]	Acceptability floor/ceiling[5]	Test/retest reliability[6]	Agreement[7]	Responsiveness[8]	Interpretability[9]	MCID[10]	Time[11]	Burden[12]
Sialorrhea scales															
DSFS	Thomas-Stonell and Greenberg,[10] Heine[11] — No formal validation study	n/a	No	?	?	?	?	?	?	?	?	?	?	+(est)	+(est)
Drooling rating scale	Marks et al.[12,13] — No formal validation study		No	?	?	?	?	?	?	?	?	?	?	+(est)	+(est)
SCS-PD	Perez Lloret et al.[14]	39	Yes	—	?	—	± (Compared to salivary volume, but unstimulated only)	— (May have been influenced by sample size)	?	?	?	?	?	+	+
Dysphagia scales															
SDQ	Lam et al.[15]	45	Yes (VFSS)	?	?	Cronbach's α = 0.78	?	?	?	?	?	?	?	+(est)	+(est)
SWAL-QOL	McHorney et al.[16]	52	Yes (VFSS)	+	+	Cronbach's α = 0.89 +	+	+	+	?	?	?	?	—	±
	McHorney et al.[17]	106			5th grade level	Cronbach's α = 0.8–0.94		(Except for burden and eating duration)	(Except for burden and eating duration)					14 min	
	McHorney et al.[18]	386													
	McHorney et al.[19]	368													
Constipation scales															
Rome III constipation Module	Drossman[20] — No clinimetric studies (delphinian validation)	n/a	No	?	?	?	?	?	?	?	?	?	?	?	?
Global scales															
SCOPA-AUT	Visser et al.[21]	240	No	+	± 10 pts. (grade level not reported)	?	?	?	+ ICC for the total score = 0.87 (range 0.65–0.90)	+	?	+	—	?	?
NMSQuest	Chaudhuri et al.[2]	242 (193 patients, 96 controls)	No	+	?	+factor analysis ?Cronbach's α	+	—	ICC <0.7	?	?	?	?	— 10–15 min	+

TABLE 1. (*Continued*)

Scale	Reference	Comparison to objective measures?	Number of subjects	CV[1]	R&C[2]	Int. consist.[3]	Const. val.[4]	Acceptability floor/ceiling[5]	Test/retest reliability[6]	Agreement[7]	Respon-siveness[8]	Interpret-ability[9]	MCID[10]	Time[11]	Burden[12]
									Clinimetric properties						
UMSARS	Wenning et al.[22]	No	40	?	n/a	+	+	?	?	+	— (12 min)	?	?	?	?
NMSS	Chaudhuri et al.[23]	No	242	+ Extensive sources	+? (75th grade level)	+	+	+	<0.7 for dysphagia, 0.96–0.99 for other GI symptoms	+	+	?	?	?	+

SDQ, swallowing disturbance questionnaire; DSFS, drooling severity and frequency scale; SCS-PD, sialorrhea clinical scale for PD; SWAL-QOL, dysphagia-specific quality of life scale; SCOPA-AUT, scales for outcomes in PD-autonomic; NMSQuest, nonmotor symptoms questionnaire; UMSARS, unified multiple systems atrophy rating scale; NMSS, nonmotor symptoms scale.

[1]CV, Content validity was rated as: "?" (no information found on content validity), "—" (no patient involvement in scale development).

[2]R&C, Readability and comprehension was rated as: "?" (no information found on readability and comprehension reported), "+" (readability tested or reported and result was good; scale reads at 5th grade level or below), "—" (inadequate scale testing or reading level is above 5th grade).

[3]Int. Consist, Internal consistency was rated as: "+" (adequate design, method, and factor analysis with α > 0.80), "±" (doubtful method used), "—" (inadequate internal consistency), and "?" (lacking information found on internal consistency of the rating scale).

[4]Const. Val, Construct Validity was rated as: "+" (adequate design, method, and result), "±" (doubtful method used), "—" (inadequate construct validity), or "?" (no information found on construct validity).

[5]Acceptability floor/ceiling was graded as: "+" (no floor/ceiling effects), "—" (more than 15% of respondents achieved the highest or lowest possible score), and "?" (no information found on floor and ceiling effects).

[6]Test/retest reliability was rated as: "+" (adequate design, method, and ICC > 0.70), "±" (doubtful method was used), "—" (inadequate reliability), or "?" (no information found on test-retest reliability).

[7]Agreement was rated as: "+" adequate design, method and result, "±" doubtful method used, "—" inadequate agreement, "?" information found on agreement not reported.

[8]Responsiveness was rated as: "+" (adequate design, method and result), "±" (doubtful method used), "—" (inadequate responsiveness), and "?" no information found on responsiveness.

[9]Interpretability was rated as: "+" (two or more of the types of information were presented), "±" (doubtful method/used or doubtful description), or "?" (no information found on interpretation).

[10]MCID—Minimal clinically important difference was rated as "+" (MCID presented) or "—" (no MCID presented).

[11]Time to administer rated as: "+" (less than 10 min to complete), "—" (more than 10 min to complete), or "?" (no information found on time to complete the scale).

[12]Administration burden was rated as: "+" (easy, e.g., summing up of the items), "±" (moderate, e.g., visual analogue scale (VAS) or simple formula), "—" (difficult, e.g., VAS in combination with formula, or complex formula, "?" (no information found on rating method).

SCS-PD Advantages: The SCS-PD scale is specifically designed for assessing sialorrhea-related discomfort in PD patients, and its validity has been preliminarily demonstrated through saliva volume measurements in PD patients and healthy volunteers. With only seven questions, SCS-PD appears easily administered, and therefore has the potential to be adopted as one of the routine clinical scales for measuring sialorrhea-related discomfort in PD patients. Construct validity was not explicitly discussed in the validation study, but rating scale correlation with saliva production was investigated in PD patients and healthy control subjects. Although administration burden was also not specifically addressed, the scale has only seven questions and likely imposes only slight burden.

SCS-PD Limitations: Several clinimetric properties were not addressed in the validation study. In the SCS-PD, unidimensionality is an important assumption, that is, all seven questions/items are measuring the same dimension/factor (the degree of sialorrhea-related discomfort in PD patients). This assumption is critical for future investigation of the psychometric properties of this scale. However, no confirmatory factor analysis (CFA) of this assumption is done in the article. With regards to readability and comprehension, the SCS-PD is originally written and administered in Spanish, and then translated into English. Language translation might be an important factor that contributes to measurement bias, e.g., differential item functioning (DIF). The DIF of language has been detected in the MMSE.[37] With regard to acceptability, floor effects (>15% with lowest possible score) were present in several of the items. The scale also has problems with representativeness due to small sample sizes and lack of demographic information on the sample (race, ethnicity, etc). If we assume that the studies were implemented on Hispanics only, then the representativeness of this sample may be impaired. Additionally, given the small sample size, it is likely that the results obtained from this sample cannot be popularized to the PD patients worldwide properly. Finally, with regard to interpretability, to ensure the SCS-PD to be a reliable scale across diverse populations of PD patients, it is necessary to do DIF test (Test of possible Measurement Bias) over important demographic characters, e.g., race, gender, age, education, etc.

Conclusions—Assessment of Sialorrhea in PD

According to the preestablished criteria, DSFS meets criteria for Suggested because it has been used by multiple investigators and has been applied specifically to PD, but does not have adequate clinimetric evaluation to warrant the "Recommended" designation. The Drooling Severity Scale meets a weaker level of "Suggested" status because the only criteria it met is previous use in PD studies. The SCS-PD can also be graded as "Suggested" because it has demonstrated good internal consistency and validity and has been applied to PD patients, although the sample size was small. It has not been tested by another group beyond the original report, and therefore falls short of the criteria for "Recommended."

Dysphagia

Results—Assessment of Dysphagia in PD

Although the VFSS evaluation[3,4,38] is the "gold standard" for detecting dysphagia in patients with PD, only one clinically-based rating scale for dysphagia in PD was identified.[39] Speech pathologists routinely assess: (1) duration of dysphagia (less than 6 months vs. more than 6 months), (2) solid versus liquid dysphagia, (3) level with which the patients senses food or fluid "sticking" in their chest, (4) the frequency with which symptoms occur (constant (with every bite) vs. intermittent), and (5) whether such associated symptoms as melena, regurgitation, vomiting, pain, gastroesophageal reflux disease (GERD) symptoms, etc., are present.

Two reports have evaluated swallowing in relation to either VFSS or endoscopic swallowing evaluation.[15,39] In a multivariate model, Lam et al.[15] concluded that three clinical parameters—Hoehn and Yahr stage, low body mass index, and a positive answer to the question, "Do you have trouble keeping food in your mouth?" independently predicted dysphagia on VFSS. The question regarding keeping food in the mouth was one of 14 in a swallowing symptoms questionnaire described by Nathadwarawala et al.[40] However, the sample size in Lam's study was small and no formal clinimetric evaluation of the questionnaire in PD was included in the report. The limited clinimetric data available from the recent comparison[39] of a Swallowing Disturbance Questionnaire (SDQ) to objective swallowing assessments is discussed later.

Given the paucity of PD-specific dysphagia scales, other generic scales in the literature were also considered for critique: dysphagia-specific quality of life and quality of care scales (SWAL-QOL and SWAL-CARE)[16–19] as well as a functional dysphagia scale reported by Han et al.[41] Because the Han functional dysphagia scale is based on the VFSS and has limited validation in stroke patients thus far, we chose not to

evaluate it further. The SWAL-CARE is directed at quality of care rather than dysphagia symptom impact and is not discussed further here. SWAL-QOL is discussed later. Other dysphagia scales[42–44] have not been extensively validated nor widely used and thus were not further critiqued here. Within the community of specialists treating gastrointestinal disorders, specific criteria for assessing esophageal-related dysphagia (the Rome III criteria) have been developed[20,45,46] via a delphinian method. However, no published studies have clinimetrically evaluated these criteria (See Supplemental material C).

Swallowing Disturbance Questionnaire—(See Supplemental Material G for Scale Details). *Concept Model*: This questionnaire was developed to use as a screening tool for dysphagia with hopes of detecting dysphagia prior to an episode of aspiration pneumonia.

SDQ Advantages/Disadvantages: Internal consistency was very good. Although the time to administer was not formally assessed, it has 15 questions that likely would require 10 min or less to administer.

The sample size was relatively small, content validity was not formally discussed. It is unclear whether patients as well as experts were consulted in the questionnaire development. Most clinimetric properties were not assessed or reported, and further testing of the questionnaire into other languages should be completed.

Generic Scale for Dysphagia-Related Outcomes (Quality of Life)—SWAL-QOL (See Supplemental Material H for Scale Details). *Concept Model*: The SWAL-QOL is a 44-item dysphagia-specific outcomes tool that addresses impact on dysphagia-related outcomes in 10 quality-of-life domains important to patients—food selection, burden, mental health, social functioning, fear, eating duration, eating desire, communication, sleep, and fatigue. The conceptual framework is discussed in detail by McHorney.[16]

SWAL-QOL Advantages: The SWAL-QOL has several clinimetric advantages, including good content validity. Except for fear (Cronbach's alpha = 0.79), the 10 domains of SWAL-QOL demonstrated acceptable internal consistency, suggesting that the scale is appropriate for group-level research. Also, construct validity (convergent validity) evaluation reveals good agreement between the dysphagia-specific SWAL-QOL and generic measures from the MOS (r = 0.50–0.56).[18,47,48] The average correlation between the SWAL-QOL and generic measures was almost twice the average correlation between the SWAL-CARE and generic measures, suggesting good discriminant validity. In evaluating acceptability, only "burden" (16%) and "eating duration" (19%) exhibited excess floor effects.[49] "Social function-

ing" and "eating desire" ceiling effects were high due to relatively "healthy" composition of the reported sample PD patients' "relative health" may vary more widely from "healthy" (in samples of patients with H&Y stages I–II) to "less healthy" (in samples of patients with disease severity H&Y III–IV), and thus ceiling effects may not be as high in a PD population.

SWAL-QOL scale is specifically designed for assessing dysphagia-related impact in patients, and its validity has been preliminarily proven in varied samples of patients, including patients with neurodegenerative diseases. Thus, the SWAL-QOL appears to be a potentially useful scale which would offer more detailed assessment of the impact of dysphagia symptoms in PD.

SWAL-QOL Limitations: Population samples in which validation studies were completed are largely English-speaking, white and male, raising readability, generalizabity and comprehension issues. As discussed earlier, language translation might be an important factor that contributes to measurement bias. Although they included about 10 to 12% patients with degenerative neurological conditions, the sample was specifically selected for patients with static dysphagia problems, thus interpretability in the PD population may be limited. Also, if dysphagia associated with PD fluctuates (as most PD symptoms do), the reported sample may not have adequate representativeness. With regard to well-known groups validity, the SWAL-QOL differentiated patients with varying degrees of dysphagia (normal to tube-feeding dependent), but no information on varying groups of PD is available. Average time to complete the SWAL-QOL is slightly longer than the desired 10 min, but the administrative burden is light.

Conclusions-Assessment of Dysphagia in PD

The SDQ is considered as "Suggested" because it has been tested in a single PD population and some clinimetric data is reported. The SWAL-QOL is considered as "Suggested" because it is not specifically validated in the PD population, but has been clinimetrically tested in broad dysphagia populations and performed robustly in most clinimetric testing. This scale should be studied further in the PD population because the results of the validation studies reported to date are promising.

Constipation

Results—Assessment of Constipation in PD

Unlike sialorrhea and dysphagia, which are sign/symptom complexes, constipation is primarily reported

as a symptom in movement disorders clinics. It is one of the most common autonomic symptoms of PD and may precede diagnosis by decades.[50,51] In clinical settings and the literature, the term "constipation" has a variety of meanings. Non-PD specific gastrointestinal symptom questionnaires that focus on constipation in the context of irritable bowel syndrome[52–56] appear to have been replaced by the Rome criteria and questionnaires.[45,57,58] The Rome II criteria[59] and subsequent Rome III revisions[45,58] (See Supplemental Material I for details) were developed through international consensus to enable more consistent evaluation of epidemiology, physiology, and treatment response of constipation and are widely accepted in the gastroenterological community. In a pilot prevalence using the Rome II criteria, Kaye et al. reported that constipation occurs about three times more often in patients with PD as in controls.[60]

Objective measures to investigate constipation in PD include colon transit study, defecography, anorectal manometry, and electromyography; however, these measures require specialized equipment and expertise and are not commonly available to movement disorders clinicians and researchers. A variety of questionnaires have been used in published studies, including: gastrointestinal symptom and bowel movement frequency questionnaires[61,62] as well as diaries.[63] However, none of these are validated in the PD population, and only the most recent[60] pilot used Rome criteria or questionnaires. Although the Rome criteria and questionnaires are widely recognized and accepted within the gastroenterological community,[57] references specifically reporting validation procedures for the constipation module are not published.

Conclusions-Assessment of Constipation in PD

No scales or questionnaires met criteria for "Suggested" or "Recommended" for constipation. The Rome II Criteria has been recently used in PD literature to define constipation, but has not been validated in this population. Given the wide acceptance of the Rome criteria within the gastroenterology community, further work is needed to clinimetrically validate the updated Rome III criteria and constipation module in PD populations.

RESULTS—GLOBAL SCALES ADDRESSING DYSAUTONOMIA AND NONMOTOR SYMPTOMS

Although few scales address PD-related sialorrhea, and no validated questionnaires or scales specifically address PD-related dysphagia or constipation, more comprehensive symptom scales that include item rating the gastrointestinal domain of nonmotor and autonomic symptoms in parkinsonian disorders for which clinimetric properties have been reported. They include:

1. The Scales for Outcomes in PD-Autonomic (SCOPA-AUT),[21]
2. Nonmotor symptoms questionnaire for PD (NMSQuest),[2]
3. Nonmotor Symptoms Scale (NMSS).[23]

Scales for Outcomes in PDs-Autonomic (see Supplemental Material J for Scale Details)

Concept Model: This self-administered scale was the first scale designed to evaluate the presence and frequency of autonomic symptoms in PD. This scale has 25 autonomic symptom-focused items that assess the following domains: gastrointestinal (7 items), urinary (6 items), cardiovascular (3 items), thermoregulatory (4 items), pupillomotor (1 item), and sexual (2 items for men and 2 items for women). The four response options for each item range from 0 (never) to 3 (often) with higher total scores reflecting worse autonomic functioning.

SCOPA-AUT Advantages: The scale has good content validity. Construct validity—Although the SCOPA-AUT does not appear correlated with electrophysiologic autonomic measures,[64] SCOPA-AUT has good known-groups validity and discriminates between control, mild, moderate, and severe PD groups. The correlation of the SCOPA-AUT with the HY scale was satisfactory ($r_S = 0.60$), ranging from 0.20 to 0.70 for regions. Well-known groups validity (controls and 3 groups of patients with different severity stages) was satisfactory. Test-retest reliability/agreement was satisfactory). Although the time to administer/administrative burden is not specifically stated, estimated time to complete is 10 min.

SCOPA-AUT Limitations: Internal consistency responsiveness, MCID, language, and acceptability were not reported.

Nonmotor Symptoms Questionnaire for PD (See Supplemental Material K for Scale Details).

Concept model: The PD NMSQuest[2,65] is the first PD-specific, validated, global nonmotor self-administered questionnaire and not intended to evaluate the effect of treatment. NMSQuest is designed to aid clinical management by providing a rapid screening tool for the presence problematic NMS in PD. The 30 NMSQuest items are scored as "yes/no" and assess 10

domains. Three of the nine gastrointestinal tract domain items assess sialorrhea, dysphagia, and constipation.

NMSQuest Advantages: The validation studies included patients and controls recruited worldwide and highlight the usefulness of NMSQuest in 545 PD patients across all stages.[23,66] Content validity was appropriate and readability and comprehension were formally assessed; both patients and caregivers demonstrated high rates of agreement (92–100%) that the questions were clearly worded. The correlation of the NMSQuest with the HY scale was satisfactory ($r_S = 0.31$, $P = 0.006$), suggesting good construct validity. As an assessment tool, floor/ceiling effects were not evaluated. However, the response distribution by PD patients and age matched controls reveal that the questionnaires as a whole and the questions on sialorrhea, dysphagia, and constipation have good discriminant properties. The NMSQuest appears to correlate well with disease progression, indicating good responsiveness and interpretability. Administrative burden is low.

NMSQuest Limitations: Internal consistency, test-retest reliability/agreement were not evaluated. MCID was also not addressed as the NMSQuest is intended as an evaluation tool, not a tool to assess changes in response to treatment.

Nonmotor Symptoms Assessment Scale for PD (See Supplemental Material L for Scale Details).

Concept model: To provide a method to quantify NMS, the NMSS was developed.[23] This scale is divided in nine major domains containing 30 questions (See Supplementary Material K). The NMSS reflects the questions flagged in the NMSQuest and is aimed to be a practical measure for use by health professionals. Item scoring is obtained by multiplying the severity score (ranging 0–3) and the frequency score (ranging 1–4). The scale can, therefore, capture symptoms that are severe but relatively infrequent (e.g., hallucinations) and those less severe but persistent (e.g., constipation, fatigue, or low mood).

NMSS Advantages: Content validity was excellent. Clinical use of the NMSS as judged from validation study suggests that the scale can be used in a clinic setting and effectively translated to non-English-speaking patients. The testing hypothesis for construct validity was clearly stated and the scale performed adequately.

Test-retest reliability/Agreement—Although the ICC for dysphagia was below 0.70, it was high for the other GI symptom questions (0.96–0.99) and the overall GI tract domain (0.84). Responsiveness and Interpretability,

the NMSS appears correlates moderately well with disease severity/progression as measured by the UPDRS III and H&Y scores (Spearman coefficient 0.33–0.35). Correlation with the NMSQuest and PDQ-8 was excellent (r = 0.7). MCID was estimated in part by examining the standard error or the mean (SEM) and standard deviation (SD). In the gastrointestinal domain (where the ICC was high), the SEM was less than [1/2] the SD. The gastrointestinal domain was specifically maintained because it addresses clinically relevant symptoms of "saliva dribbling", dysphagia, and constipation. The questionnaire is moderately easy to score and has moderate administrative burden. The NMSS has good clinimetrics in spite of complex construct and correlates modestly with motor measures and disease duration and closely with quality of life and NMSQuest.

NMSS Limitations: Internal consistency for the whole NMSS was acceptable though the gastrointestinal domain showed weak internal consistency. The scale as a whole demonstrates good acceptability, although the floor and ceiling effects for the gastrointestinal domain were not reported. It has not yet been reported in studies other than the validation study.

Conclusions-Global Scales Addressing Dysautonomia and Nonmotor Symptoms

According to the preestablished criteria, the SCOPA-AUT and NMSQuest may be considered "Recommended" because they have been clinimetrically tested with success and reported in studies outside the original validation study.[64,66] NMSS may be considered "Suggested" because it has been clinimetrically examined and specifically studied in PD, but has not yet been reported outside the original study.[64,66]

PD-specific scales for such isolated symptoms as dysphagia are lacking, and there are specific PD scales for the whole autonomic spectrum, but clinimetric properties have been demonstrated for global nonmotor scales. Such global scales as the SCOPA-AUT or questionnaires as the NMSQuest may, therefore, be used for assessing the presence and frequency of dysphagia symptoms. Both the SCOPA-AUT and the NMSQuest, as part of a holistic measure of nonmotor symptoms of PD, specifically provide standardized measures for the presence or absence of sialorrhea, constipation, and dysphagia.

RESULTS AND CONCLUSIONS—SINGLE ITEMS FROM COMPREHENSIVE SCALES

Single items addressing each symptom within the context of a comprehensive scale include UPDRS Item

TABLE 2. *Suggested and recommended scales for sialorrhea, dysphagia, constipation, and global dysautonomia or nonmotor symptoms that include the three target symptoms*

Scale	Successful clinimetric testing	Reports outside original description	Utilization in PD	Designation
Sialorrhea				
DSFS	No	Yes	Yes	Suggested
DRS	No	No	Yes	Suggested
SCS-PD	Yes	No	Yes	Suggested
Dysphagia				
SDQ	No	No	Yes	Suggested
SWAL-QOL	Yes	Yes	No	Suggested
Constipation				No scales meet criteria
Global Dysautonomia				
SCOPA-AUT	Yes	Yes	Yes	Recommended[a]
Nonmotor symptoms				
NMSQuest	Yes	Yes	Yes	Recommended[a]
NMSS	Yes	No	Yes	Suggested[a]

[a]Note that this scale is not specifically focused on target GI symptoms of sialorrhea, dysphagia, and constipation.

no. 6 for sialorrhea, UPDRS Item no. 7, UMSARS Item no. 2 for dysphagia, and UMSARS Item no. 12 for constipation.

Clinimetric properties for the UPDRS as a whole are established, and the original concept was the UPDRS would be a core assessment tool, supplemented by individual scales or measures that were focused on specific outcomes of interest.[67] As such, clinimetric evaluations of individual items are more limited. However, both Item no. 6 (for sialorrhea) and no. 7 (for swallowing) had excellent interobserver reliability, even when self-administered.[68]

Similarly, UMSARS was specifically designed to be applied in Multiple System Atrophy as an equivalent to the UPDRS for PD.[22] As such, it has not been specifically tested in PD, but it still would have validation clinimetric data in the primary condition. However, it is not specifically focused nor weighted on dysautonomia, and there is no clinimetric data on the cluster of gastrointestinal symptoms.

CONCLUSIONS AND RECOMMENDATIONS

- There are remarkably few scales or questionnaires specifically focusing on sialorrhea, dysphagia, and constipation in PD (Table 2).
- Although commonly used, VAS scales have not been validated. However, given this frequency with which VAS scales are used in sialorrhea and other gastrointestinal dysautonomia symptoms (GIDS) research as outcome measures and their ease of administration, we strongly recommend a particular

VAS scale be clinimetrically validated before including it as a primary outcome measure.

- Depending on the situation, broader, nonmotor scales (SCOPA-AUT and NMSQuest) may offer a method of quickly ascertaining presence and frequency of sialorrhea, dysphagia, and constipation, but may have limited ability to quantitative changes.
- Of the existing scales, most have not been validated or have not been fully validated (DSFS, SWAL-QOL, Rome III) in parkinsonian patients.
- The NMSS has recently been developed and may offer a global tool for evaluating response to therapy for NMS, but has not yet been widely used.
- Quantitation of severity, symptom progression, and response to interventions for sialorrhea, dysphagia, and constipation in clinical studies should probably include physiological measures (e.g., VFSS for dysphagia) until more detailed rating scales can be validated and/or developed.

REFERENCES

1. Gulati A, Forbes A, Stegie F, Kelly L, Clough C, Chaudhuri KR. A clinical observational study of the pattern and occurrence of non-motor symptoms in Parkinson's disease ranging from early to advanced disease. Mov Disord 2004;19 (Suppl 9):S406.

2. Chaudhuri KR, Martinez-Martin P, Schapira AH, et al. International multicenter pilot study of the first comprehensive self-completed nonmotor symptoms questionnaire for Parkinson's disease: the NMSQuest study. Mov Disord 2006;21:916–923.

3. Bushmann M, Dobmeyer SM, Leeker L, Perlmutter JS. Swallowing abnormalities and their response to treatment in Parkinson's disease. Neurology 1989;39:1309–1314.

4. Stroudley J, Walsh M. Radiological assessment of dysphagia in Parkinson's disease. Br J Radiol 1991;64:890–893.

5. Logemann JA, Blonsky ER, Boshes B. Editorial: dysphagia in parkinsonism. JAMA 1975;231:69–70.

6. Robbins JA, Logemann JA, Kirshner HS. Swallowing and speech production in Parkinson's disease. Ann Neurol 1986;19:283–287.

7. 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 Ageing 1994;23:251–254.

8. Carroll CB, Bain PG. Do on-off variations cause discrepancies in the historical items of the UPDRS? Mov Disord 2004;19:605.

9. Goetz CG, Fahn S, Martinez-Martin P, et al. Movement disorder society-sponsored revision of the unified Parkinson's disease rating scale (MDS-UPDRS): process, format, and clinimetric testing plan. Mov Disord 2007;22:41–47.

10. Thomas-Stonell N, Greenberg J. Three treatment approaches and clinical factors in the reduction of drooling. Dysphagia 1988;3:73–78.

11. Heine RG, Catto-Smith AG, Reddihough DS. Effect of antireflux medication on salivary drooling in children with cerebral palsy. Dev Med Child Neurol 1996;38:1030–1036.

12. Marks L, Weinreich J. Drooling in Parkinson's disease: a novel tool for assessment of swallow frequency. Int J Lang Commun Disord 2001;36(Suppl):288–291.

13. Marks L, Turner K, O'Sullivan J, Deighton B, Lees A. Drooling in Parkinson's disease: a novel speech and language therapy intervention. Int J Lang Commun Disord 2001;36(Suppl):282–287.

14. Perez Lloret S, Piran Arce G, Rossi M, Caivano Nemet ML, Salsamendi P, Merello M. Validation of a new scale for the evaluation of sialorrhea in patients with Parkinson's disease. Mov Disord 2007;22:107–111.

15. Lam K, Lam FK, Lau KK, et al. Simple clinical tests may predict severe oropharyngeal dysphagia in Parkinson's disease. Mov Disord 2007;22:640–644.

16. McHorney CA, Bricker DE, Kramer AE, et al. The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults. I. Conceptual foundation and item development. Dysphagia 2000;15:115–121.

17. McHorney CA, Bricker DE, Robbins J, Kramer AE, Rosenbek JC, Chignell KA. The SWAL-QOL outcomes tool for oropharyngeal dysphagia in adults. II. Item reduction and preliminary scaling. Dysphagia 2000;15:122–133.

18. McHorney CA, Robbins J, Lomax K, et al. The SWAL-QOL and SWAL-CARE outcomes tool for oropharyngeal dysphagia in adults. III. Documentation of reliability and validity. Dysphagia 2002;17:97–114.

19. McHorney CA, Martin-Harris B, Robbins J, Rosenbek J. Clinical validity of the SWAL-QOL and SWAL-CARE outcome tools with respect to bolus flow measures. Dysphagia 2006;21:141–148.

20. Drossman DA. The functional gastrointestinal disorders and the Rome III process. Gastroenterology 2006;130:1377–1390.

21. Visser M, Marinus J, Stiggelbout AM, Van Hilten JJ. Assessment of autonomic dysfunction in Parkinson's disease: the SCOPA-AUT. Mov Disord 2004;19:1306–1312.

22. Wenning GK, Tison F, Seppi K, et al. Development and validation of the Unified Multiple System Atrophy Rating Scale (UMSARS). Mov Disord 2004;19:1391–1402.

23. Chaudhuri KR, Martinez-Martin P, Brown RG, et al. The metric properties of a novel non-motor symptoms scale for Parkinson's disease: results from an international pilot study. Mov Disord 2007;22:1901–1911. DOI: 10.1002/mds.21596.

24. Proulx M, de Courval FP, Wiseman MA, Panisset M. Salivary production in Parkinson's disease. Mov Disord 2005;20:204–207.

25. Bateson MC, Gibberd FB, Wilson RS. Salivary symptoms in Parkinson disease. Arch Neurol 1973;29:274–275.

26. Turk-Gonzales M, Odderson IR. Quantitative reduction of saliva production with botulinum toxin type B injection into the salivary glands. Neurorehabil Neural Repair 2005;19:58–61.

27. Pal PK, Calne DB, Calne S, Tsui JK. Botulinum toxin A as treatment for drooling saliva in PD. Neurology 2000;54:244–247.

28. Dogu O, Apaydin D, Sevim S, Talas DU, Aral M. Ultrasound-guided versus 'blind' intraparotid injections of botulinum toxin-A for the treatment of sialorrhoea in patients with Parkinson's disease. Clin Neurol Neurosurg 2004;106:93–96.

29. Lagalla G, Millevolte M, Capecci M, Provinciali L, Ceravolo MG. Botulinum toxin type A for drooling in Parkinson's disease: a double-blind, randomized, placebo-controlled study. Mov Disord 2006;21:704–707.

30. Friedman A, Potulska A. Quantitative assessment of parkinsonian sialorrhea and results of treatment with botulinum toxin. Parkinsonism Relat Disord 2001;7:329–332.

31. Jongerius PH, van Hulst K, van den Hoogen FJ, Rotteveel JJ. The treatment of posterior drooling by botulinum toxin in a child with cerebral palsy. J Pediatr Gastroenterol Nutr 2005;41:351–353.

32. Hassin-Baer S, Scheuer E, Buchman AS, Jacobson I, Ben-Zeev B. Botulinum toxin injections for children with excessive drooling. J Child Neurol 2005;20:120–123.

33. Ellies M, Gottstein U, Rohrbach-Volland S, Arglebe C, Laskawi R. Reduction of salivary flow with botulinum toxin: extended report on 33 patients with drooling, salivary fistulas, and sialadenitis. Laryngoscope 2004;114:1856–1860.

34. Mancini F, Zangaglia R, Cristina S, et al. Double-blind, placebo-controlled study to evaluate the efficacy and safety of botulinum toxin type A in the treatment of drooling in parkinsonism. Mov Disord 2003;18:685–688.

35. Porta M, Gamba M, Bertacchi G, Vaj P. Treatment of sialorrhoea with ultrasound guided botulinum toxin type A injection in patients with neurological disorders. J Neurol Neurosurg Psychiatry 2001;70:538–540.

36. Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson's disease. Neurology 2004;62:37–40.

37. Jones RN. Identification of measurement differences between English and Spanish language versions of the mini-mental state examination. Detecting differential item functioning using MIMIC modeling. Med Care 2006;44(11 Suppl 3):S124–S133.

38. Ali GN, Wallace KL, Schwartz R, DeCarle DJ, Zagami AS, Cook IJ. Mechanisms of oral-pharyngeal dysphagia in patients with Parkinson's disease. Gastroenterology 1996;110:383–392.

39. Manor Y, Giladi N, Cohen A, Fliss DM, Cohen JT. Validation of a swallowing disturbance questionnaire for detecting dysphagia in patients with Parkinson's disease. Mov Disord 2007;22:1917–1921.

40. Nathadwarawala KM, McGroary A, Wiles CM. Swallowing in neurological outpatients: use of a timed test. Dysphagia 1994;9:120–129.

41. Han TR, Paik NJ, Park JW. Quantifying swallowing function after stroke: a functional dysphagia scale based on videofluoroscopic studies. Arch Phys Med Rehabil 2001;82:677–682.

42. Clarke CE, Gullaksen E, Macdonald S, Lowe F. Referral criteria for speech and language therapy assessment of dysphagia caused by idiopathic Parkinson's disease. Acta Neurol Scand 1998;97:27–35.

43. Fujimoto Y, Matsuura H, Kawabata K, Takahashi K, Tayama N. Assessment of swallowing ability scale for oral and oropharyngeal cancer patients. Nippon Jibiinkoka Gakkai Kaiho [J Otorhinolaryngol Soc Jpn] 1997;100:1401–1407.

44. Salassa JR. A functional outcome swallowing scale for staging oropharyngeal dysphagia. Dig Dis 1999;17:230–234.
45. Longstreth G, Thompson W, Chey W, Houghton L, Mearin F, Spiller R. Functional bowel disorders. In: Drossman DA, Corazziari E, Delvaux M, et al., editors. Rome III: the functional gastrointestinal disorders, 3rd ed. McLean, VA: Degnon Associates; 2006. p 1–1048.
46. Galmiche JP, Clouse RE, Balint A, et al. Functional esophageal disorders. Gastroenterology 2006;130:1459–1465.
47. Ware JE, Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–483.
48. Stewart AL, Hays RD, Ware JE, Jr. The MOS short-form general health survey. Reliability and validity in a patient population. Med Care 1988;26:724–735.
49. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res 1995;4:293–307.
50. Ashraf W, Pfeiffer RF, Park F, Lof J, Quigley EM. Constipation in Parkinson's disease: objective assessment and response to psyllium. Mov Disord 1997;12:946–951.
51. Abbott RD, Petrovitch H, White LR, et al. Frequency of bowel movements and the future risk of Parkinson's disease. Neurology 2001;57:456–462.
52. Drossman DA, Sandler RS, McKee DC, Lovitz AJ. Bowel patterns among subjects not seeking health care. Use of a questionnaire to identify a population with bowel dysfunction. Gastroenterology 1982;83:529–534.
53. Hale WE, Perkins LL, May FE, Marks RG, Stewart RB. Symptom prevalence in the elderly. An evaluation of age, sex, disease, and medication use. J Am Geriatr Soc 1986;34:333–340.
54. Talley NJ, Phillips SF, Melton J, III, Wiltgen C, Zinsmeister AR. A patient questionnaire to identify bowel disease. Ann Intern Med 1989;111:671–674.
55. Drossman DA. A questionnaire for functional bowel disorders. Ann Intern Med 1989;111:627–629.
56. Shaw M, Talley NJ, Adlis S, Beebe T, Tomshine P, Healey M. Development of a digestive health status instrument: tests of scaling assumptions, structure and reliability in a primary care population. Aliment Pharmacol Ther 1998;12:1067–1078.
57. Drossman DA. The functional gastrointestinal disorders and the Rome II process. Gut 1999;45(Suppl 2):II1–II5.
58. Gastroenterology. In: Philidelphia: Elsevier; April 2006. Gastroenterol J.
59. Thompson WG, Longstreth GF, Drossman DA, Heaton KW, Irvine EJ, Muller-Lissner SA. Functional bowel disorders and functional abdominal pain. Gut 1999;45(Suppl 2):II43–II47.
60. Kaye J, Gage H, Kimber A, Storey L, Trend P. Excess burden of constipation in Parkinson's disease: a pilot study. Mov Disord 2006;21:1270–1273.
61. Edwards LL, Quigley EM, Harned RK, Hofman R, Pfeiffer RF. Characterization of swallowing and defecation in Parkinson's disease. Am J Gastroenterol 1994;89:15–25.
62. Abbott RD, Ross GW, Petrovitch H, et al. Bowel movement frequency in late-life and incidental Lewy bodies. Mov Disord 2007;22:1581–1586.
63. Zangaglia R, Martignoni E, Glorioso M, et al. Macrogol for the treatment of constipation in Parkinson's disease. A randomized placebo-controlled study. Mov Disord 2007;22:1239–1244.
64. Verbaan D, Marinus J, Visser M, van Rooden SM, Stiggelbout AM, van Hilten JJ. Patient-reported autonomic symptoms in Parkinson disease. Neurology 2007;69:333–341.
65. Naidu Y, Schapira AH, Martinez-Martin P, et al. International validation study of the first comprehensive unified nonmotor symptoms scale (NMSS) for Parkinson's disease (PD). In: 10th International Congress of Parkinson's Disease and Movement Disorders. Kyoto, Japan: Wiley Interscience; September 2006. pS613.
66. Martinez-Martin P, Schapira AHV, Stocchi F, et al. Prevalence of nonmotor symptoms in Parkinson's disease in an international setting; study using nonmotor symptoms questionnaire in 545 patients. Mov Disord 2007;22:1623–1629.
67. The Unified Parkinson's Disease Rating Scale (UPDRS): status and recommendations. Mov Disord 2003;18:738–750.
68. Louis ED, Lynch T, Marder K, Fahn S. Reliability of patient completion of the historical section of the Unified Parkinson's Disease Rating Scale. Mov Disord 1996;11:185–192.
69. Kline RB. Principles and practice of structural equation modeling, 2nd ed. New York: The Guilford Press; 2005.
70. Carmines EG, Zeller RA. Reliability and validity assessment: quantitative application in the social sciences. Beverley Hills, CA: Sage Publications; 1979.