The AMC Linear Disability Score in patients with newly diagnosed Parkinson disease

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ABSTRACT

Objective: The aim of this study was to examine the clinimetric properties of the AMC Linear Disability Score (ALDS), a new generic disability measure based on Item Response Theory, in patients with newly diagnosed Parkinson disease (PD).

Methods: A sample of 132 patients with PD was evaluated using the Hoehn and Yahr (H&Y), the Unified PD Rating Scale motor examination, the Schwab and England scale (S&E), the Short Form-36, the PD Quality of Life Questionnaire, and the ALDS.

Results: The internal consistency reliability of the ALDS was good ($\alpha = 0.95$) with 55 items extending the sufficient item-total correlation criterion ($r > 0.20$). The ALDS was correlated with other disability measures ($r = 0.50$ to 0.63) and decreasingly associated with measures reflecting impairments ($r = 0.36$ to 0.37) and mental health ($r = 0.23$ to -0.01). With regard to know-group validity, the ALDS indicated that patients with more severe PD (H&Y stage 3) were more disabled than patients with mild (H&Y stage 1) or moderate PD (H&Y stage 2) ($p < 0.0001$). The ALDS discriminated between more or less severe extrapyramidal symptoms ($p = 0.001$) and patients with postural instability showed lower ALDS scores compared to patients without postural instability ($p < 0.0001$). Compared to the S&E (score 100% = 19%), the ALDS showed less of a ceiling effect (5%).

Conclusion: The AMC Linear Disability Score is a flexible, feasible, and clinimetrically promising instrument to assess the level of disability in patients with newly diagnosed Parkinson disease.

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GLOSSARY

ADL = activities of daily living; **ALDS** = AMC Linear Disability Score; **ANOVA** = analysis of variance; **H&Y** = Hoehn and Yahr; **IRT** = item response theory; **PD** = Parkinson disease; **PDQL** = PD Quality of Life Questionnaire; **S&E** = Schwab and England scale; **SF** = Short Form; **UPDRS** = Unified PD Rating Scale.

The impact of a disease on a patient's level of activities of daily living (ADL) is generally considered as an important outcome measure in clinical studies.¹ This is not different in patients with Parkinson disease (PD).^{2,3} Frequently used (disease-specific) disability scales, such as the ADL part of the Unified PD Rating Scale (UPDRS-ADL),⁴ are sumscore-based. Consequently, all items have to be presented to all patients irrespective of their level of disability, which means that able patients as well as more disabled patients will be presented the same items, which may lead to ceiling and floor effects.⁵⁻⁷ Another disadvantage is that each scale contains different items, response options, and scoring rules, which hinder direct comparisons of interventions.⁸ An alternative approach is the use of ordinal indexes, such as the Schwab & England Activities of Daily Living Scale (S&E),⁹ which are less sensitive for subtle changes in a patient's condition.

Currently, interest is moving toward the more flexible framework offered by item response theory (IRT). An item bank is a collection of items for which the measurement

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properties of each item are known.¹⁰⁻¹² Since IRT centers on the measurement properties of individual items, rather than the instrument as a whole, it is not essential for all respondents to be examined using all items when using an item bank. It is possible to select items for individual patients using small sets of items tailored to the disability level of the patients.¹³ This can reduce the burden of testing considerably for both patients and researchers. Examples of other disability item banks are developed by Haley et al.¹⁴ and Ware et al.¹⁵

Using modern clinimetric methods based on IRT¹¹ we developed a linear outcome scale which can be used in both mildly and severely affected patients.^{8,16,17} The AMC Linear Disability Score (ALDS) is a generic, non-disease-specific item bank consisting of 77 ADL items hierarchically ordered from simple to complex. By using a small number of items, tailored to the ADL level of patients, a sufficiently detailed clinical picture can be obtained. Even if different sets of items are used for different groups of patients, ALDS scores can still be compared within or between medical specialties.

Assessment of early signs of disability becomes increasingly important in the context of current research on neuroprotection and symptomatic treatment in PD.¹⁸ The objective of this study was therefore to examine the clinimetric properties of the ALDS item bank in patients with newly diagnosed PD in terms of internal consistency reliability, validity, and the presence of a ceiling effect. In line with this objective and in agreement with our previous studies,^{19,20} we hypothesized that the ALDS 1) has an internal consistency reliability exceeding the 0.80 coefficient alpha value, 2) is moderately correlated with other disability measures and lower correlated with instruments that measure other aspects of health, 3) is able to distinguish between clinical different groups, and 4) shows less of a ceiling effect compared to the often used S&E index.

METHODS Subjects. The study sample comprised 133 consecutive patients with newly diagnosed PD, recruited from the neurology outpatient clinics of six general hospitals in the Netherlands (Meander Medical Center Amersfoort, Medical Center Alkmaar, Academic Medical Center Amsterdam, St. Lucas-Andreas Hospital Amsterdam, Slotervaart Hospital Amsterdam, and OLVG Amsterdam) between July 2002 and March 2005. ALDS data from 132 patients was available and used for analysis. The clinical diagnosis of PD was based on internationally accepted diagnostic criteria.²¹ Patients were excluded if they were aged 85 years or older, had insufficient proficiency in the Dutch language, or had a somatic illness and a life expectancy of less than a year. The patients in this study were participants in a longitudinal research project investigating the course of functional status and its determinants in PD. The data presented here were obtained at the baseline assessment. Written informed consent was obtained from all subjects after the nature of the study had been fully explained. The study was approved by the local ethics committees of the participating hospitals.

Procedure. Neurologic examination of all patients was performed to confirm the diagnosis of PD. Information about demographic characteristics, duration of the disease (time between the appearance of the first symptom of PD as reported by the patient and the moment of assessment), initial symptoms and side of onset of disease, medication, and response to levodopa (L-dopa) therapy was obtained with a semi-structured interview. As this was a cohort of newly diagnosed patients without “on”–“off” response fluctuation it was not necessary to perform a standardized “on”–“off” scoring.

The severity of extrapyramidal symptoms was rated using the motor examination part of the UPDRS (UPDRS-ME).⁴ The stage of disease was determined with the Hoehn and Yahr staging scale (H&Y).²² Functional status (disability and quality of life) was evaluated using the S&E,⁹ the Medical Outcome Study 36-Item Short-Form General Health Survey (SF-36),²³ the PD Quality of Life Questionnaire (PDQL),²⁴ and the ALDS.

Motor impairment assessment. The UPDRS consists of four components: 1) mentation, behavior, and mood; 2) activities of daily living; 3) motor examination; 4) complications of therapy.²⁵ The UPDRS-ME quantifies type, number, and severity of extrapyramidal signs. For each sign a five-step severity gradation is used, with zero representing absence and four representing the maximum severity of that sign. The total number of items is 27 with total scores ranging from 0 to 108. The H&Y is the standard disease-staging index for PD and consists of five levels: 1) unilateral symptoms only; 2) bilateral symptoms, without balance impairment; 3) bilateral symptoms with definite impairment of postural reflexes; 4) severe disability, but still able to walk or stand unassisted; 5) wheelchair-bound or bedridden.

Disability and quality of life. The S&E was specifically designed for patients with PD and reflects the patient's ability to perform daily activities in terms of speed and independence. ADL ability is measured on an 11-point scale ranging from 0% (vegetative function) to 100% (complete independence). The SF-36 consists of eight health concepts: physical functioning (SF-36 PF), role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and men-

tal health. The eight scales define two distinct components: the physical component score (SF-36 PCS) (SF-36 PF, role limitations caused by physical problems, bodily pain, general health) and the mental component score (SF-36 MCS) (vitality, social functioning, role limitations caused by emotional problems and mental health). Each dimension is scored from 0 to 100. A high score suggests good health. The PDQL consists of total score and four subsections: parkinsonian symptoms (14 items), systemic symptoms (7 items), social function (7 items), and emotional function (PDQL EF) (9 items: score range 9 to 45). The items are scored on a five-point Likert scale (score range 37 to 185). Higher scores indicate a better quality of life.

We consider the S&E and the SF-36 PF as disability measures, the SF-36 PCS as a generic “perceived” functional status measure, and the SF-36 MCS and the PDQL EF as instruments focusing on the psychological aspects of quality of life.

AMC linear disability item bank. The ALDS item bank was developed to quantify functional status in terms of the ability to perform ADL using an IRT framework.¹⁶ The items were obtained from a systematic review of generic and disease-specific functional health instruments.⁸ Both the item difficulty and the patient’s ability are arranged on a single hierarchical linear scale. The current version of the item bank consists of 77 items, ranging from relatively easy to difficult¹⁹ (see appendix E-1 on the *Neurology*[®] Web site at www.neurology.org for further details). Researchers can use their clinical judgment to select items from the item bank that are applicable to the population they are investigating. This flexible approach results in a range of individual constructed scales specifically targeted to the patient’s ability level. Hence, these tailored scales may be quite different from even patient to patient, but all assess the construct of interest because the items are all selected from an item bank which has previously been calibrated.¹³ Consequently, items which have a similar difficulty grade are interchangeable and can be used to assemble scales with items that may be of interest for different patient groups. In this way the item bank can be used to assess patients with a wide range of conditions and levels of functional status, without putting undue strain on them. The methodology¹⁶ (appendix E-2), the psychometrics of the ALDS in terms of dealing with missing data,²⁰ differences between item measurement characteristics of the item bank in relation to age and sex,²⁶ and the metric properties of ALDS items in mixed types of patient groups,¹⁹ as well as the statistical power to detect given effect sizes in clinical trials using IRT outcome scales,²⁷ have been examined in depth.

In this study, depending on his or her ability level, each patient was assessed with a number of the 77 items in the current version of the item bank (ranging from 7 to 43 items per patient; 35 items on average in the present study) to estimate his or her functional status. Beforehand different item sets were composed by two of the authors (N.W., R.d.H.). If only limited information was available on the ability status of the patient a selection of items covering the whole range of the item bank was presented. Mildly disabled patients were presented with more difficult items because those were likely to provide more information. On the other hand, more easier items lower on the scale were presented to more disabled patients. Some patients were assessed with only seven items because there were no remaining items that should have

given additional information to the estimation of the patient’s disability level (patients at the ceiling or the floor of the distribution). The items were administered by trained nurses and had two response options: “I can carry out the activity” and “I cannot carry out the activity.” Participants were asked to indicate whether they could perform the activities now in the same way that they would at home or in the location where they were residing. If an activity had never before been performed by a patient (e.g., “travel by local bus or tram”), or the patients’ response was “I do not know,” “not applicable” was recorded.

The original units of the ALDS scale are (logistic) regression coefficients, expressed in logits (appendix E-1). To make the results easier to interpret, the logit scores are linearly transformed (the interval level stays preserved) into values between 0 (dead) and 100. The value 1 represents the lowest level and the value 100 the highest level of functional status possible. (The complete item bank, psychometric properties of the individual items, and scoring rules are available upon request.)

Clinimetric evaluation. The clinimetric properties of the ALDS were studied in terms of internal consistency reliability, validity, and the presence of a ceiling effect. Internal consistency refers to the statistical coherence of the scale items. One measure of internal consistency is the Cronbach α coefficient,²⁸ based on the (weighted) average correlation of items within a scale. Internal consistency is considered to be good if $\alpha \geq 0.80$.²⁹ We also calculated item-total correlations, which represent the correlation of a single item with the sum of all other items. Correlations ≥ 0.20 or more were considered to be sufficient.³⁰

With regard to the validity of the ALDS we focused on both its construct validity and clinical validity (also known as known-groups validity). Construct validity was assessed by measuring the extent to which the ALDS correlates with measures (S&E, SF-36 PF, SF-36 PCS) that address the same concept and measures (H&Y, UPDRS-ME, SF-36 MCS, PDQL EF) that address conceptually different aspects of health. We assumed that in order for the ALDS to be valid, the ALDS scores had to show a decreasing pattern of associations, with higher correlations with the other disability-oriented scale scores, intermediate correlations with neurologic impairments, and lower correlations with the psychological aspects of quality of life. A scale demonstrates clinical validity if it discriminates between groups of patients with known differences in clinical status, in this case disease severity based on the H&Y, severity of extrapyramidal symptoms based on the UPDRS-ME, and the presence of postural instability (item 30). Absence of posture instability was defined as score 0 (normal); a score ≥ 1 (1 = retropulsion; 2 = absence of postural response) was defined as postural instability. With regard to a ceiling effect, the percentage of patients that reached a maximum score on the S&E and ALDS was presented.

Statistical analysis. Patient characteristics, outcome scores, and ceiling effects were analyzed using descriptive statistics. Scores on the ALDS instrument were calculated using previously published item properties¹⁹ and algorithms implemented in BILOG-MG³¹ and SPSS. ALDS items that a patient had not responded to or had answered not applicable were treated as if they had not been offered to that patient.²⁰ Values of Cronbach α were obtained using an IRT method that allows for missing item responses^{28,32} implemented in

Table 1 Clinical characteristics of the 132 patients with newly diagnosed PD

Clinical variables	Total (n = 132)
Gender (men) (%)	74 (56%)
Age at onset of symptoms, mean y (SD; range)	65 (10.4; 30.9–83.5)
Age at diagnosis of PD, mean y (SD; range)	66.3 (10.4; 32–84.6)
Age at examination, mean y (SD; range)	66.7 (10.4; 32.4–84.9)
Duration of symptoms at examination, mean mo (SD; range)	19.9 (11.2; 4.7–83.9)
Symptoms at start of the disease (%)	
Tremor	60 (45)
Bradykinesia/rigidity	61 (46)
Tremor/bradykinesia/rigidity	11 (8)
Side of symptom onset*	
Unilateral (R+L)	98 (48+50)
Two sides asymmetric	13
Two sides symmetric	19
Receiving dopaminergic therapy (%)	84 (64)
LED when receiving dopaminergic therapy, mean (SD, range)	152 (148; 0–600)
Sum score UPDRS-ME, mean (SD, range)	17.5 (8.2; 5–40)
H&Y score (%)	
1	47 (36)
1.5	7 (5)
2	40 (30)
2.5	22 (17)
3	16 (12)
4	0
5	0

*Side of symptom onset is missing for two patients.

PD = Parkinson disease; LED = levodopa equivalent dose; UPDRS-ME = Unified Parkinson's Disease Rating Scale motor examination; H&Y = Hoehn and Yahr.

TESTFACT.³¹ Item-total correlations, as well as the associations between the ALDS scores and the other measures, were expressed in Pearson (r) or Spearman correlation coefficients (r_s), when appropriate.

Normality tests showed a normal distribution of the ALDS. Therefore, the data were analyzed using parametric statistics. Differences between mean ALDS scores (with 95% CI) were analyzed using an independent t test or one-way

analysis of variance (ANOVA), including post hoc Tukey HSD tests (significance level 0.05). The concerning effect size for ANOVA main effect result was expressed in Cohen f and for the independent t test in Cohen d . The original ALDS logits were used in all analyses but for the sake of clarity only the linearly transformed ALDS scores (0 to 100) are presented.

RESULTS The study included 132 patients with newly diagnosed PD, 74 (56%) of whom were men. The mean age at onset of symptoms was 65 (SD $\pm$ 10.4); the patients' mean age at examination was 66.7 (SD $\pm$ 10.4 years). Mean disease duration at examination was 19.9 (SD $\pm$ 11.2) months. Eighty-four (64%) patients were taking L-dopa. Further clinical characteristics of the sample are shown in table 1.

The internal consistency reliability of the ALDS was good (Cronbach α = 0.95). Of the 77 items, 55 items showed item-total correlations with values ranging from r = 0.20 to r = 0.68, all exceeding the ≥ 0.20 standard. Sixteen items had no score variation; consequently, no correlations could be calculated (e.g., "take off a T-shirt"), whereas five items showed item-total correlations < 0.20 (range -0.03 to 0.19).

Table 2 presents the descriptive statistics of the instruments and the correlation coefficients between the ALDS and the other scales. The highest associations occurred between the ALDS and other disability measures: S&E (r_s = 0.50), SF-36 PF (r = 0.63), and SF-36 PCS (r = 0.55). Additionally, the ALDS showed a decreasing pattern of associations between the scales measuring neurologic impairments (H&Y; r = -0.36 , UPDRS-ME; r = -0.37) and mental health (SF-36 MCS; r = -0.01 , PDQL EF; r = 0.23).

With regard to the clinical (known-group) validity (table 3), ALDS scores registered an association between the severity of PD as determined by H&Y classification and impaired disability status (one-way ANOVA; F = 12.06, p < 0.0001; Cohen

Table 2 Descriptive statistics of the instruments and correlations between the ALDS and other Parkinson disease measures

	S&E (n = 132)	SF-36 PF (n = 130)	SF-36 PCS (n = 122)	H&Y (n = 132)	UPDRS-ME (n = 132)	SF-36 MCS (n = 122)	PDQL EF (n = 123)
	90 (60–100)	66.1 ($\pm$ 24.1)	43.7 ($\pm$ 10.1)	2 (1–3)	17.5 ($\pm$ 8.2)	44.5 ($\pm$ 12)	35.9 ($\pm$ 5.9)
ALDS 82.7 ($\pm$ 8.67)	0.50	0.63	0.55	-0.36^*	-0.37^*	-0.01^*	0.23

Score values are mean ($\pm$ SD), except for the S&E and the H&Y, which are presented in median and range; correlation values are Pearson correlation coefficient and calculated with the ALDS logits, with the exception of the association between the S&E and the H&Y, which are expressed in Spearman correlation coefficient.

*Since higher H&Y and UPDRS-ME scores indicate more neurologic deficits, signs of the coefficients are the opposite of those of other scales.

*All correlation coefficients are significant at the 0.01 level, except for the correlation with SF-36 MCS (p = 0.94).

ALDS = AMC Linear Disability Score; S&E = Schwab and England scale; SF = Short Form; H&Y = Hoehn and Yahr; UPDRS = Unified PD Rating Scale; PDQL = PD Quality of Life Questionnaire.

Table 3 Score distributions of the ALDS between groups of patients with known differences in clinical status: Clinical validity

	No.	ALDS	p Value	Effect size
H&Y			<0.0001	0.60
Stage 1 (mild)	54	84.6 (±6.2; 83.0–86.3)		
Stage 2 (moderate)	62	83.1 (±9.5; 80.7–85.4)		
Stage 3 (severe)	16	75.2 (±8.9; 70.5–79.6)		
UPDRS-ME*			0.001	0.62
<15.5	66	84.8 (±8.2; 82.8–86.7)		
≥15.5	66	80.7 (±8.7; 78.6–82.8)		
Posture (item 30)*			<0.0001	0.65
Score 0	92	84.6 (±5.2; 83.6–85.7)		
Score ≥1	40	78.3 (±12.6; 74.9–81.6)		

Score distributions are presented in mean (±SD; 95% CI); differences in mean logit scores are calculated using one-way analysis of variance (ANOVA) (H&Y), and an independent t test (UPDRS-ME, posture item 30). Effect size for ANOVA was expressed in Cohen *f*, for the independent t test in Cohen *d*.

*UPDRS-ME was dichotomized on base of the median value of the scores.

*Score range of item 30 was 0 to 2; 0 = normal; 1 = retropulsion; 2 = absence of postural response.

ALDS = AMC Linear Disability Score; H&Y = Hoehn and Yahr; UPDRS = Unified PD Rating Scale.

$f = 0.60$). Patients with H&Y stage 3 had lower ALDS scores compared to H&Y stage 2 (Tukey HSD; $p < 0.0001$) and H&Y stage 1 (Tukey HSD; $p < 0.0001$). However, the ALDS scores were not different between H&Y stage 1 and stage 2 (Tukey HSD; $p = 0.36$). The score distributions of the ALDS reflect that patients with more severe extrapyramidal symptoms (UPDRS-ME ≥ 15.5) were more disabled (independent *t* test; $t = 3.53$, $p = 0.001$; Cohen $d = 0.62$) than patients with less severe extrapyramidal symptoms (UPDRS-ME < 15.5). Additionally, the ALDS showed an association between postural (in)stability and disability level (independent *t* test; $t = 4.30$, $p < 0.0001$; Cohen $d = 0.65$).

Six patients (5%) had a maximum ALDS score; the percentage of patients scoring at the ceiling of the S&E (score = 100%) was substantially higher (19%). The figure presents the measurement range of the ALDS items in case of a maximum S&E (100% score). These less disabled patients could still be differentiated with seven ALDS items, ranging from walking in the woods to heavy household tasks.

DISCUSSION In this study we expanded the psychometric evaluations of the ALDS^{8,16,17,19,20,26,27} to patients with early PD. We showed the ALDS has promising clinimetric properties in terms of internal consistency reliability, construct and clinical validity, and absence of ceiling effects.

The internal consistency of the ALDS was high

(Cronbach $\alpha = 0.95$). Though Cronbach alpha is a well-established measure of internal consistency, it is dependent also on the number of items in the scale. In this study 35 items were assessed at average. Therefore, the high alpha must be interpreted with certain caution. Nevertheless, 70% of the ALDS items exceeded the item-total correlation standard of 0.20, reflecting good internal consistency as well. Six percent of the items were below the required level. No item-total correlations could be calculated in 20% of the items. These were 16 items mainly at the lower end of the scale. All patients were able to perform those items and indicate the high ability level of the patients with PD studied. This does not mean that they should be omitted from the ALDS. First, these items have psychometric qualities,¹⁹ and second, an assessment of those items could provide useful clinical information in more disabled patients with PD. However, we advise not to apply those items in a newly diagnosed PD patient group.

The correlations between the ALDS on the one hand and the S&E and physical aspects of the SF-36 on the other indicate that these scales largely focus on the same construct, which is disability. The decreasing correlation between the ALDS and measures of neurologic disturbances and psychological well-being demonstrates the ALDS is less focused on conceptually different aspects of health in terms of impairments or quality of life.

Figure Measurement range of AMC Linear Disability Score items in patients with a maximum Schwab and England scale score 100% ($n = 25$)

Our findings that the ALDS scores differentiate between moderate and severe disease as well as more or less extrapyramidal symptoms indicate that the ALDS is sufficiently sensitive to distinguish different patient groups. However, between mild and moderate patients, we did not find differences in ALDS scores. This can be due to the reason that impairments in early PD (H&Y stage 1 and 2) lead to no or subtle differences in disability. Moreover, patients with postural instability showed significantly lower ALDS scores compared to patients without postural instability.

By administering the ALDS only those items relevant to a person's disability status is used, thereby reducing patient burden in time and effort. The ALDS will form a good foundation for a computerized adaptive testing procedure, allowing for shorter questionnaires where the difficulty level is automatically adapted per question depending on the individual patient's ability to perform the questioned activity.³³ Obviously, this is an initial study on the use of the ALDS in PD which provides the basis for further testing.

A limitation of our study is that we did not compare the ALDS with the currently most widely used UPDRS-ADL score.³⁴ The patients in this study were participants in a longitudinal research project investigating the course of functional status and its determinants in PD. Unfortunately, this study did not include the evaluation of functional status by this scale.

In our inception cohort of newly diagnosed patients, severe disease stages (H&Y 4 and 5) have not been represented. We showed in our study that the ALDS, compared to the S&E, had a smaller amount of ceiling effect. For example, patients with an S&E score of 100% can still be differentiated by ALDS items. However, potential floor effects should be investigated in future research.

Investigating the clinimetric properties of a scale is an ongoing process. The present study is a first step in the validation process of the ALDS in patients with PD. Further studies are needed to investigate whether the ALDS provides consistent scores over time and between observers (test-retest, inter/intrarater reliability), to compare the ALDS with the UPDRS-ADL, to follow patients who reflect the whole severity spectrum of the disease, and to examine the responsiveness of the ALDS to measure changes in disability over time. Good responsiveness is likely due to the scale's linearity, its absence of ceiling effects, and its flexibility to choose among a wide range of patient tailored items.

The ALDS is a new, generic, non-disease-specific scale consisting of 77 ADL items. Our data show that the ALDS has good internal consistency reliability, did not demonstrate a ceiling effect, and indicates good construct and clinical validity in patients with newly diagnosed PD. Currently, we are extending the psychometric properties of the item bank to a variety of other neurologic diseases and by calibrating more items especially at the floor and the ceiling of the item bank.

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