

Demonstrating the clinical value of MANAGE-PD tool in assessing symptom control of Parkinson's disease patients: Evidence from G7 Countries

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BACKGROUND

- A lack of universal definition and absence of standard testing leads to challenges in identification and symptom management in advanced Parkinson's disease¹.
- Tools that can assist clinicians in identifying patients whose symptoms are inadequately controlled on oral medications or who are eligible for advanced PD therapies are important for routine clinical practice².
- Making Informed Decisions to Aid Timely Management of Parkinson's Disease (MANAGE-PD) is a validated³⁻⁵, web-based tool designed to support healthcare providers in identifying patients with PD that may be inadequately controlled on oral medications.
- The MANAGE-PD tool is available for access by U.S. Healthcare Professionals only. The tool can be accessed here: www.managepd.com.
- The tool was developed using a mixed-method approach⁶, building on consensus clinical indicators of advanced Parkinson's disease identified by leading movement disorder specialists¹, and demonstrated strong validity using hypothetical patient vignettes^{3,4} and real-world patient-level data⁵.

OBJECTIVE

- To evaluate the clinical value of using the MANAGE-PD tool for assessing PD symptom control in a real-world setting.

METHODS

Population

- A secondary analysis using data from the multi-country Adelphi Parkinson's Disease Specific Programme (DSP) was conducted. The Parkinson's DSP is a cross-sectional survey of neurologists and their patients with Parkinson's Disease (PD) conducted across G7 countries (US, France, Germany, Italy, Spain, UK, Japan). The DSP is a published methodology⁷.
- A sample of device-aided therapy-naïve PD patients from G7 countries who were on oral therapy only and managed by movement disorder specialists were included.

Measures

- Patients were evaluated in clinical practice and independently grouped into 3 categories based on MANAGE-PD scoring algorithm and physician judgement: (i) adequately controlled on oral therapy; (ii) inadequately controlled on oral therapy and consider oral optimization only, (iii) inadequately controlled on oral therapy and consider evaluation for DAT along with oral optimization [Figure 1].
- Demographics, clinical characteristics, and measures of disease severity and burden were evaluated for all patients.
 - Measures included daily hours of OFF-time; weekly hours of overall caregiver support, hospitalization rate in the last 12 months, cognitive impairment using Mini-mental state examination (MMSE), quality of life using Parkinson's Disease Questionnaire (PDQ-39), and caregiver burden using Zarit Burden Index (ZBI).

- Concordance between MANAGE-PD and clinician judgement was evaluated.

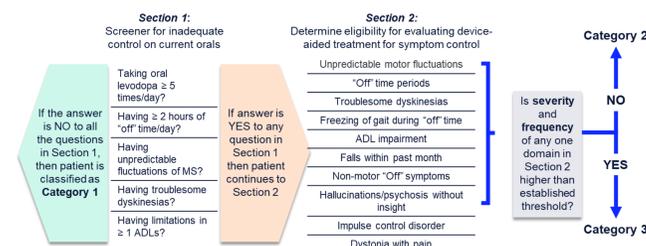
- Amongst the discordant cases, accuracy was assessed based on comparing known measures of disease severity between patients scored as higher severity by MANAGE-PD with patients scored as higher severity by clinician judgement.

Statistical Analysis

- Known group comparison using t-tests, chi-squared, and Fisher's Exact to compare between patients scored as higher severity by MANAGE-PD with patients scored as higher severity by clinician judgement.

METHODS (CONTINUED)

Figure 1: Overview of the MANAGE-PD tool



Notes: The MANAGE-PD tool is available for access by U.S. Healthcare Professionals only. The tool can be accessed here: www.managepd.com.
Category 1: adequately controlled on oral therapy; Category 2: inadequately controlled on oral therapy and consider oral optimization only; Category 3: inadequately controlled on oral therapy and consider evaluation for DAT along with oral optimization.

Abbreviations: MANAGE-PD: Making Informed Decisions to Aid Timely Management of Parkinson's Disease

RESULTS

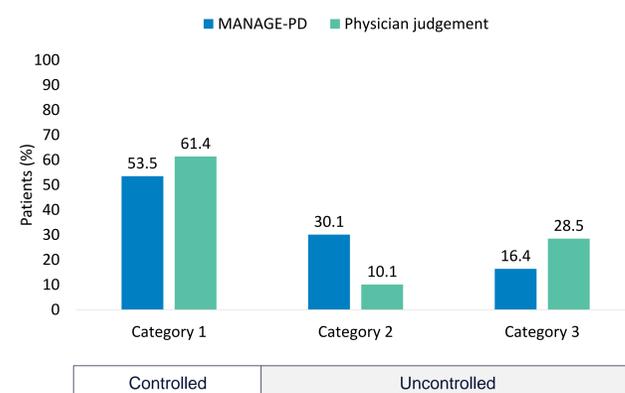
Patient Characteristics

- From the analytical sample (n=2016), 13% patients were classified as being advanced PD by the physicians' judgement.
- Patients had a mean age of 69 years and mean time since diagnosis of 4.7 years.
- Majority of patients were included from EU5 (United Kingdom, France, Spain, Italy, and Germany) 1513 (75%), with 447 (22%) patients from Japan and 56 (3%) from the US.

Patient Categorization

- Based on physician judgement, 1238 (61%) patients were classified as Category 1, 203 (10%) as Category 2, and 575 (29%) as Category 3 [Figure 2].
- Based on MANAGE-PD, 1079 (54%) patients were classified as Category 1, 607 (30%) as Category 2, and 330 (16%) as Category 3 [Figure 2].

Figure 2: Patient classification based on MANAGE-PD tool and physician judgement.



Notes: Category 1: adequately controlled on oral therapy; Category 2: inadequately controlled on oral therapy and consider oral optimization only; Category 3: inadequately controlled on oral therapy and consider evaluation for DAT along with oral optimization.

Abbreviations: MANAGE-PD: Making Informed Decisions to Aid Timely Management of Parkinson's Disease

Concordance

- Of the analytical sample, 858 (43%) patients had a mismatch in level of clinical control between MANAGE-PD and clinical judgement [Table 1].
- Among mismatched cases, there was an almost equal distribution of patients rated as higher severity by clinician judgement (Group B; n=418) and patients rated as higher severity by MANAGE-PD (Group C; n=440) [Table 1].

RESULTS (CONTINUED)

Table 1: Concordance of patient category based on independent assessment using MANAGE-PD tool and clinician judgement.

Physician Judgement (3 level)	Manage PD (3 Level)		
	Category 1	Category 2	Category 3
Category 1	866	310	62
Category 2	43	92	68
Category 3	170	205	200

- MANAGE-PD = Physician Judgement (Group A)
- MANAGE-PD lower severity; Physician Judgement higher severity (Group B)
- MANAGE-PD higher severity; Physician Judgement lower severity (Group C)

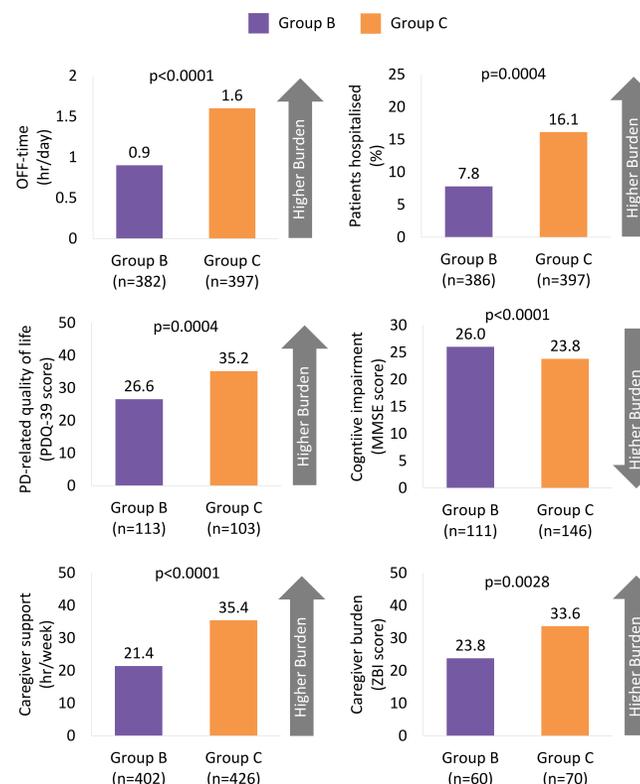
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Clinical Value

- Patients rated as higher severity by MANAGE-PD (Group C) were observed to have: (i) nearly twice as much daily OFF-time on average (1.6 hours vs 0.9 hours, p<0.0001), (ii) twice the likelihood of having been hospitalized in the last 12 months (16% vs 8%, p=0.0004), (iii) higher cognitive impairment (MMSE score 23.8 vs 26.0, p<0.0001), (iv) poorer PD-related quality of life (PDQ-39 index score 35.2 vs 26.6, p=0.0004), (v) greater number of hours of caregiver support per week (35.4 hours vs 21.4 hours, p<0.0001), and (vi) higher caregiver burden (ZBI score 33.6 vs 23.8, p=0.0028) [Figure 3].

Figure 3: Comparison of known disease severity and burden measures between patients classified as higher severity by physician judgement (Group B) and patients classified as higher severity by MANAGE-PD (Group C)



Notes: Hospitalization rate is based on percentage hospitalized in last 12 months, caregiver support includes weekly professional and non-professional caregiver use.

Abbreviations: MANAGE-PD: Making Informed Decisions to Aid Timely Management of Parkinson's Disease; MMSE: Mini-mental state examination, PDQ-39: Parkinson's Disease Questionnaire; ZBI: Zarit Burden Index.

DISCUSSION & CONCLUSIONS

- In this large, real-world, international population, patients rated as having higher severity by MANAGE-PD tool demonstrated incrementally higher disease burden.
- Lack of routine standardized testing in current clinical practice means these inadequately controlled PD patients may not be identified and managed in a timely manner.
- This study reinforces the clinical value of MANAGE-PD in timely identifying patients whose symptoms are sub-optimally controlled with oral treatment and who may benefit from optimization and/or advanced treatment approaches.
- Limitations include: the sample is not random, and this could introduce bias; and the quality of data partly depends on the accurate reporting of information, which may result in recall bias.
- However, this large, international dataset is derived from the Adelphi DSP, which offers a robust sample of patients receiving care in real-world settings.
- In addition, the MANAGE-PD tool is based on robust quantitative and qualitative evidence from a panel of leading PD specialists across multiple countries³⁻⁶.
- Clinical use of the MANAGE-PD tool may facilitate identification and management of symptoms, and could lead to timely discussions between clinicians and patients resulting in possible improvement in patients' quality of life.

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AUTHOR DISCLOSURES

- Angelo Antonini has received compensation for consultancy and speaker related activities from UCB, Bial, GE, Boehringer Ingelheim, AbbVie, Zambon, Neuroderm, Kyowa, Roche, Biogen. He also received research support from Chiesi Pharmaceuticals and Lundbeck.
- Ali Alobaidi, Yash J. Jalundhwal, Koray Onuk, Jorge Zamudio, and Pavnit K Kukreja are employees of AbbVie and may own stocks/shares in the company.
- Per Odin has received compensations for consultancy and speaker related activities from AbbVie, Bial, Britannia, Ever Pharma, Lobsor, Nordic Infucare, Stada, and Zambon. Odin has received royalties from Uni-Med Verlag.
- F. Cubillos is an employee of the Parkinson's Foundation.
- P. Schmidt was an employee of the Parkinson's Foundation at the time of the study.
- Eddie Jones and Jack Wright are employees of Adelphi Real World, a consulting company that was hired by AbbVie to perform analyses on the Adelphi Disease Specific Programme database.
- H. Fernandez has received research support from and has served as consultant/scientific adviser and lecturer for AbbVie.

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