**PROBAST**

Study:

Comparing Objective and Subjective Measures of Parkinson's Disease Using the Parkinson's KinetiGraph

Step 2: Type of prediction study

**Is the study a diagnostic or a prognostic study?**

Diagnostic

**Is the study a development only, development and validation or validation only study?**

Development only

**What is the model of interest?**

Multiple linear regression

**What is the outcome of interest?**

PD severity

Step 3: Assess risk of bias

**Domain 1: Participants**

**Describe the sources of data and criteria for participant selection**

We examined 34 patients with mild to moderate Parkinson’s disease (Hoehn and Yahr scale 2–3 in ON state) aged 50–75 years who had had symptoms of Parkinson’s disease for 3–7 years and had no dementia

**1.1 Were appropriate data sources used, e.g. cohort, RCT or nested case-control study data?**

**Y**

**1.2 Were all inclusions and exclusions of participants appropriate?**

Y

**Risk of bias introduced by selection of participants:**

Low

**Rationale of bias rating**

Appropriate eligibility criteria for PD

**Domain 2: Predictors**

**List and describe predictors included in the final model, e.g. definition and timing of assessment**

The PKG accelerometer measured bradykinesia and dyskinesia levels during 2-min epochs from 5:00 a.m. to11:00 a.m.

**2.1 Were predictors defined and assessed in a similar way for all participants?**

Y

**2.2 Were predictor assessments made without knowledge of outcome data?**

Y

**2.3 Are all predictors available at the time the model intended to be used?**

Y

**Risk of bias introduced by predictors or their assessment**

Low

**Rationale of bias rating**

Accelerometer data used are independent and easily applicable

**Domain 3: Outcome**

**Describe the outcome, how it was defined and determined, and the time interval between predictor assessment and outcome determination:**

The MDS-UPDRS part II provides a clinical measure of ADL-impairment and has been shown to highly correlate with other disability rating scales (13). The rating system quantifies motor experiences of daily living using 13 self-assessed items. A score was determined foreach patient using the scale 0 = normal, 1 = slight, 2 = mild, 3 =moderate, and 4 = severe to assess each item, yielding an overall possible score range of 0 to 52.

Four of these eight questions asked thepatient if they felt their ADLs were significantly impactedby the respective symptoms; these questions constituted thesubjective component of the questionnaire. The remaining fourquestions asked if the patient had demonstrated the respectivesymptoms according to the PKG measurements; these questionswere completed by the clinician, and constituted the objectivecomponent of the questionnaire. For each question, a responseof “no” corresponded to a score of 0, and a response of “yes” corresponded to a score of 1.

**3.1 Was the outcome determined appropriately?**

Y

**3.2 Was a pre-specified or standard outcome definition used?**

Y

**3.3 Were predictors excluded from the outcome definition?**

N

**3.4 Was the outcome defined and determined in a similar way for all participants?**

Y

**3.5 Was the outcome determined without knowledge of predictor information?**

N

**3.6 Was the time interval between predictor assessment and outcome determination appropriate?**

Y

**Risk of bias introduced by the outcome or its determination**

High

**Rationale of bias rating**

Predictor information was used to determine outcome

**Domain 4: Analysis**

**Describe number of participants, number of candidate predictors, outcome events and events per candidate predictor**

Thirty-four patients fulfilled the required criteria and completed the data collection period. All patients received typical drug combinations of levodopa, dopamine agonists, MAO-B, and/or COMT inhibitors, with 32 out of 34 (94%) patients receiving levodopa

**Describe how the model was developed, predictor selection and risk group definition**

Multiple regression analysis was performed with UPDRS part II score as the output variable, modeled by three input variables. The first input variable, called BK change, represents the change in the before-medication average bradykinesia score and the after-medication average bradykinesia score using a medication response time of 30 min. The second variable, called DK average, is the patient’s overall average dyskinesia score over 6 days. The third variable, called subjective, is the sum of the responses to eight questions in the questionnaire where, for each question, a response of “yes” equals 1, and a response of “no” equals 0.

**Describe whether and how the model was validated, either internally (cross validation, random split sample) or externally (e.g. temporal validation, geographical validation, different setting, different type of participants)**

No validation used

**Describe the performance measures of the model, e.g. calibration, discrimination, classification, net benefit, and whether they were adjusted for optimism**

Pearson correlation coefficient

**Describe any participants who were excluded from the analysis**

None

**Describe missing data on predictors and outcomes as well as methods used for missing data**

Not described

**4.1 Were there a reasonable number of participants with the outcome?**

N

**4.2 Were continuous and categorical predictors handled appropriately?**

Y

**4.3 Were all enrolled participants included in the analysis?**

Y

**4.4 Were participants with missing data handled appropriately?**

PY

**4.5 Was selection of predictors based on univariable analysis avoided?**

Y

**4.6 Were complexities in the data (e.g. censoring, competing risks, sampling of controls)**

**accounted for appropriately?**

Y

**4.7 Were relevant model performance measures evaluated appropriately?**

PN

**4.8 Were model overfitting and optimism in model performance accounted for?**

N

**4.9 Do predictors and their assigned weights in the final model correspond to the results**

**from multivariable analysis?**

U

**Risk of bias introduced by the analysis**

High

**Rationale of bias rating**

Small amount of outcomes. No validation.

**Overall Risk of bias**

High