Abstract

The Unified Parkinson's Disease Rating Scale (UPDRS) is widely used for the clinical evaluation of Parkinson's disease (PD). Our objective was to determine if the stage of PD (early vs advanced) affected rater performance on UPDRS section III - motor examination.

Methods

Videos of two patients (with early and advanced PD) were rated by raters (N=243) participating in a global rater training program.

Results

Ratings assigned by raters (N=433) were compared to the gold consensus ratings (GCR) generated by two US based independent experts. For the videos of early PD patient 7.8% of the raters (N=19) scored outside the acceptable range established by the expert trainers, whereas for the advanced PD patient video, 4.1% of the raters (N=10) scored outside the acceptable range. Ratings from raters outside the acceptable range were further analyzed and it was found that the early PD patient's performance was "overrated". That is, the patient's mean total score given by the raters was an increase of 12.9 points greater than the GCR. For the advanced PD patient, the mean of the total score was 4.2 points lower than the GCR.

Conclusions

Results showed that raters found it more difficult to accurately rate an early PD patient compared to advanced PD patient. The poor performance of the raters was due to a tendency to over rate patient's mild PD symptoms.

Introduction

The Unified Parkinson’s Disease Rating Scale (UPDRS) is the most widely used scale for clinical trials in Parkinson's disease (PD). The four parts of the scale are: Part I – Movement; behaviour and mood; Part II – Activities of daily living (ADL); Part III – Motor examination (ME); Part IV – Complications of therapy.

For the assessment of motor function in PD the UPDRS III (motor examination) is an accepted and validated scale (EMEA, 2008). It is increasingly used as a gold standard reference scale to assess PD (Goetz et al 2003). Most clinical trials rely on the motor examination Section III as the primary outcome measure. Thus, rating accuracy of raters on Section III of UPDRS is critical to the study outcome.

A rater training and certification program was conducted for two phase III multicenter studies on early and advanced PD.

Methods

A global rater training program was designed with both live Investigator Meeting (IM) and online (web-based). Familiarization and training components were provided on all sections of the UPDRS, but certification was required only for Section III.

The Raters

243 raters from 199 sites in 37 countries participated. Online training was provided before the start of the study to all raters.

Rater's experience

Previous experience on UPDRS ranged from 1 month to 23 years with mean experience of 6 years and 2 months.

Geographical distribution of raters

Raters participated from 6 continents, the highest number was from Europe (N=125) and lowest from Africa (N=1). Geographical distribution of raters with mean UPDRS experience is presented in table 1.

Table 1 Geographical distribution of raters with mean UPDRS experience

<table>
<thead>
<tr>
<th>Region</th>
<th>N</th>
<th>%</th>
<th>Mean Experience on UPDRS (in years and months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>41</td>
<td>16.9</td>
<td>10.0</td>
</tr>
<tr>
<td>Asia</td>
<td>56</td>
<td>23.2</td>
<td>14.7</td>
</tr>
<tr>
<td>Australia and New Zealand</td>
<td>49</td>
<td>20.6</td>
<td>16.1</td>
</tr>
<tr>
<td>Europe</td>
<td>120</td>
<td>51.4</td>
<td>9.9</td>
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<tr>
<td>North America</td>
<td>9</td>
<td>3.7</td>
<td>7.0</td>
</tr>
<tr>
<td>South America</td>
<td>29</td>
<td>12.0</td>
<td>12.2</td>
</tr>
<tr>
<td>Total</td>
<td>243</td>
<td></td>
<td>10.6</td>
</tr>
</tbody>
</table>

Training program

The curriculum was developed by two US based expert trainers, using a combination of online and live training at investigators’ meetings.

Videos of English-speaking American patients (with early and advanced PD) interviewed by an American neurologist were prepared for training and certification sessions. All videos were subtitled into 19 languages.

Raters had to meet the pass criteria on two certification videos, namely: Patient 2 (early PD) and Patient 3 (advanced PD) to certify as raters in the study.

GCRs were set by two US based independent experts in PD.

Training and certification activities

Before the IM

A study specific interactive training website was created which hosted learning material including those on the UPDRS sections I, II, III & IV.

Raters completed the first training session by observing video of Patient 1 online and submitting their ratings online. Group ratings on Patient 1 were collected for analysis and discussion at the IM.

At the IM

Training by an expert trainer was provided on all sections of UPDRS, with emphasis on section III; and on those items of variance which were identified during the online training.

The certification session at the IM included two videos: Patient 2 (early PD) and Patient 3 (advanced PD) examined on section III of the UPDRS. Raters had to meet the pass criteria for both the videos in order to certify on the UPDRS. Raters viewed and independently rated the videos and entered ratings on rating sheets.

After the IM

Ratings were compared to the GCRs and performance was categorized as pass or fail.

Raters who did not meet the pass criteria for Patient 2 and/or 3 had individual (remediation) sessions with the expert trainer via the telephone, and using web conferencing facilities.

After remediation, the raters were provided with another opportunity to certify with two additional videos Patient 4 (early PD) and Patient 5 (advanced PD).

Training and certification process is illustrated in Figure 1.

Results

Pass and fail percentage

We observed that in the first opportunity at certification for the early PD patient, 19 (7.81%) raters failed, while for advanced PD patient only 10 (4.11%) raters failed.

The fail percentage in the early PD case was almost twice when compared to the advanced PD case (Figure 2).

Only 3 (1.23%) raters failed on both of the videos (early and advanced PD).

Overall, the pass-fail ratio was good, as 92% of raters passed at their first attempt (certification session 1).

All raters who failed in the first certification session successfully completed the second attempt (certification session II patient video 4 and 5) and certified after an additional training remediation session which involved one to one discussion with the expert trainer on the items of variance.

Fall percentage by region and years of experience

The amount of previous experience on the UPDRS did not affect raters competency on UPDRS certification for this study as, on average, all raters who failed had extensive previous experience on the scale. For Patient 2 video (early PD), mean experience was 5 years 4 months; and for Patient 3 video (advanced PD), mean experience was 9 years 9 months.

Table 2 Failed percentage by region for patient video 2 (early PD)

<table>
<thead>
<tr>
<th>Region</th>
<th>N</th>
<th>%</th>
<th>Mean Experience on UPDRS (in years and months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>1</td>
<td>52.6%</td>
<td>12.9</td>
</tr>
<tr>
<td>Asia</td>
<td>14</td>
<td>6.1%</td>
<td>6.1</td>
</tr>
<tr>
<td>Australia &amp; New Zealand</td>
<td>25</td>
<td>10.5%</td>
<td>6.8</td>
</tr>
<tr>
<td>Europe</td>
<td>21</td>
<td>8.7%</td>
<td>10.0</td>
</tr>
<tr>
<td>North America</td>
<td>1</td>
<td>4.1%</td>
<td>5.9</td>
</tr>
<tr>
<td>South America</td>
<td>15</td>
<td>6.2%</td>
<td>6.0</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td></td>
<td>8.7</td>
</tr>
</tbody>
</table>

For patient 2 (early PD), the highest number of raters who failed were from North America (Canada), whereas for patient video 3 (advanced PD), the highest number of raters who failed were from Asia and Australia & New Zealand (14.28%), (table 2 & 3).

Performance on patient video 2 (early PD)

The ratings of raters who failed on Patient 2 video were further analyzed and the reasons for not meeting the pass criteria were evaluated. 52.63% (N =10) of raters failed due to committing more than acceptable number of errors on individual items and 100% (N =19) failed on unacceptable range on the total scores.

On the total score, 79% (N = 14) of raters scored higher than the total GCR (mean = 12.711). Only 20.31% (N=5) of raters scored lower than the total GCR (mean = 5.2 ). It was evident that most of the failures were due to over-rating of the patient’s mild impairments.

Difficult-to-rate items

Patient video 2 early PD

Incorrect ratings were mostly observed for finger taps (84.21%), leg agility (73.68%) and hand movements (57.89%).

The easiest items to rate were tremor at rest (0%), gait (5.2%), facial expression (5.2%), and action or postural tremor of hand (6.2%).

Patient video 3 advanced PD

Difficult items to rate were: rapid alternating movements of hands (90%), leg agility (80%) and rigidity-neck (60%).

The easiest items to rate were body bradykinesia and hypokinesia, gait, tremor at rest, action or postural tremor of hands (0%).

Item "leg agility" was difficult to rate on both the videos and the easiest item was "tremor at rest".

Conclusions

Results showed that raters found it more difficult to accurately rate an early PD patient than an advanced PD patient. Poor performance of the raters was due to a tendency to over-rate the patient’s mild PD symptoms as 79% of raters who failed over-rated the patient’s mild symptoms.

The difference in performance on two different patient videos makes it critical for raters to undergo intensive rater training on UPDRS with emphasis on different patient vignettes (early and advanced PD).

One-to-one remediation training proved to be beneficial, leading to better performance, as all raters who failed on their first attempt, passed on the second attempt following remediation sessions (via teleconference) focusing on specific items.

References