Severity Rating in Restless Legs Syndrome: Validation of the RLS-6 Scales

Ralf Kohnen1, Heike Beneš2, Julia Hülsmann1, Wolfgang H. Oertel3, Karin Stiasny-Kolster3, Claudia Trenkwalder4

1Research Pharmaceutical Services Inc., Fort Washington PA, USA and University of Erlangen-Nuremberg, Nuremberg, Germany; 2Tomi bne Institute for Clinical Research and Sleep Medicine, Schwering and Department of Neurology, University Rostock, Germany; 3Department of Neurology, Philippus University, Marburg, Germany; 4Paracelsus-Elena Klinik, Centre for Parkinson Syndromes and Movement Disorders, Kassel and Department of Clinical Neurophysiology, University of Goettingen, Germany

INTRODUCTION

Restless Legs Syndrome (Willis-Ekbom Disease, RLS) is a sensorimotor disorder which affects approximately 10% of the Caucasian populations. Patients are suffering from an urge to move with or without dysesthesias which is engendered by rest, relieved by movement and follows a circadian rhythm (worse in the evening and at night). Disturbed sleep, impaired mood, cognitive impairment as well as low quality of life are longterm consequences of this chronic disease.

The RLS-6 scales have been used as efficacy endpoints to measure severity of RLS symptoms at various periods during the day in many clinical trials for different RLS treatments. A re-evaluation of the validity and reliability of the RLS-6 scales is presented.

METHODS

The RLS-6 scales are 6 global self-ratings scales (Table 2) using 11 categories from 0 = “no symptoms” to 10 = “maximum” severity. Four scales assess the severity of RLS “at bedtime”, “during the night”, “during daytime when at rest”, and “during daytime when engaged in activities”. Additionally, two scales rate patients to their “satisfaction with sleep”, and severity of “daytime tiredness/sleepiness”. All scales are evaluated separately, no total or sub-scale scores are defined.

RESULTS

Evaluation was performed with the pooled data of four clinical trials (893 subjects, Table 1).

Reliability: There was a high test-retest-reliability on the basis of a 1-day interval, ranging from r=.63 (satisfaction with sleep) to r=.96 (severity at bedtime, Table 2).

Convergent validity: Mean baseline correlations between the RLS-6 items and the IRLS total score were highest for “severity during the night” (r=.65) and smallest for “severity during the day when engaged in activities” (r=.38). For change from baseline to LOCF correlations were similar, ranging from r=.30 (severity during the day when engaged in activities) to r=.74 (severity during the night) (Table 3).

Discriminant validity: RLS severity classification according to CGI-Severity and the IRLS total score showed a close connection to the RLS-6 severity categories (p<.0001 for all tests, Figure 1).

Table 2. Test-retest-reliability of the RLS-6 scales in a diary setting

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<th>Severity Rating in Restless Legs Syndrome: Validation of the RLS-6 Scales</th>
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<td>Table 3. Correlation of Baseline (BL) and for the difference between BL and the last visit (last observation carried forward, LOCF) between the RLS-6 and criteria scales</td>
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CONCLUSION

The RLS-6 scales show the expected correlations to other RLS specific criteria, indicating a high convergent and discriminant validity. The scales are able to identify changes over time and their test-retest-reliability is high. In addition to the IRLS scale, the RLS-6 scales may cover special qualities of treatments, like influence on daytime symptoms.