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Validation of the Augmentation Severity Rating Scale (ASRS): A multicentric, prospective study with levodopa on restless legs syndrome ☆

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Abstract

Background: Augmentation is the main complication during long-term dopaminergic treatment of restless legs syndrome (RLS) and reflects an overall increase in RLS severity. Its severity varies considerably from a minor problem to a devastating exacerbation of disease. Despite its clinical relevance, systematic evaluations have rarely been undertaken and there has been no development of methods to assess the severity of augmentation. To fill this gap, the European RLS Study Group (EURLSSG) has developed the Augmentation Severity Rating Scale (ASRS), using three items that assess the degree of change in three specific dimensions of augmentation. The changes in each dimension are summed to give an ASRS total score.

Methods: The ASRS was developed to cover the basic dimensions defining RLS augmentation. The items were developed by an interactive process involving professional and patient input. The ASRS that was evaluated included four major items and two alternative forms of one item. The validation was conducted using 63 (85%) mostly untreated RLS patients from six centers, who were treated for six months with levodopa (L-Dopa) (up to 500 mg/day, as clinically needed).

Two consecutive assessments before and at baseline measured test–retest reliability. Consecutive ASRS ratings by two independent raters on a subsample of patients evaluated inter-rater reliability. Comparison with clinical severity ratings of two independent

experts provided external validation of the ASRS. Comparison of patients with and without augmentation with regard to the items and the total score of the ASRS added discriminant validity.

Results: Sixty patients (63% females, mean age: 53 years, baseline International RLS Severity Rating (IRLS) score 24.7 ± 5.2) were treated with a median daily dose of 300 mg L-Dopa (range: 50–500 mg). Thirty-six patients (60%) experienced augmentation. Item analyses indicated that one item could be removed as it did not contribute significantly to the test score and only one form of the duplicated item needed to be used. The final ASRS then included three items. Test–retest reliability for the total score was $\rho = 0.72$, and inter-rater reliability was $r_{cc} = 0.94$. Cronbach's α was 0.62. Validity as assessed by the correlation between the worst ASRS total score during the trial and the expert rating was $\rho = 0.72$. ASRS total score differed between patients without versus with augmentation (mean: 7.4 (standard deviation (SD) = 4.0) vs. 2.0 (2.7) ($P < 0.0001$).

Conclusions: The ASRS is a reliable and valid scale to measure the severity of augmentation. Due to the need to systematically quantify augmentation for both long-term efficacy and tolerability, the ASRS may become a useful tool to monitor augmentation in future clinical trials.

1. Introduction

Since the introduction of dopaminergic treatment for restless legs syndrome (RLS) over 20 years ago [1], numerous studies investigated firstly levodopa (L-Dopa) and, in recent years, dopamine agonists [2]. In general, both L-Dopa and dopamine agonists are efficacious and well tolerated in the short- and mid-term [3–11]. However, the longer-term use of these medications revealed an unexpected complication characterized by an increased intensity and earlier onset of RLS symptoms. This problem was termed augmentation by Allen and Earley [12], and was defined by four possible features [12]: (a) an anticipation in the time of onset of symptoms to earlier in the afternoon, (b) an expansion of symptoms to the upper limbs, (c) a shorter latency to symptoms when at rest, and (d) an overall increase in symptom intensity. Taken together, these symptoms reflect an increase in overall RLS symptom severity during long-term dopaminergic treatment. The paper by Allen and Earley suggested that augmentation reflected a general exacerbation of the underlying dopaminergic pathology in RLS and, therefore, affected all of the RLS symptoms.

In 2003, a National Institutes of Health (NIH)-sponsored Workshop [13] established for the first time an operational diagnostic definition for the clinical identification of augmentation (Table 1). Although the wide range of severity of augmentation from tolerated worsening of symptoms to a need for discontinuation of the current therapy was recognized, no criteria were defined to assess its severity. The degree of augmentation becomes relevant as it determines the treatment response, ranging from minor adjustment of dosage schedule to a change in the type of medications being used; accordingly, there exists a compelling need for a standardized method to assess augmentation severity. Facing such a need for an evaluation tool, the European RLS Study Group (EURLSSG) has developed a rating scale for the assessment of the severity of augmentation

during long-term treatment of RLS. The Augmentation Severity Rating Scale (ASRS) has been specifically designed to be used prospectively in clinical trials and the psychometric evaluation is based on a clinical trial targeting detection and evaluation of augmentation. The objective of this study was to test the validity and reliability of the ASRS to measure the severity of augmentation in RLS patients being prospectively treated with L-Dopa for six months. Both the development of the scale and its psychometric evaluation from this clinical trial are presented in this paper.

2. Methods

2.1. Development of the ASRS

The ASRS was designed to provide a quantitative measure of the severity of augmentation during clinical studies. In agreement with the definition of augmentation as a worsening of RLS symptoms during treatment [13,14], the ASRS is based on the prospective assessment of changes by comparing the severity of cardinal features of RLS augmentation symptoms at different time-points during treatment. As a baseline for the assessment of any changes, the pre-treatment level prior to the initiation of any RLS therapy is compared to subsequent monthly assessments during treatment. Thus, worsening was defined as an increase in severity in the items of the ASRS between the baseline and the post-baseline ratings and was represented by an ASRS total score (for items and evaluation of the ASRS, see Appendix).

The selection of items for the ASRS was based upon the diagnostic criteria for augmentation as described in the literature [12–14] (see Table 1). Nevertheless, two exceptions were made: (a) no item was related to changes in the dose of the RLS medication (Table 1), as in clinical studies strict dosing schedules are usually applied; and (b) similarly, no polysomnographic criteria were included in the scale, as it is not feasible to perform

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Baseline Examination

Augmentation Severity Rating Scale (ASRS)

INSTRUCTIONS: The examiner will ask the patient the following questions. The examiner will read the questions, explain the question, assist the patient in finding the answer, and mark the patient's answer on the form. However, it will be the patient's decision to determine which is the final answer.

Item 1 During the past week, at what time did your RLS symptoms usually start?

Please write down the time when the symptoms usually started (e.g.: 22:45).

<input type="text"/>	:	<input type="text"/>	24-hr clock
HH		MM	

Item 2 During the past week, at any times you were sitting or resting (for example in a car, plane, theatre or watching TV) how soon afterwards did your RLS symptoms usually start?

Please indicate the time it takes for symptoms to start at various times during the day (late morning, early afternoon, late afternoon, evening before taking any RLS medication).

- 2a** When sitting in the late morning (i.e., before noon), your symptoms usually started...
- 2b** When sitting in the early afternoon (i.e., 12:00 – 15:00), your symptoms usually started...
- 2c** When sitting in the late afternoon (i.e., 15:00 – 18:00), your symptoms usually started...
- 2d** When sitting in the evening (after 18:00, before taking the first dose of RLS medication), your symptoms usually started...

Evaluation

Augmentation Severity Rating Scale (ASRS)

I. Item 1: EARLIER ONSET OF RLS SYMPTOMS

Please copy the value of item 1 according to the baseline and post-treatment evaluation sheets.

- A. at baseline (hrs.)
- B. at present (hrs.)
- C. Provide the time difference between A and B (e.g., A-B=20:45-17:30=3:15).

Please transform the value of C into a score according to the following scale (in case B > A, mark 0!):

<1 hrs:	0
1 - <2 hrs:	1
2 - <3 hrs:	2
3 - <4 hrs:	3
4 - <5 hrs:	4
5 - <6 hrs:	5
6 - <7 hrs:	6
7 - <8 hrs:	7
≥8 hrs:	8



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