Somnologie 2009 · 13:37–42
DOI 10.1007/s11818-009-0402-z

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Validierung des Fragebogens zum Screening auf Restless-legs-Syndrom

Restless legs syndrome (RLS) is a sensorimotor disorder affecting 5–10% of the general population. It is characterized by a desire to move the legs and is usually associated with unpleasant sensations in the lower extremities. RLS symptoms are worse or exclusively present while being at rest in the evening or nighttime, with at least partial and temporary relief by activity. As a consequence, many RLS patients suffer from severe sleep disturbances with impaired quality of life [11].

In 1995 the International RLS Study Group defined four minimal diagnostic criteria: (1) a desire to move the limbs, usually associated with paresthesias/dysesthesias; (2) motor restlessness; (3) worsening of symptoms at rest, with at least partial or temporary relief by activity; and (4) worsening of symptoms in the evening and/or during the night [10]. In 2003 these minimal criteria were revised for a more precise description of the symptoms: The previous criterion 2 was omitted, and criterion 3 was split into two separate criteria, provocation at rest and relief with activity (**Tab. 1**; [1]). Three further clinical features are supportive for the diagnosis of RLS: (5) a positive family history, (6) a positive response to dopaminergic therapy, and (7) the presence of periodic leg movements as measured by nighttime polysomnographic recordings.

Finally, the typical clinical course (i.e., intermittent symptoms at the beginning, with progressive worsening with age), the presence of sleep disorders, and a normal neurological examination may be helpful associated diagnostic features for the clinician. Accordingly, in the majority of RLS patients, the diagnosis of RLS can be established by medical history if at least the four essential diagnostic criteria are fulfilled. Diagnostic problems may arise if the medical history is difficult to obtain due to insufficient information; for example, a patient may deny improvement by movement if the symptoms are mild or misunderstood due to their temporary occurrence, and in advanced cases, RLS symptomatology changes to some extent (e.g., worsening at night may not be noticed in RLS with severe daytime symptoms). On the other hand, other disorders such as polyneuropathy, nocturnal cramps, or parkinsonian symptoms may satisfy some or all of the diagnostic criteria and mimic RLS [7].

However, in most patients a thorough medical history enables a correct diagnosis, at least for a physician experienced with RLS, and additional diagnostic procedures such as polysomnographic studies or an L-dopa test [9] are rarely necessary. In this setting, a questionnaire that assesses the clinical features of RLS could be a useful tool in the diagnosis of RLS. Various questionnaires with varying numbers of questions have been used to diagnose RLS according to the revised criteria, either for clinical practice or in epidemiological studies. Most of these questionnaires have either not been validated [4, 8, 3, 2] or have had only their sensitivity assessed [6]. From a diagnostic perspective, however, an appropriate instrument should have both high sensitivity (to support the RLS diagnosis) and, particularly, high specificity (to exclude disorders mimicking RLS). Data on the validation of an RLS screening questionnaire (RLSSQ) are presented and compared with expert diagnosis of RLS.

Patients and methods

A diagnostic questionnaire that was developed on the basis of the clinical features of RLS (**Tab. 1**) was completed by patients with definite RLS according to the International RLS Study Group criteria (2003) and by control subjects from the general population (GP; control group) in whom RLS symptoms were excluded by an RLS expert (KSK). In addition, the RLSSQ was applied to patients with Parkinson's disease (in whom RLS was also excluded by expert history (PD; control group). For the RLS and PD groups, we consecutively recruited subjects who attended the outpatient clinic for RLS and PD and who were willing to fill out the questionnaire in the waiting room after giving informed consent. The patients then returned the questionnaire to a study nurse. RLS was diagnosed or excluded independent of the questionnaire results. Apart from the presence of RLS (RLS group) or the absence

Tab. 1 Essential diagnostic criteria for restless legs syndrome [3]

1) An urge to move the legs, usually accompanied or caused by uncomfortable and unpleasant sensations in the legs; sometimes the urge to move is present without the uncomfortable sensations, and sometimes the arms or other body parts are involved in addition to the legs
2) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as sitting or lying down
3) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues
4) The urge to move or unpleasant sensations are worse in the evening or night than during the day or occur only in the evening or night; when symptoms are very severe, the worsening at night may not be noticeable but must have been previously present

Tab. 2 RLS screening questionnaire (RLSSQ)

Question	Answer
English	yes/no
1. Do you sometimes have unpleasant sensations (i.e. twinging, stinging, crawling sensation, pain) or an unspecific disagreeable sensation in the legs or arms?	
2. Do you often have the urge to move your legs or walk around?	yes/no
3. Do these symptoms usually occur in relaxed situations (i.e. while lying or sitting)?	yes/no
4. Are your symptoms or were your symptoms previously more pronounced at night than during the daytime?	yes/no
5. Can your symptoms be relieved or do they completely disappear by activity (i.e. moving the legs, walking around)?	yes/no
6. Do you have difficulty falling asleep or maintaining sleep?	yes/no
7. Do you feel drowsy, fatigued, or tired in the daytime?	yes/no
8. Do your legs sometimes twitch or move involuntarily while asleep or at rest in the daytime?	yes/no
9. Do/did your symptoms not occur regularly, but do/did you have days or nights without any symptoms?	yes/no
10. Are there any other persons in your family who have similar symptoms?	yes/no
German	ja/nein
1. Kommt es vor, dass Sie Missempfindungen (z. B. Ziehen, Stechen, Kribbeln, Schmerzen) oder ein schwer zu beschreibendes, unangenehmes Gefühl in den Beinen oder Armen haben?	
2. Haben Sie häufig den Drang, die Beine zu bewegen oder umherzulaufen?	ja/nein
3. Treten Ihre Beschwerden überwiegend in entspannten Situationen (z. B. im Liegen oder Sitzen) auf?	ja/nein
4. Sind Ihre Beschwerden oder waren Ihre Beschwerden früher nachts stärker ausgeprägt als tagsüber?	ja/nein
5. Können Ihre Beschwerden durch Bewegung (z. B. Bewegen der Beine, Umhergehen) gelindert oder ganz zum Verschwinden gebracht werden?	ja/nein
6. Haben Sie Schwierigkeiten beim Einschlafen oder nachts durchzuschlafen?	ja/nein
7. Fühlen Sie sich tagsüber unausgeschlafen, erschöpft oder müde?	ja/nein
8. Kommt es vor, dass Ihre Beine während des Schlafes oder tagsüber in Ruhesituationen zucken oder Bewegungen durchführen, die Sie nicht beeinflussen können?	ja/nein
9. Treten oder traten früher Ihre Beschwerden nicht regelmäßig auf, sondern gibt/gab es auch Tage bzw. Nächte ohne Beschwerden?	ja/nein
10. Gibt es in Ihrer Familie noch andere Personen, die ähnliche Beschwerden haben?	ja/nein

of RLS (control groups), no specific inclusion or exclusion criteria were applied.

Restless legs syndrome screening questionnaire (RLSSQ)

The RLSSQ is a 10-item patient self-rating instrument assessing the subject's symptoms with short questions that have to be answered by either "yes" or "no" (**Tab. 2**).

Items 1–5 address the minimal criteria of RLS, whereby minimal criterion 1 was divided into two questions separately addressing the unpleasant sensations and the urge to move the legs. Items 6 and 7 assess sleep disturbances and daytime sleepiness. Item 8 asks about involuntary leg movements. Item 9 focuses on the course of the complaints and item 10 on the family history. The maximum total score of the RLSSQ is 10 points.

Outcome measure

The primary outcome measure was the difference in the RLSSQ total score between the patients with RLS and the GP control group.

Statistical analysis

Sample means of the RLSSQ total score in RLS patients and the control groups were compared by *t*-test. Sensitivity and specificity for different cutoff points were calculated and presented by means of a receiver operating characteristic (ROC) function. The diagnostic value of the RLSSQ was calculated by the area under the curve (AUC), which was independent of an arbitrary choice of a cutoff point, and was tested for statistical significance using the Mann–Whitney *U*-test. The response patterns are presented descriptively. Furthermore, internal consistency was shown by means of Cronbach's alpha coefficient and corrected correlations of each single item versus the RLSSQ (the corrected correlation was calculated as Spearman's rank correlation of each item with the total score without inclusion of the analyzed item). The test–retest reliability of the RLSSQ was assessed for individual items by means of kappa statistics and for the sum scores by means of the intraclass correlati-

on coefficient. Spearman's correlations of the sum score with age and disease duration were also calculated.

To establish internal validity of the questionnaire, a factor analysis was performed both for the complete questionnaire and for its short form (see below).

Results

Patients

A total of 329 patients with definite RLS (116 male and 213 female; mean age 62.6±11.8 years, range 25–89 years) and 187 patients without RLS (74 male and 113 female; mean age 50.0±13.4 years, range 20–79 years, GP control group) participated. In RLS patients, the symptoms had been present for 15.8±15.2 years (range 1–74), and 218 patients (66%) were already being treated for their RLS symptoms; 120 patients (36.5%) had a positive family history for RLS.

The PD control group consisted of 118 patients with Parkinson's disease (74 male and 44 female; mean age 65.1±9.8 years, range 33–82 years) in whom RLS had been excluded by medical history. Seventy-six patients had Parkinson's disease of the equivalent type, 33 had Parkinson's disease of the akinetic-rigid type, and nine had tremor-dominant Parkinson's disease.

For the assessment of test–retest reliability, 75 patients from the RLS group and 24 subjects from the GP control group filled out the RLSSQ a second time after approximately 4 weeks.

RLSSQ

The *t*-test revealed a highly significant difference between the RLS group and the GP control group. The mean RLSSQ score in the RLS group was 8.5±1.0 (range 5–10) points, compared with 2.2±2.1 (range 0–7) points in the GP control group ($p<0.0005$). An ROC plot that was calculated to evaluate the discriminant threshold of different cutoff values revealed an optimal cutoff point of 7 points, where the ratio between sensitivity and specificity was at its optimum. Considering an RLSSQ score of 7 points or more a positive test result, we found a sensitivity of 97.9% and a specificity of 96.2%. Accor-

Zusammenfassung · Abstract

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Validierung des Fragebogens zum Screening auf Restless-legs-Syndrom

Zusammenfassung

Hintergrund. Obwohl die Diagnose des Restless-legs-Syndroms (RLS) weitgehend auf dem Vorliegen der 4 Hauptkriterien basiert, gibt es keinen validierten diagnostischen Fragebogen zum Einsatz in epidemiologischen Studien oder klinischer Praxis.
Methoden. Daher validierten wir einen Selbstbeurteilungs-Patientenfragebogen mit 10 Unterpunkten (Gesamthöchstwert: 10 Punkte), der die klinischen Merkmale des RLS abdeckt und die Hauptkriterien enthält (Unterpunkt 1–5). Das Hauptkriterium 1 wurde in 2 Fragen unterteilt, die getrennt auf die unangenehmen Empfindungen (Unterpunkt 1) und den Bewegungsdrang (Unterpunkt 2) abzielen. Eingesetzt wurde der RLS-Screening-Fragebogen (RLSSQ) bei 329 Patienten mit RLS (213 w.; Alter im Mittel 62,6±11,8 Jahre), 187 Kontrollen aus der Allgemeinbevölkerung (113 w.; Alter im Mittel 50,0±13,3 Jahre) und 118 Parkinson-Patienten (44 w.; Alter im Mittel 65,1±9,8 Jahre), bei denen ein RLS ausgeschlossen worden war.
Ergebnisse. Im Mittel betrug der RLSSQ-Wert in der RLS-Gruppe 8,5±1,0 Punkte im Vergleich zu 2,2±2,1 Punkten in der Kontrollgruppe aus der Allgemeinbevölkerung ($p<0,0005$). Betrachtet man einen RLSSQ-Wert von 7 Punkten als positives Testergebnis, so stellten wir eine Sensitivität von 97,9% und eine Spezifität von 96,2% fest. In der Kontrollgruppe mit Parkinson-Krankheit war der mittlere RLSSQ-Wert (3,72±2,04) ebenfalls signifikant niedriger als in der RLS-Gruppe ($p<0,0005$), was einer Spezifität von 93,2% entspricht.
Fazit. Wegen seiner hohen Sensitivität und Spezifität erwies sich der RLSSQ als nützliches diagnostisches Instrument.

Schlüsselwörter

Restless-legs-Syndrom · Epidemiologie · Screening-Fragebogen · Sensitivität · Spezifität

Validation of the restless legs syndrome screening questionnaire (RLSSQ)

Abstract

Background. Although the diagnosis of restless legs syndrome (RLS) is largely based on the presence of the four essential criteria, no validated diagnostic questionnaire exists for use in epidemiological studies or clinical practice.
Methods. For this purpose we validated a 10-item patient self-rating questionnaire (maximum total score 10 points) covering the clinical features of RLS and including the essential criteria (items 1–5). The essential criterion 1 was divided into two questions to separately address the unpleasant sensations (item 1) and the urge to move (item 2). The RLS screening questionnaire (RLSSQ) was administered to 329 patients with RLS (213 female; mean age 62.6±11.8 years), 187 control subjects from the general population (113 female; mean age 50.0±13.3 years), and 118 patients with Parkinson's disease (44 female; mean age 65.1±9.8 years) in whom RLS was excluded.
Results. The mean RLSSQ score in the RLS group was 8.5±1.0 points, compared with 2.2±2.1 points in the general population control group ($p<0.0005$). Considering an RLSSQ score of 7 points as a positive test result, we found a sensitivity of 97.9% and a specificity of 96.2%. In the Parkinson's disease control group, the mean RLSSQ score (3.72±2.04) was also significantly lower than in the RLS group ($p<0.0005$), revealing a specificity of 93.2%.
Conclusion. Because of its high sensitivity and specificity, the RLSSQ proved to be a useful diagnostic instrument.

Keywords

Restless legs syndrome · Epidemiology · Screening questionnaire · Sensitivity · Specificity

Tab. 3 Test characteristics of single items on the restless legs syndrome (RLS) screening questionnaire (RLSSQ; comparison of RLS positives vs. normal controls)

RLSSQ item	Sensitivity	Specificity	Kappa [confidence interval]	Corrected correlation (sum score)
1	98.2%	62.6%	0.84 [0.70; 0.98]	0.751 (p<0.0005)
2	100%	81.8%	0.970 [0.91; 1.03]	0.824 (p<0.0005)
3	99.7%	85.6%	0.97 [0.90; 1.03]	0.872 (p<0.0005)
4	98.5%	93.6%	0.94 [0.86; 1.02]	0.875 (p<0.0005)
5	99.1%	85.6%	0.94 [0.85; 1.03]	0.849 (p<0.0005)
6	95.1%	61.0%	0.78 [0.61; 0.94]	0.637 (p<0.0005)
7	83.5%	55.6%	0.65 [0.50; 0.81]	0.461 (p<0.0005)
8	72.3%	94.1%	0.62 [0.46; 0.78]	0.623 (p<0.0005)
9	70.2%	65.8%	0.49 [0.32; 0.67]	0.413 (p<0.0005)
10	36.5%	93.5%	0.73 [0.58;0.88]	0.33 (p<0.0005)

dingly, 97% of the patients were correctly diagnosed. The AUC was 0.995±0.13 with a 95% confidence interval (CI) of 0.992–0.999; compared with the minimum possible score of 0.5, the difference was highly significant (p<0.0005). There were no differences in the mean RLSSQ scores between untreated (n=75) and treated RLS patients (8.57±0.98 points versus 8.52±0.95 points, p=0.798). In addition, we found a positive Spearman's correlation between the RLSSQ total score and the duration of RLS (r=0.223, p=0.0005) and a nonsignificant correlation with age (r=0.013, p=0.405).

Single-item analysis revealed the highest specificity for item 8 (involuntary movements during rest), item 4 (pronounced symptoms during the night), and item 10 (affected family members) compared with the GP control group. Kappa statistics for test–retest reliability for individual test items are given in **Tab. 3**. The intraclass correlation coefficient for the sum score was 0.945, with a 95% CI of 0.919–0.9963, which can be judged as very good test–retest reliability. Internal consistency was established by a Cronbach's alpha coefficient of 0.903 and by means of corrected correlations of each single item versus the RLSSQ by Spearman's rank correlation testing (**Tab. 3**). A factor analysis revealed a single factor with an eigenvalue >1, which explains 57% of the variance. This shows that there is a single latent factor (the presence or absence of RLS) that influences the answers to the 10 items.

When calculating the score on the basis of the first five questions (i.e., the short form of the RLSSQ addressing only the minimum criteria), we found a sensitivity of 95.4% and a specificity of 100% when a positive answer to questions 1–5 was considered a positive test result. Accordingly, 97% of the patients were correctly diagnosed. The internal consistency of the short-form RLSSQ resulted in a Cronbach's alpha of 0.95. The corrected correlations were 0.752 (item 1), 0.865 (item 2), 0.909 (item 3), 0.891 (item 4), and 0.898 (item 5), with p<0.0005 for all items. The intraclass correlation coefficient for the short form was 0.986, with a 95% CI of 0.986–0.991. Factor analysis of the short form revealed a single factor with an eigenvalue >1, which explains 83% of the variance. The fact that 83% of the variance is explained by the factor suggests a very high internal validity. The sum score of the short form did not significantly correlate with disease duration (r=0.055, p=0.347).

When a positive answer to questions 2–5 was considered a positive test result (i.e., disregarding sensory symptoms), we found a sensitivity of 97.3% and a specificity of 99.5%, providing a correct diagnosis in 98.1% of the patients. Seven subjects in the GP control group had symptoms of polyneuropathy. All of them were positive for item 1, but none fulfilled all of the minimum criteria. Three had nocturnal muscle cramps; none fulfilled all the minimum criteria, but two were positive for items 1, 3, 4, and 5. Four patients had radiculopathy, one of whom fulfilled all minimum criteria.

PD control group

The mean RLSSQ score in the PD control group was 3.72±2.04 (range 0 –8) points and was somewhat higher than in the GP control group (p<0.0005). Differences in the RLSSQ score between the PD control group and the RLS group were also significant (p<0.0005). Based on this control sample, the RLSSQ revealed a specificity of 93.2% when using a cutoff value of 7 points. When using the short form of the RLSSQ in PD patients, we found a specificity of 98.3% when a positive answer to questions 1–5 was considered a positive test result. Accordingly, 96.2% of the patients were correctly diagnosed. When a positive answer to questions 2–5 was considered a positive test result, the RLSSQ revealed a specificity of 98.3%, providing a correct diagnosis in 97.5%.

The analysis of PD patients revealed that 65 (55.1%) answered positively to item 1 (unpleasant sensations), 39 (33.1%) to item 2 (urge to move), 30 (25.4%) to item 3 (symptoms at rest), 14 (11.9%) to item 4 (pronounced symptoms at night), and 38 (32.2%) to item 5 (relief by movement; **Fig. 1**). Two PD patients answered positively to items 1–5.

Discussion

This study evaluated the diagnostic value of a newly developed questionnaire for RLS. Using a cutoff value of 7 points on the RLSSQ as a discriminatory variable, the questionnaire revealed a sensitivity of 97.9% and a specificity of 96.2%. When the usefulness of the RLSSQ in a control group of patients with Parkinson's disease was investigated, the specificity of 93.2% was also considerably high. Thus, the RLSSQ proved to be an appropriate tool to diagnose or exclude RLS with high accuracy. Due to its high specificity, the RLSSQ when used as a screening tool is also qualified to exclude RLS mimics.

According to clinical experience, the presence of the four essential criteria as assessed from a patient interview is highly sensitive. To avoid a false negative diagnosis, a thorough medical history that includes exact phrasing of specific questions must be obtained; for instance, the sometimes temporary character of improvement by movement must be emphasized, and the enhancement of symptoms at nighttime may be present only at disease onset. Taking these details into account, the short form of the RLSSQ

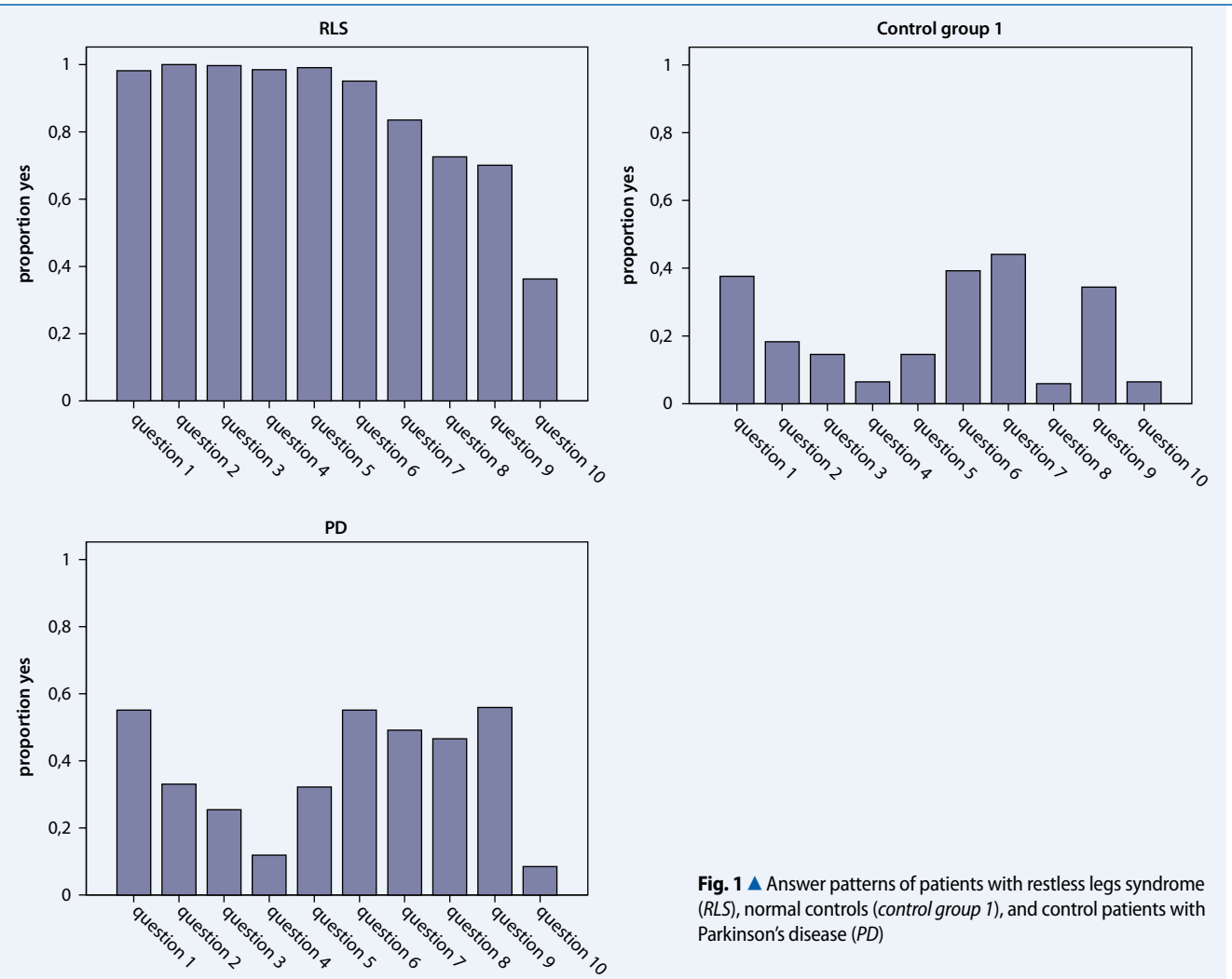

Fig. 1 ▲ Answer patterns of patients with restless legs syndrome (*RLS*), normal controls (*control group 1*), and control patients with Parkinson's disease (*PD*)

showed a high sensitivity of 95.4% and 97.3%, respectively. Of the RLS patients, only six gave a negative answer to question 1, but none gave a negative answer to question 2. One RLS patient answered in the negative to question 3 (he additionally had a pain syndrome that was also present when moving); three patients answered in the negative to question 4 (in all of them, the severity of RLS symptoms at night and during the day had slowly converged, but the patients had not read the question carefully enough: "or *were* your symptoms *previously more pronounced* …"); and two patients gave false negative answers to question 5 (referring to only temporary relief by movement).

To account for the accuracy of the diagnostic criteria (i.e., sensory symptoms do not necessarily need to be present), addressing items 2–5 would be sufficient. However, to screen for RLS in the general population, including subjects with sensory symptoms of different kinds, assessment of items 1–5 is more appropriate.

When we developed the questionnaire, we supposed that assessing only the minimal criteria would be insufficient to differentiate potential mimics of RLS such as polyneuropathy, nocturnal cramps, parkinsonian symptoms, positional discomfort, or others that may satisfy some or even all of the minimal diagnostic criteria. Therefore, we decided to validate a 10-item version to achieve as high a specificity as possible. Considering an RLSSQ score of 7 points or more a positive test result, we found a specificity of 96.2%. But surprisingly, the short RLSSQ had a perfect specificity of 100% and 99.5%, respectively, when considering positive answers to questions 2–5, since only one potential mimic of the GP control group with radiculopathy fulfilled all of the minimal criteria. This was also true for the PD control group, in whom the short RLSSQ revealed a specificity of 98.3%. The sensitivities of both versions were also very similar, with 97.9% for the 10-item version versus 95.4% for the short form.

Although the test variables were excellent in both versions, the 10-item questionnaire provides some advantages. Items 6–10 provide additional information that may be useful in epidemiological studies to assess the presence of sleep–wake disturbances, leg movements, the course of the symptoms, and family history. The long version may also be used for studies looking at families, such as for genetic research. The fact that only the sum score of the long but not the short version correlated with disease duration indicates that patients in whom additional features are present suffer from more severe RLS. In clinical practice, the 10-item RLSSQ may help to diagnose or exclude RLS at a glance and may therefore shorten the interview. We prefer to use the long version of the RLS-

SQ in clinical practice because it provides some more information. However, especially in patients with potentially incipient RLS, particular attention should be paid to the responses to questions 1–5 to avoid a false negative diagnosis.

For screening for RLS, even a single question has been used [5]. Although this question—"When you try to relax in the evening or sleep at night, do you ever have unpleasant, restless feelings in your legs that can be relieved by walking or movement?"—allows no differentiated assessment of the minimal criteria, it revealed a sensitivity of 100% and a specificity of 96.8%. The RLSSQ has the advantage that it is the only validated diagnostic questionnaire that assesses the new criteria with the minimal criterion 1 being divided into two items. The separate assessment of sensory symptoms (item 1) may be particularly helpful to better differentiate subjects with neuropathy or other kinds of pain syndromes and to detect mimics of RLS. It is unknown whether the single question [5] would still feature a sufficiently high specificity in a larger study within the general population, since subjects with neurological disorders or other major diseases potentially mimicking RLS were excluded. If a stepwise approach is appreciated, we recommend using question 2 of the RLSSQ (sensitivity of 100%) as a filter. One further advantage of the RLSSQ is that it also addresses symptoms in the past and may be used to detect lifetime symptoms, such as during pregnancy.

Overall, this validation study shows that other symptoms or disorders may mimic RLS, but more in the sense of "RLS-like symptoms," rarely fulfilling all of the minimal criteria. Accordingly, this term should be avoided unless an exact definition is given.

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Conflict of Interest. None declared.

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