

Clin-IQ Project

Clinical Question: 'In adults what is the best diagnostic test for restless leg syndrome'.

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Answer: Yes

Level of Evidence for the Answer: A

Search Terms: Restless leg syndrome, best diagnostic test, diagnostic criteria

Date Search was Conducted: August 2012

Inclusion and Exclusion Criteria:

Inclusion Criteria: Published clinical reviews, systematic reviews/meta-analysis and clinical research trials on diagnostic criteria and algorithm for Restless Leg Syndrome (RLS).

Exclusion Criteria: Other sleep-related disorders that do not meet the diagnostic criteria for RLS

Summary of the Issues: (186 words)

Restless leg syndrome (RLS) is a common yet frequently underdiagnosed disorder. This condition comprises the symptoms of spontaneous continuous leg movements associated with unpleasant paresthesias.¹ These symptoms occur only at rest, and are relieved by movement.

RLS is divided into 2 categories, primary where etiology is idiopathic, and secondary, most commonly associated with iron deficiency anemia, uremia, diabetes mellitus, and rheumatoid arthritis.³

The diagnosis of RLS is missed because there is no single test that can diagnose this condition. The International Restless Legs Study Group has proposed following 4 criteria essential in diagnosis of RLS⁴:

1. An urge to move the legs, accompanied with or caused by unpleasant sensations in legs. Sometimes urge is present without unpleasant sensations, and sometimes these sensations are present in arms;
2. Urge to move legs is present when resting or inactive;
3. Urge to move legs is partially or totally relieved with movement;
4. The urge to move or unpleasant sensations is worse at night time as compared to day or only occurs at night time.

Confirmation of diagnosis can be supplemented with family history and positive response to dopaminergic drugs.

False positive diagnosis of RLS have been reported in more than 10% of the investigated populations including other conditions such as nocturnal cramps and various neuropathies. In addition, RLS may be underdiagnosed because of poor recognition of symptoms. No manual has been published describing how the criteria should be applied and there is a lack of information about how essential and supportive criteria or associated features are related.

Summary of the Evidence: (510 words excluding figure)

A diagnostic algorithm for the diagnosis of RLS, the RLS-Diagnostic Index (RLS-DI), has been validated for use by non-experts.² The RLS-DI:

- a) Identifies patients with a definite diagnosis of RLS;
- b) Excludes the diagnosis of RLS in other patients; and
- c) Sorts out a subgroup of patients in whom RLS is possible and cannot be safely excluded or confirmed at the time of the interview without further diagnostic information.

The RLS-DI consists of 10 items which are related to the essential diagnostic criteria established by the International Study Group as well as their supportive criteria and features associated with RLS. Items have to be completed using three categories per item that address

frequency of occurrence of symptoms or certainty of presence or absence of other diagnostic information. Negative weights were given when the clinically most relevant items were not present. The sensitivity and specificity of the 10 RLS-DI was based on the clinical expert diagnosis which represented the “true” diagnosis. According to RLS DI any patient who presents with insomnia or sleep problems due to a need to move, unpleasant sensations in legs should be screened for RLS. Five questions (Essential criteria) should be asked of the patient as mentioned in Figure 1 below. If answers to all 5 questions are yes then patient is given a diagnosis of RLS. If patient answers yes to question 1,3 and 5 in essential criteria, then supportive criteria should be put in consideration. If answer is yes to any question in supportive criteria, diagnosis of RLS is given. If patient answers yes to question 1,3 and 5 in essential criteria and all answers are no in supportive criteria then other diagnosis should be considered as possible etiology of patient symptoms. If patient answers no to all questions in essential criteria or no to questions 1,3 and 5, then other conditions should be considered as cause of his sleep related problems. The RLS-DI was administered in a telephone interview to 179 patients (86 with RLS, 93 with other sleep disorders) from one sleep center in Germany.² The study was conducted on patients who attended the sleep lab for sleep related disorders between Jan, 01,2003 and September, 30, 2004. Written invitation was mailed to patients to participate in this survey lasting for an hour. To improve quality of interview and this study, interview questions were mailed beforehand, to patients who agreed to participate in this study. Two extensively trained interviewers conducted the interviews between November 2004 and January 2005. These interviewers were not sleep experts. Items 8,9 and 10 in RLS DI were answered from sleep lab data. Two senior physicians who were sleep specialists provided RLS expert diagnosis for each patient. Statistical factor analysis was performed after conduction of the study. The results demonstrated a sensitivity of 93.0%, specificity was 98.9%. Correct diagnosis occurred in 96.1% of the patients. Specificity was higher in items related to essential criteria (95.7%) than

in those related to the non-essential diagnostic criteria (81.7%). Patients with RLS scored a higher RLS-DI than those with primary insomnia or other neurological or psychiatric disorders.

Diego Garcia-Borreguero et al⁴ reanalyzed the data from a validation study of the RLS DI using a logistic regression model to determine the extent of accuracy of the diagnosis of RLS. This analysis identified three out of the original five criteria that were associated with RLS. Items 1, 3, and 5 had the most diagnostic value. Adding the response to dopaminergic medication improved the accuracy of the diagnosis of RLS. If RLS is suspected, the results of this study justify a hierarchical or adaptive diagnostic algorithm (see Figure 1).

Figure. The RLS Diagnostic Algorithm

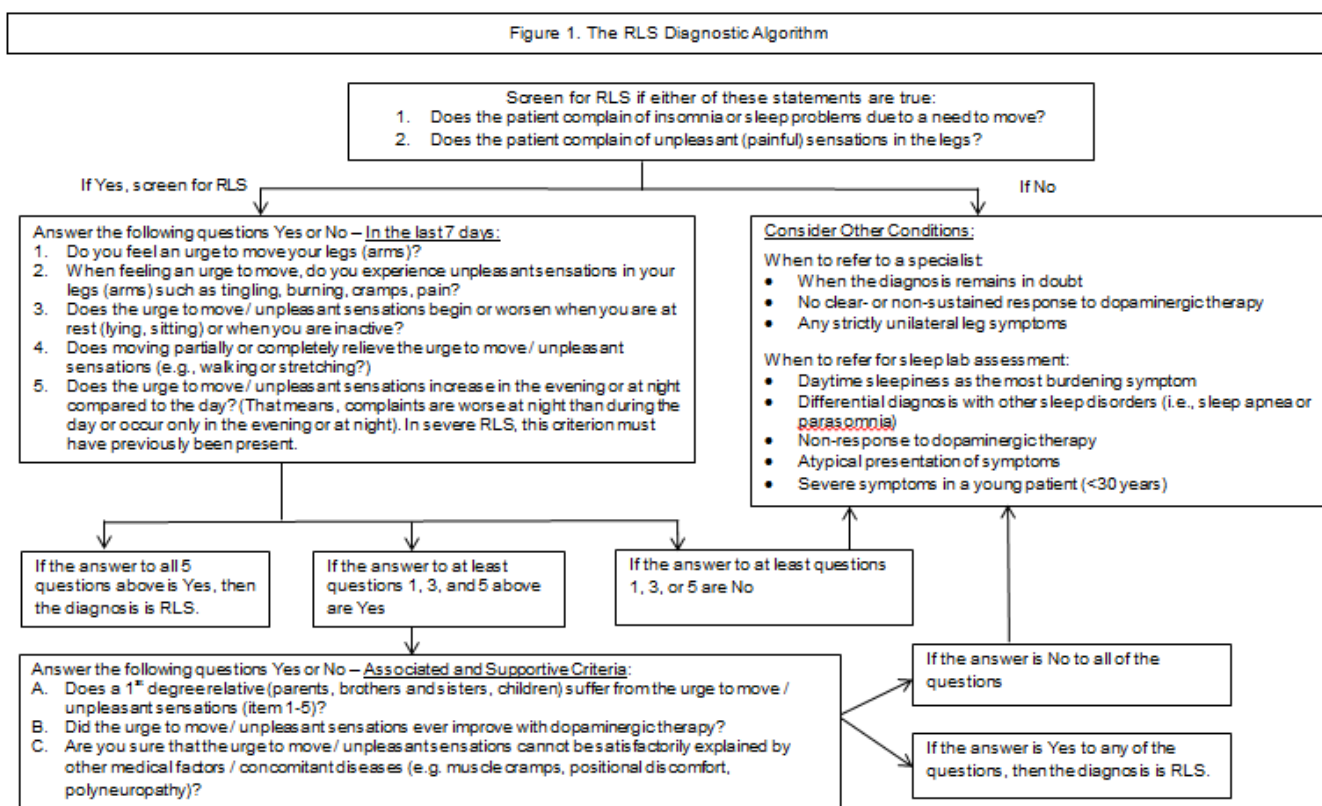


Figure adapted from Diego Garcia-Borreguero et al: Algorithm for the diagnosis and treatment of restless legs syndrome in primary care. BMC Neurology 2011,11:28

Conclusion: (173 words)

RLS is a common yet frequently underdiagnosed disorder. Given the impact of RLS on quality of life and the therapeutic efficacy of current treatments in improving these symptoms, its early identification and treatment is highly relevant. Thus, it is important for primary care providers to be familiar with these criteria and adaptive diagnostic algorithm that improves the diagnosis of RLS.

Based on the diagnostic algorithm above, if a patient says yes to all questions 1-5 under the diagnostic index, then the patient has RLS. If the patient answers yes to at least questions 1,3 and 5 then proceed to items 6 to 8 which are the associated and supportive criteria. In addition to positive responses to questions 1,3 and 5 above, if the patient answers yes to one or more questions (6-8) then it is likely that they have RLS. When there is a high suspicion of RLS, the patient should be given a trial of dopaminergics, response to medications will support diagnosis of RLS and will help exclude other disorders that mimic RLS.

After reviewing RLS DI, if any patient presents in clinic with symptoms concerning for RLS, we will consider screening him with essential and supportive criteria explained in RLS DI to better diagnose this condition.

Reference List (1-2 review articles, 2 evidence articles):

1. Allen RP, Picchiatti D, Hening WA, Trenkwalder C, Walters AS, Montplaisir J: Restless legs syndrome: diagnostic criteria, special considerations, and epidemiology. A report from the restless legs syndrome diagnosis and epidemiology workshop at the National Institutes of Health. *Sleep Med* 2003, 4(2):101-119.
2. Benes H, Kohnen R: Validation of an algorithm for the diagnosis of Restless Legs Syndrome: The Restless Legs Syndrome-Diagnostic Index (RLS-DI). *Sleep Med* 2009, 10(5):515-523.
3. Benes H, Kohnen R: Empirical evaluation of the accuracy of diagnostic criteria for Restless Legs Syndrome. *Sleep Med* 2009, 10(5):524-530.
4. Diego Garcia-Borreguero et al: Algorithm for the diagnosis and treatment of restless legs syndrome in primary care. *BMC Neurology* 2011,11:28.

