



Symptom Severity of Restless Legs Syndrome Predicts Its Clinical Course

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ABSTRACT

OBJECTIVE: This study examines the clinical course of restless legs syndrome according to its severity and factors associated with the remission of restless legs syndrome symptoms.

METHODS: The remission or persistence of restless legs syndrome symptoms was investigated by considering patients with restless legs syndrome at the sleep clinic of Seoul National University Bundang Hospital. All subjects were observed for at least 18 months, and an incidence of remission was defined as having no restless legs syndrome symptoms for at least 1 year. Restless legs syndrome severity was evaluated by the International Restless Legs Syndrome Study Group Rating Scale.

RESULTS: A total of 306 patients participated in this study. Over the observation periods of 4.1 ± 1.6 years, the cumulative incidence of remission is 32.5% (95% confidence interval [CI], 27.0-38.0) and decreased with baseline restless legs syndrome severity ($P < .001$): 60% (95% CI, 44.9-75.1), 44% (95% CI, 34.4-53.6), and 16.7% (95% CI, 10.6-22.8) in mild, moderate, and severe to very severe restless legs syndrome cases, respectively. Most cases of remission (82/96) were observed within 1 year, and the remission occurred sooner for mild restless legs syndrome. The hazard ratios of remission by Cox proportional hazards model were lower for moderate (0.556; 95% CI, 0.340-0.909) and severe to very severe (0.193; 95% CI, 0.108-0.343) restless legs syndrome than for mild restless legs syndrome. The remission incidence was lower for those patients who had a family history of restless legs syndrome and were older at restless legs syndrome diagnosis.

CONCLUSIONS: Mild restless legs syndrome severity, no family history, and young age at restless legs syndrome diagnosis were significant predictors of restless legs syndrome remission. More than 80% of patients with severe restless legs syndrome showed a chronic clinical course.

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KEYWORDS: Clinical course; Remission; Restless legs syndrome; Severity

Restless legs syndrome is a common sensorimotor disorder occurring in 5% to 10% of the general population and characterized by an unpleasant sensation in limbs that

appears or worsens during rest and nighttime, and disappears or improves with movement.¹⁻³ Restless legs syndrome not only disturbs sleep, impairs daytime activity, and reduces the quality of life but also leads to medical and psychiatric comorbidity and increases mortality.^{1,3-8} However, the clinical courses and prognostic factors are generally not well defined in comparison with epidemiology, cause, or treatment of restless legs syndrome, although several studies have considered the natural course of restless legs syndrome.⁹⁻¹¹

Walters et al⁹ considered a sample of 138 patients with restless legs syndrome. They observed a full remission of symptoms for 1 month or more in at least 15% of the

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subjects, and the progression of symptom severity and frequency in more than 65% of the sample. However, they did not define the factors associated with the remission or persistence of symptoms. In a follow-up study, Kagimura et al¹⁰ showed that only 40% of restless legs syndrome-positive subjects had related symptoms after 2 years, demonstrating symptom frequency as a risk factor in symptom persistence, and Juuti et al¹¹ investigated the relationship between the frequency and the persistence of symptoms at 10-year intervals. Both studies showed a significant relationship between the frequency and the remission of restless legs syndrome symptoms, but restless legs syndrome symptom severity may be another essential factor for influencing the clinical course of restless legs syndrome. According to clinical experiences, severe restless legs syndrome is more likely to show chronic symptoms, whereas mild restless legs syndrome will show a remission of symptoms or transient symptoms.¹² In addition, the relationship between restless legs syndrome and cardiovascular diseases or mortality has been found to be stronger in patients with restless legs syndrome with greater restless legs syndrome symptom frequency or severity.^{5,7}

Previous studies considering the natural course of restless legs syndrome have several limitations, including the use of no standardized scales for severity,¹¹ community samples of mild restless legs syndrome severity,^{10,11} and short observation periods.⁹ In this regard, there is a need to determine whether the severity of restless legs syndrome is related to the clinical course of restless legs syndrome on the basis of standardized severity scales and samples of clinical significance. Therefore, the present study considers a retrospective cohort by conducting a survival analysis of patients with restless legs syndrome who visited a sleep clinic from 2004 to 2011 to examine the clinical course of restless legs syndrome according to symptom severity and factors associated with the remission of restless legs syndrome symptoms. In addition, we have focused on primary restless legs syndrome cases, excluding secondary restless legs syndrome cases.

MATERIALS AND METHODS

Subjects

For the sample, patients with restless legs syndrome who visited the sleep clinic of Seoul National University Bundang Hospital (SNUBH) from November 2004 to November 2011 were considered. All participants were evaluated with the International Restless Legs Syndrome Study Group Rating Scale for Severity (IRLS),¹³ and their

baseline serum ferritin concentrations were measured. Those individuals with no available IRLS or serum ferritin data, with a serum ferritin level less than 50 ng/mL or chronic renal failure, or who were pregnant were excluded. The study protocol was approved by the Institutional Review Board of SNUBH (B-1307/210-112).

CLINICAL SIGNIFICANCE

- Most cases of remission (82/96) were observed within 1 year.
- Mild restless legs syndrome severity, no family history, and young age at restless legs syndrome diagnosis were predictors of restless legs syndrome remission.
- More than 80% of patients with severe restless legs syndrome showed a chronic clinical course.

Baseline Assessment

Eligible subjects underwent a clinical examination and psychiatric evaluation, and completed sleep questionnaires at initial diagnosis. Restless legs syndrome was diagnosed by 2 sleep experts on the basis of the essential criteria for restless legs syndrome recommended by the National Institutes of Health (NIH).¹² Although the criteria excluding restless legs syndrome mimics,¹⁴ such as myalgia, venous stasis, leg edema,

arthritis, neuropathic pain syndromes, leg cramps, and positional discomfort, were not included in the NIH criteria used in this study, we have taken the concern for restless legs syndrome mimics seriously and have excluded restless legs syndrome mimics by clinical examination and mimics-related questions. Restless legs syndrome severity was evaluated by total IRLS scores (mild, 0-10; moderate, 11-20; severe, 21-30; very severe, 31-40). In addition, the frequency of restless legs syndrome symptoms was assessed using item 7 of IRLS (0, none; 1, ≤ 1 day a week; 2, 2-3 days a week; 3, 4-5 days a week; 4, 6, to 7 days a week). The Pittsburgh Sleep Quality Index was used to evaluate subjective sleep complaints¹⁵; the Epworth Sleepiness Scale, daytime sleepiness¹⁶; and the Beck Depression Inventory, mood symptoms.

Follow-up Protocol

Baseline demographic and clinical data were obtained from medical records at initial diagnosis, and the current state of restless legs syndrome symptoms was investigated through face-to-face or telephone interviews. These interviews were conducted by physicians participating in this study. For those participants who have been regularly followed up at the sleep clinic from their initial diagnosis, data on their current state were obtained from face-to-face interviews, and the others were contacted by telephone. The observation period was at least 18 months from the initial diagnosis to the current investigation time, and the state of restless legs syndrome symptoms was divided into remission or persistence as a primary outcome. Remission was defined as having no restless legs syndrome symptoms for at least 1 year, whereas taking any medication for controlling restless legs syndrome symptoms was regarded as symptom persistence. The telephone interview included the following

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