



RLS Patient Odyssey Survey II: Executive Summary

Overview

Restless legs syndrome (RLS) is a serious, chronic disease with no cure. Many RLS patients endure chronic, unrelenting nightly symptoms that have a devastating impact on their quality of life. While four FDA-approved treatments are available, none provides life-long relief.

The RLS Patient Odyssey Survey II (ODYSSEY II) study shows that people with RLS have substantially higher risks of depression and suicidal thoughts than those with other chronic health conditions, and extensive delays in diagnosis and treatment. These findings underscore the urgent need for clinician education, universal screening in primary care, and research to find better treatments and a cure.

Background

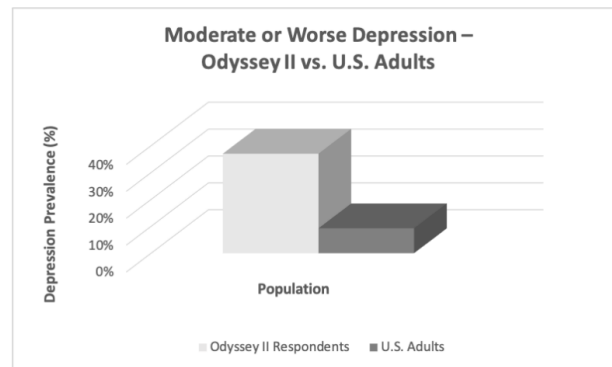
In 2020, supported by an educational grant from Azurity Pharmaceuticals, the RLS Foundation conducted ODYSSEY II to evaluate the challenges of people living with RLS. The study was comprised of a patient survey and a spouse/partner survey, with questions about RLS diagnosis and severity, associated medical conditions, RLS treatment responses, and opinions of RLS care. In all, 3,003 patients and 432 spouses/partners participated.

Primarily living in the US, the group was 70% female and had an average age of 66. Many were highly educated; 76% had graduated from college; 38% also had completed graduate or professional school. In the patient group, 2,745 were confirmed as having RLS. Just over half had severe RLS, indicating high RLS severity is modestly overrepresented in this study compared with national norms.

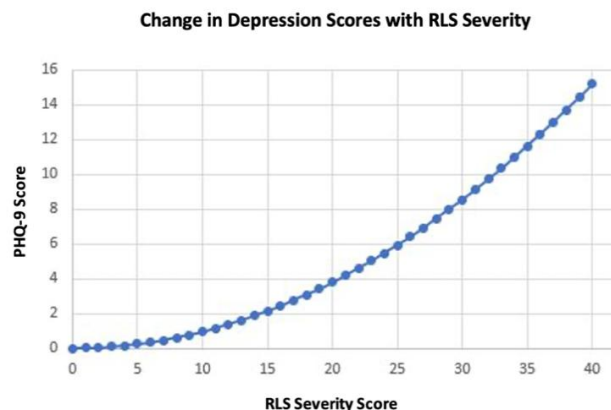
Key findings: Patients

RLS is more common and severe than many other chronic health conditions. Depression and suicidal thoughts are major consequences of RLS, in addition to the widely recognized issues of sleep loss and its effects on daily life.

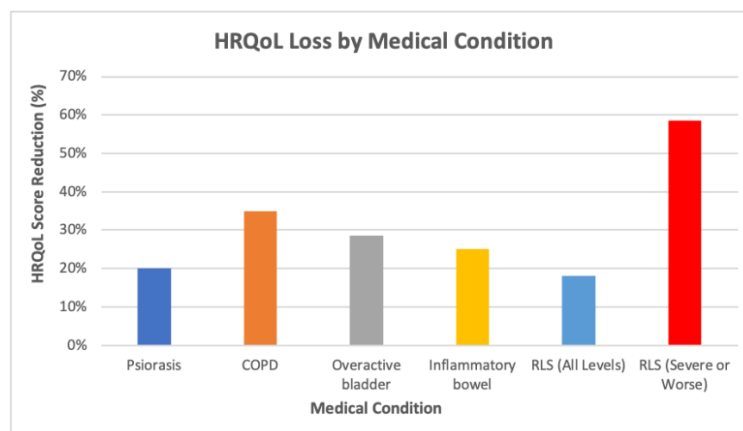
- Among the respondents, 37% had depression that was moderate or worse — a rate four times that of the general US adult population.ⁱ



- Likewise, 15% of participants reported having suicidal thoughts — about four times the national average.ⁱⁱ
- Depression level rose exponentially with RLS severity.

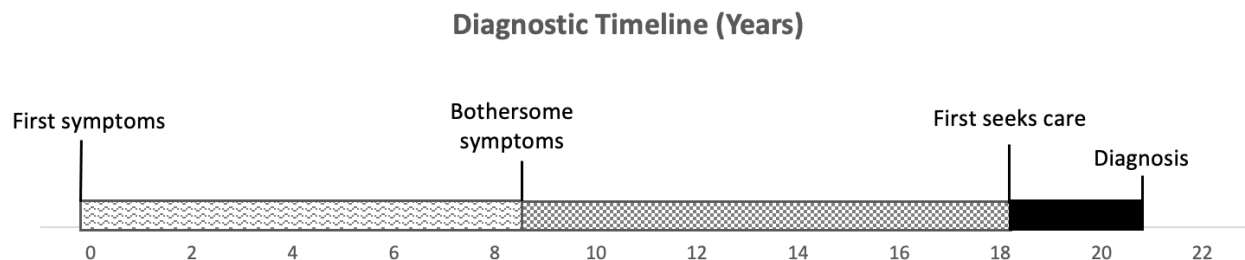


- Based on depression levels alone, respondents with “moderate” severity and worse had less than half the health-related quality of life, or HRQoL, of healthy people.



People with RLS experience excessive delays in diagnosis and treatment.

- The average time from first symptoms to bothersome symptoms was 8.8 years, and from bothersome symptoms to seeking treatment was 9.8 years. From there, the average time to diagnosis was 2.2 years.



- The average age that participants began experiencing symptoms was 32, and the average age at diagnosis was 44 — a 12-year gap.
- Half of respondents experienced an average delay of 7 years between first symptoms and diagnosis, and one-fourth had a delay of 23 years.
- Almost half (43%) reported their primary care providers did not take their condition seriously.

RLS treatment options and medical care are inadequate.

- Current RLS medications were primarily dopaminergics (59%), alpha-2-delta ligands (34%), opioids (31%) and benzodiazepines (9%).
- Respondents who reported that their medications worked “very well” or “somewhat well” included 75% of those taking dopaminergics, 65% of those taking opioids, and 61% of those taking alpha-2-delta ligands. All other drugs had far lower benefits.
- Many patients stopped taking dopaminergics; 41% did so because of untoward side effects (primarily a serious side effect called augmentation). The new RLS treatment algorithm published July 2021 in *Mayo Clinic Proceedings* recommends alpha-2-delta ligands and iron therapy as first-line treatments and relegates dopaminergics to second-line therapy because of augmentation.
- Concerningly, 2.2% were taking antimalarial drugs for RLS, a therapy that lacks evidence of benefit and carries risks of injury and fatality.
- Of the patients using opioid drugs, 21% reported medication access issues such as difficulty obtaining prescription renewals.
- Those who received treatment at certified RLS Quality Care Centers rated their providers as excellent or good 67% of the time, whereas only 24% of those using non-certified providers gave the same ratings. Almost half (43%) reported their primary care providers did not take their condition seriously.

Key findings: Spouses/partners

RLS adversely affects spouses and partners.

- Partners' lives were impacted in areas including sleep (38%), social events (29%), travel (27%), relationships with their partners (25%), mood and happiness (23%), and sex (20%).
- Over half said that their work productivity was affected at least “somewhat.”
- About one-third (30%) of partners had moved into separate beds, and almost 1 in 20 (4.5%) said that their partners' RLS was disruptive enough to consider ending the relationship.

Recommendations

- 1) **Conduct an ODYSSEY III survey that directly measures HRQoL** in RLS patients and their partners. ODYSSEY II highlights issues where further knowledge is needed. Direct HRQoL data will strengthen advocacy for research, education and systemic improvements in RLS care.
- 2) **Institute universal screening for RLS in primary care practices** to shorten the diagnostic timeline. Strategies might include protocol revision, alerts in electronic health records, a short-form RLS screening test, and adding RLS screening to U.S. Preventive Services Task Force recommendations.
- 3) **Conduct implementation and dissemination research** to identify methods to increase the use of RLS diagnosis and treatment protocols by providers — for example, by automating proper protocol use for screening, diagnosis, treatment and referral to RLS Quality Care Centers.
- 4) **Incorporate RLS education into clinician training** to reinforce treatment guidelines, such as the use of alpha-2-delta ligands as a first-line therapy. Dopamine agonists are no longer recommended as a first-line therapy due to risk of augmentation. Guidelines also outline appropriate use of opioids in low total daily doses to treat refractory RLS.
- 5) **Increase and expand RLS research.** Basic science and clinical studies are urgently needed to understand the causes and clinical pathways of RLS and to develop more effective treatments. Epidemiological research is needed to explore the role of genetics in treatment response.

ⁱ Patel JS, Oh Y, Rand KL et al., “Measurement Invariance of the Patient Health Questionnaire- (PHQ-9) Depression Screener in U.S. Adults Across Sex, Race/ethnicity, and Education Level: NHANES 2005-2016, *Depression & Anxiety* 2019; DOI: <https://doi.org/10.1002/da.22940>

ⁱⁱ <https://www.samhsa.gov/data/sites/default/files/NSDUH-DR-FFR3-2015/NSDUH-DR-FFR3-2015.htm>