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NATIONAL RLS OPIOID REGISTRY: FOUR-YEAR DOSE STABILITY, EFFICACY AND TOLERABILITY

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Introduction: Refractory or augmented restless legs syndrome (RLS) is often treated with opioids. Despite their short-term efficacy, concerns about long-term efficacy, dose stability, and tolerability persist. The National RLS Opioid Registry is a longitudinal, observational study tracking the long-term efficacy, dose stability, and tolerability of opioids for RLS.

Methods: Extensive interviews were conducted with a baseline population of 500, from 44 US states and 4 countries. All participants have a history of therapeutic response to dopamine agonists–a majority experienced augmentation–and take prescribed opioids for RLS (median duration at BL=2-years). Biannual self-report questionnaires track opioid dosage, side effects, RLS severity, and other relevant factors. No clinical guidance or intervention is provided.

Results: At 4-years, 423 participants continue opioid treatment and study participation (5.8% lost to follow-up or withdrew, 2.4% died, 6.6% stopped opioids). Methadone and oxycodone are the two most common opioids (taken by 54.7% and 21.9% of 4-year participants, respectively). Mean RLS severity (baseline IRLS=13.0; 4-year IRLS=13.3) and sleep disturbance (baseline ISI=10.5, 4-year ISI=9.9) were stable from baseline to 4-years in the Registry. Median daily opioid dose is also unchanged, at 30 MME (equivalent to methadone 7.5 mg or oxycodone 20 mg). Opioid doses were increased by 49.4% of participants (median increase=11.3 MME) and decreased by 19.2% (median decrease=10.5 MME). Large dose increases (25-50 MME or >50 MME) occurred in 5.0% and 5.4% of participants, respectively. Several factors were associated with larger dose increases, including switching opioid medications (OR=3.61, 95% CI [1.80 7.27]), under one year on opioids at baseline (OR=2.03, 95% CI [1.00-4.09]), significant baseline depression (PHQ-9>4)(OR=2.57 95% CI [1.27-5.51]), use of opioids for comorbid pain conditions (OR=3.18, 95% CI [1.21-7.89]), dopamine agonist addition (OR=3.06, 95% CI [0.92-8.77]) or discontinuation (OR=3.16, 95% CI [1.13-8.26]) since baseline, and painful RLS at baseline (OR=3.85, 95% CI [1.26-16.79]). Side effect profiles were unchanged from baseline.

Conclusion: Low-dose opioids effectively control severe RLS symptoms over 4-years of observation. Nearly 50% of participants increased their dose, though most changes were small, with larger dose increases associated with specific risk factors.

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