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Pregabalin effectively treats restless leg syndrome with less risk of worsening symptoms

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A report in the Feb. 13 *New England Journal of Medicine* confirms previous studies suggesting that long-term treatment with the type of drugs commonly prescribed to treat restless leg syndrome (RLS) can cause a serious worsening of the condition in some patients. The year-long study from a multi-institutional research team found that pregabalin – which is FDA-approved to treat nerve pain, seizures, and other conditions – was effective in reducing RLS symptoms and was much less likely to cause symptom worsening than pramipexole, one of several drugs that activate the dopamine neurotransmission system and are FDA approved for treatment of RLS.

"Our key finding is that dopaminergic drugs, while very effective for many people with RLS, can worsen symptoms in some patients over time, while non-dopaminergic pregabalin is not associated with this disturbing side effect," says John Winkelman, MD, PhD, of the Massachusetts General Hospital Department of Psychiatry, senior author of the study. "Those treating RLS patients with dopaminergic drugs need to be aware of this common complication and exercise caution if their symptoms worsen."

RLS is a neurological disorder characterized by an uncontrollable urge to move the legs that occurs when resting – usually during the evening or at night – and is temporarily relieved by movement. Because RLS interferes with normal sleep, affected individuals may have chronic

exhaustion that interferes with work, personal relationships and activities of daily living. Serious RLS affects 2 to 3 percent of the U.S. and European populations and is commonly treated with drugs that activate the dopamine system.

While it has been known for several years that over one-third of RLS patients on long-term treatment with these drugs develop more frequent and intense symptoms that can extend to the upper extremities, many physicians treating RLS patients are unaware of the risk, Winkelman explains. In addition, it has not been clear whether symptom augmentation reflects a natural progression of the condition or is the result of treatment with dopaminergic drugs, which also have movement-related side effects when used to treat Parkinson's disease and other conditions. The current study was designed to answer that question and to investigate whether a different type of drug could relieve symptoms without leading to augmentation.

Conducted at more than 100 sites in the U.S. and Europe, the study enrolled more than 700 adults experiencing moderate to severe RLS symptoms 15 or more nights a month for 6 months or longer. All participants had stopped taking any medications for RLS for at least two weeks before beginning the study. For the first 12 weeks of the study participants were randomly assigned to one of four treatment groups that received daily doses of either 0.25 mg of pramipexole, 0.5 mg pramipexole, 300 mg of pregabalin – all dosages currently used for FDA-approved applications – or a placebo. After the first phase, all participants receiving placebo were randomly assigned to one of the active drug groups for the remaining 40 weeks of the study period. At regularly scheduled study visits, participants submitted symptom diaries they had compiled during the week before each visit and were assessed with standard scales measuring RLS symptoms and their augmentation.

At the end of the 12-week, placebo-controlled phase, patients receiving

pregabalin had significantly greater symptom improvement compared with those receiving placebo, as did those receiving the higher pramipexole dose. Over the full study period, only 2 percent of those receiving pregabalin experienced symptom augmentation, compared with almost 8 percent of those on the 0.5 mg pramipexole dose and around 5 percent of those getting 0.25 mg of pramipexole. The longer participants were taking any of the tested drugs, the more likely they were to develop augmentation.

"Pregabalin is not FDA-approved for the treatment of RLS, but a number of published treatment guidelines do list it as a first-line treatment option. Another medication in that class, gabapentin enacarbil, has been FDA-approved for RLS," notes Winkelman, an associate professor of Psychiatry at Harvard Medical School. "Probably the most important message for physicians treating patients with RLS is to be aware of the risk of augmentation with dopaminergic drugs, to regularly follow up with patients and not to just increase dosage if symptoms worsen. We're going to be working to improve our understanding of the mechanism behind augmentation and whether we might be able to predict which patients are at risk of this complication."

Provided by Massachusetts General Hospital

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