Initiation of Pharmacotherapies for Newly Diagnosed Early-Onset Idiopathic Restless Legs Syndrome (RLS) from 2012-2019

Brianna Costales, PhD[1]; Scott M. Vouri, PharmD, PhD[1]; Joshua D. Brown, PharmD, PhD[1]; Barry Setlow, PhD[2]; Amie J. Goodin, PhD[1]

[1]Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida; [2]Department of Psychiatry, College of Medicine, University of Florida

Objective

1) To assess treatment initiation of pharmacotherapies initiated for newly diagnosed early-onset idiopathic restless legs syndrome (RLS).
2) To estimate persistence of initiated therapy during 1 year of follow-up.

Methods

Data Source
IBM MarketScan® Commercial Claims and Encounters Databases, from 2012 to 2019

Study Design
New-user retrospective cohort study and a cross-sectional sample of the cohort

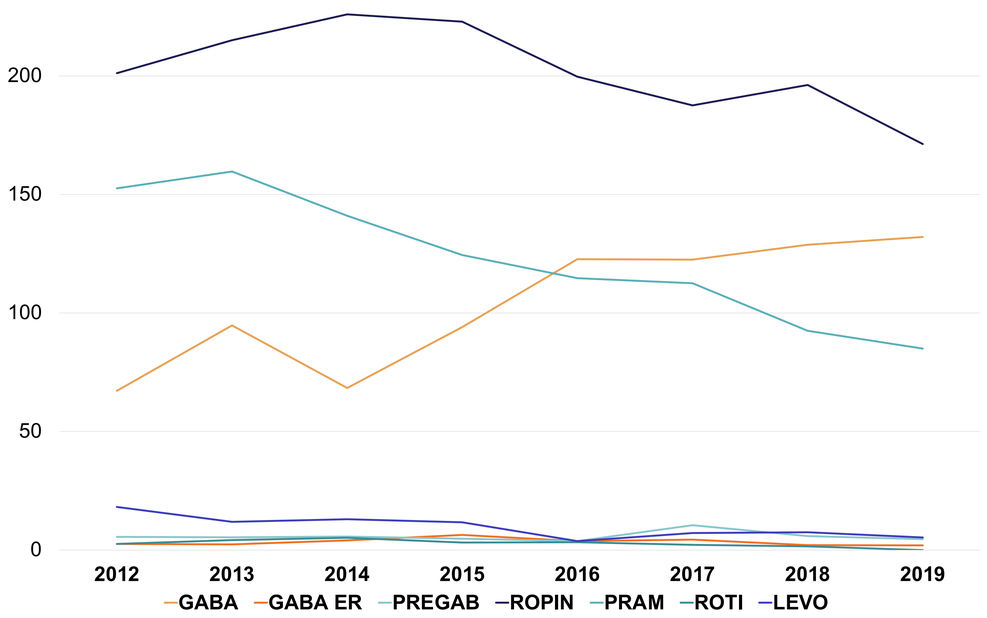
Study Population
Adults ages 18-44 years, newly diagnosed with presumptive idiopathic RLS and who initiated RLS study drugs within 60 days of first diagnosis

Study Drugs
- Gabapentinoids (gabapentin, gabapentin enacarbil, pregabalin)
- Dopamine agonists (ropinirole, pramipexole, rotigotine)
- Carbidopa/levodopa

Treatment Outcome Measures
- Annual prevalence of treatment estimated for initiated monotherapy
- Mean time on initiated therapy calculated as a measure of persistence

Results

Annual prevalence of treatment for initiated monotherapy



Y-axis: RLS pharmacotherapy users per 1,000 early-onset idiopathic RLS patients

Persistence of initiated monotherapy treatment with permissible gap of 14 days

Pharmacotherapy initiated (# initiators)	Mean (SD) time on initiated therapy in days[1]
Gabapentin[2] (n= 975)	176.9 (170.4)
Gabapentin enacarbil (n= 46)	139.2 (143.1)
Pregabalin[2] (n= 54)	166.2 (152.8)
Ropinirole (n= 2,124)	176.3 (164.1)
Pramipexole (n= 1,303)	179.5 (166.3)
Rotigotine (n= 29)	185.4 (161.4)
Carbidopa/levodopa[2] (n= 107)	138.6 (143.5)

[1]Maximum time possible for persistence was 365 day
[2]Recommended by guidelines but not FDA-approved for RLS

Conclusions

Ropinirole, pramipexole, and off-label gabapentin were initiated most often for newly diagnosed early-onset idiopathic RLS.

Use of evidence-based first-line treatments (gabapentin enacarbil, pregabalin, and rotigotine) was minimal.

Persistence was low for all study drugs examined, consistent with past literature.

Selected References

1. Hankin C et al. Increased risk for new-onset psychiatric adverse events in patients with newly diagnosed primary restless legs syndrome who initiated treatment with dopamine agonists: a large-scale retrospective claims matched-cohort analysis. *J Clin Sleep Med* 2019;15(09):1225-1232.
2. Garcia-Borreguero D et al. Guidelines for the first-line treatment of restless legs syndrome/ Willis-Ekbom disease, prevention and treatment of dopaminergic augmentation: a combined task force of the IRLSSG, EURLSSG, and the RLS Foundation. *Sleep Med* 2016;21:1-11.
3. Winkelman JW et al. Practice guideline summary: treatment of restless legs syndrome in adults: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. *Neurology* 2016;87(24):2585-2593.

Follow on Twitter: @UFCoDES @ResearchBri

Contact Email: b.costales@ufl.edu

Disclosures and Acknowledgements
This work was supported by the National Institute of Mental Health (grant number R36MH127826 awarded to BC). Authors SMV, JDB, BS, and AJG report no disclosures.