

Title: Real-World Idiopathic Hypersomnia Total Health Model (RHYTHM): Clinical Burden of Patients Diagnosed With Idiopathic Hypersomnia

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ABSTRACT

Introduction: Idiopathic hypersomnia (IH) is a rare neurologic disorder that can cause debilitating symptoms, including excessive daytime sleepiness, severe sleep inertia, prolonged nighttime sleep, long and unrefreshing naps, and cognitive dysfunction. Limited research has investigated the clinical burden associated with IH. This study compared the clinical profile of patients diagnosed with IH versus matched non-IH controls.

Methods: MarketScan[®] administrative claims were analyzed between December 2013 and February 2020. Eligible patients were aged ≥ 18 years upon cohort entry and had 365 days of continuous medical coverage (gaps ≤ 30 days allowed) before and after cohort entry. IH cases entered the cohort upon the first medical claim containing an IH diagnosis and without history of cataplexy. Non-IH controls were matched 5:1 to patients with IH on age, sex, region, payer type, and cohort entry date. Prevalence estimates of Clinical Classification System Multilevel (CCSM) categories and comorbid conditions during the 2-year study period were compared between cohorts using logistic regression. Odds ratios (ORs) and 95% confidence intervals (CIs) were reported.

Results: The final cohorts included 11,428 and 57,138 patients with IH and non-IH controls, respectively. Approximately two-thirds of the sample was female (65.0%); median age was 45 years. Compared with non-IH controls, patients with IH experienced significantly higher prevalence of all CCSM categories. Prevalence estimates of conditions associated with sleep disorders, such as sleep apnea (OR: 26.1 [CI: 24.8, 27.6]), mood disorders (OR: 3.7 [CI: 3.6, 3.9]), and headache/migraine (OR: 2.9 [CI: 2.7, 3.0]), were higher among patients with IH. Similarly, cardiovascular conditions, including cardiovascular disease (OR: 2.2 [CI: 2.1, 2.4]), stroke (OR: 2.2 [CI: 2.0, 2.4]), major

adverse cardiovascular events (OR: 2.2 [CI: 2.0, 2.4]), a composite of hypertension diagnosis or use of antihypertensive medications (OR: 2.0 [CI: 2.0, 2.1]), and heart failure (OR: 2.0 [CI: 1.8, 2.3]), were significantly more prevalent among patients with IH.

Conclusion: Patients with IH experience a significant burden of psychiatric and medical comorbidities, including acute and chronic cardiovascular illnesses. This is consistent with observations in other sleep disorders, namely, narcolepsy. Holistic treatment strategies for IH patients are needed, requiring careful consideration of patients' overall clinical profile when selecting therapies.

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Disclosures

P Lillaney is a former full-time employee of Jazz Pharmaceuticals who, in the course of this employment, received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals.

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