

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

Prasheel Lillaney, PhD^{1,*}; Ragy Saad, MSc^{1,*}; Deb Profant, PhD¹; Douglas S. Fuller, MS²; Trevor Alvord, MPH³; Patricia Prince, MPH³; Marisa Whalen, PharmD²; Wayne Macfadden, MD²; Weiyi Ni, PhD¹; Jed Black, MD^{1,4}

¹Jazz Pharmaceuticals, Palo Alto, CA, USA; ²Jazz Pharmaceuticals, Philadelphia, PA, USA; ³Aetion, New York, NY, USA; ⁴Stanford University Center for Sleep Sciences and Medicine, Palo Alto, CA, USA. *P Lillaney and R Saad are former employees of Jazz Pharmaceuticals.

Introduction

- Idiopathic hypersomnia 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 dysfunction¹
- Patients with idiopathic hypersomnia report cognitive, psychological, and functional problems² that may be associated with comorbidities
- Limited research has investigated the clinical burden associated with idiopathic hypersomnia

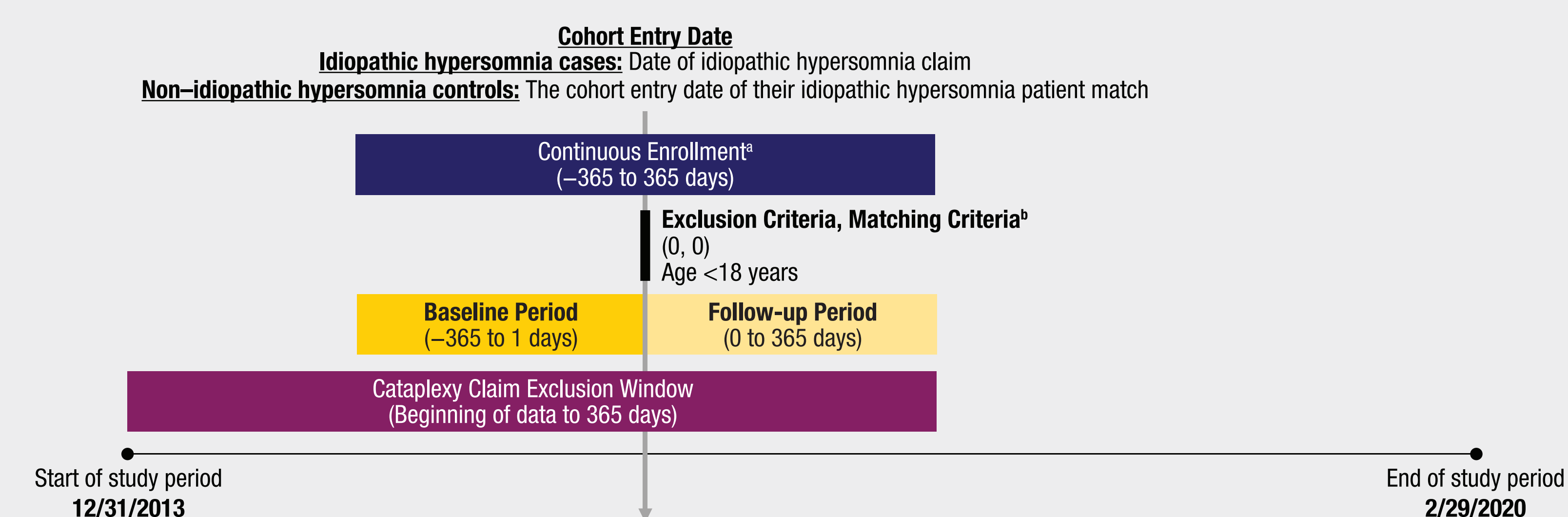
Objective

- To compare the clinical profile of adult patients diagnosed with idiopathic hypersomnia versus matched controls

Methods

- Merative™ MarketScan® administrative claims were analyzed from 12/31/2013 to 2/29/2020
- Eligible patients were ≥18 years of age and had 365 days of continuous medical coverage (gaps ≤30 days allowed) before and after cohort entry
- Patients with idiopathic hypersomnia entered the cohort upon receipt of their earliest medical claim for idiopathic hypersomnia (ICD-9-CM, 327.11, 327.12; ICD-10-CM, G47.11, G47.12) in any position, and without history of cataplexy^{3,4}
- Controls were matched 5:1 to patients with idiopathic hypersomnia on age, sex, geographic region, insurance type, and cohort entry date
- Odds ratios of comorbid conditions during the 2-year study period were compared between cohorts using unconditional logistic regression; covariates used in the model were the same as those used for matching

Figure 1. Study Schematic



³30-day gaps allowed.
⁴Each patient with idiopathic hypersomnia was matched with up to 5 non-idiopathic hypersomnia controls based on age, sex, geographic region, insurance type (ie, commercial, Medicare, or Medicaid), and calendar month and year of cohort entry.

Results

Table 1. Demographic Characteristics of Idiopathic Hypersomnia and Matched Non-Idiopathic Hypersomnia Control Cohorts

	Idiopathic Hypersomnia Cohort (n=11,412)	Matched Non-Idiopathic Hypersomnia Cohort (n=57,058)
Age, years		
Mean (SD)	44.3 (14.0)	44.7 (14.1)
Median (IQR)	45.0 (34.0, 55.0)	45.0 (34.0, 55.0)
Sex, n (%)		
Male	3992 (35.0)	19,970 (35.0)
Female	7420 (65.0)	37,088 (65.0)
US region, n (%)		
Northeast	1075 (9.4)	5380 (9.4)
North Central	2351 (20.6)	11,754 (20.6)
South	4700 (41.2)	23,490 (41.2)
West	943 (8.3)	4719 (8.3)
Unknown/Missing ^a	2343 (20.5)	11,715 (20.5)
Insurance type on cohort entry date, n (%)		
Commercial	8557 (75.0)	42,785 (75.0)
Medicare ^b	528 (4.6)	2638 (4.6)
Medicaid	2322 (20.3)	11,610 (20.3)

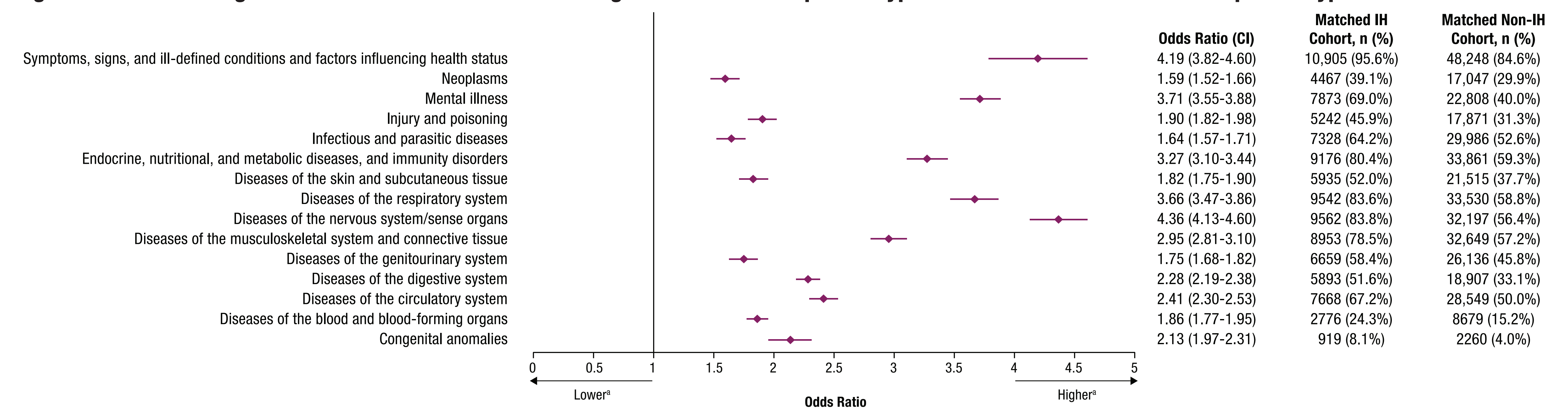
^aDemographic information, such as region, is excluded from Medicaid supplemental tables.
^bBecause of a small sample size, the "Commercial and Medicare" group was incorporated into the "Medicare" group for analysis.
 IQR, interquartile range; SD, standard deviation.

- The final cohorts included 11,412 patients with idiopathic hypersomnia and 57,058 controls
- Approximately two-thirds of the sample was female (65.0%); median age was 45 years

Conclusions

- Patients with idiopathic hypersomnia experience a significantly higher burden of psychiatric and medical comorbidities, including acute and chronic cardiovascular illnesses
- The odds of cardiovascular disease-related comorbidities, such as sleep apnea, hyperlipidemia, hyperuricemia, edema, diabetes, and obesity, were also higher in patients with idiopathic hypersomnia
- These results are consistent with observations in other sleep disorders, namely, narcolepsy⁵
- Careful consideration of patients' overall clinical profile is needed when selecting therapies

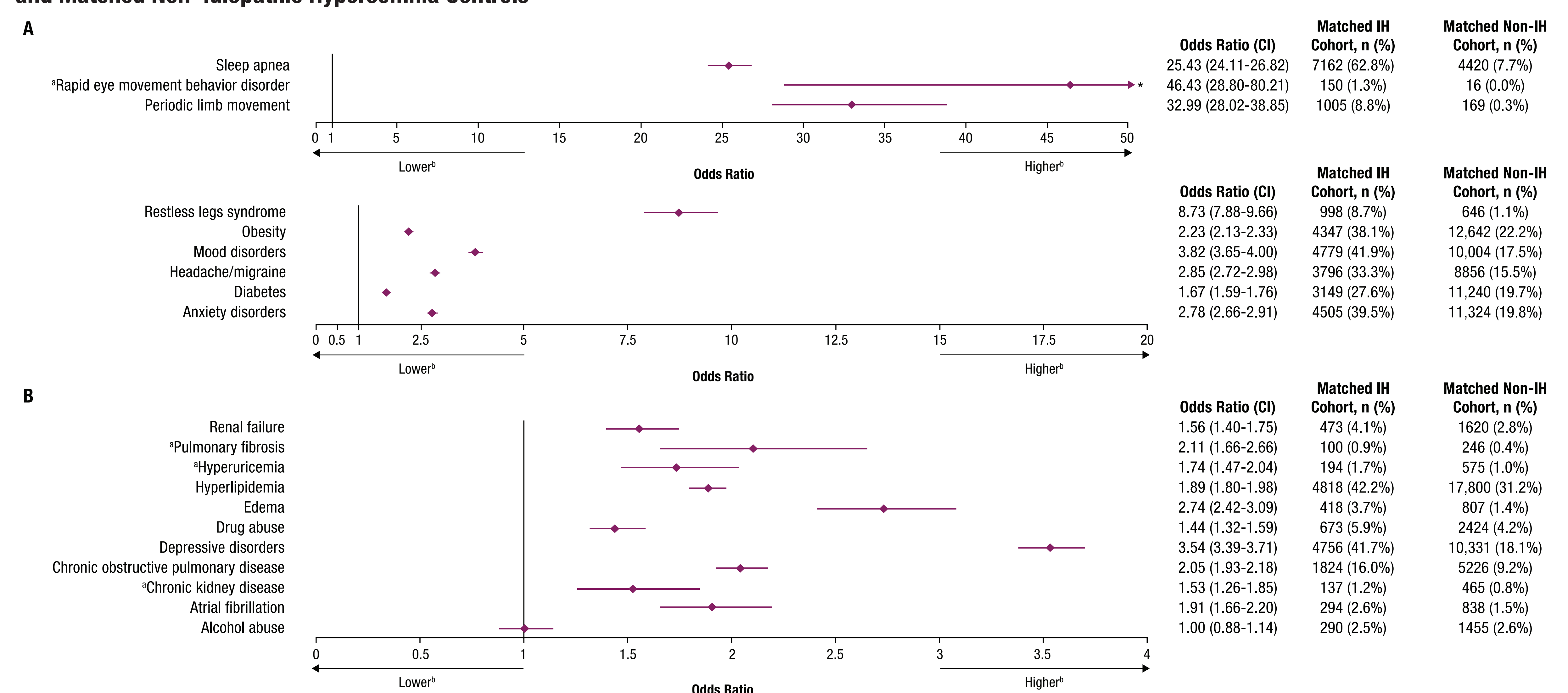
Figure 2. Odds of Categories of Clinical Comorbidities Among Patients With Idiopathic Hypersomnia and Matched Non-Idiopathic Hypersomnia Controls



^aPrevalence in idiopathic hypersomnia.
 CI, confidence interval; IH, idiopathic hypersomnia.

- Patients with idiopathic hypersomnia experienced significantly higher odds of all comorbidities, ranging from 59% higher odds of neoplasms to nearly 4.5 times the odds of diseases of the nervous system/sense organs than for controls

Figure 3. Odds of Conditions Associated With Sleep-Related Disorders (A) and Other Clinical Conditions (B) Among Patients With Idiopathic Hypersomnia and Matched Non-Idiopathic Hypersomnia Controls

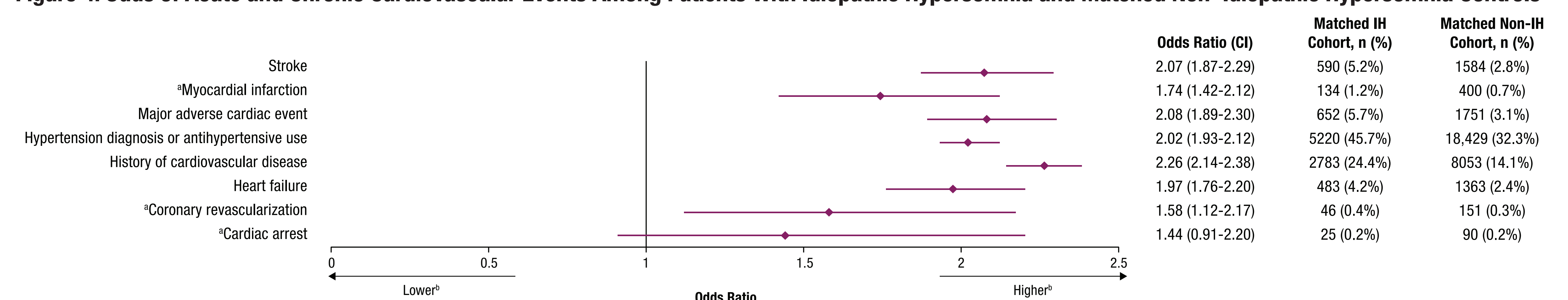


^aAs this outcome had fewer than 250 total events across both cohorts in at least one population or time frame, it was analyzed in a Firth regression model that included year (instead of year and month) of cohort entry. Additionally, the CIs for this outcome were generated using the formula for Firth regression, not using the sandwich estimator, which may cause a decrease in variance due to not taking into account the matching of the data. All matching variables (age, sex, geographic region, insurance type, cohort entry year) and IH status were included in the model as covariates.

^bPrevalence in idiopathic hypersomnia.
^cScale has been adjusted, and the value of this error bar extends to 80.21.
 CI, confidence interval; IH, idiopathic hypersomnia.

- Patients with idiopathic hypersomnia had higher odds of all conditions associated with sleep disorders compared to those of controls
- Odds of comorbid cardiometabolic conditions, such as diabetes, hyperlipidemia, and obesity, were higher in patients with idiopathic hypersomnia compared to controls

Figure 4. Odds of Acute and Chronic Cardiovascular Events Among Patients With Idiopathic Hypersomnia and Matched Non-Idiopathic Hypersomnia Controls



^aAs this outcome had fewer than 250 total events across both cohorts in at least one population or time frame, it was analyzed in a Firth regression model that included year (instead of year and month) of cohort entry. Additionally, the CIs for this outcome were generated using the formula for Firth regression, not using the sandwich estimator, which may cause a decrease in variance due to not taking into account the matching of the data. All matching variables (age, sex, geographic region, insurance type, cohort entry year) and IH status were included in the model as covariates.

^bPrevalence in idiopathic hypersomnia.
 CI, confidence interval; IH, idiopathic hypersomnia.

- Odds of cardiovascular conditions, including a history of cardiovascular disease, stroke, major adverse cardiovascular events, a composite of hypertension diagnosis or use of antihypertensive medications, and heart failure, were higher among patients with idiopathic hypersomnia compared to controls

References: 1. Trotti LM. *Sleep Med Clin*. 2017;12:331-44. 2. Vernet C, et al. *J Sleep Res*. 2010;19:525-34. 3. ICD-9-CM. Organic sleep disorders. <http://www.icd9data.com/2015/Volume1/320-389/320-327/327/default.htm>. Accessed March 28, 2023. 4. ICD-10-CM. Sleep disorders. <https://www.icd10data.com/ICD10CM/Codes/G00-G99/G40-G47/G47->. Accessed March 28, 2023. 5. Black J, et al. *Sleep Med*. 2017;33:13-8.

Support and Acknowledgments: This study was supported by Jazz Pharmaceuticals. Under the direction of the authors, Nicole Boyer, PhD of Peloton Advantage, LLC, an OPEN Health company, provided medical writing and editorial support for this poster, which was funded by Jazz Pharmaceuticals.

Disclosures: P Lillaney and R Saad are former full-time employees 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, plc. D Profant, DS Fuller, M Whalen, W Macfadden, and W Ni are full-time employees of Jazz Pharmaceuticals who, in the course of this employment, have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. T Alvord and P Prince are full-time employees of Aetion, Inc. and hold stock options or equity in Aetion. J Black is a part-time employee of Jazz Pharmaceuticals and a shareholder of Jazz Pharmaceuticals, plc.



Scan this code to access this poster online.
 This code is not for promotional purposes.