Clinical Profile of Patients Treated with CGRP mAbs: An Evaluation of Proximate Migraine Diagnosis
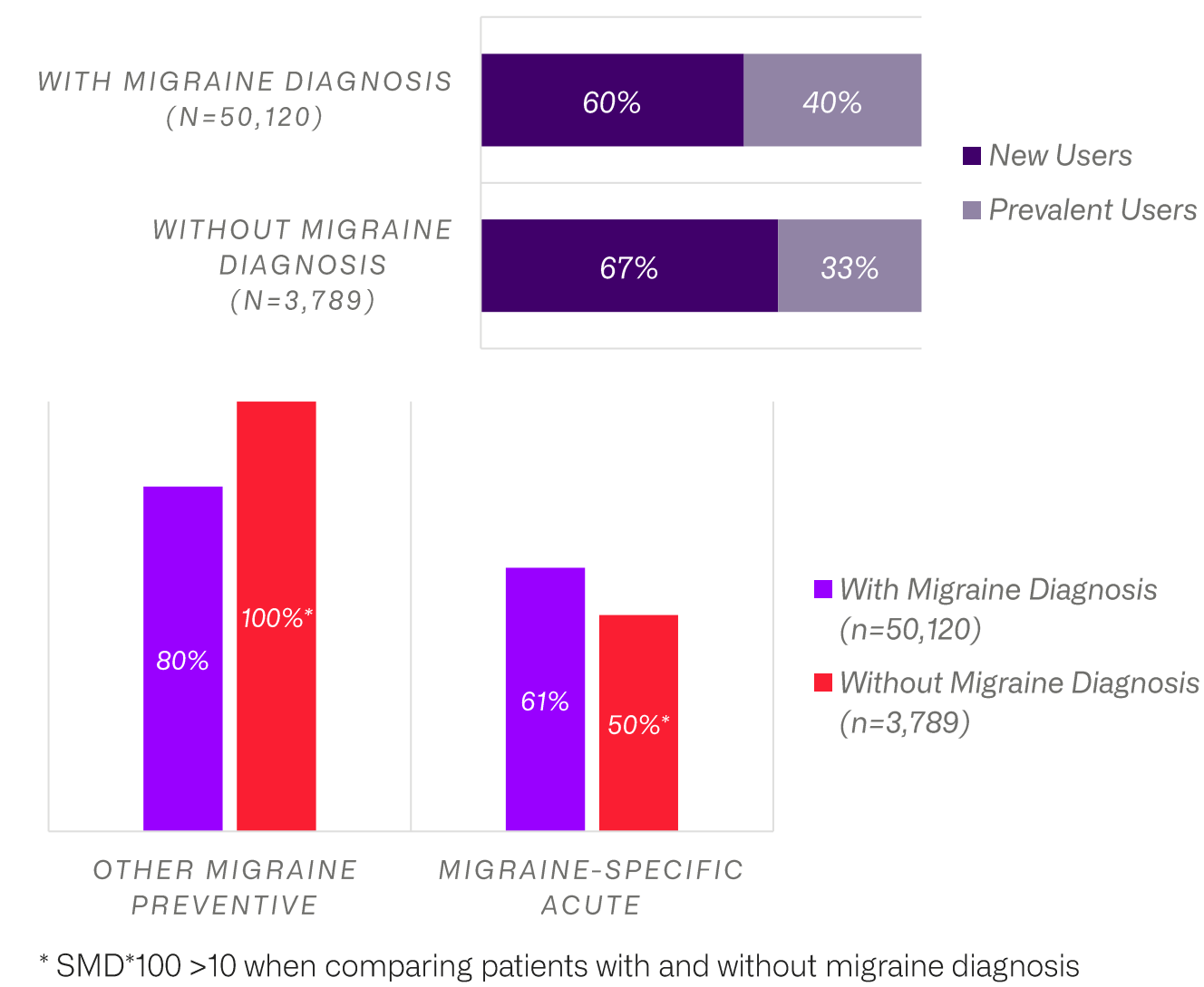
Elizabeth R. Packnett[1], Julie Park[1], Brenna Brady[1]
[1]Merative, Real World Data Research & Analytics, Cambridge, MA, USA

MarketScan by MERATIVE

Study Summary

Study Question: How do the baseline characteristics of patients using CGRP mAbs (calcitonin gene-related peptide antibodies monoclonal antibodies) differ in patients with and without a proximate migraine diagnosis?

Study Results: Patients without a baseline migraine diagnosis were more likely to be new users of CGRP mAbs and were more likely to use other migraine preventive medications, despite similar comorbidity profiles among patients with and without a migraine diagnosis.

WITH MIGRAINE DIAGNOSIS (N=50,120): 60% New Users, 40% Prevalent Users
WITHOUT MIGRAINE DIAGNOSIS (N=3,789): 67% New Users, 33% Prevalent Users

OTHER MIGRAINE PREVENTIVE: With Migraine Diagnosis 80%, Without Migraine Diagnosis 100%*
MIGRAINE-SPECIFIC ACUTE: With Migraine Diagnosis 61%, Without Migraine Diagnosis 50%*

With Migraine Diagnosis (n=50,120)
Without Migraine Diagnosis (n=3,789)

* SMD*100 >10 when comparing patients with and without migraine diagnosis

Conclusion: Treatment with CGRP mAbs may be considered when developing claims-based algorithms to identify patients with migraine, particularly when statistical power is a concern.

Background

- Identification of patient cohorts in administrative claims can rely on a variety of variables, including the presence of diagnoses and or prescriptions. In some cases, patients with a prescription fill do not have evidence of the indicated diagnosis.
- Validated claims-based algorithms can be used to identify patients with migraine [1-3], but use of algorithms may unnecessarily reduce sample size and limit statistical power.
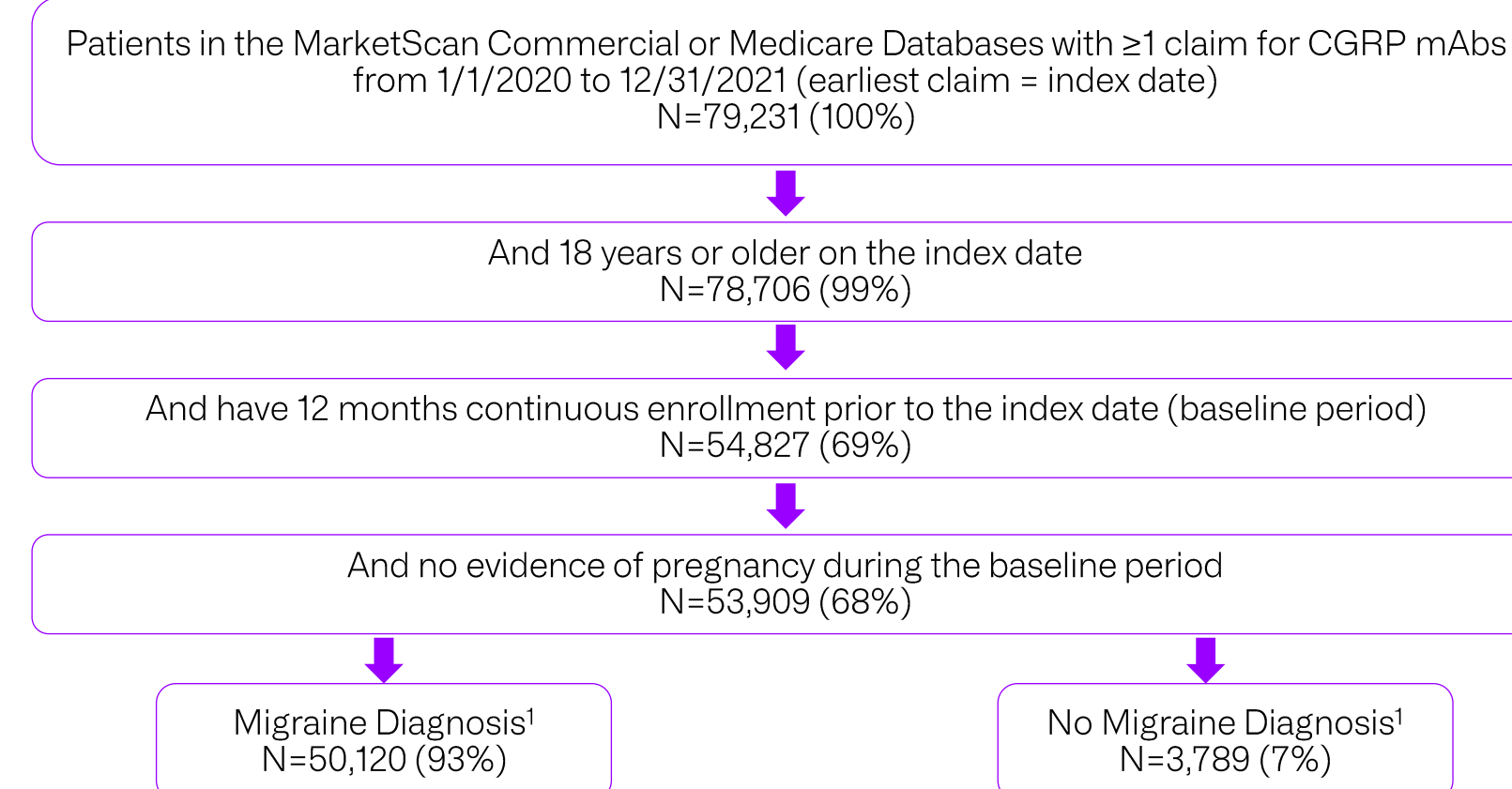- This exploratory analysis investigated the impact of relying on prescriptions to identify patient cohorts.

Objective

- To compare baseline characteristics of patients using CGRP mAbs with and without proximate migraine diagnoses.

Methods

- This retrospective cohort study of adults with a medical or pharmacy claim for CGRP mAbs used data from the Merative™ MarketScan® Commercial and Medicare Databases spanning 1/1/2020 to 12/31/2021. (Figure 1)
- Date of first medical or pharmacy claim for CGRP mAbs was the index date.
- Two cohorts of patients with and without an ICD-10 diagnosis code for migraine (G43) in the 12 months prior to the index date (baseline period) were identified.
- Demographic and clinical characteristics – measured on the index date and during the baseline period, respectively – were compared between patients with and without a migraine diagnosis.
- Use of migraine preventive medications and migraine-specific acute medications, presence of other headache diagnoses, and all-cause healthcare resource use (HCRU) in the baseline period were also compared.
- Standardized mean difference (SMD) was calculated to compare the characteristics of the two cohorts; SMD*100 ≥10 were considered significant.

Figure 1. Patient Selection

Patients in the MarketScan Commercial or Medicare Databases with ≥1 claim for CGRP mAbs from 1/1/2020 to 12/31/2021 (earliest claim = index date) N=79,231 (100%)

And 18 years or older on the index date N=78,706 (99%)

And have 12 months continuous enrollment prior to the index date (baseline period) N=54,827 (69%)

And no evidence of pregnancy during the baseline period N=53,909 (68%)

Migraine Diagnosis[1] N=50,120 (93%)

No Migraine Diagnosis[1] N=3,789 (7%)

[1] Migraine diagnosis was captured during the baseline period.
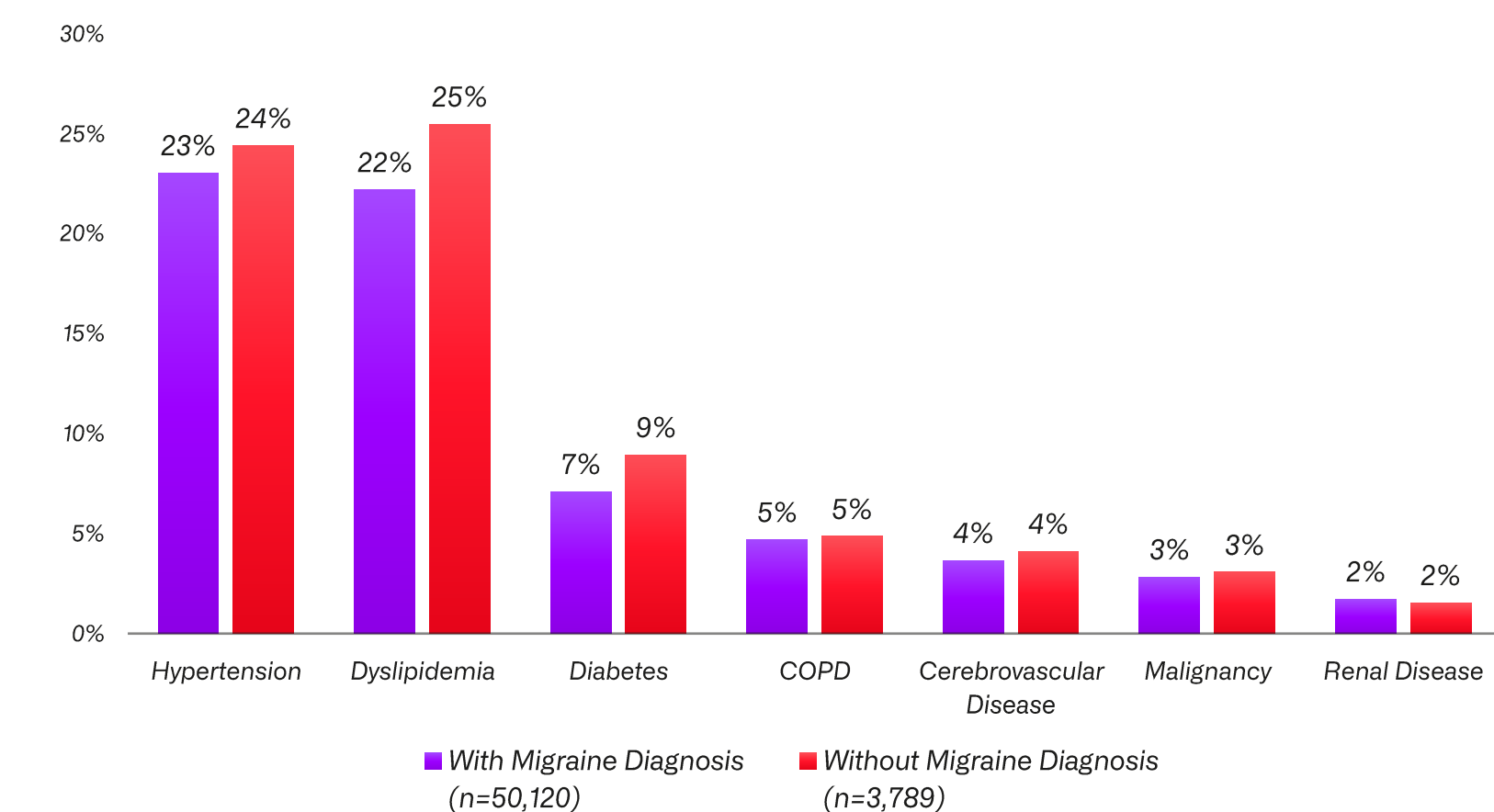
Results

- Most patients (93%) had a diagnosis of migraine during the baseline period.
- Patients with a migraine diagnosis were more likely to have prior claims for CGRP mAbs (40% vs. 33%, SMD=16.3). Use of other migraine preventive medications during baseline was more common in patients without a migraine diagnosis (80% vs. 100%, SMD=70.2) while use of migraine-specific acute medications was more common in patients with a migraine diagnosis (61% vs. 50%, SMD=22.2). (Study Summary)
- Except for sex, demographic characteristics of CGRP mAbs patients with and without a migraine diagnosis were similar (SMD <10). Patients with a migraine diagnosis were more likely to be female. (Table 1)
- DCI score and prevalence of baseline comorbid conditions were similar (SMD <10 for all) in patients with and without migraine diagnosis. (Figure 2)
- Patients with a migraine diagnosis were more likely to have ER and outpatient office visit utilization than patients without a migraine diagnosis, and were more likely to have neurologist visit during baseline (48% vs. 28%, SMD=40.9). (Figure 3)
- Cluster headaches were more commonly diagnosed during the baseline period in patients without a migraine diagnosis (SMD=41.3). Prevalence of tension and other headaches were similar (SMD <10) in patients with and without a migraine diagnosis. (Figure 4)

Limitations

- This study was based on patients with commercial health coverage, and results may not be generalizable to CGRP mAbs patients with other types of insurance or without health insurance coverage.
- CGRP mAbs use based on pharmacy claims indicated that a drug was filled but does not confirm patients took treatment as directed.
- Diagnoses on claims may be mis-coded, potentially resulting in misclassification of patients with and without migraine, other headache diagnoses, and baseline comorbidities.

Table 1. Characteristics of CGRP mAbs patients by migraine diagnosis

	With Migraine Diagnosis N=50,120		Without Migraine Diagnosis N=3,789		
	N/Mean	%/SD	N/Mean	%/SD	SMD
Age (Mean, SD)	45.0	12.1	46.0	12.5	8.14
Median	45		46		
Sex (N, %)					
Female	43,316	86.4%	2,782	73.4%	32.89
Male	6,804	13.6%	1,007	26.6%	
Insurance plan type (N, %)					
EPO/PPO	27,244	54.4%	2,049	54.1%	0.56
HMO	1,824	3.6%	115	3.0%	3.36
CDHP/HDHP	12,050	24.0%	873	23.0%	2.36
Other/Unknown	4,348	8.7%	373	9.8%	4.03
Geographic region (N, %)					
Northeast	10,433	14.4%	717	16.3%	5.36
North Central	10,433	20.8%	717	18.9%	4.76
South	26,546	53.0%	2,013	53.1%	0.34
West	5,908	11.8%	436	11.5%	0.87
Unknown	28	0.1%	5	0.1%	2.49
Residence (N, %)					
Urban	43,674	87.1%	3,308	87.3%	0.51
Rural	6,446	12.9%	481	12.7%	
DCI Score (Mean, SD)	0.5	1.0	0.5	1.2	2.67
Median	0		0		

CDHP/HDHP, consumer-directed health plan/high-deductible health plan; DCI, Deyo-Charlson Comorbidity Index; EPO/PPO, exclusive /preferred provider organizations; HMO, health maintenance organization; SD, standard deviation; SMD, standardized mean difference
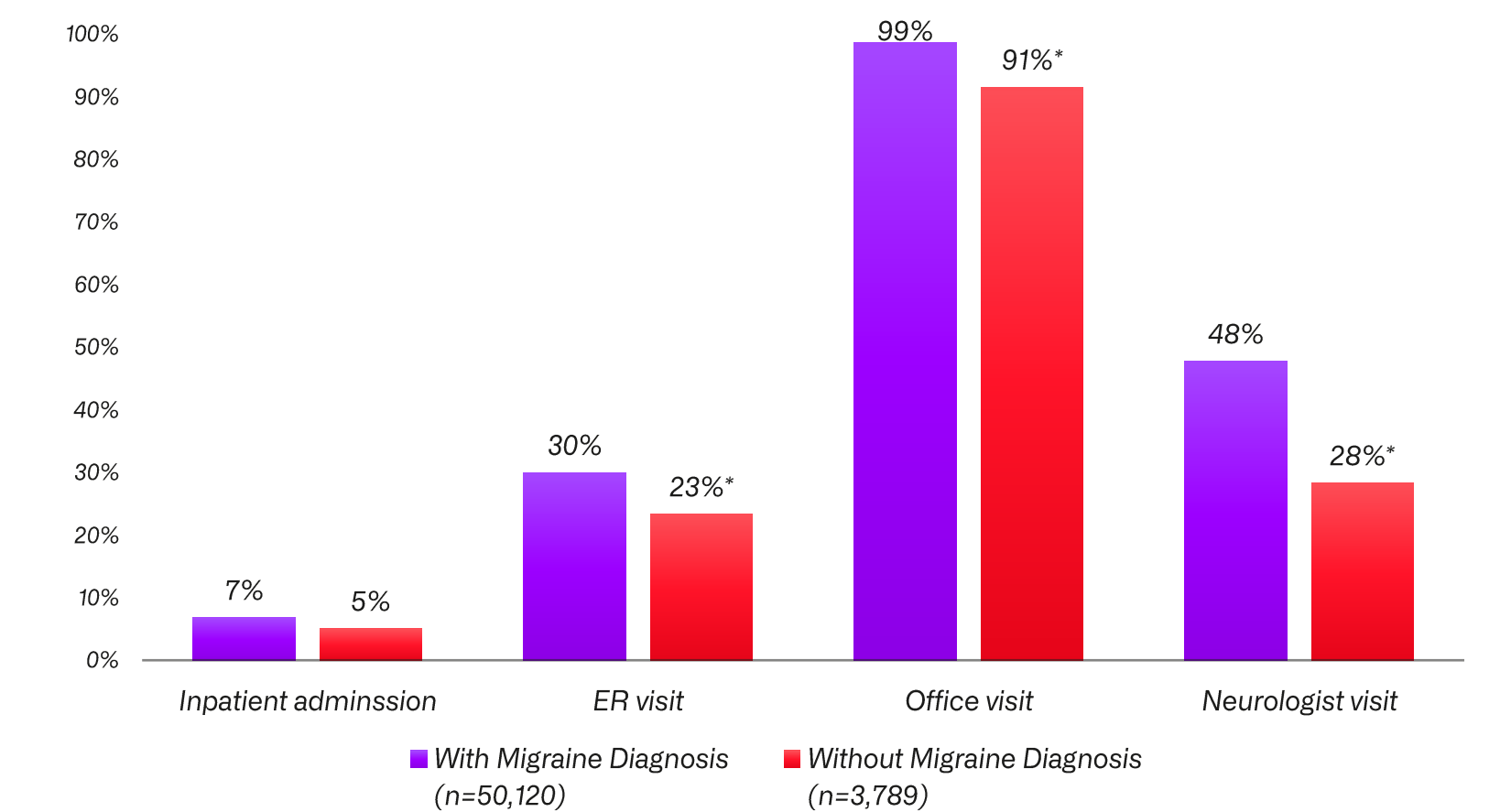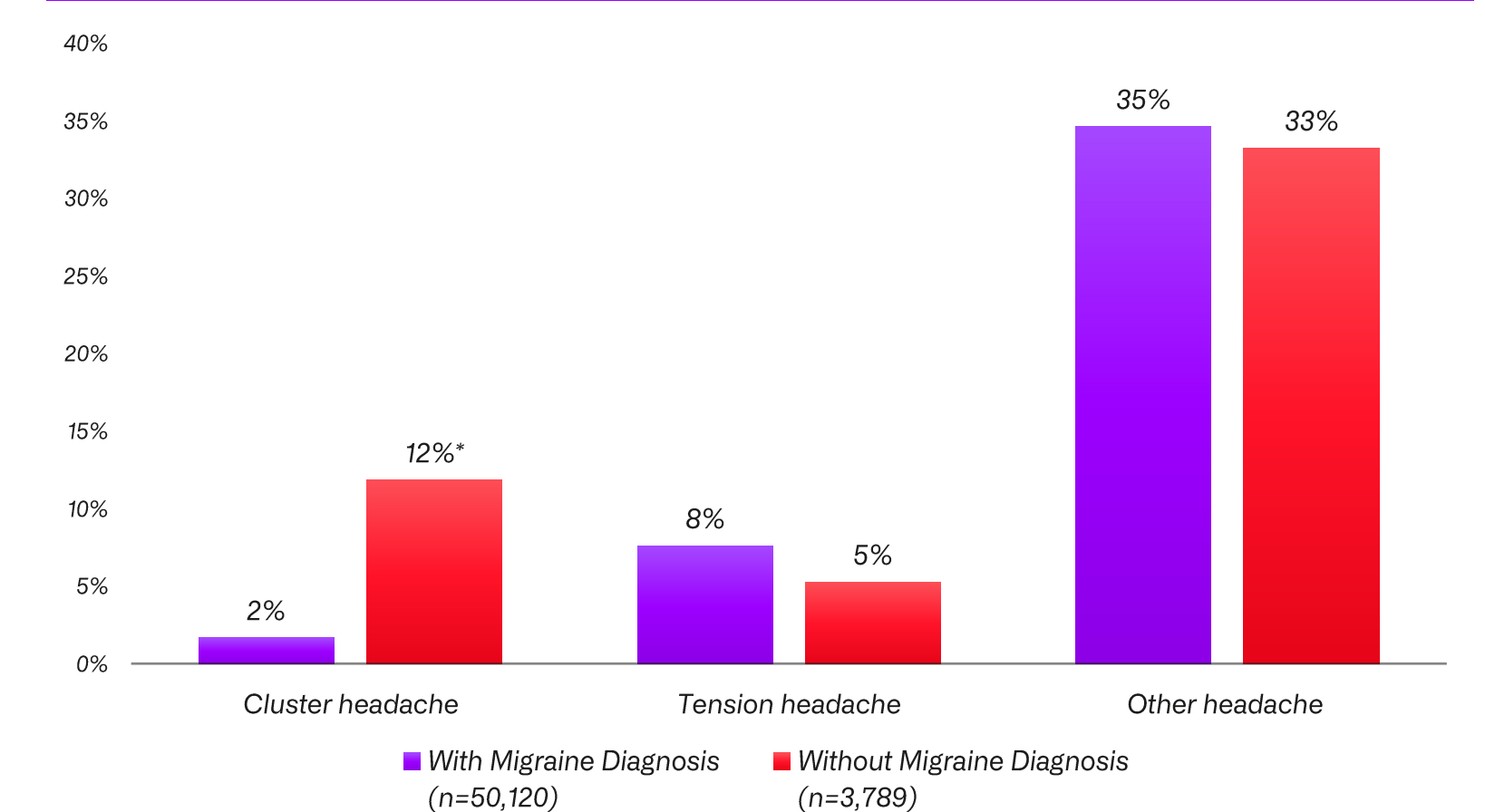
Figure 2. Comorbidities in CGRP mAbs patients by migraine diagnosis

Hypertension: 23% / 24%
Dyslipidemia: 22% / 25%
Diabetes: 7% / 9%
COPD: 5% / 5%
Cerebrovascular Disease: 4% / 4%
Malignancy: 3% / 3%
Renal Disease: 2% / 2%

With Migraine Diagnosis (n=50,120)
Without Migraine Diagnosis (n=3,789)

Figure 3. All-cause HCRU in CGRP mAbs patients by migraine diagnosis

Inpatient admission: 7% / 5%
ER visit: 30% / 23%*
Office visit: 99% / 91%*
Neurologist visit: 48% / 28%*

With Migraine Diagnosis (n=50,120)
Without Migraine Diagnosis (n=3,789)

* SMD*100 >10 when comparing patients with and without migraine diagnosis

Figure 4. Prevalence of other headache diagnoses by migraine diagnosis

Cluster headache: 2% / 12%*
Tension headache: 8% / 5%
Other headache: 35% / 33%

With Migraine Diagnosis (n=50,120)
Without Migraine Diagnosis (n=3,789)

* SMD*100 >10 when comparing patients with and without migraine diagnosis

Conclusions

- The baseline demographic and clinical profile of patients treated with CGRP mAbs is generally similar in patients with and without a migraine diagnosis.
- Patients with a baseline migraine diagnosis were more likely to be prevalent users of CGRP mAbs and less likely to be males; inclusion criteria requiring baseline migraine diagnosis may therefore introduce a selection bias toward prevalent users and female patients.
- Treatment with CGRP mAbs may be considered when developing claims-based algorithms to identify patients with migraine, particularly when statistical power is a concern.

References
[1] Pharmacoepidemiol Drug Saf. 2018; 27(12): 1309-1315.
[2] Cephalalgia. 2019; 39(4): 465-476.
[3] J Clin Epidemiol. 2004 Sep; 57(9): 962-72.

MERATIVE