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Adherence and Persistence to Preventive Migraine Treatments over 12 Months Follow-Up for Patients with Migraine: Calcitonin Gene-Related Peptide Monoclonal Antibodies versus Other Preventive Treatments

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BACKGROUND AND OBJECTIVE

Background

- Patients receiving current preventive therapies for migraine often fail to achieve optimal efficacy or become intolerant to the medicine. Consequently, most of the patients receiving migraine preventive medication (oral non-calcitonin gene-related peptide [non-CGRP] mAbs) discontinue its use within 12 months of treatment[1-4]
- The FDA has recently approved CGRP monoclonal antibodies (CGRP mAbs) that target the CGRP pathways associated with migraine attacks
- Because of recent availability, there is limited evidence on effectiveness of CGRP inhibitors compared with other preventive migraine treatments

Objective

- This study compared treatment adherence, persistence, discontinuation, and re-initiation among adult patients with migraine initiating CGRP mAbs versus non-CGRP mAbs as well as among adult patients with migraine initiating galcanezumab (GMB) versus non-CGRP mAbs

KEY RESULTS (POST-MATCHING)

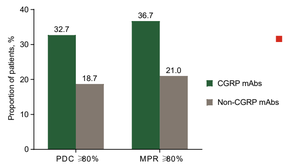
Treatment Adherence, Persistence, Discontinuation, and Restart (CGRP mAbs vs. non-CGRP mAbs)

Characteristics	CGRP mAb patients (N=3,082)	Non-CGRP mAb patients (N=3,082)
PDC for index treatment, mean (SD)	0.55 (0.31)*	0.35 (0.34)
MPR for index treatment, mean (SD)	0.58 (0.33)*	0.37 (0.36)
Days of persistent use (60-day gap), mean (SD)	212.5 (139.7)*	131.9 (140.2)
Patients that discontinue index drug (60-day gap), %	58.8*	77.6
Patients that restart index drug after discontinuation (60-day gap), %	27.3*	35.0

*Comparisons are statistically significant (p<0.001).
CGRP=Calcitonin gene-related peptide; MPR=Medication possession ratio, PDC=Proportion of days covered; SD=Standard deviation.

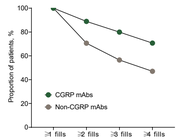
- Treatment adherence, (PDC and MPR) was significantly higher among patients receiving CGRP mAb than non-CGRP mAb
- Days of persistent use were significantly greater among CGRP mAb group than non-CGRP mAb group
- Proportion of patients who discontinued and restarted index drug was significantly lower among patients receiving CGRP mAb than non-CGRP mAb

Proportion of Adherent Patients (CGRP mAbs vs. non-CGRP mAbs)*



- A significantly higher proportion of patients receiving CGRP mAb were adherent than patients receiving non-CGRP mAb

Proportion of Patients with Index Drug Fill (CGRP mAbs vs. non-CGRP mAbs)*



- Number of prescription fills were significantly higher among patients receiving CGRP mAbs than patients receiving non-CGRP mAbs

*All comparisons were statistically significant (p<0.001).
Abbreviations: CGRP mAbs=Calcitonin gene-related peptide monoclonal antibodies; MPR=Medication possession ratio; PDC=Proportion of days covered.

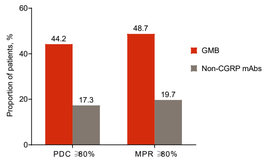
Treatment Adherence, Persistence, Discontinuation, and Restart (GMB vs. non-CGRP mAbs)

Characteristics	GMB patients (N=421)	Non-CGRP mAb patients (N=421)
PDC for index treatment, mean (SD)	0.64 (0.31)*	0.34 (0.34)
MPR for index treatment, mean (SD)	0.66 (0.32)*	0.36 (0.36)
Days of persistent use (60-day gap), mean (SD)	252.3 (140.6)*	127.3 (139.4)
Patients that discontinue index drug (60-day gap), %	43.2*	79.3
Patients that restart index drug after discontinuation (60-day gap), %	31.9	37.1

*Comparisons are statistically significant (p<0.001).
Non-CGRP mAbs=Non-calcitonin gene-related peptide monoclonal antibodies; GMB=Galacanezumab; MPR=Medication possession ratio, PDC=Proportion of days covered; SD=Standard deviation.

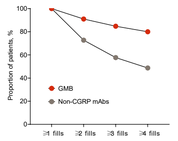
- Treatment adherence (PDC and MPR) was significantly higher among patients receiving GMB than non-CGRP mAb
- Days of persistent use were significantly greater among GMB group than non-CGRP mAb group
- Proportion of patients who discontinued and restarted index drug was significantly lower among patients receiving GMB than non-CGRP mAb

Proportion of Adherent Patients (GMB vs. non-CGRP mAbs)*



- A significantly higher proportion of patients receiving GMB were adherent than patients receiving non-CGRP mAb

Proportion of Patients with Index Drug Fill (GMB vs. non-CGRP mAbs)*



- Number of prescription fills were significantly higher among patients receiving GMB than patients receiving non-CGRP mAbs

*All comparisons were statistically significant (p<0.001).
Abbreviations: CGRP mAbs=calcitonin gene-related peptide monoclonal antibodies; GMB=galcanezumab; MPR=medication possession ratio; PDC=proportion of days covered.

CONCLUSIONS

- Patients on CGRP mAbs were significantly more adherent and had a significantly higher rate of treatment persistence and restart, and lower rate of treatment discontinuation than patients on non-CGRP mAbs
- Similarly, patients on GMB were significantly more adherent and had a significantly higher rate of treatment persistence and significantly lower rate of treatment discontinuation than patients on non-CGRP mAbs
- Number of prescription fills were significantly higher among patients receiving CGRP mAbs or GMB than non-CGRP mAbs

Methods

Study Design

- This was a retrospective observational cohort study conducted using administrative claims from the IBM® MarketScan® Commercial and Medicare Supplemental Databases

Participants

- Adults with ≥1 claim for a CGRP mAb (GMB, erenumab, fremanezumab) or non-CGRP mAb treatment (antidepressants, beta-blockers, anticonvulsants, or neurotoxin) between May 1, 2018, and June 30, 2019, were included
- The date of the earliest claim for CGRP mAb or non-CGRP mAb was the index date
- Patients were required to have continuous enrollment in medical and pharmacy benefits for ≥12 months pre- and post-index period
- Additionally, patients had ≥1 inpatient or ≥2 outpatient claims with a migraine diagnosis (ICD-10-CM codes in G43.xx range) during the 12-month pre-index period
- Patients with evidence of their index drug class during the 12-month pre-index period or with evidence of pregnancy, epilepsy, cancer, cluster headache, or treatment for cluster headache during the study period were excluded

Outcomes

- Treatment adherence was assessed as proportion of days covered (PDC) and medication possession ratio (MPR) over a 12-month post-index period
- Treatment persistence was assessed as number of days of continuous therapy from index until the end of the 12-month post-index period, allowing for a maximum gap between fills of 60 days
- Treatment discontinuation was assessed as failure to refill the index medication within 60 days after the depletion of the days' supply from previous fills
- Treatment restart was defined as patients who had fills for their index medication after the discontinuation date and no later than the end of the study period

Statistical analyses

- Descriptive analyses were conducted on all study measures. Chi-square test was used for categorical variables and Student's t-test for continuous variables
- CGRP mAb patients were matched to non-CGRP mAb patients (1:1), and GMB patients were matched to non-CGRP mAb patients (1:1) using propensity score matching
- Propensity scores were estimated using multivariable logistic regression on baseline characteristics

Results

Demographic and Clinical Characteristics (CGRP mAbs vs. non-CGRP mAbs)

Characteristics	CGRP mAb patients (N=4,528)	Non-CGRP mAb patients (N=10,897)	Std Diff	CGRP mAb patients (N=3,082)	Non-CGRP mAb patients (N=3,082)	Std Diff
	Pre-Matching			Post-Matching		
Age, years, mean (SD)	45.1 (11.3)	41.3 (12.3)	0.32	44.4 (11.3)	44.2 (12.0)	0.02
Women, %	86.2	85.1	0.03	85.7	86.8	0.03
DCI, mean (SD)	0.4 (0.9)	0.4 (0.9)	0.03	0.5 (0.9)	0.4 (0.9)	0.01
Chronic Migraine, %	69.0	21.6	1.10	56.7	54.8	0.04
Provider Type, %						
Neurology	31.2	25.9	0.12	30.6	32.2	0.03
Primary Care	22.6	42.0	0.43	26.0	25.0	0.02
Acute Care Hospital, ER	6.8	5.0	0.08	6.0	6.1	0.00
Radiology, Laboratory, Pathology	4.4	2.6	0.10	4.3	2.9	0.07
Other/Unknown	34.9	24.4	0.23	33.1	33.7	0.01

CGRP=Calcitonin gene-related peptide; DCI=Deyo-Charlson Comorbidity Index; ER=Emergency room; mAb=Monoclonal antibody; SD=Standard deviation; Std diff=Standard difference.

- CGRP and non-CGRP cohorts were well-balanced after matching
- Post-matching, around 50% of patients in both treatment groups had chronic migraine
- Majority of provider type in both groups was neurology and primary care

Demographic and Clinical Characteristics (GMB vs. non-CGRP mAbs)

Characteristics	GMB patients (N=426)	Non-CGRP mAb patients (N=10,897)	Std Diff	GMB (N=421)	Non-CGRP mAb patients (N=421)	Std Diff
	Pre-Matching			Post-Matching		
Age, years, mean (SD)	43.8 (11.4)	41.3 (12.3)	0.21	43.7 (11.4)	43.2 (11.8)	0.05
Women, %	86.4	85.1	0.04	86.2	88.6	0.07
DCCI, mean (SD)	0.5 (1.1)	0.4 (0.9)	0.11	0.5 (1.1)	0.6 (1.1)	0.04
Chronic Migraine, %	58.5	21.6	0.81	58.2	59.6	0.03
Provider Type, %						
Neurology	29.8	25.9	0.09	29.9	33.3	0.07
Primary Care	26.1	42.0	0.34	26.4	26.4	0.00
Acute Care Hospital, ER	9.4	5.0	0.17	9.0	7.8	0.04
Radiology, Laboratory, Pathology	4.5	2.6	0.10	4.3	2.1	0.12
Other/Unknown	30.3	24.4	0.13	30.4	30.4	0.00

CGRP mAb=Calcitonin gene-related peptide monoclonal antibody; DCCI=Deyo-Charlson Comorbidity Index; ER=Emergency room; GMB=Galcanezumab; SD=Standard deviation; Std Diff=Standard difference.

- GMB and non-CGRP cohorts were well-balanced after matching
- Around 60% of patients in both treatment groups had chronic migraine
- Majority of provider type in both groups were neurology and primary care

Limitations

- Administrative claims data were subject to data coding limitations and data entry error
- Assessment of treatment patterns was based on prescription fill data; confirmation of actual consumption of medicines by patients was not possible
- Reasons for discontinuing treatment and restarts are unknown
- Results of this study may not be generalizable to patients who have a different type of insurance or lack insurance coverage

References: 1. Diamond S, et al. Headache 2007;47:355-63. 2. Loder E and Rizzoli P. Headache 2011;51:1336-45. 3. Berger A, et al. Pain Pract 2012;12:541-9. 4. Woolley M, et al. Headache 2017;57:1399-1408.

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