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Migraine-Free Days Following Acute Rimegepant Treatment in the Real-World: Findings From CONFIDENCE

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INTRODUCTION

- The interictal period describes the time between migraine attacks. Though this period can be associated with some milder neurologic symptoms and anxiety about the next attack, patients with migraine who experience longer interictal periods have a lower disease burden than those with shorter interictal periods.[1-3]
- Rimegepant is approved for the acute treatment of migraine and prevention of episodic migraine in several countries.[4,5] It is taken "as needed" to acutely manage attacks that have already started, or every other day as a preventive treatment.[4,5]
- Trials evaluating preventive therapies typically focus on measuring the monthly migraine count, rather than the time between attacks.[1,6,7]
- Evidence from clinical studies suggests that long-term use of rimegepant for the acute treatment of migraine may reduce the number of monthly migraine days over time.[8-10] This could also mean a longer period of migraine freedom between attacks.
- CONFIDENCE was a prospective observational study evaluating the effectiveness of acute rimegepant treatment over multiple migraine attacks. Preventive treatment was permitted. During the 28-day observation period, participants reported on all migraine attacks, irrespective of the acute treatment used.
- This analysis evaluated the odds of migraine freedom (ie, no attacks) during the consecutive days following treatment with rimegepant vs alternative acute migraine medication(s) in CONFIDENCE.

METHODS

STUDY DESIGN

- CONFIDENCE (NCT06467370) was a prospective, observational, survey study in people who used rimegepant for the acute treatment of migraine in the United States.
- The study comprised screening and baseline questionnaires, a 28-day diary-based observation period, and an end of study questionnaire.

PARTICIPANTS

- Participants were recruited via the Migraine Buddy® app. The study was completed in a bespoke study module that was only accessible to participants.
- To enroll in CONFIDENCE, participants were required to meet the following criteria:
  - Age ≥18 years.
  - 3 to 14 headache days in the 30 days preceding enrollment.
  - Rimegepant prescription for the acute treatment of migraine and plan to use rimegepant to treat a migraine attack during the next 30 days.
  - Not using rimegepant as preventive treatment (most others were permitted).
  - No diagnoses of cluster headache, post-traumatic headache, new daily persistent headache, hemicrania continua, or chronic daily headache.

ANALYSES

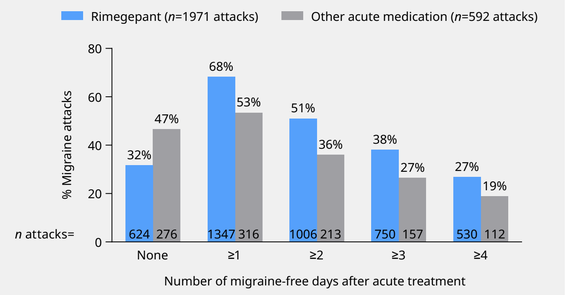
- Participants reported on the occurrence, characteristics, treatment, and outcomes of migraine attacks on each day of the 28-day observation period.
- This analysis included all treated attacks that occurred >3 days before the end of the study and had complete daily diary data up until the next attack.
- Each participant could contribute >1 qualifying attack to the analysis.
- Attacks where rimegepant was the only acute medication used or where rimegepant was taken alongside ≥1 other acute medication (not necessarily at the same point in time) were considered rimegepant-treated.
- Attacks treated with ≥1 acute treatment not including rimegepant were considered other acute medication-treated.
- Other acute medications included those reported by the participant as an "OTC medication (aspirin, acetaminophen, Excedrin, Advil…)", "triptan (Imitrex, Maxalt, Zomig…)", "prescription medication (pain killer, ergot, DHE, opioid, barbiturate…)", or "other" medication used to treat the attack. The brand/generic name of the medication was not captured.
- Odds of having ≥1, ≥2, ≥3, or ≥4 consecutive migraine-free days following an acutely treated attack were assessed using generalized linear mixed models with binomial distribution, a logit link, and a random intercept for participant.
  - The first model evaluated the odds of consecutive migraine-free days following treatment with rimegepant vs other acute medication.
  - The second model included covariates for activity impairment at the time of treatment (4-level scale as reported by the participant: no disability to severely impaired), headache pain level at the time of treatment (7-level scale as reported by the participant: no pain to extremely severe pain), and number of days with a migraine attack during the study (count).

RESULTS

CONSECUTIVE MIGRAINE-FREE DAYS

- 429 participants recorded 2563 eligible migraine attacks during the 28-day observation period (minimum: 1; maximum: 24 migraine attacks).
- Independent of the acute treatment used, 65% of all 2563 migraine attacks were followed by ≥1 (*n*=1663), 48% by ≥2 (*n*=1219), 35% by ≥3 (*n*=907), and 25% by ≥4 (*n*=642) migraine-free days.
- 1971 attacks were treated with rimegepant; 436 (22%) were also treated with an over-the-counter medication, 116 (6%) with a triptan, 98 (5%) with another prescription medication, and 66 (3%) with an unknown or other medication.
  - 68% (*n*=1347) of rimegepant-treated attacks were followed by ≥1, 51% (*n*=1006) by ≥2, 38% (*n*=750) by ≥3, and 27% (*n*=530) by ≥4 migraine-free days (**Figure 1**).
- 592 attacks were treated with other acute medications (without rimegepant):
  - 320 (54%) were treated with an over-the-counter medication, 129 (22%) with a triptan, 91 (15%) with a prescription medication other than rimegepant or triptan, and 52 (9%) with an unknown or other medication.
  - 53% (*n*=316) were followed by ≥1, 36% (*n*=213) by ≥2, 27% (*n*=157) by ≥3, and 19% (*n*=112) by ≥4 migraine-free days (**Figure 1**).
- Rimegepant attacks were treated at a slightly higher level of activity impairment and pain intensity than those treated with other acute medication (**Table 1**).

Figure 1: Proportion of attacks with consecutive migraine-free days following treatment with rimegepant or other acute medication



Number in each bar shows the number of migraine attacks achieving the described number of migraine-free days.

Table 1: Attack characteristics and treatment

	Rimegepant *n*=1971	Other acute medication *n*=592
Acute treatment, n (%)		
Rimegepant taken alone	1255 (63.7)	0 (0)
Rimegepant as first acute treatment before another acute medication	474 (24.0)	0 (0)
Before an OTC medication	261 (13.2)	0 (0)
Before a triptan	86 (4.4)	0 (0)
Before a prescription medication other than triptan/ rimegepant	77 (3.9)	0 (0)
Before an other or unknown medication	50 (2.5)	0 (0)
Rimegepant taken after another acute medication	242 (12.3)	0 (0)
After an OTC medication	175 (8.9)	0 (0)
After a triptan	30 (1.5)	0 (0)
After a prescription medication other than triptan/ rimegepant	21 (1.1)	0 (0)
After an other or unknown medication	16 (0.8)	0 (0)
OTC medication	0 (0)	320 (54.1)
Triptan	0 (0)	129 (21.8)
Prescription medication other than triptan/rimegepant	0 (0)	91 (15.4)
Other or unknown medication	0 (0)	52 (8.8)
Pain intensity at the time of treatment, n (%)		
Not present	52 (2.6)	17 (2.9)
Very mild	120 (6.1)	51 (8.6)
Mild	479 (24.3)	167 (28.2)
Moderate	769 (39.0)	216 (36.5)
Moderately severe	373 (18.9)	96 (16.2)
Severe	147 (7.5)	33 (5.6)
Extremely severe	31 (1.6)	12 (2.0)
Activity impairment at the time of treatment, n (%)		
No disability	256 (13.0)	108 (18.2)
Mildly impaired (can still do everything but with difficulty)	903 (45.8)	249 (42.1)
Moderately impaired (unable to do some things)	592 (30.0)	174 (29.4)
Severely impaired (unable to do all or most things, bed rest may be necessary)	220 (11.2)	61 (10.3)
Preventive medication background, n (%)		
None	321 (16.3)	69 (11.7)
OPM only	313 (15.9)	136 (23.0)
OnabotulinumtoxinA (with or without OPM)	692 (35.1)	212 (35.8)
CGRP monoclonal antibodies (with or without OPM)	645 (32.7)	175 (29.6)

Note: Specific form of other acute medication was not captured, ie, brand or generic name.
CGRP=calcitonin gene-related peptide; OPM=oral preventive medication; OTC=over-the-counter

ODDS OF CONSECUTIVE MIGRAINE-FREE DAYS FOLLOWING ACUTE TREATMENT

- In models that evaluated the effect of acute treatment only, rimegepant was associated with a significantly higher chance of migraine-freedom of all durations vs other acute medication (**Table 2**).
- In models that controlled for activity impairment at the time of treatment, pain level at the time of treatment, and number of days with migraine attacks during the study, rimegepant was independently associated with a significantly higher chance of ≥1 (54%), ≥2 (48%), and ≥3 (30%) consecutive migraine-free days following the attack vs other acute medication (**Table 2**, **Figure 2**).
  - A higher number of days with a migraine attack during the study was associated with lower odds of migraine freedom of any duration (18% to 26% lower odds for every additional day with a migraine attack reported in the study).

CONCLUSIONS

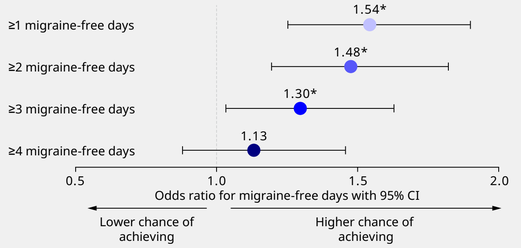
- In the real world, rimegepant was associated with higher odds of migraine freedom in the 3 days following an attack vs other acute migraine medication.
- These findings suggest a potential longer-term benefit with rimegepant vs other acute medications for the treatment of migraine.

Table 2: Odds of consecutive migraine-free days following an acutely treated migraine attack

	Odds ratio (95% CI) of consecutive migraine-free days			
	≥1 day	≥2 days	≥3 days	≥4 days
Model 1 – Only including acute treatment as the independent variable				
Rimegepant (vs other acute medication)	1.77 (1.43, 2.19) *P*<0.001	1.71 (1.39, 2.11) *P*<0.001	1.58 (1.26, 1.99) *P*<0.001	1.44 (1.11, 1.87) *P*=0.005
Model 2 – Addition of covariates				
Rimegepant (vs other acute medication)	1.54 (1.25, 1.90) *P*<0.001	1.48 (1.20, 1.82) *P*<0.001	1.30 (1.03, 1.63) *P*<0.001	1.13 (0.88, 1.46) *P*=0.335
Higher activity impairment at treatment (4-level categorical)	0.99 (0.87, 1.13) *P*=0.888	0.99 (0.87, 1.12) *P*=0.850	1.03 (0.91, 1.17) *P*=0.850	1.05 (0.91, 1.20) *P*=0.541
Higher pain level at treatment (7-level categorical)	1.02 (0.93, 1.13) *P*=0.632	1.06 (0.97, 1.16) *P*=0.184	1.02 (0.93, 1.13) *P*=0.184	0.97 (0.87, 1.07) *P*=0.504
No. of migraine days during the study (count; 1 to 24)	0.82 (0.80, 0.84) *P*<0.001	0.79 (0.77, 0.81) *P*<0.001	0.76 (0.74, 0.78) *P*<0.001	0.74 (0.71, 0.76) *P*<0.001

Assessed using generalized linear mixed models with binomial distribution, logit link, and random intercept for participant. In model 2, covariates were used to calculate adjusted odds ratios.

Figure 2: Adjusted odds of consecutive migraine-free days following an attack treated with rimegepant vs other acute medications



* *P*<0.05. Assessed using generalized linear mixed models with binomial distribution, logit link, and random intercept for participant. Covariates of activity impairment at the time of treatment, headache pain level at the time of treatment, and number of days with a migraine attack during the study were used to calculate adjusted odds ratios.

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DISCLOSURES

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