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Treatment Outcomes With Rimegepant Versus Other Standard of Care Acute Migraine Medications in the Observational CONFIDENCE Study

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INTRODUCTION

- Several acute treatment options are available to treat people with a migraine attack that has already started. These include over-the-counter (OTC) medications; triptans; gepants, including rimegepant; and other prescription drugs.[1,2]
- The prospective observational CONFIDENCE study evaluated the effectiveness of acute treatment with rimegepant over multiple migraine attacks.
  - Concomitant preventive therapy was permitted (except rimegepant), and the choice of acute treatment for each attack was freely decided by the participant.
  - Outcome data were collected for each attack over a 28-day observation period, including attacks treated with rimegepant or another acute medication.

OBJECTIVE

- This analysis used CONFIDENCE data to explore the real-world effectiveness of rimegepant vs other acute medications in attacks reported by subgroups of participants with different preventive therapy backgrounds.

METHODS

STUDY DESIGN

- CONFIDENCE (NCT06467370) was a prospective, observational, survey study in people who currently used rimegepant for the acute treatment of migraine in the United States.
- Participants were recruited via the Migraine Buddy® app and completed all study activities in a bespoke module. This module was only accessible to participants.
- Screening questionnaires collected data relevant to enrollment criteria, including use of preventive therapies.
- Quota sampling was used to enroll up to 468 participants, including 75 with no current preventive therapy, 71 with current oral preventive medication (OPM) use (including non–migraine-specific medications and gepants other than rimegepant), 156 with current calcitonin gene-related peptide monoclonal antibody (CGRP mAb) preventive use (with or without an OPM), and 156 with current onabotulinumtoxinA preventive use (with or without an OPM).
- Following a baseline questionnaire to collect further demographic and clinical characteristics, enrolled participants were invited to complete a 28-day observation period in which migraine characteristics and treatments were recorded in a daily questionnaire every evening.
- There were no restrictions on the use of acute medications during the observation period. Participants treated each attack as they wished.
- After completion of the observation period, participants were invited to complete an end of study questionnaire.

PARTICIPANTS

- Key inclusion and exclusion criteria included:
  - Aged ≥18 years.
  - 3 to 14 headache days in the last 30 days.
  - ≥3 migraine attacks in the last 30 days.
  - Rimegepant prescription for the acute treatment of migraine and plan to use rimegepant in this context during the next 30 days.
  - Not using rimegepant as a preventive therapy. Stable use of other preventive therapies was permitted (including atogepant), per enrollment quota, except for the concurrent use of onabotulinumtoxinA with a CGRP mAb.
  - No diagnoses of cluster headache, post-traumatic headache, new daily persistent headache, hemicrania continua, or chronic daily headache.

OUTCOMES AND ANALYSES

- This analysis included all attacks reported by participants who treated ≥1 attack with rimegepant during the 28-day observation period.
- Attacks were considered to be rimegepant-treated when rimegepant was the only acute medication used or when rimegepant was taken alongside ≥1 other acute medication (not necessarily at the same point in time).
- 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 their attack. The brand/generic name of the medication was not captured.
- All attacks treated with ≥1 OTC, triptan, or prescription medication other than rimegepant were considered to be other acute medication-treated.
- During the daily questionnaire, multiple choice questions asked about the time interval between acute migraine treatment and the achievement of meaningful pain relief (MPR) and meaningful functional improvement (MFI), each as determined by the participant.
- Outcome questions were completed in relation to rimegepant for rimegepant-treated attacks and to the most recently taken medication in other acute medication-treated attacks.
- Analyses assessed the proportion of attacks achieving the following outcomes:
  - MPR within 2 h or within 4 h of acute migraine treatment.
  - MFI within 2 h or within 4 h of acute migraine treatment.
- Differences in the proportion of attacks achieving each outcome with rimegepant vs other acute medications across distinct preventive therapy backgrounds were compared using Pearson's chi-square tests.
- The analysis did not control for participant or attack characteristics.

RESULTS

ATTACK CHARACTERISTICS

- During the study, 416 participants reported 2169 migraine attacks treated with rimegepant; 203 of these 416 participants reported a combined total of 559 attacks treated with other acute medication.
- Of the 2169 attacks treated with rimegepant, 83% (*n*=1809) were reported by participants who took preventive medication (**Table 1**).
  - Of the 559 attacks treated with other acute medication, 90% (*n*=504) were reported by participants who took preventive medication.
- In 88% of the 2169 rimegepant-treated attacks, rimegepant was either taken as the only acute treatment (63%; *n*=1375), or as the first acute treatment (24%; *n*=529; **Table 2**).
- In 12% of the 2169 rimegepant-treated attacks (*n*=265), another acute medication had previously been taken.
  - The relative timing of each medication administration was not fully captured.

Table 1: Background preventive therapy at the attack level

	Acute treatment	
***n* (%)**	**Rimegepant *n*=2169**	**Other acute medication *n*=559**
None	360 (16.6)	55 (9.8)
OPM only	340 (15.7)	131 (23.4)
OnabotulinumtoxinA (with or without OPM)	765 (35.3)	202 (36.1)
CGRP mAb (with or without OPM)	704 (32.5)	171 (30.6)

CGRP mAb=calcitonin gene-related peptide monoclonal antibody; OPM=oral preventive medication

Table 2: Attack and acute treatment characteristics

	Acute treatment	
	Rimegepant *n*=2169	**Other acute medication *n*=559**
Treatment combination, *n* (%)		
Rimegepant taken alone	1375 (63.4)	NA
Rimegepant as first acute treatment before another acute medication	529 (24.4)	NA
Before an OTC medication	290 (13.4)	NA
Before a triptan	97 (4.5)	NA
Before another prescription medication	87 (4.0)	NA
Before an 'other' or 'unknown' medication	55 (2.5)	NA
Rimegepant taken after another acute medication	265 (12.2)	NA
After an OTC medication	187 (8.6)	NA
After a triptan	35 (1.6)	NA
After another prescription medication	23 (1.1)	NA
After an 'other' or 'unknown' medication	20 (0.9)	NA
OTC medication	NA	331 (59.2)
Triptan	NA	132 (23.6)
Prescription medication other than rimegepant	NA	96 (17.2)
Headache pain at the time of treatment, *n* (%)		
Not present	59 (2.7)	9 (1.6)
Very mild	133 (6.1)	53 (9.5)
Mild	520 (24.0)	168 (30.1)
Moderate	848 (39.1)	200 (35.8)
Moderately severe	413 (19.0)	87 (15.6)
Severe	161 (7.4)	30 (5.4)
Extremely severe	35 (1.6)	12 (2.1)
Performance of daily activities at the time of treatment, *n* (%)		
No disability	284 (13.1)	97 (17.4)
Mildly impaired (can still do everything but with difficulty)	991 (45.7)	243 (43.5)
Moderately impaired (unable to do some things)	653 (30.1)	161 (28.8)
Severely impaired (unable to do all or most things, bed rest may be necessary)	241 (11.1)	58 (10.4)

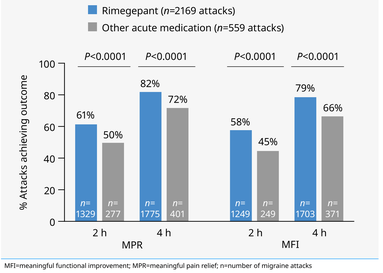
Note: Specific form of other acute medication was not captured, ie, brand or generic name.
NA=not applicable; OTC=over-the-counter

- Among the 559 attacks treated with another acute medication, the most common was an OTC medication (59%; *n*=331), followed by a triptan (24%; *n*=132), or other prescription medication (17%; *n*=96). The identity of each medication was not fully captured.
- Attacks treated with rimegepant were slightly more severe than those treated with other acute medication.
  - Attacks were treated when they caused moderately severe, severe, or extremely severe pain in 28% (*n*=609/2169) of attacks treated with rimegepant and 23% (*n*=129/559) of attacks treated with other acute medications.
  - Attacks were treated when they caused moderate or severe functional impairment in 41% (*n*=894/2169) of attacks treated with rimegepant and 39% (*n*=219/559) of attacks treated with other acute medication.

OUTCOMES

- Irrespective of background preventive therapy, higher proportions of migraine attacks treated with rimegepant achieved MPR and MFI within 2 h and within 4 h of treatment vs those treated with other acute medication (*P*<0.0001; **Figure 1**).
- Among all participants, MPR was achieved within 2 h of treatment in 61% (*n*=1329) of the 2169 attacks treated with rimegepant and 50% (*n*=277) of the 559 attacks treated with other acute medication (*P*<0.0001). Corresponding proportions within 4 h were 82% (*n*=1775) and 72% (*n*=401; *P*<0.0001).
- MFI was achieved within 2 h of treatment in 58% (*n*=1249) of the 2169 attacks treated with rimegepant and 45% (*n*=249) of the 559 attacks treated with other acute medication (*P*<0.0001). Corresponding proportions within 4 h were 79% (*n*=1703) and 66% (*n*=371; *P*<0.0001).

Figure 1: Treatment outcomes with rimegepant vs other acute medication across all preventive therapy backgrounds



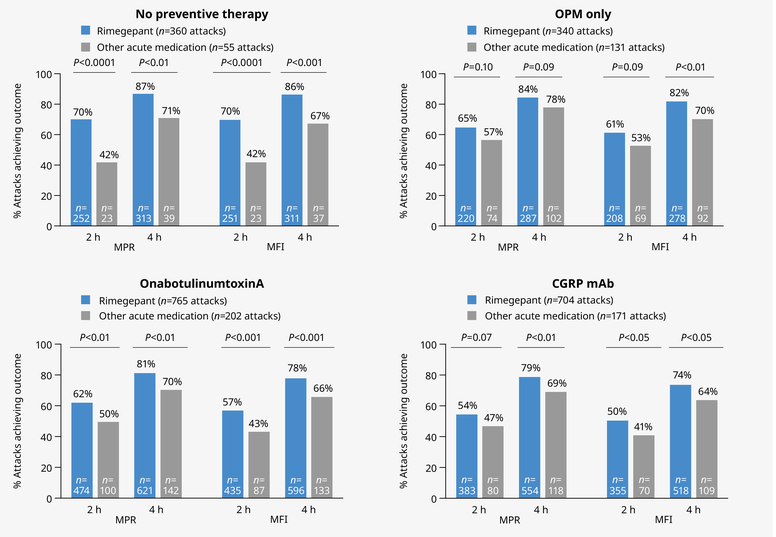
MFI=meaningful functional improvement; MPR=meaningful pain relief; n=number of migraine attacks

- Similar findings were seen in attacks reported by participants who took no preventive therapy (all comparisons *P*<0.01) or onabotulinumtoxinA preventive therapy (all comparisons *P*<0.01; **Figure 2**).
- Among users of CGRP mAbs, all outcomes except MPR within 2 h (*P*=0.07) were achieved in significantly higher proportions of attacks treated with rimegepant vs other acute medication (all *P*<0.05).
- Among users of OPM (only), MFI was achieved within 4 h of treatment in a higher proportion of attacks treated with rimegepant than other acute medication (*P*<0.01). Other comparisons favored rimegepant but were not statistically significant.

CONCLUSIONS

- In this observational study of multiple real-world migraine attacks, rimegepant was more commonly associated with favorable treatment outcomes than other acute medication. These outcomes included meaningful pain relief and meaningful functional improvement within 2 and within 4 h of treatment.
- Statistically significant treatment differences were seen for all outcome measures in subgroups of attacks reported by participants who took no preventive therapy or onabotulinumtoxinA preventive therapy, and for most outcomes measures in attacks reported by participants who took CGRP mAb preventive therapy.
- Findings show that participants chose to treat slightly more severe migraine attacks with rimegepant rather than other acute medication. This was not controlled for in our analyses and could have led to an underestimation of the relative effectiveness of rimegepant.
- Future studies might explore the role of participant and attack characteristics on the choice of acute treatment and associated outcomes in the real world.

Figure 2: Treatment outcomes with rimegepant vs other acute medication by preventive therapy background



CGRP mAb=calcitonin gene-related peptide monoclonal antibody; MFI=meaningful functional improvement; MPR=meaningful pain relief; n=number of migraine attacks; OPM=oral preventive medication

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DISCLOSURES

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