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Calcitonin Gene-Related Peptide Monoclonal Antibody Treatment in Nine Cases of Persistent Headache Following COVID-19-Infection

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ABSTRACT

Background: The coronavirus disease 2019 (COVID-19) pandemic has underscored the need for effective treatment for post-infectious complications, including headaches. Owing to the variable nature of post-COVID headaches, identifying effective therapies through clinical trials is challenging and the burden on patients is often severe. This study aimed to summarize the presentation of post-COVID headache in clinical practice and evaluate its response to treatment with calcitonin gene-related peptide (CGRP) monoclonal antibodies (mAbs).
Methods: In this retrospective cohort study, medical records obtained between March 2022 and May 2024 from two centers were analyzed. The study included nine patients with new-onset or significantly worsening or altered patterns of previous headaches lasting more than one month after COVID-19 infection who subsequently received CGRP mAbs. Demographics, headache frequency and severity, medication use, and quality of life were assessed before and after CGRP mAb treatment.
Results: All patients were female (median age, 48 years), and 88.9% had headaches for more than three months despite conventional preventive therapies. Headache Impact Test-6 (HIT-6) scores were greater than 60 in all patients, and the headaches were unilateral (66.7%) and pulsating (22.2%). After CGRP mAb treatment, the monthly headache days, headache severity scores, and monthly medication days decreased significantly (median with interquartile range: 25 [15–28] to 5 [4–10], $P = 0.012$; 8 [7–9] to 3 [2–4], $P = 0.011$; 16 [15–20] to 5 [4–10], $P = 0.017$). The HIT-6 (65 [60–68] to 48 [48–60], $P = 0.017$) and Patient Health Questionnaire-9 scores (14 [5–15] to 10 [4–12], $P = 0.028$) also decreased significantly after treatment.
Conclusion: CGRP mAbs may be considered a potential treatment option for persistent headaches following COVID-19, especially the long-COVID headaches. Their use may contribute to an improved burden of headache and quality of life and may help alleviate the psychological symptoms associated with persistent headaches.

Keywords: COVID-19; Headache; CGRP Monoclonal Antibodies; Treatment; Effectiveness; Safety

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Disclosure
The authors have no potential conflicts of interest to disclose.

Author Contributions
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INTRODUCTION

The World Health Organization declared the end of coronavirus disease 2019 (COVID-19) as a public health emergency in May 2023, but the complications of COVID-19 infection continue to be a personal burden.[1] Among the various complications of COVID-19 infection or vaccination, headaches are typically common occurring in approximately 25–31% of individuals.[2-6] Most infection-related headaches improve with time unless they involve serious complications, such as cerebral venous thrombosis, encephalitis, or increased intracranial pressure.[7] However, long-lasting COVID-19-related headaches are common in people with a history of migraine because appropriate and effective treatments for these headaches are scarce and not well-established.[8] Corticosteroids, acetaminophen, ibuprofen, and triptans have been used to relieve these headaches.[9-11] Despite these treatment options, some headaches do not improve and have been reported as among the serious long-term COVID complications.[11,12]

Calcitonin gene-related peptide (CGRP) monoclonal antibodies (mAbs) are used to treat migraines by directly targeting their pathophysiology,[13] with an advantage over conventional therapies in terms of efficacy and adverse events (AEs). CGRP is involved in neuroinflammation and pain; therefore, it has been reported or tested in the treatment of other secondary causes of headaches, such as benign intracranial hypertension, post-traumatic headaches, and cluster headaches.[14-16] For COVID-19 infection or vaccine-related headaches, only two case reports of a dramatic response to galcanezumab have been published.[17,18] In this retrospective cohort study, the effectiveness and safety of CGRP mAbs for COVID-19 infection-related headaches were investigated using real-world data.

METHODS

Subjects

In the present study, medical records obtained between March 2022 and May 2024 from 2 independent centers were retrospectively reviewed. Inclusion criteria were new onset of headache after COVID-19 infection with a type that was not previously present, new onset of headache with a different presentation from the previous headache after COVID-19 infection, headache lasting more than 1 month (defined as COVID-19 infection-related headache), and patients prescribed CGRP mAbs for the first time.

Variables associated with COVID-19 infection-related headaches

The collected data included demographics, history of migraine attacks, including monthly headache days and monthly medication days, COVID-19 vaccination status, date of COVID-19 diagnosis and variant type, onset and phenotype of COVID-19 infection-related headache, presence of long-COVID headache (COVID-19 infection-related headache persisting for more than 3 months), and type and total number of doses of CGRP mAbs received. Monthly headache days and monthly medication days at 3 and 6 months after discontinuation of CGRP mAbs were collected retrospectively from the clinic or via telephone interviews.

To identify the characteristics of COVID-19 infection-related headaches, characteristics such as duration, laterality, and phenotype, as well as the associated symptoms and medications, were assessed before CGRP administration. The effectiveness and side effects of the CGRP mAb treatment were evaluated based on follow-up of monthly headache days, pain severity

scores (visual analog scale), abortive and preventive medications, and monthly medication days. Headache was evaluated using the Headache Impact Test-6 (HIT-6) score, while depression and anxiety were assessed using the Patient Health Questionnaire-9 (PHQ-9) and General Anxiety Disorder-7 (GAD-7) scores, respectively, before and after CGRP mAb treatment.[19-22] Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the brain were performed to exclude other secondary headaches.

Statistical analysis

Descriptive statistics were used for statistical analyses. Continuous variables were presented as medians (interquartile range; IQR). Categorical variables were expressed as numbers and percentages. To compare pre- and post-COVID headache characteristics (monthly headache days and monthly headache medication days) and pre- and post-CGRP mAb treatment outcomes, including quality of life and psychological effects, the Wilcoxon signed rank test was performed. All statistical analyses were conducted using SPSS software (version 29.0; IBM, Armonk, NY, USA), with statistical significance defined as a 2-sided *P* value of < 0.05.

Ethics statement

The Institutional Review Board of the Seoul Hospital of Ewha Womans University approved this study (SEUMC 2022-08-030). All participants provided written informed consent before participating in the study.

RESULTS

In the present study, a total of 49 patients with COVID-19-infection-related headaches were identified, and nine received CGRP mAbs (seven from Ewha Seoul Hospital and 2 from Dongtan Sacred Heart Hospital) (**Fig. 1**). All nine patients were female, and the median age was 48 years. These headaches were unilateral (66.7%) and pulsating (22.2%), and all showed

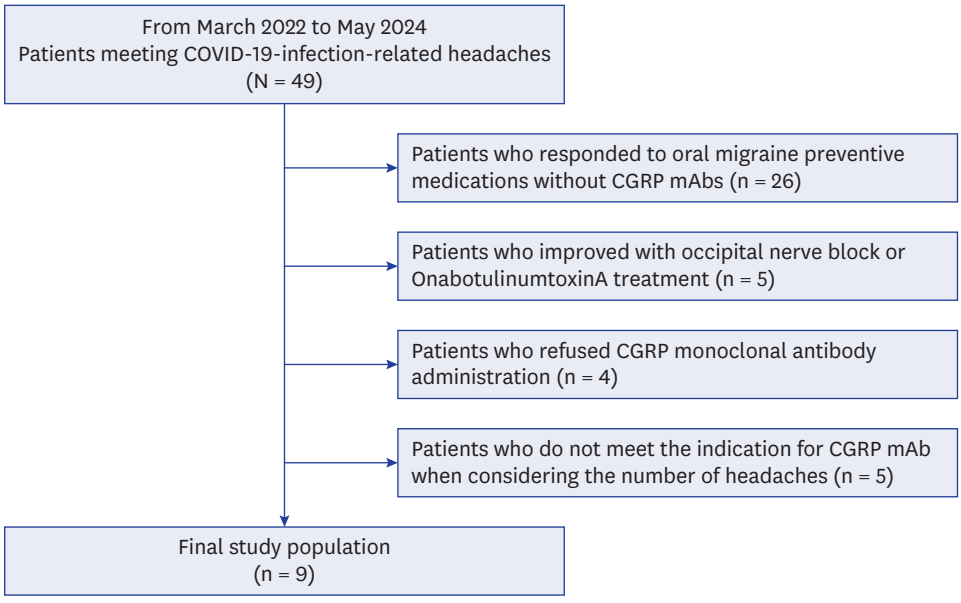


Fig. 1. Flowchart of the study.
COVID-19 = coronavirus disease 2019, CGRP = calcitonin gene-related peptide, mAb = monoclonal antibody.

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Table 1. Clinical characteristics of patients with post-COVID headache (N = 9)

Patient number	Age	Sex	BMI, kg/m^2	Hx of migraine	Past headache history		Variation of COVID-19	Duration from the onset of post-COVID headache to CGRP mAb injection, days	Diagnosis of long COVID-19[a] (≥ 3 months)	Total number of CGRP mAb injection
					Monthly headache days	Monthly medication days				
1	27	Female	19.0	Yes	1	0	Omicron	51	No	2
2	83	Female	21.5	Yes	2	2	Omicron	56	Yes	4
3	48	Female	26.4	Yes	10	8	Omicron	371	Yes	3
4	57	Female	19.5	Yes	4	2	Omicron	93	Yes	3
5	44	Female	20.0	Yes	2	0	Alpha	833	Yes	4
6	44	Female	21.5	Yes	10	6	Omicron	44	Yes	3
7	57	Female	19.7	Yes	8	5	Omicron	342	Yes	10
8	22	Female	21.8	Yes	2	0	Omicron	233	Yes	5
9	64	Female	23.2	Yes	8	4	Omicron	97	Yes	11
Total	48 (44–57)	9 (100.0%)	21.5 (19.7–21.8)	9 (100.0%)	4 (2–8)	2 (0–5)		97 (56–342)	8 (88.9%)	4 (3–10)

Values are presented as numbers (%) for categorical variables and medians (interquartile ranges) for continuous variables.
COVID = coronavirus disease, BMI = body mass index, Hx = history, CGRP = calcitonin gene-related peptide, mAbs = monoclonal antibodies.
[a]It is defined as the continuation or development of new symptoms 3 months after the initial severe acute respiratory syndrome coronavirus 2 infection.

features of migraine. Regarding the duration of headaches, eight patients (88.9%) had headaches lasting more than 3 months (i.e., long-COVID-19 headaches). As for the COVID-19 variants, 1 patient (11.1%) had an alpha variant, while the remaining 8 (88.9%) patients had omicron and its variants.

Medication overuse headache was identified in 7 patients (77.8%), with medications such as cafergots, non-steroidal anti-inflammatory drugs (NSAIDs), and triptans. Brain MRI and MRA were performed in all 9 patients, and no abnormalities were found. Information on CGRP mAb dosing is presented in **Table 1**. All 9 patients received fremanezumab, including one patient who received 2 doses of fremanezumab and then switched to galcanezumab for 10 doses. The median duration from the onset of post-COVID headache to CGRP mAb injection was 97 days (IQR, 56–342 days). The total number of injections ranged from 2 to 18 (median, 4) during a median treatment duration of 107 days (IQR, 64–340 days). When comparing pre- and post-COVID-19 infections, monthly headache days increased from 4 (IQR, 2–8) to 25 (IQR, 15–28) days (P = 0.008), and monthly medication days increased from 2 (IQR, 0–5) to 16 (IQR, 15–20) days (P = 0.006; **Tables 1** and **2**). Before CGRP mAb treatment, abortive medications included acetaminophen in 5 patients (55.6%), NSAIDs in 5 (44.4%), triptan in 4 (44.4%), cafergot in 1 (11.1%), and a mixture of tramadol and paracetamol in 1 (11.1%). After CGRP mAb treatment, the abortive medications included acetaminophen in 5 patients (55.6%), NSAIDs in 3 (33.3%), triptan in 3 (33.3%), and lasmiditan in 1 (11.1%).

Table 2. Comparison of headache characteristics pre- and post-CGRP mAb treatment

Characteristics	CGRP mAb treatment		*P* value
	Pre-status	Post-status	
Monthly headache days	25 (15–28)	5 (4–10)	0.012
Monthly medication days	16 (15–20)	4 (2–10)	0.017
Severity of headache	8 (7–9)	3 (2–4)	0.011
HIT-6 score	65 (60–68)	48 (48–60)	0.017
PHQ-9 score	14 (5–15)	10 (4–12)	0.028
GAD-7 score	5 (2–7)	4 (2–7)	0.059

Values are presented as medians (interquartile ranges) for continuous variables. *P* values are based on the Wilcoxon signed-rank test.
CGRP = calcitonin gene-related peptide, mAb = monoclonal antibody, HIT-6 = Headache Impact Test-6, PHQ-9 = Patient Health Questionnaire-9, GAD-7 = General Anxiety Disorder-7.
*P < 0.05.

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For preventive medications before CGRP mAb treatment, tricyclic antidepressants (TCAs) were used in 4 patients (44.4%), beta-blockers in 4 (44.4%), calcium channel blockers in 2 (22.2%), antiepileptic drugs in 4 (44.4%), and Botox in 1 (11.1%).

After CGRP mAb treatment, the same categories of preventive medications were maintained: TCAs were used in 3 patients (33.3%), beta-blockers in 3 (33.3%), calcium channel blockers in 2 (22.2%), and anti-epileptic drugs in 5 (55.6%). Three patients (33.3%) did not take oral preventive medications before or after CGRP mAb treatment.

The number of monthly headache days decreased steadily after 1 month of CGRP mAb treatment and continued to decline after 2 and 3 months (**Fig. 2**). Three months after CGRP mAb treatment, the number of monthly headache days decreased from 25 (IQR, 15–28) to 5 (IQR, 4–10) (P = 0.012), headache severity scores decreased from 8 (IQR, 7–9) to 3 (IQR, 2–4) (P = 0.011), and monthly medication days decreased from 16 (IQR, 15–20) to 4 (IQR, 2–10) (P = 0.017; **Table 2**). When comparing pre- and post-CGRP mAb treatment regarding quality of life and psychological effect, HIT-6 scores decreased from 65 (IQR, 60–68) to 48 (IQR, 48–60) (P = 0.017), PHQ-9 scores decreased from 14 (IQR, 5–15) to 10 (IQR, 4–12) (P = 0.028), and GAD-7 scores showed a non-significant decrease from 5 (IQR, 2–7) to 4 (IQR, 2–7) (P = 0.059).

One patient experienced daily headaches for 51 days after the COVID-19 infection, recovered after two doses of CGRP mAbs, and discontinued further treatment. Seven patients discontinued mAbs after 3–12 doses of CGRP mAbs, and the remaining patients continued CGRP mAb treatment until the last follow-up of the 18th injection. However, AEs and serious adverse events (SAEs) related to the safety of CGRP mAbs were not reported.

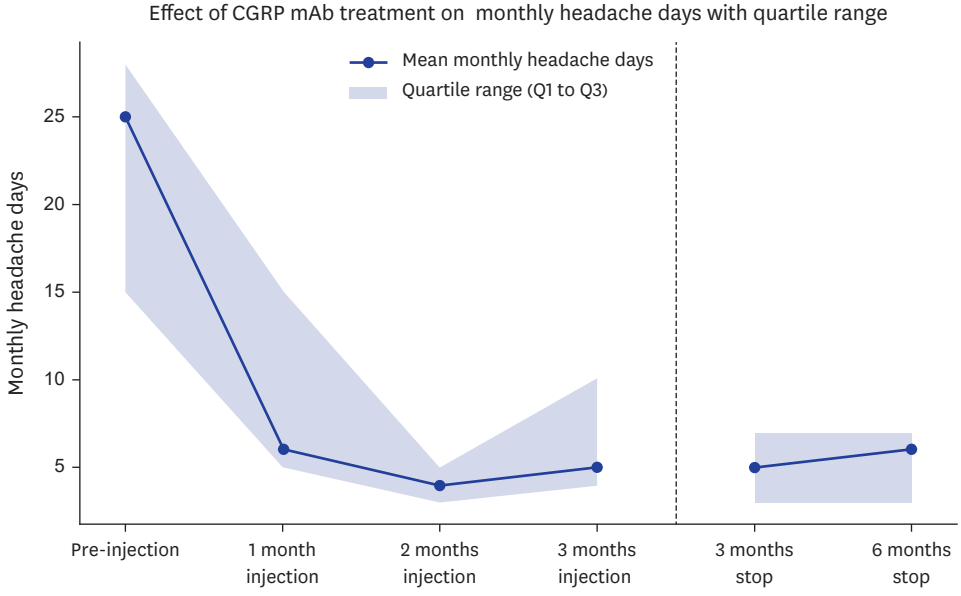


Fig. 2. Effect of CGRP mAb treatment and clinical course after discontinuation on monthly headache days with quartile range.
The figure illustrates a steady decrease in monthly headache days after 1 month of CGRP mAb treatment, with continued improvement at 2 and 3 months. Among the 7 patients who discontinued CGRP mAb, the median number of monthly headache days was 5 (IQR, 3–7) at 3 months and 6 (IQR, 3–7) at 6 months.
CGRP = calcitonin gene-related peptide, mAb = monoclonal antibody, IQR = interquartile range, Q1 = First quartile, Q3 = Third quartile.
Two patients: one continued CGRP mAb treatment, and 1 was lost to follow-up.

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The clinical course after the discontinuation of CGRP mAb was available in 7 patients (1 ongoing with CGRP mAb and 1 lost to follow-up). Three months after discontinuation, the median number of monthly headache days was 5 (IQR, 3–7), and the median number of monthly medication days was 3 (IQR 2–7). At 6 months, the median monthly headache days were 6 (IQR, 3–7), and monthly medication days were 3 (IQR 2–6).

DISCUSSION

This study provides valuable insights into the effectiveness and safety of CGRP mAbs for treating COVID-19 infection-related headaches. CGRP mAbs significantly reduced the frequency and severity of COVID-19-infection-related headaches without significant AEs and SAEs. This treatment may be an effective and safe option for patients experiencing persistent headaches following COVID-19 infection, particularly those with characteristics similar to migraines.

Patients in this study reported a significant increase in both monthly headache days and medication days following COVID-19 infection, highlighting the substantial effect of COVID-19 on headache frequency and severity. Most patients (88.9%) experienced headaches lasting > 3 months, which is considered as long-COVID headaches. This is in agreement with previous research indicating that neurological complications, particularly headaches, are common in long-COVID cases.[23,24]

One of the key findings of this case series was the marked improvement in headache-related outcomes after CGRP mAb administration. The number of monthly headache days significantly decreased from 25 to 5, and the headache severity scores decreased from 8 to 3. A few reports and only one or two case series have investigated the efficacy of CGRP mAbs in the treatment of COVID-19 infection-related headaches; thus, the evidence remains insufficient.[17,18] The efficacy of CGRP mAb treatment in COVID-19-related headaches indicates a partially shared pathophysiology with migraines, such as trigeminal activation. This possibility is supported by protein mimicry between CGRP receptors and antibodies against severe acute respiratory syndrome coronavirus 2 spike protein and elevated alpha-CGRP levels in patients with COVID-19.[17,25]

The study also found that the CGRP mAb significantly improved patients' quality of life and mental health. The significant decrease in HIT-6 and PHQ-9 scores indicated reduced headache impact and improved mood, respectively. Although the decrease in GAD-7 scores was not statistically significant, the trend toward decreased anxiety levels suggests that the treatment had an overall positive psychological impact on patients with long-term headaches. Furthermore, the safety profile of the CGRP mAbs in this patient population was favorable, with no reported AEs or SAEs. This was consistent with the generally well-tolerated nature of CGRP mAbs in migraine treatment, even during the COVID-19 pandemic.[26]

All patients included in this study were female, reflecting the higher prevalence of both migraines and post-COVID headaches in women.[27-29] The predominance of the omicron variant (88.9%) aligned with the global prevalence during the study period.[30,31] The high incidence of medication overuse headaches (77.8%) before CGRP mAb treatment highlights the challenges in managing COVID-19-related headaches with conventional therapies. The significant reduction in medication use after treatment with CGRP mAb suggests

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that these antibodies may effectively disrupt the cycle of medication overuse and improve symptom management.

Despite these promising results, this study had several limitations. The small sample size including only 2 centers and the homogeneous patient population (all female, mostly with a history of migraine) limit the generalizability of our findings. Additional limitations include the retrospective observational design, which is subjected to potential recall bias, lack of long-term prognostic data, and regional constraints of only two available CGRP mAbs (galcanezumab and fremanezumab) in South Korea. Future research should include prospective studies with larger cohorts to validate these findings and explore the underlying pathophysiology of COVID-19-infection-related headaches.

In conclusion, the results of this study provide preliminary evidence supporting the use of CGRP mAbs as a potential treatment option for COVID-19 infection-related headaches, improving the quality of life of patients and reducing the psychological burden associated with persistent headaches.

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