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Changes in Anxiety, Sleep, and Need for Rescue Medications in Migraine Patients on Fremanezumab Therapy: Patient Survey Results Following Completion of a 1-year Extension Study

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CONCLUSIONS

- **>50% of migraine patients reported improvements from baseline in anxiety and/or sleep quality and decreases in acute medication use for migraine during fremanezumab treatment for ≥1 year**
- **Limitations: Results may be limited by recall and participation bias; however, the sample was representative of the overall treatment population, and results were similarly distributed regardless of diagnosis (episodic migraine [EM] vs chronic migraine [CM]) or dosing regimen received (quarterly vs monthly)**

INTRODUCTION

Anxiety disorders

>2× more common in migraine patients[1]

Sleep disturbances

affect **>50%** of migraine patients[2]

- Fremanezumab, a fully humanized monoclonal antibody (IgG2Δa) that selectively targets calcitonin gene-related peptide (CGRP),[3] has proven efficacy for preventive treatment of migraine in adults[4,5]
- A 52-week extension study evaluated long-term safety and efficacy of fremanezumab

OBJECTIVE

- A retrospective web-based questionnaire evaluated perceived impact of fremanezumab treatment on anxiety, sleep, and the need for rescue medication in a subpopulation from the extension study

METHODS

Study Design

- In the 52-week extension study, adults ≥18 years of age with CM or EM were randomized:

Quarterly fremanezumab (675 mg) | **Monthly fremanezumab (225 mg)***

*Some CM patients received a loading dose of 675 mg fremanezumab in the monthly arm

- All patients were blinded to treatment received during the extension study
- Patients were recruited at 41 US extension study sites

Study Assessments

- From 1 to 24 months after the last extension study visit, patients completed an online patient experience survey (~20-40 minutes), including questions on treatment impact on anxiety, sleep, and the need for rescue medication (**Table 1**)
  - Improvement was defined as a score of ≥6 for the anxiety and sleep dimensions and a score of ≤4 for acute medication use

Table 1. Survey Questions and Response Options to the Perceived Impact of Fremanezumab Treatment on Anxiety, Sleep, and the Need for Rescue Medication

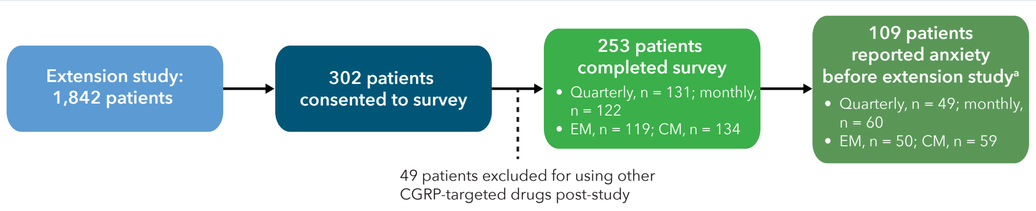
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly worse and 10 significantly better, how much change in anxiety level did you feel while you were taking the study medicine?[a]											
Significantly worse					No difference						Significantly better
0	1	2	3	4	5	6	7	8	9	10	
While you were taking the study medication, did your overall sleep quality change? On a scale of 0 to 10, where 0 is significantly worse and 10 significantly better, how much worse or better was your sleep quality while you were taking the study medicine compared to the 3-month baseline period before the first injection?											
Significantly worse					No difference						Significantly better
0	1	2	3	4	5	6	7	8	9	10	
Compared to the 3-month baseline period before the first injection, on a scale of 0 to 10, where 0 is significantly less and 10 significantly more, how much did you rely on rescue or abortive medicines that stop migraine symptoms (ex: Imitrex, Amerge, Maxalt) and over-the-counter medicines while you were taking the study medicine?											
Significantly less					No difference						Significantly more
0	1	2	3	4	5	6	7	8	9	10	

[a]Impact of fremanezumab treatment on anxiety was only evaluated for patients with self-reported anxiety prior to the study.

RESULTS

Patients

Figure 1. Study design for recruitment of the survey population.



EM, episodic migraine; CM, chronic migraine; CGRP, calcitonin gene-related peptide.
[a]Patients included in this subgroup answered "Yes" to the survey question: "Before you entered the clinical trial, did you experience anxiety, whether or not it was associated with your migraine?"

- 109 patients had self-reported anxiety prior to the extension study (**Figure 1**)
- All patients received fremanezumab during the extension study, with 134 also receiving fremanezumab during the prior phase 3 (HALO EM and HALO CM) trials

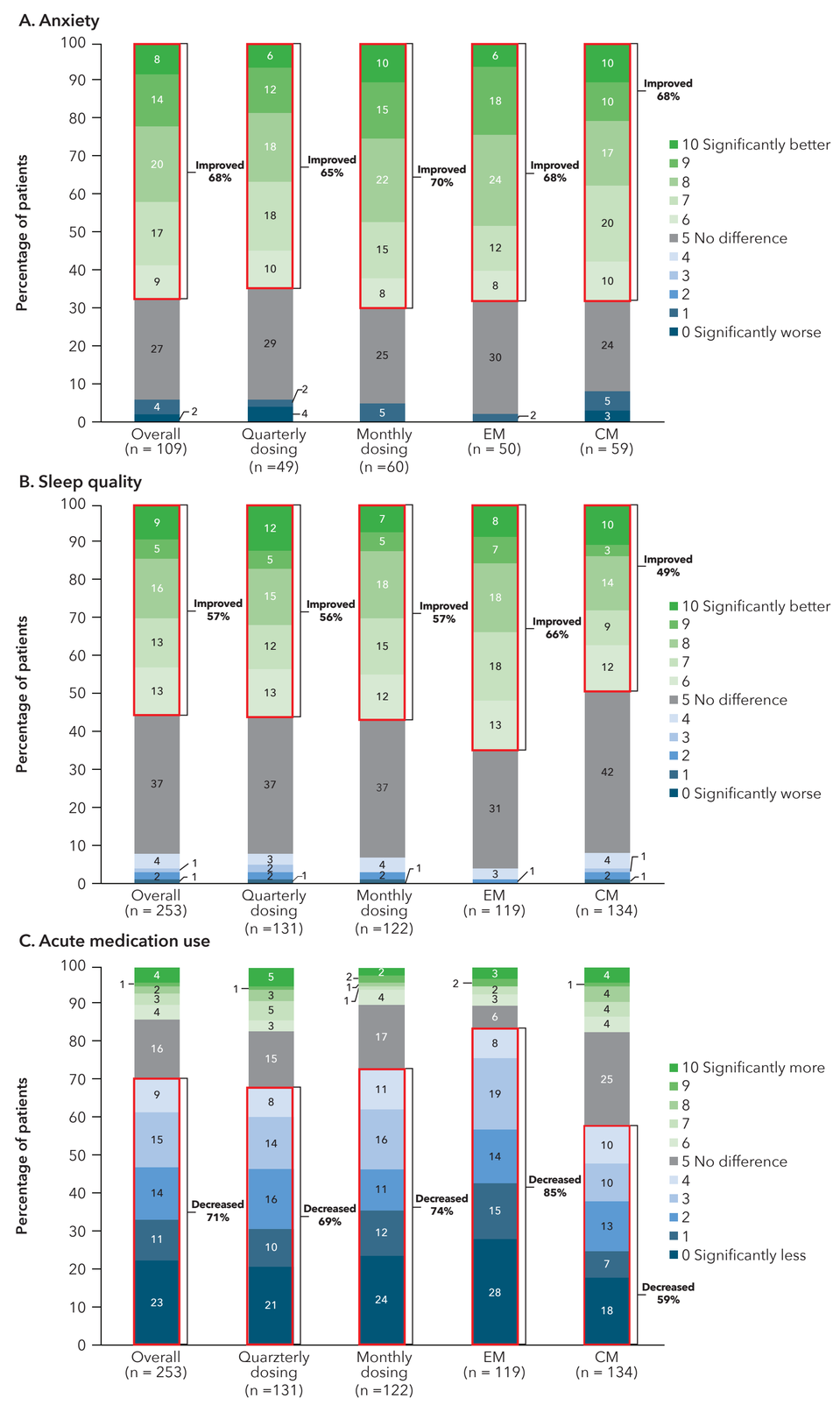
Table 2. Baseline Demographics of Patients in the Migraine Patient Survey Study and Overall Long-term Study Population

	Migraine patient survey study population N = 253		Overall long-term study population N = 1,890	
	EM n = 119	CM n = 134	EM n = 780	CM n = 1,110
Age, years, mean	46.9	45.2	44.0	43.1
Female sex, %	87	90	86	88
Quarterly dosing, %	52[a]		51	50
Monthly dosing, %	48[a]		49	50

EM, episodic migraine; CM, chronic migraine.
[a]Data available only for the overall population (EM and CM patients).

Impact of Fremanezumab Treatment on Anxiety, Sleep Quality, and Acute Medication Use

Figure 2. Patient perceptions of changes from baseline[a] during fremanezumab treatment in A) anxiety,[b] B) sleep quality, and C) acute medication use for migraine.[c]



EM, episodic migraine; CM, chronic migraine.
[a]3-month baseline period before the first injection during fremanezumab treatment.
[b]Impact of fremanezumab treatment on anxiety was only evaluated for patients with self-reported anxiety prior to the study.
[c]Percentages may not total 100% due to rounding.

- Results of this survey were generally consistent in the quarterly and monthly dosing groups and in the EM and CM patient subgroups (**Figure 2**)
  - However, the greatest subgroup improvements observed for each of the 3 dimensions were: anxiety, monthly dosing (70%); sleep quality, EM patients (66%); acute medication use, EM patients (85%)

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